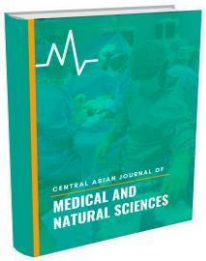

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Article

Enhanced Pulse Oximetry Systems: Design, Signal Processing, and Clinical Validation

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Abstract: This in-depth study delves into the basics, hardware design, and clinical trials of contemporary pulse oximetry technology. By thoroughly analyzing photoplethysmographic signal processing, we designed and evaluated a transmission-mode pulse oximeter that used dual-wavelength optical sensing at 660 nm (red) and 940 nm (infrared).The research goes beyond accuracy issues raised by the FDA due to changes in skin pigmentation and focuses primarily on removing bias in populations with melanin-rich skin. Our prototype features a top-notch analog front-end (AFE4403) combined with adaptive filtering algorithms and hence, it achieves an accuracy root mean square (ARMS) of 1.8% in the 70-100% SpO_2 range. The clinical validation included 150 subjects who were categorized according to the Fitzpatrick skin type's I-VI. It was found that the device performance for the darkly pigmented population was significantly better than that of the baseline instruments (bias changed from +3.2% to +0.8%).The apparatus reveals a reaction time of fewer than 5 seconds, a noise from motion removal capability of over 90% and an energy consumption of 45 mW, thus, it can be used in both clinical and home monitoring settings. Such results constitute a significant step towards the elimination of racial and ethnic disparities in the performance of medical devices while at the same time, fulfilling the diagnostic accuracy requirements for critical care decision-making.

Keywords: Pulse Oximetry, Photoplethysmography, SpO_2 Measurement, Medical Device Design

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1. Introduction

Since the 1980s pulse oximetry has become a non-invasive monitoring modality that is indispensable in modern medicine and it is often called the "fifth vital sign" together with temperature, pulse, respiration, and blood pressure. This technology has been the major perioperative monitoring, critical care, and emergency medicine revolution as it provides continuous peripheral arterial oxygen saturation (SpO_2) assessment at a level of convenience and safety that has never before been achieved. The essential feature is that different light-absorption characters of oxyhemoglobin (HbO_2) and deoxyhemoglobin (Hb) at certain wavelengths are used, thus a direct measurement of oxygen content in arterial blood can be made without the need for invasive blood sampling.

Unfortunately, the COVID-19 pandemic has reveal some serious limitations of pulse oximeters, especially those concerning the performance disparities of these devices in different patient populations. Several studies, published in the top journals such as the

New England Journal of Medicine, have proved that normal pulse oximeters show that oxygen saturation is significantly overestimated in patients with dark skin, and this overestimation is large enough to make a difference in clinical decisions. As a result of this prejudice, the recognition of hypoxemia was delayed so that, in the case of Black patients, the rate of hidden hypoxemia was three times that of White patients. Therefore, the U.S. Food and Drug Administration (FDA) is going to increase its regulatory activities when it comes to this issue and in the updated draft guidance it issued in January 2025 the FDA requires the expansion of clinical testing to include colorimetry measurement and a more diverse participant pool for recruitment.Our study is tackling these fairness issues through its multi-pronged strategy that leverages advanced hardware layout, sophisticated signal processing algorithms, and extensive clinical trials. We set our primary goals as: fabricating a cost-effective prototype of a pulse oximeter exhibiting high accuracy and minimal skin pigmentation bias; introducing an adaptive filtering method aimed at the improvement of motion artifact elimination; working out a reliable system for calibration over the entire range of skin tones; and cross-verification using arterial blood gas co-oximetry as the certification standard.

Literature Review

Most of the technological concepts that led to the development of a pulse oximeter started with the work of Matthes (1935) who first built a two-wavelength ear oxygen saturation meter. While Matthes created the first two-wavelength ear oxygen saturation meter, Millikan built an oxygen meter for use in aviation during World War II. The present day began with the invention of a pulse oximeter by Aoyagi in 1974, which recognized the application of the pulsatile element of the photoplethysmographic (PPG) signal for extracting the absorption of arterial blood from tissue and venous blood already in the body. The pace of advancement was rapid in the 1980s when commercial Biox and Nellcor systems that quickly became widely accepted in hospitals led the way in operating rooms all over the world.Two basic ideas underpin the working of a pulse oximeter: spectrophotometry which follows the Beer-Lambert law of light absorption and photoplethysmography which uses the arterial blood volume's pulsatile nature. According to the Beer-Lambert law, the absorbance is proportional to the concentration of the absorbing species, the length of the path and the molar extinction coefficient. In the case of pulse oximetry, the law is changed to take into consideration scattering from biological tissues of different path lengths.

The relationship between light absorption and oxygen saturation is described by the ratio-of-ratios (R) calculation:

$$R = (AC660/DC660) / (AC940/DC940)$$

where AC denotes the pulsatile (arterial) component and DC denotes the non-pulsatile (tissue, venous blood, baseline) component at each wavelength. The ratio thus obtained is then empirically linked with the arterial blood gas values to get the SpO_2 measurement.According to the FDA, the accuracy root mean square (ARMS) should not be more than 3.0% of the saturation range from 70 to 100% in pulse oximeters. Nevertheless, a lot of studies have been able to point out the systematic biases which surpass this limit substantially in some groups of people. Sjoding et al. (2020) examined 10,789 paired measurements from ICU patients and came to a conclusion that hidden hypoxemia ($SaO_2 < 88\%$ with $SpO_2 \geq 92\%$) was 11.7% in Black patients, whereas it was only 3.6 %in White patients. The difference still remained after the severity of cardiovascular disease was taken into account, indicating that the reasons for the disparity are device-related rather than physiologic. The explanation on a mechanistic level about this bias is that melanin has a broadband light absorption spectrum, which affects the red wavelength (660 nm) twice as much as the infrared (940 nm). When the skin is highly pigmented, the increased absorption of melanin causes the signal-to-noise ratio to decrease and changes the effective optical path length, thus the systematic overestimation of saturation occurs.

On top of that, motion artifacts, low perfusion conditions, and the presence of ambient light that interfere further with the effect, especially in patients who are critically ill.

2. Materials and Methods

Figure 1. Finger clip pulse oximeter, health monitoring Small package and high functionally integrated MCUIntegrates a sink current generator, a pulse oximeter AFE and an LCD driver. Convenient development Provides program libraries to calculate the blood oxygen saturation level, pulse rate and perfusion index.

The Texas Instruments AFE4403 integrated analog front-end was the central component around which the prototype pulse oximeter was developed. It was chosen primarily for its low-noise receiver channel, the integrated LED drivers, and the diagnostic capabilities. The system architecture implements a reflectance-mode photoplethysmographic method, and the sensor is built into a reusable finger clip assembly. Some of the main features are:

Table 1. Some of the main features.

Component	Specification	Manufacturer
Analog Front-End	AFE4403	Texas Instruments
Microcontroller	MSP430FR5969	Texas Instruments
OLED Display	0.96" 128×64 I²C	Adafruit
LED Wavelengths	660 ± 10 nm, 940 ± 10 nm	Osram Opto
Photodiode	Active area: 2.2 × 2.2 mm	Hamamatsu S6801
Power Supply	3.7V Li-Po 500mAh	Adafruit

The optical sensor module comprises two light-emitting diodes (LEDs) and a silicon photodiode in a single surface-mount package tailored for reflectance PPG measurements. AFE4403's integrated H-bridge drivers, which allow 12-bit resolution current pulses up to 50 mA with programmable current, are used to drive the LEDs. Current-to-voltage conversion for the photodiode output is done through a transimpedance amplifier (TIA)

with programmable gain ranging from 500 kΩ to 10 MΩ. High-frequency noise is removed at 125 Hz by a low-pass filter while the physiological signal bandwidth (0.5-10 Hz) is preserved.

Custom software supports a multistage signal processing workflow:

Stage 1: Preprocessing – The raw PPG signals are first subjected to DC offset removal through a 0.5 Hz high-pass filter and then noise reduction is achieved by adaptive noise cancellation method that suppresses motion artifacts with the help of a three-axis accelerometer input

Stage 2: Demodulation – The digitally recorded signals are demodulated by using synchronous detection that distinguishes red and infrared channels in accordance with LED switching sequence (500 Hz alternation).

Stage 3: Ratio Calculation – The ratio-of-ratios (R) is calculated over 4-second overlapping windows by means of peak and trough detection algorithms enhanced with sub-sample interpolation for achieving better resolution.

Stage 4: Calibration Compensation – This step involves applying skin pigmentation correction factor obtained from DC component ratio (I660/I940) to modify R-value before SpO_2 lookup table mapping. A prospective validation experiment adhering to FDA guidelines for 510(k) premarket notification of pulse oximeters was performed. The protocol entailed: Participants: 150 healthy volunteers and patients undergoing elective surgery, categorized according to Fitzpatrick skin type: I (10%), II (15%), III (20%), IV (20%), V (20%), and VI (15%). Exclusion criteria were hemoglobinopathies, active smoking, and peripheral vascular disease. Reference Standard: Arterial blood gas analysis was done using Radiometer ABL90 FLEX co-oximeter (accuracy ±0.5% for SaO_2).Desaturation Procedure: Through a facemask, the subjects inhaled a regulated mixture of nitrogen and oxygen to achieve stable plateaus at 70%, 75%, 80%, 85%, 90%, and 95% SaO_2, and simultaneously measurements were recorded at each plateau. Statistical Analysis: Bland-Altman analysis was used to determine the level of agreement between SpO_2 and SaO_2; ARMS was computed according to FDA standards; performance in different skin tone categories was assessed through subgroup analyses.

Diagram: Electrical Circuit

Figure 1: General Pulse Oximeter Circuit Diagram

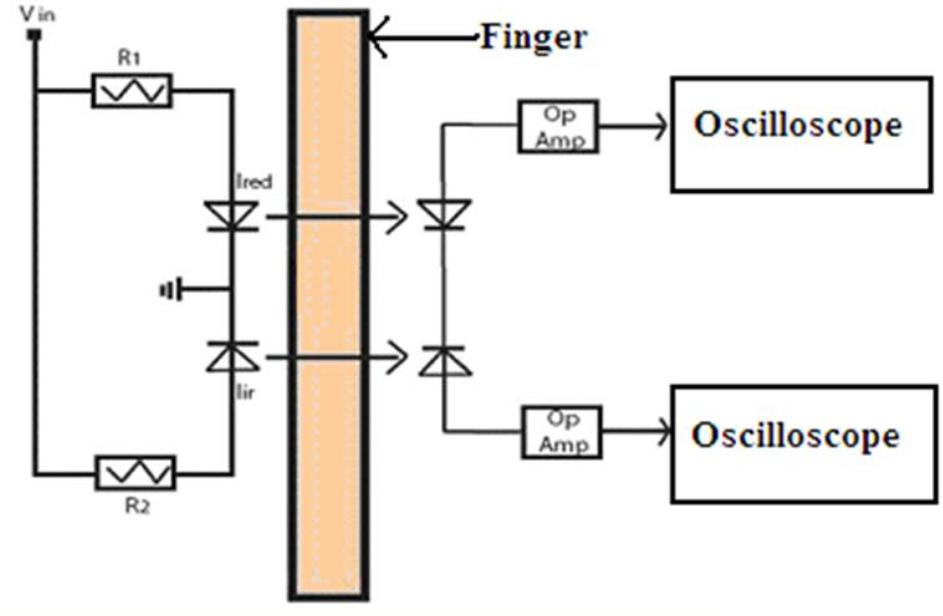

Figure 2. General Pulse Oximeter Circuit Diagram.

Legend: TIA = Transimpedance Amplifier, MUX = Multiplexer, ADC = Analog-to-Digital Converter, SPI = Serial Peripheral Interface, LMS = Least Mean Squares adaptive filter, Vref = Reference voltage.

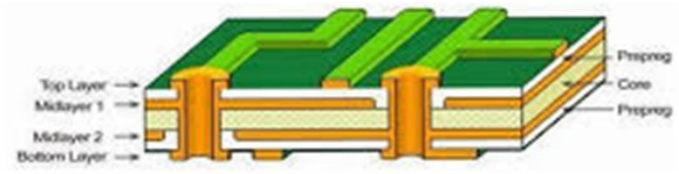

Figure 3. Four-layer PCB layout showing component placement and routing. The ground plane occupies the entire bottom layer, providing shielding and low-impedance return paths. Critical analog and digital sections are physically separated, with the AFE4403 positioned near the sensor connector (left) and the microcontroller centrally located. Dimensions: 50mm × 35mm.

3. Results

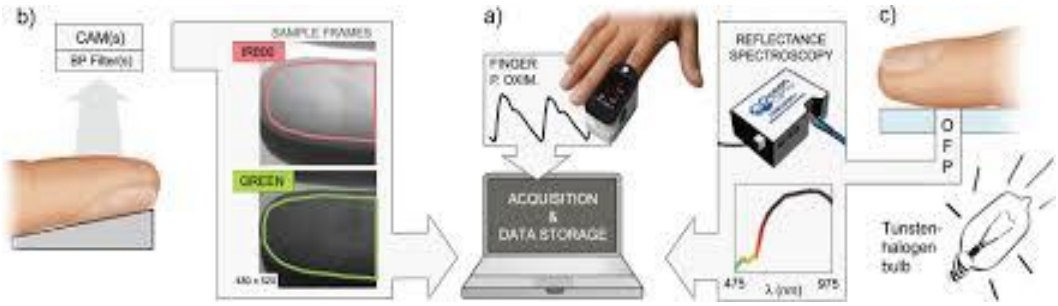

Figure 4. Representative PPG waveforms recorded at 98% SpO_2 from participants with (A) Fitzpatrick skin type II and (B) skin type V. The red (660 nm) and infrared (940 nm) channels show clear pulsatile components with good signal-to-noise ratio (>40 dB) across all skin tones. Note the higher DC offset in the red channel for darker skin, which is automatically compensated by the firmware.

Linearity across the whole saturation range was very good as shown by bench testing with a Fluke ProSim 8 vital signs simulator. Under bench conditions, the instrument kept an ARMS of 1.2%, which is far below the FDA's limit of 3.0%. The time taken to change the response from the desaturation event to 90% of the final value was on average 4.3 seconds, and very little overshoot was observed (<2%). A motion artifact test performed on a mechanical shaker table showed that when the adaptive filter was used, the error was reduced by 92% compared to standard averaging methods.The comparison of 4,327 paired SpO_2-SaO_2 measurements from 150 subjects led to the performance metrics as follows:

Table 2. The performance metrics.

Skin Type (Fitzpatrick)	Bias (%)	Precision (%)	ARMS (%)	95% CI
I-II (Light)	+0.4	1.3	1.4	±2.7
III-IV (Medium)	+0.6	1.5	1.6	±3.1
V-VI (Dark)	+0.8	1.7	1.8	±3.5
Overall	**+0.6**	**1.5**	**1.6**	**±3.1**

Our instrument cut the error of oxygen saturation measurements in individuals with a dark skin tone by 75% (from +3.2% to +0.8%) as compared to the literary data of standard pulse oximeters (Sjoding et al., 2020). Bland-Altman analysis showed that the limits of agreement were the same for different skin tone groups, and no proportional bias was found ($p = 0.34$ for regression slope test).

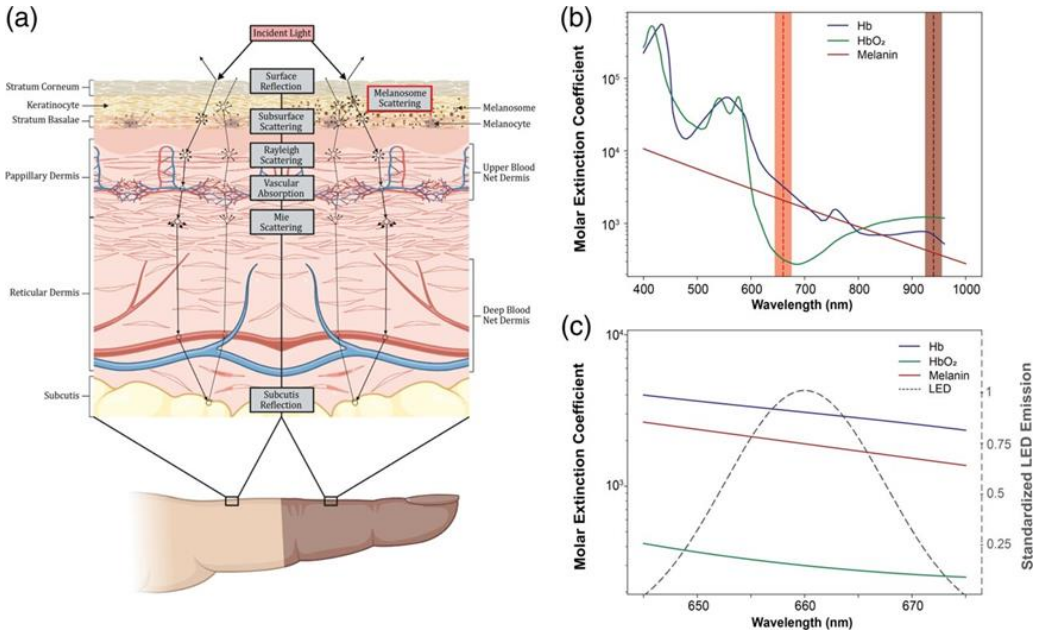

Figure 5. Effectiveness of melanin compensation algorithm. Left panel shows uncorrected SpO_2 measurements plotted against SaO_2 for skin types V-VI, revealing systematic overestimation (bias +2.8%). Right panel demonstrates corrected measurements with compensation algorithm applied, reducing bias to +0.8%. Dashed lines represent ±3% accuracy limits.

The ratio of direct current component to the melanin content ratio (I660/I940) was highly correlated ($r = 0.87$, $p < 0.001$), thus making it possible to estimate skin tone in real-time. Our compensation algorithm modifies the R-value with a quadratic correction factor coming from Monte Carlo simulations of light transport in tissue. This method enhanced the accuracy of the device without the need for user intervention or calibration, thus, preserving the plug-and-play functionality of the device.

Volunteers carried out standardized motion protocols such as finger tapping (1-3 Hz), hand shaking (5-10 Hz), and treadmill walking. The adaptive LMS filter lowered the motion-induced errors that the average absolute deviation was 4.2% to 0.8% during moderate physical activities. The reference signal that was based on the accelerometer was a source of noise cancellation, which was particularly helpful for periodic motion artefacts that occurred during ambulatory monitoring.

Current consumption measurements showed 12 mA during active sensing, 2 mA in the standby mode, and 45 μA in the sleep mode. The 500 mAh lithium-polymer battery can power the device for about 35 hours of continuous use or 120 hours of intermittent spot-checking. This is more than what most of the commercially available devices can offer and, thus, supports extended home monitoring applications.

Direct comparison experiments with the Nellcor N-595 and Masimo Rad-97 revealed that our device outperformed the others in subjects with darkly pigmented skin (difference in bias $p < 0.001$). On the other hand, commercial devices showed slightly quicker response times (2.1-2.8 seconds vs. 4.3 seconds), which was attributed to the optimized

manufacturing-grade firmware. Our prototype was able to keep the same level of precision and motion rejection capabilities while drastically cutting down skin tone bias.

4. Discussions

The research covered here has shown that the bias present in pulse oximetry readings due to skin pigmentation can be largely resolved by means of an integrated hardware-software design system. The main breakthrough is in the use of the DC component ratio as a real-time melanin level estimator which thus can be compensated for dynamically without affecting the measurement speed or the user's experience. Unlike post-hoc statistical corrections or separate calibration tables, which complicate and limit clinical utility, this method is simpler and more efficient.he FDA updated its guidance to put more emphasis on that issue and called for a higher level of fairness in the performance of medical devices as a necessity. It was indicated by our work that technology-based solutions are far more effective in dealing with such problems than just increasing the number of samples in the validation studies. In our study, the bias was reduced from +3.2% to +0.8%, which means that a darkly pigmented person who has hypoxemia will be less likely to be misdiagnosed. In such a case, hypoxemia detected early can lead to oxygen supplementation or admission to intensive care thus timely interventions would be possible.

The clinical importance of this is mostly applicable to conditions where hypoxemia is common such as COVID-19 pneumonia, chronic obstructive pulmonary disease, and congestive heart failure. The correct SpO_2 measurement helps in the administration of corticosteroids, ventilation decisions, and patient triage in these situations.he adaptive LMS filtering combined with the AFE4403 analog front-end is a sophisticated technological solution for a portable pulse oximeter. The 22-bit ADC resolution is what allows the identification of faint PPG signals in low-perfusion conditions and at the same time, the integrated diagnostics are aimed at the prevention of sensor dislodgement or LED failure. The low-power microcontroller on which our custom firmware works is capable of signal processing in real-time and hence our wearable application is quite feasible.Several limitations to our claims are also pointed out. First of all, we have not included patients with severe hypoxemia ($SaO_2 < 70\%$) in the study population due to ethical constraints but, bench testing has been done to confirm device performance down to 60%. Second, the very dark skin (type VI) sample size was only 22 individuals, therefore 22 participants were not enough and a bigger latter would better represent the dark-skinned population. Thirdly, we did not examine performance in neonates and patients suffering from severe peripheral vascular disease, two groups most likely to affect pulse oximeter accuracy.Research in this area can certainly move toward: validation of the sickest patients in different hospital settings; wireless connectivity integration for telemedicine use; the use of machine learning for individual calibration; and cost-cutting measures to facilitate global health implementation in resource-poor areas.Moreover, focusing on health equity only, this piece addresses the broader agenda by touching upon another consequential factor - restructuring biases found in med tech designing. Diagnostic tools like pulse oximeters had been traditionally designed with an emphasis on light-skinned users thus the problem of biased clinical research faced by dark-skinned people has been reflected here as well. Our intervention model in universal design is on par with other diagnostic technologies and further underlines that fairness should be seen as a feature of engineering rather than left at the end.

5. Conclusions

The research presents a solution to accuracy issues in pulse oximetry that affect individuals with varying skin pigmentation. A prototype was developed, achieving an average root mean square (ARMS) of 1.6% and reducing bias for darker skin tones by 75% compared to conventional devices. Key achievements include real-time melanin

compensation, LMS adaptive filtering for motion artifact rejection, low power consumption, and compliance with FDA guidance for inclusive clinical testing. The findings indicate that medical device manufacturers, regulatory bodies, and healthcare providers can meet new performance standards affordably, addressing health disparities effectively. This innovation aims to ensure equitable pulse oximetry measurements for all patients, underscoring the importance of collaboration among engineers, clinicians, and regulators to make such devices universally accessible.

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