Mobile Phototherapy Suit

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1 Introduction

1.1 Objective

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. The current treatment of phototherapy is effective in lowering bilirubin levels but is very inconvenient for both the infant and the parents [5]. Phototherapy requires an infant to be undressed and placed upon a bed under an intense blue light where they must remain for up to a week. Additionally, the infant has to wear an uncomfortable eye covering to prevent retinal damage from the lights [6]. Additionally, the uncontained blue light interferes with sleep. During this time, the infant is separated from their parents, leading to distress and anxiety for the entire family. While phototherapy is very effective in lowering bilirubin levels, the treatment method duration can lead to an expensive and exhausting extended hospital stay for the family. The problem here is that the current treatment is bulky and immobile. Since jaundice in newborns is quite common, a solution that is mobile, safe, and affordable would save parents significant amounts of trouble.

Our goal is to make a mobile phototherapy suit for infants: a full-body wearable cloth suit with integrated blue LEDs. Current commercial devices are situated some distance away from the child, waste a lot of light/energy, and can be costly. Our solution will have light sources that are in near proximity to the skin for maximum therapeutic intensity while completely contained inside the suit. Inside the suit, there will be a clear, thin, disposable layer between the lights and the skin to allow for reusability, safety, and diffusion of light. The suit will replace the uncomfortable eye covering used in traditional phototherapy with an open face to allow for beneficial parent-child interactions, especially nursing. Instead of extending the hospital stay, the system will be portable enough for parents to take home. While at home, the system will have the ability to remotely monitor usage and other sensor data through an application.

1.2 Background

Neonatal hyperbilirubinemia is defined as a total bilirubin level above 5 mg per dL [1]. Bilirubin is a substance that is produced when the liver breaks down old red blood cells, which will later be removed through feces [2]. 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) [1]. While extremely high levels of bilirubin necessitate blood transfusion, the moderate level expressed in the vast majority of newborns is adequately treated with phototherapy.
To avoid such neurological problems the newborn must be treated immediately with phototherapy. As mentioned above, current phototherapy treatment is done with a newborn intensive care unit. Above the incubator there is an intense blue light which illuminates the infant. This is an immobile and inefficient solution and forces the patients to remain in hospital, occupying unnecessary space inside the hospital which could otherwise be better utilized.

Aeroflow Healthcare currently has a portable phototherapy blanket, called the Biliblanket[8], 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, and the lights will be completely contained in 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 three thousand dollars. This also would ideally be paired in a hospital setting with a more intensive blue light overhead. Our solution will use blue LEDs instead of fiber optics to make it more affordable and easier to replace.

In principle, existing solutions might be utilized for 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 Physical Design

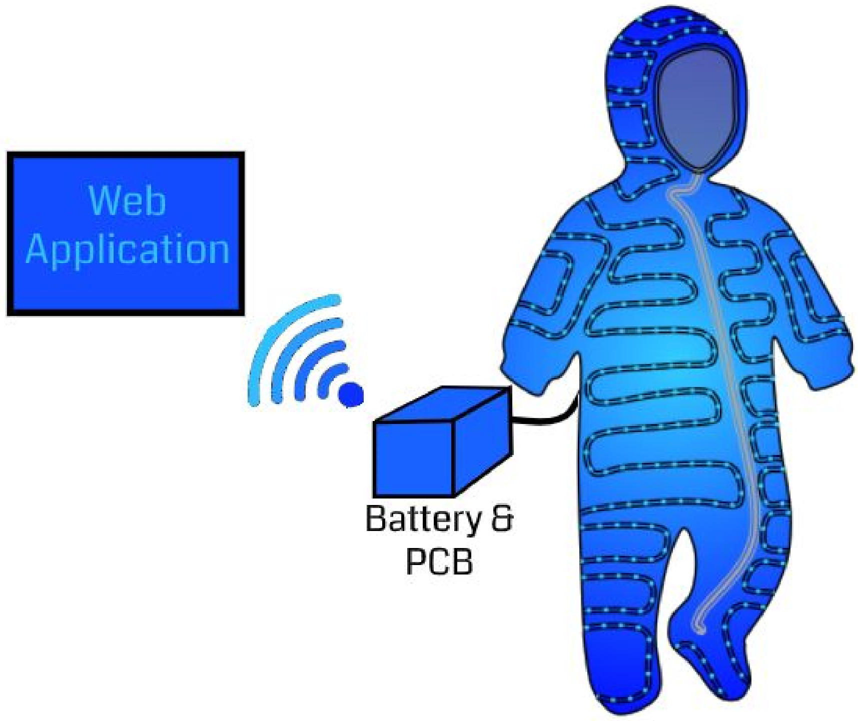

Figure 1. Physical Design

The concept above illustrates how we plan on connecting the different components to deliver the final product.

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.
- Using a robust design to prevent safety hazards. Monitoring temperature and automatically shutting off the unit when necessary to prevent damage to the infant or the unit.
- The ability of a healthcare provider to monitor usage and safety data either through remote access or retrieval from the portable unit.

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 12 volts. 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.

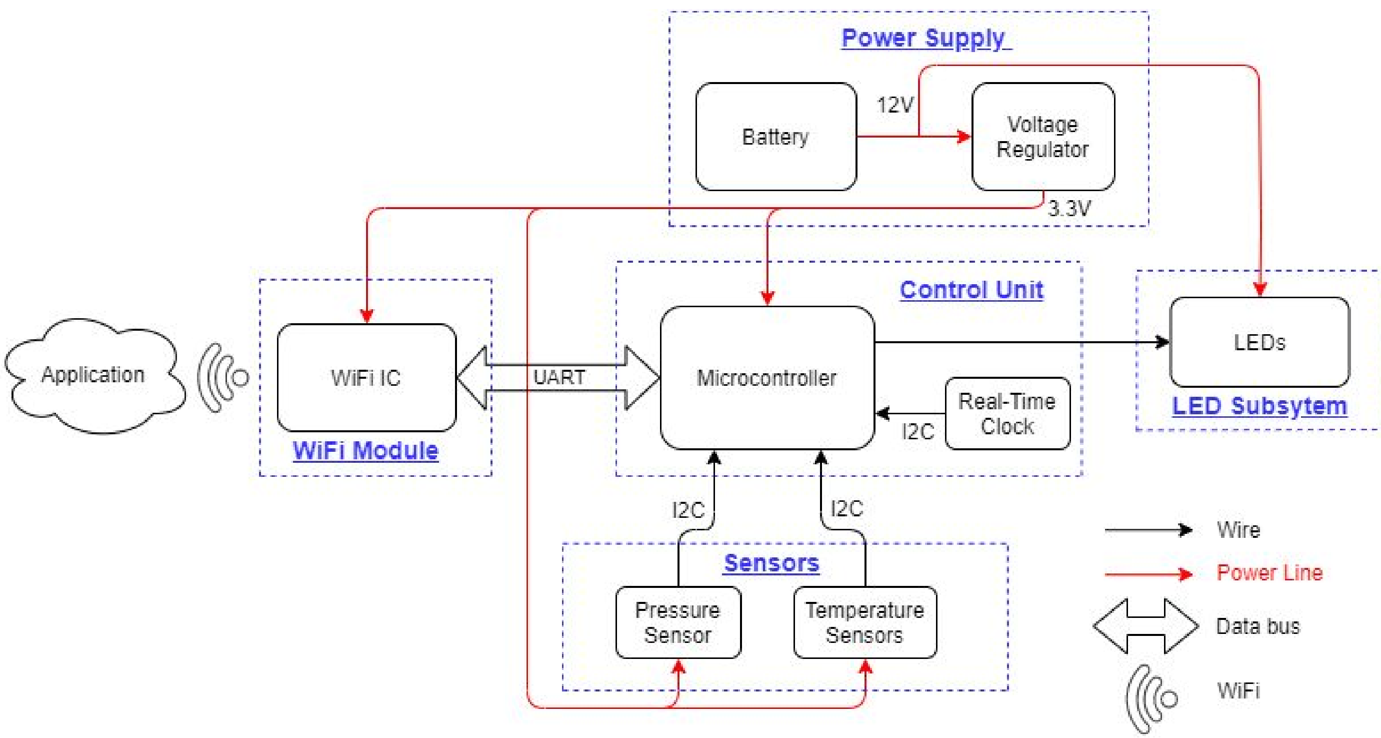

Figure 2. Block diagram

2.2 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 step down to 3.3V.

2.2.1 Battery

This will be a rechargeable 12V lithium ion battery. The battery must be able to supply the LEDs and other components with enough power to stay on for a long duration.

Requirement: The battery must be ~10,000mAH for 6 hours of use.
Requirement: The battery must be 12V battery to power LEDs.
Requirement: Temperature must be below 45C to ensure safety of the user.
Requirement: Battery must be replaceable and rechargeable

2.2.2 Voltage Regulator

This circuit will step down the battery's 12V to 3.3V for the PCB components and sensors.

Requirement: Must provide 3.3V +/- %5 from the 12V battery pack.
Requirement: Temperature must be below 50C to ensure safety and stability of the system.

2.3 LED Subsystem

The LED Subsystem is comprised of the LED strips that will be inside the suit. These will be illuminated given that the suit is in operation, an infant is in it, and the temperature is in an acceptable range. The LEDs will be powered directly from the 12V battery.

2.3.1 LED Strips

There will be multiple LED strips through the suit to get the most surface array covered as possible. The LEDs must be the proper wavelength within the blue spectrum for effective phototherapy.

Requirements: Must output light with wavelength between 400-550nm [4].
Requirements: Light intensity must be approximately 2 mw/cm^2.
Requirements: Ability to turn off if overheating detected by temperature sensors.

2.4 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.

2.4.1 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 simple TCP/IP connections.

Requirement: Receive data signals from the microcontroller unit on UART I/O pins.
Requirement: Communicate with a server over 802.11b/g/n protocol.
Requirement: Data logged from sensors should be transmitted to the server every hour.

2.5 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 and sent to the WiFi module. The communication between the microcontroller and the WiFi module will be through UART.

2.5.1 Microcontroller

The microcontroller unit will be the PIC 32 chip embedded into the control unit PCB. The PIC will receive data from the sensors through I^2C and will send a signal for the LED strips to turn on and off. 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.

Requirement: Must match the caching and wait states to the clock cycle speed, which will be efficient at around 60Hz.
Requirement: Must use 3.3V +/- 5% for power, and will need to draw < 2A.

2.5.2 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.

Requirement: Consume 350 nA when on standby.
Requirement: Must operate at 32.768kHz.

2.6 Sensors

The sensors will be connected to the microcontroller through I^2C and the microcontroller will handle the data. The sensors we will use are a pressure sensor to detect if the infant is in the suit and a temperature sensor to monitor the temperature of the suit for safety.

2.6.1 Pressure Sensor

A pressure 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 408 to achieve this.

Requirements: Should be able to detect the presence of a baby. Threshold of 3lbs with under 30% sensitivity should suffice.
Requirements: Must be around 40cm long to sense pressure over a big enough area.

2.6.2 Temperature Sensors

The temperature sensors will monitor the temperature between the LEDs and the baby. This is mainly for safety reasons and to possibly control the intensity of the LEDs. We will use the TMP36 sensors to achieve this.

Requirements: Needs between 2.7 - 5.5V to operate.
Requirements: Track temperature at 5+ points at risk of overheating.
Requirements: Must be smaller than 5mm to fit in the suit.

2.7 Risk Analysis

The LED subsystem provides the greatest risk to the completion of the project. LEDs will be producing heat which will be increasing the temperature within the suit. While safety shut offs will be implemented through sensor detection, the treatment will be compromised if this is triggered frequently. We will need to ensure a balance between the temperature in the suit during operation while allowing for effective treatment.

Current products either place the LEDs farther away from the infant in an open unit, which allows for much greater heat dissipation, or use fiber optics to illuminate an infant's skin with minimal heat production. While these approaches point towards challenges in using LEDs in near proximity to an infant, there may be certain benefits to doing so. Placing LEDs farther from an infant requires for a higher power output to achieve the same levels of illumination as our approach. Additionally, infants need to be kept warm in general so the heat produced by the LEDs could be more beneficial than harmful.

The specific LEDs we use and their layout will greatly determine the temperature within the suit during operation. If we find that any LEDs we use produce too much heat to be considered safe, we will need to consider modifying the design to account for that. This will likely be in the form of changes to the physical design to allow for more ventilation where heat is accumulating or reducing the number of LEDs in the suit. If more significant heat production mitigation is required we will consider switching to using fiber optics as done in some existing products mentioned in Section 1.2.

3 Ethics and Safety

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 being 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.

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 ..." [9].

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." [10] 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 IEE Code of Ethics, #1: "to hold paramount the safety, health, and welfare of the public" [9].

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