Pulse Edge

by Pulse Ox (Group 8)

BME 60C

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Problem Definition

A pulse oximeter measures a user's heart rate and blood oxygen saturation level continuously in real time. The user inserts a finger into the device and remains motionless as a multicolor LED transmits Red and Infrared wavelengths through the finger to a photodiode which measures the remaining light frequency. Vital signs are then calculated using these measurements. This product, Pulse Edge, is a non-mobile desktop unit designed to be used by medical practitioners during procedures involving anesthesia or sedation, especially for patients with preexisting medical conditions (such as heart failure), and other needs [1]. For the user, the pulse oximeter must be comfortable, accurate, and easy to use. Our pulse oximeter must be designed to minimize external light, be lightweight and durable, cheap to manufacture, and easy to mass produce via modern construction techniques such as injection molding of ABS plastic.

Market and Value Proposition

This device is designed to solve the trade-off between accuracy and high costs. As of 2012, the pulse oximeter market has been growing steadily at 10.4% per year and is projected to continuing growing at this rate until 2025. As of 2015, the market value of the device is around $1.5 billion per year, but is projected to grow to $2.3 billion by 2020 and $2.8 billion by 2025. Our competition includes large companies such as Philips Healthcare, CAS Medical Systems, Covidien Plc, and Masimo Corporation. Retail values of pulse oximeters on the market currently range from $177 to $600. To offset these companies, we will sell our product for $120, which will be attractive to healthcare facilities in lower-income areas. If we can obtain the necessary funds, we will be able to expand to third-world countries, such as those in Asia and the Pacific, which have the highest growth rates for pulse oximetry due to new regulations that promote the use of pulse oximeters. This will be advantageous for us as resources in these countries are limited and clients would be especially attracted to our low selling point [2].

Product Concept

The Pulse Edge is designed to maximize accuracy while minimizing costs. The finger clip, made out of inexpensive ABS plastic, contains a hole in the front large enough to accommodate the average finger, which has an approximate width of 1.6 to 2.1 cm and a radius of 0.7 to 0.9 cm [3]. It has an adjustable hinge, opening 0.26 in to accommodate larger fingers, and is easily locked in place by tightening an inexpensive bolt and nut [Figure 3]. The shelled design preserves the light emitted from the multicolored LED inserted through the top half of the finger clip, while minimizing the background light interference to improve accuracy. A multicolored LED will be selected instead of 2 LEDs in order to reduce the distance between the Infrared and Visible Red emitters, which would affect the accuracy of the reading. Directly below, the photodiode is placed inside the bottom half of the finger clip to reduce the amount of light lost due to background noise, improving accuracy. It is positioned so that the finger makes direct contact with the photodiode when the finger clip is secured shut, enclosing the finger

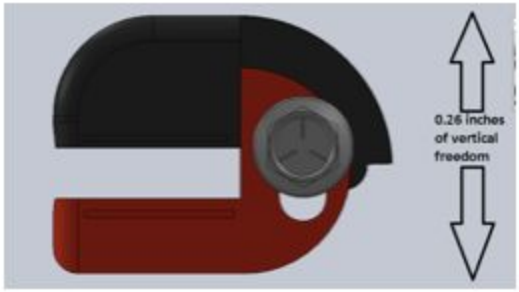

Figure 5. Vertical Freedom of Hinge

inside a light-preserving shell. A shielded multicore cable connects the LED and the photodiode to the Arduino board inside the main box, which will be described later. The shielding reduces background noise and preserves information as the data acquired from the photodiode is sent through 2 feet of cabling to the Arduino inside the box, discussed next.

For the box, there is a pyramid-shaped top half, containing the breadboard, secured to the bottom lid, where the Arduino is attached, by four screws and nuts. A miniature breadboard is placed in the small trough above the Arduino hardware so that the manufacturing time and cost of the box is reduced, and the box itself is lightweight and durable. The box also contains a round hole for the shielded cable to run through to the Arduino, and a rectangular hole behind to run a red USB cable from the Arduino to a desktop computer. This allows clients to run the Pulse Ox software designed using LabVIEW to record data from the hardware. The Pulse Ox LabVIEW software itself is designed to be easy for clients to use and read results from. With the press of the large button on the front panel, the heart rate and blood oxygen saturation level are displayed after 15 seconds [Figure 4].

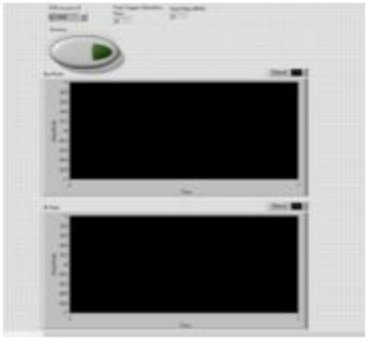

Figure 4. Pulse Ox LabVIEW.

Manufacturing Plan

First, a prototype of the device will be built using ABS Plastic and injection molding for the 4 plastic components: the top and bottom half of the finger clip, discussed first, and the top and bottom half of the Arduino box. The LED will be inserted through the central hole in the top half of the finger clip, and the photodiode will be inserted into the trough in the bottom half. They will be soldered to the multicore cable, which will then be connected to their corresponding positions on the Arduino board in the main box as shown in Figure 5. A foam bed will be adhered to the bottom of the finger clip, securing the photodiode in place. The bolt and nut will then be screwed on, joining the two halves together.

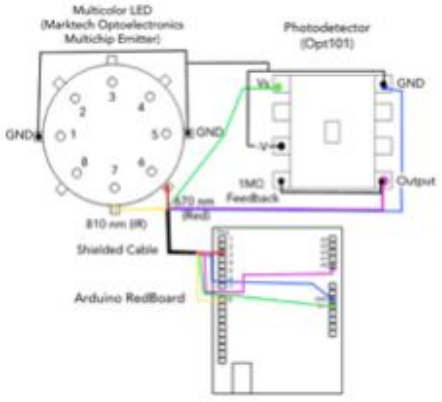

Figure 5. Wiring Diagram

Afterwards, the main box will be assembled. The Arduino, with its wires facing the top half, will be adhered to the bottom half, and the multicore cable wire will be fed through the round hole in the top half. The breadboard will be attached to the top half, with the red cable extended outward through the rectangular hole, ready to be connected to the Labview software. Finally, four screws and nuts will be used to connect the top half to the bottom half, assembling the box.

After finalizing the design, an injection mold of all four plastic parts will be created to make the device easier to mass produce. Additionally, the LED, Arduino, multi-core cable, red cable, and photodiode will be produced by Pulse Ox to reduce costs. After quality control and FDA approval, the device will be ready to be sold for $120.

Works Cited

[1] Many Uses of Pulse Oximeters [Online]. Available: http://www.healthcare4home.com/oximeter-many-uses/p.html

[2] J.W. Jung, et al., "Fingernail Configuration," APS, vol. 42, no. 6, pp. 753-760, Nov. 2015

[3] Pulse Oximeters Market Trends [Online]. Available: http://www.strategyr.com/MarketResearch/Pulse_Oximeters_Market_Trends.asp