February 21, 2018

Dr. Andrew Rawicz
School of Engineering Science
Simon Fraser University
Burnaby, British Columbia
V5A 1S6

CHRONOTECH SYSTEMS

Re: ENSC 405W Project Proposal for M-Brace

Dear Dr. Rawicz:

The following document contains functional specifications for *M-Brace* by ChronoTech Systems, which was prepared as a requirement for the course ENSC 405W. Our goal is to help people who suffer from early stages of carpal tunnel syndrome and people who are concerned with developing the disorder later in life. M-Brace is a lightweight device that monitors pressure being applied on the user's median nerve to mitigate the symptoms of early CTS or help prevent the condition altogether.

This document is meant to provide a high-level outline of the functions and requirements for M-Brace. The following specifications include a system overview, the requirements list, engineering standards, information about safety and sustainability and an appendix that details what features are to be expected for the proof of concept in April. This document will serve as a guide during the development of our product.

ChronoTech Systems consists of hardworking engineers with a diverse set of skills and passions that complement one another. Michelle Ho, Ying Hsin Lan, Princess Krizia Macanlalay, and Randel Argel Rivera form the foundation upon which ChronoTech Systems is built.

Thank you for taking the time to review our documentation for *M-Brace*. Please direct any questions or concerns to our Chief Operations Officer, Michelle Ho, by email at mmh12@sfu.ca.

Sincerely,

Randel Argel Rivera
Chief Executive Officer
ChronoTech Systems

Requirements Specifications for *M-Brace*

Project Team
Michelle Ho
Ying Hsin Lan
Princess Krizia Macanlalay
Randel Argel Rivera

Contact Person
Michelle Ho
mmh12@sfu.ca

Submitted to
Dr. Andrew Rawicz – ENSC 440
Steve Whitmore – ENSC 405W
School of Engineering Science
Simon Fraser University

Published Date
February 21, 2018
Revision 1.0

Table of Contents

1.0 Introduction 1

1.1 Scope 1

1.2 Intended Audience 1

1.3 Requirement Classification 2

2.0 System Overview 3

2.1 Physical Design Overview 3

2.2 Hardware Design Overview 4

2.3 User Interface Design Overview 5

3.0 System Requirements 6

3.1 Physical Design Design Requirements 6

3.2 Hardware Design Requirements 7

3.3 Software Requirements 9

3.4 Miscellaneous Requirements 12

4.0 Engineering Standards 13

5.0 Safety 14

6.0 Sustainability 15

7.0 Conclusion 16

8.0 References 17

9.0 Appendix A 20

10.0 Appendix B 21

List of Tables

Table 1 Section Code with Corresponding Section Description 2
Table 2 Phase Code with Corresponding Phase Description 2
Table 3 A List of Physical Design Requirements 6
Table 4 A List of Circuit Design Requirements 7
Table 5 A List of Microcontroller Requirements 8
Table 6 A List of Power Requirements 8
Table 7 A List of Hardware Testing Requirements 9
Table 8 A List of User Interface Requirements 10
Table 9 A List of Data Transmission Requirements 11
Table 10 A List of Software Testing Requirements 11
Table 11 A List of Miscellaneous Requirements 12
Table 12 A List of Engineering Standards 13
Table 13 A List of Medical Standards 13
Table 14 A List of Safety Requirements 14
Table 15 A List of Potential Sensors 22

List of Figures

Figure 1 Conceptual Overview of the System 3
Figure 2 A Pinched Median Nerve Provided 3
Figure 3 Range of Wrist Joint Movement 4
Figure 4 Conceptual Diagram of the Hardware Design Overview 4
Figure 5 Use Case Diagram 5
Figure 6 UI Hand Outline with Potential Sensor Placement 5
Figure 7 Wrist Brace Design 6
Figure 8 Flexor Carpi Radialis 20
Figure 9 Generic Glove Design 20
Figure 10 Metacarpophalangeal Joint 21

Glossary

Android	An open-source smart device operating system
C2C	An abbreviation for Cradle-to-Cradle, which is a methodology for products and systems with an emphasis on sustainable designs
CSA Group	An abbreviation for Canadian Standards Association Group
CTS	An abbreviation for carpal tunnel syndrome - a chronic disorder that causes pain in the hands due to excessive pressure on the median nerve
EOL	An abbreviation for end of life
IEC	An abbreviation for International Electrotechnical Commission
IEEE	An abbreviation for Institution of Electrical and Electronics Engineers
iOS	A mobile device operating system released by Apple Inc.
ISO	An abbreviation for International Organization for Standardization
Median Nerve	A nerve from the brachial plexus that passes through the carpal tunnel
Microcontroller	A computer on an integrated circuit dedicated to executing a specific task
PCB	An abbreviation for printed circuit board
Proof of Concept	A sample product assembled to explore the feasibility of a concept
Prototype	A preliminary model or release of a product
SI Units	An abbreviation for International System of Units - used in this document
UI	An abbreviation for user interface

1.0 Introduction

Many people are unaware of their gripping habits while doing repetitive hand movements. When people perform such habits on a daily basis, they are prone to developing carpal tunnel syndrome (CTS) because of the excessive pressure exerted on the median nerve. Currently, there are a few options for assisting the disorder. One common solution is wrist splinting, which is only effective in the early stages of CTS. Although surgery and medication do exist as well, these treatments are only temporary methods for controlling the numbness and pain caused by CTS.

ChronoTech Systems envisions a wearable device, M-Brace, to assist people who are at risk of developing CTS. The main target groups of M-Brace are sports enthusiasts and professional athletes who need to do repetitive hand movements throughout the day. The purpose of M-Brace is to remind users to take frequent breaks, to encourage users to exercise with counter-movements, and to notify the user of the pressure exerted on their median nerve. Similar to training supersets in the gym, the trainee should complete triceps extension after a biceps curl; this allows the trainee to perform with opposing muscle groups. For example, if the M-Brace user is flexing their wrist during their daily routine, the user interface would recommend the user to extend the wrist after a certain extended period.

1.1 Scope

The target development for M-Brace will occur over three main phases. ChronoTech Systems promises to produce a proof of concept by April 9, 2018 and a prototype for sports use by August 3, 2018. Further analysis with medical professionals is needed to improve on the data reliability and accuracy of the prototype for the assembly of the final product.

This document outlines the system overview and the requirement specifications of M-Brace in the initial two phases. The requirement specifications must be met by its proposed deadline for a successful completion of M-Brace. Furthermore, ChronoTech Systems has included a detailed description of the engineering, safety and sustainability standards, which the company aims to achieve with M-Brace.

1.2 Intended Audience

This documentation is intended to be reviewed by the team members of ChronoTech Systems and by other experts interested in the product, M-Brace. The requirement specifications will be referenced by the firmware, hardware, and software design engineers throughout the research and development phase of M-Brace. The quality of M-Brace will be validated by ensuring all engineering standards and safety, sustainability and design requirements are met by the ChronoTech System design team.

1.3 Requirement Classification

Each functional requirement is denoted with the following system coding scheme convention:

[R <Section Code>.<Subsection Code>.<Identification Code> - <Phase Code>]

The first letter ***R*** is an abbreviation for requirements. As the document is formatted in hierarchical order, the **<*Section Code*>** is an integer value corresponding to the categorized root section number. Similarly, the **<*Subsection Code*>** corresponds to the subsection number within the root section. Table 1 below provides a legend of all sections containing functional requirement specifications.

<Section Code>.<Subsection Code>	Section Title
3.1	Physical Design Requirement
3.2	Hardware Requirement
3.3	Software Requirement
3.4	Miscellaneous Requirement
5.0	Safety Requirement

Table 1 Section Code with Corresponding Section Description

Furthermore, the **<*Identification Code*>** is an integer assigned to each requirement, while the **<*Phase Code*>** corresponds to the development phase at which the function requirement is expected to be met. Table 2 outlines the three main phase codes of M-Brace.

Phase Code	Development Phase Description
I	The requirement applies to the proof-of-concept
II	The requirement applies to the prototype
III	The requirement applies to the final product

Table 2 Phase Code with Corresponding Phase Description

For example, the second physical design requirement would have the value 3 for **<*Section Code*>**, 1 for **<*Subsection Code*>**, and 2 for **<*Identification Code*>**. If this is a prototype requirement, then the **<*Phase Code*>** is II. Therefore, it would be labelled as [R 3.1.2 - II].

2.0 System Overview

M-Brace is a wearable device that monitors the amount of pressure exerted to the user's median nerve. The product design has been divided into three main categories: the physical wearable component, the hardware component, and the user interface component. The design of the wearable component must be able to collect data in regards to the strain on the nerve. This data would be wirelessly transmitted to a user interface, where the user can intuitively track the graphical data, as illustrated in Figure 1.

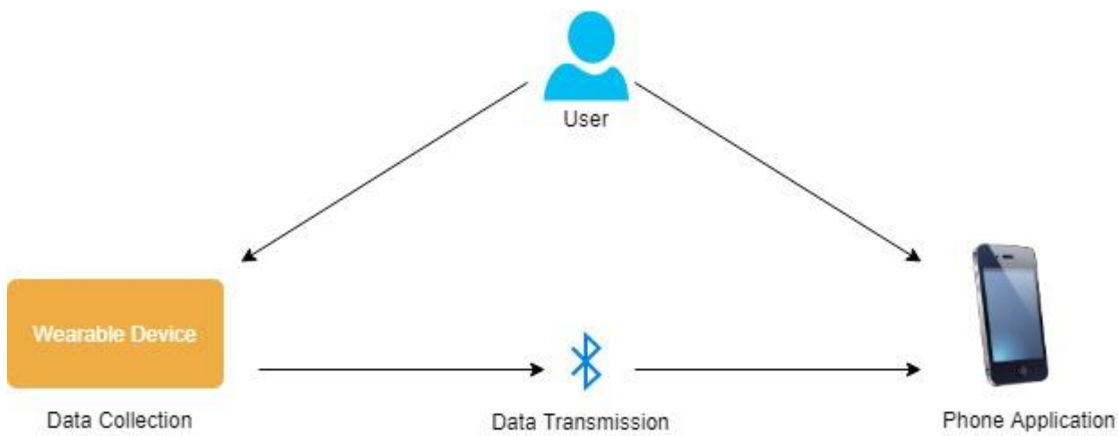

Figure 1 Conceptual Overview of the System

The following section outlines the system overview of M-Brace prototype. The target demographic of the product would be sports enthusiasts and professional athletics.

2.1 Physical Design Overview

The median nerve starts at the brachial plexus, located in the upper limb, and travels down the arm into the palm, where it ends on either side of the index and middle fingers, and the thumb-side of the ring finger [1]. The primary affected area of the pinched median nerve is around the wrist, as shown in Figure 1. Therefore, the sensors inside the wearable must be able to collect information about the strain experienced on the user's palm and the tension applied on the user's wrist at flexion and hyperextension, as shown in Figure 3.

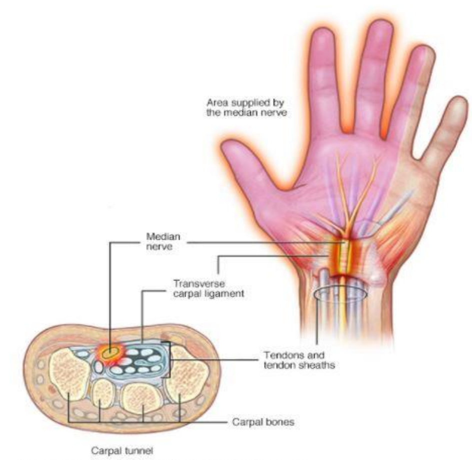

Figure 2 A Pinched Median Nerve Provided [2]

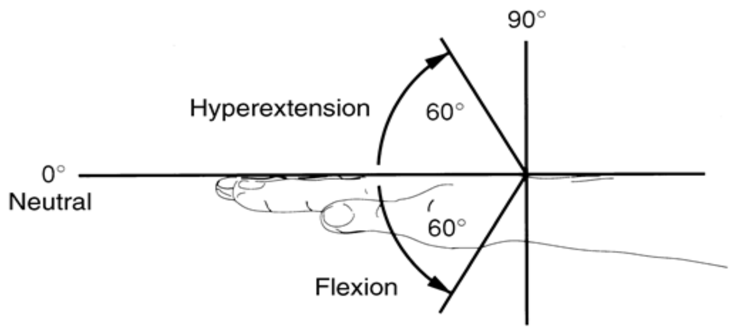

Figure 3 Range of Wrist Joint Movement: Flexion-extension and Hyperextension [3]

To properly monitor the pressure on the user's median nerve, the user is required to wear M-Brace while completing tasks. Thus, M-Brace is designed to have minimal mobility restriction. The module is lightweight, the fabric chosen is breathable, and the sensors used is flexible.

2.2 Hardware Design Overview

A microcontroller is used to collect data from the sensors through thin wires. Since M-Brace requires low voltage applied to the sensors and the microcontroller, a removable battery is attached to a custom PCB with a power isolation circuit and a voltage regulator. For safety concerns, the microcontroller unit and its battery are stored in an enclosed plastic box. Figure 4 below shows a conceptual relation between each component.

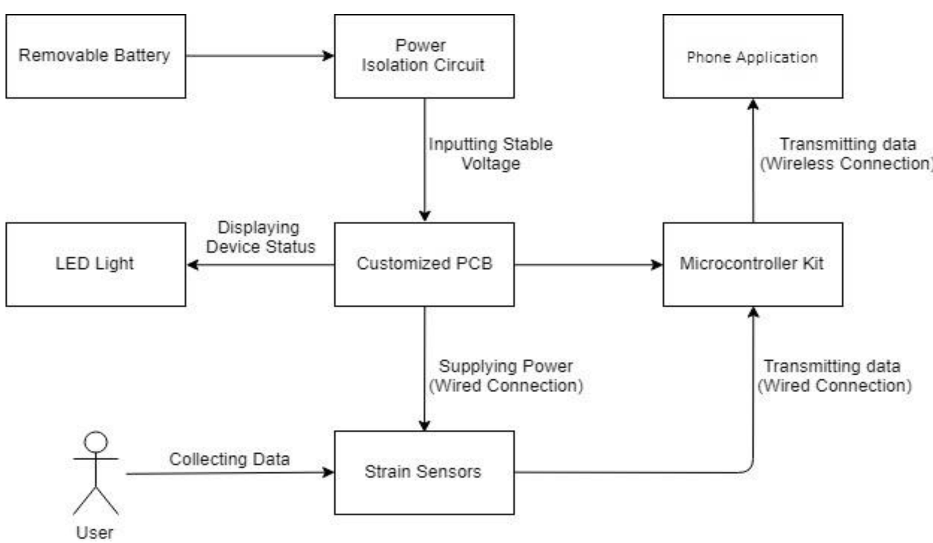

Figure 4 Conceptual Diagram of the Hardware Design Overview

2.3 User Interface Design Overview

M-Brace physical module can be paired to a phone application on both iOS and Android interface. Figure 5 is a use case diagram of the user interface design overview.

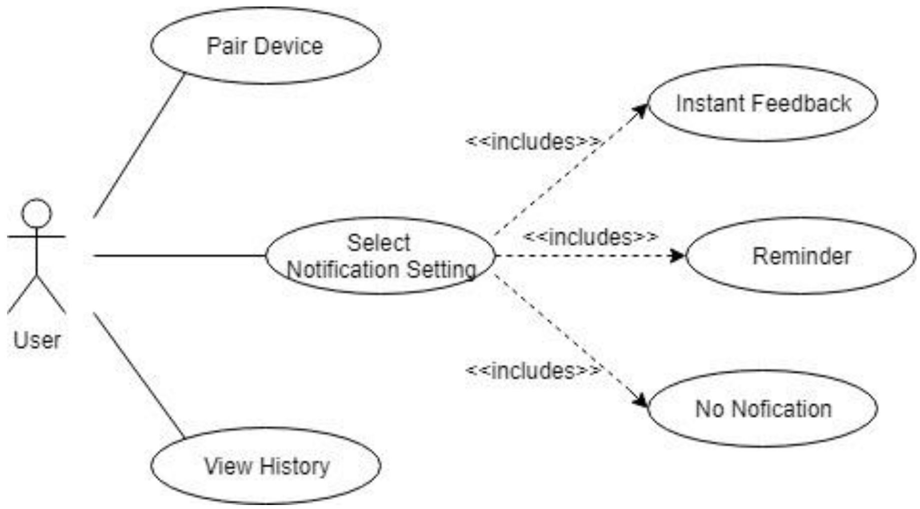

Figure 5 Use Case Diagram of the Software Design Overview

The user can view a real-time graphical feedback of the pressures applied on different sensors. The location of the sensors on the screen outlining both hands - as represented as blue dots in Figure 6 - resemble the location of the sensor in the wearable. The application provides a linear colour feedback based on the pressure of the sensors: with green representing no pressure to an acceptable amount of pressure applied, and red representing an excess amount of pressure applied.

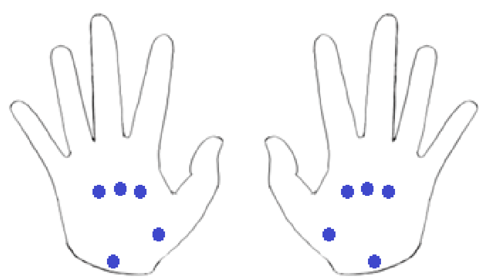

Figure 6 UI Hand Outline with Potential Sensor Placement

Furthermore, M-Brace allows the user to choose between two notification settings. The recommended setting allows instant notification when too much tension is applied. This helps the user to lessen the grip of an item or to assist in the correction of the posture. If the task requires the user to exert more pressure over an extended period, the user may choose the second setting, which allows the user to set a reminder for counter-movement exercises.

3.0 System Requirements

This section discusses the functional system requirements of the outlined components at each development phase. This section consists of three subsections: Physical Design Requirements, Hardware Design Requirements, and Software Design Requirements. As stated in section 1.3, each requirement will be met at certain development phases.

Note: Requirements marked with '' are not carried over into subsequent development phases*

3.1 Physical Design Requirements

In the first phase of the product development, ChronoTech Systems aims to acquire the ideal sensor placement and to test the sensor sensitivity with a layer of fabric of a generic glove. Since M-Brace is designed to be used for an extended period of time, the design team proposes a more secure design that resembles a wrist brace, where the wrist and half of the palm be would covered, as shown in Figure 7.

Figure 7 Wrist Brace Design [4]

The following table outlines the physical aspects of M-Brace for each development phase.

Requirement ID	Physical Design Requirement Description
[R 3.1.1 - I]	The device should not restrict wrist movement by having flexible sensors
[R 3.1.2 - I]	The sensors should be minimally intrusive to the user
[R 3.1.3 - II]	The brace should not pass the distal transverse arch (Appendix B)
[R 3.1.4 - II]	The brace should be easy to set up for users of all technical backgrounds
[R 3.1.5 - II]	The device should be comfortable to wear for extended periods of time
[R 3.1.6 - II]	The brace should have a wrist circumference of 15cm to 22cm in order to fit the majority of the ChronoTech Systems team for testing the comfortability *
[R 3.1.7 - II]	The weight of the device should not exceed 200g for easy transportation *
[R 3.1.8 - II]	The device should be secured to the user's wrist and palm
[R 3.1.9 - II]	Sensor movement should be minimized to 0.5cm when pinpointing the wrist and each part of the hand for minimal error in data collection
[R 3.1.10 - II]	The sensor and the microcontroller must be connected with robust wires of less than 2.54mm in diameter [5] *
[R 3.1.11 - II]	The maximum size for the PCB should be 4cm by 9cm to fit on the user's forearm and to avoid impeding movement *

[R 3.1.12 - III]	The brace should be available in different sizes for adults with wrist circumferences between 15cm to 24cm [6]
[R 3.1.13 - III]	The weight of the device should not exceed 120g to put less strain on the user
[R 3.1.14 - III]	The sensor and the microcontroller must be connected with conductive thread of less than 0.4mm in thickness [7]
[R 3.1.15 - III]	The maximum size for the PCB should be 4cm by 5cm to fit on the dorsal side of the user's hand and to avoid extending beyond the hand

Table 3 A List of Physical Design Requirements

3.2 Hardware Design Requirements

Due to the pinch on the median nerve, the wrist and fingers are commonly affected by CTS pain as shown in 2. At least one sensors should be placed around the wrist area to monitor the flexion and the hyperextension of the wrist. At least four additional sensors should be placed to detect the pressure associated to the thumb, the index, the middle, and the ring fingers. Thus, a minimum of five sensors would be embedded in the brace to track strain and tension.

During Phase I, a breadboard circuit is constructed with an Arduino Uno - R3 board to experiment with the functionality and feasibility of various types of sensors and the general circuitry. The circuit will be optimized by using a Cypress Semiconductor microcontroller for Phase II as the microcontroller will be able to connect to a smartphone via bluetooth connection. For the final product, M-Brace should be constructed on a single microcontroller chip. The following set of requirements pertain to the M-Brace hardware component, which has been split into 4 main categories: circuit design, microcontroller, power, and hardware testing.

Requirement ID	Circuit Design Requirement Description
[R 3.2.1 - I]	The circuit should be able to withstand drastic changes in current and voltage
[R 3.2.2 - I]	The circuit should include thermal management to prevent overheating
[R 3.2.3 - I]	The circuit should have at least one LED to indicate system status
[R 3.2.4 - I]	The wires should be insulated and grounded for safety
[R 3.2.5 - II]	The PCB should be customized for the circuit
[R 3.2.6 - II]	The PCB circuit design should be compatible with the microcontroller
[R 3.2.7 - III]	The circuit should be mass-produced to lower production costs
[R 3.2.8 - III]	The circuit design should be optimized for space on the PCB

Table 4 A List of Circuit Design Requirements

Requirement ID	Microcontroller Requirement Description
[R 3.2.9 - I]	The device should be running on an Arduino Uno - R3 for easier testing *
[R 3.2.10 - I]	The microcontroller should have at least 5 I/O ports for connecting to sensors
[R 3.2.11 - I]	The microcontroller should be able to collect data from sensors
[R 3.2.12 - I]	The microcontroller should send the data via serial port for testing purposes
[R 3.2.13 - I]	Real-time data transmission should be provided for allowing instant feedback
[R 3.2.14 - II]	The device should be running on a microcontroller kit that allows for flexible configurations and function implementations *
[R 3.2.15 - II]	The microcontroller should have bluetooth capability to improve user mobility
[R 3.2.16 - II]	The device should have a sampling rate and transmit rate of at least 30Hz *
[R 3.2.17 - III]	The device should be running on a single microcontroller chip without unnecessary hardware components
[R 3.2.18 - III]	The device should have a sampling rate and transmit rate of at least 1kHz as the product will eventually be marketed to medical professionals

Table 5 A List of Microcontroller Requirements

Requirement ID	Power Requirement Description
[R 3.2.19 - I]	The device should be powered via serial port for better cord management *
[R 3.2.20 - I]	The device should have enough current to power all the sensors
[R 3.2.21 - I]	The input voltage from Arduino UNO to the device should not exceed 5V *
[R 3.2.22 - I]	The power consumption should not exceed 0.05W (Appendix B)
[R 3.2.23 - II]	The input voltage from a removable battery should not exceed 5V
[R 3.2.24 - II]	The device should have a runtime of at least 2 hours on a full charge to test all the functionality of the prototype requirements *
[R 3.2.25 - II]	The battery should be stored and fitted in an enclosed compartment
[R 3.2.26 - II]	The device can be turned on and off with a mechanical switch for each microcontroller for convenience and for safety
[R 3.2.27 - III]	The battery size should not exceed the PCB size to minimize the footprint
[R 3.2.28 - III]	The device should have a runtime of at least 4 hours on a full charge for the user to play the full-length of a common sports game

Table 6 A List of Power Requirements

Requirement ID	Hardware Testing Requirement Description
[R 3.2.29 - I]	The sensors should be able to detect the force pressure variance
[R 3.2.30 - I]	Sensor should not exceed ±3% single part force repeatability (Appendix B)
[R 3.2.31 - I]	The collected data should be consistent to ensure the precision of the device
[R 3.2.32 - I]	The main circuit should be tested on a standard breadboard
[R 3.2.33 - I]	The currents and voltages applied to each component should comply with its respective datasheet to minimize risks of failure
[R 3.2.34 - I]	The functionality of the force sensors should be tested with a dome-shaped padding to substitute human testing
[R 3.2.35 - I]	The functionality of the tension sensors should be tested by bending the glove in a manner that mimics a hand flex or extension (Figure 3)
[R 3.2.36 - II]	Components should be tested independently to ensure requirements are met
[R 3.2.37 - II]	The functionality of the force sensors should be tested by inflating a balloon placed inside the wrist brace to substitute human testing
[R 3.2.38 - II]	The overall functionality of the device should go through black box user testing without the user wearing the glove *
[R 3.2.39 - III]	Empirical testing should be done by the intended end-users to gain feedback

Table 7 A List of Hardware Testing Requirements

3.3 Software Requirements

This subsection details the software aspects that need to be implemented in conjunction with M-Brace through each software development phase:

Phase I - Proof of Concept

The proof of concept should be able to take data from each sensor and display the points on their respective plots over time. The application should be running on an emulated version of iOS 10 or later. The deliverable for this phase would be on April 9, 2018.

Phase II - Prototype (Pre-alpha)

The emulated version of the iOS application would be able to receive data from the microcontroller via bluetooth connection. At this stage, the application should also alert the user whenever their hands have been in the same position or repeating the same motion for an extended period. These alerts should be automatic, at regular intervals, or specified by the user.

Phase II - Prototype (Alpha)

The aim for the prototype is to create an intuitive and user-friendly interface for users of any technical background. The application should be able to display the collected data on a colour map superimposed on hands, refer to Figure 6.

Phase II - Prototype (Beta)

The application would run on a smart device operating on iOS 10 or later. The strength of the bluetooth connectivity between the phone application and the wearable device should be strong enough to allow the end-users who cannot keep their phones on their body to track their activities. The deliverable for this phase would be at the end of August 3, 2018.

Phase III - Final Product

The application for the final product should be available on all major platforms and have access to a cloud-based server to securely store user data.

The requirements for this companion application are broken down into the following categories: user interface, data transmission, and software testing.

Requirement ID	User Interface Requirement Description
[R 3.3.1 - I]	The sensor data can be accessed from an emulation of a phone
[R 3.3.2 - I]	The application should provide numerical feedback of the sensor readings
[R 3.3.3 - I]	The application should be available on iOS for the ease of accessibility
[R 3.3.4 - I]	The application should provide timestamps, based on the clock of the user's phone, for each data packet received from the device
[R 3.3.5 - II]	The sensor data can be access from a phone running on iOS
[R 3.3.6 - II]	The application should have an intuitive UI design for the ease of operation
[R 3.3.7 - II]	The application should provide graphical feedback of the sensor readings
[R 3.3.8 - II]	The UI should display the location of the sensors that correspond to where they are physically located on the device
[R 3.3.9 - II]	The application should notify the user upon successful connection with device

[R 3.3.10 - II]	The application should notify the user when it detects excessive pressure
[R 3.3.11 - II]	The application should notify the user when it detects that their hand has been performing the same movements for an extended period
[R 3.3.12 - II]	The application should have the option to set reminders
[R 3.3.13 - II]	The collected data should be saved onto the user's phone and be kept in data logs for a week to avoid filling up the phone's memory *
[R 3.3.14 - II]	The application should load the user's data within 2s of the request
[R 3.3.15 - III]	The application should be available on iOS, Android, and desktops via a framework to optimize time on the development and accessibility to user
[R 3.3.16 - III]	The application should allow cloud service for data storage scalability
[R 3.3.17 - III]	The application should require a login authentication to protect user information

Table 8 A List of User Interface Requirements

Requirement ID	Data Transmission Requirement Description
[R 3.3.18 - I]	The software should consistently receive data packets from the microcontroller
[R 3.3.19 - I]	The emulation of the phone should receive data packets via serial port
[R 3.3.20 - II]	The application should obtain data within 4m of distance via bluetooth [8] *
[R 3.3.21 - II]	The maximum latency between receiving and displaying data should be 1s *
[R 3.3.22 - III]	The data should be transmitted over Wi-Fi to increase device coverage
[R 3.3.23 - III]	The maximum latency between receiving and displaying data should be 0.1s

Table 9 A List of Data Transmission Requirements

Requirement ID	Software Testing Requirement Description
[R 3.3.24 - I]	The software should receive data at a consistent sampling rate
[R 3.3.25 - I]	The received data should be consistent to ensure the precision of the device
[R 3.3.26 - I]	The numerical output should match the received data values
[R 3.3.27 - I]	White box testing should be performed by at least 2 team members
[R 3.3.28 - II]	All functionalities should be operational before hardware integration
[R 3.3.29 - II]	All functionalities should be operational after hardware integration
[R 3.3.30 - II]	The device should be able to establish and maintain a stable bluetooth connection in stress tests

[R 3.3.31 - II]	The error tolerance for colour mapping should not exceed 1% (Appendix B)
[R 3.3.32 - II]	Sensor positions should be accurately represented on the application's UI
[R 3.3.33 - II]	Black box testing should be conducted on software components to verify functional requirements are correctly implemented
[R 3.3.34 - II]	Stress testing by placing weights (1kg – 5kg) on the device while it transmits the data to the application for 24+ hours
[R 3.3.35 - II]	Regression testing should be performed when new features are added to the application to check if the new code affects more than intended
[R 3.3.36 - III]	The application should be tested by intended end-users for user feedback

Table 10 A List of Software Testing Requirements

3.4 Miscellaneous Requirements

The following table outlines other miscellaneous requirements of M-Brace that need to be achieved for each development phase.

Requirement ID	Miscellaneous Requirement Description
[R 3.4.1 - II]	The brace should not strain, compress, or discomfort the user's wrist and hand
[R 3.4.2 - III]	The product should have clear instructions on how to wear the brace correctly
[R 3.4.3 - III]	The brace should have a removable electronic component pouch to separate the electric components from the fabric to allow users to wash the brace
[R 3.4.4 - III]	The product should come with clear instructions on how to separate the electrical component pouch from the brace
[R 3.4.5 - III]	The brace should have labels for the user to put back the electrical component pouch correctly
[R 3.4.6 - III]	The retail price of the device should cost no more than $300 [9]

Table 11 A List of Miscellaneous Requirements

4.0 Engineering Standards

Standards from professional organizations provide the assurance of quality and reliability of electronics. M-Brace will be designed to meet various engineering standards published by the IEEE [10], the IEC [11], the ISO [12], and the CSA Group [13] to ensure performance and safety. Engineering standards taken into account include hardware, software, power standards and safety regulations for wired and wireless wearables. M-Brace is not intended to be a biomedical product and is not designed for medical application; however, medical standards are also reviewed because ChronoTech Systems plans to design for medical purposes in the future.

Standard ID	Description of Engineering Standards
IEC 60950-1	Safety standard of battery-powered information technology equipment with a rated voltage not exceeding 600V
IEC 61508	Standard for functional safety of electronic safety-related systems
IEC 62133	Standard for batteries in portable applications/lithium battery safety testing
IEEE 802.15	Standard for bluetooth communication
IEEE 1074	Standard for developing a software project life cycle process
IEEE 1451	Standard for smart transducer interface for sensors and actuators
IEEE 2700	Standard for sensor performance parameter definitions
IEEE 29148	Standard for systems and software engineering requirements
IEEE P360	Standard for wearable consumer electronic devices
ISO 9001:2015	Standard for customers to receive consistent, excellent quality products

Table 12 A List of Engineering Standards

Standard ID	Description of Medical Standards
IEC 60601-2-49	Medical electrical equipment standard – requirements for the basic safety and essential performance of multifunction patient monitoring equipment
IEC 62304	Standard for medical device software life cycle process
IEC 62366	Standard for application of usability engineering to medical devices
IEEE 11073	Standard for personal health/point-of-care medical device communication
ISO 80001	Standard for risk management of safety, effectiveness, and security in the implementation and use of connected medical devices or health software
ISO 80002	Standard for validation of medical device software quality systems

Table 13 A List of Medical Standards

5.0 Safety

The goal of M-Brace is to obtain accurate results from the sensors while still providing comfort and ease of use. Thus, safety is an essential part of the development of the device as users may wear this device during their daily activities. To produce a reliable product with all these specifications, M-Brace will satisfy the following safety requirements:

Requirement ID	Safety Requirement Description
[R 5.0.1 - I]	The current limit should not exceed 10mA to avoid shocking the user [14]
[R 5.0.2 - I]	The device's electrical connections should be contained
[R 5.0.3 - II]	The device should be free of hazardous or toxic materials and chemicals
[R 5.0.4 - II]	The brace and its electrical components should not have sharp edges
[R 5.0.5 - II]	The device should have a thermal control component to reduce overheating and prevent risks of burns to user
[R 5.0.6 - II]	The device should shut down within 1ms with a mechanical switch [15]
[R 5.0.7 - II]	The hardware should be enclosed in a rigid plastic case to restrict the user's access to any crucial electronic components
[R 5.0.8 - III]	The fabric of the brace should consist of allergen-free material
[R 5.0.9 - III]	The brace should be water resistant to eliminate risks of electric shock

Table 14 A List of Safety Requirements

6.0 Sustainability

At ChronoTech Systems, minimizing the company's ecological footprint is an important element in designing our products. In order to develop wearable technology, it is essential that our company follows the Cradle-to-Cradle (C2C) design to ensure our products will not consist of harmful materials or chemicals to our users and the environment [13]. This methodology to design products and systems aims to minimize waste and encourage the reuse of materials [16].

Our company will also follow the guidelines of managing the EOL of our devices from the Canadian Standards Association (CSA). The CSA code under Life Cycle Assessment offers a guideline to recycle a range of EOL products [17]. From the moment users obtain our products and until the end of the product's lifetime, our company will prioritize that our devices can be easily taken apart for recycling.

ChronoTech Systems aims to use these approaches throughout the development of M-Brace in order to design a sustainable device and also encourage other designers in the industry to aim for these standards.

The proof-of-concept version of M-Brace will only consist of a few electronic parts. Those parts are an Arduino Uno R3, solid core wiring, resistors, fabric, and the sensors. All these components can be disassembled, reused, or recycled. A more compact microcontroller will be used in the prototype. The prototype version will also have a PCB, a rechargeable battery, sensors, and fabric. The microcontroller and sensors can be reused in future projects. For the rechargeable batteries, it reduces the number of disposable batteries and thus, provides better sustainability. After the completion of the prototype, it can also be taken apart and reused in other projects or be recycled through Call2Recycle, a North American wide program to recycle all types of batteries and portable electronic devices [18]. As PCBs contain various metals, the component should not be disposed in a landfill. Many areas in North America offer a local technology-recycling center to properly separate and take care of PCBs and other electronic recycling programs [19]. As for the fabrics needed to put together the brace, they can be reused as a stylish glove or recycled in accordance to CSA's guidelines for EOL textiles [17]. As M-Brace progresses into mass production, ChronoTech Systems will ensure that the materials used to build the final product can be disassembled for easy recycling for the users.

ChronoTech Systems is committed to minimizing waste in our products and our impact on the environment while still providing a comfortable and reliable product. By incorporating C2C design and CSA standards, our company hopes that our users will appreciate the level of quality we set for our products, as well as to encourage others to aim for more sustainable solutions.

7.0 Conclusion

M-Brace will be a comfortable and effective device that allows athletes to control further progression of CTS without restricting their ability to play sports. It is easy to forget to take breaks or to do symptom preventative exercises and M-Brace is a solution that could help monitor the user's hand behaviour. ChronoTech System hopes the lightweight and practical design of M-Brace will encourage users to wear the brace regularly with minimal discomfort. The user will be able to easily analyze and monitor their gripping habits and their hand and wrist postures when playing sports as the product incorporates wireless mobile features. The device will also measure variances in the pressure applied to the tendons and nerves surrounding the median nerve. Excessive pressure exerted on the median nerve can lead to the gradual development of CTS; therefore, M-Brace will include features that alert users of their current condition if an unhealthy amount of tension is detected.

This document has covered the system overview, device requirements, engineering standards, product sustainability, and safety regulations for M-Brace. The specifications define the expected capabilities and requirements of the M-Brace device at the proof of concept, prototype, and final product phases. The proof of concept will be delivered by April 9, 2018 and a prototype will be delivered by August 3, 2018. The final product will be further customized for medical use in the future. The user's safety is top priority and the product will be designed to meet power regulations and other risk managements specified by the standards of IEC, IEEE, and ISO. During the production of M-Brace, ChronoTech Systems aims to follow the CSA guidelines to create a brace that will minimize environmental waste. Our company plans to utilize the functional requirements proposed for each stage of the project in this document to deliver a safe, reliable, and user-friendly product with an ergonomic design and sustainable materials.

8.0 References

[1] O. Jones, “The Median Nerve,” *TeachMeAnatomy*, 27-Dec-2017. [Online]. Available: http://teachmeanatomy.info/upper-limb/nerves/the-median-nerve/. [Accessed: 31-Jan-2018].

[2] “Pinched Median Nerve,” *mayoclinic.org*, 2017. https://www.mayoclinic.org/pinched-median-nerve/img-20006136. [Accessed: 31-Jan-2018].

[3] N. Hamilton, W. Weimar, and K. Luttgens, *Joint Range of Motion*. The McGraw-Hill Companies, Inc., 2012

[4] “DonJoy Boomerang Wrist Brace,” Donjoy Boomerang Wrist Brace | The Brace Shop. [Online]. Available: https://www.braceshop.com/product/donjoy-boomerang-wrist-brace. [Accessed: 31-Jan-2018].

[5] A. Industries, “Premium Female/Female Jumper Wires - 20 x 6" (150mm),” *adafruit industries blog*. [Online]. Available: https://www.adafruit.com/product/1950. [Accessed: 16-Feb-2018].

[6] J. W, “Average Wrist Size For Men & Women - The Ultimate Bracelet Wrist Size Guide,” *Wbracelet Exclusive Jewelry*, 31-Jul-2017. [Online]. Available: https://wbracelet.com/average-wrist-size-men-women-ultimate-bracelet-wrist-size-guide/. [Accessed: 21-Feb-2018].

[7] A. Industries, “Stainless Thin Conductive Yarn / Thick Conductive Thread - 30 ft,” *adafruit industries blog*. [Online]. Available: https://www.adafruit.com/product/603. [Accessed: 9-Feb-2018].

[8] J. Wright, "Dispelling Common Bluetooth Misconceptions," *Sans Technology Institute*, fig. 1, 2015. [Online]. Available: https://www.sans.edu/cyber-research/security-laboratory/article/bluetooth. [Accessed: 9-Feb-2018].

[9] “The SensoGlove - the first and only computerized golf,” *SensoGlove*. [Online]. Available: http://www.sensoglove.com/en/. [Accessed: 30-Jan-2018].

[10] “Browse Standards by Topic,” *IEEE Standards Association*. [Online]. Available: https://standards.ieee.org/findstds/standard/. [Accessed: 16-Feb-2018].

[11] “List of International Electrotechnical Commission standards,” *Wikipedia*, 05-Feb-2018. [Online]. Available: https://en.wikipedia.org/wiki/List_of_International_Electrotechnical_Commission_standard. [Accessed: 14-Feb-2018].

[12] “Standards catalogue,” *International Organization for Standardization*, 29-Aug-2017. [Online]. Available: https://www.iso.org/standards-catalogue/browse-by-ics.html. [Accessed: 14-Feb-2018].

[13] “Cradle to Cradle Certified™ Banned List of Chemicals,” *Cradle to Cradle Products Innovation Institute*. [Online]. Available: http://www.c2ccertified.org/resources/detail/cradle-to-cradle-certified-banned-list-of-chemicals. [Accessed: 16-Feb-2018].

[14] P. Giovinazzo, “The Fatal Current,” *Electrical Safety: The Fatal Current*, Feb-1987. [Online]. Available: https://www.physics.ohio-state.edu/~p616/safety/fatal_current.html. [Accessed: 14-Feb-2018].
[15] “Mechanical Relay Primer,” *Phidgets*. [Online]. Available: https://www.phidgets.com/docs/Mechanical_Relay_Primer#Switching_Speed_and_High-Frequency_Switching. [Accessed: 14-Feb-2018].
[16] W. McDonough and M. Braungart, *Cradle to cradle: remaking the way we make things.* New York: North Point Press, 2002.
[17] “SPE-890-15 - A Guideline for accountable management of end-of-life materials,” *ShopCSA*, 2015. [Online]. Available: http://shop.csa.ca/en/canada/life-cycle-assessment/spe-890-15/invt/27038462015. [Accessed: 12-Feb-2018].
[18] “Recycle Your Batteries,” *Call2Recycle®*. [Online]. Available: https://www.call2recycle.ca/. [Accessed: 12-Feb-2018].
[19] N. Faubert, “PCB materials: Recycle, reuse, dispose?” *EDN Network*, 13-Dec-2013. [Online]. Available: https://www.edn.com/electronics-blogs/all-aboard-/4426020/PCB-materials--Recycle--reuse--dispose-. [Accessed: 12-Feb-2018].
[20] “Flexor Carpi Radialis Muscle,” *Wikipedia*, 11-Feb-2018. [Online]. Available: https://en.wikipedia.org/wiki/Flexor_carpi_radialis_muscle. [Accessed: 16-Feb-2018].
[21] “Polypro Fingerless Gloves,” *Kathmandu* 2015. [Online]. Available: https://www.kathmandu.co.nz/polypro-fingerless-gloves.html. [Accessed: 16-Feb-2018].
[22] “Metacarpophalangeal Joint,” *Wikipedia*, 11-Feb-2018. [Online]. Available: https://en.wikipedia.org/wiki/Metacarpophalangeal_joint. [Accessed: 16-Feb-2018].
[23] ”FSR Sensor Datasheet,” *Biosignal Plux*, 24-Apr-2015. [Online]. Available: http://biosignalsplux.com/datasheets/FSR_Sensor_Datasheet.pdf. [Accessed: 17-Feb-2018].
[24] *Interlink Electronics*, 2014. [Online]. Available: https://www.digikey.ca/product-detail/en/interlink-electronics/30-49649/1027-1000-ND/2476465. [Accessed: 17-Feb-2018].
[25] *Interlink Electronics*, 2014. [Online]. Available: https://www.digikey.ca/product-detail/en/interlink-electronics/30-81794/1027-1001-ND/2476468. [Accessed: 17-Feb-2018].
[26] *Interlink Electronics*, 2014. [Online]. Available: https://www.digikey.ca/product-detail/en/interlink-electronics/30-61710/1027-1003-ND/2476472. [Accessed: 17-Feb-2018].
[27] “TPE-500 - Round Force Sensing Resistor - Short Tail,” *Tangio Printed Electronics*. [Online]. Available: https://tangio.co/products/7mm-round-force-sensing-resistor-shunt-mode. [Accessed: 21-Feb-2018].
[28] “TPE-501 - Round Force Sensing Resistor - Long Tail,” *Tangio Printed Electronics*. [Online]. Available: https://tangio.co/products/7mm-round-force-sensing-resistor-shunt-mode-1. [Accessed: 21-Feb-2018].

[29] “TPE-503 - Round Force Sensing Resistor - Long Tail,” *Tangio Printed Electronics*. [Online]. Available: https://tangio.co/products/13mm-round-force-sensing-resistor-shunt-mode. [Accessed: 21-Feb-2018].
[30] “FlexiForce Standard Model A401,” *Tekscan*, 07-Aug-2017. [Online]. Available: https://www.tekscan.com/products-solutions/force-sensors/a401. [Accessed: 17-Feb-2018].
[31] “FlexiForce Standard Model A201,” *Tekscan*, 07-Aug-2017. [Online]. Available: https://www.tekscan.com/products-solutions/force-sensors/a201. [Accessed: 17-Feb-2018].

9.0 Appendix A

The following list is the deliverables for the proof of concept by April 9, 2018:

1. The wearable device should start 5cm below the wrist, at the flexor carpi radialis – as shown in Figure 8.

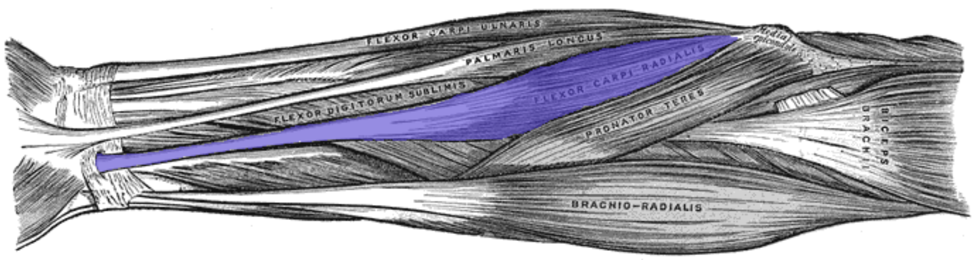

Figure 8 Flexor Carpi Radialis (shown in blue) [20]

2. The wearable device should stop at the proximal phalanges, similar to the generic fingerless glove shown in Figure 21.
3. The suitable flexible sensors should be chosen for the wearable module.
4. The circuit should be constructed on a breadboard.
5. The sensors should be connected to an Arduino Uno - R3 board via analog ports.
6. The device should be powered by the serial port on the Arduino board.

Figure 9 Generic Glove Design [21]

7. The circuit should have an LED that indicates the device's status.
8. The device should send data from each sensor and graph the results.
9. The data transmission should be done via serial port.
10. The companion application should run on an emulated version of iOS 10 and later.
11. The application should plot the sensor data to their respective graphs on shared axes.
12. The application should display the numerical values of the received data on the iOS.

10.0 Appendix B

The following section contains the justification for the requirement specifications:

[R 3.1.3 - II]
The brace should not pass the distal transverse arch

The distal transverse arch is formed by the metacarpophalangeal (MCP) joints, as illustrated in red in Figure 10. As the thumb and the four fingers fold at the MCP joints, any fabric or material on the distal transverse arch would impede movements, such as gripping on an object. Therefore, the wrist brace, designed in the prototype development phase, will not extend beyond the distal transverse arch to minimize mobility restrictions.

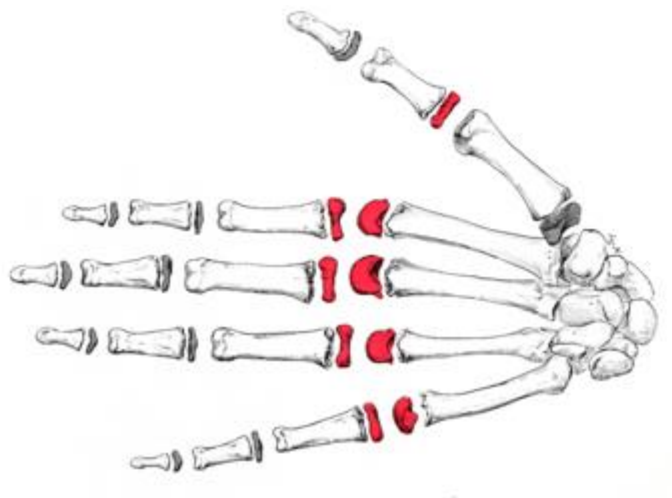

Figure 10 Metacarpophalangeal Joint [22]

[R 3.2.22 - I]
The power consumption should not exceed 0.05W

Due to the safety requirement [R 5.0.1 - I], the current limit is set to be less than 10mA. During the proof of concept phase, the team will be testing the feasibility of the product with an Arduino UNO, which outputs either 3.3V or 5V voltage. Thus, the maximum input voltage should be 5V as listed under the power requirement [R 3.2.21 - I].

To find the maximum power required for the device, the team follows Ohm's Law:

$$P_{max} = VI = (5V)(0.010A) = 0.05W$$

[R 3.2.30 - I]
Sensor should not exceed ±3% single part force repeatability

The following table is a list of available FSRs listed by manufacturers, the corresponding part number, and the provided single part force repeatability.

Manufacturer	Manufacturer Part Number	Single Part Force Repeatability
Biosignals Plux	FSR 24042015 [23]	±2.5%
Interlink Electronics	30-49649 [24]	±2%
Interlink Electronics	30-81794 [25]	±2%
Interlink Electronics	30-61710 [26]	±2%
Tangio Printed Electronics	TPE - 500 [27]	±2%
Tangio Printed Electronics	TPE - 501 [28]	±2%
Tangio Printed Electronics	TPE - 503 [29]	±2%
Tekscan	FlexiForce A401 [30]	±2.5%
Tekscan	FlexiForce A201 [31]	±2.5%

Table 15 A List of Sensors and Its Corresponding Single Part Force Repeatability

[R 3.3.31 - II]
The error tolerance for colour mapping should not exceed 1%

Each colour pixel displayed contains 32 bits - 8 bits for red component, 8 bits for green component, and 8 bits for blue components. Thus, each component would have integer value ranging from 0 to 255.

The team will choose a suitable resistor value in the voltage divider, where the sensor would provide an analog input range greater than 255. Then, the sensor value would be mapped to a pixel colour by linear interpolation. This mapping method would create decimals; however, each other component must be rounded or truncated to an integer. The round-off error from a floating point to an integer would be $-0.5 < \varepsilon < 0.5$, whereas the truncation error would be $-1 < \varepsilon < 1$.