Design and Development of a Novel Neonatal Transilluminator

By
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Thesis

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This thesis by Kabisa Baughen is accepted in its present form by the Department of Biomedical Engineering as satisfying the thesis requirements for the degree of Master of Science

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Preface

This thesis was completed towards partial fulfillment of the requirements for the degree of Master of Science in the Department of Biomedical Engineering at Brown University from September 2017 to May 2018. The work is part of a project to develop a neonatal transilluminator medical device that began in 2016 and is ongoing. The proof of concept of the device was produced in Brown University's undergraduate Biomedical Engineering Capstone course in the fall semester of 2016. This master's thesis outlines the previous work done and details continued development and testing of a prototype.

Acknowledgements

I extend many thanks to those who have supported and assisted me throughout the completion of this thesis.

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I also owe thank you to all of the employees of Bay Computer associates who took the time to help me, especially with learning the Mentor Graphics software, and were always willing to answer my questions.

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1. Background and Medical Need

History of Project

This report details the research, design, and development of a medical device that is intended to improve the quality of care delivered to neonatal patients. This project began as an undergraduate capstone project for Brown University's Biomedical Engineering ScB degree and has been expanded upon to fulfill the requirements of a Master's degree. During the capstone course Dr. Ravi D'Cruz, a neonatologist at Women and Infants Hospital in Providence, Rhode Island, presented a need for an assistive device for neonatal blood draws that is more user-friendly and effective than existing devices. With a group of three other students—Christina Andrews, Shannon Crowley, and Sarah Syrop—we began the design and development process and produced a proof of concept model. The whole group has continued to work toward intellectual property protection through patenting and commercialization in partnership with Brown University's Industry Engagement and Commercial Ventures Office while I have taken on the continued development of the device as my Master's thesis.

Neonatal Vascular Access

The neonatal period is the first 28 days after birth, and this population is often extremely vulnerable. In this period, babies can often require specialized medical care and long stays in a neonatal intensive care unit (NICU) with monitoring by hospital staff that are dedicated to serving solely this population. Many neonatal patients are placed in incubators or isolettes that control temperature, humidity, and oxygenation and may protect from infection. Babies in isolettes are treated primarily through two armholes on

the side of the container. The first neonatal intensive care unit was opened in 1960 at Yale University's Hospital by Dr. Louis Gluck[1], and since that year, the neonatal mortality rate in the United States has dropped from 18.73 deaths per 1000 live births to 3.7 deaths per 1000 live births in 2016 [2]. There are an estimated 20,000 NICU beds across approximately 1,500 NICUs in hospitals in the United States[3]. Almost all patients admitted to a NICU will undergo blood draws or vascular access procedures to place arterial and venous catheters. In a 1995 study in a NICU in the United Kingdom, 3283 invasive procedures were performed on 54 patients over a 3-month period. Sixty-nine percent of those invasive procedures involved venous or arterial puncture, and 79% were performed on babies under 31 weeks gestation[4]. Vascular access procedures, though common, have low success rates, and the small size and undeveloped nature of neonatal blood vessels make this population even more challenging. The rate of success of peripheral intravenous insertion has been reported as varying from 44% to 74%[5]. This only accounts for one type of vascular access and includes all pediatric patients, not just neonates, but the success rates are likely to be even lower for neonates specifically. Additionally, since premature infants often have underdeveloped respiratory systems and trouble breathing, arterial blood gas evaluation is continuously or frequently measured in most NICU patients to monitor oxygenation of the blood and functionality of the respiratory system. Drawing blood from arteries can be more challenging than drawing from veins due to a more limited number of accessible locations. On neonates, the radial artery, located in the wrist, is often used for arterial blood draws or placing arterial lines. Palpation is often used to find arteries in adults or larger pediatric patients when a pulse is obvious, but this is often an ineffective method of finding an artery in a neonatal patient. To

ease the procedure and increase the likelihood of first-time success, devices such as transilluminators are often used.

Transillumination

Transillumination is the process of directing light externally through the skin and tissue surrounding a blood vessel to provide visual contrast that allows the vessel to be located for needle insertion. The optical properties of materials determine how much light is transmitted, absorbed, or reflected by the material, and the differences in absorption coefficients of blood and surrounding tissue make transillumination effective.

There is a notable amount of evidence that suggests transillumination improves the success rate of blood draws in populations with poor vascular access [6,7,8]. These populations include neonatal and pediatric patients as well as elderly or obese patients. In a 2017 prospective randomized control trial on adult patients with history of difficult venous access, the use of transillumination resulted in 97.8% of successful venipuncture within two attempts as opposed to 30.4% success with conventional venipuncture without transillumination [6].

In addition to improving the success rates of blood draws, the use of transilluminators can lead to more accurate test results by reducing the inaccuracies caused by venous stasis resulting from tourniquet usage. Often tourniquets are used in the blood draw procedure to temporarily stop circulation and amplify blood pressure near the needle insertion site to make vascular access easier. The venous stasis that this causes—even for short periods of time—has been shown to significantly affect the measured concentration of several analytes in the blood. In 2005 Lippi et. al examined whether there were significant differences in measurements of 12 analytes measured in routine

biochemical testing with and without tourniquet usage and found that with 1 minute of tourniquet usage there were significant differences in 7 of the 12 analytes and with 3 minutes of tourniquet application there were significant differences in 10 of the 12 analytes [7]. Similarly, the effects of tourniquet use on hematologic testing were examined by Lima-Oliveira et al. in 2011 showing that with 60, 90, 120 and 180 seconds of tourniquet application significant increases were observed in the measurements of platelets, red blood cells, haemoglobin, hematocrit, white blood cells, neutrophils, lymphocytes, eosinophils, and basophils as compared to blood collection using a transilluminator device and no tourniquet[8].

Clinical Observations

Prior to the start of this Master's project, the group had developed a conceptual design and proof of concept model of a novel transilluminator. To begin the design process at that stage, it was important to understand the procedure that we were intending to improve and to understand how existing devices are used. The group aimed to learn what the major advantages and faults of existing transilluminators are and what users—primarily NICU nurses and doctors—desire in a new solution. Shadowing in the NICU at Women and Infants allowed an understanding of how transilluminators are used to assist in radial artery blood draws and other procedures. We observed many procedures and spoke with transilluminator users. For many of the procedures clinicians are caring for babies in isolettes. In these instances they work with their arms through two holes in the side of the container. To begin the radial artery blood draw procedure the ventral side of the patient's wrist is disinfected and may be palpated to check if the radial artery is easily found. Then, the transilluminator is placed underneath the wrist so that the light shines

from the dorsal side through to the exposed ventral surface. Depending on the transilluminator being used different methods may be used to hold the device in place. Once the transilluminator is in place the free hand then picks up the sterile needle that will be used. Once this needle is unwrapped and picked up it cannot be put down in order to free up a hand for readjusting the transilluminator because that could compromise the sterility of the needle. For most procedures the lights in the room are dimmed by another attending clinician and then, with the transilluminator causing the location of the arteries to appear dark relative to surrounding tissue, the professional performing the procedure inserts the needle at an acute angle to the limb aiming to enter the artery without going completely through the vessel. If necessary the needle can be adjusted slightly underneath the skin to find the vessel. When the needle enters the artery a flash of blood is seen entering the hub of the needle. Once the needle is successfully inserted a syringe is attached to the hub to receive the necessary blood.

Transilluminators can also be used for visualization of veins for venous blood draws, intravenous catheter placement, and identification of pneumothoraces, or collapsed lungs, in neonates. For intravenous needle placement the device is used in a similar way as for radial artery blood draws, though veins can also be found in the arm and the foot. To identify pneumothoraxes, the light source is placed on the chest wall on either side of the sternum. If there is no pneumothorax present, there will be seen only a small symmetric halo of light around the light source extending less than a centimeter, while if a pneumothorax is present the chest cavity will appear to glow as it is illuminated by the light source.

Existing Transilluminators

There are several transilluminator devices currently on the market and used in many hospitals that are intended to help clinicians visualize arteries and veins for vascular access procedures. Often, though, nurses and doctors find that the devices do not smoothly integrate into the procedure as it was taught in training so they choose not to use the device or attempt to use the device but with poor results. There are two devices currently used in the NICU at Women and Infant's hospital that will be reviewed.

The Venoscope Neonatal Transilluminator features a light source that contains four white LEDs that is connected by a long wire to a battery pack. The wire from battery pack to light source is about 24 inches long and is advertised as making it easy to maneuver around the patient, but there are many reports of the battery pack and cord being dropped or being in the way of the procedure, especially when the patient is being treated inside of an incubator Venoscope sells a detachable cord on its website and claims it "was introduced because of excessive breakage of the attached cord due to pulling and twisting"[9]. Although the introduction of the detachable cord may be an effective way to prevent breakage of the cord, there are clearly significant flaws in the design and usability of this device and these have been confirmed by consultation with several clinicians who use the Venoscope product.

The Wee Sight by Philips[10] is another neonatal transilluminator on the market. This device is cordless and contains two white and two red LEDs that are embedded in a half-cylindrical body with a short handle. This device is used by placing it on a surface such as the neonate's hospital bed and then placing the area to be transilluminated, such as the

wrist, on top of the device. Although this device can be hand held, it is bulky and difficult to maneuver while in the middle of a blood draw procedure.

Figure 1. Venoscope Transilluminator

Figure 2: WeeSight by Philips Transilluminator

Previous Work to Develop Proof of Concept

One of the most obvious challenges with the existing devices perceived from clinical observations and conversations with clinicians is the addition of equipment to the blood draw procedure that requires additional training or slows down the procedure. A need for a more ergonomic design to allow for seamless integration with the blood draw procedure as it is already performed directed the design iterations. To that end the device is designed as a wearable transilluminator with the power source packaged into a wristband that is connected by a wire to a finger-mounted light source. This concept allows for the physician to add a transilluminating light source to the procedure without having to grasp any additional pieces and essentially making the light an extension of the clinician's hand. Additionally, placing the battery in a wrist strap minimizes the length of wire and allows for easier use in isolettes. The shortening of the wire also significantly reduces any potential choking hazard that a long wire poses in a neonatal unit. In the proof of concept model, tape attaches the battery holders into a silicone Apple Watch replacement strap to create the wristband and the 3-LED board is taped to a silicone rubber ring to create the finger-mounted light.

Previous research had identified 660nm as an optimal wavelength within the visible light spectrum to penetrate biological tissue and provide contrast between blood flow and surrounding biological tissue. The proof of concept device consists of three 660nm LEDs connected in series powered by four 1.5V coin cell batteries held in two battery holders with on/off switches. The voltage source is wired to a force sensitive resistor that is mounted to the back of the board on which the three LEDs are mounted. This force

sensitive resistor was intended to act as a pressure switch that caused the LEDs to turn on only when the device was pressed to the patients skin.

Design Testing of Proof of Concept Model

Although the proof of concept model was not testable in a clinical setting, several parameters were tested to assess the device's adherence to certain parameters. The heat generation of the LEDs was tested and compared to that of the two transilluminators currently in use in the Women and Infant's NICU—Philip's Wee Sight and Venoscope Neonatal Transilluminator—by recording the temperature on the surface of the light source continuously for 10 minutes of operation. Our device showed the lowest heat generation and remained well below the threshold temperature of 35°C as shown in Figure 6. This threshold temperature was chosen because burns have been shown to occur over extended time periods at temperatures as low as 37.8°C [11] and although this device is not intended to be used for extended periods of time, data indicates that neonates' and infants' skin burns more easily than adult skin, so a relatively low threshold was implemented to ensure safety despite varying reports of safe temperatures. The IEC60601 International Standard for Medical Electrical Equipment requires that applied parts of medical electrical equipment that are in contact with a patient for one to ten minutes do not exceed 48°C, so the device complies with this standard[12].

Preliminary testing was also done to assess the visual contrast provided by the LEDs. Since clinical testing on neonates was not possible, preliminary testing of contrast was done on my own hand. The transilluminators were shined through the palm of the hand between the thumb and forefinger under dimmed light and photos were taken of the

hand with each transilluminator. Conditions of each photo were as similar as possible and then Red-Green-Blue (RGB) Scale analysis was done in Photoshop to compare the image color in regions of the artery and regions of surrounding tissue. Our prototype model showed the greatest contrast from this method.

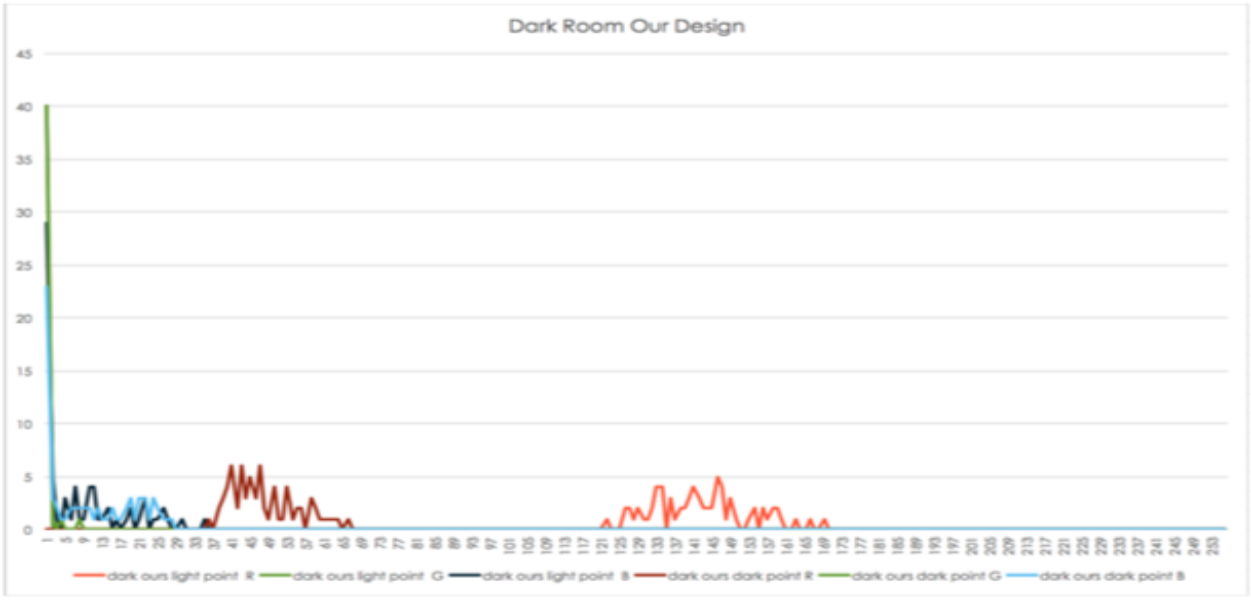

Figure 3: RGB Graphs derived from our device. The distance between red and orange peaks represents the contrast.

Figure 4: RGB graphs derived from Venoscope. The distance between red and orange peaks represents the contrast.

Figure 5: RGB graphs derive from the WeeSight. The distance between red and orange peaks represents contrast.

As a proof of concept model this stage of the device had several shortcomings. Primarily the device cannot be effectively sterilized between uses and there are exposed pieces of wire and solder that would make it unsafe to use in a clinical setting. Additionally, the force sensitive resistor required too much force to allow the necessary current, leading to concern that a user may press hard on the neonates arm in order to generate a bright enough light and could potentially cause injury. Lastly, the proof of concept model does not have the appropriate circuitry to consistently and safely power the LEDs for an appropriate lifespan of the device.

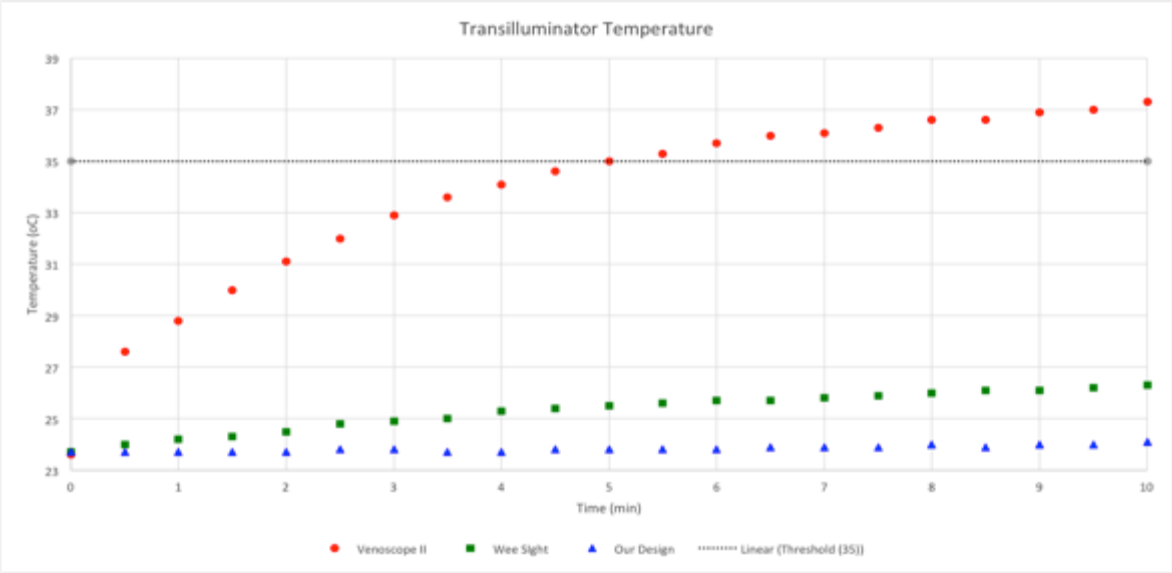

Figure 6: Temperature testing of proof of concept model compared to Venoscope Transilluminator and WeeSight Transilluminator

Figure 7: Images of proof of concept model

2. Specific Aims

The work completed towards this thesis is part of project to develop a novel neonatal transilluminator with improved ergonomics and sufficient visual contrast relative to existing transilluminators that is more easily and successfully used by clinicians to improve the success rates of neonatal blood draws and vascular access. Building on the work done to create and test the proof of concept this Master's thesis intends to advance the development to a clinically testable prototype.

The specific aims of this thesis are:

1. To design and test the electronic components of the neonatal transilluminator to create a safe, effective, and robust device.
2. To create a functional prototype that contains the electronic components designed to satisfy Aim 1.

3. Electronics Design

For the development of the electronic components of the prototype a development process was followed and is described in the following paragraphs. The circuit was designed as a printed circuit board (PCB). PCBs are common in almost all electronics as they allow for production of small scale, easily replicated electronic systems. Since I lacked previous experience in electronics design, this portion of the project required that I learn the fundamentals of schematic capture and PCB layout design as well as gain proficiency in a set software tools for PCB design. MentorGraphics software was used to design the circuit boards for this prototype. First, the schematic of the circuit was designed in DxDesigner and then PADS Layout was used to move the schematic into a layout design that could be

fabricated and assembled by third party contractors. The PCBs were fabricated by Sunstone Circuits and assembled by Screaming Circuits.

Requirements

To begin designing the schematic of the circuit, the requirements of the device must be understood. From these requirements the relevant components can be extrapolated. The primary function of the circuit in the transilluminator device is to safely and effectively power red LEDs that can transilluminate through a neonatal wrist. The LEDs must be on a circuit board that is small enough to be a finger mounted light source. The power supply and the rest of the circuit should be separate and able to be incorporated into a wearable wristband. The requirements of the electronics are listed and explained in this section.

1. *The LEDs in the circuit shall have a wavelength near 660nm.*

Biological tissue scatters and absorbs less light at longer wavelengths than at shorter wavelengths, which results in red and near infrared wavelengths having better penetrance of biological tissue than other visible wavelengths[13]. In order to create a simple device that does not require external detectors the wavelength used must be in the visible light spectrum between 390nm and 700nm. This will allow for optimal visualization of arteries due to the high penetrance of red light through biological tissue and sufficient contrast between blood vessels and surrounding tissue.

The Beer-Lambert law can be used to calculate the intensity of light, I, at a specified wavelength after it passes through a material with relation to the initial intensity, I_0, the material absorption coefficient at the specified wavelength, μ_a, and the path length of the light, x.

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

The difference between the absorption coefficient of blood flowing in vessels and that of the surrounding biological tissue results in a contrast between the intensity of light when a transilluminator is shined through a patients limb to be used for vascular access. The blood vessel appears darker than surrounding areas because blood has a higher absorption coefficient than fatty tissue. At 660nm the absorption coefficients of oxygenated blood and deoxygenated blood are $0.15mm^{-1}$ and $1.17mm^{-1}$, respectively[14]. The absorption coefficient of subcutaneous adipose tissue at 660nm is approximately $.015mm^{-1}$[15].

2. The circuit shall contain a constant current LED driver to ensure the current through all LEDs is held constant at an appropriate value.

Light emitting diodes are P-N junction diodes that convert electrical energy into electromagnetic radiation. A P-N junction diode is a semi conductor device with negatively charged (N-type) semi conductor material adjacent to positive (P-type) material. When no current is applied across the diode the extra electrons in the negatively charged N-type material fills “holes” in the positively charged “P-type” material, which creates a “depletion region” where the semiconductor material is reverted to nonconductive silicon. When the negative terminal of a battery is connected to the N-type region and the positive terminal is connected to the P-type region current flows. Electrons in the N-type region move towards the P-type region and holes move across the junction in the opposite direction. This applied voltage forces the electrons in the depletion region to move out of the holes and flow freely. As these electrons flow they occasionally fall into holes, which results in them dropping to a

lower energy orbital and releasing the excess energy in the form of a photon. The photons frequency, and therefore wavelength and color of the light, is determined by the value of the gap between energy levels. The material that the diode is made of can determine the size of the gap and therefore the frequency of photon emitted and resulting color of light.

The forward current of LEDs varies with the voltage applied and once the voltage exceeds the threshold voltage required to turn on the LED the current increases rapidly with small changes in voltage. The intensity of the light varies with varying current and if the current exceeds the maximum current rating of the LED device it will cause destructive failure of the LED. To protect the LED and maintain constant light intensity a constant current LED driver should be integrated into the circuit. Both linear and switch mode drivers can be used and the most appropriate type of driver depends on the application. Although switch mode drivers are generally more expensive and more complex than linear drivers they can offer much greater efficiency. Switch mode drivers are produced in several different modes including buck mode, boost mode, buck-boost mode, or fly-back mode, which vary by whether the output voltage or current is higher or lower than the input. Simply, though, all drivers use a feedback input and a switching mechanism to control and regulate the output at a constant current[16] The LED driver used in this device is a boost, or step-up, driver.

3. *The circuit shall include a voltage regulator to stabilize the voltage delivered by the power supply.*

Voltage regulators work similarly to constant current regulators except that they are intended to convert a variable input voltage into a constant fixed output voltage. Since the

power supply is a battery and therefore the voltage will decrease over time it is beneficial to add a voltage regulator to the circuit to reduce the variability of the input voltage. The voltage regulator will come before the constant current driver to provide a fixed voltage into the LED driver and maintain a more efficient system.

4. *The power supply of the device shall be a battery and the circuit should have appropriate power management components to ensure safety and effectiveness of the battery.*

Since this is intended to be a portable device it needs to be powered with a battery. In any battery-powered device reverse polarity protection should be incorporated into the circuit to ensure that the device shuts off and no catastrophic failure occurs if the battery is accidentally connected incorrectly with the positive and negative terminals reversed. Although this device will have a rechargeable battery that cannot be removed by the user, which reduces the possibility of the battery being connected incorrectly, including this protection prevents dangerous failures in manufacturing and allows for easier conversion to primary (replaceable) batteries in the future if that becomes preferable. The circuit should also contain a "shut-off" segment that breaks the circuit if the voltage supplied by the battery drops below 3V. This will ensure that the battery does not discharge to far before recharging and cause damage or a shortened lifespan.

5. *The device should be compatible with wireless charging capabilities.*

For this device rechargeable batteries were chosen over replaceable batteries to make them more easily incorporated into the hospital setting, with recharging being a less laborious and expensive task than replacing batteries. Ease of sanitization with disinfecting

wipes has been noted through previous research and observation as an important feature of a new device to be used on multiple patients within the NICU and reducing the number of openings in the cover of the device will help with this. To that end, incorporating wireless charging with inductive coils in the device eliminates the need for a charging port. The implementation of wireless charging also mitigates some electrical hazards that can be posed by a corded charging system. Wireless charging requires a transmitter and receiver coil as well as appropriate circuitry to manage the power transfer and ensure that the battery is charged to the appropriate level without damaging the battery or device. For the scope of this prototype the wireless charging receiver coils and circuit boards will be purchased as developed components with compatible charging transmitter components. For further development, to lower costs and consolidate the electronics to one circuit board the battery management components can be designed into the primary PCB.

6. *The device should include a switch in the finger mounted light source that turns the LEDs on when pressed against a patient and off when released as well as a power switch to disconnect the battery.*

The circuit should contain a switch that turns the LEDs on only when the light source is pressed to the patients' arm or a surface. For this iteration of the prototype a momentary push button switch will be used that is in the "ON" configuration when pressed down and "OFF" when released. This switch will be positioned centrally on the light source PCB so that the pressure of gently pressing the finger-mounted light to a patient's limb will turn the light on and removing the light from the patient will turn the light off. This will prevent both the patients and clinicians from having the bright LEDs accidentally shining into their

eyes. For the clinicians this can be distracting and make the procedure more difficult if it occurs while repositioning in the middle of the procedure. The accidental exposure of the eye to the light can also cause retinal damage, especially to the neonates. A 2010 study by Miller et. al evaluated the relative damage to the retina caused by LED transilluminators. Although it was shown that longer wavelength LEDs such as red and orange are less damaging than white LEDs, exposure to red light can cause damage to neonatal retinas over a shorter time than adults since they are more sensitive and have a less developed response to avert their eyes from the light[17].

A power switch to completely disconnect the battery when the device is not in use will prevent quiescent current draw of the components from draining the battery.

7. *The PCB that will be in the wristband power supply should be no larger than 30mm x 50mm and the finger mounted PCB should be no larger than 30mm x 25mm.*

This requirement is set forth to ensure that the PCBs that are designed are of appropriate size to be incorporated into the wristband for the power supply and into a ring attachment for the light source. If the electrical components are too large the device will be too bulky for its intended use.

Components

With an understanding of the electronic components of the transilluminator device, appropriate components were chosen to meet these requirements. For each of the requirements there are many commercially available components that will meet the requirements so appropriate components were selected at this stage of development, but as development and testing continues the circuit will be continuously evaluated to ensure

that the most appropriate components are being used. Some of the required components are integrated circuits (ICs), which are small electric circuits housed in a package designed to be easily soldered to the surface of a circuit board assembly. The constant current LED driver, voltage regulator, and a few other components are integrated circuits. The major components such as the LEDs, the ICs, and the connectors were identified and then, with the guidance of the manufacturers data sheet and research into the operation of electronics circuits, the rest of the passive components such as resistors and capacitors were then added as necessary. The table below identifies and briefly describes the major components used in the circuit, including all active components and the key passive components.

Component Type	**Description**	**Manufacturer/Part Number**	**Schematic Reference Designator**
JST Connector	Shrouded header connector to be used to connect the battery to the primary PCB. This connector was chosen because it matches the connector on the chosen battery.	JST/S2B-PH-SM4-TB	J3
FFC Connector (x2)	These are FFC bottom connectors to pair with a flat flexible cable to connect the two separate PCBs.	Hirose/ FH12-6S-0.5SH(55)	J1,J2
Buck-Boost DC/DC converter	This DC/DC converter serves as a voltage regulator to convert the input voltage from the 3.7V battery to a constant 3.3V output to the rest of the circuit.	Linear Technology/LTC3440EMS#PBF	U2
Constant Current LED Driver	This step up DC/DC converter serves as a constant current LED driver that can drive 2-6 LEDs in series. It uses a 1.2MHz switching frequency and has a low 0.1V feedback voltage to minimize power loss.	Diodes Inc./ AP5724WG-7	U5

Light Emitting Diode	These red LEDs have a wavelength of 660nm, luminous intensity of 2800mcd, and forward voltage of 30mA. Five of these are placed in series in the circuit and are driven by the LED driver.	Lumex/ SSL-LX5093SRC/E	D3, D4, D5, D6, D7
Voltage Reference	This is a low noise micro power voltage reference that is used in a part of the circuit that ensures the device shuts off when the voltage from the battery drops below 3V to prevent excessive discharge of the battery.	Analog Devices/ ADR291GRZ	U6
Comparator	This comparator is also part of the shut off circuit and is used to compare the voltage supplied by the battery to the reference voltage and shut off the circuit when the voltage is below the threshold.	National Semiconductors/ LMV331M5	U3
Push Button Switch	This switch is a momentary push button switch with an actuation force of 340gf that is used to switch the LEDs off and on. The LEDs remain off when not pressed and on for as long as the button is held down.	C&K Components/ KMT031_NGJ_LHS	SW1

Figure 8: Table of components

PCB Schematic Design

With the requirements of the device outlined and the major components identified a few further design considerations were made when developing the schematic. Although the final product includes two separate circuit boards, they were designed as one board that could be separated after production to minimize the cost of fabrication and assembly. In order to keep the PCB that houses the LEDs as small as possible the number of components on that board was minimized. For functionality, LEDs and the switch needed

to be on the smaller boards and given the way the LED driver connects between the switch and the LEDs it is logical for the driver and closely connected passive components to be on the smaller board. This requires connectors between the two boards.

The battery is connected to the larger board by a JST connector and this power supply will connect to a reverse polarity protection circuit that includes a fuse, transient-voltage-suppression (TVS) diode, and metal-oxide-semiconductor field-effect transistor (MOSFET). The MOSFET prevents current flow when reverse biased, the fuse prevents catastrophic failure from excessive current and the TVS diode prevents voltage spikes.

As long as the polarity is correct, the battery supplies the input voltage to a buck-boost DC/DC voltage regulator that outputs a constant voltage of 3.3V. The buck-boost system is configured in a way that is able to either decrease (buck) or increase (boost) the input voltage in order to reach the intended output voltage, which allows optimization of battery usage. This output voltage connects to positions 1 and 2 on the FFC connector on the larger board. Positions 1 and 2 on the FFC connector on the smaller board connect through the push button switch to the input of the LED driver, which then powers the five LEDs in series.

The power supply from the positive terminal of the battery connection also connects to a voltage divider configuration of resistors with the output voltage connecting to a comparator that compares the output voltage from the voltage divider to a reference voltage of 2.5 that is powered only when the switch is pressed. The voltage divider is configured so that a 3V input voltage results in a 2.5V output voltage. With that configuration any battery voltage less than 3V will result in a LOW comparator output. The comparator connects to the “enable” pin on the LED driver and a LOW input on the enable

pin will switch off the driver and LEDs. This comparator circuit is in place in order to prevent draining of the battery beyond its specified discharged cutoff voltage of 3.0V because that will cause reduction of battery life or failure of the battery.

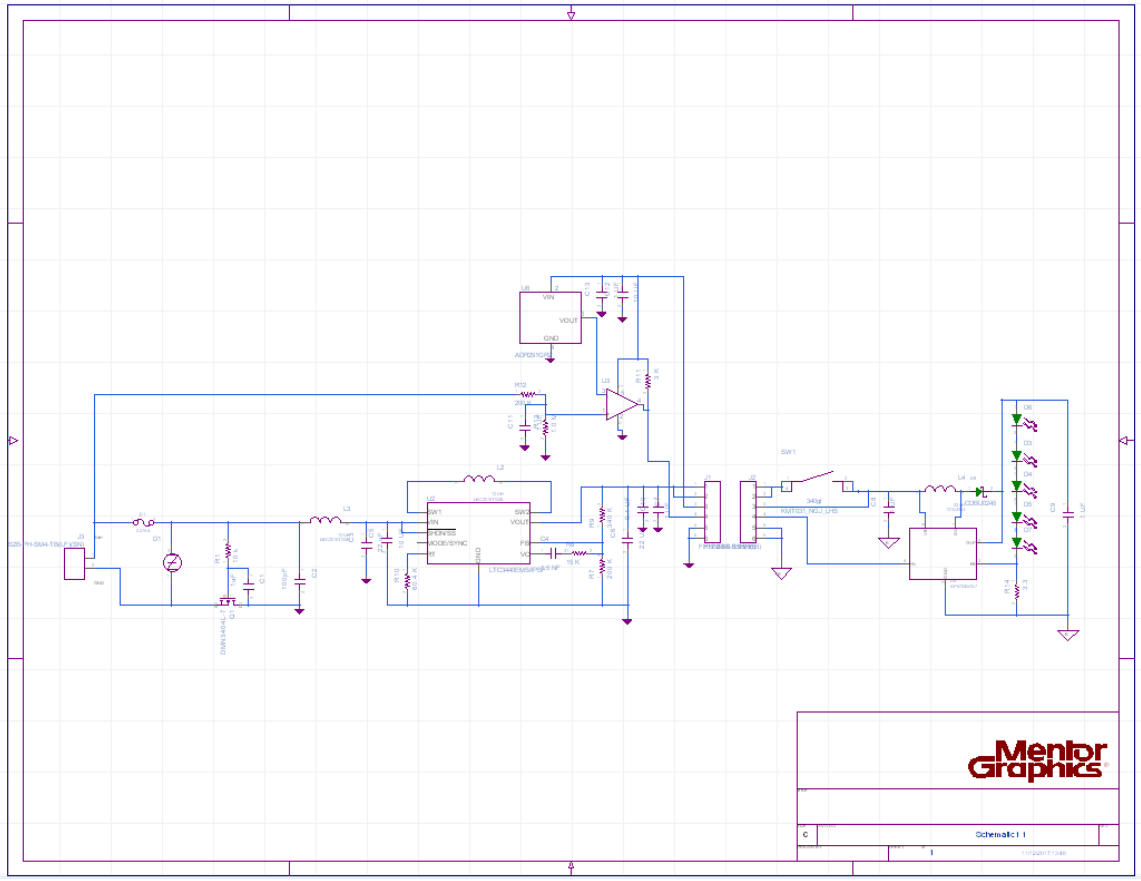

Figure 9: PCB Schematic

PCB Layout Design

The PCB layout defines the actual positioning and configuration of all of the components and connections in the schematic. The schematic identifies how each component connects to the other components and using Mentor Graphics software the schematic designed in DxDesigner can be exported to a PCB Layout file in PADS Layout.

PADS Layout configures each component to its footprint—the size and shape of the space it will take up on the board. The surface mount layers consist of an insulating material on top of a conductive material. Connections, or traces, between components are created by etching a path from a terminal of one component to another to expose the components to the conductive material. Vias are holes drilled through the board that allow connection from one layer to another to extend the area available for traces or to join reach a common ground or power supply connection. Due to the relative simplicity of this circuit all of the components are placed on the top of the board and the bottom is only used for traces. The PCB will also have two interior copper layers for power and ground.

The shape of the board was determined by the size requirements of each part. A large cutout as well as "mouse-bite" holes, which create a perforation, were designed into the board between the part of the board intended for the wristband and the part intended for the finger-mounted light source. After production the boards can be separated along these perforations.

When laying out the components and traces acute angles were avoided in the traces to prevent "acid traps" that could result in failure. The traces are made with an acid etch process and it is likely in acute angle junctions that the acid etching solution will become trapped in the junction during the fabrication process resulting in eventual failure. Electrical spacing is also an important safety consideration in PCB layout design. Creepage and clearance are two measurements of electrical spacing. Creepage is the distance over an insulating surface between conductive elements and clearance is the distance through air between conductive elements, although clearance is often used as a general term for all

spacing rules in software tools. This device is relatively low voltage so the clearance and creepage values can be smaller than in higher voltage circuits.

The image below shows the final layout of the PCB. The blue indicates conductive elements—components and traces—on the top layer and the red indicates conductive elements on the bottom layer. The grey is outlines of components and reference designators, or labels, which are printed on the surface of the PCB when it is fabricated to indicate which component corresponds with each footprint for assembly.

After the design was completed the appropriate files were sent out for production. The fabrication step creates a PCB of the correct size and shape with the appropriate outlines, annotations, traces, and conductive solder pads for the components to be attached to. After fabrication, the assembly step is when the components are placed and soldered to their appropriate locations.

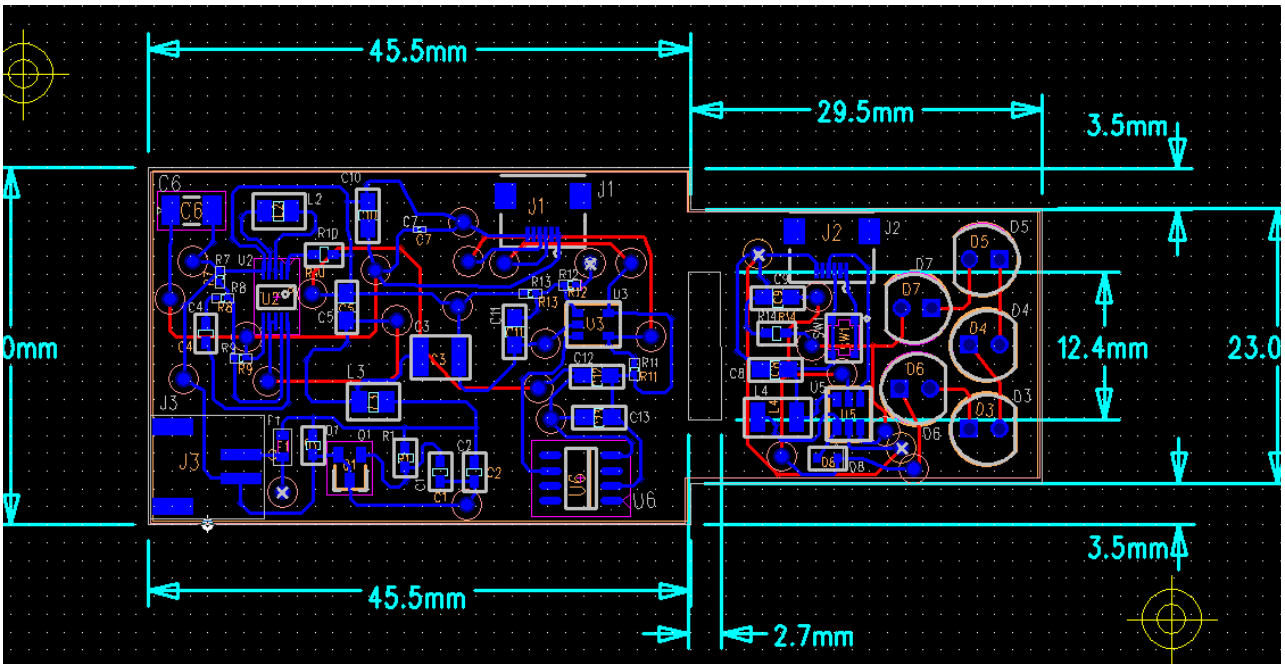

Figure 10: PCB layout design

4. Prototype Construction

Once the PCBs had been developed, all of the components were packaged into a prototype that aims to be more robust and testable than the first proof of concept model. In order to make the device as easy to sanitize as possible, the design of the prototype aimed to be completely able to be wiped down with sterilizing wipes with minimal small crevices for bacteria to grow. The prototype was designed in two parts—the power supply wristband and the finger mounted light source. The process of building this prototype required that I expanded my proficiency in SolidWorks 3D modeling and the mold making and silicone molding process.

Wristband

The wristband part of the device holds the battery, the wireless charging components and the larger PCB, which contains the majority of the circuit components. The wireless charging system used in the device is STEVAL-ISB039V1 evaluation kit from STM Microelectronics. The kit includes the transmitter coil and circuit board and receiver coil and circuit board. The wireless charging receiver circuit board and coil are both attached to one piece of acrylic, which made integration into the prototype simple. The V_{out} and ground terminals on the charging receiver board were soldered to the power and ground connections on the main PCB. The battery was then connected to the PCB with the JST connector and the boards and battery were layered with insulating tape to prevent accidental shorting and taped together to hold them in place. A 6-position 7.87” flat flexible cable was connected to the FFC connector on the PCB.

Once all of the components were assembled together they were molded into a silicone wristband. For this stage of prototyping a generic replacement silicone strap for a smart watch was used to create the fastening of the wristband. A mold that would fit the strap and electrical components was designed in SolidWorks and rapid prototyped with help from the Joint Engineering and Physics Instrumentation Shop at Brown University and is pictured below. The electrical components and the strap were placed into the mold, putty was used to seal the edges, and the liquid silicone was poured into the open mold and allowed to set overnight. The silicone used was clear platinum-cure Ecoflex 00-30 Super Soft Platinum Silcone purchased from Smooth-On, which cured at room temperature and pressure. This silicone is certified "skin-safe" biocompatible to the ISO 10993-10 standard, so it is safe to be used in clinical testing.

Light Source

The PCB containing the LEDs was molded in silicone into a ring form that allows it to be worn on one or two fingers by the clinician depending on the users hand size and preference. After several iterations, the ring part of the device was eventually designed to be nonadjustable, but the silicone is elastic enough to fit many users. The ring part of the device only required molding the smaller PCB attached to the cable with no other electronic components. The mold was designed with two open sides in order to mold the connector cable into the device and leave the mold open on the top of the light source to prevent a rough texture on the silicone that would lower the clarity of the light. An actuator post was 3D printed and glued to the push button switch before molding in silicone, so that pressure on the surface of the silicone will press down the button and turn on the light. The

board was placed with the LEDs facing up and the cable was wrapped around the ring to come out on the opposite side of the board so that the device is worn with the cable running along the back of the hand and the light shining away from the palm. One open side of the mold was sealed with tape before the silicone was poured. The same silicone was used for the ring as for the wristband.

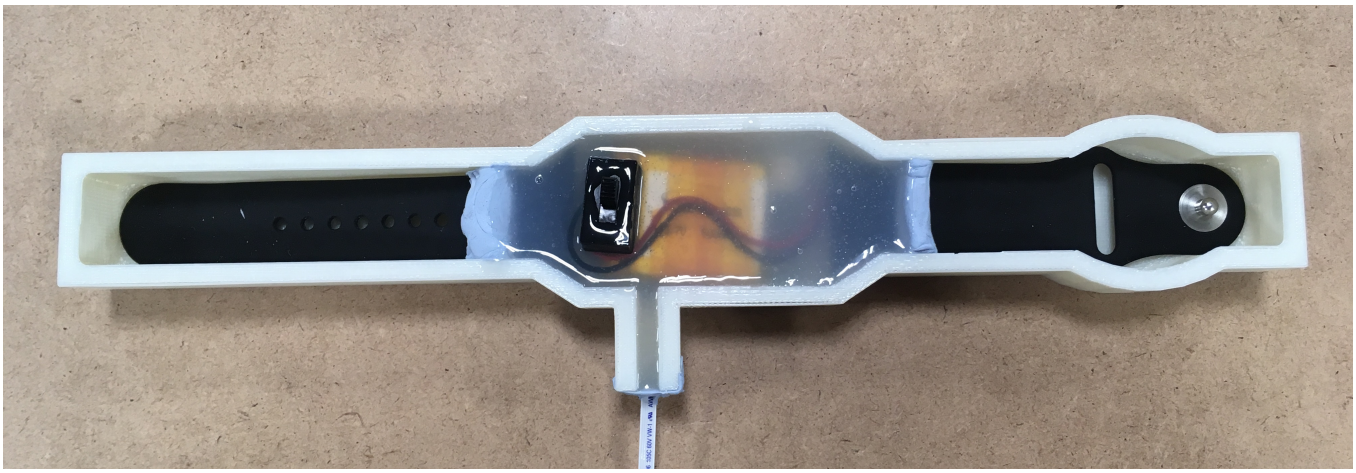

Figure 11: Wristband mold with electronic components and silicone.

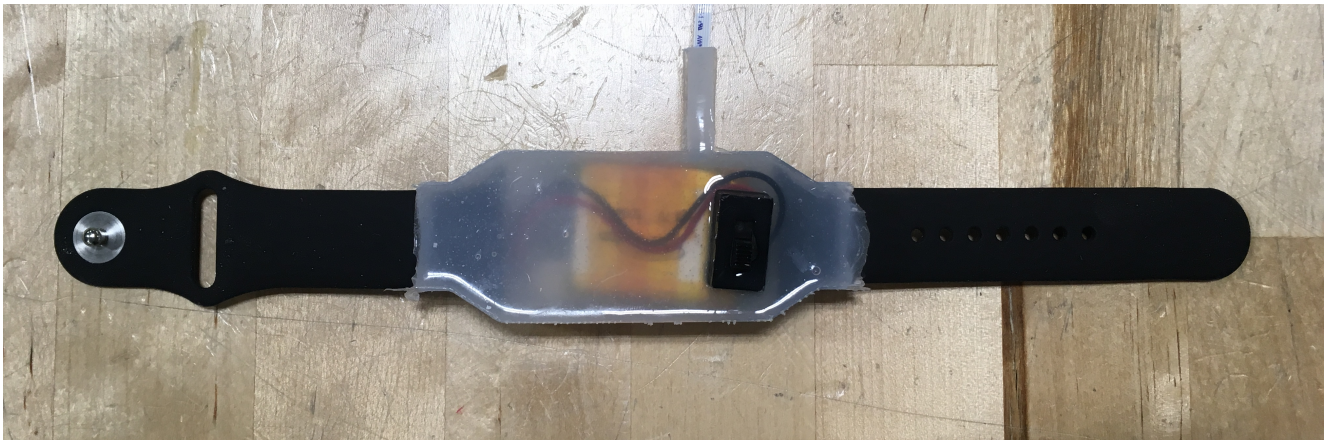

Figure 12: Completed wristband with electronics out of mold

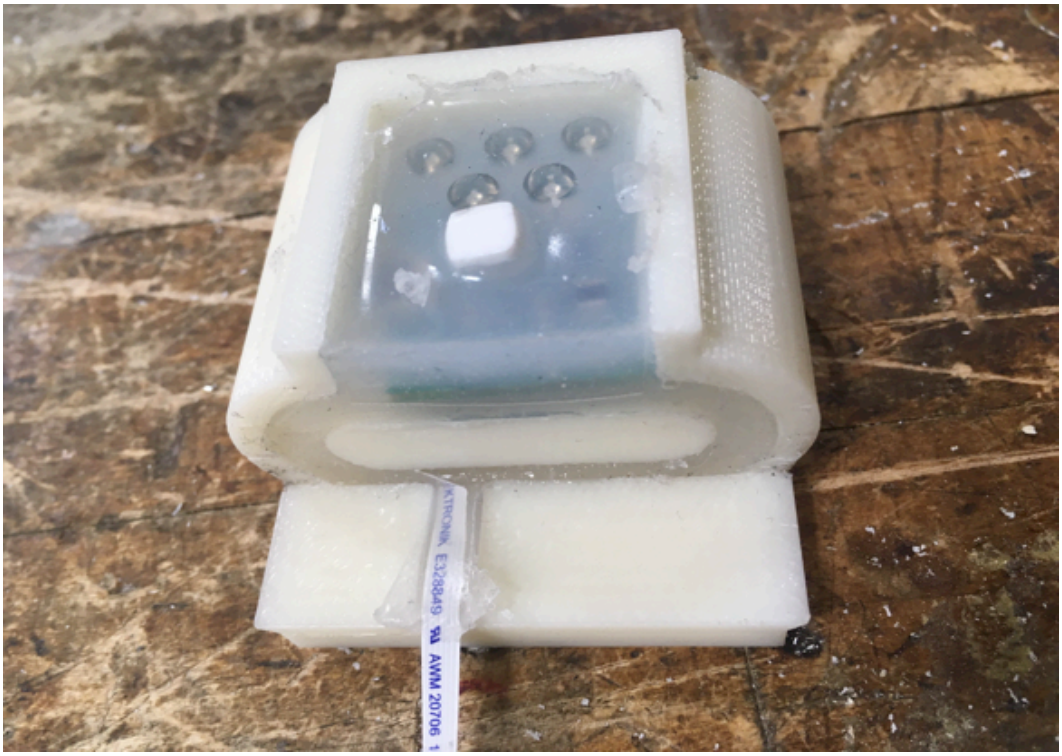

Figure 13: Mold used to make ring

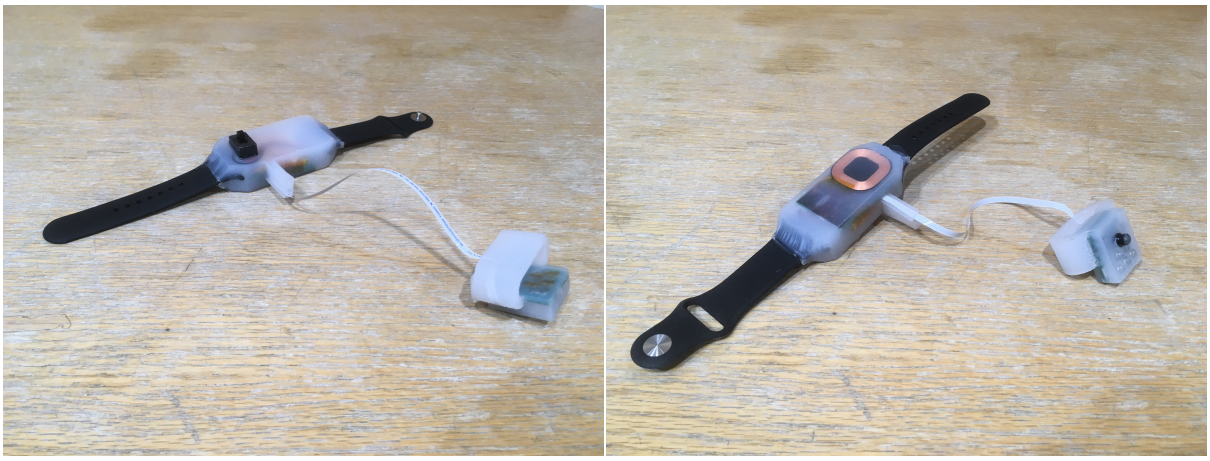

Figure 14: Top-view and bottom-view images of current prototype

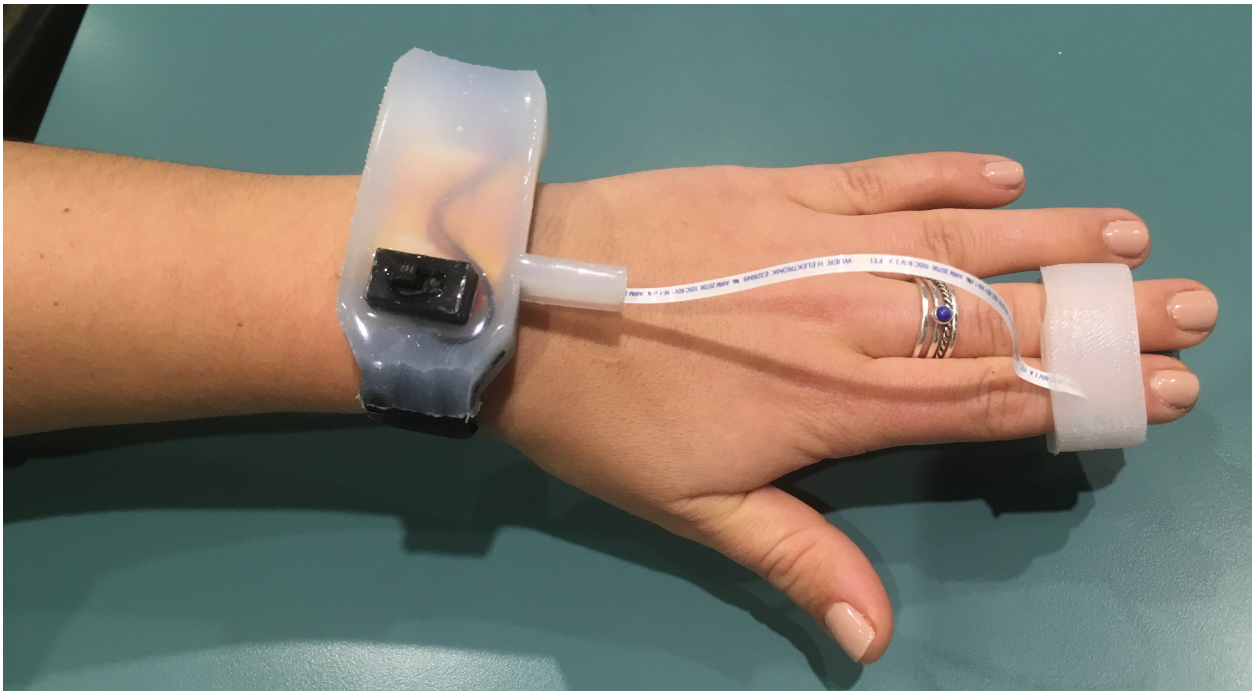

Figure 15: Current prototype worn on left hand.

5. Testing and Results

In order to ensure that the functional requirements of the device as well as the electrical requirements and expectations of the circuit are met, a test plan was developed and carried out. Each test targets a specific requirement or component and has specified pass and fail criteria.

Technical Requirements and Testing

The device has several functional and safety requirements that must be tested. The light source of the device must not produce excessive heat as this is in contact with the patients skin. The device will be tested to ensure that the surface does not exceed a temperature of 35°C over a 10-minute period of continued use.

The battery should power the device for 2.5 hours of use before requiring recharging. If we assume that the device is used for 5 minutes at a time for each procedure a 2.5-hour battery life, each device would be able to complete 30 procedures between charges.

Electrical Circuit Testing

Certain tests were used to confirm that the design of the circuit provides the expected signals at specified locations, while other tests confirm that the signals at certain pins on the components are within acceptable ranges for safety and effectiveness of the components as defined by the manufacturer. For the scope of this work one board was tested and considered representative of the feasibility of the device, but for future manufacturing of the device, consistent testing of multiple devices would be required. All tests will be completed while powered with the intended 3.7V Lithium ion battery

DC-DC Converters

The circuit of this device contains two DC-DC converters that are intended to regulate the voltage and current through the circuit to effectively power the LEDs. As described in the components table, one is a voltage regulator and one is a constant current LED driver. The voltage regulator should maintain a constant voltage output of 3.3V. The LED driver (U5) should provide a constant current output between of 30mA, which is the forward current of the LEDs.

Light Emitting Diodes

The current through each of the LEDs should be the same and should remain constant over time. The current should not exceed 30 mA. The forward voltage across each LED should be in the range of 1.7-2.2 V.

Reverse Polarity Protection and Shut-off

The circuit contains several components— fuse, diode, transistor, capacitors and resistors—that are intended to provide reverse polarity protection. Testing of this should ensure that no current flows if the battery terminals are reversed and there is no catastrophic failure of the device. The testing should also confirm that the device still functions correctly once battery is connected correctly after the polarity reversal.
The circuit is also designed to prevent current flow when the voltage supplied by the battery is less than 3 V. This prevents excessive variation in current and allows for appropriate recharging of the battery. This will be tested with an external variable power supply to ensure that the shut off occurs within an acceptable tolerance.

Testing Results

Temperature

The device met the requirements of the temperature testing by not exceeding 35°C over a 10-minute period. The highest temperature recorded at the surface of the LEDs during the test was 28.8°C. The results of the temperature test are graphed below.

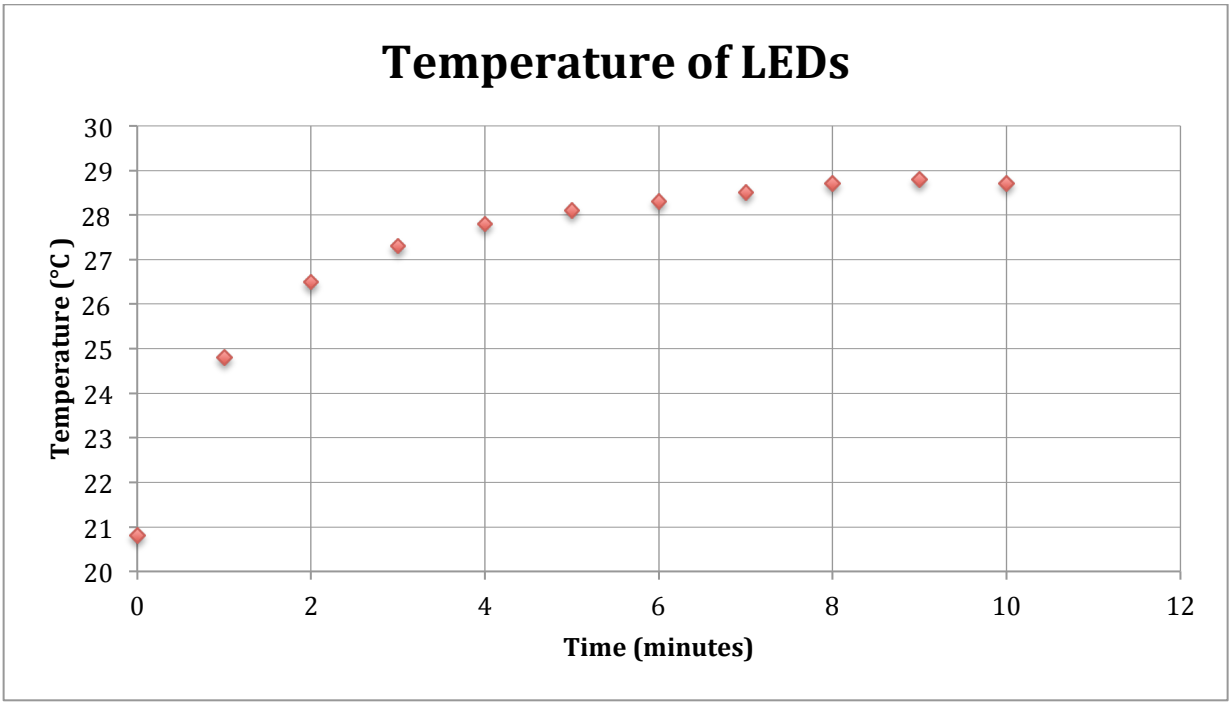

Figure 16: Temperature testing of current prototype

Circuit Testing Results

The results of the circuit board testing are displayed in the table below. All measured values fell within 2% of the expected values demonstrating that the circuit functions as designed. The DC-DC converters are appropriately regulating voltage and current from the battery supply to power the five LEDs in series.

Component	Test Point (unit)	Measured Value	Expected Value	Percent Error
LEDs	LED #1(mA)	30.45	30	0.02
	LED #2	30.44	30	0.01
	LED #3	30.42	30	0.01
	LED #4	30.41	30	0.01
	LED #5	30.47	30	0.02
Voltage Regulator	Output Voltage (V)	3.25	3.3	-0.02
Constant Current LED Driver	Output Current(mA)	30.45	30	0.02

Figure 17: Table of circuit testing results

The battery life and reverse polarity protection of the device will be tested in the future.

The table below outlines several relevant characteristics of neonatal transilluminators compared among the device designed throughout this project, the Venoscope Transilluminator, and the Philips WeeSight.

	This Device	**Venoscope Neonatal Transilluminator**	**Philip's Wee-Sight Transilluminator**
Max temp over 10 min. use	28.8°C	37.5°C	26.7°C
LED color	5 Red (660nm)	4 White	2 Red, 2 White
Biocompatible material	Yes	Yes	Yes
Soft surface on light source	Yes	No	No
Battery	Wireless rechargeable	Primary (replaceable)	Primary (replaceable)
Power Switch	Momentary On/Off push button located on top of light source and on/off power switch	On/Off toggle located on battery pack separated from light source by 24" wire	On/Off button located on back of light source

Maneuverability during procedure	Easy. Device moves with hand.	Medium. Light source can be moved but is often dropped and difficult to position.	Hard. Once placed on a surface moving this device may not be possible while maintaining sterility of procedure.

Figure 18: Table comparing key characteristics of novel device with Venoscope Neonatal Transilluminator and Philips WeeSight

6. Future Directions

Future work for this project should include further prototype iterations and user testing.

Further Prototype Iterations

As the prototype has been developed and tested for this scope of work some remaining areas for improvement have been identified. The reverse polarity protection segment of the circuit should be modified to not include a fuse since it is not easily replaced if the fuse melts to break the circuit. Additionally, the pushbutton switch should be replaced with a switch with a lower actuation force in order to reduce the amount of pressure required to turn on the LEDs. The LEDs used in the current stage of the prototype are through-hole with 8mm tall lenses. These should be replaced with shorter surface mount LEDs to make the light source thinner and more comfortable to use.

The currently used silicone is safe for clinical testing and offers appropriate strength and flexibility, though for further production the silicone choice could be further optimized. The silicone used to make the device should be upgraded to optically clear silicone covering the light source, as the current silicone is transparent but not completely optically clear. The silicone used to make the wristband should be upgraded to a silicone that is less soft but still as strong, or a sealant should be applied to the wristband so that the surface is

less tacky and easier to clean with sanitizing wipes. This silicone could also be colored and opaque to improve the appearance of the device by hiding the electronics. The most appropriate silicones were more expensive than was justified for this stage of prototyping but are a feasible upgrade when producing at a larger scale. Additionally, when produced on a larger scale, more sophisticated processes such as injection molding should be used and the device should be molded entirely as one device with all surfaces covered. Currently the cable is exposed leaving potential for fatigue and breakage.

Future Testing

User testing should begin with the existing device. This user testing can begin with use on mannequins to gauge the clinician approval of the newly designed wearable transilluminator, then, after approval is granted by the hospital's review board, testing should be done on NICU patients to gauge effectiveness compared to other transilluminators and no transilluminator use.

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