

The Effects of Skin Pigmentation and Low Saturation in Oximetry

Nonin PureSAT® Oximetry Technology Provides Superior Accuracy in Low Saturation and Dark Skin Pigmentation Patients

Summary

In a controlled laboratory study of 36 subjects with varying skin pigments, leading researchers at the University of California San Francisco found that accuracy of pulse oximeters varies depending on skin pigmentation, especially in combination with low oxygen saturations. In the study, the Nonin PureSAT® oximeter with clip sensor was not affected by skin pigmentation compared to competitive products tested. The Nonin PureSAT® oximeter with clip sensor had excellent accuracy and the lowest bias compared to the gold standard, blood gas or co-oximetry, throughout the oxygen saturation levels and for all skin pigmentations. Of particular note, the authors state “clinically important bias should be considered when monitoring patients with saturation below 80%, especially those with darkly pigmented skin”. In the environment of low saturation (SaO₂ 70% to 80%) and dark skin pigmentation, the bias for Nonin PureSAT® oximetry with the clip sensor was minimal at -0.6 ± 1.2 and the accuracy was excellent. This is in contrast to the competitors’ results with a mean bias of 2.6 ± 2.6 and 2.6 ± 3.0 in the same subgroup.

Table 1: Using co-oximetry measurements as a benchmark, sensors with PureSAT technology provide the most consistent readings for patients with dark skin pigmentation (lower values indicate closer matching)

	Nonin			Nellcor			Masimo		
	Bias (Mean)	Precision (SD)	Accuracy (A _{rms})	Bias (Mean)	Precision (SD)	Accuracy (A _{rms})	Bias (Mean)	Precision (SD)	Accuracy (A _{rms})
>90%	-0.5	1.0	1.1	1.3	1.4	1.9	1.4	1.7	2.2
80–90%	-1.1	0.8	1.4	2.4	1.7	3.7	2.5	2.6	3.6
70–80%	-0.6	1.4	1.6	2.6	2.6	3.7	2.6	3.0	3.9
60–70%	0.5	1.8	1.8	1.5	2.8	3.2	2.6	3.5	4.4
All Saturation Levels	-0.6	1.2	1.3	2.0	2.1	2.9	2.1	2.9	3.6

- Bias (Mean) = Mean Differences Between Oximeter Readings and Co-Oximeter
- Bias is the mean of the differences between oximeter readings and the functional SpO₂ values as measured by a co-oximeter from an arterial sample. Positive bias means the test oximeter overestimates saturation. Negative bias means the oximeter underestimates the saturation. Units are in % saturation.
- Precision (SD) = Standard Deviation of Differences from Co-Oximeter Measurements
- Precision is the standard deviation of the difference between oximeter readings and the functional SpO₂ pt values as measured by a co-oximeter from an arterial sample. Units are percent saturation.
- Accuracy (A_{rms}) = Combination of Both the Bias and the Precision
- The A_{rms} accuracy is a standard method for reporting pulse oximeter accuracy which combines both the Bias and the Precision into a simple term for reporting the accuracy of the pulse oximeter. Accuracy in terms of A_{rms} is equivalent to the Square Root of the (Bias² + Precision²).

Methods

Thirty-six healthy, non-smoking subjects underwent a standard breathe-down protocol to achieve arterial oxygen saturation between 70% and 100%. The pulse oximeters tested included: Nonin Avant® 9700, Masimo Radical®, and Nellcor OxiMax® N-595. 17 subjects were categorized with dark skin pigmentation, 7 with intermediate skin pigmentation, and 12 with light skin pigmentation.

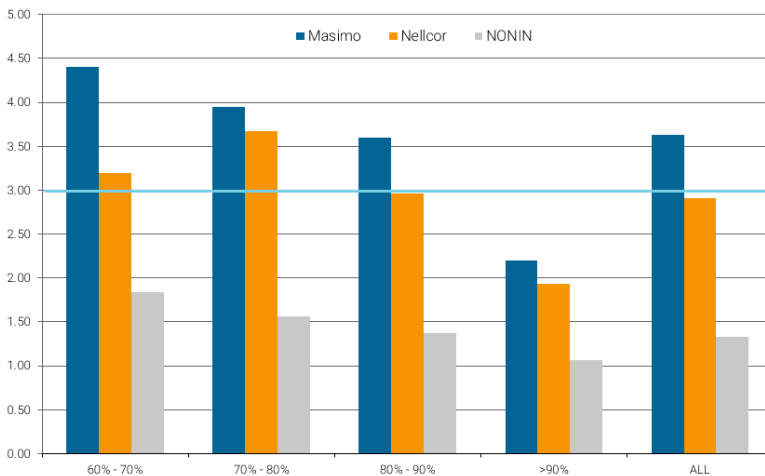
The mean and precision (SD) of the bias compared to arterial oxygen saturation, were computed. Accuracy is reported as A_{rms} , a computed value based on mean and SD of bias per FDA standards for pulse oximetry accuracy ($A_{rms} = \sqrt{\text{Bias}^2 + \text{SD}^2}$).

Results

At 70% to 80% oxygen saturation, the mean bias (\pm S.D.) in dark skin pigmentation was minimal for Nonin's oximeter with the clip sensors at $-0.6\% \pm 1.4$, compared to the mean bias for Masimo ($2.6\% \pm 3.0$) and Nellcor ($2.6\% \pm 2.6$) oximeters with clip sensors. (Table 1)

Accuracy—a combined measure of error and variability—was excellent with the Nonin oximeter and clip sensor in dark skin pigmentation subjects even with low oxygen saturation (SaO₂ less than 80%). (Figure 1)

Figure 1: Nonin PureSAT® Reusable Sensors Have Superior Accuracy in Patient Population with Dark Skin Pigmentation (Lower Values Indicate Superior Accuracy)



$A_{rms} < 3.0$ per FDA oximeter standards

A_{rms} calculated from Mean and SD of Bias¹

¹ "Dark skin decreases the accuracy of pulse oximeters at low oxygen saturations: effects of oximeter probe type and gender", John Feiner, et al. Anesthesia & Analgesia, December, 2007.

Nonin Medical, Inc.
13700 1st Avenue North
Plymouth, MN • 55441-5443 • USA

Tel: +1.763.553.9968 1.800.365.8874
Fax: +1.763.577.5521
Email: info@nonin.com

Nonin Medical B.V.
Doctor Paul Janssenweg 150
5026 RH Tilburg • Netherlands

Tel: +31 (0)13-79 99 040
Fax: +1 (0)13-79 99 042
Email: infointl@nonin.com



nonin.com