February 7th, 2019

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

RE: ENSC 405W/440 Requirements Specification for ACLeeve

Dear Mr. Scratchley,

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

ACLeeve will monitor the user's movements of both quadriceps using surface EMGs (SEMGs) and Strain Sensors. 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.

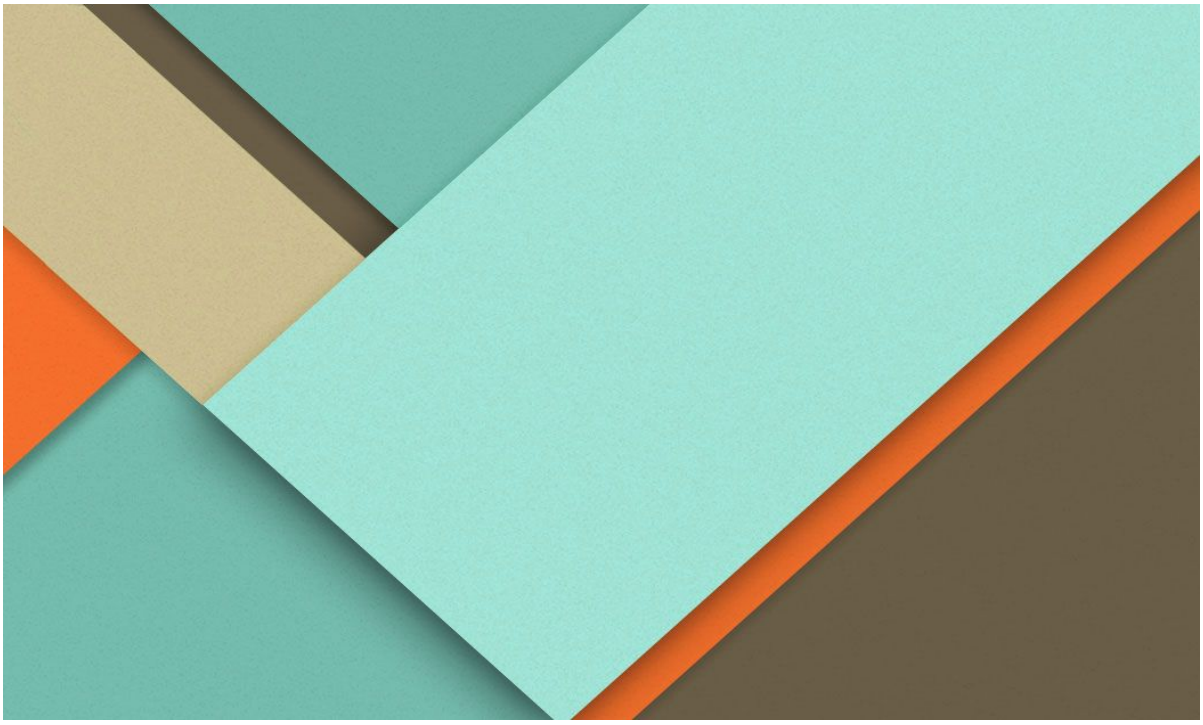
This requirements specification document will first of all contain an introduction to our ACLeeve product and the purpose behind the project. Secondly, this document will outline the various sets of requirements for each stage in our product design. The specific stages include the following: proof-of-concept prototype, engineering prototype, and production prototype. Thirdly, this document will present specific requirements relating to the following areas: physical design, hardware, software, economic, documentation, engineering standards, sustainability, and safety standards. Lastly, this document will outline the specific engineering standards that apply to our product ACLeeve, and will further expand on the analysis of applicable sustainability and safety issues.

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

Sincerely,

Nathan Batke

Nathan Batke
Embrace Technologies



ACLeeve Requirements 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 electromyography (EMG) device to be used during ACL injury recovery to aid in the rehabilitation process. The ACLeeve is wrapped around the user's leg using a knee sleeve and electrodes, and then wirelessly transfers data to the user's phone or laptop. To achieve this, the ACLeeve must be small and lightweight, with electronics and software capable of detecting EMG readings and then transmitting them over a secure wireless connection. As well, the ACLeeve must be safe for the user and conform to all relevant standards. The quantitative requirements to achieve these goals are outlined in this document.

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Glossary

ACL: anterior cruciate ligament

ACLR: anterior cruciate ligament reconstruction

ADC: Analog-to-Digital Converter

API: Application Programming Interface

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.

I2C: Inner-Integrated Circuit

Quadriceps: Shorthand for the Quadriceps Femoris muscle group

SPI: Serial Peripheral Interface

WPA2: Wi-Fi Protected Access 2

1. Introduction

One of the most common knee injuries is a sprain, or in the worst 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 ACLR recovery is the strengthening of the muscles surrounding the knee joint. According to scientific literature, “limb symmetry is an indicator of patient progress” [1], more importantly it can be used as one of the criteria for returning to sport post injury [2].

We wish to create a product that will help patients monitor their progress as they strive towards a minimum of 80-90% limb symmetry over the long term. The product will be accessible to the user in a non-clinical setting during rehabilitation exercises. The short term application of 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.

2. System Overview

The ACLeeve will consist of three major major components: a flexible knee sleeve with built in connections for electrodes, a sealed electronics enclosure which includes a microcontroller, and an external device provided by the user for data analysis. The primary goal of this device is to create an EMG monitoring tool to help with ACL injury recovery, that is cheaper, less invasive, and can possibly be used by just the user without requiring assistance from a physiotherapist.

The ACLeeve will use EMG to measure the activity of the quadriceps via surface electrodes. These electrodes will be attached to the electronics enclosure by snap leads and attached to the user along the quadriceps muscles, as well as the knee to provide a reference voltage. Each of these electrodes will transmit their measurements to an amplifier and filter, and the result is passed on to an electronics enclosure.The enclosure contains the main control hardware of the device, an ADC attached to a microcontroller. The resultant signal from the filters and amplifier is then fed into this control hardware. This data transmission pipeline is the highest risk element of ACLeeve. The electrodes and the pipeline must be able to withstand the stress from user movements and continual use, as well as be resistant to sweat. Possible design challenges will be acquiring useful EMG data from the electrodes. This will be addressed by making the path between the electrodes, filters and amplifiers as small as possible, to minimize signal artifacts.

The microcontroller will act as an intermediary between the EMG data from the electrodes and software endpoint to which the data will be delivered. The microcontroller (and attached electronics) will be powered by a battery located inside the enclosure. Data collected from all sensors will be uploaded to a real-time database via Wi-Fi and a cloud-based machine learning model will be used to detect anomalies in data. The software endpoint will be an app on an Android device which calls the cloud API to request data and services.

The requirements for ACLeeve are listed below; these requirements encompass the scope of the device and list the quantitative limits that the product must meet. They are separated into five main sections: functional, hardware, software, economic, and documentation. Subsections within those sections are provided when further clarity is needed. A short explanation is provided in each section to give context to those requirements.

Requirements are listed in the following format:

[Req X.Y.Z-i] Requirement Information

In this format, **X** and **Y** represents which section the requirement belongs to, **Z** will represent the requirement number, and **i** will represent the design stage at which the requirement is expected to be met. There will be 3 design stages, which will be represented with three letters: **a** for the proof-of-concept, **b** for the engineering prototype, and **c** for the production version of the product.

An example of a requirement for this upcoming section would be **[Req 3.1.1-a]**; this means that the requirement is in section 3.1, is the first requirement of the section, and is to be completed in the proof-of-concept stage of development.

2.1 Physical Requirements

The physical requirements detail the structure of the device, including the breakdown into different components and the requirements of each. The general characteristics of the device, including a limit on the weight, overall dimensions, and normal operating conditions, are also outlined. The focus here is on creating a device that is lightweight and small enough to not interfere with the user's movement, so as to allow the device to be used while a patient is performing therapeutic exercises (leg extensions, squats, etc.).

[Req 2.2.1-b] The device will consist of a knee sleeve with an attached electrodes and an electronic component.

[Req 2.2.2-a] The electrical component will be small enough to be worn directly on the knee sleeve.

[Req 2.2.3-b] The electrodes will be user-friendly and easy to apply to the quadriceps.

[Req 2.2.4-b] The electrodes will be single use.

[Req 2.2.5-b] The knee sleeve will be able to support the electronics and electrodes.

[Req 2.2.6-c] The device will weigh no greater than 1.3 kg.

[Req 2.2.7-c] The device will not cause discomfort for a wearing period of 6 hours.

[Req 2.2.8-b] The snap leads connecting the electrodes to the electronics will be 15 cm long from the sleeve.

[Req 2.2.9-b] The electronics component will be encased in a sweatproof plastic enclosure.

[Req 2.2.10-b] The electronics component will withstand sanitization by being wiped down with cleansing liquid but not full submersion or heat treatment.

[Req 2.2.11-b] The electronics component will be removable, so the knee sleeve component can be washed.

[Req 2.2.12-a] The electrodes will be pre-gelled, disposable electrodes.

[Req 2.2.13-a] The device will be able to operate within the temperature range of 0℃ to +40℃.

[Req 2.2.16-a] The device will not restrict the range of motion of the user's leg.

[Req 2.2.17-b] The knee sleeve must conform to the user's leg such that it will be a comfortable fit that prevents slipping.

2.2 Hardware Requirements

The hardware section outlines the components that we will need to perform the EMG of the quadriceps, as well as the processing to make the data useful to the user and the transmission of the data from the device to an external application. This section will also include all that will be present in the electronics.

2.2.1 Electrodes

[Req 2.3.1-a] The electrodes must be able to detect EMG readings from the quadriceps via the surface of the skin.

2.3.2 Amplifiers

[Req 2.3.2-a] The device will use differential amplifiers connected to the electrodes.

[Req 2.3.3-b] The differential amplifiers will have a gain of at least 1000 or 60 dB.

[Req 2.3.3-a] The differential amplifiers will be able to amplify signals as small as 1 mV.

[Req 2.3.4-a] The differential amplifier will have a Common mode Rejection Ratio of at least 100 dB [3]

[Req 2.3.5-b] The differential amplifier will draw no more than 10 mA of current at 4.5 V.

2.3.3 Filters

[Req 2.3.6-a] The device will use a band-pass filter with cutoff frequencies of 20 Hz and 500 Hz to remove low and high frequency noise [4]

[Req 2.3.7-a] The filter will draw no more than 10 mA of current at 4.5 V.

2.3.4 ADC

[Req 2.3.8-a] The device will use an ADC with at least 10 bit precision.

[Req 2.3.9-a] The ADC will have a sample rate of at least 1 kHz.

[Req 2.3.10-a] The ADC will support either SPI or I2C output interface.

2.3.5 Chip

[Req 2.3.11-b] The microcontroller will draw no more than 500 mA of current.

[Req 2.3.12-a] The microcontroller will operate at a voltage range between 3.6 V and 4.5 V.

[Req 2.3.13-a] The device will transmit Wi-Fi data using WPA2 encryption.

[Req 2.3.14-b] The device shall provide Bluetooth Classic and Low Energy standards of at least version 4.0.

[Req 2.3.15-a] The microcontroller must be able to communicate via SPI or I2C to external peripherals.

[Req 2.3.16-a] The microcontroller must have a minimum of 8 MB on-board flash storage.

2.3.6 Battery

[Req 2.3.18-b] The battery will be a rechargeable lithium ion cell.

[Req 2.3.19-b] The battery will have the capacity to support at least 12 hours of continuous use.

[Req 2.3.20-a] The battery will have an output voltage of at most 4.5 V.

[Req 2.3.21-a] The device will have a discrete On/Off switch.

[Req 2.3.22-a] The device will display a power-on status through an LED.

[Req 2.3.23-b] The device will display power-on/battery charge status through multi-colour lighting.

[Req 2.3.24-b] The device will have an easily accessible charging port.

2.4 Software Requirements

The software aspect of the project can be broken down into three main parts: a daemon process, a database server, and an Android dashboard. The daemon process collects data from multiple surface EMG sensors and transmits the data to a cloud database server. The database synchronizes the real-time data between the Android dashboard and the embedded device. To maximize the lifespan of the flash memory on the embedded device, the daemon process will only save a limited amount of data on flash memory if the WiFi signal is lost. As shown in Figure 1, the communication channels between the embedded device and the mobile application are bidirectional.

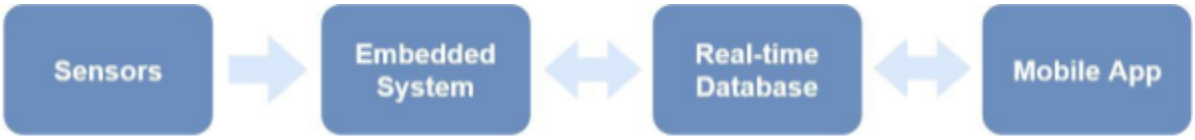

Figure 1: High Level System Model

To access the dashboard from a mobile device, the user must log into the system with a valid username and password. After that, the user will be able to send either “start collecting” or “stop collecting” command to the embedded device via Bluetooth. Once the “start collecting” command is sent, the mobile app will launch a page to display the real-time data. The mobile application will provide feedback to the user after a task is completed. By keeping the user dashboard simple and interactive, the user will find the app easy to use the first time around.

The requirements for the different parts of the software system are listed below:

2.4.1 Embedded Software Requirements

[Req 2.4.1-a] The microcontroller shall conduct a boot-up in less than 60 seconds.

[Req 2.4.2-a] The microcontroller shall wait for a command to start the data collection process.

[Req 2.4.3-a] The microcontroller shall collect data from all of the sensors simultaneously.

[Req 2.4.4-a] The microcontroller shall transmit data to the server in real-time via WiFi.

[Req 2.4.5-c] The microcontroller shall store data offline in the absence of WiFi.

2.4.2 Mobile App Requirements

[Req 2.4.6-a] The application shall have the functionality to start/stop recording data.

[Req 2.4.7-a] The application shall display the real-time data in a waveform-display.

[Req 2.4.8-b] The application shall notify the user when signal-to-noise ratio has exceeded the limit value.

[Req 2.4.9-c] The application must be able to tolerate some difference between the legs.

[Req 2.4.10-b] The application shall be able to compare quadriceps muscle activity in real-time.

[Req 2.4.11-c] The application shall recognize that the user has reached 80-90% of symmetry between muscle groups.

[Req 2.4.12-b] The application shall provide symmetry feedback to the user in visual form.

[Req 2.4.13-b] The device shall be able to display the potential of the muscles over a long period of time.

[Req 2.4.14-c] The application shall not be larger than 500 MB.

[Req 2.4.15-b] The application shall be available on Android 6.0 and above.

[Req 2.4.16-c] The application shall support exporting of user data to CSV format.

[Req 2.4.17-a] The application shall retrieve data from the cloud database and display it within 1 second.

[Req 2.4.18-c] The application shall notify the user within 3 seconds when abnormalities are detected.

[Req 2.4.19-b] The application interface shall be easy to learn and navigate the first time around.

[Req 2.4.20-c] The application shall provide instructions for calibrating the SEMG sensors.

[Req 2.4.21-b] The application shall display analyzed data in a user-friendly fashion.

2.5 Economic Requirements

[Req 2.5.1-c] The final product will cost no more than $200 USD.

2.6 Documentation Requirements

It is important for every medical device to come with a manual, including an intended use statement. This is so users can be properly educated in how to operate the device and how to setup the device properly. The ACLeeve will come with such a manual, which will include information on properly handling and cleaning the device.

[Req 2.6.1-c] The manual will depict an image of where the electrodes should be placed.

[Req 2.6.2-c] The manual will explain how to turn the device on and off.

[Req 2.6.3-c] The manual will show how the user can connect external devices to the ACLeeve and start/stop monitoring.

[Req 2.6.4-c] The manual shall notify the user of all parts that should have been included in the packaging.

[Req 2.6.5-c] The manual shall contain an “intended use” and “indication for use” statement.

3. Engineering Standards

The ACLeeve, as a medical device, will need to conform to many strict regulations and standards. In order to ensure this device meets the standards for the market, we will primarily focus on the US and Canada. The most relevant standards are from the International Organization for Standardization (ISO), and the International Electrotechnical Commission (IEC) [5], along with any derivatives of these standards that are relevant to the ACLeeve. As this device will initially be marketed in Canada, we will also focus on the Canadian Standards Authority (CSA), and its adaptations of the international standards. These standards were chosen to allow scalability to be quite simple, as the standards in most other markets deviate very little from these international standard [6].

Medical devices must also be classified based on the the risk they present to the patient. In Canada, devices are classified by Health Canada, and are divided as Class I, II, III, and IV; in the United States, devices are classified by the Food and Drug Administration (FDA), and are classified by Class I, II or III. Each of these classifications will have stricter or more lenient regulations [6]. In order to determine which class a product falls under, a preliminary classification must be assigned based on the intended use of the device. Based on the guidance documents for Health Canada, the ACLeeve would be subject Rule 10(1) and be considered a class II device [7]. In the United States, the ACLeeve would also be a Class II device, as per FDA classification strategies and the Code of Federal Regulations Title 21, Volume 8, Part 890, Section 890.1375 [8].

Ensuring that our device is aligned with the following standards will permit the ACLeeve to be sold on the North American market and provide consumers with confidence in the efficiency and safety of the device. Hence, this section will highlight the particular standards that this device will comply with.

3.1 Operational Safety and Performance Standards

[Req 3.1.1-a] The device shall follow ISO 60601 - Section 1-11 - General medical device requirement for basic safety and essential performance [9].

[Req 3.1.2-a] The device shall follow IEC TR 60513 Fundamental aspects of safety standards for medical electrical equipment [10].

[Req 3.1.3-a] The device shall follow CAN/CSA C22.2 NO. 60601-1:14 (R2018) - Derivation of ISO 60601 with Canadian deviation [11].

[Req 3.1.4-c] The device shall follow AAMI TIR 69: Association for the Advancement of Medical Instrumentation - Risk Management of Radio-frequency Wireless Coexistence for Medical Devices and Systems [12].

[Req 3.1.5-c] The device shall follow ISO 14971 - Application of risk management to biomedical devices [13].

[Req 3.1.6-c] The device shall follow IEC 82304-1:2016 - Health Software - Part 1: General Requirements for product safety [14].

[Req 3.1.7-c] The device will follow IEC 62353:2014 - Recurrent test and test after repair of medical electrical equipment [15].

3.2 Electrical Standards

[Req 3.2.1-a] The device shall be a low-voltage system following standard IEC 60038 [16].

[Req 3.2.2-c] The device shall conform to IEC 60950-1 - General Information Technology equipment safety [17].

3.3 Medical Device Software Standards

[Req 3.3.1-a] The device shall follow IEC 62304:2006 outlying the software life cycle process [18].

[Req 3.3.2-c] The device shall follow IEC TR 80001-2-3:2012 [19].

3.4 Wireless Communication Standards

[Req 3.4.1-a] The device shall follow IEEE 802.11 WiFi standards [20].

[Req 3.4.2-a] The device shall follow IEEE 802.15 Bluetooth Standards [21].

3.5 Sterilization Standards

[Req 3.5.1-c] The device shall follow ISO 17664:2017 - Processing of health care products [22].

3.6 Usability

[Req 3.6.1-c] The device shall follow CAN/CSA-C22.2 No. 60601-1-6:11 (R16) - Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability [23].

[Req 3.6.2-c] The device shall follow IEC/TR 62366-2:2016 - Medical devices -- Part 2: Guidance on the application of usability engineering to medical devices [24].

3.7 Environmental Conscious Design Standard

[Req 3.7.1-c] The device's components shall follow CAN/CSA-C22.2 NO. 60601-1-9:15 - Medical electrical equipment - Part 1-9: General requirements for basic safety and essential

performance - Collateral standard: Requirements for environmentally conscious design (Adopted IEC 60601-1-9:2007, edition 1:2007 consolidated with amendment 1:2013, with Canadian deviations) [25].

3.8 Quality Management & Risk Management Standards

[Req 3.8.1-c] The device will conform to ISO 13485:2016 - Medical devices -- Quality management systems -- Requirements for regulatory purposes [26].

[Req 3.8.2-c] The device will conform to ISO 14971:2007 - Medical devices -- Application of risk management to medical devices [27].

[Req 3.8.3-c] The device will conform to IEC 60529-2004 - Degrees of protection provided by enclosures (IP Code) [28].

3.9 Battery Standards

[Req 3.9.1-c] The device shall follow IEEE 1625-2008 - IEEE Standard for Rechargeable Batteries for Multi-Cell Mobile Computing Devices [29].

4. Sustainability and Safety

4.1 Sustainability

At Embrace Technologies, we wholefully care about how our product may affect the environment, so at Embrace Technologies we will take initiative and responsibility by adhering by a “cradle to cradle” design. To achieve this, our products at Embrace Technologies will be made of recyclable materials, when possible, while having long lifetimes and being highly re-usable.

Our ACLeeve product is designed for licensed practitioners (e.g. Physiotherapists) to be given to their patients, so it is meant to be reused many times. To achieve this, the sleeve must be removable from the electronic components so that the sleeve may be washable and as an added benefit either part can be independently replaced, which allows for reusability of working components.

[Req 4.1.1-c] Electrical components shall be removable or waterproof such that the brace sleeve is washable.

[Req 4.1.2-b] The product should be designed to be re-used by multiple patients.

[Req 4.1.3-b] Lifetime of the product should be at least the 4 months required for recovery of ACL injuries [30].

[Req 4.1.4-a] The device’s battery will be removable, so as to allow replacement and recycling.

[Req 4.1.5-b] The device’s enclosure will be made of recyclable medical grade ABS plastic.

[Req 4.1.6-c] The device’s circuitry will be made with lead free solder and components that can be recycled by an electronics recycling depot.

4.2. Safety

At Embrace Technologies, it is our highest priority to ensure that the user is safe. The main concern for ACLeeve is the electronic components attached to the user, so we have to take certain measures to ensure that the user cannot be harmed by our product.

4.2.1 Physical

[Req 4.2.1-b] The device’s analytical electronics will be housed inside a rigid case that conforms to IEC 60529-2004 [28].

[Req 4.2.2-c] The device’s enclosure will not have sharp edges/burrs and it will be made of insulated plastic to reduce the risk of injuries or electrical shorts.

[Req 4.2.3-c] The device’s battery housing shall be resistant to puncturing.

[Req 4.2.4-b] The device will be made up of components that conform to the RoHS [31].

[Req 4.2.5-c] The device shall be able to withstand drops from 1m onto hard surfaces and remain functional.

[Req 4.2.6-a] The device will be insulated such that heat exhaust from the electronics will not harm the user.

4.2.2 Electrical

[Req 4.2.7-c] The device's battery shall conform to IEEE 1625 [29].

[Req 4.2.8-b] The leakage current of the device shall conform to CAN/CSA-C22.2 NO. 60601-1-11:15 [32].

[Req 4.2.9-c] The device shall conform to FCC Part 15 or EN55022/CISPR 22 EMI Standards [33].

4.2.3 Biomedical

[Req 4.2.10-b] The users of the device will have to undergo orientation and training before using the device.

By considering these requirements, we believe the risk that the ACLeeve potentially poses will significantly be reduced.

5. Conclusion

Embrace Technology aims to create a portable, user friendly rehabilitation assistant device for ACL injury. This requirement specification document outlines ACLeeve's device functionality and general requirements. In addition, the document specifies the list of engineering, safety, quality management and sustainability standards our device follows. As a medical device, it is crucial certain standards and protocols are strictly followed to ensure our device upholds quality and assures user safety.

The device shall be developed over an 8 month period and shall be divided into two main stages, the prototype proof of concept and engineering prototype. Each requirement previously listed indicates the stage at which it shall be fulfilled. The proof of concept is scheduled to be finished by April 2019, and a test plan will be appended to the end of this document. It will contain test cases for all relevant parameters and be mapped to the corresponding requirement.

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7. Technical Appendices

Acceptance test

The acceptance criteria for the proof-of-concept deliverable is as follows:

Hardware Components

REQ ID	Expected Result	Pass/Fail
Req 2.3.21	Does the On/Off switch turn the device on?	
Req 2.3.20	Is the device battery powered?	
Req 2.3.1	Do all the surface EMG sensors work?	
Req 2.3.22	Does the LED indicate that the device is on?	

Embedded System

REQ ID	Expected Result	Pass/Fail
Req 2.4.1	Does the microcontroller boot-up in less than a minute?	
Req 2.4.4	Does the microcontroller have WiFi connection?	
Req 2.4.3	Does the microcontroller collect sensor data in real-time?	
Req 2.4.4	Does the microcontroller upload all the data to the cloud database?	

User Dashboard

REQ ID	Expected Result	Pass/Fail
Req 2.4.6	Does the start/stop recording data button work?	
Req 2.4.7	Does the waveform-display show real-time data?	

Presentation Demo Plan

The specific project deliverable is as follows:

- The test user will be able to put the device on their knee and power on the device.
- The microcontroller will be powered through an external battery.
- The microcontroller will collect data from the surface EMG sensor and Strain sensor.
- The data from the sensors will be uploaded to a cloud database via WiFi.
- The data exchange will be completed in a reasonable amount of time.
- The test user will be able to visualize their muscle activity in real-time.

The following requirements will be presented during the demo:

REQ ID	**Description**
Req 2.2.2	The electrical component will be small enough to be worn directly on the knee sleeve.
Req 2.2.12	The electrodes will be pre-gelled, disposable electrodes.
Req 2.2.16	The device will not restrict the range of motion of the user's leg.
Req 2.2.21	The device will display a power-on status through an LED.
Req 2.2.12	The microcontroller will operate at a voltage range between 3.6 V and 4.5 V.
Req 2.4.1	The microcontroller shall conduct a boot-up in less than 60 seconds.
Req 2.4.2	The microcontroller shall wait for a command to start the data collection process.
Req 2.4.3	The microcontroller shall collect data from all the sensors simultaneously.
Req 2.4.4	The microcontroller shall transmit data to the server in real-time via WiFi.
Req 2.4.6	The application shall have the functionality to start/stop recording data.
Req 2.4.7	The application shall display the real-time data in a waveform-display.
Req 2.4.17	The application shall retrieve data from the cloud database and display it within 1 second.