A Reflectance Sensor Holder for PPG Measurements from the Chest

A Major Qualifying Project
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in
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By

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Table 1: Authorship table.

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Executive Summary	TC, CF
Introduction	TC
Literature Review	Team
Project Approach	NM
Design Process	TC, NM
Design Verification	CF, NM
Design Validation	TC, NM
Discussion	TC, CF
Conclusion	TC
Appendices	Team

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Abstract

We present a project that focused on creating a wearable medical device that uses photoplethysmography and pulse oximetry technology. The pulse oximeter sensor holder was designed to be mounted on the chest using adhesive tape and a threaded holder that the cover turns into to increase pressure on the sensor. Our holder can apply a pressure range of 0-51 mmHg. The range for greatest PPG amplitudes from the chest is 10-30 mmHg. The reflectance type pulse oximeter housed in the holder was able to read pulse rate to within approximately ± 1.35 BPM compared to the EKG heart rate signal. Industry standards for finger pulse oximeters read pulse rate with ± 3 BPM accuracy. The device was not tested for oxygen saturation due to time constraints and IRB approved testing.

Table of Acronyms

Table 2: Complete terms of common acronyms in the report.

Term	Acronym
Photoplethysmography	PPG
Oxygen Saturation	SpO_2
Light-emitting diode	LED
Photodiode	PD
Pulse Rate	PR
Heart Rate	HR
Evaluation Module	EVM
Hemoglobin	Hb
Oxyhemoglobin	HbO_2
Intercostal	IC
Food and Drug Administration	FDA
International Standard Organization	ISO
Texas Instruments	TI
Graphical User Interface	GUI
Analog Front-End 4404 Evaluation Module	AFE4404EVM
National Instruments	NI
Automatic Peak Detection	AMPD

Executive Summary

Photoplethysmography (PPG) is the technique of shining light into the tissue and measuring pulsatile changes in light absorption; this can be used to calculate oxygen saturation (the ratio of oxyhemoglobin to total hemoglobin in the blood, shortened to SpO_2) and pulse rate (PR). There are primarily two types of PPG: transmittance and reflectance. Transmittance PPG uses a light-emitting diode (LED) to shine light through tissue to a photodiode (PD) on the other side of the tissue, while reflectance PPG places the LED and PD on the same side of the tissue. Pulse oximetry measures the difference between the absorption of two wavelengths of light sent into the tissue, which can be used to calculate SpO_2 and PR.

There are limitations of pulse oximeters on the market for finger probes and forehead probes. Transmission type sensors like the finger probe can have signal disruption from the finger moving within the finger clip and limited mobility of the user's hand. Reflectance type sensors like the forehead probe can limit patient mobility if connected to a monitor and also have limited measurements. The main issue is limited patient mobility and motion artifact. The chest is a promising location for a pulse oximeter sensor because the measurements are being taken from the core body instead of the peripheral body like finger and forehead probes. Patients with compromised peripheral blood perfusion would be able to get accurate PR and SpO_2 measurements with a sensor on the chest. A chest PPG sensor is closer to the heart where oxygenated blood is pumped out of the left side of the heart. The chest is also a good location for a reflectance PPG sensor because of the location of the sternum bone.

Our final holder design prototype is termed a Spin-to-Lock design because the cover twists into the threaded holder ring. The holder ring is attached to the chest with medical adhesive and houses the reflectance sensor. The cover twists into the holder making contact with the sensor and applies pressure moving the sensor closer to the tissues.

For signal acquisition, reference heart rates were recorded using an EKG sensor. Pulse rate was measured using the Texas Instruments AFE4404EVM, and a force transducer connected to a National Instruments ELVIS II board, where the output voltage was recorded and used to calculate pressure.

The first experiment conducted by the team was one which related contact pressure to PPG waveform amplitude. To do this, the team placed the device on a subject's chest and twisted the holder to specific pressure values. The PPG waveform was then recorded, then imported into MATLAB where its amplitude was calculated. From this, the team saw a prominent peak in amplitude between 10 and 30 mmHg, and therefore set that pressure as the goal for the holder.

The next experiment conducted by the team was a turn angle test, to check if the device could exert pressures between 10 and 30 mmHg. The device was placed on a flat surface, and the cover was twisted to specific angles, where the pressure was recorded. The team found that the cover exerted pressures between 0 and 51 mmHg, which covers the 10-30 mmHg range while allowing for variability between users.

To validate the design, the team compared pulse rate measured from the device to heart rate measured with EKG. To do this, the subjects lied in a supine position, where the team's device and EKG leads were attached. The subject stayed still for two sets of five minutes while recordings were taken from PPG and EKG. These measurements were imported into MATLAB, where motion artifacts were removed manually. A peak detection algorithm was run, followed by one that calculated heart rate and pulse rate from the peak locations of those signals. The team found that, typically, the heart rate and pulse rate differed by about 0.1 BPM, with a 95% confidence interval of 1.36 BPM, which is within the standard of 3 BPM. Based on this data, the team determined that the project was successful.

1 Introduction

The field of wearable medical devices is growing, and brings solutions and information to patients, doctors, and caregivers. This project focuses on pulse oximetry, the technology that monitors the user's oxygen saturation (SpO_2) and pulse rate (PR).

Photoplethysmography (PPG) is the technique of sending light into tissue and measuring the changes in pulsatile light absorption. This is very useful in obtaining pulsatile information noninvasively. The two main methods that are used for photoplethysmopgraphy are transmittance and reflectance.

Transmittance PPG uses a light emitting diode (LED) and a photodiode (PD) placed on opposite sides of the tissue. The most common type of transmittance pulse oximeter is a finger probe that can measure both SpO_2 and PR. This is mainly used in hospitals to monitor a patients SpO_2 and PR levels but can be used at home for daily monitoring.

Reflectance PPG also uses an LED and a PD, however the components are placed on the same side of the tissue. The most common example is wristwatches that have LEDs and PDs on the back for optical heart rate measurements to keep track of the user's fitness. This lets the user have freedom of their hands to do daily tasks.

Wearable medical devices can help the user monitor their health while not limiting their movement. Currently, sensors are only attached to peripheral measuring sites like the finger or the forehead. There is a need to attach a PPG sensor to the core body and measure PR and SpO_2. The initial goal for this project was to create a pulse oximeter that would read PR and SpO_2 from the chest unlike a chest EKG monitor that only measures the heart rate.

The finger pulse oximeter is a medical device that uses transmittance PPG to obtain pulse oximetry data. There are many different finger probe models on the current market that measure SpO$_2$ and PR. The user clips the finger probe onto the tip of their finger and the LED inside sends light through the tissue and is picked up by the PD on the opposite side of the clip. There are finger pulse oximeters that are wireless and can be worn by users at home or on the go, most models have a small LED display on the clip for the signal outputs. The data can be saved to a computer via USB or Bluetooth. The finger probe uses transmittance PPG to obtain data for SpO$_2$ and PR.

Pulse oximeter finger probes are available from companies like Nonin, Contec Medical Supply, iHealth, and FORA TN'G. The Nonin Go2 finger probe can measure SpO$_2$ and PR and disply real time data on a small LED display located on the front of the wireless clip. The measuring range for SpO$_2$ is 0-100% and for PR is 20-250 BPM. The specifications for the for SpO$_2$ are within $\pm 2\%$ and for PR are within ± 3 digits. Nonin has also developed pulse oximeters that have a wrist strap with a LED display for the finger probe, such as the WristOx2 3150.

Pulse oximetry is useful in recording blood oxygen saturation and has also been used to obtain pulse rate. The location of the finger probe can limit the movement of the subject's hand wearing the sensor and can limit the length of data recordings. Finger probes can also have increased signal noise when the finger moves within the clip.

Attaching the sensor to the body is a vital part of having a successful product. A wearable chest pulse oximeter would be closer to the heart, more comfortable to users, and could be concealed under clothing. A chest pulse oximeter will also be able to measure accurate SpO$_2$ and PR values for patients with compromised peripheral blood pressure. The initial goal of the project was to use a pulse oximeter sensor on the chest that would be able to record SpO$_2$ and PR. Our team was only able to focus on processing the PR data from the chest

in the interest of time.

2 Literature Review

The purpose of this section is to give a broad, yet thorough, background on the topics related to the project.

2.1 Photoplethysmography

The sensor being developed by Josh Harvey and Prof. Mendelson will be a pulse oximeter sensor. With pulse oximetry, the oxygen saturation in the blood can be measured along with pulse rate.

Transmittance PPG is the method of measuring volumetric changes in the blood vessels where the LED is positioned on one side of the device's surface and transmits through the tissue to the PD on the opposite surface of the device. This is the method commonly used in a hospital setting, with the LED transmitting through the index finger's tissue. The pulse oximetry finger probe closes around the finger and the LED shines through the tissue to the PD as seen in Fig. 2.1. One problem with the finger probe is that the movement of the finger inside the clip and against the sensor can disrupt the PPG signal. Also, the finger probe is uncomfortable for a patient staying in a hospital long-term, because it limits the use of the hand wearing the probe. A transmittance PPG would not work on the chest because of the size of the torso; the light from a theoretical chest-based PPG sensor would need to transmit across the torso, having the LED on one side of the torso and the PD on the opposite side. In addition, within the chest there are also ribs wrapping around the organs; this would create a lot of light deflection from the source.
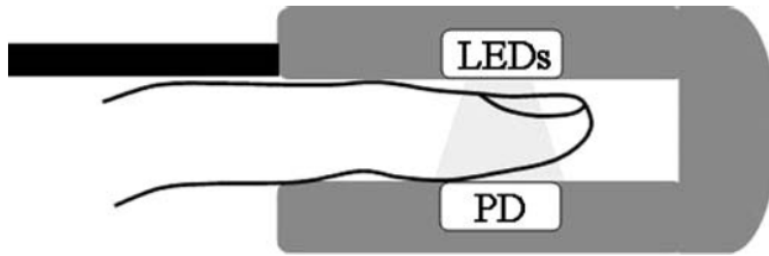
Figure 2.1: Transmittance PPG [1]

Reflectance PPG places the LED and PD side-by-side on the device surface, with a space between the components. A schematic of the reflectance PPG can be seen in Fig. 2.2. When the sensor is placed on the patient, the LED shines light on the tissue and the reflected light from the tissue and or bone is picked up by the PD. A pulse oximeter on the chest has the LED and PD placed over the sternum. As the light enters the tissue, it is reflected off the bone and picked up by the PD. One drawback of reflection PPG is that light back-scatters, or bounces off the tissue in unpredicted ways, causing some of the transmitted light to not be reflected back onto the PD. This back-scattering effect can be counteracted by changing the distance between the LED and PD. The holder produced from this project will house a reflectance type PPG sensor.

Figure 2.2: Reflectance PPG [1]

2.2 Blood Oxygen Saturation

Pulse oximetry is the measurement of arterial blood oxygen saturation from the arterial pulse. Blood oxygen saturation measures the amount of oxygen (O_2) in the arterial blood [1]. In the blood, 98% of oxygen is carried by the protein hemoglobin (Hb) [1]. This protein combines with O_2 in a reversible chemical reaction, oxidizes, and forms oxyhemoglobin (HbO_2). The calculation for blood oxygen saturation is Eq. 1, where $[HbO_2]$ is the concentration of oxyhemoglobin, and $[Hb]$ is the concentration of hemoglobin [1].

$$\text{Oxyhemoglobin Saturation}(\%) = \frac{[HbO_2]}{[Hb] + [HbO_2]} \times 100 \tag{1}$$

The essential equation for pulse oximetry (Eq. 2), describing the light intensity, comes from the Beer-Lambert Law. In this equation, I_t describes the intensity of the transmitted light, I_0 describes the incident light, ϵ describes the wavelength-dependent molar absorptivity, c describes the substance, and d describes the light's path length.

$$I_t = I_0 \times 10^{-\epsilon c d} \tag{2}$$

Then, the equation for SO_2 can be determined from Eqs. 1 and 2, where A and B are derived from the specific extinction coefficients of Hb and HbO_2, and OD is defined as the optical density of the substance [1]. Therefore, the oxygen saturation of the blood can be determined by measuring the transmitted light intensities in a homogeneous blood sample containing unknown concentrations of Hb and HbO_2 [1].

The difference between oxygenated and deoxygenated blood is the basis for pulse oximetry; the difference between oxygenated and deoxygenated blood can also be measured using light absorption [1]. The process of sending light into the tissue to detect changes in absorption based on the oxygenated-deoxygenated blood difference is called PPG. The oxygenated blood is bright red in color whereas deoxygenated blood is a dark red color. The difference in optical

absorption can be used to calculate the oxygen saturation. The oxygen saturation is found using a wavelength around 660nm, red light, that measures the large difference between Hb and HbO_2 and a wavelength between 880 and 940nm, infrared light. The oxygen saturation can then be calculated using the ratio between the optical densities of the red light and infrared light.

2.3   History of Pulse Oximetry

Pulse oximetry was invented by Takuo Aoyagi in the early 1970s [2]. At the time, he was studying a way to measure cardiac output by using dye dilution in the ear. In trying to cancel out the pulsatile variations in the color of the blood, he discovered that these variations were related to the works of Millikan and Wood in the field of pulse oximetry. It was his use of light at 900nm, instead of the isobestic wavelength of 805nm, that allowed him to make this discovery and set the precedent for pulse oximetry using light [2]. These findings showed that arterial blood oxygen saturation could be found using the optical densities of the tissues with red and infrared light.

The first application of pulse oximetry measured blood oxygen saturation from the volumetric pulsatile changes in the ear lobe. The first oximeter to use this, the OLV-5100, can be seen in Fig. 2.3. These pulsatile variations were used by comparing the optical densities of the tissue at red and infrared wavelengths.

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Figure 2.3: The OLV-5100 pulse oximeter [2].

The finger probe uses transmittance PPG sending light across the finger's tissue into the PD. The location of the finger probe is very beneficial to the PPG measurements due to the vessel network in the tips of the finger [1]. An illustration of this method can be found in Fig. 2.1.

Some of the work of R. Dresher and Y. Mendelson, along with G. Agashe et al. explores the forehead application of pulse oximetry [8,9]. The forehead sensor uses two LEDs and a PD configuration to be used for reflection PPG. The sensor is usually attached by an elastic headband [10]. The bone in the forehead reflects light well and the arteries in the forehead and thin layer of skin allow for the LEDs to measure the pulse from the displacement of the blood vessels. For the example shown in Fig. 2.4, the sensor is attached to the forehead with an adhesive instead of a strap.

Figure 2.4: Example of a forehead pulse oximeter [3].

R. Haahr and S. Duun have conducted research on the applications of reflectance pulse oximetry, the foundations of which come from Y. Mendelson in [5, 11]. Haahr and Duun, along with their colleagues, explore an application of pulse oximetry: what they call an "electronic patch" that can be worn on the skin and used for monitoring of patients. The method they devised was to use an annular backside silicone photodiode to minimize power consumption, and have a disposable hydrocolloid polymer adhesive so that the patch itself could be disposable and the electronic components could be reused. This medical patch is in the clinical trial phase and has not gone to market.

2.4 Circulatory Anatomy of the Torso

The chest or back is the intended surface for attachment of the reflectance sensor holder. The blood vessels in this area are fewer in number and in lesser volume compared to the blood vessels in the typical measuring site of the fingertip. In the body, arteries carry oxygenated blood from the heart and distribute it throughout the body, while veins carry deoxygenated blood back to the heart [12].

The vessels that surround the sternum are the anterior intercostal (IC) arteries. There are also posterior IC veins and, as well as anterior subclavian veins but these do not pulse like the arteries The lateral thoracic artery, which can be seen in Fig. 2.5, is on the lower part of the chest and lies vertically over the ribs. The layout of the vessels follow the bone structure in the body, which is important to utilizing the reflectance PPG sensor [12]. The general anatomy is similar between people but it changes between genders as found from Kuhlman [13].

Kuhlman's article focused on the factors effecting the diameter of IC arteries found that the posterior IC arteries were larger than the anterior IC arteries [13]. The research in the article also compared the IC arterial physiology between females and males, finding that males had a greater IC arterial diameter. The data was collected from adult cadavers, 18 males and 24 females [13]. This information is helpful in determining whether the back or chest are better locations to locate vessels. The difference in male and female anatomy is important to determining the location of the holder, but the vessel size should not affect the readings significantly as males also have greater chest muscle mass in comparison to females [13]. The location of the vessels is important and the layout of vessels will generally be the same between males and females [13].

There are also large vessels located in the upper torso area around the shoulders and neck. The suprascapular artery (Fig. 2.5) arises from the subclavian artery and travels to the posterior where it lays over the scapula [12]. The suprascapular artery would be the vessel measured if a sensor was placed on the upper back on the shoulder blade. The intercostal arteries are located below the scapulas on the back as they wrap around posteriorly from the sternum. The large veins of the upper torso include the subclavian vein and brachiophalic veins, both arise from the superior vena cava [12].
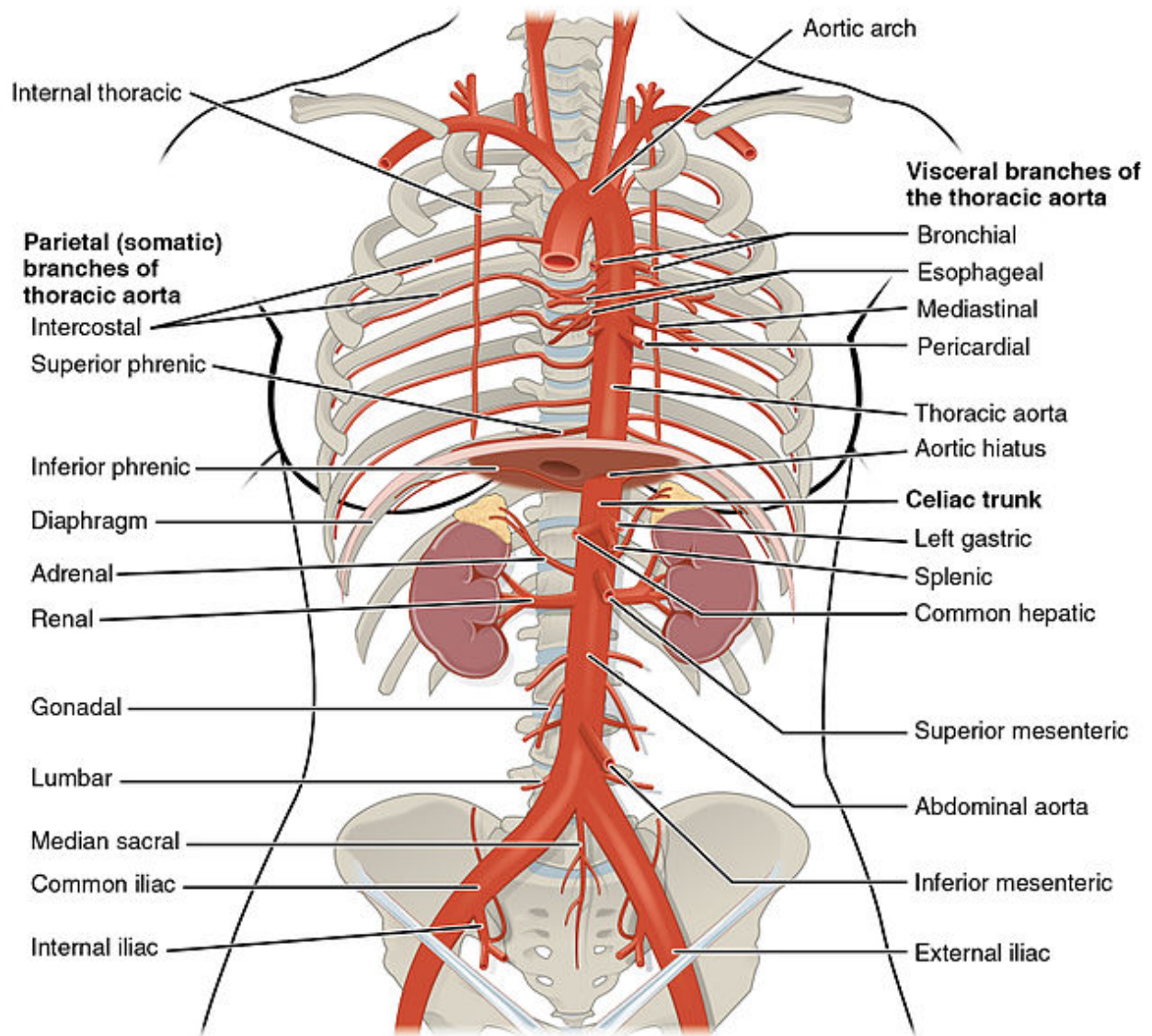
Figure 2.5: Arteries of The Upper Torso [4].

Larger vessels like the subclavian artery are not as reliable as smaller vessels when making PPG measurements. The large size of the vessels causes more motion artifact to the sensor. Larger blood vessels like the subclavian vein and subclavian artery are not as reliable compared to smaller vessels because they are more likely to distort the signal in a reflectance sensor [14]. The best vessels for placing the sensor will be the intercostal arteries, because of their many locations as well as their proximity to the sternum or the intercostal bones. Hav-

ing the holder on the sternum will record PPG signals from the anterior intercostal arteries and allow for a user adjustable holder design.

2.5   Signal Acquisition

In order to acquire the SpO_2 and PR signals, the device must apply some amount of pressure to the skin. If too much pressure is applied, the circulation of the area near the device is cut off, preventing blood flow, which prevents the device from reading the arterial pulse. With no pressure the SpO_2 and PR signals can still be read but as the pressure increases the optical module gets closer to the tissue and vessels and the PPG signals improve. The sensor could move around in the holder if the design does not evenly apply pressure to the reflectance sensor, causing motion artifacts or other loss of data. The literature indicates that the best amount of pressure for a pulse oximeter on the forehead is in the range of 8-12 kPa which is about 60-90 mmHg [10]. This pressure range was helpful in testing the holder design for the chest because, like the forehead sensor, the reflectance sensor for the sternum was mounted on a layer of tissue with dense bone directly underneath it.

For this project the sensor was tested while volunteers were in a stationary position i.e. supine, sitting, or standing and the motion artifacts due to them moving during recording were removed during signal processing. The motion artifact from respiration was filtered out by removing the DC component of the PPG signals.

3 Project Approach

This chapter describes the various considerations of the design project, and the development of the client statement.

3.1 Initial Client Statement

The initial client statement was provided to give the team a general idea for the project. This statement changed after going through the project, but the initial client statement was: design a pulse oximeter sensor holder that can be mounted on the chest.

3.2 Experiments

In order to complete the client statement, the team needed to know what pressure had to be applied to the sensor on the chest to maximize the PPG Amplitudes so accurate measurements could be recorded.

For our proof-of-concept experiments, we used the six-LED PD pulse oximeter that was provided to us by Joshua Harvey (Fig. 3.1). This device has six LEDs with one PD in the middle. The sensor gets connected to a laptop using a micro-USB connection allowing the signals measured to be recorded onto a computer.
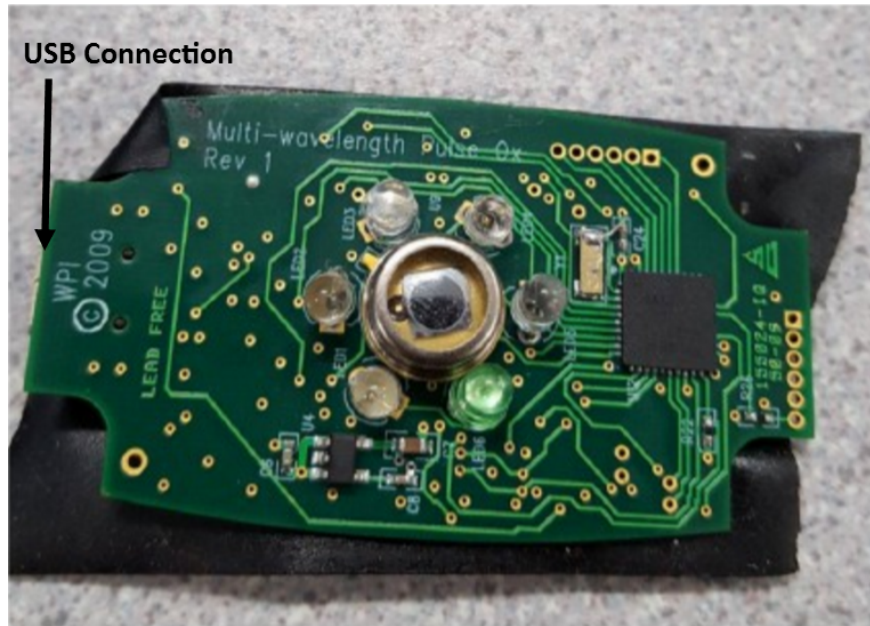
Figure 3.1: 6 LED Sensor Used in Proof-of-Concept Experiments

3.2.1 Procedure

What follows is the procedure for our proof-of-concept experiment. It assumed that the LED-PD sensor had a force transducer attached to the base. The force transducer was attached to the six-LED PPG forehead sensor with electrical tape. The PPG sensor was also covered in electrical tape to help avoid sharp edges on the volunteer's chest. The PPG sensor was connected to a laptop that recorded the output waveforms, the force transducer was connected to an oscilloscope to measure the output voltage. The force transducer was mounted on top of the LED sensor and a popsicle stick was laid over the transducer. The popsicle stick was secured to the team member's chest with medical tape seen below in Fig. 3.2.
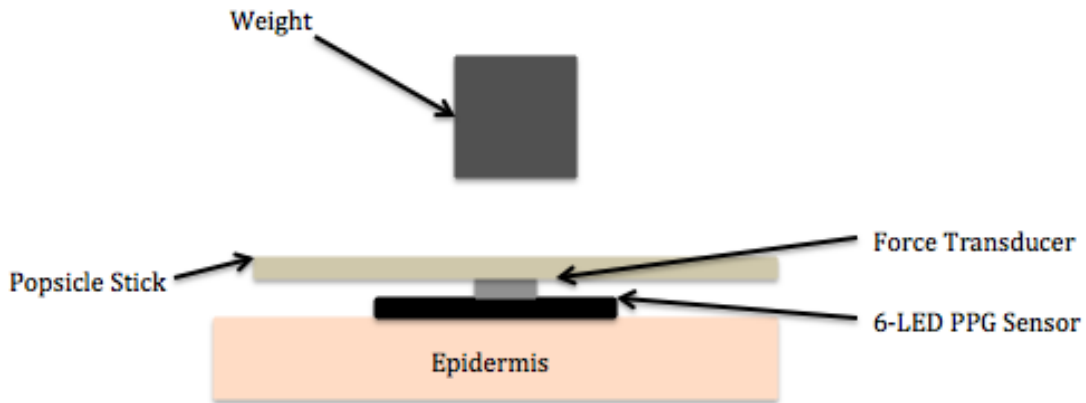
Figure 3.2: Proof-of-Concept Experiment Setup

1. Connect the force transducer (Fig 3.3) to a supply voltage of 5V, PIN 1 $(+V_s)$ and PIN 3 $(-V_s)$. The pins that will be measured for the force transducers output are PIN 2 $(+V_o)$ and PIN 4 $(-V_o)$. The pulse oximeter sensor is connected by a micro-usb to the laptop that contains the drive software to measure the output waveforms.

2. Attach the device two inches below the suprasternal notch, centered on the sternum.

3. Measure the output waveforms of the LED-PD device for 30 seconds by using the driver software for the six-LED sensor. The recorded output will have six plots, one for each LED in the pulse oximeter sensor. A popsicle stick was placed on top of the force transducer to create a level measuring platform. A 250 gram weight was used to apply the pressure on the volunteer's chest for each measurement. One person presses on the force transducer, pressing down on the sensor and the chest to obtain a set output voltage range. The output of the force transducer is kept in the range of the voltage step by reading the oscilloscope.

4. Instruct the volunteer to hold their breath while applying pressure to the sensor and

force transducer on the skin for 30 seconds (step 2). The volunteer may breathe once the 30 seconds have passed.

5. Increase the pressure such that the output voltage raises by 50 mV, then repeat steps 2 and 3. This process was repeated in 50mV steps starting at 0mV (no pressure) to a 350mV output measured by the oscilloscope from PINS 2 and 4.
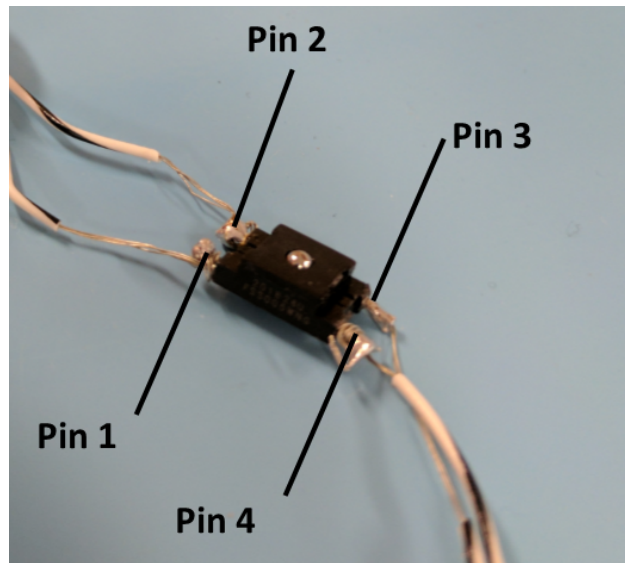
Figure 3.3: Force transducer used in testing

3.2.2 Results

The final graph for this experiment can be found in Fig. 3.6. This is the raw data for the experiment, as well as a description of the techniques used for processing.

Table 3: Pressure experiment raw data (no breathing).

Trial	Start Time [mm:ss]	Transducer Output [mV]	Time Stop [mm:ss]	peak_trough output
1	0:43	0	1:13	0.59
2	3:50	50	4:20	16.1682
3	6:15	100	6:45	15.4295
4	8:54	150	9:24	13.9176
5	11:10	200	11:40	9.5829
6	13:30	250	14:00	0.395
7	16:00	300	16:30	0.2534
8	18:42	350	19:12	0.2211

The force transducer was calibrated by increasing the weight placed on the sensor and recording the output voltage (Fig. 3.4 and 3.5). The weight started at 50g and was increased by 20g intervals. Three measurements for output voltage were recorded at each weight. This information was compared to the Honeywell FSS-SMT Series specification sheet and used to estimate the force applied throughout the chest pressure experiment. After going to 250 grams, we then calculated the output voltage and the corresponding weight for max force on the force transducer which is five Newtons. The force transducer output was converted from Volts to mmHg using Eq. 3 and Eq. 4.

$$\text{Force} = \frac{V_O}{0.1663} * 5 \tag{3}$$

$$mmHg = \frac{Force}{219.1} * 7500.61683 \tag{4}$$
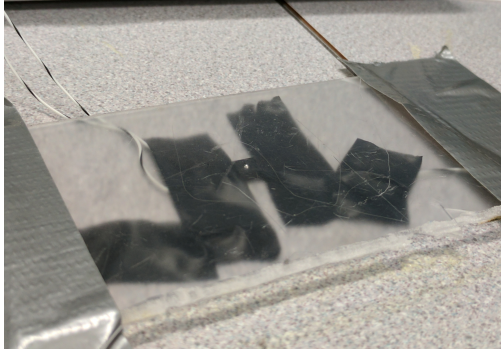
Figure 3.4: Calibration Test Setup
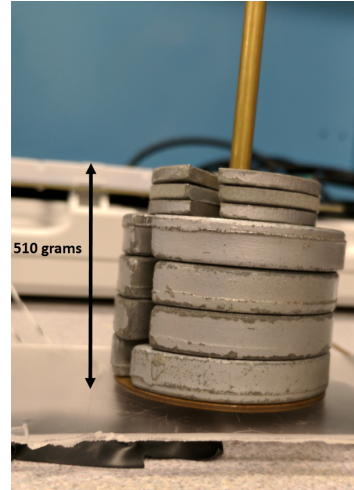
Figure 3.5: Calibration Test Setup with Max Weight

Table 4: Force Transducer Calibration Test

Weight[g]	Voltage Output [mV]	Force [N]
50	16	.480
70	20	.610
90	28	.850
110	32	.970
150	56	1.70
190	62	1.88
230	86	2.61
250	102	3.09
510	166.3	5.00

3.3   Technical Design Requirements

For the reflectance pulse oximeter holder to be as effective as other reflectance based pulse oximeters on the market, there were three main areas of focus: motion artifacts, pressure, and adhesion. These three areas were crucial to develop an accurate device that could meet,

or exceed, the capabilities of current devices.

3.3.1 Motion Artifacts

A motion artifact is an error that occurs from movement of the sensor. Artifacts can occur from any movement such as breathing. As with most pulse oximeter sensors, they are prone to motion artifacts. Our device was not tested for ambulatory movement and the motion artifact from respiration was filtered out when the DC component was removed during signal processing.

3.3.2 Pressure

The efficacy of the device was affected by the pressure exerted by the sensor on the skin. If too much pressure was applied, signals from the device became weak because the vessels were occluded. Likewise, if not enough pressure was applied the PPG signals were weaker because the optical module was only sitting on the skin and was farthest away from the vessels compared to when pressure was being applied. From an experiment the team conducted, the team found that the best range of pressures was from 75-100 mmHg. The results of this experiment can be found in Fig. 3.6, and the process can be found in Section 3.2.
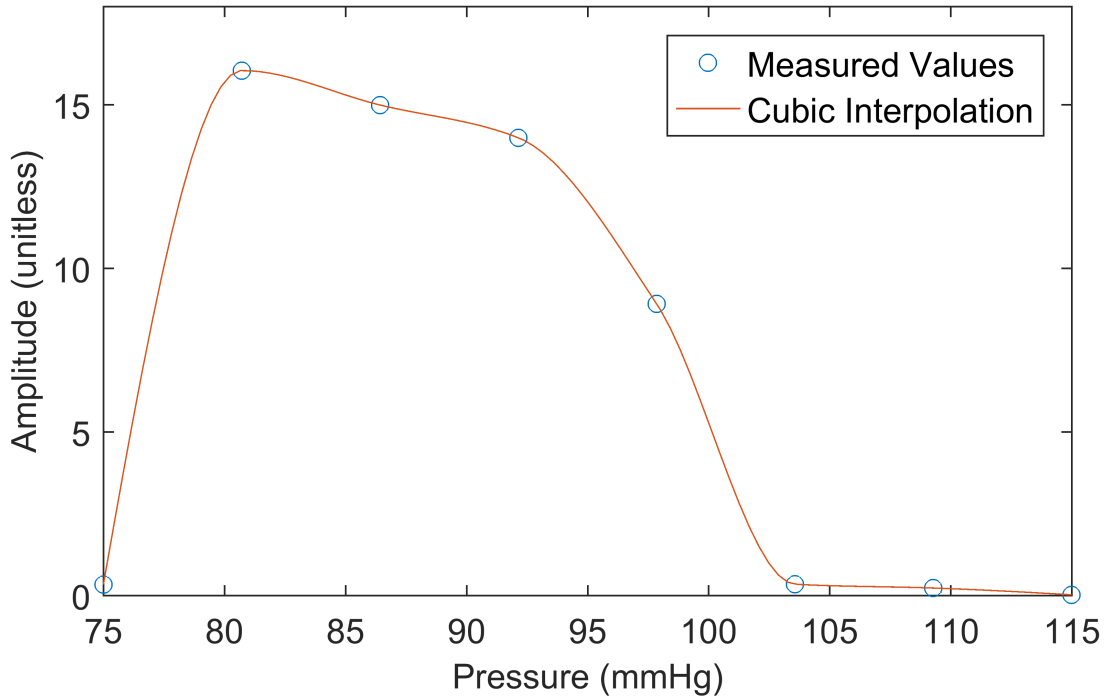
Figure 3.6: Output amplitude vs. applied pressure.

3.3.3 Device Adhesion

Current medical devices that use an adhesive to stay on the chest, such as an EKG patch, helped in determining what kind of adhesives could be used to attach our holder to the chest. One adhesive that could be used are hydrocolloid adhesives because of their water-resistant properties [15]. Hydrocolloid adhesives are composed of a rubbery elastomer (e.g. polyisobutylene) to adhere to the device and a swellable hydrocolloid material to absorb moisture [16].

For reflectance sensors, most adhesion methods use a patch on the forehead. The forehead sensor is adhered to the patient's forehead and then usually a strap is wrapped around the forehead. This only applies one pressure and can not be adjusted for comfortability. If it is adjusted wrong, the signals being recorded are not a true representation. Another reflectance sensor used daily are ones used in wristbands, like the FitBit. The wristband sensors usually

only use a green LED because it can penetrate deep enough to sense blood pulsations and is less influenced by DC components of tissues. This also happens as the forehead sensor: only one pressure is applied and if that pressure changes, the data stored is not reliable.

3.4   Legal and Standard Design Requirements

If this device was intended to be put on the market, it would have to be cleared by the Food and Drug Administration (FDA). The FDA has several pre-market requirements that would need to be met. The first standard for FDA approval is the classification of the medical device. There are three classes of medical devices: Class I, Class II, or Class III. Seeing as this device will be a reflectance pulse oximeter, the team would look to the classification for an oximeter. In [6], it is stated that an oximeter is a Class II device. This means an oximeter's general controls alone are insufficient to provide a reasonable assurance of safety and effectiveness [17]. Because the team created a holder for the pulse oximeter, the holder needed to have an adhesive back to secure the sensor to the intended location. Adhesives are Class I devices [18]. Another need for premarket approval is a 510(k) submission. A 510(k) is a premarket notification that a manufacturer will propose to the FDA before they are able to go to market [17]. For pulse oximeters, a 510(k) is needed for market approval.

All of the standards above are for the pulse oximeter as a whole. The next part was to go piece-by-piece and make sure that the material was safe to the user. All of the material that we used needed to be biocompatible. The main part of the pulse oximeter was the adhesive, which would be attached to the user. This adhesive would need to be already FDA approved which meant that it had already been tested and had met requirements for multiple properties. The team used the International Standard Organization (ISO) 10993 guidance sheet when determining the biocompatibility of the device [19].

3.5 Revised Client Statement

To create a non-irritating holder for a wireless pulse oximeter to be worn on the user's chest for up to 24 hours. The holder will encompass the sensor which will be approximately 3 cm by 3 cm. The holder will have to maintain a contact pressure between 60-90mmHg on the chest to acquire accurate readings.

3.6 Device Requirements

From talking to our advisor on numerous occasions, the device must meet certain design requirements in order to be comparable to devices already on the market: maintain a stable pressure, and be wearable on the chest. There are numerous attributes that a pulse oximeter needs to be successful. These include the device performance, electrical safety, biocompatibility, and re-usability [6]. Using Table 5 from the *Pulse Oximeter-Premarket Notification Submissions [510(k)s]* [6] the team determined the necessary specifications for the device's use and features.

Table 5: Example of New and Predicate Devices [6]

Description	Your Device	Predicate Device
Intended patient population, such as neonate, infant, pediatric, adult		
Intended application site, such as finger, ear, foot, hand, forehead, back, nose		
Performance Specifications (including use under motion and low perfusion conditions, if applicable, and any indices or signals provided to the user)		
Safety Specifications (e.g., electrical, mechanical, environmental)		
Features (e.g., alarms, display and indicators, modes)		

Even though these comparisons are for the pulse oximeter itself, these descriptions are helpful in determining the overall appearance of the device. Then, that gave us a better understanding of how the holder would need to operate. The team also looked at other pulse

oximeter specifications to determine a baseline for what the device would need to output. Looking at previous MQP reports advised by Professor Mendelson, past teams have already made a specification table for a pulse oximeter that will rest on the chest [7] which can be seen in Table 6.

Table 6: Chest pulse oximeter project specifications [7].

Effective Measuring Range

Saturation	70-100%
Pulse Rate	20-250 BPM
Resolution	1 digit

Accuracy

Saturation	$\pm$ 3 or $\pm$ 2% digits
Pulse Rate	$\pm$ 3 or $\pm$ 3% digits

Display

Saturation	2 Characters
Pulse Rate	3 Characters
Power Requirement	3V Lithium Battery (coin sized batteries)
Battery Life	Minimum 24 hours continuous

Table 6 gives the team a baseline for what the pulse oximeter should be able to output. The holder must be made so that the sensor is able to generate reliable signals that are within the ranges in table 6.

4 Design Process

4.1 Concept Generation and Screening

After completing the preliminary research, the second phase of the project was used for concept generation and screening. Using the knowledge of past and present pulse oximeter models, we created three different holder concepts: a simple patch design, a hook design, and a clamp design. We believed that these concepts would help apply enough pressure for accurate PPG signal measurement from the chest. After testing those three designs, a final design was chosen and 3D printed for prototype testing. The design was first tested on ourselves and then once we confirmed that it was consistent in applying a pressure between 0-50 mmHg , volunteers were asked to participate in two experiments. The team chose a pressure range between 0-50 mmHg because, from the test in Fig.5.10, these pressures generated the largest PPG amplitudes. The next sections will go into more detail for each process of the Design phase.

4.2 Needs Analysis

To develop a functional device, its materials had to be safe, its size had to be small, and, according to early tests, it had to apply a pressure of 0-50 mmHg. Safety needs included rounded edges for the sensor board and the sensor holder, with an access port for the wires of the sensor, and medical grade adhesive to connect the holder to the body. The size of the device had to be small because of its location on the center of the chest. It also had to fit under clothes comfortably and discreetly. A smaller device would allow the user to move more freely, especially relative to the current finger probe design. Finally, in order to get a clear signal for pulse rate and oxygen saturation levels a consistent amount of pressure had to be applied to the sensor from the cover.

4.3 Prototype Sensor

Before we could determine the feasibility of these designs, we developed our own custom sensor. For the first part of the design phase, a 6 LED PPG sensor was used for experiments (Fig. 3.1). The sensor given to us was used in previous projects on the forehead, not the chest. We used the given sensor for a proof of concept but the sensor did not work well on the chest. Even though the setup did not work, multiple factors were changed for future work: use proper medical tape, minimize movement for cleaner signals, and create step-by-step processes for experiments. The team bought 3 LEDs green (530nm), red (660nm), infrared (940nm) and 3 silicon (Si) photodiodes (PDs) which were used to create our custom sensor (Fig. 4.1).
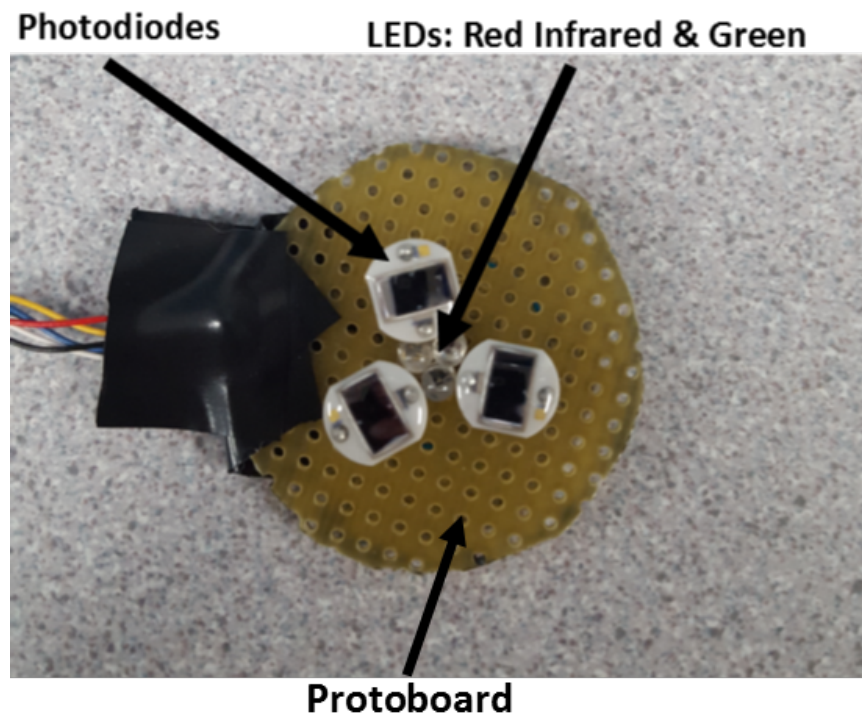
Figure 4.1: Prototype Sensor

For the optical module, the LEDs and PDs were soldered on to the protoboard and were connected to a Texas Instrument (TI) AFE4404EVM development board for data acquisition

(Fig. 4.2). The AFE4404EVM is suited for measuring heart rate and oxygen saturation. The prototype sensor has its components soldered to wires which are soldered to another connection point on the gray wire. The gray wire is connected to the AFE4404EVM, analyzes the signals coming from the PDs, and then transmits them to the computer. The computer runs a Graphical User Interface (GUI) which allows the user to interact with electronic devices with the help of visual indicators. In the GUI, there are multiple sections that are used to change the values of the LED current and gain value (Fig. 4.3 and 4.4). It also lets the user watch the signal being measured in real time letting the user know if any problems arise (Fig. 4.5).
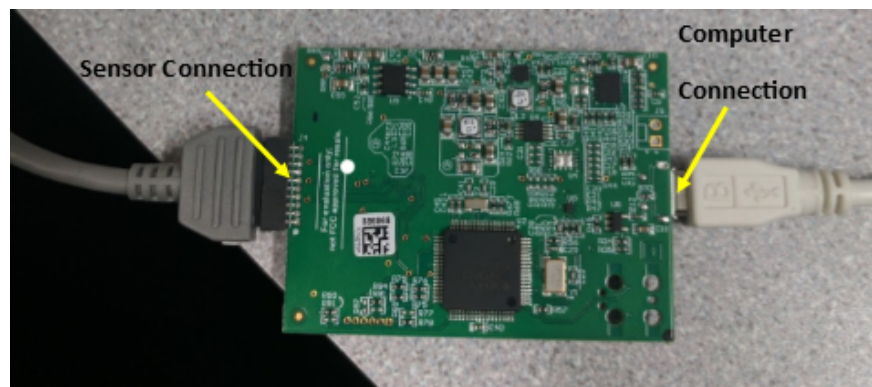
Figure 4.2: TI AFE4404 Evaluation Module (AFE4404EVM)
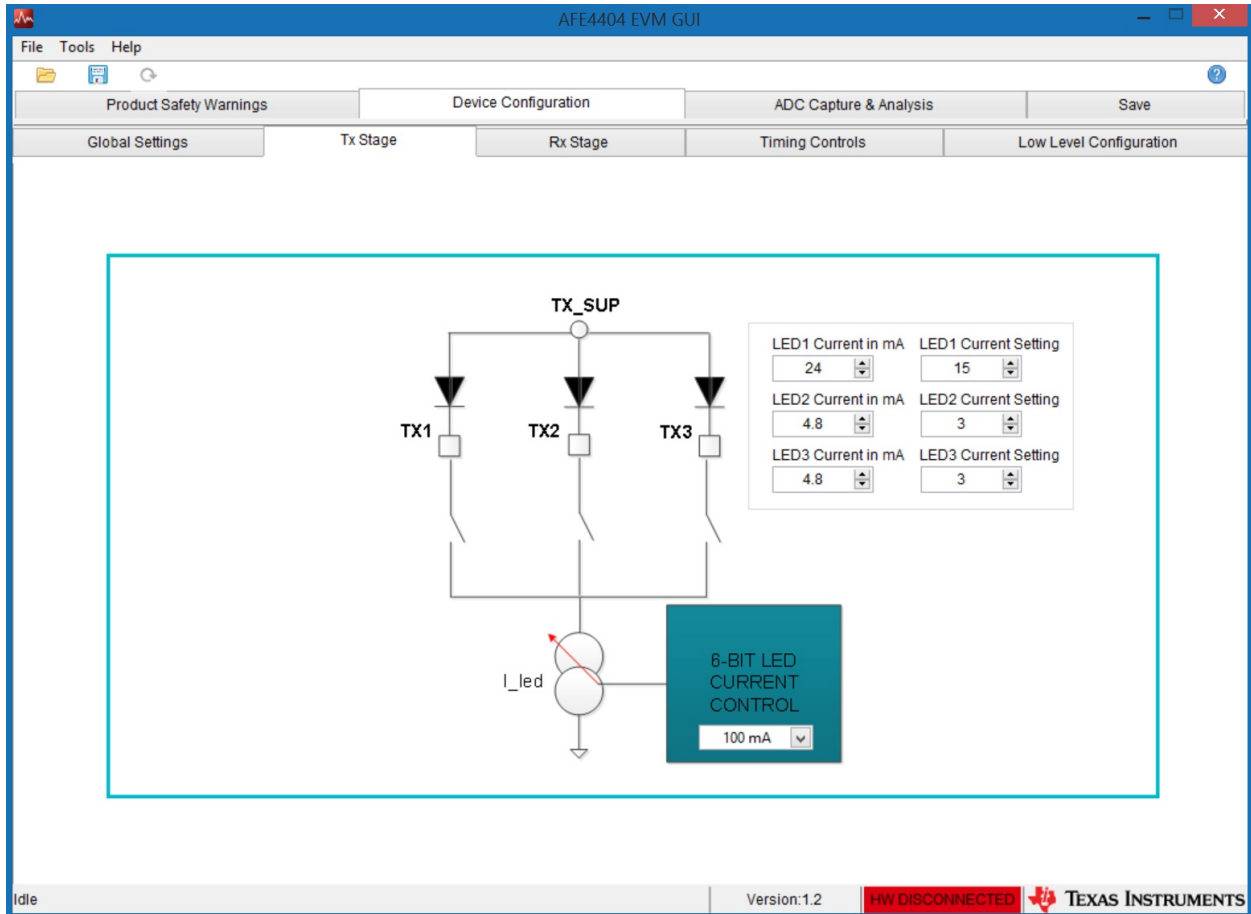
Figure 4.3: AFE4404EVM GUI Transmission Page

On the transmission page of the GUI, the user can change the LED current values. Each LED number corresponds to a different color: 1-Infrared, 2-Green, 3-Red. For our experiments, we first got values for each team member shown in Table 7 and used those as a baseline for volunteers.

Table 7: Chest LED Settings

Team Member	LED1 Current Setting	LED2 Current Setting	LED3 Current Setting
Tori	2	16	3
Nick	5	19	6
Cobi	2	12	3
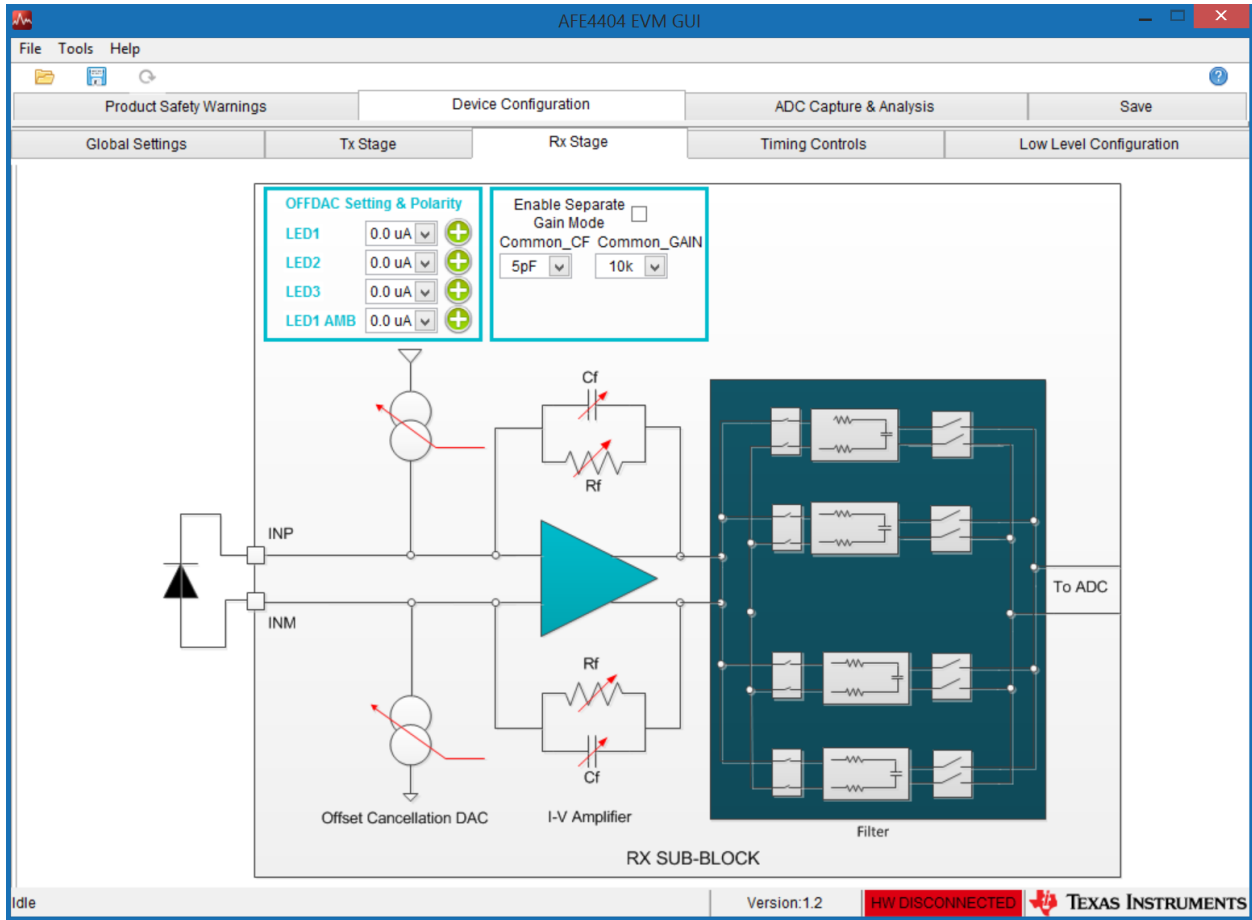
Figure 4.4: AFE4404EVM GUI Receiver Page

For all the tests done, the gain was set to one common gain of 10K. When using separate gain, certain LED signals would not appear.

Figure 4.5: AFE4404EVM GUI Signal Page

The same proof-of-concept tests were performed and showed that signals can be acquired from the chest. This proved that the sensor worked properly and could be used for future testing.

4.4 Design Alternatives

After addressing the device needs, the team generated three different design concepts for housing the sensor. These concepts were later used to build our final prototypes. The three concepts the team made were a simple patch design (one-piece adhesive), a hook or clamp design (two-piece adhesive), and a strap design.

4.4.1 One-Piece Adhesive

Our first design concept was a simple patch design. Everything would be adhered to the chest under one adhesive strip that covers the entire device. The team looked at Haahr's design for an adhesive patch that could be used as a model for the housing of our sensor (Fig. 4.6) [5].
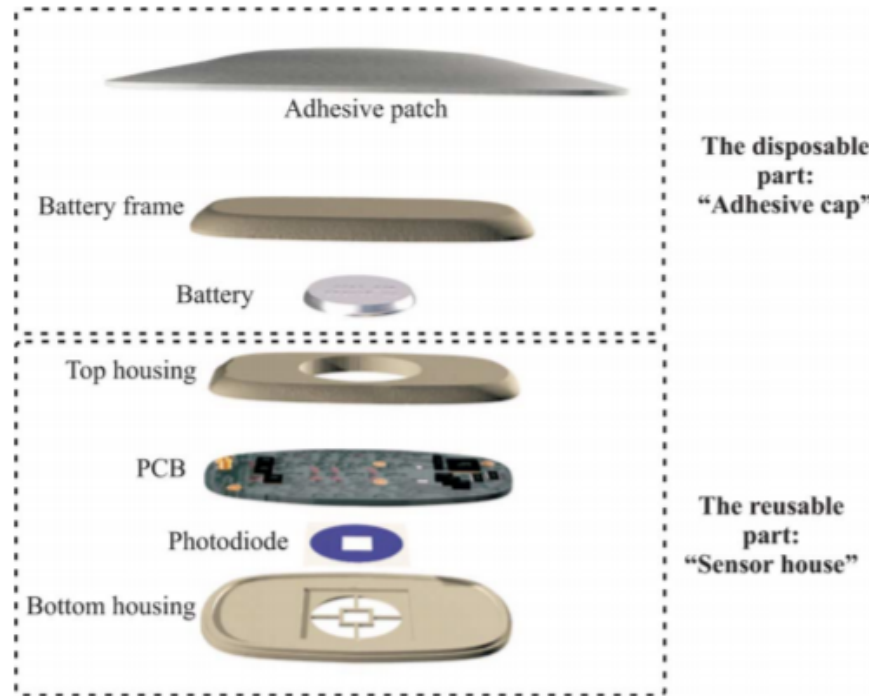
Figure 4.6: Electronic Patch Design [5]

Haahr's design would help keep the optical module and adhesive together and would not be bulky on the chest. Using the prototype sensor, we placed multiple strips of adhesive tape over the optical module, taping it to the chest. We found that having only tape over the sensor did not administer the right amount of pressure to produce clean PPG signals from the reflectance sensor. The signals coming from the TI board resulted in small PPG amplitudes. Even though it was not bulky, there was no way to get consistent pressure or adjust the pressure on the optical module.

4.4.2 Two-Piece Adhesive

The second design concept was a hook design or a clamp design. There were two parts to this design: a disposable adhesive and a reusable housing unit. One advantage to this is that the whole unit does not get disposed of when the adhesive no longer functions. The reusable sensor housing is ideal if the user needed to monitor for an extended period of time, or if they wanted to monitor with the pulse oximeter at different discrete times. The other advantage between this and Haahr's model is that these designs would have ways to apply and change the pressure by being adjusted.

The clamp design, in theory, would have two clamps attached to the outside of the holder. The angle that the clamps sit at would be adjusted to let people manually apply different pressures on the holder. That pressure on the holder would push down the sensor that is sitting inside of the holder. Figure 4.7 is a rough sketch of the clamps connected to the housing unit which do not apply an outside pressure. Instead, the clamps would have had to be placed on an extender located on both sides of the holder.
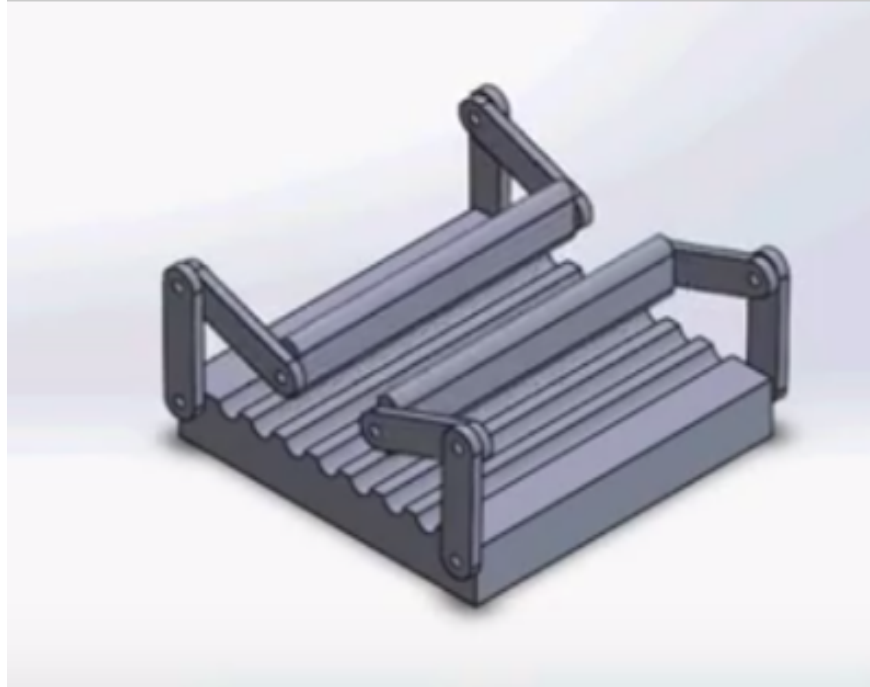
Figure 4.7: SolidWorks Model of clamp design

The hook design (Fig. 4.8) was based off of a glucose sensor device that a team member uses daily. The housing unit has hooks on each side of the device that are locked into place by multiple hook insertions. The housing unit was made of a rubber like material while the insertions were hard plastic. This lets the user move the insertions around the upper chest and then the housing unit is stretched to the appropriate length to apply the pressure based on the stretch.
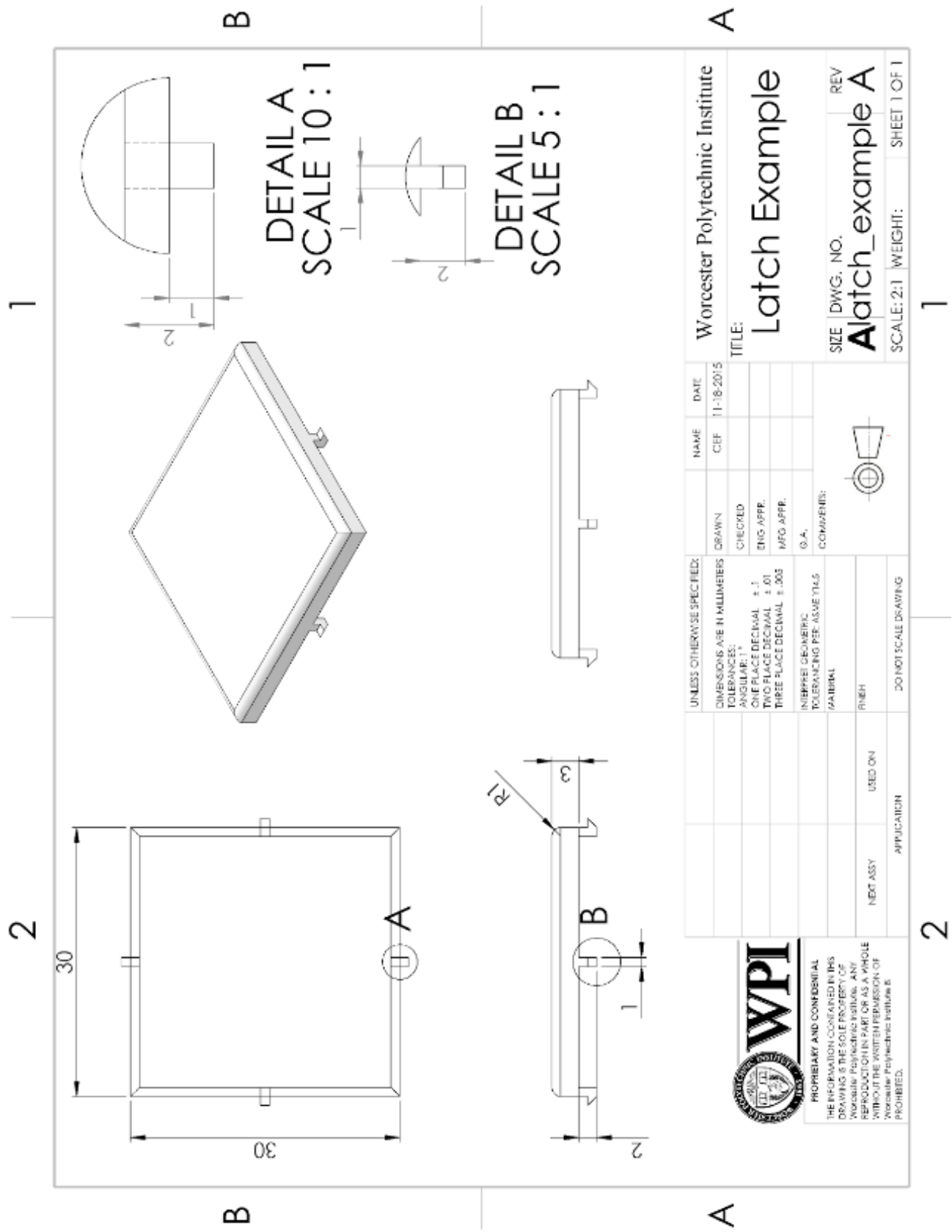
Figure 4.8: SolidWorks Sketch of Hook Design

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TITLE:
Latch Example

DETAIL A
SCALE 10 : 1

DETAIL B
SCALE 5 : 1

SIZE DWG. NO.   REV
A   latch_example A
SCALE: 2:1 WEIGHT: SHEET 1 OF 1

UNLESS OTHERWISE SPECIFIED:

DIMENSIONS ARE IN MILLIMETERS
TOLERANCES:
ANGULAR: 1°
ONE PLACE DECIMAL   ± .1
TWO PLACE DECIMAL   ± .01
THREE PLACE DECIMAL ± .005

INTERPRET GEOMETRIC
TOLERANCING PER ASME Y14.5

MATERIAL

FINISH

	NAME	DATE
DRAWN	CEF	11-18-2015
CHECKED		
ENG APPR.		
MFG APPR.		
Q.A.		
COMMENTS:		

DO NOT SCALE DRAWING

NEXT ASSY   USED ON
APPLICATION

WPI

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Both designs would be attached to the adhesive ,which would have a hole on the bottom so that the LEDs and PDs could acquire data. If the adhesive did not have the cutout, then light would have to penetrate the adhesive coating as well as the skin, which would weaken the strength of the signal. These designs were the most feasible for applying a consistent pressure and allowed the user to change that pressure. The only downside was that they are bulky and the team needed to find a way to decrease the dimensions.

4.4.3 Strap

The third design concept was a strap design. The sensor would be attached to the strap that was getting wrapped around the user's chest. There are multiple heart monitors that are designed with straps that are used for daily monitoring. The strap is a simple way to attach the sensor to the chest and can be done in two ways: going around the torso perpendicular to the sternum or over the shoulder and around the torso (Fig 4.9). In either design issues could come up with comfortability and movement. If the strap was not tightened enough the sensor would move around on the skin's surface and no reliable measurements would be recorded.
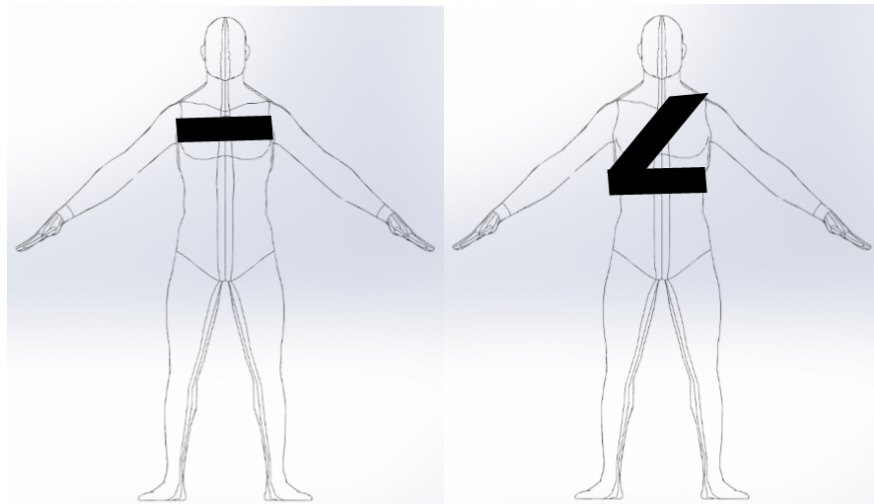
Figure 4.9: Strap design

Our group did not pursue any design solutions with a strap because we felt the user of the device would be more frustrated with a strap around their torso compared with a small patch-like design. The respiration would also cause a difference in applied pressure across the strap which would cause noise in the PPG signals or even possible signal loss.

4.5 Conceptualization

During the design phase the team made numerous decisions on how the holder would be created, what the sensor would look like, and how the sensor would perform. The holder needed to meet certain specifications from the client statement without causing harm to the user before being considered a properly working device. The team generated multiple options for prototype designs; these options were used to conceptualize a final design. Many of the options are stated in Section 4.2 but a thorough list would include:

1. Shape of the Protoboard

2. Selection of the Sensor Components

3. Materials used for Holder Prototype

4. The Design of the Holder

5. Sensor Connections to AFE4404EVM are Safe

6. Pressure Application on Sensor

The next sections discuss the team's approach to prototype design decisions.

4.5.1 Shape of Protoboard

The shape of the protoboard is primarily an aesthetic concern; the components will work so long as they are soldered correctly. The concerns of potential users and the final design will be affected by the shape of the protoboard. The holder will be built around the protoboard,

most likely mimicking its shape. Table 8 lists advantages and disadvantages of the different protoboard shapes.

Table 8: Sensor Protoboard Shape Design

	Sensor Shape		
	Rectangle	Circle	Triangle
Advantages	Easy to create with machine Holder for sensor would be simple Complimentary to chest	Easy to create with machine Allows for holder to have extra ways of applying pressure Rounded Edges Complimentary to Chest	Easy to create with machine Different shape compared to most medical devices could lead to different designs
Disadvantages	Depending on holder shape integration could be a problem No rounded edges Smaller area	No edges to grab	Not complimentary to chest No rounded edges Only have a small area to fit all components

The protoboard was cut into a rectangle and a circle in the machine shop on campus. The final factor in choosing the protoboard were the areas of the two shapes. The rectangle cut had an area of 1.39in^2 and the circle cut had an area of 1.84in^2. The circle was selected because it had a greater area to distribute the force over the sensor. The circle cut of the protoboard was an easier shape to work with if the design was going to have a circular base and cover.

4.5.2 Selection of Sensor Components

As stated in the background: pulse oximetry is the measurement of blood oxygen saturation through differences in the blood, that occurs when the arterial blood pulses, by sending light into the tissue. Optical methods for measuring the blood oxygen saturation relies on two wavelengths: 660 nanometers (nm) and a spectrum between 880 nm and 940 nm which is why red (660) and infrared (940) were chosen [1]. Red and infrared LEDs are the most commonly used LEDs when measuring blood oxygen saturation levels. They have also been used to record PR data but the team decided to use a green LED instead based on two different studies that showed green LEDs are less affected by motion artifact and have less

error between PR and HR compared to red and infrared LEDs [20] and [21].

Photodiodes were chosen because they can process the light being emitted from each diode. Three PDs were used to increase the amount of reflected light that was detected from the LEDs. The PDs were connected in parallel which means they act as one PD sending the information detected from each PD into the AFE4404EVM as one signal. With three PDs there is a larger surface area of the reflected light that is captured.

4.5.3 Prototype Design

The next part of the design phase was to decide what material would be used to make the holder. The material should be durable seeing as it could be worn on the chest for a long period of time and needed to maintain a constant pressure between the sensor and the skin. The holder should also adhere to the chest which means a strong adhesive had to be used so the holder would not fall off the chest. After that was determined, the team made various models on paper and made those designs in SOLIDWORKS® for accurate representations.

4.5.4 Materials

The device was split into two main parts: the adhesive and the housing. Each part of the device had its own constraints that needed to be handled when considering its materials. For the adhesive, the constraints were the ability to continuously stick to the user without causing damage to the skin such as a rash. The tape also had to be safe and not damage the skin when being removed. Throughout this phase, we acquired multiple adhesive samples from several different companies: 3M, Berry Plastics, and MediPurpose. The majority of the adhesives that we acquired were double-sided, which is good for connecting to the user and keeping the holder in place. One problem that the adhesives face is having a reliable connection to the user if the user has hair in the area. Hair is a secondary problem for the holder because it could cause difficulty for the adhesive connection and could cause discomfort to the user when the adhesive is taken off.

4.5.5 Prototype Design

The next part of the material selection was determining what would be used to create the housing. The team decided that the housing would be 3D printed on campus using one of the materials provided. The housing needed to be able to keep the sensor in place while also providing a way for pressure to be generated. Two materials were considered for rapid prototyping based on the type of two-piece design concept: TangoBlackPlus for the hook and ABS plastic for the clamp, which was later changed to a locking method. After initial tests with the TangoBlackPlus material, the team decided to switch to ABS Plastic for creating future designs due to its improved durability and ability to keep the sensor in place. Once the materials were selected for the device, the team needed a prototype design. The team developed two housing unit ideas that were created from the first three design alternative concepts. The two housing unit ideas we developed were a hook-and-latch and a spin-to-lock design. The team theorized how each housing unit could perform the necessary tasks.

The first design that was conceptualized was the hook-and-latch design. This built upon the design shown in Fig. 4.8. The holder shown in Fig. 4.8 was 3D-printed, but the latch pieces were too small. The Rapid Prototyping team printed this model in a cheaper, more rigid material before printing it out of the rubber material requested; this was to ensure that the small hooks were on purpose. Therefore, the design had to be altered for larger pieces. By using the original design, an improved holder was made that was larger in size; this design is shown in Figure 4.10.
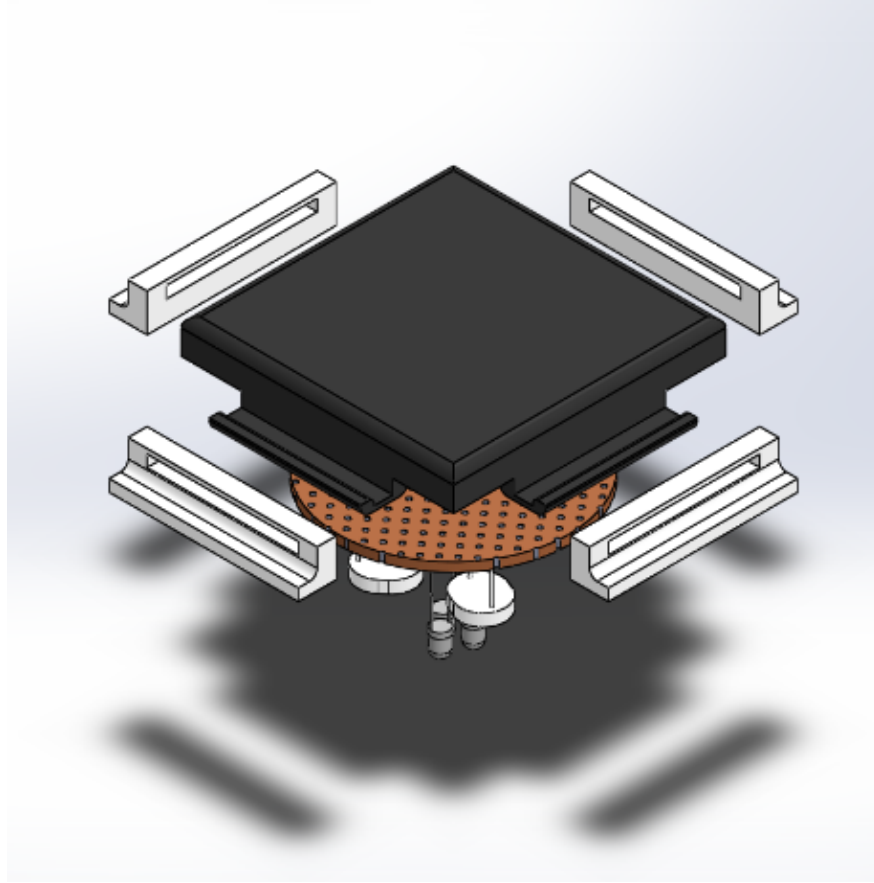
Figure 4.10: SolidWorks Sketch of 2nd Hook Design

The two aspects of the device that changed were the height of the housing, in order to accommodate the sensor more fully, and the size of the hooks, to be more realistically-sized. The change in height also prevented a specific problem not prevented in the original design; the sensor wires would break off if enough pressure was applied. To prevent that, its height was increased and the team planned on padding the interior with foam. The sensor wires also needed to exit the holder to connect to the equipment used for measurements. This meant that the holder would either need to have a hole at the top for an exit point or the wires would go underneath the holder. Once the sensor is placed into the unit, the team would be able to make a decision. The hooks changed because with the original design, the latches were too small and could be easily lost. Making the hooks, and therefore the latches, larger solved this problem.

The second design that was conceptualized was the spin-to-lock design. This was also built based on Fig. 4.8 but instead of a latch method, it twists into grooves within the housing unit. The design consisted of a plastic cover with rubber material on the bottom and a rubber housing unit for the sensor. The rubber material was to apply the pressure to the soldered side of the sensor with the optical module resting on the epidermis. The pressure applied to the sensor would change based on where the cover is locked into the slots of the housing unit. The cover is shown in Fig. 4.11 and the cross section of the housing unit is shown in Fig. 4.12.
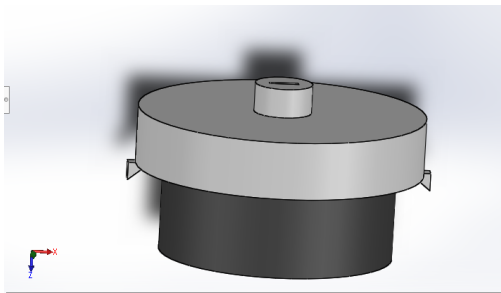
Figure 4.11: Cover for Lock Design
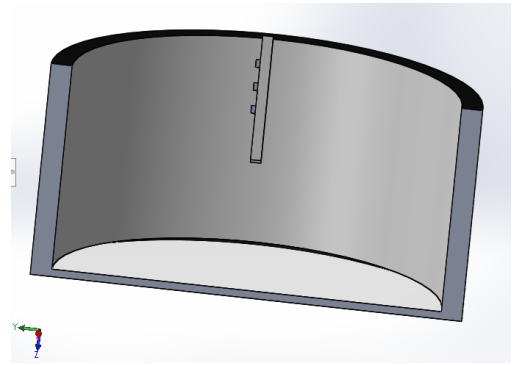
Figure 4.12: Housing Unit Cross Section

The sensor would be placed in the housing unit while the rubber on the cover would be pushed down on the sensor. Once the user had the cover in a position they wanted, they would twist the cover to lock it into place. The concept was developed to have the clip and groove measurements match up to have a working model. With this design, the wires coming from the sensor were clustered underneath the rubber part of the cover. Those wires needed to have an exit point cut into the housing unit so they would not be bunched up and lower the chance of wires breaking.

4.5.6 Sensor Connections to the AFE4404EVM

Another concern for the sensor were the soldered connections on the protoboard. The back of the sensor has wires soldered to the LEDs and the PDs; if those connections are broken, no data can be sent to the AFE4404EVM. Our solution to this was adding padding, a circular piece of cardboard, between the sensor and the force transducer (Fig. 4.13). Proving to be effective in protecting the soldered points of the sensor, the next challenge was the wire connections to the AFE4404EVM. To keep a secure connection, the team wrapped each point with electrical tape. This was to ensure a secure connection between the wires and the EVM.
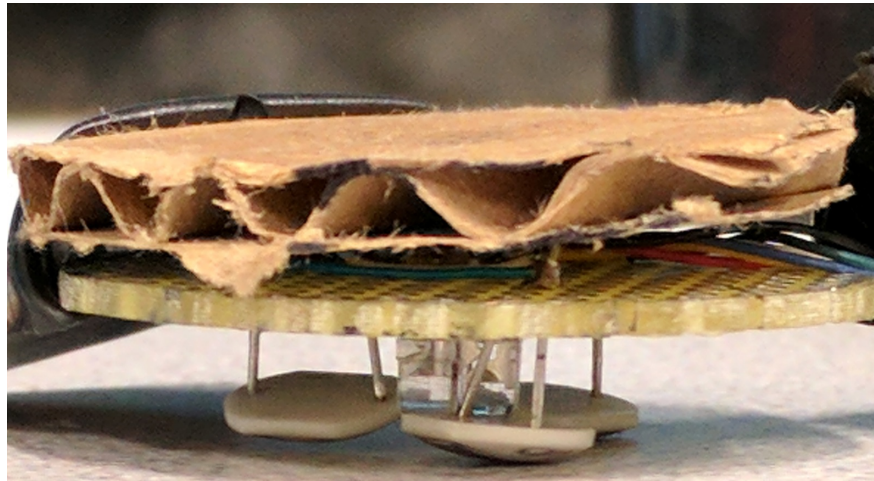
Figure 4.13: Prototype Sensor with Cardboard Padding

4.6 Final Design Selection

After drafting rough ideas for the designs, the team created a comparison chart to determine if the devices met quantifiable criteria. The criteria have to be quantifiable either by experiments or inspection of the device. For example, instead of using the blanket term safety, the device had to have rounded edges and no exposed wires.

Table 9: Weighted Objective Table

x = 1 point	Adjustable Pressure	No Exposed Wires	Rounded Edges	Hypoallergenic Adhesive	Biocompatibility	Sterilization	Total
6-LED PPG Sensor		X			X		2
Reflectance Sensor w/ Holder & Adehsive	X		X	X	X	X	5
Reflectance Sensor w/ Adhesive Only				X	X		2

The attributes we believe are important to our final design was the pressure reproducibility, not having exposed wires, rounded edges, hypoallergenic adhesive, biocompatibility, and sterilization. The pressure reproducibility was tested in C and D term to verify that the design was able to apply the ideal pressure to obtain PPG waveforms. The sensor had wires that connect to the TI AFE4404EVM; they were soldered and the joints were covered in electrical tape and did not effect the user. The edges of any of the components in this design should be rounded to avoid harming the user. The adhesives used to secure the design should be hypoallergenic and tested for use on the skin. The materials used in the design should be safe for use on humans and for use on the epidermis. The last attribute was sterilization; this was done by using alcohol wipes to clean the area of application. Based on the chart, the team concluded that the best device to use would be a holder and adhesive combination. The two designs that the team pursued were the designs discussed in section 1.4.3: Prototype Design.

These housing units had the sensor shown in Figure 4.13 placed inside with the soldered side of the protoboard facing up. The team planned on putting a thin window layer between the optical module and the users skin. This thin window layer would slightly disrupt the light coming back to the photodiodes but would keep electrical components away from the user. For testing purposes, the force transducer was placed inside the holder on the bottom of the cover. The force transducer could potentially be kept in the design to let the user know what force is being applied. Before determining if and how these additional designs could be implemented, the team needed to see if the holder designs produced reliable data

during experiments.

4.6.1 Device Holder Adhesive

The sensor holder needs to be adhered to the user's sternum with medical grade tape. The designs that were pursued for prototyping require a double stick tape to adhere the device to the skin. From previous research our group obtained a sample of Polyken 3577C double-coated foam tape from Berry Plastics. The adhesive meets ISO 10993 standards and is considered a non-irritating tape. This was the tape that was used to implement all of the prototypes.

4.6.2 Hook and Latch Holder

The hook and latch design was printed by the Rapid Prototyping Lab at WPI. The material used for the cover was Tango Black and the material used for the four latches was Vero White ABS plastic. The shape of the cover was a square and the reflectance sensor fit inside the cover contacting the inner edges. The cover had four hooks extending from each side that fit into the Vero White latches (Fig.4.14). The latches were adhered to the medical tape that was on the user's chest.
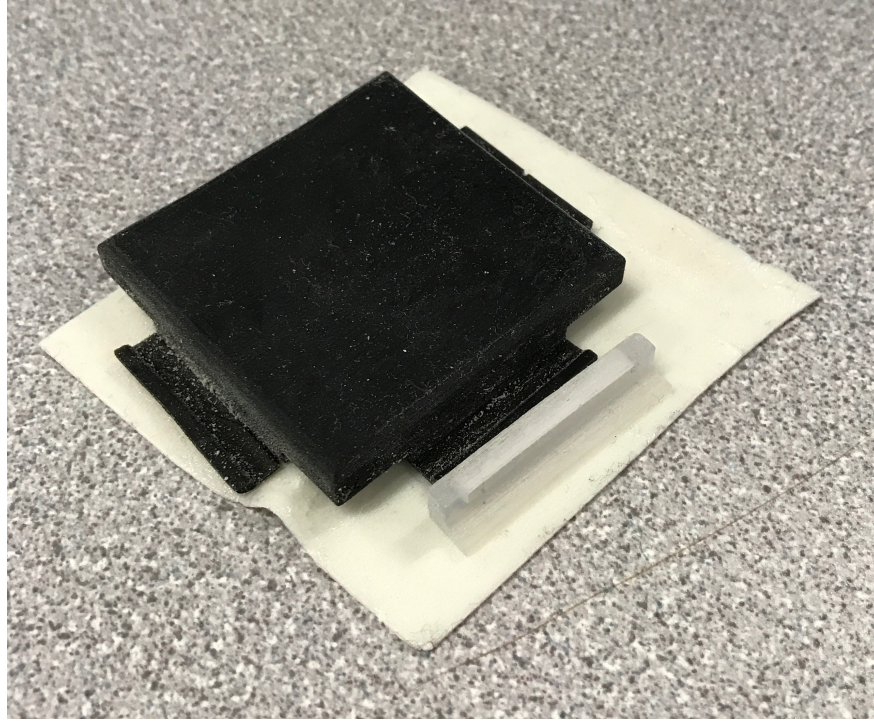
Figure 4.14: Prototype of Hook and Latch Holder

The cover material was very elastic and did not apply enough pressure to the sensor and the hooks did not lock into the latches securely. The sensor fit into the cover with the optical module extending out from the cover through the opening on the adhesive to make contact with the skin. The cover fell apart and tore after being worn for experiments to obtain data from the reflectance sensor. The edges of the cover were tearing from the force put on them from the plastic latches. This design was not robust enough for the application of putting a reflectance sensor on the chest.

4.6.3 Spin-to-Lock Holder

The spin-to-lock holder was 3-D printed with black ABS plastic. The holder was hollow in the center with a thread at the top, and the cover was also circular with two tabs on the bottom that could be fed into the threaded holder. The cover also had a smaller circular extrusion in its center to allow the user to turn the cover into the thread. The tape is cut

into a ring that fits on the bottom of the holder. The reflectance sensor sits inside of the holder, with the wires coming out of the top.

4.6.4 Prototype 1

This design was more robust than the hook and latch and did not show any wear after a round of testing with the reflectance sensor in the holder. The holder had a height of 1.5 inches and created a torque pulling the adhesive tape away from the sternum. The inner dimensions of the holder and cover were the same so the outside of the cover had to be sanded in order to fit in the cuff. After sanding the cover, it fit inside the holder but was difficult to turn into the thread. Having the wires underneath the holder made it difficult to have full contact between the skin and the tape. The modifications after initial testing were to shorten the holder, add a lip at the bottom of the cuff for medical tape, decrease the diameter of the cover for a better fit in the holder thread, and design the adjustment knob to be more ergonomic.

Figure 4.15: First Prototype of Spin-to-Lock holder

4.6.5 Prototype 2

After modifications, the holder was decreased to a third of its original height and the cover was able to move freely within the thread. The cover was easier to turn after creating a figure eight shaped adjustment knob. When testing the spin-to-lock there was room for the wires of the reflectance sensor and the force transducer to be fed out the top of the holder. When adjusting the cover into the holder there was not a lot of room because the thread was short and did not extend from the top of the holder to the bottom. The tabs on the cover also started to show signs of wear after adjusting the sensor and applying some pressure to the chest. After testing the holder with the force transducer on the bottom of the cover, it became apparent that the cover would rock back and forth on the force transducer.

Figure 4.16: Second Prototype of Spin-to-Lock Holder

4.6.6 Final Prototype: Spin-to-Lock

For our most updated iteration of the spin-to-lock holder, there were modifications made to the cover and the holder. The height of the holder was 1.25 inches to allow more room for adjustment and a longer thread. The cover was modified to have three access points for screws that fit into the thread of the holder. The screws were drilled into the cover and fit into the thread allowing the cover to apply constant pressure to the sensor. This spin-to-lock design was the most successful in applying a constant pressure at each adjustment of the cover.

A piece of cardboard was cut into a circle to fit over the soldered side of the sensor creating a flat surface for the force transducer to be in contact with. The holder remains adhered to the chest with medical tape when the cover is being adjusted. However, the tape was cut into smaller pieces and was laid over the top surface of the holder lip instead of the bottom. This was done because with the tape adhered to the bottom of the lip the holder was not able to withstand the pressure from the sensor pushing on the skin, resulting in the holder coming away from the skin.

Figure 4.17: Final Prototype of Spin-to-Lock Holder

Figure 4.18: SolidWorks Sketch of Final Spin-to-Lock Cover

Figure 4.19: SolidWorks Sketch of Final Spin-to-Lock Holder

SECTION A-A
SCALE 1 :2

Spin-To-Lock
Holder, v3

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SECTION A-A
SCALE 1 :2

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3

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10

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2

R0.50

84.50°

5

5

5

UNLESS OTHERWISE SPECIFIED:

DIMENSIONS ARE IN MILLIMETERS
TOLERANCES:
ANGULAR: 1°
ONE PLACE DECIMAL ± .1
TWO PLACE DECIMAL ± .01
THREE PLACE DECIMAL ± .005

INTERPRET GEOMETRIC
TOLERANCING PER: ASME Y14.5

MATERIAL

FINISH

NAME | DATE
DRAWN | CEF | 11-18-2015
CHECKED
ENG APPR.
MFG APPR.
Q.A.
COMMENTS:

TITLE:

Spin-To-Lock
Holder, v3

SIZE | DWG. NO. | REV
A | s2l_holder_v3 | A

SCALE: 1:1 | WEIGHT: | SHEET 1 OF 1

NEXT ASSY | USED ON

APPLICATION

DO NOT SCALE DRAWING

The advantages and disadvantages between all of the holder prototypes produced is summarized in Table 10. Our final prototype's main disadvantage is that the tape to apply the holder to the chest sticks to the plastic very well and makes it hard to remove. The stickiness of the tape can cause problems when trying to move it from the lab bench to the holder and in the process the tape gets stretched and loses some stick.

Table 10: Holder Advantages and Disadvantages

	Hook and Latch	Spint-to-Lock 1	Spint-to-Lock 2	Final Spin-to-Lock
Advantages	lightweight small	robust adjustable pressure	space for wire	applies constant adjustable pressure
Disadvantages	cannot adjust pressure on sensor	cuff too heavy cover too wide	weak tabs	tape is not easy to apply or remove

4.7 Economics

As of right now, the final design needs more testing before going to market. The holder and sensor would need to meet different standards before being marketable: Premarket submissions 510(k) for pulse oximeters [6] and ISO 10993 for biocompatibility [19]. Once those standards are met, the device has the potential of being available on the market. The team sees the device as being used in medical situations and not as a way-of-life. Further development could lead to a more accurate and more portable device that could be worn at any time.

4.8 Environmental Impact

The plastic of the holder is not biodegradable. The tape being used is not reusable and creates waste. However, the plastic of the holder is reusable, so the only waste the product creates is through the adhesives that require replacements. The cover and holder will wear down with use, however replacements would be needed on a time scale that is significantly longer than that of the adhesive.

4.9   Societal Influence

This type of application for a pulse oximeter could be very useful in hospitals because it is measuring from the core body. On a bigger scale, this could lead to a healthier society because of devices that follow the lead of this device. A chest pulse oximeter would improve treatment options for people who need to use a pulse oximeter and have compromised peripheral blood perfusion. Putting our device on the market would give users of pulse oximeters more options when choosing a device that fits to their needs better.

4.10   Political Ramifications

This product would influence the global market for pulse oximeters by expanding the types of devices available.

4.11   Ethical Concerns

A chest pulse oximeter would improve quality of life for people that use pulse oximeters in their daily lives and those with compromised peripheral blood perfusion. This type of pulse oximeter would allow them free movement of their hands, be small enough to fit under clothes, and self-adjustable. The team did not prioritize ethical concerns because the device is noninvasive. If the device's ability to measure SpO_2 was calculated, ethical concerns would need more serious consideration. This is because tests involving SpO_2 require the volunteer's SpO_2 to change, which involves breathing deoxygenated gases or holding their breath, which require much more caution than the PR calculation tests performed by the team.

4.12   Health and Safety Issues

This project would influence the health and personal safety of people by creating a pulse oximeter that can be worn under clothes and not limit the movement of their hand. This pulse oximeter sensor could be used in a healthcare system and would need to have an alarm

system implemented. Christiana Care is a healthcare facility that needed to implement a monitoring system and improve alarm systems [22]. In the report from Christiana Care updating their alarm systems for devices such as heart monitors included turning off alarms that did not require action, improved patient safety was a result from the updated system [22]. Deploying this type of device into a healthcare setting would require setting up an alarm system to ensure patient safety. To test an alarm system for medical equipment IEC 60601-1-8:2006, a document containing system requirements and specifications created by International Electrotechnical Commission could be used [23].

4.13   Manufacturability

The design of the Spin-to-Lock holder could be easily reproduced and manufactured using the SolidWorks files. The reflectance sensor would also be easy to reproduce and the parts are relatively inexpensive. In addition, the optical module and force transducer could be printed as a printed circuit board, further reducing the cost and increasing the manufacturability.

4.14   Sustainability

The design could be produced in a facility powered by renewable energy sources but currently the materials, ABS plastic, used in the design are not renewable and would take a long time to decompose if not disposed properly. The plastic used for the holder could be recycled by being melted back down, the tape would be thrown away after use.

5 Design Verification

5.1 Initial Testing

Before testing on volunteers, the team performed various tests on themselves to ensure that the devices and tests would be functional when used with volunteers. Using the final prototype design, a force transducer was connected to the bottom of the cover to push down on the sensor when the cover was turned (Fig. 5.1). This setup was used for future testing. For signal acquisition, reference heart rates were recorded using an EKG sensor, pulse rate was measured using the TI EVM, and the force transducer was connected to a National Instruments ELVIS II board where the output voltage was recorded and used to calculate contact pressure (Fig. 5.2)
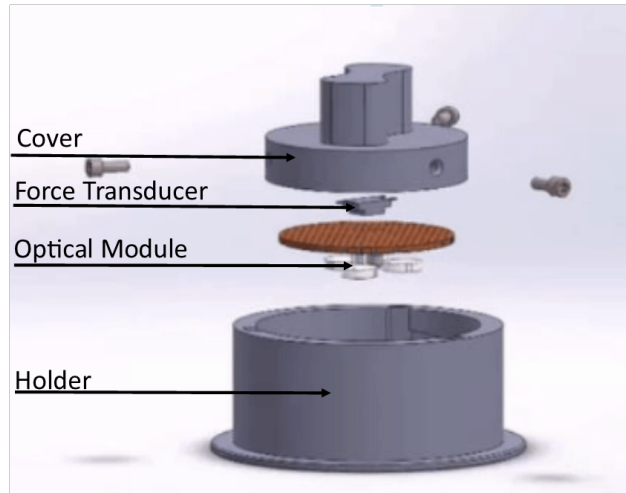
Figure 5.1: Layout of Holder used for Testing
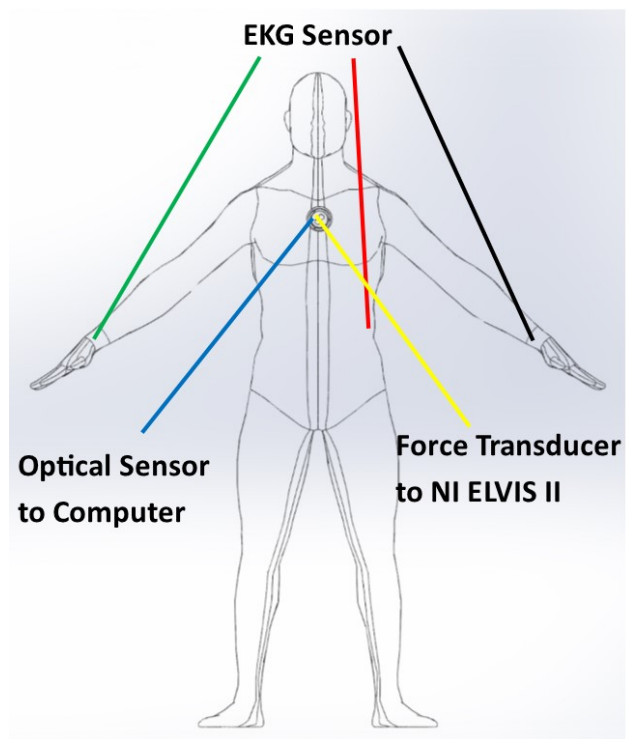
Figure 5.2: Layout of signal acquisition

5.1.1 Pulse Rate Testing

To test the pulse rate, the team attached the sensor to the sternum and then the thumb while heart rate (HR) measurements were taken with the Vernier EKG sensor. The EKG was setup using the LoggerPro software and connecting electrodes to the user's left and right wrists, as well as the left side of the user's chest. Using the reflectance sensor's green LED data captured by the photodiode, the PR from the sensor was calculated using a peak detection algorithm in MATLAB. The HR from the EKG signal was calculated using MATLAB by calculating the R-R intervals. The results from this can be seen in Figs. 5.3 and 5.4.
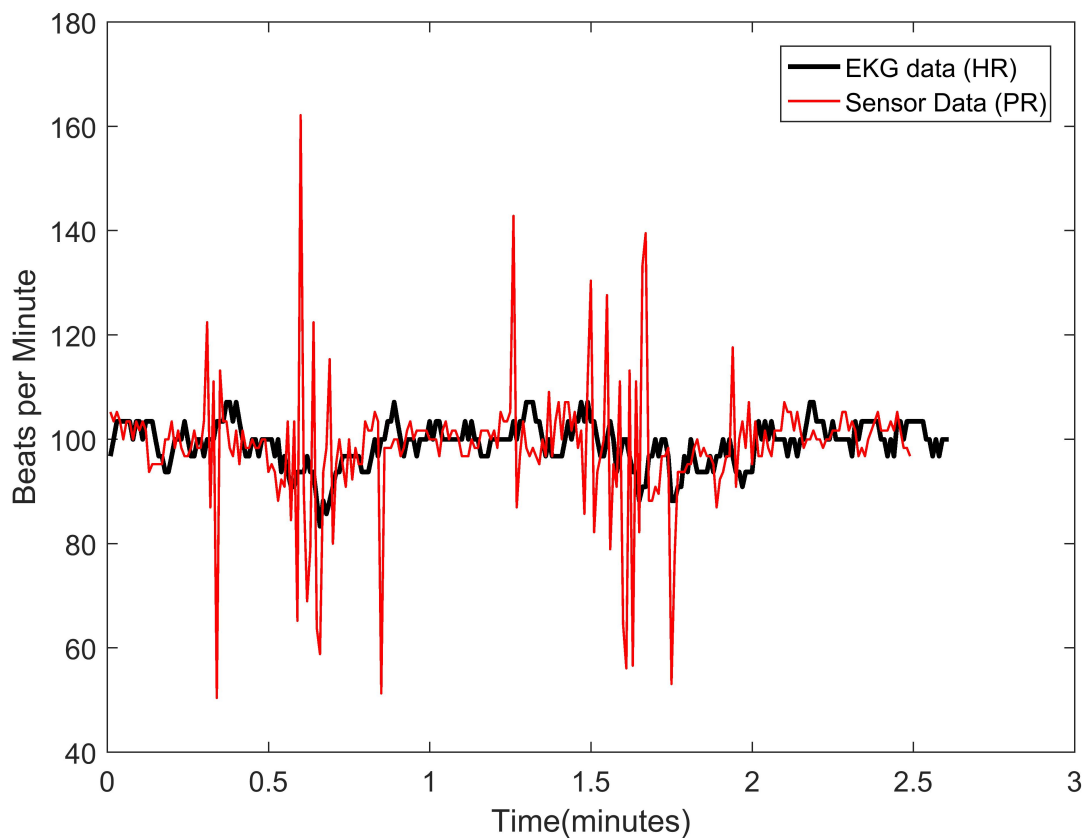
Figure 5.3: BPM over Time from Sensor and EKG-Chest

Fig. 5.3 shows the sensor PR from the chest over the EKG data. Overall, the graph

shows several areas where the PR signal from the sensor lined up with the EKG HR signal. However, there are several unwanted peaks within the data. This was either from movement or general noise due to random electron movement from the sensor. After looking at the chest, the team decided to take readings from the thumb, shown in Fig. 5.4.
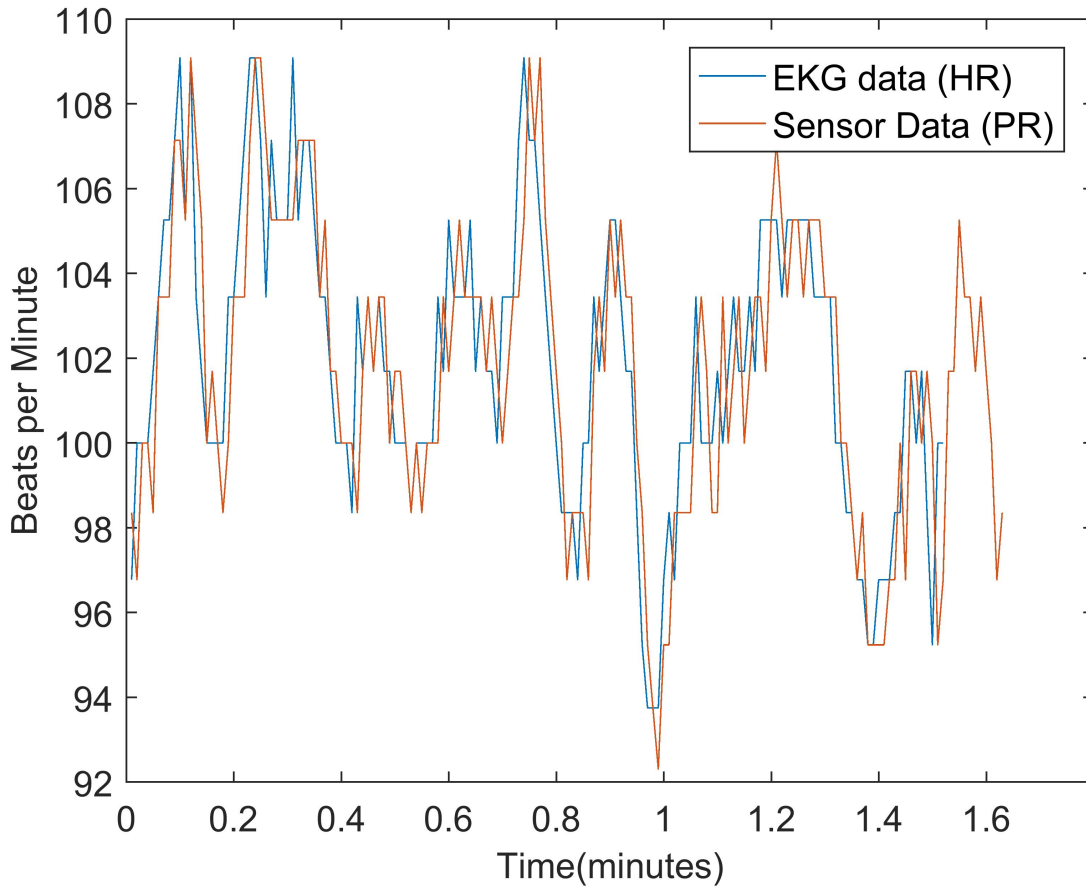
Figure 5.4: BPM over Time from Sensor and EKG-Finger

Fig. 5.4 shows the sensor PR from the thumb over the EKG HR data. Again, the sensor's PR data for the thumb lags behind the HR data from the EKG, because of the propagation of blood pressure from the heart to thumb capillaries. Looking at this figure, the sensor PR and the EKG HR are almost equivalent. They followed the same trend and had no large spikes in amplitude like the recordings from the chest showed.

Looking at both figures, the data showed that the sensor was still having problems while

placed on the chest. This could most likely be from how the holder was keeping the sensor in place. If the sensor was moving around in the holder, then it would cause fluctuations in the signal. Even with the noise showing on the chest BPM, the data showed that it was accurate but not very precise. Therefore, the setup of the sensor needed to be improved.

5.1.2 Force Transducer Testing

Two tests were conducted using the force transducer:

1. Amount of force in relation to turn angle of the cover

2. Amount of force in relation to amplitude of the signals.

The first test that was conducted using the force transducer with the holder was a calibration test. For this test, the holder was taped to the lab bench and a cardboard cutout was placed on top of the sensor. A cutout of a unit circle was placed around the holder on the table and was used to measure the turn angle (Fig. 5.5). Every 30 seconds, the cover was turned 15° to apply force to the cardboard cutout. The team did not see any constant output voltage until a 45 degree turn was applied. The initial output is in voltage but equations 3 and 4 converts it to N/mm² and mmHg.
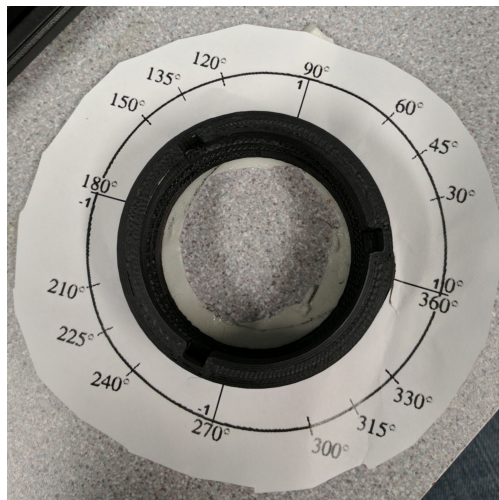
Figure 5.5: Setup for Force versus Turn Angle Test

The team found a comparatively large increase in pressure from the second test while increasing the turn angle than was seen in the other tests (Fig. 5.6). The team concluded that this would skew results and decided to remove the increasing second test from analysis. Tests one and three did not produce any results due to malfunctions with the force transducer. The new data is shown in Fig. 5.7 while the mean and standard deviation for all the data combined is shown in figures 5.8 and 5.9. In figures 5.6 and 5.7, every 30 seconds is sectioned off using vertical lines.
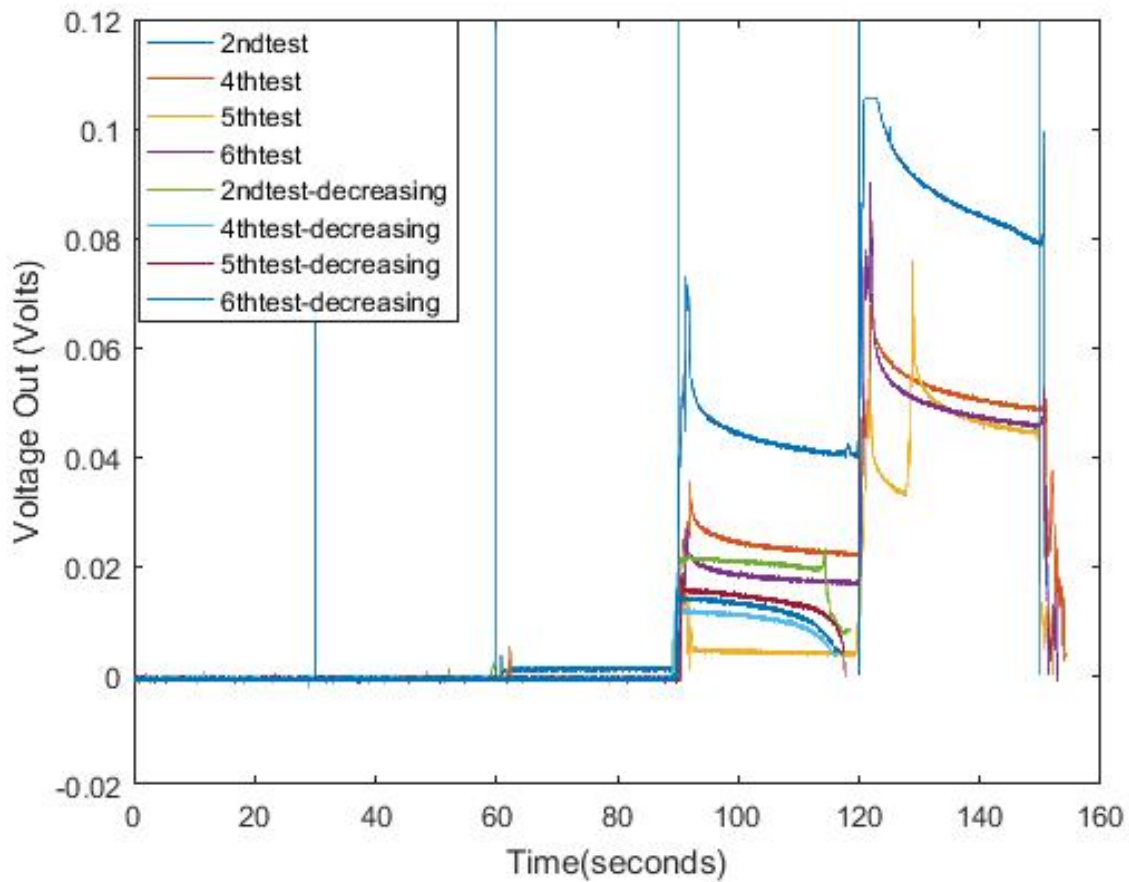
Figure 5.6: Output Voltage over time based on turn angle with spike

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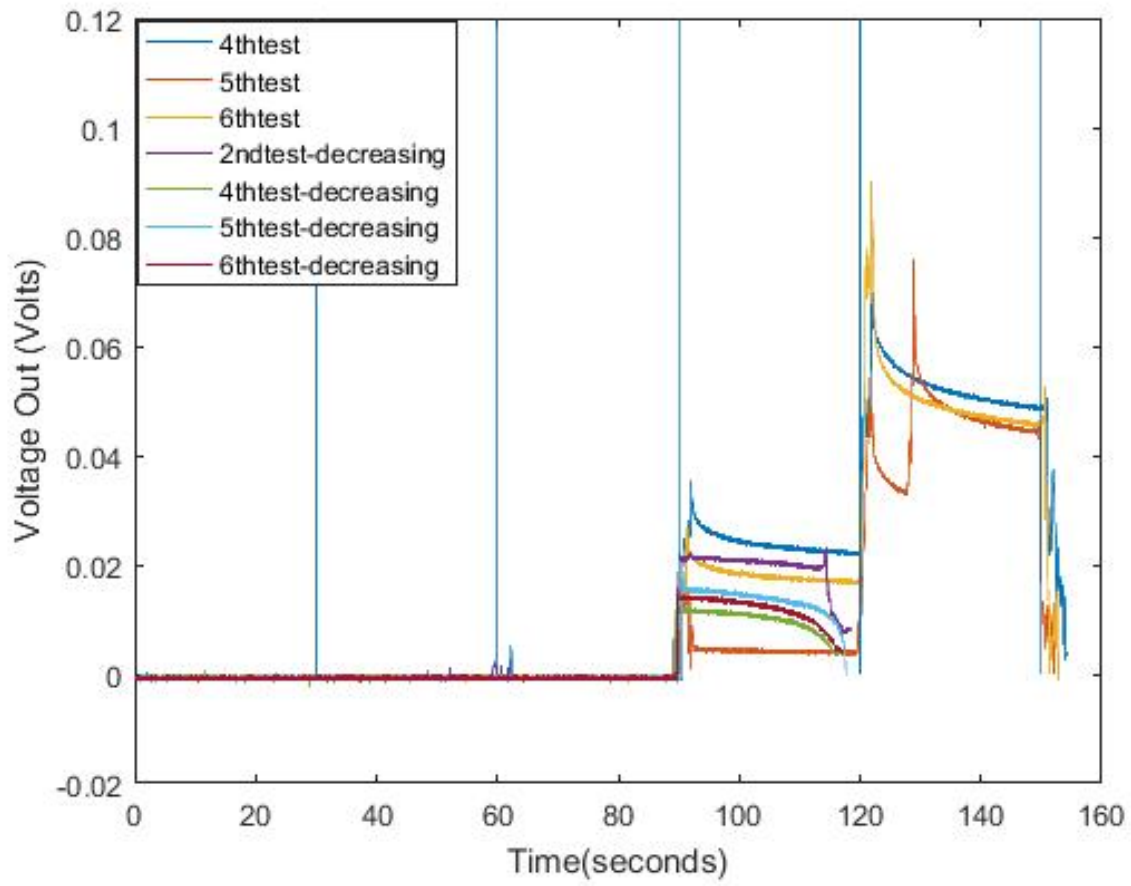
Figure 5.7: Output Voltage over time based on turn angle without spike
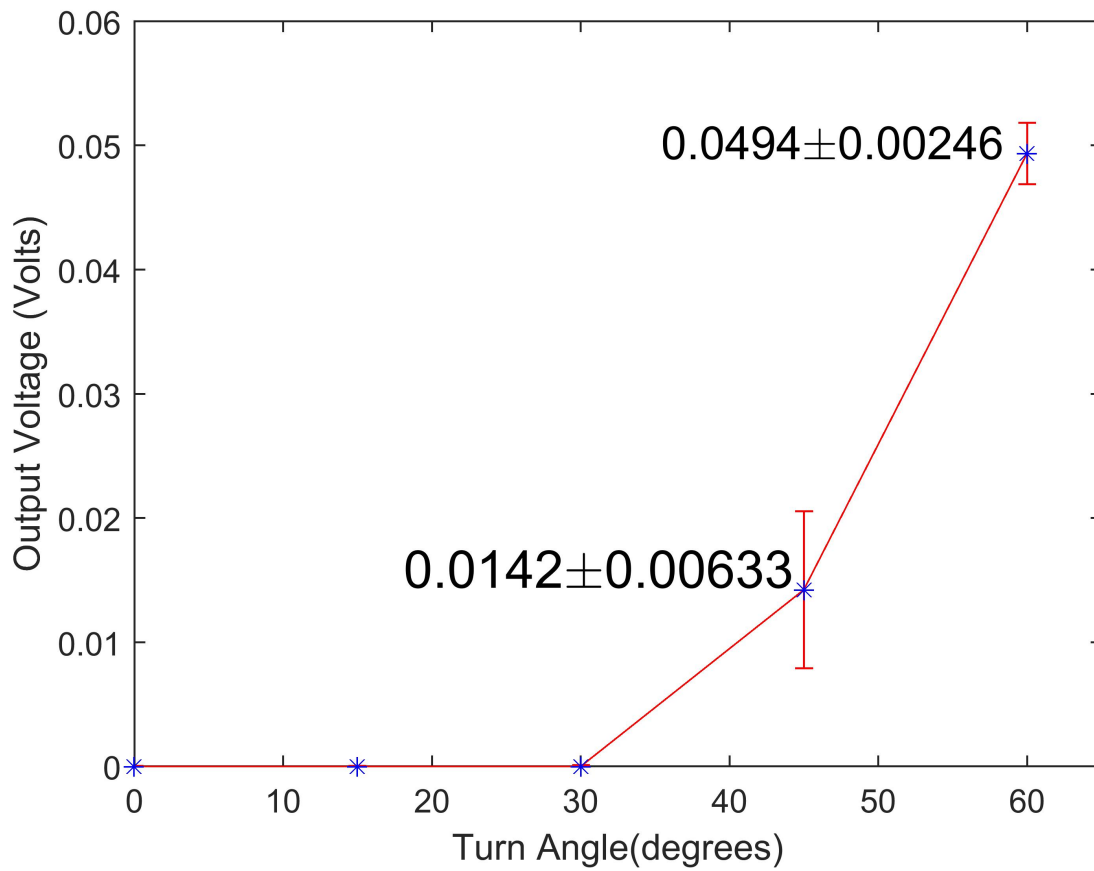
Figure 5.8: Output Voltage Mean and Standard Deviation for all Tests
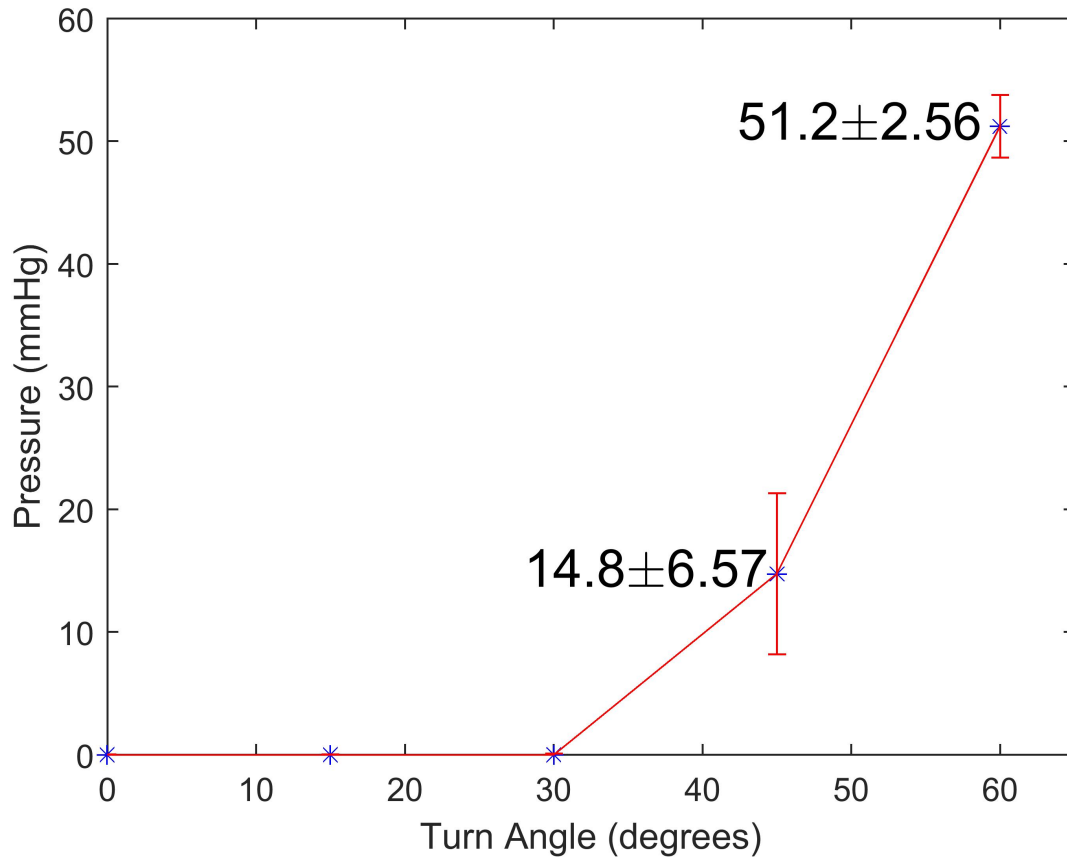
Figure 5.9: mmHg Mean and Standard Deviation for all Calibration Tests

Table 11 shows the mean and standard deviation of output voltage, force, and pressure for each turn angle measured. The force transducer output was converted from Volts to mmHg using Eq. 3 and Eq. 4 in Section 3.2.2.

Table 11: Total Averages for Turn Angle Outputs

Turn Angle	Avg. Voltage Output (V)	Avg. Force (N)	Avg. Pressure (mmHg)
0	0 ± 2.16e-5	0 ± 6.55e-4	0 ± 22.4e-3
15	0 ± 2.55e-5	0 ± 7.72e-4	0 ± 26.4e-3
30	0 ± 1.08e-4	0 ± 3.3e-3	0 ± 0.112
45	0.0142 ± 6.3e-3	0.43 ± 0.191	14.76 ± 6.57
60	0.0494 ± 2.5e-3	1.50 ± 74.6e-3	51.22 ± 2.56

The second test was measuring how an increase in force affects the PPG amplitudes (Fig. 5.10). The holder was placed on the chest two inches below the top of the sternum. At 10 second intervals, the cover was turned to increase the force being applied to the sensor. The graph shows that at about 45 mmHg, the PPG amplitudes begin to decrease.
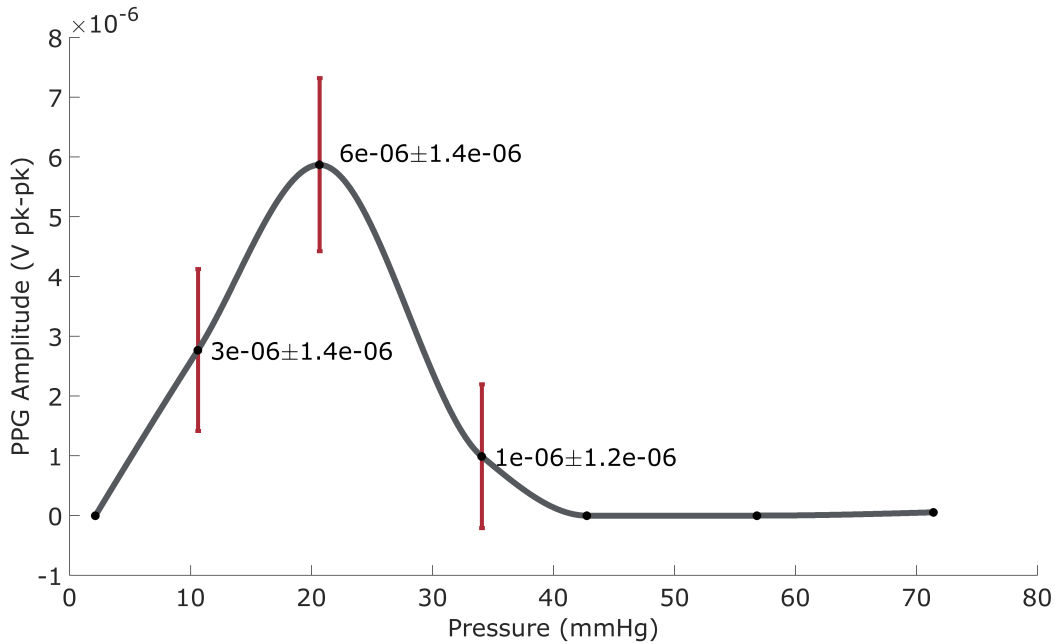
Figure 5.10: Graph of pressure vs. amplitude on one person

6 Design Validation

6.1 Volunteer Testing

Volunteer data was collected to confirm the following objectives and acquire the following data:

- That the holder would remain adhered to the user's chest for one hour

- That the cover would continuously apply the indicated pressure

- That the indicated pressure for each volunteer was enough to get PR values

- How well the cover would keep pressure during movement

6.1.1 Pressure Reproducibility Test

For this test, the team tested to confirm that a pressure of 20-50mmHg could be applied to the user for a minute. From previous experiments on ourselves, the team chose a range of 30-50mmHg because this range resulted in the strongest amplitude. Using this information for testing on volunteers, the cover was turned until the voltage output of the force transducer displayed on the Datalogger was within the range found by the group. This was performed 15 times with one minute of rest in between each recording. Our IRB approved test protocol can be found in appendix A.1.

In MATLAB, the data from each volunteer was loaded and then sectioned off into their individual tests based on the times that were recorded when force was applied to the sensor. After being sectioned off, peaks were found for each test using ampd.m found in appendix B.5. Mean and standard deviation were taken for each vector of peaks. Using the same sectioned time, the force transducer output was averaged and then converted to mmHg using 3 and 4. Fig 6.1.1 shows the PPG amplitude and the pressure for each test. More figures can be found in appendix D.1 and if there are tests missing, it means that the sensor

malfunctioned and the EVM got an error or the force transducer malfunctioned and were
no longer getting any reliable data.
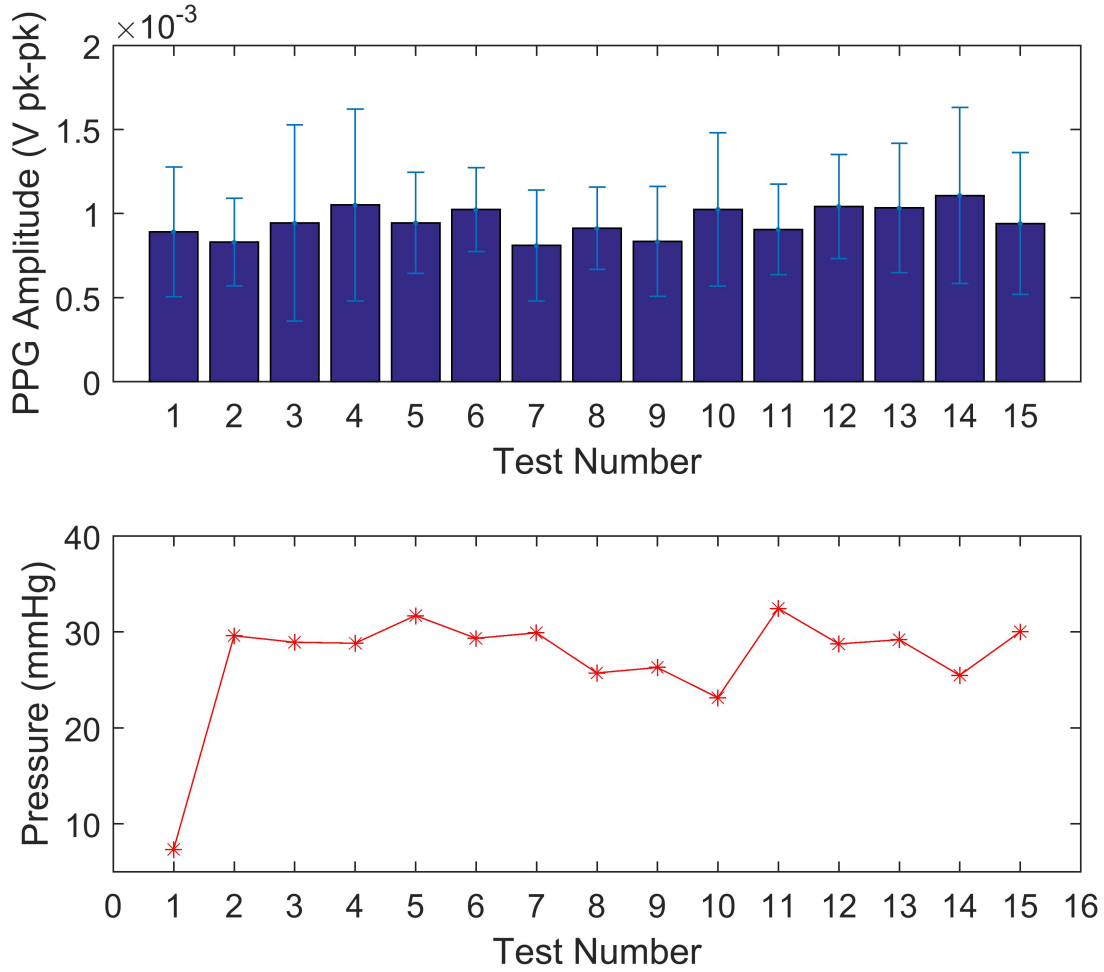
Figure 6.1: Pressure Reproducibility Results for Volunteer 2

Table 12 below shows the values that were calculated for Fig 6.1.1.

Table 12: Volunteer 2 Pressure Reproducibility Results

Test	PPG Amplitude (V pk-pk)	Pressure (mmHg)
1	8.92e-04± 3.86e-04	7.36
2	8.30e-04± 2.61e-04	29.62
3	9.44e-04± 5.84e-04	28.94
4	.0011± 5.71e-04	28.84
5	9.47e-04± 3.02e-04	31.72
6	.001± 2.50e-04	29.36
7	8.10e-04± 3.30e-04	29.93
8	9.12e-04± 2.45e-04	25.75
9	8.17e-04± 3.34e-04	26.31
10	.001± 4.56e-04	23.17
11	9.06e-04± 2.69e-04	32.46
12	.001± 3.10e-04	28.78
13	.001± 3.85e-04	29.21
14	.0011± 5.24e-04	25.50
15	9.41e-04± 4.23e-04	30.21

6.1.2 Timed Trials Experiment

For the timed trials test, the volunteers were tasked with assuming supine, standing, and sitting positions throughout testing to show the variability of PR for each position. The volunteers were then asked to move through each position while recording to measure how user movement affected the PPG signal. The volunteer had the holder adhered to their chest and the cover was turned to the voltage output range specified for the force transducer based on the test in section 5.1.3 (Fig. 5.10). The IRB approved test protocol can be found in appendix A.2.

These data were then imported into MATLAB. Motion artifacts were removed manually based on visual inspection. Then, the data was filtered using two band-pass infinite impulse response Butterworth filters: one for each signal. The PPG signal was filtered using a pass band between 0.66 and 10 Hz, while the EKG signal was filtered using a pass band between 0.66 and 50 Hz. An automatic peak detection (AMPD) algorithm was run, followed by an algorithm that calculated the heart and pulse rates based on the separation in time of peaks. The heart rate calculation algorithm used a running window average of three seconds to calculate heart rate. The algorithm splined, then smoothed the calculated values such that the output more closely matched the gradual change of heart rate. Both of these algorithms can be found in Appendix B. Finally, statistical analysis was run: this resulted in a figure comparing HR and PR over time (e.g. Fig. 6.2, as well as a Bland-Altman plot comparing the two sources (e.g. Fig. 6.3).

The results for this test came in two forms: a waveform of pulse rate and heart rate over time, and a Bland-Altman plot. These are shown in Figs. 6.2 and 6.3, respectively. Volunteer 7 was chosen to demonstrate for their typicality. That is, their data was the median of all data collected, which is summarized in Table 13. Volunteer T was Tori Claverie, volunteer N was Nicholas McNary. Positions labeled all was for the recordings of volunteer during changes in positions, SIT was for sitting datasets, STA was for standing datasets, and SUP was for supine datasets.
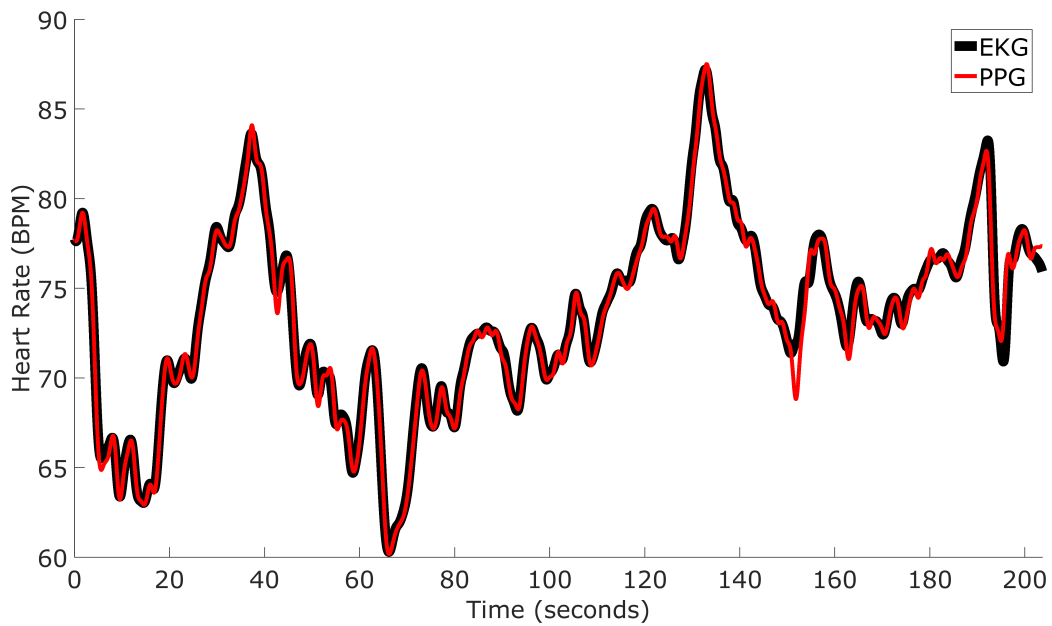
Figure 6.2: Graph of pulse rate (PR, red) against heart rate (HR, black) over time for Volunteer 7 (region 1)
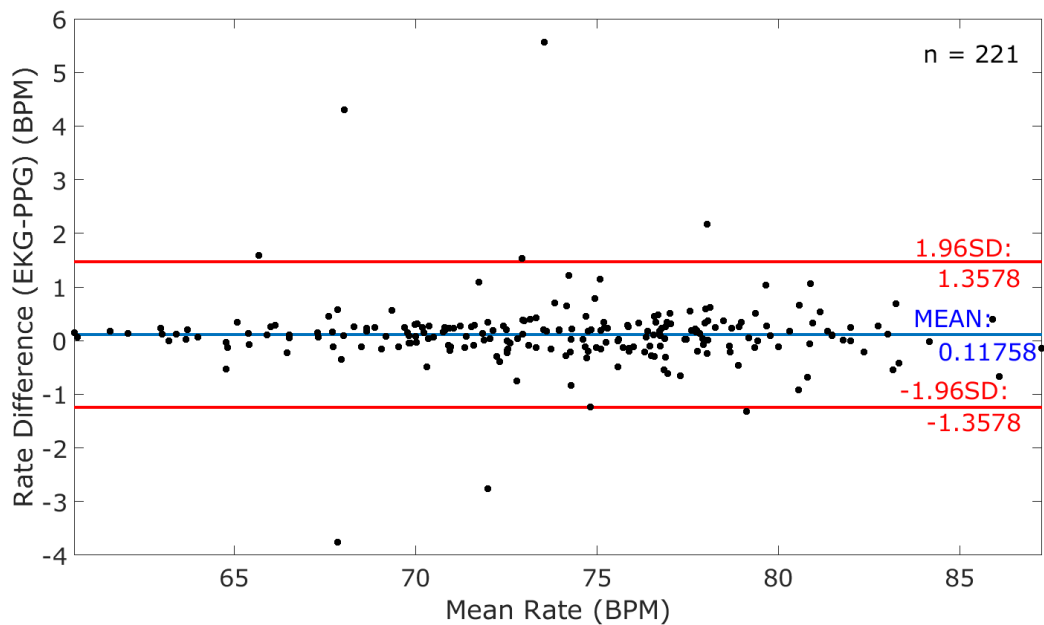
Figure 6.3: Bland-Altman plot for HR and PR data for Volunteer 7 (region 1)

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Table 13: Complete mean and standard deviation dataset for time trial.

Mean	STD	Volunteer #	Position	Test #
9.57	15.25	2	ALL	3
6.40	14.53	4	ALL	5
3.43	10.17	4	ALL	4
3.70	9.62	4	ALL	3
3.16	8.51	4	ALL	6
2.80	8.48	4	ALL	2
4.57	8.29	2	ALL	2
-0.81	4.38	2	ALL	1
0.12	0.30	4	ALL	1
123.23	24.32	7	SIT	1
119.41	20.00	7	SIT	1
89.54	41.42	7	STA	1
108.25	39.07	7	STA	2
10.55	10.79	4	SUP	2
2.79	6.97	6	SUP	2
1.88	6.95	2	SUP	2
5.31	6.23	3	SUP	1
7.97	5.57	4	SUP	1
1.09	5.46	7	SUP	1
1.11	5.03	5	SUP	1
0.075	4.55	2	SUP	1
0.65	3.18	7	SUP	2
0.47	2.51	T	SUP	2
-0.012	2.41	3	SUP	2
0.13	1.21	T	SUP	1
0.13	0.99	N	SUP	2
0.09	0.87	N	SUP	1
0.079	0.69	5	SUP	2

The sitting and standing tests were not considered, as these tests repeatedly returned erroneous results for heart rate, even when two different algorithms for peak detection (AMPD and a QRS detection algorithm) were used. Take the examples shown in Figs. D.13 and D.14 (Appendix B), which show Bland-Altman plots for volunteers in the sitting and standing positions, respectively. The means are upwards of 120 BPM and the standard deviations are up to 60 BPM. This was because the EKG of the volunteer was erroneously reported at much

higher than the PPG, as shown in Fig. D.12. The team, due to the volume of volunteers, used low-quality EKG pads that shifted and began to fall off when the volunteers switched positions.

6.2   Objectives

For validation of our holder design, we looked at how our holder and sensor performed based on the objectives from our revised client statement. Our original goal was to maintain a pressure between 60-90 mmHg, have the holder adhered for 24 hours, and obtain accurate PPG signals from the reflectance sensor.

From our PPG Amplitude vs. Pressure tests the results showed that a pressure range from 10-30 mmHg was needed to obtain the best PPG amplitudes. Next we tested our holder prototype and found that it was capable of applying pressure between 0-50 mmHg, encompassing the pressures needed to produce clear PPG signal amplitudes. Although it is not the pressure range of 60-90 mmHg we defined from the literature review, we found through testing that this pressure range was redefined for the location of the chest pulse oximeter.

Next, we wanted the holder to remain adhered to the user's skin for at least 24 hours. We were not able to test this length of time on volunteers; our IRB approved tests for volunteers lasted for a maximum of two hours. The holder was able to stay adhered throughout the two hours of testing but was not tested for periods longer than this.

Finally, we wanted to get accurate PPG measurements. We were able to obtain accurate PR results, but unfortunately, did not have enough time to show that our sensor can also measure accurate SpO_2. Our results as indicated in Chapter 5 were best for volunteers in the supine position. The typical PR measurement for supine position had an error of ±1.36 BPM which is within typical pulse oximeters on the market that read PR within ±3 BPM.

7   Discussion

Our reflectance sensor holder prototype was constructed to apply pressure to the optical module and mount it on the chest. The 3D printed holder is able to apply a pressure range of 0-51mmHg on the sensor. With adhesive tape the prototype was mounted to the chest. The length of time the tape stayed adhered was not tested as the interest of the project was to obtain clean PPG signals and find an ideal pressure range. The team calibrated the force at each turn angle and found that once the cover was turned clockwise 60 degrees past starting, the maximum pressure threshold of 50mmHg was reached.

The results from the calibration curve (Fig.5.9) and the PPG amplitudes vs. pressure (Fig.5.10) prove that our holder was able to apply the maximum pressure needed to obtain better PPG amplitudes. The maximum pressure the cover could apply on the lab bench was 50mmHg, and the pressure threshold for strong PPG amplitudes was 40mmHg. Our holder was capable of applying the right range of pressures to the sensor in order to obtain strong PPG amplitudes. The increased pressure is related to the increased PPG amplitudes because the sensor is becoming closer to the vessels as it is getting pressed into the skin. When the pressure exceeds 50mmHg the vessels begin to get crushed and this is why the PPG signal amplitudes become very small and the signal becomes very weak.

The limitations of our tests were the small volunteer pool, and only having PR data. There were a total of seven volunteers for testing plus two of the group members for a total of nine subjects. Though having the volunteers made our statistics more robust, the results would be improved if the number of subjects was increased to at least fifteen. Also, the EKG data from subjects that were standing or sitting at the time of recording were improperly acquired, and the data was not considered for further analysis.

8 Conclusions and Recommendations

The holder design of this project was successful in applying the ideal pressure range to the sensor needed to produce PPG signals with larger amplitudes than the PPG signals with no pressure on the sensor.

Our team designed two experiments that were approved by the WPI IRB, if our team were to continue testing this prototype we would create tests to monitor the longevity of the sensor as well as the tape. The next step would be to design a test that would result in a larger range for HR such as increasing the heart rate from exercise or having the subject hyperventilate, this would also create a test for the range of SpO_2.

An improvement to the holder design would be to decrease the size. With a decreased size the holder would fit under clothing and could be concealed while monitoring SpO_2 and PR. The holder would also have an access port on its side for the wires that connect the sensor to the EVM to be feed through. This would alleviate the problem of the sensor wires having to be fed through the bottom of the holder. Adding a pressure sensor to the cover that alerts the user it is in the range of 20-45mmHg with a green LED would make it self-adjustable. The current adhesion method of the holder is a double stick foam tape that is cut to fit along the edge of the holder. This method is wasteful and double stick tape no longer seems necessary, a one-sided foam tape would be sufficient or tape that could be printed in a ring to fit the holder shape.

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Appendix A   IRB Tests

A.1   Pressure Reproducibility Test

The objective of this test is to test whether or not our sensor holder can apply the right amount of pressure on the skin to obtain reliable PR and SpO2 data from a custom reflectance sensor holder. This test will measure the pressure being applied to the sensor by the cover of the holder. The cover is supposed to apply a force of 6.9 Newton (about 1.5 lbs). This force was calculated from previous tests the team ran on the force transducer [1]. The following procedure will be followed:

1. Each volunteer will be presented with our informed consent before they decide to participate.

2. Each volunteer will be asked to sign the consent form.

3. The investigator will secure the Honeywell FSS005WNGB force transducer on top of custom sensor inside the holder. The force transducer and the Texas Instruments AFE4404EVM GUI will be connected to the National Instruments Data Acquisition board (DAQ). The pressure data will be collected from the DAQ.

4. The investigator will attach a reference pulse oximeter to the subject's left pointer finger.

5. The volunteer will be asked to wipe their sternum area with an alcohol wipe to sanitize the area.

6. The reflectance sensor holder will be taped on the volunteer's sternum two inches below their clavicle. The cover will be placed on the holder. If the volunteer has chest hair, we will ask the volunteer to shave a 2-inch area on the center of the chest. The volunteer will be shown where the device will be placed and what area to shave. The volunteer will be provided a disposable razor to shave the area.

7. Once the sensor cover is attached, the time will be recorded.

8. The volunteer will be asked to sit and remain still for one minute while recording.

9. After one minute of recording, the cover of the device will be removed from the volunteer's chest.

10. The volunteer will have one minute to rest.

11. This procedure will be repeated for a total of 15 times.

12. At the end of 15 tests, the tape will be removed. The volunteer will be advised to monitor the skin that was in contact with the adhesive during the experiment. If any irritation persists, they should use their own discretion whether to seek medical attention.

A.2   Timed Trials Experiments

The purpose of these experiments is to determine if reliable data can be gathered for a certain period of time as outlined below.

1. Each volunteer will be presented with our informed consent before they decide to participate.

2. Each volunteer will be asked to sign the consent form.

3. Each volunteer will be asked to wipe their sternum area with an alcohol wipe to sanitize the area.

4. The volunteer will tape the sensor holder to their sternum two inches below their clavicle. The sensor cover will be placed on the holder. If the volunteer has chest hair, we will ask the volunteer to shave a 2-inch area on the center of their chest. The volunteer will be shown where the device will be placed and what area to shave. The volunteer will be provided a disposable razor to shave the area.

5. The investigator will attach a finger pulse oximeter to the volunteer's left pointer finger to acquire reference reading.

6. The data will be recorded continuously from the DAQ connected to the NI ELVIS board. PPG waveforms will be collected while the subject breathes normally.

7. The volunteer will breathe normally while going through four different tests. These tests will be conducted to determine if reliable PPG waveforms can be recorded for different body positions as follows.

   - Supine position:
     - The holder will be taped to the volunteer's upper chest and the sensor will be connected to the computer to record the signals.
     - The volunteer will also have a pulse oximeter sensor attached to their finger to obtain reference reading.
     - The volunteer will be asked to lie down on their back and remain motionless for the duration of the test.
     - The volunteer will be asked to breathe normally for 5 minutes.
     - The volunteer will have 1 minute to rest. This supine test will be repeated for a total of two times.
   - Sitting
     - The volunteer will be asked to sit up.
     - Each volunteer will be asked to breathe normally for 5 minutes. The volunteer will have 1 minute to rest. This sitting test will be repeated for a total of two times.
   - Standing
     - The volunteer will be asked to stand up.

- The volunteer will be asked to breathe normally for 5 minutes. The volunteer will have 1 minute to rest. This test will be repeated for a total of two times.

- Supine-to-Sitting-to-Standing Positions

  - For this test, the volunteer will be asked to move through each position beginning with supine, then sitting, and finally standing.

  - The volunteer will be asked to return to the supine position, lying on their back.

  - After 100 seconds in supine position the volunteer will be asked to move from lying on their back to sitting position.

  - After 100 seconds in a sitting position, the volunteer will be asked to move from their seat into a standing position.

  - The volunteer will have 1 minute to rest.

  - This test will be performed a total of two times.

8. At the end of the experiment, the tape will be removed from the subject's chest. The volunteer will be advised to watch the skin that was in contact with the adhesive during the experiment and if any irritation persists they should use their own discretion whether to seek medical attention.

Appendix B   MATLAB Code

B.1   Finger and Chest BPM

```matlab
%% new test
% close all;
%load('Instant HR from EKG')
%If data comes from Sensor:
clear all; close all; clc;
%load('ekgvsensor.mat'); %Should hold ChLED2, EKG, and Time
%ChLED2 used here
input_signal=ChLED2; %(1:12001); can be specific
fs = 100 ;
trun = 5 ;
debugFlag = 1 ;
[AC,DC] = ppg_filter_jrh(input_signal,fs,trun);
[peak,trough] = ppg_peakdet_jrh_ampd(AC,fs,debugFlag);
ans=diff(peak);
pr=ans(:,1)/fs;
pr2=[];
k=1;
while k<length(pr);
    prwant=(1/pr(k))*60;
    pr2=[pr2 prwant];
    k=k+1;
end
figure;
plot(pr2);
save('Sensordata.mat', 'pr2');
```

```matlab
% sample=1:length(AC(1200:end)); %Can put AC data through next part but
% %need to change the specifics
% Fs=100;
% Time=sample/Fs;


%%
% EKG and Time used down here
Time1=Time;%(1200:11002); can be specific
EKG1=EKG;%(1200:11002);
figure;
plot(Time1,EKG1)
i=2;
hold on;
peaks=[];
trophs=[];
ploc=[];
tloc=[];
while i<=(length(Time1)-1);
    if EKG1(i)>EKG1(i-1)
        if EKG1(i)<EKG1(i+1)
            i=i+1;
        else
            peaks=[peaks EKG1(i)];
            ploc=[ploc Time1(i)];
            plot(Time1(i),EKG1(i),'*r');
            i=i+1;
        end
    else
```

```matlab
        if EKG1(i)<EKG1(i+1)

            trophs=[trophs EKG1(i)];

            tloc=[tloc Time1(i)];

            plot(Time1(i),EKG1(i),'*g')

            i=i+1;

        else

            i=i+1;

        end

    end

end


%% Getting rid of Peaks (needs work)

k=1;

deletethese=[];

while k<=length(peaks)

    if peaks(k)<.4; %specific

        deletethese=[deletethese peaks(k)];

    end

    k=k+1;

end

peaks2=peaks;

ploc2=ploc;


for k2=1:length(peaks)

    if k2<=length(peaks);

        for d2=1:length(deletethese)

            if peaks(k2)==deletethese(d2)

                peaks(k2)=[];

                ploc(k2)=[];
```

```matlab
            end

        end

    end

end


figure;

plot(Time1, EKG1);

hold on;

plot(ploc, peaks, '*r');

plot(tloc, trophs, '*g');


%% Take R-R intervals

q=1;

distance=[];

while q<length(ploc)

    distance(q)=ploc(q+1)-ploc(q);

    q=q+1;

end

%% instaneous hr

instant=[];

p=1;

deletethese2=[];

while p<length(distance)

    instant(p)=(1/distance(p))*60;

    if instant(p)>200; %specific

        deletethese2=[deletethese2 instant(p)];

    end

    p=p+1;

end
```

```matlab
for k2=1:length(instant)
    if k2<=length(instant);
        for d2=1:length(deletethese2)
            if instant(k2)==deletethese2(d2)
                instant(k2)=[];
            end
        end
    end
end
figure;
plot(instant);
save('EKGdata.mat', 'instant');




clear all; close all; clc;
%% Overlays the Sensor PR and EKG HR
%% Sensor on Finger
load('EKGdata.mat');
load('Sensordata.mat');
plot(instant(1:163)) %specific
hold on;
plot(pr2)
legend('EKG data', 'Sensor Data');
fs=100;
fs2=100;
samples=1:length(instant);
samples2=1:length(pr2);
time=samples/fs;
```

```matlab
time2=samples2/fs2;

figure

plot((time(12:163)-.11),instant(12:163)); %Specific

hold on;

plot(time2, pr2);

legend('EKG data (HR)', 'Sensor Data (PR)');

xlabel('Time(minutes)');

ylabel('Beats per Minute')


%% Sensor on Chest

load('EKGdata.mat');

load('Sensordata.mat');

plot(instant)

hold on;

plot(pr2)

legend('EKG data', 'Sensor Data');

fs=100;

fs2=100;

samples=1:length(instant);

samples2=1:length(pr2);

time=samples/fs;

time2=samples2/fs2;

figure

plot(time,instant);

hold on;

plot(time2, pr2);

legend('EKG data (HR)', 'Sensor Data (PR)');

xlabel('Time(minutes)');

ylabel('Beats per Minute')
```

B.2   Force Transducer Calibration

```matlab
close all; clear all; clc;
load('calibrationdata.mat');


%Put first section of data into struct
realdata =
    struct('Test2',NIsecondtest,'Test4',NIfourthtest,'Test5',NIfifthtest,'Test6',NIsixthtest);
fields=fieldnames(realdata);
%flip the last section of the data and move it to line up with each section
x=flip(NIsecondtest(15200:end));
decreasingsecond=[NIsecondtest(1:5000)' x'];


q=flip(NIfifthtest(15210:end));
decreasingfifth=q(2001:end);


k=flip(NIsixthtest(15300:end));
decreasingsixth=[NIsixthtest(1:3000)' k'];


decreasingfourth=flip(NIfourthtest(15420:end));


%Put that data in its own struct
decreasingdata=struct('Test2neg',decreasingsecond,'Test4neg',decreasingfourth,'Test5neg',decrea
decreasfields=fieldnames(decreasingdata);


%Get sample nuber to time domain
samples=1:length(realdata.Test2);
```

```matlab
Fs=100;

t=samples/Fs;

t=t';

samplenumber= [15199 15419 15209 15299];

samplenumdecreasing= [length(decreasingsecond) length(decreasingfourth)
    length(decreasingfifth) length(decreasingsixth)];


%PLot all the data on one graph
for i = 1:numel(fields)
    plot(t(1:samplenumber(i)),realdata.(fields{i})(1:samplenumber(i)));
    hold on;
    plot(t(1:samplenumdecreasing(i)),decreasingdata.(decreasfields{i})(1:samplenumdecreasing(i
        '*');
end
legend('2ndtest', '4thtest', '5thtest', '6thtest',...
    '2ndtest-decreasing', '4thtest-decreasing', ...
    '5thtest-decreasing', '6thtest-decreasing');
xlabel('Time (sec)');
ylabel('Voltage Out (Volts)');


%plot the force and pressure graphs
figmmHg=figure;
figforce=figure;
for i = 1:numel(fields)
    figure(figforce)
    force1=(realdata.(fields{i})(1:samplenumber(i)))/7.2;
    force2=(decreasingdata.(decreasfields{i})(1:samplenumdecreasing(i)))/7.2;
    plot(t(1:samplenumber(i)), force1);
```

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```matlab
    hold on;

    plot(t(1:samplenumdecreasing(i)),force2, '*');

    legend('2ndtest', '4thtest', '5thtest', '6thtest',...
        '2ndtest-decreasing', '4thtest-decreasing', ...
        '5thtest-decreasing', '6thtest-decreasing');

    xlabel('Time (sec)');

    ylabel('Force (Newtons)');



    figure(figmmHg);

    mmHg1=(force1/.583)*7500.61683;

    mmHg2=(force2/.583)*7500.61683;

    plot(t(1:samplenumber(i)), mmHg1);

    hold on;

    plot(t(1:samplenumdecreasing(i)),mmHg2, '*');

    legend('2ndtest', '4thtest', '5thtest', '6thtest',...
        '2ndtest-decreasing', '4thtest-decreasing', ...
        '5thtest-decreasing', '6thtest-decreasing');

    xlabel('Time (sec)');

    ylabel('Pressure (mmHg)');

end
```

B.3   peak_trough.m

```matlab
function [pt, stdv] = peak_trough(data,zone,Fs)

% PEAK_TROUGH Find peaks and troughs of a waveform.

%% Set variables

x = (zone)./Fs; %time axis

y = data(zone); %data axis
```

```matlab
delta = (zone(end)-zone(1))/60; %set time range


%% Find peaks

[ppks, plocs] = findpeaks(y); %find peaks

[tpks, tlocs] = findpeaks(y.*-1); %find troughs

plocs = plocs./80 + x(1); %make sample-scale a time scale for peak locations

tlocs = tlocs./80 + x(1); %same but for trough locations

figure %initial plot with no peaks

    plot(x,y)

    axis ([x(1) x(end) -inf inf])

    hold on


% Thresholding

thplocs = []; % make empty thresholded arrays

thppks = [];

thtlocs = [];

thtpks = [];

thresholdp = input('Input positive threshold: ')

thresholdpmax = input('Input positive threshold maximum: ')

thresholdn = input('Input negative threshold(absolute value): ')

thresholdnmax = input('Input negative threshold max (absolute value): ')

for i = 1:length(ppks) % cut out thresholded values

    if ppks(i) >= thresholdp && ppks(i) <= thresholdpmax

        thplocs = [thplocs plocs(i)];

        thppks = [thppks ppks(i)];

    end

end

for i = 1:length(tpks)

    if tpks(i) >= thresholdn && tpks(i) <= thresholdnmax
```

```matlab
            thtlocs = [thtlocs tlocs(i)];

            thtpks = [thtpks tpks(i)];

        end

end

mtp = mean(thppks); %mean peaks and troughs

mtt = mean(thtpks);

sdtp = std(thppks); % standard deviations

sdtt = std(thtpks);


%% Display results

hr = (length(plocs)/delta)*60; %heartrate (not to be trusted)

disp('HR?: ') %display heart rate

disp(hr)

pt = mtp - mtt; %set output variable

stdv = mean([sdtp sdtt]);

    plot(thplocs,thppks,'o')

    plot(thtlocs,thtpks.*-1,'o')

    hold off

end
```

B.4 ttplots_cef.m

```matlab
function [m, s, bpf_ekg, bpf_ppg] = ttplots_cef(PPG, EKG, regions,pflag,

    bpf_ekg, bpf_ppg)

%% set up data, regions

rlength = length(regions);


if (~exist('bpf_ekg') || ~exist('bpf_ppg')) % create a band pass filter if it

    doesn't exist yet
```

```matlab
        bpf_ekg = designfilt('bandpassfir', 'StopbandFrequency1', .25,...
            'PassbandFrequency1', .4, 'PassbandFrequency2', 49,...
            'StopbandFrequency2', 50, 'StopbandAttenuation1', 60,...
            'PassbandRipple', 1, 'StopbandAttenuation2', 60, 'SampleRate', 100);
        bpf_ppg = designfilt('bandpassfir', 'StopbandFrequency1', .25,...
            'PassbandFrequency1', .66, 'PassbandFrequency2', 10,...
            'StopbandFrequency2', 12, 'StopbandAttenuation1', 60,...
            'PassbandRipple', 1, 'StopbandAttenuation2', 60, 'SampleRate', 100);
    end
    if (~exist('ppg_f') || ~exist('ekg_f')) % filter the data if it hasn't...
        % been filtered already
        ppg_f = filtfilt(bpf_ppg, PPG);
        ekg_f = filtfilt(bpf_ekg, EKG);
    end
    % buffer to make up for filter step response, buffer with moving window
    % length


    %% peak detection
    P_ppg = cell(rlength,1); % set up empty cells for peak indices for HR_Calc...
    P_ekg = cell(rlength,1); % ahead of time to improve performance (inputs)

    PPGHR = cell(rlength,1); % same for outputs
    EKGHR = cell(rlength,1);


    for idx = 1:rlength
        P = ampd(ppg_f(regions{idx}), 100, [], pflag); % calculate PPG peaks
        P_ppg{idx} = P(:,1);
        [PPGHR{idx},~,~,~] = HR_Calc(P_ppg{idx}, 100, 3, pflag); %put those in cell
```

```matlab
        P = ampd(ekg_f(regions{idx}), 100, [], pflag); % calculate EKG peaks
        P_ekg{idx} = P(:,1);
        [EKGHR{idx},~,~,~] = HR_Calc(P_ekg{idx}, 100, 3, pflag);
end


if(pflag > 0)
    figure % plot both peak detections
    plot(ppg_f, 'blue')
    hold on
    plot(ekg_f, 'red')
    plot(P_ppg{1}, ppg_f(P_ppg{1}), '*m')
    plot(P_ekg{1}, ekg_f(P_ekg{1}), '*yellow')
    hold off
    legend('PPG Signal', 'EKG Signal', 'PPG Peaks', 'EKG Peaks')
end


%% regression calculations
m = zeros(rlength,2);
x = cell(rlength,1);
y = cell(rlength,1);


for idx = 1:rlength
    if length(EKGHR{idx}) > length(PPGHR{idx}) %truncate measurements
        EKGHR{idx} = EKGHR{idx}(1:length(PPGHR{idx}));
    else
        PPGHR{idx} = PPGHR{idx}(1:length(EKGHR{idx}));
    end


    m(idx,:) = polyfit(EKGHR{idx}, PPGHR{idx}, 1); %slope, y-offset
```

```matlab
    x{idx} = linspace(40, 120, length(EKGHR{idx})); %x

    y{idx} = polyval(m(idx,:), x{idx}); %y

end


%output variables

Emean = zeros(rlength, 1);

Pmean = zeros(rlength, 1);


for idx = 1:rlength

    Emean(idx) = mean(EKGHR{idx});

    Pmean(idx) = mean(PPGHR{idx});

end

%% create plot

m = zeros(1,rlength);

s = zeros(1,rlength);


% Bland-Altman plot

for idx = 1:rlength

    figure

    differences = EKGHR{idx}(1:100:length(EKGHR{idx}))-...

        PPGHR{idx}(1:100:length(EKGHR{idx}));

    means = (EKGHR{idx}(1:100:length(EKGHR{idx}))+...

        PPGHR{idx}(1:100:length(EKGHR{idx}))))./2;

    plot(means, differences, '.');

    hold on

    mbar = mean(differences);

    stdvbar = std(differences);

    line([min(means) max(means)], [mbar mbar]);

    text(max(means)-3, mbar+0.5*stdvbar, 'MEAN:', 'Color', 'blue');
```

```matlab
    text(max(means)-3, mbar-0.5*stdvbar, num2str(mbar), 'Color', 'blue');

    line([min(means) max(means)], [mbar+1.96*stdvbar mbar+1.96*stdvbar],...
        'Color', 'red')

    text(max(means)-3, mbar+1.5*stdvbar, '1.96SD:', 'Color', 'red');

    text(max(means)-3, mbar+2.5*stdvbar, num2str(1.96*stdvbar),...
        'Color', 'red');

    line([min(means) max(means)], [mbar-1.96*stdvbar mbar-1.96*stdvbar],...
        'Color', 'red')

    text(max(means)-3, mbar-1.5*stdvbar, '-1.96SD:', 'Color', 'red');

    text(max(means)-3, mbar-2.5*stdvbar, num2str(-1.96*stdvbar),...
        'Color', 'red');

    text(min(means)+3, mbar+1.5*stdvbar,...
        ['n = ', num2str(length(differences))],'HorizontalAlignment',...
        'center')

    hold off

    axis([min(means) max(means) -inf inf])

    m(idx) = mbar;

    s(idx) = stdvbar;

    xlabel('Mean Rate (BPM)')

    ylabel('Rate Difference (EKG-PPG) (BPM)')

    title('Typical Bland-Altman Plot')

end

regend = 0;

for idx = 1:rlength

    figure

    hold on

    x = (regend:length(EKGHR{idx})+regend-1)./100;

    plot(x, EKGHR{idx},'r')

    plot(x, PPGHR{idx},'b')
```

```matlab
    legend('EKG','PPG')

    xlabel('Time (seconds)')

    ylabel('Heart Rate (BPM)')

    axis([x(1) x(end) -inf inf])

    line([regend/100 regend/100], [60 90], 'Color', 'black')

    regend = length(EKGHR{idx})+1;

    title('Overlapping PPG and EKG Waveforms')
end
```

B.5   ampd.m

```matlab
% AMPD. An Efficient Algorithm for Automatic Peak Detection in Noisy

% Periodic and Quasi-Periodic Signals

% Felix Scholkmann *, Jens Boss and Martin Wolf

% Algorithms 2012, 5

%

    ////////////////////////////////////////////////////////////////////////

% JRH, December 8, 2016

% INPUT:

% x = SIGNAL as a row vector [x1,x2,....xn] of a periodic or quasi periodic

    signal

% fs = Sample Frequency

% mws = Max Window in Seconds (max window width)

% OUTPUT:

% Peaks = For 1 Input Signal, Matrix P = [PeakLocations, PeakValues]

%        For 2+ Input Signals,

%            Cell P = {[PeakLocations,PeakValues]},{[PeakLocations, PeakValues]},

    etc....

function [Peaks] = ampd(x,fs,mws,plotFlag,detrendFlag)
```

```matlab
if ~exist('fs') || isempty(fs) % sampling frequency

    fs=100;

end

if ~exist('mws') || isempty(mws) % maximum window width (seconds)

    mws=log(length(x));

end

if ~exist('plotFlag') || isempty(plotFlag) % Plot Results

    plotFlag=0;

end

if ~exist('detrendFlag') || isempty(detrendFlag) % Detrend Data. 1 = True, 0

    = False

    detrendFlag=1;

end


% Orient Data

[row,col] = size(x);

if row>col  % Assume more data than sensors

    x = x';

    nsigs = col;

else

    nsigs = row;

end



for signum = 1:nsigs

    % Calculating the local maxima scalogram (LMS)

    % Linearly Detrend x

    if detrendFlag==1
```

```matlab
        y = detrend(x(signum,:)); % removes the mean value or linear trend

            from vector

    else

        y = x(signum,:);

    end


    %Local Maxima via Windowing

    N = length(y);

    alpha = 1;

    maxk = round(mws*fs/2);

    M = zeros(maxk,N); %LMS

    for k=1:maxk   % window length of 2*k

        for i=1:N

            if (i>=k+2 && i<=N-k+1)

                if (y(i-1)>y(i-1-k) && y(i-1)>(y(i-1+k)))

                    M(k,i) = 0;

                else

                    M(k,i) = rand + alpha;% uniformly distributed random number

                        in the range [0, 1] + alpha

                end

            else

                M(k,i) = rand + alpha;% uniformly distributed random number in

                    the range [0, 1] + alpha

            end

        end

    end

    % Rescale LMS

    [~,lambdaI] = min(sum(M,2)); % scale with the most local maxima

    if ~isempty(M(lambdaI+1,1))
```

```matlab
        M(lambdaI+1:end,:) = []; % Remove all elements in M where k>lambdaI

    end


    % Find Peaks

    sigma = std(M);

    plocs = find(sigma==0)-1; % find 0 std, shift index by 1.

    pvals = y(plocs);


    if plotFlag ~=0

        figure;subplot(2,1,1);plot(x(signum,:));hold

            on;plot(plocs,x(signum,plocs),'r*');title(['AMPD Signal

            ',num2str(signum)]);

        subplot(2,1,2);plot(y,'color',[0 0.5 0]);hold

            on;plot(plocs,y(plocs),'r*');title(['AMPD Detrended Signal

            ',num2str(signum)]);xlabel('Samples')

    end


    if nsigs == 1

        Peaks = [plocs',pvals'];

    else

        Peaks{1,signum} = [plocs',pvals'];

    end

    end

end
```

B.6   HR_Calc.m

```matlab
% Calculates Heart Rate

% Input:
```

```matlab
% x           Peak location indices
% fs          Sample Rate
% avg_t       Averaging window width (seconds)
% plotFlag    Plot HR
% Output:
% HR2         Smoothed HR
% HR          Splined HR
% iHR         Instantaneous HR
% t           Index vector


% JRH 3/15/2017
function [HR2,t,HR,iHR] = HR_Calc(x,fs,avg_t,plotFlag)
if ~exist('avg_t') || isempty(avg_t) % average window (seconds)
    avg_t = 5;
end
if ~exist('plotFlag') || isempty(plotFlag) % plot flag
    plotFlag = 0;
end
%% Orient Data into column vectors
[row,col] = size(x);
if row<col  % Assume more data than sensors
    x = x';
    nsigs = row;
else
    nsigs = col;
end
% Find NaNs
NaNFlag = sum(sum(isnan(x)));
if NaNFlag>0
```

```matlab
    x(isnan(x))=[];
    warning('HR_Calc: NaNs detected and removed.')
end
if avg_t<0.01
    warning('HR_Calc: Small average window may cause errors')
end
%% Calculate HR
RR = diff(x,1,1); RR = [RR(1,:);RR]; % RR Internal
iHR=(60*fs)./RR; % Instantaneous HR (bpm)


%% Spline HR and Smooth
avg_s = round(fs*avg_t); % Average Samples
havg_s = round(avg_s/2);
t = x(1):x(end); % Index Vector
HR = spline(x,iHR,t)'; % Splined HR
HR2 =
    filter(ones(avg_s,1)./(avg_s),1,[HR(1)*ones(avg_s,1);HR;HR(end)*ones(avg_s,1)]);
    % Smoothed HR (extended)
HR2 = HR2((havg_s+avg_s+1):(end-havg_s)); % Smoothed HR (truncated)
[~,I] = min([length(t),length(HR2)]);
    if I==1 % if HR2 longer, delete end entries
        HR2 = HR2(1:length(t),:);
    else    % if t longer, append HR entries
        HR2 = [HR2;HR2(end)*ones(length(t)-length(HR2),1)];
    end


if plotFlag~=0
    figure
    plot(x,iHR,'*');hold on;plot(t,HR,'r');plot(t,HR2,'g')
```

```matlab
    smooth_string = ['Smoothed HR: ',num2str(avg_t),' seconds'];

    xlabel('Sample #');ylabel('HR (bpm)');legend('Instant HR','Spline
        HR',smooth_string); hold off
end
end
```

Appendix C   Pulse Oximeters on the Market

Table 14: Finger Pulse Oximeter Comparison

	iHealthAir	CMS-50E	FORA TN'G TestN'Go SpO2 Finger Pulse Oximeter
Websites	https://ihealthlabs.com/ fitness-devices/wireless -pulse-oximeter/	http://www.pulseoximeter.org/ cms50e.html? utm_source=googlepepla&utm_ medium=adwords&id=18283950120	https://www.fora-shop.com/ products/fora-tng-testngo-spo2- fingertip-pulse-oximeter? utm_medium=cpc&utm_source= googlepla&variant=23073428353
SpO2 Range	70-99%	0-99%	
SpO2 Accuracy	±2%	±2% for 70-99%	±2% for 80-100%, ±3% for 70-79%
PR Range	30-250bpm	30-240bpm	30-250bpm
PR Accuracy	±2bpm	±2bpm	±1bpm
Battery Life	3.7V Li-ion, 300mAh	3.7V rechargeable Li interior battery	2 AAA batteries, can be used continuosly for 8 hours
Chargeability	USB charging cable	USB cable or wall outlet	no
Data Storeage	iHealth mobile app	up to 24 hours, can be uploaded to computers	memory
Data Extraction	iHealth mobile app	real-time data can be transmitted to computer	download to phone or computer, software download
Wireless	Bluetooth 4.0 BLE	Bluetooth or Wireless Transmitter&Receiver (RF), software download	bluetooth
Lifetime	365 day warranty, 6 hr battery, 10000 spot checks - roughly 3 yrs	1 year warranty	12 months, warranty card
Additional Features		Alarms if measurement out of set limits, low voltage, or finger out of probe	
Phone Number	1-855-816-7705	1-847-234-0754	1-888-307-8188

	NonIn GO2	FL-50B	NonIn Onyx 9590	NonIn WristOx2 3150
Websites	http://www.nonin.com/ Finger-Pulse-Oximeter/Nonin-GO2-Achieve	http://www.pulseoximeter.org /fl50b.html?utm_source=googlepepla& utm_medium=adwords&id=18283950120	http://www.nonin.com/ documents/8529-001-02%20Onyx%20 Vantage%20Spec%20Sheet.pdf	http://www.nonin.com/ OEMSolutions/WristOx23150-OEM
SpO2 Range	0-100%	0-100%	0-100%	0-100%
SpO2 Accuracy	±2%	±2% for 70-100%	±2digits for 70-100%	±2digits for 70-100%
PR Range	20-250bpm	25-250bpm	18-321 bpm	18-321 bpm
PR Accuracy	±3 digits	±2bpm	±3 digits for 20-250 bpm	±3 digits
Battery Life	1 AAA battery, 24hr continuous	2 AAA batteries, 30 hours normal operation	2 AAA batteries, 6000 spot checks for 36 hours	53hrs w/o bluetooth, 21hrs w/ bluetooth
Chargeability	no		no	
Data Storeage	battery life storage 6 months		battery life storage 12 months	±3 digits
Data Extraction	no	PHMS Contec Medical Systems smartphone app	no	4 sec rate-1080hrs 2 sec rate-540hrs 1 sec rate-270hrs
Wireless	yes		yes	bluetooth 2.0
Lifetime	2 year warranty?	1 year warranty	4 year warranty	3 year warranty
Additional Features			fits all, pediatrics to adults	
Phone Number	1-763-553-9968	1-847-234-0754	1-763-553-9968	1-763-553-9968

Appendix D   Additional Figures

D.1   Pressure Reproducibility

The following images represent the results from the pressure reproducibility tests from volunteers and group members.
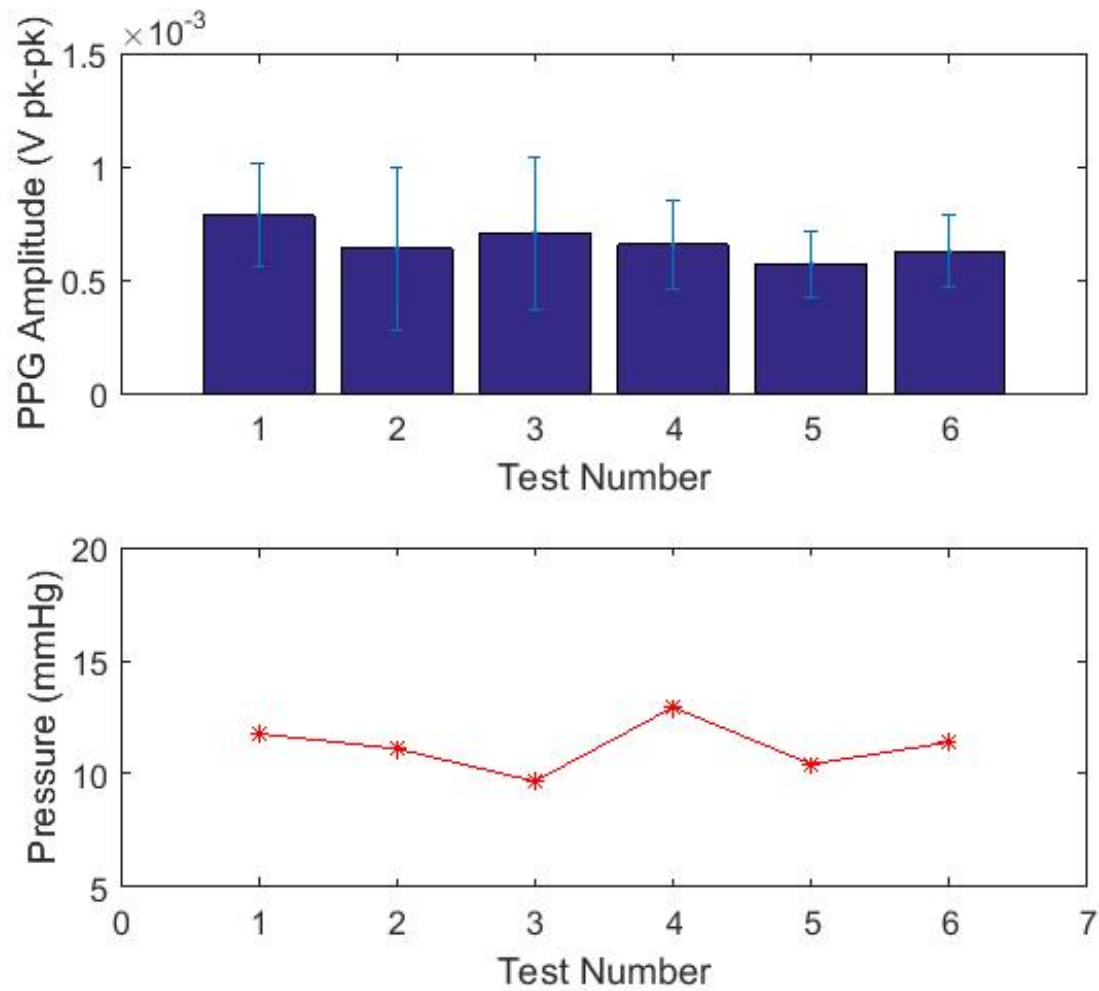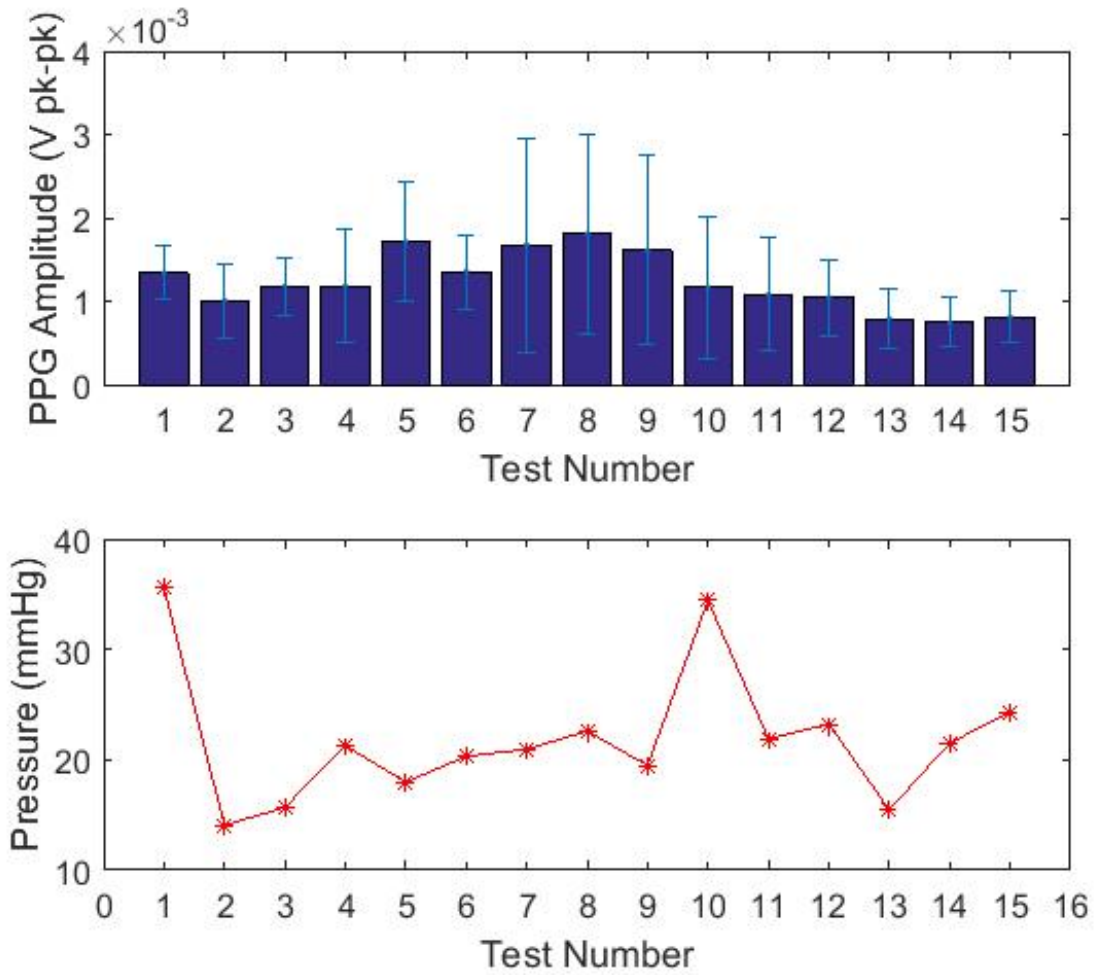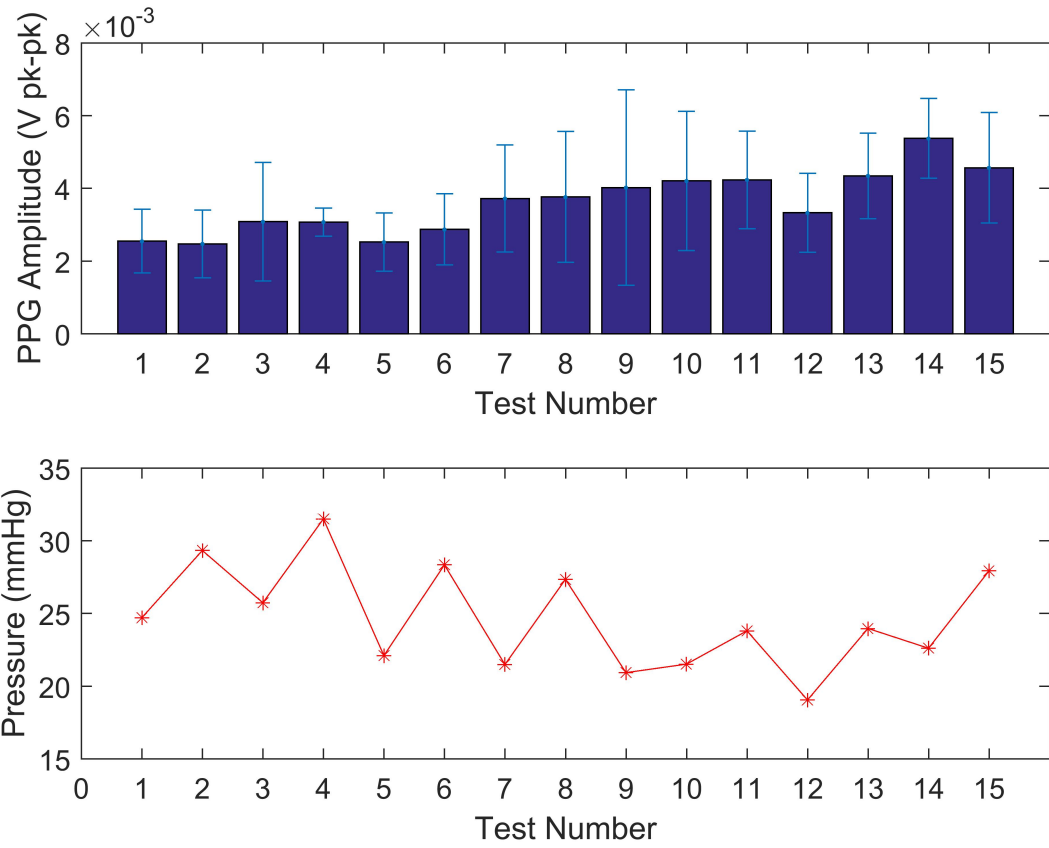

Figure D.1: Pressure Reproducibility Results for Volunteer 1

Table 15: Volunteer 1 Pressure Reproducibility Results

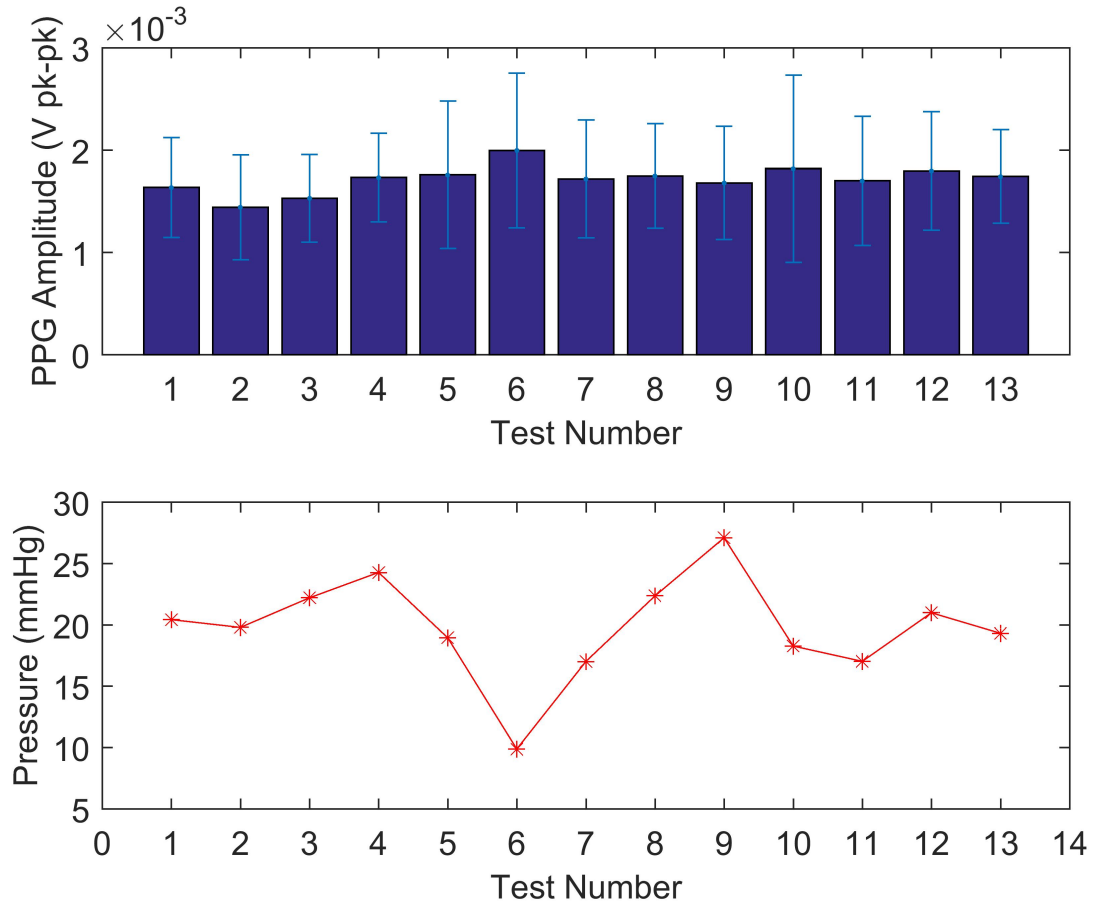| Test	PPG Amplitude (V pk-pk)	Pressure (mmHg)
1	7.86 e-04 ± 2.30 e-04	11.78
2	6.36 e-04 ± 3.58 e-04	11.11
3	7.07 e-04 ± 3.34 e-04	9.67
4	6.55 e-04 ± 1.92 e-04	12.94
5	5.68 e-04 ± 1.42 e-04	10.43
6	6.23 e-04 ± 1.60 e-04	11.40

Figure D.2: Pressure Reproducibility Results for Volunteer 3

Table 16: Volunteer 3 Pressure Reproducibility Results

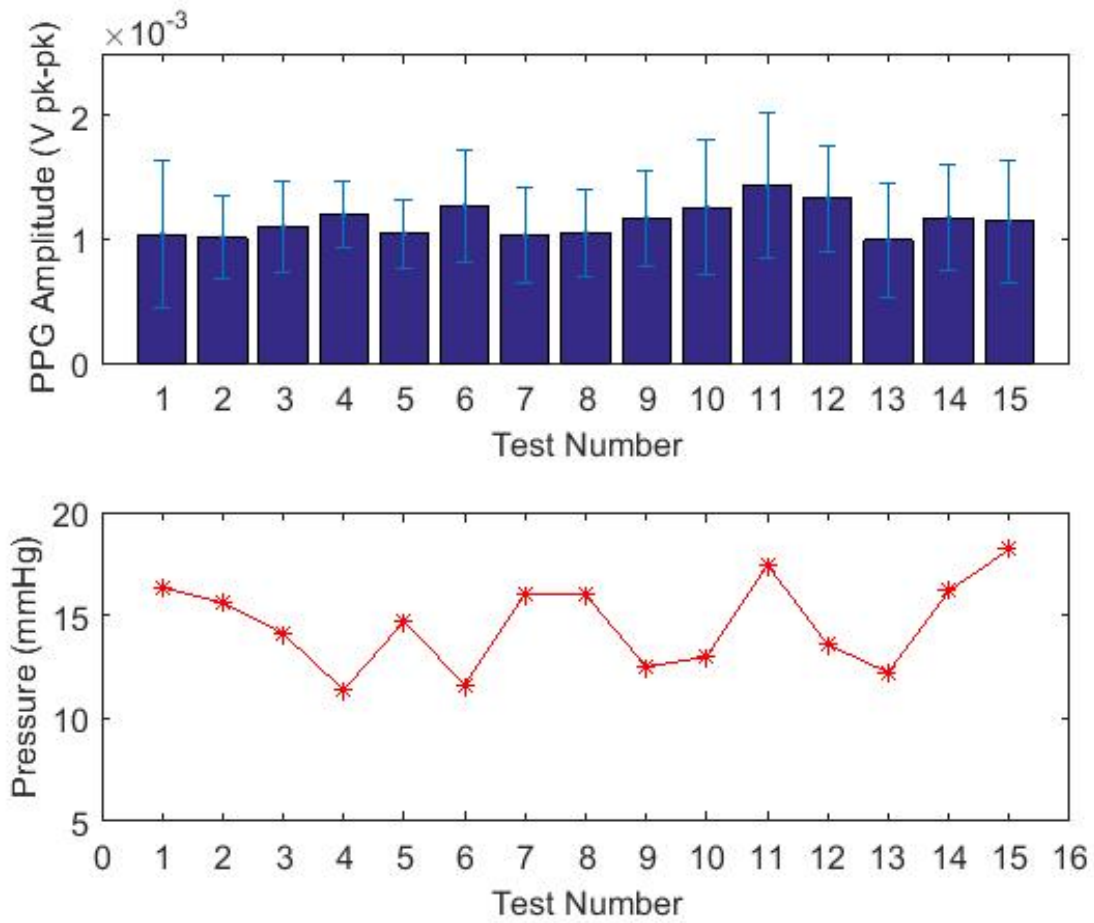| Test	PPG Amplitude (V pk-pk)	Pressure (mmHg)
1	.0013±3.21e-04	35.57
2	9.71e-04±4.32e-04	14.07
3	.0012±3.50 e-04	15.69
4	.0012±6.89 e-04	21.28
5	.0017±7.11 e-04	17.98
6	.0014±4.44 e-04	20.32
7	.0017±.0013	20.95
8	.0018±.0012	22.59
9	.0016±.0011	19.50
10	.0012±8.68 e-04	34.42
11	.0011±6.81 e-04	21.88
12	.0010±4.56 e-04	23.22
13	7.89e-04±3.56 e-04	15.48
14	7.43e-04±2.96 e-04	21.52
15	8.10e-04±3.15 e-04	24.30

Figure D.3: Pressure Reproducibility Results for Volunteer 4

Table 17: Volunteer 4 Pressure Reproducibility Results

Test	PPG Amplitude (V pk-pk)	Pressure (mmHg)
1	.0025±8.77 e-04	24.72
2	.0025±9.24 e-04	29.34
3	.0031±.0016	25.75
4	.0031±3.85 e-04	31.52
5	.0025±8.03 e-04	22.11
6	.0029±9.80 e-04	28.36
7	.0037±.0015	21.50
8	.0037±.0018	27.36
9	.0040±.0027	20.94
10	.0042±.0019	21.53
11	.0042±.0013	23.82
12	.0033±.0011	19.06
13	.0043±.0012	23.98
14	.0054±.0011	22.62
15	.0046±.0015	27.94

Figure D.4: Pressure Reproducibility Results for Volunteer 6

Table 18: Volunteer 6 Pressure Reproducibility Results

Test	PPG Amplitude (V pk-pk)	Pressure (mmHg)
1	.0016±4.86e-04	20.47
2	.0014±5.13 e-04	19.84
3	.0015±4.27 e-04	22.23
4	.0017±4.31 e-04	24.27
5	.0017±7.15 e-04	18.96
6	.0020±7.57 e-04	9.93
7	.0017±5.75 e-04	17.01
8	.0017±5.10 e-04	22.37
9	.0017±5.54 e-04	27.11
10	.0018±9.17 e-04	18.26
11	.0017±6.16 e-04	16.95
12	.0018±5.81 e-04	21.02
13	.0017±4.54 e-04	19.32

Figure D.5: Pressure Reproducibility Results for Volunteer 7

Table 19: Volunteer 7 Pressure Reproducibility Results

Test	PPG Amplitude (V pk-pk)	Pressure (mmHg)
1	.0010±5.97e-04	16.35
2	.0010±3.44e-04	15.62
3	.0011±3.67e-04	14.10
4	.0012±2.72e-04	11.37
5	.0010±2.75e-04	14.71
6	.0013±4.55e-04	11.62
7	.0010±3.88e-04	16.05
8	.0010±3.56e-04	15.98
9	.0012±3.83e-04	12.51
10	.0013±e5.44-04	12.98
11	.0014±5.87e-04	17.44
12	.0013±4.28e-04	13.58
13	9.90e-04±4.62e-04	12.22
14	.0012±4.23e-04	16.18
15	.0011±4.94e-04	18.19
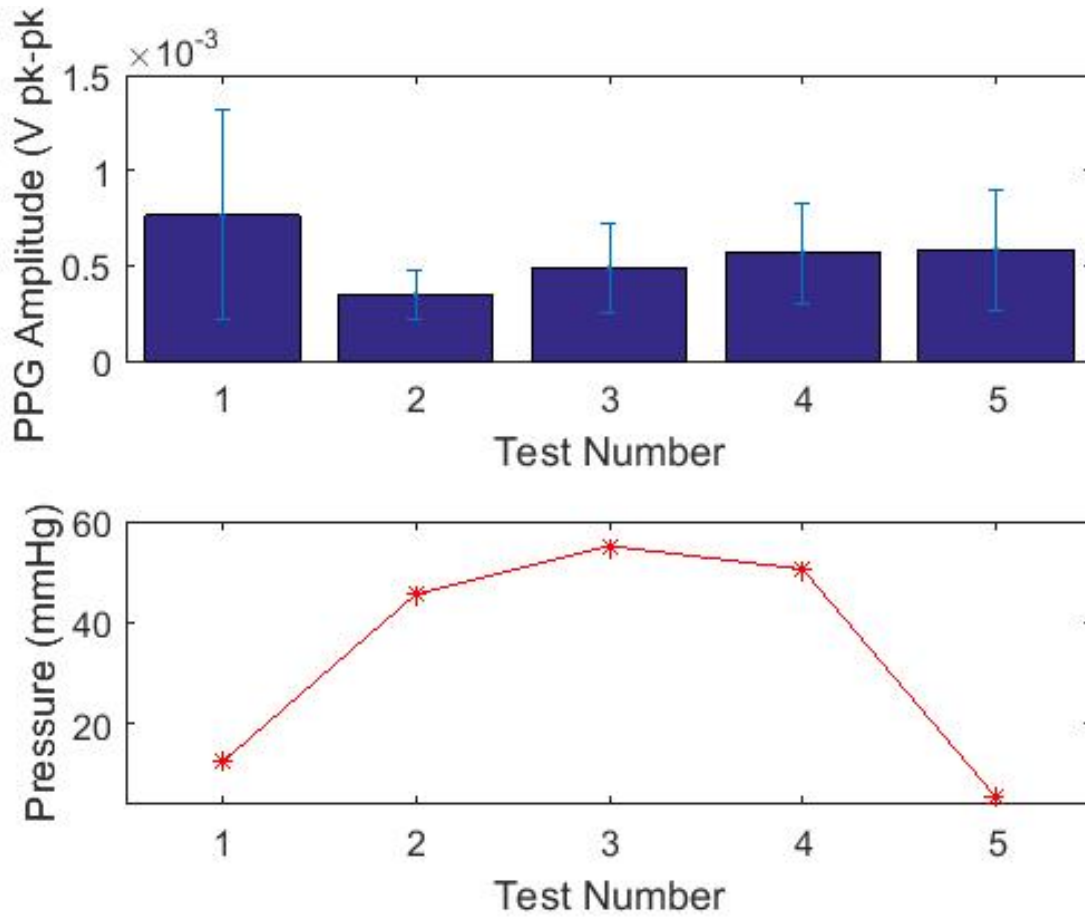
Figure D.6: Pressure Reproducibility Results for Nicholas McNary

Table 20: Pressure Reproducibility Results for Nicholas McNary

Test	PPG Amplitude (V pk-pk)	Pressure (mmHg)
1	7.6 e-04±5.5 e-04	12.41
2	3.45 e-04± 1.31 e-04	45.56
3	4.85 e-04± 2.31 e-04	55.13
4	5.68 e-04± 2.64 e-04	50.53
5	5.84 e-04± 3.16 e-04	5.42
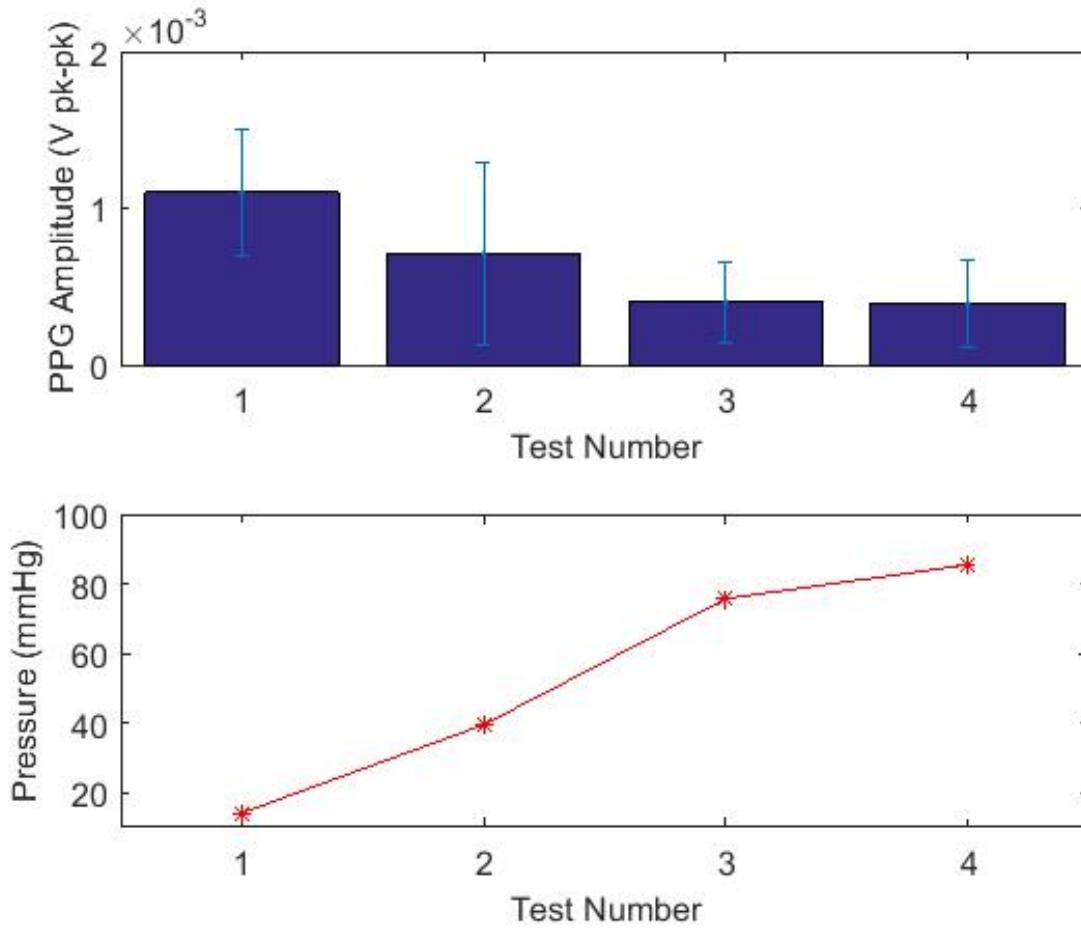
Figure D.7: Pressure Reproducibility Results for Tori Claverie

Table 21: Pressure Reproducibility Results for Tori Claverie

Test	PPG Amplitude (V pk-pk)	Pressure (mmHg)
1	.0011±4.06 e-04	14.14
2	7.08 e-04± 5.82 e-04	39.49
3	4.01 e-04± 2.60 e-04	75.73
4	3.91 e-04± 2.77 e-04	85.44

D.2 Time Trials

What follows is a series of images representing the Bland-Altman plots from various volunteers. The "Typical Bland-Altman Plot" title was added automatically; the following volunteers were not typical of all subjects.
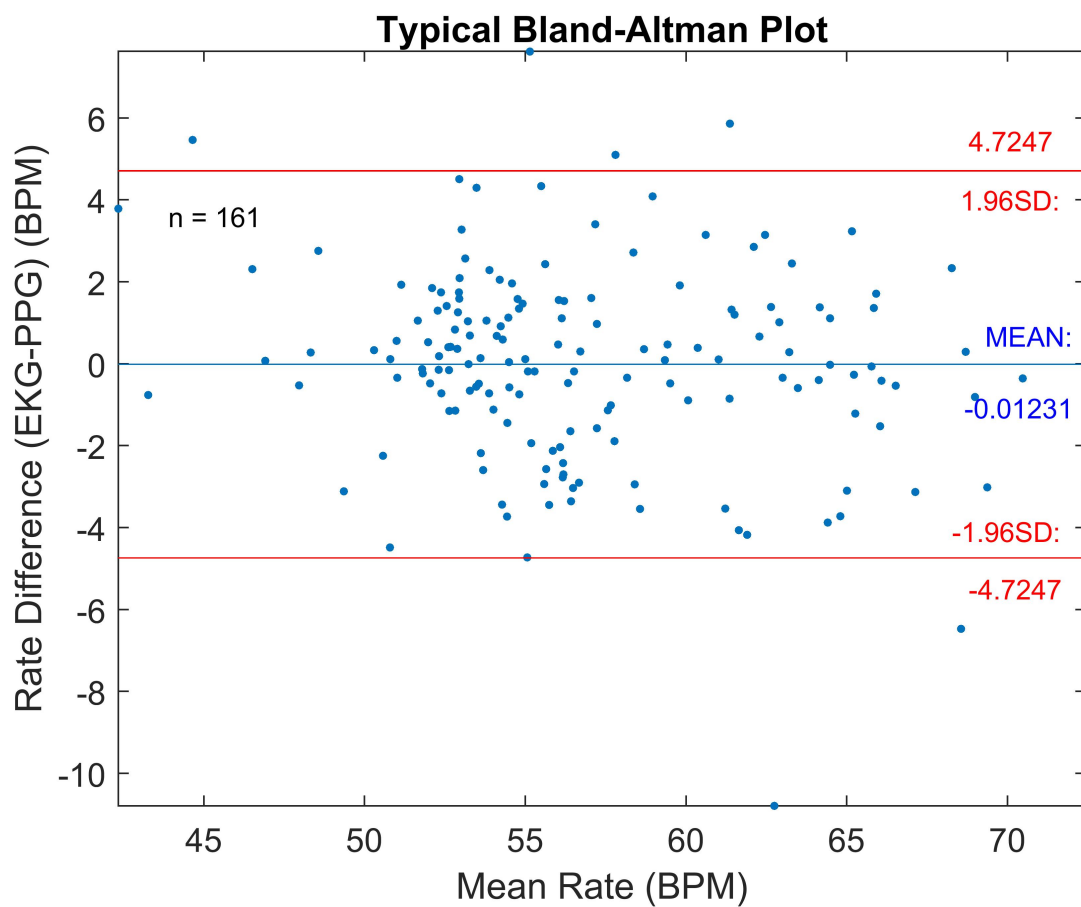
Figure D.8: Bland-Altman plot of volunteer 6 (supine, region 2)
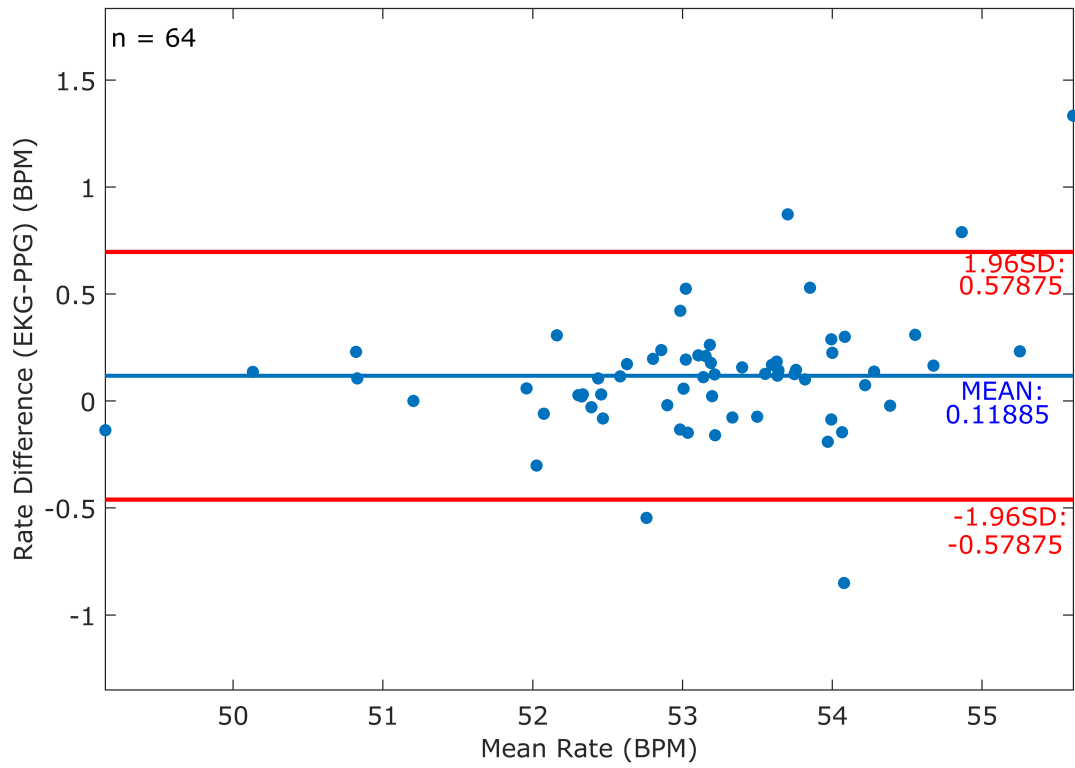
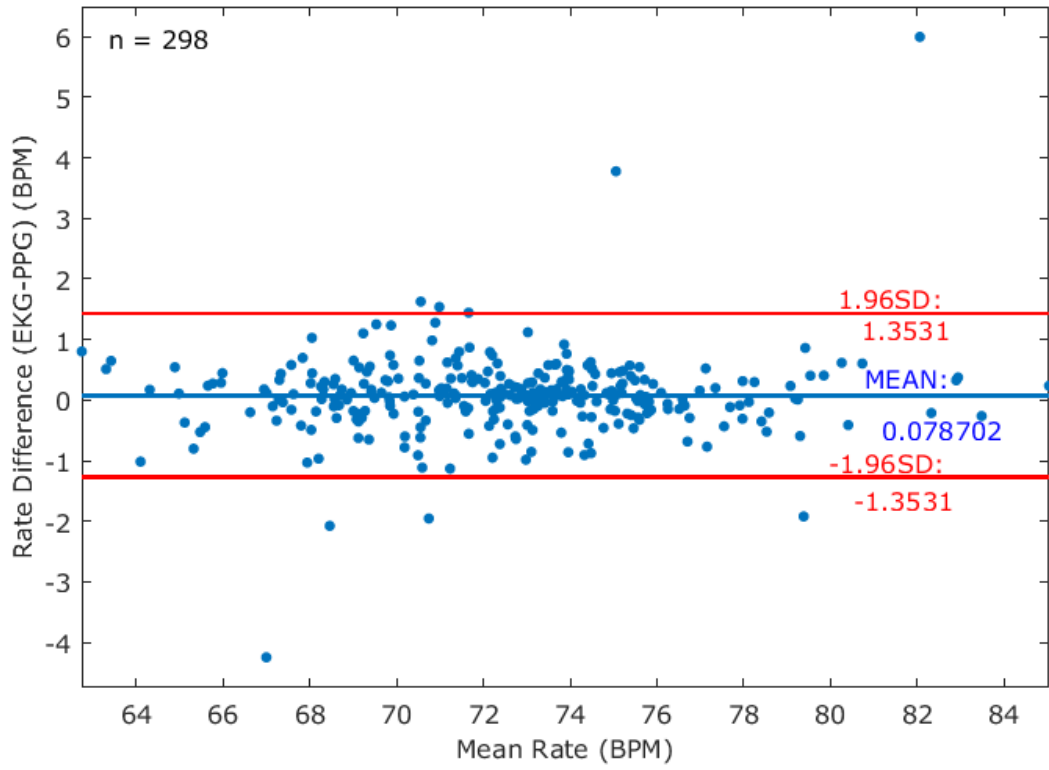Figure D.9: Bland-Altman plot of volunteer 4 (all 3, region 1)

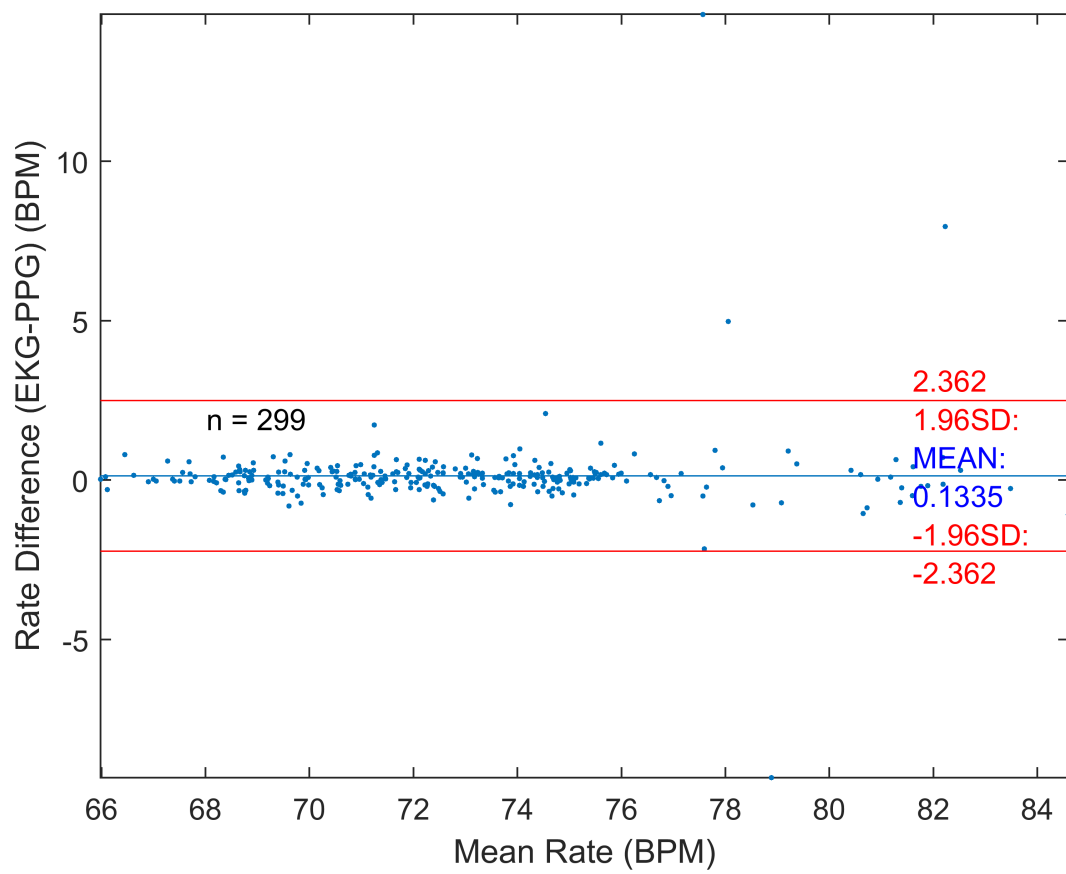Figure D.10: Bland-Altman plot of volunteer 5 (supine, region 1)

Figure D.11: Bland-Altman plot of Tori Claverie (supine, region 1)
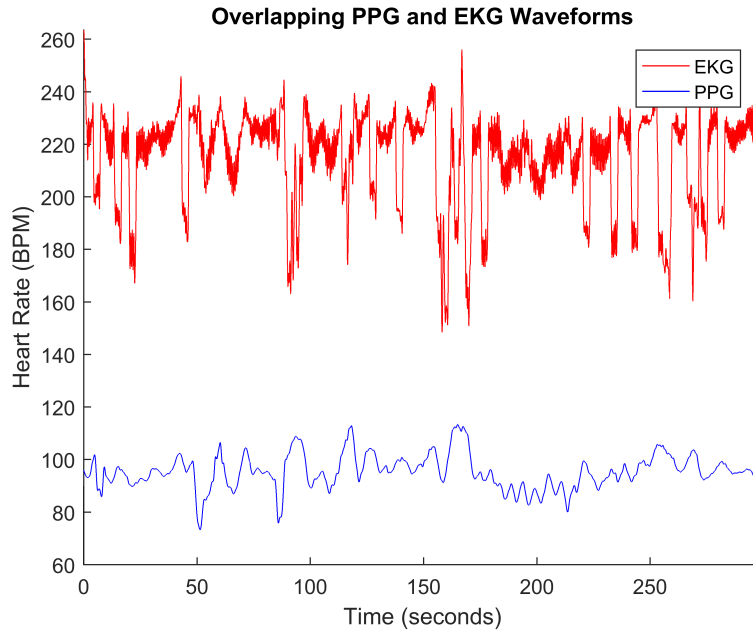
Figure D.12: Comparison of heart rate and pulse rate over time for volunteer 7 (standing, region 1)
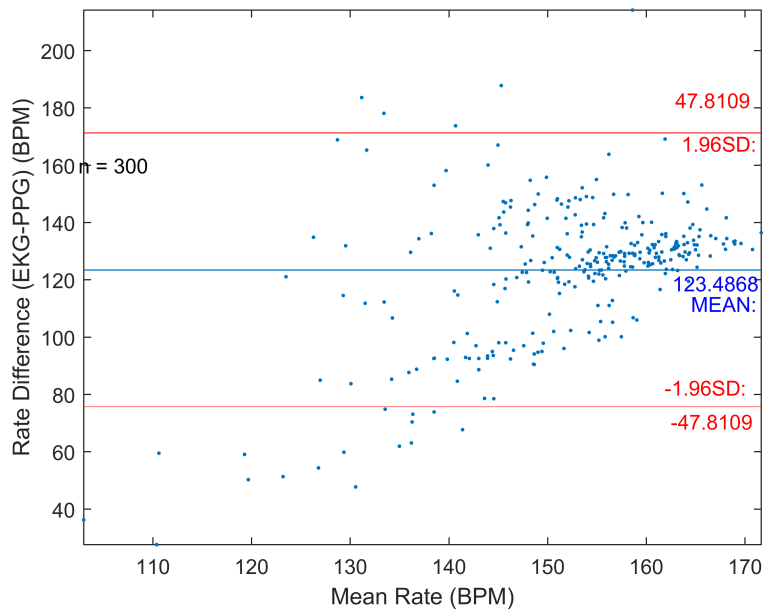

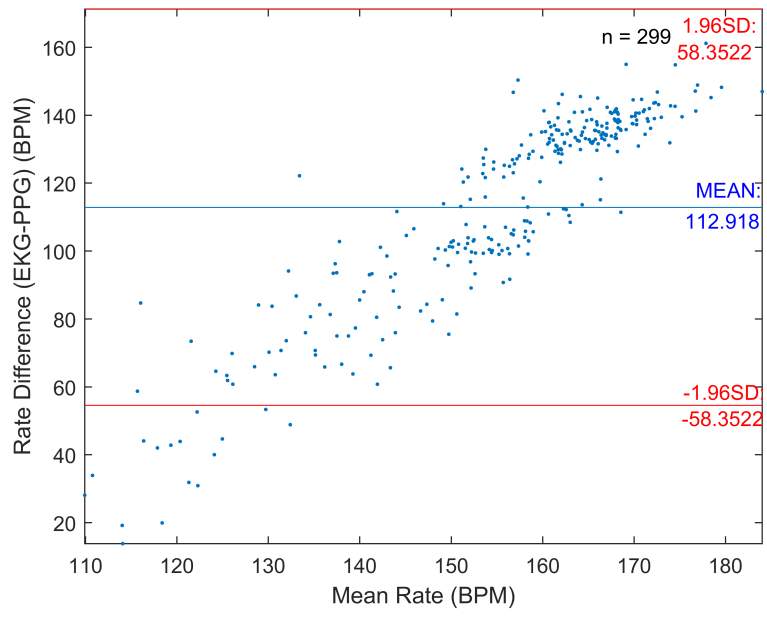Figure D.13: Bland-Altman plot of volunteer 7 (sitting, region 1)

Figure D.14: Bland-Altman plot of volunteer 7 (standing, region 1)