Neonatal Phototherapy and Vitals Monitoring Device

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Abstract

With the invention of blue LEDs, phototherapy for jaundice treatment is more cost-effective than ever. While several startups are taking advantage of this discovery and applying to healthcare in developing countries, all fail to include components for neonatal vitals monitoring and temperature regulation. Addition of these modules still allow the device to be low cost while attacking several problems healthcare providers in developing countries face, i.e., short-staffed in hospitals, inadequate or broken heating lamps for newborn babies, lack of thermometers, pulse oximeters, and beds despite a constant high influx of patients daily, etc. The solution we propose is a neonatal incubator which provides phototherapy, a regulated temperature environment, and monitors vitals of the infant in real-time. This device, while seemingly simple, is complex in the overall systems design, hardware, and integration and attacks several problems faced by hospitals in developing countries face today.

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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 µW/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).

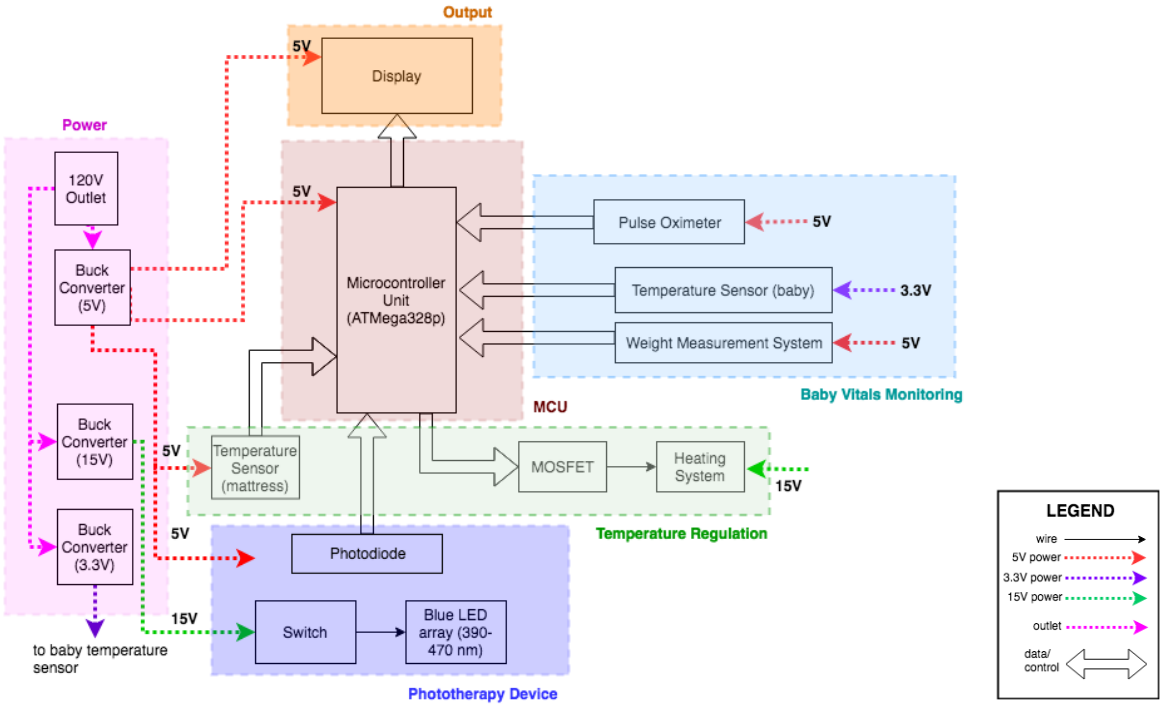

Figure 2.1.a: High level block diagram

2.2 Physical Diagram

The design of the structure is as follows: a plastic container is slotted into a wooden structure as shown below. Attached to this structure is a metallic arm, which supports a rectangular PCB with an array of LED's facing downwards. The arm is able to pivot outwards so that it would be easier to place the baby in or remove the baby from the incubator. Inside the plastic container, there are several levels. On the bottom, there is a wooden holding up a foam mattress containing a heating mechanism, as well as three temperature

sensors to measure surface/ambient temperature. The heating mechanism being used is a series of small heating pads being controlled by an automated feedback loop. Beneath the heating mechanism there's another wooden block fitted with force sensor to measure the infant's weight. The container also has an anklet attached to it, which is fitted with a temperature sensor and a pulse oximeter. The PCB with these sensors is circular so the infant is not exposed to any sharp edges. The data from the sensors are fed into a microcontroller. The PCBs and LCD are mounted onto a wooden base underneath the container.

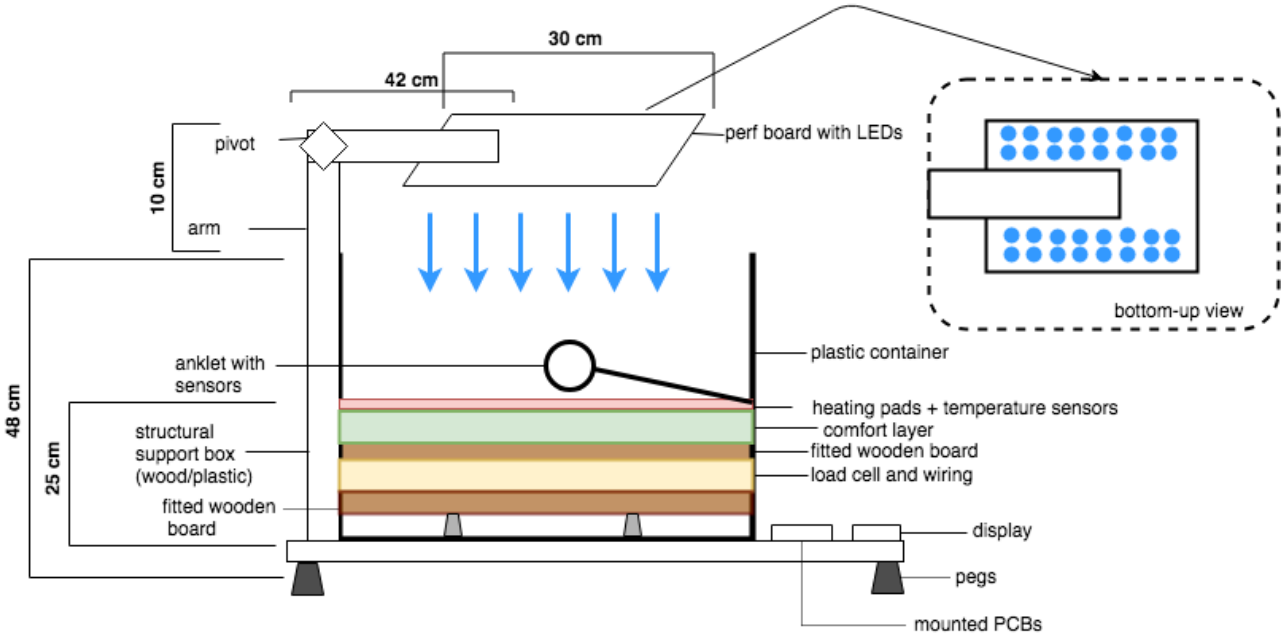

Figure 2.2.a: Physical diagram of the system

2.3 Module Design and Verification

2.3.1 Power

Power Design

The power circuit was chosen to possess a power supply from the wall outlet. As a design consideration, if this device were to be used in hospitals of developing countries, it would be optimal to use the wall outlet as a power source since this is the norm for medical devices and hospital equipment as this makes the device easier for troubleshooting and repairing. Since this device was made in the U.S., the outlet power used is the same for North and South America, however, simple changes would need to be made for the device if it were to be used in other continents.

We purchased a pre-assembled AC-DC power supply to step down from 120V AC to 15V DC. Our power stage originally consisted of an AC-DC power supply, followed by two buck converters stepped down the 15V inputs into 5V and 3.3V. The design will be specified as per Texas Instruments guidelines. The converters have most of their components integrated. In other words, resistors and capacitors are the only required passive components on the board. The values for all of the passive components match the specifications for the buck converter used (Figure 2.3.1a).

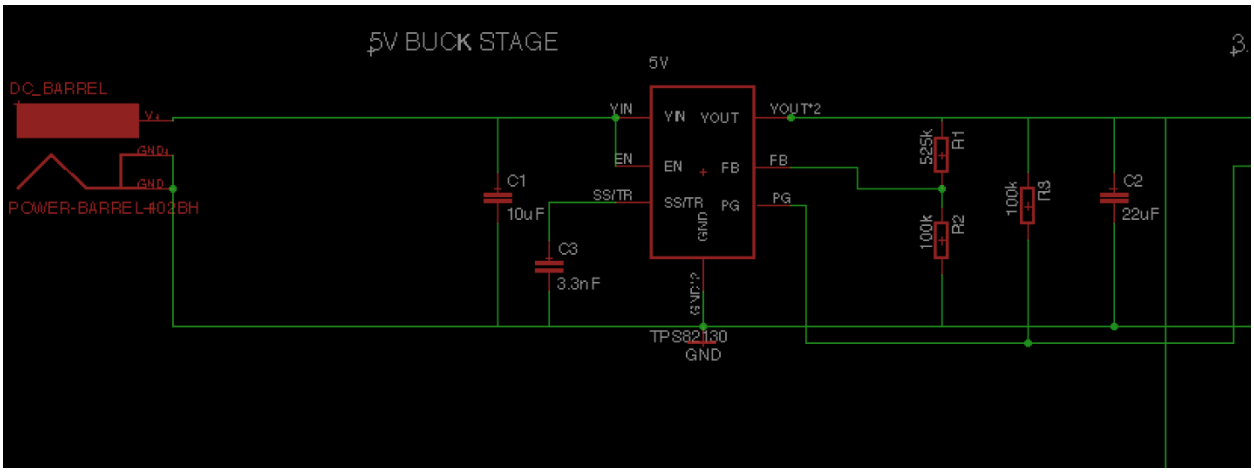

Figure 2.3.1a: Power Circuit PCB Layout for the 5V Buck Stage.

Due to the power profiles of all the modules, the power circuit is required to output 5V and 3.3V, therefore two buck stages were used. The specifics in the power consumption for each device was calculated and the type of AC-DC power supply was purchased accordingly (Table 2.3.1a). The array we choose to place the LEDs and pads was the largest power sink in our design. The other components are low power and have very little power consumption.

Table 2.3.1a: Power Consumption of Components

Component	V_{in} (V)	I_{in} (mA)	Quantity	I_{TOTAL}	Power (W)
Skin Temperature Sensor	3.30	.6000	1.00	0.0006000	0.00198
Ambient Temperature Sensor	3.30	.0045	3.00	0.0000135	0.00004455
Heating Pads	5.00	600.0	6	1.8000000	9
ADC	3.30	90.00	1.00	0.0900000	0.297
Instrumentation Amplifier	5	.0500	1.00	0.0000500	.00025
Load Cell	5.00	50.00	1.00	0.0500000	0.25
LCD Display Panel	5.00	1.600	1.00	0.0016000	0.008
Microcontroller	3.30	.2300	1.00	0.0002300	0.000759
Blue LEDs (200)	3.20	20.00	200.00	1.00	15
Buck Converter	5.00	.0200	3.00	0.0000600	0.0003
Op Amp Chip	5.00	.1700	3.00	0.0005100	0.00255
BJT	5.00	200.0	1.00	0.2000000	1
IR Sensor	5.00	50.00	1.00	0.0500000	0.25

Power Verification

The verification process to deliver the correct power within the required frequency were hindered by the lack of remaining in stock ICs. The PCB design for the buck converters were incorrect, resulting in the buck converters burning out without enough time to order more. As such we were unable to collect data on switching frequency as we had to use linear regulators instead to step down to the required rail voltages. As getting correct output voltages to power our device was the number one priority we were willing to operate

with a lower efficiency as long as we had functionality. We were successfully able to produce three rails with outputs 15V, 5.05V, and 3.35V. All of the voltage regulators were tested and resulted in the required voltage output ± 0.1V, therefore enabling integration of the power module with all of the other components of the system and resulting in successful verification of the power module despite the design change.

2.3.2 Pulse Oximeter

Pulse Oximeter Design

Normally, pulse oximeters measure blood oxygen saturation levels and heart rate using the reflectance of red and infrared (IR) light. The reflectance of these parameters directly corresponds to the amount of absorbance of red light into the blood, which, in turn, tells us the amount of bound hemoglobin on red blood cells and therefore the amount of blood oxygenation levels. However, for the purposes of our design, we are only measuring heart rate and not the additional blood oxygenation parameters. This decision was made because creating a device which accurately measures blood oxygen saturation levels would take a much longer time in addition to all the other modules.

Heart rate can be read by counting the peaks of the A/C signal of the reflectance of IR light off of the skin instead of needing the additional red light reflectance. Due to this, we chose to use the TCRT1000 sensor since it possesses an IR diode and a photodetector in one chip, and outputs a pulsatile 50-400 mV amplitude signal corresponding to heart rate [3]. The chip automatically filters noise above 40 Hz, therefore not requiring a 60 Hz notch filter. The signal outputted by the TCRT1000 has a DC and AC component, therefore filtration stages are implemented to filter out the DC signal (considered as unwanted noise since the DC component is simply skin impedance) and minimize noise. Figure 2.3.2a shows the overall schematic for the first design iteration of the pulse oximeter.

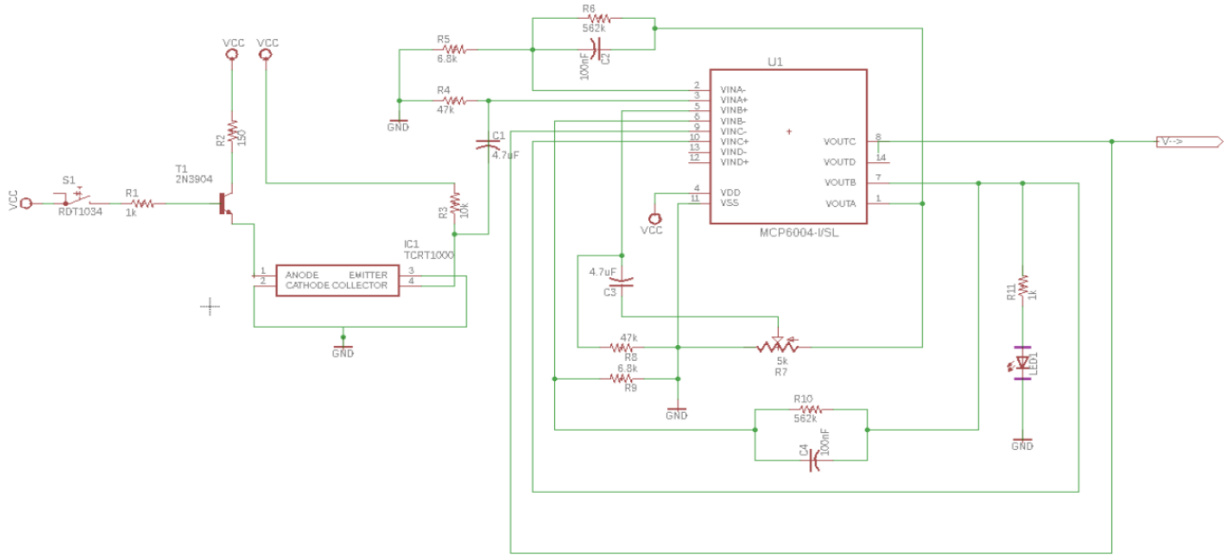

Figure 1.3.2a: Initial Pulse Oximeter Schematic. Two chips are used in the design: (1) the TCRT1000 sensor and (2) the MCP6004 operational amplifier for signal filtration and amplification.

In order for the microcontroller to accurately read the patient's heart rate, the ideal output signal for the pulse oximeter module will be a near transistor-transistor logic (TTL) signal. Therefore, clipping of the physiological signal is ideal so that the peaks of the A/C component can be clearly read. Designing the filtration portion of the circuit to have a high gain enables a near-TTL signal, allowing for a clear heart rate to

be read even in the presence of high noise (Fig. 2.3.2b). Cascaded filters are utilized in order to (1) increase the gain of the TCRT1000 output enough to be clipped and (2) narrow the bandwidth so that as much noise as possible can be filtered out. Enacting a cascaded filtration system allows for a narrower bandwidth, therefore refining the output signal of the pulse oximeter.

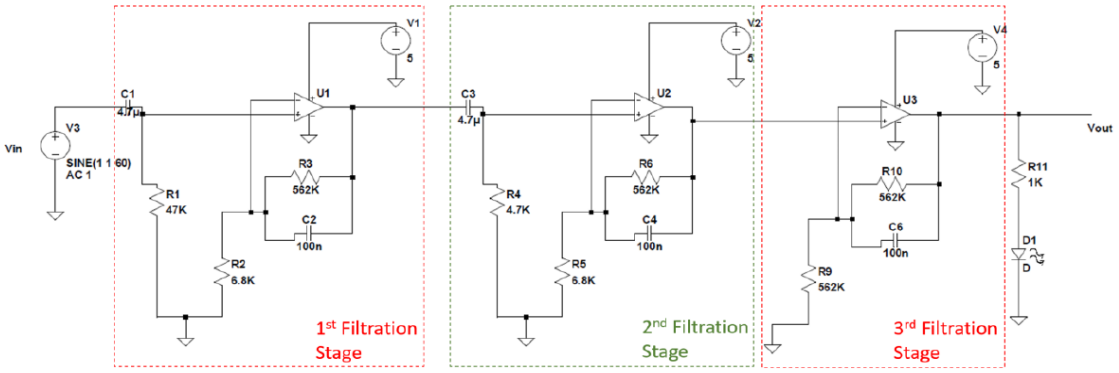

Figure 2.3.2b: Filtration Stages of the Pulse Oximeter Following the TCRT1000 Output. The three stages of bandpass filtration and amplification of the TCRT1000 output signal is shown. Vout leads to the microcontroller.

Since there may be fluctuations in the current into the pulse oximeter circuit, a BJT is used to steady the input signal and control the current into the TCRT1000 sensor (shielding the sensor from damage). After the signal from the TCRT1000 passes through the filtration stages, a non-inverting operational amplifier circuit with a gain of one is used to lower the current outputted by the overall pulse oximeter module in order to prevent damage to the microcontroller. Therefore, the systems interfacing the pulse oximeter are protected and vice versa.

Pulse Oximeter Verification

Testing of the first design of the pulse oximeter has shown successful results in terms of the verification and requirements previously set. To verify that the first pulse oximeter design passed the requirements, three main tests were performed. The first test validated that the TCRT1000 sensor was able to output an A/C pulsatile waveform with an amplitude of 0-400 mV. To test this, the output of the TCRT1000 was connected to an oscilloscope. Human data was collected over the span of about 3-5 seconds and the amplitudes were averaged. Table 3.2.3a shows the data collected from this testing procedure. As can be seen from the results, the output amplitude of the TCRT1000, while lower than expected, fall within the desired range.

Table 3.2.3a: Verification of the TCRT1000 Sensor.

	Repeat 1	Repeat 2	Repeat 3	Average Amplitude
Amplitude [mV]	50.5	70.2	40.1	53.6 ± 15.3

The second and third tests validated the performance of the pulse oximeter's overall output. The second test verified that the entire circuit outputs an A/C pulsatile waveform with an amplitude between 1.5-4.5 V, given that the voltage powering the circuit is 3.2-5.1 V. The third test verified that the entire circuit outputs a frequency of 0.7-2.83 Hz given that the sensor received human data (placed a finger on the sensor). For both tests, the pulse oximeter circuit was powered with 3.5 V. For testing methods, the pulse oximeter output was connected to an oscilloscope, data was collected for about 3-5 seconds, and the data (output amplitude and frequency, respectively) was averaged (Table 3.2.3b). Results show that the output heart rate is within the range we expect: 50-150 BPM.

Table 3.2.3b: Verification of the Overall Pulse Oximeter Circuit.

	Repeat 1	Repeat 2	Repeat 3	Averages
Amplitude [V]	3.46	3.47	3.46	3.463 ± 0.006
Frequency [Hz]	1.71	0.698	0.608	1.01 ± 0.61

Screenshots of the oscilloscope were also taken to verify that the output is pulsatile, clipped, and within the ranges desired (Fig. 2.3.2c). The pulse oximeter possesses the output desired in that the peaks can be clearly measured by a microcontroller, are clipped, and have an output voltage necessary to be read by the microcontroller. Therefore, according to all the requirements by the pulse oximeter module, the device can successfully and accurately measure the patient's heart rate (see Appendix A).

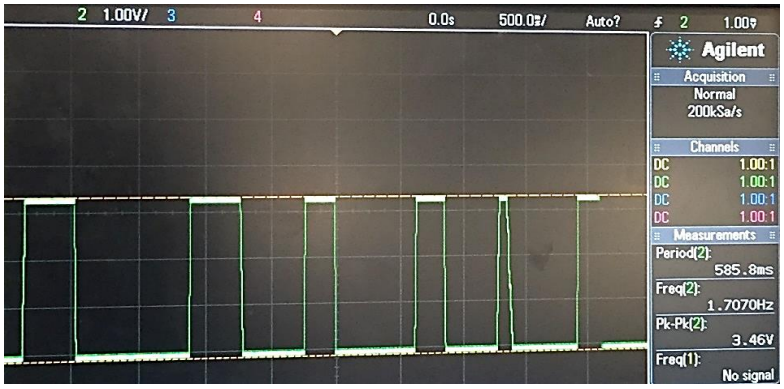

Figure 2.3.2c: Verification of the Overall Pulse Oximeter Output Signal.

Pulse Oximeter Software

The analog signal obtained from the pulse oximeter subsystem is the input to analog pin A0 of the MCU in order to calculate the heart rate.

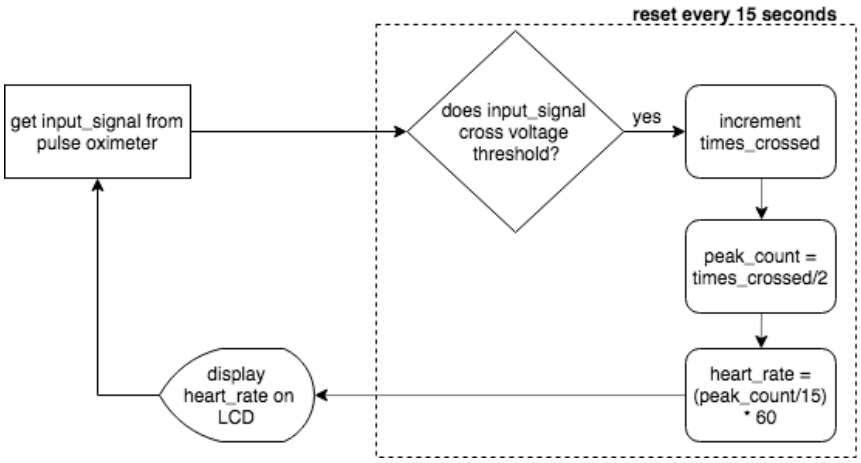

Figure 2.3.2d Heart Rate calculation algorithm

The algorithm counts the number of times the pulse signal crossed a certain voltage threshold obtained through experimentation to calculate the number of peaks that occur in 15 seconds, which corresponds to the number of heartbeats (Figure 2.3.2d). This data is then extrapolated to represent heart rate over 60

seconds by finding the number of beats per second and multiplying this value by 60. Appropriate delays are added in the code to avoid overcounting of peaks.

Table 2.3.2c: Verification of heart rate calculation by MCU

	Trial 1	Trial 2	Trial 3
Actual Heart Rate (BPM)	78	73	79
Output Heart Rate (BPM)	82	72	76

From the results it is evident that the MCU calculates the pulse rate within the accuracy of +/- 4.8%, which is within the required range detailed in the RV table (Table 2.3.2c) (Appendix A: Table 5).

2.3.3 Weight Measurement System

Weight Measurement System Design

A load cell module was used for the weight measurement system due to the norm of using load cells for measuring weight. Only one was needed due to the small weight of neonatal infants. However, this weight module needed to be calibrated to the needs of our system, the calculations of which are shown below.

The weight measurement system consisted of a Degraw 5kg straight bar micro load cell suspended between two layers of wood. The load cell directly connects to ground, Vin, and the microcontroller according to the specifications sheet. The load cell wheat-stone bridge captured the differential across the resistors when weight was applied. This allowed us to relate the output voltage with the weight of the object. The microscopic output of the load cell required an instrumentation amplifier to amplify the ΔV across the Wheatstone bride. With a 5V input we were able to meet the set requirements (see Appendix A).

$$.1\text{kg granularity} \Rightarrow \Delta\ .1\text{mV} \quad (1)$$

$$\text{ADC output} = \Delta V / (2^{\text{RESOLUTION}} * V_{\text{REFERENCE}}) \quad (2)$$

$$\text{ADC output} = .1 / (2^{14} * 3.3)$$

$$\text{ADC output} = 124$$

A change of .1V results in a change of binary 124 in the output of the ADC. This implies we need at minimum a gain of 100 to track the change. A higher gain would imply better tracking from our load cell. We can set our resistive values and gain with the following equation for our instrumentation amplifier:

$$\text{Gain} = 1 + (100k\Omega / R_g) \quad (3)$$

We set our gain by the selection of the Rg value. The chosen resistor value was 165 Ohms. We computed the gain by simply dividing our output voltage by our input voltage. This resulted in a calculated gain of 604.8. Again, this was within the required gain ranBut ge (see Appendix A).

Weight Measurement System Verification

The weight measurement system load cell was tested using a 5V input and placing several objects with known weights into the system. The conversion of voltage measured by the weight system to grams is shown in Eq. (4).

$$\left(\frac{Vin}{0.607}\right)1000 = weight\ [grams] \quad (4)$$

The results received from the load cell module had expected results well within the ±200 grams tolerance limit set in the high-level requirements (Table 2.3.3a). These results verify that the weight measurement system was successful in the module integration within the entire device.

Table 2.3.3a: Weight Measurement System Verification Results.

Item	Actual Weight	Scaled V_{out}	Measured Weight
iPhone	146 g	3.07 V	126.06 g
Textbook	610 g	3.38 V	637.89 g
Wooden Platform	4.93 kg	2.99 V	4.95 kg

2.3.4 Patient Temperature Sensor

Patient Temperature Sensor Design

The patient temperature is measured using a MAX30205 skin temperature sensor powered by a 3.3 V rail (Figure 2.3.4a). This sensor was chosen because it has a high-accuracy digital output and can communicate with the MCU using the I^2C protocol, thus eliminating the need for a designated analog input pin. The sensor also has an associated library developed for Arduino usage, so to read the temperature from the sensor, a simple call to a readCelsius() function is made that reads the binary output from the pertinent I^2C address (0x27) and converts it to a temperature reading in Celsius. When displaying on the LCD, 1°C is added to the final result to estimate body temperature as a more useful metric than skin temperature.

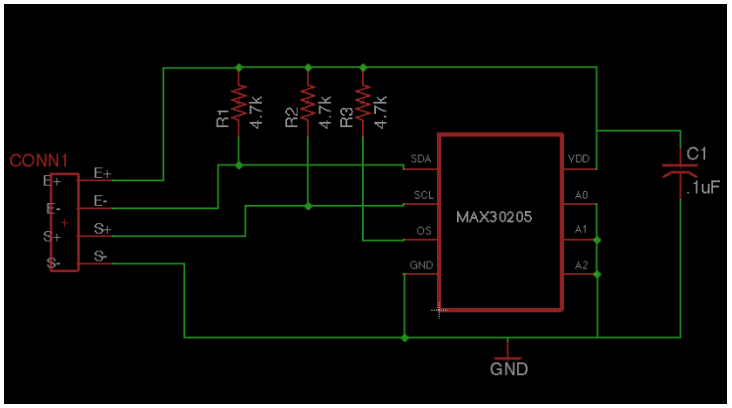

Figure 2.3.4a: MAX30205 PCB Layout.

Patient Temperature Sensor Verification

The skin temperature read from the sensor was verified against readings placed in the same position using a temperature probe. These values are without the addition of 1°C. For these readings the probe and the temperature sensor are placed under the arm of a human test subject (Table 2.3.4a).

Table 2.3.4a: Patient Temperature Sensor Verification Results.

	Trial 1	Trial 2	Trial 3	Trial 4	Trial 5
Temperature (MCU)/°C	33.57	35.78	34.67	35.20	34.23
Temperature (Probe)/°C	34.0	35.9	34.8	35.7	33.9

The values recorded from MCU are within +/- 0.5°C at the 3.3V input power level, thus fully meeting the requirements stated in the RV table for this subsystem (Appendix A: Table 3).

2.3.5 Microcontroller Unit

MCU Design

The MCU used in our device is the ATMega328p, powered by a 5V rail. There are several analog and digital inputs and outputs to the MCU as shown in Figure 2.3.5a. The MCU provides several integral functions, including reading the inputs from the various sensors, as well as running the feedback control loop for temperature regulation (Section 2.3.6) and heart rate calculation from the pulse oximeter subsystem (Section 2.3.2). While the pulse oximeter, force sensor, incubator temperature and photodiode are simple voltage analogRead() pin inputs to the ATMega328p, the MAX30205 skin temperature sensor and the LCD communicate with the MCU using the I^2C digital communications protocol.

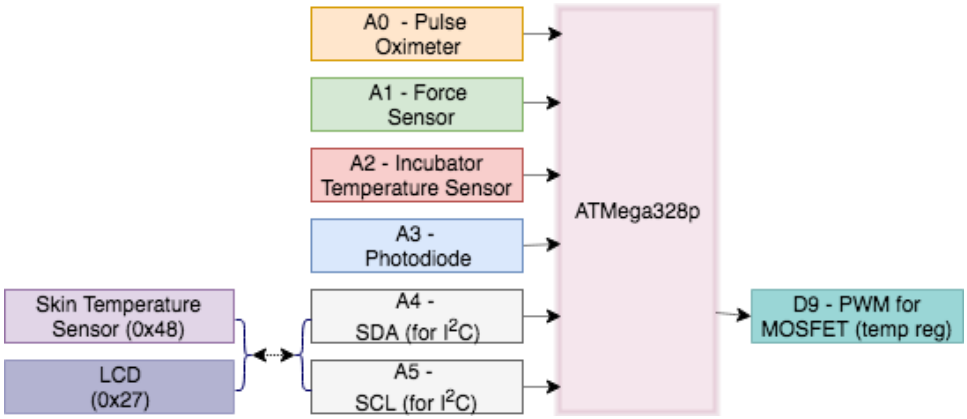

Figure 2.3.5a: Inputs and Outputs to the ATMega328p.

The MCU PCB has a fairly simple schematic, consisting primarily of the ATMega328p IC, a 16MHz oscillating crystal for timing purposes and some peripheral resistors and capacitors (Figure 2.3.5b). This design is the minimum required for the microcontroller to function as desired, limiting power consumption from any extraneous and unnecessary components. More complicated designs would allow for easier debugging, but adding to overall complexity and power consumption. Another iteration of the design was using the TI MSP430 family of microcontrollers, however issues arose in terms of software portability limiting the chip's reliability.

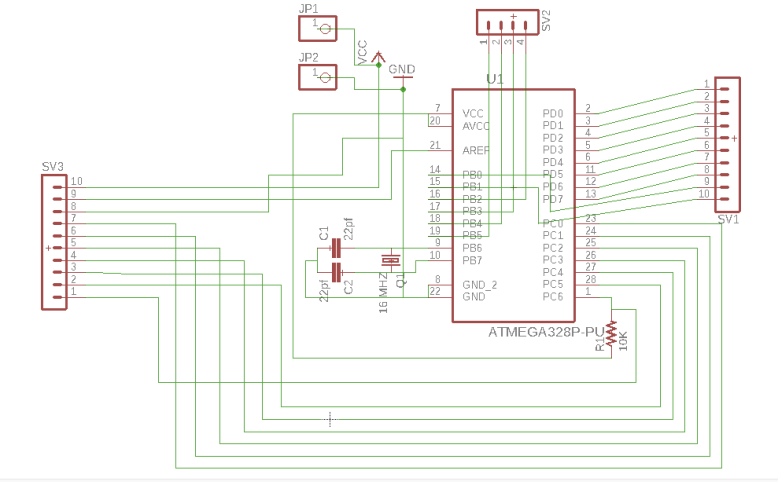

Figure 2.3.5b: PCB schematic for MCU system.

MCU Verification

The verification for the MCU comes through the verification of the other systems functioning as expected. The MCU itself has trivial verification (Appendix A: Table 5), as the requirements for storage capacity and operating frequency are inherently met through the ATMega328p chip and oscillating crystal. The verification for pulse calculation requirement is detailed in Section 2.3.2.

2.3.6 Temperature Regulation System

Temperature Regulation System Design

A major module in the device is the temperature regulation system. The surface contact temperature of the incubator must be maintained at 36°C ± 1°C to ensure a safe and stable environment for the infant. Providing heat in a system designed for infants is extremely dangerous, so when designing this system safety was a priority. These specific heating pads were chosen because of their heating profile – allowing them to cool down very quickly as soon as current stops flowing through the pads. Furthermore, they are well-insulated and safe-to-touch which both contribute to the safety of the system. Another design being considered was some form of heating lamp to maintain internal incubator temperature, however heat lamp-type systems are far more dangerous and must meet far stricter requirements from medical device regulatory bodies.

The design of the temperature regulation subsystem involves both hardware and software. The major components of the system are three TMP36 temperature sensors, and LM741 op-amp, a RFP30N06LE MOSFET, the ATMega328p microcontroller and SparkFun heating pads. The following algorithm is implemented on the ATMega328p MCU, which controls the PWM signal being output from digital pin 9.

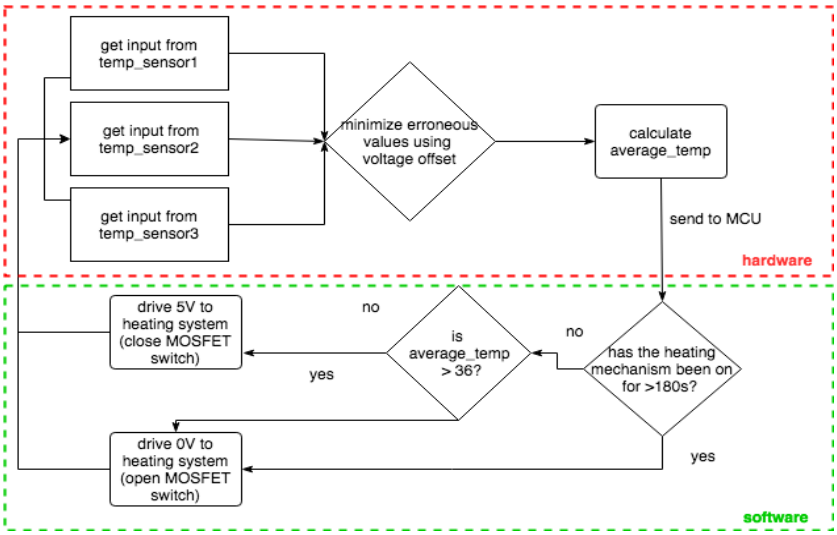

Figure 2.3.6a Control loop for temperature regulation

The flowchart in Figure 2.3.6a details the overall algorithm for the feedback loop used to regulate the surface contact temperature of the incubator. The average temperature of the incubator is measured using a system of 3 TMP36 analog temperature sensors with a voltage offset to minimize erroneous values (Appendix B)**.** This average temperature is fed into the MCU by connecting this voltage output to analog pin A2. To convert from the value read by the analogRead() function, Eq. (5) is applied.

$$ambTemp = \frac{\left(ambtempSensor * \frac{5.0}{1023.0}\right) - 0.5}{0.01} \quad (5)$$

According to the calculated value, the PWM is either set to 0 (always off) or 255 (always on). This drives either 0V or 5V out from pin 9 of the MCU. This is not sufficient, since the heating pads require a 15V power input. To account for this, instead of driving the heating pads directly, the MCU drives the source voltage to a RFP30N06LE logic level MOSFET (Figure 2.3.6b).

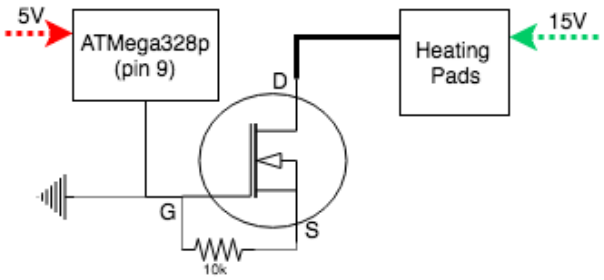

Figure 2.3.6b Circuit schematic for MOSFET system controlling heating pads

When 5V (PWM 255) is driven to the system, the circuit is completed through the ground of the heating pads, and they are turned on. Else, the circuit is incomplete and they remain turned off. In this design there are several major safety features that are implemented. The first is triple modular redundancy using 3 temperature sensors with a voltage offset to increase system reliability and ensure that the incubator does not overheat in the case of single sensor failure. The second safety feature implemented is a timer system, which asserts that the heating mechanism must turn off after a specified 180 seconds regardless of the feedback suggestion. This override ensures that the temperature does not exceed the recommended values

in the situation we have multi-system/sensor failure. Finally, to ensure we adhere to safety standards, the feedback loop for the temperature regulation system is implemented within the software. Having the feedback loop for the system within hardware can increase the chances of failure, due to shorter-life components thus potentially compromising the safety of the infant.

A design decision that was made was to average the three temperature sensors in hardware as opposed to software. The reason this decision was made was to limit the number of analog inputs going into the ATMega328p, since the chip is only fitted with 6 internal ADCs. However, in future iterations of this project the recommendation would be to obtain the temperature in software as it is more reliable and any inconsistencies in a single temperature sensor would be more immediately obvious.

Temperature Regulation System Verification

Table 2.3.6a: Temperature Regulation System Verification Results.

	0s	10s	30s	60s	180s	600s	1800s
Temperature (MCU)/°C	24.32	29.81	34.50	36.32	35.97	37.03	36.36
Temperature (Probe)/°C	24.1	29.4	34.5	36.1	35.9	37.0	36.2
Heating Pad Status (ON/OFF)	ON	ON	ON	OFF	ON	OFF	OFF

The results in Table 2.3.6a show that in surface contact temperature is maintained to 36°C ± 1°C with a temperature overshoot less than 2°C when applied 5V of power for 30 minutes (1800s) as stated in the RV table (Appendix A: Table 6). Figures 2.3.6c/d show these values on the LCD display, as well as the status of the heating pads in the bottom right corner.

Figure 2.3.6c: Display Showing Temperature Above 36°C. The display shows that when the temperature is above the threshold, the heating pads are turned off.

Figure 2.3.6d: Display Showing Temperature Below 36°C. The display shows that when the temperature is below the threshold, the heating pads are turned on.

2.3.7 Phototherapy Device

Phototherapy Design

The phototherapy unit is composed of a panel of 200 high powered blue (455-465 nm) LEDs and a photodiode to measure the intensity of the light given off by the LEDs. The number of LEDs used was primarily chosen by the amount of power consumption of the entire system; higher than 200 LEDs causes the system to draw too much power and would cause the cost to exponentially increase. The layout is of ten 4 x 5 grids of LEDs, where each row of four LEDs are independently connected (Figure 2.3.7a). This enables modularity in the system and minimizes failure of the entire panel in the case of a few LEDs failing.

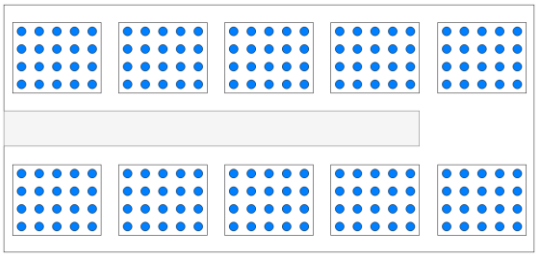

Figure 2.3.7a: Close-up layout of LED panel.

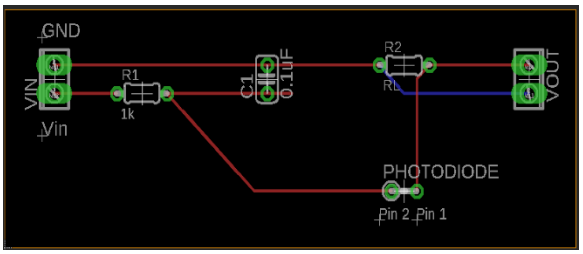

Figure 2.3.7b: Photodiode Circuit.

The photodiode measures the irradiance level of the blue LEDs hitting the surface where the baby would rest. This is to make sure that full dosages of phototherapy are being administered, to effectively treat jaundice. The voltage out of the circuit would be processed by the MCU and the irradiance level would be displayed on the LCD (Eq. 5). The photodiode had to be catered towards visible light in order to register the intensity of the blue light. For the final schematic, a load resistor of 0.5 MΩ was used in order for the output voltage to be high enough for the MCU to register variations and a resistivity value of 0.2499 A/W was used in MCU calculations, using Eq. (6), for the irradiance (Figure 2.3.7b).

$$Vout = P(Resistivity)R_L \quad (6)$$

Phototherapy Verification

Testing of the phototherapy system was mainly performed with the photodiode since the LEDs are known to output 455-465 nm. Since in the physical design, the infant is kept at a distance of 30 ± 5 cm away from the LED array, the photodiode registered the irradiance for this specified location in order to validate the jaundice treatment. For the treatment to be effective, the spectral irradiance has to be within the range of 15-40 µW/cm^2/nm and the photodiode has to accurately measure within this range by ±10% (see Appendix A). The results of the module were successful even with numerous locations of the photodiode, validating the photodiode's capacity and the ability of the LED array to generate enough irradiance to treat jaundice (Table 2.3.7a).

Table 2.3.7a: Photodiode Verification Results.

Photodiode Position:	**Irradiance [µW/cm^2/nm]**
Facing Ceiling	3.20
Facing Ground	0.33
Facing Ground w/ LEDs	21.61

2.3.8 Display

Display Design

The display is a simple 20x4 LCD connected to the ATMega328p microcontroller using the I^2C bus. It has the address 0x48. The initial design decision was to choose the smallest LCD screen that would successfully display all the required data to limit power consumption. Other iterations of the design could involve LED monitors, or even using Wi-Fi/Bluetooth to display the data to a computer. However, these technologies would add significant costs to the system which contradicts our goal of making this device cost-effective and accessible in developing countries. One recommendation would be to use a slightly larger LCD display – the final amount of data being displayed is much more than initially anticipated, thus the layout of information displayed is too compact.

Display Verification

As shown in Figure 2.3.6c and Figure 2.3.6d, the display outputs all pertinent metrics calculated by the microcontroller are clearly visible and understandable by the user, thus meeting all requirements (Appendix A: Table 8).

Cost

The total cost of the project includes labor costs shown in Eq. (7) and the bill of materials shown in Table 1.

$$\left(\frac{\$40}{hour}\right)\left(10\frac{hours}{week}\right)(9\ weeks) = \$3,600\ per\ person \quad (7)$$

$$(\$3,600\ per\ person)(3\ people) = \$10,800\ Total\ Labor$$

Table 1: Bill of Materials

Component	Part Identification	Quantity	Base Cost	Total Cost
Skin Temperature Sensor	MAX30205	1	$1.80	$1.80
Ambient Temperature Sensor	TMP36	1 package (1-9)	$3.50	$3.50
Heating Pads	Sparkfun	9	$4.95	$44.55
DAC	ADC121C021	4	$1.58	$6.32
Instrumentation Amplifier	INA333	1	$4.32	$4.32
Load Cell		1	$8.00	$8.00
N-Channel MOSFET		1	$0.95	$0.95
Photodiode		1	$15	$15
2.1mm Power Barrel	CUI Inc. PJ-202A	1	$0.60	$0.60
AC-DC Wall Adapter		1	$15	$15
LCD Display Panel	RioRand RRLCD204WB	1	$7.99	$7.99
Microcontroller	ATMEGA328P	1	$12.66	$12.66
Container	Generic	1	$6.50	$6.50
Blue LEDs	100F5T-YT-WH-BL	1 package (100)	$6.63	$6.63
Resistors			$2.00	$2.00
Comfort/Anklet Fabric	Generic	-	$10.00	$10
PCB	PCBWay Designed	3	$4.50	$13.50
Switches	MTS-5	4	$1.35	$5.40
Buck Converter	TI TPS82130	3	$5.03	$15.09
Op Amp Chip	MCP6004	1	$0.89	$0.89
5k Potentiometer		1	$3.12	$3.12
Red LED	Generic (from lab)	1	$0.05	0.05
BJT	2N3904	1	$0.10	$0.10
IR Sensor	TCRT1000	1	$1.26	$1.26
4 Lead Connector/Jumper		1	$3.00	$3.00
Total Cost		---	---	**$188.23**

Total Cost: $10,800 + $188.23 = 10,988.23

Conclusion

This project was made in compliance with the IEEE Code of Ethics. Adhering to the safety of the patient is considered the utmost importance [14]. Therefore, we hope to provide safety warnings on the device during use in order to advise the user of potential safety risks [14]. However, from a medical device perspective, this project does not need to undergo high regulation standards since high voltage nor current will not be near the patient and only physiological data will be recorded from the patient. Therefore, there are no substantial safety risks to using the device. Additionally, extensive documentation has been kept in order to adhere to the honesty standards set forth by the IEEE Code of Ethics [14]. This is to ensure that the building of the device is validated by reliable sources and by the extensive testing done through prototype iterations.

Overall, while there were many unexpected obstacles faced in creating the neonatal phototherapy and vitals monitoring device, in the end we were successful in complete system integration. Most requirements and verification points were met in addition to systems engineering and design concepts which were necessary to consider for the device considering its application use. The neonatal incubator is meant to provide phototherapy, a regulated temperature environment, and real-time vitals monitoring of the infant. Interviews of nurses and doctors in Juan Antonio Brenes Palacio Hospital in Somoto, Nicaragua, revealed several design constraints which need to be considered for medical devices, such as modularity, low-cost, open design, and simple user interface. All modules within the device directly target common issues hospitals in developing countries face, namely: short-staffed in hospitals, inadequate or broken heating lamps for newborn babies, lack of thermometers, pulse oximeters, and beds despite a constant high influx of patients daily. Additionally, jaundice is known to cause 5-10% of newborn mortality worldwide [2]. All these major problems were key targets in our solution. The neonatal phototherapy and vitals monitoring device solves several issues hospitals in low-resource environments face today.

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Appendix A: Requirements and Verification Tables

Power Verification Table

Table 1: Power Module Requirements-Verification Table

Module	Requirement	Verification
Power Block (4 points)	1. Buck converters must demonstrate slow startup 2. Demonstrate ≤ 10% steady state voltage deviation 3. Nominal operation at 2 ± .4 MHz switching frequency 4. Supply: ○ 15 ± 1.5V rail ○ 5 ± .5V rail ○ 3.3 ± .3V rail	1) a. Looking on the oscilloscope for a single startup cycle we should see that the buck converter start-up should show linearity 2) a. The steady state output on the oscilloscope for the buck converter should remain within the absolute value of 10% of its input 3) a. Looking at the PWM/PFM operation of the device, we should be able to distinctly show on the oscilloscope that at full load the frequency of the output signal is near 2MHz. 4) a. The output rails can be tested with test points that will be on the PCB. Checking these test points with a multimeter should show the follow rail specifications.

Pulse Oximeter Verification Table

Table 2: Pulse Oximeter Requirements-Verification Table

Module	Requirement	Verification

Pulse Oximeter (10 points)	1) The TCRT1000 outputs an A/C pulsatile waveform with an amplitude of 0-400 mV 2) Whole schematic outputs an A/C pulsatile waveform with an amplitude between 1.5-4.5 V, given input 4.8-5.3V. 3) Whole schematic outputs a frequency of 0.7-2.83 Hz given an adult human subject	1) a. Connect the TCRT1000 output to an oscilloscope. b. Collect data from a human subject over the span of 3-5 seconds. c. Average the amplitudes of the waveform. 2) a. The input voltage and current would be measured using an oscilloscope, making sure that the pulse oximeter gives valid results sweeping over the given voltage range. b. Connect the pulse oximeter output to an oscilloscope. c. Collect data from a human subject over the span of 3-5 seconds. d. Average the amplitudes of the waveform 3) a. Connect the pulse oximeter output to an oscilloscope. b. Collect data from a human subject over the span of 3-5 seconds. c. Find the average frequency of the waveform.

Patient Temperature Sensor Verification Table

Table 3: Patient Temperature Sensor Requirements-Verification Table

Module	Requirement	Verification
Patient Temperature Sensor (3 points)	1. Detect skin temperature ± 0.5°C given input voltage 2.7-3.3V, 600 uA.	a. The input voltage and current would be measured using an oscilloscope, making sure that the temperature sensor gives valid results sweeping over the given voltage range. b. Body temperature data will be collected from a human test subject using an infrared thermometer c. The temperature readings from the patient temperature sensor would be read by connecting it to a computer via standard breadboard d. The values from the sensor and the infrared thermometer are similar within the given error range, then the device is verified. e. This procedure will be repeated several times to ensure reliability.

Weight Measurement System Verification Table

Table 4: Weight Measurement System Requirements-Verification Table

Module	Requirement	Verification
Weight Measurement System (3 points)	1. Must be able to output weight up to 4kg ± 0.2kg given input voltage 4.8-5.3V 2. We will output a desired gain of 600 ± 2.5% error 3. The weighing system should output 3V at maximum force 4. Granularity minimum of .1kg. A .1kg weight change should be displayed accurately	a. The input voltage and current would be measured using an oscilloscope, making sure that the load cell gives valid results sweeping over the given voltage range b. We will place a 4kg weight to verify. The maximum expected weight of new born is 4 kg c. Divide V_{out}/V_{in} of the amplifier to find gain d. Placing 5kg on the scale should output 3V ± .2kg e. Placing a 100g weight should be reflected on the scale

MCU Verification Table

Table 5: Microcontroller Unit Requirements-Verification Table

Module	Requirement	Verification
Microcontroller Unit (10 points)	1. The microcontroller turns on given input voltage 4.8 - 5.5V. 2. Microcontroller operates at 16MHz frequency 3. The microcontroller can store up to 16kB±5% of data (an estimate for the maximum storage size of all required programs) 4. The microcontroller can successfully process code and function according to programmer's specifications 5. Must be able to calculate human pulse rate with accuracy±8%	1) a. The input voltage and current would be measured using an oscilloscope, making sure that the MCU turns at all voltages in the range. 2) a. A program with timers would be coded, one using the on board 32kHz clock from a microcrystal, and one using the high speed clock at 16MHz. The timing differences would then be compared to see if the range is valid. 3) a. The microcontroller will be loaded with a program with a known size of slightly below 16kB (since the 16kB will not be completely available). The program must successfully run to completion in order to verify functionality. 4) a. A simple "hello world" program will be written in C and tested on a known working platform. This program would then be loaded onto the microcontroller, with the output pins connected to the computer to verify that the program runs as

		expected. This may be repeated using other simple programs such as adding two integers, blinking LED's etc. 5) a. The input voltage and current would be measured using an oscilloscope. b. A program following the flowchart shown in Section 2.4 (Software Flowcharts) will be loaded onto the MCU. c. The pulse oximeter will be attached to a human test subject. d. Simultaneously the human test subject will be wearing a heart rate monitor. e. The output voltage as well as calculated bpm will be displayed on an oscilloscope/computer. f. The calculated values will be compared to those from the heart rate monitor. If the bpm's match within the accuracy range, the device is verified. g. The procedure will be repeated several times to ensure reliability.

Temperature Regulation System Verification Table

Table 6: Temperature Regulation Requirements-Verification Table

Module	Requirement	Verification
Ambient Temperature Sensor (5 points)	1. Must be able to detect ambient temperature ±1°C given input voltage 1.9-5.5V at 3.5uA current.	a. The input voltage and current would be measured using an oscilloscope, making sure that the temperature sensor gives valid results sweeping over the given voltage range. b. The temperature of the incubator will be measured in 3 different locations for a duration of 60 minutes, while the heating system is turned off. c. This will be recorded using an electronic temperature measurement system, and recorded using a data logging software. d. If the temperatures over the 60 minutes measured by the designed system correspond to the values obtained from the electronic measurement system within the specified error range, the device is verified. e. The experiment will be repeated to ensure reliability.

Heating Mechanism (1 point)	1. Must be able to maintain ambient temperature of the incubator at 36°C ± 1°C for 30 minutes, given input voltage of 4.8 - 5.3V. 2. Overshoot of the temperature within the incubator should not be greater than 2[Symbol]C	1) a. The input voltage and current would be measured using an oscilloscope, making sure the heating pads show valid temperature increases with a sweep over the 4.8-5.3V voltage range. (**exact temperature range unspecified on datasheet, will be obtained through testing) b. The temperature of the incubator will be measured in 3 different locations for a duration of 30 minutes, while the heating system is turned on and connected to the MCU. c. This will be recorded using an electronic temperature measurement system(**pending specifications and approval from UIUC physics dept.), and recorded using a data logging software. d. If the temperature is over the 30 minutes measured by the designed system correspond to the values obtained from the electronic measurement system within the specified error range, the device is verified. e. The experiment will be repeated to ensure reliability. 2) a. Measuring the overshoot of the system will consist of using an external temperature sensor and computer. b. We will turn on the incubator and record the data from the external , testing sensor. c. When graphed, we will be able to record our overshoot.
Timer Mechanism (1 point)	1. Must be able to override the temperature sensors and turn off the heating mechanism after a specified time around 90 seconds (exact time to be determined after manual testing). Current flowing through heating pad is close to 0 (exact value unspecified on data sheet, will be calculated after manual testing).	a. The input voltage and current would be measured using an oscilloscope. b. A program with an algorithm that drives the output voltage to 0V after a specified time will be coded onto the MCU.

Phototherapy System Verification Table

Table 7: LED array Requirements-Verification Table

Module	Requirement	Verification
Blue LED Array (8 points)	1. Must be able to emit 390-470 nm wavelength light and 20-45 µW/cm²/nm irradiance level at a 30 ± 5 cm distance, given input voltage 3.0-3.2V, operating at 20 mA.	a. The input voltage and current would be measured using an oscilloscope, making sure all LEDs turn on with a sweep of voltage between 3.0-3.2V. b. The distance is verified by virtue of the dimensions of the whole product, the position of the LED array is at a static height. c. A spectroradiometer (pending specifications and approval from UIUC physics dept.) probe will be placed in 3 different locations on the surface where the baby would be placed. d. The LED array would be turned on and measurements for spectral irradiance will be taken directly under the LEDs as well as at the peripherals, using barriers to mitigate effects arising from room lighting.
Photodiode (2 points)	1. Must be able to correctly detect irradiance (±10%) given input voltage between 3.0-3.3V.	a. The input voltage and current would be measured using an oscilloscope, making sure all LEDs turn on with a sweep of voltage between 3.0-3.3V. b. The distance is verified by virtue of the dimensions of the whole product, the position of the LED array is at a static height. c. A spectroradiometer (pending specifications and approval from UIUC physics dept.) probe will be placed in 3 different locations on the surface where the baby would be placed. d. The irradiance level from the photoresistor would then be compared with that obtained from the spectroradiometer.

Output Display Verification Table

Table 8: Display Module Requirements-Verification Table

Module	Requirement	Verification
Display (3 points)	1. Must be able to display the human subject's skin temperature (±0.5°C), heart rate (±10%), weight between 1-4 kg (±200g) and irradiance simultaneously, with a given input voltage 5.0-5.5V.	a. The input voltage and current would be measured using an oscilloscope, making sure that the characters on the LCD display are clearly visible from a 40cm distance over the whole voltage range. b. Initially the output of the MCU detailing the baby vitals would be displayed on a laptop using a USB/UART connection.

		c. The values displayed on the laptop would be cross-checked against the values being displayed on the 20x4 LCD display. d. If the values match given error ranges, the device is verified.

Appendix B: Diagrams and Figures

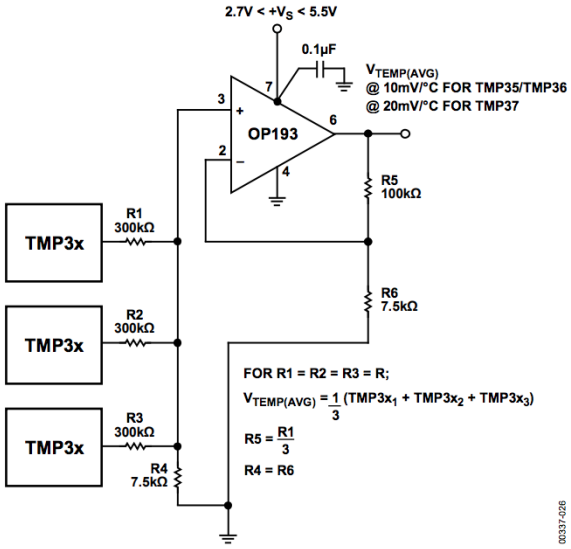

Figure 28. Configuring Multiple Sensors for Average Temperature Measurements