Mobile Phototherapy Suit

ECE 445 Final Report Fall 2020

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Abstract

Phototherapy has been used for decades to save infants from disability and death. While still proving to be effective at treating hyperbilirubinemia, phototherapy is due major improvements. Using recent advancements in technology, we created a portable cloth suit embedded with LEDs which shine blue light onto an infant's skin which can be taken out of the hospital. Through the use of temperature and pressure sensors, we developed multiple levels of emergency shutoffs to ensure the safety of an infant while treatment is being administered in the suit. Remote monitoring through a web application keeps healthcare professionals involved. This approach to phototherapy removes many of the sources of emotional, physical, and financial stress involved in traditional forms of phototherapy while maintaining treatment intensity.

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1. Introduction

1.1 Background

A diagnosis of neonatal hyperbilirubinemia can quickly turn a joyous event into a nightmare. About 50 percent of newborn babies develop jaundice, which is a consequence of the heightened bilirubin levels associated with neonatal hyperbilirubinemia, and this percentage is even higher for preterm babies [1]. Left untreated, this can lead to neurodevelopmental problems and even death.

Neonatal hyperbilirubinemia is defined as a total bilirubin level above 5 mg per dL [2]. Bilirubin is a substance that is produced when the liver breaks down old red blood cells, which is later removed through feces [3]. Heightened bilirubin levels lead to clinical jaundice in newborns which, if left untreated, can in turn lead to severe illnesses such as kernicterus (a form of brain damage) [2]. While extremely high levels of bilirubin necessitate blood transfusion, the moderate level expressed in the vast majority of newborns is adequately treated with phototherapy. As previously mentioned, current phototherapy treatment is commonly administered within a Newborn Intensive Care Unit forcing the infant to remain in the hospital, occupying unnecessary space which could otherwise be better utilized. Additionally, uncontained blue light from the treatment interferes with sleep. Since jaundice in newborns is quite common, a solution that is mobile, safe, and affordable would save parents significant amounts of trouble.

1.2 Problem Statement

While current methods of administering phototherapy to combat hyperbilirubinemia are effective in lowering bilirubin levels, they are very inconvenient for both the infant and the parents [4]. Phototherapy requires placing an undressed infant within a bulky, immobile unit under an intense blue light where they must remain for up to a week. During treatment, the infant is separated from their parents and required to wear uncomfortable eye protection to prevent retinal damage, leading to distress and anxiety for the entire family during an extended hospital stay [5].

1.3 Solution Overview

We made a mobile phototherapy suit for infants: an open face cloth suit with integrated blue LEDs and safety mechanisms. Current commercial devices are situated some distance away from the child, waste a lot of light/energy, and are often expensive. LEDs are contained within the suit and in near proximity to the skin for maximum therapeutic intensity. Portable enough to be taken home, the suit will potentially replace the expensive hospital stay for many cases of hyperbilirubinemia. While at home, the system will have the ability to remotely monitor usage and other sensor data through an application and wireless communication.

Aeroflow Healthcare currently has a portable phototherapy blanket, called the Biliblanket [6], consisting of a fiber-optic pad tethered to a boxy light-source. This solution is still quite bulky and only covers the torso and arms of the infant, neglecting the head and legs which do not get the necessary coverage. Furthermore, significant light leakage from this and other products undermines its efficiency. We aim to increase efficiency and thereby shorten treatment times by maximizing the surface area illuminated by using a suit with a hood instead of a blanket, effectively containing the light within the suit.

Another machine called the Bilisoft 2.0 [7], by GE Healthcare, is also available, which also utilizes fiber optics to provide blue light into a blanket. This however is also not as portable and is potentially an expensive form of treatment, up to $3000. It is also mostly used to supplement the traditional treatment in a hospital setting. Our solution will have increased portability and aim to replace the traditional method of treatment.

In principle, existing solutions might be somewhat effective in terms of at-home treatment. However, patient compliance has historically been problematic; patients may not use the device as intended for the prescribed treatment times, especially with current device designs which do not allow for parent-child interaction (e.g. holding, nursing). Our solution represents an unprecedented improvement over extant designs in that it tracks patient usage, encouraging compliance.

1.4 Visual Aid

The illustration in Figure 1 illustrates the prototype of the suit that we designed. LED strips are lined along the suit and are connected to the external battery and PCB. The PCB communicates data to a software application over WiFi.

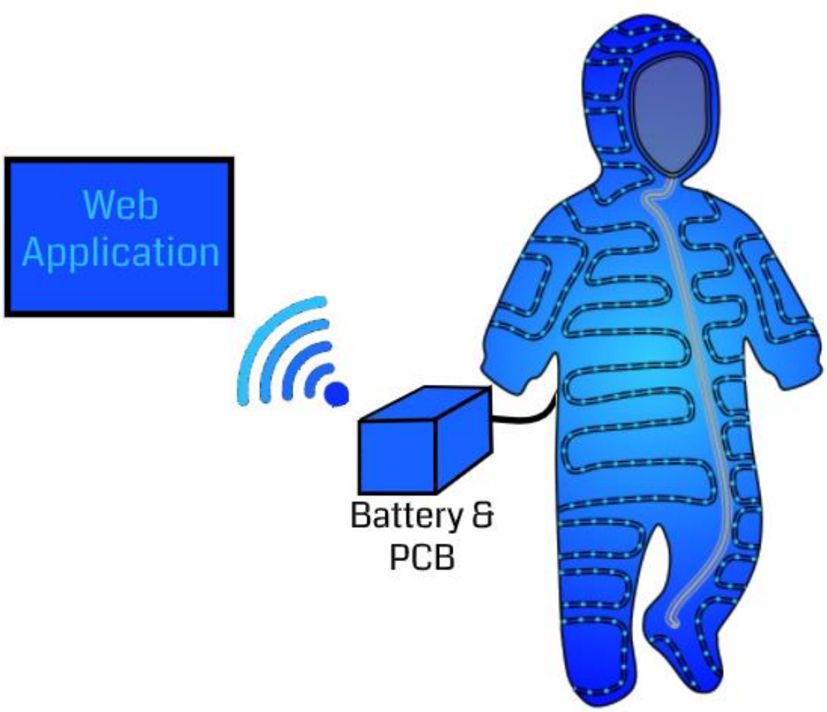


Figure 1. Visual Aid

1.5 High-Level Requirements

- Implemented the entire system to be portable and treatment times within 20% of traditional treatment times. The verification for this is shown through the use of a chemical model of bilirubin (using β-carotene) which degrades over time when exposed to blue light. Treatment times can be compared by analyzing the rate of degradation.

- Used robust electronics to prevent safety hazards. The suit monitors temperature and automatically shuts off the unit at high temperatures with a maximum latency of 5 seconds to prevent damage to the infant or the suit itself. The emergency temperature shutoff threshold is 26 ℃ +/- 2 ℃ [8].

- Launched a website for healthcare professionals to monitor usage and temperature statistics. Usage is determined as the FSR detecting 2 kg +/- 0.5 kg and the LEDs turned on. Every 2-3 minutes, temperature and usage statistics for that session are uploaded to a database. Treatment data that has been uploaded can be viewed on the website.

1.6 Block Diagram

The block diagram in Figure 2 shows the different components for full functionality: Power Supply, WiFi Module, Control Unit, Sensors, LED Subsystem, and Software Application. The Power Supply provides desired voltages to all the electronics in the suit using a 12 V battery and voltage regulators to 3.3 V and 5 V. The Control Unit consists of a microcontroller unit for processing sensor data and a load switch to control power to the LED Subsystem. The LED Subsystem provides illumination to degrade bilirubin. The Sensors block consists of three temperature sensors and a force sensitive resistor to detect operating conditions. The WiFi Module provides a remote connection to a Software Application to collect data which can be visualized by healthcare professionals.

We dropped the incorporation of a Real-Time Clock into the design as its functionality was more easily performed at the application during an upload. Additionally, we did not create an inner section for the suit as it is out of the scope of the class.

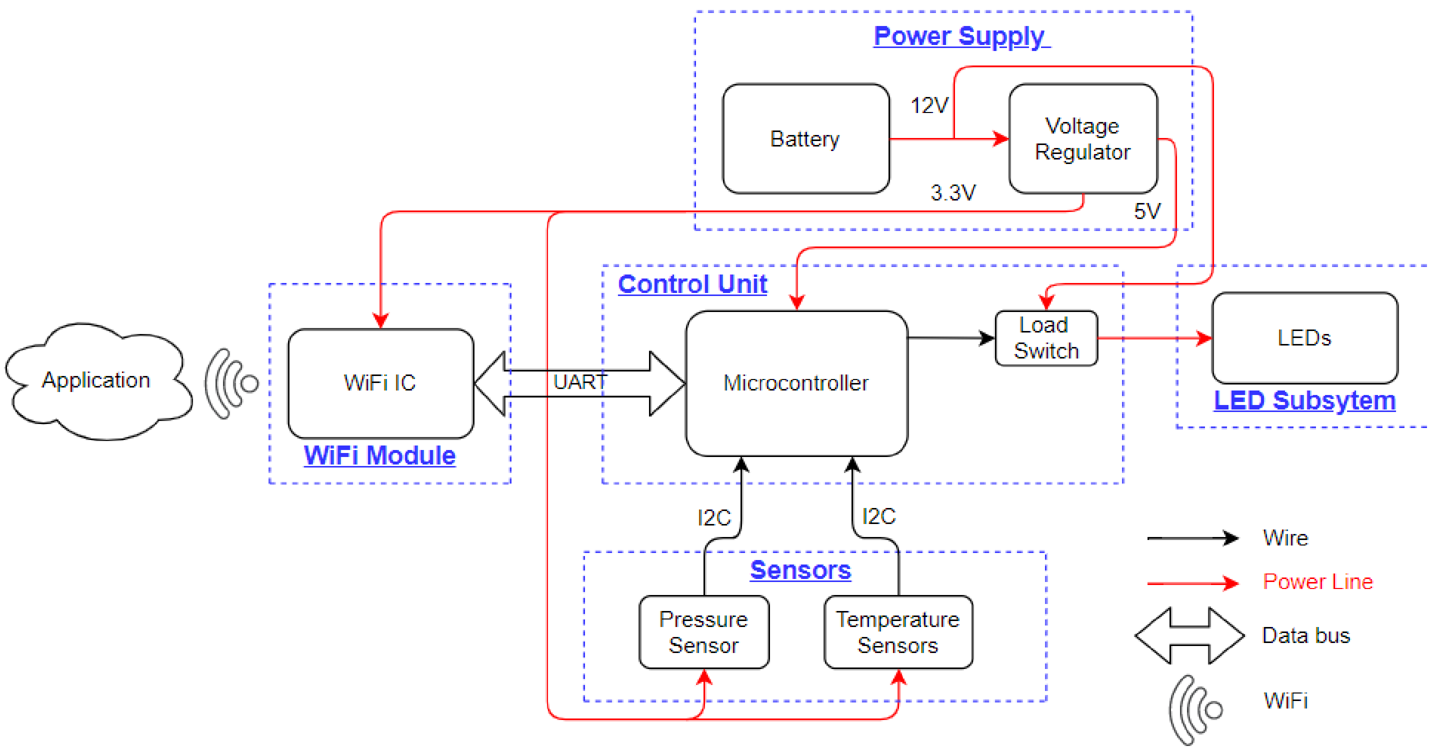


Figure 2. Block Diagram

2. Design

2.1 Power Supply

The Power Supply is required to allow usage of all components in the system. This includes the LEDs, Control Unit, WiFi Module, and Sensors. The Power Supply consists of a rechargeable battery and voltage regulator to send the proper voltage into the microcontroller and other components (5 V or 3.3 V).

2.1.1 Battery

This is a rechargeable 12 V lithium ion battery. The battery supplies power to the entire system. It is connected to two LDO voltage regulators to step down the voltage to 3.3 V and 5 V.

2.1.2 Voltage Regulator

The voltage regulator drops the battery voltage from 12 V to 5 V for the microcontroller. This also regulates the voltage for the WiFi Module and temperature and force sensors to 3.3 V. The voltage regulators are two LDOs. We made the design decision to change to LDO regulators from buck converters for simplicity and to save space on the PCB. Since the main power consumption is from the LEDs, a small loss in efficiency on the voltage regulation only affects the MCU, WiFi Module, and sensors.

2.2 LED Subsystem

We limited our design to the core of the body to simplify physical design. We used the following equations to estimate the heat produced by each foot of our LED strip which outputs 465-470 nm blue light:

The two levels of intensity of phototherapy that are defined are $I_{normal-common} = 2 \frac{mW}{cm^2}$ [9] and $I_{high-intensity} = 14 \frac{mW}{cm^2}$ [10].

We assume $\eta_{LED} = 0.22$, and $T_{room} = 20$ ℃ and we know $A_{infant-core} = 955\ cm^2$, $h_{cotton-air} = 0.0013 \frac{W}{cm^2 C}$ [11], $Q_{infant} = 8.35\ W$ where η_{LED} is the estimated efficiency of our LED strip, $A_{infant-core}$ is the surface area, $h_{cotton-air}$ is a coefficient of convection, and Q_{infant} is the heat produced by the infant, all for the area we are covering in the suit.

$$h_{cotton\text{-}air} * A_{infant\text{-}core} * \left(T_{asymptotic} - T_{room}\right) = Q_{infant} + l_{LED} * 4.4\ \frac{W}{ft} * (1 - \eta_{LED}) \qquad (1)$$

Substituting in the values into Eq. (1) we get:

$$T_{asymptotic} = 2.76\ l_{LED} + 26.7\ ℃ \qquad (2)$$

The graph in Figure 3 depicts Eq. (2) with the $I_{normal-common}$ and $I_{high-intensity}$ levels of phototherapy indicated by the vertical lines. While the conservative calculations overestimate the temperature equilibrium, we determined that we would use 2.2 feet of the LED strip in the suit.

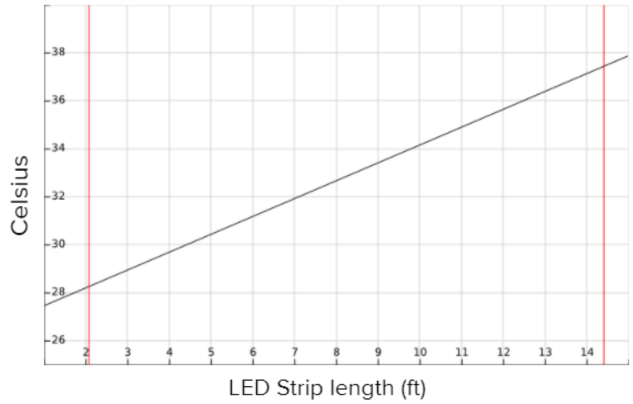


Figure 3. Equilibrium Temperature vs LED Strip Length

2.3 WiFi Module

The WiFi Module we use is the ESP-01 board which receives data from the microcontroller through a UART connection. We use AT firmware commands through the serial interface from the microcontroller to the WiFi Module. The WiFi Module comes boot-loaded with the AT commands, so there was no need to upload any programs to the WiFi Module. This made it easy to use for our case since we were only using it as a means for the microcontroller to send commands through WiFi. If there was a need for the ESP-01 to receive data from WiFi and act like a server, we would have needed to write and upload code specifically for the WiFi Module. Some design considerations for the WiFi Module on the PCB were that it requires 3.3 V and need to connect the RX and TX pins to the MCU.

2.4 Control Unit

The Control Unit collects the sensor's data and controls the LEDs. It also takes care of how the data is received from the sensors and sent to the WiFi Module. The communication between the microcontroller and the WiFi Module is through UART. The MCU is connected to the load switch enable pin.

2.4.1 Microcontroller

The microcontroller receives data from the FSR and temperature sensors. This data is then processed, and this is then sent to the WiFi Module through UART using AT commands every two minutes. To ensure safety, the MCU will calculate a maximum temperature every five seconds. If the maximum temperature reaches dangerous levels, the MCU will send a LOW signal to the load switch and turn off the LEDs. There is also a user-controlled button for the LEDs, and the microcontroller sends the appropriate signal to the load switch enable pin. The LEDs only turn on when the FSR detects a baby present and the user button is toggled on.

The microcontroller circuit design, shown in Figure 4, was based on having the ATmega328P be as simple as possible for our application. The only necessary components were attaching a reset switch for ease of testing and a 16 MHz oscillator for the clock. All other I/O pins were left open to connect as many peripherals as desired.

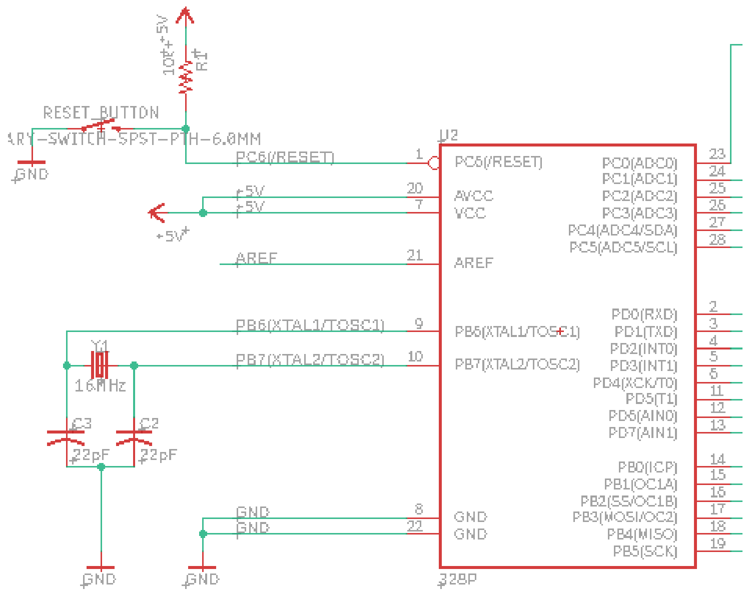


Figure 4. Microcontroller Circuit

2.4.2 Load Switch

The load switch is the TPS22810DBVR IC that allows us to switch on and off the 12 V to the LEDs based on a control signal from the MCU. The control signal is sent from the MCU with either a button press or an emergency shutoff signal if the max temperature reading is too high. The circuit of the load switch is shown in Figure 5. This chip is directly soldered to the PCB as a surface mount part.

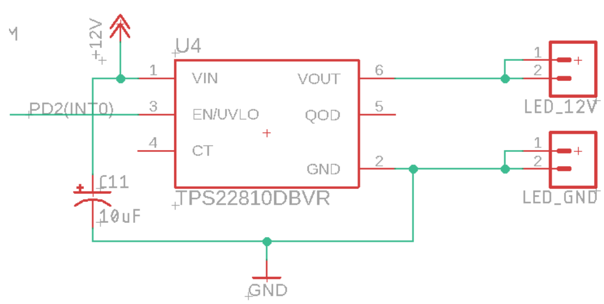


Figure 5. Load Switch Circuit

2.5 Sensors

We use a force sensor to detect if the infant is in the suit and temperature sensors to monitor the temperature of the suit for safety. The temperature sensors are connected to the microcontroller's digital I/O pins. The force sensor, or FSR, is connected to the analog pins of the microcontroller.

2.5.1 FSR

The force sensitive resistor is used to detect the presence of a baby in the suit. To allow for the microcontroller to read the change in force of the FSR, we needed to place it in a voltage divider with a 10 kΩ resistor shown in Figure 6. We chose a 10 kΩ resistor because it was a good value to see a measurable change in the VOUT of the voltage divider with our FSR resistance changes. The VOUT will feed into the MCU and will interpret these values.

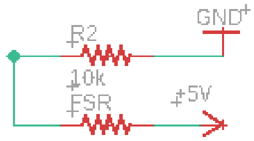


Figure 6. FSR Voltage Divider

2.5.2 Temperature Sensors

The temperature sensors monitor the temperature between the LEDs and the baby inside the suit. This is mainly for safety reasons to make sure that the temperature does not go above 26 °C +/- 2 °C. We decided on only using three sensors because we placed them in areas that are prone to high temperatures. The areas we used are the mid back and armpits. There are insulated wires that are connected to the sensors that run out of the suit and go to the PCB.

2.6 Physical Design

We used a generic cloth baby suit for the physical design shown in Figure 7. To integrate all the electronics, we cut a small hole for the wires to go from the PCB to the suit. The sensors were mounted with adhesive tape and the LEDs were mounted using velcro. We chose velcro instead of tape because the LEDs are heavier and require a stronger mechanism to stay in the suit. Large images of the completed suit are shown in Appendix C, Figures 15 and 16.

Figure 7. Physical Suit Design

2.7 Software Application

We integrated IoT functionality into the suit to allow healthcare professionals to remotely monitor the status of treatment. This addresses the tradeoff of healthcare professionals having less accessibility to a patient if the treatment is being administered in the suit at home.

The remote monitoring is accomplished using various AWS serverless services as shown in Figure 8. We used AWS serverless services to be cost efficient while still maintaining accessibility. Uploads from the suit end in the DynamoDB database and displaying data pulls the data from the DynamoDB database to be viewed on the healthcare professional's device.

Every two minutes during operation the suit attempts to upload session data along with its Suit ID through the ESP-01 chip over WiFi to a DynamoDB table. This is accomplished by invoking an endpoint hosted by API Gateway. API Gateway provides a level of validation to the request and forwards well-formed requests to Lambda to be processed and entered into a database. The database is a DynamoDB table holding all the data for any suit.

Once data is uploaded it is available to be retrieved and displayed by accessing a website hosted by AWS Amplify using any common device and providing authentication information. Treatment data can be queried by Suit ID and providing a range of dates to be displayed in an aggregated format with temperature statistics.

Due to difficulties in getting the ESP-01 to communicate with the AWS API Gateway endpoint, we considered using AWS IoT Core to establish the communication instead. Eventually we ran into more difficulty with IoT Core and switched back to using the original approach after addressing the issue with establishing a connection.

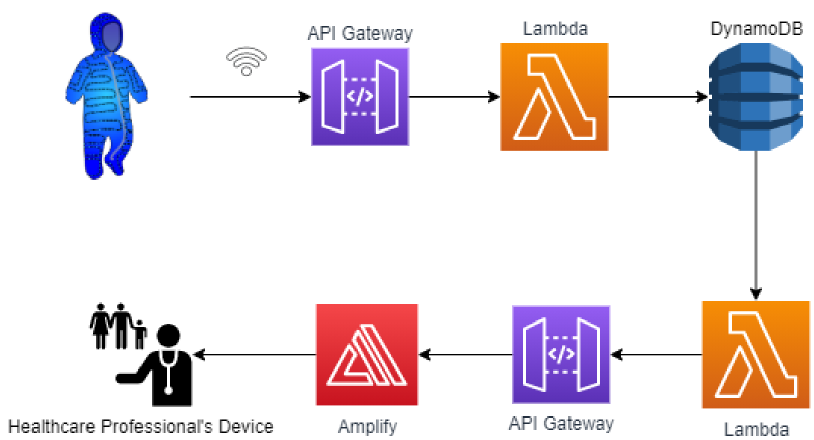


Figure 8. Software Datapath

3. Design Verification

3.1 Power Supply

The verification of the Power Supply involved ensuring that the battery and voltage regulators satisfied the requirements and verification table shown in Appendix A, Tables 6 and 7.

3.1.1 Battery

The main verification of the battery was checking for sufficient capacity. We needed to confirm that the battery could power the suit for 5-7 hours of treatment time. To test this, we plugged the battery into the PCB and turned on the LEDs. We measured the time it took for the suit to completely turn off. The battery capacity after testing with the suit was 5 hours.

3.1.2 Voltage Regulators

The voltage regulators needed to provide 5 V and 3.3 V. To test this, we created simple sub-circuits for each regulator where the input voltage was 12 V and under no load. The measured output voltage of each regulator and calculated the percent difference is shown in Table 1.

Table 1. Output voltage measured on regulators and calculated difference

Regulator	Output Voltage (V)	Difference (%)
3.3 V LDO	3.291	0.002727
5 V LDO	4.999	0.0002

3.2 LED Subsystem

The verification of the LED Subsystem involved ensuring that the LEDs satisfied the requirements and verification table shown in Appendix A, Table 8.

To verify the first requirement of the LED subsystem we tested with a 3 kg weight on the force sensor, to simulate a 3 kg newborn. We turned the battery on and then toggled the button on and off to verify the LEDs also turned on and off.

The second verification was the temperature control. We added a 3 kg weight and turned the LEDs on. Next, we heated the suit up with a hairdryer to get the temperature to exceed the maximum allowed temperature, which was 26 °C +/- 2 °C, and the LEDs shut off instantaneously.

The third verification was done by measuring the intensity of a single LED from the LED strip, which was about 22.4 mW.

We measured overall treatment intensity using $i_{LED} = 22.4\ \frac{mW}{LED}$, $d_{LED} = 18\ \frac{LED}{ft}$, $l_{LED} = 2.2\ ft$, $A_{infant-core} = 955\ cm^2$, where i_{LED} is the output power of a single LED in the strip, d_{LED} is the number of LEDs in each foot of the strip, and l_{LED} is the length of the strip in the suit.

$$P_{light} = i_{LED} * d_{LED} * l_{LED} \tag{3}$$

$$I_{treatment} = \frac{P_{light}}{A_{infant-core}} \tag{4}$$

$$I_{treatment} = \frac{i_{LED} * d_{LED} * l_{LED}}{A_{infant-core}} \tag{5}$$

$$I_{treatment} = \frac{22.4 \frac{mW}{LED} * 18 \frac{LED}{ft} * 2.2\ ft}{955\ cm} \tag{6}$$

$$I_{treatment} = 0.93\ \frac{mW}{cm^2} \tag{7}$$

Verifying the treatment intensity by measuring individual LED intensity yields a result which shows that our suit's overall treatment intensity falls short of the desired 2 $\frac{mW}{cm^2}$ by over 50%. We expected this result to vary drastically since it involved several measurements with high degrees of error. Therefore, we can still verify the treatment intensity to be satisfactory though more accurate chemical analysis.

We performed chemical analysis to verify the effectiveness of our treatment by using β-Carotene to model bilirubin since they have very similar absorption spectra as seen in Figure 9.

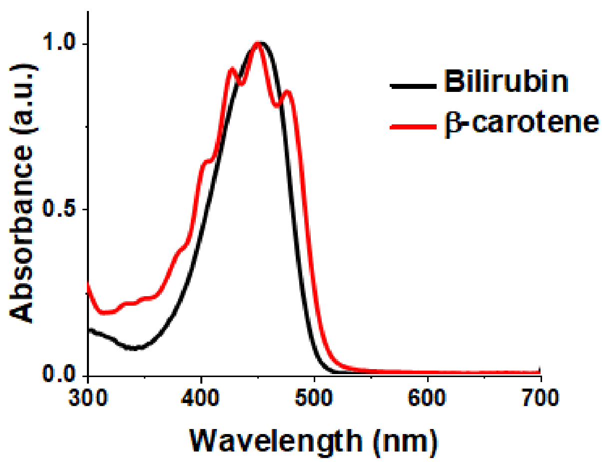
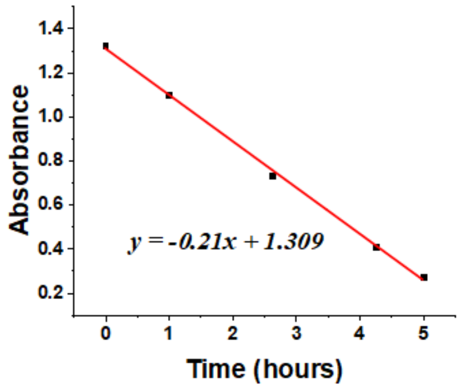


Figure 9. Absorption Spectra

We compared a reference photodegradation rate shown in Figure 10 with the photodegradation measured from running our suit with the sample of β-Carotene shown in Figure 11. We get the following value for the equation of the line in Figure 11 using units of hours for x:

$$y = -0.19x + 1.71 \tag{8}$$



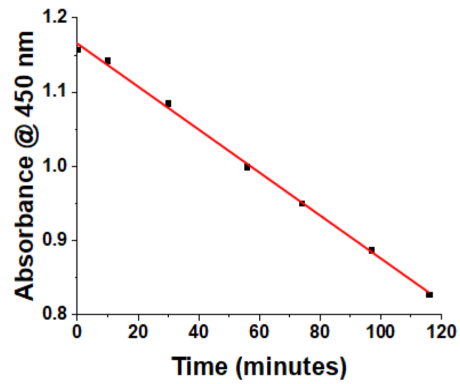


Figure 10. Reference Peak Degradation

Figure 11. Suit Peak Degradation

The slopes indicated by the two figures and Eq. (8) indicate that the difference in the rate of degradation around 20% which verifies the effectiveness of the intensity of phototherapy being administered in the suit.

3.3 WiFi Module

The verification of the WiFi Module involved ensuring that it satisfied the requirements and verification table shown in Appendix A, Table 9.

The WiFi Module was first verified by connecting to the WiFi. This was done through using the basic AT firmware commands directly through a serial interface. After the module was able to connect to the WiFi, we tested if it could receive data from the MCU and send it to a pre-built server. The pre-built server used was a ThingSpeak server, and it made it easy to connect an ESP-01 module using a TCP/IP connection. To verify the HTTP request to the AWS server, we put all the previous code together and sent the temperature and usage data from ESP-01 every 2 minutes. We changed it from 30 minutes to 2 minutes because we want to make sure there are more updated readings for the healthcare provider.

3.4 Control Unit

The verification of the Control Unit involved ensuring that the microcontroller and load switch satisfied the requirements and verification table shown in Appendix A, Tables 10 and 11.

3.4.1 Microcontroller

The microcontroller verification was completed by making sure that it had been programmed correctly for our usage. Since we were using an ATmega328P, we boot loaded it and placed it in an Arduino Uno. Then we uploaded a Blink sketch to verify that we can program it. The microcontroller needs to accurately read analog/digital data. We verified this by connecting the sensors individually to the MCU and printed the sensor results to the serial monitor as we changed the sensor readings. We also verified that it could log the usage and temperature data and store it during operation of the suit. To do this we ran the suit and printed the temperature and usage data to the serial monitor to ensure the data was changing and was being stored on the MCU.

3.4.2 Load Switch

To test and verify the load switch we prototyped the load circuit on perforated board. To simulate the control signal input for the load switch, we programmed an Arduino Uno to output a HIGH or LOW from one of its digital I/O pins. We used a 12 V external power supply as the input voltage. The output voltage was measured and shown in Table 2. This was done to verify that enough voltage was outputted from the switch to power the LEDs and when the control was low there was a low enough voltage to turn the LEDs off. We then connected the LEDs to the output voltage and added a button to toggle the signal between high and low. When the button was pressed, the LED response was less than five seconds; it was nearly instantaneous.

Table 2. Load Switch Test

Input Voltage (V)	Control Signal	Output Voltage (V)
12	High	11.99
12	Low	0.541

3.5 Sensors

The verification of the Sensors involved ensuring that the FSR and temperature sensors satisfied the requirements and verification table shown in Appendix A, Tables 12 and 13.

3.5.1 FSR

To verify the force sensitive resistor's functionality, we needed to make sure the sensor was responsive to the weight of a newborn baby. The average weight of a newborn ranged from 2.5 kg to 7.5 kg. We added forces of up to 2500 g incrementally and tested voltage in a voltage divider with a 10 kΩ resistor. Figure 12 shows the relationship between the force and VOUT.

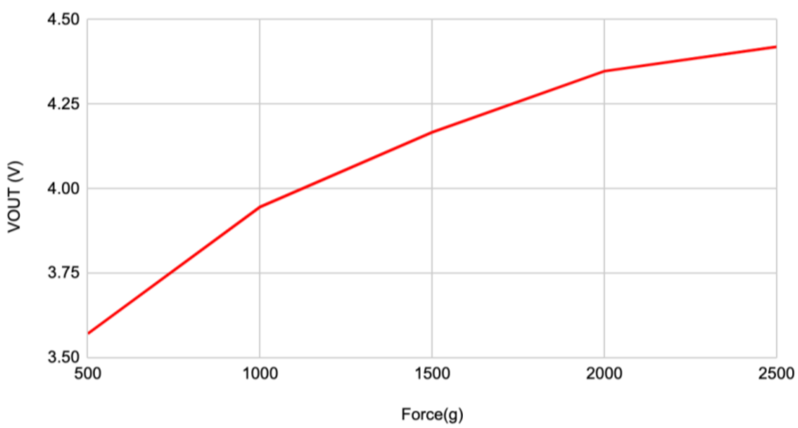


Figure 12. FSR Force vs. VOUT

3.5.2 Temperature Sensors

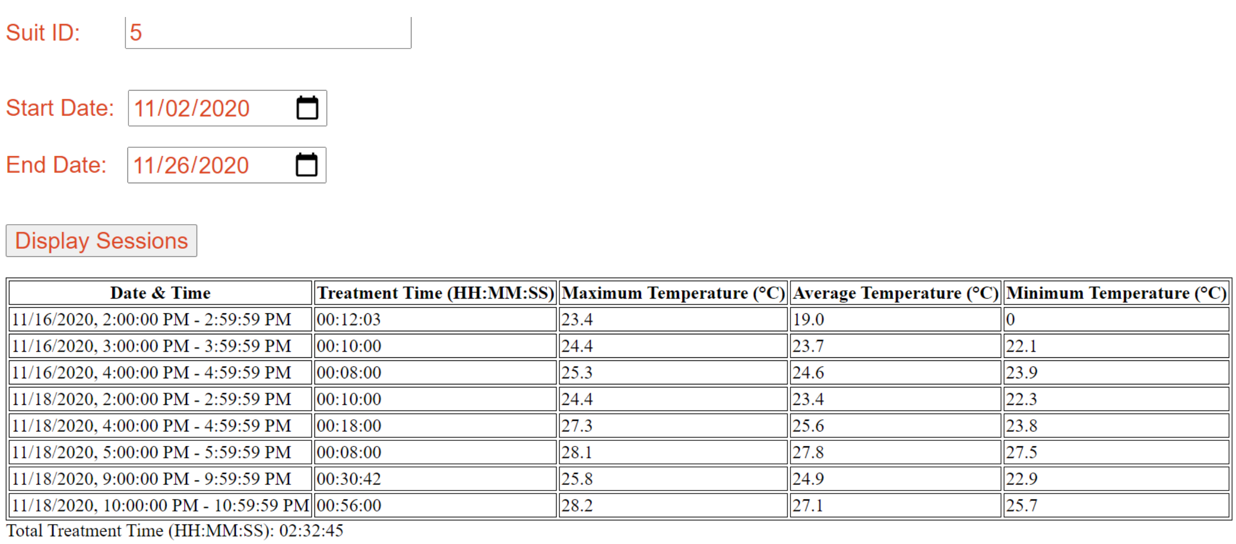
To verify the temperature sensors, we needed to ensure that they could measure between 15 °C - 40 °C. To do this we hooked one sensor up to an Arduino Uno board and created a simple circuit that took temperature readings every minute. Then, we brought it outside for cold temperatures and brought it back inside into warmer areas of the apartment. We compared the sensor readings to the thermometer readings, shown in Table 3, to verify that they were not off by more than the +/-0.5 °C threshold.

Table 3. DHT temperature vs. Thermometer Reading

DHT Temperature Reading (°C)	**Actual Temperature with Thermometer (°C)**
15.10	15.0
24.00	24.2
25.70	25.7
32.33	32.3
35.72	35.7

3.6 Software Application

We verified the functionality of the software application by visiting the website hosted on AWS Amplify and checking the output as shown in Figure 13.



Date & Time	Treatment Time (HH:MM:SS)	Maximum Temperature (°C)	Average Temperature (°C)	Minimum Temperature (°C)
11/16/2020, 2:00:00 PM - 2:59:59 PM	00:12:03	23.4	19.0	0
11/16/2020, 3:00:00 PM - 3:59:59 PM	00:10:00	24.4	23.7	22.1
11/16/2020, 4:00:00 PM - 4:59:59 PM	00:08:00	25.3	24.6	23.9
11/18/2020, 2:00:00 PM - 2:59:59 PM	00:10:00	24.4	23.4	22.3
11/18/2020, 4:00:00 PM - 4:59:59 PM	00:18:00	27.3	25.6	23.8
11/18/2020, 5:00:00 PM - 5:59:59 PM	00:08:00	28.1	27.8	27.5
11/18/2020, 9:00:00 PM - 9:59:59 PM	00:30:42	25.8	24.9	22.9
11/18/2020, 10:00:00 PM - 10:59:59 PM	00:56:00	28.2	27.1	25.7

Total Treatment Time (HH:MM:SS): 02:32:45

Figure 13. Data Displayed in Table Dynamically

4. Cost Analysis and Schedule

The cost for each part along with the total cost is shown in Table 4. The labor cost is shown in Table 5. The weekly schedule is in Appendix B, Table 14.

4.1 Parts

Table 4. Parts Cost

Part Name	Manufacturer	Cost ($)		Quantity	Actual Cost ($)
		Single	Bulk		
Power Supply					
5 V LDO Regulator	StMicroelectronics	0.95	0.17*	2	1.9
3.3 V LDO Regulator	Texas Instruments	1.54	0.63*	2	3.08
12 V Rechargeable Battery	TalentCell	65.99	n/a	1	65.99
Control Unit					
ATMEGA 328p MCU	Microchip Technology	1.9	1.58**	2	3.8
TPS22810DBVR Load Switch	Texas Instruments	0.66	0.18*	2	1.32
16 MHz Crystal Oscillator	TXC Corporation	0.3	0.15*	1	0.3
Sensors					
Extra Long Force Sensitive Resistor	Adafruit	19.95	15.96**	2	39.9
DHT22 Temperature Sensors	Adafruit	9.95	7.96**	3	29.85
WiFi Module					
ESP-01 Breakout Board	Sparkfun	6.95	n/a	1	6.95
LED Subsystem					
Blue LED flexible strip	Aspect LED	59.99	n/a	1	59.99
Physical Product					
Baby Suit	Old Navy	16.99	n/a	1	16.99
Velcro	Amazon	12.46	n/a	1	12.46
Total					242.53
*Price per/piece (2500 pieces)					
**Price per/piece (100 pieces)					

4.2 Labor

Table 5. Labor Cost Per Employee

Employee	Hourly Rate	Hours Worked	Labor Factor	Labor Cost
Abhay	$ 44.71	240	2.5	$26,826
Dhivan	$ 44.71	240	2.5	$26,826
Satwik	$ 37.50	240	2.5	$22,500

5. Conclusion

5.1 Accomplishments

We prototyped a suit with the functionality to administer phototherapy without any other external apparatus. Under appropriate operating conditions, the treatment intensity administered is close to or surpasses the current standard at most hospitals. Our suit ensures the safety of a patient and its user by ceasing operation when undesired operating conditions are detected. Displaying temperature and usage statistics for healthcare professionals to access through our website adds another level of verification to the effectiveness of treatment and safety.

We address privacy concerns raised by uploading data remotely by only uploading the minimum required information to determine the effectiveness of treatment and safety and associating the data with a Suit ID instead of any information personal to the patient.

5.2 Uncertainties

The only unreconciled analysis we encountered was an unexpected trend in the peak absorption spectrum of β-Carotene in one of our verification runs. Our previous runs resulted in an expected linear decay, while the run depicted in Figure 14 resulted in more of an exponential linear decay. Knowing that battery voltage vs state of charge has an exponential decaying relationship, we hypothesized that this caused the unexpected exponential trend.

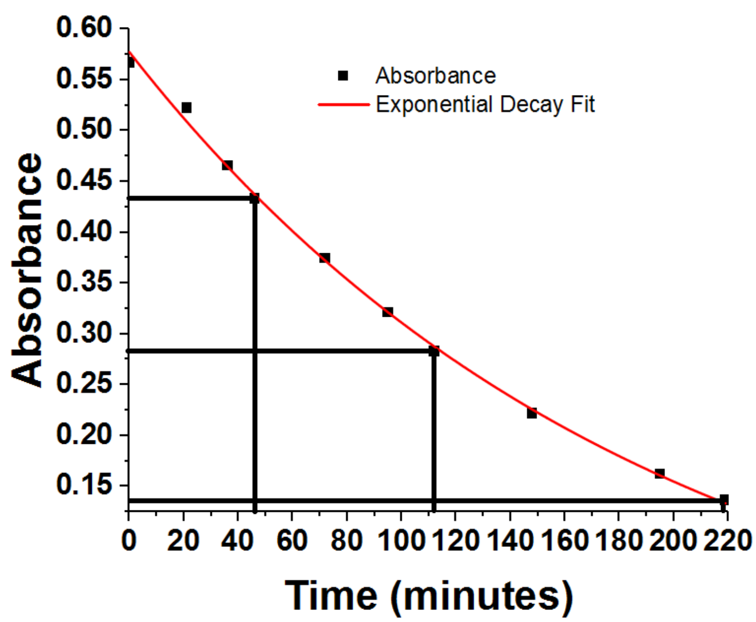


Figure 14. Long Photodegradation Trial

We check to see if this is a plausible explanation in the following equations:

$$m_{start} = \frac{0.575 - 0.43}{48 - 0} \tag{9}$$

$$m_{end} = \frac{0.28 - 0.03}{218 - 112} \tag{10}$$

$$slope_{\%-change} = 100\ \% * \frac{m_{start} - m_{end}}{0.5 * (m_{start} + m_{end})} \tag{11}$$

$$slope_{\%-change} = 21.3\ \% \tag{12}$$

We obtained measurements 10.5 V and 12 V from measuring the battery's voltage at no charge and full charge, respectively.

$$battery_{\%-change} = 100\ \% * \frac{12 - 10.5}{0.5 * (10.5 + 12)} \tag{13}$$

$$battery_{\%-change} = 13.33\ \% \tag{14}$$

The results from these calculations show that our hypothesis for the unexpected trend is plausible but we could not make a conclusion since we did not perform further verification to confirm the cause or rule out other causes.

5.3 Future work

Future design iterations can make improvements to each aspect of the suit; physical, electrical hardware, and software.

Potential improvements to the physical design consist of textile engineering to incorporate the LEDs or a more effective source of illumination directly into the cloth of the suit. Additionally, a clear inner sheet which can be disposed or cleaned between uses that still allows for illumination to pass through should be engineered.

In regard to the electrical hardware, some existing components can be switched out to enable greater functionality. The illumination source should be replaced with something that is more uniform and at a lower general intensity. This will allow for better heat distribution and even coverage. The uniform coverage will also make the treatment more effective [12]. Higher efficiency technology, LED sheets instead of strips, or a compact version of fiber optics would be more suitable as a source of illumination. In addition to the improvements to the source of the illumination, the ability to control the brightness of the source of illumination should be added by replacing the load switch with a PWM controller. Using a PWM controller will make it so that overall treatment intensity can be changed without having to make physical modifications to the suit.

Software plays a major role in ensuring the viability of the treatment in the suit when compared to traditional forms but does arise concerns about privacy. Even though the data collected and uploaded from the suit is minimal and non-personal, some families may not be in favor of having an electronic device that can be remotely monitored at any time in their home. In this case, an option to make more frequent visits to their physician and have the suit's data retrieved in the office through a Bluetooth connection should be implemented. Additionally, a mapping from Suit ID to Patient ID should be added so data uploads can be associated with a patient rather than the suit, so a healthcare provider does not get confused seeing a past patient's treatment data or expose another patient's treatment data on mistake.

5.4 Ethical Considerations

There are several potential safety concerns associated with our product. While temperature and heat concerns are addressed through monitoring operation, the physical design of the suit itself will need to avoid presenting a risk to an infant. Parts of the LED subsystem failing, or electronics exposed to an infant's bodily fluids would create an electrical hazard.

The LED subsystem is designed such that a failure in one part of the system will not cascade through the rest of the system and normal operation can be continued without the risk of an electrical hazard.

While the temperature within the suit has been compared to the temperature inside a NICU, we have not analyzed how the suit will compare to a NICU in terms of relative humidity control. Improper humidity levels could pose a health risk to infants in the suit. The design of our suit addresses this concern by keeping the face of the infant exposed to the surrounding environment following the principle of the ACM Code of Ethics, 1.2: "When that harm is unintended, those responsible are obliged to undo or mitigate the harm as much as possible" [13].

This design resembling a onesie also addresses concerns involving ingestion hazards. A snug fit at the forehead and chin will be required for containing the blue light and prevents the infant from chewing on the suit.

Adding a disposable clear inner sheet in the future will isolate the electronics from any of the infant's bodily fluids. Additionally, the electronics will be integrated into the suit in a robust manner to protect against damage from disturbance caused by an infant's infrequent movement or parents picking the unit up. These measures are in line with the IEEE Code of Ethics, #9: "to avoid injuring others ..." [14].

A major ethical concern to get our product into practice is the testing phase. As a device used to treat infants, care taken must be even greater than usually taken for human trials. Before testing on infants, extensive testing simulating the occupation of the suit by an infant is required. The safety mechanisms in the suit and the chemical model we have to simulate the treatment effectiveness avoid directly testing the product on infants until as late as possible. These procedures strongly echo what is stated in the ACM Code of Ethics, 1.1: "An essential aim of computing professionals is to minimize negative consequences of computing, including threats to health, safety ..." [13].

While our product provides many benefits to the family in terms of convenience, health professionals will have a harder time ensuring an infant is receiving proper treatment. In order to monitor treatment undergone, usage data will be logged within the product. This data will then be communicated through a WiFi connection to a server for healthcare professionals to use when evaluating treatment. To align with privacy concerns, especially important in a medical field, only usage time and temperature data will be logged and sent to be reviewed. Once the data is sent and confirmation is received, it will be purged from the logs and healthcare professionals will determine their own retention. These practices will follow the ACM Code of Ethics, 1.6: "Only the minimum amount of personal information necessary should be collected in a system.

The retention and disposal periods for that information should be clearly defined, enforced, and communicated to data subjects." [13] to protect the privacy of users.

As discussed up till this point, ensuring the protection of the infant, providing information about the suit's functionality effects, and collecting the data necessitating the need for a medical device are also the same steps the FDA follows when considering medical devices to be used for or around infants [15].

By making design choices to maximize safety and privacy while still providing a product which can effectively improve the experience of phototherapy, we are embodying the IEEE Code of Ethics, #1: "to hold paramount the safety, health, and welfare of the public" [14].

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Appendix A - Requirement and Verification Tables

Table 6. Battery

Requirements	**Verification**	**Verification Status (Y/N)**
1. Battery capacity will power suit for 5-7 hours (Initial calculations indicate a 9000-12000 mAH capacity)	1A. Ensure the battery is charged and insert it into the suit to power it. 1B. Turn the LEDs on. 1C. Measure how long the battery lasts using a timer to make sure it is within 5-7 hours of operation time.	Y
2. The battery temperature must be strictly below 50°C during operation to ensure safety of the user.	2A. This verification is performed along with the verification for capacity. 2B.Every 30 minutes during the 5-7, hours use an IR thermometer to ensure that the battery is below 50°C.	Y

Table 7. Voltage Regulator

Requirements	**Verification**	**Verification Status (Y/N)**
1. Must step down 12 V battery voltage to 5 V +/- 5% for the MCU and RTC.	1A. Ensure the battery is charged and insert it into the suit to power it. 1B. Measure output voltage from the regulator with an oscilloscope, making sure that the output voltage is within 5% of 5 V	Y
2. Must step down 12 V battery voltage to 3.3 V +/- 5% for the WiFi Module and sensors.	2A. Insert battery to power the entire suit and PCB. 2B. Measure output voltage from the regulator with an oscilloscope, making sure that the output voltage is within 5% of 3.3 V	Y
3. Maintain thermal stability below 50°C, when the entire unit is powered and connected.	3A. This verification can be done along with Power Supply verification. 3B. Every 30 minutes during the 5-7, hours use an IR thermometer to ensure that the battery is below 50°C.	Y

Table 8. LED Subsystem

Requirements	Verification	Verification Status (Y/N)
1. LEDs can be turned off and on through button press when an infant (2.5 +/- 0.5 kg.) is present in the suit	1A. Ensure the battery is charged and insert it into the suit to power it. 1B. Verify LEDs do not respond to button press when weight no more than 2 kg. is present on the force sensor. 1C. Verify LEDs respond to button press when weight over 3 kgs. is present on the force sensor.	Y
2. LEDs shut off within 5 seconds when the temperature sensors exceed 26°C +/- 2°C.	2A. Ensure the components from the block diagram have been assembled and the battery is inserted. 2B. Turn on the LEDs. 2C. Heat any of the temperature sensors to 37°C and check to see that the LEDs shut off within 5 seconds. This can be done through the use of a hair dryer, IR thermometer, and any reliable, precise timer of choice	Y
3. Light intensity from the blue LEDs should be 2.0 +/- 0.5 mW/cm^2	3A. This verification will be done by the partner project lead using chemical modeling which is out of the scope of the class.	Y

Table 9. WiFi Module

Requirements	**Verification**	**Verification Status (Y/N)**
1. Data logs are sent every 30 minutes +/- 5 minutes to the server over the 802.11b/g/n protocol.	1A. Connect the microcontroller unit output pins to the UART pins on the WiFi IC. 1B. Connect WiFi Module to remote server 1C. Send a test message to the chip and once the WiFi Module starts transmitting we get the acknowledgement signal. 1D. Wait for the data to be received on the server and verify its accuracy every 30 minutes.	Y

Table 10. Load Switch

Requirements	**Verification**	**Verification Status (Y/N)**
1. Must be able to stop applying 12 V to LEDs based on the control signal from MCU within 5 seconds.	1A. Connect the power module to the microcontroller. Connect the load switch input to microcontroller, 12V to Vin of load switch, and LEDs to Vout of load switch. 1B. Turn LEDs on. 1C. Create a test program to send a low signal to the enable input of the load switch. 1D. Verify that the LEDs turn off within 5 seconds.	Y

Table 11. Microcontroller

Requirements	**Verification**	**Verification Status (Y/N)**
1. Log usage and temperature data at emergency shutoff and every 50-70 seconds during operation.	1A. Ensure the battery is charged and insert it into the suit to power it. 1B. Check the web server and wait till a packet of data has been received. 1C. Turn the LEDs on. 1D. After 2 minutes have passed, turn off the LEDs. 1E. Wait for the next packet to be received by the web server and check to see that 1-3 minutes of usage data have been recorded since the packet before.	Y
2. Accurately read analog/digital sensor data (from temperature and pressure sensors.	2A. Ensure the battery is charged and insert it into the suit to power it. Connect temperature sensor to microcontroller. 2B. Write a small program to print the sensor values to a monitor. 2C. Simulate different temperatures and forces. This can be done with weights and a hair dryer. Verify that the values printed correspond to measurements taken by an IR thermometer or label on the weights.	Y

Table 12. FSR

Requirements	**Verification**	**Verification Status (Y/N)**
1. The force range we are targeting is 34N +/- 3. The sensor must be able to detect this range of force with a resistance error of +/- 10%.	1A. Create a simple circuit to test the resistive force sensor. 1B. Apply the force of at least 37 N to the sensor and use an ohmmeter to verify the proper resistance as indicated in figure 4 within an error range of +/- 10%.	Y

Table 13. Temperature Sensors

Requirements	**Verification**	**Verification Status (Y/N)**
1. Must be able to measure temperature between 15°C - 40°C.	1A. Ensure the battery is charged and insert it into the suit to power it. 1B. Simulate temperatures within the range of 15°C and 40°C. 1C. Verify the accuracy of the measurements using an IR thermometer.	Y

Appendix B – Schedule

Table 14. Schedule

Week	Objective	Dhivan	Abhay	Satwik
9/21- 9/27	Finish design document check.	Finish DDC	Finish DDC	Finish DDC
9/28 - 10/4	Finalize control switch for LEDs, get feedback from design doc check, and finish design document	Finalize which buck-boost voltage regulator, add this to RV tables. Schematic for regulator	Fix block diagram and refine RV tables. MCU schematic as well	Research what type of control we can use for LED. Refine ethics and safety with any new concerns form DDC. Refine tolerance analysis
10/5 - 10/11	Design Review. Get feedback from the review and order all parts and start designing PCB	Start PCB design Order parts with Abhay	Start PCB design Order parts with Dhivan	Initiate web server creation
10/12 - 10/18	Continue designing PCB, add components onto PCB as we test everything. Test WiFi Module verifications with an Arduino board that we already have. Test sensors as well, work on the web application side as well.	Design PCB; add MCU, RTC, and any other logic to PCB. Switched to LDO regulator from buck	Test WiFi Module with the premade Arduino board and verify that our requirements are met.	Look into how to connect an application to the ESP-01 chip, and work hand on booting up some type of server and application to receive the signal from the WiFi Module.
10/19 - 10/25	Continue verifying all the subsystems with the Arduino board and finish this week, and place PCB order. time for PCB to arrive.	Verify voltage regulator and battery. Both Abhay and Dhivan verify MCU and RTC.	Work on WiFi to AWS connection with Satwik	Work on AWS booting

Table 14. Schedule (Cont.)

10/26 - 11/1	If anything on PCB order goes wrong, order here. Start getting the LEDs into the suit and doing any temperature measurements.	Continue looking at optimal ways to send signals back and forth through MCU	Start figuring out configurations of the wires between suit and PCB	Create DynamoDB table for data collection on AWS server
11/2 - 11/8	Provide progress report, at this point PCB should be here and we can put the entire unit together	Work with Abhay and get PCB and power module connected to the LEDs and suit	Work with Dhivan and get PCB and power module connected to the LEDs and suit	Continue testing WiFi connection to the suit, and provide a clean GUI.
11/9 - 11/15	Mock demo this week. Continue refining the unit as it should be functional at this point	Finish making product presentable	Finish making product presentable	App should be functioning at this point, put security protections
11/16 - 11/22	Monday and Tuesday work on perfecting demonstration so it goes smoothly.	Practice how we will present our data and demonstrate the product	Practice how we will present our data and demonstrate the product	Gather any data Dhivan and Abhay forget about from lab notebooks and create a document for it
11/23 - 11/29	Work on presentation	Prepare slides and any data for presentation	Prepare slides and any data for presentation	Prepare slides and any data for presentation
11/30 - 12/6	Refine presentation with feedback from mock presentation after Monday and Tuesday	Divide who will talk when and cover what topics	Divide who will talk when and cover what topics	Divide who will talk when and cover what topics
12/7 - 12/13	Final Report due this week	Finish and submit report	Finish and submit report	Finish and submit report

Appendix C – Physical Design Pictures

Figure 15. Suit closed with LEDs on

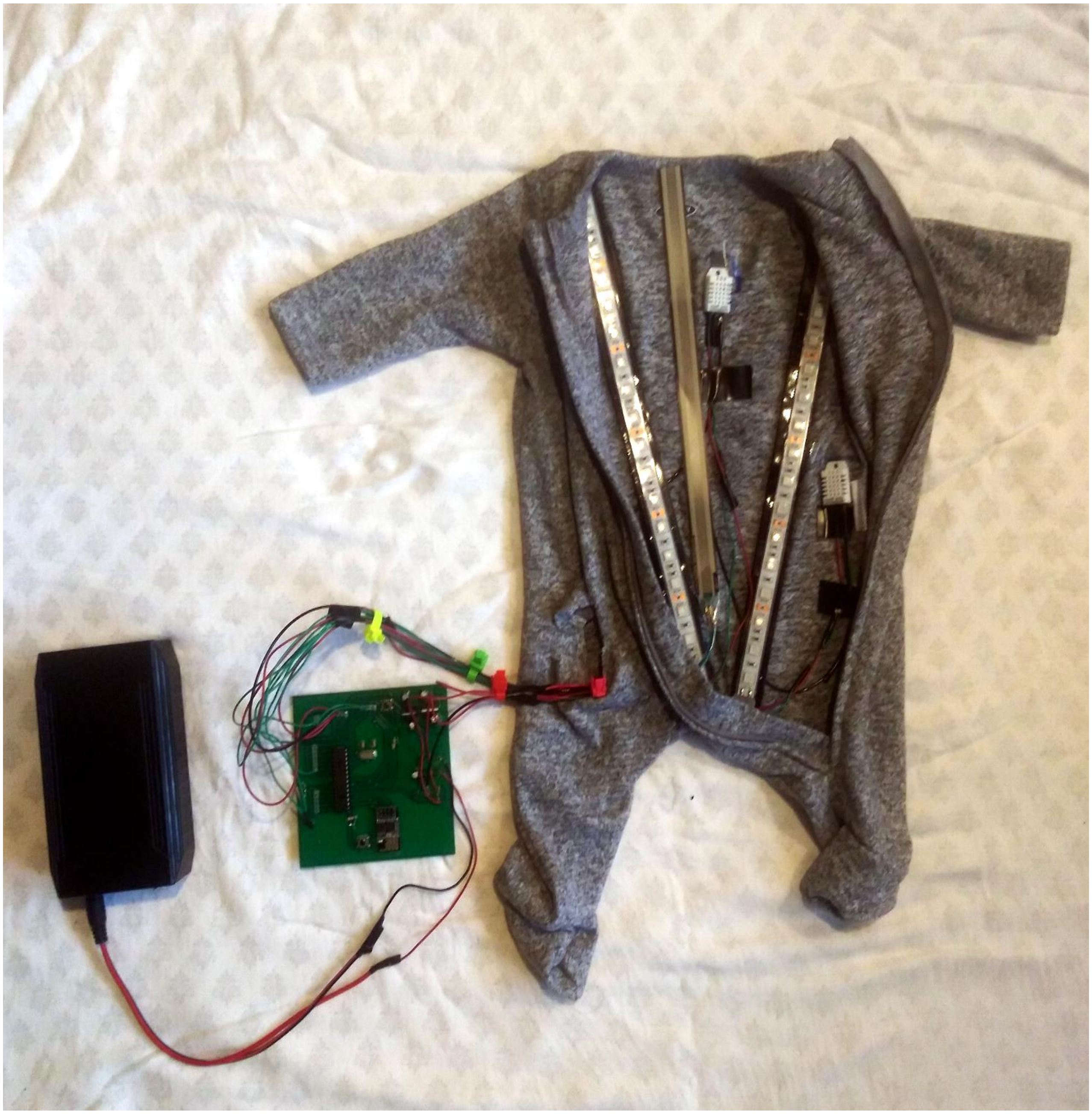

Figure 16. Suit open with PCB