CUSTOMER-DRIVEN REMANUFACTURABILITY DECISION-MAKING IN THE MEDICAL DEVICES SECTOR

By

DAMOLA IKEOLUWA AKANO

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Department of Design, Manufacture and Engineering Management
University of Strathclyde
Glasgow, UK

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Declaration of author's rights

'This thesis is the result of the author's original research. It has been composed by the author and has not been previously submitted for examination which has led to the award of a degree.'

Signed: Date:

To those who know the value of knowledge.

To every individual driven by scientific curiosity.

"To accomplish great things, we must not only act, but also dream; not only plan, but also believe." – Anatole France

Acknowledgement

Appreciation goes to everyone, past and present, who have contributed to my journey so far. To mention the name of everyone would be exhausting so a big apology to anyone whose name didn't come to mind while writing this acknowledgement.

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Abstract

Remanufacturability decision-making has been studied by many researchers, mostly from business and core supply perspectives. Moreover, much of the research have been mono-methodical which present a singular perspective and focus on the electromechanical remanufacturing sector. Despite the importance of customer acceptance and the growing body of research on medical devices remanufacturing, there remains a lack of evidence on how customer considerations impact remanufacturability decision-making. Therefore, this research aims to understand how remanufacturability decision factors can be modelled to improve customer acceptance in the medical devices remanufacturing sector.

This research takes the form of a mixed research methodology and adopted a pragmatic philosophical paradigm. Quantitative and qualitative approaches were used in the explanatory sequential mixed methods research design adopted in this thesis. By employing a quantitative mode of enquiry in the first phase, key remanufacturability decision factors were analysed and ranked from customers' perspective using inputs from six highly experienced medical devices practitioners. In the second phase, a qualitative multiple case study approach was adopted to explore the nature of remanufacturing and remanufacturability decision-making in four companies within the medical devices sector.

This research identified seven important customer decision factors that influences remanufacturability decision-making including quality (32.38%), price (19.00%), warranty (15.12%), brand equity (12.24%), available information (10.61%), added value service (6.65%) and environmental considerations (4.00%). This provided support for the development of a framework to influence customer behaviour regarding remanufactured medical devices. This is the first study to investigate the interactions between customer considerations and remanufacturability decision-making in the medical devices sector. There are several important areas where this research makes an original contribution. First, it explores remanufacturability from multiple perspectives of the customer and the remanufacturer through a mixed-methods design. Second, it presents a comprehensive customer-driven remanufacturability decision framework which was validated by practitioners. The framework presents a novel perspective on the subject and has direct practical relevance for practitioners as it could contribute to improving customer acceptance in this sector. Third, it presents a hierarchical analysis of decision factors based on customer opinions in the medical devices sector. Fourth, this research provides the first investigations into the nature of remanufacturing in the medical devices sector.

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List of publications from this work

Journal publications

Akano, D., Ijomah, W. & Windmill, J. (2021). "Hierarchical analysis of factors influencing acceptance of remanufactured medical devices," Cleaner and Responsible Consumption, vol. 2, no. November 2020, p. 100017, 2021, doi:https://10.1016/j.clrc.2021.100017.

Akano, D., Ijomah, W. & Windmill, J. (2021). "Stakeholder Considerations in Remanufacturability Decision-Making: Findings from a Systematic Literature Review," Journal of Cleaner Production, vol. 298, pp. 1–25, 2021, doi:https://doi.org/10.1016/j.jclepro.2021.126709.

Conferences

Workshop

Akano, D., Ijomah, W. & Windmill, J. (2021). Medical Devices Reprocessing. An organised session (workshop) at the: EcoDesign 2021 International Conference, Japan.

Paper Presentation

Akano, D., Ijomah, W. & Windmill, J. (2021). Increased personal protective and medical equipment manufacturing to fight COVID-19: An egregious approach for the environment. Paper presented at the: EcoDesign 2021 International Conference, Japan.

Poster Presentation

Akano, D., Ijomah, W. & Windmill, J. (2019). Remanufacturing of Neonatal Incubators: A sustainable option to providing affordable incubators. Poster presented at: 2019 Biomedical Engineering Conference; September 2019; London. United Kingdom

Glossary of terms

ACS - American College of Surgeons

AHP - Analytical Hierarchy Process

BfArM - German Federal Institute for Drugs and Medical Devices

CAD - Computer Aided Design

CE marking - means that the manufacturer has confirmed that the product meets the EU safety, health, or environmental requirements

CE - Circular Economy

CNC - Computerized Numerical Control

COCIR - European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry

Core - Used or Pre-owned devices

CI - Consistency Index

CR - Consistency Ratio

CR - Contract Remanufacturer

CT - Computed Tomography scanner

DDDM - Data-Driven Decision-Making

DEMATEL - Decision-Making Trail and Evaluation Laboratory Methodology

DfRem - Design for Remanufacture

DHR - Device Health Record

DOI - Digital Object Identifier

DRRA - Design for Remanufacturing and Remanufacturability Assessment tool

DSS - Decision Support System

DVT - Deep Vein Thrombosis

EBS - Electronic Braking System

ECG - Electrocardiogram device

eDHR - Electronic Device Health Record

EKG - Electrokardiogram device

ELV – End of Life Vehicle

EPR - Extended Producer Responsibility

ER - External Remanufacturer (which could be a contracted remanufacturer or a third-party remanufacturer)

EU - European Union

FE – Field Engineers

FDARA - Food and Drug Administration Reauthorization Act of 2017

FIFO - First In First Out

FMEA - Failure Mode and Effect Analysis

GBP - Great Britain Pounds

GDM - Grey Decision Making

GHG - Green House Gases emissions

GRP - Good Refurbishment Practice

HMRS - Hybrid Manufacturing and Remanufacturing System

ICE - Intracardiac Echocardiography

IT2FAHP - Interval Type-2 Fuzzy Analytical Hierarchy Process

IVDR - In-Vitro medical Devices Regulation

JIRA - Japan Industries Association of Radiological Systems

MCDM - Multi-Criteria Decision-Making

MCHM - Multi Criteria Hierarchical Model

MDPM - Markov Decision Process Model

MDR – Medical Devices Regulation

MITA - Medical Imaging & Technology Alliance

MLCS - Multi-Life Customization Scenarios

MR - Magnetic Resonance

MRI - Medical Resonance Imaging Device

NHS - United Kingdom National Health Services

OE - Original Equipment

OEM - Original Equipment Manufacturer

PET - Positron Emission Tomography scanner

PI - Purchasing Intention

PM - Preventive Maintenance

PMA - Premarket Approval

POX - Pulse Oximeter

PPC - Production Planning and Control

PR-MCDT - Product Recovery Multi-Criteria Decision Tool

QA - Quality Assurance

QFD - Quality Function Deployment

QMIP - Quadratic Mixed Integer Programming

QMS - Quality Management System

RCS - Royal College of Surgeon

RDMF - Remanufacturing Decision-Making Framework

REPRO2 - Remanufacturable Product Profile

RI - Random Index

RoHS – Risk of Hazardous Substances

RQ - Research Questions

RUP - Remaining Useful Potential

RUL - Remaining Useful Life

SAGES - Society of American Gastrointestinal and Endoscopic Surgeons

SIL - Shipping Information List

SLR – Systematic Literature Review

SME - Small and Medium-sized Enterprises

SPA - System Performance Assessment

SPT - System Performance Testing

SUDs - Single Use Devices

TOPSIS - Technique for Order Preference by Similarity to Ideal Solution

TPR - Third-Party Remanufacturer

UK - United Kingdom

UK MHRA - United Kingdom Medicines and Healthcare products Regulatory Agency

UML - Unified Modelling Language

US FDA - United States Food and Drug Administration

USITC - United States International Trade Commission

V&V - Validation and Verification

WEEE – Waste of Electrical and Electronics Equipment

WHO - World Health Organisation

WTP - Willingness to Pay

XA - Company A's remanufacturing operation

XB - Company B's remanufacturing operation

XC - Company C's remanufacturing operation

XD - Company D's remanufacturing operation

Chapter One: Introduction

1. Chapter One: Introduction

1.1.Background

The paradigm shift from a perspective of unlimited resources and regenerative capability of the environment towards the realisation that available resources are indeed limited is reshaping every aspect of human lives (Garetti & Taisch, 2012). This, coupled with increasing awareness of environmental pollution and degradation (Pawlik et al., 2013), is leading the drive towards a circular economy. Moving from a linear to a circular economy has the tendency to generate an overall yearly benefit of €1.8 trillion within the EU (Sundin et al. 2020). Over the past decade, research effort in product end-of-life management through sustainable recovery options such as reuse, repair, refurbish and remanufacture has grown parallel to activities such as reverse logistics, and closed-loop supply chain. The European Remanufacturing Council has forecasted an increase in the adoption of remanufacturing over the next 10 years and forecasted a growth from €30 billion in 2020 to €90 billion by 2030 in revenue (Sundin et al. 2020).

Remanufacturing has been defined as a sustainable manufacturing operation that returns a used product (or core) to a condition similar to that of new, with a matching warranty (Ijomah, 2002; Salah et al., 2021). The remanufacturing process is shown in figure 1-1. Remanufacturing has existed for more than 80 years as a means of restoring old/used products to as good as new performance; thereby reducing pollution and landfill impact, and saving energy and conserving resources such as materials, labour and value associated with original manufacturing (Ijomah, 2009; Omwando et al., 2018; Ropi et al., 2021). Remanufacturing offers significant benefits to the environment (through lower environmental impacts, resource, material, and energy conservation), businesses (through return on investment, expansion to different customer groups, and regulatory alignment), and the customers (through lower priced products). These remanufacturing benefits have been discussed extensively in literature, especially in terms of the triple bottom lines of sustainability: *economic*, *environmental,* and *social* benefits (Bras & Hammond, 1996; Q. W. Deng et al., 2017; W. Deng, 2019; Duberg et al., 2021; Goodall, 2014; Guide, 2000; Jensen et al., 2019; Karaulova & Bashkite, 2016; King et al., 2006; Okorie et al., 2021; Smith & Keoleian, 2004; Zacharaki et al., 2021).

The impact of remanufacturing as an important approach to sustainable development has been well documented in literature (Gehin, Zwolinski, and Brissaud 2008; Gunasekara, Gamage, and Punchihewa 2020). However, any end-of-life recovery strategy may well become a deterrent for sustainability if customer acceptance is low. Alongside customers, the original equipment manufacturer (OEM) and the external remanufacturer (ER) are the key stakeholders whose requirements are critical in remanufacturability decisions.

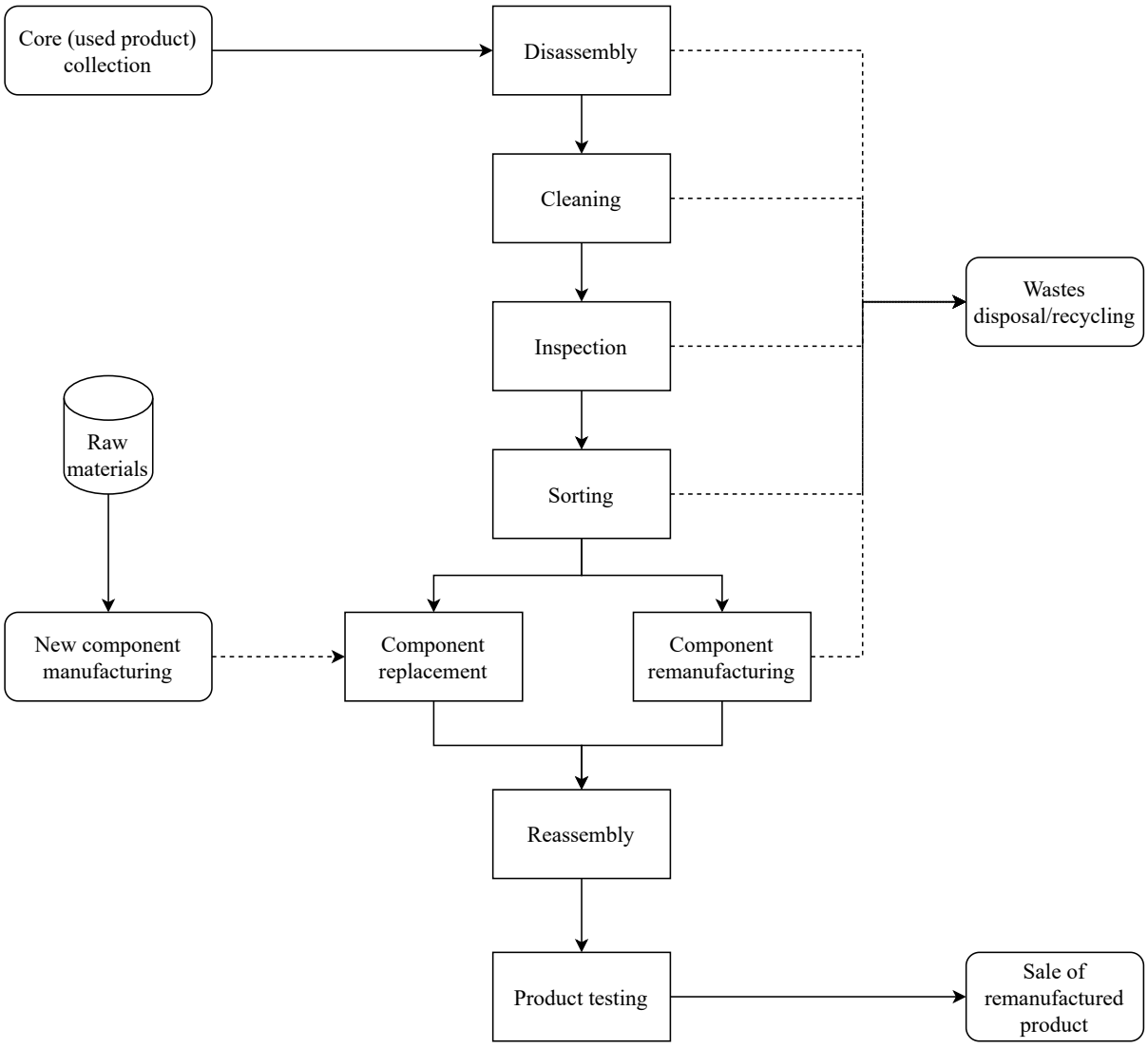

Figure 1-1: The remanufacturing process

1.2.What is remanufacturability decision-making?

The term "*remanufacturability decision-making"* is used to describe the process whereby decision makers in remanufacturing businesses assess whether, or not, a product can and should be remanufactured (X. Zhang et al., 2021). In other words, remanufacturability decision-making is product-based and it focuses on assessing both the viability and

feasibility of remanufacturing a product or specific product categories (M. Ding & Zhang, 2021; Omwando et al., 2018a; Otieno et al., 2020). This area of remanufacturing research is not new, and researchers have proposed criteria, tools and methods that can be used during the decision process. The earliest recorded work on remanufacturability decision-making was by Amezquita et al., in 1995 which assessed remanufacturability solely from a design perspective (Amezquita et al. 1995). This was immediately followed by research by Bras and Hammond in 1996 which introduced the design for remanufacturing as a key remanufacturability consideration (Bras and Hammond 1996). Over the years, design considerations have been a driving factor for remanufacturability.

However, with the growth of remanufacturing research, remanufacturability considerations have greatly expanded. They cover other factors across the entire remanufacturing business. The shift from a solely design-based remanufacturability decision-making to a broader multi-factor decision process was first discussed by (Guide 2000). Some of the remanufacturability decision factors that have been discussed in literature include quality, quantity and timing of returns (Farahani et al., 2020; Panagiotidou et al., 2017; Sun et al., 2018), reverse logistics considerations (Qiu et al., 2018; Erfan, Ghomi and Sajadieh, 2021), disassembly issues (Fang et al., 2015; Schäfer et al., 2020), product durability and material quality (J. Liu et al., 2022; S. Zhao et al., 2021), market demands and economic considerations (Afshar-Bakeshloo et al., 2021; Y. Zheng et al., 2022), and environmental considerations (X. Zhang et al., 2020; H. Zheng et al., 2019). The wide range of factors that are considered during remanufacturability decision-making reflects the change from assessing remanufacturability from the remanufacturer' single stakeholder perspective to a more comprehensive multi-stakeholder viewpoint. A consequence is the continuous optimisation and improvement of the decision process, and the inclusion of more factors to improve the effectiveness of remanufacturing decision systems for the decision makers.

Although the importance of considering stakeholder factors during remanufacturability decision-making has often been discussed (Östlin, Sundin, and Björkman 2009; Guide 2000), there is lack of a comprehensive understanding of how the requirements of the different stakeholders have been considered in the remanufacturability decision process, particularly within the medical devices remanufacturing sector. Further, consideration of customer requirements during the assessment of product remanufacturability has not been well established in literature despite the criticality of customer acceptance to the success of remanufacturing business (Barker & Zabinsky, 2008; Eze et al., 2019; Guidat et al., 2020).

However, there have been some indications of customers' impacts on remanufacturing decision processes (Boorsma et al., 2020; Li et al., 2017; Schmidt et al., 2015). The direction of existing literature reveals the growing need to put the customers at the foreground of the decision-making process. This approach has been suggested for remanufacturing sectors with high customer safety and quality requirements such as the medical devices industry (Barker & Zabinsky, 2008; Eze et al., 2019). However, there is little published data on both medical devices remanufacturing and customer considerations in remanufacturability decision-making.

1.3.Research overview

The goal of this PhD research is to connect two areas of remanufacturing research – customer research and research on remanufacturability decision-making. These research areas have been separated in existing literature, as if the remanufacturing business can exist without the customers. However, by bridging the gap between the remanufacturing decision makers and the customers, this research provides an opportunity to improve customer acceptance of remanufacturing, especially in sectors where acceptance is currently low.

The medical devices sector presents a fascinating application for this research within the remanufacturing domain. Eze *et al.,* (2020) suggested that customer considerations play a big role in this sector (Eze et al., 2020). However, there is currently no research to back up this assertion. Moreover, the acceptance of remanufactured products in this sector is currently low, with remanufacturing intensity in the medical devices sector being as low as 0.5% (USITC 2012). Therefore, this PhD research, which explores how customer considerations drive remanufacturability decision-making, would be very useful in driving the growth of remanufacturing in the medical devices sector.

1.4.Research question

The main question answered in this thesis is:

How can remanufacturability decision be modelled to improve customer acceptance in the medical devices remanufacturing sector?

This question was broken down into seven (7) simpler questions so that they can be more directly investigated. They are listed below:

RQ1: What is the relationship between remanufacturability decision-making and customer acceptance?

RQ2: What are the key decision factors for assessing remanufacturability and how do they influence customer acceptance?

RQ3: What is the relative importance of decision factors that affect customer acceptance of remanufactured medical devices?

RQ4: What is the nature of remanufacturing in the medical devices sector?

RQ5: What are the key decision factors that are currently used in medical devices sector to assess remanufacturability and how can this be improved?

RQ6: How can the new knowledge be presented to others?

RQ7: Is the new knowledge valid?

This research highlights the importance of incorporating customer considerations in remanufacturability decision-making. This research proposes that if a customer-driven approach to remanufacturability decision-making is taken, the effectiveness of the decision process and overall acceptance of remanufactured products can be optimised.

1.5.Beneficiaries

The research reported in this thesis benefits practitioners in the remanufacturing industry and academics who are involved in teaching and research. The following benefits are reported:

1.5.1. Academics

This thesis provides:

- an up-to-date review of remanufacturability decision-making
- the state-of-art in medical devices remanufacturing
- a clear and comprehensive description of remanufacturing activities in the medical devices sector
- a customer-driven remanufacturability decision framework which can be used for teaching and research purposes.

1.5.2. Industry

This thesis proposes:

- A comprehensive customer-driven remanufacturability decision framework that can support practitioner in their decision process and can improve their relationship between relevant stakeholders.
- Identifies specific issues in the medical devices remanufacturing sector.

1.6.Research scope

1.6.1. General research focus

This PhD was initially intended to focus on the research area of "remanufacturability decision-making", with the aim of advancing knowledge in this area. However, after comprehensive and systematic literature reviews, this PhD project was designed to adopt mixed methods research to bring together three areas of remanufacturing: "*remanufacturability decision-making*" and "*customer considerations*" while focusing on the "*medical devices remanufacturing*" sector, as shown in figure 1-2. Bringing together these three has a wide-ranging importance in literature.

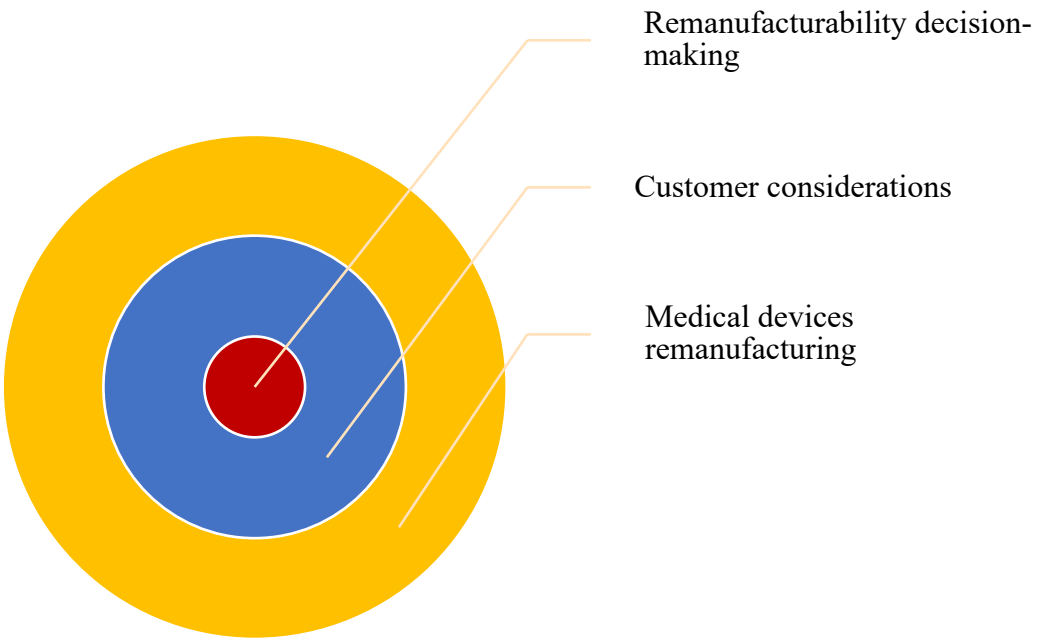

Figure 1-2: PhD research focus

At the core level, this research focuses on *remanufacturability decision-making*, and seeks to build on what is currently known in this area. The importance of performing a comprehensive remanufacturability assessment prior to remanufacturing has been discussed in literature. For example, an effective remanufacturability decision-making process has the tendency to improve the overall ease of the remanufacturing operation (Goodall, Rosamond, and Harding 2014; Kafuku et al. 2016). Other benefits include optimising the remanufacturing process, resource planning and market situations (Lahrour & Brissaud, 2018; Ong et al., 2016; Sherwood et al., 2000). The research presented in this thesis identified decision factors that have been used by practitioners in the medical devices

remanufacturing industry to evaluate product remanufacturability. Presenting an improved approach to remanufacturability decision-making would increase the profitability of the remanufacturing business, improve the growth of the remanufacturing sector and contribute to customer acceptance of the remanufactured products.

At the next level, the customers are focused upon. *Customer considerations* area of remanufacturing research has been treated as a detached area, leaning more towards consumer behaviour and related research rather than to research in the remanufacturing domain. Publications on customer considerations of remanufactured products have focused on topics such as willingness to pay (WTP), customer perceptions, purchasing intentions (PI) on remanufactured products, and customer return behaviour on used devices, especially in the electronics remanufacturing sector. The insufficiency of the connection between this area of research and research on remanufacturability decision-making may be used to explain the low level of acceptance of remanufactured products in some sectors.

The *medical devices remanufacturing* sector is a good application for remanufacturing. Despite being one of the early areas where remanufacturing technique was applied, the growth of remanufacturing in this sector has been limited. However, recent discussions and increasing awareness of sustainability issues in healthcare has been a major motivation and drive towards remanufacturing in this sector. As remanufacturers improve their operations in this sector to cover more products and target more market regions, there is need to breakdown the complexity of customer acceptance issues in remanufacturability decision-making. This enables them to make more effective decisions on what products to remanufacture.

To successfully bridge the gap between the customers and the remanufacturers within the medical devices sector, it is imperative that this comprehensive and multi-perspective research is performed to examine, clarify, and improve how customer considerations drive (or can drive) remanufacturability decision-making in the medical devices remanufacturing sector.

1.6.2. Stakeholders considered

Freeman and Parmigiani (2011) described stakeholders as “a group of individuals” whose actions influence or who can be impacted by decisions within a business, organisation, process, or industry (Freeman et al., 2010; Parmigiani, Klassen and Russo, 2011). In this thesis, primary stakeholders within the remanufacturing business include the OEM, ER and

the consumer whereas secondary stakeholders include, but not limited to, designers, sales vendors and distributors, core collectors and suppliers, local communities, and governments etc (Guide & van Wassenhove, 2009; Sarkis, 2003; Schenkel et al., 2015).

Customers, in this thesis, refer to medical devices experts who make the decisions on the procurement, use, and/or maintenance of remanufactured medical device. They include the clinicians, surgeons, supply chain professionals, maintenance specialists and funding organisations. The four categories of customers whose requirements are considered in this thesis are shown in table 1-1.

Table 1-1: Customer categories in this thesis

Category	Description
Medical device maintenance experts	These are highly skilled and trained engineers that are responsible for the inhouse maintenance and minor repairs of medical devices. They are usually based in the medical engineering departments of hospitals or healthcare centres. They are responsible for ensuring that medical devices are functional and ready to be used by clinicians or radiographers
Radiographers	They are the clinical technicians who use imaging medical devices such as the magnetic resonance imaging (MRI) device, computerised tomography (CT) scanners and ultrasound scanners etc. to take images for medical purposes.
Clinicians	This includes surgeons, radiologists or physicians who interpret the images from the imaging device to make diagnosis. This category also includes medical practitioners who use single-use medical devices.
Supply Chain professionals	This includes personnel who manage the contracts and oversee the purchase of clinic tools and devices for medical purposes.

While the clinicians and radiographers are mostly focused on the safety equivalence of the device, supply chain professionals mostly focus on the economic aspects. The medical device maintenance experts are mostly interested in technical details such as the ease of repair, disassembly, and maintenance of devices.

1.6.3. Research participants

A total of nineteen (19) personnel participated in the research reported in this thesis, they are:

- **Medical device experts**: This includes six (6) skilled and highly experienced medical device experts who oversee maintenance and servicing activities on medical devices and are based in hospitals across the U.K. (three (3) each in Scotland and England). As such, they are very familiar with the requirements for remanufactured medical devices,

from the standpoint of the customers. They have a total of 194 years of experience and an average of 32.33 years' experience making decisions related to medical devices.

- **Representatives of medical devices remanufacturers**: This include thirteen (13) representatives from four (4) companies who are involved in remanufacturing activities on medical devices (2 original equipment manufacturers (OEMs) and 2 third-party remanufacturers (TPRs)). They have a total of 186 years' experience in the medical devices sector and an average of 26.6 years' experience. Devices currently remanufactured includes capital imaging devices (e.g., magnetic resonance imaging (MRI) device, Positron Emission Tomography/Computed Tomography scanner (PET/CT), and Ultrasound etc) and single-use devices (e.g., trocar, diagnostic catheters, Electrocardiogram (ECG) leads etc).

1.6.4. Research domain

Goodall et al., (2014) stated that assessing remanufacturability is concerned with a comprehensive understanding and application of the key factors that are involved the decision process (Goodall, Rosamond and Harding, 2014). The approach of different companies, their technological capabilities and company policies play a significant role in this decision-making process. This research looks to contribute to the improvement of remanufacturability decision-making in medical devices sector to include key considerations of the customers so that the decision process can be more effective and remanufactured products are more acceptable to the customers. Thus, this research falls within two domains: Decision Making research and Operations Management research.

1.6.5. Geographical location covered

The research reported in this thesis has been designed to focus on medical devices remanufacturing in the UK. Thus, the quantitative AHP study focused on medical devices practitioners based in hospitals in England and Scotland. These participants are representative of the customers (i.e., personnel who are involved in the procurement, use and maintenance of medical devices) because of their lengthy experience working in different hospitals across the UK. The medical devices remanufacturing sector in the UK is not fully developed. However, a few organisations exist outside the UK that target these customers, procure used devices from, and sell remanufactured medical devices to the UK. Therefore, the qualitative case study included companies based in the UK, EU, and the USA, where medical devices remanufacturing is more common.

The UK is focused on in this research for two of reasons. First, the UK has an ageing population(Office for National Statistics, 2018). Young (2005) and Caley and Sidhu (2011) have discussed some of the implications of this (Caley & Sidhu, 2011; Young, 2005). One of the issues identified by Fares et al., (2021) as a result of an ageing populations is the strain on healthcare delivery including primary care, emergency, specialty, surgical and long term care (Fares et al., 2021). This can be directly associated with increased demand for medical devices. Second, the poor performance of the global economy, which has translated to the reduction of public spending in the UK (Cummins, 2018), means that hospitals can no longer afford to replace all their old or dysfunctional medical devices with new ones. Remanufacturing produces medical devices that have "like-new" or better functionality compared to new but are considerably cheaper than new devices (Chapman et al., 2008, 2009; Ijomah, 2002).

1.6.6. Research timeline

The research reported in this thesis was conducted over a 37-month period between December 2018 to December 2021 as shown in the figure 1-3. The literature review started in December 2018, followed by the research design between July 2019 and January 2020. The quantitative AHP study was performed between June and October 2020 while the qualitative case study was conducted between January and September 2021. Finally, the research was validated between November and December 2021.

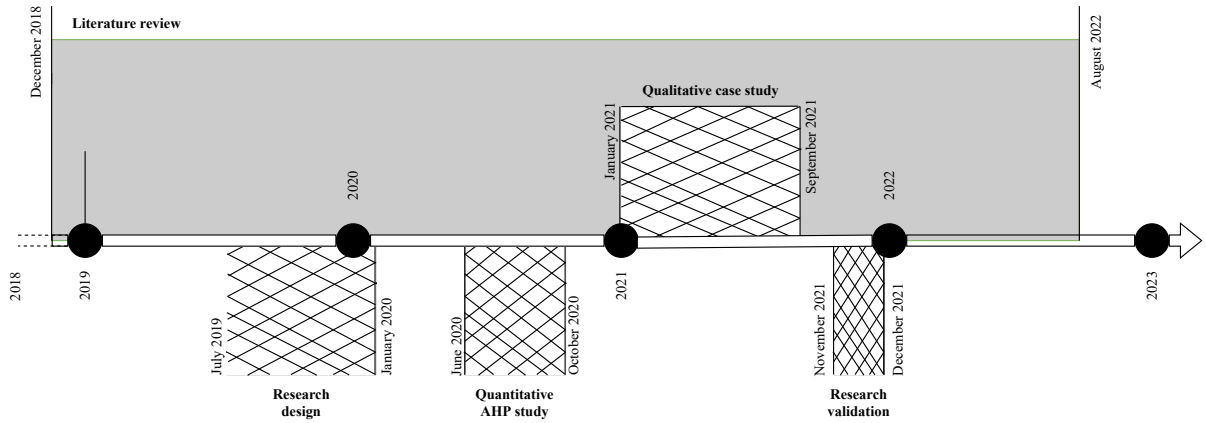

Figure 1-3: PhD research timeline

1.7.Thesis structure

The content of this thesis and the research questions were addressed is described in this section. This thesis is structured into nine (9) chapters as shown in figure 1-4. These chapters are described below.

Chapter 1 presents a background to this research, stating the research questions, and the scope of the research reported in this thesis.

Chapter 2 This chapter describes the literature reviews conducted in this thesis. It presents the state-of-art on stakeholder considerations in remanufacturability decision-making. It describes the decision factors currently used in remanufacturability decision-making and how they cover the requirements of key stakeholders in the remanufacturing business. It also presents a comprehensive literature review of medical devices remanufacturing. The review presented in the chapter describe several aspects of the medical devices remanufacturing sector including key definitions, other end-of-life recovery activities, remanufacturing process, decision-making, and customer considerations.

Taken together, this chapter discusses the state-of-art in these two topics and identify knowledge gaps in existing literature. The findings from this chapter shaped the research reported in this thesis both theoretically and methodologically.

Chapter 3 describes how the research has been designed to answer the specific research questions. It discusses the philosophical underpinnings of this research including introductory discussions on research paradigms and the different components of a paradigm. Specific topics such as the ontology, epistemology, axiology, rhetoric, and methodology of research paradigms are discussed. The rationales for a pragmatist paradigm adopted in this research are also presented. This chapter also discusses the methodology of the research and presents discussion on the mixed research methodology. The chapter describes the selected mixed research methodology, presents rationales for the selection, and describes the process of designing the research. The overall research strategy is also discussed including how the qualitative and the quantitative phases were conducted. This chapter also discusses how the qualitative and quantitative phases are mixed and the criteria for judging the quality of the research.

Chapter 4 presents the results obtained from a quantitative study which uses the analytical hierarchical process (AHP) to rank the criticality of customer factors. The quantitative data were collected using a survey delivered via mail to skilled and experienced personnel within

medical and healthcare sectors across the U.K. The findings from this chapter answers research question 3 (RQ3).

Chapter 5 presents the findings from a qualitative study which uses the case study research approach to collect information on the nature of remanufacturing in the medical devices sector. This answers research question 4 (RQ4). This chapter presents data obtained from four (4) case study companies who remanufacture imaging devices (such as MRI, CT, Ultrasound, and x-rays, etc) and single-use devices (such as surgical tools, trocar, catheters, ECG/EKG leads, etc). Further, this chapter presents findings on the key factors that are considered during remanufacturability decision-making at the companies. A cross-case analysis of the companies is performed to identify similarities and differences across companies on how customer considerations drive remanufacturability decision-making.

Chapter 6 present discussions on the combination of the qualitative and quantitative studies. It describes how the findings from both studies were mixed and offers explanations on the implications of these findings.

Chapter 7 presents the discussion on the development of the customer-driven remanufacturability decision framework using the factors identified in this research. The framework is presented to serve as a guide to assist decision-makers during remanufacturability decision-making.

Chapter 8 describes the validation criteria, process, and results of the proposed framework. This chapter assesses the accuracy, sufficiency, clarity, and practical relevance of the proposed framework using seven factors – problem-driven, important, timely, novel, not too costly, implementable, and non-obvious suggested by (Svanberg 2020).

Chapter 9 presents the conclusion to this thesis.

1.8.Conclusion of chapter 1

This introductory chapter has presented the background to this thesis, and it sets the scene on remanufacturing, and remanufacturability decision-making. This chapter has described the research questions of this PhD, the beneficiaries, research scope and the structure of this thesis. The next chapter presents the literature review which form the theoretical basis for this research.

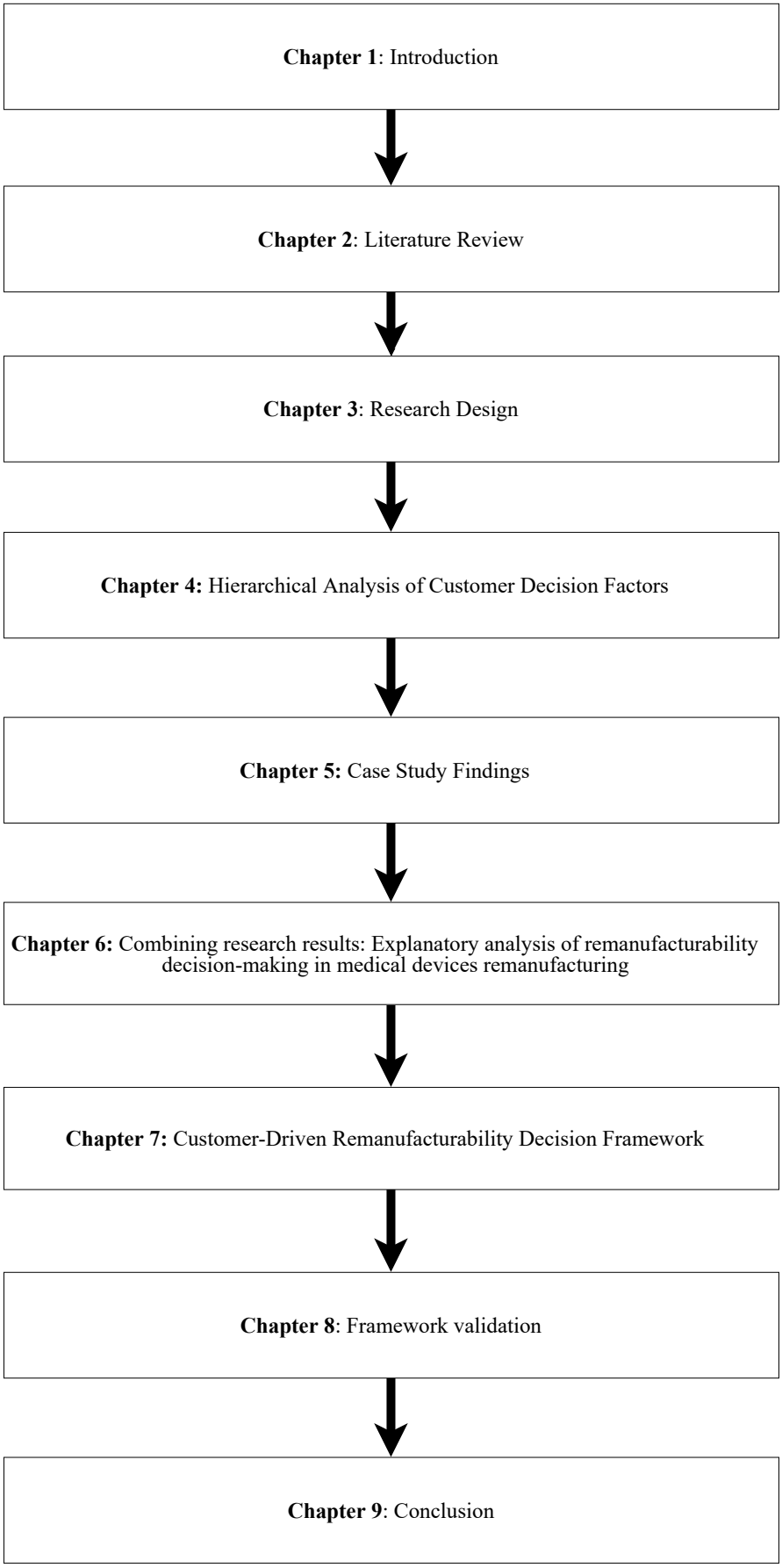

Figure 1-4: Thesis structure

Chapter Two: Literature Review

2. Chapter Two: Literature Review

Existing knowledge or literature is the foundation upon which every academic research is built. Literature review has been described as a "systematic approach to collect, synthesize, analyse, and understand knowledge contained in previous research (Baumeister and Leary, 1997; Tranfield, Denyer and Smart, 2003; Snyder, 2019). As described by Snyder (2019), there are 3 main approaches to conducting a literature review: systematic, semi-systematic and integrative. However, other approaches such as meta-analysis (Liberati et al., 2009; Davis et al., 2014) and the snowballing approach (Wohlin, 2014) have also been described in literature.

This chapter attempts to answer RQ1, and RQ2. It also provides some background on RQ3 and RQ4. Thus, it provides the theoretical background upon which this research is built. This rest of this chapter is structured as follows. Section 2.1. presents the state-of-art in remanufacturability decision-making and section 2.2. presents a review of medical devices remanufacturing. The conclusion of this chapter is presented in section 2.3.

2.1.State-of-Art in Remanufacturability Decision-Making

2.1.1. Introduction

Remanufacturability decision-making is a critical process for businesses engaging (or planning to engage) in remanufacturing to assess the viability and feasibility of remanufacturing a product. Evidence from existing research has shown that remanufacturability decision-making is a complex topic which requires consideration of different factors. This section sets out to perform a review of stakeholder considerations in remanufacturability decision-making.

This section uses the systematic literature review approach and presents the state-of-art in remanufacturability decision making, focusing on the key stakeholders, and their considerations during the decision process. A systematic literature review (SLR) is an autonomous study that reviews existing research following a systematic, clearly defined, rigorous and logical protocol with the aim of answering specific research question (Linnenluecke et al., 2020; Okoli & Schabram, 2012).

2.1.2. Review method

Remanufacturability decision-making is an active area of research, and discussions have been ongoing for more than 30 years. Early researchers such as Hammond, Amezquita and Thierry laid the groundwork for research on this topic with their publications (Amezquita et al. 1995; Thierry et al. 1995; Bras and Hammond 1996). Over the years, the number of publications in this area of research have increased significantly. The figure 2-1 below shows the number of publications per year, from 1998 to 2022, which contained "remanufacturability decision-making".

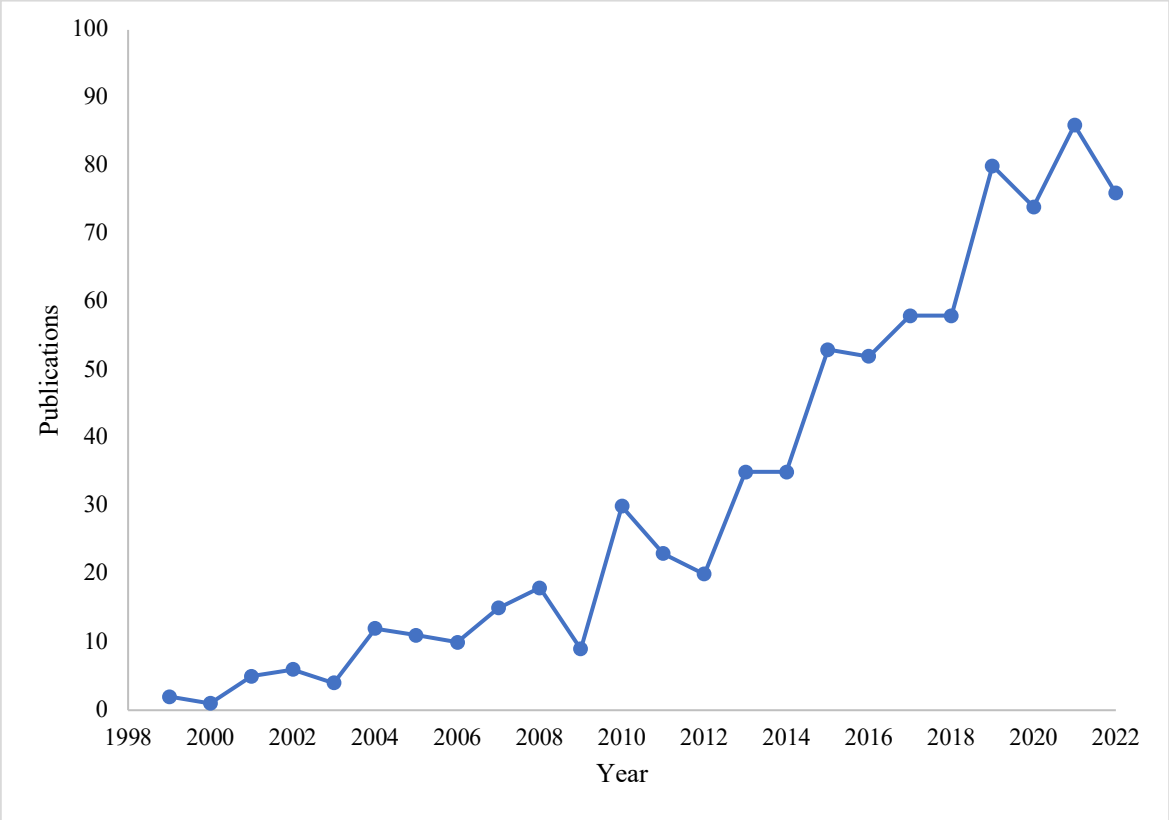

Figure 2-1: Publications per year on Scopus database searching the keyword "remanufacture AND decision AND making" – 1999 to 2022*

Therefore, a systematic approach to literature review method is adopted in this section due to its rigor, transparency, and robustness (Davis et al., 2014; Kraus et al., 2020). The systematic literature review method has been suggested to be useful in managing large amount of information or data in existing publications (Linnenluecke et al., 2020; Suchek et al., 2021; van Dinter et al., 2021). In the remanufacturing research domain, the use of a systematic literature review method is common, and it has received wide adoption among scholars in the field such as (Goodall et al., 2014; Maqbool et al., 2019; Ni et al., 2021;

Sitcharangsie et al., 2019). More so, its adoption in a PhD or doctoral thesis has been discussed (Sambunjak and Puljak 2010; Pickering and Byrne 2014).

This section uses the guideline to systematic literature review described by (Snyder 2019). The systematic literature review was conducted in four steps: a) designing the review approach, b) searching literature, c) criteria for including publications, and d) analysis of the selected publications.

2.1.2.1. Design of the review approach

The overall aim of this section is to identify and assess remanufacturability decision factors from the viewpoint of the stakeholders whose considerations are critical to the effectiveness of the decision process. The author aims to search existing databases that contain publications in the remanufacturing domain where this research is situated. The specific search keywords are related to remanufacturing or remanufacturability, and "decision-making" can be used interchangeably with "assessment" or "evaluation" in remanufacturing literature.

2.1.2.2. Literature search

The effectiveness of systematic literature review is in its strict and transparent approach to literature search and article selection (Kitchenham and Charters, 2007). The depth and rigour of a systematic search is reflected in the selection of keywords and the search databases (Snyder 2019).

2.1.2.2.1. Search keywords

Keywords selected for the literature search were *"remanufacturability", "remanufactur* decision factor", "decision making", "decision support", "remanufactur* factor"*, *"remanufacturability assessment"* and *"remanufacturability evaluation"*. These keywords were selected because they relate directly to the research topic and provide comprehensive coverage that would help the author achieve the aim of this review. The wildcard "*" was used to increase the inclusiveness of the search and ensure that words like remanufacture, remanufacturing, remanufacturability, remanufacturable and remanufactured are included through the keyword *"remanufactur*"*.

2.1.2.2.2. Search databases

Search databases selected for this section were the *Scopus*, *Web of Science* and *ProQuest* databases. These databases are widely used in remanufacturing literature, and they index peer-reviewed journals and international conferences that publish materials on remanufacturing. Since neither database has everything, a combination of the three provides exhaustive search results. Moreover, these databases rely on robust criteria set by editors to select good quality publications across journals and conference proceedings (Burnham 2006).

2.1.2.3. Criteria for including publications

Inclusion criteria are important in systematic literature review because it would be tedious to review all the publications returned in initial literature searches. Also, it is important to ensure that all the materials reviewed meet specific criteria that are critical to the research focus and helps in developing a comprehensive understanding of remanufacturability decision-making from the perspectives of the stakeholders. Research publications that meet the following criteria were included in the review:

- Peer-reviewed publications written in English language, published in journals or international conferences
- Articles relating to end-of-life recovery strategy planning and articles that discuss remanufacturing decision making of "*whether or not*" to remanufacture a product in their abstracts.
- Articles that deal with specific topics such as product designs, remanufacturing technology, sustainability, OEMs, TPRs and customers focusing on product remanufacturability decision-making.
- Articles published not later than August 2022.
- Articles with full texts available online

2.1.2.4. Analysis of selected publications

The results from the initial search returned a total of 13444 publications and is shown in table 2-1.

Table 2-1: Keyword search results

Keywords	Web of Science	Scopus	ProQuest
Remanufacturability	103	142	208
Remanufactur* decision factor	309	267	5191
Remanufactur* and "decision making"	665	727	3958
Remanufactur* and "decision factors"	6	6	60
Remanufactur* and "decision making factors"	2	3	23
Remanufactur* and "decision support"	74	99	1164
Remanufacturability assessment	30	39	143
Remanufacturability evaluation	35	48	142
TOTAL	**1224**	**1331**	**10,889**

The results were assessed in seven stages. The search results from the three databases were merged and the duplicates were removed. Articles that were not written in English language were excluded. Further, articles with incomplete information, such as missing author details, doi, titles and abstracts, were also removed. The titles and abstracts were then assessed to eliminate unrelated studies. Afterwards, articles with full-texts inaccessible by the author were removed. Then a 'bird-eye' scanning of the downloaded full-texts articles was performed, and unrelated articles were removed (Priyono, Ijomah, and Bititci 2016). The final articles were further screened against the inclusion criteria to ensure that they are appropriate for this study. The systematic literature search process is shown in figure 2-2.

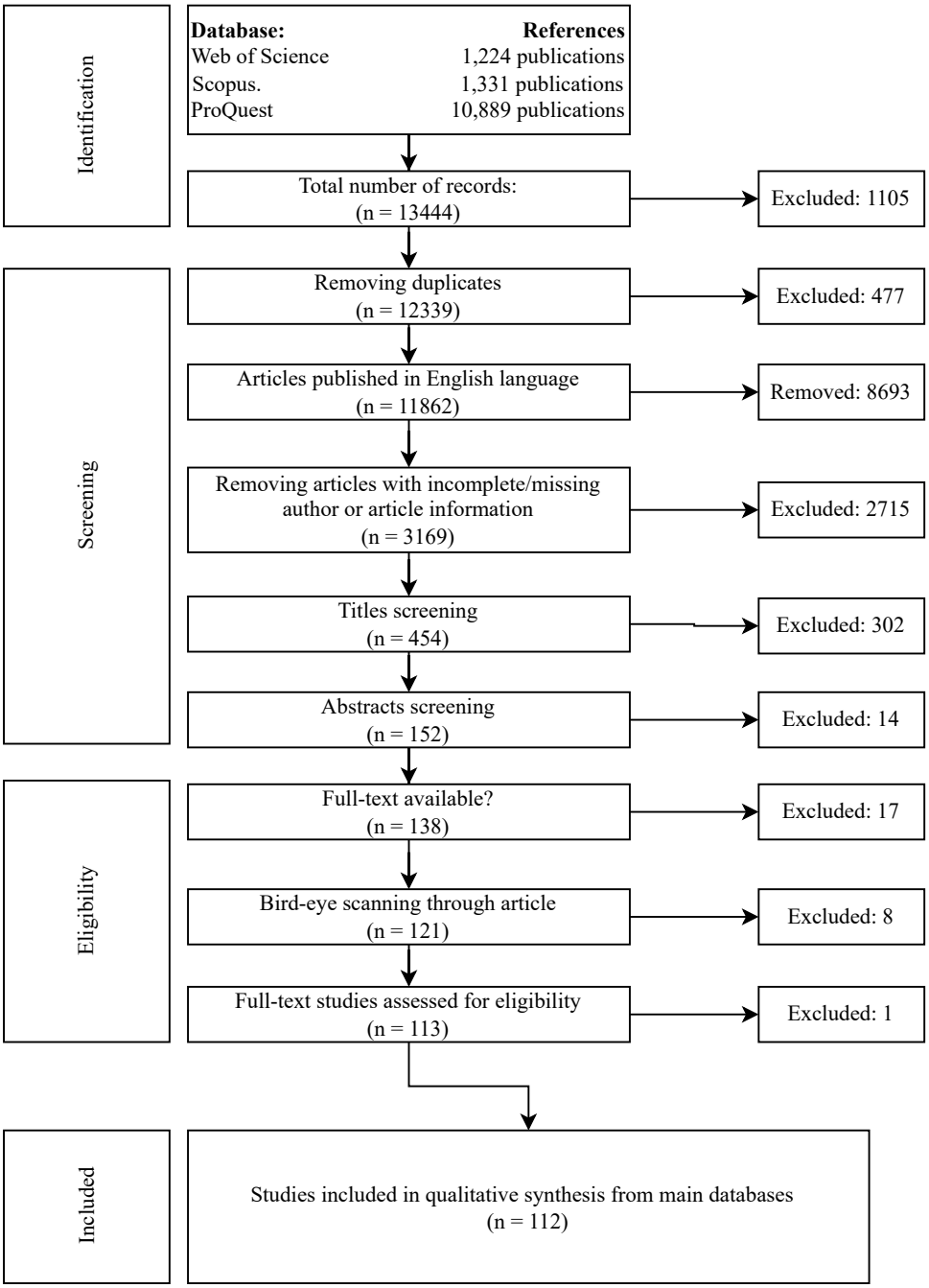

Figure 2-2: Results of systematic literature search

A total of 112 publications were included in the literature review. The number of publications per year reviewed in this section are shown in figure 2-3 and this shows the increase of research focus in this area over the past 10 years

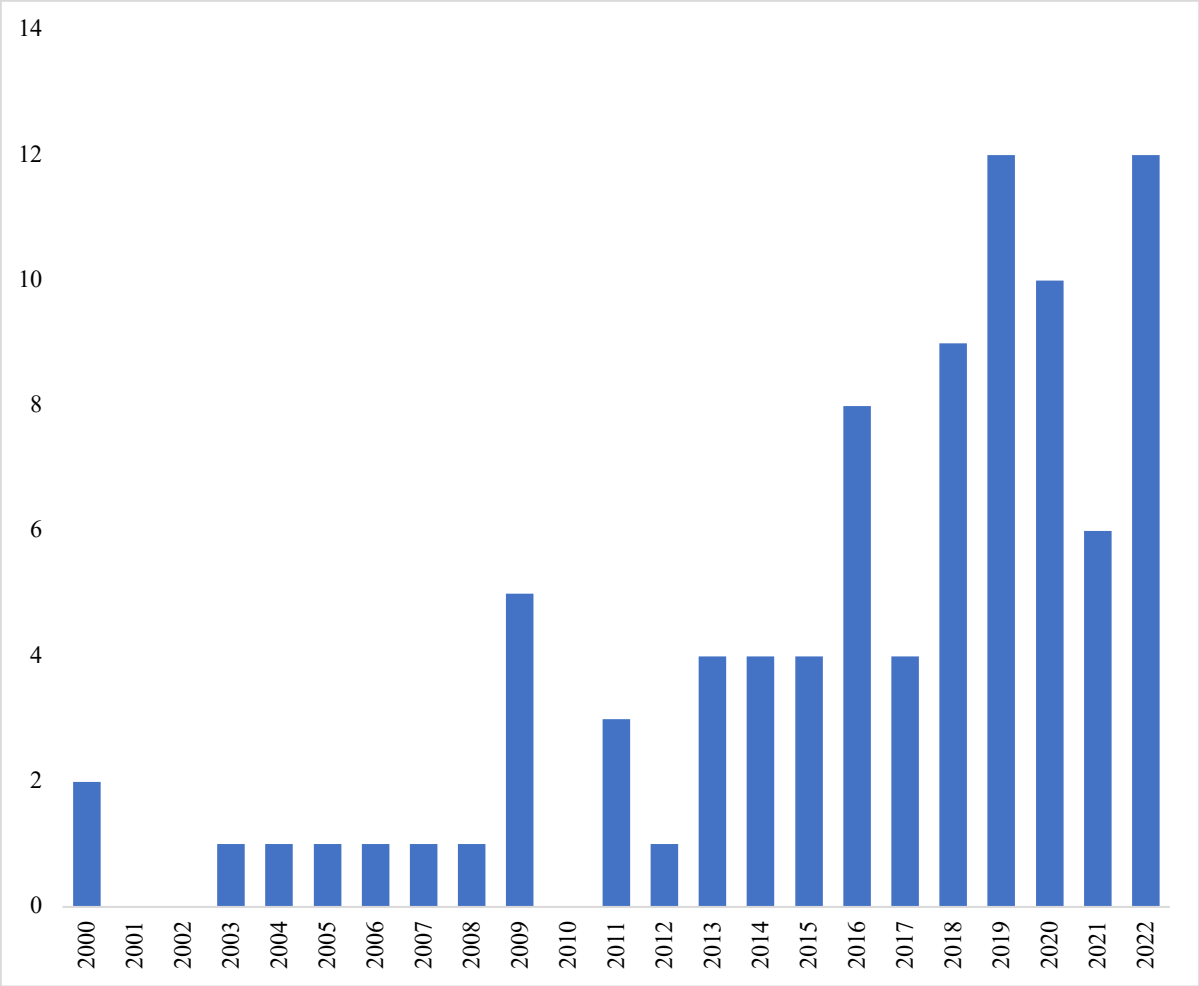

Figure 2-3: Publications per year reviewed in this section – 2000 to 2022

2.1.3. Remanufacturability decision-making factors

The review of existing literature performed in this section identified three key assessment areas contained in remanufacturability decision-making. They are:

1. Sustainability models,
2. Product models and
3. Technology models

These assessments involve a holistic understanding and comprehensive assessment of different factors which are critically evaluated during the remanufacturability decision process. Sustainability assessment of remanufacturability covers economic, environmental, and social factors; product assessment covers product design factors, and management of returned products (or cores); technology assessment covers the ease of performing the remanufacturing operation factors and the technological capability of companies to

remanufacture specific products. Further discussions on these models are presented in the following sub-sections and is shown in figure 2-4.

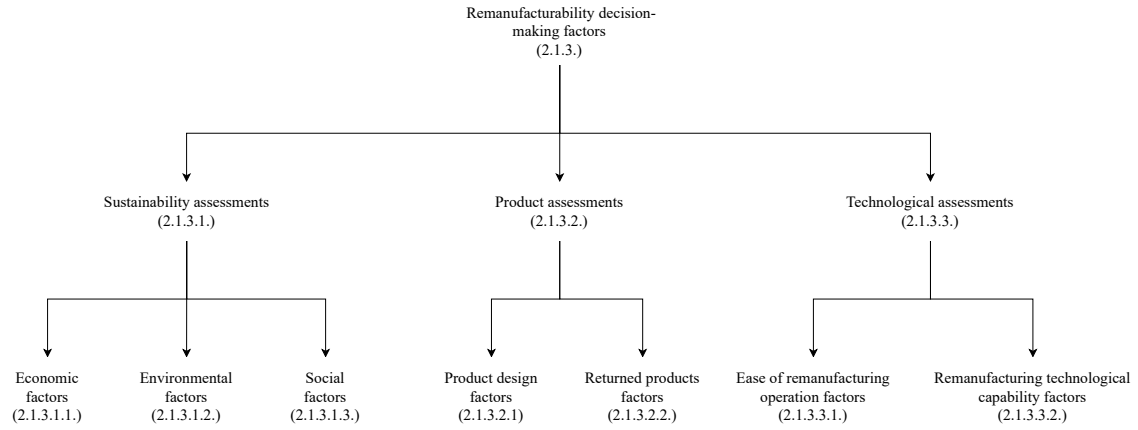

Figure 2-4: Overview of remanufacturability assessment factors

2.1.3.1. Sustainability assessment

Existing literature on sustainability assessment of remanufacturability is extensive and focuses particularly on the triple bottom lines of sustainability shown in figure 2-5 (Alhaddi, 2015; Okorie et al., 2021; Slaper & Hall, 2011). Existing literature on sustainability remanufacturability assessment has established the importance of sustainability factors (i.e., economic, environmental, and social factors) when assessing the viability of remanufacturing. The overall aim of the sustainability remanufacturability assessment is to answer the question, "*will remanufacturing a product improve the economic, environment and social situations*?"

The first discussions and analyses of factors used in sustainability assessment of remanufacturability emerged during the 1990s when Amezquita et al., (1995) identified key remanufacturability decision factors such as economic and environmental (Amezquita et al. 1995). The study established specific criteria for remanufacturing automobile doors. These criteria focused on product design factors, economic considerations, and environmental factors. The importance of sustainability considerations in remanufacturability decision-making is still well discussed. These factors have been established as the basic requirements for assessing the viability and feasibility of remanufacturing a product. More recently, Goodall et al., (2014) highlighted the importance of sustainability factors when assessing the feasibility of remanufacturing (Goodall, Rosamond, and Harding 2014). Golinska et al. (2015) took the discussion further by proposing a holistic remanufacturability decision-making tool based on the three pillars of sustainability (Golinska et al. 2015). Also,

Karaulova and Bashkite (2016) used sustainability factors in their proposed integrated remanufacturability assessment method for used industrial equipment (Karaulova and Bashkite 2016). Further, Golinska and Kuebler (2014) discussed a comprehensive sustainability model for assessing remanufacturing operations of SME's (Golinska and Kuebler 2014). Alamerew and Brissaud (2019) proposed a Product Recovery Multi-Criteria Decision Tool (PR-MCDT) to evaluate product recovery alternatives at the strategic level (Alamerew & Brissaud, 2019). The study used environmental, economic, and social indicators to evaluate product end-of-life alternatives. Otieno et al., (2020) also developed a framework for assessing the remanufacturability of office furniture using sustainability criteria (Otieno et al., 2020). Collectively, these studies outline the critical role of sustainability considerations when assessing product remanufacturability.

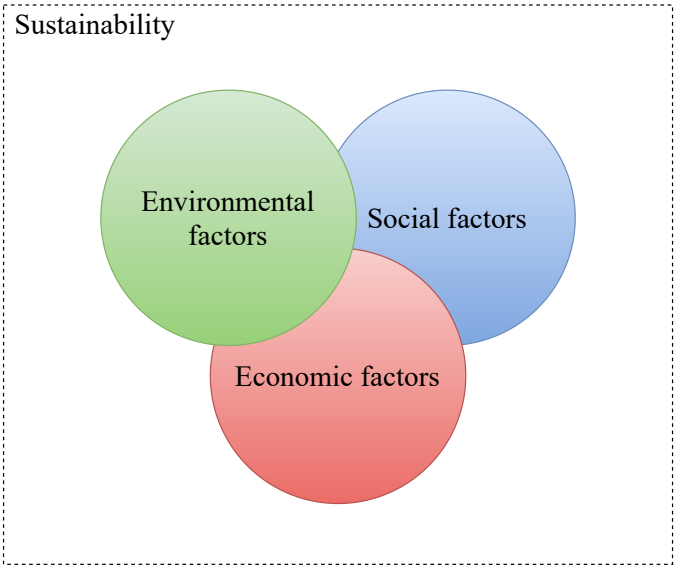

Figure 2-5: Triple bottom line of sustainability assessment

Further discussions on the decision factors that make up sustainability remanufacturability assessment are presented in three sub-sections: economic, environmental, and social factors discussed below. Table 2-2 highlights these decision factors, and includes the methods, product or industry, and the stakeholder considered in the assessed literature.

Table 2-2: Summary of the sustainability metrics used for remanufacturability assessment

References	**Sustainability factor considered**			**Description**				**Stakeholder considered in study**		
	Economic	Environmental	Social	Aim of study	Method	Level of decision	Product/ Industry	OEM	TPR	Customer
(H. C. Zhang et al. 2004)	Costs, Profit	Unclear	N/A	Assess remanufacturability	Quantitative	Product	Desktop computer	✓		
(González and Adenso-Díaz 2005)	Profit	Resources consumption, Waste generation	N/A	End of life strategy selection	Quantitative	Product	Mobile phone	✓		
(Gehin, Zwolinski, and Brissaud 2008)	N/A	Regulations, Material consumption, Pollution from process	N/A	Improve design for remanufacturing (DfRem)	Qualitative	Products	Cement Mixer	✓		
(Subramoniam, Huisingh, and Chinnam 2009)	Cost, Price	Regulations, Firm's green image	N/A	Improve remanufacturability decision-making process	Qualitative (Review)	Product	Automotive industry	✓		✓
(Jiang et al., 2011)	Costs	Process waste emission, energy efficiency, material consumption	N/A	Remanufacturing technology selection	Quantitative	Company	Valve stem	✓		
(Subramoniam et al. 2013)	Financial impact, Disposal costs Product value	Regulations, Green perception	N/A	Assess remanufacturability	Quantitative	Product	Automotive aftermarket	✓	✓	✓

(Ng et al. 2013)	Recovery costs	GHG emissions	No of workers, Skill, Salary	Assess remanufacturability	Quantitative	Product	Hair dryer		✓	✓
(Goodall, Rosamond, and Harding 2014)	Costs, Value	Waste generation, Energy consumption, Legislations	Human factors Societal factors	Assess remanufacturability	Qualitative (Review)	Unspecified	1. Wind turbine gearbox 2. Automotive parts 3. Industrial machine parts 5. Gearboxes	✓	✓	
(Yang, Ong, and Nee 2015)	Costs	Material consumption, Energy consumption, Wastes generated Toxicity discharged	N/A	Assess remanufacturability	Mixed	Component	1. Alternators 2. Hedge trimmer		✓	
(Golinska et al. 2015)	Costs	Energy consumption, amount of wastes generated, material recovery rate, and amount of generated emissions	Employment Hazards on workers Level of innovation	Measuring company's sustainability level	Quantitative	Company	Automotive remanufacturing sector		✓	
(Yang et al., 2016)	Reman process cost, Added value	Regulation, Energy consumption	N/A	Assess remanufacturability	Mixed	Product	Desktop phones		✓	✓
(Karaulova and Bashkite 2016)	Costs	Material consumption, Energy consumption, Pollution	N/A	Assess remanufacturability	Quantitative	Product	Used Industrial equipment		✓	
(Y. Gao et al., 2018)	Costs, Profit	Material environmental impact	N/A	Assess remanufacturability	Quantitative	Product	Electric Motor		✓	

(van Loon and Van Wassenhove 2018)	Costs	Environmental impact	N/A	Assess remanufacturability	Quantitative	Company	Chassis manufacturer	✓		
(Farahani, Otieno and Barah, 2019)	Costs, Revenue	N/A	N/A	Assess remanufacturability	Quantitative	Product	Personal Computer		✓	
(Pazoki & Zaccour, 2019)	N/A	N/A	Impact of regulations	Remanufacturing decision support system	Quantitative	Industry	Unspecified		✓	
(Alamerew & Brissaud, 2019)	Recoverable value Costs	CO2 emissions SO2 emissions Energy consumption	Number of employees Exposure to hazardous materials	Assess remanufacturability	Qualitative	Product	Light fiat engine	✓		
(Z. Hong et al., 2020)	Costs	N/A	N/A	Remanufacturing decision support	Quantitative	Unspecified	Unspecified	✓		
(Jiang et al., 2020)	Costs	N/A	N/A	Remanufacturing decision support	Quantitative	Product	DH220 excavator	✓	✓	
(Otieno et al., 2020)	Cost	Energy savings	Customer acceptance	Assess remanufacturability	Quantitative (fuzzy TOPSIS)	Product	Three pieces of furniture	✓	✓	✓
(H. Deng, 2020)	Remanufacturing process costs	Pollution Material Energy consumption Wastes generated	N/A	Remanufacturing decision support	Quantitative	Product	CNC machine tool		✓	
(S. Kim & Kwak, 2020)	Costs	N/A	N/A	Assess remanufacturability	Qualitative	Product	Cell phone		✓	
(Phuluwa et al., 2021)	Costs	Recovery rate	N/A	Assess product recovery alternatives	Quantitative	Product	Railcar bogie		✓	
(Kuik et al., 2022)	Warranty policy	N/A	N/A	Remanufacturing decision support	Quantitative	Product	Machine tool	✓		
(Gong et al., 2022)	Costs	Energy consumption Fuel consumption GHG emissions	Social recognition	Assess remanufacturability	Quantitative	Product	Machine tool		✓	
(Bhide & Akarte, 2022)	Costs	N/A	N/A	Assess remanufacturability	Quantitative	Product	Unspecified		✓	

2.1.3.1.1. Economic factors

For the past three decades, the profitability of remanufacturing for both the business and the customers have been demonstrated as a major remanufacturability consideration. An assessment of the possibility of remanufacturing a product, such that the remanufacturer makes reasonable profit and customers can be offered cheaper alternatives has become a common practice. This process is referred to as economic remanufacturability assessment, and it has been applied exhaustively in academic literature. The two leading economic remanufacturability decision factors are *costs* and *price*. Cost has been described as the financial implication of remanufacturing a product, whereas price is the monetary value which the remanufactured product is offered to the customer.

When assessing economic factors for remanufacturability, the aim is to analyse the financial burden of conducting remanufacturing (S. S. Gan et al., 2019; Ullah et al., 2016). Goodall et al., (2014) suggested that the cost of remanufacturing is attributed to the steps and processes involved in remanufacturing, such as the cost of core acquisition, cost of disassembly, cost of cleaning, cost of inspection and sorting, cost of part remanufacturing, cost of reassembly and the cost of testing(H. Deng, 2020; Golinska et al., 2015; Goodall et al., 2014; Karaulova & Bashkite, 2016). Bhide and Akarte (2022) further assessed the feasibility of a hybrid manufacturing and remanufacturing system (HMRS) for essential commodities in the context of COVID-19 using reverse logistics, inspection and holding costs. These costs also include labour cost, material cost and other overheads (Goodall, Rosamond, and Harding 2014; Karaulova and Bashkite 2016), costs of disassembly, cost of cleaning and cost of replacement parts (Gong et al., 2022). These costs were modelled as a quadratic mixed integer programming (QMIP) problem in the decision support tool developed by Farahani et al., (2019) as operational cost, purchasing and under-stocking cost, setup or idle cost and revenue.

Subramoniam et al., (2009, 2013) identified key factors in remanufacturing decision-making through case study research and ranked these decision factors using the analytical hierarchical process (AHP) methodology. They further proposed a remanufacturing decision-making framework (RDMF) based on the ranked decision factors. Financial impact factor, which is synonymous to economic assessment, was ranked as the most significant factor in the decision-making model. The findings by Subramoniam (2013) further affirmed the importance of economic assessment in remanufacturability decision-making. It has been suggested that economic remanufacturing factors are affected by the quality of returned core

items, original design of the product, skill of the technician, available tools, machines, and remanufacturing technology (Alamerew & Brissaud, 2019; Golinska et al., 2015; Goodall et al., 2014; X. Hong et al., 2020; Kin et al., 2014). This inter-relationship between remanufacturability decision factors is critical to optimising the decision-making process.

As a result, several methods, frameworks, and models have been proposed to assess remanufacturability of products from an economic standpoint. Zhang et al., (2004) proposed a web-based tool for product end of life decision support which uses cost and profit function to assess the economic viability or feasibility of remanufacturing. Deng (2020) also developed a web-based machine tool remanufacturing decision management system which estimates remanufacturing process costs as major remanufacturability factor. The remanufacturability decision support tool developed by Yang et al., (2016) incorporated economic index by assessing the added-value and the overall cost of remanufacturing a product. They further deployed economic assessment at the component-level remanufacturability assessment. The component-level economic index was quantitatively measured as a trade-off between the costs of disposal and the cost of returning the individual product components to like-new condition. Jiang et al., (2011) also focused on component remanufacturability and developed a multi-criteria decision-making (MCDM) model based on the AHP methodology for selecting appropriate remanufacturing technology. Jiang et al 2020 proposed a data-driven method to analyse and predict remanufacturing cost as a critical step in evaluating the viability of remanufacturing and focused on certain products. Phuluwa et al (2021) proposed mathematical models for estimating costs associated with remanufacturing and other end of life product recovery strategies. Recently, Kim and Kwak (2020) and Kuik et al (2022) developed an economic optimisation model for remanufacturing decision support system (DSS). While Kim and Kwak (2020) assessed product factors such as product line, model age, and the end-of-life quality, Kuik et al (2022) evaluated warranty options as a critical economic. These tools and models have included direct and indirect economic factors for remanufacturability and have included approaches to assess the economic viability and feasibility of remanufacturing. These studies have highlighted the importance of cost-effectiveness and the profitability in remanufacturability decision-making. The studies presented so far provide evidence, mostly from viewpoint of the remanufacturers, on the economic factors that are assessed during remanufacturability decision-making. However, very little is known about how economic considerations that

relate to the customers (e.g., purchase price, maintenance costs, disposal costs etc) influence or improve economic remanufacturability assessment.

2.1.3.1.2. Environmental factors

The disposal or incineration of end-of-use or end-of-life products pose significant environmental challenges (Vaverková, 2019; H. L. Zhao et al., 2021). With remanufacturing, used items are redirected through multiple lifecycles and thus reducing wastes sent to landfill. Also, since used products serve as raw materials for the remanufacturing process, limited resources (including the materials, energy, and costs) are required for the recovery process. Assessing the environmental impacts of remanufacturing has been a leading consideration in remanufacturability decision-making. Researchers, over the years, have assessed the environmental impact of both used products and the remanufacturing process as the basis for evaluating the viability of remanufacturing (Gong et al., 2022; González & Adenso-Díaz, 2005).

Assessment of environmental factors in the product remanufacturability decision-making has been prioritised by researchers. For example, Subramoniam et al., (2009) identified environmental factors as a key strategic decision factor for remanufacturing. As a follow-up to their study, they proposed a remanufacturing decision-making framework (RDMF) which ranked environmental consciousness as the fourth most critical factor for businesses in manufacturing and remanufacturing sectors. This reiterates the criticality of assessing environmental metrics, especially during remanufacturability decision-making.

Many remanufacturability environmental assessment methods have been proposed in literature. These remanufacturability models include different environmental factors. Jiang et al., (2011) proposed a multi-criteria decision-making (MCDM) model for selecting technological approach for remanufacturing certain products. The proposed model assessed the environmental impact of remanufacturing by measuring the process waste emission, energy, and material consumption. Yang et al., (2015) presented a decision tool to assess remanufacturability at the component level. In the model, the environmental assessment was based on similar factors of material usage, energy consumption, quantity of wastes and toxic substances discharged. Golinska et al., (2015) presented a set of assessment criteria to evaluate the sustainability of remanufacturing companies by applying the Grey Decision Making (GDM). They further proposed a remanufacturability decision-making tool which measured environmental performance using energy consumption level, quantity of wastes

generated, material recovery rate, and amount of generated emissions per remanufactured item. Similarly, Alamerew and Brissaud (2019) proposed a Product Recovery Multi-Criteria Decision Tool (PR-MCDT) to evaluate product recovery alternatives using a combination of different factors. Environmental factors in the proposed model include SO_2 and CO_2 emissions, and energy consumption requirements. Karaulova and Bashkite (2016) developed a remanufacturability assessment model based on technological, environmental, and economic factors. The environmental assessment component of the model analysed the benefits of remanufacturing from a material and energy saving and pollution reduction standpoint. Yang et al., (2016) then proposed a design for remanufacturing and remanufacturability assessment (DRRA) tool to be incorporated during the product development phase. The DRRA tool consider environmental factors as a critical consideration and assessed the environmental viability of remanufacturing a product and/or its component by measuring the energy consumption during the remanufacturing process. Van Loon and Van Wassenhove (2018) proposed a quick decision support tool for remanufacturing organisations to assess the economic and environmental impact of remanufacturing.

Taken together, these studies highlight the importance of environmental factors in remanufacturing decision-making. They have included factors such as the quantity of wastes generated and energy consumption during material extraction and original manufacturing process, and GHG emissions as key factors driving remanufacturability. Further, environmental legislations have continued to drive research and industrial activities in remanufacturing. As a result, some scholars have taken a legislative approach to assessing environmental remanufacturability factors. Gehin et al., (2008) reviewed the concept of extended producer responsibility (EPR) regulations in Europe, which include the End-of-life Vehicle (ELV) and the Waste of Electrical and Electronic Equipment (WEEE). The presence of these regulations has resulted in original manufacturers improving their product designs to reduce environmental impact. Further, Seitz (2007) assessed the driving motives for remanufacturing, with a focus on the impact of existing legislations (such as WEEE and ELV). The study found that the impact of existing legislations on remanufacturing or remanufacturability decisions is minimal compared to other factors such as profitability (covered in the economic models), warranty, spare parts supply, and brand protection (Seitz 2007). Contrarily, Subramoniam et al., (2009) argued that these EPR regulations can be a major determinant for remanufacturing decision-making. However, in a follow up study,

they ranked the impact of government regulations on remanufacturing decision-making as 6th (out of 9 factors) which corroborates the previous study by Seitz (2007), and it signifies a relatively low impact of regulation/legislations on remanufacturing decisions (Pazoki & Zaccour, 2019; Subramoniam et al., 2013). Yang et al., (2016) took this a step forward when they included compliance with local legislation as an important consideration when assessing remanufacturability of a product.

These studies indicate the direct impact of assessing environmental factors in remanufacturability. There remain several aspects of environmental remanufacturability models about which relatively little is known. For example, existing discussions on environmental assessment is lacking a perspective of the customers view of the environmental benefits of the remanufactured product or the green image of the remanufacturing organisation and how that affects the company's remanufacturability decisions. Also, customers' environmental involvement, which plays a critical role in customer acceptance (Singhal et al., 2019), has not been adequately catered for in existing environmental remanufacturability models. Existing models tend to focus on the remanufacturer which could be indicative of the original manufacturer/remanufacturer (OEM) or a third party (TPR).

2.1.3.1.3. Social factors

Assessment of social factors in remanufacturability models have focused on the impact of remanufacturing on the people and the local community. This has less to do with the product and more on the remanufacturing process and remanufacturing organisation. Goodall et al., (2014) identified two dimensions of social impact assessment, which are the human factors and societal factors. The human factor relates to the individuals within the remanufacturing business. These include employees, customers, and business partners etc. Societal factors focus on the immediate community where the remanufacturing operation is conducted or the direct beneficiaries of the remanufactured products. Remanufacturing operations are mostly manual or semi-manual operations which requires high level of manual labour (Ijomah 2002). Moreover, remanufacturing organisations rely on judgement and experience of technical personnel in making business decisions (Golinska and Kuebler 2014).

Although, economic and environmental factors have been at the fore front of remanufacturability decision-making, social factors have not received much attention. Goodall et al., (2014) described social remanufacturability decision factors as the least

explored in sustainability assessment. Social considerations require more research effort to better define social perspectives under circular and product recovery strategies (Sassanelli et al., 2020; Zarte et al., 2019). Social remanufacturability decision factors that have been discussed in literature include low-cost alternatives, additional job creation, safety of remanufacturing process, customer satisfaction, workplace design, ergonomics and safety, training and development of employees, innovation management, corporate image (Golinska and Kuebler 2014; Goodall, Rosamond, and Harding 2014; Dowlatshahi 2005; Seitz 2007). The social performance assessment framework proposed by Golinska et al., (2015) used factors such as employment, hazards related to the remanufacturing process, and level of innovation. Raz et al., (2017) assessed the decision trade-off between environmental and social impacts of remanufacturing. With focus on the impact of regulations, Pazoki and Raccour (2019) proposed a general too to incorporate regulations in remanufacturing decision support system. This tool targets social planners and assesses the impact of subsidies and penalties on remanufacturing and remanufacturability.

Overall, there seems to be some evidence to indicate that researchers are beginning to understand the importance of assessing social factors in remanufacturability (Raz, Ovchinnikov, and Blass 2017). However, there remain several aspects of social impact assessment which has not yet been investigated. For example, customers are usually a part of the social aspect of remanufacturing, however the social impact of the customers has not been comprehensively assessed nor included in existing remanufacturability decision-making models.

2.1.3.2. Product assessment

Apart from sustainability models, researchers have also adopted a product-focused remanufacturability decision-making approach. Remanufacturability product assessment evaluates the feasibility of remanufacturing a product based on the conditions and characteristics of that product. This covers an assessment of the product structure or product design and the condition of the returned products (cores). Product assessment models have been used as far back as 1995 and 1996 when Amezquita et al., (1995), and Bras and Hammond (1996) proposed methods to assess remanufacturability based on specific characteristics of the product (Amezquita et al. 1995; Bras and Hammond 1996). The literature on remanufacturability product models has highlighted the many ways in which the characteristics of products have been used to assess remanufacturability. Thus, different tools, methods and frameworks have been proposed in existing literature to aid the decision

on the feasibility and viability of remanufacturing a product. In the following sub-sections, two product assessment factors are discussed – product design factors, and core (or used product) management factors.

2.1.3.2.1. Product design factors

Much of the literature since the mid-1990s have emphasised the importance of product design on remanufacturability. In recent years, the volume of literature that have assessed the impact of product design on the feasibility or viability of remanufacturing has increased. In 2009, Subramoniam et al., (2009) identified product design as a critical factor in strategic decisions to remanufacture a product (Subramoniam, Huisingh, and Chinnam 2009). Their follow-up study ranked product design relatively low on importance when compared to other factors in the decision to remanufacture (Subramoniam et al. 2013). Conversely, many chains of evidence in literature have supported initial assertion about the impact of product design on remanufacturability decision-making (Balamuralitharan, 2022; Fang et al., 2015; Hatcher et al., 2013; Rentizelas & Trivyza, 2022; Shi et al., 2016; Subramoniam et al., 2009). Growing body of literature in remanufacturing have focused on design for remanufacturing (DfRem) as an approach to improve remanufacturability. The evidence reviewed suggest a pertinent role for product design on the ease of remanufacturing. The focus of the discussion in this section is not on design for remanufacturing as an area of remanufacturing research. Therefore, only a few studies that have applied design for remanufacturing (DfRem) principles in product remanufacturability are discussed. Some literature review articles on DfRem include Fegade et al., (2015) which reviewed the different methods and tools that have been used in design for remanufacturing with a focus on its impact on remanufacturing decision systems (Fegade, Shrivatsava, and Kale 2015). Prendeville and Bocken (2017) explored design for remanufacturing and remanufacturing business models (Prendeville and Bocken 2017). In the same vein, Noor et al., (2017) reviewed existing design for remanufacturing techniques (Mohamed-Noor et al., 2017). Wahab et al., (2018) reviewed design for remanufacturing with specific applications in the marine sector (Wahab et al. 2018). Boorsma et al., (2020) reviewed the impact of technical design management on the implementation of design for remanufacturing (Boorsma et al. 2020). Sassanelli et al., (2020) further explored design contributions towards circular economy within a remanufacturing system (Sassanelli et al., 2020).

A few tools, methods, and models for remanufacturability have prioritised design considerations. These studies have used design data to examine remanufacturability. For

example, Ding et al., (2020) proposed an integrated multi-criteria decision-making (MCDM) approach that combines improved analytic hierarchy process (AHP) and connection degree-based technique of ranking preferences to guide designers when assessing remanufacturability at the strategic level. Further, James et al., (2021) proposed a remanufacturability index based on the design attributes. This tool is intended to enhance the performance of automobile systems at their end-of-Life thereby promoting remanufacturability. Kim et al., (2022) proposed an integrated methodology for design for remanufacturing by comprehensively including customer analysis and efficiency of the remanufacturing process. Xing et al., (2022) proposed an optimization model of product design scheme with a focus on remanufacturability. This model focused on improving the remanufacturability of waste lathe machine tools (Xing et al., 2022). In all these studies, breaking down the complexity of implementing design for remanufacturing is seen as a critical step to improving remanufacturability decision-making for both the OEMs and TPRs.

Methodologically, early studies have utilised qualitative approaches. For example, Ijomah (2009) proposed a design for remanufacturing (DfRem) guideline using qualitative case studies and workshop to assist designers in improving the feasibility of remanufacturing. Specific design characteristics considered in the guideline were the impact of material selection, assembly and joining technique, and product structure on the ease of remanufacturing processes. Similarly, Hatcher (2013) used case study research to highlight the operational factors that affect design for remanufacturing. The factors identified were related to the customers, designers' knowledge of remanufacturing process, suppliers, and OEM business requirements. In recent years, remanufacturability assessment of product design has become quantitative. For example, Yang et al., (2016) proposed a quantitative four-step decision model for assessing the viability of remanufacturing a product and its components. The component-level analysis in the proposed model quantitatively evaluates the impact of product design on remanufacturing feasibility. Also, Gehin et al., (2008) developed a remanufacturable product profile (RePro^2) tool to be used early in the design process to ensure that products are designed for sustainability, thereby improving remanufacturability. However, Chakraborty et al., (2017) took the discussion further when they developed a hierarchical model using Fuzzy AHP methodology to assess the remanufacturability based on specific design criteria. They focused on design characteristics that affect each step in the remanufacturing process. For example, design characteristics for

ease of disassembly may include fastener design, part accessibility, design modularity and number of parts.

Collectively, these studies outline a critical role for product design in remanufacturability decision-making. Studies reviewed in this section have highlighted design-related considerations such as materials selection, fastener design, product structure and accessibility of components as the common design factors assessed during remanufacturability decision-making. Based on the findings in literature on remanufacturability decision-making based on product design, the level of research in this area can be described is mature. However, the customer aspects of the importance of product design have not been considerably researched. Questions such as "*How does design for remanufacturing affect the customers?"* and "*To what extent does product design influence the customer's acceptance/perception of the remanufactured product?"* have not yet been answered. Existing research in this area also seem to have focused solely on the electro-mechanical remanufacturing sector, leaving other sectors unexplored. A summary of literature reviewed in this section is presented in table 2-3.

Table 2-3: Summary of product design remanufacturability models

References	Description	Method	Approach	Design criteria for remanufacturability assessment	Product/Industry considered
(Zwolinski, Lopez-Ontiveros, and Brissaud 2006)	Proposed an integration approach for remanufacturing challenges in the product design process	Qualitative	Case study	Design for remanufacturing factors	Multiple products
(Gehin, Zwolinski, and Brissaud 2008)	Proposed a RePro2 approach that can be used early in the design phase to improve product remanufacturability at its end-of-life.	Quantitative		Design for remanufacturing	Cement mixer
(Ijomah 2009)	Proposed a design guideline to improve remanufacturability of product designs	Qualitative	Case study Workshop	1. Material selection 2. Assembly technique 3. Product structure	Mechanical and electronic products
(Hatcher 2013)	Developed a method to help OEMs assess their design for remanufacturing maturity	Qualitative	Case study Semi-structured interviews	1. designer motivation 2. Designer knowledge and understanding 3. Management commitment 4. Design priorities 5. Product design specifications 6. design reviews 7. design tools	1. Diesel engines 2. Oil pump 3. Off-road equipment
(Subramoniam et al. 2013)	Proposed a remanufacturing decision-making framework based on strategic factors	Quantitative	Analytical Hierarchical process	Design for remanufacturing	Automotive aftermarket
(Yang et al., 2016)	Developed a decision support tool for planning product end of life recovery strategy	Mixed methods	Multi-stage approach using Case studies	Design viability	Desktop phones
(Chakraborty, Mondal, and Mukherjee 2017)	Proposed hierarchical model to evaluate remanufacturability based on design criteria	Quantitative Fuzzy AHP Fuzzy AD	Survey	1. Fastener design 2. Design modularity 3. Part accessibility 4. Product geometry 5. Material selection 6. Surface finishing 7. Part durability 8. Part restorability	Automotive diesel engine remanufacturing plant

				9. Part identification 10. Standardised parts 11. redundant parts	
(Wahab et al. 2018)	Reviewed design for remanufacturing issues in the marine industry	Qualitative	Literature review	1. durability of the materials, 2. product geometry, 3. design architecture, 4. design complexity and, 5. reliability of components and assemblies.	Marine or offshore components and structures
(Z. Ding et al., 2020)	Proposed an integrated MCDM approach to guide designers in evaluating product options	Quantitative AHP TOPSIS	Case study	Design characteristics	Machine Tool
(James et al., 2021)	Developed a remanufacturability index based on the design attributes	Quantitative	Case study	1. Re-assembly characteristics 2. Recoverability characteristics 3. Separability characteristics 4. Accessibility characteristic 5. Handling characteristics	Gearbox
(J. Kim et al., 2022)	Proposed an integrated DfRem methodology to solve bi-objective optimization problems	Quantitative		Design for disassembly	Mobile phones

2.1.3.2.2. Core management factors

Effective management of cores through efficient acquisition strategy, storage and handling approach is critical to a successful remanufacturing endeavour. It is now well established, that core management is critical in evaluating the viability and feasibility of remanufacturing. Wei et al., (2015) reviewed the adoption of quantitative models in the management of core acquisition. The study identified several key topics such as "acquisition control, forecast return, return strategies, quality classification and reverse channel design" (S. Wei et al., 2015). These topics have been translated into different factors for assessing product remanufacturability in literature such as the condition, quantity, and timing of returned cores or used products. A few studies have assessed product remanufacturability using these core management factors. An earlier study by Guide (2000) had highlighted uncertainty in timing and quantity of returned core items as one of the complicating characteristics of remanufacturing (Guide 2000). However, preliminary research linking core management with remanufacturability was undertaken by Subramoniam et al., in 2009 which suggested core management, represented by core availability or the ease of acquiring used items, as a backbone for successful remanufacturing activity and should be considered during remanufacturability assessment. They subsequently ranked core management as second most critical factor considered during remanufacturability assessment. This establishes the criticality of core management in the remanufacturability decision-making process.

Recent studies have attempted to integrate core management factors into existing remanufacturability models. Ostlin et al., (2009) incorporated difficulties and uncertainties involved with obtaining cores into the end of life decision-making. The study assessed the impact of timing and quantity of returned items on balancing the supply and the demand sides of the remanufacturing operation. A product-level feasibility analysis of remanufacturability proposed by Yang et al., (2016) evaluated the supply of cores needed to drive the remanufacturing process. The study assessed core supply using return potential of used products, which also deals with the timing, quantity, and quality of returned items. Zhao and Zhu (2017) proposed a mathematical model for managing reverse supply chain based on previous remanufacturability rates and potential demand situations (Zhao and Zhu 2017). Kim and Kwak (2020) assessed the remanufacturability of a cell phone using three product factors: product line, model age and the end-of-life quality of the device (S. Kim & Kwak, 2020). Ecer (2022) proposed interval type-2 fuzzy environment (IT2FAHP) model

to solve supplier selection problem in remanufacturability evaluations. Overall, these studies highlight decision factors such as the quantity of cores received in the remanufacturing facility and the time of receiving the cores as key remanufacturability decision-making considerations.

On the other hand, some studies have focused on the physical conditions or quality of returned cores. One of the early works, Sherwood et al., (2000) discussed the impact of failure and scrap modes of returned products on remanufacturability decision-making (Sherwood, Shu, and Fenton 2000). Teunter and Flapper (2011) described how the remanufacturability decisions are more difficult for poor quality cores compared to the relative ease of remanufacturing associated with good quality cores (Teunter and Flapper 2011). Kin et al., (2014) measured product remanufacturability by assessing the condition of returned cores using the FMEA approach. Yang et al., (2015) proposed a tool to assist decision-makers in assessing the remanufacturability of components. The first step in the decision tool involved a physical assessment of the returned cores to identify defects, failures, and damages of the part. Gao et al., (2018) focused on component-level remanufacturability assessment by evaluating the quality condition of returned items. They also assessed the uncertainty criteria associated with the quality condition of components of returned cores which forms a strong basis for the proposed model. Farahani et al., (2019) proposed a quality grading approach for returned core items using a case study of computer remanufacturing. They proposed a decision support tool which begins with an evaluation of the quality and quantity of retuned products. Bentaha et al., (2020) further proposed a decision tool for remanufacturability assessment under variability of the end-of-Life product quality. The tool focused on applying the remaining useful potential (RUP) of a product to evaluate the feasibility of remanufacturing the product. Wu et al., (2022) proposed a data-driven decision-making (DDDM) method based on Multi-Life Customization Scenarios (MLCS) (Wu et al., 2022). Moon et al., (2022) and Liu et al (2022) have also proposed the frameworks for remanufacturing decision-making based on the remaining useful life prediction of a product. One important theme that emerges from the analysis of these studies is how the quality or physical condition of cores influence the ease of remanufacturing, and consequently impacts the remanufacturability decision process. A summary of the reviewed articles is presented in table 2-4.

Table 2-4: Summary of literature on returned product assessment

References	Description	Method	Approach	Core management remanufacturability considerations	Products/Industry considered
(Guide 2000)	Identified and discussed certain characteristics that complicate end of life strategy planning for remanufacturing firms.	Quantitative	Survey	1. uncertainty in timing of return 2. quantity of returned cores	1. automotive. 2. aerospace, 3. machinery, 4. office equipment, 5. bearings, 6. gears, 7. pumps
(Sherwood, Shu and Fenton, 2000)	Analysed the waste stream of remanufacturing firms to understand the impact of failure modes on remanufacturability	Quantitative FMEA	Numerical example	Failure modes	Automotive
(Subramoniam, Huisingh, and Chinnam 2009)	Reviewed literature to identify gaps in automotive remanufacturing	Qualitative	Case study Semi-structured interview	Unclear	Automotive aftermarket
(Östlin, Sundin, and Björkman 2009)	Addressed the impact of balancing supply of cores and demand for remanufactured products on remanufacturing operations and firms	Qualitative	Case study Semi-structured interview	1. Timing of returned core 2. Quantity of returns 3. mean product lifetime, 4. rate of technical innovation 5. failure rate of components	1. Forklift trucks 2. Toner cartridges 3. Soil compactors 4. Filling machines 5. Engines 6. Automotive components
(Subramoniam et al. 2013)	Proposed a remanufacturing decision-making framework based on strategic factors	Quantitative Analytical Hierarchical process		Core Management	Automotive aftermarket
(Kin et al., 2014)	Assessed condition of returned cores for optimal remanufacturing operation planning	Quantitative FMEA	Numerical examples	Quality of returned core	Camshafts
(Yang, Ong and Nee, 2015)	Proposed a decision support tool to assess component remanufacturability after the product is disassembled to different components	Mixed Methods	Case study	Quality of returned core	1. Alternators 2. Hedge trimmer

(Yang et al., 2016)	Developed a decision support tool for planning product end of life recovery strategy	Mixed methods	Multi-stage approach using Case studies	1. return potential 2. remaining useful life	Desktop phones
(Y. Gao et al., 2018)	Proposed a multi-criteria decision-making method to find the best EOL options of component	Quantitative AHP	Numerical example	1. Quality condition a. physical condition b. obsolescence condition	Electric motor
(Farahani, Otieno and Barah, 2019)	Presented a framework to assist decision makers decide whether to remanufacture or replace parts during product remanufacturing	Quantitative	Case study (Numerical illustration)	Quality of returned core	Personal Computer remanufacturing
(S. Kim & Kwak, 2020)	Assessed the remanufacturability of a cell phone	Qualitative	Case study	1. product line, 2. model age 3. end-of-life quality of the device	Mobile phone
(Bentaha et al., 2020)	Proposed a decision tool for disassembly process planning under uncertain product quality	Quantitative	Mathematical modelling and case study	Remaining useful potential	Electronic Braking System (EBS)
(Ecer, 2022)	Proposed an interval type-2 fuzzy environment (IT2FAHP) model for solving supplier selection problem considering green concepts	Quantitative AHP	Fuzzy-AHP Case study	Reverse logistic issues	Home appliance
(Moon et al., 2022)	Proposed the framework for remanufacturing decision making based on the remaining useful life of a product	Quantitative	Process simulation	Remaining useful life	Gas Insulated Switchgear
(D. Liu et al., 2022)	Proposed a residual life prediction evaluation model based on a nonlinear continuous fatigue damage model	Quantitative	Analytical modelling	Remaining useful life	CAK5085 CNC lathes

Although critical aspects of core management such as quantity, quality and timing of return issues have received considerable research attention, there remains some customer-focused aspects of core management remanufacturability decision-making about which relatively little is known. For example, the impact of customers' return behaviour on the supply of cores has been neglected. Also, the nature of customers' use pattern across different sectors and its impact on the quality or timing of returns has not been dealt with in much detail.

2.1.3.3. Technological assessment

Remanufacturing involves many different activities such as core collection, disassembly, cleaning, sorting, reworking, reassembly, and testing. The overall goal of every remanufacturing operation is to return a used product to a condition similar to that of new with a matching warranty (Ijomah, 2002) by taking it through these activities. Therefore, a critical consideration during remanufacturability decision-making is the technological or technical factors that affect remanufacturing. These have been described in literature using two main themes: ease of performing remanufacturing operation and the technological capability of the remanufacturer. These two considerations are discussed below.

2.1.3.3.1. Ease of remanufacturing

The ease of remanufacturing is often directly linked to the design of the product. The aim of this assessment is to evaluate the ease of putting a used product through the various activities involved in remanufacturing. One of the early works in the area was by Amezquita et al., (1995) who developed a remanufacturing guideline that emphasises the ease of disassembly, ease of cleaning, ease of inspection, ease of part replacement and ease of reassembly (Amezquita et al., 1995). A broader perspective was adopted by Bras and Hammond (1996) who identified design metric as an important tool to measure product remanufacturability based on the ease of the remanufacturing process (Bras and Hammond, 1996). This metric includes assessment of disassembly and reassembly, assessment of inspection and testing, assessment of cleaning, and assessment of part refurbishment or replacement. These assessments were combined using factor weights obtained from pairwise comparison to give the overall remanufacturability index of a product. Further, Gonzalez and Adenso-Diaz (2005) proposed a model for determining the appropriate recovery strategy based on the product structure obtained from CAD representation (González and Adenso-Díaz, 2005). The model based on product design information

determines the disassembly sequence, disassembly depth and best end of life strategy for each component of a returned product.

Although many early studies on the ease of remanufacturing have been qualitative, recent studies have adopted a quantitative approach. The proposed remanufacturability decision tools by Ong et al., (2016) and Fang et al., (2014) included metrics for assessing the ease of remanufacturing. The assessment model for product remanufacturability proposed by Ong et al., (2016) was based on design information from CAD software, and it involved quantitative evaluation of factors that influence the ease of remanufacturing a product such as disassembly complexity, fastener accessibility, disassemblability and recoverability. These factors include the relative ease of disassembly, cleaning, part remanufacturing and reassembly. Karaulova and Bashkite (2016) proposed a decision support framework to quantitatively assess product remanufacturability using technological assessment, economic assessment, and environmental assessment. The technological assessment in they included measured the ease of steps in the remanufacturing process such as disassembly, cleaning, inspection and sorting, part reconditioning, and reassembly. Chakraborty et al., (2017) proposed a method for remanufacturability assessment which evaluated the ease of conducting each step of the remanufacturing process based on design characteristics. For example, the criteria for ease of cleaning can be evaluated using design surface smoothness, product geometry and material selection; criteria for inspection and salvaging can be evaluated using ease of part identification, part durability and restorability.

Results obtained from workshops and case studies conducted by Ijomah et al., (2004) provided deeper insights into specific product features and characteristics that affect the ease of the remanufacturing process. Over the years, researchers have focused on the different aspects of this remanufacturability assessment. However, disassembly activities have received considerable research attention. Refer to (Bentaha et al., 2020; de Fazio et al., 2021; Kroll et al., 1996; Vanegas et al., 2018). A review of remanufacturing production planning by Guide (2000) highlighted disassembly or disassemblability of cores as a critical factor that makes remanufacturing more difficult. Similarly, Zhang et al., (2004) developed a web-based end of life decision support tool for remanufacturability assessment. The tool identified ease of disassembly as one of the five key functions to assess remanufacturability. Gao et al., (2018) studied the uncertainty associated with the complexity of disassembly activity in two phases: joint type complexity, and technical complexity of components of returned products. Bentaha et al (2020) took this further when they developed a decision

tool on the disassembly process planning taking to tackle the complexity and criticality of disassembly activity in remanufacturing operations.

Other researchers have proposed tools to assist remanufacturers and decision makers with specific issues during the remanufacturing process. For example, Ng et al., (2013) proposed an OEM-focused decision support framework to assist decision makers during product disassembly, sorting and inspection phases of remanufacturing. Kafuku et al., (2016) proposed an evaluation framework for selecting remanufacturing technology or manual operations involved in the remanufacturing process. Lahrour and Brissaud (2018) presented a framework for assessing additive remanufacturability of components based on specific product characteristics which include the type of defects that a returned cores has and the ease of component remanufacturing using additive technology. More recently, Bentaha et al., (2022) proposed an optimisation disassembly decision tool using product quality and uncertainty of remanufacturing processing times. The proposed tool will assist decision makers during remanufacturability decision-making with a focus on the disassembly process.

2.1.3.3.2. Technology capability

Assessing the technological capability of a remanufacturer is critical in remanufacturability decision-making. This is because the feasibility of remanufacturing depends on the presence of manufacturing skills, expertise, and a technical understanding of the requirements of remanufacturing (Mukherjee and Mondal, 2009). Aside external factors such as the product design, the remanufacturability of a product is also influenced by the remanufacturer's organisation, technical, legal and process capability. Jiang et al., (2011) developed a multi-criteria decision model (MCDM) for selection and implementation of appropriate remanufacturing technology. The studies assessed provide evidence that factors such as the experience of the company in remanufacturing, presence of skilled staff, access to cores, technical understanding of product recovery and organisational production planning and management are critical technological factors. However, this area of research has not received enough attention.

A summary of literature reviewed to understand technology factors used in remanufacturability decision-making is presented in table 2-5.

Table 2-5: Summary of technological remanufacturability assessment factors

References	Description	Method	Approach	Technological remanufacturability considerations	Product/Industry considered
(Guide, 2000)	Identified and discussed certain characteristics that complicate end of life strategy planning for remanufacturing firms.	Quantitative	Survey	1. Disassembly of returned core 2. Material recovery uncertainty 3. Reverse logistics issues 4. Materials matching difficulties	1. Automotive. 2. Aerospace, 3. Machinery, 4. Office equipment, 5. Bearings, 6. Gears, 7. Pumps
(Zhang et al., 2004)	Presented a web-based tool to assess remanufacturability of end-of-life products	Quantitative (Numerical Analysis)	Case study	1. Product disassembly 2. Materials recovery 3. Recycling management	Desktop computer
(González and Adenso-Díaz, 2005)	Proposed a new approach for EOL strategy selection using information from 3D CAD representation, BOM, economic and technical data	Quantitative (Scatter Search Metaheuristics)	Case study	1. Disassembly sequence 2. Disassembly depth	Mobile phone
(Ijomah 2009)	Presented the findings of a study to understand product characteristics that complicate remanufacturing	Qualitative	Workshop	1. Core cleaning 2. Strip core (disassembly) 3. Component cleaning 4. Components remanufacture 5. Component storing 6. Product assembly 7. Product Testing	Automotive industry
(Jiang, Zhang and Sutherland, 2011)	Developed a multi-criteria decision model for selection of remanufacturing technology	Quantitative (AHP)	Illustrative examples	Company's technological capabilities	Valve stem
(Ng et al., 2013)	Proposed a product assessment framework for the OEM	Quantitative (Computation)	Case study	1. Product collection 2. Product sorting and inspection 3. Part disassembly 4. Part verification and value determination	Hair dryer

(Fang et al., 2014)	Proposed a remanufacturability assessment method based on 3D CAD representation	Quantitative (Numerical Analysis)	Case study	1. Disassembly complexity 2. Fastener accessibility 3. Disassemblability 4. Recoverability	Automotive alternator
(Karaulova and Bashkite, 2016)	Proposed an integrated method for evaluating remanufacturability of used industrial equipment.	Quantitative (Computation)	Case study	1. Ease of disassembly 2. Cleaning assessment 3. Inspection and sorting 4. Assessment of part reconditioning 5. Possibilities for machine upgrade 6. Ease of reassembly	Used Industrial equipment
(Kafuku et al., 2016)	Proposes a holistic framework to assess the feasibility of remanufacturing operation	Quantitative (multi-input-multi-outputs (MIMO) parameters in fuzzy logic)	Case study	1. Technology functions 2. Technology quality 3. Technology flexibility	Cylinder head for automotive engine
(Yang et al., 2016)	Developed a decision support tool for planning product end of life recovery strategy	Mixed methods	Multi-stage approach using Case studies	1. Remanufacturing know-how 2. Remanufacturing capability	Desktop phones
(Ong et al., 2016)	Proposed a remanufacturability assessment method based on 3D CAD representation	Quantitative (Numerical Analysis)	Case study	1. Disassembly complexity 2. Fastener accessibility 3. Disassemblability 4. Recoverability	Electric motor reducer
(Chakraborty, Mondal and Mukherjee, 2017)	Proposed hierarchical model to evaluate remanufacturability based on design criteria	Quantitative Fuzzy AHP Fuzzy AD	Survey	1. Disassembly 2. Cleaning 3. Inspection and salvaging 4. Reassembly	Automotive diesel engine remanufacturing plant
(Y. Gao et al., 2018)	Proposed a multi-criteria decision-making method to find the best EOL options of component	Quantitative AHP	Numerical example	1. Disassembly complexity a. Joint type of component b. Technical complexity	Electric motor
(Lahrour and Brissaud, 2018)	Proposed a framework to assess remanufacturability of components using additive technology	Unclear	Unclear	1. Product failure and inspection 2. Part remanufacturing	Unspecified

(Bentaha et al., 2020)	Developed a decision tool for disassembly process planning under product quality uncertainty	Quantitative (Numerical modelling)	Case study	Complexity of disassembly	Electronic Braking system
(Bentaha et al., 2022)	Proposed an optimisation tool to select the optimal disassembly process and depth	Quantitative (Mathematical modelling)	Case study	Disassembly depth	Hammer- drill Washing machine HG5-20 triaxial five speed mechanical transmission Mouse

2.1.4. Remanufacturability decision-making stages

Remanufacturability decision-making involves a consideration of many different factors which have been discussed in the previous section. These factors are often easily linked to different stages of the remanufacturing operation and the different stakeholders whose requirements are covered by these factors. Based on the extensive review of literature, the key stakeholders whose requirements are critical in remanufacturability decision process are the original manufacturer, the remanufacturer, and the customers. Zhang et al., (2017) explored remanufacturing of automotive parts in China focusing on the acquisition of cores, activities in the remanufacturing operation and marketing of remanufactured products (Zhang, Yang and Chen, 2017). They assessed the relationship between critical remanufacturing stakeholders such as the government, OEMs, external remanufacturers (ER which could be a contracted or a third-party remanufacturer), dealers or other players along the supply chain and the customers.

A successful remanufacturing operation hinges on the stakeholders playing their parts. For example, the OEMs are responsible for the product development and new manufacturing which impacts product design or structure, the customer returns the used product which makes the core available for remanufacturing, reverse logistics professionals have the duty to collect cores and make it available to the remanufacturer while the remanufacturer takes the used product to like new condition and provides a matching warranty for their customers.

The decision factors identified in literature have been categorised under three stages of remanufacturability decision making which are: strategic, tactical and operation decision stages. These stages (strategic, tactical, and operational) have been discussed extensively in (Goodall, Rosamond and Harding, 2014; Misni and Lee, 2017; Chakraborty, 2020). A description of the decision stages is shown in table 2-6 and it shows the remanufacturability decision factors identified in literature and the stakeholder that is covered during these stages.

At the *strategic stage*, decisions are made on the remanufacturability of a product fundamentally from a product design perspective. A critical consideration in strategic decisions is how organisations (i.e., OEM) ensure the remanufacturability of their products right from the initial planning or product development stage. The decision maker in this stage is the OEM and the considerations are mostly from the sustainability standpoint including the economic, social, and environmental factors (Abdulrahman et al., 2015).

The *tactical stage* is a level beyond the strategic stage, and it focuses on establishing the viability of remanufacturing. The key decision maker is the entity or organisation performing or intending to perform the remanufacturing. The key considerations during this stage are the product design and sustainability considerations from the organisations' point of view. This includes the expected profit/revenue, environmental impact of remanufacturing and the social impacts. The product design assessment evaluates the ease of remanufacturing based on the product design (Rizova, Wong and Ijomah, 2020).

The *operational stage* focuses on the technical feasibility of remanufacturing. At this stage, decision makers explore remanufacturability based on operational parameters such as the product structure and the ease of remanufacturing, core acquisition management and the technological capability of firms to perform remanufacturing. These operational decisions are usually made by the remanufacturer at the remanufacturing facility, and they focus on the process and product factors.

Table 2-6: Remanufacturability decision stages

Decision Stage	**Description**	**Stakeholder considered**
Strategic	Strategic decision stage targets early phases of product development to ensure and assess the viability of remanufacturing. Strategic models have included assessment metrics such as: 1. *Sustainability metric* including factors such as economic, environmental, and social considerations.	OEM
Tactical	Tactical decision stage focuses on product design as a tool to assess remanufacturability. Tactical remanufacturability metrics include: 1. *Product design metric* focusing on considerations such as the effect of product design on the ease of remanufacturing. 2. *Sustainability metrics*: in some cases, focusing on economic and environmental assessment.	Original Remanufacturer (OR) and External Remanufacturer (ER)
Operational	Operational decision stage focuses on the actual remanufacturing operation. Decision metrics used in this stage include: 1. *Core management metric* such as the quality, quantity, and timing of returned cores 2. *Ease of remanufacturing metric* such as the ease of disassembly, ease of cleaning, ease of inspection, ease of cleaning, ease of part remanufacturing, ease reassembly and ease of product testing. 3. *Technological capability metric* such as size of the facility, production capacity, technical know-how and available skills and expertise	ER (e.g., TPR or CR)

2.1.5. Stakeholder considerations in remanufacturability decision-making

The detailed review of remanufacturability decision-making performed in this section has indicated that the original manufacturer and external remanufacturers have received the most research attention. Many remanufacturability assessment models have used factors that are specific to these stakeholders and the consequence is a higher level of acceptance among these professionals. Organisations are now more willing to engage in remanufacturing, to reduce the complexity of their products and to assist in the collection of cores and marketing of remanufactured products (Saidani et al., 2020). While, the OEM is mostly involved in the early stages of product development, the remanufacturer is more involved in the actual remanufacturing process. However, the requirements of the customers in the remanufacturability decision mix have not been the focus of much research. Since customers are an integral part of sustainable development (Simpson and Radford, 2012), remanufacturing will only reach its full potentials when the requirements of all major stakeholders have been appropriately factored into the decision process.

OEM considerations are mostly covered in the strategic remanufacturability decision stage. In most cases, sustainability factors are used in the decision process. For example, OEMs want to ensure that remanufacturing a product can contribute to their sustainability targets e.g., net-zero emissions, and zero wastes to landfill etc. (Yan et al., 2018; Qian et al., 2020). Thus, their requirements typically include environmental considerations, economic incentives, and the social impact of remanufacturing (Kurilova-Palisaitiene et al., 2020). These factors are assessed at the organisational level, and they tend to include technological capability of the remanufacturing entity. Sustainability and product factors have been discussed extensively in literature. Some researchers have developed decision tools to support OEMs in their remanufacturability decision-making using specific product features and product design characteristics (Sherwood, Shu and Fenton, 2000; Hatcher, Ijomah and Windmill, 2011; Ng et al., 2013). Increasing research on OEM considerations have led to the development of remanufacturable product characteristics or design guidelines that reduce the difficulty of the remanufacturing process.

On the other hand, considerations of the third-party *remanufacturer* in remanufacturability assessment have been well covered in the tactical and operational decision stages. As a structural entity, the remanufacturer is interested in the sustainability impact of remanufacturing, the product design, core management and its own technological capability to engage in remanufacturing. Longitudinal analysis and discussions on third party

remanufacturing decisions by Zhou et al., (2013) and Zhang et al., (2020) have highlighted sustainability considerations, such as economic and environmental assessments, as critical requirements of the remanufacturer (Y. Zhang et al., 2020; Zhou et al., 2013). This has subsequently resulted in the development and use of tools and methods to assess the condition of returned items for remanufacturability. Table 2-7 shows a summary of clusters of decision factors that have been used in remanufacturability assessment and the specific remanufacturing stakeholders whose requirements are covered.

In view of the above, remanufacturing a product without comprehensively considering the requirements of the different stakeholders during the remanufacturability decision-making process may be unsustainable (Gehin, Zwolinski and Brissaud, 2008), especially if customer acceptance is low as in the medical devices industry. In terms of customer acceptance, remanufacturing sectors such as the medical devices sector have recorded very low level of adoption of remanufactured devices (Leung et al., 2018). Although extensive research has been carried out on remanufacturability decision-making, only a few studies have attempted to include customer requirements in the decision-making process. More discussion is provided in the next section on customer considerations in remanufacturability decision-making.

Table 2-7: Remanufacturability factors associated with different stakeholders

Stakeholder	Remanufacturability Assessment factor	References
Original manufacturer (OEM)	**1. *Sustainability Assessment*:**	
	Economic factors	(Alamerew & Brissaud, 2019; González & Adenso-Díaz, 2005; Z. Hong et al., 2020; Jiang et al., 2011, 2020; Kuik et al., 2022; Otieno et al., 2020; Subramoniam et al., 2009, 2013; van Loon & van Wassenhove, 2018; Yang et al., 2015; H. C. Zhang et al., 2004)
	Environmental factors	(Alamerew & Brissaud, 2019; Gehin et al., 2008; González & Adenso-Díaz, 2005; Goodall et al., 2014; Jiang et al., 2011; H. Liao & Deng, 2018; Otieno et al., 2020; Subramoniam et al., 2009, 2013; van Loon & van Wassenhove, 2018; Yang et al., 2015)
	Social factors	(Alamerew & Brissaud, 2019; Goodall et al., 2014; Otieno et al., 2020)
	2. *Product Assessment*:	
	Product design factors (Design for remanufacturing)	(Gehin et al., 2008; Hatcher et al., 2013; Ijomah, 2009; James et al., 2021; J. Kim et al., 2022)
External remanufacturer (ER)	**1. *Sustainability assessment:***	
	Economic factors	(Bhide & Akarte, 2022; H. Deng, 2020; Farahani et al., 2019; Y. Gao et al., 2018; Golinska et al., 2015; Gong et al., 2022; Jiang et al., 2020; Karaulova & Bashkite, 2016; S. Kim & Kwak, 2020; Ng et al., 2013; Otieno et al., 2020; Phuluwa et al., 2021; Subramoniam et al., 2013; Yang, Ong, et al., 2016)
	Environmental factors	(H. Deng, 2020; Y. Gao et al., 2018; Golinska et al., 2015; Gong et al., 2022; Karaulova & Bashkite, 2016; Otieno et al., 2020; Phuluwa et al., 2021)
	Social factors	(Gong et al., 2022; Otieno et al., 2020; Pazoki & Zaccour, 2019)
	2. *Product assessment:*	
	Product design assessment	(Chakraborty et al., 2017; Z. Ding et al., 2020; Hatcher et al., 2013; Subramoniam et al., 2013; Wahab et al., 2018; Yang, Nasr, et al., 2016; Zwolinski et al., 2006)
	Returned product factors	(Bentaha et al., 2020; Ecer, 2022; Farahani et al., 2019; Y. Gao et al., 2018; Guide, 2000; S. Kim & Kwak, 2020; D. Liu et al., 2022; Moon et al., 2022; Östlin et al., 2009; Sherwood et al., 2000; Subramoniam et al., 2009, 2013; Yang et al., 2015)
	3. Technology assessment:	
	Ease of remanufacturing factors	(Bentaha et al., 2020, 2022; Chakraborty et al., 2017; Fang et al., 2014; Y. Gao et al., 2018; González & Adenso-Díaz, 2005; Guide, 2000; Ijomah, 2009; Jiang et al., 2011; Kafuku et al., 2016; Karaulova & Bashkite, 2016; Lahrour & Brissaud, 2018; Ng et al., 2013; Ong et al., 2016; Yang, Nasr, et al., 2016; H. C. Zhang et al., 2004)
	Technological capability factors	(Jiang et al., 2011; Mukherjee & Mondal, 2009)

2.1.6. Customer considerations in remanufacturability decision-making

Customer decision-making is at the heart of the theory of planned behaviour proposed by Icek Ajzen (Ajzen, 2011). This theory has been considerably explored in remanufacturing literature when examining the customers behaviour towards the purchase and use of remanufactured products. Customers are at the centre of remanufacturing supply chain (Ansari et al., 2022). However, existing research on remanufacturability decision-making have not appropriately included customer requirements. Only a few studies presenting remanufacturability assessment models have included customer requirements. Customer requirements have mostly been represented using the supply and demand factors. The supply side covers customers' willingness to return their used items which serve as cores for the remanufacturing operation (Östlin, Sundin and Björkman, 2009). Supply factors are often linked to core management factors which evaluate the availability of cores in terms of the timing, quantity, and quality of used products. On the other hand, demand factors cover issues relating to customer perception and acceptance of remanufactured products which is critical to the success of remanufacturing (Zhu et al., 2016; Gan et al., 2017). Guide (2000) highlighted the need to balance supply and demand in remanufacturing planning to ensure maximum profitability. Ostlin et al., (2009) also discussed the importance of balancing the supply of cores with the demand for remanufactured products to increase customer acceptance. They discussed the possibility of improving the relationship between the customers and remanufacturer so that potential products can be better identified for remanufacturing. Evaluating customer acceptance and market demands for remanufactured devices is a critical step when assessing the viability of remanufacturing.

Existing studies which have discussed customer factors in relation to remanufacturing decision-making are highlighted in table 2-8. However, the specific make-up of customer decision factors (such as pricing, quality, branding, warranty, risks, and benefit perceptions) has not been duly incorporated into remanufacturability decision-making (Milios and Matsumoto, 2019). There is always a risk with customer acceptance or rejection of remanufactured product, especially when customer considerations are not comprehensively accounted for. When remanufactured products are not accepted, the embedded energy and resources associated with the original manufacturing and subsequent remanufacturing activities are forfeited and there is a greater pressure on the environment. Also, costs associated with obtaining and remanufacturing returned items are unrecoverable, causing significant economic loss to the remanufacturer. As noted by Sarkis (2003), there is a need

to include customer requirements when making decisions such as the location of distribution systems to ensure the efficiency of distribution networks, to attain significant cost savings and to reduce environmental pollution associated with transportation. They went further to discuss the impact of this on the long-term growth and profitability of remanufacturing operations. Subramoniam et al., (2013) took the discussion further by asking experts in remanufacturing business the question: *"Do OE customer specifications and requirements with respect to remanufacturing influence your decision to reman?"* The results from the study contained a pairwise comparison of key factors and ranked the impact of customer product requirements on remanufacturability decision-making as 5th (out of 9 factors). This describes the viewpoint of practitioners in automotive remanufacturing sector regarding the importance of customer considerations in their decision-making process. The opposite has been suggested for remanufacturing sectors, like the medical devices, where customer involvements is higher (Sloan, 2007; Hanson and Hitchcock, 2009).

Recent studies in remanufacturability assessment have begun to include customer considerations in the decision-making process. For example, Yang et al., (2016) included market acceptance into the remanufacturability decision mix of mobile phones considered in the study. Li et al., (2017) incorporated customer perception into remanufacturing production planning and investigated the impact of customer considerations on OEM and TPR remanufacturing strategies. Gao et al., (2018) included customer reference in the multi-criteria decision model (MCDM) for remanufacturability assessment, focusing on the market value and customer acceptance of the remanufactured product. Otieno et al., (2020) developed an evaluation model using sustainability factors. Although customer acceptance has been modelled as a social consideration, it has not been included in the seven key factors considered in the remanufacturability of furniture reported in the study. Kim et al., (2022) proposed a decision support tool that includes specifications to meet customer requirements when assessing the viability of remanufacturing operations.

Table 2-8: Literature on customer factors in remanufacturability decision-making

References	**Description**		**Sustainability Metrics**			**Product and Technology Metrics**			**Considers customer requirements?**
	Method	Product/ Industry	Economic	Environment	Social	Product Design	Technological Assessment	Core Assessment	
(Guide, 2000)	Qualitative	N/A					✓	✓	Yes
(Sarkis, 2003)	Quantitative	N/A	✓	✓				✓	Yes
(Subramoniam, Huisingh and Chinnam, 2009)	Qualitative (Review)	Automotive aftermarket	✓	✓			✓		Yes
(Östlin, Sundin and Björkman, 2009)	N/A	N/A	✓	✓	✓		✓		Yes
(Subramoniam et al., 2013)	Quantitative	Automotive aftermarket	✓	✓		✓		✓	Yes
(Yang, Nasr, et al., 2016)	Mixed	Desktop phones	✓	✓		✓	✓	✓	Yes
(Li et al., 2017)	Quantitative	Apple MP3 Player	✓						Yes
(Y. Gao et al., 2018)	Quantitative	Electric Motor	✓	✓			✓	✓	Yes
(Otieno et al., 2020)	Quantitative	Furniture	✓	✓	✓				Yes
(J. Kim et al., 2022)	Quantitative	Mobile Phone				✓	✓		Yes

The behaviour and inter-relationship between producers and the customers are critical in a remanufacturing decision system (Goyal et al., 2022). Customer acceptance is key to successful realisation of goals of remanufacturing and is therefore critical in remanufacturability decision-making. Despite the documented benefits of remanufacturing, customers' disinclination to purchase, use and recommend remanufactured products continue to stall growth in key remanufacturing sectors. Research effort on customer acceptance of remanufactured products have intensified over the past 10 years as remanufacturers and decision makers become more aware of the need to include customer considerations in their decision-making process. There exists a direct relationship between customer acceptance and remanufacturability of products (Jiménez-Zaragoza et al., 2021). This means that when customer acceptance of a product is high, the viability of remanufacturing the product is high. Several customer factors which directly impact acceptance or purchase decisions on remanufactured products are discussed below.

2.1.6.1. Customer acceptance of remanufactured products

Three kinds of customers have been identified in literature: *green-conscious*, *performance-conscious*, and '*newness-conscious' customers* (Jiménez-Parra, Rubio and Vicente-Molina, 2014; Gaur et al., 2015; Wang et al., 2019).

1. The green-conscious customers are more interested in the 'green-ness' level of the products. Green quality describes the environmental friendliness of a product and the sustainable strategies employed by the producer.
2. Performance-oriented customers seem to be more interested in the functionality of the product and are mostly focused on the warranty or guarantee provided.
3. The newness-conscious customers are more thrilled by the 'newness' of a product. They are the least likely to purchase or use a remanufactured product.

Customer acceptance of remanufactured products is based on the trade-off between customers' perceived risks and perceived benefits (Milios and Matsumoto, 2019; Singhal, Jena and Tripathy, 2019). Research issues relating to customers purchase intentions of remanufactured items have been discussed extensively in literature (Duan & Aloysius, 2019; Gaur et al., 2015; Muranko et al., 2019; Shu et al., 2017; Singhal et al., 2019; Subramanian & Subramanyam, 2012). Customer's purchase intention is negatively impacted by perceived risk (Van Weelden, Mugge and Bakker, 2016; Singhal, Jena and Tripathy, 2019). Abbey et al., (2019) described *risk* as customer's judgement of the probability of failure of

remanufactured item and the relative effect of such defect on the end-user which would include both the hospital and patient in the case of medical devices remanufacturing. Further, Wang et al., (2019) described perceive risk as having the largest negative impact on customers' purchase behaviour (Abbey et al., 2019; S. Wang et al., 2019).

Customers risk perceptions relates to quality, performance, appearance, and financing (Singhal, Jena and Tripathy, 2019), safety and disposal (Van Weelden, Mugge and Bakker, 2016; Baron, 2017), and serviceability (Milios and Matsumoto, 2019) of remanufactured products. Perceived risks may include breakdown risks, technology/obsolescence risks, financial risks, and safety risks (especially in high-risk sectors such as medical devices). These risks are also associated with fear of frequent servicing, increased operating costs, higher safety concerns, and sudden breakdown (Singhal, Jena and Tripathy, 2019).

However, customers' perception of financial risks is relatively low (Van Weelden, Mugge and Bakker, 2016). This is because remanufactured devices generally cost lower than new ones. Despite this advantage, customers may be concerned about higher operational, maintenance and disposal costs of devices. Also, when new technology is introduced, old ones become obsolete. As newer product technology is made available, remanufacturing older devices may keep old outdated and unsustainable technology running (Gutowski et al., 2011). Since new technologies boast better designs, lesser energy consumption, easier maintenance and robust monitoring systems, customers may fear higher technological risks associated with the use of remanufactured devices.

On the other hand, the benefits of remanufacturing have been extensively discussed in literature (Hanson & Hitchcock, 2009; Li et al., 2017; Nasr & Thurston, 2006). The financial benefit of remanufactured devices as a cheaper alternative to new products is considered to be a major motivation for customers. Van Weelden et al., (2016) reported that financial benefit as opposed to financial risks was an important consideration by customers. Other factors are environmental benefit, absence of undesirable features, unique product features, and a higher performance than other second-hand products (Duberg et al., 2021; Ijomah, 2009; Okorie et al., 2021; van Weelden et al., 2016).

Customers' perception of the financial and environmental benefits plays an influential role in customers' decision. When customers perceive higher benefits associated with using remanufactured devices, their intention or willingness to purchase and use remanufactured products may increase (Milios and Matsumoto, 2019). This may imply a direct relationship

between perceived benefits and customer acceptance. Existing studies have highlighted environmental conservation, lower price, high performance, and warranty similar to that of new as the key benefits of using a remanufactured product (Ijomah, 2009; Hatcher, 2013). However, the applicability of these findings to the medical devices sector remains unknown.

2.1.6.2. Customer risk-benefits trade off

When making decisions, customers try to balance their perceptions of the risks and benefits. Milios and Matsumoto (2019) suggested that a balance of risks and benefits influence how customers perceive the quality, safety and warranty of remanufactured product when compared to that of new product. Several factors have been highlighted in literature which include *functional performance or product quality* (Abbey et al., 2017; Hosseini-Motlagh, Nematollahi and Nouri, 2018; Vafadarnikjoo et al., 2018), *environmental friendliness* (Wang et al., 2018; Duan and Aloysius, 2019), *brand equity* (Li et al., 2017; Govindan et al., 2019; Singhal, Jena and Tripathy, 2019), *warranty* (Alqahtani and Gupta, 2017, 2018; Gan and Chen, 2019), *available product information* (Duan and Aloysius, 2019; Milios and Matsumoto, 2019), *services* (Gaur et al., 2015; Van Weelden, Mugge and Bakker, 2016) and *price* (Jiménez-Parra, Rubio and Vicente-Molina, 2014; Bittar, 2018; Govindan et al., 2019), as shown in figure 2-6. These factors are described in the following sub-sections.

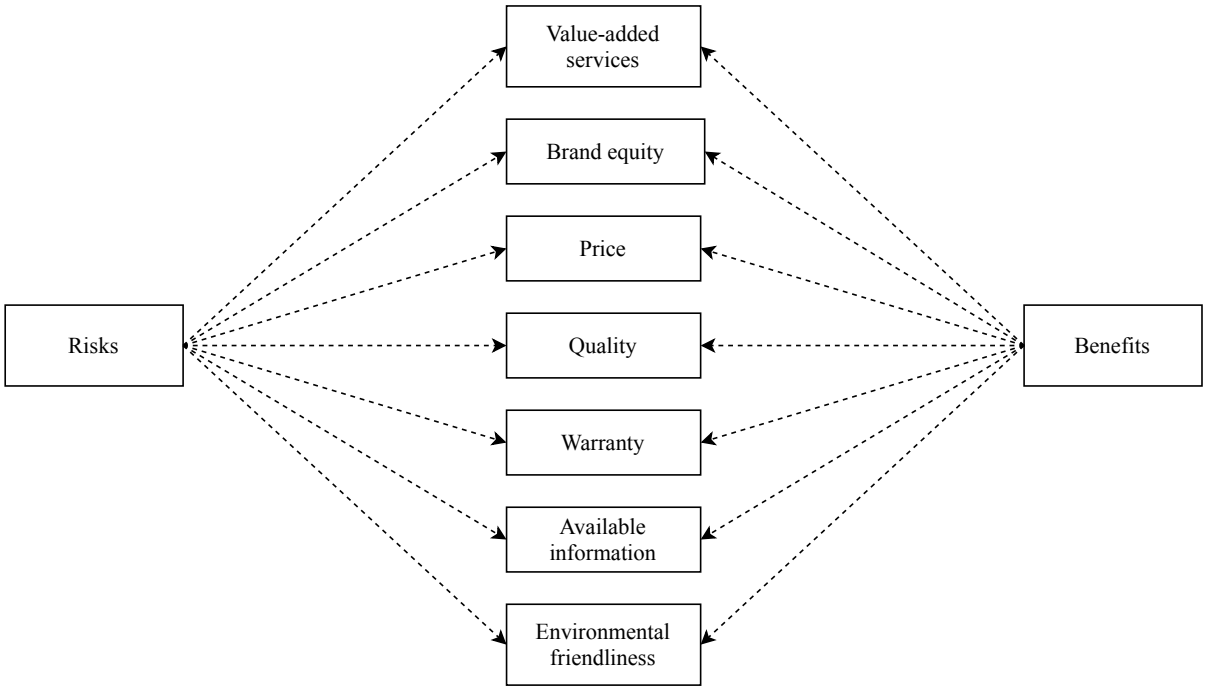

Figure 2-6: Factors influencing the trade-off between risks and benefits (Van Weelden, Mugge and Bakker, 2016)

2.1.6.2.1. Quality of product in terms of performance and safety

As a product-related factor, quality is critical to customers and significantly impacts their decisions to procure and use remanufactured devices. The impact of remanufactured product quality on customer acceptance has been highlighted in existing literature (Van Weelden, Mugge and Bakker, 2016; Abbey et al., 2017; Hosseini-Motlagh, Nematollahi and Nouri, 2018; Vafadarnikjoo et al., 2018; Duan and Aloysius, 2019; Gan and Chen, 2019). When compared to other product recovery strategies (such as repair, reconditioning and refurbishment), remanufacturing offer devices with higher functionality, and appearance which in most cases is similar to that of an equivalent new product (Ijomah, 2009; Paterson, Ijomah and Windmill, 2017). Product quality customer decision factors include product performance, product physical condition or appearance, safety in the use of a product, and technology of the remanufactured device. In the medical devices sector, this quality factor would cover issues such as the risk of infection, failure probability, limitations on use, decontamination, and disposal procedure (Leung et al., 2018).

2.1.6.2.2. Available information (e.g., previous use, expected life, quality certification)

Sonar et al., (2022) attempted to identify the key barriers to more efficient decisions in remanufacturing supply chain management (Sonar et al., 2022). The study identified lack of information sharing on practices, and complexity of remanufacturing operations as important barriers. Information provided by remanufacturers to customers plays a vital role in their acceptance of remanufactured products. Presence or lack of information helps in forming customer opinions about the risks and benefits associated with using such products. Information provision through product quality certification and eco-labelling etc., plays an important role in customers' decision in the electronics sector (Duan and Aloysius, 2019; Milios and Matsumoto, 2019). Available information factors that influence customer decisions include information about the remanufactured product such as its use history, reason for remanufacturing, number of remanufactured/replaced components, age in lifecycle, results of tests performed as part of the remanufacturing process and quality certification (Van Weelden, Mugge and Bakker, 2016; Vafadarnikjoo et al., 2018).

2.1.6.2.3. Price in terms of acquiring, operating, and maintaining remanufactured devices

Bittar (2018) discussed the concept of remanufactured product 'price ratio' which is described as the ratio of the price of remanufactured product to that of an equivalent new product, expressed as a percentage (Bittar, 2018). Van Weelden et al., (2016) illustrated that although lower pricing was a major motivation for customers' decisions, adjusting the price beyond a specific threshold will flip the balance between their risk and benefit perceptions (Van Weelden, Mugge and Bakker, 2016). For example, customers may perceive remanufactured item as having poor quality if priced significantly lower than new. On the other hand, a higher price for remanufactured product does not imply higher quality but may increase consumers' perceived financial risks associated with using the device (Van Weelden, Mugge and Bakker, 2016). The price factors that influence customer decisions include the cost of procuring remanufactured device, the day-to-day operating cost, maintenance and repair costs, and disposal costs of the remanufactured device. The price factors may also include failure and training costs, which may be particularly high in the medical devices sector.

2.1.6.2.4. Warranty provided on the remanufactured device

Alqahtani and Gupta (2018) defined warranty as a contract between the seller (or the remanufacturer) and the buyer of the remanufactured device regarding the liabilities and expectations from both parties in the event that the purchased remanufactured device breaks down or does not function as expected (Alqahtani and Gupta, 2018). They are a major consideration in customer decision to purchase or use remanufactured devices. Kuik et al., (2022) identified the provision of extended product warranty as a major offering to drive acceptance of remanufactured products (Kuik et al., 2022). Providing warranty on remanufactured products can improve customer confidence in the proposed benefits of remanufacturing. This has serious implications the growth of the remanufacturing sector, increased interests in reverse logistics from the customer perspective, and the realisation of the potential value for product remanufacturing (X. Sun et al., 2020; X. Zhu et al., 2019). The warranty factors critical to customer decision-making include the length of warranty, the cost of warranty, trade-in value of remanufactured device, and repair and other services as a warranty.

2.1.6.2.5. Added value services including post-sales technical services

This includes technical support and additional services to support warranty provision. Remanufacturers may offer several value-added services such as scheduled preventive maintenance and repairs to improve product performance and prevent unexpected failure of components (Alqahtani and Gupta, 2017). The post-sales services may also include the provision of replacement parts, software updates, advice and help and user training (Eze et al., 2020).

2.1.6.2.6. Brand equity in terms of who performs the remanufacturing operation

Bittar (2018) described brand equity as the extra value that a remanufactured device attracts based on who performed the remanufacturing. Van Weelden et al., (2016) argued that consumer's perceived risks of using a remanufactured device depends on the seller's reputation rather than the identity of the remanufacturer. The term 'brand' in remanufacturing may refer to the seller, manufacturer, or remanufacturer, what matters, however, is the specific name(s) under which the remanufactured device is offered to buyers (Govindan et al., 2019).

2.1.6.2.7. Environmental friendliness in terms of waste generated material and energy consumption

Environmental issues relate to the scarcity of finite resources, population growth and climate emergency. The increased awareness of sustainability and a focus on reducing waste generations has been reported to influence customers decisions with respect to remanufactured devices (Lahrour and Brissaud, 2018). Most studies in remanufacturing literature have emphasized the significant environmental friendliness of remanufactured products (Bras & Hammond, 1996; Milios & Matsumoto, 2019). However, Gutowski et al., (2011) argued that product design and manufacturing trends ensure that new products are more energy efficient and that remanufacturing old devices with lesser energy efficiency is not environmentally friendly (Gutowski et al., 2011). Hong et al (2020) discussed how the environmental consciousness or green awareness of customers and the presence of government environmental subsidies affects remanufacturability decisions (Z. Hong et al., 2020). Zhou et al (2022) discussed the importance of green innovation efforts on customer acceptance and the environmental awareness of customers on remanufacturing decision-making (Y. Zhou et al., 2022). However, the impact of environmental considerations in customer decisions in the medical devices sector remains unknown. The environmental

friendliness factor assessed in this study covers waste generated, material consumption and energy consumption savings.

2.1.7. Summary of section 2.1.

This section has discussed the results obtained from a systematic literature review which aimed to understand the factors and considerations in remanufacturability decision-making from the viewpoint of the stakeholders. The findings from this section reflects the approach of existing research, which have mostly focused on the requirements of the OEM and the remanufacturer when it comes to assessing remanufacturability. However, this approach has been criticised in (Y. Gao et al., 2018; Yang et al., 2016), which have called for a more holistic approach to assess remanufacturability. Some knowledge gaps identified in this literature review are discussed following sub-sections.

2.1.7.1. Stakeholder considerations in remanufacturability is a prime area of research

Liu et al (2022) suggested that product remanufacturability only focuses on a company's capability to remanufacture and the quality of returned product. This position has been held by many researchers in the field (Bentaha et al., 2020; James et al., 2021; C. Liu et al., 2022; D. Liu et al., 2022; Zacharaki et al., 2021). As such existing research on remanufacturability decision-making have mostly been limited to the requirements of the OEM and the remanufacturer. However, market acceptance of remanufactured products poses a significant threat to the goals of remanufacturing (Gehin, Zwolinski and Brissaud, 2008) and sustainability (Hede et al., 2013). Thus, it should be considered early in the remanufacturing process planning and decision-making. Therefore, effort should be made to ensure that customer requirements are included in remanufacturability decision-making by both the original manufacturer and the remanufacturer (Li et al., 2017).

2.1.7.2. Research on customer considerations in remanufacturability decision-making is currently lacking

Despite increasing discussions about the need to consider customer requirements in remanufacturability decision-making, the actual makeup of customer considerations in remanufacturability assessment is not clear. The general terms “market acceptance”, “customer perception” and “customer reference” etc. are broad topics which must be further evaluated and included in the decision process. It is not surprising that customer considerations and requirements in remanufacturability decision suffers from a lack of research since customers are not directly involved in the decision-making. However, for

remanufacturing to be completely sustainable, there must absolute acceptance of remanufactured products. With the direction of existing research, understanding how to best fit customer requirements into remanufacturability decision-making are important to drive acceptance and to reduce the time required to market remanufactured products (Li et al., 2017). To assist the building of customer-focused remanufacturing operations, researchers should focus on determining how specific customer requirements can be included in the remanufacturability decision mix. Also, remanufacturing organisations must begin to pay more attention to the complex issue of customer behaviour, which is plagued by rapidly changing technology and unstable world economy.

2.1.7.3. Industry perspective

The automotive industry is the most mature remanufacturing sector, and it has received scrutiny from researchers (Golinska and Kuebler, 2014; Golinska-Dawson and Kübler, 2018). Therefore, it is not surprising that the literature reviewed in this section have mostly focused on the automotive, and electrical and electronics remanufacturing sectors. However, several other sectors hold huge promise for remanufacturing such as the marine and offshore (Wahab et al., 2018) and medical devices (Eze, Ijomah and Wong, 2019). Research on medical devices remanufacturing has only received a limited amount of discussions, despite the huge potentials of this sector. The medical devices sector is one of the remanufacturing sectors with very low acceptance of remanufactured products (Centre for Remanufacturing & Reuse, 2008). One may associate this low acceptance to the lack of customer considerations in the remanufacturability decision-making, amongst other factors. Therefore, to improve acceptance of remanufactured products (Östlin, Sundin and Björkman, 2009), especially in sectors where equipment performance is tied to safety (e.g., due to the human element) such as the medical devices industry, customer considerations must be included in the remanufacturability decision process.

2.1.7.4. Methodological perspective

Existing studies have adopted either a quantitative or qualitative approach to remanufacturability assessment and have been limited to a set of stakeholders. The monomethodic approach of most published research on this issue is problematic. One shortcoming of this approach is a lack of a comprehensive understanding of the subject across multiple perspectives using a variety of methods. Although mixed methods approach is relatively new in remanufacturing research, it has been applied by Yang et al., (2015).

Findings from this literature review indicate move towards a more pragmatic, mixed method research to solve key problems in remanufacturing decision-making.

2.2.Review of Medical Devices Remanufacturing

2.2.1. Introduction

This section presents a review of existing literature on remanufacturing within the medical devices sector. The review was conducted to understand the state-of-art and dynamics of remanufacturing in the medical devices sector with the aim of identifying areas where useful knowledge can be contributed.

The need to ensure that medical devices are, not just available and affordable, but importantly sustainable should be taken with seriousness. Researchers in the fields of sustainable manufacturing, medical economics, and biomedical engineering, have sought ways to make medical devices more available, affordable, and sustainable. Yet, these aspects have not improved in real life applications within the healthcare sector. As research effort intensifies, especially towards delivering sustainable medical care, the prospect of returning used products to good performance and quality conditions are examined.

2.2.2. Review method

Adopting an appropriate review method is critical to any research (Tranfield, Denyer and Smart, 2003). According to Williamson (2001), a review method is dependent on the nature and maturity of the research topic and the inclination of research within a specific domain (Williamson, 2001; Gulpinar and Gucal Guclu, 2014). Based on the lack of research on this topic, A traditional, non-systematic review approach provides a guideline to search literature, identify relevant publications and to analyse findings on a research topic in a way that is simple and linear (Rozas and Klein, 2010; Senivongse, Bennet and Mariano, 2017).

In the traditional approach adopted in this section, a multi-staged search technique was used across multiple databases. The breakdown of the search approach including the search stage, keywords, and search results from the different databases is shown in table 2-9. In the first stage, a generic search of the key phrase "*medical devices remanufacturing*" was performed on selected search databases. The aim of this initial search was to obtain a general overview of the nature of research on this topic. The search results were underwhelming indicating a lack of research in this area. Thus, at the second search stage, a combination of keywords –

*remanufactur** AND "*medical devices*" were used. While this search returned varying degree of results across the databases, many of the publications were not directly related to this research area. To streamline the results in the previous stage, the third stage was performed by including the keyword "*decision making*" to the search terms in the previous stage. This stage returned zero results in most instances and the results from ProQuest were on topics outside the research interest such as on clinical practices, and regulatory documents.

The results from the first three stages of literature search implied that this research area is not mature. Thus, the search was broadened by replacing the term "remanufacturing" with "reprocessing" with the aim of understanding the level of work done beyond remanufacturing in the medical devices sector but within the scope of product recovery. Stage 4 search returned a total of 1740 articles relating to clinical practice, hospital management of medical devices, servicing of medical devices while in use and quality management systems for medical devices. Stage 5 search streamlined the results from the previous stage to obtain a volume that is more manageable and include publications that discuss "decision-making".

Literature search and selection of appropriate articles was continuous process (Wybo, Robert and Léger, 2009). However, in order to begin the literature review process, articles containing "*medical devices*", "*remanufacturing*" and "*reprocessing*" in their titles, abstracts and or keywords were selected. A two-way approach was used including cross-referencing and recommendations from academic colleagues.

Table 2-9: Literature search approach

Search stage	**Keyword**	**Search results**		
		Scopus	ProQuest (All databases)	Web of Science (All databases)
Stage 1	*"Medical devices remanufacturing"*	2	0	0
Stage 2	*Remanufactur** AND "*medical devices"*	13	145	4
Stage 3	*Remanufactur** AND *"medical devices"* AND *"decision making"*	0	50	0
Stage 4	*Reprocess** AND *"medical devices"*	558	911	271
Stage 5	*Reprocess** AND *"medical devices"* AND *"decision making"*	10	121	0

Up to 57 publications, which appeared in peer-reviewed journals, international conferences, and book sections, were reviewed to develop insights into the state of art in medical devices

remanufacturing and decision-making in medical devices remanufacturing. However, only 16 articles were specifically about remanufacturing in the medical devices sector and decision-making in medical devices remanufacturing. This further corroborates the earlier assertion about the low maturity of research in this area. This also implies that the research topic is relatively new and mostly unexplored. The other articles assessed in this review section fell under the following categories:

- Medical devices reuse decisions (without emphasis on the end-of-life recovery strategy)
- Medical devices maintenance and servicing decisions (i.e., when to service, when to return to the OEM or TPR or when to send to the landfill?)
- Reverse logistics issues in the medical devices sector
- Other relevant end of life recovery technique that has been applied to medical devices and published in literature such as relocation, repairs, refurbishment, and recycling.

2.2.3. Sustainable product recovery in the medical devices sector: Understanding the key definitions

What qualifies as a medical device has been discussed in a broad manner in academic, trade, regulatory, and organisational publications. Discussions about the nature, use and reuse of medical devices has been ongoing for the past two decades. In this section, the adopted definition of medical device is as proposed by World Health Organisation (WHO). They described medical device as

"Any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for diagnosis, monitoring, prevention, treatment of diseases and injuries, for investigation, replacement, modification or support of the anatomy or of a physiological process, for supporting or sustaining life, for control of conception, for disinfection of other medical devices, or for providing information by means of in vitro examination of specimens derived from the human body" (World Health Organization, 2017).

This definition has been widely adopted in existing publications (Santos et al., 2012; Eze, Ijomah and Wong, 2019; Bayrak and Soylu, 2021) and is similar to the definitions of

medical device in the US FDA, U.K. MHRA and the EU medical devices regulations (EU Council, 2007; Wood, 2009; Medicines & Healthcare products Regulatory Agency, 2017). This definition covers an extensive variety of products currently in the market. However, not all these products can be safely and sustainably recovered.

In the past, design and manufacturing of medical devices only focused on the functionality of the device and the ease of use by the healthcare worker, and less on sustainability and material conservation consideration (Miclăuş et al., 2020). In the modern market, design and manufacturing requirements are rapidly changing towards more customer and environmentally friendly options. This is evident in the growing steer towards understanding product recovery options such as repair, refurbishment, remanufacturing, and recycling, and how they can be applied to medical devices (Garrett & Winfrey, 2019; Oturu et al., 2021). However, there is currently a high level of ambiguity in medical devices sector in this area. In this section, different perspectives on the definitions of the different recovery options in the medical devices sector are presented, drawing from regulatory frameworks, companies and trade bodies' documentations and existing literature.

2.2.3.1. Reprocessing

Across the world, there is no common acceptance of what constitutes reprocessing of medical devices. A synthesis document by the European Commission in 2007 proposed a definition for reprocessing. However, the term only became popular after the (EU) 2017/745 Medical Devices Regulation (MDR) and (EU) 2017/746 In-Vitro Medical Device Regulation (IVDR) were published in 2017.

> *"A process carried out on a used device in order to allow its safe reuse. It includes its cleaning, disinfection, sterilisation and related procedures, as well as testing and restoring the technical and functional safety of the used device."* (European Commision, 2007)

In the United States, the Food and Drug Administration defined reprocessing of medical devices as:

> *"Validated processes used to render a medical device, which has been previously used or contaminated, fit for a subsequent use."* (Food and Drug Administration, 2017)

Based on this, reprocessing can be described as any kind of operation performed on used (or pre-owned) medical devices that makes it functional and safe for use in a second lifecycle until a maximum cycle is reached (Bayrak and Soylu, 2021). According to Bayrak and Soylu

(2021), reprocessing usually involves "*transportation to reprocessing facility, cleaning, disinfection, repair, testing, packaging, sterilization, and final inspection*." (European Commission et al., 2017; Bayrak and Soylu, 2021). The FDA through the Food and Drug Administration Reauthorization Act of 2017 (FDARA) classified refurbishment, reconditioning, rebuilding, remarketing, remanufacturing, and servicing operations as a form of reprocessing medical devices.

On the contrary, the Medicines and Healthcare products Regulatory Agency (MHRA) of the United Kingdom focused the term reprocessing on single-use medical devices.

> *"Reprocessing SUDs is where a person or organisation, contrary to the manufacturer's instructions, cleans and sterilizes the medical device and it goes back into the healthcare environment. The reprocessed medical device has all the markings of the original manufacturer. There might be nothing to show that the device has been used before, nor any indicators that the reprocessing method is effective."* (Medicines and Healthcare products Regulatory Agency, 2016).

The position of the U.K. MHRA presumes reprocessing as a lower form of operation performed on medical devices. This view contrasts with the positions of other definitions which takes "reprocessing" as an umbrella terminology for product recovery operations. Another European Commission guideline adopted a similar view to the U.K.'s MHRA that the term "reprocessing" is applicable only to single use medical devices (SUDs) and not the likes of medical imaging devices (European Commission et al., 2017). However, it is possible to settle this debate by looking at the contexts of the proposed definitions. On one hand, the U.K. MHRA and the European Commission's descriptions of reprocessing focuses on single-use medical devices (SUDs) whereas, other definitions (e.g., the FDA definition) cover all kinds of devices that are covered in the definition of medical devices which includes imaging devices, patient monitoring and point of care devices.

2.2.3.2. Relocation or remarketing

Relocation is identified as remarketing in the FDA guideline and is described as "*the act of facilitating the transfer of a previously owned device from one party to another by sale, donation, gift, or lease*" (Food and Drug Administration, 2018). Usually, between the source and destination facilities, some level of repair, reconditioning and secondary activities may be performed on the device. There is little published information on this product recovery strategy.

2.2.3.3. Repairing

The term repairing in the medical devices sector has been ambiguously taken to refer servicing and maintenance activities on medical devices. The popular definitions of repairing are proposed by the Global Medical Imaging Industry and the US FDA.

The Global Medical Imaging Industry defined repairing as:

> *"The restoration of an equipment or system by a service provider to its original function, in response to the failure of the equipment or system. The repair process may also include servicing, reconditioning, modification and refurbishment"* (Global Medical Imaging Industry et al., 2009).

The US FDA defined repairing as:

> *"A type of servicing that returns a component to original specifications, including replacing non-working components or parts outside of routine or periodic upkeep for the current owner of the device"* (Food and Drug Administration, 2018).

2.2.3.4. Refurbishment

Refurbishment, as a product recovery operation on medical devices, appears to be well established in literature, industry and in legislations. However, existing works, discussions and publications on medical devices refurbishment tend to focus on larger capital medical devices such as imaging systems e.g., the Magnetic Resonance (MR), Computerised Tomography (CT), Xray and ultrasound systems and not as much on single-use medical devices (SUDs) (European Commission et al., 2017). The definitions of refurbishment are presented below:

The US Food and Drug Administration describe refurbishment as synonymous with reconditioning and rebuilding:

> *"Refurbish/Recondition/Rebuild restores a medical device to the OEM's original specifications or to be 'like new.' The device may be brought to current specifications if the change(s) made to the device do not significantly change the finished device's performance or safety specifications or intended use. These activities include repair of components, installation of software/hardware updates that do not change the intended use of the original device, and replacement of worn parts."* (Food and Drug Administration, 2018)

The Global Medical Imaging Industry represented by the European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR), Japan Industries Association of Radiological Systems (JIRA) and Medical Imaging & Technology Alliance (MITA) defined refurbishment as

> *"A systematic process that ensures safety and effectiveness of the medical equipment without significantly changing the equipment's or system's performance, safety specifications and/or changing intended use as in its original registration. Any upgrade processed during GRPMD (Good Refurbishment Practice for Medical Device) refurbishment shall be performed in a manner consistent with the original product specifications and service procedures defined by the manufacturer for that device or medical device"* (Global Medical Imaging Industry et al., 2009).

This definition is adopted by various organisations and governing bodies such as the European Commission (European Commission et al., 2017) and the Malaysian Ministry of Health Medical Devices Authority (Ministry of Health Malaysia, 2016). However, the European Commission guideline through the EU Medical Devices Regulation (MDR) distinguishes refurbishment from recondition and full refurbishment. They defined reconditioning as a mere maintenance of the aesthetics and part replacement whereas full refurbishment was defined as:

> *"The complete rebuilding of a device already placed on the market or put into service, or the making of a new device from used devices, to bring it into conformity with this regulation, combined with the assignment of a new lifetime to the refurbished device"* (European Commission et al., 2017).

Fully refurbishing medical devices is only regulated within the European Economic Area and is based on the requirements of the Medical Device Directive (93/42/EEC) (The European Parliament and the Council of the European Union, 2007; Tricker, 2020). Further, the EU guideline (European Commission et al., 2017) admits that OEMs do not perform "reprocessing" or "full refurbishment" as in the withdrawn IEC 63077 requirements but only refurbish their own medical imaging devices. This complicates the already existing ambiguity in this sector. The term "full refurbishment" as contained in the EU MDR guideline has been described as being synonymous with the term "remanufacturing" which is described in the next section.

Baron (2017) defined refurbishment as "*a practice aimed at returning a product, which has been in use, to its original performance level at its time of first sale*" (Baron, 2017). The key point from the various definitions of refurbishment is that the process is performed such that the characteristics (quality, aesthetics, safety, service, and warranty) of the product is consistent with the original specifications of the original manufacturer when it was first put on the market. Unlike in the automotive industry, Baron noted that refurbishment of medical devices is usually performed on used but highly functional (in terms of performance or quality) medical devices and not on end-of-life products (Baron, 2017).

2.2.3.5. Remanufacturing

The U.K. MHRA's definition of "remanufacturing" is in line with the position of the European Council which associate remanufacturing only to single use devices.

> *"Re-manufacturing SUDs involves a company, prior to placing the product on the market, confirming the conformity of the re-manufactured SUD to the relevant Medical Device Directive and place a CE-mark on their product."* (The European Parliament and the Council of the European Union, 2007; Medicines and Healthcare products Regulatory Agency, 2016).

On the other hand, the Food and Drug Administration (2018) adopts a holistic view of remanufacturing and defined it as:

> *"To process, condition, renovate, repackage, restore, or any other act done to a finished device that significantly changes the finished device's performance or safety specifications, or intended use"* (Food and Drug Administration, 2018).

The Global Medical Imaging Industry, which focused on medical imaging devices, also described remanufacturing in its Good Refurbishment Practice (GRP) guideline as:

> *"Actions taken, such as processing, conditioning, renovating, repackaging, etc. on a used medical device or medical device, that significantly changes the devices or medical device's performance, safety specifications, or intended use"*(Global Medical Imaging Industry et al., 2009).

This definition is adopted by the Malaysian Ministry of Health Medical Devices Authority (Ministry of Health Malaysia, 2016). Conversely, the European guideline assumes remanufacturing to mean the same as "reprocessing" and described it as a process "*where*

actions taken significantly change the device's performance, safety specifications or intended use" (European Commission et al., 2017).

Publications in literature have shed lighter on what remanufacturing entails or should entail in the medical devices sector. Baron reiterated the definition of remanufacturing from the Circular Economy Communication as *"a series of manufacturing steps performed on an end-of-life part or product in order to return it to like-new or better performance with a corresponding warranty"* (Baron, 2017). Eze et al., (2019) defined remanufacturing as:

> *"The industrial process by which a used equipment is restored to at least, original equipment manufacturer's performance and safety specifications from customers' and regulatory perspectives; with the resultant product capable of performing its intended use and given a warranty as well as provision for professional post-sales services that are at least as good as those given to an equivalent new one"* (Eze, Ijomah and Wong, 2019).

Growing discussions of remanufacturing in the medical devices literature tend to pave ways for a new string of research in the medical devices sector. As a higher form of product recovery (Ijomah, 2009; Paterson, Ijomah and Windmill, 2017), remanufacturing is adopted in this thesis as the preferred options for medical devices. Subsequently in this section, a discussion of remanufacturing in the medical devices sector is presented.

2.2.4. The state of remanufacturing in the medical devices industry

Discussions on the remanufacturing and reusing medical devices has recently increased. This is due to increasing waste generation in the healthcare sector (Kwakye, Pronovost and Makary, 2010; Leung et al., 2018) coupled with reducing funding for healthcare expenditure and growing pressure to keep down cost of healthcare (Sloan, 2007) by governments, hospitals, and healthcare boards. This can also be associated to increasing awareness of sustainability and the need to reduce wastes sent to the landfill (Ischinger et al., 2002). Accordingly, the necessity of recovering medical devices is embedded in ensuring patient safety and saving costs (Ischinger et al., 2002). Bao e al., (2022) studied remanufacturing lead time planning for medical devices with focus on three steps: disassembly, sterilising, and reconditioning (Bao et al., 2022).

The medical devices sector presents a fascinating research application for remanufacturing. However, in the overall remanufacturing industry, medical devices remanufacturing only accounts for 0.5% intensity (Gehin et al., 2008; Widera & Seliger, 2015). This can be

associated with a low level of understanding of the benefits of remanufacturing and the high level of ambiguity currently existing in this sector. Despite the advantages of remanufacturing medical devices, both to improving sustainability and healthcare (Kwakye, Pronovost and Makary, 2010), critics continue to misunderstand the process and raise issues surrounding the safety of the patient. Some have argued that patient consent should be sought before remanufactured devices can be used on them (MacPherson, 2010). These, coupled with the biases of OEMs, who fear reduced revenue and market share (Sloan, 2007; Widera and Seliger, 2015), continue to discourage the growth of remanufacturing.

Conversely, proponents of remanufacturing have claimed that there is no known evidence associating the use of remanufactured medical devices to increased risk to patients (Kwakye, Pronovost and Makary, 2010). Coincidentally, Amadi et al., (2010) recorded a decline in neonatal mortality in healthcare centres where digitally 'recycled' incubators were used (Amadi et al., 2010). Remanufactured circular mapping catheters by Leung et al., had good mechanical performance when tested against the specifications of the OEM and its use did not put patient safety at risk (Leung et al., 2018). Also, MacPherson (2010) emphasized that safety of patients is a mandatory consideration in procurement frameworks used by healthcare boards and that obtaining patient consent may not be necessary as devices that put patient at risk would not be purchased in the first place.

Globally, the awareness and acceptance of such sustainable practices remains critically low. Most health care providers and institutions have expressed concerns about the hygiene, safety, functionality, ethics, and legality of remanufacturing medical devices, especially those labelled "single-use" by the manufacturer (Leung et al., 2018). However, tightening legislations (e.g., by the U.K. MHRA Guidance on remanufacturing single-use medical devices, the German Medical Devices Act on reprocessing medical devices, guidelines of the Robert Koch Institute, the U.S. FDA on regulating medical devices reprocessing) have increased scrutiny of remanufacturing and other recovery operations which ensures the innovativeness and safety of product recovery techniques (World Health Organization, 2017; Melvin and Torre, 2019; Gautam and Sahney, 2020; Gu et al., 2020; Narmada, Venkatesh and Balamuralidhara, 2020; Peter et al., 2020).

The regulatory approach on medical devices remanufacturing operations and activities may vary across countries or regions. In some countries, remanufacturing remains highly unregulated (Wei et al., 2018). Wei et al., (2018) reviewed the regulatory perspective on remanufacturing single-use medical devices. Since the medical devices sector is highly

regulated especially in the Germany, UK and US, organisations that (or intend to) engage in any form of recovery operations on medical devices are subject to strict standards by appropriate bodies, depending on the location of the remanufacturing facility and the destination of the remanufactured devices (Chang et al., 2019). In Germany, legislations on recovery activities on medical devices were proposed in 2001 (Klosz, 2008). This legislation is the DIN EN ISO 13485:2003 which is focused on "reprocessing of medical devices" and is enforced by the German Federal Institute for Drugs and Medical Devices (BfArM) as it relates to the "Hygiene requirements for reprocessing of medical devices" (Klosz, 2008). The UK guidance on remanufacturing medical devices is proposed by the MHRA (Medicines and Healthcare products Regulatory Agency, 2016).

Disinfection/sterilisation and the testing of medical devices are critical factors and activities during recovery operations. Reusing medical devices comes with a risk of carrying biological organisms that may transfers infective agents (Chang et al., 2019; Leung et al., 2018). Therefore, a multifarious cleaning and disinfection process, coupled with an understanding of disinfection/sterilisation requirements on specific types of medical devices is important for the remanufacturing process. Chang et al., (2019) spelled out the disinfection requirements by the risk level of medical devices, for example, "*high risk devices require sterilisation, semi-critical devices require high level disinfection and non-critical devices require intermediate to low-level disinfection*". Testing the performance and functionality of medical devices is a critical activity during medical device remanufacturing. It is a regulatory requirement for functional tests to be carried out individually on medical devices during verification and validation of the remanufacturing operation. Kraft (2008) described that functional testing is important to ensure that no damage or other structural changes inhibit the quality or performance of the medical device (Kraft, 2008). The testing procedure adopted during remanufacturing depends on the specific product, the current technological standard, and the process of restoring the used medical device.

2.2.5. Remanufacturability decision-making in medical devices sector

Although discussions on the recovery of used medical devices have been going on for the past 2 decades, it is only recently that researchers began to explore remanufacturing and to propose ways to reduce the complexity for remanufacturers (Foley et al., 2006; Leung et al., 2018; Eze, Ijomah and Wong, 2019; Jensen et al., 2019). Despite existing regulatory limitations of medical devices remanufacturing, researchers have identified factors which are critical to remanufacturing practice. Widera and Seliger (2015) highlighted key barriers

in core acquisition, steps in the remanufacturing process and selling of remanufactured devices (Widera and Seliger, 2015). Jensen et al., (2019) assessed sustainable values created through the end-of-life recovery programs of 3 manufacturers, one of which is a medical devices OEM (Jensen et al., 2019). Although these offer solutions to specific problems for OEMs, they do not assess the critical factors that influence decision making in medical devices remanufacturing. As the interest in medical devices remanufacturing increases, organisations (manufacturers, third parties and hospitals) are becoming more involved in collection, remanufacturing, and reuse of medical devices. As such, there is a need for a comprehensive understanding of techniques and factors considered when assessing the feasibility and viability of remanufacturing, which is termed remanufacturability decision-making.

Remanufacturing is not suitable for all products. Thus, every case has be critically assessed. In literature, remanufacturability decision-making has been established to depend on the product characteristics and the remanufacturing process factors (Goodall, Rosamond and Harding, 2014). Unlike in the automotive sector, medical devices are complex and have higher safety and ethical requirements (De Leon, 2016; Duncan, 2020). Some remanufacturability considerations for medical devices discussed in literature are *market factors* (Raihanian Mashhadi, Esmaeilian and Behdad, 2015; Vockley, 2016), *regulatory perspectives* (Kojima, 2017; Damha et al., 2019), *safety and effectiveness* (Hogan and Colonna, 1998; Leung et al., 2018; Renton, Denk and Varban, 2018), *cost considerations* (Carey, 2001; Renton, Denk and Varban, 2018; Eze, Ijomah and Wong, 2019), *ethical considerations* (Sloan, 2007; MacPherson, 2010; Renton, Denk and Varban, 2018; Narmada, Venkatesh and Balamuralidhara, 2020).

Existing research in this sector has failed to address specific issues on remanufacturability decision-making for medical device. For example, Taghipour et al., (2011) focused on maintenance decisions for capital imaging devices and developed a multi-criteria decision model (MCDM) to rank the criticality of medical devices and prioritize their maintenance or reprocessing (Taghipour, Banjevic and Jardine, 2011). Also, Hede et al., (2013) presented a multicriteria hierarchical model (MCHM) to incorporate the triple bottom line of sustainability (environment, economic, social) into the development of medical devices (Hede et al., 2013). Due to a lack of research in this area, existing publications which focus on a similar topic are discussed in the next sub-sections. A summary of these published articles is presented in table 2-10.

Table 2-10: Research related to remanufacturability decision making for medical devices

Reference	Study focus	Method	Decision factors considered					
			Regulations	Business factors	Supply of used devices	Product factors (Age, design etc)	Safety	Customer
(Taghipour, Banjevic and Jardine, 2011)	Proposed a multi-criteria decision-making model (MCDM) that prioritises maintenance of medical devices based on device criticality	Quantitative				✓	✓	
(Hede et al., 2013)	Proposed a multi-criteria hierarchical decision model (MCHM) focused on medical devices development with reference to economic, environmental, and social sustainability factors	Mixed	✓	✓		✓		
(Renton, Denk and Varban, 2018)	Evaluated the impact of reprocessed single devices on cost, environment, and patient safety	Literature review		✓			✓	
(Sloan, 2007)	Proposed a Markov decision process (MDP) mathematical model to assess the trade-off between cost and safety in using new or reprocessed medical devices.	Quantitative		✓			✓	
(Widera and Seliger, 2015)	Proposed a business model canvas to evaluate specific barriers for OEM remanufacturing across different industries	Quantitative		✓	✓			
(Jensen et al., 2019)	Mapped different factors to develop approaches that can drive successful remanufacturing	Case study		✓		✓		✓
(Leung et al., 2018)	Evaluated the performance and safety of remanufactured catheters within a healthcare facility	Quantitative					✓	✓

(Hanson and Hitchcock, 2009)	Proposed a methodology to analyse lifecycle and improve design of medical devices	Qualitative		✓	
(Amadi et al., 2010)	Assessed the impact recycled neonatal incubators in hospitals	Quantitative			✓
(Xie et al., 2016)	Assessed reverse exchange systems for used medical devices	Multiple case study	✓		

2.2.5.1. Original equipment manufacturers (OEMs)

It is generally accepted that OEMs play an important role in a product life cycle. Their responsibilities start from the product development phase, which strongly influences product remanufacturability. For a device to be remanufactured, the product development stage should consider criteria that makes remanufacturing less difficult. However, the nature of remanufacturing operations in the medical devices industry is not well documented in academic literature. The inherent difficulty of the remanufacturing operation, coupled with the requirements for the remanufacturing process, are not well known. Eze et al., (2019) developed a model-based definition for medical devices remanufacturing. This definition provides a clear description of how remanufacturing operation in medical devices sector should be performed. Also, Widera and Seliger (2015) aimed to reduce the complexity of the remanufacturing operation for OEMs in this sector by using the business model canvas. They focused on the OEMs and described them as the ideal candidate to remanufacture their own products such as the insulin pump, CT, MRI, and X-ray set up. They also highlighted the key barriers in core acquisition, remanufacturing process, and marketing remanufactured products. Further, Jensen et al., (2019) assessed the business operations of three industry case studies of manufacturers who remanufacture their products. The assessment compared the operations at the 3 organisations with rest to the triple bottom-line of sustainability which are economic, environment, and social. They identified and connected business factors that can improve remanufacturing activities using a case study approach. The study revealed how the assessed companies can create more sustainable value through their product remanufacturing programmes.

Although these studies (Widera and Seliger, 2015; Jensen et al., 2019) solved specific problems for OEMs, they failed to identify factors that are critical to improving the remanufacturability decision-making process. As most manufacturers consider end-of-life option for their products, it is important to explore remanufacturability decision-making especially with a focus on customer requirements.

2.2.5.2. Supply of used devices

Remanufacturing thrives on the availability of used devices. There is varying degree of abundance of used medical devices across hospitals, regions, and countries. Systemic planning means that used medical devices in high resourced regions are returned to the manufacturer, sold to a third party, disposed of appropriately using an accredited medical

waste vendor or donated to low-resourced settings that cannot afford new systems but could still derive some value in these devices (Gatrad, Gatrad and Gatrad, 2007; Piaggio et al., 2020). The consequence is an overwhelming quantity of dysfunctional devices in low-resourced settings. For example, Amadi et al., (2007) described how hospitals in developing regions are littered with obsolete and dysfunctional neonatal incubators. Piaggio et al., (2020) described the harsh conditions in developing countries, coupled with the fact that donated systems do not always meet international quality standards which severely impact the performance of the systems (Piaggio et al., 2020). Unfortunately, medical devices remanufacturing is not feasible in these regions due to low technical, marketing and capital requirements.

Supply of used devices is critical for remanufacturing. Heese et al., (2005) developed a mathematical model to predict the circumstance under which product takeback may be considered profitable, and the impacts of product take-back on firms, industry, and the customers. They used two case studies of manufacturers specialising in hospital beds. The results of the study implied that the manufacturers that offer product take-back increase their market share, gain competitive advantage, gain traction into new markets, and increase their income. Further, Xie et al., (2016) explored reverse exchange for medical devices in the UK National Health Services (NHS). They suggested operational attributes that hospitals can use to improve reverse management of medical devices to save cost and improve environmental friendliness. Both studies (Heese et al., 2005; Xie et al., 2016) have suggested ways to improve supply of used medical devices for remanufacturing. However, the responsibility is on the remanufacturers to liaise with hospitals on the supply of used devices.

In terms of assessing remanufacturability, supply of used cores is very critical. In the wider remanufacturing literature, issues with the supply of used products have received considerable research attention. Core supply in remanufacturing has been improved by legislations (e.g., WEEE, ELV and RoHS) that place additional responsibilities on the manufacturers for the end of life of their products. However, these legislations do not extend to medical equipment absolving medical equipment manufacturers of the need to take-back their used medical devices and improve their sustainable recovery strategies as a mandatory responsibility.

2.2.5.3. Product structure

The suitability of a product or product category for remanufacturing is dependent on the structure or design of the product. To contribute to product design in medical devices Hanson and Hitchcock (2009) performed lifecycle and functional analysis on medical devices with the aim of reducing the environmental impact and improve the sustainability of single-use devices (Hanson and Hitchcock, 2009). No single study exists which assesses the impact of the design of medical devices on the recovery option the device is put through.

Olson and Caldwell (2010) focused on designing a low-cost neonatal incubator specifically for low-resourced countries (Olson & Caldwell, 2010). Other researchers have pushed for creating product designs specifically for developing regions for example, Ehsan-ul-Haq et al., (2011) developed a low-cost neonatal incubator which will run efficiently on a 12volts battery (Ehsan-ul-Haq et al. 2011). This idea led researchers and students to use local and readily available materials in product designs which mostly put the functionality and safety of the device at risk (Banerjee et al., 2012). Although a conservative low-cost design can be helpful in providing affordable and accessible medical devices globally, there are ethical and medical concerns with any form of product recovery on these devices.

Mirkouei et al., (2017) proposed a multi-criteria decision-making framework to assess and improve design and manufacturing practices for medical devices (Mirkouei, Silwal and Ramiscal, 2017). The framework included economic and environmental factors and focused on a standardised information sharing of design and manufacturing processes. Cheong et al., identified the drivers, challenges, and innovative strategies for ensuring sustainability in medical devices design and manufacturing sector in China (Cheong et al., 2020).

2.2.5.4. Customer considerations

Customer considerations is critical in remanufacturability decision-making for medical devices. Existing publications in remanufacturing literature have mostly ignored the impact of customer considerations in remanufacturability assessment. However, a few studies have assessed decision-making with some focus on the customers. For example, Sloan (2007) used numerical examples of orthopaedic blades, cardiac catheter, compression sleeves and trocar to validate a Markov decision process model (MDPM) (Sloan, 2007). Using this model, the customer (hospitals, clinicians and others tasked with the purchase and use decisions of remanufactured medical devices) can compare the costs, probability of failure and cost of failure both for new and remanufactured devices. Although this model gave

useful insights into the key concerns of customers, it failed to connect customer factors to the remanufacturers' decision.

Leung et al., (2018) evaluated the performance of remanufactured cardiac catheters on 100 consecutive patients (Leung et al., 2018). The study reiterated the findings of existing studies on the key considerations of customers which include cost saving, good performance, and low failure probability. Amadi et al., (2013) assessed the performance and impact of recycled neonatal incubators after a six-year period. The authors highlighted good performance, ease of maintenance, expected lifespan of remanufactured device and significant cost reduction as key considerations of the customers. Customer perception and acceptance is an area where more research efforts should be directed.

2.2.6. Summary of section 2.2.

This section has discussed the state-of-art in medical devices remanufacturing. It has attempted to present ongoing discussions regarding the growth of remanufacturing in the medical devices, regulatory perspectives, and remanufacturability decision-making in the medical devices sector. The following research gaps were identified.

2.2.6.1. Ambiguity in definitions

The nature of the medical devices industry warrants strict regulation on recovery activities. However, existing guidelines on recovery techniques for medical devices are not consistent. For example, the definitions of 'refurbishment' and 'remanufacturing' are not consistent with globally accepted definitions of both activities across different sectors e.g., automotive, electrical and electronics, and marine machines or systems. Further, some guidelines describe 'reprocessing' as a lower form of product recovery, instead of the widely accepted position of 'reprocessing' being an umbrella term for recovery activities that aims to put used products in a functional state. This ambiguity may contribute to the significantly low acceptance of remanufactured medical devices.

Definition of product recovery operations in the medical devices sector is riddled with so many ambiguities. There is a different perspective, application and meaning of the different recovery operations depending on the geographic location, political and industrial affiliations. This ambiguity limits recovery activities in this sector and it confuses customers on what to expect from remanufactured medical devices. After identifying a lack of 'acceptable' definition for medical equipment remanufacturing, Eze et al., (2019) proposed a definition for remanufacturing by considering current perspectives on medical device

legislation as it relates to remanufacturing in the EU and the USA. This definition presents a clear path in reviewing previous research done in this sector. However, the terms are still commonly used interchangeably in literature and in organisations in the industry.

2.2.6.2. Customer acceptance and remanufacturability decision-making

A common theme across the different definitions are the high requirements for the safety and performance of recovered devices in this sector. Also, the perspective and cooperation of the customers (hospitals, clinicians, and healthcare boards) is very significant to the success of any recovery operation. For example, legislative requirements for reprocessing, repair, remarketing/relocation, refurbishment, and remanufacturing, as described in the previous section, implies that the device must be:

1. safe for use on patients
2. of good performance, such that it can meet the demands of the customers
3. easily used by the healthcare worker
4. backed up by warranty and service for a limited period.

It is a common knowledge in literature that medical devices sector is a high-risk sector with very high safety requirements (Amadi et al., 2007; Widera and Seliger, 2015; Baron, 2017; Zlamparet et al., 2018; Eze, Ijomah and Wong, 2019). The nature of these requirements, the importance of the different factors, how this affects the customers decisions and how customers decisions can affect the remanufacturers' decision has not been investigated.

Existing decision models have provided insight on the nature of decision making in medical devices sector, stating the key players, boundaries, and considerations. However, these studies have failed to assess the considerations of customers or medical experts. Since remanufacturing decisions are dependent on consumer acceptance, the concerns of hospitals, medical professionals and devices experts are expected to have huge impact on the decision process. Till date, there is no understanding of the criticality of factors that may impact customers' decision on remanufactured medical devices.

Remanufacturability decision-making in the medical devices sector has not been treated in much detail. The nature of this decision-making is largely unknown. Publications assessed in this section failed to consider the impact of customer requirements on the remanufacturability decision-making. Further, only a few researchers have been able to draw on any systematic research into decision-making in medical devices remanufacturing indicating a wide knowledge and methodological gap.

2.3.Conclusion of chapter 2

This chapter set out to achieve two things: first, to present the state-of-art in remanufacturability decision-making from the perspectives of the different remanufacturing stakeholders; and second, to present background on remanufacturing in the medical devices sector based on existing literature. Both the systematic and traditional literature search approaches have been used to identify related literature which are analysed and discussed in the two main sections of this chapter. Knowledge gaps were identified based on the two literature reviews reported in this chapter. In stakeholder consideration in remanufacturability decision-making there is insufficient research on including customer considerations in remanufacturability decision-making. Moreover, the need for a broader multi-perspective study to optimise decision-making in the remanufacturing domain has been established. From the medical devices remanufacturing literature, it is clear that the lack of adequate research in this area has led to a high level of ambiguity in definition. Also, customer acceptance is low for remanufactured medical devices. The next chapter presents the research design which includes a discussion on the research philosophy and the research methodology.

Chapter Three: Research Design

3. Chapter Three: Research Design

According to Jonker and Pennink (2009), a research design refers to "… a flexible set of assumptions and considerations leading to specific contextualised guidelines that connect theoretical notion and elements to dedicated strategy of inquiry supported by methods and techniques for collecting empirical materials."

At the starting point of every research, a research design is inexistent mostly due to a lack of sufficient knowledge about the problem area, existing works, existing theories, and the available tools to answer unknown questions. However, during the research, the researcher tries to connect three 'building blocks' which makes up the research design. These are: the research question, existing theories, and the research methodology. However, these blocks are strongly influenced by the researcher's underpinning philosophy. A researcher's design is informed by the research paradigm (abstract) and research methodology (concrete) (Jonker and Pennink, 2009).

Therefore, the research design chapter in this thesis includes two sections:

- Section 3.1.: Research Philosophy
- Section 3.2.: Research Methodology

3.1.Research Philosophy

This section presents a comprehensive discussion on the philosophy of the research reported in this thesis. It covers topics which include a brief description of research philosophy and paradigms, the components of a research paradigm, and the different types of research paradigms. This section presents the philosophical underpinnings of this research (pragmatism) and discusses the rationale for adopting a pragmatic approach.

3.1.1. Introduction to research philosophy and paradigm

Every researcher is guided by their underlying behaviour and belief (directly or indirectly) of how they can 'know the world'. In making a connection to this 'world' – or the context in which the research question occurs – an interesting perspective suggested by Easterby-Smith et al., (2018) is how the researcher's behaviour, believes and worldview shapes their research approach, data, and theory with the aim of answering the questions being investigated (Easterby-Smith, Thorpe and Jackson, 2018). The philosophy of a researcher, guided by the adopted paradigm, helps the researcher to clarify the research design, reduce

the complexity of the research process and helps to avoid pitfalls (Hallebone and Priest, 2009; Saunders, Lewis and Thornhill, 2009; Easterby-Smith, Thorpe and Jackson, 2018). A research paradigm is a perspective or a way in which the researcher looks at the research problem.

Several attempts have been made to describe research paradigm. One such effort is by Gummesson (2000) who referred to paradigm as the values and rules under which the thinking and attitude of the researcher is governed (Gummesson, 2000). A paradigm is composed of the researcher's view on the 'nature of reality', 'nature of knowledge', 'nature of value' and 'quality' (Burrell & Morgan, 1979; Denscombe, 2008; Johannesson & Perjons, 2014; Roux & Barry, 2009). Jason (2022) further described paradigm as a set of beliefs or facts that is commonly shared by a group of researchers or professionals within a certain research area, and their assumptions of reality or assumed way of conducting research (Jason, 2022). Thus, paradigms make it possible for people within a domain and research area to communicate seamlessly.

3.1.2. Types of Research Paradigms

Paradigms are social constructions – a generalisation about how a group of people present their worldview to influence research (Elkrghli, 2010; Lee, 2012). Through basic assumptions and research principles, paradigms have served as a guide for discoveries in the scientific era (Park, Konge and Artino, 2020). In literature, research paradigms have been grouped under many different taxonomies such as positivism, interpretivism, critical paradigm and pragmatism (Rehman and Alharthi, 2016; Kivunja and Kuyini, 2017; Kaushik and Walsh, 2019; Bogna, Raineri and Dell, 2020). Burrell and Morgan (1979) discussed 4 paradigms (radical humanism, radical structuralism, functionalist sociology and interpretive sociology) and 2 approaches (subjectivist and objectivist) (Burrell and Morgan, 1979). Grey and Lowe (2000) identified four research 'discourses' (dialogic, critical, normative, and interpretive) (Grey and Lowe, 2000). Guba and Lincoln (1994) discussed 4 paradigms based on ontology, epistemology, and methodology (positivism, post-positivism, constructivism, and critical theory) (Guba and Lincoln, 1994). Weber (2004), Ryan (2018), and Alharahsheh and Pius (2020) identified positivism and interpretivism as the key dominant research paradigms (Alharahsheh & Pius, 2020; Ryan, 2018; Weber, 2004).

Purists on either side of the two early paradigms (positivism and interpretivism) have engaged in debates, often termed "paradigm wars" (Johnson and Onwuegbuzie, 2004),

about which paradigm is ideal for research. These debates have degenerated into some form of "*incompatibility thesis"* which argue that positivist and interpretivist paradigms should never be mixed because they are incompatible (Johnson and Onwuegbuzie, 2004). An example of such debate is presented in the next paragraph and summarised in table 3-1.

Pure positivists believe that the researcher is separated from the research, inquiry should be objective and social observations should be evaluated as numerical or physical entities and that hypotheses should be tested empirically. On the other hand, pure interpretivists rebuff assumptions in positivism and argue for subjective multi-constructed realities and practical impossibility to separate the researcher from what is being investigated and that research is influenced by value, time, and context (Johnson and Onwuegbuzie, 2004). For more discussions on the paradigm wars, refer to (Gage, 1989; J. Greene, 2006; House, 1991; Hughes & Sharrock, 2016; Tashakkori & Teddlie, 2003; Teddlie & Tashakkori, 2003). In the next sub-sections, positivism and interpretivism paradigms are discussed from the content of existing literature.

Table 3-1: Positivism vs Interpretivism Paradigms Adapted from (Tashakkori and Teddlie, 2003; Elkrghli, 2010; Park, Konge and Artino, 2020)

	Positivism	**Interpretivism**
Ontology	Realism	Relativism
Epistemology	Objectivism Knower and known are separated	Subjectivism Impossible to separate the knower from the known
Methodology	Quantitative	Qualitative
Axiology	Value-free inquiry	Value-bound inquiry
Logic	Deduction	Induction
Causal linkage	Real causes of social occurrences can be reliably and validly determined	In is impossible to fully separate causes and effects of social occurrences
Generalisation	Time- and context-free generalisations are achievable	Time- and context-free generalisations are not possible

3.1.2.1. Positivism

Positivist thinking and ideology is still more prominent in modern research, although its starting point goes back to the 17th century during the enlightenment era. Auguste Comte (1798–1857) is wildly accepted as the founder of positivism, however the paradigm has been greatly influenced by philosophers such as René Descartes, John Locke, Nicolaus Copernicus, Galileo Galilei, Karl Popper, Willard Van Orman Quine and Thomas Kuhn (J. W. Creswell, 2013; Easterby-Smith et al., 2018; Goldkuhl, 2012; Park et al., 2020; K. Richards, 2003). Positivism tends towards gathering objective knowledge, backed by

evidence from a scientific research or experimentation, as in physical sciences (Kumar, 2019).

Positivism argues that direct scientific actions and experiments ought to be the only valid means of discovering knowledge in terms of the '*truth'* which exists out there (Guba and Lincoln, 1994; Gall, Gall and Borg, 2006; Hetherington, 2006; Jonker and Pennink, 2009) and that humans are distinctly separated from reality (Rehman and Alharthi, 2016). Jonker and Pennink (2009) suggested that researchers with a positivist paradigm mostly follow these three steps: diagnose, design and implement (Jonker and Pennink, 2009). First, they develop concise research problem, questions, and hypothesis, then design a solution or a course of action to produce answers or test the hypothesis, and finally to implement the solution. An important point in positivism is that the focus of the researcher is on the implementation of the research results.

Research studies situated within positivist philosophy rely on deductive logic of reasoning and follow the scientific process of research (Saunders, Lewis and Thornhill, 2009; Kivunja and Kuyini, 2017). With respect to the key elements of a paradigm, positivism has a realist ontology, objective epistemology, measurement, prediction and control strategy, value-free axiology and quantitative approaches or experimentation as its methodology (Easterby-Smith et al., 2018; Patterson & Williams, 1998; Reich, 1994; Saunders & Tosey, 2013; Toledo-Pereyra, 2012; Zaidi & Larsen, 2018). Research conducted within this paradigm can be validated using internal & external validity, reliability, and objectivity (Guba and Lincoln, 1994; Kivunja and Kuyini, 2017). Research within the positivism paradigm mostly uses numerical or quantitative data to answer research questions (Gall, Gall and Borg, 2006; Easterby-Smith, Thorpe and Jackson, 2018). However, many scholars have criticised the positivist approach which has led to the emergence of post-positivist paradigm (refer to (Gage, 1989; Richards, 2003; Gris, 2004; Gall, Gall and Borg, 2006; Rehman and Alharthi, 2016)

In remanufacturability decision-making literature, positivist approach is strongly influenced by the need to use quantitative data to answer research questions. Adopting the scientific approach to research, Amezquita et al., (1995) identified the metrics to quantify the remanufacturability of engineering systems (Amezquita et al., 1995). The research questions were answered through an experiment-driven case study of an automobile door which confirmed that the metrics for remanufacturability assessment actually works. By pursuing an objective search for facts (demonstrating an objective epistemology) and accepting an

approximate reality (demonstrating a critical realist ontology), the authors' philosophy fits within the post-positivist philosophical paradigm. Research by Fang et al., (2014) rested on the formulation and testing of hypothesis to evaluate remanufacturability based on design information(Fang et al., 2014). The research tested the metric developed by the author to quantify and evaluate the remanufacturability of a product. In the study, contexts were not considered, and the author aimed to establish the generalisability of the model presented. Several other studies in remanufacturing literature that have adopted the positivist paradigm are (Sherwood and Shu, 2000; Sundin, Björkman and Jacobsson, 2000; Inderfurth, 2005; Zhai et al., 2013; Singh and Jain, 2019; Akano, Ijomah and Windmill, 2021a).

3.1.2.2. Interpretivism

Interpretivist paradigm disagrees fundamentally with the positivism and argues that there is no such thing as a single or unique truth which exists independently of the observer (Goldkuhl, 2012; Creswell, 2013; Cherwitz and Johnstone, 2014; Easterby-Smith, Thorpe and Jackson, 2018). Interpretivism holds the assumption that reality is socially constructed. Also, phenomenon can have multiple interpretation based on the experience of individuals (Guba and Lincoln, 1994). Interpretivism has been called different names including constructionism, deconstructionism, conservativism, naturalism, and phenomenalism (Butler, 1998; Elkrghli, 2010). The central theme of an interpretivist research is to create knowledge through the subjective understanding of human experience (Williams, 2000; Edley, 2001; Curry, 2020). Thus, the social reality under study cannot be separated from the researcher (Rehman and Alharthi, 2016). By adopting this paradigm, the researcher interacts with the phenomenon being researched and places emphasis on understanding the topic from the viewpoint of the experts and professionals (Cohen, Manion and Morrison, 2017).

The interpretivist paradigm has a relativist or constructionist ontology, subjective epistemology, value-laden axiology, inductive approach to understand or communicate, and a constructionist or naturalist method (Alharahsheh & Pius, 2020; Goldkuhl, 2012; Orlikowski & Baroudi, 1991; Patterson & Williams, 1998; Pulla & Carter, 2018; Toledo-Pereyra, 2012). Interpretivist research often produce qualitative data through interviews, discourse and reflective sessions. (Creswell, 2013; Kivunja and Kuyini, 2017). Interpretivist research can be validated based on their credibility (i.e., internal validity), dependability (i.e., reliability), confirmability (i.e., objectivity) and transferability (i.e., external validity) (Guba & Lincoln, 1994; Lincoln & Guba, 1985). Popular criticism of interpretivism is the

lack of generalisability of theories from interpretivist research and the absence of objectivity due to the researcher's attachment (Williams, 2000; Gris, 2004).

Interpretivism adopt methods that can yield qualitative data such as semi-structured or unstructured interviews, observation, case studies, qualitative surveys, field notes etc. Most of remanufacturing research fall under the interpretivist paradigm and have mostly adopted the case study approach since remanufacturing is by nature case-specific (Gehin, Zwolinski and Brissaud, 2008). Using the case study approach, Thierry and Salomon (1995) assessed the impact of four product recovery strategies on a firm by observing the processes and activities at the firm (Thierry et al., 1995). The authors believed that factors within specific contexts should be considered in order to fully understand what is being studied. The authors discussed several other factors that may influence the study hereby dismissing the idea of a single 'reality' within product recovery management. Bras and McIntosh (1999) explored the multiple nature of realities within remanufacturing research (Bras and McIntosh, 1999). The study identified direction of existing research and made recommendations based on what was observed from literature. The authors analysed and explored the perspectives of other researchers within the field and believed that the knowledge created from the study needs to be explored by future research. Guide (2000) adopted an inductive approach, using a piloted survey instrument to explore the nature of production planning and control (PPC) in remanufacturing firms (Guide, 2000). The author concluded that the context of remanufacturing operation occupies larger segments than previously conceived. The key findings of the research provided insights into the complicating characteristics of remanufacturing operations. This qualitative study understands and accepts that the researcher cannot distant himself from the research therefore qualifying his paradigm as interpretivism. Some more recent publications in remanufacturing literature which have adopted the interpretivist paradigm are (Seitz, 2007; Ijomah, 2009; Saavedra et al., 2013; Lechner and Reimann, 2015).

3.1.3. Pragmatism as a Research Paradigm

Instead of focusing on the positivism vs interpretivism debate, Johnson and Onwuegbuzie (2004) presented a case for pragmatism by seeking to combine quantitative and qualitative research components (Johnson & Onwuegbuzie, 2004). The debate for a more holistic and combinatory method has been discussed extensively in literature by (Morgan, 2014; Visser, 2019). Researchers have considered the possibility of tapping into the strengths of combining two methods and mixing paradigms as the desirability of pragmatism has

increased in recent years. Refer to (Greene, Caracelli and Graham, 1989; Biesta and Burbules, 2003; Bryman, 2003; Tashakkori and Teddlie, 2003; Creswell and Piano Clark, 2007; Johnson, Onwuegbuzie and Turner, 2007; Morse and Niehaus, 2009; Teddlie and Tashakkori, 2009; Ngulube, 2010; Goldkuhl, 2012; Hammond, 2013; Dalsgaard, 2014; Morgan, 2014; Bazeley, 2015; Curry and Nunez-Smith, 2017; Visser, 2019).

It is acknowledged among researchers that knowledge produced from research should be germane to current practices both in academia and in industry (Biesta and Burbules, 2003). According to early proponents of pragmatism, previous researchers have reduced their scope and lessened the impact of their research by being limited to a specific mindset, worldview, way of thinking, method or approach as would be within either the pure positivism or interpretivism paradigms (Bryman & Bell, 2007; Johnson & Onwuegbuzie, 2004). However, adopting pragmatism ensures enough flexibility to identify useful key points that will facilitate good research. Pragmatist paradigm focuses on "workability" of the research study (Bryman, 2003; Kivunja and Kuyini, 2017). The underlying aim of pragmatism is to get the problem solved without much attention to preferences regarding the method (Elkrghli, 2010). The pragmatist paradigm permits the researcher to adopt methods, techniques, and approaches that best meet the requirements of their research rather than focus on the foundational provisions of either the positivist or interpretivist paradigms. Pragmatic research can have objective and/or subjective ontology, relational epistemology, and mixed methodology of research. The logic of inference is mostly abduction or "retroduction" (Biesta & Burbules, 2003; J. Creswell & Piano Clark, 2007; J. W. Creswell, 2013; Dalsgaard, 2014; Kivunja & Kuyini, 2017; Rorty, 1980).

In the pragmatist research paradigm, research assumptions are driven by practical applicability of the problem and as such, the researcher should be flexible with selecting appropriate methodologies, approaches, mode of inquiry, etc. within particular a context without being constrained by philosophical assumptions (Elkrghli, 2010). The paradigm is based on the need to perform more holistic research, exploring the research problem from multiple worldview, philosophical or methodological assumptions, method, and design perspectives, therefore ensuring a more practical impact for research.

Over the years, researchers have supported the claim that pragmatist paradigm seems to be the perfect paradigm to justify combining methods or approaches in a mixed methods or multi-methods research (Creswell and Piano Clark, 2007; Teddlie and Tashakkori, 2009). However, there has been some criticisms. Refer to (Rawls, 1997; Bergman, 2008; Webb,

2012; Plante and Voy-Gillis, 2015; Maarouf, 2019; Dybowski, 2020). More discussions on the mixed methods research approach adopted in this thesis are presented in section 3.2 of this chapter.

3.1.4. Pragmatism in Remanufacturing literature

Decision-making issues in remanufacturing research has been treated as a multicriteria problem. The multicriteria nature of remanufacturability decision-making should aim to ensure that factors inherent to key decision makers are well taken care of. Some recent research in remanufacturing which adopted the pragmatist approach are (Subramoniam et al., 2013; Golinska-Dawson et al., 2018; Kalverkamp and Raabe, 2018; Kosacka, 2018; Stumpf, Schöggl and Baumgartner, 2020). For example, Subramoniam et al., (2013) adopted a multi-method research process combining case study research with analytical hierarchy process (AHP). Following a similar approach, some other studies have used a multi-stage, multi-objective research design which is deeply rooted within the pragmatist paradigm. However, their ontology, epistemology and method may vary and may be inconsistent, which is expected in the pragmatist paradigm.

3.1.5. Researcher's philosophical choices

There are the five main components of paradigm identified by Lincoln and Guba (1985) and they are described in this section (Lincoln & Guba, 1985). These components have been further described by Ijomah (2002) and Krishna (2020). They include ontology, epistemology, axiology, rhetoric, and methodology. Understanding the components of research paradigm is critical to understanding how the researcher's worldview impacts the research process. The interaction between these components is such that based on the nature of the research questions and the researcher's stance on what can be researched (ontology), closely linked with the researcher's knowledge of the subject and what would count as new knowledge (epistemology) impacts how the researcher plans to perform the research and acquire the knowledge (methodology).

3.1.5.1. Ontology

Ontology has been described as the "nature of reality" and "study of being" (Spielmann and Lin, 1977; Burrell and Morgan, 1979; Crotty, 1998, 2020; Gummesson, 2000; Creswell, 2013). Further, Poli and Seibt (2010), and Al-Ababneh (2020) described ontology as what can be "rationally understood" (Al-Ababneh, 2020; Poli & Seibt, 2010). Thus, ontological assumptions in research attempts to answer questions such as "what is the nature of reality?"

and “is there a reality out there waiting to be discovered, or is it created based on experience of individuals?”

Snape and Spencer (2003) identified three ontological positions which are realism, idealism and materialism (Snape and Spencer, 2003). Bryman and Bell (2007) suggested that ontological assumptions exist on a spectrum with objectivism on one end and constructionism on the other (Bryman & Bell, 2007). Whereas Easterby-Smith et al., (2018) identified realism, relativism, and nominalism as ontological positions (Easterby-Smith, Thorpe and Jackson, 2018). For more discussions on ontology refer to (Al-Ababneh 2020; Khatri 2020; Sniukas 2020).

The nature of reality in this research is critical realism in line with the description in (Gris, 2004; Yucel, 2018). The assumption of a critical realist ontology is that although reality is assumed to be separated from the observer, the nature of reality can be influenced by the researchers’ beliefs and values. With a focus on the research problem, the researcher believes, to certain extent, that reality can be objective and/or subjective, depending on the phase and stage of the present research. Thus, reality is epitomised in an expansive critical investigation. The main idea of critical realism is that it sits between positivist and interpretivist ontologies and is thus appropriate for this study.

3.1.5.2. Epistemology

Epistemology is described as the “nature of knowledge”. Burrell and Morgan (1979), and Crotty (1998) described epistemology as the way in which knowledge (i.e., what we know) is acquired, interpreted and disseminated (Burrell and Morgan, 1979; Crotty, 1998; Norström, 2015; Wang, 2020) and as such providing a philosophical backing for what is known and not known (Bridges, 2016) which influences the design of a research (Singh and Walwyn, 2017). In describing epistemological assumptions in research, attempts are made to answer questions such as “what counts as knowledge?” “What is the relationship between the researcher, and what is being researched?” and “is the researcher’s source of knowledge intuitive, authoritative, logical or empirical?”

Different epistemological positions have been described in literature. Similar to ontology, Bryman and Bell (2007) described epistemological positioning as a continuum ranging between strong positivism and strong interpretivism (Bryman & Bell, 2007) whereas Easterby-Smith et al., (2018) identified positivist and social constructionist epistemologies (Easterby-Smith, Thorpe and Jackson, 2018). More recent publications such as (Kinsella,

2007; Hill, 2014; Singh, 2019; Stänicke, Zachrisson and Vetlesen, 2020) have identified epistemological positions such as postmodernism, empiricism, rationalism, essentialism, and constructivism. For more discussions on epistemology refer to (Al-Ababneh, 2020; Hetherington, 2006; Khatri, 2020; Norström, 2015; V. Singh & Walwyn, 2017; J. Wang, 2020).

The adopted epistemology in this research is the relative objectivism and is described as the acquisition of knowledge through sampling, measurements, interviews, focus group, questionnaire etc. With the problem in mind, the researcher is inclined to believe that knowledge on improving remanufacturing decision-making is out there waiting to be discovered however, some level of interaction is expected. The researcher also believes that it is impossible to separate the inquirer from what is known and what would be known. Although meaning exists within the subject, the interpretation can faulty and based on the objects that form the core parts of the research. As a result, the researcher believes that the phenomenon should be studied across multiple viewpoints (i.e., the customers, industry, and academic practitioners) to understand it.

3.1.5.3. Axiology

Axiology is described as the "theory of value" and is concerned with the 'meaning-ness' of knowledge or the economic, moral, logical and social value of knowledge (Zaidi & Larsen, 2018). Axiology answer questions related to what is favourable for humans and how this influences researchers' choices. It focuses on questions such as "what is the value of the new knowledge created?" "what is the meaning of this research for education?" and "what are the social, environmental and economic value of research?"

Different descriptions of axiology have been presented in literature. Biedenbach and Jacobsson (2016) described three types of values: intrinsic, extrinsic, and systemic values (Biedenbach and Jacobsson, 2016). Patterson and Williams (1998) described axiology based on positivist paradigms (explanation, prediction, and control) and interpretivist paradigms (understanding and communication) (Patterson and Williams, 1998). However, Ijomah (2002) maintained a standpoint that researcher's values are excluded from a quantitative study whereas qualitative research is "value-laden" (Ijomah, 2002).

This research is axiological because the value of the researcher affects philosophical and methodological decisions. However, the influence of the researcher's value is minimal on the research results and discussions. From Patterson and Williams, the axiological

commitments underlying this research include explanation, understanding and control (Patterson and Williams, 1998).

3.1.5.4. Rhetoric

Rhetoric is described as the language or the specific way in which research is presented (written or spoken) (Horton, 1995; Cherwitz and Johnstone, 2014; Seigel, 2015; Constable, 2018). The rhetoric of research is very strongly influenced by the type of research data and the skill of the researcher (Creswell, 2013). Ijomah (2002) highlighted that quantitative research often adopt a formal rhetoric while qualitative research allows for more subtle informal rhetoric (Ijomah, 2002).

A formal rhetoric is preferred by the author and is adopted in this thesis based on the acceptable norms within this research field.

3.1.5.5. Methodology

Methodology focuses on understanding how the research will be performed. According to Crotty (1998), methodology refers to the actual strategy, course of action or designed process that link the adoption of specific research methods to the research problems (Crotty, 1998). In other words, methodology provides a philosophical basis for selecting a specific data collection approach (Al-Ababneh, 2020; Haradhan, 2018; Puri, 2019). The methodology of research is well informed by the worldview of the researcher, and it has been described as "intimately connected" to the researcher's ontological, epistemological, and axiological assumptions (Reich, 1994; Saunders & Tosey, 2013). Methodology as a component of research paradigm answers questions such as "How will I design my research?" and "What approach, procedure, logic of reasoning will be used to answer the research questions?"

Some of the types of methodology in literature are experimental, quasi-experimental, phenomenology, action research, survey, grounded theory, case study, historical, causal-comparative, content analysis and discourse analysis (Creswell, 2013; Easterby-Smith, Thorpe and Jackson, 2018; Al-Ababneh, 2020).

The goal of this research is to improve the effectiveness of remanufacturability decision making process by including the considerations of the customers. However, since remanufacturing is case-specific and customer preference usually vary across sectors, a qualitative case study and quantitative analytical hierarchical process (AHP) approaches are adopted in this research and the findings combined. To solve the research problem, a multi-

stage, multi-objective research approach is most appropriate using different data collection methods such case study, survey, focus groups, semi-structured interviews, workshops, and observation. The nature of this research requires a mixed-method approach.

3.1.6. Rationale for adopting Pragmatist Paradigm for this research

The rationales for adopting a pragmatist paradigm are highlighted below.

3.1.6.1. Nature of research

The primary factor behind the adoption of pragmatism in this thesis is because of the nature of the research problem. This research aims to present a comprehensive understanding of remanufacturability decision factors in the medical devices sector covering the requirements of the customers. Previous researchers such as Bras and Hammond (1996), Goodall (2014), and Omwando et al., (2018) have attempted to describe the complexity of the decision factors (Bras & Hammond, 1996; Goodall et al., 2014; Omwando et al., 2018). However, these studies have adopted a singular worldview or philosophical approach. Thus, the pragmatist approach presented in this thesis provides a unique and original approach to the research area. Moreover, pragmatism fits in the requirement of research within this operations management research domain (Cameron and Molina-Azorin, 2011; Bazeley, 2020).

3.1.6.2. Philosophical flexibility

Johnson and Onwuegbuzie (2004) reiterated the standpoints of Brewer and Hunter on the compatibility of quantitative and qualitative paradigms through pragmatism (Brewer & Hunter, 1989; Bryman & Bell, 2007; Johnson & Onwuegbuzie, 2004). Pragmatism offers philosophical flexibility which is not possible in pure interpretivism or post-positivism. The consequence of this is the practical benefits of research to applied discipline from solving the same problem by asking different set of questions, and combining and selecting appropriate worldviews, methods, and approaches to inquiry (Brewer and Hunter, 1989).

3.1.6.3. Focuses on strength rather than on weaknesses

Pragmatism offers a unique research approach by tapping into the strengths of positivist or interpretivist paradigms while avoiding, to a great extent, the inherent weaknesses of mono-methods or singular paradigms. Sale (2002) and Liu (2022) revisited the qualitative-quantitative debate and highlighted the sufficiency of sameness and connection in the fundamental values and basic assumptions in positivism (quantitative) and interpretivism

(qualitative) paradigms, which paves the way for stronger results of combining methods (Y. Liu, 2022; Sale et al., 2002).

3.1.6.4. Embraces mixed-methods research

Pragmatism provides a philosophical basis for mixing research methodology. Its approach to philosophical components such as ontology and epistemology presents a very practical way of doing research especially in applied disciplines (Shah et al., 2018).

3.2.Research Methodology

3.2.1. Introduction

The previous section presented the philosophy of research and highlighted the philosophical position adopted in this thesis. This section describes how this research is conducted including a brief description of research methodology, mixed methods research, the rationale, design, and strategy employed in this mixed methods research. Research methodology refers to a set of ideas about how to conduct a research based on the research paradigm adopted by the researcher (Bryman, 2003; Creswell, 2013; Easterby-Smith, Thorpe and Jackson, 2018). Basically, the methodology comprises of methods, techniques, and approaches. A research method is a direct course of action that needs to be systematically executed to answer the research questions. Research techniques refer to the specific tool or instruments that can be used to generate, collect, analyse, and interpret research data (Al-Ababneh, 2020; Bryman, 2003; J. W. Creswell, 2013; Easterby-Smith et al., 2018; Noor, 2008).

3.2.1.1. Understanding research methodology?

Etymologically, the word methodology is derived from the Greek word '*methodos'* (= *meta hodos*) which refers to a course of action or the 'way in which'. Thus, methodology of research describes the way in which a researcher attempts to answer the research questions. Research methodology is strongly influenced by problem stakeholders described by Jonker and Pennink (2009). These problem stakeholders include the problem creators, problem sponsors, problem owners, problem solvers and problem subjects (Jonker & Pennink, 2009). Thus, the overall methodology used in research depends, to a large extent, on the nature of the research questions and the researcher underpinning assumption of what constitutes 'good' research (Sheehan, 1986; Holden and Lynch, 2006; Novikov and Novikov, 2013).

Every research methodology has a starting point, a direction or path to follow, specific action plans and technique appropriate for collecting, analysing, interpreting, and reporting data. The purpose of a research methodology is to structure research actions based on the nature of the proposed questions and the answers that are desired (Meredith, 1993; Novikov and Novikov, 2013; Giedre and Jolita, 2020). The research questions addressed in this thesis are related to the improvement of remanufacturability decision-making in medical devices remanufacturing. Finding answers to these questions involve the combination of existing theories and methods.

3.2.1.2. Types of research methodologies

Researchers often try to draw the line between the 'two' types of research methodology: *quantitative* or *qualitative*. These are discussed below.

Quantitative methodology is often attached to the purely scientific way of conducting research. It is repeatable, specific, and fact-based which often results in exact figures or numbers. Data collection in quantitative research may be through survey and experiments. Researchers who adopt the quantitative methodology adhere strictly to established traditions and are guided by 'closed' type of research questions. Knowledge development using quantitative methods is based on conceptualising hypothesis and testing, often 'through the eyes of the researcher' (Brewer, Newman and Benz, 1999; Markus, 2007; Wang et al., 2013). Quantitative researchers usually adopt the positivist or postpositivist philosophical paradigms as discussed in the previous section.

On the other hand, **qualitative** methodology is guided by open questions with the aim of seeing 'through the eyes of someone else'. Qualitative methodology is more concerned about meaning and value of research and is descriptive in nature with more emphasis on fieldwork rather than on experiments. Some qualitative approaches are participant observation, unstructured interviews, group discussion and case studies (Bricki & Green, 2007; Bryman, 2003; Gear et al., 2018; Janis et al., 2020; Lincoln & Guba, 1985). Qualitative methodology is closely associated with the interpretivist or the naturalist paradigms.

Although debates about what type of methodology a researcher should adopt has been ongoing for decades, the important point is that the choice of methodology is strongly influenced by the nature of the research question(s). In some cases, neither the quantitative

nor qualitative approach are sufficient to answer the question(s). Thus, a third research methodology, 'mixed methodology' is adopted in this thesis.

3.2.1.3. Choice of methodology for this research

A mixed research methodology was chosen for this research. In order to improve decision making for remanufacturability, it is necessary to understand the decision factors, the key stakeholders, the decision process, and the relationship between them. For research of this nature where the researcher is not fully aware of all the factors and the extent of the phenomenon, Bryman (2003) suggested combining quantitative and qualitative methodologies allowing for a comprehensive, multi-perspective examination of the phenomenon. This tends to improve research in remanufacturing domain where majority of publications and thesis have adopted a mono-method or purist paradigms. The mixed methodology allows for a combination of insider and outsider perspective on a phenomenon which produces a general picture.

3.2.2. Mixed research methodology

Mixing methods refers to the use of at least two theoretically different approaches to develop and facilitate a better understanding of a concept or theory (Turner, Cardinal and Burton, 2017). The most important component of a mixed methods research is the 'mixing', 'integration', or 'blending' of at least one quantitative and one qualitative component in single research. Several definitions exist for a mixed methods research design. Creswell and Clark (2007) defined mixed methods research "… as a research design (or methodology) in which the researcher collects, analyses, and mixes (integrates, combines or connects) both quantitative and qualitative data in a single study or a multiphase program of inquiry" (Creswell and Piano Clark, 2007). Greene (2006) defined mixed methods research as *"... an approach to investigating the social world that ideally involves more than one methodological tradition and thus more than one way of knowing, along with more than one kind of technique for gathering, analysing, and representing human phenomena, all for the purpose of better understanding*" (Greene, 2006). In the words of Leech and Onwuegbuzie (2009), mixed methods research *"...involves the collection, analysis and interpretation of both quantitative and qualitative data in a single study or a series of studies that investigate the same underlying phenomenon"* (Leech and Onwuegbuzie, 2009). Johnson and Onwuegbuzie (2004) defined mixed methods research as *"... class of research where the researcher mixes or combines quantitative and qualitative research techniques, methods,*

approaches, concepts or language into a single study or set of related studies" (Johnson and Onwuegbuzie, 2004). The definition below is adopted in this thesis because it perfectly infuses several existing definitions into one acceptable definition. Also, this definition has been adopted by other researchers such as (Ramlo, 2022; Terrell, 2012; Vebrianto et al., 2020).

> *"Mixed methods research is the type of research in which a researcher or team of researchers combines elements of qualitative and quantitative research approaches (e.g., use of qualitative and quantitative viewpoints, data collection, analysis, inference techniques) for the broad purposes of improving understanding and corroboration"* (Johnson, Onwuegbuzie and Turner, 2007).

Adopting mixed methods research approach has several advantages which include the potential to explore different perspectives and answer complex questions. It can result in a more complete understanding of the phenomenon under study and eliminate over-reliance on one set of data which can strengthens the findings of a research. A more comprehensive account of social reality can be realized with a well-planned and systematic use of both quantitative and qualitative approaches. Other benefits include the development of valuable insights and better understanding of existing theoretical insights (Bryman, 2003; Johnson, Onwuegbuzie and Turner, 2007; Jonker and Pennink, 2009; Bergman, 2011; Cameron and Molina-Azorin, 2011; Shorten and Smith, 2017; Hopper, 2019).

Mixed methods research is not limited to any specific discipline and it has been adopted across a variety of research disciplines such as education research (Johnson & Onwuegbuzie, 2004; Onwuegbuzie & Weinbaum, 2017; Rocco & Plakhotnik, 2009) environmental management research (Timma, Blumberga and Blumberga, 2015; Molina-Azorín and López-Gamero, 2016; Hopper, 2019), psychology research (Bishop, 2015), sociology (Pearce, 2012; Timans, Wouters and Heilbron, 2019), health sciences research (Meissner et al., 2011; Curry and Nunez-Smith, 2017), nursing research (Morse, 1991; Doorenbos, 2014; Shorten and Smith, 2017), management and organisational research (Molina-Azorin, 2012; Bazeley, 2015; Molina-Azorin et al., 2017), and library and information science research (Fidel, 2008; Ngulube, 2010; Granikov et al., 2020).

In the next section, the rationales for adopting mixed methods approach in this thesis is discussed.

3.2.3. Rationales for combining quantitative and qualitative research

In remanufacturing research, combining quantitative and qualitative methods is not commonplace as existing research have relied on simple mono-method approach of either quantitative or qualitative methods. The growing trend towards the use of mixed methods in research stems from the realisation of the completeness and rigour that mixing research methods bring (Molina-Azorin et al., 2017). A few scholars in remanufacturing field which have used the term "mixed methods", they include Bates and Walsh (2017) who analysed workflow within a remanufacturing facility using the mixed methods approach, and Golinska-Dawson (2018) who presented a mixed methods approach to assess sustainability of the remanufacturing process using the Grey Decision Making (Bates and Walsh, 2017; Golinska-Dawson et al., 2018). In this section, the following rationales for adopting a mixed methods research approach are discussed:

1. Research characteristics
2. Research uniqueness
3. Research robustness

3.2.3.1. Characteristics of this research

The choice of research design (philosophical paradigm and methodology) was not clear early in this research. However, after reviewing and assessing extant literature on the subject, the author decided that a combination of qualitative and quantitative methods would present an original approach to the research questions and would be appropriate to answer the research questions. In selecting a research methodology, Ijomah (2002) identified four specific characteristics of a research discussed by Thomas and Tymon, they are: nature of research, inclination of existing methodology, researchers' involvement, and the need of practitioners (Thomas and Tymon, 1982; Ijomah, 2002). These characteristics are adopted in this thesis to justify the author's decision to combine quantitative and qualitative methods. They are discussed below.

3.2.3.1.1. Nature of the research

The literature review in chapter 2 identified possible areas of future research to improve remanufacturability decision-making in the medical devices sector. Although all these options present unique problem areas for the growing sector, due to the time and resource constraints, it is not possible to explore all these areas in one single PhD project. Therefore, this thesis focuses on connecting two areas of remanufacturing research:

remanufacturability decision-making and customer acceptance. As a result, careful consideration is given to the nature of research within these two areas in describing the nature of this present research.

This research aims to improve remanufacturability decision-making (decision-making research) using inputs from customer considerations (consumer behaviour research). The nature of this research requires a need to "see" from the eyes of both the researcher and the practitioners. The researcher, with experience in remanufacturing and medical devices research, plays a critical part in the research. On the other hand, the practitioners include both the customers and the businesses currently performing remanufacturing activities in the medical devices sector. Practitioners hold a key stake in determining the importance of this research vis-à-vis partnering with the researcher, exploring the contribution of the research, and validating the research findings. The mixed-methods research methodology has demonstrated its usefulness in research of this nature and is therefore appropriate for this PhD research.

3.2.3.1.2. Inclination of existing literature within the research field

The research methodology must be suitable to answer the research questions. Both ***quantitative methods*** (e.g. surveys (Ma et al., 2017; Vafadarnikjoo et al., 2018), simulations (Calvi et al., 2015; Gaspari et al., 2017), numerical analysis (Ge, Liu and Liu, 2014; Haolan Liao and Deng, 2018), DEMATEL (Singhal, Tripathy and Kumar Jena, 2018; Eze, Ijomah and Wong, 2020) and AHP (Ghazalli and Murata, 2011; Chakraborty, Mondal and Mukherjee, 2017)) and ***qualitative methods*** (e.g. case studies (Ogushi, Kandlikar and Dowlatabadi, 2006; Ijomah, 2009), interviews (Dowlatshahi, 2005; Sakao and Sundin, 2019) and focus groups (Priyono and Idris, 2018; Tarrar, Despeisse and Johansson, 2021)) have proven to be suitable in remanufacturing research. Therefore, a combination of quantitative and qualitative approaches is in line with existing literature in these research areas.

3.2.3.1.3. Researcher's involvement

The author has had previous experiences in remanufacturing and the medical devices sector. For the purpose of this research, the author has not been employed by any of the case study companies and has no previous affiliations with any of the medical devices experts which were engaged in this research. This ensures there is no bias or conflict of interest.

Depending on the mixed methods research design, the researcher must be able to maintain a balance between qualitative and quantitative epistemologies. This is because the underpinning epistemology of pragmatism paradigm does not equate knowledge with reality (Rorty, 1980) but instead knowledge is constructed to manage existence and experience the world (Goldkuhl, 2012). Therefore, the research is performed in different phases that include "seeing through the eyes of the researcher" (quantitative study) and "seeing through the eyes of someone else" (qualitative study) as is required in mixed methods research.

3.2.3.1.4. Practitioners need

Thomas and Tymon (1982) described a practitioner as any actor within an organisation that is directly involved with the phenomenon under study. With respect to this research, practitioners are those directly involved in making decisions on the remanufacturability and remanufacturing of products, purchase, use and maintenance of remanufactured medical devices in hospitals. These differing group of practitioners require a different means of engagement to maximise such interactions. The need for relevant research is a concern for every applied discipline. Thus, when doing a research of this nature, relationship between academic and practitioners is important to 'generate, validate, and disseminate knowledge across boundaries' (Rynes, Bartunek and Daft, 2001). Toffel (2016) described relevant research as one that seeks to answer research questions that directly address problems found in practice and uses variables within the control of practitioners (Toffel, 2016). Thomas and Tymon (1982), Timpel and Harst (2020), and Engell et al., (2021) reiterated that an important contribution of a practical and organisational research is the development of methods, connections and results with which decision-makers can improve the effectiveness of their operations (Engell et al., 2021; Thomas & Tymon, 1982; Timpel & Harst, 2020; Toffel, 2016).

Therefore, to ensure that research meets the needs of industry practitioners, Thomas and Tymon (1982) proposed five (5) components of a relevant research which are: descriptive relevance, goal relevance, operational validity, non-obviousness, and timeliness. These five components have been used by researchers within the remanufacturing research domain. Refer to (Ijomah, 2002; Hatcher, 2011; Priyono, 2015; Pawlik, 2019). However, a more recent and comprehensive seven (7) criteria for measuring the practical relevance of a research has been proposed by Svanberg (2020), they are: problem-driven, timely, important, implementable, non-obvious, novel, and not too costly (Svanberg, 2020). These

7 criteria are adopted for this research because they are more robust, more recent and are particularly applicable in disciplines that relate to sustainability or closed loop supply chain.

1. *Problem-Driven*: This is described as the extent to which the research is driven by specific problems or phenomena faced by problem stakeholders and practitioners (Thomas and Tymon, 1982; Svanberg, 2020). This is described as "descriptive relevance" by Thomas and Tymon (1982), and it covers both internal validity and external validity considerations (Thomas and Tymon, 1982). Other problem-driven measurement constructs include: "*research based on practice*" (Stentoft and Rajkumar, 2018), "*resolves practical problems*" (Liu and McKinnon, 2019), "*addressing real world problem*" (Rosemann and Vessey, 2008), "*strategic problems faced by decision makers*" (Shrivastava, 1987) and "*research significant to the real world*" (Klein, Jiang and Saunders, 2006).
2. *Timely*: Timeliness of a research measures the promptness of research findings for use by practitioners. Examples of time constructs presented by Svanberg (2020) are: "*findings delivered in time to deal with problems*" ((Thomas and Tymon, 1982), "*research useful at the time of publication*" (Benbasat and Zmud, 1999), "*research currently significant to real world*" (Klein, Jiang and Saunders, 2006), "*that the research area is still hot and not two or three years ago*" (Pearson, Pearson and Shim, 2005) and "*available to practitioners at the time they require it*" (Ijomah, 2002).
3. *Important*: This measures the impact of the research on businesses or industries under study. The importance construct has been described as "*research that practitioners care about*" (Svanberg, 2020), "*goal relevance – uses factors practitioners wish to influence*" (Thomas and Tymon, 1982), "*relevant to the goals of managers and business owners*" (Shrivastava, 1987), "*tied to business value*" (Bartunek and Rynes, 2010), "*provides competitive advantage*" (Jaworski, 2011) and that the research has direct implications for practitioners (Toffel, 2016).
4. *Implementable*: This measures the ease with which "*practitioners can make use of the findings*" (Bartunek and Rynes, 2010; Svanberg, 2020). Other measurement constructs are: "*operational validity*" (Thomas and Tymon, 1982), "*findings which can (actually) be implemented*" (Shrivastava, 1987; Benbasat and Zmud, 1999), and

"*research can be applied to practice*" (Rosemann and Vessey, 2008; Liu and McKinnon, 2019).

5. *Non-Obvious*: This measures the inventiveness of the research and that it goes beyond common sense that is available or currently being used by the practitioner (Thomas and Tymon, 1982; Shrivastava, 1987; Bartunek and Rynes, 2010; Svanberg, 2020).
6. *Novel*: The novelty of research to practitioners is such that the "*theoretical construct is new to practitioners*" (Vermeulen, 2007) and that the research "*provides novel insights*" (de-Margerie and Jiang, 2011).
7. *Not Too Costly*: This measures that implementing the findings of the research is affordable to the business/company (Shrivastava, 1987) and that the "*cost do not outweigh the benefits*" (Lo, Nagappan and Zimmermann, 2015).

3.2.3.2. Originality of research

A considerable amount of work in literature has been attempted to understand, describe, and improve the remanufacturability decision-making from a design standpoint. For example, Bras and Hammond (1996) proposed a design metrics for assessing product remanufacturability. Also, Fang and Ong proposed an assessment model for remanufacturability based on product design information from CAD diagram (Fang et al., 2014; Ong et al., 2016). Chakraborty et al., (2017) proposed a hierarchical model for remanufacturability assessment based on design information using the AHP and axiomatic design. More recently, researchers have begun to adopt a holistic approach to remanufacturability through original research and literature review. Liu et al., (2019) proposed a new approach for remanufacturability assessment of parts based on four metrices: economic indicator, product quality indicator, available resources indicator, and environmental indicator. Zhang et al., (2021) also reviewed remanufacturability assessment based on technology, economy, and environment. Abdullah (2020) modelled a remanufacturability assessment approach for CNC machine tool. However, these studies are flawed due to their philosophical and methodological underpinnings. These studies have approached this issue from a single standpoint usually from the viewpoint of experts and practitioners who perform decision-making. This leaves significant gaps as the intentions, stakeholders, industry specificity, and timing of such decisions have mostly been overlooked.

Mixed methods research is more than just a combination of different methods. However, the purpose of adopting a mixed methods approach is that results from a mixed methods approach will be better than those from either quantitative or qualitative methods. Therefore, combining quantitative and qualitative approaches provides a unique approach to the subject matter and lays the foundation for future work on remanufacturability decision-making. Mixed methods approach has been reported to contribute to the uniqueness of a study, especially in a field where existing approaches have been singular (Cameron and Molina-Azorin, 2011; Prabhu et al., 2021), as in the remanufacturing field.

3.2.3.3. Contributes to the robustness of this research

As described in Greene et al., (1989), the rationales for combining quantitative and qualitative methods in a research study can be explained using five (5) points: triangulation, complementarity, development, initiation, and expansion. However, a comprehensive list of rationales was provided by Bergman (2011) which include offset, completeness, process, different research questions, explanation, unexpected results, instrument development, sampling, credibility, context, illustration, utility, diversity of views and enhancement. The combination of rationales from Greene et al., (1989) and Bergman (2011) provides a wide basis on which to justify the robustness of combining quantitative and qualitative research approaches (Greene, Caracelli and Graham, 1989; Bergman, 2011). However, it is impossible to include all these rationales within a single study. Therefore, this thesis identified and described four (4) key rationales for adopting the mixed methods research approach which contributes to the robustness of this thesis:

1. ***Development***: More often, the findings from mono-method research often leads to asking more questions causing a need to conduct further research. In this research, findings from the quantitative phase were employed to develop a comprehensive approach for the qualitative phase.
2. ***Complementarity***: 'Complementarity' as a rationale for combining quantitative and qualitative methods research includes the need the elaborate, illustrate, clarify, and enhance the findings from one research method using the procedure and findings from the other method. In this thesis, results obtained from quantitative (customer focused), and qualitative (remanufacturer focused) studies were found to be complementary. This is critical to the implementation of the research findings.

3. ***Triangulation***: Triangulation is the main historical rationale for mixing research methods in that the quantitative research and qualitative research are combined so that the findings may be mutually corroborated (Fetters, Curry and Creswell, 2013). Triangulation can be investigator-based (when more than one researcher is involved), theory-based (when multiple theoretical perspectives is employed) or methodology-based (when multiple methods are employed) (Wang and Duffy, 2009). In this research, a methodological triangulation is adopted. The results from both the quantitative and qualitative phases are triangulated and the interpretations are made based on the triangulated findings.
4. ***Completeness***: By mixing methods, researcher can improve the robustness of a study by seeking a more comprehensive account of the phenomenon under study. This is the first time a complete understanding of remanufacturability decision-making is presented within the research field because this research obtains the perspectives of the key stakeholders which include: the practitioners (remanufacturing companies), customers (clinicians and devices experts at hospitals) and regulatory experts.

3.2.4. Designing the mixed method research

Despite the many positives of adopting a mixed methods research approach, one of the many challenges of mixed-methods research is its design. Teddlie and Tashakkori (2003) highlighted the design of mixed methods research as one of its unconsolidated issues (Teddlie and Tashakkori, 2003). There are different approaches to designing mixed methods research:

- "As a product" in terms of typological or taxonomic design, or
- "As a process" in terms of a dynamic or interactive design.

As a product, typological design follows the principles in existing mixed methods typologies. The challenge, however, is the overwhelming existence of several typologies of mixed methods designs. For example, Tashakkori and Teddlie (2003) discussed 35 mixed methods research designs, Leech and Onwuegbuzie (2009), and Morse and Niehaus (2009) discussed 8 mixed methods research designs. Other researchers have developed numerous typologies of mixed methods research. Refer to (J. W. Creswell & Plano-Clark, 2011; J. C. Greene et al., 1989; Maxwell & Loomis, 2003; Morse, 1991).

As a process, the dynamic approach to designing mixed methods research is expected to produce a design in which the goals, conceptual framework, research questions, methods

and validity are coherently combined (Maxwell and Loomis, 2003). This approach is reported by Creswell and Plano Clark (2011) to be particularly suited for early researchers. A common pitfall of designing as a process is the tendency to get lost as the researcher works independently on the different components of the design process (Schoonenboom and Johnson, 2017). Designing mixed methods research involves a consideration of different components of research and the issue of validity can be problematic for interactive designs.

A typological approach is adopted in this thesis. Following the discussions in (Leech and Onwuegbuzie, 2009; Morse and Niehaus, 2009; Schoonenboom and Johnson, 2017), mixed methods research designs can be a function of three key points: 1) *level of mixing* (partially vs fully mixed); 2) *timing* (concurrent or sequential), and 3) *level of importance* (equal vs dominant status). The level of mixing refers to the extent to which the research design mixes quantitative and qualitative approaches in data collection, analysis, and interpretation. Timing refers to the occurrence of either the quantitative or qualitative phases with respect to the other. If both phases are performed at the same time, the design is concurrent, else it is described as sequential. The level of importance refers to the emphasis on, or relative importance of either the quantitative or qualitative phases. A mixed method design could be equal status or dominant status.

Based on the description above and the typologies described in Leech and Onwuegbuzie (2009), the mixed methods research design adopted in this research is a "***partially mixed, sequential, dominant status design***", represented by the notation: ***quant → QUAL***. The notations are adopted from (Morse, 1991). This design is also described as *"Explanatory sequential mixed methods research design"* (Schoonenboom and Johnson, 2017). This has also been described as a *qualitatively driven mixed methods research* by (Morse and Cheek, 2014). The research design is explained in the next sub-sections using four considerations: purpose of research, theoretical drive, timing, and point of mixing (Morgan, 1998; Ivankova, Creswell and Stick, 2006; Schoonenboom and Johnson, 2017).

3.2.4.1. Purpose of research

The starting point of every research is understanding the purpose of the study. This purpose may be theoretical, methodological or a combination of both (Turner, Cardinal and Burton, 2017). In most cases, the theoretical purpose is closely linked to the research questions and is described in the next section as the *theoretical drive*.

The underlying aim of conducting mixed methods research is to invigorate research findings and strengthen the conclusions from such study (Creswell and Plano-Clark, 2011). The main research question in this thesis is:

How can remanufacturability decision-making be modelled to improve customer acceptance in the medical devices remanufacturing sector?

The overall goal of this research is to bridge the gap between remanufacturability assessment and customer acceptance in the medical devices remanufacturing sector. The main research question is broken down into a few shorter questions which can be simply investigated using either quantitative or qualitative approaches. This approach is common in literature for sequential mixed method studies (Tashakkori and Creswell, 2007). The specific research questions addressed in this thesis are stated and described below:

RQ1: **What is relationship between remanufacturability decision-making and customer acceptance?**

RQ2: **What are the key decision factors for assessing remanufacturability and how do they contribute to customer acceptance?**

The starting point of this research is a comprehensive review of existing literature. This thesis is, thus, theory-driven in line with (Eisenhardt and Graebner, 2007). The idea behind these two (2) questions is to understand what currently exists in literature. To answer this question, an expansive literature review to understand the state-of-art on the phenomenon was performed.

To answer both RQ1 & RQ2, the author performed a systematic literature review and content analysis to understand the state-of-art of remanufacturability decision-making from the viewpoint of the stakeholders. The answers to these questions formed a theoretical basis of this research and contributed to the identification of research gap which this research attempts to fill. Throughout the research, the researcher continuously interacted with literature, identifying the patterns, the decision factors, stakeholder involvement and customer considerations in remanufacturability decision-making.

RQ3: **What is the relative importance of decision factors that affect customer acceptance of remanufactured medical devices?**

This question was answered using analytic hierarchy process (AHP) to analyse the relative importance of the decision factors. Decision factors were obtained from literature and from early interactions with medical devices experts in hospitals. The AHP study equipped the author with the quantitative understanding of important customer considerations ahead of the qualitative phase where the author engaged with remanufacturing businesses in medical devices sector.

This quantitative study investigated the interaction between the decision factors identified in literature and through interactions with hospital-based medical devices experts. It analysed their decision-making process and ranked the factors that are critical to the customers. Data is collected through a survey process using a questionnaire that is sent to each participant. Highly experienced medical devices experts were engaged and invited to complete the questionnaire. A deductive approach was taken to interpret the data obtained as is expected under a positivist philosophy.

RQ4: **What is the nature of remanufacturing in the medical devices sector?**

A comprehensive review of existing literature on the subject is performed and reported in chapter 2. Further description of the nature of remanufacturing in the medical devices sector is presented the qualitative results chapter 5.

RQ5: **What are the key factors that are currently used in medical devices sector to assess remanufacturability?**

Attempts to answer these questions (RQ4 and RQ5) were performed in the qualitative phase. In this phase, the author builds on the findings from the quantitative phase to develop an approach to effectively answer these questions. This phase involves the use of in-depth semi-structured interviews with experts and technicians at companies that recover medical devices through the remanufacturing technique. This allow the researcher to capture information about the medical devices remanufacturing process (which is currently lacking in literature) and their understanding of the factors that influence remanufacturability decision-making. Since very little information is available on remanufacturing in medical devices sector, qualitative research is a suitable approach for exploring the research phenomenon with the aim of developing a novel knowledge (Strauss and Corbin, 1998; Corbin and Strauss, 2012).

A qualitative case study approach was adopted to answer these questions based on the recommendations of (McCutcheon and Meredith, 1993; Voss, Tsikriktsis and Frohlich, 2002; Eisenhardt and Graebner, 2007; Yin, 2018). A multiple case study approach was adopted to improve the researcher's understanding of the population which in turn yields more robust research. The case study approach is preferred for this phase because it suits the nature of the research and the inclination of the research field (Yin, 2018). Furthermore, the case study approach is suitable to understand the nature of events that the researcher does not have any control or influence over (Meredith, 1993; Stuart et al., 2002; Voss, Tsikriktsis and Frohlich, 2002).

Findings obtained from answering these questions are critical to building new theories within the remanufacturing field. This phase adopts an objective epistemology as is done when an interpretivist paradigm is used.

RQ6: **How can the new knowledge be presented to others?**

The importance of a pragmatist research is that it should aim to solve real life problems. Bearing in mind that one of the rationales for adopting mixed methods research is the need to meet the needs of the practitioners, it is therefore important that the findings of this research be presented in a format that is acceptable to the practitioners. Thus, a comprehensive customer-driven remanufacturability decision framework is developed to capture the key factors which should be considered during remanufacturability decision-making.

RQ7: **Is the new knowledge valid?**

The aim of this research question is to assess the validity of the knowledge obtained from this research and presented in the form of a framework. Due to the comprehensive nature of this research, different set of evaluation metrics are used to check the validity of this knowledge. Two categories of participants were invited to partake in the validation exercise:

1. **Industry practitioners**: those who are directly involved in making decision related to the remanufacturing of medical devices. This is made up of highly experienced experts who currently work in a company that remanufactures medical devices. They include representatives of the case study and non-case study companies.
2. **Academics**: those who have in-depth knowledge of remanufacturing and as such can provide useful comments to the author on the issue of validity of the research.

The participants in the framework validation exercise were asked to answer specific questions regarding the validity and usefulness of this new knowledge in line with (Amel-Zadeh et al., 2021; Hayashi et al., 2019; MacDermid et al., 2009; Pyett, 2003).

3.2.4.2. Theoretical drive

In mono-method research designs, theoretical drives could either be "*exploration-and-description*" (= inductive or qualitative research) or "*testing-and-prediction"* (= deductive or quantitative research) (Schoonenboom and Johnson, 2017). There are two main components of theoretical drive for a mixed methods research design: "*core*" component and the "*supplemental*" component (Schoonenboom and Johnson, 2017). Schoonenboom and Johnson (2017) suggested that the core or dominant theoretical component should be rigorously implemented and independent due to its decisive nature. Contrarily, they also argued that a key criterion of mixed methods designs is the need to meet multiple validities and legitimation. There are three different theoretical drives for a mixed methods study as suggested by (Johnson, Onwuegbuzie and Turner, 2007): 1) Qualitative dominant or qualitatively driven; 2) Quantitative dominant or quantitatively driven, and 3) Equal status or interactive approach.

The theoretical drive entails the analysis and interpretation of the main research question, clearly explicating its qualitative and quantitative components. A qualitative dominant theoretical drive is adopted in this thesis. The discussion presented in the following sub-sections entail why a **qualitatively driven** approach is desired for this research. The qualitative dominant drive is discussed below using the "core" and "supplemental" components proposed by (Morse and Niehaus, 2009).

3.2.4.2.1. Core Component: "Exploration-and-description"

The critical objective of this research is to explore remanufacturability decision-making in the medical devices sector. Given that there is currently no published information on this topic in literature, the importance of this phase of the research was clear to the researcher from the beginning. When a researcher investigates a phenomenon, the least known approach or area or question becomes the core component while the more known becomes supplemental (Morgan, 1998; Creswell, 2013). This is because the least known or the unknown would create a new knowledge which has the tendency significantly advance research and practice in the field. The research questions that address the core component are RQ4 and RQ5 which require a qualitative approach to answer. Thus, the priority in this

thesis is given to the qualitative study. Qualitative research, and especially the case study approach, is highly recommended in literature for the study of complex and/or unknown phenomenon (Dyer and Wilkins, 1991; Fletcher and Plakoyiannaki, 2000; Dul and Hak, 2007; Eisenhardt and Graebner, 2007). Research in the medical devices remanufacturing sector is still very much at its infancy, and there is a shortage of theoretical background for research in this field. Besides, knowledge about the relationship between customer factors and remanufacturability decision-making has not been previously investigated. A qualitative approach is more appropriate in such instances especially through in-depth interview, focus group discussions and participant observations.

3.2.4.2.2. Supplemental Component: "Testing-and-prediction"

As part of the preparatory stages for the core research component, the author needed to answer RQ3 which aims to develop a better understanding of the customers in the medical devices sector. This research phase tests the hypothesis that there is an imbalance of importance between factors that affect customer decisions. While research of this nature has been previously performed, it has mostly been limited to the electrical and electronics industry. Thus, it is not clear if the findings obtained in previous studies apply to the medical devices sector, especially given the differences between remanufacturing sectors that have been described in literature. Due to the nature of this research and the relative abundance of literature on consumer behaviour, purchasing intention (PI) and willingness to pay (WTP) for remanufactured products, this research component is treated as supplemental.

The weighting decisions on the research components are very strongly based on practicality of the research and resources available for this research. During the research, the author continually assessed the resources and time available for the research. This to ensure that the researcher is not engaged in an endless journey towards the creation of knowledge as knowledge itself is a time construct.

3.2.4.3. Timing of research components

Timing as a design component for mixed methods design entails the order in which the quantitative and qualitative phases of the research are completed (Greene, Caracelli and Graham, 1989; Creswell and Piano Clark, 2007; Molina-Azorín and López-Gamero, 2016). Guest (2013) described the two aspects of timing in mixed methods design: *simultaneity* and *dependence* (Guest, 2013). The "simultaneity" aspect distinguishes a concurrent and a sequential design. In concurrent designs, both quantitative and qualitative phases occur

simultaneously (or almost at the same time) and the appropriate notation is "+" according to (Morse, 1991). On the other hand, a sequential design involves one phase conducted after the other phase has been completed and the notation used is " → " to signify precedence. The subject of "dependence" is in place when any component of either the quantitative or qualitative phase depends on the results and interpretation of the data analysis of the other phase. The "dependence" aspect is linked to the core and supplemental component of the theoretical drive.

In this thesis, a **sequential design** is adopted in which the qualitative data is collected after the quantitative phase has been completed. The implication of this is that the author first obtained and analysed quantitative data after which qualitative data is collected and analysed (Ivankova, Creswell and Stick, 2006; Johnson, Onwuegbuzie and Turner, 2007). A sequential design is adopted due to the nature of the research (theoretical) and the purpose of the research (practical) which is for "development, complementarity, triangulation and completeness" in line with (Creswell and Piano Clark, 2007).

Another rationale for adopting a sequential design is due to the practicality of the research. The quantitative study relies on a survey research of medical devices experts based in healthcare facilities responsible for the purchase and use decisions of remanufactured medical devices. The qualitative phase is reliant on case study research of existing medical devices remanufacturing facilities. Both studies significantly pose completion challenge to the author due to the nature of the sector. One of the difficult tasks was identifying experts through a professional networking platform (www.linkedin.com), sending a request and an invitation to participate in the quantitative study while the author anticipated their response. While that proceeded quicker, the most difficult part of this PhD was finding companies that are willing to participate in the case study qualitative research. Also, through professional networking platform (www.linkedin.com), the author compiled a list of companies and contact persons who were sent direct cold emails, explaining the purpose of the study, and inviting them to participate in this Ph.D. research. Further, the process of waiting to get companies on board and scheduling site visits and interviews with experts and professionals took a long time. Also, this PhD research was conducted during the COVID-19 pandemic when lockdown rules were in place for a long period. Thus, if both the quantitative and qualitative components were to be completed concurrently, it would be impossible to complete the research reported in this thesis during the duration of a Ph.D. Therefore, a sequential design is most appropriate.

3.2.4.4. Point of mixing

Guest (2013) and Morse and Niehaus (2009) described the point of integration of mixed methods research as the point(s) at which the quantitative and qualitative components are combined or connected in some form (Morse and Niehaus, 2009; Guest, 2013). Every mixed methods research has at least one point of mixing. It is the "point(s) of integration" that justify that the research is indeed mixed methods research (Bryman, 2003; Creswell and Piano Clark, 2007; Schoonenboom and Johnson, 2017). However, it is not simply 'mixing' but this process may be described by these words: integrated, combined, meshed, blended, merged or fused (Bergman, 2011). Two points of integration identified by (Morse and Niehaus, 2009) are the 'results' and 'analysis' sections. However, depending on the research strategy, quantitative and qualitative components can be mixed at any point across the research process, such as during the conceptualisation, methodological, experimentation, analysis, and interpretation stages (Teddlie and Tashakkori, 2009).

In concurrent studies, researchers can often combine the quantitative and qualitative phases during any of the research stages (Schoonenboom and Johnson, 2017). However, in this thesis, a sequential design is adopted, and the qualitative and quantitative components are combined during the interpretation stage after the separate data has been collected and analysed (Bazely, 2009; Mertens, 2011). The three ways in which quantitative and qualitative components were combined in this study are:

- Analysis of the quantitative set of data are used to develop the data collection approach for the qualitative research phase
- Research data and analysis of the quantitative study were embedded within the larger design and procedure of the qualitative phase
- Findings from both quantitative and qualitative data are combined to develop a holistic understanding of the research problem. The combined findings discussed in chapter 6 are used to develop the framework discussed in chapter 7 which answers the research question RQ6.

As a result, a partially mixed design is adopted in this thesis. Quantitative data were obtained through questionnaires in survey research while qualitative data were collected through a semi-structured interview in case study research. The factors evaluated in the quantitative study are helpful in the development of interview questions and topics in order to explore the opinions and perspectives of the company representatives on customer considerations in

remanufacturability decision-making. On the other hand, the results from the qualitative study are used to explain the low acceptance of remanufactured medical devices obtained from the quantitative research.

3.2.5. Judging the research quality

The metrics used to judge the quality of research is situated within a particular paradigm (Healy and Perry, 2000). One major limitation of mixed methods research is that they are often insufficiently justified (Bergman, 2011). Judging the quality of a research strategy should be based on: (1) generalizability, (2) precision in control and measurement, and (3) authenticity of the context (McGrath, 1982). The 3 factors can be used to address issues relating to the reliability and validity of a mixed methods research.

Scholars have adopted different terms to describe these reliability and validity issues in research. Four key factors proposed by Yin (1994) are generally used to judge the quality of qualitative research: are construct validity, internal validity, internal validity, and external validity (Yin, 1994). These factors have been used extensively in remanufacturing research (Hatcher, 2011; Priyono, 2015; Symonds, 2015; Pawlik, 2019). Johnson and Onwuegbuzie (2004) adopted this to mixed methods research and replaced internal validity with credibility, external validity with transferability, reliability with dependability and construct validity with confirmability (Johnson & Onwuegbuzie, 2004).

For example, to judge the internal validity of research, a method that offers precision in measurement and control may be adopted, whereas an approach that maximises generalizability can be used to deal with threats of external validity (Turner, Cardinal and Burton, 2017). Further, authenticity of context can contend with issues related to reliability and construct validity can be taken care of by a careful combination of different approaches.

The techniques employed to judge the quality of this PhD research and the research stage where the techniques were applied are shown in table 3-2. This highlights the level of structure and clarity employed in this study to assess the quality of this mixed methods research.

Table 3-2: Techniques for judging the quality of this research

Factor	Technique	Stage during research where technique was applied
Construct validity	Using multiple sources of evidence	Data collection
	Establishing a chain of evidence	Data collection
	Practitioners' validation of research findings and output	Research validation process
Reliability	Clear and concise description of research strategy and approach	Data collection
	Using research methods and data collection instruments reported in literature as reliable across many studies	Data collection
	Evaluation of the consistency, accuracy, and reliability of research data	Data collection
Internal validity	Triangulation of findings	Data analysis
	Explanation building	Data analysis
	Participant validation	Data analysis
External validity	Using multiple participants and case study companies	Research design
	Validation by review	Research validation

3.2.5.1. Construct validity

Assessing construct validity of a mixed methods research is concerned with evaluating whether the research is believable and true, and whether it focuses on the phenomenon it set out to focus on (Zohrabi, 2013). Construct validity is critical in ensuring the quality of a mixed methods research and is generally associated with the data collection technique(s) that is employed in the research (Perez, 2019). That is, it establishes that the construct of a mixed methods research (the operational guideline and research strategy) is valid (Yin, 2003).

In this thesis, to address construct validity issues, the author used multiple data collection instruments across both quantitative and qualitative methods. This allowed the author to develop a "chain of evidence" (Ijomah, 2002) as results obtained from different instruments can be continuously compared. Keen attention was given by the author to construct validity when developing instruments for data collection instrument. Also, the findings and key outputs from the research were validated by practitioners which include key contributors to the research thus reducing the threats of construct validity.

3.2.5.2. Reliability

Reliability of research is a measure of the repeatability of the current study. Reliability assesses that if the study is repeated under the same circumstance, the same results will be obtained. Reliability in mixed methods research is concerned with the accuracy, consistency, dependability, and replicability of the overall findings of research (Troudi and Nunan, 1995; Zohrabi, 2013).

In this thesis, several techniques are used to achieve reliability. First, a clear and comprehensive description of the research design (timing, weighting, and importance), rationale for the study, rationale for the design approach, research method, data collection instruments, rationale for the specific instruments, the selection of participants and cases, rationale for selection decisions and the approach for combining findings has been presented in previous sections. Clarity on the researcher's positioning has been suggested to greatly impact the reliability of mixed methods research (Lincoln & Guba, 1985; Merriam, 1998).

Second, the researcher used research methods and data collection instruments that have been reported in related literature to enhance the reliability of research. By drawing on the rationales and justification for reliability already discussed in existing literature within the domain where similar approaches have been used, the threat of reliability is reduced.

Third, during the data collection process attempts were made to avoid biases and reduce errors by using the consistency ratio in the quantitative study and validation and verification of interview reports by interviewee. This ensures that the data collected are consistent, reliable, and accurately represent the participant's opinion. Also, this removes the researcher's bias in data collection and analysis.

3.2.5.3. Internal validity

Internal validity of a research measures the accuracy of the measurement constructs of research. It is particularly suitable in explanatory studies in which the causal relationship between concepts is presented to represent the social reality (Yin, 1994; Tashakkori and Teddlie, 2003).

In this thesis, the researcher focused more on the threats of internal validity during the data analysis and mixing stages. To address internal validity issues, three methods were used. First, findings across different phases of the study were triangulated to improve validity of the data and findings. Research data were collected across multiple sources including

questionnaire and semi-structured interview. During the mixing phase of the research, the quantitative and qualitive findings were corroborated thus ensuring the validity of the data.

Second, the researcher used a series of explanation building techniques during the mixing phase to evaluate the validity of the data obtained. Also, unexpected findings in the quantitative study were elaborated upon in the qualitative study and the overall findings of this research implied that the research is internally valid.

Third, the participant validation approach suggested by Merriam to improve internal validity was also employed (Merriam, 1998). Across different stages of this PhD, key research data, interpretations and outputs are presented to participants for confirmation and validation. Although this technique is more focused on the reliability of a study, its impact on internal is high since the feedback from participants can severely impact the overall validity of the data and interpretations.

3.2.5.4. External validity

External validity is concerned with the generalisability of a research. That is, the validity of the main findings across different contexts (Bryman, 2003; Creswell and Plano-Clark, 2011). External validity is well understood across several research fields and is generally considered during the research design process (Troudi and Nunan, 1995; Healy and Perry, 2000; Tashakkori and Creswell, 2007; Fàbregues and Molina-Azorín, 2017).

The two methods used to ensure external validity of this research are multiple participants and validation by review. The first approach involves designing the research such that the research data is obtained across multiple participants and multiple companies. This ensures a diversified view on the subject and also ensures the researcher's efforts to address external validity issues early in the research.

Second, a comprehensive validation of the research and the key output is performed involving practitioners who did not contribute to the data used in the research. They include practitioners in non-case study, academia, and participants in an international conference where the findings of this research were presented. Results from the validation exercise implied that the findings of this research transcend the study participants and are valid to external companies or practitioners within the research area.

3.3.Conclusion of chapter 3

This chapter described the philosophical underpinning and methodological approach of the research conducted in this PhD and reported in this thesis. It presented background discussions on research paradigms and the basic components of a paradigm as well as different methodologies that can be employed in research. This chapter presented and described pragmatism and mixed research methodology – the adopted philosophical and methodological approaches in this thesis. The rationales for adopting both pragmatism and mixed methods have also been discussed in this chapter. In the next chapter, results are presented.

Chapter Four: Quantitative Results: Hierarchical Analysis of Customer Decision Factors

4. Chapter Four: Quantitative Results: Hierarchical Analysis of Customer Decision Factors

This chapter is based on a published work of the author as part of the project undertaken during his PhD study. The chapter has been published as a research article in the Journal of Cleaner and Responsible Consumption (doi:https://10.1016/j.clrc.2021.100017).

4.1.Introduction

This chapter presents the findings from the quantitative study performed in this PhD research. The aim of this chapter is to present the hierarchy of factors that influence customers purchase or use decisions on medical devices. Using the Analytical Hierarchical Process (AHP), this chapter ranks the relative importance of factors considered by medical devices practitioners, based in hospitals and healthcare facilities, when deciding whether or not to use, recommend, repair, or perform any related activities on remanufactured medical devices. This rest of this chapter is structured as follows: A description of the research strategy is presented in section 4.2, followed by the results of the AHP in section 4.3. A discussion is presented 4.4 and conclusion in section 4.5. The completed pairwise comparison of each participant can be found in Appendix A (appendices A-1 to A-6) at the end of this thesis.

4.2.Research Strategy

In a AHP research, data can be collected through an interview, questionnaire or focus groups (Wadjdi, Sianturi and Ruslinawaty, 2018). The AHP approach has been broadly used by decision-makers and researchers across different fields (Saaty and Vargas, 2012). Most importantly, the AHP has been to prioritise factors, tasks, designs, and processes. Thus, as required by the nature of this study, the AHP is useful in ranking decision factors that influence the customers of medical devices when deciding whether or not to purchase, use and recommend a remanufactured medical device.

The AHP technique, proposed by Thomas L. Saaty, is not new in remanufacturing research (Saaty and Kearns, 1985). Subramoniam et al., (2013) ranked strategic decision factors using AHP and proposed a remanufacturing decision-making framework (RDMF) based on the results of the AHP. Gaur et al., (2017) proposed a pragmatic decision framework based

on the results obtained from a pair-wise comparison of consumer-related factors that affect core acquisition using the AHP technique. While these two studies proposed decision frameworks based on the factor ranks, some other studies have used factor weights obtained from AHP to develop models and methods for remanufacturing decision-making. For example, Jiang et al., (2011) proposed a planning method for selecting remanufacturing technology portfolio. Du et al., (2012) proposed a remanufacturability assessment method for used machine tool to calculate technological feasibility, economic feasibility, and environmental benefits of remanufacturing. Both studies used factor weights from AHP.

Data were collected using questionnaires sent to participants via email between March 2020 and July 2020. This study captures decision factors such as quality, price, warranty, brand equity, available information, value-added services, and environmental considerations. This research presents a quantitative insight into the nature of customer decision-making for remanufactured medical devices, which should be captured in remanufacturability decision-making to improve customer acceptance.

Designing the AHP study requires that the researcher understands and defines the specific problem, the need for and importance of the decision, the possible criteria and sub-criteria and the possible outcomes or decision alternatives (Saaty, 2002; Wang and Chen, 2005; Russo and Camanho, 2015). The AHP performed in this thesis follows five key steps in line with guidelines in existing remanufacturing literature (Subramoniam et al., 2013; Ahmed et al., 2016; Chakraborty, Mondal and Mukherjee, 2017): 1) Developing structural hierarchy for decision problem, 2) Understanding the scale of importance, 3) Pairwise comparison, 4) Hierarchic analysis and rank, and 5) Testing for rationality and consistency (Saaty and Kearns, 1985; Saaty, 2002). These steps are described in the following sub-sections.

4.2.1. Developing structural hierarchy for decision problem

The AHP attempts to answer RQ3 which aims to understand the relative importance of customer decision factors that affect remanufacturability. The first step in this study is to develop the structural or problem hierarchy. To do this, the nature of the decision is examined including the specific factors (obtained from a systematic literature review and interview with medical devices experts), the stakeholders and groups affected, the timing and importance of the decision. A top-down approach has been adopted in this AHP study and the structural hierarchy is shown in figure 4-1.

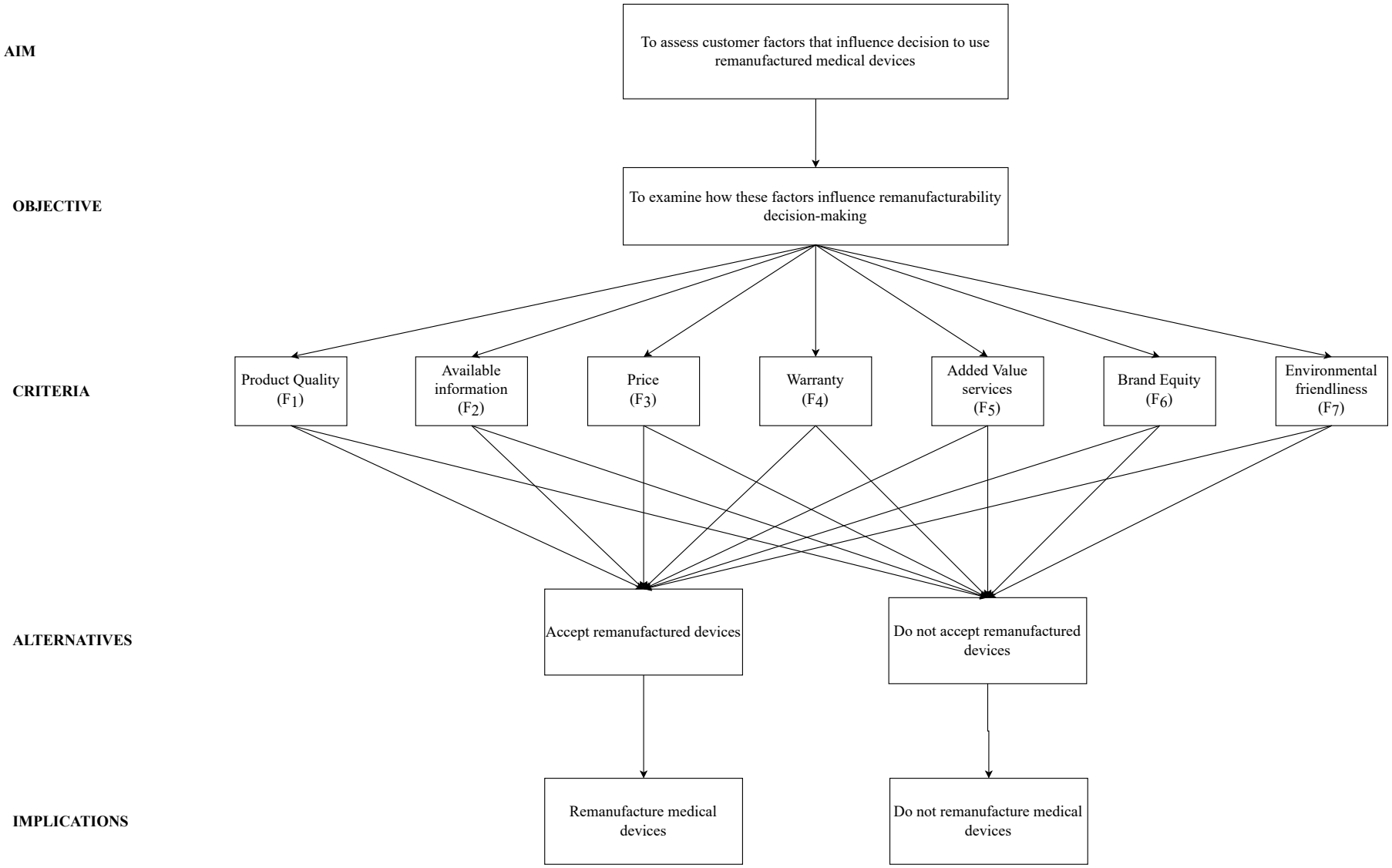

Figure 4-1: Structural hierarchy of decision problem

At the top level, the overall aim of this quantitative study is to assess the relative importance of factors that influence customer decisions to purchase and use remanufactured medical devices in caring for their patients. The objective is to examine how the relative importance of these factors can influence/improve remanufacturability assessment. Seven criteria are considered in this study which are quality of product (in terms of performance and safety) (F1), available information (e.g., previous use, expected life, quality certification) (F2), price (in terms of acquiring, operating and maintaining remanufactured devices) (F3), warranty provided on the remanufactured device (F4), value-added services (including post-sales technical services) (F5) brand equity (in terms of who performs the remanufacturing operation) (F6), and environmental friendliness (in terms of waste generated, material and energy consumption) (F7). More discussions on each of these factors have been presented in the literature review chapter 2. At the lower level, the set of alternatives is the customers decision to use remanufactured medical devices which directly translates to the remanufacturer's decision to remanufacture a product or not.

4.2.2. Understanding the scale of importance

The scale adopted in this study is the fundamental scale of relative importance proposed by Saaty and Kearns (1985). This scale has been adopted widely in practice and literature, especially in remanufacturing literature by (Ahmed et al., 2016; Chakraborty et al., 2017; Du et al., 2012; Gaur et al., 2017; Jiang et al., 2011; Subramoniam et al., 2013). This scale, shown in *table 4-1*, uses numerical values from 1 – 9 to represent linguistic terms that describe the relative importance of one factor over the other. For example, when assessing the relative importance of the factor *i* over factor *j*, a number x_{ij} is used. x_{ij} can be any number between 1 and 9 depending on the relative importance represented in *table 3-2*. Also, even numbers (2, 4, 6, 8) are intermediate values between the odd numbers and can also be used in the pairwise comparison. Consequently, the relative importance of *j* over *i*, x_{ji} is the reciprocal of x_{ij} as shown in equation below. Further discussions on the AHP method and pairwise comparison can be found in literature (Saaty and Kearns, 1985; Korhonen and Voutilainen, 2006; Saaty and Vargas, 2012).

$$x_{ij} = \frac{1}{x_{ji}}$$

Table 4-1: Scale of relative importance (Saaty and Vargas, 2012)

Level of importance	Linguistic terms	What this means
1	Equal Importance	The two factors contribute equally to the objectives
3	Moderate Importance	Your experience and judgement slightly favour one factor over the other
5	Strong Importance	Experience and judgement strongly favour one factor over the other
7	Very strong or demonstrated importance	One factor is favoured very strongly over the other factor, and this has been demonstrated in practice
9	Extreme importance	The evidence that favours one factor over the other has the highest possible level of affirmation

4.2.3. Construction of pairwise comparison matrix

The next step is the construction of a pairwise comparison matrix to capture the relative importance of one factor over the other. Using the key customer decision factors F1 to F7, the pairwise comparison matrix (shown in table 4-2) makes a direct comparison between the factors on the vertical axis and factors on the horizontal axis.

Table 4-2: Pairwise comparison matrix

Factors	F1	F2	F3	F4	F5	F6	F7
F1							
F2							
F3							
F4							
F5							
F6							
F7							

Also, the number comparisons each participant would make is calculated using the equation below, and this depends on the number of factors (n). In this study, 7 factors were considered, therefore 21 pairwise comparisons are performed by each participant.

$$\gamma = \frac{n(n-1)}{2} = \frac{7(7-1)}{2}$$

$$= \frac{7(6)}{2} = 21$$

The completed pairwise comparison matrix X which measures the relative importance of factor *i* over factor *j* using numerical values (x_{ij}) in the scale of importance (*Table 4-1*) is shown below.

$$X = \{x_{ij}\} = \begin{bmatrix} x_{11} & x_{12} & x_{13} & \cdots & x_{1n} \\ x_{21} & x_{22} & x_{23} & \cdots & x_{2n} \\ x_{31} & x_{32} & x_{33} & \cdots & x_{3n} \\ \vdots & \vdots & \vdots & \ddots & \vdots \\ x_{n1} & x_{n2} & x_{n3} & \cdots & x_{nn} \end{bmatrix}$$

4.2.4. Selection of participants

The participants in this study are six (6) medical devices experts. In any AHP study, there are two key methods of dealing with group participants: 1) the experts form a focus group and give a unified response to each cell in the pairwise comparison matrix; 2) each participant completes a separate pairwise comparison matrix and returns to the researcher. In this study, the second option – everyone completes separate pairwise comparison matric – is adopted. Their responses are collected and analysed individually. An analysis of the group response is also performed.

The nature of the medical devices sector is such that the repair and maintenance of medical devices require the services of highly trained and experienced professionals. As such, they are directly involved in decisions regarding the purchase, use and maintenance of remanufactured medical devices. Moreover, these experts have worked in the healthcare setting for several years maintaining and offering important technical services on medical devices. Their experience puts them in a good position to answer questions relating to the safety, functionality, and warranty requirements for remanufactured medical devices. Therefore, it is sufficient that this assessment is performed by a small group of highly experienced professionals (Korhonen and Voutilainen, 2006).

In total, fifteen (15) potential candidates were contacted by email (mostly based on referral) and invited to participate in the study. They were followed up within two weeks by email, clearly highlighting the importance of their response and the impact of such serving as a basis on which to improve medical devices remanufacturing. Six (6) completed pairwise comparison were obtained from six (6) participants described in table 4-3.

Table 4-3: Characteristics of participants

Title	Area of specialisation	Location	Number of years of experience
Head of Service, Medical Equipment Management	Medical Equipment Asset Management	Scotland, UK	37
Acting Head of Medical Equipment Management	Anaesthetics and ventilation	Scotland, UK	28
Head of Electromedical Equipment Services	Equipment management	Scotland, UK	30
Head of Medical Physics & Clinical Engineering	Diagnostic Imaging	England, UK	30
Chairman	Asset management and policy	England, UK	30+
Independent Medical Devices Professional	Medical Equipment Management	England, UK	39

4.2.5. Delivery of comparison matrices

The AHP pairwise comparison matrices were delivered to participants in the form of a questionnaire (Koyun and Ozkir , 2014; Chakraborty, Mondal and Mukherjee, 2017). Beforehand, participants were not familiar with the AHP method, therefore a comprehensive explanation of the method was given and three (3) examples of the AHP pairwise comparison process were presented to as supporting document to each participants.

4.2.6. Testing for rationality and consistency

To test the consistency and rationality of the AHP comparison matrix, the use of consistency ratio (CR) and consistency index (CI) has been recommended in (Saaty and Kearns, 1985; Saaty, 2002) since the AHP methodology requires consistent and logical responses from the participants. Different thresholds of acceptable CR (τ) have been recommended in literature depending on the number of factors considered in the study (Saaty and Kearns, 1985; Saaty, 1987, 2002). When three factors (n = 3) are considered, CR must not exceed 5% ($\tau = 0.05$), a 9% ($\tau = 0.09$) threshold when the number of factors does not exceed four (n = 4) and 10% ($\tau = 0.1$) when more than four factors ($n > 4$) are considered. When these thresholds are exceeded (i.e., CR > τ), the comparison is considered inconsistent and unreliable, the pairwise comparison must be repeated, and CR recalculated until CR < τ (Saaty and Vargas, 2012). In this study, CR was computed for the pairwise comparisons by each participant in line with (Korhonen and Voutilainen, 2006; Saaty and Vargas, 2012). The procedure for calculating the consistency ratio is outlined below.

Once the pairwise comparison matrix *X* is completed, the eigenvector (W) is calculated.

$$W = (w_1, w_2, w_3, \dots w_n)$$

The CI is calculated using the equation below:

$$CI = \frac{\lambda_{max} - n}{(n-1)}$$

n is the number of factors considered in the study, λ_{max} is the result of the product of the row column sum and the eigenvector matrix, W.

$$\lambda_{max} = [C_{1s}\ \ C_{2s}\ \ C_{3s} \ldots\ldots C_{ns}] \begin{bmatrix} W_1 \\ W_2 \\ W_3 \\ \vdots \\ W_n \end{bmatrix}$$

$C_{1s},\ C_{2s},\ C_{3s}$ are the sum of column 1, 2, 3 up to the sum of the nth column C_{ns}

$$CR = \frac{CI}{RI}$$

Where RI is the random index which depends on the number of factors considered in a study. The RI table given by Saaty (Saaty and Kearns, 1985) is shown in table 4-4.

Table 4-4: RI for number of factors considered (Saaty and Kearns, 1985)

n	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
RI	0	0	0.58	0.90	1.12	1.24	1.32	1.41	1.45	1.49

4.3.Results

4.3.1. Consistency of responses

The overall result of the consistency ratio (CR) for each participant is presented in the table 4-5. In the first attempt, two (2) out of the six (6) respondents were inconsistent and CR was estimated to be greater than 0.1 (i.e., CR = 0.14 for participant 4 and 0.27 for participant 6). The participants were asked to re-do the pairwise comparison clearly stating the importance of consistency of judgement in the AHP approach and providing further examples on how the AHP is performed. In the second attempt, all the responses were consistent, and CR were less than 0.10. Therefore, the results presented in this chapter are consistent and valid in line with the requirements in (Saaty, 1987, 2002).

Table 4-5: CR for each participant

Participants	Estimated consistency ratio (CR)	
	First Attempt	Second Attempt
Participant 1	0.08	0.08
Participant 2	0.08	0.08
Participant 3	0.09	0.09
Participant 4	0.14	0.09
Participant 5	0.09	0.09
Participant 6	0.27	0.06

4.3.2. Robustness of decision factors

The respondents were asked if the factors listed in the pairwise comparison matrix were sufficient and cover their key requirements when making the decisions to purchase, use, recommend or perform maintenance activities on remanufactured medical devices, depending on their role. A majority of the participants (67%) suggested that the seven factors (F1 to F7) used in this research would cover their key considerations. Other participants listed considerations such as human factors and availability of replacement parts. Human factors relate to the ease of use, training provided on remanufactured devices and the likelihood of user making error while operating device. On the other hand, availability of replacement parts takes into consideration the level of product-service guarantee that is provided on remanufactured devices. It is argued in this study that both human factors and availability of spare parts have been covered by the added value services factor F5.

4.3.3. Hierarchical analysis of aggregated matrix

The pairwise comparison matrix of each participant (shown in Appendix A-1 to Appendix A-6) are aggregated using the geometric mean approach, which was proposed in (Saaty and Kearns, 1985; Saaty, 1987) and generalised in (Dong et al., 2010; Krejčí and Stoklasa, 2018). In this study, the geometric mean approach is preferred to the arithmetic mean when aggregating group judgement. The geometric mean approach preserves the reciprocal symmetry of the individual pairwise comparisons which is not the case in the arithmetic mean approach. The aggregated pairwise comparison matrix is shown in table 4-6 and is normalised, to produce the normalised matrix in table 4-7.

Table 4-6: Aggregated pairwise comparison matrix

Factors	Quality	Available information	Price	Warranty	Added value services	Brand equity	Environmental friendliness
i. *Quality* of product in terms of performance and safety	1.00	4.74	2.22	2.29	3.89	2.57	5.97
j. *Available information* (e.g., previous use, expected life, quality certification)	0.21	1.00	0.44	0.91	2.44	0.82	3.13
k. *Price* in terms of acquiring, operating, and maintaining medical devices	0.45	2.28	1.00	1.05	2.99	2.14	5.38
l. *Warranty* provided on the medical device	0.44	1.10	0.95	1.00	2.67	1.22	4.97
m. *Added value services* including post-sales technical services	0.26	0.41	0.33	0.37	1.00	0.53	2.80
n. *Brand equity* in terms of who performs the remanufacturing operation.	0.39	1.22	0.47	0.82	1.87	1.00	4.82
o. *Environmental friendliness* in terms of waste generated material and energy consumption	0.32	0.32	0.19	0.20	0.36	0.21	1.00
SUM	3.06	11.07	5.60	6.64	15.21	8.49	28.07

Table 4-7: Normalised matrix (X^N)

Factors	Quality	Available information	Price	Warranty	Added value services	Brand equity	Environmental friendliness
i. *Quality*	0.3264	0.4283	0.3966	0.3446	0.2556	0.3026	0.2127
j. Available information	0.0689	0.0904	0.0784	0.1371	0.1602	0.0963	0.1116
k. *Price*	0.1470	0.2059	0.1786	0.1579	0.1968	0.2520	0.1916
l. Warranty	0.1426	0.0992	0.1702	0.1505	0.1753	0.1439	0.1769
m. Added value services	0.0839	0.0371	0.0596	0.0564	0.0657	0.0630	0.0997
n. Brand equity	0.1270	0.1104	0.0834	0.1231	0.1229	0.1178	0.1718
o. Environmental friendliness	0.1042	0.0288	0.0332	0.0303	0.0235	0.0244	0.0356

Table 4-8: Ranking of user-related factors using weights obtained from AHP

Rank	Factor	Relative Weight	Cumulative Weight
1	Quality of product in terms of performance and safety	0.3238	32.38%
2	Price in terms of acquiring, operating, and maintaining medical devices	0.1900	51.38%
3	Warranty provided on the medical device	0.1512	66.50%
4	Brand equity in terms of who performs the remanufacturing operation.	0.1224	78.74%
5	Available information (e.g., previous use, expected life, quality certification)	0.1061	89.35%
6	Added value services including post-sales technical services	0.0665	96.00%
7	Environmental friendliness in terms of waste generated material and energy consumption	0.0400	100.00%

The relative weight of each factor is estimated by taking the average of each row in the normalised matrix (X^N) presented in table 4-8 using the equation below:

$$Factor\ weight = Row_{average}[X^n]$$

$$Factor\ weight\ = \begin{bmatrix} Average & (0.32640.42830.39660.34460.25560.30260.2127) \\ Average & (0.06890.09040.07840.13710.16020.09630.1116) \\ Average & (0.14700.20590.17860.15790.19680.25200.1916) \\ Average & (0.14260.09920.17020.15050.17530.14390.1769) \\ Average & (0.08390.03710.05960.05640.06570.06300.0997) \\ Average & (0.12700.11040.08340.12310.12290.11780.1718) \\ Average & (0.10420.02880.03320.03030.02350.02440.0356) \end{bmatrix}$$

Table 4-8 shows the ranking, relative and cumulative weights of the factors based on the factor scores obtained from the AHP process. The result is shown in figure 4-2. The cumulative weights of the factors show that the first 4 factors (quality, price, warranty, and brand equity) account for 78.74%. Also, the weight of product quality factor exceeds a third (1/3) of the total weights. This further shows the importance of quality of remanufactured devices especially in the medical devices industry where safety of device is paramount.

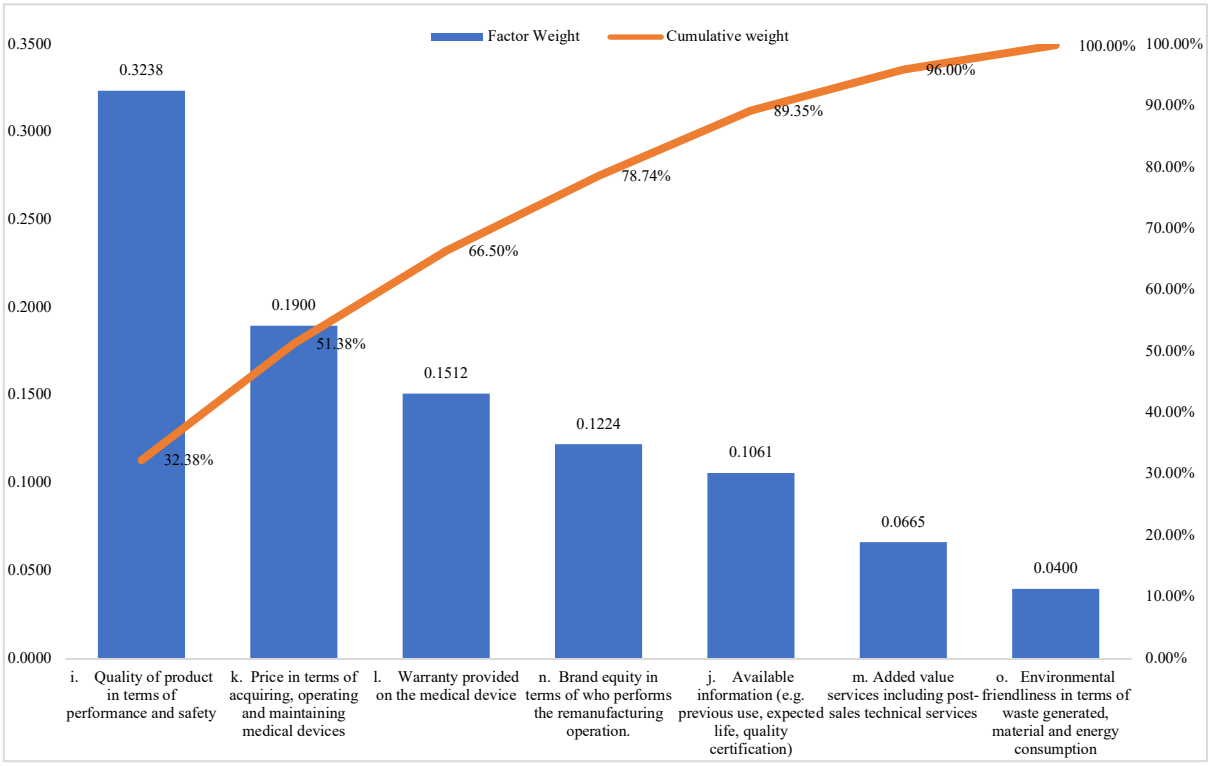

Figure 4-2: Cumulative sum of factor weights obtained from AHP

Table 4-9: Hierarchical analysis of individual pairwise comparison

Factors	**Factor Weight *(Ranking)***					
	Participant 1	Participant 2	Participant 3	Participant 4	Participant 5	Participant 6
i. Quality of product *in terms of performance and safety*	30.15% *(1)*	38.10% *(1)*	21.78% *(2)*	30.56% *(1)*	33.37% *(1)*	27.21% *(1)*
j. Available information *(e.g., previous use, expected life, quality certification)*	3.82% *(6)*	12.02% *(4)*	8.69% *(5)*	19.66% *(2)*	7.19% *(5)*	19.17% *(3)*
k. Price *in terms of acquiring, operating, and maintaining medical devices*	19.84% *(3)*	26.88% *(2)*	22.20% *(1)*	8.86% *(6)*	14.72% *(3)*	21.05% *(2)*
l. Warranty provided on the medical device	15.33% *(4)*	12.82% (3)	13.10% *(4)*	16.65% *(3)*	21.07% *(2)*	12.22% *(5)*
m. Added value services *including post-sales technical services*	8.03% *(5)*	3.24% *(7)*	7.74% *(6)*	10.92% *(4)*	6.82% *(6)*	4.99% *(6)*
n. Brand equity *in terms of who performs the remanufacturing operation.*	20.72% *(2)*	3.36% *(6)*	21.62% *(3)*	10.38% *(5)*	13.32% *(4)*	12.80% *(4)*
o. Environmental friendliness *in terms of waste generated material and energy consumption*	2.11% *(7)*	3.57% *(5)*	4.86% *(7)*	2.97% *(7)*	3.51% *(7)*	2.56% *(7)*

4.3.4. Hierarchical analysis of individual pairwise comparison matrix

To understand the disagreements among experts' preference, a separate hierarchical analysis was performed for the pairwise comparison collected from individual experts. The individual pairwise comparison is analysed and presented in table 4-9. This analysis shows some similarity between respondents. For example, five out of six (5/6) participants ranked quality as the most critical factor and environmental friendliness as the factor least influential on their purchase or use decisions. Further discussion is presented in the next section.

4.4.Discussion

Results from the AHP ranked the seven factors evaluated in this chapter. These factors influence customer acceptance of remanufactured medical devices and are listed in order: *quality*, *price*, *warranty*, *brand equity*, *available information, added value service* and *environmental friendliness*.

4.4.1. Product Quality

Quality was ranked as the most critical factor that influences acceptance of remanufactured medical devices. The overall factor weight of product quality (32.38%) underscores the underlying cause of a low acceptance of remanufactured medical devices because experts are wary of sudden failure, safety issues, accuracy of measurements, contamination, and the impact of the remanufactured devices on the patients. Individually, five out of the six experts ranked product quality as the most critical factor with the sixth participant ranking it second only behind the pricing structure of remanufactured devices. More so, four out of the six participants ranked quality first with factor weights more than 30% demonstrating the level of importance attached to the quality of remanufactured medical devices. A focus on ensuring that medical systems are remanufactured to a quality standard that is as good as new may increase customer acceptance.

4.4.2. Price

On the whole, price remains a key factor that drives customers towards remanufactured systems, and it was ranked as the second most critical in this study, with an overall weight of 19.00%. Customers expect that the price of remanufactured devices will be lower than that of new. Lower pricing of remanufactured devices appeal to customers as a benefit. This has contributed to increasing its desirability of remanufactured products (Milios and Matsumoto, 2019). *Pricing* and quality of remanufactured devices are two cardinal factors

that influence customer acceptance in medical devices industry (Starr et al., 2020). This is validated in this study with both factors accruing more than half of the overall factor weights (51.38%). Also, analysis of each participant's pairwise comparison showed the sum of factor weights for quality and pricing as 49.99%, 64.98%, 43.98%, 39.42%, 48.09% and 48.26%, which further reiterates the importance of these two factors combined. However, one participant ranked price as the 6th critical factor only above environmental factor. In the health and social care setting, more attention may be placed on other factors such as quality, available information, warranty, added service, and brand above the price of the device. For example, pricing may be the least critical consideration on life support or highly infectious devices (Health Devices, 2004; Shandilya and Nagi, 2008). Developing an effective pricing strategy is necessary for firms venturing into remanufacturing operation. However, there is need for a deeper insight on the pricing of remanufactured medical devices.

4.4.3. Warranty

In line with the definition of remanufacturing, customers expect a warranty similar to what is obtainable on a new device, or even better. The provision of warranty tends to reduce customer's perceived risks associated with using the remanufactured device. This, in turn, improves acceptance and may influence the remanufacturer's decision to remanufacture the device. The extent to which customer acceptance of remanufactured medical devices is influenced by *warranty* provision is reflected in the factor weight obtained in this study (15.12%) which ranks warranty as the third most critical consideration. This result reflects those of Vafadarnikjoo et al., (2018) and Van Weelden et al., (2016) who also described warranty as a critical motivation to purchase a remanufactured device (Van Weelden, Mugge and Bakker, 2016; Vafadarnikjoo et al., 2018). While customers' expectations of warranty are clear, the remanufacturers' view on warranty provisions is mostly unexplored.

Disagreements between participants on the relative importance of warranty is reflected in the varying level of importance associated with warranty. However, since warranty and added value service goes together in the medical sector, the sum of factor weights for the two factors is fairly consistent across participants and close to the value obtained on the analysis of aggregated pairwise comparison matrix 21.77%.

4.4.4. Brand

Brand equity was ranked fourth with a relative weight of 12.24%. This finding is consistent with data obtained in a study by Vafadarnikjoo et al., (2018) which ranked remanufacturer and retailer's reputation as fifth and seventh respectively in the automotive sector, and Gan and Chen which ranked remanufacturers and retailer's reputation as fourth and fifth, respectively (Vafadarnikjoo et al., 2018; Gan and Chen, 2019). In medical devices sector, branding is an important consideration especially when the users have little or no knowledge of, or experience with remanufactured medical devices (Lee, 2010; Torney et al., 2018). Customers' knowledge of who performs the remanufacturing may influence their choices, within the context of deciding whether or not to purchase and use a remanufactured product. However, customers' risk perceptions may reduce, even if only to certain extent, when a remanufactured product has been tested and certified by professional organisations (Van Weelden, Mugge and Bakker, 2016).

This study indicates a lower relative weight for brand equity when compared to other factors such as product quality, price, and warranty. More so, remanufacturing literature has not sufficiently considered issues related to branding, especially during the early planning and remanufacturability assessment stages.

4.4.5. Available information

Available information on the remanufactured medica device is ranked as the fifth critical factor with a weight of 10.61%. Knowledge of remanufacturing operation remains low in many sectors, more so in medical devices sector. The results from Wang et al., (2019) reflect a low mean value of product knowledge of remanufactured products whereas Milios and Matsumoto (2019) reported that up to two-third (60%) of their participants were not aware of auto parts remanufacturing and a whooping 76.4% have never used remanufactured auto parts (Milios and Matsumoto, 2019; Wang et al., 2019). Customers' negative perception about the quality level of remanufactured devices may be improved by issuing quality certification to gain user confidence, referred to as 'functional quality labelling or certification' (Abbey et al., 2017; Singhal, Jena and Tripathy, 2019).

4.4.6. Added value services

Customers consider warranty policy and added value *services* such as the availability of spare parts, repair, and maintenance services only after assessing the price and quality of the remanufactured product. In most cases, service agreements are embedded within the

warranty policy at least for the duration of the warranty. This is reflected in the relatively low ranking of added value services as sixth with a weight of 6.65% only ahead of environmental friendliness. Added value services such as user training and replacement part availability were suggested by participants in this study. This shows the slight importance attached to the provision of technical services in the medical devices sector.

Researchers have described warranty and service as a major 'risk reliever', 'builder of consumer trust' and a source of added value to the consumers (Van Weelden, Mugge and Bakker, 2016). High service quality has often been associated to a positive perception of a remanufactured device (Gaur et al., 2015). Service contracts on remanufactured devices imply that the remanufacturer is willing to stand behind their products. This particularly important in the medical devices sector. However, the nature and extent of the product-service guarantee remain largely unknown.

4.4.7. Environmental considerations

Environmental friendliness is the least ranked factor with a weight of 4.00%, despite increasing discussions on sustainability in the medical and healthcare sector. This is another factor which received the same ranking (7th) across five of six participants. Duan and Aloysius (2019) suggested that industries with high environmental consciousness perceive remanufactured products to be of good and acceptable quality and vice versa (Duan and Aloysius, 2019).

Duan and Aloysius (2019) suggested that industries with high environmental consciousness perceive remanufactured products to be of good and acceptable quality and vice versa (Duan and Aloysius, 2019). The low relative environmental consciousness in the healthcare sector may partly explain the low acceptance of remanufactured medical devices. This finding supports previous arguments on the impact of environmental benefits on customer acceptance in the medical devices industry (Kadamus, 2008; Compton et al., 2018; Cheong et al., 2020). This finding also highlights possible inaccuracies in existing remanufacturability decision-making approaches which have environmental considerations as a critical factor.

4.5.Conclusion of chapter 4

This chapter set out to analyse the criticality of seven customer decision factors. To achieve this, pairwise comparison of the customer decision factors was performed using the AHP method. Results show that the responses from the participants were consistent and rational. They ranked product *quality* in terms of performance, appearance and safety as the single most critical factor that influence customer acceptance of remanufactured medical devices followed by pricing, warranty, available information, brand equity, added value services and environmental friendliness. The approach adopted in this quantitative study is limited because the participants were only presented seven decision factors to rank. The next chapter presents findings from the qualitative case study of remanufacturing organisations in the medical devices sector.

Chapter Five: Qualitative Results from Case Study Research

5. Chapter Five: Qualitative Results from Case Study Research

5.1.Introduction

The previous chapter presented the findings from a quantitative study which used the Analytical Hierarchical Process (AHP) to rank key customer considerations on remanufactured medical devices. This chapter builds on the previous chapter by performing a multiple case study research focusing on organisations involved in the recovery of used medical devices. The term "*recovery*" is used as an umbrella term in this chapter to include end-of-life operations such as remanufacturing and refurbishment. The ambiguity of remanufacturing in the medical devices sector has been discussed in the literature review chapter 2. Each company assessed in this chapter describe their operations using different terms although they fit in the existing guidelines for remanufacturing in literature. The companies A, B, & C are involved in the recovery of medical imaging devices such as MRI, PET/CTs, Xray and ultrasound systems while company D recovers single-use medical devices.

Medical imaging devices are the very expensive devices that play a significant role in the day-to-day operation of a hospital. Due to the high initial cost of purchasing new imaging devices, the prospect of providing a low-cost, high quality recovered device can easily be the motivations for these companies. On the other hand, single-use devices are cheap and are used in large quantities by hospitals daily. As such, there is the potential to tap into the huge supply of cores.

The companies A, B, C and D contributed directly to this research by making key personnel within their organisation available for interview. The rest of this chapter is structured as follows. The qualitative research strategy is discussed in section 5.2 followed by the findings of the case study companies A, B, C and D in section 5.3, 5.4, 5.5 and 5.6 respectively. A cross-case analysis is presented in section 5.7. The conclusion of this chapter is presented in section 5.8. The verbatim transcriptions of each semi-structured interview can be found in Appendix B (from Appendix B-1 to Appendix B-12).

5.2.Research Strategy

The overall aim of a qualitative study is to explore, understand and describe a phenomenon (Harrison et al., 2017). Case study research has been described as an effective method when a complex or relatively unknown phenomenon is being studied by exploring specific details in their real-life settings (Casey and Houghton, 2010). The qualitative case study approach used in this thesis is underpinned by an interpretivist paradigm based on (Stake, 1995, 2006). The focus is on seeking explanation for the quantitative findings and also exploring remanufacturability decision-making in the actual context.

A multiple case study research was performed. This study relied on data collected from 4 companies in line with the recommendations of Eisenhardt's (1989) on using between four (4) to ten (10) cases for case study research (Eisenhardt, 1989). The rationale for using four (4) case study companies is to provide for a greater depth of observation and focus, and this has been supported in literature by (Dyer and Wilkins, 1991; Narasimhan and Jayaram, 1998; Stuart et al., 2002; Voss, Tsikriktsis and Frohlich, 2002; Boblin et al., 2013).

The case study approach is commonly adopted in remanufacturing literature because remanufacturing is by nature case-specific (Gehin, Zwolinski and Brissaud, 2008). The robustness and effectiveness of the case study approach within the remanufacturing research has been well demonstrated. Refer to (Liao, Shen and Wang, 2020; Curvelo Santana et al., 2021; Guo et al., 2021). In this thesis, medical devices remanufacturers were selected based on their size and involvement medical devices in remanufacturing. Selection is also based on their availability and willingness to participate in this research. This approach has been reiterated by Stuart et al (2002) that selection of cases should be focused on the potential of each case and their contribution to answering the research questions, rather than by concern for randomness (Stuart et al., 2002). The case study data were collected between December 2020 and September 2021. During this period, the researcher continuously engaged with engineers, decision makers, and managers across different levels in the four companies.

The procedure for the multiple case study research in this thesis follows an aggregated guideline proposed by (Yin, 2003; Stake, 2006; Crowe et al., 2011) which includes the following steps: 1) Selection of cases, 2) Designing data collection tools and protocol, 3) Collecting data, 4) Analysing data, 5) Writing case reports (individual and cross-case). These steps are discussed in the following sub-sections.

5.2.1. Selection of cases

Based on the previous work done in this research, organisations that have the tendency to contribute to improving understanding of remanufacturability decision-making in medical devices remanufacturing settings were identified. Identified organisations include original remanufacturers and third-party companies who are directly involved in the remanufacturing process of medical devices and parts. Companies were selected on their own merit in an intrinsic study (Stake, 1995). Thus, in this thesis, case companies are selected because of their distinctiveness, accessibility, and the nature of their engagement with the research community which is germane to case study research (Crowe et al., 2011). Although the selected cases can be argued as being representative of key players in the industry, this is not the driving factor behind the case selection. Also, the multiple case study approach allows comparison of the different cases across different levels.

The four (4) companies selected in this qualitative case study cover the different categories of remanufacturers. One is a prominent medical device OEM that has been involved in remanufacturing its own devices since 1997 (Company A). The second company is a third-party vendor typically involved in remarketing medical devices as a recovery activity and are currently scaling up their activities to remanufacturing (Company B). The third company is another medical devices OEM that has been involved in remanufacturing for over 12 years but are currently scaling back on their remanufacturing activities and focusing on other recovery activities (Company C). The fourth company is also a third-party remanufacturer who remanufacture single-use medical products irrespective of the original manufacturer (Company D). This variation in sampling provides a diversified and heterogeneous viewpoint, and a comprehensive outlook on the information required in this research (Curtis et al., 2000; Abdulrahman et al., 2015).

5.2.2. Designing data collection tools and protocol

When designing the data collection protocol for case study research, the goal should be on identifying tools that allow the researcher to identify processes and factors that contribute to the phenomenon (Yin, 2018). It is also important that while crafting the protocol, attention should be paid to the validity and reliability of data collected through the specific tool (Eisenhardt and Graebner, 2007). In this study, the main goal is to understand remanufacturability decision-making at the organisational level. However, it is also

important to gain a holistic knowledge about remanufacturing operation at the company since existing knowledge in the area is currently lacking.

Popular approaches to collecting data in case study research are analysis of company archives, direct observations, participant observations, interviews, questionnaires, and documentation. These methods have been widely discussed in literature. Refer to (Yin, 2003, 2018; Kumar, 2010; Boblin et al., 2013). Due to the nature of the research questions and available resources at the time of the research, the semi-structured interview protocol is used in this research. The rationale for a semi-structured interview protocol is because it enables a focus on specific topic, provides the opportunity to clarify ambiguity and misinformation, is effective for an in-depth research within a short time span and it does not require the researcher's physical presence on ground (which has become generally difficult due to COVID-19 global travel restrictions) (Marshall and Rossman, 1999; Kumar, 2010; Easterby-Smith, Thorpe and Jackson, 2018; Yin, 2018).

Interviews can be structured, semi-structured or unstructured depending on the nature of the research and the philosophical underpinnings of the researcher. Semi-structured interviews were used as the primary data collection protocol throughout the qualitative research phase. The findings from the quantitative research assisted in the development of the qualitative data collection protocol through specific themes and areas of discussions. Semi-structured interviews are more useful to gain an objective understanding of the research problem while also extracting knowledge and key data from practitioners in selected cases whose participation in actual research is limited. The design of the semi-structured interview is such that the specific themes and discussion topics are identified ahead of the interview. However, these can be easily changed, and the order of the questions is not fixed. In most cases, questions asked in the interview depend on the previous responses of the interviewee and the direction of the discussion. This approach gave some flexibility to the researcher and assisted in digging in and gaining as much information as possible about the phenomenon. Interviewees are highly experienced experts who have knowledge across different roles in the organisation and have interacted with the research problem (remanufacturability decision-making) in different capacities within the organisation which provides diverse perspectives during the interview.

The semi-structured interview protocol (shown in *figure 5-1*) covered the characteristics of the organisation, medical devices recovery operations carried out at the organisation, their remanufacturing process, remanufacturability decision-making and objective opinions

about customer factors that may influence remanufacturability decision-making. These questions sufficiently cover key areas that are critical in this study. The interview questions can be directly related to research questions RQ4 and RQ5.

Semi-structured interviews were conducted with 12 participants representing the four case study companies. The number of representatives from each company varied depending on their commitment to the research and the available resources. Top level and middle level management personnel were involved in the interview. Also, the level of detail presented for each company depended on public and non-confidential information shared by the companies.

Research themes	Interview questions
Characteristics of organisation	1. What is the type/size/location/age of organisation? 2. What remanufacturing/recovery business model does the company employ? 3. What products are commonly remanufactured? 4. What are the key target customer regions?
Understanding the nature of medical devices reprocessing at organisation	1. Can you describe the nature of product recovery at the organisation? 2. What are the major product recovery activities engaged in (i.e. repair or reconditioning or refurbishment or remanufacturing)? 3. Which regulatory bodies, definitions and standards followed by organisation to differentiate recovery activities (ISO 13485, IEC 63077:2019 etc)?
Remanufacturability decision-making	1. What is the nature of remanufacturability decision-making at the organisation? 2. What key factors are considered (or that should be considered) during decision-making? 3. What frameworks/models/methods guide their decision making?
Customer considerations at organisation	1. What types of customers are targeted by the organisations? 2. What are the characteristics of these customers (in terms of size, location, etc)? 3. What are the critical customer factors that influence organisation's product recovery activities? 4. What is the nature of relationship with their customers?
Medical devices remanufacturing process	1. What are the steps involved in recovering medical devices? 2. How is recovery terminology differentiated between products? 3. What quality evaluation steps are taken during their recovery operation? 4. What specific customer considerations impact their product recovery operation?

Figure 5-1: Semi-structured interview protocol used in this research

5.2.3. Collecting data

The researcher scheduled one-on-one interviews with nominated member of each organisation. Each interview lasted an hour, and the conversations were recorded using an audio recorder. Permission was granted by the participants before recording. This allowed the researcher to focus more on the interview and the interviewee rather than being

distracted with note taking. The recordings were transcribed verbatim, and the findings analysed and used to prepare the case report.

5.2.4. Analysing data

Evidence collected from the semi-structured interviews are used to answer the research questions with the aim of developing a better understanding of medical devices remanufacturing, understanding the nature of remanufacturability decision-making in the sector and highlighting the impact of customers on remanufacturability decision-making. Semi-structured interview generates a large amount of data, analysing this data is one of the biggest challenges of a qualitative case study research (Eisenhardt, 1989; Ijomah, 2002; Yin, 2014). In the qualitative study, the overall goal is building explanation and highlighting the patterns. According to (Yin, 2018), five analytic techniques can be applied in case study research: pattern matching, explanation building, time-series analysis, logic models and cross-case synthesis. In this thesis, pattern matching, and cross-case analysis are used to analyse case study evidence. While pattern matching is ideal when multiple data sources (or multiple interviewees) are used within a single case, cross-case analysis is ideal when a multiple case study research is performed (Saunders, Lewis and Thornhill, 2009; Easterby-Smith, Thorpe and Jackson, 2018; Yin, 2018). These two data analysis approaches are therefore appropriate for this study, and they contributed to the effective management of the large amount of data obtained from the semi-structured interview protocol.

Data collected from the participants within an organisation during the semi-structured interviews were analysed separately to ensure that the author had full understanding of each interview. Also, the transcripts of the meeting were shared with each participant to ensure that what was captured accurately describes their opinion and judgement. The pattern of response within an organisation were matched as in a within-case analysis and a case study report is produced for each case companies. The author maintained the same pattern and discussion points across the different cases to ensure consistency and comparability of collected evidence. Across cases, the author aimed to search for patterns of similarities and differences since no two cases are identical. The author first aimed to build a discussion about how each case are comparable along the key themes of this case study research to allow for sufficient similar findings across cases. Also, building on the similarities, the author identifies key divergent factors, practices and processes that are common within the separate cases. Thus, the author constructed plausible interpretative arguments that answer

the research questions and create new knowledge which enhances the validity and reliability of collected data.

5.2.5. Reporting case studies (individual and cross-case)

In an intrinsic qualitative case study research, the focus is on developing explanations and presenting a comprehensive understanding of a phenomenon rather than testing a hypothesis. The final step is drawing conclusions, interpreting, and reporting findings (Merriam, 1998; Yin, 2014). Reports were prepared across different levels of the research to ensure that the opinions and judgement of each interviewee is correctly captured, and that practices within an organisation captured in the research are accurate, and that there is an overall synergy between cases. The case reports for each company are sent to their representative for review and feedback. This allows the researcher to ensure the validity of the information captured during the research.

5.3.Company A

The first case is of a dedicated medical device recovery facility of a major original equipment manufacturer. Data used in this study is collected through semi-structured interviews with multiple professionals across different levels of the organisation. Also, company documentations were collected, analysed, and included in this study.

5.3.1. Key personnel

Table 5-1 shows the characteristics of participants in this case study research of company A, including their positions (at the time of the research) and their years of experience.

Table 5-1: Characteristics of participants at company A

S/N	Position	Description of Participant responsibilities	Years at company	Years in current role
1	Remanufacturing Technology Director (Head of engineering)	Leads a global team with Engineers in the US, India, China, Hungary and Brazil for the company's remanufacturing and refurbishment business.	22	10
2	Plant Manager	Oversees the repair facility where recovery is performed	20+	3
3	Global Segment Leader – (Women's Health, Interventional, X-Ray & Molecular Imaging)	Is the product manager for CTs and MRs recovery Manages all business operational and product management aspects of the company's Healthcare's preowned Detection & Guidance Solutions (Rad, R&F, Mammo & Interventional), Nuclear and PET/CT product portfolios globally.	20+	11
4	Global Segment Leader (Ultrasound business)	Manages all aspect of ultrasound equipment refurbishment, re-manufacturing and distribution globally including customer satisfaction and complaints, product strategy, new product releases, revenue growth, cost, quality, inventory, service levels and sales support.	9	6
5	Global Asset Management Leader	Manages inventory of all used equipment that's coming in for the company's remanufacturing or refurbishment operation. making decisions about the disposition alternatives of used medical systems	15	2
6	General Manager – Recovery Business for SHS Region (India, Southeast Asia & Africa)	Oversees recovery business for India, Africa, and the ASEAN region.	20+	3

5.3.2. Company background

Company A is based in the United States and is part of a leading medical devices original manufacturer with several manufacturing facilities globally. Apart from the case study site, the parent OEM has 2 other recovery facilities in the US. Outside the US, the company has recovery facilities in Austria, Germany, and France. The case study site recovers (through refurbishment and remanufacturing) medical imaging devices such as the X-rays, CT (computed tomography) scan, MRI (magnetic resonance imaging), nuclear medicine imaging, including positron-emission tomography (PET) whereas other facilities recover ultrasound systems, patient monitoring etc.

Company A started its recovery operation in 1997 mainly to handle used products that were coming off lease at the time. Before then, used medical devices manufactured by the parent OEM were mostly brokered to third-party companies who would handle and resell (directly) to another customer. As the volume of returns increased, the company recognised the

business opportunity to handle their own products and provide more support to customers, mostly driven from a financial standpoint. Thus, their initial goals were to:

1. Tap into the growing market for low-cost and affordable medical systems
2. Get more value for their end-of-use systems
3. Control the quality of products going to customers with their company logo
4. Protect their brand and gain more customer confidence

However, recent improvements and growth of recovery activities in the medical and healthcare devices industry has seen the company increase its portfolio of recovered medical devices. At the time of this research, the company recovers more than 100 active models of ultrasound equipment and about 10 models of the CT/MRI systems.

5.3.3. Business Scenario

The company uses the make-to-order production approach in which the core recovery operation begins after customer order is received. Company A sells to the global market and focus on different customer segment. Some of their key targets are specific outpatient clinics with higher volume, specific types of budgets and are looking to add more capacity to their current equipment. Also, Company A operates product recovery and part recovery as different units within the same facility. The implication of this for the product recovery operation is that parts that fail to meet the quality requirements always undergo replacement either with a recovered part or an equivalent new one. However, the removed/replaced parts are sent to the part recovery arm of the business where they are recovered and stored in the inventory for the next use. The business scenario at company A is described below using key points such as procuring cores, product offering, marketing approach, warranty, and pricing.

5.3.3.1. Procuring cores

Most of the cores recovered at company A are obtained off lease, as part of a trade-in or are purchased directly from customers with an upgrade offer as discussed below:

Demo systems: These are devices which served as demonstration during marketing of new products. They are generally moved from one customer site to the other with the aim of providing an illustration of how the new system works. After the product has moved through several customer sites for a couple of months, it is returned to the company's recovery facility where it is taken through their specialised recovery operations.

Pre-owned systems: These are systems that have been purchased and used by customers for a certain period of time. These systems are often part of a trade-in agreement during the sale or purchase of a new or recovered system. The product is returned to the company's recovery facility, and it is taken through their recovery operation.

Dealers return systems: In some cases, the company loses the bid to purchase customers' old system, usually because a third party or another company offered better price point or value to the customer. Thus, as the system moves around, company A may receive an offer from a third-party, dealer or another OEM to procure one of its old systems. In that case, company A purchases the system and take it through its recovery operation.

5.3.3.2. Product offering

Typically, company A targets products that can be recovered and offered to customers as a competitive offering with a reasonable sales margin and profit to the company. As a result, premium products are usually targeted for the recovery operation. However, in certain situations, the company recovers signature, performance, and value products (with lower sales margin) when customer demand can be established through a business case analysis.

When assessing the product offerings, the company assesses similar existing products offered by the parent OEM to prevent cannibalisation of similar products. A common issue in the industry is when a customer has to make the decision between purchasing a brand-new performance system or a pre-owned recovered super premium product at the same or similar price. This company avoids this situation as much as possible.

5.3.3.3. Marketing approach

The company uses the same marketing team for both new and recovered systems. That is, the same marketing or sales team for a new system are responsible for marketing the equivalent recovered system. An interviewee explained further:

> *"We don't sell them to our customers any different. We tell them you're getting our company branded recovered system. So, for example, when they (our marketing team) are discussing with a customer, they say you could get the brand-new MRI or CT system at this price OR you could get a premium remanufactured same device, same quality, same warranty at this lower price depending on your budget."*

Overall, recovered medical devices by this company can be marketed in two ways: *direct marketing* (using internal sales team) and *dealer channel* (using external vendors, dealers, and distributors).

Company A's Direct Marketing

This is what happens in most cases, the company's sales team directly markets the recovered product to the customer. This is the preferred marketing channel for recovered medical devices by this company. The US market is by far the biggest market for company A because they can obtain the highest value in the US. The direct marketing channel is particularly for customers based in countries where the company has sales representation in. An interviewee explained further:

"You can imagine some other markets around the world, whether it'd be India or China or some of these other markets and you know you're just not going to get the same price point for a recovered system that you can get in the United States or in Europe, so the US and Europe are the two biggest, but the US by far but then Europe right in behind it"

Company A's Dealer Channel or Third-party

The company has a number of approved dealers and distributors contracted to sell their medical systems in regions or countries where the company has little or no sales representation in. By using a dealer or distributor, the company increases the reach of its recovered products thereby spreading awareness of its offerings and increasing its revenue.

5.3.3.4. Warranty

This company provides the same warranty on all recovered devices as offered on equivalent brand-new products. Customers expect that the recovered device can be backed up by an equal warranty because it competes with brand new products. The warranty also extends to parts that are recovered within the part recovery unit of the facility.

5.3.3.5. Pricing

Recovered medical devices at company A are offered to customers at an average of about 20% less than what the product was sold when it was new. The price ratio is not fixed, and it usually depend on a number of factors that are unveiled during planning process and recovery operation. These factors include the source of the cores (demo systems, trade ins, etc), the age of the system and the overall cost to recover it. However, on the average, recovered items (products and parts) cost between 20 – 60% of the costs of new items.

5.3.3.6. Different recovery operations

In this chapter, the term "recovery" is used as an umbrella term to cover the company's activities such as refurbishment and remanufacturing. Both operations follow the same steps or activities, thus making it difficult to differentiate one from the other based on the physical work done in the facility. However, the company adopts the definitions of refurbishment and remanufacturing presented by the U.S. Food and Drug Administration (FDA) which differentiate the two process by the need for a new registration document referred to as the 510(k) (Santhosh and Kamaraj, 2018). The company adopts a generalised name for its recovery operation and products (hereafter referred to as 'XA' operation and 'XA' products respectively). More discussions on the different recovery operations are provided in the next sub-sections

5.3.3.6.1. Refurbishment

Refurbishment operation at company A is such that the dimensional or performance characteristics of the medical system is the same as when it was first placed on the market. According to the U.S. FDA, the refurbishment process is synonymous to servicing operations because significant changes or upgrades are not made to the device. As a result, refurbished products retain the initial registration document (510(k) clearance). An illustration is presented below:

"For example, if we bring back a recent ultrasound and after taking it through our recovery operation, we have not significantly altered its functionality, so it is basically the same performance as when it was new, it retains the old 510(k) document, and we call it a XA refurbished system."

5.3.3.6.2. Remanufacturing

Remanufacturing at this company involves making significant changes or upgrades to an old medical system such that it is outside the initial 510(k) medical devices registration document or has a different intended use. Below is a description of remanufacturing at this company.

"If we add an upgrade kit, that causes us to go from one 510(k) to the next 510(k) then that's remanufacturing. If it is really what our customers want and it's the best use of our assets coming back, then we feel comfortable to remanufacture."

A further description of the XA remanufacturing operation is presented below:

"So, if we have a piece of Xray equipment that we bring back and originally it was just an analogue Xray machine where you would manually print the films and read it. If we take that equipment back and change it to a digital model where you could read the images on a screen, that significantly changes how the customer uses the product and that would be classified as a remanufactured XA system."

Another illustration is provided to enhance understanding of remanufacturing at this company:

"Let's say we take back a CT machine which previously had the capability to do certain scans e.g., orthopaedic scans or for more basic scans like bone structuring etc. Now, if we add an upgrade kit so we upgrade the machine so that it can now perform cardiac scans or liver scans or it can do cardiovascular type scans. This upgrade kit has changed the intended use and the process would be considered as XA remanufacturing operation. We may also change the performance so in the past if it was a 4-slice system (which is a slower system) and we put an upgrade package on it and then it becomes a 16-slice or a 32-slice system. We have significantly improved the performance through the upgrade package and the product is considered as a XA remanufactured device."

The implication of remanufacturing medical devices, and the need to use a new 510(k), is that the company would be subjected to the same audit and scrutiny as an original manufacturer. A majority of the recovered products at this company are refurbished, while a smaller amount is remanufactured.

5.3.3.6.3. Differentiating refurbishment from remanufacturing

The distinguishing factor could be as much a software upgrade as it is a hardware upgrade. In terms of the actual recovery activities, there is no distinguishing remanufacturing from refurbishment. Physically, both refurbishment and remanufacturing are performed within the same space. They go through the same process paths and activities, and they end up at the same places. The key differentiating point is the difference between the core and the product at the end of the recovery operation as explained by an interviewee:

"So, what is most important is where the core started (what the core looked like originally) and where we want to end. So, for example, we could have two systems that we need to do

the same upgrades on but because they started at two different spots, one is remanufactured while the other is refurbished."

From a warranty standpoint, the company gives the same warranty on recovered medical systems as they do for new. Also, the remanufacturing and refurbishment processes are the same and thus the same warranty is provided. However, some slight differences can be observed in the work content, cost of procuring cores and operation cost between remanufacturing and refurbishment as illustrated in figure 5-2. The company applies a label to the product to indicate whether it has been remanufactured or refurbished. The company does not necessarily sell either remanufactured or refurbished devices separately neither do they market remanufactured or refurbished versions of their recovered systems.

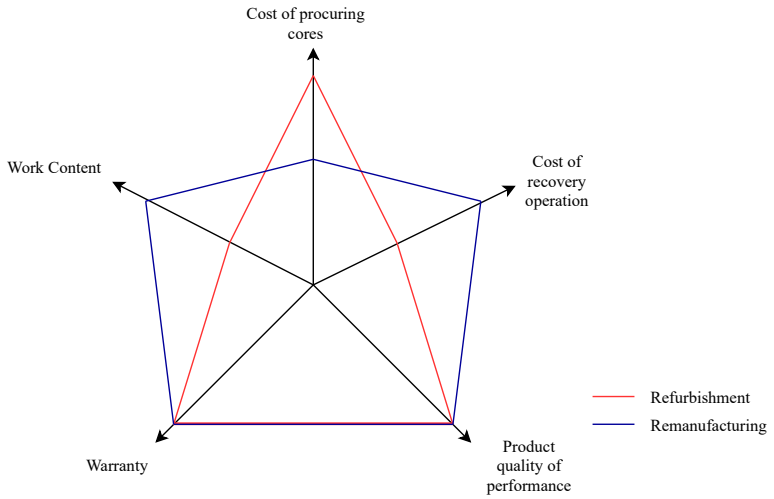

Figure 5-2: Company A's medical devices recovery activities

5.3.4. Description of company's recovery operation

When a system arrives at the recovery facility, the field service history, the condition of the returned system and specific issues with the system (or its modality) are assessed. A specialised process, developed by the design and engineering team, is used to take the device from the return condition to a "like-new" condition. This involves four (4) process phases as shown in figure 5-3: *Phase A*: Initial preparation of cores; *Phase B*: product recovery; *Phase C*: Testing. After the three phases are completed, the system is moved to *Phase D* where it is packaged into shippable format and sent to the customer site where it is installed by the same install team for new products. This process is described in more detail in the next sub-sections.

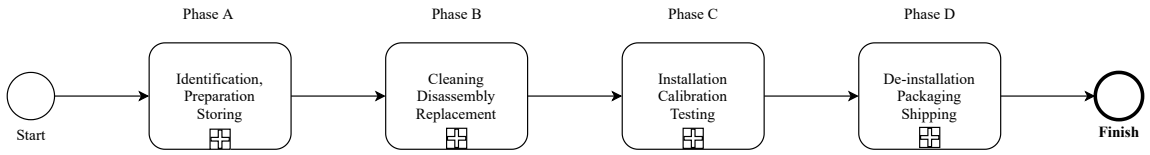

Figure 5-3: Process diagram of recovery operation at company A

5.3.4.1. Phase A: Initial preparation

The phase A activities include selection of cores, de-installation at the customer site and shipping to the facility, inspection and storing. These activities are shown in the process model figure 5-4.

Figure 5-4: Process diagram of phase A activities

5.3.4.1.1. Equipment selection

The recovery operation starts with the selection of used medical devices (or cores) to be used in the remanufacturing operation. Cores may be obtained through three modes. The selection decision is accompanied by the product disposition decisions. The disposition decision identifies the product recovery options through which a used medical device or its components would be put through. Returned medical devices at company A can go through these 3 recovery options:

1. **Product recovery**: the product is taken back, recovered (refurbished or remanufactured) and then sold to a new customer.
2. **Part harvesting**: specific components are extracted and used to support customers who have similar products already in their install base but require parts which there is little or no supply. In other cases, products which are considered unsuitable to return to an install base, either because of the age, performance, or spare parts supply, may also be treated through part harvesting. An interviewee described further:

"If a product has some significant issues, for instance, let's say somebody literally drops it off the back of a truck or something like that, or down a step, or the frame gets bent. You know it's expensive to tear the whole thing apart to replace the frame. So that's one part that let's see if that comes in and it's bent, and it would need to be replaced. It's just not worth it.

You're almost building a whole new system anyway. So, in that case we can harvest the system. What I mean by harvest is, so we know the frame is bent, but you know the monitor is still good, the user interface is still good, the CPU portion is still good. So, then we do a comprehensive recovery on these parts and test them rigorously. When they pass all those tests then we can use these parts in remanufacturing a different system or even used as part of new product development."

3. **Recycling**: The device is stripped down to the lowest material levels and then recycled. This is done when the product is not required to support any existing systems (as in part harvesting) and recovering the product is not worthwhile.

In describing the impact of these three product disposition options, and participant stated:

"As I look at the portfolio, our product remanufacturing programme is by far the best financial piece for the business, harvest is the best to help us support customers long term and recycling is doing our part for the best of the environment."

5.3.4.1.2. De-installation

Core selection occurs when the system is still at the customer site. Thereafter, plans are made to remove the system from the customer site and ship it to the recovery facility. The de-installation is performed either by the company's field engineers or by a third-party company. In most cases, the de-installation of an old equipment happens around the same time as the installation of a replacement/new medical system to minimise downtime for the customers. Sometimes, the old equipment is often a part of a trade-in or upgrade agreement between the customer and the OEM or another company.

Specific issues during de-installation may include the destruction of certain parts which may complicate the remanufacturing operation. Also, de-installation engineers do not always give keen attention to the packaging and shipping of the system and may omit parts which may be essential to recover the system. The consequence is that the device may become more difficult to recover, and in most cases requiring more materials and resources. An interviewee explained further using another example:

"Yes, we refurbish this system right and we put it on the market and the first three systems have been missing a bracket. There's a bracket that's required to hook on to a cover like a cover on that hold on to a gantry so it's not really an essential function, but it's needed for

the full cosmetic package and the first three systems coming back as cores have all been missing this bracket, and it's like a $5 (£3.59) bracket, so that is tremendously painful. Then we went back to our process, and we found out that bracket usually doesn't come back because when they de-install the system, instead of leaving the bracket on, they take the bracket off with their cover so the cover in the bracket gets thrown out instead of being left on to the cover. We realised there's a problem, our manufacturing engineering team were engaged, we fixed our process to now make sure we have that back where it needs to be."

5.3.4.1.3. Inspection

The first level of inspection performed on the system after it arrives at the facility is a physical inspection of the system, followed by an assessment of the financial viability of performing any recovery operation on the system. This inspection process ensures that only high quality, high value products are taken through the recovery operation. Also, at this point, the experts assess that the parts can be successfully recovered. This inspection covers every component and sub-component of the product. If the part/item is already on the list of items that can be recovered, then the knowledge and expertise required to recover it is available, requiring lesser time and lower resources.

5.3.4.1.4. Storing

Storing signifies the end of phase A recovery activities. The core is stored as a whole, with all the components securely attached to the core system. The focus of the recovery operation is on the core, i.e., the entire product itself.

5.3.4.2. Phase B: Product recovery

As a make-to-order business, core recovery begins after a customer order has been received. The order is assessed by the recovery team and a corresponding raw asset (stored core) in the inventory is pulled out. In most cases, when there are multiple options and different stored asset that can be used to fulfil an order, the first-in first-out (FIFO) principle is used. At this point, two documentations are generated, one for the product (device history records (DHR)) and the other for the recovery operation (work instruction document). The work instruction document guides the operators at different stages on what to do and how to do it. The device history record tracks the product journey through the recovery facility. The phase B activities are shown in the figure 5-5. An interviewee described the work instruction document in this way:

"The work instructions document is specific to the model or to the product family, right? For example, this is what we do for all CTs. So, when it comes into decontamination, we have a work instruction for decontamination that covers all systems, but at that point the operator at that station will start the DHR, which will start to track all the work that they are doing on the product. So, they use the work instruction, and that's what tells them the steps to take."

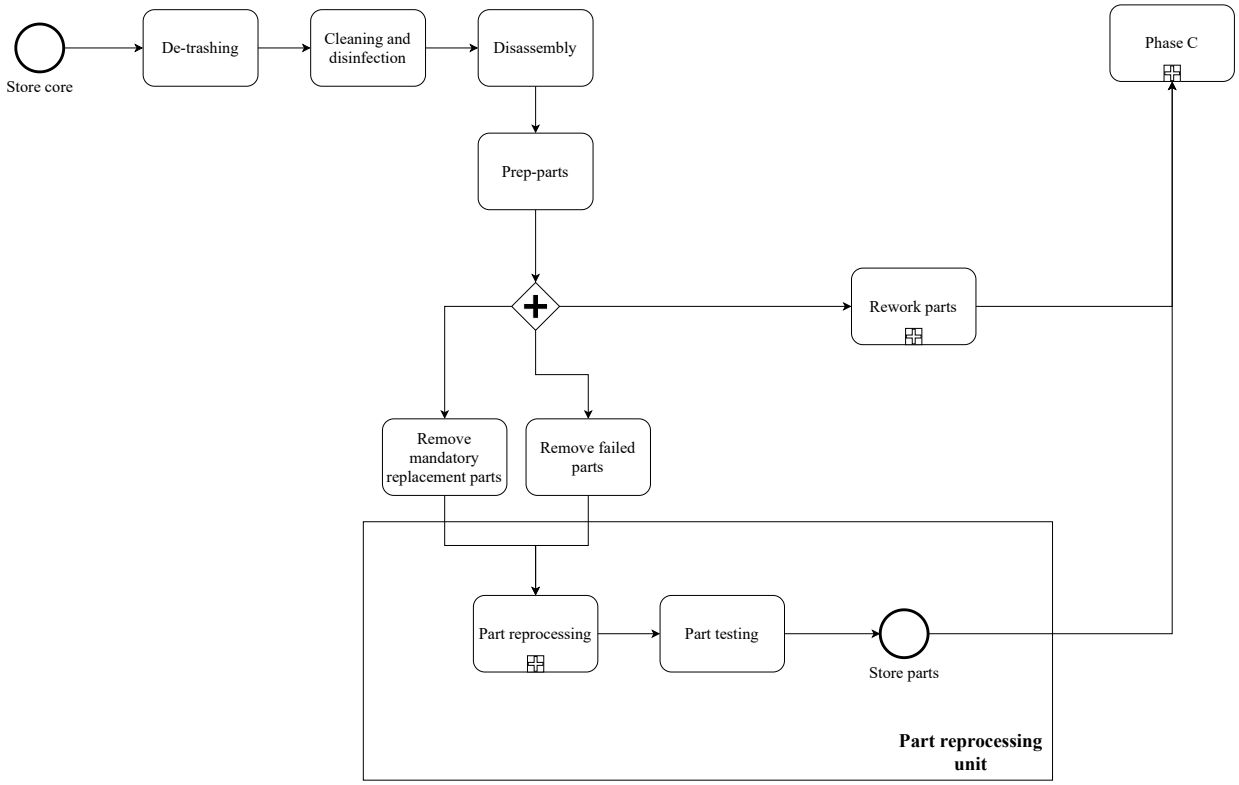

Figure 5-5: Process diagram of phase B activities

5.3.4.2.1. De-trashing

The de-trashing process is the first cleaning activity performed on the core when it arrives at the production floor. Typically, used systems are returned with components and trashes that would not be reused. An interviewee described the de-trashing process below:

"An example is, when an MRI comes back, it comes with its table, the table that sits outside the scan room or where the technician sits. We don't throw it away immediately, but we hold on to it until we are sure we are going to refurbish/remanufacture the system. Because if we need to recover or reuse the system some other way, we're going to want to sell the whole package. But we know that when we sell a refurbished or remanufactured system, it comes with a new table. Our XA offering has a brand-new table all the time."

At this point, every part of the system that is not needed is removed but may be stored separately for future reuse such as the table sets that comes with the MR system. The de-trashing process is a physical removal of dirt or unrecoverable components of the core, and it prepares the raw asset for the subsequent comprehensive cleaning activity. At the end of the de-trashing process what is left is the real core system which is the main physical framework upon which the entire system is built.

5.3.4.2.2. Cleaning

During this cleaning activity, the core system is placed on one of the cleaning pads and the personnel refers to the work instruction of the specific model for cleaning such as what to clean with water, chemical or air. In most cases, an automated vacuum cleaning system (a negative pressure blowing system) is used to remove dirt from the system. During the cleaning process, the nook and cranny of the system is cleaned, locations where the customer would not normally touch or clean, are blown and cleaned using the vacuum blower. Water or chemical is then applied to clean specific parts as specified in the working instruction. During this cleaning activity, the personnel update the DHR with the activities completed.

5.3.4.2.3. Disassembly and parts preparation

After the system has been thoroughly cleaned, it goes through the next process which is called “prep-parts” at company A. During this process, the core is disassembled, and parts are prepared, reworked, or replaced depending on the conditions at the time of operation. This is also the step in which parts are repainted and other cosmetic finishes.

The work instruction specifies what to do at this phase including the mandatory replacement parts, mandatory paintings, specialised repair tools, materials, and parts compatibility etc. Part reworking or replacement is specific to different systems and parts currently recovered in the facility. There are two types of parts that are commonly replaced during this operation:

1. **Parts on the engineering replacement list**: these are parts that the engineering team in the forward manufacturing or the field service team have deemed as “*must replace*”. These are usually high wear items with short useful life and parts where there’s a lot of motion such that the wear is very likely on a used product. These parts are replaced 100% of the time. The removed parts are sent to the part recovery unit of the facility.
2. **Parts on the recovery team replacements list**: these are parts that the recovery team have reported as having a higher failure rate than normal when recovered and

used in a recovered system. In that case, recovering these parts are not deemed worthwhile, and they are replaced with new.

The number of parts on these two lists is not exhaustive and can vary across product families. For example, if a part is being replaced on a specific MR, it would likely be replaced on other modalities within the product family. Also, during the part preparation process, available materials and resources are efficiently planned to complete the recovery task. The material and product planning are based on predictable usage pattern. Parts and products are assessed to understand the current stage in lifecycle, remaining useful life, age etc. Sensitive parts, with high risk of contamination are usually replaced with new or recovered parts. It is important that critical components are replaced during the part preparation phase to avoid failure during testing at the facility or at the customer site. All through this activity, the personnel would update the DHR and refer to the work instruction.

5.3.4.2.4. Part recovery

Direct replacement of part is preferred because it reduces the lead time for the operation and reduces uncertainty caused by part recovery. Replacement parts are mostly parts removed and recovered from other devices as they are taken through the part recovery unit of the facility. The part recovery team focus on a comprehensive recovery of the different parts to at least as new conditions. All recovered parts go through extensive testing to make sure they work properly and can be backed by warranty. An interviewee described further:

"Once we identify parts we want to replace every time, what we replace it with is not always brand new. On one side of my plant, I have an entire wing, an entire organisation that repairs field replacement, things that would go into my recovered systems. So, what we do is we take the potentially defective part, we will need to replace it with a brand-new version or recovered version, and then I'll send the removed part, the defective component, to my repair team with the right expertise to recover it. Then it will become the replacement part on the next system."

Part recovery is especially critical for older products as described by an interviewee:

"When parts begin to get very old, we may go with recovery, even if it's more expensive than new because we know long term new is not going to be available. And then new price is no longer an option for our customer from a vendor, a third-party organisation, which would

usually be incredibly expensive. So, we try to balance those things, or we think about it from a supply chain overall effectiveness."

5.3.4.3. Phase C: Testing

Next, the system is passed on to the testing phase. Before the tests are performed, the system is installed, calibrated, and assessed for safety. The process diagram is shown in figure 5-6. That testing process today takes about three weeks for an imaging device but is highly variable depending on the type of system CT, Xray, MR system. It is during this activity that parts with a high likelihood of failure are identified. This phase is conducted on any of the testing bays in the testing area. The testing bays are product-specific and provides certain infrastructure required by different modalities. As in the other activities, the personnel refer to the work instruction and updates the DHR. However, the work instruction changes from having a detailed picture of the tools for each activity to become more a list of steps that need to happen and the link to the service manual that gives a more detailed testing instruction.

5.3.4.3.1. Installation

The first step is to install the system on the specialised bay in the testing area. The install activity is a mechanical and very linear process which is performed in a manner similar to the actual product installation at the customer site. An interviewee put it this way:

"This is where we're bolting everything to the ground, we're hooking up all high voltage, returning power under the system, and then we go as far as doing some of our safety checks. So early on in this step, we make sure the e-stop buttons work."

The installation process requires special skills and is usually performed by more than one person. Using an example of the CT, during the installation, the spinning process is performed gradually from zero to as high up as 2 rotations per second. It is during these preliminary checks that the personnel identify if something is missing or if a bolt is loose or other issues that can cause serious damage. The system is then balanced by varying the mass ratio on all sides of the gantry to ensure smooth and consistent spinning.

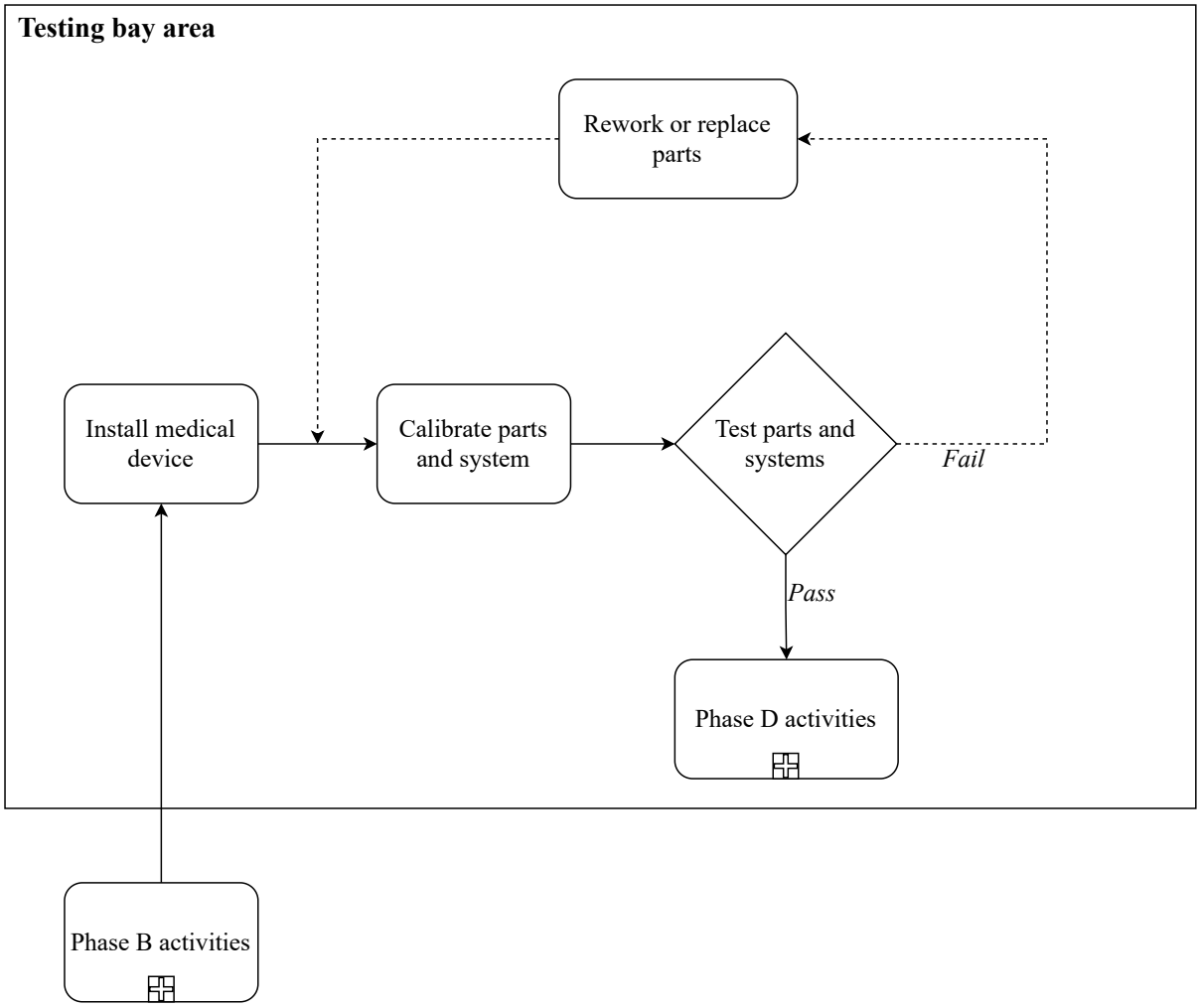

Figure 5-6: Process diagram of phase C activities

5.3.4.3.2. Calibration

During the **calibration** stage, a series of system and component level diagnostics are performed. These diagnostics are performed first on the individual parts and then moved up to the overall system. The purpose of the calibration step is to give each part a specific function and to ensure that they can perform the required functions within the whole system. An interviewee described the calibration process this way:

> *"So, things like calibrating the focal spot of the CT tube or making sure the table when it goes in and out, goes out and goes into the right place at the right time."*

The entire system is calibrated to ensure that all the parts work well together. The power systems, the safety features, the spinning features etc are calibrated and validated as the process goes on. An interviewee put it this way:

"So, we're doing those kinds of calibrations. We continue to check other safety setups as we add more functionality to the system. We verify that it can spin slowly before we start spinning fast. We validate that as we apply power, we apply power in step to make sure that we don't go from zero to 100 within the second which can result in a severe incident."

Also, during the calibration phase, the system is also loaded with the latest software and capabilities with improvements and security enhancements.

5.3.4.3.3. Testing

Next, a series of acceptable tests are performed on the system to verify that the system has been recovered and is now in good working condition. The process followed for the testing activities and the kind of tests performed are described in an engineering controlling document specified by the engineering team of the new production team to ensure that recovered products conform to the standards of new ones. The guidance document specifies what "new performance" looks like for the specific product and the tests that must be performed. For example, in a medical imaging device, the imaging component is tested to check the quality of the images and ensure that the recovered product takes the image equivalent to what it was taking when it was shipped as new. The tests performed, the experts who performed the tests, all the quality checks, tools used and the entire journey of the system at the recovery facility are recorded in the device history record (DHR). The test results are verified by an independent QA team. The QA team will ensure that device history record meets all the specifications that are required, and all tests have been completed. An interviewee described this way:

"We have a whole imaging test that we run to make sure the image quality is good. We have tests that we run to make sure the system is reliable and can run like a day in the life of a system. Which means I'm going to run a couple of images. I'm going to sit for an hour. I'm going to run a couple more images to make sure a normal day is sustainable. These tests, the tests that we do here, once again the work instruction-wise, service manuals via that work instruction checklist and everything is documented in the devices history record."

If the system fails any of the tests, it is re-calibrated, some parts may be replaced, re-calibrated and tested. An interviewee put it this way:

"If it doesn't pass, we just continue to calibrate it. If something were to fail the acceptance testing, we must go back to calibration. Because when you replace whatever broke we need to redo something and that includes re-calibration and testing."

5.3.4.4. Phase D: Packaging and shipping

The phase D activities include system labelling, de-installation, and packaging into shippable format. The product is then sent to the customer site. Figure 5-7 shows the process diagram of phase D activities.

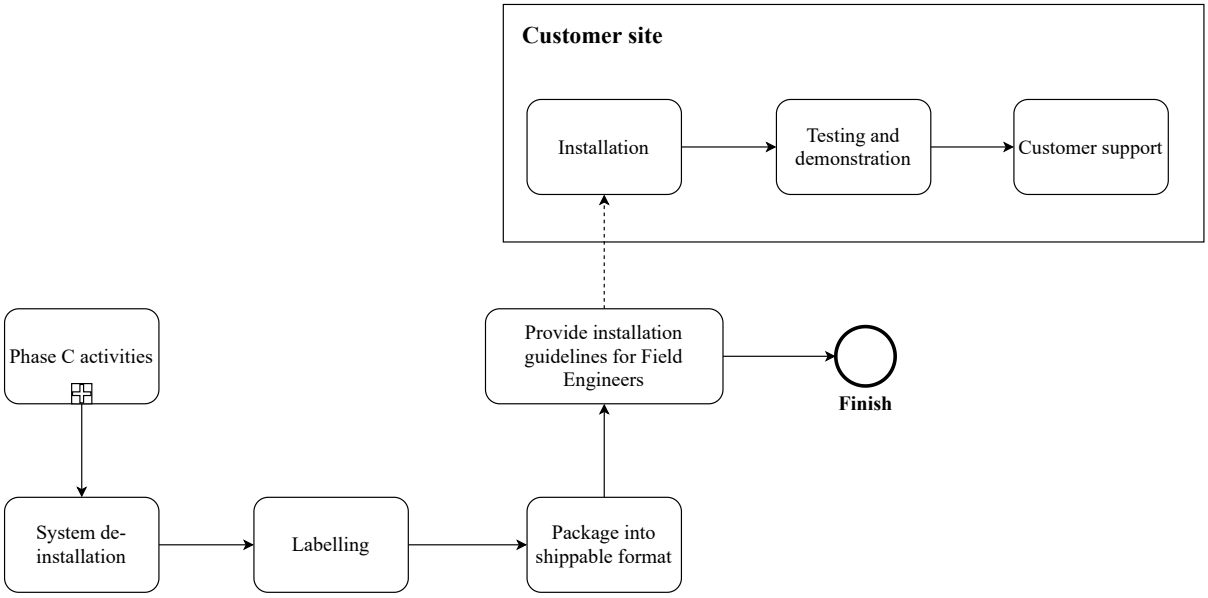

Figure 5-7: Process diagram of phase D activities

5.3.4.4.1. De-install

After the device has been tested, the system is stripped down and sent to the customer. Also, during this phase, the device history record is reviewed to ensure that all the appropriate checks and tests have been completed. The recovered medical device is disassembled into smaller units and packaged systematically, such that it is easy for the field engineers to locate parts and install the system.

5.3.4.4.2. Labelling

The results of the tests coupled with the type of upgrade that was performed on the system and the replacement parts used would inform the labelling of the product as either refurbished or remanufactured. This prompts the need (or not) to use a new registration document (e.g., the 510(k)). However, the product is not presented to the customer as refurbished or remanufactured but as simply company A branded "*XA recovered medical*

system". The necessity of the labelling described in this paragraph is only from a regulatory standpoint and does not connote a quality or warranty difference for the recovered product.

5.3.4.4.3. Final Packaging

As the system gets de-installed, it is packaged into shippable format. The packaging is usually accompanied by the shipping information list (SIL) which is a very detailed list with pictures of what the product should look like and every part that should be received by the install team. This shipping information list is very similar to what is used by the forward manufacturing team for shipping new products.

The expanded process diagram is shown in figure 5-8.

5.3.5. Company A's remanufacturability decision-making process

At company A, deciding what product or part is viable and feasible for recovery usually begins long before the system is ever received at the facility. Most of the time, this decision is supply and demand-driven, focusing on the quantity of used medical devices that can be obtained versus the actual customer demand for the recovered device. Through a network of experienced professionals, the company decides how a used medical device will be dispositioned when it arrives at the recovery facility. Apart from the supply of cores and demand for recovered devices, other considerations may include what new products are being sold, customers' expectation of the recovered system, and what value can be added to the core without incurring significant costs. A detailed discussions on remanufacturability decision-making at this company is provided in this section.

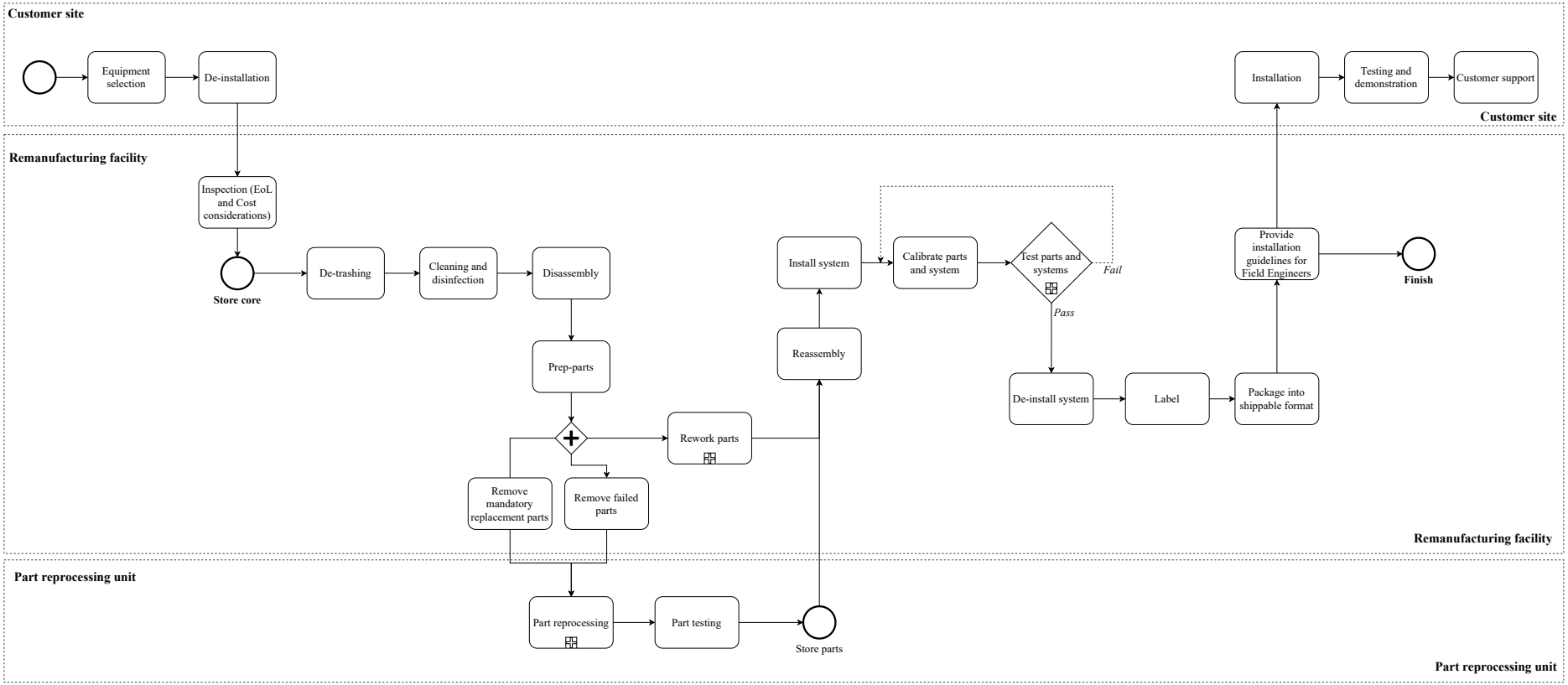

Figure 5-8: Expanded process diagram of recovery operation

5.3.5.1. Disposition options

During the recovery planning process, key issues such as how to source for cores, what to do with the received cores and where to sell the recovered devices are assessed. In most cases, this decision-making begins as early as 9 – 12 months before the actual recovery operation is ever performed. Used medical devices at this company can go into *4* options. However, at any time, used medical devices of the company can go through at least two (2) of these options.

1. ***Product recovery***: The whole system can be put through the company's recovery operation where the system is taken through a series of activities to return it to a condition that is similar to that of new.
2. ***Harvest***: The used medical device is broken down for parts. The harvested parts are stored in the inventory and can be used to service an existing customer, used as part of the recovery operation, or used by the new product team.
3. ***Sale to third-party company***: Having established that the company does not have need for the used device at the time, but the device still has some residual value which may be useful to third-parties, the company may decide to sell the product as appropriate.
4. ***Renewable resources***: Products which cannot be put through any of the three previous options are treated through the renewable resources area of the business where they get broken down for recycling. This is usually the final option for products after multiple lifecycles.

5.3.5.2. Decision-making factors

5.3.5.2.1. Sales margin

The recovery cost is a critical consideration when deciding whether to remanufacture a device. During the planning phase, a business case is first made for recovering any device. The key factor in this business case is the sales or profit margin that can be obtained on the device. The sales margin compares the cost of purchasing the used core, cost of recovering it and the price it is offered to the customer. The focus of the sales margin is the financial implications and rewards of recovering the medical system. Premium products usually have higher sales margin on recovered devices and are therefore the preferred candidates for

recovery. While performance products are intermediate, value products have the least sales margin.

Typically, demo systems are usually the easiest and cheapest to recover because they are returned in good physical and performance condition. Moreover, they do not cost the company any money to purchase, and the company is able to generate maximum sales margin.

5.3.5.2.2. Product Age

The age of a product at the point of recovery significantly affects other factors such as the vitality, technology, and the demand. Depending on the product modality, technology of a device may change rapidly. For example, if an ultrasound system is five to seven years old, it is already behind in its image quality and workflow capability. Whereas for Xray system, with relatively stable technology, 5 – 7 years old products are not far behind and can be recovered. Thus, older medical systems are unlikely to be recovered. However, they could be easily put through part harvesting or the sustainable recycling options. Harvested parts can be recovered and used to support other customers who still have that system in their instal base. An interviewee described this point as:

"You know the fact that a system runs an old Windows platform say Windows 97 or something like that, customers just don't want those because they're not secure and they don't want it on their network. So, when a system gets older and we're talking older than five years for an ultrasound system, then the market really plays in."

As a system get significantly older e.g., >10 years for MR or CT devices, it's likely to have performance and quality-related issues which are critical in the medical devices industry.

5.3.5.2.3. Vitality of the product

The product vitality addresses situations along the product lifecycle focusing mostly on the current and future availability of parts and service to support customers. In the medical devices industry, parts are almost handmade devices and are basically not mass produced. On the average, medical systems have a lifespan of about 10 years, depending on the modality. Medical systems 5 – 10 years old that are already running into part availability problems are usually not recovered because there may not be parts available to support customers in the future. An interviewee put it this way:

"So, if we have 400 of a particular system in the field right now and unfortunately the supplier or the company that made the computer is no longer available to produce or supply parts. This means we will have troubles servicing the ones currently in sockets and the system won't be available for much longer. In that case we would chose not to do our recovery program on that product."

Another interviewee explained further:

"Parts availability is another critical factor we consider when deciding what device to recover. Because the technology changes so fast that a computer chip, integrated circuit chip board that was in full production in 2015 may have been obsoleted by the supplier and so parts availability becomes a real issue for us. This is usually the case with systems 7 plus years old. Sometimes parts are not available and if we cannot get parts, obviously we don't recover the systems."

5.3.5.2.4. Quality

The second-life quality of the product family or modality influences the decision to take a product through the recovery operation. Products that have experienced lots of problems or significant complaints from customers are usually not good candidates for the medical devices' recovery operation. The quality metric used by this company cover factors such as customer complaints, service requests, failure rate within the first 90 days and number of parts replaced during service. An interviewee explained further:

"We are not going to recover a system if there are 100 open customer complaints on it or the service cost is three times higher than what we thought it would be and we're replacing parts much more frequently than we had thought we would."

Another participant described further:

"Let's say there's a system on which we've had a lot of issues, and when we put a new software, it functions quite well, but may still tend to fail or have random undiagnosed issues, and maybe it's an older system. We may just make the decision not to recover. This product would likely be treated through part harvesting or renewable resources option."

5.3.5.2.5. Supply of used cores

Traditionally, company A guarantees the supply of cores through wilful customer returns, off-lease products, as part of a trade in for new system or cores purchased directly from customer. However, in some cases the recovery facility receives fewer newer systems (called the "*too new too few*") maybe due to customer payment default or other similar situations. For cores obtained through the traditional means, the products are taken through the full recovery operation. However, the "*too new too few*" products do not usually require a full recovery activity. They are subjected to specific functional and performance turnover testing to ensure that they conform to new standards and are resold to another customer.

Supply of used medical systems is a critical consideration in the decision-making. While preparing a business case for recovering medical devices, the company may consider factors such as the production plans on the device, quantity of the device currently in a socket and its geographical location, quantity of device currently not sold and the track record of its customers when it comes to returning an old system.

5.3.5.2.6. Demand for recovered products

A high volume of returns may not necessarily imply a low demand for the product (new and/or recovered). However, according to the company experts, when a specific product modality is received at the recovery facility in large quantities, it is usually because there is a corresponding demand for similar products. For example, specialist hospitals need specialist tools and devices for their daily operations so when such device is returned to the recovery facility, it is because they are replacing it with a new or a recovered one. Also, the returned system is recovered, upgraded, and sold to another customer. An interviewee described it this way:

"When we're getting a lot of a specific product back… say these assets are like a 5- to 8-year-old and they've started leaving the install base because we're selling new products to the socket and so we have a steady stream of these products. This easily means there's demand from some other customers for low-cost alternative."

Thus, an important consideration is the demand for that specific product modality. For example, when a lot of customers are asking about an old system or less-costly alternatives to specific product modalities, this indicates (to certain extent) the potential demand for that product when it is recovered. Continuous communication with the sales and marketing team on the demand situation influences the decision-making. As the demand for a medical device

change, the company also adjusts its recovery programme. Older systems (aged > 10) may be dropped from the recovery programme to allow for the recovery of more recent models which have a higher demand and a higher price point. This approach has been adopted by the company to keep up with its new production team.

5.3.5.3. Customer considerations in decision-making

Company A understands customers' desire for a cost-effective solution on medical devices with great value without compromising quality. From the company's point of view, they can offer the best recovered products to customers because they understand their devices and have records and history of the device's previous performance including specific issues associated with that product family; issues a third party would not be aware of. When asked about the factors that may influence customers demand for remanufactured medical device and how the company consider those factors, an interviewee put it this way:

"Well, from my perspective it's definitely cost, and customers are very cost-conscious (most of them). In the past there used to be a kind of a competition between large medical groups about having the latest technology. But it's moving away from that now and what they want is to have good equipment at a great value. They don't always have to have the newest thing, so value is important. And that's where these recovered products come in."

Apart from the cost, another representative of the company believes that quality is another key factor influence customer decision. The quality of the recovered products or parts, or concerns about the quality is a key factor of consideration. However, with company A being an OEM remanufacturer, customers expect them to uphold the highest quality possible.

Customer experience strongly influences their all-round perception of a recovered medical device. Company A has, over the years, adjusted its processes or offerings to improve how its customers interact with the products. An example is the inclusion of free spare parts (e.g., CT tube, bracket, etc.) as an extra offering on its remanufactured CT systems. For example, if the CT tube fails, the customer gets a replacement tube free of charge. Despite the positive intentions of that approach, customer concerns were more on the possibility that, if the tube fails, another component will fail next. As a result of this customer concerns, the company added CT tubes to the mandatory replacement list and thus customers get a standard warranty as in new.

Overall, Company A's decision model is represented in the figure 5-9.

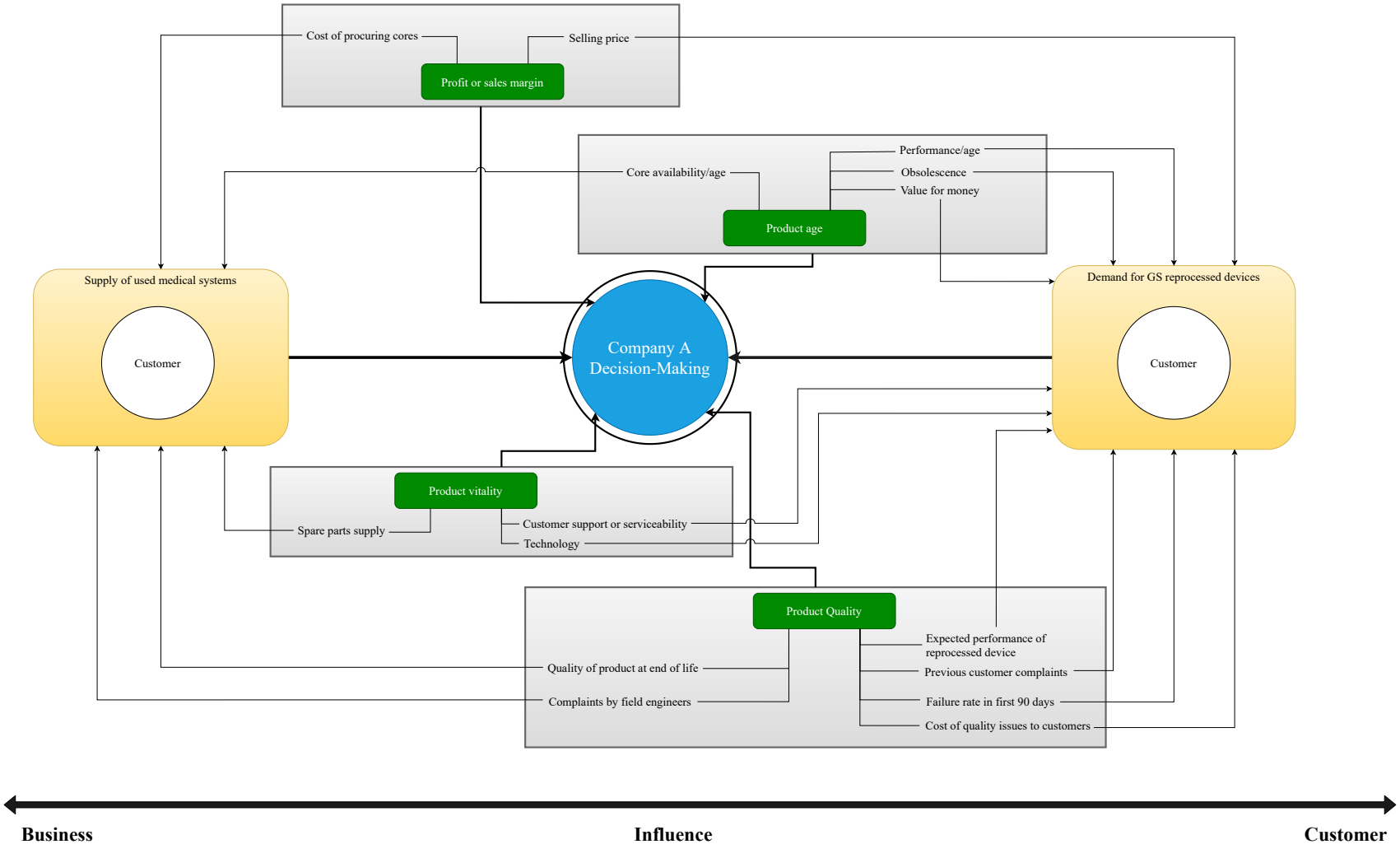

Figure 5-9: Company A's remanufacturability decision model

5.3.6. Summary

Medical systems such as Computer Tomography (CT), Magnetic Resonance (MR) imaging and ultrasound systems targeted by company A's recovery activity are mostly the company's *premium products* of two to three years ago. In some situations, especially in the ultrasound business, performance and value products can be recovered. The key points from this case study are discussed in the following sub-sections and they include hybrid systems, quality standards and quality evaluations.

5.3.6.1. Standards

The company's recovery operations and recovered products are in line with the ISO and IEC standards. The company ensures that its recovered products meet the standards specified for new medical devices in the *ISO 13485: Medical Devices*, to ensure the safety and quality of medical devices in general. The standard that guides this company's recovery of medical imaging systems is *IEC 63077: 2019: Good refurbishment practices (GRP) for medical imaging equipment*. The GRP standard ensures that recovery activities on medical imaging systems are performed to the highest standard, reducing the risks and safety issues associated with using recovered medical devices.

5.3.6.2. Quality evaluation of recovered Products

From a regulatory perspective, Company A's remanufacturing facility is regulated by the federal Food and Drug Administration (FDA) in the United States. The FDA has remanufacturing/refurbishment standards as well as standards for products that are recovered. Depending on where the recovered products are sold, the documentations, specifications and product standards may vary. The company aligns the output of its testing and recovery operations to ensure that they meet the recovery regulatory standards as well as the requirements for an equivalent new product. The FDA audit/inspection is routine, and it happens randomly at the facility. Also, remanufactured products require another registration 510(k) document. The regulatory body (US FDA, EU, or UK bodies etc) may conduct pre-approval inspection after the company submits application documents to market a remanufactured product within the region.

Apart from the FDA regulation, the company engages a third party to conduct an ISO 13485 audit. Also, the quality team of the parent OEM audits the remanufacturing operations annually to ensure that the procedures and quality requirements within the company are met.

The medical devices industry is highly regulated with stringent requirements on what can be used within healthcare environments. As such, the product quality evaluation of recovered medical systems is driven mainly by engineering tests and requirements of new products. The engineering team generates a product-specific system performance assessment (SPA) document indicating the tests to be performed and with the results expected, decisions are made in the final acceptance tests during the recovery operation.

5.3.6.3. Critical Issues

During the research, investigations were undertaken to understand the nature of remanufacturability decision-making at this company, to identify the factors that are considered, how these factors interact among themselves and the consequence of these factors and their interactions on customers' acceptance of remanufactured medical devices. When assessing the viability and feasibility of recovery a used medical device at this company, supply and demand appears to be the main drivers at the high level. At the lower level, factors such as product age, product maturity, technology and vitality appear to play a significant role. As it relates to the customers, factors such as the quality, pricing, warranty, and services appear to secondary considerations which are directly impacted by the primary considerations stated above. However, these considerations can be brought to the foreground of the decision-making process at this company. Further, some other critical decision factors such as uncertainty in core supply, design issues, and packaging issues are discussed below.

5.3.6.3.1. Uncertainty in supply of cores

Recent changes in the market, coupled with specific customer factors mean that the supply of cores has become challenging for this company. Customers are holding onto their systems a little longer mostly because of the cost of purchasing new systems every couple of years. Also, more third-party organisations are beginning to offer more than OEMs to buy used systems from customers. As a result, the uncertainty in the supply of used medical systems has increased. The supply of cores is critical when assessing the viability of recovery used medical systems. Thus, uncertainty in supply of preferred cores in terms of quality, quantity and timing makes the decision-making more unpredictable.

5.3.6.3.2. Design for recovery issues

Product recovery in this company is viewed as part of the service business. The service side of the business refers to extra activities provided to support the customer after initial

manufacturing. This often includes, device maintenance and servicing, de-installation, and removal. As such, design for recovery (e.g., design for remanufacturing or design for refurbishment) are generally "accommodated" within the design for service. While design for service can potentially improve the ease of recovery, it may not adequately cater for other factors such as transportation, cleaning, part recovery, part-level testing which are not commonly associated with servicing operations.

5.3.6.3.3. Packaging issues

An efficient packaging approach is adopted to optimise space, prevent part damage, and provide easy or safe handling for the personnel transporting and unpacking the parts. The packaging approach makes each box as dense as possible with spaces well use. This becomes a searching exercise for the install team at the customer site. Also, packaging is not currently done consistently with the boxes and crates being of different sizes and boxes are usually not labelled in a way that makes it easy for the install team to locate every part. In some cases when the system is received by the customer, due to space constraints, they may decide to remove the packaging, change the arrangements, or alter it in such a way that it becomes a daunting task for the install team to get through.

5.4.Company B

5.4.1. Key personnel

The table 5-2 below describes the characteristics of the personnel at company B who participated and were interviewed during this research. They comprise mainly of senior members of the organisation with an in-depth knowledge and expertise in the operations and decision-making that relates to the specific research problem.

Table 5-2: Characteristics of participants at company B

S/N	Position	Description of Participant responsibilities	Years at company	Years in current role
1	Operations Manager (Commercial Sales Director)	Oversees the entire commercial activities of the company and has a general overview of different projects	9	2
2	CEO	Is the founder of the company and oversees the entire operations conducted by the company	10	10
3	Engineer (Magnet Specialist)	Is the company's key engineering personnel mostly in charge of the product testing	5	5

5.4.3. Company background

Company B, which started in 2012. The idea behind the company was to build a network of engineers basically for servicing diagnostic medical imaging devices such as Magnetic Resonance (MR), Computer Tomography (CT) and Xray imaging systems. Over time, the company went through the path of trading medical imaging devices. This company also operates as a third-party for major OEMs in the industry such as Philips, Siemens, and GE. Company B is a small to medium organisation with 10 to 25 employees based in the United Kingdom. The company has done many projects across the UK and in Europe. They deal pre-owned medical devices (purchase, lease and/or sell) as long as they pass the rigorous quality testing criteria adopted by this company. The company prides itself as having an in-depth understanding of the used/recovered medical devices market and that it can offer better solution to the customers.

5.4.4. Business Scenario

What initially started off as a trading company for used medical devices has slowly grown and now offers extra services to the supply, installation, and servicing of medical devices. The business scenario in this organisation is discussed below.

5.4.4.1. Procuring cores

This company procures its cores in two main ways:

1. **Directly from hospital**: Company B may purchase its used medical devices directly from hospital, health boards or private clinicians. The medical systems would usually have been used and maintained by the owner for some years (5 – 10 years).
2. **From OEMs through trading platforms**: Company B may also procure its cores from OEMs who have removed an old medical device from a customer and do not have any use for it. In this case, company B will usually bid for a medical device through an online platform or via direct communication with the OEM.

This company works closely with OEMs and other companies on their trading platforms to negotiate for pre-owned medical devices. An interviewee provided further explanation on the issue.

"So, we primarily source our cores on trade desk – the trade desks of the major OEMs such as Philips, GE, and Siemens. They will just say look, we're bidding on this project wherever it may be. So, whenever they do projects, I'm talking about when they're installing their new

systems, they need to take out an old system. So, what they do is they say to us – we want to win this new business and we need sell this old system to win this new business. So, they say to us, look what would you bid for this? Then we make a bid and then we have to wait and see if the manufacturer gets it."

5.4.4.2. Customer segment

The company's key target customers are medical device dealers, usually other third-party companies, or sole proprietorships (ex-engineers of major OEMs) who understand the market and who deal directly with clinics and hospitals that require pre-owned medical systems for their day-to-day operations. The target customers are mostly based in Europe (Spain, Ukraine etc), USA, Asia (mostly India) and parts of Africa. These companies (company B's target customers) are usually experts in providing direct service contracts to their own customers which absolves company B of the need to offer such services. Company B's main responsibility to their customers is providing good quality, and functional pre-owned medical devices while their customers take care of the rest and deal directly with hospitals and clinics.

5.4.4.3. Marketing approach

The company's marketing process begins after the QA inspection. This is because the company only fully understands the condition and quality of the medical system after the initial inspection phase has been completed. An interviewee stated briefly:

"We start marketing the product once we get the QA inspection report ideally because then we have actually checked it ourselves. What we don't want to do is sell a product to our customer when we're not quite sure ourselves of what it is."

The nature of customer orders received by this company may vary, i.e., it may be for the whole system or for specific parts. This is mostly because of the targeted customer segment discussed in the previous section. Specific parts of medical imaging devices can have higher demands, and thus a higher value and increased motivation to procure and recover them. For example, a representative of this company described how CT tubes and digital scanners of medical imaging devices have high demands:

"We try to respond to our customers' needs as much as possible. Some of our customers are businesses who only supply spare parts and may not require the entire system. We tend to work out the best solutions for them. So, for instance, we had a customer for a system, say a

Philips 3Tesla Rex magnet zero boiler helium, they wanted the magnet itself in Korea and all other components sent to Canada. So, these are the kinds of situations we deal with."

5.4.4.4. Warranty

The company currently does not match the warranty provided on new devices or parts by the original manufacturers. However, they understand the importance of warranty provision and have made significant stride to scale up their warranty offerings. Depending on the situation, the type of system and the nature of the customer, the company may offer some warranty on parts that are critical to the performance of the system. This warranty is often in the form of providing replacement parts. An interviewee described the company's efforts when it comes to providing warranty:

"We do give some form of warranty, that is maybe a year's warranty on the equipment but not on all the parts. We don't usually warranty the tube or the very expensive components. Sometimes what we do is to offer warranty on the components to provide spare parts for the customer, but the customer would have to pay labour costs of the engineers. So, at the moment we are working more than usual in that respect."

Another interviewee described further.

"Now, when we sell a system into Africa, we would send some spare parts with it so that during the one-year warranty on the system we can easily fix and resolve issues if the parts are already available there."

5.4.4.5. Recovery operations

The recovery operation this company engages in is termed "remarketing" where used medical devices are moved from one customer site to another. However, between different customer sites, the company may perform series of engineering activities on the system such as de- and re-installation, calibration, comprehensive testing, and part repairs. An interviewee described below:

"We have an inventory of coils at the warehouse in Spain (which most of the coils have actually been sold). Now the issue is what we're doing is we're only testing the coils when they are part of the system. We make sure that we do the system QA, and we test the coils to see if they are operational within the system. So, what we're looking to do now is do

something for bench testing within our Spanish warehouse, just to see if these coils can pass these electrical tests so that we can give our customers longer warranties on these parts."

Relocation implies the "remarketing" of medical devices. In the medical devices industry, relocation requires a robust process framework and a comprehensive implementation or project strategy. The term "relocation" is not exclusively contained in the medical devices recovery frameworks as is remanufacturing or refurbishment by the EU, UK MHRA and US FDA bodies. However, every medical device intended for use within clinical settings are expected to meet safety requirements before installation, commissioning and use on patients. Another interview described further:

"So, when we remarket, there's some form of risk mitigation because we need to ensure the system works at the new customer site, irrespective of its performance at the old site. So usually, when we de-install we may identify specific issues that we can fix, parts that need replacement, cleaning, etc. We also add a bit of risk mitigation side because if the MRI is working at Hammersmith Hospital and you're sending to Nigeria, well, you cannot just unplug it and take it. So, we have a robust process for de-installation, then we take it into a warehouse and even if we just change a few covers, we pack it, we do a few alterations and then we send it to Nigeria, then we send the team to install it. That is a complicated procedure, as simple as it may sound."

5.4.5. Description of recovery operation

The six-step recovery operation of this company is shown in figure 5-10 below. More discussions on the recovery operation are presented in the following subsections.

5.4.5.1. Procure cores

Used medical devices can be procured either directly from hospitals or clinicians, from another third-party organisation or from the original manufacturers who are installing a new device in a socket and want to dispose of the old device. The procurement strategy may be either privately sourcing cores or by bidding for used devices on public domains. This company positions itself on the trading platforms of major OEMs where they bid on used devices. Most of the time, the company is provided with a specification sheet by the OEM.

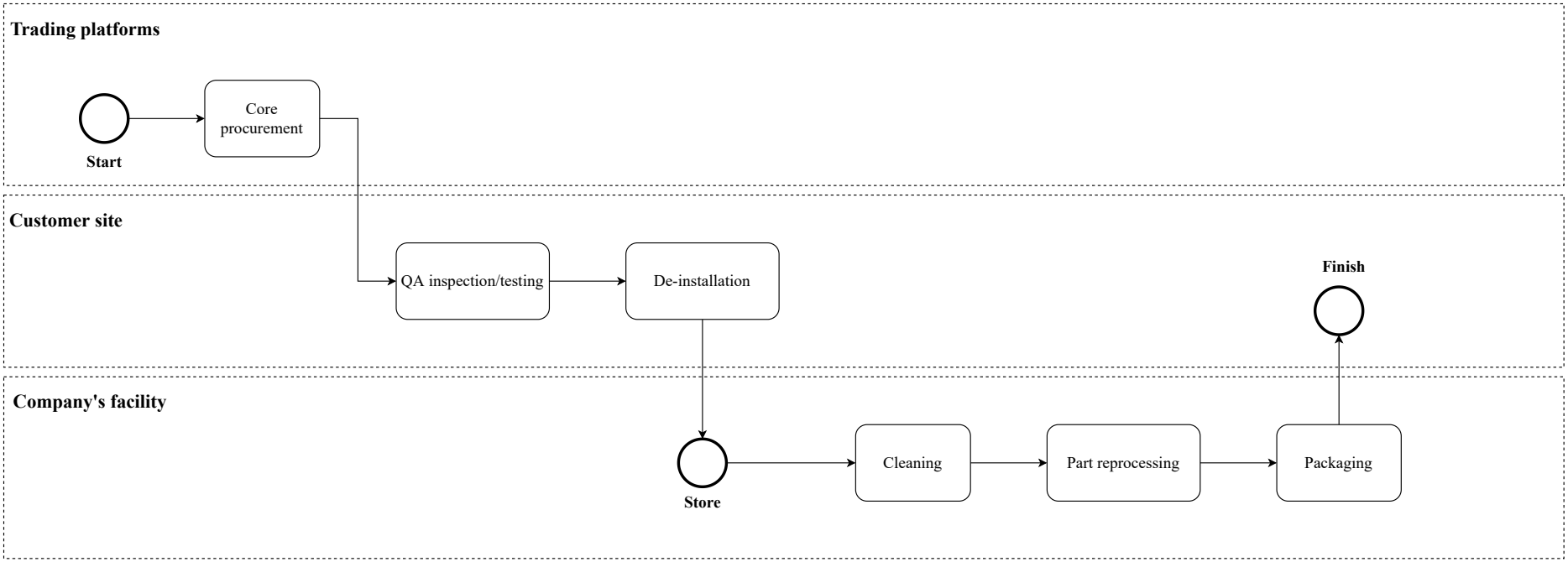

Figure 5-10: Process diagram of company B's recovery operation

5.4.5.2. QA inspection of cores on site

After the bid has been won and the used medical device has been secured, the company would send its engineers to the site to perform a quality assurance inspection on the system at the customer site based on the specification sheets obtained from the OEM. The QA inspection at this company is performed in two levels:

1. **Physical check**: The purpose of the on-site inspection first, is to verify the information provided for the system on the trading platform
2. **Performance testing**: The second inspection level then assesses the system performance and that of valuable parts.

That QA inspection/testing activity will effectively create a report showing the tests performed on all aspects of the system. An interviewee described it this way:

"We will send our engineer from our team or, you know, a consulting engineer that we know and say, look, can you go and perform these tests? Okay, because that then enables us to market that product."

The company has separate test protocols for different systems, e.g., an MRI or CT system or Xray system. The test protocols are usually OEM-certified protocols of acceptance testing which are performed on an equivalent new device before/during installation. Representatives from this company describe the QA inspection operation as part of a comprehensive validation and verification (V&V) process. Some of the testing include shielding, safety testing, noise levels, exposure to radiations and the performance of the device. Another interviewee described further:

"So as an example, an MRI system and, probably, CT, if you're going to be removing that system, we want to make sure that electronics, obviously the electronics is performing in the way it should perform. An inspection report is prepared which forms part of the marketing document for the product. Of course, if it was not performing, the system would be down. So, in the MR example, we would run test to make sure the coils function properly and that there is not any part of the coil that is defective. This is important for us from a quality and regulatory standpoint."

During the QA inspection, the engineer would also look at how the system is used (referring to the system logbook) and may also engage with the technicians, and/or radiographers to understand quality and performance of the system over time. This would assist the engineer

to spot specific issues with the system so that it can be fixed before sending to another customer. Also, the engineer refers to the preventative maintenance (PM) log to see the service history, what has been changed and what is due to be changed in the system.

The information provided by the OEM in the specification sheet is not always accurate. When this happens, the system could become more difficult for this company to recover and relocate to a new customer. An interviewee explained how they deal with such situation:

"For instance, that Rex system that we were taking out of Granada, they said it would be in service by Philips, but it was not. But what happens then is with the relations, we go back to the trade desk and say look, this is what you said it was. We did our own inspection and found it was not true. Then now we need to renegotiate the selling price."

A consequence of the renegotiation is that the initial cost of procuring the cores may be reduced and could lead to a higher profit margin for this company, if/when they are able to recover the device and sell to another customer.

This on-site inspection is perhaps the most critical activity performed by this company to ensure that the device received by their customer is fully functional and can be backed up by warranty. The company utilises a checklist template for both CT and MR systems. This list is similar to what is used by OEMs during inspection and ensures standardised inspection and testing for their products. However, as a third-party, they do not have access to high level information that the original manufacturers may have. As the medical devices industry is highly fragmented, competition for sales is very high and OEMs maintain strict competition between themselves causing very little information sharing in the industry.

5.4.5.3. De-installation

Upon completion of the QA inspection report, the engineering team proceeds to de-install the machine. The de-installation is performed according to the specifications of the OEM which is contained in the supporting document sent to the company. Moreover, the de-installation is usually performed by highly skilled and experienced engineers, most of whom have worked for OEM companies in the past and have good knowledge of the specific systems such as MRI, CT or Xray systems.

De-installation is a highly technical and intricate process. As such, there may be complicating situations such as quenching magnets, and removing cold heads etc. An

interviewee described in further details the nature of these situations and how they are approached:

"Sometimes we may need to run down the magnet which cost extra money. For that we need to get power supply. Alternatively, we may let the helium escape or do a controlled quenching of the magnet. We do this (i.e., running down magnet and releasing helium) because sometimes (especially on systems that need a complete overhaul) it is the cheapest de-installation approach for us… What we are doing is we are trying to have a process that allows us to recover some of the helium which we would later use during the recovery operation."

5.4.5.4. Core storage

The de-installed system is sent to the warehouse facility. The cores received at the facility are stored cold in the company's facility in Spain. However, the company tends to hold stock across Europe: Poland, Germany, France, UK, and Spain. An inventory of systems, parts and where they are stored is kept by the company to aid other parts of the business such as the part recovery (in some cases), logistics, customer support and services.

5.4.5.5. Part recovery

Specific issues noted during the QA inspection inform the company's decision to recover certain parts. The form of recovery performed are usually minor repairs on critical parts such as the MRI magnets, the CT scanner, topping up the helium level of tubes etc. The skill and expertise required for this level of repair is usually not available in-house and the company may need to engage an external personnel with in-depth knowledge of handling specific components made by specific manufacturers. An interviewee explained this way:

"Let's say the company wants to repair this keyboard but we don't have the competency to repair it. We need to bring in somebody who knows how to repair it. We could get another example: Let's say now there is a Toshiba system. I don't know anything about Toshiba systems, so it won't make any sense in going having a look at a Toshiba if I don't know what to look out for in a Toshiba system. Yes, I may be able to do a few things if it's a CT or MR, I could probably switch on and I could identify it, you know the component password but won't be messing around with it. So, what we will do is to get a Toshiba-trained engineer to do repair on that system/component."

5.4.5.6. Final packaging

The system is packaged into shippable format and sent to the customer. Now, because of the nature of the customer, the device may be delivered either to the hospital where it will be installed or to another company's facility where it will be handled appropriately. The system may be transported in a set of pallets constructed to house the system (e.g., CT, MRI, or Xray) and the patient table which can be easily separated.

5.4.6. Company's B remanufacturability decision-making process

This company encounters some limitations in its approach for deciding what medical device can be and should be recovered, given the low resources and uncertainty in recovering used systems. As a result, the remanufacturability decision making at this company typically follows the market and is based on factors such as customer (or expected) demand, accessibility, performance, and profit margin. These four factors are described in the following sub-sections and illustrated in figure 5-11.

5.4.6.1. Customer demand

Establishing a customer demand for specific products or parts is complicated. One of the company representatives also stated that the difficulty in matching supply with demand often lead to difficulties along the operation line. However, due to their experience in this market, the company may adopt a flexible procurement and recovery strategy that best suit the nature of the demand for used medical devices. Establishing customer demand for recovery or any form of added value services to the core system is a critical consideration during the decision-making at this company and is described further by an interviewee:

"We need to know that adding value to the raw asset (through remanufacture or refurbishment) would be accepted by our customers… when we do cosmetic retouch (e.g., spraying), we want to be sure our customers actually want that added value and the same goes for any recovery activity. If the market does not want us to remanufacture or refurbish, you cannot spend 10s of thousands of euros fulfilling that service, and in the end the customer doesn't really want it and then you wasted resources."

The decision-making of this company relies greatly on the market dynamics which vary across regions or countries. Some of the market factors such as regulations on pre-owned medical systems, restrictions on servicing and spare parts supply etc., can affect their decision-making. Another interviewee described further:

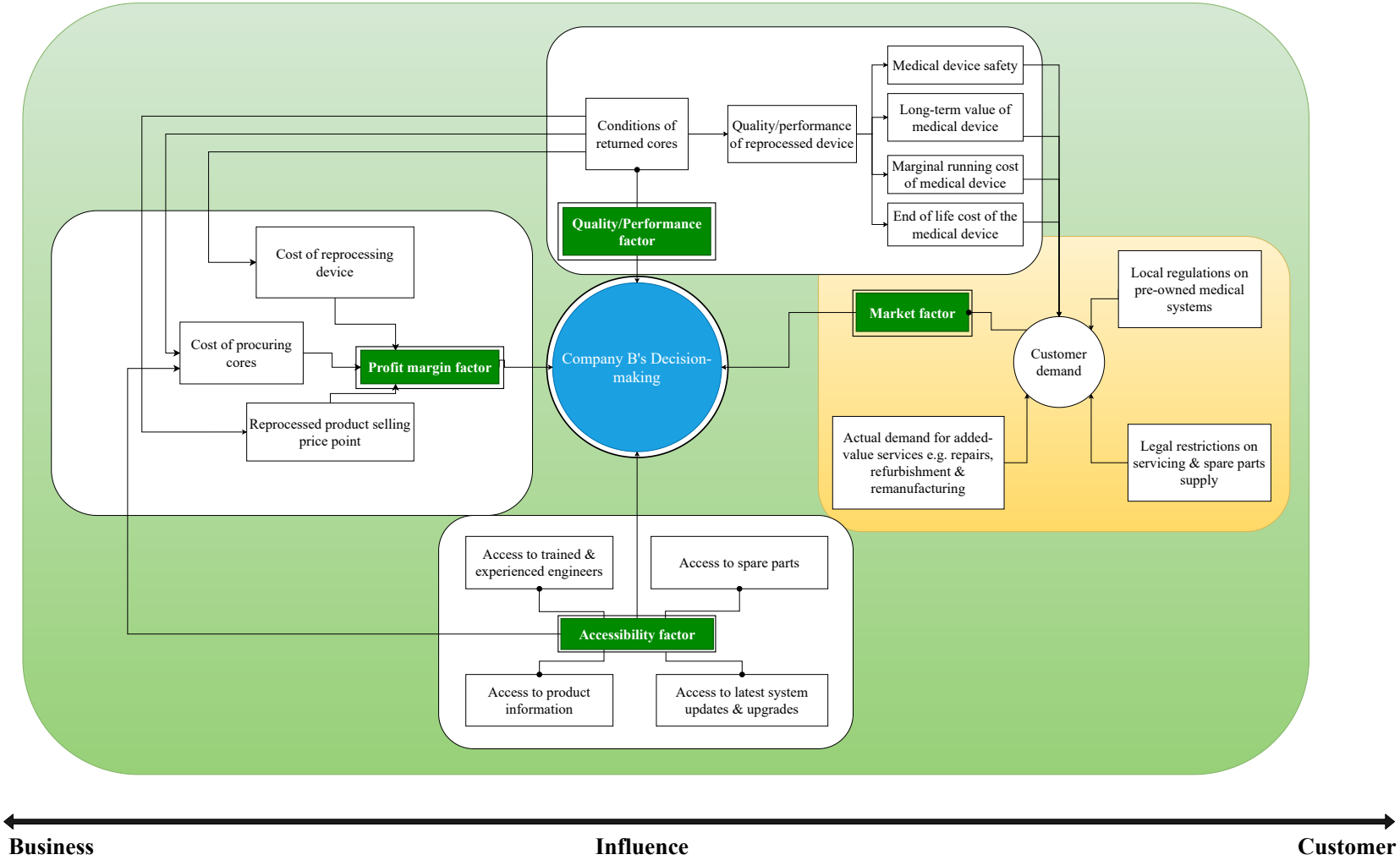

Figure 5-11: Process diagram of company B's recovery operation

"For example, our key markets are Europe, Asia, and Africa. These can be very restrictive markets which have their own laws or regulations on pre-owned medical systems. Any of these markets can change their regulations at any time, so it's about understanding that if we've sold five recovered MRIs to India and then suddenly the laws change and we cannot do that anymore, it means we've got no market, even though the demand may be there, but we cannot fulfil it and we may not be able to support our existing customers."

5.4.6.2. Accessibility

The accessibility factor in the decision-making for recovering a medical device involves the company's assessment of the level of access, information or support it can get on the particular system. As a third-party organisation, the company is limited in its operations on medical systems beyond the support of the original manufacturer. Since medical devices are complex electronics systems, recovery requires an in-depth understanding of the different parts and components. Therefore, this company considers how much access it has, or can have on a medical device, to be able to offer the medical device, as an upgraded or recovered option to their customers. Other accessibility factors include access to highly trained and experienced engineers (to perform services on medical systems by modality and by manufacturer), and access to third-party parts (at low cost to both the company and customers).

5.4.6.3. Performance

Through the QA inspection/testing performed on-site, the engineers can assess the performance and quality level of the device. The performance or quality of the medical device and its components is a critical consideration in the decision-making especially when considering the selling price point, the added value services that will be performed and the support or warranty that will be provided to customers. The quality level of the medical system influences the decision of how the medical device is handled, either to resell the system directly, harvest the parts and sell separately, perform minor upgrades, repairs, or replacements on the system, or to return to the seller, renegotiate the price of the deal or renege on the order. As a rule of thumb, the company aims for and targets high quality medical systems with good resale value.

5.4.6.4. Profit margin

Overall, the company's decision to recover a medical device is driven by profitability. A company representative noted the importance of having a positive net profit on recovering

used medical devices, especially as a small business. Thus, there is a need to balance the cost of procuring the used device with the price at which it can be offered to customers bearing in mind the other costs associated with the recovery operation. Naturally, medical imaging systems are capital devices, and their prices can run into tens and hundreds of thousands (or even million) pounds (GBP). The company is currently seeking ways to improve the cost effectiveness of their entire process and the affordability of their systems to customers in low-resourced regions of Africa and Asia where financial support may be lacking.

5.4.7. Critical issues

During the case study research of this company, the author aimed to understand the structure of the organisation, the nature of their recovery operation, and identify the key factors or considerations in their remanufacturability decision-making. Bearing in mind the relatively small size of the company, the key considerations in the decision making are component level testing and recovery, access to information, and access to spare parts to support customers which are discussed below. Also, the nature of the decision-making is non-linear and often causes disagreements across different levels of the organisation.

5.4.7.1. Part recovery

Currently, the recovery activity in company B does not include part recovery. The QA inspection is performed on the system to understand how the system works as a product, rather than a quality test of the individual components. While the company's current approach works, it increases the difficulty of identifying specific issues with parts which may impact the functioning of the system in the long run. The issue of component-level recovery is critical in the decision-making process and is an area this company is currently exploring. In the long term, the company aims to improve their technical capabilities and delve into recovering specific high value components of medical imaging devices such as the tubes, digital scanners, generators etc. due to their criticality and cost. An interviewee described further:

"On one-part tubes are very expensive. I think for a refurbished tube in the Indian market, you could charge about 10 to $12,000. On the other hand, when tubes are not commissioned or not being used on a regular basis, you lose confidence in the tube. It cannot sit on a shelf for a year waiting to be put into a system. So, we hope in the long term we would be able to recover them, but we have to start from somewhere."

5.4.7.2. Available information

Due to the nature of the industry, OEMs and customers do not easily provide information about used products to third-party organisations. Moreover, most OEMs recover their own products and may see the activities of a third-party organisation as a competition. This makes it difficult for third parties to acquire cores and access support. More often, OEMs discourage third parties from targeting the same customer segments thus reducing competitive offering for the customers. Most OEMs don't always provide technical information on specific systems which complicates product or part recovery for third parties. Development of industry standards for product development, design, and manufacturing across governments and regions can potentially create level playing ground for third parties.

5.4.7.3. Access to spare parts to support customers

This company does not always have access to sufficient spare parts to support their customers. In this situation, spare parts from manufacturers may be too expensive and the company does not currently boast of a robust inventory of parts. This becomes problematic in situations where customers require urgent maintenance, replacement and/or repair of certain parts.

5.4.7.4. Lack of structured decision-making process

This company is small sized relatively young organisation. As a result, they currently lack deep insight into the nature of recovery in the medical devices. Their business has a high level of uncertainty, and the decision process is difficult to characterise. The author believes that this company does not currently take a structured approach to remanufacturability decision-making. It is mostly based on the experience of medical device practitioner or engineer, and/or the financial implication of recovery.

5.5.Company C

The third case is an OEM recovery facility based in Germany. Data used in this case study are collected through available public information provided by the company followed by a semi-structured interview with a participant from this company. The table 5-3 below shows the detail of the participant, their current role, and years in the industry and experience in current role.

Table 5-3: Characteristics of participant at company C

S/N	Position	Years at company	Years in current role
1	Sourcing Manager for Company C's refurbishment operations	30+	11

5.5.1. Company Background

Company C is a major medical devices original manufacturer which currently recover their own products. The company runs a product recovery program concurrently with the original manufacturing in a hybrid manufacturing-remanufacturing environment. The major motivation for this company getting into the product recovery was to assist hospitals cope with increasing expectations of customers on functional but relatively low-cost medical devices. In recent years, the product recovery operation has grown mostly due to the growing economic and environmental pressure on healthcare facilities and hospitals to keep costs low. The business scenario is described below, highlighting the procurement process for used devices, product offerings, warranty, and pricing of the recovered medical devices.

5.5.2. Business Scenario

5.5.2.1. Procuring cores

Used medical devices are generally procured from the previous owners who want to dispose of their old system. The company procures cores in three main ways:

5.5.2.1.1. Customer Trade-in

The customer trade-in is when devices are purchased from the customer as part of an agreement to replace the old system with a new one. This is usually performed through the customer loyalty program which offers value for the customers' old product as part of a trade-in for an upgrade. Customer trade-in is reported to be the largest source of used medical devices recovered by this company. The interviewee explained further:

> *"When we market our recovered devices, we offer customers a value for their old system, and we take this value out of the cost of the recovered medical system. In some cases, we may actually buy the system and send the cash to the customer."*

5.5.2.1.2. Direct customer returns

Another source of used medical devices is through direct customer return. Customers may return their used medical systems to the manufacturer when they do not have any use for it. Direct customer returns are usually dysfunctional devices or devices at their end-of-life which the OEM did not offer any value on. In some cases, customers may return systems

directly to the company for recycling as a sustainable option rather than sending to the landfill. In this case, the company will break down the device to the smallest material unit and put it through their material recycling business.

5.5.2.1.3. Secondary market

The third core sourcing strategy is through the secondary or third-party market. This is common when the company does not have in its inventory specific parts or products that are required to fulfil a customer's order. In certain cases, for example when the supply of cores certain device product modality is low but there is a high demand from their customer, the sourcing manager may contact other players in the secondary market such as third-party companies, or other OEMs which may be in possession of one of their systems. The interviewee explained:

"So, I phone up third parties or other companies that may have our system because when we lose a product in the install base it is because another player won the contract to supply a new equipment which means that they have our system. We have our own trade in platform but most times, I just phone up these other companies that have our system and try to get it back."

5.5.2.2. Product offering

Based on the company's location in the EU, its major recovery operation is described is "refurbishment" in line with the regulatory guidance provided by the European Council (European Commission et al., 2017). The specific modalities of medical devices recovered by this company are medical imaging devices such as Molecular Imaging (PET/CT, SPECT, and SPECT/CT), Magnetic Resonance Imaging (MRI) and X-ray products. These devices are recovered to the quality and performance standards of the devices when it was produced as new. In most cases, recovered medical devices are marketed side-by-side with their equivalent new products and are usually more favourable to customers because of the lower pricing.

5.5.2.3. Warranty

The company provides a warranty and service agreement similar to what is provided on a new equivalent product. The company provides a warranty period of 1 year and guarantee the supply of spare parts for the refurbished device for a minimum of 5 years . The company

believes the provision of the warranty and spare parts supply guarantee plays a significant part in their customers' decisions.

5.5.2.4. Pricing

Typically, this company offer recovered systems to their customers at an average price of 20% lesser than new products. However, the price may vary between 10% – 40% depending on the modality.

5.5.3. Company C's recovery process

Company C recovers medical imaging devices at its manufacturing facility in line with the IEC63077: Good Refurbishment Practice (GRP) for medical imaging devices (Global Medical Imaging Industry et al., 2009) and has been described by (Plumeyer and Braun, 2011). The recovery process of this company also adheres to the ISO 13485: 2016 quality management of medical devices (International Organization for Standardization, 2016). The company's focus on refurbishment operations, as specified in existing legislation, imply that the previous registration or marketing documents will be used for the refurbished medical device and as such do not need a premarket approval (PMA), a new 510(k) in the US or a new CE marking in the EU markets. Further, their refurbishment operation is focused on the entire system level. This company does not focus on part-level refurbishment.

The recovery operation of this company involves four major activities which are described in the following sub-sections and highlighted in figure 5-12.

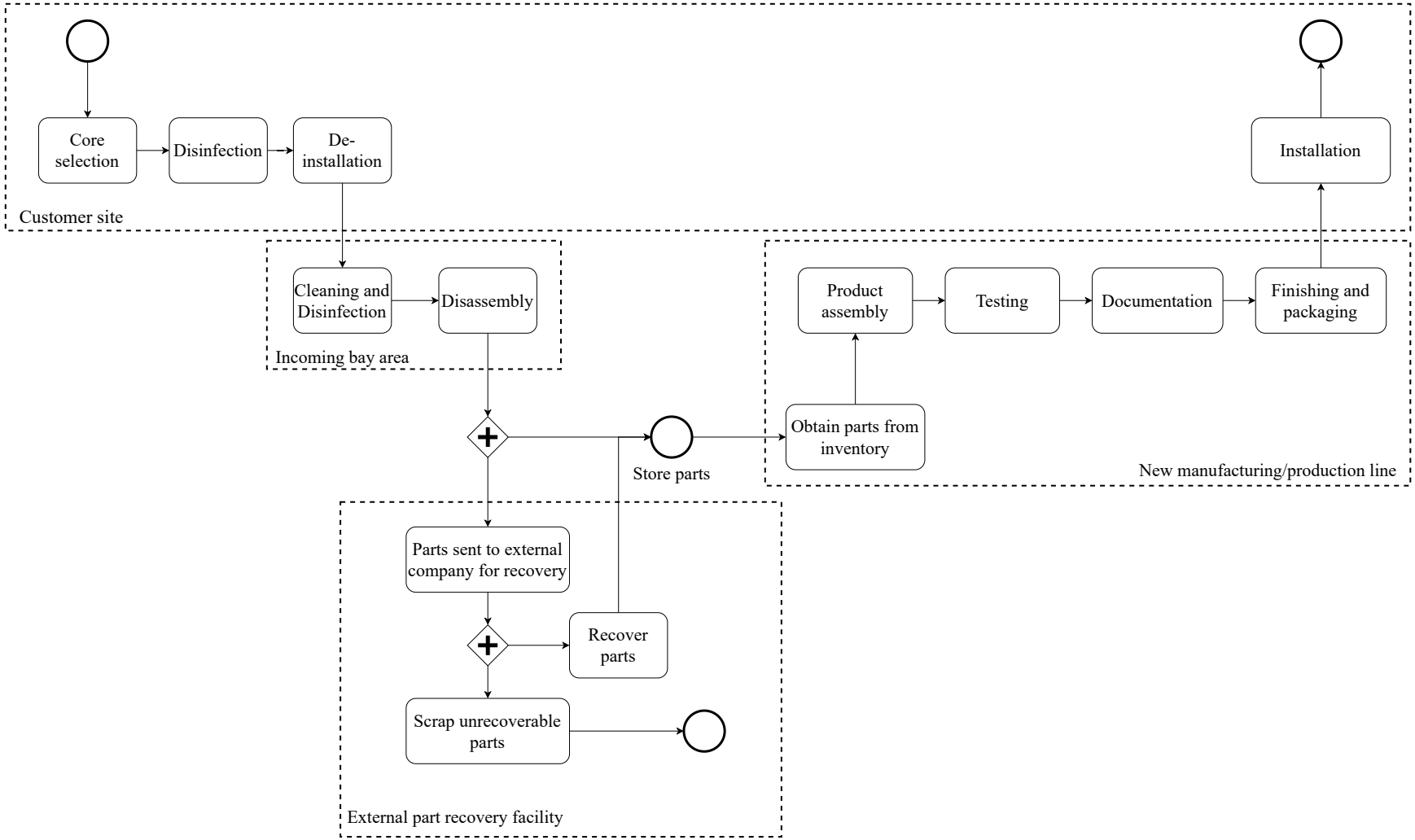

Figure 5-12: Company C's product recovery operation

5.5.3.1. Product selection

The recovery operation at this company begins long before the used medical device arrives at the manufacturing site. The company targets high quality cores, which are less than five (5) years old for its recovery program. Usually, products older than five years are not desirable for refurbishment because they may be unable to support customers during the warranty or guarantee period. Also, products less than five years old can be easily recovered because the technology is more recent. A company representative stated that products older than five years may lack the structural components or hardware to run their latest programs or software features that enhance performance and security. The key considerations by this company during the product selection activity are:

a. Condition of the returned product
b. Age
c. Service history
d. Technology level

5.5.3.2. De-installation

After the product selection process, they move on to the de-installation phase. The de-installation process occurs at the customer site where the medical device is professionally removed by highly trained engineers for the specific modality. These field engineers are regularly involved in the installation and servicing of such devices and are usually familiar with the de-installation procedure of the device. This ensures that the device is correctly de-installed without damaging any components which may be critical to the recovery operation.

During the de-installation, initial cleaning and disinfection is performed at the customer site before the device is packaged and transported to the manufacturing facility. According to the company representative, the initial cleaning, along with other disinfection documentations, are a legal requirement to transport used medical devices within the European Union.

5.5.3.3. Recovery operation

The recovery operation takes place in the manufacturing facility – the same facility where new devices are produced. The operation is performed on the same manufacturing line and by the same experts and personnel who are involved in the new manufacturing process. This ensures some level of consistency in the production process. The recovery operation at this company is therefore a hybrid manufacturing-remanufacturing operation.

When the medical device from the previous activity arrives at the manufacturing facility, the first point of call is the "incoming bay area" where the system is comprehensively cleaned and disinfected. This cleaning phase is a sequel to the mandatory preliminary disinfection at the customer site. The following comprehensive cleaning ensures that the device can be safely worked on by the personnel at the manufacturing facility without risks of contamination. After the cleaning operation, an inspection activity is performed to assess the condition of the device. This inspection activity focuses on the physical conditions of the returned items rather than on the performance or functionality of the product which would require a comprehensive testing procedure.

When the inspection is completed, the system is disassembled into smaller units, components, and sub-systems. After disassembly, the different components are sent to different external locations where they get repaired and sent back to the facility. These external locations are usually the suppliers or manufacturers of these components who have the adequate expertise to recover the parts. Company C does not perform any recovery activity on the returned product nor any of its components. Also, the company does not have so much information about what goes on with the parts after they are sent to the external vendor. This is because the company relies on part recovery organisations to handle their own products. The parts are recovered and sent back to the company C. If the parts cannot be recovered, a new or replacement part are sent. The received components are stored and kept in the company inventory awaiting the next activity. An interviewee described what happens after the disassembly below:

"For example, the magnet is removed and sent to the factory of the magnet supplier, the flex coils are removed, and other parts are removed as well. The parts are sent to different places where they fix them, and they send to us when they complete their process."

When a customer order comes in for a recovered system, the different components that are required to make the system are identified and obtained from the inventory and put on the factory production line. This production line is the same for the production of new systems, so the recovery process typically follows the same process, same experts, and same time as for new production. During this process, the parts are assembled, and the product is tested. The quality assurance process is based on the "four-eyes" principle where the test results are validated by at least two people: one from within the factory and another person usually the QA team. They may observe the testing process and compare the results with what is

expected of a new product. This is the final step before the product gets packaged for shipping to the customer.

The recovery operation is performed using the same process, methods, tools, and staff as in the manufacturing of new products. Therefore, in most cases, recovered devices by this company are only distinguished by the structural framework upon which the system is built. Recovered systems rely on pre-owned structural core whereas new products use brand new structure. The recovery operation is mostly manual and is labour-intensive.

5.5.3.4. Installation

After the assembly and testing process, the recovered product is sent to the customer site where it is installed like a new system. The installation is performed by highly trained technicians who are involved in the installation and de-installation of such system.

5.5.4. Company C's remanufacturability decision-making

The key factors that affect the remanufacturability decision-making process at this company are described below. These key factors and considerations are highlighted in figure 5-13.

5.5.4.1. Condition of the returned product

The company assesses the quality level of the products that are desirable for its recovery program, long before the recovery operation begins. They may refer to customer complaints, notable component failures or risk assessment reports of the specific product model to estimate the condition at the end of its present use. On the other hand, the condition of the used medical device is assessed at the point of procuring and de-installing the core from the customer site. According to the company personnel, the condition of the used devices plays a significant role in their decision to recover specific medical devices.

When assessing the condition of the returned device, the company will evaluate the current performance of the system. For medical devices returned directly by the customer, the company performs an in-depth assessment of the performance or quality conditions of the medical device. The company representative described it this way:

"If a system of 2 years old comes back to me, I'll be asking what happened to the system. If it failed, if somethings wrong with it, if the customer has reported some issues with it that's when I would assess if it were possible for me to recover it to a safe and effective condition. But the ideal age for us would be systems at least 5 years old and systems we can support for another 5 years through warranty and spare parts supply."

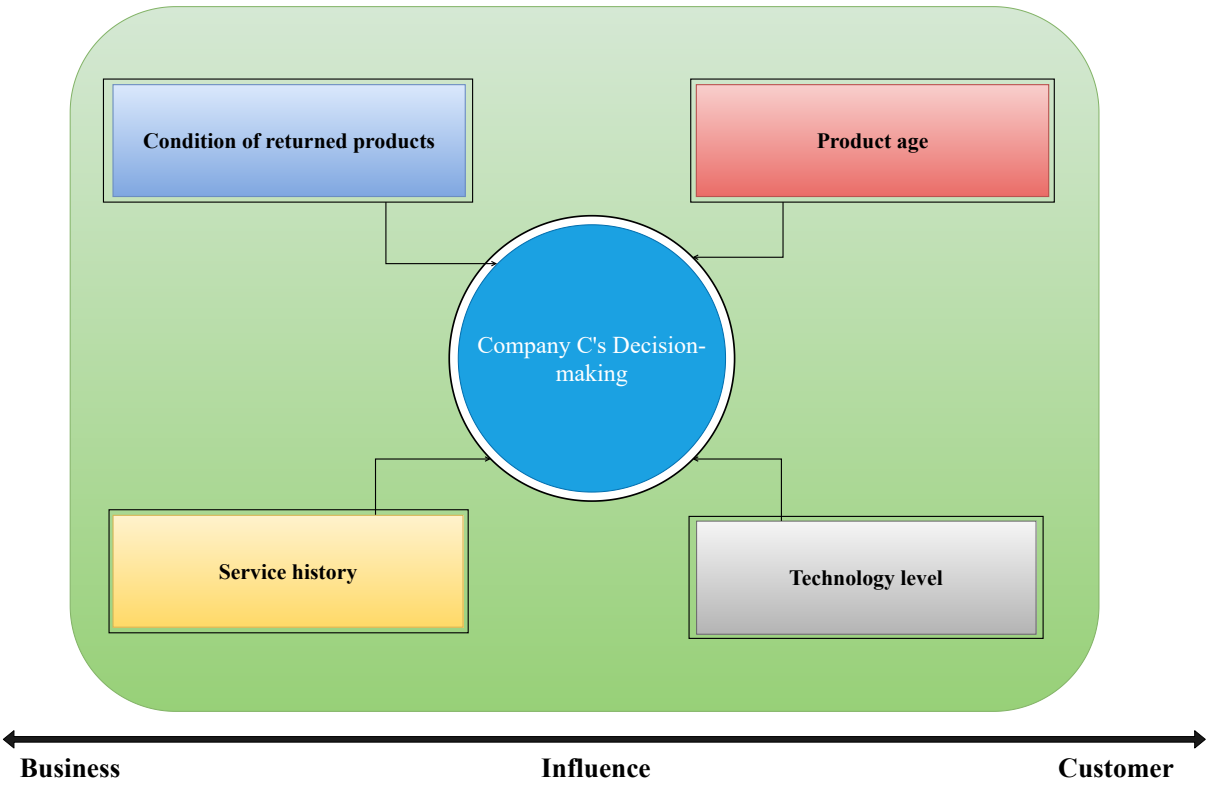

Figure 5-13: Remanufacturability decision-making at company C

5.5.4.2. Age

Typically, the company targets medical devices that are less than five (5) years old for their recovery operation. The age of the device affects several other key considerations such as the technological compatibility, customer acceptance and the ease of refurbishing the product. As such, the company prioritises the age of the device because they believe this is critical to their ability to deliver high-quality recovered systems. However, in certain cases, the company may recover older devices if it passes the other requirements.

5.5.4.3. Service history

When procuring systems for the remanufacturing operation, the company assesses the level and quality of service that has been given to the system. Whether the system has been maintained and serviced by the company or a third-party, the kind of servicing procedure that has been performed, and the timing or interval of the service, etc. The company assesses the service history to be sure that the system has adequate preventive maintenance as specified by the OEM which may increase the ease of the recovery operation. If a medical device has not been appropriately maintained or if the servicing or maintenance organisation is not on the approved sub-contractors list by the OEM, the product would most likely not be refurbished.

5.5.4.4. Technology level

Technological innovation for medical devices developed by this company is fast growing. The technological level of the system is a function of the age and may affect the decision to recover the system. The key consideration when assessing the technological level is an assessment of the upgradeability of current technology of the product to the latest version without significantly changing the performance or functionality of the device. This ensures that the recovery operation doesn't exceed the refurbishment standard and the initial registration document can be used.

5.5.5. Critical issues

This company does not involve itself in the recovery of key parts for its medical devices' recovery operations. This responsibility is mostly given to the original supplier or manufacturer of the parts. However, in most cases, used parts are not recovered and new equivalents are used in building the company's recovered system. While this approach is understandable, based on the need to provide customers with good quality and high-performance devices, the overall sustainability of their recovery operation is questionable. The inherent value (material and energy) in the used parts is lost and more resources would be required to manufacture the new replacement parts. It can be argued that their recovery operation is not really "refurbishment" but rather reconditioning.

Another critical issue with this company is the nature of its remanufacturability decision-making. The consideration of the decision process at this company is driven mostly by the characteristics of the product. As such, less consideration is given to other key factors which may influence customer acceptance or perception of the recovered medical device.

5.6.Company D

The previous sections (5.3, 5.4 and 5.5) presented the findings from companies that focus on medical imaging devices such as MRI, CT, Xray and PET/CTs. This section presents the case study findings from an organisation that recovers single-use medical devices such as surgical tools, hospital mattresses, catheters etc.

5.6.1. Key personnel

Three key personnel from company D contributed to this case study research. Table 5-4 describe the characteristics of these personnel. They are high-level management personnel with a good understanding of the company's product recovery operations. As such, they are

able to provide deep insights that are critical to this research. In total, they contributed 6 hours of interview over the period of three months.

Table 5-4: Position and experience of participants

S/N	Position	Description of Participant responsibilities	Years at company	Years in current role
1	Sustainability Lead	Works directly with customers (who are hospitals or healthcare systems) to understand and achieve their sustainability goals.	6	1.5
2	Director of Advanced Engineering	Works with the marketing team to decide, from the customers' perspective, what medical devices would be desirable to recover and then translate it to an actual business process.	19	1
3	Director, Upstream Marketing & Business Development	Directly involved in the remanufacturability decision-making at this company	1	1

5.6.2. Company background

Company D is a third-party recovery organisation with several facilities that focus on recovering single-use medical devices. They are the reprocessing arm of a group of semi-autonomous organisations bounded by a similar structure and quality systems. The company is headquartered in the United States where they operate two recovery plants. They began their recovery operation in 2009 after they were acquired by the parent company. They are large business with more than 1,200 employees. The company runs a service business targeting hospitals and healthcare boards in North America. In recent years, they have partnered with a few hospitals in Japan where they collect and recover used medical devices. They partner with healthcare providers and hospitals to assist them achieve their sustainability and cost saving goals. Out of about 6,000 hospitals in the US, the company currently partners with over 3,000 hospitals which means they hold the market majority of customers in terms of collecting used single-use devices and recovering them.

Another arm of the parent company is involved in the manufacture of single-use medical devices. Company D (the sustainability and recovery division of the parent company) is in the top five divisions for the highest products volume of all the other business units. Also, the company is a major producer of pulse oximetry sensors, DVT compression sleeves and electrophysiology catheters. The consequence of this is the large volume of medical wastes that are recovered which otherwise would have been incinerated or sent to the landfill.

5.6.3. Business Scenario

5.6.3.1. Procuring cores

The devices that this company recovers are typically designed by the OEM to be disposed of after a single use. Therefore, an effective core procurement strategy has to be organised. This company works directly with their customers (hospitals and clinics) to collect used single-use medical devices. They install collection containers close to patient point of care where these devices are mostly used.

The company directly reaches out to hospitals that have large usage of single use devices, are concerned, to certain extent, about the sustainability of their operations and are looking for cost saving measures. Company D would describe the advantages and opportunities that are associated with recovering used devices and they estimate the potential economic savings for customers and the environmental conservation when they recover their used devices through company D. This introduction plays some role in overcoming the initial resistance of clinicians to product recovery, especially in hospitals with anti-reprocessing language. An interviewee described the core collection strategy below:

"So, we approach hospitals, clinics or health boards and say, we have regulatory approval from your country's (or region's) to reprocess certain devices. These approvals are very device specific, so it would be, for instance, a harmonic scalpel – a directed energy device used in laparoscopic general surgery… and so we would say we have the ability to reprocess this device two times."

After the initial contact has been established, the company sends its representatives to the specific hospitals to evaluate the level of usage of these single use medical devices and work directly with hospital staff and administrators to determine the best collection points for used medical devices. An interviewee explained further:

"If the hospital is interested, we would send our service associate to go and assess their usage and where within the hospital that particular device is being used and we would install collection containers that cannot be punctured by a sharp medical device or harm someone while in transit, something that doesn't leak, and something that is not likely to topple over and spill content. They are placed as close as possible to the point of care for easy accessibility e.g., in operating rooms where possible."

The service associate trains hospital staff on how to use the collection points by disposing of used single use devices into the specified containers. The service personnel routinely visit the hospital to collect, package and ship the collected cores to a dedicated recovery facility. These personnel are very critical to the collection strategies of this company. An interviewee described further.

"We make sure that we have enough sales reps and service associates covering each area so that they're not overwhelmed and can give enough detailed and specialised attention to each customer, so that require, essentially, a lot of boots on the ground people, so we have a pretty extensive employee base of service associates to keep the core collection running smoothly."

The collection and transportation of used cores follow strict guidelines which are put in place by appropriate regulatory bodies. This is to reduce risk of spreading infection and is best explained by a regulatory personnel at the company.

"So, for instance, for our surgical devices, they are contained within our advantage container. This is essentially a trash can that cannot be permeated. It comes with a lid on it, those lids are zipped tight and placed in a double bag and then put in a corrugated box. So, all those safety protocols for our service associates or the shipping individuals have to be followed."

5.6.3.2. Product offering

The company collects tonnes of single use devices as a market leader in product recovery, and they partner with majority of the hospitals in the US. They are able to offer their customers a higher value on product recovery. The company offers thousands of recovered products under three franchises listed below as shown in figure 5-14. The two largest franchises recovered by this company are the surgical and the patient care. However, by volume, the patient care product franchise is bigger than the surgical franchise.

1. **Patient care**: include products such as pulse oximeter (POX), ECG leads, DVT, Fall alarm sensor pads, tourniquet cuffs, and patient transfer mattresses.
2. **Surgical**: include devices such as LigaSures, trocars, ultrasonic scalpels, and MyoSure tissue removal devices.
3. **Vascular**: includes devices such as EP catheters and cables, catheter introducer sheaths, ViewFlex, and ICE catheters.

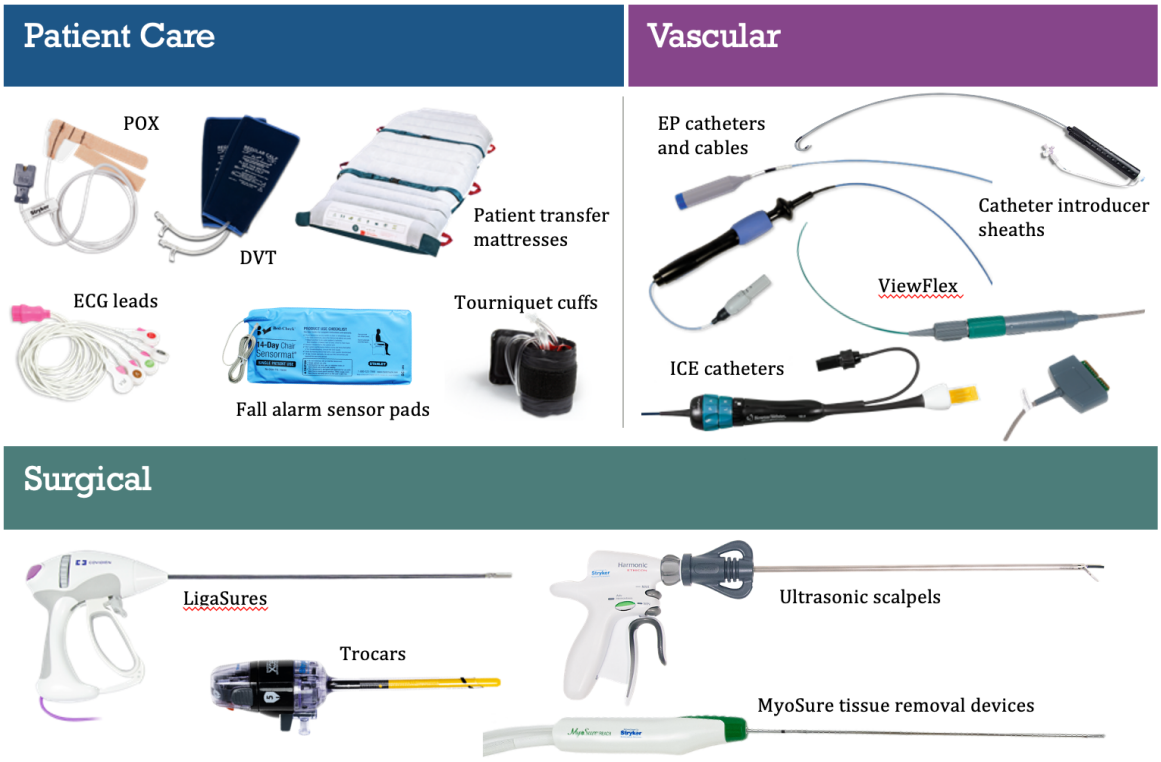

Figure 5-14: Company D's recovered product offering

5.6.3.3. Marketing approach

This company markets its products in the US, Israel, Canada, Japan. However, a vast majority of their customers are based in the US. Alongside the US market, the Israel and Canada markets for recovered single use devices are classed as very mature and provide unique business opportunities for the company. Every region has a different regulatory approach. Experts from the company noted how stringent regulatory barrier in Europe limits their activities within the regions.

One of the unique points from this company is its sales force who work closely with their customers to find the best solutions to achieve their clinical outcomes and financial goals.

5.6.3.4. Warranty

One of the ways company D take ownership of the devices they recover is by absorbing all the legal liabilities that is given by the original manufacturer as at when it was produced new. Thus, the warranty provided on their recovered is the same as new. Also, the company provides a similar technical support to their customers.

5.6.3.5. Different recovery operations

The recovery operation on single-use medical devices performed by this company is described as "*remanufacturing*". However, depending on the specific markets, the actual meaning of this term may vary. For example, an interviewee stated:

"In the United States we have to refer to it as reprocessing, whereas in Europe you call it remanufacturing, so in my mind they mean the same thing I know there are some technicalities that make it different, but when we say reprocessing, we essentially mean remanufacturing."

Therefore, to this company these operations (remanufacturing or reprocessing) do not mean different things. They do not represent different levels of work content, quality, or warranty of the end products. In most cases, they are used interchangeably within the organisation. For the rest of this report, the product recovery operation conducted by the company is referred to as the "*XD recovery operation*". The term "recovery" is preferred to avoid confusing the readers and to ensure consistency in the use of terminology in this chapter.

5.6.4. Description of company's recovery operation

The XD recovery operation on single-use medical device involves disassembly, cleaning, part replacement, reassembly, testing, inspecting, validation, packaging, and sterilisation. The test results, inspection details and validation proofs are packaged in the form of a 510(k)-registration (USA FDA) document which is a dossier of scientific validation information on the medical device. More details about the recovery process are presented in this section and are structured into 9 activities as shown in figure 5-15.

5.6.4.1. Core collection

The core collection strategy of this company has been described in the previous section. The company takes a lot of the responsibility for collecting used devices from hospitals rather than tasking the hospital staff who already have a difficult job and could be very busy. An interviewee described further:

"So, we set up collection modalities for single use medical devices in these hospitals. We have a variety of collection bins that are placed throughout the hospital from the general patient care floors to the ORs and the EP Labs and each collection modality is different based on the types of devices that we are aiming to collect in them."

For effective collection, the company representatives would educate hospital staff such as nurses, technicians, clinicians etc., on how and what to dispose of into these bins. The overall expectation is that when hospital members of staff have finished using the device on patients, they understand how best to dispose of specific devices in collection containers rather than in the regular waste bin which ends up in the landfill. An interviewee described:

"So once the bins are full, our service personnel will go to the hospital, depending on how big it is, maybe twice a week, maybe every other week, and depending on usage. But they'll go in there and collect the bins, take them into the shipping dock of the hospital and then ship those devices from the hospital to our reprocessing facilities in the US."

5.6.4.2. Receiving and sorting

The point of arrival of the collection containers is the sorting and receiving area of the recovery facility. The received devices are tracked back to the hospital to take inventory of the devices collected and appropriate credit is given. The devices are sorted and classified based on what can be recovered and what cannot be recovered. This sorting is performed by highly trained operations personnel who have undergone several weeks of extensive training. Also, the sorting and receiving operation is performed using specialised protective equipment and following stringent safety procedure, especially since the core bags are usually not decontaminated or cleaned at this point. An interviewee described:

"They gear up in their shoes and gloves, they use their face coverings, they're completely gowned as well, and so it does take a while for these individuals to be trained and come up to speed on what to do in the sorting and receiving area. We basically put the returned bins on a table, and essentially layout the devices and then the operations personnel will sort through it with tongs and other tools to separate the devices that can be recovered from those that cannot be recovered."

There is a high level of detail and scrutiny during the sorting operation as the operators have to carefully assess every device in the bag. Thus, the process is manual and labour intensive. The devices that can be reprocessed are sent to the next step which is disassembly while those that cannot be recovered are either recycled or discarded.

"Every container that we get back is filled with completely different material than the one before, so our personnel really have a keen eye for the devices that we're looking for, you know they have to distinguish, for example, the different types of trocars."

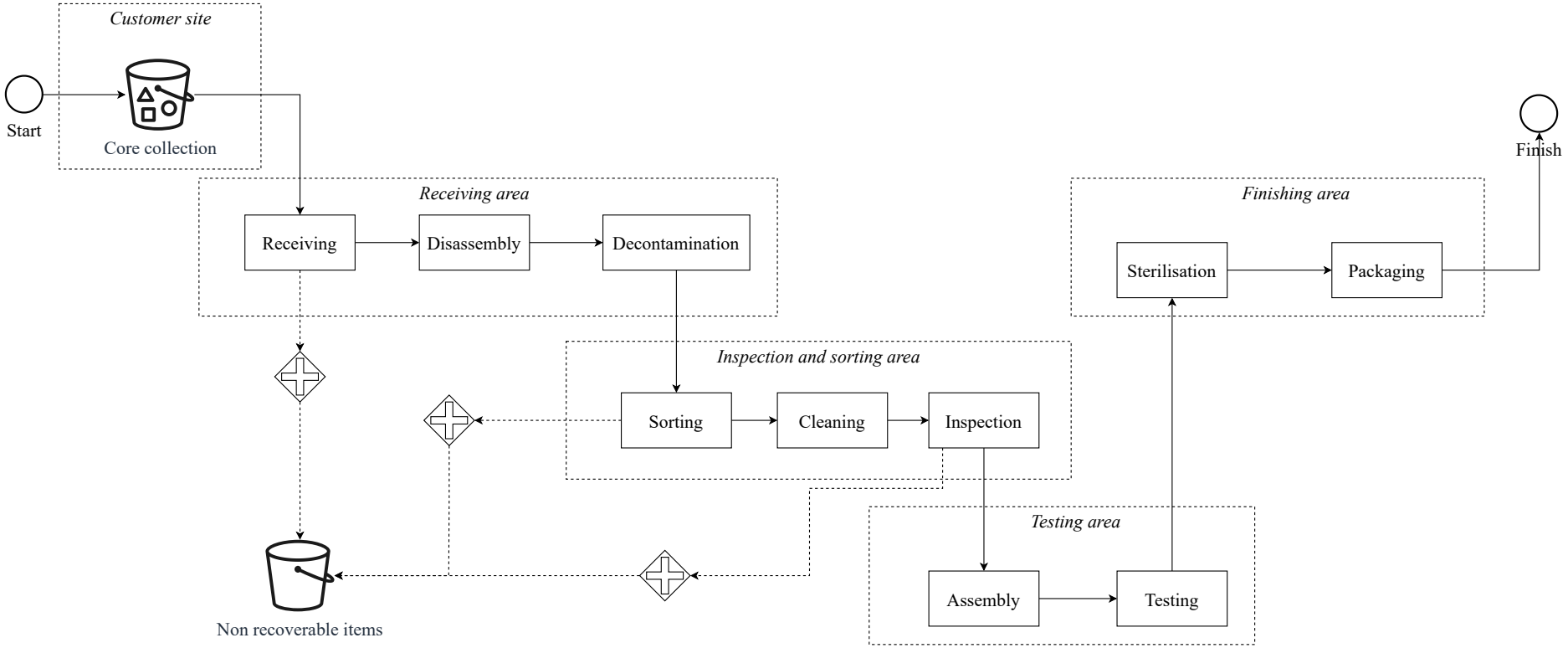

Figure 5-15: Company D's product recovery process

5.6.4.3. Disassembly

During disassembly, the device is broken down into smaller units. Not every device recovered by this company is disassembled to the lowest component level. However, a majority of the devices are disassembled piece by piece, to the smallest bolts and nuts.

5.6.4.4. Decontamination and cleaning

The next step is a comprehensive cleaning and decontamination procedure on all the devices that can be recovered. Specialised chemicals and treatments are used in the decontamination process. A second level of cleaning activity is performed using specialised cleaning modalities for the different parts.

5.6.4.5. Inspection

The recoverable assets are moved on to the inspection section of the facility. During this activity, a careful examination of the device is undertaken to identify parts of devices that are "objectable" due to gross aesthetic or mechanical irregularities. Worn parts are also rejected and are not processed further. Also, during this activity, further inspection is performed on parts to segregate them into different categories, types, models, and sizes. Parts are examined to ensure that they meet the company's quality system. Replacement parts are introduced at this point into the recovery operation.

5.6.4.6. Assembly

The parts are put back together systematically by trained technicians.

5.6.4.7. Testing

Every device is tested against the specifications of new equivalents to ensure that they are functioning as they should. As part of the regulatory approval process, the results from the testing process (mostly the failure rates) are used to demonstrate the safety of the recovered device and prove its equivalence to new. The company is obliged to demonstrate that the clinical performance or the failure rates of the recovered devices is as good as, or better than new.

5.6.4.8. Packaging

The devices are packaged and prepared to be sent to the customer.

5.6.4.9. Sterilisation

The devices are treated through a final sterilisation stage.

5.6.5. Company's remanufacturability decision-making process

When planning the recovery of any medical product, this company considers many factors, which directly linked to the customer. However, the decision process is severely influenced by the type of the device, the regulatory requirements amongst other considerations.

5.6.5.1. Disposition options

Depending on the nature of the device, the obtained quantity and demand situation, used medical devices received at the recovery facility of this company can be taken through any of these four (4) routes:

1. *XD Recovery operation*

In this route, the product is taken through an advanced recovery operation termed "remanufacturing" or "reprocessing" depending on the region in which the product is sold. The recovery operation has been described in the previous section and a process flow diagram is presented in figure 5-15.

2. *Recycling*

Another route for end-of-life single use devices is through the sustainable recycling option. During the recycling operation, these devices are broken down to material levels and used to produce new items. Large volumes of specific items are collected at the facility over a period and are sent to a recycling vendor who processes them sustainably. The POX and ECG leads are recycled when they reach their maximum turn cycle or are rejected in the recovery process. The company recycles 100% of the rejected POX and ECG leads.

3. *Waste to energy*

A third disposition route for used medical devices is through the waste to energy option. The waste to energy programme at this company is handled by another organisation. Used medical devices are used to generate energy. Patient transfer mattresses are mostly treated through the route because of the nature of the materials.

Although the company aims to recover as much as possible, there are situations where a device cannot be directly recovered such as when it has reached its maximum return cycle. Other situations include products that are defective beyond repair and devices for which the company doesn't have regulatory clearance to recover. The company aims to divert medical wastes from landfills as much as possible and may generate useful energy from waste devices. An interviewee described further:

"So, for instance with our Pulse Oximeter (POX) and ECG leads, if we cannot reprocess them maybe because they've reached their max turn cycle or are rejected on our reprocessing line for any reason, we collect those and store those at our facility until we have enough volume to send a recycler. So, 100% of our POX and ECG leads are recycled and annually we have about 150,000 pounds of POX and ECG's that are recycled. Other products are sent to our waste to energy providers, but we are continuously looking for additional solutions."

4. *Autoclaved and landfilled*

This is the final and the least desirable option. Products or parts that cannot be treated through any of the three routes above are autoclaved and landfilled.

5.6.5.2. Remanufacturability decision-making

Company D aims to maximise value for their customers at the first instance and then for the business at the second instance. To a large extent, the company's decision to recover certain products is based on the customers. For example, what products are the hospitals using and what's their quantity, what products can they buy recovered and which ones are preferred new, and what is the potential discount on those products. Some of the factors considered during the remanufacturability decision making at this company are described below and illustrated in figure 5-16.

5.6.5.2.1. Supply of used devices

For company D, the availability of used devices is a critical consideration when making remanufacturability decisions. Before developing a recovery programme for any device, the company assesses the level of supply that would be obtained. This can be performed through comprehensive research on the device within the specific target region. With this, the company understands the production volume, the hospitals that use the largest volume, the number of procedures performed with the device daily, weekly, or monthly. Thus, they are able to plan recovery operation for an approximate quantity of devices.

For the customers to realise extra cost savings, they must, first of all, be able to collect their used devices and be able to purchase them at a discounted price. To maximise value and optimise cost savings from the recovery operations, the hospital should aim to collect a large proportion of their used items. The recovery operation becomes more viable when a large quantity of cores is collected.

5.6.5.2.2. Price

Customers are often interested in innovative ideas that has the tendency to push down costs and assists in achieving their annual cost-saving targets. During the decision process, the company assesses how it can maximise value for its customers. Some of the way the company offer value to its customers for their partnerships are:

- *Premium on collected products*: The company may pay a small amount of money to the customer for collecting certain devices
- *Waste diversion*: The company helps hospitals to sustainably dispose of waste of certain medical devices which otherwise would have been sent to the landfill or incinerated at cost to the hospital. Thus, the company reduces the total volume of wastes that they have to deal with.
- *Discount on purchase*: The bulk of the value to the customer happens when they buy XD recovered devices. The recovered devices are usually priced 30 – 60% lower than a new equivalent.

The price at which the recovered device is offered to customers significantly influences the company's decision to recover medical devices. This is because the sales price influences the profit margins which is important to both the company and its customers. The company assesses this pricing issues early on in the decision process to ensure that recovering the product is viable for the business and for the customers.

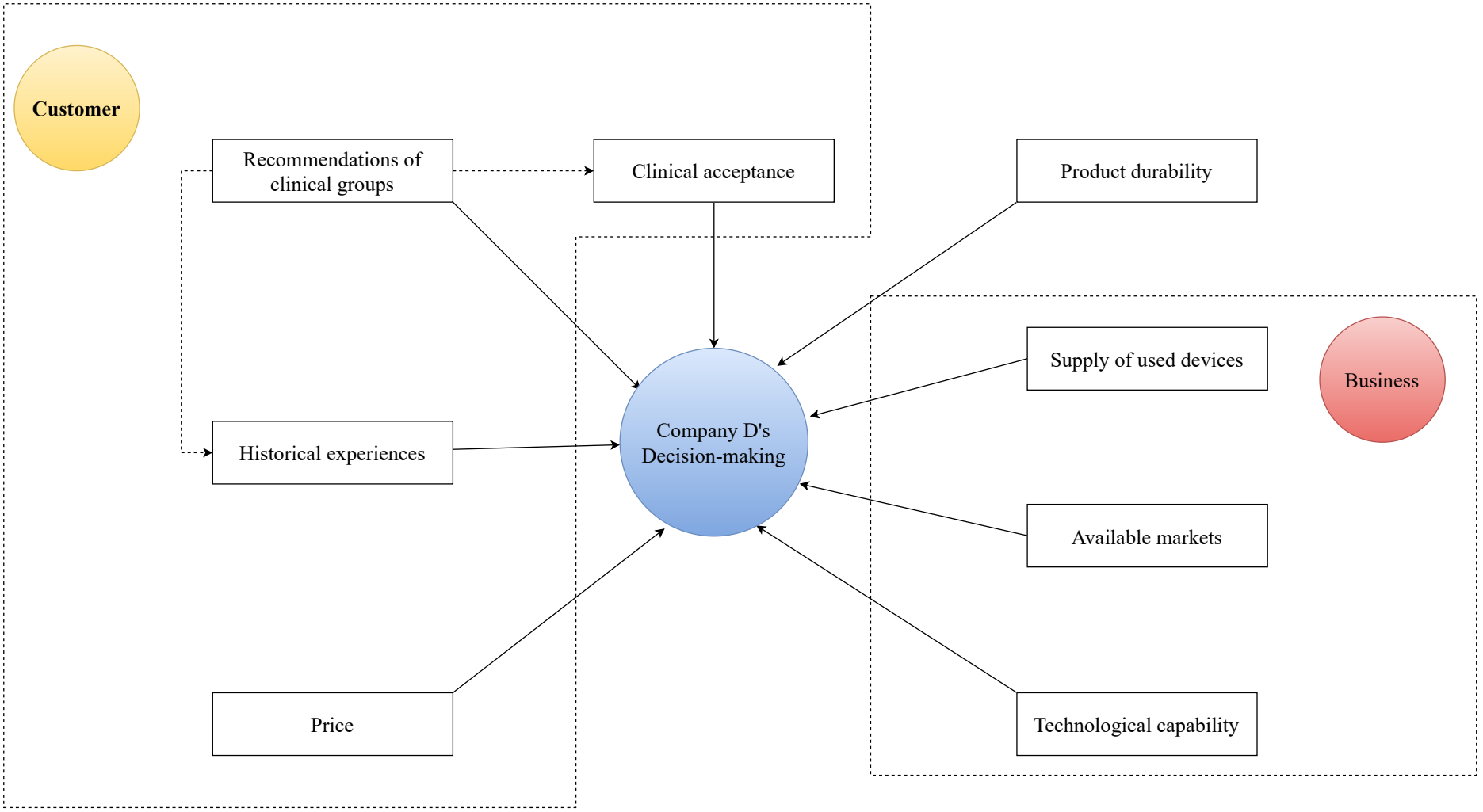

Figure 5-16: Company D's remanufacturability decision factors

5.6.5.2.3. Technical capability

Company D is an organisation with a long history of recovering low-cost devices which are used in large quantities by hospitals. The company has technical capability to recover electrophysiology devices, surgical devices, patient care devices, simple monitoring tools e.g., O_2 sensors and ECG leads. The company ensures that they can confidently create (or have created) a process that can recover specific medical devices safely, consistently and at scale. Also, the company assesses if it has the regulatory approval to reprocess these devices or needs to make a new application to that effect.

5.6.5.2.4. Available markets

Another critical remanufacturability consideration at this organisation is the available market for the recovered product. The decision makers assess if the market is substantial enough that they can sell at a low price and still meet the objectives of their customers. Having the tendency to meet the financial saving targets of the customers can potentially drive customers decision to prioritise product recovery. Thus, the company picks product categories that have a higher tendency to assist hospitals in reaching their objectives.

The available market factors are very dependent on the specialty and on the specific hospital being targeted. For example, they may assess the profitability of the specific procedures performed by each hospital. For highly profitable procedures, the pressure to reduce cost is usually low and the focus of the hospital is to keep the surgeons happy and busy rather than driving down costs. However, on the less profitable procedure where the pressure to drive down cost is higher, recovered products may be more acceptable, thus driving the company's decision to create a recovery programme for the device.

5.6.5.2.5. Product durability

Any product that the company decides to collect, take to their facility, and recover has to be sufficiently robust to survive the recovery process. The durability of the products they recover depends on the design, and the materials used. Since these products are mostly designed for single use, recovering them can prove to be a tedious task. This is why specific products targeted for the recovery operation are sufficiently durable and can safely go through a multiple life with a quality and performance similar to that of new.

5.6.5.2.6. Clinical acceptance

The acceptance of recovered devices by clinicians is critical to the decision-making. According to a participant from this company, product recovery in some medical specialties have lasted more than a decade and generally clinicians understand the safety and efficacy of these devices, having taken part in clinical trials for recovered devices. However, in some other specialties, especially where product recovery is usually not discussed, clinical acceptance would be low. For example, a colorectal surgeon or a general surgeon may have a different perspective on product recovery than a urologist or a dermatologist. As a result, the company would usually not recover products where clinical acceptance is low. Over time, their adoption may increase and the willingness of consultants and surgeons to trial recovered devices may rise, thus the company keeps itself up to date with the market and continuously engages with professionals in hospitals.

5.6.5.2.7. Recommendations of clinical groups

Every clinical specialty has its own group or organisation where they may advice their members on the current practices including the use, or not, of recovered devices. This may impact clinical acceptance factor and customers' historical experiences. When making recovery decisions on specific products, the decision makers at this company often look at the position of the clinical groups on product recovery. A positive outlook on recovery by these groups (such as the American College of Surgeons ACS, Royal College of Surgeon RCS, Society of American Gastrointestinal and Endoscopic Surgeons SAGES, etc,.) often indicate a positive clinical acceptance which may encourage decisions to recover the product.

5.6.6. Summary

The organisation aims to drive sustainability in the healthcare industry by partnering with hospitals globally. Given that the volume of recoverable medical wastes from hospitals have increased over the past two decades, the growth opportunities for this organisation is limitless. The company quantitatively evaluates the impact of its recovery operation through a "waste diversion" metric, which is a measure of the volume of wastes of single use devices that is being diverted from the landfill by their customers when they purchase recovered devices. The approach by this company and its direct relationship with customers position the company as one of the leading recovery and sustainability giants within the medical devices sector.

5.6.7. Critical issues

Customers are always at the foreground of decision making in the medical devices sector. While this ensures that remanufacturing businesses tailor their decisions specifically to meet customer needs, customers often retain some bias against the use of recovered products. For example, a participant from company D described how some customers, after obtaining details about the potential financial savings from recovering used devices would go back to renegotiate with the vendors of the new devices to try and get a better deal. This is one critical issue faced by this company. However, in its remanufacturability decision-making, the company effectively puts customers at the foreground.

5.7.Cross-case analysis

The companies assessed in this qualitative phase are focused on remanufacturing medical devices which include imaging devices such as the MRI, CT, Xray and Ultrasound, and single-use devices . Medical imaging devices are typically very expensive to purchase, and single-use devices are used in large quantities. This provides an economic basis to remanufacture both classes of medical devices.

Table 5-5 illustrates the factors considered in the remanufacturability decision-making process of the companies assessed in this chapter. The findings from this chapter highlighted economic considerations and returned product factors as the key decision factors when assessing the remanufacturability of used medical devices. This is an indication of the impact of cost factors (such as the cost of procuring core, cost of recovery operation and the running cost of the recovered device) in the medical devices remanufacturing sector. Representatives from the four companies highlighted how profit or sales margin obtainable from remanufacturing a product is one of the key factors when assessing remanufacturability. The results from this case study research also highlights the impact of customer considerations in remanufacturability decision-making. For all the factors highlighted in table 5-5, the decision makers keep the customers at the foreground of their assessments. Representatives across the different companies described that the overall decision is based on customers seeing value in the remanufacturing operation and consequently willing to make the financial commitments to remanufacture the medical device. Other factors such as the significance of clinical acceptance, recommendations of clinical groups and previous experiences with using remanufactured devices were also highlighted.

Table 5-5: Summary of decision factors

Characteristics	**Company**			
	A	**B**	**C**	**D**
Company type	OEM/OER	TPR	OEM/OER	TPR
Sustainability factors				
Environmental	N/A	N/A	N/A	Waste diversion
Economic	Cost of procuring used medical device	Cost of procuring used medical device	Cost of procuring used medical device	Price of the recovered products
	Cost of product/part recovery operation	Cost of product/part recovery operation	Cost of product recovery operation	Organisational costs for service associates, logistics, and recovery operation
		Actual customer demands and market situations		Available markets
Social	N/A	Supplying hospitals in low-resourced settings	N/A	N/A
		Local employment opportunities for people		
Product Factors				
Product Design	Designed second-life quality	N/A	N/A	Product durability
Returned product factors	Age/maturity of product compared to current industry standard	Access to spare parts	Technological compatibility of product	Number of recovery cycles a product has already been put through
	Performance with respect to age	Performance of product at end of current use phase	Reported customer complaints	End of use quality of the device

	Failure rate during the first lifecycle	Result of QA testing	Notable component failures	Supply of used devices or quantity of returns
	Level of servicing received, and number of parts replaced during service		Product risk assessment report	
	Production plan on new equivalent device		Level and quality of service given to product	
	Quantity of device currently in a socket versus quantity not sold to customer			
	Quantity of the used medical device obtained for recovery			
Other product factors	Current and future availability of parts or customer support	Availability of spare and replacement parts	Ability to obtain appropriate parts from suppliers	
Technological factors				
Ease of remanufacturing	N/A	N/A	N/A	N/A
Remanufacturing capability	N/A	Access to highly trained and experienced personnel	N/A	Technological capability
		Available information about specific products		Regulatory approval to recover specific products
Does the company consider customer requirements?	Yes	Yes	Yes	Yes

A notable difference in the remanufacturability considerations between the cases is the assessment of remanufacturing capabilities. Both companies A and C are OEM/OER and as such do not seem to consider the presence or lack of the ability to remanufacture specific products i.e., their remanufacturing or technological capabilities. This can be associated to high-level knowledge of their own products and the skills transferrable from the new product development and forward manufacturing team to the remanufacturing team.

On the other hand, companies B and D are TPR, and they assess, to a great extent, their technical capability to remanufacture specific medical devices and/or its parts. Both companies are unconcerned about the brand or name of the original manufacturer of the devices that they remanufacture. They simply focus on their own abilities to successfully remanufacture and market the product. This is noted in company B's description of its lack of access to product information, service history and experienced personnel to work as major limitations in its recovery operation.

A key takeaway is the lack of sufficient product design considerations, in the remanufacturability decision-making. Product design has been described in existing literature as playing a major part in remanufacturability decisions. However, the companies assessed in this research do not seem to pay much attention to the product design in the decision process. This can be associated to two possibilities, that :

1. products in this sector are usually designed for multiple lifecycles and as such the design does not play significant part in the decision to remanufacture them; or
2. regardless of the design, products in this sector can be remanufactured if there is sufficient financial motivation and customer demand for it.

Remanufacturing operation in the medical devices sector require significant financial investments and customer acceptance plays a critical role in the decision of organisations to enter the remanufacturing business. Table 5-6 underscores the different customer factors or considerations that drive remanufacturability decision-making at the companies assessed in this chapter. The factors were grouped under the categories identified and quantitatively ranked in the chapter 6. These considerations are assessed from the viewpoint of the customer by the decision makers. This further highlights the importance of customer consideration in remanufacturability decision-making in this sector. Decision makers believe that their customers are cost-conscious, and remanufacturers should be able to offer the remanufactured devices to the customers at a price lesser than a new equivalent.

Table 5-6: Customer considerations in remanufacturability decision-making

Customer factors (from quantitative study)	**Company**			
	A	**B**	**C**	**D**
Quality factors	Previous customer complaints	Product performance at the end of previous use phase	Number of customer complaints during the previous use phase	Product durability
	Open service request	Results from quality testing of the product	Notable component failures/replacements	
	Failure rate within the first 90 days		Product quality at the end of previous use phase	
	Number of parts replaced during service			
	Highest quality or performance level the used product can upgraded to			
Pricing factors	Price at which recovered product is offered to customer	Price at which recovered product is offered to customer	Selling price of recovered product	Price of recovered device
Warranty factors	N/A	The level of warranty that is acceptable on that product	N/A	N/A
Branding factors	Level of recovery operation that can be performed compared to third parties		Competition in the market	Technological capability and market dominance

Available information factors	Information available to customer about low-cost alternative to specific product modalities	Other alternatives available to customers	Customer's awareness of low-cost offerings by competitors	Customer awareness of the potential cost-savings for using recovered devices
Added value service factors	Customer support available after product recovery Spare parts that can be provided	Customer demand for value added services	Part supply guarantee for five years	Staff training Continuous customer support
Environmental factors	N/A	N/A	N/A	N/A
Other customer considerations?	Spare parts that can be provided	Regulations and legal restrictions on pre-owned medical devices.		Historical experiences and clinical acceptance

On the average across the four companies, remanufactured devices cost 20 – 60% less than the current value of equivalent new products. Therefore, pricing considerations are a critical requirement during remanufacturability decision-making. Apart from the price, decision makers also noted the importance of quality factors in a number of ways. In some cases, the companies compared the expected quality of products at the end of their current use phase with the actual quality of the core received by them. Several factors such as customer complaints, failure rate, product quality or performance at the point of recovery, product durability and the expected upgrade required for the product to attain acceptable market standard were also considered. These quality factors are critical in this sector, especially given the impact of quality on the acceptance of remanufactured medical devices.

On the other hand, warranty factors don't seem to bear much significance, and this may be due to the companies' regulatory expectation to provide a warranty that is as good as new on their remanufactured products. In this sector, warranty provision is seen as a basic and legal requirement. Experts in the medical devices sector believe that customers expect manufacturers or remanufacturers to back their products with competitive warranties. Other factors such as branding, added value services guarantees and available information are noted to be of mild importance whereas environmental considerations do not seem to play any major role in the decision process. Other factors such as the previous experience of the customers, legal regional restrictions and clinical acceptance were also noted.

5.7.1.1. Remanufacturing process

The four medical devices remanufacturing companies A, B, C and D assessed in this thesis demonstrated their understanding of remanufacturing and other product recovery strategies. However, they highlighted that there are no tangible differences in the activities involved in the different product recovery operations e.g., between the remanufacturing and refurbishment process. Also, products are not marketed to customers as either "remanufactured" or "refurbished". Typically, the important requirement for recovery in this sector is the safety, warranty, and services as suggested by (Akano, Ijomah and Windmill, 2021a) and the companies achieve this, irrespective of the terminology used to describe the recovery operation.

Medical device remanufacturing typically requires more steps of inspection, cleaning, and sterilisation. This extra attention to the cleaning and sterilisation process is demonstrated in the remanufacturing processes of the companies A, B, C and D discussed in chapter 7. The

proposed generic remanufacturing process for medical devices includes nine steps which are: core selection, de-installation/collection, cleaning, disinfection, disassembly, part reworking or replacement, reassembly, testing, and packaging as shown in figure 5-17.

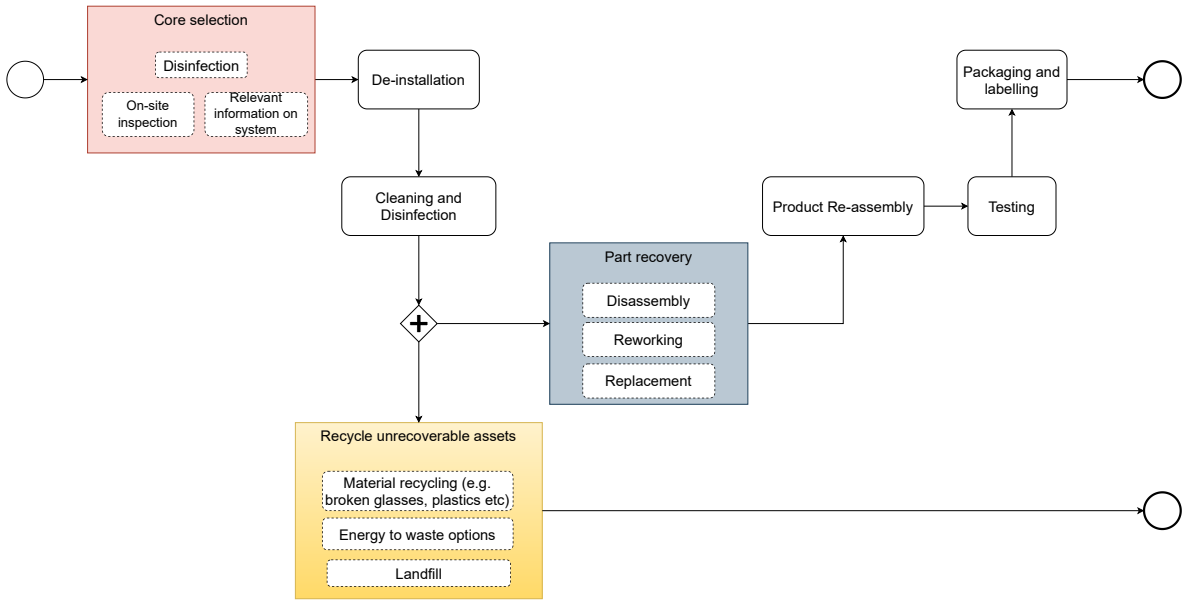

Figure 5-17: Generic medical devices remanufacturing process

5.8.Conclusion of chapter 5

This chapter presented the findings from a multiple case study research of medical devices remanufacturing companies. The term "*recovery*" has been used as an umbrella term to describe the remanufacturing operations of each company, only to avoid confusing the reader. Due to regulatory ambiguity, the companies may refer to their operations using a number of keywords such as reprocessing, refurbishment, and remanufacturing. In most cases, the description of their processes meets the definition for remanufacturing.

This chapter presented the qualitative findings from each case including the flowchart of their remanufacturing operations and diagrams illustrating their remanufacturability decision-making. It has also discussed how customer requirements have been considered by the companies in remanufacturability decision-making. The major finding from this chapter is the deviation of the requirements in the medical devices sector from what has been described in existing literature in other sectors such as automotive, aerospace, electrical and electronics etc.

Chapter Six: Combining Research Findings: Explanatory analysis of remanufacturability decision-making in medical devices remanufacturing

6. Chapter Six: Combining research results: Explanatory analysis of remanufacturability decision-making in medical devices remanufacturing

6.1.Introduction

The research methodology adopted in this thesis is an explanatory sequential mixed methods design which enables more than one study to be conducted separately and across different time frames (Schoonenboom and Johnson, 2017). A mixed approach where the qualitative study has a dominant status is used. However, the findings of the quantitative research informed the development of the approach and theme for the qualitative research phase. The key rationale for adopting this approach is to ensure completeness of research findings. In mixed methods research, researchers would often compare the research data, findings, analysis, interpretations, and discussions from both qualitative and quantitative studies. Mixing or combining research findings allows the researcher to remove the limitations in existing studies and balance perspectives across quantitative and qualitative approaches due to the nature of research on this topic (i.e., the complex nature of remanufacturability decision-making in the medical devices remanufacturing).

The mixing process varies across different mixed method research designs. In this thesis, the quantitative and qualitative studies are complementary and focus on achieving a complete or holistic understanding of the phenomenon. For example, the quantitative study provided an understanding of the nature of customer requirements in remanufacturability for medical devices industry from the viewpoint of the customers while the qualitative study aimed at understanding remanufacturability decision-making, the nature of the decision process and the key factors from the viewpoint of the decision makers in remanufacturing organisations. The findings presented in this thesis present a complete view of customer-focused remanufacturability decision-making in the medical devices sector which is the central theme of this PhD research. This relation is shown in figure 6-1.

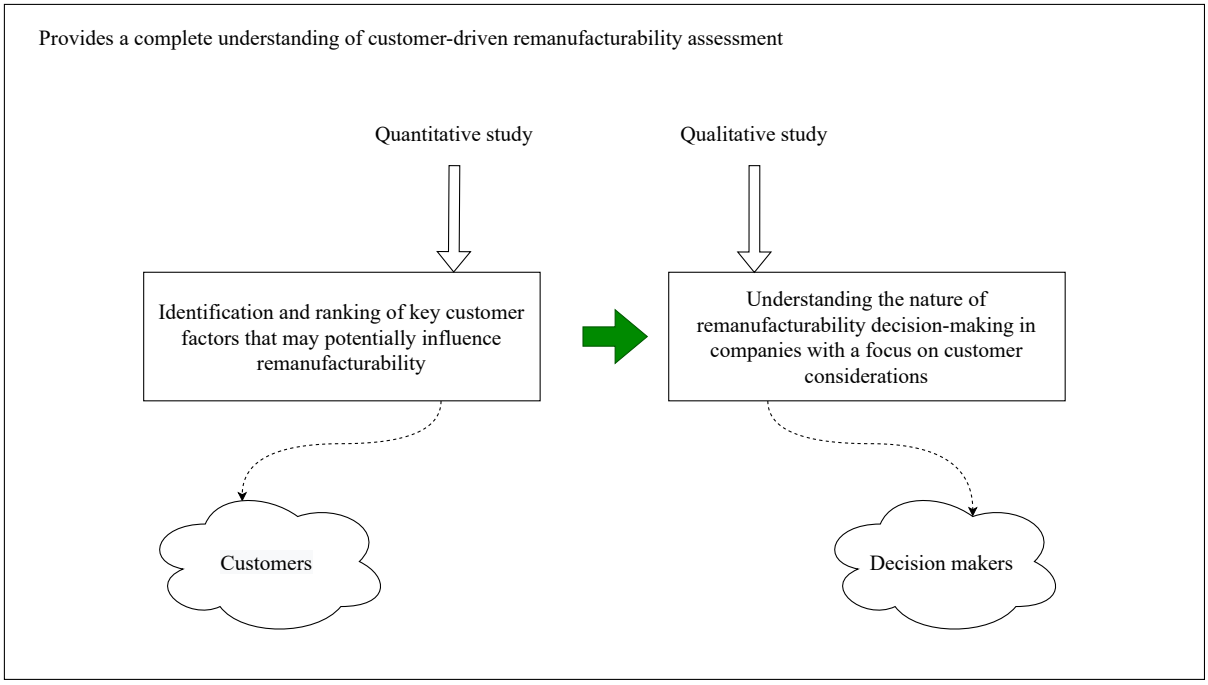

Figure 6-1: Combining quantitative and qualitative findings

This rest of this chapter is structured as follows. The results mixing approach is described in section 6.2. Section 6.3. describes the combined findings from the quantitative and qualitative studies and the conclusion of this chapter is presented in section 6.4.

6.2.Results mixing approach

The mixing process in this thesis is performed at the interpretation level, after the results from the individual studies have been assessed and analysed. The purpose of this is to ensure that the mixing is performed at a high level rather than at the data level when the raw data might not be well understood. Also, this approach is preferred in sequential designs when both quantitative and qualitative are performed across different timelines. In this sense, findings from the first study (a quantitative research) were used to develop a qualitative data collection approach for the second study (a case study research). This approach signifies the relative importance of the qualitative phase in line with (Schoonenboom and Johnson, 2017). Overall, the findings from both studies are cross-examined and interpreted to identify key factors that are critical to improve the effectiveness of remanufacturability decision-making in the medical devices sector.

The mixing process is achieved by analysing the data from each individual study separately and then bringing the findings side by side. Findings from the quantitative and qualitative studies were compared by seeking similarities and differences, and then offering

clarifications and explanations for the findings. The seven customer factors evaluated in the quantitative study (product quality, pricing, warranty, branding, available information, added value services and environmental friendliness) were compared with the remanufacturability decision factors identified from the case study research.

Specifically, the mixed findings highlight the similarities of the criticality of decision factors considered by both the customers and the remanufacturers. It describes the peculiar nature of remanufacturability decision-making in the medical devices remanufacturing sector, and it explores the inadequacies and limitations of the current approach. The key points for improving remanufacturability decision-making to focus on the requirements of the customers are identified. The diagram shown in figure 6-2 shows the node-based representation of the mixed findings which are discussed in the next sections.

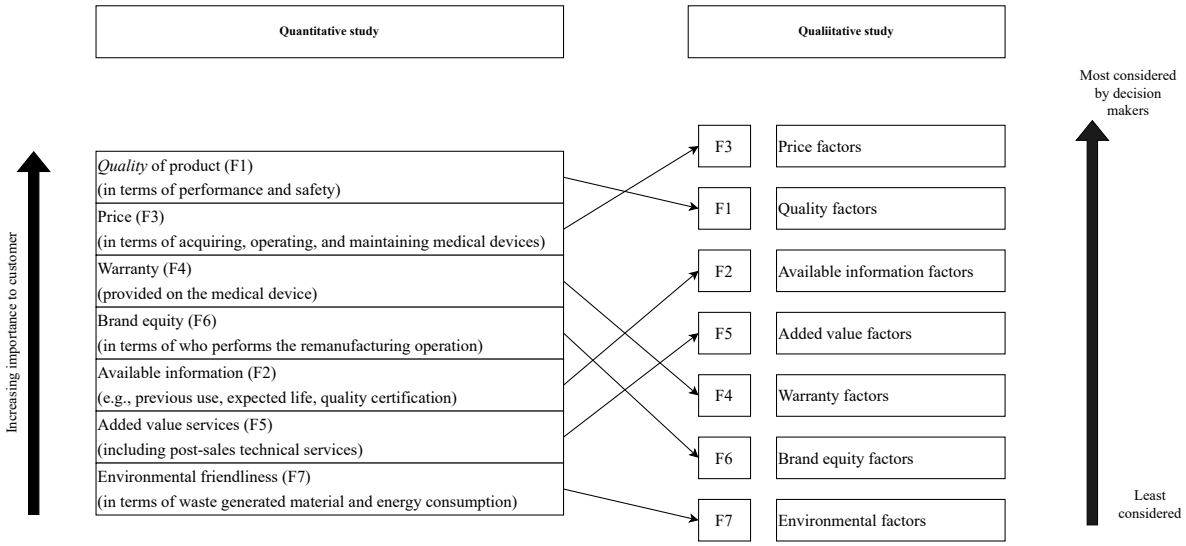

Figure 6-2: Node-based diagram of the mixed or combined findings

6.3.Customer factors in remanufacturability decision processes

Findings from this research highlights how practitioners in the medical devices remanufacturing sector already include key customer considerations in their decision process. The increasing adoption of this approach can be correlated with the rapidly growing market for remanufactured medical devices globally and the high level of regulatory requirements.

The peculiarity of this industry (in terms of the customers' safety, quality, and price requirements) makes customer considerations important in the remanufacturability decision-making process. In the next section, the mixed findings are presented with discussions on the seven key customers identified in literature, quantitatively assessed in the

AHP study, and qualitatively evaluated in the case study research. The overall aim of this chapter is to present discussions on the mixed findings and highlight their significance.

In the following seven sub-sections, each for the seven factors (F1 to F7), the mixed findings are presented. The discussions are linked to the node diagram shown in figure 6-2 and are based on factors assessed in the separate studies.

6.3.1. The criticality of pricing factors (F3)

The criticality of pricing factors in remanufacturability decision-making from the two studies were combined by comparing the quantitative and qualitative findings. The first view of the analysis revealed the high criticality of pricing factors from the perspectives of both the customers and remanufacturers. What stands out is the general agreement on what the pricing for remanufactured medical devices should be. All four companies assessed in the qualitative study evaluated pricing factors using the *"price at which product is offered to the customers"*. Although price is dependent on the cost of procuring used medical devices and the remanufacturing costs, there are several other cost considerations which were identified across the two studies. These considerations include the running costs of the remanufactured medical device, repair or maintenance costs and the disposal costs of the device at the end of its second use phase. Closer inspection of the findings reveals a greater significance of pricing factors in decision-making in remanufacturing, especially from the viewpoint of the customers who ranked price as the second (2^{nd}) most critical factor with a weight of 0.19 in the quantitative study.

From the mixed findings, it can be seen that the greatest consideration is on the pricing requirements in remanufacturing. Above any other considerations, pricing plays a major role in establishing a business case for remanufacturing, and also in terms of establishing the supply of cores and the potential demand for a remanufactured device. A similar finding was reported in (Abbey et al., 2015) and the importance of pricing as it relates to acceptance of remanufactured products has also been discussed by (Gaur et al., 2015; Phantratanamongkol et al., 2018; Vafadarnikjoo et al., 2018). Critical pricing consideration is not just the cost of procuring a used devices but the actual cost a customer would have to pay for a remanufactured device. A representative from one of the case study companies described how, for example, an MRI system originally manufactured five years ago costs £1,000,000. Over five years, the value of the product reduces and using the units of production method for calculating depreciation, the current value of the same new device is,

let's say, £650,000. When that device is remanufactured, the remanufactured product price competes against the £650,000 value and not the original selling point of £1,000,000. Therefore, the decision makers assess the possibility of remanufacturing the device and offering it to customers at 20-60% less than the current price of new (£650,000). Other participants in the qualitative study highlighted how they would break down the prices and estimate the possible selling point for a remanufactured medical device. This highlights the criticality of pricing factors in remanufacturability decision-making.

The importance of this factor may explain the relatively good correlation between remanufacturing and cost savings both to the customer and the business. This point has been discussed extensively in literature and (Anthony & Cheung, 2017; Goodall et al., 2015; Gutowski et al., 2011; Sutherland et al., 2010), 2011; Sutherland et al., 2010). Another possible explanation is that while customers and businesses may have a leeway with other remanufacturability considerations, they are very unlikely to have any such freedom with pricing considerations. These findings cannot be extrapolated to other industries or product categories.

It is important to bear in mind the potential bias in customers' responses in the quantitative study. Customers (hospitals, clinicians, and decision makers) are seeking cost-effective solutions to deliver high quality state-of-the-art medical systems for use within their facilities. In the U.S., the use of remanufactured medical devices is already commonly accepted, whereas in regions like the EU and the U.K., the acceptance of remanufactured devices in the health and social care setting is currently low, which is influenced by the perceived quality or performance risks. This explains why pricing was ranked second in the quantitative study. This study also supports evidence from (Callea et al., 2017) which highlights the importance of pricing on the procurement and selection of medical devices. As remanufacturing businesses expand to regions with low acceptance of remanufactured medical devices, they would need to prove the cost-effectiveness of remanufactured medical devices in terms of price of the device, running cost, service or maintenance costs, disposal costs compared to equivalent new devices. This combination of results provides some support for the conceptual premise that pricing factors should be elaborated upon and comprehensively included in remanufacturability decision-making. Further studies, which take these variables into account, will need to be undertaken.

6.3.2. A variety of quality considerations (F1)

Although the significance of quality factors was established across both studies, there were more similarities between the six (6) participants in the quantitative study and the four (4) participating companies in the qualitative study. Participants in the AHP study mostly ranked quality factors as the most critical consideration with weights of 0.30, 0.38, 0.22, 0.31, 0.33 and 0.27. In the aggregated quantitative results, product quality was ranked as the most critical factor with an overall weight of 0.32 – a third of total factor weights. This result may be explained by the fact that customers on the receiving end, especially in the medical devices industry, are poised to assume a lower quality for pre-owned or used devices irrespective of the recovery strategy. The particular concern about product quality may translate to a poor-quality perception of remanufactured medical devices among majority of the participants, even though there are no published records of quality concerns of remanufactured medical devices (Leung et al., 2018).

From the perspectives of the remanufacturers in the qualitative study, quality considerations are very critical to remanufacturability. At company A, considerations such as the existing customer complaints, open service requests, recorded failure rate, parts replaced during its previous use phase and the technological upgrade that can be performed assists the remanufacturer to understand specific quality or performance issues that have been associated with the device. With these, they can assess whether their ability to provide good quality remanufactured medical devices using specific cores. Company B focuses on the end of use quality and performance of the device. This is described by the company in terms of the results from the QA inspection of the device while at the customer site. Company C also assess notable component failures/replacements, expected quality at end of life and customer complaints during the previous use phase. Company D evaluates the durability of a product, recoverability of the materials and historical experiences of the device. All these considerations have focused on assessing the performance or expected performance of a medical device at its end of life, its physical appearance, safety, and technology of the device. This may account for the increasing considerations of the level of servicing or maintenance that a device received during its use as this is noted to impact the product remanufacturability.

The observed direction of quality considerations in remanufacturability decision-making and customer acceptance might be explained in terms of quality and performance requirements in this sector which is incomparable to other sectors such as automotive,

electrical and electronics etc. As such, all stakeholders are very cautious of quality factors and have adopted a variety of quality considerations for remanufacturability decision-making. The overall goal of the decision is to ensure that a used medical device can be remanufactured to a good performance and safety standard.

This result is likely influenced by the poor-quality perception of remanufactured devices in other sectors such as electronic devices and the automotive industry. This finding is backed by existing research (Van Weelden, Mugge and Bakker, 2016; Abbey et al., 2017; Hosseini-Motlagh, Nematollahi and Nouri, 2018; Vafadarnikjoo et al., 2018; Duan and Aloysius, 2019; Gan and Chen, 2019). The results obtained on quality considerations aim at building customer confidence and improving customer perception of remanufactured medical devices. Some other dimensions of quality factors which have come up during this research are the risks of infection, failure probabilities, use limitations and sterilisation or decontamination procedure. For all these considerations, a comparison would be made to what is obtainable from using new devices. This variety of quality remanufacturability considerations would justify current approaches and customers' expectations, even though a more comprehensive evaluation of quality factors would have potentially improved the overall outlook and acceptance of remanufactured medical devices. This finding has important implications for improving medical devices remanufacturing and for developing a robust decision-making tool that is driven by customer acceptance. This new approach would potentially increase customer perception and acceptance of remanufactured medical devices rather than relying solely on the quality conditions at the end of previous use.

6.3.3. The more information shared, the better (F2)

Unlike in the other sectors, there is a range of information available on used medical devices. Due to the nature of products in this sector, manufacturers and customers collect, analyse, and process several performance and maintenance data on the medical devices during use such as the use cycle, maintenance history, expected lifespan, current condition of the components and the risk level of the device. Although these details might influence remanufacturability decisions, the amount of information that can be shared with the customers after remanufacturing is a major concern for the remanufacturer. The possible interference of available information on remanufacturability and customer acceptance cannot be ruled out. Customers are likely to accept associated risks with remanufactured devices if comprehensive and accessible information is provided (Van Weelden, Mugge and Bakker, 2016). This information may include the product use history, rationale for

remanufacturing, percentage of remanufactured components, age in lifecycle, results of tests performed as part of the remanufacturing process and quality certification (Van Weelden, Mugge and Bakker, 2016; Vafadarnikjoo et al., 2018). However, the practicality of such approach in the medical devices remanufacturing sector is currently unknown.

From a customer perspective, available information factors have both positive and negative sides. On the positive side, customers are able to assess the conditions of the device at the end of its previous use phase and compare with the condition of the remanufactured device. They are also able to identify the lifespan and the number of cycles a device can be put through and its current stage in the lifecycle. This would enable the customers assess the level of recovery that has been performed on the device and to justify their investment in the remanufactured medical device. This is also good from a confidence-building standpoint, and it assists customers in comparing the quality of the remanufactured device with what is obtainable on new devices. On the negative side, the impact of information sharing on customer acceptance is largely unknown. One of the issues that emerge from these findings is how much information remanufacturers (especially third parties) have and can share with customers to maximise customers potentials. Some remanufacturers believe sharing specific information with customers may contribute to their negative perceptions. They expressed concerns about customers discriminating certain devices because of their previous use conditions or locations. They argued that by sharing certain information with customers, the focus is taken away from the remanufacturing process (or remanufactured product) and placed on the history of the device.

In the quantitative study, information provision was ranked relatively lower compared to other factors as the fifth (5^{th}) most critical factor with a weight of 0.11. However, individually, participants in the quantitative study ranked information provision differently with weights ranging between 0.038 and 0.20 – from 6^{th} to 2^{nd} most critical. This inconsistency may be due to the current approach taken by key players not to include some product details as part of marketing documents and the customers' ignorance of what information to expect on remanufactured products. Although difficult to explain, this result might be potentially related to other key factors such as branding, quality perception and pricing considerations.

The qualitative study probed a little further into the issues identified from the quantitative research and presented possible explanations for the rather contradictory stance on information provision as a critical consideration for remanufacturability. The current

approach to assessing remanufacturability in the medical devices sector, with respect to information provision, seems to edge on a competitive standpoint. That is, remanufacturers are conscious of the level of information that is available to customers from their competitors on remanufactured medical devices. The companies in the qualitative study focused on considerations such information about the age or stage in lifecycle, use history, test results and remanufacturable component lists. The age or stage in lifecycle considerations influences the remanufacturability of the medical device as it influences the technological level of the device, acceptability in the current market scenario and price of the device. For example, a medical device with a maximum lifespan of 12 years would very likely not be remanufactured after ten (10) years. The performance, technological and pricing changes that would have taken place in the market over the 10 years may outweigh the need to remanufacture from an economic and technological point of view. The information about the use history can be obtained by the remanufacturers – mostly the OEM/OER but not so much by the third-party organisations. These specific customer considerations can be described as having notable impact on remanufacturability.

Some other product information which are critical to remanufacturability decision-making are design information and information about the process to efficiently remanufacture certain products. While most OEMs/OERs can easily obtain product design and remanufacturing information, this may be difficult for the third-party remanufacturer. These details may influence the disassembly sequence, decontamination, or sterilisation procedure.

These findings raise intriguing questions regarding the nature and extent of information provision in the remanufacturing field. This supported by data published in existing literature on the importance of information sharing in remanufacturing, particularly between remanufacturer and customer (Huang & Wang, 2017; Nie et al., 2021; Pokharel & Liang, 2012). The results need to be interpreted with caution – that while information provision plays a vital part in remanufacturability, assessing the level of information that can be provided to customers should be given more considerations.

6.3.4. The warranty basis (F4)

The warranty requirements in the medical devices industry are seen as a basic offering. From a regulatory perspective, remanufactured medical devices are expected to be ‘warrantied’ by the remanufacturer. This warranty requirement may be explained by the nature of this sector where failure of a product or its components may be fatal – delaying patient care,

slowing down healthcare delivery and ultimately leading to patient death. Industry players also view warranty as a major risk-reducer, especially for remanufactured devices. A 'like-new' warranty may include scheduled preventive maintenance and repairs to improve product performance and prevent unexpected failure of components (De Santana et al., 2018). Warranties are provided for a fixed period and do not impose additional costs on the customer. However, extended product warranty is an approach currently gaining grounds in this sector where customers pay an extra cost for the servicing and repair of remanufactured devices beyond the initial warranty period.

From customers' point of view in the quantitative study, warranty provision was ranked as the third (3rd) most critical consideration. However, opinions of individual participants seem to differ as to the importance of warranty in their respective decisions. One participant ranked warranty as second (2nd) with a weight of 0.21, two participants ranked it as third (3rd) with weights 0.13 and 0.17, two participants also ranked it as fourth (4th) with weights 0.15 and 0.13 while the final participant ranked it as fifth (5th) with a weight of 0.12. A recurrent theme in the pairwise comparison was a sense amongst participants that warranties should normally be offered on medical devices and remanufacturers should provide warranties on their products. Provision of warranty may reduce customers' perceived risk associated with using remanufactured devices, especially in high-risk sectors such as the medical devices (Docters et al., 2010).

To most remanufacturers, the issue of warranty should not be debatable. What constitutes warranty and the length of such warranty may vary across companies, but the general understanding is that warranty provision is critical on remanufactured devices. As such, remanufacturers do not currently include any assessment of warranty in their remanufacturability decision-making. One concern expressed regarding warranty by third-party companies B and D was whether they company could match or better the OEMs' warranty as a competitive offering. However, for both companies A and C who are OEM/OER, issues related to warranty were not particularly prominent during their decision-making. Both companies offer a warranty similar to that of new – which is 1 year warranty. Company B on the other hand focuses on specific components and may offer similar warranties on specific products. Company D provides a legal backing for the failure rate of their remanufactured products. However, it is important to bear in mind the possible biases of the OEM/OER companies whose remanufacturing operation may be different from the

TPRs in terms of the percentage of components recovered, and accessibility to specific product information etc.

Warranty details the duties and responsibilities of the remanufacturer and the customer within a limited period. Warranty in the medical devices remanufacturing sector details specific components, failure types and customer support that are covered. However, the critical part of any warranty is in the case of device failure during the warranty period which may impact the hospitals healthcare delivery. The responsibility of the remanufacturer on supporting the customer during the device downtime (clinical downtime), the associated cost of the downtime, repairs, and the cost of repairs are all critical considerations while assessing the warranty factors. While this seems seamless from an OEM/OER perspective, the TPR would usually struggle with getting every component of the warranty covered. Some have argued that remanufacturers may gain more customer confidence by improving their guarantee rather than warranty offering.

These findings may help to further distinguish medical devices remanufacturing from other sectors. It also brings to attention the relatively low consideration given to warranty provision in remanufacturability decision-making, despite the criticality of the warranty offering. The nature of warranty in terms of the length, coverage and costs of warranty tends to improve the effectiveness of remanufacturability decision-making. The implications of warranty in remanufacturing decision-making have been discussed in (B. Liao, 2018; Tang et al., 2020; X. Zhu et al., 2018, 2019).

Warranty provisions should not be confused with product/service guarantees in medical devices industry. While warranty is a legal agreement between the seller and the customer, a guarantee is a promise on the value of the remanufactured device – an offering which may not be offered on new equivalents. Many times, guarantees on remanufactured devices have been confused with warranty which leads to ambiguity in what should be expected from the remanufacturer. Guarantee is treated as an added value service in this thesis and is discussed in the next section.

6.3.5. Differentiating added value services from warranty provision (F5)

Remanufacturing companies in the medical devices and healthcare sector may offer added value service guarantees such as service agreements, minimum spare parts supply, unlimited training, skills development, and end of use management of the device. These provisions have often been regarded as a form of warranty but differ in its purpose and the expectations

of customers. Added value service guarantees are offered to customers after product sale and are aimed at supporting the customer beyond the initial warranty period. Compared to other remanufacturing sectors, medical devices remanufacturing has very robust post-sales service offerings. This further underscores the distinctness of this remanufacturing sector.

The participants of the quantitative study ranked added value services as the 6th most critical with a weight of 0.067. Compared to other factors, added value services didn't seem to be very critical in customer decisions. However, majority of the participants seem to agree with the ambiguity that exists between added service guarantee and legal warranty agreement. This is reflected in the pairwise comparisons of warranty against added services guarantee where most participants ranked them as having equal importance.

On the other hand, remanufacturers actively evaluate the nature of added value services that can be offered to customers on remanufactured medical devices. For example, a participant at a case study companies described how they now include a spare tube and bracket on its remanufactured CT devices. Another company guarantees spare part supply for five years. Further, company A assesses the amount of support that is obtainable by customers and specific spare parts that can be provided. A representative of company B described their assessment of specific customer demands for added value service, which influences the nature of recovery work done and the cost of the device. This is because most of their customers are hospitals with biomedical engineering departments that oversee the maintenance and repair of their devices. Therefore, it is important for this company to understand the kind of services that the customer actually require. Company C assesses the current state of parts of the device and ensures it can provide 5 years supply guarantee to its customers. Company D offers more guarantees on the performance of their products than is obtainable on new devices. Despite these interesting results, added value service factors are not seen as critical consideration in the remanufacturability decision-making. A possible explanation for the relatively good correlation between customers' considerations and the remanufacturers' decisions is that the ambiguity between service guarantees and legal warranties affect both the remanufacturer and the customers alike.

Despite the existing low level of importance in remanufacturability decision-making being given to service guarantees, results in this research identify the need to further distinguish warranty from guaranteed provisions. This has been discussed in existing literature (Hong et al., 2020; Vafadarnikjoo et al., 2018). Guaranteed offerings on remanufactured medical devices have the tendency to improve customer acceptance and thus should be

systematically assessed in remanufacturability decision-making processes. Further, remanufacturers should consider added-value service guarantee considerations such as spare part supply, remote customer support, logistics or tracking support, employee training, upgrades, clinical decision support, patient risk stratification, and analysis of clinical operations.

6.3.6. The issue of branding in medical devices sector (F6)

Branding factors in remanufacturability decision-making focus on the market, competition and how competitive offerings may impact a company's decision to remanufacture medical devices. A desire of customers is the need to have alternatives so that decisions can be based on the trade-off between several factors and considerations. Some dimensions of branding issues which are identified in this research include brand awareness, brand trust, brand association and brand loyalty. Awareness of the quality level of products and services offered by specific brands lead to some level of trust or belief whereas consistent trust in a brand builds association which consequently develops into brand loyalty. Brand loyalty is not a key factor in remanufacturing decisions but brand equity, which is the extra (usually positive) value that a remanufactured product attracts based on who performs the remanufacturing. In this sector, OEM/OER have higher equity and customers are usually more inclined towards medical devices remanufactured by them.

Overall, the participants of the quantitative study ranked brand equity as the 4th most critical factor with a weight of 0.12 in their decision process. The individual ranking of each participant also signifies the relative importance given to the specific brands or companies marketing the remanufactured devices. However, a key theme in the pairwise comparisons is that brand equity is ranked lower than price and product quality by all participants.

When assessing remanufacturability, remanufacturers mostly focus on internal branding factors and less on competitive forces in the market. Both OEM/OER companies A and C assess the level of recovery operation that can be performed on medical devices and the existing competitive offerings in the market. There is a constant look at the market situation because both companies A and C position their remanufactured medical devices as competitive alternatives to their customers who require a low-cost solution. A typical brand equity consideration for the companies in the qualitative study is if customers are willing to purchase a remanufactured device because the remanufacturing was performed by them.

However, remanufacturers always seem to consider good pricing solutions to match existing market competitions.

This finding raises intriguing questions regarding the nature and extent of brand influence on decision-making in the medical devices remanufacturing sector. This, and similar issues, have been discussed in existing literature (Choi, 2017; Z. Wang et al., 2020). From a customer standpoint, the possession of medical devices from a specific brand may motivate their decisions to purchase remanufactured medical devices from the same brand for systems compatibility. From a remanufacturer's perspective, branding is essential for their remanufactured offerings to beat off competitions from new and remanufactured equivalents.

6.3.7. Are environmental factors really important? (F7)

It has been argued that customers' perception of the quality of remanufactured devices is entirely dependent on the customer's environmental involvement or green consciousness (Duan and Aloysius, 2019) and consumers' previous experiences (Mashhadi, Esmaeilian and Behdad, 2016). Prior to this research, environmental considerations have been described as a major factor considered in remanufacturing decisions – both from the customers' and the remanufacturers' point of view. However, this study has been unable to demonstrate that environmental factors play any major part in remanufacturability decisions.

Despite growing awareness of sustainability in healthcare settings, customers (i.e., hospitals) may be inclined towards remanufactured devices not because of the environmental friendliness but mostly because of the six (6) other factors discussed earlier. The aggregated pairwise comparisons of the participants ranked environmental considerations as the least (7^{th}) critical with a factor weight of 0.04. Individual pairwise comparisons support this evidence with five out of six participants ranking environmental factors as 7^{th} with weights less than 0.04. The overall level of importance of environmental considerations among customers in this industry differ significantly from other remanufacturing sectors.

The remanufacturers assessed in the qualitative study do not currently consider environmental factors in their remanufacturability decisions. When asked about their motivations for getting into the remanufacturing business, a representative from company A described their entry into the sector mostly based on a business opportunity and not from an environmental standpoint. Company C described their intentions to provide more support

for their customers while company B also described how market factors impact their decisions and not environmental factors. Company D described how the potential volume of used devices and the growing demand for remanufactured low-cost devices have mostly influenced their decisions. From these findings, it is clear that environmental considerations do not play a major role in the remanufacturability decision-making for medical devices.

This finding is contrary to previous studies which have suggested that environmental considerations are critical factors in reman (X. Gao, 2019; Jayakrishna & Vinodh, 2017; Subramanian et al., 2010) 2017; Subramanian et al., 2010). Although exclusion of environmental consideration in remanufacturability decision-making in the medical devices sector has been highlighted, it is important to note that this result may be peculiar to the medical devices remanufacturing sector.

6.4.Conclusion of chapter 6

This chapter puts together the findings across multiple perspectives of the customers and the remanufacturers as it relates to two key issues – remanufacturability decision-making and customer acceptance. The quantitative findings in the AHP study (chapter 6) were contextualised and explained using the qualitative results discussed in the case study (chapter 7). It is the result from this mixing process that underscore how important customer factors have not been adequately factored in existing remanufacturability decision-making models. This has also prompted a call for an effective decision management system where customer considerations are adequately incorporated in remanufacturability models. Comparisons were made between individual participants in the quantitative study and companies assessed in the case study research. The representations of key customer factors in existing models and their shortcomings have been presented in table 6-1. Based on the findings, a first draft of the remanufacturability framework is presented in figure 6-3.

This chapter has explored further into the nature of factors that affect remanufacturability beyond what currently exists in literature. It has also highlighted the gap existing between the remanufacturers and the customers in terms of what is expected from remanufactured products. This chapter shows the way forward to ensure the long-term success of remanufacturing in driving a circular economy in the medical devices sector. Building on the findings of this chapter, the next chapter will attempt to model the seven decision factors into a theoretical framework for remanufacturability decision-making for medical devices.

Table 6-1: Summary of mixed findings

Factors	Quantitative weight	Qualitative considerations				Mixed findings	Representation in existing models	Shortcomings
		A	B	C	D			
Product quality factors	**0.32**	Previous customer complaints	Product performance at the end of previous use phase	Number of customer complaints during the previous use phase	Product durability	Several remanufacturability factors are required to adequately assess product quality to improve customers' acceptance. This is in the top 2 factors considered by remanufacturers and that influence customer decisions.	1. Product models: a. product design factors b. returned product factors	Despite the significance of the findings, existing considerations do not include critical factors such as the risk of infection, failure probability considerations such as risk of infection, failure probability, limitations on use, and decontamination procedure
		Open service request	Results from quality testing of the product	Notable component failures/replacements	Expected quality level or performance of the device			
		Failure rate within the first 90 days		Product quality at the end of previous use phase				
		Number of parts replaced during service						
		Highest quality or performance level the used product can upgraded to						

Pricing factors	**0.19**	Price at which recovered product is offered to customer	Price at which recovered product is offered to customer	Selling price of recovered product	Price of the recovered device	Severe cost-consciousness is found in this remanufacturing sector. Remanufacturability decisions are mostly based on pricing and economic factors. This is the other of the top 2 factors considered during remanufacturability decision-making.	1. Sustainability models a. economic factors	As a core requirement, this consideration lack an assessment of remanufacturing a medical device on the day-to-day operating cost, maintenance and repair costs, and disposal costs
Warranty factors	**0.15**	N/A	Length of warranty What is covered in the warranty?	N/A	Failure rate on remanufactured device.	This consideration has been established as a basic offering in medical devices remanufacturing sector. As such it is not considered a very critical consideration during remanufacturability. However, before remanufacturing a product, remanufacturers must be able to assure prospective customers that warranty provided will be as good as new.	None	This consideration doesn't currently exist in remanufacturability models. Warranty considerations should be included in remanufacturability decision-making as a basic offering.

Branding factors	**0.12**	Level of recovery operation that can be performed compared to third parties	Competitive offerings currently available in the market	Level of competition in the market	Available markets	This consideration is mildly considered. However, it is significantly impacted by available competition in the market and its importance can be ignored when a high quality remanufactured medical device is provided at a great price.	None	This factor currently lacks visibility in existing models. The level of competition on specific products must be assessed and the unique offering of remanufacturing a medical device must be evaluated during remanufacturability decision-making.
Available information factors	**0.11**	Information available to customer about low-cost alternative to specific product modalities	Other alternatives available to customers	Customer's awareness of low-cost offerings by competitors	Clinical acceptance Historical experiences	This consideration seems to play an important role in remanufacturability decision-making. Remanufacturers tend to assess the amount of information that is available to them and their customers. Information about specific product design information and characteristics of returned products are assessed.	1. Product models: a. product design factors b. returned product factors	Existing considerations do not currently assess the level of information that can be shared with customers. This may potentially play a vital role in the decision process and in customer decisions.

Added value service factors	**0.067**	Customer support available after product recovery Spare parts that can be provided	Customer demand for value added services	Part supply guarantee for five years	N/A	Added value services or guarantees are a critical consideration and have been assessed based on the amount of technical support or guarantees that can be given to customers on remanufactured medical devices.	None	This consideration is currently not included in remanufacturability models but have notable impact on both remanufacturability and customer acceptance
Environmental factors	**0.04**	N/A	N/A	N/A	N/A	This consideration does not play a major role in the remanufacturability decision-making for medical devices.	1. Sustainability factors a. Environmental factors	In future research, the lack of environmental consideration in remanufacturability decisions for medical devices should be studied. However, it is impossible to take away the background importance of environmental impact assessment in remanufacturability decisions.

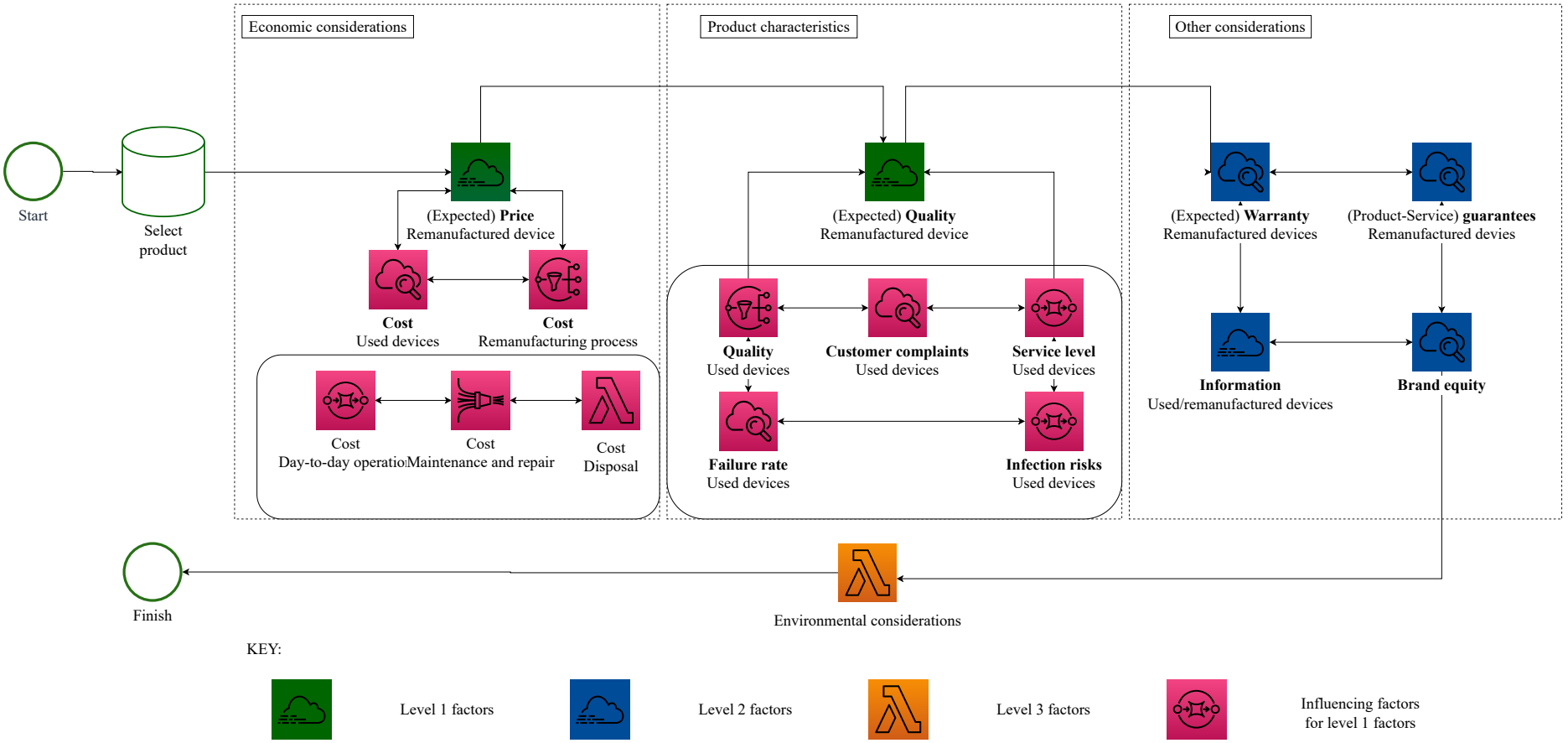

Figure 6-3: Remanufacturability Decision framework based on customer factors

Chapter Seven: Customer-Driven Remanufacturability Decision Framework

7. Chapter Seven: Customer-Driven Remanufacturability Decision Framework

7.1.Introduction

The previous chapter presented the mixed findings from this research. The discussion focused on the seven factors that are critical to customer acceptance of remanufactured medical devices and are influential in remanufacturability decision-making. In this chapter, the previous findings are incorporated into a multi-factor customer-driven framework of remanufacturability decision factors. This framework is developed to answer the research question of this PhD thesis and to present a clear and comprehensive visual representation of the findings from this research. Further, it presents a complete view of remanufacturability decision-making in the medical devices remanufacturing sector which forms a basis for future work in this sector.

The customer-driven remanufacturability decision framework involves the original manufacturer, the customer, and the remanufacturer of the medical devices, as shown in figure 7-1. The framework is modelled as a multi-factor decision system consisting of different levels of factors ranging from the four core factor categories (shown in figure 7-2) to other remanufacturability assessments factors already described in chapter 2. The aim of the framework is to present a set of requirements for remanufacturability decision with a focus on the customers in this sector. The framework is intended to be used as a foundation for expanding knowledge in the medical devices remanufacturing sector. By itself, the framework is not sufficient to evaluate product remanufacturability. However, it can assist decision makers in breaking down the complexity of customer acceptance during remanufacturability assessment.

7.2.Framework building techniques for decision problems

Building a framework from research findings is a systematic task which is substantively dependent on the research topic (Miles and Huberman, 1994). The planning, designing, and implementation of frameworks from research results is critical to theory building, information sharing, knowledge dissemination and monitoring. Also, it is important that a framework is intelligible, uncomplicated, and user-friendly (Hatcher, 2011; Ijomah, 2002; Priyono, 2015; Stewart, 2017). However, choosing appropriate framework building technique is very important.

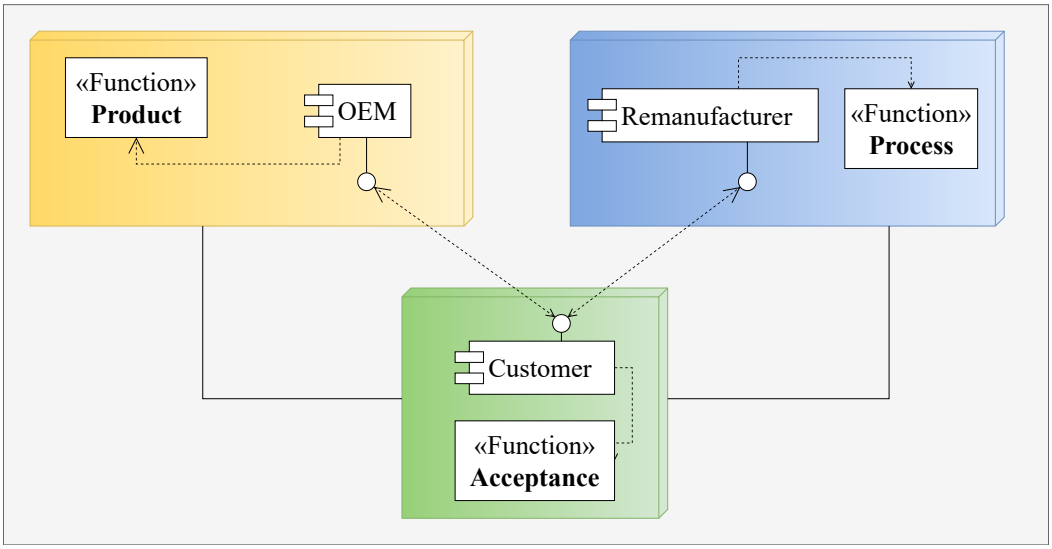

Figure 7-1: Remanufacturability Decision for Medical Devices Remanufacturing

Pettigrew et al., discussed three categories of framework building approaches – cognitive approaches, social approaches, and multi-faceted approaches. They described how cognitive approaches focus on the personnel as the key driver of the represented information, whereas social approaches focus on the meaning and values of the framework in a social context and multi-faceted approaches adopt a pragmatist development process based on multiple viewpoints. Given that this PhD research already adopts a pragmatic philosophical paradigm, a multi-faceted approach is adopted for building the framework and it examines the following key points as described by (Pettigrew, Fidel and Bruce, 2000):

- The operational context of the research findings
- The research domain and existing knowledge in the area
- Organisations and personnel that contributed to the findings upon which the framework is built
- The intended purpose of the framework
- The key factors or considerations that are used in the development process.

Several discussions have been presented in literature on the multi-faceted or multi-factor or multi-criteria frameworks for remanufacturing decision problems. Subramoniam et al., (2013) developed a multi-criterion remanufacturing decision-making framework (RDMF) using strategic factors in the automotive industry. Alghamdi et al., (2017) developed a decision framework for remanufacturing processes which was supported by quality function deployment (QFD). Zhou et al., (2013) developed a conceptual framework of decentralisation in manufacturing-remanufacturing decisions. Barker and Zabinsky (2008)

proposed a conceptual framework to evaluate trade-offs in reverse logistics decisions based on findings from a multiple case study research.

Development of frameworks in PhD thesis is not uncommon in the remanufacturing domain. Ijomah (2002) developed a generic model of remanufacturing using findings from a multiple case study research. Hatcher (2011) developed a network model of relationships between operational remanufacturing factors. Stewart (2017) developed a conceptual framework of reverse logistics from findings of a multiple case study of automotive remanufacturers. Priyono (2015) developed a framework of disassembly approaches in remanufacturing based on a multiple case study research.

The important criteria which form the guiding principles for developing the customer-driven remanufacturability decision framework presented in this chapter are shown in the table 7-1. Tigelaar et al., (2004) asserted that frameworks require appropriateness or validity of its content, information, organisation, and science. He et al., (2011) discussed key criteria of content, construct, and convergent validity. Holweg and van Donk (2009) identified six criteria for a framework which are selectivity, specificity, comprehensiveness, novelty, meaning and use of variables (Holweg and van Donk, 2009).

Table 7-1: Criteria for building frameworks for decision problem

Criteria	Description
Variables used	Few variables are used, focusing on the very important factors in the decision process.
Meaningful content	The content of the framework is useful and meaningful to the specific research domain and remanufacturing sector under study.
Completeness	The framework presents a complete understanding of the phenomenon under study. It takes into consideration all the elements that are critical to the purpose of the framework
Originality	The framework is original and presents new insights. It provides significant improvement on what is currently available in existing literature.
Simple and concise	The framework is simple and can be easily understood and used by relevant practitioners. It can be easily modified and improved upon in future research.

7.3.Customer-driven remanufacturability decision framework

It has been established in the previous chapter that a customer-driven remanufacturability decision should cover customer factors that influence product remanufacturability. These important considerations are connected to existing remanufacturability considerations. Based on the results obtained in the mixing phase, a further analysis of the seven customer factors showed that they can be put into four core categories: product, sustainability,

support, and other customer considerations. These four categories form the major components upon which this framework is built and are shown in figure 7-2. Further, within each category, the different factors could be described as the main elements or sub-elements. For example, the quality of remanufactured device would be the main element in the product considerations while the quality of used devices, existing customer complaints, service level, infection risks and failure rate would be the sub-elements.

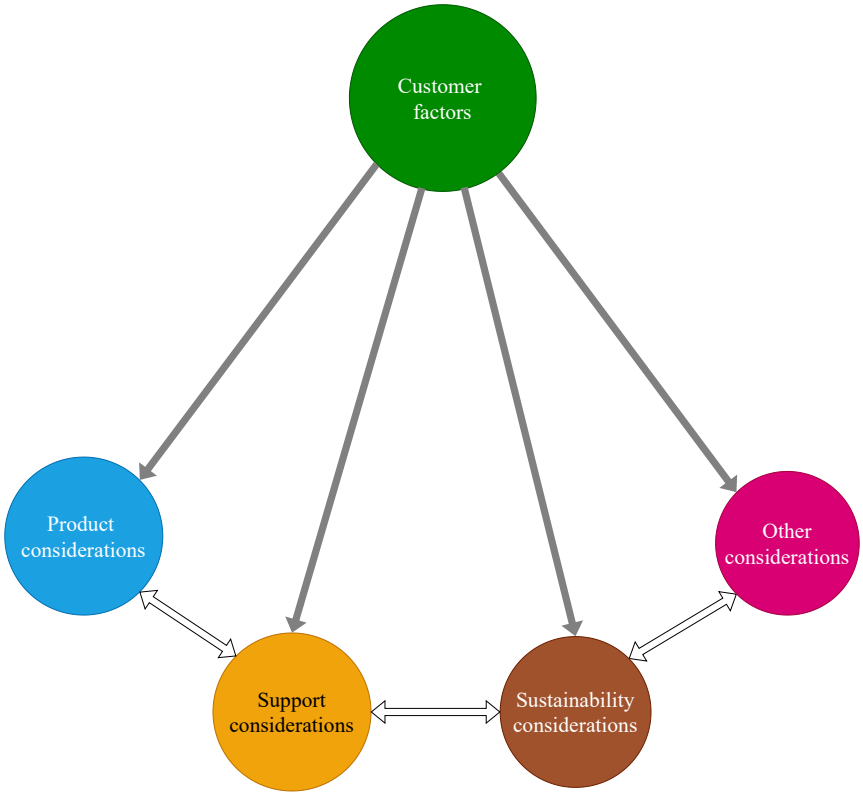

Figure 7-2: Factor clusters in the customer-driven remanufacturability framework

To develop the customer-driven framework around these four constructs while appropriately highlighting the core considerations, main elements and sub-elements, and the inter-relationships, the first draft of the framework presented in chapter 6 (figure 6-3) was adjudged as insufficient. An updated version of the framework is thus presented in this chapter and is shown in figure 7-3. This version has been modelled to optimise remanufacturability decision-making in the medical devices sector. This framework has been aligned with the categorisation of decision factors both at the primary and secondary levels. The contents of the customer-driven remanufacturability framework are described in the next section.

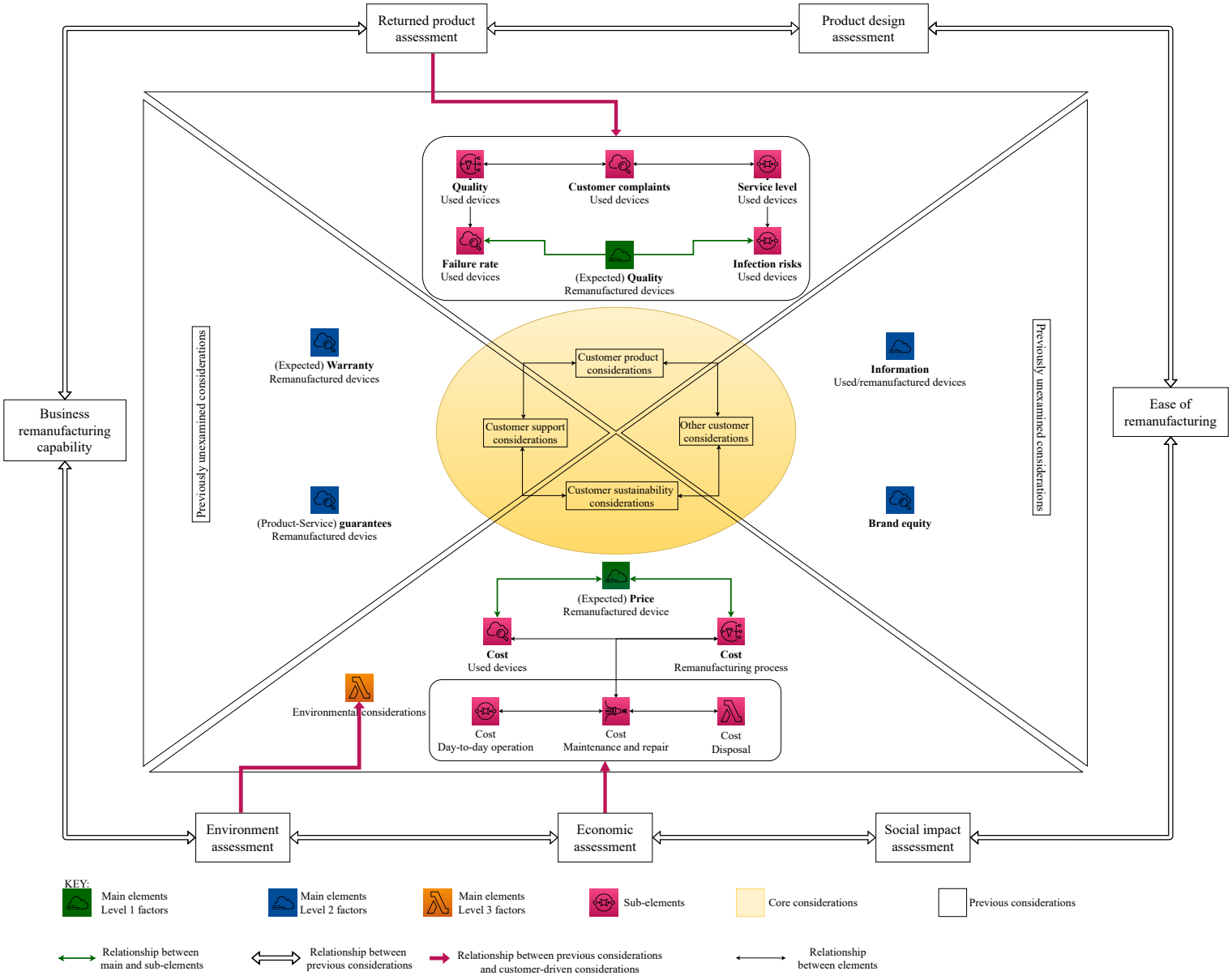

Figure 7-3: The customer-driven remanufacturability decision framework

7.4.Description of the customer-driven remanufacturability framework

In the framework, the green, blue, and yellow boxes indicate the main elements across different hierarchy of importance obtained from this PhD research. The green boxes represent the highly critical considerations, whereas the blue boxes represent considerations with medium criticality and the yellow box represents the low-criticality consideration. The red boxes indicate the sub-elements of the framework and represent the considerations that expand on the main elements within the core considerations. The four core considerations of the framework are highlighted in figure 7-4. These core factors are linked to the 7 critical customer remanufacturability factors assessed in this research and to other factors which are not established to be customer-driven. Different types of arrows are used to describe different levels of relationship between the elements of the framework. For example, the green arrows describe the sort of relationship between the main (level 1) elements and their sub-elements in an attempt to describe the flow from the main element to the sub-elements. While the red arrows indicate a flow from previous remanufacturability factors to the customer-driven considerations, the white arrows indicate the interaction between existing remanufacturability considerations. The other arrow indicates the relationship between the elements in the framework.

The discussions presented in the following sub-sections describe the framework and are based on the four core considerations of product, sustainability, support and other remanufacturability considerations. Each sub-section describes the core considerations, highlights the main and sub-element for each core consideration and describe how each element function within the framework. A combination of web-based mind mapping and object-oriented Unified Modelling Language (UML) tools were used in building the framework. However, the focus of these discussions is on the application of the framework rather than the tools that were used in the development process.

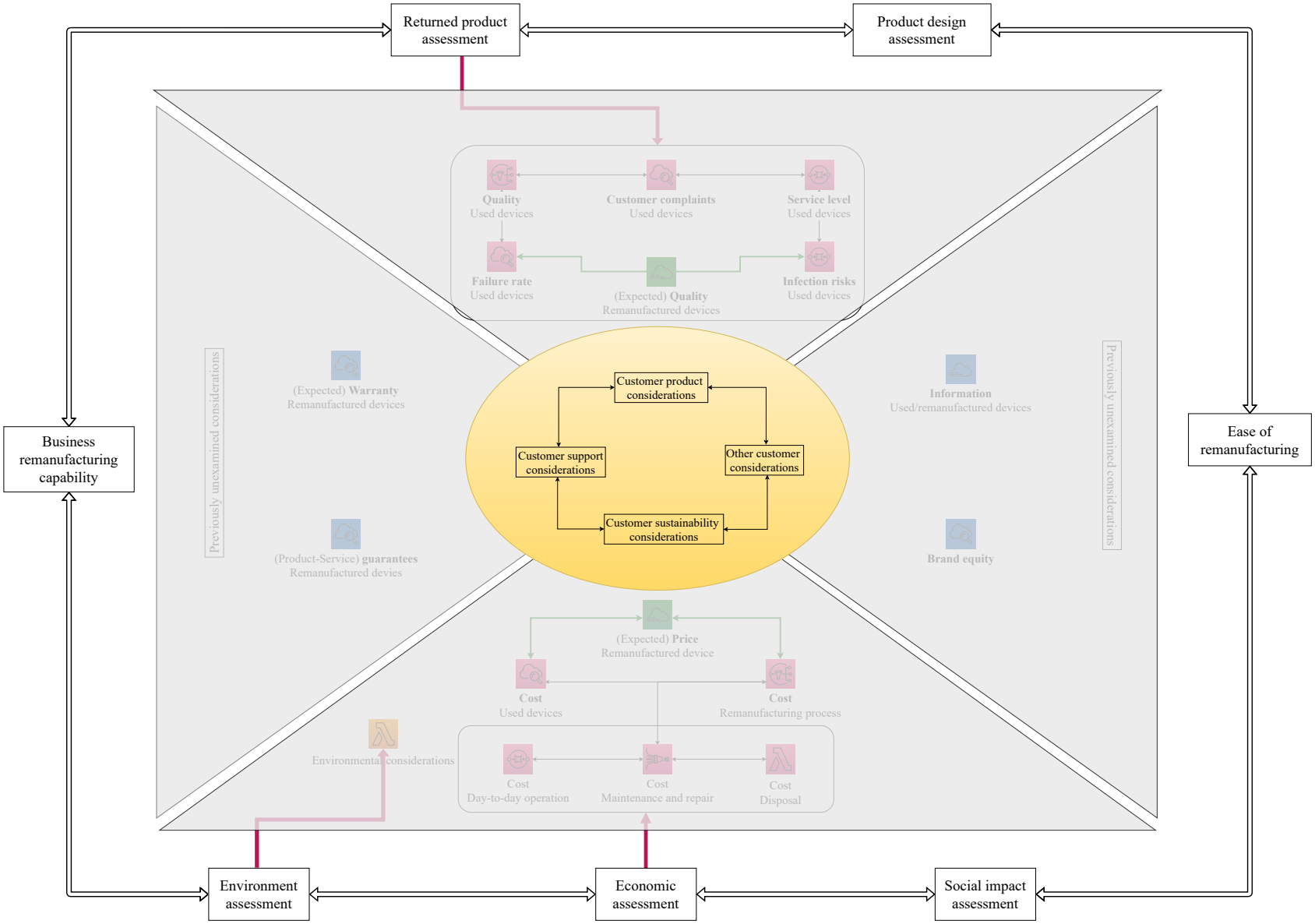

Figure 7-4: Core considerations in the customer driven framework

7.4.1. Customer product considerations

Product characteristics, as a prevalent term in remanufacturability decision-making, has been described in existing literature as a very critical consideration. The findings from this research corroborate this position of criticality for product considerations. However, the inclusion of the customers' standpoint in product evaluation makes a significant improvement to remanufacturability decision-making. To describe the core product consideration, the expected quality of remanufactured devices is used as the main element.

Using this factor, remanufacturability decision makers, which may include the product managers, sourcing managers, remanufacturing facility manager and the engineering or production personnel, assess what the expected quality of the used device would be after remanufacturing. The decision maker decides whether the device is returned to its performance or quality "*as at when new*" or "*as the latest equivalent*", if possible. This impacts the need to obtain a new registration document, as described in chapter 7. Also, the decision makers are able to refer to the design of such device in order to assess what the performance would look like (figure 7-5).

To comprehensively address customers' concerns about the expected quality of the remanufactured products, the decision makers would assess five sub-elements which include: the *failure rate* of the device during its previous use phase, *quality or performance* at the end of the previous use phase, the number and types of *complaints* raised by customers during its previous use, the level of *service* or maintenance the device has received and the *risk of infections* that can be associated with using the device after remanufacturing. The failure rate of the device is obtained in the device log and can be assessed through the customers' service, maintenance, or repair requests. Also, a history of minor (non-severe) component failures and the service or maintenance records can be obtained from the customers through the personnel in charge of operating or maintaining the device. Most organisations perform end-of-use/end-of-life testing or inspection of the used device to ascertain the quality of the device before the decision to remanufacture. The test results establish the performance or quality of the used device. Decision makers also give more attention to complaints received during the use of the device. When customers make repeated complaints on a device, it could be an indication of a broader issue or a highlight some performance-related problems. Thus, the nature of the complaint needs to be carefully examined to ensure that the device, when remanufactured, does not pose similar issues to the customer.

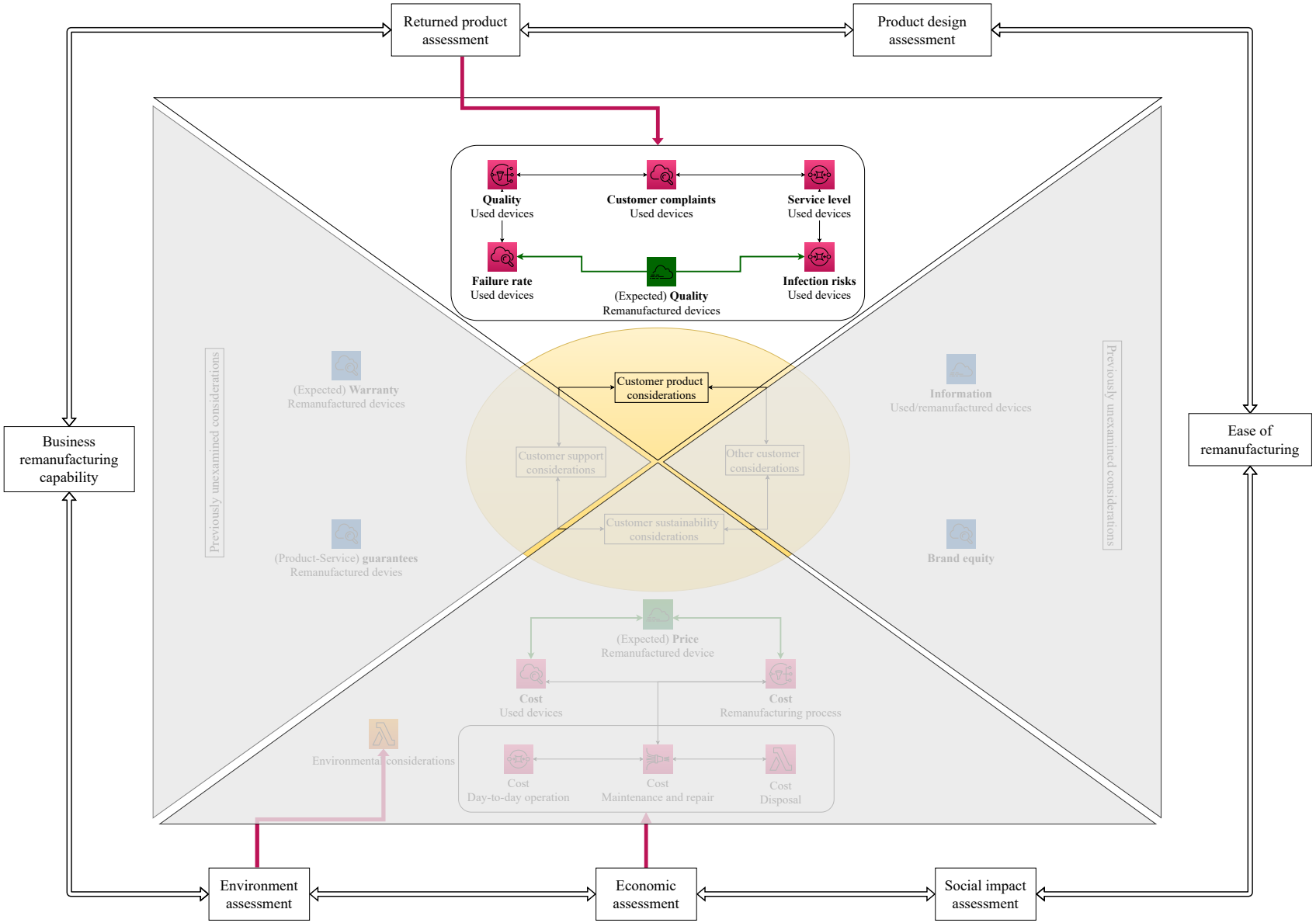

Figure 7-5: Customer product considerations

With the knowledge created in this PhD research and highlighted in the framework, decision makers can focus on the impact on customers when assessing remanufacturability. The decision makers assess if, given the existing information about the sub-elements, the device can be successfully remanufactured to a quality or performance standard (main element) acceptable to customers. Further, the factors in this core product considerations can be directly aligned with returned product assessment in existing remanufacturability models.

7.4.2. Customer sustainability considerations

Although, sustainability considerations in existing remanufacturability models have been separated into environmental, economic, and social considerations, the findings from this PhD research have given prominence to economic considerations as the most critical of the sustainability factors. As such, the sustainability component of this framework is dominated by economic (or pricing) considerations with little or no discussions about environmental and social considerations when assessing remanufacturability. The main element in this core sustainability consideration is the (expected) price of the remanufactured device as in figure 7-6.

The price of the remanufactured device can be influenced by a number of cost factors, some of which relate directly to the remanufacturer while the others relate to the customers. In this framework, decision makers assess the cost of used devices and the cost of remanufacturing while also bringing to the foreground the cost implications of the remanufactured device on the customer. For example, factors such as the running, maintenance, and disposal costs of the remanufactured devices are critical considerations to the customers which may influence remanufacturability. Other considerations are the energy efficiency of remanufactured devices, the ease of performing maintenance activities and the ultimate disposal costs when it reaches its end of use. These key customer considerations can be assessed during remanufacturability to influence the overall price at which the remanufactured device is offered to customers.

In the past, decision-makers have been unaware of customer considerations during remanufacturability decision-making. Moreover, existing remanufacturability assessments have been based on factors that relate to the business. However, with the inclusion of the four key customer economic considerations (1 main element and 3 sub-elements), the possibility that remanufactured devices will become more acceptable to customers is higher.

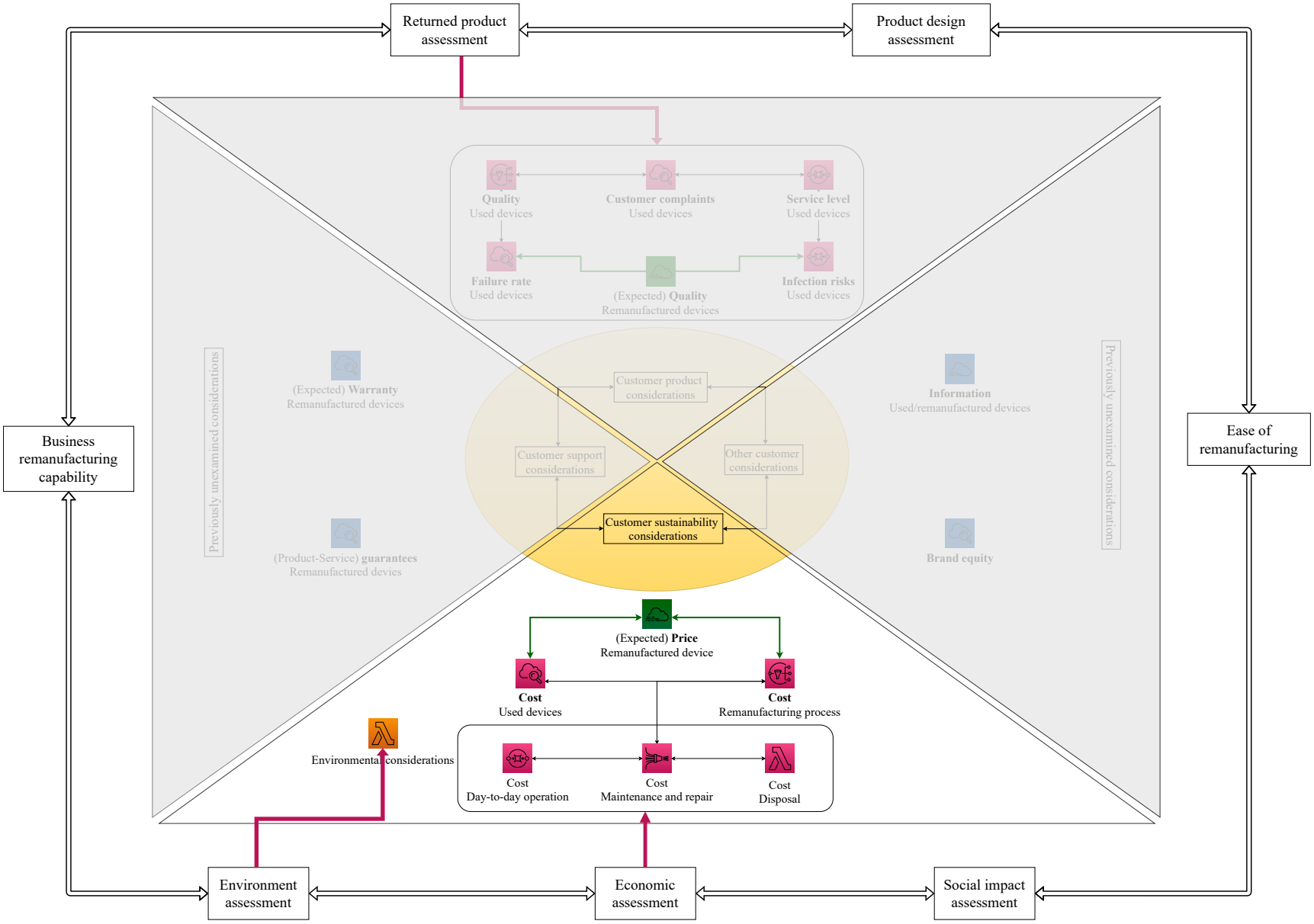

Figure 7-6: Customer sustainability considerations

On the other hand, environmental and social considerations have not pulled much weight in remanufacturability decision-making. Although this thesis, recognises the environmental and social impact of remanufacturing, their relative places in remanufacturability decision-making could not be established. Thus, the framework is void of any social considerations while the 'environmental considerations' is unspectacularly represented.

7.4.3. Customer support considerations

A conscious remanufacturability decision-making requires an assessment of the kind of support that can be provided to customers. While this has nothing to do with the actual remanufacturing operation, it significantly impacts the remanufacturing activities that can be performed on certain devices. Decision makers try to avoid the situation where a remanufactured device cannot be adequately supported. Also, this factor is also critical to customers and plays a critical part in the decisions.

The support core consideration is represented by two main elements: warranty and product-service guarantees (figure 7-7). Although these two considerations have been wrongly used interchangeably in literature, the distinctions have been comprehensively discussed in chapter 9. During remanufacturability decision-making, acceptable warranty and product-service guarantees should be assessed. From a customers' standpoint, these two factors are critical, especially on a remanufactured medical device. In the framework, decision makers assess the support available to customers during remanufacturability considering the warranty requirement on the device and the nature of product-service guarantees that customers actually need on specific devices. For example, decision makers can assess if a wide coverage warranty similar to or better than what is obtainable on new devices can be provided on a remanufactured device. Also, product-service guarantees can be employed as a major risk-reducer and used to build customer confidence in remanufactured devices.

Over time, the warranty and product-service guarantee situations on specific devices may change which is the main reason decision makers should continually assess this factor. Also, these considerations can be assessed at the organisational level as well as at the product/systems level. While the organisational level approach provides a simple, one-off evaluation of support, the product/system level approach allows the remanufacturer some flexibility in terms of what it can actually offer based on the exact customer needs. For example, single use devices do not require a one-year warranty. The level of product-service guarantees may therefore vary, depending on the nature, use and criticality of the device.

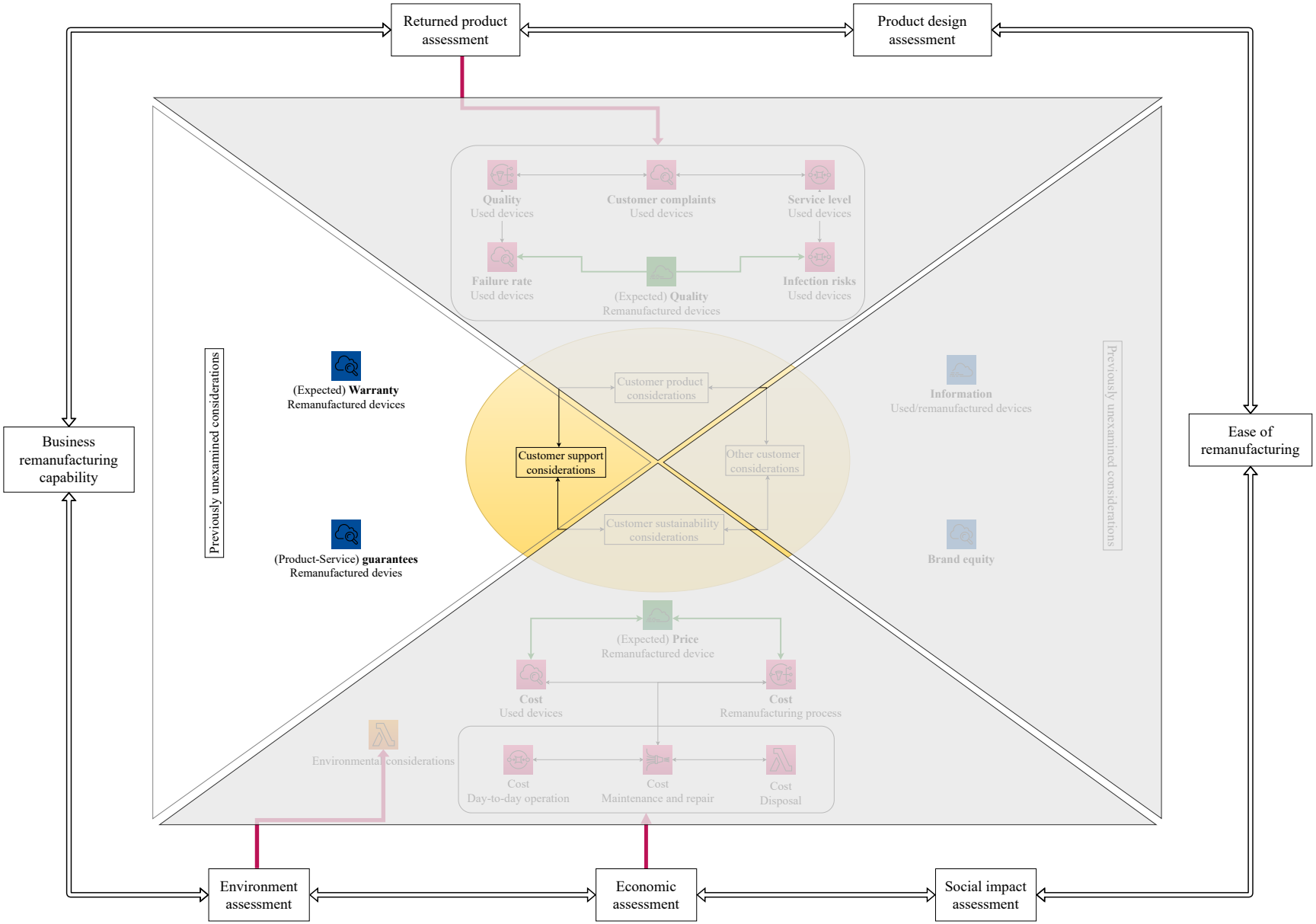

Figure 7-7: Customer support considerations

The direct link between support considerations and business remanufacturing capability was not established in this study. However, the ability of an organisation to provide support to its customers, through warranty and product-service guarantees, significantly influences their decisions to engage in the remanufacturing business which provides a justification for the connection represented in this framework. Thus, it is important that while assessing the support that can be offered to customers, the decision makers assess other business capability factors that have been discussed extensively in literature.

7.4.4. Other customer considerations

The other customer considerations are two main elements which have important roles in remanufacturability decision-making (figure 7-8). The first factor is information, which is twofold in terms of the information that is available to the remanufacturer about the device to be assessed, and the level of information that can be provided to the customers upon successful remanufacturing. The second factor is brand equity**,** which is customers' perception of remanufactured device depending on who performed the remanufacturing. Taken together, these two considerations impact a remanufacturer's decision to remanufacture specific devices.

Information, in remanufacturability decision, is about transparency from the original manufacturer to the remanufacturer and from the remanufacturer to the customer. The amount of information that can be accessed by all parties and shared across the remanufacturing business model is critical when assessing product remanufacturability. The first aspect of information deals with the remanufacturers' understanding of the product design and its design for remanufacturing. Such access significantly impacts the ease of remanufacturing a device. Although this factor has been discussed to certain extent in existing literature, the second aspect of information which relates to the information sharing and the nature of details about the remanufacturing process, tests conducted, performance at end of end of previous and previous use situations have not been included in the remanufacturability mix. One key point that has been noted about customers in the medical devices sector is their demand for information, not just about the remanufacturing process, but about the device that has been remanufactured and offered to them. As such, decision-makers must carefully assess the nature of information that can be accessed and passed down to customers.

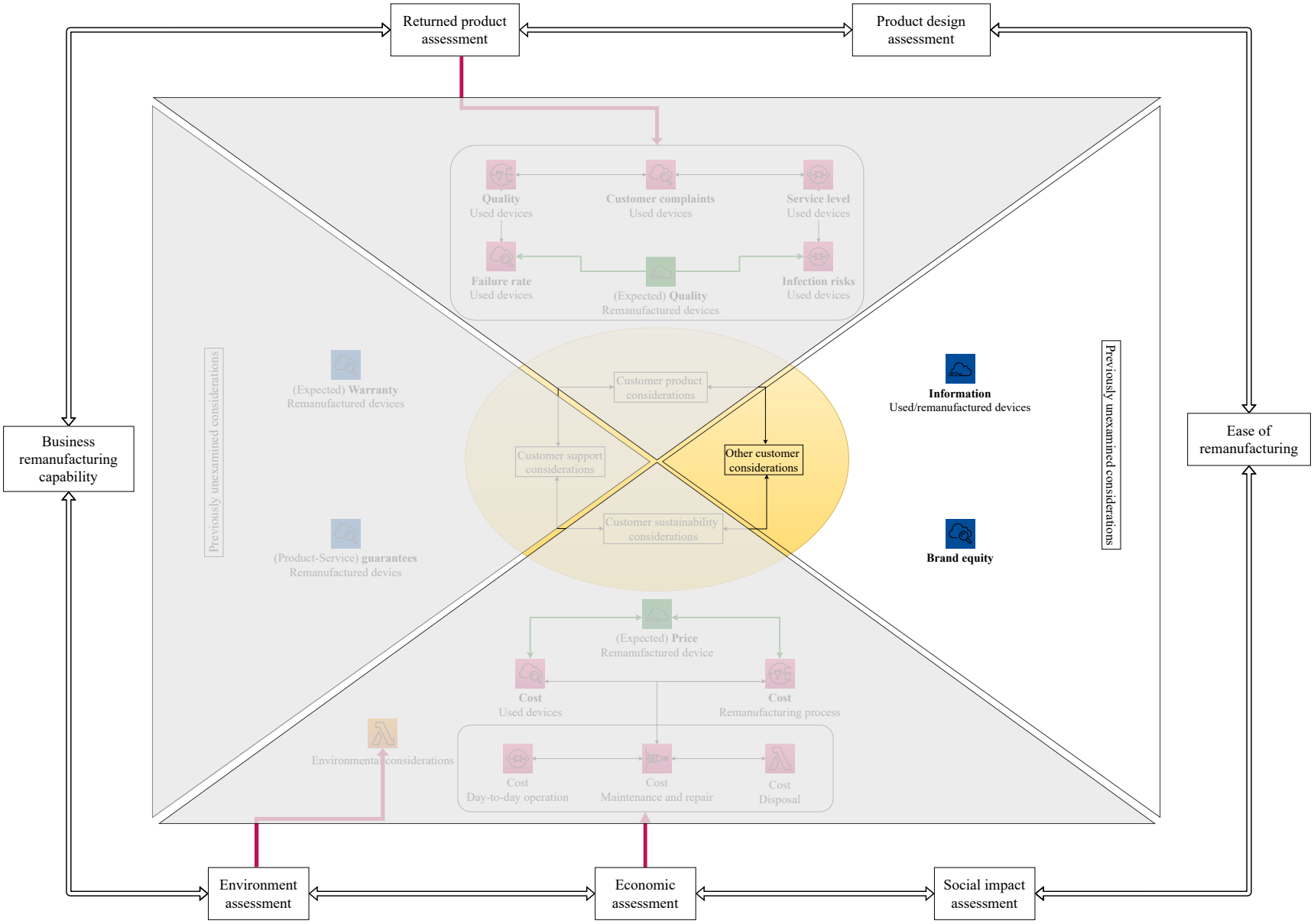

Figure 7-8: Other customer factors

The brand equity considerations aim for decision makers to evaluate their competitive offering and establish their place in the market. The end goal of remanufacturing is that products are accepted by customers and therefore, decision makers should assess the brand power of their devices, remanufacturing outlook, and societal participations. The details of this construct favours OEMs/OERs who have established a dominant presence in the market and are thus primarily customer favourites. However, third-party organisations can, with this framework, systematically identify specific product or component areas to target to build their brand power.

The interactions between the factors are critical to explore causal relationships between the other factors, the ease of remanufacturing and the remanufacturability of a medical device. This draws direct link to factors used in existing remanufacturability models. The improvements provided by including a customer viewpoint in the assessment allows for a comprehensive analysis of the remanufacturability of a device.

7.5.Applications of the framework

The framework provides a comprehensive representation of customer-driven remanufacturability decision factors, based on mixed findings from quantitative and qualitative studies. It highlights the key factors in remanufacturability models and improves upon existing considerations, especially from the viewpoint of the customers. However, it does not provide a step-by-step guideline on making remanufacturability decisions because organisations have different approaches, techniques, and principles for the decision process. It is the companies' own decisions how they decide to approach remanufacturability decision-making, in terms of their degree of "customer-driven'ness". However, this framework sets out the important considerations (from a customer standpoint) for remanufacturability and highlights the hierarchy of the different factors. Also, it makes direct links with existing remanufacturability considerations which provides a more solid foundation for this framework. The following sub-sections will describe the applications of the customer-driven remanufacturability framework developed based on the findings of this research.

7.5.1. A simple guide for remanufacturability decision-making

The customer-driven remanufacturability framework presented in this chapter provides a simple approach to remanufacturability decision-making, which identifies the key considerations, main elements (across different levels) and sub-elements. The framework

breaks down existing ambiguity on remanufacturability decision-making and provides a direct guideline on the critical decision factors. When used during early remanufacturing planning and remanufacturability assessment, the framework can serve as a touchstone and eliminate possible presumptions and uninformed hopefulness about customer acceptance.

7.5.2. A tool to improve customer-remanufacturer relationship

One way to potentially improve customer acceptance of remanufactured devices is to bring their concerns to the foreground of remanufacturers during remanufacturability decision-making. This approach has been extensively used in the medical devices remanufacturing sector often leading to a more customer-involved remanufacturing practice. The success of the remanufacturing business in medical devices sector is highly dependent on the key players which include the customers and remanufacturers. As such, the interaction and relationship between these two stakeholders should normally be assessed early during the remanufacturing process planning. The customer-driven framework can be applied to bridge the gap between customers and remanufacturers and can potentially improve the customer-remanufacturer interaction and relationship. The framework can also serve as another way in which remanufacturing organisations can demonstrate commitment to their customers through transparency and inclusiveness in the remanufacturability decision-making. Such approach would likely improve customers' awareness of the remanufacturers' efforts to ensure a safe and functional remanufactured device is presented to them.

7.5.3. A tool for disseminating medical devices remanufacturing knowledge

Findings from the literature review in chapter 2 showed the relatively low levels of knowledge in the medical devices remanufacturing sector. This customer-driven remanufacturability framework provides a holistic tool that can improve understanding, knowledge, and training in decisions in medical devices remanufacturing. The simple layout of factors and description of relationships, influencing factors and links to existing models adds to the simplicity of the framework and demonstrates its applicability as a tool for effective knowledge dissemination. This framework would benefit both remanufacturing organisations and academic scholars on the key customer remanufacturability factors. For the organisations, this framework can drive knowledge attainment for professionals. The inclusion of a customer-driven remanufacturability training programme would give assistance to the reinforcing and refining of knowledge on customer acceptance amongst

remanufacturing personnel. For the scholars, the framework can be adopted as a teaching and training tool on remanufacturability decision-making in the medical devices sector.

7.6.Conclusion of chapter 7

This chapter has described a novel customer-driven remanufacturability framework that incorporates customer considerations in remanufacturability decision-making. The framework was developed based on the mixed findings across different studies involving both the customers and the remanufacturers. The framework has been developed out of the need for an industry-wide standard approach for bringing customer considerations to the foreground of remanufacturability decision-making. The framework also provides a basis for future improvements in medical devices remanufacturing. New knowledge has been created based on a finite number of customers (in the quantitative study) and companies (in the qualitative study). Therefore, there is a need to assess the validity and usefulness of the framework.

Chapter Eight: Framework Validation

8. Chapter Eight: Framework Validation

8.1.Introduction

The previous chapter 7 presented discussion on the development of a customer-driven remanufacturability framework. The framework presents a structured and comprehensive representation of the findings from the mixed methods research performed in this PhD. This presents a novel approach to bridging the gap between the customers and the remanufacturers through an inclusive remanufacturability decision-making process.

8.2.Background

The customer-driven remanufacturability framework comprises of a multi-level, multi-factor decision mechanism through which decision makers can breakdown existing barriers between the customers and the remanufacturers. The core considerations, main elements (across 3 levels) and sub-elements holistically represent findings from a quantitative AHP study (chapter 6) and a multiple case study (chapter 7). The framework is used as a form of representation to illustrate complex ideas, issues, or topics in such a way that it is easier to understand (O'Cathain, 2015). The framework can be used by decision makers to support the remanufacturability decision process and to eliminate the complexity of customer requirements. Also, the framework would aid in disseminating knowledge about medical devices remanufacturing and for teaching and training purposes.

Judging the quality of a mixed methods research is complex and researchers have argued choosing between individual study level validation or th(J. W. Creswell, 2013; Johnson & Onwuegbuzie, 2004; Sale & Brazil, 2004; Shorten & Smith, 2017; Teddlie & Tashakkori, 2009)017; Teddlie & Tashakkori, 2009). These discussions have led to the development of approaches to validate the findings from mixed methods research, some of which have been discussed by (Dellinger and Leech, 2007; Giddings and Grant, 2009; Légaré et al., 2011; O'Cathain, 2015). Generally, validating the outputs of a mixed methods research include verifying its correctness, usefulness, lack of ambiguity and sufficiency.

This chapter details the quality criteria that are used, how the validity and reliability of the research is established and a discussion of results of the validation exercise.

8.3. Validation approach

Several approaches for validating outputs of a research, which may be a tool, framework, model, or an algorithm, have been discussed extensively by (Barth, Caillaud and Rose, 2011). Some of the approaches include application, comparison, focus groups, questionnaire, simulation, and statistical analysis. Sargent (2010) described four basic approaches for validating a research framework or model which are internal validation (where the model validates itself), subjective validation decision (where several tests are conducted during the development process to validate the final output), validation by users of the model or framework, and independent or third-party validation (Sargent, 2010). While several of the approaches have been adopted in literature, there has been no description of which approach may be best. However, this decision depends on the researcher and how they decide to validate their research, or the research domain and how research is commonly validated in the field (Dellinger and Leech, 2007; Légaré et al., 2011; Le Dain, Blanco and Summers, 2013; Isaksson et al., 2020).

The framework was validated by review based on the opinions of the research stakeholders. The review approach is influenced by the early work on research output validation by (Landry, Malouin and Oral, 1983). Several recent studies have employed this review approach to validate their research outputs. Refer to (Lombardi et al., 2017; Eker et al., 2018; Nawaz, 2019; Sadeghi and Goerlandt, 2021; Schindler and Dionisio, 2021; Stone et al., 2021). The review was performed using a combination of interview and questionnaire instruments to seek feedback from practitioners.

8.4.Validation criteria

Before a research output can be validated, the researcher must first understand what needs to be validated. The specific criteria for judging the quality of a research are critical to establishing its accuracy, usefulness, simplicity, sufficiency, and practical relevance. In this thesis, the more recent seven criteria for establishing practical relevance of research identified by Svanberg (2020) are used to validate the framework. These criteria are problem-driven, timely, important, implementable, non-obvious, novel and not too costly (Svanberg, 2020). These criteria are described in table 8-1.

Table 8-1: Validation criteria

Criteria	Description	How practitioners judge
Problem-driven	Assesses the significance of the research to the real world. The goal is to assess if the framework is driven by actual problems, phenomenon, challenges, or topics faced by practitioners	*Based on their practice, does the framework address actual phenomenon encountered by practitioners?*
Timely	Evaluates the suitability of the research at the present time. That is, to assess if the framework is delivered at the right time to address current issues faced by the practitioners.	*Is this framework useful at the present time?*
Important	Assesses if the research focuses on specific topics that practitioners care about. That the framework provides a revelation in line with the organisation's goals or provides competitive advantages.	*Does the framework address issue that practitioners want to influence?*
Implementable	Evaluates the operational validity of the research output. That is, to assess if the framework is applicable and can be implemented in actual practice.	*Are practitioners able to understand and implement the framework in their operations?*
Non-obvious	Addresses the unfamiliarity or unusualness of the research. It assesses if the framework goes beyond the practitioners' common sense which may be already used in their practice.	*Is this framework or the idea behind it something practitioners already have in their arsenal?*
Novel	Addresses the newness of the construct to practitioners. That is, it assesses if the framework provides a novel insight or perspective on the specific issue in the field.	*Does the framework present a novel perspective to the practitioners?*
Not too costly	Evaluate the cost to implement versus the benefits of the framework.	*In terms of using or implementing the framework, does the cost outweigh the potential benefits?*

8.5.Validating participants

In the previous sections, the word "practitioners" have been used to describe specific groups of people that are critical to research. O'Cathain (2015) described these stakeholders as research funders (if any), users of the research output (e.g., policymakers, other companies or people affected by the research issues), research participants (i.e., representatives of the case study company), teachers and other researchers in the field, and evidence synthesizers. Validating a framework by review requires a comprehensive evaluation by a variety of the research stakeholders.

To validate the customer-driven remanufacturability framework, the participants was selected similar to what was employed by (Ijomah, 2002). This is made up by representatives of the case study companies, non-case study companies, academics, and other practitioners in the industry (table 8-2). This allowed for a comprehensive review of the outputs of the research across multiple perspectives. For example, with the case study companies, the researcher was able to verify again that the information obtained during the

research were accurate and that they agree with the researcher's interpretation and overall use of the data. On the other hand, non-case study companies allowed the researcher to test the generalizability of the framework in the medical devices remanufacturing sector. Whereas academics (teachers and researchers) are able to verify the usefulness of the framework for teaching and training purposes while also establishing the research as a meaningful contribution to the research field.

8.6.Validation procedure

To justify the practical relevance of the research output, the validation was conducted in two phases described in the following sub-sections. In both phases, the researcher describes the research and the framework followed by the delivery of a web link to a questionnaire set up on Qualtrics to collect their feedback. The validation procedure is shown in figure 8-1.

8.6.1. Phase 1 validation

In the first phase, the researcher set up a one-on-one discussion with each participant of the framework review exercise – shown in table 8-2. The discussion took place over the internet using Zoom, Microsoft Teams and Google Meet, as it was appropriate for each participant. During this discussion, the researcher presented the framework to the practitioner, stated the purpose, describe each factor, and explained how the framework functions. This is to ensure that the participants correctly understand the framework before collecting their feedback. After each discussion, link to the questionnaire is sent to the participant where they provide their feedback.

Table 8-2: Participants in framework review exercise

Organisation	Current role	Years of experience
Case study companies		
Company A	Remanufacturing Technical Director	12
	Segment Manager – Molecular Imaging, Women's Healthcare and X-Ray	10
Company B	Commercial Sales Director	3
Company D	Sustainability Lead	1.5
Non-case study companies		
Company E	Business Development Manager	15
Academics		
Imperial College London	Professor and Principal Consultant	4 & 20
University of Strathclyde	Research Associate	1.5
University of Strathclyde	Doctoral Researcher	5
EcoDesign 2021 workshop		
Completed questionnaire		1

8.6.2. Phase 2 validation

The framework was presented to participants in an international conference (EcoDesign 2021). The discussion happened during a workshop specifically set up for medical devices remanufacturing and to validate the findings from this research. The workshop lasted 80 minutes and it included a robust discussion amongst the participants on the usefulness of the research and the practical relevance of the framework. After presenting the framework, the researcher shared a web link with the audience where they can input their responses on a questionnaire that tests the validity of the research.

8.6.3. Validation documents

The following documents are presented to the participants in the framework validation exercise:

1. A copy of the complete customer-driven remanufacturability decision framework.
2. A brief description of the framework highlighting the different modifications and interpretations. The purpose of this document is to enhance the understanding of the framework.
3. A questionnaire with 20 questions used to record the participants' evaluation of the framework. The questions were delivered as an internet-based questionnaire to

answer practical relevance questions based on (Svanberg, 2020). More discussion is presented in the next section on the questionnaire development.

4. An electronic thank you card and recommendations for improving practice based on the findings of the research.

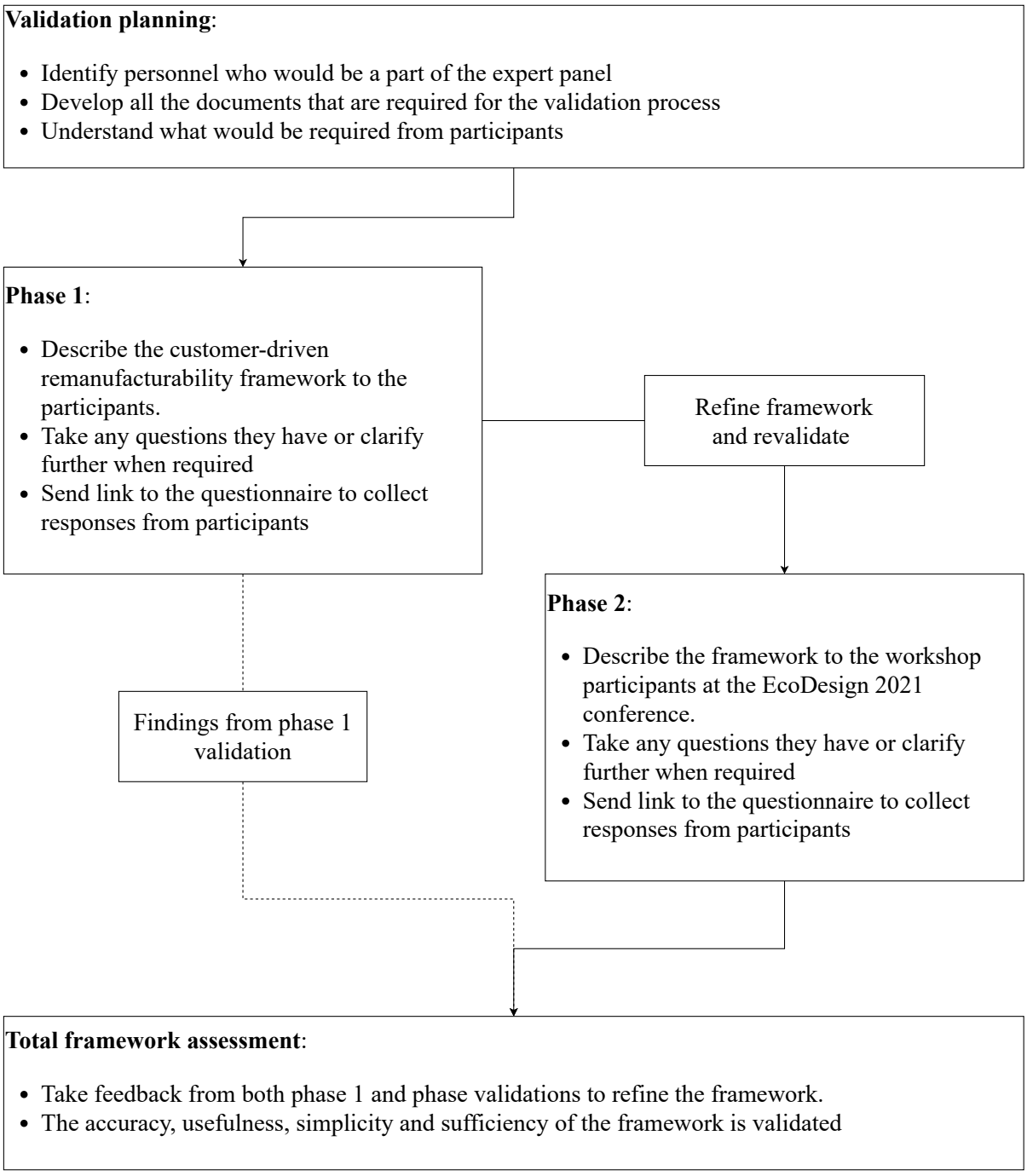

Figure 8-1: Validation procedure

8.6.4. Questionnaire development

The questionnaire was based on the seven criteria for assessing practical relevance of a research output presented by (Svanberg, 2020). The questions are designed to test if the framework is problem-driven, timely, important, implementable, non-obvious, novel and not too costly, or otherwise, as shown in figure 8-2. The questionnaire is structed into two parts: First, some information about the participant is collected including their organisation and position. Second, 20 questions are presented which focused on validating the framework using the seven criteria. The length of each question did not exceed 20 words and the total number of questions did not exceed 20 to improve response rate, in line with the suggestions in (Errington, 2009; Millar et al., 2018).

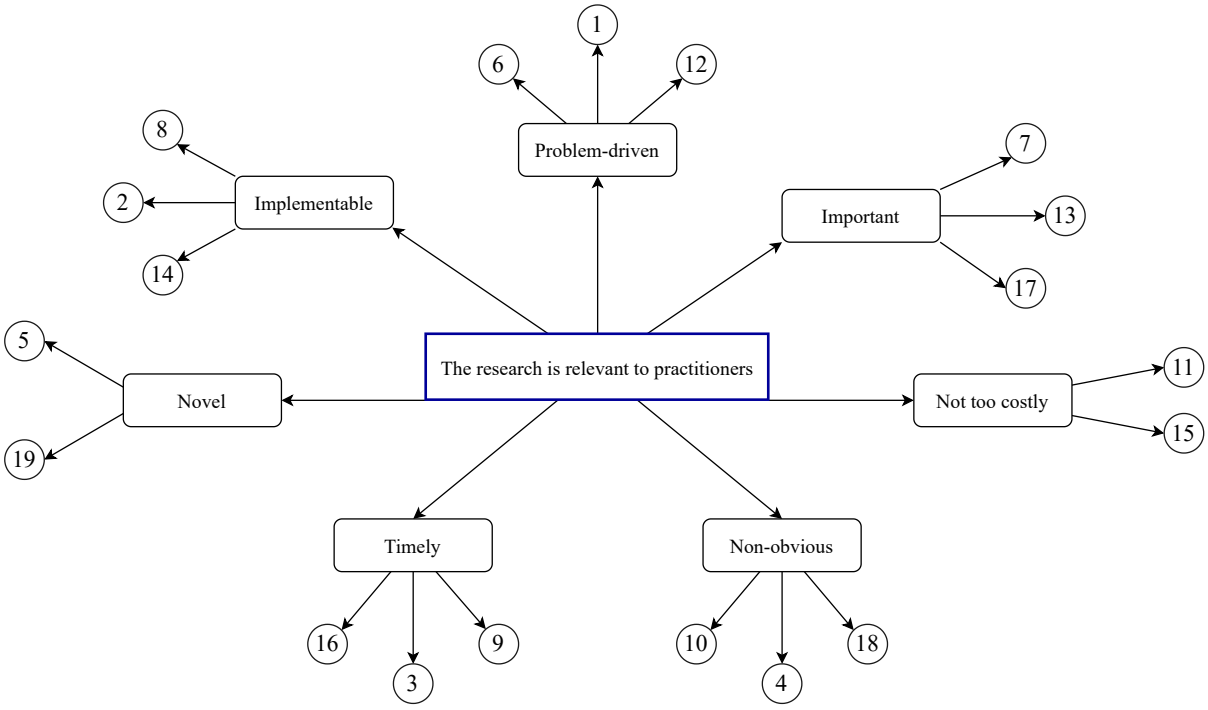

Figure 8-2: Validation questions categories

Responses in the second part of the questionnaire were collected using a five-point Likert scale (from strongly disagree to strongly agree) plus one open ended question used to collect additional comments about the framework. The researcher preferred the five-point Likert scale to other scales (e.g., four points, six points, and seven points, etc) because it increases the accuracy of measurement (Asún et al., 2016) and is coherent with research validation questionnaires in remanufacturing literature (Ijomah, 2002; Priyono, 2015; Chaowanapong, Jongwanich and Ijomah, 2017; Arredondo-Soto et al., 2019; Chiappetta Jabbour et al., 2020). The initial draft of the validation questionnaire was piloted with two colleagues who

were fellow PhD colleagues, one senior academic (a lecturer at another university) and one industry practitioner. Based on the results of the pilot tests, the questionnaire was further refined to enhance the feasibility of the validation exercise. The results from the pilot exercise were not included in the analysis.

8.7.Validation results

A summary of the results of the validation exercise conducted in this chapter is presented in table 8-3. The validation sheet from each participant can be found in appendix C-1 appendix C-10. Overall, the participants believed the framework was generally valid and practically relevant. More discussion is presented in the following sub-sections on the results by each of the seven criteria.

8.7.1. Problem-driven

The participants believed that the framework is significant to the real world and driven by current practices in the medical devices remanufacturing sector. Also, they believed that the framework is driven by actual problems, phenomenon, challenges, or topics that are faced by practitioners. The participants either strongly agreed (11.11%) or agreed (88.89%) with the accuracy of the framework and believed that it strongly represents key factors that drive remanufacturability in the medical devices sector. Another question probed further to understand if the decision factors in the framework represent their key considerations for remanufacturability. Their responses were in favour of the accuracy of the factors with 8 out of 9 respondents either strongly disagree (33.33%) or disagree (55.56%). The final question evaluating this criterion focused on the current practices in the medical devices sector and enquired if the framework provides a solution for the problems currently faced by practitioners. One participant strongly agreed while seven participants (77.78%) agreed that this framework actually provides a solution for current challenges faced in the sector.

8.7.2. Important

The participants believed that the framework is important because it focuses on a specific area that practitioners care about. Also, the key points presented in the framework are factors which the practitioners wish to improve upon to improve the customer acceptance of their products. The participants either strongly agreed (44.44%) or agreed (55.56%) with this. The question was flipped to ensure that the participants were intentional in their previous response. 44.44% of the participant each disagreed and strongly disagreed that the factors in the framework are not important to the decision makers. This is consistent with their

response to the previous question and further reiterates the importance of the framework and the problem it focused on. The third question evaluating this criterion assessed the relevance of the framework to the goals and values of remanufacturing organisations in this sector. The participants either strongly agreed (33.33%) or agreed (66.67%) that the factors are important to the business values of remanufacturing organisations. This established the importance of customer acceptance to business values.

8.7.3. Implementable

The operational validity of the customer-driven remanufacturability framework was assessed using three questions. The participants either strongly agreed (33.33%) or agreed (66.67%) that the framework can be used to improve the remanufacturability decision-making process in remanufacturing organisations. Further, all participant believed that the framework can be implemented into real practice in the remanufacturing sector. 44.44% of the participants strongly agreed while 55.56% agreed. However, when the question was reversed, 33.33% disagreed and 22.22% strongly disagreed that the framework would not be easy to implement constituting a majority (>50%) of responses establishing that the framework can be easily implemented. This also implied that practitioners can easily understand and use the framework within their remanufacturability decision processes. Although the remaining responses were a minority (i.e., 22.22% of the participants held a neutral position while 22.22% agreed that it will not be easily to implement), the researcher investigated the participants' responses. However, they did not provide any comments on how to improve the ease of implementing the framework. The results obtained on the 3 questions can be taken as a proof that the framework is operationally valid and can be implemented.

Table 8-3: Validation results

S/N	Questions	Strongly Agree	Agree	Neither	Disagree	Strongly Disagree
1	The framework is an accurate and comprehensive representation of the customer-driven factors that influence remanufacturability.	1 (11.11%)	8 (88.89%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
2	The implications of this framework can be used to improve the remanufacturability decision processes in remanufacturing companies.	3 (33.33%)	6 (66.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
3	The framework is useful to remanufacturing companies at the present time	2 (22.22%)	6 (66.67%)	1 (11.11%)	0 (0.00%)	0 (0.00%)
4	More critical decision factors have been omitted in this framework.	0 (0.00%)	0 (0.00%)	1 (11.11%)	8 (88.89%)	0 (0.00%)
5	The framework presents a new theoretical construct to practitioners in this sector	1 (11.11%)	7 (77.78%)	1 (11.11%)	0 (0.00%)	0 (0.00%)
6	The framework does not correctly describe the factors that remanufacturers would consider when deciding to remanufacture in the medical devices sector.	0 (0.00%)	0 (0.00%)	1 (11.11%)	5 (55.56%)	3 (33.33%)
7	The framework highlights factors that are useful to remanufacturing companies who wish to improve their customer acceptance	4 (44.44%)	5 (55.56%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
8	The framework is not going to be easy to implement.	0 (0.00%)	2 (22.22%)	2 (22.22%)	3 (33.33%)	2 (22.22%)
9	Currently, the customer-driven remanufacturability framework is not applicable but can be useful in the next two to three years.	2 (22.22%)	1 (11.11%)	1 (11.11%)	5 (55.56%)	0 (0.00%)
10	I believe the framework captures remanufacturability decision factors that are driven by the customers.	1 (11.11%)	8 (88.89%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
11	It’s just not worth it, the cost outweighs the benefit of implementing the framework.	0 (0.00%)	0 (0.00%)	0 (0.00%)	6 (66.67%)	3 (33.33%)
12	The framework is based on current practice and presents a solution for the problems currently faced by practitioners.	1 (11.11%)	7 (77.78%)	1 (11.11%)	0 (0.00%)	0 (0.00%)
13	The factors in the framework are not important to the decision makers in remanufacturing companies.	0 (0.00%)	1 (11.11%)	0 (0.00%)	4 (44.44%)	4 (44.44%)

14	The framework can be implemented in real practice in the remanufacturing sector.	4 (44.44%)	5 (55.56%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
15	This framework does not require too many resources for its implementation	1 (11.11%)	5 (55.56%)	3 (33.33%)	0 (0.00%)	0 (0.00%)
16	Customer-driven remanufacturability consideration was a hot issue like two or three years ago.	0 (0.00%)	0 (0.00%)	3 (33.33%)	5 (55.56%)	1 (11.11%)
17	The customer-driven remanufacturability framework address issues that is important to remanufacturing business values	3 (33.33%)	6 (66.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
18	The framework helps to better understand how to improve remanufacturability decision making.	3 (33.33%)	6 (66.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
19	The framework does not present anything new for the practitioners.	0 (0.00%)	0 (0.00%)	1 (11.11%)	7 (77.78%)	1 (11.11%)

8.7.4. Timely

Questions were included in the questionnaire to assess the timeliness of this research and of the remanufacturability decision framework. It is important that this framework is delivered at the right time to address current issues faced by the practitioners. The participants strongly agreed (22.22%) and agreed (66.67%) that the framework is useful to remanufacturers at the present time. Further, the participants disagreed (55.56%) or strongly disagreed (11.11%) that the area of research was critical two or three years ago, implying that this current research and the customer-driven framework is timely and is useful to practitioners at this present time. The last question on this criterion was flipped to ensure consistency of responses. The answers to the statement that the framework is not applicable right now but can be useful in two to three years was strongly agree (22.22%), agree (11.11%), neutral (11.11%), and disagree (55.56%). The implication of the answers provided by the participants on this question is twofold: 1) majority (55.56%) of the participant disagreed that the framework is not currently applicable, thus establishing the timeliness of this research, 2) 33.33% of the participant either strongly agreed or agreed that the research would be useful in two to three years. The answers to the three questions assessing the timeliness of the framework provides strong evidence that this research and the framework is timely and also has future relevance.

8.7.5. Non-obvious

The aim of this criteria is to addresses the unfamiliarity or unusualness of the participants to the framework or the findings of this research. Three questions were asked to assess if the framework goes beyond the practitioners' common sense which may be already used in their practice. First, the participants disagreed (88.89%) that the framework omits more critical decision factors. This further confirms that accuracy of the framework while also establishing the participants' knowledge about what is being studied. Answers to the second question showed that the participants either strongly agreed (11.11%) or agreed (88.89%) that the factors captured in the framework are primarily driven by customers. In the third question, the participants strongly agreed (33.33%) or agreed (66.67%) that the framework helps them to better understand how to improve their current understanding of remanufacturability decision making. These findings established that the customer-driven remanufacturability framework is non-obvious.

8.7.6. Novel

This criterion addresses the newness construct of the research output to practitioners. Two specific questions were asked. The participants believed that the framework presents a new theoretical construct to practitioners as it helps them to focus more on their customers when deciding what products to remanufacture. 11.11% strongly agreed while 77.78% agreed with this. In the second question, this statement was flipped. The results were the same as was initially obtained i.e., 77.78% disagreed and 11.11% strongly disagreed that the framework does not present anything new for the practitioners. This established that the framework provided a novel insight or perspective on remanufacturability decision-making in the medical devices remanufacturing sector.

8.7.7. Not too costly

Having demonstrated that the framework can be implemented in current practices in this sector, this criterion assesses the opinion of the participants on the costs versus the benefits of implementing the framework. Two questions were asked in the questionnaire. All the participants disagreed (66.67%) or strongly disagreed (33.33%) that the cost of implementing the framework outweighs the benefits. Further, a majority of the participants strongly agreed (11.11%) or agreed (55.56%) that the framework does not require too many resources for its implementation. Based on these findings, it has been established that the framework is not too costly to implement.

8.8.Conclusion of chapter 8

The researcher found that practitioners agreed with the validity of the research output. This implies that the research conducted in this thesis and the customer-driven remanufacturability decision framework is problem-driven, important, novel, timely, non-obvious, not too costly and can be implemented. This answers the final research question RQ7 of this PhD research.

Chapter Nine: Conclusion

9. Chapter Nine: Conclusion

The previous two chapters presented discussions on the development (chapter 10) and validation (chapter 11) of the customer-driven remanufacturability decision framework. This framework was developed based on the mixed findings discussed in chapter 9. This chapter presents the conclusion of this thesis. The following key points are discussed: thesis summary, research contributions, originality of research, research limitations, and future research.

9.1.Thesis summary

Remanufacturing a product, following a comprehensive assessment of its remanufacturability, can lead to the availability of high quality and affordable (low-cost) devices which have great environmental, and social advantages. The remanufacturing process takes a used product, through a series of activities, to the quality and warranty standards of equivalent new products (Thierry et al., 1995; Ijomah, 2009). The remanufacturing process involves several activities such as disassembly, cleaning, reworking, reassembly, and testing (Amezquita et al., 1995). However, decision makers need to assess the feasibility and viability of remanufacturing before the operation begins. Despite best efforts, remanufactured devices may not necessarily be accepted by the customers reducing profitability to business, increasing wastages (material and energy resources) and the overall environmental impact of the products. Therefore, a comprehensive evaluation of customer considerations and customer acceptance should be performed during remanufacturability decision-making.

Due to the low intensity of remanufacturing in the medical devices sector, research activities have not fully explored this area of research. Discussions on remanufacturability decision-making in this sector are not well established in literature. This has led to several assumptions in literature about the definitions, safety, quality, and customer involvement in the medical devices remanufacturing sector. In other sectors (e.g., automotive and electronics products), a systematic understanding of how customer considerations contribute to remanufacturability decision-making is still lacking.

The purpose of this research was to explore customer considerations in remanufacturability decision-making focusing on the medical devices remanufacturing sector. This is in contrast to existing studies which have mostly assessed remanufacturability from business and

process standpoints, without paying much attention to customer acceptance. This research was undertaken to understand the nature of medical devices remanufacturing and to evaluate the remanufacturability decision-making in this sector. Discussions are presented below on how each of the seven research questions in this PhD research was answered.

9.1.1. RQ1: What is the relationship between remanufacturability decision-making and customer acceptance?

To understand the relationship between remanufacturability decision-making and customer acceptance, a review of existing literature was performed and reported in chapter 2. This chapter reported that a few existing remanufacturability models have represented customer requirements using the supply and demand functions. It was established that improving the relationship between the customers and remanufacturer can reduce existing challenges in customer acceptance. One such way to improve this relationship is through the consideration of customer decision factors in remanufacturability decision-making. However, these factors (such as pricing, quality, branding, warranty, risks, and benefit perceptions) have not been appropriately incorporated into remanufacturability decision-making (Milios and Matsumoto, 2019). Based on this finding, the direct relationship between customer acceptance and remanufacturability decision-making was established thus answering RQ1.

9.1.2. RQ2: What are the key decision factors for assessing remanufacturability and how do they influence customer acceptance?

The findings from literature review in chapter 2 highlighted the key factors that have been used in remanufacturability decision-making. Remanufacturability decision factors identified in literature were grouped into three main categories: sustainability, product, and technological considerations. These considerations were further divided into economic, environmental, and social factors for the sustainability considerations; returned product management and product design factors for the product considerations; and ease of remanufacturing and company's remanufacturing capability for the technological considerations. Taken together, these remanufacturability decision factors are shown in literature to impact customer acceptance of the remanufactured products.

Findings from the review showed that customer considerations have not been adequately included in remanufacturability decision-making when compared to the requirements of other stakeholders (such as the OEM or TPR). The review chapter 2 established that the link between customer acceptance and remanufacturability decision-making has not been

previously explored indicating a knowledge gap on how customer acceptance can be improved early in the remanufacturing planning and decision-making process, thus answering RQ2. The necessity of this research, which sought to comprehensively address and bridge the gap between customers and remanufacturing businesses, was established.

9.1.3. RQ3: What is the relative importance of decision factors that affect customer acceptance of remanufactured medical devices?

Specific factors that influence customer acceptance of remanufactured medical devices were identified in literature review reported in chapter 2. These factors were quantitatively assessed in chapter 4 using the Analytical Hierarchical Process (AHP). The chapter examined the nature of the decision factors and established the relative importance of factors that are critical to customer acceptance of remanufactured medical devices. These factors are ranked in order: quality (32.38%), price (19.00%), warranty (15.12%), brand equity (12.24%), available information (10.61%), added value service (6.65%) and environmental considerations (4.00%).

The findings from the quantitative study established that quality and price factors of the remanufactured medical device are the most critical factors for the customers. Other factors such as warranty, brand, available information and added value services are noted to have relatively medium level criticality whereas environmental factors are reported to play a minimal role in customer decisions. This answers RQ3. This study also highlighted the need to understand the importance of customer considerations from the viewpoint of the remanufacturers and formed the basis for the qualitative reported study in chapter 5.

9.1.4. RQ4: What is the nature of remanufacturing in the medical devices sector?

A background was presented on the nature of remanufacturing in the medical devices sector in the context of existing literature in chapter 2. One of the major findings include the presence of a high level of ambiguity in that sector. This ambiguity may contribute to the significantly low acceptance of remanufactured medical devices. Another key finding is that existing studies have failed to assess the considerations of customers or medical practitioners in remanufacturability decision-making. Particularly, medical practitioners who have high impacts on the purchase or use decisions on remanufactured medical devices. Chapter 5 builds on existing literature through qualitative case study of four remanufacturing companies. This study further described the nature of medical devices remanufacturing in practice. Some key points identified include a higher level of customer

involvement, higher safety concerns, multiple cleaning and disinfection activities and robust product selection process. These key points differentiate remanufacturing in the medical devices sector from other sectors such as automotive, and electrical and electronics devices sector, thus answering RQ4.

Prior to this research, there was a lack of information on how remanufacturing sectors compared. Findings from this thesis can serve as a basis for this comparison and a springboard for future research.

9.1.5. RQ5: What are the key decision factors that are currently used in medical devices sector to assess remanufacturability and how can this be improved?

The quantitative study (chapter 4) and the qualitative study (chapter 5) were combined at the interpretation level in line with the mixed methods research design adopted in this thesis. Using the mixed findings discussed in chapter 6, the specific customer factors that drive remanufacturability decision-making were discussed. These factors include the product quality, price, warranty, product/service guarantees, brand equity, information, and environmental consideration. The customer factors were placed into four levels of criticality as they drive the remanufacturability decision process. They are high criticality (price and quality), upper medium criticality (warranty and product/service guarantees), lower medium criticality (information and brand equity), low criticality (environmental conservation).

The findings presented in chapter 6 established the importance of customer factors in remanufacturability decision-making, and therefore answers RQ5. It made an argument for the inclusion of customer considerations in remanufacturability decision-making, without discarding the factors that have been previously used. Other factors that influence the key customer considerations that drive remanufacturability were also established in the research.

9.1.6. RQ6: How can the new knowledge be presented to others?

Based on the findings from this research, a framework was constructed to describe the customer-driven remanufacturability factors in the medical devices sector. The customer-driven remanufacturability decision framework was developed in chapter 7 as a means to present the knowledge created in this research with the aim of answering RQ6. The framework described the key customer factors that drive remanufacturability decision-making in the medical devices sector. The specifications, applications, and limitations of the framework were also discussed within chapter 7.

9.1.7. RQ7: Is the new knowledge valid?

The framework was validated by review through feedback from nine (9) practitioners in the medical devices sector, which included representatives from the case study companies, non-case study company, academics whose research are situated within the medical devices remanufacturing domain and a participant at the EcoDesign 2021 online conference where this research was presented. The validation exercise assessed the accuracy, usefulness, simplicity, sufficiency, and practical relevance of the customer-driven remanufacturing decision framework. The results established that the framework is problem-driven, important, timely, non-obvious, novel, not too costly, and implementable for remanufacturability decision-making, thus answering RQ7.

9.2.Research contributions

This PhD research has contributed both to knowledge and practice in numerous ways by answering the research questions. The two primary and three secondary contributions from this research project are discussed below:

The two primary contributions of this research are:

1. **The development of a novel customer-driven remanufacturability decision framework**

While much of research have studied remanufacturability decision-making, this is the first to do so with a focus on the customer requirements that influence remanufacturability. This is a timely and important research that addresses current issues on improving customer acceptance within the medical devices sector by ensuring that specific requirements of the customers are taken care of in the planning and decision process. The framework can be applied in the following ways and can therefore be useful to future researchers who wish to develop tools specifically for the medical devices remanufacturing sector.

a) When used during early remanufacturing planning and remanufacturability assessment, the framework can serve as a touchstone to eliminate assumptions about customer acceptance.
b) The framework can be applied to bridge the gap between customers and remanufacturers and can potentially improve the customer-remanufacturer interaction and relationship. The framework can also serve as another way in which remanufacturing organisations can demonstrate their commitment to their customers through transparency and inclusiveness in the remanufacturability decision-making.

c) This framework provides a comprehensive understanding of the key customer remanufacturability factors which would benefit both remanufacturing organisations and academic scholars. For the organisations, this framework can drive knowledge attainment for professionals.

2. **A comprehensive description of the nature of remanufacturing in the medical devices sector**

For the past two decades, the nature of remanufacturing in the medical devices sector in literature has been vague. The unclear characteristics of medical devices remanufacturing, and its customers has increased presumptions on the nature of this remanufacturing sector. For a long time, researchers have generalised the term "remanufacturing" across several sectors and have proposed tools and methods for different activities. The findings of this research project have presented insights into the distinct nature of medical devices remanufacturing and offer multiple perspectives on remanufacturability decision-making.

The three secondary contributions that this research has made are:

3. A comprehensive review of decision factors in remanufacturability decision-making
4. A hierarchical analysis of factors that influence customer' decisions on remanufactured medical devices
5. A comprehensive description of remanufacturing operation and remanufacturability decision-making in four case study companies

The issue focused on in this research has not been sufficiently treated in existing literature. While some earlier studies have performed reviews of remanufacturability decision-making, researchers have not been able to draw on any systematic review of the subject with a focus on how the requirements of the different stakeholders have been accommodated. A description of the stakeholder considerations in remanufacturability decision-making has been presented in chapter 2. This research has been formatted into a paper published in the journal of cleaner production (Akano, Ijomah and Windmill, 2021b).

Remanufacturing research to date has tended to focus on the automotive and electronics remanufacturing sectors. Very few studies were found to focus on remanufacturing within the medical devices sector. Therefore, this research provides a comprehensive state-of-art of medical devices remanufacturing in chapter 3. The findings from the quantitative research presented in chapter 6 assessed the relative importance of factors influencing customers' decisions. This provides a novel understanding of the customers and also offers an indication

on decision-making in the medical devices remanufacturing sector. This research has been used to draft a research article which is published in the journal of cleaner and responsible consumption (Akano, Ijomah and Windmill, 2021a).

9.3.Originality of research

The originality of this PhD research rests on expositions from existing literature that this is the first time that:

1. Remanufacturability decision-making has been assessed from the viewpoint of the customers. Up to this point, existing studies on remanufacturability decision-making have mostly focused on assessing the process and the product for remanufacturability paying very little attention to customer acceptance.
2. Multiple case studies have been used to describe the actual nature of remanufacturing in the medical devices sector. Existing literature have mostly operated based on the assumption that remanufacturing in the medical devices sector is the same as that in other sectors such as the automotive and electronics industry. This research has broken down the complex nature of medical devices remanufacturing by also comparing it with other sectors.
3. A quantitative insight into the nature of customers in the medical devices remanufacturing sector is presented.
4. A comprehensive framework for remanufacturability decision factors has been developed and validated by practitioners. The customer-driven remanufacturability decision framework presented in this thesis presents a novel perspective to remanufacturability decision-making and allows an easily understandable and implementable dissemination of this knowledge. This framework has direct practical relevance for practitioners within this sector and could contribute to increasing customer acceptance in this sector.
5. A mixed research methodology has been employed on the subject of remanufacturability decision-making. This presents a holistic perspective on the research area by obtaining inputs from both the customers and the remanufacturers within the medical devices sector.

9.4.Research limitations

The research was carried out rigorously to eliminate limitations as much as possible. However, there were a few limitations which include the generalisability of the research findings across other sectors, the number of companies used in the qualitative case study, the number of participants used in the quantitative AHP study and the order of the research components.

- Generalisability of research findings

This research has only covered participants in the medical devices remanufacturing sector. These participants include the customers, remanufacturers, and academics. By being limited to this sector, this research cannot be generalised to other sectors such as the automotive, electrical and electronics, marine, furniture, and aviation sectors. Although there may be some similarities between the sectors, it is important that a comprehensive evaluation of the validity of these findings in other sectors be performed before any generalisation is presented. Also, both the quantitative and qualitative studies should be expanded to include practitioners across the different sectors to improve the external validity of this research.

- Number of case study companies

The qualitative case study research included four companies. While a minimum of three companies are required in a multiple case study research, involvement of more companies could improve the robustness of this research (Yin, 2018). However, given the nature and fragmentation of the medical devices sector, it was impossible to include a larger number of companies. Also, as this research was performed by only one person who was limited by time and resources, including more companies would have generated more information which would have overloaded the researcher.

- Number of participants in the quantitative AHP study

Quantitative studies are usually based on larger sample sizes. However, due to the time and resources limitations of this research, only six experts participated in the quantitative study. The researcher accounted for this with the experience of the participants (which is intangible). However, given the nature of this sector, information from a few highly experienced personnel is likely to be more relevant than numerous lower experienced personnel, even though the later may be more statistically significant. However, this research could benefit from more participants with high skill and experience level.

- The order of the research studies (i.e., choice of research design)

In this research the *quan* $\rightarrow$ *QUAL* design was adopted. One would wonder how the findings of this research might have been different had the research adopted a different design e.g., *qual* $\rightarrow$ *quan* or perhaps a concurrent design. However, given the available resources at the time of this research, the overall aim, the nature of research in this field and the exigency of developing tools to support remanufacturers, the adopted research design can be described as appropriate for this research. This would be an interesting area for future research.

Overall, in spite of the limitations described in this section, this research has provided insights and outputs which can be improved upon by researchers in the academic community.

9.5.Future research

This research has provided a basis for developmental works. The future research are discussed under two focus areas, the first is related to research on medical devices remanufacturing while the second focuses on the wider remanufacturing industry.

9.5.1. Future research on medical devices remanufacturing

The question raised by this research is the level of customer involvement in remanufacturing planning and decisions. As discussed in chapter 3, there remains a number of avenues where research can be directed to drive growth in the medical devices sector. To follow up on the findings of this research, a natural progression is a further analysis of the decision-making performed by remanufacturing companies in other aspects of the remanufacturing business to understand how the different requirements of the customers have been accounted for. These aspects include reverse logistics issues, initial product assessment at remanufacturing facility, disassembly activities, part reworking, testing, and marketing activities. This would help to develop a better understanding of decision-making in the medical devices remanufacturing sector which would move the debate forward.

Several questions still remain to be answered on customer acceptance of remanufactured medical devices. The precise impact of the use of the customer-driven remanufacturability decision framework on customer acceptance needs to be comprehensively assessed. This could be performed quantitatively using numerical or mathematical models, or by direct application at a remanufacturing company. This would be a fruitful area for further work, and it could contribute to the long-term growth in this remanufacturing sector.

Greater focus on specific medical devices and geographical regions could produce interesting findings. This could improve understanding of the impact of medical devices remanufacturing on the affordability, accessibility, and sustainability of medical devices, especially in low-resourced settings. Also in this sector, while some products have received considerable remanufacturing attention, some other critical products have not been adequately considered. An interesting area of research would be to elucidate the precise mechanisms of remanufacturing specific medical devices.

9.5.2. Future research on the wider remanufacturing industry

This research has thrown up many questions in need of further investigation. For example, a question like “how can customer considerations in remanufacturability decision-making improve acceptance of remanufactured auto parts or electronics products?” “How can customers be adequately factored into the decision processes of auto remanufacturers, especially the OEMs and TPR with large customer databases?” More broadly, research is needed to determine the impact of customer considerations on the design process or new product development.

Further studies need to be carried out in order to validate the outputs of this research in other sectors. Although a customer-driven remanufacturability decision framework has been developed and validated in this thesis, further research is required to determine whether the framework is practically relevant within other remanufacturing sectors.

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Appendices

Appendix A: Participant response to AHP questionnaire

Appendix A-1: Completed pairwise comparison for participant 1

Part A: Background

1. What is your current position in your organisation?

Independent Medical Devices Professional

2. What is your area of specialisation relating to medical device?

Medical Device Management, End of life and Charity Donations

3. Where are you located?

Bridlington, England, United Kingdom

4. How many years of experience do you have working with medical devices?

39 years

Part C: Pairwise comparison chart

Factors	i. Quality	j. Available information	k. Price	l. Warranty	m. Added value services	n. Brand equity	o. Environmental friendliness
i. **Quality of product** in terms of performance and safety	1	7	2	3	4	2	9
j. **Available information** (e.g. previous use, expected life, quality certification)		1	1/7	1/7	1/2	1/5	3
k. **Price** in terms of acquiring, operating and maintaining medical devices			1	1/2	3	2	8
l. **Warranty** provided on the medical device				1	1	1/3	6
m. **Added value services** including post-sales technical services					1	1/4	5
n. **Brand equity** in terms of who performs the remanufacturing operation.						1	9
o. **Environmental friendliness** in terms of waste generated, material and energy consumption							1

Does this study cover all the factors you would consider when deciding to use/purchase remanufactured medical devices?

- **Yes**

If you answered 'No' to the question above, what other factors would you like to include?

Appendix A-2: Completed pairwise comparison for participant 2

Part A: Background

1. What is your current position in your organisation?

Head of Service, Medical Equipment Management

2. What is your area of specialisation relating to medical device?

Medical Equipment Asset Management

3. Where are you located?

Queen Elizabeth Hospital, Glasgow

4. How many years of experience do you have working with medical devices?

37

University of Strathclyde

Part C: Pairwise comparison chart

Factors	i. Quality	j. Available information	k. Price	l. Warranty	m. Added value services	n. Brand equity	o. Environmental friendliness
i. **Quality of product** in terms of performance and safety	1	9	2	4	8	8	6
j. **Available information** (e.g. previous use, expected life, quality certification)		1	1/5	3	5	3	3
k. **Price** in terms of acquiring, operating and maintaining medical devices			1	2	8	8	8
l. **Warranty** provided on the medical device				1	5	5	5
m. **Added value services** including post-sales technical services					1	1	1
n. **Brand equity** in terms of who performs the remanufacturing operation.						1	1
o. **Environmental friendliness** in terms of waste generated, material and energy consumption							1

Does this study cover all the factors you would consider when deciding to use/purchase remanufactured medical devices?

o Yes o No

If you answered 'No' to the question above, what other factors would you like to include?

Appendix A-3: Completed pairwise comparison for participant 3

Part A: Background

1. What is your current position in your organisation?
   Acting Head of Medical Equipment Management

2. What is your area of specialisation relating to medical device?
   Anaesthetics and ventilation

3. Where are you located?
   East of Scotland

4. How many years of experience do you have working with medical devices?
   28 years.

University of Strathclyde

Part C: Pairwise comparison chart

Factors	i. Quality	j. Available information	k. Price	l. Warranty	m. Added value services	n. Brand equity	o. Environmental friendliness
i. **Quality of product** in terms of performance and safety	1	3	1	3	3	1	3
j. **Available information** (e.g. previous use, expected life, quality certification)		1	1/3	1	2	1/2	1
k. **Price** in terms of acquiring, operating and maintaining medical devices			1	4	2	1	3
l. **Warranty** provided on the medical device				1	3	1	5
m. **Added value services** including post-sales technical services					1	¼	4
n. **Brand equity** in terms of who performs the remanufacturing operation.						1	8
o. **Environmental friendliness** in terms of waste generated, material and energy consumption							1

Does this study cover all the factors you would consider when deciding to use/purchase remanufactured medical devices?

o **Yes** o **No**

If you answered 'No' to the question above, what other factors would you like to include?

Human factors; ease of use / likelihood of user making as error.

Appendix A-4: Completed pairwise comparison for participant 4

Part A: Background

1. What is your current position in your organisation?

Head of Electromedical Equipment Services

2. What is your area of specialisation relating to medical device?

Equipment management

3. Where are you located?

Scotland

4. How many years of experience do you have working with medical devices?

30

University of Strathclyde

Part C: Pairwise comparison chart

Factors	**i. Quality**	**j. Available information**	**k. Price**	**l. Warranty**	**m. Added value services**	**n. Brand equity**	**o. Environmental friendliness**
i. Quality of product in terms of performance and safety	**1**	**5**	**3**	**2**	**2**	**2**	**8**
j. Available information (e.g. previous use, expected life, quality certification)		**1**	**3**	**2**	**3**	**2**	**5**
k. Price in terms of acquiring, operating and maintaining medical devices			**1**	**½**	**1**	**1**	**4**
l. Warranty provided on the medical device				**1**	**3**	**2**	**5**
m. Added value services including post-sales technical services					**1**	**3**	**2**
n. Brand equity in terms of who performs the remanufacturing operation.						**1**	**7**
o. Environmental friendliness in terms of waste generated, material and energy consumption							**1**

Does this study cover all the factors you would consider when deciding to use/purchase remanufactured medical devices?

XYes ~~o No~~

If you answered 'No' to the question above, what other factors would you like to include?

Appendix A-5: Completed pairwise comparison for participant 5

Part A: Background

1. What is your current position in your organisation?

Head of Medical Physics & Clinical Engineering

2. What is your area of specialisation relating to medical device?

Diagnostic Imaging

3. Where are you located?

Epsom & St Helier University Hospitals NHS Trust

4. How many years of experience do you have working with medical devices?

30 Years

University of Strathclyde

Part C: Pairwise comparison chart

Factors	i. Quality	j. Available information	k. Price	l. Warranty	m. Added value services	n. Brand equity	o. Environmental friendliness
i. **Quality of product** in terms of performance and safety	1	6	5	2	3	3	5
j. **Available information** (e.g. previous use, expected life, quality certification)		1	1/4	1/3	2	1/2	3
k. **Price** in terms of acquiring, operating and maintaining medical devices			1	1/3	3	2	4
l. **Warranty** provided on the medical device				1	4	2	4
m. **Added value services** including post-sales technical services					1	1/4	4
n. **Brand equity** in terms of who performs the remanufacturing operation.						1	5
o. **Environmental friendliness** in terms of waste generated, material and energy consumption							1

Does this study cover all the factors you would consider when deciding to use/purchase remanufactured medical devices?

- o **Yes**
- o No

If you answered 'No' to the question above, what other factors would you like to include?

Appendix A-6: Completed pairwise comparison for participant 6

Part A: Background

1. What is your current position in your organisation? Chairman

2. What is your area of specialisation relating to medical device? Asset management and policy

3. Where are you located? Bedfordshire

4. How many years of experience do you have working with medical devices? Over 30 years

University of Strathclyde

Part C: Pairwise comparison chart

Factors	i. Quality	j. Available information	k. Price	l. Warranty	m. Added value services	n. Brand equity	o. Environmental friendliness
i. **Quality of product** in terms of performance and safety	1	2	2	1	6	3	7
j. **Available information** (e.g. previous use, expected life, quality certification)		1	1	2	7	1	7
k. **Price** in terms of acquiring, operating and maintaining medical devices			1	2	5	3	7
l. **Warranty** provided on the medical device				1	2	½	5
m. **Added value services** including post-sales technical services					1	½	3
n. **Brand equity** in terms of who performs the remanufacturing operation.						1	5
o. **Environmental friendliness** in terms of waste generated, material and energy consumption							1

Does this study cover all the factors you would consider when deciding to use/purchase remanufactured medical devices?

- Yes
- No

If you answered 'No' to the question above, what other factors would you like to include?

Regulatory compliance, Spare parts availability, Maintenance training, and User training.

Appendix B: Transcripts of semi-structured interviews

Appendix B-1: Semi-structured interview transcript for participant 1 (Company A)

Meeting 1

Interviewer:

Participant 1: Did you get a chance to go through the public information that I sent you earlier?

Interviewer: Yes, I did… I was going to start by thanking you for sharing that wonderful piece of information with me. I have gone through the documents and videos and have employed them in drafting topics or areas I would like to discuss with you today.

Participant 1: Great.

Interviewer: I have read quite a bit about what has been written about the background to COMPANY A's refurbished systems through the COMPANY A XA programme, which I think is very fascinating. As a start to this discussion, could you give me a brief background about COMPANY A's XA Programme?

Participant 1: The COMPANY A XA Programme started in 1997 (about 24 years ago) and the reason it started (at the time) was to handle products that were coming off lease for us. At the time, we were simply brokering these systems out to other companies to go and sell. However, as we looked like we had more and more volume of these systems coming back, we saw the business opportunity for ourselves to be able to sell them ourselves and to add value by doing the refurbishment and then selling them to *similar customer bases that we were already reaching out to.*

We just thought we could get more value for the products as well as control the quality of our products and our brand in the install base if we would do the refurbishment and remanufacturing ourselves instead of just brokering them out to a third-party who would most likely just directly sell the equipment to another customer. So, part of it was financial and part of it was protecting our brand, protecting the COMPANY A product brand without customers.

Interviewer: Hmmm, I'm just wondering, back in 1997 knowledge of sustainability and environmental conservation, reprocessing has not fully developed so I'm wondering, how was COMPANY A able to develop and fully explore the idea of

refurbishment or remanufacturing? To develop standards and business procedure, how did the business get on back then?

Participant 1: We were driven mainly from a financial standpoint. Our products have a high residual value and so really it was financial at the time and not much from a sustainability standpoint. When the sustainability become more popular, that's when we started to look more at recycling options for items that we could refurbish or parts that we are replacing then we moved more from a financial standpoint. Most importantly, the business started from a financial opportunity and to protect our business name so that we don't have COMPANY A medical equipment go to a customer, but they wonder why it's not working correctly because maybe it's been refurbished by a different company and there may be parts missing when we ended up sending them through these brokers.

So, it wasn't driven in 1997 from an environmental or sustainability standpoint. It was more from a business opportunity and protecting our brand and ensuring we have good quality products in the hand of our customers whether we sold them or somebody else sells it to them.

Interviewer: From the points you've raised, it shows that customers are very important for COMPANY A as a business. Also, I did read about how customers are at the core of COMPANY A's refurbishment operations. I'm just wondering from what you've said and what I read in the materials you sent me, about ISOs (independent Service Operators) which would be like third-party vendors, does COMPANY A engage ISOs or third parties?

Participant 1: We do not have third parties refurbish for us at COMPANY A, so we do the refurbishment ourselves. We do have a part of our business where we service competitive equipment so we may use independent service organisations to do that which I believe is out of the scope of what we are talking about. But when we talk about our refurbishment operation, we do not outsource our refurbishment activities.

We may outsource the painting process, or the servicing of a particular component but we do not outsource the entire refurbishment operation.

Interviewer: Thanks for shedding light on that. The next thing I'll like to know more about, as a background to COMPANY A's XA operation is the type of reprocessing

operations that COMPANY A XA entails. I have read several publications where it was called repair operations, refurbishment, remanufacturing and even recycling. Would you be able to shed lighter on that?

Participant 1: Yes, so when equipment come back, we have a disposition criterion. Depending on what the equipment, it could be refurbished or remanufactured and I'll go into the difference between the operations.

Equipment that we know our customers want to purchase in the future and it has a high residual value, we'll refurbish or remanufacture it and sell it again. If it's equipment that our service business needs part from, we'll send it through our part servicing process. So, the system will get tested and sometimes the sub-assemblies also get tested, and we'll use that system for parts to be able to supply our service business. Or parts that may be obsolete or high-valued parts that we need to use to make sure our customers are up and running. SO those are two different areas.

And then, if we don't need the system for our XA business for refurbishment, remanufacturing and our service business doesn't need the system then it goes through our renewable resources area of the business where it gets broken down for recycling. When we go through the business of recycling. We try to get whatever we can out of that system.

So those are really the three areas that a returned system could go through.

Interviewer: If I got you correctly, you've said that return systems could go through either the refurbishment, remanufacturing or recycling route depending on the type of medical equipment that it is. However, if your business service units, you would harvest the parts and get them sent to the service business and not send the system through your refurbishing, remanufacturing or recycling process within the repair facility.

Participant 1: All three operations happen at out site in Oak Creek County near Milwaukee Wisconsin and Participant 2 could tell you more about those processes as they all happen within his factory.

Interviewer: Ohh great, I'll speak more about that topic with Participant 2 then.

Participant 1: Or maybe I can speak more about the difference between refurbishment and remanufacturing in the US healthcare market. So, the FDA has a definition for

remanufacturing. The definition for remanufacturing for medical imaging equipment is: If we bring back a specific product and we make significant changes to the product and then sell it again so its outside of its original registration, has a different intended use then that's determined to be remanufactured.

So, if we have a piece of Xray equipment that we bring back and originally it was just an analog Xray machine where you would read films, you know, printed film and you'll read it. If we take that equipment back and change it to a digital model where you could read the images on a screen, that significantly changes how the customer uses the product and that would be remanufacturing.

Another way to look at it is, when we register a product, it's under what's called a 510(k) – that's just a process the FDA uses – a form of registration. So, when we bring back a certain product and it becomes a different 510(k) or a different registration, for us that is remanufacturing. This is specific to the US market and is specific to the US FDA.

So that's why we use different terms between refurbishment and remanufacturing.

Now if we bring a product back that we refurbish, you know, that we reprocess it through our reprocessing facility and it's the same registration, same 510(k) then we call it refurbishment.

And then the difference to the FDA is that if you remanufacture products, then you are subject to the same FDA oversight, audits and scrutiny as a regular manufacturer. So, if you're a remanufacturer, the FDA treats you like a manufacturer. So, they can come in and audit your products and go through. A full audit with you from an FDA standpoint. If you refurbish product, you are more likely to be seen as a servicer. And there are different requirements for a servicer than for a manufacturer of medical imaging equipment.

In the site we have at Oak Creek, we both refurbish and remanufacture so it is really considered a remanufacturing site so the FDA could really come in and audit us at our site.

That's why you hear different terms of refurbish and remanufacture. Most companies would try to make sure that they're only involved in refurbishing because then they would be subject to less oversight, less scrutiny and less risks of the FDA coming in to audit.

But in some cases, it makes sense for us to remanufacture because those are the products our customer really wants. If we add an upgrade kit, that causes us to go from one 510(k) to the next 510(k) then that's remanufacturing. If it's really what our customers want and it's the best use of our assets coming back, then we feel comfortable to remanufacture.

The process that we use, it all flows through the same activities. It's just how we label it and segregate if for discussions with the FDA.

Interviewer: You talked about making significant changes to the product and different intended use, does it mean that it is impossible to remanufacture, for example, a CT scanner such that it retains the initial intended use? That is, a CT scanner retains the intended use of a CT scanner after remanufacturing? Or does it have to be specifically a different purpose? Like, an equipment which used to be a CT scanner now functions as an Xray equipment after remanufacturing. I think I could use some more clarifications here.

Participant 1: Let me try and explain again. We may take back a CT machine and may have the capability to do certain scans, maybe this CT is suitable for orthopaedic scans or for more basic scans like bone structuring and things like that etc. Now, if we take it back and we have an upgrade kit so we upgrade it so it can also do cardiac scans or liver scans, or it can do vascular type scans. Now someone may say you are changing the intended use of how that original product was put out. Now that is considered remanufacturing. We may also end up changing the performance so in the past if it was a 4-slice system so maybe a slower system and then we put an upgrade package on it and then it becomes a 16-slice or a 32-slice system, now we are changing the performance by adding an upgrade package and now that can be considered remanufacturing.

We work with our regulatory team to determine whether the upgrade or the changes we are making to the product is or is not remanufacturing.

Interviewer: Ohh okay, I think the FDA definition (and COMPANY A's remanufacturing operation) is consistent with the UK and EU definitions of remanufacturing and the key point is remanufacturing is such that a remanufactured product has same features and performance as an equivalent new product. For example, we a product initially manufactured in 2003 is remanufactured, the standard or quality

output of the equipment would be like the 2020 (or latest) model of the same product. Of course, the consequence of this would be an increased functionalities and different technological upgrades so that would be remanufacturing. But by keeping it at the same 2003 standard or upgrading to around 2010 or later versions (or any other version asides the latest model) would fit in as refurbishment. Would not it?

Participant 1: Even though we are refurbishing it may still meet today's standard. I mean, from my standpoint, it is not necessarily the specific standard its more about how the product was originally registered. Even within Europe it is similar. In Europe they don't have the 510(k) but they have the DoC (Declaration of Conformation) or the CE markings and so it's the same thing Europe since really, we need to stay within the same declaration of conformance of what the product was originally in other for us to sell it back into the market.

So, I think in other industries, they may have a different definition or sometimes, refurbishment remanufacture rebuild are all the same but it's in the US and healthcare industry, there's a specific definition from the FDA on remanufacturing so we really must follow those laws.

Interviewer: I'm sure there is a similar and corresponding definitions for that Europe and in the UK

Participant 1: Yeah, in Europe in the medical devices directives it is called fully refurbishment instead of remanufacturing because they don't use the term remanufacturing (they call it fully refurbishment).

Interviewer: Ohh that is very correct. However, in the U.K. guidance through the MHRA has remanufactured medical devices but the definition is just a little too much to the extreme to discourage remanufacturing of medical devices. But they do have remanufactured medical devices, but I believe it's not very clear and a bit to the extreme to prevent people getting into it.

But thanks very much for giving that extra clarification. I will also refer to the FDA definitions of these processes…

Participant 1: The other point I wanted to make is that when we do remanufacture, we don't create any new product that has not been install base for COMPANY A. So XA doesn't create any brand-new products. Even if we remanufacture, we upgrade

the system to be something like what we are already selling in our install base. So, we don't create any brand-new products, we just upgrade it to something we are already selling today. So, we don't create a new 510(k) or a new registration for our products in XA, it something that already exists from the COMPANY A new product group.

So, what customers could do is that: so, they've got a product they bought 10 years ago from COMPANY A, let's say and MR system they may buy a new system and trade in the old one or they may just upgrade the old one. And so, there is upgrade kit that we will sell to them and install for them so it's like a new product, but they don't have to return the expensive magnets and rip apart their whole hospital, they can just upgrade all the electronics cabinets. So, what we do within the XA business is we do that same systems upgrade but it's on a system that came back to us from another customer, we add that service upgrade kit and then we sell to another customer. But it's really the same process that the service business does for existing customers if they want to upgrade their technology.

Interviewer: What are the target areas market areas for COMPANY A XA business? You mentioned earlier something about reaching the same customer bases for the newly manufactured systems. I'm asking this because what's been written is that reprocessed medical devices are usually targeted for low-resourced settings such as sub-Saharan Africa, Asia etc. Also, some businesses and charity organisations seek to send/donate second hand, pre-owned or pre-used medical devices to these regions, rather than into their own markets or the developed economies.

Participant 1: So, I can tell you my perspectives of this, but you can and should ask Participant 3 too since he's the plant manager, he can maybe give you more details.

We focus on many different customers segments. It's not typical for a research hospital to buy from XA. Typically, they have very high capital budget, and they want to buy the latest technology equipment. So, a big research hospital like Stanford or Duke University in the US, they typically will not purchase a XA system, they'll buy brand new.

But we do focus on the US market, the European market the Japanese market as well as some of the other developing markets. Typically, we are going to specific outpatient clinics where they may be higher volume and they are looking to add some capacity to their current equipment, or they are on some specific types of budgets.

We do go to the developed markets and then from a developing market standpoint, we don't just divert all our equipment to the developing market like sub-Saharan Africa or to India or some other regions that are in more of a developing mode. But we do use pretty much the same sales reps for the new equipment as we do for the XA equipment.

We have pretty good business in India, that's one of the developing markets where we do well. We don't do so well in Africa and sub-Saharan Africa and part of it is some regulatory constraints that happen but it's difficult to do business in those regions. Some of it is in the past, we've sold equipment but there's not necessarily trained individuals to run the equipment. We could even donate equipment but if we don't have a good service presence there or there aren't enough trained doctors and technicians to run the equipment then it's not very useful to sell or to donate equipment in some of those areas. So, in those areas it might be better to have a simpler equipment like an ultrasound that is simple to operate but to install very expensive and complex machine like an MRI machine then sometimes that's very difficult to do if we don't have trained technicians, if we don't have very good service presence in those areas even if there is a very urgent need and the government hospitals want to purchase them.

So, I would say, we don't just target developing markets and lower price sensitive customers just because its XA equipment, we really go after many different segments and many different countries, and we leverage our broad sales team to do that. So basically, they will position new products and then if the discussion goes to price and we're losing on price, then we will have discussions around our XA options. So, we still have very good quality equipment with many of the different options that they need but the price will be less. Participant 3 would give you more details about that.

Interviewer: To chip this in very quickly, I taught a course this last semester on sustainable manufacturing and there was an idea about remanufacturing medical devices and operating out a service-based business model in Nigeria. The student's assignment produced really good results some of which include the problems with running/operating such a business in developing countries like Nigeria. Poor infrastructure, troublesome logistics, insecurity, poor training, and lack of skills to operate and maintain the medical equipment.

Before we go further, could you make a quick clarification between refurbishment and remanufacturing and recycling in terms of the work content (input), in terms of the warranty, in terms of the price and in terms of the functionality (Or performance)?

Participant 1: From a warranty standpoint, we give the same warranty on our XA refurbished equipment as we do for new. For us, remanufacturing, refurbishment is the same. From a commercial standpoint, the warranty is the same as a new piece of equipment. Typically for an imaging equipment, the warranty is 1 year and there's always the service contract. Normally when we sell an MRI machine, the customer will purchase the equipment and purchase the service contract. The first year there is a warranty and subsequently there's a service contract that covers the customer and there's different levels of service contracts.

Interviewer: What about in terms of the work content, price and performance of the equipment? Which of refurbished or remanufactured equipment is higher if at all there's any difference?

Participant 1: For the most part, the activity for us is the same for refurbished and remanufactured equipment. The system goes through the same factory, done by the same individuals, the only difference is that the remanufactured equipment may have an upgrade on it that would take it from one 510(k) to another 510(k). So, it's possible that remanufacturing could involve more labour hours with that upgrade kit. It's possible that it may cost more because we may have to purchase the upgrade kit internally from another COMPANY A factory most likely or maybe the resources may come from a supplier. So, it may be a little bit more costly, a little bit more labour hours for remanufactured equipment but really, we process it the same within our factory and the only real difference is that we put a label on it that says it's been remanufactured and for the refurbished equipment we put a label on it that it's been refurbished. However, within the factory itself and what the customer sees as far as the quality of the equipment, there's no real difference between refurbished and remanufactured. Its more how we segregate it from a regulatory standpoint and how we report it to the FDA.

Interviewer: So, I imagine the performance of the refurbished and remanufactured equipment will be very similar if not the same, is not it?

Participant 1: Correct.

Interviewer: I think the last set of topics to talk about to just how important customer consideration is decision-making about what to refurbish or what to remanufacture based on your opinion. From you experience, how important do you think customer considerations in decision-making is to COMPANY A Healthcare?

Participant 1: When we refurbish an equipment, we really refurbish it to a standard level before we offer it to the marketplace. So, we don't technically find a customer, ask them what they want and then refurbish it to their standard. We have a certain CT product, and we will refurbish it a certain way, we put it in the inventory and then we sell it that way to a customer. We can always add different add ons and software and things like that but from our marketing teams, we understand what our customers are looking for, what kind of options they are looking for, what's critical to them, etc. Sometimes, there are regulatory concerns that come out that drive our decision-making. For instance, in the US for certain reimbursements, there needs to be a package on the CT system which can capture information from a radiology standpoint on how much radiation a patient is receiving and being able to change the algorithms so that you're not giving such high dose to the patient. So really its all-round dose management and our customers will want to have specific dose management package and the hardware to go along with it. So those are the kind of input we get from a general standpoint from our marketing team, and we make sure that if we get an equipment back that doesn't have this dose management package that we upgrade it to be able to meet those requirements of our customers. So, some of it is just from a spec's standpoint and certain types of scans that our customers want to do, or volume or speed or projectivity and some of them are driven from a regulatory standpoint as well.

Interviewer: Are there specific types of equipment that are refurbished or remanufactured because customers would demand it or some specific equipment you do not put through the XA process because customers would not purchase it.

Participant 1: I think some of them is dependent on age or features and I don't think there's a single piece of medical equipment or modality that we don't refurbish because if the customers are buying in new then they will buy it as refurbished as well from an imaging standpoint. However, if the equipment (e.g., Xray equipment) is 20

years old and you can't read the exams digitally, we're probably not going to try to refurbish it and sell it because nobody is going to want to buy that equipment. Also sometimes, the new equipment would be less expensive to purchase anyway than the 20 years old equipment remanufactured. But I can't think of a certain equipment or modality that we won't just refurbish because customers won't demand it. I mean, if they are buying replacement parts for that same modality and they are trading it to us, typically there'll be a market for it, if it not too old and the technology has passed by.

Interviewer: Just a recap of what you've said so far, COMPANY A XA products is done to certain specified standards which is equivalent to the standards of a new product. Typically, the goal of COMPANY A refurbishment or remanufacturing is to produce the highest standard equipment rather than targeted towards specific customer requirements.

Let's say for example, a certain hospital somewhere needs a piece of MR machine for a certain operation only. Could be because they do not really need the machine to perform those other functions but really need it to do specific functions. Say out of 10 functions, they would only require 5 in the reprocessed product. Is that even possible in your facility?

Participant 1: Yes, we could do that if wherever we end up with it, so we make these changes and that's already a product that we sell new and exists in our install base for some customers. So, if it doesn't create a brand-new product for COMPANY A, and we are just making it like some other products that we have in COMPANY A then we can do it.

Within the XA business, we do not have the design expertise like the new product group to create something brand new.

Interviewer: On the information you sent me discussed about a process of evaluating machines if they can be upgraded. This, in remanufacturing, is referred to as remanufacturability assessment but I imagine assessing upgradeability would be more appropriate in this situation. Could you discuss, based on your experience, how is this process performed?

From what we've discussed up to this point, factors such as the age, features and technology, I'm just wondering, is there any other factor that you'll like to add to this?

Participant 1: Yes, I believe that for the older equipment, key factors would include parts availability and the obsolescence of equipment as well as the cost to do the upgrade. So, I think those are some of the concerns and the issues. So, if we get a very old piece of equipment back and we want to assess it to see if we can upgrade it to be able to meet the requirements of what our customers want us to be able to sell to them. If an equipment has quality issues or concerns before, we don't want to reintroduce these concerns back into the marketplace and if there are obsolete component that we cannot get or uses, let's say we have like a tape drive or a DVD drive or some type of drive that is not common anymore because its computers have evolved.

So, I think some of the decisions is about cost, some of it is around the availability or obsolescence, so there's a lot of different factors that we use besides just the age of equipment.

Interviewer: One would think that since most of the equipment are manufactured by COMPANY A, it would be easier for your engineers to assess specific components in a system, including for example the ease and depth of disassembly. I'm just curious here, now that Design for environment is a big topic, how much of COMPANY A products are designed for reprocessing (refurbishment and remanufacturing)?

Participant 1: I know there is a very big effort from COMPANY A to design products for service so design for serviceability is a thing at COMPANY A. Our equipment must go through preventive maintenance, they are technically complex, and we sell service contracts to our customers so we need to make sure that our equipment can be serviced appropriately.

As the design owners, use the input from the service team for design for service, supports us from a refurbishment and a remanufacturing standpoint because the activities we are really doing to the equipment is servicing. So, when we disassembly it, it's like the way that a service field engineer will disassemble and maintain the equipment in the field. So, we do have inputs into our new product introduction process, the XA business does but a lot of what we benefit from are the design for serviceability. So, design for service will help us for refurbishment as well as for recycling and a lot of it has to do with the ease of disassembly, using

common components, using components that won't become obsolete, easily being able to access critical items that need to be swapped out especially from a preventive maintenance standpoint, and platforming the equipment. So being able to build off generations that add upgrades to the equipment.

Interviewer: One thing we didn't really talk about is the depth of disassembly. Just wondering how deep the disassembly operation at XA is. In one of the materials, you sent to me, it seems to me that there are specific components that are looked out for, such as the magnetic components, and those other parts that have common failure concerns. It didn't look to me like much attention is paid to the disassembly process. For example, in the UK automotive remanufacturing industry, a requirement for remanufacturing is that the disassembly process must be complete. i.e., the product is fully disassembled to scratch and built up from this scratch. What can you say about that?

Participant 1: We do not do complete disassembly at XA unlike in other industries. You will see in other industries such as automotive, e.g., when caterpillar remanufacture their engine, they completely tear it down and they remanufacture it from scratch. But typically, the engines that they get back and remanufacture in these other industries are defective items. These are items that have failed in the field, they've replaced it with another remanufactured one and is coming back for them to remanufacture. So, they need to break it down to the lowest components because it's a damaged equipment. On the other hand, almost all the equipment that we have coming back to us either off lease or trading are already good working equipment. There's really no need to take an electronic cabinet for an MRI system and take all the boards out, and completely disassemble it and take all the components out and then rebuild it again. If we can test the equipment to make sure that it's working correctly then we don't have to take the whole cabinet apart and take the whole component off. So, since we have known-good system coming back to us, we break it into sub-assemblies, we may test those sub-assemblies and then we'll test it at the larger level, we'll do all the preventive maintenance that needs to be done to the equipment, we'll take all the covers off, so aesthetically it looks good since all those covers will be repainted. We'll replace any of the worn-out items like the tube of an x-ray or a CT and everything that the customer really touches like the keyboard, monitors, any of the user interface – all those

things would be brand new. So, you're right we don't completely disassemble right down to the component level and reassemble again from a remanufacturing standpoint and then send to a customer because there's more threat for us to do damage and cost quality issues by disassembling something we don't need to disassemble. It's just more efficient for us to test and make sure that the equipment is running correctly then we don't disassemble it any further than that.

Interviewer: Just wondering if it's not possible for a functional equipment at the time of testing to dysfunctional by the time it gets to the customer. My concern her is if the quality of an entire sub-component is certified by performance testing rather than individual part evaluation plus testing. Based on the concept of remaining useful life, is not it possible that a primary part (with 2 months remaining useful life) used in a subcomponent test correctly and is then used in a remanufactured equipment and given a 1-year warranty. All things being equal when that part fails within 1 month of use (there will be concerns about the quality of refurbished medical devices. Is this not the case, or what do think about that?

Participant 1: We look at that. So, when we create a program for our XA product, we identify mandatory replacement parts. So, anything that is under preventive maintenance schedule are replaced for sure then we also look at the history of that product and any quality issues that there may have been in the past then we will proactively replace those components. So, we don't just take the equipment, test it and send it out if it's okay. We have a process and components that we will replace because of either quality issues or preventive maintenance issues or because of the useful life of the items which usually will be in the preventive maintenance schedule. However, if it's not and we see the history of this product and see certain items fail more often then we'll just replace those items automatically as new. So, if we see a circuit board that has been failing more often than others and we also know there's a new generation of that circuit board then we'll replace it.

Interviewer: Juts to have this on note, the replacement is performed with brand new OEM parts, correct?

Participant 1: yes, it will be the OEM new parts, or it could also be a harvested part.

Interviewer: The harvested parts, what process do you go through to make them reusable? What I'm talking about here is refurbishment or remanufacturing at part or component level.

Participant 1: The system will be tested at a high level to ensure that they are working correctly and then there will be specific tests at the sub-systems level and then sometimes at the parts level so it depends on what the components is but there is a whole process around qualifying that part to be able to be either repaired or simply used again. So, if it's a bracket that just holds on a cover, it might just be in the inspection, if it's the circuit board that has some critical processing to it there may be a board-level test that we need to run to confirm that this board is still of high quality and is working the way it's supposed to.

So sometimes we do that because we can get this component anymore, the supplier may be out of business who used to make this specific board, it may have obsolete components on it so we may need to harvest parts so that we can continue to service our customers and then we may also leverage those parts in our XA business. Most of the time, we'll replace with new but if we're not able to get the parts from parts new because they're not produced anymore then we may need to use a harvested part.

Interviewer: Thanks very much for that and for taking time out of your busy schedule to assist with my research and to contribute to existing knowledge on medical devices reprocessing. Thank you

Participant 1: You're welcome, Damola. When do you speak with Participant 3 and with Participant 2?

Interviewer: My meeting with Participant 2 is 17th February while Participant 3 is on 26th February. What I've done is to put a week in-between the meetings. This will allow me prepare reports for individual meetings, send through to you and get enough time to prepare for the next meeting. The goal of sending the meeting report is to serve as an extra layer of proofing and verifying the validity of the collected information. I would appreciate if you can take your time to go through the reports, make comments, corrections and even additions. Also, it would be a

good idea when you read the reports to note possible NDA issues before it sent to Nathalie for her written approval.

I would usually send the report within a week.

Participant 1: Thanks very much Damola. This is an important topic for me. I am very passionate about it so if you need to discuss further about this, feel free to reach out to me and we can talk more.

END OF MEETING 1

Meeting 2

Interviewer: Thanks for meeting with me again today. I have just a few more points I want you to go over. So, COMPANY A started reprocessing in 1997 (I believe), I am hoping to create a timeline of products that re commonly refurbished and their quantities over the years, I'm not quite sure about the sensitivity of that information but it'll be good to have an idea (maybe a range, or percentage or something of sorts) to reflect the growth of refurbishment operations at COMPANY A.

The second point I would like to discuss with you is the refurbishing standard at COMPANY A… could it be ISO13485, or are there specific FDA regulations that govern the reprocessing operation at COMPANY A

Participant 1: I don't have the growth numbers all the way back to when we started back in 1997, but I do have some growth numbers from 2016 to 2019. SO, I know that we've grown like 18% during that timeframe over the 4 years 2016, 2017, 2018 and 2019. So maybe like 5-6% a year. So, we have had some good growth over the last 4 years. That part I know but as far as going back to the beginning in 1997 I don't have those numbers. But if you wanted to try and get more details on those growth numbers from Siva. You know, like what you might be able to say and draw out from that standpoint. So, once you've finished with each of us individually, it might be good to go through some of that with Siva and ask him from a growth standpoint what he would be able to show and what would be good to… He'll be able to complete the story that you're trying to tell.

Interviewer: Brilliant, that is right. As soon as I finish this round of interviews, I'll reach out to Siva to schedule a meeting to go over what I've gotten from everyone.

Participant 1: It's just to focus on the high point of the discussion you've had so far, to keep him a little abreast with the activities and the progress.

Interviewer: Something just came to mind now, and that is Participant 2 mentioned about other COMPANY A reprocessing facilities apart from the one in XXX… can you comment about that?

Participant 1: Yes, one is in Indianapolis IN, that's the one that Participant 4 Marker relates to, so he's located there. So, he could maybe even give you information about the site as well because that's where he's located and that's where we do our ultrasound products.

Interviewer: What about the one at El Paso? I remember Participant 2 said they are more involved in-patient monitoring systems.

Participant 1: I'm not very familiar with that… Participant 4 and that group… I think it's low volume and they don't do as many activities so it a forward production site which has a small area where they also do refurbishment. Whereas Participant 2's site, the only thing they work on is refurbishment of medical equipment. Same with the one in Indiana, it's pretty much dedicated to refurbishment. But I think the one at XXX is small and not as significant as what you would see in the one near XXX where Participant 2 is or the one in Indianapolis where Participant 4 Marker is.

Interviewer: You have not yet made any comment on the refurbishing standards.

Participant 1: I can talk about them a little bit. So, you're right that any of our sites where we do refurbishment, we have certificate for ISO 13485. So that's the certification that we have. There's also an IEC standard and that is IEC 63077. So, it is a standard for refurbishment of medical devices. The ISO is more of a process standard while the IEC is specific to refurbishment.

So ISO13485 is a standard on medical devices in general whereas the IEC 63077 is specific to the refurbishment of imaging medical devices.

Interviewer: Thank you for that contribution. In my discussion with Wayne, I asked about efforts by COMPANY A to improve the ease of refurbishing or remanufacturing their products. One of the easiest things to note is Design for X which could be

Design for refurbishment, design for remanufacturing, design for service etc. Do you have any comments about that?

Participant 1: Yes… So, a lot of where we fit in for design for remanufacturing or design for refurbishment or design for disassembly is really… it really coincides with the design for service. So, I would say that COMPANY A has a very large effort around design for service because the imaging product that we produce and sell, there's a big service business for it and the product needs preventive maintenance, it needs service. The service of the equipment is important to make sure that the equipment is working the way it's supposed to, and it lasts if it's supposed to and that it's safe and effective. So, under the umbrella or the flag for design for service we have design for refurbishment as well. So, if they make the product easier to service, easier to disassemble, it will make it easier for us to refurbish or remanufacture it. So, if they make it easier to be able to take out major components and replace it (like the tube in an Xray) that makes it easier for us to refurbish and remanufacture it.

So that's part of the reason why as an organisation, our refurbishment business falls under service. So organisationally, we align with the service business and as we do design for service our refurbishment team of our XA business have inputs to the NPI (New Product Introduction) products through the service business. So, there us design for refurbishment and remanufacturing as a part of our overall design for service effort.

END OF MEETING 2

Appendix B-2: Semi-structured interview transcript for participant 2 (Company A)

Meeting 1

Interviewer: Introduces self, describes research and presents how the interview will proceed.

Participant 2: Welcomes researcher, exchange pleasantries, and is ready to discuss with the researcher.

Interviewer: Basically, I would like you to talk to me today about 1) the XA operation itself, 2) what happens when an equipment comes back for reprocessing? 3) decision-making in the XA operation.

However, before you get started, I would like to present a brief background of my research and what I'm focusing on. Basically, what I'm looking at is the process of assessing the upgradeability of a returned medical system. Take for example, when a piece of MRI machine come back to the factory for reprocessing which could be repair, refurbish or remanufacturing, you go through a process to assess the returned system, the quality, damages, parts etc. I think this process was referred to in a public video about XA as the "stringent selection process". This is what I would like to know a lot about – the stringent selection process. Also, to understand how you make decisions during the activities of the XA operation and how that affects the output which is what the customer gets. So that background is for you to be aware of what I'm focusing on in the research.

So, when you're ready, I would like you to start by talking about the XA process, the operations practised at COMPANY A Healthcare, the steps in the different operations. In my earlier conversation with Participant 1, he talked about how COMPANY A performs repair, refurbishment, remanufacturing and even recycling, So today, I would like to know more about each of these operations, how do you differentiate them, what are the steps involved etc.

I have very little experience in medical devices reprocessing, however I have previously engaged actively in automotive remanufacturing. So, I would appreciate every information and detail that you can provide. Later, I would require a separate meeting to talk me through the entire process for documentation purpose. This, I believe, is something I would observe physically on factory floor during a visit.

Participant 2: Maybe the best place to start is:

A system gets identified as part of a trade in and an order and this is how most of our systems come back. Although, we do also go out and buy directly from customers especially those who are looking to trade their systems in. But most of the time, to make it covert to the automotive model, it's to us when customers want to upgrade their products to something newer and they have this system on site, and we work out a deal for estimating its value.

This is very similar to how you would trade in your car when you're looking to get a new one. So, based on the system, system type and age, we will take it through 3 different paths. First, the most preferred path is the *"XA*" path when we take it back, we refurbish it and sell it to a new customer. That's the most lucrative part. The second path is through our program called "*Harvest*" where when we bring a system back and maybe based on its age, we don't want to put it back through the install base. You would hear me say install base a lot. So, we don't want to put it back through the install base, but we do want to use it to support our customer who currently have a system in the install base that matches it. So, we will do some testing on site, before it gets deinstalled and then based on the test report, we will be able to extract certain parts. What that allows us to do as a business is support our older install base where maybe the repair part or the replacement part is no longer available. We also can do it at a lower cost. The third angle is recycling, that's when we don't have any need for the product in our install base, we don't have any system we want this thing to support and we don't want to reprocess it and we also don't want this thing to go to the *garbage*, thus we will strip it down to as lower levels as we can and try to get it through some form of reuse or remanufacture.

As I look at the portfolio, XA is by far the best financial piece for the business, harvest is the best to help us support customers long term and recycling is doing our part for the best of the environment. The thing about recycling is that everything eventually goes to the harvest, the core goes through recycling as well.

*Asides the XA recycling, we do recycle for all kinds of COMPANY A sites all around the US.

One thing we're very proud of is, about 88% by weight of what comes into the building for recycling leaves through some form of recycler or reuse. So, we are

actually really proud of that. Realistically, what makes up that 12% that we can't recycle are mostly wood scraps like wood edge, skates, pallets etc.

So, once I have this system coming back, it arrives at our warehouse and we do *two levels of inspection.* The first thing we do we call the "*EOL inspection*" which could mean life cycle solutions and realistically what happens there is we are verifying what the customer said they were trading in is what we received. Think about in the automotive world, it's like we are doing the VIN check, we ensure that the VIN number that customer traded in, that we inspect is what we received. The second piece we do in inspection we do, and this is what we've been working in a couple weeks, is called the "*financial inspection"* and we call it the financial inspection because we want to keep it out of the QMS world (the quality management system). This is where we are looking at: is this system financially viable for me to refurbish so we're looking for critical to quality parts, expensive parts, *we also make sure that the part number serial numbers are on our refurbishable list.* I'm going to use the CT scanner as an example, that's one of our core products, one any given system there are close to 80 traceable items. So, things that are considered medical devices (this is where the medical device piece and the automotive piece kinds of differentiates) there's about 80 different items we track and trace throughout their entire life and we need to make sure those items are there and are on our list to refurbish. Sometimes, if they aren't, it's an easy fix for us because over the course of a product life, part numbers will change, product numbers will change, model numbers etc but the core system stays the same. A prime example is in the 2010s the EU market went through a life-free requirement called the RoHS and so a lot of our product models changed part numbers to signify they've made that jump but bottom-line the system is still the same, still refurbish able, and we may sometimes still look if the part number is still on our list, and we catch it there through our inspection. So once that is done and we've accepted the asset as it is, we store it. In previous years, that could be 6 – 8 months, currently our average time for waiting to come to the line is just 2 weeks. So, we've really tried to take wastes out of that process and our inventory. So now I have my system, its coming, we've identified it at the trade in, it's for a refurbished system, it's been inspected to make sure we got the VIN correctly,

that the product received is correct and also that it is refurbish able asset, and that it still has all the critical items.

At that point if we don't have the critical items, we could do a couple of things, we can still accept it and try to go source those critical items we could reject it and go back to the team who accepted the trade in and say "your system is not what we thought it was, it's missing these things" but generally speaking, we don't go back to the customer. We handle that internally. At that point, the customer has already sent it to us, we don't go back and ask them for more, or less we handle that internally. Most of the time we try to make that system reusable. We've committed hours to it already, and in a lot of cases we already know our plans and we're trying to go sell it. So, the system now is in the shop floor.

Based on our orders, *we are make-to-order business*, the order comes in, we then go pull the asset that we need to go make it. I'm not sure how familiar you are with our CT product models, we have the "discovery 750", we have optimus 660, and we have optimus 540, so we start with those three models. Soo, we have families of products that will fit into those models, so when the orders come in we'll grab the asset, and we start the refurbishment process.

Interviewer: Can I ask this, when you said you're a make-to-order business, what happens is you get a new core, strip it down to the component level and store these components in your inventory?

Participant 2: We store the whole system; we don't strip down the whole system. It stays together and we store it as the core.

Interviewer: Ohh good.

Participant 2: So, this is where I think the automotive example and our medical devices example really differ. So, my experience, I'm not sure (You're in the UK, correct?) what it's like in the U.K. but here in the U.S. a dealer selling used cars don't take orders for a vehicle they don't have, they only take orders for what they have. We (our medical devices reprocessing facility) sell products we don't necessarily even have yet. That to me is a fundamental issue, as I look at our model, it is troubling for me as it does drive some friction. But this kind of have some advantage. In the used car model, you clearly distinguish between who sells

a new car vs who sells refurbished so that when you need either of the two, you just go straight to your preferred. In our medical devices model, we use the same marketing team for both new and refurbished systems. That is the same person selling new CT sells refurbished CT. So, when they're discussing with the customer, they say you could get the brand new Discovery 750HD at this price OR you could get a refurbished one at this price. Right, so the way our sales channel work is different and that is why we differentiate ourselves from the sales channel rather than through the supply chain model. And as a result, we accept some certain level of risk that I'm selling something I may not have yet. What Participant 4, and his organisation have gotten exceptionally better at over the years is that we're reducing inventory so one way we would solve that is that if I'm selling what I don't have then you have a lot of inventory, so I don't have to worry about selling too many of a model if I always have 10 of them on my shelf. But that's not sustainable either from a cost perspective. So, Participant 4's organisation has done a tremendous job of driving out that cash. They've done a really good job and we're getting better and better and every quarter feels like the automobile demand and supply. So that is what I am selling what my customers want and that changes how I go and procure assets. So, think about it this way, because of the demand for a 2003 Porsche cayenne, we now go on looking for the 2003 Porsche cayenne and we're offering customers a 2015 model to return their 2003 cayenne. So, Participant 4's team has done a really good job to make that cutting connection to let our demand drive what we're doing to bring back in assets. It is not correct because I'm trying to convince someone to try and sell me something versus a new production and I just go buy more raw materials. I know my raw materials are limited but in the meantime I can go buy what I need. Here we are trying to get more and better signals to the buying team, the asset recovery team on what they need to go get and we've made that connection a lot better. So that gives me some hope that we can be made to order because we have a stronger connection from the order to what I'm going to try and recover.

Interviewer: Yes, that makes a lot of sense, because your business gets easier and better as you try to find the right balance between demand and supply. If I may ask, you mentioned something about selling assets you do not currently have in stock, are

you referring here to the product model or the quantity of the specific product because I believe these are two distinct things, aren't they?

Participant 2: The quantity, it's the quantity.

So, for example, we walk into this year this quarter specifically, with demand for 10 Optimus 660 and we only have 3 in our inventory. So, we're betting on ourselves that we'll go recover 7 more this quarter head. Of our lead time to be able to turn whereas in the automotive example, that will never happen. I am positive there's some analytics in the automotive industry environment where they are saying, see I want to get this kind of car. This kind of car is going to drag more value for me than others. I can imagine they would be calling different people with 2003 cayenne asking, "would you like to trade in your car?" That's what we do, that's the model that we use.

Interviewer: Just to add to what you've said, a stark difference in the U.K. automotive remanufacturing is that they go source for specific products, inspect it and strip it down into the basic component and then store the parts. For make to order businesses, they would begin to remanufacture the product when the order comes in whereas make to stock businesses would remanufacture the product and store the remanufactured product.

Participant 2: Correct. That is correct. So, the focus of our operation is the core, the entire product itself. When the order comes in, I process it. I know what I have, pull it out and go start the refurbishment process.

You asked this question earlier, refurbishment vs remanufacturing:

Basically, there's very little difference but to me (us) what makes the difference is when COMPANY A releases a product, they go through a process submission here with the FDA, called the 510(k) and that identifies the critical features of the product. As we look at XA, we look at the whole product portfolio and we look at what we're offering today brand new, and we look at what do we want to offer in our core XA products. Sometimes, some of the offerings we want to put in our XA products were not originally available in what we originally started with in our core. So, we need to go from the core system to the offering we want to make so we may have to move from one 510(k) submission to a new, a more recent version and whenever you cross over that submission, that's when we deem it

remanufacturing. So, it basically means now we're changing the original Ness of the product to another more of a new product. Otherwise, if we stay inside that same 510(k) then it is refurbishment. So, the remanufacturing option can be as much as a software option as it is a hardware option. Say for example, there's a new software technique that is not originally available in the old system. Sometimes, it is about upgrading a system from what we got it at to current day's version. Almost exclusively, the processes we're doing in those spaces, are released to be done by our field engineers in site. So, there are upgrade parts that our field engineers or our customers could buy.

So, for our discovery 750 model, we have a base model that we launched in 2007, we have a model we just released here in 2021. There is an upgrade part from 2007 to 2021. It may be a lot of stuff but there is an upgrade part. So, depending on where on the manufacturing journey our core system was created, it may cross the 510(k) to get to the new version and it may not. Because sometimes, we just modify what is already out there when we release a new product. If I think about it in the automotive model, it's like the year models of vehicles and we offer tweaks, we repaint, offer LEDs, or change certain parts. Sometimes, it's the whole model change, where we change the front, or the way the bumper works, we modify the engine to maybe go from a v6 to a v8, so these slight tweaks, the interior changes, the LEDs etc might not change the 510(k) but adding a new engine, changing the safety features might and if we have to add those safety features which is really important to us, we would be remanufacturing rather than refurbishing.

Interviewer: Just to add to what you've said, it is this key point that you've just mentioned that clearly differentiates automotive from medical devices industry. Whereas in automotive, remanufacturing is performed at part level, medical devices remanufacturing occurs at product level. For example, an automotive remanufacturer would sell a remanufactured engine block, or remanufactured crankshaft rather than sell a remanufactured Porsche cayenne. In contrast, in the medical devices industry, we sell refurbished CT, or MR system.

Participant 2: Correct

Interviewer: I was going to ask the other time, so refurbishment and remanufacturing having discussed the differences in the end products, do they necessarily go through the same steps, or do they involve different process paths?

Participant 2: So physically, they're all done within the same spaces. Typically, they go through the same process paths and end up at the same places. However, the way we differentiate them is that there are some upgrades that we will do on the product that will be the difference between remanufacturing vs refurbishments. Also, we may do as upgrades but install as refurbish. So, what is most important is where the core started (what the core looked like originally) and where we want to end. So, for example, we could have two systems that we need to do the same upgrades on but because they started at two different spots, one is remanufactured while the other is refurbished. However, *we don't sell them to our customers any different*. We don't tell our customers, you're getting a remanufactured system, we tell them you're getting a XA Discovery 750 HD whether it is remanufactured or refurbished. So, what is an essential part of our sales pitch is the system capability that we have said is core to our offering. Does that make sense? So, in the automotive sense, we would say this is a reprocessed v6 engine rather than advertising as a remanufactured v6 or a refurbished v6 engine.

Interviewer: Yes, that makes a lot of sense. Something just popped in my mind, and I thought I should ask, so the upgrades you talked about, remanufacturing vs refurbishment, are they based on customer requirements. So, for example, a customer comes to COMPANY A and says that they need a discovery 750 HD with certain features which would cause it to jump from one 510(k) to another 510(k).

Participant 2: Yes, so if that's a requirement from one specific customer, our product management team will make a call to us as to what is our core product system so that will dictate refurbishment vs remanufacturing.

It is also possible that we sell a discovery 750 hd and a customer specifically says, "I want the 5 functions". Say we sell it as a refurbished system, it gets delivered and is on the previous 510(k), our field engineers may perform activities that will take it to the next 510(k). But once it's in the field, it won't be refurbished or remanufactured it would just be that we're upgrading the system.

Interviewer: That makes a lot of sense, and I can infer that there's a very thin line between refurbished and remanufactured and that line is the 510(k) but every other thing is basically the same. In other industries, such as the automotive, marine and aeronautics, the factors they use to differentiate refurb from reman are the work content, the price or cost of operation, the warranty and the performance. So, we would say something like remanufacturing is more expensive that refurbishment which I would imagine that would not be the case in XA operations.

Participant 2: Well, generally it can be. We can take it down that line too if we want to. *If I know I want to buy a vintage 2019 system and I need to get it to my current offering today and it's going to be remanufactured, we will pay less for that system. We might pay more for a 2020 system that doesn't need remanufacturing. So, we will value the systems separately because I know that I need to add extra labour or extra material to get it to my current offering. So, to me it's actually worth less than the system I don't have to add that much to.* So that's how we kind of operate, so that in the end we can have a common price point for remanufactured or refurbished. Now there are a couple of differences and exemptions to that rule. There are cases when we offer a better warranty. Up until last year, when you buy a refurbished CT system, it came with a one year warranty, or you could pay a little bit more and get a 2-year warranty. We seem to have gotten rid of the one-year and moved onto a 2-year warranty, now that's our only offering. Now there's a part in our MRI system when you can get new coils or refurbished coils for your system upgrade. So, there's different price points there but the core system is still refurbished.

Interviewer: So, are you saying that using a new coil in the upgrade is remanufacturing while using the refurbished coil is refurbishment?

Participant 2: Fundamentally, they would have the same process based on what the core system is, whether they are remanufacturing or are refurbished. But we could differentiate to our customers, do you want new coils or refurbished coils? And we say this because the coils are only refurbished. We don't remanufacture them. So, we say you can either get refurbished coils or brand new coils as part of your refurbished systems. Refurbishment has a higher price point because we get them back from the system for free. We don't do any repair on them; we just test them and send them along.

The other thing we allow because of how we sell our systems (in that we sell within the new product supply chain) is that we sell you the core system and then you can add anything that is commercially available to it. So, take the automotive example, if I bought a used/refurbished Cadillac and I want to add these extra features to it e.g. I want to add a premium audio package to my used car, I want the cargo neck in the trunk, I want a roof rack and we allow all that customisation in our refurbished or remanufactured systems. It's one advantage of selling the products the way we sell it, and it arrives with our core offering. You're always going to get the core offering and you can add other features that you want that is commercially available. And what is critical to our core offering is driven by our product management team. Have you met with Participant 3 yet?

Interviewer: Meeting with Participant 3 is scheduled for next week 26th February.

Participant 2: So, Participant 3 is our product manager molecular and Xray systems. So, he's looking at it and I believe he's looking at it from "what is the new order selling at, what is core part of our new orders, what does our customer expect to see as part of the core system, and what can we add value to and drive differentiation of the market without adding significant cost?"

I think all business models struggle with the, how much do I put into my core offering, how much do my customers want or are willing to pay and how much do I let them be a la carte.

Interviewer: Exactly, one of the main motivations for my research is to understand how customers' requirements, mostly their willingness to pay and their purchase intentions will affect the operations you would perform in the factory. For example, you pick up a neonatal incubator for refurbishment, just an oversight but do you refurbish the neonatal incubator?

Participant 2: Here at the rock, or at COMPANY A, I don't think anyone refurbishes the neonatal incubator at COMPANY A. We just don't refurbish it. However, we may refurbish patient monitoring and side monitors but not the whole system.

Interviewer: I thought about for example, how customer's demand may affect the amount of work you put into a particular refurbishment or remanufacturing process.

Decisions like are customers going to buy this refurbished. If we do it this way or that way, which one would be more acceptable to customers? In my research I identified a number of factors that may play a huge part in customers decision making and the idea now is to investigate actually how much of these factors are actually put into the reprocessing operations. So, I'm putting this to you, for me to try and understand which key factors are important in your refurbishment or remanufacturing operation and then to see if these factors correspond with what customers are saying and how we can (one way or the other) improve the decision-making process to make sure that customer requirements are catered in the reprocessing operation.

Participant 2: *As a manufacturing shop floor guy, one of the things I have always wondered is "we as a COMPANY A business, are we internally competing with ourselves for no reason. I hear things like new price dropped so we need to correspondingly drop ours. Because I just wonder if we are competing with ourselves for no specific reasons.*

We know what our customer wants, do we treat ourselves, our entire portfolio of CT for example as a true portfolio or do we treat ourselves as the XA business. Are we internally competing and we put the sales guy out there. I'll be interested in seeing where you end up with that. When I talk to Participant 3, Participant 3 has got a really hard job, trying to figure out what do the customers want, how do you price it to both drive our sales guys to go sell it and to make it competitive. Now, that is not only competing against Siemens, Philips etc, it's also competing against our brand new and that friction, I wonder if sometimes it makes us be better or sometimes we just fighting ourselves.

Interviewer: Wow, you opinion is actually very current but I do believe that entry of different sizes of businesses, big, small and medium sizes, into the refurbishment or remanufacturing of medical devices shows that there is great market for it especially in some developed countries, US especially and some developing countries of Africa and Asia – India for example. I actually do believe that reprocessing is a business of the future.

Participant 2: Yeah, I 100% agree. There is clearly a market. Not every customer needs our CT revolution platform, the million-dollar CT, if everyone had that, we'll probably be overserving the market. A lot of customers just need the 6460 scanner

that they can run 20 hours a day because they don't need it for any special purpose. They just need a CT scanner they can trust and I think we need to understand that better and we need to offer those value proposition to our customers like you can get a brand new 660 for $200,000 more but maybe they don't need that, maybe they would rather spend that $200,000 on new patient monitors or ultrasound systems or I can get you this different CT offering etc.

We also have those numerary customers right, the Stanford's, the Dukes presbyterian hospitals right, who want to upgrade the CT every 3 months, they need to be on the cutting edge.

Interviewer:

Participant 2: So, I have my order, I have my system and I am ready to begin the refurbishment process. The first thing we do to start the refurbishment process is to start cleaning, so the first day and half to two days is the cleaning operations. Cleaning and de-thrashing and we do de-trashing first. *So, when a system comes in it will come in with a lot of stuff that we will never reuse* b*ut we don't throw any of it away until we are sure we are going to refurbish the system.* An example is, a system comes back, it comes back with its table, the table that sits outside the scan room or where the technician sits, we don't throw it away. We hold on to it until we are sure we are going to refurbish the system. Because if we need to recover or reuse the system some other way, we're going to want to sell the whole package. But we know that when we sell a new one, we sell with a new table. Our refurbished offering has a brand-new table all the time. So, we do the dethrashing, get all the stuff that is not needed, table sets, things that we know we are going to replace garbage. And generally speaking, at that point you end up with the core system, that's the real core, physical components of the system.

We then go through our negative pressure blow, it's got the wind curtain that sucks air to one side, and we blow off the dust, the dirt, the grim. What we see at this point, there's a lot of services that has not seen a light of day in the entire time it was in the install base. Because of how the system goes together, there's as cover there just what you'll see at the bottom of a refrigerator with a cover on it that has never been cleaned. But when you get a new refrigerator, you want to make sure that the system is clean, and so in our refurbishment process, we go through that process to ensure that all those nooks and crannies, places where the

customer won't normally touch or cleaned, we blow out, we remove dust, clean and try to get it brand new.

After that, it goes through what we call prep-parts, and this is where the process deviates a little bit and its more specific to the system in front of them. We have two list of parts 1) that engineering has deemed we need to replace - these are generally high wear items, things that have a lot of motion on them that do wear over time, that we replace. The second list is 2) parts we deem (as we look at our refurbishing process) that fail, that have higher than normal failure rate while we test the system, so we say that it's just not worth trying to save this part, we're going to replace it. So that two list. And that list can vary as there are some strong themes across product families. So, if we're going to replace this item of 750hd its probable that the item will also be replaced on all CT items. This is also the point where we begin to plan our materials. Those items get planned very rigorously because we know we're going to need them. We have a predictable usage pattern. So, we do that. This is also where we look at rusts because we have some metal surfaces, so we clean rusts off, we grind rusts clean. We take a much stronger look at the traceable items. If they are over 2 years old in some cases depending on the part, we'll replace. We have some age statements, that also come along at this point of the process. We think about it two fold, one we want to prevent it from failing in the field or in our bay, two I am positive that for every customer that buys our system takes a look at some of these things and whether it is right or wrong, these dates make them feel good or bad about the system they're getting.

Once we've completed that, all our cleaning process and all the mandatory replacement components have been done, then we go into our **testing** phase. From there we follow a process specified by our engineering team by what the acceptance activities test and the work that we need to do to get ourselves to the spot where we can do the acceptance activities test. So, for example, in a CT system, there is the imaging component we want to make sure it takes a good image and takes the image equivalent to what it was taking when it was shipped new. However, in order to get it to that process, you need to *install it*, you need to *calibrate the system*, you need to do *some safety checks*, so you need to do a series of processes before we can even get to our acceptance activities. That process today takes about three weeks for a CT but is highly variable based on

the type of system CT, Xray, MR, and the quality of the system because this is where (in the we have something we call Murphy's Law: if anything can go wrong, then it will go wrong), this is where Murphy's law exists. We see those less than 100% replacements, those parts that can fail one out of every three or one out of every 10, this is where we see it. This is also where I would say the heroics of XA exists. This is where our team try to go and source for products with zero lead time. This is also the part where we are doubling down in 2021 thinking, how do we make this process easier? How do we get smarter? We're going to welcome knowledge here and also in our install base, the systems that are brand new, they have a track record in the install base and track how often we replace items, and we need to use these two sets of data to be able to be smarter. The reason it is important to us is these are the drivers of significant lead time impact. So, this is where a system goes from 3 weeks in the bay to 5 weeks because we can't get the part. And those 3 weeks to 5 weeks push, a lot of time, because we are made to order that will mean a 2 week delay on the customers install. So, this is where our guys from the customer services and the delivery perspective that we want to go test.

So now the system has completed all testing we will then tear the system down into its shippable format and send it to our customer. In that process, there is also a documentation review. Then we go through the device history record. It's the story of the system, all the quality checks we did, who did them, what tools they used, so we document that system's life with us at the rock. And we do a verification that we did all the test and that all tests passed, that there was nothing abnormal about the system, that we won't mind sending it to our customers.

Interviewer: And at what point in the reprocessing operation do you decide whether you need a new 510(k) or sell it with the old one.

Participant 2: So, we do that before the system ever starts. So as part of our program, as part of launching the offering, we determine what's refurbishment and what's remanufacturing so we do that before we even start. Everything I talked about, the cleaning, the coil replacement, etc its all the same. In the bay, there may be upgrades we do that will make it a remanufacture what happen in the bay. Because generally, in those cases, we are not remanufacturing, we are using new components to upgrade the system, and a lot of time you need the system up and

running with power on it to be able to verify that the upgrade has happened. And that at the very end there is a decision we make we do a labelling step, and the labelling will either be a refurbishment label or a remanufacturing label.

Interviewer: If I may, where is this labelling step? Is it after the testing activities or

Participant 2: Yes, it's after the testing, right before packing up. But we know the label that's got to go on the system when we pull the core. We know when we pull a core that it's going to be remanufactured, but I don't put the remanufacturing label until I'm done. Generally speaking, when we last did it, we watch this closely because remanufacturing is the reason, we need to register on FDA site, refurbishment is not required for it in the US and we're down to like 4 or 5 products that we remanufacture.

Interviewer: Can I ask please, what are those 4 or 5 products that you remanufacture?

Participant 2: we are down to 4 I think our remanufacturing offerings, there is the portable Xray and there are 3 MRIs most every other thing we do are just refurbishment. This is something we watch closely because therefore we have the certification. My regulatory site leader will say she would rather stop remanufacturing because we won't have to go through this whole certification. But it's a competitive offering for us as a business. And I think of it as what it allows us to do as a site, now that we have the registration, it allows me to do the things that I would not have been able to do if I didn't. And we can look at other growth opportunities. And we can really have our mind open as a business, as we carry out the certification. If we didn't have the certification, it will limit what we can do for our customers. And that's different.

XA used to be in another facility, and it moved here two years ago, that facility was a new CT manufacturing site so it was already a registered site with the FDA. When we came here, we had to register the rock and now that we're registered, my two cents are, it doesn't change my everyday philosophy and why compliance and meeting our regulatory requirements we would have the same level of quality and hold the same requirement whether we're registered or not. To me, the site registration doesn't change that. What the FDA asked us to do makes me better, so I'm going to keep doing it. To me, I don't think it changes much of our day-to-day actions but it would mean we would have one less potential risk.

Interviewer: Hmmm, which means if you keep offering remanufacturing you're open to the FDA visits to audit and scrutinise what you do.

Participant 2: So, I've been in this job over 2 years and I've had 2 audits so far. It is actually that the factory before this was a much larger site with a lot more products registered there. So, they would come in for like 3 weeks and they were rough audits. They were all so good but they were intense. Here, the guy came for 3 days and it was a much friendly audit. We have a small percentage but when he looks through the door, he looks at everything but to be very honest, not that I watch him look at everything but that I know what we require of my team doesn't change whether you're remanufacturing or refurbishing and that's one thing we talk about. Our processes are very similar because my standard is the same. I expect them to be documented correctly, I expect us to do what we say, I expect us to see defects correctly and treat them quickly, so it doesn't mean much that we're registered because we have the same high standard no matter what.

Interviewer: Just one last question, I didn't have the time to ask Participant 1, how many XA facilities are in the US, or globally as a matter of fact?

Participant 2: So up until 6 months ago, we were the only facility that did XA. There is now a factory in XXX that refurbishes, they also make brand new, but they also refurbish patient monitoring systems. That doesn't fall under Participant 4 and the XA team. They sell it separately and are sold a little differently. There is a third one, an ultrasound refurbishment site.

I do here imaging equipment, so you think of Xray, CT, parts, molecular imaging. My counterpart in Indiana does ultrasound consoles, and the El Paso facility now refurbishes patient monitoring systems like bedside monitors, they are small systems. It makes sense for him to do it because he does it new.

Interviewer: Just wondering, are there any sort of collaborations between your facility and these other two new facilities?

Participant 2: Each site has a core function, but we all do other functions. One of my core functions outside of XA is that I'm the returns man for everything in the US. Because of my recycling operations, I get all the trainings for life care solutions, patients monitoring come here but I store the raw materials for the XA operations

they do down in El Paso. So, we're all linked in that way, but they are the product experts, they have their own product management team and engineering team that support their operations and because of how the products differentiates if that makes sense.

I would also look in from the outside, their product management team holds both new and refurbished together there. Our own part management team here at the Rock holds just refurbished and there's a new product management team version of them that holds the new products.

SO, in some ways, that part of the gaps I was talking to you about, maybe we should hold our business as a wide variety of offerings all our offerings together, and I'm hopeful that the patient monitoring business is taking it a bit that way. The reason I'm hopeful is that the people who started the XA operation that refurbishes patients monitoring didn't come from Participant 4's organisation, it came from the product management team who holds those products in new. So, I'm hopeful that's how they view it, but I don't know.

Interviewer: There is a good chance we would need to meet again, to discuss further…

Participant 2: Yes sure, no problem…

Interviewer: I would write a report of this meeting, try to get a good perspective of everything we discussed and highlight key areas for further discussion. This is likely to come after my discussion with Participant 3. I'll send it to you to have a look and make corrections or validate that what I have written is correct and clearly reflects the information you have provided during this discussion. Or we can see if we need to discuss further about that.

Participant 2: Yeah, depending on how deep you want to go on testing, like talk about the testing, there is a couple other folks on my team I could bring in who can provide a little bit more detail on why we test what we test and what we are looking for. So, depending on how deep you want to go after you talk to Participant 3, let me know and we can make sure you have the right experts all the way down to the floor guys or the operators.

The researcher rounds up and appreciates the participant.

END OF MEETING 1

Meeting 2

Interviewer: In the last meeting we talked about the XA process, correct me if I'm wrong, there are 3 main phases of the XA process: the first phase would involve the selection, deinstallation, and transportation where it is stored, the second phase involves the dethrashing, cleaning, disassembly, reworking, testing and packaging. The third phase has to do with the sales team – sales, installation etc.

What I noticed is I didn't really get a lot of information about the controls and mechanisms and detailed description of each of those activities we talked about. So today I would like you to take your time and describe as comprehensively as you possibly can about the processes involved from when the order is received till the completion of the refurbishing process.

Participant 2: So, let's say we start with an order that we need to fulfil. The order is going to be in the finished good level catalogue. First thing we do is to look at the order and then we pull out the inventory a corresponding raw asset which is called the GS because the part number nomenclature starts with GS which stands for XA. For any one specific order type or finished goods, there may be multiple GS options that can be used to remake it. So, if you think about there may be one CT offering, but we could have three or four different GS numbers that could make that CT offering, so we will pull. We will generally pull in FIFO order so the 1st in will be the first GS that we pull into our cleaning area.

CLEANING AREA

So, once it gets to the cleaning area, we are talking about two different types of documentations. There what we call work instruction. And then there's the DHR, which is device history record. So, the working instruction is very simple. It's what the operator follows that tells him what to do. And the DHR, the device history record is how we track… how we capture both regulatory information as well as who completed tasks. It's kind of like our Chuck's checklist on all things that we did, right? The work instructions document depends on the steps, could be specific to the model, like to the GS that you're doing or to the product family, right? So hey, this is what we do for all CTs. So, when it comes into decontamination, we have a work instruction for decontamination that covers all

systems right, but at that point the operator at that station will start the DHR, which will start to track all the work that they are doing. So, they use the work instruction, and that's what tells them the steps to take.

CLEANING PADS

From there, it moves to our cleaning pad, so we have two of them here, this is what we call the cleaning pad one and two. Today they get all the work done at one pad, so the clean part one and two are identical. Okay, they go to one or the other. They don't go to that makes sense. So now they have another set of work instructions that are now very specific to the model that they are cleaning that tells them a couple things where to clean water, clean. What chemicals and tools to use to do it and then what parts we need to replace.

Now I want to tell you I would love to be able to tell you it is very detailed. At this point. We're still working on getting to the right level of detail. Alright, but we try to match the detail we're mixing with pictures. Meanwhile, as they complete the tasks, they will be filling out their DHR with what they've done, and this is also where the DHR will start to change. So, the first station coz it's very generic the decontamination the DHR is relatively the same but when it gets the next station the DHR will specifically call out for the tools they are using, what they're replacing that are better matched to the system that they're working on. This is also the station where material goes out to be painted. But they have a list of these are all the cosmetic covers I need to send out to paint.

In both these stations. I should go one level more detail for CT for example because I think it's the highest volume there, the poor components that they're cleaning and disassembling and replacing, the CT Gantry which is by far the largest, the table, the console and a thing called the PDU which is the Power Distribution unit. So really, the CT system has just four major components that all go through these stations, but they go together so they all go through station decontamination together. Then they all go through cleaning prep, landing pad one together.

So, at this point right, the primary documentation. It also wants to do the work instruction primary where they document the work is the DHR or eDHR and you

hear me, I apologise. I use a bunch of acronyms to travel devices to record. We use a system called EDHR.

TESTING PHASE

So now I have everything cleaned all the 100% parts replaced from there. It will go into a CT bay. So, we have 5 CT bays, so COMPANY A has 17 total bays. The bays are product specific in some cases because the type of infrastructure a MR system needs is different from a CT and is different from an Xray system.

So, I take it to one of my 5C T bays. Once again, throughout the entire next steps of the process, eDHR are the device history record that does not change. However, the work instruction process does change a little bit, so at this point rather than having more detailed tool picture driven work instructions, the next steps become more of a list. Right, but what we have been working on in all cases, creating work instruction, but that work instruction is not more detailed step by step. Instead, it is a list of steps that need to happen and the link to the service manual that gives the more detailed level instruction. So, in this CT bays where we're doing testing, we leverage the released work instructions, the released service manuals that will tell the engineers or customers how to service their equipment. However, we do match the that with our electronic devices to record, so we can prove a document our test results along the way right being one of those things that being a regulated industry and regulatory environment, we need to make sure that only do we do all the tests that we record the data that proves the tests are passed.

So, from there the system goes through what I'm going to call the 4 major phases. The first phase install, it's mostly a mechanical exercise, it's where we're bolting everything to the ground, we're hooking up all high voltage, returning power under the system, and then we go, and I would say it goes as far as some of our safety checks. So early in the process, we make sure the e-stop buttons work. We do a process to start spinning the CT, so our CTs, depending on the model, could spin up to 2 rotations a second, which is 0.5 second a rotation, so we don't know right there, because if something were loose, we're going to do some serious damage. So, we do a process to spin it up slowly. We also do a process to balance the system. Doing that because for it to spin very consistently, we need to have

the right mass ratio on all sides of the gantry to maintain smooth spin, right? So, the team is going through a process of slowly ramping it up as well as slowly balancing it to make sure it can spin at that 2 second of rotation and not to damage. So, once we've done that, that process is probably some of our most consistent, it is very mechanical, very linear.

The next step is our calibration phase, so we run a series of system level diagnostics, but not just on the system itself but also on the individual components of the system to ensure everything is functioning and is calibrated where we give us a best result possible when we get to the next step. So, things like calibrating the focal spot of the CT tube or making sure the table when it goes in and out goes a set and goes into the right place at the right location. So, our CT system is designed so the table will move outside the room move the table in and out in and out of the city and for you to do that you need to train the table to where in and out looks like. So, we're doing those kinds of collaborations we're doing some other things on from work, continue to check other safety setups as we add more functionality to the system. So yeah, just like we, we found that we verify that it can spin slowly before we start spinning fast. We validate at as we apply power, we applied power in step to make sure that we don't go from zero to 200 hundred kilometres an hour and have a severe incident.

And so, we do a series of tests, but the next step is where I'm going is what I would call our acceptable testing. This is where we run, what ends up becoming the important tests that validate the system is refurbishing and working conditions. So, a couple like there's a test that we run... We have a whole imaging test that we run to make sure their image are good. We have tests that we run to make sure the system is reliable and can run like a day in the life of a system. Which means you I'm going to run a couple of images. I'm going to sit for an hour. I'm going to run a couple images right to make sure a normal day is sustainable. These tests, the tests that we do here, once again the work instruction-wise, service manuals via that work instruction checklist I was talking about everything documented devices history record, the test that we run here, though, are specified in a document called the CDMR. So, if you talk to Participant 4, you maybe have come up that is our engineering controlling document. It tells us what

good looks like. The CDMR is what tells us what's the system and then what's the requirements.

So, we matched those together. it's the final level of acceptance testing during this phase and into 4th place is deinstall. So, we move through the system front steps backwards. Deinstall is the place where our work instructions are probably this probably the least detailed right. We kind of leverage the fact that we're going to do the install process backwards as much as we can, there is not great service manual and service documentation around Deinstallation of the system. So, we do deinstall right, so now I would you have it *installed* it *calibrated*, *tested* it *deinstalled* it. Now I do the final packaging.

FINAL PACKAGING

So, this is a space where we will take parts that were not used in the tests testing but are needed at the site and they get packaged together with the core system that we didn't need to test. And then we do device history record review. So, this is where an independent party. Our QA team here will look at that device history record and ensure that all the test meets spec, everything is completed fully, the expertise that we hold ourselves to is that the document can stand on its own. So, in a perfect world, right? If we're doing it well, the DHR would tell the full story of the system all by itself. Alright, so you would not need human to interact to interpret the data to share. It would be that right? We're not there. That's like the high-level vision. That's where we want to be, but that there's two advantages right? By having someone outside do it outside of our normal operating if their independent right? And showing that level of independence is important when we talk about how we make sure our customers are always. And 2 because they are technical experts on the process itself. If we can build a DHR that speaks to them and explains what happened and explains how we solve problems or didn't solve problems, or that we met all our requirements we’re closer to a DHR standing on its own.

While that is going on, usually in parallel we will be doing the final creating packaging of the system, so we talked about like there's some parts of consolidate things like that. And then there are some larger crate or larger packaging boxes that will put over parts of the system just to make sure there's cosmetically sound

between us and the customer. That documentation there, we have a thing called the SIL – Shipping information list. It is a very large checklist with pictures of what the product should look like when it leaves the building. It used to be just a checklist of what is needed to install the system say we have a list of 100 parts in the checklist. Now we've gone a little bit more detailed to pictures. We're trying to figure out if we can get consistent enough packaging to be able to take one like one picture like the product and be able to show people where everything is, if that makes sense. Right now, our packaging is not consistent like our raw material boxes aren't the same size all. That's where we'd like to go, right? Cause it not only for us does it say I have everything. That's probably important, but it could theoretically also be used as a map to the field engineer on where everything is that they need, right? As we continue to work on this process, one thing we're really trying to focus on this year is how do I package the product in a way that makes the most sense to my field engineers, so we package it based on space today? How do I fit how I create the densest packaging possible right? Every Nook, cranny, filled? But that maybe ends up becoming like a searching exercise for the effort to find the things you need. It will be a little better off being a little less dense, but more strategic about how we group material. So, we have the use the parts as we pack them right if that makes sense, right? Exactly, and so if we could. The SIL could be the IKEA instructions, right? And we could organise it in a way were so. And there's levels here, right? Not every install's the same and not every site is the same, right? So, there are some unique setups and some more hospitals. But one thing that the CMR business is trying to do is like hey, can I have a pallet of all the material that is not needed inside the magnet room? Could it go? Could I deliver it separately, right? Yeah, right, and so we're trying to like we do that right? Could we group the material based on where it's needed. And that way it makes this a little bit easier for the field engineers or the mechanical install teams to do their work. One of the things we run into is the system is not necessary received by a COMPANY A person when it arrives, 2. the customer doesn't always have space for all this garbage. So, the first thing people want to do is they want to remove all that packaging. And that's why by the time a COMPANY A person looks at it, it might not look like we sent it. The third thing is between the COMPANY A FE (field engineer) and the delivery. When the COMPANY A FE team show up, there's also a mechanical install team. So we

need to understand… one of the things we're trying to figure out how do we understand all the needs of the customer, of the project and can we package it accordingly, like if we if we had just a box that was mechanical deinstall only guys and the mechanical install guys that's the only place I need to go to look to get everything I need, maybe they would not go tearing the other boxes while trying to find what they need, right? I think in the end like we intend, like the field teams are intending to do all the right things. We don't support them as well as we could with process and packaging, so we end up with a mess trying to figure it out. Alright, we had them a bag of hardware rather than like the, you know, the package like sets of hardware that are needed to do the job, as an analogy, right? So that is 1 space. We're really looking closely at. It's also the modality the forward production group are looking at, and if I can beg borrow just blatantly copy what they are doing. So, for example, the part of product I'm shipping to the field has already been shipped before the field, right? And so, if I can just use what forward production is doing with my products, I don't need to invent this every time right? Forward production is trying to get there, when they get there. I think we'll get better instantaneously and then we just need to remediate the stuff that is not in forward production right now.

Interviewer: So, I thought about it also. I mean if the refurbished or the remanufactured product is very similar in terms of everything to the new product, why not just use the? You know the shipping information list for the new products for the installation manual or the service manual and all those basic things.

Participant 2: So, for the work instructions we do. So, service manual, device manner we do, right? The tricky piece a little bit on it is the service manuals are not always written with the level of detail that you may want, or we may want our technicians to have, for a couple of reasons. 1. They are written to be translated, so the level of depth that they go into is not always as deep as you would like to if you could write. 2. They are written very generically to cover for some product change and while that's helpful from a strategic servicing perspective, maybe it’s not as helpful for us when we look at very specific, doing the same thing multiple times. So, we’re kind of stuck in the middle a little bit. We're trying to figure out where do we need to apply more detail and where we can use the service manual. But

we have not even… in the lack of either one or the lack of having a detail, we always use this old manual.

Recently, the forward product modalities team spent more time thinking about install and parking for install, so when they get better at that we will immediately grow, but for our products that aren't in forward production right now we shouldn’t wait… so we're kind of moving those along while we wait that the MI-CT business figure out CT packaging.

Interviewer: Yeah, so I can imagine for hybrid systems, it would seem. There's no such shipping information for hybrid products because you've literally just come up with them during the refurbishment or the remanufacturing process. So, you are literally new ones for that.

Participant 2: Our offerings at the new system level are the same or similar. And we don't always match it in the underlying structure. So, for example every one of our systems gets a table pad. It goes across the carbon fibre surface, so it's not as uncomfortable. So, in the forward production order that is an accessory that gets shipped along later. Oh, so it's shipped along with the system. In my offering it is part of my core offering so I package it here and part of the reason for that is as you change colour schemes the materials change colour, forward production only has one colour scheme, right? They only shipping new with grey. I may ship this offering with blue or with grey. So, if I did it outside of my refurbished offering, I might send the wrong colour. So, in those cases where there is an “either or” choice? We've tried to be pull those “if or” decision into the site into the factory into the operation because they can see the cover, so they see the gantry said this is a blue gantry and get the blue covers or the blue pad. Ohh, this is a grey gantry, I will get the grey pad and our process allows them to do “either or”. Just so they need a mattress If it's blue, use this one If it's grey, use this one and the technician when he picks the grey one, he cheques the grey box.

Interviewer: Well, so is that where it ends with the mechanical install team, they install it and… I don't know, is that where the process ends?

Participant 2: So, my short-sighted tunnel vision would be the process ends with Ivan when my system is picked up by a logistics carrier to go to go to the customer. Where we really end, where we COMPANY A should say it really ends is when the

system is installed, and it is turned over to the customer. So, the differences between whatever I'm saying it ends, where they and where it should end, and I really do believe it ends right is logistics carrier delivering, the mech install team installing, and the FE doing the final system level calibration? So, in a lot of ways a portion of the work I do here at the Rock it's really done at the site. Alright, because we need to do so, so we need to some of the lot of the install work here just to make sure the system works and when it gets that they need to reduce some of that installed and some of that calibration right and we talked about like the safety checks to make sure it spins fully, for the same reason we do it here the FE doesn't take for granted that everything is fine. They do that same process slowly spin it and that at matches in order to make sure we end up with a safe/same outcome.

Interviewer: So, from what you said I have here about you know the different considerations the other time I told you about. You know looking at customer considerations in your operation and over the weeks I've had a second thought about it because you don't have any problem with your direct customers or the people you would make you would consider during the operations at the you know the install team, the Mech install team, the field engineers to the service guys. Those are your own customers in there is not it? Those are the people you're doing things for. Those other people you are refurbishing for, so it's easy for them when they want to. Maybe install it. Or maybe when they want to service it or something like that. So, from the packaging perspective that you've just talked about is covered a lot of things for me in terms of your you know your considerations of who's going to get this instrument, this device so you make life easy for them by going through all this proper documentation and all parts for them. So, I was just thinking in other processes that you go to problem the testing or in the reworking are there any other considerations that you make with, you know with the service guys with the service engineers over the install team at the background of your mind.

Participant 2: Yeah, I'm in a perfect world, right? We want to make it as easy for the Mech install team and the field engineers to do what they need to do right? I'm working a much more controlled environment. We have much more controlled and supportive environment than our customers do, right? than our field engineers do,

or our Mech install team do, right? I can draw a lot of variables that there are lots controllable at the customer site. So, we try to focus heavily on how do I make my outputs as reputable as they can to make their process downstream a little bit easier? So, there's obviously like we want to make sure our end user customer gets with. Indeed, those were not understood, but for us to be able to do that as a COMPANY A team, we really need to be making sure the Mech Install team and the Field Engineers don't have to feel like their heroes all time, right? At COMPANY A we talk about our field engineers being heroes and they really are right like they're doing some amazing things. Success for me and my team looks a little bit like how to make him feel like that they're being a hero a little bit less. We have instances like an MR, for example, where this environmental concerns that play into our teams, ability of variance between what we see and what the customer sees. This is not about the XA system, but this is about three or four years ago. I'm getting old and this is a site I never had small, and the FE couldn't figure out its okay, the system would work for a couple of minutes for 45 minutes to 15 minutes and then when I run a scan, I get this huge image artefact. And it was three storeys up in a hospital and I really had great view of the city and I was half paying attention. When I was looking out the window and the guy and I think there was again and as he says that I look out and there's a huge bus that's driving down the street and I was like hey how do the buses run, and he was like they run every hour and I was like well there's your problem. So, every hour this bus will drive by. So, there is this huge piece of metal driving through this magnetic field because they hadn't properly shielded the room because of those great windows I was looking out of. His first thought when we were doing this was like there's something wrong with the system. Okay, right, and we knew at the site our site. It wasn't the system because we never saw that right. But my environment well controlled: the room is the same every time, I will have shielded it if there were buses coming through things like that, whereas our sites don't have those same environmental control that I do right and so the more and more consistent my output could be that could drive high confidence in that consistent output. It will allow our teams to focus, eliminate variables to focus on what they're really seeing. With that engineering mindset, you want to limit variables right here? You want to hold many variables constant, test that one. Okay, hold one constant and test the next one right and Success for me as I said earlier is like no one doubts

the system works right? and we take that variable off the table that is a pie in the Sky hope but that's where we want to go, right? We want to remove the variable that the systems refurbishment was the problem, right? And I want to do it not because I keep telling people that's not the problem. I won't do it because they know it, they trust the work we've done.

Interviewer: I'm not sure if you noticed this but a lot of businesses right now are trying to get into medical devices refurbishment or remanufacturing. COMPANY A, Philips and Siemens have been at the forefront of this business for a while, and you know new business are coming up with massive tech that requires massive investment and all that. They're not even manufacturing any products but what they do is basically buy used medical systems, and take it through their own resources, and operations etc. and they come up with something that is good and that can compete with you know, COMPANY A Siemens and Philips products. That's impressive. I was saying to one of the other companies I was speaking to you should keep doing what you're doing, keep improving your work and in a few years, you'll be doing as good as the likes of Philips, COMPANY A, Siemens and be given your customers better offerings and making more sales and you know, it's very impressive. So, I mean if you can improve on what you've said, it would help your business.

Just one of the things I noted here was when you talked about the installation on site in the factory installation, calibration and testing and installation, it's all the part of the testing phase or is it different from the testing phase or are there more other steps you would go through? What I'm trying to do here is to put everything on a list just to make it easy for me to, you know, get the flow of the products or of this process flow for the refurbishment operation and I'm trying to see if the installation on site the calibration, the testing and the de-installation can all fall under the testing phase or if each of them should be separate phases, they are all separate steps anyways, or exist as separate phase on their own. What do you think about that?

Participant 2: So, are you trying to connect to Deinstall that happens at the customer site before we refurbish the system?

Interviewer: No, I'm just looking at what happens in your own facility that includes the installation. Yep.

Participant 2: so, the install work happens in the same physical location that the calibration and performance testing happens except assessment with the same exact individuals. So, from where we said install to where we said deinstall it's the same person doing all of that. I would just be breaking it up to give you another level of detail, right? So, it is not just like it goes in the beta comes out two weeks later inside the Bay, it goes through these four steps in our process, right? But we didn't talk about is what happens when it doesn't pass… when it fails in one right? So, for example, the very little failure to install and calibration. If it doesn't pass, we just continue to calibrate it. If something were to fail and acceptance testing more likely than not, we must go back to calibration. Because when you replace whatever broke we need to redo something. Another thing we've been looking at is how we can blend Calibration and acceptance testing together right so? So, you could see the calibrate and then acceptance test and calibrate and acceptance testing, calibrating acceptance right so that way it during some failures something breaks. You only must go back a little bit. You don't go back the whole way. Right, so it's a concept called you know you want to commercial poka-yoke (mistake-proofing) theoretically, but also moving your test, moving your variation for upstreaming the process as you can. What that gives us is better reliability when it comes to delivery. And that way it helps us provide better confidence, but I to answer your original question. They all happened in the same spot physically the same in the same geography, so I think you could group them together. I just broke them up to give you a little bit the next level of detail.

Interviewer: Thanks, thanks for that. Can I take you back to when you talked about the dethrashing or the cleaning process, you didn't say anything about a disassembly phase. I wonder what level of detail is available about product disassembly in your refurbishment process.

Participant 2: So that happens in a prep area, CT pads. We do cleaning, disassembly and replacement all in one location. We have work instructions that works them through it, that lists the tools that are required. And then they document that in the device history record. I think I might have done when we were talking about it was as part of cleaning and then 100% replacement items. So as part of cleaning

we do some disassembly and then went on and then when we do a replacement of an item, we obviously do some disassembly. And we have a sequence we try to sequence that works sometimes. Yes, you must in other to clean this you need to take this piece out right, and then you may want, well, that's all you may want to replace. The part that's behind it, right? So, we try to sequence cleaning and disassembly and replacement altogether like we were talking about earlier.

Interviewer: Yeah, Okay, just another thing. So now I have established the fact that the disassembly is not a clear-cut process, of course we said at the last meeting it's not like in the automotive example where you literally need to breakdown into different parts and then open that. So now I want to ask about the replacement part, because usually what we would have been so example the automotive example, the heavy-duty goods, heavy duty machines example would be instead of replacements, you would have reworking of parts. So, to you, do you rework parts? Or do you have situations where parts are reworked? It could be any operation, such that a removed component is reworked to a reusable condition with same warranty as that of new. It could be anything, but I saw you went straight for replacement. I mean replacement parts. The part is that is it that you don't bother is impossible to walk some parts or because I just wanted to know more about the replacement process. Are not really reworking process.

Participant 2: So, my XA team is very little component repair. So, we do 2 things. One we identify parts we want to replace every time, what we replaced it with is not always brand new. In the mechanical wear state, so in other parts of replacing, because overtime they mechanically fail. Those are almost always brand new. They also, in a lot of cases, a lot cheaper, less expensive items. Other parts we know they fail so we will pull them and replace them, but we might replace them with a refurbished item or repaired item. Right now, we have confidence. Confidence will last longer based on our refurbished or repair standards of the vendor that did the work. When I said vendor, I use it generically, because that could be someone external to my plant, but on the when you get to come visit, you'll see on one side of my plant I have an entire wing, an entire organisation that repairs field replacement, things that would go into my CT scanners. So, what we do is we take that this potentially defective part. We will need to replace it with a brand-new version or repaired version, and then I'll send my replaced part,

my removed parts to my repair team to fix. Right, so what that allows me to do is refurbish for cheaper. Or in some cases refurbish what I couldn't refurbish before. So, for example, being that I can't get that part brand new anymore, right? It's old enough where the only way to get it is repaired. Right? so we will do that. My XA technician or employees doing the work is not pulling it out and fixing it, they're pulling it out, replacing it, and we're sending that defective to the right expertise in my organisation, fix it and then it will become the part. Our place on the next system.

Interviewer: can I take you back to just to let you know? Just leave this for a moment and go to the parts reprocessing. You said (correct me if I'm wrong), it's a different operation on its own, but of course it's still within the XA repair facility and how does that repair process work? I mean how does the parts repair process work? because I'm thinking if it's possible, for example, in a few years. COMPANY A says we want to repair products and repair parts for sale, so we're not just repairing the parts for COMPANY A XA, we repair, we refurbish or remanufacture parts to sell to anybody, could be our customers. It could be even our competitors if they want it. You know something like that.

Participant 2: So, we do that today. So primarily, we repair for our own COMPANY A usage to support our contractors and customers, right? There are wings of our business that will repair and then we will sell to a third party or directly to our customers. But the majority 90 plus percent is for internal use. So, the repair side of my facility fits into two different business models. One is COMPANY A-owned material, so it came back off a failed system in the field that was under contract. We fix it, put it back on the shelf to support the next customer, right? Primarily? That's one of my two models. The second model is I'm working on a piece of equipment that is my customers'. So, they it to me. I fixed it. I sent it back to them. Like you send your phone back to Apple to have them fix this give it back to you right? In those cases, the product is entirely the customer's, right? They're paying us the service to do to fix and to replace the part, right? In those cases, the models where I have customer owned equipment like that, it's generally when they're finished medical devices. SO, think of it like a patient monitor that sits on a bad side, right? Or ultrasound probe, customers own equipment, it's the full piece of equipment they sent me the whole thing. I fix it and send it back. So,

we do both those models at the other repair site already. What we did here in the last six months is we've reconnected that models of component level repair with the demand stream that XA could create for that? In the past we would do is I repair it at send it to our service network and then XA would buy from our service network. Right and then it would. The process would cycle, right? We try to cut that out because why would I send the part to a warehouse to then bring it back? So, the risk is inventory to be sure we are not overdriving the chain of repair with lots of material waiting to be used. Over savings, a bunch of logistics, a bunch of material handling, passing material back and forth.

Interviewer: What's the inventory like for the component repair arm. What's the parts reprocessing inventory situation. Because I remember the last time, we made the last time we were at a meeting, you talked about Siva's organisation bringing down the inventory. So, you don't necessarily have piece of equipment just sitting in your facility installed, occupying space and not necessarily any plans to send them out within the year. So, I'm thinking about that other part level. How do you? How do you handle that at the part level? Or how does the inventory look like to you?

Participant 2: So, for two different groups. So XA specifically components right where we manage it to create the same level of flow that we were talking about an asset, right? We've gotten better and better at ordering smaller and smaller amounts, but just what we need? Being more and being more consistent about buying the metal door level, if we need to. So, for example the repaired version apart is generally cheaper than the new version. By moving some of our products over repair as a source rather than brand new, we can save a lot of money. The parts network, right? So, people want to print them, and on my repair side, right? Or looking at very similarly. The reason repair makes sense is on average our repaired items are about 55% of the costs or new items. So, if we must buy a brand-new parts vs repair part for me to launch or repair it generally must be about 55% of the new item. So, there are some caveats, right? When parts beginning to get old, we may go with repair, even if it's more expensive than new because we know long term new is not going to be available. And then new price is no longer new from a vendor, it's from a third party, which is incredibly expensive. So, we try to balance those things, or we think about it from a supply chain overall effectiveness, right?

Do I have concerns about this product? Is there other supply chain stability issues that we need to be aware of?

Interviewer: And what's the quality of the repaired parts, like I mean.

Participant 2: The expectation is that they should last a minimum of one year and I think the new part warranty is about the same, yeah.

We should focus on total life to be very honest expression, our current focus only think about product quality is less about current as well thought out they just follow total life, but about failure on arrival (FOA). So today we measure ourselves to is: 1, against new. So, there's a 'prime'. a prime is the same as in new part. If there's a new part, do I have the same or better FOA rate on my used part. so, it's one of my measures. So, 2 of my measure is overall I want my FOA rate to be at 6% this year. We came into the year at 8%. Most of my parts have less than a 1% FOA rate or smaller, right? Some of the parts that drag down my FOA rate are some of the older parts or stuff you can't get new anymore, right? So, we're doing our very best to maintain every single part we possibly can, and that may not always be the best, best answer. So, the FOA is our measure of… in terms of the first seven days of arrival and installation, does it fail? Alright, so this is not just out of box but it's the first seven days. We also measure infantile failure rate (IFR). We call it, which is valued in the 1st 90 days. But our real focus has been when you open the box up you as the customer. Do you get what you expect, and does it work?

Interviewer: So technically the XA business the product refurbishment is technically the customer of the component repair, is not it? And it goes on and on and on like that. Someone talk about the component repair part of the business. It's always been about another product repair product repair and now at all that.

Participant 2: So, Siva's organisation is focused on product refurbishment. The component repair I do I don't do for Siva; majority of customers are the part sellers. So let me give you this …….

Interviewer: I don't know if it's possible to get at list of part that you repair or parts that you are currently planning to introduce to the repair arm of your business. This is just for record's sake?

Participant 2: *so, there's the dock, there's the power supplies, there a part was a part of the ICN (The image computing node), the CT colorimeter, Mammography Detectors, and counterpoise it's an Xray part, called the counterpoise. And the Longitudinal drive, Computers is a huge family of computers. Yeah, we have a lot of Hewlett Packard computers that run our systems and we repair all our Hewlett Packard computers.*

Interviewer: I'm probably going to send a Mail again to you tomorrow just to see if you can get me an updated list of more elaborate list of parts that you know you repair. Because I'm writing a paper right now on medical devices and trying to breakdown the complexity and clarify the misinformation about the processing and medical devices industry. So, over the years where scholars have done basically is to talk about medical devices reprocessing and are thinking from an automotive POV. Remember the first meeting we had I told you comment with my automotive mindset and now I've got in. Yet I'm seeing that it's completely wrong to try and define medical devices processing from the automotive points of view. So, I'm trying to make it least of you know this point that point. Coming up with something writing something, and so the proposition I'm doing, I'm thinking about right now is to use my case study with COMPANY A to you know to do this. If that's okay by you, what that would mean anyway would be. You probably would need to. Or maybe I should speak to Participant 4 about to anyway, but I would need someone in COMPANY A to go through it to be sure that.

END OF MEETING 2

Meeting 3

Participant 2: I mean he's right. It can vary on why. Sometimes it's asset condition, right? Sometimes that is the type of system that we were looking at. It is an opportunity to refurbish. So, the why whether it's refurbishable can change.

Interviewer: That's good to know. So today I was hoping to talk to you about quality evaluation and testing. Basically, we talked a little about testing the other time. I just want you to go into more details about, you know, assessing the quality of the reprocessed products and the quality evaluation. How do you check for the quality?

I know you talked about; you know working documents you know the eDHR devices history record DHR. So, this got me thinking, is it possible there is deeper information about the method of? You know the quality evaluation and how deep do you go into it? What are the things you look out for, what's method you use just as deep as you can go to. So that's basically the only thing I've got. You know, hoping to talk about today so.

Participant 2: So, I break up quality as we look at it into four different groups, **so in** COMPANY A We use quality to talk both about product quality as well as regulatory compliance. So, our quality organisation kinds of sees both. So, for a long time our quality organisation was really focused on regulatory compliance and to their credit they've taken a much broader view and people we call "total quality" now both product quality as well as compliance quality, right? So, when I say break up before, so I'll take the first bucket is regulatory right? So, from that perspectives it's both what do we need to do to prove our systems are safe and meet our requirements as well as meet our regulatory obligations, right? Then the other three I'm going to say are really product quality driven. So, the first is what does engineer determined? The second is what do we do as an organisation as a manufacturing organisation determined and I'm going to keep details soon and then the last is an external look at what are QA tells us how our systems are performing to make sure the first three buckets are meeting the need what we call external product quality.

So, we go to the first bucket, we call we call it the regulatory quality. Depending on where the products going and most of my product almost 90% of it goes to the US so We'll, talk about it in the terms of FDA right? The FDA has remanufacturing/refurbishment standards right, as well as our products have a standard that we say they will meet to meet the FDA's requirements. So, we must align our testing right and our process to ensure that we need both those what the refurbishment standards is as well as what the new standard is for the FDA in the regulatory space. I would say primarily it's the FDA defining what is the standard and then we build our process to meet them. So, for example, like there is, there is radiation testing that we do to make sure our system is radiating in the way we expect. So, everything almost everything I make shoots radiation, right? So, we need to make sure that one the radiation is blocked and only going the direction we expected to, that's scattering. And then two that my system can control the radiation

in the dose the patient feels or exhibits as we say it should be. So, for example, think about it like the odometer in a car, or a speedometer when the car going 60 miles an hour or 60 kilometres an hour, you want the odometer or the speedometer to say 60 miles an hour, or similar process here on that the dose my patient is getting is that what the system says it's getting, that makes sense, right? That's a critical requirement to be FDA to make sure we are not overexposing our patients. And exposure they're getting is what we say it is. So, there's two primaries that I think of there, one of them is dose. So, radiation dosage, right? And the second piece in the CT space, which we're kind of talking about here is related to FMI (field modification instructions). So, these are field issues or issues that have been identified during the life of the product that we want to make sure before our product goes back out. it has all those completed. Think of it like a car lot. I'll make it auto example again. Doing them doing the mandatory recall work on a used car before they sell it. So, I imagine my Honda dealership is going to make sure all that all the recalls on my 2019 Honda car have been completed before they sell it to me as a used car. So those are the two big things on the regulatory side, right on top of that, there is the stuff we have talked about. DHR recording what we did and who did it, but I imagine those are standard everywhere in any regulated environment, specifically in healthcare. The second group of product quality is engineering-driven, so these are the tests and the requirements that engineering has stated is what's required for us to say this system is refurbished? They heavily rely on what new product; new engineering has deemed for this system means it is in spec. So, they will create a document that says these are the tests and these are the expected requirements or the range upper and lower. The system must meet all of these before we can ship. The document that you have you talked to, Participant 1. I think it's called the SPA I think is what they were called at. So, I think it's a system performance assessment (SPA), but I'm not positive that we just called the SPA. It's a document generated by Participant 1's larger team, so I think Participant 1 as an Engineering Leader of this firm, and his team, generates a document, is heavily reliant on what forward production says, right? But it gives us tests Upper and lower spec. So, when we talked about it like this for our conversation last week. In the SPA they will say you need to run this test and here's the upper and lower spec. That falls to like the third step of our bay process. The calibration phase they don't necessarily spec. Because this is final acceptance, the calibration is what I need to

do to get myself into final acceptance. So, engineering team inspect final acceptance, not necessarily the calibration phase required to get us there, so make sense?

Interviewer: It does make sense. I'm just wondering why don't they do that? Why don't they give you that information? Or is it not necessary for you too?

Participant 2: It is not necessary. That is not necessary for us because we will be based on the task, we would know the pre-requirements. So when they say you got to run imaging test inside the test it will say pre requirements to run this test are calibration A, calibration B, and calibration C. so I think from that perspective we try to keep the signal clean from our engineering on this is the requirement that means it's good and then we… my teams knows what do I have to do to get it to a space where we can meet that requirement? It is a conversation we have with them, and we talked through but for the most part they are stuck in the end state and we're in our job is to make it mean it. Then there is the manufacturing product quality. So, this is a continuous work we do on products on what we're seeing fail. Right, and so we are continually iterating our process internally to ensure we reduce the rework cycles or repair cycles by being smarter about what we need about what we need to repair replace. So, think about this: Engineering still says this is the finish line, right? We are trying to figure out in manufacturing product quality that bucket: How do I get to the finish line faster with less rework cycles and we're balancing cost versus rework? So, for example, you may have a part that fails 80% of the time Right? that's the case we probably would just replace it from the start. The rework time outweighs the 20% of the time about replacing something that's good. If I have another part that fails 20% of the time, we might say the 20 for savings of not replacing it, outweighs the one out of five times I need to do the rework. And that scale is very dependent on the cost of the part and the time to rework. So, for example a very expensive part that's right might make less sense to replace it. It is so expensive it could pay for a lot of reworks. So, we continue to work on that right? We believe that internal product quality data, so that is what is failing while I still have the system in my possession.

Last piece of product quality is the external. In a lot of ways this would be most painful, most visible. This is the part I don't want to see stuff fail because my customers not seeing the pain. This is the car rolls off the lot and 2000 miles in it

has a nice new engine. Right, incredibly painful, incredibly impactful to your customer. Sticks in their head as to why they may never buy our product again, right? I'm over exaggerating a little bit but it the stuff that our customers remember so for example in 2020 we would sell our systems with the tube. The CT tube that was on it when it came back. if it passes our testing it didn't matter if the two bad a week left on it or a year left on it a life, we sell with a $2.00 on it. Every XA system kind of got a free tube. So, if that tube were to fail inside the first 18 months or first either a year or two years, I forgot what the range was we would give them a free tube. It is built into their product, right? So that tube that we didn't replace makes it to three years COMPANY A ends up ahead? Can you beat it? If it fails inside of the warranty period, we put a brand-new tube on it. The customer feels like they got a deal. That was the perception, right? That was the COMPANY A looking at it and we're going to give them what we're going to make them whole. We sold it to them with that idea, right? But if one of these tubes makes it, we win. So, by the way, the CT tube is just about $30,000, it's like 10% of the total cost of the system. So, it's an expensive part, if we can get it through if we get it all the way to last through the warranty period, phenomenal, right we're ahead. What did our customers experience? My brand new (to me) CT tube fails inside of a year, I don't care who pays for it, the tube failed. You got justice, you care about quality? That's the customer perception. Even though they didn't pay for it, even though it was built into their total cost, we were going to give them a free tube, by the way, now they ended up with a tube that was brand new put on their system so that tube is going to last even longer, alright? But they viewed it as: You sent me a tube…a system that a massive failure inside the first year. When will something else break? Right, I mean like if I bought us, if I bought a car and it said, hey, I don't know how long, I'm just in the last, but if it dies inside the first year, I replaced it, and it dies. The first thing to think about is what's going to fail next, right? No matter how we try to position it, right? So, this year we changed it. We now put a brand-new tube on every system. And other things alright. We don't tell them anything right? We don't go to the customer, so you get free tubes. They don't get a tube, they get the standard warranty now, right? But the idea was that tube will last. You don't have to deal with the customer relationship loss on my tube failed right even though financially it was free to the customer. They don't see that way, and this ensures that like you know, the tube fails, the system goes down, material left and it takes

a day to get it back up like there it wasn't without pain to the customer, don't get me wrong, but the way we perceive our customers experience totally different than what they were seeing actually, right?

So now the total product quality we're talking about is that kind of stuff. We're really looking at is that kind of stuff, right? We are also looking at when the system shows up what parts do our FE's still need to order? So do the field engineer gets everything they need to install the system or they're missing something. when are they installing the system just something break, and they need to be replaced right? So, when we say external quality is not necessarily just what our end hospital customer experiences, it's what our mechanical install teams and field engineers too experience in the process to deliver and turnover the system.

So, we're looking at all that data. We look at that on a weekly basis to understand we need to make changes to our process. Do we need to pack differently? Do we need to make… so much more recent examples is, we have a new product launch. *Yes, we refurbish this system right and we put it in the market and the first three systems have been missing a bracket. There's a bracket that's required to hook on to a cover like a covering that hold on to a gantry so it's not really an essential function, right? But it's needed for the full cosmetic package and the first three systems have all been missing this bracket, and it's like a $5 bracket, right? But tremendously painful, right? It took us to get to 3 because the first one missed it and the next two installed at the same time. We realised there's a problem, our manufacturing engineering team are engaged we fixed our process to now make sure we now have that back where it needs to be. Then we're looking for it right as we found out that bracket usually doesn't come back because what happens is that when they deinstalling the system, instead of leaving the bracket on, they take the bracket off with their cover and we don't reuse that cover so the cover in the bracket get thrown out instead of the bracket being left on to the cover.* That does say that makes sense.

Interviewer: So yeah, it does. It does make sense.

Participant 2: The install team doing what they think is right. We're doing what we think is right after he doesn't get what they need, right? So, these are the... That is why we look so heavily at external focus external quality because

A: it’s the most visible through our customer, so that's important, but

B: there's a lot of moving parts and we can't test everything all the time.

Financially, on time delivery, productivity-wise it just would not work. So, we need to take a risk-based approach on where are we seeing problems and what are we going to do right? So, for example, there was another situation where…So we have this Xray tube that hangs off the ceiling on our Xray system and we bolt it to the crane, ships looks in a crate to the customer and is bolted. The 4 bolts that hold the Xray fixture in the crate are the same four that you need to use to install it. But no one knows that. So, both get taken out, they get lost. They going to install the thing. Some of this stuff works. But don't have my bolts? So, what we do now, when we ship, is we now provide five 4 bolts onto the tube itself, so that right where they need to be when the when the FE goes to install it to make sure they have what they need. Its low cost, solves the problem, right? We’re then asking these teams to do some major coordination inside the hospital, how do we make it easy for them to do what they need to do? If these bolts were $2000 pieces of hardware, we would talk differently, right? But they are only a quarter apiece. The right thing to do is to give them, give them a penny.

Interviewer: I was just going to take you back to the tube part. You said it's very, very expensive and I was just wondering when you remove the tubes now what do you do with the removed part? Do you dispose of it, or do you just do try to repair it or? What you do?

Participant 2: This is a great question coz we are looking at whatever time for what we do with this. So, their couple things going on. So, COMPANY A is struggling, tubes are becoming important to our business and so we have a lot of demand as we've come out of COVID, we've seen demand spike. So, what we're doing right now is there's a test done when the system gets to deinstall that will tell us whether we can harvest the tube or not. And by harvest this means we could use the tube on a different system. Right, but sell it as a used offering. Right, we're looking at that. The difference here is even though the system, even though our XA systems are used towards customer than new right, but I use the term a lot “new to you”, right? *It's new to our customers*, right? So, while we talk about tube replacements earlier on, right? If it's new to me, I don't want that to fail inside of a year, right? When

we delivered to a customer and we're working with them on. How do we keep their system back up and running and giving them their cost options? And we say we have harvested solution here. I can sell to you for a little cheaper, but it has a different life expectancy. Are you okay with that, right? And we tell them what we do to make sure the tube is good right? And the tube does come with some level of warranty, but it's different than a brand-new team, so we look at harvesting options. We also look at… and our engineering teams use tubes as part of development, so you can think of… So, the tube is a high wear item, right? Inside of this tube there is a pair of bearing and a shaft that is spinning at 10,000 rotations a minute. Right and generally, what happens is the bearings will seize up, and that's what else, right? So, and once the tube powers up on the systems on that bearing shaft is continuously spending, even if you're not shooting an Xray. It doesn't stop, it's always spins. So, what we do a lot of times as well is we'll give our tubes that wear off to engineering so they can use them as part of the design development of the next system rather than having to buy new tubes to wear them in. It's a way for us to reduce the cost of developing of the new product because they don't have to continually buy new tubes as they burn. They can use our half-life or quarterlight tube things like that. If the image quality is still good. It's an opportunity for them to use it.

Interviewer: is there a way you could check that the remaining useful life of the tubes because you said something about when the system comes back, there's several tests you could run it to know the ….

Participant 2: Yeah, so yeah. Well, this is something that goes up. There are some tubes that have some harvest capability. The problem is our tubes today don't record their life, so we have odometer on the full system. But we don't even odometer on the tube. So, and odometer on the full system is only as good as the last time the system reset. So, think about this… Like think about if you could do like a hardware reset on your car and odometer would go back to 0. That's what our software driven odometers or usage models on our CT systems do. It wasn't until some of the newer versions of product that we now have odometers on two major wear components. One is the tubes, some of our newer tubes track their own usage so we can get a better life expectancy and then 2 now CT gantry. It's a huge bearing of spinning around it. It also tracks revolutions so that we can tell how much wear is on the

system, right? There's important things because not only does it cost as we try to build like the profile how long can this stuff last? It's important to get some of this data, so part of our engineering design process on tubes and on CT systems is running it non-stop that you think called highly accelerated stress testing (HAST for short) and the goal is like how long… should I figure out how long will this last under normal hospital environment? But it's simulation, not real right? In fact, so I do it. I've been with COMPANY A now for almost 20 years now. My first job with COMPANY A as 18-year-old intern was working in the tubes plant and highly accelerate stress testing. And my first day on the job of tube blew up, filled the room with graphite dust because that's what the target is. Firs day on the job, I thought I would not have a second day on the job. And follow it up. My manager came to me on my day 2. Not sure what was going to end. Prepared to clean my desk outright. He said we got a job for you and so it means that your job is to break stuff. But what I have done in that case there's like a heat exchanger system where we're pumping oil in and out of the tube to keep it cool and the oils bring through a large radiator right air cool, right? I forgot to plug the fans in on the heat exchanger, so I was just pumping hot oil and wasn't cooling oil at all but when they looked at me like, but this happens, this happens in our field error with our customer, but we'd rather have them happen with us first, so we know what happened right? And we realised if a patient is on the table and the tube exploded and was leaking hot oil and exploding graphite dust in the air that would be bad. That would be catastrophically bad, right? It's very bright here and you're good at breaking things, so break some more stuff for us.

Interviewer: Is not my good job title – the breaker?

Participant 2: It was great. It was a great job for me at 19, like you know. I probably cost COMPANY A 1,000,000 bucks, within six months on stuff I broke, but we found stuff out. We got better and we were able to redesign the case for the CT tube to ensure if that would happen it would stay inside. So that that graphite dust spinning is inside something that's inside something else, and when it when it popped because of the heat. The other containments devices also failed, and that's how I got out because the strategy is it should all stay contained inside the larger steel casing. But we found a weakness in the steel casing as a result, right? It's incredibly important iterating, so we use these tubes. Sorry to come back. Now back to the

original question. Yeah, we use these tubes to kind of an opportunity to do that kind of testing to understand, but the reason we're kind of trying to get real life expectancy on these tubes is so we know. the second real reason to do it is imagined… So, I got a new car there, but my wife and I bought a brand-new Honda. Before this, my I was driving in 2008 and now I'm driving in 2003. Only Guy who upgrades to upgrade my go back having. my wife now has a brand new 2020 £100 a pilot right so she was shot with a shot with the first five in XX. I can't fathom what it's doing all day or one of the things it does is oil changed. So, oil change me was able to dominate hits 4000 miles. We have changed it off right now the system is continually taking note of the oil and when it gets to a certain level it tells you to get on change. Right so this is no longer built on mileage, but now on the level and condition of the oil. And so, if you think about it. What we're trying to do with the CT tubes is very similar. I want to be able to tell when that tube is going to die and change it before it dies, right? From a customer standpoint, right? I want to be able to change the tubes during normal scheduled maintenance when I'm not impacting this customer schedules the patient schedules and that comes off so much more proactive. However, on a $30,000 piece of equipped. I don't want to be changing it out to change it out, I need to change it when it's going to fail. So, you want to get as much life out of that tube seemingly as maximum as possible, because that would be better for the Customer and better for COMPANY A Right? So, one of the reasons of putting this odometer is trying to figure out how do we proactively understand tube life? Today we don't have that. So today we take either take aggressive approaches on when it fails and buy them a new one model. Or we take a conservative approach of I'm going to put a brand new one on there and then I'll find another use for this tube, right? So, if that goes engineering and last week it was still free to do for them. They don't care. If they last two years, they're ecstatic right?

Interviewer: So, apart from the tube what other parts of the CT… let's say for example, the CT machine is expensive, very expensive. So apart from tube, what other expensive parts, do you know of?

Participant 2: Yeah, so the next based on dollars is the generator is what creates the potential across the tube the 140 kilovolts between anode and cathode to create the radiation. That is another spot where we're trying to figure out life, so we have seen over the

course of time, right? Different generators behave differently with age, so for a while now we have had a two-year limit. So, if the generator is of its 2 years old, we replace it. It's more of a guess than necessarily an exact science let me put it that way. But there's other spots, so like there's a thing. So, the way our CT work is, see there's a rotating piece and spinning around the customer and you have a stationary side, and you need to be able to pass high voltage, so the power as well as data from the stationary side to the spinning side. So, the technology where there's a circular, we call it **"slip ring"** it's a ring that spins on the rotating side and there are these fingers that sit in the tracks. And that's how electricity and information are passed back and forth. It's a wear item, right? They are barely rubbing, but they're rubbing right. To replace this in a field of its kind of a pain, you got to do a lot of disassembly, right? So, this is one of the things that we replace every time here because we know over the course of time it will fail and it's an invasive repair, so why bother, we're going to do it here? And it's cheap. It's cheap, but I feel time in the customer downtime is expensive, right?

Interviewer: What do you call the name again? Is it a slip ring or what? Did you call it?

Participant 2: The slip ring. It's the brushes on the slippery.

So, another part. It's an actual encoder, so it's what someone else… I told you about how we have a software odometer today that tells us how often something spinning. That's what that's what helps the system to determine how fast it's going. It's a set of gears and gears on gears. And so, it wears and the actual encoder, the smaller pieces has rubber gears, whereas the bearing members connecting with is metals, so it wears. So, we replace that too, right? Because it's highly invasive. Easier for me to do it than to do with the customer and we know it's got an expected life that will fail. So, like I said, we do a variety of cost expensive dollars, components critical to system function and we do other things that are relatively inexpensive piece part wise, but it's easier for me to do during my cleaning process or when I have the system disassembled than for a field engineer to do right. Or I have the right tools, right? I have I put standard work around this repair rather than having FE trying to figure out how to do it on site. So, when we look at the manufacturing piece, right? That's part of it. Yesterday we talked our last week about 100% replacement items. This is where those two conversations overlap. The Harvesting replacement list is the equivalent of things that we have found in our product and

therefore branches of product quality that we know we want to replace before the customer sees it. Sometimes they are driven by engineering, sometimes they are driven by us.

Interviewer: I am thinking here, if you replace most of the expensive parts in a system how do you manage to keep the cost low. I mean you replace the tube, replace the generator and replace their slip ring and all the expensive parts and still end up selling the product at a lower price.

Participant 2: one of it is our margins are great right? Following that, what is happening here is the asset we buy back has a cost on it that is significantly less than what the worth is or what the brand-new version would be.

So, there is one part we have not talked about and that is the most expensive part. So, while the CT tube is like 10%, the detector is by far the most expensive part of the CT system. So that becomes a critical piece. Now it has many, many smaller components that can be replaced. So, we will talk about the tube being like an anode and a cathode. I said right at Steelcase. I can't replace anything in that. It's a sealed, completely sealed environment. The detector, on the other hand, I can replace circuit boards. Suddenly on a $350,000 detector I can replace $200 components on, and I can get it working. You know, I guess that we have a pretty good size margin overall and in the medical device space. Some of that is because There's a lot of R&D that goes into the system, right? So, it is awkward because we are working with customers on buying back in our trading basis, right?

Second, these just like when I used car lot, right? It's our margin the certified pre-owned business the reason Honda Toyota do it is it's tremendously lucrative for now they probably were getting resources, they're probably getting cars back two different ways, and we're getting back too, we get back multiple ways, but mostly on trade-ins, whereas I think the automotive dealership get some traders, but they also really get them on of leases. So, I would imagine the used car model kind of built as part of the business case when I'm doing it right. That's different here in the healthcare space. We do get some back off leases, right? But that's a smaller portion most of the time it allows us to sell something new. So, we go to a customer who's got a 5-year-old CT system? Hey, way to upgrade racing, do you want something new. We can give you X for your old system so you're better entering a little bit

less. So, it's something Apple is starting to do. But I've got my I got a new iPhone 12. Whatever my wife, I spent lots on my phone, so I got that. I got the brand new the best phone, but it gave me 300 bucks for my iPhone X. So, I would say our models more like the iPhone Apple model that is the automotive model because we are not using the lease model. We use the lease model, customers do lease our equipment it's a much smaller percentage of our business, I think.

Interviewer: Yeah, yeah, those I spoke to the other time. One of my early conversations with Participant 1. He talked about most some of the products you get for the XA come off lease. I know that, but of course you know your business is not lease-based business, but you sell the products. You don't lease it to the customers but in the automotive industry, for example, the law requires that even though you've purchased it, I'm talking about the ELV end of life vehicle or the waste of electric and electronics WEEE. So, although the customer bought the product the responsibility remains with the manufacturing to take responsibility for end-of-life management of their products. That's why it feels like Apple, even some Android devices such as Samsung and other ones have started to, you know, put a buy-back scheme into their products and IKEA does it. You know return an old system to IKEA and they sell you new ones. But they don't give you cash for it anyways; they just give you like a voucher. You can use in-store. Thank you so good.

Participant 2: Yeah, it's a good, good stuff. I mean, there's a lot of variations in this model right when you start looking at the Use Refurbished model and its kinds of work right? When I look at it from COMPANY A's perspective, there's margin on our deals, and there are certain products that where are offering fits our refurbished offering fits the price point our customers need. Not every customer can spend $4 million on the CT system. Right, and that's not many do. That's like our top-of-the-line premium of premium systems, right? That's the. It's the Tesla XY or whatever, right? The $100,000 vehicle, right? Or the Bentley? So, there are a lot of customers that would want something new, right? And our trade-in allows them to do that. And then there's a whole other set of customers that, like I don't need the top of the line. I need something that I can use every single day to take care of my customers at. But I have a $500,000 price point, right? And that may not get them

We have more and more educated ourselves. It's a needed functionality to observe the hospitals that just couldn't afford it. We look at it personally as we I want my

customer to not care that it's five years older, 10 years old. I want them to… I want to meet their expectations of what a new system would you like to you. Just because they can't get 1,000,000 bucks for a CT system doesn't mean that they shouldn't get one that's reliable, works every day. It would not have the bells and whistles that AI and all the other stuff that we sell on brand new ones. But maybe-maybe not depending on the model they go. But it should work for them. It should work every day, it should be predictable, right? The confidence of I'm going to put a patient on it and they're going to get a great image you would know this if they're spending $4million on a system or $1m on the system. When we frame that as our guiding light here in goal too, I think that changes people's perception on you. We're trying to turn this stuff to make a deal. Now in the end, like visit customers needed to test and scan their patients and so sometimes it's easy to dismiss because we don't make the big million-dollar revenue. We fit a customer need that the rest of COMPANY A maybe doesn't do.

Interviewer: I did the research recently about the factors that customers in the UK anyway would consider when they want to use a reprocessed medical device or it pre-used pre-owned something like that. So, seven factors were presented to them anyway, and the most significant factor to most of the customers. Most of this NH S leaders, you know the managers in NHS and all that where the quality, the safety, and the quality and safety performance of reprocessed medical devices, and, well, I don't know. If it was because they were not to enlighten about medical divider process, medical devices, or they're just very sceptical about it, but then I also realised our most. Companies getting into reprocessing medical devices are not based in Europe and the UK, Europe. Most of them are in America and so there's very little information about the quality process. How good you put effort into re process and medical devices so they can be sure that yet what we're getting is as good as near so mean as you said about equality qualities. For me anyways, the most important and very. Smith, can you know parts that factor will consider when deciding to use reprocessed medical device. So, I mean if we can get that communication out of customers that the quality of the product is as good and even in some cases better than, is not it? An equivalent new product because. An extra, for example an extra produced 10 years ago would probably do mono images, but right now the same model of extra would take digital images, would not it? So, for me that would be

better than you know that would be better than when it was new. So, I think it's a good thing and I think it's important to keep them up like let customers know what we do and what you are doing and make it easy for them to make the decision about the quality of knew and then compare that with the price. The price point of remanufactured new product. So, I've just got one. One other question. I don't know if you have anything to say about that. Before I go for after this other question.

Participant 2: No, I don't. That makes sense to me.

Interviewer: Yeah, so I was going to ask about. We've talked about equality evaluation. Are you assist equality? I'm just not very clear about the method itself of evaluating the quality, so it sounds to me like it's more of a checklist. Kind of a thing or an OK so that it's more of a checklist. You have several points to take note of. Is there any other method which you assist the quality of process systems in your in your facility?

Participant 2: This the engineering SPA control, right?

And then there's the field book right failure on arrival data. Those are probably two major ways we assess quality. Yeah, those are two clear measures.

Interviewer: So yeah, I just wanted to be sure it's.

Participant 2: It's just those two. Like one is proactive, the engineering piece, the other one unfortunately is reactive, which is the understanding what our customers are experiencing.

I appreciate this time we spend together. It has got me thinking about our business a little differently. And probably more excited as I think about going to business. So, thank you, but I have nothing this time. Alright, that's set now. I've asked for a list of some of the parts to expensive parts and those, especially those ones, are currently not being repaired. Reworked re 4. Just an old art and I would be looking at the possibility of doing research on, you know.

Remanufacturing repair refurbishing this part, so they don't have to go to low price option. So, we could probably repair them. Re manufacture them, you know, but then of course that would take some serious research and development, so whatever would see what can be done. If it's possible, I'll send you an email, probably contact Participant 1 and we can talk about the possibility of doing research together too.

See to assess driven factor ability on see if there are methods of ways we can, you know, prevent that from going into less priced alternatives and then we can probably use them in the cold steel business, or probably even in the new business so.

So that's it. That's it for me. Thank you very much for your time and I appreciate everything. Thank you very much.

END OF MEETING 3

Appendix B-3: Semi-structured interview transcript for participant 3 (Company A)

Interviewer: Thank you Mr. Participant 3 for taking your time to meet with me. I'm very honoured to have someone of your skills and experience in this discussion. So, I will go straight to the topics for discussion. So, because we only have 30 minutes to discuss today, we'll see how much we can talk about today and maybe schedule a meeting for another day.

Participant 3: Yes, we can reschedule the meeting for next week on Wednesday, we can have more time next week to discuss better. So, what time on Wednesday is best for you?

Interviewer: Well, any time after 4pm on Wednesday is fine by me.

Participant 3: How about Wednesday 9:30 my time. What time would that be over there?

Interviewer: Well, that should be around 4:30pm UK time so that should be fine by me. Can you send me a meeting invite on Microsoft Teams? Thank you.

Participant 3: Yes, sure I will, I am on it right now.

Interviewer: Oh, nice. Thanks very much for that. Given that we have about 5-10 minutes left on this meeting, would you like me to talk you through my research.

Participant 3: Sure.

Interviewer: My research focus is on customer considerations in medical devices reprocessing which often include, repair/servicing, refurbishment and remanufacturing. By that, I am looking at how customers' requirements have been incorporated into the reprocessing activities of COMPANY A from conception to completion. I've learnt that COMPANY A's reprocessing activities include repair, refurbishment and remanufacturing. So, I'm looking at how customers are catered for in the decision-making processes. Not just in the reprocessing activities but as early as product selection for reprocessing and as late as sending them out after reprocessing has been completed.

So, I've had meetings with Participant 1 and Participant 2 separately and these meetings have been insightful. Based on your experience and of course your

position as the senior product manager, I'll be looking to understand the customer-focused considerations for new products and how can you compare that with reprocessing medical systems. How do you as the product manager ensure that product selection for reprocessing is customer oriented. How do you ensure that, throughout the reprocessing operation, customer considerations are well taken care of. What I am not sure of is if this is a responsibility of the product management team that you lead. However, I would like to know everything about XA operations from the viewpoint of the customers.

Participant 3: So, some of it depends on where we are in the world and where we are selling to.

In the US, the products that I primarily target for the XA operation are usually last year's premium products. So, in diagnostic imaging, at least. The way COMPANY A views it, there's kind of the premium, performance and value products. The toughest product for XA to resell are value products because those are lower cost when they come out. So, some of those I tend to avoid, and we will basically bring them back and harvest them for parts for service delivery to help service those products that are still in the install base. Because what a lot of XA customers are looking for is, they are competing against the academic, top medical research hospitals and things like that, and they usually buy (like the PET/CT for example) they buy the latest system and most expensive that they can get, you know with all the bells and whistles. So, when they advertise that 'you shou come for your *melanoma staging* because we have the latest equipment'. However, if I can get those systems off say a two-year lease from some customer and then refurbish it and resell it to a free-standing diagnostic imaging centre, they would really like that because I will sell it at 30% less than what the current new product is selling for. And then they install it and because the academic across the street – his own is 2 years old and he has not refreshed his product yet, the free-standing kind of competitive imaging centre can say 'look we have the same machine that he has', right? So those are very attractive. What was the premium products from COMPANY A two-three years ago, if I can get that back in through a trade or a lease and then resell that, that's a very attractive sweet spot for my business. Does that make sense?

Interviewer: Yes, it does makes sense

Participant 3: And also, once an attractive business prospect and the new product has created an upgrade. So, I can buy say an older system say its 5 years old or 4 years old and I can get an upgrade which they now offer to the install base customers which I had during refurbishment. So, for example, today we buy what we call the mobile Xray systems and previous COMPANY A system was Optima 600. So, via upgrade, I can take that Optima 200 which is maybe 5-years old and convert it to an Optima 240 Gen 2 which is the latest and greatest the new modality is selling. And so, the salespeople have the option to either sell the new system to the customer but in some cases some customers want the new system, but they can't afford it and they want to bring down our price then they will prop up the price with the XA offering. So, you say I can't get you the brand new Optima240 Gen 2 at that price, but I can get you a late model slightly used pre-owned system that's been fully refurbished at that price.

So that's kind of the overall strategy and then generally also you must look at the entire product portfolio in your product space of what COMPANY A offers. So if the new modality team (because there is a product manager that decides what we should sell new), if he has created a value product or a performance product that is the same price as my XA product then it makes it tougher for me to sell then the customers are having to sort of make a trade-off between should I buy a new Toyota Camry or a preowned Lexus 350 at a similar price then that is tougher.

The good thing in some of the modalities that I cover (so I cover PET/CT, Nuclear, Xray, Cardiovascular, Mamo, and what's called the R&F). I am really the only product in town because COMPANY A only sells premium products whereas if you look at the CT which another product manager (John Bird) runs for XA now, he has run into some trouble because the CT business itself now creates the premium CT, a performance CT and a value CT and that value and performance product is priced at about the same price as the XA version of what was two-years ago premium product so then it's tougher to sell the product. One of the things that we do to make sure that the customer has confidence in what we resell is I always give a one-year warranty which is essentially the same as a new product. In terms of pricing, I usually try to make sure that I am at least 20% less average sales price than what the product was sold at when it was new because 20% seems to be enough of delta that motivates customers to want to

give the XA version a try. Otherwise, if its less than that then they would probably just go with the new system

Interviewer: Yes, that makes sense, and this discussion today will be a very good basis on which further conversations would be had. I would send you a brief list of topics that I would like to talk about ahead of the next meeting so you can prepare a little for it.

Participant 3: That's okay.

The other thing that I have been doing in my modality very successfully (so the Nuclear, PET/CT are called modalities within the COMPANY A) is to what is called the hybrid and that has been very successful in the MR also. So, if you look at an MR system or even like some of the Xray systems, the expensive part in the MR is the magnet. So, what we do is we sell a pre-owned magnet with new electronics so basically everything except for the magnet is new but the magnet was harvested basically reclaimed from a previous system, refurbished, and recalibrated. So, what I do in the Xray is: in the Xray there is the digital detector normally in the product and that is a big portion of the cost. I mean the Xray tube, the patient table, patient monitor, the generator etc, those things have become somewhat commoditised, but the real technology is in the detector. So, what I do is that I bring back something called the flash pad which is like an Xray film cassette but its digital. We used to slide in the cassette when you take Xray, and it will make films so now you just slide the digital detector in, and it basically just takes images and videos in 802.3 Wi-Fi to the main system and then to the packs. What I do is that I give a trade-in for those detectors, we send them back to the factory they take the covers off, refurbish them and then we sell a new Xray system with a XA detector and we're getting a lot of traction on that also because we are impressed about it. Yes, the system is new but the expensive detector I pay 45k for it instead of 75k and it comes with the same one-year warranty. So, hybrids is a big part of our business also.

Meeting 2

Interviewer: What do you think are the critical issues for medical devices reprocessing at COMPANY A?

Participant 3: One point I would talk about is the design for refurbishment and I would say we at COMPANY A are not very good at that. I am guilty as charged because I used to lead all PET new product development before I came. I have not been at XA if the other folks like Participant 1 Schmitt who you may have talked to already. I was on the new side and unfortunately on the new side you're busy just trying to keep up with the competitors and you're not thinking much about reprocessing. It's been quite an uphill battle to try and get our new product development team to do this. Normally they would think about an install procedure and that gets worked on, developed, verified and validated but we never did a de-install procedure and now that I work on the XA side, there's a lot of things I could have done on the new product side that would make the refurbishment much better like when the teams, I don't know if you know the concept of field replaceable unit?

Interviewer: No.

Participant 3: So, it's like when you create a new product you tag the parts whether there would be a field replaceable unit or not. But the new development teams, they purely base it on only thinking about the new product, they are not based on what happens when the system comes back and gets refurbished and resold. Because for example like covers, if you're a new development team you think on the cover is once the field engineer gets them on, nothing should happen to them, and that means service doesn't touch them. But when you. Deinstall it and you transport it back sometimes those covers get cracked or they get damaged or things like that, it's hard for us to get the covers because the new development team did not think of the fact this product may have a second or third lifetime and then you may need those, so that's one area I think we can dive in to. I have a lot of ideas. But really, our new product development process only treats refurbishment process in a very tertiary light weight and there's a lot of improvement that should happen. For me, mostly the type of improvements that should happen in the refurbishment needs to happen when the product is designed, way upfront

END OF MEETING 1

Meeting 2

Interviewer: Were you able to have a look at the email I sent you some days ago?

Participant 3: Yup, I did.

Interviewer: So now, just before we start today's discussion, I would like to say that the conversation we had the last week was a good start. As I went back to it, I found a lot of quality information you provided last week.

Today, I just want to sit back and enjoy our discussion on your product selection process, your considerations and your decision factors basically. So, I'm looking at those factors that you would consider. So, when I told you last week about my research, that my research focuses on customer considerations in decision-making in medical devices reprocessing I wasn't necessarily referring to those decisions that the customers are involved in making. To put it simply, I don't expect any such thing as 'we would go ask our customer this and that and then incorporate in our refurbishment process.' No, I am talking about your normal day to day decision making so take for example, you want to refurbish this product, you start with selecting a product (a premium product as you said in the previous week). What are the factors that you consider when you make these decisions and then my research will aim to uncover how all the factors you have listed cover the requirements of the customers. So, from you to me, I want to know as much as I can about the considerations and the factors that you would consider when making decisions relating to medical devices reprocessing.

Another example is perhaps the pricing of the product which influences customers perception of the quality of the products. For example, if a product is priced too low, customers quality perception may become negative, so usually the price ratio is usually kept around 40-60% of the price of new.

So today, based on your experience and current role, I would like us to start this discussion by talking about your product selection process. If I remember correctly, last week you said that you only go for the premium products, so what are the factors you consider when making the decision about what product to go for? So that's basically the starting point for today's discussion with you.

Participant 3: Sure, so like I said, it's not black and white that its always the premium product but generally it's the premium product. One of the things to understand is that the premium products, usually our company makes more margin on those. You understand about margin, right? So, the way COMPANY A calculates margin is we have something called the ICV – Internal Carrying Value. Our sales margin

is what its selling for minus the internal carrying value divided by what you sell it for is the sales margin in percentage. So, the reason I usually look at more on the premium products is that there is more margin to be made on those. When you look at like a value product, when you look at the margins, they are very thin to start with even when the product is new. So, when you go to refurbish it there is not a lot of room for profit. So, let's say a very inexpensive Xray room, and the margin on the new products is only 20%, if I bring it back there really is no room for me to make any margin. So that is probably one of the biggest driving factors. The other thing is looking at the entire portfolio …

Interviewer: Just before you proceed with that, can I quickly ask about the sales margin? Just need this cleared up, the margin you talked about, is it about the price of the product or the profit your company makes on it or is it both? I feel like I need more clarification on the concept of sales margin used at COMPANY A.

Participant 3: We have a concept called sales margin which is just the sales price minus the internal carrying value which is kind of what has it cost us to build this product, divided by the sales price. So, let's say you sell something for $100k and the ICV is $50k then the sales margin on that is 50%. But that is not our profit because there are other things like the variable costs, overheads and marketing but it's kind of the margin that COMPANY A uses called sales margin. For example, let's say in PET/CT world, you know they sell a brand new one sometimes for $2million and the ICV is maybe (and I'm just using approximate numbers) maybe $600k so you can see the sales margin is good. It's like 70% possibly. On some products, this is just historical stuff but then if you want to bring it back and refurbish it, if they're selling at $2million then there's a lot of room for you to refurbish it and still make margin. So, let's say I give a trade in value, and someone wants to sell to us at $200k, originally the production cost was $600k but long term I can't give a higher trade-in. It's kind of like what happens in cars once you drive it off the lot, it's not worth what it was just five minutes ago. I mean if I pay you $600k for it, how am I going to be able to resell it at a profit. So, PET/CT is a very good example so let's say it's a very high-end premium product and it's sold at $2million (none of these are actual numbers because I can't really disclose to you what we really do so this is really just an example) and let's say the ICV is $600k. So, the sales margin is $1.4m divided by $2m multiplied by 100%, so the sales margin is 70% so that's a very profitable product.

So let's say somebody buys it on a 5-year lease and then they return it 5 years later to me, so let's say I pay them $200k for a trade in and a new COMPANY A system which they buy a new one I get it back for $200k and let's say I put about $100k in to refurbish it so now the cost is $300k but now its 5-years later and the selling price of that product has depreciated. It was $2million when it started, and it goes down 10% each year, it would be about $1.3million today but that would be new product. So, let's say the market can bear $800k for the preowned PET/CT that originally sold for $2million and was 5 years old. Now I resell it at $800k now the sales margin is 800k-300k divided by 800k which is 63%. That is a good margin.

Whereas if you look at another example, let's say an Xray room where we sell it for $100k and the ICV is, with the detectors and the digital detectors, let's say $70k so now you're talking about 30% sales margin on the new product. So now, five years later let's say the customer expects a trade in of $40k and that Xray room $40k and I must put $20k in it to refurbish it so now my cost is $60k but that original sales price of $100k has gone back to say $65k and it cost me $60k. So now 65 – 60 divided by 65 leaves 7% sales margin. It's called the squeeze. Preowned stuff gets squeezed a lot and it's probably why when you go look at cars, they love to get like a Lexus back because the sales price is higher and when they originally sold it the sales margin were high so then they can sell the difference between wholesale fair market value and what they can resell it for retail is larger. So, then they can make more margin, so it really is driven by margin. Margin from a financial standpoint.

And then the other thing is the PET/CT product we're going to sell at $800k if there is no other offering from like COMPANY A, or Siemens or Philips at that price then that's really golden because then… for example in our CT product space (which I don't cover, but I know the problem) is in CT where we have our preowned offerings they have now created like a brand new performance product at almost the same price point so that'll be for example if the PET/CT product group created a brand new PET/CT that you could buy for $800k then the choice is do I want the brand new one of $800k or do I want the preowned 5 year old super-premium at $800k and then it becomes tougher for customers to decide. So, if there is no other… so that's why you need to do a left right check on the portfolio on what does the marketplace look like. So, I'm constantly working with

the new sales team on what are you selling the new products for, at what price and then as long as I have a 20% gap in the preowned offering from the new then I still think its viable.

SO now the only other thing to think about in the Xray scenario is … remember we're an entire like franchise company right… we not only sell new equipment we also sell service, and we make a lot of money on service. So, you may consciously say 'I'm okay with that 7% sales margin as long as the customer is going to buy a service contract when we sell it'. Because then let's say if we make 50% sales margin on the service contract when you add it all up at the end of the day it was worthwhile doing because you retained the socket. See one of the things that is very important in our business is called *sockets* which is basically how many systems we have in the install base. So, like let's say we have 1000 COMPANY A PET/CTs installed in the world, one of the things we monitor is 'is that number going up, staying the same or going down'. And XA can play a huge part in socket retention. Because there's all these third-party brokers in the world that are buying systems that have become available and they're competing against us and often they have their own service delivery capabilities so they want to sell the systems so they can get service contracts. So, we may consciously say … but then we want to still sell that Xray room at 7% sales margin because if we don't sell it, they'll buy it from somebody else – a third party broker and we won't capture that service contract continuity which is helpful for our business. Does that make sense?

Interviewer: Yes, it makes sense

Participant 3: Now, some of the other considerations on the product is 'what is the vitality of the product?' Like that PET/CT we talked about that's five years old. If it's already running into parts availability problems, then service kinds of come to me and says 'don't resell that system because we need to like to bring it back and harvest parts from it because we already have 400 of those in the field right now and unfortunately Hewlett Packard who made the computer say it can provide anymore so we are having troubles servicing the ones we have. So, its kind oof what we call, I must do a left right look on what the lifecycle situation of the product is (the entire life cycle). So, if from a business case there's margin to be made or we are okay with the margin because we know we'll capture the service

contracts, and the product has good vitality that it's going to be around for quite some time because the last thing we. Want to do is sell a pre-owned system to a customer and then a year later COMPANY A comes to them and says, 'we are going to end service contract because it's an old product.' So, I must monitor that too.

That's one of the things that I think is unique to the medical business that I don't think is in automotive business. I mean, in the automotive stuff, you can get parts for 1952 VW Beetle. In our business, the only real place because they're almost like hand-made devices basically and not mass produced in millions so we're talking hundreds of thousands maximum, it's hard to get parts and the only people that can get you parts easily from are COMPANY A and we don't carry parts so the life span of a lot of these products is only about 10 years depending on what type of product is. Ultrasound is even faster and then Nuclear and PET/CT, I'm sure there are some that have been around for 20 years and are still operational, but they don't have a very long-life cycle. So, if I'm getting the system back and I know that our team is going to start telling people 'You need to buy a new system because we can't service it anymore and we won't give you a service contract on it then that's another reason why I may choose to not do a refurbishment program on that product.

Another reason is quality. I have a situation where the product group has come to me and said, 'we have experienced a lot of problems with this product, so we really don't want you reselling it to customers.' So, an example would be like a car that has had lots of recalls and lawsuits about it, they may say if somebody trades one in just send it in let's just break it down for parts, let's not resell it because we want the install base to contract on that product.

Interviewer: So just to be clear, the quality of the product that you have just mentioned is it a function of the vitality or is it a standalone factor that you would give a separate consideration?

SO, you mentioned sales margin as the first factor, and then the vitality of the product as the second factor. Under the product vitality you talked about the age, lifecycle situation, availability of parts and serviceability of parts. Now you just started discussing quality as a consideration, so what I want to know is if the

quality factor is a sub-factor linked to the vitality considerations or is it a standalone, separate considerations that you would make.

Participant 3: So, the quality factor is a separate consideration. We collect all kind of quality metrics, so we collect like… FDA mandates that we must collect like *customer complaints*, and the other thing is I can get from the service team how many *service records* on average like in the first 90 days of life of the product were generated and then I'm going like how much or what is the *cost to service* the product… so we get all kinds of metrics. We get like customer complaints, service requests (to come and service the product), we monitor something called the IFR90 (infantile failure rate 90), so we know like how many parts had to be replaced on the system in the first 90 days. That's kind of an important metrics for us because once it gets out the 90 days and it seems to be operational, a lot our stuff, once it starts to burn in and get fully functional within 90 days without any issues then we are good. So, we monitor that. And then we know I can pull… like the PET/CT what's the average service cost on every PET/CT and if it's much larger than what we thought it would be… the service team is doing that then they would just come to me and say 'I don't think you should resell that product because something didn't go right in the development of it because the service cost is three times higher than what we thought it would be and we're replacing parts at a much more frequent rate than we had thought we would.' So, we have all kinds of… we have a whole team of people that are just gathering data, informatics data on the product quality.

Interviewer: Just wondering here, what sort of technology do you use to track and collect data and informatics about the performance of the product? I mean do you use any embedded sensors that automatically collect this data or is it based on the reports that are made by the users?

Participant 3: Well, the service record is like in a different system because the *service engineer must log it*. But we can… some of the products… *we have air logs* and things like that, and we'll get figures from the system itself like uptime… and one other thing to remember is some of the service contracts that are sold in it, it has uptime guaranty. So, we can measure like how many minutes was this system down and unavailable for use or things like that and we have remote access to almost all our devices so we can pull use case patterns on how customers are using it, failure

dates from air logs, but that's usually not the refurb team, that would be the product development team is doing that. So in every product development group there is always a team called the install base support team, they are doing that but they give me the summary that I can look at so really the quality thing doesn't really come from me, it would come from another group where they're saying… because I tell them 'hey guys xyzzy PET/CT I want to create a XA offering for it'… and usually we have to follow what is called the face review discipline to create a new offering so we have to like develop the business case and then present it to people…and there's usually like a service leader for PET/CT and he would get invited to that and he would say 'I think this is a bad idea because I know we are having lots of quality issues with this system' and its fair for me to say show me the data then he would go bring the data and say look 'this product is failing three times more than other PET/CTs and we really would like to get it out of the install base because we have a 100 open customer complaints on it' and things like that.

Remember that my role is product manager… so like I'm an individual, I have no direct reports, I have no team, I have nobody that works for me so I kind of sit at the crossroads of the entire…what we call the total product ownership kind of like from the inception of the idea of that product to its roll out to definition to when it's basically phased out. But I don't have any resources, but product managers are usually very experienced persons who have worked in all aspects of the business and understands the entire business from end to end.

Interviewer: *talks about the report from Participant 2 describing how hard the job of Participant 3 is.*

Participant 3: I think he's referring to I cover many products. My peers like 'one' he just covers CTs and the other one has just MRs and I cover everything else in diagnostic imaging. So, their businesses are very different than mine, so CTs…they about 5 product offerings and they sell 40 of every year refurbished. MR is the same they have very tight portfolios because it's just MRs whereas I cover PET/CT, Nuclear, radiology, radiology fluoroscopy, mamo, vascular… so I'm the opposite of them, I have like 45 product offerings and in some cases, I only sell four of them each year. But I've been doing this for a long time, but I like to think I'm very efficient. I create more product offerings in XA… I think

the part which I cover which is called molecular imaging, women's healthcare, intervention and Xray… I think I create more product offerings than any other manager in COMPANY A healthcare. Because I create a lot of product offerings. Remember there's two different thread that go on in our business, there's one thread that is like we're getting a lot of these back…these assets is like a 5 to 8 year old product they've started coming back and leaving the install base because we're selling new products to the socket and so we have a steady stream of these products and then we do a nice program around it, so in essence we can sell as many as come back and there's demand from customers. But the other tread that we have is… I call it the "shit happens stuff" … people buy like brand new PET/CTs, because we sell it to them, and they take a loan on out for it let's say like $2million and then something like a pandemic happens and so nobody comes in to do image so they default on the loan, but COMPANY A holds the paper for the loan… so then what is COMPANY A going to do? We can't just write-off the system, so they come to me and say 'hey you got to resell it' so I must quickly put an offering together and then we resell them. So, we call all those kind 'too new too few' products so we have like a separate process for those 'too new too few' products.

So, imagine like a brand-new PET/CT that is only 2 years old, we call those products 'too new too few' products and we have a process to be able to resell those too. So, what we do is we have a big facility called…in a perfect world your school should fly you, you should come in and see how big our repair operation is, there's like robots running around and it's amazing view and it is huge. There, they're doing not only repair of parts but also refurbishment of products and that is in Oak Creek Wisconsin… so the system will go through the repair operations centre but in a slightly different way. We don't have time to do like a full new product development refurbishment product so what we do is really lightweight like what is needed within the system, what are the tests that are performed out in the field on the system to requalify it that it can be sold to another customer then in many cases what we do is we put it in our test bay in the repair operation centre and the repair operation centre leader of XA, he calls the service leader in our local region and has a field engineer come to the repair operation centre and test the system out like he would have if he received on the customer side, so we call it like turnover testing and then we document all that and we put into the device

history record and then we pack up the system and ship it to the next site. But those are kind of we only have a handful, and we are not ready to do…like we don't have all the refurbishment parts all waiting we have to go, and we must go and get those if needed. But really are the two threads that run through us:

1. The traditional, we get a lot of these systems, we're doing them everyday
2. The "Too new too few" process

They are basically similar, it's just. I think we are when it's like a product that is only 1,2,3,4 years old and really there's not a lot of refurbishments that must happen because it's not that old of a product. It's just making sure that everything is performing according to spec as it was originally released by us in the new factory as the OEM.

Interviewer: We were talking earlier about the factors and considerations you would consider when you make the product selection decision. You talked about the sales margin, the vitality of the product and the quality of the product, are there any other factors you put in place or that you consider when making that decision to reprocess a medical system?

Participant 3: Primarily these are the main factors, but I also talk to our sales force about … see like 'is anybody asking for…' lots of time we get calls from the sales force, customers would come in and say 'hey, have you got any preowned PET/CTs of this vintage, I would like to buy one?' So, we always want to touch base with the sales force and say, 'do you think you're going to be able to resell this product?' because especially now there's huge focus on the inventory cost because…I don't know if you've reading about COMPANY A, the big thing that everybody (investors) are worried about is COMPANY A's cashflow. Nothing reduces your cashflow mire than holding your inventory, so we have really reduced our inventory over the past five years. It used to be we were just kind of…if a system gets traded in, we were just kind of like put it in the warehouse even if we don't have a plan for it, we'll keep it then in the future we'll figure it out, but we don't do that anymore. Now if we don't have a plan for it at the time, we don't bring it in and hold it in a warehouse because we used to have such a huge warehouse, now our warehouse is one-fifth of the size it was like five years old. A lot of that was (…have you talked to Participant 4?) led by Participant 4 really driving… we need to get to a bare inventory position and now we're always looking at what we

call raw assets, those that have not been refurbished, we are looking at like how old are they, how aged are they, why are they ageing this quick, why aren't we moving them? So, inventory terms are very important. So now that's another thing… I may turn a product away just because I know that I won't be able to get it programmed on in time, by the time I get it programmed on there won't be much demand for the product in the first place so… because we can't do unlimited programs so I have to be judicious about what we … have you met with Participant 1 Schmitt… so he only has so many engineers and people that can work on new product offerings so I have to be cognisant of the… what is really my top priority, so I may not do some products. The other thing is sometimes I skip over some products like if … an Xray. The example on the Xray was everything was changing so fast on the digital detectors that they like brought out a quick. Succession of products but they didn't really ship of one configuration, and we are already getting back the next generation. Then when I talked to the harvest team do, we really need those, so we didn't do a XA program on that. So sometimes they release a product and then a year later they are like 'oh we've got this new digital detector technology' and they only did a hundred of the one say product A and then B comes in quick succession I mean why would I waste all my people's time to do a program on product A when the install base is… I mean that's another factor. How many are there in the install base? And how many do we think we are going to get back? So like product A if it's only a hundred but in it we ship for one year and then they start with product B and there's already 500 of them in the install base I'll just skip over A and go to B because they would really be in the same spot in the portfolio as a rad room that can take 2 digital detectors with one standing on a table so that's another thing that happens. It's a complicated… that's what Participant 2 meant when you cover too many products it's a very complicated thing. I must go nights without sleep because I want to run the analysis myself. I just know that after many years in the medical imaging industries I know what I think is going to make money and what I think is not going to make money.

Interviewer: But do you think the decision process would be…generally on the outside…the same as it would be for all other products? This is considering the decision

process for the different products, MR, Xray, CTs, PET/CTs etc or do you think other product managers would have slightly different decision process.

Participant 3: Well, I think the ones that I talked about are the same the sales margin… because they always must do a business case first, they would be concerned with the vitality and quality of the product. They don't have to worry about like jumping over the volumes because those businesses like ultrasound, there's many out there. But when he takes them…I think he does skip over some products because the technology changes very fast and COMPANY A tries to bring the BT (breakthrough) product every year and launch it at our centre. So basically, the one from the year before becomes obsolete very quickly. I think he may skip over some products when he kinds of see why…we didn't really sell any of these, I'm not going to waste any time. We'll just send all of those to harvest. The harvest thing has really opened a new avenue, I mean…one of the things I'm always working with our asset's recovery leader is what is called the disposition for a product that is in the install base and maybe is coming back. *Do we want to bring it back for refurbishment and resell it? Do we want to release to harvest for service?* Because what our service does is they…we test it before it gets deinstalled and then they bring it to the repair centre, they harvest the parts and they put them back on the shelves for service delivery. Or number 3, *do we want to sell it to a third-party or a broker*? Or number 4, *do we just want to bring it*…we can bring it to the repair operation centre and there is a part of the repair operation centre called 'renewable resources'…and then the asset just gets broken down into its basic elements like the copper is extracted from it, the gold, the metals etc and then it is sold like basically almost like recycling. *So, we recycle it.*

So, I think they have similar decisions just that they don't have as many products and their volumes are usually much larger, but I have been able to…so when I took over 7 years ago at my end Xray for sure the margins were lower on refurbished systems and now my margins in the products that I cover are higher than CT and MR and it used to be the opposite big time. So, a lot of it is making judicious decisions on what products you want to resell, picking the low hanging truth and going after that and really managing the costs that you're going to put into the product. What you pay for trade in is often the primary cost in the cost of refurbishing the system. So that whole section is like…what are you going to pay

for a PET/CT that is 5 years old. Because it's not really like there's a market like in the automobile… there really is not a market because if we're selling 3 our 4 of them a year, is that really a market? Guess maybe it's a spot market for a definition (if there's anything like that) because it's very small sums but… so we try to…and I guess I feel there's some product where we're just going to get them back as long as our price is reasonable because people don't want to go through that…it's a bigger hassle for them to sell the system to a third party broker, otherwise if they buy a COMPANY A new system we just take care of it for them and it's right there on the order. So, they see the price of the new one, the price of the trade in, the price of the XA, we pick up the old system and install the new one and we're done.

And then there're are some people who really want to like work on what they are really going to get for it and sometimes we lose those systems. They do some through a third-party broker and maybe they get a higher value built we kind of monitor that then if it happens a lot then we will raise our trade in value.

Interviewer: Earlier in our discussion, you talked about a disposition criterion or something of sort… so when an equipment comes back you need to make the decision of what happens to it, where it goes, who handles it etc. I'm just thinking here, do you have an existing framework for such decision or is it based off common sense… the thinking is…if someone other than yourself needs to make that decision, they will be properly equipped with the decision framework.

Participant 3: yes, there is a whole team that does that (the disposition decision and planning), and they do it long before the system arrives to us. We're doing it the minute that we find out about the system, maybe it's quoted…so the way medical equipment works is first you go to the customer, and you give them a quote like this is the new and this would be the trade-in, we see those quotes, so we already gave them a value and we already tagged the disposition on it, sometimes it's 9 months in advance. So, there is a whole team…there's a guy named Mart Moor on our team, that is what he does like his job is to like to know we want to sell like 10 of this type of PET/CT but we only really need 10 but suddenly if we get like 15 he starts adjusting the plans and changes the disposition, I mean he kinds of consult with me but he is empowered to do that and… I'm surprised Participant 4 didn't talk about, we have an automated like an app you can run of your phone called tix –

trade-in experience, it's all automated. That team just loads in all the value and disposition, when a salesperson wants to find out how valuable a system is he just takes his system ID, and he puts it in and it tells him right away that this is the value for it and this is what we want to use it for. So, there is a whole team of COMPANY A digital people who are working on that whole process itself kind of like the customer sales facing group on trade-ins and dispositions and where would the asset go when it comes back and that is that… sometimes we change it just prior to arrival but that is happening long before the system ever comes near the site.

"So, it'll almost be like you'd be telling somebody you want to buy a car in 9 months, and we'll be giving you a trade-in on your current car and behind the scenes we'll be saying we want to send that one to auction. Or if that one is clean, we're going to put that one into the lot. We are doing that like 9 months in advance"

Using the automotive analogy, I just wanted to show you how sophisticated our app is now in terms of the trade in and all that stuff

Interviewer: Good stuff. I can infer from what you've said that obsolescence is a problem to medical devices reprocessing and it directly influences decision-making, is not it?

Participant 3: Yes, very huge

It's probably one of my number problems with… I mean I can give some examples like; I think we talked about the digital detector in Xray, we get those back and refurbish it and it's really a great business. The problem is to put it on some of the older Xray systems you need something called the digital upgrade kit and fortunately the computer that is inside f that has gone end of life so even though I don't want to stop selling it, I've got to stop selling it because it can't get those digital upgrade kits because those computers are end of life. And see, the new development team, it's a constant battle with… the new development team want to move on and do the latest, greatest sexy new products, they don't want to be stuck with the old ones because if you had your own business, you would say "just qualify the new computer" but at some point you got to say "woo, we've got the new digital detector" beyond the one that you're selling XA…we want to do that, we want to keep going forward so what happens is even though I can

continue to sell those digital detectors I can't get the digital upgrade kits so I have to end it premature for what I would like to do it and then move on, so what I try to do is ahead of time I start saying "we have to start selling those digital detectors to harvest or harvest won't take them…we'll have to sell them to brokers".

So, it is a very…I have to say entrepreneurial kind of business for us…with all the different roles I've had in COMPANY A this one kind of feels like you're running your own business because you're making sorts of decisions like "start this one, stop this one etc "and it is always changing, there's always something new in the refurb world.

Interviewer: Nice…on a personal note, from you based on your experience working in XA, how do you view customers demand, customers perception etc. What do you think about customers demand for it…just wondering here, how does reprocessed medical devices sit with customers?

Participant 3: I think in the US very well but a lot of it depends on what customer segment you're talking about. If you're talking about academics, the key opinion leaders they don't want to do anything with preowned medical devices that's just in their DNA, they want the newest and the greatest… I mean if you go write a paper like about the latest findings on PET/CTs for detecting single pulmonary nodules you don't want to let people know that you bought a preowned system. But in the US because the medical delivery system as a whole is very diversified…there's academics, there's regional hospitals and in the US there's nothings stopping people from just creating what is called the free-standing clinics they just decide I want to make a business I want to host some MRs and I'm going to scan people and I'm going to hire a doctor or a radiologist some techs too. So, it really depends on the segment. I think if you're in academics key opinion leaders they don't value it but anything below that…my experience is if they can save money for their organisation and they've had a good experience… so a key thing is had they done it before and do they have a good experience, if they have, I think they'll be willing to try it again. Like I said because we give a 1-year warranty they really don't… you know they know COMPANY A is always going to stand behind it. It's kind of like buying a certified automobile or just buying the automobile from somebody, I think when it comes from COMPANY A as the OEM and they know COMPANY A is going to stand behind it, they are comfortable with it, and I think

they really see the value. like I said, in many cases they can save 20% for sure over a new one and in most cases it's not like they get reimbursed for patient scan, they get the same reimbursement. So, if you do your proforma like I want to start PET/CT free standing imaging clinic and we're going to do like 8 patients a day and you start with well my machine costs me $2million or my machine costs me $800k just think about the timeframe for the breakeven how much difference it is… I mean if you go for the $800k option you'll probably break even in the first 9 months, you'll have the machine paid for and after that it's just operating costs versus operating income and you're making profit. If you had an outlay with $2million it could be 3 years before you can end up in profit. So, I think that's it. I think the acceptance is good and there are just groups of customers that are willing to buy preowned and they buy it often and there's a group who would never buy it. They would just never buy a preowned medical equipment. But I think once they get a taste of it, they are much more open to it.

Interviewer: Cool… do you think customers may be influenced by available information…or to ask this first, do you provide information on the previous usage of reprocessed medical devices including, for example, the previous user group, age of core etc? Just wondering here, how much information the new customer gets about the previously owned medical devices? Or generally, what's your view on providing information on the previous use to the new customers? And do you think that providing information (or not) influences customer decisions?

Participant 3: I'm sure it would but I don't know what Participant 1 told you, but we don't share any of that information. We don't even share vintages because it's not like in cars when you have 2019, 2018… like if there is a product called the discovery 690 and it was built for 6 years, we don't what year it was, I mean they'll find out eventually when they see the rating plate, but we don't disclose it, it's a 690. Participant 1 and his team, through all these iamers and all these organisations they feel that the refurbishment process that we go through in XA it doesn't matter what the quality was before or what the age is, it should meet all the specifications when it shipped brand new when it leaves our refurbishment facility. We don't open the year because what will happen is some of the customers would say "oh you have a 2015 and a 2014, okay I'll take the 2015" and suddenly 2014s are sitting in the warehouse and nobody wants it anymore. So, in our view it really is

not a different product, it's not like cars where they are changing their features even though it was built for 5 years, it's still discovery 690 and basically it is the same product.

I always go back to the thing is we always give a one-year warranty. I think without the one-year warranty it would be a whole different equation. That one-year warranty is kind of like…you know when you get a certified preowned most customers just think "I'm going to work out any issues in one year of use."

Interviewer: Cool. So, you mentioned briefly about the quality which I believe is I believe is very important to customers, or what do you think about that? I mean the group of customers who have used preowned devices and have experiences using it, what do you think their quality perceptions are like?

Participant 3: For us, if we have problems, it's usually in the beginning at the installation things like that but once the system is up and running, I really think that they think that it is as good as any other system that was in the install base or that is new. I mean the bigger problem for us really is our own engineers – the field engineers, they have a perception "Ohh God here comes the XA system" because they want to just deal with the new ones. It's kind of like I guess maybe like if you are an auto mechanic, here's the brand-new system and then here's the one that came in from a different site so yeah. We track our quality; our quality is just as good as that of the new product. Once it's up and running, we track it so it should as good, it's the same design we don't change anything in the design. We're not allowed to change the design, we only use service procedure so we are basically doing service so it should be because the system comes into us, we refurbish it for service procedure and we put it back in the install base, eventually it just blends in with the statistics of the install base. We can't see any outliers… when you look at the data you can't see "Ohh see the subset here" or like if you do a dart plan or something "Ohh see this grouping, that's the XA systems" that doesn't happen. In many cases, the XA systems are more reliable because they've had some serious upgrades on the critical parts and the key things have been refurbished. Another thing that we do is that we are looking at the install base so like let's say for example civic PET/CT we are looking at what parts are being used in the install base, what failures are common and then during refurbishment we try to ensure that we replace that part, put a new one in before we send it to a new

customer so it actually should have a better uptime than if they had bought the system new 3 years before and it was operational on their site the whole time because we know that that one part has a failure every 3 years and when they get the XA it's already been replaced with the new one so their 3 year old system that is operational is likely going to fail than the newly refurbished XA product.

Interviewer: I just want to know about the progress that COMPANY A has made in medical devices reprocessing. I am looking to get numbers on the flow of medical systems in and out of the refurbishment facility across different years. I'm just not sure if this question would be better put to Participant 1 or somebody else?

Participant 3: Participant 1 would be the best guy because he may release some stuff to iamers but technically we're not supposed to release all our numbers. The data gets out eventually because it gets reported through some of these groups and things like that so Participant 1 might be best to speak to point you to the right person to get the numbers from.

Interviewer: Cool, in my meeting with Participant 2, he said that COMPANY A does not refurbish the neonatal incubator but when I did research on the internet about refurbished neonatal incubators, several businesses/companies market "COMPANY A refurbished". Neonatal incubators and I was confused for a second. But generally, how does COMPANY A cope with the other businesses who purchase decommissioned devices, refurbish it and sell it as COMPANY A refurbished products? Or would you rather recommend Participant 1 to answer this question?

Participant 3: Yes, Participant 1 would be in the best position to answer that question but really anyone can refurbish any medical device. We just kind of decided we don't want to refurbish those neonatal incubators because they are low cost… I mean we used to do the bone densitometry machines refurbishment, but we don't do that anymore because they are so low cost and things like that, and we have limited resources so a broker can do it. Another thing you want to know is that those neonatal stuff they're hard to disinfect and stuff like that, so we try to stay away from that. Anything that comes back that we call ancient product or operator touch, so we replace that. So, we must replace those things that get touched. The incubator…and other big thing is we must make sure customers are confident that

we have disinfected the system or things like that. Incubators…people are very wary about buying those because of where it was, how it was disinfected and things like that. That's my only thought about that but Participant 1 would be a good one. He's our interface to iamers which is the international refurbishment group.

Interviewer: Finally, what are the critical issues with medical devices reprocessing at COMPANY A. In our discussion last week, you mentioned how "design for reuse" is not a thing at COMPANY A?

Participant 3: Yes, the first is the design for refurbishment and the other one is what we talked about is the product vitality parts availability but the two kinds of goes hand in hand. Because remember new production, when they are done with the product they want to shut everything down, they want to give it all the inventory…we have not even gotten any of those systems back from the customer to refurbish so it's really that whole product vitality thing like we go and we want to resell it and we can't get the new cables, we can't get the new computers so it's always this competition…and in the new product, getting the inventory what about when the system gets back in and when you want to resell it, where are we going to get the part from. In many cases the new manufacturing has already shut down the supply chain and all the parts. See our needs are somewhat different from service delivery. The first thing that you need to refurbish a system that you won't need when it's in the install base from the customer side and that's the piece where it gets tough. Okay?

Interviewer: Yes, very okay. Thank you very much for taking your time today.

Participant 3: Sure, let me know if you need anything else and if I can help and I hope I've given you some food for thought and it helps in your research project

Interviewer: Yes, you have contributed to my research, and you've got me thinking.

Participant 3: Take care

END OF MEETING 2

Appendix B-4: Semi-structured interview transcript for participant 4 (Company A)

Interviewer

Yep, so thanks for meeting with me just to start way, can you tell me what your position and your years of experience is I don't. I don't like the way this is sounding coz you know when you're interviewing someone for a job you know. Sorry about that. Can you just tell me about your position? Your years of experience so I can note that down, yeah?

Participant 4

So, my team I report up to Participant 5 I think so just the backup. Yep, make sure you talk to Participant 1 Schmidt, right? And he told you to. Okay so Participant 1 and I both report up to Participant 5. so, my team is responsible for managing the inventory for XA. I have a part of my team that does direct buying so. I don't know how familiar you are with the XA business, but basically, we are taking used equipment and then determining what to do with them, whether we refurbish it and we resell it, whether we sell it Out to the Open market or whether we bring it back and we break it apart to use the parts for repairs to other systems that are still in the field. So, my team again we manage the inventory of all the assets that are coming in all the used equipment that's coming in. We done… my team. I also have a direct by team so they are responsible for Systems that are in high demand and high need from the business, whether it's to refurbish and resell, or whether it's service needs them for parts and we're not getting enough back through trade-in, my team will go and work with the customers or with other third party Brokers or resellers to try to see if they can get supplemental equipment, Get more back so you know. For example, if we need 10 optimus 660s and we're only getting 3 back from trade-in so we need to go and find 7 more so my team would go out and do that globally. Then I asked… my team is also responsible for what we call blue book pricing or trade-in pricing. So, when someone wants to trade in their equipment. You know we're the ones that are kind of analysing the market, understanding all the dynamics and determining what that price should be. And Lastly Me personally, in my group we kind of do What we call xxx and that's just the supply and demand dynamics. So that kind of drives what we call dispositioning. And so how? What are we going to do with the equipment? How much are in? Again, it's supply and demand driven, so it’s we are getting more supply than our demand. And therefore, we need to lower the price and dispositioning them we're selling them off to other people that might want them. Or are we not getting enough supply and we have a higher demand and therefore we need to increase

price and make sure that we keep everything we get back. And then your years of experience I've been with COMPANY A for about 13 years now. I've been with XA since 2017, so right around four years and the prior nine years, I was mostly in commercial operations for the US region. And then I did spend about a year and a half or two years on a large project converting our corporate accounts so.

Interviewer

Alright, that's good. Thanks very much for giving me some background there. So, from what you said and from what I've made up from my previous meetings with Participant 3 and Participant 1. so, you're basically in charge of the disposition decisions, gets a new getting product back into the facility, retrieving products so.

But what I just want to know, basically is about you know the considerations you take. The factors were taken to consideration when you make that decision. So, from what you said so far, I could imagine that there would be of course lots would be about supply and demand for the products. Well, apart from the supply and demand that there are other factors taken into consideration. The requirements of the customers' requirements of the business or other things generally, but there I just want to know about the factors anyway, that that influence your decision making and how you make that decision. Do you have a framework you know? Is that a method? What mechanisms to use? What are the challenges? What systems do you could do you use? And those things? Just general details and probably as deep as you can so.

Participant 4

Okay, sure, so I think you know to start. We have we must understand what disposition options there are for the equipment and what I mean by that is, you know, so Participant 3. You mention when he's a product manager, Participant 1 runs the engineering team, so they have, you know, a select portfolio that from a refurbishment standpoint so you know I'm just going to call XA cause that's what that's what we frame it around. Here XA is XA, is when we take a used piece of equipment back, we refurbish it, try to bring it back to the same quality as it was new, and resell it to a customer. So, there's only certain products and it changes, you know, new ones are launched, and old ones kind of stop going down this path, so there's only a certain Select portfolio that we have, right? So, if I look at you know for example if I look at CTs right now, we don't have a programme anymore. We used to in the past, but the equipment kind of got old and the demand wasn't there anymore, and the

customers weren't really as interested in it as much anymore, so it wasn't worth the effort to continue to refurbish it and have Technicians skilled in doing it and trying to hold on to parts that would be needed to replacement and so on and so forth. So, something like for CT. The CT 64 two years ago we used to refurbish that we used to repair, refurbish it and sell it off. And you know probably about a year and a half two years ago we stop doing that because you know it just didn't make sense to continue to do it. We had another product called the Optimus 660 coming in that was, you know, was sold as new 10 years ago and people are starting to turn those in so we said, OK, we're going to stop refurbishing the CT 64. We're not going to do that anymore. We're going to move our plans to refurbish Optimus 660s, so part of that is part of that drives this positioning decisions, because if a CT 64 comes back now. I don't have the option to the disposition those gold still anymore. You know you know where with optimus 60. If that comes back, I still have that option, so that's one piece that drives the disposition decisions is what are my options, so I have. Is the product in the gold steel portfolio and is it actively being refurbished so that's one piece.

The other pieces it's the same story goes for what we call harvest. So, harvest is when we bring a used piece of equipment back and we break it down for parts and they inventory those parts and they you know they have them available. If system breaks bound to be able to replace any damaged parts. Likewise, harvest has the same thing, right? So, they have equipment where… now it's kind of like a waterfall effect. You know the first time it comes in our door; it'll likely go to XA first for a few years, and harvest doesn't even have a plan yet. They don't have the ability to break it down for parts, so again, something like The Optimus 660 if that comes back right now. Even if we have too many of them, harvest cannot afford to take them and they cannot break them down for parts, but they don't have the programme. So that kind of drives. You know what I'm trying to get to is that the first thing is you have to understand for each product, what are my disposition options, because a lot of times you don't have, you know there's basically four options you can either XA it, you can either harvest it for parts you can either sell it off to what we call brokers or third party companies that might want it, or you can scrap it. Those are basically the four options we have. Now very part of it comes in the door does not always have those four options available, so part of the disposition decision is what are my options? That's the first thing you must understand and then from there, that's where it really gets down to as you kind of mentioned, the supply and demand piece of it, right so? Every product. Every product is always going to have at least two of those options are always going to have the ability to

just be scrapped and they're only going to have the ability to try to sell it off to some third-party broker or somebody outside of COMPANY A. So those options are always there. But then the harvest and the XA piece. That's where it really comes down to the supply and demand equation. So, what's my demand for XA? And then what's my supply? And that's what's going to drive to this position, and same thing with harvest.

Interviewer

And how do you assess the supply and demand. Just if I may ask.

Participant 4

Yeah, so good question. There's a couple of points that we do so. So, the first metric of what determines our demand is our plan or operating plan or OP plan. So, we start in roughly total November every year and we develop a plan for the following year and we and what we do is we basically go out to all the regions. And we say, okay, this is ours. This is our portfolio. This is the product that we're going to have as an offering as a refurbishment offering how many and here's our price point so we'll kind of give them. This is around where our price is going to be for this and that and that you know… let's back up a second our price how we determine that as we basically must understand, what's the cost to get the system back? What's the cost average cost to refurbish it? And then what margins do we want? And then that kind of tells us. OK, if I'm if I'm going to bring an optimus 660 back and they pay the customer $100,000 to trade it in. Then I'm going to go send it to the refurbishment warehouse, they're going to have to spend hours in parts and it's going to cost them $100,000. So now it costs $200,000 And we need to make $100,000 on the system of target price is going to be 300,000, and that's what we get to the regions. And we say, okay, here's what we have available. You know, as an option, here is our price point, how many do you think you could sell in your region at that price point? And so that's the first piece in all the regions and it takes a couple of months, right? So, they reach out to their sales regions, and they say hey, XA's going to have these product cheers our price points. Based on your customers. What do you think? How many do you think we're going to need? How many think we can sell? And so, we roll that all up and that's our first kind of metric of our demand and then throughout the year what we do is, you know, on a regular basis, we kind of see how we're performing against that plan. So, if I go to the US and I say hey guys, The Optimus 660 is going to be $300,000. How many do you think you can sell? And they say I think I can sell 20 of them. And so, they will kind of watch, right? We'll see how many orders are they

booking? If we're if we were, you know, four months go by, and they booked one order. Then we kind of say, okay. You're not, you're not on pace to sell your 20, so let's have that discussion. Let's understand if four months go by and they've already booked 16 orders, then we know, hey, you guys are really going to. You guys are really going to exceed that 20. We need to adjust so that's kind of up to demand side and supply side how we measure our supply and how the analyse supply is you know basically the first pieces that the trade in. So, for a customer to trade in a system they are ordering a new system from COMPANY A and that takes time, right? They're going to order it today, and COMPANY A must make this system and the customer must get their site ready and coordinate the install and everything else. So, it's going to take them 6, 9, 12 months or more When they placed the order to when they're going to be ready to give up their old system and get the new one. And so, we have a tool It's called Tix. It's it stands for trade in experience. Yeah, and that tells us what's expected to come in and when. So, we kind of use that as our guide to say, okay? We look back with Okay the region saying they want twenty. We look in our trade in funnel and we see that we have 5. And then we make the decision of okay, what do we need to do? How do we get that supply up to the 20 that we need? Do we raise the blue book price? Do we go out? Do we have my team go out and direct buy from customers that aren't trading it in because you know? Siemens might go in and win a new deal, and then they're going to get our equipment. So, somebody out there is going to have our CT and will reach out to Siemens will reach out to other brokers. Must say hey, you know, we know we lost the new sale, but you took out one of our equipment. You know we were interested, and so that's how my direct buy team kind of works. But that's really how we it's an on-going thing because it changes very rapidly in all the time. But we tried to kind of measured that on what's our demand looking like and again it starts with a plan, but then it really very quickly goes to what are the actual orders where was being booked, and then we again then we looked at what's coming in on trades and you know how can we get our supply?

Interviewer

If I may ask very quickly how far back to you, how long does it take this, all planning process? You said sometimes it takes several months to do that, like how long to you? How long does it take planning this product recovery asset recovery? You know, just give me an idea of how long it takes.

Participant 4

Yeah so. There’s so many steps. From a product offering standpoint that takes a few months, you know just to understand kind of what they want to offer and then Participant 1’s team would get involved in. You know they must go through engineering, you know, put the plan together of how we're going to create this offering, so that takes a couple of months, but that's done one time, you know when their product is launching from a XA standpoint, once that's done. Then the product managers, so would be Participant 3 and his counterparts, they determine. Here's my offering and that takes, you know, they work with me a little bit and we kind of put together. It takes maybe a couple of weeks originally to say, Okay, here's the offerings were going to have for 2021 and we go through, and we put together the list. Then we put together all the codes and everything, so it takes a week or two and we when we start to put together the pricing and an understanding cost. But then from that point when we start reaching out to the regions and we say, okay guys, here's our offering. Do you want that? Would takes several months and up and a lot of it is because… They might have an opinion of how much they can sell, but then the business and leadership is always going to push them for a certain number right? So, they may come back and say, well, I can sell $10 million worth of CT and leadership is going to come back and say, well you know what you sold $15 million last year, and We can't lose business, we can't go down, so you must find a way to get you know 15, 16, 17 million. So go back and look again and that's what takes a couple of months for that process because it's a lot of you know, going back and analysing and tweaking and saying, okay, you know I think I can sell maybe a couple and I'm good. I'm listening and they'll go back with the regions, will talk more and those kind of you know they'll have to push. So, I must go back to the regions and say hey guys like what we demanded here is not good enough. It is not high enough. How can we do more? What do we need to do better? And then they'll give us their feedback too. They might come back and say, well, you know what? Because it's a two-way St. We might they might come back and say hey I can sell 50 optimus 660s, and we might go to them and say, guys, we know for sure we're not going to get 50 back. There's no way we're going to get 50 back. We feel comfortable we can get 30. So don't put 50 in your plan and so for them they need to take their plan down and then they need to find how do I make up that revenue. So, with some other product. So that's kind of why it takes a few months as it's a lot of back and forth from both sides saying what do I feel comfortable? Saying that, I can demand a water we feel comfortable that we can commit to supply them.

Interviewer

Okay, that's great, thank you. Are you going to go back to the factors that you were we were talking about earlier.

Participant 4

Yeah, so yeah. So again. So, starts with the offering, then goes to supply and demand and then another obviously big key pieces is the market price so… There's there are cases where it… and it happens more so on the harvest side where the harvest will come to us and say we could take 50 of these systems. We need the parts we could take 50 of them, however the value that they are able to pay Is only $10,000 let's say and we look in the market and we see people selling them or people buying them for $50,000. So, we have to go to harvest and say guys, you know, we understand that you really want these but you're only able to pay $10,000 and we're not going to be able to buy them that cheap, and there's a lot of people selling them for a much higher value at 50,000, so that can help determine his position as well is the value. So, if we if we look at it, we say you know what, even though we would like to this vision as harvest it just economically doesn't make sense for the business you know, or for our sales team, because the other piece of this is whatever price we give is a tool for the sales team to go and try to sell. It's like when you know you have your car right. If I'm going to buy a new car and one dealer has only offered me $1,000 from my old car and one dealer is offering me 8,000 for my old car. I'm probably going to the person that is offering the 8000, right? So that's where we need to be careful. You know, we don't necessarily always have to match or be as high, but we have to be competitive, you know, and that's where is harvest is only offering ten and everybody else is offering 50 it's hurting our sales team trying to win that new business if we say okay, we're going to give us the harvest just because they need it so that the third factor, that kind of goes into the dynamics of dispositioning.

And I'll say that you know this is kind of the general. There's always other things that can come into play from a specific asset, right? So, if a system was used on animals, we can't resell it so that you know, even though we might resell optimus 660s, if one of them was used on an animal, we can't refurbish and resell it, so for that specific system we would have to scrap it. if something was you know, damage or not operational, or vice versa. If it has a certain feature, or you know technology on it, we might say, OK, you know, a good example is some of our new nuclear medicine cameras. There's certain tables. Where is the exact? It's of entry system is the exact same system, but if it has a certain table, will disposition it to gold eel. If it doesn't have this table will send it to harvest or will sell it to a broker, so

there's, you know. In some cases, more granular configuration cycles into the decision as well. But I would say the biggest, the biggest factor is really the supply and demand and making sure that we are because As a business our biggest challenge is making sure that we're not hanging on to inventory for a long time, which is basically tying up a lot of cash for the business. We want it to come in we want it to get out as quickly as possible and so if we if we start you know, stockpiling a lot of systems that I'm not selling as fast we're just tying up cash, so that's you know, supply and demand is really the biggest key that goes into our decisions into how we disposition.

Interviewer

Um, is it just those factors You said? the supply and demand is the main one? Is not it just meant factor that you'd constantly?

Participant 4

Yeah, supply and demand is yeah for sure and then like I said and then it's the other is the price point in the market. It’s the options the offerings like which systems can go to XA, which systems can go to harvest and then and then. Like I said the other factor would be that it gets a little more specific but it would be down to like configuration differences within the product. I mean just to back up to demand is always driven by the customer as well, you know.

Interviewer

So, you kind of you mentioned like do you get feedback from your customers and do you take that into consideration.

Participant 4

So, if we know that it's a product that a lot of customers really, really want, we know that we're going to demand more of it, and we will build a plan accordingly to say. And we hear this themselves. They basically say will sell as many as you can give us. You know, give us as many as you can and will sell them. And then we have other products where they'll say the customers are really not interested in it. Or it you know it just is not beneficial for them and we don't really get a lot of interest from customers, so the customers are kind of the ones who are ultimately driving the demand metric.

Interviewer

And the demand drives to decision that you make, doesn't it? So technically customers actually drive the whole disposition decision of you know whether or not to re manufacture, refurbish a product or something like that is correct?

Participant 4

Yeah, yeah. I mean ultimately yes. And then we you know our team goes through our sales team to try to get that information so you know, that's where we kind of work with them and we try to understand and say you know we put it on them, but we say “do you guys have a plan for this” and we work with them and say if we get if we get twenty of these systems back? are you going to be able to resell them to your customers? And that's where you'll they'll give us our feedback and they might say you know, not at that price. You know it's too high. If you could bring it down $100,000, then I could probably, or they might say no. there's no interest this, you know, this is such a unique product that there's not enough customers out there that are interested. Or they might say, yeah, absolutely. I could sell 50 of them if you could get him back so, but it's really we're going through the sales team. But they should be getting their information ultimately from the customer. So, the customers you know to your point is really driving the demand.

Interviewer

Oh OK, good just a second. Like area of question is when you think about factors like the quality of the of the reprocessed product, the proposed you talked about, the price to quality, the warranty, the services you can provide for such a products, and the environmental impact of that, the products, probably the environmental impact on recycling or disposing it, and they just want to, does that affect your decision in anyway? So, cos, I notice you've said a lot of things about other factors Demand and supply disposition options in the market value, but I just wanted to know if when you make that decision, do you do you think about what the quality is and what quality you can get out of the refurbishment process? You know how much warranty can you get? Can you match the warranty on the new one? If you do go into remanufacturing this products? I just want to know if this other factors influence your decision and one way or the other.

Participant 4

So from my role, personally, not really, that dynamic that you're talking about is really done more earlier in the process, and that that's where you know Participant 3, and Participant 1 Schmidt and his team and then also the modality itself, because the you know the modality

launch the product so some years ago, so that's where Participant 3 is the product manager need to understand those elements in those pieces of it, you know and I know I am nearly sure that it does go into their decisions on which product to refurbish and put programmes behind. And that's the other thing, right? there's a big portfolio but we don't always create refurbishment programmes for all of them and so Participant 3 would be kind of the key person to work with and with my team to say okay we have 15 systems to pick from, but we can only do because of capacity. And you know engineering, bandwidth and so on. We can only take seven of them, which seven make the most sense, right? So, and I'm, I'm sure warranty and reliability because there are there has been systems and you know. And I know and when would be a better one that maybe give me the detail. But there has been systems where someone like Participant 3 or his counterpart have said this process had so many quality issues when it when it was new, when it first launched that I don't want to bring it back in and try to refurbish it and sell it back out because it's just it's very highly likely that we're going to have the same issues that. He had, when the new product launched. So why would I want to bring that back in? Go through all the process, all the work to refurbish it and send it back out. And then the second customers going also had the same issues. And then you know. And then I know there are in some areas there are regulations from the environment standpoint and… It doesn't impact my decision because it should have been done up front in Participant 3 and Participant 1 and others deciding what products I have a programme around anyway and once they decide that and once, they have a programme together, that's where my team would kind of go from there and say okay does it have a refurbishment you know now. Now that being said we do and then it'll be a factor of demand. You know as well. But as we start bringing these back, maybe the system when it was new didn't have any issues. It was a good quality. Everything was going well, right? But when we bring it back and we go through the refurbishment process and everything and it goes out for some reason the systems are failing more and we can we find out we don't find it out. You know, for a while, but you can kind of see well, we won't take that into consideration. Where we'll say, okay, you know what we had a planned, or alternatives to refurbish and we've actually done that where we've shut programmes down and we said, you know, a good example is we had some MR Systems where we were bringing him back and we were reselling them and there was like three in a row where it had really bad install quality, the magnet suddenly clinched the customer had huge issues and we just said you know what something's going on here. We need to change our decision we're not going to bring these in and we're not going to refurbish them anymore. We're going to sell them off

to the broker market, so those will happen in although you know the programme was put together and we had everything in place but something happened with the quality after it went to refurb and we made the decision to change our disposition strategy.

Interviewer

Alright, thank you, so go. The extent of what you do does not involve the kind specific type of product or process which is asked to do with understanding what product you need to reprocess. You go get it balance the demand under the under supply and the market value no doubts right now, good?

So, what do you, just a side note from what I plan to this course, what do you think are the challenges with making that the product disposition decisions that you make. The limitations, the methodology of you know doing such a thing, of making such a decision because it seems to me over-reliant on the market on the demand forecasting actually, and the supply itself, demand and supply forecasts. And sometimes that can be wrong can't it? So, I'm just thinking about the challenges to you. Do you know what? What difficulties do you see in the way The current way that that decision is made?

Participant 4

Yeah, there's. There's a lot of challenges, so I think, you know one challenge is that. Because of the nature of our business, we are not a normal supply chain and what I mean by that is: If sales goes and books five orders, I can't just go to somebody or some sort, and buy 5 systems you know I'm dependant on when the customers want to trade them back in, you know what's available in the market so that that's a big challenge because timing, you know. If you go back three years in the past three years, what you would see is that there's been product's and a good one is like Optimus 660… well actually let me see if I have a slide that I might be able to share. So, what you'll see is that our supply and demand is not that gradual? It's very, you know, goes up and down very rapidly and we have to make decisions. I'm frequently changing training. *(Screen shared)* This is a good example so I wish I could look back so the red line is our supply, so blue lines are our demand so this don't know why this bubbles on the way here and this is a power of PDFs. I can't move it but just here on the right-hand side this blue line is zero and basically what this is saying is the redline is supply versus demand, so if I come here on this line here, this means that I have 15 more assets than I have demand for right? And then when I'm down here, this is saying I have demand for 12 more than I have supply for. But you see that was a Participant 4er of a year right

where we went from, we had 15 more than we wanted and then we had 12 less than we needed with him and within a year's time frame rate. And that's because we don't have, you know, we must build up our supply overtime, and the demand is not necessarily at the same rate. So, it's like how do you… again…I can't… when I'm in this scenario, when I have 12 orders and I don't have any systems to send them, I can't go to a store and say okay, give me 12 systems because I have orders right? So now I have these 12 orders that are that customers lot that they're waiting for now we have to try to find this supply overtime and likewise here I couldn't stop these from right. I mean I can buy disposition into; you know, I could sell them off, I can scrap them. But I don't have the ability to just stop them from coming in there. There is trade in, they're going to come in when they come in, right? So, my inventory is building up, building up, building up, and I didn't have the same orders going out the door. So, my decisions, you know my disposition here was still going to XA and at this point basically we said OK, we've built inventory up way too much. What we did is we dropped the price and we started dispositioning and, selling them off to brokers even though it was an offering for us, right? So, what happened is 15 that we had an inventory. We basically closed the doors and we said we're not taking them anymore and we started selling them off. And you know, in one quarter I know what this number is. Probably around 8. You know we sold out seven, you know then somehow we got another one and then we sold them all off and we start… We kind of stopped taking them in so, so that's a big challenge for dispositioning because I can't just look at my order backlog and say, okay, I need I need three this quarter I need 5 this quarter I need two in Q4 and I can go in and keep my inventory levels at that. It pays right. If I get 10 this quarter. You know what do I do? Do I hang on to them and hope that I, even though I only need three this quarter? Do I go? Do I hang on through the extra 7 and hold on to the inventory and hope that I eventually sell them? Because leadership, you know they don't like the big inventory numbers. They don't like things sitting in inventory for a long time, so, you know, those are things where that that's very difficult because you know how you make that decision on how to this position. Because If I make the decision to say, you know what I'm closing, I'm closing my door. I'm not bringing these in for XA anymore. I'm going to sell off everything that I get and then tomorrow sales books 5 orders for them. It's too late. I don't have the ability to go out and get these now. So that's one big factor. That's a very, very challenging. It's just that we're very dependent on customers trading it in. We don't have the ability to just go and get them whenever we want. The other big challenge is honestly price, for COMPANY A there's a couple factors, We are not, When we are short on supply, we are not competitive in price a

lot of times and the reason being is that if a broker buys the system. They're not going to go through and refurbish it to the level that COMPANY A is. So, I'll use it, I use an example of Optimus 660. Again, you know we want to buy it at $100,000 and we want to re-sell it for $300,000 that's COMPANY A's model right? We're going to buy for 100. We're going to resell for 300, but a broker can come in and they could offer the customer 150. So, they're going to beat our price already. They're going to pay more. The customer is going to sell them more, and then they're going to go and re sell it for 200 or 250 because they don't have all the extra refurbishment costs. They don't necessarily need as high margins, so they're winning on both sides right there. They're buying it for more and selling it for less so they can turn it a lot quicker. They have the ability to be more competitive, so that's very challenging in making our disposition decisions because you know our supply is driven by our trade in price and the fact that we try to be as competitive as possible but we can't get there because of the business demands from a margin standpoint. So those are things that are really challenging because I don't have a normal supply chain and I'm not always competitive on price.

Interviewer

Yeah, I am just thinking here when you said something about the decision making do you is there? Is there friction sometimes between your decision and the decision of the engineering team. So say for example you have decided that this product goes to harvest and you know eventually when he arrives at the repair facility, Participant 2 looks at it and it's like, you know what, we're just going to refurbish this whole process is all products or let's say you've decided that this product should go through the XA and you get it to the factory, the repair facility and the person in charge looks at it and says there's no way we're going to do this. We just going to have to take it through the harvest. Does that happen sometimes and you know, just curious to know if that happens.

Participant 4

Yeah, it does. Actually, we just had a call yesterday on a very similar situation, so one of our one of our PET products PET 690. Engineering were telling us that they did not want to refurbish a certain type of console on this product. Even though we have a programme in place and it's qualified and everything else, but engineering was saying we were bringing them in and we were trying to refurbish them and that's how we disposition that and then it would get to the factory and it would get in a Bay and the technical team was saying why

are we doing this? We really shouldn't be because these consoles are not very reliable. And our challenge was we agreed with but we didn't have really any other option because we couldn't get the upgraded console because there wasn't enough supply of it and we couldn't. We couldn't harvest, did not want it because it was so expensive for them to take. So, there was that conflict where it was. You know, the feedback was we made the decision to this position as XA and engineering are saying why are we doing this? This is, this is not what we should be doing, so there's that side and then to your point. There's also the other side where we have harvest saying why are you selling these systems off to brokers, we desperately need these parts. We desperately need these systems and there is that friction. Can we come back? And we say OK, but your price is not, your prices is not competitive, and somebody needs to make that up like. So, we have to get together. We have to come to solution and say harvest. You know you're only willing to pay 10,000, but these are selling for 50,000. Who's going to make up that $40,000 difference? Are you going to do it? Are you expecting us to do it? Are you expecting sales to do it, but like somebody's going to have to make that up? Because if we just drop it down to 10. We're not going to get them back anyway, so we're getting them back in 50 and were signed into brokers, yes, but that's not ideal and you really want them, but you know, we don't really have another option, so there is always that little in it. It's usually, yeah, good discussion in the teams come together and we try come to a solution and how we can do it. And sometimes you know harvest might come and say okay, well you know what will pay 50,000 for four or five of them because we need that bad. So go ahead and keep your price of 50,000. Or they might say can you come down to 45,000 and meet us part way and will have those discussions. But it there is some potential friction there at times.

Interviewer

So, the last thing the last question, of course, is what mechanism? Not sure if there is any mechanism anyway, but what method like to for example, the Tix platform that that you used to COMPANY A uses to estimate the price of the product and some other things. Just as such method or framework or mechanism with which you make this decision. So, are they sorted based on your judgement, right? Do you understand?

Participant 4

Yeah, so we have multiple operating mechanism meetings that we review along the way… so we have a weekly inventory call. So, every week we go when we look at what's in our

inventory and we look at that and we try to understand… is in. just know from a few samplings. So are the inventory we have, and this is this is raw material that's not refurbished yet but is trade in, but it's roughly about $14 million… So, every week we go, and we look, and we say, okay, we have $14 millions of inventory. How much of it has orders? You know how much of it is planned to go out in this quarter and next quarter how? How much of it has orders in the future, and how much of it doesn't have orders at all? So, there's that… that's done weekly, and so that's decision. We make decisions on that kind of drive decisions say okay if I have 10 Xray systems and only three of them have orders the next one that comes in I shouldn't bring it into inventory because I already have so many, so that's done weekly, and we will meet with you know sales or will have those discussions with the product managers you know. So, in that case, for example, let's say that the operating plan was for 15 of them, but again, we have 10 in inventory only orders on 3 even though we don't have enough for operating plan. We might make the decision to say we're still good for a while here. Let's let this one go. Let's sell it off. Let's not bring into inventory. Let's disposition to a broker, even though we have not met our plan yet. So that there's that done that, that piece is done weekly, and then a monthly basis, um, there's multiple calls, but it's kind of a monthly cycle, but there's three or four calls that are done where we meet with sales, and we meet with the refurbishment team and then they go through their plan. So, what are they building this quarter? What are they shipping out? And we understand that piece of that on a monthly basis. And then on a monthly or quarterly basis we get together with the sales team and the second managers of the product managers as well and we go through kind of an overview of what's in inventory, what's in the build plan or the refurbishment plan? What's in harvest plan and then what's coming in? So, we called minus site, so we say what's what is coming in trade in? What are we going to be getting soon down the road? And we do that on a monthly basis and then that kind of drives, you know, that's a review of the supply and demand peace, and that drives a decision. So, we say, okay, you know what we have enough of these? Let's start dispositioning these to brokers and then the following month we might come back and say, okay? We've sold off some of these now, but let's not send it the brokers anymore. Let's turn them back on and start bringing them into XA or Harvest again so it's very dynamic and we meet very regularly. Like I said, it's different some meetings are weekly summer monthly, summer quarterly by there's multiple optics.

Interviewer

Alright, starts it thanks that's it. I've asked all the questions I've got; do you have any question for me?

END OF MEETING

Appendix B-5: Semi-structured interview transcript for participant 5 (Company A)

Interviewer

Let me start by saying that one of the documents I was sent by Participant 1 was a link to YouTube video which had you talking about the XA programme, and that was several years ago and that was really, impressive, good stuff you guys are doing. So uhm I spoke to Participant 3, and he told me about the side of the Pet/CT products that he covers, and I've been made to understand that you're the go to person for the ultrasound business, which is why I want to have more discussions with you about the business, about the XA process. So, I'm going to tell you what my research basically focusing on right now. So last year did the research in the UK about the acceptance of reprocessed medical devices and I found out that in the UK especially the acceptance is very low, and I thought about how to improve this acceptance. So, I did another research to qualify the factors that matter to customers in the UK and found that one of them was quality followed by the pricing with brands and some other key things, and I thought about how can…What is the status of the quality considerations in COMPANY A's recovery with other top ones, COMPANY A, Phillips Siemens and other ones. Is there anything lacking in this process? Is something that can be improved because most times, as you know, the negative perception is because customers don't have full understanding of the effort you put into this process. So that's why I want to really know what It is like making this decision. So first I want to talk about the decision making of what to refurbish or what not to refurbish and to talk about how these considerations may affect the customers. And that's basically just the two topics I would like you to cover as a product manager from the ultrasound business. And I was made to understand that you're the sales and marketing person again, so that's quite a lot for just one person, is not it? So, I won't get it keeps you busy. I just want to know about how do you go about marketing XA products to customers you know and how does this affect customers decision to purchase it or not approaches it? So that's basically everything. So, the floor is yours so.

Participant 5:

Okay, well I have four marketing documents that I can send you that really try to summarise the products we offer and the XA process that there's a XA Document I can send you as well if we didn't already send it, it's it covers all the product's versus just ultrasound, but so I can

send you those documents and those are what we use. We rely on the sales team. For the most part, to communicate that to the customer. You know we don't do advertising or anything like that really. We rely on the sales team.

Then myself and there's another person, Sue McGinnis, in a she's on our part of our sales team, but she's sales support for selling XA and the two of us have been working to get on team meetings with the teams of salespeople to make sure they are aware of what we do and that they have those documents to be able to give to customers to try to help customers feel more confident.

Just quickly, though, I can tell you. Well, let me see here. I have a pull one of these up really quick. And then there's that video. You know, it would be great to update it. Unfortunately, it wasn't cheap to make and so. Yep. We have not really updated it, but it's still accurate. What's in there has not changed? Some of the people have moved to new roles. That's the biggest change, but here, let me see. So let me share this document here so that you can see it. So, I'll send this to you what you'll notice on all potentially 55 brochures. 5 documents are just two pagers, this information is the same and this really tries to explain. You know how we understand their need for a cost-effective imaging solution. But we understand quality is important, you know, and a great value. And the one thing I will say is that when you buy from COMPANY A. And honestly, I would expect this to apply to other companies as well. And I guess just a quick comment on that Phillips had what they called Diamond Select and I heard recently that they have scaled that back way back that they're not doing as much Diamond Select anymore. So, I don't know for sure if that's true, but that's what I've heard recently. And Siemens I don't believe was involved very much in refurbished equipment. So, COMPANY A really has had for a long time and ultrasound, and I'm talking specifically Ultrasound here has had a leadership position in terms of pre-owned refurbished equipment, but anyway. When a customer buys from COMPANY A and if they were buying Diamond Select from Phillips or something from Siemens, I would believe this to be true as well. They should have more confidence in it than when they buy from a third party because there are things, we know about issues that have happened in the field with different components of systems that a third party is not aware of. And so, when the systems come in, we're taking all those things into consideration. All our field service history that we have, and so when that system comes in, if it has had specific issues like lets one of the biggest things is what we call a DOA or dead-on arrival. Some people call it FOA failure on arrival, but the bottom line is the system shows up with the customer and the field engineers and the

applications team can't get it to function properly to train the customer. When that happens, you know it may be a simple thing like a cosmetic issue on the keyboard or something like that. And the field engineer will replace a part and then you know they'll move on. But if it goes beyond that and they have issues and they just can't get it to work properly for the customer, that system comes back to COMPANY An Ambassador Medical and in Noblesville which is just North of Indianapolis IN, and we go through that system in detail to try to find the root cause And we're going to fix it. And we have a process working with the design team that make centre and our engineering team and ambassador to evaluate every one of those systems and determine you know, if we found the root cause, we know what it is. Say it's a circuit board. We replaced that circuit board and then we run it through a full battery of tests. That's another thing that some of the third parties can't run all the tests that we can run. We run it through a full battery of tests and if it doesn't pass all those tests then that system is almost always scrapped. You know we just we don't move forward with it so, but if we can find the root cause if we can fix the problem in the system passes all of those tests then it will be refurbished and at the end of the refurbishment line it gets tested again and we go through all those tests again and every system we refurbished goes through all those tests at the end of the process And we will not ship unless it passes all of those performance tests including actual imaging with probes, so we'll hook up multiple probes an image on a Phantom to make sure that we're getting the images the way they should be no dropouts, no other issues. Before that system ships, so that knowledge that we have of the system and the testing that we do to verify that it's got the highest quality. The one other thing we do that third parties may not always be aware of. As you know, software gets re-released, you know, on a regular basis, with improvements and upgrades and security enhancements and all those things when we set. When we refurbish system, it always goes out with the latest software. Third party may not have access to that software may not even know what the latest release is, so there's a real risk there to customers. The other thing is that systems can be upgraded. So, there are upgrade kits available, but really only within COMPANY A, so that upgrade kit is available to us at COMPANY An Ambassador. It's available to the field engineers so customer can say hey I've got what we call a breakthrough. Some of the systems you call it a revision, but I'll use BT17 so that would mean it's a system that was released in 2017 and if that if the customer says "hey I want to buy an upgrade to the 2019 functionality" an in its upgrade that exists, then the field team can sell that, field Engineer will go in the install that upgrade. It can include hardware Um; you know some cosmetic pieces. It can include multiple things and software, so a third party sometimes will

try to upgrade the system. Usually, the only thing they can get their hands on is the software. So, they'll try to load the software for the system, but they may not know that there's a circuit board that should have been replaced. There's other parts that should have been replaced, so when a customer buys from a third party, sometimes everything goes great. But not always, and we get horror stories of where the third party didn't know what they were doing. They tried to alter the machine, upgrade the machine, they didn't do it properly, and now the customer is trying to use one of our new probes or trying to use some of the new functionality and it doesn't work. You know when it comes to quality? Like I say when you go to the OEM, I think you've got a much better chance of getting the best quality than when you buy from a third party. And that's when things look… and the third-party market is significant? There's a lot of people out there getting their hands on used ultrasound equipment trying to refurbish it and resell it, but there's a lot more risk to the customer. It may be lower price, probably is a lower price, but there's a lot more risk than they assume when they buy it from.

Interviewer

Can I just go back to the third-party that you mentioned. I don't quite get it, when third parties refurbished COMPANY A Systems do they retain COMPANY A labels, COMPANY A brands or do they need to take it out and put there's on it? Faulty systems would not be the responsibility of COMPANY A, or would it?

Participant 5

Yeah, they don't take the brand off the system, so it's still a COMPANY A system, but you know when we sell a system to a customer. We are responsible for the system as it was sold as soon as a third party gets a hold of that system and starts modifying it or doing things to it. I'm not going to say that someone couldn't come back and try to hold COMPANY A responsible, but for the most part We don't have full responsibility anymore because the third party got in and started doing things they weren't authorised to do. It would be different if they were authorised, but we don't have very many authorised third parties. we sell through some third parties that are not authorised to service the systems so they can sell them, but they know the customer needs to come back to COMPANY A for the service. We have a very small number in the US of approved distributors. But again, that approval is almost always for sales, not for service. That helps a little bit.

Interviewer

And this third party you talked about, are they also involved the sales of refurbished products. For example, third party vendors do they assist in the sales of refurbished systems or does not only apply to new systems.

Participant 5

No, refurbished. So, we have three channels to market for our products used products. And when used because used includes products that aren't had never been sold that, but they are used for demonstrations. So, we will send systems to customer sites. The sales personal go in and do a demonstration. Sometimes it's a side by side with a Phillips machine or a Siemens machine showing the customer the advantages of our system over the competition. When after that system has gone to multiple customers in over a period of months, it'll come back to COMPANY An Ambassador. If it's in the Americas and it'll come back to COMPANY An Ambassador, we will refurbish that system and resell it as what's called a demo system. So, it's always been owned and maintained by COMPANY A. It's never been sold and will sell that as demo. That's one channel to market, and those are almost always sold By the COMPANY A sales team directly to the customer in the United States. In some other countries, those will be sold through third parties or distributors. So that's the first channel to market in the US. Those are sold direct to a customer.

Then we have what we call XA Direct and that those are systems that were preowned. So, they're customer bought them. And use them at some point. Decided to trade it in for another system so they instead of, for instance, that customer was talking about. He's got a 2017 system or a BT17 system and he wants the functionality of the of the 2019 system or the 2020 system. Or a brand new, you know 2021. He'll trade in at 2017 system and buy the new one, and then we take that one that was traded in, and we go through the XA refurbishment process and then we resell that directly. Our sales team sells it directly to an end customer. That's XA direct.

But then we also have one other channel to market for used equipment and that is the XA dealer channel. So, we still refurbish. It comes back we refurbish it through the XA process, all the quality testing and everything else, and we put a label on the back of it that says that it's a refurbished by COMPANY A System and then we have dealers and a couple of distributors that are under contract to sell those for us, and they sell them to end customers and they usually take our, you know, brochure. The one that I was sharing and, you know, the fact that its labelled as a refurbished system by COMPANY A and they use that to sell

to customers and say yes, you know I'm at the… something refurbished by the OEM directly And that you're buying, not something that I refurbished or somebody else refurbished, so they'll use that quality to sell to the end customer for us and the reason we use them as our sales team? You know we have hundreds of salespeople, but their focused, obviously their primary target is larger accounts, so they'll work with the Mayo Clinics and the large healthcare companies in the Women's Health Side, they will also sell to some smaller Women's Health offices, but there's still usually part of a larger network, so we use this dealer channel to go after the independent doctors. So, you may have, you know some independent doctors and Women's Health where they're not part of a network there, just you know it's a doctor, maybe 2 running their own practise and within our we don't have enough salespeople to cover all of them. And that's where we use the dealers, and they go to those smaller offices and try to reach them and sell our equipment.

Interviewer

So, I just want to ask again about you talked about testing earlier. You said when the system gets to you, you're running full tests on it. And if it feels that test, you will most likely dispose of the system. Now that's even before taking the product through the refurbishment process, is that correct?

Participant 5

Correct, yep.

It is in a repair area, so in other words, if we're you know we're doing all that testing, and if it fails and it's a known failure. Like I said, we can identify the root cause and we can replace a circuit board or some other part to fix that system. And then you know, test it again and determined that it functions properly. You know then will move it through the refurbishment process, but it doesn't. It doesn't make any sense to spend all the money to replace broken parts or damaged parts. You know wheels monitors other stuff like that. If you know the system doesn't even function properly. So that's why we make sure it functions properly before we send it through the rest of the refurbishment process. And then once it's completed the refurbishment process, we test it again to make sure that somehow through the process that refurbishment process includes tearing the whole system down, cleaning it thoroughly, putting it back together, replacing any broken parts or You know bringing them back to like-new and you know if somehow through that process of tearing it down and putting it back together, we accidentally did something to it. We want to catch that and that's why we go

through a complete battery of tests again to make sure the systems functioning properly before we ship it.

Interviewer

Yeah, I've had some discussion with Participant 2 who is the plant manager for the for the refurbishment facility the rock. And of course, talked me through that the refurbishment process in a very comprehensive manner, which is good, but a question I've got for you as the product manager for ultrasound is how you decide what products to refurbish, in the first place,

Participant 5

well obviously, it's you know market demand drives that so that the product that you know the customers are asking for.

The cost to refurbish is a factor, you know, that that say that we have a system were. You know we're having issues with a specific part on its an older system, I guess. One of the things I should say you a demo system is typically less than a year old. You know we were we demo it to different customers and things like that, but typically that it's less than a year old. Not always, that's not a hard and fast rule, but that's a typical thing and those systems they virtually all get refurbished unless the system as an individual specific issue like I was talking about its DOA and we can't for whatever reason, it just will not function properly and we scrap it but you know 99% of those get refurbished and resold coz they are almost new and then the XA Direct. Those are also typically three years older so or less and they virtually all get refurbished because there's a market for them, customers want them, we can resell those. Then the systems that get traded in that are older than that you know, let's say in the 4,5,7 years old. You know, there's not always a demand for those. The technology changes so rapidly that in some cases if it's five or seven years old, it's far enough behind in its image quality and capability workflow, Technology where you know we're introducing artificial intelligence on the systems, all kinds of security enhancements. You know the fact that systems run an old Windows platform. You know Windows 97 or something like that. You know customers don't want those because they're not secure. They don't want them on their network. So those are really the factors is when it gets older and we're talking older than three or four years, then the market really plays in, you know someone is willing to pay $3000.00 for the system even if it’s refurbished because of how old it is. You know if we're talking about a large system that doesn't make any sense. You know, handhelds, different

story. You know those are run at a much lower cost, but when you're talking about the larger systems, it that's really the factor. And then again, this doesn't happen often with COMPANY A thankfully. But let's say there's a system where you know we've just had a lot of issues with it, and even with new software you know yes, it'll function properly, but maybe it still tends to fail or have random issues, or whatever. It's and like. I say it's an older system, we may just make the decision. It's not worth it. You know I don't want to put a system out in the field that I don't have confidence. It's going to be a quality system, and it's going to be reliable for the customer. So, you know again as a system age, it was like that if it starts having issues then we just won't refurbish it and resell it.

Interviewer

Are there any other factors you would like to add to that?

Participant 5

Um?

Yeah, you know, like I said,

1. cost to refurbish, that's a big one.
2. Market demand and
3. reliability of the system.

Those are probably the three. Oh, fourth would be:

4. parts availability,

So, the other issue we run into is that you know these have the latest technology and monitors and circuit boards and all that. But again, that technology changes so fast that a computer chip, Integrated circuit chip auto board that was in full production in 2015. That supplier may have obsoleted that part and so parts availability becomes a real issue for us when you get out there, you know with these systems 7 plus years old. Sometimes parts are not available and if we can't get parts, obviously we don't refurbish the systems.

Interviewer

So, in my discussion with Participant 3 and he talked about you know COMPANY A having three different kinds of product are premium products, performance products and value products. Wonder what category the ultrasound system falls into.

Participant 5

Well, we have the same, it's. It's not that the ultrasound system falls into one of those categories. It's that the ultrasound has those categories. So, can you still see the brochure?

Interviewer

Yes, I can.

Participant 5

Okay, so this is our Women's Health category. And by the way, we have well let me. I've got another slide I can share with you quick. So, this slide right here shows are different segments and some of our competitors have stopped doing this, but it's been an advantage for us, so there are five primary markets that we target

1. There's the women's health: For obstetrics and gynecology and we have a line of products to serve that market. The workflow in the software, the way that we layout that what we call the user interface. Some people call it the keyboard or whatever, but that the way we lay that out is all designed on the way that a stenographer is going to be doing imaging for obstetrics and gynecology. You know, what needs to be closest to their left hand, you know, while their imaging on the patient, that kind of a thing. Or you know if it's the other way around, they're going to be using their right hand on the system and imaging with their left you know. So, we take those things into consideration and try to make a design that is going to be. The easiest to use for the stenographer doing that
2. But then we have cardiovascular, and those procedures are different and so we have a different system design layout targeted after the cardiovascular market and
3. Then we have general imaging: Within that we have a product that sounds like it should be Women's Health, but it's the automated breast ultrasound.
4. And then we have other systems for there, primarily for radiology, so you know doctors trained Look at the bone structure etc.
5. And then we have products that we call point of care and primary care. Primary care tends to be some of our smallest most value products. Okay, pointed care is a little bit higher end. But also, you know this these are products designed for, you know in hospital rooms in ambulances. You know, different things like that or doctors that that may even veterinary doctors that may be travelling to different locations to work with patients.

So, these are our primary five categories that we target after, and you can tell me the systems are similar but they are different. But okay, with all that said, so I wanted to let you understand the different segments, but with all that said. Within each segment we have premium products. We have a, you know, the kind of the mid-tier and then our lower value product.

1. So, the volume sign, we call it the expert series. That's the top of the line most premium product.
2. Then we have the signature series which is the mid-range product. Still very capable but you know some features are stripped down to make him a little more cost effective and
3. then we have their performance series which you know has a lot less features and capability, but you know it's a lot more affordable and for certain applications, that's the right product. You know they don't need the high-end product, and
4. then of course we have our hand-held product that we sell across all, and you know that's the lowest value product, but on the other hand has amazing capability we just released the beast can air which is a. It's almost like the probe can communicate wirelessly with your cell phone or your iPad and that becomes your screen. And so, it's very, very portable. You know you could literally stick it in your pocket and be able to do image in remote locations. Or like I said in ambulances, tight spots where they're trying to rescue patients. Different things like that so you know it's our lowest value product, but it's also our most portable product.

Interviewer

okay and do you refurbish all of them? I mean all do you refurbish products in these different categories?

Participant 5

We do, yeah, for ultrasound it makes sense for us to do that, so even these V scans, this is the piece can extend, which was the latest one that still had a probe that was wired to our device, even those they sell in the $7000-$8000 range, I think usually and you know our let's see our initial testing process is more of them fail than on the higher end, not because they don't pass the test, but will would say will look at this and the probe has some significant gouges or damage to it. You know it's expensive to replace that whole probe. And at that point we just would not refurbish it because it's a low-cost system. You know, with these

systems the user interface can have significant damage and will but will still replace the user interface because it's still worth it. You know there's still enough value there to the customer even if we put that kind of cost in it that we can still resell it and it profitably. But when you get down here to one of these, you know if there's significant screen damage or the probe is damaged, we're not going to refurbish it, but if it comes back in decent condition then we'll run the tests and if it passes the test you know we will refurbish it that you know this outer shell over the main system may need to be replaced. That's one of the most common things that we do. You know, upgrade the software and resell it, but so that's you know as the value or the price level goes down in the systems Then you know the amount of refurbishment we're willing to do goes down as well as we don't want to get to where we're just losing money. That doesn't make any sense to refurbish and sell it for less than it costs us to refurbish it.

Interviewer

Okay, yeah, that's true. I think when talked about Participant 3 and Participant 1 talked about the sales margin, you know technique that you used to estimate and to justify you know whether it's worth it to refurbish something. And I was just wondering about you know this product when you make the decision to refurbish them. Does the category affect how deep you go into the recovery or refurbishing operation? for example for premium products do you try to like, explore like have more process steps. Do you go through, strip it down into different components you know go into the component level repair. Now that's and does he reduce as you go on or it's basically the same process and it doesn't really matter?

Participant 5

Yeah, we go through the same detailed process on all of these, but we will stop the process if we get to the point where we find enough parts that need to be replaced that as Participant 3 said, our sales margin is not there, you know it's going to be a negative sale, then we do not know will stop and we won't refurbish it will. There's another thing that we do in addition to scrap if the system functions fine, but it's got some significant issues. For instance, let's say that it got dropped, which can happen. All you know, somebody literally drops it off the back of a truck or something like that, or down a step, or in the frame gets bent. You know it's expensive to tear the whole thing apart to replace the frame. Or in one of these them because the frame is the base. Plus, it goes up the back and so it's a lot of work to tear everything off it to replace the frame. So that's one part that let's see if that comes in and it's

bent, and it would need to be replaced. It's just not worth it. You know you're almost building a whole new system anyway, and so you know, yes, there are as we go through that refurbishment process. If we find certain high-cost issues we'll stop and say, OK, this one's got more damage than we thought it had, and then we have two options at that point, we can harvest the system. What I mean by harvest is, so we know the frame is bent, but you know the monitors still good. The user interface is still good, the CPU portion is still good. So, then we've got another system coming through that's you know the same version as this one. We have some detailed rules of how we can test to verify that the monitor is really working right at the user interface is really working. Right, and when it passes all those tests then we can remove these parts and use them to fix a different system that has a good frame and doesn't have that set. The you know those issues so we can. We can harvest parts or just scrap the system.

Interviewer

Another thing here, the refurbishment operation, do you do the part level? Yeah, part level refurbishment operation. Or do you just focus on the product to? The question I'm trying to ask basically is when you look at some products you naturally need to replace some parts, right? So those parts that you remove from that from the product, do you just automatically dispose of it, or do you try to restore that? That part or any form of component level refurbishment shopping?

Participant 5

Yeah, at COMPANY A. You know we do a lot to try to extend the life cycle, reduce the amount of you know when I say we scrap that system. I don't want you to get the idea that a lot of them get scrapped. We do as much as we can. Like I said, to harvest parts off it to reuse. And we also have an ambassador, an expert team of board level repair people so and we also have some at the rock. They may not have told you that, but there's a whole repair team at the Rock, so if some circuit board is bad and there's the integrated circuit, parts are still available to fix it. Our repair team, what will do basically is they're always repairing boards, so they'll remove the bad part. They'll put a new circuit chip on the board, then they'll test that bored again. Everything goes through extensive testing. So, after they repair aboard, it'll go through extensive testing to make sure that it is working properly, and at that point it's like a harvested part that we can put back into our inventory to use to refurbish other systems. So, in that way we reduce you know that the only thing that got scrapped at that

point as the little integrated circuit chip but the board was repaired and we can reuse it on other systems.

Interviewer

Okay, Okay, Okay, just wanted to be sure about that. Also, part of the consideration and Alright, so the portfolio size coz I see if you've talked about number of products, and I can say you've got like more products in your portfolio modality of products. You refurbish done other product managers and I was just wondering. I mean do you have like growth numbers of products are you refurbish so for example in 2010 you used to refurbish let's say 10 and then now you now refurbished 20 a year or just trying to see if it's possible to place the growth in their processing operation at 4 ultrasound products.

Participant 5

Yeah, there's probably about 100 active models that we're refurbishing an ultrasound so it's a lot so you can see in this slide I was showing here before. This is not every product. By the way, this is just representative, but there are more products in some of these segments that are shown, but in typically we have five or six products in each segment. OK, so if you think about that in current production, you know we've got about 30 systems that are being manufactured new 30 models that are being manufactured new as we speak today. For each of these we're refurbishing Um, and there's a new launch for most of these systems, at least every other year. Okay, so we're refurbishing probably four or five for instances Value signing 10, there are for that one, let me think. There are five different levels. Okay, going back over the last six or seven years that we refurbish. So, add ambassador. There's over 100 different models that we are refurbishing at this point just to give you a feel for the variety that we have versus CT or MRI where they know they have maybe 10 here. It's not. It's nothing like this so it's a lot of different models that are being refurbished.

Interviewer

Okay, and compared to ten years ago or 20 years ago, how would you describe the growth of the recovery operation at COMPANY A on ultrasound systems?

Participant 5

That's a good question. There have been some changes in the market so. We used to get more systems back earlier than we do now. A lot of the customers are starting to hang on to systems a little bit longer because of the cost. You know to buy a new system every couple

of years, and so there's been some changes. Now with that, there's still been growth, but I guess what I'm trying to say is our supply coming in the back door from trades of these systems has gone down somewhat. But we have found ways to bring in systems from other regions, even Europe. You know Japan, now we do refurbishment there in Europe. I don't know if you know that or not, but we refurbished systems in France, we Refurbish Systems in Austria, and we refurbish systems in Germany, so there's three different sites in Europe that are refurbishing equipment and for me and you know, they may have gotten better at sharing. Again, it's probably the best way to say it where it used to be that the US market in the European market were disconnected, and they were just focused on what they got back. Now we share a little bit more so they may get some more value signing 10spec back that they don't need will move those to the United States and refurbishment and resell them here. The US market is by far our biggest market and we're able to get the highest value out of the equipment in the US market. *You can imagine some other markets around the world. You know whether it be India or China or some of these other markets. You know you're just not going to get the same price point for a system that you can get in the United States or in Europe, so the US and Europe are the two biggest, but the US by far. But then Europe right in behind that* and so with all that, you know we've been able to… you know Covid was a huge reset… you know. But if you take that out, we've had, you know steady growth, let's say since 20, 2012 is how long I've been involved in it. I got involved in 2012, and since then we've had steady, profitable growth through that period.

Interviewer

OK, so you've been. You've been working in XA for the past nine years, is that correct?

Participant 5

Yep.

Interviewer

And your current position is the product manager and or do you have any other Position?

Participant 5

Yeah, I'm the…, so I'm not just the product manager but responsible for the business globally. So, everything that's pre-owned or demo in ultrasound is my responsibility. Whether it's being sold in the US or it's being sold in Tokyo or sold in Shanghai or wherever it's being sold so you know. And again, it's a big role I must coordinate with our sales teams

and marketing teams and all of those different regions. And then You know, make sure we're hitting the sales targets, The SM targets that Participant 3 was talking about, making sure that you know are maintaining our quality. We're not doing anything that's going to allow our qualities slip in those regions, and that we're providing good service, you know, consistently to our customers timely, delivering the products on time and at high quality.

Interviewer

Okay, just a final question. Well, second to the last question, what factors do you think are very important to customers? And how does COMPANY A try to fulfil those factors those requirements I'm asking about customer requirements, customer expectations of a refurbished products and how does COMPANY A meet those expectations.

Participant 5

Well, I think we address that kind of in this brochure. Yep. It's definitely cost, and You know the customers are you are very cost conscious, most of them. There are some that still pride themselves on having the latest technology. So, every time we released a new system they want that system. But more and more it's moving away from that. It used to be that way especially in the United States. I think there was even kind of a competition between large medical groups you know where well we've got the latest technology and we're better than them Cos we've got the brand new equipment that's not the case as much anymore. You know. Now they want to have good equipment. They don't always have to have the newest thing, so value is important. And that's where these products come in. There's one other slide that I can't share. Well, let me share this with you really quick.

There's two other things related to quality that that you should be aware of We are an FDA Regulated, you know Company A as an OEM manufacturer in the United States. The FDA federal Food and Drug Administration, the United States comes in and audits our facilities, including COMPANY An Ambassador Medical, which you can see here. So, we are randomly audited by the FDA, so that's part of what… Also can should give the customer confidence that you know we're maintaining our quality because we have to pass those audits. If you don't pass those audits, they shut you down. So that's part of it.

And then we hire a third party to do ISO 13485 certification for us. So, we also maintain that and then in addition to that, our quality team at other at the headquarters will come audit us every year to make sure that we're meeting all the procedures and quality requirements within COMPANY A and the FDA. *So, we go through two audits every year. The ISO audit,*

the internal audit, and the FDA randomly as they choose to come in and audit us. So that's one other thing for quality assurance that I wanted to mention to you. But let me see here if I can quickly Share one other slide. Yeah, I think this slide is good.

So, to answer your question, what we try it tell our sales team, so these are, you know, sales prices for the product and this is not exact. This is rough, just trying to kind of show where the product's fit so don't want you to think it's exact but if we've got new products, value sign E10, The Expert series, you know premium product and then we've got a value sign E10, you know, BT19 we got the Eve where they were, you know. Still selling had some 19 is left over. They were selling so I put this slide together at last year. But just wanted to give you an idea. So, this is where the new product line up on the average price for sale sales. So, you can see that the expert series is up here at the top you know. I mean they sell for over $120,000. They had the option of a customer. At this point they were still had some left over 2019 systems that they were selling at a lower Price and then you get into the P8 E6 the S10. This is the signature series. The Signature S8 and then the performance series. The P8 down here. So, where demo and Gold Seal fit in is you know, because that with these systems were used as demos. Will sell it at a lower price. So, let's say the customer you know is okay with taking something that's used or gold seal their confident in our quality and they need a lower price than the sales team can offer them. This demo system and they get the same performance as a brand-new system that's $130,000, but they can get it for $90k to $100,000 OK. And then if that still doesn't work, but they need those features. There's the XA option, so you know that we don't have a BT20 XA, but the prior version, the BT19. We've got a few of those that have been traded in, and they can get those basically the same performance for you know, $70k to $80,000. So that's where the depending on where the customer is in terms of their need for a brand-new system Versus their Cost consciousness and in the price point that they need to hit. That's how these different products help us meet those customer needs. so, they could buy a brand-new value signee E8 BT19. But if they're willing to take a XA that's a couple years old, they can get a E10 with the highest level of features that we have for that and for that same price. I don't know if that helps a little bit.

Interviewer

Yeah, it does. It also helps just sticking up the volume E18, B19 on the near side on the demo side and on the XA does it look to them in the difference in the price? Doesn't look too much. If it was a customer, I'd rather go for the new one than the XA because I mean the difference in price is not very significant, it's just about 10,000 or something like that.

Participant 5

It depends on the system. The higher end it is, it’s kind of like you know you depreciation on a car. If you buy an expensive car as soon as you get home, it starts to depreciate quickly so you know it depends when you get into the mid-range, you're right. The difference is not very much. But when the with the premium product, there's a little bit more difference and you know customers are more motivated to save a little money and go with the demo or the gold seal.

Interviewer

Okay, so from what you said, I mean, it looks like it's just the cost, is not it? Do you think of any other factors that may influence customers decision?

Participant 5

Well cost and quality I think are the two biggest for sure, but the third would be delivery so you know the other thing that can happen is. Let's say the customer needs this system at this price point so they can't spend over $80,000, but they need the full functionality the expert series they need this system. The unfortunate thing you load up here at the top you know there's limited availability and we must remind our sales team because we are dependent on the trades that come back in, and we go out and try to target different customers that have equipment that we need. You know we send the sales team out and say hey kind of like in the US, at least a car dealer may send a marketing flyer to you saying hey, you know if you've got a, so what I want to say at 2019 Ford Focus, you know we need that car. We're paying extra money for trades right now. You know, consider trading it in on a new one will do some of that same thing. Where will go to customers and that have these systems and say, hey you know, are you interested in getting a newer system and upgrading it and trading that one in? but again, there's still a limited supply of these, so you can't necessarily deliver it as fast. Where I've got, you know, demo and new in finished goods ready to go. Customer needs that I can ship at the same week you know or whatever with XA that may not be the case because the supply is more limited so on time delivery would be the other big factor. I would say you've got price. You've got quality and you've got your availability. Is really the other big factor I think, and overall features. So, one of the things that really helps us is the fact that we've got advanced, and we really do a lot of product development. I am, it's one of the most exciting things being in COMPANY A Healthcare on the product side, especially ultrasound. Just constantly innovating and improving image quality and

improving the security of the system and all those things because of all those new features that are always coming out. You know there's a lot of demand for COMPANY A product globally, especially this Women's Health product is in high demand all around the world.

Interviewer

Okay, but I mean the continuous studies 430 already. I can imagine you may have something else to go to so.

Participant 5

Well, that's okay. If you got a couple more questions, I could try to answer him.

Interviewer

Yeah, I was going to ask about. The fact that products have continued continuously released on, you know, probably every year or twice every year or something like that. Those don't you think that may affect your recovery operations? Because there could be a new product offers the same thing as refurbished 2019 would do, but it's probably at the same price and start off their refurbished one. I'm just seeing out there, you know, continuous production, continuous updates of new system could affect the processing operation for OEM like COMPANY A.

Participant 5

There you know there is some of that what we would call cannibalization. So, in other words, you know what if we didn't have that value sign E8 system, for instance, which is between the E6 and the E10. You know, if you didn't have that system, then yes, it would be easier to sell the demo or the XA. You know there are there are customers though. What has driven us to have such a broad new product offering? You know that really are focused on like you said, well, I really want a new system, but I don't want to pay 120,000 and I don't need all those features. But I really want new and that's why we have these product offerings. So, it has made it more challenging to sell the demo and XA but not too challenging. It's been manageable and at this point it still makes sense. So, one thing about this that's amazing is because we do this refurbishment and XA… Like I said we have XA direct and XA to dealers where you've got even older systems that are in the mix here at lower prices. We potentially can get a system and sell it as demo, take it back on trade, sell it as XA direct. And get it traded in again and sell it at XA through a dealer. I've seen that happen many

times, so there aren't too many markets you know and product's where there's a such a variety of customers needing different performance at different price points that allow you to sell systems two or three times profitably. So, when I was in the energy business COMPANY An Energy before coming to healthcare, you know we didn't play in this used market. All we did was sold new and the third parties had this entire market, you know is so all we sold it once and that was it, you know. And then the third parties took all the profit after that. So, we in healthcare the fact that we do this Significantly increases the overall size of our business. I think it also makes us more in tune to quality for our new products. So, as we see issues as systems age Um, you know, we feed that back to the design team and was there developing new products they can take that into account to try to make the products more reliable. The less that were directly involved in this, the less we know about issues that happen overtime as the systems age you can do accelerated highly accelerated life test, Our whole testing, but it's nothing like you know, a system actually being used in the application over 5,6,7,10 years and getting that system back and being able to see you know what happens, what cosmetic parts tend to be damaged or you know, performance issues, that kind of thing and we feed all that back to the new equipment team to help make our new products even better. That's it. That's another piece of quality. You know, really, it's the fact that we're involved it through over the whole life cycle of the product, and so we are very aware of what's going on.

Interviewer

Alright, alright, alright, that's good just to add to the customer consideration. Several other factors like warranty like available information and warranty, Available information and environmental, say environmental friendliness or the fact that recovery or reusing contributes towards sustainability and all that I don't know. Do you think those three factors warranty, additional information and environmental friendliness? Do you think they affect the customers decision in anyway.

Participant 5

There absolutely some customers that you know are very environmentally conscious and they like the fact that you know we do this process and so they are attracted to COMPANY A because of that, because of our environmental concerns, I don't see that as the most significant that you know. Like I say, it still seems to be price, quality, availability and then you know somewhere in there you start to see the environmental consciousness come in and

then, like you said, information availability is definitely, you know, we have within each of these Segments we have actually clubs, value sign clubs, Siva Club, cardiovascular club that so we have these clubs that customers can join and it's kind of like a user group, you know, and you know they can share information. They've got availability to different publications that we have an information that's available. So yes, I think you know the fact that we provide a lot of that information to our customers. You know helps our systems.

So, some customers have their own Biomed departments. A lot of the larger customers do, so they will try to service their own equipment while they have it. And you know, we have warranties. We provide service contracts or will service the product for them, so there's a lot of flexibility there. We try to be very competitive with our warranties. Some of our newer products have, you know, 2,3, 4 or even five-year warranties depending on you know the market, especially some of these portables though their logic E, right here the logic E portable mind ray some of the other competitors you know had extended warranty to try to get customers to be more confident in their equipment. And we've matched that, you know just to show that. You know they can have the same confidence in COMPANY A, where you will stand behind our product, so we've got you know five-year warranties on some of these. It just depends. You know what the market demand is. So, warranty ranges from one year basically out to five, I believe is our longest warranty right now. So yes, we provide the warranty. We stand behind our products with service. I think we have for ultrasound at least one of the largest service networks in the Americas and even in Japan. And a lot of other countries, India and that customers do come to us because they know we can. We can support them. This service with parts with warranty.

Interviewer

Okay, that's good. That's good to know. Thanks. Thanks very much for providing those insights. Was wondering if it's possible. I mean, you talked about sharing some of this document with me. Do you think that's possible or no?

Participant 5

Yeah, I can. I can share this this slide for sure with you and I will send our brochures to you so that you have that. Like I say it gives. Yeah, well, one other thing. So, we talked about a lot of this. The one thing we didn't talk about his training. COMPANY A Healthcare offers train all kinds of training. You know there's online training available for basic information about systems of theirs training. Where will go to the customer site and do training if they

have a lot of biomes or other people that need the training with almost every system we install, especially these higher end systems. When we install it, we send what we call an applications person in there really a trainer? And they'll spend time with the stenographer showing them all the functionality of the system, answering questions about how it compares, maybe to a competitor system they were using before and where they can find the information, they need so the systems come with the new ones come with training. A lot of it. So training is another differentiator we have a training week. All the healthcare Institute up in xxxxx and it's a training site where customers you know when you're not in this covid situation, a lotta customers will come to us at the Healthcare Institute and spend 2,3,5 days in a training course on their System, A biomed to learn how to repair it or is it stenographer to learn how to use it? So, we've got all different levels of training that we offer as well.

Interviewer

Okay, that's good thanks. Thanks very much for that. Just for you to know. I mean I've got NDA with COMPANY A Siva team so any Information you provide anywhere is covered by the NDA, so just so you are aware of that, I'm not sure if Participant 1 mentioned that to you, but just wanted you to know about.

Participant 5

Yes, yeah, I think he did. I think he did. These are these are you know, public documents. These are commercial sales Flyers. There's no issue with that at all. Some of this is more internal, but there's nothing on here that is not released yet, so that's what I was looking at quick to make sure I didn't put something on there that wasn't released. This is to give you a feel for the variety in each segment, but again, let me restate this is not comprehensive. We there are more products in some of these segments that are not shown just because of space limitations and the same thing. You know I will send you this slide. I've got take the price is often just see to say lower higher, but I'll send you this slide and again, definitely not all the products are listed here.

Interviewer

Thanks very much for that and thanks for meeting with me today and I appreciate your time and I appreciate your you know everything. So, thanks very much.

No problem, hopefully it was helpful.

END OF MEETING

Appendix B-6: Semi-structured interview transcript for participant 6 (Company B)

Interviewer

So, I just want to know about you Company B, the background to it, what kind of business do you do? The business scenario? You know when did you start?

Participant 6

Company B was originally named Engineering exchange, engineering exchanges (it's coffee machine in the background) and the original conception idea is Participant 7 had worked in the healthcare market, mainly diagnostic imaging so CT, MRI, ultrasound still degree and the original conceptual idea was that he thought that he could look at potentially building up a network of engineers that could go and carry out sort of work and so forth. That was the theoretical avenue of engineer exchange, but rather than exchanging engineers, what happened was it got developed into basically trading Medical equipment, so we are now… We have been for a few years… The trade desks for Philips, Siemens and GE. So, in Europe. So, what that means essentially when they win projects in Europe or even sometimes with doing some work in Australia to supply the customer, either clinician or the hospital with a new piece of equipment or their own equipment. They would then remove the old equipment, which we will bid on and then purchase at that point. And then sometimes we have to do the deinstallation and remove it, Sometimes it will be deinstalled and we just picked up but mainly we do the deinstallation and then their team will come in install their new equipment for the company. So that allows us to sell the equipment you know elsewhere or redeploy it. So that's the trading side business. We are now looking at developing a stronger ties with place in Africa, namely Kenya, whereby we will supply the equipment. We will install it and we will give some form of warranty. Maybe a year's warranty on on on the equipment. Not all parts. Maybe sometimes we don't warranty the tube or the very expensive components. And sometimes what we will do is we will warranty the components for spare parts but not the labour costs of the engineers and so forth. So, we are working more than users in that respect. And another aspect I think I mentioned you'd be with trying to get into spare parts more. We have an inventory of coils at the warehouse in Spain, which most of them actually been sold, now the issue is what we're doing is we're only testing the coils when they are part of the system. So, when the system is, you know, for your door, you know it's been commissioned. We test that we do QA and we test the coils to see if they are operational there. But I understand and you know soon the engineers that when that coil

that is then transported to our warehouse things can occur to the coil which you know maybe they are not good and you cannot go by that test. So, what we're looking to do now is do something for bench testing within our Spanish warehouse, just to see if these coils can pass some electrical tests to give our customers a bit more. And by so, somehow we just give warranties of 30 days, but I want to do some more because essentially if you do some form of reprocessing, you can actually charge a higher price point as well, so that adds to our quality management system and also explain what we're looking to do is with looking to hold magnets cold. So, look at a storage facility in our own warehouse. Maybe one or two magnets. I met up with xxx in Spain, and this is the Department who goes to customers selling the new equipment in Spain so we work with them when we're buying the old stuff. So, we bought something from them, which was a a terrible project because, well, just example we bought a Philips three Tesla MRI, Which is supposedly and it is, a rex magnets and an upgrade to Rex Magnet, which means it should be 0 boil off of helium and be high on that we I think we end up paying about 125,000 euro's. But there was problems with it… so my engineer went to do the deinstallation, the ramp down he found those ice in the magnet, hadn't been serviced by Philips so we tend not to like to do those things where we don't know exactly what's going on. But because we want to build a relationship with Siemens which said Okay will take the hit on this but will lose some money on but we want you to bear that in mind in future. So, he came to the warehouse, had a meeting with it when I was in Spain, and it was interesting whereby you know, just showing around the warehouse and he was quite interesting sometimes what happens with Siemens is they need to store a magnet for a few months before their customers ready to have it installed. So, and there's something that I don't know, it's some accounting, but they need it out of Germany. They need it out of Germany out of their books so they are happy to pay storage with us rather than have it in Siemens because I think what it essentially means is when that product leaves a warehouse, it has been sold or accounting wise expensive.

Interviewer

It's got to do with the inventor cost, so most people trying to keep down their inventory cost as much as.

Participant 6

Yeah.

Yeah, yes, so they don't hold it off as stock as soon as it goes off now and then. Yeah, so lets you know where we're working with them. So in nutshell, you know it's a trading business fundamentally core, but we're looking to move away from that and and and in in in because the problem with trading is it's very volatile, said fluctuates too. So we're looking at your reoccurring revenue streams in terms of dealing with end users on a long term basis. Also, spare parts, but we're not there with spare parts. We need to have better processes, and that's where you can come in very good use and say look, this is what you know. The key things are there on the call with the Tunisians and GE knows this as well and. I think Siemens are slightly different when they do a refurbishment, but I think from the he was a GE engineer and he will send it. I've been there. What they tend to do is that they te'd to have a checklist as they look business them. This is what we want to replace. This is what we look at the condition of and will assess it and say if it's okay and we just use it. So that's the GE process but Siemens Process is when they refurbish a product they fundamentally changed most of the components and then look at you know everything. But there's a lot more. I would say the threshold is a lot higher in terms of what they would consider a refurbished than perhaps GE and maybe even Philip. So you know we were not going to get to see that we're not going to be able to do what they do, but we want just understand basic so that's why one of the things I was saying to you earlier, Maybe the tubes? Cuz you know if we could just do a reprocessing of tubes that maybe something so you don't have to do everything or a reprocessing of coils. I know there's companies that do the reprocessing of coils, reprocessing of cold heads, American companies do that you know so. But we just looking at different things but tube is just quite an easy one, potentially to do.

Interviewer

That's that's a good one. So one of the criteria for reprocessing would be that the product has to have like very critical value in terms of monetary terms, in terms of function, and so on. I think the tube actually fits that description, doesn't it. Its very expensive, is not it?

Participant 6

Yeah. Seems very expensive. I think you know, for a refurbished tube in the indian market, I think you could charge about 10 to $12,000 and it may only cost, you know depending what you cost it, but it will depends on the supply chain of the inserts and making sure that you don't hold on too much stock as you were saying, the shelf life of those inserts and even even to the point where you know just we were on a call with Tunisia and Participant 2 made

a point and he said, look when tubes are not commissioned or not being used on a regular basis, you lose confidence in the tube. You know, it can't sit on a shelf for a year waiting to be put into a system. So those are the sorts of things and you know the stock that you hold would be very low. But then if you say to clinician, I could give me you a tube, I'll have it for a week, then I'll get it back to you. But they'll be like but I can't scan for a week. You know they want a donor tube to go to them Or a replacement tube to be sent to them? As you know it needs to be that sort of smooth.

Interviewer

And of course, these systems need to… there's a certain number of days where you need to use the system, and after you've purchased and you've installed it, the system needs to run very well for a couple of days, and you know if it doesn't work well during that time, there is a good chance it's not going to last the warranty period, or even the the actual life but it's very important to keep it running, which is what most of this customers don't do. They just you know, because yeah, equipment is expensive. They don't want to just run it and run it and run it. Which is actuallywhat they should do.

Participant 6

And you know the thing is interesting, the engineers… look for an MRI what's the optimal number of scans? And he said look to be honest with you, there's no limit. Because you just want to do it, you can do as many as you want, realistically.

Participant 6

When you are supposed to do as many as you can just existing running, yeah, but they do as little as they can. I'm not sure if that's correct, but they try to do less just to make the system last longer whereas they should actually do more scans to make it last longer, so it's just it is what it is. They don't really know better than that.

Interviewer

I've just got question, whats your position in the company now?

Participant 6

I would say I'm operations Manager now but I am addressed as the commercial sales director. I do get involved in sales but mine is just in general overview of different projects.

Interviewer

How many years have you been in that role now?

Participant 6

Two years, it'll be two years in July and it's yeah. I mean it's it's just. Yeah, I'd say in the last year it's been easy to understand the business we doing and how.

Interviewer

There's always a learning phase, is not it?

Participant 6

Yes, there is actually. There's always a new thing to learn. Thing is it was really good to go and see… so I was with the engineer, and I said… I can tell from listening to that cold head that this machine is not working. There's been a loss of helium and then it is true because you know, if you're around these things regularly you'll understand and it's interesting because you know the way he was just sort of exploring and explaining saying that this is how we going to resolve this situation. Very straight forward. There's only a few things that you can look at. You gotta do your tests, just different stages and pass through.

Interviewer

What's the company size? How many employees do you have?

Participant 6

These 12 employees and there's two over in Europe actually they're three now in Europe but nine in the UK.

Interviewer

Can I say just 10 to 25 then?

Participant 6

Yeah, 10-25.

Interviewer

Fine then. Then to ask about the… Do you keep inventories or do you?

Participant 6

Yes, we do we do we do? We do hold stock and at the moment holding quite a bit of MR just because of the markets. So yeah, we're holding some stock there. Not so much CT at

the moment but then we have got one in stock in Germany. But yeah we do. We do have stock.

Interviewer

Okay, so I'm just going to ask about the progress you've made over the years from when the business started. I'm not sure if I've got the year you started the business.

Participant 6

2012

Interviewer

What about the progress you've made so far, how many products… Have you made a growth in the number of installations you to deinstallations and all that? Do you have the number? So even if it's just a range.

Participant 6

Yeah, you know. Deinstallations, I mean we did projects in the UK in Edinburgh that was a veteran hospital and so we de-installed the MR and that was Edinburgh, there was an installation at Nottingham, there was an installation at Northwick Park, there was an installation now in Madrid. So I've said, we're not a company focused on installation and I'm being honest with you and we're trying to do that. The UK is a bit more difficult because of the NHS. You gotta go in supply chains, the tender process. We trying to work in markets where we don't…we are working with people in the local market so we work in Kenya with somebody in Kenya who then has, you know, background in sort of diagnostic imaging so they understand system and they go and deal with the doctor directly and then we support that guide. Some assistants of… and that's how we were tending to mould business more now. There's work in the UK sometimes people do come to us and say can you supply system, or can you help with this? But it's just not… and the other problem we find is when you start trying to operate in the UK with the NHS, that's when you're going up against the OEMs and that's when they start to not like you. Yeah, so they don't mind me selling stuff or installing stuff in you know Kenya. They're not bothered by that and that's all-bad things. But they don't want me getting it in the UK. And that is a big issue when we supplied some equipment to Nottingham University where they just really really did not want to help at all. So, because we taking their business and that's, you know, the Siemens guy that's selling to

the NHS. He’s gotta look at his numbers and think well I don't want dirty or anyone coming into the picture, you know so that's a thing.

And we don’t we don’t want to also upset Siemens because in another part of the world we work with them. So we work with on trade desk. So we have to have a very you know I’m an understanding of what we can do and what they don’t want us to do? You know I think that’s best way I could probably describe it and they’re not worried about Africa at the moment, but they will be because the market will be turning that afterward that Africa is an easy and their growth figures but at the moment. You know that the bottom line, but the moment no.

Interviewer

Now I think it’s it’s more about the competitive advantage that they currently hold of a small business because they just don’t just sell the system, they also offer warranty, services and all that. So I mean, if you’re taking out their own system and they replaced it with yours, then they’re not just losing the business, they losing the socket, there is not it? So they’re actually loosing a lot of things.

Participant 6

And then also the potential future businesses are scared. And yeah look, it’s it’s very difficult at the moment cos a customer migfht say what advantage do you offer rather than Siemens or so forth. Although the thing is because we understand the market, we may be able to offer a better solution to them and it’s almost like when I go through a mortgage broker because they understand that mortgage market. So maybe I’ll go discuss with Siemens, Philips and GE, say look what you can offer. No, I don’t like that. Maybe you can offer… so you find package that’s better for the hospital. So I mean one thing so they came to me, NHS Trust Mid-Essex Trust and they said that we want a radiology sort of partnership. What that meant from my understanding was they wanted us to you work with them to support them when they were looking at, you know, upgrading their MRI or CT. Now that doesn’t just necessarily we supply the equipment, they could just mean look. Why don’t you negotiate on Siemens, GE, you know, with them because you understand the market better than we do. We tell you what we want and you try and go to them and getting there and get price for servicing to do that. They actually… as much as I had to show how we were vendor-neutral, the contract was awarded to Phillips. And that doesn’t make any sense whatsoever. I asked them 10 questions like, what are your processes, howe can you show you are vendor neutral?

But the very simple way that I shown vendor neutral. It's very simple and we work with GE, Phillips and Siemens, we are on their trading desk. So if I was vendor specific I would say I won't work with this company or that company. So you know the simple truth that we are business partner and we just thinking. Well we want to do what's best for us. What's best for our customer, you know? Whereas Siemens? How are you going to tell me that they are vendor neutral?

Interviewer

Okay, so. How do you get your contracts for used medical devices that you reprocess and resell?

Participant 6

So look, we primarily work on trade desk. So what happens on a weekly basis? Okay, all the trade desk? Okay, that's Philips GE Siemens. They will just say look, we're bidding on this project wherever it may be. So wherever they doing projects, answer whenever they're installing their new systems they need to take out an old system. Okay, that's not part of their… it may not be a GE system, but it might be. It might be a GE system and they say no but they just they don't work with the use department they're not in contact. So they're not really, they just send. So what they're doing is we want to win this new business and we gotta sell this whole system to win this new business. So some of thius projects have not been won by the manufacturer so that manufacturer's just saying to us, look what would you bid for this? Then we make a bid and then we must wait and see if the manufacturer gets it. That's one way.

But the call we had with the Tunisians today. You know he's… You know he's not even a supplier of equipment MR/CT in Tunisia, and you know that they've come across some GE systems that they want to sell. They said that we just want to sell this. So then we work with other brokers and say okay if you got some… Yeah our business. We need systems to sell. So that is our needs, so we have to have a supply chain. So we work with both… the most of our… 80 maybe even 85% comes from either the trade desk or leasing companies so we do a bit of work in the UK with ShawBrook, so when they are, you know leasing to the NHS or something like that. They also look we've got this old quipment now is, you know, in removed, what would you want to get on it? You know something like that?

Interviewer

So when you… I'm just trying to go through the process, so after you've got the contract you've won the contract and got the old system, So what happens after that?

Participant 6

When we win a contract, so say for instance if we win a contract, the first thing we want to do is we want to do a QA or inspection report on the system and that ideally, we want to do that and a couple of weeks before this new system is trying to be installed. Like I say, we will send an engineer from our team or, you know, a consulting engineer that we know and say look, can you go and perform these tests? Okay, because that then enables us to market that product. That's all sales document later to customers. But this is what we got these the data. This is the data. Are you interested? So that's the first stage we do the QA then we deinstall. Okay, we tend to carry out the deinstallations ourselves.

Interviewer

Can I take you back to the QA and inspection that you mentioned earlier. I'm just thinking here that you've already won the contract, already purchased the system is already under contract, but then you go back and do a QA inspection. What happens if things don't go right?

Participant 6

What happens is… what happens is now when you on the trade desk they will provide you with the specification sheet. Not always is that specification sheet accurate sometimes its quite wrong. Okay, so yeah, for instance that that Rex system that we were taking out of Granada, they said it would be in service by Philip but it wasn't. So you know there are inaccuracies. But what happens then is with the relations, we go back to the trade desk and say look, this is what you said it was. We did our own inspection and found it wasn't true. Then now we need to renegotiate that price so we bid on something, it's a bid and we do back it up. We don't… know somebody said that we're not giving any money and… but you know it's subject to, the the information they provided being correct, its subject to us doing the deinstallation, us doing the QA and finding this is not major faults, but that said the offer that we make is a conditional offer essentially. Then, once we do all the tests and were happy with it, if we're happy we just say yeah. Come we're happy with the offer blah blah blah we send it to them. If you have any issues then we have to go back and renegotiate. But then it's a two way street. If we always renegotiate so there's a bit of a scratch as there's this there's that, they're not going to sell you stuff because I was too much headache because

they always come back and want to renegotiate etc. But if you're honest and say, look in a week said certain things like this on system in Granada- the Rex yeah, we we accepted that it wasn't the price that we should have paid, but we still paid it. But you know, we said look in future, you bear that in mind. So that's it's a relationship.

Interviewer

So the inspection happens on site doesn't it.

Participant 6

So yeah inspection we obviously need to test the coils to test the console test Everything in the report we need to have an active system. We don't want to ramp down an MRI and then realise, Oh no, we need to check something and then you can't do that anymore. Yes, we also want to check and meet with the radiographer. Sorry so look. Have you had issues with the system but were they do deserve so you know it's always it's trying to get as much information as you can realistically so we don't want to do is we don't want to renegotiate prices too often and we don't want to sell systems that have problems, But then I can come back to us, you know? So we want to try and do a good job as possible trying much and then mitigate any complaints or issues that might come after.

Interviewer

Alright, so the inspection you must have a checklist for that don't you?

Participant 6

Yeah, yes we have a template for CTs for MRs and so forth, but then again, you know, in an ideal way going forward. What we want is we want to know for a particular system or your particular MR, but whatever it may be, it for particular manufacture, we do the additional checks that are important. So what valuable components have you checked this? How we do know this too? But that only comes with time, but we're looking year, years to come to have our CRM just… you know you've won this system or it's a Philips, you know 3/2 system. Make sure that you do this and make sure you've done this, you know. And although that check it goes to the engineers you know quick.

Interviewer

Yeah, I think that there is a system that some other companies use. So it's like an app that has been programmed with information about all the products within a company portfolio or something like that where you just put in the model of the for example Optimus 660 or

then soon as you put it that generates all the information associated with this. The manufacturing year, the number of services, the performance, you know and some other things and it also gives you the trade in value. It also gives you a lot of a lot of things not.

Participant 6

I'm assuming manufacture's have that, yeah?

Interviewer

Yeah, the manufacturers have that the manufacturers have and it could be something that amend their business in a few years. Could look into you know of and collection catalogue of some particular type of systems and you know some specific things and details and look up.

Participant 6

What you can do is, from the serial number if you have friendly people that have been working at Siemens. They may be able to check on that system, so we have that to a degree, but it's not open to us if you've got what I mean? I can't go on my phone and try to get it? No, we have to go through our network. So in that aspect, it's slightly closed, and we don't have access to that information. But you know what should happen is with the EU and you know, world authorities should say that look they should say no, that should be. If you're selling a product, it should be available information to people that are buying this product or reselling or whatever, it should be freely available data. It's not doing things. Do you know?

Interviewer

It's actually one of the key points and it's actually one of the key points in my research about. You know given off information about the products. For example, design information. If you don't have it, there's not much you can do to deinstall approach. If you don't have information about the type of system, the different components, the location of different components, you know the life cycle, the useful life and those that you can't do much but instead. But then they need to get it out. There has to be. You know, for example in the automotive and electrical and electronic product you can't get this information easily.

Participant 6

Which is the way it should be? Because you know, when I'm drinking this water, you know if I don't drink, the water should get a fine, what's in there or what the component parts are making choices so. It should be yes. You know, and it will happen.

Yeah, basically I was just going to say you know the problem is because Germany so powerful new year and Siemens, the German company. Basically, you know because there is so intertwined, they would not let it happen because it's just that's the sort of fail-safe, you know, right?

END OF MEETING

Appendix B-7: Semi-structured interview transcript for participant 7 (Company B)

Interviewer

Found out recently the Siemens because what they do in the refurbishing operation is to completely like overhaul the system, so they take out the components almost all the components and the products. Now that's in contrast to GE they have a list of parts that they must replace. The other parts are just left there the way is. So, what Siemens does right now is to work with third-party vendors. And so, they have the kind of agreement with them. That all the harvest parts go directly to third party vendors. So, this third-party vendor could decide to resell directly, repair and resell, refurbish and resell whatever they want to do. And I think that that kind of makes sense to, you know buy at lower price from Siemens. And then you can use it to service order Siemens Systems or other Philip Systems or other systems that you may have you know and stuff like that, which I think is a fascinating idea to want to go into because there's opportunity there. What do you think?

Participant 7

Yeah, yeah, I do. The thing is now how do Siemens operate with these third parties? Is it you know just German companies that working with says it's a closed network or they work with international. There's all the refurbishment to Siemens I assume takes place in Germany.

Interviewer

John, yeah, the doors take place in Germany. I think they may have they have some facilities also, some facilities in the US, but they're not as advanced, they do not do so much product as they do in Germany. So, it's the same way GE is based in the US, but they also have facilities in Europe, Australia and Germany and France, yeah.

Participant 7

I even looked up. I think it's called “book” is where they have there, they have a refurbishment plan there so GE do refurbishment in or in Europe. I think their main facility is in the US. I've forgotten the name of it an but yeah, so it's interesting how they operate, but. Yeah, but I mean it. You know what do GE and what do Siemens do with the, you know, discarded parts.

Interviewer

I don't… I mean I don't know really have too much information about the kind of agreement they have with these third parties. I just know that's what they do….

Participant 7

Hello hey how you doing?

Participant 7

Can you speak?

Interviewer

Hi Participant, 7, how are you?

Participant 7

So even better Interviewer you give a background and then after you give it their background another then.

Interviewer

All right, well, you're welcome, Participant 7.

So, I'm doing my PhD on Medical Devices Reprocessing and are basically covers remanufacturing, refurbishing the know you know better remote factory processing, repair, anything you can do to return a used medical device to like to good condition in such a way that can be reduced by new customer and may not necessarily be new. May not necessarily be used medical devices, it could be. You know, demo systems or those that had faults during manufacturing, but anything any process or to have you know, take some medical devices from a current used condition to like new condition that can be reused. So that's basically what I'm looking at an unnoticed from my early research that in the UK acceptance of refurbished medical devices is actually very low. So, I notice that men can consent for this experts NHS, medical equipment managers and all parts in the UK is the quality of medical devices. Of course, they are motivated by price, while the impact of price is much is their concerns about the quality of reprocessed, remanufactured repair refurbish medical devices so started doing this research to understand the amount of effort that we process them, people who are involved in the remanufacturing business, you know, put into the business, and one of the key points is not is directly involved in it. But there are other players that are more that involved under, you know, trading of medical devices. But in the real sense, they're taking it from one current use phase two, a new use phase which is also, part

of my research, so I've been speaking to Participant 7 for about few a few weeks a few months a couple months, yeah, just to try and understand your business, to try and understand that as a standby. Anyway, to understand your business, understand how the process looks like. And once I've gotten through to Participant 7 but was undone with Participant 7, I would come straight to the engineer and you ask you about the actual operation when it comes to deinstallation of medical devices, Now I know before you deinstall, you need to run some tests. So, what kind of test to you to watch the quality evaluation methods? How do you assess the this is good, to resell? This is not good, to dispose of this is, you know, all those things. I just want to know as deep as you can share with me the information about a reprocessing operation you do what you do in your business daily.

Participant 7

If there's any type of medical equipment prior too tired to commit to removing that device and we must do what we call a quality assurance test so that that. That QA test which will effectively create a report we will be testing all aspects of the system. Now, whether it's an MRI or CT system Xray, obviously we would have what is called the test protocols. The test protocols really mirror What would have been done in a factory prior to the system being Sent to the customer site for installation so it's…in fact the best way of describing it is part of the v&v process. So, you got the validation verification process with which in fact is, well, the OEMs would do so we mirroring that. So as an example. An MRI system and I dare say probably similar CT. I mean, I can't comment too much on the CT, but I know there are similarities on an MRI system. If you're going to be removing that system, we want to make sure that electronics, obviously the electronics is performing in the way, how? So, it should perform now. Of course, if it wasn't performing, the system would be down. So really, we know we've been passed up at that hurdle. But because there is so many interchangeable parts with an MR system in terms of the coils that are used, so I don't know how familiar you are with magnetic resonance. When I say MR and I talk about magnetic resonance. Yeah, Okay, so obviously you've got the head coils and then you will see what the coils for the lumber or extremity coils doing, so we would I would run test to make sure the coil functionality that there is not any part of the coil that is defectives. I'm talking about making element on the coil. What I also do? And I find this to be valuable is to look at the way how the system is being used prior to it being sold, meaning to say the system logbook. So of course, the users of the system, the radiographers are, if there are any issues, they

would make a note of it such that if when that service provider go there, they would address certain points on the system. I also look for the PM - The preventative maintenance we wants is to see what has been was being changed and of course it does anything that is due to be changed. In terms of the, you know, like I know your area you're talking about that remanufacturing. I mean, I'll probably have to look a bit more into exactly what you're doing, but I can only explain to you. You know, the criteria are that that I would be looking for. And obviously, Participant 7 has employed me to look at a system. Then I must be truthful and say, well, you know Is it is the system working? You know it's going to be? Yes, it's working. However, we need to look at A, B, C, D or E as the case may be. I can give you an example. I went to Spain; it was in the summer to deinstall the system. And I noticed that on the MRI system that the helium level was quite low, and I was thinking. Why is it so low? Anyhow, you know after doing some research I found out that the system itself was not covered on a maintenance contract, so it's almost like they've taken their eye off the board a little bit. If that made sense. Again, and because I was also asked to dig in to help deinstall the system after ramp down the actual MRI magnet, so I went down there to do that. So, on the 1st issue, when he when he refilled the helium, I found that there was some form of contamination It was ice inside the actual scanner. So of course, prior to the de-energization that ice had to be removed, so it's effectively decontaminating the system. So, these are things that you could turn into. You know this is what I report to say prior to it for that system being sold on or if it's going to be remanufactured, is search into an into another system or something coz the actual MRI magnet is a component of the whole MRI a system. You know, it's almost like a refurbishment of the actual MRI magnet, meaning to say a complete de-ice, make sure there's no contamination. How did that contamination happen in the 1st place? Was there any type of leak which allowed the ingress of air, and you know all these things? So, there's a whole checklist is uniquely for everything now that makes sense?

Interviewer

Do you mind if I ask you about what kind of systems do you specialise? And yeah, or what specific systems. Do you have any specific systems you specialise in?

Participant 7

Are You talking about the Company yeah about the company. Yeah or?

Participant 7

I mean, Participant 7. No, we don't specific system. Do I avoid riding? Provide an assist aiding?

Participant 7

You know, Participant 7 I described you as a magnet specialist person you've worked with GE, but in terms of having spent some time with Participant 7, I you might get some, but they would not know everything about the system. You have different parts of the system as Participant 7 would say that you know, the magnet, RF, CM etc and there'll be specialities within those areas. But Participant 7 would be …

Participant 7

Maybe let me understand your question better. When you talk system do you mean are you talking about different modalities? Will it be Xray, nuclear medicine, magnetic resonance CT scanners is looking about?

Interviewer

Exactly, I thought maybe you.

Participant 7

Company B deal with medical, find and lease medical equipment providing it is cut… providing that equipment passes the quality test criteria and that is effectively what is set in place by the OEM. So that's it. If it doesn't pass it can't be sold on as it would be fit for purpose.

To complete a system there's also what they call the system performance tests, which you're probably familiar with because you need to do your reengineering or you remanufacturing and is if you are in GE and Siemens they build that into their system so they so if an engineer is going to want to test no matter what device it is, they have an function, which is a full system performance test to make sure that for clinical medical applications that it still conforms because obviously these devices are regulated okay.

As Participant 7 just said if it is identified that there is a system it is not going to be resold. Then what would happen? These components, parts that are going to console, we then have their individual component tests. So as an example, you must check that up to make sure that the amplifier goes through the specified tests that have been set in place by the manufacturers. Hopefully you know one of the main amplifier manufacturers, they will have their test protocols. Providing that protocol for that component parts. If that passes the test,

then you can certify to say that that component has passed, it conforms to these tests, which would be in place.

Interviewer

Can I just ask you; a man comes from what you said right now it feels like. Yeah, you've got two options to do it to any system. You could either directly sell it, or you could harvest the parts. Do you do any form of repairs on any of these parts? For example, do something as simple as one of these screws out, do you? Do you do any form of repairs whatsoever?

Participant 7

Or you know what? Because in my capacity and more of a consultant for the company, but it was if there was a repair that was needed. If the company, does have that level of competency for an individual to I mean let's take an example. Let's say they wanted to repair this keyboard but don't have the competency to repair this keyboard. Then again, they need to bring in somebody who knows how to repair it, if that makes sense. So, in terms of messing around with somebody, you have absolutely no understanding of then we would not. We would not be. We would not be doing this, so it would be trained personnel. I mean the structure of the organisation is that… we could get an example. Let's say now there is a Toshiba system. I don't know anything about Toshiba systems, so it won't make any sense in going having a look at a Toshiba I don't know if Toshiba do a CT scanner. Yes, I will be able to tell you it's a CT scanner could probably switch on and I could identify it, you know the component password, but do I have the in-depth knowledge of that system? Have I been product trained? No, I have not really been. I would not be the person to it said on that. So, what they will do Is to get a Toshiba trained engineer to do you do repair on that system. Part of that system, if that makes sense, yeah. Because basically? I mean this on the engineering side of it, I mean what I emphasise is that you know we are selling medical equipment, so this must be fit for purpose. You're dealing with people. Yeah, you deal with people's lives here, you can't just get in something… Even you know a lot of this equipment may find its way going to some countries in Africa within Asia or, wherever it goes to, in Europe, etc. But believe it or not, I've seen some equipment going back to the United States because, you know, the United States doesn't have an NHS like what we do, so it's beneficial sometimes within to be able to buy something that they know works. And it goes United States, and you then have that brand new. Do you see where I'm going with this? Whether that is whether that piece of equipment is brand new from this country or whether that

equipment has been used for the last five or ten years as the case maybe we must make sure that it's fit for purpose. If it's not fit for purpose, then of course, it can't be… it can be installed but it can't be commissioned. Again, it comes to that that system performance testing (SPT), if it doesn't pass the test you cannot be used. Does that make sense?

Interviewer

I know there is a strict requirement by the MHRA for equipment Or medical equipment that can be used so if it does not pass the, it's definitely not going to go through.

Participant 7

Yeah, basically I mean. There are different criteria for different types of equipment, equipment and then all of this actually links into the QMS the quality management system because if there were to be an audit then He will be found out if you're not doing it. If you're not compliant. There is regulation on this.

Interviewer

Okay, so I've got this question. Have you ever encountered at refurbished or remanufactured medical devices? Medical device on site before?

Participant 7

This is quite interesting because Participant 7 actions cheese with this remanufacturing. Pardon me when I say this or my stupidity. What do you mean by mean remanufacturing? I mean, in terms of the remanufacturing I mean. Do you. Actually, have like a definition for remanufacturing, such as something I'm not really looked I'll be honest with you, I'm not.

Interviewer

Nice, it's alright. There's a definition for it. In fact, there are several definitions for the remanufacturing, but the basic definition is that it's a process. It could be an industrial process and it could be a simple process, so takes a used product to like new condition so the target here is to make sure that the end product of the remanufacturing operation, the end product itself, is similar to that of new condition in terms of the quality in terms of the warranty that you give and in terms of the service. So basically, when we talk about quality, we talking about the performance, the physical, and any other quality related issues. So the whole idea behind there is that you want to take a used product, take it through some processes, and then give out a remanufactured products and offering it to customers in such a way that this is "like-new" it can compete with the new products and we're giving it the

same warranty as that of new and… but of course that has been …in the medical devices sector that's slightly different because refurbishment remanufacturing are basically similar in medical devices, especially in the US. And the only thing that differs those changes whether something is refurbished or remanufactured is the requirement of the registration document. So, let's say if you've got an Xray system 10 years five years ago they used to be the manual scan you printed on paper on the on The way it called on that paper, not paper anyway, but you print it out and then you go with it, and then you refurbish. Or you re manufacture it to a kind of status kind of condition where images are now digitally taken and then transferred on the 802 Wi-Fi system to a computer. So that's been defined as remanufactured because you've upgraded it alright.

Participant 7

Now I understand what you are saying. I'd be honest with you; I didn't fully understand when you said remanufacturing. see with me with manufacturers, but OK if I'm going to make this, you know, I'm not going to lose. Make this this roller Sellotape. But what you're saying is in terms of the remanufacturing. And I saw this Saturday in Birmingham where they had some X. What's it like to see me now to see Xray and these were the analogue? In other words, for them to upgrade the images out. Must connect it to and then transfer.

Interviewer

Yes, so that's part of the upgrade kit that most of this OEM sell, but the whole idea of this is that we don't just want to dispose of systems, don't just want to send them to be recycled. We want to instead of doing that, we can still … you know medical devices have very… most of them have long useful life so and the components are very long useful life. So instead of doing what Siemens do which is to just completely overhaul the product, why can't we repair some of the parts? I maybe could refurbish, remanufactured, whatever we want to do, but…

Participant 7

See, so when you say remanufacture, in the case of this CR I was talking about there is, there is an option that you can make it digital by installing the play, the upgrade kit so well, supposedly if you do that in a way you could, technically, say you could say you have. remanufactured. That's my understanding, but when something is, I mean. But when something is… my understanding prior to that remanufacture is like physically remakes and re-manufacture something.

Interviewer

No, I think now that the problem now is there is a conflict of industry. So, in the automotive industry, remanufacturing is very similar to what you think it is. It is actually what you think it is so take for example, turbocharger or gear box or automotive engine for example, if you want to re manufacture them. So you basically take it to the warehouse to the factory completely break it down to the simplest of parts and then you test each of the single parts to the smallest part of screws to bolts, you check them check the tread depth, check, everything and then you put them, assemble it and then by the time you finish to remanufacturing process, if you put remanufactured and the new one they look exactly the same. You give the same warranty on that.

Participant 7

But then the problem is what I see there we going to do all that work for the old one. Then it's likely going to be costlier than new ones. Shouldn’t the remanufactured be cheaper.

Interviewer

That makes sense. I mean, don't talk about for that example with. Yes, it looks like that but the fact that you don't have to purchase raw materials and the example I gave explained that to make it look like it's a long process. Most of the remanufacturing operation has been automated so you don't… apart from the disassembly and reassembly. Most other parts of it which must include the cleaning, the inspection, the part replacement, and they're mostly automated there is like AI system does cancel the parts detect when there's the thread depth is not efficient. When this is good. When that is good, you know it passes here and there arranged and then just put it together so.

Participant 7

Maybe through this incident, let me throw this incident into the equation. Have you ever heard okay, let's say now you went and got you got this keyboard yeah bought this keyboard. You going to say you're going to be remanufactured keyboard. but the keyboard works. Would you still remanufacture it even though it still works?

Interviewer

Well, in that case there's no need to remanufacture it if it works right.

Participant 7

In the case of a medal in the case of the CR, I've just spoken to you and obviously I can gauge that you understand the CR I mean even though I'm not an Xray engineer, but it's something we've got some kind of synergy there that… You've got the CR that works, would you still take it apart and put it back together again?

Interviewer

Well, depends on the on the warranty that I want to offer, so I'm going to use this example, so I see how this equipment has worked for like 5 years and usually when its purchase new they give a one year warranty plus extra service agreements for several years as long as you want. During that time, parts may be replaced and not that and it's possible that after five years some of the components might have passed might be very close to the end of life. Which, if I do, if I don't go through the process of testing each of the component, probably breaking it out.

Participant 7

Yeah, I get you now. I mean you hit the nail on the head immediately. You didn't need to go to your saying is OK if you take it apart, so you'd have to have a process of process to check to see when was this component manufactured and how long? What is the life expectancy of this component? And suppose you're going to have some criteria like, if the life of this component, if it can last another three years, we keep it in. If not, then you going to take it out because if you're going to give the system a warranty then you're going to have to make sure that every component passes that exam, and it will last for at least the length of time of the warranty?

Interviewer

Yep, Yep, that's correct. And one of the differences between the automotive example that I gave and they medical devices stop saying in the automotive you tend to completely disassemble it but in the medical devices you don't. In fact, disassembly is not a special process in the medical devices industry. You don't disassemble per say, you. You focus on the cleaning and when you cleaning, you're removing parts. You focus on inspecting, so you're looking at different components. But before you get there, you need to disassemble. So, disassembly in medical devices is different completely from the automotive industry. You want to bring it down to the smallest part but in medical devices you want to bring it down to the simplest functional parts.

Participant 7

Well, they see. You just mention this because I've just returned from Spain and there's an initiative with the coils that are used on MRI scanners. And I'm thinking that maybe… I mean, I don't know. I don't know where you're going to with this with Participant 7 or with Harry. I see that there is a possibility maybe with some component parts to are stored that Company B have but they possibly don't have any customers. Now we need to identify why they don't have any customers. Now, maybe those parts where it's clear that there is no customer with what you're thinking and do what you're doing. I mean, I can recommend to Participant 7 to say, Okay, well. How about Just particular product. We use it as it is a device, the remanufactured and if we can prove that it's been remanufactured and give that assurance with a warranty. Then try and sell it and see this. See what happens. I mean does that make sense, right? Maybe you write up, so I mean, if you want me to help you on that one, what I would look at maybe is to identify what the actual product would be for you to have that as a remanufacturing project, and you know. And then change it from a project into a saleable item. And the reason why I say this with the coils see with the coils that these are there. What are used with the MR Systems? These are radiographers always a plug it onto the system and better patient in there and a user there is continual use if that makes sense. Sometimes they get bash to get dropped or something happens and they are defective, so this might be ideal for you to remanufacture, I don't know.

Interviewer

Okay, exactly, yeah. There are some characteristics of product should be, you know that our favourable for remanufacturing. So, one of them is that it has to be high value parts or high value components. So, the coil is the coil is really high value, is not it? You're going to say.

Participant 7

I mean. It's valuable because it's something that is continually being used does that makes sense. If its continually being used, then it obviously has a value. It's almost I would not call it a consumable part it's something that you know there would always be the demand for it. There are other things as well that needs to be investigated, I mean boards for system, but I mean, I couldn't recommend that you remanufactured board because you can go and get a board from China, I mean. I mean, I'm sorry but it's actually known where you're going to compete with those guys. I mean they're going to bang those things out bum. I'll be honest, I know. You could do that to say well, I've done it, but that's it. But if you if you were going to use that as they make a living where you would not make a living.

Interviewer

Nah, you will last long doing that, yeah.

Participant 7

Right, yeah, you need to look at something that is going to have a business case. It is going to be economically viable if there's no economic viability and it doesn't make any sense in you doing it.

The classic one is… well there is many… but they call this one refurbishment on cold heads. The cold head that is used on the MRI system, but he looks at the OEMs the original equipment manufacturers, how much they charge and if you could remanufacture that, and basically….

Participant 7

But another colleague in the company of Father works Siemens, so I'm going to copy you in and with her and hopefully. You know, Participant 7 can help you potentially. Be sure to ask you the question before and contact their dad.

Participant 7

So, I was just going to just let Participant 7 know that, um, what we discussed. So maybe some of the components we have we need to identify what's not being sold can it be remanufactured basically, what Interviewer is saying is that you take it apart, you look at the components with. So therefore, there for you if you could, if basically you know that it's going to be at least three years for all of the components that are in that particular device. Then you can sell it. You can say as a remanufactured head coil and coil or cold head or whatever it may be.

Participant 7

He thinks it should be interesting fact there are distinctions within the industry between reprocessing, refurbishing and remanufacturing. There are different tiers are they Interviewer of what you must achieve? Can you specify? In an email say I could look at that because you. Yes, so we know what. the difference is here.

Interviewer

I could send you an email on that, but I would just like to point out really quick. I mean, they're all reprocessing operation starts. The most important part, so different types of

processing, and it's as simple as you know, directly reselling it that's still in form of reprocessing. Because you've taken it through a process, the process may not be as complex.

So, another one is the repair. So, under repair you find faulty parts, so the parts that have already been deemed as damaged or faulty. You just replace them? Or you try to repair them, you know, do some basic things to you know, take them back to useful condition, but you can't guarantee this going to last for 10 months or one year or two months. I mean, when you repair something that could last one month and that's it, they bring again for repair, so repair is not very favourable. But it's too good it's still better than the direct resale. And then the next one is to refurbish it. The refurbishment is… well in the medical devices industry, refurbishment, remanufacturing is very similar. In fact, there is no difference between the process that you take the product. What matters is the outputs of the process. Now if the output has been changed significantly in such a way that the corresponding new product is different from the product of district processing operation, then it is re manufactured. So what I mean by that as it's as I said to you Participant 7 is it go vintage Xray system which when you take scans on it you need to print the image and then taking the file to whatever to the radiologist then you remanufactured and then you put in a digital detector in it and then when it's done so that basically becomes a remanufactured system because the initial use was manual but now it's been upgraded to digital so that's remanufactured. but it technically follows the same process, and what matters there is, instead of putting a manual detector, you replace it with a digital detector, and you could use digital detector from any other systems it could be from a similar Xray system. It could even be from a different modality. So that's what differentiates what remanufactured.

Participant 7

Send me an email because there's a couple of system, I'm thinking of a fact you we I've got a four in actual fact, but as to whether it will go into position or not, I'm not sure, but I guess you trying to get anywhere.

Interviewer

Okay, I was going to ask Participant 7 about the regulation, so if it's possible my can I schedule a meeting separately with you. I mean answer the email just too obvious comprehensive discussion, but yeah.

END OF MEETING

Appendix B-8: Semi-structured interview transcript for participant 8 (Company B)

Participant 8

So here is where we get most of our systems from trade desk or the server as some may say and then we need to verify that information and we do that by going to the site where the system is it is still operational and run some tests. So basically, to assess the performance of the system. If it is a CT, the valuable part is the tube, so we see the year the tube manufacture was, record the serial numbers, the tube type and other valuable information about the key part. For the MR system, we look at the number of coils, and just do... you know we need the system keys to be able to go into the system log to see what the system history was to be able to decide what price... we bid on it but then we can also go back on it later if we find something wrong and take that as an error. So, then we do the QA/inspection.

If everything is okay, we proceed with the removal and generally we would do the removal. We remove the system and then take it into our storage or whatever we decide. If it sold directly, we pack it up and just ship it directly to where it's sold.

Interviewer

Can I take you back quick? So, when you say you remove the system, are you referring to the deinstallation process?

Participant 8

That's right, we deinstall the system and there are situations such as if the system is not valuable enough, to run the magnet down costs quite a bit of money., You need to get power supply and so forth. So, we may just let the helium escape or do a controlled quenching of the magnet because there is no value in it. So, we just remove the system anyway we can remove it. And it's not good, I don't think it's the best way or a good process to do but what we are trying to do is we are trying to have a process that when we do that, we can recover some of the helium, so try and do some helium capture but then it's not always that easy to do that. So sometimes we just must let the helium escape. We try not doing them but again it all depends on the economics of that, if we are not doing that... you know we can't spend 10,000 deinstalling a system when we can only sell the system for 2,000 it doesn't make any sense. So that's where we come into that. So, we keep these things cold. So, now we got 2 MRI cold, 4 but some of them have been sold, while some have not. And we had a discussion today, whether to.... one of the MRs the helium level was about 10%… so do we

have it go warm and just sell it warm because if you try to sell it cold, you're going to have to top up the helium and that will cost you some money. So, it all depends.

And then there was a question mark over parts. For us, the problem with parts now is that we are on Philips multivendor so what's happening now is that every day we'll get some request from Philips saying, "have you got this part or that part?" But you need to have a process that is quite quick and efficient if you want to have any chance of getting that part out there. We are not there yet. We are not quite there but we want to be there. Other people do it better and you just have to recognise at some point that you're not yet at that point.

So, what we tend to do is... and I think I've said this to you before... when we sell a system into Africa which we do now, it's been a long time, but we are doing that, we are just going to send some spare parts with it. We do a year's maintenance with the system. So, if the part is already there, it's easier for us to then fix and resolve. So that's our model and what we're trying to work at. So yeah, it really depends on the situation.

Interviewer

So, after the removal of the system, you send it to the storage, warehouse or facility. I just want to know; how do you store it? Do you keep inventory?

Participant 8

Yes, we have our own warehouse facility in Spain, and we tend to hold things all over Europe: Poland, Germany, France, UK, and Spain and yeah, we do have inventory of where a particular system is stored and so forth.

Interviewer

So, when you store the core, I'm talking here about the received used item at your facility. DO you do any sort of activity on it? I mean, do you clean it, disinfect, inspect again or any sort of activity or processing or do you basically just store it?

Participant 8

We take it and store it and monitor it in terms of the helium levels and there's a bit of issue with the storing, recently what we've had is... and this is because we lend our own storage facilities. These facilities belong to third parties... so maybe we've lost a bit of helium and maybe they don't have service level agreement with us and say look "if it's our fault that that helium is lost then we will cover that cost." Yeah, that system in a specific location lost about 20% helium and we know why... we know the mostly widely reason as to why, it was

moved by the storage facility., They had to move it for an old storage facility to a new one and during that move, something's obviously happened and its lost 20%. So now we are trying to get things together and speak to them and say look, you caused this.

So, on the reprocessing, we do some certain things on some occasions for instance we had a system.... depending on what the customer wants, there's an MRI system that was sold to a client based in Canada, but he just wanted the magnet sent to Korea and all the other parts sent to Canada, so he was going to use the parts elsewhere. Now that does happen and generally at the request of the customer where...

Interviewer

So, after storing it... I'm just trying to understand the process, after storing it then the customer order comes in. I just want to know at what point does the order come in for what you have and how do you deal with this?

Participant 8

We start marketing the product once we get the QA/inspection ideally because then we have checked it ourselves. What we don't want to do is sell a product to our customer when we're not quite sure ourselves of what it is. As an example, we've just sold a CT system to a client in eastern Europe and the system came from Tunisia. We sent somebody to go and see the system in Tunisia, but he wasn't really an engineer, he was a project manager. He took some photos, and we did it on trust. Now, the customer at the other point... we didn't take it into our storage. We did the transport from Tunisia to the customer and now the customer's saying there's these issues with it so that's one of the problems you have without inspecting yourself or checking it.

Also, what can happen is when did the problem arise? that can be a very difficult thing to ascertain because you can say did it happen when it was removed? Did it happen when it was transported? Did it happen when the customer received it and they transported it? so there's various links and possibilities here.

Interviewer

So, I just wonder, how do you transport it? I'm thinking about, you know when you say removal of the system. I'm looking for example at a giant CT or MR system, I'm not sure if it's possible to send as is. Or how do you handle this?

Participant 8

You have obviously the patient table, that which you separate easily. And a set of pallets that are constructed to house the system. For instance, some of these systems, the gantry on that Philips system, they need special tools to remove the gantry. To logistically remove the gantry from one site to another and if they're not used, that gantry can be damaged. So, this is the thing, and you must use people that know what they are doing and, on that system, and for different systems and that's where the OEMs the manufacturers know how to remove their own systems. But there's plenty of engineers and what happens is that work for the OEMs and then they've come out of the manufacturer roles and now own their own business. The knowledge and know-how are there, but you just got to be sure to use it. Another example, we removed the CT tube from a PET/CT, and we didn't do it the correct way and we could've just asked few questions knowing how to do it correctly and we would've been fine, but we didn't, and that tube had been damaged and had to be repaired. So, it's just understanding what you're doing because it's not the same for each system.

Participant 7 (you spoke to him the other time) he's a very good engineer. He's a magnet specialist but he's not a systems specialist. He worked for GE, but GE is his wheelhouse, but Siemens and Philips are slightly different and that's where… we use participant 7, but sometimes we must get support from other colleagues. These main things to look out for and so forth.

Interviewer

So, after the customer order comes in and it's been processed, what happens after that? The deal will be subject to a certain level of helium let's say in an MRI so we may have to top up the helium. And as I said, sometimes, people say look we just want a part of it, so could you send the parts here, remove these parts. It happens with CT itself, sometimes, people need the tubes quickly. We remove tubes from CTs and then ship them independently so it's one of those things where we must respond to our customer's needs. If they don't require the entire system, sometimes we work with a lot of people that do supply parts as well, so it really depends on what the need is. So, for instance, let's say a Philips 3Tesla Rex magnet 0 boiler helium, they just want the magnet itself in Korea and all other components sent to Canada. So, you know that was the deal that the person that we sold it to… you know we don't tend to deal with the end user so much so then we are driven by what the other dealers in the market want but we are trying to. Because obviously you make more money dealing with the customer.

Interviewer

I can imagine there's a lot of liabilities involved, is not it? Medical liabilities and all that?

Participant 8

Yes, you can cover lots of it because, you know… in terms of the warranty of the system. Medical liabilities yes, we've got public liability insurance so that's not a problem, if anything happens, we're covered. But it's more of a fact that if anything happens, we should be okay but it's more of the parts and the research and so on and so forth.

Interviewer

How does branding issues affect your business. I'm asking this because I can imagine if you're reselling a GE, Philips or Siemens system. If you keep the brand name of the OEM, the possibility is that you don't have your brand names on any of the equipment. You know, to say that no one sees your brand on these systems. Something like oh so we've got this Company B CT machine, it was originally GE, Philips or Siemens.

Participant 8

Yes, I mean… you are right but then in the industry because we are dealing in the used market, and we are the third-party and it's just about getting out there. So, what we are trying to do in Africa is that the people selling the new CTs or things that rank highly essentially. But then, lots of people are trying to do the same thing because it is a big market. There's lots of money involved but we're trying to do it the right way, we're trying to stick by the customer and not a race to profit for us. Look the fortunate thing we get to notice is the strategic aspect of our business is, we get the supply of the equipment at a very good price. That's the basis of our business and the thing is to have that supply, you've got to hold stock essentially. You can't just broker that deal… so if I say to siemens, or Philips or GE that look, I'll make this bid of 50,000 euros for your system but I'm not going to buy this system from you but I'm basically going to sell it for 60,000 before the deinstallation or before I must pay you, so I don't have to physically hand you 50,000 and wait to collect 60,000. And you know… we don't operate like that because the problem is sometimes, your customer might fall through, you may have to hold the order for longer and so forth, but the OEMs are saying where's my money? You know, and then you're not going to cancel deals on them. Once you've agreed a deal with them, don't go back and say I don't want that anymore because then they'll say I don't want to deal with you anymore. Do you get what I mean?

There is a good aspect to that which is the supply, but you must be an honourable person as well in terms of respecting the deals that you make. So yeah, it's just working with them, and you know and following it through.

Interviewer

So, the customer order comes in, you process it, and you send it to the customer. Sorry to go back to this but I just want to know, do you do some sort of checks on the system. So, I'm looking here at an ideal situation, where the product leaves the hospital and comes to your warehouse where it is stored. I know most of the time, it's a direct transport from the pickup site to the next customer but I'm looking at an ideal situation here where the product first comes to your storage facility and from there you process the order.

Participant 8

Yes, that would be a more ideal way to be able to do…. Going forward because what you could do if you found out that, essentially, this system is better than what you anticipated, we've always gone with the philosophy and what's happened is… obviously it's cost effective, if you test it at the removal site and you remove it correctly and you transport it correctly then there shouldn't be any issues that would arise but there can be. There can be and you just must try and reduce those as much as possible but if you have a system that has been set there for a while, especially the CT. Ideally you want to run some tests on them but to create a testing facility, that's another level. And there are people that do it, I mentioned block imaging to you before. They do parts, they give warranties. And you get lots of companies that do refurbishment cold heads, compressors and things like that but yeah, that's the basis…. And not on buying and selling MR. So, I just want to say their business models are different. Block imaging do buy and sell too but they also refurbish and deal in parts as well.

Interviewer

So, it gets to the customer…after it gets to the customer, how do you set that up at the customer's site?

Participant 8

Generally, what's happening is, if you sell to another dealer, they don't want you to know their customer because obviously they would say you could go directly to them. So basically, we very rarely do ay installation if we've sold it to a dealer, we just don't. because

they would usually have their own network to do the installation. However, when we deal with the end user, we would do the installation. You try and mitigate as much as possible in terms of risks… so for instance, the deal in Kenya, we're going to do the shipment to Kenya, but the customer must clear customs because that's something we're not specialists in, that's a lot of headaches so we leave that to the customer, so they'll deal with the customs. And, because we have not done a site survey, of where the clinic is, where the installation is going to take place. So, we just made the decision that, look let the customer do the transportation from port to clinic and have the system in the clinic and we'll just go and install it. And they must make sure that they have the correct power, and everything is in place for us to have that system installed. So, we'll go and do it. In an ideal world, we would handle the logistic costs but, in this case, because we're not local on ground, we won't know which logistic companies to deal with and how to deal with them. And we say to the customer, you must ensure the product for the value of the product so that if anything happens during transportation then the insurance company is going to take it.

Interviewer

Well, that's it from me. Thanks very much for your time.

Participant 8

Where we are now and where we want to be is two different things and it just has to be commercially viable and that's why if we are going to be reprocessing certain aspects or doing certain things to the system… look this Kenyan one when we're sending to the end user, yes we did, we tidied the system up, we got an engineer in, we tidied the system up, made sure it looked clean and good. So, we did do a bit of reprocessing because we are doing the final installation for the end user. But the problem is, other dealers, they're looking to make their cuts so theirs is a race to the bottom, they don't care if it's clean and tidy because they can do it by themselves. So, they're not going to pay an extra 10,15k for you to do some reprocessing operations. Because the way it works is, If I must pay someone to do it for 5k in my facility, then I'll have to charge the customer 10 because there's no point and it. Doesn't make any sense. So, we are doing more of the reprocessing when we do the installation.

END OF MEETING

Appendix B-9: Semi-structured interview transcript for participant 9 (Company C)

Interviewer

Introduces self, describes research and presents how the interview will proceed.

Participant 9

Welcomes researcher, exchange pleasantries, and is ready to discuss with the researcher.

Interviewer

Thank you for sharing the answers to those specific questions that you did through Christina. They have been helpful, especially with me getting a good grasp of what Company C does with refurbishing medical equipment. I think I just want to know in more details what happens with Company C refurbishing operations.

Participant 9

So, our refurbishing operation typically follows the five-process listed on our website and that includes the product selection, de-installation, refurbishment, installation and services.

The process starts with the de-installation of the systems at the customer site where the system is professionally de-installed by highly trained personnel. These are usually people who are regularly involved in the installation of the system so they are usually very familiar with the system and would deliver it intact. So then when we get the system, we refurbish it and then we use the computers and software to update it.

Interviewer

Can I just take you back a little and ask this question, how do you obtain used systems? What methods or operations do you employ in getting back medical devices for your refurbishment operation.

Participant 9

- We have customer loyalty program.
- Sometimes when we want to seal a new system to a customer, we collect the old system from the customer.
- In some other cases, customers come up to us directly and give us back their systems for refurbishment.
- In some cases, customers may want to upgrade their system to the latest version, so they come to us with the old system.

- The final option is through the secondary market. This is where I phone up third parties or other companies that may have our system. Because when we lose an install base because another player wins the contract to supply a new equipment, then they have our system. We have our own platform but most times, I just phone up this other companies that have our system and try to get it back.

Interviewer

So, can you talk me through the refurbishment process at Company C?

Participant 9

When a system arrives at our facility, it usually lands at the incoming bay area. At the incoming area we will look at the system and try to break it down into smaller units and components and then we send the different components to different places to get them repaired and we keep them in our inventory awaiting order.

So, the first **cleaning** and disinfection steep occurs at the customer site, but this is usually at the surface level. Because you can't transport an infectious equipment as that would be illegal and would require extra documents and more money. So, you need to wipe it down first at the customer site before it is transported to our factory.

When it gets to our factory, we do a deeper cleaning because the cleaning that the customer does is usually at the surface. So, we do a comprehensive cleaning and disinfection of the system.

Interviewer

Okay then, so after the cleaning what happens to the system afterwards?

Participant 9

The system is disassembled into smaller parts and components. For example, the magnet is removed and sent to oxford, the flex coils are also removed, and other parts are removed. The parts are sent to different places where they fix them, and they send to us when they complete that process. So, we keep the parts and store them in our inventory awaiting customer order.

In our facility, we do not do anything relating to the parts. We don’t do anything; we just strip the system down and send them out to where they can be fixed. In some cases, the parts are scrapped.

Interviewer

Can I ask you this about the refurbishment process, does it happen only at the system level or do you sometimes do part refurbishment.

Participant 9

We do both. We generally refurbish the system. When we refurbish the system, we do this at the whole system level, and we use parts that are new or have been refurbished. So, the parts in our systems are usually a mixture of new and refurbished parts.

Interviewer

Does Company C have a repair centre where they repair parts within the facility

Participant 9

NO, that's why I said we don't do anything to the parts in our facility. We just break down the system and send the parts out, we collect the parts and store it. This is because we rely on our third-party partners to deal with this part level issues. In most cases, it is impossible to get back the parts as they cannot be refurbished so we just use new parts in the refurbishment process.

Interviewer

Can you tell me about the channels into which different parts/systems are put? So, what I mean here is, when you receive a used system, what alternatives do you have for the system and its parts?

Participant 9

- We break down the system and send it to the repair center where can be fixed. These repair centers are usually external. So, when they return the part, we use it to refurbish the product and use it for our XC products.
- We do not use refurbished parts in new products.
- The parts may also be used to service our other systems to support our customers
- The third option is to recycle the part through our recycling company.

The parts are stored up in the inventory.

Interviewer

SO, what happens after the order comes in?

Participant 9

When the order comes in, we find the different components or assets that can be used to make the order from our inventory and then we put it on the factory line. This happens in the same factory where we produce new systems so everything is basically the same as new and follows the same process.

At this point, the parts are then **assembled** by the same staff that perform the production of new systems so basically there is no difference. The **testing** is performed by the same team, and they follow the same process as for new manufacturing.

Interviewer

I'm thinking here, as in the automotive manufacturing where forward production happens on the manufacturing line is mostly automatic, how do you fit in the refurbishment operation through an automatic process.

Participant 9

No, the process is manual. Yes, some are automatic but most part of it are manual and it involves someone doing the process. The testing is manual and is not performed by robots. The testing is performed in the testing area using the same testing equipment and testing documents as that of new. What we do for our quality assurance is based on the "Four Eyes Principle" which means someone from the factory and another person from the QA team looks at the testing documents and decide if the system is okay or not and then it gets moved to the customer.

Interviewer

I just wonder, what standards or legislations does the Company C XC refurbishment follow?

Participant 9

You know about the GMP – Good manufacturing programme, so that's what we follow. And there is also this one that covers specifically the refurbishment process and that is the Good Refurbishment Practices (GRP).

Interviewer

I just wonder here, in the US some companies/product require a new registration 510(k) document, what's your take on that?

Participant 9

So, you need a new 510(k) if you have made significant changes to the document. In our case we don't require a new 510(k) as the system is basically the same and is the same as it is when it was new. So, we do not need to apply for a new 510(k).

Interviewer

About the factors that you would consider in the selection process, there is the age, condition, etc of the system. What age of a system would you consider beyond refurbishment?

Participant 9

I think that depends on a lot of factors. First if a system 2 years old comes back to me, I'll be asking what happened to the system. If it failed, if somethings wrong with it, if the customer has reported some issues with it and that's when I would access if it were possible for me to refurbish it to a safe and effective condition. But the ideal age for us would be systems at least 5 years old and systems we can support for another 5 years through warranty and spare parts.

END OF MEETING

Appendix B-10: Semi-structured interview transcript for participant 10 (Company D)

Interviewer

Can you tell begin by telling me about yourself?

Participant 10

We are a reprocessor and remanufacturer of single use medical devices and we have about 1200 employees in our specific division of Company D. We are currently located in xx. We have a headquarter office in xx, a manufacturing plant in xx and then also an additional manufacturing plant in xx.

Participant 10

Company D acquired our predecessor company in late 2009 – December 2009. So that is when Company D acquired the reprocessing organisation.

Interviewer

Can you describe your remanufacturing business model?

Participant 10

And then so when you talk about remanufacturing business model, are you talking about you know how We collect and then remanufacturing. So back the devices. Are you talking more so…? What are you trying to get with this question.

Interviewer

Alright, so I'm referring to your remanufacturing business. what I'm trying to get from this is to understand the nature of recovery activities at your company. for example, do you remanufacture, or do you repair and refurbish? Basically, I want to understand what kind of recovery activity your organisation engages in.

And then after that we'll go on to discuss how you get your used medical devices, how do you market them so the whole journey of the recovery operation from getting the cores to selling the remanufactured product.

Participant 10

Gotcha, I can just touch on the latter part of that question, and I think the first part, you know, distinguishing like how the FDA classifieds, reprocessing, remanufacturing all of that. I think that would be a good question for Participant 11 who has some experience in

that, but a high-level overview of our business model is that a service personnel, both sales representatives and service associate will go into hospitals and set up collection modalities for single use medical devices, so we have a variety of collection bins that are placed throughout the hospital from the patient care floors. The general patient care floors to the surgical and emergency units and labs etc. Each collection modality is different based on the types of devices that we are aiming to collect in them up, so we go and educate nurses, technicians, hospital staff on how, how and what to collect in these bends. So, the idea is that when they are done using these items on a patient, they understand that they need to be putting those single use items in our reprocessing bins versus in the regular garbage. So once those divide or once the bins are full, our service personnel will go to a hospital. Depending on how large it is, maybe twice a week, maybe every other week, just depending on usage. But they'll go in there and collect the bins, take them into the shipping dock of a hospital and then ship those devices from the hospital to our reprocessing facility either in xx or in xx depending on which type of device it is

feel free to stop me at any point if you have additional questions.

Interviewer

OK

Participant 10

And so, once we receive the singling devices in our recovery facility, will then go through multiple stages.

Well, you know sorting and receiving. We track back the devices to the hospital so the hospital can clearly know how many devices that they're collecting and get credit for them.

The sorting and receiving area of our facility, where we will sort out the reprocessable devices versus things that we cannot reprocess the reprocessable devices go onto disassembly, where we will break down the device to component level pieces. Things like nuts and bolts or directed energy devices separating the shafts to make sure that we can really get in there and clean every single aspect of the device after disassembly.

We will go to decontamination. This is where the actual cleaning of the parts happens. All along these lines we are also looking for things that are rejectable. So, if there is like a grossly aesthetic, marking on a device that can't come out, we will usually reject it. And so, when they're ending contamination, they're going through various stages depending on what

type of device it is, through ultrasonic cleanings, brushings. You know pressurised cleaning modalities to make sure that we are getting in every nook and cranny of these parts. After decontamination, it'll go into inspection, so again, there's a whole. There's a whole section. I think we need to make sure that these devices are up to our quality system. And then they will go into assembly. So, putting the devices back together, testing every single device, make sure it's functioning as it should be and then finally it'll go to packaging and sterilisation. So, once it's in your sterilised we can send them out back to customers.

00:06:55 Interviewer

Alright, that's a compact description of the process, and it makes a lot of sense to me. I have a lot of questions from the beginning from the start till the end, but I wanted you to finish just so I don't break the flow of you know your communication, so at the start where you collect, you place bins at hospitals. Do you use from the start member of staff from your company. Or do you use a third-party waste collected firm to do that?

Or how do you? How do you do that here? But hospitals and how many hospitals general? I'm just thinking because I'm sure there's a lot I can't say, but there's more than 100,000 of those in the US and I can imagine how much more we have in Europe, and you know and all that.

So, it looks like a lot to me. How do you manage that? That's what I'm trying to know from that question.

Participant 10

Yeah, so they are Company D employees, but our sales represented in our service associates who are doing they are Company D employees.

Uhm, and we really hope on the fact that we are wanting to do, you know, not we're not. We're trying not to ask our customers to do that much added work.

They're already super busy. They have stressful jobs. They're running around, and so we are trying to make it as easy as possible to do business with us.

And take a lot of that responsibility.

Or collecting shipping out the device we do have Company D employees going in there on the daily to make sure that the bins are not overflowing. We're getting our reprocessed devices shipped back to the remanufacturing facility and everything like that.

Interviewer

I'm just thinking again, yeah, the second part of that question is about managing such huge number of hospitals and collectibles, and I'm just thinking about how? How do you? How do you manage now? Do you? I'm probably saying this because I don't know how you, how you do it in your organisation, but I'm thinking about how many hospitals they're on the US, and I'm like it's probably a million sites where you can't collect these 10s and press probably hundreds of thousands of sites where you currently collect used medical devices and how do you track holders different sides and how do you coordinate them after you?

Interviewer

Do you not have any competitors at all?

Participant 10

Yeah, so there are about 6000 U.S. hospitals across the nation. We are in over 3000 forms, so we do hold most customers in terms of reprocessing and so really the organisation. We have, you know, East and West area directors who are laser focused on our sales and service people, so making sure that we have enough sales reps and service associates covering each area so that they're not overwhelmed can give enough detailed attention, specialised attention to each customer, so that does require a lot of essentially boots on the ground people, so we have an extensive employee base of Service associates.

Interviewer

That's good competitive strategy. How do you beat your competitors or how do you get? I don't know what I feel like I'm just going back to this same question, but if you feel like you've answered, just let me know so I can go to the next one. But how do you do you provide any form of incentive or things like that too? Hospitals and nurses. Or you know, just so just so they're more encouraged to through this inside every processable bins rather than just the normal baggage bins, baggage or something.

Participant 10

Yeah, so it depends on who you think our competitor is. If you think it's different reprocessor we have a different strategy for that which I can touch on. So, one of our big differentiators here at Company D is our service and sales personnel. So how branded? Them is we call them out on track programme management. A lot of other reprocessor have as an extensive sales and service organisation but we don't have that detailed. Personal connexion with the

company. They'll rely on third parties to get their devices back, or they just don't have the extensive network that we do, so that is a huge differentiator. For us, our sales people especially are focused on, you know, overcoming physician assistance to reprocessing, helping hospitals work through on tracks that might have anti reprocessing language, and they're written looking at what the total opportunity of savings is for a hospital. If they focus on different areas or franchises that we offer. And then again, our service associates are the ones that are making sure to collect the devices and send them back. So, which is critical?

Well to our entire business model. So that's a really, big differentiator that we have when compared to other reprocessor. Additionally, on that same vein, I would say that at sustainability solutions we have an incredible scale. We have scalability. So, like I mentioned, we are the market leader we are in the majority of hospitals throughout EU which means we are collecting a tonne of devices and since we are collecting a time that's that we provide back a lot more than our competitors can so you know our customers can rely on this for scale for getting product back to them and really delivering off on those reprocessing, savings and environmental savings.

Interviewer

Just thinking here… Is it possible? Can you put on a scale for example? Out of all the products that are produced by your parent company – The original manufacturer –how many, how much of that do you collect from these hospitals?

Interviewer

You know how much I want, but what I'm trying to say, so I'm just basically trying to understand the percentage of the products that you collect back that you're able to at least bring back to your facility for reprocessing at the start.

Participant 10

So, I don't have exact numbers on that. That might be a good question for participant 11 or someone in our operations team. That might be able to give you a little bit more detail on that.

Interviewer

Yes, so I think the next question would be shipping and I'm not sure what the shipping restrictions are in the US, but I've been made to understand from or some other companies that shipping used medical devices may be against the regulation, especially in or about

Germany, where some companies are located so you can't. According to them, you can't export already used medical device from a side to the order so you need to do some form of sterilisation or disinfection or reprocess before you can move it from the customer side to your reprocessing facility, for example, how do you undo that is out there.

Participant 10

Great question and as you were asking it, I think another good person to get more into the details of this would be Participant 12. He's our regulatory expert and very well versed in all the regulations and everything associated with reprocessing. But from my understanding, it is not classified as medical waste since it is intended to be sold back, so we do obviously have to follow very strict and stringent regulations on how we are shipping it. So, for instance, in our surgical devices they are contained within an advantage container. It's essentially in trash can that's, you know, can't be permeated with a lid on it. And then those lids are then zip tight and then it is double bag and then put in a corrugated box so all of those you know safety protocols for our own service associates, or the shipping individuals must be followed up, but Participant 12 will know much more about the you know regulatory side of.

How is this waste classified? What you know. Department of Transportation deems as acceptable to ship and everything like that.

Interviewer

Oh OK, I will take that up with. Participant 12 it's, I'm sorry to say this. It's just I like the name.

Participant 10

He's great and he's with the organisation for a really, long time, so he has so much historical background too.

Interviewer

That's pretty good. I mean, I hope I can speak to him sometime soon, so that's. And yeah, so you talked about when the device gets to your facility, and it gets to be sort in a receiving area. And yeah, so bot happens at the sorting and receiving area. How? How would you describe the process? I didn't get it very, very well. Are you sort this different part? Because I think one of the key things for me was. You said you sort them and then the decontamination comes in later. So well, I was thinking or based on my experience or based

on my knowledge, I was thinking you want to decontaminate it before you start handling it in any way.

Participant 10

Yep, so after sorting personnel are over, our most highly trained operations personnel they undergo nine weeks of extensive training to make sure that they are identifying devices that are re processable versus not reprocess able and taking every safety precaution, so they have specialised protective equipment. Up in their shoes or gloves that they use in their face coverings, they're completely gowned as well, and so it does take a while for these individuals to be trained and come up to speed on what to do in the sorting and receiving we will put the bins On a table, essentially layout the devices and then the operations personnel will sort through it with tongs and other tools to separate the devices from RE processable versus not.

Interviewer

I can imagine that process is very labour intensive. It's manual, is not it?

Participant 10

I don't know for sure. I would say it would be very, very difficult to automate this. I was recently at our production facility in xx and just the level of detail and scrutiny that these operations personnel must give to every single device is impressive. So, they must distinguish, you know you can Trocar versus another pro car. I really have a keen eye for the devices that we're looking for and every container that we get back, you know is filled with completely different material than the one before.

Interviewer

well, that's true. OK, now I ask about the automation because certification and inspection are beginning to look like the odd area now in automotive industry so in automotive industry what happens in the automotive industry is kind of like what you've just described, where it's so specialised, especially if you're working with different brands and different companies.

00:20:52 Interviewer

It's so difficult to you know, know how to do this, but there's they've made some really good progress, especially bitter automotive automatic inspection process so I'm hoping over the next few years. Maybe we would and the medical devices industry would get to that point

where we can, you know, automate some of those things so maybe there is instead of 20 people doing the job they would have maybe just two or five or something lesser.

Participant 10

There are areas within our processes that we have a tonne of automation specifically in the cleaning the assembly, the disassembly, so we do. We've invested around, you know, $35 million in automation and robotics just so that we can increase our speed, efficiencies and everything like that throughout our entire reprocessing process.

Interviewer

Oh, so you said cleaning up assembly, reassembly and all that is not it.

Participant 10

And there's some automation and disassembly so when you sort it you decide what can be remanufactured.

Interviewer

And what can't be remanufactured? What happens to the ones that can't be remanufactured? How do you deal with them?

Participant 10

So, it depends on the type of device that it is Stripe recycle as many devices as possible. So, for instance with our POX and ECG leads, if we can't reprocess them if they've reached their Max turn cycle. If they are rejected on our line for any reason, we collect those and store those at our facility until we have enough volume to send a recycler, so 100% of our POX and ECG leads are recycled and annually.

Participant 10

We have about 150,000 pounds of POX and ECG's that are recycled, which is great. Other products that we do have we send to waste to energy providers so that we are trying to divert from the landfill, create usable energy from those devices and having a better solution there, and you know, we are continuously looking for areas of improvement and one goal that we have set for our manufacturing sites is to reduce our waste to landfill by 20% by the year 2025. So that is a strategic goal for the organisation and something that we're continuing to evaluate.

Participant 10

OK, great, so here's the devices that are under our Patient Care franchise. When I was speaking to earlier that are 100% solid gold, our pulse oximeters and our ECG leads. And then I was talking about Trocars earlier and our surgical franchise. And then here's our Vascular franchise, which is more EP catheters and cables.

Interviewer

You recycle 100% of all the surgical and the patient care.

Participant 10

Just the pulse oximeters and the ECG leads. They have metals inside of them, so they are a great candidate for recycling. These other ones are harder to recycle because they are mixed plastics with fabric and then I was talking about our waste to Energy programme that is centred around our patient transfer mats. So, we send our patient transfer mats waste to energy. We recycle 100%. The POX and ECG leads. It we are striving to do more but it is so hard to find viable sustainable solutions for these specific materials. You have no hazard ways. Can you have the mixed plastic? You have mixed metals and so it makes it hard to find a viable solution, but it's something that we're committed to and finding and just growing that year over year.

Interviewer

OK, and notice this medical device industry tend to use a lot of plastics and one problem with plastics is most types of plastics are not recyclable. They're not biodegradable, so and it's difficult to reprocess them so thinking about how in the future you know medical devices can go from pure plastics to something different, but I can't imagine having you know legal shows or true cars with papers or something else. It would not work with it.

Participant 10

Right great, we do have the original manufacturers also have to comply with, you know medical grade plastic, so there's a lot of policy behind the materials that they are choosing and making sure that it is very sturdy can be patient contacting and lives up to the standards of medical grade.

Interviewer

OK, do you know what percentage of your surgical tools you will process at Company D? Of our surgical device, what percentage we reprocess comparative too, so I will say the two

largest franchises that we have are the surgical and the patient. Care by volume patient care is higher than surgical.

Participant 10

I think that would also be a good question. For we need to have, uh, maybe have some more context or detail on that.

Interviewer

What is remanufacturing at Company D.

Participant 10

We are based in the United States. You must refer to it as reprocessing over in Europe. We must refer to it as remanufacturing so in my mind, they mean the same thing. I know there are some technicalities that make it different, but when we say reprocessing, we essentially mean remanufacturing.

Interviewer

thank you very much for clarifying… there's a, there's a lot of ambiguity in the term reprocessing and remanufacturing, especially when it comes to medical devices. You know, I'm not sure what the what the what the FDA guideline says about reprocessing single use devices. But do you know the remanufacturing of medical imaging devices is? Different from what the regulation says about, you know single use devices and they bought medical devices, but You know different kind, different standards and it's the same thing in in the Europe is different wars. In the UK you know, refurbishment and fully refurbishment and you know.

Participant 10

Would be I don't have as much experience on the sales side of our organisation, so that would be a great question for participant 12, our upstream marketing director or some of the marketing managers that I can set you up with who do were previously sales reps.

Interviewer

Alright thank you.

END OF MEETING

Appendix B-11: Semi-structured interview transcript for participant 11 (Company D)

Interviewer

Can you give a brief introduction about yourself? Thank you.

Participant 11

So, I'm currently the director of xxx. The title probably is not as important as you know, just the expectation that I work with the marketing team who decides, you know from the customer's perspective, what devices would be would be desirable to recover, translate that into an actual process for reverse engineering dismantling the device, cleaning it, introducing replacement components, reassembling testing, inspecting sterilising the device and making sure that we can validate them that the device is safe and effective for a subsequent use. And that it is substantially equivalent to a predicate device. Then we take all that information in the form of a 10K file, which is just a dossier of scientific validation information. Everything that you could want to know you know from an engineering. You know just other technical disciplines up from those perspectives. Work with our regulatory affairs team to trans. Put those into or format those into. Submissions appropriate for either the US or Japanese regulatory bodies, and then ultimately transfer those processes over to our production facilities whether they are in Florida, Mexico, or Arizona. In the United States.

Interviewer

Oh, OK. Thank you very much for that. How many years have you been at Company D?

Participant 11

So, the Company D bought this. It's a. It's a similar story, probably for a lot of the different business units at Company D Company Ds of serial, acquirer of other device companies. I entered this industry in 2002.

It was called something else, but it's still the same business. Company D bought the business from us in 2009 and I've been.

You know, just my entire adult life in in this business. Sustainability in healthcare.

It's cool.

Interviewer

Alright, thank you very much for that, can I just ask again about the locations of your of your facilities and then you mentioned something about. Do you have multiple locations but down the US or do you have? Just one large. I just want to know about the ball about you.

Participant 11

So, we have currently xx locations in the US, x in xxx and we have a manufacturing facility in xx. Headquarters for the business unit is in xx. And we also have a recovery, or we call it manufacture but a recovery facility in Tijuana, Mexico.

Interviewer

OK. The question what I'm looking at answer is to know the kind of model that the business model, the recovery model. Not sure if that's the correct terminology for that or do you run recovery as a separate business distinct from the original manufacturer or are you attached?

Participant 11

So, I would say that 99% of what we do is a service business. Where we will approach acute care facilities in North America. So, the United States and Canada with our ability to recover their single use devices. In recent years we have also partnered with several hospitals in Japan, so we collect from.

Participant 11

I don't know, it might be a couple of 100 hospitals in Japan and sell recovered items back to us. A smaller subset of them. That business is really just, you know, in its infancy in our market development. So we would go to. So, we used to, you know, do business in the UK at. Uh St. Georges was, you know, one of our early customers, so we would approach them and say, you know we have approval from the… right to recover a certain device and because those technical files are very device specific, so it would be, for instance, a harmonic scalpel, right is one, you know, directed energy device used in laparoscopic general surgery and so we would say we have the ability to recover this device two times the regulatory approval spans you know six SKUs, and here is our price sheet, right? So, what we would do is. If the hospital is interested, we would send a service associate to go and assess usage. Assess where in the facility that device is being utilised and install a collection modality and just really just a think of it as a large sharp's container, right? Something that can't be punctured by a sharp medical instrument. And you know, harm someone while in transit. Something that doesn't leak, something that's not likely to topple over and spill contents.

Those would be placed usually as close to the point of care as possible. We like to install the collection modality inside the operating room.

If that's not possible, you know we work with the facility to figure out what is that. Service associate then trains the hospital staff to after use, put that instrument into our collection container and then the service associate comes on a routine basis, collects it and ships it to one of those facilities in the United States, right?

Interviewer

OK, alright thank you very much. It makes sense, but it's sounds kind of complicated to me right now So I'm just wondering, do you have any public documents or any information details available in public domain about your processing activity about product recovery at Company D just so I can prepare for the next meeting. And I'm also looking ahead of the next meetings. I would be asking real questions about the kind of products.

The I mean the names of the product, the type of the product, modalities. If there's anything like that that you focus on and why you do that. And, I would still need more explanation about the business process, the remanufacturing, the recovery business process just for me to actually get my hands on it.

But the most important thing for me now is, do you have any kind of documents or public? Publicly shared information that you can share with me to make me be better prepared for the next meeting with you.

Participant 11

Just thinking through our marketing collateral, we can probably send you some brochures that just go over the business at a you know 20 feet elevation look and then that would probably give you some good context going into your next meeting. Things we can also, I'm sure you've been able to see our sustainability solutions websites, so that has some good information within it as well. But I would be happy to share some marketing collateral with you.

Interviewer

Alright, thank you very much for that and I'll look forward to that, but just came to mind. Now there is a lot of metrics now used to measure sustainability quantitatively. I wonder if you as a source and ability leader involved, or do you actively try to quantify your

sustainability effort at Company D and how customers or customers considerations affects that decision process.

Participant 11

Yep, absolutely. So, we do have a lot of good data points on, you know, waste diversion from the landfills so quantifying how many pounds of waste are being diverted from the landfill by our customers purchasing recovered devices. So, extending the useful life of a single use device instead of. Just throwing it away and then going to the landfill and that's something that we have elite out with customers with the larger Company D organisation and with external stakeholders.

Interviewer

That's good, thank you, thank you very much for that. That's really that's really very helpful. Yep, so let's talk to you to decide the sequence of meetings. I think I don't know who would be my contact person at strike it so I can easily relate, wait, and, you know, make plans and catch up with a few times, yeah?

Participant 10

Yeah, I think to be your main point of contact. Do you have anything else in mind that we should loop into the interview process?

Participant 11

So, I think someone from manufacturing. Uh, would be helpful. I don't know if that would be king or someone else. We can figure that out, OK?

Interviewer

Well, decision makers specifically, I think I would be looking more at those were involved in making the decisions, like here would work very closely with the very on deciding what product to re manufacture to recover and why to do that. So I would also appreciate if we could put down into your considerations.

Participant 11

Yeah, absolutely. So, we can. We can figure that out. I guess the reason I was thinking of you know someone from manufacturing is that they can give you some perspective as to, you know, just the volume of recovered items compared to the new items that are sold.

Participant 11

It just for some context, as Company D is a very large medical device company, and we sell a lot of devices. Our Sustainability solutions division five of the we produce five of the highest volume products of all of the other Company D business units.

Participant 11

Right, so we are. We are the third largest producer in the world of pulse oximetry sensors, DVT compression sleeves and electrophysiology catheters.

Interviewer

Wow, that's impressive, is not it?

Participant 11

No, I don't say that to boast or brag it. It really is more, you know when we talk about the environmental impact of you know everything we do these turn into literally tonnes and tonnes of medical waste that otherwise would be incinerated or go into the landfill.

Participant 10

And additionally, the avoidance of having to extract raw materials to make new devices to like that's completely or for the most part loaded when recovery.

Interviewer

OK, thank you very much just to another point that I've been talking about for the past few months. Most of our efforts seems to be focused now, not just you as a business, but most people tend to focus on fixing the problem. Rather than making sure we don't have the problem at all, so I'm thinking about, you know the forward manufacturing the new manufacturing T, but their considerations of remanufacturing, for example, the common one is the design for remanufacturing, or the design for environment or design for sustainability.

Interviewer

Those kinds of considerations involved under new product developments at Company D.

Participant 11

So, they certainly are, and Danny actually was instrumental in working with our R&D engineers to implement in our design control or new product development process scorecards as well as other metrics to improve upon the sustainability aspects of the devices that we recover. I would say that the instruments that we collect, clean refurbish, etc, they're

made to be disposable, right? And so when we have the opportunity to improve on that, divide that design for sustainability, you know we try to take that opportunity whenever possible and you know, we can explain further what that means. But to you to your point about, you know solving the problem.

As opposed to making sure the problem didn't exist in the 1st place, I do think you know at some point in this process it would be important for you to talk to you, you know someone. At you know, Company D, right that are on the production side of the single use devices and understand so you know what they're looking at as well. I, it's hard to. I don't want to demonise some of these, you know, medical device manufacturers who are producing good devices. But to your point, they are single use. The number is actually very low, is not very few of them recover their equipment, and that's really pathetic, but at least we have people we have businesses like Company D to do the to do the recovery. The remanufacturing which is pretty good business and another thing.

Interviewer

What year did company D start recovery medical devices what yeah?

Participant 11

Company D acquired this business in 2009 at the very end of 2009.

Interviewer

Well, thanks very much for that. I don't want to take too much time. I don't want to overstay over of a stable welcome just so you don't turn me off the other time next time. So, thank you very much for that, Participant 10 and 11. I would expect some documents from you anytime this week or when it's convertible for you, but I would also need to be able to schedule meetings for you to discuss.

Properly one and one and then with Participant 11 one on one. So let me know you have an ability for this week or for next week or whenever it's comfortable for you. But I'm looking to get all the data icon from Company D between now and the end of September.

Interviewer

Alright, sounds good, thank you

Yeah, sure will. Thank you very much and enjoy the rest of your day.

END OF MEETING

Appendix B-12: Semi-structured interview transcript for participant 12 (Company D)

Interviewer

Can you start first for by telling me about yourself? Your current role at Company D years of experience, years in that road? Just so I can take a note of that. And you know, walk without thank you.

Participant 12

Yeah, I mean my pleasure. I guess first just to level set for the conversation I'm happy to share and help you as much as I can. I can't speak on behalf of Company D, so this is just kind of for your information to kind of guide your work, This is purely me presenting you my background which is a long time medical device experience, so I was a salesman for a different part of Company D for about 8 years, and then I've done seven years in in both inside and outside of Company D in marketing and business development roles and the last year I've been with Company D doing upstream, which is focused on In portfolio revenue.

Interviewer

OK, thanks very much for that. How many years have you been on that role?

Your role seems to be kind of closer to the customers and in the market and kind of expert, so I'm just going to be focusing on that aspect and, you know, be asking you some areas. I would just like you to be as elaborate as possible and you know give me based on your experience anyway and you've been there, done that, spent several years on this same thing so you would know the in depth some details about this, and so I think one of my biggest concerns when I spoke to participant 10 was how do you present yourself to customers or Company D present itself to the customers?

And what kind of recovery operation does it say it does to its customers? Is it remanufacturing or reprocessing, or refurbishment?

Participant 12

Yeah, it's a good question and I think there's two parts that are important. The first part is who is the customer, and so there's really a few different folks involved in these purchase decisions. There's the end user which is most often for us, a surgeon or a physician of some type. Then there are the supply chain professionals, then it managed the contracts, and they have very different interests in this, both overall understand. And they need to see a financial

benefit, the Clinician is going to be very focused on safety equivalency. And the supply chain folks are going to be far More focused on the economics.

They will sort of take for granted that an FDA approval or regulatory body approval means it's equivalent, and so they're looking for different things.

In terms of how we present it to the customer We refer to ourselves generally as a reprocessing company. But there is, depending on the market that you're in, there is a specific meaning to reprocessing versus remanufacturing, and so that's going to be a little bit market specific in terms of what the regulatory path is and what specific language we must use.

Interviewer

OK, initially I was thinking about the ambiguity, and I know different complaints. That present themselves in different ways, so I just wanted to know exactly how you, you know, market your product. So, from what you've said, you basically use two key terms and not reprocessing and remanufacturing, is that correct? So, you don't do refurbishment or repair or anything like that.

Participant 12

Yeah, so I'm not a regulatory expert so I don't want to speak out of turn, but in the US, we refer to it as the reprocessing. We're a reprocessing company, but there is a different meaning for those things, and it can vary by product. That varies by company. It varies by market, so it's just it's a nuanced which is something to be aware of.

Interviewer

No, no, no worries. Thank you very much for that. And OK you were saying something about the customers you saw. It depends on the kind of customers, and you said it could be either the clinicians or supply chain. And can you give me more details about your customers? You know, just more characteristics and all that about the customers?

Participant 12

Yeah, so like most medical devices, it's not one person that makes a purchasing decision and in the case of reprocessed medical devices, there's usually two different kinds of customers. Two different people in the same hospital that are both going to have to be supportive to drive forward with a decision to use repurchase product. It can start in either place, but both are going to be equally important. There's the clinician and that's the surgeon

that's going to pick the device up and use it, and if they're not confident in the safety and efficacy of the device, then the conversation we usually stop right there. Even if the clinician is supportive, supply chain is tasked with driving and savings very often have a savings target for the year, and so they're going to prioritise the opportunities that drive the most substantial savings. So, if reprocessing of a certain device can drive substantial savings and substantial is important because it it's going to be compared to all the other contracts that they must potentially renegotiate, then they can become a champion. They can try and influence the clinicians and they can ultimately try and renegotiate contracts with the vendors of the new devices to make sure that they can have access to both.

Interviewer

And do you focus on any specific geographical location? the US, UK, EU. Do you have any specifics?

Participant 12

So, most of our business is in the US. We do have business in Israel, Canada and Japan.

Interviewer

Is it possible to put numbers behind that, just you know, like percentage of your customers? I'm not sure if that's possible, but I mean I'm thinking he could probably like 90% of your customers are in the US just so I can put a number behind each location.

Participant 12

Most of Our customers are in the US. so, we have business in Israel and Canada. Those are Mature reprocessing facilities and then we also have a little bit of business in Japan. Every region has a different regulatory approach to reprocessing. Those are the most mature. There's not a significant amount of reprocessing in Europe, at least to date, and so we have not.

Interviewer

OK, just to comment on that, there's there was an article I read some time ago. And they talked about using remanufactured circular mapping catheters, and apparently, they were manufactured remanufactured by Company D, and but they used in the UK. They used and I think St. Georges or speed to warn other hospital like that in the UK. So, I mean it kind of gave the impression that the hospital support remanufactured medical devices and so makes

tend to also give the impression that it might be popular in some specific hospitals in the UK. Do you have any out there out there?

I would say marketing goes in the UK, is it? As I know you've said it's not a lot, there's not a large amount anywhere in the UK, but I'm imagining it because. What am I trying to say? Like you would do business in the UK so.

Participant 12

To be honest, there's been regulatory barriers that span the UK and Europe, and that's probably limited. Some of our historical focus there. My role is US, centric so I'm just not as close to the international markets to give you great insights there, to be honest.

Interviewer

So, for the US market and can I ask about your marketing approach?

Participant 12

I think every company you know very similarly is focused on getting the FDA approval and then that will drive what you're allowed to say and who you're allowed to say it to. So, like other medical devices. That's kind of the first step.

Rely very heavily on our sales force, and Company D prides itself on having a best-in-class sales force that can work closely with the customers to understand how our reprocessed portfolio can help them meet their, you know, clinical outcomes and financial goals for facility.

Interviewer

OK and can you give me some details about the pricing for Yeah, the price and the warranty and some product offerings and that's comparing them with the new products or new devices or something like that.

Participant 12

Yep, so we have a broad portfolio and so in each product category it's going to look a little bit different they Consider, and this is where this I think becomes an interesting equation to figure out the things to consider in terms of the value you derive from. They should do different variables, so which products is the hospital using? Which products can they buy reprocess? What's the discount on those products? And then the one that I think is overlooked but is the most important is what is the availability of those products, so to be

able to save money on reprocessing the first thing a hospital must do is collect their used devices. Bring them back to us so we can reprocess them, and then they purchase them back at a discount to new. If they're not doing a great job with their reprocessing partner of collecting those devices and if the reprocessing company doesn't have an optimised. A manufacturing process that generates a high yield. Then the rest doesn't matter, and just as a you know, for conversation's sake, sort of example, if you. Uh, huh, good new device xx dollars each and I is reprocessor come and say I can. I can sell you that device for $300.

That sounds great, but if you use 1000 and I only get 200 of them put in my container to come back to my factory, then we've lost access to 80% of the volume. And if my factory through the remanufacturing or reprocessing can only yield 50%. Then you really can only buy 100 devices at $300. Your total savings opportunity is a fraction, and that's something that's I think, interesting to look at, because very often when hospitals compare processors, they'll tend to look at the spreadsheet and say, OK, well, three companies offer the reprocessed product.

Interviewer

It's fascinating.

Participant 12

And this company has the best prices, so that's my best partner. And the reality is that it is not always the same they may have A lower price. But if they Don't have this Supply the rest doesn't matter, and when you get to sort of the scale of the bigger reprocessing companies, you know we're sourcing products from a lot of other places to be able to supplement the supply. So, you probably know all that, but that's some of the things that we think about a lot.

Interviewer

I'm trying to get an idea of the pricing compared to that of new. I know you talked about a discount or something like that but let me let me get this. Uh and hospital purchases new devices new single use device that could be plugs or you know sensor parts or whatever and they collect it. Do you buy you from them or do they just give it to you for free? Is there any value kind of transfer between the hospital? To you and then back to them. And then also the price of which you sell it back to these hospitals or to whoever is purchasing it. How much lower is it compared to that of new? Yep, both good questions, so there's a few product

categories where we will pay 4 devices that are just very hard to come by, and we'll basically pay a collection product still pay and it varies.

Participant 12

So, I don't want to give you A number because. It's the numbers range, but just for conversation's sake, say we pay $10. So, there might be some devices where for at least a period we'll be willing to pay a small amount for them to collect for us. The hospitals get value by having us Even when we're not paying. They otherwise are paying per pound to dispose of these things, so at the bare minimum we're taking we're diverting a waste stream and making sure it has an environmentally friendly end of life solution. So, there's if nothing else happens. Everything we take and some products where we will pay a collection credit for it. But the bulk of the value for the customer exists when they buy back. So, when we come full circle, we collect it. We bring it in. We make it as new quality and they buy it. That's where they realise the biggest financial benefit and based on the products and categories. All different, it could be ballpark from 30 to 60% discount from the original Manufacturer product.

Interviewer

Oh, OK, and I know also that there is a common thing, especially in the medical devices industry about warranty and obviously legal responsibilities in case something goes wrong and all that, do you? I mean, there's company D offer Warranty on reprocessed product and if they do How much until they give compared to that of new?

Participant 12

So, in this is not just right here. This is true for all the companies we must take ownership of the product when we sell it. So, whether we were manufacturing it new ourselves or we're reprocessing it and selling it back now that we sell it to the customer, all liability becomes our own. And so, it's Exactly the same as other devices and our yeah, our support of it is going to be the same as the manufacturers. That's near oh OK, so if the manufacturer gives

Interviewer

so does the warranty necessarily last for a certain period, but for a particular single use. Is that correct? Can you give me more details about the warranty, yeah.

Participant 12

There's not so Much about it, yeah so it is a warranty on a single use device, so we must as part the approval process, we take data to demonstrate that Our failure rates are equivalent. Yeah, so with single use devices we don't usually Call it a warranty. We'll talk about the failure rate And for the FDA approval process and what really created this industry was when the regulation changed to allow for the reprocessing of single use devices, we must prove equivalency. So, we must demonstrate that the clinical performance is as good or better or the failure rates are as good as new or better and that's really what the FDA will look at to grant the approval and. The warranty - There's nothing personal warranty, but I think failure rate is probably the closest comparator and we must be as good or bad.

Interviewer

Better all right that's good. I also want to know just a different one. Anyway, your kind of your level of involvement in remanufacturability and decision making that we talked about earlier. And when I say this and how when you when they assess the viability and the feasibility of remanufacturing? Or reprocessing the product or medical device. What's your level of involvement in that decision making and how? How do you take part in that? That's I just want to know that to stop it. Thank you.

Participant 12

So just so I understand the question you're asking how we pick the products that we decided to reprocess is that.

Interviewer

Yes, that's one of it. That's really one of it. So, the re manufacture ability decision making. I'm looking out as two components to it, and one is the viability and the other one is the feasibility. So of course, standard organisations have very comprehensive methods and ways of assessing both the viability, it could be economic or environmental, societal, and then the feasibility in terms of the product design or other things that you look at so. But first, I'm just keen to understand your level of involvement, your arm. And you do, and then to go into the factors that are considered during this remanufacturing process during this decision making, sorry.

Participant 12

Yep, so I'm very involved in that part of it and in in a simple way. I think we do what any business does, and we try to maximise the value for our customers 1st and ourselves 2nd.

And so, we look at the devices. That we have A technical capability and there's a long history of reprocessing Electrophysiology devices. Best energy devices in surgery and then what we call patient Care devices, which are sort of low dollar. More simple monitoring tools, things like O2 sensors and ECG leads. And so, we have a technical ability to do it. Do it well, do it the same. Quickly and then again, like really any business we look at, which products have a substantial enough market, and we can sell at a low enough price that we can meet the objectives of the hospitals so that they're going to want to prioritise it. Because when they think about, you know, generating savings. Worry they can work with every processor. They can also just go back to the original vendor and say I want a better contract and that way I won't reprocess it, so they've always got those options and then sometimes they're picking between categories. So even if this is the best option in Canada. Or if there's the bigger category at the end of the year, they need to hit a financial savings target and so they must prioritise. So, we try and pick products and categories that will help the hospitals meet their own objectives.

Interviewer

OK, So what factors? I understand picking products and different categories, but I'm just I just. I'm just curious to know the other factors that you know you would use apart from and picking different products and different categories to help the hospital reach their goals. So, what other factors?

Participant 12

Yep, so the market size. You know there's medical device products that are in $25 million categories and $2 billion categories. We're going to tend to pick their bigger categories because there's just more savings opportunity. And oftentimes, a higher sales price means there's more margins, so to me We can pull more dollars out. Meaningful to the hospital and then durability. So, if we must be able to collect it, bring it back and it's got to be sufficiently robust to survive that process without being so damaged that we can't put it through our process. And those are probably the three most important. The 4th is probably clinical acceptance. In in markets or with surgeon have. Had you known a decade of exposure to reprocessing, they understand that it's safe.

They've been exposed to it, they're familiar with it and so their willingness to trial. Those products and adopt those products are going to be much different than in some specialties where they've never seen it before. And it's not to say that we won't approach those

specialties, because we certainly do, but we must be thoughtful to know that their adoption curve is going to be a lot longer. It's going to take. A lot more evidence and a lot more time.

Interviewer

OK, it looks to me like this factor's kind of like focus on the viability of reprocessing this the single devices. Do you have any? You know factors in mind about the feasibility of the products. For reprocessing, I'm just trying to get as much information and as many factors and that that I can get as much as possible from you and that's why.

Participant 12

Sure, so when you say yeah, so when you say feasibility. You're talking more about the, like the technical ability to reprocess it. Yeah, so that's one of the very first things we look. At is we Have to know with confidence that we can create a process that can do it safely, safely, consistently, and at scale. And said the best from a business standpoint, we'll first look and say is it desirable? If we can do it and then we look technically and say, can we do it? And then we put those together and we decide to move forward. With the project or not?

Interviewer

So, OK, that's good. Then you said something about clinical acceptance, and that's going to be my final question for this evening. How do you know clinical acceptance varies across geographical locations across states across hospitals and across clinicians, personally, but how do you see the impact of that on the industry? And I'm also thinking about what, what factors do you think are critical too? A clinical acceptance.

Participant 12

Yeah, that's another good question. So, it varies across all the factors that you said and then there's A lot, so very tremendously by surgical or physician specialty. So, a colorectal surgeon or a general surgeon is going to have a different approach to reprocessing than a urologist or dermatologist. And those are just silly examples, but you get the idea so in each of those groups their willingness. To look at reprocessed is based on sort of their historical experiences, so have they ever used reprocessing and was their first experience? As if then they're going to look for the recommendations of their clinical groups. So almost every surgical specialty has its own clinical organisations.

So, in the US, for general surgery the ACS, the American College of Surgeons, is a big one. Sage is the society of advanced general and endoscopic surgeons is another big one, so

they'll look to the recommendations of those organisations to see if they support it and the first two levers that the whole they may look if those are positive, then they're going to want evidence. So, at minimum we can use the FDA submissions, which in our case are incredibly detailed and there's an enormous amount of data. And then there's some occasions where we will be Able to provide You know additional white papers. Those sorts of things that can provide even more context or sort of more specific detail. So that's sort of the whole continuum there's a lot of work to be done, I would say on the on a part of industry to sort of increase the comfort and confidence and it's going to be those tools plus more I think is reprocessing grows in the market. We've got to spend even more time training clinicians just giving them hands on personal experiences. And then a big part What are skills will allow them to trial it in practise? So, if they go through this sort of analysis in their minds and they look at their resources, the thing that they're always going to want to do is put it in their hands. Make sure they're comfortable with it. It performs their expectations before they make it any sort of commitment on behalf of the hospital.

Interviewer

Alright, OK, and from you from your own experience I'll I know you've said it's mostly the clinicians on the supply chain, but out significant or how important. Some other clinicians and this decision-making process. I think what I'm trying to get is to put them on a scale and to see which one of the two has more here.

Participant 12

so, it's a good question and what's interesting is that it depends based on the specialty and at the hospital, and a few things that you sort of look at are the procedures that they're doing highly profitable. The more profitable the procedures are, the less pressure the hospital will have to drive out cost so. There's a lot of reprocessed products used in electrophysiology. Those tend to be very profitable procedures for hospital, so it's not necessarily the 1st place that they're going to go and try and find additional savings. They frankly just want to keep them happy and working and busy, and that's more important than you know, an incremental Percent of savings There's other specialties and procedures that are very pressured. The reimbursements are closer to the costs and so in those instances the physicians will always have the ability to say absolutely not, but they're going to get a higher level of pressure from the hospital that says, you know, we have to find a way to make this work we need You to work with us and so, so those dynamics change and then I would say the newness of the

technology you're talking about. So, if it's a very mature market and there's two or three competitors, and that's an important piece too.

The willingness of any one of those competitors or the hospital to sort of go hard against reprocessing is less if it's a very new technology. The vendors that created it are going to have a lot more influence on the market and it's going to be much harder to reprocess. They're going to be working more closely with the physicians. The positions will oftentimes be relying on them to support it.

They're going to be less willing to not have that person there doing that, so the challenges for reprocessing Become much higher.

Interviewer

And something just came to mind now yeah, this is a personal one anyway and I know that big, larger machines like the CT scans the surgical to robotic surgical tool systems MRs and all that. They tend to also go through some form of a process, and, on the other hand, we've got smaller single use devices like the Patient Care devices, you know, vascular crew Physiology, and all that. And do you think that the clinical perception or the clinician's perception varies between Remanufacturing single use devices and remanufacturing medical imaging devices. Do you think there's an imbalance now to feel about this too? Or do you? What do you think about that, generally, yeah.

Participant 12

So, you probably have as much perspective on that as I do. You know, without any data to support it, I say that there is and the example I would point That you know the capital products used across the hospital. There's been third party repair companies, which is different. It's a different thing, but there's been third party repair companies for decades, so you could buy a $2,000,000 machine from xx and pay xx for a service contract Or you could have A local company come in and service it and I think the perception of the clinicians has always been that it's a xx product originally and so the quality is going to be the same and it doesn't really matter who services it, so they've been less sensitive to that. Now I do think over time that it trends back those.

Those decisions the performance the companies aren't always as good as the original manufacturer because they're not regulated in quite the same way as the single use. So those experiences will vary widely, and I'm sure there's some of the third parties that do a great job. There's a lot that don't it, and it ends up having a poor reflection on the original vendor.

And then the service will probably come back to them, and that's all sort of unfortunate single use. Reprocessing is so much more regulated and controlled. It is unfortunate because I think it gets more visibility from the clinicians you know. They can repair an MRI, and nobody knows if they put different parts inside every device, we sell has to say Company D on it so they're very aware when it's reprocessed versus not, so that's and it's an interesting question and I think yes is probably the answer.

Interviewer

Yeah, probably takes several years to get to that point where clinicians are very open about the safety and efficacy of single use devices, it's probably going to take a while to get there.

Participant 12

In some markets, I think they're there in new markets. It does take a few years before a few key opinion leaders will do it. The hospital bills will sort or that experience and then it becomes more accepted, and you know, sort of the rest of the adoption curve comes through.

Interviewer

OK, thank you very much for your time. And one final one, is Company D is on OEM our day or the third party reprocess and organisation.

Interviewer

Of major OEM's? Or are they necessarily part of the Company D manufacturing for the?

Participant 12

It's another good question, and Company D is an interesting organisation. It's very decentralised so Company D is really A big group of semi-autonomous companies, so we're bound together by some common structures. Our quality systems, for example Are the same as everyone else is, so there's the infrastructure and the expectations and the safety and the performance is the same.

But we act independently as a as a third party reprocessor and we're agnostic of who makes the Product at this point.

Interviewer

OK Alright That's good thanks. Thank you very Much for your, for your time

END OF MEETING

Appendix C: Practitioners response to validation questionnaire

Appendix C-1: Completed questionnaire for participant 1

Q1. Please state the name of your organisation

GE Healthcare

Q2. Please state your current position in your organisation

Remanufacturing Technology Director

Q3. How many years of experience do you have working in your current position

12

Q4. Please tick as appropriate

	Strongly Agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
The framework is an accurate and comprehensive representation of the customer-driven factors that influence remanufacturability.	◉	○	○	○	○
The implications of this framework can be used to improve the remanufacturability decision processes in remanufacturing companies.	○	◉	○	○	○
The framework is useful to remanufacturing companies at the present time.	◉	○	○	○	○
More critical decision factors have been omitted in this framework.	○	○	○	◉	○
The framework presents a new theoretical construct to practitioners in this sector.	○	◉	○	○	○
The framework does not correctly describe the factors remanufacturers would consider when deciding to remanufacture in the medical devices sector.	○	○	○	○	◉
The framework highlights factors that are useful to remanufacturing companies who wish to improve their customer acceptance	◉	○	○	○	○
The framework is not going to be easy to implement.	○	○	○	◉	○
Right now, the customer-driven remanufacturability framework is not applicable but can be useful in the next two to three years.	○	○	○	◉	○
I believe the framework captures remanufacturability decision factors that are driven by the customers.	◉	○	○	○	○
It's just not worth it, the cost by far outweighs the benefit of implementing the framework.	○	○	○	○	◉
The framework is based on current practice and presents a solution for the problems currently faced by practitioners.	○	◉	○	○	○
The factors in the framework are not important to the decision makers in remanufacturing companies.	○	○	○	○	◉
The framework can be implemented in real practice in remanufacturing companies.	◉	○	○	○	○
This framework does not require too many resources for its implementation.	○	○	◉	○	○
Customer-driven remanufacturability consideration was a hot issue like two or three years ago.	○	○	◉	○	○
The customer-driven remanufacturability framework addresses an issue that is important to remanufacturing business values.	◉	○	○	○	○
The framework helps to better understand how to improve remanufacturability decision making.	○	◉	○	○	○
The framework does not present anything new for the practitioners.	○	○	○	◉	○

Q5. Please provide any additional comments below:

Appendix C-2: Completed questionnaire for participant 2

Q1. Please state the name of your organisation

University of Strathclyde

Q2. Please state your current position in your organisation

Doctoral Researcher

Q3. How many years of experience do you have working in your current position

5

Q4. Please tick as appropriate

	Strongly Agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
The framework is an accurate and comprehensive representation of the customer-driven factors that influence remanufacturability.	○	◉	○	○	○
The implications of this framework can be used to improve the remanufacturability decision processes in remanufacturing companies.	○	◉	○	○	○
The framework is useful to remanufacturing companies at the present time.	○	◉	○	○	○
More critical decision factors have been omitted in this framework.	○	○	○	◉	○
The framework presents a new theoretical construct to practitioners in this sector.	○	◉	○	○	○
The framework does not correctly describe the factors remanufacturers would consider when deciding to remanufacture in the medical devices sector.	○	○	○	◉	○
The framework highlights factors that are useful to remanufacturing companies who wish to improve their customer acceptance	○	◉	○	○	○
The framework is not going to be easy to implement.	○	○	○	◉	○
Right now, the customer-driven remanufacturability framework is not applicable but can be useful in the next two to three years.	○	○	○	◉	○
I believe the framework captures remanufacturability decision factors that are driven by the customers.	○	◉	○	○	○
It's just not worth it, the cost by far outweighs the benefit of implementing the framework.	○	○	○	◉	○
The framework is based on current practice and presents a solution for the problems currently faced by practitioners.	○	◉	○	○	○
The factors in the framework are not important to the decision makers in remanufacturing companies.	○	◉	○	○	○
The framework can be implemented in real practice in remanufacturing companies.	○	◉	○	○	○
This framework does not require too many resources for its implementation.	○	◉	○	○	○
Customer-driven remanufacturability consideration was a hot issue like two or three years ago.	○	○	○	◉	○
The customer-driven remanufacturability framework addresses an issue that is important to remanufacturing business values.	○	◉	○	○	○
The framework helps to better understand how to improve remanufacturability decision making.	○	◉	○	○	○
The framework does not present anything new for the practitioners.	○	○	○	◉	○

Q5. Please provide any additional comments below:

The framework may be improved by including an assessment of the impacts and correlations relating to each factor

Appendix C-3: Completed questionnaire for participant 3

Q1. Please state the name of your organisation

Vanguard AG

Q2. Please state your current position in your organisation

Business Development Manager

Q3. How many years of experience do you have working in your current position

15

Q4. Please tick as appropriate

	Strongly Agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
The framework is an accurate and comprehensive representation of the customer-driven factors that influence remanufacturability.	○	◉	○	○	○
The implications of this framework can be used to improve the remanufacturability decision processes in remanufacturing companies.	○	◉	○	○	○
The framework is useful to remanufacturing companies at the present time.	○	◉	○	○	○
More critical decision factors have been omitted in this framework.	○	○	○	◉	○
The framework presents a new theoretical construct to practitioners in this sector.	○	◉	○	○	○
The framework does not correctly describe the factors remanufacturers would consider when deciding to remanufacture in the medical devices sector.	○	○	○	○	◉
The framework highlights factors that are useful to remanufacturing companies who wish to improve their customer acceptance	○	◉	○	○	○
The framework is not going to be easy to implement.	○	○	○	○	◉
Right now, the customer-driven remanufacturability framework is not applicable but can be useful in the next two to three years.	○	○	○	◉	○
I believe the framework captures remanufacturability decision factors that are driven by the customers.	○	◉	○	○	○
It's just not worth it, the cost by far outweighs the benefit of implementing the framework.	○	○	○	◉	○
The framework is based on current practice and presents a solution for the problems currently faced by practitioners.	○	◉	○	○	○
The factors in the framework are not important to the decision makers in remanufacturing companies.	○	○	○	○	◉
The framework can be implemented in real practice in remanufacturing companies.	◉	○	○	○	○
This framework does not require too many resources for its implementation.	○	◉	○	○	○
Customer-driven remanufacturability consideration was a hot issue like two or three years ago.	○	○	○	◉	○
The customer-driven remanufacturability framework addresses an issue that is important to remanufacturing business values.	○	◉	○	○	○
The framework helps to better understand how to improve remanufacturability decision making.	○	◉	○	○	○
The framework does not present anything new for the practitioners.	○	○	○	◉	○

Q5. Please provide any additional comments below:

luck of the new upcoming circular economy establishment and considerations is to little addressed in here as it will gain more importance over the next years. It is a current status but less focus on what is coming or supporting future decision making, for some already is it.. Highly important.. It reflects you pervious paper with purchases questioner of "150 year experience" but not the future changes which are necessary.

Appendix C-4: Completed questionnaire for participant 4

Q1. Please state the name of your organisation

Imperial College London & Neonatal Concerns for Africa

Q2. Please state your current position in your organisation

Professor & Principal Consultant

Q3. How many years of experience do you have working in your current position

4 years & over 20 years

Q4. Please tick as appropriate

	Strongly Agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
The framework is an accurate and comprehensive representation of the customer-driven factors that influence remanufacturability.	○	◉	○	○	○
The implications of this framework can be used to improve the remanufacturability decision processes in remanufacturing companies.	◉	○	○	○	○
The framework is useful to remanufacturing companies at the present time.	○	◉	○	○	○
More critical decision factors have been omitted in this framework.	○	○	○	◉	○
The framework presents a new theoretical construct to practitioners in this sector.	○	○	◉	○	○
The framework does not correctly describe the factors remanufacturers would consider when deciding to remanufacture in the medical devices sector.	○	○	○	◉	○
The framework highlights factors that are useful to remanufacturing companies who wish to improve their customer acceptance	◉	○	○	○	○
The framework is not going to be easy to implement.	○	○	◉	○	○
Right now, the customer-driven remanufacturability framework is not applicable but can be useful in the next two to three years.	◉	○	○	○	○
I believe the framework captures remanufacturability decision factors that are driven by the customers.	○	◉	○	○	○
It's just not worth it, the cost by far outweighs the benefit of implementing the framework.	○	○	○	○	◉
The framework is based on current practice and presents a solution for the problems currently faced by practitioners.	○	◉	○	○	○
The factors in the framework are not important to the decision makers in remanufacturing companies.	○	○	○	○	◉
The framework can be implemented in real practice in remanufacturing companies.	◉	○	○	○	○
This framework does not require too many resources for its implementation.	○	◉	○	○	○
Customer-driven remanufacturability consideration was a hot issue like two or three years ago.	○	○	○	○	◉
The customer-driven remanufacturability framework addresses an issue that is important to remanufacturing business values.	○	◉	○	○	○
The framework helps to better understand how to improve remanufacturability decision making.	◉	○	○	○	○
The framework does not present anything new for the practitioners.	○	○	○	◉	○

Q5. Please provide any additional comments below:

Appendix C-5: Completed questionnaire for participant 5

Q1. Please state the name of your organisation

VERTU MEDICAL LIMITED

Q2. Please state your current position in your organisation

COMMERCIAL SALES DIRECTOR

Q3. How many years of experience do you have working in your current position

3

Q4. Please tick as appropriate

	Strongly Agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
The framework is an accurate and comprehensive representation of the customer-driven factors that influence remanufacturability.	○	◉	○	○	○
The implications of this framework can be used to improve the remanufacturability decision processes in remanufacturing companies.	◉	○	○	○	○
The framework is useful to remanufacturing companies at the present time.	○	◉	○	○	○
More critical decision factors have been omitted in this framework.	○	○	○	◉	○
The framework presents a new theoretical construct to practitioners in this sector.	○	◉	○	○	○
The framework does not correctly describe the factors remanufacturers would consider when deciding to remanufacture in the medical devices sector.	○	○	○	◉	○
The framework highlights factors that are useful to remanufacturing companies who wish to improve their customer acceptance	○	◉	○	○	○
The framework is not going to be easy to implement.	○	◉	○	○	○
Right now, the customer-driven remanufacturability framework is not applicable but can be useful in the next two to three years.	○	○	◉	○	○
I believe the framework captures remanufacturability decision factors that are driven by the customers.	○	◉	○	○	○
It's just not worth it, the cost by far outweighs the benefit of implementing the framework.	○	○	○	○	◉
The framework is based on current practice and presents a solution for the problems currently faced by practitioners.	○	◉	○	○	○
The factors in the framework are not important to the decision makers in remanufacturing companies.	○	○	○	◉	○
The framework can be implemented in real practice in remanufacturing companies.	○	◉	○	○	○
This framework does not require too many resources for its implementation.	○	○	◉	○	○
Customer-driven remanufacturability consideration was a hot issue like two or three years ago.	○	○	○	◉	○
The customer-driven remanufacturability framework addresses an issue that is important to remanufacturing business values.	○	◉	○	○	○
The framework helps to better understand how to improve remanufacturability decision making.	○	◉	○	○	○
The framework does not present anything new for the practitioners.	○	○	○	◉	○

Q5. Please provide any additional comments below:

Appendix C-6: Completed questionnaire for participant 6

Q1. Please state the name of your organisation

GE Healthcare - Lifecycle Solutions

Q2. Please state your current position in your organisation

Segment Manager - Molecular Imaging, Women's Healthcare and X-Ray

Q3. How many years of experience do you have working in your current position

10

Q4. Please tick as appropriate

	Strongly Agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
The framework is an accurate and comprehensive representation of the customer-driven factors that influence remanufacturability.	○	◉	○	○	○
The implications of this framework can be used to improve the remanufacturability decision processes in remanufacturing companies.	○	◉	○	○	○
The framework is useful to remanufacturing companies at the present time.	○	◉	○	○	○
More critical decision factors have been omitted in this framework.	○	○	◉	○	○
The framework presents a new theoretical construct to practitioners in this sector.	○	◉	○	○	○
The framework does not correctly describe the factors remanufacturers would consider when deciding to remanufacture in the medical devices sector.	○	○	◉	○	○
The framework highlights factors that are useful to remanufacturing companies who wish to improve their customer acceptance	○	◉	○	○	○
The framework is not going to be easy to implement.	○	○	◉	○	○
Right now, the customer-driven remanufacturability framework is not applicable but can be useful in the next two to three years.	○	○	○	◉	○
I believe the framework captures remanufacturability decision factors that are driven by the customers.	○	◉	○	○	○
It's just not worth it, the cost by far outweighs the benefit of implementing the framework.	○	○	○	◉	○
The framework is based on current practice and presents a solution for the problems currently faced by practitioners.	○	○	◉	○	○
The factors in the framework are not important to the decision makers in remanufacturing companies.	○	○	○	◉	○
The framework can be implemented in real practice in remanufacturing companies.	○	◉	○	○	○
This framework does not require too many resources for its implementation.	○	◉	○	○	○
Customer-driven remanufacturability consideration was a hot issue like two or three years ago.	○	○	◉	○	○
The customer-driven remanufacturability framework addresses an issue that is important to remanufacturing business values.	○	◉	○	○	○
The framework helps to better understand how to improve remanufacturability decision making.	○	◉	○	○	○
The framework does not present anything new for the practitioners.	○	○	◉	○	○

Q5. Please provide any additional comments below:

Appendix C-7: Completed questionnaire for participant 7

Q1. Please state the name of your organisation

Stryker's Sustainability Solutions division

Q2. Please state your current position in your organisation

Sustainability Lead

Q3. How many years of experience do you have working in your current position

1.5

Q4. Please tick as appropriate

	Strongly Agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
The framework is an accurate and comprehensive representation of the customer-driven factors that influence remanufacturability.	○	◉	○	○	○
The implications of this framework can be used to improve the remanufacturability decision processes in remanufacturing companies.	○	◉	○	○	○
The framework is useful to remanufacturing companies at the present time.	○	◉	○	○	○
More critical decision factors have been omitted in this framework.	○	○	○	◉	○
The framework presents a new theoretical construct to practitioners in this sector.	◉	○	○	○	○
The framework does not correctly describe the factors remanufacturers would consider when deciding to remanufacture in the medical devices sector.	○	○	○	○	◉
The framework highlights factors that are useful to remanufacturing companies who wish to improve their customer acceptance	○	◉	○	○	○
The framework is not going to be easy to implement.	○	○	○	◉	○
Right now, the customer-driven remanufacturability framework is not applicable but can be useful in the next two to three years.	○	○	○	◉	○
I believe the framework captures remanufacturability decision factors that are driven by the customers.	○	◉	○	○	○
It's just not worth it, the cost by far outweighs the benefit of implementing the framework.	○	○	○	◉	○
The framework is based on current practice and presents a solution for the problems currently faced by practitioners.	○	◉	○	○	○
The factors in the framework are not important to the decision makers in remanufacturing companies.	○	○	○	○	◉
The framework can be implemented in real practice in remanufacturing companies.	○	◉	○	○	○
This framework does not require too many resources for its implementation.	○	◉	○	○	○
Customer-driven remanufacturability consideration was a hot issue like two or three years ago.	○	○	○	◉	○
The customer-driven remanufacturability framework addresses an issue that is important to remanufacturing business values.	○	◉	○	○	○
The framework helps to better understand how to improve remanufacturability decision making.	○	◉	○	○	○
The framework does not present anything new for the practitioners.	○	○	○	○	◉

Q5. Please provide any additional comments below:

Appendix C-8: Completed questionnaire for participant 8

Q1. Please state the name of your organisation

Strathclyde University

Q2. Please state your current position in your organisation

Research Associate

Q3. How many years of experience do you have working in your current position

About 1.5 years

Q4. Please tick as appropriate

	Strongly Agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
The framework is an accurate and comprehensive representation of the customer-driven factors that influence remanufacturability.	○	◉	○	○	○
The implications of this framework can be used to improve the remanufacturability decision processes in remanufacturing companies.	◉	○	○	○	○
The framework is useful to remanufacturing companies at the present time.	◉	○	○	○	○
More critical decision factors have been omitted in this framework.	○	○	○	◉	○
The framework presents a new theoretical construct to practitioners in this sector.	○	◉	○	○	○
The framework does not correctly describe the factors remanufacturers would consider when deciding to remanufacture in the medical devices sector.	○	○	○	◉	○
The framework highlights factors that are useful to remanufacturing companies who wish to improve their customer acceptance	◉	○	○	○	○
The framework is not going to be easy to implement.	○	○	○	○	◉
Right now, the customer-driven remanufacturability framework is not applicable but can be useful in the next two to three years.	○	◉	○	○	○
I believe the framework captures remanufacturability decision factors that are driven by the customers.	○	◉	○	○	○
It's just not worth it, the cost by far outweighs the benefit of implementing the framework.	○	○	○	◉	○
The framework is based on current practice and presents a solution for the problems currently faced by practitioners.	◉	○	○	○	○
The factors in the framework are not important to the decision makers in remanufacturing companies.	○	○	○	◉	○
The framework can be implemented in real practice in remanufacturing companies.	◉	○	○	○	○
This framework does not require too many resources for its implementation.	◉	○	○	○	○
Customer-driven remanufacturability consideration was a hot issue like two or three years ago.	○	○	◉	○	○
The customer-driven remanufacturability framework addresses an issue that is important to remanufacturing business values.	◉	○	○	○	○
The framework helps to better understand how to improve remanufacturability decision making.	◉	○	○	○	○
The framework does not present anything new for the practitioners.	○	○	○	◉	○

Q5. Please provide any additional comments below:

Great framework

Appendix C-9: Completed questionnaire for participant 9

Q2. Please state the name of your organisation

Waseda University

Q2. Please state your current position in your organisation

Professor

Q3. How many years of experience do you have working in your current position

2years

Q4. Please tick as appropriate

	Strongly Agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
The framework is an accurate and comprehensive representation of the customer-driven factors that influence remanufacturability.	○	◉	○	○	○
The implications of this framework can be used to improve the remanufacturability decision processes in remanufacturing companies.	○	◉	○	○	○
The framework is useful to remanufacturing companies at the present time.	○	○	◉	○	○
More critical decision factors have been omitted in this framework.	○	○	○	◉	○
The framework presents a new theoretical construct to practitioners in this sector.	○	◉	○	○	○
The framework does not correctly describe the factors remanufacturers would consider when deciding to remanufacture in the medical devices sector.	○	○	○	◉	○
The framework highlights factors that are useful to remanufacturing companies who wish to improve their customer acceptance	◉	○	○	○	○
The framework is not going to be easy to implement.	○	◉	○	○	○
Currently, the customer-driven remanufacturability framework is not applicable but can be useful in the next two to three years.	◉	○	○	○	○
I believe the framework captures remanufacturability decision factors that are driven by the customers.	○	◉	○	○	○
It's just not worth it, the cost by far outweighs the benefit of implementing the framework.	○	○	○	◉	○
The framework is based on current practice and presents a solution for the problems currently faced by practitioners.	○	◉	○	○	○
The factors in the framework are not important to the decision makers in remanufacturing companies.	○	○	○	◉	○
The framework can be implemented in real practice in remanufacturing companies.	○	◉	○	○	○
This framework does not require too many resources for its implementation.	○	○	◉	○	○
Customer-driven remanufacturability consideration was a hot issue like two or three years ago.	○	○	◉	○	○
The customer-driven remanufacturability framework addresses an issue that is important to remanufacturing business values.	◉	○	○	○	○
The framework helps to better understand how to improve remanufacturability decision making.	◉	○	○	○	○
The framework does not present anything new for the practitioners.	○	○	○	◉	○

Q5. Please provide any additional comments below:

As I am not familiar with the medical field, I cannot vouch for the accuracy of my assessment of your framework on medical devices.