1. SOP Category

Clinical

2. Staff Category

Clinical

3. Purpose

The purpose of this SOP is to instruct all unit staff on the correct procedure for obtaining the knee flexion/extension data using flexible electrogoniometer and Strathclyde University data logging system (SUDALS) from patients and volunteers participating in research trials, therefore promoting uniformity within the Glasgow clinical research facility. The flexible electrogoniometer is an instrument for measuring joint angles. This device together with SUDALS allows range of motion (ROM) and max/min knee joint angles to be recorded during range of activities of daily living (ADL) in a free living environment.

4. Procedures

Preparation of Equipment

- Attach the 2 green end plates of the flexible electrogoniometer to 2 plastic strips provided (200 mm in length) using double sided medical tape.
- Then attach the double sided medical tape to the other side of the plastic strips.

Preparation of Subject

- Give 'The subject information' sheet to the participants prior to the experiment.
- Obtain informed written consent from the participants.
- Request the participants to wear shorts or knee length skirt so that their lower limbs are accessible.
- Prior to the equipment being attached to the participants, ask the subjects to remove shoes and socks. Once the equipment is attached, shoes and socks will be replaced by staff members, so that the connections are not dislodged.

Note: No special preparation of the subjects, especially men with excess hair in the knee areas (such as shaving of the hair) is required prior to equipment attachment.

Equipment attachment

- Ask the participants to sit / lie on a bed so that the soles of their feet are visible.
- Tape 2 flat footswitches (pressure sensors) to the soles of each foot – one on the heel area and the other at the ½ metatarsal area. Then the socks are replaced to keep the cables and footswitches in place.
- Ask the participants to stand with their lower limbs as straight as possible.
- Attach the green end plates prepared to the lateral border of the individuals' lower limb using the plastic strips with double sided tape.
- Ensure that the green end plates are positioned at an equal distance from the centre of the knee joint bend.
- Then wrap Velcro strap around the green end plates; one at the thigh and one at the shin to give additional support.
- Loop the cables from the footswitches into the straps to prevent them from a trip hazard.
- Now follow the connection protocol for connecting the sensors to the SUDALS as listed below.

Connection Protocol

- The 6 channels of SUDALS are labelled as; EG CH1, EG CH2, F1H CH3, F2T CH4, F3H CH5, F4T CH6.
- Connect both the electrogoniometers to the channels; EG CH1 & EG CH2 of SUDALS hooked onto a waist belt worn by the participant via the connecting cables provided.
- Similarly connect the labelled footswitches to the channels labelled; F1H CH3, F2T CH4, F3H CH5, F4T CH6.
- Then connect the bluetooth transmitter dongle to the socket marked 'T'.
- Ensure that the sliding switch on this dongle is facing towards the antenna.
- Before commencing the test, ensure all sensors are correctly positioned and not hindering the participant from movements.
- Now switch on the SUDALS and as an indication, the LED corresponding to the Zero function is illuminated and the two LED's (blue and red) on the bluetooth transmitter dongle is also illuminated indicating that the unit is powered and is properly paired with the receiver dongle on the PC. If the dongles are not paired then the LED's on the transmitter dongle keep blinking. Report such circumstances to the staff member who will be available during the test session.

Using SUDALS for recording activities

<u>Note</u>: **SUDALS is a two component system comprising of a data logger and a key fob.**

- SUDALS has five main functions corresponding to data collection; Record, Scrap, Transmit, Zero and Reset.
- When SUDALS is switched on, the LED corresponding to the Zero function is illuminated initially and following this the LED's corresponding to the functions Zero and Record keep flashing alternatively.

- Ensure that the control area is left uncovered and the key fob is in line of sight of the control area.

- To select any of the desired functions, the key fob must be held in line of sight of control area, when corresponding LED is illuminated.

- Before every new trial / subject/ patient recording the data logger must be zeroed.

- When zeroing, make sure that the equipment is connected to the SUDALS and the participant is standing as straight as possible without bending the knees.

- When the system has been zeroed, the LED corresponding to the Record function is illuminated. This function can be selected as above.

- Once the record function is selected, wait until the LED goes out and then commence the functional test.

- Once the ADL is completed, stop the recording by pressing the switch on the key fob in line with the 'control area'. Acknowledgement of the recording process being completed, the Zero LED is illuminated. This is the same for all completed functions on the logger.

- The record LED is then illuminated. This permits the user to make a recording for the second ADL.

- Scrap, Transmit and Reset functions are only available after a single recording has been made.

- The completion of one function and the initiation of the next function in the sequence is accompanied by a 'Beep'. This corresponds to a specific function time out and helps the user to avoid clicking the key fob for unwanted functions by mistake.

- Once, an ADL is recorded and if the user is satisfied with the recordings made, the data should be transmitted to the PC.

- If the memory becomes full, all the LED's on the SUDALS will blink continuously. If the memory becomes full, the system will still transmit all the previous recordings other than the current recording. This helps in preventing the loss of data.

- When the data transmission is completed, the zero LED illuminates again. Check for the transmitted data with the staff member at the PC end (receiving end) and if

all the data recorded were transmitted, then save the data in the PC and then Reset the SUDALS (using the 'Reset' function) before starting the next set of data collection.