

## The Effects of Dark Skin Pigmentation and Low Saturation in Oximetry

# NONIN PureSAT® Oximetry Technology Provides Superior Accuracy in the Most Challenging Environments

### SUMMARY

In a controlled laboratory study of 36 subjects, leading researchers at the University of California San Francisco found that dark skin can result in decreased accuracy of pulse oximeters, especially in combination with low oxygen saturations. In the study, the NONIN PureSAT oximetry 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 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 this most challenging environment of low saturation (SaO<sub>2</sub> 70% to 80%) and dark skin pigmentation, the bias for NONIN PureSAT oximetry with the clip sensor was minimal at  $-0.6 \pm 1.2$  and the accuracy was excellent. This is in contrast to the competitor’s results with a mean bias of  $2.6 \pm 2.6$  and  $2.6 \pm 3.0$  in the same subgroup.

**Table 1: NONIN PureSAT Reusable Sensors Have Less Error/Bias in Most Challenging Patient Population: Dark Skin Pigmentation (Lower Values Indicate Superior Performance)**

Nonin				Nellcor				Masimo			
	Bias (Mean)	Precision (SD)	Accuracy (A <sub>rms</sub> )		Bias (Mean)	Precision (SD)	Accuracy (A <sub>rms</sub> )		Bias (Mean)	Precision (SD)	Accuracy (A <sub>rms</sub> )
>90%	-0.5	1.0	1.1	>90%	1.3	1.4	1.9	>90%	1.4	1.7	2.2
80% – 90%	-1.1	0.8	1.4	80% – 90%	2.4	1.7	3.7	80% – 90%	2.5	2.6	3.6
70% – 80%	-0.6	1.4	1.6	70% – 80%	2.6	2.6	3.7	70% – 80%	2.6	3.0	3.9
60% – 70%	0.5	1.8	1.8	60% – 70%	1.5	2.8	3.2	60% – 70%	2.6	3.5	4.4
ALL Saturation Levels	-0.6	1.2	1.3	ALL Saturation Levels	2.0	2.1	2.9	ALL Saturation Levels	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 SpO<sub>2</sub> 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 SpO<sub>2</sub> pt values as measured by a co-oximeter from an arterial sample. Units are percent saturation.

**Accuracy (A<sub>rms</sub>) = Combination of Both the Bias and the Precision**

The A<sub>rms</sub> 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<sub>rms</sub> is equivalent to the Square Root of the (Bias<sup>2</sup> + Precision<sup>2</sup>).

## METHODS

Thirty-six normal subjects underwent a standard breath-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. Seventeen subjects were categorized as “dark skinned” and are included in this report.

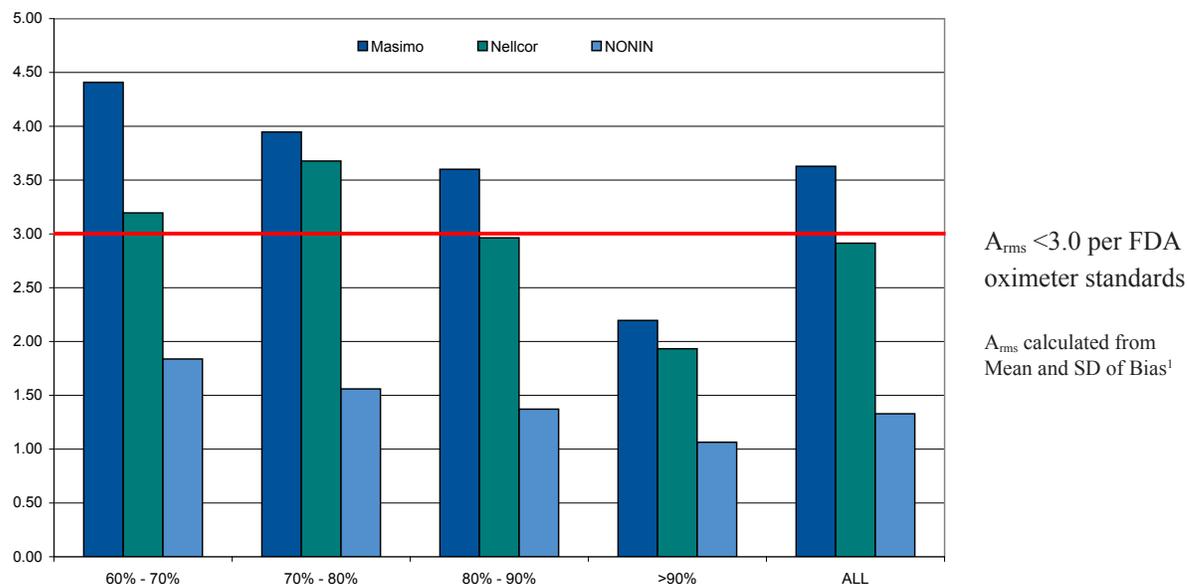
The mean and precision (SD) of the bias compared to arterial oxygen saturation, were computed. Accuracy is reported as  $A_{rms}$ , a computed value based on mean and SD of bias per FDA standards for pulse oximetry accuracy ( $A_{rms} = \sqrt{\text{Bias}^2 + \text{SD}^2}$ ).

## 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 subjects throughout the most challenging environments. NONIN’s oximeter with the clip sensor maintained acceptable variability (per FDA Standards:  $A_{rms} < 3.0$ ) in the most challenging environment of dark skin pigmentation and  $\text{SaO}_2$  less than 80%. (Figure 1)

**Figure 1: NONIN PureSAT Reusable Sensors Have Superior Accuracy in Most Challenging Patient Population: Dark Skin Pigmentation**  
(Lower Values Indicate Superior Accuracy)



<sup>1</sup> “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.

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