Neonatal Phototherapy and Vitals Monitoring Device

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Introduction

1.1 Objective

Jaundice is the number one reason newborns are readmitted to hospitals worldwide [1]. 5-10% of newborn mortality worldwide is due to jaundice [2] and every year over 6 million babies with severe jaundice are not receiving adequate treatment [1]. Phototherapy is a known treatment for jaundice and works by emitting blue light over the patient's skin and, through photo-oxidation and photoisomerization, converts bilirubin molecules to a less toxic, isomeric form [3]. Following molecular form conversion, bilirubin is easily excreted through urine. Bilirubin (the molecule which causes the trademark skin yellowing for jaundiced patients) has a naturally higher level in infants, therefore hyperbilirubinemia, or jaundice, is more easily apparent in neonatal cases [4]. Within the first week of life, jaundice occurs in 60% of all normal newborns, and this percentage only increases in cases of premature birth [5].

The neonatal period, defined as the first 28 days of life, is especially critical for survival in developing countries. In 2016, as much as 2.6 million infants died within the first month of life, globally [6]. This statistic is especially prevalent in developing countries. For example, a child in South Asia is nine times more likely to die during the first month compared to that of a child from a high-income country [6]. With the simplicity of jaundice treatment, at first glance it seems senseless that such a significant percentage of neonatal mortality in developing countries are from jaundiced cases. Here we propose building a system which uses phototherapy to treat jaundice, takes vitals important to neonatal health (i.e., temperature, weight, and heart rate), and contains temperature regulation for neonatal care in developing countries.

1.2 Background

Following the emergence of blue LEDs, phototherapy systems geared towards use in low-resource hospitals are becoming more of a priority. Examples include: Firefly, a newborn phototherapy device specifically design for use in rural hospitals [2]; and D-Rev's Brilliance, designed to target the current lack of effective phototherapy in treating neonatal jaundice around the world [1]. Even with these existing solutions, NGO's and other non-profit organizations, such as Engineering World Health, still recognize the prevalent need in an affordable and effective treatment for phototherapy for use in low-resource settings [7].

Therefore, while simplistic phototherapy technologies currently exist for targeting low-resource hospitals, an inexpensive system of treating neonatal jaundice and monitoring vital signs simultaneously does not exist. The added vitals monitoring component enables healthcare workers (doctors and nurses) to be able to spend more time treating patients as opposed to having to take the time to measure and take temperature, heart rate, and weight. This is especially useful for hospitals in developing countries, wherein nurses and doctors are continuously severely understaffed. Temperature and heart rate are important vitals for patients of any age, however, weight is an especially important measurement to take for neonatal care. Alongside serving as a general health measure, weight is used as an indication for dehydration, which is the common concern with jaundice [8] since maintaining hydration is essential in flushing out excess bilirubin. A newborn is especially susceptible to hypothermia (defined as a newborn's internal temperature dropping below 37°C [9]), therefore, we propose building a temperature regulation system in conjunction with the vitals monitoring. Having a phototherapy system as well as general monitoring and maintenance of health factors are especially important for jaundiced cases and neonatal care in general.

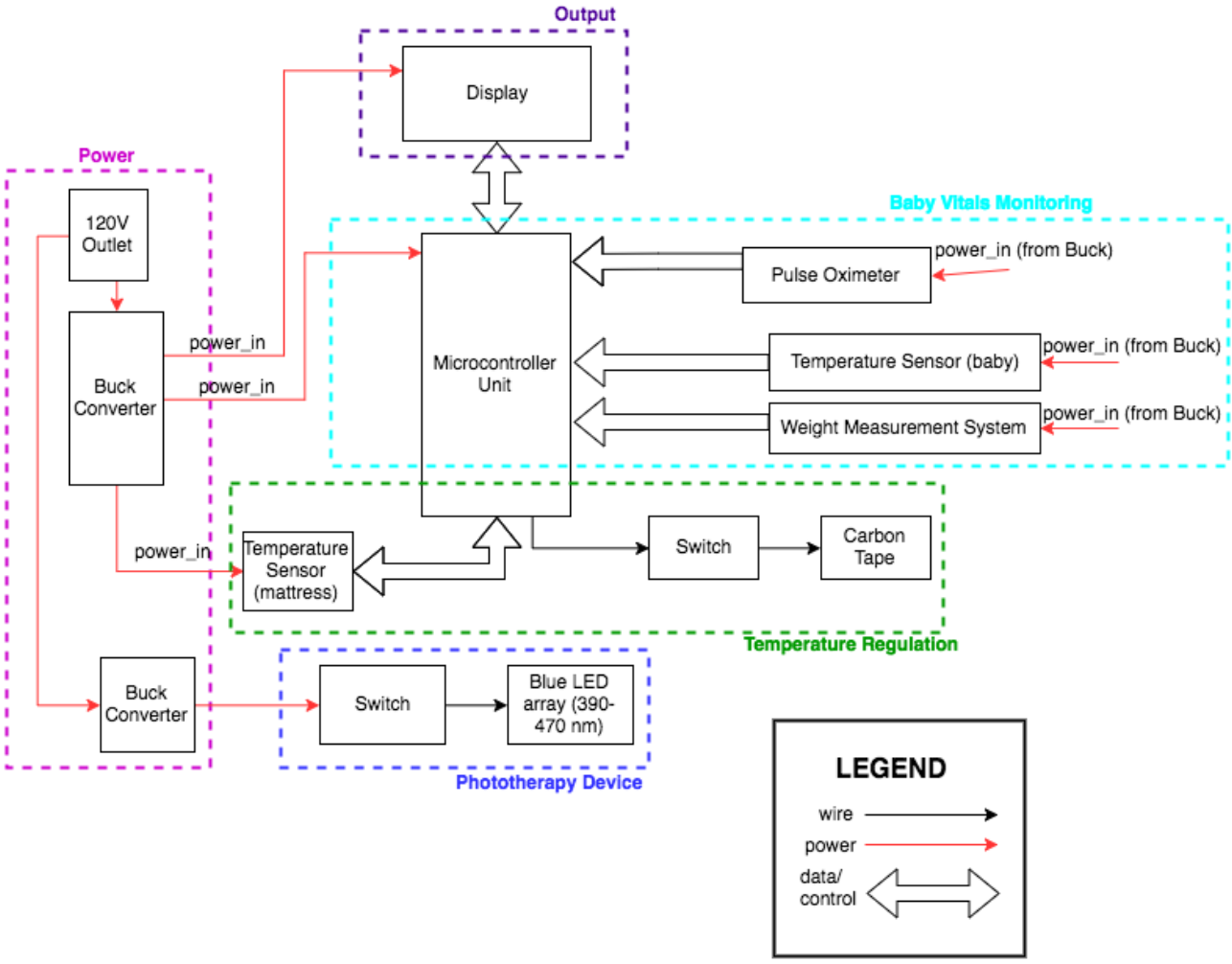
1.3 High-Level Requirements List

- The phototherapy component will involve an LED set-up with 390-470nm wavelength range and 15-40 $\mu W/cm^2/nm$ irradiance level at a 30 ± 5 cm distance [1,2].
- The temperature regulation system must be able to maintain 33-37 °C [10].
- The vitals monitoring component must be able to detect temperature (within ± 3 °C), heart rate (within 10% difference [11,12]), and weight (within ± 200 grams [13]).

Design

2.1 Block Diagram

Our device is composed of three subsystems: means for neonatal vitals monitoring, temperature regulation, and phototherapy. All of these subsystems require a power source, which will be from a 120V outlet. The temperature regulation unit and vitals monitoring system require processing of data and therefore will be connected to a microcontroller unit. The phototherapy device only requires a power input as this subsystem's output is the light-based treatment for the patient. The general output of the entire device will be a display which shows the user pertinent information about the patient's vitals (heart rate, weight, and temperature).



2.2 Functional Overview/Requirements

I. Power

The power comes from a 120V outlet. We plan to use an integrated power supply from STMicroelectronics. We plan to use this premade component to ensure safety of our components and of the device. The alternative strategy is to make the AC/DC supply ourselves using a flyback buck converter and the appropriate capacitors and inductors.

Once we have acquired a stable DC signal we intended on using a series of buck converters to deliver the appropriate power to all our devices. We will most likely have two type of buck converters – those outputting 5V and those outputting 3.3V. We will attempt to purchase integrated buck converters as to avoid having the need to purchase an external inductor.

Requirement: Produce a stable (± 10% of nominal value) DC signal integrated with an optional circuit breaker in the situation of surge current.

II. Baby Vitals Monitoring

Pulse Oximeter

The pulse oximeter set-up involves measuring reflectance of infrared and red photodiodes off the patient's skin [11]. The input of this system will be our power source and output of this system will be a current, which will be converted to voltage and sent to the microcontroller for processing into heart rate. The output signal will be pulsatile waves driven by voltage differences along each time point, thus counting the peaks for this signal output (called the SpO_2 signal or blood oxygenation signal) correlates to the patient's heart rate. Expected current or voltage ranges cannot be given for this sub-block since specific ranges depends on the gain used to obtain the signal, the diodes used, and on the inherent resistance variance between people [11,12].

Requirement: Must be able to produce an A/C SpO_2 signal that correlates to a heart rate within 10% accuracy.

Temperature Sensor

We plan on having two temperature sensors – one for the infant and one for the surroundings. We chose to have an ambient temperature sensor as to avoid having the incubators regulate temperature based solely on that of the infant's. We intend to use either a temp sense IC or thermistor to monitor the baby's temperature as these types of thermos resistors are simpler to use, operate with low power, and are accurate for our endeavor. Moreover, we plan on using a digital temperature sensor depending on our need for an ADC (I.e. whether our MCU will have available ports). Will be powered by 3.3V rail.

Requirement: Must be able to detect skin temperature within +/- 3°C.

Weight Measurement System

Depending on the load cell used for the project we may be required to use an instrumentation amplifier to more precisely measure the signals. Our goal is to have the load cell or force sensor located within the mattress. We will calibrate the sensor to a value of zero on an empty bed. The data from this sensor will be send to the MCU and displayed externally. Will be powered by 3.3V rail.

Requirement: Must be able to output weight within +/- 200 grams

Microcontroller Unit

The MCU will either be an Arduino or the TI MSP430. Both options offer optimum performance. The MCU will be powered by a 5V rail. The MCU will collect data from the pulse oximeter, temperature sensor, and display. The MCU will also be connected to a switch that controls the heating unit within the incubator. This switch will act as an override kill switch for the heating. The MCU acts as a data collection and regulation unit to connect the various sensors together in order to display this data.

Requirement 1: Must be able to process the oxygenation signal to heart rate within 8% accuracy.

Requirement 2: Must be able to send and receive the appropriate signal as to control the remaining circuitry.

III. Temperature Regulation

Temperature Sensor

We plan on using this temperature specifically to measure the temperature of the surrounding. We intend to use a temp sense IC as these are simpler to use, operate with low power, and are accurate for our endeavor. Moreover, we plan on using a digital temperature sensor depending on our need for an ADC (I.e. whether our MCU will have available ports). Will be powered by 3.3V rail.

Requirement: Must be able to detect ambient air or skin temperature within +/- 3°C

IV. Phototherapy Device

Switch

The switch will be electrically controlled by the MCU. The switch will in effect as a kill switch for the device. A high signal will disable the heating unit by disabling the power being sent to the unit.

Blue LED Array

The LED array consists of store bought LEDs that will be attached to a perf board. The LED columns will be powered in parallel by the power supply. The external switch will be used by nurses to turn on and off the LED array. The LEDs must be connected in columns as to prevent all the LEDs from loosing power in the situation a few LED in series loose power.

Requirement: Must be able to output 390-470 nm wavelength light and 20-45 μW/cm/nm irradiance level at a 30 ± 5 cm distance.

V. Output

Display

Powered by a 5V rail. The display will most likely be a 7-segement display. Once we begin packaging we will like to place an LCD monitor. The display will have to hold the signal it receives. Thus the 7-segment display will need an integrated data line. The data line will be a one way communication channel that the display will hold.

Requirement: Must be able to display patient’s temperature, heart rate, and weight

2.3 Risk Analysis

The following are the three sub-blocks which equally pose the greatest risk to the development of this project:

Heating Regulation: We have narrowed our option to using either a heated coil or heated air flow. We are currently exploring both options in unison to determine which one would be safest for the baby but also cost-effective. This unit is controlled via a feedback loop. This implementation (normally done digitally) will depend on the robustness of our feedback network and on our signal integrity.

Micro-Controller Unit: The MCU is the controller and the data collection hub. The proper implementation of the MCU will be critical to achieve a fully functioning incubator. The functioning of this unit may prove to be our bottle-neck.

Signal Integrity and Integration: Ideally the sensors that we are working with would be placed on the same PCB, with minimum distance between the sensor and the microcontroller. As longer traces and wires are used signal delays and integrity becomes an issue. Wires and external circuitry can add stray inductance and this can lead to issues in receiving and sending signals. Since our sensors will be located some distance away from the PCB – near the infant and the incubator – we may face issues with getting the sensors to work in unison with the MCU.

Ethics

There exist many possible safety hazards with respect to our project, especially since its intended use is for extremely young infants. By choosing to power the incubator through the outlet, there are significant risks of electrocution and/or high temperatures, unless the voltage is successfully regulated, using transformers or Buck converters. Another issue would be the possibility of burns due to the heating mechanism of the device. In order to prevent this, we're going to perform robust testing and use metal meshes to separate the heating mechanism from any surface that the infant would have direct contact with. We're also measuring the temperature of the surface that the infant would be resting on, and are implementing an auto turn-off feature to turn off any heating mechanism if the measured temperature exceeds 37°C. Another safety measure we would take into account as to not harm the child's eyesight is to require any infant being placed in the incubator to be wearing standard shaded phototherapy goggles that blocks UV light shorter 500nm[15]. Though we plan to implement all of these safety features, no actual clinical trials on any living being will take place to ensure safe and ethical development practices[14].

In order to comply with the IEEE Code of Ethics[14] #2, safety warnings detailing risks of using this device to make sure all users are aware of the potential health and safety risks associated with it. We believe that our project, as a prototype of a medical device, exemplifies the importance of the health and safety of the public above all else and is therefore worth pursuing. Though we cannot control the user-base of the device being built, our goal is to discourage any possible discrimination against any race, religion, gender, disability, age, national origin, sexual orientation, gender identity, or gender expression[14] by making sure that if this project ever reaches market level, the product would be available for purchase

regardless of any discriminating factors. Every part of our development procedure is being documented formally to make sure that #3 (...honest and realistic in stating claims...) and #7 (...to seek, accept, and offer honest criticism of technical work…) of the IEEE Code of Ethics [14], to make sure that any scientific claims that are made during this project can be substantiated and verified by reliable sources.

For the scope of this class, we cannot adhere to all the FDA regulations for neonatal incubation devices [16], but the major issues mentioned above will be mitigated and in the future, more stringent restrictions can be put into place (e.g. physical durability restrictions, biocompatibility of materials etc)[16]. The clinical trial and FDA approval process generally takes several years, which is far beyond our time frame, so this device is intended to be a first prototype, as opposed to the final product. In future iterations of this project, when this initial prototype is taken to product-level the proper guidelines for regulatory bodies will be complied with, to ensure that no consumer would ever make use of the device before its safety is certified.

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