Light Dose Tensegrity Medical

Engineering Calculations Summary

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 and Jeff Saville

Instructor: Jim Clark

1.0 Introduction

To date, our team has made significant progress in demonstrating the feasibility of our design for a medical device that leverages photo-biomodulation (PBM) technology to improve cardiovascular health. We established requirements through client collaboration and created iterative CAD models informed by a Quality Function Deployment (QFD) analysis. Comprehensive research on PBM principles, LED wavelengths, and material properties has guided our design decisions, ensuring optimal performance and safety. Engineering calculations have validated our material choices and system parameters, Initial prototyping provided insight into component integration and refinement. Our efforts have culminated in a functional prototype design ready for further development.

2.0 Design Summary

As stated before, through clients and goal discussing we established a set of requirements and constraints that have guided our design process. Using these constraints, we developed several CAD designs and QFD iterations. These iterations have led us to a well-refined solution for this semester's capstone. The team must create a final physical product that is about 4” x 6”. This class 2 Photo-biomodulation Medical Device is noninvasive and will aid in monitoring and improving blood flow and blood oxygen levels. The Engineering team was successful in creating an initial design shown in Figure 1 and Figure 2 while adhering to the client's request.

2.1 CAD Model

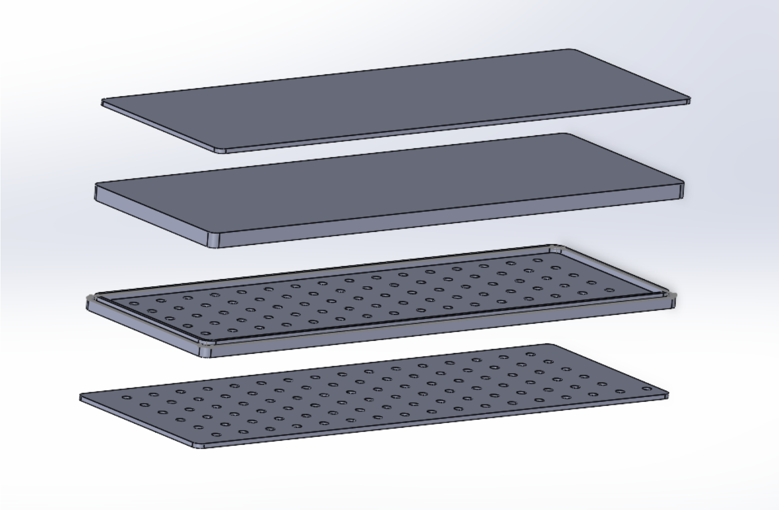


Figure 1: Exploded view of CAD

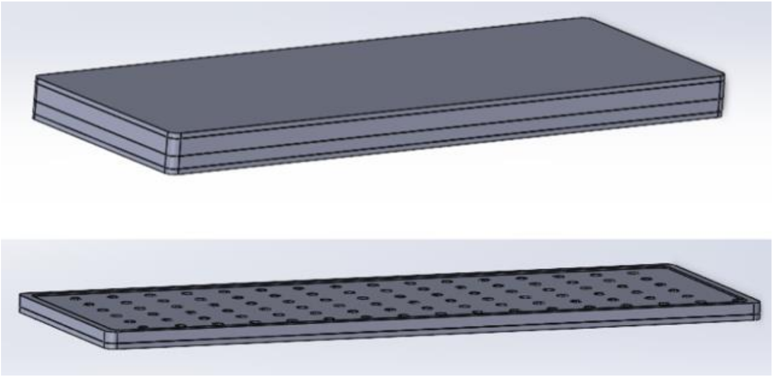


Figure 2: Full and Section view CAD Model of device

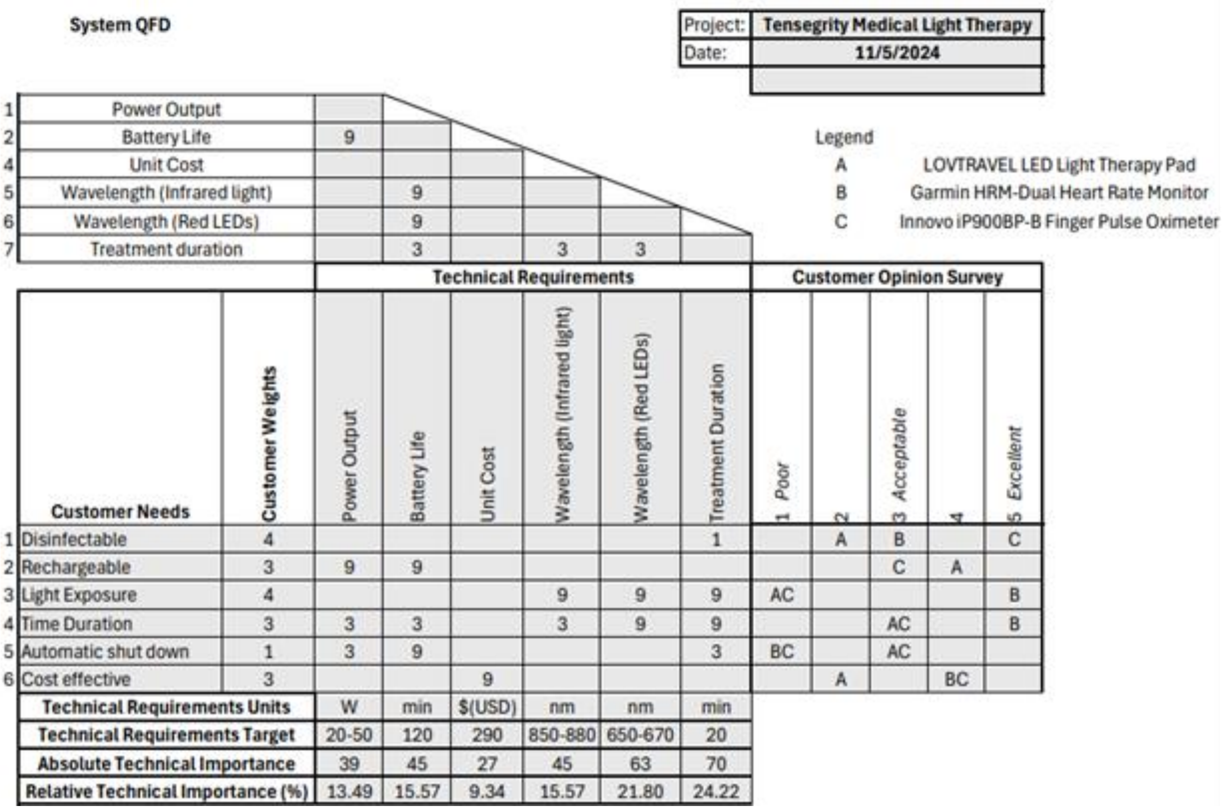
This Initial Design was constructed of medical grade materials. We specifically tested thermoplastic elastomer (TPE) and thermoplastic polyurethane (TPU). It will feature a circuit housing and LED components, enabling light emission from one side (the side in contact to the body). The design incorporates up to three distinct layers: an inner layer closest to the body, insulation layer housing the circuits, and an outer layer containing the battery component. These layers provide a clear visual of how the medical device will be assembled and function, helping the engineering team identify and organize subcomponents effectively.

This semester we plan to make several adjustments to refine the design. These include securely adhering the subcomponents using medical grade adhesives and modifying design elements such as shape and flexibility to ensure the device is comfortable and suitable for patient use.

2.2 Updated QFD

Our device is designed to meet key customer requirements given to us by our client. It must be disinfectable as well as rechargeable for repeated use, deliver appropriate light exposure for therapeutic benefits, operate for a specified time duration, automatically shut down after treatment or when user vitals improve, and remain cost-effective.

Engineering requirements were derived from these needs, including power output (20–50 watts) to support light therapy, battery life of up to 120 minutes, and a manufacturing cost of up to $290 per unit. The device must emit light within specific wavelengths: 850–880 nanometers for infrared and 650–670 nanometers for red LEDs, ensuring effective therapy. Additionally, treatment duration is set at approximately 20 minutes, aligning with automatic shutdown and operational efficiency.



System QFD

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

Legend

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

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

	Customer Needs	**Customer Weights**	**Technical Requirements** Power Output	Battery Life	Unit Cost	Wavelength (Infrared light)	Wavelength (Red LEDs)	Treatment Duration	**Customer Opinion Survey** 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 3: QFD

The team developed the House of Quality to analyze the relationships between customer and engineering requirements, system benchmarks, and technical correlations. The customer requirements were weighted on a 1–4 scale based on importance, with disinfectability rated 4 (high importance) and automatic shutdown rated 1 (lower importance). The team used a 1, 3, or 9 ranking system to measure the correlation between customer and engineering requirements, with blank cells indicating no correlation. For example, battery life and rechargeability had a high correlation (rated 9), as battery life impacts how long the device can operate before recharging.

The QFD also detailed engineering requirement units, targets, and technical importance, emphasizing which aspects were critical to device development. For instance, a 20-minute treatment duration was set based on professional recommendations for LED light therapy. Benchmarking of three existing devices evaluated how well they met customer requirements on a scale of 1 to 5, identifying the device that best aligned with customer needs.

3.0 Summary of Standards, Codes, and Regulations

The design of our photo-biomodulation (PBM) medical device adheres to a comprehensive set of standards, codes, and regulations to ensure safety, performance and regulatory compliance. Key standards include ISO 80601-2:2017 [1] and IEC 60601-2-57:2023[2], which govern the safety and performance of therapeutic light devices, and ASTM D5470-17[3], which ensures proper thermal management. Battery safety is addressed through IEC 62133-3[4], while the FDA's 21 CFR Part 820 defines the quality management requirements for medical devices. Additional regulations, such as ISO 14155:2020[5], outlines clinical investigation practices, and ISO/IEC 17025 [6] ensure testing accuracy.

Critical equations, including those for flux/power density, oxygen content in blood, and heat transfer, guide our engineering analysis, ensuring the LED's output, thermal properties, and material performance are optimized. Engineering requirements such as power output wavelength, and a 120-minute minimum battery life align with customer demands for a disinfectable, rechargeable, and cost-effective device.

4.0 Summary of Equations and Solutions

4.1 Flux/Power Density, Battery Capacity, & Heat Transfer Analysis (Alicia Corona)

4.1.1 Flux/Power Density

The flux or power density indicates how much energy the medical device is consuming per area. Equation 1 was used to calculate the energy consumption, where P_{light} is the total power of the light source, measured in watts, and A is the area illuminated by the light, measured in centimeters squared.

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

(1)

This calculation informs us how much energy the device utilizes. Moreover, this calculation helps the team better understand how to make the device more energy efficient and is relevant information when ensuring the device lasts the targeted time duration of 120 minutes.

4.1.2 Battery Capacity

The battery capacity is the amount of energy a battery can store and release. The medical device needs to be wireless, so a battery will be needed to power the device. Equations 2 and 3 were used to calculate the battery capacity, where Q is the battery charge capacity, measured in amp-hours. I is the current that runs through the circuit, measured in amps and t is time, measured in hours. E is the battery energy capacity, measured in watt-hours and $V_{Battery}$ is the battery voltage, measured in volts.

$$Q = I * t$$

(2)

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

(3)

Battery capacity directly affects the battery life and knowing how much energy the battery can handle will help the team understand how to prolong battery usage. This calculation, along with the flux density is beneficial when creating the circuit board.

4.1.3 Heat Transfer Analysis

A heat transfer analysis was conducted to ensure the safety of the medical device as the heat from the circuit and LED lights can potentially burn the patient's skin. Equations 4 through 11 were used in this analysis. Equations 4 through 7 are the thermal resistances of the outer layer (R_O), the casing (R_C), the inner layer (R_I), and the air (R_{air}) all measured in kelvin per watt. Equation 8 calculates the power dissipation ($P_{dissipation}$) and equation 9 calculates the total heat transfer (Q_{total}), both measured in watts. Equations 10 and 11 calculate the overall inner ($\Delta T_{I,surf}$) and outer ($\Delta T_{O,surf}$) surface temperatures, measured in degrees Celsius.

$$R_O = \frac{t_O}{kA} \quad (4)$$

$$R_C = \frac{t_C}{kA} \quad (5)$$

$$R_I = \frac{t_I}{kA} \quad (6)$$

$$R_{air} = \frac{1}{h_{air}A} \quad (7)$$

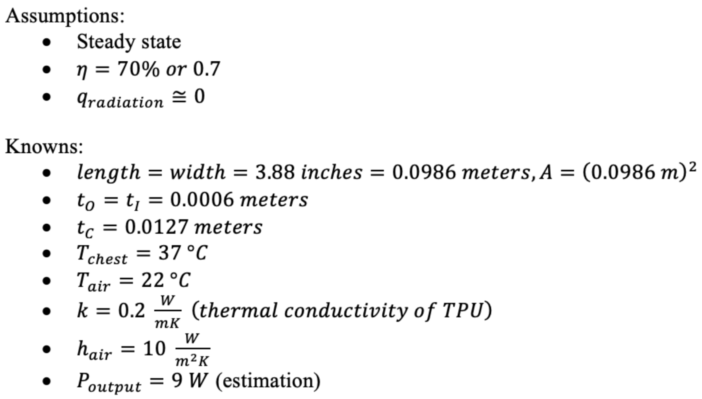
$$P_{dissipation} = Q_{total} = P_{output} * (1 - \eta) \quad (8)$$

$$Q_{total} = \frac{\Delta T}{\Sigma R} \quad (9)$$

$$\Delta T_{I,surf} = \Delta T_I + T_{chest} \quad (10)$$

$$\Delta T_{O,surf} = \Delta T_O + \Delta T_C + T_{air} + \Delta T_{I,surf} \quad (11)$$

The following figure shows a list of assumptions that were applied when conducting the heat transfer analysis.



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)

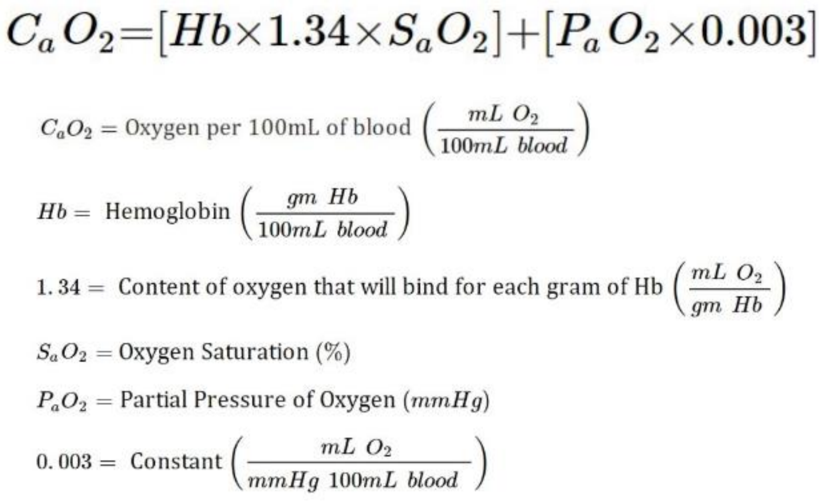
Figure 4: Assumptions and known values

The results of the heat transfer analysis allow the team to adjust the medical device in case the device either overheats or is above the allowable temperature the device needs to be in order to not burn the patient. Additionally, it proves that the material used for the casing, inner and outer layers can withstand the heat from the electrical components.

4.2 Blood Oxygen Level Calculation and LED Energy Exposure Calculation (Claire Mitchell)

4.2.1 Blood Oxygen Level Calculation

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 [10].



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

$C_aO_2 =$ 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 $\left(\frac{mL \; O_2}{gm \; Hb}\right)$

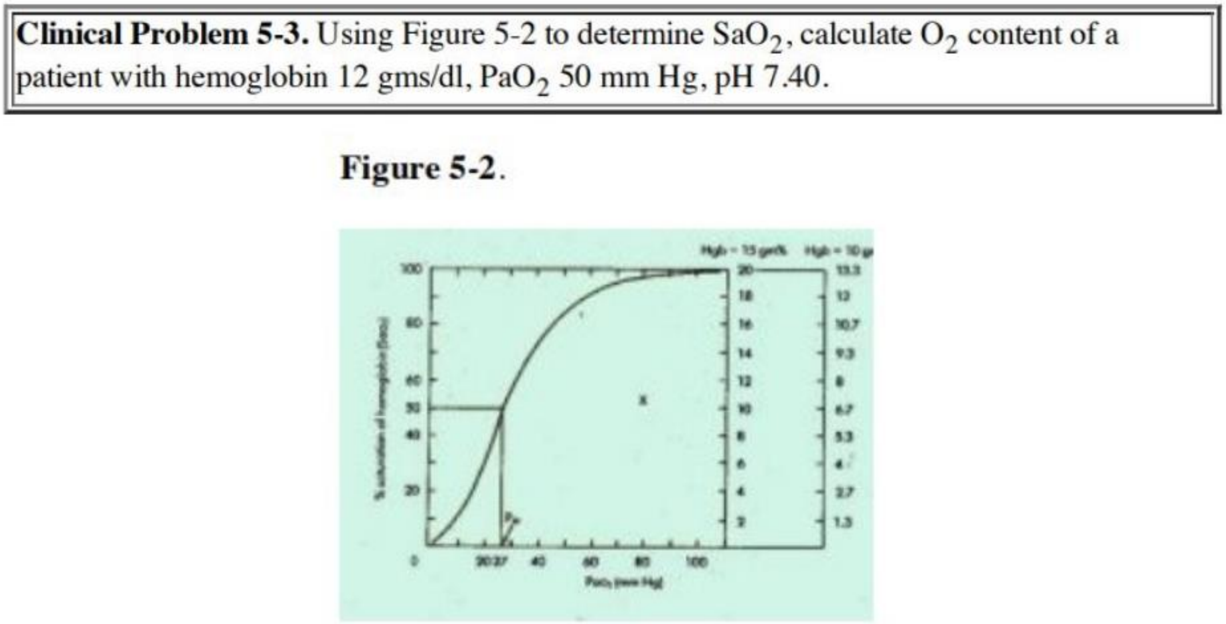
$S_aO_2 =$ Oxygen Saturation (%)

$P_aO_2 =$ Partial Pressure of Oxygen $(mmHg)$

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

Figure 5: 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 [10].*

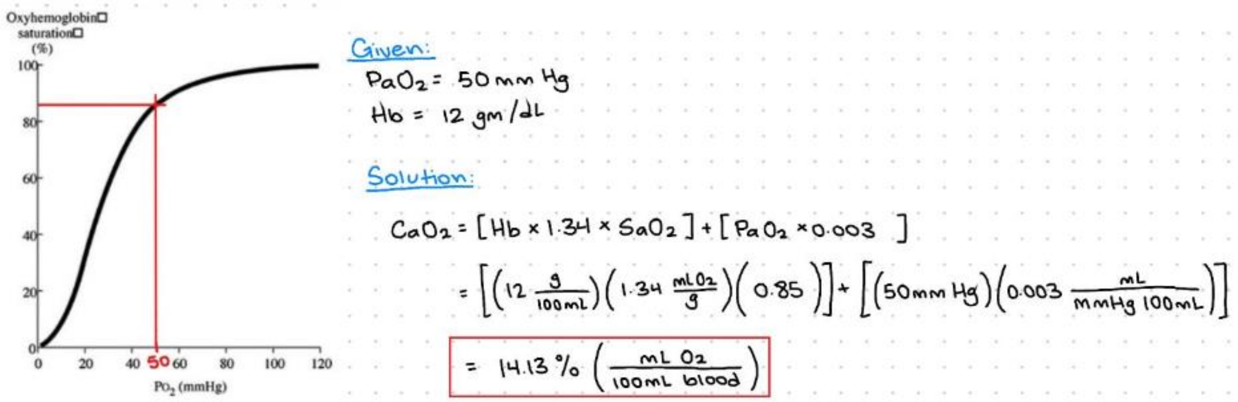


Clinical Problem 5-3. Using Figure 5-2 to determine SaO_2, calculate O_2 content of a patient with hemoglobin 12 gms/dl, PaO_2 50 mm Hg, pH 7.40.

Figure 5-2.

Figure 6: 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:

$PaO_2 = 50\ mm\ Hg$

$Hb = 12\ gm/dL$

Solution:

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

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

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

Figure 7: 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.

4.2.1 LED Energy Exposure

Another value we needed to know for the development of our device was how much power it would output based on the parts we selected to use for the prototyping. In order to find the specific number for exposed energy, I used the three equations below: total power equation, irradiance equation, energy exposure equation.

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

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 8: Total Power Equation with Specified Values

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

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 9: Irradiance Equation with Specified Values

$$E = I \times t$$

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 10: Energy Exposure Equation with Specified Values

Using these equations as well as the specifications given from the LEDs and IRs we purchased, I was able to get a total power calculation of the LEDs we would use in just one device. For one device, a total of 16 ed LEDs would be used, and a total of 32 infrared LEDs would be used

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

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

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

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

$$P_{total} = 3.36W$$

Figure 11: Total Power Calculation

After finding the total power, I estimated the area we were going to use for the entire device then converted the units to fit the irradiance equation.

$$4in = 0.1016m$$

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

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

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

Figure 12: Irradiance Calculation

After finding the irradiance, I converted the units to fit the energy output equation.

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

$$E = I \cdot t$$

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

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

Figure 12: Energy Exposure Calculation

After completing all the necessary steps, I found the total energy exposure of our device based on all the LEDs used as well as the surface area of our device.

4.3 Stress-Strain Analysis, Light Absorption, and Material Parameters (Norma Munoz)

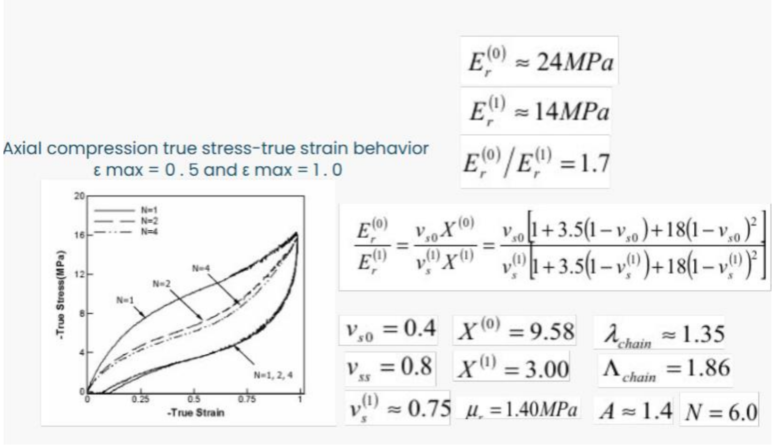
4.3.1 Stress-Strain Analysis

A stress-strain analysis was conducted to understand the mechanical behavior of thermoplastic polyurethane (TPU) under various loading conditions. The analysis evaluated TPU's elasticity and ability to withstand mechanical stress while maintaining durability. The true stress (σ) and true strain (ϵ) relationship was calculated using Equation #12:

$$\sigma = E * \epsilon \qquad (12)$$

where E is the material's Young's modulus. Assumptions for this analysis included a durometer hardness value of 92A and a 3 mm thickness for TPU samples.

Cyclic uniaxial compression tests were performed to evaluate the material's hysteresis and cyclic softening behavior, as shown in the stress-strain graph (Figure 13). These results informed us of the material's suitability for the device's flexible components.



Axial compression true stress-true strain behavior
ε max = 0 . 5 and ε max = 1 . 0

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

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

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

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

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

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

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

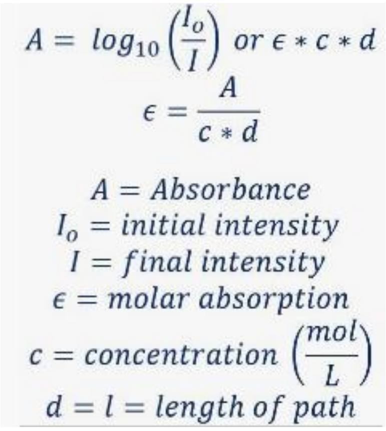
Figure 13: Stress-Strain calculations for Polyurethane Elasticity

4.3.2 Light Absorption Using the Beer-Lambert Law

To analyze light penetration and absorption through biological tissues, the Beer-Lambert Law was applied. This calculation is essential for determining how effectively red and infrared light penetrates the skin for photo-biomodulation therapy. Equation 13 describes the relationship:

$$A = \epsilon * c * l \tag{13}$$

Where A is unitless absorbance, ϵ is molar absorptivity, c is concentration, and l is path length



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

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

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

Figure 14: Beer-Lambert Law for Light Absorption

4.3.3 Material Parameter Identification

The behavior of TPU under hyper elastic conditions was modeled using Equation 14 for hyperplastic rubbery softening:

$$W = \frac{C_1}{2}(\lambda_1^2 + \lambda_2^2 + \lambda_3^2 - 3) + \frac{D_1}{2}(J - 1)^2 \tag{14}$$

Where $C_1$and D_1 are material parameters (constants determined through experimentation), λ is the stretch ratio in principle directions, and J is a determinant of the deformation gradient

5.0 Moving Forward

Although the team has conducted extensive calculations and analyses, a few additional evaluations are required to fully validate the medical device. Specifically, further analysis is needed to assess bending strain, bending stress, and material life cycles. The life cycle analysis is essential to determine whether the device can endure repeated use when placed on the patient's body. Additionally, the bending strain and stress analyses are crucial to understand the device's flexibility and its ability to withstand various bending loads without breaking, ensuring it can conform to different body parts. These assessments will also help determine the device's durability and the number of uses it can sustain before requiring replacement.

References

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