

Masimo SET® Pulse Oximetry Accurate Across Black & White Subjects, Even in Low Perfusion



Masimo announced the findings of a retrospective, peer-reviewed study published in the Journal of Clinical Monitoring and Computing in which Dr. Vikrant Sharma, along with Dr. Steven J. Barker, Dr. William C. Wilson, and colleagues at Masimo performed a focused analysis of previously published data to evaluate the impact of low perfusion on the performance of Masimo SET® pulse oximetry across a variety of skin pigmentations.¹ The analysis demonstrated that Masimo RD SET® sensors accurately measured oxygen saturation (SpO₂) for both Black and White subjects when perfusion index (Pi) was normal and when Pi was low – adding to the body of evidence that Masimo SET® pulse oximetry delivers accurate values across the skin tone range, with no clinically significant difference in accuracy or bias, even in challenging conditions.

In a study published in 2023, Drs. Barker and Wilson analyzed Masimo laboratory data obtained from self-identified Black and White volunteer subjects to evaluate differences in Masimo pulse oximetry accuracy and bias on the basis of skin tone. To do so, they reviewed more than 7,000 paired data samples (collected between 2015 and 2021) from 75 subjects (39 Black and 36 White) and found no clinically significant difference in accuracy or bias.²

For this newly published study, noting that low peripheral perfusion is a “recognized confounder of conventional pulse oximetry” and in light of concerns that low perfusion combined with dark skin pigmentation might decrease pulse oximetry’s accuracy, the investigators sought to determine whether accuracy on Black or White subjects was impacted by a subject’s perfusion index (Pi) with Masimo SET® pulse oximetry. To that end, they abstracted Pi values from their dataset, and divided them into “low perfusion” (Pi ≤ 1) and “normal perfusion” (Pi > 1) groups. They then performed statistical analyses to determine bias (the mean difference between SpO₂ and arterial oxygen saturation [SaO₂]), precision (the standard deviation of the difference), and accuracy (root-mean-square error, or A_{RMS}*).

The researchers found that in the normal perfusion group, comparing SpO₂ to SaO₂ values, there was overall bias and precision of +0.18% ± 1.34%, with accuracy of 1.37% A_{RMS}. For the subset of Black subjects, there was bias and precision of -0.26% ± 1.37%, and for White subjects, -0.12% ± 1.31%. In the low perfusion group, there was overall bias and precision of 0.48% ± 1.59%, with accuracy of 1.64% A_{RMS}. For Black subjects, bias and precision were 0.19% ± 1.53%, and for White subjects, 0.91% ± 1.57%.

Based on their analysis, the authors concluded, “Masimo SET® pulse oximeters with RD SET® sensors are accurate for individuals of both Black and White races when Pi is normal, as well as during conditions when Pi is low. The A_{RMS} for all conditions studied is well within FDA standards. This study was conducted in healthy volunteers during well-controlled laboratory desaturations, and results could vary under certain challenging clinical conditions.”

However, the authors noted that controlling conditions in the laboratory setting helps “minimize confounders that are present in clinical scenarios, allowing for greater focus on the topics of skin tone and Pi. Indeed, abnormal hemoglobin species (e.g., carboxyhemoglobin and methemoglobin) [known clinical SpO₂ confounders] were measured and reported in the earlier paper by Barker and Wilson, and the values were similar (statistically the same) between Black and White groups.² Also, one can only ethically conduct desaturation studies using healthy volunteer subjects in a safe setting.”

Source: [Masimo](#)

References

© For personal and private use only. Reproduction must be permitted by the copyright holder. Email to copyright@mindbyte.eu.

1. Sharma V, Barker S, Sorci R, Park L, Wilson W. Racial effects on Masimo pulse oximetry: impact of low perfusion index. *J Clin Monit Comput*. 19 Jan 2024. DOI: 10.1007/s10877-023-01113-2.
2. Barker SJ, Wilson WC. Racial effects on Masimo pulse oximetry: a laboratory study. *J Clin Monit Comput*. 2023 Apr;37(2):567-574. DOI: 10.1007/s10877-022-00927-w.
3. Published clinical studies on pulse oximetry and the benefits of Masimo SET[®] can be found on our website at www.masimo.com. Comparative studies include independent and objective studies which are comprised of abstracts presented at scientific meetings and peer-reviewed journal articles.
4. Castillo A et al. Prevention of Retinopathy of Prematurity in Preterm Infants through Changes in Clinical Practice and SpO₂ Technology. *Acta Paediatr*. 2011 Feb;100(2):188-92.
5. de-Wahl Granelli A et al. Impact of pulse oximetry screening on the detection of duct dependent congenital heart disease: a Swedish prospective screening study in 39,821 newborns. *BMJ*. 2009; Jan 8;338.
6. Taenzer A et al. Impact of pulse oximetry surveillance on rescue events and intensive care unit transfers: a before-and-after concurrence study. *Anesthesiology*. 2010;112(2):282-287.
7. Taenzer A et al. Postoperative Monitoring – The Dartmouth Experience. *Anesthesia Patient Safety Foundation Newsletter*. Spring-Summer 2012.
8. McGrath S et al. Surveillance Monitoring Management for General Care Units: Strategy, Design, and Implementation. *The Joint Commission Journal on Quality and Patient Safety*. 2016 Jul;42(7):293-302.
9. McGrath S et al. Inpatient Respiratory Arrest Associated With Sedative and Analgesic Medications: Impact of Continuous Monitoring on Patient Mortality and Severe Morbidity. *J Patient Saf*. 2020 14 Mar. DOI: 10.1097/PTS.0000000000000696.
10. Estimate: Masimo data on file.
11. health.usnews.com/health-care/best-hospitals/articles/best-hospitals-honor-roll-and-overview

*A_{RMS} accuracy is a statistical calculation of the difference between device measurements and reference measurements. Approximately two-thirds of the device measurements fell within +/- A_{RMS} of the reference measurements in a controlled study.

Published on : Thu, 8 Feb 2024