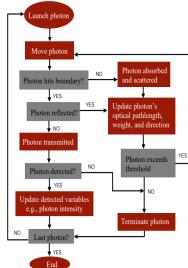
## Monte Carlo Simulation of the Effect of Melanin Concentration on Light-Tissue Interactions for **Transmittance Pulse Oximetry Measurement**

Raghda Al-Halawani<sup>1</sup>, Meha Qassem<sup>1</sup>, Panicos Kyriacou<sup>1</sup> <sup>1</sup>Research Centre for Biomedical Engineering, City, University of London, London, United Kingdom

**Background**. Questions about pulse oximeter technology and its accuracy when used in individuals with darker skin pigmentation have resurfaced, notably due to the effect of high melanin concentration on red light transmission [1]. Potential solutions to mitigate pigmentation bias have included the use of narrowband light sources and monochromatic light [2][3], and the greater enrolment of individuals with higher levels of pigmentation in calibration studies [4]. However, the current study aims to present a Monte Carlo (MC) simulation of light-tissue interactions to show the feasibility of integrating corrective measures into pulse oximeter designs to enhance SpO2 accuracy against the influence of skin pigmentation.

**Methods.** A Monte Carlo algorithm was developed to govern the movement of photons between the source and the detector (Figure 1). The model simulated a human finger [5], including an epidermal layer to alter the concentration of melanin based on three skin groups classified by the Fitzpatrick scale [6]. All the optical properties at red (660 nm) and infrared (940 nm) light were extracted from the literature. Systolic and diastolic intensities were used to calculate the ratio of ratios for a SpO2 range between 70% and 100%.



Results. Using the data generated from the Monte Carlo simulation, three calibration curves were obtained for light, moderate, and dark skin (Figure 2). Moderate and dark skin calibration curves exhibit a 'red shift' compared to light skin due to a decrease in normalised transmittance at 660 nm.

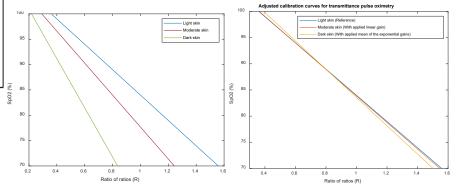


Fig. 1. Monte Carlo algorithm flowchart

Fig. 2. Simulated calibration curves for light, moderate, and dark skin



Upon experimental validation of the simulated results, a gain of 1.23 and 1.8 were applied to moderate and dark skin, respectively. This resulted in significant adjustments that brought all calibration algorithms for the three skin types into close proximity (Figure 3).

Discussion and Conclusion. The data generated from the current Monte Carlo model suggests that a single pulse oximeter algorithm may not be universally acceptable for all skin types, and provides quantitative evidence to rectify the 'red shift' occurring in moderate and darker skin pigmentations. Moving forward, this can be considered by pulse oximeter manufacturers by applying in-built corrections and conducting re-testing procedures.

# **Key references**

- P. A. Kyriacou, P. H. Charlton, R. Al-Halawani, and K. H. Shelley, "Inaccuracy of pulse oximetry with dark skin pigmentation: clinical implications [1] and need for improvement," Br. J. Anaesth., vol. 130, no. 1, pp. e33-e36, Jan. 2023, doi: 10.1016/j.bja.2022.03.011.
- [2] M. S. Rea and A. Bierman, "Light source spectra are the likely cause of systematic bias in pulse oximeter readings for individuals with darker skin
- pigmentation," *Br. J. Anaesth.*, vol. 131, no. 4, pp. e101–e103, Oct. 2023, doi: 10.1016/j.bja.2023.04.018. A. M. Cabanas, P. Martín-Escudero, and K. H. Shelley, "Improving pulse oximetry accuracy in dark-skinned patients: technical aspects and current regulations," *Br. J. Anaesth.*, vol. 131, no. 4, pp. 640–644, Oct. 2023, doi: 10.1016/j.bja.2023.07.005. [3]
- [4] M. S. Arefin, A. P. Dumont, and C. A. Patil, "Monte Carlo based simulations of racial bias in pulse oximetry," vol. 11951, p. 1195103, Mar. 2022, doi: 10.1117/12.2610483.
- [5] S. Chatterjee and P. A. Kyriacou, "Monte Carlo Analysis of Optical Interactions in Reflectance and Transmittance Finger Photoplethysmography," Sensors, vol. 19, no. 4, p. 789, Feb. 2019, doi: 10.3390/s19040789.
- [6] V. G. Kanellis, "A review of melanin sensor devices," Biophys. Rev., vol. 11, no. 6, pp. 843-849, Dec. 2019, doi: 10.1007/s12551-019-00581-8.

### <u>Title - Understanding the effect of tissue optical properties on pulse oximetry through Monte Carlo</u> <u>simulations.</u>

Suvvi K. Narayana Swamy<sup>1</sup>, Chenyang He<sup>1</sup>, Chong Liu<sup>1</sup>, Ricardo Correia<sup>1</sup>, Barrie R. Hayes-Gill<sup>1</sup>, Daniel J. Clark<sup>2</sup>, Sarah Green<sup>2</sup>, and Stephen P. Morgan<sup>1</sup>

<sup>1</sup>Optics and Photonics Research Group and Centre for Healthcare Technologies, University of Nottingham, University Park, Nottingham, UK

<sup>2</sup> Clinical Engineering Department, Nottingham University Hospitals NHS Trust, Nottingham, UK

**Background and Aims:** Varying performance of pulse oximeters (POs) across different skin tones has gained significant attention. These devices often overestimate oxygen saturation levels in individuals with darker skin tones, leading to occult hypoxemia. The primary goal of this study is to understand the theoretical underpinnings of this bias observed in darker skin using a 3D, 4-layer Monte Carlo (MC) based finger tissue model. A comprehensive understanding of these factors is crucial for the development of POs that provide accurate readings across all skin colours.

<u>Methods</u>: Using the open-source software MCmatlab, we developed a four-layer semi-infinite cuboid model that included epidermal, dermal, and bone layers, as well as two arteries. Skin tone variations were modelled by adjusting melanin's optical properties in the epidermal layer, while pulse changes were represented by altering the blood volume to be twice as high in systole than in diastole. The 'Ratio of Ratios' (R) was determined from the ratio of normalised detected perfusion indices at specific wavelengths (660nm for red light and 940nm for infrared).

<u>**Results:**</u> In Transmission mode – the source and detector were positioned opposite to each other (co-linear manner). We observed no change in SpO<sub>2</sub> vs R curves due to change in skin colour (b).

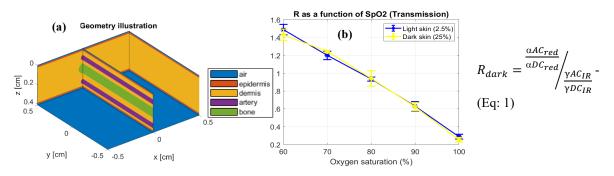


Figure 1: a) Geometry of the 4-layer Tissue model. b) SpO<sub>2</sub> vs R curves for light and dark skin. Note: In Eq1,  $\alpha$  and  $\gamma$  represent the attenuation factors due to skin colour at red and IR wavelengths.

Contrarily in Reflection mode (where source and detector were placed on the same side of tissue surface) we observed significant variations in SpO<sub>2</sub> vs R curves due to varying melanin in the epidermal layer (a). Moreover, with increase in source-detector (SD) distance the difference in SpO<sub>2</sub> vs R curves due to skin tone reduced (b & c).

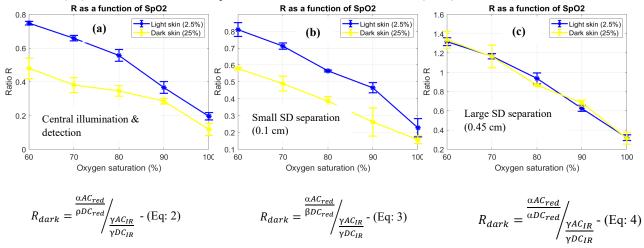


Figure 2: SpO<sub>2</sub> vs R curves shown for a) Central illumination and detection. b) small SD separation (0.1cm). c) Large SD separation (0.45 cm). Note:  $\alpha$ ,  $\gamma$ ,  $\rho$ , and  $\beta$  all represent different attenuation factors due to skin colour at red and IR wavelengths (*Attenuation factors*  $\rho > \beta > \alpha$ ).

**Discussion:** In transmission mode, varying melanin levels equally attenuated both AC and DC components at red and IR wavelengths, resulting in no measurable change in the R and SpO<sub>2</sub> (Eq. 1). Conversely, in reflection mode, IR AC and DC components (Eqs. 2, 3, and 4) were uniformly attenuated. However, at red wavelengths, a differential attenuation was observed—specifically, greater attenuation of the red AC compared to DC (Eqs. 2 and 3), leading to a reduced red PI, a lower R, and an overestimated SpO<sub>2</sub> for darker skin. As the SD separation increased, so did the penetration depth of light, which intensified the DC attenuation at red wavelengths. The greatest SD separation yielded results comparable to those in transmission mode (Eq. 4 = Eq. 1).

<u>Conclusion</u>: This study does not conclude that melanin does not impact SpO<sub>2</sub> readings in transmission mode; further planned research using more complex models of the tissue. However, in reflection mode increasing the SD separation may mitigate the effect of melanin on SpO<sub>2</sub> readings.

Key words: Pulse oximeter, oxygen saturation, transmission-mode, occult hypoxemia, racial bias, melanin, skin colour, Monte Carlo.

#### **Acknowledgements**

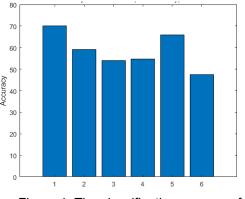
This work was partially funded by the NHS @home programme and the Medical Research Council (UK) under Grant MR/T025638/1. Suvvi Swamy is funded by a PhD studentship from the Engineering and Physical Sciences Research Council (UK).

**Title of Study**: Does skin tone affect the accuracy of machine learning classification applied to photoplethysmography signals? Prof Philip J. Aston, Department of Mathematics, University of Surrey, Guildford, GU2 7XH, UK

**Background**: A recent report [1] highlighted what has been known for some time that pulse oximeters give inaccurate readings of blood oxygenation for patients with darker skin tones, which can have serious consequences due to misdiagnosis. Photoplethysmography (PPG) signals from pulse oximeters and a wide range of wearable devices are now widely used with machine learning to predict many other physiological parameters such as blood pressure or blood glucose. We investigate what effect skin tone has on machine learning classification results.

**Methods:** We consider one machine learning problem, namely a simple binary classification of blood pressure as high or not high. We consider blood pressure to be high if it equals or exceeds 140/90 mmHg [2] and here we just consider systolic blood pressure. We use the Aurora BP dataset [3], which contains PPG signals together with blood pressure readings. Additionally, Fitzpatrick skin tone is available for many, but not all, records. Symmetric Projection Attractor Reconstruction (SPAR) is used to extract features from the PPG signals. Ten-fold cross validation was performed using signals with Fitzpatrick skin tone 1 (lightest skin) in order to give a benchmark classification performance. A single model was then trained using all of the signals with Fitzpatrick skin tone 1 and tested using data for all other skin tones to see if skin tone has any effect on machine learning accuracy in this simple case.

**Results**: The classification accuracy for each of the Fitzpatrick skin tone classes is shown in Fig. 1 which shows a significant drop in accuracy for all other skin tones in comparison to the accuracy for skin tone 1 (except for class 5!).



**Discussion**: While it is known that variations in skin tone have an effect on the collected PPG signal, it was not known whether this translates into inaccurate machine learning results for models trained only on lighter skin tones. For a simple binary classification, we have shown that this does represent a serious problem.

Figure 1: The classification accuracy for each skin tone class.

**Conclusion**: Many publicly available PPG datasets do not include the Fitzpatrick skin tone of the subjects, but it is very likely that the majority of subjects had lighter skin tones. When using such datasets, it is not possible to assess any bias due to skin tone. In future, it is important that skin tone is recorded along with the PPG signals. Instead of recording the subjective Fitzpatrick skin tone, it would be better if a direct measurement of skin tone at the PPG collection site could be made. When training machine learning models using PPG signals, the training data should ideally include a uniform distribution of skin tones in order to avoid any bias. An alternative approach would be to train separate machine learning models for different subgroups of skin tone. Further work in this area is required.

[1] Equity in Medical Devices: Independent Review (2024)

https://www.gov.uk/government/publications/equity-in-medical-devices-independent-review-finalreport

[2] High blood pressure (hypertension) (2023) <u>https://www.nhs.uk/conditions/high-blood-pressure-hypertension/</u>

[3] B. Mieloszyk, H. Twede, J. Lester et al. (2022) A comparison of wearable tonometry, photoplethysmography, and electrocardiography for cuffless measurement of blood pressure in an ambulatory setting. *IEEE J. Biomed. Health Inf.* 26, 2864-2875.

# Title of Study: Is the ear-canal the optimum site for racially equitable oximetry?: Discussion of EarMetrics

Submitters details: Dr Nick Gompertz MBChB, CEO EarSwitch Ltd

### Talk: Overview

Dr Nick Gompertz (a former NHS doctor) developed in-ear sensors for handsfree control for communication for people with motor neurone disease. However the ear-canal represents a unique site for oximetry and other biometrics being both core/ central (less affected by peripheral factors, such as those causing peripheral cyanosis) and not being affected by skin pigmentation (irrespective of skin colour) (personal communication from clinicians).

Nick will present the theory behind EarMetrics including the anatomy of the ear canal, its vascular supply, unique skin structure and discuss the novel approach to monitoring non-contact photoplethysmography and broader health metrics from the ear.

Slides will include evidence from a small UKRI funded study with University of West of England, showing the racial equity of the ear-canal as a site, with examples of physiological signals interpreted from the EarMetrics sensors, including heart rate, heart rate variability, respiratory rate and pattern, oxygen saturation, ballistocardiography and pulse transit time.

### Brief Description of Study

30 healthy volunteers were recruited with aim of recruiting across full range of skin colours to objectively confirm the racial equity of the inner 2/3<sup>rd</sup> of the ear canal. EarMetrics prototype devices, consisting of CMOS camera sensors with white LEDs within ear-buds were applied to the subjects. Data acquisition consisted of video streams from the in-ear camera, and synchronised oximetry readings from medical grade finger and ear-lobe oximetry. Subjects were tested at rest and during breath-hold in full expiration to generate hypoxaemia. Post-hoc analysis was carried out to demonstrate comparisons in response time and magnitude of change between finger, ear-lobe and in-ear measurements, and investigate alternative algorithms for oximetry based on different wavelength comparison for the CMOS cameras.

Results, across people of 5 of 6 Fitzpatrick skin tones confirmed that the inner 2/3rds (bony) earcanal is the same colour irrespective of external skin colour. Early results suggested that ear-lobe and in-ear oximetry are comparable in response time; both showing a more rapid response to hypoxaemia compared to finger oximetry.

This pilot study gave support for the EarMetrics approach targeting within the ear canal; with potential benefit over finger oximetry - 1) potential racially equitable site and 2) a more responsive central site.

## Future Developments

Subsequent UKRI Healthy Ageing grant funding has enabled live presentation of multi biometrics from the EarMetrics devices, akin to an ITU monitor, which will be demonstrated during the presentation.

The inclusion of EarMetrics-Oximetry, as one of eight innovations, in the UK pilot "Innovative Device Access Pathway" will be discussed; a collaboration between MHRA, Department Health and Social Care, and NICE (and other national equivalent bodies) to attempt to accelerate health care innovations through regulatory and health tech assessments to NHS patients.

Routes to validation of oximeters including the relevant ISO standards will be discussed (including the very limited validation they provide; consisting of 10 subjects and only 200 data points) and the need for much larger and more equitable clinical studies to truly confirm racial equity.