Abstract

Background: Respiratory disease is a leading cause of infant deaths worldwide, with 74% of these deaths occurring in developing countries.[1]
Problem: Although these conditions are typically screened with transmission based pulse oximeters – which measure heart rate and blood oxygen saturation – pulse oximeters made for neonates are unaffordable for low resource settings (LRS) due to the use of expensive consumables. A single disposable probe for neonates costs approximately $30--well over the annual health expenditure per capita in low income countries.
Design Solution: Our team has created the Luminox – a handheld, low-cost, reusable, reflectance-based pulse oximeter that clinicians can use to quickly spot-check and screen many neonates and children for respiratory diseases. The current prototype is housed in laser cut acrylic with an LCD screen. It features a force sensor to optimize the application pressure as well as an analog circuit and Arduino microcontroller for signal processing.
Evaluation: Preliminary testing of 12 different body parts on a single individual showed that using the palm as the tissue sample maximizes the Luminox's accuracy, achieving an average error of 3.7 beats per minute (bpm) with 100% reproducibility. No statistically significant trend was observed in an analysis of the effect of melanin on accuracy. The device weighs 395g and has a battery life that lasts over 100 uses.

Problem Statement

Background

Due to the high burden of disease and limited supply of oxygen therapy for treatment in low-resource settings, there is a need to develop an easy-to-use screening tool to quickly assess respiratory function in children and neonates. We focused on Malawi as an initial target population since we have an established relationship with central and district hospitals in Malawi and have obtained data on neonatal care at almost all public and private hospitals in Malawi.

In Malawi, transportation, power supply, and medical technology supply chains are not reliable. Only 45% of roads in Malawi were paved in 2003 (most recent year for which data are available), and only 7% of the population currently has access to electricity.[2] These infrastructural metrics constrain medical facilities' access to key resources. According to respondents to the WHO's Survey on Access to Medical Devices conducted in 2012, another major barrier to access is the procurement process.[3]

Additionally, Malawi has the highest rate of preterm births in the world, with 18.1 preterm births per 100 live births. A common complication that accompanies premature birth includes respiratory distress syndrome. With the prevalence of preterm births and only 0.3 nurses and 0.02 physicians per 1000 people,[4] another constraint to providing care is the limited number of skilled healthcare providers.

Current Solutions

Current solutions for pulse oximetry at central and district hospitals in Malawi include one stationary Welch-Allyn Spot Vital Signs unit per NICU ward and handheld Devon Medical

devices. Welch-Allyn units are continuous monitoring devices commonly used in hospital wards, but they are not portable, preventing physicians from using it to quickly check many patients. The portable Devon Medical model is designed for neonates but requires disposable probes that introduce a high cost of maintenance due to decreased performance with each use and failure after 30 uses on average.[5] These probes are also not easily sterilizable, and an unreliable supply chain plus high costs (approximately $30 per probe) hinder procurement.

The Lifebox pulse oximeter is designed for patients in LRS. While it is a low-cost and portable option, the transmission-based probe design limits sampling areas to thin appendages such as the finger or feet. This limits accuracy in patients with low blood perfusion to the extremities — a common situation for neonates.[6] Covidien offers a disposable reflectance-based product that enables use on multiple body parts, but it is too expensive for implementation in LRS.

Other existing options for pulse oximetry include fingertip pulse oximeters that can be purchased for as little as $10. However, these probes are designed to clip onto an adult-sized finger and are incompatible with neonates.

Mission Statement

Because pulse oximeters on the extant market are either non-reusable, designed for continuous monitoring, rely on disposable parts, or are incompatible with neonates, no effective pulse oximeter exists that can meet the needs of low-resource settings in screening for respiratory disease in neonates. Our team is tasked with designing an affordable, reusable, neonatal pulse oximeter for spot checking respiratory function.

Design Solution

The Luminox device consists of three key components — device housing, circuitry, and microcontroller. The device housing encloses the unit and prevents it from becoming damaged by the external environment. The Arduino Uno microcontroller powers light-emitting diodes (LEDs). The reflected light is detected by a photodiode (PD) and the current produced is processed by internal circuitry to a 0–5 V range that the Arduino reads and processes to compute oxygen saturation and heart rate. These values are displayed on a color LCD screen.

Device Housing

The device housing consists of a contoured plastic body that the user holds and a probe that protrudes from the device and which is placed against the skin (Figure 2). The device exterior also contains a single-pole-single-throw power switch, non-latching button to initiate operation, and a female USB-B connector for the Arduino Uno microcontroller. The housing is constructed in layers with 15 laser-cut, ⅛”-thick acrylic cross-sections that are glued together and capped with symmetric plastic faces. The LCD screen and the protruding probe are placed on opposite faces (Figure 1).

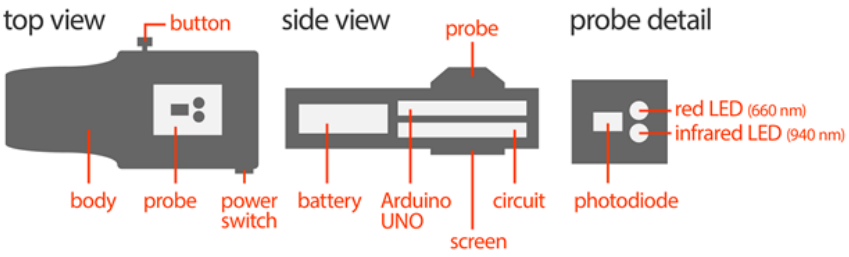

Figure 1 Simplified diagram of device housing highlights key design components.

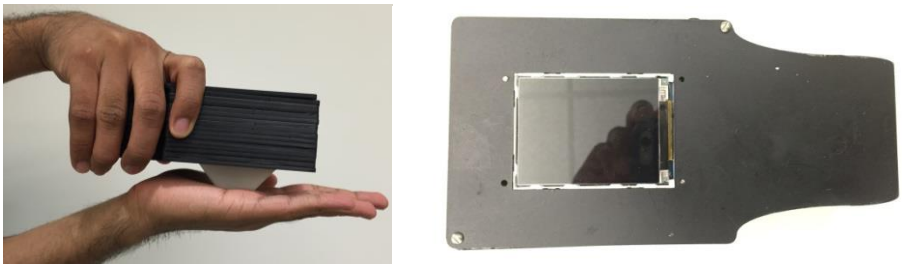

Figure 2 Photograph of intended Luminox placement (left) and the laser-cut top and bottom faces of the device into which the LCD screen and probe are placed (right).

The probe consists of two LEDs separated from a PD by a sheet of aluminum baffling that prevents light from the LED from directly striking the PD without first traveling through patient tissue. A force sensor on the surface of the probe measures how much force is applied by the probe on the patient's skin (Figure 3).

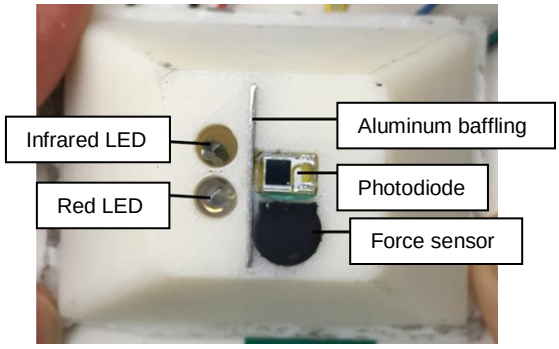

Figure 3 The probe face consists of a number of components to acquire data from a patient.

The batteries, circuit, and Arduino are contained within the device (Figure 4).

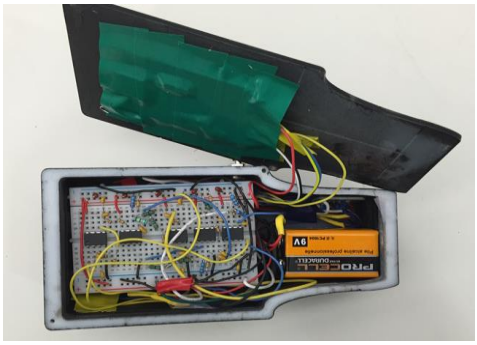

Figure 4 Photograph of inside of Luminox device.

The device is powered by two primary cell 9V batteries connected in parallel, which provide up to 1000 mAh. These may be easily swapped out for rechargeable batteries or replaced to extend device operation time.

Circuits

The circuit accomplishes four main tasks— powering the device, driving the LEDs, processing the PD output, and enabling user interaction with the Arduino.

Reflected light from the tissue is detected by a 2.5 V reverse-biased PD connected to a transimpedance amplifier. The output of the transimpedance amplifier contains both a DC voltage component and an AC voltage component which varies in amplitude based on oxygen saturation among other factors. The transimpedance amplifier output is connected to the Arduino, which then reads the DC voltage component of the signal. After the transimpedance amplifier, the signal goes through a high and low-pass filter and is split into a low-gain and high-gain channel configured for 80 dB and 75 dB, respectively.

Software

The Arduino Uno microcontroller turns on each LED, acquires data from them, and analyzes the results to display them on the screen (Table 1).

Table 1 Sequential flow of the device function.

Device initialization	1	Power on device
	2	Screen displays “Ready” screen
	3	Button press starts signal reading if pressure exceed threshold
Red LED data acquisition	4	Red LED turns on for 2 seconds
	5	Arduino acquires 100 points at 30.3 Hz for 6.7 seconds for 2 channels
	6	Red LED turns off
	7	Arduino calculates and stores AC, DC, and BPM for red LED
IR LED data acquisition	8	Infrared LED turns on for 2 seconds
	9	Arduino acquires 100 points at 30.3 Hz for 6.7 seconds for 2 channels
	10	Infrared LED turns off
	11	Photoplethysmogram waveform stored from red LED
	12	Arduino calculates and stores AC, DC, and BPM for infrared LED
Results display	13	Arduino combines LED data to produce SpO_2 and BPM
	14	Screen displays SpO_2, BPM, and photoplethysmogram waveform
Termination	15	Button press returns to “Ready” screen

Device usage

The user places the device on the palm of a subject's hand. The button on the top of the device is pressed, and the screen indicates to the user to apply more pressure if the force sensor indicates that insufficient pressure has been applied. Over the next 19 seconds, a signal is acquired while the LCD screen displays a status bar. Once the data is processed, the Arduino displays the output to the screen. The screen shows the heart rate, oxygen saturation, and photoplethysmogram (a waveform indicating pulsatile flow in the arteries). However, to ensure patient safety, if the AC voltage is less than 30 mV peak-to-peak, the Arduino will display an error message that also shows the photoplethysmogram to aid the clinician in choosing an appropriate next step (Figure 6).

Figure 6 (left) The final output of Luminox on the LCD color screen. (right) An error message indicates a potentially erroneous reading.

Evaluation

To evaluate the Luminox, we sought to demonstrate device functionality at a range of parameters to determine if we met each of our design criteria (Table 2 and Figure 7). Table 3 lists each of our design criteria based on the identified user needs and the current Luminox specifications. Note that all variables are listed in chronological order of testing, and the pressure and brightness were tested simultaneously by evaluating all LED brightness and pressure combinations in 12 subjects. All testing was approved by the Rice University IRB (Protocol 14-114E).

Table 2 Summary of accuracy testing parameters

Variable	Range of values	Key result
Sample tissue	12 body parts with arteries close to the skin	Palm maximizes device accuracy
Pressure	10 kPa, 20 kPa, 30 kPa (in 12 subjects)	20 kPa and 30 kPa are sufficient. At 10 kPa, a usable signal is not consistently obtained
Brightness	Low, medium, and high, corresponding to 47%, 67%, and 87% LED duty cycle, respectively (12 subjects)	Low brightness (47% duty cycle) maximizes accuracy
Melanin	17 subjects of varying skin tones (based on RGB values computed in MATLAB)	No statistically- significant trend ($p< 0.001$)

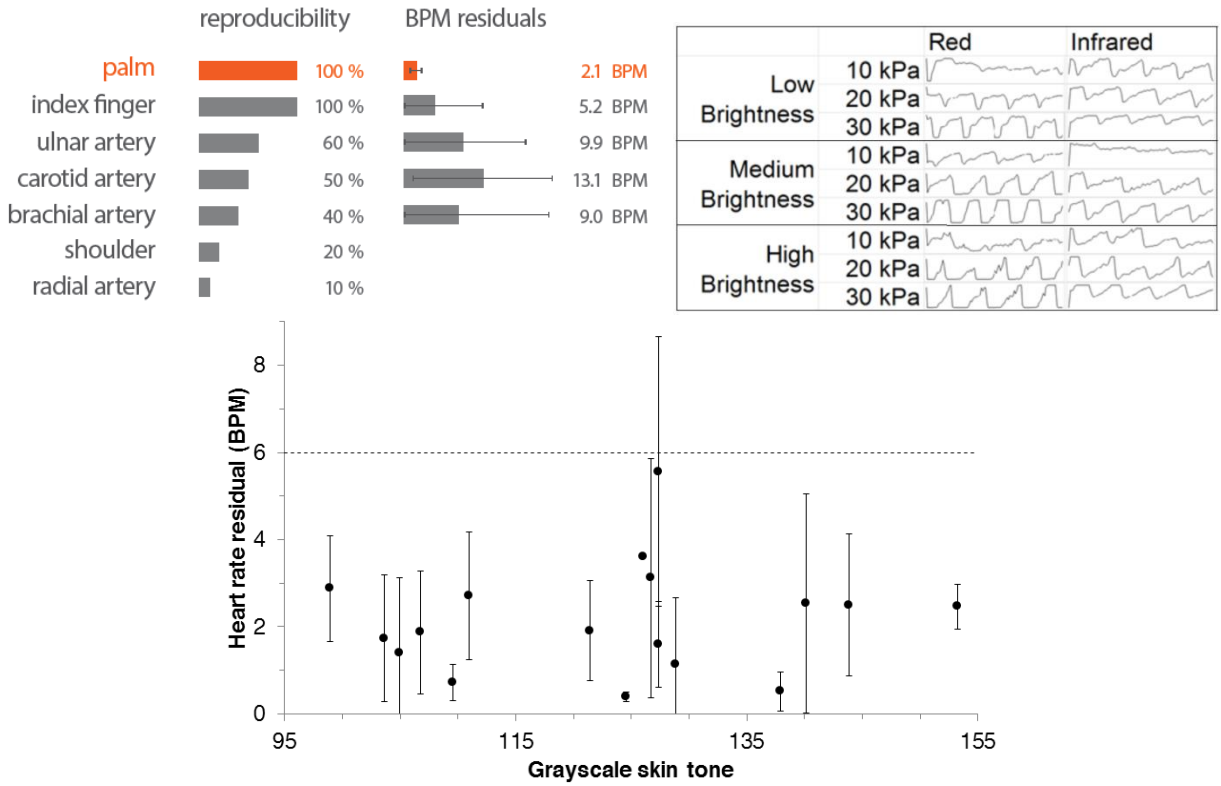

Figure 7 Graphs of data collected from accuracy testing. (top left) Reproducibility and accuracy of readings for each body part that produced a readable signal shows that the palm maximizes accuracy. (top right) Representative photoplethysmograms show signal quality of tests on the palm for differing brightness and pressure for one individual. (bottom) Accuracy of readings across subjects of different skin tones shows no correlation between accuracy and skin tone

Table 3 Design criteria and specifications based on user needs.

User Need	Target Design Criteria	Actual Value
Accurate	±2 % SpO_2* and ±6 BPM	Mean – 3.7 BPM Standard deviation – 4.3 BPM
Cost Effective	< $300 per unit (labor and materials)	$93 projected for 20k units $118 projected for 500 units $342 projected for 10 units
Fast	< 30 seconds operating time	19 seconds operating time
Power Efficient	100 uses	at least 100 uses
Lightweight	< 500 g	395 g
Durable	> 3 years before replacement	projected lifespan of >3 years
Maintenance	>1 year before replacement of parts	Parts projected to last >3 years

*Unable to evaluate SpO_2 with statistical significance due to a limited range of SpO_2 values in healthy adult subjects

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