January 31, 2018

Dr. Andrew Rawicz
School of Engineering Science
Simon Fraser University
Burnaby, British Columbia
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Re: ENSC 405W Project Proposal for M-Brace

Dear Dr. Rawicz:

The following proposal for *M-Brace* by ChronoTech Systems is an overview of our Capstone project which was prepared as a requirement for the course ENSC 405W. Our goal is to help people who suffer from preliminary 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 will provide information about the M-Brace prototype, including potential risks and benefits associated with the device. It outlines the current market and competition, budget and schedule.

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 proposal 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

CHRONOTECH SYSTEMS

Project Proposal for *M-Brace*

Project Team

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Submitted to

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Executive Summary

Carpal Tunnel Syndrome (CTS) is a medical condition that causes pain, numbness and weakness in the hands. CTS is caused by excessive pressure being exerted on the median nerve. Many factors can cause this pressure, including, but not limited to, obesity, pregnancy, and arthritis. ChronoTech Systems is primarily concerned with the pressure caused by repetitive motion and improper hand posture.

When people are unaware of their gripping habits, they are prone to developing CTS and there are very few solutions for fixing the disorder. There are relatively cheap options, like wrist splinting, but they are only effective in the early stages of CTS. Although surgery and medication do exist, these treatments are only temporary methods for controlling the numbness and pain caused by CTS.

ChronoTech Systems proposes to develop a device that will assist in the treatment during the early stages of carpal tunnel syndrome by monitoring the behaviour of the user's hands. The device will be lightweight and comfortable to avoid loss in productivity. It will have sensors collecting data at key points on the user's hand to determine if pressure is being applied to the median nerve. The user will have the option of sending the data to an application on their smartphone or their personal computer. The application will then process and display the data in a visually intuitive form. The user also has the option to set reminders, either at regular intervals or specific times, to take breaks and do stretches that help with carpal tunnel syndrome. The primary demographic of M-Brace is athletes because it is easier to analyze their biomechanics.

ChronoTech Systems is made of up four talented undergraduate engineering students with a wide range of skills. Each member has their own specialty that makes them integral parts in the development of M-Brace. The team has experience in mechanical and structural design, low level programming, circuit design and analysis. The Chief Executive Officer also has many connections in the medical field to act as consultants while researching and designing M-Brace.

The M-Brace device will be seen through the research, design and assembly through the course of an eight-month period beginning in January 2018. The team has set specific milestones and due dates in order to spread the workload. M-Brace has a tentative budget of about $205. ChronoTech Systems will obtain funding from the Engineering Science Student Endowment Fund, the IEEE Canadian Foundation Special Grants, and other resources.

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1.0 Introduction

Carpal tunnel syndrome (CTS) is a common disorder that causes pain and loss of strength in the hand due to the compression of the median nerve. Carpal Tunnel Syndrome is commonly diagnosed in people who perform routine activities that require regular repetitive motion of the hand and wrist. Due to the repetition of sudden flexion and extension movements with their hands, many workers in the garment, construction, art, and sports industry are affected by CTS [1]. As technology and computing devices become a mainstream integration into society, there is also an increased percentage of people at risk of developing CTS by using electronic devices for extended periods of time.

The current treatments for CTS are designed to manage the chronic pain, but do not fix the disorder. These treatments include surgery, pain medication, wrist splints, myofascial release massages, and injections of anti-inflammatory steroids. Some of these interventions are intrusive methods for treating the symptoms of CTS and the effectiveness of these treatments varies. Currently there is insufficient education and motivation for preventing the progression of CTS and the treatment for the symptoms are not effective enough. The idea for this project was influenced by personal connections with patients who are suffering from carpal tunnel syndrome and did not have a good understanding of methods that could help prevent the development of CTS.

To minimize the risks of the development of the CTS disorder that reduces workplace productivity and the quality of life, hand stretching-based exercises are advised by experts. However, the motivation to exercise decreases easily and habits of repeatedly using hands without breaks are hard to correct. The product is designed to remind the user to take breaks, to exercise, and to be aware of the amount of pressure they are applying to their palm and wrist. The product design resembles the shape of a wrist brace but is made with flexible, lightweight and breathable material to allow unrestricted movement of the hand. With a wireless, compact and ergonomic product design, M-Brace will effectively encourage users to comfortably monitor their daily activities and succeed in the market as a tool that aids in the prevention of developing severe carpal tunnel syndrome.

The following proposal will describe in detail the design features, target users, risks and advantages of the product, M-Brace. Comparison with the current treatments and products available in the market is used to highlight the benefits of M-Brace. An estimated timeline and budget is also included. The company profile emphasizes the skills and experience each member will bring to the project.

2.0 Market and Competition

2.1 Medical Background

Carpal Tunnel Syndrome is a medical condition caused by pressure exerted on the median nerve. The median nerve starts at the root of the neck 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 [2]. The condition is often the result of factors that reduce space for the nerve in the carpal tunnel. Obesity, pregnancy, diabetes, arthritis and tendon inflammation all contribute to this compression [3]. Common professions have ingrained unhealthy habits into humans that contribute to CTS. Workers who perform repetitive motion are at a higher risk. Typing on keyboards for long periods of time, gripping golf clubs, holding a paintbrush are all examples of repetitive motion that can apply pressure on the median nerve. Those with a family history of CTS are more likely to develop the condition. Studies have determined that women are three times more likely to develop CTS than men, and this probability increases during menopause [4].

People who suffer from CTS experience numbness, pain, loss of dexterity, and in extreme cases, permanent nerve damage. Often, patients are informed they have CTS when the symptoms have already become severe. Those who exhibit the more classic symptoms of CTS may need surgery. Even if the surgery is successful, the patient may still experience residual symptoms [5]. Approximately 75-90% of the patients who underwent a surgical intervention will continue to experience pain and paraesthesias [6]. If the condition is caught early, nonsurgical methods such as splinting, non-steroidal anti-inflammatory drugs (NSAIDs), corticosteroids, and stretching can be used to reverse the damage. Splinting is the act of securing the wrist in the proper posture to prevent pressure from being applied on the median nerve. This method is most effective when the patient is sleeping because they are not performing activities that require any mobility and dexterity. This, of course, is impractical in the workplace. NSAIDs are drugs like Advil and Motrin IB; however, there is not much evidence that suggests the medication can fully treat CTS. Corticosteroids help with the inflammation and swelling around the median nerve but are usually administered via injection because oral corticosteroids are not as effective for treating the CTS symptoms [7]. Periodically stretching the hands is one of the most effective and the cheapest method to improve CTS. Unfortunately, most people neglect taking breaks from their daily activities to perform stretches that help counter the symptoms of the disorder.

2.2 Brief Product Overview

M-Brace is a monitoring device that the user wears throughout the day. Sensors on the device collect data from key points on the user's hand to calculate how much pressure is being exerted onto the median nerve. The device comes with a downloadable phone application that allows the user to set reminders, either at specific times or in intervals, to take a break and stretch their hand. The application allows the user to visualize the points on their hand that are experiencing constant pressure and in response, suggest suitable counter-movements to alleviate or prevent soreness.

2.3 Market

As of right now, ChronoTech Systems is solely focused on helping professional athletes and sports enthusiasts; however, there is a much wider demographic that would benefit with M-Brace. Those people with daily routines that require any amount of pressure to the wrist can use M-Brace to monitor their habits. Artists, musicians, and textile workers are prime examples of professionals who require grip strength and dexterity but are at a high risk of developing CTS by the very nature of their jobs.

Eventually, ChronoTech Systems would like to work with more medical experts to help improve the accuracy of the device to aid in research on other medical conditions like arthritis and gout. ChronoTech Systems would like to help patients suffering from chronic pains and monitor the development of their conditions with later iterations of M-Brace.

2.4 Competition

Some of the products on the market are listed as follows.

- **StringyBall**

  StringyBall is a stress ball on a string, as shown in Figure 1. The user can tether this ball to their wrist so that they can perform hand exercises on the go without fear of losing the ball. However, this only allows the user to exercise their hand for as long as they wear the product. Additionally, a ball tied to one's wrist at all times would be inconvenient and impractical.

Figure 1 Illustration of StringyBall [8]

➔ **Wrist Splinting**

Wrist splints are common devices used to secure the user's wrist in ideal positions to limit the pressure applied to the wrist and the median nerve. Companies like Tensor and DJO Global produce affordable and effective splints. An illustration of the Tensor™ Splint Wrist Brace is shown in Figure 2. Unfortunately, the wrist splints' main feature is also a major drawback. Wrist splints severely reduce hand mobility; therefore, are recommended to be used while sleeping.

Figure 2 Tensor™ Splint Wrist Brace [9]

➔ **SensoGlove**

SensoGlove is a cabretta leather glove with a built-in computer that constantly measures the grip pressure of the user, as shown in Figure 3. The device aims to teach its users how to properly hold a golf club to optimize their swings. The product resembles a regular golf glove so there is not much to grow accustomed to if the user already wears golf gloves when playing. However, SensoGlove has no other uses off the golf course.

Figure 3 Illustration of SensoGlove [10]

➔ **Grip™ System**

Grip™ is a device developed by Tekscan that measures static and dynamic pressures from grasping objects, as shown in Figure 4. It measures pressure applied on the human hand and fingers to assess comfort, design, and ergonomics. Some applications for this device include studying CTS and repetitive motion syndrome, gathering information to develop more ergonomically sound products, and analyzing the human hold on various objects. Both tethered and wireless models are available, and data can be transferred to a PC regardless of the connection type. If the user is not within 100m of their PC, the collected statistics can be sent to a dedicated data logger and transferred to a PC at a later time. The Grip system, as a whole, is not designed for the average user. It is relatively bulky and is mainly used for research and development.

Figure 4 Illustration of Grip™ System [11]

3.0 Project Details

3.1 Product Design Requirement

ChronoTech Systems aims to assist users who are at risk of developing chronic pains. The main target groups of M-Brace are sports enthusiasts and professionals who are required to do repetitive movements throughout the day. The product design requirements have been divided into two main categories.

Hardware Requirements

- **Comfortability**
  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, and the fabric chosen is breathable.

- **Adaptability**
  M-Brace resembles a wrist brace, where the wrist and half of the palm would be covered. Velcro is used to allow wrist adjustments. The overall design is similar to the DonJoy Boomerang Wrist Brace as shown in Figure 5. The prototype for M-Brace is designed to fit small to medium adult wrist sizes, ranging from 6 to 8 inches in width.

Figure 5 Wrist Brace Design [12]

- **Safety**
  M-Brace requires low voltage to be applied to the sensors and the microcontroller. For user safety, a removable LiPo battery is required to power the physical module and no landline power consumption is used. The microcontroller is soldered onto a PCB with a power isolation circuit and a voltage regulator. The microcontroller unit and its battery are stored in an enclosed plastic box. Thin wires connect the microcontroller unit and the sensors, which are located in between two layers of fabric.

- **Affordability**
  M-Brace is marketed for the general public who are at risk for CTS due to sports related activities; therefore, ChronoTech Systems ensures that the product has optimal efficiency and only contains crucial components to minimize fabrication cost.

Software/Firmware Requirements

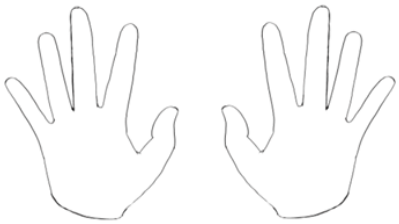

Figure 6 UI Hand Outline

➔ **Visualization**

M-Brace will be paired to a phone application on both Android and IOS interface. There will be a visual feedback to the pressures applied on different sensors. The location of the sensors on the screen outlining of both hands - as shown 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: green represents no pressure to an acceptable amount of pressure applied, and red represents an excess amount of pressure applied.

➔ **Personalization**

M-Brace allows the user to choose between two notification settings. The recommended setting allows instant feedback when too much tension is applied. This alerts the user to adjust their grip on an item or to correct their posture. If the user must apply extra pressure over an extended period of time, they may choose the second setting, which allows them to set a reminder to relax and practice counter-movement exercises.

➔ **Reliability**

As a monitoring device, M-Brace analyzes real-time sensor data to provide accurate feedback. The product is designed to have a minimum of 30 Hz of sampling frequency and transmitting frequency between the wearable and the user interface to achieve the first notification setting.

3.2 Scope

M-Brace is a wearable device that monitors the amount of pressure exerted to the user's median nerve. The high-level design for the product is shown in Figure 7's flow diagram.

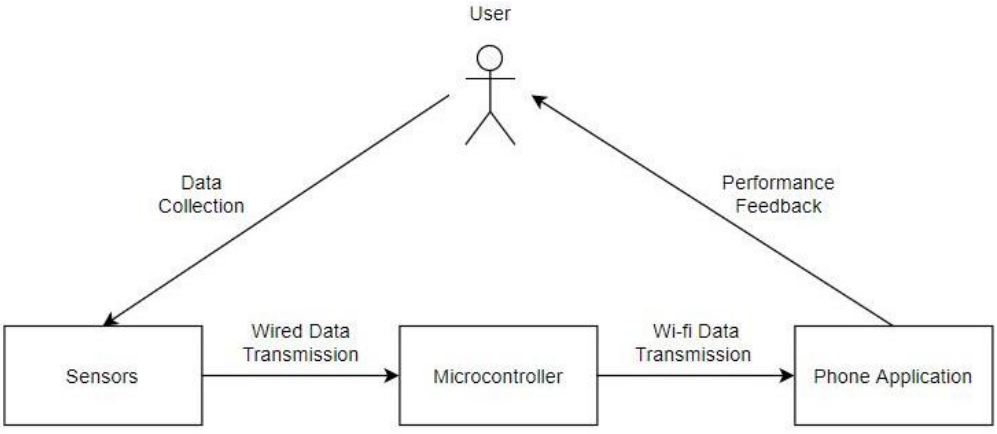

Figure 7 High-level Flow Diagram of M-Brace

The M-Brace module has embedded sensors to collect data from key points of the wrist and palm. The sensors are wired to the microcontroller. The microcontroller powers the sensors and enables data collection and sensor data transmission. After data collection is completed, the microcontroller transmits the data to the phone application wirelessly for further analysis.

ChronoTech Systems promises to produce a proof of concept by the end of March 2018. The main tasks would include:

- ➔ Choosing the suitable sensors, microcontroller, and fabric for the final product
- ➔ Designing the basic circuitry for the microcontroller unit
- ➔ Allowing wired data transmission between the microcontroller and the user interface
- ➔ Completing the basic user interface for PC

ChronoTech Systems aims to develop a feasible product for sports use by the end of August 2018. The main objectives would include:

- ➔ Embedding six flexible sensors inside the M-Brace module
- ➔ Allowing wireless data transmission between the microcontroller and the user interface
- ➔ Minimizing the size of the microcontroller unit
- ➔ Fabricating the physical product
- ➔ Completing the user interface for both IOS and Android

Further analysis with medical professionals is needed to improve on the data reliability and accuracy for medical applications.

3.3 Benefits

ChronoTech Systems envisions a device to assist people who are required to do repetitive hand movements during their daily routine. The main purpose of M-Brace is to remind users to take frequent short breaks, to encourage users to exercise with counter-movements, and to be aware of the user's pressure exerted on the median nerve. Similar to training supersets in the gym, the trainee can complete a biceps curl followed by a triceps extension; 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 UI would recommend the user to extend the wrist after a certain extended period.

This product can be further improved upon for a vast range of potentials, such as a medical device for people who are at risk for carpal tunnel syndrome. It can allow users to monitor their condition and to prevent further development of the issue.

3.4 Risk Assessment

ChronoTech Systems has evaluated the risks that the team may potentially encounter during the development of M-Brace. A risk severity scale is used to categorize the risks by severity:

- **Critical**
  If the risk event occurs, the potential failure could result in having one or more critical objectives not achieved and/or result in requiring rework on the operation.
- **Significant**
  If the risk event occurs, the potential failure could result in achieving one or more critical objectives with minimum satisfaction and/or result in disruption to subsequent operations.
- **Minimal**
  If the risk event occurs, the potential failure could result in achieving one or more critical objectives with slight dissatisfaction.

The potential risks are listed from the most critical to the least critical as shown in Table 1.

Risk	Severity	Probability	Impact	Mitigation Strategy
Inaccurate data results	Critical	Highly Likely	Do not meet product expectation	Test with different sensors
Incorrect or non-robust module parts	Critical	Probable	Delay due to repurchasing parts	Research for parts specifications in detail
Building Limitation	Critical	Probable	No physical product can be fabricated	Test with a variety of module materials
Integrate failures	Critical	Probable	Fail to transmit data between the module and user interface	Test the integration with dummy data at the early stage of develop
Incomplete testing	Significant	Unlikely	Delay in the subsequent process	Allow extra time
Delayed parts shipment	Significant	Probable	Delay in prototype built-time	Order parts early
Overspending	Minimal	Probable	Not enough budget to purchase extra parts	Over budget

Table 1 Risk Assessment for M-Brace

3.5 Sources of Information

To analyze and research carpal tunnel syndrome, information will be obtained from various sources such as the Simon Fraser University (SFU) kinesiology and engineering faculties, the library, the internet, patients diagnosed with CTS, as well as a team member's colleagues from the medical research field.

Dr. Andy Hoffer, a kinesiology professor at SFU, has provided us with some insight on the basics of carpal tunnel syndrome as well as the current market interest on preventing CTS in the golfing industry. Some undergraduate students in Engineering Science are also knowledgeable about biomedical device requirements and can be consulted for technical inquiries. For example, Homan Lam and Julian Lo, are biomedical engineering students at SFU who have hands on experience with developing medical devices for their classes.

Both the library database of medical research papers and the Internet will be valuable resources for researching technical and medical information. Other important sources of information include the medical experts and patients in the team's network. One team member is able to contact Mr. John Colin Anthony Cruz Rey, a kinesiology graduate student at Trinity Western University, and Dr. Andre Rodriguez, the head of rheumatology at Makati Medical Center, for information regarding the human body and user ergonomics. As the project was inspired by personal connections, the team will also consult friends and family members, who are suffering from CTS, for their opinions on the user design and desired features.

4.0 Project Timeline

The project timeline for M-Brace is specified in the Figure 8 below. Each bolded task represents major portions of the project development. Beneath each major task are the subtasks for the portion. Hardware assembly and testing will begin once the parts are received. While the software phone application implementation will be developed, such as the basic GUI and data connection. Once the integration between the hardware assembly and the basic software application is complete, the testing process will proceed. The project timelines are estimated durations for each corresponding task and may take longer or shorter than expected.

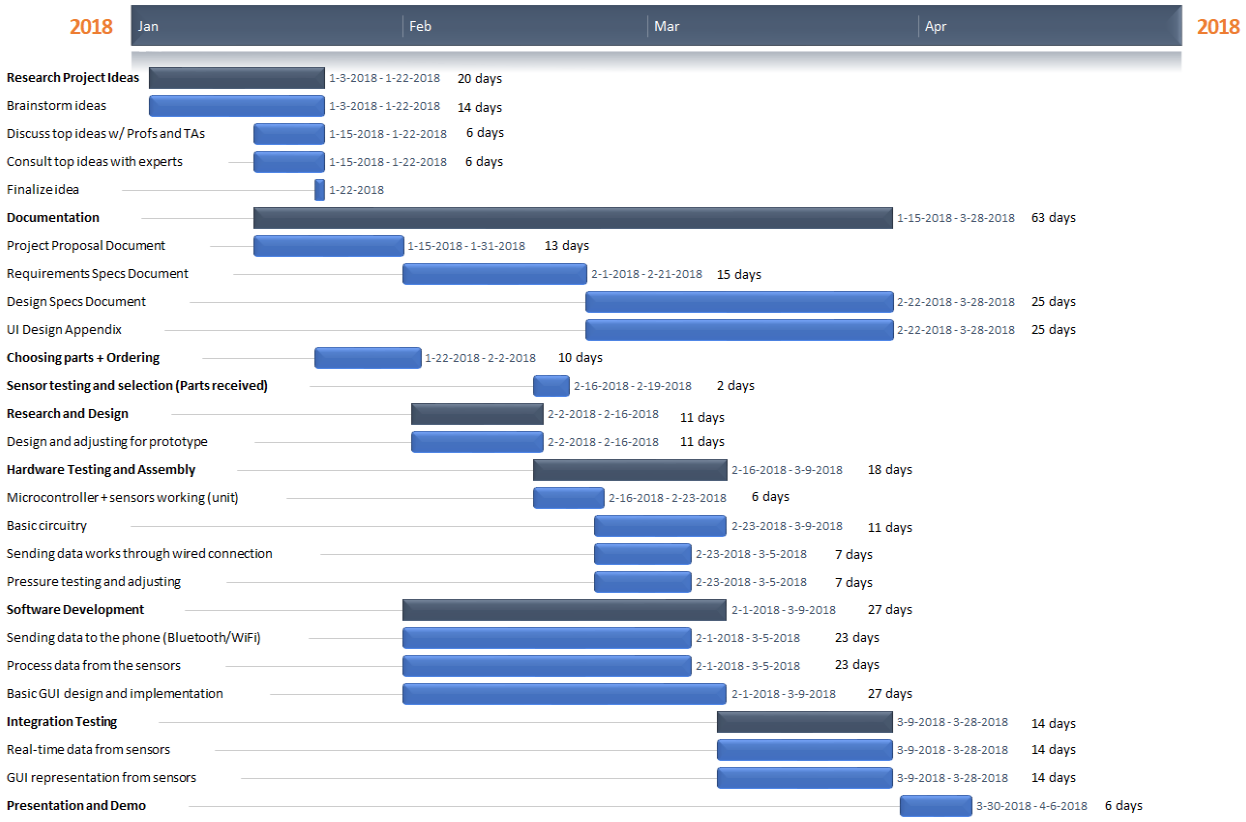

Figure 8 Gantt Chart of M-Brace

To summarize, the summarized milestone timeline for M-Brace is shown in Figure 9. It indicates the due dates of all the major documentation and the key tasks to the development of the project.

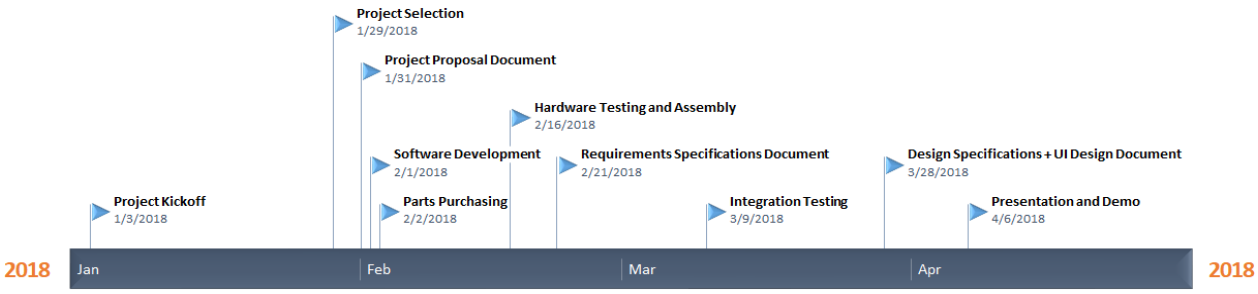

Figure 9 Milestone Timeline of M-Brace

5.0 Logistics

5.1 Budget Estimation

The outline for the cost of developing the proof-of-concept is shown in Table 2. For the first four months, the team plans to test a few sensors from different manufacturers in order to find the most suitable sensor for the final prototype. For the microcontroller, the Arduino Uno R3 board will be used to help test these sensors with the phone applications. Since the goal is to make M-Brace comfortable, the Arduino board will only be used for testing purposes and a smaller microcontroller will be used in the final prototype. Apart from the hardware components, the software tools will be free-to-use applications.

Proof-of-Concept Components	Cost (CAD)
Adafruit Industries LLC 2773	$6.76
Interlink Force Sensing Resistor 400 FSR (0.3" Circle)	$7.59
Tangio Printed Electronics TPE-500C	$6.72
Spectra Symbol Flex Sensor 2.2”	$7.95
Arduino Uno R3	$3.20
Jumper Wires	$0.00
Through-Hole Resistors	$0.00
Shipping and Handling	$10.00
Subtotal	**$42.22**
Contingency (20%)	$8.44
Grand Total	**$50.66**

Table 2 Cost for M-Brace Proof-of-Concept

The budget also considers a contingency of 20% of the subtotal to account for any other additional costs such as taxes and additional components.

Table 3 is a list of the final parts that may be required for the final prototype. At this phase of the development, it is too early to accurately calculate the budget cost for the final prototype. The table below lists the approximate prices for the corresponding components and may not reflect the actual bill of materials for the finalized device.

Final Prototype Components	Estimated Cost
Sensors x12	$100.00
Microcontroller Kit x2	$30.00
LiPo Battery x2	$15.00
Breathable Fabric (1 yard)	$10.00
Minor Electronics and Other Accessories	$50.00
Grand Total	**$205.00**

Table 3 Cost for M-Brace Prototype

5.2 Funding and Resources

To cover the funding required to build the prototype, the team will apply for the Engineering Science Student Endowment Fund (ESSEF), the IEEE Canadian Foundation Special Grants, and the Wighton Fund during the second term of the project's progression. Since the expenses are not expected to be fully covered by these funds, the remaining cost will be shared evenly by the team to ensure the development of M-Brace.

6.0 Company Overview

Randel Argel Rivera - Chief Executive Officer

Randel is a fifth-year Systems Engineering student at Simon Fraser University. He worked at Sierra Wireless Inc. for an 8-month co-op as a software validation engineer. The time spent at Sierra allowed him to develop a meticulous work ethic and the confidence to thrive in almost any work environment. He has honed his skills in Python, C++, C, and VHDL. His interests also lie in circuit analysis and structural design.

Ying Hsin Lan - Chief Technology Officer

Ying Hsin is a fifth-year Systems Engineering student at Simon Fraser University. She has gained hands-on experience with firmware during her research co-op at MENRVA lab; she had programmed Cypress microcontroller in C, designed PCB with EAGLE, and modeled parts with CAD tools to create a research prototype. As the Chief Technology Officer, her expertise in the field would be an asset.

Princess Krizia Macanlalay - Chief Financial Officer

Princess is a fifth-year student at Simon Fraser University as a Computer Engineering Major with a Computing Science Minor. She worked as a Software Test Engineer at Sierra Wireless for an eight-month co-op where she developed her software and firmware testing skills and her scripting skills for stress testing. Her role in ChronoTech Systems is to manage and plan the finances of the project as well as to contribute in the software development of M-Brace.

Michelle Ho - Chief Operating Officer

Michelle is a fifth-year Systems Engineering student at Simon Fraser University. She enjoys robotics, interactive device design, and software development. From her co-ops at Sierra Wireless and Translink, she has acquired software testing, data analysis, and scripting skills. She is also experienced with creating test plans and reports. Michelle's role will be to oversee the daily operations and product design in ChronoTech Systems.

7.0 Conclusion

Driven by the afflictions of family members with carpal tunnel syndrome, ChronoTech Systems is motivated to help people at risk of developing CTS and requiring treatments for temporary pain control. The excessive pressure exerted on the median nerve will lead to the gradual development of CTS. In the preliminary stages of CTS, the symptoms can be improved upon with treatment, exercise, and awareness. ChronoTech Systems proposes a solution to encourage symptom preventative exercises for CTS. As a lightweight and practical product that monitors and alerts the user of their hand and wrist posture, M-Brace will be beneficial for athletes.

Based on the team's research, none of the current competition can effectively warn people about their gripping habits and control further progression of CTS. ChronoTech Systems has analyzed the potential risks and benefits associated with the development of M-Brace and have proposed project milestones, timelines, and budgets with which the team is committed to achieving. With the combination of the expertise of the engineering students in the team, the feedback from patients suffering from CTS, and the guidance from medical professionals in our network, M-Brace has the potential to improve the quality of life for people suffering from CTS.

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9.0 Appendix

9.1 List of Tables

9.2 List of Figures