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 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).

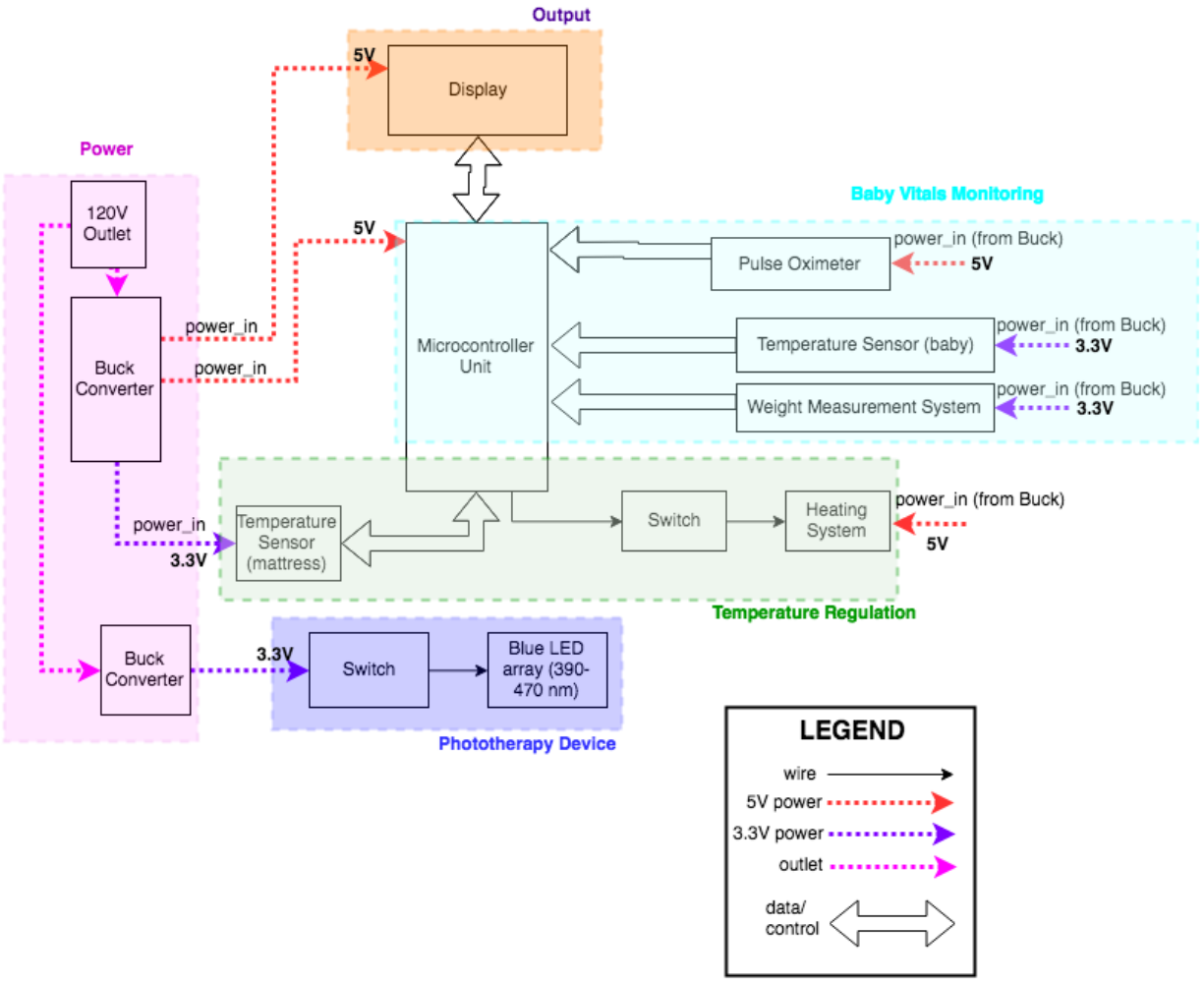

Figure 2.1.a: *High level block diagram*

2.2 Physical Diagram

The design of the structure is as follows: a plastic container would be slotted into a wooden structure as shown below. Attached to this structure is a wooden arm, which supports a rectangular PCB with an array of LED's facing downwards. The arm would be 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 metal mesh holding up a heating mechanism. The heating mechanism being used is a series of small heating pads being controlled by an automated feedback loop. On top of the heating mechanism there's another metal mesh holding up some comforting material fitted with load cells to measure the infant's weight, as well as 3 temperature sensors to measure surface/ambient temperature. The container will also have an anklet attached to it, which is fitted with a temperature sensor and a pulse oximeter. The data from the sensors would be fed into a microcontroller. The PCB with the microcontroller as well as a large part of the wiring would be contained in a box attached to the outside of the structure. Finally, there will be a LCD module attached to the outside of the structure to display the vitals (weight, temperature and heart rate) of the baby.

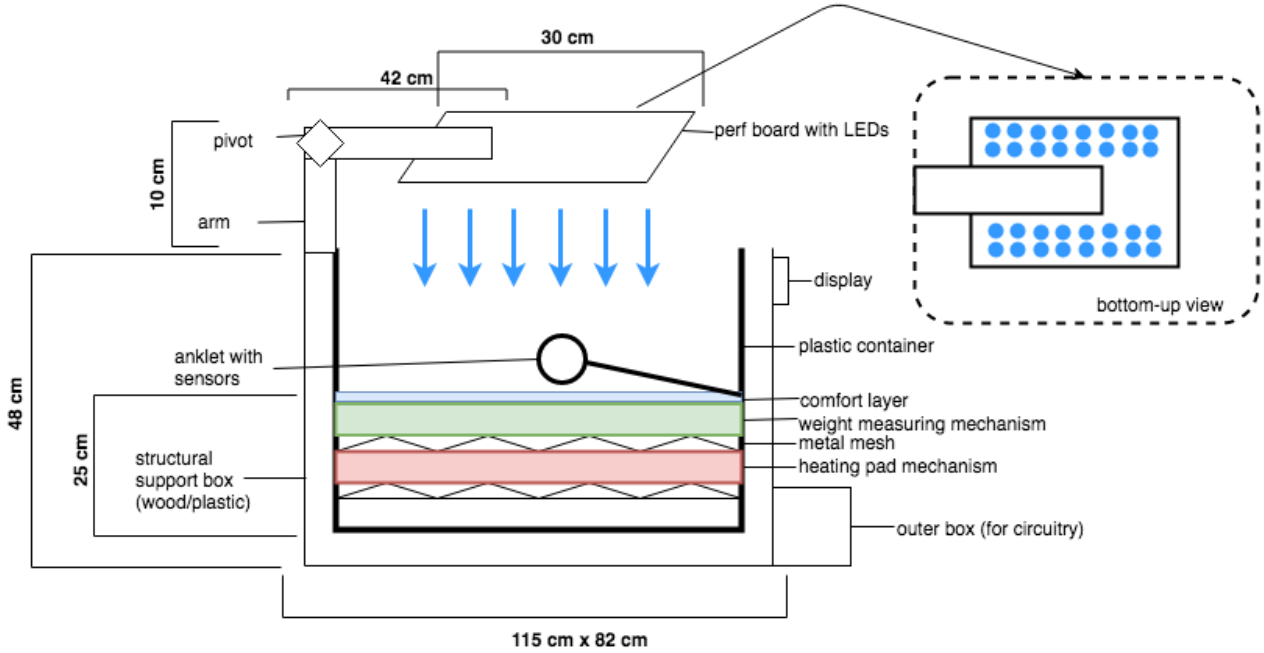

Figure 2.2.a: *Physical diagram of the system*

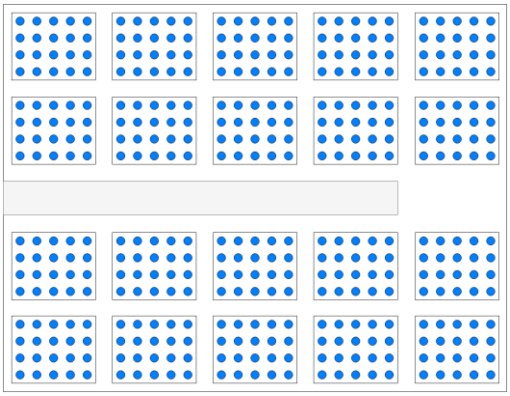

Figure 2.2.b: *Close-up layout of LED panel*

2.3 Functional Overview/Requirements

2.3.1 Power

There are a larger number of pieces on the board that each consume different amounts of power. As we are using an outlet, we intend to purchase a pre-assembled AC-DC power supply to step down from 120V AC to 15V DC. Our power stage will consist of an AC-DC power supply, followed by 2 buck converters that will step down the 15V inputs into 5V and 3.3V, given $\pm$ 10% margin.

The buck converters are 3A maximum buck converters, that should be more than sufficient for the purposes of this project. We will need to ensure that the converters are switching at the correct frequency and produce stable outputs within the steady state requirements.

Module	Requirement	Verification
Power Block	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.

The power profiles of our devices can be found below:

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	3.00	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	80.00	1.6000000	5.12
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

This power profile is not static as we are currently in the process of rearranging the LEDs and heating pads to maximize efficiency and minimize cost. The array we choose to place the LEDs and pads will be the largest power sink in our design. The other components are low power and have very little power consumption.

2.3.2 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. This heart rate can also be found by the following equation: 60*f = BPM (beats per minute). Exact 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].

An example output for a pulse oximeter is shown below (Figure 2.3.a). Counting the peaks for the pulsatile signal will correlate to heart rate of the patient.

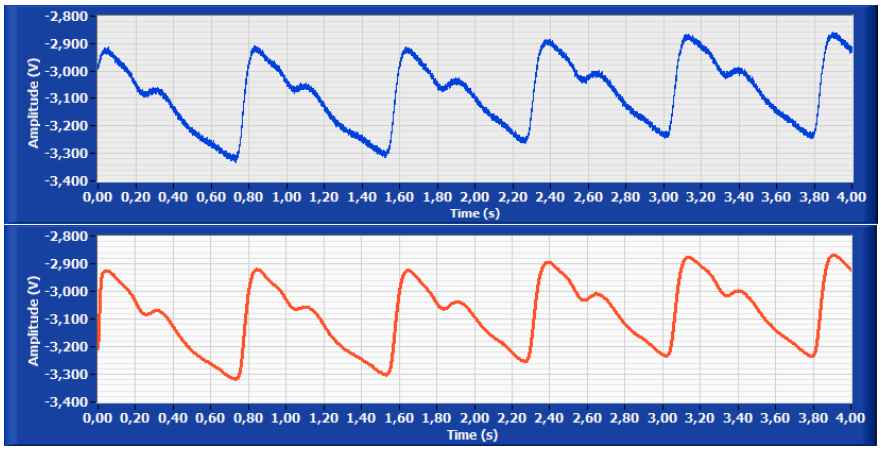

Figure 2.3.a *Pulse Photoplethysmograph (PPG) Signal. (Top) Raw PPG signal. (Bottom) Filtered PPG Signal. [17]*

Module	Requirement	Verification
Pulse Oximeter	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

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.

Module	Requirement	Verification
Patient Temperature Sensor	1) Detect skin temperature $\pm$ 0.5°C given input voltage 2.7-3.3V, 600 uA. (**Integrated ADC makes it difficult to test voltage-temperature relation. Output of the temperature sensor is in binary directly corresponding to °C)	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.

2.3.3 Weight Measurement System

We will be using a 5kg straight bar micro load cell. The load cell will rest between two trays of wood, suspended 1 inch from both pieces (as per the sensor specifications). We will calibrate the sensor to a value of zero on an empty bed. The data from this sensor will be sent to the MCU and displayed. This device will require an instrumentation amplifier to amplify the ΔV from the change in resistance of the Wheatstone bride. We will be using Texas Instruments INA333 precision instrumentation amplifier. The load cell and amplifier will have 5 $\pm$ .1 V input.

Module	Requirement	Verification
Weight Measurement System	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 $\pm$ .25% error	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

	3. The weighing system should output 3V at maximum force 4. Granularity minimum of .1kg. A .1kg weight change should be displayed accurately	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 $\pm$ .2kg e. Placing a 100g weight should be reflected on the scale

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

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

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

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

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:

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

2.3.4 Microcontroller Unit

The MCU will be 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.

Module	Requirement	Verification
Microcontroller Unit	1) The microcontroller turns on given input voltage 3.3-3.6V. 2) Microcontroller operates at 16MHz frequency 3) The microcontroller can store up to 16kB±5% of data 4) The microcontroller can successfully process code and	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

	function according to programmer's specifications 5) Must be able to calculate human pulse rate with accuracy±8%	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.

2.3.5 Temperature Regulation System

We plan on using this temperature sensor specifically to measure the temperature of the surroundings. We intend to use a temp sense IC as these are simpler to use, operate with low power, and are accurate for our endeavor. We plan to implement triple modular redundancy using 3 temperature sensors to increase system reliability and ensure that the incubator does not overheat in the case of single sensor failure. In this system, the values from the 3 temperature sensors will be fed into the microcontroller and the average of the two closest values will be taken. By doing so we will be eliminating anomalies and providing forward error correction. The second safety feature being implemented is a timer system, which asserts that the heating mechanism must turn off after a specified period of time (determined after testing) regardless of the feedback suggestion. This override will ensure that the temperature does not exceed the recommended values in the situation we have multi-system/sensor failure.

To ensure we adhere to safety standards, the feedback loop for the temperature regulation system will be implemented within the software (see Section 2.4). Having the feedback loop for the system within hardware can increase the chances of failure, which would possibly endanger the safety of the infant.

Module	Requirement	Verification
Ambient Temperature Sensor	1) Must be able to detect ambient temperature ±1°C given input voltage 1.9-5.5V at 3.5uA current. (**Output of the temperature sensor is in binary directly corresponding to °C)	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 (**pending specifications and approval from UIUC physics dept.), 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) Must be able to maintain ambient temperature of the incubator at 37°C ± 1°C for 60 minutes, given input voltage of 4.8 - 5.3V. 2) Overshoot of the temperature within the incubator should not be greater than 2°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 60 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 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. 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) 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.

2.3.6 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 large PCB 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 losing power in the situation a few LED in series lose power.

The justification for the chosen appropriate spectral irradiance comes from the following figures.

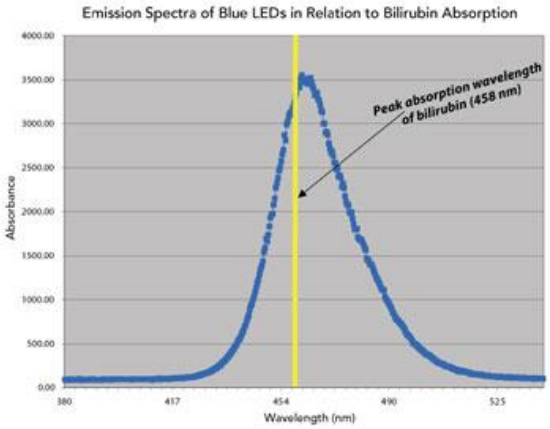

Figure 2.3.a: *Absorption of bilirubin vs phototherapy wavelength [21]*

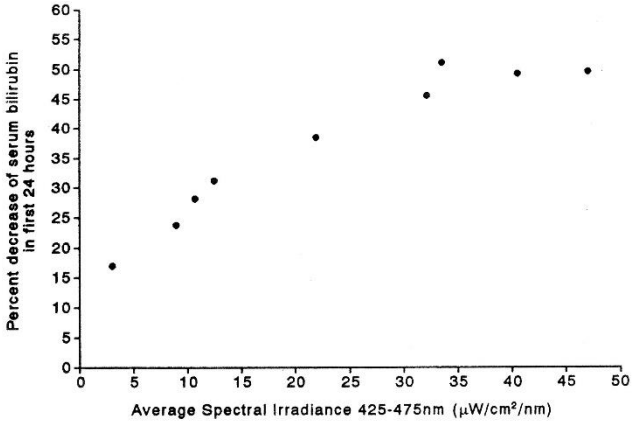

Figure 2.3.b: *Absorption of bilirubin vs spectral irradiance [22]*

Module	Requirement	Verification
Blue LED Array	1. Must be able to emit 390-470 nm wavelength light and 20-45 $\mu W/cm^2/nm$ 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.

2.3.7 Output Display

Powered by a 5V rail. The display will most likely be a 20x4 LCD. The display will have to hold the signal it receives. Thus the LCD display will need an integrated data line. The data line will be a one way communication channel that the display will hold.

Module	Requirement	Verification
Display	1. Must be able to display the human subject's skin temperature (±0.5°C), heart rate (±10%) and weight between 1-4 kg (±200g) 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.

2.4 Software Flow Charts

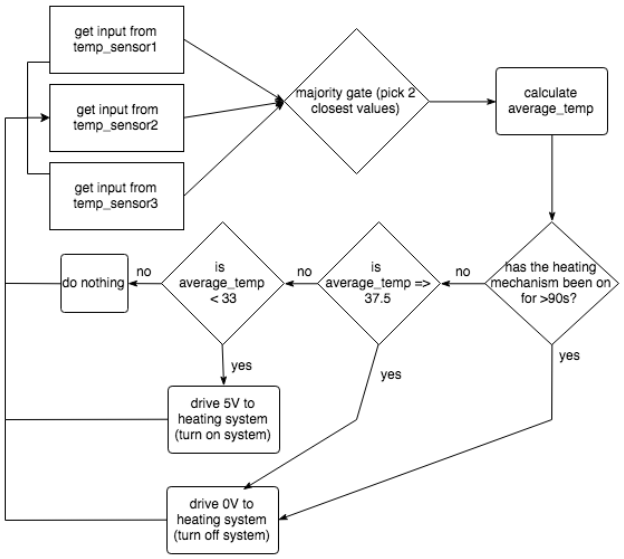

Figure 2.4.a: *Heating system feedback loop algorithm*

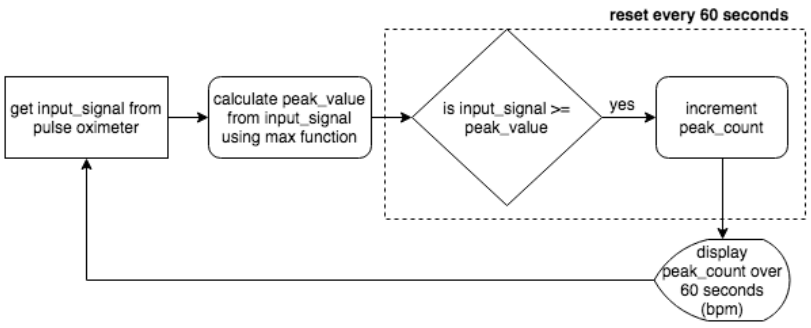

Figure 2.4.b: *Pulse oximeter beats per minute calculation algorithm*

The heating system feedback loop will be critical to the performance of the incubator. Based on the data we get from the 3 temperature sensors, we plan to choose the two closest temperatures to protect against any single outlier. With the average of the previously two selected temperatures we will determine whether to turn on or off the heater based on our upper and lower temperature thresholds. This rudimentary feedback loop has proven to be effective with lightbulbs and we expect to see similar results in our project. Nonetheless, we plan to test our heating pads response prior to this form of implementation, and expect to see a first order system. We are currently waiting to receive the pads. Finally, in the situation multiple sensors fail, we plan to use a time as a redundancy check to ensure that the pads have not been on for too long. If the clock exceeds a certain threshold time, the MCU will override the feedback circuit and turn off the heating pads.

The pulse oximeter beats per minute calculation would be done by getting an input signal from the pulse oximeter. This signal would be in the form shown in Figure 2.8.e, with distinct peaks. These peaks represent pulses, and they must be measured over one minute intervals to return the metric in beats per minute. This algorithm finds the approximate value of the peak signal, using a timer to start/stop counting over a period of one minute. This value is calculated in the MCU and then displayed on the LCD monitor.

2.5 Schematics

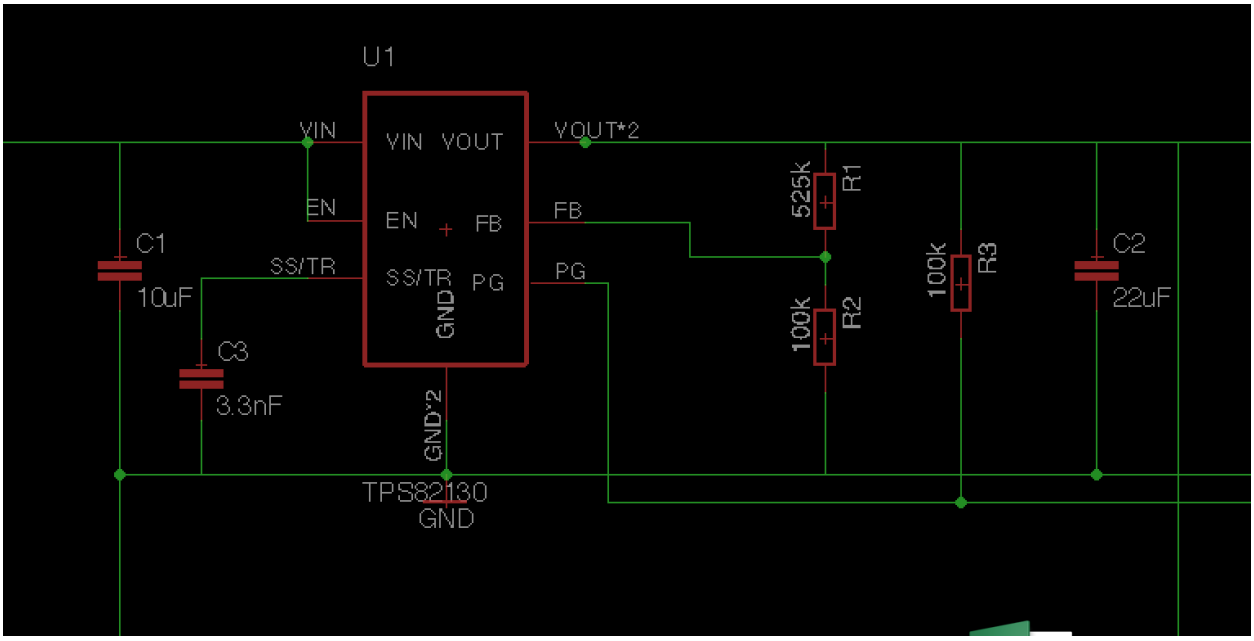

Figure 2.5.a: *5V output buck stage*

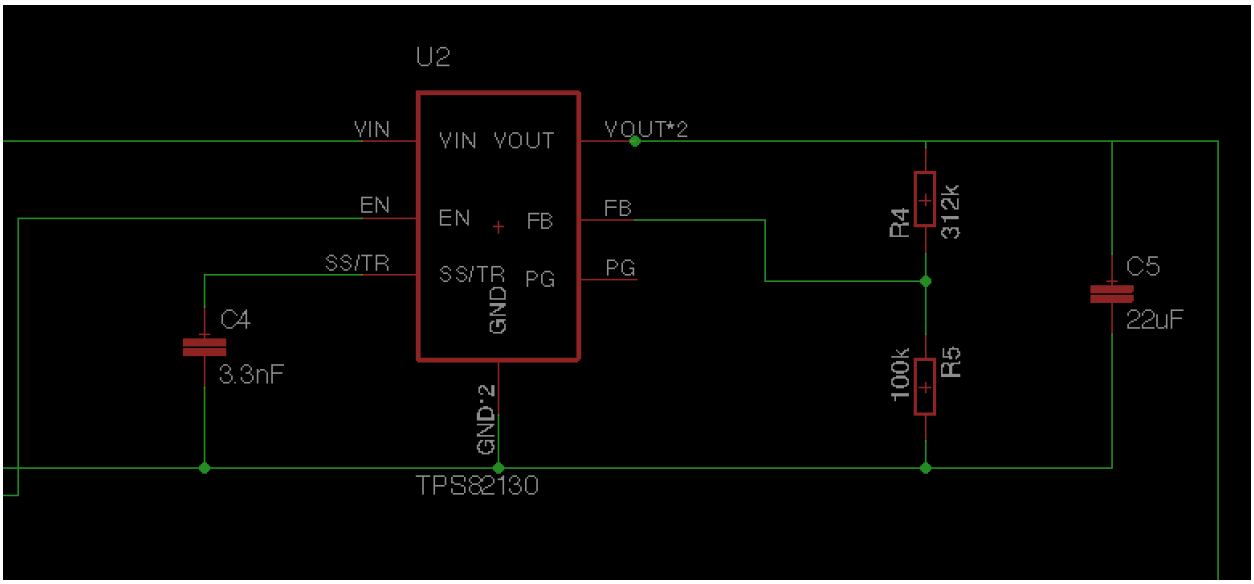

Figure 2.5.b: *3.3V output buck stage*

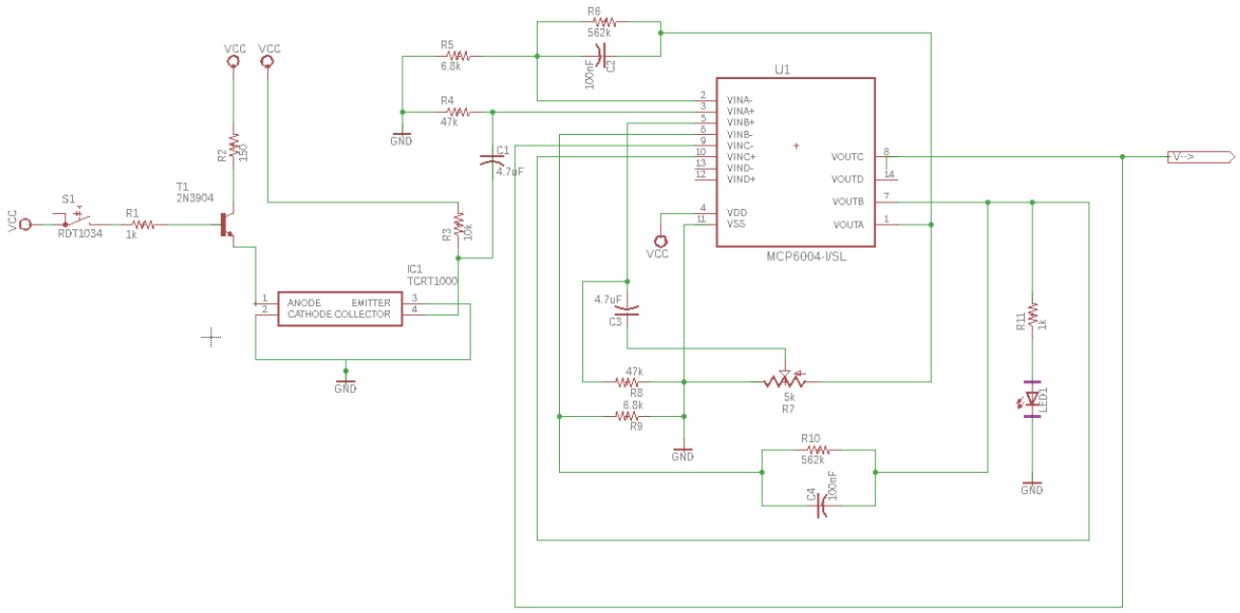

Figure 2.5.c: *Pulse Oximeter*

2.6 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.

2.7 Calculations and Simulations

2.7.1 Pulse Oximeter

The pulse oximeter measures the reflectance of the infrared (IR) LED light off of the patient's skin, which corresponds to the absorbance of oxygenated hemoglobin and therefore the amount of blood passing through. The photodiode which measures the reflectance outputs a variable current which, after converting to current, outputs a pulsatile A/C signal which corresponds to heart rate (see Design: Pulse Oximeter for more detailed theory). This is all done within our TCRT1000 chip. Front-end analog processing is required after acquiring this signal to filter bodily noise, filter 60 Hz, and amplify the 50-400 mV amplitude A/C signal for software analysis to obtain the patient's heart rate.

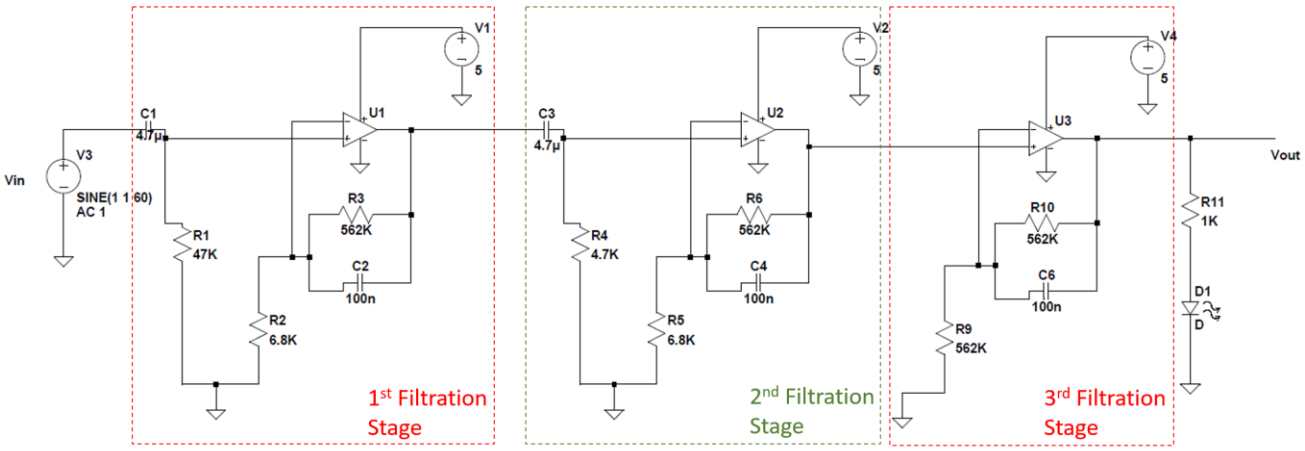

Figure 2.7.a. ***Analog Front-End Circuit for the Pulse Oximeter.*** The filtration and amplification process for the TCRT1000 signal output is shown. Vout goes to the microcontroller.

The first and second filtration stages are bandpass filters: a passive high pass filter and an active low pass filter (Figure 2). The third filtration stage is only an active low pass filter. The cutoff frequencies and gain had to be derived for this system knowing the output range we want. This cascaded filter layout is necessary to have more accurate cutoff frequencies for a less noisy output. Calculations are shown below.

$$Beats\ per\ Minute\ (BPM)\ range\text{: } 40 - 170\ BPM$$

First and Second Filtration Stages:

$$\text{Passive High Pass Filter: } f_c = \frac{40\ BPM}{60\ s} = 0.7Hz = \frac{1}{2\pi RC}$$

$$R1 = 47\ k\Omega \quad C = 4.7\ \mu F$$

$$\text{Active Low Pass Filter: } f_c = \frac{170\ BPM}{60\ s} = 2.83\ Hz = \frac{1}{2\pi RC}$$

$$R1 = 562\ k\Omega \quad C = 4.7\ \mu F$$

$$Gain = \frac{R1}{R2} = \frac{562{,}000\ \Omega}{6800\ \Omega} = 82\frac{V}{V}$$

Third Filtration Stage:

Active Low Pass Filter: $f_c = \frac{170\ BPM}{60\ s} = 2.83\ Hz = \frac{1}{2\pi RC}$

$$R1 = 562\ k\Omega \qquad C = 4.7\ \mu F$$

$$Gain = \frac{R1}{R2} = \frac{562{,}000\ \Omega}{562{,}000\ \Omega} = 1\frac{V}{V}$$

Therefore, for the pulse oximeter, the cutoff frequencies for the bandpass filters allow for the range [0.7-2.83] Hz to pass through, which corresponds to an output range of 40-170 BPM. All of these values are shown in the circuit diagram (Figure 2) and the schematic. The total gain for this system is

$$Gain = 82 * 82 * 1 = 6724\frac{V}{V}$$

This high gain allows for the 50-400 mV amplitude A/C signal outputting the TCRT1000 so that the peaks of the signal are clipped and allow for a near transistor-transistor logic (TTL) signal. Finding the frequency of the pulses for this TTL-like output will allow us to calculate BPM more easily in the microcontroller (60*f = BPM).

Using LTSpice, a simulation of the pulse oximeter circuit from Figure 2 was performed (Figure 3). A sine wave was used to simulate the output signal of the TCRT1000 sensor since a modified sine wave is a simplified form of a normal pulse signal using pulse oximetry (Figure 1). In order to more accurately simulate the physiological signal, the sine wave was given a DC offset of 1V, an amplitude of 100mV, and a frequency of 1.67Hz (which corresponds to 100 BPM). As can be seen by the output, the DC offset was successfully filtered out and the output signal is near-TTL. Additionally, the peaks of the output correctly correspond to the frequency of the input and are greatly amplified. These are all indicators of a successful simulation for the pulse oximeter.

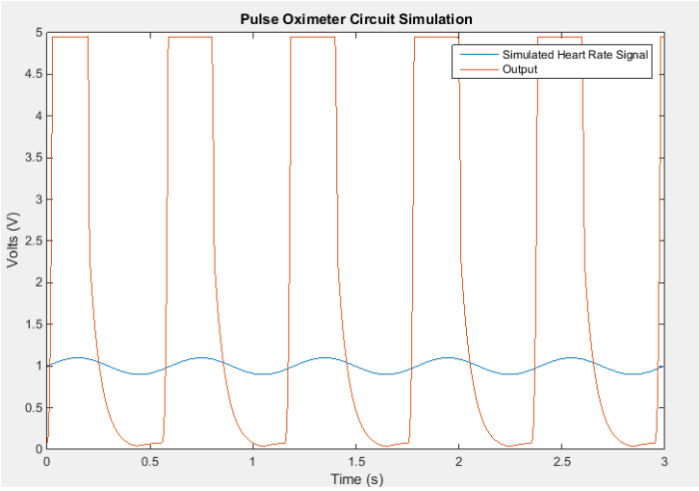

Figure 2.7.b: *Pulse Oximeter Circuit Simulation.* Following the circuit diagram in Figure 2, the input is the signal outputted by the TCRT1000 sensor (also known as the heart rate signal) and the output goes to the microcontroller.

2.7.2 Power

WEBENCH simulations of our 5V buck converter have been performed and can be seen below. We assumed a 15V input, 5V output with a 1A load. The circuit can also be found below:

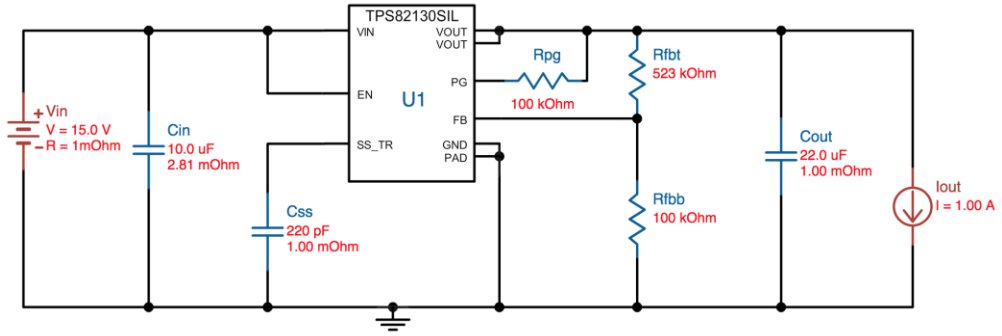

Figure 2.7.c: *Circuit diagram TPS82130 5V, 1A output buck converter*

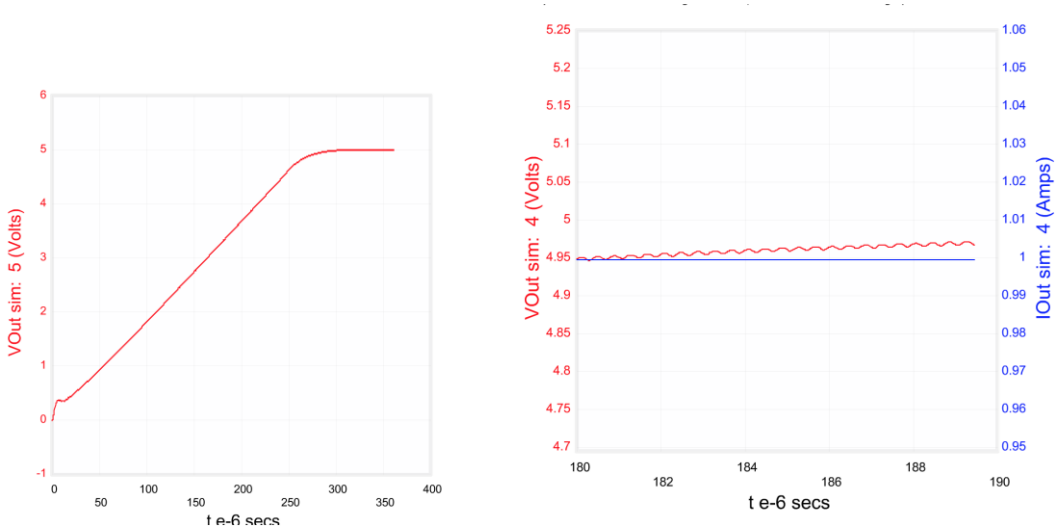

Figure 2.7.d: *TPS82130 Startup Response (Left) and TPS82130 steady state response (Right).*

Power consumption can be broken primarily into 3 sections. The power consumption from our LEDs, from our heating pads, and from the remaining micro-electronics. The general shape of our pads can be seen below; moreover, from this figure we can determine the pad power dissipation.

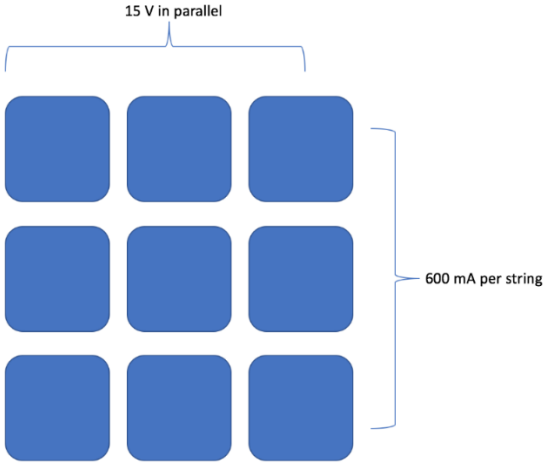

Figure 2.7.e: *Power Distribution for the 9 Heating Pads.*

We readily see that $P_{TOTAL,PADS}$ = 3* 15 * .6 = 27 W. Our LEDs would also be arranged in a similar fashion to minimize power dissipation, and adhere with the maximum current rating our AC to DC converter. As such we expect to see no more than 14.8W dissipated from our LEDs.

To summarize:

$$P_{PADS} \leq 27 \text{ W}$$

$$P_{LEDS} \leq 14.8 \text{ W}$$

$$P_{OTHER,PARTS} \leq 3 \text{ W}$$

$$P_{TOTAL} \leq 44.8 \text{ W}$$

2.8 Tolerance Analysis

Heart Rate Sensor

An important tolerance for the pulse oximeter is the output range for the TCRT1000 (the LED/photodiode sensor) since that is the sensor obtaining the heart rate. Failure of this device means failure of the entire pulse oximeter module. The ideal output range for the TCRT1000 is at least 100-300 mV amplitude for the A/C component. This corresponds to about 200 mV minimum output for the total collector current.

According to the TCRT1000 datasheet, this ideal collector current corresponds to a sensing range of 0.3-4 mm (Figure 2.8.a).

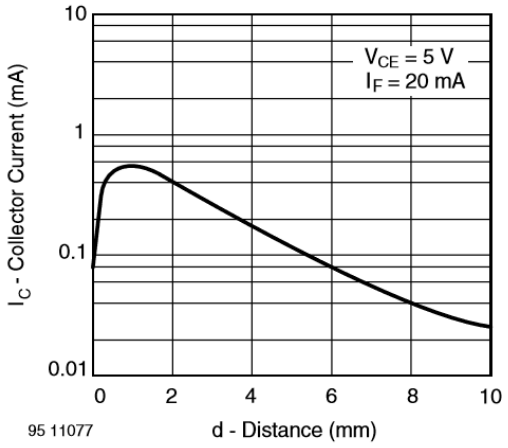

Figure 2.8.a: *Current vs Distance Relationship of TRCRT1000*

The exponential decay relationship between distance and collector current output of the sensor is due to the exponential decay apparent in the intensity of transmitted light through a medium:

$$I = I_0 e^{-\alpha x}$$

Where, in this case, I_0 is 7.5 mW/sr from the TCRT1000 data sheet, the distance is x. and the attenuation coefficient of skin is 2925 1/cm [19].

The range of skin thickness for infants is 0.9-2.1 mm [20]. This range of skin thickness has been shown to not significantly vary with age and therefore confirms the ability to test the system on adult fingers [20]. The range of skin thickness (0.9-2.1 mm) falls within the ideal sensing range. However, since the most ideal sensor distance is 1 mm, this system would operate under the most efficiency if the sensor (TCRT1000) were pressed against the skin hard enough to both bring the sensor closer to the vasculature under the skin and to block all unwanted light. Therefore, in order to get the maximum amount of collector current emitted by the sensor, we would need to press the chip into the skin instead of letting it rest on the skin.

Analog Filtration and Amplification

Another worst case for the pulse oximeter is failure of majority of the operational amplifiers or majority of the filtration stages. In this case, the signal may not be filtered enough for the microcontroller to be able to calculate a heart rate. See figure 2.7.a for the circuit diagram of the three stages of filtration. Simulations have been done to test for the case using LTSpice if two out of the three filtration stages fail:

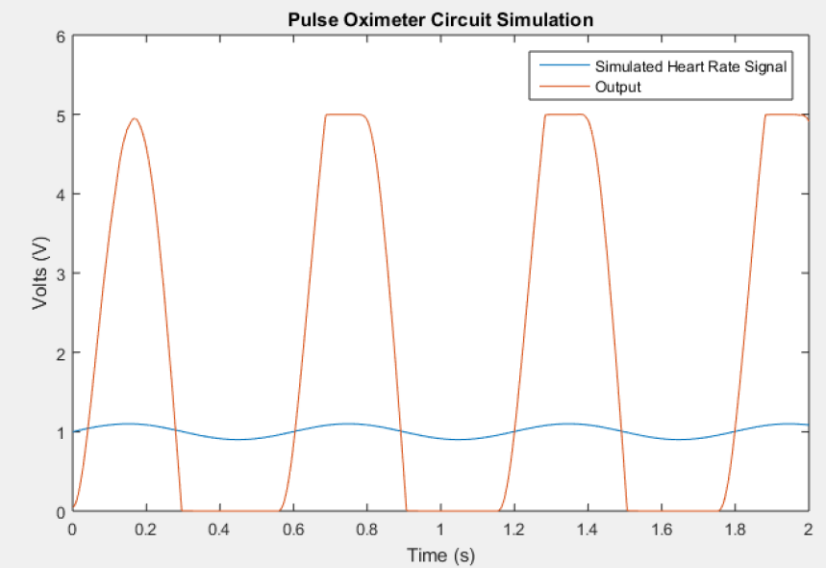

Figure 2.8.b: *Simulated Pulse Oximeter Output for Only First Stage of Filtration.*

The input for this simulation is a sine wave with a DC offset of 1V, amplitude of 100 mV, and frequency of 1.67 Hz. Given that only the first stage of filtration works, the output is shown to not guarantee to have clipping and therefore not have the near-TTL signal desired for ideal microcontroller processing. Therefore, having a TCRT1000 output of below 100 mV will not have enough gain to easily find the frequency of the signal peaks given a sufficient amount of physiological noise. In this scenario, the microcontroller would not be able to find an accurate heart rate.

This issue can be avoided if the algorithm used to find the patient's heart rate considered too much noise in the system. The microcontroller therefore should know to only count a data point as a peak after a certain time range. Given that the range of BPM to be sensed by the pulse oximeter is between 40-170, then the range of waveform frequency that will be outputted by the device will ideally be between 0.7-2.83 Hz. Therefore, after finding and recording a peak at a specific time point, the code should wait at least (40 BPM) * (60 min) = 2400 seconds until registering another peak. It is unfeasible if the patient had a BPM below 40, therefore this should be set as the minimum threshold.

Cost & Schedule

3.1 Schedule

Weeks	Dates	Marty	Hiba	Parul
1	1/16 - 1/23	• Timeline, project idea, block diagram, etc.	Timeline, project idea, block diagram, etc.	
2-3	1/24 - 2/7	• In-depth block diagram • Begin Eagle designs • Order parts	• Algo/Math • Research pulse oximeter • Testing procedures • Order parts	• Identify and purchase microprocessor • Begin testing setup with MSP430 • Order relevant parts
4-5	2/8 - 2/22	• Breadboard and begin initial testing	• Algo/Math • Research pulse oximeter • Testing procedures	
6	2/23 - 3/2	• Solder and build • Test	• Solder and build • Test	• Begin programming sensors • Begin programming LCD
7-8	3/3 - 3/17	• Revise design • Order parts • Debug		
9	3/18 - 3/25	• Spring Break		
10	3/26 - 4/8	• Rebuild, debug, and verify		
11 - 12	4/2 - 4/9	• Work on final report		
13	4/16 - End	• Buffer Week		

3.2 Cost

Labor:

Marty: $40/hour * 10 hours/week * 9 weeks = $3,600

Parul: $40/hour * 10 hours/week * 9 weeks = $3,600

Hiba: $40/hour * 10 hours/week * 9 weeks = $3,600

Total: $10,800

Bill of Materials:

Component	Part Identification	Quantity	Base Cost	Total Cost
Skin Temperature Sensor	MAX30205	1	$1.80	$1.80
Ambient Temperature Sensor	TMP116	1 package (1-9)	$3.50	$3.50
Heating Pads	Sparkfun	9	$4.95	$44.55
DAC	DAC5311	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
FTDI Chip (potentialy)	---	---	---	$0
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	TI MSP430	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		---	---	**$173.23**

Total Cost: $10,800 + $166.23 = 10,973.23

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. Furthermore, all members of the team have completed the standard lab safety training and are committed to adhering to the guidelines, to ensure safe practices during development.

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