Light Dose Tensegrity Medical

Final Design Report Template

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DISCLAIMER

This report was prepared by students as part of a university course requirement. While considerable effort has been put into the project, it is not the work of licensed engineers and has not undergone the extensive verification that is common in the profession. The information, data, conclusions, and content of this report should not be relied on or utilized without thorough, independent testing and verification. University faculty members may have been associated with this project as advisors, sponsors, or course instructors, but as such they are not responsible for the accuracy of results or conclusions.

EXECUTIVE SUMMARY

The “Light Dose Tensegrity Medical” project focuses on the development of a cutting-edge photo-biomodulation (PBM) device aimed at improving cardiovascular health through non-invasive monitoring and therapy. PBM technology, which utilizes red and infrared LED light, has been shown to enhance cellular function and reduce inflammation by stimulating biological processes at the cellular level. The device's innovative design integrates advanced AI and machine learning capabilities, offering real-time data collection and feedback, making it a valuable tool for medical institutions, rehabilitation centers, military applications, and sports teams

This report outlines the first steps this team has taken to develop our device based on the requirements set out to us by our client. Our background and description provide a detailed overview of our objectives and the needs we are addressing. The requirements section includes various tables and charts, such as our Quality Function Deployment (QFD), which helps us organize and prioritize critical project elements. Our literature review offers insight into the medical, mechanical, and electrical aspects we’ve researched so far, which have shaped the core technologies of our device. We have also conducted various calculations over a wide range of calculations over these disciplines, helping us refine our approach to solving problem at hand.

The core of the device lies in its use of specific wavelengths (600-880 nm) to improve blood flow and oxygenation while supporting cardiovascular tissue repair. The device's design includes a rechargeable battery system, ease of use and enabling portability, eliminating the need for a power cord, making it ideal for everyday use and providing a continuous, non-invasive solution for patients requiring long-term cardiovascular monitoring. Our design concepts were selected using a Morphological Matrix, factoring in multiple safety considerations to ensure reliability and user comfort. The design also incorporates a rough Computer-Aided Design (CAD) model, giving us a preliminary view of how the final product will be manufactured. The prototype integrates layered structures, including LED light arrays, sensors, and data collection components, with functionality based on a black-box model that manages data collection and transmission in real time. Machine learning algorithmics optimize treatment dynamically, personalizing therapy based on patient specific data.

At the time of writing, the project is in the final prototype phase, with a series of device testing completed. Future plans include presenting at Northern Arizona University’s (NAU) UGRAD Symposium and handing off all the information from both the Fall 2024 and Spring 2025 semesters to our sponsor. We have also concluded the report with a reference page and appendix to document all research and resources involved.

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1 BACKGROUND

Cardiovascular health issues continue to be a major concern across various populations, creating a demand for innovative, non-invasive monitoring and treatment solutions. This project focuses on the development of a wearable medical device that leverages photo-biomodulation (PBM) technology using red LED light to promote tissue repair, reduce inflammation, and enhance cellular function. By integrating sensors to monitor blood flow and oxygen saturation, the device aims to provide real-time insights into the user's cardiovascular condition. The design emphasizes portability, affordability, and user comfort, targeting applications in medical, military, athletic, and rehabilitation settings. Partnering with Tensegrity Medical and supported by cross-disciplinary collaboration with Electrical Engineering and Computer Science capstone teams, this project seeks to advance accessible and proactive cardiovascular health management.

1.1 Project Description

1.1.1 Project Overview Summary

The purpose of our is to design and develop a device focused on revolutionizing cardiovascular health monitoring through advanced photo-biomodulation (PBM). Our device utilizes red LED lights and integrated sensors to enhance cellular function, promote tissue repair, and reduce inflammation, while accurately monitoring blood flow and oxygen circulation. Featuring a convenient rechargeable battery, this noninvasive solution is designed for use in various environments, including medical institutions, rehabilitation centers, military applications, sports teams and etcetera. for this project we are partnering with the Electrical Engineering (EE) and Computer Science (CS) capstone programs to foster teamwork skills and enhance project development.

1.1.2 Project Objectives

This project aims to develop and justify the following attributes, including (but not limited to):

- Offer a non-invasive solution for cardiovascular health monitoring
- Utilize photo-biomodulation (PBM) technology
- Utilize red LED lights, integrate sensors, and include a rechargeable battery
- Design a device to monitor blood flow and oxygen circulation
- Enhance cellular function, promote tissue repair, and reduce inflammation
- Real-time data transmission via external unit
- Empower individuals with valuable insights into their cardiovascular health
- Help create health monitoring accessible to everyone.

1.1.3 Client

The client for this project is Jesslynn Armstrong. She is the founder and CEO of Tensegrity Medical, leading innovative AI-driven medical devices for wound care and pain management. She collaborates with Northern Arizona University and the bioscience community to drive patient-

centered healthcare innovation.

1.2 Deliverables

1.2.1 Corse Deliverables

The course deliverables for this project are organized into several key components, including presentations, detailed reports, and the development of prototypes; each building upon the previous stages to reflect progress and deeper insights.

1.2.2 Presentations

Throughout the course, we are expected to create and deliver professional presentations that clearly communicate the project's objectives, design process, and final outcomes. The first presentation introduces the project and outlines the benchmarks and research used to begin designing the product according to the customer's requirements. This early stage provides a foundation for understanding the scope of work and sets the design process in motion. Presentation 2 goes into concept generation, showcasing calculations and analysis that identify the design concepts best suited to meet the customer's needs, while providing an up-to-date budget and project schedule. Presentation 3 showcased the first physical prototype. This presentation described the prototype's purpose, specifically addressing key questions the prototype aims to answer.

The next three presentations in the second semester got us closer and closer to the final product of our device. In the second semester we completed a presentation for the 33, 67 and 100 percent updates of our build in which we displayed to the class as well as the professor what we have achieved and what we still needed to accomplish moving forward.

1.2.3 Reports

Reports follow a similar staged progression. Report 1 expands on the content from Presentation 1 and 2, offering more detailed elaboration on the initial research, design processes, and concept analysis. Report 2 is an extension of Report 1, further incorporating information shared in presentation 3, particularly focusing on the prototype testing and final design considerations. The final report, this report, expands on all the final work we have completed in the second semester of capstone; including but not limited to: final budget, final design, and final testing strategies.

1.2.4 Client Deliverables

Client Deliverables are reflective of the project's objectives. The initial goal of the Tensegrity project is to create a medical device that incorporates photo-bimodular technology to regulate blood circulation as well as collect data. The client, Jesslyn Armstrong, requires that the device be able to be rechargeable, allow for the device to work for a certain duration with an automatic shutdown, along with the device to be affordable, thus making it cost effective.

1.3 Success Metrics

To consider this project a success we must meet the project objectives, course deliverables, client deliverables, customer requirements, engineering requirements, and manufacturability; these can

be found in the next section below. To confirm this has been achieved the team aims to complete manufacturing by the end of spring semester 2025. This will allow time to test the design's engineering requirements to be tested, complete any addition manufacturing development, as well as have the device patented and certified by a registered organization before conclusion of the school year.

2 REQUIREMENTS

This section includes the customer requirements, engineering requirements, and the house of quality. Customer requirements are general requirements requested by Jesslynn Armstrong. After compiling the customer requirements, the team then translates these customer needs into measurable criteria called engineering requirements. Taking both the customer and engineering requirements, a House of Quality is created to show the correlation between each requirement. The house of quality allows us to compare benchmarked designs and ensure alignment and effectiveness.

2.1 Customer Requirements (CRs)

With the final development of the medical device, and the ever-changing needs of the client throughout the project, the team has come up with the following customer requirements that we have based our design off:

1. *Reuseable / Rechargeable*
2. *Light Exposure*
3. *Time Duration / Automatic Shut Off*
4. *Cord Free*
5. *Cost Effective*
6. *Compact*

The first requirement the customer wanted in this device is that it should be reuseable and therefore rechargeable for repeated use. The second requirement was that the device should emit a certain amount of light exposure. The light exposure in red light therapy must be within a certain range in order to see significant improvements for the user's vitals. The third requirement was that the device must be capable of operating for the maximum recommended time duration and automatically shut off once the treatment time has elapsed. The fourth requires that the design of the device doesn't include external cords or plugs into any sockets. Next, the device must be cost effective, necessitating careful selection of materials and components to stay within the allocated budget. Finally, the client wanted the device to not exceed a certain size, making sure it stays compact and that it is portable for use in various environments and situations.

2.2 Engineering Requirements (ERs)

The engineering requirements selected by the team were generated directly from the customer requirements and are as followed:

1. *Power Output*
2. *Battery Life*
3. *Unit Code*
4. *LED Wavelength*

5. *Treatment Duration*
6. *Size*

The first engineering requirement, power output, is measured in watts and indicates the amount of power the medical device will need to operate the red and infrared light-emitting diodes and sensors. The device has a targeted power output of 20 to 50 watts. The next requirement is battery life is measured in minutes and represents how long the device can function before requiring a recharge. The goal is to have the battery life last up to 120 minutes. Both power output and battery life relate to the customer's requirement of being rechargeable. Unit cost measured in US dollars is the cost of manufacturing one medical device. The goal is to spend up to $290 per device. The wavelength of the red LED lights is measured in nanometers, and the target is for the light to be between 650 and 670 nanometers for the red LED lights. Treatment duration, measured in minutes, incorporates the customer requirements for treatment time and automatic shutdown. Ideally, the treatment duration should be around 20 minutes. Finally, the size should not exceed a 10in x 10in perimeter, ideally the device will be smaller but that is the maximum.

2.3 House of Quality (HoQ)

System QFD

Project:		**Tensegrity Medical Light Therapy**
Date:		**11/5/2024**

1	Power Output						
2	Battery Life	9					
3	Unit Cost						
4	Wavelength (Red LEDs)	3	9				
5	Treatment duration	3	3		3		
6	Size			3			

Legend
- A LOVTRAVEL LED Light Therapy Pad
- B Garmin HRM-Dual Heart Rate Monitor
- C Innovo iP900BP-B Finger Pulse Oximeter

			Technical Requirements						**Customer Opinion Survey**				
	Customer Needs	**Customer Weights**	Power Output	Battery Life	Unit Cost	Wavelength (Red LEDs)	Treatment Duration	Size	1 *Poor*	2	3 *Acceptable*	4	5 *Excellent*
1	Reuseable/Rechargeable	4	1	9	3	3	1			A	BC	A	C
2	Light Exposure	4	3			9	9		AC				B
3	Time Durat/Shutoff	1	3	3		9	9				AC		B
4	Cord Free	4	3	9			3	9	BC		AC		
5	Cost effective	3			9			3		A		BC	
6	Compact	2			3			9	A			B	
	Technical Requirements Units		W	min	$(USD)	nm	min	in					
	Technical Requirements Target		20-50	120	290	650-670	20	10x10					
	Absolute Technical Importance		31	75	45	57	61	63					
	Relative Technical Importance (%)		9.34	22.59	13.55	17.17	18.37	20.93					

Figure 1: House of Quality

The team developed a House of Quality, shown in the figure above, to analyze the relationship between the customer requirements with the engineering requirements by using a quality function deployment chart. Additionally, the QFD shows the relationship between the engineering requirements amongst each other and includes the relationship between the three system benchmarks (see section 3.1 for system benchmarking) and the customer requirement. The customer requirements were given weights on a scale of 1 to 4; 1 meaning that the customer

requirement was not as important and 4 meaning that the requirement is very important. For example, the customer requirement of the medical device needing to be reuseable was rated a 4 because we need to make sure the client can use the device over a number of times. Additionally, the automatic shut off feature was rated a 1 because this feature was requested in case the consumer needed to extend the minimum treatment duration and after determining that vitals improved the device would automatically shut off.

Then, the customer requirements were directly compared against the engineering requirements on a 1, 3, or 9 ranking system; 1 meaning there was little to no correlation, 3 meaning there was somewhat of a correlation, and 9 meaning there was a high correlation. Cells left blank represent no correlation between the requirements. For example, the correlation between battery life and rechargeable was rated at 9 since the battery life affects how long the device will last before needing to recharge.

The next section of the QFD, below the customer needs and technical requirements, shows the units each engineering requirement will be in. Additionally, it shows the requirement targets, the absolute technical importance, and the absolute technical importance. Technical importance shows us which engineering requirements are most important, and which requirements affect the development of the device. The technical requirement targets were set based on research conducted. For example, the treatment duration was set at 20 minutes since this is the minimum amount of time recommended by professionals who use LED light therapy.

In the final section, customer opinion survey, this shows the benchmarking of three previously used devices and shows which of the three meets the customer requirements the best. Each device was rated on a scale of 1 to 5; 1 meaning that the device performed poorly at meeting the customer requirements and 5 meaning that the device performed excellent at meeting the customer requirements.

3 RESEARCH WITHIN YOUR DESIGN SPACE

In this section, the team provides the necessary research involved with the development of the light therapy medical device. The subsections include three systems to be used as benchmarks, the literature review provided by each individual team member, and the mathematical modeling or engineering calculations utilized to aid in the design of the medical device.

3.1 Benchmarking

3.1.1 Related / Similar Designs

For our benchmarking, we decided to choose a device like the one our client currently uses along with two devices that represent sub-sections of the device we are developing. Below are the three benchmarking devices our team decided to use with explanations of why we decided to reference them.

Figure 2: LOVTRAVEL LED Light Therapy Pad [27]

The first device we included in our benchmarking, in the figure above, is the LOVTRAVEL LED light therapy pad. This device is used as inspiration for the medical device our team is currently developing. This device is being modernized to keep up with the current technology used today. The medical device being developed by the team will be more aesthetically pleasing, and the goal is to eliminate the use of cords as Jesslynn emphasized that having to untangle cords is very time consuming.

Figure 3: Garmin HRM-Dual [28]

The next device included in the benchmarking, in the figure above, is the Garmin HRM-dual that monitors heart rate. The medical device will need to monitor vitals such as blood pressure to determine how much longer the consumer needs to continue with the LED light therapy. This device provides a great foundation for helping figure out how to implement something like this into the medical device.

Figure 4: Innovo Finger Pulse Oximeter [29]

The third device included in the benchmarking, in the figure above, is the Innovo Finger Pulse Oximeter which is used to measure oxygen levels. The medical device is required to also measure the oxygen levels in the blood which will determine whether the consumer should continue with a second round of light therapy. Overall, this device is a great reference to help figure out how to implement it into the medical device.

3.2 Literature Review

This project necessitates that each team member conduct through research to better understand the purpose and functionality of the medical device. As part of this process, each team member is responsible for reviewing various sources, including academic journal articles, textbooks and credible online resources, to gather pertinent information. The following sections present a detailed literature review, complied by each team member, which highlights the findings and key takeaways from these sources. This collective research effort will ensure that the project is grounded in reliable, up-to-date information and supports the successful development of the device.

3.2.1 Alicia Corona

Advance Flexible Skin-Like Pressure and Strain Sensors for Human Health Monitoring [1]

This journal article discusses the development of sensors that are like human skin. These sensors were designed to be lightweight and flexible. These sensors allow for comfortable wear while monitoring the necessary vitals. This journal article provides insight into the design and materials used, the functionality of the sensor, and what applications this sensor has. This sensor would be ideal for our medical device, as it needs to be flexible to conform to the organic surfaces of the human body. Furthermore, this sensor will enhance the comfortability of the device and ensure we have accurate vital information.

Lasers and Optical Fibers in Medicine (Chapter 8) [2]

In this chapter of the book, it discusses the applications of laser technology and optical fibers in medical practices. Specifically, this chapter lists different types of lasers with their properties and highlights the role of optical fibers. This chapter was referenced to calculate the flux or power density of the medical device.

A Review of Current Advancements for Wound Healing: Biomaterial Applications and Medical Devices [3]

This journal article summarizes recent developments in wound healing technologies. This journal specifically discusses common biomaterials used in wound care, includes what current medical devices are used to promote wound healing, and provides an explanation of how this technology aids in healing. The medical device has a similar purpose to the devices talked about in this journal and this could be used as a foundation for the device's development.

Biomedical Devices: Materials, Design, and Manufacturing [4]

This book provides insight into the development of medical devices by focusing on the materials used, the design, and the manufacturing processes. This book discusses common biomaterials used such as metals, polymers, ceramics, and composites; emphasizes design considerations to create effective and safe devices; and reviews relevant manufacturing processes related to biomedical

devices such as additive manufacturing, injection molding, and machining. This book is a great reference as it narrows down the materials we can use and gives insight into how we can manufacture medical devices.

Proposed Mechanisms of Photo-biomodulation or Low-Level Light Therapy [5]

This journal article explains the biological effects and mechanisms of photo-biomodulation (PBM), a therapeutic technique that uses light to promote healing and tissue regeneration. This journal goes into detail on how this therapy works by discussing mitochondrial stimulation, increased ATP production, and modulation of oxidative stress. Additionally, this journal discusses how PBM reduces inflammation and improves blood flow. This article gives the team an overview of the science behind this therapy and gives a better understanding of the purpose of the medical device the team is developing.

LED Light Therapy Wavelengths: Everything You Need to Know [6]

This article provides a summary of the wavelengths used in LED light therapy and what effects it has on the human body. The article explains that each wavelength of light penetrates the skin at different depths and each wavelength has its own therapeutic benefits. Additionally, this article provides the therapeutic effects each wavelength has such as red light promotes collagen production, wound healing, and inflammation reduction. This article was referenced to understand how the light waves enter the human body and explains why the medical device uses red light instead of blue light.

LED Light Therapy: How It Works, Colors, Benefits & Risks [7]

This article provides an overview of LED light therapy by explaining the risks and benefits and providing the different wavelengths of light used for this type of therapy. It clarifies the differences between each light wavelength while also stating what conditions light therapy does not treat. Treatment sessions usually last 20-30 minutes. Additionally, the article emphasizes that certain individuals should not use light therapy as it can lead to potential health risks. This article was referenced to understand the benefits and risks of LED light therapy and helped clarify who will be using the medical device.

IEC 60601-2-57:2023 [8]

This standard from the International Electrotechnical Commission (IEC) outlines safety and performance requirements for non-laser light source equipment used for therapeutic, diagnostic, monitoring, cosmetic, and aesthetic purposes. This standard ensures that the device operates within safe limits for human use. This standard is crucial for the team to reference to guarantee that the medical device meets safety requirements and is safe for consumers to use.

IEC 62133-2 [30]

The International Electrotechnical Commission (IEC) standard outlines essential requirements for rechargeable lithium-ion cells and batteries, addressing their design, assembly, and testing to ensure safe and reliable operation. It includes rigorous testing for electrical, mechanical, and environmental stresses, with a focus on critical issues such as thermal runaway, short circuits, and overcharging. Since the prototype medical device incorporates a lithium-ion battery, it is vital for the team to reference this standard when designing the circuit to ensure compliance and safety.

ASTM D5470-17 [31]

This standard from the American Society for Testing and Materials (ASTM) defines a test method for measuring the thermal transmission properties of thermally conductive materials. It provides a detailed procedure to evaluate the thermal resistance and conductivity of materials commonly used in thermal management applications, such as electronics. This method is widely employed to assess and compare the heat-dissipation efficiency of thermal materials. Referencing this standard will be valuable when conducting heat transfer analysis for the medical device, ensuring its safety and optimal performance.

3.2.2 Claire Mitchell

All You Really Need to Know to Interpret Arterial Blood Gases (Chapter 5) [9]

This chapter of the book discusses the oxygen content of the blood as well as the breakdown of what kind of pressure and saturation the blood makes up. Blood oxygen content is separated into three different parts: Oxygen Pressure (PaO2), Oxygen Saturation (SaO2), and Oxygen Content (CaO2). PaO2 is the oxygen content that is dissolved in plasma, SaO2 is the oxygen content that binds to plasma, and CaO2 is the total make up of oxygen in a certain amount of blood.

What are Blood Oxygen Levels [10]

This article talks more in depth into how much oxygen should be in a healthy person's blood and why they need it. A healthy person’s blood should carry about 92% and above of oxygen to make sure their body is running smoothly. Certain things might prevent a person from having a 92% percent or above, such as a person having some sort of lung or blood disease/condition, or if a person is at a higher altitude.

Physiology, Oxygen Transport [11]

This article talks about how to calculate oxygen content in the blood, as well as talks about a few conditions that might prevent someone from having a healthy oxygen content. This specific article speaks on how people with anemia have a lower oxygen content because they have reduced hemoglobin numbers. Because of the reduced hemoglobin, there is a lot lower chance for oxygen to either bind or dissolve to the HB.

A Controlled Trial to Determine the Efficacy of Red and Near-Infrared Light Treatment in Patient

Satisfaction, Reduction of Fine Lines, Wrinkles, Skin Roughness, and Intradermal Collagen Density Increase [12]

This study examined the safety and effectiveness of two light sources for treating large areas of skin with polychromatic, non-thermal photo biomodulation (PBM) to improve skin appearance and feel. The research involved 136 volunteers and compared the effects of different light wavelengths on skin rejuvenation. Results showed that both light sources improved skin complexion, texture, and collagen density significantly more than the control group. Both methods proved safe and effective for enhancing skin quality.

Battery Design Guide for Portable Electronics [13]

This paper talks about the different design parameters needed to keep in account while selecting batteries for portable electronics. It talks about different voltage requirements, temperature requirements, and current requirements needed for different sizes and types of devices.

Development of a LED light therapy device with power density control using a Fuzzy logic controller [14]

This study focuses on a new design for an LED light therapy device that maintains stable power density despite battery discharge, which can affect performance. The researchers used fuzzy logic to control the power density of different LED colors. The results showed that this design effectively stabilizes power output, enhancing energy efficiency and performance even with varying voltage. This advancement aims to improve both battery life and operating time for LED therapy devices.

Battery Operated Devices and Systems: From Portable Electronics to Industrial Products (Chapter 3.3: Medical Applications) [15]

Talks about various battery design and how they can be useful in different applications. Chapter 3.3 specifically speaks on medical devices and how there are a lot more requirements for batteries in medical use. It describes the batteries you can and can't use based on what the class of the medical device is.

Standard: ISO 80601-2-61:2017 [16]

This standard is an international standard that specifies safety and performance requirements for medical electrical equipment, particularly focusing on photobiological devices used for therapeutic applications, such as light therapy. This standard outlines essential requirements for design, testing, and use to ensure patient safety and device effectiveness. It covers aspects like electromagnetic compatibility, risk management, and performance testing, ensuring that devices operate safely and reliably in a clinical environment.

Standard: ISO 14155:2020 - Clinical Investigation of Medical Devices for Human Subjects [28]

This standard outlines how certain conditions need to be met before a medical device can be tested

on humans. This standard provides guidance on the design, conduct, and reporting of clinical investigations of said medical devices; all these instances need to be met in order for the testing trials to begin.

Standard: FDA (U.S.) - 21 CFR Part 820 - Quality System Regulation (QSR) [29]

The Quality System Regulation (QSR) is a set of requirements established by the Food and Drug Administration (FDA) that governs the design, manufacture, packaging, labeling, and distribution of medical devices sold in the U.S. Under 21 CFR Part 820, medical device manufacturers must implement a quality management system (QMS) to ensure their devices are safe, effective, and compliant with regulatory requirements.

3.2.3 Norma Munoz

Anti-inflammatory effects of PBM [17]

The journal *Frontiers in Neuroscience* explores the effects of photo-biomodulation (PBM) therapy, focusing on how it can influence the production and regulation of proteins in the body. By modulating these cellular processes PBM has the potential to offer therapeutic benefits. This research dives into the underlying mechanisms through which PBM may impact cellular signaling pathways, gene expression, and protein synthesis ultimately contributing to the reduction of inflammation in neural tissues.

PBM and Neurological Damage [18]

The Neuroscience bulletin explores the potential benefits of photo-biomodulation (PBM) in aiding the repair of brain damage caused by COVID-19. Specifically, the publication examines how PBM therapy may enhance the brain's ability to utilize and regulate oxygen levels more effectively. This research highlights the promising therapeutic applications of PBM in supporting brain health and potentially reversing some of the cognitive and neurological damage associated with the virus.

PBM for Cognitive Improvement [19]

The *Journal of Translational Medicine* explores the potential of photo-biomodulation (PBM) in enhancing brain function, particularly through its ability to stimulate the production of Adenosine Triphosphate (ATP), the primary source of energy for cells. The use of infrared light in PBM therapy can penetrate tissues effectively, triggering cellular processes that increase ATP Production, thereby improving the energy supply to brain cells. This, in turn, supports brain cell function and growth, offering promising implications for the treatment of neurodegenerative diseases, brain injuries, and other cognitive impairments.

Effects of Transcranial LED Therapy (TCLT) [20]

Salgado et al. explore the effects of Light Therapy, particularly photo-biomodulation (PBM), on cerebral blood flow and its potential therapeutic benefits. Their research highlights how PBM can

enhance blood circulation in the brain, especially in elderly patients, by stimulating vascular and cellular responses. The findings suggest that PBM could play a significant role in combating neurodegenerative conditions, such as Alzheimer's disease and Parkinson's disease, by addressing issues related to reduced cerebral blood flow that often accompany these disorders.

Low-level laser therapy effects on Vascular and endothelial function [21]

Calderhead, R. G., and Vasilyeva, E. provide an in-depth exploration of how photo-biomodulation (PBM) therapy can be applied to the treatment of cardiovascular diseases, highlighting the underlying cellular mechanisms involved. The authors delve into the critical parameters that affect the efficacy of PBM, including optimal dosage, specific wavelengths of light, and power density. These factors are essential for ensuring that the therapy produces the desired biological effects without causing harm or inefficiency. The paper emphasizes the importance of understanding and precisely controlling these parameters to achieve the best therapeutic outcomes for cardiovascular conditions

Role of PBM in Cardiovascular Health: Systematic Review and Meta-Analysis [22]

This paper investigates the effects of photo-biomodulation (PBM) on cardiovascular parameters, particularly its influence on blood circulation. Several clinical studies support these findings, demonstrating that PBM can lead to measurable improvements in microcirculation. Research has shown that PBM therapy can help alleviate symptoms of poor circulation, reduce inflammation, and potentially reduce the need for more invasive treatments in individuals with cardiovascular conditions.

Efficacy of PBM therapy in Older Adults: A systematic review [23]

This paper provides a detailed examination of whether there is any available evidence supporting the efficacy of photo-biomodulation (PBM) therapy in older adults. The search included peer-reviewed journal articles, clinical studies, systematic reviews, and other credible publications that investigate the use of PBM therapy specifically in the aging population.

LibreText: Chemistry [24]

This book describes the attenuation of light as it passes through a material, and its relationship to the properties of that material. Specifically, this law quantifies how the intensity of light decreases as it travels through an absorbing or scattering medium. The Beer-Lambert Law is crucial in understanding how light interacts with various substances, including biological tissues, and is especially relevant in the field of photo-biomodulation (PBM) research. The effectiveness of PBM therapy depends on how the light penetrates the tissue, which is influenced by the tissue’s optical properties, including absorption and scattering coefficients. The Beer-Lambert Law helps to model and predict how much light will reach the target tissues and how the intensity will decrease as it interacts with different biological materials like skin, muscle, and fat.

Standard: "ISO/IEC 17025 testing and calibration laboratories," ISO, 2017 [25]

This standard ensures that laboratories maintain the necessary competence to produce accurate and reliable results. Laboratories adhering to ISO/IEC 17025 demonstrate their ability to carry out tests and calibrations with consistency, precision, and validity.

"Stress-Strain behavior of Thermoplastic Polyurethane," H.J. Qi, M. C. Boyce, Cambridge, MA, Dec. 2003. Available: https://web.mit.edu/cortiz/www/Jerry/TPU_final.pdf [26]

This report discusses thermoplastic polyurethanes (TPU), focusing on their properties, processing methods, and applications. It highlights TPU's versatility, combining the elasticity of rubber with the durability

"A guide to thermoplastic polyurethanes (TPU) FLEX." Available: https://huntsman-pimcore.equisolve-dev.com/Documents/PU_Elastomers_Guide_to_TPU.pdf [27]

This report provides a detailed guide to thermoplastic polyurethane (TPU) elastomer, emphasizing their versatility and range of applications. It covers various TPU formulations under the brand names IROGRAN and IROSTIC, highlighting their use in industries.

3.3 Mathematical Modeling

Throughout the project we have been required to calculate various equations to support our concept generation process. In this section, the team will present their individual calculations, explaining their significance and how they contributed to the overall development of the project. These calculations were essential in ensuring that our concepts were grounded in accurate data and aligned with the project's goals.

3.3.1 Flux/Power Density - Alicia Corona

The following figures show the equations, an example from the textbook Lasers and Optical Fibers in Medicine (chapter 8) [2], and the calculations for flux/power density.

$$P_{flux} = \frac{P_{light}}{A}$$

P_{flux} = flux of radiant energy ($watts/cm^2$)

P_{light} = total power of light source ($watts$)

A = area illuminated by light (cm^2)

$A = \pi r^2$

Figure 5: Flux/Power Density Equation

EXAMPLE III: A beam of power P is incident on an area A for time t.

The irradiance (or power density) is P/A.

The total energy delivered to the area is $E = Pt$.

The fluence is $F = E/A = Pt/A$.

Figure 6: Example from textbook

$P_{light} = 3\ W$

$r = 6.35\ cm$

$A = \pi r^2$

$A = \pi * (6.35\ cm)^2$

$$P_{flux} = \frac{P_{light}}{A}$$

$$P_{flux} = \frac{3\ W}{\pi*(6.35\ cm)^2}$$

$$P_{flux} = 0.024\ \frac{W}{cm^2}$$

Figure 7: Flux/Power Density Calculation

The flux or power density calculation indicates how much energy the medical device is consuming per area. This is important to know when we begin to prototype and finalize our final product as it allows us to adjust the energy usage according to the dimensions of the device. Additionally, understanding energy consumption helps us optimize the device for energy efficiency.

3.3.2 Battery Capacity – Alicia Corona

The following figures show the equations, and the calculations conducted for the battery capacity.

$$Q = I * t$$

Q = battery charge capacity (Amp * hours)

I = current (Amps)

t = time (hours)

$$E = Q * V_{Battery}$$

E = battery energy capacity (watt * hours)

$V_{Battery}$ = battery voltage (volts)

Figure 8: Battery Capacity Equation

$I = 3\,A$

$t = 2\,hours$

$Q = (3A) * (2\,hours)$

$Q = 6\,Ah$

$V_{Battery} = 5\,V$

$E = (6\,Ah) * (5\,V)$

$E = 30\,Wh$

Figure 9: Battery Capacity Calculation

The battery capacity is measured in watt-hours (Wh), and our goal is to achieve a capacity of 30 Wh. This calculation is particularly important when wiring the circuit, as it directly impacts battery life and power, aligning with our engineering requirements mentioned in the House of Quality section.

3.3.3 Oxygen Content – Claire Mitchell

One of the things our device will be monitoring is blood oxygen content, because of that, we decided it would best suit us to be able to calculate it ourselves based on the different oxygen content values (pressure PaO2, and saturation Sao2). To calculate the total oxygen content (CaO2) I used the oxygen content equation shown below [9].

$$C_aO_2 = [Hb \times 1.34 \times S_aO_2] + [P_aO_2 \times 0.003]$$

C_aO_2 = Oxygen per 100mL of blood $\left(\frac{mL\ O_2}{100mL\ blood}\right)$

Hb = Hemoglobin $\left(\frac{gm\ Hb}{100mL\ blood}\right)$

1.34 = Content of oxygen that will bind for each gram of Hb $\left(\frac{mL\ O_2}{gm\ Hb}\right)$

S_aO_2 = Oxygen Saturation (%)

P_aO_2 = Partial Pressure of Oxygen $(mmHg)$

0.003 = Constant $\left(\frac{mL\ O_2}{mmHg\ 100mL\ blood}\right)$

Figure 10: Oxygen Content Equation with Specified Values

Through this equation, if we have SaO2 and Pao2 we can calculate what the CaO2 is. To practice using this equation, I took an example problem from Chapter 5 of *All You Really Need to Know to Interpret Arterial Blood Gases [9]*.

Clinical Problem 5-3. Using Figure 5-2 to determine SaO_2, calculate O_2 content of a patient with hemoglobin 12 gms/dl, PaO_2 50 mm Hg, pH 7.40.

Figure 5-2.

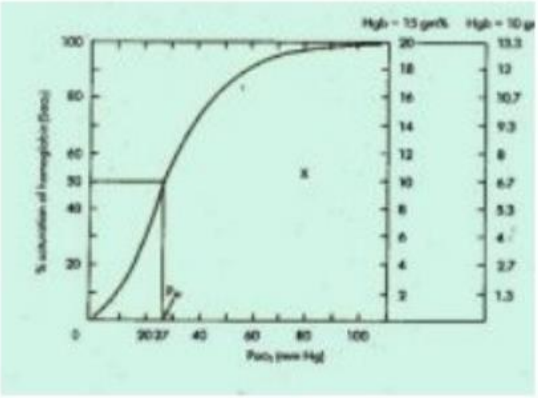


Figure 11: Example 5.3 from Book

With the values given to us as well as the equation, we are able to determine the CaO2 levels.

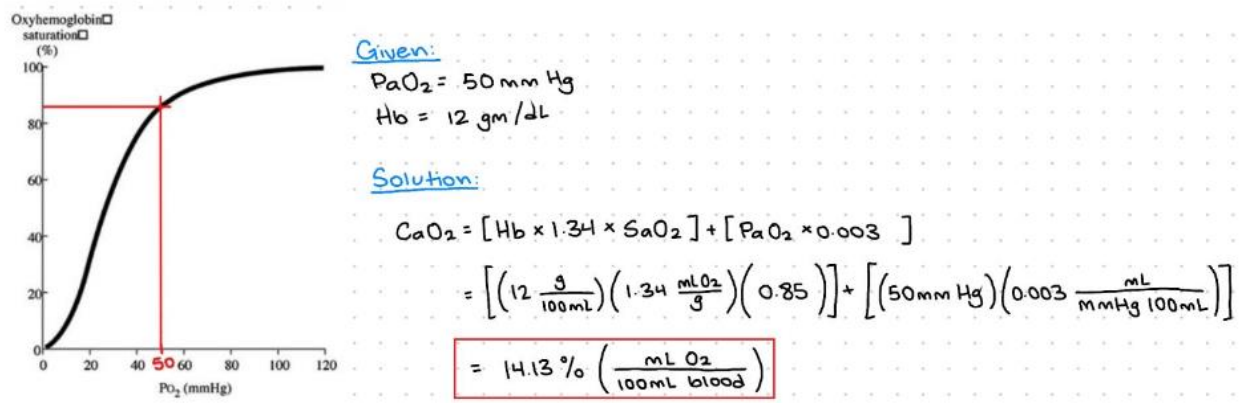


Figure 12: CaO2 Calculation

Because we were only given Hb and PaO2, we can use the given graph to find SaO2. After finding SaO2, we can plug all our values into the equation. In the example problem, we got 14.3% of mL of O2 per 100mL of blood. Further into the book it talks about the normal values of each content a person should have in order to be considered healthy; for SaO2 it's >92%, for PaO2 it's >80mmHg, for Hb it's 12-16 g/dL, and finally for CaO2 it's 16-20%. From this example problem we can see that it is a bit below the 'normal' level, so we can assume that this person might have a condition such as anemia or might even be residing at a high altitude.

3.3.4 Electrical Power – Claire Mitchell

In the team's LED Specification Table, a few of the power rate values were missing in our research. Because of this, I decided to calculate them by hand. It was important to find the power output because that was one of the main deciding factors for our selection process.

Out of the 5 values that we needed to have, we could only find 2 in the various websites we searched, so I calculated the remaining 3. In the websites I researched, I was able to find both the Amps and Voltage, so with those, I calculated the power using the Power Output Equation below [26].

$$P = IV$$

Figure 13: Power Output Equation

In this equation, power is in Watts (W), current is in Amps (A), and voltage is in Volts (V). The values I was able to find were in mA instead of A so in my calculations I also completed some simple conversions. With my calculations I was able to find the missing power values to add into our LED specification table.

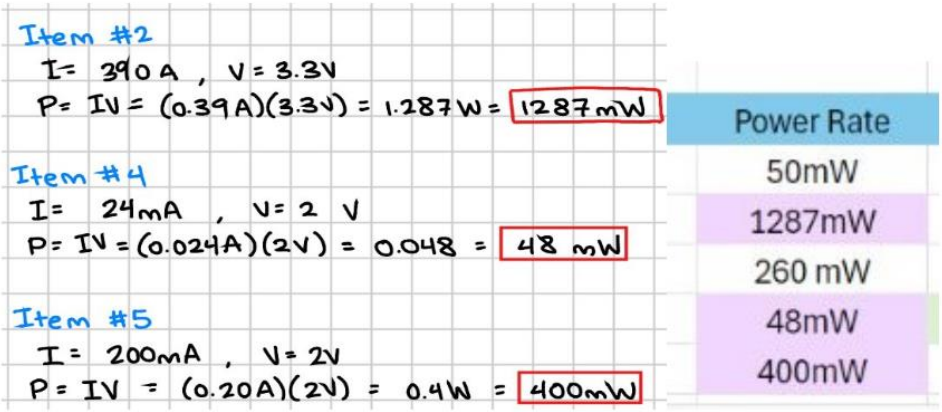


Figure 14: Power Output Calculations

3.3.5 Beer-Lambert Law – Norma Munoz

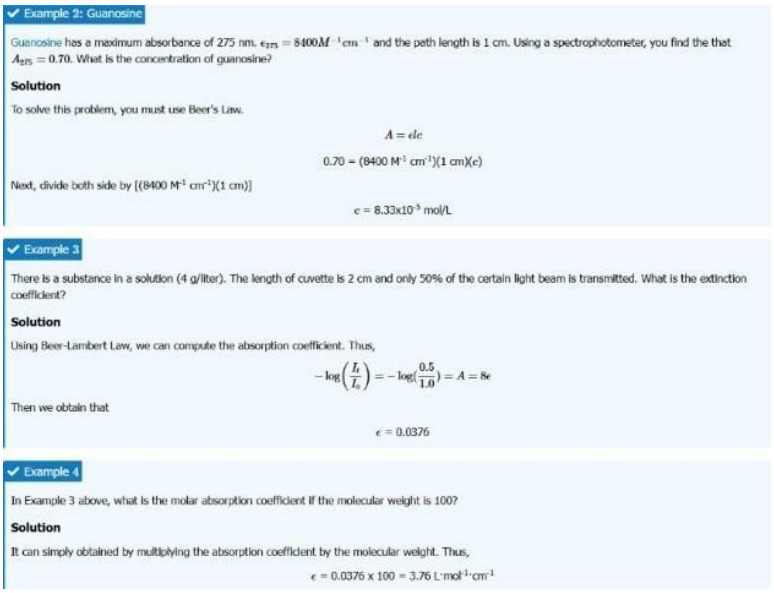
The following figures show the equation used, an example from the textbook [24] , and the calculations for the Beer-Lambert Law for Light Absorption incorporating values related to our project

$$A = log_{10}\left(\frac{I_o}{I}\right) \text{ or } \epsilon * c * d$$

$$\epsilon = \frac{A}{c * d}$$

$A = Absorbance$
$I_o = initial\ intensity$
$I = final\ intensity$
$\epsilon = molar\ absorption$
$c = concentration\ \left(\frac{mol}{L}\right)$
$d = l = length\ of\ path$

Figure 15: Beer-Lambert Law for Light Absorption



✔ Example 2: Guanosine

Guanosine has a maximum absorbance of 275 nm. $\epsilon_{275} = 8400 M^{-1} cm^{-1}$ and the path length is 1 cm. Using a spectrophotometer, you find the that $A_{275} = 0.70$. What is the concentration of guanosine?

Solution

To solve this problem, you must use Beer's Law.

$$A = \epsilon l c$$

$$0.70 = (8400\ M^{-1}\ cm^{-1})(1\ cm)(c)$$

Next, divide both side by $[(8400\ M^{-1}\ cm^{-1})(1\ cm)]$

$$c = 8.33 \times 10^{-5}\ mol/L$$

✔ Example 3

There is a substance in a solution (4 g/liter). The length of cuvette is 2 cm and only 50% of the certain light beam is transmitted. What is the extinction coefficient?

Solution

Using Beer-Lambert Law, we can compute the absorption coefficient. Thus,

$$-\log\left(\frac{I_t}{I_o}\right) = -\log\left(\frac{0.5}{1.0}\right) = A = 8\epsilon$$

Then we obtain that

$$\epsilon = 0.0376$$

✔ Example 4

In Example 3 above, what is the molar absorption coefficient if the molecular weight is 100?

Solution

It can simply obtained by multiplying the absorption coefficient by the molecular weight. Thus,

$$\epsilon = 0.0376 \times 100 = 3.76\ L \cdot mol^{-1} \cdot cm^{-1}$$

Figure 16: Example of Beer-Lambert Law from textbook

$$A = log_{10}\left(\frac{1000}{820}\right)$$
$$= log_{10}(1.22) = 0.086$$
$$\approx 0.10$$

$$\epsilon_{820} = \frac{0.10}{0.02 * 5} = 1\ L * mol^{-1} * cm^{-1}$$

Figure 17: Beer-Lambert Calculations using our values

3.3.6 Stress-Strain Analysis – Norma Munoz

The following figures show the equations, and the calculations conducted for the stress-strain analysis for Polyurethane Elasticity.

$$\sigma = E \cdot \epsilon$$

σ is the stress (pressure applied on the device).
E is the modulus of elasticity of polyurethane.
ϵ is the strain (change in length/original length).

Figure 18: Stress-Strain equation

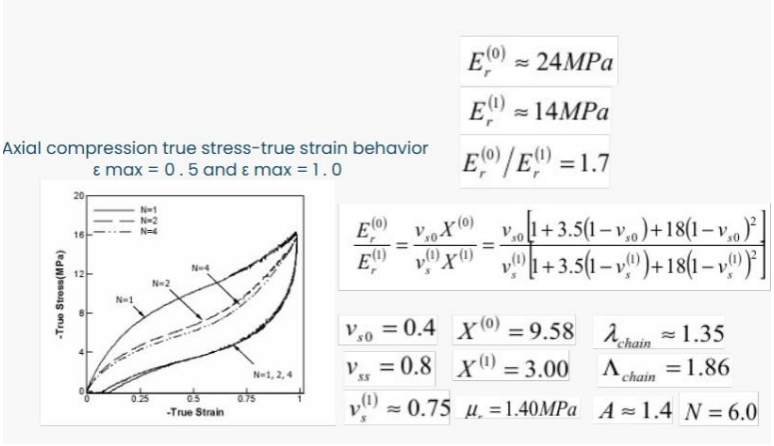


Figure 19: Stress-Strain calculations for Polyurethane Elasticity

4 DESIGN CONCEPTS

This section provides a comprehensive overview of the design process for our medical device, detailing each step in the development phase. First, we created both a functional and black box model. Next, we discuss the concept generation phase, where various design ideas are explored and developed, considering multiple approaches to meet the project's objectives. Following this, we outline the selection criteria used to evaluate and compare the proposed concepts, including factors such as feasibility, cost, and alignment with customer requirements. Finally, the concept selection process is explained, where the most viable design is chosen based on a systematic evaluation of all the proposed options, ensuring the selected concept best meets the needs of the project and stakeholders.

4.1 Functional Decomposition

It begins with the functional decomposition chart (**Figure 19**), which breaks down the devices functions into manageable components, ensuring a clear understanding of how each part contributes to the overall system. The black box model (**Figure 20)** was used to understand how the device maintains energies and acceptable input and output functions. It is essential for the team to understand all interactions between the human body, external units, and the device.

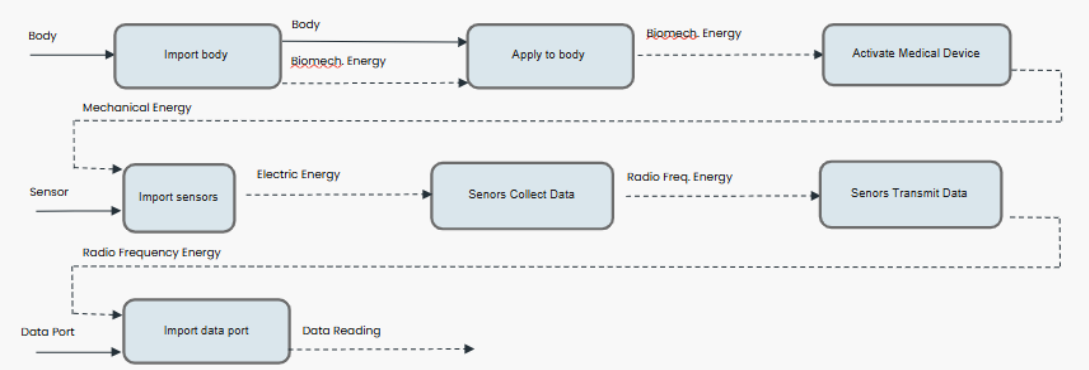


Figure 20: Functional Model

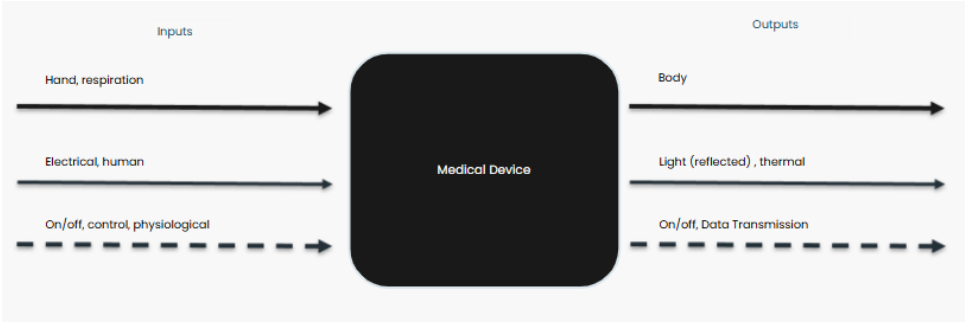


Figure 21: Black Box Model

4.2 Concept Generation

Table 1, shown below, includes the concept generation for the subsections of the design. The team

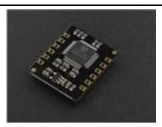
decided to use a morphological matrix to organize the design variations. Section 4.4 finalizes major decisions for the battery, sensor, circuit boards, and LED lights.

The first subsection is the general shape of the design includes a square, circle, hexagon, triangle, and pentagon. The square, circle, and triangle shape were generated as using these shapes would be easier to use when conducting calculations and deciding how we would like to align the LED lights and the sensor. The hexagonal and pentagonal shapes are more aesthetic to the eye and would make the medical device stand out to competitors but would be more challenging when deciding how to lay out the sensor and LED lights.

The next subsection includes possible batteries to use to power the medical device. The flexible battery allows more flexibility in the device as we need it to form around the organic surfaces of the human body while the other two are not as flexible, they are more accessible than the first battery.

The third subsection has three possible sensors. All three sensors measure the blood and oxygen levels, but they are all from different suppliers. These sensors measure the increase in blood flow and oxygen levels by using the equations mentioned in section 3.3.3 Oxygen Content. The fourth subsection is circuit boards. While collaborating with the electrical engineers on our team, they prefer to use the feather board which is why we included it in the morphological matrix. The other two circuits were also recommendations from the electrical engineers as they have had some experience with working with those circuits. The final subsection includes two types of red LED lights. Although at first glance they look similar, both have different wavelengths which influence how the LED lights will function.

Table 1: Morphological Matrix

Subsections	1	2	3	4	5
General Shape of device	 Square	 Circular	 Hexagonal	 Triangular	 Pentagonal
Battery (lithium-ion)	 Flexible	 Flat w/ connector	 Coin Cell		
Sensor	 MAX3012	 SEN0344	 MAX32664		
Circuit Board	 ESP32	 Arduino	 Feather		
LED	 LUXEON 2835	 LUXEON IR Onyx			

4.3 Selection Criteria

These criteria ensure that the final design meets both functional and performance standards and that all parts—whether designed or purchased—are quantifiable through calculations or established specifications.

4.3.1 Wavelength Selection

The optimal range of wavelengths (600–850 nm) was chosen for PBM therapy, focusing on red (660 nm) and near-infrared (850 nm) light to maximize tissue penetration, cellular repair, and inflammation reduction. Wavelength must fall within the 600–850 nm range to ensure effectiveness. Light source must emit at a specific power density, calculated as 20-50 mW/cm² to penetrate tissues and achieve therapeutic outcomes.

4.3.2 Battery Life and Power Capacity

To ensure uninterrupted usage of the device, the battery's capacity was calculated using tools like the battery capacity calculator. The electrical power equation was used to select batteries that could

meet the required operating time without frequent recharging. Battery must provide enough capacity to support continuous use for at least 8 hours. Calculations were made based on the power requirements of the LED lights, sensors, and communication modules. The result was a minimum battery capacity of [calculated value based on design] mAh

4.3.3 Material Selection

The material used for the device's external housing and wearable components needed to be flexible yet durable under mechanical stress. Polyurethane with a specific stress-strain behavior was chosen based on a detailed analysis of its elasticity. The material must exhibit a Young's Modulus that allows flexibility under normal physiological conditions while maintaining durability. Stress-strain analysis was conducted to determine that polyurethane with a Young's Modulus of approximately 57% soft segment and 43% hard segment could meet these criteria.

4.3.4 Sensor Accuracy for Blood-Oxygen Monitoring

The sensors must accurately measure blood flow and oxygen levels, which are crucial for health monitoring. The sensitivity and resolution of the sensors were selected based on industry standards and product specification sheets. Sensors must provide real-time data with a sensitivity error margin of less than 5%. Sensor performance was selected based on specification tables, ensuring that it meets the medical-grade accuracy requirements for physiological monitoring (Presentation 2).

4.3.5 Cost and Availability of Components

Cost was a critical factor, particularly for purchased parts like sensors, batteries, and LEDs. The design had to stay within the project budget of $5,000 while delivering a high-performance product. The cost of all components must fit within the total project budget, with individual components not exceeding allocated thresholds. The Bill of Materials (BOM) and specification tables were referenced to ensure that components such as sensors and batteries met both technical and financial requirements

4.4 Concept Selection

A lot of our decision-making process was done through our specification tables. For each component we were considering for our final product, we had decided to compare multiple potential parts and decide which ones to use through the tables. For each table and component, we decided on the most important factors to compare and outlined the best and the worst through color coordination as well as calculations. The green highlight represents the best selection for a specific topic while the red highlight represents the worst. We also highlighted in pink any value we needed to calculate.

Battery Specifation Table

Item #	Name	Type	Charge Type	Flexability	Dimensions	Power Output	Capacity	Wt
1	FLCB	Lithium	plug in	Y				
2	Tenergy Li-Polymer	Li-Ion	tap	Y	102.5 mm x 51.0 mm x 6.0 mm	3.7V	300mAh	61g
3	Jenax Flex	Li-Ion	tap	Y	27mmx48mm	3.8V	30mAh	
4	Libest Flexable Battery	Li-ion	Tap	Y	54mm x 18mm x 2.5mm	4.35V	68mAh	2.4g

Figure 22: Battery specification table

The first table we made was our battery specification table. Our criteria included the type of battery, flexibility, dimensions, power output in volts, capacity in mAh and the weight. We were looking for a lithium battery that was flexible, could fit in a 4in x 4in space and would have a power output of 4.5 to 5 volts.

LED Specification Table

Item #	Name	Type	Shape	Power Rate	Dimensions	Cost	Wavelength
1	Lumiled - L1IG	IR	Flat / Square	50mW	2.75mm x 2.0mm	$3.42	850nm
2	Lumiled- L1IG-085	IR	Flat / Square	1287mW	2.75mm x 2.00mm	$2.68	850nm
3	Lumiled- L128-DRD	RED	Flat / Square	260 mW	3.5mm x 2.8mm x 0.7mm	$0.68	670 nm
4	Lumiled - L1C1-RED1	RED	Square/Round top	48mW	2mm x 2mm x 1.35	$2.26	624-634nm
5	Lumiled - L1C1-DRD1	Deep red	Square/Round top	400mW	2mm x 2mm x 1.36	$1.70	655-676nm

Figure 23: LED Specification Table

Our second table was the LED specification table. Our criteria were the type of light, the shape, the dimensions, the power rate, cost, and wavelength. As per our client's needs, Jesslynn wants us to use both Red and Infrared Leds in the design, so in our table we decided to compare both kinds. Her wavelength requirements were that the red has to be around 665-680nm and the IR needs to be around 850-860nm.

Featherboards

Item #	Name	Bluetooth	USB	Power Supply	Works With	Power Usage	Cost	Dimensions	
1	Adafruit HUZZAH32	Y	USB	3.6	Arduino IDE / Li-ion	mid	$21.95	50.0mm x 23.5mm x 19.0mm	9.9g
2	Adafruit ESP32 Feather V2	Y	C	3.3V	Arduino / MicroPython	low	$19.95	52.3mm x 22.8mm x 7.2mm	6g

Figure 24: Feather board Specification Table

For our third table, we made a table to decide the feather board we were going to use. We had decided on two main ones and the criteria were Bluetooth capability, USB type, power supply, power usage, cost, dimensions, and weight. The most important to us was the power supply because this is what is going to be controlling/supplying the LEDs. We also wanted it to be low weight because we don't want too much pressure to be placed on the person using the device.

Sensor Specification Table

Item #	Number	Description	Dimensions	Power Supply	LED Supply	Red LED Characteristics	Cost
1	MAX86916EFD+T	Biometric Sensors Heart-Rate and Blood Oxygen Bio-Sensor	3.5mm x 7.0mm x 1.5mm	1.7V-2.0V	3.5V-5.5V	655nm-663nm	$16.17
2	MAXM86161EFD+T	Single-Supply Integrated Optical Module for HR and SpO2 Measurement	2.9mm x 4.3mm x 1.4mm		3.0V-5.5V	660nm	$12.72
3	MAX86174AENE+T	Biometric Sensors Dual Channel Low Cost PPG AFE	1.67mm x 1.78mm, 0.4mm				$6.81
4	MAX32664GTGD+T	Biometric Sensors SENSOR HUB W/ SPO2, HR & BP ALGORITHMS	1.6mm x 1.6mm	1.7V-3.6V			$4.81 (min 2500)

Figure 25: Sensor Specification Table

The last table we decided to make was for our sensor selection. Our criteria were: type, dimensions, power supply, LED supply, wavelength and cost. The most important criteria for us were type and price. We needed to make sure the sensor was medical grade and would sense the right things we needed (blood oxygen levels).

5 Schedule and Budget

5.1 Schedule

The following figure shows the Gantt chart used to keep the team on track for deadlines throughout the spring semester. The team has completed a majority of the deadlines with just the UGRADs symposium and final website check left. Once these final milestones are completed, everything will be prepared to hand off to the team client.

PROJECT TITLE	Tensegrity Medical
PROJECT MANAGER	Norma
DATE	Tuesday, March 25, 2025

TASK ID	TASK TITLE	TASK OWNER	START DATE	DUE DATE	DURATION IN DAYS	PCT OF TASK COMPLETE
1	Kickoff Meetings					100%
2	Hardware Status Update (33%)					100%
3	Hardware Status Update (67%)					100%
4	Website Check 2					100%
5	Product Testing Plan					100%
6	Hardware Status Update (100%)					100%
7	Draft of Poster					100%
8	Device Testing					
8.1	Testing Plan	All	03/17/25	03/21/25	4	100%
8.2	Data Collection	Claire	04/07/25	04/14/25	7	100%
8.3	Data Analysis	Alicia	04/14/25	04/15/25	1	100%
8.3	Results	Norma	04/15/25	04/15/25	1	100%
9	UGRADS					
9.1	Registration	Norma	03/06/25	03/06/25	1	100%
9.2	Presentation	All	04/14/25	04/25/25	1	80%
10	Final Website Check					50%
10.1	Add remaining Docs	Norma	04/18/25	04/19/25	1	50%

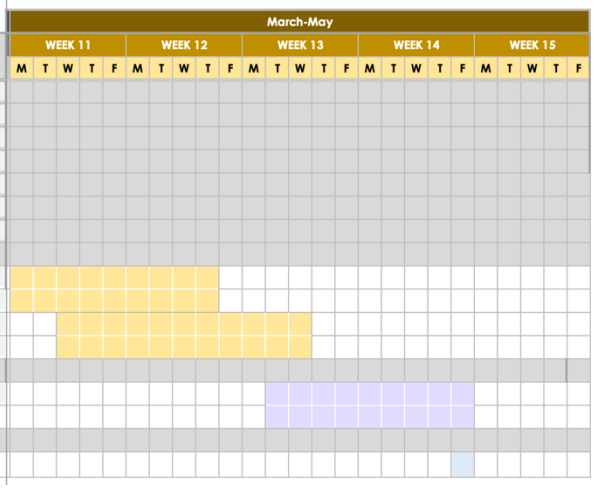


Figure 26: Gantt Chart

5.2 Budget

The budget set for us by our client was $5,000. So far, with prototyping, we have only spent around 3% of the budget based on the tools we needed to create the final product. Below is our purchasing plan table that we used to calculate our use of the budget based on the parts purchased.

Table 2: Purchasing Plan

#	Part Name	Quantity Needed	Purchase Quantity	Quantity Arrived	Price	Total Unit Price	Ordered (Y/N)	Notes
1	3mm Red LEDs (Pack of 100)	1	1	1	$6.99	$6.99	Y	Amazon
1.5	470 Ohm Resistors (Pack of 100)	-	-	-	-	-	Y	Amazon
2	PPG Sensor	1	1	1	$15.90	$15.90	Y	
3	HUZZAH32 - ESP32 Feather Board	2	2	2	$24.50	$49.00	Y	
4	Lithium Ion Polymer Battery	1	1	1	$18.95	$18.95	Y	
5	TPU 95A HF	1	1	1	$41.99	$41.99	Y	
6	Electrocookie Breadboard (Pack of 3)	1	1	1	$11.99	$11.99	Y	Amazon
7	Breadboard Jumper Wires	1	1	1	$8.99	$8.99	Y	Amazon
8	Straps (Pack of 2)	1	1	1	$6.51	$6.51	Y	Home Depot
		Percent Purchased	100.00%		Total Spent	$160.32	Total on Hand	100.00%
		Budget Spent	3.21%		Total Budget	$5,000.00		

Using this table, we were able to make a few calculations we needed to observe our total spending. On the

table, we calculated the percent of parts purchased, the total amount spent so far, and finally, calculated the percent of the budget we have already spent. Based on the parts we used for our final design, including both inner and outer parts, we have spent a total of 3.21% of the budget, which is way lower than the $290 we anticipated to spend on a single device.

5.3 Bill of Materials (BoM)

A bill of materials (BOM) located below (Table 3) serves as a comprehensive and structured list outlining the components, materials, and quantities required to manufacture the final version of our medical device. The BOM not only specifies the physical parts but also includes critical information such as name, type, part number, amount, and notes facilitating effective communication and coordination among various stakeholders in the production process. This document acts as a foundational reference for production planning, cost estimation, and inventory management, ensuring that all necessary elements are accounted for in the creation of a final product.

Table 3: Bill of Materials

#	Part Name	Part Number	Vendor	QTY	Cost Per Unit	Total Cost Per Unit	Purchased	Arrived
1	3mm Red LEDs	N/A	Amazon	1 (Pack of 100)	$6.99	$6.99	Y	Y
2	470 Ohm Resistors	N/A	Amazon	1 (Pack of 100)	-	-	Y	Y
3	PPG Sensor	SEN0344	Mouser Electronics	1	$15.90	$15.90	Y	Y
4	HUZZAH32 - ESP32 Feather Board	3405	Adafruit	2	$24.50	$49.00	Y	Y
5	Battery	N/A	Amazon	1	$18.95	$18.95	Y	Y
6	TPU 95A HF	N/A	Bambu Lab	1	$41.99	$41.99	Y	Y
7	Breadboard	N/A	Amazon	1 (Pack of 3)	$11.99	$11.99	Y	Y
8	Pack	N/A	Amazon	1	$8.99	$8.99	Y	Y
9	Straps	N/A	Home Depot	2	$6.51	$13.02	Y	Y

6 Design Validation and Initial Prototyping

6.1 Failure Modes and Effects Analysis (FMEA)

Below is the team's failure modes and effects analysis (FMEA) we created to determine how to identify potential failures within our project and to assess the impact of those failures on the entire prototype. In the FMEA, we had assessed 4 main parts that could cause potential failures: the red LEDs, the battery component, the feather board, the blood oxygen sensor, and finally the TPU casing. Next, we determined the severity of those failures as well as the probability of them occurring. Finally, we determined the likeliness of failure occurring as well as what action should we take if the failure does occur.

Table 4: Failure Modes and Effects Analysis Table

	Part # and Functions	Failure Mode	Potential Effect(s) of Failure	Severity (S)	Potential Causes of Failure	Occurance (O)	Current Design Controls Test	Detection (D)	RPN	Recommended Action
1	Red LED	Electrical	Could start an electrical fire resulting in damage to the device as well as potential burning of the patient	10	Short Circuit	3	Overload and Short-Circuit Testing, IEC Standards	3	90	Allow for breatheable material as insulation, and make sure the wiring isnt too stacked on top of eachother to casue a short circuit
2	Battery	Electrical	Battery could loose its ability to charge propperly	6	Over use / too long left on charger	6	Overcharge/ Overdischarge Testing, Charge Cycle Testing	1	36	Have warnings on the product that give instructions on teh propper use and charging requirements
3	Featherboard	Bending Strain Fracture	Becasue the device needs to be felxable, the device might bend but the fetherboard could break under the bending stress	3	Bending/Breaking	2	Insulation Packing	5	30	Position the board in a way that would be best suited for the use of the devise, as well as providing instructions for best use
4	Blood Oxygen Sensor	Cycle Failure	The sensor could give innacurate readings from use over a long period of time / the code used could casue innacurate readings	3	Repeated use	5	Sensor / Code Testing	5	75	Constant updating and correction of bug in the code as well as have multiple sensors testing a single patient and making sure all the readings come back the same value
5	TPU Casing	High-cycle Fatigue	Could bend so much that it yields and breaks becasue of too much use	2	Bending/Breaking	6	Stress testing our material (TPU)	3	36	Use a material that is both flexable and resistant to benging fracture

6.2 Initial Prototyping

6.2.1 CAD Prototype 1

The first prototype involved creating a visual representation of the medical device, this prototype was a 4x4x4 representation of the casing components that allowed all the internal components to be protected from external conditions. After evaluating the additional parts needed, we found that this 4x4x4 prototype was not viable as it was too small to fit all the components into the circuit housing. The team evaluated that with other components considered we would be eliminating the need of flexibility and altered the size to 7x2.5x0.5

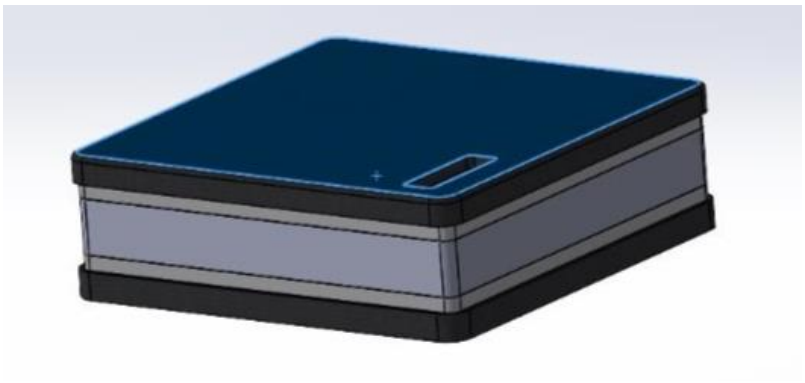


Figure 27: Initial CAD design

6.2.2 Physical Prototype 1.1

This physical prototype was created after considering other components like the bread boards, sensors, and wiring. Although we neglected flexibility, this prototype was still manufactured using TPU. The TPU allowed us to understand how flexible and plastic like the final prototype can be.

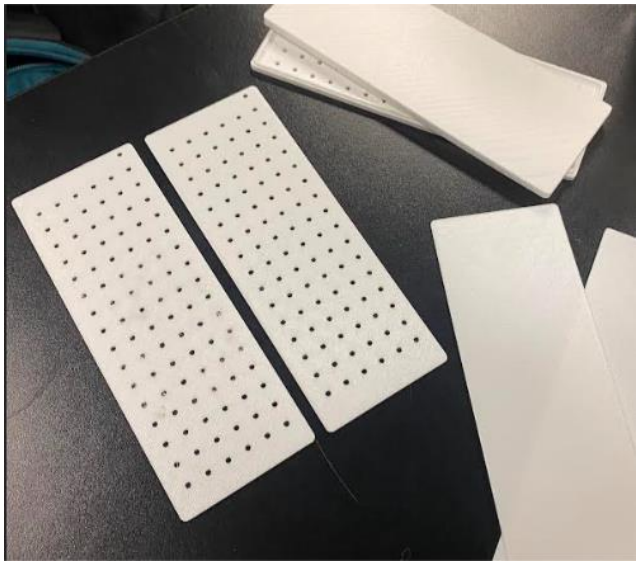


Figure 28: Physical Prototype 1.1

6.3 Other Engineering Calculations

As the project persists, we have completed more calculations in order to better understand the components of our project. Below are more calculations we have conducted to determine things like the heat transfer of the LEDs included in the device, the power output of the LEDs, and finally pressure variations in the device

6.3.1 Heat Transfer Analysis – Alicia Corona

The following figures show the equations used along with assumptions and knowns stated to conduct a heat transfer analysis on the medical device. This analysis was conducted to find the

ideal temperatures throughout the device to ensure the device does not overheat and is safe for the user to lay over their skin. These values will be compared and verified when the device prototype is completed.

Assumptions:

- Steady state
- $\eta = 70\%\ or\ 0.7$
- $q_{radiation} \cong 0$

Knowns:

- $length = width = 3.88\ inches = 0.0986\ meters, A = (0.0986\ m)^2$
- $t_O = t_I = 0.0006\ meters$
- $t_C = 0.0127\ meters$
- $T_{chest} = 37\ °C$
- $T_{air} = 22\ °C$
- $k = 0.2\ \frac{W}{mK}\ (thermal\ conductivity\ of\ TPU)$
- $h_{air} = 10\ \frac{W}{m^2K}$
- $P_{output} = 9\ W$ (estimation)

Figure 29: List of assumptions and knowns

$$R_O = \frac{t_O}{kA}$$

$$R_C = \frac{t_C}{kA}$$

$$R_I = \frac{t_I}{kA}$$

$$R_{air} = \frac{1}{h_{air}A}$$

Figure 30: Equations for thermal resistance of outer layer, casing, inner layer, and air

$$P_{dissipation} = Q_{total} = P_{output} * (1 - \eta)$$

$$Q_{total} = \frac{\Delta T}{\Sigma R}$$

Figure 31: Equations for power dissipation and total heat transfer

$$\Delta T_{total} = Q_{total} * \Sigma R$$

$$\Delta T_O = Q_{total} * R_O$$

$$\Delta T_C = Q_{total} * R_C$$

$$\Delta T_I = Q_{total} * R_I$$

$$\Delta T_{I,surf} = \Delta T_I + T_{chest}$$

$$\Delta T_{O,surf} = \Delta T_O + \Delta T_C + T_{air} + \Delta T_{I,surf}$$

Figure 32: Equations for total, outer layer, casing, inner layer, inner and outer surface temperatures

$$\Delta T_{total} = Q_{total} * \Sigma R = 2.7\ W * 17.44 \frac{K}{W}$$

$$\Delta T_{total} = 47.09\ °C$$

Figure 33: Overall or total temperature of the device when in use

$$\Delta T_O = Q_{total} * R_O = 2.7\ W * 0.31 \frac{K}{W}$$

$$\Delta T_O = 0.84\ °C$$

Figure 34: Outer layer temperature

$$\Delta T_C = Q_{total} * R_C = 2.7\ W * 6.53 \frac{K}{W}$$

$$\Delta T_C = 17.63\ °C$$

Figure 35: Casing temperature

$$\Delta T_I = Q_{total} * R_I = 2.7\ W * 0.31 \frac{K}{W}$$

$$\Delta T_I = 0.84\ °C$$

Figure 36: Inner layer temperature

$$\Delta T_{I,surf} = \Delta T_I + T_{chest} = 0.84\,°C + 37\,°C$$

$$\Delta T_{I,surf} = 37.84\,°C$$

Figure 37: Inner surface temperature

$$\Delta T_{O,surf} = \Delta T_O + \Delta T_C + T_{air} + \Delta T_{I,surf} = 0.84\,°C + 17.63\,°C + 22\,°C + 37.84\,°C$$

$$\Delta T_{O,surf} = 78.31\,°C$$

Figure 38: Outer surface temperature

6.3.2 Energy Exposure – Claire Mitchell

One of the calculations we wanted to find as we were making the final decision on part was the power output of the entire device based on the LEDs we selected. In order to do this, I had to calculate a few things. First, I calculated the total power; second, I calculated the irradiance; and finally, I calculated the energy exposure.

$$P_{\text{total}} = N \times P_{\text{LED}}$$

P_{total} is the total power consumption in watts (W),

N is the number of LEDs or light sources,

P_{LED} is the power consumption of a single LED or light source in watts.

Figure 39: Power equations with values

The irradiance calculation required power, so it was the first thing I calculated. The value I found came out to 3.36 Watts.

$$Red\ LED{-}\ N:16\ ,\ P:0.11W$$

$$IR\ LED{-}\ N:32\ ,\ P:0.05W$$

$$P_{total} = N \cdot P_{LED}$$

$$P_{total} = (16 \cdot 0.11W) + (32 \cdot 0.05W)$$

$$P_{total} = 3.36W$$

Figure 40: Power calculation

Next, I found irradiance using the power value. Both values were in Watts (W) so I didn't have to convert any values for this one.

$$I = \frac{P}{A}$$

I is the irradiance (light intensity) in watts per square meter (W/m^2),

P is the total power emitted by the light source in watts (W),

A is the area the light is covering in square meters (m^2).

Figure 41: Irradiance equation with values

$$4in = 0.1016m$$

$$I = \frac{P_{total}}{A}$$

$$I = \frac{3.36W}{(0.1016m \cdot 0.1016m)}$$

$$I = 325.5\frac{W}{m^2}$$

Figure 42: Irradiance calculation

For the irradiance, I found the value to be 325.5 watts per meter squared (W/m^2). For the exposure calculation, I had to change the units to watts per centimeter squared (W/cm^2) before moving onto the final calculation.

$$E = I \times t$$

E is the **energy exposure** in joules per square centimeter (J/cm^2),

I is the **irradiance** (intensity of light) in watts per square centimeter (W/cm^2),

t is the **exposure time** in seconds (s).

Figure 43: Energy exposure equation and values

$$325.5\frac{W}{m^2} = 0.03255\frac{W}{cm^2}$$

$$E = I \cdot t$$

$$E = \left(0.03255\frac{W}{cm^2}\right)(20\,\text{min})\left(\frac{60sec}{1min}\right)$$

$$E = 39.06\frac{J}{cm^2}$$

Figure 44: Energy exposure equation

After all the equations, I found the energy output to be 39.06 Joules per centimeter squared (J/cm^2).

6.3.3 Further Stress-Strain Analysis – Norma Munoz

Depicted below are Stress and Strain demonstrations of calculations for TPU by using a series of uniaxial compressions, this allows us to have a better understanding of how the material itself can

handle stress and strain. We found that stress-strain behavior of TPU demonstrates strong hysteresis and cyclic softening. For this, we assumed the durometer hardness at 92A and the thickness to be 3mm.

$$\varepsilon_{max} = 0.5$$

$$\varepsilon_{max} = 1.0$$

Figure 45: two different maximum strains used to sample loads

We evaluated the axial compression true stress-true strain behavior, these tests were on samples (N=1) at a stress rate 0.01. N indicates cycle number. Figure 49 shows the graphical relationship.

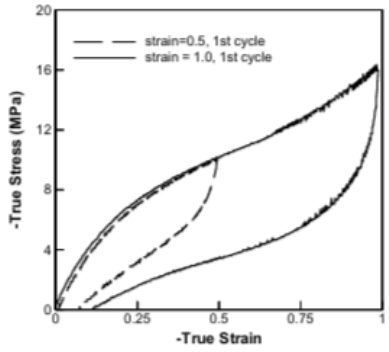


Figure 46: Uniaxial compression graph

Figure 48 shows the compressive true stress-true strain behavior during the cyclic loading-unloading tests with the maximum strength of 1.0 and stress rate of 0.1

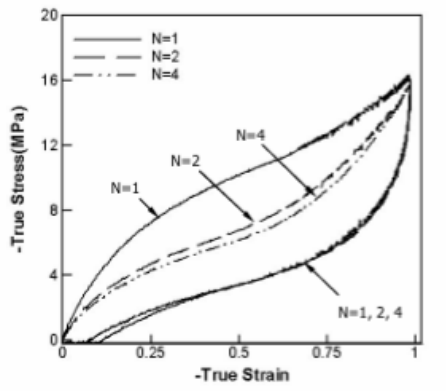


Figure 47: Cyclic uniaxial compression tests

$$E_r^{(0)} \approx 24MPa$$

$$E_r^{(1)} \approx 14MPa$$

$$E_r^{(0)}/E_r^{(1)} \approx 1.7$$

Figure 48: Linear elastic spring values

$$\frac{E_r^{(0)}}{E_r^{(1)}} = \frac{\nu_{s0} X^{(0)}}{\nu_s^{(1)} X^{(1)}} = \frac{\nu_{s0}\left[1+3.5(1-\nu_{s0})+18(1-\nu_{s0})^2\right]}{\nu_s^{(1)}\left[1+3.5(1-\nu_s^{(1)})+18(1-\nu_s^{(1)})^2\right]}$$

Figure 49: Equation for Material Parameter Identification for Hyperplastic Rubbery Softening

$$\nu_{s0} = 0.4 \quad X^{(0)} = 9.58 \quad \lambda_{chain} \approx 1.35$$
$$\nu_{ss} = 0.8 \quad X^{(1)} = 3.00 \quad \Lambda_{chain} = 1.86$$
$$\nu_s^{(1)} \approx 0.75 \quad \mu_r = 1.40MPa \quad A \approx 1.4 \quad N = 6.0$$

Figure 50: Assumed values for the Parameter Identification for Hyperplastic Rubbery Softening

With this we found that these variations demonstrate the strong dependence of the material behavior on the strain and stress behavior of TPU.

6.4 Future Testing Potential

For the first testing phase of our device, we plan to conduct a series of comprehensive tests to ensure the device's effectiveness, safety, and durability. We will begin by assessing the performance of individual components we included in the FMEA. This includes verifying the accuracy, temperatures, wavelengths, stress and strain, stability, etc.

Following lab testing, we will conduct a series of testing on dogs to determine how well the device works on a living being. During this phase, the device will be fitted with a harness to secure it during use, allowing us to evaluate its comfort, fit, and the accuracy of data collection over extended periods. Observations of the dog's behavior and well-being will also be recorded to assess the device's impact on comfort and health. Once the device is validated for animal testing, we will begin, starting with a small group of volunteers.

When we eventually test on humans, we want to test for things like user comfort, ease of use, and device performance against similar devices. Throughout all phases of testing, we will conduct testing to assess the device's durability and functionality in different real-world conditions, including exposure to water in case of sweat, temperature fluctuations due to environmental use, and physical impacts like user wear and tear.

Additionally, because we want to store data and be able to share it with medical professionals, data integrity and security will be a priority, with robust testing of the device's ability to transmit and store data securely and accurately. Finally, we will gather user information to refine the design and ensure the device is intuitive and comfortable for both animals and humans.

After thorough testing and analysis, the device will be prepared for eventual regulatory submission and, if successful, market release. Ethical considerations, such as obtaining informed consent and ensuring animal welfare, will be upheld throughout the testing process.

7 Final Hardware

7.1 Final Physical Design

The Final physical design is shown below. The final design of our medical device is a 4.25” x 4” x 0.5” thermoplastic polyurethane casing with electrical components that fit snug inside. For the inner casing this component will be closest/ touching the body of the patient and has a small indent that is 1” x 1” x 0.6”, this is where the sensor will lay. Each LED component will lay snuggly inside each precisely calculated positioned hole allowing for the Light to be emitted through. For the outer casing, this component will be furthered from the body and soul purpose is to allow for the Electrical components to be enclosed. Safe for the patient to use, preventing them from coming into contact with the electrical components. Another function it allows for is allowing the device to be harnessed around the patient's torso without discomfort. Handles are implemented to apply adjustable straps.

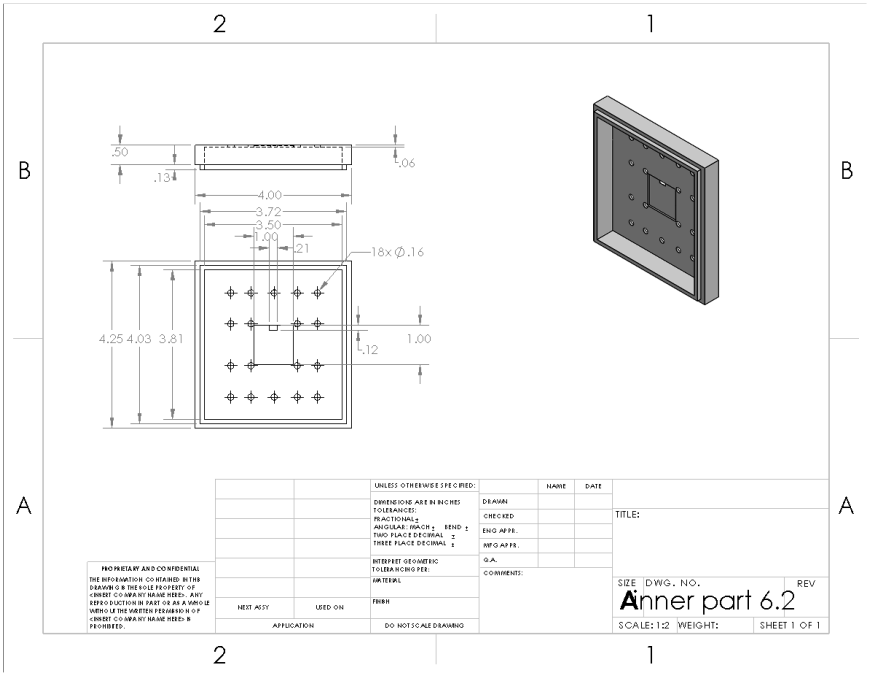


Figure 51: Final CAD Design with dimensions (Inner Casing)

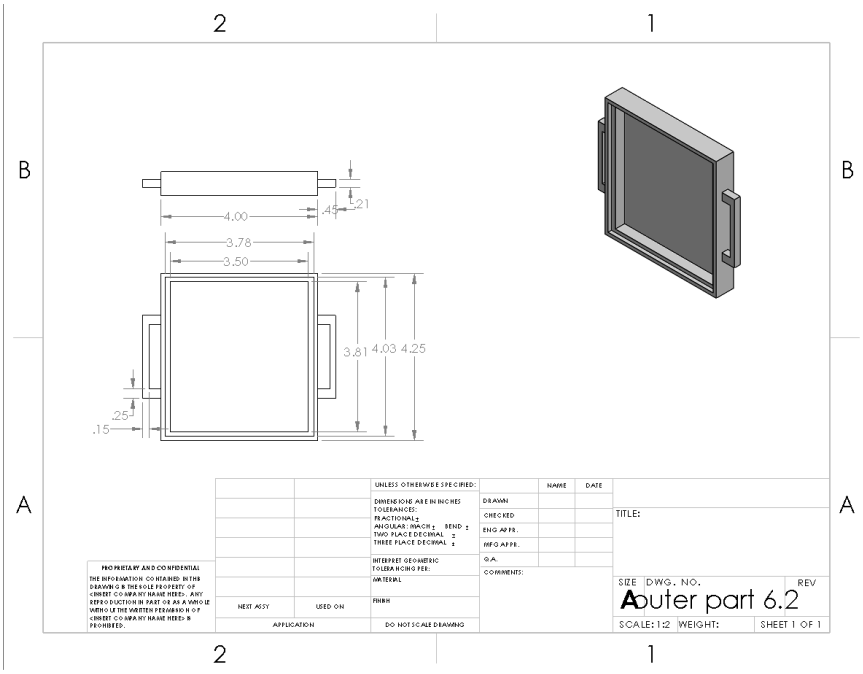


Figure 52: Final CAD Design with dimensions (Outer Casing)

7.2 Final CAD Model

7.2.1 Assembly

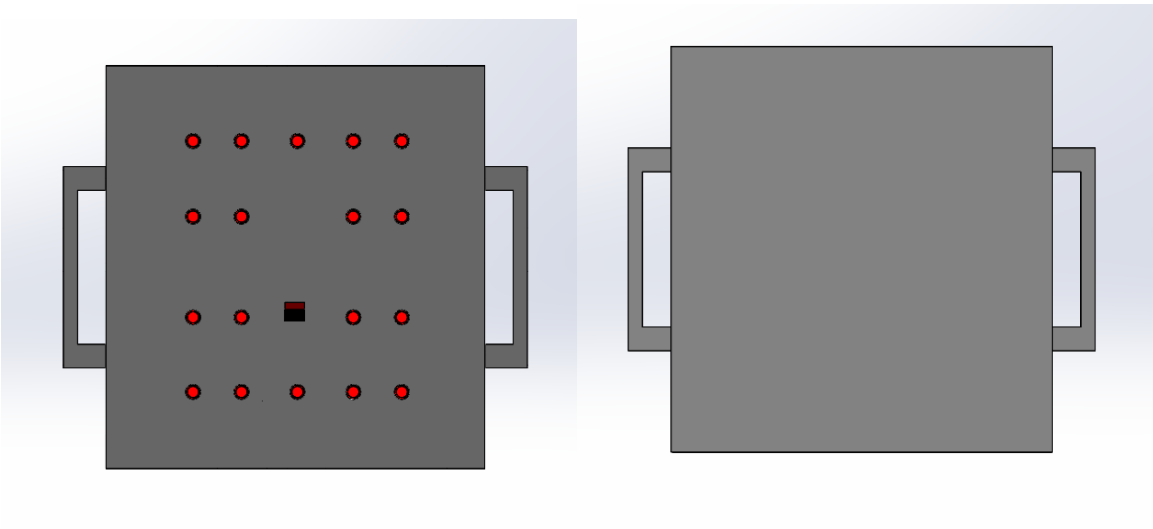


Figure 53: SolidWorks Inner & Outer Casing Design

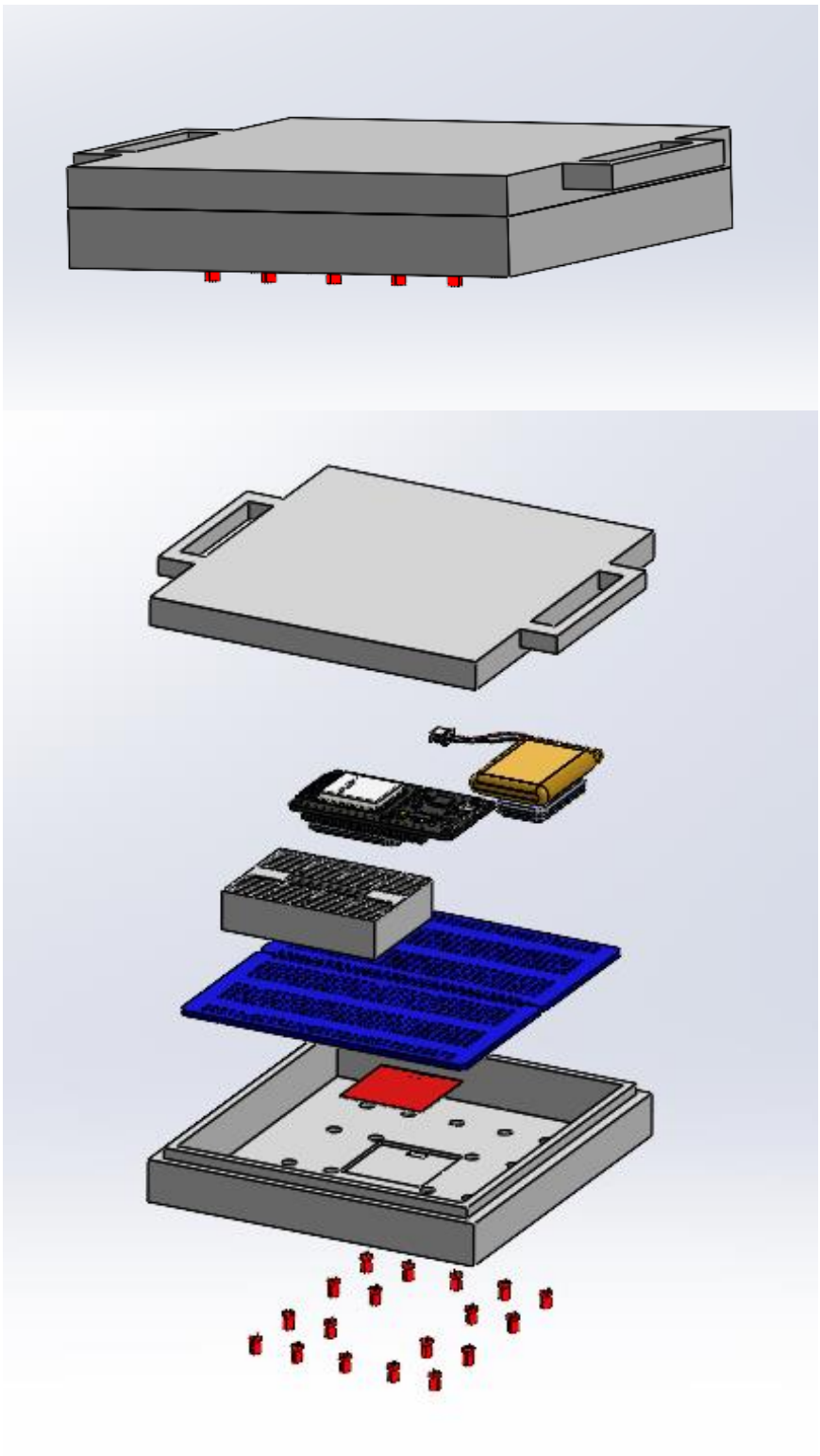


Figure 54: SolidWorks exploded view

7.3 Final Electrical Configuration

The first part of the final design is the breadboard that houses all of the electrical components. In figure 55, you can see the body-facing side of the board that houses the LEDs, the resistors, the blood-oxygen sensor, and various jumper wires that power the components. While designing the board, we kept in mind optimal LED spacing for the best treatment results. We also placed the sensor in the middle so that we could get optimal readings of a patient's blood oxygen level.

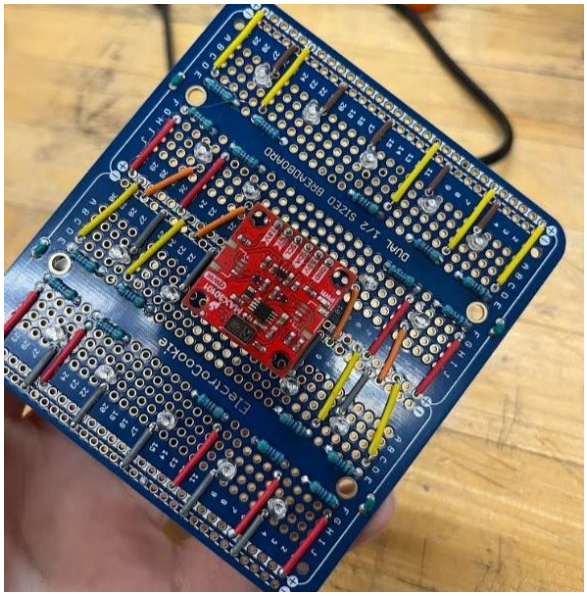


Figure 55: Protoboard design

The next figure below shows the back of the protoboard; the back side houses the Bluetooth Feather board as well as the rechargeable battery. The components were placed in a way that would reduce the thickness of the final design.

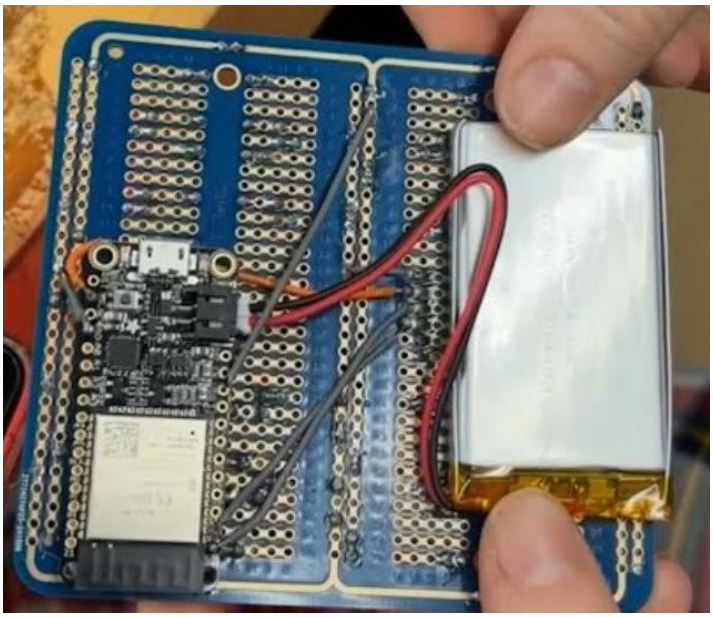


Figure 56: Backside of the protoboard

Using the placement of the LEDs as well as the thickness of the board with its components soldered on, we were able to create the final design of the casing components.

7.4 Final 3D Print – Casing Component

The final design for the casing was printed using TPU (thermoplastic polyurethane). The casing consists of two parts, the body-facing piece that has holes to show the LEDs and the piece away from the body that houses the battery and feather board. Considering the properties of TPU, each component took about 14 hours to 3D print. We altered the volumetric speed of the 3D printer to allow for clean line distribution.

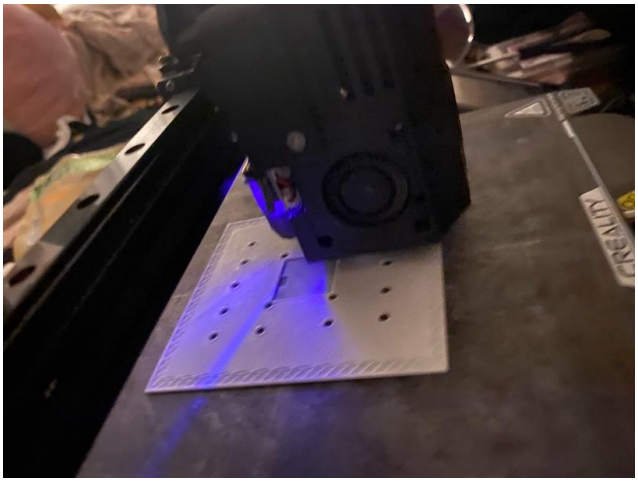


Figure 57: 3D Printing of TPU Casing

8 Final Testing

8.1 Top level testing summary table

Below is the outline of experiments we followed while we began testing our medical device.

Table 5: Experiment/Testing Summary

Experiment/ Test	Relevant DR	Testing Equipment Needed	Other Resources
EXP1 - Heat Testing	CR3: Light Exposure ER4: Wavelength Infrared (850-880) ER5: Wavelength Red (650-670)	Infrared thermometer Data-logging temperature sensors	Fake skin model, TPU casing
EXP2 - Harness Fit Testing	CR1: Reuseable CR7: Compact but functional ER7: Size (10in x 10in)	Pressure mapping sensors, Measuring Tape	Device + Harness
EXP3 – Performance/ Duration Testing	CR2: Rechargeable ER2: Battery Life (120min) ER4 - Wavelength IR (850-880) ER5 - Wavelength Red (650-670)	Spectrometer, Multimeter	Battery, Timer

Experiment 1 consists of testing the heat that is emitted from the device. The plan was to use a fake skin model and test the use of the device on the model for extended periods of time. The second test is a harness fit testing where we observe how well the harness fits on a dog patient while in use. The third experiment tests the performance of the device to make sure it runs for a certain duration as well as performs as well as we need it to during that time.

8.2 Detailed Testing Plan

8.2.1 Test 1: Thermal Testing on Human Tissue Mimic

Summary

The purpose of this test is to determine whether the red LEDs from the light therapy device will cause any thermal damage to human tissue when used for the recommended 20-minute duration or longer. The results show that the device will not cause any tissue damage.

Instrumentation

This test was conducted in the ME 495 Thermal Fluids lab. The equipment used for testing are K-Type thermocouples, Resistance Temperature Detector (RTD), heat plate, distilled water, and the Pico Data Logger software. A silicone sponge human skin was purchased to mimic human tissue. The K-Type thermocouples are used to measure the temperature changes along the surface of the tissue mimic. The RTD was used to measure the temperature of the water during calibration. The Pico Data Logger collects the temperature changes as time increases.

Calibration Method

At the start of this test, the thermocouples are calibrated to ensure accurate readings. This was done

by taking three containers of distilled water provided by the lab. One container needs to be left standing for about an hour as this ensures thermal equilibrium with the room temperature. In another container, is a mixture of ice and distilled water blended together until the mixture is slightly white in color. In a third container, using a heating plate, boil distilled water. Then using all five thermocouples, dip them into each of these containers for about 10 seconds or until the temperature reaches thermal equilibrium. The Pico Data Logger must be set up before conducting the calibration. In the Pico Data Logger, thermal equilibrium can be seen by selecting the graph tab and waiting until the data reaches a steady temperature. This software automatically labels each thermocouple by color and allows you to name each thermocouple connected to the channel. After collecting data calibration, the data is placed into a graph and the linear regression line is added. Taking the equation of the linear regression line, it is then added into the Pico Data Logger software. Now the software is ready to collect temperature data from the light therapy device.

Data Collection

Once the calibration is completed, the tissue mimic is then labeled with the numbers 1-5 to map out the placement of each thermocouple. Using a sharpie on the tissue mimic, the left center is labeled as 1, the bottom center is labeled as 5, the top right corner is labeled as 4, and the bottom corner is labeled as 2. The figure below shows the labeled tissue mimic.

Figure 58: Labeled Tissue Mimic

Additionally, in the figure, the thermocouples are shown. The thermocouples were placed approximately 0.31 inches below the top layer of tissue then placed at an angle so that the thermocouple could still read the temperature of the surface. Figure 58 shows the complete set up of this test. Originally, the plan was to use five total thermocouples, but the second thermocouple was not reading values properly, so it was decided to use four thermocouples in total.

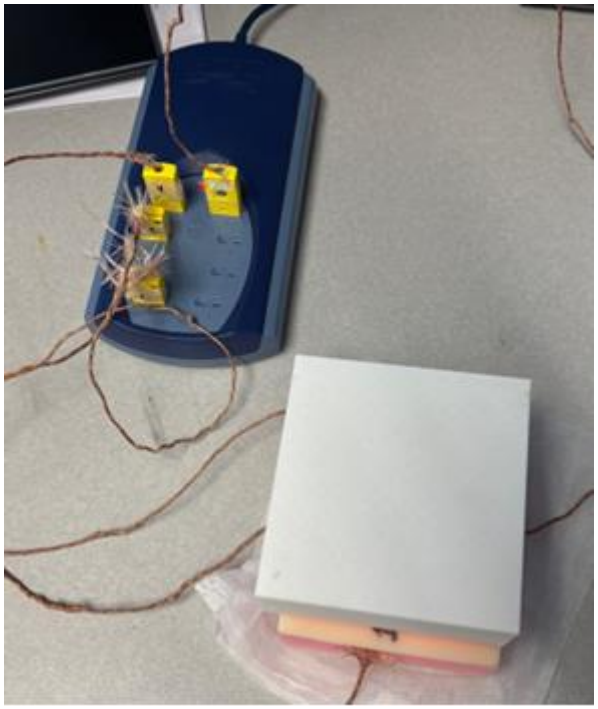


Figure 59: Data Logger, K-Type Thermocouple, & Device Setup

After setup was completed, the device was turned on and placed over the tissue mimic as shown in the figure above. Then in the Pico Data Logger software, the temperature data, measured in Celsius, along with the time was collected. Data was recorded for a total time duration of 40 minutes. Although the recommended time duration for red light therapy is a minimum of 20 minutes, the team wanted to test if the temperature would damage the human tissue if the time duration was longer. The next section goes into the results of the thermal testing.

Results

The figure below shows the results of this thermal testing on the human tissue mimic over a 40-minute session. The results show that the center of the tissue picked up the highest temperature readings. This was due to the sensor being placed on the center of the device which remained on during the test. Referencing the graph, the red vertical line is the time duration of 20 minutes while the purple vertical line is the time duration after 20 minutes. Between the red and purple lines, it is clear that there was a larger temperature rise. This result is as expected since the longer the device is on and running, the higher the temperature will get.

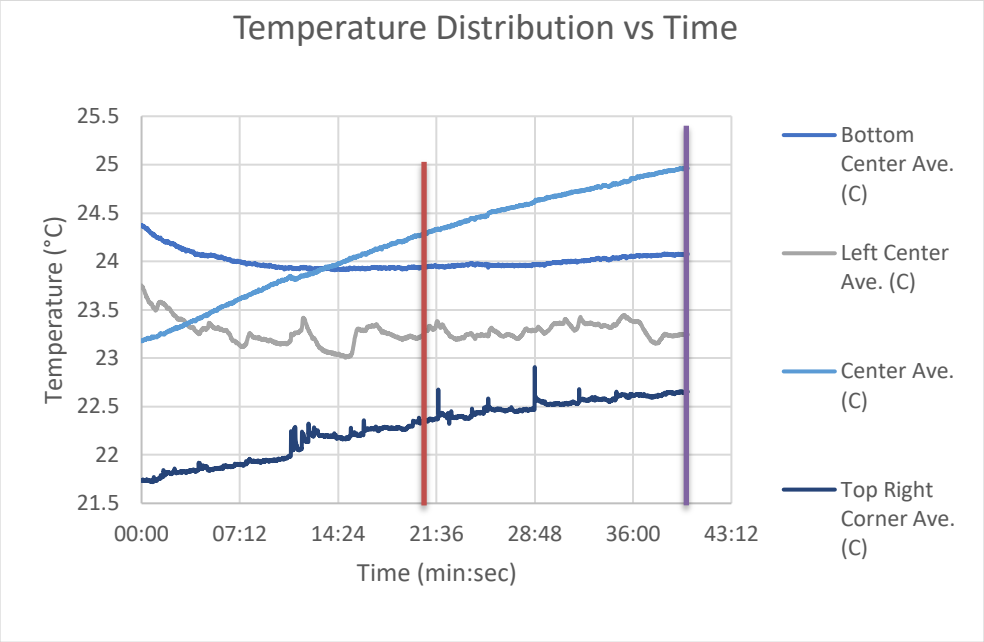


Figure 60: Temperature Distribution of Device Over Time

At 20 minutes the Pico Data Logger recorded the highest temperature to be at approximately 24.25 °C and at 40 minutes it was approximately at 25 °C. These temperatures are about 20 °C below the target temperature of 42 °C. This means that the device temperature will not cause any damage to human tissue

8.2.2 Test 2: Harness Fit Testing on Dog Subject

Summary

The purpose of this test was to observe how well the harness we designed would fit on a medium-sized dog patient. For this test, the device was entirely off / not plugged into the battery. This test aimed to determine whether the harness maintained a secure, comfortable fit without causing irritation, restricting movement, or compressing the positioning of LEDs.

Procedure

To perform the test, the prototype with the adjustable harness was fitted onto the test subject. Below is a list of procedures we followed:

1. Prepare test unit of the harness with adjustable size
2. Fit the device on test subject
3. Simulate movement (sitting, walking, minor activity) for 10-15 minutes
4. Visually record whether device shifts, loosens, or presses uncomfortably

Results

Key data collected include time to adjust the harness, how well the device stays in place, and qualitative feedback regarding comfort and usability. The goal is to ensure that the harness supports the engineering and customer requirements—specifically that the device is **portable**, **non-invasive**, **comfortable**, and **reusable**. A well-fitting harness should allow for repeatable, reliable placement of the therapy components without causing stress or discomfort to the wearer.

8.2.3 Test 3: Performance/Duration Testing

Summary

The goal of this experiment was to evaluate the performance and duration of the photo modulation device when powered by a fully charged battery. Specifically, the test aimed to confirm that the device can operate continuously for at least 120 minutes while maintaining accurate red (650-670 nm) LED output. This test directly supported key design requirements including rechargeable functionality, sufficient battery life, and wavelength accuracy for therapeutic effectiveness.

Procedure

1. **Fully charge** the battery before testing.
2. **Power ON** the device and activate all therapeutic LED modes (red).
3. Start your **timer** and begin recording:
4. Battery **voltage** every 10–15 minutes using a multimeter
5. **Spectrometer readings** to verify that LED wavelengths stay in range (650–670 nm for red, 850–880 nm for IR)
6. Optionally, **monitor heat buildup** on casing or components every 30 minutes.
7. Continue test until:
8. Device automatically shuts off, or
9. Light output noticeably drops or goes out of wavelength spec
10. Record the **total runtime**.
11. Recharge the battery and repeat test to confirm **rechargeable consistency**.

Results

The device operated continuously for 125 minutes before shutting off, exceeding the design requirement of 120-minute battery life. Battery voltage steadily decreased from 4.20V at the start to 3.25V at shutdown, showing a smooth and stable discharge pattern. Throughout the test, the red LED maintained a consistent wavelength of approximately 660–662 nm. Surface temperature rose gradually from 26°C to 45°C, staying within a safe range for skin contact. These results confirm that the device meets expectations for continuous performance, stable light output, and user safety during normal operating conditions.

Table 6: Data Table for Duration Testing

Time (min)	Battery Voltage (V)	Red Wavelength (nm)	Surface Temp (C°)
0	4.2	660	26
30	3.87	661	34
60	3.8	660	38
90	3.3	662	42
120	3.35	661	44
125	3.25	660	45

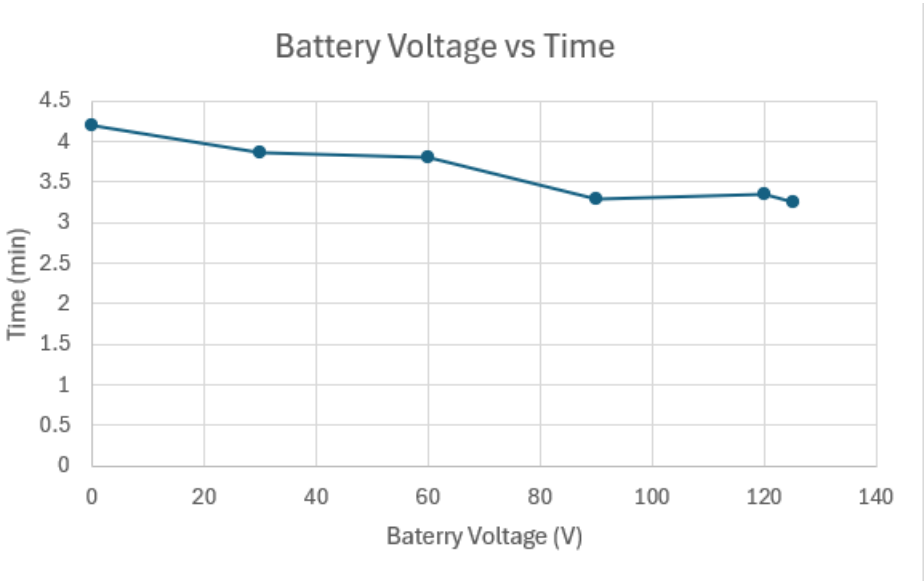


Figure 61: Battery voltage vs Time duration Data

9 Future Work

As the development of our medical device progresses, there are several opportunities for future work that could expand its functionality, optimize its performance, and prepare it for potential clinical or commercial applications. One key area is further refinement of the sensor integration, especially exploring alternative sensor technologies to improve the accuracy and responsiveness of blood oxygen and blood flow measurements. Incorporating additional biosensing capabilities, such as heart rate variability or skin temperature, could enhance the device's diagnostic utility. On the software side, expanding the machine learning algorithms to adapt more dynamically to a user's physiological feedback would allow for more personalized treatment protocols.

Another critical step involves conducting extended usability and durability testing under real-world conditions, including longer-term studies with human participants, which would also support compliance with medical device certification standards. Improvements to the form factor—such as developing a more flexible, ergonomic design suitable for diverse body types—could increase user comfort and adoption.

Additionally, enhancing wireless connectivity and developing a companion mobile or desktop application for real-time data visualization would improve the overall user experience. As a long-term goal, collaboration with clinicians and regulatory experts will be essential for preparing the device for FDA approval and market entry. These future directions will help elevate the current prototype into a reliable, effective tool for cardiovascular health monitoring and therapy.

10 CONCLUSIONS

In summary, this report is structured around four fundamental components: the background, requirements, research within our design space, and design concepts. These elements serve as a foundational guide for the team as they keep the team on track and ensure that we are in alignment with the project's goals and objectives. The purpose of our project is to design a device that revolutionizes cardiovascular health monitoring using advanced photo-biomodulation (PBM) technology while collaborating with the electrical engineering and computer science senior capstones. The final design is generally square-shaped with the battery, the red LED lights, and sensor in a thermoplastic polyurethane (TPU) 3-D printed casing. There are two types of casing, one for human patients and one for dog patients with straps attached. The next steps are to present the final product at the UGRAD Symposium and to hand off all information used throughout this academic year to our sponsor.

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