Mobile Phototherapy Suit

ECE 445 Design Document Fall 2020 Team 19

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1 Introduction

1.1 Problem and Solution Overview

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 [1]. Phototherapy requires an infant to be undressed and placed 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 [2].

Our goal is to make 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 can be costly. The LEDs will be 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.

1.2 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 [3]. Left untreated, this can lead to neurodevelopmental problems.

Neonatal hyperbilirubinemia is defined as a total bilirubin level above 5 mg per dL [4]. Bilirubin is a substance that is produced when the liver breaks down old red blood cells, which will later be removed through feces [5]. 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) [4]. 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. 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 as one would think and can be 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.

1.3 Visual Aid

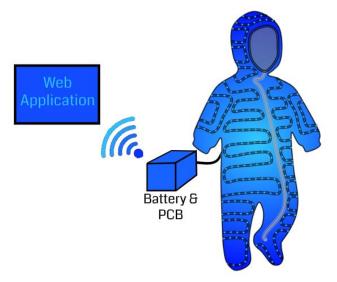


Figure 1. Visual Aid

The concept in Figure 1 illustrates how the blanket/suit will look as a prototype. The LEDs will be lined along the suit and will connect to the battery and PCB which are external. The PCB will then use wi-fi to connect to a software application.

1.4 High-Level Requirements

- Implement the entire system so that it will be portable and treatment times will be shorter
 or not significantly changed (within 20% of non-portable treatment times). This
 comparison can be independently shown through the use of a chemical model of bilirubin
 (β-carotene) that will degrade over time when exposed to blue light and analyzing the rate
 of degradation.
- Use a robust design to prevent safety hazards. The device will monitor temperature and automatically shut off the unit with a maximum latency of 5 seconds to prevent damage to the infant or the unit. The emergency temperature shutoff threshold will be 26°C +/-2°C [8].
- Allow for a healthcare provider to monitor usage and temperature statistics through wireless communication. Usage will be determined as the FSR dropping below half its reference value and the LEDs being powered. Every 25-35 minutes, average temperature, max temperature, and min temperature for the session will be sent to a web server.

2 Design

2.1 Block Diagram

The suit requires different components for full functionality: Power Supply, WiFi Module, Control Unit, Sensors, and an LED Subsystem. The power supply guarantees power for the suit and corresponding circuitry by providing it with 12V. The illumination provided by the LED subsystem will reduce levels of bilirubin. The control unit consists of a microcontroller unit for data handling and a real time clock for the microcontroller to timestamp the data collected. The sensors include temperature and pressure sensors to continuously ensure safety and detect presence. The WiFi Module allows for remote connection to an application to collect data which can then be visualized by healthcare professionals.

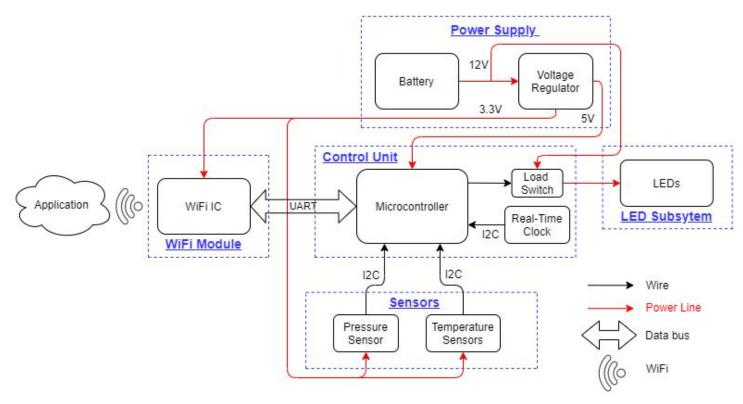


Figure 2. Block diagram

2.2 Usage Flow Diagram

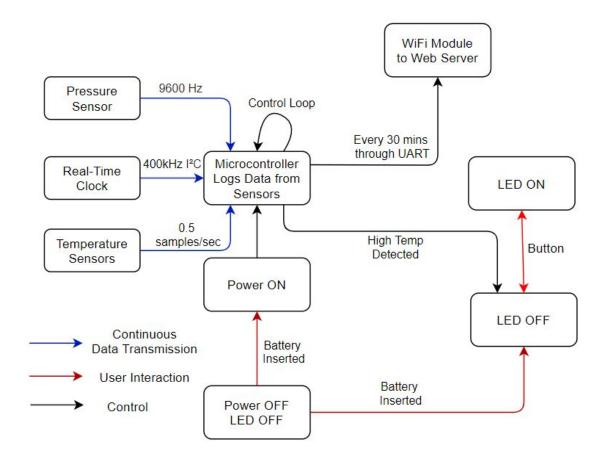


Figure 3. Usage Flow Chart

2.3 Power Supply

The power supply is required to allow usage of all components in the system. This includes the LEDs, microcontroller, WiFi IC, RTC, pressure sensor, and temperature sensors. The power supply will consist of a rechargeable battery and voltage regulator to send the proper voltage into the microcontroller and other components(5V or 3.3V).

2.3.1 Battery

This will be a rechargeable 12V lithium ion battery. The battery will be supplying the power to the entire system. It will be connected through a voltage regulator to step down the battery voltage.

Requirements	Verification
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.
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.

2.3.2 Voltage Regulator

The voltage regulator will regulate the battery voltage from 12V to 5V for the microcontroller and RTC. This will also regulate the voltage for the WiFi IC and temperature and force sensors to 3.3V. The voltage regulator will be two switching regulators to go from 12V to 5V and 12V to 3.3V. This will be done using the TPS63070RNMT ICs.

Requirements	Verification	
1. Must step down 12V battery voltage to 5V +/- 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 5V	
2. Must step down 12V battery voltage to $3.3V + 5\%$ 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 3.3V	
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.	

2.4 LED Subsystem

Power delivery to the LEDs will be controlled through the microcontroller using sensor data. The LEDs will use the 12V supplied by the battery. The LEDs will be connected to the microcontroller via a TPS22810DBVR load switch to control the power to the LEDs.

2.4.1 LED Strips

The LED Subsystem will have an array of LED strips embedded within the suit. These strips will have manufacturing specifications such that, when powered, they will emit blue light between 450-490nm.

Requirements	Verification	
1. LEDs can be turned off and on through button press when an infant (2.5 +/- 0.5 kg.)	1A. Ensure the battery is charged and insert it into the suit to power it.	
is present in the suit	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.	
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	
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.	

2.5 WiFi Module

The WiFi module will be responsible for receiving data through UART from the microcontroller in the control unit and transmitting that data across a wireless network for remote monitoring. It will send a timestamp and sensor readings to the server. The power supply module will power the WiFi IC with 3.3V.

2.5.1 WiFi IC

The WiFi IC will be the ESP8266 chip that is made by Espressif Systems. This chip will allow data transmission through a wireless network with TCP/IP connections.

Requirements	Verification	
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 chip 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	

2.6 Control Unit

The control unit needs to be able collect the sensor and RTC data and control the LEDs. It will also take care of how the data will be received from the sensors and sent to the WiFi module. The communication between the microcontroller and the WiFi module will be through UART. It will be connected to the TPS22810DBVR load switch to control the LEDs.

2.6.1 Microcontroller

The microcontroller unit will be the ATmega32U4 chip embedded into the control unit PCB. The ATmega32U4 will receive data from the sensors through I²C and will send a signal to the load switch to turn on and off the LEDs. It has on-chip memory that can be used to store sensor information which will intermittently be communicated via the UART to the WiFi module.

Requirements	Verification
1. Log usage and temperature data at emergency shutoff and every 50-70 seconds during exerction	1A. Ensure the battery is charged and insert it into the suit to power it.
during operation.	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.
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.

2.6.2 Real-Time Clock

The real-time clock(DS3231 IC) will be used to keep track of the internal time of the suit. Specifically, we plan to use this to timestamp the data that is sent to the WiFi module.

Requirements	Verification
 Make sure the real time clock sends accurate time values to the microcontroller. 	1A. Connect the power module to the microcontroller and connect the RTC to the microcontroller. Insert battery to power the system.1B. Write a program to read in the data from the RTC via the microcontroller and print it to a monitor. Verify that the real time is accurate.

2.6.3 Load Switch

The load switch will be the TPS22810DBVR IC that will allow us to switch on and off the 12V to the LEDs based on a control signal from the MCU. The control signal will be for the automatic shut-off if the temperature is becoming too high.

Requirements	Verification	
 Must be able to stop applying 12V 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.	

2.7 Sensors

The sensors will be connected to the microcontroller through I²C and the microcontroller will store and send the data to the WiFi module. The sensors we will use are 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 sensor will be powered by the power module and the force sensors are simply a resistor so they will not need to be powered.

2.7.1 Force Sensor

A force sensor will be used to detect if an infant is in the suit while in operation. This combined with when the LEDs are on will be used to track the time an infant is receiving treatment for. We plan to use an FSR 400 Series to achieve this. As the force is increased on the sensors the resistance decreases. We see this inverse relationship in **Figure 4**, from the FSR 400 datasheet. This means we will be able to detect if an infant is in the unit or not by taking advantage of this resistance change.

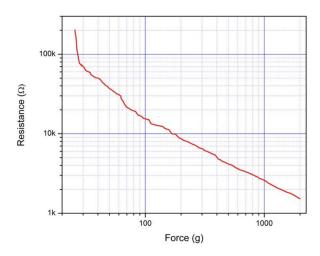


Figure 4, Resistance vs. Force for Force Sensor

Requirements	Verification
 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%.

2.7.2 Temperature Sensors

The temperature sensors will monitor the temperature between the LEDs and the baby. This is mainly for safety reasons to make sure that the temperature does not go above 26 degrees Celsius +/- 2 degrees. We will use 8 DHT22 sensors to achieve this by placing them in areas such as the armpit, groin, and other areas around the suit that are prone to high temperatures.

Requirements	Verification	
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.	

2.9 Web Application

While this is mostly outside the scope of this class, we will provide a brief description of the role of the web server/application to provide context.

The web server will receive packets of data being sent from the device through the WiFi IC. These packets will contain data about a session of usage of the suit. A session is defined to be a period in which the suit is continuously powered. A start time, end time, length of treatment during the session and temperature data will be sent in the packets. This data will be available to be viewed by a healthcare professional by visiting the server.

The User Interface developed during this class will be very simple (no style sheets) as software is not a focus of the class. The implementation of the server will be handled with HTML and Javascript and hosted on a common cloud service provider like Amazon EC2 or Google Cloud.

2.10 Tolerance Analysis

The most sensitive part of our design for the success of this project will be the asymptotic temperature reached within the suit during operation. If the safety of the infant is compromised due to too high a temperature our product will not have the validity to replace existing treatments. We make a conservative estimate of that asymptotic temperature using the following equations indicating thermal equilibrium only accounting for major contributors to heat production and heat dissipation.

$$Q_{in} = Q_{out} \tag{1}$$

$$Q_{in} = Q_{infant} + Q_{LED} \tag{2}$$

$$Q_{LED} = Intensity_{skin} * A_{skin} * (1 - \eta_{LED})$$
(3)

$$Q_{out} = h_{cotton-air} * A_{suit} * \Delta T$$
(4)

Substituting in Eq. (3) into Eq. (2) and then equation Eq. (2) and Eq. (4) into Eq. (1), we get: $h_{cotton-air} * A_{suit} * (T_{asymptotic} - T_{room}) = Q_{infant} + Intensity_{skin} * A_{skin} * (1 - \eta_{LED})$ (5)

We assume $A_{suit} = A_{skin}$, $\eta_{LED} = 0.2$, and $T_{room} = 20^{\circ}$ C.

Additionally, we know $Intensity_{skin} = \frac{2 mW}{cm^2}$ [9], $A_{skin} = A_{suit} = 2400 cm^2$ [10], $h_{cotton-air} = 0.0013 \frac{W}{cm^2C}$ [11].

That leaves finding Q_{infant} in order to solve for $T_{asymptotic}$. We can overestimate Q_{infant} assuming all calorie consumption is converted into heat with $Consumption_{infant} = 125 \frac{kcal}{day kg}$ [12], $m_{infant} = 3.5 kg$ [13], and do the following conversion:

$$Q_{infant} = Consumption_{infant} * \frac{1 \, day}{86400 \, s} * m_{infant} * \frac{4184 \, J}{1 \, kcal} \tag{6}$$

After evaluating substituting numerical values into Eq. (6) and evaluating we get:

$$Q_{infant} = 21 W$$

Substituting in numeric values into Eq. (5):

$$0.0013 \frac{W}{cm^2C} * 2400 \ cm^2 * (T_{asymptotic} - 20^{\circ}\text{C}) = 21 \ W + \frac{0.002 \ W}{cm^2} * 2400 \ cm^2 * (1 - 0.2)$$

Evaluate and solve for $T_{asymptotic}$:

$$T_{asymptotic} = 28.0^{\circ} C$$

Through this analysis we can expect the temperature in the suit to be under 28.0°C (conservative max). While this may seem too warm given the lower ambient temperatures adults are comfortable with, this is not the case for infant's who struggle to retain heat and need to be kept warm. NICUs are commonly set to 26°C [8]. Measurements from experimental data are likely to be closer to if not under 26°C for the same conditions as used in our conservative calculations (especially in regards to heat produced by an infant and efficiency of LEDs). Infants may even need further warmth provided even when in the suit if our conservative calculations were too extreme of overestimates. This problem can be solved easily by wrapping a blanket or other cloth around the suit. If we observe that normal operation of the suit is exceeding the temperature threshold set for safety, we can further mitigate the temperature inside the suit in various ways. This can be done by increasing ventilation, obtaining a cloth suit made of different materials, or producing less heat from the LEDs. This can involve obtaining more efficient LEDs, or decreasing the number or intensity of the LEDs in the suit.

2.11 Schematics

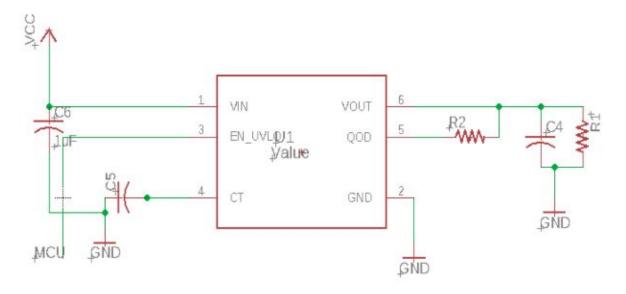


Figure 5, Load Switch Schematic

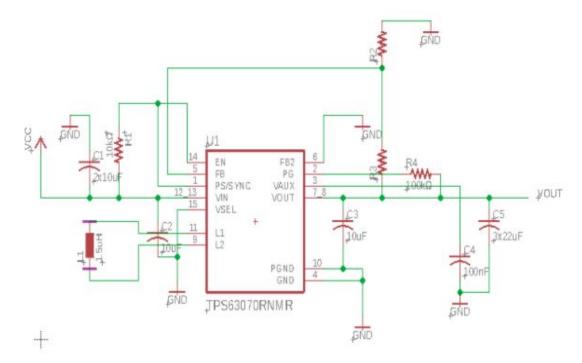


Figure 7, Voltage Regulator Schematic

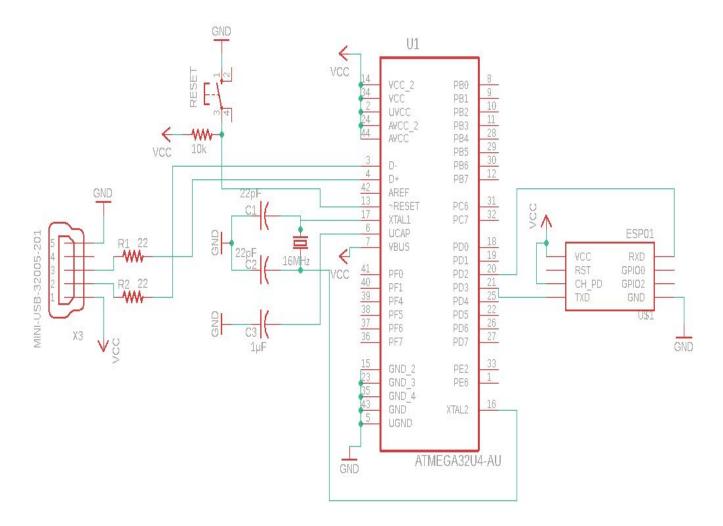


Figure 8, Microcontroller and WiFi module Schematic

2.11 Covid-19 Contingency Planning

If the University transitions to entirely online classes earlier than expected, we will cut out supplementary features of our product to allow for completion of core features.

Depending on how much progress we have made by that time a group member can take all physical hardware parts with them to try and finish the implementation at home or if we have functioning hardware we can leave it with the project lead from the Carle Health Maker Lab. In the case of leaving the hardware with the project lead, verification can be performed using his chemical model and maintaining frequent communication with him.

The project can be split up into these 5 features:

- 1. Power Subsystem and LEDs embedded into the suit
- 2. Temperature sensing
- 3. Automatic emergency overheating shutoff
- 4. Pressure sensing
- 5. Web server software and communication with it

Of the above 5 list items, 1-3 are core features and 4-5 are supplementary features. 4 is supplementary since the negative effect of removing pressure sensing is the possibility of powering the LEDs when the infant is not in the suit. This will allow for energy to be wasted if parents don't turn the LEDs off themselves but will not pose a medical danger. 5 is supplementary since it is mostly outside the scope of the class and is introducing statistics that aren't crucial to the effectiveness of the treatment.

As needed, items 4-5 will be cut out of the immediate implementation for the class and can be resumed outside of the scope of the class. This leaves the core functionality of the light from LEDs treating hyperbilirubinemia and emergency shutoff to ensure safety during the treatment as our remaining high-level requirements.

3 Cost and Schedule

3.1 Cost Analysis

In the academic year of 2017-2018, the average annual salary was \$93,000 for a Computer Engineering major and \$78,000 for an Electrical Engineering major from the University of Illinois at Urbana-Champaign [14]. We calculate hourly rates by assuming a 40 hour work week. Estimating 15 hours worked per week for the 16 weeks of the class, each group member works a total 240 hours during the semester.

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

Labor Cost Per Employee

Parts Acquisition

Module	Parts	Cost Per Unit	Why is this needed?
Control Unit	ATMEGA32U4-AU	\$4.00	Microcontroller for managing peripherals/sensors and I/O between WiFi module.
Control Unit	DS1307 Real Time Clock	\$7.95	Create an internal timestamp for data being read from sensors.
Control Unit	TPS22810DBVR Load Switch	\$0.63	Ability to stop providing power to LEDs based on a control signal from MCU.

Sensors	DHT22/AM2302 Digital Temperature Sensor	\$6.53	Monitor the temperature in the suit for safety.
Sensors	Extra-long force-sensitive resistor (FSR) - Interlink 408	\$19.95	Detect and monitor if the baby is present inside the suit.
Power Supply	TalentCell Rechargeable 12V Battery	\$34.99	Provide 12V power to the suit.
Power Supply	TPS63070 2-V to 16-V Buck-Boost Converter	\$2.60	Step down voltage from battery to 3.3V or 5V.
WiFi Module	ESP8266	\$6.95	Connect to a web-server and send logged data from the suit using WiFi.
LEDs	aspectLED - Blue Flexible LED Strip Light	\$59.99	The LED strips to be used in the suit for phototherapy.
Misc.	Resistors, Capacitors, Inductors, Crystals, etc.(Estimated Cost)	\$10.00	Used in nearly all parts of the PCB to make ICs operational.

The total cost of parts will be \$201.90. This factors in using 8 temperature sensors and 2 voltage regulator chips. The total labor cost is \$76,152. The grand total will be **\$76,353.90**.

3.2 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.	Test WiFi module with the premade arduino board and verify that our requirements are met.	Design PCB; add MCU, RTC, and any other logic to PCB. We can verify the design with TA William Zhang.	Look into how to connect an application to the ESP2866 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	Verify voltage regulator and battery. Both Abhay and	Verify sensors with LEDs. Both Abhay and Dhivan verify	Provide MCU code for support of Abhay and Dhivan

	this week, and place PCB order. This must be done asap since it takes time for PCB to arrive.	Dhivan verify MCU and RTC.	MCU and RTC.	
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. Also get the thin layer and do testing on the material.	Start figuring out the best configuration of LED strips in the suit.	Find a thin layer of fabric to put between LEDs and skin. Buy and test with Dhivan	Continue looking at optimal ways to send signals back and forth through MCU
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	Finish and	Finish and	Finish and
	this week	submit report	submit report	submit report

4 Discussion of Safety and Ethics

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 will be 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" [15].

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 will in turn also prevent the infant from chewing on the suit.

Using a disposable clear inner sheet 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 inline with the IEEE Code of Ethics, #9: "to avoid injuring others ..." [16].

A major ethical concern to get our product into practice is the testing phase. Being 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 will need to be performed. 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 ..." [15].

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." [15] to protect the privacy of users.

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" [16].

5 References

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