#G15: Low-Cost Increased Accuracy Pulse Oximeter For People With a Darker Skin Complexion

FISCHELL DEPARTMENT OF BIOENGINEERING

Mehul Donthi, Ananth Nair, E.J. Dorsie, Laena Nho, David DeGuzman, Ryan Jerome

Mentors: Dr. Siddhartha Dante, Dr. Adrian Holloway, University of Maryland Baltimore, Dr. Brian Blair, University of Maryland

A. JAMES CLARK SCHOOL OF ENGINEERING

Motivation

Need for equitable and accurate healthcare tools for underserved communities

- Pulse oximeters inaccurately overshoot blood oxygen saturation readings for patients with darker skin tones.[1]
- 12% of Black participants produced a false negative reading for hypoxia compared to 4% of white participants (Children's Hospital of Philadelphia study).
- **Leads to a disproportionate amount of colored individuals being denied access to critical care**
- **Goal:** Improve pulse oximeter accuracy to support equitable healthcare access.[2]

Design Specifications

Design Specification	Justification
Functional Red, IR, UV LED wavelengths	Optimal readings using red light wavelength ~660 nm, infrared light wavelength ~940 nm, and ultraviolet light wavelength within UVA levels, ~335 nm.
Adaptable Pulse Oximetry Correction Factor (Improved Programming)	Skin complexion correction factor (unique to each patient). Continuously collect data to make this correction factor more accurate. We aim to minimize the measurement overshoot by the pulse oximeters to ~3% for patients. (Impossible to completely mitigate the issue)
Quantify melanin concentration in patient	Detects melanin concentration by pulsing a UV LED at the patient's skin and using an external GUVA S12SD UV light sensor to quantify how much light is reflected of the skin. The lower the reflection value (indicative of darker skin), the higher the correction factor that is loaded.

Figure 1. Design Specifications Table

Methods

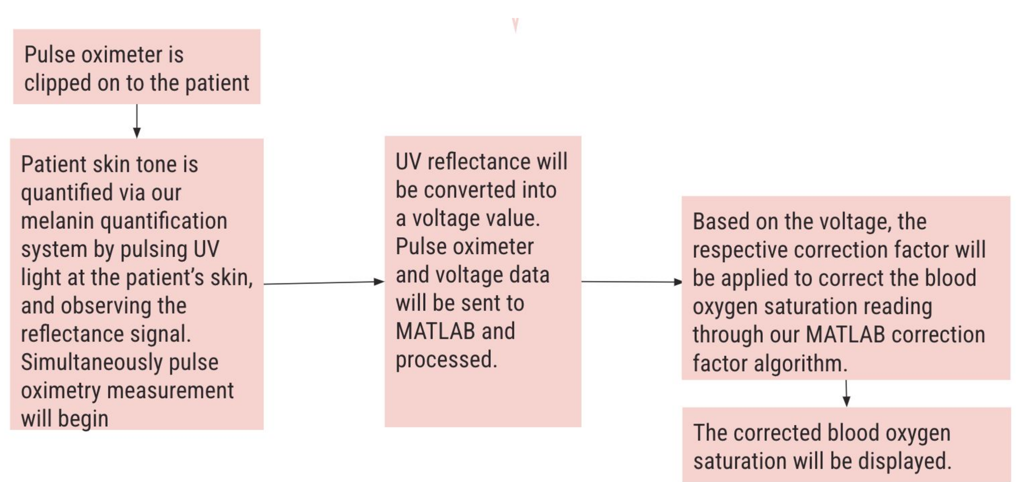


Figure 2. Functional method framework of operating the device

```
function corrected_02 = fixedcorrectionalgorithim(pulse_ox, voltage)
    % Define correction factors based on Fitzpatrick scale (Type I to VI)
    % Lower reflectance = darker skin = higher correction
    % Reflectance range assumed: 0 (dark) to 1 (light)

    if voltage <= 5.001
        fitzpatrick_type = 'Type I'; correction = 0.5; % white
    elseif voltage <= 4.167
        fitzpatrick_type = 'Type II'; correction = 1.0; % white
    elseif voltage <= 3.333
        fitzpatrick_type = 'Type III'; correction = 1.5; % white
    elseif voltage <= 2.500
        fitzpatrick_type = 'Type IV'; correction = 2.0; % Asian/Hispanic typically falls in this group
    elseif (voltage > 0.883 && voltage < 1.667)
        fitzpatrick_type = 'Type V'; correction = 2.5; % Indian/African American typically falls in this group
    else
        fitzpatrick_type = 'Type VI'; correction = 3.0; % African American
    end

    % Apply correction
    corrected_02 = pulse_ox - correction;

    % Display result
    fprintf('Original Pulse Ox: %.2f%%\n', pulse_ox);
    fprintf('Correction Applied: %.2f\n', correction);
    fprintf('Corrected Oxygen Saturation: %.2f%%\n', corrected_02);
end
```

Figure 3. Correction factor algorithm

- The MATLAB correction factor algorithm receives pulse oximetry data and melanin quantification data from our arduino system.
- This data will be processed and the respective correction will be applied to the pulse oximetry measurement.

Final Design

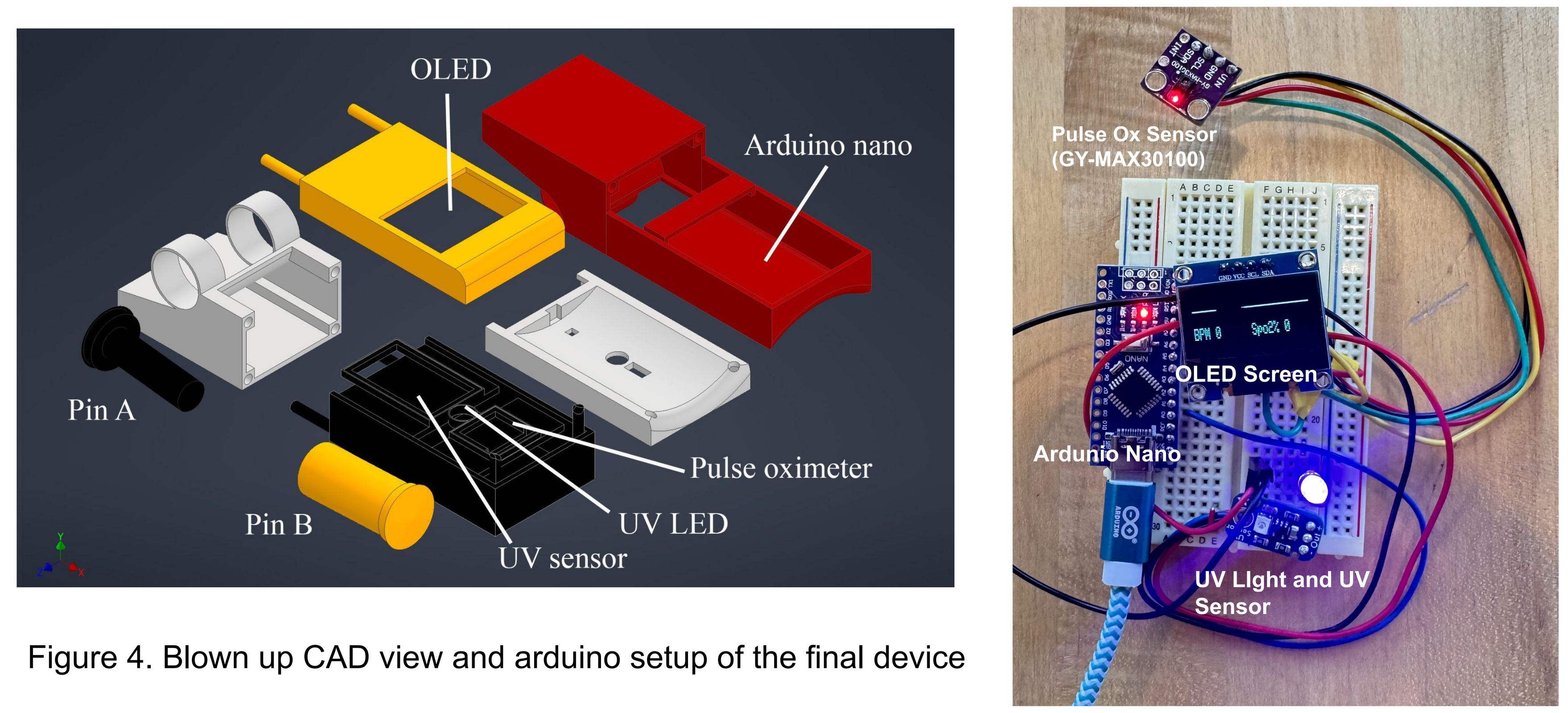
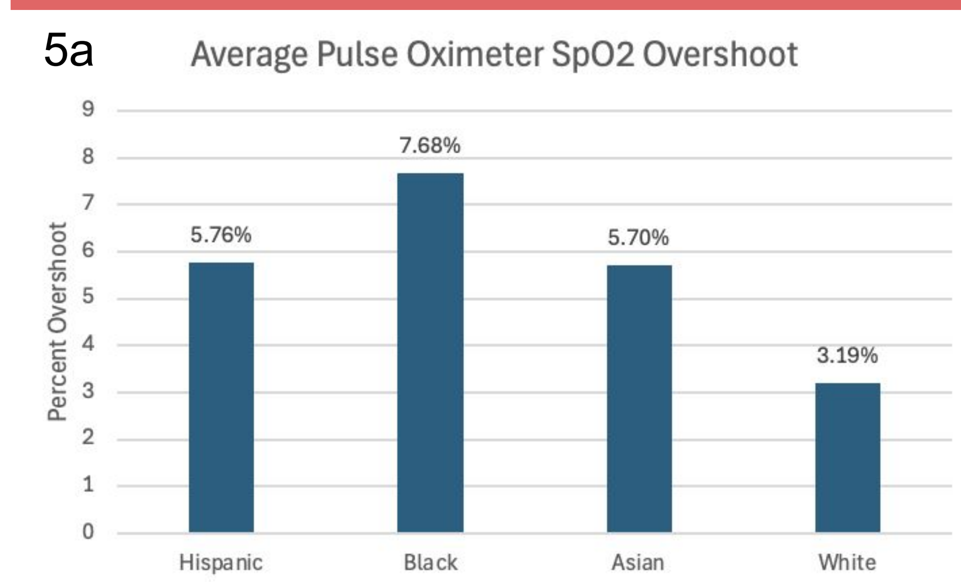


Figure 4. Blown up CAD view and arduino setup of the final device

Results

5a



5b

Baseline Correction Factor	Percentage
White	0.50-1.50%
Asian	2.00-2.50%
Hispanic	2.00-2.50%
Black	2.50-3.00%

5c

```
SSD1306 128x64 OLED TEST
Voltage: 2.103 V
UV Index: 4.00
Initializing pulse oximeter..SUCCESS
Beat!
BPM: 23
Orginal Measurement: 0
Correction Factor: 2.0
Adjusted Measurement: -2.0
------------------
Beat!
Beat!
Beat!
Beat!
Beat!
BPM: 66
Orginal Measurement: 77
Correction Factor: 2.0
Adjusted Measurement: 75.0
------------------
Beat!
Beat!
Beat!
Beat!
Beat!
BPM: 47
Orginal Measurement: 95
Correction Factor: 2.0
Adjusted Measurement: 93.0
------------------
Beat!
Beat!
Beat!
BPM: 54
Orginal Measurement: 96
Correction Factor: 2.0
Adjusted Measurement: 94.0
```

Figure 5a. Variance between pulse oximetry and arterial saturation measurement. 5b. Baseline correction factors for each race. 5c. Functionality observed with our melanin quantification and pulse oximeter systems.

- We received patient data from critical congenital heart disease (CCHD) patients, where hypoxia is a telltale sign of CCHD, emphasizing the importance of accurate pulse oximetry measurement.
- We averaged the difference between a patient's blood gas analyzed arterial saturation and pulse oximetry measurements. Then, we separated these differences by race and found the average blood oxygen saturation measurement through pulse oximetry.
- To meet our design specification of minimizing the overshoot to ~3%, we established baseline correction factors that will get optimized as we acquire more patient data.
- We are close to meeting our design specification of being able to quantify melanin in a person's skin; however, the level of accuracy is highly variable at the moment.

Bioethical Implications

Increase equity during a crucial stage of disease diagnosis in clinical settings

- Reduction of healthcare disparities that disproportionately impact certain groups, thus eliminating racial and ethnic biases.
- Long-term cost savings are made by reducing misdiagnoses and repeat tests.
- However some potential health care concerns are prolonged UV exposure, as this may lead to unknown effects.

Conclusions and Future Work

- We were able to develop a pulse oximeter and melanin quantification system through arduino that could successfully communicate acquired pulse oximetry and skin color metrics with a MATLAB correction factor algorithm, and reflect "corrected" values.
- However, after prototyping and testing our device, our ability to quantify melanin is not optimal, which leads to inaccurate correction factors being applied.

Testing & Validation

- Main point of validation is the melanin quantification system and comparable pulse oximetry measurement to the clinical standard.
- We plan to test the efficacy by developing an artificial porcine skin module with varying melanin concentrations and oxygenation levels using squid ink and porcine blood.
- This will allow us to test our device's ability to detect different melanin levels as well as properly measuring SpO2.
- Overall, our device and algorithm need to optimized for more accurate melanin quantification with more patient data and refined to reduce signal noise that can interrupt our measurement.

Commercialization

- Market device to healthcare providers in the Sub-Saharan African population
- Complete clinical trials to prove accuracy and safety.
- Apply for FDA approval and other certifications.
- Prioritize low cost components and materials to make the device affordable for low-resource communities

Figure 8. Pulse oximeter shell

Significant References: [1]Al-Halawani, R., Charlton, P. H., Qassem, M., & Kyriacou, P. A. (2023). A review of the effect of skin pigmentation on pulse oximeter accuracy. Physiological measurement, 44(5), 05TR01. https://doi.org/10.1088/1361-6579/acd51a, [2]Winny, A. (2024). The Problem with Pulse Oximeters: A Long History of Racial Bias. Johns Hopkins Bloomberg School of Public Health. https://publichealth.jhu.edu/2024/pulse-oximeters-racial-bias, [3]Al-Halawani, R., Qassem, M., & Kyriacou, P. A. (2024). Monte Carlo simulation of the effect of melanin concentration on light-tissue interactions in transmittance and reflectance finger photoplethysmography. Scientific reports, 14(1), 8145. https://doi.org/10.1038/s41598-024-58435-7, [4]Keller, M. D., Harrison-Smith, B., Patil, C., & Arefin, M. S. (2022). Skin colour affects the accuracy of medical oxygen sensors. Nature, 610(7932), 449–451. https://doi.org/10.1038/d41586-022-03161-1, [5]Alam, M. (2024).