February 7th, 2019
Dr. Andrew H. Rawicz
School of Engineering Science
Simon Fraser University
V5A 1S6

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

Dear Dr. Rawicz,

Please find attached the requirements document 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 aims to outline the 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.

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: Requirements Specification for FlexTech TechBrace

Requirements Specification

For FlexTech TechBrace

"The results will shock you!"

February 8th 2019

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Abstract

Knee injuries, specifically ACL injuries, are the most common form of injury [1] over a variety of sports, including skiing, basketball, and soccer, and can remove athletes from training for over a year. Severity of these injuries may require different treatments, ranging from rest to surgery, but in all cases there is a resulting instability in the knee joint. This instability can lead to compromised knee positions, which can result in further injury. Currently, the most prevalent solution is strengthening exercises that build up the supporting muscles [1], which help train those muscles over the short period of time that the person is consciously engaged in a rehabilitation program. However, in the average person's daily life, proper knee position is not at the forefront of focus, which can lead to greater risk of improper movement.

The FlexTech TechBrace aims to minimize this risk by helping the user engage stabilizing muscles when the knee goes into these dangerous positions without direct user input, thereby strengthening the muscles and the subconscious neural pathway. The system we propose consists of three main subsystems: the sensing unit, the muscle activating electrodes, and an interactive app. First, the user calibrates the device to their custom measurements and needs, and then the brace can be used to simultaneously avoid potential reinjury while rebuilding the biological knee support system.

This document outlines the functional requirements of the device including general, hardware, angle sensor, muscle activation, app, engineering standards, and sustainability and safety requirements. The sections are designed in such a way that we can work with individual components while maintaining coherence in the overall product.

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1 Introduction

Knee injuries are one of the most common problems facing athletes of all levels, with a very high proportion of the injuries being ligamental. Anterior Cruciate Ligament (ACL) tears, for example, contribute almost a quarter of a million injuries yearly in Canada and the United States [2]. The recovery time for an ACL injury, particularly if surgery is required, can be over year including the surgery waitlist, meaning that the athlete cannot train or compete for the duration of their recovery [3]. This is not only a year of training lost, but many athletes also use sport for social and health benefits, so being torn away from that can be very damaging. For professional athletes, injuries like ACL tears are even more serious since it is not only a disruption of their athletic progress, but also a disruption of their livelihood. For these reasons the physiotherapy/rehabilitation industry has become invaluable, with a main goal of getting athletes back to functioning form in a little time as possible.

The TechBrace developed by FlexTech is designed to limit dangerous motions of the knee that could lead to reinjury, while simultaneously training the stabilizing muscles and the neuromuscular pathways to help the user recover proper knee functionality in less time. The brace is designed for users who are able to walk without crutches but are still lacking stability in the joint; this may be pre- or post-operation. For users who have just had surgery, the brace can be modified to limit the range of motion in the saggital plane so the reconstructed ligaments can heal without unnecessary strain. Knee stability is mainly governed by the quadriceps, hamstrings, and gluteal muscles. However, after injury these muscles atrophy from disuse and become weak, leading to instability [4]. Because of the nature of the ACL, a very common side effect of the injury (and resulting muscle atrophy) is unwanted valgus motion, which puts excess strain on the compromised ligaments of the knee and may lead to reinjury or slow recovery. Conventional methods to counteract this side effect are functional knee braces and rehabilitation exercises that aim to build strength in the muscles, so they are better able to stabilize the knee. However, functional knee braces can lead to increased joint stiffness, which reduces range of motion and can lead the wearer to rely on the brace instead of their own body [4]. The prescribed exercises are very controlled movements for which there is constant attention placed on proper motion, but what happens when the person is out doing daily activities, not thinking about their knee positioning? Who is monitoring the motion of the knee and the engagement of the proper muscles? The TechBrace is designed to address these concerns by sensing when the critical

deviations occur and initiating the muscular response without requiring the user's conscious attention.

As a way to quantify the user's improvement, we also propose an app that will track the number of deviations of the knee over time and visually give the user proof of their recovery. Physical therapists could also use this information to create more effective exercise programs that better target their patients' needs.

1.1 Background

The TechBrace system is composed of three main subsystems: an angle sensor, electrodes, and an interactive app. The angle sensor monitors the medial position of the knee related to the baseline position to determine when the knee is in potentially damaging angles. The critical angle at which this occurs is determined by the relative angles of the femur and tibia and how they deviate from the user's normal position. The knee joint is a hinge-type joint that is used to support movement in the saggital plane, so movement in the coronal plane is supposed to be minimized with proper function of the knee [5]. By directly measuring the medial-lateral deviation, it is thus possible to quantify the dysfunction and take steps to remedy it.

The TechBrace will use electrical stimulation to target the muscles that ensure that the wearer's knee stays out of dangerous angles. This will be accomplished through the use of Neuromuscular Electrical Stimulation (NMES); a system that has been increasing in popularity since 1961 [6].

NMES works by sending electrical impulses to peripheral motor nerves through the skin that incite an action potential, leading to the contraction of the muscle [7]. NMES is commonly used to retrain muscles and recover lost strength [8]. More specific to the case of ACL reconstruction, NMES has been repeatedly shown to prevent muscle atrophy linked to the months of immobilization after surgery [9]. This disuse atrophy applies to the neurons that control the muscles in a similar way.

Plasticity in the brain allows humans to reinforce and optimize the pathways that are used more often, so by contracting the muscles that have atrophied, more receptors for neurotransmitters are delivered to the synaptic location. This causes increased input sensitivity, which helps facilitate muscle contraction [10],[11]. There also is evidence demonstrating that electrostimulating strength training, such as with NMES, can increase the force of a maximal voluntary contraction (MVC) due to modification of the

excitability of specific neural paths [12]. Thus, the use of NMES increases maximal force production in the quadriceps and the excitability of their neural pathways.

1.2 Intended Users

The requirements listed in this document are intended for the team members of FlexTech to use as guidelines in the development of the TechBrace, as well as for the TAs and professors supporting us. Note that this is an internal document, not designed for users outside of the Faculty of Applied Sciences. This document will serve as a reference throughout the development stages of the TechBrace to ensure that the product meets the requirements outlined below. Failure to do so will result in revision of this document.

1.3 Classification

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

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

Where:

- **Req** stands for requirement.
- **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	Engineering Standards
9	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

The TechBrace will perform three main functions during its operation: sensing the orientation of the upper and lower portions of the leg to calculate the valgus angles, stimulating the muscles in the leg when a critical angle is detected, and communicating with a smartphone app for the purposes of calibration and logging. These functions divide the design of the brace into five major subsystems:

- Angle Deviation Sensor

  Detects the orientation of the upper and lower leg in space, and determines the valgus angles. Will require at least two sensors, which will be implemented with either accelerometers or more accurate absolute orientation sensors based on preliminary testing.

- Muscle Activation System

  Activates specific muscles in the upper leg based on inputs from the microcontroller. Will be implemented with the help of an off-the-shelf or OEM NMES machine. Will require three electrodes adhered to specific locations on the wearer's thigh.

- Microcontroller

  Implements the main control logic of the device, and serves as the communication hub for all of the other subsystems.

- Smartphone App

  Implements the main user interface for the brace. Allows the user to view the status of the brace, and walks the user through device calibration. Communicates with the microcontroller via Bluetooth.

- Supporting Hardware

  Includes the knee sleeve, to which most of the electronic components will be attached. Also required:

  - Bluetooth module for communication with the smartphone app
  - Battery to power electronic components of the brace
  - Battery charger and connector
  - Status LED
  - Power switch

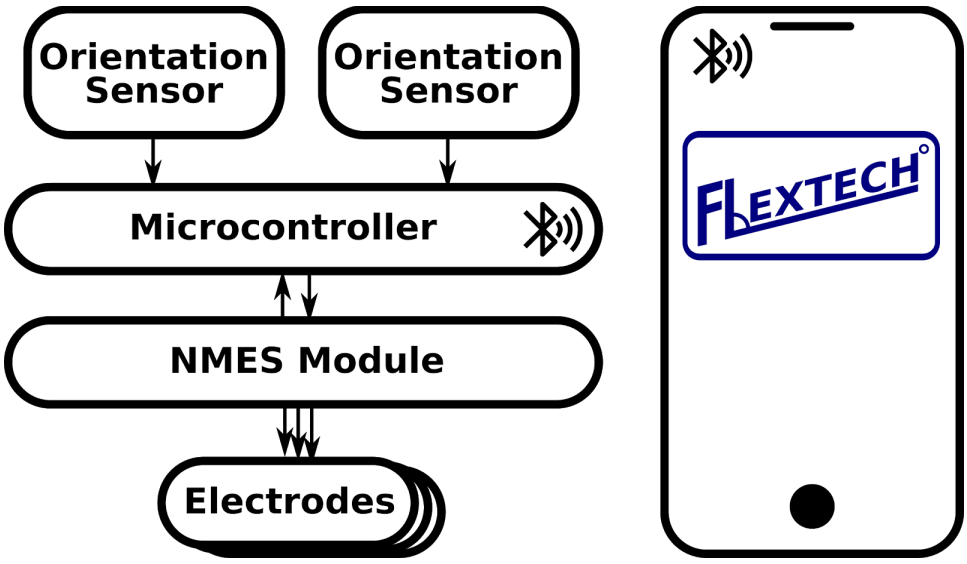

Figure 1: System Design Diagram

3 General Requirements

3.1 Overall Performance

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

3.2 Usability

[REQ 3.2.1-A-PR] The brace shall not cause discomfort for the majority of wearers when worn for up to 6 hours.
[REQ 3.2.2-A-PR] The brace, including all components, electrodes, and batteries, shall not weigh more than 500 grams.
[REQ 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.
[REQ 3.2.4-A-PR] The brace shall be sweat resistant.
[REQ 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

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

4.2 Temperature

[REQ 4.2.1-A-PT] The brace shall function to specification in an ambient temperature range of -5 to 50 degrees Celsius.
[REQ 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.
[REQ 4.2.3-A-PT] The sensors will have a working temperature range of -5 to 50 degrees Celsius.

4.3 Status LED

[REQ 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 4: LED statuses

4.4 Power

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

5 Angle Deviation Sensor

5.1 Sensing Unit

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

5.2 Angle Sensing Algorithm

[REQ 5.2.1-A-PC] The angle of the knee shall be determined from the sensor data.
[REQ 5.2.2-A-PC] The angle determined on the left side for valgus motion will increase from the baseline value.
[REQ 5.2.3-A-PC] The angle determined on the right side for valgus motion will decrease from the baseline value.
[REQ 5.2.4-A-PC] The angle will be determined with respect to the natural q-angle of the user [13].

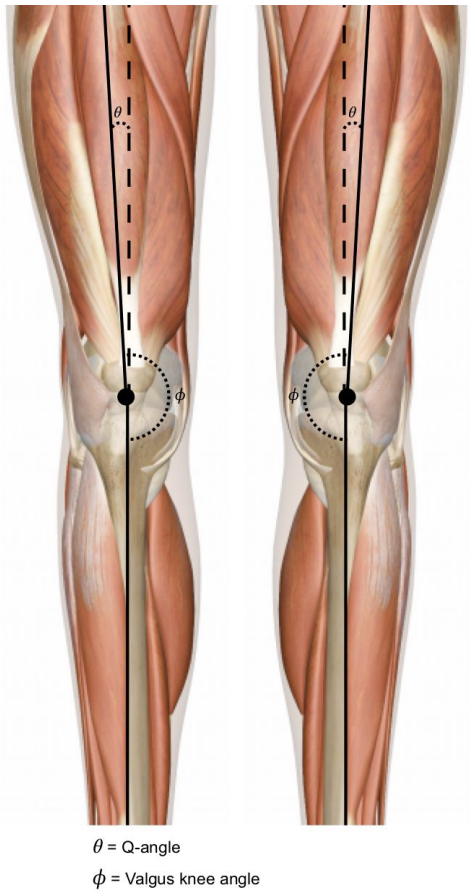

Figure 2: Angles on the leg - base image from [14]

[REQ 5.2.5-A-PC] A correction event will be initiated when the valgus angle exceeds 5 degree deviation from the baseline.
[REQ 5.2.6-A-PC] The sensor will measure valgus angles for controlled movements, like body weight squats.
[REQ 5.2.7-A-PR] The sensor will measure valgus angles for combined movements, like walking up stairs.

6 Muscle Activation System

6.1 Muscle Group

[REQ 6.1.1-A-PT] The correction event shall activate the femoral nerve every time there is critical deviation [15],[16].
[REQ 6.1.2-A-PC] The correction event shall generate enough stimulation to specifically activate the quadricep femoris of the wearer and possibly the VMO [8],[17].

[REQ 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 [9].

6.2 Electrodes

[REQ 6.2.1-B-PT] The electrodes shall be of type Ag-AgCl or other.
[REQ 6.2.2-A-PT] The electrode size shall be big enough the electrical stimulation will not be painful to the user [18].
[REQ 6.2.3-C-PT] There shall be two square electrodes and a rectangular electrode.
[REQ 6.2.4-C-PT] The square electrodes shall have a size of 2” by 2” and the rectangular electrode shall have a size of 2” by 5”.
[REQ 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 [18].
[REQ 6.2.6-A-PC] The cathode electrodes shall be positioned distally and the anode electrode shall be positioned proximally [19].
[REQ 6.2.7-B-PT] The electrodes shall easily connect to and disconnect from the electronics on the brace.
[REQ 6.2.8-C-PR] The electrode connector shall be rated for at least 2000 uses.
[REQ 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.

6.3 Electrical Stimulation

[REQ 6.3.1-A-PT] The correction event shall consist of pulses with a frequency of 30 to 50 Hz [20].
[REQ 6.3.2-A-PT] The correction event shall generate pulses of 400 to 600 µs [20].
[REQ 6.3.3-A-PT] The correction event shall generate a current with amplitude between 30 to 80 mA [20],[21].
[REQ 6.3.4-A-PT] The correction event shall have a failsafe to stop electrical stimulation and prevent overstimulation (muscle fatigue).
[REQ 6.3.5-A-PT] Each pulse of the correction event shall be a biphasic symmetrical square waveform as seen in Fig 3 [22]-[24].

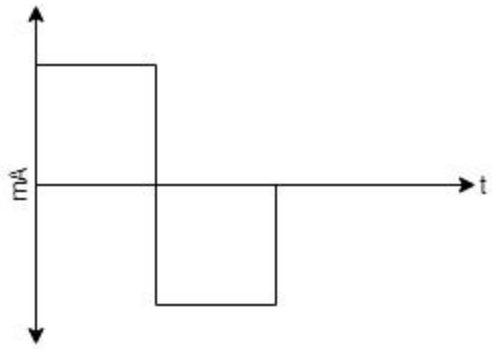

Figure 3: Pulse waveform

7 App

7.1 Home Page

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

7.2 Calibration

(The brace requires calibration because q-angle differs between users)

[REQ 7.2.1-A-PT] The app calibration 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.
[REQ 7.2.2-B-PR] The app calibration section shall provide detailed instructions on how to properly put on the brace and calibrate it.
[REQ 7.2.3-A-PR] The app shall communicate with the brace to begin taking calibration measurements.

7.3 Documentation/User Guide

[REQ 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.

7.4 Linking

[REQ 7.4.1-C-PR] The app linking section shall teach the user how to link via bluetooth, including information leading them to the button on the brace, and the bluetooth settings button on the phone.
[REQ 7.4.2-C-PR] The app linking section shall display a positive message if the phone is linked to the brace.

7.5 Tracking

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

7.6 Misc

[REQ 7.6.1-C-PR] The app shall communicate with the brace via bluetooth.
[REQ 7.6.2-C-PR] The app settings section shall store on which leg the brace is being used and allow for the user to toggle it.
[REQ 7.6.3-C-PR] The app shall support one brace at a time.
[REQ 7.6.4-C-PR] The brace shall notify the app of correction events within 1 second.
[REQ 7.6.5-C-PR] The brace battery life display shall be no older than 15 minutes.

8 Engineering Standards

8.1 Safety and performance standards

[REQ 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) [25].

[REQ 8.1.2-A-PR] The brace shall comply with the requirements of medical electrical equipment - Recurrent test and test after repair of medical electrical equipment in IEC 62353:2014 [26].

[REQ 8.1.3-A-PR] The brace shall comply with the general requirements for product safety stated in IEC 82304-1:2016 [27].

[REQ 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 [28].

[REQ 8.1.5-A-PR] The brace shall comply with general requirements for basic safety and essential performance - Collateral standard: Usability,stated in CAN/CSA-C22.2 NO. 60601-1-6:11 [29].

[REQ 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 [30].

8.2 Medical Device Software

[REQ 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 [31].

[REQ 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[32].

8.3 Battery Standards

[REQ 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 [33].

8.4 Wireless Communication Standards

[REQ 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 [34].

[REQ 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 [35].

9 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.
The key to developing our 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.

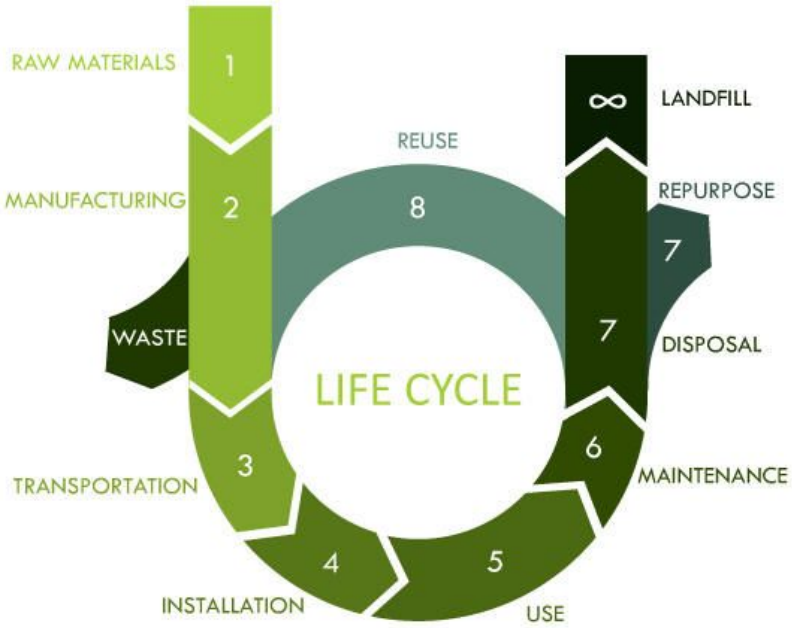

Figure 4: Product Life Cycle [37]

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 which 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 in sections 8.1 and 8.2. 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.

10 Glossary

Atrophy: the loss of muscle mass and transition of muscle fibres to fast-fast fatigable muscle fibres. In the context of nerve atrophy, refers to loss of nerve fibres.
Correction Event: the incident of stimulation delivered to the muscle to correct the knee position.
Coronal plane: the plane dividing a body into front and back portions. See figure 5.
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.
Femoral nerve: “the main nerve of the anterior compartment of thigh” [15]. It innervates the quadriceps.
Hinge type: A type of joint that facilitates movement in one axis [36].
Medial: the side of the knee that is closer to the midline of the body.

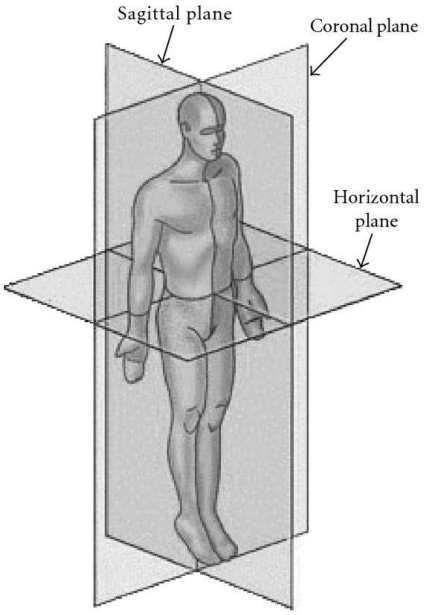

Figure 5: Planes of the body [38]

Proximal: the situation of a muscle, bone, or limb that is closer to the center of the body or point of origin.
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.
User: the person using the FlexTech TechBrace.
Vastus lateralis: a muscle in the quadricep femoris muscle group.
Vastus medialis: a muscle in the quadricep femoris muscle group.

11 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 system. A product developed to protect ACL patients from further injury and help them recover. The requirements listed in this document specify the boundaries and guidelines for the TechBrace system.

A brief summary of the requirements is provided below:

1. **Hardware Requirements**
    - The brace shall incorporate a soft sleeve which shall not limit normal motion.
    - The brace shall function in the range of -5 to 50 degrees Celsius and shall not generate heat up to 20 degrees above the ambient temperature.
    - The brace shall incorporate LED to indicate its status.
    - The brace shall have a battery life of 6 hours and be rechargeable via micro-USB.
2. **Angle Deviation Sensor Requirements**
    - The sensing unit of the brace shall accurately measure the motion of the femur and tibia.
    - The sensing algorithm shall work with the sensors to accurately detect when the user's knee has critically deviated from normal position.
3. **Muscle Activation System Requirements**
    - The muscle activation system shall generate sufficient stimulation to activate the muscle group to correct the user's knee position.
    - The electrodes shall be size of 2" by 2" or 2" by 5" and placed in the vastus configuration.
    - The electrodes shall be able to generate pulses with frequency of 30 to 50 Hz and amplitude of 30 to 80 mA, incorporated with a fail-safe protocol.
4. **App Requirements**
    - The app shall have a homepage with sufficient information about the product and link icons to direct the user to different functions or pages.
    - The app shall be able to receive data from the brace via bluetooth and establish a baseline from which to calibrate the brace.
    - The app shall record the number of corrective events occurring in each session to help the user improve cognition of their improvement.
5. **Engineering Standards**

- The hardware, electrical, software, and environmental standards published by acclaimed organizations shall be followed by the FlexTech team.

6. **Sustainability and Safety**
    - The brace production shall be environmentally friendly, with a focus on reusability and sustainability.
    - Safety shall be a top priority during the design process, since the brace works as a tool to help ACL patients.

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

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Appendix

Acceptance Test Plan

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

[REQ 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

[REQ 4.1.1-A-PC] The brace shall incorporate a soft knee sleeve which wraps the knee.
[REQ 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

[REQ 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

[REQ 5.2.1-A-PC] The angle of the knee shall be determined from the sensor data.
[REQ 5.2.2-A-PC] The angle determined on the left side for valgus motion will increase from the baseline value.
[REQ 5.2.3-A-PC] The angle determined on the right side for valgus motion will decrease from the baseline value.
[REQ 5.2.4-A-PC] The angle will be determined with respect to the natural q-angle of the user.
[REQ 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

[REQ 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

[REQ 6.1.2-A-PC] The correction event shall generate enough stimulation to activate the quadricep femoris of the wearer and possibly VMO. [8,16]
[REQ 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. [9]
[REQ 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. [18]
[REQ 6.2.6-A-PC] The cathode electrodes shall be positioned distally and the anode electrode shall be positioned proximally. [18]

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
