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***She leads interdisciplinary research programmes through partnerships with the NHS, industry, regulators and government, translating human-centred innovation into healthcare practice. She currently leads RADIANT-CERSI, one of seven UKRI Centres of Excellence in Regulatory Science and Innovation for Human Health, and co-directs the Smart Technology Advancements in Health and Rehabilitation (STAHR) Research Centre. She is also a member of the Home Office Scientific Advisory Council. As an educator, she has pioneered challenge-based and interdisciplinary learning through Brunel's Design for Health programme, connecting students across Design, Computer Science and Health***



***Michele Walsh** is a Lecturer in Physiotherapy at Brunel University of London, specialising in neuro rehabilitation. She brings several years of clinical experience within the NHS, with a particular focus on rehabilitation for people with neurological and acquired brain injuries. Her clinical background informs her teaching and research, enabling her to bring a strong practice-based perspective to physiotherapy education. Michele is currently also undertaking a PhD, further developing her research expertise and contributing to the evidence base in rehabilitation and physiotherapy.*

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# Design and Development of a Wireless Electrical Stimulation Device for Shoulder Pain Management - Case Study Practice-Based Paper

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## Abstract

**This report outlines the design process of a wireless electrical stimulation device intended for patients with shoulder pain following brain injury. To ensure the solution is clinically relevant and beneficial, extensive primary and secondary research was conducted in collaboration with key stakeholders. A clinical champion and supervisors provided ongoing guidance and facilitated access to specialist lectures and practical sessions, where existing rehabilitation devices were evaluated first hand. In addition, discussions with a competitor market product user provided insight into current solutions and their clinical adoption. An observational visit to Hillingdon Hospital enabled direct understanding of rehabilitation environments and patient interactions. Meetings with neurophysiotherapists from London Northwest University Healthcare NHS Trust helped define current pain points faced by clinicians and opportunities for improvement.**

**The proposed solution consists of four electrode pods and a silicone cuff, with teal and purple elements indicating channel 1 and channel**

**2 stimulation. In dual-channel operation, one channel targets the anterior and posterior deltoid muscles, while the second targets the supraspinatus and middle deltoid stabilising muscles. Channel 1 utilises a closed-loop magnetic connection embedded within the cuff between two pods, while channel 2 integrates its closed-loop system within the scapular pod, connected via a fabric-covered wire to the supraspinatus pod. Both channels wirelessly connect to the Avira+ app, providing an accessible and intuitive user interface for clinicians and patients.**

**Key design decisions prioritise patient safety, usability, and treatment adherence. Pre-approved clinician ES sessions prevent unintended changes to stimulation parameters, addressing risks observed in clinical environments such as muscle burns or spasms. An information hierarchy within the app improves accessibility by reducing reliance on complex medical terminology. Capacitive proximity sensors within the electrode pods detect loss of skin contact and alert the user. The wireless design eliminates trailing wires found in existing ES devices, improving mobility, usability, and patient engagement during rehabilitation.**

## Keywords

***Electrical Stimulation (ES), Shoulder Pain. Supraspinatus Deltoid, Wearable Medical Devices, Neuro Rehabilitation***

## Introduction

**This project forms part of a collaborative brief with Design for Health for a major design engineering project. The brief involves working alongside a clinical champion, Michele Walsh, who is currently conducting research related to electrical stimulation (ES) and shoulder following brain injury. The brief, titled *Electrifying Recovery: Stimulating Shoulder Stability Post Brain Injury to Reduce Pain and Increase Function*, addresses the clinical challenge of shoulder pain, a common complication following brain injury e.g. stroke. This condition often leads patients to adopt protective behaviours, avoiding movement of the affected shoulder due to pain, which can subsequently limit engagement in rehabilitation activities and slow recovery outcomes.**

**The design brief outlines how electrical stimulation can support shoulder stability by facilitating muscle activation and improving joint alignment. Electrical stimulation also provides sensory input which may impact pain receptors and neuroplasticity.ES is therefore positioned as a potential intervention to enhance functional recovery and reduce pain associated with shoulder weakness. However, existing commercial ES devices are often bulky, rely on trailing wires, and are not easily usable by patients independently in real-world settings (Walsh et al., 2026).**

**The primary aim of this collaborative brief is therefore to design a wireless, dual-channel ES device, supported by a digital interface, that improves usability and patient independence while maintaining clinical effectiveness. This article will provide a reflective account of the design project, discussing the research process, iterative**

**development, and key decisions that shaped the final proposed solution.**

## Literature review

## Stroke and Shoulder Pain

**Approximately 13.7 million people worldwide experience a stroke each year. These conditions can result in damage to the upper motor neurons and the neural pathways connected to them. Stroke patients can have difficulties in movement, walking and performing activities of daily living (Kristensen, Busk and Wienecke, 2021).**

**Stroke is one of the leading causes of long-term disability worldwide, and shoulder pain is a common complication that can significantly affect recovery. Hemiplegic shoulder pain (HSP) affects up to 84% of stroke survivors. HSP usually develops within the first two to three months after a stroke and can reduce upper limb function, limit participation in rehabilitation, lower quality of life, increase the length of hospital stays and add to healthcare costs (Murie-Fernández *et al*., 2012; Royal College of Physicians, 2023). The condition has several possible causes, including muscle weakness, spasticity, shoulder subluxation, rotator cuff injuries, adhesive capsulitis (frozen shoulder), changes in muscle tone and pain caused by damage to the central nervous system (Harrison and Field, 2015; Winstein*et al*., 2016). Because there are many possible causes, managing post-stroke shoulder pain requires early assessment and a combination of treatments. These may include correct positioning of the arm, therapeutic exercises, functional electrical stimulation, pain relief, and patient education to help improve recovery and reduce further**

**complications (Winstein*et al*., 2016; Royal College of Physicians, 2023).**

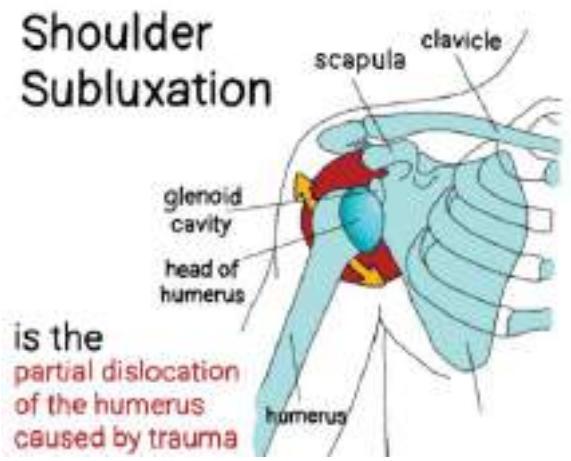



***Figure 1 Shoulder Subluxation visual diagram with labelled associated muscles (Illustrated by A. Sripathy,2025)***

**Shoulder Subluxation is a frequently found complication after a stroke which results in the loss of voluntary control of shoulder muscles affecting up to 81% of patients(Kumar and Swinkels, 2009).**

**Shoulder Subluxation can be detected due to an increased gap between the acromion of the scapula and head of the humerus. Electrical stimulation can be applied to help increase properties in the muscle akin to strengthening reducing the painful effects of shoulder subluxation (ES& Shoulder Subluxation Odstock medical, 2024). Electrodes are placed on the supraspinatus and deltoid muscles before the ES device is turned on. The muscle contractions and movement that occur during ES therapy allow the humerus bone to be lifted back into the glenohumeral socket.**

**ES devices currently on the market are not particularly suited for extended use during activities of daily living. The devices can be too bulky to carry in pockets which most lounge and hospital wear does not include, along with trailing wires that can catch onto wheelchair armrests causing inconvenience (M. Walsh, 2025).**

## Stroke Recovery




***Figure 2: In the physio lecture that the student attended a diagram outline was shown showing the large team of people involved to support patient recovery and rehabilitation process.***

**A stroke causes weakness or paralysis on one side of the body and problems with movement and carrying out everyday activities (Stroke Association, 2024). Recovery and rehabilitation are different for everyone and can depend on various factors such as the severity of the stroke along with the overall health of the patient and intensity of the rehabilitation program (Bence, 2023).**

**The first few days and weeks, after a stroke patient is stabilized in a hospital, is defined as the Acute Phase (The Royal Buckinghamshire Hospital, 2025). During the Acute phase, the patient is in the most effective time for rehabilitation where neuroplasticity is most likely to occur. The Sub Acute phase is the first 6 months post stroke and is the most important for recovery and in which time patients will see the most improvement (Raghavan, 2022). In the chronic phase of a stroke, which begins around six months after the event, the focus shifts to long-term management of residual disabilities and adaptation to new routines (Majithia, 2024).**

**Neurophysiotherapists Interview (London Northwest University Healthcare Trust NHS) – Highlighting Key Pain Points**

**An interview was conducted with two neurophysiotherapists from**

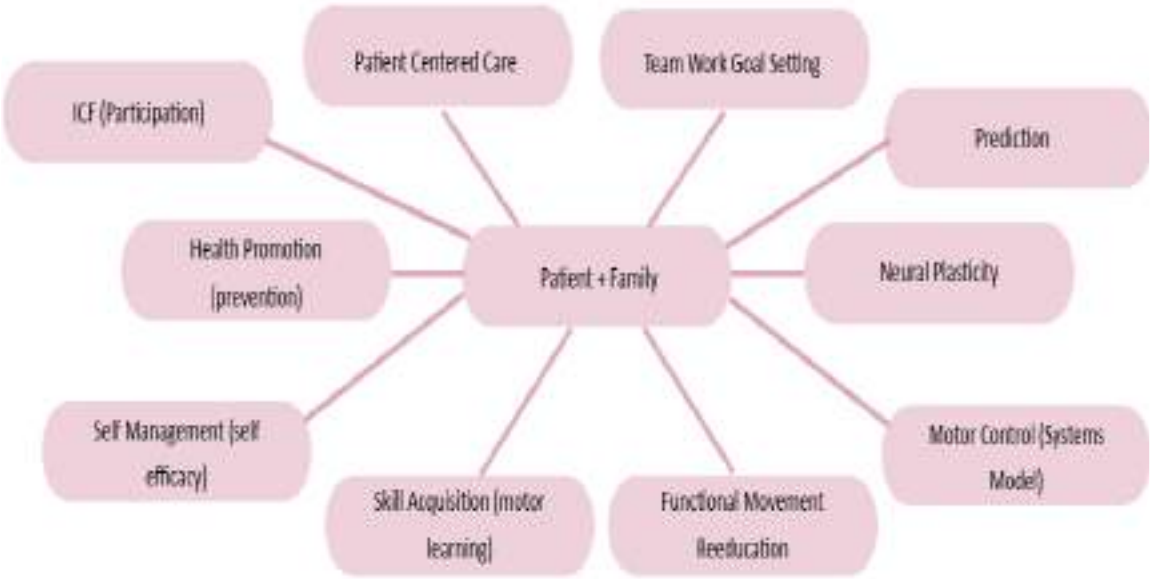



***Figure 3: Principles for Neurological Rehabilitation - In the physio lecture that the student attended the principles of Neurological Rehabilitation were provided in a neat diagram. This interlinks with the Team work diagram showcasing just how extensive the patient neuro rehabilitation process can be (Lennon et al 2018 Physical Management)***

**London Northwest University Healthcare NHS Trust to inform them about the development of the ES device for shoulder pain rehabilitation. The discussion highlighted that hemiplegic stroke is the primary patient group requiring upper limb rehabilitation and ES intervention with Traumatic Brain Injury (TBI) as the secondary cohort.**

**Clinicians reported that ES is introduced in the subacute phase of stroke recovery commonly between three to four months post injury. A key insight from the consultation was the importance of monitoring patient compliance and usage of the devices once patients are sent**

**home. Treatment adherence was mentioned as a key pain point for clinicians alongside the lack of reliable methods for tracking stimulation duration and pad usage in current systems. Clinicians highlighted that device usage data identified as a valuable tool for clinical decision-making and treatment optimization.**

**Why is dual channel ES required for shoulder pain?**

**For an effective outcome, 6 – 8 weeks of treatment may be required with stimulation applied two times a day for up to 6 hours (ES Mobility Channel, 2019). An asymmetrical waveform is used with current intensity to patient tolerance – channel 1 active electrode over the anterior deltoid & channel 2 active electrode over the middle portion of the deltoid (ES Mobility Channel, 2019). This combined stimulation lifts the humeral head into the glenoid fossa from multiple angles, promoting alignment without excessive shoulder abduction (VR, 2025b).**

## Methodology

### Market Research

**By evaluating current products on the market, gaps were identified, uncovered unmet user needs, and determined how Avira + could be positioned against competitors. The analysis revealed a lack of wireless dual-channel ES devices with intuitive companion apps, instead relying on overfilled instruction booklets - highlighting an opportunity to improve accessibility and user experience.**



*Figure 4: SaeboStim One £128 (SaeboUK, 2026)*

**The device offers a portable, wireless design for electrical stimulation (ES), with multiple size options, ultra-thin wing-like electrode placements, a rechargeable battery, reusable electrodes, and suitability for home use. However, its functionality is limited by single-channel stimulation and the absence of a companion monitoring app, while effective use depends on accurate electrode placement and adhesion, often requiring clinical guidance. Additionally, electrode storage is inefficient, and the device provides less powerful and versatile stimulation than comparable alternatives such as the SaeboStim Pro.**




*Figure 5: SaeboStim Pro £239 (SaeboUK, 2026)*

**The device provides dependable dual-channel stimulation and supports NMES, ES, and TENS therapies for muscle re-education, targeted training, and strength recovery. Its programmable parameters, including pulse width, frequency, and ramp settings, enable treatment customization. However, wired electrodes can be inconvenient for home use, accurate electrode placement is essential, skin irritation and storage issues may occur. The absence of a companion monitoring app may reduce patient engagement and motivation.**



*Figure 6: MicroStim 2V2 £128.00 (Odstock, 2025)*

**The device offers dual-channel stimulation with ten preset treatment modes, including dedicated programs for reciprocal muscle activation, while also allowing clinicians to customize output intensity across a range of stimulation parameters. However, the bulky wired design can restrict mobility during treatment, and accurate electrode placement is essential, with stimulation settings requiring adjustment for one muscle at a time.**

## Physiotherapists Focus Group Survey Results

**A survey was created by the student to gain feedback on the current devices used additional results can be found in Appendix B. The survey included responses from nine participants, predominantly physiotherapists, alongside physiotherapy students and one occupational therapist. Most respondents used ES primarily with stroke patients, with several also treating individuals with traumatic brain injury, spinal cord injury, and other neurological conditions. The MicroStim 2V2 was the most frequently used device and was generally rated positively for overall usability, reliability, and ease of clinician setup. Respondents highlighted its consistent stimulation performance and straightforward operation once familiar with the device. However, a recurring limitation was poor patient independence, as electrode placement often required assistance and could be time-consuming. Additional comments also identified difficulties with electrode positioning, limited integration with**

**functional activities, and the potential for accidental adjustment of stimulation settings.**

**The SaeboStim Pro received mixed evaluations, with users appreciating its flexibility and trigger functionality but noting that it could be more complex to configure and did not perform consistently across all patients. The SaeboStim One received the least favourable feedback, with several participants describing it as limited by its single-channel design, restricted functionality, and the need for regular user interaction during prolonged treatment sessions. When considering the design of a new ES device for shoulder subluxation, respondents consistently rated simple setup, portable home use, comfortable electrodes, patient independence, adjustable stimulation parameters, long battery life, and integration with rehabilitation programmes as highly important. These findings suggest that future device development should prioritise ease of use for both clinicians and patients while maintaining reliable stimulation performance and supporting independent use in home-based rehabilitation.**

**Direct Competitor Review**

**The clinical champion kindly arranged a demo of this device with one of her colleagues who is also a physiotherapist. The student was able to view the Valkyrie eir in person close up observing the manufacturing styles. Below are photos taken during the session and critical design evaluation notes.**



***Figure 8 After the pods were connected the physiotherapist explained the need for the device to adapt to inferior subluxation too. The clinical champion mentioned that as much as she preferred the exoskeleton concept for encasing all the electrode pods there would be minimal movement of freedom. The cuff concept is able to offer adjustability for inferior, anterior and***



***Figure 7 - This image shows the Clinical Champion attaching the device onto the physiotherapist's shoulder. The arrangement of which was for anterior subluxation. The strap which connected the pods together was not very flexible and due to the physiotherapist's measurements being on the higher end of the percentile it was difficult to get the pods to connect.***



***Figure 9 The student noticed that the design decision to make the pods slightly flexible to conform to the shoulder anatomy has been interpreted in a similar way by this product. Valkyrie eir had a curvature on the underside of the pod instead. LEDs were used to distinguish Channel 1+2 whereas the student has decided to colour them directly. Adjustability has been redesigned instead of using multiple button pin***

## Ethics Approval

**This project followed Brunel University London's research into ethics procedures. Participant Information Sheets and Consent Forms were created for the clinician and patient participants, and risk assessments were completed throughout the project to identify and manage any potential risks. The ethical documentation and research process were reviewed by my first supervisor. Informed consent was**

**obtained from the clinician and patient before the observational study at Hillingdon.**

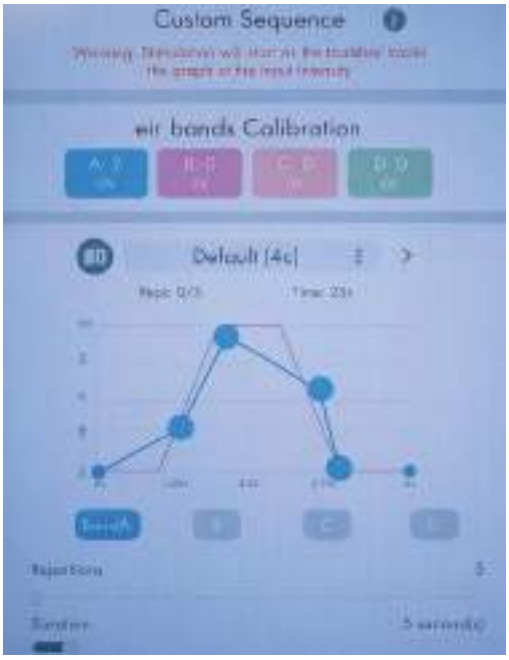



***Figure 10 Shown on the left is the UX/UI for the pairing application. The clear layout with minimal changes in font and clear colour indications create ease of access. The wireframes specifically shown are those that allow the clinician to test out various cycle times and device settings. Custom calibration is an availability that is offered clinician side that has encrypted access. A similar ideology is one the student has adopted having an information accessibility hierarchy between the***

## Observation at Hillingdon Hospital

**The clinical champion, Michele Walsh, kindly arranged a meeting at Hillingdon Hospital to allow the student to observe an ES session with a recovering stroke patient. During the visit, the student observed a range of physical resources used for post-stroke muscle rehabilitation, including resistance bands, cones, and jars. These tools were used alongside the GRASP program, which the student noted as a structured approach to upper-limb recovery.**

**Several key design-relevant pain points were identified during the session. The patient experienced difficulty putting their T-shirt back on once the ES device had been set up, highlighting challenges related to device bulk, wearability, and ease of use during everyday activities. The clinician also noted that patients can unintentionally or**

**intentionally adjust device settings, either due to involuntary movement or a lack of medical understanding, indicating a need for clearer control hierarchies and safeguards within the system. The form of the device was a significant inconvenience, particularly the bulkiness of the unit and the presence of trailing wires. Electrode placement was critical to the effectiveness and comfort of the therapy, requiring clinician expertise and initial verbal feedback from the patient regarding electrical impulse sensations. These observations underline the importance of intuitive setup guidance, real-time feedback and reassurance within a digital pairing application. These insights informed the design of a companion app focused on monitoring, patient engagement, and motivation, with an emphasis on usability, safety, and reducing cognitive and physical burden for stroke patients.**



***Figure 13 Electrodes being applied: Patients sometimes can change settings due to involuntary movement or lack of medical knowledge.***



***Figure 14 Controls for the existing ES devices are not very patient,friendly, and welcoming.***



***Figure 11: Clinician struggles to put patient's t-shirt back on due to trailing wires everywhere getting tangled.***



***Figure 12: Device simply has a label for misuse which the design student noticed was not enough of a deterrent.***

## Physiotherapy lecture

**During a physiotherapy teaching session, the student gained hands-on experience using the SaeboStim One and SaeboStim Pro electrical stimulation (ES) devices. This provided valuable insight into their clinical application alongside rehabilitation techniques such as mirror therapy and splinting.**

**Practical interaction with the devices enabled a critical evaluation of their usability, accessibility, and user interface, identifying opportunities to improve product interaction for both clinicians and patients. In particular, the current method of storing the adhesive electrode pads on a reusable plastic sheet was found to be impractical for long-term use, as it can be easily misplaced. This resulted in storage solutions within the concept development. User guides for the devices were very extensive, and it was doubtful if patients/clinicians would find it easy to refer to it for continued safety.**

**The session also provided an understanding of the products' manufacturing methods, including their button mechanisms and injection-moulded components, which informed the feasibility and direction of the subsequent design concepts.**



***Figure 15: Extensive user booklet thirty-five plus pages long along with wires that can get easily tangles SaeboStim Pro***



***Figure 16: Student trialed out SaeboStim One on arm to understand safety disclaimers to include within pairing application e.g., uncomfortable tingling sensation.***



***Figure 17: female and male buttons pin to connect the components together.***



***Figure 18: Twist lock mechanism to separate the adhesive pads from main unit***



***Figure 19: A flimsy plastic sheet provided for the electrode pads to be placed on after each session.***



***Figure 20: Mirror therapy trialed by the student during a physiotherapy lecture.***



***Figure 21: SaeboStim one electrical connection shown using snap buttons.***

***Figure 22: Splints worn by the student during physiotherapy lecture.***



***Figure 23: SaeboStim One being used on another physiotherapy student to see the muscle contractions that help neuro rehabilitation patients with shoulder pain.***

## Design

# Initial Concepts

**The student created a range of design concepts to explore how the electrode pods and app system could be placed together. The top three concepts were included in a survey that was sent out to neurophysiotherapists where they were able to give their professional opinion and rank each concept based on accessibility, usability, easy to clean etc. The full product design specification can be found in Appendix A.**

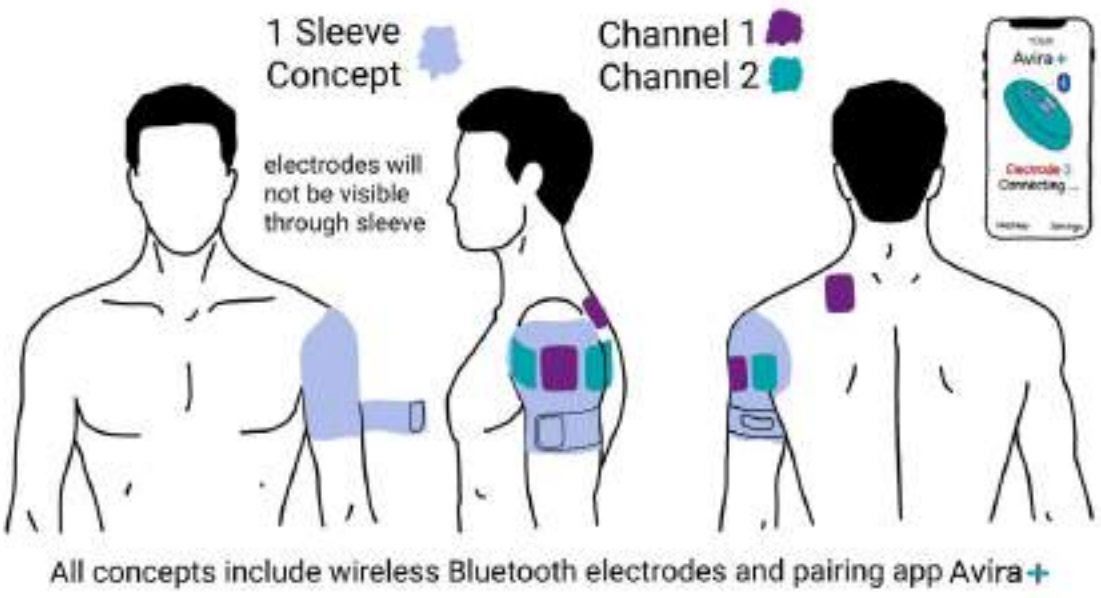



***Figure 24: Illustration drawn by student to visualize concept 1. The colored blocks shown in purple and teal are the electrode pod of which the technology and design will be explained further down.***

**The electrodes would be placed on the patient's shoulder, and a sleeve would be worn on top. Adjustable strap on the sleeve determines the tightness to secure the sleeve in place. The sleeves and electrodes**

**remain unattached. Once the sleeve is comfortable, the patient/carer can connect Avira+ and begin their exercises. Materials would include a derma silk lining to ensure breathability and patient skin safety during longer periods of wear. The sleeve can be removed and machine washed.**

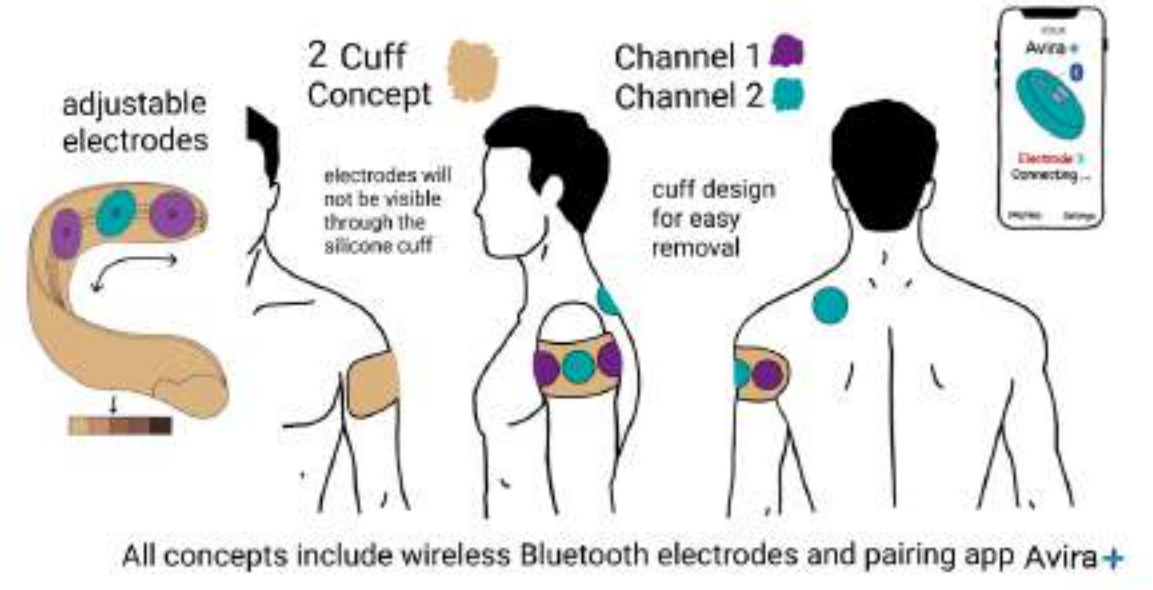



***Figure 25: Design illustration by student to show concept two which became the chosen one to be developed further.***

**The patient/carer can adjust the electrodes by sliding them across the cuff. Once the placement of electrodes is finalized, the cuff can be placed on the shoulder and wrapped around. Once the cuff is comfortable the patient/carer can connect to Avira+ and begin their exercises. The silicone cuff would be made from similar material to modesty pads and stay attached to patient. Electrodes can slide out of the cuff, and the cuff can be hand washed.**

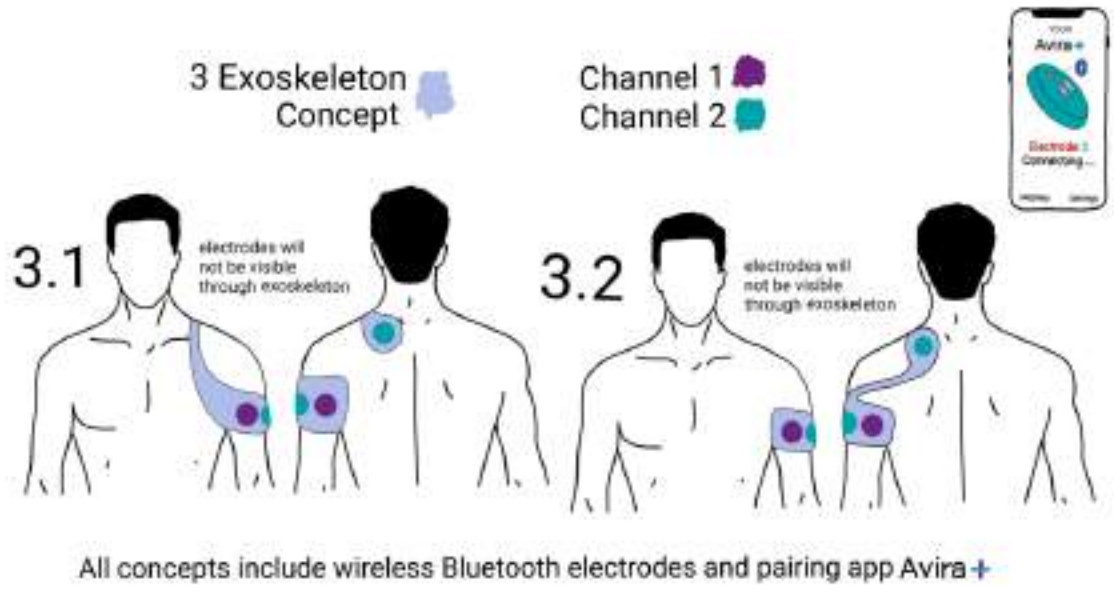



***Figure 26: Illustration shows concept 3.1 and 3.2 of the exoskeleton concept which the student wanted to explore further but due to tie constraints and the clinician's enthusiasm towards concept two, this design remains unexplored.***

**The patient/carer can adjust the electrodes by sliding them across the exoskeleton. Once the placement of electrodes is finalized, the exoskeleton can be placed on the shoulder. Once the exoskeleton placement is comfortable, the patient/carer can connect with Avira+ and begin their exercises. The hard yet flexible silicone exoskeleton would be made with various hardness of materials to try and ensure that patient has the widest range of motion. Electrodes can slide out of exoskeleton, and the exoskeleton can be hand washed.**

**Initial Product Design Specification – Appendix A**

**The student identified a set of key product requirements to guide the design and development process. These requirements were established to ensure the final product meets the needs of the**

**intended users while satisfying the functional, usability, and performance objectives of the project.**




***Figure 27: Product Design Specification Initial***

## Stakeholder Mapping

**Stakeholder mapping helps the student understand everyone involved in or affected by a healthcare rehabilitation device. In healthcare design, this is especially important to ensure patient safety. (ISO, 2019). The student also explored the stakeholders involved if this product were to make it into a commercial stage. For example, a clinician may want advanced features, while a patient may want something more simple to understand. Mapping key stakeholders helps the**




***Figure 28 Stakeholder Mapping***

**student see these differences and make compromises before product development begins.**

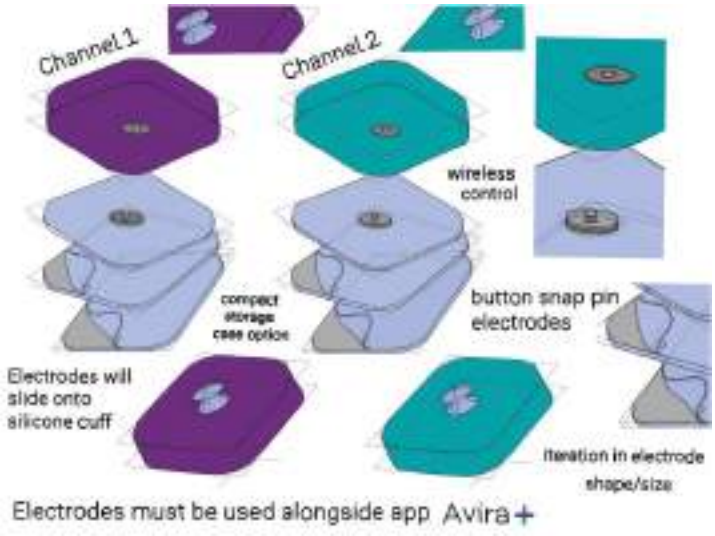



***Figure 29:The Electrodes connect to the adhesive pads similar to the way TENS electrodes work with a button pin. This ensures that each unit is connected with its own electronic Bluetooth module allowing for the Avira+ app to function.***

***The electrodes are colour coded for easy identification of both channels. The Bluetooth unit will remain with the patient during their use over the years and the patient will only have to***

## Design Development – Low Fidelity

**The low fidelity prototypes meant that the student was able to see scale and form more easily. Results from the survey aided in terms of refinement and further iteration through modelling + CAD. The student explored the cuff form and development through sketches and paper prototyping. The shoulder breadth (BI deltoid) is the distance across the shoulders at the widest point (outer deltoids). The shoulder breadth (Biacromial) is the distance between the acromion processes (bone landmarks on the shoulder) (ISO 7250-1:2017). These measurements were vital for the student while developing the three initial concepts. Contextual images shown (Roymech, 2020)**

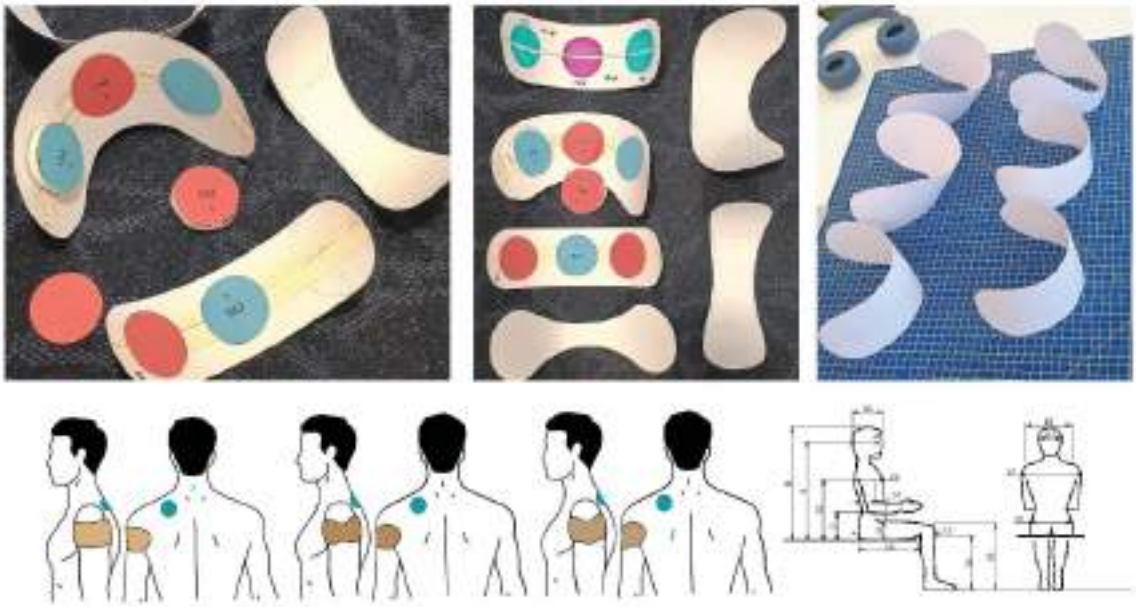


*Figure 30: Images show low fidelity paper prototyping and student's use of anthropometric measurements. Shape and sizing were effectively explored to support development process of Avira+*

## Open Loop ES

**Open-loop electrical stimulation (ES) refers to a mode of ES in which electrical stimulation is delivered using pre-defined parameters (such as intensity, duration, and timing) that do not change in response to real-time physiological or biomechanical feedback from the user (Teslasuit, 2023). In an open-loop ES system, the control action is independent of the actual muscle activity or movement achieved, meaning the stimulation settings are set in advance by a clinician or programmed into the device and remain unchanged during a session regardless of how the muscles respond or how the task is performed (Wolf and Schearer, 2017).**

**Within this Avira+ predefined parameters will be clinician approved before being accessed by the patient. Adopting Open - loop ES in the pairing app ensures patient safety reducing the risks of muscle**

**fatigue, spasms, or burns. Patients like the one that the student observed at Hillingdon Hospital will not be able to change the setting either due to involuntary movement and or lack of medical device knowledge.**

## Design Development – Electronics

**The student used an Arduino Nano to demonstrate the four electrodes, initially including manual controls for parameters such as amplitude. Later the design changed to just the digital app and wireless cuff to increase portability and range of movement for the patient. After the design changed so that the clinician would pre-program the FES cycles, the manual controls were removed, and the electronics were rearranged onto a smaller breadboard to better represent the electrode pods. The code was updated to include ramp-up and ramp-down times, an emergency stop added, and BLE-controlled operation so the FES cycle only ran when connected to the application. Avira+ will turn on only when the device is in contact with the skin. This will be achieved using capacitive proximity**

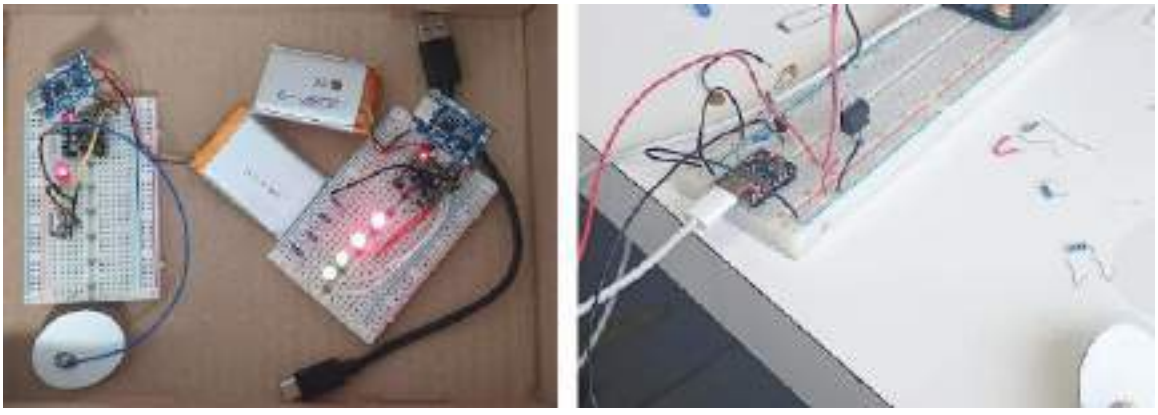


***Figure 31: Figure showing electronics development and proof of concept created using 10V battery rather than full voltage due to health and safety risk assessment. Bluetooth ramp up and ramp down feature visibly shown using LEDs.***

**sensors similar to the ones used on ECG devices. TENS electrodes were also used in the proof of concept to demonstrate interaction with the ESP32.**

## Design Development – Prototyping and CAD

**The student produced an initial foam model to test the size of the ESP32-C3 Mini and evaluate how the electronics could fit within the design. The images show the development from using LEDs to demonstrate ramp-up and ramp-down, to creating simple electronics for a single pod, and then visualizing the complete system. The ESP32-C3 Mini proved to be a suitable microcontroller due to its compact size and BLE functionality. In the final commercially available device, a**



***Figure 32: Images show foam modelling and 3D printed PLA prototyping to explore size, thickness and adjustability. Lateral adjustment was the final choice after clinician's input.***

**custom PCB would be used to achieve overlapping ramp-up and ramp-down dual-channel stimulation. The student interacted with the models in the same way a user would assess usability. As the foam**

**models were not flexible, they were used only to demonstrate form and size. Following this stage, small design changes were made, including reducing the thickness and corner fillet dimensions. Both lateral and vertical adjustment concepts were also explored.**

**The student created a curved CAD model to demonstrate how the cuff would flex around the arm and how the electrodes could be adjusted using the slot feature. This model was for the final render. The design shows three electrode pods attached to the cuff, along with a cross-section that highlights the proof-of-concept manufacturing considerations. The fourth electrode pod is shown separately and is positioned on the scapular muscle at the back of the shoulder, where the neck meets the shoulder.**

**For technical drawings of the electrode POD and silicone cuff refer to Appendix D and E.**

## App Development Design Goals



***Figure 33: Image showing the CAD model prerender to explore the final design curvature of the silicone cuff conce and electrode pods.***

**The final Avira Plus application successfully meets the original design goals by providing a simple, accessible interface that reduces**

**cognitive load through the use of clear navigation, intuitive icons, and a consistent colour scheme. Patients can securely log in using their unique ID to access clinician-programmed FES sessions within the calendar, while session feedback, pain scores, and perceived muscle strength can be recorded after each treatment and reviewed by the clinician.**

**The app also incorporates gamification through achievements and progress statistics to encourage engagement and long-term adherence to therapy. Safety is enhanced with notifications that alert users if electrode contact is lost, and BLE connectivity ensures stimulation sessions only operate when the device is correctly connected. Clinicians can remotely configure treatment parameters, including stimulation intensity and ramp-up/ramp-down timings, removing the need for manual adjustment by the patient. In addition, the app supports clinician communication and provides a convenient way for patients to purchase replacement accessories, creating a comprehensive platform for home-based FES therapy.**

## Patient Safety and Risk Management

**Another major health and safety risk can be seen from the contextual images the student provided from the observation at Hillingdon hospital. A label is simply placed on top of the device stating that others beside the patient should not use it. Due to being a weak barrier, a key design decision taken to have a unique patient ID sign in allows for a higher level of protection and privacy. A unique clinician ID could be implemented further down the line of product development for a more medically orientated feedback view. Only the patients who have a valid ID will be able to sign in and access control of their device and their personal ES sessions. This feature could be**

**used by patients who have shoulder subluxation not due to a stroke but sports related injuries.**

## Why do we have a device control and feedback viewing hierarchy?

**As seen by the student during the Hillingdon hospital observation patients can change the settings of the ES device during a physiotherapy session either due to involuntary movements or a lack of medical knowledge. A key decision by the student to have clinician approved preprogrammed sessions reduced the health and safety risk of the patient accidentally causing themselves muscle fatigue or muscle burns (Muhammad Ahmed Khan et al., 2023b). To allow the patients to have a clear understanding of their recovery journey, Avira+ helps patients view a different style of feedback compared to the clinician. Less medical heavy and a motivating approach will aid with patient engagement in their sessions and improve the outcomes of their physiotherapy.**

**Due to preprogrammed sessions set by the clinician the patient need not worry about experiencing muscle fatigue or spasms due to incorrect device setting being used. Reducing the cognitive load and convenience for patients will make them more likely want to continue their treatment. The student has made the decision that the sessions will be accessed by a calendar –a familiar user interface. The student will gain feedback on the wireframes and evaluate the usability of older age groups.**

## Physical Prototyping and Materials

**The student used medical grade silicone for the cuff geometry to encase the electrode pods as they sit upon the patient's shoulder. The light adhesive tendency of the silicone material along with the biocompatible adhesive of the electrode patches will ensure minimal movement, reducing the risk of the patches falling off or the wrong**




***Figure 34: Image showing the medical grade silicone process. The student created the mould learning about various elements such as air vent holes and lubrication release agents and more.***

**muscles being stimulated. The student gained inspiration from modesty pads, and the curvature is of which was initially modelled up. The student purchased 20A - 30A Shore Hardness skin Safe silicone to ensure conformity around the shoulder anatomy.**

**During the Valkyrie Demo with the clinical champion and the technician consultation the student discussed the possibility of a custom 3D print for the patient depending on their desire of personalization and cost they were happy to pay. The technology for 3D printing medical grade silicone exists along with 3D scanning such as Reality CR-Scan; both can work hand in hand to create a more**

**custom user experience. For off-the-shelf purchasing and minimal spending, the cuff will be available in three to four sizes and be cast at a large scale.**

## Additional Conceptual Renders

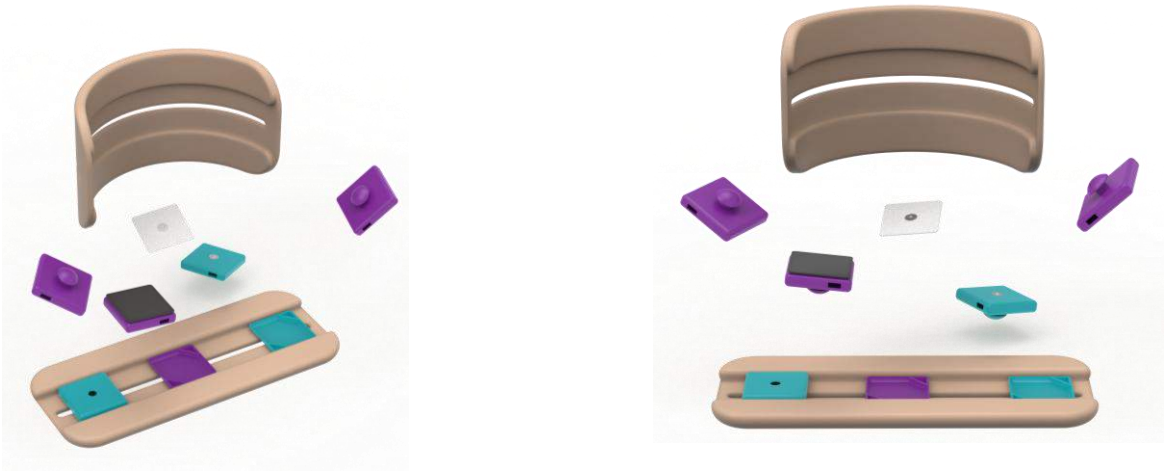


***Figure 35 Images show final renders completed by the student to show product features on the presentation boards.***

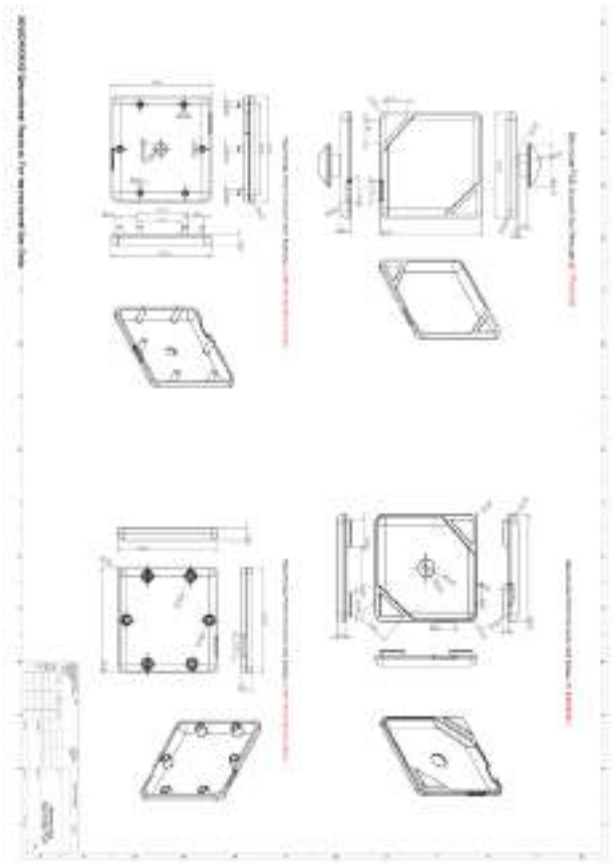


***Figure 36: Technical drawing of electrode pods for Avira+ which slot onto the silicone cuff***

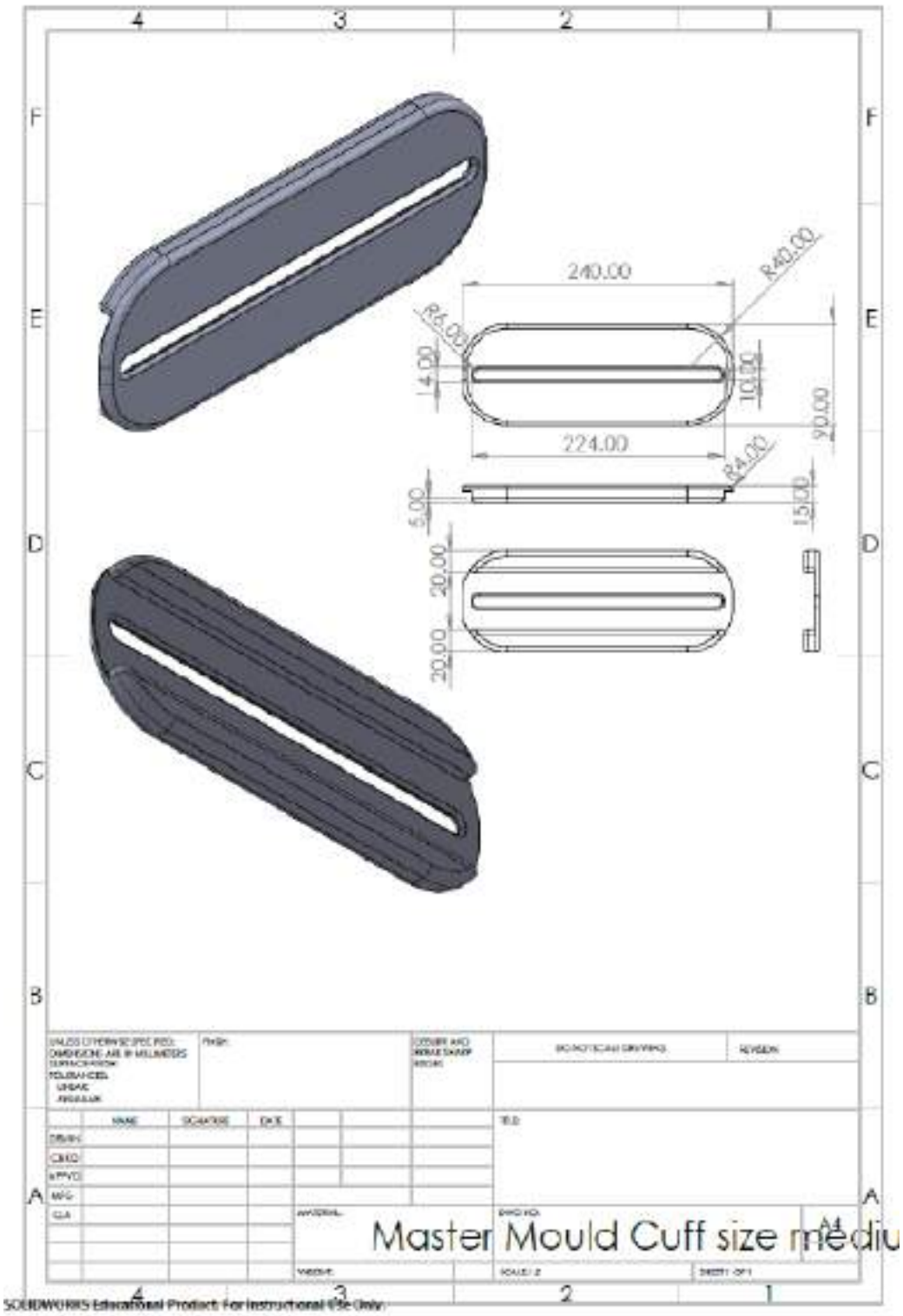



***Figure 37: Technical drawing of Silicone cuff size medium with lateral adjustment slot after design has been fully developed alongside clinical champion.***

## Final Concept Electronics

**The electrode button provides the connection between the pod and the electrode itself. To provide channel one for the deltoid muscles the closed loop system is embedded within the cuff to connect magnetically via pogo pins between the two pods. The electronics for the channel two have its closed loop system embedded in the middle deltoid and a fabric covered wire that attached across to the supraspinatus pod. Both channel one and channel two connect wirelessly to the Avira+ app providing a more accessible and intuitive user experience.**

## PDS Evaluation

**The student evaluated the initial product design specification by rewriting the statements that were made prior to the development process. Avira+ was unable to be tested on the patients directly due to electronic limitations and safety. Proof of concept was created to test the basic electronics involved. Capacitive proximity sensors allow detection of skin contact which activates the ramp up ramp down sequence. This ensures that patient safety is placed first and foremost.**

**Due to university safety regulations, full operational testing of the prototype at its intended voltage was not possible. Therefore, some design requirements remain unverified. The student designed the product with these requirements in mind and carried out research into the relevant Class 2b requirements, expected service life, and electrical safety considerations throughout the design process.In particular, Class 2b compliance, the expected 3–5-year functional life,**

**and electrical safety at full operating voltage could not be experimentally demonstrated within the scope of this project.**

**These requirements should therefore be considered design expectations and future targets, rather than confirmed characteristics of the current prototype. If the Avira+ were to be further developed towards a commercial stage, appropriate testing and certification would be required to demonstrate compliance, establish its expected service life, and confirm safe operation at the intended voltage.**




***Figure 38 Final product design specification***

## App Evaluation + Feedback

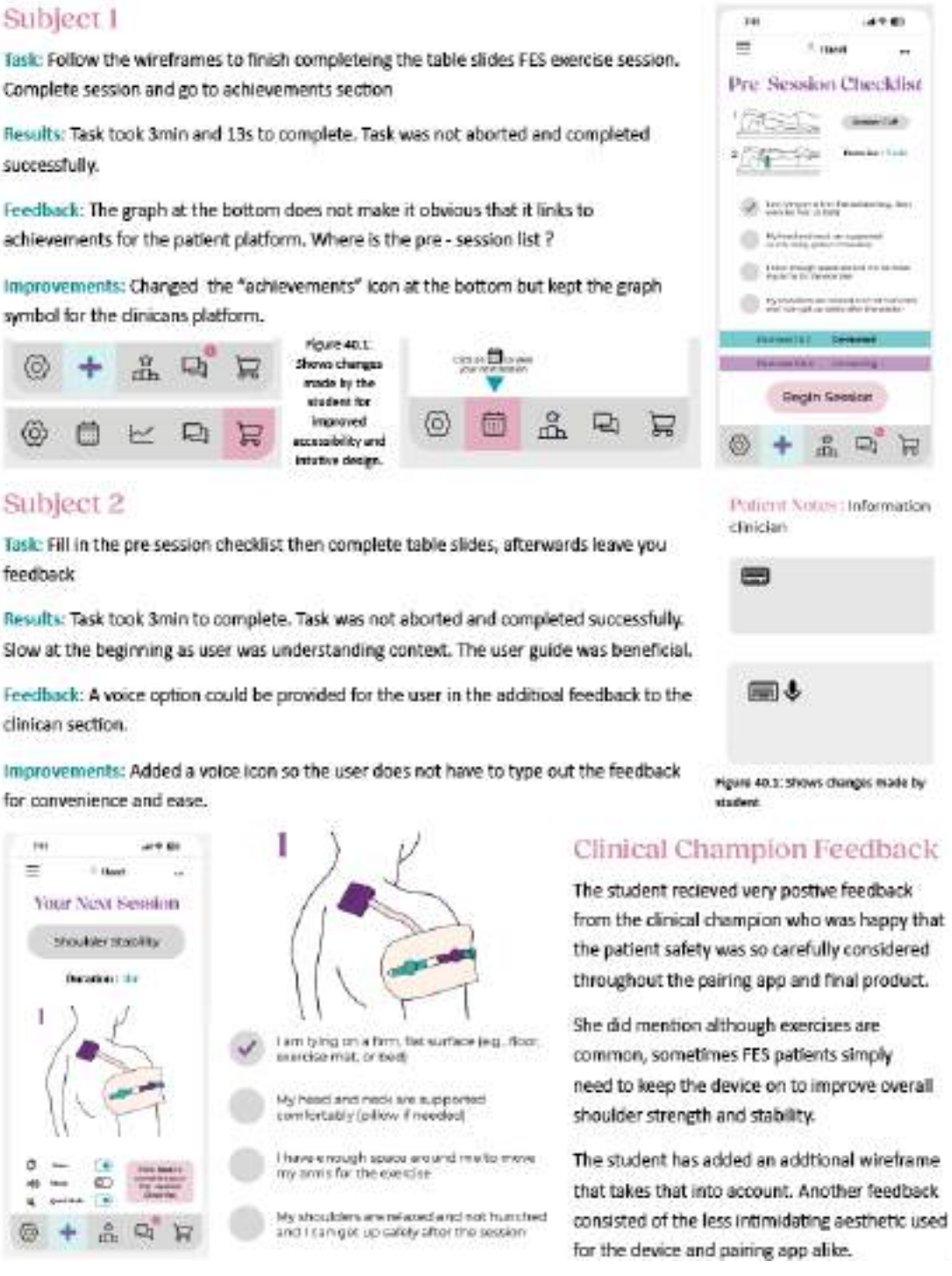



***Figure 39: Figure showing user testing completed by the student on the Avira+ wireframes and direct feedback from the clinical champion.***

**The student tested the Avira+ app to evaluate its usability, functionality, and overall user experience. The wireframe design was updated based on observed user behaviors while the app was being used by participants from various age groups, ensuring the interface better met the needs of different users. In addition, the student received direct feedback from the clinical champion, whose insights helped validate the design decisions and identify further improvements to enhance the app's usability and effectiveness.**

## Physiotherapists Clinicians Feedback

**Following the project presentation, nine clinicians completed an anonymous feedback survey evaluating the proposed Avira+ FES device and companion app. Overall, the responses were highly positive, with most ratings ranging from 4 to 5 out of 5 across all evaluation criteria. Clinicians agreed that the clinical purpose and intended benefits of the device were clearly explained, with ratings predominantly of five, and most believed that the device could provide meaningful benefits in clinical practice. The usability of both the FES device and companion app was also rated favorably, with respondents indicating that the system appeared easy to set up, navigate, and use. The device's comfort, practicality, and safety were consistently rated highly, and clinicians agreed that the companion app would be useful for configuring, monitoring, and managing treatment.**

**Importantly, all respondents indicated that they would consider using or recommending Avira+ in clinical practice once fully developed, with scores ranging from 4 to 5 out of 5. Qualitative feedback suggested only minor improvements, including providing a training guide for digitally inexperienced users, addressing considerations for multi-patient use, reviewing the necessity of safety checks before each**

**exercise, expanding educational content explaining the rationale for FES, and exploring the device's thickness and compatibility with other supports. Overall, the survey findings demonstrate strong clinician confidence in the concept, usability, and potential clinical value of the Avira+ system.**

## Conclusion

**This project has been one of the most valuable learning experiences I have had, both academically and personally. Coming from a non-medical background, I had limited knowledge of stroke rehabilitation and medical device design. Throughout the development of this project, I had to independently research and learn about the challenges stroke survivors face during recovery, as well as the clinical environments and rehabilitation processes that support them. Through speaking with physiotherapists, clinicians,and stroke survivors, I gained a much deeper understanding of the importance of accessibility and patient-centered design within healthcare. These conversations and experiences continuously shaped the direction of the project and helped me develop a more informed and human centered approach to Avira+.**

**Throughout the design process, I considered the different needs and priorities of patients, carers and clinicians, including how each group would interact with the device and what requirements they desired. I maintained frequent communication with the clinician to ensure that professional requirements and clinical needs were continuously considered. Alongside this, I carried out ongoing research into patients' and carers' needs and how they would interact with the product. I used this information to identify commonalities and differences between the three user groups, which I represented**

**through a Venn diagram. This allowed me to balance the requirements of patients, carers and clinicians and incorporate as many of their shared needs as possible. These design requirements were continually revisited throughout each iteration, allowing me to refine and adapt the product based on new findings and feedback. By considering all three perspectives throughout the process, I was able to develop what I considered to be the optimum version of Avira+**

**A major part of this learning process came from direct engagement with professionals and real clinical settings. I visited Hillingdon Hospital for an observational visit, which gave me valuable exposure to real rehabilitation environments and patient interactions. Meeting with neurophysiotherapists from North West University Healthcare NHS Trust helped me identify further clinical requirements and areas**

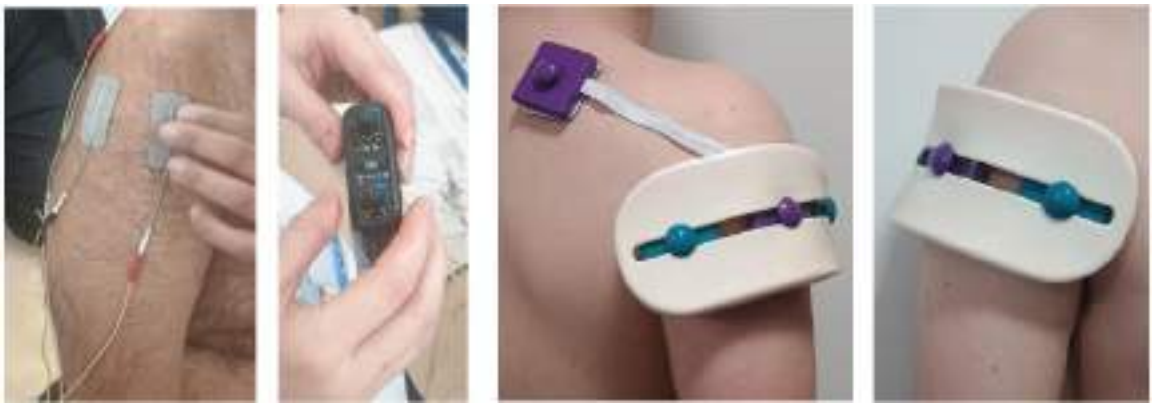


***Figure 40: Image showing the before and after of the application of the ES device as opposed to the MicroStim 2V2 used at Hillingdon Hospital***

**where the proposed solution could solve the current issues faced.**

**This project was strongly influenced by personal experience and family engagement. Having a close family member who is a stroke survivor gave me additional motivation to ensure the solution is as intuitive and accessible as possible. In particular, supporting a stroke survivor with limited English proficiency highlighted the importance of reducing language barriers and creating interactions that rely less**

**on complicated instructions or medical terminology. This encouraged me to focus on making the experience simple, inclusive, and easy to understand for a wider range of users. Overall, this process has taught me a significant amount about healthcare design, communication, research, and stakeholder collaboration, and it has reinforced my interest in developing meaningful solutions within rehabilitation and assistive technology. I look forward to continuing to develop this project further during my postgraduate studies in Innovation Design Engineering MA/MSc at Royal College of Art and Imperial College London.**



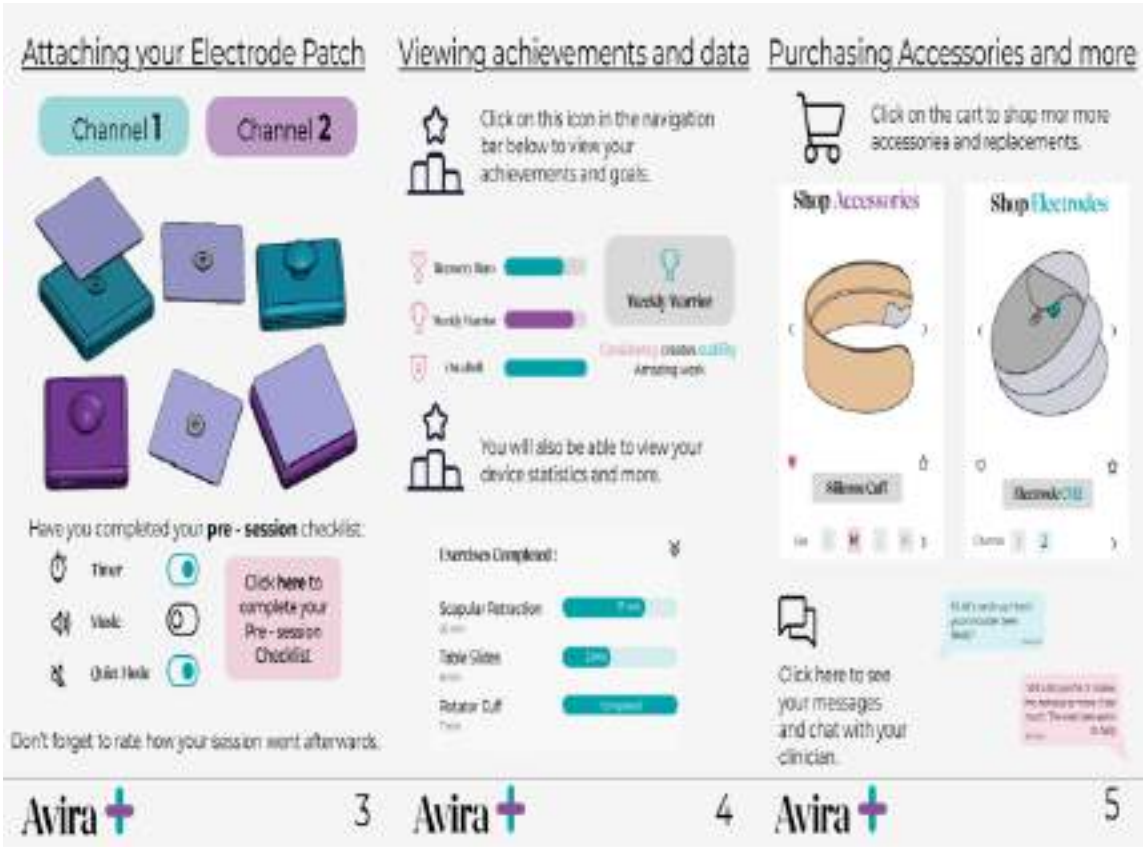




***Figure 41: Figure showing User guide concept developed near the end of the project to provide easy guidance to the app. As a concept this does not include the disclaimers and safety warnings, but the aim is to make the booklet far shorter approximately 16 pages rather than the commonly found 30+ pages.***

***Conflict of Interest: Co-contributor and Guest Editor***

***The author's supervisor is a co-contributor to this manuscript and also serves as the Guest Editor for the relevant issue. This relationship is disclosed for transparency. The author declares that no other conflicts of interest exist in relation to this manuscript.***

***List of Figures***

***Figure 1. Shoulder Subluxation Anatomy — Visual diagram illustrating shoulder subluxation and the key muscles involved in electrical stimulation .....124***
***Figure 2. Stroke Rehabilitation Team — Diagram illustrating the multidisciplinary team involved in stroke rehabilitation and patient recovery ..... ..125***
***Figure 3. Principles of Neurological Rehabilitation — Diagram outlining the key principles involved in neurological rehabilitation..... ..126***
***Figure 4. SaeboStim One — Existing single-channel electrical stimulation device used for rehabilitation .....128***
***Figure 5. SaeboStim Pro — Existing dual-channel electrical stimulation device for muscle re-education and rehabilitation ..... .128***
***Figure 6. MicroStim 2V2 — Existing clinical electrical stimulation device used for neurological rehabilitation .....129***
***Figure 7. Valkyrie Eir Clinical Demonstration — Demonstration of competitor device placement on the shoulder during clinical evaluation ..... ..131***
***Figure 8. Competitor Design Evaluation — Evaluation of competitor device adjustability for different types of shoulder subluxation ..... .131***
***Figure 9. Competitor Pod Design — Detailed view of competitor pod geometry, flexibility and channel identification ..... 131***
***Figure 10. Existing Pairing Application — Existing clinician interface demonstrating application layout, controls and information hierarchy ..... 132***
***Figure 11. Trailing Wire Challenge — Illustration of difficulties associated with trailing wires during use of existing electrical stimulation devices ..... 133***
***Figure 12. Existing Safety Labelling — Existing device safety label intended to discourage incorrect or unauthorised use ..... ..133***
***Figure 13. Electrode Application — Demonstration of electrode placement during an electrical stimulation therapy session ..... .133***
***Figure 14. Existing Device Controls — Existing electrical stimulation controls highlighting accessibility and patient usability considerations ..... 133***
***Figure 15. Existing User Manual — Existing extensive user documentation illustrating the length and complexity of current device guidance ..... 135***
***Figure 16. Student Device Trial — Practical evaluation of an existing electrical stimulation device to assess user experience and safety considerations ..... 135***

*Figure 17. Button Connection Mechanism — Existing male and female button-pin mechanism used to connect device components ..... 135*
*Figure 18. Electrode Storage Mechanism — Existing twist-lock mechanism used to separate and store adhesive electrode pads ..... 135*
*Figure 19. Electrode Pad Storage — Existing plastic storage sheet used for adhesive electrode pads, highlighting storage and usability limitations ..... 135*
*Figure 20. Mirror Therapy Demonstration — Practical demonstration of mirror therapy during a physiotherapy teaching session ..... 135*
*Figure 21. Electrical Connection Detail — Close-up of the snap-button electrical connection used by the SaeboStim One ..... ....136*
*Figure 22. Rehabilitation Splints — Examples of rehabilitation splints used during physiotherapy teaching and practical activities ..... 136*
*Figure 23. Electrical Stimulation Demonstration — Demonstration of electrical stimulation and resulting muscle activation during rehabilitation ..... 136*
*Figure 24. Concept 1 – Sleeve Design — Initial wearable sleeve concept exploring electrode placement and integration with the rehabilitation garment ..... 137*
*Figure 25. Concept 2 – Adjustable Silicone Cuff — Selected wearable cuff concept developed for adjustable electrode positioning and patient use ..... 138*
*Figure 26. Concept 3 – Exoskeleton Design — Alternative exoskeleton concepts exploring adjustable electrode positioning and shoulder support ..... 139*
*Figure 27. Initial Product Design Specification — Initial product requirements established to guide the development of the Avira+ system ..... 140*
*Figure 28. Stakeholder Mapping — Mapping of key stakeholders involved in the development and use of the healthcare rehabilitation device ..... 141*
*Figure 29. Low-Fidelity Prototyping — Paper prototypes and anthropometric studies used to explore the form, scale and sizing of the Avira+ device ..... 143*
*Figure 30. Electronics Proof of Concept — Electronics development demonstrating Bluetooth control, stimulation sequencing and ramp-up/ramp-down functionality .....143*
*Figure 31. Foam and PLA Prototyping — Physical prototypes used to refine product form, size, thickness and adjustment mechanisms ..... 145*
*Figure 32. CAD Development — CAD development of the final silicone cuff geometry and integration of the electrode pods ..... 146*
*Figure 33. Silicone Manufacturing Process — Development of the medical-grade silicone cuff, including mould preparation and manufacturing considerations .... 148*

*Figure 34. Final Concept Renders — Final Avira+ product renders illustrating the overall appearance and key product features ..... 151*
*Figure 35. Electrode Pod Technical Drawing — Technical drawing detailing the final electrode pod design and its integration with the silicone cuff ..... 152*
*Figure 36. Silicone Cuff Technical Drawing — Technical drawing showing the final adjustable silicone cuff design and lateral adjustment slot ..... 153*
*Figure 37. Final Product Design Specification — Evaluation of the final Avira+ design against the original product requirements ..... 153*
*Figure 38. App User Testing — User testing of the Avira+ application wireframes and feedback provided by the clinical champion ..... 154*
*Figure 39. Device Comparison — Comparison of the proposed Avira+ device with the MicroStim 2V2 used at Hillingdon Hospital .....155*
*Figure 40. User Guide Concept — Concept for a simplified and accessible Avira+ user guide designed to provide clear guidance for application use ..... 155*

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