January 20, 2016

Dr. Andrew Rawicz
School of Engineering Science
Simon Fraser University
8888 University Drive
Burnaby, BC
V5A 1S6

Re: ENSC 440/305W Project Proposal for OxiTrak-5001

Dear Dr. Rawicz,

Please find enclosed the proposal for OxiTrak-5001 as part of the requirements for completion of ENSC 440/305W, Capstone Engineering Science Project.

The vision for our project is to design a real-time oximeter that will be recommended by healthcare professionals to patients with pre-existing respiratory and cardiac conditions. This device will be able to measure the user's heart rate and blood oxygen levels, and provide analyzed feedback along with an emergency algorithm system implemented on a mobile device.

The enclosed document will provide detailed research on the risks and benefits of OxiTrak, as well as our current market competition and existing solutions to similar problems. It will carefully explain areas of improvement that our product will cover regarding oximeters present in the medical industry, thereby highlighting our target market. This proposal will also include the company's estimated budget and project timeline.

The motivated OxiTrak team consists of Doasay Igiri, Johnny Chou, Mohammad Ahmad, Shahzada Randhawa and Rasha Abu Alzuluf, five experienced senior engineers in the biomedical, electronics, systems and computer fields. This diversity in background ensures a variety in skill set required to cover every aspect of design for successful completion of the project.

We do hope that this proposal will meet your approval. Please feel free to contact us at oxitrakteam@gmail.com.

Sincerely,

Johnny Chou
Chief Executive Officer - OxiTrak

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PROJECT PROPOSAL FOR OXITRAK-5001

"Track the Rhythm, Keep it Beating"

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Submitted to: Dr. Andrew Rawicz
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School of Engineering Science
Simon Fraser University

Issued On: January 25th, 2016
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1. Executive Summary

Your heart is the main source of provision of life. A life with a healthy heart is a necessity that some of us take for granted. Many people all over the world are derived from this wonderful gift and deal with life-threatening cardiac conditions. Once an individual is diagnosed with a cardiac condition, they will have to deal with it for the rest of their life.

Figure 1: A person suffering from cardiac complications

The constant worrying of losing one's life have triggered for the development of a real-time emergency oximeter. OxiTrak, an integrated emergency system, provides the user with oxygenated blood levels and heart pulse data in seconds as well as the option of sending a text to their caregiver in case of an emergency. Another application settings provided to the user by OxiTrak is geolocation tracking; which is an option given to the caregiver to track the user and save their lives in case of a cardiac of respiratory medical crisis..

At OxiTrak, a team of diverse fifth year engineers at Simon Fraser University work on revolutionizing the medical wearable devices industry and produce an emergency system that a user confines in fully. Biomedical, computer, systems and electronics engineers all work together on different aspects of the product and present the prototype by April 1, 2015. An estimated budget of $380 has been requested through the ESS

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2. Introduction

Lub, dub; the motion, the sound that we take for granted. The beating heart; sometimes it falls short of the tremendous task that is asked of it. Most of the time that rhythmic pulse goes on without fault, but not all are so lucky. Among us are those who have uncertain functioning of heart and who carry with them the fear of it failing on them without a notice. In such cases and situations, constant alertness and rapid actions are of utmost importance. This is where our product comes in handy. By implementing continuous monitoring of user's pulse rate and oxygen level, it keeps track of the user's well-being in order to help improve the quality of life of patients with cardiovascular problems, and ultimately minimize the side effects that come with these problems such as high blood pressure, angina and diabetes. This indirectly lessens the burden on the healthcare system and the government at large, in terms of hospitalization and post-trauma care costs -- a win-win situation for everyone, it appears!

The most efficient way to monitor a person's cardiac system is by using a pulse oximeter. Pulse oximetry is an easy way to obtain a heart rate and oxygenated blood levels (SpO2). A sensor is attached to the subject's thumb, toe or earlobe and laser is shone using two different wavelengths to detect the difference of blood oxygenation. Absorbance of the wavelengths provide input data of arterial blood. Pulse is also detected through the interval of light transmission. This method is safe, non-invasive, and inexpensive. It also provides correct data to detect any heart dysfunction.

The lack of medical investment in both third world and developed countries have called for the creation of a low-cost integrated cardiac monitoring system. This integrated system collects real-time data for people with cardiovascular conditions and delivers information to doctors and medical employees so that they can track the user and deliver the correct procedures and treatments needed to save lives.

The lack of emergency real-time medical device for patients with cardiac history has led to the development of OxiTrak. Incorporated with real-time heart rate and oxygen level monitor, OxiTrak is not only able to detect optimal blood oxygen levels and heart rate, but also communicates this data with the consumer's personal health care professional, in order to alert them of critical emergency situations. These emergencies include, but are not limited to, low oxygen level detection and alarming pulse rates. The mechanics of our product also allows for easy usage by the

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consumer, ensuring it can be implemented while carrying out daily routines such as fitness schedules, and during sleep. Stroke, asthma, hypoxia and sleep apnea are some of the conditions OxiTrak monitors. Sufferers of these conditions can use OxiTrak to send notification to caregivers in a situation where their oxygen level has dropped below desirable conditions. The product will be carefully designed in such a way that it is easy to wear and use by any individual, and will be able to prevent vibrations and light interference that may obscure accurate measurements of blood oxygen level, as well as pulse rate.

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3. Project Scope, Risk and Benefits

3.1 Proposed Design Solution

For the design of this system we are proposing a fitted device that attaches onto a user's ear, and optically measures the blood oxygen level as well pulse rate. The device will use an infrared LED to capture these signals. This information is then processed through a microprocessor and transmitted via Bluetooth to a smartphone. The smartphone will run software to perform analytics on the data received and display it in an intuitive interface.

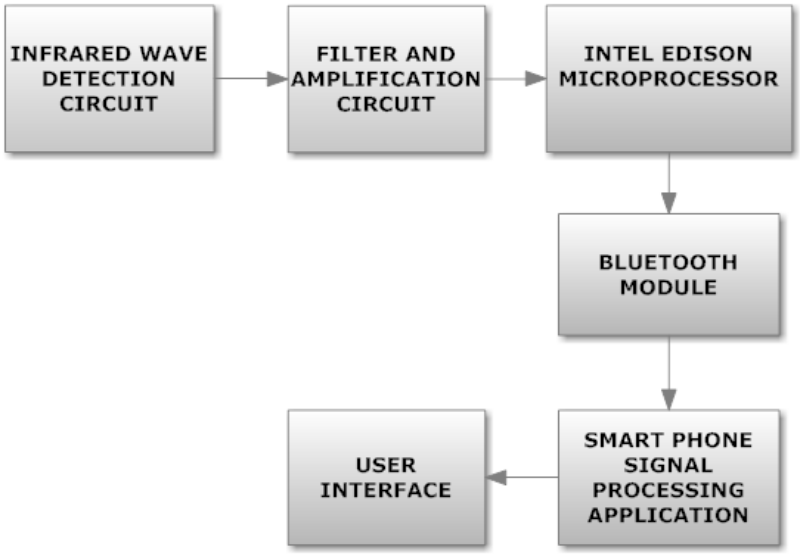

Figure 2: High level diagram of proposed design

A challenge with the design will be modularity, due to the fact that this device will need to be relatively small, and package it in a stable way. This will significantly impact our design as we will need mechanically sound packaging to record accurate readings. In addition to our technical design challenges, the social aspect may just as much, if not more challenging. The development of an intuitive and engaging user interface which brings the data to the user in an innovative manner is crucial. The software must be intelligent enough to analyze the incoming data in real time and notify the user of trends or sudden changes. This will be hugely beneficial to the fitness section, who can now track their oxygen levels and pulse

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rate during intense exercise. It is clear that the usability and feature richness of our software will be instrumental in the success of our design.

3.2 Scope

The following features will be integrated into the scope of our design:

1. **Pulse Oximeter**: Optical detection of blood oxygen and pulse rate fitted in a mechanically stable casing.
    a. Infrared LED circuit used to detect raw signal
    b. Electronic processing circuit to extract accurate readings from detection Circuit, by using Band pass Filters in conjunction with instrumentation amplifiers

2. **Intel Edison Microprocessor** to sample signal and convert analog signals to transmittable binary data
    a. Microprocessor will be fed a stabilized signal and output processed data to a Bluetooth module
    b. The Bluetooth Module block of Intel Edison will transmit this data to a paired smartphone

3. **Analytic Software**
    a. Android application that will process incoming Bluetooth data
    b. Data will be sampled and processed in real time and presented to the user in a creative and natural manner. Features Include:
        - History Graph
        - Trend Notification:
            - User typically experiences drops in oxygen levels at these times
            - Alert user when sudden drops or spikes occur
        - Emergency algorithm as an optional setting to automatically contact the caregiver in case of hazardous pulse level or drop of blood oxygen levels.

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3.3 Risks and Benefits

The main risk in this product is being able to be accurate. The connection of taking accurate data and presenting it to the user in a way that is useful to him or her. This starts with accuracy of results. To ensure we have an accurate device we will need to put it through extensive testing and identify under what conditions anomalies occur. Using this data we can improve upon our design. One of the issues we can already foresee is the mechanical stability of the device in order to take accurate readings. Another risk is how it will fit into everyday wear and tear such as being outside in the rain or being dropped repeatedly over a period of time since this device is intended to be worn for long hours.

The benefits to this product are exciting to say the least. The ability to introduce analytical software to process the incoming pulse oximeter data is truly unique. From an overall health perspective it gives the user new insight as to how well they are breathing during various activities. If a user, through this software, can catch trends such as drops in Oxygen saturation levels during their weekly runs, they can make adjustments to correct it. It will also be boon for sufferers of respiratory and cardiac diseases, where they will be able to provide their healthcare professional with detailed data of their oxygen levels and heart rate from their day to day activities. This information will prove invaluable to the medical industry and change the way we diagnose and treat diseases.

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4. Market, Competition and Rationale

4.1 Market

Health and Stroke foundation statistics states that cardiac stroke is the third main cause of death, and around 40,000 patients encounter heart attacks and heart failures per year in Canada alone [1]. As a result, a layman's first glance at an oximeter would rightly suggest that it is a device used in hospitals by patients with related issues. It could conveniently leave out the world of fitness and athletics, and even the aviation industry i.e. pilots who need to operate in non-pressurized aircrafts at high altitudes, due to the assumption that most oximeters are critical for emergency medicine, especially patients with respiratory or cardiac problems, or sleep disorders such as apnea or hypopnea. It is, therefore, quite uncommon for a healthy individual to see the need for an oximeter, albeit a preventative measure. In attempt to maximize profits in the long run, OxiTrak will be designed as an emergency system used mainly to protect and monitor users with cardiac medical history. It will be focusing on the medical industry as its primary market by promoting the product as a doctor-recommended device for users with pre-existing cardiac or respiratory problems. Its integrated real-time monitor will allow such users to exercise and perform daily tasks and activities including athletics, without having to worry about their condition or immediate vicinity of their health care givers.

As of 2013, the market value of pulse oximeters was $605.4 million, and is expected to reach $1.3 billion by 2018. This prediction depicts the substantial positive growth and exponentially rising awareness levels within the medical industry. Unlike Asia experiencing a relatively low growth due to lack of awareness regarding related diseases, North America accounted for the largest pulse oximeter market share back in 2012, suggesting a highly lucrative market region. [6]

4.2 Existing solutions and current competition

Upon research, it is safe to say that there are numerous oximeters in the market already. The World Health Organization (WHO) carried out detailed research on the existence of pulse oximeters in their *Global Pulse Oximetry Project.* This 2008 data collation covers primitive oximeters used in operating rooms alone, and does not include oximeters that can be used as a standalone unit, outside of hospitals [3].The chart below depicts the immediate market estimate for pulse oximeters in 25 countries. These numbers will certainly have been updated over the years, so putting it lightly, the competition is quite steep.

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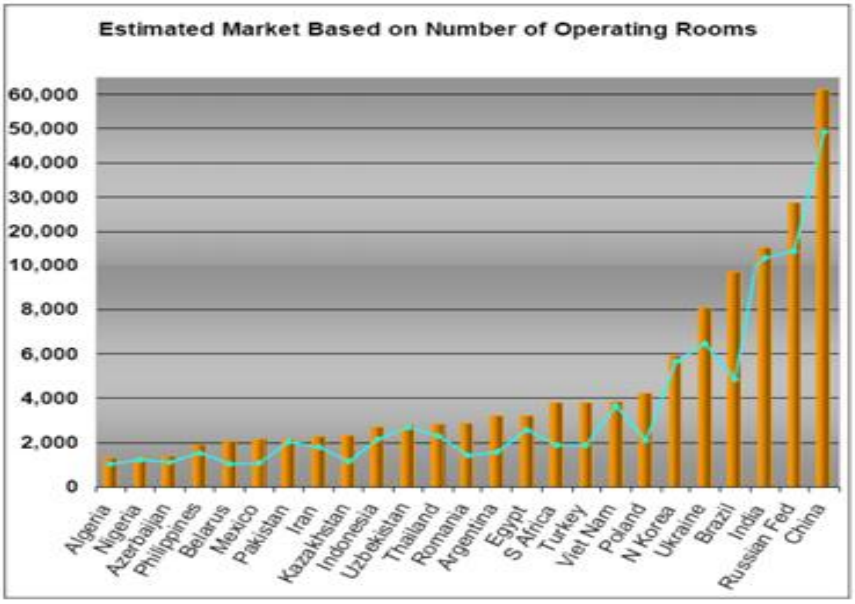

Figure 3: Immediate Market for Pulse Oximetry (blue line) [3]

Primitive oximeters have been long present in the industry to obtain measurement of a onetime oxygenated blood levels and heart pulse. Recently, Bluetooth ear-worn oximeters have been developed by some companies such as:

FreeWavz: A worn earpiece fitness device developed by a surgeon in Orlando provides the user with updates of heart rate and calories burnt. Heart rate is read by light through the thin tissue of ear lobe and calculating the density of light absorbed by the sensor, placed at the back of the ear. A non-medical feature that FreeWavz provide is the ability of hearing the surroundings while listening to music; which is useful for exercising outdoors. FreeWavz is also connected to Siri and you can inquire any actions to be taken with hands free communication with your mobile device.[4]

BioSport: powered by Intel, is another heart-rate ear-worn monitor that allows you to records your heart pulse while sleeping, walking or exercising. With a built-in optical sensor, it continuously measures the heart rate despite any intense workout or movement taken. Noise signals caused by body motion and light interference are filtered and exercise pattern is recorded. BioSport provides the user with exercise advice utilizing their exercise pattern. In addition, the ear-piece is sweat and water resistant [5]

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The aforementioned companies lack emergency system notifications in the application developed for the device. Furthermore, they either target the fitness or the medical industry but not both. Our device is incorporated to target both industries, provides real-time emergency notification and ensures users with heart problems to confidently carry out their daily life activities by communicating directly with caregivers in case of critical health situations. The emergency unit will communicate with the user through a smartphone and inquire of the safety in the presence of mal-data. If the user fails to respond to the safety notification, the device will automatically notify their caregivers of the emergency. With the incorporation of a GPS tracker, the patient's geolocation information will be to their registered caregiver. This complete emergency system will insure the user is notified in the presence of an emergency and can be saved through the geolocation feature.

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5. Company Details

The following members are currently working on OxiTrak-5001 at OxiTrak:

Rasha Abu Alzuluf - Founder and Senior Software Developer
Rasha is a fifth year biomedical engineer. She has worked as a Software Developer at Metro Vancouver and a QA Automation Engineer at Absolute Software. She is skilled in Java and C++ programming languages, and has experience with Web Automation using Selenium and Mobile Automation using Selendroid. As a Biomedical Engineering student, she has proficiency in Biomedical design and implementation, and possesses great written and oral communication skills.

Doasay Igiri - CFO and Senior Software Developer
Doasay is a fifth year Systems Engineer who has worked at Blackberry as a Hardware Design Co-op student on the Thermal R&D team. She is proficient in C and C++ Programming Languages, Shell Scripting, Image Processing with Matlab and has intermediate understanding of Python. She also possesses excellent written communication skills.

Johnny Chou - Chief Executive Officer (CEO)
Johnny is a fifth year Systems Engineer. He possesses great leadership skills and is good with managing time and organizing a group of people. Johnny has worked at Head Injury Prevention Lab as a Research Assistant, and is currently at Broadcom as a Hardware Engineer. He is skilled in electronics and with hardware components, such as microcontrollers and processors.

Shahzada Randhawa - Chief Technical Officer (CTO)
Shahzada is a fifth year Electronics Engineer who has worked at Blackberry Ltd. as a Wireless Protocol Associate and is currently working as a Certification Engineer at NETGEAR Ltd. He has excellent electronic circuitry skills and has sound knowledge of embedded systems. He is also a very confident speaker and has great presentation skills.

Mohammad Ahmad - Technical Advisor and Senior Software Developer
Mohammad is a fourth year Computer Engineer. He has experience with software development life cycles, embedded systems and documentation. He has worked with programming languages such as C and C++, database languages like SQL and XML, and web development with HTML, CSS and JS. He also has good written and oral communication skills.

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6. Project Planning

Our project's timeline and milestones can be split into three categories:

Documentation

With each report, we will roughly spend a full two weeks, splitting up the categories amongst the team members, going through first and second draft, then finalizing our paper as a group.

ID	Task Name	Projected Start	Projected Finish	Duration
1	Funding Proposal	11/01/2016	19/01/2016	7d
2	(10%) Project Proposal	04/01/2016	25/01/2016	16d
3	(20%) Functional Specification	01/02/2016	15/02/2016	11d
4	(20%) Design Specification	22/02/2016	07/03/2016	11d
5	(5%) Written Progress Report & Test Plans	14/03/2016	28/03/2016	11d

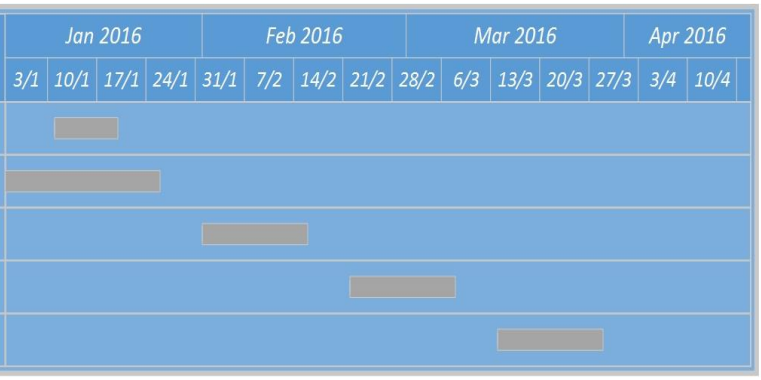

Table 1: *Documentation Timeline*

Hardware/Firmware

1. Design Prototype Circuit: Spend time researching and designing a circuit for an oximeter.

2. Gather all Hardware: Find all the components needed for our design and have them shipped.

3. Assemble Prototype: Put together all the components and get a working prototype on a breadboard where we are able to produce an amplified signal for Edison.

4. Program Edison for Static Calculations: Successfully program Edison, a microprocessor, to calculate the oxygen level and heart rate of a static fingertip.

5. Continuous Hardware Support: To get accurate readings, changing the passive components and filters will be necessary.

6. Customize Production Product: Custom build a PCB where the oximeter will be a size of a quarter, small enough to be a wearable (no longer on a breadboard).

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7. Assemble Production Product: Assemble an oximeter on the PCB, with surface-mount technology (SMT), using the same value passive components and filters as our prototype.

8. Program Edison for Dynamic Calculations: With the wearable oximeter, we want to be able to process the additional noise from motion and not let it affect the oxygen and heart rate measurements.

ID	Task Name	Projected Start	Projected Finish	Duration
1	Design Prototype Circuit	04/01/2016	15/01/2016	10d
2	Gather all Hardware	18/01/2016	22/01/2016	5d
3	Assemble Prototype	25/01/2016	05/02/2016	10d
4	Program Edison for Static Calculations	01/02/2016	26/02/2016	20d
5	Continuous Hardware Support	08/02/2016	26/02/2016	15d
6	Customize Production Product	15/02/2016	26/02/2016	10d
7	Program Edison for Dynamic Calculations	29/02/2016	18/03/2016	15d
8	Assemble Production Product	29/02/2016	18/03/2016	15d

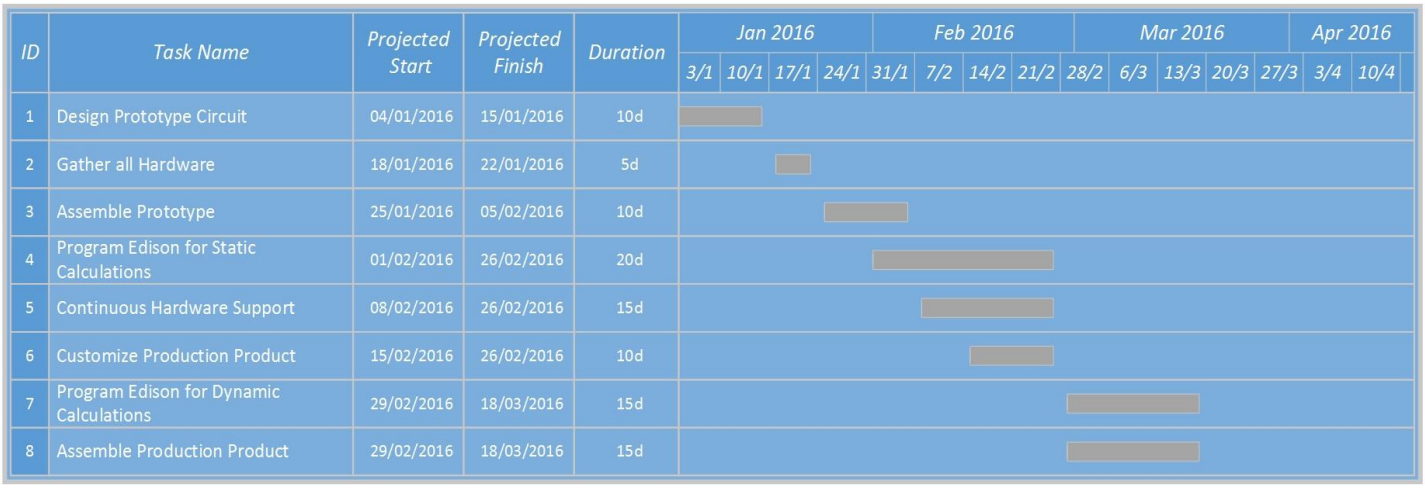

Table 2: *Hardware/Firmware Design Timeline*

Software:

1. Developing an App: Have an app up and running on our android phones, working on the back end of software development. Starting with just the essentials, such as Bluetooth connection, data processing and data visuals.

2. Retrieve/Send Data through Bluetooth: Create necessary API's to connect android devices with Intel Edison and send data wirelessly. Process the received data into meaningful information i.e. pulse rate and oxygen level.

3. Implement Interactive User Interface: User registration along with essential bio, such as age, condition and emergency contact. Display a real time graph of the oxygen level and heart rate through graphs, and the critical levels for both measurements.

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4. Implement different App Settings: Notification to the user and her/his health care professional, geolocation, critical level settings and emergency caregiver notification algorithm.
    - Geolocation feature (incorporation with GPS).
    - Emergency caregiver notification algorithm, which works as following in case of mal-data:
        - Inquiry of user input "Are you feeling Okay"
        - Wait few 10 seconds for a response.
        - No user response? Caregiver is contacted.
        - Send data and geolocation information to caregiver

ID	Task Name	Projected Start	Projected Finish	Duration	Jan 2016				Feb 2016				Mar 2016					Apr 2016	
					3/1	10/1	17/1	24/1	31/1	7/2	14/2	21/2	28/2	6/3	13/3	20/3	27/3	3/4	10/4
1	Developing App	26/01/2016	10/02/2016	12d															
2	Retrieve/Send Data through Bluetooth	03/02/2016	10/02/2016	6d															
3	Implement Interactive User Interface	10/02/2016	19/02/2016	8d															
4	Implement different App Settings	08/02/2016	26/02/2016	15d															

Table 3: *Software Design Timeline*

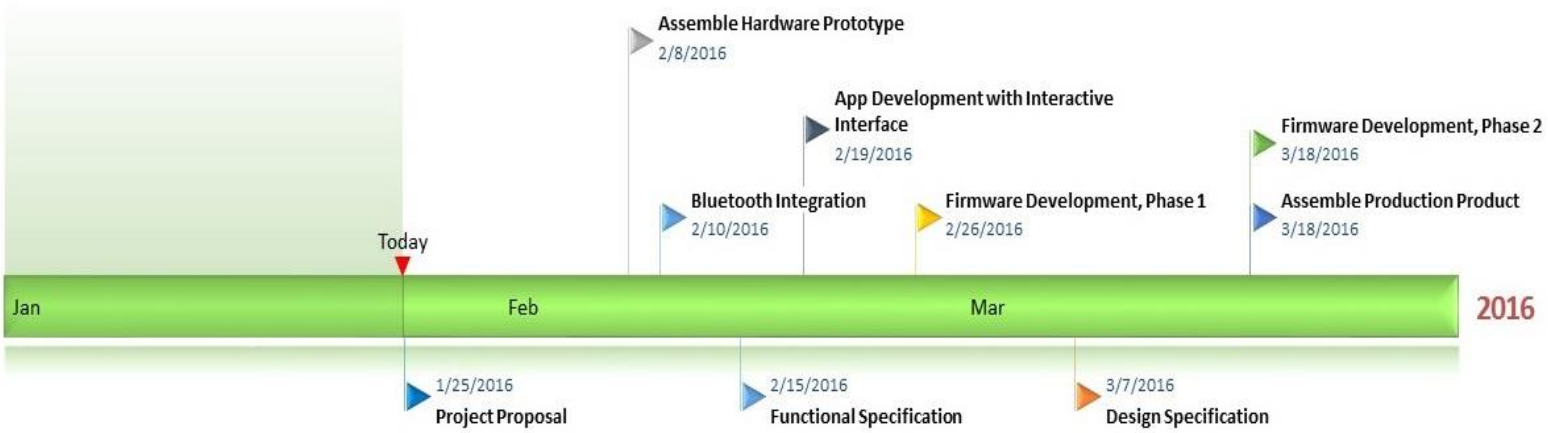

Table 4: *Milestones Chart*

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7. Cost Considerations

Our following cost estimates are from SparkFun, Mouser Electronics and Omni Circuit Boards.

Equipment List	**Estimated Unit Cost**
Intel Edison and Mini Breakout Kit	$112.50
Intel Edison Battery Block	$37.50
Intel Edison OLED Block	$37.50
Intel Edison Hardware Pack	$4.50
Intel Edison 9 Degrees of Freedom	$52
Texas Instruments OPT101 (IC)	$26
Different types of red and infrared LEDs	$25
Custom PCB quote from website	$60
Filters, resistors and capacitors	$25
Total Cost	**$380**

Table 5: *Budget Breakdown for OxiTrak-5001*

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8. Conclusion

The number of cardiac arrests have increased to 40,000 per year in Canada compared to 70,000 for heart attacks, based on research carried out by the Heart and Stroke Foundation. When heart attacks occur, more than 85% of individuals are usually outside of hospitals and healthcare professionals' sight [1]. With an estimated 62,000 cases per year, stroke is the third leading cause of death in Canada [2], and out of these cases, about 13,000 will result in death. Other cases might not lead to death but could eventually lead to some sort of disability and malfunction of brain cells. According to Heart and Stroke Foundation, heart diseases and strokes are the main cause of adult disability, and the quality of cardiovascular patients' lives actively decreases due to the many side effects that come with these conditions. The OxiTrak team has carefully evaluated the situation at hand, and believes it is essential to have a system in place that will be able to notify the user and their caregivers instantly, if heart rate and oxygen levels are less than optimal.

The goal is to nip the incident in the bud before it escalates, ensure immediate care is administered as deemed necessary and essentially, save lives.

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