Light Dose Tensegrity Medical

Finalized Testing Plan

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Fall 2024-Spring 2025

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1 Design Requirements Summary

This section outlines the customer requirements (CRs), and engineering requirements (ERs) compiled throughout the first and second semesters. The customer requirements are based on requests from our client, Jesslynn Armstrong, reflecting her needs and goals for the medical device we are creating. After compiling the customer requirements, the team then translated these customer needs into measurable criteria called engineering requirements. Using both sets of requirements, we created a House of Quality (QFD) to illustrate the correlation between them. Our customer requirements as well as the engineering requirements are listed below.

CR1: Reuseable

CR2: Rechargeable

CR3: Light Exposure

CR4: Time Duration / Automatic Shut-off

CR5: Cord-free

CR6: Cost Effective

CR7: Compact but functional

The first customer requirement is that the medical device needs to be reuseable, meaning it should be easily sanitized, set up, and user friendly, allowing for repeated use. The second customer requirement is that the device must be rechargeable, enabling multiple uses and eliminating the need for constant power connection during operation. The third requirement is light exposure. The light exposure in light therapy must be within a certain range in order to see significant improvements for the user's vitals. This device must also be capable of operating for the maximum recommended time duration and automatically shut off once the time has elapsed or when the user's vitals improve. The device must be cost effective, necessitating careful selection of materials and components to stay within the allocated budget. Finally, she wants the size of the device to not exceed a certain size as well as it have minimal moving parts for optimal use of the device, aka she would like the device to be cord-less.

With the customer requirements set out, we came up with corelating engineering requirements for them.

ER1: Power Output (20-50W)

ER2: Battery Life (120min)

ER3: Unit Cost (Around $290)

ER4: Wavelength Infrared (850-880)

ER5: Wavelength Red (650-670)

ER6: Treatment Duration (20min)

ER7: Size (10in x 10in)

The first engineering requirement, power output, is measured in watts and indicates the amount of power the medical device will need to operate the red and infrared light-emitting diodes and sensors. The device has a targeted power output of 20 to 50 watts. The next requirement is battery life is measured in minutes and represents how long the device can function before requiring a recharge. The goal is to have the battery life last up to 120 minutes. Both power output and battery life relate to the customer's requirement of being rechargeable. Unit cost measured in US dollars is the cost of manufacturing one medical device. The goal is to spend up to $290 per device. The wavelength of the infrared and red LED lights measured in nanometers must be between 850 to 880 nanometers for the infrared lights and 650 to 670 nanometers for the red LED lights. Treatment duration, measured in minutes, incorporates the customer requirements for treatment time and automatic shutdown. Ideally, the treatment duration should be around 20 minutes. Finally, since we wanted the size to be comfortable during use, we wanted the device to not exceed a 10-inch by 10-inch parameter for optimal use of the device.

2 Top Level Testing Summary

Below is the list of experiments we intend to compile when we begin testing our medical device on dog patients.

Table 1: Experiment/Testing Summary

Experiment/ Test	Relevant DR	Testing Equipment Needed	Other Resources
EXP1 - Heat Testing	CR3: Light Exposure ER4: Wavelength Infrared (850-880) ER5: Wavelength Red (650-670)	Infrared thermometer Data-logging temperature sensors	Fake skin model, TPU casing
EXP2 - Harness Fit Testing	CR1: Reuseable CR7: Compact but functional ER7: Size (10in x 10in)	Pressure mapping sensors, Measuring Tape	Device + Harness
EXP3 – Performance/ Duration Testing	CR2: Rechargeable ER2: Battery Life (120min) ER4 - Wavelength IR (850-880) ER5 - Wavelength Red (650-670)	Spectrometer, Multimeter	Battery, Timer
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	
EXP5 - Ease of Use	CR1: Reuseable CR7: Compact but functional ER7: Size (10in x 10in)	Observational measures	

3 Detailed Testing Plans

Test 1: Thermal Safety (Heat Testing)

- Question: Does the LED harness raise the dog's skin temperature to unsafe levels?
- DRs being tested: Skin temperature must not exceed 40°C during or after use.
- Equipment needed: Infrared thermometer, data-logging temperature sensors.
- Variables measured: Skin and fur temperature (°C).
- Variables calculated: Maximum temperature rise (ΔT) over time.

Procedure:

1. Place harness on canine subject with temperature sensors in contact with skin.
2. Turn on the LED device and run a 20-minute cycle.
3. Record temperatures every 30 seconds.
4. Use the thermal camera to capture temperature distribution after 20 minutes.
5. Remove harness and continue recording skin temperature for 5 minutes to observe cooling.

Results:

- Desired outcome: Max skin temperature ≤ 40°C.
- Equation: $\Delta T = T_{final} - T_{initial}$.
- Anticipated range: $T_{initial} \sim 33°C$, $T_{final} \leq 38–40°C$.

Test 1.1: Photobiological Safety

- Question: Are the emitted wavelengths and intensities safe for canine skin and eyes?
- DRs being tested: Wavelength in the range of 630–660nm; irradiance below 50mW/cm².
- Equipment needed: Spectroradiometer, optical power meter.
- Variables measured: Wavelength (nm), irradiance (mW/cm²).
- Variables calculated: Total light exposure (J/cm²).

Procedure:

1. Set the harness LEDs to full power.
2. Use a spectroradiometer to verify wavelength.
3. Measure irradiance at distances of 0 cm, 1 cm, and 2 cm.
4. Calculate total light exposure over a 20-minute cycle.

Results:

- Desired: 630–660nm range; irradiance ≤ 50mW/cm².

- Total dose = Irradiance × Time = 50mW/cm² × 1200s = 60J/cm² max.

Test 2: Harness Fit Testing

- Question: Does the harness fit securely without causing pressure points or discomfort?
- DRs being tested: Pressure must not exceed 5 kPa.
- Equipment needed: Pressure mapping sensors
- Variables measured: Contact pressure (kPa).
- Variables calculated: Average and peak pressure zones.

Procedure:

1. Fit harness on test dog.
2. Place pressure sensors between harness and skin.
3. Record data while the dog walks, sits, and runs.
4. Use video to analyze potential discomfort.

Results:

- Desired: Max pressure ≤ 5 kPa.
- Anticipated pressure range: 1–4 kPa, depending on activity.

Test 3: Performance Testing

- Question: Can the harness withstand canine movement without damage?
- DRs being tested: Withstand 50 lbs tension and 10,000 cycles of abrasion.
- Equipment needed: Tensile testing machine
- Variables measured: Load at failure (lbs), number of abrasion cycles.
- Variables calculated: Safety factor (SF = Load at failure / required load).

Procedure:

1. Attach harness straps to tensile tester.
2. Pull until failure.
3. Run abrasion cycles and check for wear.

Results:

- Desired: Load at failure > 50 lbs, SF ≥ 1.5.
- Anticipated load at failure: 75–100 lbs.

Test 4: Behavioral Testing

- Question: Does LED light sufficiently penetrate fur to reach the skin?
- DRs being tested: At least 30% of light reaches skin.

- Equipment needed: Optical detector probe, synthetic fur models.
- Variables measured: Incident and transmitted irradiance (mW/cm²).
- Variables calculated: Penetration percentage.

Procedure:

1. Place synthetic fur between LED source and detector.
2. Measure irradiance before and after.
3. Repeat with different fur lengths.

Results:

- Desired: ≥30% transmission.
- Equation: Penetration % = (I_transmitted / I_incident) × 100.
- Anticipated range: 35–50%.

Test 5: Ease of Use Test

- Question: Can owners apply and use the harness easily?
- DRs being tested: Setup time under 2 minutes, no errors.
- Equipment needed: Video recording, user questionnaires.
- Variables measured: Setup time (s), number of errors.
- Variables calculated: Average setup time and error frequency.

Procedure:

1. Provide harness and instructions to users.
2. Record video of setup and removal.
3. Time the setup and note any mistakes.
4. Collect user feedback.

Results:

- Desired: Setup time < 2 minutes, zero critical errors.
- Anticipated time: 1–1.5 minutes.

4 Specification Sheet Preparation

4.1 Customer Requirements

The following table shows the customer requirements needed for the device to work successfully. The CR Met and Client Acceptable columns will be filled out with either a check mark indicating the requirement was met or acceptable and an X if the requirement was not met or not acceptable.

Table 2: Customer Requirements Summary

Customer Requirement	CR Met (✓ or X)	Client Acceptable (✓ or X)
CR 1- Reuseable		
CR 2- Rechargeable		
CR 3- Light Exposure		
CR 4- Time Duration/Shutoff		
CR 5- Cord Free		
CR 6- Cost Effective		
CR 7- Compact		

4.2 Engineering Requirements

The table below lists the engineering requirements, target values, tolerances, measured/calculated values, whether the requirement was met, and whether it is client acceptable.

Table 3: Engineering Requirements Summary

Engineering Requirement	Target	Tolerance	Measured/Calculated Value	ER Met (✓ or X)	Client Acceptable (✓ or X)
ER 1- Power Output	20-50 W	-/+ 10 W			
ER 2- Battery Life	120 minutes	-/+ 10 minutes			
ER 3- Unit Cost	$290 (USD)	N/A			
ER 4- Wavelength (Infrared Light)	850-880 nm	-/+ 30 nm			
ER 5- Wavelength (Red LEDs)	650-670 nm	-/+ 20 nm			
ER 6- Treatment Duration	20 minutes	-/+ 10 minutes			
ER 7- Size	10x10 inches	-/+ 2 inches			

5 QFD

System QFD

									Project:		Tensegrity Medical Light Therapy			
									Date:		11/5/2024			
1	Power Output													
2	Battery Life	9							Legend					
3	Unit Cost									A	LOVTRAVEL LED Light Therapy Pad			
4	Wavelength (Infrared light)		9							B	Garmin HRM-Dual Heart Rate Monitor			
5	Wavelength (Red LEDs)		9							C	Innovo iP900BP-B Finger Pulse Oximeter			
6	Treatment duration		3		3	3								
7	Size													
			Technical Requirements							Customer Opinion Survey				
	Customer Needs	Customer Weights	Power Output	Battery Life	Unit Cost	Wavelength (Infrared light)	Wavelength (Red LEDs)	Treatment Duration	Size	1 Poor	2	3 Acceptable	4	5 Excellent
1	Reuseable	4		3				1			A	B		C
2	Rechargeable	3	9	9								C	A	
3	Light Exposure	4				9	9	9		AC				B
4	Time Durat/Shutoff	1	3	3		3	9	9				AC		B
5	Cord Free	4	3	9				3	9	BC		AC		
6	Cost effective	3			9				3		A		BC	
7	Compact	2			3				9	A			B	
	Technical Requirements Units		W	min	$(USD)	nm	nm	min	in					
	Technical Requirements Target		20-50	120	290	850-880	650-670	20	10x10					
	Absolute Technical Importance		42	78	27	39	45	61	27					
	Relative Technical Importance (%)		14.38	26.71	9.25	13.36	15.41	20.89	9.75					

Figure 1: QFD

The team developed a QFD, shown above, to analyze the relationship between the customer requirements with the engineering requirements. Additionally, the QFD shows the relationship between the engineering requirements amongst each other and includes the relationship between the three system benchmarks. The customer requirements were weighted on a scale of 1 to 4; 1 being of little importance, and 4 being of the greatest importance. For example, the customer requirement of the medical device needing to be reuseable was rated a 4 since we need to make sure the device can be used repeatedly for better treatment while the automatic shut off feature was rated a 1 because even if the device does not shut off by itself, the user can still shut it off on their own after their intended use time.

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.

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 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.