March 17th, 2019

Craig Scratchley
School of Engineering Science
Simon Fraser University
British Columbia, V5A 1S6

RE: ENSC 405W/440 Design Specification for ACLeeve

Dear Mr. Scratchley,

This design specification document for ACLeeve was written by the members of Embrace Technologies for the Simon Fraser University capstone course ENSC 405W/440. Our capstone project will develop the product called ACLeeve; which is a Smart Sleeve that will significantly improve and shorten the rehabilitation process relating to ACL injuries.

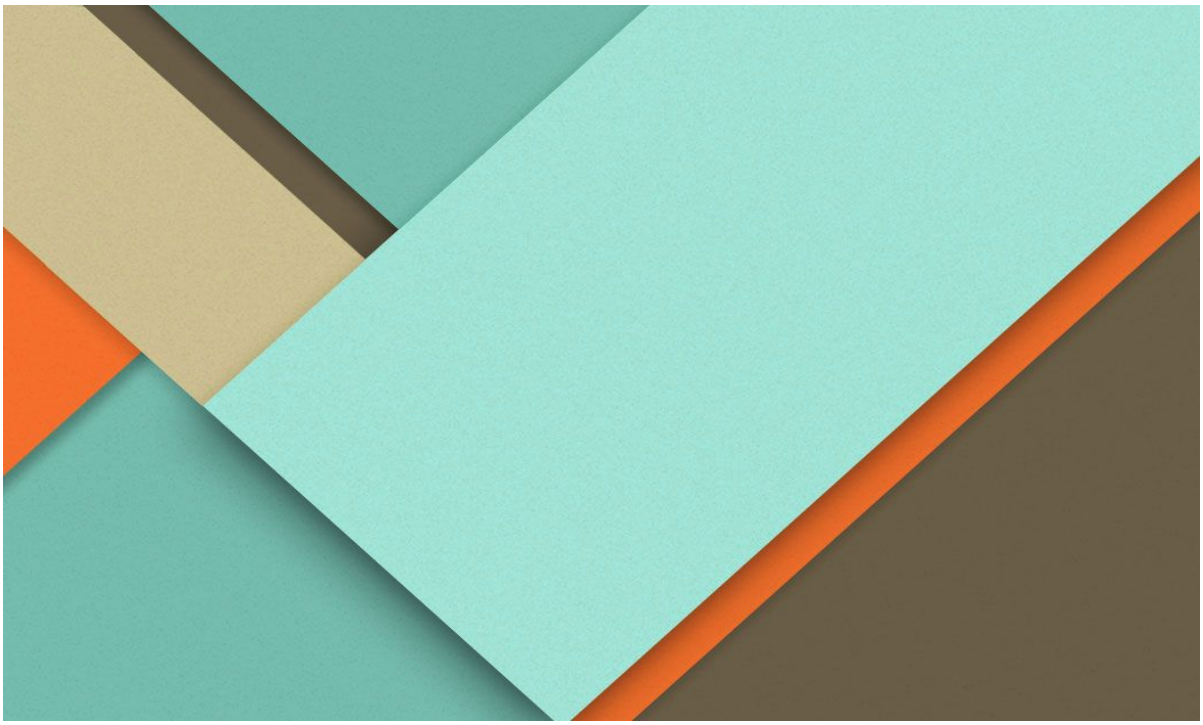
ACLeeve will monitor the user's movements of both quadriceps using surface EMGs (SEMGs). These aforementioned devices will be actively transmitting the collected data to a microprocessor, which will then process and send the data to an external device for further software analysis. The ACLeeve will then provide real-time feedback to the user (audio or visual) regarding the performance of their movements, which will allow the user to physically adjust in order to achieve better long-term results. Furthermore, our software will perform long-term analyses which will evaluate the progress of obtaining the goal of 80-90% asymmetry between the user's ACL-injured quadricep and their other healthy quadricep.

This design specification document will first of all contain an introduction to our ACLeeve product and the purpose behind the project. Secondly, for the majority of this document we will outline, explain, and justify the specific design approaches chosen for each design specification. These design specifications will be mainly related to our Proof-of-Concept (PoC) prototype, but we will also provide details about our Engineering prototype where necessary. These design requirements will specifically relate to the following areas: physical design, hardware, software, economic, documentation, engineering standards, sustainability, and safety standards. Additionally, this document will provide supporting test plans (Appendix A) to allow proper testing of numerous design details that are significantly important to the overall system design. Lastly, a User Interface (UI) Appendix B will be included for the purpose of providing a more in-depth understanding of user interactions with the ACLeeve.

All members from Embrace Technologies greatly appreciate your willingness in taking the time to read our design specification document for our product ACLeeve. If you have any questions, please do not hesitate to email me at nbatke@sfu.ca.

Sincerely,

Nathan Batke
Embrace Technologies



ACLeeve Design Specification

EMBRACE TECHNOLOGIES

Members: Maria Celkova, Gary Chung, Angus Chen, Harry Draaisma, Peter Xu, and Nathan Batke

ENSC 405W :: Capstone Group :: Team 5

Abstract

The ACLeeve is a portable and easy-to-use surface electromyography (SEMG) device, and it is to be actively used during ACL injury recovery to significantly aid and speed-up the rehabilitation process. The ACLeeve is wrapped around the user's leg using a knee sleeve and SEMG electrodes. During physical exercises, the ACLeeve will wirelessly transfer the SEMG data, using Bluetooth and WiFi connections, to an external server and the data can then be viewed by the user on their mobile device through our specifically designed ACLeeve App. Furthermore, our App will display the progress the user has gained towards obtaining 80-90% symmetry between the user's injured leg and the healthy quadricep. To achieve proper functionality, the ACLeeve must be small, lightweight, easy-to-use, have the required electronics and software capable of detecting accurate SEMG readings, have the capability of transmitting this data over a secure wireless connection, and also have a user-friendly ACLeeve App that will correctly and efficiently display the user's data. Furthermore, the ACLeeve must be safe for the user to use and conform to all relevant standards. All design requirements that are required to achieve these aforementioned goals are outlined, explained, and justified in this design specification document with respect to our PoC prototype and Engineering prototype. Additionally, this document will provide supporting test plans to allow proper testing of the specific design details that are significantly important to the overall functionality of the ACLeeve. Lastly, a UI Appendix B will be included for the purpose of providing a more in-depth understanding of user interactions with the ACLeeve.

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Glossary

ACL: Anterior cruciate ligament

ACLR: Anterior cruciate ligament reconstruction

ADC: Analog-to-Digital Converter

API: Application Programming Interface

App: Short for Application

AWS: Amazon Web Services

CMRR: Common Mode Rejection Ratio

DynamoDB: Dynamo Database

Electromyography: the recording of the electrical activity of muscle tissue, or its representation as a visual display or audible signal, using electrodes attached to the skin or inserted into the muscle. Commonly abbreviated to EMG.

Electrocardiography: the process of producing an electrocardiogram (ECG or EKG), a recording - a graph of voltage versus time - of the electrical activity of the heart using electrodes placed on the skin

GPIO: General Purpose Input/Output

GUI: Graphical User Interface

I2C: Inner-Integrated Circuit

IoT: Internet-of-Things

JSON: JavaScript Object Notation

MQTT: Message Queuing Telemetry Transport

OS: Operating System

PoC: Proof-of-Concept

Quadriceps: Shorthand for the Quadriceps Femoris muscle group

SPI: Serial Peripheral Interface

SEMG: Surface Electromyography

WPA2: WiFi Protected Access 2

1. Introduction

One of the most common knee injuries is a sprain, or in the worst-case scenario, a complete tear of the anterior cruciate ligament (ACL). Often times, surgical reconstruction is necessary in order to return the patient to their previous quality of life. During the postoperative period, it is common for the patient to experience arthrogenic muscle inhibition in the quad muscle as well as other muscle imbalances. Due to this phenomenon, one of the main areas of focus during ACL recovery is the strengthening of the muscles surrounding the knee joint. According to scientific literature, “limb symmetry is an indicator of patient progress” [1]. And more importantly, limb symmetry can be used as one of the criteria for returning to sport post injury [2].

Our product ACLeeve will help patients monitor their ACL rehabilitation progress as they strive towards a minimum of 80-90% limb symmetry, specifically the quadriceps, over the long term. Achieving this specific percentage of limb symmetry means that the patient has finally reached the stage of a good recovery. Furthermore, the product will be accessible to the user in a non-clinical setting during rehabilitation exercises. Regarding the short term application, the product will give the user sensory feedback as rehabilitation exercises are completed and alert the user when they are not using their injured muscles in an effective manner. On the other hand, the product will track the user’s progress over the long term with the purpose of being used as a motivational tool to speed up the recovery process. Furthermore, the ACLeeve will quicken the rehabilitation process because the long term data will provide the user a basis in order to make important decisions on when/if to change their types of rehabilitation exercises.

1.1 Intended use of the ACLeeve

The ACLeeve is meant to be used as an aid in post-ACL injury recovery. The device monitors the EMG activity of quadriceps as the user engages in rehabilitative exercise. The EMG data provides a quantifiable way to measure muscle activity, and by comparing this activity with the uninjured leg it provides the user a quantifiable measure as to how well their recovery is going. The ACLeeve is meant to be used by the patient in conjunction with a physiotherapist and physiotherapy, to motivate recovery by showing improvements over time. Also, the ACLeeve will alert the patient of possible issues regarding if they need to adjust certain physical movements, or if the ACLeeve’s metrics stall out and reorientation of the ACLeeve is required by the user.

2. Design Overview

2.1 High Level Design Overview

The design of ACLeeve is broken down into two overall components: the hardware and the software. The hardware includes the physical components such as knee sleeve and electrodes, as well as the circuitry leading up to and including the microcontroller.

For hardware, the design must work around the constraints of weight and battery life, while also holding human safety and usability as top priorities. As well, a high signal-to-noise ratio (SNR) is important to provide high quality data to end-users. For software, the design aims to provide an intuitive, simple interface for the user to control the ACLeeve, as well as providing low power communication.

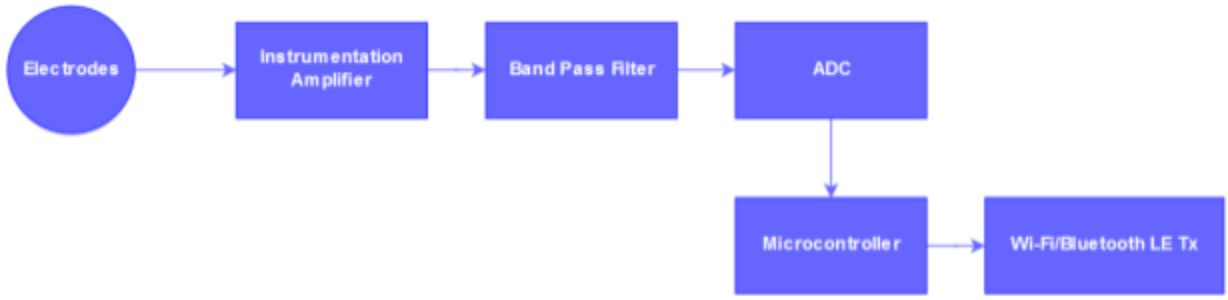

Figure 1: Functional Block Diagram of the ACLeeve

2.2 Structure

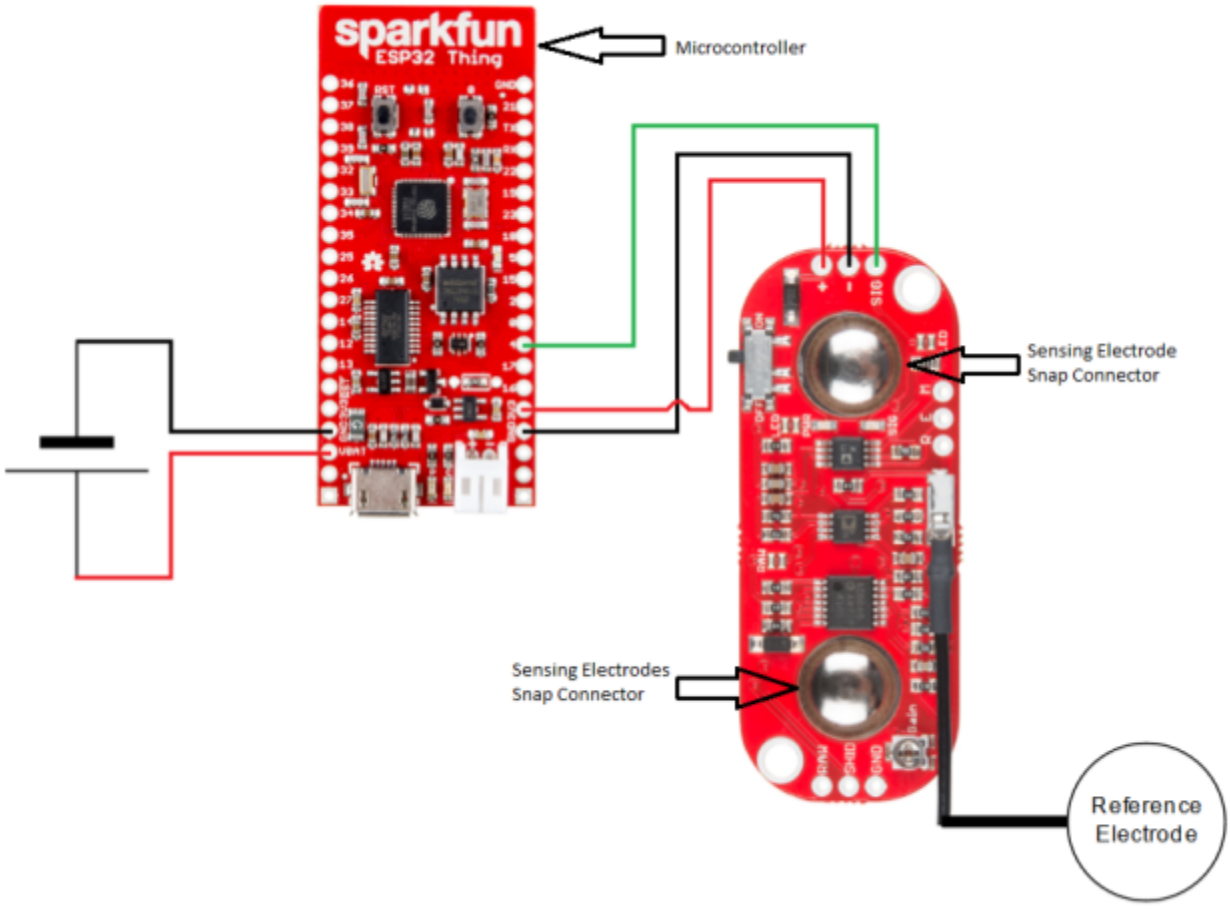

Figure 2: Overall Schematic of Proof of Concept ACLeeve (not to scale)

For the proof of concept, the structure of the device will follow closely to what is shown in Figure 2. There will be no enclosures shielding the electronics, and only enough of a “sleeve” in so far as to show the entire system can be worn on the leg without issue and still allows for the wireless transmission of EMG data.

For the engineering prototype, the entire system shall be integrated into a knee sleeve. Most of ACLeeve’s structure will be isolated from the user, the exceptions being the battery (to allow for replacement) and the electrodes (which the user will have to place after the sleeve is put on). The sensing electrodes will be physically connected to each other and kept in a separate area from the reference electrode. The reference electrode will have a shortened connection to prevent it from being attached anywhere outside of the optimal placement location. The rationale behind these decisions is included in the UI Appendix B, which is attached at the end of this document.

The ACLeeve structure shall be entirely housed on the knee sleeve. The structure shall be flexible enough to not interfere with the user's natural movements, while also not being heavy enough to create discomfort.

An appearance prototype has been developed to demonstrate how the engineering prototype may look. It can be seen in Figure 3 below:

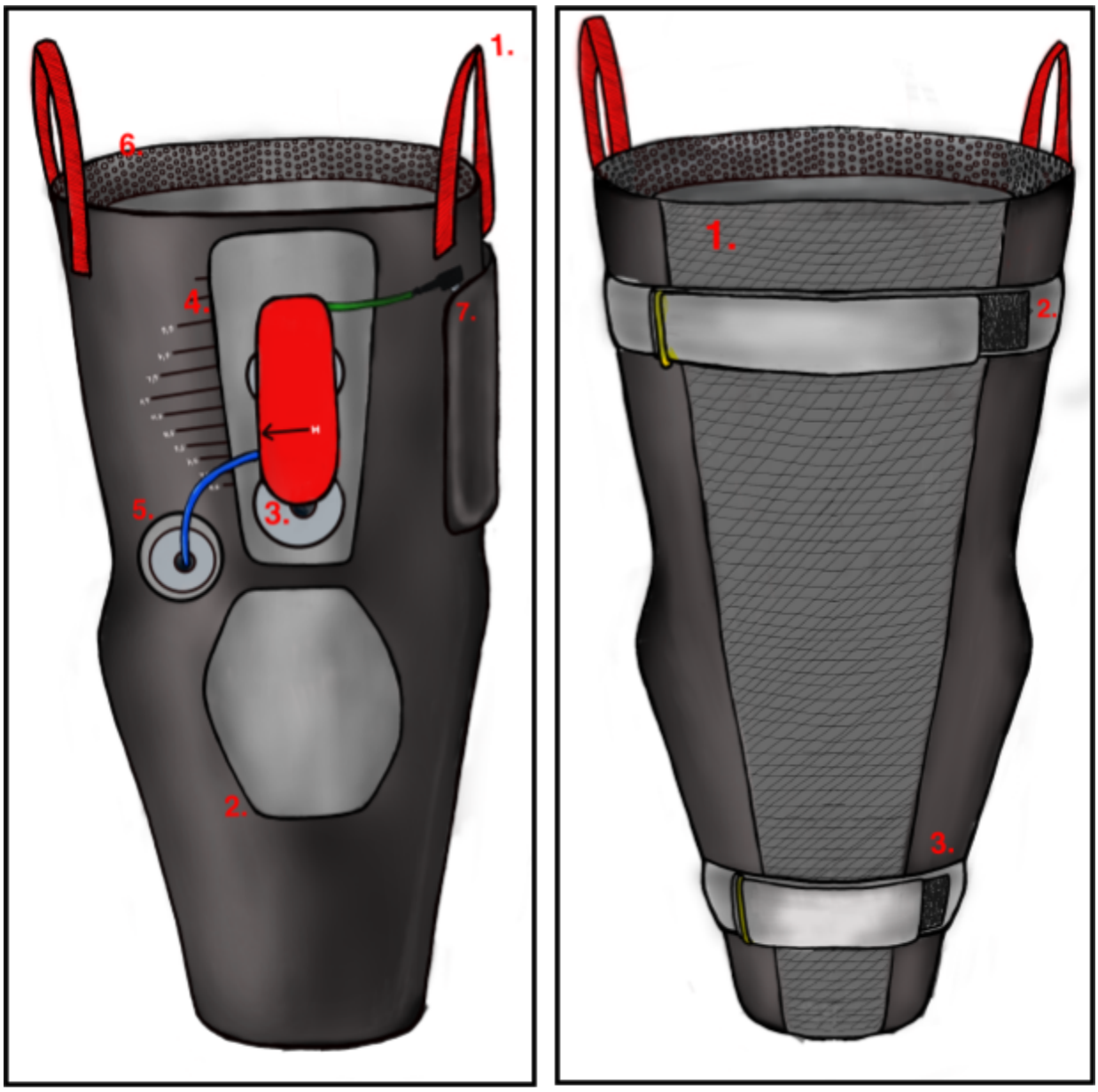

Figure 3: Appearance Prototype of ACLeeve
Frontal View (Left) and Rear View (Right)

2.3 Proof of Concept Hardware Specifications

2.3.1 Proof of Concept Sensor

For the PoC prototype, we are using a pre-built EMG sensor, the MyoWare Muscle Sensor [3]. The device can be seen below:

Figure 4: Myoware Muscle Sensor [3]

Unfortunately, the MyoWare sensor is not open source, and as such no official documents can be obtained which contain details of its design. However, based off of the principles of EMG signal detection, the data sheet, and the physical characteristics of its construction all provide plenty of information as to how the device works.

The MyoWare sensor consists of a differential amplifier, which is used for common mode (or noise) rejection and for boosting the small (in the range of milli- and microvolt) signals picked up by the attached electrodes. The Common Mode Rejection Ratio (CMRR) of the amplifier is 110 dB [3]. These characteristics of the MyoWare sensor fulfill [Req 2.3.2-a], [Req 2.3.3-a], and [Req 2.3.4-a] of the technical requirements given in [4]. The device also includes a band pass filter, most likely with cutoff frequencies at 20 Hz and 500 Hz as those frequencies are where EMG activity reside [5], satisfying [Req 2.3.6-a] of [4]. Since the device nominally draws 9 mA of current, this also fulfills [Req 2.3.7-a] related to the power consumption of the filters.

Although other sensors of this style with similar characteristics are available on the market, the MyoWare was chosen for a variety reasons. The first was that it was the only sensor we could find available that had significant documentation which not only included its characteristics, but also instructions for optimal signal capture and use. Secondly, the built-in gain adjustment and

signal rectifying guaranteed a signal which can be easily handled by the ACLeeve's microcontroller. Finally, the sensor's distributor, SparkFun, had a known reputation for providing reliable components and provided easy shipping options to Canada, which many other distributor's of similar sensors lacked.

2.3.2 Proof of Concept Microcontroller

For the PoC, we are using a ESP32 Thing Development Board [6] as the main microcontroller. The device can be seen in Figure 5 below:

Figure 5: ESP32 Thing Development Board [6]

The ESP32 Thing is a comprehensive development board for the ESP32 chip, which is a WiFi and Bluetooth enabled microcontroller. It also includes many features found on most publicly available microcontrollers, including a 12-bit Analog-to-Digital converter (ADC), General Purpose Input/Output (GPIO) interfaces, and has a Serial Peripheral Interface (SPI). The microcontroller operates at a voltage range between 3.3V to 5V. These features fulfill [Req 2.3.8-a], [Req 2.3.9-a], [Req 2.3.10-a], [Req 2.3.12-a], [Req 2.3.13-a], and [Req 2.3.15-a] of [4].

Other alternatives for a microcontroller were considered, including an Arduino Uno and Raspberry Pi system on a chip, but the ESP32 Thing was chosen over them for two main reasons. The first is that the ESP32 Thing is much lighter and smaller than the other considered boards, which makes it considerably easier to integrate into a knee sleeve without creating problems for the user by being too heavy or unwieldy. The second is that the ESP32 Thing requires no extra software or hardware to utilize it's built-in WiFi and Bluetooth capabilities, saving on cost and time in implementation.

2.3.3 Proof of Concept Battery

In order to fulfill [Req-2.4.4-a] of [4], the device will have to be battery powered so as to fully demonstrate the wireless data transmission capabilities. The power requirements for the PoC ACLeeve are fairly straightforward, and only require that the battery allow the device to work and does not have a maximum output voltage greater than 4.5V (as per [Req 2.3.20-a]). To that end, the PoC prototype will be powered by a set of 3 AAA batteries, providing approximately 4.5V of power to the device. The batteries will be attached to a discrete power switch to fulfill [Req 2.3.21-a].

2.3.4 Proof of Concept Electrodes

The only requirement required of the electrodes is that they must be able to detect EMG signals (as per [Req 2.3.1-a] of [4]). For convenience in interfacing with our sensors, the electrodes chosen are Coviden Arbo H124SG Electrodes (see Figure 6 below). These electrodes were chosen as they were recommended to be used with our chosen sensor by the distributor.

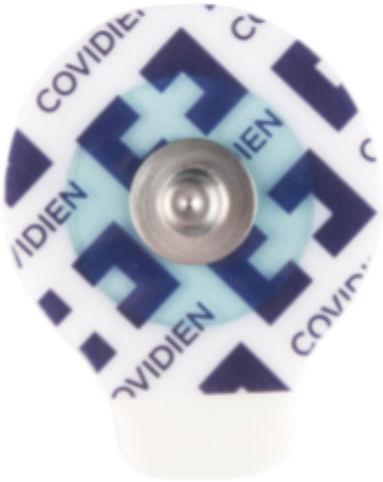

Figure 6: Coviden Arbo H124SG Electrodes [7]

2.3.5 Proof of Concept Sleeve

Since the PoC does not have any explicit requirements for a knee sleeve, a basic fabric wrap around the leg will be used, mostly to show how the components may be arranged on the leg, and satisfy [Req 2.2.2-a] and [Req 2.2.16-a] of [4].

2.4 Engineering Prototype Hardware Design

2.4.1 Hardware Overview

The engineering prototype, scheduled for August, 2019, will be a significantly more mature version of our ACLeeve product. While retaining the overall design, it will include additional signal processing capabilities and a customized Printed Circuit Board (PCB) instead of the MyoWare muscle sensor used in the PoC prototype.

Analog signals acquired from the electrodes need to be amplified and filtered before converted to digital signals for processing. The amplification stage will boost the signal strength using a instrumentation amplifier, and the band-pass filter will filter out high frequency noise and avoid aliasing problems. The general analog signal flow can be seen in Figure 7 below:

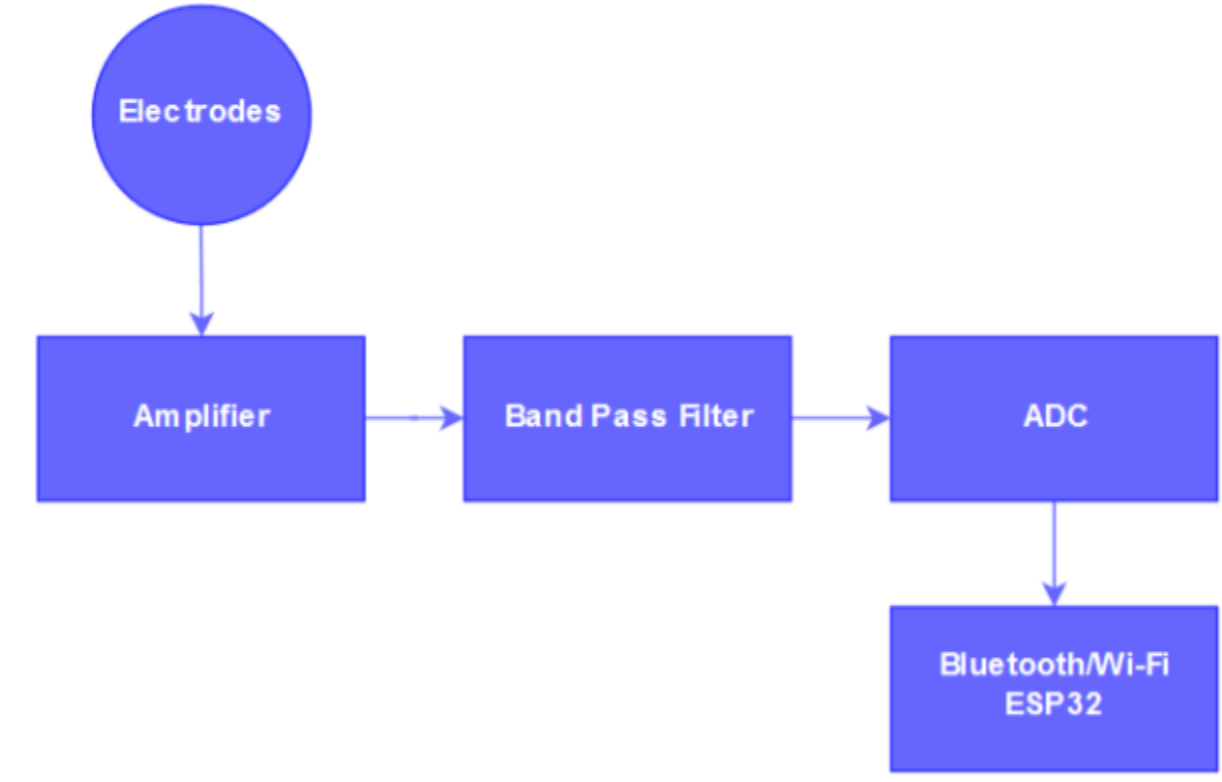

Figure 7: EMG Signal Acquisition and Flow Diagram

2.4.2 Amplifier Design

The raw EMG recordings from electrodes are in the order of microvolts, as such, amplification is necessary to perform any reasonable signal processing.

The INA821 precision instrumentation amplifier is the design choice we selected as it offers a large common mode rejection ratio of 112 [8] per [Req 2.3.4-a], and it will also be able to provide a high signal gain per [Req 2.3.3-b].

Figure 8 below shows the INA821 precision instrumentation amplifier schematics [8]:

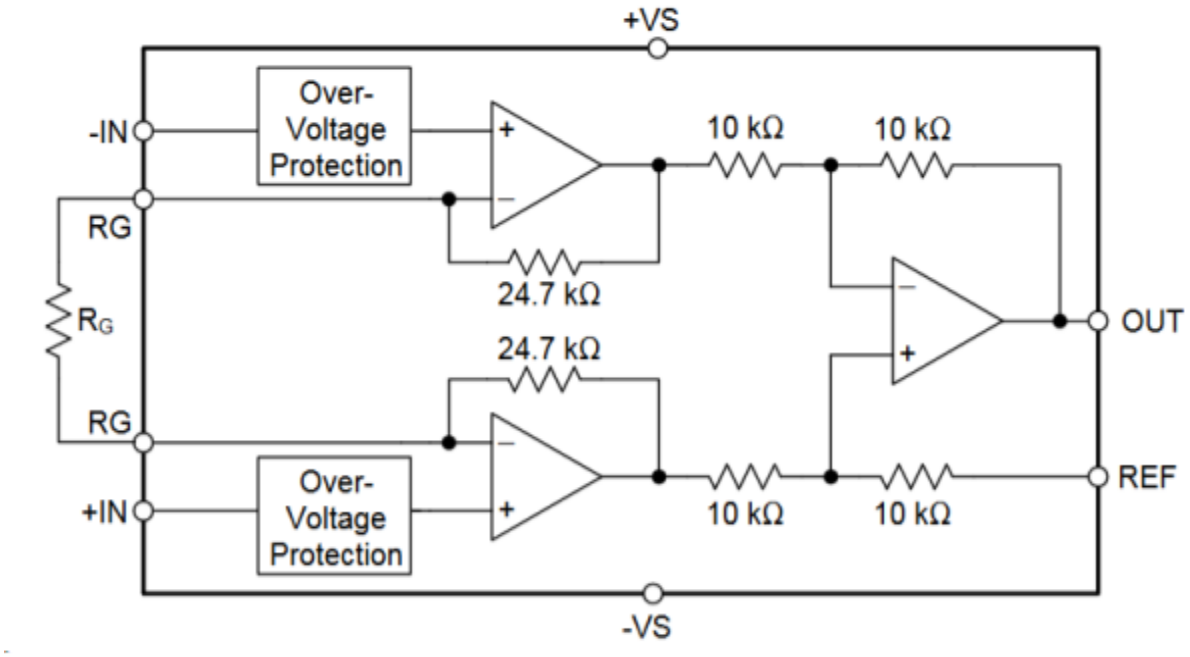

Figure 8: Schematic of INA821 Precision Instrumentation Amplifier

The gain of this configuration is modelled by the following equation:

$$Av = Vout/(Va - Vb) = (1 + 2 * 24.7K/Rg)$$

Setting the external gain resistor to 50 Ohms we can achieve the desired 60dB gain.

The Common Mode Rejection Ratio (CMRR) provided with this schematic is 112 when the gain is above 10.

2.4.3 Filter Design

Prior to signal processing, it is necessary to filter out the contaminated noise that has also been amplified by the instrumentation prior. Following the recommendation of International Society of Electrophysiology and Kinesiology (ISEK) [9], we will use a high pass filter with a cutoff frequency of 20Hz followed by a low pass filter with a cutoff frequency of 500Hz, together creating a passband between 20-500Hz [Req 2.3.6-a]. Although there will be 60Hz noise, we

cannot filter it out as EMG signals contain relevant information at 60Hz. The following schematic (Figure 9 below) shows the non-inverting active bandpass filter for our design:

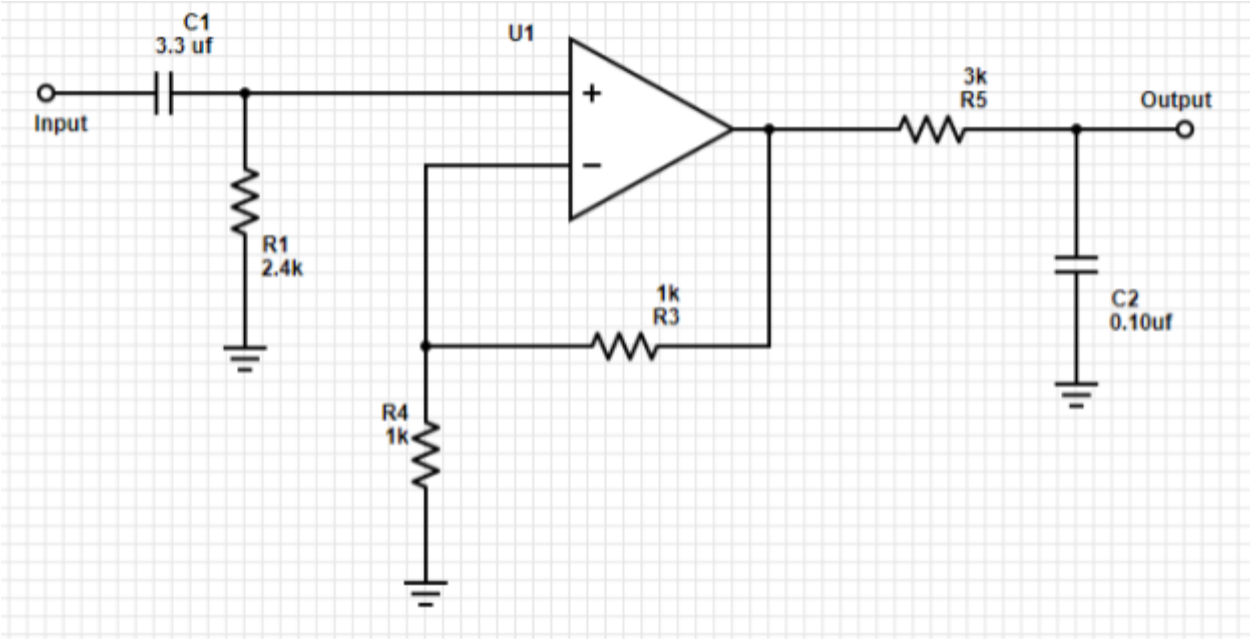

Figure 9: Schematics for Band Pass Filter

The first stage is the high pass filter, controlled by the capacitor C1 and the resistor R1. The cutoff frequency is calculated by $1/(2 * \pi * R1 * C1)$, using 2.4kΩ and 3.3uF. Therefore, the result of the cutoff frequency is 20Hz. Following that is the non-inverting amplification stage and the gain is calculated by $1 + R3/R4$. Finally we have the low pass stage controlled by capacitor C2 and resistor R5. The cutoff frequency using 3kΩ and 0.1uF will be equal to 500Hz.

The reason we chose an active filter over a passive one is because it is more economical, has a smaller size, and it handles lower frequencies better than passive components.

2.4.4 Microcontroller

The main job of the microcontroller is to digitize the signal for signal processing. The ESP32 Thing development board fits the needs of our project decently well. First of all, to avoid aliasing problems when digitizing the signals, we need to oversample the analog signal. The recommended sampling frequency is roughly five times the maximum frequency component, which in our case is 500Hz [10]. The ESP32 Thing board is equipped with a 12 bit ADC [Req 2.3.8-a] capable of sampling at the rate of 6kHz [Req 2.3.9-a].

Secondly, the board comes with Bluetooth Low Energy (BLE) capabilities to transmit the EMG data from the filter to the coupled Bluetooth device [Req 2.3.14-b].

2.4.5 Signal Processing

For the PoC, we will forego the signal processing part and just prove that we can obtain an EMG signal output.

For the Engineering Prototype, our product will need to be able to recognize the difference between muscle activation and muscle rest, as well as the extent of muscle activation between an injured knee and good knee (relating to the ACL injury).

To accomplish this we will analyze the repetition of our rehabilitation exercise in set time frames. Given the EMG data within the time frame, we can take the root mean square (RMS) of the signal to obtain the power of the signal [8]. To obtain the RMS we use the formula below [11]:

$$x_{\mathrm{rms}} = \sqrt{\frac{1}{T_2 - T_1}\int_{T_1}^{T_2} [f(t)]^2\, dt}$$

The common method for distinguishing the on/off time from the processed signal is by comparing the signal with a threshold with a trained eye [12]. The single threshold method is the simplest method where a pre-set threshold is compared against, but it suffers in detection probability. The double-threshold method will perform better in detection probability but has larger overhead and requires higher computational resource [12]. This tradeoff will be analyzed further in the later stage of development to determine what is best for our application.

2.4.6 Other Potential Hardware

As the engineering prototype is still being planned out, there is a distinct possibility that other components may be utilized so as to provide better data to the user. One possibility is to include strain sensors in an included resistance band, that quantify the user's mechanical power over an exercise, along with their muscle activity. Another is to embed strain sensors within the knee sleeve itself, so as to quantify other data that may be useful during recovery, such as the user's maximum comfortable inflexion angle. These hardware changes may be applied to the engineering prototype, but until the need for such a change becomes apparent, the design will continue as described earlier in this section.

2.5 Software Design

Software System Overview

The software aspect of the project can be divided into three sub-systems: embedded system, cloud system, and mobile app. The embedded system collects data from multiple sensors and uploads sensor readings to the cloud. The cloud system processes the data in real-time and provides an interface for the mobile app to access its resources. The mobile app presents data to the user through an interactive dashboard and highlights the training performance.

Software System Design Considerations

To reduce computing requirements of the embedded device and mobile app, we chose a design that puts all the functions related to data processing on the cloud system, which is hosted on the AWS Cloud. The design choice is motivated by the pay-as-you-go pricing model and scalable solutions to connect devices and analyze data. By reducing maintenance time on IT infrastructure, we hope to create more-effective data analysis tools to support interactions with the user and physiotherapist. It is possible for the physiotherapist to monitor recovery progress from anywhere by creating a separate dashboard, but that is out of scope for this project.

Embedded System Design

The embedded system is a component that collects data from multiple sensors over Bluetooth and sends it to the AWS IoT Core via MQTT protocol. Each device is connected securely via X509 Certs authentication. For the Proof-of-Concept design, SparkFun ESP32 Thing development board is utilized in conjunction with MyoWare sensors to collect and transmit data to the Cloud System. C++11 will be used as the programming language to develop the embedded application that runs on Mongoose OS, which is an IoT development framework for ESP32 Thing, and ready for cloud integrations.

For the engineering prototype, while the individual microcontroller may change to fit other design constraints, the software component on the embedded system will still act more or less the same: to act as a bridge between the embedded system and the Cloud System. So with the exception of a change firmware, the overall functionality will remain the same.

Cloud System Design

The Cloud System is a component that analyzes data from IoT devices and prepares data for the user dashboards. The Cloud System uses AWS IoT as front door and Amazon Kinesis as a hub for incoming data streams. The sensor's data will be pumped into Amazon DynamoDB, which will provide data to a lambda function, which gets triggered when the mobile app sends API calls to request for data. The results and data will be returned in JSON format.

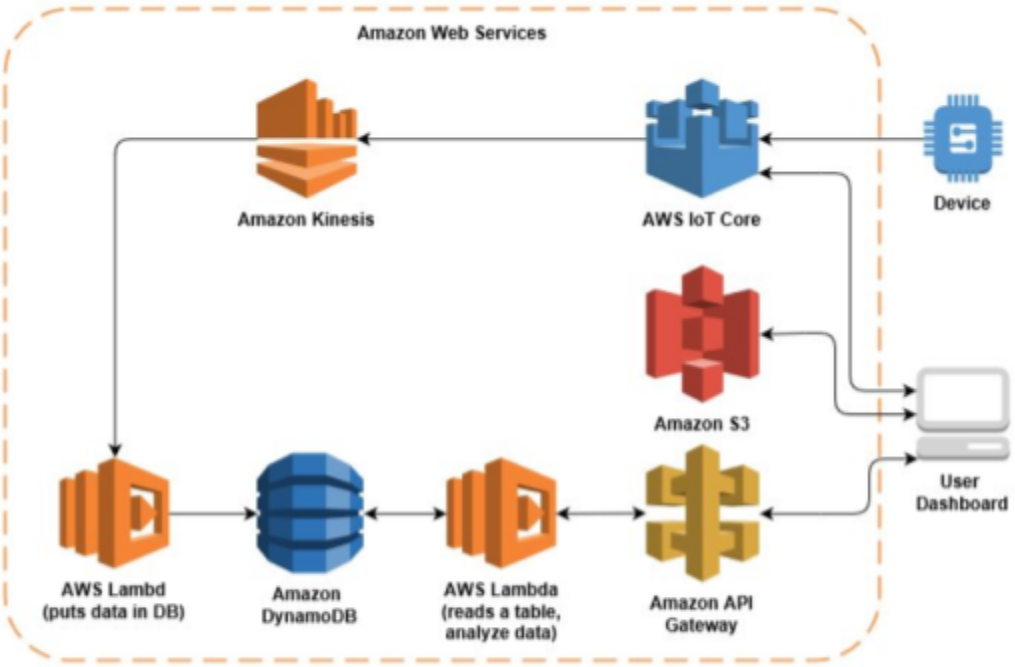

Figure 10: High Level Overview of Cloud System on AWS

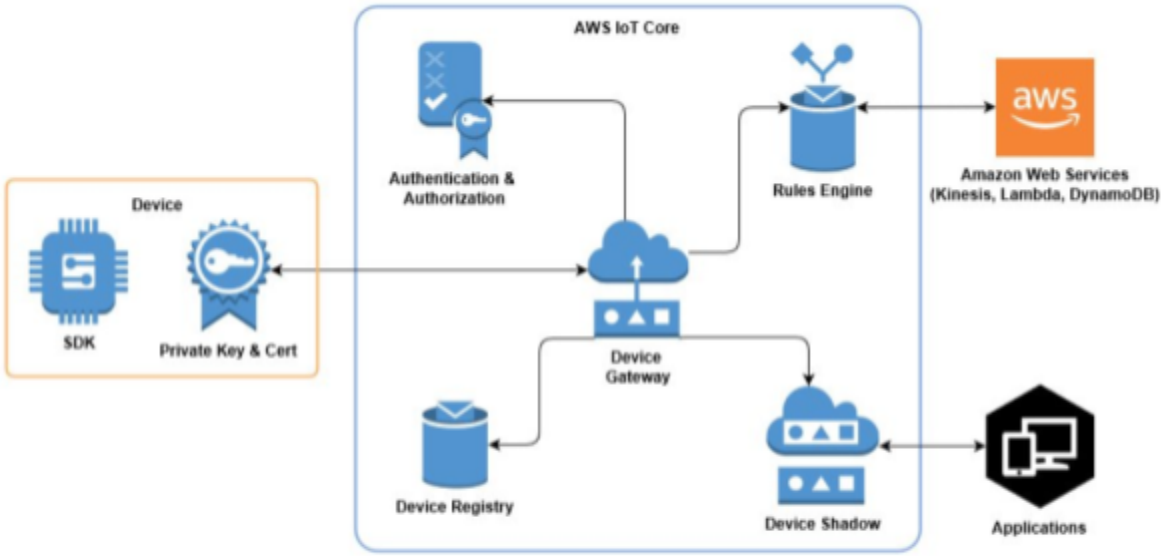

Figure 11: High Level Overview of AWS IoT Core

Each device publishes on a different MQTT topic, and the payload contains rules that pushes data to Amazon Kinesis data streams. After that, a AWS lambda function is triggered to write the data into different tables.

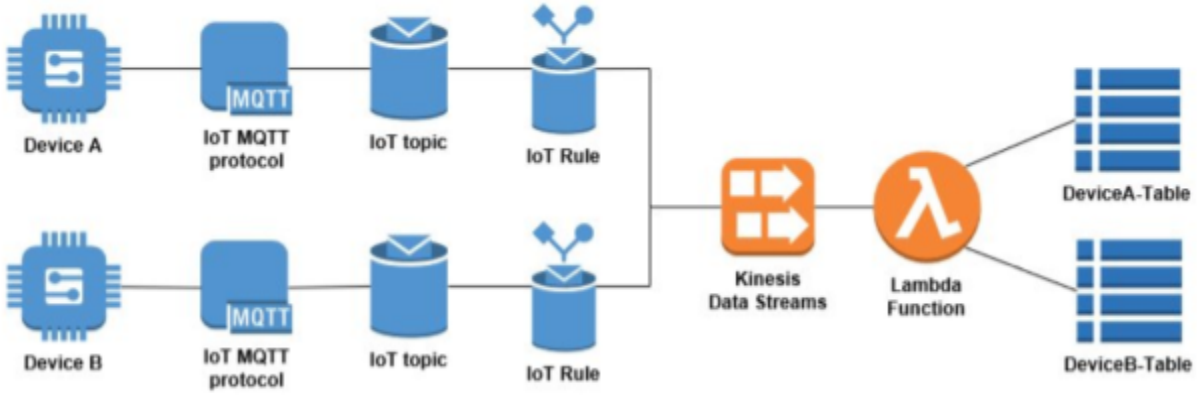

Figure 12: High Level Overview of AWS Security

The embedded system reports status information to Device Shadow, which caches the status information. The mobile app can then access the status information and control the devices by sending requests to the AWS IoT Core via RESTful API.

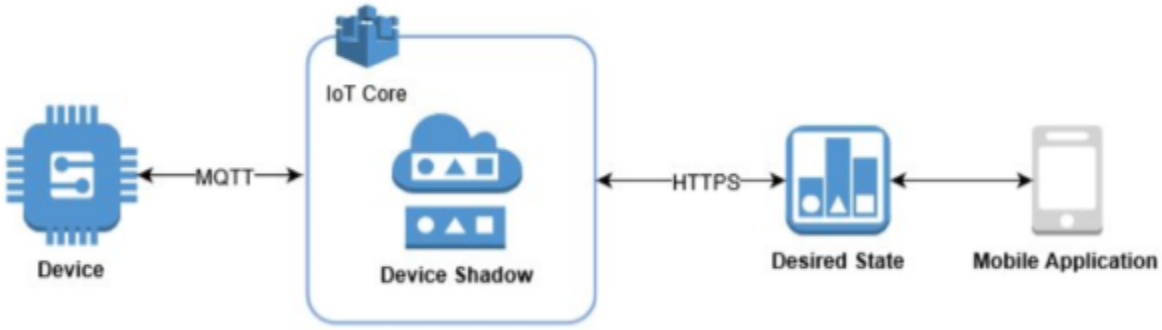

Figure 13: High Level Overview of ACLeeve Software Communication

2.5.2 Mobile App Design

The primary purpose of the android application is to provide a graphical user interface for the user that allows them to control the sleeve and monitor their progress in ACL rehabilitation. The application will be written in Java using Android Studios IDE and will be communicating with the sleeve via Amazon Web Services. We decided to make the application simple but being characteristic of any modern application so anyone with mobile application experience should instinctively know what to do. The application would consist of login/sign-up screens, device setup screens for initial setup of the sleeve, a main screen for real time information and collecting data, and a history screen for the purpose of tracking the user' ACL recovery progress over time.

Below is the main screen that the user is taken to after signing in. This screen is used to collect data, view real time visualized data, and access all other screens and options.

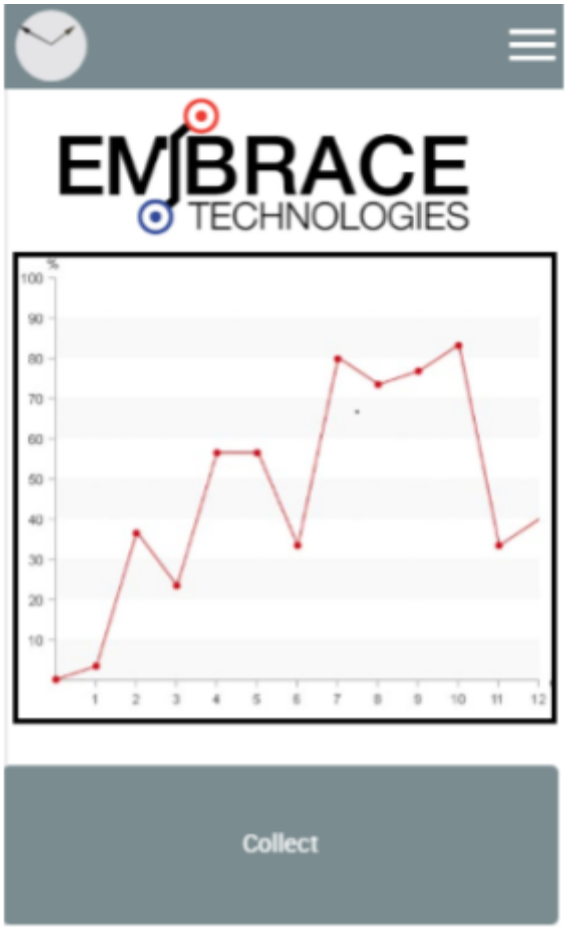

Figure 14: Appearance Prototype of ACLeeve Companion App

3. Design Verification Test Plans

Design verification will be executed on the engineering prototype to ensure efficacy, safety and ease of use of the device. These test plans, which are outlined in Appendix A at the end of this design document, detail the procedures and acceptance criteria for verifying whether or not the device behaves as intended.

4. Conclusion

In summary, our product ACLeeve consists of three major classes: physical, hardware and software.

Regarding the physical aspect (refer to Figure 3), our ACLeeve will consist of a regular knee sleeve that is comfortable and flexible enough for the average person to wear. Attached to the side of the knee sleeve will be a designated slot where the microcontroller and battery will be stored. On the front of the knee sleeve there will be additional slots where the electrodes and MyoWare muscle sensors will be embedded into the sleeve. Furthermore, each slot will have openings for the external wires that connect between the electrodes, MyoWare muscle sensors, microcontroller (ESP32 Thing), and the battery.

Concerning the hardware aspect, as already mentioned, we will be using single-use electrodes to attach to the user's quadricep and read in the electrical signals produced by the muscle excitations of the quadriceps during the user's rehabilitation exercises. The MyoWare sensors will have three electrodes attached to them; two directly connected to the MyoWare muscle sensor using snap leads, and the other connected to the reference electrode provided by the MyoWare muscle sensor. These MyoWare muscle sensors will then be wired to the microcontroller (ESP32 Thing), which will then be connected to the battery.

Concerning the software aspect, the ESP32 Thing will send the processed data to an external server, using Bluetooth and WiFi, which will perform further analysis before displaying the final output to the user through our Android ACLeeve Companion App; which the user can download and use on their personal device of choice.

Overall, with all the various mentioned aspects working together properly, our product ACLeeve will improve the user's ACL recovery process in regards to two major methods: increasing the user's motivation to perform their required exercises by showing their progress towards full rehabilitation status, and increasing the rehabilitation rate (decreasing the time it takes to become fully recovered i.e. 80-90% quadricep symmetry) by providing constructive feedback to the user in how they should perform their exercises in a more effective way through visual and auditory methods.

5. References

[1] “Quadriceps symmetry after ACL reconstruction,” November, 2015 [Online] Available: https://lermagazine.com/article/quadriceps-symmetry-after-acl-reconstruction [Accessed January 2019]

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Appendix A: Design Verification Test Plans

6.1 TP-HW-001 Power On/Off Testing

Objective: Test the power on/off usability of the device. Verify process is intuitive.

Test Setup: ACLeeve is charged/battery is connected and ready to transmit data. Device does not need to be attached to a user. Receiving database is online and connected to same network as device.

Operator Name: _____

Test start date/time (DD/mm/YYYY; HH:MM AM/PM): _____

Instructions	*Acceptance Criteria*	*Outcome*
1. Turn Power Switch into "On" Position	Green power LED glows on the device.	☐ PASS / ☐ FAIL
2. Check receiving database	Database indicates that device is attempting to connect.	☐ PASS / ☐ FAIL
3. Wait for device to connect. Check receiving database	Database indicates that device is connected and ready to be set up.	☐ PASS / ☐ FAIL
4. Begin transmitting data	Blue LED turns on, data received by database.	☐ PASS / ☐ FAIL
5. End transmitting data	Blue LED turns off, data collection in database stops.	☐ PASS / ☐ FAIL
6. Turn power switch into "Off" position	Database indicates that device is no longer connected.	☐ PASS / ☐ FAIL

Test end date/time (DD/mm/YYYY; HH:MM AM/PM): _____

Comments (optional):

TEST OUTCOME: ☐ PASS / ☐ FAIL

Signature: _____

6.2 TP-SW-001 Software and Security

Objective: Test efficacy and security of data both in database and application.

Test Setup: ACLeeve is charged/battery is connected and ready to transmit data. Device is attached either to test subject or equivalent simulator. Receiving database is online and connected to same network as device. Receiving device running application is charged and within 10 feet of ACLeeve.

Operator Name: _____

Test start date/time (DD/mm/YYYY; HH:MM AM/PM): _____

Instructions	*Acceptance Criteria*	*Outcome*
1. Power up ACLeeve	Device powers up without issues. Green power LED glows on device.	☐ PASS / ☐ FAIL
2. Enter invalid credentials on Login Screen	Incorrect username or password message is displayed.	☐ PASS / ☐ FAIL
3. Enter valid credentials on Login screen	Smooth transition into Home screen. User successfully logs in to the app.	☐ PASS / ☐ FAIL
4. Select Setup Device	Smooth transition into Setup Device screen. A list of currently connected bluetooth devices are displayed on screen. User can identify ACLeeve from the list.	☐ PASS / ☐ FAIL
5. Select ACLeeve-Serial-#	Smooth transition into Enter WiFi Password screen. ACLeeve-Serial-# is displayed on screen. Prompts user to enter WiFi password.	☐ PASS / ☐ FAIL
6. Select Finish Setup	Smooth transition into Home screen. User can see “ACLeeve-Serial-# is connected” message. The following user options are available: START, STOP, PROGRESS REPORT	☐ PASS / ☐ FAIL
4. Select START	Data transmission begins, and app indicates it is receiving data. Blue LED glows indicating that data are being transmitted.	☐ PASS / ☐ FAIL
5. Select SHOW LIVE DATA	Live data is displayed to app.	☐ PASS / ☐ FAIL
6. Select HIDE LIVE DATA	App returns to basic data collection page.	☐ PASS / ☐ FAIL
7. Select STOP	Data transmission ends gracefully, displaying results to screen within 1 min. Loading icon is displayed to screen informing user that processing is occuring.	☐ PASS / ☐ FAIL

	Blue transmitting LED turns off.	
8. Wait for processing to complete	Results of transmission session is displayed. User is prompted to SAVE or DISCARD data.	☐ PASS / ☐ FAIL
9. Select SAVE. Navigate to file storage	Saved file is present.	☐ PASS / ☐ FAIL
10. Return to home screen and select PROGRESS REPORT	Data from previous sessions is shown in graph form.	☐ PASS / ☐ FAIL
11. Return to home screen, press START, wait 5 seconds, select STOP. Selected DISCARD and navigate to file storage	Most recent file is not saved.	☐ PASS / ☐ FAIL
12. Exit application	Information is not accessible without logging in again.	☐ PASS / ☐ FAIL

Test end date/time (DD/mm/YYYY; HH:MM AM/PM): _____

Comments (optional):

TEST OUTCOME: ☐ PASS / ☐ FAIL

Signature: _____

6.3 TP-HW-002 Comfort Over Extended Periods and Long-Term Battery Usage

Objective: Test the comfort and battery life of wearing the device over an extended period of time.

Test Setup: ACLeeve is charged/battery is connected and ready to transmit data. Device is attached to test subject. Receiving database is online and connected to same network as device.

Operator Name: _____

Test start date/time (DD/mm/YYYY; HH:MM AM/PM): _____

Instructions	*Acceptance Criteria*	*Outcome*
1. Power up ACLeeve. Set up for data transmission. Press START	Device powers ups without issues, transmission starts smoothly.	☐ PASS / ☐ FAIL
2. Wear device for 6 hours	Device remains firmly attached to user.	☐ PASS / ☐ FAIL
3. Check battery life	Battery remains viable for the duration of the scan. Predicted remaining time is displayed on the app.	☐ PASS / ☐ FAIL
4. Examine the predicted remaining battery life	Battery has more than 50% life remaining	☐ PASS / ☐ FAIL

Test end date/time (DD/mm/YYYY; HH:MM AM/PM): _____

Comments (optional):

TEST OUTCOME: ☐ PASS / ☐ FAIL

Signature: _____

6.4 TP-HW-003 Electrical Safety: Leakage Current

Objective: Ensure that the electrodes do not exceed max leakage current, as defined by IEC 60601-1 standard. Will be tested in normal conditions and single fault conditions.

Test Setup: ACLeeve is charged/battery is connected and ready to transmit data. Device does not need to be attached to a user. Receiving device/database is not necessary. Will make use of a measuring device. Connect measuring device to the ACLeeve, attaching ground connection to the ground electrode and the other electrodes as per measurement device instructions.

Operator Name: _____

Test start date/time (DD/mm/YYYY; HH:MM AM/PM): _____

Instructions	*Acceptance Criteria*	*Outcome*
2. Patient Leakage Current Test (Normal Conditions)	Leakage current is < 0.5μA per electrode	☐ PASS / ☐ FAIL
3. Patient Leakage Current Test (Single Fault Conditions)	Leakage current is < 0.5μA per electrode	☐ PASS / ☐ FAIL
4. Ground Leakage Current Test (Normal Conditions)	Leakage current is < 1μA per electrode	☐ PASS / ☐ FAIL
5. Ground Leakage Current Test (Single Fault Conditions)	Leakage current is < 1μA per electrode	☐ PASS / ☐ FAIL
6. Enclosure Leakage Current Test (Normal Conditions)	Leakage current is < 0.8μA per electrode	☐ PASS / ☐ FAIL
7. Enclosure Leakage Current Test (Single Fault Conditions)	Leakage current is < 0.8μA per electrode	☐ PASS / ☐ FAIL

Test end date/time (DD/mm/YYYY; HH:MM AM/PM): _____

Comments (optional):

TEST OUTCOME: ☐ PASS / ☐ FAIL

Signature: _____

6. Appendix B: User Interface Design

7.1 Introduction

7.1.1 Purpose

The purpose of this Appendix is to provide the readers with a more in-depth understanding of user interactions with the ACLeeve. This document will go over the considerations taken by our design team, all members of Embrace Technologies, as we developed the ACLeeve in all related aspects: physical, hardware, and software.

7.1.2 Scope

In this document we will discuss the various considerations taken when designing the ACLeeve. We will start by discussing our target users and the knowledge that they need to have to properly operate the device. Following this, we will provide a technical analysis of the UI, breaking it down into the seven elements of UI interaction. This will provide detailed insight on the considerations which were taken when designing our device; this includes: interface components, discoverability, feedback, conceptual model, affordances, signifiers, mappings and constraints.

Additionally, we will discuss the engineering standards which have been considered for safe and intuitive operation. We will also provide an in-depth discussion of the analytical testing undertaken, which is focused on the theoretical analysis of the UIs of marketed devices. This research allowed us to make design choices to eliminate these issues. Also discussed is the empirical testing we plan to undertake, which will also serve as a verification test: does the device work well for the user?

7.2 User Analysis

This section accomplishes the objective of outlining “the required user knowledge and restrictions with respect to the users’ prior experience with similar systems or devices and with their physical abilities to use” our product ACLeeve. [1]

[7.2.1] An obvious but legitimate restriction is that the user must have two quadriceps so that proper data analysis comparisons can be made between the injured and healthy quadriceps.

[7.2.2] Because the ACLeeve will have two velcro straps, that the user will need to wrap around their quadriceps, the user will be required to look at the provided ACLeeve Companion App which will have visual instructions for how to position the ACLeeve properly on their quadriceps.

[7.2.3] The user will be required to have an electronic mobile device that can use Android Apps so that they can use the various functionalities in our ACLeeve Companion App.

[7.2.4] The UI of our ACLeeve Companion App will be easy-to-use, but the user may have difficulty navigating menus and performing specific operations if they have never used a Mobile App before. As a result, previous experience with any Mobile App is preferred.

[7.2.5] When the battery of the ACLeeve needs to be replaced, the user will need experience in how to disconnect and connect a simple battery to the ACLeeve. For the engineering prototype we will have a rechargeable battery, therefore, the user must know how to connect a charging cable to the appropriate location on the ACLeeve.

[7.2.6] When replacing the ACLeeve's battery, the user is required/highly recommended to open the ACLeeve Companion App and navigate through certain menus to figure out what specific battery they need to use.

[7.2.7] When performing the rehabilitation exercises, the user must restrict their movement so that the ACLeeve will not change its positioning/orientation on the user's quadriceps, because that will affect the system's analyses and results (both short and long term).

[7.2.8] While the user is performing their rehabilitation exercises, specifically in-between each set of a fixed amount of repetitions, the user is required/highly recommended to open our specifically designed ACLeeve Companion App to check on the currently displayed data relating to the set that was just competed by the user.

[7.2.9] Additionally, the user is highly recommended to view the constructive feedback, which will be displayed to the user in the ACLeeve Companion App, after each set of exercises. As a result, the user can then incorporate this feedback into their next set of exercises in order to increase rehabilitation effectiveness.

[7.2.10] An obvious but legitimate requirement is that the user should make sure the battery life of the ACLeeve is enough to last throughout all their rehabilitation exercises. To accomplish this, for the engineering prototype, the user will need to either check the LED indicators on the ACLeeve, or the ACLeeve App will also display this data.

7.3 Technical Analysis

Technical Analysis for the ACLeeve, taking into account the "Seven Elements of UI Interaction", can be broken down into two parts: the ACLeeve itself and the GUI software that works with the sleeve. Before continuing further with this topic, it is important to mention the seven elements of UI interaction: discoverability, feedback, conceptual models, affordance, signifiers, mappings and constraints [2]. This section will discuss how the design of the ACLeeve applies these principles to provide the best user experience possible. The following text references the front and back views of the ACLeeve as shown in Figure 3 in section 2.2. That figure is also shown below, to allow for easier referencing.

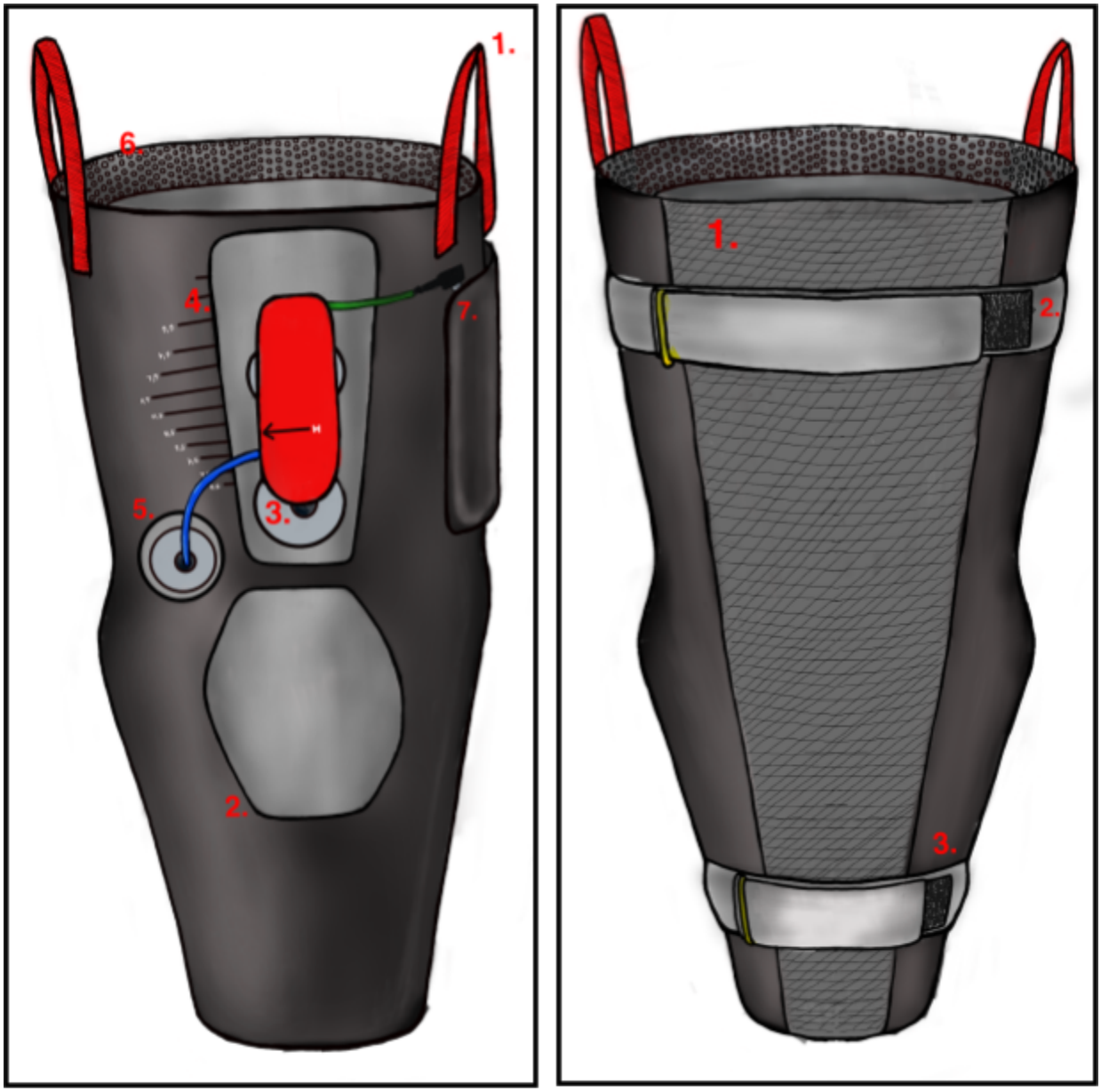

Figure 3: Appearance Prototype of ACLeeve
Frontal View (Left) and Rear View (Right)

7.3.1 Signifiers and Affordance

The design of the ACLeeve sleeve itself provides a strong indication for how this product should be worn. For example, the pull-on loops at the top side of the sleeve (Label 1; Frontal view) allow the user to grasp the ACLeeve by putting their hands through the loops and pulling the sleeve on like a stocking. Once the user has started pulling the sleeve up their leg, they will know how far to pull it up because the large hole at the front of the sleeve matches the shape of the patella (kneecap). This signifies the correct placement to the user. Once the hole has slotted over the user's kneecap the sleeve is at the correct height, and the velcro straps can then be

fastened using the hook and loop fasteners (Label 2 and 3; Rear view). These are all examples of affordances. Based on the previously mentioned features and the users familiarity with daily tasks, such as getting dressed in the morning or fastening a pair of velcro shoes, these affordances allow the user to instantly recognize that the sleeve is for wearing on their knee and that the velcro straps are for fastening.

7.3.2 Constraint

Constraints also play a major role for how the user perceives the ACLeeve. For example, the size of the sleeve limits the possibilities of where on the body the sleeve can be worn. More importantly, once the sleeve is in the correct location, constraints guide the user for where to place the electrodes. The large cut out trapezoid shape, (Label 4; Frontal view), on top of the thigh limits the placement of the electrodes to the central part of the quadricep. The user is also guided by a ruler that helps determine the correct height at which to place the electrodes based on the user's height. The 3rd reference electrode is limited to being placed in a round cut-out, away from the users quadricep, forcing the placement near a bony prominent spot on the knee (Label 5; Frontal view).

7.3.3 Conceptual Model

The user will be able to get a high level conceptual model of the sleeve portion of the system through basic interaction with the device. Once the user has put on the sleeve and connected the electrodes, it will be easy to see how the system is connected by following the wire starting at the electrode end. The wire from the electrodes lead to the electromyograph unit (Label 3; Frontal view), and from here the wire continues to the electronics pocket (Label 7; Frontal view). The electronics pocket contains the battery and the microcontroller. Since this system follows the linear thought process of first collecting data then sending data onwards for other steps, the user's mental model matches the actual conceptual model without needing additional details. The portion of the device that deals with the data processing is on the other hand abstract. In order to operate the device correctly the user only needs to know that the metrics obtained by the ACLeeve are then displayed on their smartphone as part of a Graphical User Interface (GUI). For this reason, if the reader needs to have a clear understanding of the entire system, a detailed description will need to be included in the user manual. This is because what happens in the Cloud is invisible to the user, and it is impossible for the user to learn about it through just the use of the device. It is also questionable whether or not the average user needs to be made aware of this portion of the system, since it could be intimidating and overwhelming for many users.

7.3.4 Mapping, Feedback

Continuing on with the electronics pocket; since this is the area housing the electronic components it is also the area connected to the power switch. This is the only button on the ACLeeve that is directly accessible to the user from the sleeve itself. So, its mapping is pretty straightforward. Even if the user is unaware of the button's purpose, a simple flick of the switch

gives the user instant feedback by turning on a green LED. Based on this observation the user will be able to tell that the switch controls the power to the ACLeeve (as without power the LED would not have turned on) and based on cultural understandings will know that a green light signifies a positive outcome.

7.3.5 Affordance

The GUI portion of the software also takes into consideration these principles; however, since this portion of the product is abstract, extra care needs to be taken to insure that correct interaction with the product can be achieved. In this case “abstract” means that the user can not look at the ACLeeve and see whether or not data is currently being collected or transferred without additional help from the GUI. Since the GUI is the main link for interacting with the data collected by the ACLeeve, the design of the interface plays a crucial part in the user experience. Luckily, in this day and age many customers will already be literate in interacting with apps on their smartphones; therefore, they will instantly know that the the login screen affords the creation, or signing into their accounts, etc. These points are trivial and the mapping of these prompts should be obvious to the user.

7.3.6 Constraints

The user experience for interacting with their data will be made enjoyable by streamlining the experience and providing a clean barebones graphical approach. We will strip away anything that is not of value in the display, guiding the user through their interactions by providing a limited or constrained set of actions that may be taken.

7.3.7 Mapping and Visibility

The mapping between buttons and actions will be made obvious through the use of clear language, or in some cases pictograms. For example, “Start Collecting” and “Stop Collecting” could be used to interact with the data collection feature of the app, and the significance of these buttons will be made clear by using the colours red and green. Alternatively, we may decide to use a video recorder style of buttons for this application. This is because the “record” and “stop” buttons already have clear and defined meanings when related to digital media. Therefore, the purpose of these buttons would be instantly recognizable for the users and provide visibility in the sense that the user would automatically know what is meant to happen once these buttons are pushed.

7.3.8 Feedback

Since most of the interaction with our product is done through the GUI, and since it is otherwise impossible to tell whether or not a task has been carried out, it is important to update the user on the status of their actions through the use of feedback. For example, when the user pushes a button on the user interface it can change colour to show if it’s in the up or down state, likewise we will provide auditory feedback for when certain buttons are pushed and an action is completed from the result of this button press.

Another area that is a focus of our attention is on determining the best possible way to visually represent the collected data. The style of graph is crucial to the success of our product, but we have yet to settle on a particular method for displaying this specific information. Besides the graph representation for symmetry, after each set of exercises, the user will also get visual feedback on their exercise in the form of a green checkmark or a red “x”. The cultural significance of these icons is once again obvious, self-explanatory, and the user will instantly understand whether the feedback was positive or negative.

7.3.9 Discoverability

Since the features of our device are quite limited in quantity, it is not difficult to ensure that each button maps to a single task. In a limited number of scenarios a drop down menu may be required, but a user who has previous experience with smartphone apps will be able to discover the features of the app with ease, simply through visual cues and language prompts.

Taking the above points into consideration when designing the finished product is valuable because it assures a comfortable stress free environment for the end user.

7.4 Analytical Usability Testing

Analytical usability testing is used to address the inefficiencies and major usability issues prior to receiving user feedback. To accomplish this, we examined similar EMG devices which are already present on the market. To get industry feedback, we established contact with a physiotherapist who would work with patients going through rehabilitation after an ACL injury. Drawing from our teams' own experience in working with EMG devices and the conversation with a physiotherapist, we were able to draw conclusions about the existing usability issues and incorporate respective solutions into our device.

7.4.1 Aids to Post-ACL Injury Recovery

Figure 15: BREG Recover Knee Brace, a knee sleeve for aiding with post-ACL injury/reconstruction recovery [3]

The majority of post-ACL injury devices are mobility aids that take weight off of the injured leg and/or provide compression to manage pain and swelling. Many of these aids help in the initial recovery phase right after the injury, and if recovery is going well, gradually weaned off as the leg heals.

Pros: These devices provide the patient with mobility and some injury management within the first month after the injury.

Cons: After the first month post-injury, these devices may no longer be needed by the patient, as the leg may be healed enough to put their whole weight on it. There are no devices that can be used for the rest of the recovery period (which can be several months [4]) or provide

quantifiable information on how the recovery is going. Recovery reporting requires the patient to “wait and see” and issues are dependent on patient self-reporting.

Design Choices: The lack of quantifiable metrics outside of the initial stages of recovery was the inspiration for this project - we wanted to create a device that provides an objective measure of a patient’s recovery post injury. By utilizing the EMG signals of each leg, the degree of symmetry between the muscles’ activations (measured through EMG) allow us to quantify the recovery process [5]. By having this EMG sensor in a knee sleeve, it would also allow us to provide some level of compression for pain and swelling management.

7.4.2 EMG Sensors

Figure 16: Consensys EMG Unit and Dock, an EMG sensor kit using single use electrodes [6]

EMG sensor systems are mostly targeted toward research, and come bundled with other features (such as being able to act as an ECG monitor, built-in accelerometers, etc.) to be more enticing to potential buyers. We were interested in applying how they processed EMG data, as well the ease-of-use and portability of these systems.

Pros: Currently available EMG sensors are geared to being used by the general public, allowing them to be portable and easy to set-up. They allow the users to set-up the system without requiring additional help.

Cons: The sensors are prohibitively expensive to the general public (a single Consensys sensor and dock cost nearly $840 CAD). This is most likely due to the extra features included in the design that do not pertain to EMG measurements. The sensors are also built to be used for as

many configurations as possible for EMG testing over a variety of muscles, not specifically tuned for monitoring certain muscles.

Design Choices: From the current commercially available EMG sensors, we incorporated the features geared toward personal use: portability and simplified setup. The drawbacks motivated us to create a system solely for EMG detection so as to allow it to be cheap enough to be sold to the general public. We also wanted to specifically design the entire ACLeeve such that it maximised the ability to read EMG activity from the quadriceps, while minimizing the potential that it would be incorrectly set-up on the quadriceps; relating to its position and orientation.

7.5 Empirical Usability Testing

7.5.1 Initial Testing

The initial testing will be executed internally by Embrace Technologies and associates for basic usability testing that would apply to any human being regardless if they have an ACL injury. Testing in regard to the sleeve itself will consist of comfortability, complexity of operation (i.e. Setup/Takedown and electrode replacement), safety, and reliability. For the software side, our testing will include user interface testing (ease-of-operation) and reliability testing (i.e. connectivity, latency, reactivity, etc). After testing, all critical issues shall be fixed for the next implementation, and minor issues shall be fixed before the final product.

7.5.2 End User Testing

The end user testing shall be executed with the assistance of end users such as ACLR patients and physiotherapists. The testing will be performed with the end user's situation in consideration as their injuries may affect usability of the sleeve significantly. Factors such as comfort, ease-of-use, and safety are crucial due to the difficulties ACLR patients are already facing.

Sample Questions for Testers:

1. What are your first impressions of the device?
2. Is the ACLeeve comfortable?
3. How valuable is it to you to be able to track your ACLR progress on a daily basis?
4. How difficult was setting up and taking off the device?
5. Complexity of using the device?
6. Complexity of the phone application?
7. Any recommendations for the device?

Feedback will then be taken into consideration and solutions shall be implemented into our final version of the ACLeeve.

7.6 Engineering Standards

As a biomedical device, the ACLeeve must conform to a set of engineering standards to ensure the safe operation for the users. The user will interact with the knee sleeve and also the android application that displays the data.

The physical knee sleeve will conform to IEC-TR 60513 [Req 3.1.2-a] [7], covering the fundamental aspects of safety standards for an electrical biomedical device. It will also conform to ISO 60601 - Section 1-11 [Req 3.1.1-a] [8], a general medical device requirement for basic safety and essential performance. It will also adhere to CAN/CSA-C22.2 No. 60601-1-6:11 (R16) [9], which are general requirements for basic safety and essential performance for the device. These are in place to prevent the user from injuring themselves from electrical hazard, such as excessive leakage current. The device must adhere to ANSI-IEC-60529 [10], outlining protection against physical hazard by the device enclosure.

The android software shall adhere to IEC 62304:2006 [11], a standard that outlines the software life cycle process for biomedical softwares. This will ensure the software has been correctly verified and validated for functionality and provide a smooth operating experience for the user.

The device as a whole must also conform to communication standards since it requires the transfer of data from knee sleeve to mobile. The key standards to follow are IEEE 802.11 [12] covering WiFi, and IEEE 802.15 [13] covering Bluetooth.

7.7 Conclusion

This appendix outlines the UI Design for both the proof of concept and the engineering prototype ACLeeve. Currently, the ACLeeve is nearing completion on its PoC phase. This involves the underlying circuitry of an EMG combined with an app that provides basic functionality.

In terms of hardware, this means that although the EMG sensors are fully operational, none of the encapsulating ACLeeve components (such as the knee sleeve) have been created. Therefore, the hardware side of the user interface, which deals mostly with the setup of the ACLeeve, is currently only the MyoWare Sensor. Therefore, almost the entire hardware user interface will need to be created over the next semester.

The current software UI requires further development, but currently the user is able to connect with the ACLeeve in order to read and display data for the user to view. However, it is entirely possible next semester that we may need to use a different microcontroller or system on a chip to handle our device and thus the app may need to be entirely rebuilt from the ground up to accommodate it.

Essentially, what currently exists is a working proof of concept version of the ACLeeve, with bare circuitry rather than it integrated into a knee sleeve, and a rudimentary app. Added on next semester will be the necessary encapsulation to provide a seamless user interface, and a rebuilt app that will be the basis for an intuitive and simple to use ACLeeve.

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