April 6, 2021

Dr. Craig Scratchley
School of Engineering Science
Simon Fraser University
Burnaby, BC, V5A 1S6

Re: ENSC 405W Proposal for Harp Blood Pressure Monitor

Dear Dr. Craig Scratchley,

The following document contains the proposal for the Harp Blood Pressure Monitor. Our goal is to construct a non-invasive device that can measure diastolic blood pressure continuously. The device is intended to be comfortable enough to be worn throughout the day and be usable during most daily activities.

The proposal will provide an overview of the planned project, including the scope, risk and benefits; a market analysis which discusses the competition and existing technologies; the cost estimate, including our potential sources of funding; the timeline for the project. Lastly, an introduction to our company members is also provided.

Thank you for taking the time to review our proposal for the Harp Blood Pressure Monitor. If you have any questions or concerns regarding our document, please contact Khalil Ammar, our Chief Executive Officer.

Sincerely

Khalil Ammar
Chief Executive Officer

Chiron Solutions Inc.

Project Proposal

Harp Blood Pressure Monitor

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Executive Summary

According to Statistics Canada, Hypertension, better known as High blood pressure, affects 1 in 4 Canadian adults [1]. The diagnostic plan sometimes includes at-home tests and multiple visits to the doctor for blood pressure readings, as your blood pressure can fluctuate through the course of a day. You could also be prescribed a hefty ambulatory monitor that you can carry around and will take readings at certain intervals of the day [2]. This constant monitoring allows patients to track how their daily activities affect their blood pressure and allow their doctors valuable insights into their health, which is why constant monitoring of blood pressure in hypertensive individuals is a more accurate predictor of cardiovascular events [3]. In addition to the hefty price, with current ambulatory monitors, there is a discomfort experienced by the patients due to the high cuff-pressures involved in taking a measurement, which can also affect the accuracy of the reading due to increased patient anxiety [4].

Given the prevalence of this disease, the blood pressure monitoring market is very big. However, it is currently dominated by cuff-based blood pressure monitors which have numerous shortcomings[5]. The current products are not only bulky and restrictive, but they also inflate the cuffs to an uncomfortable degree while in use. This leads to the second major drawback, which is the inability to provide the user with continuous readings of their blood pressure, which is very important for patients to help manage their hypertension better. Our product, the Harp Blood Pressure Monitor, aims to cover those shortcomings and provide users with a more seamless blood pressure measurement experience that does not hinder their daily lives while providing accurate and continuous measurements of their blood pressure to give them better insight into their health condition.

The device will be wearable and will be composed of two main subsystems: The first subsystem is a wearable hardware subsystem which will go on the user's chest and contain three sensors, namely Electrocardiogram (ECG), Seismocardiography (SCG), and Photoplethysmography (PPG) and a microcontroller with a Bluetooth module to communicate with the second subsystem. The second subsystem consists of software in the form of a mobile app that will receive the data from the wearable device, analyze it, and store and display the results to the user using various formats.

Chiron Solutions is very proud to provide the Harp Blood Pressure Monitor as an effective solution to constant and comfortable blood pressure monitoring. As a company of six motivated and skilled engineering students having experience in both the software and hardware aspects of our fields, we hope to revolutionize the Blood Pressure Monitoring with our product, the Harp Blood Pressure Monitor, which will continue to be refined in the coming months as it takes it shape as a marketable product.

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Glossary

Term	Definition
DBP (Diastolic Blood Pressure)	The lowest/minimum arterial pressure occurring each heartbeat.
ECG (Electrocardiogram)	A graph of voltage versus time of the electrical activity of the heart using electrodes placed on the skin.
PEP (Pre-Ejection Period)	The time period between the onset of left ventricular depolarization (the onset of QRS complex on electrocardiogram (ECG), and in particular the ECG Q wave when available) and the opening of the aortic valve.
PPG (Photoplethysmography)	Optical technique used to detect volumetric changes in blood in peripheral circulation
PTT (Pulse Travel/Transit Time)	The time it takes a pulse wave to travel between two arterial sites.
SBP (Systolic Blood Pressure)	The highest/maximum arterial pressure occurs in each heartbeat.
SCG (Seismocardiography)	The non-invasive measurement of accelerations in the chest wall produced by myocardial movement

Table 1: Glossary

1. Introduction

Nowadays, 1.13 billion of the population have hypertension [6]. As an effective and convenient method, blood pressure monitors have a great contribution to the prevention and treatment of hypertension. The current market is filled with a variety of manual and automatic cuff-based blood pressure monitors, including ambulatory monitors. However, the current cuff-based products on the market are facing a certain degree of inconvenience, such as requiring users to align their arms horizontally with the heart and keep still. Some users hope to have more convenient and efficient blood pressure monitors.

On the other hand, home/wearable ambulatory blood pressure monitors are still a blank in the market. With the development of technology, it is feasible to design a wearable ambulatory blood pressure monitor. Based on the need of user and feasibility of technology, Chiron solutions aim to design such a wearable ambulatory blood pressure monitor called "Harp Blood Pressure monitor"

The Harp Blood Pressure Monitor can collect medical data by fixing the sensors on the user's chest, and then transmitting it to the mobile application through a microcontroller and Bluetooth module. In this process, users can view a series of data such as blood pressure on the app at any time, and can carry out daily activities without inconvenience.

In this proposal, we will first introduce the project overview as the main part of the proposal. In the project overview, we will briefly introduce the background at the beginning. Then in section 2.2, we will introduce the scope of our product. Next, section 2.3 and section 2.4 respectively will outline the risks and benefits of developing our product. In section 3, we will analyze the current market and our competition. Following that, in section 4, we will estimate the cost associated with bringing the product to market and explore our possible sources of funding. Finally, we will present a comprehensive project plan detailing the various milestones and deliverables in the form of a Gantt chart in section 5.

2. Project Overview

2.1 Background

Hypertension and related cardiovascular diseases are an important issue of people's healthcare. Ambulatory blood pressure measurement (ABPM) plays an important role in blood pressure measurement as a predictor of risk [7].

As an effective and convenient method of prediction and monitoring, blood pressure monitors have a great contribution to the prevention and treatment of hypertension[8]. The home blood pressure measurement device has become a household necessity, which also has a large potential in the market [9]. With the development and progress of technology, the market is filled with a variety of manual and automatic cuff-based blood pressure monitors, including ambulatory monitors. On the other hand, home/wearable ambulatory blood pressure monitors are still a gap in the market. With the development of technology, it is feasible to design a wearable ambulatory blood pressure monitor[10]. In this case, our team aims to design such a wearable ambulatory blood pressure monitor.

The target of our continuous blood pressure monitoring system is to fill the gap in the current marketplace. The device will be work on your chest or hands (keep the same level of heart) and will use 3 sensors, namely, a heart rate sensor for Electrocardiogram (ECG), an accelerometer for Seismocardiography (SCG), and an oximeter pulse for Photoplethysmography (PPG) [10].The data of sensors will be then synced to our software application on the user's phone through bluetooth. After syncing, the readings will be used in the PTT-based algorithm to estimate the user's diastolic blood pressure [10]. The user can track current trends in their blood pressure, get notified of a too high or low reading or even look at historical data in the smartphone application. From cuff to cuff-less, our device can provide more long-term data with more flexibility.

2.2 Scope

The scope of Harp Blood Pressure Monitor details the design, prototype and testing of the prototype. Our engineering prototype has the following features while its appearance is shown in figure 1 and figure 2:

1. Wearable sensor module is easily placed on a patient's chest without any distractions.
2. The size of the wearable sensor module should have 110x72x7.7 mm dimensions.
3. Measure the data in real-time.
4. Transmit the raw data of ECG, SCG and PPG from wearable sensor module to mobile application using BLE.

5. Display diastolic blood pressure, Heart rate, and %SpO2 on the mobile application.
6. The blood pressure data will be displayed every 3 minutes.
7. Accurate to within +/- 5mm/Hg in reference to cuff monitors [11].
8. Store and save the final processed data on the user's phone for future medical expertise.

The data will be stored on the patient's smartphone for the first prototypes, and our team is planning to migrate the data to a dedicated database after achieving core milestones successfully.The testing of the final product will be conducted in compliance with Engineering and Safety Standards.

Furthermore, according to the left part of figure 1, the wearable sensor module consists of a few sensors:

1. The heart rate sensor (ECG) will use electrodes to collect the ECG data.
2. The oximeter pulse sensor (PPG) has a biosensor to collect the PPG data.
3. The accelerometer measures the vibration in the arteries as the SCG data through putting against the skin.
4. All three sensors provide data continuously when the integrated sensor is working.
5. All three sensors will be located around the user's chest and collect the data continuously.
6. The raw data of 3 sensors will be sent to the software application using the bluetooth module.

Then according to the right part of figure 1, the mobile application is responsible for data extraction:

1. The raw data transmitted by Bluetooth will be received by the application.
2. The data transmission will be conducted every 3 minutes.
3. The app will only support the Android platform.
4. The transmitted data will be demonstrated on the home page in real-time
5. The statistics button in the navigation tool will redirect the user to the page where the graphs with BP, PR, and %SpO2 measurements for the specific period.
6. The users will be able to choose the period to analyze the data for that specific time.

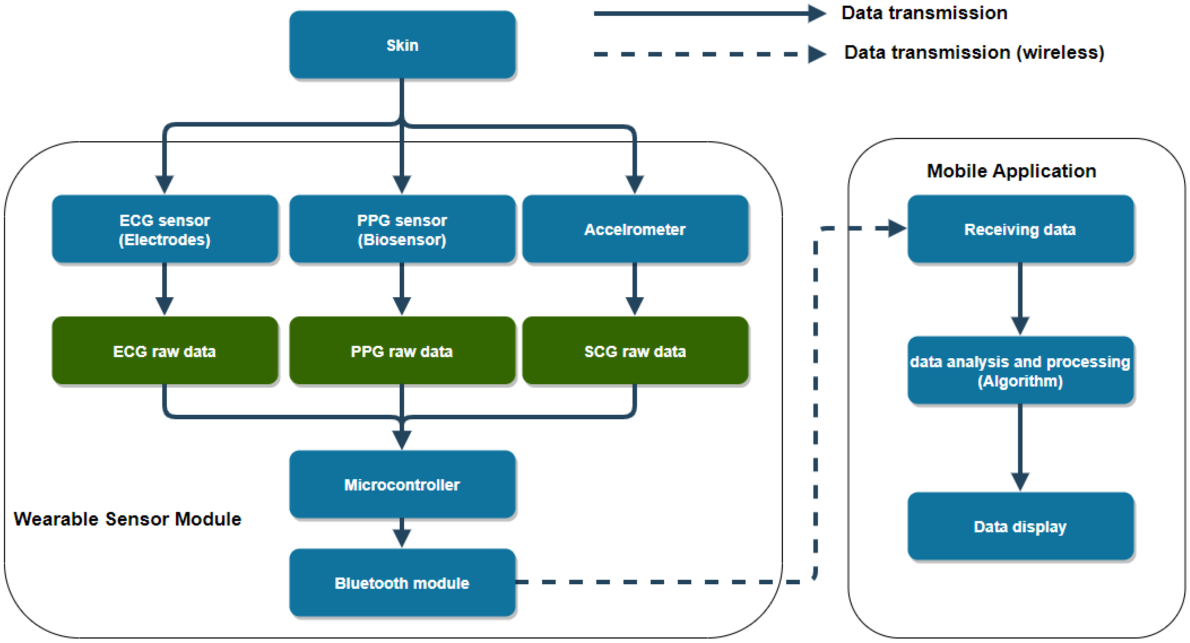

Figure 1: System overview (chart)

In figure 2, we try using a belt (red one) to fix the wearable sensor module, and the wearable sensor module will transmit the data to the APP through Bluetooth.

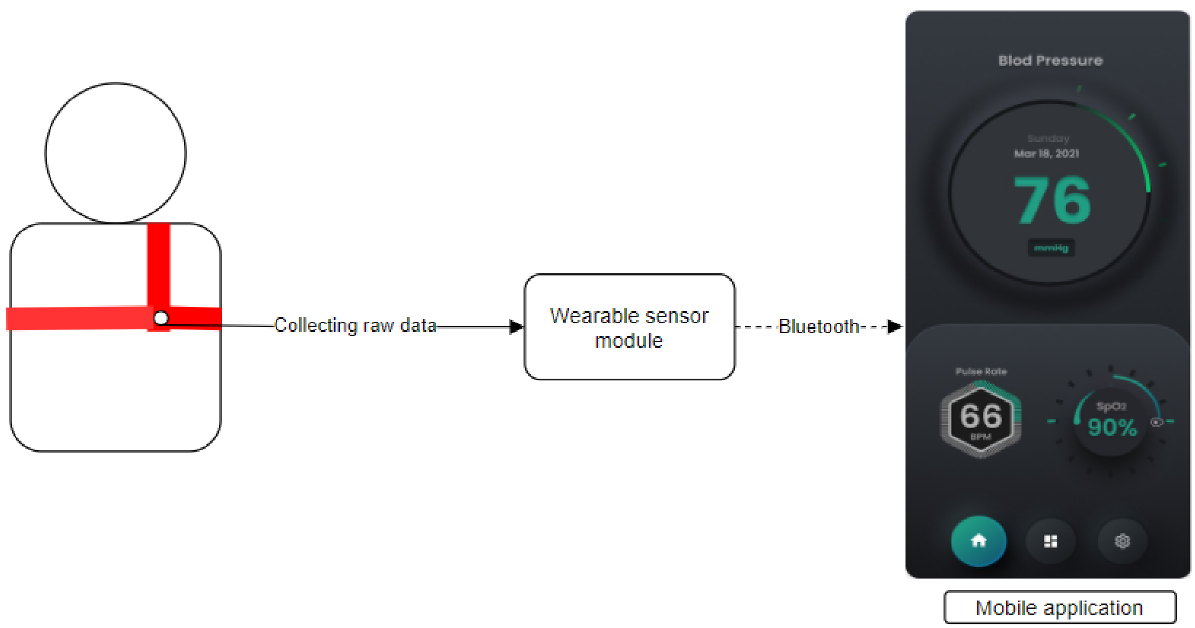

Figure 2: System overview (actual)

2.3 Risks

Chiron Solutions has identified a couple of risks that the Harp Blood Pressure Monitor might face and have already taken steps to mitigate them. One of risks is the potential to have inaccurate or irregular data be provided to the user, whether it was from an error of application or error from the device. This is an issue because inaccurate reports may lead to a wrong diagnosis by the patient or caretaker when they analyze the data.

Another risk that has been identified is the potential for an electrical hazard to occur from the device. As an electrical device, the Harp Blood Pressure Monitor will follow all necessary engineering standards to ensure that it is the most safe it can be, and reduce any risks of power surges or burn out from the device.

Finally, there is a risk of data breach of private medical data. Since none of the actual processed data is stored on the hardware device, the main concern will be securing the mobile application. As the Harp Blood Pressure Monitor app will not currently offer any export feature, there is minimal risk in having a data breach other than having the mobile device be compromised.

2.4 Benefits

2.4.1 Patients

The Harp Blood Pressure Monitor aims to improve the daily lives of seniors or patients who are at risk of high blood pressure. By offering a diastolic blood pressure measurement device that is continuous, patients will be able to immediately know if there is a rise in blood pressure and be able to take action. This instant feedback will also help patients know what does and doesn't increase their blood pressure, giving them more control over their health, data, and life. Similar to other cuff-based blood pressure measurement devices out in the market, the Harp Blood Pressure Monitor should require minimal user knowledge to operate. Patients should simply be able to pick up the device, and follow the instructions to be able to use it effectively.

2.4.2 Healthcare system

Another benefit is the fact that most continuous blood pressure measurement devices on the market are invasive and expensive. While the Harp Blood Pressure Monitor can only take the diastolic blood pressure, it is a cheaper alternative to having an all-functioning blood pressure measurement device which some people may not be able to afford. This may also alleviate some burden in hospitals where typically a patient might have needed to stay to take a continuous blood pressure measurement.

2.4.3 Stakeholders

From a uniqueness standpoint, there currently is no competing product out there in the market that offers a continuous blood pressure measurement other than other startups still in development. From market analysis, it can be seen that there is demand and interest in such a device.

3. Market Analysis

3.1 Market

The economic cost of hypertension is about $13.9 billion according to the estimation by the population and data from Alberta. In 2020 this number is expected to increase to $20.5 Billion [9]. Due to the Covid-19, more people are lacking sports and this number can be more than expected. In Alberta, as a single province of Canada, the cost of hypertension is $1.42 billion in 2010 and is projected to rise to $2.8 billion in 2020 [9].

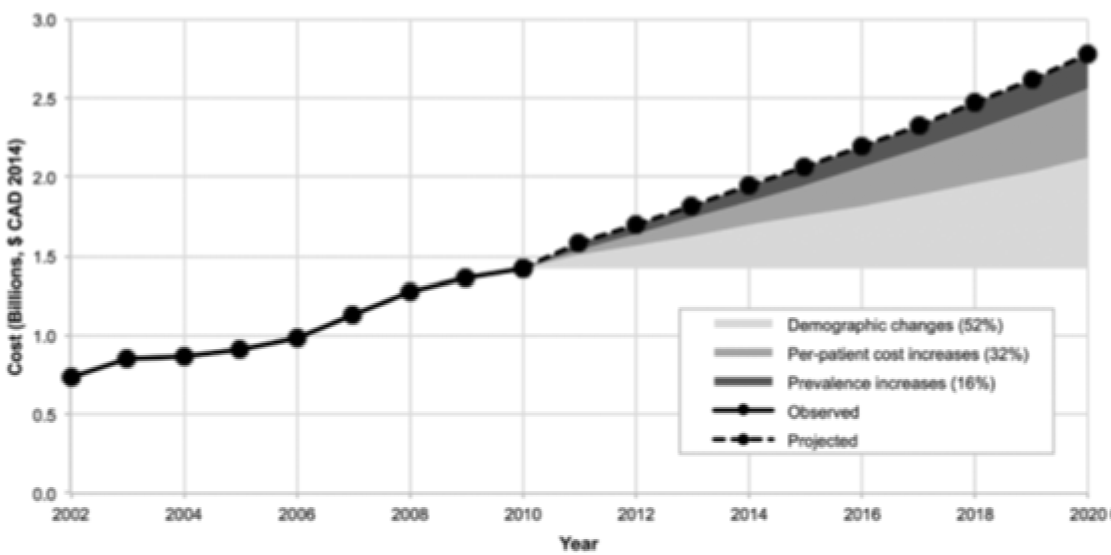

Figure 3: Population healthcare costs attributable to hypertension in Alberta, by source of projected cost increase [9]

Contributor to Cost	2010	2020
Adult prevalence, %	25.0[2,21]	29
Individuals with hypertension (millions)	6.75[2]	8.60[2,19]
Estimated per person attributable cost of hypertension ($, 2014 CAD)	2053*	2400*
Population attributable cost of hypertension (billions $, 2014 CAD)	13.9	20.5

Table 2: Attributable Costs of Hypertension in Canada [9]

The blood pressure monitors are from $40-50. According to the data, the total cost for hypertension per patient is around $5000, so the market for the devices is around $205 million in Canada, 2020 [9]. Our device will compete with other traditional blood pressure devices in this market.

The number of blood pressure devices in the market is hard to predict. The reason is there are too many similar devices in the market and there are too many routes to buy one. They can be sold in online markets, medical device shops or the common shops. For now, there are mainly two kinds of devices in the market. One is the manual blood pressure devices. They are mainly used by the hospital and their number is decreasing due to the toxic material they are using. The other one is the electrical blood pressure monitors. They are easy to buy, and they take the main part of the market. Both kinds of the devices are using cuffs to measure the blood pressure. Our cuff-free products will take some of the current market by targeting the current users who are using other products but feel cuff-based designs are uncomfortable.

As the main target of our product is hypertension patients who need to keep the continuous measurements of their blood pressure during daily life, the main competitors are those wearable electrical products in the market. The main difference between our device and others is that our product can give customers both real-time feedback in case of a sudden rise in blood pressure and continuously long-term record. The long-term record can give customers the trend of blood pressure, thus helping them prevent or mitigate hypertension. This feature targets the elders and the adults who are at risk of hypertension.

3.2 Competition

The competition in the blood pressure measurement device markets is quite simple. Almost all devices are maintaining the same function of measuring blood pressure. The main competition is about price, accuracy, and usability. For our product, we focus on competing with other products with the usability and the new features that other devices do not have.

In the current market, there are some products that are wireless, wearable and able to communicate with the smartphone and send the test results to the application [12]. There are also some products that can continuously record the data when the user is lying on the bed without moving [13]. According to the interviews, the target users want a blood pressure testing device that is wearable, continuous, and comfortable to help them prevent the risk of hypertension in daily life. However, none of the current products can record the information continuously while the user is doing something else without interrupting them. Besides, most of the current devices are testing the Systolic blood pressure by increasing the cuff pressure to a high level, which makes the customers uncomfortable. There are still no such products in the market, and our product will compete with the current products to fill this gap.

Figure 4: One of the competing wearable devices [12]

4. Cost Considerations

4.1 Cost Estimate

Table 3 introduces the cost estimate for the proof-of-concept build based on what we have bought already. Table 4 contains the items necessary for the functional prototype and an estimated cost from preliminary research. Parts used in the functional prototype that are also from the proof-of-concept build are not included as they will not need to be purchased again. Additionally, the current values are the upper estimate to ensure we do not underestimate the research costs, where additional alternative components may need to be bought if changes are made.

Component	Description	Estimated Cost (CAD)
Arduino board	Arduino board to collect the sensor data together	24
ECG	ECG sensor, used to measure the electrical signals from the heart	29
PPG	PPG sensor, used to measure blood volume using a pulse oximeter	20
Accelerometer	Accelerometer sensor, used to measure the vibrations in the blood vessel in terms of acceleration	10
misc. wires	Miscellaneous wires to connect the components together	10
Total		**93**

Table 3: Proof-of Concept estimated component costs

Component	Description	Estimated Cost (CAD)
Custom PCB	Custom PCB designed to handle the filtering of the raw PPG, ECG, Accelerometer data	10
Bluetooth module	Bluetooth module to send the data to the mobile application	20

LEDs	LED indicators for on/off, and low power states	5
Rechargeable Battery	Portable battery that can be recharged to power the device	20
Physical Casing	Physical Casing to hold the components and sensor	10
misc. strap	Physical strap to hold the physical casing to the users chest	15
Total		**80**

Table 4: Functional Prototype estimated component costs

4.2 Funding

4.2.1 Engineering Science Students Endowment Fund

While the current cost estimates are within the teams personal budget, an additional potential source of funding for Chiron Solutions comes from the Engineering Science Students Endowment Fund (ESSEF) awarded by the SFU Senate Undergraduate Awards Adjudication Committee and managed by the SFU Engineering Science Student Society (ESSS). Also known as the Engineering Science Undergraduate Student Project Award, Chiron Solutions fits two of the outlined categories, namely, Category B (Entrupenal) and Category C (Class) [14][15].

4.2.2 Wighton Development Fund

Another source of funding is the Wighton Development Fund which was created by the late Dr. J. L. Wighton. The local contact for the fund is Dr. Andrew H. Rawicz. The fund is awarded based on practicality and on a competitive basis. Projects that will benefit society will be preferentially treated such as biomedical projects [16]. As the Harp Blood Pressure Monitor is meant to help patients with medical needs, it should meet the aforementioned the criterias.

5. Project Planning

The lifecycle of Harp Blood Pressure Monitor will consist of three main phases:

- Conception, Design, and Proof of Concept
- Engineering Prototype
- Final Product

The conception, design and proof of concept implementation stages will be completed by the end of ENSC 405W. Some of the relevant milestones in this phase are the drafting of the requirements specification, design specification, project proposal as well as the implementation of a proof of concept to showcase the core functionalities of the final product. These functionalities include:

- Data collection from the ECG, PPG and SCG sensors
- Preprocessing and extraction of relevant metrics
- Implementation of the blood pressure estimation algorithm
- Initial calibration of device

Along with the proof of concept, an appearance and UI prototype will be developed to showcase how the expected appearance for the final product.

The engineering prototype will be developed by the end of ENSC 440. This version will build on the proof of concept to expand its functionalities and add extra features such as:

- Mobile app to simplify the user interface
- Data transmission using BLE
- Improved calibration
- Additional health metrics such as heart rate and blood oximetry
- Custom PCB for a smaller and more portable package.

The final product phase will include further improvements building on the engineering prototype as well as the addition of new features such as:

- Voice-over capabilities
- Improved estimation techniques
- More robust design

Figure 5 below outlines the task scheduling for the first two phases and provides a legend to clarify the meaning of each element in the Gantt chart.

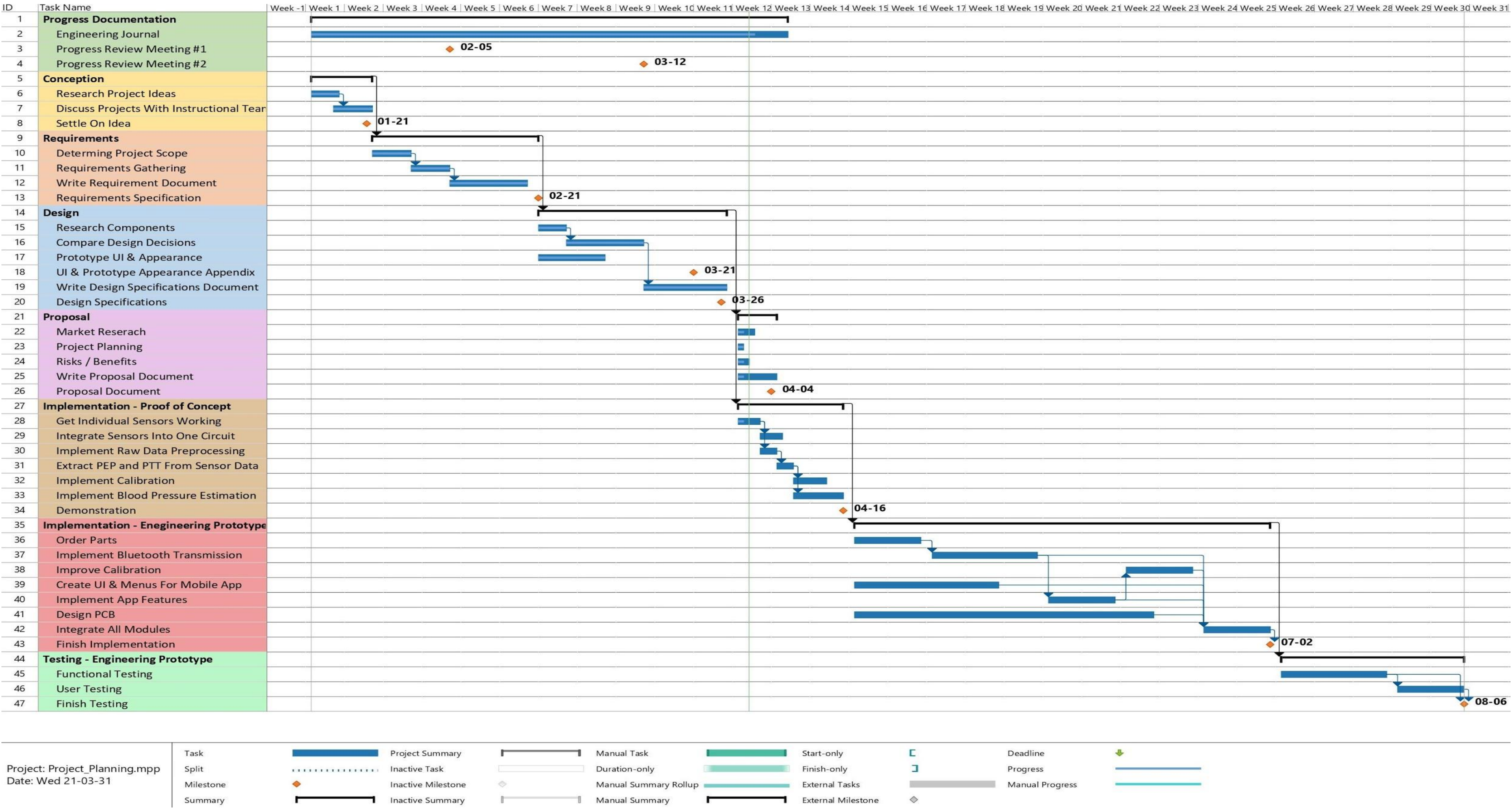

Figure 5: Gantt chart and legend

6. Company Details

6.1 Alikhan Zhansykbayev (CMO)

Alikhan is a fifth-year Systems Engineering student at Simon Fraser University. He has experience in testing and troubleshooting industrial and manufacturing PLC-based robots. Currently, Alikhan and another student from SFU Mechatronics department are working on the launch of the domestic pulp and paper production factory, which will remove the need of exporting cellulose from Russia and China. With his experience in marketing strategies and combination of communication skills, the team came to the decision to appoint him as Chief Marketing Officer.

6.2 Akshay Kumar (CTO)

Akshay is a fifth-year Computer Engineering student who is also pursuing a Minor in Business Administration at Simon Fraser University. His experience includes working with FPGAs, application design in iOS, working with various machine-learning models, image processing, as well as circuit analysis and PCBA diagnostics and repair. His skill-set allows him to understand how various technologies can integrate together to provide a seamless end-user experience. With extensive experience in both the hardware and software domains of the field, he is a well-suited candidate for the Chief Technology Officer position.

6.3 Daniel Wan (COO)

Daniel is a fifth-year Computer Engineering Science student currently studying in Simon Fraser University. He has experience in software development and quality assurance. He has experience working with Agile Development in a team oriented setting. This includes problem solving, communication, and organizational skills to make sure a team is on track and operating efficiently. The combination of organization and planning skills makes him a good candidate for the Chief Operating Officer.

6.4 Khalil Ammar (CEO)

Khalil is a fifth-year Computer Engineering student in Simon Fraser University and he is passionate about software development and cloud computing. He has had experience with developing cutting-edge features for the Azure Data Factory service during his two internships at Microsoft. On top of his problem-solving skills, he has honed his leadership and communication skills by leading several projects that required extensive collaboration amongst team members. This combined set of skills makes Khalil the best candidate to take charge in leading this project as the company’s CEO by setting its vision, delegating tasks as well as overseeing and orchestrating the development efforts.

6.5 Licheng Bao (CFO)

Licheng is a fifth-year Computer Engineering Science student currently studying at Simon Fraser University. He has working experience in software development and hardware design. He has experience working in both team and individual environments. During the previous Co-op work experience of hardware design, he was assigned to design the hardware circuit and calculate the cost of products. The combination set of working, team, and financial skills supports him to be a good candidate for the Chief Financial Officer.

6.6 Tianhao Li (CIO)

Tianhao is a fifth-year Computer Engineering Science student currently studying in Simon Fraser University. He has working experience in software development and quality assurance. He has experience working in both individual and team oriented environments. Due to the complex situations, he has applied his skills to organize and process information. The combination of working and organization skills in information makes him a good candidate for the Chief Information Officer.

7. Conclusion

Hypertension and other blood-pressure diseases affect a large portion of the global population and one of the most effective ways to deal with these diseases is prevention [6]. However, their prevention requires constant monitoring of the patient's blood pressure making blood pressure monitors designed for personal use indispensable [17]. Unfortunately, the market has been stale for a while with the cuff-based monitors being the go-to product for anyone who wishes to keep track of their blood pressure [5].

Our Harp Blood Pressure Monitor aims to rejuvenate the blood pressure monitor market by introducing a feature-rich product capable of providing continuous readings of the user's diastolic blood pressure all while being more mobile and more comfortable than the current products offered in the market.

Chiron Solutions Inc. members are excited to endeavour in the design and development of this innovative product as part of our Capstone Project at Simon Fraser University. Our team is composed of a diverse set of skilled and passionate engineers who are confident that they can bring this product to life.

Capstone is the most important phase of our undergraduate studies where we put everything that we have learned into practice and experience the lifecycle of a product from inception to launch. That is why we would like to thank Dr. Craig Scratchley, Dr. Andrew Rawicz and the entirety of the ENSC 405W and ENSC 440 instructional team for supporting us and guiding us throughout this journey.

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