Light Dose Tensegrity Medical

Conceptual Design Report

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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 development phase, with ongoing collaboration among engineering teams working on refining the design and functionality. Future plans include further research, testing, budgeting, and approval by regulatory bodies. Our current financial status reflects careful management of a $5000 budget, with about $1500 spent so far on materials and initial prototyping. We have also concluded the report with a reference page and appendix to document all research and resources involved.

TABLE OF CONTENTS

1 BACKGROUND

The background of this project will be divided into three key areas: The project description, deliverables, and success matrix. This section will serve as a comprehensive reference point throughout the duration of the project, ensuring that the design team remains aligned with the overall objectives and meets the established deliverables. The project description will provide a detailed overview of the goals, context, and scope, offering clarity on what the team aims to accomplish. The deliverables portion will specify the tangible outcomes expected at various stages of development, guiding the team's progress and ensuring that milestones are met. Finally,

the success matrix will offer a clear framework for evaluating the project's performance, outlining key indicators of success, timelines, and benchmarks to measure whether the project is progressing as intended. Together, these elements will function as a foundational guide, helping the team stay focused on achieving the desired results in an organized and efficient manner.

1.1 Project Description

1.1.1 Project Title: Light Dose Tensegrity Medical: Tense Med Mechanics

1.1.2 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 and Infrared 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.

1.1.3 Project Objectives

The project objectives include 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/infrared 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
- Promote proactive management and prevention while making advanced health monitoring accessible to everyone.

1.1.4 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 Course 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. By the time of Presentation 3, the first physical prototype will be introduced. This presentation will describe the prototype's purpose, specifically addressing key questions the prototype aims to answer, and detail the final design that has been selected after careful evaluation.

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

1.2.4 Prototypes

The first prototype consisted of a virtual model aimed at determining critical factors. This will involve pressure simulations using SolidWorks and Ansys CFD analysis. The second prototype will mark the beginning of the actual manufacturing process, with a focus on testing the structural elements needed for the design.

1.2.5 Client Deliverables

Client Deliverables are reflective pf 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 disinfected before every use, 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.

1.2.6 Key Deliverables

The project will deliver a range of key documents and materials including:

- Comprehensive literature review
- Detailed project proposal
- Engineering analysis report

- Detailed specification table

1.3 Success Metrics

To consider this project a success it 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 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 development of the medical device, the team set the customer requirements as the following:

1. Disinfect-able
2. Rechargeable
3. Light Exposure
4. Time Duration
5. Automatic Shutdown
6. Cost Effective

The first customer requirement is that the medical device needs to be sanitary, meaning it should be easily sanitized after each use, allowing for repeated use. The second customer requirement is that the device must be rechargeable, enabling multiple uses and eliminating the need for constant power connection during operation. The third requirement is light exposure. The light exposure in light therapy must be within a certain range in order to see significant improvements for the user's vitals. This device must also be capable of operating for the maximum recommended time duration and automatically shut off once the time has elapsed or when the user's vitals improve. Finally, the device must be cost effective, necessitating careful selection of materials and components to stay within the allocated budget.

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 Cost
4. Wavelength (Infrared lights)
5. Wavelength (Red LEDS)

6. Treatment Duration

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 infrared and red LED lights measured in nanometers must be between 850 to 880 nanometers for the infrared lights and 650 to 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.

2.3 House of Quality (HoQ)

System QFD

								Project:	**Tensegrity Medical Light Therapy**				
								Date:	**11/5/2024**				
1	Power Output												
2	Battery Life	9						Legend					
4	Unit Cost							A	LOVTRAVEL LED Light Therapy Pad				
5	Wavelength (Infrared light)		9					B	Garmin HRM-Dual Heart Rate Monitor				
6	Wavelength (Red LEDs)		9					C	Innovo iP900BP-B Finger Pulse Oximeter				
7	Treatment duration		3		3	3							
			Technical Requirements					**Customer Opinion Survey**					
	Customer Needs	**Customer Weights**	Power Output	Battery Life	Unit Cost	Wavelength (Infrared light)	Wavelength (Red LEDs)	Treatment Duration	1 *Poor*	2	3 *Acceptable*	4	5 *Excellent*
1	Disinfectable	4						1		A	B		C
2	Rechargeable	3	9	9							C	A	
3	Light Exposure	4				9	9	9	AC				B
4	Time Duration	3	3	3		3	9	9			AC		B
5	Automatic shut down	1	3	9				3	BC		AC		
6	Cost effective	3			9					A		BC	
	Technical Requirements Units		W	min	$(USD)	nm	nm	min					
	Technical Requirements Target		20-50	120	290	850-880	650-670	20					
	Absolute Technical Importance		39	45	27	45	63	70					
	Relative Technical Importance (%)		13.49	15.57	9.34	15.57	21.80	24.22					

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 disinfected was rated a 4 since we need to make sure the device stays clean with each use while 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 a small 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. Similarly, the section above the technical requirements shows the correlation between the engineering requirements amongst themselves and used the same ratings. Positive numbers showed a positive correlation, and negative numbers showed negative correlation.

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 Current 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 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

These sources were used to not only inform myself about what photo-biomodulation entails, but also how we can incorporate certain engineering practices to our project as a whole

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

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

$$t = 2\,hours \qquad Q = 6\,Ah$$

$$V_{Battery} = 5\,V \qquad E = (6\,Ah) * (5\,V)$$

$$E = 30\,Wh$$

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.

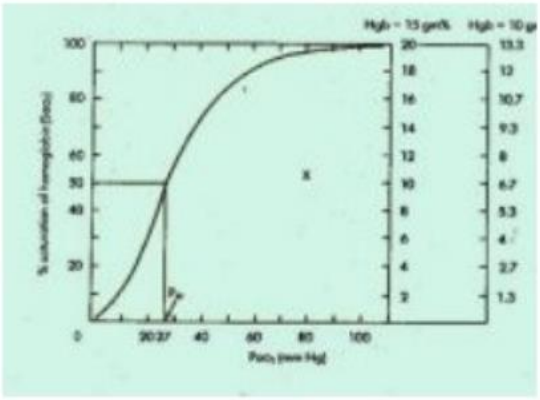


Figure 11: Example 5.3 from Book

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

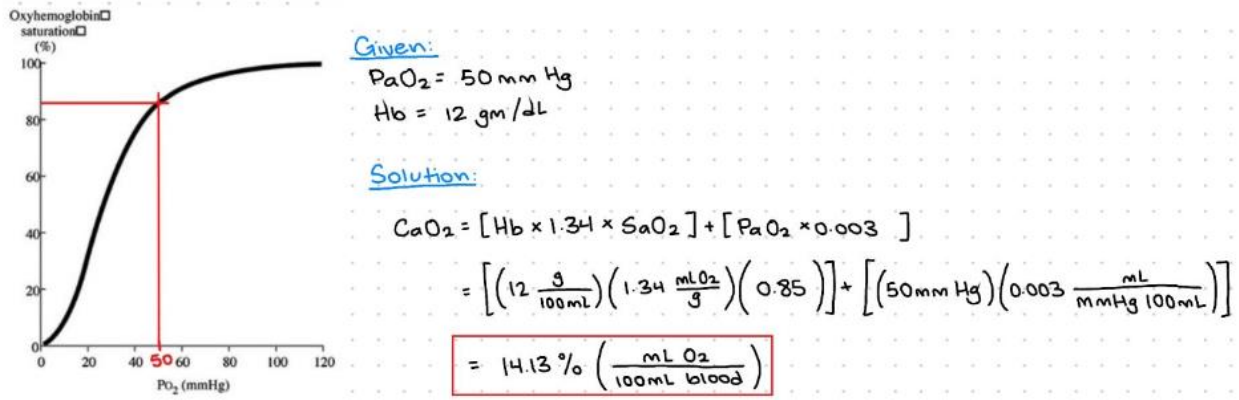


Figure 12: CaO2 Calculation

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.

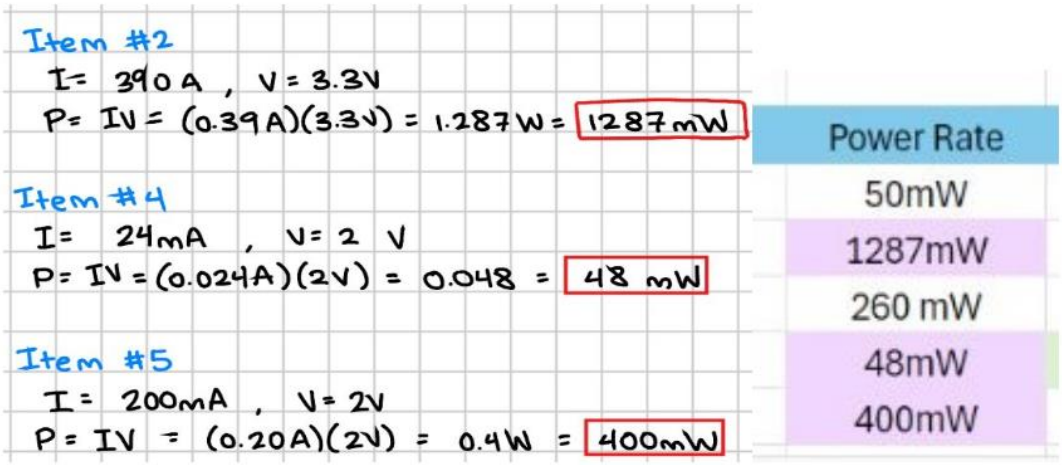


Figure 14: Power Output Calculations

3.3.5 Beer-Lambert Law for Light Absorption – Norma Munoz

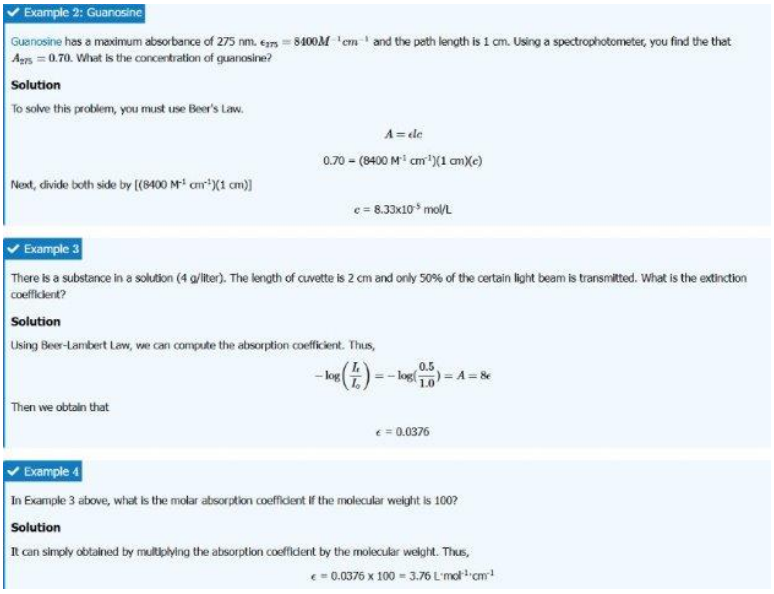
The following figures show the equation used, an example from the textbook [24] , and the calculations for the Beer-Lambert Law for Light Absorption incorporating values related to our project

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

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

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

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

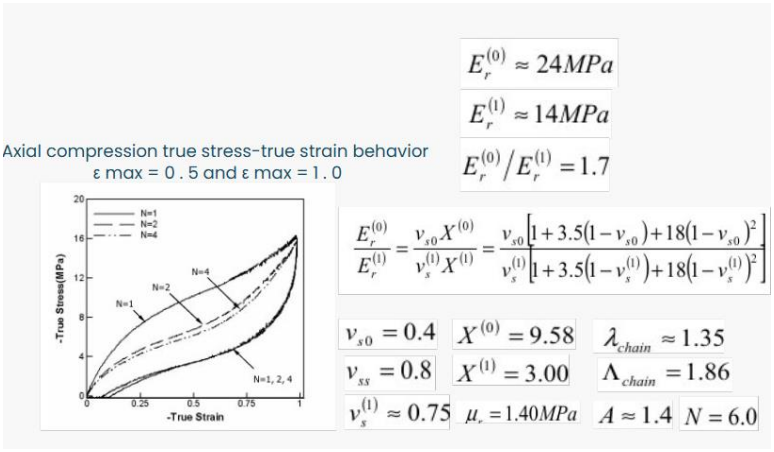


Figure 19: Stress-Strain calculations for Polyurethane Elasticity

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

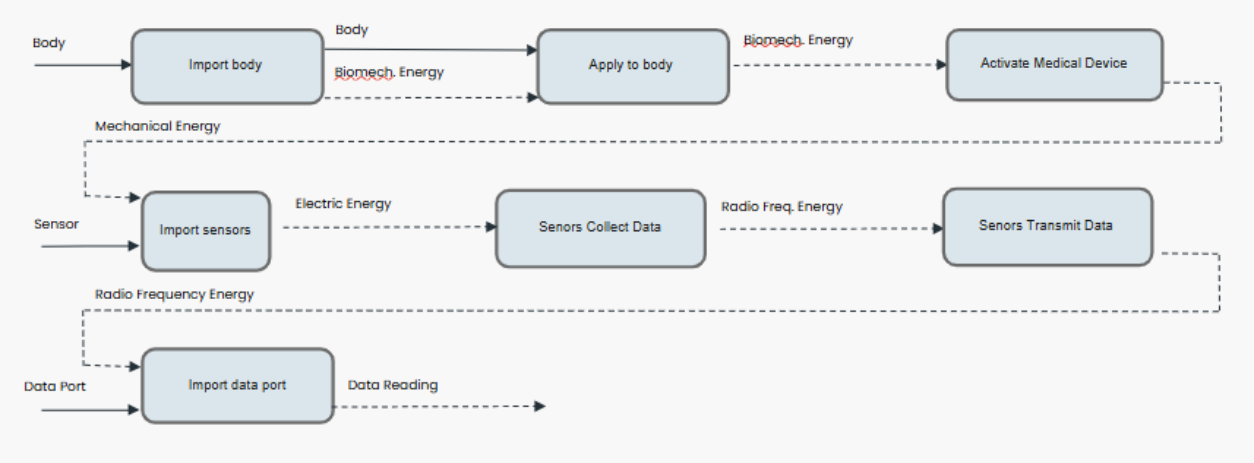


Figure 20: Functional Model

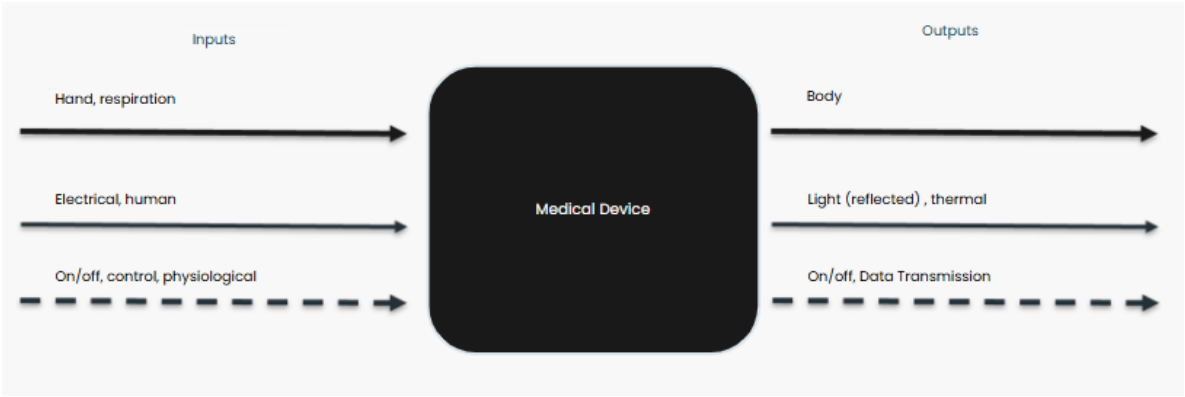


Figure 21: Black Box Model

4.2 Concept Generation

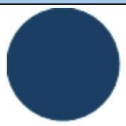
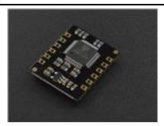
Table 1, shown below, includes the concept generation for the subsections of the design. The team decided to use a morphological matrix to organize the design variations. Section 4.4 finalizes major decisions for the battery, sensor, circuit boards, and LED lights.

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 Performance of Light Therapy (PBM)

4.3.2 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/cm^2 to penetrate tissues and achieve therapeutic outcomes

4.3.3 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

4.3.4 Material Selection for Flexibility and Durability

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.

4.3.5 Sensor Accuracy for Monitoring Blood Flow and Oxygen

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).

4.3.6 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	02.5 mm x 51.0 mm x 6.0 mn	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: 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).

4.5 Computer-Aided Design

After the team evaluated the highest rated concept generation, the CAD model (Figure 26 and 27) was created. The design of the device will be a 7x2.5x0.5 square made from medical grade materials like thermoplastic polyurethane (TPU). While the CAD model is subject to change, it does help the team visualize the final design and have an idea of how it will look.

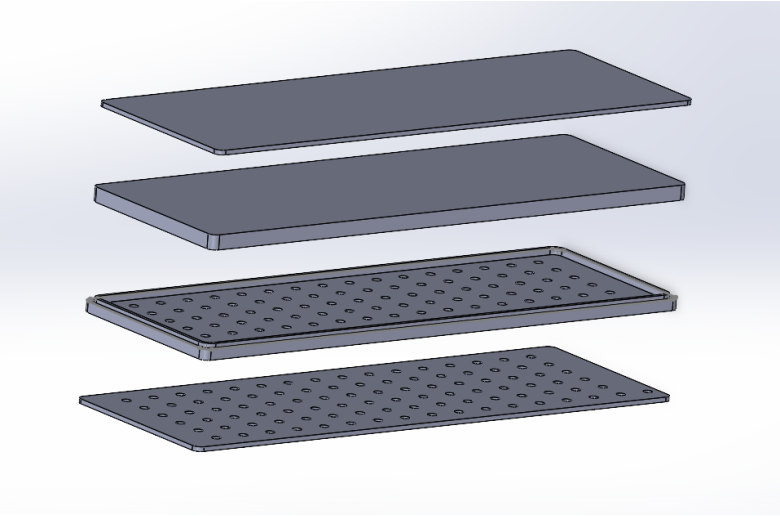


Figure 26: Exploded view of CAD

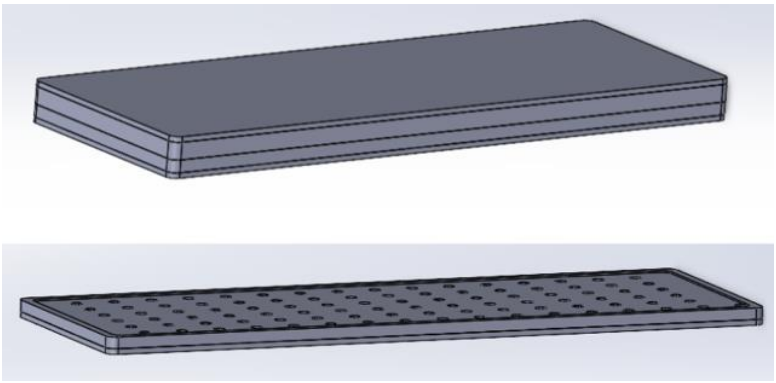


Figure 27: Full and Section view CAD Model of device

5 Schedule and Budget

5.1 Schedule

To keep track of important tasks and deadlines, the team has created a Gnatt chart shown in Table 2. This chart shows the remaining weeks of the semester with important deadlines such as the second prototype, the final CAD design, and the website check. To view the entire Gnatt chart for the semester reference Appendix A.

TASK ID	TASK TITLE	TASK OWNER	START DATE	DUE DATE	DURATION IN DAYS	PCT OF TASK COMPLETE
6	Report 2					
6.1	Schedule & Budget	Alicia	11/12/24	11/27/24	15	100%
6.2	FEMA	Claire	11/12/24	11/27/24	15	100%
6.3	Initial Prototyping	Norma	11/13/24	11/28/24	15	100%
6.2	Calculations	All	11/14/24	11/29/24	15	100%
6.3	Future Testing	Claire	11/15/24	11/30/24	15	100%
6.4	BOM	Norma	11/16/24	12/01/24	15	100%
6.5	CAD Model	Norma	11/17/24	12/02/24	15	100%
7	Final CAD Design					
7.1	Circuit Dimensioning	TBD	11/15/24	12/03/24	18	100%
7.2	CAD Model	TBD	11/15/24	12/03/24	18	100%
8	Prototype Demo 2					
8.1	Virtual Prototype	TBD	11/18/24	12/03/24	15	0%
8.2	Physical Prototype	TBD	11/18/24	12/03/24	15	0%
8.3	Meet with EE	All	11/19/24	12/03/24		0%
9	Website Check 2					
9.1	Team Photos	All	12/06/24	12/07/24	1	0%
9.2	Upload files & photos	Norma	11/21/24	12/07/24	16	0%
9.3	Add mentors bio	All	11/27/24	12/06/24	9	0%

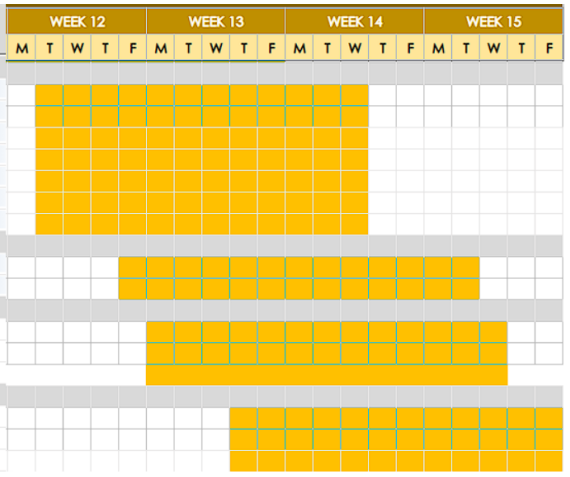


Table 2:1st Semester Weeks 12-15 Gantt Chart

The ME team is planning a meeting with the EE team to discuss the final prototype of the semester. At this meeting, there will be a discussion of what the goal for this prototype is and how we plan to execute it. After this meeting, the ME team will create a final prototype CAD model to help visualize how the device will look like. The next task is to update the website with individual photos of the ME team, sponsor, and mentors. Additionally, the documents and presentations used in class will be uploaded to the website along with photos of the development of the project.

To keep the team on track for the spring semester, a second-semester Gantt chart will be drafted. Below is the Tentative Schedule for the spring. This schedule lists important deadlines the team needs to complete. These deadlines will then be created into smaller tasks amongst the team.

ME 486C – Mechanical Engineering Design II

Spring 2023 - Tentative Schedule

(subject to change – check Bb Learn for the current schedule)

Week	Week Starts	In-Class Agenda	UGRADS (whole team)	Individual Assignments	Team Assignments
1	16-Jan	486C Kickoff meetings (team/staff)*		Self-Learning or Individual Analysis	Project Management
2	23-Jan	Team/Staff Meetings			Engineering Model Summary
3	30-Jan	Team/Staff Meetings			
4	6-Feb	Team/Staff Meetings			
5	13-Feb	Hardware Status Update - 33+% build		Peer Eval 1 due	
6	20-Feb	Team/Staff Meetings			
7	27-Feb	Team/Staff Meetings			Website Check #1
8	6-Mar	Hardware Status Update - 67+% build	UGRADS Registration	Peer Eval 2 due	*Start writing your testing plan!*
	13-Mar	***Spring Break!!!***			
9	20-Mar	Team/Staff Meetings	Draft of Poster		*Continue writing your testing plan! (order testing equipment)*
10	27-Mar	Team/Staff Meetings			Finalized Testing Plan (order testing equipment)
11	3-Apr	Hardware Status Update - 100% build	Final Poster & PPT	Peer Eval 3 due	Final CAD Packet
12	10-Apr	Initial Testing Results			
13	17-Apr	Product Demo & Final Testing Results			Final Report & Final Website Check
14	24-Apr	Practice presentations in class, Symposium on Friday, time TBD			
15	1-May			Peer Eval 4 due	Client Handoff - Spec Sheet & Operation/Assembly Manual
Finals	8-May				

Figure 28: Spring Tentative Schedule

5.2 Budget

The team has a budget of $5,000 provided by Jesslynn along with an additional $500 from fundraising. Currently the team has used $410 for prototyping materials. As of now the estimated amount to manufacture one device is $290. Jesslynn emphasized that she wanted the team to manufacture at least five devices. The cost to manufacture five devices is about $1,450. Below is an overview of the amount spent along with the anticipated expenses.

Total Budget	$5,500
Spent	$410
Future Spending	$1,450
Remaining Amount	$3,640

Figure 29: Budget Overview

[Show your total project budget including prototyping, final design build, travel, and any other expenses.]

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 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

Checklist	Subsection for Prototype	Name	Product Type	Part Number / Product ID	Amount	Unit Price (Before Tax and Shipping)	Note
New MAX (3)	circuit housing	MAX30102EFD+T	PPG Sensor	MAX30102EFD+T	2	$26.22	A PPG sensor that can measure oxygen levels and heart rate
out of stock	circuit housing	SEN0344	PPG Sensor	SEN0344	2	$31.80	A PPG sensor that can measure oxygen levels and heart rate
1 strip (32)	LED Strip	LUXEON 2835 Color Line, Deep Red	Red LEDs	L128-DRD1003500000	16	7.104	Red LEDs that have a wavelength range of 650nm - 670nm and a beam angle of 130 degrees
1 strip (32)	LED Strip	LUXEON IR Onyx	Infrared LED Emitter	L1IG-0750100000000	32	196.48	Infrared emitters that have a wavelength of 750nm - 1000nm, a beam angle of 120 degrees, and is medical grade
1	Battery	Jenax J-FLEX Battery	Rechargeable Li-Ion Battery	N/A	1		Flexible battery suitable for wearables, 3.8V, 30 mAh capacity, contains over 1000 cycles at 80% charge capacity
1 pk (10)	circuit housing	IRLZ44N MOSFET	MOSFETs	IRLZ44N IRLZ44NPBF	3 5pcs	$29.88	To handle the higher current without overloading the Arduino. Switch that allows on/off and brightness control
1 pk (32)	circuit housing	AL8861WT-7 (Cut Tape)	LED Drivers	AL8861WT-7DICT-ND • Cut Tape (CT)	15	6.75	To regulate the current flowing to the LEDs and IR emitters, so they are protected from overcurrent
2 pk(10 total)	circuit housing	MT3608 Boost Converter	Boost Module	MT3608-Type C USB	2	$0.96	Needed to increase battery voltage from 3.7V to 5V to ensure stable power for all components, type c usb input to charge battery if needed
2	circuit housing	Adafruit HUZZAH32	Control Unit	AF-3405	2	$47.90	Will control the LEDs and IR and process data given from the sensors. Built-in Wi-Fi and Bluetooth. More capabilities compare to Arduino Uno
Already have	circuit housing	Resistors	Resistor	N/A		Already obtained, do not need to purchase	Will need resistors to safely convert the 5v signal from the SEN0344 to the 3.3V level from the Adafruit HUZZAH32. R1 = 5.1k or 4.7k, R2 = 10k
6 total (2 3pk)	circuit housing	ElectroCookie PCB Prototype Board	PCB	N/A	2	23.98	Physical foundation for prototype, that will hold and connect all the components that we will be using. It is also much thinner and flexible compared to usual breadboards
1	Insulation	Black PRO Series Flex - 1.75mm Flexible TPE (0.5kg)	3D Printing Filament	N/A	1	$60.00	Used for insulation
1	Inner & Outer	TPU 95A HF	3D Printing Filament	N/A	1	$41.99	Used for insulation

6 Design Validation and Initial Prototyping

6.1 Failure Modes and Effects Analysis (FMEA)

For each individual part included in the prototype, we decided to do a failure modes and effects analysis (FMEA) 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 included below, we had assessed a total of 7 individual parts: the two types of LEDs, the battery, the feather board, the Arduino, the 3D printed shell, and finally the sticker adhesive. First, we determined in what way the part could potentially fail as well as the cause and effects of those failures. 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: FMEA

	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	IR 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	2	60	Allow for breatheable material as insulation, and make sure the wiring isnt too stacked on top of eachother to casue a short circuit
3	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
4	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
5	Arduino	Failed Circuitry	Wires could disconnect from the arduino to the featherboard	4	Mistreatment/ movement of product	5	Circuit Testing	2	40	Have propper chackes during the manufacturing process to make sure parts dont come loose
6	Holding shell/component	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
7	Sticker Adhesive	Adhesive Wear	Could loose its stickability after multiple uses	4	Loose Stick	8	Adhesive Strength Testing	5	160	Find a material that is reuseable while also being able to keep its stick

6.2 Initial Prototyping

6.2.1 Virtual 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

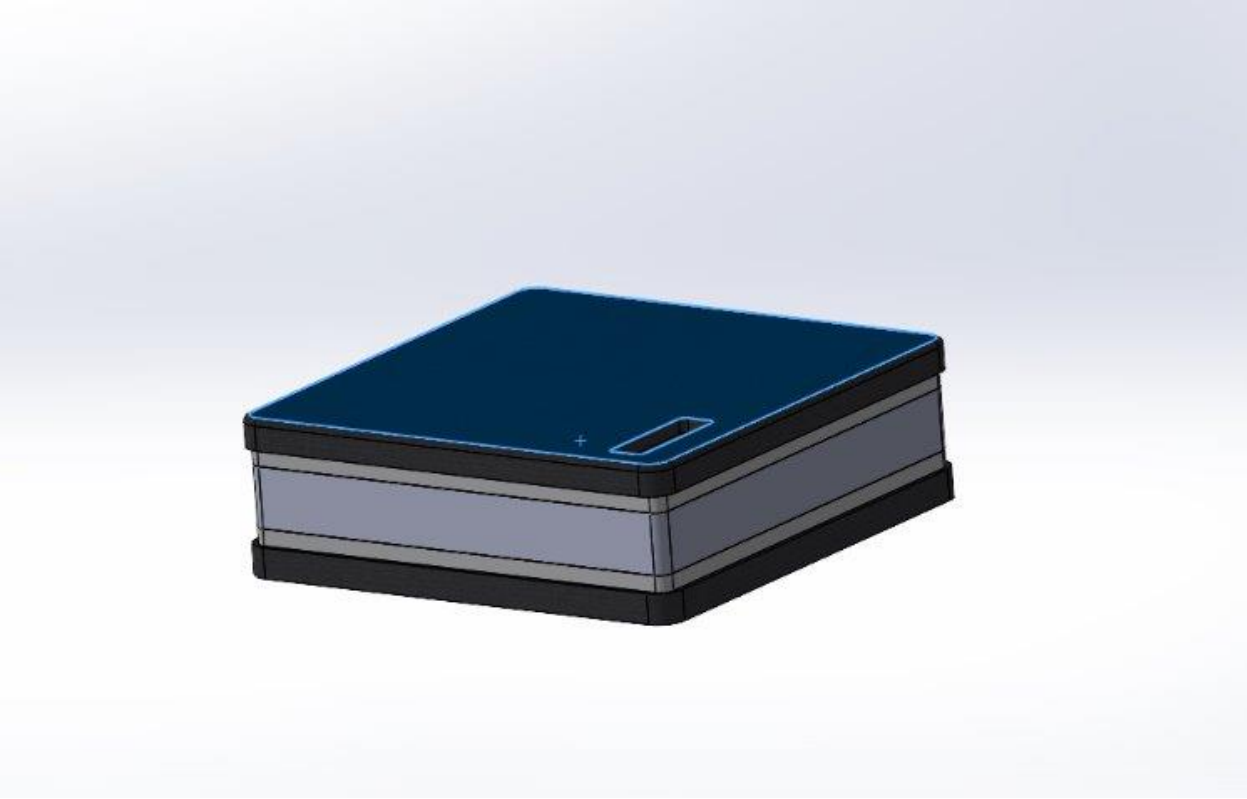


Figure 30: Initial virtual CAD design

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.

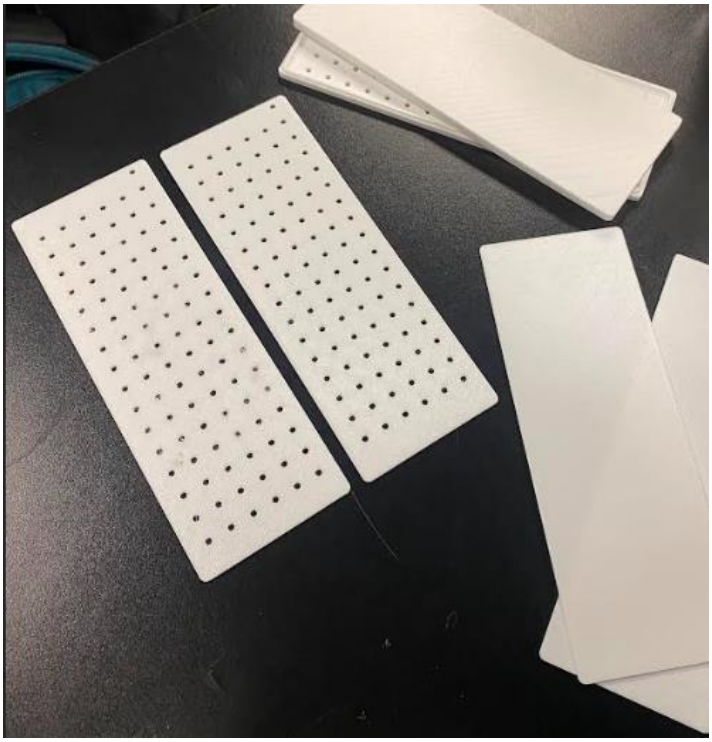


Figure 31: Physical Prototype 1.1

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 32: 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 33: 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 34: 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 35: Equations for total, outer layer, casing, inner layer, inner and outer surface temperatures

Overall device temperature difference:

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

$$\Delta T_{total} = 47.09\ °C$$

Figure 36: Overall or total temperature of the device when in use

Outer layer temperature difference:

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

$$\Delta T_O = 0.84\ °C$$

Figure 37: Outer layer temperature

Casing temperature difference:

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

$$\Delta T_C = 17.63\ °C$$

Figure 38: Casing temperature

Inner layer temperature difference:

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

$$\Delta T_I = 0.84\ °C$$

Figure 39: Inner layer temperature

Inner surface temperature difference:

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

$$\Delta T_{I,surf} = 37.84\ °C$$

Figure 40: Inner surface temperature

Outer surface temperature difference:

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

$$\Delta T_{O,surf} = 78.31\ °C$$

Figure 41: 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 42: 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 43: 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 44: 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 45: 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 46: 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 47: 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.

Assumptions

- Durometer hardness value is 92A
- 3mm in thickness

Figure 48: List of assumptions and knowns

$$\varepsilon_{\max} = 0.5$$

$$\varepsilon_{\max} = 1.0$$

Figure 49: 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 # shows the graphical relationship.

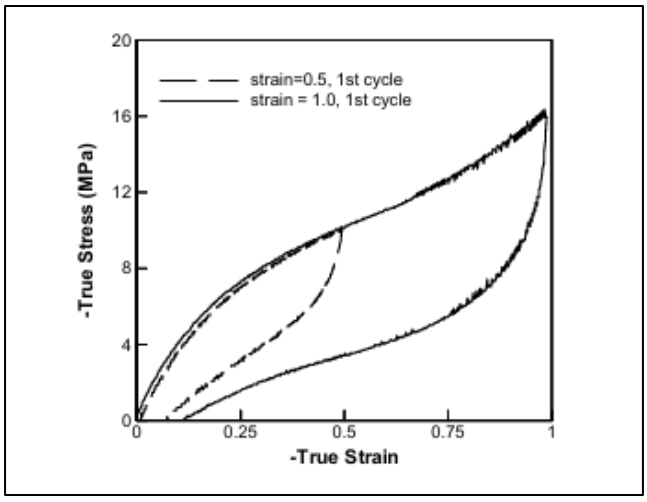


Figure 50: Uniaxial compression graph

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

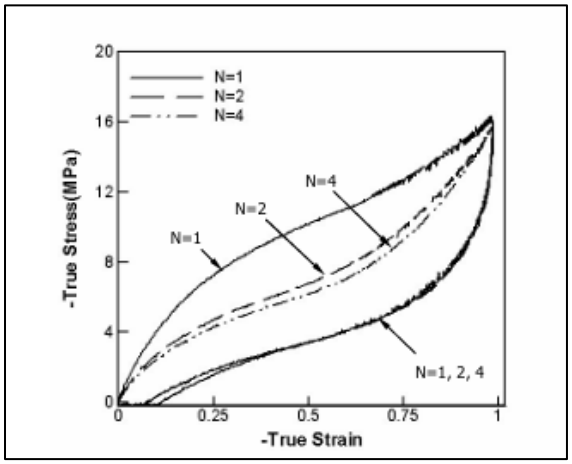


Figure 51: Cyclic uniaxial compression tests

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

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

$$E_r^{(0)} / E_r^{(1)} = 1.7$$

Figure 52: Linear elastic spring values

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

Figure 53: Equation for Material Parameter Identification for Hyperplastic Rubbery Softening

$\nu_{s0} = 0.4$ $X^{(0)} = 9.58$ $\lambda_{chain} \approx 1.35$

$\nu_{ss} = 0.8$ $X^{(1)} = 3.00$ $\Lambda_{chain} = 1.86$

$\nu_s^{(1)} \approx 0.75$ $\mu_r = 1.40MPa$ $A \approx 1.4$ $N = 6.0$

Figure 54: 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 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 insulation layered between the circuit housing and the red LED lights and sensor. The next step involves prototyping by utilizing 3-D printing for the materials and finalizing any dimensions for the medical device.

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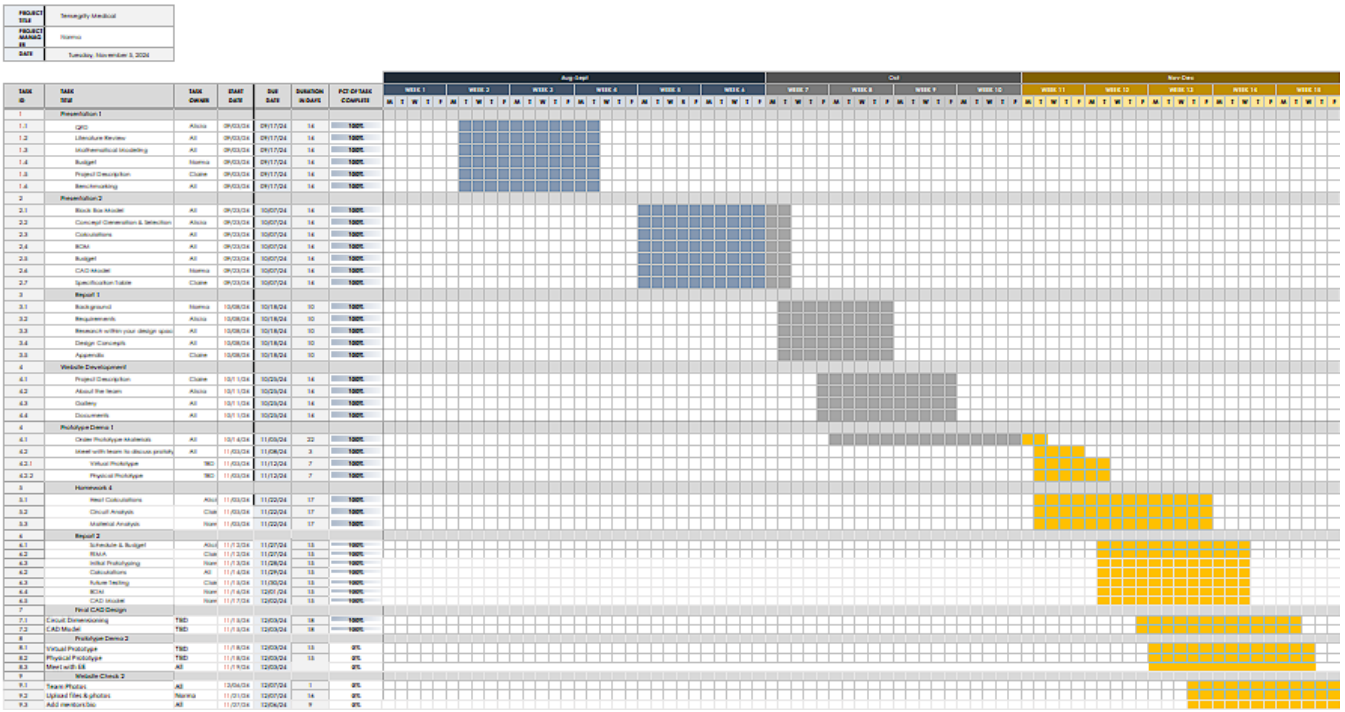
9 APPENDICES

9.1 Appendix A: Fall Semester Gantt Chart



PROJECT TITLE	Tensegrity Medical
PROJECT MANAGER	Norma
DATE	Tuesday, November 5, 2024