Low Cost Pulse Oximeter Probe

In Conjunction with Engineering World Health and the MedeCal Project

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Abstract

Many hospitals in the developing world lack necessary medical equipment. Often, equipment that is cheap and disposable in developed nations is hard to obtain in the developing world. The goal of this project is to design a cheap, accurate, durable, and easy to use pulse oximetry probe that is able to interface with a multi-purpose, low-cost medical computer (the MedeCal). To meet this goal, we have constructed a transmittance probe usable as an ear or finger clip. It costs less than $8.00, and is usable on a range of ages and ethnicities. In the future, we plan to make minor mechanical changes to increase the probe's versatility and durability, and further test it to ensure its durability and accuracy.

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Introduction

In 2007, $6,096 per capita was spent on healthcare in the United States (United Nations, 2007/2008). In 28 developing countries, an average of less than $100 per capita was spent. These countries are primarily in Africa, including Haiti and Yemen. The average life expectancy in these countries ranges from 26 to 49 years while countries with leading life expectancies range from 62 to 74 years, with the US at 70 years (Murray, 2000). Though this is alarming, it is important to note that some of these developing countries spend as much as 5% of their GDP on healthcare, where some developed countries spend as little as 3.5% of their GDP on healthcare (World Health Organization, 2009). This demonstrates the stark contrast in the abilities of these developing countries to provide necessities to their people.

Engineering World Health (EWH), an organization based out of Duke University, is dedicated to improving healthcare and living conditions throughout the developing world through the development of medical technology. Our clients, Amit Nimunkar and Jonathan Baran, are working in conjunction with EWH to create a low-cost medical computer, the MedeCal. This device will process and display data from a variety of medical devices, including a low-cost digital thermometer, an electrocardiogram (ECGs), digital spirometers, and a pulse oximeter. The MedeCal will power these devices, and contain their circuitry, thus reducing their cost.

Our project this semester was to develop a probe for the MedeCal pulse oximeter. This probe houses only the optical electronic components (LEDs, photodiodes, and calibration resistors); all other circuitry (i.e. digital logic) will be housed within the MedeCal device and associated components, which are being built by our clients.

For the probe to be useful in a developing world context, a variety of factors were considered, including cost, reliability, durability, versatility, simplicity, and ease of integration. Hospitals in the developing world frequently function on a very low budget, and a ten dollar purchase is considered expensive (Fortney, 2009). Thus, for our probe to be useful, it had to be low-cost, with a target cost of under eight dollars (Fortney, 2009). Second, as with all medical instrumentation, the probe had to yield reliably accurate results. Our maximum tolerance was 5%, with a target tolerance within 3% (Fortney, 2009). Hospitals in the developing world also frequently lack the expertise or funds to repair or replace equipment when it breaks (Doherty, 2009). Thus, the equipment must be durable enough to last long enough to make it worth the investment. This is especially a concern as the probe would be used in most cases for frequent spot-checking, rather than continuous monitoring, and thus would undergo greater wear.

It should also be noted that due to a lack of funds, many hospitals in the developing world will probably only be able to afford one probe. Thus, the probe must be usable on virtually all of the patients that the hospital serves. This includes a wide variety of patients, from neonates to large adults. It also includes a wide range of skin colors.

An additional problem in many developing world countries is a lack of technical training for healthcare providers. Thus, our probe had to be intuitive and convenient to use, as many technicians will probably only receive minimal training before using it.

Finally, our probe must interface with the MedeCal system. The MedeCal will power the probe, and receive its input as an analog voltage signal.

Background

Pulse oximeters measure blood oxygenation. This is particularly important for detecting hypoxemia, a condition in which the arterial blood is not sufficiently oxygenated. Early detection of hypoxemia can prevent many complications such as systemic CO_2 buildup and tissue damage from oxygen deprivation.

Many factors can lead to hypoxemia. Drug misuse is one example. If an overdose of barbiturates is taken, the medullary respiratory center can become depressed and cause the pulmonary alveoli to become inadequately ventilated. This results in a buildup of CO_2 and depression of O_2 in the bloodstream. Problems with the cardiovascular system are more common causes of hypoxemia. One example of this is a physiological shunt, in which blood goes through the pulmonary vasculature without coming into any contact with alveolar air. This is often seen in conditions such as pulmonary edema, pneumonia, and collapse of a portion of the lung (pneumothorax) (Mayo Clinic Staff, 2008).

Pulse oximetry is particularly important when patient feedback is limited. This includes cases where a patient is under anesthesia or unconscious. Oxygen saturation measurement is also important in newborn infants, especially after premature birth (Askie LM, 2003).

Operational Principles

A pulse oximeter relies on light transmission through tissue to measure oxygen saturation. The light is absorbed and reflected by multiple components including skin, muscle, and blood vessels. Light absorption by tissues remains fairly constant over long periods of time. Light absorption due to arterial blood flow varies on a short time scale. When the heart beats, blood is pushed into the arteries, causing them to expand. Because of the influx of blood, the total amount of tissue between the oximeter's light source (an LED) and detector increases, and so does light absorption. This principle can be used to measure a patient's pulse (photoplethysmography).

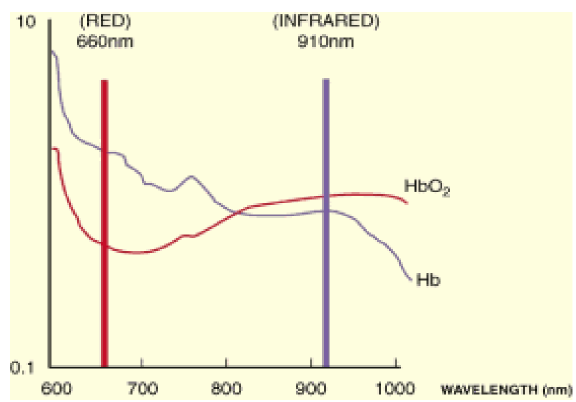

Figure 1. Absorption of oxygenated and non-oxygenated hemoglobin at different wavelengths (Oximetry.org).

Additionally, hemoglobin has different absorption spectra depending on whether or not it is carrying oxygen. The spectra of oxygen-saturated and unsaturated hemoglobin are shown in Figure 1. This effect can be seen with the unaided eye; hemoglobin in arterial blood is mostly saturated and appears red, while venous blood, which is mostly unsaturated, appears darker because it absorbs more red light. This effect is taken advantage of in oximetry by using two LEDs with different wavelengths (typically 660 and 940 nm) and shining them through the tissue. By applying the principles of photoplethysmography and examining only the changing components of light absorption, the pulse oximeter is able to determine which components of light absorption are due to hemoglobin in arterial blood versus light absorption due to other surrounding tissues. The ratio of absorption at the two wavelengths is then used to determine the percent of saturated hemoglobin. Reference tables based on experimental data exist but the calculation is beyond this text.

There are two approaches to developing an oximeter probe. The first uses transmitted light, the second uses reflected light. The difference is in the way the elements within the probe are positioned (see Figure 2). A transmittance probe has two LEDs on one side and a photodiode (light detector) on the other. The tissue to be analyzed (commonly a finger or an ear) is inserted between the two. Transmittance probes are commonly placed on a finger or ear and are very convenient to attach and remove.

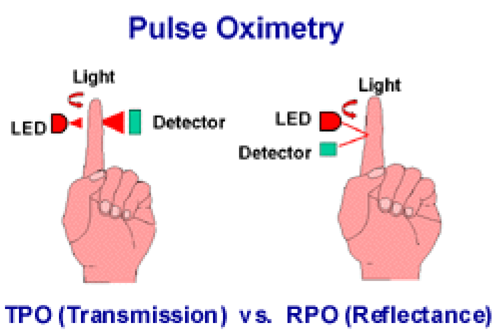

Figure 2. Transmittance vs. reflectance pulse oximetry setups. (AG&R Distributors, Inc.)

A reflectance probe has the LEDs and the photodiode(s) on the same side. It must be placed over a point with underlying bone. Light is emitted by the LEDs, passes through tissue and blood vessels, reflects from the bone, passes through the tissues again, and is then detected.

Probes utilizing reflectance have the advantage that, regardless of the patient's size (infants to very large adults), the attachment site is always similar. However, attachment of a reflectance probe is, in general, more difficult than attachment of a transmittance probe, and proper attachment of a reflectance probe is essential to ensure its signal quality. Also, properly attaching a reflectance probe is quite time consuming which may lead to improper use. Both the transmittance and the reflectance probes are used clinically, though the transmittance probe is more common due to the convenience of attachment, and better signal quality.

Basic Probe Electronics

For ease of replacement, the circuit is split into three components: the probe, the adapter, and the low cost central processing device (the MedeCal) which the adapter plugs into. The probe itself contains minimal circuitry (Figure 3). The LEDs used are 660 and 940 nm. They are normally powered with less than 3 V. The voltage may be adjusted for different ear and finger thicknesses as well as different skin colors. The wavelength of light emitted by the LEDs may deviate from the specified value by as much as ±5%. Therefore, a resistor with a certain value is used in the probe to specify the deviation of the LED wavelengths and introduce the correction when the MedeCal calculates the ratio of absorbed red and IR light. Thirdly, the probe contains the photodiode which detects the light. It contains an internal amplifier that can be run with up to 5 V. The photodiode-amplifier setup outputs voltage as signal. Under normal operational conditions, it can run at 3.3 V, the same voltage that powers the adapter circuit that plugs into the MedeCal. In total, the probe will connect to a bundle of six wires. The wires are as follows:

- the calibration resistor
- the two LED inputs
- the power for the photodiode
- the photodiode output
- the ground reference

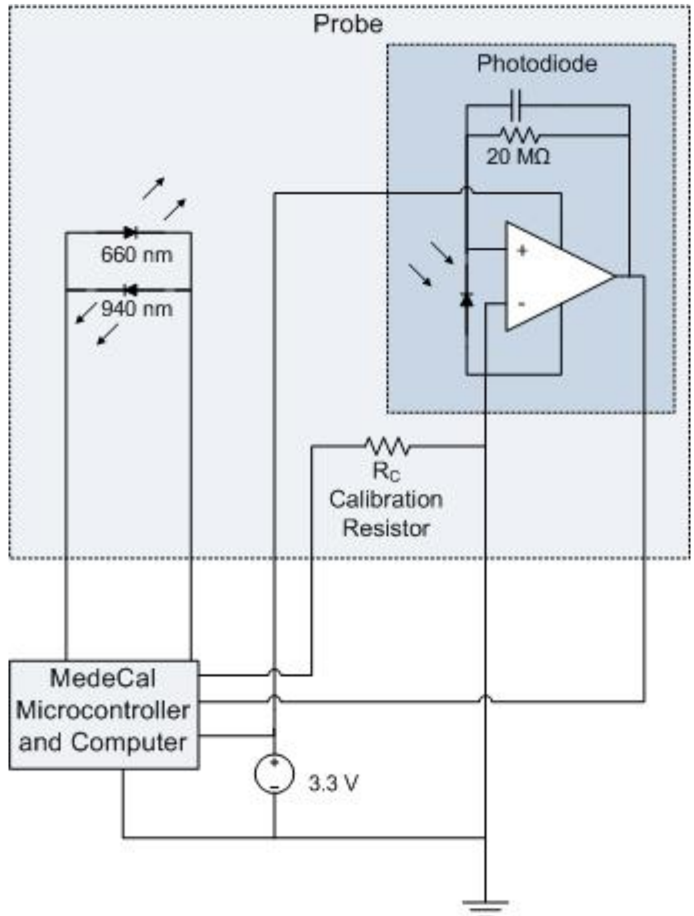

Figure 3. Basic layout of electronic components housed in pulse oximeter probe.

The adapter and the MedeCal will be constructed by the client. The MedeCal will perform all the processing, such as the pulse and oxygen saturation calculations. One adapter unique to a device type (oximeter, spirometer, thermometer, etc.) will be plugged into the MedeCal at a time. The device being used will plug into the adapter via a serial port. Thus, a damaged probe can be replaced without replacing a significant amount of circuitry. The adapter contains the driving circuit that flashes the LEDs, as well as the pre-processing elements (see Figure 4). It is powered by the MedeCal which is intended to run on a battery.

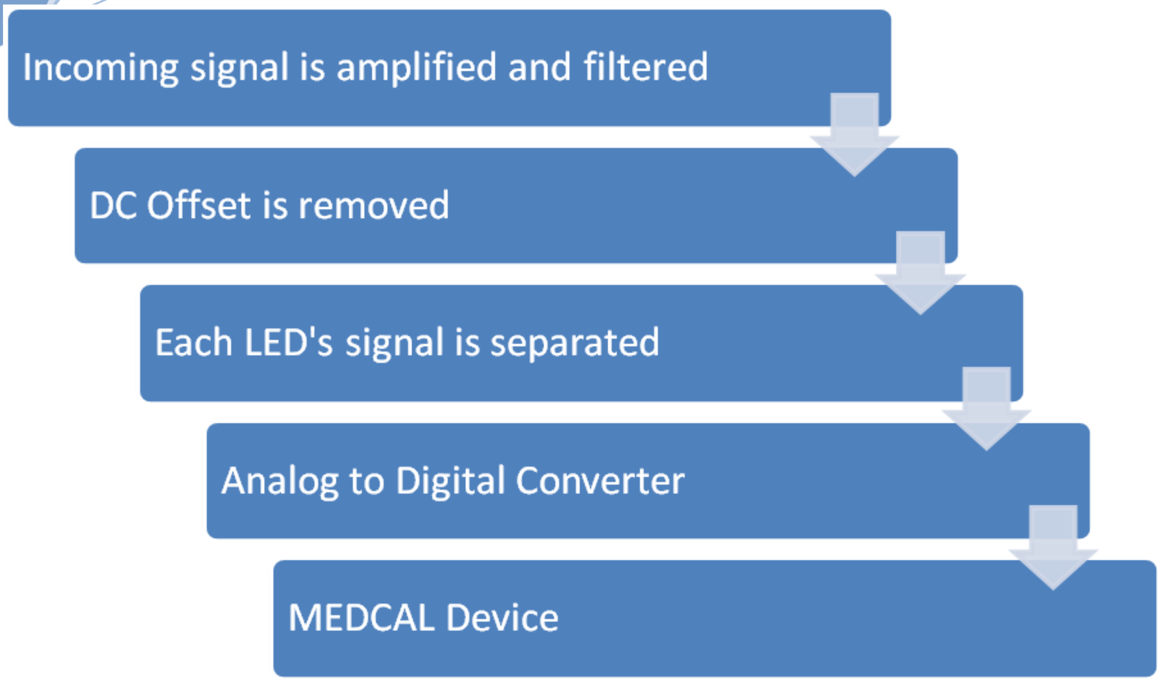

Figure 4. Basic information flow from pulse oximeter probe to the adapter and then to the MedeCal device.

A microcontroller is used to time the LEDs, alternating between three states. In the first, only the red LED is turned on, in the second only the IR, and in the third, both LEDs are off. The switching between the states occurs at 480 Hz. The timing signal is also sent to the adapter circuit. First, the circuit verifies that the signal level is sufficient. If not, it sends feedback to the driver circuit to increase LED voltage, leading to an increase in brightness. Once the input from the photodiode is received, it is amplified, and the DC component and high frequency noise are removed using a bandpass filter. Then, the signal is separated into the red, IR, and ambient light components and the latter is removed. Lastly, the signal is converted into digital form and sent to the MedeCal.

In total, the MedeCal receives several input signals including the offset resistances from the probe, the signal from the photodiode, and a device ID that identifies the oximeter adapter as unique from any other device that may also be interfacing with the MedeCal. The MedeCal provides power for the microcontrollers in the driver and pre-processing circuits.

Design specifications

The probe had to fulfill the following requirements:

1. **Durable enough to withstand the heavy use that it may encounter in hospitals of the developing world**
2. **Cheap enough to be sold for under $8.00**
3. **Be accurate to within ± 5% (ideally to within ±3%) of the oxygen saturation calculated by an FDA approve pulse oximeter** (Fortney, 2009)

4. **Suitable for use with a variety of patients (most age and ethnic groups)**
5. **The probe must be able to interface with the MedeCal device; in conjunction with the MedeCal, it must be able to:**
    a. **Obtain a photoplethysmograph signal**
    b. **Obtain a heart rate reading**
    c. **Obtain an oxygen saturation reading**
6. **The probe must be convenient for medical personnel to use to prevent misuse and disuse**
7. **The probe must be optimized for "spot checks" rather than long term patient monitoring** (Fortney, 2009)

Design Options

To fulfill the design criteria, we considered three primary design options, and settled on a combination of the last two. The design options were: a forehead reflectance probe, a finger transmittance probe, and an ear transmittance probe.

Option 1: Forehead Reflectance

In reflectance pulse oximetry, the LEDs and photodiodes are on the same side of the tissue; the photodiodes measure light reflected off of subcutaneous tissues (typically bone). The best locations for reflectance pulse oximetry are where a relatively thin region of well-perfused tissue covers bone, as the bone reflects the light. Common regions include tissues covering the skull or sternum. Of these regions, several studies indicate that the forehead is the best location (Branche, Johnston, Pujary, & Mendelson, 2004).

Studies also indicate that in reflectance pulse oximetry, the ratio of AC to DC signal acquired by the photodiodes increases almost linearly with the distance between the LEDs and photodiodes. Greater separation between the optical elements means that more tissue is able to absorb and reflect light. However, as the separation between the elements increases, the LED power required to produce a good signal increases almost exponentially. Thus, the ideal separation between the optical elements involves balancing signal quality and power consumption (Mendelson & Ochs, 1988). Several studies also indicate that a better signal quality can be achieved when a ring of photodiodes is used to collect the light from a central source (Mendelson & Pujary, 2003).

Thus, the reflectance probe design we considered is a disc attached to the forehead with a headband. The face of the disc has a red and an infrared LED in its center, surrounded by a ring of three or four photodiodes, as shown in Figure 5.

The forehead probe presents several significant advantages, including the following:

- It has no moving parts and very few stress concentrations, and is thus very durable.
- It can be used on practically all age groups, and if necessary, on multiple sites on the body.

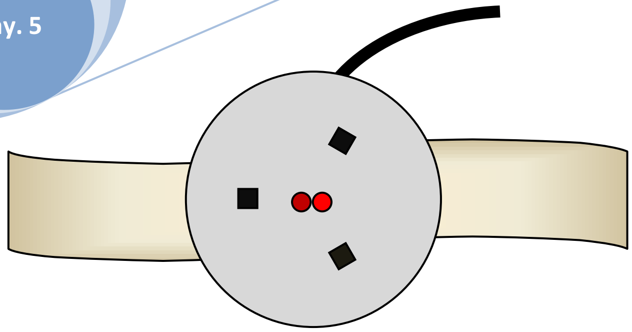

Figure 5. The forehead reflectance probe, with the LEDs located in the center of a disc, and radially surrounded by three photodiodes.

• It relies on circulation to the head, which remains perfused even in cases of severe shock, in which the patient's peripheral circulation may be cut off.

The forehead probe design also presents several significant drawbacks. One major problem is that the signal resolution offered by reflectance is lower than transmittance, creating a higher possibility of an inaccurate measurement.

Another problem is that the probe is not well suited for spot checks; the headband would need to be adjusted frequently between patients. This is a major cause of concern, as the pressure applied to the probe affects its accuracy (Dresher & Mendelson, 2006). Also, with constant readjustment, the headband would wear out and need to be periodically replaced. For doctors to apply the probe with the right amount of force, they would need training, which may not be available.

Thus, the forehead reflectance design was rejected in favor of a transmittance-based design.

Transmittance

The two primary transmittance options we considered were finger transmittance and ear transmittance. Transmittance through the finger is currently the most popular probe design in the United States, largely due to the finger's convenient accessibility.

Transmittance pulse oximetry offers several significant advantages over reflectance pulse oximetry, including higher signal amplitude (and thus higher signal-to-noise ratio), more convenient access, and less pressure dependence.

Two sites commonly used for transmittance pulse oximetry are the ear and the finger. The finger is the most convenient site, and is often the most comfortable for the patient. However, there are a variety of situations in which it is inappropriate, including the following:

- In patients wearing fingernail polish, light transmission through the finger is blocked.
- The fingers and toes of neonates are sometimes so small that adult finger probes cannot be used on them.
- In patients with poor or reduced perfusion (for example, due to cold ambient temperatures), the blood flow through the finger may be too low.
- Most importantly, when patients experience severe trauma, bleeding, or very low blood pressure, the body cuts off circulation to the periphery, making finger plethysmography unsuitable (Fortney, 2009).

Ear pulse oximetry is more reliable in situations where the patient is undergoing severe trauma. As part of the head, it is perfused even when circulation to much of the periphery is cut off (Fortney, 2009). This makes it more reliable, especially for potentially traumatic procedures such as surgery.

Design Matrix

Our design matrix is shown in Table 1. As the matrix indicates, we decided to use an ear transmittance probe design, primarily because it uses a more dependable blood supply than the finger transmittance probe, yet is more convenient and has a higher signal resolution than the forehead reflectance probe.

Table 1. Design matrix comparing finger, forehead, and ear probes.

	Weight	Finger	Forehead	Ear
Cost	10%	7	7	8.5
Accuracy	25%	5.5	6.5	7.5
Ease of Use	20%	9	5.375	6.25
Range of Use	20%	8.5	7.625	6.25
Durability	25%	4.375	7.625	7.25
Total	100%	66.7	68.3	70.4

Upon further consideration, however, it was easily seen that all three design options scored very similarly in this matrix. Due to this fact, the idea of combining different designs to make one probe that could be used in more than one location on the body was considered. The combination of a finger and ear probe seemed very possible and indeed very useful. Therefore, the decision was made to construct a probe that was useable on both the ear and finger.

Final design

Our final design is a clip that can be used on either the ear or the finger (see Figure 6). The two prongs of the clip are connected with a U-shaped plastic spring. The probe's optical elements are housed at the ends of the prongs, and are shielded by rubber sheaths from mechanical damage and optical interference. The rubber sheaths also prevent the optical elements from pressing into the tissue, which would reduce blood flow in the tissue around them.

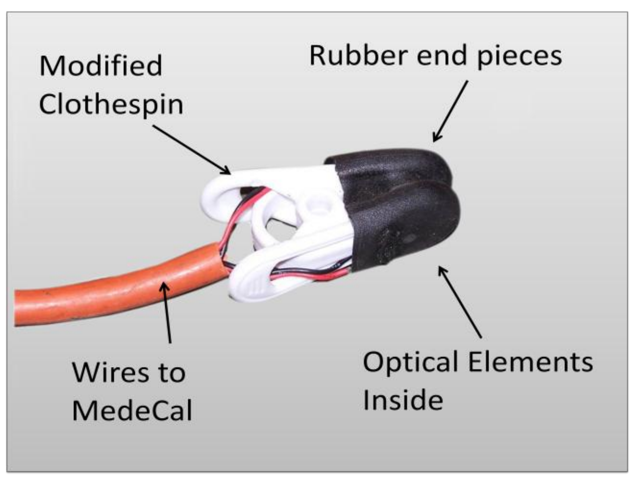

Figure 6. Pulse oximeter probe prototype.

One drawback of using a probe for transmittance through either the finger or the ear is that it is difficult to provide adequate optical shielding for both cases. Fingers are cylindrical, so many finger probes incorporate semicircular grooves into both prongs of the probe for the finger to rest in, thus encasing the finger in the probe. This design would not work well for the ear, which is predominantly planar; the semicircular grooves would distance the optical elements from the tissue, thus increasing the risk of optical interference. For this reason, we needed a planar arrangement. We experimented with rubber wings extending out from the sides of the probe, but found that this made the probe difficult to position on the ear. Thus, instead of using the rubber wings, we recessed the optical elements behind holes in the rubber sheaths.

Results

As shown in Table 2, we met our cost requirement. The designed probe costs under $8.

Though the accuracy of the probe cannot be quantitatively measured because the MedeCal processing algorithm has not yet been developed, its photoplethysmographic signal is comparable to the signal yielded by a commercially-produced Nellcor® finger probe. Our probe functions with both red and infrared wavelength.

Our probe has been tested on a range of subjects with different ear and finger sizes, morphologies, and skin colors. A good signal can be achieved in all of these cases with gain adjustment.

Table 2. Cost breakdown of the pulse oximeter probe.

Item	Cost
Photodiode	$0.72
Two LEDs (on the same mount)	~ $0.33 x 2 ($15.00 for prototype)
Plastic clip	$1.50
Cord and serial connector	$2.00
Rubber sleeves	$1.00
Total	**$5.88**

Though the probe still exerts too much force on the finger for long-term monitoring, it has been worn for an hour on the ear without significant discomfort.

Future Work

Though we have constructed a pulse oximeter probe that, upon initial use and testing appears to satisfy the goals of this project, much work must still be done to ensure that this design will satisfy all of this project's requirements. Several mechanical improvements must be made to enhance the utility and longevity of the probe. Much mechanical testing must also be conducted to ensure that the probe will be durable enough for the heavy use that it will encounter. Also, the accuracy of the oxygen saturation measurement that it is able to produce has yet to be evaluated. The accuracy of this measurement must also be evaluated in many situations such as during states of low blood oxygen saturation and poor perfusion in the ear or finger.

Certain mechanical improvements, such as replacing the current plastic spring with a metal spring, will be made before the probe is ready for use in a developing country's hospitals. Mechanical testing will be done to ensure that the spring used in the final design has a low enough spring constant so that the probe is comfortable enough so that it may be used for long-term patient monitoring and not just spot checks. Though not requested by our client, being able to use the probe for long-term monitoring will increase the versatility of this probe.

Because the client's circuit is not currently able to calculate oxygen saturation, this aspect of the probe was not evaluated. Once this part of the MedeCal circuitry is complete, the accuracy will be compared against the reading of a commercial, FDA approved pulse oximeter. The probe's accuracy must also be tested in situations where oxygen saturation is low and/or blood perfusion of the area being monitored is low. For testing purposes, a person's blood oxygen saturation can be lowered by having them breathe a mixture of air and nitrogen. Reducing blood perfusion to the finger or ear involves using cold temperature (i.e. cold water). Blood oxygen saturation measurements must also be carried out on many different people of different age groups, ethnicities, and morphologies to ensure that accurate readings can be obtained on virtually every person.

Conclusion

We decided that the best pulse oximeter probe design to satisfy our goals was one which works on the principle of transmittance through the ear or finger. A clothespin-type design was decided upon and a prototype was constructed. Not only is the design cheap and durable, but it is also fairly straightforward to use. It is also very versatile being able to be used on either the finger or the ear. Spot checks can be done easily with this probe. Also, patients can be safely monitored for at least an hour without significant discomfort. Furthermore, this design easily interfaces with the MedeCal device.

The accuracy of the blood oxygen saturation measurements taken by this probe were unable to be evaluated during this semester because our client's circuit is not yet capable of processing such information. Nonetheless, the client's circuit, when interfacing with our probe, was able to operate in photoplethysmograph mode, demonstrating that the MedeCal successfully interfaced with our probe. Though further testing will be conducted, thus far the probe has met our client's goals and the goals of this project. In the near future, this probe may be deployed with the MedeCal device to significantly improve healthcare conditions in the developing world.

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Appendix A

Product Design Specifications

EWH Pulse Oximeter

Version: 3.1
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Function

The purpose of this project is to develop a low-cost pulse oximeter for use in developing countries. It will be integrated with the MedeCal, which records and displays patient data. The oximeter must be rugged, durable, and inexpensive.

Design requirements

1. Physical and Operational Characteristics

c. *Accuracy and Reliability*:

- The probe must be precise to increments of 1% SpO_2.
- The pulse oximeter must be accurate to within 5% SpO_2 (Fourtney).
- Must contain one resistor per LED which specifies the LED's deviation from the specified wavelength

f. *Operating Environment*:

- The device must be operable in 100% humidity.
- The device must operate in a temperature range of 0°C to 38°C.
- The device must be rugged.
    - The device must be able to be dropped from 1.5 m onto concrete without breaking.

h. *Size and weight*:

- Size: the probe should be smaller than 4 cm × 4 cm × 4 cm.
- Weight: the probe should be lighter than 100 g

j. *Materials*:

- Must be mass-producible.

k. *Attachment:*

- Must attach to the ear or the finger, with LEDs on one side of the ear or finger and a photodiode on the other.

2. Production Characteristics

a. *Quantity*: Mass produced.

b. *Target Product Cost*: under $8. Though this is our target cost, our prototype can be above this specification.

3. Power and Data Transfer

- The device must interface with a central processing unit for both power and data transmission.

- The device must run on ±3.3V.

3. Miscellaneous

- The device must withstand sterilization with isopropyl alcohol or a weak bleach solution (Fortney).

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