Non-Invasive Medical Device for Health Monitoring

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Project Overview

- **Client**: Jesslynn Armstrong, Light Matter Solutions, LLC
- **Summary**: Design and develop a wearable medical device that uses red and infrared LED lights to monitor blood flow and oxygenation via photo biomodulation (PBM).
- Device includes real-time data transmission and rechargeable battery

- Non-invasive, wearable medical device
- **Uses red LEDs**
- Monitors cardiovascular health
- Real-time wireless data transmission
- **Rechargeable battery-powered**

Deliverables & Sucess Metrics

Deliverables

- Functional, wearable PBM device prototype
- PCB with embedded LEDs and sensors
- App/external receiver unit
- Intergrated software for monitoring heart rate & blood oxygen

Sucess Metrics

- **Meets power (20-50W) and treatment time (20 min)**
- **Battery Life > 120 min**
- **Safe skin temperature Light exposure levels**
- **Data accuracy within 5% error**
- **Non-invasive, reusable, Bluetooth enabled**
- **Wavelength precision**

Customer & Engineering Requirements

Customer Requirements

- Reuseable / Rechargeable
- Safe Light Exposure
- Time Duration/Automatic shutoff
- Cord Free
- Cost Effective
- Lightweight / Compact

Engineering Requirements

- **Red LED Wavelength: 650-670 nm**
- **Safe Skin Exposure (<42° C)**
- **Battery Life ≥ 120 min**
- **Treatment duration: 20 min**
- **Power Output: 20-50W**
- **Size: less than 10in x 10in**

Quality Function Development

- Battery Life and Light Wavelengths are highest priority ERs aligned with top CRs.

System QFD

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

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

Legend

A LOVTRAVEL LED Light Therapy Pad

B Garmin HRM-Dual Heart Rate Monitor

C Innovo iP900BP-B Finger Pulse Oximeter

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

House of Quality

Background & Benchmarking

LOVTRAVEL LED
Light Therapy Pad

- **Function**: Photobiomodulation therapy
- **Note**: Not integrated with sensors

Garmin HRM-Dual

- **Function**: Heart rate monitoring
- **Note**: No light therapy capability

Innovo Finger Pulse Oximeter

- **Function**: Oxygen saturation monitoring
- **Note**: Not wearable long-term

Product 1 Reference [26], Product 2 Reference [27], Product 3 Reference [28]

Literature Reviews

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

i. Discusses the invention of a sensor that is flexible enough to wrap around the human body instead of using bulky sensors.

[2] Book 1: Lasers and Optical Fibers in Medicine (Chapter 8)

i. Used to help calculate power density. Discusses lasers and optical fibers used in the medical field.

[3] Journal 2: A Review of Current Advancements for Wound Healing: Biomaterial Applications and Medical Devices

i. Discusses common materials used in medical devices for wound healing.

[4] Book 2: Biomedical Devices: Materials, Design, and Manufacturing

i. Provides insight on materials used in biomedical devices and different techniques for designing and manufacturing.

[5] Journal 3: Proposed Mechanisms of Photobiomodulation or Low-Level Light Therapy

i. Provides an explanation of the science that goes into photobiomodulation and discusses near-infrared light.

[6] Online Source 1: LED Light Therapy Wavelengths: Everything You Need To Know

i. Gives an overview of the common wavelengths used in 3

ii. light therapy and how far into the tissue the wavelength reaches.

[7] Online Source 2: LED Light Therapy: How It Works, Colors, Benefits & Risks

i. Provides an explanation of how light therapy works, the colors/wavelengths used, what are the benefits and who should not use it for medical reasons.

[8] Standard 1: IEC 60601-2-57:2023

i. Provides safety and performance of using non-laser light sources for equipment that are used for therapeutic purposes.

Literature Reviews

[9] Book 1: All You Really Need to Know to Interpret Arterial Blood Gases (Chapter 5)

i. Describes how to calculate oxygen content in the blood as well as describes the contents of the blood

[10] Article 1: What are Blood Oxygen Levels

i. Outlines how much oxygen should be in the blood as well as talks about what to do when you have high/low blood oxygen levels

[11] Article 2: Physiology, Oxygen Transport

i. Talks about how oxygen moves through the blood and how it may differ based on someone with a blood deficiency such as anemia

[12] Paper 1: 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

i. Paper based on a trial regarding how well red-light therapy worked on the skin

[13] Paper 2: Battery Design Guide for Portable Electronics

i. Talks about how you should design a battery with certain components in mind: voltage requirement, capacity, runtime, etc.

[14] Paper 3: Development of a LED light therapy device with power density control using a Fuzzy logic controller

i. Describes a test done on how the skin reacts to different colors and different wavelengths of LEDs

[15] Book 2: Battery Operated Devices and Systems: From Portable Electronics to Industrial Products (Chapter 3.3: Medical Applications)

i. Outlines how with medical devices, you need more requirements as well as more safety when designing a battery

[16] Standard: ISO 80601-2-61:2017 Medical electrical equipment

[17] Article 1: Anti-inflammatory effects of PBM

i. ***Frontiers in Neuroscience* examine PBM effects, by adjusting how proteins are produced and controlled in the body; potentially providing therapeutic benefits in neuroinflammation**

Literature Reviews

[18] Article 2: PBM and Neurological Damage

i. *Neuroscience Bulletin* investigates how PBM might help repair brain damage from COVID-19 by improving how the brain uses and balances oxygen levels; supporting better brain function and recovery

[19] Article 3: PBM for Cognitive Improvement

i. *Journal of Translational Medicine* focuses on how PBM can improve brain function by boosting the production of Adenosine triphosphate (ATP; source of energy) encouraging growth of brain cells by using infrared lights

[20] Book 1: LibreText: Chemistry

i. **Describes Beer Lambert law—attenuation of light to the properties of the material through which the light is traveling-- and how it relates to photobiomodulation research**

[21] Book 2: low-level laser therapy effects on Vascular and endothelial function

i. ***Calderhead, R. G., & Vasilyeva, E.* discuss how PBM works on cardiovascular deseases and cellular mechanisms; they go into depth on dosage, wavelengths, and power density**

[22] Paper 1: Effects of Transcranial LED Therapy (TCLT)

i. *Salgado et al.* Explores the effects of Light Therapy on cerebral blood flow. Where PBM enhances blood flow in elderly patients, potentially combating neurodegenerative conditions

[23] Paper 2: Role of PBM in Cardiovascular Health: Systematic Review and Meta-Analysis

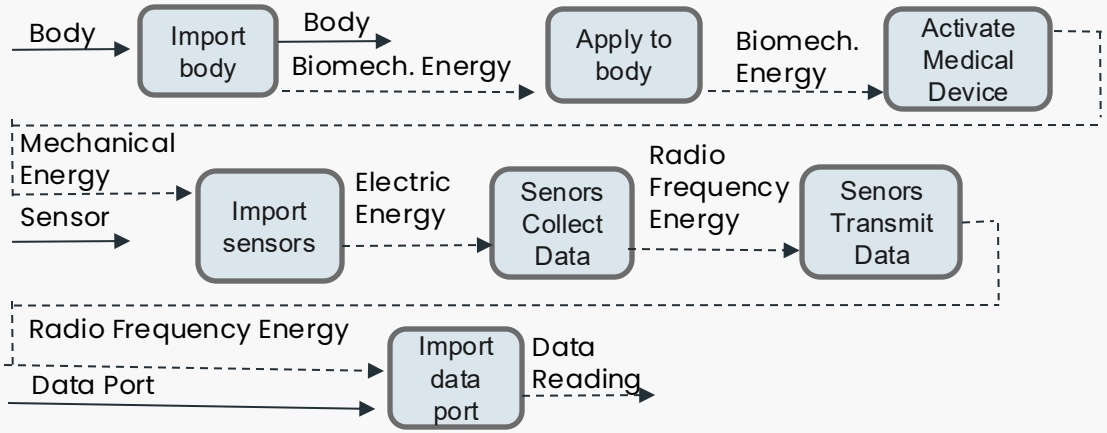
i. Details how PBM impacts cardiovascular parameters, such as blood circulation. Providing information on clinical studies that confirm PBM's ability to enhance microcirculation in patients with cardiovascular conditions

[24] Paper 3: Efficacy of PBM therapy in Older Adults: A systematic review

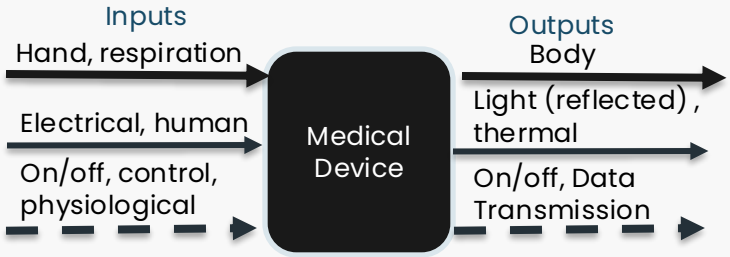
i. Details whether there is any available evidence on the efficacy of PBM therapy in older adults, by holding literature searches.

[25] Standard: "ISO/IEC 17025 testing and calibration laboratories," ISO, 2017. https://www.iso.org/ISO-IEC-17025-testing-and-calibration-laboratories.html

Functional Model

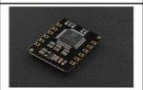


Black Box Model



Concept Generation & Selection

- **Selection Criteria**:
  - Light penetration
  - Battery efficiency
  - Comfort/flexibility
  - Manufacturability
- **Top concepts**: LED layout, casing design, power source
- **Chosen Concepts**: flexible circuit with embedded sensors

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			

Morphological Matrix

Specification Table

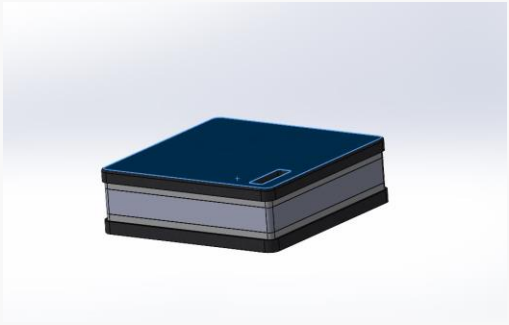
Item #	Name	Type	Charge Type	Flexability	Dimensions	Power Output	Capacity	Wt	
1	FLCB	Lithium	plug in	Y					
2	Tenergy Li-Polymer	Li-Ion	tap	Y	02.5 mm x 51.0 mm x 6.0 mn	3.7V	300mAh	61g	
3	Jenax Flex	Li-Ion	tap	Y	27mmx48mm	3.8V	30mAh		
4	Libest Flexable Battery	Li-ion	Tap	Y	54mm x 18mm x 2.5mm	4.35V	68mAh	2.4g	
Item #	Name	Type	Shape	Power Rate	Dimensions	Cost	Wavelength		
5	Lumiled - L1IG	IR	Flat / Square	50mW	2.75mm x 2.0mm	$3.42	850nm		
6	Lumiled- L1IG-085	IR	Flat / Square	1287mW	2.75mm x 2.00mm	$2.68	850nm		
7	Lumiled- L128-DRD	RED	Flat / Square	260 mW	3.5mm x 2.8mm x 0.7mm	$0.68	670 nm		
8	Lumiled - L1C1-RED1	RED	Square/Round top	48mW	2mm x 2mm x 1.35	$2.26	624-634nm		
9	Lumiled - L1C1-DRD1	Deep red	Square/Round top	400mW	2mm x 2mm x 1.36	$1.70	655-676nm		
Item #	Name	Bluetooth	USB	Power Supply	Works With	Power Usage	Cost	Dimensions	
10	Adafruit HUZZAH32	Y	USB	3.6	Arduino IDE / Li-ion	mid	$21.95	0mm x 23.5mm x 19.0r	9.9g
11	Adafruit ESP32 Feather V2	Y	C	3.3V	Arduino / MicroPython	low	$19.95	.3mm x 22.8mm x 7.2r	6g
Item #	Number	Description	Dimensions	Power Supply	LED Supply	1 LED Characteris	Cost		
12	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		
13	MAXM86161EFD+T	Module for HR and SpO2 Measurement	2.9mm x 4.3mm x 1.4mm		3.0V-5.5V	660nm	$12.72		
14	MAX86174AENE+T	Biometric Sensors Dual Channel Low Cost PPG AFE	1.67mm x 1.78mm, 0.4mm				$6.81		
15	MAX32664GTGD+T	Biometric Sensors SENSOR HUB W/ SPO2, HR & BP ALGORITHMS	1.6mm x 1.6mm	1.7V-3.6V			$4.81 (min 2500)		

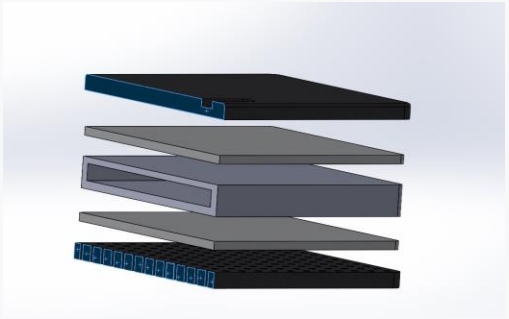
BOM

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

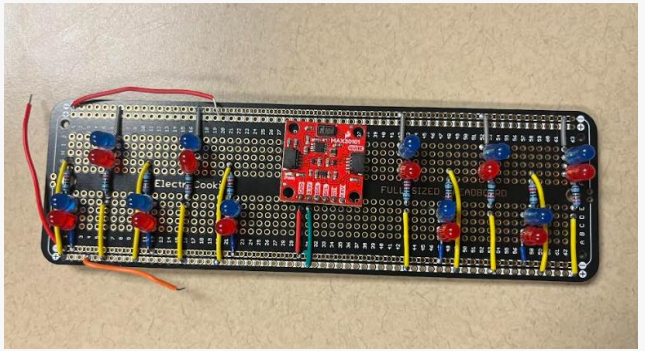
Bill of Materials Table

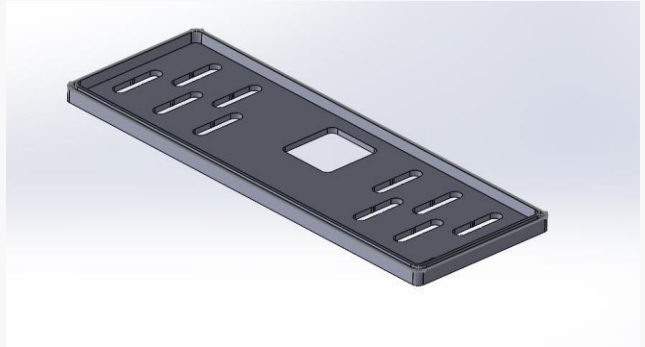
Initial CAD/Prototyping





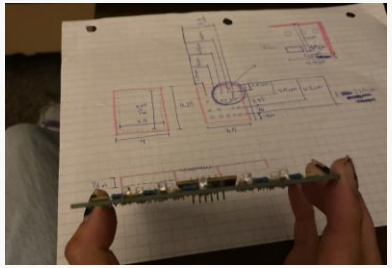
- **Prototype A**: Focused on thermal regulation
- **Prototype B**: Focused on LED placement
- **Insight Gained**:
  - Insulation with TPE was not necessary
  - Some components required repositioning
  - Flexibility was limited depending on size

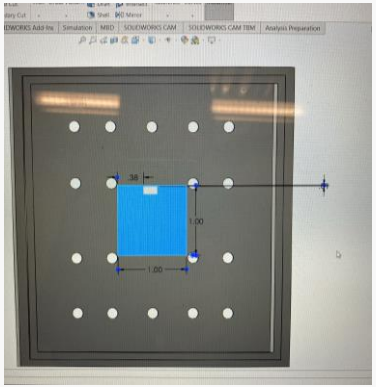


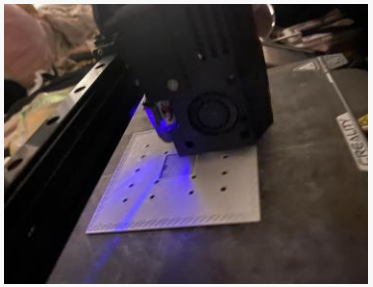


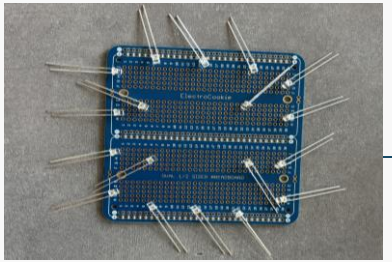
*Houses the LEDs and sensor

Prototyping & Manufacturing





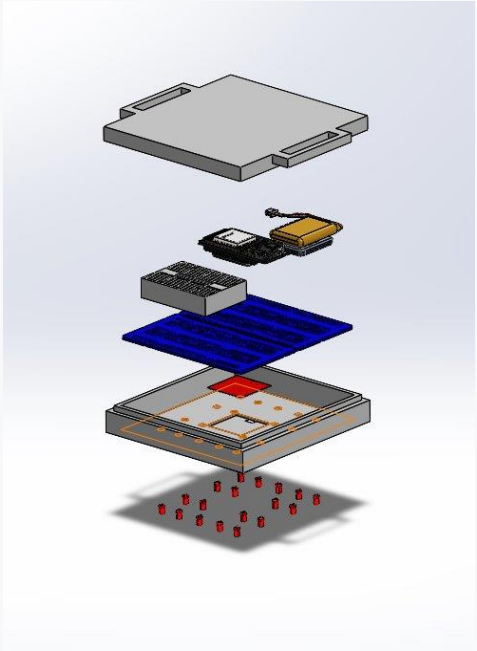


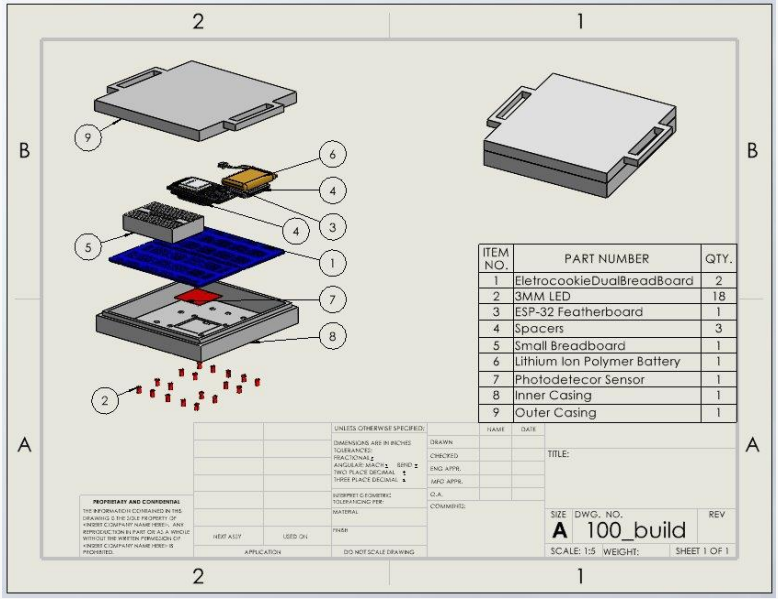


- Played with Protoboard designs
- Tested different configurations of LEDs
- Included a harness for wearable use
- Printed casing with various thicknesses

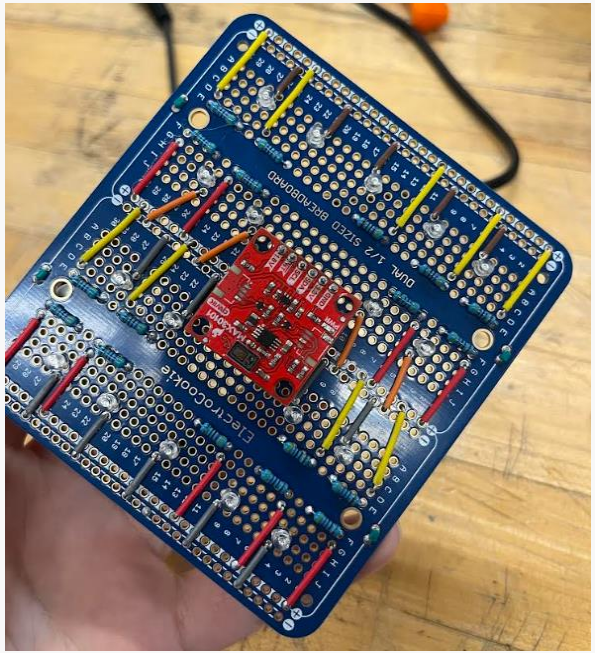
Final CAD Design

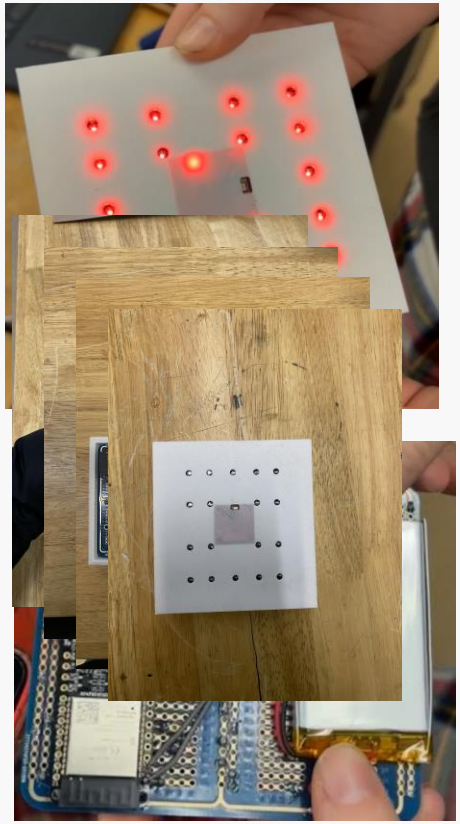
- CAD includes casing with LED/sensor housing
- Board prototype to PCB

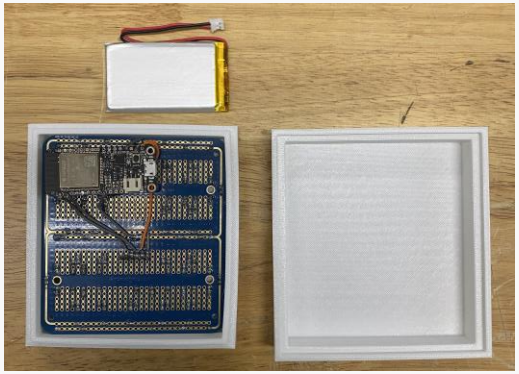




Final Prototype







Failure Modes & Effects Analysis

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

Failure Mode and Effect Analysis Tabe

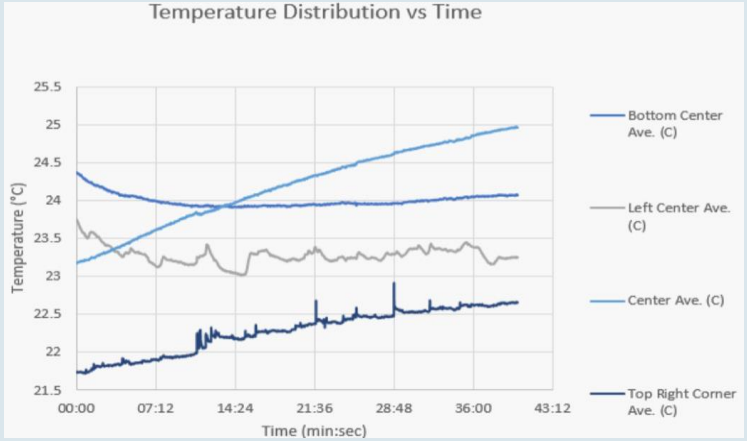
Testing

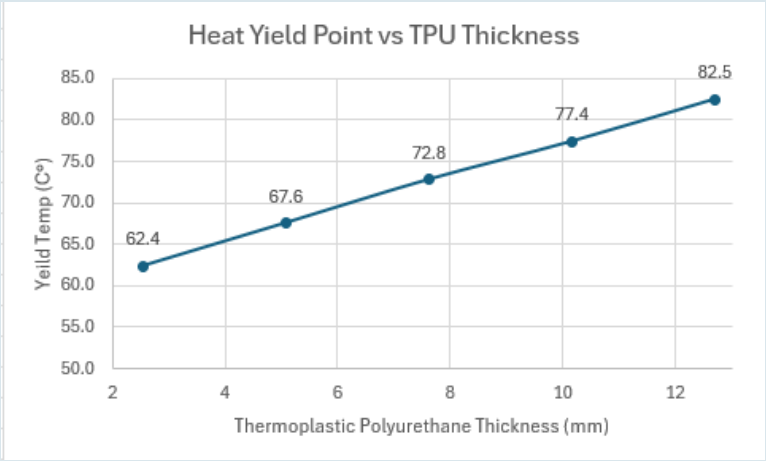
Experiment/ Test	Relevant DR	Testing Equipment Needed
EXP1 - Heat Testing	CR3: Light Exposure ER4: Wavelength Infrared (850-880) ER5: Wavelength Red (650-670)	Infrared thermometer Data-logging temperature sensors
EXP2 - Harness Fit Testing	CR1: Reuseable CR7: Compact but functional ER7: Size (10in x 10in)	Pressure mapping sensors, Measuring Tape
EXP3 – Performance/ Duration Testing	CR2: Rechargeable ER2: Battery Life (120min) ER4 - Wavelength IR (850-880) ER5 - Wavelength Red (650-670)	Spectrometer, Multimeter
EXP4 – Behavioral Testing	CR1: Reuseable CR2: Rechargeable ER1: Power Output (20-50W) ER2: Battery Life (120min) ER6: Treatment Duration (20min)	Dog activity trackers Thermal imaging camera Veterinary monitoring equipment — to check vitals and comfort

Major Experimental Trials Table

- Thermal Behavior of TPU Casing
  - Determine deformation temperatures across thicknesses (1mm–3mm)
  - Ensure structural integrity and safety margin during device operation
- LED Thermal Safety on Skin
  - Monitor surface temperature of tissue mimic during 20-min session
  - Verify device remains within safe skin-contact temperature (<42°C)
- Harness Fit and Mobility (Dog Trial)
  - Assess comfort, fit, and shift of device during movement and rest
- Battery Life and Thermal Load
  - Evaluate duration and monitor temperature every 5 minutes
  - Validate 120-min performance claim under repeated use
- User Experience and Comfort
  - Observe human/canine behavior during active session
  - Record feedback on comfort, warmth, and usability

Final Testing Results





- Heat distribution testing
- Animal Harness fit testing

Thicker TPU (10–12.7mm) is ideal for thermal insulation and safe outer casing use.

Budget

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

- Total spent on a single device is around $161
- Significantly less than the $290 per device that we anticipated

Potential Future Work

- Optimize internal / battery design
- Clinical trials for accuracy testing
- Clinical-grade validation
- App development for patient monitoring
- Miniaturize circuit for comfort
  - flexible PCB integration
- Enhanced real-time signal processing

Thank You, Questions?