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.

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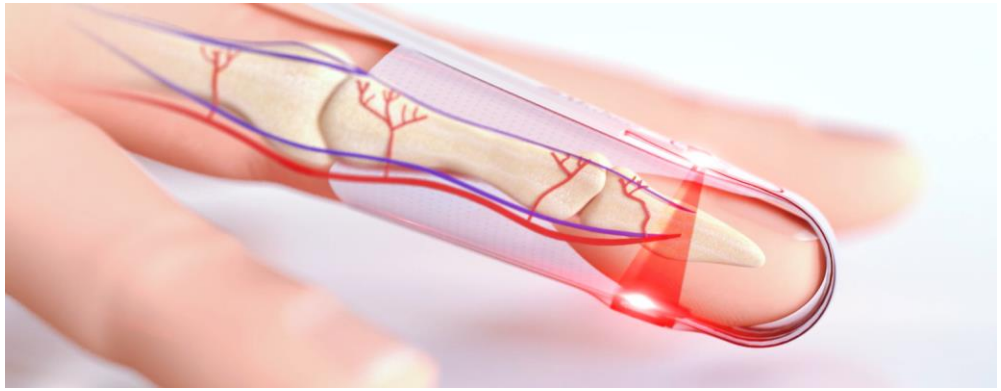
Executive Summary

- 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.

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Racial Effects on Masimo Pulse Oximetry: A Laboratory Study

Springer

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

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Study Methods

- Data from volunteers October 2015 - July 2021
- Masimo SET® pulse oximeters with RD SET® sensors
- Volunteers underwent stepwise hypoxemia, with arterial SaO_2 down to 70%
- SpO_2 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

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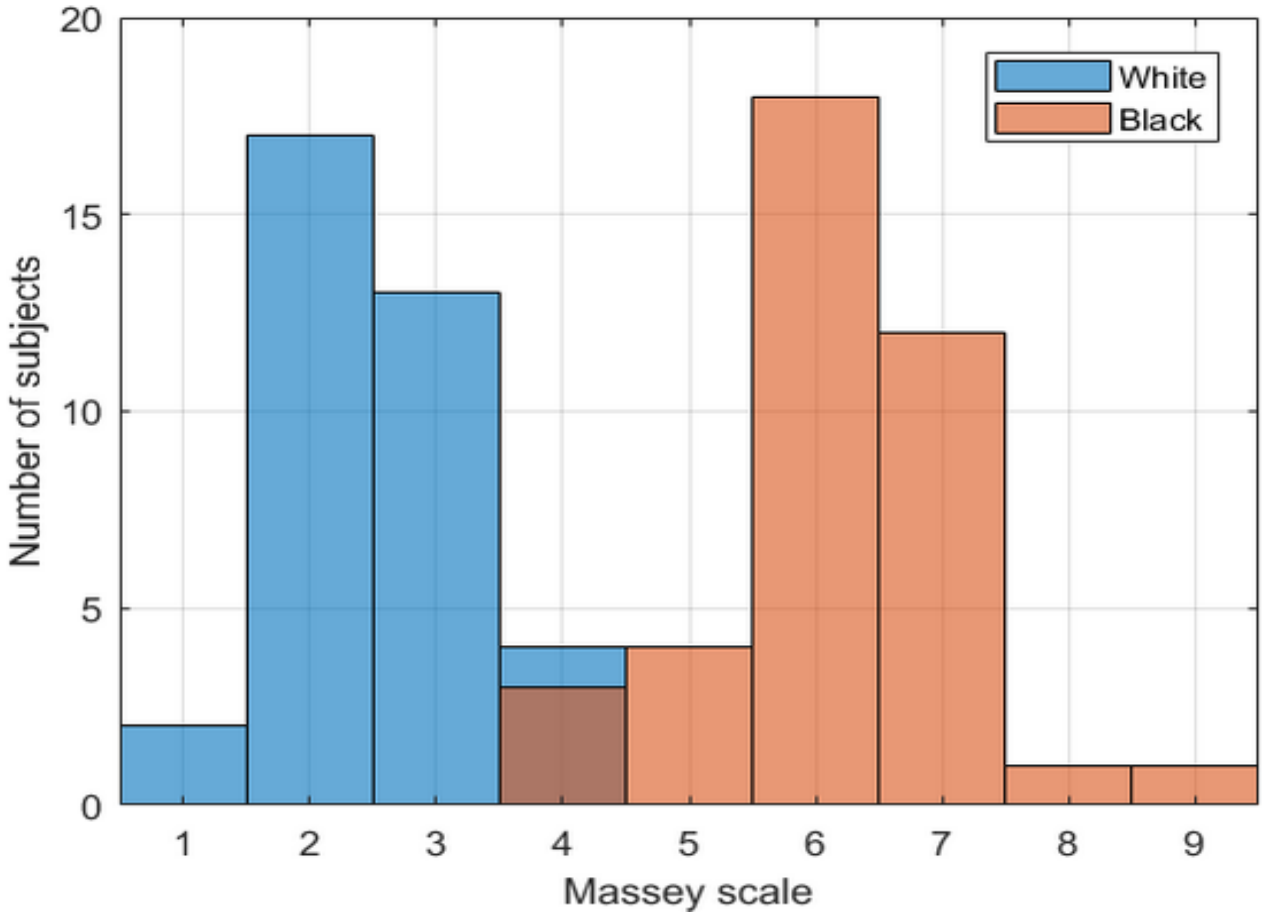
Study Participant Skin Color Distribution Histogram (Massey-Martin Scale by Self-identified Race)



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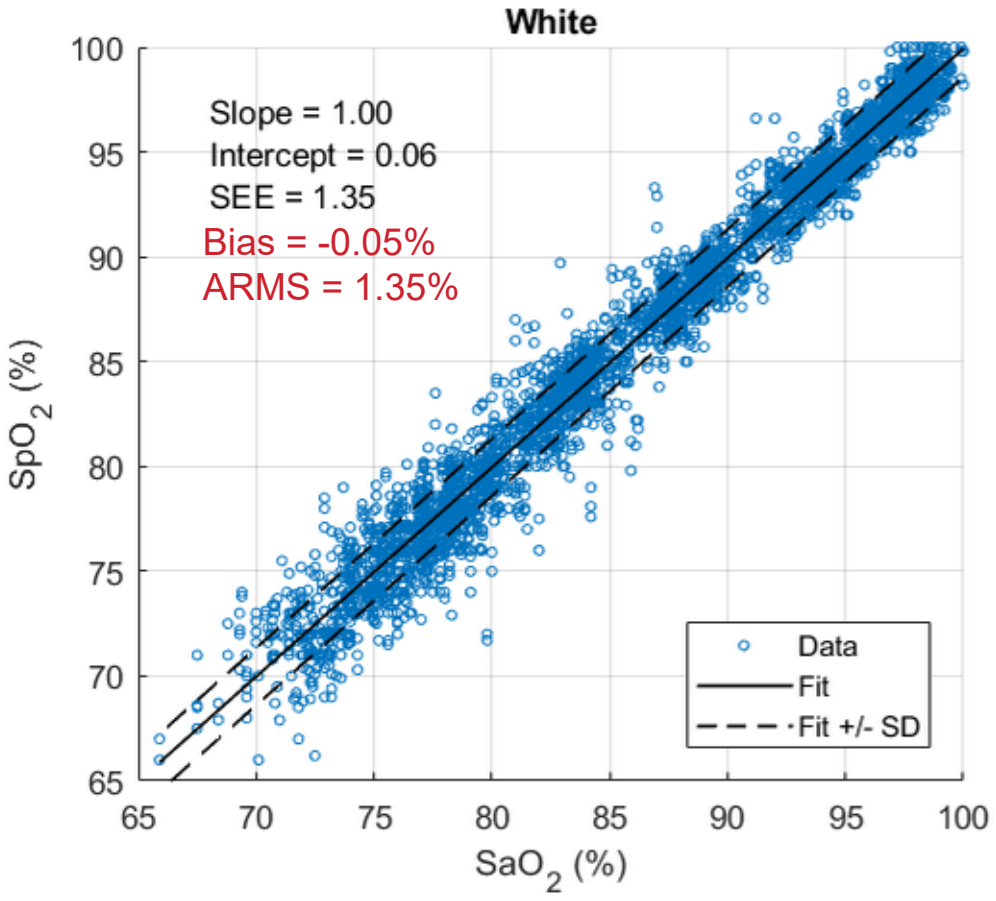
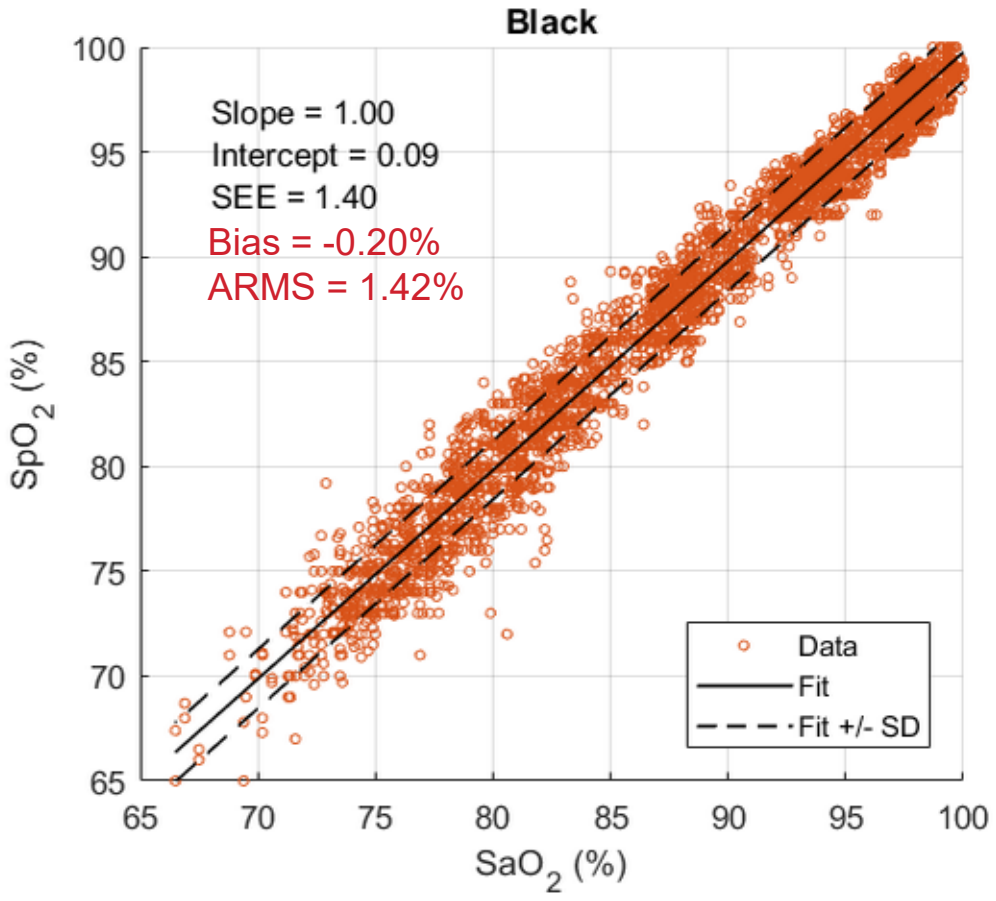
SpO_2-SaO_2 Results

Bias Difference of 0.15% is NOT Clinically Significant.

(n = 3,982)



(n = 3,201)



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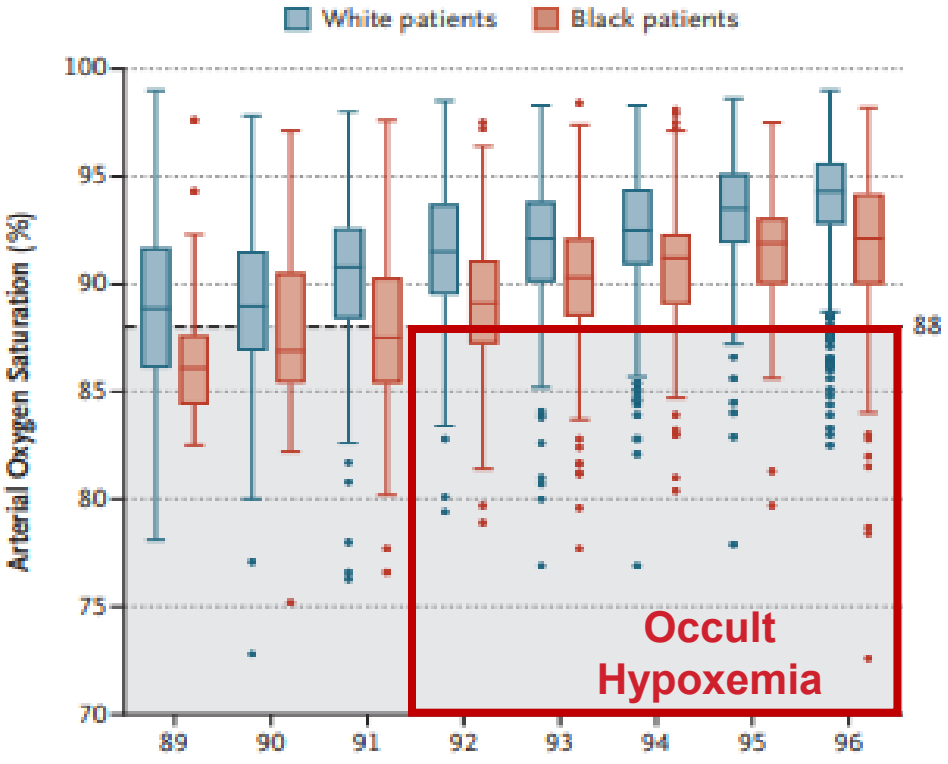
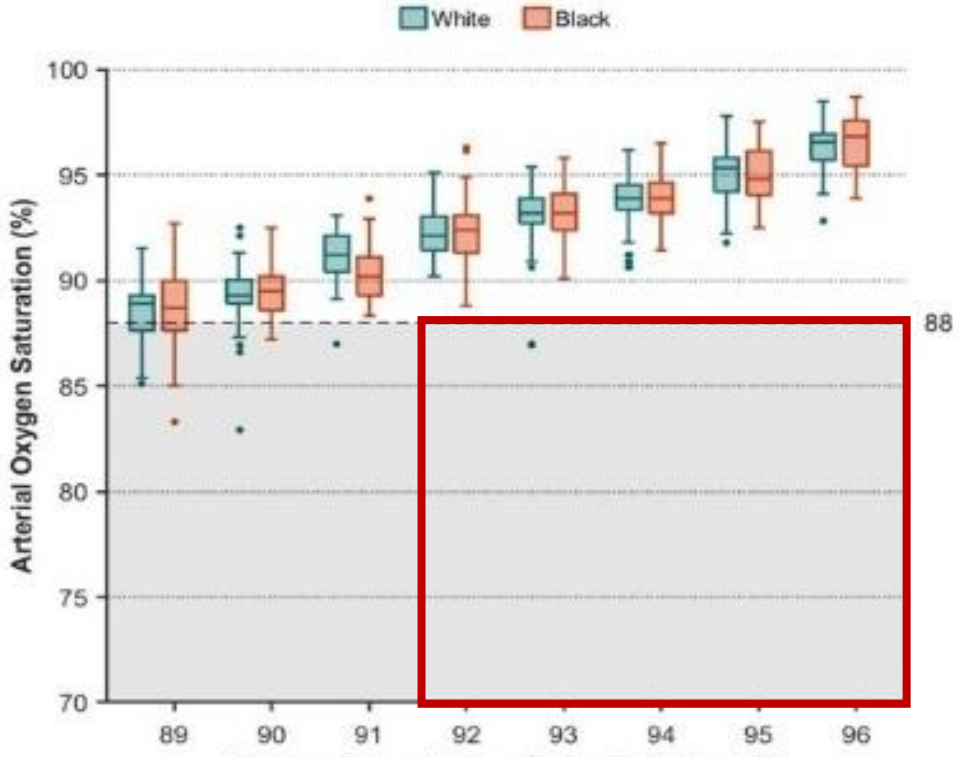
Occult Hypoxemia Results: Sjoding vs. Masimo
(Box Plots in 1% Bins)



No. of Paired Measurements	89	90	91	92	93	94	95	96
White patients	88	168	219	296	411	530	625	770
Black patients	17	45	59	82	118	124	176	213

Sjoding, et al.[1]



No. of Paired Measurements	89	90	91	92	93	94	95	96
White	155	100	66	93	165	283	121	198
Black	123	68	68	115	164	190	128	127

Masimo RD SET[2]

[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

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Study Conclusions

- The SpO_2-SaO_2 difference (bias) of 0.15% is <u>not</u> clinically significant because 0.15 is approximately 1/7 of 1% and the SpO_2 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.

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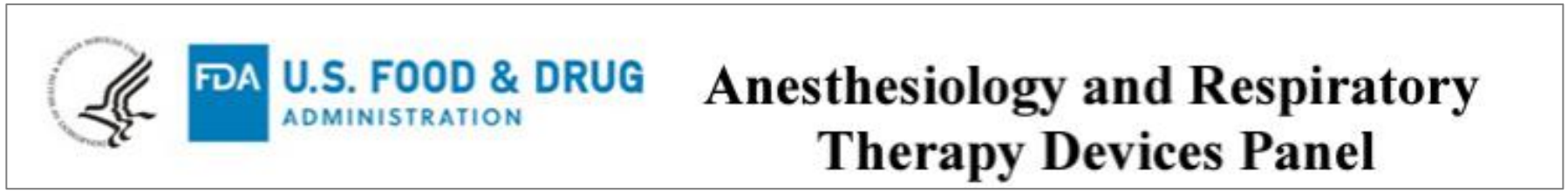
FDA Advisory Meeting

- 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.



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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.

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

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