## 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 ($SpO_2$) 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 $SpO_2$ and arterial oxygen saturation [$SaO_2$]), 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 $SpO_2$ to $SaO_2$ 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 $SpO_2$ 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**

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*$A_{RMS}$ 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.

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