Phys 371: Design Like a Physicist

Pulse Oximeter Calibration Study

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Abstract

Pulse oximeters have been known to exhibit errors in their readings for people with darker skin pigmentation, especially during the COVID pandemic where blood oxygen content was an important factor in determining the health of patients. Calibration to correct this error would reduce racial disparities in healthcare and improve the well-being and care of colored people.

We hypothesize a few methods of calibration for this error utilizing a spectrometer to correct for the absorption of the skin. Using measurements at wavelengths that give similar absorptions for both oxygenated and deoxygenated hemoglobin, we can perform heuristic analysis via regression methods and extrapolate data from the regression to calibrate measurements at the wavelengths the pulse oximeter takes advantage of to calculate pulse oxygen.

Introduction

Can medical technology have a racial bias? Believe it or not, pulse oximeters indeed do! Pulse oximetry is a non-invasive method of measuring a person's pulse and oxygen saturation level. It is precise enough to detect minuscule changes in blood oxygen levels.



Figure 1: Consumer-Grade Pulse Ox

Pulse oximetry is critical since a low oxygen saturation or irregular pulse can be an indicator of several conditions and can often be the first step in diagnosing a patient. However, in patients with darker skin pigmentation, there is a limitation in the standard non-invasive pulse oximeter. It has been found that these devices will return imprecise oxygen saturation (SpO2) readings with the readings becoming more and more imprecise the darker the patient's skin pigmentation is. This bias tends to result in higher than accurate blood oxygen estimates. As current pulse oximeters are calibrated for lighter skin subjects, it is vital to improve pulse oximetry devices in order to more equitably represent a larger portion of the world's population.

There is also evidence to suggest that the skin color bias that pulse oximeters have is associated with disparities in care. A research paper we found suggests that when administering

supplemental oxygen; Black, Asian, and Hispanic patients were administered significantly less oxygen. This results in non-white patients often receiving lower-quality care. While fixing the pulse oximeter won't nearly solve everything, flawed pulse oximetry may be playing a small part in these racial disparities. There is already widespread knowledge that in the field of medicine there are varying factors for racial disparities in medical care.

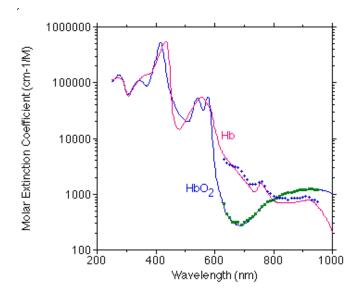
We believe it is possible to correct this flaw by analyzing the light spectra of the patients' skins. This would have a variety of different benefits including ease of use, ease of manufacture, and most importantly, will allow the device to remain non-invasive in nature. The fact that the standard pulse oximeter is non-invasive is the biggest reason why it's so widely used by medical institutions worldwide. Using the light spectra, we may be able to construct some sort of calibration method for existing pulse oximeters without requiring a change to the fundamental technology. And this will only require the addition of one other sensor; a relatively inexpensive color sensor. In small amounts, this kind of device can cost 16 dollars, but purchased in larger amounts for mass production drives the price down to around 13 dollars. This device alone costs almost as much as a consumer grade pulse oximeter from Amazon, but we must remember the use case of our device is in a professional hospital or clinic setting in order to provide patients with better care. The benefits of such a device would highly outweigh a 13 dollar price hike, especially for medical institutions which will likely see this as a small price to pay for a significant increase in quality of care. We hope that this kind of solution can help everyone receive more equitable and fair healthcare. Even though the world is full of injustice, we can at least address small issues on a technological level to make the world more liveable for everyone.

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Methods:

Data Acquisition Goal

What we hope to accomplish in our data collection is to gather skin pigmentation data on a subset of people with a wide range of skin tones. This may be difficult since the STEM field doesn't exactly have a reputation for being the most diverse field, and our friends alone won't be able to provide us with enough useful data to meet our goal. It may also be useful to gather control data. Unfortunately, we do not have a precise way to measure a control blood





oxygenation as such devices are not in our arsenal of tools. This is of course not ideal since not having a way to gather control data puts a limit on our level of precision, which is the point of this project, but we may still be able to build a model based solely on color data, and what we know about the spectra of oxygenated and deoxygenated blood. We know there are sections of the hemoglobin spectra that don't change very much when its oxygenation changes. We may be able to exploit this quirk of hemoglobin to calibrate the device since the only thing impacting the spectral readings of the color sensor would theoretically be the skin pigmentation. After gathering this data, we may be able to use some sort of regression model to develop a theoretical model for the absorbance spectrum of the subject's skin. We think this will work well since the wavelength a standard pulse oximeter uses (~680nm) is pretty close to the wavelengths we will use to build the calibration line or curve.

Breakdown of Sensors

Our device consists of a total of four modules. Firstly, we have our microcontroller. We started the project with an Arduino Mega. But as we progressed in our project, we realized it would be nice to have a much smaller form factor as pulse oximeters tend to be small. Therefore we opted to switch to the much smaller Adafruit Feather M0. Aside from its small form factor, another benefit of switching to this microcontroller is that it has an onboard SD card shield.



Figure 3: Feather M0 Microcontroller

This means that not only will we save space from the microcontroller, but we also won't need to use a separate SD card module. We ran into issues with the feather though, Adapting our code to fit the new microcontroller wasn't straightforward. We spent a lot of time troubleshooting issues with the feather. Once we adapted to the device though, we were able to make a relatively small version of our pulse oximeter. The feather also supports a separate lithium-ion battery and we thought it would be appropriate to put one on our device so that it could function without an external power source.

The second module on our device is a sensor: the pulse oximeter itself. We chose the Max 30102 pulse oximeter from Sparkfun.

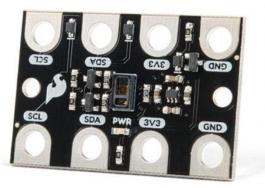


Figure 4: MAX 30102 Pulse Oximeter

While this version of the sensor is rather large, we chose it because it was similar in size to our color sensor and would be much easier to work with than a smaller one. The sensor can sense a person's pulse, as well as their blood oxygen concentration. It is important to note that this pulse oximeter uses the reflectance spectra of the finger to calculate the subject's blood oxygen concentration instead of through transmittance, so we will need to adjust the calibration parameter we obtain from our data accordingly. Similarly, we could also obtain a calibration parameter for a pulse oximeter that works through transmittance so our device would work for both types of pulse oximeters.



Figure 5: TFT Display

The third module on our device is a TFT LCD display. This is a color display that we use to display the pulse, SpO2, and other information we think would be useful for the device. Setting up the device proved to be tricky at first, but after we learned how it worked we managed to get it to display rudimentary data. We initially hoped to program a graph onto the display but we opted to spend more time on improving the vital functions of our device.

The fourth and final module on our device is the most important part of our project, the color sensor. We chose the AS7341 spectral sensor from Adafruit. The sensor has the ability to sense 11 different wavelengths of light. A few of these wavelengths were useless to us, but opting for a sensor with more wavelengths afforded us a great amount of flexibility in what we could detect.

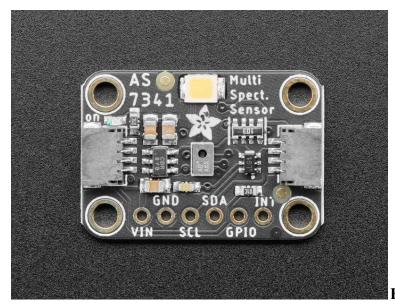


Figure 6: AS7341 Color Sensor

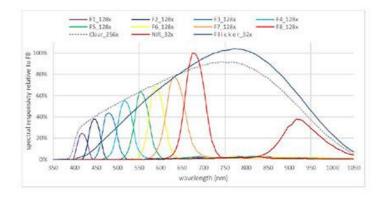


Figure 7: AS7341 Spectral Range,

which covers 415, 445, 480, 515, 555, 590, 630, 680nm, as well as IR (~900nm)

What we will be measuring is called the "molar absorption coefficient", which is a value that essentially describes how a certain chemical substance reacts with light. The sensor can detect 8 narrow wavelengths of light, and 3 more broad wavelengths which serve little purpose to us. Our initial idea was to use the NIR (near IR) wavelength since oxygenated and deoxygenated hemoglobin intersect at around 800 nm. Unfortunately, we found that the NIR sensor was so broad that the data it gave us was very difficult to interpret. With a different color sensor, however, the molar extinction intersection point can possibly provide us even more insight if we use it in conjunction with the data we are currently gathering from the sub 600 nm portion of the spectrum. But for now, with this sensor, we will be working with what we can detect.

Code

Our code for the pulse oximeter, aside from the calibration method, is purely a mixture of already existing code from the libraries we used. Both the pulse oximeter and colorimeter had implementations that were suitable for our application.

We collected spectrometer data from all available wavelengths as well as the pulse oxygenation for each sample in order to analyze any possible correlations between the two. Storing these data into a CSV (comma separated variable) file made it easy to view data via Microsoft Excel or Google Sheets, which provided simple plotting capabilities for heuristic analysis.

The pulse oximeter code utilizes zero crossing (when the signal changes from negative to positive or vice versa) to detect heart rate and runs this calculation:

$$R = \frac{\frac{AC_{red}}{DC_{red}}}{\frac{AC_{infrared}}{DC_{infrared}}}$$

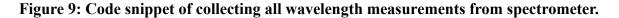
Which is a ratio of the ratios of the AC and DC components of the readings from the red and IR LEDs on the pulse oximeter. It then calculates the SpO2 by plugging this ratio into a quadratic polynomial with calibration coefficients determined by the manufacturer, in our case the coefficients match up with that of the MAX30101, another pulse oximeter made by the same manufacturer.

$$SpO_2 = a \cdot R^2 + b \cdot R + c$$

The calibration factors for the MAX30101 are: a = 1.5958422 b = -34.6596622c = 112.6898759

Figure 8: Calibration coefficients and SpO2 equation.

```
if (!wrote && count < trials) {</pre>
    if (!as7341.readAllChannels())
        Serial.println("Error reading all channels!");
        return;
    as7341.setLEDCurrent(4); // 4mA
    as7341.enableLED(true);
    Serial.println(count);
    // auto sample = sensor.readSample(1000);
    // float current_value_red = sample.red;
    // float current_value_ir = sample.ir;
    float current value red = sensor.getRed();
    float current value ir = sensor.getIR();
    double curr480;
    double curr515;
    double curr590;
    data.print(millis());
    data.print(',');
    data.print(as7341.getChannel(AS7341_CHANNEL_415nm_F1));
    data.print(',');
    data.print(as7341.getChannel(AS7341_CHANNEL_445nm_F2));
    data.print(',');
    curr480 = as7341.getChannel(AS7341 CHANNEL 480nm F3);
    sum480 += curr480;
    er.learn(480.0, curr480);
    data.print(curr480);
    data.print(',');
    curr515 = as7341.getChannel(AS7341_CHANNEL_515nm_F4);
    er.learn(515.0, curr515);
    data.print(curr515);
    data.print(',');
    data.print(as7341.getChannel(AS7341_CHANNEL_555nm F5));
    data.print(',');
    curr590 = as7341.getChannel(AS7341 CHANNEL 590nm F6);
    sum590 += curr590;
    er.learn(590.0, curr590);
    data.print(curr590);
    data.print(',');
```



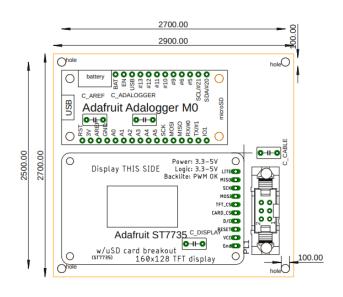
Similar code for collecting data from pulse oximeter.

Device Design

The prototype for our pulse oximeter was designed using the CAD software SolidWorks and produced by 3-D printing the parts. When designing the prototype, there were three main challenges that we faced. The design had to be portable and comfortable for multiple finger sizes, ensure that the user's finger maintained a constant pressure against the pulse oximeter (MAX30102) to produce accurate spo2 measurements, and the colorimeter had to be fixed at an appropriate distance from the finger so that the color measurements would not be saturated by the on-board LED, which is quite bright.

PCB Boards

The MAX30102 spo2 sensor, as7341 colorimeter, and Feather M0 + TFT LCD display were all attached to separate PCB boards to be mounted inside two 3-D printed cases.



PCB

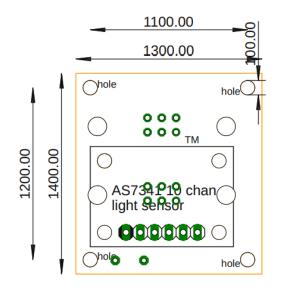


Figure 10: Feather M0 + TFT Display

Figure 11: AS7341 Colorimeter PCB

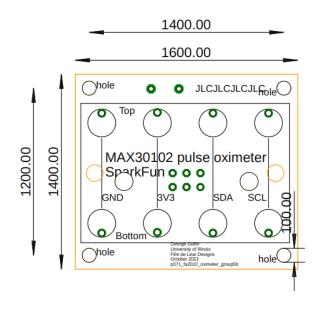


Figure 12: MAX30102 spo2 sensor PCB

Display Case

We decided to have the Feather M0 and Display in a separate case from the other sensors so that the pulse oximeter would be small enough to easily fit someone's finger. The display case includes windows to view the TFT display, access the SD card and micro USB port on the Feather M0, and a reset button to quickly start new trials.

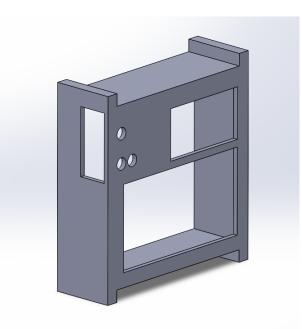


Figure 13: Display Isometric view

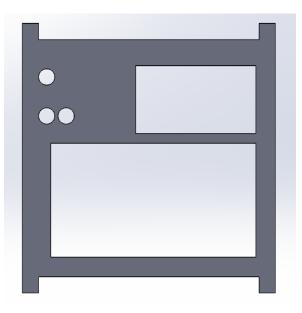


Figure 14: Display Front view

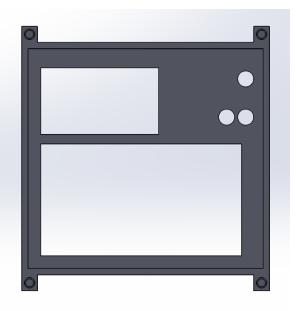


Figure 15: Display Back view

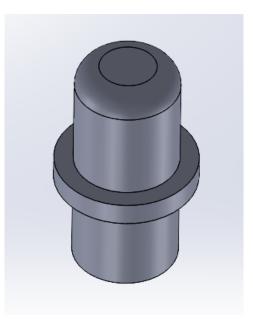


Figure 16: Reset Button Isometric view

Pulse Ox Finger Holder

To ensure the finger holder would be comfortable and fit multiple finger sizes, we based the design partially on existing pulse oximeters since they are used by a wide variety of people differing in size and age. We mounted the MAX3010 and AS7341 sensors in line along the length of the pulse oximeter. The MAX3010 sensor is positioned at the fingertip, while the AS7341 sensor is positioned in the middle of the finger between the knuckles. This part of the finger is the same color as the tip of the finger, ensuring that both sensors act on parts of the skin with similar melanin content.

To ensure that constant pressure is applied on both sensors, we designed a top half to the finger holder. The two halves of the finger holder squeeze the finger with a constant force produced by rubber bands that connect both halves.

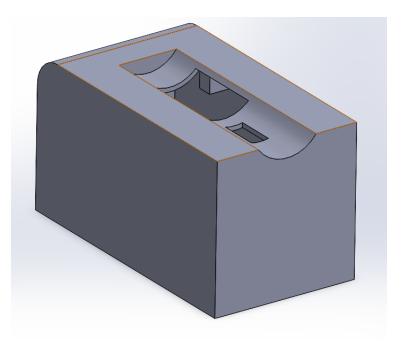


Figure 17: Finger Holder Isometric view

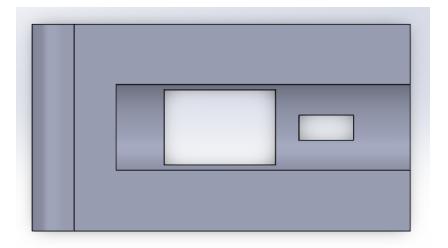


Figure 18: Finger Holder Top view

0	

Figure 19: Finger Holder Bottom view

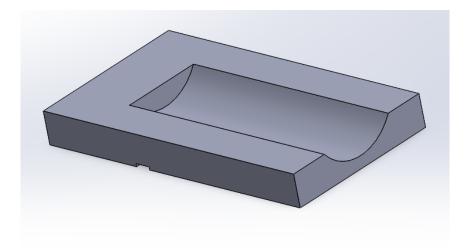


Figure 20: Finger Holder Cover Isometric view



Figure 21: All 3D printed parts with devices installed

Data Collection

In order to collect useful data, we needed to test the pulse oximeter on a diverse population. This was accomplished by testing the device at the engineering library and the physics building. The device took 250 samples of skin color and 10 samples of spo2 content.

415	445	480	515	555	590	630	680	CLEAR	NIR
23	40	87	98	24	41	89	99	185	56
5012	31449	29935	39801	49679	50858	64734	45694	65535	15081
5016	31408	29921	39755	49647	50823	64770	45695	65535	15110
5004	31365	29872	39669	49655	50818	64734	45679	65535	15124
5005	31356	29887	39672	49674	50858	64705	45674	65535	15108
5002	31322	29862	39623	49589	50785	64662	45648	65535	15100
5006	31352	29892	39667	49585	50765	64673	45631	65535	15097
5007	31377	29922	39690	49591	50801	64691	45657	65535	15097
5008	31366	29914	39685	49649	50816	64697	45626	65535	15105
5001	31348	29884	39636	49707	50844	64667	45648	65535	15102
5003	31377	29900	39664	49655	50790	64632	45609	65535	15099
5017	31485	29993	39788	49694	50837	64644	45634	65535	15112

Figure 22: Colorimeter data: Top row represents the wavelength (nm) of light reflected

68	0	98
68	0	98
69	0	98
68	0	98
66	0	98
64	0	98
64	0	98
63	0	98
65	0	98
64	0	98
64	0	99
63	0	101
62	0	100
62	0	100
62	0	99

Figure 23: Spo2 data: left column is heart rate, right column is blood oxygenation

Method 1

We first attempted to find a correlation between skin color and blood oxygenation by using the pulse oximeter on both the front and back of the finger. There is a slight color difference between the two sides of the finger and if the trials are done back to back, the oxygen content in the blood should be the same. However, this method failed to provide accurate results because the MAX30102 sensor read vastly low spo2 readings when used on the back of the finger. This is likely due to the fact that the only way it could be positioned under the fingernail or knuckle. These are not good spots to measure spo2 with a sensor that measures reflected light because fingernails are shiny enough to mess with the sensor and the knuckle does not contain enough capillaries to provide an accurate reading.

Method 2

We instead measured only the bottom (palm side) of the finger and attempted to use the absorption spectrum of melanin to discern how the spo2 readings should be adjusted. To measure the melanin content of the skin, we selected three wavelengths of light that are not affected by whether or not the blood is oxygenated or not. These were 590 nm, 555 nm and 415 nm. As seen in the figure below, the 555 nm and 590 nm light reflectances were the biggest indicators of a difference in skin color.

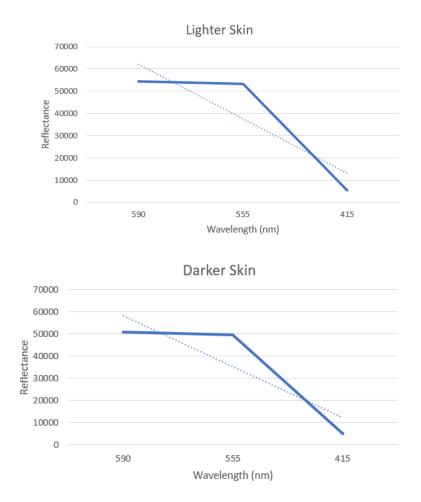


Figure 24: Data on two different skin tones: 590 nm and 555 nm light is reflected more in lighter skin than darker skin. Reflectance units are arbitrary, the data is just output straight from the colorimeter

Using this data we found a line of best fit for each sample with the goal of using the differences

in slope to calibrate the pulse oximeter for different skin tones.

Results

Calibration Method

We initially had two ideas of how to implement a calibration method. In Figure 2, we see that the absorptions of oxygenated (HbO2) and deoxygenated (Hb) hemoglobin are different past 600 nm. This region is what a pulse oximeter takes advantage of to calculate blood oxygenation. More specifically, a pulse oximeter generally takes measurements at two wavelengths of light, one around 650 nm and one around 900 nm, to take advantage of the differences in the magnitude of the absorption of the two types of hemoglobin. However, there are two distinct wavelengths where the absorptions of the two compounds crossed, around 600 nm and 800 nm. One idea was to take the measurements at these points and use these as a basis for representing the absorption spectrum of skin. In theory, the higher wavelengths should have a lower absorption compared to the lower wavelengths (based on the assumption that melanin is the major contributor to the absorbance spectrum of human skin), which means that we might be able to represent skin pigmentation using measurements at these two wavelengths. We had difficulty determining how accurate a representation this method would be, which is why we didn't decide to abandon this method.

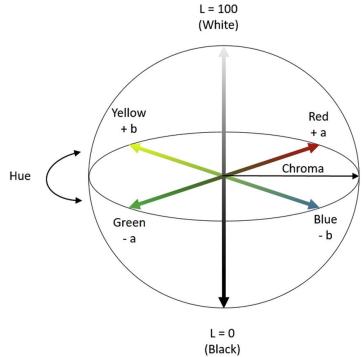


Figure 25: CIELab Color Space

Our second idea was to utilize a color space known as CIEL*a*b*, which would numerically represent the luminance and hue of the skin tone of a subject. Using this color space, we can calculate a parameter known as the individual typology angle which seems to correlate relatively well with the melanin content of a person's skin (Ly). We then planned on taking samples of healthy people and matching up each individual's skin tone to their respective ita. We faced difficulty in acquiring the required mathematical distributions (e.g. color standards and luminance standards regulated by the CIE, or International Committee on Illumination) as they were behind a paywall, not to mention the lack of a fully functional lab spectrometer. The method we ended up settling on was similar to the first idea of taking measurements where the absorbances of oxygenated hemoglobin and deoxygenated hemoglobin crossed. However, we decided to use the wavelengths 480 nm, 515 nm, and 590 nm, as the absorbance at these three wavelengths should be approximately the same across not only the oxygenated and deoxygenated hemoglobin but as well as across the three wavelengths. This means that any variations in the spectrometer measurements can probably be attributed to the absorbance of the skin. We took the measurements from these three wavelengths and calculated an exponential regression to fit the data as best as possible to represent the absorption spectrum of the skin. Our calibration method relies on taking the exponential regression of the AS7341 spectrometer data at three points, more specifically at 480nm, 555nm, and 590nm. This exponential regression represents the absorption spectrum of the skin, which is used to calibrate the red and IR measurements of the MAX30102 pulse oximeter. We utilized the Regressino library from GitHub developed by cubiwan to generate an exponential fit. This library provides us with simple functionality to input points to the model and form the model while in the process of collecting data. This model is then used to extrapolate the absorption at the wavelengths we want (red and IR wavelengths). The exponential regression is done by taking a linear regression on the logarithm of our data points and then exponentiating the result from the generated line of best fit to extrapolate data.

One of the drawbacks of this method is the small number of samples we base this model on, making generating an accurate model difficult due to the increased variation we subject the exponential fit to.

We decided to use an exponential fit as the absorption spectrum of melanin, which we assumed to be a decent representation of the absorption spectrum of skin in general, seemed like it would be approximated well by an exponential curve. The readings would form an exponential growth function as opposed to the seen decay function in Figure 24, as the melanin at lower wavelength measurements would absorb light better, reflecting back less light, resulting in a lower measurement.

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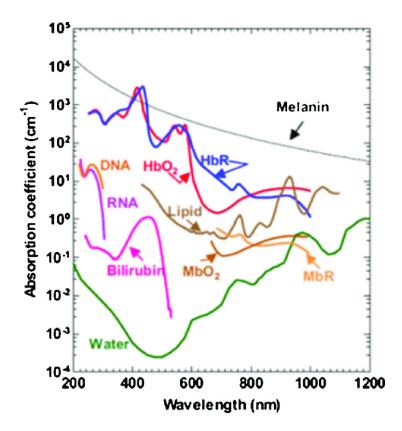


Figure 26: Absorption spectrum of melanin and other skin components

Discussion

Calculation Limitations

Our method of calculating the pulse oximeter relies on the idea that oxyhemoglobin and deoxyhemoglobin should have different luminosities when you shine a light on blood suspended in water. This difference in luminosity varies with wavelength, though, and we thought we could exploit this property at certain wavelengths to isolate the spectral properties of anything that could be altering the SpO2 values in subjects with darker skin. After we determine what the subject's finger looks like at these wavelengths we then apply a regression method to those values in order to attempt to extrapolate the theoretical molar absorption extinction coefficient at the key wavelength of 680 nm; which is the wavelength used by most pulse oximeters on the market to determine oxygenation of blood. One glaring limitation of this method is that we can't possibly know for sure the spectral composition of the subject's skin, and our current method of exponential regression doesn't take into account particular details at other wavelengths. We are fairly certain from our research that the apparent absorption spectrum of melanin is fairly exponential at the wavelengths we are working with, which is why we decided to go with this method. However, we had issues with scaling the measurements from the pulse oximeter as the data did not match the specified measurement size on the manufacturer's website, so we had no way of quantifying a reasonable calibration "factor". We were unable to gather sufficient evidence to make a conclusion on how the absorption spectrum of human skin changes with skin pigmentation. And without proper instrumentation to control for changes in blood oxygen concentration, there is no way for us to collect this data on our own. After all, the absorption spectrum of lighter skin is certainly not the same as the spectrum of darker skin.

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Sources of Error

While we weren't successful in our attempt to calibrate the pulse oximeter, we have come across various possible sources of error that could affect the calibration of a pulse oximeter.

The pressure exerted on skin, especially a finger, will change the visible color of the skin, which will make spectrometer measurements vary significantly. This is especially true since our design is bulky, making it difficult to maintain a constant pressure.

The distance of the sensors to the finger also showed drastic impact on measurements. The spectrometer's sensor is meant to be set a distance away from the sample in order to take advantage of the reflected light, while the pulse oximeter requires the light to bounce off of the patient's bone so as to interact with the blood in the blood vessels. This dependence on distance should be further researched to develop a more robust design that is less prone to error.

Light from the environment also has a significant impact on both sensors, as both rely on sensitive photodetectors to make their measurements. The reflectivity of the devices surfaces, as well as the opacity of the materials themselves, contribute a lot of noise. This could be accounted for by calibrating the readings to a dark current or other control (measurement when there is supposedly no input/light). An unfortunate oversight on the design of one of the sensors, the spectrometer, is that it comes with a bright green LED as a power indicator, which significantly alters its ability to perform accurate measurements. It was possible to disable it via physical intervention (scratching the LED until it broke), however we had yet to make these changes to the main prototype.

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