Light Dose Tensegrity Medical

Initial Design Report

Alicia Corona

Financial Manager, Test Engineer & CAD Engineer

Claire Mitchell

Manufacturing Engineer, Test Engineer & CAD Engineer

Norma Munoz

Project Manager, Website Developer, Logistics Manager, Test Engineer & CAD Engineer

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TENSE MED MECHANICS

Project Sponsor: Jesslynn Armstrong

Sponsor Mentors: Devon Martindale, Jeff Saville, and Jim Silverman

Instructor: David Willy

DISCLAIMER

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.

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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 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

1.1.5 Client

The client for this project is Jesslynn Armstrong. She is the founder oand 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.

1.1.6 Timeline

The project is designed to extend over the course of two semesters, providing ample time for in-depth research, detailed planning, and the careful, methodical execution required for the development of the device. This extended timeline ensures that each phase from the initial design and material selection to the final testing and implementation, can be approached with the necessary precision. The two-semester structure allows the team to incorporate iterative feedback, refine the design, address any unforeseen challenges, and ensure compliance with regulatory parties, ultimately resulting in a high-quality and fully functional product.

1.1.7 Budget

Our client has graciously set aside a $5,000 budget for the team to design, prototype, and develop our device. We are confident that this amount will be sufficient to complete the project while fulfilling all the requirements she has set for us. In addition to this funding, we aim to fundraise 10% of the total budget ($5000) through various sponsorships, grants applications, and potential fundraising events., further supporting the successful development of the device.

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 will be 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 closely aligned with the project's primary objectives, specifically the production of a PBM medical device.

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. Tp confirm this has been achieved the team aims to complete manufacturing by 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 our client 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 to compare benchmarked designs, and ensure alignment and effectiveness.

2.1 Customer Requirements (CRs)

Based on our initial meeting with our client, Jesslynn Armstrong. The team set the customer requirements as the following:

1. Sanitary
2. Rechargeable
3. Elimination of on/off switch
4. Time duration
5. Automatic shutdown
6. Non-invasive
7. Reusable
8. Cost effective

Our first customer requirement is that our medical device needs to be sanitary, meaning it should be easily sanitized after each use, allowing for repeated use. Leading to our seventh requirement: Reusability, allows the device to be used multiple times. 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 to eliminate the need for an on and off switch, preventing users from accidentally turning off the device during light therapy treatment. 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. A critical requirement is that this device needs to be non-invasive, meaning that the device must rest on the treatment area without entering the body at any point. 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. Battery Power
2. Battery Life
3. Sanitation Time
4. Treatment Duration

5. Portability

The first engineering requirement, battery power, 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 next requirement is battery life, measured in minutes and represents how long the device can function before requiring a recharge. Both battery power and battery life relate to the customer's requirement of being rechargeable. Sanitation time, measured in minutes, aligns with the customer's requirement for the device to be sanitary and ensures the device can be properly cleaned. Treatment duration, also measured in minutes, incorporates the customer requirements for treatment time and automatic shutdown. The final engineering requirement is portability. Our client mentioned eliminating the use of cords and by doing so this improves comfortability and allows the consumer to use the device anywhere they prefer.

2.3 House of Quality (HoQ)

The team developed a House of Quality, shown in Appendix A, 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 1: LOVTRAVEL LED Light Therapy Pad [reference]

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. Basically, we are modernizing this device to keep up with the current technology used today. Our version of this device will be more aesthetically pleasing, and the goal is to eliminate the use of cords as our client emphasized that having to untangle cords is very time consuming.

Figure 2: Garmin HRM-Dual [reference]

The next device included in our benchmarking, in the figure above, is the Garmin HRM-dual that monitors heart rate. For our medical device we 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 us figure out how we can implement something like our medical device.

Figure 3: Innovo Finger Pulse Oximeter [reference]

The third device included in our benchmarking, in the figure above, is the Innovo Finger Pulse Oximeter which is used to measure oxygen levels. In our medical device we are 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 us figure out how we would like to implement it into our 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 our 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. Our medical device has a similar purpose to the devices talked about in this journal and this could be used as a foundation for our device 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 our medical device.

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 us a better understanding of the purpose of the medical device we are 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 we are using 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 our consumers are.

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 our team to reference as we aim to guarantee that our medical device meets safety requirements and is safe for consumers to use.

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 (PaO_2), Oxygen Saturation (SaO_2), and Oxygen Content (CaO_2). PaO_2 is the oxygen content that is dissolved in plasma, SaO_2 is the oxygen content that binds to plasma, and CaO_2 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.

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.

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 fata 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 4: 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 5: 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 6: 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 7: Battery Capacity Equation

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

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

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

$$\boxed{E = 30\,Wh}$$

Figure 8: 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].

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

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

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

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

$$S_aO_2 = \text{Oxygen Saturation } (\%)$$

$$P_aO_2 = \text{Partial Pressure of Oxygen } (mmHg)$$

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

Figure 9: 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.

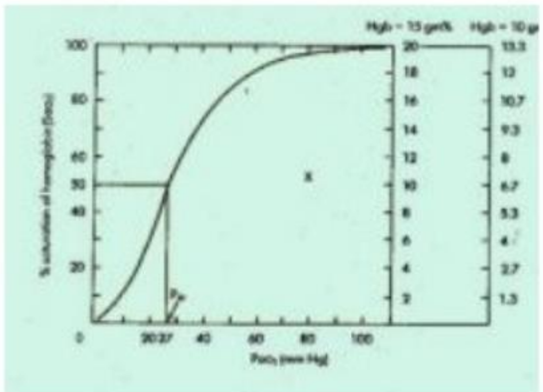
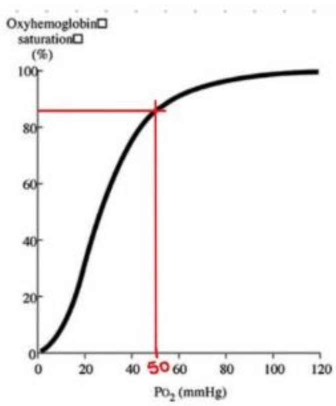


Figure 10: Example 5.3 from Book

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



Given:

$PaO_2 = 50 \text{ mm Hg}$

$Hb = 12 \text{ gm/dL}$

Solution:

$$CaO_2 = [Hb \times 1.34 \times SaO_2] + [PaO_2 \times 0.003]$$

$$= \left[\left(12 \frac{g}{100mL}\right)\left(1.34 \frac{mL\,O_2}{g}\right)(0.85)\right] + \left[(50mm\,Hg)\left(0.003 \frac{mL}{mmHg\ 100mL}\right)\right]$$

$$= 14.13\% \left(\frac{mL\ O_2}{100mL\ blood}\right)$$

Figure 11: 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 12: 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.

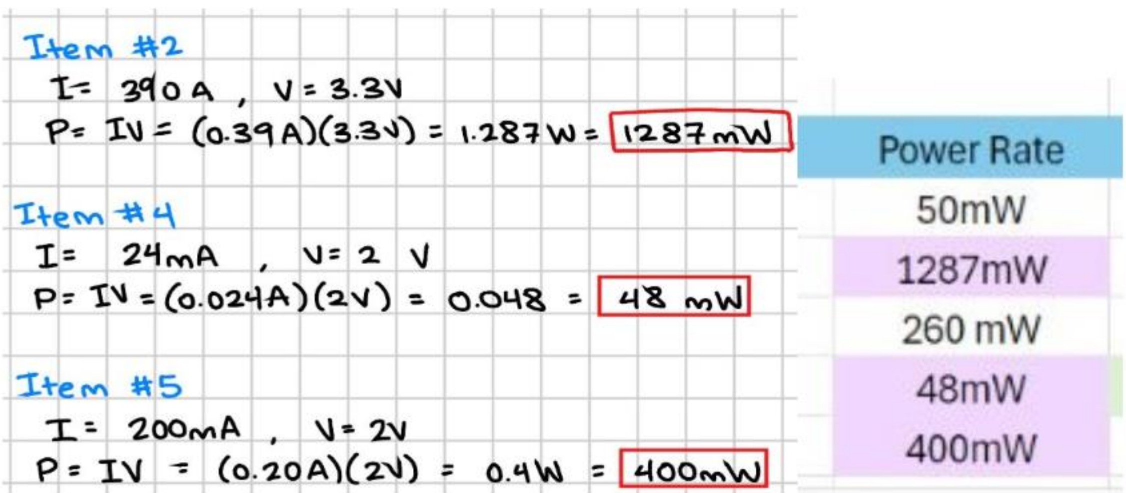


Figure 13: Power Output Calculations

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 14: 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 15: 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 16: 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.

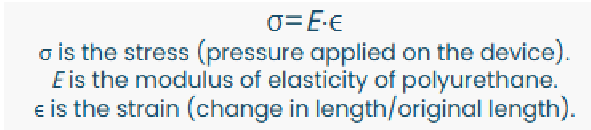


Figure 17: Stress-Strain equation

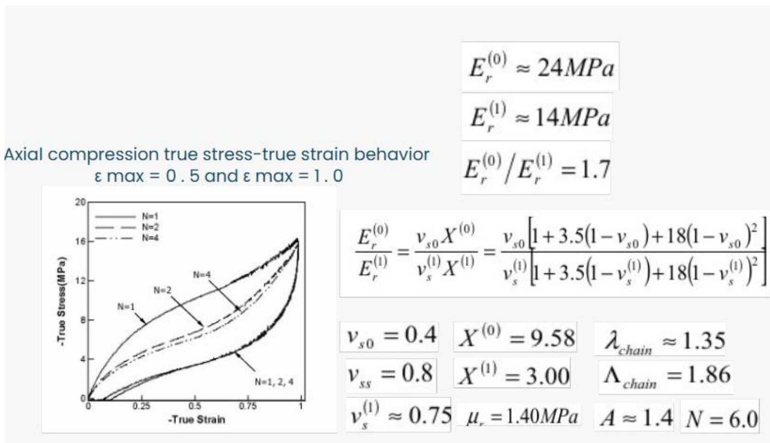


Figure 18: Stress-Strain calculations for Polyurethane Elasticity

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 a functional and black box model is created. 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

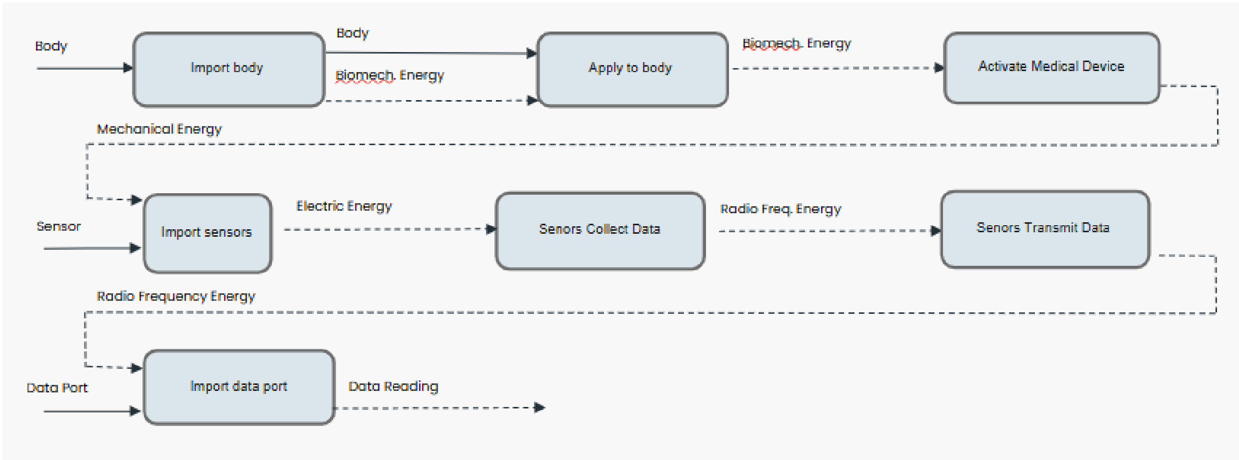


Figure 19: Functional Model

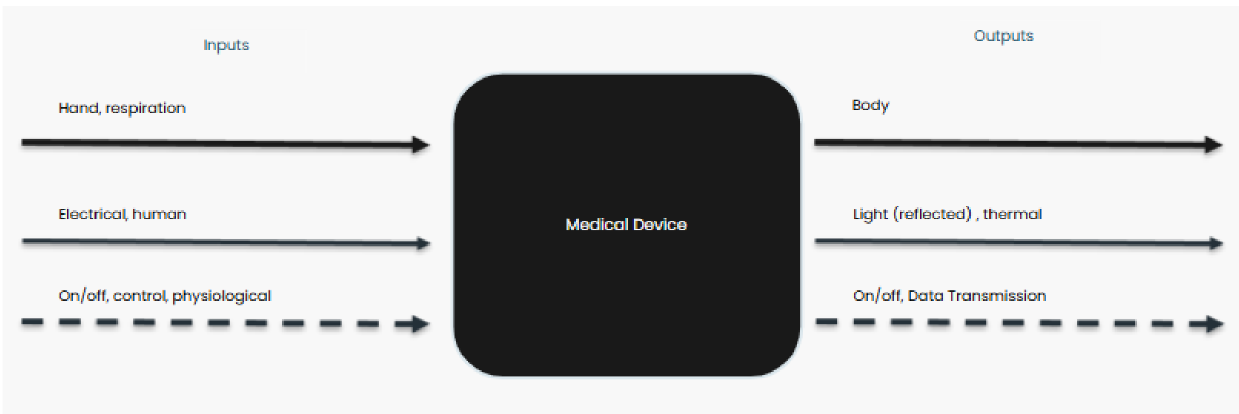


Figure 20: Black Box Model

4.2 Concept Generation

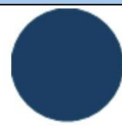
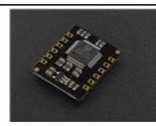
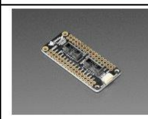
Table 1, shown below, includes the concept generation for the subsections of the design. The team decided to use a morphological matrix to organize the design variations. Section 4.4 finalizes major decisions for the battery, sensor, circuit boards, and LED lights.

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. 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/cm² 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	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 21: 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 22: 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 #[]: 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 23: 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 # and #) was created. The design of the device will be a 4x4x1 square made from a medical grade materials like thermoplastic polyurethane (TPU), and polylactic acid (PLA). 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.

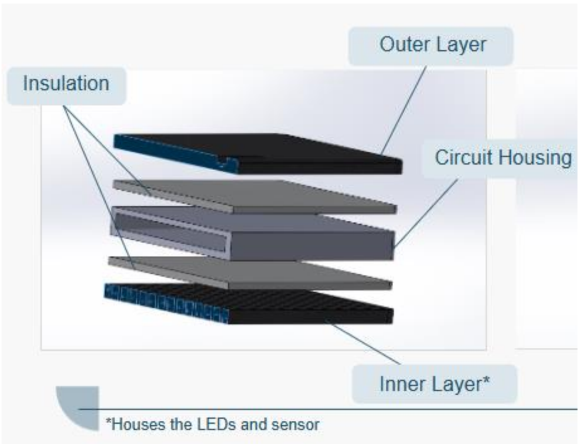


Figure 24: Exploded view of CAD

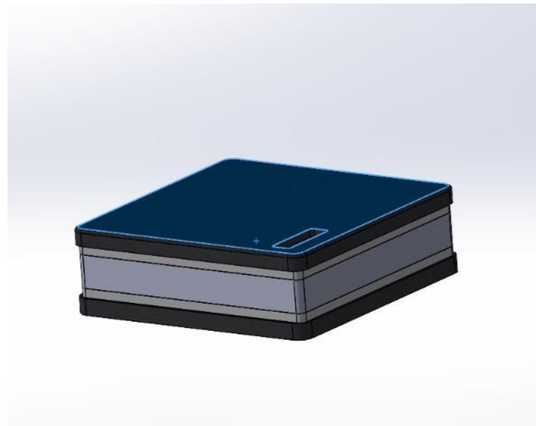


Figure 25: CAD Model of device

5 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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7 APPENDICES

7.1 Appendix A: House of Quality

System QFD

Project:	Tensegrity Medical Light Therapy
Date:	9/17/2024

Legend

A	LOVTRAVEL LED Light Therapy Pad
B	Garmin HRM-Dual Heart Rate Monitor
C	Innovo IP900BP-B Finger Pulse Oximeter

#	Technical Requirement	1	2	3	4	5
1	Battery Power					
2	Battery Life	9				
3	Sanitation Time					
4	Treatment Duration	3	9			
5	Portability	3	9		3	

#	Customer Needs	Customer Weights	Battery power	Battery Life	Sanitation Time	Treatment Duration	Portability	1 Poor	2	3 Acceptable	4	5 Excellent
			Technical Requirements					Customer Opinion Survey				
1	Cleanable	4			9				A	B		C
2	Rechargeable/battery life	3	9	9		3				C	A	
3	Without need of on/off switch	4					9	AC				B
4	Time Duration	3			3	9				AC		B
5	Automatic shut down	1	3	9				BC		AC		
6	Non-invasive	4				1						ABC
7	Reusable	3	3	9								ABC
8	Cost effective	3							A		BC	
	Technical Requirements Units		W	min	min	min	mts					
	Technical Requirements Target		20-50	120	5	20	-					
	Absolute Technical Importance		39	63	45	40	36					
	Relative Technical Importance (%)		17.49	28.25	20.18	17.94	16.14					

Figure A.1: Medical Device House of Quality