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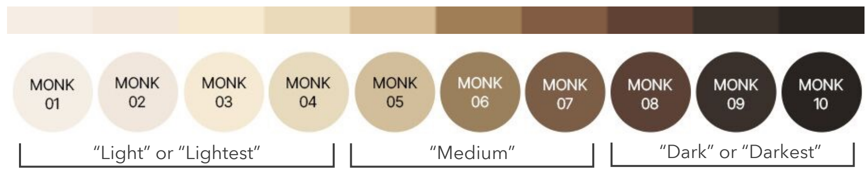
EVIDENCE SUMMARY

Accuracy and bias of pulse oximeters in patients with dark skin pigmentation

Compare frequently cited evidence on Nellcor™ pulse oximetry and Masimo pulse oximetry performance on patients with the darkest skin tones.



Monk Skin Tone (MST) Scale, a more inclusive scale recommended by regulatory bodies.

Darker skin pigmentation is correlated with increased risk of inaccurate SpO_2 readings and occult hypoxemia.[1,2]

The risk for occult hypoxemia is greatest for the darkest skin tones (MST 8-10; ITA 5-6; Fitzpatrick V-VI). We caution researchers from making conclusions on pulse oximetry performance for dark skin tones should not be largely based on results from Medium skin tones (MST 5-7, ITA 3-4, Fitzpatrick III-IV) or from using self-reported race as a substitute for skin pigmentation.

Certain studies conclude there is no bias in pulse oximeter performance due to skin pigmentation but have **notable limitations**.

Explanation of table criteria can be found on other side.

Article	Findings	Key Methods	a. Non-healthy or Low Pi	b. Prospective study	c. Concurrent ABG & SpO_2 samples	d. No COI with manufacturer	e. % of subjects with darkest skin
Foglia et al. 2017 J Pediatr.[3]	There was no significant difference in systemic bias based on skin pigment for either oximeter (p value = 0.39). Key Limitation: dark pigment group was significantly older (median age 118 days vs. 6 days for light) and had a greater mean arterial blood pressure.	Tested Masimo Radical 7 and Nellcor™ OxiMax™ to compare pulse oximetry bias between hypoxemic infants (n=36) with either dark or light skin, as determined by the Munsell System Soil Color Chart, without disclosure of distribution or average color value of subjects.	✓	✓	✓	✓	†
Sharma et al. 2024 J Clin Monit Comput.[4]	Device was accurate for individuals of both Black and White races under both normal and low Pi conditions. Key Limitation: For Black participants, median Massey scale value was 6 (1-10 scale), with **only 2** out of 37 Black participants falling into the falling into the three darkest skin tones out of ten (Massey-Martin Scale 8-10).	Sub-analysis of Barker et al 2023[5] that tested Masimo SET®* pulse oximeters on healthy Black and White volunteers (n=75) during normal and low perfusion (Pi) conditions.	✓	X	✓	X‡	2.7%
Marlar et al. 2024 J Clin Monit Comput.[6]	This retrospective, single institution review did not find a clinically significant difference in the accuracy of pulse oximeters with respect to skin pigmentation. Key Limitation: **Only 4** out of 579 patients (<1%) fell into the three darkest skin tones out of ten (Massey-Martin Scale 8-10).	Evaluated clinical trial data using Masimo SET® technology to compare most proximate SpO2 readings with SaO2 values from ABG results of trial participants (n=579).	✓	X	X	X§	0.7%

Existence of disparate patient outcomes[7,8] contradict the conclusions above. The following studies show how different results can be when more rigorous study criteria is put into practice:

Nellcor™ pulse oximetry performs better than Masimo in recent, independent, and prospective studies that assess performance in dark skin pigmentation.

Explanation of table criteria can be found on other side.

Article	Findings	Methods	a. Non-healthy or Low Pi	b. Prospective study	c. Concurrent ABG & SpO_2 samples	d. No COI with manufacturer	e. % of subjects with darkest skin
Gudelunas et al. 2024 Anesth Analg.[◊,1]	In this study from a leading hypoxia lab, Nellcor™ pulse oximetry had **31% greater precision** than Masimo for subjects with darkly pigmented skin and low perfusion. Nellcor™ pulse oximetry **missed 74% fewer hypoxemic events** than Masimo for this group.	Tested Masimo Radical-7 with a DCI clip-type reusable finger sensor or ear clip sensor and Nellcor™ N-595 with a reusable DS-100A finger sensor on healthy subjects (n=146) to compare impact of skin pigmentation and perfusion (Pi) on pulse oximeter errors. Study was not designed for head-to-head comparison. 43 subjects fell into the dark skin pigmentation category (Fitzpatrick class V and VI).	✓	✓	✓	✓	29.5%
Starnes et al. 2025 N Engl J Med.[◊,2]	In this prospective, observational, single institution study, Nellcor™ pulse oximetry demonstrated **40% lower bias and 23% greater accuracy** than Masimo in the darkest skin tone group.	Tested Masimo Rad-G and Nellcor™ disposable adhesive sensor with a Philips monitor on a pediatric population (n=320; median age 3.28 years) undergoing cardiac catheterization. Study was not designed for head-to-head comparison. 75 subjects fell into ITA 5 or 6 ("darkest") skin pigmentation category.	✓	✓	✓	✓	23.4%

† This study did not disclose participant skin tone distribution.
‡ This study was funded by Masimo and performed by Masimo employees.
§ Two authors from this study have previously received support for contracted research from Masimo.
◊ This study was not funded by Medtronic. Values were calculated by Medtronic as a percent difference and should be interpreted as hypothesis generating only.

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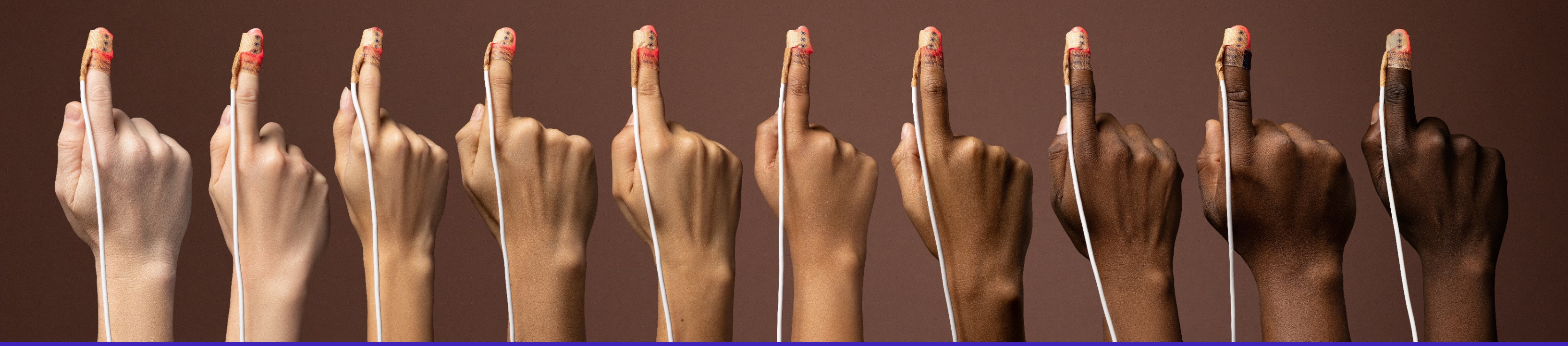

Study design characteristics: what does a checkmark ✓ indicate?

a. Study accounted for real world conditions, either by studying non-healthy subjects in a hospital setting or by investigating the impact of low perfusion on device accuracy. This is important due to compounding effect of real patient conditions such as low perfusion on accuracy of SpO_2 readings.[1]

b. Study is a prospective clinical study.

c. Study used paired SpO_2 and SaO_2 readings taken at the same time.

d. Study does not report any conflicts of interest with a manufacturer of pulse oximeters.

e. Percentage of subjects with dark skin. The latest FDA draft guidance has proposed at least 25% of subjects should fall into the darkest skin pigmentation category. For subjective skin tone measures, darkest skin tone groups are categorized as Monk Skin Tone (MST) 8-10, Massey-Martin 8-10, and Fitzpatrick V-VI. For objective skin tone measures, darkest skin tones are defined by an ITA reading between 10 and -60 degrees (falling into categories ITA 5 and 6). Studies that draw conclusions based on binary categories such as Black/White or dark/light may not sufficiently identify pulse oximetry bias due to skin pigmentation.

Nellcor™ pulse oximetry monitoring should not be used as the sole basis for diagnosis or therapy and is intended only as an adjunct in patient assessment.

References

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