



Masimo SET[®] Pulse Oximetry and Skin Pigmentation

Supplemental Slides

For professional use. See instructions for use for full prescribing information including indications, contraindications, warnings and precautions.
Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

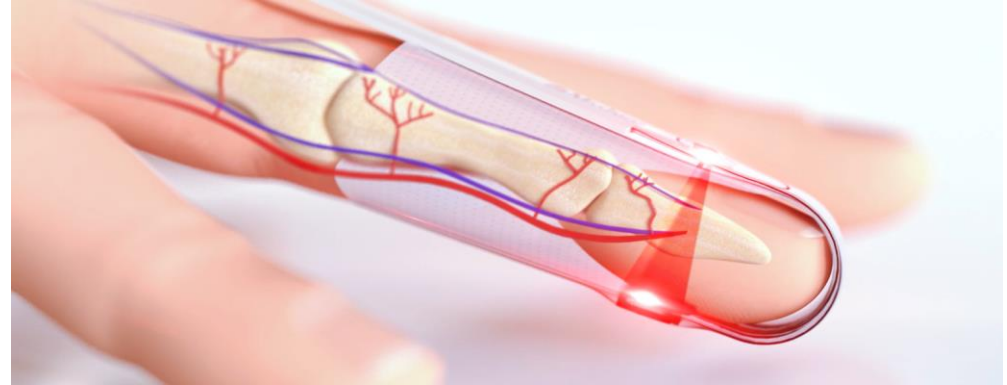
Background

The purpose of the following supplemental slides is to provide additional information on Masimo SET[®] performance in varying skin pigmentations.



Executive Summary

> Masimo invented Measure-through Motion and Low Perfusion™ pulse oximetry using **Signal Extraction Technology® (SET®)** over three decades ago to address these known pulse oximetry confounders.



- > SET® also addresses skin pigmentation and other static absorbers such as skin thickness and bone density.
- > Our data, detailed in the following slides, demonstrates that Masimo SET® pulse oximeters are equally accurate for individuals of all skin tones.
- > Despite the currently excellent accuracy across all skin tones provided by Masimo SET®, we will continue to improve our accuracy and reliability.

Racial Effects on Masimo Pulse Oximetry: A Laboratory Study



Journal of Clinical Monitoring
and Computing



- > **Barker** SJ – Chief Science Officer and **Wilson** WC – Chief Medical Officer
- > Retrospective analysis of Masimo SET[®] data
- > Abstract presented at Society of Technology in Anesthesiology (STA) Annual Meeting in January 2022
- > Full Manuscript in *J Clin Monit Comput* (published Nov. 12, 2022)
- > Read the full study here: <https://link.springer.com/article/10.1007/s10877-022-00927-w>

Study Methods

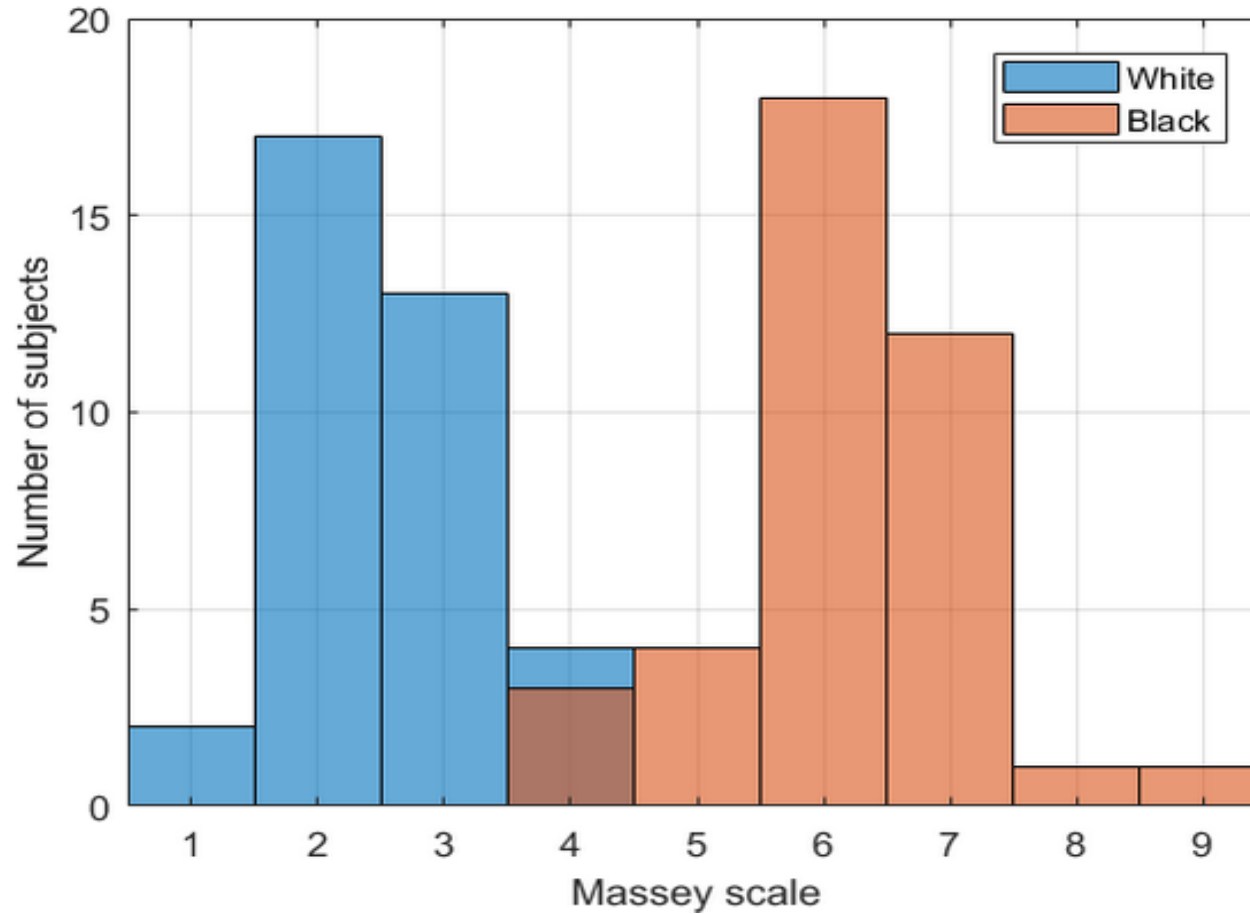


- > Data from volunteers October 2015 - July 2021
- > Masimo SET[®] pulse oximeters with RD SET[®] sensors
- > Volunteers underwent stepwise hypoxemia, with arterial SaO₂ down to 70%
- > SpO₂ values time-matched with ABG samples within 5 seconds

Masimo SET [®]	N	Paired Samples	Age Mean range	Sex	Massey Scale	tHb (g/dL) mean range	CoHb % mean range	MetHb % mean range
Black	39	3,201	34.8 21-50	25M 14F	4-9	14.5 11.3-18.2	1.1 0.3-1.8	1.1 0.3-1.6
White	36	3,982	30.4 18-44	23M 13F	1-4	14.5 11.2-18.1	0.9 0.3-1.6	1.1 0.3-1.5
All	75	7,183	32.7 18-50	48M 27F	1-9	14.5 11.2-18.2	1.0 0.3-1.8	1.1 0.3-1.6

Barker, S.J., Wilson, W.C. Racial effects on Masimo pulse oximetry: a laboratory study. *J Clin Monit Comput* (2022). Available on-line at: <https://doi.org/10.1007/s10877-022-00927-w>

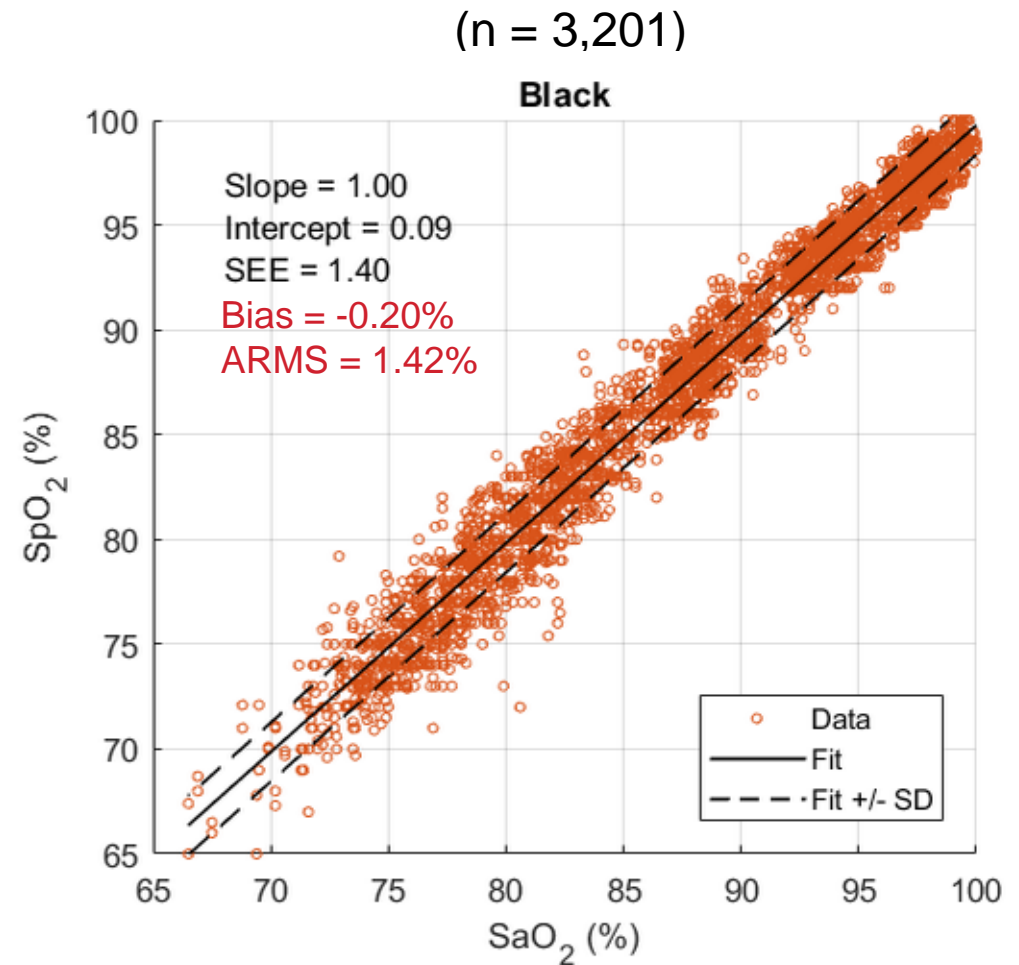
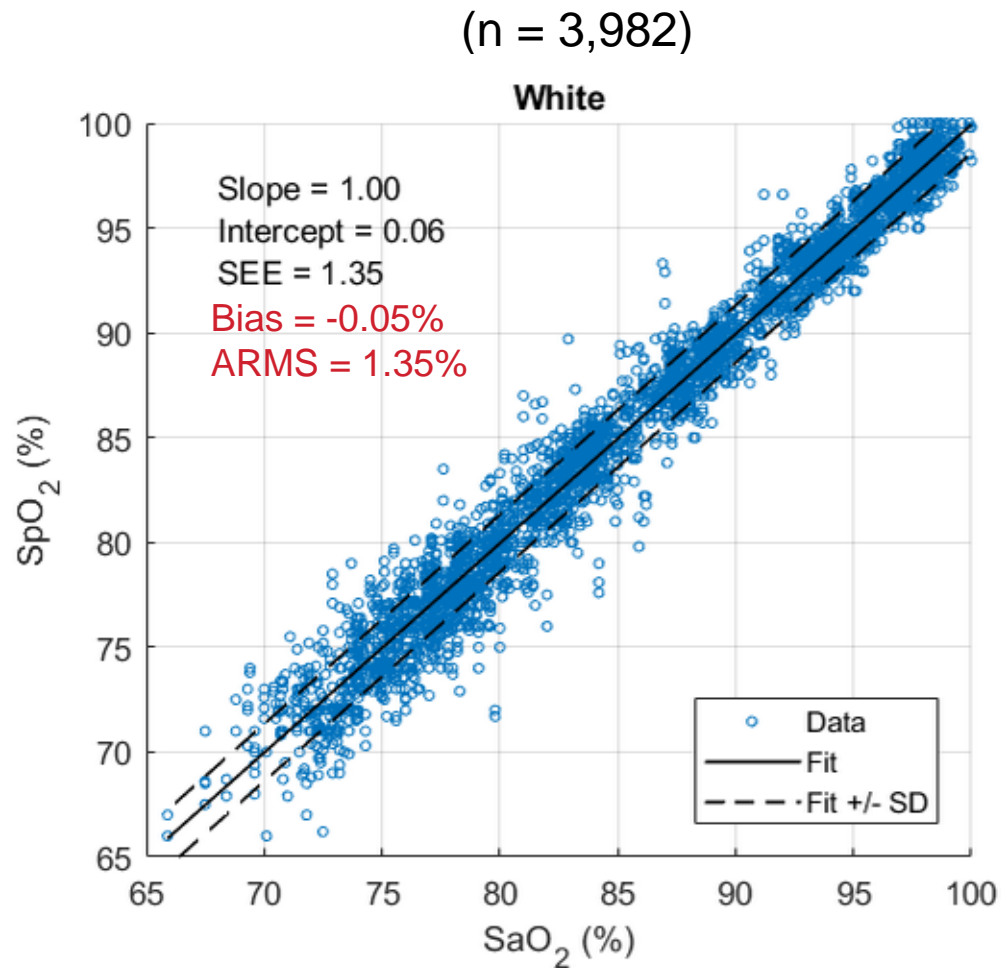
Study Participant Skin Color Distribution Histogram (Massey-Martin Scale by Self-identified Race)



Barker, S.J., Wilson, W.C. Racial effects on Masimo pulse oximetry: a laboratory study. *J Clin Monit Comput* (2022). Available on-line at: <https://doi.org/10.1007/s10877-022-00927-w>

SpO₂-SaO₂ Results

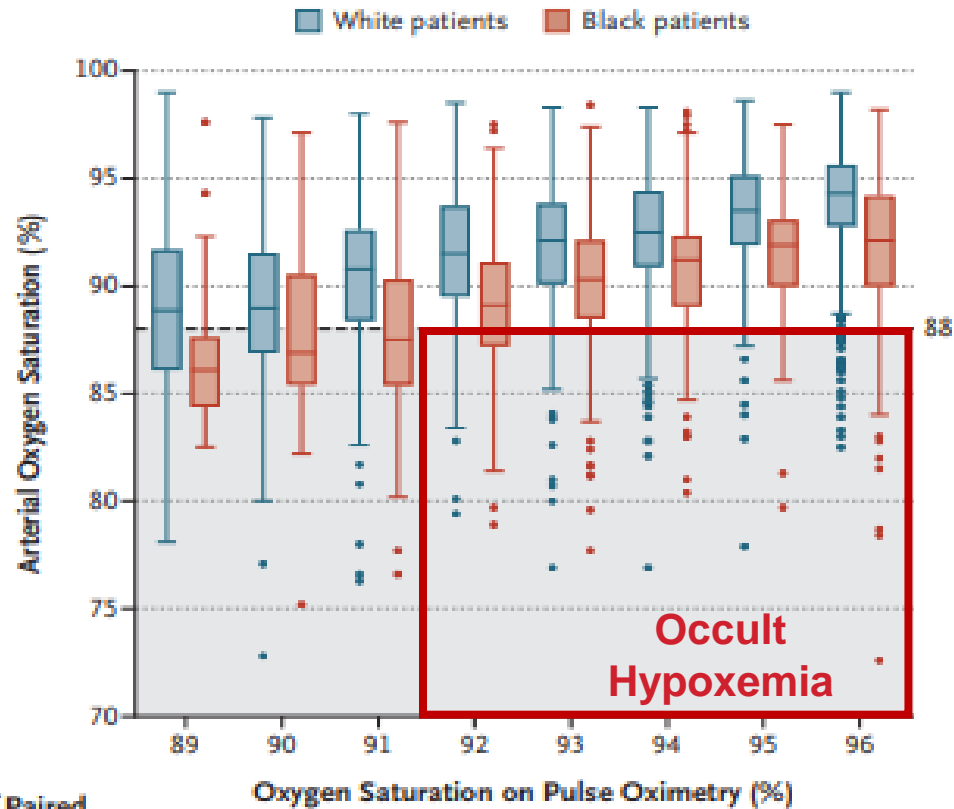
Bias Difference of 0.15% is NOT Clinically Significant.



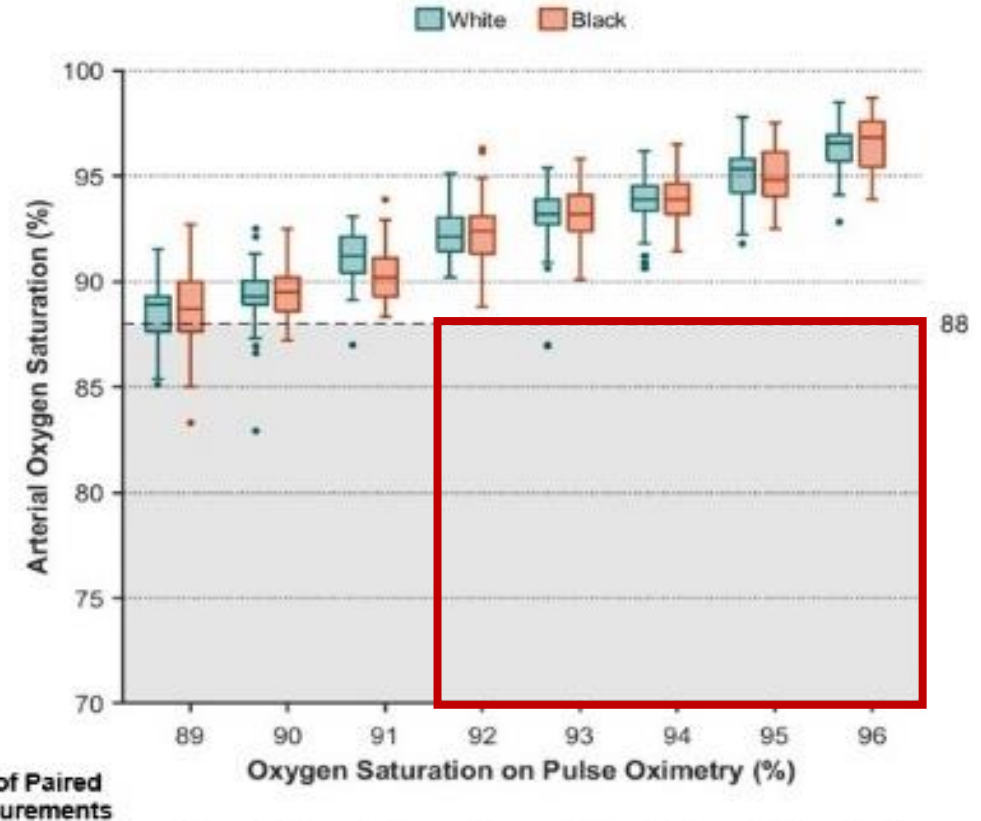
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Occult Hypoxemia Results: Sjoding vs. Masimo

(Box Plots in 1% Bins)



Sjoding, et al.¹



Masimo RD SET²

¹ Sjoding MW, et al. *N Engl J Med.* 2022;383(25):2477-2478.

² Barker, S.J., Wilson, W.C. Racial effects on Masimo pulse oximetry: a laboratory study. *J Clin Monit Comput* (2022).

Available on-line at: <https://doi.org/10.1007/s10877-022-00927-w>

Study Conclusions

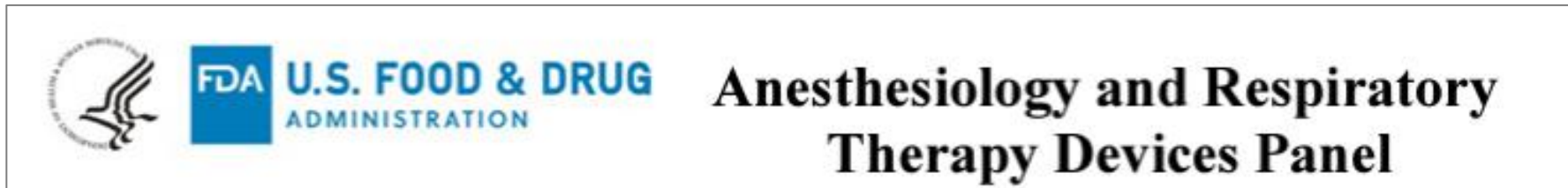
- > The SpO₂-SaO₂ difference (bias) of 0.15% is not clinically significant because 0.15 is approximately 1/7 of 1% and the SpO₂ display resolution on all pulse oximeters is 1%.
- > There was no clinically significant difference in the accuracy or bias between Black and White subjects monitored with Masimo SET[®] pulse oximetry and RD SET sensors.
- > Masimo RD SET is highly accurate and can be used with assurance in people with all skin pigmentations.



Barker, S.J., Wilson, W.C. Racial effects on Masimo pulse oximetry: a laboratory study. *J Clin Monit Comput* (2022). Available on-line at: <https://doi.org/10.1007/s10877-022-00927-w>

FDA Advisory Meeting

- > Masimo applauds the FDA's decision to convene an Advisory Meeting on Pulse Oximetry on November 1, 2022 to discuss the real-world performance of pulse oximeters and factors impacting accuracy in diverse populations.
- > The information provided is under consideration by the FDA in their deliberations on improving regulatory oversight of pulse oximeter devices.



Masimo's Call to Action

As a key contributor to this panel, Masimo believes that it is in the public interest to implement the following policies for gaining 510(k) clearance of medical-grade pulse oximeters:

- > More stringent A_{RMS} accuracy requirements.
- > Greater diversity of skin tones for validation studies. The current FDA guidance calls for a minimum of 2 subjects or 15% of the study pool (whichever is larger).
- > More rigorous skin pigmentation benchmarks. For example, a validated skin pigment categorization such as the Massey-Martin Scale, as well as quantitative measures (e.g. spectrophotometric skin tone assessment), should be used to ensure skin tone diversity in data.



Conclusion

- > Masimo is currently pursuing prospective clinical studies to a) confirm our laboratory data showing excellent accuracy across all skin tones and b) continue to improve both accuracy and reliability.
- > There is abundant evidence that non-medical-grade pulse oximeters are being purchased and used for medical decision-making outside of the hospital, which should be regulated.
- > All pulse oximeters should be required to meet the same minimum accuracy requirements as current medical-grade pulse oximeters.





Visit www.masimo.com/rd-set-sensors to learn more about RD SET sensors

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