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Vital Sensory Kit For Use With Telemedicine In Developing Countries

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Departments of Bioengineering and Electrical Engineering

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ENTITLED

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VITAL SENSORY KIT FOR USE WITH TELEMEDICINE IN DEVELOPING COUNTRIES

By

Alejandra Pacheco, Jose Hernandez, Antonio Maldonado-Liu, Natalie Arrizon

SENIOR DESIGN PROJECT REPORT

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Abstract

In many developing countries, a large percentage of the population lacks access to adequate healthcare. This is especially true in India where close to 70% of the population lives in rural areas and has little to no access to hospitals or clinics. People living in rural India often times cannot afford to pay to see a doctor should they need to make the journey to a hospital. Telemedicine, a breakthrough in the past couple decades, has broken down the barrier between the patient and the physician. It has slowly been implemented in India to make doctors more available to patients through the use of video conferences and other forms of communication.

A compact and affordable kit has been developed that will be used to take a patient’s blood pressure, heart rate, blood glucose concentration and oxygen saturation. Our most novel contribution is the non-invasive glucose sensor that will use a near-infrared LED and photodiode in the patient’s earlobe. Currently millions of diabetics do this by pricking their finger. By wirelessly sending data results from the vital sign kit, the first essential part of a treatment can be carried out via wireless communication, saving the doctor and patient time and money.

Acknowledgements

We would like to thank the Santa Clara University School of Engineering for providing us with a large portion of the funding for the completion of our project. Thank you to Elizabeth Sweeny and the Engineering World Health program for providing extra funding for the project. We would also like to thank Dr. Ashley Kim and Dr. Tokunbo Ogunfunmi for advising our project, and for making time on a weekly basis to meet with us to provide guidance. Dr. Emre Araci was vigilant in his push for continuous progress, which helped keep us on track for the duration of the project. A huge thank you to Nicholas Mikstas, for meeting with us at late hours in the prototyping lab to help us troubleshoot at every step of the way. Thank you to Dr. Shoba Krishnan for aiding in the troubleshooting process at various stages as well. Lastly, thank you to Katy Ashe and Noora Health for providing us with information to help narrow and focus the scope of our project.

TABLE OF CONTENTS

LIST OF FIGURES AND TABLES

Chapter 1: Introduction

1.1 Background

In many developing countries, a large percentage of the population lacks access to adequate healthcare. This is especially true in India where close to 70% of the population lives in rural areas and has little to no access to hospitals or clinics. In addition, the doctor to patient ratio is 0.7 to 1000 [1], meaning a large percentage of the population in India has no access to a doctor or clinic [2]. This means that people living in rural India are left without access to a nearby hospital and often times cannot afford to pay to see a doctor if they do make the journey to a hospital [3]. Telemedicine, a breakthrough in the past couple decades, has broken down the barrier between the patient and the physician. Telemedicine has slowly been implemented in India to make doctors more available to patients through the use of video conferences and other forms of communication. According to Amrita Pal, telemedicine is highly needed for India's rural population. Currently, patients usually have a late diagnosis of their illness, cannot get to their care provider in time, and do not get the treatment they need from the right providers [4]. However, a shortcoming of this is that the doctor still has no direct access to a patient's information, other than descriptions, x-rays, etc.

1.2 Project Goal

Our objective is to develop a kit equipped with sensors that will be used to take a patient's vital signs, such as blood pressure, heart rate, blood glucose concentration, and blood oxygen saturation. It will be inexpensive and accessible to people in rural areas of developing countries. In such scenarios, this device would replace the first steps of any standard medical checkup. Instead of traveling all the way to a hospital to have baseline vitals measured, you would measure them with this device, and send them to a physician for review to help determine whether an in-person appointment is necessary. This frugal device gives under-resourced families the opportunity to take care of their health and live a better life. Although our device could be applicable in almost any region with lack of access to healthcare, we believe India would be the region that would benefit the most from our device, which is why most of our research and project will focus with India in mind.

By having a medical kit that takes many important vital signs, even people who do not have insurance or easy access to a hospital will be able to monitor their own vital signs and those of their family members. This solution is better than others currently available because it is much smaller, cheaper, and more intuitive in design and use. Current devices include carts that are used in most hospitals here in the US, that are about three feet tall, and cost in the range of hundreds to one thousand dollars. An example of this commercial monitor is the Welch Allyn Vital Sign

Monitor that is commonly used in hospitals, at the price of $300 [4]. There are a number of other available devices, but they are expensive, and generally only have one or two types of sensors. FDA approved pulse oximeters only have one function of measuring oxygen saturation, yet they cost about $100. The proposed device is targeted to cost no more than $150, will contain at least four sensor types, and be connectable to a mobile device such that data can be sent wirelessly to a physician via Wi-Fi or SMS. Communities can share multiple vital sensor kits and split costs accordingly to make the device even more affordable. We strongly believe that by making this device low-cost and simple to use for developing countries, communities and families will be much happier and healthier because they will be able to get the medical attention they need from doctors without having to have the financial burden of paying for multiple hospital visits and transportation costs.

1.3 Review and Critique of Literature

Device from 2015-16 Senior Design

The device produced by last year's team had similar goals to this year's team, with the exception of an additional parameter. Their device focused on blood pressure, pulse oximetry, and heart rate measurements [6]. While the blood pressure measurements were relatively accurate, there was notable error with the other two parameters, especially the pulse oximeter, which retained an error of 13% relative to commercial pulse oximeters. This team was also unable to reach the stage of connecting to a mobile device for sending data. The final prototype of last year's team's device is shown in figure 1. As stated above, this year's team seeks to utilize the prototype from last year's team as a baseline, and seeks to improve it by:

- Adding additional sensor (blood glucose monitoring)
- Changing the Arduino Mega microcontroller and breadboard to a PCB method
- Integrating device with mobile system for sending data

Figure 1-1: Last Year's Team's Final Prototype

With these additional sensors added to the device, it will serve as a more accurate diagnostic tool, such that physicians can get a better idea of the condition of the patient, to better determine the best intervention without requiring the patient to necessarily make an expensive and tedious journey all the way to a hospital.

Without yet having spoken directly with the potential users of this device, research has been done into rural parts of India, to examine as a case study what sorts of illnesses are prevalent, in order to determine what sorts of sensors would be of greatest use to the users. For example, were cardiovascular disease to be very rare in rural India, it would be a waste of resources to make efforts to include a blood pressure sensor in the device, as that is the primary function of that particular sensor[7]. Upon examination, there is prevalence of lung disease, cardiovascular illnesses, and diabetes in India, which lead to our inclusion of the blood pressure sensor for the cardiovascular illnesses, the pulse oximeter for lung disease, and a blood glucose meter for the diabetes.[8]

1.4 Sensor Designs

Commercially available vital sensor devices are quite expensive, with accurate and reliable individual sensors each costing well over one hundred USD each. There are also devices, such as those currently used in hospitals, which are multi-sensor "carts" which cost over one thousand USD for the cart. For this reason, it was decided by this year's team that in order to make a more frugal device, different designs would be needed to reduce the overall cost of the device, while still maintaining accuracy and efficiency. This involves learning the inner workings of how commercial sensor devices, and replicating these functions with less expensive parts, and making up for discrepancies in more expensive technologies with simplistic yet effective hardware and software enhancing and filtering systems.

1.4.1 Proof of Concept Sensors

Included among the sensors that this year's team is connecting to the device is the non-invasive blood glucose meter, which is not yet commercially available. However, due to the high demand for a sensor of this kind and its relevance to rural India, it was determined that this sensor would be very useful to include in the device.

Given the fact that this sensor is not commercially available, it is to be constructed from proof of concept designs found in various journals. For the non-invasive blood glucose meter, near-infrared light functions in a way that is similar to the pulse oximeter, which is to use light transmittance as a means of measurement, as the transmitted light is linearly correlated to the blood glucose levels [9]. Given the prototype-nature of this sensor, it may be prone to error.

However, should they be functional, they would serve as incredible tools to serve the rural communities of India.

1.4.2 Non-Invasive Glucose Meter

As of 2008, there were thirty-nine companies doing active research and development with the purpose of producing a functional, commercially viable non-invasive glucose monitoring system[10]. Of these thirty-nine, nineteen were focused on utilizing some form of spectroscopy, with eight of them pursuing near-infrared spectroscopy. There is also a wide range of parts of the body focused upon for the measurement of the blood glucose concentrations, ranging from tears measured by contact lenses to forearm skin. As of 2016, there are at least two companies that are in the process of receiving FDA approval for their devices[11]. It appears that this technology is not too far from the market, but these devices will likely be very expensive, due to the extremely high demand for a non-invasive glucose meter.

1.4.3 Telemedicine Multi-Sensors

Today, there are no telemedicine multi-sensors of the variety that we are producing on the market. However, there is one company that is expected to receive FDA approval in 2017 called MedWand[12], which is an all-in-one sensor that measures heart rate, blood oxygen saturation, temperature, and serves as a digital stethoscope and camera as well. This device has a very similar mission to that of our device, to save the patient time and money, and provide data to a doctor that is engaging with telemedicine. However, the MedWand is expected to be more expensive than our device, and also does not come with a method for measuring blood pressure or blood glucose, although it has bluetooth capabilities that allow for connection to bluetooth enabled blood glucose meters and blood pressure monitors. The lack of these sensors would further increase the price of the device if one was to purchase additions for the MedWand, and requires the use of a computer or tablet. This involves a bit of an access barrier, as there are fewer people that have regular access to a laptop or tablet than there are those who have smartphones. This is particularly true in areas outside the United States, such as rural India, which has a well established cell phone infrastructure, but less access to computers.

1.5 Expected Results

The end goal of the product is to be able to successfully measure blood pressure, blood oxygen saturation, heart rate, and blood glucose concentration of a patient within 5% error. There are two physical sensors to be built that are to be used to gather the data for the patient in question. The above four vitals signs are to be measured with an ear clamp sensor and a blood pressure cuff. The measured results are to be measured and displayed on an external device, such as a mobile device or computer. The expected results we hope to gain are accurate readings of the four vital signs that are able to be read easily by the user. We expect to make a fairly easy to use device that is intuitive to use by the user.

1.6 Backup Plan:

For the Oximeter, we have ensured that if our ear lobe clamp in development does not work, we can quickly modify the PCB to at least be able to connect and use a Nellcor DS-100A sensor. The Nellcor DS-100A, is a finger clamp that we can use to implement an oximeter with our designed PCB. By measuring at least 2 of the vital signs desired and we can move forward with the data transmission part of the project. At the same, we could use a breadboard and Arduino Uno board to altogether create a different circuit for our sensor, in case there is a small but salvageable error in our design. While it would be expensive to acquire a Integrated Analog Front End for Pulse Oximeters (AFE4490), we also have that option, which would allow us to replace our overall circuits and use the AFE4490 to drive the LEDs for the Oximeter and possibly the Blood Glucose sensor. The back up plan for the Blood Pressure Sensor is to use a breadboard and Arduino Uno combination.

1.7 Significance

The successful completion and implementation of this project will bring further scientific progress to making healthcare affordable. In addition, a major component of this project is that blood glucose will be able to be detected non-invasively, which will completely transform the way diabetics monitor their blood sugar levels. This device that affordably measures the important vital signs [13] and blood sugar levels will ultimately help many people in poverty be able to take care of family members and also communicate to health experts more easily.

Chapter 2: System Level

2.1 System Level Overview

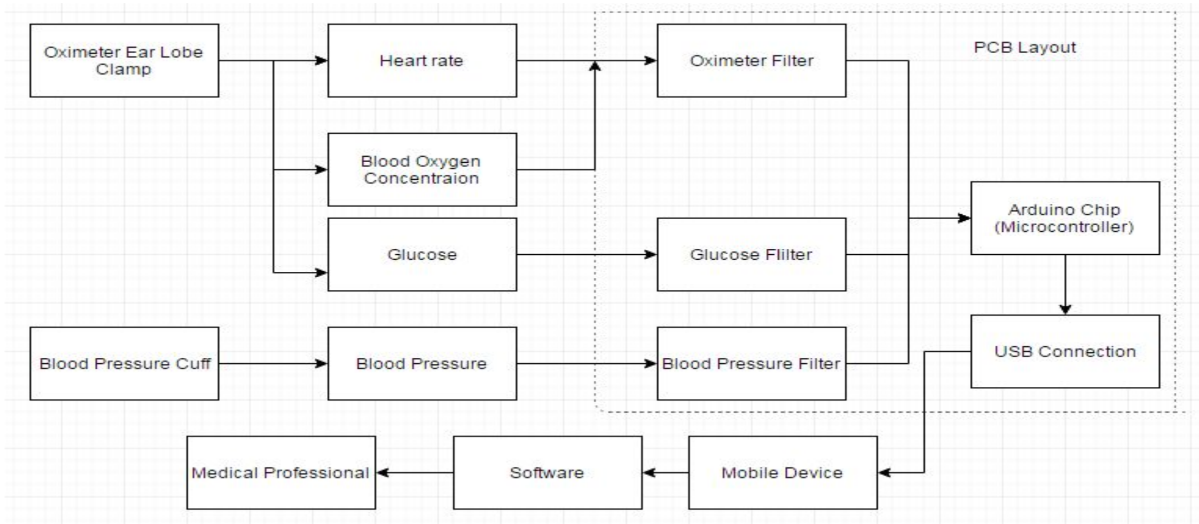

Figure 2-1: System Level Overview

2.2 System Level Requirements

In order to make a well-rounded product, there were various concerns that needed to be addressed in the creation of our device.

Table 2-1: Economic, Ethical, and Ergonomic Considerations

Consideration	Reasoning	Device Requirement
Commercial Cost	Device should be affordable so that communities are able to buy it in developing countries, specifically India.	- Maximized efficiency of components - Total cost of device should not exceed $200
Ethical Concern for Device not to Harm Patient	Use of the medical device should not cause negative side effects or hurt patient	- Add in acrylic plastic between LED and skin to eliminate skin-electronics contact. - LED wires of device are insulated so that patient does not touch them.
Manufacturing Consideration	The materials should be environmentally sound and affordable.	- Material chosen should be affordable, non-toxic, and recyclable to eliminate waste. - Device should be able to be intuitively put together to optimize manufacturing process.

2.3 Benchmarking Results: The major goals of our project was to create a device that is simple to use and affordable for the communities where aim to introduce our device. At the same time the device needs to as accurate as most commercial individual sensor alternatives in the market, to ensure it meets the standards of safety. Taking into consideration the necessity for our device to be connected to a cell phone to transmit the data, another goal was to ensure that the device can connect to most mobile devices in the market, however, due to the capabilities of a smartphone over a regular mobile device we aimed to prioritize the smartphone compatibility of our device due to time constraints.

Accuracy: Because of the importance of taking the vital signs correctly, accuracy is one of the major requirements in our device. The way we went about ensuring we obtained our desired accuracy for each of our sensors is that we bought a market alternative for each sensor to have something to compare our measurement data to. Each market alternative was chosen based on price range and reliability of the device based on professional reviews. Our goal then was to ensure that each of our sensor measurements was within a 5% error margin of the measurements from the market alternative.

Price: In terms of price, something to consider is that our device needed to be as affordable as possible from the perspective of the community we want to introduce it to. India only spends around 4% of it's GDP in healthcare, around half of the average percentage spent by most countries [1]. Therefore most patients have to pay from pocket to be able to see a doctor and paying for private healthcare is really expensive. Taking this into consideration our goal was to make our device cost to be between $100-$150 which is roughly the price of a cell phone in India (7000-1500 rupees is the range of prices for low to high end cell phones) [18]. With the idea that mass manufacture of our device would drive the price even further down and that our business plan is centered around the idea of a whole community using our device, we saw this range of prices as quite affordable for a community.

Portability: One of our aims was to make the device as small and light as possible so that it can be carried by any adult or teen in a moderate size backpack or bag. The encasing for the device previously developed was about 8x6x4 inches, the reason for this size has mostly to do with the size of the breadboards used for the controller. For our controller we aimed to use a PCB board which would be a lot smaller and therefore not need as much space. Overall our project should be easy to carry and fit in any moderate size backpack or purse.

Simplicity: The communities that we are aiming introduce our device to might not have any knowledge of how to use each sensor separately. One possible solution we looked into developing, is to possibly add a manual or a set of instructions on how to use our device. Taking into consideration the business plan for our device, this set of instructions would be for an individual that together with a bit of training should be capable of using the device. Because of the language differences, we would need to rely on images or very short phrases that will give some background information on how to use the device. While each sensor is not hard to use if having some knowledge of how it works, a manual would ensure the patient has some understanding of how to use it. Since we our aim was to make each sensor in our device very similar to their more well known market alternatives, a medical professional should be able to use it quite comfortably.

Mobile Phone Penetration: Our decision to use a cell phone for wireless communication as opposed to a PC is that we took into consideration the mobile phone penetration rate vs PC penetration of the region. While PC penetration is only at 9% in India, meaning 9% of the population has access to a PC or knows how to use one, the mobile market is at an impressive %80 in comparison[18]. Furthermore, India is now considered the second largest mobile market in the world, with an estimated 900 million mobile connections.

Smartphone Compatibility: It is important to take into consideration the difference between any mobile device and smartphones. While around 80% of the population in India owns some form of mobile device, only 30% of those devices are smartphones[18]. This percentage is expected to increase, however, and as it currently stands it forced us to consider whether our device needed to be developed for a smartphone device or for any mobile device. A smartphone device would be certainly easier to use since there are already many apps that have similar functions to what we need to create. However, if we made our device capable of transmitting the information through a non-smartphone device it would follow that it could be easily used by a smartphone device and therefore our device would be easier to integrate and use in any community. Taking into consideration this information, our goal was to formulate a plan to connect our device with any mobile device, if this proved to be too difficult then we would move towards using a smartphone as the means of communication for our device.

2.4 Functional Analysis

Table 2-2: General and Specific Functions of Each Device Component

Subsystem (Top down)	Function
Overall Prototype (PCB + Ear Sensor + Blood Pressure Sensor)	This system works together in conjunction with a computer to be able to send the data from the sensor to Arduino to Matlab for processing.
PCB & Arduino Uno	The PCB is the heart of the device, where all

	the electrical circuits needed for the sensors are located.
Ear Sensor, Blood Pressure Sensor, Glucose Sensor	The ear sensor is composed of three LEDs and two photodiodes. It is housed in an ABS 3D printed ear clamp. The glucose sensor is also housed in the ear clamp. Blood pressure sensor is connected on one end to the PCB and to the cuff/pump on the other end.

2.5 Team and Project Management

This project required thorough organization, communication amongst team members and with our advisors throughout the whole school year. We kept organized by taking notes during meetings and keeping a gantt chart to stay on top of deadlines [refer to Appendix E]. A challenge that was encountered at some points throughout the project was working to build an affordable device that also could provide accurate results. The budget for this project was $668. The glucose sensor was the most experimental for the vital sign kit, and resultingly, the electrical components were very expensive. We dealt with this challenge by only buying what we were able to with our funding options and buying more components if all others were non-functional. In addition, having a small budget to ensure the device stayed at a low overall cost taught us to thoroughly research the properties of the electrical components used so that we have optimal use of our device.

Furthermore, the design process continued to evolve throughout the school year. The main sections that were needed at the beginning were the electrical circuits for the blood pressure, pulse oximeter and glucose sensor. Then, the ear clamp housing was designed to put the device together. As we tested our device with several patients, we noted how we can improve the ear sensor and PCB housing to make the product more compact and easy to use.

2.6 Risks

This project did not pose a risk to any people that use the product. In order to use the medical device on other patients, we had to be approved by the Santa Clara Institutional Review Board. This involved an extensive application with details on why, how, and what we intended to test. We did trainings and also require consent forms for patients to sign before they could be tested. For testing people's heart rate, we do require that the person do a form of moderate exercise for 30 seconds to get the heart rate elevated. If for some reason the patient suffered an injury for this part of testing, that would be our major concern. There is no danger in being tested for blood sugar, glucose and oxygen saturation because it is all non-invasive.

Chapter 3: Subsystems Level

3.1 Blood Pressure Sensor

3.1.1 Role/Requirements

The blood pressure sensor functions based on the fluid pressure found in the patient's arterial walls. There are two points of interest to be monitored as the patient's heart beats: When the patient's heart is contracted a high pressure is to be monitored, which is known as the systolic pressure, and when the patient's heart is relaxed, the lower pressure, known as diastolic pressure can be measured. The blood flowing through an artery between these systolic and diastolic pressures causes vibrations in the arterial wall that can then be detected and measured through voltage signals[14].

3.1.2 Options and Trades

Since this project was an adaptation of the previous year's prototype, we decided to work with the current blood pressure cuff and pressure transducer to reduce the price of purchasing new components. These components functioned well on their own and their accuracy outweighed the cost of purchasing new components [See Appendix F for components].

3.1.3 Design Description

The initial approach was to reconstruct the blood pressure circuit from breadboard design that it was previously implemented on. This included recreating the blood pressure circuit on a breadboard to begin with, as the previous team did not leave proper schematics for our referral. The main blood pressure schematic that became our reference is shown below in Figure 3-1. This was taken from Freescale's articles on design of medical devices [17]. [See Appendix D for ExpressPCB designs]

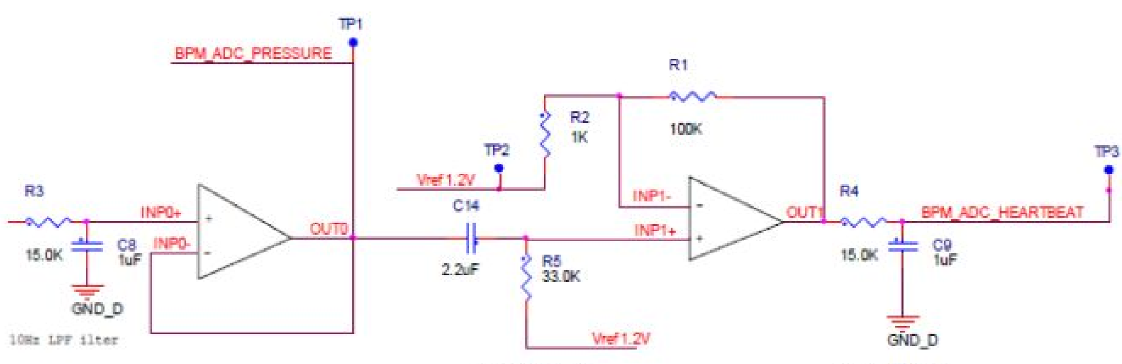

Figure 3-1: Freescale Blood Pressure Circuit Design

As we referred to this ideal schematic, our breadboard design began to come together with our various components. The approved circuit design at our first stage of testing is shown below in Figure 3-2.

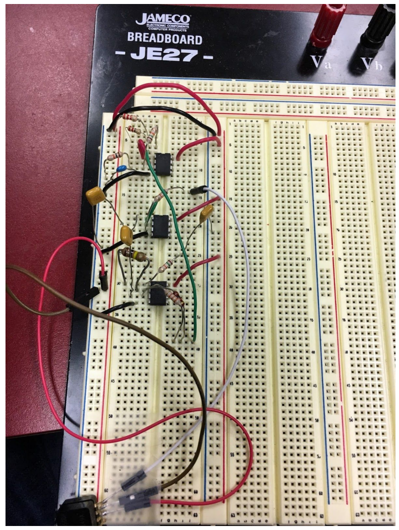

Figure 3-2: Breadboard Blood Pressure Circuit Design

3.1.4 Supported Analysis

The overall process of blood pressure testing began once the circuit implementation was completed. The design was finalized into the PCB schematic implementation and final testing began once our overall PCB was constructed. Results from both our group and various test subjects can be seen in Appendix C.

3.1.5 Test Procedures

The testing procedures for the blood pressure followed the testing procedure that would be encompassed in all of our sensors. Our patient would first take their blood pressure from our commercialized blood pressure sensor, so that we would have a baseline to compare their results against our prototype. Once this was done, our patient would use our blood pressure cuff so that we could measure our own data through our device. As a group member would manually pump the blood pressure pump, corresponding data would appear through our Arduino code. An example plot is shown below in Figure 5.

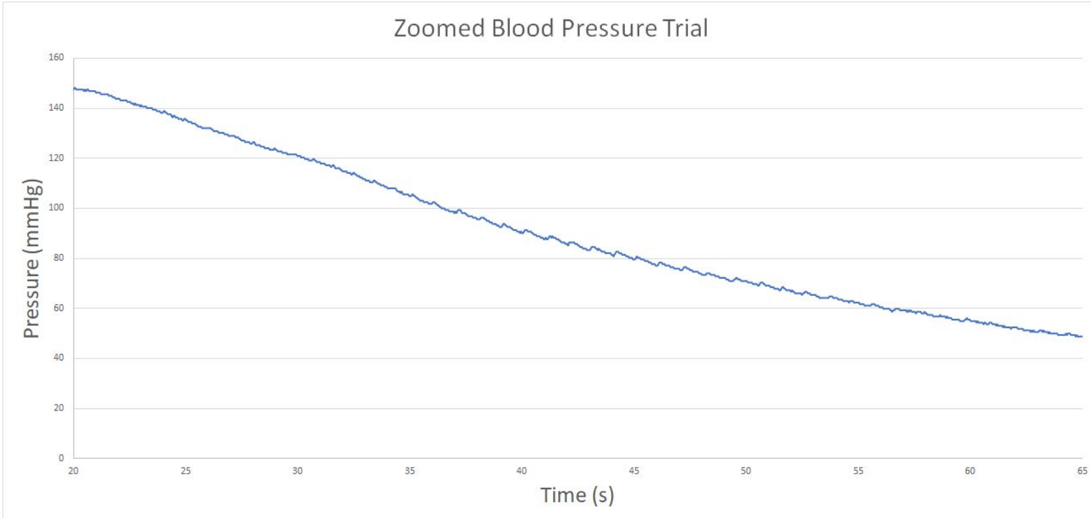

Figure 3-3: Arduino Plotted BP Results

The above plot would then correspond to data points that would be measured through Excel. These data points would then be converted into a plot to be analyzed to find the patient's corresponding systolic and diastolic values. An example to this data is shown in Appendix A.

The bumps on the right half of the plot correspond to the patient's heart rate and this data can also be measured through the blood pressure analysis.

3.2 Glucose Sensor

3.2.1 Role/Requirements

This subsystem is the non-invasive blood glucose sensor. It functions to measure the blood glucose concentrations of a patient. The requirements for this sensor are as follows:

- Non-invasive (no blood draw, no damage to patient tissue)
- Accurate measurements (as measured on glucose standard solutions)
- Small in size (to fit in the ear sensor with the pulse oximeter)

3.2.2 Options and Trades

Options for the development of this sensor were very limited. Due to the experimental nature of this technology, there are very few companies that sell the components that could be used to fit the determined design for this device. The reason for choosing the wavelength of LED that we did is due to the maximized glucose interactions, and minimized water interactions while still maintaining a feasible path length (see figure 3-7). The photodiode was selected based on its ability to absorb the desired wavelength (see Figure I-2, in Appendix I), its cost, and its size. Since the purpose of the device as a whole is to be portable and inexpensive, the size would need to be minimal and its price be as low as possible as well.

3.2.3 Design Description

The glucose sensor is composed of a single near-infrared (NIR) LED that emits a wavelength of 1550 nm, and a light receiver, in this case being a photodiode that receives the 1550nm wavelength. These two components are positioned within the ear sensor, with the NIR LED positioned on the same side as the pulse oximeter LEDs, and the photodiode positioned on the same side as the pulse oximetry photodiode, with them positioned directly across from each other.

Figure 3-4: 1550nm LED

Figures 3-5: Glucose Photodiode [21]

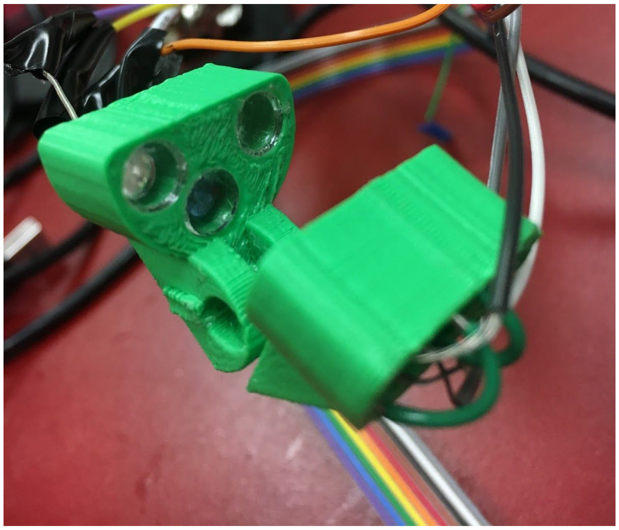

Figure 3-6: Glucose LED and photodiode in place in ear sensor housing

The novelty of this approach is the non-invasive nature. While normal sensors require exposure and direct testing of patient blood, the spectroscopic nature of the NIR LED-photodiode method removes the need for any tissue damage, or need for direct exposure to body fluids. Instead, the 1550 nm wavelength is able to pass through the tissue of the patient with minimal interactions with the water (see figure 3-7) and tissue components [9] of the patient, and maximal interactions with the glucose dissolved in the blood, while maintaining a path length great enough to travel through the entire tissue, in this case being the ear lobe. This method reduces sanitation concerns, reusability concerns, as well as general safety and health concerns for the patient associated with the testing process relative to commercially available methods.

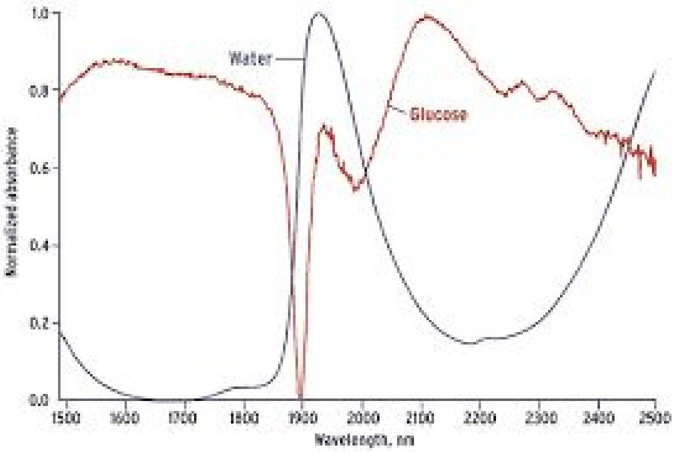

Figure 3-7: Absorbance spectra of glucose vs. water [22]

Glucose molecules reflect light at a wavelength of 1550 nm, indicating that as the glucose concentration increases, the amount of light received by the photodiode on the other side of the tissue or glucose solution is reduced, as more of the NIR photons are reflected back towards the LED instead of passing all the way through the tissue or solution.

3.2.4 Supporting Analysis and Test Procedures

The glucose sensor was tested by using several glucose solutions in water of a predetermined concentrations to obtain raw voltage readings from the device, and then correlating each of those glucose solutions to their respective glucose solutions to produce a standard curve. This standard curve would then be used to correlate voltage readings from patients to the appropriate blood glucose levels. The glucose solutions used were in units of milligrams per deciliter: 30, 50, 70, 80, 90, 100, 125, 150, 200, 2000. These particular concentrations were selected for their physiological relevance; 70-100 mg/dL is generally considered to be a healthy blood glucose concentration before eating a meal, and 30 and 50 mg/dL are both considered very low blood glucose concentrations (hypoglycemia). 125, 150, and 200 mg/dL are all considered to be high blood sugar (hyperglycemia). 2000 mg/dL was a concentration selected in order to ensure the sensor was responsive, and to help detect the linearity of the standard curve.

Figure 3-8: Glucose solutions in glass bottles. Arranged left to right; 30, 50, 70, 80, 90, 100, 125, 150, 200 mg/dL

The glucose solution was put into a small container composed of black acrylonitrile butadiene styrene (ABS) plastic and transparent acrylic plastic. This container was a small box in which the glucose solution was put in to provide a fixed path length (5mm) for the glucose LED and photodiodes to be placed against. Each glucose solution was put into the black box for measurement by the glucose sensor to form the standard curve.

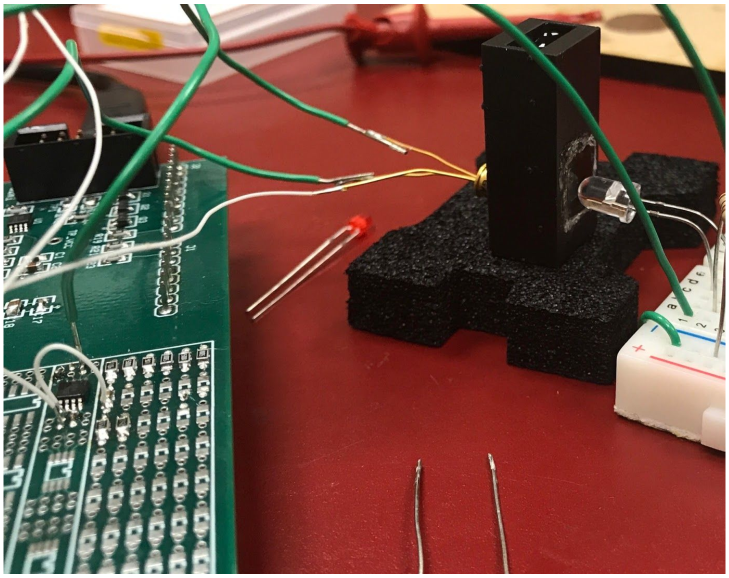

Figure 3-9: Black glucose solution testing box in testing

The standard curve produced by our device did not provide data to support a linear correlation between the glucose concentration and the voltage output of the glucose sensor, following several attempts throughout the academic year. One of the last trials did produce a correlation, but following trials were not able to replicate those results.

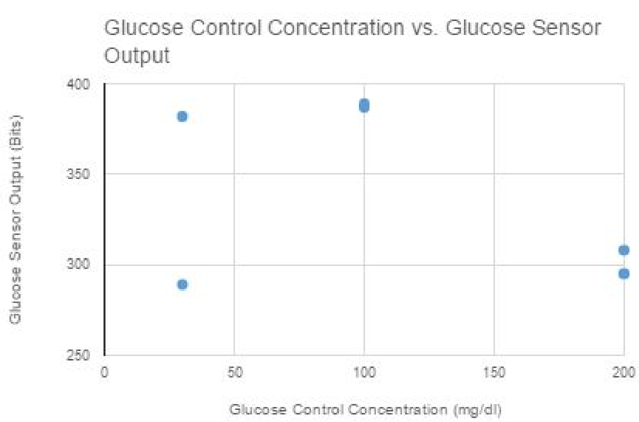

Figure 3-10: Trial 1 of Glucose sensor

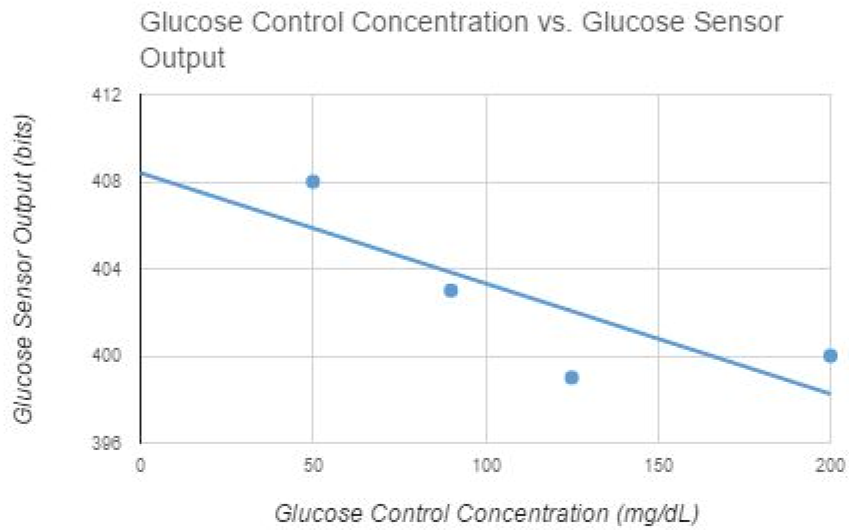

Figure 3-11: Trial 5 of Glucose sensor

The expected results based on literature research is that with the increasing glucose concentrations, the voltage output by the glucose photodiode would be reduced, as the transmission of light is reduced with the greater number of glucose molecules blocking the path of the 1550 nm photons. However, the data retrieved by the glucose sensor demonstrate a seemingly random voltage output for each glucose concentration, instead of the expected negative correlation.

3.2.5 Verification

Due to the nature of the glucose sensor we produced, it is non-invasive; it does not require direct access to blood or damage to body tissues for measurement to occur, thereby meeting the requirement of being non-invasive. However, following the various tests performed on the sensor, no accurate replicable standard curve was obtained, thereby indicating a lack of accurate glucose measurements. The size of the sensor, on the other hand, was appropriately sized, and was able to fit into the ear sensor, eliminating the need to make a separate housing/sensor for the glucose sensor to be an independent component.

3.3 Pulse Oximeter

3.3.1 Roles and Requirements

The device is intended to be compact, simple, and accurate.

Requirements:

- Ear lobe is designated path for oxygen saturation measurement because of less light reflection and diffraction (no bones or thick tissue for light to penetrate).
- Non-invasiveness is required to limit harm to patient and improve ease of use.

- Affordability of pulse oximeter components allows for overall price of device to stay low.

3.3.2 Options and Trades

When considering how to design this sensor, we could have chosen the finger or the ear. However, since we wanted to have multiple sensors on one clamp, we chose to design our device based on the decision of testing through the earlobe. There was no ambiguity in the types of LEDs that we could have used because literature has shown that 650 nm and 940 nm wavelengths will yield the best results in calculating oxygen saturation levels. For the chosen photodiode, there were multiple options in the market, but the one that was chosen was based on what the previous year's team did. This photodiode worked well in the preliminary testing and was kept for final testing.

A pulse oximeter measures the oxygen saturation in the blood stream. Oxygen is necessary for the body's survival, and so it is an important sign to keep track of. Hemoglobin is a molecule that transports oxygen molecules to the desired locations. The way this is done with our device is one of the most common methods of detection, light spectroscopy.

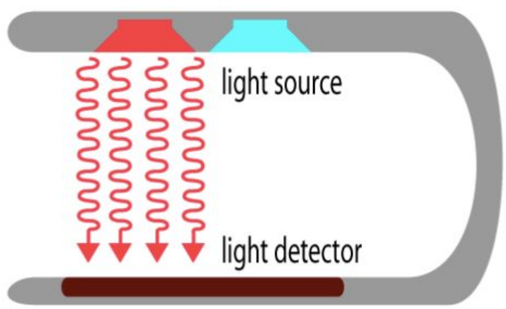

Figure 3-12: Two-LED pulse oximeter setup. Two LEDs and a photodiode (receiver of light) to detect oxygenated and deoxygenated blood cells. [23]

There are two LEDs that are used to measure the oxygenated hemoglobin and deoxygenated hemoglobin in the blood stream. Commercial devices often test oxygen saturation through the finger, but our device tests through the ear. This should have no impact on the oxygen saturation measurement. The ear was chosen to be tested because there are no bones in the earlobe and this limits light scattering. Two LEDs, at wavelength 650 nm and 940 nm were chosen because literature shows that red light is most absorbed by deoxyhemoglobin and least absorbed by oxyhemoglobin, while at 940 nm, oxyhemoglobin has the highest absorption and deoxyhemoglobin has the least absorption.

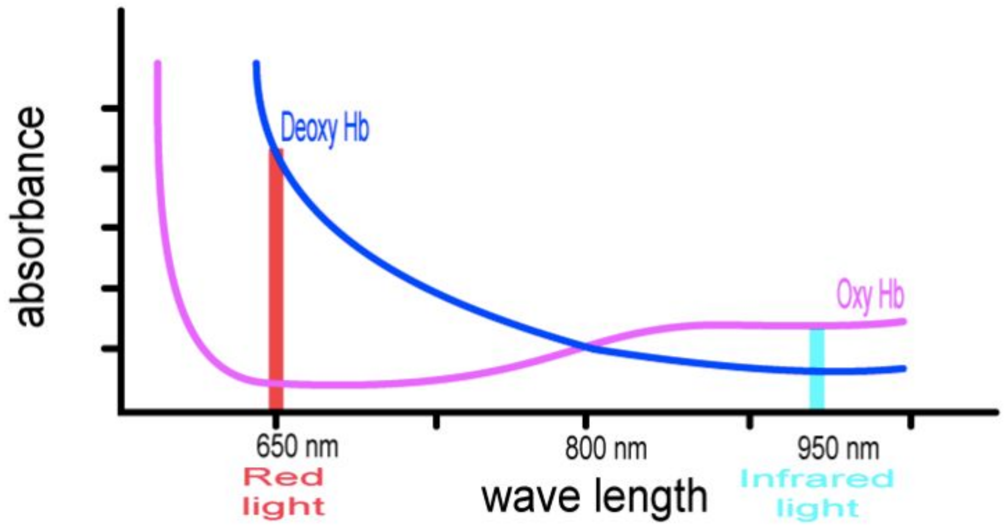

Figure 3-13: Oxyhemoglobin vs. deoxyhemoglobin absorption spectra [23]. This image shows the maximal absorption of oxyhemoglobin and deoxyhemoglobin at different path lengths. 650 nm (red light) and 950 nm (infrared light) LEDs were chosen because of their optimal results. Data is taken with each LED in which the arterial blood flow is measured. The relationship between the absorbance of oxy- and deoxy-hemoglobin is quantified to calculate the oxygen saturation. The data is taken from the LED readings and then uploaded to Matlab for further processing. [Refer to Appendix A for Matlab code].

$$R = \frac{\log_{10}(I_{ac})_{\lambda 1}}{\log_{10}(I_{ac})_{\lambda 2}}$$

Figure 3-14: Pulse oximeter equation. This equation calculates the oxygen saturation by taking the log of the number of peaks (AC component only) for the red LED divided by the log of the number of peaks (AC component) of the infrared LED. This ratio is multiplied by 100 to get the final oxygen saturation percentage.

3.3.3 Design Description

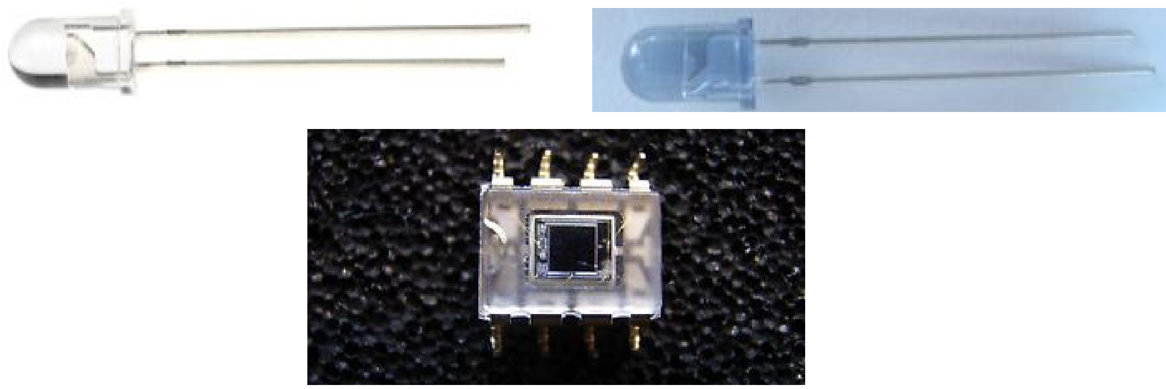

Figure 3-15: Pulse oximeter components. The main components needed for the pulse oximeter are shown above: 650nm LED (top left), 940nm LED (top right), OPT101 Texas Instruments photodiode (bottom).

The circuit design for the pulse oximeter was based on Freescale's articles on medical devices [16]. The circuit design is shown in Figure 3.16 below. [See Appendix D for ExpressPCB circuit design].

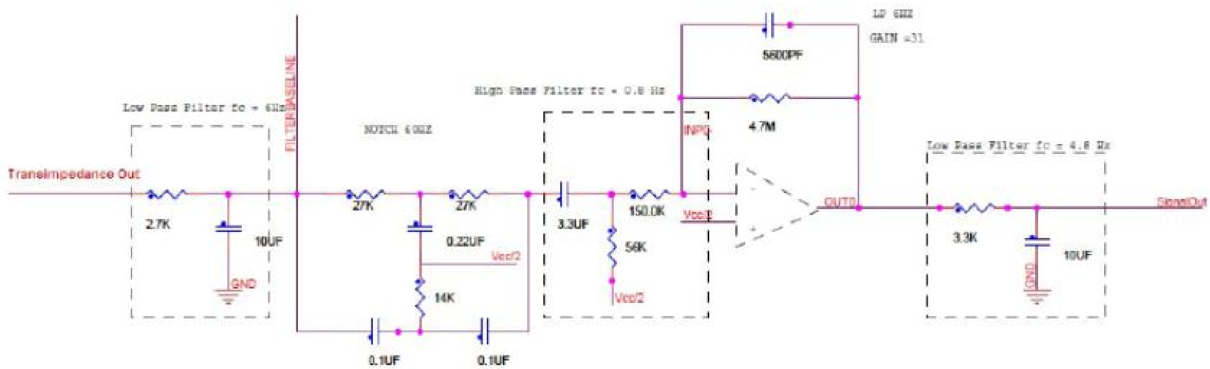

Figure 3-16: Freescale Pulse Oximeter Circuit Design

Initially out testing of the circuit design was done on a breadboard and then the circuit design was implemented in a 4 layer PCB. Please refer to Appendix C & D for details on circuit design and implementation.

3.3.4 Supported Analysis and Testing Procedures

The pulse oximeter testing was conducted in two states, with a resting and elevated heart rate. Testing oxygen saturation and heart rate both when a patient is at rest and then after doing moderate exercises further broadens the ability of the sensor to be able to accurately detect oxygen saturation and heart rate.

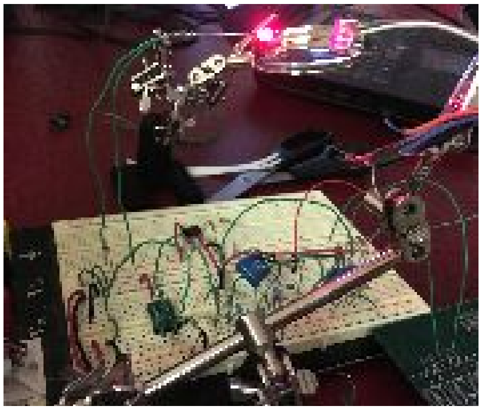

Figure 3-17: Initial pulse oximeter testing setup. Red shining LED with photodiode across it (also shining in red). Finger was placed in gap between LED and photodiode.

Initially, testing oxygen saturation with the device prototyped on the breadboard was difficult because there was not a set path length and the finger was put between an LED and photodiode to see if the arterial blood flow could be detected. The finger was initially tested because the ear clamp SolidWorks design had not yet been created. Arduino serial plotter was used to get real-time results of arterial blood flow when finger was placed between LED and photodiode.

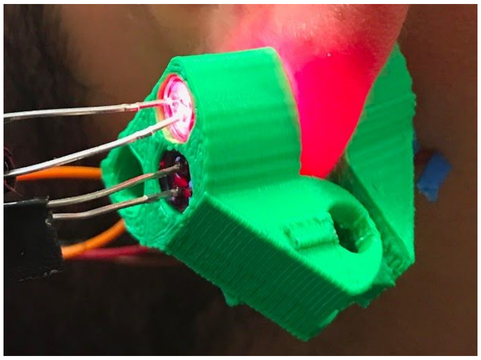

Figure 3-18: Finalized pulse oximeter testing setup. The finalized testing setup with fixed path length between LEDs (red LED is shining) and photodiode.

The final testing setup was used with the ear clamp to house the LEDs from outside light as best as possible, and the photodiode on the other half of the ear clamp. In addition, the LED's were directly connected to the PCB (no longer designed on a breadboard).

Table 3-1: Pulse oximeter and heart rate data from trial 1.

HR	1	2	3	4	5	6
Our Sensor	76	72	60	52	76	52
Commercial	66	82	57	55	81	56
% Error	13%	14%	5%	6%	6%	7%
Avg. Error	9%					

O2 Levels	1	2	3	4	5	6
Our Sensor	98%	98%	97%	97%	100%	96%
Commercial	98%	98%	98%	98%	99%	99%
% Error	0%	0%	1%	1%	1%	3%
Avg. Error	1%					

Oxygen saturation and heart rate were tested six different times, where the average error of both the heart rate and oxygen saturation are under ten percent compared to commercial products. There are promising results from this sensor; the next step is to test the pulse oximeter accuracy when the patient has an elevated heart rate.

Table 3-2: Pulse oximeter and heart rate data from trial 2.

Percent Difference Patient 0		
HR:	Resting	35%
	Elevated	11%
Percent Difference Patient 1		
HR:	Resting	6%
	Elevated	n/a
Percent Difference Patient 2		
HR:	Resting	1%
	Elevated	2%

Note: The heart rate was calculated in MATLAB from the LED raw data [Refer to Appendix A for further detail].

There is an outlier in this data set where Patient 0 has a resting heart rate difference of 35%. This is the only point where this has occurred, and it is hypothesized that the error is because of the sensitivity of the commercial sensor. However, the average error for the elevated heart rate is

6.5% for two out of the three patients. Patient 1's elevated heart rate could not be calculated because one of the data sets did not save correctly and could not be processed.

3.4 Microcontroller

3.4.1 Role/Requirements

An essential component in our device is a microcontroller that is able to take in the analog signals of each of our sensors and transform the signal into a digital signal. The digital signal is then is then analyzed by the software of the device connected into the microcontroller and turn into the calculations of the measurements of the patient's vital signs. At the same time there are filters, amplifiers and buffers that need to be implemented to clean the incoming signal from each of our sensors.

3.4.2 Options and Trades

Taking the requirements into consideration we decided on a set of possible implementations for our microcontroller and the implementation of our circuit designs:

- **Breadboard and Arduino Uno:** What the previous team did was to implement all of the circuit designs into a breadboard and connect this breadboard to the sensors and to an Arduino Uno Microcontroller. This method of implementation had a number of issues since the breadboard components could fall off and had a greater error margin in treating the signals. At the same time, while the Arduino Uno is an excellent microcontroller that could supply all the needs of the project, it is also a component that is relative expensive to the overall project.
    - Pros
        - Easy to Implement
        - Easy to modify
        - Inexpensive implementation of circuit designs
    - Cons
        - Expensive microcontroller
        - Wide error margin with measurements
        - Convoluted wiring and loose parts in implementation of circuit design
- **PCB:** Taking into consideration what the previous team did, we decided that the best solution was to design and order a PCB that included all of our circuit designs, as well as the required components to implement a simpler microcontroller. By implementing a simpler microcontroller we would be cutting down on the cost of using an Arduino Uno microcontroller. The component that we would be using would be the Arduino Uno chip that would require coding to ensure it works as we need it. A PCB with surface mount

components would give us better accuracy due to the smaller margin of error of the surface mount components and a more sturdy implementation of our circuit designs.

- Pros
  - Inexpensive compared to alternatives
  - Smaller margin of error with surface mount components
  - Study implementation of circuit designs
- Cons
  - Harder to modify
  - Harder to implement due the necessity to code

- **PCB and Arduino Uno:** For the implementation of our project we made some adjustments were we decided to implement all of our circuit designs into a PCB shield for the Arduino Uno. Essentially we created a PCB that can be connected to the Arduino Uno, the reason for such a modification is that due to time constraints we would not be able to fully implement the microcontroller into our PCB. At the same time we added a section in our PCB that allowed us to modify our circuit design for our Glucose Sensor which did not work as expected. (See Appendix D for PCB Layout).
  - Pros
    - Smaller margin of error with surface mount components
    - Study implementation of circuit designs
    - Capable of modification
    - Easier to implement
  - Cons
    - More expensive overall due to the need for a microcontroller

Chapter 4: System Integration, Tests, and Results

4.1 PCB

In the beginning, it was imperative that our requirements would include improving overall accuracy of the device as compared to last year while reducing the price as well. The major decision was then made to implement our own PCB design. Including this PCB would make the following improvements:

- Increase accuracy
- Reduce Size
- Refine usability

As a result of this decision, the overarching system to be integrated and tested first was the PCB. Since the PCB would allow for the capability of all of our sensors to function efficiently, it was vital that this would be the initial system to be integrated into our prototype. The finalization of our PCB came along in the following steps:

- Recreation of circuit for each sensor on a breadboard
- Additional and various filtering
- Overall PCB design and schematic finalization
- Printing of board and soldering of components

The final PCB design is shown in Figure 4-1 below, which integrates each sensor and its various components and attachments.

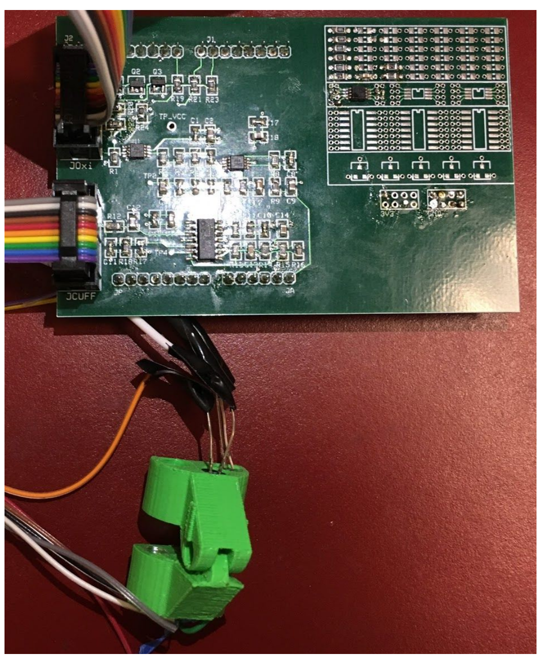

Figure 4-1: Final PCB Design with External Components

4.2 Breadboard Iterations

There were three main circuits implemented on each breadboard: the Blood Pressure circuit [Figure D-1], Pulse Oximetry circuit [Figure D-2], and the Glucose circuit [Figure D-3]. The various schematics were implemented onto three separate breadboards, that allowed for simple modification [Appendix C]. A lot of our initial predictions were obtained from the simple calculations we performed prior to our schematic design. Blood Pressure testing was deemed correct when we were able to fully measure patient's data from the breadboard and the same was done for the Pulse Oximeter. Testing for the Glucose sensor required much more custom iterations. Once our breadboard implementations were cleared they were implemented on the PCB to conduct further testing.

4.3 Blood Pressure

Blood Pressure testing began by utilizing our PCB design [Figure D-1 Appendix D] . Through our testing, our accuracy with the systolic and diastolic pressures compared against the commercial device were found to be within 3-7%, which correlates to our requirement of improving the accuracy of this sensor as compared to last year. Various results through our volunteers are recorded in [Table C-1].

4.4 Pulse Oximeter

Pulse Oximetry testing is shown in [Table 3-1 and 3-2]. Our breadboard testing was done by taking data being measured through the patient's finger, as opposed to the earlobe sensor that would later be implemented. Our main contribution to enhancing the accuracy of this sensor was the inclusion of the aforementioned earlobe sensor. Below in Figure 4-2 is the housing that we created for the earlobe sensor to house the LEDs and photodiode.

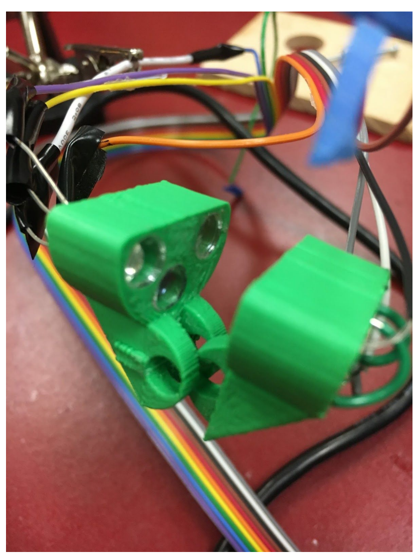

Figure 4-2: Ear clamp Sensor

We then measured patient data through this process. The heart rate recorded as compared against our commercial product was found to be within 8% accuracy, and our blood oxygen saturation levels all fell within 1% accuracy [Table 3-1 and 3-2].

<u>4.5 Glucose</u>

Glucose was the most difficult sensor to implement, and the testing required constant variation throughout the year. Testing was done through measuring the difference between various concentrations of pure glucose in a water solution. As shown in Figure 3-8, we began with having these solutions in a latex balloon, which would allow for more light to go through so that we could gain a more realistic measurement to that of the skin. As time went on, we decided to design an opaque container with a clear opening to allow for the glucose to be seen. This approach is shown below in Figure 4-3.

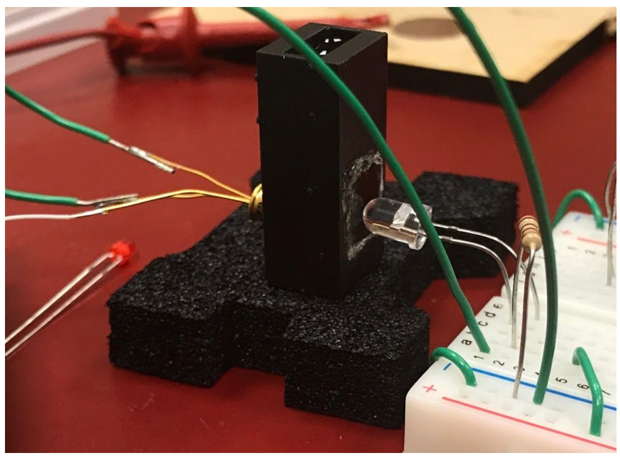

Figure 4-3: Opaque Glucose Container

This slightly increased the correlation of data read to that of the various solutions, but our group decided to move forward and begin testing with our PCB design. We created a test pad on the right half of the PCB to allow for alterations [Figure D-6].

Chapter 5: Cost Analysis

Table 5-1: Overall Cost of Project

Component	Number of Items	Price per Unit	Total Cost	*Order Cost
Commercial Pulse Oximeter **Santamedical SM-240 OLED Finger Pulse Oximeter**	1	$54.95	$54.95	
Commercial Blood Pressure Monitor **Omron 7 Series Upper Arm BP Monitor**	1	$64.99	$64.99	
Commercial Glucose Monitor **One Touch Ultra Diabetes Testing Kit - One Touch Ultra Meter, 100GenUltimate Test Strips, 100 30g Lancets, 1 Lancing Device and 100 Alcohol Prep Pads**	1	$40.95	$40.95	
Commercial Thermometer **Beyoung Axillary Thermometer**	1	$6.99	$6.99	$178.03
Custom 4-layer circuit board from ExpressPCB.com (PCB boards)	3	$25.00	$75.00	$110.93
5mm Red LED (660nm)	10	$0.29	$2.90	$10.20
5mm IR LED (940nm)	10	$0.68	$6.80	$21.06
Glucose Meter LED **LED1550E - Clear Epoxy, 1550 nm, 2mW**	8	$17.95	$143.60	$197.41
GPD Optoelectronics GAP 136 in GaAs Photodiode (900-1650nm)	5	$20.00	$100.00	$191.78
TI OPT101P Photodiode (400-1100nm)	2	$7.46	$14.92	$26.71
Honeywell ASDX015PDAA5 Pressure Transducer	1	$11.69	$11.69	$20.43
Hand Pump: **Omron Digital Blood Pressure Parts & Accessories**	1	$14.95	$14.95	$14.95

Pressure Cuff: **`ComFit Cuff 9" 17" for HEM773AC & HEM780**	1	$18.95	$18.95	
2nd Hand Pump: **Santamedical Adult Deluxe Aneroid Sphygmomanometer**	1	$13.95	$13.95	
2nd Commercial Pulse Oximeter: **Santamedical Generation 2 OLED Fingertip Pulse Oximeter**	1	$18.95	$18.95	$52.98
Condoms (for testing):**Trojan ENZ NonLubricated Condoms, 12 Count**	1	$5.97	$5.97	$10.81
MATLAB and Simulink Student Suite	1	$99.00	$99.00	$99.00
Chip Components: Resistors, Capacitors, Inductors, etc. (DigitKey.com)	See Table of Components	$23.53	$23.53	$40.33
Arduino Mega Microcontroller	1	$40	$40	$40
		Total cost:	$758.03	$1014.62

*Including shipping and cost

Table 5-2: Cost of Device

<u>**Item**</u>	<u>**Cost**</u>
Blood Pressure ● 3Way Dump Valve ● Handpump & Pressure Cuff ● ASDX015PDAA5 Transducer	<u>**Total = $ 47.53**</u> $2 $14.95 + $18.89 = $33.84 $11.69
Glucose ● LED1550E ● GAP 136 Photodiode ● Spring for Ear Clamp	<u>**Total = $ 38.95**</u> $17.95 $20 $1
Oximeter ● TI OPT101P Photodiode ● 5mm Red LED (660nm) ● 5mm IR LED (940nm)	<u>**Total = $ 8.43**</u> $7.46 $0.29 $0.68
PCB	$25

Arduino Uno	$40
Surface Mount Component (Res, Caps)	$4.49
Surface Mount Components (Op-Amps, Mosfets)	$8.13
Acrylonitrile-Butadiene-Styrene (ABS)	Free*
<u>Total Cost</u>	**$133.58 or $172.53 (Glucose)**

* Donated by the Frugal Lab

Chapter 6: Patent Search and Business Plan

Table 6-1: Patent Search

Patent ID	Patent Title	Description
US 8676284 B2	Method for non-invasive blood glucose monitoring	Using metabolic heat measurements to measure blood glucose levels
US 20150112170 A1	Device and method for non-invasive glucose monitoring	Transmission of terahertz waves through a tissue to be received by a sensor on the opposite side
US 8135450 B2	Noninvasive glucose sensing methods and systems	Using electromagnetic waves or ultrasound waves, dependent on tissue thickness, length, width, diameter, etc.
US 6556852 B1	Earpiece with sensors to measure/monitor multiple physiological variables	Pulse oximeter ear sensor positioned against rear wall of the ear canal
US 8588880 B2	Ear sensor	Optical assembly sensors used at concha of the ear
US 5931791 A	Medical patient vital signs-monitoring apparatus	Portable ultra-lightweight multisensor including ECG, pulse oximetry, and blood pressure
US 8235897 B2	Device for non-invasively measuring glucose	Ear clamp noninvasive blood glucose sensor using ultrasonic, electromagnetic, and thermal methods

Business Plan

The team had initially designed our device to be sold for individual purchase in India to a certain amount of people in a community. We were able to get into contact with NOORA Health [19], who suggested that our business model could function as follows: Patients would only be charged per test rather than purchasing an entire model of our device. Implementation would then require that our components would be assembled in India, which would also reduce the overall cost of our device. Since our device was intended to be financially responsible, this business model functions well for our requirement.

Chapter 7: Professional Issues and Constraints

7.1 Ethical:

A number of ethical questions needed to be raised with the development of this device. The first question is about the access to a device like this; while it is significantly less expensive than currently commercially available multi-sensors, it is still relatively expensive for low-income families. As such, there is a question of whether this device contributes to the problem of access to health care. While this device wouldn't be that inexpensive, it is the sort of thing that multiple users can pool money together to buy, as there is little concern for sanitation issues with respect to this device.

Another concern to be considered is that since this device is designed to be used with mobile devices, this doesn't increase the access to health information for those in greatest need for increased access. Areas in the world that do not have cell phone towers in place, or in areas where most people are too poor to afford luxuries such as mobile devices, this device serves very little purpose. While it does address a large population of people that could use the help of this device, it does very little to aid the most vulnerable people in communities around the world.

One last concern is with increased access to health information such as this, there is also an increased need for professionals who can help users interpret the data they are receiving from the device. Similarly to getting one's genome sequenced without the consultation of a doctor or genetic counselor, such data can mean very little, or even cause users to form false opinions/diagnoses of themselves, as they may not seek out the appropriate individuals that can help users make decisions with the data they measure themselves.

7.2 Health and Safety:

Given that products such as the one produced as a result of this project are made for use by the general public, there is a need to ensure that the product meets certain safety standards.

In general, a product should be safe enough that an adult can use the product for normal functions without any risk of damage to their body, those around them, or any property around them. This implicates things such as making sure it doesn't produce too much heat, that there are no exposed wires that could potentially shock the user, and that the light intensity produced by the LEDs is low enough that no damage would come to the user for looking into it for a moment. However, the assumption that there will be those who will use the device for purposes other than that which it was made for, and a reasonable amount of precautions should be taken to prevent harm in those functions too. This includes ensuring that there aren't any small parts that can easily come off and be swallowed by infants or animals, as well as that there are no fire hazards associated with the product.

For the sensors that involved the use of LEDs, all were checked by Santa Clara University's Safety staff to ensure that there is no concern associated with looking into the LEDs directly, and that there would be no direct contact with any parts that have potential to heat up.

The question does come up, to what extent does one increase the cost of a product to cover for safety concerns that fall outside of normal use. This becomes a problem, largely because almost anything can be used incorrectly to cause harm to a person, so a product could never be completely safe, so a line must be drawn to ensure that and reasonably possible concerns are covered, such as burns, sharp edges or corners, damage to eyes, or electrical shocks.

7.3 Environmental Impact:

The primary environmental impacts as pertain to this device are the proper disposal of the components used to make the device. On a per-use basis, this device produces no waste whatsoever. Additionally, this device has an approximate minimum life expectancy of five years based on the lifespan of the more fragile components. However, once the device is no longer functional, there are a number of components that need to be disposed of properly. This includes a number of plastics and rubbers that are used to make the housing and tubing for the device, as well as wiring and various small electrical components (LEDs, photodiodes, capacitors, resistors, etc.).

The production of the photodiode for the glucose sensor has an indium-gallium-arsenide alloy. Producing this alloy involves the use of a highly toxic gas [20], which is an environmental concern. However, once this gas is deposited onto a substrate, it is inert.

7.4 Science, Technology, and Society:

This product is targeted to communities in developing countries that are far away from hospitals and clinics, but has implications even in developed countries where people are far away from hospitals and clinics, but still have access to mobile devices. The development and implementation of this device has the potential to provide communities with a greater degree of health independence by giving users access to their vital sign information in their towns or homes, help them save time and money by reducing the frequency of unnecessary doctor's appointments, and has the potential to reduce costs even of emergency medicine companies that commonly use multi-sensors.

There are some potential negative consequences in these communities as well. Giving people greater access to these tools does give people greater opportunities to learn to track their own vitals, but also leaves potential for people to do so incorrectly, and potentially key details that result in spending money on going to see a doctor when not necessary, or avoiding the hospital when a visit is necessary. Additionally, with an implemented telemedicine component, unless encryption of the medical information is very well developed, there is potential for users' health information to be stolen through the use of mobile devices, which poses a serious risk to users, as this data can be sold to health insurance companies.

7.5 Civic Engagement:

A medical device such as the device produced in this project would require FDA approval before the device could be sold commercially here in the United States, and would have to go through similar health regulation agencies in whatever country this product is to implemented in. This is particularly true with respect to the glucose sensor portion, as the rest of the sensors are simply cheaper/adapted forms of technologies that are already FDA approved. The glucose sensor technology being used for the glucose sensor in this device is not yet approved by the FDA; there are a number of companies that are in the FDA approval process at the time of this writing that use a similar technology. This means that in the next few years as these technologies are approved, it will be easier to push this device through as similar technologies have been approved; the primary difference of this device is the reduced cost and simplicity. Additionally, testing on a greater number of subjects before trying to get FDA approval would increase the chances of receiving the approval, as data demonstrating the efficacy of the technology of this device would be helpful, as well as tests on the safety of the glucose sensor technology as a potential danger would be necessary for approval.

Chapter 8: Summary and Conclusions

8.1 Conclusions

The objective of this project was to develop an affordable kit equipped with sensors that will be used to take a patient's vital signs, such as blood pressure, heart rate, blood glucose concentration, and blood oxygen saturation. This kit is intended for developing countries such as India in order to help alleviate the health care issues of people not being able to check on how their overall health is doing. This device, in the future, could detect if a person would need to make the arduous trip to go to the doctor. Our vital sign kit is compact and also easy to use. We found that on average, the pulse oximeter and heart rate sensor had less than 10% error compared to commercial products. The blood pressure sensor average is in the range between 10% -20% compared to the commercial sensor, however, we know that our current limitation that is preventing us from reaching less than 10% error is the Matlab code that processes the data. In the future, that can be assessed and fixed. Furthermore, while our glucose sensor is not functional, we have learned what new directions students could go in to make the sensor work if they chose to continue this project.

8.2 Future Work

Some possible directions to go in the future include:

- **Microcontroller Implementation:** Due to time constraints we were not able to implement the microcontroller into our PCB. While we did developed a possible schematic for implementation, there is more work that needed to be done in terms of coding before we got a fully functional microcontroller. Due to time constraints we opted to continue to use the Arduino Uno as our microcontroller. For future development of the project, a team could potentially implement this change which would bring down the overall price of the project by getting rid of the need for an Arduino Uno. (See Appendix D for Microcontroller Circuit Design)
- **Software Development:** For most of our computations we use an assortment of software including Arduino Software and Matlab. A goal for the future is to create a iOS or Android app that is able to do all of the necessary calculations to send the data results to another mobile device.
- Adding in respiratory sensor.
- Using a new methodology to test glucose levels.

Chapter 9: Ethical Analysis

When it comes to engineering, it can be easy to lose oneself in the excitement of new and upcoming technologies. At times, however, these ideas can overshadow the equally important concept of ethical considerations. Just as important as the newest medical treatment are the questions that surround it, such as who has access to this treatment, whether the risks outweigh the benefits, and other such ethical questions that helps draw the line between a "good" technology and a "bad" one. The technology in question is the Vital Multi-Sensor Kit, which will measure vital signs such as heart rate, blood pressure, and other baseline vitals, and be connectable to a mobile device to be sent to a physician for diagnosis.

To start off, it is important to understand the fundamental moral argument for pursuing the senior design project that this team is undertaking. This argument is that every person has a fundamental dignity, and that dignity extends to a right to medical care. Basic human dignity means treating every life as if it matters, whether that is socially, intellectually, or physically. So long as a life matters, that means that there must be certain steps that we as people must be prepared to take to uphold this dignity. With this in mind, we sought to make it easier for people to get access to the health care they need, even if it is just for the sake of treating them with basic human dignity. Beyond that yet, there are an immense number of people around the world who take their access to healthcare for granted, primarily in the developed world. If there are so many who believe healthcare is a right as opposed to a privilege, then we should treat it as such, and work to defend this right for those who cannot necessarily do so themselves.

Moving onto the product itself, the ethical duty that this team has to the potential users must be considered. Ideally, the product this team is working towards producing would target a very large demographic, which is those who do not have easy access to a doctor or hospital, but do have access to a smartphone or other such mobile device. This could be easily in the millions of people. What is owed to these potential users is that the data they retrieve from the device is accurate to the best of our ability. Inaccurate data could result in either a false sense of security in one's health, or an unnecessary amount of time and resources spent on getting to a hospital when such a visit is not necessary. This is not to say that absolute accuracy can be achieved for this product, but it is to say that it is the ethical duty of this team to work towards the greatest accuracy given the time and resources allotted, and provide the appropriate specifications for the percent error they would be likely to encounter. Another duty to the potential users is that the product should be made to fulfill the requests and needs as much as possible. Given that we will be contacting some of the potential users of this product, it is our duty to provide them with a product that at least attempts to meet the user's' needs, as opposed to whatever desires this team may have for the product.

Yet another important ethical consideration when engineering a product is the risks that may be associated with it. To the best of our ability, we are ensuring that this device would not be able to malfunction to the extent that it could cause physical harm. While there are a few parts that have the potential to heat up when overused that could burn the skin, we are going to minimize the risk of that within the circuitry of the product. This occurrence will also be minimized by the elimination of physical contact with any electrical components that could heat up. There is also a risk associated with the product with regards to confidentiality. Since the purpose of this device is to collect baseline vital signs that could be indicative of health concerns, the data retrieved by the device would be considered confidential.The purpose of this product is to collect and send health data to a desired person via mobile device; at least in part, steps ought to be taken to ensure that this data cannot be acquired by unauthorized viewers, which could be accomplished with data encryption methods. This is a concern because this confidential health data could be indicative of health concerns, which is data that is valuable to health and life insurance companies, as well as other parties that could misuse the data. Lastly, there is the risk brought up earlier, about the potential harms of inaccurate data. Should the product provide data that is indicative of no health concerns when there are in reality concerns, there is potential for the user to miss out on treatment for an ailment they may be suffering from. At the same time, if the product provides data that is indicative of a health concern when there is no health risk, the user may make arrangements to make their way to a hospital without the need for a potentially costly trip.

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Appendix A: Raw Data

Heart Rate & Pulse Oximeter Data

Table A-1: Pulse Oximeter and Heart Rate Data from Trial 1.

HR	1	2	3	4	5	6
Our Sensor	72	72	52	52	76	52
Commercial	66	82	57	55	81	56
% Error	8%	14%	10%	6%	6%	7%
Avg. Error	8%					

O2 Levels	1	2	3	4	5	6
Our Sensor	98%	98%	97%	97%	100%	96%
Commercial	98%	98%	98%	98%	99%	99%
% Error	0%	0%	1%	1%	1%	3%
Avg. Error	1%					

Table A-2: Pulse Oximeter and Heart Rate Data from Trial 2. Elevated heart rate and oxygen saturation measurements are also shown. [SD = Senior Design Device]

Patient 0	HR	80
	O2	98
	HR_SD	52
	O2_SD	99
	HR0_elev	97
	O2_elev	98
	HR_SD_elev	108
	O2_SD_elev	99
Patient 1	HR	64
	O2	99
	HR_SD	68
	O2_SD	98
	HR_elev	62
	O2_elev	98
Patient 2	HR	95
	O2	99
	HR_SD	96
	O2_SD	99
	HR0_elev	110
	O2_elev	98
	HR_SD_elev	108
	O2_SD_elev	98

Blood Pressure Data

Table A-3: Trial 1 and Trial 2 of Blood Pressure Sensor Measurements

Trial 1	Person 1	Person 2	Person 2	Person 4
Commercial BP:	119/77	102/70	107/72	103/65
Sensor:	110/65	98/72	100/67	98/67
% Diff (Systolic)	8%	4%	7%	5%
% Diff (Diastolic)	16%	3%	7%	3%
Trial 2	Person 1	Person 2	Person 2	
Commercial BP:	116/72	98/73	100/60	
Sensor:	92/63	100/67	93/61	
% Diff (Systolic)	21%	2%	7%	
% Diff (Diastolic)	13%	8%	2%	
Avg. Error Systolic		8%		
Avg. Error Diastolic		7%		

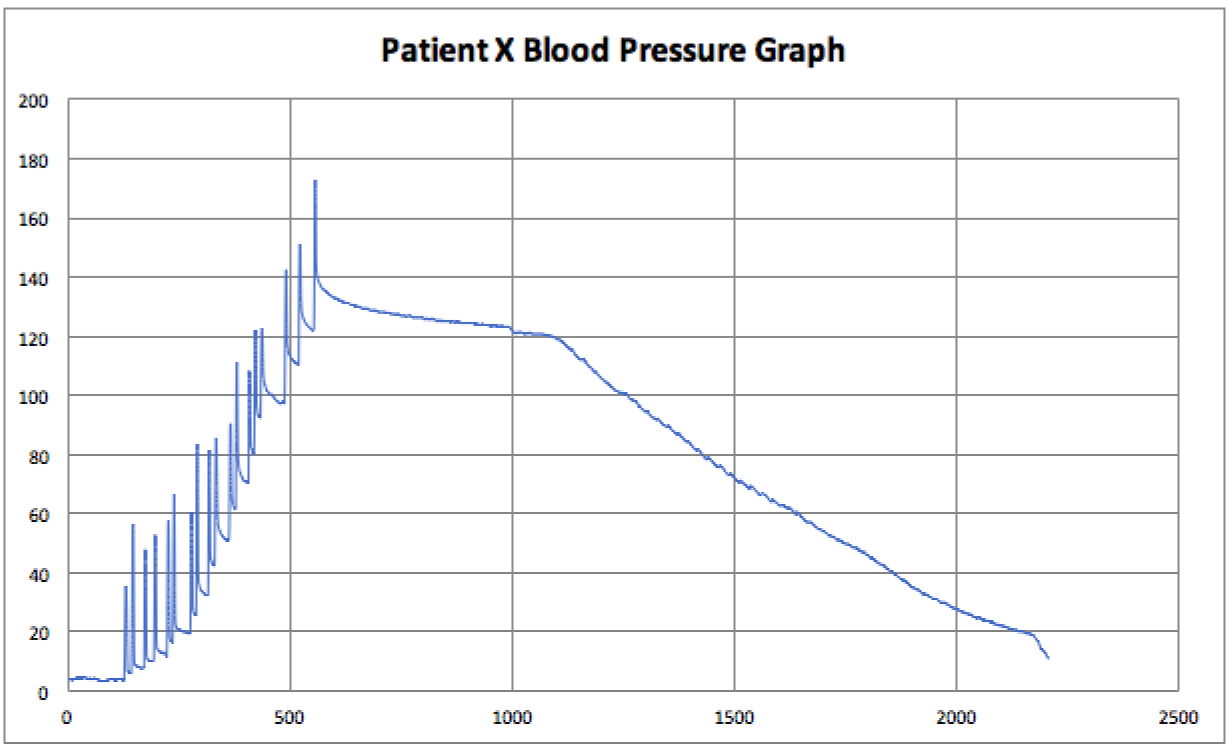

Figure A-1: This is an example graph of the blood pressure sensor readings. The beginning of the heart rate marks the systolic pressure, and the diastolic pressure is where the heart beat ends. Heart beats are most visibly seen around 1500 (in the x-direction).

Glucose Sensor Data

Table A-4: Glucose Sensor Raw Data Trial 1

Trial 1	Glucose Concentration (mg/dL)	Signal (0 to 1023)	Baseline (bits)
	200	660	837
	90	655	839
	50	656	839

Table A-5: Glucose Sensor Raw Data Trial 2

Trial 2	Glucose Concentration (mg/dL)	Signal (bits)	Baseline (bits)
	30	22	735
	50	10	728
	70	11	722
	100	10	727
	125	10	705
	200	9	696

Table A-6: Glucose Sensor Raw Data Trial 3

Trial 3	Glucose Concentration (mg/dL)	Signal (bits)	Baseline (bits)
	100	387	696
	30	289	700
	200	308	700
	200	295	700
	100	389	670
	30	382	699

Table A-7: Glucose Sensor Raw Data Trial 4

Trial 4	Glucose Concentration (mg/dL)	Signal (bits)	Baseline (bits)
	30	634	650
	50	636	651
	70	636	651
	80	634	651
	90	636	651

Table A-8: Glucose Sensor Raw Data Trial 5

Trial 5	Glucose Concentration (mg/dL)	Signal (bits)	Baseline (bits)
	50	408	585
	90	403	584
	125	399	584
	200	400	584

Table A-9: Glucose Sensor Raw Data Trial 6

Trial 6	Glucose Concentration (mg/dL)	Signal (bits)	Baseline (bits)
	50	176	585
	90	N/A	584
	125	N/A	584
	200	132	584

Appendix B: Detailed Calculations

Blood Pressure Calculations:

Blood pressure data retrieved directly from the sensor without any processing is returned in the form of bits, ranging from 0 to 1023. These bits are directly correlated to the voltage output of the sensor, which can be calculated using the formula:

$$V = (\#\ of\ bits) \times \frac{(5V)}{(1023\ bits)}$$

where V is equivalent to the voltage output of the pressure sensor in volts. In order to now retrieve a pressure value from the pressure output, the voltage must be processed through a formula provided by the manufacturer of the pressure sensor (see Figure I-1), which is:

$$V_{out} = V_s \times (0.018 \times P + 0.04)$$

where V_{out} is representative of the voltage output of the pressure sensor in volts, V_s is representative of the voltage provided to the sensor in volts, and P is the pressure applied to the sensor in kilopascals (kPa). To solve for the pressure P in millimeters of mercury (mm Hg) which is standard for blood pressure sensors in the United States, the equation is changed into:

$$P = \left(\frac{V_{out}}{0.0594} - 2.222\right) \times 7.5$$

where P is pressure in mmHg, and V_{out} is the voltage output of the pressure sensor in volts.

Then, in order to extrapolate the systolic and diastolic pressures, the pressure values of a single trial must be graphed. On this graph, the relevant region of the data set is then identified, marked by the appearance and subsequent disappearance of small peaks during the slow release of pressure.

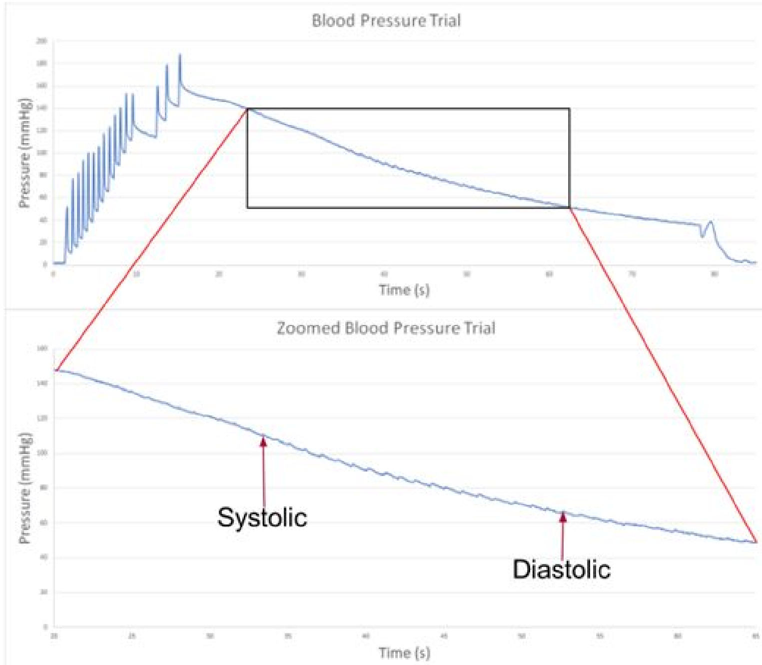

Figure B-1: Blood pressure graph breakdown

With this relevant region identified, the first and last substantial peaks are identified. The pressure of the first substantial peak is representative of the systolic pressure, and the pressure of the last substantial peak is representative of the diastolic pressure. The key with this identification of substantial peaks is the amplitude of the peaks. The very first small peaks that appear are not consistent with the systolic blood pressure, but the first peak of a relatively substantial amplitude is consistent with the systolic pressure (as measured against commercial blood pressure sensors). This analysis is the same with the diastolic pressure. Since there are variations in the amplitudes of the peaks from person to person and trial to trial, the determination of what constitutes a significant enough amplitude to qualify as a substantial peak is relatively subjective, which is the reason that at this point, the MATLAB code is not able to accurately determine the systolic and diastolic pressures from the data sets. Hence, the calculations are done through Excel and visual analysis reveals the relatively substantial peaks to indicate the pressure values of interest.

Appendix C: System-Level Descriptions

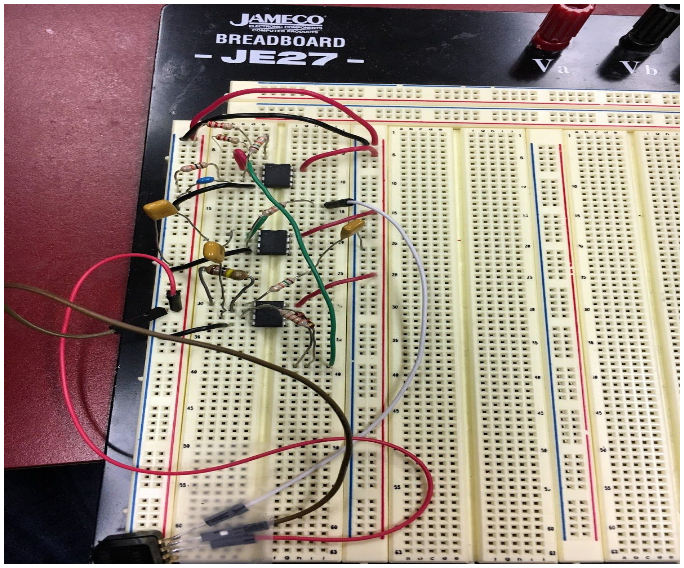

Figure C-1: Initial Blood Pressure Breadboard Design

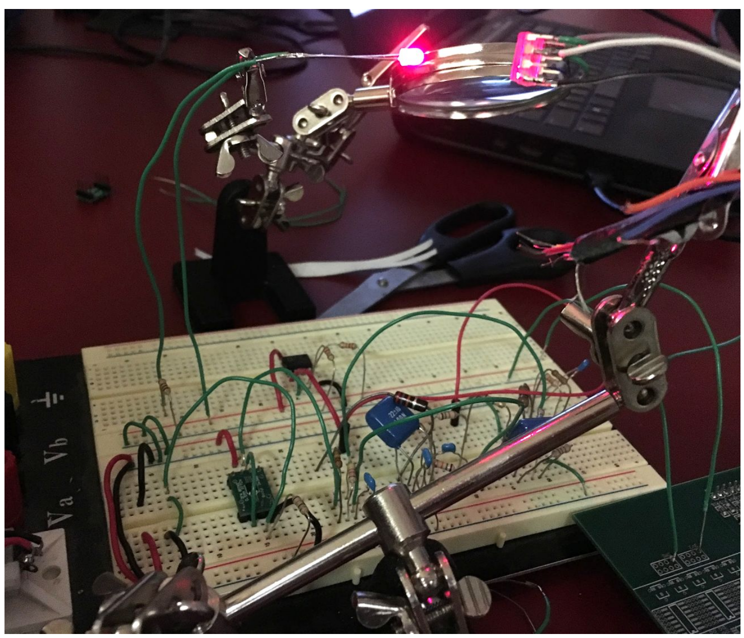

Figure C-2: Pulse Ox Breadboard Implementation

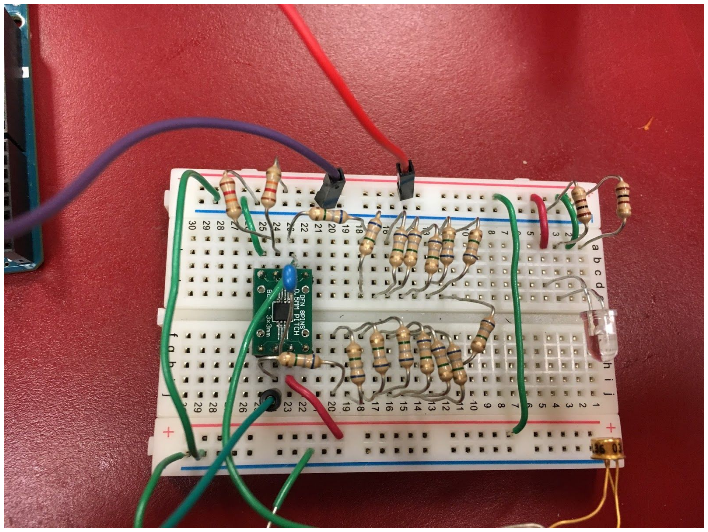

Figure C-3: Initial Glucose Breadboard Design

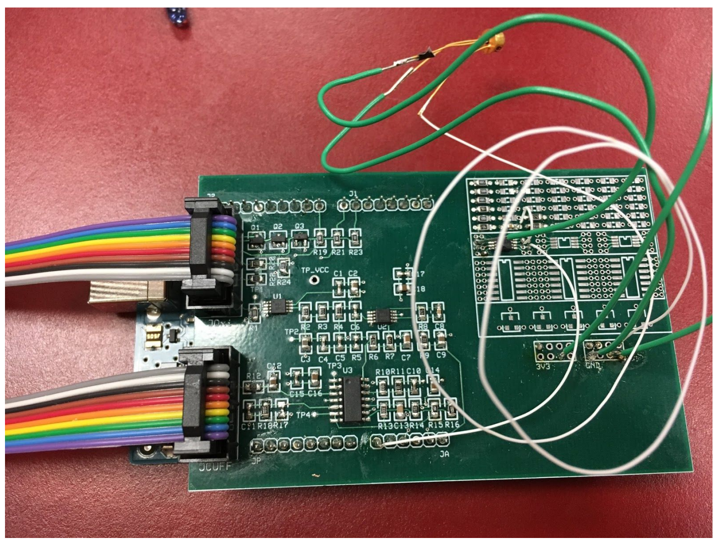

Figure C-4: Final PCB with all Circuits Included

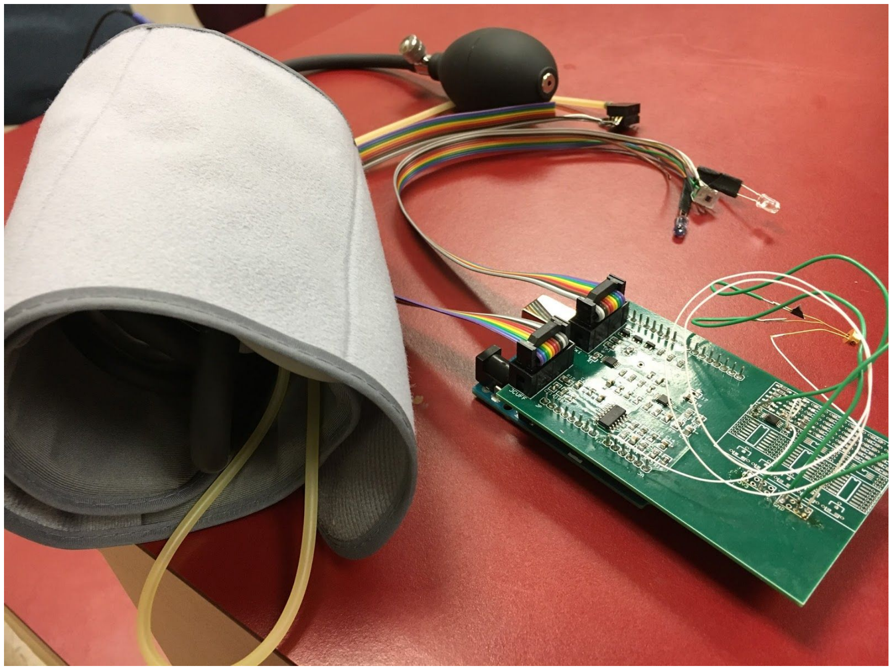

Figure C-5: Final Blood Pressure Testing

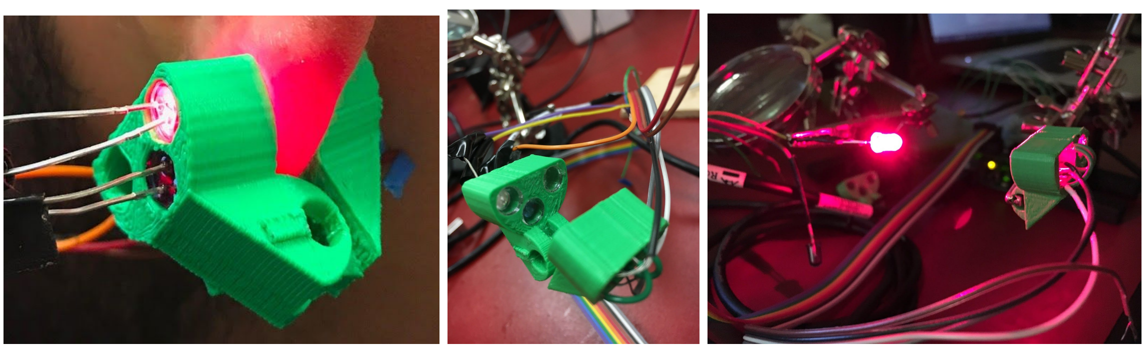

Figure C-6: Final Pulse Oximetry Testing

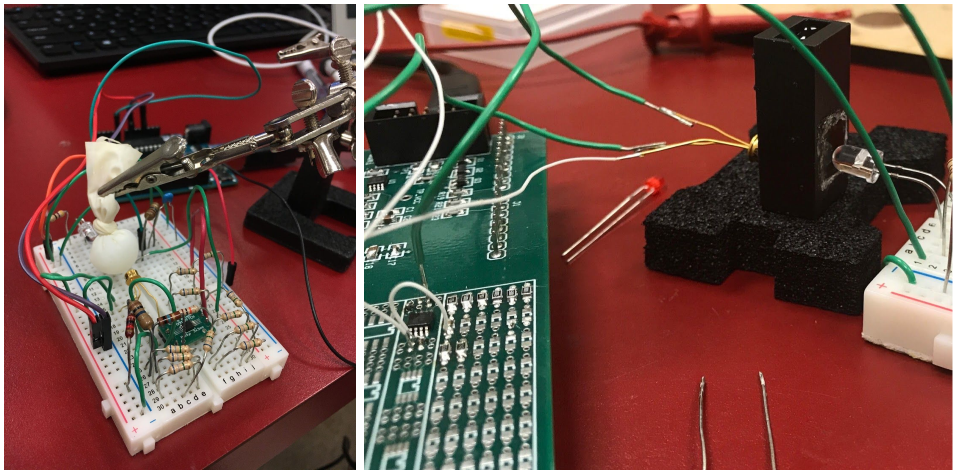

Figure C-7: Continued Glucose Testing

Table C-1: Example of Blood Pressure Accuracy Comparison

Trial 1				
	Person 1	Person 2	Person 3	Person 4
Commercial BP	119/77	102/70	107/72	103/65
Sensor	110/65	98/72	100/67	98/67
% Difference (Systolic)	7.6	3.9	6.5	4.9
% Difference (Diastolic)	15.6	2.9	6.9	3.1

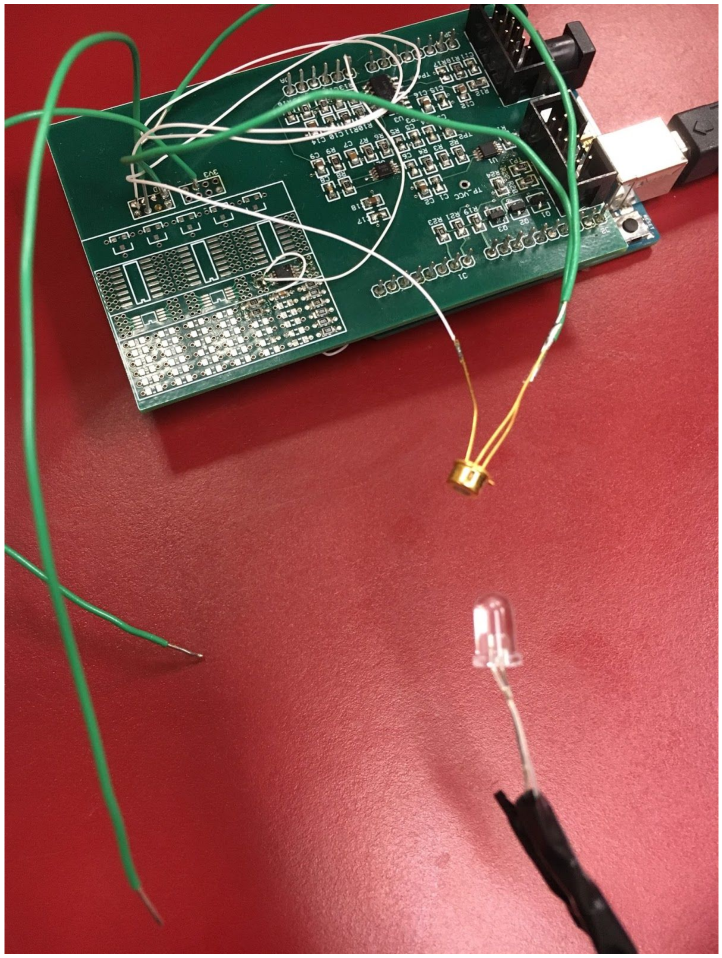

Figure C-8: Glucose PCB Implementation

Appendix D: Circuit Designs

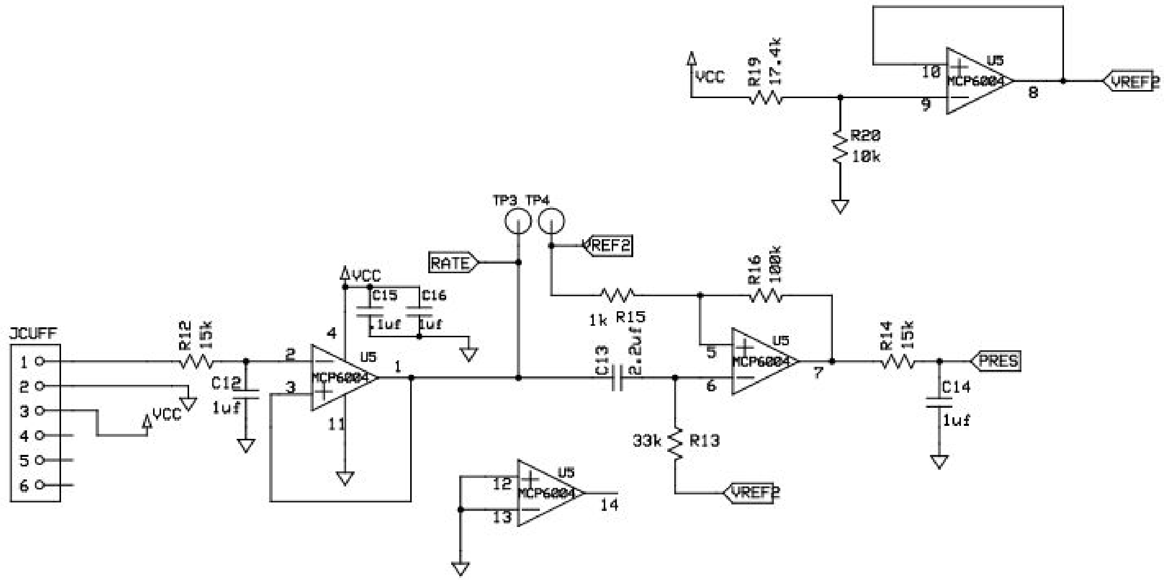

Figure D-1: ExpressPCB Blood Pressure Circuit Design

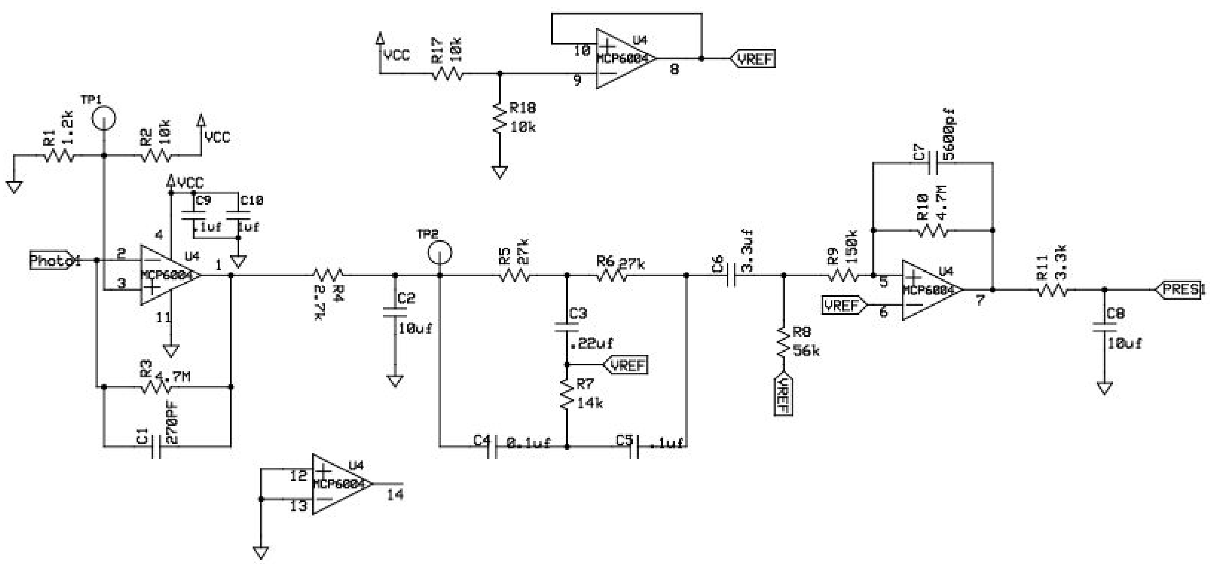

Figure D-2 : ExpressPCB Oximeter Circuit Design

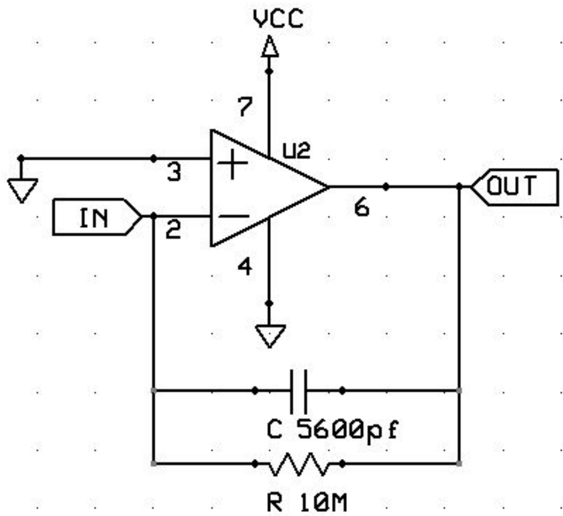

Figure D-3: Glucose Experimental Circuit Design

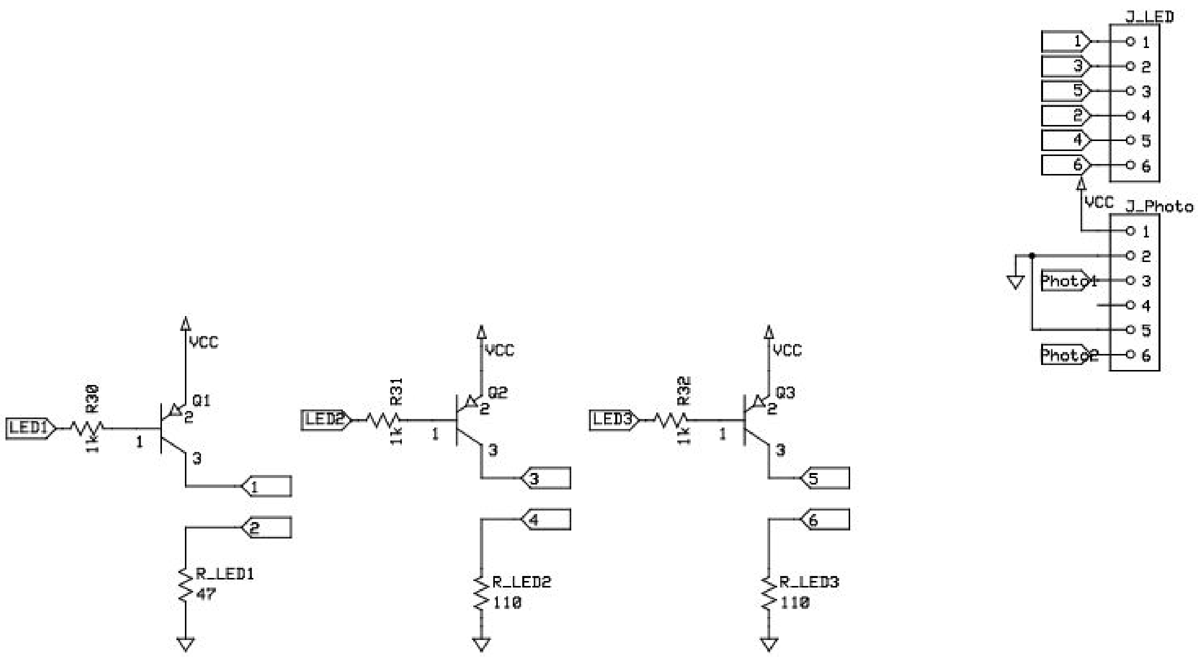

Figure D-4: ExpressPCB LED Drivers Circuit Design

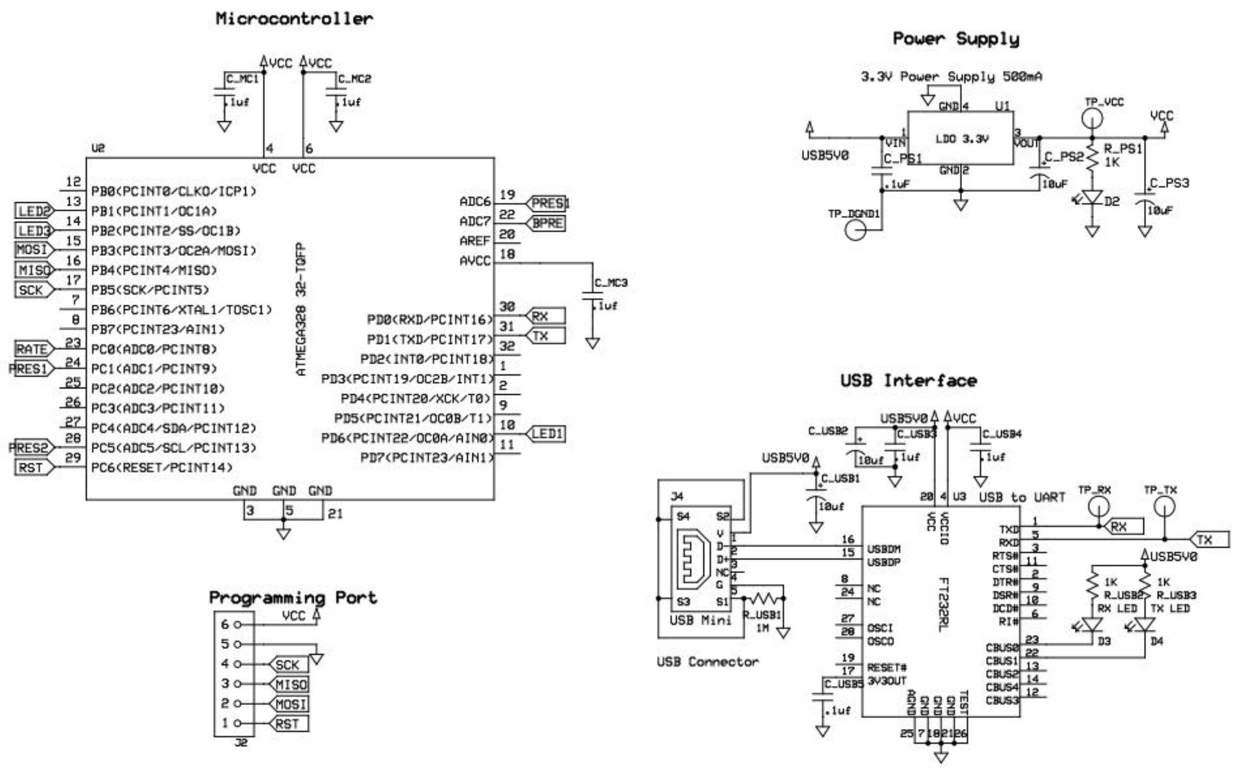

Figure D-5 : ExpressPCB Microcontroller Circuit Design

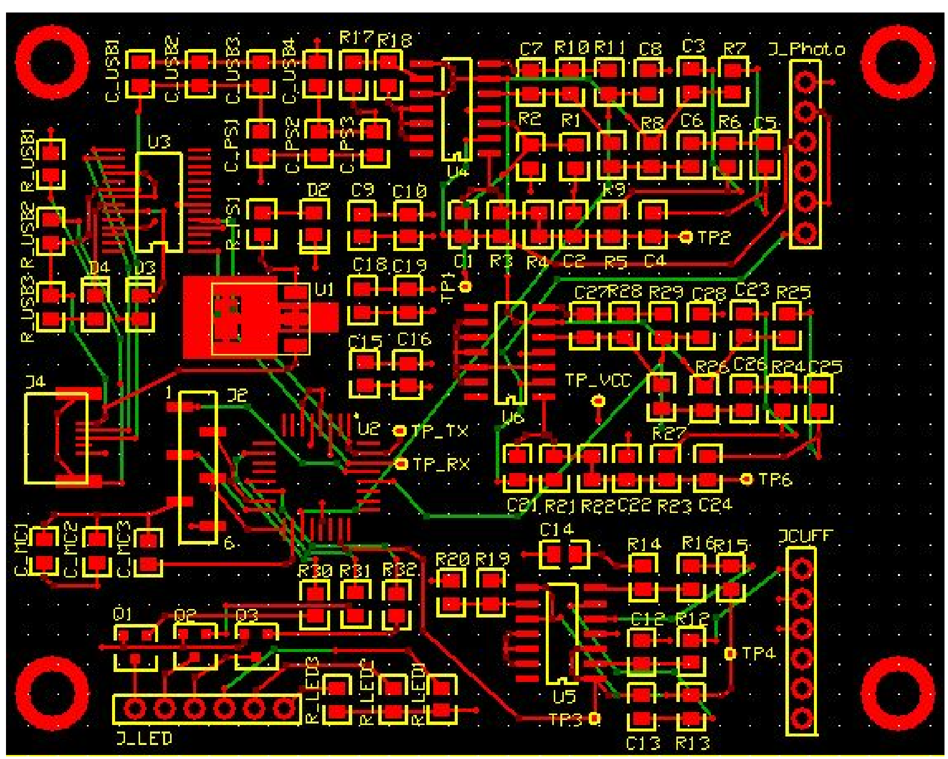

Figure D-6: PCB Layout

Table D-1: Sensor Circuit Filters, Amplifiers, and Buffers

Blood Pressure Circuit	
Type of Filter/Buffer/Amplifier	Cut Off/Gain
Low Pass	10.6 Hz
Buffer	
High Pass	2.19 Hz
Non-Inverting Amplifier	101 Gain
Low Pass	10.6 Hz
Glucose Sensor Circuit	
Transimpedance Amplifier	0.25Hz Cut Off/ 100 Gain
Oximeter Circuit	
Buffer	
Low Pass	5.89 Hz
Notch Filter	60 Hz
High Pass	0.86 Hz
Non-Inverting Amplifier	31 Gain
Low Pass	4.82 Hz

Appendix E: Project Management

Project Timeline:

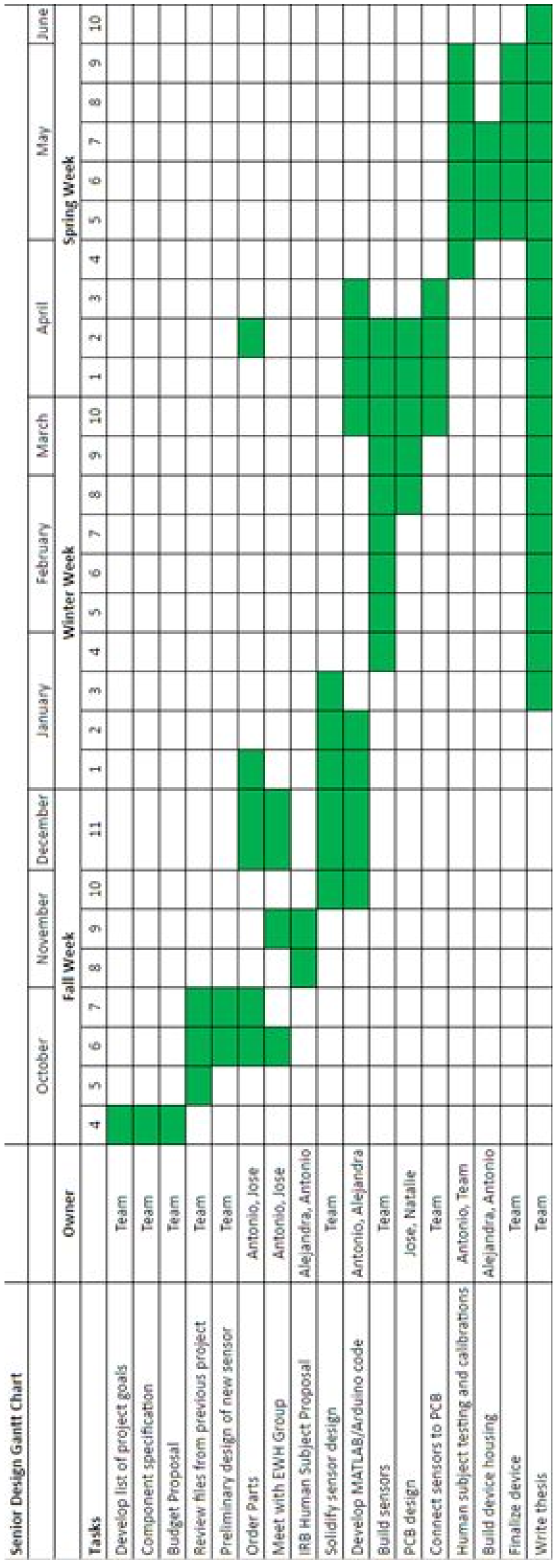

Figure E-1: Gantt Chart of Senior Design Project (Year-long)

IRB Application
Advisor: Dr. Ashley Kim
Students: Natalie Arrizon, Jose Hernandez, Antonio Maldonado-Liu, Alejandra Pacheco
IRB Application

Title: Vital Sensors Project

1. Purpose

Provide a brief explanation of the proposed research, including specific study hypothesis, objectives, and rationale.

The purpose of the research is to increase accuracy with the vital sensors kit that our team is designing. The kit will have the capability to measure up to six vital signs through the use of around 3-4 separate sensors. Testing on human subjects will help to ensure accuracy through the measured results that are collected through different patients. By collecting data with more subjects, our team will be able to increase the accuracy of the measured data by altering our original design or accounting for other setbacks or factors.

2. Background

Give relevant background (e.g., summarize previous/current related studies) on condition, procedure, product, etc. under investigation, including citations (attach bibliography in Attachments section) if Applicable.

In many developing countries, a large percentage of the population lacks access to adequate healthcare. This is especially true in India where close to 70% of the population lives in rural areas and has little to no access to hospitals or clinics. At the same time the doctor to patient ratio is of 0.6 to 1000.

Telemedicine has slowly been implemented in India to make doctors more available for patients through the use of video conferences and other forms of communication. However, a shortcoming of this is that the doctor still has no direct access to a patient's information, other than descriptions, x-rays, etc.

Around 80% of the population in India owns some form of mobile device, only 30% of those devices are smartphones. This percentage is expected to increase. Currently India is the second largest smartphone market globally.

In 2016, a team of Santa Clara students designed a vital sensory kit that could be connected to a computer to measure vital signs. The device was able to measure blood pressure, oxygen saturation, and heart rate with an average of 13% error. This year, we seek to produce a device with reduced error, and that has the capability to connect to a mobile phone for mobile vital sign monitoring.

3. Collaborative Research
N/A

4. Qualifications of Study Personnel

a) There are four students working on this kit who have qualifications well suited for the project. Two bioengineering majors help provide knowledge on how to work with the medical sensors and have the capability to read and distinguish proper results. One of the bioengineers is also EMT certified. The two electrical engineers are experienced in designing various types of circuitry and filter design.
b) The students have taken ELEN 21, ELEN 50, and other electrical engineering courses that are relevant to designing the proper circuit models and analyzing data that is collected. ELEN 21 is about logic design, and ELEN 50 is an introductory course to electricity and circuits. The two electrical engineering majors are also experienced in designing PCB boards and have training in the use of oscilloscopes, multimeters, bread boards, sensors, and other relevant programming. The bioengineering students have taken BIOE 163, which prepares students with the fundamentals for device engineering in the industry and BIOE 162, a class geared towards understanding signals and signal processing with Matlab. All members of the team are capable with working with patients in a professional and friendly manner to carry out the research necessary.

5. Subject Population
a) Describe proposed subject population, stating age range, gender, race, ethnicity, language and literacy.
The population we will be testing mostly consists of university students of an age range of 18-24. The expected sample of subjects will be chosen so that there is a diverse range of races, ethnicities and ages, and sex.

b) State total number of subjects planned for the study and how many must be recruited to obtain this sample size. Explain how number of subjects needed to answer the research question was determined.

The total number of subjects that will be tested will be 30. We will be recruiting 30 subjects to obtain the sample size. The amount of subjects to be tested was determined based on the time constraints of the project.

c) If any proposed subjects are children/minors, prisoners, pregnant women, those with physical or cognitive impairments, or others who are considered vulnerable to coercion or undue influence, state rationale for their involvement.

NA

6. Recruitment

a) Explain how, where, when, and by whom prospective subjects will be identified/selected and approached for study participation. If researcher is subject's instructor, physician, or job supervisor, or if vulnerable subject groups will be recruited, explain what precautions will be taken to minimize potential coercion or undue influence to participate.

Subjects will be randomly selected and approached during daylight hours at Santa Clara University. Each team member will also ask their friends or acquaintances to participate in the study. We will be conducting the tests in a non-agitating environment. Some subjects will be asked to exercise before testing. Over the period of time between January 2017 to March 2017.

b) Describe any recruitment materials (e.g., letters, flyers, advertisements [note type of media/where posted], scripts for verbal recruitment, etc.) and letter of permission/cooperation from institutions, agencies or organizations where off-site subject recruitment will take place (e.g., clinic, school district). Attach these documents in Attachments section.

We will be asking most subjects in an informal manner to participate in the testing of our device. Verbal confirmation will be the only thing needed as each subject being approach is a consenting adult.

7. Screening

a) Provide criteria for subject inclusion and exclusion. If any inclusion/exclusion criteria are based on gender, race, or ethnicity, explain rationale for restrictions. Provide criteria for subject inclusion and exclusion. If any inclusion/exclusion criteria are based on gender, race, or ethnicity, explain rationale for restrictions.

a) The goal is to have a diverse group to conduct our research on. We would like to have about a 50% male 50% female ratio to help detect any nuances in heart rate or blood pressure, should there be any. Our subjects will also be more varied based on age as to get a broad spectrum of results to improve accuracy within the device.

b) If prospective subjects will be screened via tests, interviews, etc., prior to entry into the "main" study, explain how, where, when, and by whom screening will be done. NOTE: Consent must be obtained for screening procedures as well as "main" study procedures. As appropriate, either: 1) create a separate "Screening Consent Form;" or 2) include screening information within the consent form for the main study.

b) There will be no screening conducted prior to the study.

8. Compensation and Costs

a) Describe plan for compensation of subjects. If no compensation will be provided, this should be stated. If subjects will be compensated for their participation, explain in detail about the amount and methods/ terms of payment.

There will be no compensation for students. Students will participate in study on a volunteer bases.

9. Study Procedures

a) Before any subject is tested they will be fully informed of the experiment, what we are doing for our project, the exact procedure they will be participating in, as well as offer an answer to any other question they might have. Without question, any subject that feels cautious or uncomfortable about participating in our study are advised not to participate. The patient then must also sign a consent form in order to participate in the experiment.

1. We will first measure the resting heart rate, blood pressure, glucose and oxygen saturation levels simultaneously, temperature, and finally elevated heart rate. The testing will be performed by Alejandra Pacheco, Natalie Arrizon, Jose Hernandez, or Antonio Maldonado-Liu unless otherwise specified. The testing will occur in Benson 1, in the basement of the Benson Center, with the exception of the blood glucose testing, which is to occur in the Cowell Center, as stated below. Testing will occur in the window of January 2017 - March 2017, between 9am - 5pm on any day of the week. Each patient will be tested no more than twice total, no more than once per week. The testing process itself should be under one hour, with the informing and consent form signing taking approximately fifteen minutes. There will be no deception or lack of full disclosure, and no audio or video recording.
    a. Elevated Heart Rate: to achieve this condition, we will ask the subject to perform any activity of their choice that will elevate their heart rate (i.e. push-ups, jog in a circle, high-knees, walking, etc.) for 1 minute.
    Resting Heart Rate: When taking readings from this condition, we will ask the subject to sit comfortably and to relax for 2 minutes so that they are as close to a resting heart rate as possible. This will likely be done first, prior to the other two conditions which should likely elevate the heart rate.
    b. Once the desired state is achieved,

2. Blood Pressure: The blood pressure cuff is placed on the non-dominant upper arm of the patient, with the sensor over the brachial artery. Antonio Maldonado-Liu will then use the hand pump to manually inflate the blood pressure cuff to approximately 160mmHg, at which point the slow release of the air pressure will be activated, and the device will measure the patient's blood pressure. After 2 minutes, the patient's dominant arm will be tested with a commercial blood pressure device, also by Antonio.
3. **Glucose levels: The measuring component for this and the pulse oximetry are the same. The earlobe component is applied to the earlobe of the patient. The measuring will be activated, and the device will measure the blood glucose levels non-invasively and spectroscopically.
4. Oxygen saturation: With the earlobe sensor in place on the patient's earlobe, the measuring is activated. The device will then measure the blood oxygen saturation of the patient spectroscopically (industry standard). The patient's blood oxygen saturation is simultaneously measured using a commercial finger pulse oximeter on the middle finger of their right hand.
5. Temperature degree: The patient places the thermometer in the armpit of the right arm, and the patient holds the thermometer in position with the right arm. The thermometer is then activated and is left in place until a stable temperature reading is reached (no change in temperature reading for 5 seconds). This measurement is taken simultaneously with a commercial axial thermometer in the patient's left armpit.

**The non-commercial blood glucose monitor that we are using in our device is experimental. Traditional commercial blood glucose devices require the exposure of blood in order to invasively measure the blood glucose concentration enzymatically. Our blood glucose device instead uses a near-infrared LED and a corresponding photodiode to measure the transmittance of the light through the earlobe tissue without the necessity of exposing any blood, and is in this way completely non-invasive.

Final note: We are in the process of designing and building a prototype of each sensor and will produce a final prototype for testing patients. The project timeline is attached in the form of a Gantt Chart.

CITI Training Report

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COMPLETION REPORT - PART 2 OF 2
COURSEWORK TRANSCRIPT**

** NOTE: Scores on this Transcript Report reflect the most current quiz completions, including quizzes on optional (supplemental) elements of the course. See list below for details. See separate Requirements Report for the reported scores at the time all requirements for the course were met.

- **Name:** Alejandra Pacheco (ID: 6022944)
- **Email:** a2pacheco@scu.edu
- **Institution Affiliation:** Santa Clara University (ID: 1235)
- **Phone:** 4086676770

- **Curriculum Group:** Basic/Refresher Course - Human Subjects Research
- **Course Learner Group:** Students - Class projects
- **Stage:** Stage 1 - Basic Course

- **Report ID:** 21780609
- **Report Date:** 19-Jan-2017
- **Current Score**:** 88

REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES	MOST RECENT	SCORE
Students in Research (ID: 1321)	19-Jan-2017	4/5 (80%)
Belmont Report and CITI Course Introduction (ID: 1127)	19-Jan-2017	3/3 (100%)
Santa Clara University (ID: 12657)	29-Dec-2016	No Quiz

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

Verify at: www.citiprogram.org/verify/?k9bee6ebe-a3cf-4b71-b22b-4cc4606c55f6-21780609

Collaborative Institutional Training Initiative (CITI Program)
Email: support@citiprogram.org
Phone: 888-529-5929
Web: https://www.citiprogram.org

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COMPLETION REPORT - PART 2 OF 2
COURSEWORK TRANSCRIPT**

** NOTE: Scores on this Transcript Report reflect the most current quiz completions, including quizzes on optional (supplemental) elements of the course. See list below for details. See separate Requirements Report for the reported scores at the time all requirements for the course were met.

- **Name:** Antonio Maldonado-Liu (ID: 6073152)
- **Email:** acmaldonadoliu@scu.edu
- **Institution Affiliation:** Santa Clara University (ID: 1235)
- **Phone:** (503) 788-3836

- **Curriculum Group:** Basic/Refresher Course - Human Subjects Research
- **Course Learner Group:** Students - Class projects
- **Stage:** Stage 1 - Basic Course

- **Report ID:** 21997738
- **Report Date:** 19-Jan-2017
- **Current Score**:** 88

REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES	MOST RECENT	SCORE
Students in Research (ID: 1321)	19-Jan-2017	4/5 (80%)
Belmont Report and CITI Course Introduction (ID: 1127)	19-Jan-2017	3/3 (100%)
Santa Clara University (ID: 12657)	19-Jan-2017	No Quiz

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

Verify at: www.citiprogram.org/verify/?k8e544f29-8faa-47e5-868a-e17f306c4e8f-21997738

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COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COMPLETION REPORT - PART 2 OF 2
COURSEWORK TRANSCRIPT**

** NOTE: Scores on this Transcript Report reflect the most current quiz completions, including quizzes on optional (supplemental) elements of the course. See list below for details. See separate Requirements Report for the reported scores at the time all requirements for the course were met.

- **Name:** Jose Hernandez (ID: 6073186)
- **Email:** jhernandez@scu.edu
- **Institution Affiliation:** Santa Clara University (ID: 1235)
- **Phone:** 7076715986

- **Curriculum Group:** Basic/Refresher Course - Human Subjects Research
- **Course Learner Group:** Students - Class projects
- **Stage:** Stage 1 - Basic Course

- **Report ID:** 21997795
- **Report Date:** 19-Jan-2017
- **Current Score**:** 88

REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES	MOST RECENT	SCORE
Students in Research (ID: 1321)	19-Jan-2017	4/5 (80%)
Belmont Report and CITI Course Introduction (ID: 1127)	19-Jan-2017	3/3 (100%)
Santa Clara University (ID: 12657)	19-Jan-2017	No Quiz

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

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COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COMPLETION REPORT - PART 2 OF 2
COURSEWORK TRANSCRIPT**

** NOTE: Scores on this Transcript Report reflect the most current quiz completions, including quizzes on optional (supplemental) elements of the course. See list below for details. See separate Requirements Report for the reported scores at the time all requirements for the course were met.

- **Name:** Natalie Arrizon (ID: 6073176)
- **Email:** narrizon@scu.edu
- **Institution Affiliation:** Santa Clara University (ID: 1235)
- **Phone:** 5623600749

- **Curriculum Group:** Basic/Refresher Course - Human Subjects Research
- **Course Learner Group:** Students - Class projects
- **Stage:** Stage 1 - Basic Course

- **Report ID:** 21997778
- **Report Date:** 19-Jan-2017
- **Current Score**:** 75

REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES	MOST RECENT	SCORE
Students in Research (ID: 1321)	19-Jan-2017	3/5 (60%)
Belmont Report and CITI Course Introduction (ID: 1127)	19-Jan-2017	3/3 (100%)
Santa Clara University (ID: 12657)	19-Jan-2017	No Quiz

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

Verify at: www.citiprogram.org/verify/?kc902cec8-5de9-4f84-69ce-f545ad9c73b8-21997778

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Web: https://www.citiprogram.org

School of Engineering Budget Proposal

Vital Multi-Sensor Kit, Funding Proposal

Group Members

Name	Major	Email
Alejandra Pacheco (Primary)	BIOE	a2pacheco@scu.edu
Antonio Maldonado-Liu	BIOE	acmaldonadoliu@scu.edu
Jose Hernandez	ELEN	jhernandez@scu.edu
Natalie Arrizon	ELEN	narrizon@scu.edu
Ashley Kim	BIOE Advisor	ukim@scu.edu
Tokunbo Ogunfunmi	ELEN Advisor	togunfunmi@scu.edu

Our Vision to Give Developing Countries Tele-mobile Access to Healthcare

The purpose of the Vital Sensors Kit is to be inexpensive and accessible to people in rural areas of developing countries, where there is no easy access to medical care. The kit is aimed to be a simple and affordable medical device that monitors vital signs such as blood pressure, blood oxygen concentration, heart rate, respiratory rate, blood glucose, and temperature without the need for a doctor's immediate assistance. In such scenarios, this device would replace the first steps of any standard medical checkup. Instead of traveling all the way to a hospital to have baseline vitals measured, you would measure them with this device, and send them to a physician for review to help determine whether an in-person appointment is necessary. This frugal device gives under-resourced families the opportunity to take care of their health and live a better life.

By having a medical kit that takes many important vital signs, even people who do not have insurance or easy access to a hospital will be able to monitor their own vital signs and those of their family members. This solution is better than others currently available because it is much smaller, cheaper, and more intuitive in design and use. Current devices include those carts that are used in most hospitals here in the US, that are about 3 feet tall, and probably cost well into the hundreds of dollars, if not over a thousand. There are a number of other available devices, but they are expensive, and generally only have one or two types of sensors. The proposed device is targeted to cost no more than $150, will contain at least four sensor types, and be connectable to a mobile device such that data can be sent wirelessly to a physician via Wi-Fi or SMS. Communities can share multiple vital sensor kits and split costs accordingly to make the device even more affordable. We strongly believe that by making this device low-cost and simple to use for developing countries, communities and families will be much happier and healthier because they will be able to get the medical attention they need from doctors without having to have the financial burden of paying for multiple hospital visits and transportation costs.

List of Funding Sources

- Undergraduate SOE Funding
    - $606

Budget

Item	Number of Items	Price per Unit	Anticipated Total Cost
Commercial Pulse Oximeter (for comparison to created pulse oximeter) **Santamedical SM-240 OLED Finger Pulse Oximeter**	1	$46	$46
Commercial Blood Pressure Monitor (for comparison to created blood pressure monitor) **Omron 7 Series Upper Arm BP Monitor**	1	$75	$75
Commercial Glucose Monitor (for comparison to created glucose meter) **One Touch Ultra Diabetes Testing Kit - One Touch Ultra Meter, 100GenUltimate Test Strips, 100 30g Lancets, 1 Lancing Device and 100 Alcohol Prep Pads**	1	$41	$41
Commercial Thermometer (For comparison to created thermometer) **Beyoung Axillary Thermometer**	1	$18	$18
Commercial Stethoscope **Omron Sprague Rappaport Stethoscope**	1	$14	$14
Electret Microphone **COM-0835 ROHS**	5	$1.00	$5
Custom 2-layer circuit board from ExpressPCB.com (PCB boards)	3	$25	$75
5mm Red LED (660nm)	10	$0.30	$3
5mm IR LED (940nm)	10	$0.80	$8
Glucose Meter LED **LED1550E - Epoxy-Encased LED, 1550 nm,**	5	$18	$90

2.0 mW, T-1 ¾			
GPD Optoelectronics GAP 136 in GaAs Photodiode (900-1650nm)	1	$25	$25
TI OPT101P Photodiode (400-1100nm)	2	$7.50	$15
Thermistor: **TI LMT70A Analog Temperature Sensor**	5	$2.80	$14
Honeywell ASDX015PDAA5 Transducer	1	$44	$44
Silver (415) - Sport Knitting Wool & Yarn	1 roll	$7	$7
Dritz 9507B Non-Roll Woven Elastic, Black, 1-Inch	2.5 yards	$3	$3
Meguiar's W0004 Foam Applicator Pad 4-1/2"	4	$4	$4
3Way Dump Valve	2	$2	$4
Valve Noninverting OpAmp	2	$1.50	$3
Handpump	5	$1	$5
Chip Components: Resistors, Capacitors, Inductors, etc. (DigitKey.com)	As needed	Resistors: $10 Capacitors: $10 Inductors: $10 Other: $10	$40
Arduino Mega Microcontroller	1	$40	$40
Breadboard	1	$9	$9
		Total cost:	$588
		Shipping and taxes	$110
		Total cost:	$698
		Total amount requested from SOE:	**$698**

School of Engineering Participation Statement

We all recognize and commit to presenting our project in poster form at Family Weekend in February, as well as Preview Weekend and Spring Engineering Education Days in April, should the Dean's Office commit any funds to this project.

Team Member Signatures

____

____

____

____

Advisor Approval Statement

I have reviewed and approve of the above budget proposal to the School of Engineering for the Senior Design Thesis.

____ Date:_____________________

____ Date:_____________________

<u>Meeting Minutes</u>

10.04.16

Members Present: Antonio, Natalie, Jose, Alejandra

- Setting up meeting with Uma and Makenzie at 1:45 in Engineering Design.
- Meet with Dr. Ogunfumi at 4 pm; EC

Meeting with Dr. Ogunfumi

- He will send us the thesis where students used body signals to make music.

Try to **aim** high and think of a lot of improvements/changes to make: creativity brainstorm session.

- Tuesday meetings 11:15 to 11:45 with Dr. Ogunfumi

10.11.16

Ideas:

- Making the pulse oximeter sensor (ring, on the ear lobe)
- Respiratory rate sensor (to figure out at least if something is wrong)
- ECG for developing countries (3 electrodes)
- Calibration-free Pulse Oximeter

Tony:

- Reduce the cost of the components
    - Get a smaller microcontroller
- Improve the accuracy of the sensors (look into doing more human testing)
- Adding another sensor (respiratory rate)
- Improving efficiency and speed of the code
- Detectable by mobile device

Jose:

- Make your own PCB
- Using Arduino UNO??
- We finally met with the EWH people and they are going to try to help us.
- Recommend taking: Mechatronics (winter), VSP (spring),
- Dr. Kim is going to contact us with the files available

10.18.16

- SOE Funding Proposal - due 10/21
- Finally got access to Google Drive

To-Do's:

- Look at Neo Panda website
- Look into Google Drive folders and look into what they did.
- Preliminary designs.

10.20.16

- **Contact Elizabeth to get to them.**
- **Set up an interview with questions that are needed.**
    - **Specific diseases or groups**
- Look into similar organizations
- Build design prototype and order everything by Christmas break.
- Add in Arduino and also other sensors for respiratory rate.
- Electrodes for respiratory rates.

10.27.16

- Email SWASTH
- Email Roberto Clemente Clinic
- Email Noora Health
    - Cc Dr. Kim
    - Having them finding the non-profit.
    - Having them both be on the call.
- No change in parameters yet.

To Do:

- Contact Noora Health directly and indirectly
- Start ordering components
- Global Innovation Exchange

11.12.16

Ear piece that would have both the pulse oximeter reading and the glucose reading
What plastics are used for pulse oximeters? We don't want the photodiode to overheat.

11.17.16

Still need to meet with Noora Health and HeMoClo people ***
Still need to decide what the goals are for the respiratory rate.
Work on the IRB application

11.30.16

Goals:

Start IRB Application
Come up with questions for meeting with Katy
Edit future timeline (for winter break)

02.01.17

Accomplishments:

Set up meeting dates with advisor

Created weekly goals for the quarter

Started the SolidWorks design.

Turned in the IRB application for human testing.

Goals:

Finish the SolidWorks design by next week and get trained in the Maker Lab to be able to print the products.

Start testing commercial equipment.

Santa Clara University Bioengineering Department
Vital Multi-Sensor Kit Consent Form

Explanation

Alejandra Pacheco, Antonio Maldonado-Liu, Jose Hernandez and Natalie Arrizon are bioengineering and electrical engineering students, working together as a senior design team here at Santa Clara University under the direction of Dr. Ashley Kim. We are conducting a research study to verify the validity of the four sensors we built to make up one affordable vital sensor kit for developing countries. Thirty subjects total will be tested. Each subject's heart rate, blood oxygen saturation and pressure will be measured with the vital sensor kit device and then measured again with the commercial devices. The glucose concentration will be measured non-invasively only with our ear sensor.

We are requesting your participation, which will involve the use of two blood pressure sensors, two pulse oximeters (one on your finger, one on your earlobe), and an experimental non-invasive blood glucose sensor which will also go on your earlobe. Each testing session will take no more than forty-five minutes, and you will be tested no more than once per week, a maximum of twice total. Your participation in this study is voluntary. If you choose not to participate or to withdraw from the study at any time, there will be no penalty. It will not affect your grade or status with the university. In addition, we will ensure that all health data will remain private. If you choose to sign the consent form, we will assign a number to your name. During testing periods, we will record all data according to your given number. Our advisor Dr. Kim will have the list of names-to-numbers and will be the only one to access the data. Upon completion of this project, the list will be destroyed. The results of the research study may be published, but your name will not be used.

The procedure is as follows:
The subject will be fully informed of the experiment, including what we are doing for our experiment, why we are doing it, as well as how each of the sensors works. Any questions that the subject has prior to beginning the measurements will be answered. To reiterate, should the subject at all uncomfortable with any part of the experiment or procedure, they are advised not to participate.

Resting heart rate: When taking readings from this condition, we will ask the subject to sit comfortably and to relax for 2 minutes so that they are as close to a resting heart rate as possible. Both pulse oximeters, one to the middle finger of the right hand, and the other to the earlobe, will be applied simultaneously to measure the heart rate of the subject in this state.

Elevated heart rate: To achieve this condition, we will ask the subject to perform any activity of their choice that will elevate their heart rate (i.e. push-ups, jog in a circle, high-knees, walking, etc.) for 1 minute. The pulse oximeters will then be applied in the same fashion as the resting heart rate condition, to record the heart rate of the subject.

Blood oxygen saturation: This measurement will occur at the same time as the resting heart rate measurement. With the subject resting and breathing normally, their blood oxygen saturation will be recorded via the pulse oximeters already reading the subject's heart rate.

Blood pressure: The blood pressure cuff is placed on the non-dominant upper arm of the patient, with the sensor over the brachial artery. Antonio Maldonado-Liu will then use the hand pump to manually inflate the blood pressure cuff to approximately 160 mmHg, at which point the slow release of the air pressure will be activated, and the device will measure the patient's blood pressure. After 2 minutes, the patient's dominant arm will be tested with a commercial blood pressure device, also by Antonio. The commercial device performs the same procedure in an automated fashion.

Blood glucose concentration: The measuring component for this and the pulse oximetry are the same. The earlobe component is applied to the earlobe of the patient. The measuring will be activated, and the device will measure the blood glucose levels non-invasively and spectroscopically.

The testing will occur in Benson 1, in the basement of the Benson Center.

Risks and Discomforts

Participation in this experiment is completely voluntary. If you choose not to participate or to withdraw from the study at any time, there will be no penalty. It will not affect your grade or status with the university. You may choose to cease the experiment at the elevated heart rate measurement, as the exercise may be uncomfortable for you. Once again, withdrawal at this stage or any other for any reason will have no penalty upon you.

Benefits of our Research

Although there may be no direct benefit to you, the possible benefit of your participation will be furthering the progress towards making blood glucose monitoring completely painless. In addition, this product seeks to increase accessibility of health data and ease health monitoring at a lower cost to the user. There will also be increased communication between health professionals and patients, for an overall reduction in unnecessary visits to the hospital and potentially increased health consciousness.

Confidentiality

The results of this research study may be published, but your name will not be used. In order to maintain confidentiality of your records, at the beginning of the data collection process, we will only have the number matching the subject's name. This will allow us to omit the names of the subjects in every part of the experiment and thesis. No names will be written down, and all consent forms collected will be delivered to Dr. Ashley Kim of Santa Clara University's Bioengineering Department, separate from the data and all other components of the experiment. This will be done to keep the subject's identity and data confidential.

If you have any questions about your rights as a subject/participant in this research, or if you feel you have been placed at risk, you can contact the Chair of the Human Subjects Committee, through Office of Research Compliance and Integrity at (408) 554-5591.

Inquiries

If you have any questions or doubts, please ask us for explanations. If the subject has any questions regarding the design they may call Alejandra Pacheco at (408) 667-6770. Or, our advisor, Dr. Ashley Kim, may be contacted at (408) 554 - 2760.

CALIFORNIA EXPERIMENTAL SUBJECTS BILL OF RIGHTS

As a research participant you have the following rights. These rights include but are not limited to the participant's right to:

- be informed of the nature and purpose of the experiment;
- be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
- be given a description of any attendant discomforts and risks reasonably to be expected;
- be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
- be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;
- be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;
- be given an opportunity to ask questions concerning the experiment or the procedures involved;
- be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
- be given a copy of the signed and dated consent form; and
- be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

<u>Representation of Health and Assumption of Risk</u>

I have read the foregoing information, and I understand the exercise procedures that I will be asked to perform. I agree to participate in exercise. I warrant and represent that I am in good health and that I am able to physically perform the exercise required of me. Knowing the risks, I hereby agree to assume such risks and to release and hold harmless all persons and entities that might be liable to me, my heirs, or assigns for damages. All questions have been answered to my satisfaction.

In order to achieve the elevated heart rate described above, we will ask the subject to perform any activity of their choice that will elevate their heart rate (i.e. push-ups, jog in a circle, high-knees, walking, etc.) for 1 minute.

Are you fit to perform this activity? Check one that applies to you. ☐ Yes ☐ No

<u>Freedom of Consent</u>

I have also been informed that the information derived from this procedure is confidential and will not be disclosed to anyone other than the researchers involved with this study. The information obtained, however, may be used for a statistical or scientific purpose with my right of privacy retained by not disclosing any identifying information.

Participant Name: ____

Signature:____ Date: ____________

<u>Person Obtaining Consent</u>

I attest that the requirements for informed consent for the medical research project described in this form have been satisfied – that the subject has been provided with the experimental Subject's Bill of Rights, if appropriate, that I have discussed the research project with the subject and explained to him or her in non-technical terms all of the information contained in this informed consent form, including any risks and adverse reactions that may reasonably be expected to occur. I further certify that I encouraged the subject to ask questions and that all questions asked were answered.

Signature of Person Obtaining Consent:

____ Date: ____________

Appendix F: Electrical Components

Component Tables:

Oximeter Filter	
C1	**270pf**
C2	**10uf**
C3	**0.22uf**
C4	**0.1uf**
C5	**0.1uf**
C6	**3.3uf**
C7	**5600pf**
C8	**10uf**
C9	**0.1uf**
C10	**1uf**
R1	**1.2k**
R2	**10k**
R3	**4.7M**
R4	**2.7k**
R5	**27k**
R6	**27k**
R7	**14k**
R8	**56k**
R9	**150k**
R10	**4.7M**
R11	**3.3k**
R_Vres_1	**10k**
R_Vres_2	**10k**

Transimpedance Op 213	**http://www.ti.com/general/docs/lit/getliterature.tsp?genericPartNumber=opa381&fileType=pdf**
LEDs Drivers	
R_LED1m	**1k**
R_LED2m	**1k**
R_LED3m	**1k**
R_LED1	**47**
R_LED2	**110**
R_LED3	**110**
MMBT2222ALT1G	**http://www.onsemi.com/pub_link/Collateral/MMBT2222LT1-D.PDF**
J_oxi, J_LED, J_Photo	**Connectors provided by the soldering lab**
Blood Pressure	
C12	**1uf**
C13	**2.2uf**
C14	**1uf**
C15	**0.1uf**
C16	**1uf**
R12	**15k**
R13	**33k**
R14	**15k**
R15	**1k**
R16	**100k**
R19	**17.4k**
R20	**10k**
C18	**270pf**
C19	**10uf**
C21	**0.1uf**

C22	**0.1uf**
C23	**3.3uf**
C24	**5600pf**
C25	**10uf**
C26	**0.1uf**
C27	**1uf**
C28	**10uf**
R21	**1.2k**
R22	**10k**
R23	**4.7M**
R24	**2.7k**
R25	**27k**
R26	**27k**
R27	**14k**
R28	**56k**
R29	**150k**
MCP6004	**http://ww1.microchip.com/downloads/en/DeviceDoc/21733j.pdf**

Order Information Links:

Resistor Value	Amount	Resistors Cost Per Unit	Resistor DigiKey links
47	1	$0.10	http://www.digikey.com/product-detail/en/yageo/RC0402JR-0747RL/311-47JRCT-ND/729431
110	2	$0.10	http://www.digikey.com/product-detail/en/yageo/RC0603JR-07110RL/311-110GRCT-ND/729649
1k	7	$0.10	http://www.digikey.com/product-detail/en/yageo/RC0402JR-071KL/311-1.0KJRCT-ND/729355
1.2k	2	$0.10	http://www.digikey.com/product-detail/en/yageo/RC0402JR-071K2L/311-1.2KJRCT-ND/729358
2.7k	2	$0.10	http://www.digikey.com/product-detail/en/yageo/RC0402JR-072K7L/311-2.7KJRCT-ND/729385
3.3k	2	$0.10	http://www.digikey.com/product-detail/en/yageo/RC0603FR-073K3L/311-3.30KHRCT-ND/730073
10k	7	$0.10	http://www.digikey.com/product-detail/en/yageo/RC0402JR-0710KL/311-10KJRCT-ND/729365

14k	2	$0.10	http://www.digikey.com/product-detail/en/yageo/RC0402FR-0714KL/311-14.0KLRCT-ND/729487
15k	1	$0.10	http://www.digikey.com/product-detail/en/panasonic-electronic-components/ERJ-2RKF1502X/P15.0KLCT-ND/194186
17.4k	1	$0.10	http://www.digikey.com/product-detail/en/yageo/RC0402FR-0717K4L/311-17.4KLRCT-ND/729494
27k	4	$0.10	http://www.digikey.com/product-detail/en/yageo/RC0402JR-0727KL/311-27KJRCT-ND/729398
33k	1	$0.10	http://www.digikey.com/product-detail/en/yageo/RC0402JR-0733KL/311-33KJRCT-ND/729415
56k	2	$0.10	http://www.digikey.com/product-detail/en/yageo/RC0402JR-0756KL/311-56KJRCT-ND/729442
110k	1	$0.10	http://www.digikey.com/product-detail/en/yageo/RC0402JR-07110KL/311-110KJRCT-ND/729366
150k	2	$0.10	http://www.digikey.com/product-detail/en/yageo/RC0402JR-07150KL/311-150KJRCT-ND/729372
1M	1	$0.10	http://www.digikey.com/product-detail/en/yageo/RC0402FR-071ML/311-1.00MLRCT-ND/729462
4.7M	4	$0.10	http://www.digikey.com/product-detail/en/yageo/RC0402JR-074M7L/YAG3304CT-ND/5282170

Capacitor Value	Amount	Capacitor Cost Per Unit	Capacitor DigiKey Links
270pf	2	$0.19	http://www.digikey.com/product-detail/en/murata-electronics-north-america/GRM1555C1H271FA01D/490-10686-1-ND/5251419
5600pf	2	$0.32	http://www.digikey.com/product-detail/en/kemet/C0603C562J5RACTU/399-7942-1-ND/3471665
0.1uf	13	$0.10	http://www.digikey.com/product-detail/en/murata-electronics-north-america/GRM155R71C104KA88J/490-6328-1-ND/3845525
0.22uf	2	$0.10	http://www.digikey.com/product-detail/en/taiyo-yuden/JMK063BJ224MP-F/587-1819-1-ND/1465289
1uf	4	$0.10	http://www.digikey.com/product-detail/en/taiyo-yuden/JMK105BJ105KV-F/587-1231-1-ND/931008
2.2uf	2	$0.10	http://www.digikey.com/product-detail/en/murata-electronics-north-america/GRM155R61A225KE95D/490-10451-1-ND/5026361
3.3uf	2	$0.26	http://www.digikey.com/product-detail/en/kemet/C0805C335K8PACTU/399-3129-1-ND/551634
10uf	10	$0.12	http://www.digikey.com/product-detail/en/murata-electronics-north-america/GRM155R60G106ME44D/490-10693-1-ND/5251412

Appendix G: Printed Housing Designs

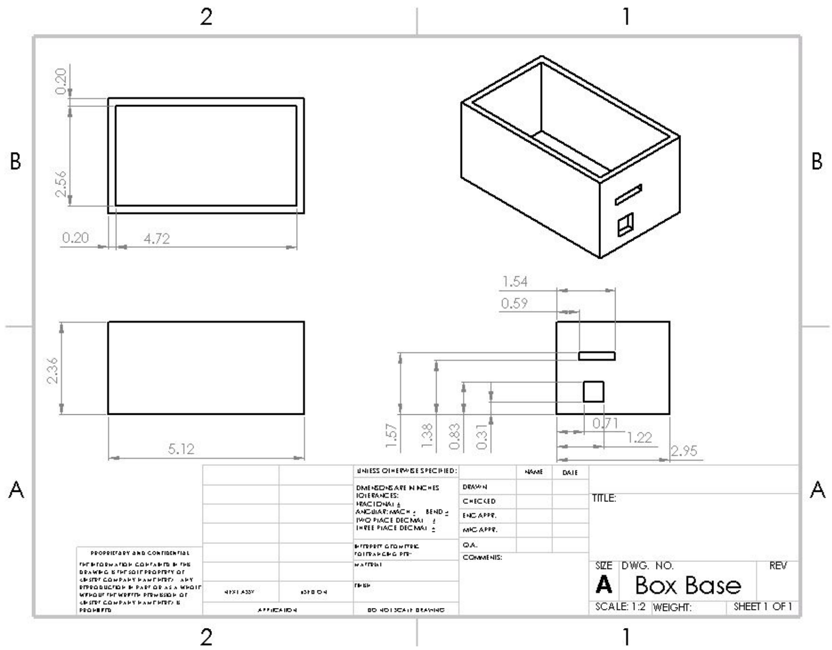

Figure G-1: Device Housing Design

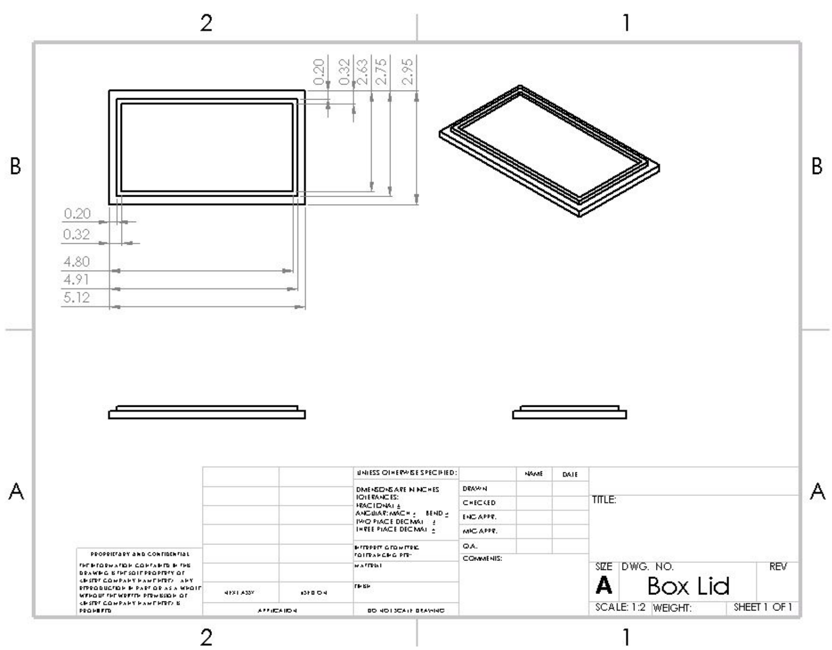

Figure G-2: Device Housing Lid Design

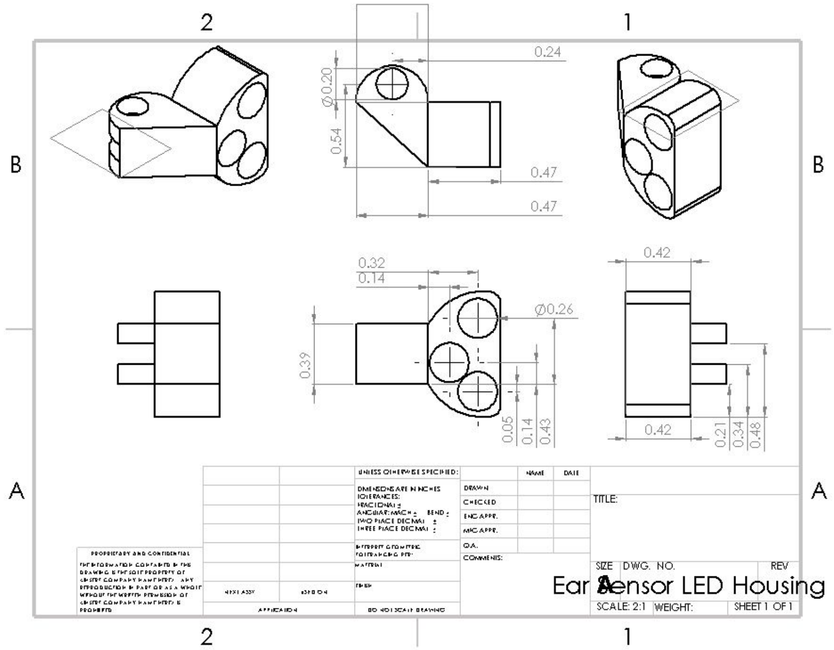

Figure G-3: Ear Sensor LED Housing Design

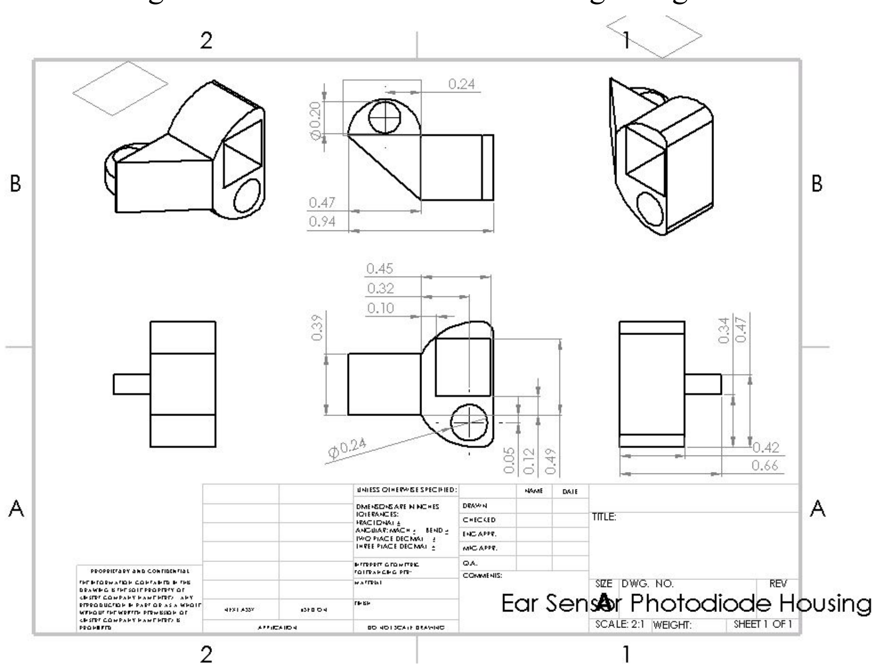

Figure G-4: Ear Sensor Photodiode Housing Design

Appendix H: MATLAB and Arduino Code

Arduino Code

```
#define Led1 13
#define Led2 12
int senRead=5; //The pin from which data is read. 5 for pulse oximeter, 2 for blood pressure.
int val= 0;
int i=0;
int PulseOx[500];
int Adata = 0;
int Bdata = 0;
int C = 0;

void setup() {
  pinMode(Led1, OUTPUT); //pin3 Output
  pinMode(Led2, OUTPUT); //pin2 Output
  Serial.begin(4800); // reads data at 19200 bits
 Serial.println("CLEARDATA"); //clears up any data left from previous projects
  Serial.println("LABEL,Acolumn,Bcolumn,..."); //always write LABEL, so excel knows the
next things will be the names of the columns (instead of Acolumn you could write Time for
instance)
  Serial.println("RESETTIMER"); //resets timer to 0
}
void loop() {
  BlinkLed1(500);
  BlinkLed2(1000);
  int val=analogRead(senRead);
  Serial.println(val);
}
 void BlinkLed1 (int interval){
   static long prevMill = 0;
   if (((long)millis() - prevMill) >= interval){
    prevMill = millis();
    digitalWrite(Led1, !digitalRead(Led1));
  }
 }
  void BlinkLed2 (int interval){
   static long prevMill = 500;
```

```
  if ((millis() - prevMill) >= interval){
   prevMill = millis();
   digitalWrite(Led2, !digitalRead(Led2));
 }

if ( Serial.available() > 0 ) {
  int Adata = Serial.read();
  Serial.print(Adata);
 }
 if ( Serial.available () > 0) {
   int Bdata = Serial.read();
   Serial.print(Bdata);
 }
 if ( Serial.available () > 0 ) {
   int C = Serial.read();
   Serial.print(C);
 }
Serial.print("DATA,TIME,TIMER,"); //writes the time in the first column A and the time since the measurements started in column B

}
```

MATLAB Code

```
%% Heart Rate

d=xlsread('Patient1_june1_ir_elevated.xlsx','C350:C700'); %will read for 15 seconds worth of data
[pks,locs,w,p] = findpeaks(d); %this finds the time points where there was maximum arterial blood flow
                               % also known as a heart beat
for k=1:length(pks) % for the length of number of heart beats
        if w(k)>=5
            pksR(z)=pks(k); % the value is stored when the distance is 5 or greater
            z=z+1;          % array is created with the stored values
        end
end

BPM=length(pks)*4 % the number of peaks times 4 to get beats per minute
```

Appendix I: Datasheets

3 On-chip Temperature Compensation and Calibration

The MP3V5050 series pressure sensor operating characteristics, and internal reliability and qualification tests are based on use of dry air as the pressure media. Media, other than dry air, may have adverse effects on sensor performance and long-term reliability. Contact the factory for information regarding media compatibility in your application.

Figure 3 shows the sensor output signal relative to pressure input. Typical, minimum, and maximum output curves are shown for operation over a temperature range of 0 °C to 85 °C using the decoupling circuit shown in Figure 5. The output will saturate outside of the specified pressure range.

Figure 4 illustrates the Differential/Gauge Sensing Chip in the basic chip carrier (case 98ASB17757C). A fluorosilicone gel isolates the die surface and wire bonds from the environment, while allowing the pressure signal to be transmitted to the sensor diaphragm.

Figure 5 shows the recommended decoupling circuit for interfacing the output of the integrated sensor to the A/D input of a microprocessor or microcontroller. Proper decoupling of the power supply is recommended.

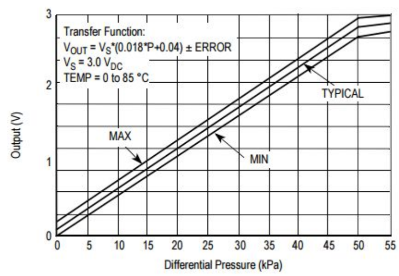

Figure 3. Output versus Pressure differential

Figure I-1: Part of Datasheet for Pressure Sensor.

GPD OPTOELECTRONICS CORP PRODUCT SPECIFICATIONS SHEET					
CUSTOMER: ANY			NO. GAP100G		
CITY: (STANDARD DEVICE)			TYPE: PHOTODIODE		
CUST. DWG.		REV.	PKG. TO-46	MAT. InGaAs	
DEVICE MARKING					
(a)	G				
(b)	GAP100G				
(c)	DC				
GROUP A AND/0R PERFORMANCE CHARACTERISTICS					
NO.	SYMBOL	CONDITIONS @23°C±2°C	MIN.	MAX.	UNITS
1	R_D	@ 850 nm	0.15	Typ 0.2	A/W
2		@ 1300 nm	0.80	Typ 0.85	A/W
3		@ 1550 nm	0.90	Typ 0.92	A/W
4	I_D	@ V_R = 5V		1.0	nA
5	C_T	@ V_R = 5V		1.2	pF
6	B_W	50Ω, -3dB, 5V	2.0		GHZ
7	t_r	RL = 50Ω, 5V		0.1	nsec
8	NEP	@ 1550 nm	(1.5E	-15 typ.)	W / √ HZ
9		Maximum Ratings			
10	V_R			25	V
11	I_R			10	mA
12	I_F			10	mA
13	T(stg)		-40	125	°C
14	T(op)		-40	85	°C
15					

Figure I-2: Part of Datasheet for Glucose Photodiode.