March 14th, 2019
Dr. Andrew H. Rawicz
School of Engineering Science
Simon Fraser University
V5A 1S6

RE: ENSC 405W/440 Design Specification for the TechBrace by FlexTech

Dear Dr. Rawicz,

Please find attached the design requirements for the FlexTech TechBrace. Our goal is to create a stabilizing knee brace that not only limits risk of injury, but also trains the user's brain and muscles to facilitate faster recovery from ACL injury.

This document outlines the specific technical requirements for a functional, comfortable, and effective brace. They are categorized as general, hardware, sensor, muscle activation, and app requirements. The engineering standards and sustainability and safety considerations are also outlined in the document, as well as design considerations for the user interface.

FlexTech consists of five passionate engineering students: Jason Fevang, Lauren Fridman, Jack Guo, Andrea Manjarres, and Nic Klassen. These students come from different backgrounds in the hopes of combining their expertise to create an innovative solution to a painful problem.

Thank you for your consideration of our product. If you have any questions or concerns please contact our CCO, Jack Guo, at yupengg@sfu.ca.

Sincerely,

Lauren Fridman
Chief Science Officer
FlexTech

Enclosure: Design Specification for FlexTech TechBrace

Design Specification

For FlexTech TechBrace

"The results will shock you!"

March 14th 2019

Project Team:

Jason Fevang
Lauren Fridman
Jack Guo
Andrea Manjarres
Nicolas Klaassen

Contact Member:

Jack Guo
yupengg@sfu.ca

Submitted To:

Craig Scratchley,
School of Engineering Science,
Simon Fraser University

Abstract

Sprains and tears of the ACL are some of the most common forms of injury over a variety of different sports [1]. This type of injury can cause an athlete to take up to a year off of training for recovery, which may include surgery. The resulting instability from the damage may lead to knee instability, which can result in further injury or delayed recovery. Currently, the most common solution is a prescribed program of strengthening exercises to build up the supporting muscles of the knee, but these exercises do not directly address the different motions that occur over a regular day.

The FlexTech TechBrace aims to help the user maintain proper knee orientations throughout the course of a day, while also developing the strength of those stabilizing muscles and the neural pathways that control them. The system we propose consists of three main subsystems: the angle deviation detection system, the muscle activating electrodes, and an interactive mobile app. First, the user calibrates the device to their custom measurements and needs, and then the brace can be used to simultaneously avoid potential re-injury while rebuilding the biological knee support system.

This document outlines the design requirements of the device including general, hardware, angle deviation detection, muscle activation, power supply, mobile app, and sustainability and safety requirements. The Appendix includes specific design considerations related to testing and the user interface. The sections are designed in such a way that we can work with individual components while maintaining coherence in the overall product.

Table of Contents

Table of Figures

Table of Tables

1 Introduction

Injuries are almost inevitable for athletes of any age, with ACL injuries being one of the most prevalent types [1]. At any level, these injuries not only set athletes back from lack of physical training, but also in terms of their confidence and mental health. It is in the best interest of athletes, coaches, and families to get the injured players healthy enough to Return To Play (RTP) as soon as possible. The TechBrace by FlexTech is a means to that end.

The TechBrace is a knee brace that senses orientation of the user's knee and provides an electrical stimulus to the supporting muscles when it goes into potentially injurious ranges of motion. This stimulus not only helps bring the knee back into healthy ranges, but also trains the muscles and nervous system of the user so that they can develop the ability to stabilize their own knee. Conventional physiotherapy and rehabilitation programs typically rely on strengthening exercises to achieve the required stability for RTP, but this can be a slow process [2]. The TechBrace is designed for long periods of day-to-day use to enable continuous rehabilitation. Additionally, FlexTech will provide an interactive app to enable progress tracking and help physiotherapists tailor their treatment to the individual's stage of recovery.

1.1 Intended Users

This document is intended for the team members of FlexTech to use as a technical guideline in the implementation of a prototype of TechBrace, as well as for the TAs and professors supporting us. The FlexTech team shall refer to this document to clear any ambiguities that may arise in the development of a TechBrace Prototype. Moreover, this document and the requirements document will be used to test the TechBrace in order to ensure our prototype meets all the specifications.

1.2 Classification

The following convention will be used to categorize and prioritize the requirements included in this document.

[DES <Section> . <SubSection> . <Req. Number> - <Priority> - <Stage>]
Description

Where:

- **DES** stands for design specification.
- **Section Number** refers to the section to which the requirement belongs, listed in the table below.

Section Number	Section Name
3	General Requirements
4	Hardware
5	Angle Deviation Sensor
6	Muscle Activation System
7	App
8	Sustainability and Safety

Table 1: Section Numbers

- **Subsection Number** refers to the subsection number within the section.
- **Priority** refers to the level of priority that is given to a requirement, listed below.

Priority	Description
A	High priority, critical features of the TechBrace
B	Medium priority, essential features of the TechBrace
C	Low priority, non-necessary features of the TechBrace

Table 2: Priority Levels

- **Stage** refers to the development stage by which the requirement shall be done. Note that the Proof of Concept will be presented during the 405W demo.

Abbreviation	Stage
PC	Proof of Concept
PT	Prototype
PR	Production Ready

Table 3: Development Stages

- **Description** refers to a brief description of the requirement.

2 System Overview

At a high level, the TechBrace has two main functions:

- Detect when the user's knee is at an unsafe or "critical" angle
- Respond to a measured critical angle with a corrective event

The angles of the knee will be measured by two IMUs embedded in the TechBrace, positioned above and below the knee. These measurements will be processed by a microcontroller that will determine whether the valgus angle of the knee at that moment constitutes a critical angle. When a critical angle is detected, the microcontroller will trigger a corrective event.

During the Proof of Concept phase, the corrective event will be implemented by a vibration motor attached to the user's leg. In the prototype phase this will be replaced by a Neuromuscular Electrical Stimulation (NMES) system. In either case, the purpose of the corrective event is to alert the user of the critical angle and trigger a muscle reflex to correct this angle of the knee. Over time, the goal is for these corrective events to re-train the user's nervous system to keep the knee at a safe angle at all times.

The complete TechBrace system will include a mobile app that can connect to the microcontroller embedded in the TechBrace via Bluetooth Low Energy (BLE). This mobile app and the knee sleeve will constitute the user interface of the TechBrace, allowing the user to calibrate the device and tune certain settings, such as the power and frequency of corrective events. The mobile app will also allow users to track corrective events over time.

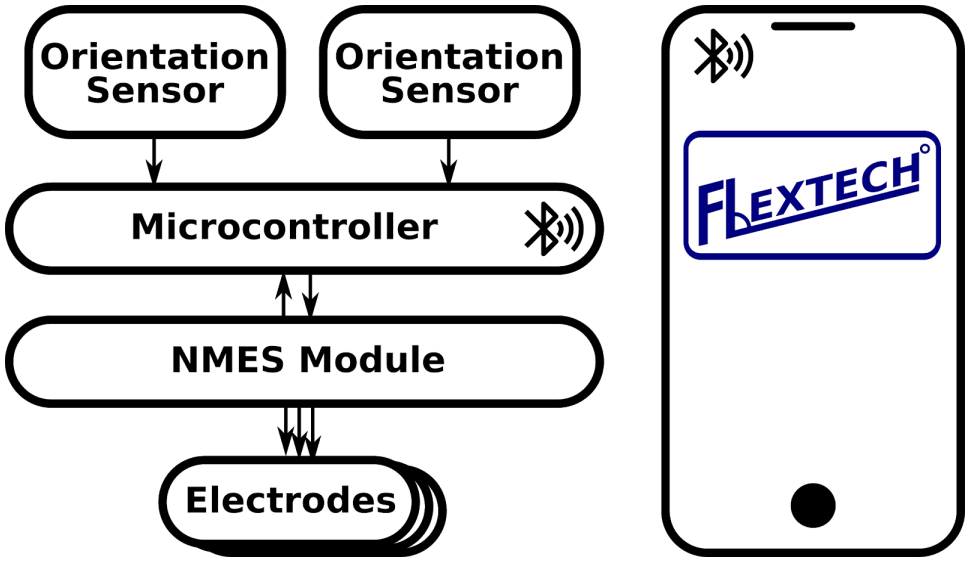

Figure 1: System Design Diagram

3 General Requirements

3.1 Overall Performance

[DES 3.1.1-A-PC] The brace shall trigger a correction event every time a critical deviation occurs.
[DES 3.2.2-A-PT] The brace shall work along with an app to allow the user to calibrate the brace and track their improvement.
[DES 3.2.3-A-PT] The brace calibration shall record the q-angle of the user.
[DES 3.2.4-A-PR] The brace shall have a microcontroller to determine whether to stimulate based on data acquired by sensors.
[DES 3.2.5-B-PR] The brace shall have reduced power consumption when there is minimal movement occurring.

3.2 Usability

[DES 3.2.1-A-PR] The brace shall not cause discomfort for the majority of users when worn for up to 6 hours.
[DES 3.2.2-A-PR] The brace, including all components, electrodes, and batteries, shall not weigh more than 500 grams.
[DES 3.2.3-A-PR] The brace shall fit on a range of leg sizes, which represents the majority of the population, or be available in a range of sizes that covers the majority of the population.

[DES 3.2.4-A-PR] The brace shall be sweat resistant.
[DES 3.2.5-A-PR] All components of the brace shall be attached to the knee sleeve, with the exception of the electrodes and their connecting wires.

4 Hardware

4.1 Knee Sleeve

[DES 4.1.1-A-PC] The brace shall incorporate a soft knee sleeve that wraps the knee.
[DES 4.1.2-A-PC] The knee sleeve shall not physically restrict normal motion of the knee.

All electronic components (besides electrodes) will be housed in a soft shell knee sleeve with a hole for the kneecap. This hole will facilitate natural movement of the knee by limiting pressure on the kneecap. Components will be secured in fitted pockets on the sleeve, but will be removable to enable easy replacement of individual components and support washing of the sleeve itself. Velcro straps will wrap around the sleeve to ensure that it stays in the right place on the leg and to help make the brace customizable to differently sized legs. The entire brace will be as slim fitting as possible, while ensuring that there are no sharp edges or areas that can catch on clothing.

Figure 2: Knee sleeve [3]

4.2 Temperature

[DES 4.2.1-A-PT] The brace shall function to specification in an ambient temperature range of -5 to 50 degrees Celsius.
[DES 4.2.2-B-PT] The brace, including all electronic components and batteries, shall not heat up to more than 20 degrees above the ambient temperature.
[DES 4.2.3-A-PT] The sensors will have a working temperature range of -5 to 50 degrees Celsius.

Sensor	Operating Temperature
SparkFun IMU	-40ºC to +85ºC
Adafruit Microcontroller	-40ºC to +125ºC

Table 4: Sensor operating temperatures [4],[5]

4.3 Status LED

[DES 4.3.1-B-PR] The brace shall incorporate a status LED that indicates the device and battery state.

Device Status	LED
On (disconnected)	Blue (solid)
On (connected to app)	Blue (flashing)
Charging	Orange (flashing)
Fully Charged	Green (solid)
Battery Critically Low	Red (solid)
Device Failure	Red (flashing)
Off	Off

Table 5: LED statuses

4.4 Power Supply

This section discusses the power supply requirements of the TechBrace, which leads to a selection of rechargeable DC power supply.

[DES 4.4.1-A-PT] The brace shall have a physical power switch mounted on the knee sleeve that turns all electronic components on and off.
[DES 4.4.2-B-PR] The brace shall have a battery life of at least 6 hours.
[DES 4.4.3-A-PR] The brace shall allow the user to charge the battery via a micro-USB port.

4.4.1 Calculations

As mentioned previously, the brace will consist of two major hardware systems: Angle Deviation Detection and Muscle Activation System. The calculation of the power consumption of each system will be calculated separately.

Angle Deviation Detection

The Angle Deviation Detection System (ADDS) consists of the microcontroller and two IMUs. The microcontroller, as previously discussed, is based on Espressif ESP32. The data for this component is shown in Table 6.

Power mode	Description	Power consumption
Active (RF working)	Wi-Fi Tx packet 13 dBm ~ 21 dBm	160 ~ 260 mA
	Wi-Fi / BT Tx packet 0 dBm	120 mA
	Wi-Fi / BT Rx and listening	80 ~ 90 mA
	Association sleep pattern (by Light-sleep)	0.9 mA@DTIM3, 1.2 mA@DTIM1
Modem-sleep	The CPU is powered on.	Max speed: 20 mA
		Normal speed: 5 ~ 10 mA
		Slow speed: 3 mA
Light-sleep	-	0.8 mA
Deep-sleep	The ULP co-processor is powered on.	0.15 mA
	ULP sensor-monitored pattern	25 μA @1% duty
	RTC timer + RTC memory	10 μA
Hibernation	RTC timer only	2.5 μA

Table 6: Data table for Espressif ESP32 [4]

The purpose of the microcontroller is to run the ADDS algorithm, send a trigger signal to the Muscle Activation System if a correction event is required, and send a signal to the user's cell phone via Bluetooth to record the number of correction events triggered.

The microcontroller will be in Modem-sleep Mode most of the time, only going into Active Mode with Bluetooth Tx and Rx on.
The recommended operating conditions are shown in Table 7.

Parameter	Symbol	Min	Typ	Max	Unit
Battery regulator supply voltage	V_{BAT}	2.8	3.3	3.6	V
I/O supply voltage	V_{IO}	1.8	3.3	3.6	V
Operating temperature range	T_{OPR}	-40	-	125	°C
CMOS low level input voltage	V_{IL}	0	-	0.3 x V_{IO}	V
CMOS high level input voltage	V_{IH}	0.7 x V_{IO}	-	V_{IO}	V
CMOS threshold voltage	V_{TH}	-	0.5 x V_{IO}	-	V

Table 7: Recommended operating conditions of Espressif ESP32 [4]

Modem-sleep Mode Power Consumption:

$$Power_{MM} = Supply\ Voltage * Current = 3.3V * 10mA = 33\ mW$$

Active Mode Power Consumption:

$$Power_{AM} = Supply\ Voltage * Current = 3.3V * 120\ mA = 0.396\ W$$

Since the microcontroller will be switching between Modem-sleep Mode and Active Mode at a frequency depending on the user's physical position, a safe assumption would be that the microcontroller will be in Active Mode for 20% of the time and Modem-sleep Mode for the other 80%.
Under this assumption,

$$Power_{MC} = 20\% * Power_{AM} + 80\% * Power_{MM} = 0.1056\ W$$

Electrical specification data for the IMU is shown in Table 8.

PARAMETER	CONDITIONS	MIN	TYP	MAX	Units	Notes
SUPPLY VOLTAGES						
VDD		2.4	2.5	3.6	V	
VDDIO		1.71	1.8	VDD	V	
SUPPLY CURRENTS						
Normal Mode	9-axis (no DMP), 1 kHz gyro ODR, 4 kHz accel ODR, 8 Hz mag. repetition rate		3.7		mA	
	6-axis (accel + gyro, no DMP), 1 kHz gyro ODR, 4 kHz accel ODR		3.4		mA	
	3-axis Gyroscope only (no DMP), 1 kHz ODR		3.2		mA	
	6-axis (accel + magnetometer, no DMP), 4 kHz accel ODR, mag. repetition rate = 8 Hz		730		µA	
	3-Axis Accelerometer, 4kHz ODR (no DMP)		450		µA	
	3-axis Magnetometer only (no DMP), 8 Hz repetition rate		280		µA	
Accelerometer Low Power Mode (DMP, Gyroscope, Magnetometer disabled)	0.98 Hz update rate		8.4		µA	1
	31.25 Hz update rate		19.8		µA	1
Full Chip Idle Mode Supply Current			8		µA	
TEMPERATURE RANGE						
Specified Temperature Range	Performance parameters are not applicable beyond Specified Temperature Range	-40		+85	°C	

Table 8: Data table for Inertial Measurement Unit [5]

The IMUs will be working in Normal Mode 9-axis, since all accelerometers, gyroscopes, and magnetometers will be collecting data in order to calculate the quaternion for each orientation. This process will be discussed in more detail in section 5 of the document.

$$Power_{IMU} = V_{DD} * I_{normal\ mode} = 2.5\ V * 3.7\ mA = 9.25\ mW$$

Total power consumption of the ADDS will be

$$P_{total} = 2* P_{IMU} + P_{MC} = 2 * 9.25mW + 0.1056\ W = 0.124\ W$$

Muscle Activation System

Considering the fact that many NMES devices on the market use AA or 9V batteries and no concrete data about the NMES device's power consumption is provided by manufacturers, rough estimations have to be made. Take Cefar Rehab x2 TENS/NMES device, for example. It is powered by two 1.5 V AA batteries and able to provide multiple 30 minute therapy sessions [6]. Since a typical Alkaline AA battery has a capacity of 2000 mAh, two AA alkaline batteries will provide the following energy:

$$Energy\ stored\ in\ two\ AA\ alkaline\ batteries = 2 * 1.5\ V * 2000\ mAh = 6\ W*h$$

Since the Muscle Activation System is triggered only when the user's knee is in a dangerous angle, the power consumption of the Muscle Activation System should be fairly small. Conservatively estimated, 1 W*h is sufficient to power the Muscle Activation System for 6 hours.

4.4.2. Selection of Power Supply

Since the ESP-32 incorporates with a JST connector, a rechargeable lithium-polymer battery would be the best option as the power supply. Depending on future design progress, 3.7V 1000 mAh and 2000 mAh batteries are good options. A 2000 mAh battery provides longer battery life, which allows users to charge the device much less frequently. However, a 1000 mAh battery is only half the size of a 2000 mAh battery, so it would be much easier to fit into the physical knee brace and be less noticeable. Dimensions and electrical data of both batteries will be provided.

Figure 3: 1000mAh Lithium-polymer battery [7]

Cell Dimension(Max, Thickness×Width×Length mm^3) 5.0 x 33.5 x 50.8 mm

*Electrical Energy Stored = 1000 mAh * 3.7 V = 3.7 W*h*

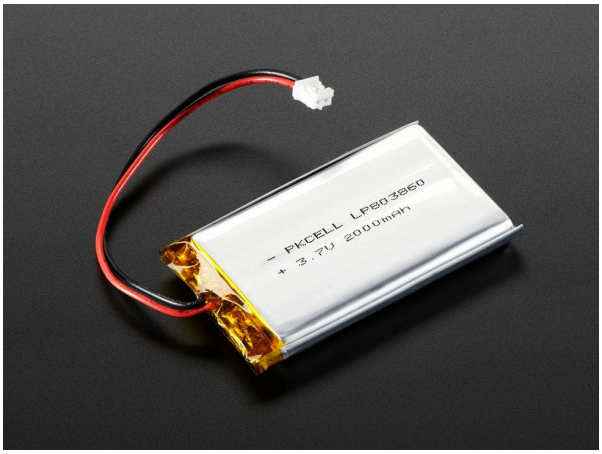

Figure 4: 2000mAh Lithium-polymer battery [8]

Cell Dimension(Max, Thickness×Width×Length mm^3) 5.8×54×60

*Electrical Energy Stored = 2000 mAh * 3.7 V = 7.4 W*h*

The power of the ADDS is approximately 0.124 W, and according to the Requirement 4.4.2 the device should have a battery life of at least 6 hours. So the Power requirement is as follows.

*Energy needed for ADD to operate 6 hours = 0.124W * 6 h = 0.744 W*h*

*Total energy of ADD and MA systems = 1 W*h + 0.744 W*h = 1.744 W*h = 47% of 1000 mAh li-po battery*

As shown, the energy needed to power the TechBrace for 6 hours is less than a half of the 1000 mAh lithium-polymer capacity, so it is substantially capable of providing power for the TechBrace for more than 6 hours.

5 Angle Deviation Detection

5.1 Hardware

[DES 5.1.1-A-PC] The sensor will measure motion/orientation of the femur and tibia.
[DES 5.1.2-A-PC] The sensors will accurately sample at 100Hz to capture walking movements.
[DES 5.1.3-A-PT] The sensors will drift a maximum of 1% per session.
[DES 5.1.4-A-PC] The sensors will remain in the specified location on the leg to maintain accuracy of measurements.
[DES 5.1.5-A-PC] The sensing units will be oriented such that valgus motion is along one of its axes.

The TechBrace will incorporate two Inertial Measurement Units (IMUs) for the purpose of measuring the valgus angle of the knee. These IMUs will be embedded into the knee sleeve and positioned such that one is above and one is below the knee.

The IMU chosen for the POC design is the SparkFun IMU Breakout - MPU-9250 [9], which incorporates an accelerometer, gyroscope, and magnetometer. These will both be connected to the device microcontroller via an I^2C connection. The microcontroller we have chosen for this purpose is the Adafruit Huzzah32 [10], which is based on Espressif's ESP32 IC. The ESP32 platform was chosen for its relatively high processing speed, built-in bluetooth connectivity, ease of development, and low cost.

5.2 Algorithm

[DES 5.2.1-A-PC] The angle of the knee shall be determined from the sensor data.
[DES 5.2.2-A-PC] The angle determined on the left side for valgus motion will increase from the baseline value.
[DES 5.2.3-A-PC] The angle determined on the right side for valgus motion will decrease from the baseline value.

[DES 5.2.4-A-PC] The angle will be determined with respect to the natural q-angle of the user.
[DES 5.2.5-A-PC] A correction event will be initiated when the valgus angle exceeds 5 degree deviation from the baseline.
[DES 5.2.6-A-PC] The sensor will measure valgus angles for controlled movements, like body weight squats.
[DES 5.2.7-A-PR] The sensor will measure valgus angles for combined movements, like walking up stairs.
[DES 5.2.8-B-PR] The sensor will measure knee flexion angle to account for increase in valgus angles with increased flexion.

In order to determine the relative orientation of the upper and lower portions of the leg, the data from the two IMU sensors will be integrated on the microcontroller in real time. This integration process will take place in four steps:

1. **Bias Correction:** First, the motion data from each of the sensors will be corrected for bias and drift, based on an initial calibration of the sensors.
2. **Filtering:** The sensor data will then be subjected to a low-pass filter in order to eliminate signal noise.
3. **Sensor Fusion:** Each IMU contains an accelerometer, gyroscope, and magnetometer. For each IMU, the readings from all of these sensors will be integrated based on the efficient and effective Madgwick algorithm in order to accurately calculate the spatial orientation of both sections of the leg [11].
4. **Relative Orientation Calculation:** The Madgwick algorithm described above uses quaternions to calculate and express the frame of reference of each IMU, as shown in Figure 5 [12]. Reference frame A is described by the $\hat{x}_A, \hat{y}_A, \hat{z}_A$ axes. Reference frame B is a rotation of reference frame A by θ around the vector $\hat{r}$, and is described by $\hat{x}_B, \hat{y}_B, \hat{z}_B$. Note that $\hat{r}$ is in reference frame A.

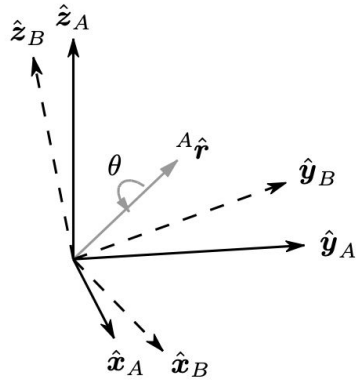

Figure 5: Quaternion reference frames [11]

The quaternion describing this orientation change from frame A to frame B is

$$\hat{\boldsymbol{q}} = [q_1 \;\; q_2 \;\; q_3 \;\; q_4] = [\cos\frac{\theta}{2} \;\; -r_x\sin\frac{\theta}{2} \;\; -r_y\sin\frac{\theta}{2} \;\; -r_z\sin\frac{\theta}{2}]$$

Where r_x, r_y, r_z are components of the vector $\hat{r}$.

Once the corrected quaternion orientations for both the upper and lower portions of the leg are known ($\mathbf{q_1}$ and $\mathbf{q_2}$), the rotation between them can be calculated by $\mathbf{q'} = \mathbf{q_1}^{-1}\mathbf{q_2}$. The rotation **q**' can then be converted to an axis-angle representation to determine the flexion and valgus angles of the knee. Quaternions have a number of convenient mathematical properties that make it easy to calculate and apply angular offsets. When the user first puts on the TechBrace, they will do an initial orientation measurement while they are standing with their leg in a natural, safe angle. This initial measurement can be used to determine the offset from the sensor orientation to the actual orientation of the user's leg. The inverse of this offset will be applied to all future orientation measurements from the IMU in order to determine the actual orientation of the leg.

At different flexion angles, the amount of tolerable valgus angle also changes due to the inherent femoral anteversion associated with hip flexion [13]. It is therefore important to consider the flexion angle of the knee because a critical angle on a straight leg may be different than a critical angle on a bent leg. Additionally, a straight leg maximizes strain on the ACL because of the maximized length in that position [14], so a compromised ACL may have a smaller range of allowable angles in the straight position.

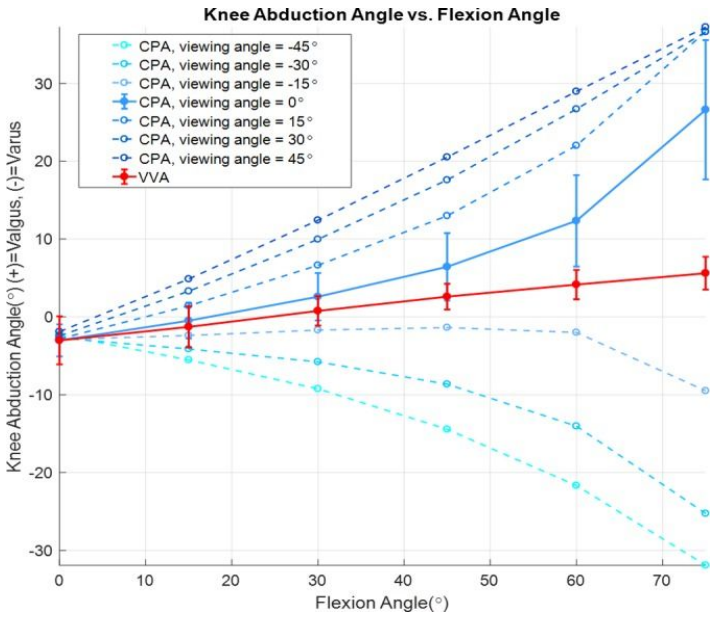

Figure 6: Differing valgus angles with knee flexion angles (solid lines are relevant here) [14]

6 Muscle Activation System

[DES 6.1.1-A-PC] The correction event shall activate the femoral nerve every time there is a critical deviation [15],[16].
[DES 6.1.2-A-PC] The correction event shall generate enough stimulation to specifically activate the quadricep femoris of the wearer and possibly the vastus medialis oblique (VMO) [17],[18].
[DES 6.1.3-A-PC] The correction event shall target the four muscles that conform the quadricep femoris. There is not sufficient literature to activate a single muscle within a muscle group [19].
[DES 6.3.1-A-PT] The correction event shall consist of pulses with a frequency of 30 to 50 Hz [20].
[DES 6.3.2-A-PT] The correction event shall generate pulses of 400 to 600 µs [20] and a 50% duty cycle.
[DES 6.3.3-A-PT] The correction event shall generate a current with amplitude of 60 mA [20],[21].
[DES 6.3.4-A-PT] The correction event shall have a failsafe to stop electrical stimulation and prevent overstimulation (muscle fatigue).
[DES 6.3.5-A-PT] Each pulse of the correction event shall be a biphasic symmetrical square waveform.

6.1 Correction Event

6.1.1 Proof of Concept

For the proof of concept, the muscle activation system will be replaced by a vibration motor in form of a disk, as depicted below:

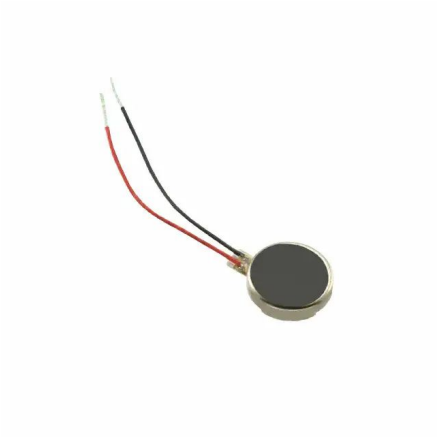

Figure 7: Vibration motor [22]

Weight	0.91g
Thickness	2mm
Diameter	10mm

Table 9: Motor characteristics

This motor will be attached to the user's skin using velcro straps. This system is intended to remind the user to engage his/her muscles to correct the knee position once a critical angle is detected. This system will be replaced with an electrode activation for the prototype stage. The motor will be powered and controlled by a microcontroller in the following way:

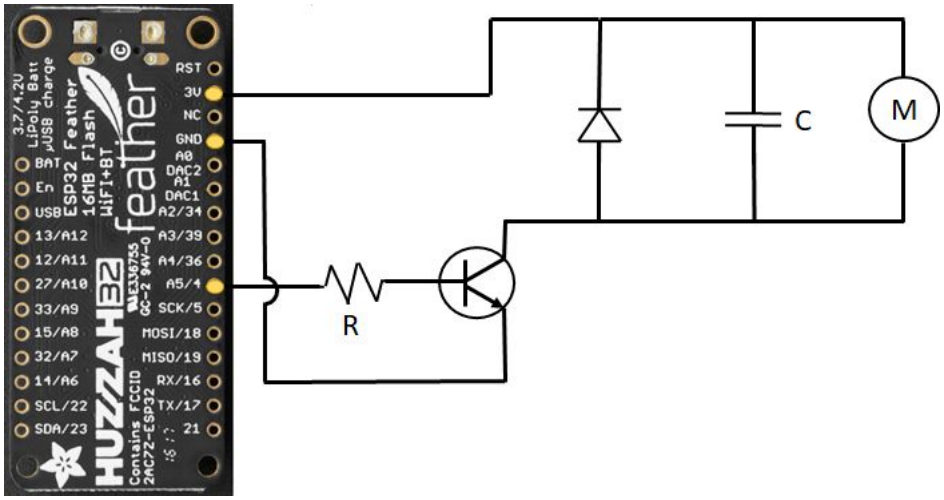

Figure 8: Circuit schematics for vibration motor system [23]

R	1000Ω
C	0.1μF
Voltage range	[3-5]V
Minimum current	75mA

Table 10: Characteristics for the vibration motor circuit

The diode and the capacitor serve to protect the microcontroller from the voltage peaks that the motor may produce. The transistor will provide current amplification since the current output of the microcontroller is low. [23]

The decision to use a vibration motor before building our own NMES machine was due to the fact that we want to concentrate on accurately measuring the sagittal angle of the knee before tackling the NMES implementation.

Furthermore, to meet requirements **[DES 6.1.2-A-PC]** and **[DES 6.1.3-A-PC]** we will do preliminary tests using a TENS/EMS machine (model PM-720). These preliminary tests will consists of putting the knee at a critical angle and then engaging different muscles with the TENS/EMS machine using the pulses specified in the requirements document. This is to determine which muscle group is the most relevant to bring the knee back to a safe angle.

Figure 9: TENS/EMS machine for proof of concept [24]

6.1.2 Prototype and Production Ready

For the prototype, we will build our own NMES machine. The User Interface and control refers to the app defined in section 7.

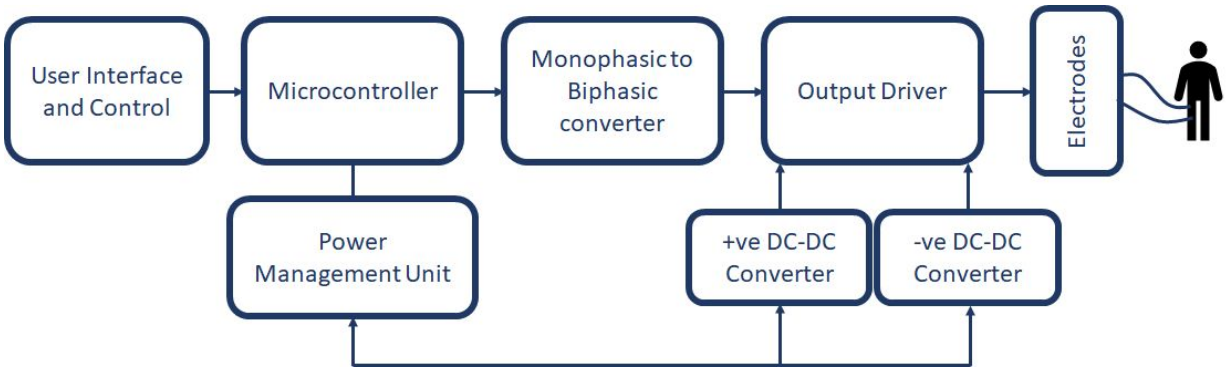

Figure 10: EMS flowchart [25]

We will assume the body resistance is 2kΩ and, as per **[DES 6.3.3-A-PT]**, the output current will be set to an amplitude of ±60mA, by adjusting a potentiometer in a feedback loop of one of the op-amps of the output driver. Using these parameters we can calculate (V = IR) that we will need a voltage of ±120V. To achieve this voltage level we will use two **LTC3787** DC-DC converters. These converters require an input voltage of at least 2.5V and can generate an output voltage up to 60V. The input signal will be generated by the Power Management Unit (PMU) [25].

To generate the biphasic current as described in the requirements above, the microcontroller will generate two independent monophasic square pulses with an amplitude of 3V. These two pulses are then fed into the monophasic to biphasic converter, which consists of a differential amp and a buffer. The output of the buffer will be a biphasic pulse, as shown below. The user will specify the frequency and duration of the pulses in the app. We modeled the first part of the monophasic to biphasic converter as shown below. [25]

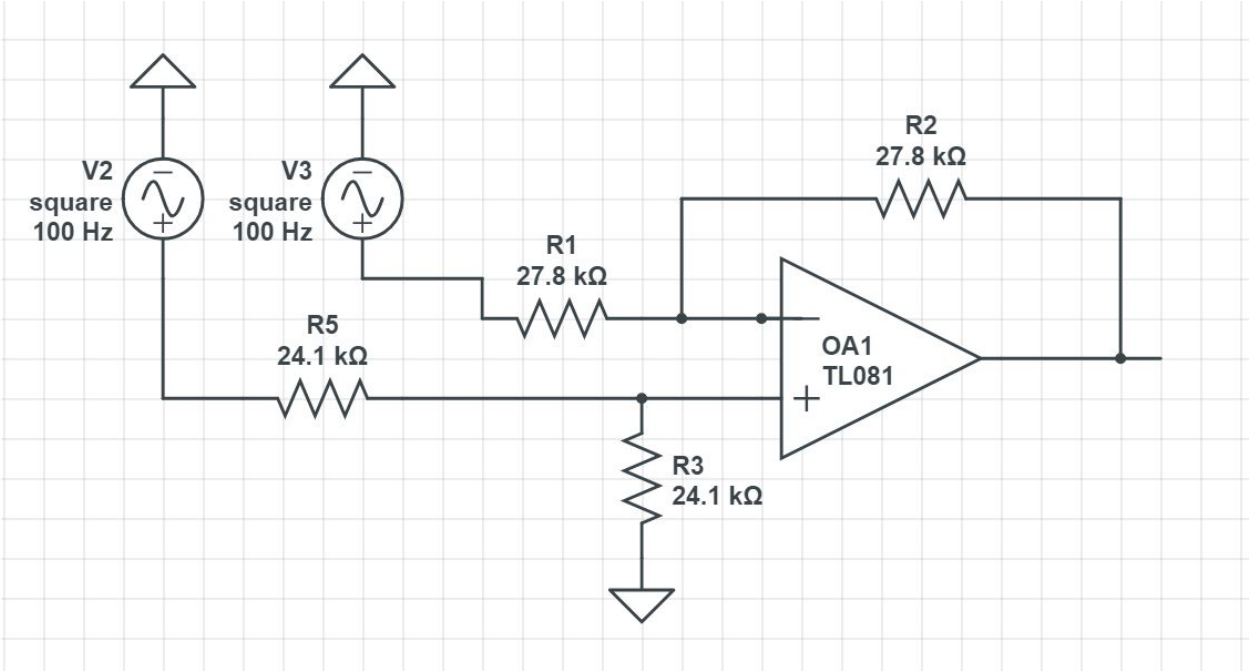

Figure 11: Monophasic to biphasic converter [25]

The voltage sources V2 and V3 were made to simulate the output of the microcontroller. The resistor values are example values at the moment. The simulated current was measured and plotted in the graph below. The differential op-amp illustrated above will be followed by a buffer to do impedance matching [25].

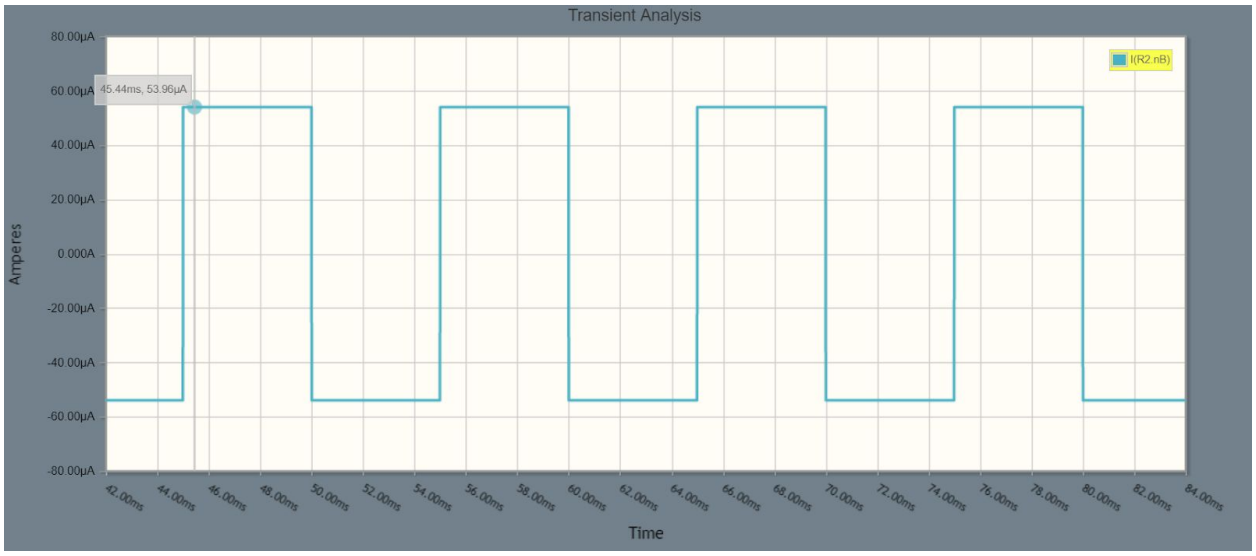

Figure 12: Monophasic to Biphasic converter output

The output current from the monophasic to biphasic converter will be fed into the output driver, which consists of an inverting amplifier and a high voltage op-amp (**PA341DF**). The inverting op-amp will have a potentiometer in the negative feedback that will allow us to set the intensity of the pulse to 60mA as described in **[DES 6.3.3-A-PT]**. The high voltage op-amp **PA341DF** will have a saturation voltage of ±120V supplied from the DC-DC converter units. The amplified signal will then be fed to the electrodes and into the body of the user. In order to ensure our safety while testing this circuit, we will include a current limiting resistor at the output of the high voltage op-amp [25].

6.2 Electrodes

[DES 6.2.1-B-PT] The electrodes shall be of type Ag-AgCl or other.
[DES 6.2.2-A-PT] The electrode size shall be big enough the electrical stimulation will not be painful to the user [26].
[DES 6.2.3-C-PT] There shall be two rectangular electrodes. This refers to **[DES 6.2.3-C-PT]** The requirement has been changed to allow for higher current levels to be passed to the patient within their pain tolerance [27].
[DES 6.2.4-C-PT] The two electrodes shall have a size of 6 x 9 cm.
[DES 6.2.5-B-PC] The electrodes shall be placed in the vastus configuration. Where the electrodes are placed over the proximal vastus lateralis and the distal vastus medialis [26].
[DES 6.2.6-A-PC] The cathode electrodes shall be positioned distally and the anode electrode shall be positioned proximally [28].

[DES 6.2.7-B-PT] The electrodes shall easily connect to and disconnect from the electronics on the brace.
[DES 6.2.8-C-PR] The electrode connector shall be rated for at least 2000 uses.
[DES 6.2.9-A-PT] The electrodes shall attach to the user's leg with a reusable adhesive, and shall be re-attachable at least 12 times.

To implement these requirements, we will use carbon electrodes pads, illustrated below. The pads are made of non-woven fabric (no plastic), they are re-usable and self-adhesive. The pads are designed to have uniform current distribution to decrease pain. They also have holes that allow for heat release to decrease discomfort. They have pigtail 2mm Pin Type Connectors.

Figure 13: Electrode pads [29]

The electrodes above will be modeled using the following circuit. The values of the impedances will be determined empirically by varying the input frequency and measuring the impedance through the electrode:

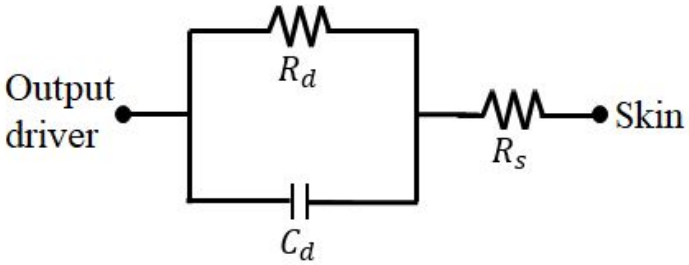

Figure 14: Electrode Model

7 Mobile App

FlexTech's TechBrace prevents users' knees from entering injurious positions that can damage the ACL and slow recovery from ACL injury. For proof of concept and prototype the Mobile App will be highly focused on functionality over form, since only the FlexTech development team will be using the app for testing and development purposes. However the Mobile App UI and design is very important for the production ready state when users will be relying on the app daily. For this reason the Mobile App design specification is separated by proof of concept, prototype, and production ready design.

7.1 Purpose

The Mobile App serves the purpose of providing nearly all user interaction with the brace, and is a friendly, intuitive way for users to interface in a familiar manner with the TechBrace.

We are aiming to minimize user interaction and setup with the device, allowing the TechBrace to provide maximum help with minimum maintenance and mental thought on part of the user. However some interaction is required, and the Mobile App aims to make this interaction as simple as possible.
The Mobile App is responsible for:

- **One-time setup of the brace**. This will generally be performed with the prescribing therapist. The setup process includes selecting the leg on which the brace is worn and calibrating the current intensity, pulse frequency, and pulse duration to properly stimulate the leg.
- **Daily calibration**. Recalibrating the angle detection sensors is anticipated to be required. The Mobile App will direct the user on how to perform calibrative actions and signal the TechBrace to perform calibration.
- **Help Documentation**. The app will contain a documentation on how to calibrate the TechBrace and troubleshoot issues.
- **Corrective Event History**. The Mobile App will display a history of corrective events as reported by the brace with the intention of showing improvement over time.

7.2 System Overview

The Mobile App will communicate with the TechBrace using Bluetooth Low Energy (BLE) implemented with the Android BLE API.

> *"In contrast to Classic Bluetooth, Bluetooth Low Energy (BLE) is designed to provide significantly lower power consumption. This allows Android apps to communicate with BLE devices that have stricter power requirements, such as proximity sensors, heart rate monitors, and fitness devices."* [30]

Figure 14 summarizes all bluetooth communication between the Mobile App and the TechBrace.

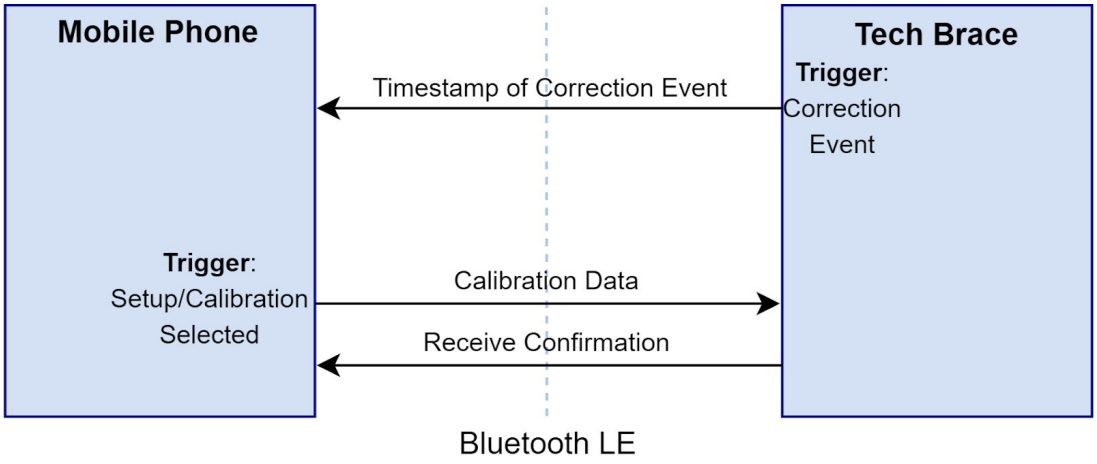

Figure 15 : Mobile Data Transfer

7.3 Development Environment

All mobile app development will be performed using Android Studio in Java, tested with JUnit Tests, and manual testing will be done on a Samsung Galaxy A5 2017. Version control and documentation will be done using GitLab. The Mobile App will be developed with backwards compatibility in mind, supporting both previous and current Android systems.

7.4 Mobile App Data Security

All data is stored on the mobile device, eliminating any risk of internet database attacks. BLE communication has built in security measures. After the pairing process is

complete, all data is encoded end-to-end, preventing snooping. The only opportunity for a man-in-the-middle attack is during the pairing procedure, and BLE devices are required to be within 30 feet of each other to pair, further reducing opportunity [31]. Additionally, FlexTech will not be storing identifying personal information in the app, only corrective event history and information pertaining directly to the brace.

7.5 Proof of Concept

In the Proof of Concept phase, the Mobile App will focus purely on functionality, namely bluetooth connectivity and data transfer, as well as a simple UI for setup and calibration. All testing will require a calibration system, and developing the app to fill this need will speed up development. Figure 15 shows the final UI layout of the Mobile App to be implemented by the Production Ready stage.

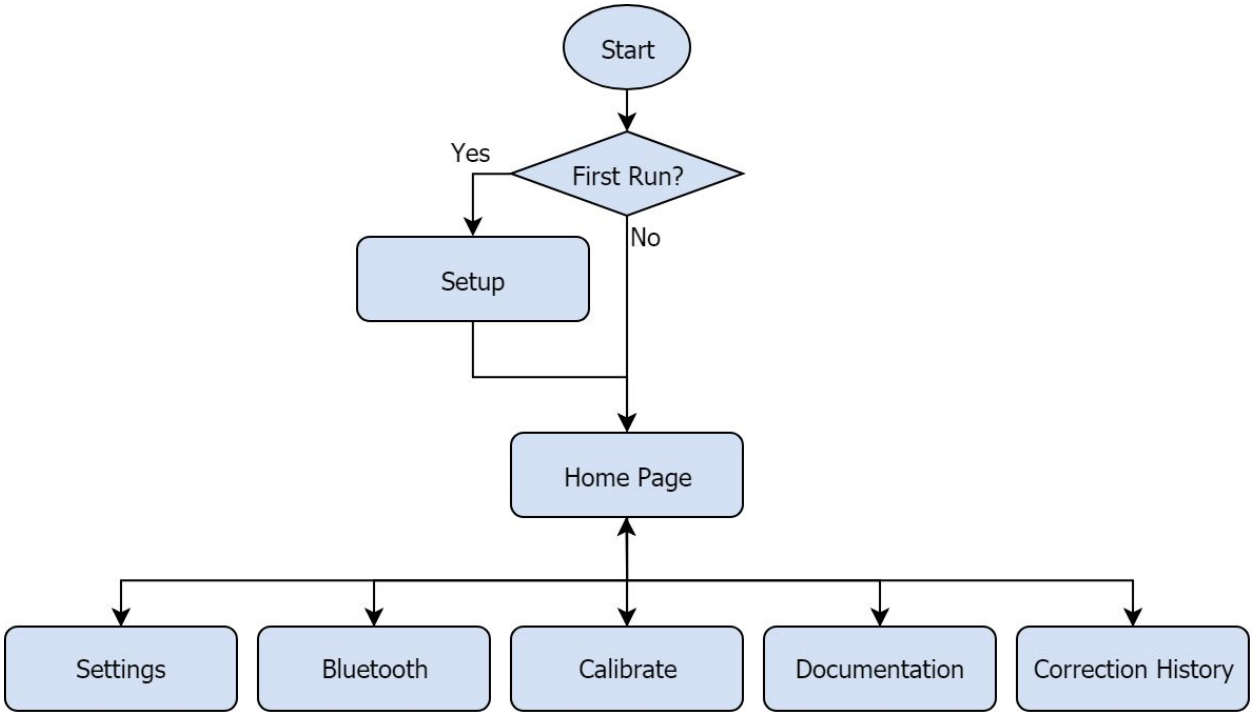

Figure 16 : Mobile App UI Layout

For Proof of Concept, the **Home Page**, **Calibrate**, and **Bluetooth** sections will be implemented and tested working. The bluetooth linking technology is the main aspect of this stage.

Home Page
[DES 7.1.1-B-PC] The app home page shall display the FlexTech logo.
[DES 7.1.2-A-PC] The app home page shall display the settings icon to go to settings.

[DES 7.1.3-A-PC] The app home page shall display the calibration icon to go to the calibration section.
[DES 7.1.4-B-PC] The app home page shall display the documentation icon to go to the documentation section.
[DES 7.1.5-A-PC] The app home page shall display the tracking icon to view tracking of correction events.
[DES 7.1.6-B-PC] The app home page shall display the linking icon to give instructions to link phone to brace.
[DES 7.1.7-C-PC] The app home page shall display the brace battery life.

Calibration
[DES 7.2.2-B-PC] The app calibration section shall provide detailed instructions on how to properly put on the brace and calibrate it.
[DES 7.2.3-A-PC] The app shall communicate with the brace to begin taking calibration measurements.

Bluetooth Linking
[DES 7.6.1-C-PC] The app shall communicate with the brace via bluetooth.
[DES 7.4.1-C-PC] The app bluetooth linking section shall guide the user to link via bluetooth, including information leading them to the button on the brace.
[DES 7.4.2-C-PC] The app bluetooth linking section shall display a success message when the phone is linked to the brace.
[DES 7.6.4-C-PC] The brace shall notify the app of correction events within 1 second.

7.6 Prototype

In the Prototype stage further UI considerations will be made, expanding to include **Correction History** and **Setup** from Figure 15. The primary development here is the bluetooth transfer of data.

Correction History
[DES 7.5.1-C-PT] The app view tracking section shall display a graph showing the current session’s correction event tracking.
[DES 7.5.2-C-PT] The app view tracking section shall congratulate the user if there are no recent corrective events.
[DES 7.5.3-C-PT] The app view tracking section shall allow for pinching to see different granularities of time: week, month, and all time.

Setup

[DES 7.7.1-A-PT] The app setup section shall ask the user on which leg the brace is for their first calibration and tell the user to go to the settings to switch legs.
[DES 7.7.2-A-PT] The app setup section shall appear when the user opens the mobile app for the first time
[DES 7.7.3-A-PT] The app setup section shall calibrate the current intensity, pulse frequency and pulse duration to properly stimulate the leg, allowing the user to trigger the stimulation from the app for testing purposes.

7.7 Production Ready

In the Production Ready stage, **Settings** and **Documentation** will be added from Figure 15 in addition to significant UI design to improve user experience. This will include animations, colouring, button size and layout, and user feedback elements throughout the mobile app.

Documentation
[DES 7.3.1-A-PR] The app documentation section shall have an interactive table of contents at the top with pressable text to jump to sections of the documentation.
[DES 7.3.2-A-PR] The app documentation section shall be searchable.

Settings
[DES 7.8.1-C-PR] The app settings section shall store on which leg the brace is being used and allow for the user to toggle it.
[DES 7.8.2-C-PR] The app settings section shall allow the user to perform the setup procedure again to recalibrate the electrical stimulation.

8 Sustainability and Safety

Sustainability

FlexTech follows a cradle to cradle sustainability philosophy. Cradle to cradle treats products as part of the environment and analyzes the entire life cycle and environmental impact of products from resource collection through to disposal.

Figure 17: Product Life Cycle [32]

The key to developing the TechBrace as a sustainable product lies in minimizing waste from use, maintenance, and disposal. Figure 4 lists and numbers the stages of a product life cycle. We will promote sustainable development by allowing our design process to be guided by a few simple design principles, categorized below.

Stages 1-3: Production

As a complex engineering project, the TechBrace has a large variety of products from all over the world, including neoprene, computer chips, hardware electronics, adhesives, and others. To reduce energy and material waste during production of the TechBrace, we will choose materials and components that are ethically sourced and minimize environmental waste.

Stage 5: Use

To reduce energy waste during use, we will design our knee brace with minimal electrical draw and require as few discardable components as possible. For example, we will select electrode pads that require infrequent replacement and maximize reusability during a user's time with the brace.

Stage 6: Maintenance

To reduce material waste during maintenance, we will design our brace with a modular design, allowing for individual components to be replaced without needing to replace large parts of the brace. For example, if the bluetooth communication component becomes faulty over time, the brace will be designed to allow replacement of that individual part without replacing unrelated electronics. Additionally, in an effort to reduce material waste during maintenance we will design the brace with components that don't require frequent replacement. The anticipated largest cause of material waste during maintenance will be replacing battery modules at the end of their anticipated life span. To mitigate battery waste we will opt for batteries that have long lifespans and recycle them after replacement.

Stage 7+: Disposal

The most important stage of the product life cycle is disposal, and at FlexTech, our brace has high potential for reusability and recyclability. After a wearer completes their six to eight week period wearing the brace, the brace is returned to the physiotherapist, who then washes the knee sleeve and electrode pads and cleans the brace, which can then be reused for the next wearer. This high reuse cycle keeps electronics from

entering landfills, which can be environmentally damaging, and is economically responsible.

Safety

As a medical device, safety is of highest priority and FlexTech will pursue safety in all stages of development and release of the TechBrace. The first step of device safety is complying with all relevant engineering safety standards, which are listed and described. The overall goal of the electric components will be to avoid pain and burns from the electrodes, while maintaining a level of comfort for prolonged use.
We will also clearly state all possible allergy and sensitivity concerns regarding adhesives and textiles.

Additionally, for proof of concept and prototype stages, we will rely on an existing electrical muscle activation system that already complies with the relevant engineering standards and is safe for market. By doing so we mitigate health risks during development and testing, which allows for easier testing. Before going to market we will seek proper certification of safety from the relevant governing bodies for electrically stimulating muscle devices.

9 Glossary

Accelerometer: sensor that measures accelerations.
Anterior Cruciate Ligament (ACL): the ligament in the knee that limits forward translation of the tibia in relation to the femur. Also provides rotational stability [34].
Axis-angle representation: parameterization of 3D rotation to a direction and an angle.
Biphasic: a pulse with two phases.
BLE: Bluetooth Low Energy. Communication protocol to transmit data wirelessly with low power consumption.
Correction Event: the incident of stimulation delivered to the muscle to correct the knee position. May be in the form of vibration (proof of concept) or electrical impulse.

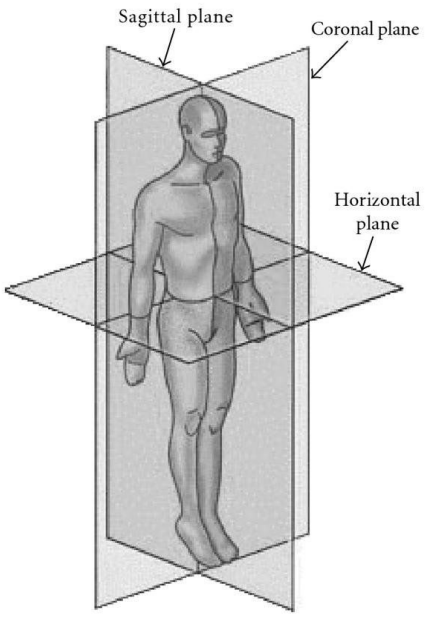

Figure 18: Planes of the body [33]

Coronal plane: the plane dividing a body into front and back portions. See figure 5.
Critical angle: the angle in the coronal plane that constitutes a critical deviation.
Critical Deviation: the incidence of exceeding valgus angles that are safe for the knee.
Distal: the situation of a muscle, bone, or limb that is farther from the center of the body or point of origin.
Doffing: taking the device off.
Donning: putting the device on.
Femoral Anteversion: inward twisting of the femur [35].
Femoral nerve: "the main nerve of the anterior compartment of thigh" [16]. It innervates the quadriceps.
Femur: the thigh bone.
Flexion: Movement of a joint in the sagittal plane that decreases the joint angle [36].
Gyroscope: sensor that measures angular velocity.
Hinge type: A type of joint that facilitates movement in one axis [37].
Inertial Measurement Unit (IMU): a device that uses accelerometers, gyroscopes, and magnetometers to measure motion and orientation.
Magnetometer: sensor that measures magnetic fields and can be used to sense rotation relative to the earth's magnetic field.
Medial: the side of the knee that is closer to the midline of the body.
Mobile App: Refers to the android mobile app developed by FlexTech to accompany the TechBrace.
Monophasic: a pulse with only one phase.
Proximal: the situation of a muscle, bone, or limb that is closer to the center of the body or point of origin.
Q-angle: the angle formed between the long axis of the femur and the vertical [38].
Quaternion: "A quaternion is a four-dimensional complex number that can be used to represent the orientation of a ridged body or coordinate frame in three-dimensional space." [12]
Quadriceps femoris: muscle bundle in the thigh that controls extension of the knee. Referred to as "quads" or "quadriceps".
Rectus Femoris: the muscle in the quadriceps femoris muscle group.
Saggital plane: the plane dividing a body into right and left portions. See figure 5.
Tibia: the shin bone.
User: the person using the FlexTech TechBrace.
Valgus angle: the angle formed between the femur and tibia in the saggital plane. Specifically refers to movement inward to the centre of the body.
Vastus configuration: a setup of electrodes where one is on the vastus lateralis and one is on the vastus medialis.

Vastus lateralis: a muscle in the quadricep femoris muscle group on the outside of the leg.
Vastus medialis (VMO): a muscle in the quadricep femoris muscle group on the inside of the leg.

10 Conclusion

With the heart and ambition of helping ACL injury patients recover faster and more safely, FlexTech is eager to develop the revolutionary TechBrace. It will incorporate the basic functions of an ordinary knee brace (protection and support), while automatically correcting dangerous valgus knee positions. The TechBrace users will be able to spend less time in rehabilitation and more time enjoying life, without consciously worrying about healthy motion of the knee joint.

This document is a functional and architectural reference for the FlexTech TechBrace. The design specifications discussed in this document specify the boundaries and guidelines for the TechBrace system.

A brief summary of the each system is provided below:

1. **Hardware System**
    - Outlines selection of knee brace and power supply and corresponding calculations and justifications.
    - Describes operational temperature and functions of the status LED incorporated on the TechBrace.

2. **Angle Deviation Detection System**
    - Outlines how hardware components and software algorithm cooperate with each other to determine user's valgus knee angle.

3. **Muscle Activation System**
    - Describes muscle activation method at different stages of the product development and corresponding technical backgrounds.

4. **Mobile App**

- Describes functions of the mobile app and different stage of the the app development.

This document will serve as a reliable reference for each phase of the project design and production to ensure the function and safety of the product.

11 References

[1] "Live Well," Unity Point Health, [Online]. Available: https://www.unitypoint.org/livewell/article.aspx?id=591d8cf1-1ee5-4cb3-b662-a5f21f6f13bc. [Accessed 10 March 2019].

[2] "Exercises After ACL Injury," CHOCChildren's, [Online]. Available: https://www.choc.org/orthopaedics/surgery/knee-ligament-repair-reconstruction/exercises-after-acl-surgery/. [Accessed 10 March 2019].

[3] "Global Sources," Big United Co. Ltd, [Online]. Available: https://bigunit.manufacturer.globalsources.com/si/6007000430962/pdtl/Sports-knee/10145287022/Knee-stabilizer.htm. [Accessed 14 February 2019].

[4] Espressif.com. (2019). [online] Available at: https://www.espressif.com/sites/default/files/documentation/esp32_datasheet_en.pdf [Accessed 13 Mar. 2019].

[5] Cdn.sparkfun.com. (2019) [online] Available at: https://cdn.sparkfun.com/assets/learn_tutorials/5/5/0/MPU9250REV1.0.pdf [Accessed 13 Mar. 2019]

[6] "FysioSupplies," [Online]. Available: https://www.zorgpunt.eu/media/productfileupload/Cefar_RehabX2.pdf. [Accessed 14 March 2019].

[7] robot-r-us.com. (2019). Polymer Lithium Ion Battery - 3.7V 1000mAh | Battery & Charger | Robot R Us. [online] Available at: https://www.robot-r-us.com/vmchk/battery-charger/polymer-lithium-ion-battery-1000mah.html [Accessed 13 Mar. 2019].

[8] Adafruit Industries (2019). Lithium Ion Battery - 3.7v 2000mAh [online] Adafruit.com. Available at: https://www.adafruit.com/product/2011 [Accessed 14 Mar. 2019]

[9] "SparkFun IMU Breakout - MPU-9250," SparkFun, [Online]. Available: https://www.sparkfun.com/products/13762. [Accessed 15 February 2019].

[10] "Adafruit HUZZAH32 – ESP32 Feather Board," Adafruit, [Online]. Available: https://www.adafruit.com/product/3405. [Accessed 19 February 2019].

[11] S. O. Madgwick, "An efficient orientation filter for inertial and inertial/magnetic sensor arrays," 2010.

[12] "Quaternions and spatial rotation," Wikipedia, 1 March 2019. [Online]. Available: https://en.wikipedia.org/wiki/Quaternions_and_spatial_rotation. [Accessed 5 March 2019].

[13] M. Kaneko and K. Sakuraba, "Association between Femoral Anteversion and Lower Extremity Posture upon Single-leg Landing: Implications for Anterior Cruciate Ligament Injury," Journal of Physical Therapy Science, vol. 25, no. 10, pp. 1213-1217, 2013.

[14] Z. A. Englander, H. C. Cutcliffe, G. M. Utturkar, W. E. Garrett, C. E. Spritzer and L. E. DeFrate, "A Comparison of Knee Abduction Angles Measured by a 3D Anatomic Coordinate System Versus Videographic Analysis: Implications for Anterior Cruciate Ligament Injury," Orthopaedic Journal of Sports Medicine, vol. 7, no. 1, 2019.

[15] L. Sheffler and J. Chae, "Neuromuscular electrical stimulation in neurorehabilitation", Muscle & Nerve, vol. 35, no. 5, pp. 562-590, 2007. Available: 10.1002/mus.20758.

[16]"Femoral Nerve", Physiopedia, 2019. [Online]. Available: https://www.physio-pedia.com/index.php?title=Femoral_Nerve&oldid=192418. [Accessed: 01- Feb- 2019].

[17] E. Simonsen et al., "Can the hamstring muscles protect the anterior cruciate ligament during a side-cutting maneuver?", Scandinavian Journal of Medicine and Science in Sports, vol. 10, no. 2, pp. 78-84, 2000. Available: 10.1034/j.1600-0838.2000.010002078.x.

[18] J. Kvist and J. Gillquist, "Sagittal Plane Knee Translation and Electromyographic Activity during Closed and Open Kinetic Chain Exercises in Anterior Cruciate Ligament-Deficient Patients and Control Subjects", The American Journal of Sports Medicine, vol. 29, no. 1, pp. 72-82, 2001. Available: 10.1177/03635465010290011701 [Accessed 1 February 2019].

[19] David A. Lake. “Neuromuscular Electrical Stimulation”, Sports Medicine, vol. 13, no. 5, pp. 320-336, 1992. Available: 10.2165/00007256-199213050-00003 [Accessed 1 February 2019]

[20] Neal R. Glaviano, “Can the Use of Neuromuscular Electrical Stimulation Be Improved to Optimize Quadriceps Strengthening?”, Sports Health: A Multidisciplinary Approach, vol. 8, no. 1, pp 79-85, 2016. Available: 10.1177/1941738115618174

[21] N. Maffiuletti, Gometti, Amiridis, Martin, Pousson and Chatard, "The Effects of Electromyostimulation Training and Basketball Practice on Muscle Strength and Jumping Ability", International Journal of Sports Medicine, vol. 21, no. 6, pp. 437-443, 2000. Available: 10.1055/s-2000-3837.

[22] Adafruit LLC (2019). 1201 Adafruit Industries LLC | Motors, Solenoids, Driver Boards/Modules | DigiKey [online] Available at: https://www.digikey.ca/product-detail/en/adafruit-industries-llc/1201/1528-1177-ND/5353637?utm_adgroup=&mkwid=sbzvjFHoN&pcrid=310970532936&pkw=&pmt=&pdv=c&productid=5353637&slid=&gclid=CjwKCAjw96fkBRA2EiwAKZjFTWfagD95MSBfYW90zpzbpJQC2m0UvDeYNTiv2XvjMIcGrtn8VCNDphoC3acQAvD_BwE [Accessed 14 Mar. 2019]

[23] Learningaboutelectronics.com. (2019). How to Build a Vibration Motor Circuit. [online] Available at: http://www.learningaboutelectronics.com/Articles/Vibration-motor-circuit.php [Accessed 10 Mar. 2019].

[24] italitymedical.com. (2019). ProMed Specialties PM-720 TENS/EMS Combination Unit PM720 | Vitality Medical. [online] Available at: https://www.vitalitymedical.com/promed-specialties-pm-720-tens-ems-combination-unit.html [Accessed 12 Mar. 2019].

[25] Shendkar, C., Kumar, R., Mahadevappa, M., Biswas, A. and Lenka, P. (2015). Design and development of a low-cost biphasic charge-balanced functional electric stimulator and its clinical validation. Healthcare Technology Letters, 2(5), pp.129-134.

[26] Jennifer E. Stevens-Lapsley, Jaclyn E. Balter, Pamela Wolfe, Donald G. Eckhoff, Robert S. Schwartz, Margaret Schenkman, Wendy M. Kohrt; “Relationship Between Intensity of Quadriceps Muscle Neuromuscular Electrical Stimulation and Strength Recovery After Total Knee Arthroplasty”, Physical Therapy, Volume 92, Issue 9, 1 September 2012, Pages 1187–1196, https://doi.org/10.2522/ptj.20110479

[27] Quad, 5. (2019). 5 Common Mistakes for Neuromuscular Electrical Stimulation to the Quad. [online] Themanualtherapist.com. Available at: https://www.themanualtherapist.com/2016/05/5-common-mistakes-for-neuromuscular.html [Accessed 13 Mar. 2019].

[28]B. Pietrosimone, N. Selkow, C. Ingersoll, J. Hart and S. Saliba, "Electrode Type and Placement Configuration for Quadriceps Activation Evaluation", Journal of Athletic Training, vol. 46, no. 6, pp. 621-628, 2011. Available: 10.4085/1062-6050-46.6.621.

[29] Amazon.ca. (2019). [online] Available at: https://www.amazon.ca/Cleared-Quality-Premium-Non-woven-Electrode/dp/B0793R5QH8/ref=asc_df_B0793R5QH8/?tag=googleshopc0c-20&linkCode=df0&hvadid=292913989560&hvpos=1o1&hvnetw=g&hvrand=8108624605132323783&hvpone=&hvptwo=&hvqmt=&hvdev=c&hvdvcmdl=&hvlocint=&hvlocphy=9060184&hvtargid=pla-624255262467&psc=1 [Accessed 16 Mar. 2019].

[30] Android Developers (2019). Bluetooth low energy overview | Android Developers. [online] Available at: https://developer.android.com/guide/topics/connectivity/bluetooth-le

[31] Work?, H. and Parker, R. (2019). How Does Bluetooth Low Energy Pairing Work? - Hashnode. [online] Hashnode.com. Available at: https://hashnode.com/post/how-does-bluetooth-low-energy-pairing-work-cjaw6h6g502oe6ywu0brbn8o9 [Accessed 14 Mar. 2019].

[32] "Southwest Environmental Limited," [Online]. Available: http://www.southwest-environmental.co.uk/further%20info/life_cycle_assessment/life_cycle_assessment_consultants.html. [Accessed 4 February 2019].

[33] S. Dilip and e. al., "A Dynamic Bayesian Approach to Computational Laban Shape Quality Analysis," Research Gate, vol. 2009, pp. 1-17, 2009

[34]"OrthoInfo," [Online]. Available: https://orthoinfo.aaos.org/en/diseases--conditions/anterior-cruciate-ligament-acl-injuries/. [Accessed 6 February 2019].

[35] "Femoral Anteversion," [Online]. Available: https://www.stanfordchildrens.org/en/topic/default?id=femoral-anteversion-90-P02759. [Accessed 11 March 2019].

[36] O. Jones, "Anatomical Terms of Measurement," Teach Me Anatomy, 22 February 2019. [Online]. Available: https://teachmeanatomy.info/the-basics/anatomical-terminology/terms-of-movement/#Flexion_and_Extension. [Accessed 11 March 2019].

[37] "Inner Body," [Online]. Available: https://www.innerbody.com/image_skel07/skel31.html. [Accessed 4 February 2019].

[38] "'Q' Angle," [Online]. Available: https://www.physio-pedia.com/%27Q%27_Angle. [Accessed 13 March 2019].

[39] D. Norman, The Design Of Everyday Things, 2013.

[40] IEC, "IEC 60601-1-11" 2015. [Online]. Available: https://www.iso.org/standard/65529.html [Accessed 06 February 2019].

[41] IEC, "IEC 82304-1" 2016. [Online]. Available: https://www.iso.org/standard/59543.html [Accessed 06 February 2019].

[42] CSA Groups, "CAN/CSA – C22.2 NO. 60601-1-11:15" 2015. [Online]. Available: https://store.csagroup.org/ccrz__ProductDetails?viewState=DetailView&cartID=&sku=2703298 [Accessed 06 February 2019].

[43] IEC, "IEC 62366-2" 2016. [Online]. Available: https://www.iso.org/standard/69126.html [Accessed 06 February 2019].

[44] Standards.ieee.org. (2019). P360 - Standard for Wearable Consumer Electronic Devices - Overview and Architecture. [online] Available at: https://standards.ieee.org/project/360.html [Accessed 14 Mar. 2019].

[45] IEC, "IEC 62304" 2006. [Online]. Available: https://www.iso.org/standard/38421.html [Accessed 06 February 2019].

[46] IEC, "IEC/TR 800001-2-3" 2012. [Online]. Available: https://www.iso.org/standard/57941.html [Accessed 06 February 2019].

[47] IEEE, "IEEE 1625" 2008. [Online]. Available: https://standards.ieee.org/standard/1625-2008.html [Accessed 06 February 2019].

[48] IEEE, "IEEE 802.11" 2016. [Online]. Available: http://www.ieee802.org/11/ [Accessed 06 February 2019].

[49] IEEE, "IEEE 802.15.1" 2016. [Online]. Available: http://www.ieee802.org/15/pub/TG1.html [Accessed 06 February 2019].

Appendix 1 - Acceptance Test Plan

The test plan below specifies how the requirements specified for the Proof of Concept phase will be tested.

[DES 3.1.1-A-PC] The brace shall trigger a correction event every time a critical deviation occurs.

Test Case	Generate critical deviation on a test device	
Expected Outcome	Hardware triggers a correction event via software	
Actual Outcome		
Comments		
Marking Instructor Initials:	PASS	FAIL

[DES 4.1.1-A-PC] The brace shall incorporate a soft knee sleeve which wraps the knee.
[DES 4.1.2-A-PC] The knee sleeve shall not physically restrict normal motion of the knee.

Test Case	Wear a knee brace and perform walking and sitting motions for two minutes, moving the knee in all positions	
Expected Outcome	The wearer can move their knee in all positions they could without the knee brace without any pain or discomfort	
Actual Outcome		
Comments		
Marking Instructor Initials:	PASS	FAIL

[DES 5.1.1-A-PC] The sensor will measure motion/orientation of the femur and tibia

Test Case	Wear a knee brace with sensors attached and move knee in various motions

Expected Outcome	Angle measurement and calculation shall accurately reflect real position and angle of knee when measured using a goniometer	
Actual Outcome		
Comments		
Marking Instructor Initials:	PASS	FAIL

[DES 5.2.1-A-PC] The angle of the knee shall be determined from the sensor data.
[DES 5.2.2-A-PC] The angle determined on the left side for valgus motion will increase from the baseline value.
[DES 5.2.3-A-PC] The angle determined on the right side for valgus motion will decrease from the baseline value.
[DES 5.2.4-A-PC] The angle will be determined with respect to the natural q-angle of the user.
[DES 5.2.5-A-PC] A correction event will be initiated when the valgus angle exceeds 5 degree deviation from the baseline.

Test Case	Wear a knee brace with sensors attached and move the knee in side to side motions	
Expected Outcome	A computer feed with the valgus angle shown. A positive angle is shown when the knee is moved to the left and negative when the knee is moved to the right. An angle greater than 5 degrees is flagged as dangerous.	
Actual Outcome		
Comments		
Marking Instructor Initials:	PASS	FAIL

[DES 5.2.6-A-PC] The sensor will measure valgus angles for controlled movements, like body weight squats.

Test Case	Wear a knee brace with sensors attached and perform squats

Expected Outcome	A computer feed with the valgus angle shown. The calculated valgus angle will accurately correspond to the wearer's valgus angle throughout the squat motion.	
Actual Outcome		
Comments		
Marking Instructor Initials:	PASS	FAIL

[DES 6.1.2-A-PC] The correction event shall generate enough stimulation to activate the quadricep femoris of the wearer and possibly VMO [17,18].
[DES 6.1.3-A-PC] The correction event will target the four muscles that conform the quadricep femoris. There is not sufficient literature to activate a single muscle within a muscle group [19].
[DES 6.2.5-B-PC] The electrodes shall be placed in the vastus configuration. Where the electrodes are placed over the proximal vastus lateralis and the distal vastus medialis [26].
[DES 6.2.6-A-PC] The cathode electrodes shall be positioned distally and the anode electrode shall be positioned proximally [26].

Test Case	Use an NMES machine to trigger electrodes that will be positioned as per described in the requirements above. The results will be measured by using an EMG or a pressure muscle activation sensor.	
Expected Outcome	The sensors shall demonstrate that the quadricep muscle contracted.	
Actual Outcome		
Comments		
Marking Instructor Initials:	PASS	FAIL

[DES 6.3.1-A-PT] The correction event shall consist of pulses with a frequency of 30 to 50 Hz [20].
[DES 6.3.2-A-PT] The correction event shall generate pulses of 400 to 600 μs [20] and a 50% duty cycle.

[DES 6.3.3-A-PT] The correction event shall generate a current with amplitude of 60 mA [20],[21].
[DES 6.3.5-A-PT] Each pulse of the correction event shall be a biphasic symmetrical square waveform.

Test Case	The output of our NMES circuit will be connected to a oscilloscope (using current probes).	
Expected Outcome	The current intensity is measured to the values described in the requirements. The frequency and duration of pulses is measured as our default values (50Hz and 600μs)	
Actual Outcome		
Comments		
Marking Instructor Initials:	PASS	FAIL

[DES 7.1.1-B-PC] The app home page shall display the FlexTech logo.
[DES 7.1.2-A-PC] The app home page shall display the settings icon to go to settings.
[DES 7.1.3-A-PC] The app home page shall display the calibration icon to go to the calibration section.
[DES 7.1.4-B-PC] The app home page shall display the documentation icon to go to the documentation section.
[DES 7.1.5-A-PC] The app home page shall display the tracking icon to view tracking of correction events.
[DES 7.1.6-B-PC] The app home page shall display the linking icon to give instructions to link phone to brace.
[DES 7.1.7-C-PC] The app home page shall display the brace battery life.

Test Case	Visit the app home page and click into each button on the home page, namely settings, calibration, documentation, corrective history, and bluetooth linking.
Expected Outcome	The homepage shall prominently display the FlexTech Logo, remaining battery power, and buttons for home page, namely settings, calibration, documentation, corrective history, and bluetooth linking. Visiting each of

	the pages linked by the buttons works and each contain a back button which goes to the home page.	
Actual Outcome		
Comments		
Marking Instructor Initials:	PASS	FAIL

[REQ 7.2.2-B-PC] The app calibration section shall provide detailed instructions on how to properly put on the brace and calibrate it.
[REQ 7.2.3-A-PC] The app shall communicate with the brace to begin taking calibration measurements.

Test Case	Visit the app calibration section and perform the daily calibration procedure.	
Expected Outcome	The app will walk the user through how to perform calibration, giving instructions to put on the brace, press the brace power button and stand in certain positions. There will be two-way communication between the app and the brace.	
Actual Outcome		
Comments		
Marking Instructor Initials:	PASS	FAIL

[REQ 7.6.1-C-PC] The app shall communicate with the brace via bluetooth.
[REQ 7.4.1-C-PC] The app bluetooth linking section shall guide the user to link via bluetooth, including information leading them to the button on the brace.
[REQ 7.4.2-C-PC] The app bluetooth linking section shall display a success message when the phone is linked to the brace.
[REQ 7.6.4-C-PC] The brace shall notify the app of correction events within 1 second

Test Case	Ensure the TechBrace is not currently linked to the phone and the brace is on. Enter the bluetooth linking section of the Mobile App. Press a button to begin scanning to link to

	the brace. Accept linking to the brace. Using a prototyping test button on the app, send a packet of data from the app to the TechBrace, and await a reply.	
Expected Outcome	The brace properly connects to the mobile phone and replies to the sent packet.	
Actual Outcome		
Comments		
Marking Instructor Initials:	PASS	FAIL

Appendix 2 - User Interface and Appearance

A2.1 Introduction

A2.1.1 Purpose

This appendix is designed to give users a better understanding of the design considerations that went into the TechBrace, specifically those concerning user interaction.

A2.1.2 Scope

The sections within this appendix encompass the different forms of analysis used in development of the TechBrace. These include user analysis, technical analysis, engineering standards, and usability testing. Each section describes a different angle from which the device should be considered, so this appendix creates a full description of the appearance and usability of the TechBrace at this stage of the project.

Figure 19: Anticipated Appearance [3]

A2.2 User Analysis

Use of the TechBrace will require some user knowledge of the quadriceps in order to place the electrodes properly. This knowledge can come from the physician that

prescribes the TechBrace to the user or from the user manual. The VMO is easily found from bony landmarks and muscle protrusions and the vastus lateralis can be found from word description. As they are both large muscles and the electrodes are large, even small misalignment of the electrodes will still produce the desired response. On the knee sleeve, all technical components will be hidden within the sleeve itself, so the only interaction with technical components would be the on/off button, monitoring of the LED status light and charging the knee sleeve each night. Information about this status light will be in a user manual, and the colours associated with each state should be intuitive (for example: green for charged, red flashing for device failure). Donning and doffing of the brace will be easily understandable with velcro patches corresponding to designated straps in both direction and placement. Each strap will reach only its corresponding Velcro patch. The hole for the kneecap will also allow the user to position the sleeve properly and consistently. Even if the hole is slightly misaligned, with some motion it should correct itself as the kneecap will direct the hole to a position of stability.

The FlexTech Mobile App requires minimal user knowledge to operate properly. Users with experience performing bluetooth pairing will be at an advantage, however new users will also be able to follow the given instructions to perform the simple bluetooth pairing procedure. The Mobile App will be developed with simplicity and familiarity at heart. By using only standard app components and layouts that are familiar to android users, our app will pose a minimal learning curve, allowing users to get right to calibrating their brace and helping their knee without any additional learning.
The Mobile App will feature a section containing documentation on all components of the brace, and is easily searchable and readable. The documentation section will help users of any technical background to easily find answers to their questions and use the brace to it's full medical potential.

Figure 20: Mobile App Home Page

A2.3 Technical Analysis

This section outlines how FlexTech's UI design complies with the "Seven Elements of UI Interaction" by Don Norman [39].

A2.3.1 Discoverability and Learnability

By minimizing the number of buttons and other components that require the user's attention, we will increase the learnability of the TechBrace. To this end we will have one on/off button and one status LED. There will also be only one place to plug a micro-USB (which has a physical constraint to ensure proper orientation).
Discoverability on the actual brace will be minimized as well so that the user cannot tamper with the electrical components and sensors.
The Mobile App will be developed with a simple user interface containing only the features necessary to use the TechBrace to its full capacity. All buttons will be labeled with intuitive icons building on current expectations of icon behaviour that will be easily adopted by users. By organizing all features of the Mobile App to be accessible from one main home page as shown in Figure 19, there are no hidden capabilities, which improves discoverability and learnability.

A2.3.2 Feedback

Feedback will come from the status LED to denote the different states of the device. These states and their associated colours are described in section 4.3. There will also be biofeedback from the electrodes to aid the user in setting the required current levels. Feedback is an important aspect of intuitive app design as well, and FlexTech's app will strongly rely on feedback for user communication. Feedback is required for:

- Bluetooth connection
- Calibration
- Setup
- Settings Changes

A2.3.3 Conceptual models

In order to create the aforementioned learnability, discoverability, and feedback, we will implement conceptual models to create an intuitive setup of buttons on the brace and the app. The separability of the brace and the app will also help solidify to the user that the two components serve different purposes and the only link between them is the

bluetooth. The user will require a basic conceptual model of the musculature of the quadriceps.

A2.3.4 Affordances

The brace will be designed such that the most convenient, comfortable, or aesthetically pleasing orientations correspond to proper function. For example, the logos on the brace will face a direction that affords the user to put the brace on right way up. The locations of the Velcro straps will afford proper strapping.
Through the use of intuitive icon design, the users will be able to understand what their actions will do before they perform them for the first time.

A2.3.5 Signifiers

The signifiers on the brace itself will help the user determine the functions of the different parts of the brace. There will be a power signifier on the power button. There will be signifiers on each of the electrodes to help the user place the current producing electrode on the VMO and the ground electrode on the vastus lateralis.
The Mobile App will have descriptive labels along with icons to aid navigation and help the user anticipate the result of the buttons they press. The calibration mode will display what action the user needs to perform through text and images.

A2.3.6 Mappings

The connections between the electrodes and the knee sleeve will be on the corresponding sides of the brace to help the user identify which electrode goes to which muscle. The Mobile App will have intuitively placed icons that match the user's conceptual model.

A2.3.7 Constraints

In order to ensure that the user connects the components properly, the electrodes will have different connectors from the battery charger. The battery charger has a physical constraint to ensure the plug-in is oriented properly. The knee sleeve will have a hole for the kneecap, providing a physical constraint for proper donning, as it will be uncomfortable for the user to wear the brace backwards.

A2.4 Engineering Standards

A2.4.1 Safety and performance standards

[DES 8.1.1-A-PR] The brace shall comply with general requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment (Adopted IEC 60601-1-11:2015, second edition, 2015- 01, with Canadian deviations) [40].
[DES 8.1.3-A-PR] The brace shall comply with the general requirements for product safety stated in IEC 82304-1:2016 [41].
[DES 8.1.4-A-PR] The brace shall comply with general requirements for basic safety and essential performance – includes Canadian deviations, stated in CAN/CSA – C22.2 NO. 60601-1-11:15 [42].
[DES 8.1.6-A-PR] The brace shall comply with the requirements stated in IEC 62366-2:2016 - Medical devices — Part 2: Guidance on the application of usability engineering to medical devices [43].

A2.4.2 Medical Device Software

[DES 8.1.6-A-PR] The brace shall comply with the requirements stated in IEEE P360 - Standard for Wearable Consumer Electronic Devices - Overview and Architecture [44].
[DES 8.2.1-A-PR] The brace shall comply with the requirements stated in IEC 62304 :2006 - Defines the life cycle requirements for medical device software [45].
[DES 8.2.2-A-PR] The brace shall comply with the requirements stated in IEC/TR 80001-2-3:2012 - Application of risk management for IT-networks incorporating medical devices - Part 2-3: Guidance for wireless networks[46].

A2.4.3 Battery Standards

[DES 8.3.1-A-PR] The brace shall comply with the requirements stated in IEEE 1625 - IEEE Standard for Rechargeable Batteries for Multi-Cell Mobile Computing Devices [47].

A2.4.4 Wireless Communication Standards

[DES 8.4.1-A-PR] The brace shall comply with the requirements stated in IEEE 802.11 – IEEE Standard for implementing wireless local area networks between computers in the 2.4GHz and 5GHz range [48].
[DES 8.4.2-A-PR] The brace shall comply with the requirements stated in IEEE 802.15.1 – IEEE Standard specification based on Bluetooth technology for portable devices [49].

A2.5 Analytical Usability Testing

For analytical usability testing, we consulted a number of resources, including physiotherapists, Biomedical Physiology professors, and engineers to discuss ways of implementing the angle sensing and the electrode configuration. The main physiotherapist consultant, head of physio at SFU, helped us discover different use cases, like motion restriction for post-operative patients and movement patterns for patients with compromised ACLs. The professors and engineers helped us find better ways of implementing the required features that the physiotherapist recommended.

We also did market research to see if there were similar products and found that there are no other instrumented knee braces that both collect data and provide muscular stimulation. Currently the only available knee braces are custom hard braces, which can be up to $1500 or generic soft braces, which range in price from $15 to $100. Initially we were concerned that there might not be a market for this type of product, but after speaking to a representative of Kintec, we are confident that an instrumented knee brace like ours would be in demand as long as it could be within the $500 price range. We are confident that we can keep the device within this range.

A2.6 Empirical Usability Testing

For the Empirical Usability Testing we developed several tests that served as guidelines on the development of the FlexTech brace. So far we have tested several components of the TechBrace both separately and together.

A2.6.1 Electrodes

The electrode configuration was tested using the TENS/EMS machine described in section 6 by manually testing on one of the FlexTech members. We looked at the intensity of the pulse required to activate the quadriceps by slowly increasing the level until the desired result was achieved. From this test we found the limiting current amplitude that was specified in section 6.

A2.6.2 Required Voltage

To confirm what was observed in the test above, the TENS/EMS machine was connected to an oscilloscope to observe the required voltage and ensure our circuit would achieve it.

A2.6.3 Pulse Generation

The monophasic to biphasic converter was simulated using circuitlab, as shown in figure 11. For the actual circuit the voltage sources will be replaced by two square pulses from the microcontroller. We confirmed that we are able to create the desired pulse. This gives us guidelines on how to design the rest of the circuit to get the desired amplification to 60mA.

A2.6.4 Orientation Sensing

Extracting orientation data from the chosen IMU was tested by graphically displaying object orientation in real time. We also tested connecting to multiple IMUs over a single I^2C connection and processing measurements from both on the microcontroller successfully, as well as trying multiple sensor fusion algorithms for calculating orientation accurately and smoothly. The Madgwick method, as described in section 5 seems the most promising.