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# Non-invasive Method to Measure Blood Oxygen Saturation Accurately for All Skin Types

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# Executive Summary:

Blood oxygen saturation (SpO2) is an important measurement used to determine the amount of oxygen in the blood at any given time [1]. During the COVID-19 pandemic, the public was using pulse oximetry devices as a way to monitor SpO2 levels [1]. These devices were used to monitor serious symptoms of COVID- 19 such as respiratory distress; and it was found that they were not consistently accurate amongst the patients [1]. It was found that the inaccuracies of the device were higher among individuals that had thicker skin, darker skin pigmentations, and/or abnormal skin texture [1]. In order to fully grasp the scope of the project, our group identified key stakeholders involved with pulse oximetry devices alongside the need analysis for an improved device. It was clear from our findings and the FDA announcement that modernization and updating current pulse oximetry devices was critical [1]. Our team was challenged to recreate a modern pulse oximetry device that works on all skin pigmentations, textures, and thicknesses.

With a defined client statement, our team conducted an in depth literature review in order to fully understand the background of pulse oximetry as well as the electrical components involved in a typical pulse oximeter circuit. In typical pulse oximetry devices, electrical components include but are not limited to photodiodes, light emitting diodes (LEDs), transimpedance amplifiers [2][3]. In this literature review, the team also identified the factors that result in inaccurate readings which included skin factors such as surface temperature, thickness, texture, and pigmentation, alongside movement and various adornments [1]. We brainstormed possible solutions and came up with mechanical and circuit changes to help solve the goal of this project. Circuit changes included changing the light source from LEDs to lasers, and mechanical changes such as re-designing a typical pulse oximetry device to fit our circuit. Our final design included a two part light source finger clamp, but we went through many designs such as a wristband, patch, and malleable finger splint. We decided to use lasers as a light source opposed to LEDs because evidence suggested lasers could be more accurate then LEDs [4][5]. Once the circuit was built and our team was able to obtain a signal, we tested our circuit using three major testing protocols alongside two exploratory testing methods.

Testing methods included having test subjects sit and gather a reading in a normal circumstance and to also apply fake tattoos and fake nails to their fingers. For exploratory purposes, our team also tested the effect of temperature and movement on the SpO2 levels of the subjects. It was determined that fake nails, tattoos, temperature, and movement inhibit the pulse oximeters to get good readings. Our data suggested that our results regarding the effects of tattoo, nails, temperature, and movement were consistent with data found during our literature review. Our device was validated in a sense that we were able to obtain a reading of SpO2 from the test subjects, but it's rather inconclusive whether the lasers performed better than the LEDs. Further testing would be needed to definitively say either way.

# Abstract

Our group was tasked with solving an inherent need in improving pulse oximetry devices. Our goal was to create a device capable of accurately measuring blood oxygen saturation for all skin pigmentations, thicknesses, and textures. The final design included various modifications to the current pulse oximeter models in addition to implementing a laser-based circuit. Our device was tested using standard and exploratory testing methods. These included observing the effects of movement, fake nails and tattoos, and skin surface temperature. We found that movement, skin temperature, fake nails, and fake tattoos affected the accuracy of the device. Our results were consistent with the known errors of these devices found in literature. However, our team was unable to conclude that the usage of lasers was optimal compared to LEDs due to our lack of data. Future recommendations include using a circuit that has the capability to use both infrared and red lasers at the same time and testing on a diverse population.

**Key words:** Blood oxygen saturation (SpO2), Lasers, Light Emitting Diodes (LEDs), Computer Aided Design (CAD), Photodiodes, Wavelength(s), Pulse Oximetry, Calibration, Hemoglobin, Pigmentation effects, Spectroscopy, and Absorbance.

# Chapter 1.0 Introduction

Without the use of medical devices to measure blood oxygen saturation levels within the blood, the typical visual signs in patients that are experiencing a lack of oxygen such as turning blue, chest pain, racing heart rate, and discomfort [1]. The COVID-19 pandemic put a particular emphasis on the importance of oxygen saturation monitoring as these devices were used in mass quantities [1]. Pulse oximeters are vital non-invasive devices used in all hospitals and by emergency personnel for measuring blood oxygen saturation in patients [1]. Despite their ubiquity, these devices have several major drawbacks that make them unreliable affecting the functionality, effectiveness, and efficacy of the device for patients [1]. These known errors resulted in pulse oximetry devices unable to accurately measure the oxygen saturation of patients with varying skin pigmentations, surfaces, and thicknesses [1]. From this information it can be concluded that a need for modernization must occur to ensure proper healthcare to patients of varying skin types.

The goal of this project was to create a working pulse oximeter prototype that functions at high accuracy on all skin pigmentations, thicknesses, and morphologies. Over the course of this project, the team compiled literature and data that was used to decide the current limitations affecting usability of pulse oximeters. Furthermore, a detailed review of the current advantages of current on-market devices, the electrical principles, and design principles within these devices was conducted. This wealth of information aided in solidifying the need for such devices and how skin variation, including thickness, texture, and pigmentation can affect that accuracy of a reading [1]. From this, we decided that there was much opportunity for modernization and optimization that can occur to make these devices universal.

Once our team established our design goals, the next fourteen weeks consisted of working on various circuits and designs to optimize the current devices. Chapters 4-8 is a sequential guide on the team's process to meeting our goals. This included multiple computer-aided designs (CAD) along with circuit modifications that included both lasers and light-emitting diodes (LEDs). Testing was then done on our designs and circuits to determine how effective and efficient they performed comparatively to the current gold standard devices. While our group was unable to definitively say that lasers worked better than LEDs, our results were consistent with what we found in the literature review validating that we were getting blood oxygen saturation readings from our testing. Future considerations were acknowledged and outlined in Chapter 8.

Through our experience during this process, our team found it to be very enlightening and rewarding to be working on such an important project and are grateful for everyone who aided us in the completion of the project.

# Chapter 2.0 Literature Review

## 2.1 Pulse Oximetry

Pulse oximetry is widely used in medical applications such as diagnostics and monitoring ranging from at home, hospital, and emergency use [1]. Pulse oximetry devices measure a patient's oxygen level, or saturation, within the bloodstream [1]. Oximetry is based on two main principles, the first being that oxyhemoglobin ($O_2Hb$) and hemoglobin (Hb) have different absorption spectra, and secondly, the pulsatile arterial blood is independent of non-pulsatile venous and capillary blood [2]. To measure oxygen saturation, a light source such as an LED emits light at a targeted portion of the skin, normally the fingertip as seen in Figure 2.1 [6]. The oxygenated hemoglobin allows for red light to pass through as it absorbs infrared light [2]. In contrast, deoxygenated hemoglobin absorbs red light, allowing the infrared light to pass through[2]. The oximeter then measures the ratio in light absorption between oxygenated and deoxygenated blood [2]. The use of this ratio is discussed in more detail in section 2.2.

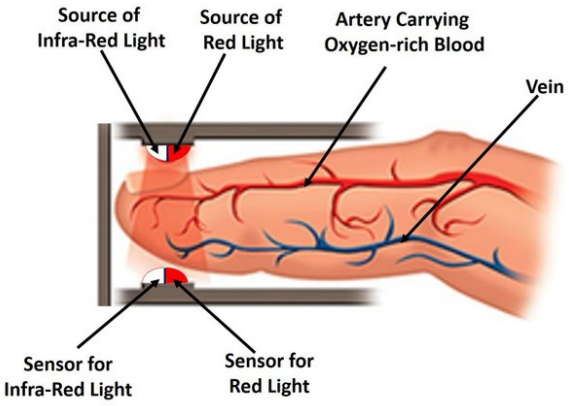


**Figure 2.1 - Emission of light through finger [6].**

Different light frequencies and colors vary in their ability to penetrate the skin; pulse oximetry devices traditionally contain two LEDs at specific wavelengths of 660 nm and 940 nm which correspond to red and infrared light on the electromagnetic spectrum [2]. In order to effectively calculate the blood oxygen saturation as a result of light measured, pulse oximeters are calibrated by using reference data [7]. This reference data is discussed in more detail in section 2.2.

There are two main types of pulse oximeters: transmissive and reflective [8]. Transmissive pulse oximeters are the most common type and are structured with the light source and photodiode parallel to each other on opposite sides of the finger [8]. Reflective oximeters are structured with the light source and photodiode adjacent and on the same side of the device as seen in Figure 2.2 [8]. Transmissive oximeters calculate blood oxygen saturation levels based on the light that passes through the finger and reaches the photodiode where it is then measured [8]. In contrast, reflective oximeters calculate the measurement based on the light that is reflected from the skin back to the photodiode [9]. These functionalities ultimately distinguish the different types of pulse oximeters from one another.

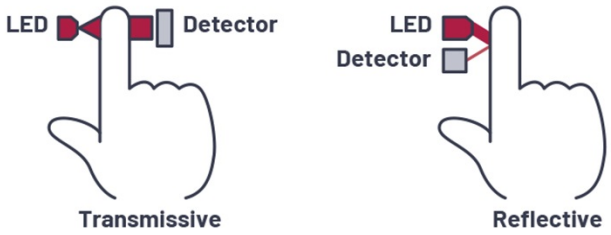


**Figure 2.2 - Transmissive vs. reflective configuration [8].**

## 2.2 Calculations

Pulse oximeters calculate the blood oxygen level using a ratio comparing the photiode's absorption reading of the red light to the infrared light [2]. The specific values being collected by the pulse oximeter involve the penetration of the LED's light into the arterial blood, venous blood, capillary blood, and stationary tissues [10]. The reading collected from the arterial penetration of the light source accounts for the oxygenated blood level and all other readings are compiled together to generate the deoxygenated blood level [11]. Once the pulse oximeter has collected this data, the following equation is used to get the blood oxygen ratio which correlates to a person's blood oxygen level [10].

$$R = \frac{AC_{Red}/DC_{Red}}{AC_{IR}/DC_{IR}}$$

Where "AC" is the pulsatile absorbance, "DC" is the non-pulsatile absorbance, and R is the resulting blood oxygen ratio [10]. The resulting ratio is then plotted to a predetermined calibration chart [10]. The calibration chart is created based on referenced data of healthy individuals ranging from 70% to 100% blood oxygen saturation [10]. The calibration chart shows the relationship between the pulse oximeter's calculated "R" ratio and the patient's SpO2, an example of this chart can be seen in Figure 2.3 [12].

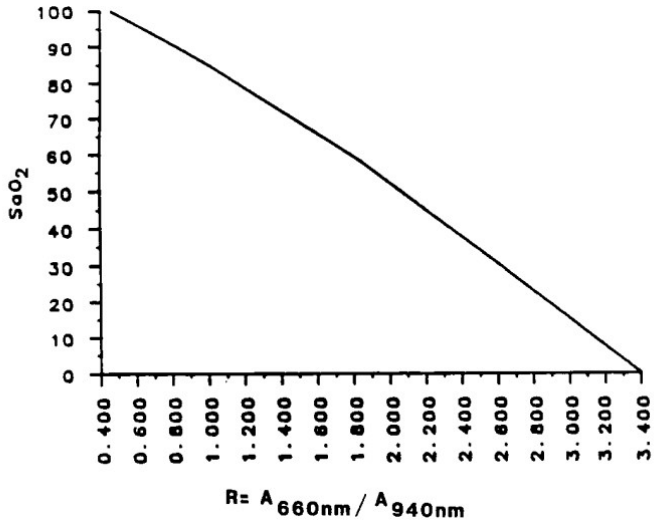


**Figure 2.3 - A calibration chart for a pulse oximeter where the calculated R value is placed on the curve to get a person's blood oxygen level [12].**

## 2.3 Electrical Components

### 2.3.1 Light-Emitting Diodes

The selection of the wavelength values used in pulse oximeters is based on absorption coefficients shown in Figure 2.4 [10]. From this graph, it can be inferred that with varying wavelengths, the absorption coefficient is greatly affected [10]. In LEDs specifically, optimization of wavelength for the desired coefficient can be extrapolated from this graph [10]. The graph shows the absorption coefficient for various types of hemoglobin based on the wavelength used.

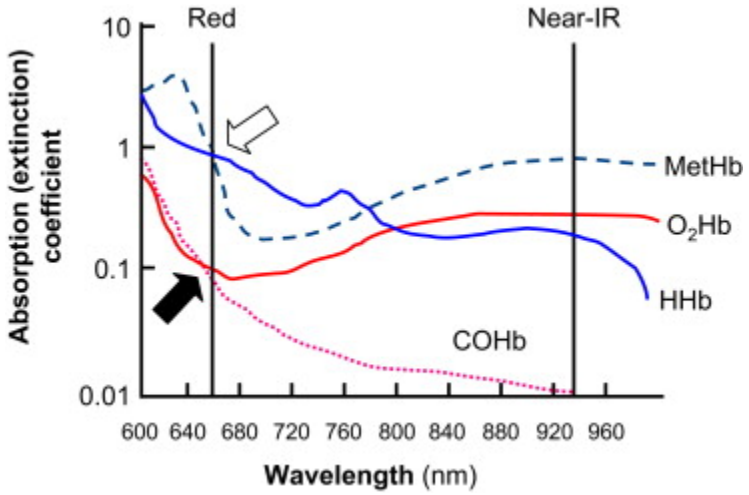


**Figure 2.4 - Absorption spectra of hemoglobin [10].**

### 2.3.2 Lasers

Laser diodes are among the most common types of laser used in the world today accounting for about 50% of these lasers [13]. These lasers have tunable spectroscopy that can be used to measure absorptions of a variety of compounds and conditions such as temperature fluctuations, pressure, and concentrations [14]. Since these lasers can measure concentrations, such as blood oxygen saturation in the body, through absorption, these lasers can be used in a variety of devices including pulse oximetry devices [15]. The main difference between an LED and a laser diode has to do with light penetration [16] [17]. Medical practices using lasers have been used in therapeutics where people with varying skin pigmentations and thickness were part of the patient pool [18]. Therapeutics are administered using laser diodes at wavelengths ranging from 635 nm to 808 nm depending on the circumstance they are used in, alongside their consistency literature [18]. These values were relatively close to the two wavelengths that pulse oximeter LEDs used.

Skin heating due to lasers has been a concern in the past due to data suggesting that darker-pigmented skin suffered more heating effects at higher wavelengths exceeding 808 nm [18]. Data suggests that lasers that result in 12 joules of energy or less in the circuit result in reduced concerns for safety, and are apparently safe for use [18]. Based on this information, lasers can be integrated into pulse oximetry safely with minimal risk to the patient [18]. With safety and clinical applications fully assessed, it was determined by our group that laser diodes could support our goal of the project well.

### 2.3.3 Photodiodes

As the LEDs shine light on a finger, an electrical component known as a photodiode must be used with the LEDs to receive the light and convert it into an electrical current through PN or PIN junctions [19]. PN photodiodes are the basic model where detection occurs in the relatively small, less sensitive depletion, or middle, area of the diode [20]. Where PIN photodiodes are very similar to PN photodiodes with additional sensitivity over a larger depletion area by including an intrinsic layer to increase that depletion area as shown in Figure 2.5 [20]. It was clear from this that carefully picking out the photodiode for our applications was going to be critical.

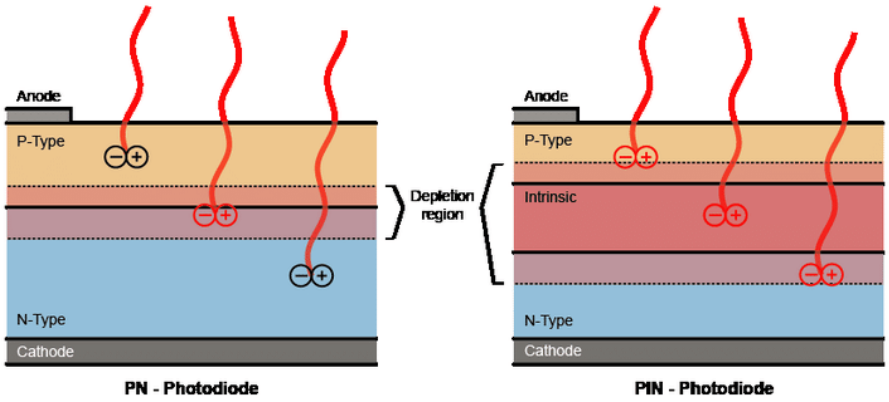


**Figure 2.5 - Difference between PN and PIN photodiodes [21].**

In light absorption applications, photodiode signals are commonly amplified through the use of a transimpedance amplifier [22]. This specific amplifier configuration acts as a current to voltage converter by modifying a simple inverting operational amplifier (op-amp) circuit [23]. This can be done by grounding the noninverting, or positive, input of the op-amp and connecting a feedback resistor to the inverting, or negative, input of the op-amp and the output as shown in Figure 2.6 [23]. Ideally, the input current would flow through the feedback resistor, whereas the op-amp would modify the voltage output to achieve equilibrium between the two [23]. Along with the feedback resistor, a feedback capacitor could also be wired in parallel to this resistor for filtering based on application frequency [24]. Using this configuration, a complete current to voltage converter has been created to amplify desired signals as shown in Figure 2.6.

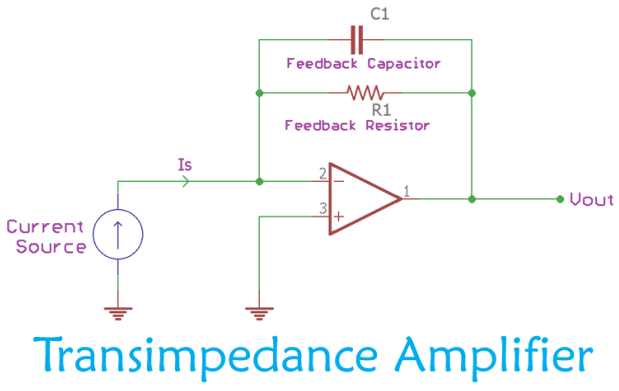


**Figure 2.6 - Schematic of a transimpedance amplifier [24].**

### 2.3.4 Transistors

Transistors can act as an on and off switch within the circuit regulating the current throughout, and furthermore be used to amplify the generated current without needing to add additional power sources [25]. Transistors come in two forms: Bipolar Junction Transistors (BJTs) and Field Effect Transistors (FETs) [25]. BJTs are current control-based transistors that amplify currents while FETs are voltage control-based transistors that amplify voltage [25]. BJTs come in two forms NPN transistors and PNP transistors [25]. Their functions are very similar as they are both focused on modifying current, but the main difference is the distribution of the electrons that travel into the transistor and where they are sent [25]. A transistor has three parts: emitter, collector, and base as shown in Figure 2.7 [25]. An NPN transistor collects the negative electrons in a current in the collector region and then sends it in a forward-biased condition to the emitter, causing the current to continue to travel through the transistor [25]. A PNP transistor amplifies the positive electrons in a current and sends them to the base rather than to the emitter, resulting in a reverse-biased condition [25]. It was clear that transistors have an important role in many electrical applications, and it's advantageous to know the differences between the types.

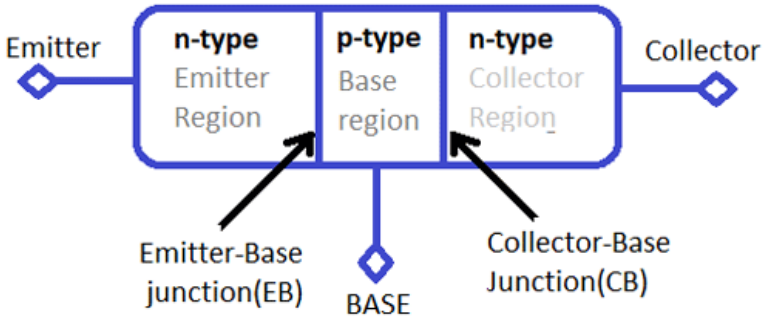


**Figure 2.7 - Formation of a typical NPN transistor [25].**

## 2.4 Known Errors

### 2.4.1 Skin factors

Many errors decrease the usability of pulse oximetry devices, however, one of the most important errors that is overlooked is skin variation [1]. Inaccuracies can be caused by anything from conditions that affect skin thickness or textures as well as various phenotypes [1]. On November 1st, 2022, the Anesthesiology and Respiratory Therapy Devices Panel of the Medical Devices Advisory Committee met to discuss the limitations of the device and common patterns that result in inaccuracies of the devices in response to the COVID-19 pandemic [1]. This meeting discussed skin pigmentation limitations, but generally, in the article below the announcement, the FDA highlighted thickness and texture variation (in a variety of capacities) as conditions that affect the accuracy of the device [1]. Based on this announcement, it was clear to our team that skin factors affecting pulse oximetry was a larger limitation than initially thought; and further modernization was needed to pulse oximetry devices.

Skin pigmentation readings having equitable accuracy amongst all patients has been an ongoing modernization of the current gold standard pulse oximetry device [26]. It was found that while errors in the measurement were not clinically significant at values above 80%, the inaccuracy grew with values decreasing from 80% blood oxygen saturation levels [1]. Blood oxygen saturation levels below 80% are

an indication of a reduction in blood oxygen in the body, and need to be treated quickly and vigorously [27]. It was found that darker-pigmented patients were three times more likely to have occult hypoxia that was not shown in pulse oximetry, but was determined in blood gas measurements [26]. It was also found that when the pulse oximetry devices read a value of 90% blood oxygen saturation levels in the body, the actual level can be anywhere from 86 % – 94 % due to the margin of error of the device [1]. It was recently strongly recommended that all clinical tests involving pulse oximetry devices have at least 15% of the testing pool to be of a darker pigmentation to help improve the accuracy of the device [1]. One can conclude from this, that if these recommendations are followed, there would be less discrepancies between the device's accuracy amongst the patient pool.

Skin thickness is another skin factor that affects the accuracy of pulse oximetry devices [1]. More specifically, it was found that the thicker the skin, the less accurate the device was compared to patients with thinner skin [28]. During an experiment performed by scientists in 2020, enamel from molars was sectioned into 4mm, 3mm, and 2 mm thicknesses; each was placed between a finger and a gold stranded finger clip pulse oximetry device [28]. It was found that the 4 mm thickness, due to ambient light increasing, had a lower oxygen measurement than what the true value was [28]. Oppositely, the 2mm thickness caused less ambient light to come through resulting in a more accurate result [28]. From this, it can be concluded that the thicker the finger, the more ambient light was able to get through, which ultimately made the reading less accurate [28]. In the case of injuries where scarring can occur, these scars can raise the skin causing a thickness change [29]. This will reduce the accuracy of the device in more than one way as data suggests from the above paragraphs.

Skin texture contributes significantly to the accuracy of the device and impacts the usage of pulse oximetry devices for a wide range of patients [30]. It was found that in burn patients, typical transmissive pulse oximetry is not a suitable medical device due to the morphology of their skin [31]. It is important that from this, and our own understatement, our team for the purposes of the project defined a textural change to the skin to be wrinkles, hair, skin conditions, and more.

Skin temperature was found to make a large impact on the accuracy for the device; a study by a group of scientists in Switzerland found that skin temperature can have an effect and lead to inaccuracies in device readings [32]. Not only does the skin temperature affect the temperature of the sensor, but the sensor temperature itself also has an effect on the accuracy of the reading [32]. If the sensor or skin is colder, then the accuracy is reduced comparatively to the skin or sensor that is warmer [32]. With all of these skin factors in mind, it became clear to our team that variability amongst patient pools should be considered on a larger scale for future application in order to help mitigate accuracy issues.

### 2.4.2 Placement of Device

Pulse oximeters have been developed for the fingers, forehead, nose, foot, ears, or toes [33]. While it is advantageous to have different locations, it can be problematic as certain tissue sites are less compatible, as they produce less reliable readings [34]. Tissue blood volume varies in different areas of the body, relative to the amount and arrangement of blood vessels in the area [35]. One could infer that if the pulse oximetry reading is high, then the perfusion of blood is high, resulting in greater accuracy of reading [36]. In clinical settings, fingertips are more common due to data suggesting transmissive circuit reliability [1]. Along with where the device is placed on the body, variations of applied pressure influence the devices reading [37]. From this, it can be concluded that transmissive devices are more accurate as they can be used on the finger and there are many considerations to be had when developing pulse oximetry devices.

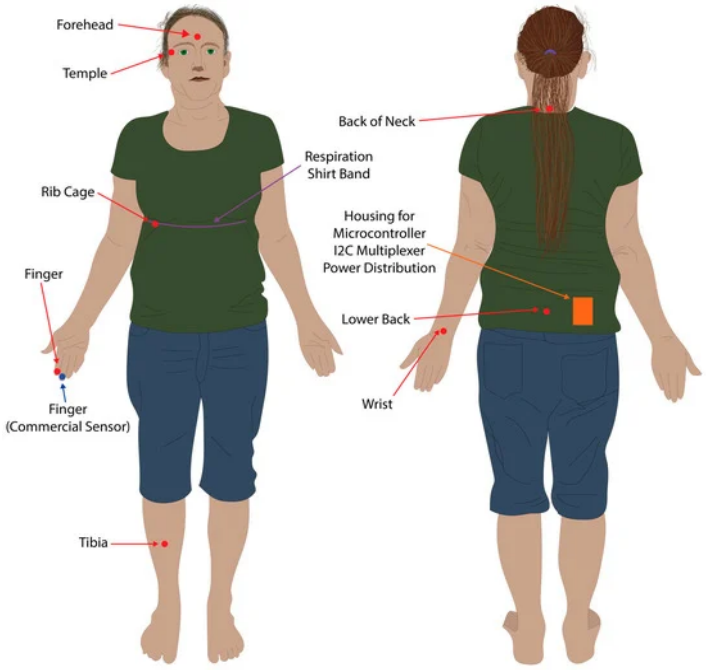


**Figure 2.8 - Ideal sensor placement locations for pulse oximeters (blue dots) compared to other sites (red and orange) [34]**

## 2.4.3 Skin Altering Adornments

Skin altering adornments have caused clinical personnel to question the reliability of pulse oximetry devices, and the FDA identified nail polish as being one of these adornments [1]. Fingernail polish hinders the ability of the light emitted from the LED to penetrate the tissue and acquire an accurate reading [38]. Research has shown that different colors of fingernail polish interfere with light penetration at different rates [38]. In fact, a study revealed that blue, green, black, and brown nail polish is most likely to cause up to a 5% underestimation in SpO2 readings [38]. Another study done on 30 healthy students found that all fingernail polish colors had some impact on pulse oximeter readings [39]. Researchers found similar results when investigating the effect of both red and black henna dye on the accuracy of pulse oximeter readings [40]. They found that red henna tattoos had no effect on the pulse oximeter reading, but there was a significantly higher amount of interference when measuring a finger dyed with black or dark henna [40]. From this it can be inferred that henna and nail polish result in inaccurate readings.

**Figure 2.9 - Example of henna [41].**

## 2.5 Current on Market Devices

In recent years, six major companies have produced and marketed these devices including but not limited to Medtronic, Masimo, Koninklijke Philips, Nonin Medical, Nihon Kohden, and Smiths Medical. Medtronic has a few patient-monitoring products for pulse oximetry [42]. They also sell sensors in the form of finger claps, finger rings, and toe rings [42]. Masimo focuses on handheld, self-monitoring pulse oximeters that are compatible with a phone app (via an app) [43]. Philips creates different devices for pulse oximetry such as a wristband design and various portable devices [44]. Nonin Medical focuses on fingertip pulse oximeters with Bluetooth compatibility [45]. Nihon Kohden has various devices and patents for pulse oximetry apparatuses that can aid in blood oxygen calibration, and use new methods for how a pulse oximeter functions [46]. Smiths Medical has several devices that combine the sensor with a handheld monitoring apparatus while also selling larger monitoring devices and smaller sensors [47].

For testing purposes, the team utilized an on-market device sourced from Amazon, the chosen device being the Zacurate Pro series 500DL [48]. Our team chose this device based on its simple portable design, black exterior, along with a display that includes the SpO2 reading, beats per minute, and the person's pulse.

## 2.6 Benefits to On-Market Devices

With various pulse oximetry devices on the market it was clear to our team that they all had similar attributes aiding in their functionality. Focusing on the common pulse oximeters used on fingertips, such as those manufactured by Medtronic and Nonin Medical, these are easy and universally used as they are clipped onto the finger of any patient for both quick readings or long-term monitoring [42][45]. Another major benefit of portable pulse oximeters is their ability to monitor one's blood oxygen saturation from anywhere and at any given time. Along with these benefits, some pulse oximeters use various sensors in their design as shown with the various examples described above [42-48]. This specifically allows for recordings to be taken from different locations of the body such as the ears and

hands as Koninklijke Philips focuses on, as well as improving the productivity and accuracy of the device itself [44]. Lastly, a relatively new benefit to most medical devices including those used in pulse oximetry is adding a Bluetooth component to them [45]. Our team believed this can be considered favorable in many applications and something future modernization could focus on.

## 2.7 Limitations of Current On-Market Devices

Based on the on-market devices referenced above; there is a clear distinction of what each company was trying to accomplish with their designs. The FDA has noted that over-the-counter devices pulse oximeters, classified as OTC (over the counter) oximeters, are not for medical use and are for monitoring purposes only [1]. It was found by the FDA that OTC are not as accurate and should not be used for medical purposes [1]. This is a major limitation as devices are used and marketed as useful, in reality they are over the counter unreliable devices. To combat the limitations above while still keeping the benefits of these various devices, it was our team's opinion that future devices should be more accessible in order to reach a larger population while also increasing accuracy with various engineering principles. We believe that the device should work regardless of surface textures or pigmentation, to optimize the device for a completely universal product.

# Chapter 3.0 Project Strategy

For this project to be successful, our team decided to use our preliminary research, initial client statement, and our revised client statement to guide the first half of our project. From this research, we were able to support our initial client statement, and then revise it to meet the needs and objectives gathered from our preliminary research.

## 3.1 Initial Client Statement

Our team was given an initial client statement that stated:

"Assess whether the current gold standard for measuring blood oxygen saturation can be modified to perform accurately for darker skin tones. Design a novel non-invasive, inexpensive method to accurately measure blood oxygen saturation or lung function for all skin tones."

Our team was tasked with coming up with a project that addressed this client statement effectively and efficiently. As a result, our project began with a literature review of current and past research regarding pulse oximeters themselves. Our aim was to better understand the device we were looking to innovate. The team explored the technical mechanics of a pulse oximeter and how it receives and relays information, and how and by whom that data is used to identify blood oxygen saturation levels. Through this, our team concluded on the following objectives, constraints, and justifications that led us to our final client statement which we used as the focus point for our project

.

## 3.2 Objectives & Constraints

Focusing on the objectives, there were eight main functions that we believed our device should have been:

1. Portable
2. Handheld
3. Lightweight
4. Usable by all age ranges capable
5. Accurate
6. Time efficient
7. Reliable

From this, our team wanted our design to encapsulate all of these goals, however there was particular emphasis on accuracy, reliability, and portability. Some possible constraints our team identified were making our device cost effective and keeping the time of measurement down. Our goal was to be as time efficient as possible, but it would be a challenge given the research that we had done.

## 3.3 Specifications

There were many design requirements that needed to be met to effectively and efficiently design our device. The main requirement was that the device had to work on all skin surfaces, thicknesses, and

pigmentations as this was the goal of the project. From our literature review, our group came up with the following requirements for our device.

1. The device must accurately measure blood oxygen saturation in the blood with little error regardless of skin pigmentation, texture, or thickness
2. The device needs to function properly on all sizes from newborns to the elderly
3. It must not depend on an electrical power source
4. The device must function properly while being easy to use
5. Create a pulse oximetry device that could read the blood oxygen saturation level accurately within two - thirty seconds
6. Optimize accuracy by reading within a 80 - 100% oxygen saturation with a maximum error of 3%

Some of these specifications, such as specification 6, were based on FDA standards and recommendations [49]. FDA currently requires an accuracy around 70 -100% oxygen saturation reading with maximum error of 6% [1]. This was our team's main specification we attempted to follow.

## 3.4 Final Client Statement

After completing our literature review and comparing the information gathered to our initial client statement, our team decided to revise our client statement to better match our findings. The revised client statement is:

"Our project aims to create a pulse oximetry device capable of effectively and efficiently achieving an accurate SpO2 reading for people of all pigmentation, thickness, and skin surface. The device should be a non-invasive, inexpensive, portable, handheld tool designed for use by the general public and the medical sector."

This made it very clear to our team that an ideal pulse oximeter should be a versatile piece of equipment that is portable, commonly handheld device, durable, and of low cost in order to increase the accessibility to underrepresented communities.

## 3.5 Project Approach

For this project, our team intended to create a handheld pulse oximeter device that would overcome the design flaws that current pulse oximeters have. To do this, our team started with primary research for the first seven weeks of this project. Our team then brainstormed and began designing a series of prototypes with each prototype highlighting one or more of the various issues discovered in our preliminary research. After all our designs had been created, we created a weight chart and gave each major function the device needed to be able to perform and each qualification the device had to meet a numerical value. The weight chart was used to compare each of our prototype designs to determine which device would meet most or all of the proper functions and qualifications. Prototype designs that did not meet all the required marks were held in reserve in case the primary idea failed.

With our primary prototype design selected, the team began constructing the actual prototype of the device and then tested the device. The tests for the prototype were created and their goal was to test if

the prototype matched our client statement, specifications, objectives, and our constraints. Data collected from the prototype's tests were used to modify the initial design or scrap the design entirely if it turns out that the design performed very poorly on all tests. This process of design, prototype construction, testing, and redesign occurred several times until a design occurred until the prototype passed all of the initial tests. The prototype would be selected as our final design and the final product would be constructed and tested again to ensure it functioned correctly and met all qualifications. If the device did not pass all the testing, modifications would be made to the device until it completed all the testing. The final product that passed all tests became our completed, fully functional device.

### 3.5.1 Gantt Chart

**Table 3.1: Gantt chart showing the team's deliverable deadlines throughout the term**

| Timeline | Month | | | | | | |
|---|---|---|---|---|---|---|---|
| | 1 (9/1 - 9/30) | 2 (10/1 - 10/31) | 3-4 (11/1 - 12/17) | 5 (1/10 - 1/31) | 6 (2/1- 2/29) | 7 (3/1 - 3/31) | 8 (4/1- 4/30) |
| Literature Review | | | | | | | |
| Project Strategy and Needs Analysis | | | | | | | |
| Conceptual Designs | | | | | | | |
| Prototyping | | | | | | | |
| Testing Methods | | | | | | | |
| Testing Prototypes | | | | | | | |
| Editing Designs Based On Test Results | | | | | | | |
| Final Design and Analysis | | | | | | | |
| Considerations and Recommendations | | | | | | | |

# Chapter 4.0 Design Process

## 4.1 Needs Analysis

### 4.1.1 Stakeholders

Based on an extensive literature review of market needs and inaccuracies of current on-market pulse oximetry devices, our group identified the following key stakeholders: doctors, nurses, end users, and healthcare personnel, using our own knowledge and experiences. We defined healthcare personnel as anyone within but not limited to, emergency medicine, concierge medicine, or other branches of medicine that would require monitoring of blood oxygen saturation. These stakeholders ultimately are our end users, who are defined by our team as anyone who is monitoring blood oxygen levels.

### 4.1.2 Needs Statement

Based on the findings of our literature review, our group had identified that our pulse oximetry device should be portable, handheld, cost effective, and work on all skin surfaces, thicknesses, and pigmentations. Other objectives or modifications that would be optimal include the device having a faster response time, being bluetooth compatible, inexpensive, lightweight, user friendly, and universal sizing. The following is a pairwise comparison chart outlining the importance of each objective. A value of 0 represents that both objectives or modifications were equal in value to each other. A value of 1 meant that the objective or modification on the left side was more important the method or modification it was being compared to. A value of -1 meant that the objective or modification on the left side was less important than the method or modification it was being compared to. The values were then summed together to determine the overall importance of a certain objective or modification.

As shown by the pairwise comparison chart in Table 4.1, usability, accuracy, and universal sizing was the most important for our device. Accuracy and universal sizing are tied at a total of 4 points. Our goal was to make a more accurate pulse oximetry device to work on all skin surfaces, thicknesses, and pigmentations. To do this, accuracy and universal sizing were critical to focus on during the design engineering portion of the project. Bluetooth was the least important objective to focus on scoring -8 total points, and the intention with the Bluetooth objective was a want not a necessity, and as such scored low compared to the other objectives. The rest of the objectives were somewhere in the middle and acknowledged and attempted to be solved during the design process.

**Table 4.1: Pairwise chart comparing each of our objectives and modifications to determine which objective(s) take priority over others**

| | Portable | Handheld | Inexpensive | Time Efficient | Bluetooth | Universal Sizing | Accuracy | Usability | Lightweight | Total |
|---|---|---|---|---|---|---|---|---|---|---|
| **Portable** | | 0 | 0 | 1 | 1 | 0 | 0 | -1 | 0 | 1 |
| **Handheld** | 0 | | 0 | 0 | 1 | -1 | -1 | -1 | -1 | -3 |
| **Inexpensive** | 0 | 0 | | 1 | 1 | -1 | -1 | -1 | 1 | 0 |
| **Time Efficient** | -1 | 0 | -1 | | 1 | -1 | -1 | -1 | 1 | -3 |
| **Bluetooth** | -1 | -1 | -1 | -1 | | -1 | -1 | -1 | -1 | -8 |
| **Universal Sizing** | 0 | 1 | 1 | 1 | 1 | | 0 | -1 | 1 | 4 |
| **Accuracy** | 0 | 1 | 1 | 1 | 1 | 0 | | -1 | 1 | 4 |
| **Usability** | 1 | 1 | 1 | 1 | 1 | 1 | 1 | | 1 | 8 |
| **Lightweight** | 0 | 1 | -1 | -1 | 1 | -1 | -1 | -1 | | -3 |

## 4.2 Mechanical Conceptual Designs

Based on the specifications and criteria for our project, we broke the project up into two parts: mechanical design and electrical design. Our electrical sections focused on designing our circuit and creating an analysis code to take the readings from our circuit and convert it to usable, qualitative data. Our mechanical section was focused on the creation of the holder which would house our electrical circuit and analysis code. Out of all the design ideas that were discussed, there were three conceptual designs that were potential solutions for our project. They are classified as “The Patch”, “The Wristband”, and the “Malleable Finger Splint”.

### 4.2.1 The Patch

Our first conceptual design created was developing an adhesive patch sensor. The physical model would use a reflective sensor which would slide and stabilize on top of an adhesive clear patch. The patch would be single use, and ordered from a manufacturer. The reflective sensor would remain the same, and a new adhesive patch would slide/stick under the sensor for each new patient. This versatile pulse oximeter patch could be placed on different locations of the body. Placement of the device is crucial for pulse oximetry readings, some areas of the body are shown to have more accurate readings [34]. The patch can be placed anywhere on the body, such as the wrist, back of neck, forehead or sole of the foot. The patch, since it sticks to the skin, requires no molding or constant pressure.

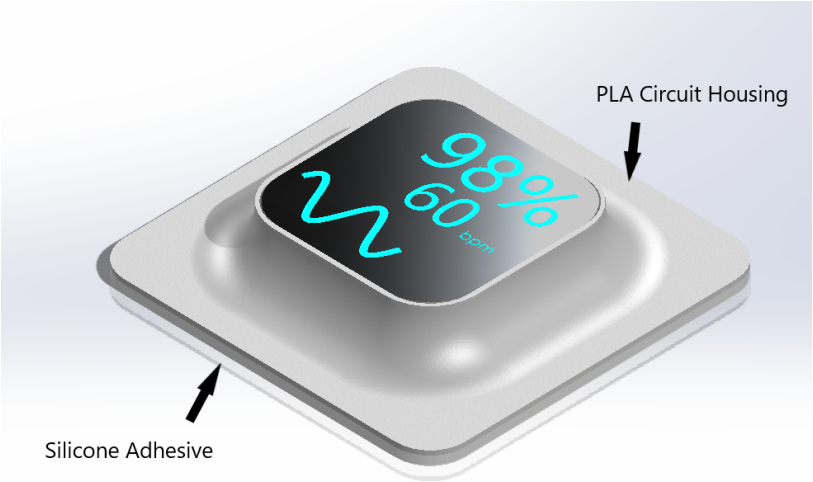


**Figure 4.1 - Exploded and assembled view of patch design modeled in Solidworks.**

### 4.2.2 The Wristband

Our second conceptual design was a wristband. The wristband is compatible and designed to be used with the universal hub. The wristband design was based on current designs of watch-style pulse oximeters, and common fitness watches. The band used for the wristband was to be made of cushioned silicone or rubber-based material and are intended to come in three sizes: small, medium, and large. These sizes were intended to make the device as universal as possible and determined by ranges of the weight of the patient. The sizes would correspond to the various sized wrists and ankles that health professionals may encounter. The main function of the wristbands is to fixate the hub to the wrist or ankle of a patient to reduce motion while acquiring a reading. The design would address two major sources of inaccuracy affiliated with pulse oximeters and make the device very versatile for emergency medicine. By having various wrist bands the oximeters can be better fitted to patients' bodies when acquiring and thus reduce light scattering, excess motion, and other factors that affect reading accuracy.

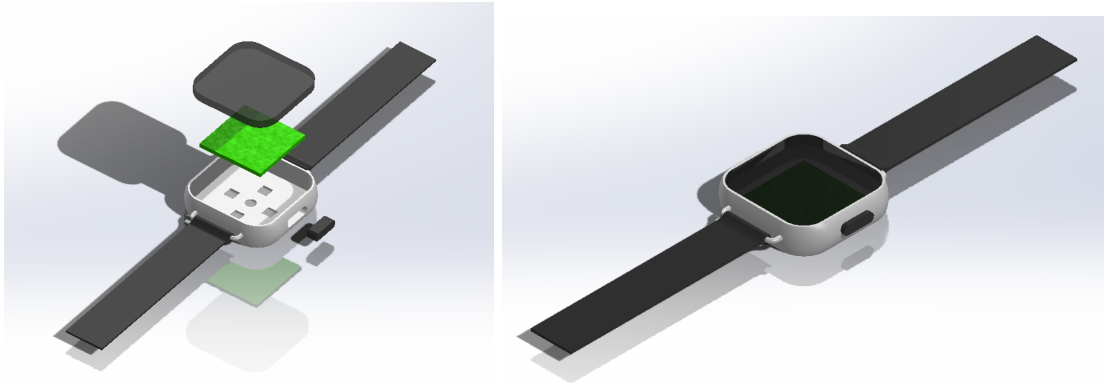

**Figure 4.2 - Exploded and assembled view of watch design modeled in Solidworks.**

### 4.2.3 Malleable Finger Splint

Our final conceptual design takes on a form very similar to splints for finger fracture fixation. The main feature of this concept is that it would have a transmissive oximetry system hub with a flexible aluminum shell and closed-cell polyurethane foam inner walls. The aluminum would allow the model to be molded around the patient's finger, ear, toe, etc. no matter the size or morphology of the subject. This would make the device accessible to individuals of all ages and enable physicians to work around most obstructions and still ensure secure attachment with the silicone strap to aid in this task as well. The foam walls could act as a second form of malleability, as it can expand around the subject to fill gaps and block ambient light, thereby potentially increasing accuracy. The foam's main purpose is for aiding in light occlusion but, the material's soft and pliable nature would also make wearing the device more comfortable for extended periods of time. The circuitry, display, and user interface will all be held in the hard polylactide (PLA) hub. The light source and photodiode are within this hard plastic casing to ensure there is not any loss of alignment when molding the outer portion. These materials were chosen not only for their mechanical properties but also for the ability to be cleansed after use and allow for the device to be transferred between different people without the risk of spreading illness. One of the major drawbacks of this malleable design is that with repeated remodeling the device could cause wear over time. This type of device may not be suitable for use by emergency services as the remodeling process would take time and the device would see significantly more abuse in this setting.

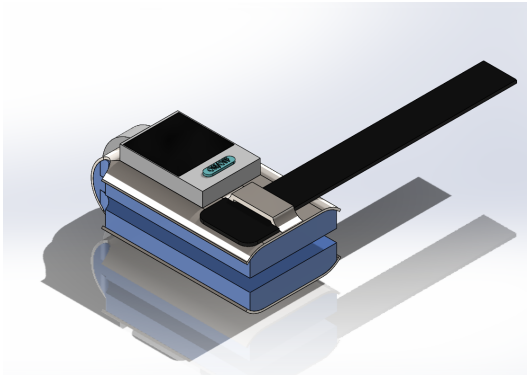

**Figure 4.3 - Isometric view of the malleable finger splint design modeled in Solidworks.**

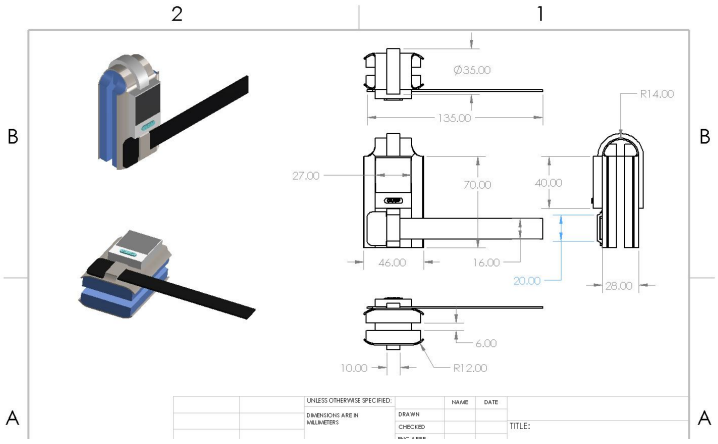


**Figure 4.4 - Schematic of the malleable finger splint design with dimensions drawn in Solidworks.**

An alteration of the same malleable device concept would feature a circuitry hub that is not directly attached to the main oximeter but instead connected via a plug as seen in Figure 4.5. This could allow for even more flexibility with attachment of the device to the subject. The main advantage of this separation, however, is to allow more space for electrical components and perhaps allow for an alternative power source.

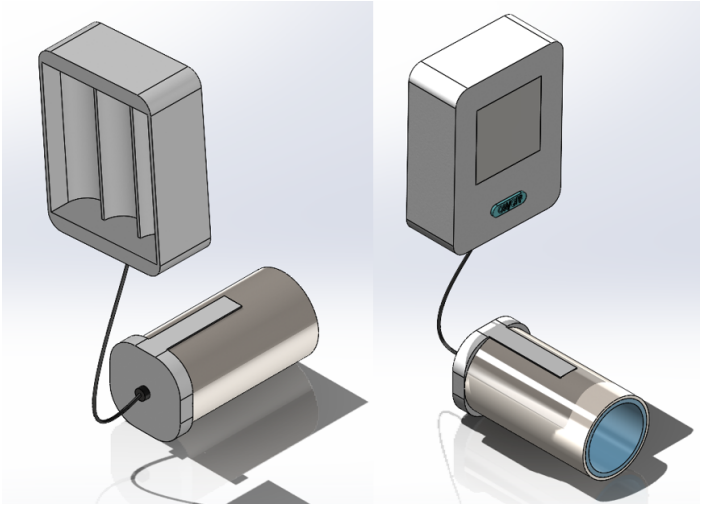

**Figure 4.5 - Front and back isometric view of potential alternative to the malleable finger splint design molded in Solidworks.**

## 4.3 Circuitry Conceptual Designs

### 4.3.1 Transistor with LED

Our first circuitry design involved putting a red LED and an infrared in parallel connected to a transistor. The goal of this circuit was to create a transmissive compatible LED circuit that would take the data generated by the two LEDs and be amplified by the transistor so that it could be read by a photodiode. Figure 4.6 shows the schematic of this circuit along with the values of the resistors and capacitors used when this circuit is powered with 5V. The calculations for these resistors and capacitor values can be seen in Appendix H.

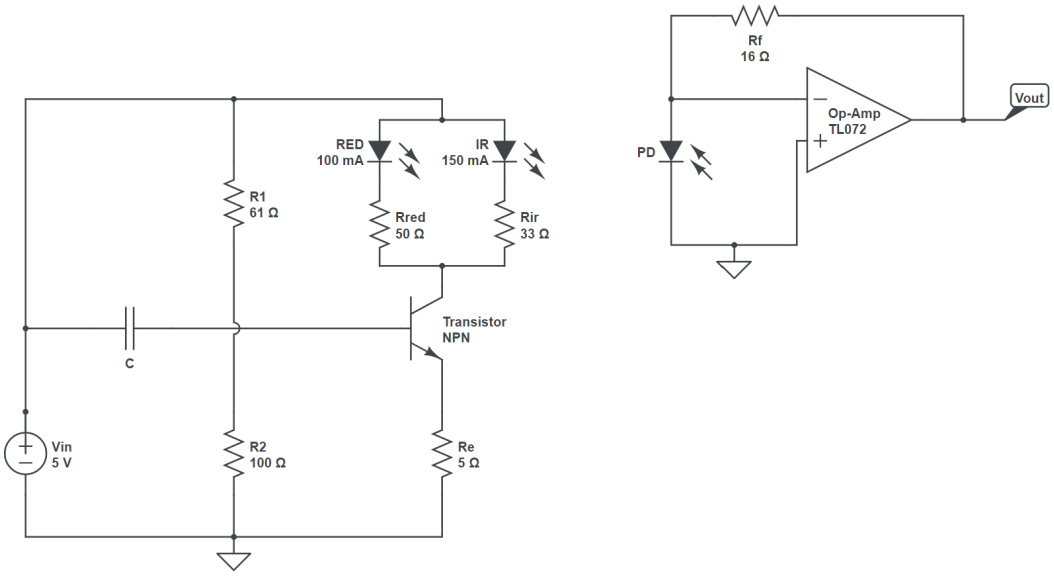


**Figure 4.6 - Circuit Schematic of LED circuit.**

The benefit of using a transistor in this way is:

1.) The circuit can be set to only read the data collected from the LEDs at a specific frequency based on the capacitor used.
2.) The current can be amplified in the circuit without needing a large external power source being added to the circuit

With these two benefits, this circuit can use a small power source (5Vs) to generate the current to power the two LEDs and the transistor to amplify the circuit to be read by the photodiode. This circuit also can be fine tuned to only look for signals at a specific frequency, and these frequencies can be set to the frequency needed to determine the amount of oxygenated and deoxygenated blood in the body. The value of the capacitance generated by the capacitor directly correlates to the frequency the circuit is set to. Our team determined this circuit had a high chance of success since most of the design was based off of currently used pulse oximeters.

## 4.3.2 Transistors with Lasers

Our second circuit design is similar to our first design, but instead of LEDs being used, laser diodes are used to determine the amount of oxygenated and deoxygenated blood in the body. The goal of this circuit was to create a transmissive compatible laser diode circuit that would take the data generated by the single laser diode and amplify it using the transistor so that it could be read by a photodiode. Figure 4.7 shows the schematic of this circuit along with the values of the resistors and capacitors used when this circuit is powered with 5V. The calculations for these resistor and capacitor values can be seen in Appendix H.

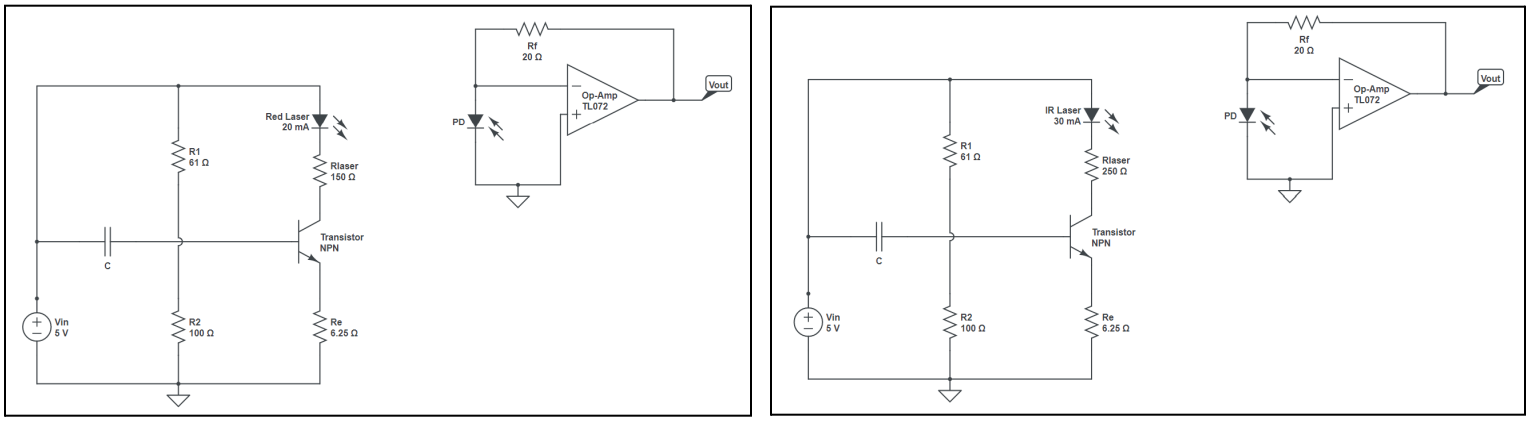


**Figure 4.7 - Circuit Schematic of both Red 660 nm Laser (Left) and Infrared 780 nm Laser (Right).**

The benefit of using a transistor in this way is:

1.) The circuit can be set to only read the data collected from the LEDs at a specific frequency
2.) The current can be amplified in the circuit without needing a large external power source being added to the circuit
3.) A laser diode could prove to be more accurate then using LEDs

Benefits 1 and 2 provide the same result as the Transistor with LED design idea and the only difference between the two ideas is the use of a singular laser instead of two LEDs.

## 4.3.3 Photodiode with Amplifier

The second half of our circuits described in the previous section consist of a photodiode and transimpedance amplifier. As the LED and laser diodes mentioned above shine light at the skin which is then absorbed by the blood, the photodiode measures how much light was absorbed [2]. In electrical terms, the LED and Laser diodes emit a current, which the photodiode then collects and amplifies using a transimpedance amplifier [25]. The only difference between this part of the two circuits is the feedback resistor used in the transimpedance amplifier.

The transimpedance amplifier, as mentioned in section 2.3.3, is used to convert the current read from the photodiode to voltage [23]. To do so, an inverting op-amp is used with a feedback resistor connected to the negative op-amp terminal and the op-amp output. Again, this feedback resistor is the only difference between the two circuits as the resistance value depends on the current read by the photodiode. In the LED circuit shown in Figure 4.6, the current produced by the two LEDs in parallel would be equal to the sum of the two individual currents, which is 300 mA in our case. With this, the feedback resistance was calculated to be about 16 ohms. As for the laser circuit shown in Figure 4.7, there is only one light source in the circuit causing the emitted current to be 250 mA and the feedback resistance to be 20 ohms.

# Chapter 5: Final Design Verification

## 5.1 Design Verification: Laser Circuit

Modern pulse oximeters utilize three main components to monitor blood oxygen saturation levels: a red LED, an infrared LED, and a photodiode [2]. Normally, these LEDs are wired in series with their own respected resistors with values calculated based on the LEDs current and in parallel to one another. The photodiode is placed directly in line with both LEDs with a space between them that allows for the finger to pass through [2]. To modify the normal pulse oximeter design, our team decided to replace the LEDs with lasers of similar wavelengths as our research states that lasers penetrate the skin better than LEDs [16][17]. The team also added a transimpedance amplifier where the photodiode would be fed into the non-inverting terminal of the operational amplifier (op-amp) used to convert its current output to voltage. This modification circuit was tested simultaneously with a gold standard pulse oximeter using the normal LED configurations so the team did not have to build two separate circuits as originally planned due to the restricted timing for the project.

To create our modified pulse oximeter circuit, our team wired 4.5 Volts directly to the laser being used as for simplicity one laser was wired at a time into our 3D printed mold. For the laser representing the red wavelength of 660nm, a 100 ohm resistor was calculated to be wired in series with the laser using Ohm's Law (Appendix H). As for the laser representing the infrared wavelength of 780 nm, a 113 ohm resistor was calculated. However, as these values worked in both theory and practice, the differences in wavelength of the two lasers was too drastic in terms of intensity that the resistor values were altered slightly as shown in the final schematic below (Figure 5.1). From here, the two resistors were connected to ground to complete the laser portion of the circuit.

Directly in line with the laser was the photodiode, wired to an op-amp to create a transimpedance amplifier. The anode of the photodiode along with the non-inverting terminal of the op-amp were connected to ground while the cathode of the photodiode was connected directly to the inverting terminal of the op-amp. With this, a 1 megaohm resistor was also connected in parallel to the photodiode to act as an input resistor for the gain calculation of the amplifier. To calculate the gain, a feedback resistor was also needed. This feedback resistor was placed between the inverting terminal of the op-amp and the output of the op-amp. This resistor was set to 8.2 megaohms for a gain of 8.2 - following the calculation in Appendix H - which allowed for the very small observed readings to be amplified and read clearly without any component reaching its max capacity.

To see the signal generated by the photodiode in the circuit, the team switched between various platforms. First, the team worked with the National Instruments Elvis Instrument tools as the software works directly with the breadboard that the circuit was built on (Elvis 2). This software was used to power the board through a variable power supply that was manually set to positive and negative 4.5 Volts. The digital multimeter application of this software was also used occasionally to check actual values of used components such as resistance, capacitance, current, etc. The next software used was Logger Pro to visually see the signal graphically. This was done by including two new circuit components; a PPG sensor that recorded one's heart rate simultaneously, and another sensor that allowed for this visualization by graphing at a sampling frequency of 2000 Hz for 70 seconds. This software not only allowed the team to visualize and analyze the raw data in real time, but also export the files for further analysis using MATLAB.

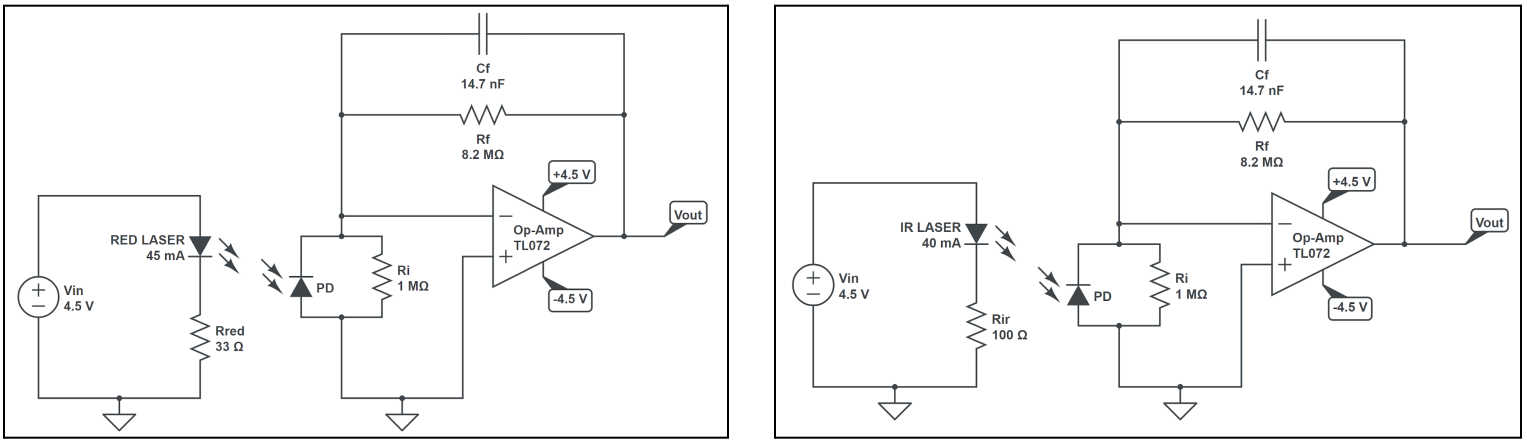


**Figure 5.1 - Final Circuit Schematic using 660 nm Laser (Left) and 780 nm Laser (Right).**

## 5.2 Design Verification: Analysis Coding

Pulse oximeters actively record the current readings from the LEDs to calculate an individual's pulse and blood oxygen level. This is done through a series of prewritten code and a pre-calibrated blood oxygen level chart in the form of an equation that functions when the device is turned on. Our team had to write up our own code to mimic the storage of data and the calculation of a person's pulse and blood oxygen level. The main difference between on the market device coding and our coding is that the team had to manually download any recorded data to a spreadsheet, edit the spreadsheet so that it was compatible with our coding, and then upload the spreadsheet to our code and run the code separately. The full code can be seen in Appendix L.

The following programs were used to work to collect, export and analyze our data:

1) MatLabR2022a for writing our code and running it with our collected data
2) Logger Pro 3.14 for collecting our data and exporting it as a spreadsheet
3) Microsoft Excel for formatting and editing our data so that it was usable in our MatLab code

The first part of the code was intended to take the collected data in a graph and remove ambient light as well as a bandpass filter operating for frequencies of 0.5 to 10 Hz. This would clean up our collected data by removing sources of noise found specifically at 60 Hz and ambient light which are sources of inaccuracy in typical pulse oximetry readings.

The next part of the initial code focused on determining a person's pulse which is a common practice for current on the market pulse oximeters. This part of the coding also involved determining the various frequencies of the collected data and seeing if there was still noise in our data. The code also showed what was the frequency of the noise (in Hz) and the resulting graphs would be used to revise the initial part of the code. During the early stages of testing the whole circuit and our code, our team would manually code in a low pass, high pass, or bandpass filter through MatLab based on the frequency of noise that was collected. The bandpass filter was the final filter we used as the noise graphs showed a large amount of noise was at a frequency of 60 Hz, and we were most interested in the information

collected between the frequencies of 0.5 Hz and 10 Hz. These graphs would not be a part of our final code as this code was purely for finding noise in our readings.

The second part of the code was used to calculate the amount of oxygenated and deoxygenated hemoglobin in the participant's blood based on the amount of absorbed red and infrared light. The first part of the code involved determining the range of the data points that would be analyzed within our large data set. This range must be identified as current on the market pulse oximeters collect instances of data (milliseconds in length) over an extended period of time. The collected instances are averaged out and used to determine a person's pulse and blood oxygen level.

This process was done at two instances in the code: once at the beginning to determine the photodiode's unobstructed reading of the light source and another instance while there is a finger obstruction. The unobstructed reading is needed to determine the total drop in voltage as a result of the oxygenated and deoxygenated hemoglobin absorbing the light and preventing it from being read by the photodiode.

The second portion of this code was used to calculate the AC and DC portions of the red and infrared light source which is used to calculate the blood oxygen level of a person. The code is written so that the peaks within the range of the analyzed data are isolated and the highest peak in the range is subtracted by the lowest peak in the range for both the AC and DC portion. With the analyzed section of data being in the span of milliseconds, the resulting value gives a relatively accurate representation. The AC and DC portion is shown by the maximum peak value and the minimum peaks value during the obstructed readings. The DC value was always smaller than the AC value. The final portion of the code is to take the AC value and divide it by the DC value to get half of the values needed for the R ratio. When this analysis is done for the red and infrared light source, the final red calculation is divided by the infrared valuation to get the R value. The final R value can then be compared to any blood oxygen calibration chart such as the one in Figure 2.3 to determine the blood oxygen level of a person.

## 5.3 Laser Verification

The data amongst a wide variety of therapeutic treatments has determined that clinical treatments can now be administered with equitable experiences across a wide range of patients [50]. Therapeutics that can now be done equitably include, but are not limited to, cosmetic rejuvenation, hair removal, and tattoo removal [50]. Laser skin resurfacing and treatment of atrophic scars have all been done and proven to have great clinical outcomes with a very minimal risk of complications [50]. Some who get skin remodeling have had no postoperative recovery, which is a significant advantage in many therapeutics for patient comfort and experience [50]. Using this information, our team had hypothesized that using laser diodes as a light source similarly seen in various therapeutics, would work to try and improve accuracy of current pulse oximeters. Lasers are more accurate than LEDs for various reasons, but the main reason being the penetration length of such lasers [16][17]. A laser's penetration varies depending on the wavelength, wavelengths between 750 – 850 nm is near infrared, and penetrate a little more than 600 -700 nm, which penetrate superficially into the skin [51]. Based on this information, our team bought the RLD78NZM5-00A 780 nm Laser Diode from Mouser Electronics as well as the RLD65PZX2-01A Laser Diode that has a wavelength of 660 nm [51][52]. Our team's hypothesis became that absorption of light, based on blood oxygen saturation levels in the body, can occur more accurately at a deeper level into the skin with the usage of lasers. In doing so, this hypothesis, if validated, will lead to an overall faster and more accurate reading from a pulse oximetry device.

## 5.4 Circuit Holder 3D Modeling and Printing

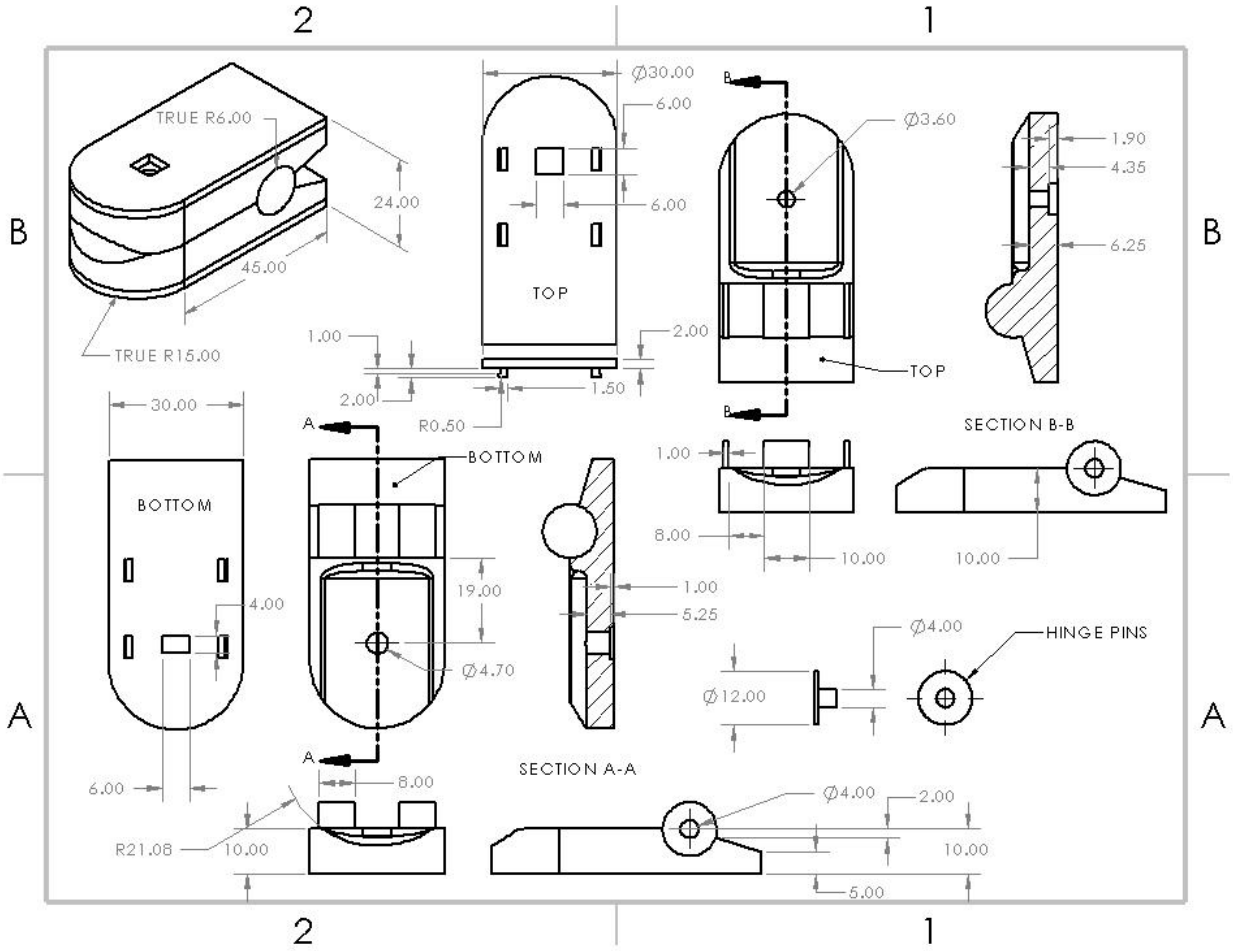


**Figure 5.2 - Solidworks sketch of the circuit cradle labeled with dimensions in millimeters.**

In order to test the capabilities of the modified oximeter circuit, our team needed to create a physical model that would simulate real pulse oximeter circuitry housing as closely as possible. To do this, an on-market pulse oximeter was studied and a simple device that closely mimics its form and dimensions was modeled via Solidworks. The on-market pulse oximeter that was used for this purpose was the Zacurate Pro Series 500DL as referenced in Chapter 2.5. The dimensions of the entire model are specified in Figure 5.2 . The main features of the device include a hinge with holes and pins to secure it and a smooth divet in each half for the fingertip to rest. There are two portals in which the laser and photodiode can sit in each half respectively. Each of these halves have a cover to secure the implanted component in place. The holes are printed to the exact dimensions of these components in order to ensure a stable securement and are aligned directly vertical of each other when the device is closed. The covers were secured via a simple hook protrusion in each corner that snapped into the divots made in the main body. Holes in the cover were made to allow the prongs of the components to be attached to wires. The dimensions of each electrical component were referenced from their respective datasheets and modeled as shown in the following diagram:

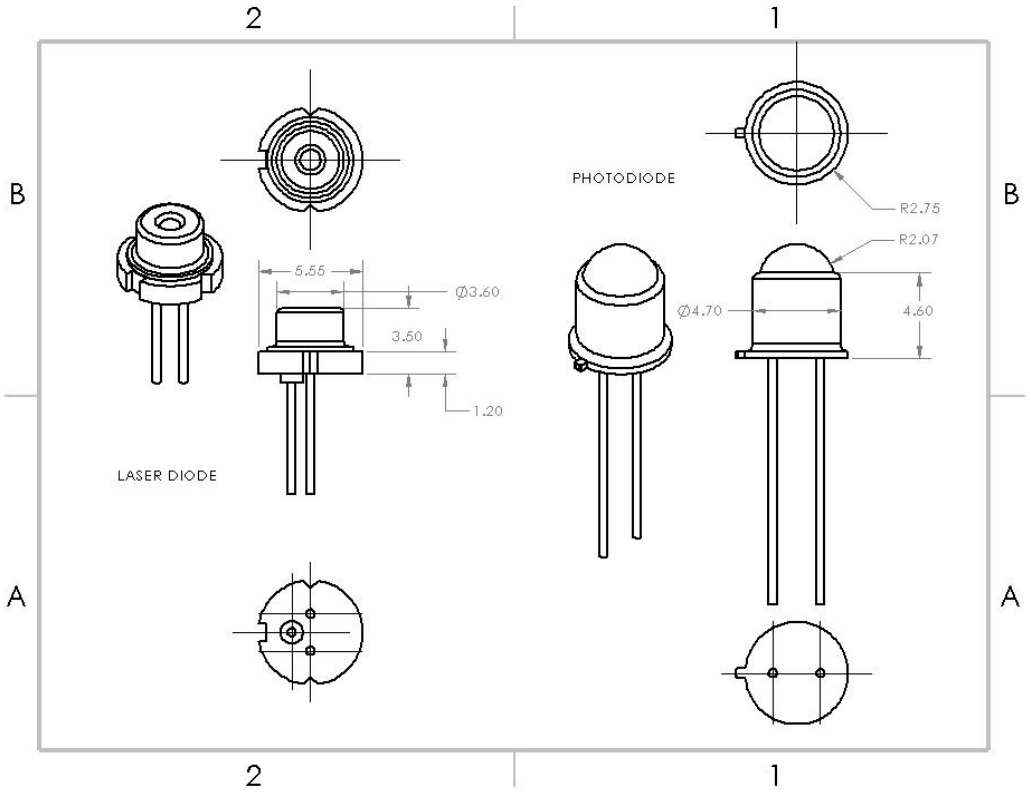


**Figure 5.3 - Diagram of the electrical components modeled.**

After modeling, the device was printed in black ABS filament on the Stratasys Dimension 1200ES as pictured below. This model was not our intended final design. While we were using this model to test our circuit, a series of other models were being developed which would culminate into our ideal final design discussed in chapter 6.

**Figure 5.4 - Photograph of model printed in ABS with implanted components.**

## 5.4.1 Updated Version #1

The first version our team came up with while trying to create our final design was modeled with the sole intention of creating a stabilization system to keep the light source and diode locked in position while testing subjects. The team attempted to accomplish this by utilizing short protrusions in the model that matched the inner and outer diameters of each component exactly. This design was also created with the intention of being easy to both disassemble and reassemble so parts could be easily interchanged when needed. This was obtained by using an modular interlocking system, which involved the creation of individual components with protruding sections that could be easily fitted into corresponding recesses on other components, resulting in a secure and stable final structure. Due to the fact that the components of the system were connected to the breadboard by means of extended wires, the cover had to have holes that fit the wires dimensions in a manner that effectively allowed the wires to be changed along with the components, while still offering sufficient stabilization  However, there were concerns regarding the amount of ambient light that would enter through these holes. To address this issue, a small tunnel was added to the top cover, allowing the wires to be fed through, while also minimizing the amount of ambient light that could enter the system.

This model despite meeting the design requirements was flawed in terms of printability. It had far too many small features and overhangs that were likely to collapse during the printing process. Many of the dimensions also needed to be modified to allow for clearance.

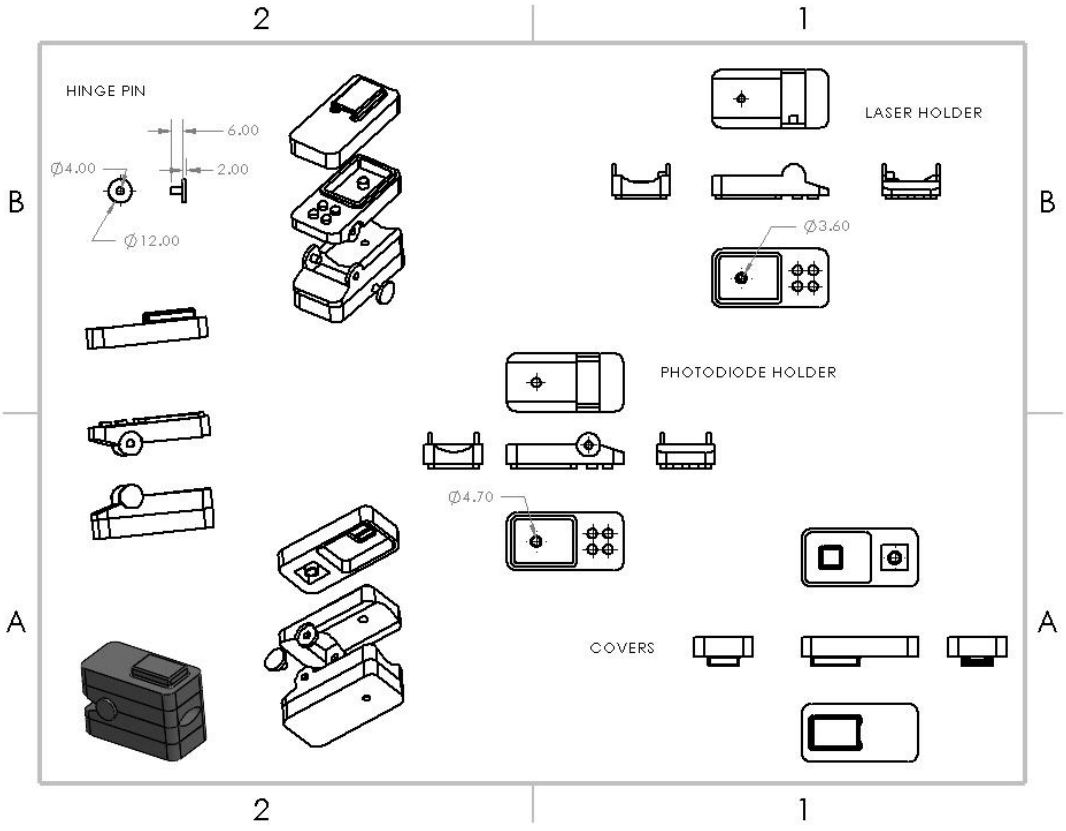


**Figure 5.5 - Sketch of version 1 of the circuit holder design.**

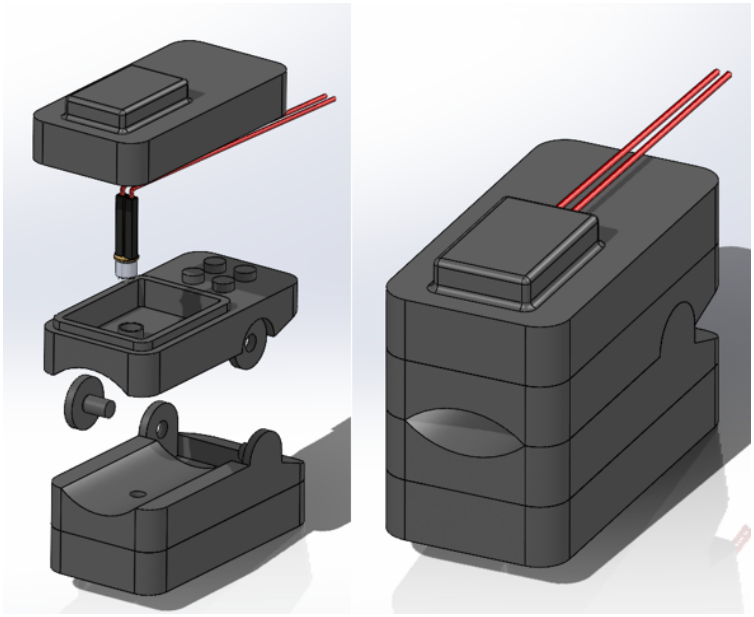

**Figure 5.6 - First version of the circuit holder exploded (left) and assembled (right).**

### 5.4.2 Updated Version #2

The second version sought to rectify the flaws of version 1 so that it could be printed and subsequently tested. The full sketch with dimensions is depicted in Chapter 5, Figure 5.7 and the resulting product is shown in Figure 5.4. This design simplified the area in which the components are placed by filling in the surrounding space and replacing the protrusions with simple holes, completely removing the overhangs of the last version. A significant simplification was made to the covers of the model by replacing the complex modular interlocking components with four small snap-fit hooks. As a result, the team was able to remove the previous unstable “wire tunnel” for the sake of accuracy. Additionally, to mitigate the risk of collapse during use, the hinge features were made more robust by adding additional mass.

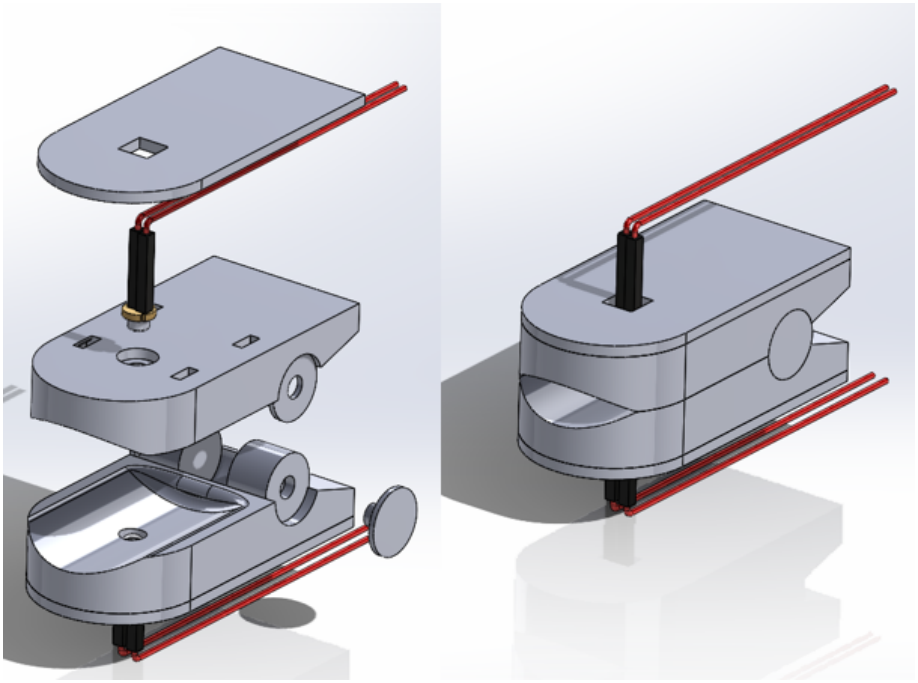

**Figure 5.7 - Second version of the circuit holder exploded (left) and assembled (right).**

### 5.4.3 Updated Version #3

The second version of the model was altered to allow for the use of two lasers simultaneously, resulting in a modified version that accommodates this requirement. The laser housing portion of the design now contained two holes to accommodate the red and infrared lasers, while the rest of the model remained the same as the second version. Figure 5.8 displays that the laser portals are both angled towards the location where the photodiode is placed. This particular design decision was necessary because, unlike typical pulse oximeters that use LEDs, lasers have very focused light beams. To ensure that both beams could directly reach the single photodiode, the holes were angled at 15 degrees. This design would be used as the groundwork for our final design where two holes for the lasers would be lined up with two holes for two different photodiodes.

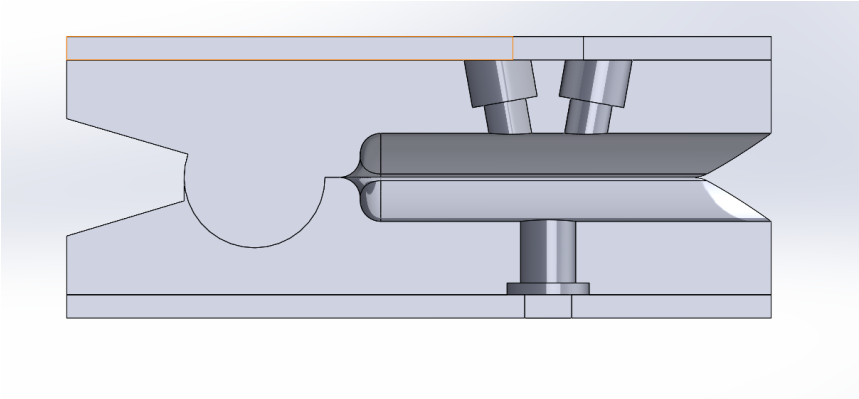

**Figure 5.8 - Section view of third version.**

# Chapter 6: Final Design Validation

## 6.1 Laser Circuit Validation

The first test with the laser circuit was to see if the lasers were able to penetrate the skin deep enough to get a clear voltage reading by the photodiode. Using our sitting testing method (Appendix C), we performed three tests with both the red laser and infrared laser. The results from this test showed that the lasers were able to penetrate the skin, allowing the photodiode to get a clear reading of voltage supplied by the unabsorbed laser.

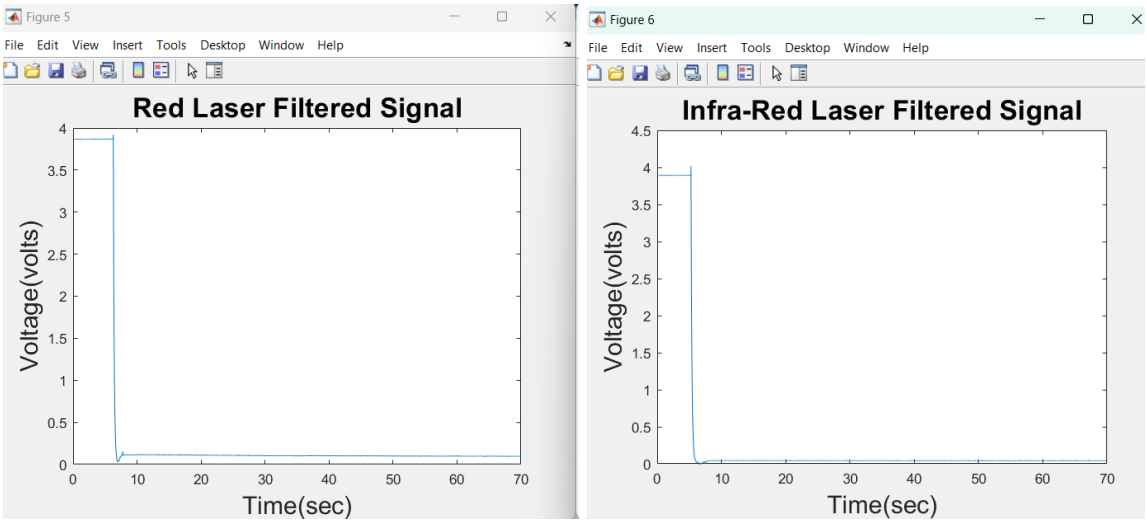


**Figure 6.1 - Red laser filtered reading and infrared laser filter single reading.**

Our second test with the circuit was determining if the laser was better at collecting a reading than an LED. Using our same sitting testing method (Appendix C), we ran three tests for each LED and laser individually. The red laser voltage readings of each test were then compared to the red LED readings, while the infrared laser voltage readings were compared to the infrared LED readings. The resulting data showed that in all instances, a more accurate reading was obtained from the laser compared to the LEDs. Despite the infrared LED signal having a high voltage reading,, this should only be the case if the red reading is higher than the infrared reading. In all cases, we saw that the infrared readings were higher than the red readings, which was unjustified by our prior research. With the laser consistently reading the red voltage higher than the infrared voltage, our team concluded that no further testing with the LEDs would be needed. We had collected the information that showed our specific circuit model measured an individual's blood oxygen level more accurately by using lasers rather than LEDs.

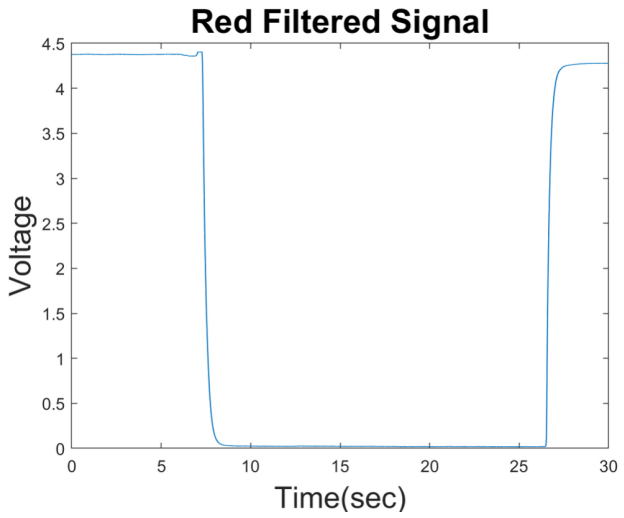


**Figure 6.2 - Red LED filtered reading.**

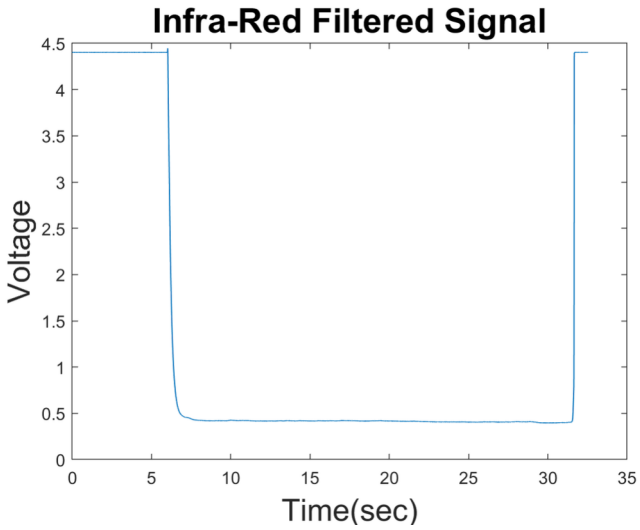


**Figure 6.3 - Infrared LED filtered reading.**

Once the laser was proven to be the superior light source for gathering a reading with our current circuit, we finished developing an analysis code that could take these voltage readings and turn it into usable, qualitative, SpO2 values.

## 6.2 Analysis Code Validation

In order to process the data obtained from the Logger Pro software, a function was written in MATLAB that would obtain the information from the both red and infrared .csv files acquired, and calculate the AC, DC, R, and SpO2 values. The function, oxygen_sat.m, could then be used in the following code to process all the data obtained in all the experiments that were run. The function is utilized in this way in the file processing code shown in Appendix K. The oxygen_sat.m function, also shown in Appendix K, accomplishes the calculation of SpO2 by first reading the red .csv file and obtaining the time and voltages from the photodiode. It then subtracts the value set as the ambient light reading which in this case was 0.013. Then it creates sample vectors of both voltage data sets based on the

defined timestamps, i.e. it creates variables with only the data from the 30s to 35s marks. To calculate AC values for both red and infrared, it utilizes the findpeaks function from the signal processing toolbox in MATLAB to find the systole and diastole peaks from the PPG sensor signal as shown in Figure 6.4.

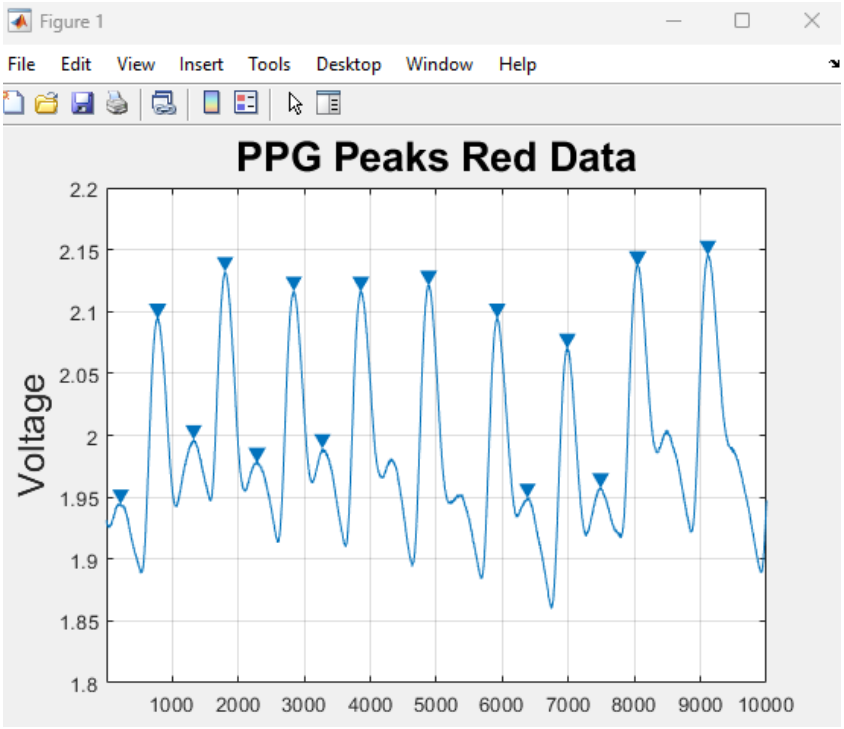


**Figure 6.4 - Annotated figure of the findpeaks function in which the arrows indicate selected peaks.**

This method is not completely reliable as the function occasionally misses the diastolic peaks since they are not dramatic as the systolic peaks. The code then takes the indices for the selected peaks and utilizes them to obtain the voltage values of the photodiode readings. The average of these values is the AC value for the data set. To calculate the DC value it simply takes the minimum photodiode voltage value of the sampled region. Once the red and infrared data sets are processed, the AC and DC values are entered into the equation for R as outlined in Chapter 2. The R value is then plugged into the calibration curve for SpO2 [53]. This code was used for all testing methods with only the time stamps being changed to analyze various sections of data.

## 6.3 Subject Testing With Our Final Circuit

A series of test were performed with the laser circuit to determine if: a) the circuit reading could be analyzed by our written code to accurately determined an individual's blood oxygen level; b) the effects of various obstructions and change in texture or pigmentation of a person's skin; c) the effects of movement; and d) the effect of temperature on our readings. For this text, six test subjects were acquired and their age, sex, and race was recorded prior to testing.

**Table 6.1: Subject demographics**

| Identifier | Age | Sex | Race |
|---|---|---|---|
| Subject 1 | 22 | Male | Caucasian |
| Subject 2 | 21 | Female | Caucasian |
| Subject 3 | 21 | Male | Middle Eastern |
| Subject 4 | 21 | Male | Caucasian |
| Subject 5 | 22 | Female | Caucasian |
| Subject 6 | 22 | Female | Caucasian |

In our first test, a subject would follow our sitting testing portion of the motion protocol (Appendix C). During this test, the subject's blood oxygen level would be taken from a gold standard, on the market, pulse oximeter while our circuit also recorded their blood oxygen level. Following the collection of the data, the data would then be imported into the code to obtain the blood oxygen level measured form our circuitand compared to the gold standard's reading. The table below shows some of the comparisons for two different test subjects. Additional tables of comparisons that show similar results can be seen in (Appendix I)

**Table 6.2: Comparison of subject 1's blood oxygen level using our circuit and analysis code compared to the reading in a gold standard device.**

| Subject-Activity | Subject 1-Sitting Blood Oxygen level % | Gold Standard Blood Oxygen Level % |
|---|---|---|
| Reading 1 | 95.7 | 95.1 |
| Reading 2 | 95.8 | 95.4 |
| Reading 3 | 95.2 | 95.8 |
| Reading 4 | 95.3 | 95.1 |
| Reading 5 | 94.4 | 96 |
| Reading 6 | 94 | 97 |
| Average Blood Oxygen Reading | 95.1 | 95.73333 |

**Table 6.3: Comparison of subject 3's blood oxygen level using our circuit and analysis code compared to the reading in a gold standard device.**

| Person-Activity (subject 3) | Subject 3- Sitting Blood Oxygen level % | Gold Standard Blood Oxygen Level % |
|---|---|---|
| Reading 1 | 95.8 | 97 |
| Reading 2 | 95.8 | 97 |
| Reading 3 | 95.6 | 97 |
| Reading 4 | 95.7 | 97 |
| Reading 5 | | |
| Reading 6 | | |
| Average Blood Oxygen Reading | 95.7 | 97 |

## 6.3.1 Effect of obstructions and skin pigmentation change.

With the circuit able to provide a real blood oxygen reading of our subject, the next set of tests focused on addressing if our laser circuit was capable of gathering accurate readings when there was an obstruction added or pigmentation change. Using several testing methods found in Appendices D and E, we once again performed these tests with our model and the same gold standard pulse oximeter. The same analysis code was used and the following table shows some of our results. Additional tables of comparisons that show similar results can be seen in (Appendix I)

**Table 6.4: Comparison of subject 1's blood oxygen level using our circuit and analysis code compared to the reading in a gold standard device with a fake nail obstruction.**

| Person-Activity (subject 1) | Subject 1 -Sitting-Nail | Gold Standard Blood Oxygen Level % |
|---|---|---|
| Reading 1 | 94 | 97 |
| Reading 2 | 79.3 | 97 |
| Reading 3 | 65.4 | 92 |
| Reading 4 | 69.6 | 98 |
| Reading 5 | | |
| Reading 6 | | |
| Average Blood Oxygen Reading | 77.1 | 96 |

**Table 6.5: Subject 1's blood oxygen level using our circuit and analysis code compared to the reading in a gold standard device with a tattoo obstruction. The gold standard device was unable to produce a reading and so no gold standard data was reported.**

| Person-Activity (subject 1) | Subject 1 -Sitting-Tattoo |
|---|---|
| Reading 1 | 73.2 |
| Reading 2 | 86.1 |
| Reading 3 | 59.2 |
| Reading 4 | 95.8 |
| Reading 5 | 95.8 |
| Reading 6 | 22.3 |
| Average Blood Oxygen Reading | 72.1 |

## 6.3.2 Effect of movement

Our last two sets of tests focused on what would happen if the environment of the measured finger changed. The first portion of these tests focused on movement, both locally at the finger and in general as if the subject was moving around. Using our motion protocols (Appendix C), the following results were obtained through our code. Additional tables of this same test can be seen in Appendix I.

**Table 6.6: Subject 1's blood oxygen level readings while the subject was moving their arm with and without a nail obstruction**

| Person-Activity (subject 1) | Subject 1-Arm Moving Blood Oxygen level % | Subject 1 - Arm Moving Blood Oxygen level % with nail obstruction | Gold Standard Blood Oxygen Level % | Gold Standard Blood Oxygen Level % with nail obstruction |
|---|---|---|---|---|
| Reading 1 | 5.8 | 72.6 | 92 | 98 |
| Reading 2 | 83.4 | 93.3 | | |
| Reading 3 | 95.6 | 95.7 | | |
| Reading 4 | 94.8 | 76.4 | | |
| Reading 5 | 95.5 | | | |
| Reading 6 | 87.6 | | | |
| Average Blood Oxygen Reading | 77.1 | 84.5 | 92 | 98 |

**Table 6.7: Subject 1's blood oxygen level readings while the subject was standing up and down with and without a nail obstruction**

| Person-Activity (subject 1) | Subject 1 -Standing Blood Oxygen level % | Subject 1 -Standing Blood Oxygen level % with nail obstruction | Gold Standard Blood Oxygen Level % | Gold Standard Blood Oxygen Level % with nail obstruction |
|---|---|---|---|---|
| Reading 1 | 83 | 86.1 | 97 | 97 |
| Reading 2 | 70.7 | 64 | | |
| Reading 3 | | 76.9 | | |
| Average Blood Oxygen Reading | 76.8 | 75.7 | 97 | 97 |

## 6.3.3 Effect of temperature change

The last test was used to see how high and low temperatures relative to room temperature affected our readings. Using both temperature testing protocols (Appendix A), we were able to see the effect of hot and cold temperatures on various subject readings. Additional readings can be seen in Appendix I.

**Table 6.8: Subject 3's readings comparing their sitting, standard reading**

| Person-Activity (subject 3) | Subject 3-Sitting | Subject 3-Cold | Subject 3-Hot | Gold Standard Blood Oxygen Level % | Gold Standard Cold Reading | Gold Standard Hot Reading |
|---|---|---|---|---|---|---|
| Reading 1 | 95.8 | 91.1 | 95.7 | 97 | 99 | 97 |
| Reading 2 | 95.8 | 61.1 | 95.7 | 97 | | |
| Reading 3 | 95.6 | | | 97 | | |
| Reading 4 | 95.7 | | | 97 | | |
| Average Blood Oxygen Reading | 95.7 | 76.1 | 95.7 | 97 | 99 | 97 |

## 6.4 Conclusion Circuit Validation With Analysis Code

Based on our analysis of our laser circuit when comparing our final blood oxygen readings to a gold standard device, we can conclude that our laser circuit seen in Figure 5.1 provides reliable, consistent results of data collection of a person's blood oxygen level. This is further validated with our final code

which was modified from the initial code which was used to validate that the readings we were getting were in fact oxygenated and deoxygenated hemoglobin. The newest code has two parts to it: a main file and a function file (see Appendix K). The main file can take any number of collected red and IF data files and, when organized in an alternating pattern of red and infrared values, can be analyzed and the person's blood oxygen level can be displayed in a spreadsheet. The function file is what data analysis produces the person's blood oxygen level. Unlike the old code, this code is simplified and is able to determine the systolic and diastolic peaks which correlates to hemoglobin moving into the finger and deoxygenated hemoglobin moving out of the finger. The recorded peaks are used to calculate the R ratio needed to determine a person's blood oxygen level on a blood oxygen calibration chart. Finally this code has its own calibration curve from [53] and the code actively calculates a person's blood oxygen level from the calculated R value. Below is a breakdown of the function code highlighting the key parts of the peak identification, R calculation, and blood oxygen level calculation.

## 6.5 Final CAD Design Validation

Our final model for the circuit avoided the angled holes in favor of two separate aligned holes for the lasers and photodiode that can be used interchangeably. This modification was made since our testing was done with this exact same model except our model had one hole at the top and bottom not two. The ideal testing situation would call for the red and infra laser working at the same time, so our final holder would have the two holes to meet the need of two lasers each with their own photodiode directly across from it. Other changes to the design were the small recesses for the covers were removed entirely and the overall height was reduced for ease of printing. Hinge clearance was also addressed and increased from 0.1mm to 0.2mm.

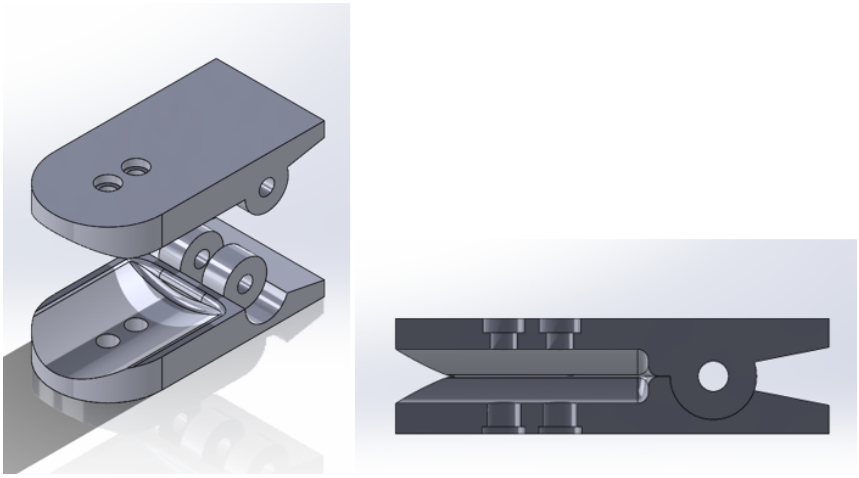

**Figure 6.5 - Exploded (left) and section (right) views of the final version.**

## 6.6 FDA Standards (510k Clearance)

To validate whether our device would be allowed to become a product, we tried to remain within the FDA standards for pulse oximeters.

The FDA describes a pulse oximeter as a "device used to transmit radiation at a known wavelength(s) through blood and to measure the blood oxygen saturation based on the amount of reflected or scattered radiation" [54]. Obviously our device falls under this definition.

The FDA recommends identifying the intended use of the device [55]. These devices can be standalone or multi-parameter modules [55]. They can be intended for both spot-checking and continuous monitoring of blood oxygen saturation [55]. The models must also be defined as either single-use or multi-use models [55]. They can be used for at-home or in-hospital purposes [55]. In addition, the FDA requires that the intended application sites are clearly defined to measure blood oxygen saturation [55].


**Figure 6.6 - FDA Cleared Pulse Oximeter Design Parameters [55].**

The FDA also requires a number of defined parameters regarding device design [55]. The science behind how the device acquires its readings and achieves its intended goals must be reported [55]. All major design features must be clearly reported and identified [55]. Examples include alarms that signal if the pulse rate or blood oxygen saturation has fallen under a certain preset benchmark [55]. In addition, the FDA requires reports of patient interface accessories if present as well as the scientific principles behind sensor configuration/geometry [55]. The FDA requires the devices to be validated. If the device is multi-parameter, all the components of the device including monitors and cables must be validated as well [55]. The FDA recommends a series of testing, inspection, and analysis, defined in ISO 80601-2-61:2017 [56]. A major part of this validation is related to electromagnetic compatibility, the device must operate in its intended environment of use without introducing excessive electromagnetic disturbances[55]. Another vital compatibility test relates to patient contacting materials on the device[55]. All components of the device that make contact with the patient must undergo material testing for irritation or intracutaneous reactivity, sensitization, and cytotoxicity [55]. The FDA requires clear guidelines regarding sanitization

and overall cleaning of the device if intended for reuse [55]. The FDA also requires labeling regarding device specifications, safety, and accuracy [55]. A device is required to have labeling outlining the device brand and model [55]. These labels must accompany clear specifications depicting the default or factory settings. There should be clear labeling covering alarm limits and ranges if necessary and writing specifying the ideal operating temperature and humidity [55]. The labeling regarding accuracy should include SpO2 accuracy in the range of 70% - 100% , with a table with measured SpO2 accuracy specification in the discrete SpO2 ranges of 70% to 80%, 80% to 90%, and 90% to 100% [55].

Our team was able to keep within the general size parameters stated by the FDA, and this report would act as our declaration of all components and accessories for our final design. It is uncertain if our design would pass their testing and inspection procedures because our testing methods required more subjects and more data to compare to the FDA standards. Our tests were also only focused on the verification and validation of our circuit with the code and did not include other FDA standards like cytotoxicity. Such tests were beyond the scope of this project due to the limited time and materials we had.

## 6.7 Ramifications

Our team performed one last analysis of our final designs by looking at the potential ramifications specifically focusing on the ethical impacts our device could have. This culminated into economic, societal, political/global, environmental, and ethical considerations. In addition to identifying potential ramifications, our team provided potential solutions to address as many potential issues that would be relevant to our final designs.

### 6.7.1 Economical Ramifications

Economically, there are many medical devices and treatments that have a large patient cost, much of which insurance does not pay for; often people in the lower economic classes and underrepresented communities cannot afford the expensive medical devices due to their financial situation. Our device, while more expensive than some lower quality devices, offers a middle of the road option for many communities by providing better accuracy at a lower price compared to high end competitors. With the proper implementation of our device, our team will be able to bridge the gap of higher quality specialty medical devices with greater financial feasibility amongst communities.

The lasers and photodiodes of our device are the most expensive and continuous purchases of our device based on orders our team made throughout the project. The 3D printer used to make the prototype of our device could be a one time purchase from a manufacturing standpoint, however, to keep with production long term, one might need multiple of these printers. This could become financially unfavorable at first. With bulk ordering and potential deals, the lasers and photodiodes could become cheaper, but overall this device would be estimated to be over $50 based on our analysis. While this is more expensive than the typical at home pulse oximeters that are on the market (the one used for our testing was less than $50), there is a cost benefit to our device. With increased accuracy, there is increased reliability in its measurements based on our findings. The measurement value could be the deciding factor in having to go to the hospital or not, which could end up saving the consumer a large amount of money in the long run. This also benefits both the healthcare professionals along with the patients as there would be a net decrease in false alarms from inaccurate medical devices leading to false visits to emergency rooms.

The major concern is that our device would be too expensive for the underrepresented communities, in this case more drastic measures could be taken. The other economical problem that is a concern for our group includes making sure that with varying skin pigmentations, conditions, textures, and thicknesses, our device maintains its accuracy and precision. In order to combat the costs, there are various recycling ideas our team has proposed, which can be seen later within this section. Along with this, the team plans to keep the electronic parts as cheap as possible by brokering deals and bulk ordering. Other than cost, constant modernization of the device is a must to keep up with the ever changing conditions or circumstances where a modern device is needed.

### 6.7.2 Societal ramifications

Our device has a positive societal impact and a negative cause and effect relationship on the market itself. The device is tailored for universal use, with a focus on addressing known errors with varying pigmentation and textures, aiding in the diagnosis of patients worldwide. This includes all social classes in an attempt to help with improving healthcare for underrepresented communities. However, since this device would be marketed as “inclusive for all”, people could ask/comment on why the pre-existing devices do not follow the same standards. Unfortunately, it is possible social ramifications brought on by this discovery may cause companies to be questioned, potentially leaving their products unable to produce the same amount of revenue yearly. This may cause small issues for manufacturers and developers as this new device would ultimately change the market in favor of the more accurate rather than the less accurate competitors. In order to combat patient wide questioning, our team would market our device as a modernized device to help increase accuracy on a plethora of variability with modern technology. This way, it is our goal that consumers understand that more recent equipment went into our pulse oximeter opposed to the equipment that other competitors had previously implemented. With proper marketing, it would be our hope that our device would gradually move the market and not cause a company stock crash or anything of similar vein. As a result, not only will our modern device help aid in healthcare diagnosis for a wide variety of patients, but it will also gradually change the market to avoid competitors being completely omitted from the market upon implementation as there are some benefits to others. It could very well be argued that competitors' devices that are currently on the market are acceptable for some applications. It is the point at which a more accurate device is needed for outstanding medical conditions where ours would be more favorable.

Another action item for our device would be to make a calibration curve that has the general public in mind in order to properly scale the numbers as accurately as possible, this would hopefully engage the public and create a large community trying to achieve the same goal for a good cause. It is important to note that in our project there were health conditions and situations that were not tested, such as smoking. More testing would need to be done in order to conclude the social implications of our device specifically.

It is our opinion that the impact of proper implementation of our device would overall be positive, however the market shift and initial implementation of our device would be the main concern of our team. It is our hope that negative outcomes would be limited with the above marketing strategies. It simply is a case of modernization using the recently developed tools available to us in order to improve accessibility for all social classes, while keeping in mind the variability between patients. Our device could ideally be seen as a specialty device while the other competitors could be considered the average at home devices.

There are many ways in which our device could be marketed for the greater good of both the market and patients.

### 6.7.3 Political/Global Ramifications

Politically, our aim was to make the devices more accessible and bring awareness to medical modernization, through cost reduction and optimized manufacturing practices. This would likely change the market in many ways when comparing our device to others. In general, with a device that works on all patients with a large amount of variability, it is our prediction that it would bring a positive change to many underdeveloped countries and communities who have not been receiving the level of care they deserve. Unfortunately, when developing medical devices, it can be a real challenge to address every variable; this is something our team was challenged to do and appreciated the difficulty in doing so. While our group believes our device has attempted to solve the lack of medical accuracy amongst a wide range of patients, there will always be more modifications that can be made. There are some negative impacts that could occur due to this, one of which is the risk of insurance companies not supplying pulse oximeters due to the expectations that it's cheap enough to be bought without insurance. It is well known that insurance can be complicated in some regard, and our team is worried that if our device is not completely medically necessary then insurance will not cover the costs. In order to solve the issue of non-insured and insured patients, our team would advocate for the need for pulse oximeter devices in every household to hopefully result in people who are insured to not have to pay out of pocket, but at the same time try to make the device as cheap as possible for patients that are not insured. While our device as stated above is not as cheap as others, the benefits do outway the slight cost increase. Ideally, our team believed that increasing the industry standard for quality components and accurate detection will influence pulse oximeters developers to adopt better practices, increasing the average cost of each sold device.

Other action items would be advocating for modernization of medical devices in general, hoping to start a movement to increase accessibility for people who actually need various medical devices. Hopefully with greater outreach and accessibility, underrepresented communities would have better medical devices, making an impactful difference for generations to come.

### 6.7.4 Environmental Ramifications

From a strictly manufacturing standpoint, we believe that making and assembling our device is rather simple, but assembly would have to involve microcircuitry; microcircuitry would be a must to create the printable circuit board (PCB) that would control our device. Optimization to increase efficiency in production would help to lower the environmental impact of our device, and in order to do this, creating efficient energy from renewable sources such as wind power would be ideal. This is a future consideration and as a result ample research would have to be done in order to grasp the feasibility of implementation.

Our product, in the attempt to make our device cost effective, has some areas where it is not environmentally friendly. Our device would be made from some type of plastic; whether it's made from acrylonitrile butadiene styrene (ABS), polylactic acid (PLA), or other plastics. Plastics are known for unfortunately not being able to decompose with ease, and often result in pollution of our oceans and land. To help mitigate the pollution caused by our device, a program could be established where recycled pulse oximeters being thrown away for defects could be disassembled and parts that are still viable can be

reused. Recycling would require energy to process, but if renewable energy is optimized then the positives of recycling could possibly outweigh the negatives of processing.

Current soldering for electrical components is done with lead wire (as we found out during the circuit building portion of our project), and lead is known in many ways to be very toxic. While our design currently uses lead, the goal would be to move away from this material and use another, less toxic metal for soldering. This could make the connections within our circuit weaker, but it would ultimately reduce the toxicity of the solder. It is possible to circumvent this issue by creating an alloy for the solder that is less toxic, more conductive, and structurally sound.

There are many ways where our device could impact the environment, but our team believes with the proposed changes it would mitigate the damage and be more sustainable then current on market devices. With better sustainability, there should be a more positive impact on the environment by not aiding in the production of greenhouse gasses and pollution as much as possible. Environmental sustainability could also help with healthcare disparities as greater sustainability ideally results in greater amounts of available and accessible devices (through the aid of recycling), hopefully reducing the cost as demand can be controlled. Less cost in waste management would hopefully reduce the overall price of the device.

### 6.7.5 Ethical Concerns and the Health and Safety of Patients

While it is unclear what the future holds, our team has made a few plausible outcomes that illustrate the health and safety concerns of our device. The first being that while our device uses lasers as a source of light, it does not mean that the device is any more dangerous then the current on market pulse oximeters (this was evident during our testing procedure). Ethically, patient safety is our number one concern when making this device. As said previously in the laser validation section, if the system itself is less than 12 J in energy, then the laser should not overheat or risk the safety and well being of any patient [18]. This is a design parameter that our team strived to ensure. However, throughout our testing it was found by the team that if the laser is found to be dying out, it is no longer safe to use and must be removed from the device before it gets too hot due to the excessive amount of current flowing through it. Our device, besides the laser, was similar to pre-existing devices, with minor changes. The amount of data from previous devices used and sold on the market suggests that this is the safest non-invasive method to accurately calculate blood oxygen saturation levels. Our proposed device was made with the health of underrepresented communities of the public in mind. Our team wanted to ensure that accurate medical care can be administered throughout the country while simultaneously maintaining and exceeding the gold standards of today's devices. As shown by our results, it can be done with just more testing and resources. It is our belief that this product could be the deciding factor in the route of treatment and ultimately aiding in a patient's recovery.

# Chapter 7: Discussion

## 7.1 Conclusion of Results

Our initial tests were able to prove that, under controlled conditions where the subject is in a room temperature environment, with little to no movement occurring and no obstructions present, a reading of the individual's blood oxygen level can be acquired. Our results also showed that the readings collected from our final circuit were able to be converted into an approximate blood oxygen level of an individual that was similar to the reading collected by the gold standard device.

It is not certain yet if our reading is a person's actual blood oxygen level as that would require comparing our device to invasive blood oxygen level testing methods. We can confirm that our circuit does work and our analysis code was able to take the voltage reading from the photodiode, analyze it, and produce a logical reading that is similar to a current device when used under the previously listed normal conditions. It cannot be concluded if our modification was able to overcome the issue of inaccurate readings as a result of different skin pigmentations. Our original test in an attempt to test different pigmentations with our limited testing pool only showed that non-skin material such as fake nails and tattoo ink negatively impacts blood oxygen readings. Color was not a clearly determined factor in inaccuracies of the reading. It is encouraged that additional tests be conducted testing a larger subject pool with a highly diverse population.

The reading inaccuracies of our temperature and motion tests are comparable to the gold standard device as it had similar moments of inaccuracies when attempting to gather data in a hot and/or cold environment, or when the subject was moving. However, our circuit results do not show an interval of inaccuracies like the gold standard devices. Therefore, a larger data pool would need to be collected to provide a more conclusive analysis of the effectiveness and accuracy of our circuit.

## 7.2 Meeting Our Specifications and Objectives

The COVID - 19 pandemic brought to surface the inaccuracies of the SpO2 measurements in typical pulse oximetry devices [1]. Inaccurate readings were seen amongst a wide range of patients who underwent monitoring [1]. Our project goal was to create a pulse oximetry device capable of effectively and efficiently achieving an accurate SpO2 reading from people of all skin pigmentations, thicknesses, and surfaces. The design criteria included making sure the device was a non-invasive, inexpensive, portable tool designed for the general public and medical sector.

Throughout our project experience, our team went through four major designs which included a patch, wristband, and malleable finger splint, with our final design being a double laser finger clamp. While our team was unable to test the final design, we believe it is a valid design because it is very similar to typical pulse oximetry devices found on the market. The only difference between the two is that our design had two holes on the top where the lasers would be located, and then two holes on the bottom where the photodiodes would be located. This helped us achieve our goals of creating a portable, handled device. Our team was also able to reach our goal of creating a non-invasive method for collecting a person's SpO2 reading since we were still using light traditional light-based pulse oximetry.

We were unable to reach the criteria of an affordable device because laser diodes are more expensive than LEDs. This was a tradeoff that we were hoping to offset by validating our results but time and material constants caused our team to be unable to reach the conclusion needed to justify a more

expensive pulse oximeter. Time and material constraints also prevented us from determining the accuracy, universal sizing, and time efficiency of our device. The accuracy was uncertain because we would have to compare our readings to invasive testing data which was beyond the tools allowed for this product. It was also not possible to determine if there were any major inaccuracies due to varying skin pigmentation due to an insufficient testing  pool. We were unable to determine if our model was great for universal sizing because we did not get to use our final model in any testing. The time efficiency to collect a usable reading with our device was uncertain because we constantly had to manually upload our collected data into our analysis code. This process did not provide a good representation of how the final device would operate. Our ideal final device would have the code already integrated into the circuit like current on the market devices to provide a real time analysis of our work.

With our successes, failures, and uncertainties in mind, our team believes that further development of the device is worthwhile and encouraged. We believe our final design can be treated as a proof of concept that can either be proven or disproved to meet our criteria set by our client statement with additional materials, time, and testing.

# Chapter 8: Conclusions and Recommendations

## 8.1 Future Considerations and Recommendations

Our team has identified a handful of ways our device could be further innovated in order to be more efficient and effective. The first consideration would be mechanical changes to the device such as redesigning the devices skeletal structure by improving its stability to reduce movement while acquiring a reading. Another consideration would be to make circuitry modifications in order to improve the accuracy by changing light sources from LED's to lasers. This also includes using microelectronics to reduce the size of the circuit so it could easily fit inside the pulse oximeter model by designing a PCB. The third consideration would be testing a large, diverse population and developing a calibration curve.

### 8.1.1 Mechanical Considerations

As shown throughout the paper, our team has done a lot of work designing physical modifications to the current gold standard devices, including changes to the skeleton that holds the circuitry. Examples of the design changes can be found in Chapter 4.2. While the patch, malleable finger splint, and wristband initial ideas were not implemented in our project to their full extent, it was determined that the three are viable ideas that should have further research done.

The patch pulse oximetry device in our opinion had a lot of benefits such as great portability, versatility, and being functional for all ages of patients. However, more robust designing would need to be done in order to see the idea to fruition. Our team identified two major problems with the proposed patch idea. The first being designing the attachment of the electrical components to the adhesive in a way that allows sufficient stabilization to get a proper reading. The second hurdle would be the reusability of the device; our team attempted to design adhesive patches that are reusable, however, fell short in completion of this task. Our team's skill set was not in chemical manipulation of adhesives, leaving a more qualified project group to yield better results. For this reason our team worked towards another design that played to our skill sets better. If one was to be able to design the device ultimately fixing these hurdles, then this would be a viable device to push through for consumer use. Recommendations to other teams replicating this particular device design would include using a biocompatible and allergen friendly adhesive that could be attached to a plastic hub (containing the circuit) and the surface of the skin. One way to possibly do this would be to have pegs, or feet, on the circuit hub that would stick to the adhesive; this would hopefully allow enough stability to attach to the skin. Then, when the time comes to remove the device, the hub should be first removed from the patch adhesive, and then using water one could remove the adhesive patch from the skin. Water could help with skin irritation. One could also leave the patch on if continuous monitoring is needed, and in this case a strong adhesive would be needed to allow a restick of the hub to the patch without compromising patient comfort.

The wristband pulse oximetry device would also be a great way to reach a wider age range of patients. Our team had a difficult time fully encapsulating what the wristband implementation would be, issues that arose were trying to pick various sizes of wristbands and how the connection into the circuit hub would work. While designing this option, the wristband size, material, and attachment method was something our team could not prove to be better than the other proposed device models. For example, some of the design limitations our team encountered was that the material for the wrist band could not stretch as far as our team originally thought or it would bridge the circuit hub resting on top of the wrist.

This would result in an increased ambient light exposure. In doing so, it is our understanding that there would be inaccuracies that are greater statistically then the current gold standard devices. Furthermore, the weight of the circuitry portion of the device was a concern of our team. The circuitry hub would have been heavier and bulkier than the wrist band itself, therefore this could have led to shifting of the hub on smaller patients where the wrist band could not be as tight. Balancing weight and stretchability while not hindering the versatility of the device is critical, and something our team believed was not the right path for our project. One method that was considered and is recommended would be to have a kit with various band lengths from multiple different materials. This would raise costs and production, however, it may work to increase the versatility while not applying too much pressure that the circuit hub would bend upwards due to force. Another recommendation would be to make the hub small in order to decrease the overall weight; this possibly could be a two part assembly to avoid the weight being too much. If one could create a strong circuit that is better or the same as the transmissive circuit typically seen, then this would be an ideal model for this purpose. Considering the difficulty of this task, the team's skill set was not being used to its full potential and for this reason it was decided to move from the wristband design to a different one.

The malleable splint idea, while the team's favorite, also had its inherent flaws. These flaws included that the device was non reusable, not time efficient, and lacked overall stability. This device would be less universal when considering smaller and younger patients as it involves using a splint-like material to press the light source downward on the finger. Smaller fingers will result in greater difficulty of stabilization. If a team wishes to pursue this device, it is our team's recommendation that the total length of the device is minimal, no longer than the lower end of average finger lengths. The material that molds around the finger should have a bendable metal insert layered in between the softer material, such as a thin sheet of aluminum, which will provide greater rigidity and structure to the device. Our team recommends that the overall material should be thin; no greater than a few millimeters as the thicker the material, the greater the risk of inaccuracies. Our team determined that for the reason of lack of versatility, that this design was not something to move forward with for the sake of the project goal.

### 8.1.2 Circuit Considerations

Alongside the work that our team had done to improve the circuit through the addition of lasers opposed to LEDs, our team recommends one other circuit modification that could increase the accuracy. Our team ran out of time to try this method, but it could be a viable way to improve accuracy even more than just using one laser. As stated above, typically pulse oximetry devices use two LEDs [2]. If one was to do the same with lasers, both a red laser and an infrared laser, then this would model gold standard LED devices almost perfectly (assuming one can get them to work at the same time). This method requires a blinking code possibly done through Arduino that turns the lasers on and off at alternating times. It is our hypothesis that the lasers would be more accurate with less percent error. Our team experimented with blinking codes but found it was best to focus on implementing one laser at a time as the project was in the preliminary stages. It would be our recommendation that a more experienced person in coding would create a code to flash the red laser for a given time (on the lines of milliseconds) first, then once the red laser shuts off the infrared laser would turn on for a given time (on the lines of milliseconds). The code should have the red and infrared lasers blinking on and off inversely, consistently, while storing the absorbance values to calculate the SpO2 values. A sample code for actively blinking the two light sources can be found in Appendix J as the team did write one in Arduino, but never officially

implemented it. The calculation ideally would run as the blinking occurs to allow for continuous monitoring. Using a standard flash code and systematically adding code to create the right conditions would be the most efficient way to complete this. Using a transistor is also an option within the circuit to act as the blinking code, data retrieval from there would be something that would need to be figured out. Our team had a transistor in the original circuit schematic, but through the progression of the project, the team decided to lean away from using a transistor and focus on operating one laser at a time. It is believed by our team that research on the functionality of the transistor in this particular circuit could be very useful for other teams to do, rather than writing code.

### 8.1.3 Calibration

In order to fully understand how the device, modeled in the paper, would work in comparison to the gold standard, a greater testing pool would be needed in order to obtain a calibration curve. Our team had a very limited testing pool, and as a result it was not possible to create a calibration curve. It would be our team's recommendation that whenever the device has sufficient preliminary data suggesting that the device will work, one should test hundreds of people and create a calibration curve that can accurately represent the true SpO2 values of a wide range of skin pigmentations.

## 8.2 Additional Testing Methods

Our team, due to lack of time, would have liked to do a few other testing methods to help prove that our device works more effectively then the current gold standard devices from a skin pigmentation, thickness, and texture point of view. The following sections outline those testing methods.

### 8.2.1 Fish Skin Testing Method and Recommendations

Evidence suggests that the inherent properties in acellular fish skin have beneficial properties that allow integration into skin grafts for treating severe burn patients [57]. According to the *International journal of molecular science*, there are limited skin donors for replacement surgeries, and as a result split thickness animal skin grafts are being used as a way to combat the lack of skin, while still providing severe burn patients treatment [58]. In various studies, it was found that using a skin graft containing the acellular fish skin promotes more effective and efficient healing at a low cost, while also being very easy to administer, and having no adverse effects or infections in patients that have received the treatment [59]. It was hypothesized that the rich Omega -3 nutrients that are abundant in fish skin can provide a healing environment resulting in limited scarring and improved wound healing [60]. Through many clinical tests done on a number of patients, fish skin was proven to reduce the inflammation response of the body while simultaneously increasing proinflammatory cytokines responsible for promoting and encouraging better healing [60]. From these promising studies and clinical trials, companies involved in regenerative medicine have been selling skin grafts containing fish skin in order to combat the lack of donors previously mentioned above [61]. One example of which is a company called Kerecis from Iceland [61].

Kerecis is a company based out of Iceland that creates acellular skin grafts from decellularized Icelandic codfish [61]. Kerecis uses fish skin to promote burn healing while also providing a non-infectious environment [61]. According to Kerecis, using codfish skin supplies proteins (similar to that of humans) to enter the wound and allow healing to occur [61]. With this in mind, our team decided

for future research teams this would be a worthwhile exploratory method to prove the efficacy of the device.

It was our team's hypothesis that patients who receive skin grafts containing animal products can result in changes to the texture, transparency, and overall thickness of their skin. In order to make a universal device, our team would recommend either getting this particular skin graft, or to use codfish skin in the testing methods to see how the device works on the new surface. Detailed methods of said testing can be found in the Appendix G. This would be a great model for skin texture change specifically due to burns.

### 8.2.2 Pig Skin Testing Method Validation and Recommendations

While fish skin is a great model and treatment option for burn patients, pig biological matter and internal organs have been used in medicine for many applications including organ transplants [62]. More modern medicine has determined that pig skin is similar to human skin in its histologic structure, and is an inexpensive and readily-available source [63]. In a comprehensive study, Red Duroc pigs were used as animal models in order to study scar therapies; this animal model was ideal due to their anatomic and biological similarity to scarring typically found in human patients [64]. In this model the pigs were treated for burns using split thickness autograft to assess skin raising due to scar formation [64]. Results of this study found that the model resulted in thick raised scars, and when treated with the split thickness grafts had less inflammation and improved healing properties [64]. The scars formed in these models were determined to be similar in appearance and structure to commonly seen scarring found in human patients, and as a result verifies this study as a good model for other therapies [64]. It was also found in another study that currently genetically engineered pigs skin grafts work just as well as allografts, and can be used in treatments [63]. Some of the advantages of using skin grafts from wild type pigs include maintaining barrier functions in early stages of treatment, reduced risk of disease or infection caused by the graft, and treatment averaging at a low cost [63]. Using this information, our team would recommend trying to remake a similar model to test the device on humans. An example would be to create an artificial scar from the pigs skin and place it on a test subject’s finger. Such testing methods can be found in the Appendix F.

## 8.3 Problems and Solutions

There were a variety of setbacks that our team had to troubleshoot in order to complete this project. The three major problems that our team encountered included difficulties in getting the data analysis code to work properly, the 3D printing clearance causing the models to concave in, and creating a stabilizing model for the circuit. Our team went through many versions of code, but even with all these variations many aspects did not work. Our code only worked when reversing the R ratio, and the AC/DC formula to solve for the R value of the final code also did not work. To fix the AC/DC portion of the code, the values used for the DC component were changed from maximum value pulled from the data to the minimum value. The values computed from the AC/DC were how they were supposed to be after changing the DC from maximum to minimum as the AC infrared value needed to be less then AC red value, and the opposite was true for the DC values. The values obtained for DC red and infrared had to be great enough for the ratio to calculate an accurate R value. When this was fixed, our team was able to obtain the SpO2 values as the calculated R values were now correct.

Our CAD models were printed with a 2mm clearance with the addition of supports. Despite a fairly reasonable clearance, the plastic still collapsed in the voids intended to hold the lasers. This was for both the Acrylonitrile Butadiene Styrene (ABS) and Polylactic Acid (PLA) models that were made. In order to combat this, our team had to change the void spaces in our design to avoid using the supports. Instead of having the holes made specifically to the wire dimensions coming from the device, the holes were left larger and the wires were taped down. This ultimately helped lower the printing complexity making the model a better suit for the project while also reducing the collapsing of the plastic into the holes for the lasers.

The third large troubleshooting our team went through was creating a model that worked to properly stabilize the circuit components. Our design originally included a cap that would hold the laser wires in place with pegs, however, this particular piece unfortunately kept breaking. This led to the wires constantly moving, causing bad connections between the components and leading to inaccurate results. To combat this, our team took the pegs from the device, opted to not have a cap, and made the model have a flat surface where duct taping the wires down would lead to more accurate results.

## 8.4 Final Thoughts and Acknowledgments

Our team would like to thank our advisors, Dr. Funmi Ayobami and Dr. Taimoor Afzal, from the department of Biomedical Engineering at Worcester Polytechnic Institute. Dr. Funmi Ayobami has great knowledge in the design process and implementation of ideas. She worked with our team in the early developmental stages of our proposed device, and offered expertise in the ethical considerations in which our team discussed and used to narrow our scope. She helped our team grow and think critically about the task at hand which aided our team greatly. Ultimately, her work helped us to complete the project in an efficient and effective manner while also building the team dynamic in the early stages of the project. Dr. Taimoor Afzal was critical in the instrumentation portion of the project. He worked with our circuit team to troubleshoot the various hurdles our team encountered, while also providing critical feedback to the testing methods portion of the project. Dr. Taimoor Afzal met with our team regularly in order to help with the implementation of the circuit into the 3D model, while also ensuring that our team was interpreting our results in the correct manner. Thank you Dr. Funmi Ayobami and Dr. Taimoor Afzal for all your hard work and dedication to the project. Our team greatly appreciates everything that you have done!

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# Appendices

## Appendix A: Temperature Testing, Cold Test

**Goal:** *This procedure is intended to test the effect of High, Low, and moderate skin surface temperatures on a pulse oximeter reading. This procedure is intended for our circuit and various gold-standard transmissive pulse oximeters.*

**Protocol:**

1. Have the participant run both their index finger  under cold water (10 degrees C or lower) for 2 minutes using a thermometer to record the temperature of the water
2. Quickly dry the participant's fingers with a towel so that there is no water on the surface of the index finger
3. Have the participant sit down and rest their fingers above the testing table surface
4. Instruct the participant to place a finger in the gold standard device and turn on the device.
5. Once the gold standard device gets a reading, begin running the recording of the data collection. After 5 to 10 seconds, have the participant rest their finger on the protype pulse oximeter. Direct the participant to remain as still and relaxed as possible.
6. Record the data for a total of 70 seconds which includes the 5-10 seconds without the participant's finger within the device. For every 5 seconds that have passed in the testing, record the gold standard device's oxygen reading and BPM.
7. When the test is done, have the participant wait five minutes so their finger returns to room temperature before proceeding with any other test or repeating this test
8. Repeat 3 times with each participant

## Appendix B: Temperature Testing, Warmth Test

**Goal:** *This procedure is intended to test the effect of High, Low, and moderate skin surface temperatures on a pulse oximeter reading. This procedure is intended for our circuit and various gold-standard transmissive pulse oximeters.*

**Protocol:**

1. Have the participant place their finger 0.5ft away from the space heater and set the space heater temperature a maximum of 80 degrees.
2. Direct the participant to remain still with the back of their finger facing the space heater for 30 seconds.
3. Once the 30 seconds have passed direct the participant to flip their finger so the front is now facing the space heater.
4. Keep still for another 30 seconds.
5. Once the hand is at the desired temperature, turn off the space heater.
6. Instruct the participant to place a finger in the gold standard device and turn on the device.
7. Once the gold standard device gets a reading, begin running the recording of the data collection. After 5 to 10 seconds, have the participant rest their finger on the protype pulse oximeter. Direct the participant to remain as still and relaxed as possible.
8. Record the data for a total of 70 seconds which includes the 5-10 seconds without the participant's finger within the device. For every 5 seconds that have passed in the testing, record the gold standard device's oxygen reading and BPM.
9. When the test is done, have the participant wait five minutes so their finger returns to room temperature before proceeding with any other test or repeating this test
10. Repeat 3 times with each participant

## Appendix C: Motion Testing

**Goal:** *This procedure is intended to test the effect of High, Low, and Moderate amounts of motion on a pulse oximeter reading. This procedure is intended for our circuit and various gold-standard transmissive pulse oximeters.*

**Protocol:**

1. Prior to starting this experiment, if there is fingernail polish present on the nail of the index finger, have the participant clean their index fingers with alcohol wipes and acetone until the polish is completely removed.
2. The participant is to be seated in a chair with their finger resting on a pulse oximeter.
3. Once the participant is in position, turn on the pulse ox and begin measuring.
4. Instruct the participant to place a finger in the gold standard device and turn on the device.
5. Once the gold standard device gets a reading, begin running the recording of the data collection. After 5 to 10 seconds, have the participant rest their finger on the protype pulse oximeter. Direct the participant to remain as still and relaxed as possible.
6. Record the data for a total of 70 seconds which includes the 5-10 seconds without the participant's finger within the device. For every 5 seconds that have passed in the testing, record the gold standard device's oxygen reading and BPM.
7. Run the sitting trail three times.
8. Repeat steps 2-6 again but instead of the individual sitting during the whole test, have the person stand up and down 6 times after the device has collected their reading for 30 seconds. Once the standing is completed, have the person sit until still until a total of 70 seconds have passed for the data recording.
9. Repeat step 8 two more times.
10. Repeat steps 2-6 again but this time after 30 seconds, have the participant move their arms up to a 90-degree angle and then down to the original resting position for 30 seconds after 30 seconds of data recording has occurred.

## Appendix D: Skin Altering Factors, Tattoos

**Goal:** *This procedure is intended to test how body art, such as tattoos affect pulse oximetry readings. This procedure is intended for our circuit and various gold-standard transmissive pulse oximeters.*

**Protocol:**

1. Prior to the test, apply a temporary tattoo around both index fingers, keeping the tattoo the same
2. Assure there is no nail polish or other obstructions that will affect the pulse oximeters reading. Make sure the skin temperature is at room temperature
3. The participant is to be seated in a chair with their finger resting on a pulse oximeter.
4. Once the participant is in position, turn on the pulse ox and begin measuring.
5. Instruct the participant to place a finger in the gold standard device and turn on the device.
6. Once the gold standard device gets a reading, begin running the recording of the data collection. After 5 to 10 seconds, have the participant rest their finger on the protype pulse oximeter. Direct the participant to remain as still and relaxed as possible.
7. Record the data for a total of 70 seconds which includes the 5-10 seconds without the participant's finger within the device. For every 5 seconds that have passed in the testing, record the gold standard device's oxygen reading and BPM.
8. Repeat the test three times.

## Appendix E: Skin Altering Factors,  Nail Polish

**Goal:** *This procedure is intended to test how nail polish and acrylic nails affect pulse oximetry readings. This procedure is intended for our circuit and various gold-standard transmissive pulse oximeters.*

**Protocol:**

1. Prior to the test have participants paint their nails with blue/green nail polish
2. The participant is to be seated in a chair with their finger resting on a pulse oximeter.
3. Once the participant is in position, turn on the pulse ox and begin measuring.
4. Instruct the participant to place a finger in the gold standard device and turn on the device.
5. Once the gold standard device gets a reading, begin running the recording of the data collection. After 5 to 10 seconds, have the participant rest their finger on the protype pulse oximeter. Direct the participant to remain as still and relaxed as possible.
6. Record the data for a total of 70 seconds which includes the 5-10 seconds without the participant's finger within the device. For every 5 seconds that have passed in the testing, record the gold standard device's oxygen reading and BPM.
7. Repeat the test three times.
8. Now have the participant glue on an acrylic nail and wait one minute for the nail to set
9. Repeat steps 2-6 three times

## Appendix F: Pig Skin Testing Methods

**Protocol:**

1. Have the participant be seated
2. Assure there is no nail polish or other obstructions that affect pulse oximetry accuracy
3. Place a small piece of pig skin on the finger, use tape on only the end closest to hand to secure the skin
4. The participant is to be seated in a chair with their finger resting on a pulse oximeter.
5. Once the participant is in position, turn on the pulse ox and begin measuring.
6. Instruct the participant to place a finger in the gold standard device and turn on the device.
7. Once the gold standard device gets a reading, begin running the recording of the data collection. After 5 to 10 seconds, have the participant rest their finger on the protype pulse oximeter. Direct the participant to remain as still and relaxed as possible.
8. Record the data for a total of 70 seconds which includes the 5-10 seconds without the participant's finger within the device. For every 5 seconds that have passed in the testing, record the gold standard device's oxygen reading and BPM.
9. Repeat the test three times.

## Appendix G: Fish Skin Testing Methods

**Protocol:**

1) Obtain codfish skin at a local shop or other resource; ideally a skin graft from a company that supplies fish skin grafts. If not available, fresh codfish would work as well for the purpose of this test.
2) Using the skin, file down the meat from the skin allowing for the following total thicknesses (including both the finger and the codfish skin), 14.1 mm, 16.2 mm, and lastly 19.0 mm.
    a) Intuition behind these specific measurements comes from average ring sizes of the general public.
3) Wrap the skin around a live object's index finger. Preferably for pulse oximetry devices use a human index finger. For animal testing purposes use a spot that has a strong pulse close to an artery
4) Perform a series of measurements using the pulse oximetry device.
    a) Series of measurements could be the following, this is completely dependant on what is trying to be obtained by these results
        i) Place finger into the Pulse Oximetry device
        ii) Press the power button and obtain a standard reading.
        iii) Do the same reading, with slight movement
        iv) Similarly, do the same reading referenced in part iii, but with colder skin and on the contrast warmer skin
5) Repeat the same set of tests without the fish skin
6) Analyze the results

## Appendix H: Circuitry Verification Calculations

| | |
|---|---|
| **780 Laser Specifications:** | |
| Operating Voltage: | 4.5 V |
| Operating Max Current: | 40 mA |
| Part Number: | RLD78NZM5-00A |
| Datasheet Link: | https://www.mouser.com/datasheet/2/348/rld78nzm500a010-e-1843523.pdf |
| | |
| **660 Laser Specifications:** | |
| Operating Voltage: | 4.5 V |
| Operating Max Current: | 45 mA |
| Part Number: | RLD65PZX2-01A |
| Datasheet Link: | https://www.mouser.com/datasheet/2/348/rld65pzx201a011-e-1843553.pdf |
| | |
| **Ohm's Law:** | **V = IR** |
| 780 Laser Resistance: | 4.5 V = 0.04 A x R |
| | R = 112.5 Ohms |
| | |
| 660 Laser Resistance: | 4.5 V = 0.045 A x R |
| | R = 100 Ohms |
| | |
| **TL072IP Op-Amp Specifications:** | |
| Part Number: | TL072IP |
| Datasheet Link: | https://www.ti.com/lit/ds/symlink/tl072h.pdf?HQS=dis-mous-null-mousermode-dsf-pf-null-wwe&ts=1679935831559&ref_url=https%253A%252F%252Fwww.mouser.de%252F |
| | |
| **Op-Amp Gain Determination:** | |
| Chosen Input Resistor (Ri): | 1 Mohm |
| Chosen Feedback Resistor (Rf): | 8.2 Mohm |
| Gain: | Gain = Rf / Ri |
| | Gain = 8.2 Mohm / 1 Mohm |

| | |
|---|---|
| | Gain = 8.2 |
| | |
| Filter Capacitor: | C <= 1/ 2 x pi x Ri x f |
| | C <= 1/ 2 x pi x 1000000 Ohms x 60 Hz |
| | C <= 2.65 pF |

# Appendix I: Raw Data

| Person-Activity (Subject 1) | Subject 1-Sitting | Subject 1-Cold | Subject 1-Hot | Subject 1-Standing | Subject 1-Arm Moving | Subject 1-Sitting-Nail | Subject 1-Cold-Nail | Subject 1-Hot-Nail | Subject 1-Standing-Nail | Subject 1-Arm Moving-Nail | Subject 1-Sitting-Tattoo |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Reading 1 | 95.7 | 95.8 | N/A | 83 | 5.8 | 94 | 12.3 | | 86.1 | 72.6 | 73.2 |
| Reading 2 | 95.8 | 95.8 | | 70.7 | 83.4 | 79.3 | 74.6 | | 64 | 93.3 | 86.1 |
| Reading 3 | 95.2 | 95.8 | | | 95.6 | 65.4 | 54.5 | | 76.9 | 95.7 | 59.2 |
| Reading 4 | 95.3 | 63 | | | 94.8 | 69.6 | 83.7 | | | 76.4 | 95.8 |
| Reading 5 | 94.4 | | | | 95.5 | | | | | | 95.8 |
| Reading 6 | 94 | | | | 87.6 | | | | | | 22.3 |
| Average Blood Oxygen Reading | 95.06666667 | 87.6 | #DIV/0! | 76.85 | 77.11666667 | 77.075 | 56.275 | #DIV/0! | 75.66666667 | 84.5 | 72.06666667 |

| Person-Activity (subject 1) | Gold Standard | Gold Standard-Cold | Gold Standard-Hot | Gold Standard-Standing | Gold Standard-Arm Moving | Gold Standard-Nail | Gold Standard-Cold- Nail | Gold Standard-Hot -Nail | Gold Standard-Standing- Nail | Gold Standard-Arm Moving - Nail | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Reading 1 | 95.1 | 97 | 96 | 97 | 96 | 97 | 97 | N/A | 98 | 92 | |
| Reading 2 | 95.4 | | | | | 97 | | | | | |
| Reading 3 | 95.8 | | | | | 92 | | | | | |
| Reading 4 | 95.1 | | | | | 98 | | | | | |
| Reading 5 | 96 | | | | | | | | | | |
| Reading 6 | 97 | | | | | | | | | | |
| Average Blood Oxygen Reading | 95.73333333 | 97 | 96 | 97 | 96 | 96 | 97 | #DIV/0! | 98 | 92 | |

| Person-Activity (subject 2) | Subject 2-Sitting | Subject 2-Cold | Subject 2-Hot | Subject 2-Standing | Subject 2-Arm Moving | Subject 2-Sitting-Nail | Subject 2-Cold-Nail | Subject 2-Hot-Nail | Subject 2-Standing-Nail | Subject 2-Arm Moving-Nail | Subject 2-Sitting-Tattoo |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Reading 1 | 93.50430347 | 81.52620662 | 91.54465748 | 62.03964522 | 69.1788396 | 95.311432 | N/A | N/A | 69.298003 | 33.4051 | N/A |
| Reading 2 | | 95.66809038 | 73.93925938 | 76.99895517 | 55.7772322 | 79.786102 | | | 68.415869 | 71.626508 | |
| Reading 3 | | 63.83440004 | 92.91699613 | 82.07400242 | 67.575769 | | | | | 93.215504 | |
| Reading 4 | | 95.32924378 | 94.58990095 | | | | | | | 91.600189 | |
| Reading 5 | | | | | | | | | | | |
| Reading 6 | | | | | | | | | | | |
| Average Blood Oxygen Reading | 93.50430347 | 84.08948521 | 88.24770349 | 73.70420094 | 64.17728027 | 87.548767 | #DIV/0! | #DIV/0! | 68.856936 | 72.46182525 | #DIV/0! |

| Person-Activity (subject 2) | Gold Standard | Gold Standard-Cold | Gold Standard-Hot | Gold Standard-Standing | Gold Standard-Arm Moving | Gold Standard-Nail | Gold Standard-Cold- Nail | Gold Standard-Hot -Nail | Gold Standard-Standing- Nail | Gold Standard-Arm Moving - Nail | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Reading 1 | 97 | 98 | 97 | 98 | 98 | 97 | 99 | | 98 | 94 | |
| Reading 2 | 98 | | | 98 | | 94 | | | | | |
| Reading 3 | 98 | | | | | 98 | | | | | |
| Reading 4 | 97 | | | | | | | | | | |
| Reading 5 | 98 | | | | | | | | | | |
| Reading 6 | 97 | | | | | | | | | | |
| Average Blood Oxygen Reading | 97.5 | 98 | 97 | 98 | 98 | 96.33333333 | 99 | #DIV/0! | 98 | 94 | |

| Person-Activity (subject 3) | Subject 3-Sitting | Subject 3-Cold | Subject 3-Hot | Subject 3-Standing | Subject 3-Arm Moving | Subject 3-Sitting-Nail | Subject 3-Cold-Nail | Subject 3-Hot-Nail | Subject 3-Standing-Nail | Subject 3-Arm Moving-Nail | Subject 3-Sitting-Tattoo |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Reading 1 | 95.79018709 | 91.05070541 | 95.67099995 | -856.7068558 | 81.8478943 | | | | | | |
| Reading 2 | 95.79549289 | 61.12050751 | 95.69690144 | -2818.453014 | 86.9273635 | | | | | | |
| Reading 3 | 95.59714864 | | | | 47.3900183 | | | | | | |
| Reading 4 | 95.66627968 | | | | | | | | | | |
| Reading 5 | | | | | | | | | | | |
| Reading 6 | | | | | | | | | | | |
| Average Blood Oxygen Reading | 95.71227708 | 76.08560646 | 95.6839507 | -1837.579935 | 72.05509203 | #DIV/0! | #DIV/0! | #DIV/0! | #DIV/0! | #DIV/0! | #DIV/0! |

| Person-Activity (Subject 3) | Gold Standard | Gold Standard-Cold | Gold Standard-Hot | Gold Standard-Standing | Gold Standard-Arm Moving | Gold Standard-Nail | Gold Standard-Cold- Nail | Gold Standard-Hot -Nail | Gold Standard-Standing- Nail | Gold Standard-Arm Moving - Nail | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Reading 1 | 97 | 99 | 97 | 96 | 97 | 99 | 98 | 99 | N/A | N/A | |
| Reading 2 | 97 | | | 98 | | 98 | | | | | |
| Reading 3 | 97 | | | | | | | | | | |
| Reading 4 | 97 | | | | | | | | | | |
| Reading 5 | 99 | | | | | | | | | | |
| Reading 6 | 97 | | | | | | | | | | |
| Average Blood Oxygen Reading | 97.33333333 | 99 | 97 | 97 | 97 | 98.5 | 98 | 99 | #DIV/0! | #DIV/0! | |

| Person-Activity (Subject 4) | Subject 4-Sitting | Subject 4-Cold | Subject 4-Hot | Subject 4-Standing | Subject 4-Arm Moving | Subject 4-Sitting-Nail | Subject 4-Cold-Nail | Subject 4-Hot-Nail | Subject 4-Standing-Nail | Subject 4-Arm Moving-Nail | Subject 4-Sitting-Tattoo |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Reading 1 | 95.8226464 | 78.65996183 | -5954.907721 | 95.81391175 | 57.9194952 | 95.488396 | -5.46973 | | 89.142665 | -301.94704 | |
| Reading 2 | 94.95166473 | 85.79283109 | -169.9300994 | 95.29777192 | 80.3548695 | 94.695528 | 95.8393 | | 95.816808 | -93.795418 | |
| Reading 3 | | | -29934.4088 | 95.79955447 | 31.5238566 | 95.779069 | | | 38.98382 | -38.210854 | |
| Reading 4 | | | -22715.34287 | 93.1745557 | 79.8356242 | 92.024112 | | | 95.796258 | 70.182491 | |
| Reading 5 | | | | | | | | | | | |
| Reading 6 | | | | | | | | | | | |
| Average Blood Oxygen Reading | 95.38715557 | 82.22639646 | -14693.64737 | 95.02144846 | 62.40846138 | 94.49677625 | 45.184785 | #DIV/0! | 79.93488775 | -90.94270525 | #DIV/0! |
| Person-Activity (subject 4) | Gold Standard | Gold Standard-Cold | Gold Standard-Hot | Gold Standard-Standing | Gold Standard-Arm Moving | Gold Standard-Nail | Gold Standard-Cold- Nail | Gold Standard-Hot -Nail | Gold Standard-Standing- Nail | Gold Standard-Arm Moving - Nail | |
| Reading 1 | 99 | 95 | 96 | 97 | 97 | 96 | 96 | N/A | 96 | 96 | |
| Reading 2 | 97 | | | 98 | | 97 | | | | | |
| Reading 3 | 97.5 | | | | | 96 | | | | | |
| Reading 4 | 99 | | | | | 96 | | | | | |
| Reading 5 | 95 | | | | | | | | | | |
| Reading 6 | 96 | | | | | | | | | | |
| Average Blood Oxygen Reading | 97.25 | 95 | 96 | 97.5 | 97 | 96.25 | 96 | #DIV/0! | 96 | 96 | |

| Person-Activity (Subject 5) | Subject 5-Sitting | Subject 5-Cold | Subject 5-Hot | Subject 5-Standing | Subject 5-Arm Moving | Subject 5-Sitting-Nail | Subject 5-Cold-Nail | Subject 5-Hot-Nail | Subject 5-Standing-Nail | Subject 5-Arm Moving-Nail | Subject 5-Sitting-Tattoo |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Reading 1 | | | | | | 95.821706 | 91.7304 | 93.9 | 84.516569 | -705.54928 | |
| Reading 2 | | | | | | 95.60159 | 82.0511 | 95.7 | 94.131099 | -239.57968 | |
| Reading 3 | | | | | | 87.792718 | | | | | |
| Reading 4 | | | | | | | | | | | |
| Reading 5 | | | | | | | | | | | |
| Reading 6 | | | | | | | | | | | |
| Average Blood Oxygen Reading | #DIV/0! | #DIV/0! | #DIV/0! | #DIV/0! | #DIV/0! | 93.07200467 | 86.89075 | 94.8 | 89.323834 | -472.56448 | #DIV/0! |
| Person-Activity (subject 5) | Gold Standard | Gold Standard-Cold | Gold Standard-Hot | Gold Standard-Standing | Gold Standard-Arm Moving | Gold Standard-Nail | Gold Standard-Cold- Nail | Gold Standard-Hot -Nail | Gold Standard-Standing- Nail | Gold Standard-Arm Moving - Nail | |
| Reading 1 | | | | | | 97 | 97 | 96 | 97 | 77 | |
| Reading 2 | | | | | | 96 | | | | | |
| Reading 3 | | | | | | 97 | | | | | |
| Reading 4 | | | | | | 97 | | | | | |
| Reading 5 | | | | | | outlaw 77 | | | | | |
| Reading 6 | | | | | | | | | | | |
| Average Blood Oxygen Reading | #DIV/0! | #DIV/0! | #DIV/0! | #DIV/0! | #DIV/0! | 96.75 | 97 | 96 | 97 | 77 | |

| Person-Activity (Subject 6) | Subject 6-Sitting | Subject 6-Cold | Subject 6-Hot | Subject 6-Standing | Subject 6-Arm Moving | Subject 6-Sitting-Nail | Subject 6-Cold-Nail | Subject 6-Hot-Nail | Subject 6-Standing-Nail | Subject 6-Arm Moving-Nail | Subject 6-Sitting-Tattoo |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Reading 1 | | | | | | 93.037211 | 46.8725 | 92.85527369 | 40.481714 | 76.547473 | 75.09359 |
| Reading 2 | | | | | | | | 95.7397335 | 25.706389 | 73.285373 | 79.433683 |
| Reading 3 | | | | | | | | 78.53707998 | | 68.281336 | 77.033442 |
| Reading 4 | | | | | | | | | | | |
| Reading 5 | | | | | | | | | | | |
| Reading 6 | | | | | | | | | | | |
| Average Blood Oxygen Reading | #DIV/0! | #DIV/0! | #DIV/0! | #DIV/0! | #DIV/0! | 93.037211 | 46.8725 | 89.04402906 | 33.0940515 | 72.70472733 | 77.186905 |
| Person-Activity (subject 6) | Gold Standard | Gold Standard-Cold | Gold Standard-Hot | Gold Standard-Standing | Gold Standard-Arm Moving | Gold Standard-Nail | Gold Standard-Cold- Nail | Gold Standard-Hot -Nail | Gold Standard-Standing- Nail | Gold Standard-Arm Moving - Nail | |
| Reading 1 | | | | | | 100 | 100 | 96 | 98 | 94 | |
| Reading 2 | | | | | | 96 | | | | | |
| Reading 3 | | | | | | 100 | | | | | |
| Reading 4 | | | | | | 94 | | | | | |
| Reading 5 | | | | | | 98 | | | | | |
| Reading 6 | | | | | | | | | | | |
| Average Blood Oxygen Reading | #DIV/0! | #DIV/0! | #DIV/0! | #DIV/0! | #DIV/0! | 97.6 | 100 | 96 | 98 | 94 | |

# Appendix J: Arduino Blinking Code

File Edit Sketch Tools Help

Arduino Uno

new led blinking.ino

```
/*MQP Blinking Code*/

// Define variables prior to using them
  // RED LED Pin and initial state (off)
    int RED = 2;
    int RED_State = HIGH;
  // IR LED Pin and initial state (off)
    int IR = 3;
    int IR_State = LOW;
  // Timer in Milliseconds for both LEDS
    unsigned long RED_Millis = 0;
    unsigned long IR_Millis = 0;
  // RED LED On and Off
    long RED_ON = 500; // milliseconds
    long RED_OFF = 500; // milliseconds
  // IR LED On and Off
    long IR_ON = 500; // milliseconds
    long IR_OFF = 500; // milliseconds

// Set Output Pins to LEDs for Blinking
void setup()
{
  pinMode(RED, OUTPUT);
  pinMode(IR, OUTPUT);
}

// Set Loop for Blinking
void loop()
{
  // Reset Timer in milliseconds
    unsigned long Current_Millis = millis();
  // Check state of RED LED
    if ((RED_State == HIGH) && (Current_Millis - RED_Millis >= RED_ON))
    {
      // Turn off RED LED
      RED_State = LOW;
      RED_Millis = Current_Millis;
      digitalWrite(RED, RED_State);
    }
    else if ((RED_State == LOW) && (Current_Millis - RED_Millis >= RED_OFF))
    {
      // Turn on RED LED
      RED_State = HIGH;
      RED_Millis = Current_Millis;
      digitalWrite(RED, RED_State);
    }
  // Check state of IR LED
    if ((IR_State == HIGH) && (Current_Millis - IR_Millis >= IR_ON))
    {
      // Turn off IR LED
      IR_State = LOW;
      IR_Millis = Current_Millis;
      digitalWrite(IR, IR_State);
    }
    else if ((IR_State == LOW) && (Current_Millis - IR_Millis >= IR_OFF))
    {
      // Turn on IR LED
      IR_State = HIGH;
      IR_Millis = Current_Millis;
      digitalWrite(IR, IR_State);
    }
}
```

## Appendix K: Data Processing Code

Function code oxygen_sat.m written in MATLAB.

```
function SPO2 = oxygen_sat(red_filepath,ir_filepath,start,finish,peakwidth,alight)
% SET VARIABLES
ambient_light = alight; % constant for ambient light
t_1 = start; % First timestamp of time frame
t_2 = finish; % End timestamp of time frame
peak_width = peakwidth; % Distance of points needed to qualify a peak, smaller width = more peaks

% Load Data File and Assign Variables (Red Data)
RED_DATA = load(red_filepath);

t = RED_DATA(:,1);  % TIME
v_laser = RED_DATA(:,2);  % VOLTAGE of laser

v_laser = v_laser - ambient_light; % Remove ambient light

v_ppg = RED_DATA(:,3); % Voltage of ppg device

time_sect = t(find(t==t_1):find(t==t_2)); % Timestamps for graphing
sample_data = v_ppg(find(t==t_1):find(t==t_2)); % PPG voltage values being sampled
v_laser_sample = v_laser(find(t==t_1):find(t==t_2)); % Laser voltage values being sampled

ppg_peak_vals = findpeaks(sample_data,'MinPeakWidth', peak_width); % Find peak systoles and diastoles
ppg_peak_vals = unique(ppg_peak_vals,'stable'); % Remove repeat peak values

% Translate raw peak voltage values into matrix indices
index = zeros(1,1);
for i = length(ppg_peak_vals)
   index = find(sample_data == ppg_peak_vals(i));
end

red_AC = mean(v_laser(index)); % Take the laser voltage values at the peak points areas and average them
red_DC = min(v_laser_sample); % Find the minimum voltage value within the sampled area

figure
plot(time_sect, sample_data)
findpeaks(sample_data,'Annotate','peaks','MinPeakWidth', peak_width);
xlabel('Time(sec)','fontsize',18)
ylabel('Voltage','fontsize',18)
title('PPG Peaks Red Data','fontsize',20)


%% Find IR values

IR_DATA = load(ir_filepath);

t = IR_DATA(:,1);  % TIME
v_laser = IR_DATA(:,2);  % VOLTAGE of laser
v_ppg = IR_DATA(:,3); % Voltage of ppg device

v_laser = v_laser - ambient_light;
```

```
time_sect = t(find(t==t_1):find(t==t_2));
sample_data = v_ppg(find(t==t_1):find(t==t_2));
v_laser_sample = v_laser(find(t==t_1):find(t==t_2));

ppg_peak_vals = findpeaks(sample_data,'MinPeakWidth', peak_width);
ppg_peak_vals = unique(ppg_peak_vals,'stable');
index = zeros(1,1);

for i = length(ppg_peak_vals)
   index = find(sample_data == ppg_peak_vals(i));
end

ir_AC = mean(v_laser(index));
ir_DC = min(v_laser_sample);

figure
plot(time_sect, sample_data)
findpeaks(sample_data,'Annotate','peaks','MinPeakWidth', peak_width);
xlabel('Time(sec)','fontsize',18)
ylabel('Voltage','fontsize',18)
title('PPG Peaks IR Data','fontsize',20)


%% Calculate SPO2

R = (red_AC/red_DC)/(ir_AC/ir_DC);
SPO2 = -22.6*R + 95.842;

end
```

Data file processing code, processing_code.m, written in MATLAB:

```
% FILE FORMAT
% Code processes each PAIR of files at once
% Alternate between Red and IR in filepath

% EXAMPLE:
% C:\filepath...
% 1_NAME_DATE_TEST_1_660_LASER
% 2_NAME_DATE_TEST_1_780_LASER
% 3_NAME_DATE_TEST_2_660_LASER
% 4_NAME_DATE_TEST_2_780_LASER
% 5...
% 6...

% Filepath must be in the same place as code !!!

clear
clc

files = dir('*.csv') ;
N = length(files) ;
```

```
SPO2 = cell(N/2,1) ;  % to save output

index = 2; % Start at second row to leave room for titles
for i = 1:2:N
   SPO2{index,1} = files(i).name;
   SPO2{index,2} = files(i+1).name;

   % FORMATTING EXCEL SHEET
   info = convertCharsToStrings(files(i).name);
   info = split(info,'_');
   SPO2{index,3} = info{2,1};
   date = info(3,1) + '/' + info(4,1) + '/' + info(5,1);
   SPO2{index,4} = date;
   SPO2{index,5} = info{6:end,1};
   % END

   SPO2{index,6} = oxygen_sat(files(i).name,files(i+1).name,30,35,80,0.013); % Files MUST be in the same folder as code AND
function
   index = index + 1;
end

% Format titles
SPO2{1,1} = 'RED FILEPATH';
SPO2{1,2} = 'IR FILEPATH';
SPO2{1,3} = 'Subject';
SPO2{1,4} = 'Date';
SPO2{1,5} = 'Test';
SPO2{1,6} = 'Result (%)';

% Dump into excel file
filename = 'testdata.xlsx';
writecell(SPO2,filename)

% Check folder for excel sheet
```

# Appendix L: Initial Filtering and Analysis Code

```
%% MQP Data Filtering  (RED LIGHT SOURCE)
%%
% Clear Everything
clear;
clc;
% Original Data
% Load Data File and Assign Variables (Red Data)
C = load('Ian_2_27_2023_SITTING_TEST_1_660_LASER.csv');
x = C(:,1);  % TIME
z = C(:,2);  % VOLTAGE
% Remove Ambient Light and recreate y
ambient = 0.013;
y = z-ambient;
% Define Sampling Rate
Fs = length(x)/(x(end)-x(1));
% % Apply Bandpass Filter
% BP = bandpass(y,[0.5 10],Fs);
% Define Recording Length
length(x)/Fs;
% Focus on 70 Seconds of Data
ind = (1:70*Fs)';
% Display Plot of Filtered Data
figure
plot(x,y)
xlabel('Time(sec)','fontsize',18)
ylabel('Voltage','fontsize',18)
title('Red Filtered Signal','fontsize',20)
%% Data Analysis for IR of the Need Values to complete the R ratio to determine blood oxygen level
%we can now set the sampling rate of the data. This sampling rate will
%allows us to easily modify the sections which chunks of data we wish to
%get the AC and DC from. We can also set which cell we want to start at.
%For example if we start getting RED LED data in the 20000 th cell,
% we can set the start to 20000 to tell the data to start analyzing
% from there
rate=2000;
start=38000;
%We also want to do this same method for getting the initial value of the
%voltage being read
Inital_rate=2000;
inital_start=2000;
% Once the sampling rate and the starting cell are set, we can determine the
% duration of the test by multiplying the number of seconds by the sampling
% rate
duration=20*rate;
%Again, we want to do the same for getting the initial value of the
%voltage being read
inital_duration=2*Inital_rate;
% Our rates and durations are set! Now for the key part. We must tell
% MatLab to isolate the region of values we want to analyze from the
% "start" value to the "duration (which is going to result in the last cell
```

```
% the code will analyze)
Readings_Analyized=y(start:duration);
%Again, we must isolate the region that we want to analyze for the initial
%voltage value
Inital_Readings_Analyized=y(inital_start:inital_duration);
%Now get the initial voltage
inital_minimum_peak_vaule_analized=min(Inital_Readings_Analyized);
inital_maximum_peak_vaule_analized=max(Inital_Readings_Analyized);
Inital_voltage = inital_maximum_peak_vaule_analized-inital_minimum_peak_vaule_analized+inital_minimum_peak_vaule_analized;
%We then gather the maximum value and minimum peak value from the
%non-initial range
minimum_peak_vaule_analized=min(Readings_Analyized);
maximum_peak_vaule_analized=max(Readings_Analyized);
% Tell it to calculate AC and DC
ACred=maximum_peak_vaule_analized-minimum_peak_vaule_analized;
DCred=minimum_peak_vaule_analized;
% And finally tell us to get part of the RedR ratio. When we have a RedR and
% IRR, we can use the ratio of RedR/IRR to get the oxygen saturation level
RedR = ACred/DCred;
display(RedR);
%% MQP Data Filtering
% Original Data
% Load Data File and Assign Variables (IR Data)
C = load('Ian_3_1_2023_SITTING_TEST_1_780_Laser_.csv');
x = C(:,1);  % TIME
z = C(:,2);  % VOLTAGE
% Remove Ambient Light and recreate y
ambient = 0.013;
y = z-ambient;
% Define Sampling Rate
Fs = length(x)/(x(end)-x(1));
% Apply Bandpass Filter
BP = bandpass(y,[0.5 10],Fs);
% Define Recording Length
length(x)/Fs;
% Focus on 60 Seconds of Data
ind = (1:70*Fs)';
% Display Plot of Filtered Data
figure
plot(x,y)
xlabel('Time(sec)','fontsize',18)
ylabel('Voltage','fontsize',18)
title('Infra-Red Filtered Signal','fontsize',20)
%% Data Analysis (INFRA RED LIGHT)
%we can now set the sampling rate of the data. This sampling rate will
%allows us to easily modify the sections which chunks of data we wish to
%get the AC and DC from. We can also set which cell we want to start at.
%For example if we start getting RED LED data in the 20000 th cell,
% we can set the start to 20000 to tell the data to start analyzing
% from there
rate=2000;
start=38000;
%We also want to do this same method for getting the initial value of the
```

```
%voltage being read
Inital_rate=2000;
inital_start=2000;
% Once the sampling rate and the starting cell are set, we can determine the
% duration of the test by multiplying the number of seconds by the sampling
% rate
duration=20*rate;
%Again, we want to do the same for getting the initial value of the
%voltage being read
inital_duration=2*Inital_rate;
% Our rates and durations are set! Now for the key part. We must tell
% MatLab to isolate the region of values we want to analyze from the
% "start" value to the "duration (which is going to result in the last cell
% the code will analyze)
Readings_Analyized=y(start:duration);
%Again, we must isolate the region that we want to analyze for the initial
%voltage value
Inital_Readings_Analyized=y(inital_start:inital_duration);
%Now get the initial voltage
inital_minimum_peak_vaule_analized=min(Inital_Readings_Analyized);
inital_maximum_peak_vaule_analized=max(Inital_Readings_Analyized);
Inital_voltage = inital_maximum_peak_vaule_analized-inital_minimum_peak_vaule_analized+inital_minimum_peak_vaule_analized;
%We then gather the maximum value and minimum peak value from the
%non-initial range
minimum_peak_vaule_analized=min(Readings_Analyized);
maximum_peak_vaule_analized=max(Readings_Analyized);
% Tell it to calculate AC and DC
ACIR=maximum_peak_vaule_analized-minimum_peak_vaule_analized;
DCIR=minimum_peak_vaule_analized;
% % And finally tell the code to get part of the IRR ratio. When we have a RedR and
% % IRR, we can use the ratio of RedR/IRR to get the oxygen saturation level
%
IRR = ACIR/DCIR;
display(IRR);
Rraito=RedR/IRR
%code is set, must change the R2 and see the change of gain, and also
%change the intensity of the lasers to get a value of 3. That way, one we
%get the intensity, we can normalize the data and prevent any cutoffs.
% -22.6*Rraito + 95.842 , formula for calibration curve to translate R to
% blood oxygen level
```