



Kardiographic Medical Solutions

Project Proposal: Kompression

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Executive Summary

Heart disease currently affects 2.4 million Canadians [1] with the number young adults being affected increasing every year. However this issue goes beyond Canadian borders. In North America, heart issues are the leading cause of death accounting for twenty five percent of all recorded deaths [2]. Many individuals do not get diagnosed in a timely manner, resulting in prolonged effects of ischemic heart disease. Wouldn't it be great if there was a tool available that could easily monitor your cardiac activity and share that information with a physician?

Kardiographic Medical Solutions (KMS) is a company set on solving early diagnosis issues for cardiac health. We were founded on the idea of being the “monitor for the world's heart”. Our goal is to provide accurate and reliable cardiac measurements that can potentially double in a clinical setting for physician diagnosis. We were created by four engineering students from Simon Fraser University set on making a change in the health and wellness market. The team brings together a diverse skill set ranging from software to biomedical electronic expertise to present our product, Kompression.

Kompression is a wearable long sleeve shirt capable of recording a 4 lead EKG and a pulse oximeter reading at any time of the day, during any type of activity. All of these measurements are transmitted via a small electronic module on the side of the shirt to a cellular device. The readings are then stored as an easily shareable file in a personal cardiac diary listing measurements by the date they have been taken. The shirt is revolutionary in its design being the among the first in development. Our competitors provide products with 1-lead EKG abilities through a chest strap or finger monitors. However, Kompression offers more leads and extra features without limiting user movement and provides a system of diagnosis linking the user with their physician.

Currently in the US, the wearable technology market size is valued at USD 29.76 billion dollars with a potential to expand at a rate of 26.4%% per year until 2027 [6]. This market is driven by individual's concerns of obesity and chronic diseases [3] and we are very optimistic about Kompression's potential. Our product has not currently hit markets; but we are projected to make \$100,000 in sales by the end of 2022 if launched in January 2022. We are currently funded by personal donations but have applied to SFU's Wighton fund and are preparing an application for BC's Ignite program.

Kompression is a game changing wearable product that will help people globally get a real grip on their health. With the amount of public interest KMS has acquired, our team is confident that our product will make a difference in people's lives and provide an effective way for early cardiac disease diagnosis.

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1. Introduction

Over 50,000 Canadians are diagnosed with heart failure every year with well over 1 million Canadians having existing cardiovascular conditions [4]. It is now more important than ever to be able to monitor your heart health so that you do not become another statistic. Most heart health monitoring systems such as electrocardiograms (EKG's) are currently limited to a trip to the doctors office; which most people will only travel to after symptoms worsen and it is too late. With these limitations, Kardiographica Medical Solutions (KMS) aims to find a solution of tracking one's heart health in a convenient manner, with the introduction of the Kompression shirt product.

Kompression is a product that will allow its user to keep track of their heart health conveniently through the implementation of a 4-lead, 5-electrode EKG monitoring system and pulse oximeter built into a compression shirt, with displayable information presented via a mobile app. Kompression will be ready for use wherever the user sees fit. Whether lifting weights in the gym, going out for a run on the track field, or simply sitting at home and resting, Kompression will be the go to option for monitoring anyone's cardiovascular system. Kompression aims to be the leader in the bodywear sector being at the forefront for computer aided diagnosis of cardiac issues.

This proposal document aims to present an in depth look at the features and details necessary for considering Kompressions viability within the market. We will start by providing a scope that will outline Kompressions capabilities and functionality. This will be followed by reviewing the benefits and risks that are involved in the creation of this project. We will then turn our focus onto the market and competition section where we will describe our efforts in integrating Kompression into an existing and very competitive wearable technology market. Project planning and cost considerations will also be covered towards the end, covering major milestones, pricing for parts and expected revenue within a specific time frame. Lastly we will conclude with information about the Kardiographica Medical Solutions team and a summary of Kompression.

2. Scope & System Overview

The end goal of Kompression is to provide the user with a high end analysis of their cardiac health via an EKG system built into a compression shirt that will transmit displayable data straight to the users mobile device (*Figure 2.1*). To accomplish this outcome the Kompression product is split up into two complementary main components: the electrical/hardware components for recording and transmitting the data, and the software components for analysing and displaying the measurement in a comprehensible form.

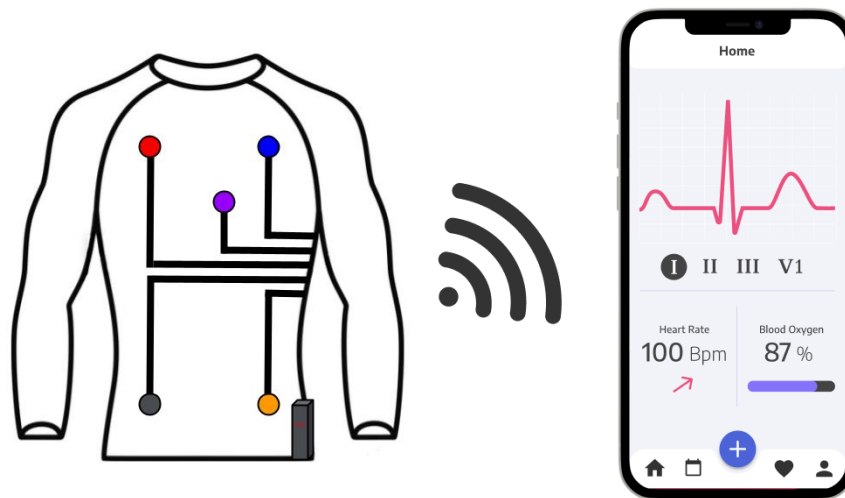


Figure 2.1 *System Overview*

Kompression will feature an intuitive mobile companion application that will show real-time EKG graphs for each of our four leads and keep track of past abnormal heart rhythm events. Furthermore it will include a preliminary diagnosis report based on previous readings the user has taken. In addition, Kompression will include a pulse oximeter sensor that will be integrated within our software application. The pulse oximeter serves to provide extra measurements and to verify correct EKG recordings. As a final product Kompression will be able to provide clear and concise EKG and pulse oximetry measurements. Our team is committed to creating an easy and intuitive system for cardiac monitoring. However, like any novel product, Kompression suffers from some limitations, covered in the Risk section below.

2.1 Hardware Overview

On the physical compression shirt, there are 4-leads composed of 5 total electrodes. One right arm electrode, one left arm electrode, and one left leg electrode making up 3 leads. This forms 3 bipolar leads recording the frontal plane of the heart. The single electrode on the chest is used as a precordial lead for a recording of the horizontal cardiac plane. The final electrode is placed as a right leg drive which filters out a majority of any noise the signals can produce. These electrodes are all connected by wiring running through the shirt and attaching into a common node where the EKG printed circuit board (PCB) and arduino nano recording device are connected. The user will be able to remove this device via connectivity pins and a locking mechanism for washing purposes.

2.2 Software Overview

The data being read in by the arduino nano is the voltage and timing data produced by the EKG circuit and leads which will be transmitted via bluetooth to the users mobile device. This data is then analysed using a real time implementation of the Pan Tompkins algorithm which is used to detect and annotate QRS complexes used for calculating heart rate and heart variability. An arrhythmia detection feature is also available for analysis of the data using a deep neural network. Different Arrhythmia will be detected and classified on recorded EKG data. This data is displayed to the user in a matter that is easy to understand such as statistical charts, graphics, and numerics.

3. Benefits

Kompression is a novel product that has the potential to better people's lives. It aims at improving the lives of young adults by increasing the ability to measure and track cardiac health.

From a user standpoint, Kompression allows a better and more efficient way to record EKG and pulse oximetry measurements. It allows the user to record a measurement at any given time of the day and during any activity. This is beneficial for users of all backgrounds and physical abilities. A more active user may want to keep tabs on his heart performance during a workout whereas a user with a more sedentary lifestyle might want periodic updates on their cardiovascular system. The ease of access to such a tool is not only key in monitoring and detecting early problems but also advantageous to those looking for performance markers in athletic training. Furthermore, Kompression's ability to store biopotential measurements allows the user to share whatever information they feel necessary with their physician. This in turn, could reduce wait times in health clinics for users actually experiencing health issues.

The entire Kompression system is intuitive and requires no previous technical experience. Electrodes and pulse oximeter sensors are clearly marked on the inside of the shirt along with the measuring device. All wires are embedded within the shirt fabrics giving Kompression a clean and neat look. This all comes paired with an application available on all platforms that stores and tracks measurements taken. Users are able to view their data instantly without waiting for results. From there, what they do with the data is their choice.

4. Risks

With a novel product like Kompression, comes a certain set of potential risks users should look out for. First, EKG measurements might not be up to clinical standards. Many different factors could cause this, but the two most common are dirty skin and constantly moving electrodes. A bad measurement would make communication between user and physician more difficult as EKG readings need to be of a certain standard.

Second, the Kompression shirt might be difficult to wash. Washing the shirt requires users to remove electrodes from their place and reattach them after the wash cycle. This reattachment process might not be intuitive and be a reason for poor measurements. The wash cycle might also damage connection ports and wiring within the shirt. Even though Kompression states that this is not an issue, it is a possible risk. Furthermore, the shirt could shrink which would be another cause for improper measurements.

Third, if proper power standards are not adhered to, the entire measuring device might break which could result in current flowing into the user. Improper powering would also result in faulty measurements. The design team has placed clear indicators next to the battery ports indicating proper device powering.

Lastly, risks of false readings and analysis might pose a large problem to users. A false reading poses huge issues to our company and product credibility. A handful of problematic measurements and analysis could result in market loss. However, our team is confident this will not be an issue. Extensive testing has not shown improper measurements.

6. Market & Competition

6.1 Wearable Technology Market

As of 2019, the global wearable medical devices market size was USD 29.76 billion and with its current growth in the last couple of years, it is projected to reach USD 197.57 billion by 2027, exhibiting a Compound Annual Growth Rate (CAGR) of 26.4% during the forecast period. [6]. This market includes a wide range of medical devices that customers can wear on their daily activities, such as, activity trackers, smartwatches, and many others. These are specially designed to monitor and collect the data of a user's health and fitness. For our product, Kompression, we are a subset of this market, as we are trying to target the wearable technology market that specializes in the use of a portable and wireless EKG monitoring device. Our product is targeted towards individuals who are looking to monitor their heart health over time and want to get a preliminary diagnosis on any abnormal heart rhythms they may experience at an early stage.

6.2 Mobile EKG Market

Kompression is a mobile EKG device as it allows the data to be transmitted wirelessly via bluetooth to our application called KardioCare, where data is processed and analyzed before giving a preliminary diagnosis to the user. Given this description, Kompression is part of the ever growing mobile EKG market. This market area has a lot of room for innovative solutions and is expected to continue its growth at a fast pace over the coming years. The mobile ECG market was valued at USD 80.50 billion in 2018 and is projected to reach USD 123.82 billion by 2026, growing at a CAGR of 5.50% from 2019 to 2026. [5], This allows us to explore and innovate around this booming market and bring our product to the hands of millions of people around the world.

6.3 Driving Forces

In the US, it has been observed that the adoption of wearable types of medical devices increased from 9.0% back in 2014 to 33% in 2018 which heavily shows how more and more people are becoming more reliable on these medical devices to keep a healthy lifestyle [6]. Similarly, with the increase of chronic diseases due to the lack of regular healthcare visits from the population, we have observed an increase in the need of wearable devices that can offer various vital sign monitoring capabilities, such as, heart rate, SpO2, blood glucose, etc. From these facts, we get that our key factors driving this market revolve around the increasing prevalence of chronic diseases and the growing awareness regarding self-monitoring and diagnosis among the population.

6.4 Competitors

In terms of competition, Kompression, faces off against many highly popular brands such as Apple with their smartwatch solution, the Apple Watch, AliveCor, with their solution, KardiaMobile, and Qardio with their QardioCore device. Looking at the Apple Watch, it allows users to monitor their heart signal and detect atrial fibrillation, which is the most common type of irregular heartbeat and a major risk for stroke. The downside of this device is that it can only replicate a single-lead EKG system which cannot accurately describe all the different views from the heart as a regular 12-lead EKG system that doctors normally use. Given that our product, Kompression, will specialize solely on perfecting the detection and classification of abnormal cardiac rhythms, it will give us an edge over these smartwatches since it will allow for a much better early diagnostic tool that people can use in the comfort of their own homes.

Another competitor is manufactured by AliveCor, an American medical device and artificial intelligence company that sells EKG hardware and software. Their latest product is called KardiaMobile 6L, which is a wireless personal EKG monitor that can take a single-lead or 6-lead EKG measurements, with access to a subscription service to get results analyzed by professionals every 30 days. Their EKG lead design is fairly innovative and they use a similar approach to what Kompression will do, by having more electrodes in the device to guarantee a better view of the heart, but by Kompression not having a subscription service and being able to provide similar features, it will attract their customers to choose Kompression over KardiaMobile.

Our other competitor is by a company named Qardio which have developed the QardioCore solution, which, from some reviews, is labeled as a 3-lead EKG system that goes in the user's chest area which mimics closely to how Kompression will be used. This device supports continuous wireless EKG monitoring, skin temperature, respiratory rate and heart rate variability [7]. This solution, however, only detects heart rate variability without diagnosis prediction which is a big difference from Kompression which will do both in a single application.

What makes Kompression a more powerful and competitive solution amongst our competitors is that we can provide more detection patterns by utilizing machine learning algorithms with data from millions of patients. We will not feature any subscription service that could act as a barrier to our customers and instead allow customers to have access to their data at any time, ready to be exported for further analysis by their own medical professional. Additionally our measurements can be taken at any moment without limiting the user's movement. Some of the key specifications differences and similarities between competitors and Kompression are outlined below in *Table 6.1*.

Device	Lead system	ADC Bits	Detection analysis	Cost (\$ CAD)
Kompression	4-lead	10-bit	Detects atrial fibrillation, 1st degree AV block, right and left bundle branch block, sinus bradycardia and tachycardia, and normal heart rhythm. Will also calculate heart rate and heart rate variability (HRV)	\$270 (based on our prototype cost estimates)
Apple Watch Series 4	1-lead	N/A	Detects only atrial fibrillation or normal heart rhythm	\$499
KardiaMobile 6L	1 or 6-lead	16-bit	Detects atrial fibrillation, bradycardia, tachycardia and normal heart rhythm	\$239
QardioCore	3-lead	16-bit	Detects continuous ECG, heart rate and HRV but without diagnosis prediction	\$556

Table 6.1 Specifications Between Kompression and its Competitors

7. Project Planning

All major processes and milestones of the Kompression shirt have been organized into two main phases: a proof of concept (PoC) prototype and an engineering prototype.

The PoC prototype will prove the viability of the foundational features of the Kompression shirt and will include:

- Application correctly connecting and displaying live EKG data from a single lead breadboard circuit
- Example validation testing of the arrhythmia detection
- An appearance prototype consisting of a shirt and device demonstrating the final size and shape

To achieve this functionality for the PoC prototype we have followed the schedule of milestones (red bars) and key processes (blue bars) presented in Figure 7.1.

After the PoC prototype has proved the main technologies, we will focus on iterating towards a full featured and integrated Kompression shirt engineering prototype.

The engineering prototype will include:

- Integration of the arrhythmia detection into the application
- Integration of HR, HRV into the application
- All four EKG leads
- Customized PCB for the device
- Custom case and battery for the device
- Integration of the electrodes, shirt and device

These objectives will be achieved by following the schedule in Figure 7.2. After the engineering prototype is complete, a future phase will only need to make minor optimizations to make the Kompression shirt market viable.

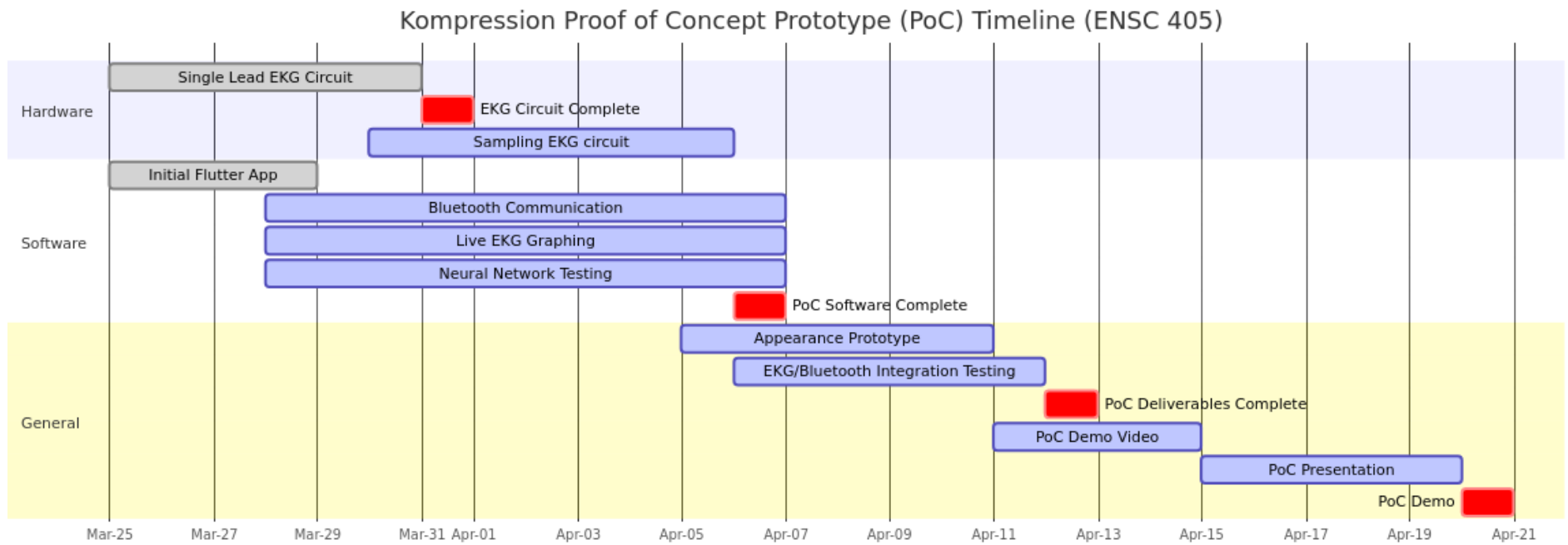


Figure 7.1 PoC Timeline (Phase A)

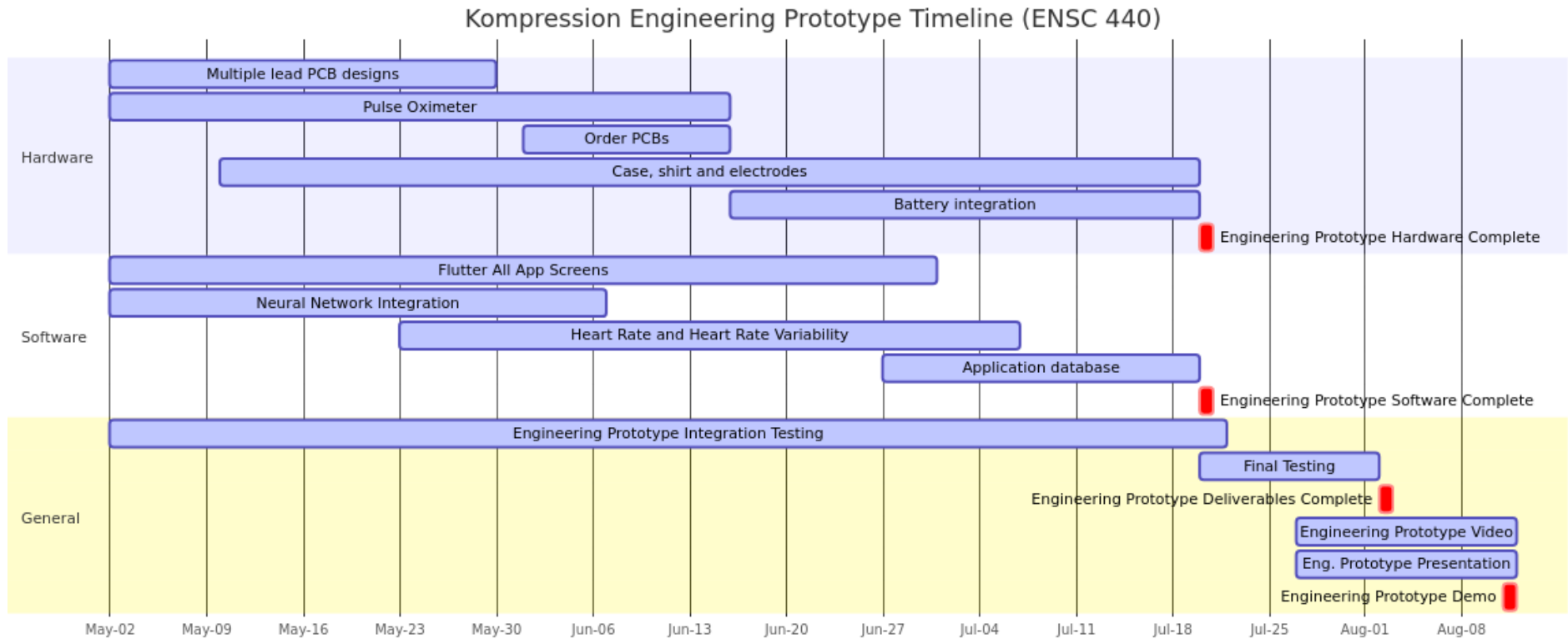


Figure 7.2 Engineering Prototype Timeline (Phase B)

8. Cost Considerations

Our base cost projections including both proof of concept phase and prototyping phase have been calculated to be ~ \$338.27 (*Table 8.1*). This of course is an estimation and can vary depending on multiple factors, which is why we will give or budget a 25% increase in contingency plans should not everything go as planned bringing our total budget to \$422.84. All costs are in \$CAD.

8.1 Cost Projections

Item	Cost/Unit	Quantity	Cost/Quantity	Phase (Alpha/Beta)
Arduino Nano	\$34.66	1	\$34.66	A/B
Bluetooth Module	\$14.99	1	\$14.99	A/B
Instrumentation Amp	\$43.00	1	\$43.00	A/B
10ft 22 Gauge Wiring	\$1.40	5	\$7.00	A/B
Bread Board	\$9.99	2	\$18.98	A
Digital Multimeter	\$30.00	1	\$30.00	A/B
Capacitor Kit	\$27.00	1	\$27.00	A/B
Resistor Kit	\$14.99	1	\$14.99	A/B
Nylon-Spandex Fabric	\$23.49	1	\$23.49	A/B
Compression Shirt	\$19.99	1	\$19.99	A/B
PCB	\$15.99	3	\$47.94	B
Casing	\$19.99	1	\$19.99	B
		Subtotal:	\$302.03	
		Tax (12%):	\$36.24	
		Grand Total:	\$338.27	

Table 8.1 Cost Projection Table

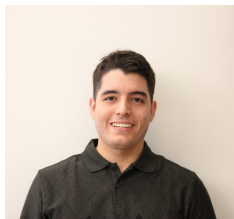
8.2 Funding

Since laboratories have been closed items such as resistors and capacitors are not readily available, causing the cost of the product to be increased. Although Kompression is not the most expensive product to prototype and manufacture, there are still many outlets in which we can cut down costs coming out of our own pockets. There are multiple funds that SFU offers that can provide assistance in cutting down the total cost of Kompression. The top three options are the Engineering Science Student Endowment Fund, the Wighton Engineering Development Fund, and the IEEE Student Project Fund. These awards all require different applications and different acceptance criteria. A version of this proposal will likely be submitted as the Wighton Engineering Development Fund application. Although this project does not completely break the bank, we will be considering these awards as a means to provide financial assistance.

9. About the Company

Kardiographic Medical Solutions was founded early in January 2021 by four engineers from Simon Fraser University. They all came together under the idea that cardiac monitoring needed to be more prevalent in people's lives. From this idea, the company motto “Monitoring the heart Health of the World” was created. This motto is what KMS stands by and strives towards.

Meet the Team:



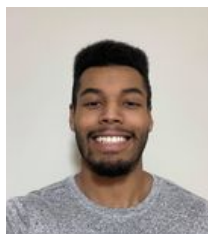
Diego Martin – Chief Executive Officer

Diego Martin is currently finishing his major in Computer Engineering at SFU and enjoys working with software, involving task automation and creating interactive games using Unity. He is part of the software team at KMS and is working on building our application that will interact with the hardware component. Has done multiple co-op experiences in both hardware and software. From his most recent co-op placement at Avigilon, as part of their firmware validation team, he has gained exposure to CI/CD practice and python scripting for automating manual tests. Outside of work, he enjoys learning new programming languages and frameworks and loves playing table tennis and foosball.



Stefan Ungurean – Chief Communications Officer

Stefan Ungurean is a 5th Biomedical Engineering student with a focus in signal processing and electronics. He is part of the hardware team at KMS and worked on designing the circuitry and signal processing algorithms for Kompresion. He prides himself in his ability to create novel products and is always excited at the possibility of furthering his technical experience. Outside of work Stefan enjoys running and is a chess enthusiast.

**Jamyl Johnson - Chief Financial Officer**

Jamyl is in his 5th year as an applied science student majoring in computer engineering. He has had the experience of working co-op jobs with three separate companies for a running total of 16 months. He has been a Junior Technical Engineer at Canadian Pacific, a Technical Services Student at Pembina and is currently working part time at Environment and Climate Change Canada as a Programmer/Data Analyst. Jamyl works closely with Stefan as a part of the Hardware team at KMS which focuses on circuitry implementation and EKG readings of Kompression. To balance his work/lifestyle he enjoys lifting weights in the iron domain and is a fine acoustic guitarist.

**Matthew Gould - Chief Technology Officer**

Matthew is a 5th year computer engineering student with experience utilizing software in interdisciplinary fields. He has created and contributed to open source projects while working with the MAGPIE (Mathematics, Genomics and Prediction in Infection and Evolution) research group at SFU. As part of the software team at KMS he will be applying his skills towards development of the EKG analysis and user interface components of the application for the Kompression device. Beyond work, he enjoys mountain biking and snowboarding.

10. Conclusion

Kompression is a novel cardiac recording device bound to change the wearable technology and wellness markets. Its ability to record EKG signals along with pulse oximetry measurements during any activity allow us to offer users more flexibility surrounding cardiac monitoring. Kompression uses a 4-lead EKG system to track heart rhythms throughout the day. All wirings and electrodes are expertly embedded within the shirt for maximum comfortability. Our hardware system paired with our easy and intuitive software makes Kompression a real contender for commercial markets. With Kompression it becomes easy to track your health and performance at the touch of a finger.

Our competitors do not offer the extent of features on their recording devices and our product does not restrict the movement of users. KMS is jumping on the growing wearable market and with Kompression, looks to be one of the best and most reliable companies in the sector. Our costs are low and we are currently well funded with high revenue projections in the coming years. Our final product looks to be developed by August 2021 with a working prototype by mid April 2021.

Despite certain risks presented, Kompression will do its best to mitigate and reduce common problems that lead to improper usage and damage. The product will come equipped with manuals and clearly labelled parts to reduce any confusion on product usability. Kompression is a product worth investing in due to its multiple health monitoring benefits and its ability to reduce waiting times in clinics. It is the new way of health monitoring and computer aided diagnosis ready to break the market. KMS is proud to be able to offer the Kompression shirt to users everywhere. The entire team is excited and ready to monitor the cardiac health of the world through Kompression.

11. References

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