ENGR9700: Masters Thesis

The Design, Development and Utility Testing of a Novel Shoulder Rehabilitation Device

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A thesis submitted in partial fulfillment of the requirements for the degree of Bachelor of Engineering (Mechanical) (Honours) / Master of Engineering (Biomedical)

College of Science and Engineering

Flinders University

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Declaration of Originality

I certify that this work does not incorporate without acknowledgment any material previously submitted for a degree or diploma in any university and that to the best of my knowledge and belief it does not contain any material previously published or written by another person except where due reference is made in the text.

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Supervisor Declaration

I certify that I have seen and commented on this work, and approve its release for submission in partial fulfilment of the requirements for the degree of Bachelor of Engineering (Mechanical) (Honours) / Master of Engineering (Biomedical) conducted by Philippa Tsirgiotis.

Name: Dr David Hobbs

Signed: D. Hobbs

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Executive Summary

Passive mobility-based rehabilitation is an important treatment for several common shoulder pathologies. While clinical outcomes are heavily reliant on rehabilitation frequency and compliance, treatment is often limited to that provided in a clinical setting. In response to this, a device called the Shoulder Mobiliser was developed to allow safe passive motion of the shoulder in the home. Two functional prototypes were previously produced, and the aims of this project were to improve the usability, viability and feasibility of the novel device.

Potential end users (n=7, aged = 63 ± 9.6) who had all undergone shoulder rehabilitation were recruited for a study to assess the usability of the device, and to guide the design of a subsequent prototype. This process produced a mean System Usability Scale score of 90.36 ± 4.71, indicating excellent usability of the most recent prototype. Potential device improvements identified by participants included variable speed options, a change in control switch, cost reduction and the addition of a display on the device itself to complement a tracking application.

A preliminary surface electromyography study was performed while using the prototype device as intended, with results indicating that the activity of surface muscles of the shoulder remains low during device usage. This indicates that the Shoulder Mobiliser may be appropriate for passive rehabilitation. However, variance across results limit the confidence of this claim.

Finally, two designs were created for a subsequent prototype of the Shoulder Mobiliser. The new designs utilised cheaper components, a new control switch, a display screen and a charging port. Production costs were reduced from AUD$1400 to under AUD$260, not including control electronics.

Future recommendations for continued development include the selection of one of the presented designs, assessment of scalability of manufacturing, clinical assessment of the device through a formal trial and a more comprehensive electromyographic study.

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List of Abbreviations

μ	Mean
ADLs	Activities of daily living
CAD	Computer-aided design
CNC	Computer numerical control
DC	Direct current
EMG	Electromyography
iEMG	Intramuscular electromyography
LCD	Liquid-crystal display
MVIC	Maximum voluntary isometric contraction
PA12	Polyamide-12
PCB	Printed circuit board
ROM	Range of motion
SD	Standard deviation
sEMG	Surface electromyography
SLS	Selective laser sintering
SPADI	Shoulder pain and disability index
SPDT	Single pole double throw
SUS	System usability scale
USB	Universal serial bus

Introduction

Shoulder pathologies pose a significant burden on the world's population, with 4.5 million primary care consultations per year in the USA alone for shoulder pain (Mather *et al.*, 2013). The impact of shoulder disfunction can be wide-reaching: pain and loss of function can often affect a sufferer's ability to carry out everyday activities, leading to a lack of independence and even reduced quality of life (Marik & Roll, 2017). The treatment of several musculoskeletal shoulder conditions can include surgical intervention, such as rotator cuff tears, bone fractures, adhesive capsulitis, subacromial impingement and advanced arthritis of the shoulder joints (Baumgarten *et al.*, 2009; Wilcox *et al.*, 2005). Post-operative outcomes often rely on mobility-based rehabilitation, which is often overseen by a physiotherapist or occupational therapist (Gilbert *et al.*, 2018). The aim of this form of rehabilitation is to gradually mobilise the shoulder in order to prevent joint stiffening and muscle atrophy (Baumgarten *et al.*, 2009). Good adherence to a rehabilitation protocol has been shown to reduce the incidence of post-operative complications, and facilitate the return of necessary function in a timely manner (Sgroi & Cilenti, 2018).

Mobility-based shoulder rehabilitation involves several stages. In the earliest stage, muscle activity is to be kept at a minimum, to protect surgical sites and allow healing (Kuhn, 2009; Sambandam *et al.*, 2015). This 'passive' rehabilitation is commonly undertaken in clinic by a therapist, who will support the arm and move the shoulder through a prescribed range of motion or to the limits of patient discomfort (Gilbert *et al.*, 2018). This allows the shoulder to be mobilised with no effort from the surrounding muscles, a requirement which prevents injury to the shoulder (Kuhn, 2009; Sambandam *et al.*, 2015). The second stage starts to involve muscle contraction, allowing the muscles around the shoulder to start to regain strength and prevent muscle wasting. This is known as 'active-assisted' or 'active' rehabilitation, depending on the degree of muscle activation (Oliva *et al.*, 2016). The final stage of rehabilitation known as 'resistive rehabilitation', focuses on further strengthening of the shoulder muscles and ensuring independence for everyday tasks (Boardman *et al.*, 2001).

With passive rehabilitation being largely limited to in-clinic appointments, there exists an opportunity to accelerate rehabilitation if passive motion can be achieved safely in the

home. This would allow more frequent joint mobilisation, which is traditionally limited by the frequency of physiotherapy visits (Eriksson *et al.*, 2011). Patient motivation has been shown to be a significant determinant of clinical outcomes, largely due to its correlation with exercise adherence. Perceived simplicity and convenience of prescribed exercises are crucial to patient adherence. Adherence has also been shown to increase with tracking of patient progress. This allows both the patient and their clinician to see improvement over time, allowing for appropriate clinical guidance and providing encouragement for the patient when progress may seem slow (Colombo *et al.*, 2007). Some passive mobilisation can be achieved in the home through the use of pulleys, however these need significant set up, usually being mounted to a door frame. This limits the portability and convenience of pulley systems. Additionally, the majority of rehabilitation tools lack the ability to track patient progress. This is especially true of those suited for at-home use, such as pulleys and canes for passive and active-assisted rehabilitation respectively. Progress tracking is achieved well by electronic devices; however, few have been developed for musculoskeletal shoulder rehabilitation and clinical uptake has been minimal, largely due to the large cost of available systems (Sicuri *et al.*, 2014). As of the writing of this thesis, the author is unaware of any electronic device suited for at-home passive shoulder rehabilitation. Those in circulation are typically used in-clinic, due to their lack of portability, relative complexity and high cost (Sicuri *et al.*, 2014).

To fill this gap in the market, a project was initiated by physiotherapist Mr Luke Mason and orthopaedic surgeon Dr Jonathan Cabot of Global Movement Pty Ltd. They proposed a portable device would allow passive mobilisation of the shoulder in the home, with progress tracking for the patient and clinician. In 2020, this device was developed to its first functional prototype by the author and a second student for their Work Integrated Learning placement. The device in question, currently referred to as the ‘Shoulder Mobiliser’, takes a form similar to a dumbbell. The user grasps the body of the device with their hand and the device drives their arm along a table surface using two DC (direct current) motors integrated into the handle of the device. The device is controlled by the index-finger sliding a small joystick. The Shoulder Mobiliser can be used in both flexion and abduction (Video 1 and Video 2).

Video 1: Device usage in flexion

Video 2: Device usage in abduction

The first prototype of the Shoulder Mobiliser included an external enclosure to house the required electronics and a three-piece handle with a transverse split (Figure 1).

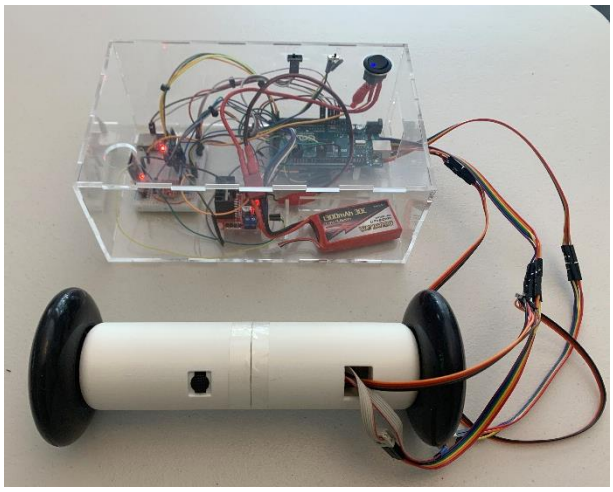

Figure 1: First prototype device

Prior to the commencement of this Masters project, the electronics of the device were optimised and mounted inside a two-piece handle by electronics consultant engineer, Dr Aaron Mohtar. Bluetooth was also incorporated into the shoulder mobiliser to allow pairing to a simple smartphone application that tracks distance travelled per session (Figure 2).

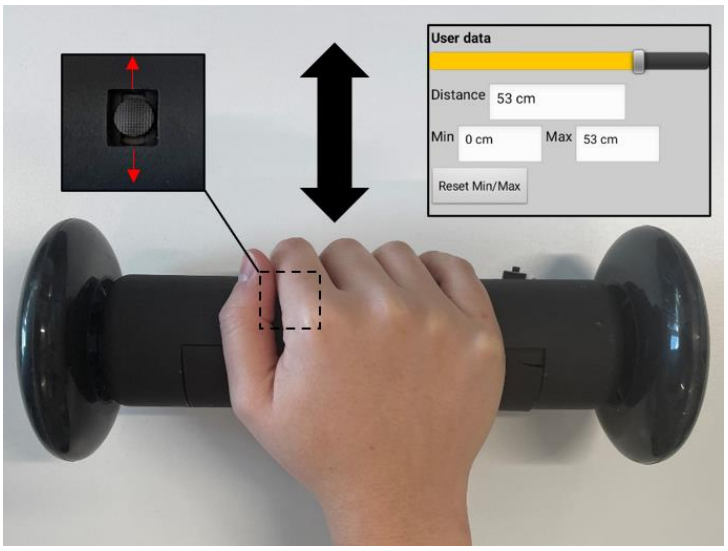

Figure 2: Second prototype device with control joystick (inset left) and application interface (inset right)

This Masters project aimed to address the next steps towards eventual commercialisation of the device, by improving the usability, feasibility and viability of the product. Chapter 1 provides a review of the current literature surrounding the project, specifically the incidence of shoulder pathologies, the role of mobility-based rehabilitation and validation of prescribed exercises, current rehabilitation protocol exercises and tools, and the importance of co-design for rehabilitation technology. The project overview, including a problem statement, objectives and methodologies is presented in Chapter 2. Chapter 3 presents a patient-centred usability study. This study aimed to collect data on ease of use and identify any potential improvements to the device. A preliminary surface electromyographic study to assess the level of muscle activation during device use is detailed in Chapter 4. This study was necessary to determine if the device is suitable for passive rehabilitation. Results from the usability study drove the redesign and analysis of a new prototype, detailed in Chapter 5. Recommendations for further development of the device are discussed in Chapter 6. Finally, the contents of this thesis are summarised in Chapter 7.

Chapter 1: Literature Review

1.1 Shoulder Anatomy and Physiology

The human shoulder is formed by the clavicle, scapula and humeral head (Nandi & St. Clair, 2020). The majority of articulation in this complex is between the humeral head and a shallow socket in the scapula known as the glenoid (Figure 3). The glenohumeral joint is classified as a polyaxial ball and socket joint, and is the most mobile joint in the human body (Srebnik, 2002).

Figure 3: Bony anatomy of the shoulder with glenohumeral joint circled

Adapted from: (Nandi & St. Clair, 2020)

The musculature surrounding the shoulder forms a complex responsible for moving and stabilising the shoulder. The deltoid muscle produces most of the motion of the shoulder (Srebnik, 2002). The rotator cuff is another important complex of the shoulder. This structure is formed by the tendons of the supraspinatus, infraspinatus, subscapularis and teres minor muscles (Boykin *et al.*, 2010). These tendons blend into the joint capsule of the

glenohumeral joint, with the main function of stabilising the humeral head during dynamic movements (Somogyi *et al.*, 2019).

Functional shoulder mobility is vital to a large number of activities of daily living (ADLs) (Namdari *et al.*, 2012). The shaded areas in Figure 4 show the typical range of motion (ROM) required for undertaking ADLs in forward flexion and extension (A), abduction (B), horizontal adduction (C), and external rotation (D) as found by Namdari *et al.* (2012). These are superimposed on the limits of normal shoulder ROM in each plane. These ROM limits are typically quoted as 0 to 170 degrees in forward flexion, 0 to 60 degrees in extension and 0 to 170 degrees in abduction (Somogyi *et al.*, 2019).

Figure 4: Normal extremes of shoulder mobility with functional mobility shaded (Namdari et al., 2012)

1.2 Surgical Intervention on the Shoulder

1.2.1 Rotator Cuff Tear Repair

Rotator cuff pathology is the leading cause of shoulder disability (Narvy *et al.*, 2016). A rotator cuff tear is defined as a partial or full tearing of one of the tendons that form this complex. Symptomatic tears result in pain and decreased strength in the affected shoulder (Sambandam *et al.*, 2015). Tearing is more common in the dominant arm and can be due to trauma or degeneration (OrthoInfo, 2007). Traumatic tearing of the rotator cuff is not uncommon; Lo and Burkhart (2003) found that 20% of all shoulder injuries are rotator cuff tears, while 8.2% of musculoskeletal injuries affect the shoulder (U.S. Bureau of Labor Statistics, 2016). Rotator cuff tears are also more common in older populations; every decade of increasing age is associated with a 2.69-fold increased risk of sustaining a tear (Tempelhof *et al.*, 1999; Yamaguchi *et al.*, 2006).

Conservative treatment of rotator cuff tears includes oral or injected anti-inflammatory agents and physical therapy. If conservative treatments fail to relieve symptoms adequately, surgical repair is often recommended. This involves suturing the torn tendon back to the underlying humeral head (Boykin *et al.*, 2010). Mather *et al.* (2013) estimate that over 250,000 rotator cuff repairs are performed annually in the USA alone, each at a societal cost of around $19,000 AUD per patient.

1.2.2 Shoulder Arthroplasty

Shoulder arthroplasty refers to replacement of the humeral head alone (partial arthroplasty) or the humeral head and glenoid surface (total arthroplasty) with prosthetic components. Depending on the configuration of the ball and socket implanted, a shoulder arthroplasty can be classified as anatomical or reverse (Figure 5). One or more of the rotator cuff tendons are often detached and reattached during this procedure depending on the surgical technique and anatomical considerations (Matache & Lapner, 2017).

Figure 5: Anatomical (left) and reverse (right) total shoulder arthroplasty (Alila Medical Media, n.d.)

Shoulder arthroplasty can be indicated for a variety of conditions when symptoms are not resolved by conservative treatments. Such conditions include osteoarthritis, rheumatoid arthritis, osteonecrosis, or humeral head fracture. This surgical intervention is usually recommended for those who have persistent pain and a loss of function due to advanced pathology of the glenohumeral joint (Wilcox *et al.*, 2005). Over 70,000 shoulder arthroplasties are performed annually in the USA (Kim *et al.*, 2011).

1.2.3 Post-Operative Complications

Post-operative outcomes vary significant depending on a number of factors including surgery performed, surgical technique, aetiology and severity of pathology, and level of post-operative rehabilitation (Wilcox *et al.*, 2005). Procedures involving the rotator cuff carry a risk of tearing of surgical sites if active movement is performed too early (Ahmad *et al.*, 2015; Boileau *et al.*, 1999; Compito *et al.*, 1994; Randelli *et al.*, 2012). On the other end of the spectrum, prolonged immobilisation can result in joint stiffness and muscle atrophy (Baumgarten *et al.*, 2009; Brislin *et al.*, 2007; Koo & Burkhart, 2010; Severud *et al.*, 2003; Tauro, 2006; Warner & Greis, 1998). Deterioration of neuromuscular control can also occur if motion is not achieved early (Ellsworth *et al.*, 2006). If joint stiffness is not addressed, it can progress to a condition known as adhesive capsulitis, also known as 'frozen shoulder'

(Sgroi & Cilenti, 2018). Adhesive capsulitis has an incidence of 11% across all elective shoulder procedures and poses a societal cost of $7000 AUD per patient (Koorevaar *et al.*, 2017; van den Hout *et al.*, 2005). This condition involves contracture of the glenohumeral joint capsule, resulting in pain and markedly decreased range of motion (Le *et al.*, 2017). While the condition has an average symptomatic duration of 2-3 years, 15% of patients who develop adhesive capsulitis will experience persistent disability (Buchbinder *et al.*, 2007; Hazleman, 1972).

1.3 Standard Post-Operative Mobility-Based Rehabilitation

1.3.1 Goals and Phases of Rehabilitation

Post-operative rehabilitation has the main goal of reducing the chance of complications, accelerating return to regular functioning, and maintaining quality of life (Sgroi & Cilenti, 2018; Zhang *et al.*, 2020). This is achieved through gradual mobilisation of the shoulder, followed by strengthening exercises (Conti *et al.*, 2009; Oliva *et al.*, 2016; Severini *et al.*, 2014). For the majority of post-operative cases, rehabilitation protocols follow a similar progression, with some differences in the timing of phases (Boardman *et al.*, 2001). Passive ROM is the first stage, characterised by mobilisation with minimal muscle activation. This phase is essential to prevent excessive stress on surgical sites and allow the healing process to continue (Baumgarten *et al.*, 2009; Conti *et al.*, 2009; Oliva *et al.*, 2016). Passive ROM can continue until the same ROM as the contralateral arm is achieved with no pain (Lee *et al.*, 2012; van der Meijden *et al.*, 2012). Other protocols use a time-based progression, with the first 6 weeks of rehabilitation focusing on passive ROM (Boudreau *et al.*, 2007; Conti *et al.*, 2009; Oliva *et al.*, 2016; Wilcox *et al.*, 2005). This phase of rehabilitation is considered essential as active ROM is limited by that achieved passively (Brems, 1994; Brown & Friedman, 1998). Following passive exercises, rehabilitation continues to active ROM, where the muscles can begin to be progressively activated. This phase is followed by resistive ROM, where motions are further strengthened by applied an antagonistic force during exercises (Boardman *et al.*, 2001).

Despite significant variation between protocols, progressive rehabilitation is strongly supported by the available literature (Seida *et al.*, 2010). There is a consensus among the

clinical community that functional outcomes rely heavily on rehabilitation (Brems, 1994; Brown & Friedman, 1998; Bullock *et al.*, 2019; Hughes & Neer, 1975; Ross *et al.*, 2014).

1.3.2 Passive Rehabilitation Methods and Tools

Passive rehabilitation is typically the most difficult to achieve independently as the weight of the arm must remain supported to prevent muscle activation. It is traditionally performed in-clinic with a physiotherapist supporting and moving the arm (Gilbert *et al.*, 2018). Continuous passive motion devices can be used to achieve this mobilisation, however, such devices are very large, costly and not suitable for at-home use (Figure 6) (Mavroidis *et al.*, 2005). If exercises are only performed in-clinic, rehabilitation is limited by the frequency of appointments, with each posing a cost to the medical system or the patient. Therefore, in-clinic rehabilitation is typically supplemented with at-home exercises.

Limited literature exists on the efficacy of supplementary at-home rehabilitation. Oliva *et al.* (2016) found minimal differences between solely in-clinic and solely at-home rehabilitation in the conservative treatment of rotator cuff pathology. Boardman *et al.* (2001) undertook a study using in-clinic rehabilitation supplemented with at-home exercises in patients having undergone total shoulder arthroplasty. They found the inclusion of at-home exercises to be user-friendly and concluded that this combination could effectively be used to maintain mobility achieved during surgery.

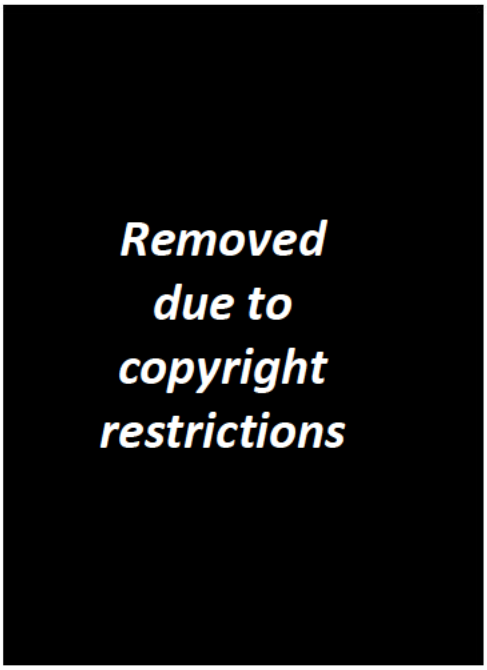

Figure 6: Typical continuous passive motion device (Access Health, n.d.)

Shoulder pulleys can be installed over doors and actuated with the opposite arm (Figure 7). This produces forward flexion. While this is generally effective, it requires setup in a doorframe which can prove difficult, especially for someone with a shoulder impairment.

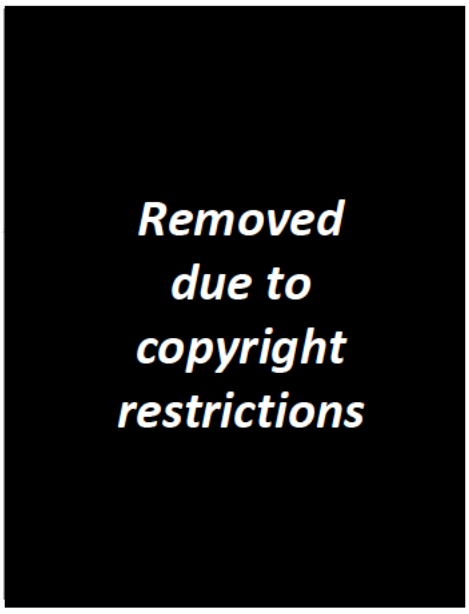

Figure 7: Shoulder pulley (Theraband, n.d.)

Pendulum or cane-assisted exercises (Figure 8) can be performed safely in the home, however, they fail to exercise a large ROM.

Figure 8: Pendulum exercises (left) and cane-assisted exercises (right)

Adapted from: (Ohio State University Wexner Medical Center, n.d.) and (American Academy of Orthopaedic Surgeons, 2017)

Table 1 summarises the passive rehabilitation methods discussed and their features. While the in-clinic options allow for a large ROM to be exercised and for usage to be monitored, these features are not available for any of the at home supplementary methods. There exists a gap in the market for a tool capable of providing effective at home rehabilitation while monitoring patient progress. This finding is significant, Gilbert *et al.* (2018) found that quantifiable measures of patient progress improve patient compliance and motivation, as well as clinical reasoning of medical practitioners.

Table 1: Comparison of common passive rehabilitation methods

Tool or Method	Suitable for in the home use	Minimal setup	Cheap	Large ROM exercised	Usage and ROM monitoring
Manual therapy	N	Y	N	Y	Y
Continuous passive motion device	N	N	N	Y	Y
Pulley exercises	Y	N	Y	Y	N
Pendulum exercises	Y	Y	Y	N	N
Cane-assisted exercises	Y	Y	Y	N	N

1.4 Electromyographic Validation of Rehabilitation Exercises

1.4.1 Electromyography Principles

Electromyography (EMG) measures the voltage produced across a skeletal muscle, caused by contraction. This is achieved through the application of electrodes to the muscle belly, which record these biopotentials. An EMG signal is presented as voltage over time, with voltage proportional to activity level (McGill *et al.*, 1985). EMG signals can be recorded either from the skin, or from within the muscle itself. These methods are referred to as surface EMG (sEMG) and intramuscular EMG (iEMG) respectively (Soderberg & Knutson, 2000). Surface electrodes are relatively easy to apply, while intramuscular electrodes must be inserted by a trained clinician. For surface electrodes, the skin is typically cleaned and abraded, and an adhesive electrode applied over the belly of the muscle of interest (Rash, n.d.). Intramuscular electrodes are comprised of a barbed wire which must be inserted into the muscle through the skin (Aminoff, 2012; Tankisi *et al.*, 2020). sEMG can only collect signals for superficial muscles, while iEMG can be used for deeper muscles (Farkas *et al.*,

2010; Soderberg & Knutson, 2000). Surface electrodes have a much larger recording area than intramuscular electrodes, making them more vulnerable to signal summation from neighbouring muscles, also known as crosstalk (Farkas *et al.*, 2010).

1.4.2 Use in Muscle Activation Studies

EMG is often used to assess muscle activation levels during particular movements. Raw EMG signals undergo a number of processing steps prior to maximum amplitude extraction. Processing varies within the literature, however most studies apply a series of Butterworth frequency filters, rectify, and then smooth the signal (Alizadehkhaiyat *et al.*, 2015; Boettcher *et al.*, 2008; Cross *et al.*, 2020; Ellsworth *et al.*, 2006). In order to compare results between participants, the amplitude of signals must be normalised. The most common normalisation method in the literature is percentage of maximum voluntary isometric contraction (MVIC) for each muscle (Edwards *et al.*, 2017; Wells *et al.*, 2016). The MVIC value for each muscle is determined by having the participant maximally contract the muscle while being resisted to prevent motion. Boettcher *et al.* (2008) investigated a number of shoulder-specific MVIC exercises to determine their ability to maximally activate the shoulder muscles. They concluded that four exercises were sufficient to determine MVIC values for all shoulder muscles. These exercises are listed in Table 2. This paper proposes a protocol including two repetitions of each exercise with a 30 second rest between repetitions and a 60 second rest between exercises to minimise muscle fatigue.

Table 2: MVIC exercises for shoulder muscles (Boettcher et al., 2008)

Exercise name	Description	Image
Empty can	Shoulder abducted 90 deg in scapular plane with internal humeral rotation and elbow extended; arm abducted as resistance applied at wrist	***Removed due to copyright restrictions***
Internal rotation 90 degrees	Shoulder abducted 90 deg in scapular plane with neutral humeral rotation and elbow flexed 90 deg; arm internally rotated as resistance applied at wrist	
Flexion 125 degrees	Shoulder flexion 125 deg as resistance applied above the elbow and at the inferior angle of the scapula attempting to de-rotate scapula	
Palm press	Shoulders flexed 90 deg bilaterally with the heel of the hands together, elbows flexed 20 deg and arms horizontally adducting	

Once MVIC data has been recorded and processed, the maximum amplitude for each muscle across all exercises can be extracted. Peak amplitudes in the data of interest can be expressed as a percent value of this MVIC value. There is a consensus in the literature that a movement can be considered passive if it produces a peak EMG amplitude less than 20%

MVIC (Cross *et al.*, 2020; Dockery *et al.*, 1998; Edwards *et al.*, 2017; Gaunt *et al.*, 2010; Long *et al.*, 2010; McCann *et al.*, 1993; Uhl *et al.*, 2010).

A number of studies have used MVIC-normalised EMG to determine the level of muscle activation in different shoulder rehabilitation exercises (Alizadehkhaiyat *et al.*, 2015; Andersen *et al.*, 2010; Cross *et al.*, 2020; Dockery *et al.*, 1998; Ellsworth *et al.*, 2006; Gaunt *et al.*, 2010; Gurney *et al.*, 2016; Long *et al.*, 2010; McCann *et al.*, 1993; Uhl *et al.*, 2010). The main objective of these studies is to quantify muscle activation during different exercises. The peak muscle activation level can then indicate if the exercise is suitable for passive rehabilitation.

1.5 Co-Design and Usability Testing in Rehabilitation Innovation

Lack of usability is a common reason for low uptake of rehabilitation tools. The concept of usability in this case refers to the ease of the device-user interface, as well as the usefulness and perceived value of the system. Usability studies are commonly used to refine design concepts prior to their commercialisation to ensure they are addressing user needs appropriately. These studies can be quantitative or qualitative in nature, with mixed methodologies allowing for larger breadth and scope, resulting in a more comprehensive understanding of users' impressions (Resnik, 2011).

Many studies have explored the usability of novel devices in the fields of rehabilitation and assistive technology. The literature consistently highlights the importance of testing with relevant users (Hobbs *et al.*, 2019), with a number of studies finding positively skewed results for healthy participants (Pei *et al.*, 2017; Tsai *et al.*, 2019).

Gilbert *et al.* (2018) undertook semi-structured interviews with physiotherapists and patients with shoulder impairment to assess the usability of an in-clinic robotic shoulder rehabilitation system. This qualitative study successfully identified both advantages and disadvantages of the system. An example of a successful quantitative study is that completed by Chun-Ming *et al.* (2012). They assessed user satisfaction of a novel shoulder wheel gaming system using a Likert scale-based questionnaire.

The most common quantitative instrument used to measure usability in this area is the System Usability Scale (SUS), developed by usability specialist John Brooke in 1986. This 11-item instrument gives a numerical score of usability and measures three facets of usability. The first is effectiveness; whether the system allows the user to complete the intended task. The second is efficiency, relating to the resources required by the user to complete the task. The third and final is satisfaction; how well the system meets user needs (Kortum & Bangor, 2013). The SUS has multiple advantages, including short completion time, high reliability and technology agnosticism (Bangor *et al.*, 2008). The SUS was successfully used to quantitatively evaluate a cable-driven exoskeleton for hand rehabilitation, ensuring that clinical needs were met by the device (Tsai *et al.*, 2019).

Several mixed methodology studies have used the SUS to obtain quantitative usability data on rehabilitation technologies. An upper-limb stroke rehabilitation device prototype was assessed by Pei *et al.* (2017), with patients, caregivers and therapists. This study used the SUS, observations, open-ended questions and video recording. The study uncovered a number of issues that guided the next design iteration and resulted in an increased understanding of patient and therapist needs. A second mixed methodology study by Hamilton *et al.* (2021) assessed eleven feedback-based technologies targeted for mobility improvement. They utilised the SUS and conducted focus group sessions which were audio-recorded and transcribed. Finally, a robot-supported gait rehabilitation system was assessed using the SUS and in-person interviews (Eicher *et al.*, 2019). All of these studies also collected socio-demographic information from participants and revealed valuable insights into the assessed systems using the SUS and open-ended interview questions.

Chapter 2: Project Overview

2.1 Problem Statement

Mobility-based rehabilitation is an important part of treatment protocols for several musculoskeletal shoulder conditions (Boardman *et al.*, 2001; Koorevaar *et al.*, 2017; Wilcox *et al.*, 2005). Current at-home options for passive rehabilitation are limited, and no cheap methods allow exercising of a large range of motion with monitoring of patient progress. A functional prototype of a device (the Shoulder Mobiliser) was developed to fill this gap prior to this thesis, in collaboration with Flinders University. This device requires validation and a redesign to improve its usability, feasibility, and viability.

2.2 Project Objectives and Methods Overview

The end point of this project was the development of a design outline for a new prototype of the Shoulder Mobiliser. This project aimed to address the usability, feasibility, and viability of the device. These three facets were addressed using three project phases (Figure 9). Firstly, to address usability, the current design required validation from an appropriate end user population. A usability study with post shoulder rehabilitation patients was used to collect information to ensure user acceptance for subsequent prototypes. Secondly, a muscle activation study was used to assess the feasibility of the device for early rehabilitation. This study quantified the activation level of shoulder surface muscles in healthy individuals while they used the device. Finally, a redesign of the prototype aimed to tie all three facets together while addressing the results of the usability study and reducing the cost of the device.

Figure 9: Overview of project goals and aims

Chapter 3: Usability Study

3.1 Introduction

The first and second prototypes of the Shoulder Mobiliser were developed within the project team, which included expertise in areas such as rehabilitation engineering, physiotherapy, orthopaedic surgery, and product design. As such, feedback from potential end users was needed to validate the functionality of the device. This feedback would allow the usability of the second prototype to be assessed, along with user acceptance. This study would also serve to identify any areas of improvement which would be addressed in a subsequent prototype redesign.

3.2 Aims

The aims of the usability study were as follows:

- Collect relevant personal and medical information from participants
- Quantify the usability of the second prototype using a standardised measure
- Assess user acceptance
- Identify areas of improvement for the next prototype
- Collect feedback on the use of a mobile application to track patient progress
- Determine an acceptable patient cost for the device
- Discuss the charging method of the device and the use of a charging dock

3.3 Methods

The research methods for this study were approved by the Flinders University Human Research Ethics Committee (Project number 4143). The full ethics application can be found in Appendix A. This study was undertaken at the premises of the Physio One Lockleys clinic.

3.3.1 Participant Recruitment

In order to target the correct user population, patients who had previously undergone mobility-based rehabilitation for a musculoskeletal shoulder condition were recruited. To

reduce risk of physical injury, acutely post-operative patients were not recruited for this study. Potential participants were identified by project team member and physiotherapist Mr Luke Mason. They were then contacted via email or hard copy letter posted to their residential address by the Practice Manager of Physio One Lockleys. This contact included the Letter of Introduction and Participant Information Sheet and Consent Form (Appendices B and C respectively). The Practice Manager was selected to initiate this contact to prevent patients from feeling obliged to take part in the study. Those contacted via email were advised to contact Philippa Tsirgiotis via her Flinders University email address if they were interested in taking part in the study. Those contacted via post were advised to return their completed Consent Form to Dr David Hobbs via an enclosed reply-paid envelope. As such, Miss Tsirgiotis and Dr Hobbs only received the contact details of those who wished to take part in the study.

3.3.2 Overall Study Flow

This study was conducted as a 45-minute one-on-one research session with each participant. Figure 10 shows the overall flow of the usability study.

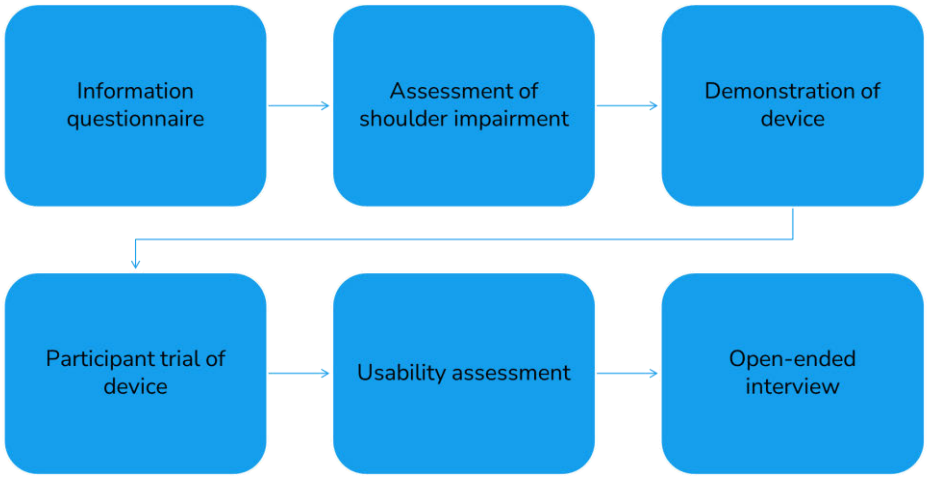

Figure 10: Usability study flow

3.3.3 Collection of Participant Information

A hard-copy questionnaire was used to collect relevant participant information (Appendix D). Demographic information was first collected, including gender, age and education level.

The questionnaire was used to collect a short summary of participants' medical history related to their shoulder condition including their duration of symptoms, any diagnoses and operations performed. The questionnaire asked which was their affected arm (left or right), and if this arm was their dominant arm. In order to gain an understanding of each participants' rehabilitation, they were asked which rehabilitation tools they had used for their shoulder condition. The list included all common rehabilitation tools as determined by physiotherapist Mr Luke Mason. Participants were also asked to indicate if they had used any electronic or robotic rehabilitation tools. Since the device currently pairs to a mobile application, participants were asked if they had access to wireless internet at home and if they owned a smartphone or tablet. A 5-point Likert scale question was used to collect self-reported confidence when using applications on a mobile phone. Finally, participants were asked to list applications they used on a regular basis.

3.3.4 Assessing Shoulder Impairment of Participants

Self-reported standardised measures of shoulder impairment were considered due to the author's lack of clinical expertise. The Shoulder Pain and Disability Index (SPADI) developed by Roach *et al.* (1991) was ultimately selected. The SPADI is non-proprietary, specific to the shoulder and assesses both pain and disability. It is quick to complete, taking between 2 and 5 minutes, and is used widely in clinical settings (Angst *et al.*, 2011; Paul *et al.*, 2004). The SPADI hard-copy questionnaire can be found in Appendix E.

3.3.5 Device Use

Participant use of the device was essential to this study design. To reduce injury risk, participants observed a demonstration of the device in flexion and abduction along with an explanation of how to control it. The device is operated by a joystick using the index finger that uses 'hold-to-run' operation. Therefore, if the participant releases the button, the device will stop. Participants were advised to use the device with their affected arm to the point of a stretching feeling, not to the point discomfort or pain. Participants were asked to consider the mobile application interface while using the device. Top-down view video

recordings were taken while each participant trialled the device. A schematic of this setup is shown below in Figure 11.

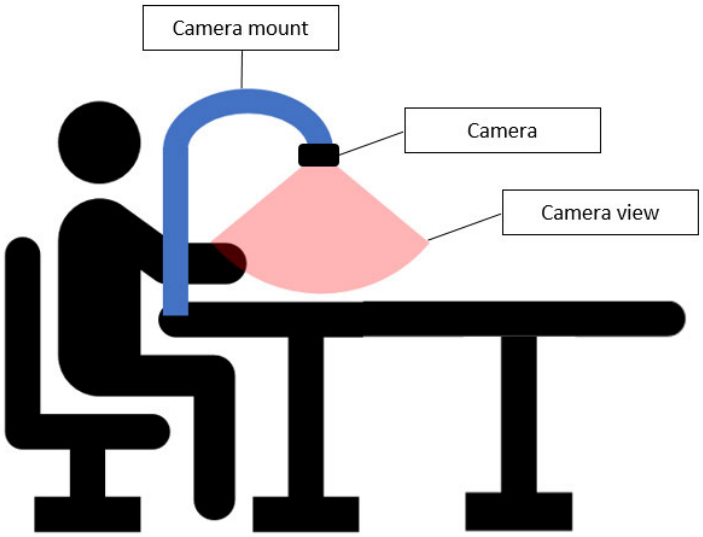

Figure 11: Filming setup for usability study device use

3.3.6 Usability Assessment

Review of the current literature revealed that the System Usability Scale (SUS) is the most common usability measure used in rehabilitation and assistive technology. This measure was used as it produces a numerical score indicative of usability and user satisfaction. Since this is a standardised and technology agnostic measure, its results can be compared to other products relatively easily. The SUS is also non-proprietary and relatively easy to score. The SUS hard-copy questionnaire can be found in Appendix F.

3.3.7 Collection of Participant Perspectives

Semi-structured interviews were used to obtain participant perspectives on several areas, as listed in the aims of this study. A list of questions was developed (Appendix G) but interviews were fluid, allowing participants to interject or add their own comments at any point. These interviews were audio-recorded for later analysis. Prepared questions covered the following topics: overall experience using the device, suggested changes to the device,

comparison to rehabilitation tools previously used, user acceptance, effect of real-time feedback, and purchase cost and renting cost of the device.

During development of the first prototype, the option of displaying real-time feedback of device usage on a screen on the handle of the device was considered. Ultimately, a mobile application was used to achieve this. Participants were asked their preference for the location of this feedback in order to assess this decision.

The last question of the interview concerned the charging method of the device, specifically the use of a charging dock versus inserting a charging cord into the device directly. A 3D printed charging dock mock-up was created and presented to participants during the interview to address this (Figure 12).

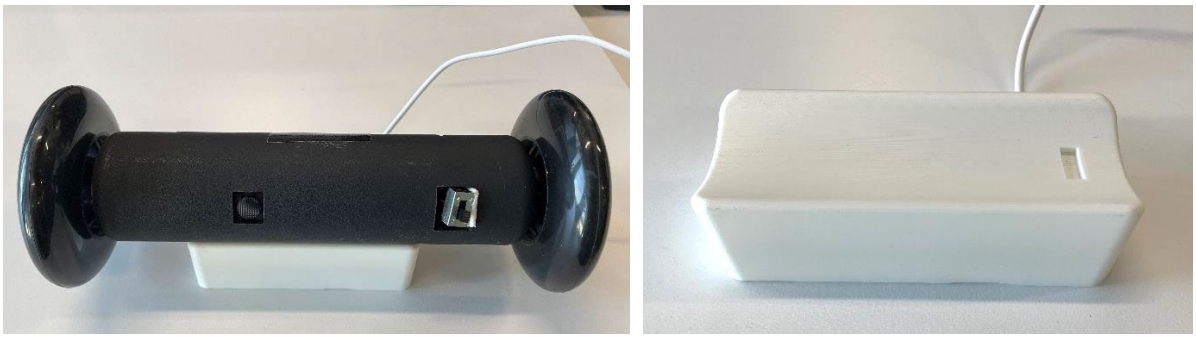

Figure 12: Charging dock with (left) and without device (right)

3.4 Quantitative Results

3.4.1 Participant Information

A total of seven participants were recruited: 5 females, 2 males, with a mean age of 63 ± 9.6 years. Participant education levels ranged from high school to doctorate. Four participants used the device with their dominant arm and three with their non-dominant arm. The results from questions 7, 9 and 10 of the Participant Information Questionnaire are shown in Figures 13, 14 and 15 respectively.

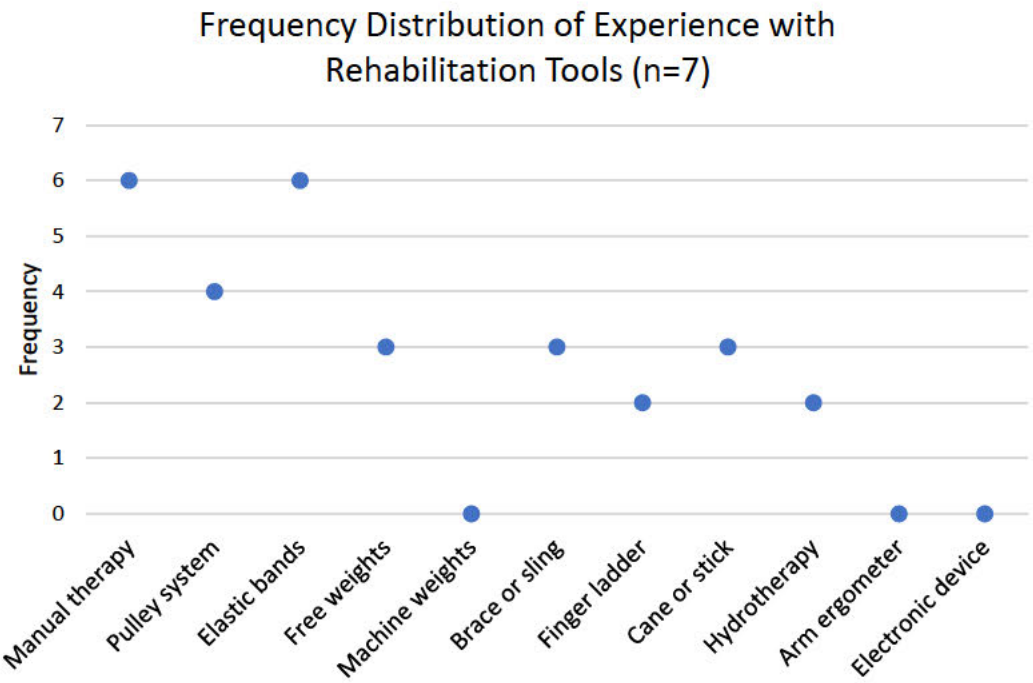

Figure 13: The frequency distribution of experience with rehabilitation tools (n=7)

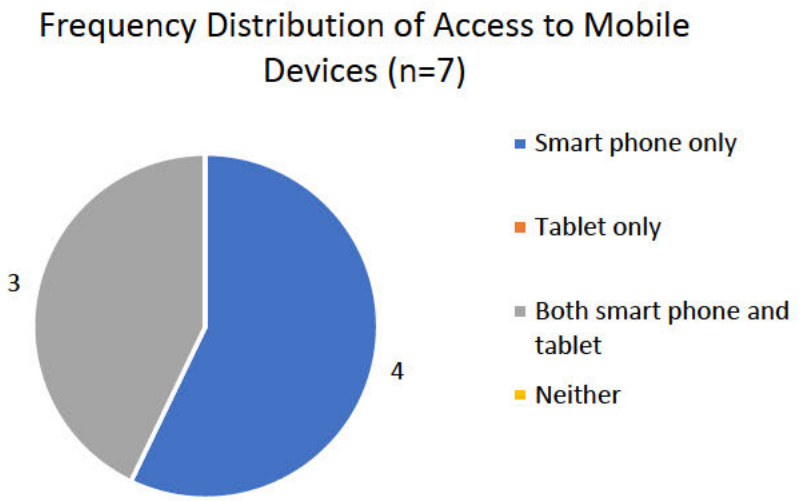

Figure 14: The frequency distribution of access to mobile devices for usability study participants (n=7)

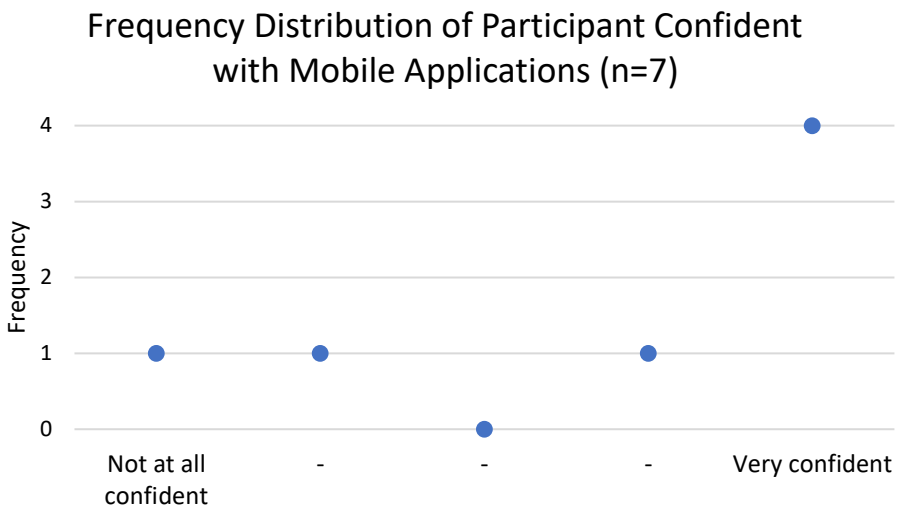

Figure 15: The frequency distribution of participant confidence with mobile applications (n=7)

3.4.2 SPADI Scores

The SPADI is separated into two sections of questions: pain and disability. Each question is scored on a scale of 0 to 10, with zero indicating no pain or no difficulty and ten indicating worst pain imaginable or so difficult that help is required. The scores for each question sum for each section of the index. This is then converted to a percentage score (0 to 100%) in each of the domains. Table 3 includes the SPADI results for each participant, as well as average scores for the group.

Table 3: SPADI results in pain and disability domains (n=7)

	Participant code							
	001	***002***	***003***	***004***	***005***	***006***	***007***	***μ ± SD***
Pain sum	1	20	3	7	2	29	27	12.7 ± 10.5
Pain score (%)	2	40	6	14	4	58	54	**25.4 ± 22.7**
Disability sum	0	24	1	30	7	3	30	13.6 ± 12.8
Disability score (%)	0	30	1	38	9	4	38	**17.0 ± 16.0**

Note. μ and SD refer to mean and standard deviation respectively. 'Pain sum' is out of a possible 50, 'Disability sum' is out of a possible 80. 'Pain score' and 'Disability score' are out of a possible 100%, with higher scores indicating higher severity.

3.4.3 SUS Results

Table 4 presents the raw and processed SUS results for each question as well as the group averages. It should be noted that odd items have a positive tone and even items have a negative tone. Item scores are on a scale of 1 to 5, with 1 corresponding to 'Strongly Disagree' and 5 corresponding to 'Strongly Agree'. The responses to the categorical SUS question, "Overall, I would rate the user-friendliness of this product as:", are shown in Figure 16.

Table 4: SUS results per question and overall score (n=7)

	Participant code							
	001	***002***	***003***	***004***	***005***	***006***	***007***	***μ ± SD***
Item 1	4	4	4	5	3	4	3	3.9 ± 0.6
Item 2	1	2	1	1	1	1	1	1.1 ± 0.3
Item 3	5	5	5	5	5	5	5	5.0 ± 0.0
Item 4	1	1	1	1	1	1	4	1.4 ± 1.0
Item 5	4	5	5	5	4	5	5	4.7 ± 0.5
Item 6	2	1	1	1	1	1	1	1.1 ± 0.3
Item 7	5	4	5	2	5	4	5	4.3 ± 1.0
Item 8	1	2	1	2	3	1	1	1.6 ± 0.7
Item 9	5	5	5	5	5	5	3	4.7 ± 0.7
Item 10	1	2	1	1	1	1	1	1.1 ± 0.3
Odd item score	18	18	19	17	17	18	16	-
Even item score	19	17	20	19	18	20	17	-
Sum of item scores	37	35	39	36	35	38	33	-
Overall SUS score	92.5	87.5	97.5	90.0	87.5	95.0	82.5	**90.4 ± 4.7**

Note. μ and SD refer to mean and standard deviation respectively. Items are scored on a scale of 1 to 5. 'Odd item score' represents the normalised sum for all odd numbered items. 'Even item score' represents the normalised sum for all even numbered items. 'Sum of item scores' represents the sum of all normalised item scores. 'Overall SUS score' represents to overall output of the measure, out of a possible 100.

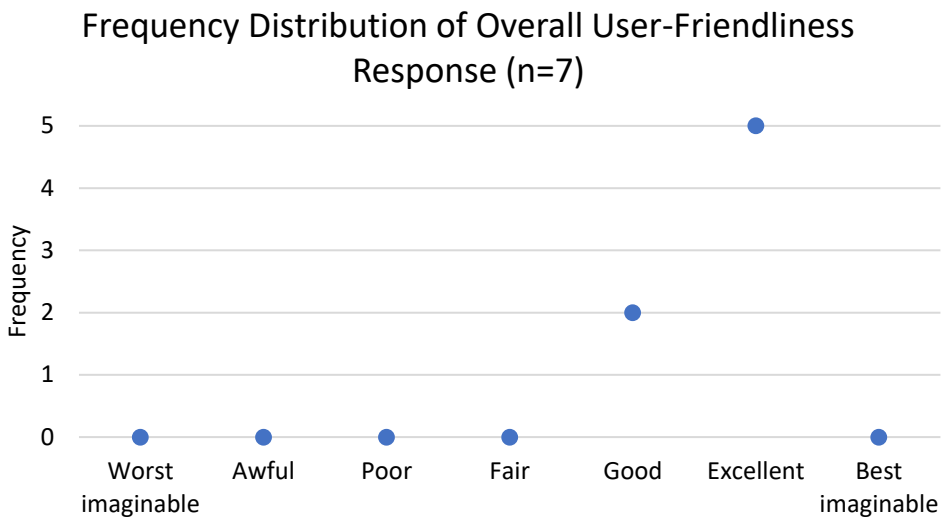

Figure 16: The frequency distribution of overall user-friendliness response (n=7)

3.4.4 Quantitative Interview Findings

Participant responses to feedback display preference and whether they would use the product during their rehabilitation are shown in Figure 17 and Figure 18 respectively.

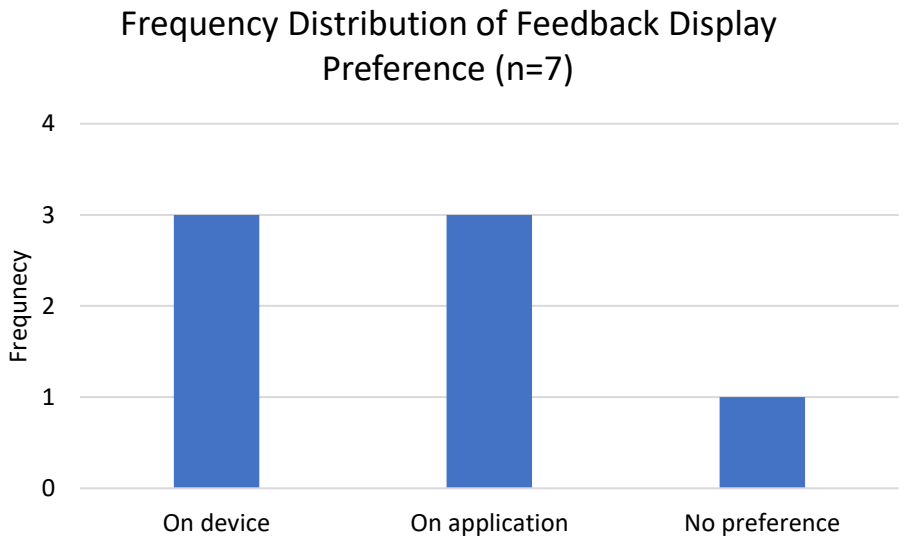

Figure 17: The frequency distribution of feedback display preference (n=7)

Figure 18: The frequency distribution of responses to "Would you have liked to use a device like this during your rehabilitation?" (n=7)

3.5 Discussion

3.5.1 Participant Information

The study recruited an older population, which can be expected as the prevalence of shoulder conditions increases with age (Tempelhof *et al.*, 1999; Yamaguchi *et al.*, 2006). A mix of dominant and non-dominant hand usage ensured both perspectives in terms of dexterity. Participants ranged from 10 weeks to 2 years following surgery for a range of shoulder conditions: bursitis, rotator cuff pathology, osteoarthritis, and adhesive capsulitis. The most common rehabilitation methods used by participants were manual therapy and elastic bands, followed by a pulley system. This shows that the majority of participants used in-clinic rehabilitation supplemented with at-home exercises. Elastic bands are not suitable for early rehabilitation as they are for resistive exercises. None of the participants had used electronic or robotic rehabilitation tools, all followed a tradition rehabilitation protocol. This is indicative of the average shoulder patient and provides a good base of experience to compare the Shoulder Mobiliser to. All participants had access to wireless internet and a smart mobile device, making the prospect of using an application to pair to the device

promising. Participants also indicated a range of confidence levels using mobile applications, indicating a suitable testing population.

3.5.2 Shoulder Impairment of Participants

On average, participants reported low-level pain as reported by the SPADI, with a mean pain score of 25.4%. Disability was also low-level, with a mean score of 17.0%. This is likely a result of participants not being in the acute phases of their conditions. However, there was noticeable variation between participants, as evidenced by the standard deviation of each score. This is not unexpected, as some participants were still in the later stages of rehabilitation, while others completed their treatment months prior. Overall, these SPADI scores suggest the testing population had some shoulder pain and disability but were not at high risk of injury if the device was used improperly.

3.5.3 Device Use

On average, participants spent approximately three minutes trialling the device. It was noticed that a number of participants struggled to push the joystick reliably, with some taking several tries to move the joystick before being successful. Participants also tended to initially use the device with an extended wrist and the fingers wrapped around the device more than the palm. A pronounced example of this is shown in Figure 19. Note that the palm is almost entirely off the device and the fingers are extended.

Figure 19: Initial device usage of one participant (006) with fingers resting on device

If this occurred for several repetitions of movement, the author re-demonstrated their hand position on the device. This redirection focused on placing the palm on the handle and wrapping the fingers around for a more secure grip. This also resulted in the device being more rotated away from the participant, that is, with the joystick closer to the surface of the table. Figure 20 shows the same participant after receiving further instruction on hand placement. Participants remarked that this positioning was more comfortable and secure, suggesting the importance of proper education and training prior to device use.

Figure 20: Corrected hand positioning of one participant (006)

The type of grip used by participants varied, with some placing their thumb on top of the handle, some placing it under the handle, and some placing parallel to the long axis of the handle (Figure 21). Participants with larger hands tended to rest their thumb on top of the handle, likely due to limited clearance with the table.

Figure 21: Variations in thumb positioning for three different participants

3.5.4 Usability Analysis

A mean overall SUS score of 90.4 was recorded, with a standard deviation of 4.7. Bangor *et al.* (2008) aggregated the data from over 200 studies and found an average SUS score of 69.69 and standard deviation of 18.00. This suggests that the Shoulder Mobiliser outperforms the average product in usability. A score of over 90 indicates excellent usability, high acceptability and is a 4th quartile result (Figure 22). Additionally, despite the relatively small sample size (n=7), a small standard deviation was recorded. This suggests low variability in perceived usability in the target demographic. This is further evidenced by low intra-item variability. While one may be tempted to assess the device based on its score for each individual item, this has been cautioned against by the author of the measure, Brooke (1995), who suggests that the overall score is the intended outcome of the SUS.

Figure 22: SUS scores by quartile, acceptability and categorical responses (Bangor et al., 2008)

3.5.5 Interview Findings

Participants raised a number of positives and areas of improvement during the semi-structured interviews. Overall, participants felt safe and secure using the device, and found it easy and comfortable to use. They found the diameter of the handle to be comfortable and many remarked that the grip size was appropriate following grip adjustment. While some participants were comfortable with the speed of the device, others felt it to be too fast and suggested variable speed options. The simple set up and portability of the device was seen to be a benefit of the device over other tools, along with its ability to track patient progress. A number of participants stated that they could appreciate the benefit of progress monitoring for both patients and clinicians. Almost all participants felt that this feature would be motivating and would encourage them to push themselves. It was suggested that

clinicians input periodic goals into the application in order to provide an aim and an expectation to attempt to meet. Interestingly, participants seemed to see more benefit to long term progress monitoring (on a day to week scale) over real-time feedback of distance travelled using the device. The most consistent suggestion across the group was to change the control switch to something other than the current low-profile joystick. Several participants struggled to use the joystick due to poor finger and hand dexterity. A participant with large hands and normal dexterity also struggled with the joystick. Suggestions for the control switch included a rocker or toggle switch, or a prouder joystick. In terms of feedback display preference, the group was split in opinion. Several participants supported having the majority of progress tracking functionality on a mobile application with real-time feedback displayed on the device itself. When asked if they would have liked to use a device like this during their rehabilitation, six out of seven participants responded positively. The participant who responded negatively felt that the device took away some of their control over the exercises. It should be noted that this participant felt the device would be useful for others but felt it would not have been necessary given how his rehabilitation progressed. In order to determine perceived value, participants were first asked what they would pay outright to purchase the device. Responses varied from 50 to 500 dollars, with most participants quoting a range. The majority of participants quoted a value around 100 dollars. They were then asked what they would pay on a weekly basis to rent the device. Again, responses varied considerably, between 5 and 100 dollars per week. The average response was around 20 dollars per week. A number of participants stated that their answer would depend on if the device reduced the need to purchase other tools, reduced the frequency of clinic visits, or was clinically proven to improve outcomes. Finally, all participants were amenable to using a charging dock. This was largely due to the fact that the dock prevents the device from rolling when not in use.

3.6 Study Limitations

This study had small sample size (n=7), limiting the ability to generalise the findings for a larger population. Since participants were recruited from a physiotherapy practice, they had all sought out physiotherapy for rehabilitation of their shoulder conditions. As such, they were all relatively compliant patients. Therefore, responses may be positively skewed

compared to the larger population of those who are indicated to have rehabilitation. The study is also limited by the inclusion criterion of non-acute patients. As such, acute patients were not surveyed. It is possible that this group may respond less positively to the device, most likely due to increased pain and guarding of potentially painful shoulder movements. Potential participants were first contacted via email, and those who did not respond were then contacted via post to their residential address. However, only those in the first group responded, that is, all participants were ultimately recruited through email. Given the older target demographic, this may have skewed results as those who are active on email may be more likely to accept new technology. Those contacted who were not amenable to the idea of a new device in this area may have also been less likely to respond to the participation invitation. Due to the nature of the study design, participants had limited device use time and were supervised throughout their use. As such, the outcomes of this study may not reflect their opinions and acceptability of the Shoulder Mobiliser in their home environment.

Chapter 4: Muscle Activation Study

4.1 Introduction

Rehabilitation exercises are often assessed using electromyography (EMG) to determine the level of muscle activation they produce. This can determine if the exercise is suitable for early rehabilitation, when all motion must be passive. This is quantified in the literature as producing less than 20% maximum voluntary isometric contraction (MVIC). This study aimed to assess the Shoulder Mobiliser's appropriateness for early rehabilitation by assessing muscle activation during use.

4.2 Aims

The aims of the muscle activation study were as follows:

- Determine superficial shoulder muscle activation during device use
- Compare results using this protocol, set up and processing methods to published results in the literature

4.3 Methods

4.3.1 Participants

This study used four participants from within the project team. As a result, as the study was low risk, ethics approval was not required. It was ensured that participants had no shoulder pathology or pre-existing pain to prevent any injury during MVIC exercises. The use of able-bodied participants is consistent in the literature, likely due to this reason.

4.3.2 Overall Study Flow

The full study protocol is included in Appendix H. The overall flow of this study is shown in Figure 23.

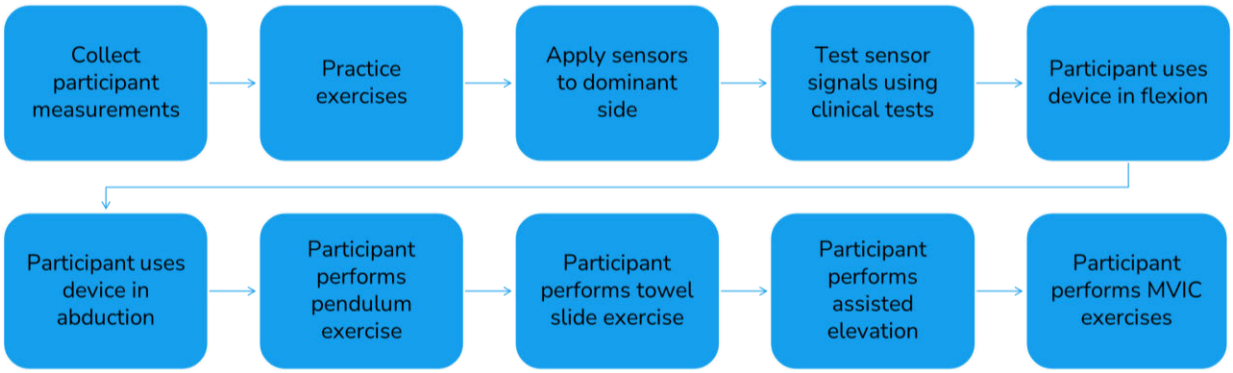

Figure 23: Muscle activation study flow

4.3.3 Collection of Participant Information and Measurements

Participants' age, height and weight were recorded. Four measurements relating to arm length were also taken: elbow-centre of grip length, forearm-hand length, lower arm length and shoulder-elbow length. These measurements served to characterise the physical variations between participants. Participants were recruited from within the supervisory team, therefore ethics approval was not required.

4.3.4 Targeted Muscles and Sensor Application

The Delsys Trigno wireless system was used to collect EMG data. These are surface sensors applied to the skin, and hence they can only collect data from superficial muscles. The main muscles of the shoulder complex are the deltoid, trapezius and rotator cuff muscles (Boykin *et al.*, 2010; Srebnik, 2002). The rotator cuff muscles lie largely beneath the deltoid and trapezius (Figure 24). As such, only the deltoid and trapezius can be targeted using the Delsys Trigno system. This selection was confirmed as appropriate by the physiotherapist and orthopaedic surgeon on the project team.

Figure 24: Posterior view of shoulder muscles (left – superficial, right – trapezius and deltoid removed) (Hansen, 2010)

This study aimed to target the anterior, medial, and posterior deltoid, as well as the upper, middle, and lower trapezius using a total of six sensors. The SENIAM guidelines for the placement of surface EMG electrodes were used to identify sensor positions (SENIAM, 1999). The relevant guidelines are included in Appendix I. These positions were identified by project member and physiotherapist Mr Luke Mason using a permanent marker on the skin of the dominant arm. The skin was then prepared using alcohol wipes to remove oil and excess skin cells prior to applying the sensors to the skin using the Delsys sensor stickers. The sensors were secured using skin-safe tape. The SENIAM clinical test for each muscle was then performed in order to check sensor positioning. These tests aimed to determine if the sensor was in the correct position and had adequate contact by selectively activating the muscle of interest. The approximate positions of the sensors are shown in Figure 25.

Figure 25: Surface EMG sensor positioning

Adapted from: (Complete Anatomy, n.d.)

4.3.5 Exercises Performed

Participants used the Shoulder Mobiliser in flexion and abduction from a seated position, with five repetitions for each motion. They were instructed to use the device to the point of a comfortable stretch; no distance limits were enforced. Three common rehabilitation exercises were chosen to be performed by participants: pendulums, towel slide, and supine assisted elevation. These were selected as several studies have collected EMG data for these exercises, and they are relatively easy to perform with limited equipment. As such, the results from these exercises could be compared with existing data in order to assess the protocol used. Participants practiced each exercise prior to data collection to become comfortable with them and warm up the muscles. Pendulums were performed at 40 beats per minute, for a total of ten seconds. The towel slide was performed from a seated position, with the elbow extended at the starting position. Participants slid the towel forward to the point of a comfortable stretch and then returned to the starting position for

a total of five repetitions (Figure 26). Supine assisted elevation was performed by interlacing the fingers and assisting using the non-dominant arm (Figure 27).

Figure 26: Towel slide exercise

Figure 27: Supine assisted elevation exercise

MVIC exercises were performed following other exercises in order to prevent fatigue. Four exercises were used, as proposed by Boettcher *et al.* (2008). These were each performed for two repetitions at maximum effort for at least three seconds. Rests of 30 seconds and 60 seconds between repetitions and between exercises respectively were enforced. A goniometer was used to measure relevant joint angles to ensure the MVIC exercises were performed appropriately.

4.3.6 Signal Processing

All data was processed in the MATLAB software package using the method shown in Figure 28. Appendix J contains the MATLAB processing code used. All filters applied were 4th order Butterworth filters. This processing method is consistent with the majority of the literature. Specific values were obtained from 'Electromyography: physiology, engineering, and non-invasive applications' by Merletti and Parker (2005) as it shares an author with the SENIAM guidelines.

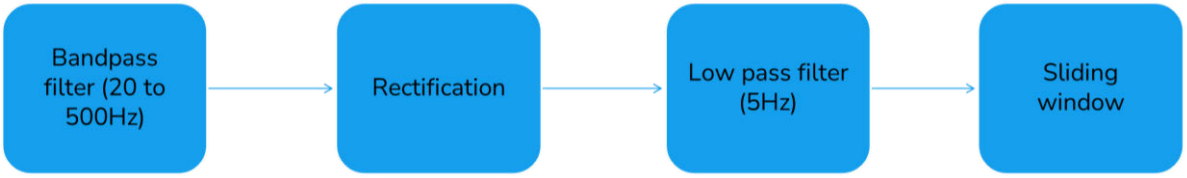

Figure 28: EMG signal processing steps

The MVIC signals were graphed against time, and the peak value for each muscle used as its MVIC value. All other data was then normalised against the MVIC value for each muscle. A graph of %MVIC over time was created for each muscle in each exercise. With the first and last repetitions eliminated, the peak value for each muscle was then extracted.

4.4 Results

Collected participant information and measurements are displayed in Table 5 below.

Table 5: Participant information and measurements (n=4)

	Participant number				
	1	***2***	***3***	***4***	***μ ± SD***
Age (years)	22	47	46	28	35.8 ± 11.0
Height (cm)	168	185	177	184	178.5 ± 6.8
Weight (kg)	62.5	80.0	85.6	76.1	76.1 ± 8.5
Elbow-grip length (cm)	34	38	36	37	36.3 ± 1.5
Forearm-hand length (cm)	45	51	50	50	49.0 ± 2.3
Lower arm length (cm)	25	29	28	26	27 ± 1.6
Shoulder-elbow length (cm)	34	38	38	37	36.8 ± 1.6

Note. μ and SD refer to mean and standard deviation respectively.

Figure 29 shows a raw EMG signal trace with the processed signal overlaid in yellow. This shows the typical results of the processing method used.

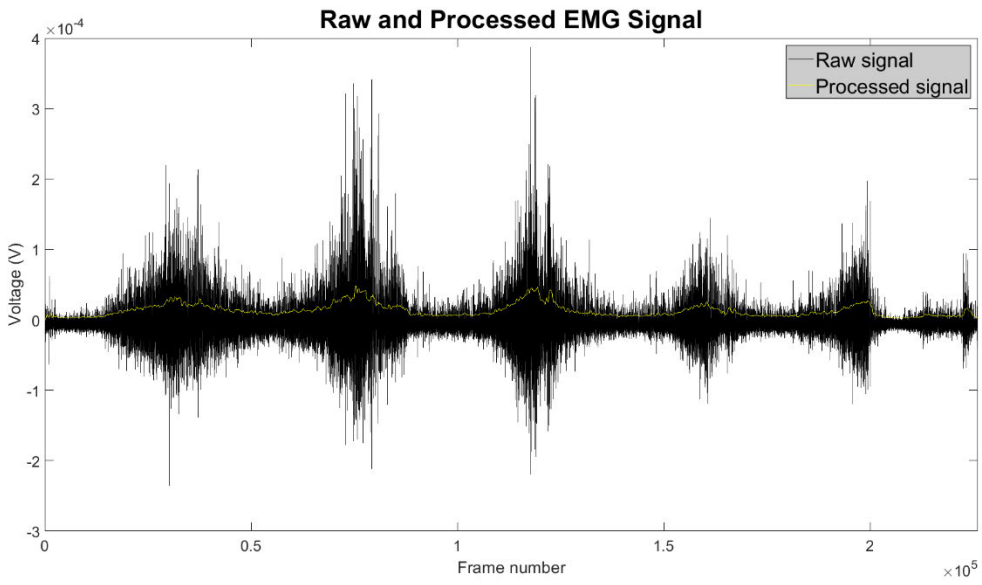

Figure 29: Example of signal processing results (data from medial deltoid during device use in flexion)

The muscle activation using the device in flexion and abduction are displayed in box and whisker plots in Figure 30 and Figure 31 respectively.

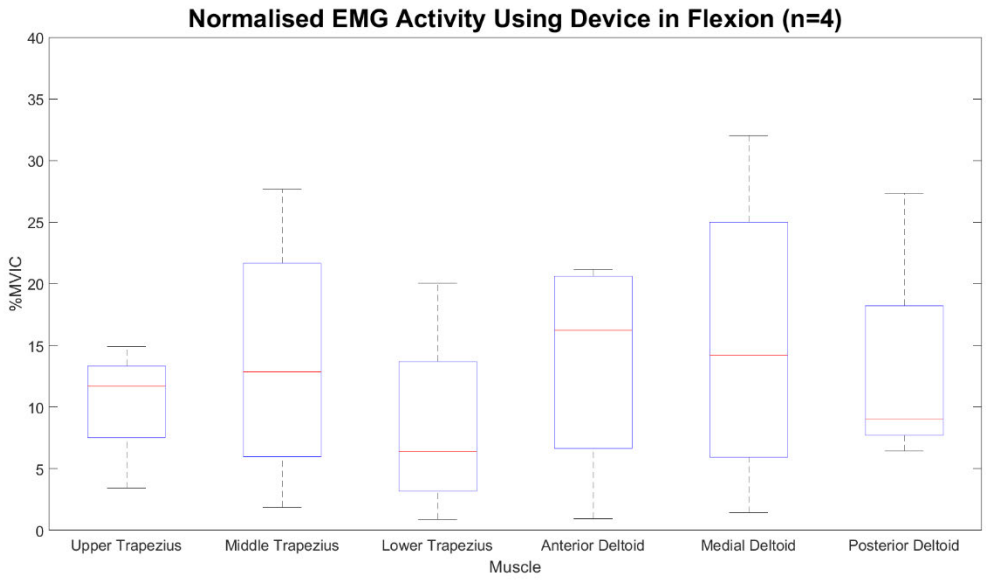

Figure 30: Normalised EMG activity using device in flexion (n=4)

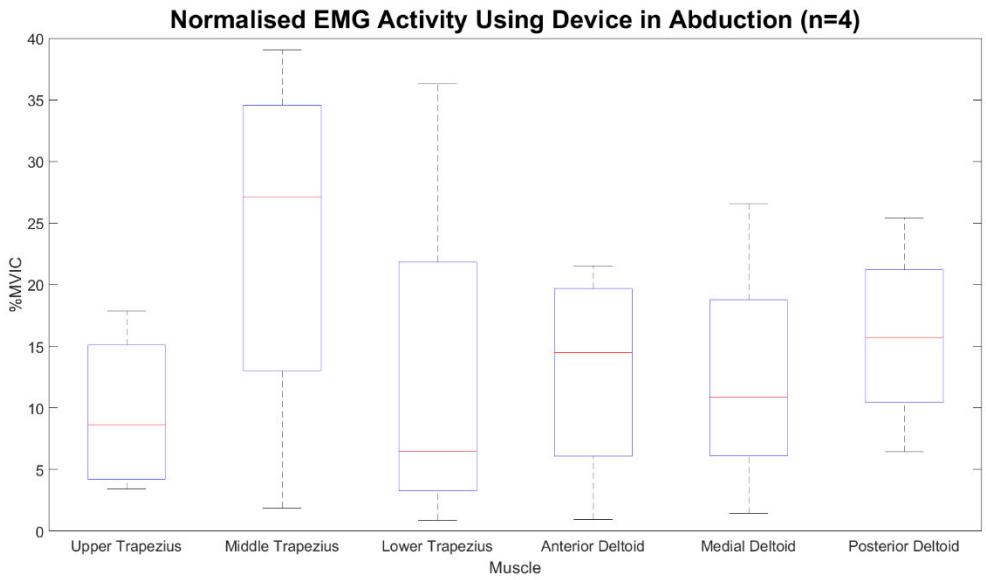

Figure 31: Normalised EMG activity using device in abduction (n=4)

Note. For Figures 30 and 31, the red line represents the median, the blue box represents the interquartile range, and the whisker bounds represent the data limits.

Figures 32, 33 and 34 compare the median muscle activation found in the present study to published studies for pendulum, towel slide, and supine assisted elevation exercises.

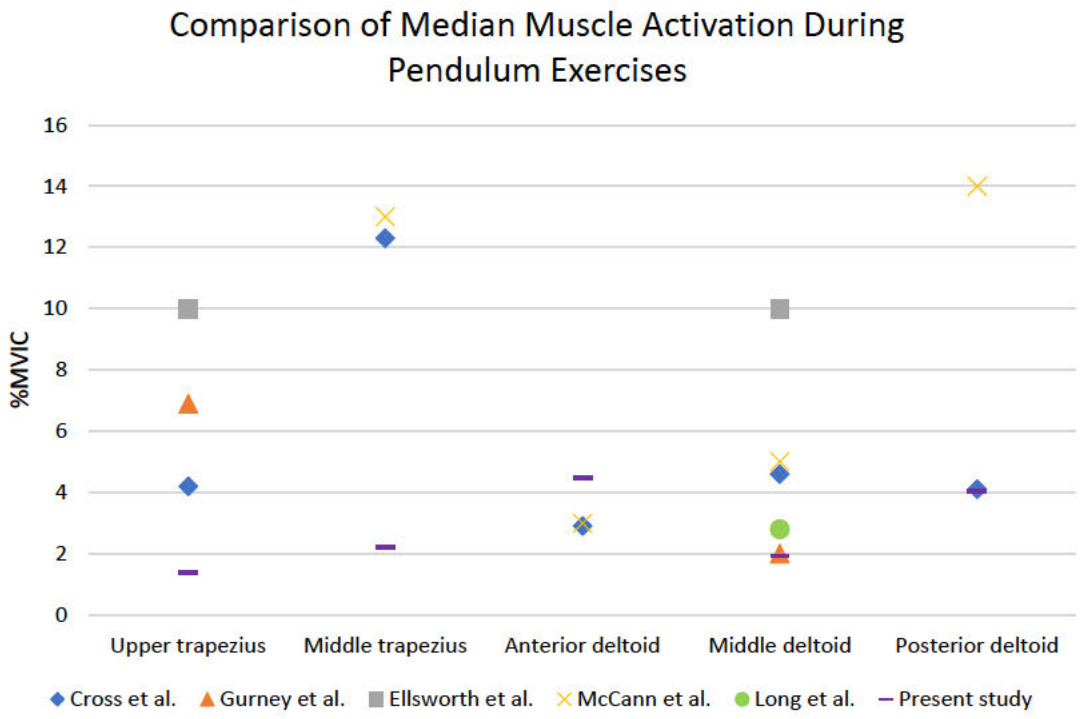

Figure 32: Comparison of median muscle activation during pendulum exercises (Cross et al., 2020; Ellsworth et al., 2006; Gurney et al., 2016; Long et al., 2010; McCann et al., 1993)

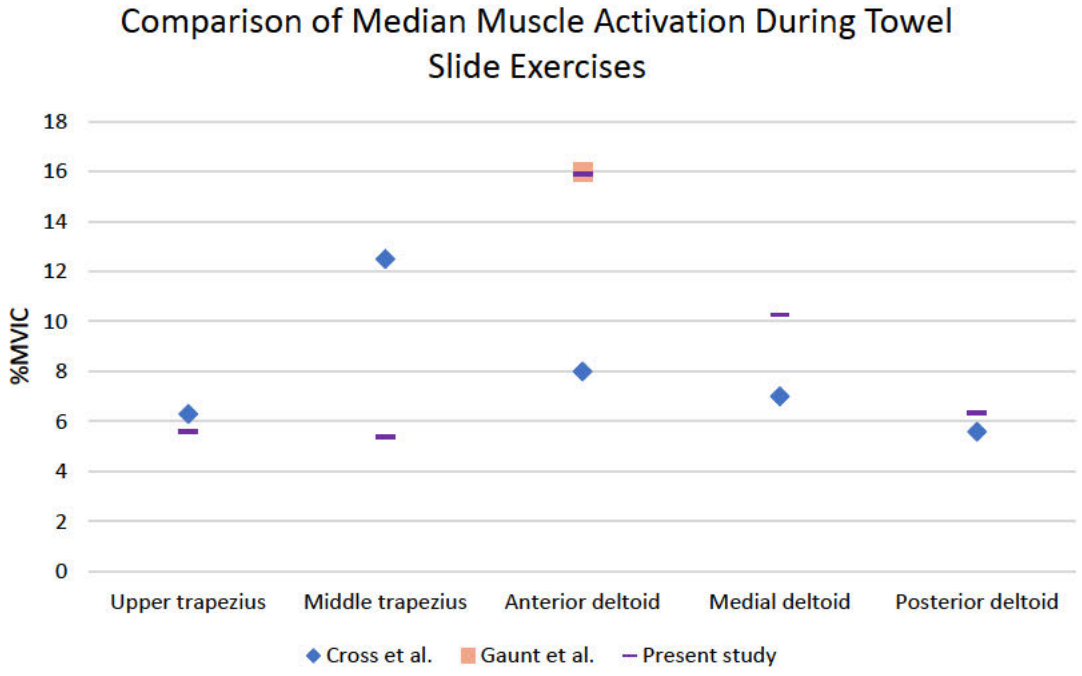

Figure 33: Comparison of median muscle activation during towel slide exercises (Cross et al., 2020; Gaunt et al., 2010)

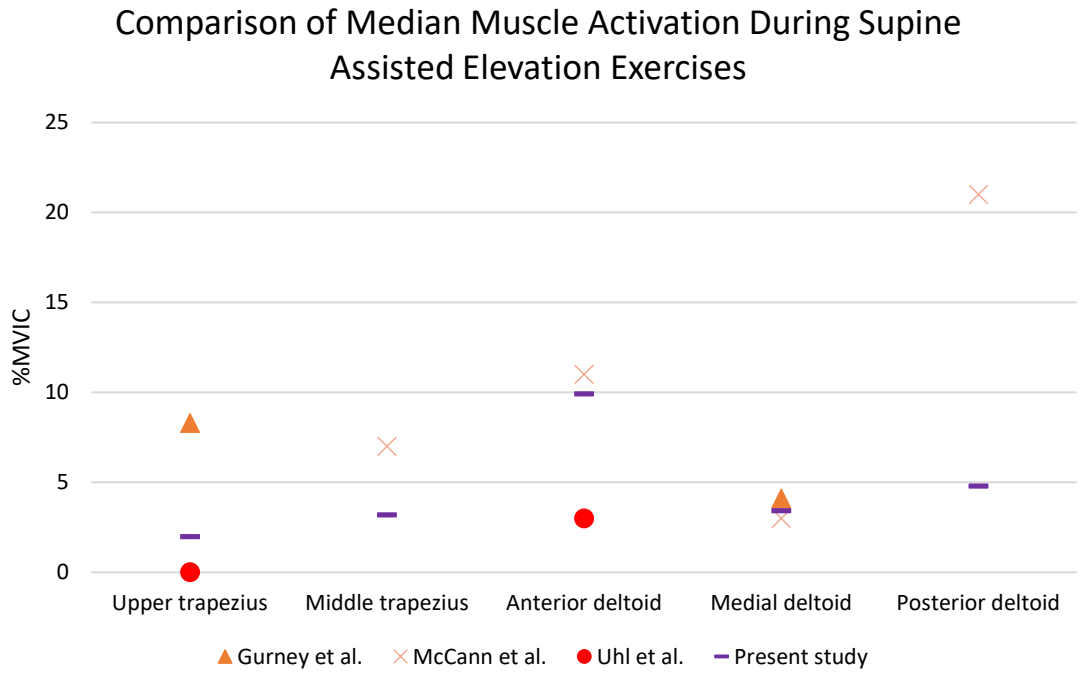

Figure 34: Comparison of median muscle activation during supine assisted elevation exercises (Gurney et al., 2016; McCann et al., 1993; Uhl et al., 2010)

4.5 Discussion

4.5.1 Participant Information and Measurements

Across the four participants, there was a mean age of 35.8 years with standard deviation of 11.0. This is a relatively young sample without much spread. Limited spread exists for the participant measurements. Therefore, the results of this study may be not appropriate for generalisation to the general population, especially given shoulder pathology incidence increases with age.

4.5.2 Muscle Activity Using Device

The median values for all investigated muscles when using the device in flexion were below 20% MVIC, indicating passive motion. This was also true of abduction, except for the middle trapezius, which recorded a median of 27.1% MVIC. This finding was discussed with the project team, which included a physiotherapist and orthopaedic surgeon. They felt that the

middle trapezius is a dynamic stabiliser of the scapula, and that a higher value is not unexpected. However, they also felt that this finding does not hold much clinical relevance due to the trapezius being rarely impacted by the surgeries prior mentioned. As such, they believed that the deltoid values were more indicative of the appropriateness of the device for early rehabilitation. While the activity of the rotator cuff muscles cannot be inferred from surface activity, they suggest that the anterior deltoid is likely the closest proxy out of the muscles measured. The anterior deltoid recorded median values of 16.2% in flexion and 14.5% in abduction, with maximum values of 20.1% and 21.5% respectively.

There was considerable spread within the data, as indicated by large interquartile ranges and data maxima and minima. Given this variation between participants, it is likely that the sample size of four was not sufficient to fully characterise muscle activity in these exercises. Comparable studies (those included in Figures 32 to 34), report sample sizes between 10 and 28. An increase in sample size may reduce the interquartile ranges and allow outliers in the data to be identified. The variation between participants is possibly due to differences in how the movements were performed. Participants received limited instructions on how to replicate each movement. As such, it is recommended that future participants be instructed by a physiotherapist to ensure they are allowing the shoulder muscles to remain relaxed. It is also possible that crosstalk from nearby muscles resulted in a summation of electrical activity at electrodes. Inter-electrode distances and angles varied depending on participant anatomy. This effect is more likely at the middle trapezius and medial deltoid electrodes. This may explain some of the increased activity seen at the middle trapezius. Another possible source of error is the effort exerted by participants during MVIC activities. If participants did not maximally activate all muscles, either due to fatigue, decreased drive or improper replication of exercises, their results may be over- or under-inflated.

4.5.3 Comparison to Published Literature

There appears to be considerable difference between the present study's results and the published literature for the three classic rehabilitation exercises (Cross *et al.*, 2020; Ellsworth *et al.*, 2006; Gaunt *et al.*, 2010; Gurney *et al.*, 2016; Long *et al.*, 2010; McCann *et al.*, 1993; Uhl *et al.*, 2010). However, there does not appear to be any pattern in these differences. This protocol did not consistently over- or under-shoot the results of other

studies, however, this analysis is limited by the small sample size of this study and that each study had a different patient cohort. This, coupled with the fact that the published studies do not report raw data, makes it difficult to make a fair and statistically sensible comparison in order to validate this study's protocol. There was also considerable spread between the results of published studies for the same exercises. This may be due to a number of factors. Firstly, studies used different electrodes and processing methods. The size of these differences varied. Some reported a similar process to the present study with variations in filter cut-off frequencies and smoothing methods, while others used recursive filters or integration methods to estimate average muscle activity. Sensor placement protocols also varied, along with the level of instructions provided to participants. It was noted that the majority of studies failed to clearly describe the exercises performed, such as the speed and size of pendulums, distance travelled in towel slides and angle of elevation reached in supine assisted elevation.

Chapter 5: Prototype Redesign

5.1 Introduction

A redesign of the Shoulder Mobiliser aimed to improve the usability, viability and feasibility of the device. Results from the usability study helped to guide this redesign, allowing participants' concerns to be addressed. The viability of the device was to be improved by reducing the cost of the Shoulder Mobiliser and adjusting the design to allow for manufacturing scalability. The end point of this goal was a completed design outline and bill of materials for the third Shoulder Mobiliser prototype.

5.2 Redesign Objectives

Issues with the second prototype were identified within the project team and from feedback collected during the usability trial. In terms of viability, the project team expressed a need to lower the cost of the subsequent prototype to a production cost of under $300 AUD. This figure was selected due to the planned business model for the Shoulder Mobiliser. Ideally, the device would be purchased by a physiotherapy clinic, who would then rent out the device to patients for at-home use during their rehabilitation. Participants from the usability study were satisfied with a weekly cost of around $20 AUD. Given the markup from production cost to selling cost and further cost reduction related to scaling of manufacturing quantities, we expect that clinics would be breakeven following around two to three patients renting the device each for approximately six weeks. The team also felt that this cost was acceptable given the societal cost of failed rehabilitation at $7000 AUD per patient developing adhesive capsulitis.

Two main recommendations were found from the usability study: incorporate a feedback display onto the device and change the mechanical switches on the device. Several participants preferred displaying real-time feedback on the device over displaying it on a mobile application. In terms of the switches, the joystick used to control the motion of the device was felt to be too difficult to actuate reliably (Figure 35). Additionally, the author aimed to integrate a more appropriate power switch as this was temporarily mounted to a wire access hole in the handle of the second prototype (Figure 36). In order to allow charging without removing the batteries of the device, a charging port was also required.

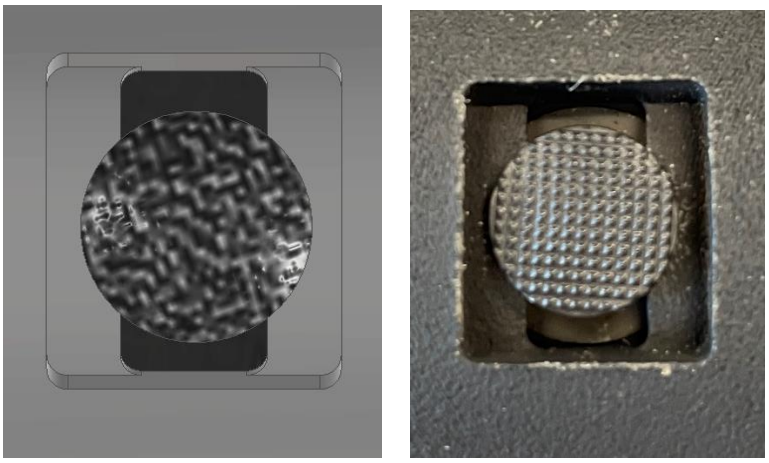

Figure 35: Second prototype control switch CAD model (left) and on device (right)

Figure 36: Second prototype power switch

A magnetic closure hatch was deemed not suitable for the end product (Figure 37). A more permanent closure mechanism was required, to ensure that users wouldn't access internal electronics while allowing the device to be disassembled for servicing. While prototypes of the Shoulder Mobiliser handle were produced using 3D printing, this was not seen as feasible for mass manufacturing. As such, the handle design needed to be adapted to be suitable for injection moulding.

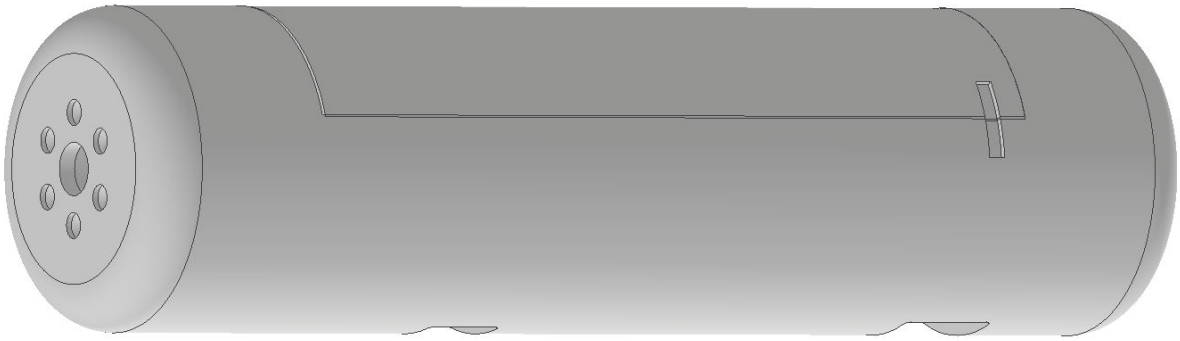

Figure 37: Second prototype handle with removable magnetic hatch

5.3 Results

5.3.1 New Motor Selection and Integration

The major viability issue of the Shoulder Mobiliser was the cost of the components. This was largely due to the motors used in the current prototype, accounting for over 90% of the $1400 mechanical component cost. Cheaper motors would likely have trade-offs relating to longevity, reliability, control capability, size and noise. In order to appropriately select new motor options, a list of required specifications was created (Table 6).

Table 6: Motor selection criteria

Specification	**Metric**
Operating torque	Approximately 1.5 Nm
Operating speed	Approximately 17 rpm
Encoder included	Yes
Motor type	Brushed DC motor
Cost	< $50 AUD
Diameter	< 49 mm
Length	< 60 mm
Shaft diameter	4 to 6 mm

The required stall torque and operating speed were determined prior to this project. Brushed DC motors with encoders were preferred as they are generally cheaper and easier

to control than brushless motors, and more energy efficient than stepper motors. DC motors are also compatible with DC batteries. Encoders would allow for tracking of patient progress based on distance travelled, as was implemented in prior prototypes. The length and diameter limits were based on having a minimum of 100 mm of length between the two motors to allow for internal electronics to fit comfortably. The author aimed to use the same 100 mm diameter polyurethane wheels as previously used. These are compatible with commercially available wheel adapters, suitable for shaft diameters between 4 and 6 mm.

Two motors were found that met of the above criteria. The first was a brushed DC gearmotor with a photoelectric encoder from Aslong for a price of AUD$16.64, with a 500:1 gearbox to achieve an operating speed of 13 rpm at an operating torque of 1.37 Nm (Figure 38). This motor has a total length of 58 mm and diameter of 25 mm.

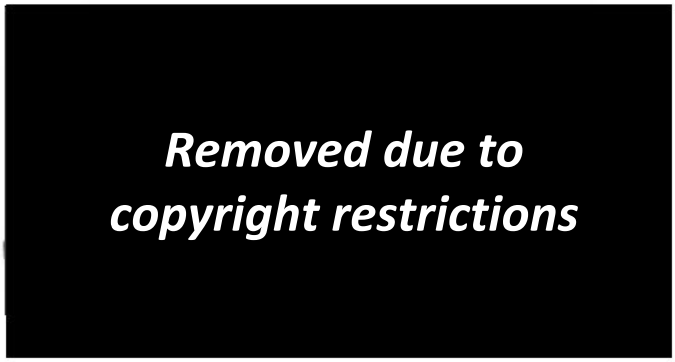

Figure 38: Aslong motor (Aslong, n.d.)

The second motor was a brushed DC gearmotor from Bringsmart with a magnetic encoder at AUD$13.46 (Figure 39). This motor is coupled to a 506:1 helical gearbox to operate at 16 rpm at 1.56 Nm. This motor has a length of 51 mm and diameter of 37 mm. However, this motor has an offset shaft, meaning that it would need to be located asymmetrically in the cross-section of the handle, effectively increasing the diameter required to 51 mm.

Figure 39: Bringsmart motor (Bringsmart, n.d.)

Since both of these motors were not able to be tested prior to the end of this project, two designs were created to accommodate for each. The Aslong motor was the preferred option due to its smaller diameter and central shaft. This will be referred to as motor option A from here on, and the Bringsmart referred to as motor option B.

For motor option A, limited changes were needed to the overall form of the device handle. The handle was lengthened from 206 to 256 mm to allow for 100 mm of free space between the motors. The inner and outer diameters of the handle remained at 49 and 55 mm respectively. The motor mounting holes at the two ends of the handle were adjusted to fit this motor (Figure 40). Figure 41 shows the overall form of this handle.

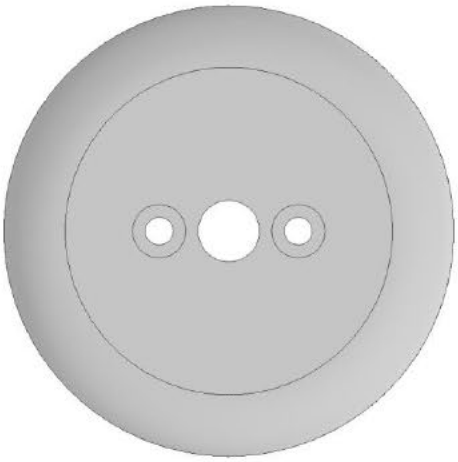

Figure 40: Side view of option A handle

Figure 41: Isometric view of option A handle form

Motor option B required a change to the overall handle form due to its offset shaft. Firstly, the motor was positioned asymmetrically to allow the motor shaft to be aligned centrally (Figure 42). Because of this offset, a larger diameter was needed to accommodate the motors. For the motors to lay flush against the inner diameter of the handle, a 51 mm diameter circular cross section was required at the ends of the handle. Since the grip size was found to be appropriate during the usability study, only the ends were flared (Figure 43). This allowed for the middle section of the handle to maintain the original grip size. 100 mm of hand width was accommodated for. According to the Anthropometric Survey of US Army Personnel published by Gordon *et al.* (1989), this accommodates up to the 98th percentile male in terms of hand width.

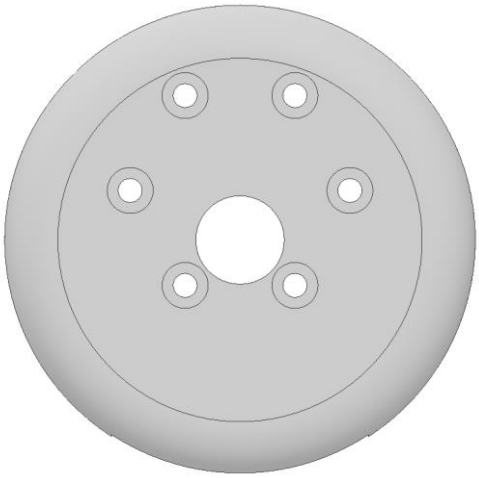

Figure 42: Side view of option B handle

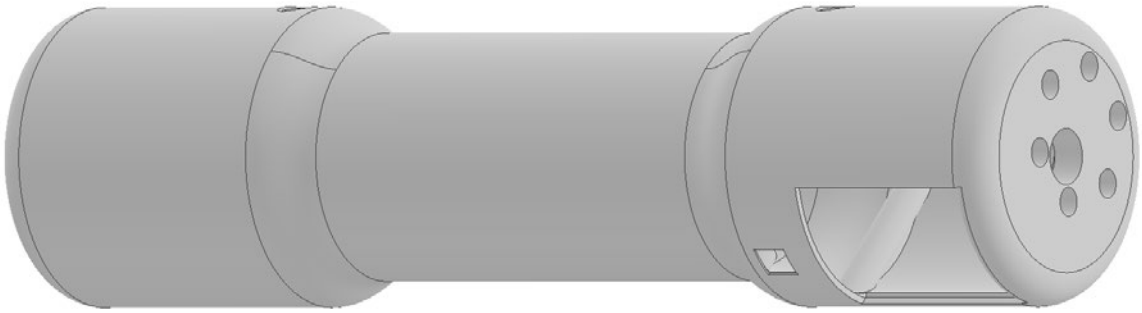

Figure 43: Isometric view of option B handle form

5.3.2 Modifications for Scale Manufacturing

In order to be injection moulded, the handles must be split into parts and assembled after moulding. This is to allow the model to be removed from the moulding die. A longitudinal split was used for both handles. This was preferred over a transverse split as this would produce a line of weakness where the user rests their hand and grips the handle (Figure 44).

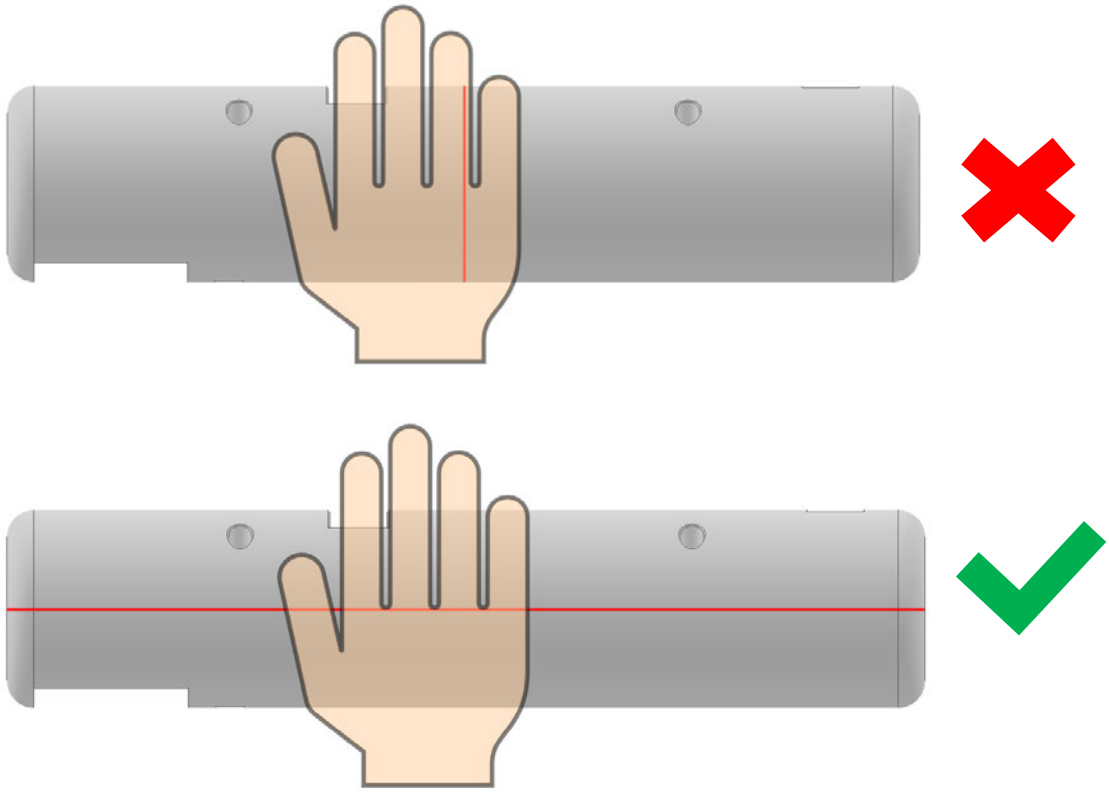

Figure 44: Transverse split (top) versus longitudinal split (bottom) with red line indicating split line

This longitudinal split would require two injection moulding dies, each producing half of a handle. Figure 45 shows the two handle halves for option A, along with the pull direction that would be used to remove them from their dies. The same process would be followed for the option B handle. The motor mounting holes at the ends of the handles would then be drilled after removing the parts from their dies.

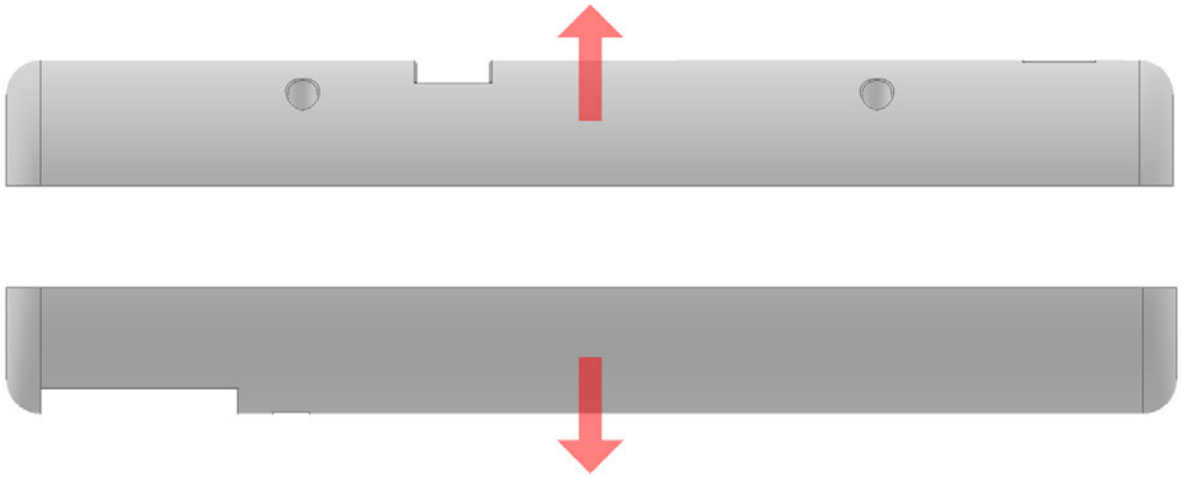

Figure 45: Handle halves for option A with pull direction indicated

This split line and pull direction dictate the shape of features within the handle halves. In order to allow the parts to be removed from their dies, features must be parallel to his pull direction.

In the second prototype, the motors were supported by cylindrical features to relieve the strain on the mounting points (Figure 46). Following discussion with the consultant electronics engineer of the project team, Dr Aaron Mohtar, it was decided to hollow the section between the motor support surface and the inner surface of the handle. This would create more space for electronics to be mounted. It would also reduce the mass of the models.

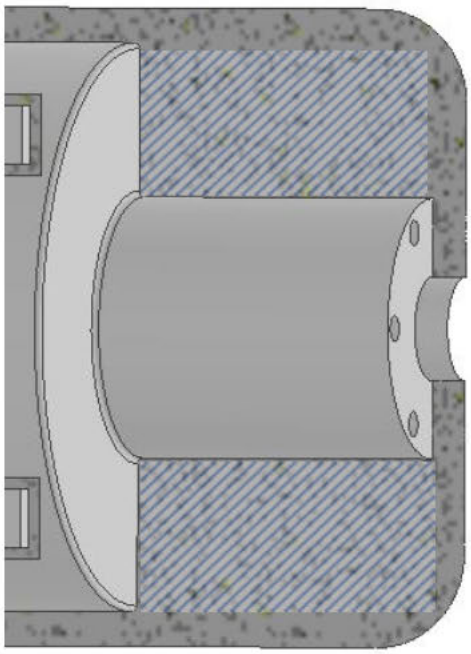

Figure 46: Second prototype motor support with wasted space hatched in blue

Originally, this was space simply hollowed out, as shown in Figure 47. However, this was not a suitable solution, as this feature would prevent the handle moulds from being removed from their dies using the given pull direction.

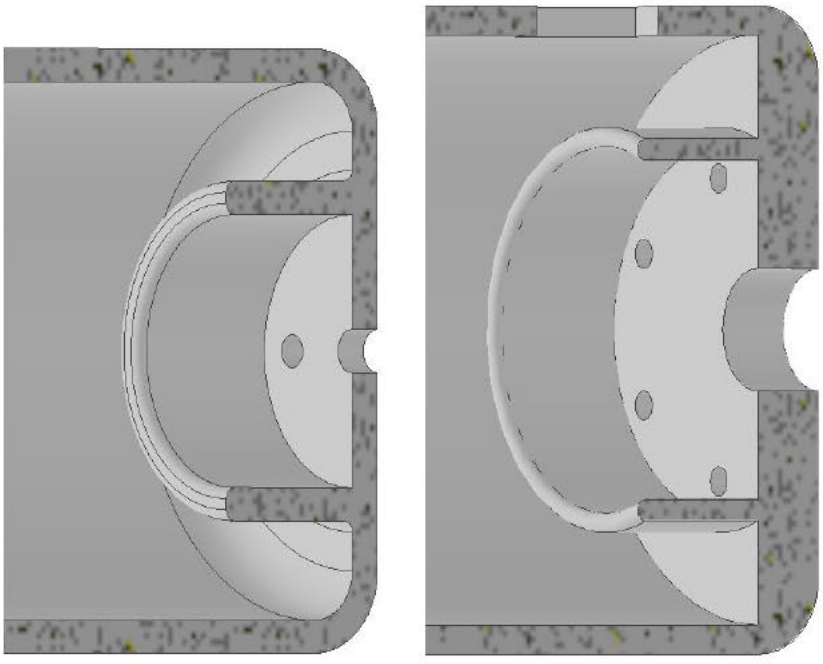

Figure 47: First iteration of motor support structure for option A (left) and option B (right)

This feature was adapted to allow for mould removal, while still allowing the motors to be supported. This feature for the two handle options is shown in Figure 48.

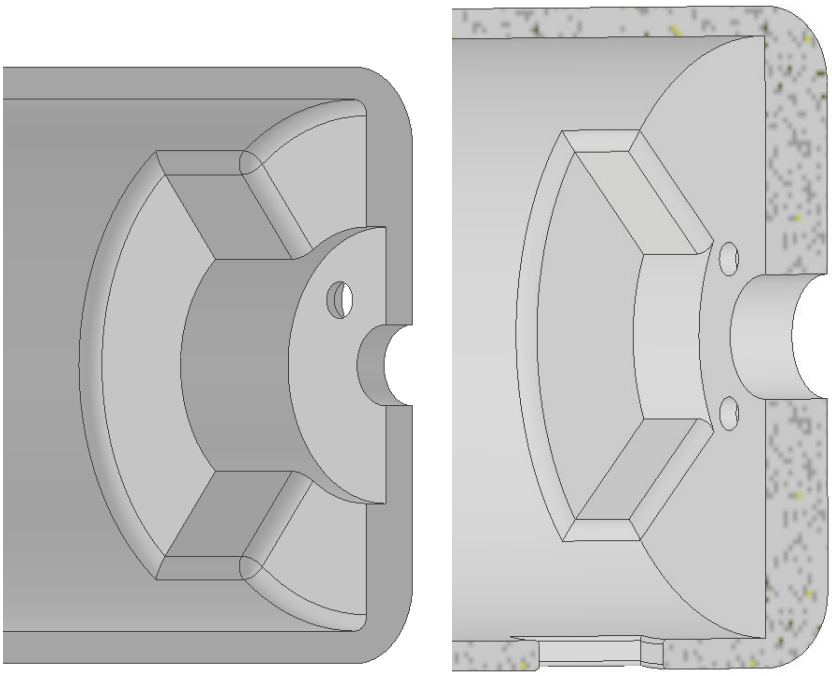

Figure 48: Final motor support structure for option A (left) and option B (right)

In order to secure the two handle halves together, four mounting bosses were added to the models (Figure 49). Four holes are located on the other handle piece to allow screws to be inserted (Figure 50). These bosses were designed to have M3 screw inserts pressed into them, to allow the two handles to be screwed together. This option was chosen over self-tapping screws as it allows for more assembly cycles.

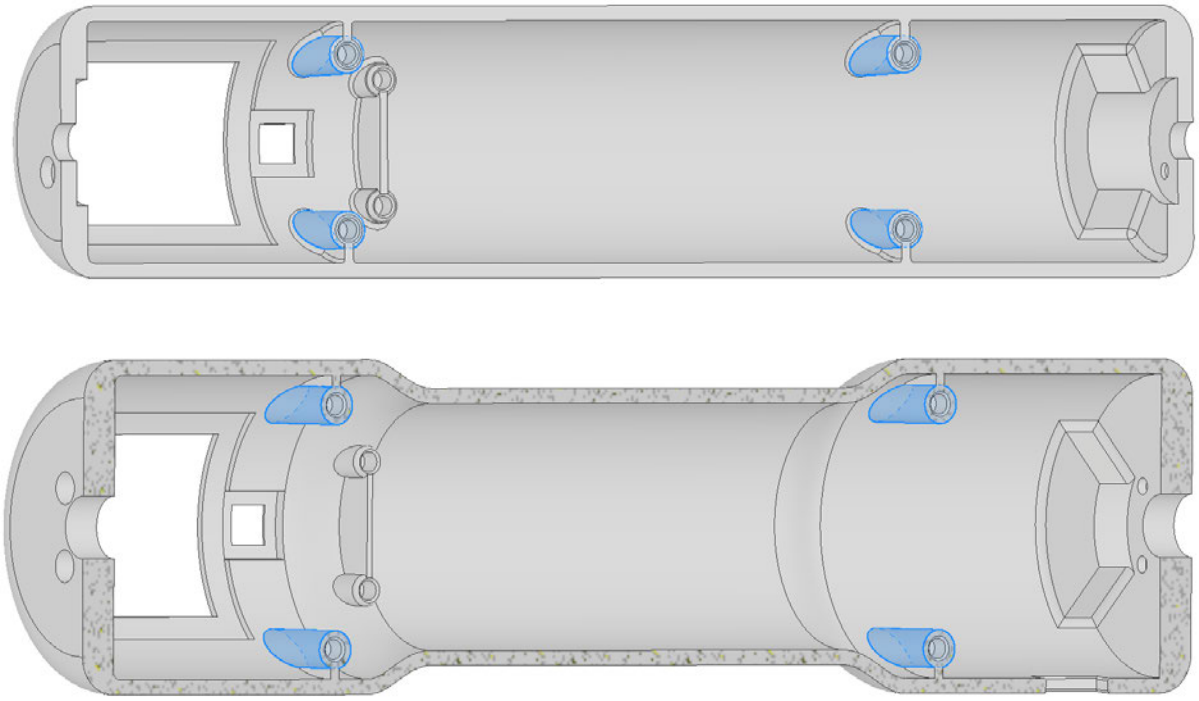

Figure 49: Handle assembly mounting bosses on option A (top) and option B (bottom) handles

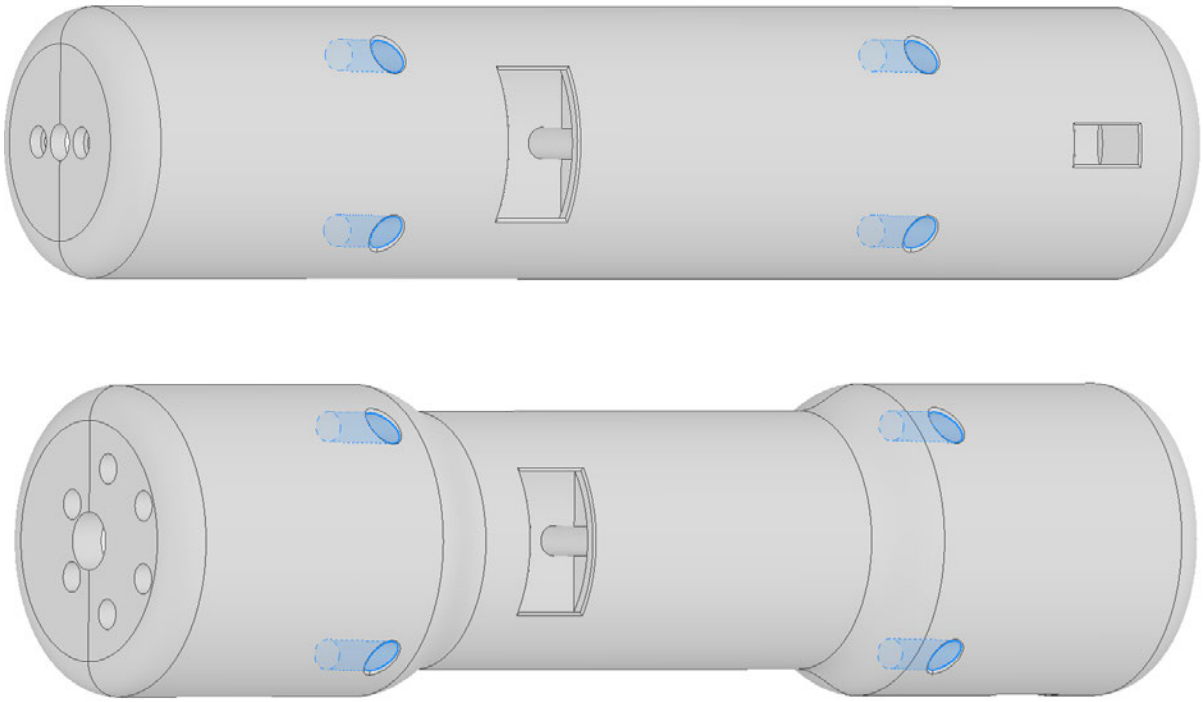

Figure 50: Handle assembly mounting boss holes on option A (top) and option B (bottom) handles

The mounting bosses were designed with a wall thickness of 1.8 mm. This fits to the general recommendation of a boss wall thickness of 60% of the surrounding wall thickness (Shelke, 2016). This standard prevents sink marks when injection moulding. Fillets of radius 0.75 mm were applied at the base and tip of all bosses. Chamfers were also included at the upper inner edge of each boss to allow lead in for the screw inserts. 2 mm thick ribs to the nearest wall ensure rigidity and improve material flow (Shelke, 2016). Finally, a 1-degree draft was applied to all bosses. This further ensure easy removal of the models.

Figure 51 below shows a cross-sectional view through two of the mounting bosses. This illustrates how the handle assembly screws are inserted and the two pieces secured.

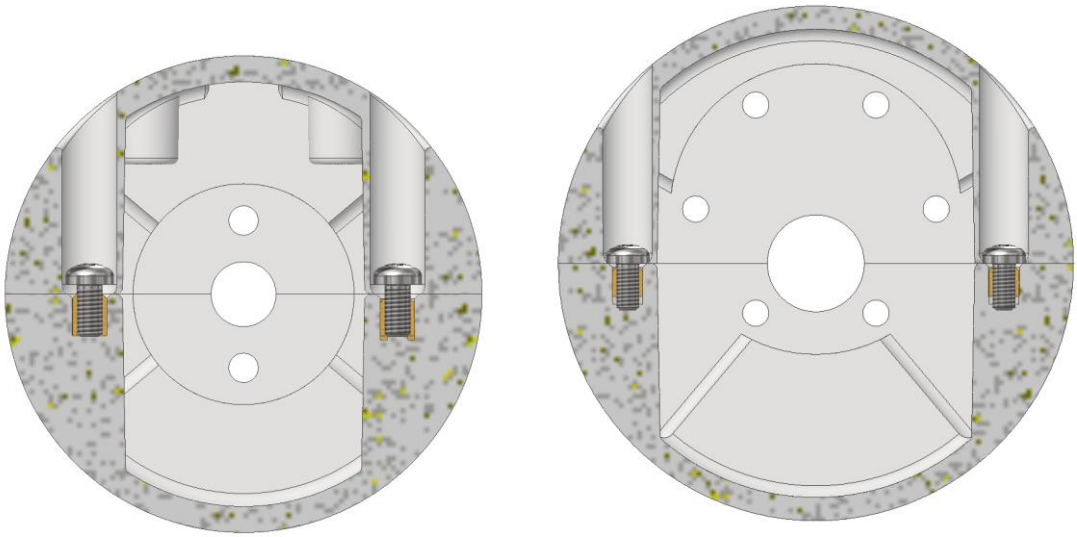

Figure 51: Cross-sectional view through mounting bosses on option A (top) and option B (bottom) handles

5.3.3 Feedback Display on Device

In order to provide real-time feedback on the device itself, a display screen was integrated into each handle. This was positioned medial to the hand position and at 180 degrees to the control switch. Screen covers were modelled to be flush with the outer surface of each of the handles and would be glued into the handle. These screen covers would be injection moulded from a transparent plastic such as acrylic or polycarbonate. An LCD was selected for use, and a support base added to each screen cover (Figure 52). This LCD could display distance travelled, number of repetitions and battery charge level. It could also act as a power and charging indicator. Figure 53 shows the handle cut-out for the screen cover on option A, while Figure 54 shows the screen cover integrated into the option A handle.

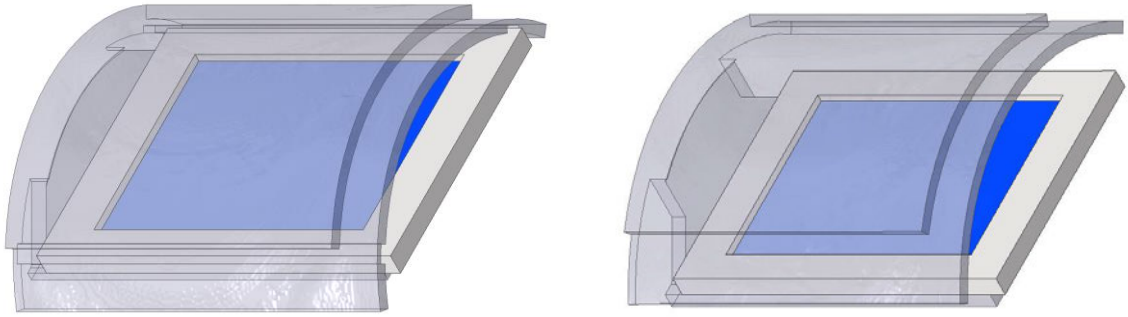

Figure 52: Option A (left) and option B (right) screen cover and LCD assembly

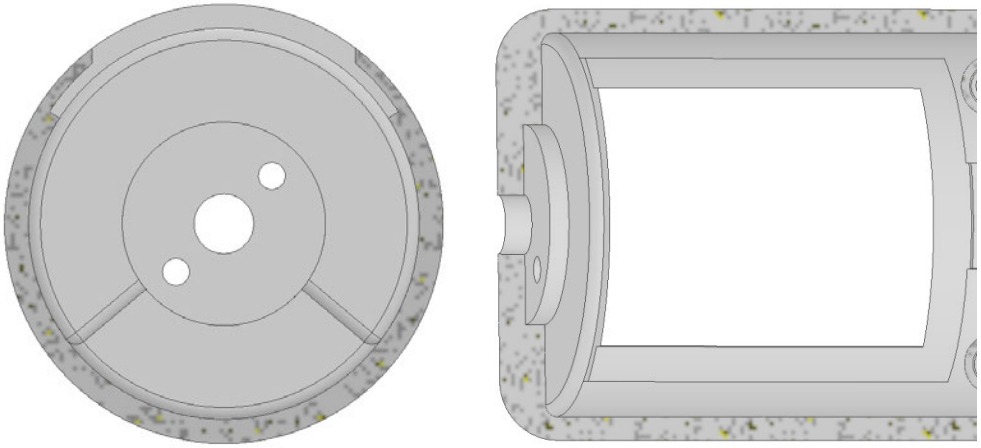

Figure 53: Option A screen cover cut-out

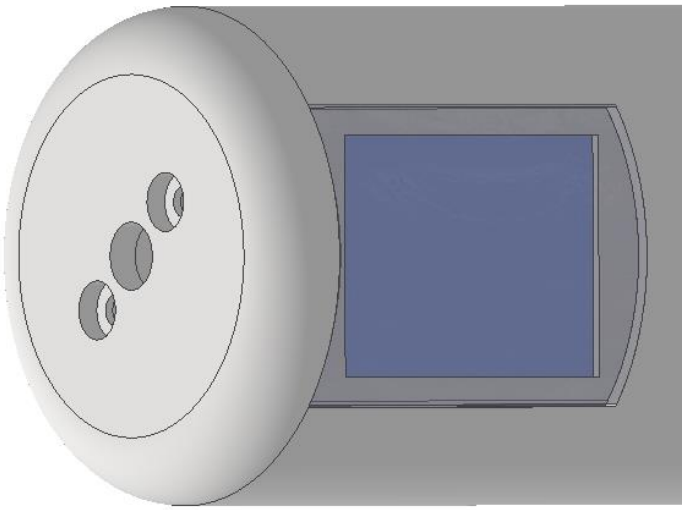

Figure 54: Screen cover and LCD integrated into option A handle

5.3.4 Switches and Charging Port

A number of requirements for the control switch were identified within the project team and the usability study participants. Firstly, the switch must be momentary, with the switch returning to neutral in the absence of input. This ensures that a constant input is required to actuate the motors. This requirement improves the safety of the device by reducing the risk of accidental activation at end range of motion. As with the previous joystick, the new switch should travel in a manner consistent with the directions of motion of the device. That is, pushing the switch away from oneself should produce motion away from oneself and pushing the switch towards oneself should produce motion away from oneself. Therefore, the switch must be actuatable in two directions. This requirement is met using a single pole double throw (SPDT) switch. Suggestions collected from the usability study included a larger switch cap, more switch travel and improved ergonomics. The size suggestion had to be balanced to ensure that the switch could fit within the handle. The most popular suggestion from the usability study was a rocker switch. A number of SPDT rocker switches were considered after sorting options based on the above requirements (Figure 55).

Figure 55: Rocker switch options: small flat rocker (left), large flat rocker (middle), paddle rocker (right)

Source: NKK Switches

3D models of these switches were printed to allow the project team to make a more informed decision. A paddle rocker switch was ruled out as the team felt it wasn't very user-friendly as the control finger would have to be lifted up and over the paddle when changing directions. Therefore, a flat rocker was preferred. Out of those considered, the longest and widest option (middle image in Figure 55) was selected in order to accommodate those with impaired dexterity. This switch was integrated into the handle models at a distance of 30

mm from the midline of the handle (Figure 56). This was the same as the second prototype, as the usability study participants felt this distance was comfortable for index finger actuation.

Figure 56: Control switch position shown on option A handle

To mount this switch, a mock PCB was created, with through-hole pads for the switch legs and two M3-sized plain holes to be mounted to bosses. Figure 57 shows the rocker switch and PCB assembly.

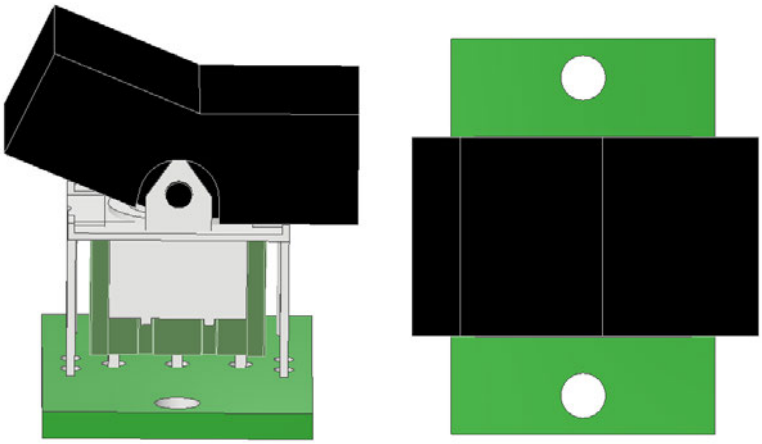

Figure 57: Rocker switch and PCB assembly isometric (left) and top view (right)

Figure 58 indicates the position of the two mounting bosses for the rocker switch assembly. Ribs were included on either side of the bosses to ensure rigidity.

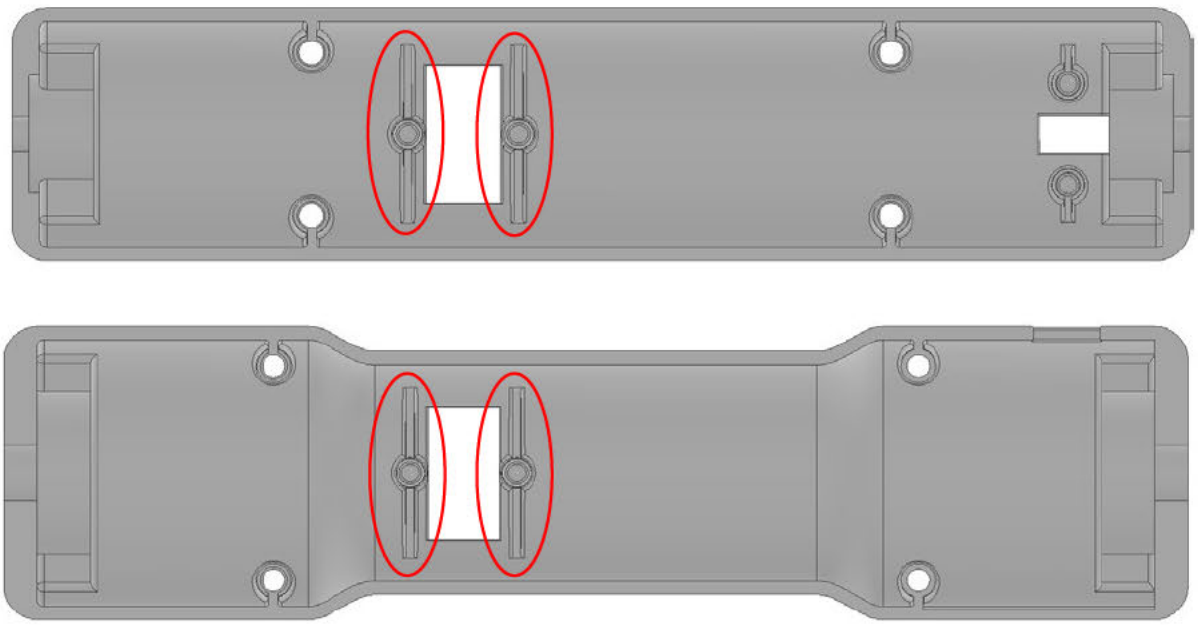

Figure 58: Rocker switch mounting bosses on handle option A (top) and option B (bottom)

The rocker switch and PCB assembly is shown mounted to handle option A in Figure 59 below.

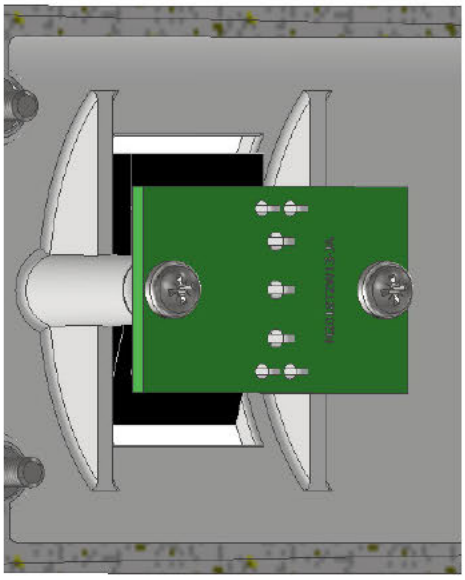

Figure 59: Rocker switch mounting to handle option A

For ease of access the power switch was located next to the screen display (Figure 60).

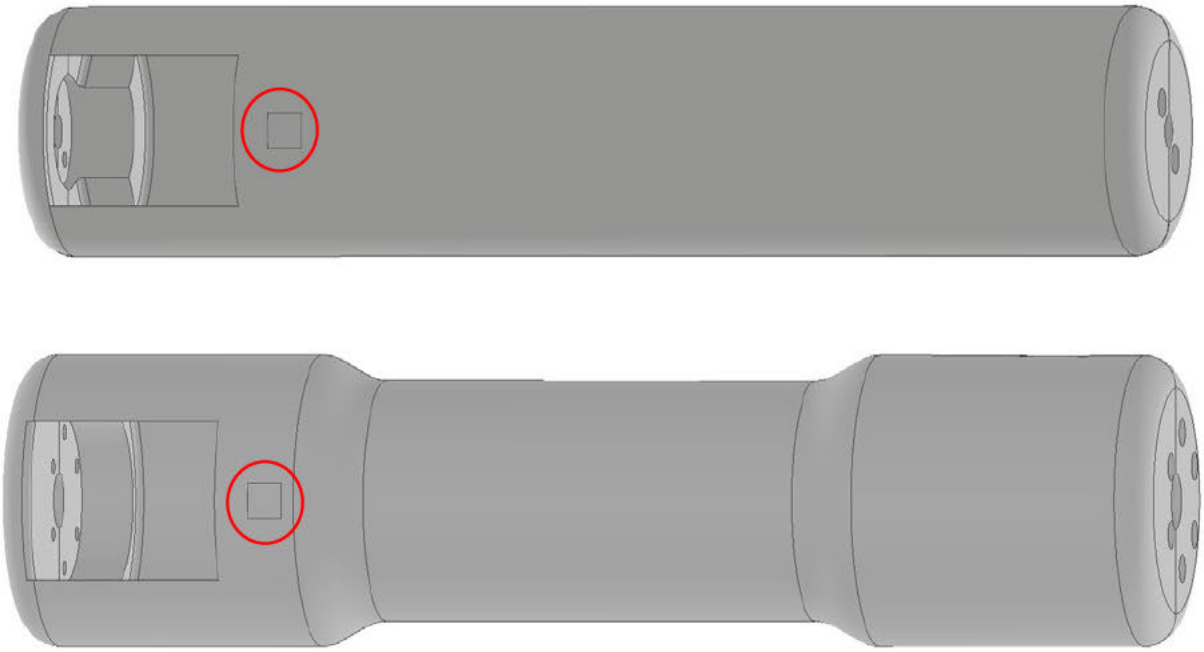

Figure 60: Power switch location on handle option A (top) and option B (bottom)

The maximum size of this switch was dictated by its proximity to the motor, screen support structure and the handle assembly bosses as shown in Figure 61. This was a more significant issue for handle option A due to its smaller inner diameter at the handle ends as compared to the option B handle.

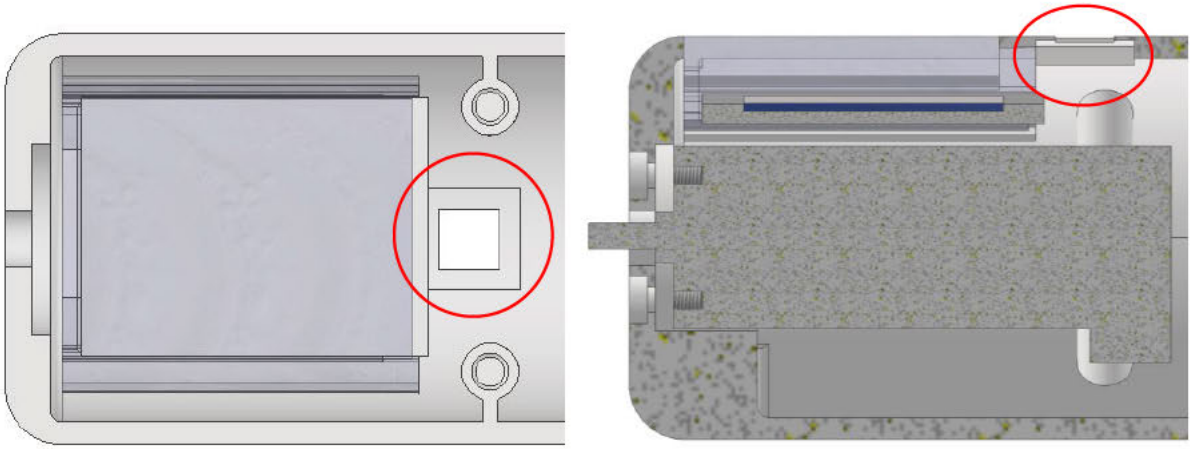

Figure 61: Power switch location (indicated in red) from cross-sectional views of handle option A, with motor removed in left image

As such, a through hole pushbutton with a full depth of around 9 mm was selected (Figure 62). Mounting this switch was another issue due to the proximity issues described above.

Figure 62: Selected power switch

Source: CW Industries

Similarly to the control switch, the power switch was coupled to a PCB with two M3 holes for mounting to bosses (Figure 63). In order to allow the pushbutton to be positioned deep enough into the created cut-out, stand offs and a plate were used between the PCB and the mounting bosses. This ensured that the assembly would fit past the end of the motors. This assembly is shown in Figure 64 below.

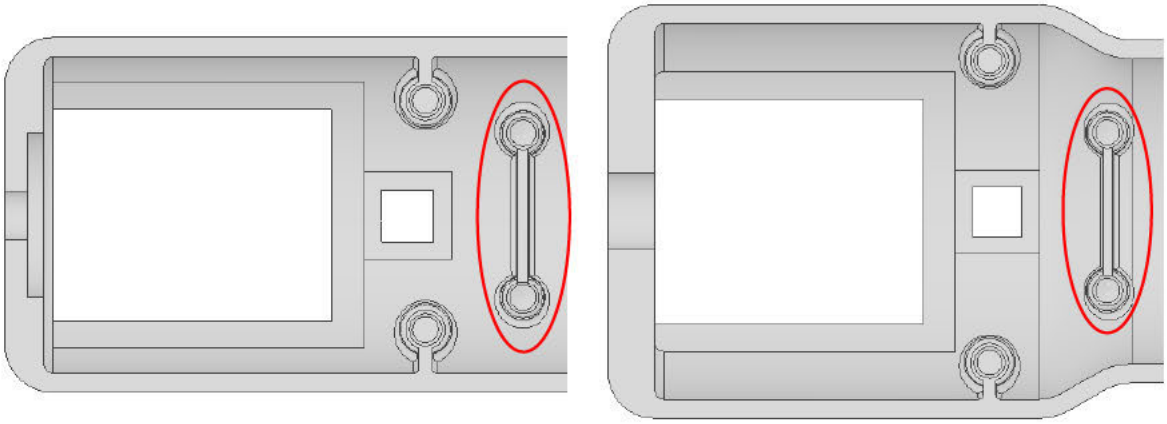

Figure 63: Pushbutton assembly mounting bosses on handle option A (left) and option B (right)

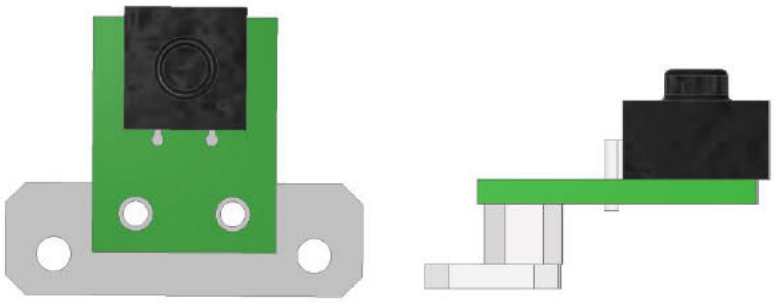

Figure 64: Pushbutton, PCB and plate assembly top view (left) and side view (right)

The assembly inserted into handle option A is shown from two cross-sectional views below in Figure 65.

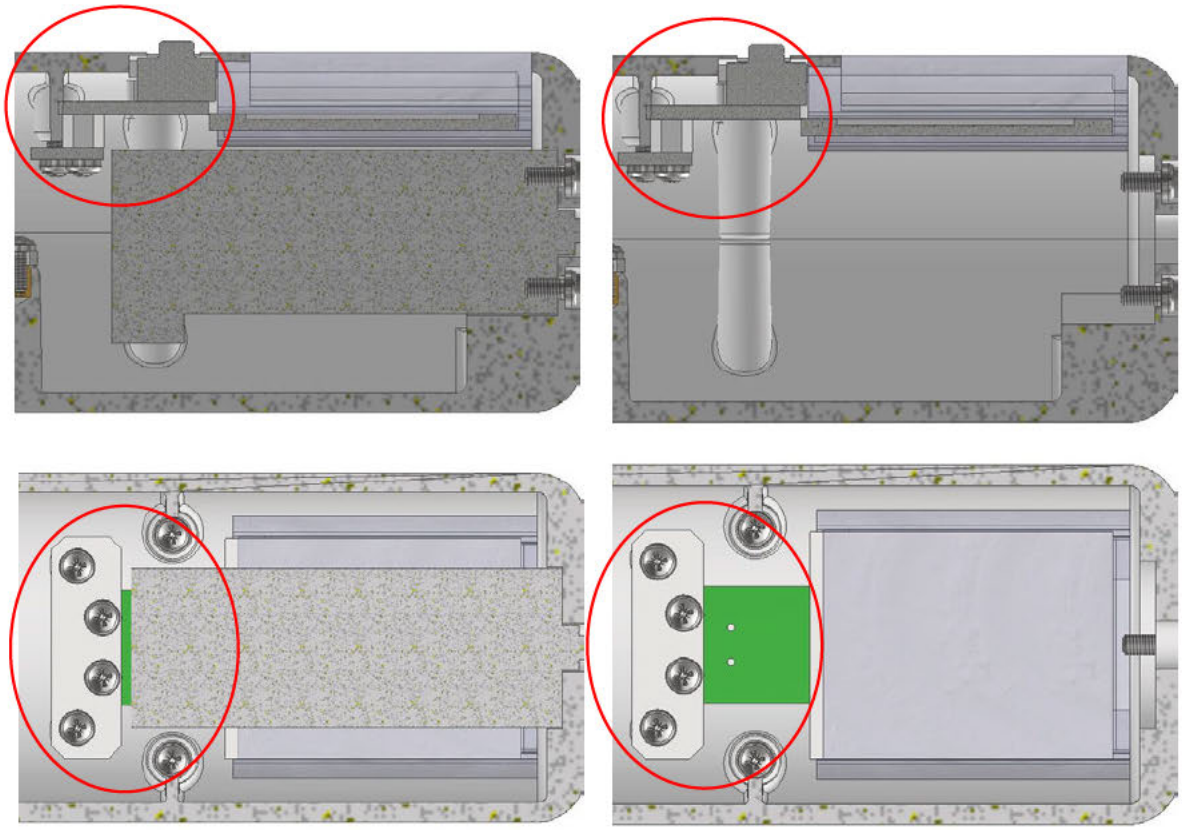

Figure 65: Pushbutton assembly in handle option A from two cross-sectional views with motor (left column) and motor removed (right column)

A cut-out for USB charging access was also included on both models. This was located on the opposite side to the display screen for handle option A. This cut-out was repositioned for

handle option B, as there was not adequate space at this position due to asymmetrical motor mounting.

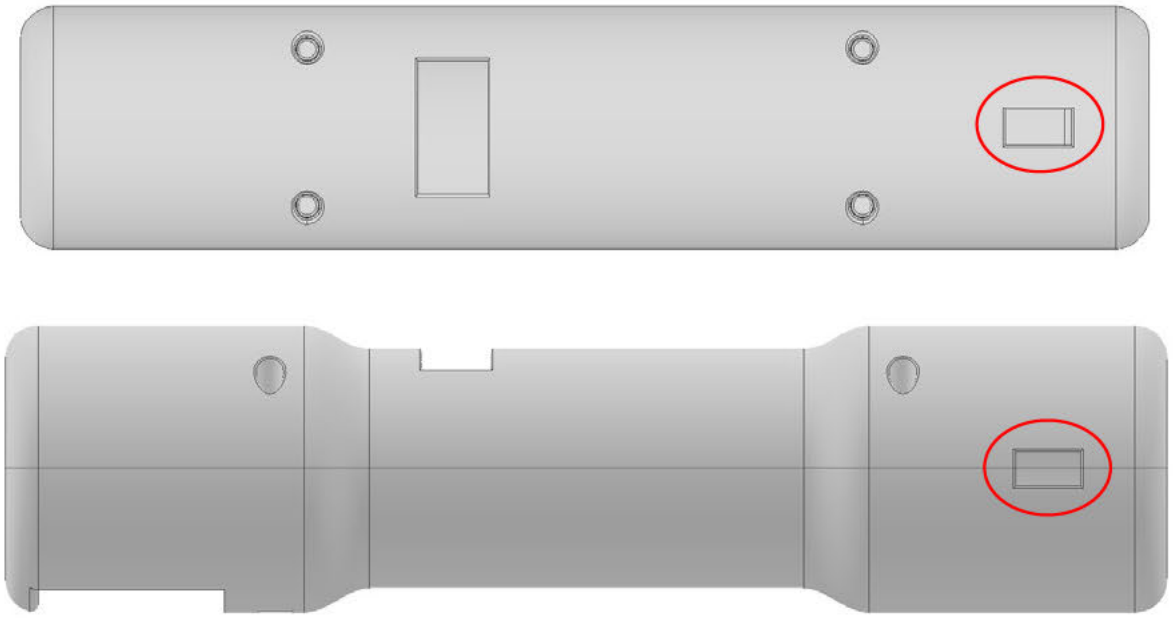

Figure 66: USB charging ports on handle option A (top) and option B (bottom)

5.4 Assembly and Bill of Materials

Figures 67 and 68 show the completed designs for option A and option B respectively. Engineering drawings of each component are included in Appendix K.

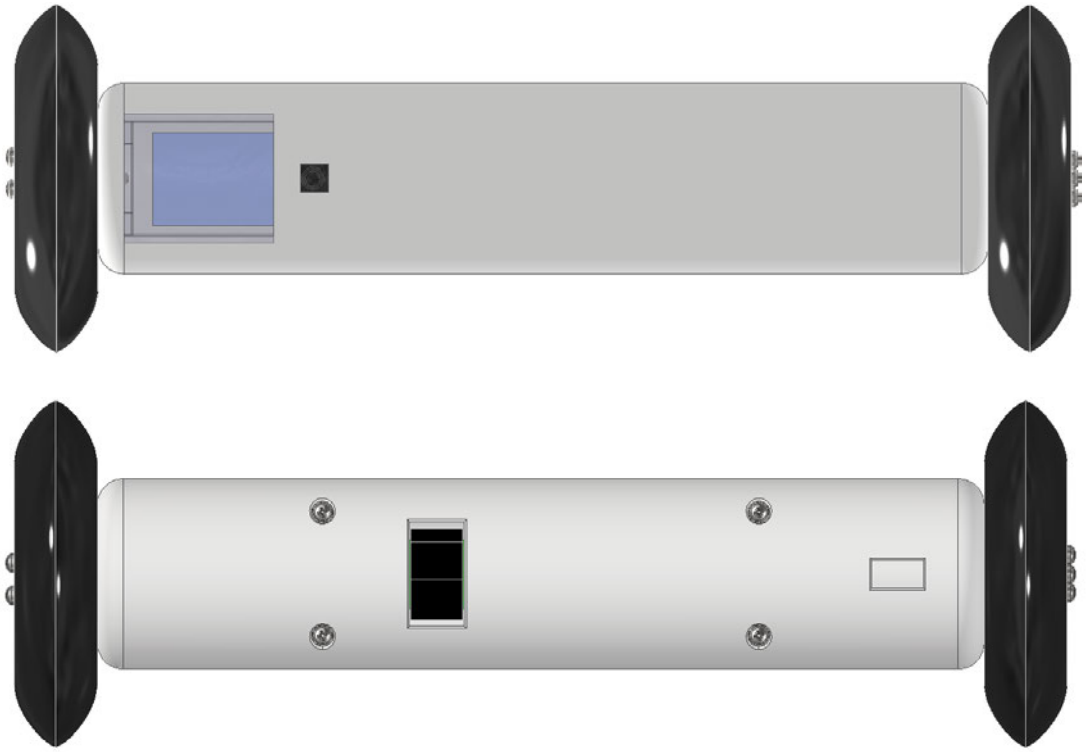

Figure 67: Option A full assembly top and bottom view

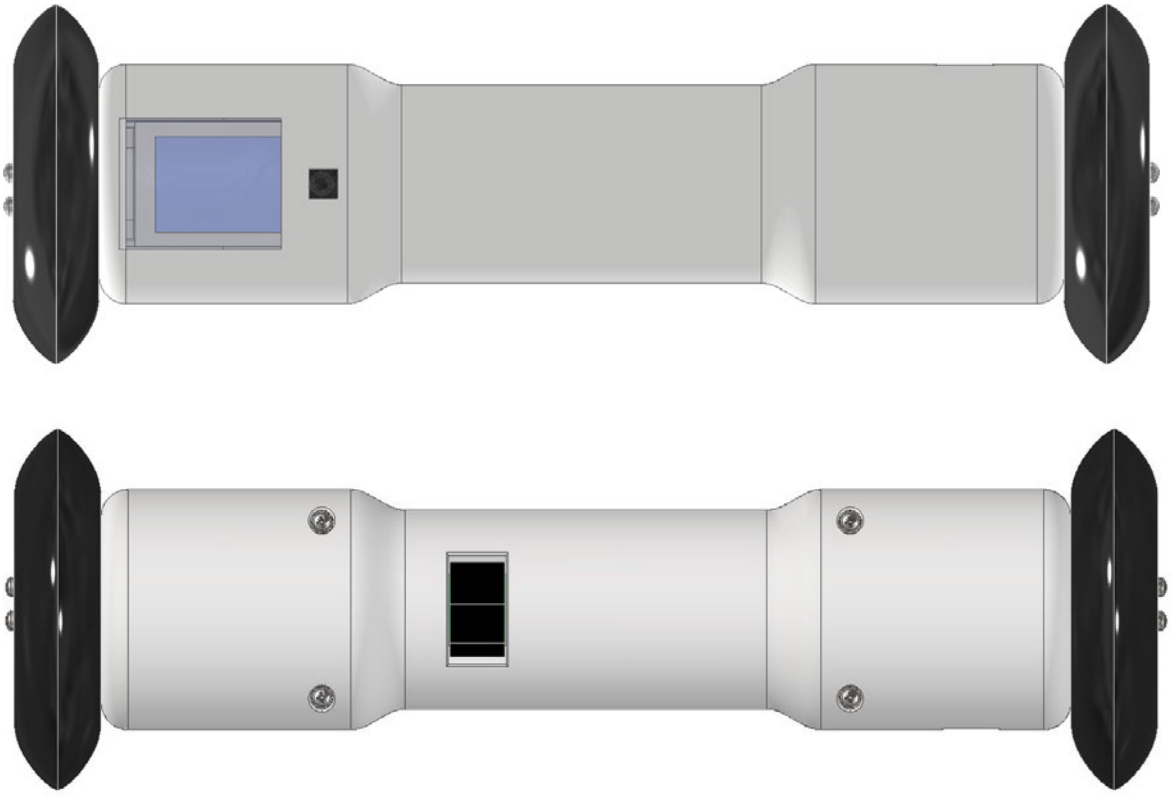

Figure 68: Option B full assembly top and bottom view

The below videos show a 360-degree view of the designs.

Video 3: Rotational view of design option A

Video 4: Rotational view of design option B

Tables 7 and 8 display the bill of materials for each of the presented designs. While the final iteration of this device is intended to be injection moulded, this method is not cost effective for small volumes, like those produced for prototyping purposes. This is because the production of injection moulding dies is an expensive process, which is only compensated for when producing larger volumes of units. As such, the handle components are indicated to be 3D printed out of polyamide-12 (PA12) using selective laser sintering (SLS). This material has excellent strength and thermal characteristics and SLS printing does not require

printing supports. The screen covers can be milled out of transparent PMMA for prototyping, again to prevent the extra cost associated with injection moulding. While a quote could not be obtained for this part, the author expects a similar cost to the pushbutton plate. Finally, since the PCBs are simply mock-ups, and do not include electrical traces, costs for these are not included.

Table 7: Bill of materials for option A prototype

Component	QTY	Cost ea	Cost total	Description	Supplier	% of total
Option A top v2.4.1	1	$49.00	$49.00	SLS PA12, black	PCBWay	20.57
Option A bottom v2.4.1	1	$53.00	$53.00	SLS PA12, black	PCBWay	22.25
Option A screen cover v3.0	1	*	*	CNC milled PMMA, to be superglued to main handle	PCBWay	*
Photoelectric dc encoder Motor DIA 25mm gearbox with 12v mini dc encoder motor with gearbox	2	$16.99	$33.98	12V 17rpm motors	ASLONG (via AliExpress)	14.27
100mm diameter scooter wheel from Pololu	1	$9.95	$9.95	Pair of wheels	Robot Gear	4.18
Pololu Aluminium Scooter Wheel Adapter for 4mm Shaft	1	$6.95	$6.95		Robot Gear	2.92
RS PRO, M3 Pan Head, 6mm Brass Cross Nickel Plated	14	$0.15	$2.17	Bag of 100 (4 for motor mounting, 10 for bosses)	RS Components	0.91
RS PRO, M3 Brass Threaded Insert diameter 4mm Depth 4.78mm	10	$0.36	$3.64	Bag of 100 (10 for bosses)	RS Components	1.53
MIDAS TFT LCD	1	$42.10	$42.10		Element 14	17.68
GPTS203211B power pushbutton	1	$2.44	$2.44		DigiKey	1.02
M2018TZW13-JA rocker switch	1	$9.57	$9.57		Mouser Electronics	4.02
Wurth Elektronik Steel Hex Standoff, Female/Female 5mm, M3	2	$0.70	$1.39	Bag of 10 (2 used for pushbutton PCB assembly)	RS Components	0.58
Pushbutton PCB	1	*	*			*
Rocker switch PCB	1	*	*			*
Pushbutton plate	1	$24.00	$24.00	Aluminium CNC milled	PCBWay	10.08
Total Cost			**$238.19**			

Note. * indicates unknown values.

Table 8: Bill of materials for option B prototype

Component	QTY	Cost ea	Cost total	Description	Supplier	% of total
Option B top v2.1.1	1	$61.00	$61.00	SLS PA12, black	PCBWay	23.86
Option B bottom v2.1.1	1	$66.00	$66.00	SLS PA12, black	PCBWay	25.81
Option B screen cover v3.0	1	*	*	CNC PMMA, to be superglued to main handle	PCBWay	*
12 Volt Geared Motor 12-1600rpm With Encoder Disk A/B Phase	2	$13.75	$27.50	12V 20rpm motors	Bringsmart (via Aliexpress)	10.76
100mm diameter scooter wheel from Pololu	1	$9.95	$9.95	Pair of wheels	Robot Gear	3.89
Pololu Aluminium Scooter Wheel Adapter for 6mm Shaft	1	$6.95	$6.95		Robot Gear	2.72
RS PRO, M3 Pan Head, 6mm Brass Cross Nickel Plated	12	$0.15	$1.86	Bag of 100 (4 for motor mounting, 8 for bosses)	RS Components	0.73
RS PRO, M3 Brass Threaded Insert diameter 4mm Depth 4.78mm	8	$0.36	$2.91	Bag of 100 (8 for bosses)	RS Components	1.14
MIDAS TFT LCD	1	$42.10	$42.10		Element 14	16.47
GPTS203211B power pushbutton	1	$2.44	$2.44		DigiKey	0.95
M2018TZW13-JA rocker switch	1	$9.57	$9.57		Mouser Electronics	3.74
Wurth Elektronik Steel Hex Standoff, Female/Female 5mm, M3	2	$0.70	$1.39	Bag of 10 (2 used for pushbutton PCB assembly)	RS Components	0.54
Pushbutton PCB	1	*	*			*
Rocker switch PCB	1	*	*			*
Pushbutton plate	1	$24.00	$24.00	Aluminium CNC milled	PCBWay	9.39
Total Cost			**$255.67**			

Note. * indicates unknown values.

The total cost for the third prototype production was projected to be AUD$238.19 for the option A design, and AUD$255.67 for the option B design. This represents a significant cost reduction, from the original AUD$1400 component cost. Therefore, this process has successfully improved the viability of the subsequent Shoulder Mobiliser prototype. The author expects cost per unit to be reduced even further when manufacturing is scaled to larger volumes. Injection moulding will likely be appropriate once the volume of units produced offsets the die cost as compared to 3D printing each component.

Chapter 6: Future Recommendations

Due to the large variability between participants in the electromyography study, the author suggests a larger study be run, with the addition of intramuscular electrodes (iEMG) to record from the deep shoulder muscles. Participants of this study should be trained by a physiotherapist to use the Shoulder Mobiliser appropriately, in order to closely mimic the experience of end-users. Internal electrodes would remove the possible effect of crosstalk from neighbouring muscles, which may have affected results in the presented study. They would also allow the rotator cuff muscles to be assessed: the activation level of these muscles is extremely relevant clinically, particularly for those who have had a rotator cuff repair.

A focus group with relevant clinicians could provide valuable insights into the business model and the application. This could allow the viability of the leasing model to be assessed and clinician's concerns regarding leasing, set up and patient progress monitoring to be addressed. A health economics report could also improve the business model and the marketability of the device.

In terms of manufacturing for market release, the handle design may need to be adjusted by an injection moulding die designer. The author has designed features with mouldability in mind, however, they expect that minor changes may be necessary to ensure high quality of the moulded handle and optimum die design.

During the later parts of this project, the Medical Device Partner Program (MDPP) staff were approached about continuing the development of the Shoulder Mobiliser. Following presentation of the concept and this project's results at an MDPP workshop and presentation to the independent assessment panel, the Shoulder Mobiliser was accepted into the MDPP. An appropriate MDPP project scope was developed in September of 2021. The MDPP staff aim to select one design of the two presented in this thesis and continue the development of the prototype. The author recommends that the motor options be assessed based on their smoothness following programming to the desired speed profile. The MDPP staff plan to implement the change to longer-lasting batteries and add the necessary control electronics. Implementing images on the LCD and creating an application for tracking usage over time are also included in their scope of work. In order to add another means of tracking

patient usage, the MDPP staff also aim to incorporate an inertial measurement unit (IMU) into the Shoulder Mobiliser.

One possible feature of the device proposed by the author is measuring the current draw to the motors. By comparing this value to the patient's 'passive baseline' in real-time an effort level could be displayed on the device or the application. This could be used to remind the patient to relax their arm if the software detects reduced current to the motors, indicating that they are pushing the Shoulder Mobiliser and therefore not moving passively. This current sensing feature has been included in the MDPP scope of work.

Ultimately, the MDPP project scope aims to produce a prototype that is ready to be used in a clinical trial. Such a trial could assess range of motion achieved by acutely post-operative patients with one cohort using the device and one control cohort. It is difficult to assess the clinical efficacy of the Shoulder Mobiliser as this would require a large study over a significant period to determine significant differences in clinical outcomes and likelihood of surgical revision compared to the control group. A range of motion metric can be easily measured at different stages in the rehabilitation protocol and act as a proxy for functional ability. With the assistance of clinicians, further metrics could be included in such a trial, such as measures of pain or other functional tests that are quantifiable.

In order to be released to the market, the Shoulder Mobiliser must also undergo the relevant medical device regulation processes for the targeted countries. It is the author's recommendation that these requirements be considered at earlier rather than later stages of prototype refinement. It is likely that some changes made during the MDPP project will relate to this. The MDPP are well placed to assess the compliance of the device due to their extensive experience in the medical device space.

Chapter 7: Conclusions

This project has aimed to improve the usability, feasibility and viability of a novel device for at-home shoulder rehabilitation. Following on from the production of a functional prototype, this work represents the next stages towards potential commercialisation of the Shoulder Mobiliser. A literature review revealed that shoulder pathologies pose a significant burden to both individuals and society (American Academy of Orthopaedic Surgeons, 2019; Hermoso & Calvo, 2009; Mather *et al.*, 2013; Narvy *et al.*, 2016). Surgery is often used as part of the treatment of musculoskeletal shoulder pathologies (Gilbert *et al.*, 2018). Mobility-based rehabilitation often plays an important role in the return to function of post-operative patients by preventing joint stiffness and scarring of the surgical sites (Severini *et al.*, 2014). The Shoulder Mobiliser provides the means for patients to perform rehabilitation exercises in their own home, at a higher frequency than would be possible with in-clinic visits alone. Review of current rehabilitation exercises showed extensive use of electromyography to validate the use of exercises in the passive stages of rehabilitation. While there was no common processing protocol across all studies, a consensus of less than 20% maximum voluntary isometric contraction (MVIC) as a qualifier for passive motion was noted. Finally, a number of studies showed the importance of co-design by undertaking studies with relevant end-users. This ultimately improved patient acceptance of novel rehabilitation tools and improved the design of subsequent prototypes. Overall, this review substantiated the place for the Shoulder Mobiliser and led to the refinement of the project aims and methods.

To assess the usability of the current Shoulder Mobiliser prototype, a study was held with a cohort of seven non-acute post-operative shoulder patients. A mean System Usability Scale score of 90.36 ± 4.71 indicated excellent usability of the current device. Open-ended interviews with each participant allowed the author to collect responses regarding charging, cost and real-time feedback display. This study provided important insights into the current design, with areas of improvement identified by participants. Potential improvements included variable speed options, a change in control switch, cost reduction and the addition of a display on the device itself to complement an application.

A preliminary muscle activation study was performed using surface electromyography to assess the suitability of the Shoulder Mobiliser in early rehabilitation. The Delsys Trigno

system was used to target the upper, middle and lower trapezius, and the anterior, medial and posterior deltoid muscles of the shoulder complex. A protocol consistent with those found in the prior literature review was used to quantify muscle activity during device usage in flexion and abduction against MVIC values. Participants also performed three well-investigated rehabilitation exercises to validate the protocol used. Median values were under 20% MVIC for all muscles, except for the middle trapezius in abduction. This finding suggests that the Shoulder Mobiliser can be used passively, however, significant variation between participants was noted, likely necessitating a larger sample size in future studies and more rigorous patient education regarding device usage.

Finally, two new prototypes of the Shoulder Mobiliser were designed, to improve the viability of the device and address the results of the usability study. Two cheaper motor options were identified, and handles designed for each motor option. The new designs included a change in control switch to a larger paddle switch, the addition of a charging port, and a display screen on the device. Adaptations were made to allow for switch mounting and features were designed to allow injection moulding of the handle in the future. Component optimisation reduced the cost of the bill of materials for one device to under AUD$260 not including control electronics.

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Appendices

Appendix A – Usability Study Ethics Application (ID: 4143)

HREC Application Form

Usability study of a novel shoulder rehabilitation device
ID:4143 Year:2021 Version:4

Project Details

Project Information

All research conducted by, and/or with, SA Health (including Southern Adelaide Local Health Network - SALHN) staff, patients, visitors, premises or data sets needs to be approved by an SA Health Human Research Ethics Committee. Once Ethics approval has been obtained from an SA Health Ethics Committee, please notify us by completing the "Cross-Institutional Approval Form" in the online system.

Teaching & Learning applications can only be submitted for the evaluation of teaching projects for research purposes.

Coursework applications can only cover student projects that are considered low risk and where research results will be disseminated beyond the University and interested parties. This **does not** cover above low risk, Honours, Masters by Research, or PhD student projects.

The World Health Organization's definition for a clinical trial can be found here.

A1. Project Title

Usability study of a novel shoulder rehabilitation device

A2. Type of Project

- (•) Research involving human participants
- ( ) Clinical trial involving human participants
- ( ) Teaching & Learning Program evaluation involving human participants
- ( ) Coursework application (Masters by Coursework student projects only)
- ( ) Research only involving existing and de-identified data sets

A3. Anticipated Start Date

The Committee cannot grant retrospective approval so data collection cannot commence until Ethics approval has been granted.

14/06/2021

A4. Anticipated End Date

The first approval period is limited to five years. However, projects can be extended at the end of the approval period if required (subject to approval of annual reports).

16/08/2021

A5. Will your project include the following types of research?

- ☐ Psychotherapeutic and/or behavioural therapies
- ☐ Health Service changes
- ☐ Preventative care strategies
- ☐ Educational interventions related to health
- ☐ Collection, or access to, physical samples from human beings (e.g. blood, tissue, cells etc.)
- ☐ Cellular Therapy
- ☐ Ionising and non-ionising radiation
- ☑ None of the above

A6. This research project is for:

- ○ University Research
- ○ PhD Research
- ◉ Masters by Research
- ○ Masters by Coursework
- ○ Honours Research
- ○ Undergraduate studies

A7. Please provide a brief lay summary of the research project.

The project involves participants trying a novel shoulder rehabilitation device, providing participant details and answering questions on shoulder impairment and device usability.

A8. Will you target participants for whom there are specific ethical considerations?

In accordance with the National Statement on Ethical Conduct in Human Research 2007 (Updated 2018), specific issues arise in the design, conduct and ethical review of research involving the categories of participants identified in this section. Please see Section 4 of the National Statement for further information.

- ☐ Children
- ☐ Indigenous communities
- ☐ People in dependent and/or unequal relationships
- ☐ People unable to give consent for health or other reasons
- ☐ People highly dependent on medical care
- ☐ People with cognitive impairment, intellectual disability or mental illness
- ☐ Women who are pregnant and the human foetus
- ☐ People who are homeless
- ☐ People who are incarcerated
- ☐ People who may be involved in illegal activities
- ☐ Victims of crime
- ☐ Migrants, refugees and asylum seekers
- ☐ Minors 16 years and above
- ☐ People with a cultural and/or religious background
- ☐ People for whom English is a second language
- ☑ None of the above

A9. Will the research involve Indigenous communities, including Aboriginal and Torres Strait Islander people?

Research projects involving or impacting Indigenous communities must outline in detail how relevant issues of research design, ethics, culture and language are addressed. Researchers must address the AIATSIS Guidelines for Ethical Research in Australian Indigenous Studies, and the Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders must also be addressed. Researchers are also encouraged to read Keeping research on track II, a companion document to Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders.

- ○ Yes
- ◉ No

Chief Investigator

Chief Investigator Details

The Chief Investigator (CI) has the overall responsibility for the design, conduct, ethical aspects and reporting of a study. The CI is also the key administrative contact for the project and must ensure that all co-investigators and other people involved in the project are fully informed of and comply with relevant policies, guidelines and procedures associated with the project, including intellectual property, confidentiality provisions and granting body's conditions as required.

Please note: Honours, Masters and Undergraduate students cannot be Chief Investigators. If this project is related to Honours, Masters and Undergraduate research, the CI must be the principal supervisor or course convenor and students must be listed in the Co-Investigator's section.

B1. Chief Investigator's details

Please provide the details of the Chief Investigator below.

Title	Dr
First Name	David

Surname	Hobbs
FAN	hobb0018
Telephone	+61882013167
Email	david.hobbs@flinders.edu.au

B1.1. Please select your College or Portfolio.

College of Science and Engineering

B1.1.1. Please select your research area.

Health

B2. Please provide the Chief Investigator's qualifications.

Bachelor of Science (Physics)
Bachelor of Science (Life Sciences) / Bachelor of Engineering (Biomedical) (Hons I)
PhD (Rehabilitation Engineering)

B3. Please provide detailed information about the Chief Investigator's research experience, including any specific skills or expertise relevant to this project.

David has bachelor degrees in Physics (1992-1994) and Biomedical Engineering (1996-2000), with First Class Honours, and a PhD (2010-2018, in Rehabilitation Engineering) from Flinders University. He has extensive experience as a Rehabilitation Engineer in the field of disability, rehabilitation engineering and assistive technologies, and is currently a Senior Lecturer and academic staff member within the College of Science and Engineering and a researcher within the Medical Device Research Institute (MDRI) at Flinders University. David has experience working in rehabilitation engineering research and industry institutions in Australia, England, Canada and the United States, holds a patent for his PhD work, and has twice won first prize in the College of Biomedical Engineers' Better Technology Awards for novel assistive technologies.

Co-Investigator

Co-Investigator Details

Co-Investigators make a significant contribution to the planning, design, conduct, ethical aspects and reporting of a study. While the Chief Investigator has the overall responsibility for the project, co-investigators must ensure that the project is undertaken in accordance with relevant policies, guidelines and procedures associated with the project, including intellectual property, confidentiality provisions and granting body's conditions as required.

B5. Are there any Co-Investigators?

(•) Yes
( ) No

B5.1. Co-Investigators' details
Please provide the details of your Co-Investigators below.

Title	Miss
First Name	Philippa
Surname	Tsirgiotis
FAN	tsir0007
Telephone	+61882013167
Email	philippa.tsirgiotis@flinders.edu.au
College or Portfolio	College of Science and Engineering

Is this Co-Investigator a Flinders University student?

(•) Yes
( ) No

Title	Mr
First Name	Luke
Surname	Mason
FAN	
Telephone	[redacted]
Email	
College or Portfolio	External Organisation

Please provide the details of the external organisation.

Physio One - Principal Physiotherapist

Is this Co-Investigator a Flinders University student?

( ) Yes
(•) No

Title	Mr
First Name	Jim

Surname: Hannon-Tan

FAN:

Telephone: [redacted]

Email: [redacted]

College or Portfolio: External Organisation

Please provide the details of the external organisation.

Jim Hannon-Tan Concept and Industrial Design

Is this Co-Investigator a Flinders University student?

- ○ Yes
- ◉ No

Title: Mr

First Name: Tom

Surname: Russell

FAN:

Telephone: [redacted]

Email: [redacted]

College or Portfolio: External Organisation

Please provide the details of the external organisation.

Jim Hannon-Tan Concept and Industrial Design

Is this Co-Investigator a Flinders University student?

- ○ Yes
- ◉ No

Other People

Other People involved in the Project

Other people involved could include mentors, research assistants, statisticians etc. who are not deemed to be co-investigators.

B6. Are there any other persons involved in the project?

- ◉ Yes
- ○ No

B6.1. Other persons involved in this project
Please provide the details of other persons involved in this project below.

Title	Professor
First Name	Mark
Surname	Taylor
Email	mark.taylor@flinders.edu.au
Role	Co-supervisor

Will this person have access to identifiable data?

- ○ Yes
- ◉ No

Title	Dr
First Name	Aaron
Surname	Mohtar
Email	[redacted]
Role	Consulting electronic enginner

Will this person have access to identifiable data?

- ○ Yes
- ◉ No

Title	Dr
First Name	Jonathan
Surname	Cabot
Email	[redacted]
Role	SA Orthopaedic Surgeon and Project Sponsor

Will this person have access to identifiable data?

- ○ Yes
- ◉ No

Locations

C1. Please provide all locations where the research will be conducted.

The research will be conducted at Physio One Lockleys (392 Henley Beach Rd, Lockleys SA 5032).

C2. Will the project involve access to Aboriginal and/or Torres Strait Islander lands?

- ○ Yes
- ◉ No

C3. Will any research be undertaken overseas?

- ○ Yes
- ◉ No

Funding

D1. How will your research project be funded?

- ☐ Internal Funding
- ☐ External Funding
- ☑ Other Funding (e.g. in-kind support, private funding etc.)

If "Other Funding", please provide more information.

This research project will use in-kind support from the co-investigators listed in this application. Access to the research location will be provided in-kind, with permission from the Physio One Lockleys practice manager.

D2. Are there any special conditions placed on funding (for example IP rights, data access and storage)?

- ○ Yes
- ◉ No

Conflicts of Interest

Conflicts of Interest

Conflicts of interest must be disclosed at the start of a project. Types of activities that can lead to conflicts of interest include, but are not limited to, consultancies, membership of committees, participation in boards or advisory groups and affiliation with or financial involvement in any entity with a direct interest in the subject matter of the research.

Please note that all conflicts of interest must also be disclosed in the Participant Information Sheet.

D3. Will the funding, administrative and/or commercial IP arrangements place any person involved in this project in a conflict of interest?

- (•) Yes
- ( ) No

D3.1. Please provide details about the conflict/s of interest and advise how they will be dealt with.

Luke Mason and Dr Jonathan Cabot may have conflicts of interest as they are funding the development of the device in question. However, Dr Cabot will not be present when the study is conducted and will only have access to de-identified data. Mr Mason may have knowledge of the participants of the study, but will not have access to identifiable data. While Mr Mason may assist with setting up participants when they arrive for the study, he will not be present when participants are answering interview questions or filling out surveys. Participant responses will be de-identified before they are made available to the co-investigators (excluding Philippa Tsirgiotis, Jim Hannon-Tan and Tom Russell, who will be present during data collection).

D4. Do any of the researchers have any pre-existing relationships with potential participants?

- (•) Yes
- ( ) No

D4.1. Please describe any pre-existing relationships with participants and any ethical considerations that need to be addressed as a result of this relationship.

The participants of this study may be patients of physiotherapist Luke Mason. Mr Mason will pass potential participant contact details on to the practice manager, who will contact each participant on behalf of the practice. If they wish to participate in the study, they will contact Miss Tsirgiotis directly to indicate their interest.

D5. Will there be any constraints on publication?

- ( ) Yes
- (•) No

Aims and Justification

E1. What are the aims of the research project?

This project allows potential users of the novel device to give their perspectives on its design and functionality. It aims to quantify the usability of the device and identify any issues or areas of potential improvement. This study is required as the device is novel (no similar devices exist) and requires feedback outside of the project team to assess its usability. The study will also allow the team to gain information about the target demographic of the device (such as their access and confidence with technology, and use of various rehabilitation tools).

E2. Please provide a justification for your research based on a literature review.

Lack of usability is a common reason for low uptake of rehabilitation tools. The concept of usability in this case refers to the ease of the device-user interface, as well as the usefulness and perceived value of the system. Usability studies are commonly used to refine design concepts prior to their commercialisation to ensure they are addressing user needs appropriately. These studies can be quantitative or qualitative in nature, with mixed methodologies allowing for larger

breadth and scope, resulting in a more comprehensive understanding of users' impressions (Resnik, 2011).

The proposed usability study will be used to assess the current prototype of the shoulder rehabilitation device developed by the project team. Research instruments include the System Usability Scale (SUS) and semi-structured interview questions.

Many studies have explored the usability of novel devices in the fields of rehabilitation and assistive technology. The literature consistently highlights the importance of testing with relevant users in order to facilitate co-design and receive validation from end users (Hobbs, Walker, & Layton, 2019), with a number of studies finding positively skewed results for healthy participants (Pei, Chen, Wong, & Tseng, 2017; Tsai et al., 2019). Gilbert, Hauptmannova, and Jaggi (2018) undertook semi-structured interviews with physiotherapists and patients with shoulder impairment to assess the usability of an in-clinic robotic shoulder rehabilitation system. This qualitative study successfully identified both advantages and disadvantages of the system. An example of a successful quantitative study is that completed by Chun-Ming, Yen-Ching, Hsiao-Yun, and Li-Wei (2012). They assessed user satisfaction of a novel shoulder wheel gaming system using a Likert scale-based questionnaire.

The most common quantitative instrument used to measure usability in this area is the System Usability Scale (SUS), developed by usability specialist John Brooke in 1986. This 11-item instrument gives a numerical score of usability and measures three facets of usability. The first is effectiveness; whether the system allows the user to complete the intended task. The second is efficiency, relating to the resources required by the user to complete the task. The third and final is satisfaction; how well the system meets the users' needs (Kortum & Bangor, 2013). The SUS has multiple advantages, including short completion time, high reliability and technology agnosticism (Bangor, Kortum, & Miller, 2008). The SUS was successfully used to quantitatively evaluate a cable-driven exoskeleton for hand rehabilitation, ensuring that clinical needs were met by the device (Tsai et al., 2019). Several mixed methodology studies have used the SUS to obtain quantitative usability data on rehabilitation technologies. An upper-limb stroke rehabilitation device prototype was assessed by Pei et al. (2017), with patients, caregivers and therapists. This study used the SUS, observations, open-ended questions and video recording. The study uncovered a number of issues which guided the next design iteration and resulted in an increased understanding of patient and therapist needs. A second mixed methodology study by Hamilton, Lovarini, van den Berg, McCluskey, and Hassett (2021) assessed eleven feedback-based technologies targeted for mobility improvement. They utilised the SUS and conducted focus group sessions which were audio-recorded and transcribed. Finally, a robot-supported gait rehabilitation system was assessed using the SUS and in-person interviews (Eicher et al., 2019). All of these studies also collected socio-demographic information from participants and revealed valuable insights into the assessed systems using the SUS and open-ended interview questions.

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Tsai, Y.-L., Huang, J.-J., Pu, S.-W., Chen, H.-P., Hsu, S.-C., Chang, J.-Y., & Pei, Y.-C. (2019). Usability Assessment of a Cable-Driven Exoskeletal Robot for Hand Rehabilitation. Frontiers in Neurorobotics. doi:http://dx.doi.org/10.3389/fnbot.2019.00003

Methodology

E3. Please describe the research approach and methods in more detail.

Firstly, the participant will complete a hard-copy questionnaire about their personal details and history related to their shoulder condition. This questionnaire will also ask about their access and confidence with technology. The participant will then complete the Shoulder Pain and Disability Index (SPADI) to determine their level of shoulder impairment. Use of the rehabilitation device will then be demonstrated by Philippa Tsirgiotis. The participant will then be allowed to use the device on the table top while under supervision, and this use of the device will be video recorded from above, looking down on the participant's shoulder and arm. The System Usability Scale (SUS) will then be administered. Following the SUS, the participant will answer the first group of semi-structured interview questions regarding the device and its accompanying app. The participant will then be shown the charging dock for the device and asked the remaining semi-structured interview questions. The participant's responses to the interview questions be audio recorded.

E4. Do you intend to withhold or disguise the purpose of the research in any way?

- ○ Yes
- ◉ No

Research Instruments

E5. Which of the following instruments will be used in your research project?

- ☑ Hard copy questionnaire
- ☐ Electronic questionnaire
- ☑ Semi-Structured Interviews
- ☐ Workshop
- ☑ Overt Observations
- ☑ Video recordings
- ☐ Movement tracking
- ☐ Performance tests
- ☐ Already existing and de-identified data set
- ☐ Telephone/verbal survey
- ☐ Focus Groups
- ☐ Structured Interviews
- ☐ Covert Observations
- ☑ Photographs
- ☑ Audio recordings
- ☐ Creative, artistic or design process
- ☐ Ethnography
- ☐ Other

Please upload the questionnaire/s.

Documents

Type	Document Name	File Name	Version Date	Version	Size
Default	SPADI	SPADI.pdf	11/04/2021	1.0	111.1 KB
Default	SUS	SUS.pdf	11/04/2021	1.0	111.1 KB
Default	Participant information questionnaire	Participant information questionnaire.pdf	12/04/2021	1.0	165.6 KB

Please upload the interview questions.

Documents

Type	Document Name	File Name	Version Date	Version	Size
Default	Semi-structured interview questions	Semi-structured interview questions.pdf	11/04/2021	2.0	68.0 KB

Will interview participants be given the opportunity to review and edit interview transcripts?

If Yes, please ensure that participants are given information about this in the Information Sheet and Consent Form.

○ Yes
◉ No

Please advise why participants will not be given the opportunity to review and edit their transcripts.

Semi-structured interviews will be audio recorded to be transcribed following data collection. Since the interview covers information that is not personal or sensitive in nature, participants will not be re-contacted to review their transcripts.

Please provide more details on how observations will take place.

Participants will be observed to see how they interact with the device. The co-investigators present (Philippa Tsirgiotis, Jim Hannon-Tan and Tom Russell) will be making these observations while the participant handles and explores the device at their own pace.

Please advise what the video recordings and/or photographs will contain (e.g. people, landscapes, locations, objects etc.).

Video recordings will be taken with framing above the table to capture a top-down view and audio will be muted. This will prevent capturing participants' faces or identifiable data (in audio or visual form). Video recordings will be initiated when participants are using the device and will be framed to include the shoulder and arm down. Philippa Tsirgiotis will be the only investigator with access to the raw recordings. She will edit the videos before they are made available to other investigators to ensure that any faces or verbalisation of participant details that have been inadvertently captured are removed. Frames of these video recordings may be extracted for use in publication materials. Participants will be asked to complete a Photographic Release Form before video recordings are initiated. Audio recordings will be captured for the duration of the semi-structured interview section to allow in-depth analysis of responses following recording.

Potential Benefits

E6. What are the benefits of the research project?

The research project will allow potential users of the device to give their perspectives on the current prototype. The researchers will be able to gain valuable insights about how users interact with the device and their confidence with technology. This is an important part of the device development as it will inform the next design iteration. Any issues that are raised during the study will highlight areas of improvement to the project team. User consultation will ensure that user needs are being addressed correctly.

E7. What research product will be created by this research project?

- [ ] Book(s)
- [ ] Book Chapters(s)
- [ ] Commercial Product(s)
- [x] Conference Paper(s)
- [x] Journal Article(s)
- [ ] Non-traditional research outputs (eg. exhibitions, performances etc.)
- [ ] Report(s)
- [ ] Therapeutic Product(s)
- [x] Thesis
- [ ] Other

Recruitment Methods and Participant Groups

P1. Will you, or a third party, recruit participants for this project?

- (•) Yes
- ( ) No

P1.1. Will you, or a third party, recruit any Flinders University undergraduate students?

- ( ) Yes
- (•) No

P1.2. Participant Categories and Recruitment Methods
Please provide information about your participants and recruitment methods below.

Participant Category
For multiple participant categories, please use the "Add Another" button.

Physiotherapy patients with a history of shoulder pathology

Recruitment Method

Other

If "Other", please provide more details.

Either via email (preferred) or by hard copy letter

Estimated Sample Size

10

F1.3. Please expand on the recruitment process and outline in more detail how participants will be recruited.

Mr Luke Mason will provide contact details of patients of Physio One who have a history of shoulder pathology and who are deemed at low risk of injury using the device to the Practice Manager of Physio One Lockleys. The Practice Manager will then contact the listed patients provided by Mr Mason and include all relevant study details and participant information (Letter of Introduction, Participant Information Sheet and Consent Form). Potential participants will be contacted via email from the Practice Manager. If the clinic does not have an email address on file, or a response is not received via email, the Practice Manager will contact them via a hard copy letter posted to their residential address. The Practice Manager has been selected to initiate this contact to prevent patients from feeling obliged to take part in the study. The Letter of Introduction and Participant Information Sheet state that their clinician will not be informed if they choose not to participate, and that their decision not to participate in the study will have no effect on their ongoing treatment. Those contacted via email will be advised to contact Philippa Tsirgiotis via her Flinders University email address if they are interested in taking part in the study. Those contacted via post will be advised to return their completed Consent Form to Dr David Hobbs via the reply-paid envelope enclosed. As such, Miss Tsirgiotis and Dr Hobbs will only receive the contact details of those who wish to take part in the study.

F1.4. Please upload all recruitment materials, including flyers, introductory emails, verbal scripts, etc.

Documents

Type	Document Name	File Name	Version Date	Version	Size
Default	Photographic release form	Photographic release form.pdf	12/04/2021	1.0	203.0 KB
Default	Letter of Introduction v1.1	Letter of Introduction v1.1.pdf	16/04/2021	1.1	48.1 KB
Default	Photographic release form v2.0	Photographic release form v2.0.pdf	06/05/2021	2.0	202.9 KB
Default	Hard copy Letter of Introduction	Hard copy Letter of Introduction.docx	09/06/2021	1.0	13.8 KB

F1.5. Will you need to obtain permission to access participants?

- ○ Yes
- ◉ No

F1.6. Will any of the recruitment information/documents need to be translated into another language?

- ○ Yes
- ◉ No

Participant Consent and Withdrawal

F2. How will participants be able to provide informed consent?

- ☐ Verbal Consent
- ☑ Written Consent
- ☐ Online consent
- ☐ Opt-Out consent
- ☐ Waiver of consent
- ☐ No consent required (existing dataset)

F2.1. Please upload a copy of the Participant Information Sheet and the Consent Form.

Documents

Type	Document Name	File Name	Version Date	Version	Size
Default	Participant information sheet and consent form v1.1	Participant information sheet and consent form v1.1.pdf	16/04/2021	1.1	245.0 KB
Default	Participant information sheet and consent form v2.0	Participant information sheet and consent form v2.0.pdf	06/05/2021	2.0	244.9 KB
Default	Hard copy Participant information sheet and consent form Final	Hard copy Participant information sheet and consent form Final.pdf	09/06/2021	1.0	246.1 KB

F2.2. Please outline in more detail how participants will be able to provide informed consent and how you will ensure that participation is voluntary.

Potential participants will be provided with the Participant Information Sheet and Consent Form. This document will outline the purpose and benefits of the study, as well as what they will be asked to do and the potential risks of participation. The research instruments will be outlined (hard copy questionnaires, semi-structured interview, video recording and audio recording), along with confidentiality, privacy and data storage information. Participants will be asked to complete a Photographic Release Form before video recordings are initiated. In order to prevent conflicts of interest, contact will be initiated by the Practice Manager of Physio One Lockleys (as opposed to a clinician or the researchers listed in this application). Those interested in participating will be asked to contact Miss Philippa Tsirgiotis directly by forwarding her their completed Consent Form. As such, their clinician (Mr Luke Mason) and the Practice Manager will not be aware whether or not the patient wishes to participate.

F2.3. Please outline in detail how participants will be able to withdraw from the research project without penalty and without feeling discomfort.

The Participant Information Sheet and Consent Form will inform potential participants of their withdrawal rights. They will be advised that they are free to decline to participate or withdraw from the study at any time without penalty. Participants will be informed that will not be required to provide a reason for withdrawal, and that any data collected up to the point of withdrawal will be destroyed.

Remuneration and Post Participation

F3. Will any payment, recognition of contribution or compensation be provided to participants?

- ○ Yes
- ◉ No

F4. Will you provide any feedback to participants?

- ◉ Yes
- ○ No

F4.1. Please advise how feedback will be provided.

A summary of the research outcomes will be provided to participants via email.

F5. Will feedback be provided to any organisations, schools and/or people who commissioned or have an interest in this project?

- (•) Yes
- ( ) No

F5.1. Please advise how feedback will be provided.

Project sponsors Mr Luke Mason and Dr Jonathan Cabot will be provided with a summary of responses to the Participant Information questionnaire, Shoulder Pain and Disability Index and System Usability Scale. A summary of responses to the semi-structured interview questions will be provided in written form. All data provided will be de-identified. Photographs of the device being used that do not capture any identifying information may be provided to the sponsors.

F6. Will a transcription service be used?

- ( ) Yes
- (•) No

Potential Burdens and Risks

G1. Please indicate the possible risk categories to the research team.

- [ ] Physical harms
- [ ] Psychological harms
- [ ] Legal harms
- [x] Other

G1.1. Please explain the risks in more detail and provide strategies for minimising these risks.

There is negligible risk to the research team.

G2. Please indicate the possible risk categories to participants.

- [x] Physical harms
- [ ] Psychological harms
- [ ] Social harms
- [ ] Economic harms
- [ ] Legal harms
- [x] Invasion of Privacy
- [ ] Devaluation of personal worth
- [ ] Risks specific to Indigenous communities, including Aboriginal and Torres Strait Islander people
- [x] Other

G2.1. Please explain the risks in more detail and provide strategies for minimising these risks.

To prevent injury risk to the shoulder, participants will observe a demonstration of the device along with an explanation of how to control it. Participants will be advised to use the device to the point of a stretching feeling, not to discomfort or pain. Participants will be supervised at all times while using the device. The device is operated by a joystick which is hold-to-run. Therefore, if the participant releases the button, the device will stop. Recruited participants will not be in the acute stages of their shoulder condition, and therefore the risk of damaging internal structures while using the device is minimal. Mr Luke Mason will use his professional judgement to select patients who are at low risk of injury using the device. The study will be conducted at a physiotherapy practice, where trained physiotherapists will be present and be able to be consulted in the unlikely event of an injury occurring.

A second physical risk is the possibility of electric shock as the device is battery powered. However, the device is powered with a low current and voltage (maximum of 8.4V). The electronic design and isolation of the power source has been undertaken by electronic engineer Dr Aaron Mohtar. As the battery used is lithium-ion, there exists a risk of overheating or fire. This risk will be managed by battery voltage being monitored carefully by Miss Philippa Tsirgiotis, as risk increases when the battery level drops below a certain level or is charged above a certain level. The application coupled with the device provides a real-time voltage reading of the battery.

To minimise the risk of invasion of privacy, participants will be informed of the information to be collected, and video and audio recordings to be taken in the Participant Information Sheet. Participants will be asked to complete a Photographic Release Form before video recordings are initiated.

To mitigate the risk of participants being disappointed with previous rehabilitation modalities that they had access to, it will be explained that this device is still in the development phase and is not yet available for clinical use.

G3. Please indicate the possible risk categories to others not participating in the research project.

- [ ] Physical harms
- [ ] Psychological harms
- [ ] Social harms
- [ ] Economic harms
- [ ] Legal harms
- [ ] Invasion of Privacy
- [ ] Devaluation of personal worth
- [ ] Risks specific to Indigenous communities, including Aboriginal and Torres Strait Islander people
- [x] Other

G3.1. Please explain the risks in more detail and provide strategies for minimising these risks.

There is negligible risk to the others not participating in the project.

Data Collection

H1. What type of data will be collected?

If health and medical information will be collected from the Aboriginal and Torres Strait Islander community in South Australia, an Ethics application must also be submitted to the Aboriginal Health Council of South Australia (in addition to this application).

- [x] Non-personal information
- [x] Personal information
- [ ] Sensitive information
- [x] Health and Medical information
- [ ] Information about the health of Aboriginal and Torres Strait Islander people

H1.1. Please advise what kind of personal and/or sensitive information will be collected.

The following information will be collected: gender, age, highest completed education level, mobile phone usage and medical history relating to the participant's shoulder condition.

H2. Does the project require the use or disclosure of information from a Commonwealth agency?

- ○ Yes
- ◉ No

H3. Will health or medical information be sought from a private sector organisation or health service funded by the State Department of Health?

- ◉ Yes
- ○ No

H3.1. Does the project require the use or disclosure of personal information?

- ◉ Yes
- ○ No

H3.2. With respect to this information, was consent obtained from all individuals to whom the information related?

- ◉ Yes
- ○ No

Data Storage & Access

H4. Please outline how long the data will be stored.

- (•) At least five years from the date of publication
- ( ) At least seven years from the date of publication if the research involves a South Australian Government Department
- ( ) Permanently if the data relates to work that has a community or heritage value, preferably within a national collection
- ( ) (For Coursework Applications ONLY) At least 12-months after the completion of the project if the research project is for assessment purposes only, such as class research projects
- ( ) Other

H5. In what format will the data be stored?

- [x] Hard-copy
- [x] Electronic copy
- [ ] Artefacts
- [ ] Other

H6. Will the data be stored at a location external to Flinders University?

- ( ) Yes
- (•) No

H7. Who will have access to the data?

- (•) Only personnel listed in this application
- ( ) Other researchers than those listed in this application

H8. Do you intend to use the data in future research projects?

Participants must be able to consent to the use of their data in future research projects. This must be clearly stated in the Participant Information Sheet.

- (•) Yes
- ( ) No

Data Sources & Identifiability

H9. What sources of information will be used in this project?

- [x] Individual participants
- [x] Relatives or associates of participants
- [ ] Medical/health/mental health records
- [ ] Electoral Roll
- [ ] Law enforcement agency
- [ ] Public Sector organisation
- [ ] Private Sector organisation
- [ ] Publicly available database
- [ ] Privately available database
- [ ] Internet
- [ ] Other

H10. Will the data be individually identifiable, re-identifiable or non-identifiable?

- ☐ Individually identifiable
- ☑ Re-identifiable
- ☐ Non-identifiable

H10.1. Please outline in detail how individually identifiable and/or re-identifiable data will be decoded and stored to protect the confidentiality and privacy of participants.

Each participant will be assigned a random code which will accompany all collected data. This code will be re-identifiable by Philippa Tsirgiotis only, who will store the decoding information in a password protected electronic file. Any data that cannot be de-identified (such as certain sections of videos) will not be shared with the project team and will be destroyed on completion of the study.

H11. Will other persons be able to identify research participants from published data or other sources?

- ○ Yes, but only with the participants' consent
- ◉ No

Documents to upload

I1. Do you have any additional attachments to upload?

- ◉ Yes
- ○ No

Documents

Type	Document Name	File Name	Version Date	Version	Size
Default	Letter of permission	Letter of permission.pdf	16/04/2021	1.0	426.5 KB
Default	Images of device prototype	Images of device prototype.pdf	16/04/2021	1.0	206.2 KB

Signature

Declaration

I, as the Chief Investigator or authorised delegate, certify that:

- All information contained in this application is true and accurate.
- I have had access to and read the National Statement on Ethical Conduct in Human Research 2007 (Updated 2018), and that the research will be conducted in accordance with the National Statement and in accordance with the ethical arrangements of the organisations involved.
- I have consulted any relevant legislation and regulations, and the research will be conducted in accordance with these.
- I have, if applicable, provided all collaborators and other persons involved in this research project with access to this application (online or PDF) and will provide them with all future amendments and reports.
- All collaborators and other persons involved in this project are aware of the requirements and conditions and will conduct the research in accordance with these.
- I will immediately report to Research Ethics & Compliance anything which might warrant review of the ethical approval of the proposal.
- I will inform Research Ethics & Compliance, giving reasons, if the research project is discontinued before the expected date of completion.
- I will adhere to the conditions of approval stipulated by the Committee and will cooperate with the Committee's monitoring requirements, including the provision of annual progress reports and final reports as required.

Please ensure you understand each statement and your responsibilities and then select "Certified" below.

☑ Certified

Please note:
Undergraduate, Honours and Masters students must request the signature of their Principal Supervisor/Course Convenor.

Signature

Signed: This form was signed by David Hobbs (david.hobbs@flinders.edu.au) on 09/06/2021 15:30

Appendix B – Letter of Introduction to Potential Participants

Dear client of Physio One,

I am writing to inform you of a research study that you may be interested to take part in. The study is being conducted by researchers from Flinders University. I am contacting you because you have been identified as a client of Physio One Lockleys who has undergone rehabilitation treatment following shoulder surgery.

The study is being conducted to gain feedback on a new shoulder rehabilitation device that is in the early stages of development. The researchers would like to assess the usability of the device in order to identify any areas for improvement. This will involve you interacting with a prototype version of the device and answering questions regarding your impressions of it. This device has been developed in conjunction with Physio One physiotherapist, Mr Luke Mason.

Participation in this study is entirely optional and your decision to participate or otherwise has no impact on the services you receive from Physio One or Mr Luke Mason.

Please find attached the Participant Information Sheet and Consent Form. If you wish to take part in this study, please email your completed Consent Form to Co-Investigator Miss Philippa Tsirgiotis at philippa.tsirgiotis@flinders.edu.au - please do not return the Consent Form to Physio One.

Once your Consent Form has been received, you will be contacted by Miss Tsirgiotis to arrange a time for you to visit the Physio One Lockleys premises for the research session. If you have any questions regarding the study, please contact the Chief Investigator, Dr David Hobbs, via phone at (08) 8201 3167.

If you decide to not take part in this study, you do not need to respond to this letter. Please remember that your decision not to participate will have no effect on any ongoing treatment you are receiving as a client of Physio One.

Sincerely,

Cassie Lawrence
Practice Manager
Physio One

Appendix C – Participant Information Sheet and Consent Form

PARTICIPANT INFORMATION SHEET AND CONSENT FORM

Title: 'Usability Study of a Novel Shoulder Rehabilitation Device'

Chief Investigator
Dr David Hobbs
College of Science and Engineering
Flinders University
Tel: +61 8 8201 3167
Email: david.hobbs@flinders.edu.au

Co-Investigators
Miss Philippa Tsirgiotis
College of Science and Engineering
Flinders University
Tel: +61 8 8201 3167
Email: philippa.tsirgiotis@flinders.edu.au

Mr Luke Mason
Principal Physiotherapist
Physio One Lockleys
Email: [redacted]

Mr Jim Hannon-Tan
Jim Hannon-Tan Concept and Industrial Design
Email: [redacted]

Mr Tom Russell
Jim Hannon-Tan Concept and Industrial Design
Email: [redacted]

Supervisor
Dr David Hobbs
College of Science and Engineering
Flinders University
Tel: +61 8 8201 3167
Email: david.hobbs@flinders.edu.au

inspiring achievement

My name is Philippa Tsirgiotis and I am a Flinders University Masters of Engineering student. I am undertaking this research as part of my degree. For further information, you are more than welcome to contact my primary supervisor, David Hobbs. His details are listed above.

Description of the study
This study is entitled 'Usability Study of a Novel Shoulder Rehabilitation Device' and aims to investigate the usability of a novel shoulder rehabilitation device. This study is supported by the Flinders University College of Science and Engineering.

Purpose of the study
This study aims to:

- Assess the usability of a new rehabilitation device
- Collect perspectives from potential users on the device design and functionality
- Collect general information about the target demographic of the device

Benefits of the study
The sharing of your experiences will help the project team developing the device to improve its design. Participating in this study will assist the development of our prototype device for use as an at-home musculoskeletal shoulder rehabilitation device.

Participant involvement and potential risks
Potential participants of this study have been identified by physiotherapist Luke Mason, as clients of Physio One Lockleys who have undergone rehabilitation treatment following shoulder surgery, and are deemed to be at low risk of injury using the device. Please note that while Mr Mason has short-listed potential participants, he will not be informed of your decision to participate or not to participate in this study.

If you agree to participate in the research study, you will be asked to attend one session at the Physio One Lockleys clinic and:

- Complete hard copy questionnaires regarding your personal information, medical history regarding your shoulder health, and familiarity with technology
- Try out the rehabilitation device
- Consent to yourself being video recorded and photographed while trying the device
- Complete hard copy questionnaires regarding your impressions of the device
- Verbally answer questions regarding your impressions of the device, which will be audio recorded.

The session will take about 30 to 45 minutes and participation is entirely voluntary.

The researchers anticipate few risks for your participation in this study. There is a possibility of shoulder pain, discomfort or injury if the device is used incorrectly. However, you will receive instructions on the safe operation of the device and be supervised at all times while you are using the device. The device is powered from a low-voltage battery and risk of exposure to electricity sources is extremely low. As the battery is lithium-ion in composition, there is a slight risk of the battery overheating or catching fire. However, this risk has been minimised through the design process to keep the battery charge at a safe level, which will be monitored carefully by researchers throughout the study.

The researchers do not expect the study to cause any harm or discomfort to you. However, if you experience feelings of distress as a result of participation in this study, please let the research team know immediately. You can also contact the following services for support:

- Lifeline – 13 11 14, www.lifeline.org.au
- Beyond Blue – 1300 22 4636, www.beyondblue.org.au

Withdrawal Rights
You may, without any penalty, decline to take part in this research study. If you decide to take part and later change your mind, you may, without any penalty, withdraw at any time without providing an explanation. To withdraw, please contact the Chief Investigator or Philippa Tsirgiotis or you may just refuse to answer any questions and leave the interview at any time. Any data collected up to the point of your withdrawal will be securely destroyed.

Confidentiality and Privacy
Only researchers listed on this form have access to the individual information provided by you. Privacy and confidentiality will be assured at all times. The research outcomes may be presented at conferences, written up for publication or used for other research purposes as described in this information form. However, the privacy and confidentiality of individuals will be protected at all times. You will not be named, and your individual information will not be identifiable in any research products without your explicit consent.

The de-identified data collected from this study will be included in Philippa Tsirgiotis' Masters of Engineering thesis and may be published in a journal article.

No data, including identifiable, non-identifiable and de-identified datasets, will be shared or used in future research projects without your explicit consent.

Data Storage
The information collected will be stored securely on a password protected computer that only Philippa Tsirgiotis will have access to. If you choose to participate, you will be assigned a random participant code that will accompany your data. This code will be re-identifiable by Philippa Tsirgiotis only, who will store the decoding information in a password protected file. All data will be de-identified before being shared with the other Co-Investigators listed above. All data will be securely transferred to and stored at Flinders University for at least five years after publication of the results. Following the required data storage period, all data will be securely destroyed according to university protocols.

Declaration of Interests of Researchers
Physiotherapist Luke Mason and orthopaedic surgeon Dr Jonathan Cabot are sponsoring the overall project that this study is a part of. However, they will not have access to identifiable data and will not be present during the study.

How will I receive feedback?
On project completion, a short summary of the outcomes will be provided to all participants via email.

Ethics Committee Approval
The project has been approved by Flinders University's Human Research Ethics Committee (Project number 4143).

Queries and Concerns

Queries or concerns regarding the research can be directed to the research team. If you have any complaints or reservations about the ethical conduct of this study, you may contact the Flinders University's Research Ethics & Compliance Office team via telephone (08) 8201 3116 or email human.researchethics@flinders.edu.au.

Thank you for taking the time to read this information sheet which is yours to keep. If you accept our invitation to be involved, please sign the enclosed Consent Form.

CONSENT FORM

Consent Statement

☐ I have read and understood the information about the research, and I understand I am being asked to provide informed consent to participate in this research study. I understand that I can contact the research team if I have further questions about this research study.

☐ I am not aware of any condition that would prevent my participation, and I agree to participate in this project.

☐ I understand that I am free to withdraw at any time during the study.

☐ I understand that I can contact Flinders University's Research Ethics & Compliance Office if I have any complaints or reservations about the ethical conduct of this study.

☐ I understand that my involvement is confidential, and that the information collected may be published. I understand that I will not be identified in any research products.

I further consent to:

☐ completing hard copy questionnaires
☐ participating in an interview
☐ having my information audio recorded
☐ having my information video recorded
☐ having my photo taken
☐ my data and information being used in this project and other related projects for an extended period of time (no more than 5 years after publication of the data)
☐ being contacted about other research projects

Signed:_____

Name:_____

Date:_____

Please return this completed Consent Form to Co-Investigator Miss Philippa Tsirgiotis, via the following email address: philippa.tsirgiotis@flinders.edu.au

Appendix D – Participant Information Questionnaire

Participant information questionnaire

Q1	Please provide your gender. ○ Male ○ Female ○ Non-binary / third gender ○ Prefer not to say
Q2	Please provide your age in years.
Q3	Please provide your highest completed education level. ○ Primary school ○ Middle school ○ High school ○ Vocational qualification ○ Diploma ○ Undergraduate degree ○ Postgraduate degree ○ Doctorate
Q4	What is your dominant arm or throwing arm? ○ Left arm ○ Right arm ○ Ambidextrous
Q5	Which arm will you be using to grip the device today? ○ Left arm ○ Right arm
Q6	Please provide a short summary of the medical history relating to your shoulder condition including the duration of symptoms, any diagnoses and operations on the shoulder.

Q7	Which rehabilitation tools have you used for your shoulder condition? ☐ Mobilisation or stretching by a healthcare professional ☐ Pulley system ☐ Elastic, resistance bands or therabands ☐ Free weights ☐ Machine weights ☐ Brace or sling ☐ Shoulder/finger ladder ☐ Cane or stick ☐ Hydrotherapy ☐ Arm ergometer (exercise bike machine) ☐ Robotic device, please specify:
Q8	Do you have access to wireless internet at home? ○ Yes ○ No ○ Unsure
Q9	Which mobile devices do you own or have regular access to? ☐ Smart phone (eg. iPhone, Android phone) ☐ Tablet (eg. iPad, Samsung tablet) ☐ Other, please specify: ☐ None
Q10	How would you rate your confidence with using apps on a mobile phone? Not at all confident ○ ○ ○ ○ ○ Very confident
Q11	Which apps do you use on a regular basis?

Participant code: _____

Appendix E – Shoulder Pain and Disability Index

Shoulder Pain and Disability Index (SPADI)

Please read carefully:

Instructions: Please circle the number that best describes the question being asked.

Pain scale:
No pain at all 0 1 2 3 4 5 6 7 8 9 10 Worst pain Imaginable

How severe is your pain?

1. At its worst?
   0 1 2 3 4 5 6 7 8 9 10
2. When lying on the involved side?
   0 1 2 3 4 5 6 7 8 9 10
3. Reaching for something on a high shelf?
   0 1 2 3 4 5 6 7 8 9 10
4. Touching the back of your neck?
   0 1 2 3 4 5 6 7 8 9 10
5. Pushing with the involved arm?
   0 1 2 3 4 5 6 7 8 9 10

Disability scale:
No difficulty 0 1 2 3 4 5 6 7 8 9 10 So difficult it requires help

How much difficulty do you have?

1. Washing your hair?
   0 1 2 3 4 5 6 7 8 9 10
2. Washing your back?
   0 1 2 3 4 5 6 7 8 9 10
3. Putting on an undershirt or pullover sweater?
   0 1 2 3 4 5 6 7 8 9 10
4. Putting on a shirt that buttons down the front?
   0 1 2 3 4 5 6 7 8 9 10
5. Putting on your pants?
   0 1 2 3 4 5 6 7 8 9 10
6. Placing an object on a high shelf?
   0 1 2 3 4 5 6 7 8 9 10
7. Carrying a heavy object of 10 pounds? (around 4.5kg)
   0 1 2 3 4 5 6 7 8 9 10
8. Removing something from your back pocket?
   0 1 2 3 4 5 6 7 8 9 10

Patient code: _____

Appendix F – System Usability Scale

System Usability Scale (SUS)

For each of the following statements, mark one box that best describes your reactions to the device today.

	Strongly Disagree				Strongly agree
1. I think that I would like to use this product frequently.	○	○	○	○	○
2. I found the product unnecessarily complex.	○	○	○	○	○
3. I thought the product was easy to use.	○	○	○	○	○
4. I think that I would need the support of a technical person to be able to use this product.	○	○	○	○	○
5. I found the various functions of the product were well integrated.	○	○	○	○	○
6. I thought there was too much inconsistency in this product.	○	○	○	○	○
7. I imagine that most people would learn to use this product very quickly.	○	○	○	○	○
8. I found the product very awkward to use.	○	○	○	○	○
9. I felt very confident using the product.	○	○	○	○	○
10. I needed to learn a lot of things before I could get going with the product.	○	○	○	○	○

Overall, I would rate the user-friendliness of this product as:

Worst imaginable	Awful	Poor	Fair	Good	Excellent	Best imaginable
○	○	○	○	○	○	○

Participant code: _____

Appendix G – Semi-structured Interview Questions

Device and application questions	
1	How would you describe your overall experience with the device?
2	What would you change about the device?
3	How would you compare this device to at-home rehabilitation tools you have used?
4	Would you have liked to use a device like this during your rehabilitation?
5	I noticed … while you were using the device. Can you tell me why you did that?
6	What are your thoughts about the impact of real-time feedback on your use of the device?
7	Would you prefer the feedback to be displayed on an app or on the device itself?
8	How would you feel about using your own phone or tablet with the device?
9a	How much would you be willing to pay for this device?
9b	If you rented this device on a weekly basis, how much would you be willing to pay per week?
Charging dock questions	
10	What are your thoughts on charging the device like this?
11	Would you prefer charging the device on a dock like this or plugging a cord directly into the device?

Appendix H – Muscle Activation Study Protocol

Materials needed:

- 6 sensors per participant
- Alcohol wipes
- Razors
- Device with battery and phone
- Camera
- Stopwatch
- Metronome (laptop)
- Goniometer
- Measuring tape
- Force plates for weight
- Towel
- Pillow
- Sharpie
- Computer with software
- Printed sensor position document and protocol

1. Collect measurements (age, height, elbow-centre of grip length, forearm-hand length, lower arm and shoulder-elbow length) and practice motions
2. Log on to computer
3. Close OneDrive
4. Open Trigno Control Utility
5. Remove sensor from box and run magnet over, repeat for 6 sensors
6. Check all sensors flashing green and connected to computer
7. Check that all sensors are collecting EMG only
8. Open Vicon Nexus 2.9.3 on desktop (click 'Retry' if error occurs)
9. Open Task Manager
10. Find 'SensorBaseController.exe' and 'Nexus' and set priority to high (under details)
11. On Vicon: Add 'Digital Device'
12. Add 'Delsys Trigno System'
13. Add 'Digital Device'
14. Add 'AMTI Gen5/Optima devices – BEGTA+9dbg'
15. Ask participant to stand on force plate and note weight
16. Expand EMG on left and set display to graph for the 6 sensors being used
17. Check each is sending data with limited latency **(restart Vicon if latency too high)**
18. Click 'Window' in toolbar, 'Reset to default'
19. Navigate to: Flinders Training > Philippa Tsirgiotis
20. Create a person
21. Shave site if necessary and clean skin surface on dominant arm using alcohol wipes
22. Stick 6 EMG sensors on dominant side, securing with tape or bandage

    a. Upper Trapezius
    b. Middle Trapezius
    c. Lower Trapezius
    d. Anterior Deltoid
    e. Middle Deltoid
    f. Posterior Deltoid
23. Note sensor numbers with corresponding muscles
24. Use clinical tests in sensor positioning document to verify sensor position/adherence
    a. Upper Trapezius
    b. Middle Trapezius
    c. Lower Trapezius
    d. Anterior Deltoid
    e. Middle Deltoid
    f. Posterior Deltoid
25. Select pie graph for a new session, give appropriate name
26. Double click on session
27. Go live
28. **Take photos of participant from anterior, lateral and posterior views**
29. Set up participant sat at seat height: 49cm / table height: 72.5cm
30. Participant right elbow flexed 90 degrees with device on edge of the table in position of FF
31. **Take lateral photo of participant in starting position**
32. *Start capture Device_FF01*
33. Move to maximum forward flexion and return to neutral for 5 reps
34. *Stop capture Device_FF01*
35. Participant change position so sat perpendicular to table
36. Place dominant elbow on edge of table to complete abduction
37. **Take photo of participant in starting position**
38. *Start capture Device_Abd01*
39. Perform abduction motion for 5 reps
40. *Stop capture Device_Abd01*
41. Set up metronome at 40bpm
42. *Start capture Pend01*
43. Participant perform pendulum for 10 seconds
44. *Stop capture Pend01*
45. Set up towel for towel slide and seat participant
46. *Start capture Slide01*
47. Participant perform towel slide 5 times
48. *Stop capture Slide01*
49. Lay participant on ground
50. *Start capture Elev01*
51. Participant perform assisted elevation with interlocked fingers 5 times
52. *Stop capture Elev01*

53. Run through Matlab code eliminating first and last cycle

Measure MVIC (Boettcher *et al.*, 2008):

1. Exercises should be held at maximum effort for at least 3 seconds
2. *Start capture EC_MVIC01*
3. Perform 'empty can' exercise with assistant
4. *Stop capture EC_MVIC01*
5. Rest 30 seconds
6. *Start capture EC_MVIC02*
7. Perform 'empty can' exercise with assistant
8. *Stop capture EC_MVIC02*
9. Rest 60 seconds
10. *Start capture IR_MVIC01*
11. Perform 'internal rotation 90 deg' exercise with assistant
12. *Stop capture IR_MVIC01*
13. Rest 30 seconds
14. *Start capture IR_MVIC02*
15. Perform 'internal rotation 90 deg' exercise with assistant
16. *Stop capture IR_MVIC02*
17. Rest 60 seconds
18. *Start capture Flex_MVIC01*
19. Perform 'flexion 125 deg' exercise with assistant
20. *Stop capture Flex_MVIC01*
21. Rest 30 seconds
22. *Start capture Flex_MVIC02*
23. Perform 'flexion 125 deg' exercise with assistant
24. *Stop capture Flex_MVIC02*
25. Rest 60 seconds
26. *Start capture PP_MVIC01*
27. Perform 'palm press' exercise independently
28. *Stop capture PP_MVIC01*
29. Rest 30 seconds
30. *Start capture PP_MVIC02*
31. Perform 'palm press' exercise independently
32. *Stop capture PP_MVIC02*
33. MVIC for each muscle is the maximum level of activation generated across all 4 tests

34. Export all captures to CSV
    a. Pipeline (grey bubbles above)
    b. Cog on right

c. Export ASCII
d. Play button

Exercise name	Description	Image
Empty can	Shoulder abducted 90 deg in scapular plane with internal humeral rotation and elbow extended; arm abducted as resistance applied at wrist	
Internal rotation 90 deg	Shoulder abducted 90 deg in scapular plane with neutral humeral rotation and elbow flexed 90 deg; arm internally rotated as resistance applied at wrist	
Flexion 125 deg	Shoulder flexion 125 deg as resistance applied above the elbow and at the inferior angle of the scapula attempting to de-rotate scapula	
Palm press	Shoulders flexed 90 deg bilaterally with the heel of the hands together, elbows flexed 20 deg and arms horizontally adducting	

Removed due to copyright restrictions

Upper trapezius

Starting posture	Erect sitting, with the arms hanging vertically.
Electrode size	Maximum size in the direction of the muscle fibers: 10 mm.
Electrode distance	20 mm
- location	The electrodes need to be placed at 50% on the line from the acromion to the spine on vertebra C7.
- orientation	In the direction of the line between the acromion and the spine on vertebra C7.
- fixation on the skin	(Double sided) tape / rings.
- reference electrode	On the proc. spin. of C7 or on / around the wrist.
Clinical test	Elevate the acromial end of the clavicule and scapula; extend and rotate the head and neck toward the elevated shoulder with the face rotated in the opposite direction. Apply pressure against the shoulder in the direction of depression and against the head in the direction of flexion anterolaterally.

Middle trapezius

Starting posture	Erect sitting, with the arms hanging vertically.
Electrode size	Maximum size in the direction of the muscle fibers: 10 mm.
Electrode distance	20 mm
- location	The electrodes need to be placed at 50% between the medial border of the scapula and the spine, at the level of T3.
- orientation	In the direction of the line between T5 and the acromion.
- fixation on the skin	(Double sided) tape / rings.
- reference electrode	On the proc. Spin. of C7 or on / around the wrist.
Clinical test	The elbow extensors and the posterior shoulder muscles must give necessary fixation in order to use the arm as a lever. Adduction of the scapula from a position of rotation in which the inferior angle is rotated laterally. To obtain this position of the scapula and to obtain leverage for the test, the elbow needs to be extended and the shoulder placed in 90 degrees abduction and lateral rotation. This rotation of the shoulder is denoted by the position of the hand with the palm facing cranially (without elevating the shoulder girdle).

Lower trapezius

Starting posture	Erect sitting, with the arms hanging vertically.
Electrode size	Maximum size in the direction of the muscle fibers: 10 mm.
Electrode distance	20 mm
- location	The electrodes need to be placed at 2/3 on the line from the trigonum spinea to the 8th thoracic vertebra.
- orientation	In the direction of the line between T8 and the acromion.
- fixation on the skin	(Double sided) tape / rings.
- reference electrode	On the proc. spin. of C7 or on / around the wrist.
Clinical test	Take care that the elbow extensors and shoulder muscles give necessary fixation to use the arm as a lever in this test. Depression, lateral rotation of the inferior angle, and adduction of the scapula. To obtain this position of the scapula in order to place emphasis on the action of the ascending fibres and to obtain leverage for the test, the arm is placed diagonally overhead with the shoulder laterally rotated. Apply pressure against the forearm in downward direction.

Anterior deltoid

Starting posture	Sitting with the arms hanging vertically and the palm pointing inwards.
Electrode size	Maximum size in the direction of the muscle fibers: 10 mm.
Electrode distance	20 mm
- location	The electrodes need to be placed at one finger width distal and anterior to the acromion.
- orientation	In the direction of the line between the acromion and the thumb.
- fixation on the skin	(Double sided) tape / rings.
- reference electrode	On the proc. spin. of C7 or on / around the wrist.
Clinical test	Shoulder abduction in slight flexion, with the humerus in slight rotation. In the erect sitting position it is necessary to place the humerus in slight lateral rotation to increase the effect of gravity on the anterior fibres. The anatomical action of the anterior deltoideus entails slight medial rotation while pressure is applied against the antero medial surface of the arm in the direction of adduction and slight extension.

Medial deltoid

Starting posture	Sitting with the position of the trunk in relation to the arm such that a stable trunk will need no further stabilization. If the scapula fixation muscles are weak the scapula must be stabilized.
Electrode size	Maximum size in the direction of the muscle fibers: 10 mm.
Electrode distance	20 mm
- location	Electrodes need to be placed from the acromion to the lateral epicondyle of the elbow. This should correspond to the greatest bulge of the muscle.
- orientation	In the direction of the line between the acromion and the hand.
- fixation on the skin	(Double sided) tape / rings.
- reference electrode	On the proc. spin. of C7 or on / around the wrist.
Clinical test	The arm should be abducted without rotation. When placing the shoulder in test position, the elbow should be flexed to indicate the neutral position of rotation but may be extended after the shoulder position is established in order to use the extended extremity for a longer lever. Pressure needs to be applied against the dorsal surface of the distal end of the humerus if the elbow is flexed or against the forearm if the elbow is extended.

Posterior deltoid

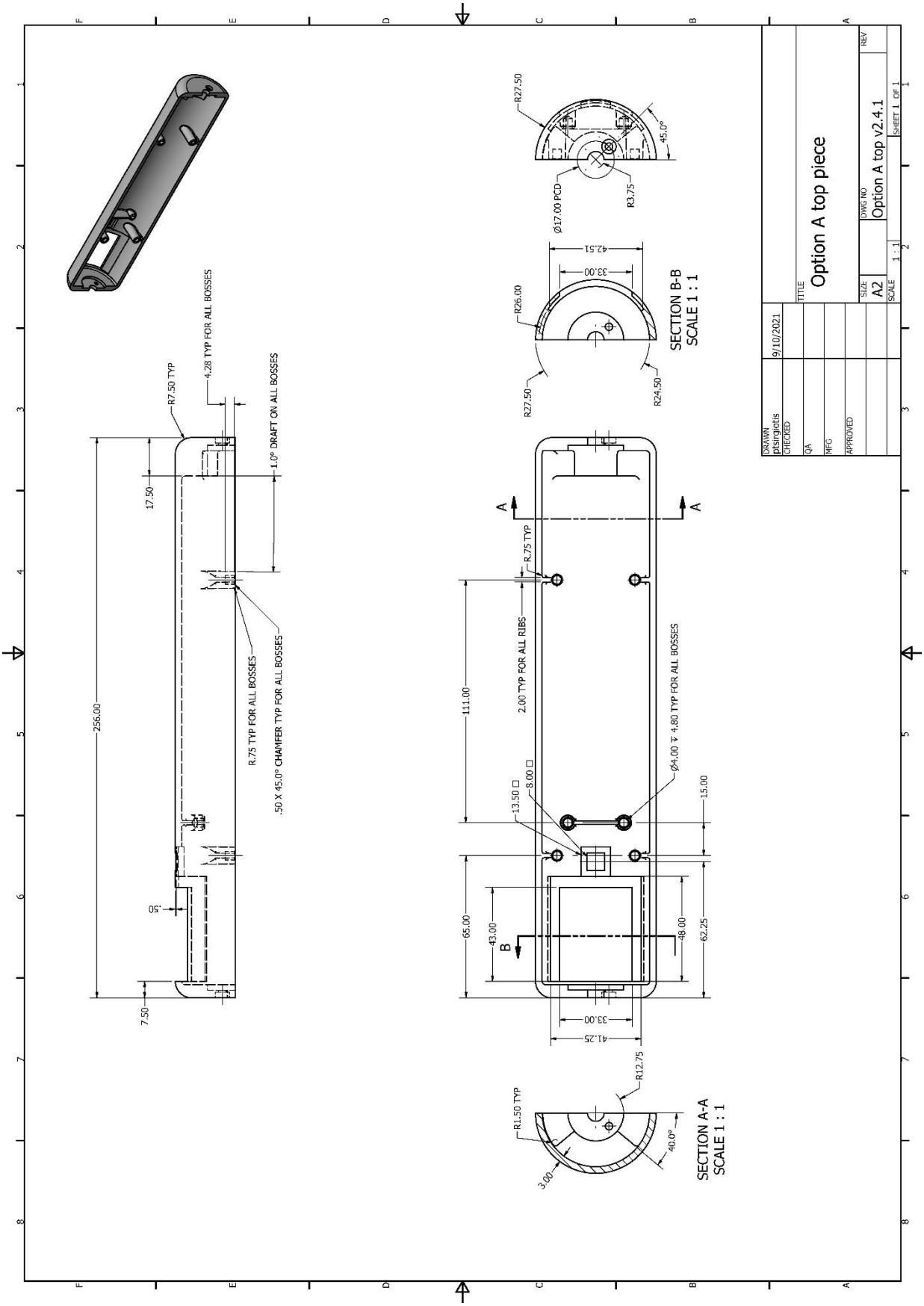
Starting posture	Erect sitting with the arms hanging vertically and the palm of the hand pointing inwards.
Electrode size	Maximum size in the direction of the muscle fibers: 10 mm.
Electrode distance	20 mm
- location	Center the electrodes in the area about two fingerbreadths behind the angle of the acromion.
- orientation	In the direction of the line between the acromion and the little finger.
- fixation on the skin	(Double sided) tape / rings.
- reference electrode	On the proc. spin. of C7 or on / round the wrist.
Clinical test	Abduct the shoulder in slight extension, with the humerus in slight medial rotation. The humerus is placed in slight medial rotation in order to have the posterior fibres in an anti-gravity position. The anatomical action entails slight lateral rotation while pressure is applied against the posterolateral surface of the arm, above the elbow in the direction of adduction and slight flexion.

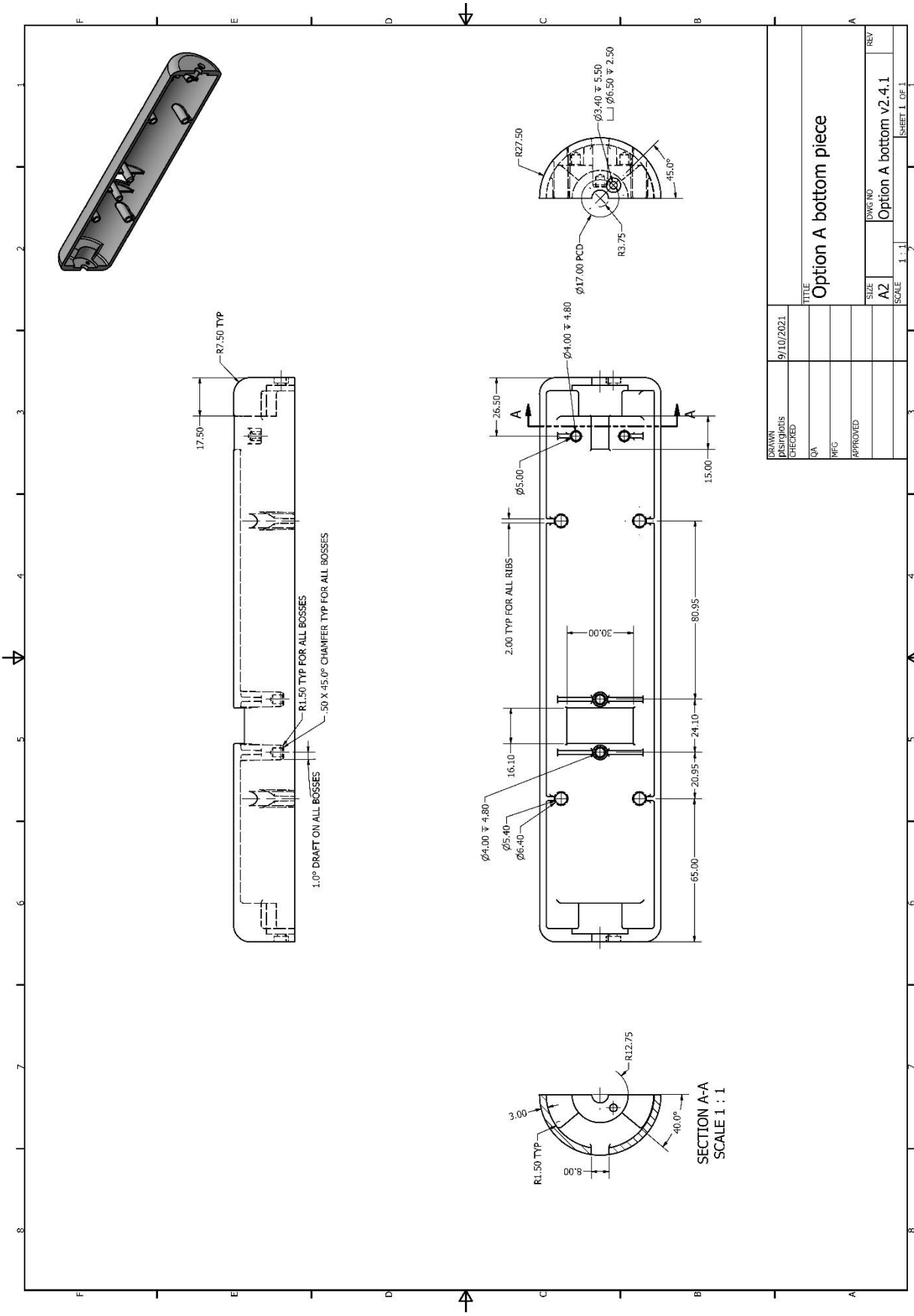
Appendix J – EMG Processing Code (MATLAB)

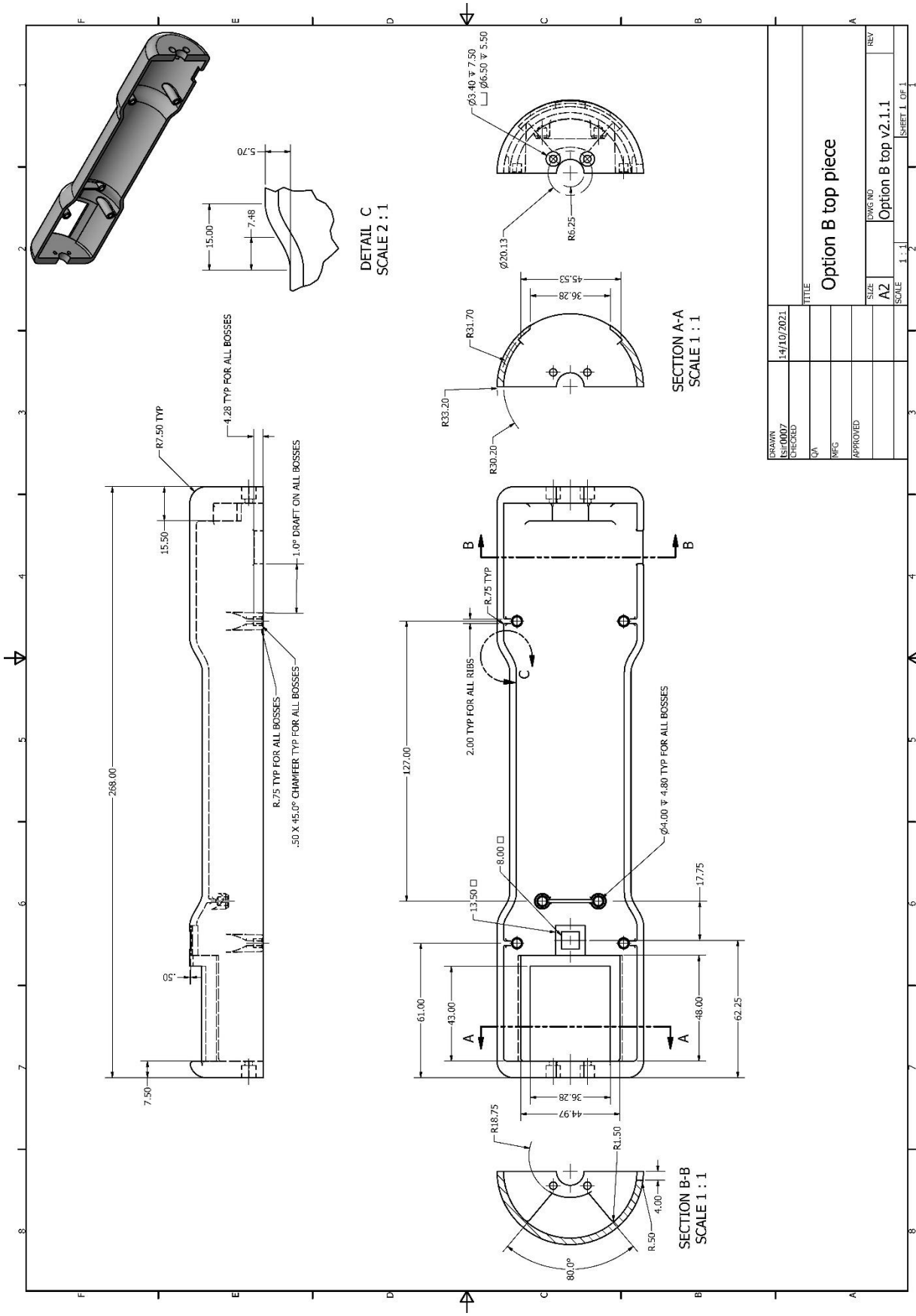
```
%% For finding MVIC values 6/9/21 PT
Muscles = {'1: UT', '2: MT', '3: LT', '4: AD', '5: MD', '6: PD'};
ind = 1;
fileNames = {'EC_MVIC01.xlsx', 'EC_MVIC02.xlsx', 'Flex_MVIC01.xlsx',
'Flex_MVIC02.xlsx', 'IR_MVIC01.xlsx','IR_MVIC02.xlsx','PP_MVIC01.xlsx',
'PP_MVIC02.xlsx'};
TrialMvicValues = zeros((length(fileNames)),6);

for j = 1:length(fileNames)
MVIC = xlsread((fileNames{j}));

fc = 20;
fs = 2000;
[ b, a] = butter( 4, fc / ( fs / 2), 'high');

MVIC_hpfiltered = filter( b, a, MVIC);

fc = 500;
fs = 2000;
[ b, a] = butter( 4, fc / ( fs / 2), 'low');

MVIC_lpfiltered = filter( b, a, MVIC_hpfiltered);
MVIC_lpfiltered = abs( MVIC_lpfiltered);

fc = 5;
fs = 2000;
[ b, a] = butter( 4, fc / ( fs / 2), 'low');
MVIC_filtered = filter( b, a, MVIC_lpfiltered);

 movwinRMS = dsp.MovingRMS( 100);

 MVIC_RMSfiltered = movwinRMS(MVIC_filtered);



 TrialMvicValues(j,:) = max(MVIC_RMSfiltered);

end

 TrialMvicValues
 MvicValues = max(TrialMvicValues)

 %% Processing and graphing trials

Muscles = {'1: UT', '2: MT', '3: LT', '4: AD', '5: MD', '6: PD'};
ind = 1;
fileNames = {'Device_Abd01.xlsx', 'Device_FF01.xlsx', 'Elev01.xlsx',
'Pend01.xlsx', 'Slide01.xlsx'};

for j = 1:length(fileNames) %cycling through each file
EMG = xlsread((fileNames{j}));

fc = 20;
fs = 2000;
[ b, a] = butter( 4, fc / ( fs / 2), 'high');

EMG_hpfiltered = filter( b, a, EMG);
```

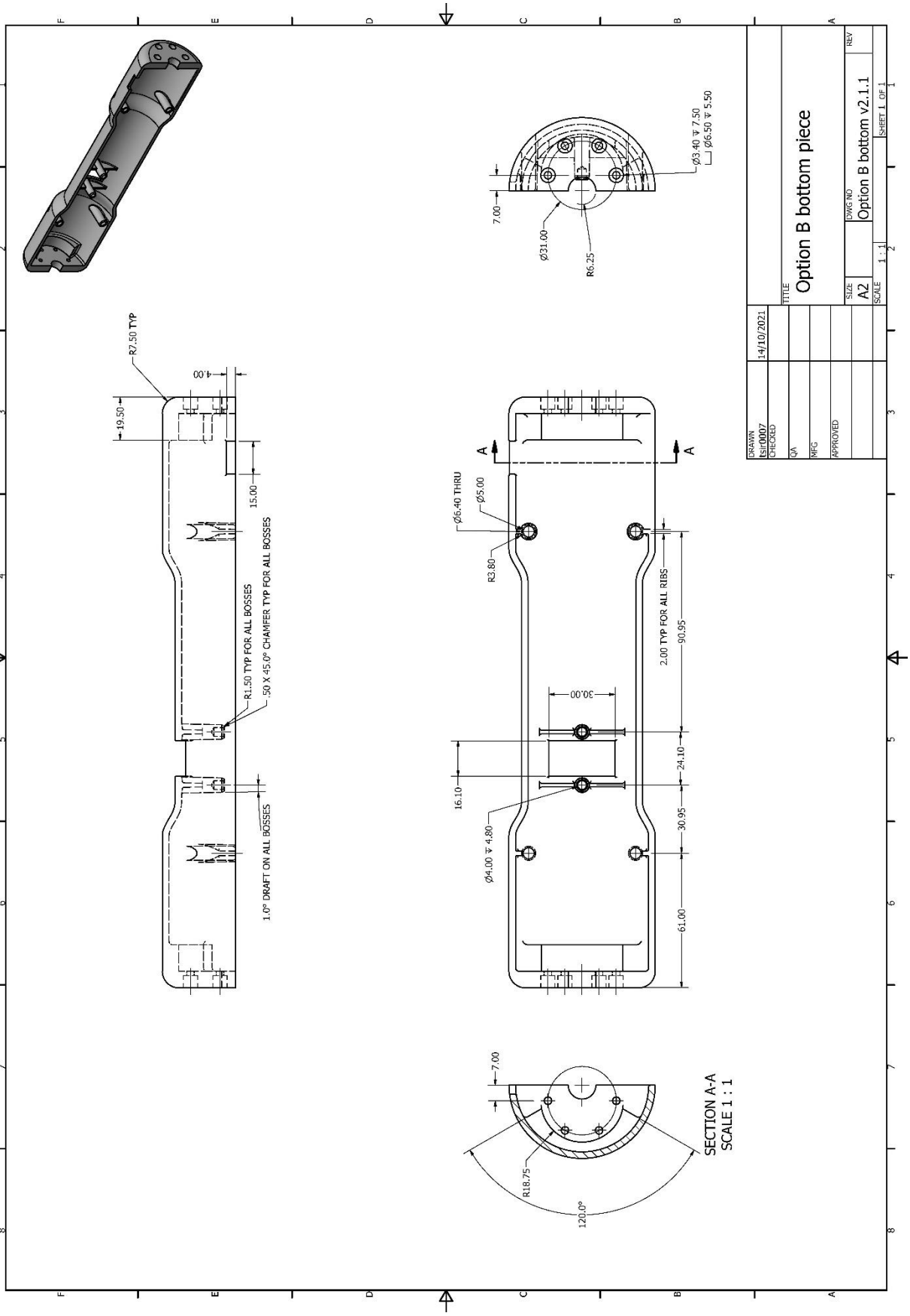
```
fc = 500;
fs = 2000;
[ b, a] = butter( 4, fc / ( fs / 2), 'low');

EMG_lpfiltered = filter( b, a, EMG_hpfiltered);
EMG_lpfiltered = abs(EMG_lpfiltered);

fc = 5;
fs = 2000;
[ b, a] = butter( 4, fc / ( fs / 2), 'low');
EMG_filtered = filter( b, a, EMG_lpfiltered);

movwinRMS = dsp.MovingRMS( 100);
EMG_RMSfiltered = movwinRMS(EMG_filtered);

figure

[r, c] = size(EMG_RMSfiltered);
EMG_normalised = zeros(r,c);

 for i = 1:6 %cycling through muscles

EMG_normalised(:,i) = 100*(EMG_RMSfiltered(:,i))/(MvicValues(1,i));

subplot(2,3,i)
plot(EMG_normalised(:,i))
title(Muscles(i))

ylabel('%MVIC');
sgtitle(fileNames{j})
 end

end
```

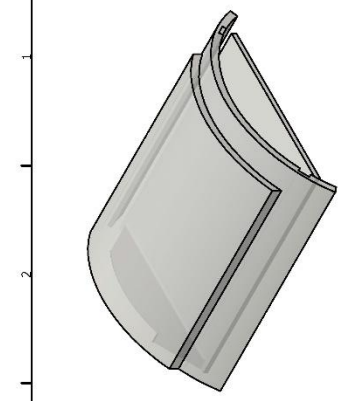
Appendix K – Engineering Drawings of Final Designs

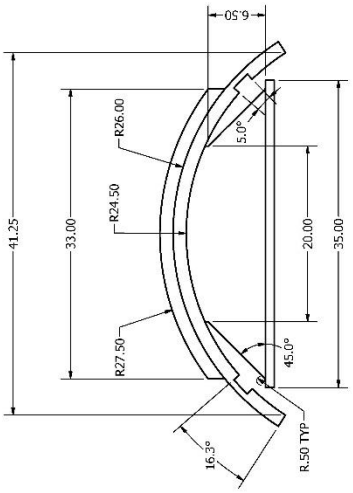



Option A bottom piece
Option A bottom v2.4.1
A2
1 : 1
9/10/2021
ptsirigiotis
SHEET 1 OF 1
R7.50 TYP
17.50
R1.50 TYP FOR ALL BOSSES
.50 X 45.0° CHAMFER TYP FOR ALL BOSSES
1.0° DRAFT ON ALL BOSSES
R27.50
Ø3.40 ↧ 5.50
Ø6.50 ↧ 2.50
45.0°
Ø17.00 PCD
R3.75
Ø4.00 ↧ 4.80
26.50
Ø5.00
15.00
2.00 TYP FOR ALL RIBS
30.00
80.95
24.10
16.10
20.95
Ø4.00 ↧ 4.80
Ø5.40
Ø6.40
65.00
R12.75
3.00
40.0°
R1.50 TYP
8.00
SECTION A-A
SCALE 1 : 1


DETAIL C
SCALE 2 : 1
SECTION A-A
SCALE 1 : 1
SECTION B-B
SCALE 1 : 1
Option B top piece
Option B top v2.1.1
DRAWN
tsir0007
14/10/2021
CHECKED
QA
MFG
APPROVED
SIZE
A2
SCALE
1 : 1
DWG NO
REV
SHEET 1 OF 1
TITLE
R7.50 TYP
4.28 TYP FOR ALL BOSSES
1.0° DRAFT ON ALL BOSSES
R.75 TYP FOR ALL BOSSES
.50 X 45.0° CHAMFER TYP FOR ALL BOSSES
2.00 TYP FOR ALL RIBS
Ø4.00 ⌅ 4.80 TYP FOR ALL BOSSES
268.00
127.00
61.00
43.00
48.00
62.25
17.75
15.50
7.50
.50
R.75 TYP
8.00 □
13.50 □
Ø3.40 ⌅ 7.50
Ø6.50 ⌅ 5.50
Ø20.13
R6.25
R31.70
R33.20
R30.20
45.53
36.28
5.70
15.00
7.48
R18.75
R1.50
R.50
4.00
80.0°
44.97


Option B bottom piece
Option B bottom v2.1.1
A2
1 : 1
14/10/2021
tsir0007
R7.50 TYP
4.00
19.50
15.00
R1.50 TYP FOR ALL BOSSES
.50 X 45.0° CHAMFER TYP FOR ALL BOSSES
1.0° DRAFT ON ALL BOSSES
Ø6.40 THRU
Ø5.00
R3.80
2.00 TYP FOR ALL RIBS
90.95
30.00
16.10
24.10
30.95
61.00
Ø4.00 ∓ 4.80
Ø3.40 ∓ 7.50
Ø6.50 ∓ 5.50
7.00
Ø31.00
R6.25
R18.75
120.0°
SECTION A-A
SCALE 1 : 1



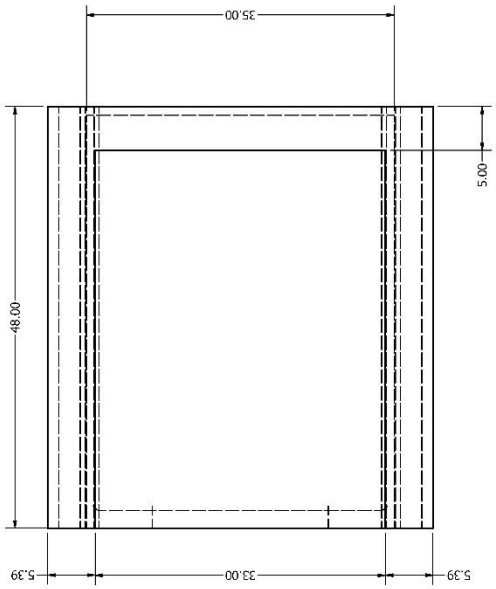


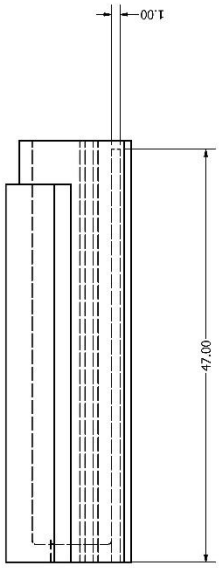
DRAWN	tsir0007	27/09/2021	
CHECKED			
QA			
MFG			
APPROVED			

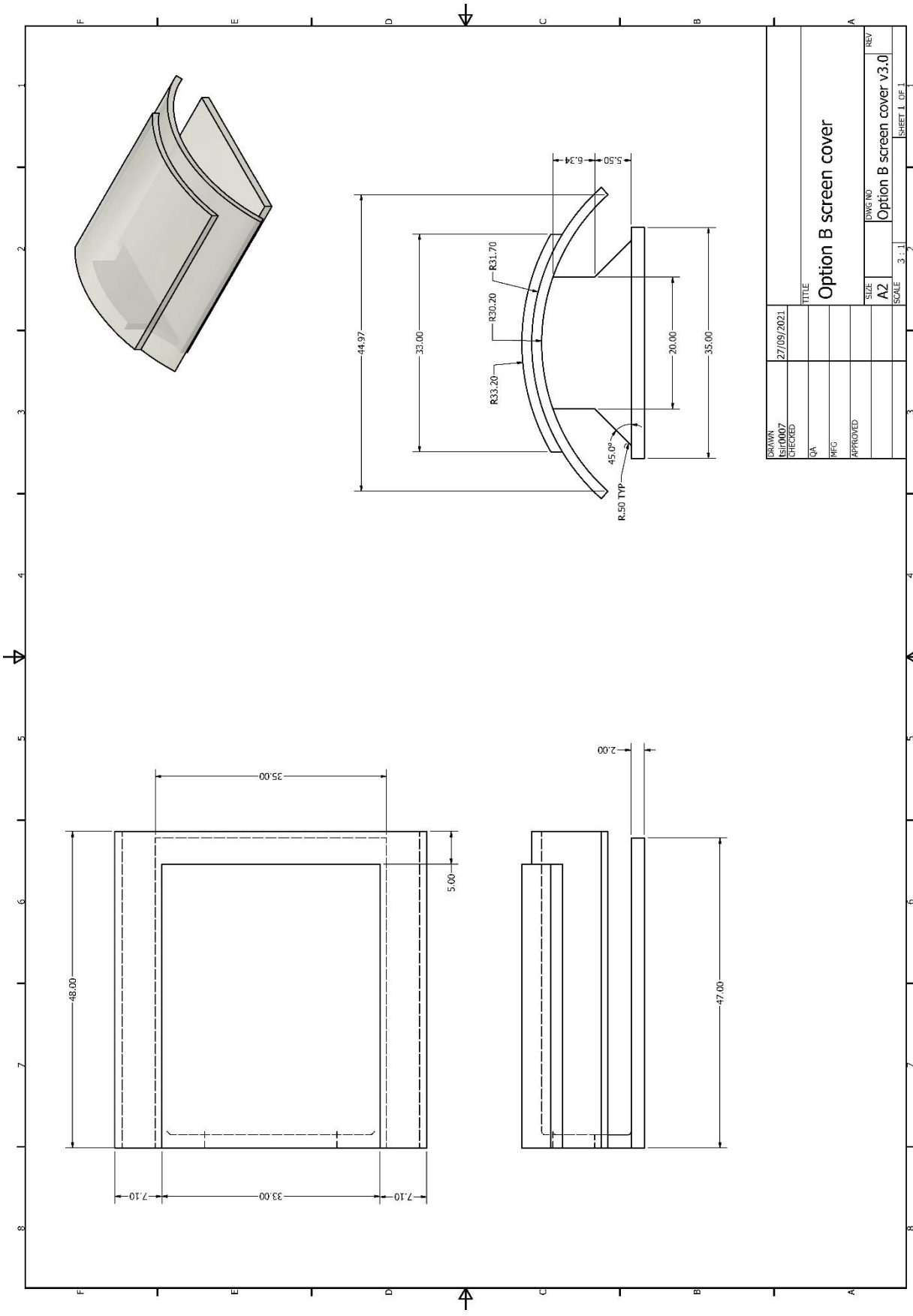
TITLE: Option A screen cover

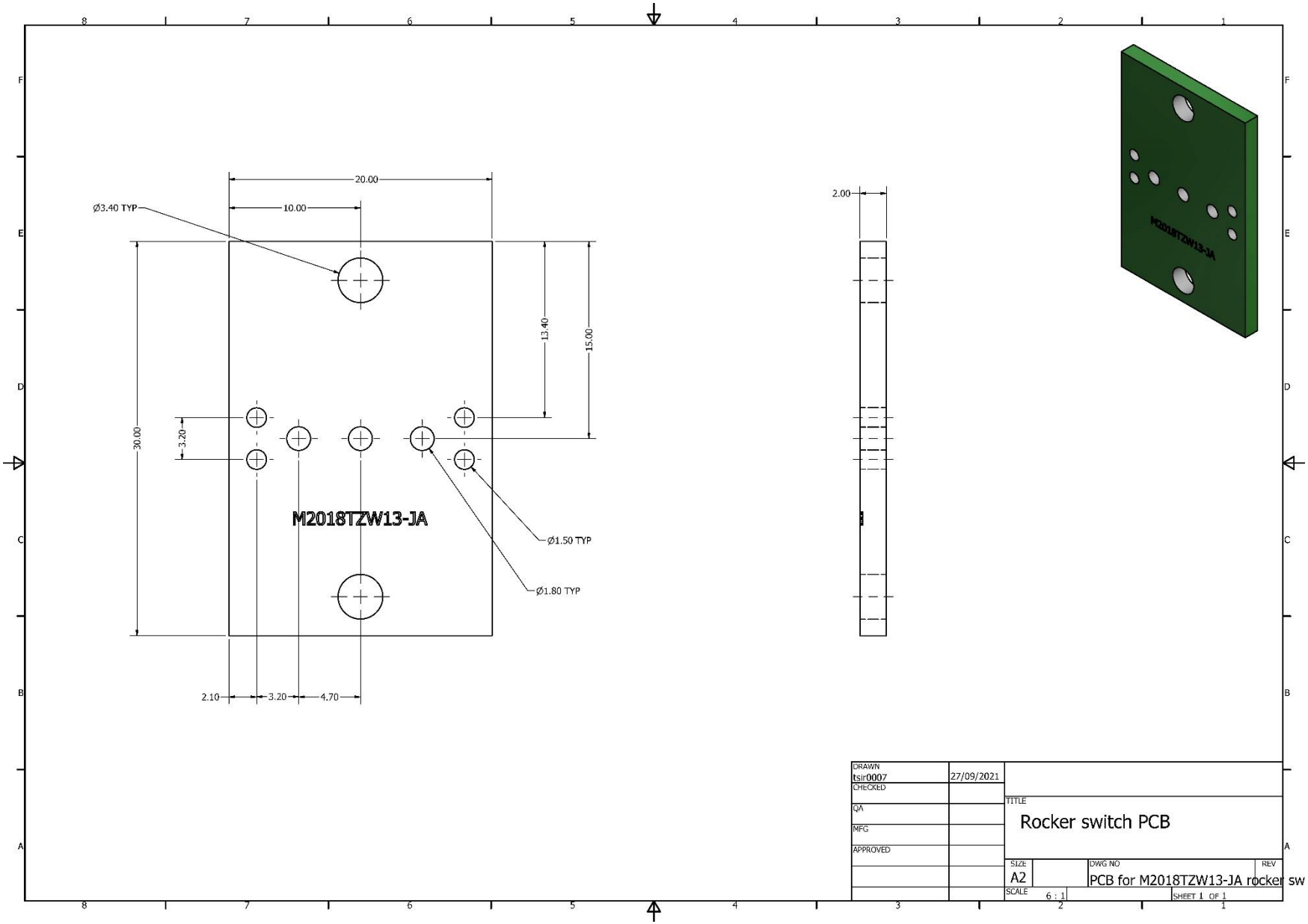
SIZE: A2 | DWG NO: Option A screen cover v3.0 | REV

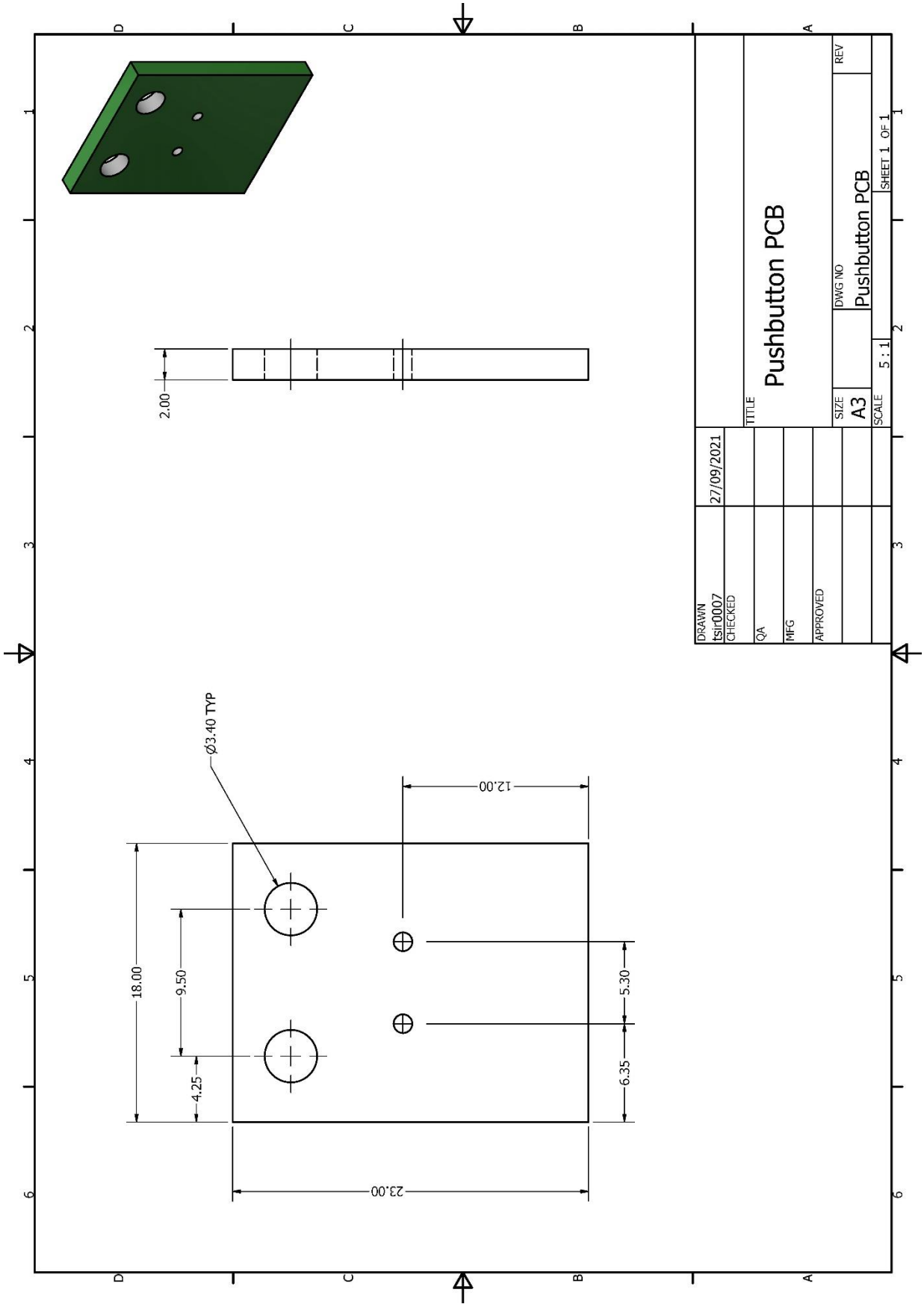
SCALE | SHEET 1 OF 1

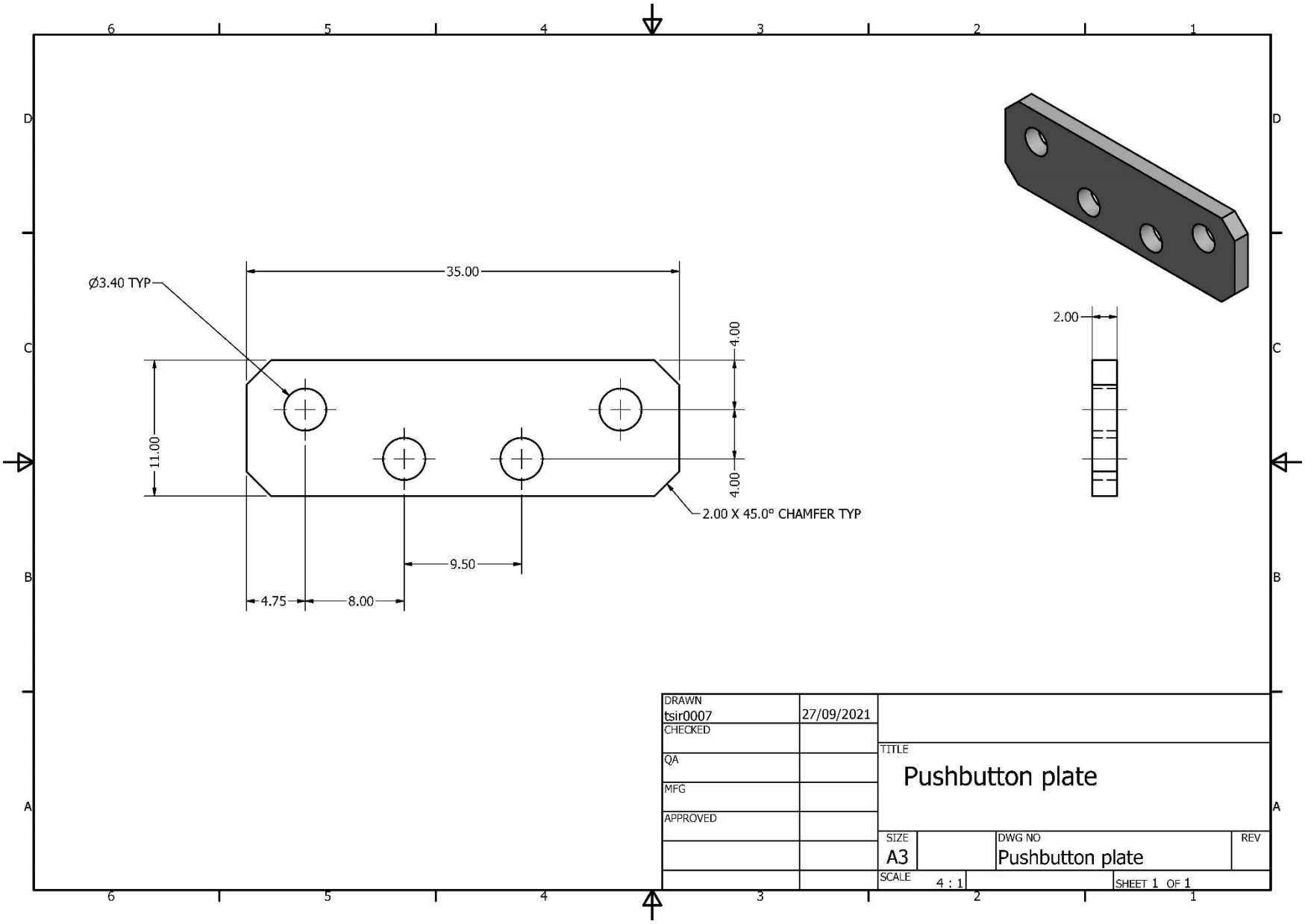





Option B screen cover
Option B screen cover v3.0
A2
27/09/2021
tsir0007
5.50
6.34
R31.70
R30.20
R33.20
44.97
33.00
20.00
35.00
45.0°
R.50 TYP
35.00
5.00
48.00
7.10
33.00
7.10
2.00
47.00


20.00
10.00
Ø3.40 TYP
13.40
15.00
30.00
3.20
M2018TZW13-JA
Ø1.50 TYP
Ø1.80 TYP
2.10
3.20
4.70
2.00
M2018TZW13-JA
DRAWN
tsir0007
27/09/2021
CHECKED
QA
MFG
APPROVED
TITLE
Rocker switch PCB
SIZE
A2
DWG NO
PCB for M2018TZW13-JA rocker sw
REV
SCALE
6 : 1
SHEET 1 OF 1


Pushbutton PCB
DRAWN
tsir0007
27/09/2021
CHECKED
QA
MFG
APPROVED
TITLE
Pushbutton PCB
SIZE
A3
DWG NO
Pushbutton PCB
REV
SCALE
5 : 1
SHEET 1 OF 1
2.00
Ø3.40 TYP
12.00
18.00
9.50
4.25
5.30
6.35
23.00



DRAWN tsir0007	27/09/2021	
CHECKED		TITLE: Pushbutton plate
QA		
MFG		
APPROVED		
SIZE A3	DWG NO Pushbutton plate	REV
SCALE 4 : 1	SHEET 1 OF 1	