

Nonin PureSAT® Oximetry Technology Shown to Have Superior Accuracy

SUMMARY

A study comparing the accuracy of Nonin’s WristOx® 3100 with PureSAT technology to two competing wrist worn devices — was conducted at the University of California-San Francisco Hypoxia Research Laboratory (UCSF). Accuracy was determined using an industry standard breathe-down protocol of induced hypoxia in twelve normal subjects and co-oximetry analysis of arterial blood samples. These devices were selected in order to represent the range of low-cost to high-cost oximeter devices — the goal was to determine if other wrist-worn oximeters were able to deliver comparable accuracy in measuring oxygen saturation levels. The Nonin WristOx was found to have superior accuracy with pulse oximetry readings within its published specifications of plus or minus two percentage points (+/-2) of the arterial sample readings while both competing devices were found to be plus or minus four percentage points (+/-4). (**Figure 1**)

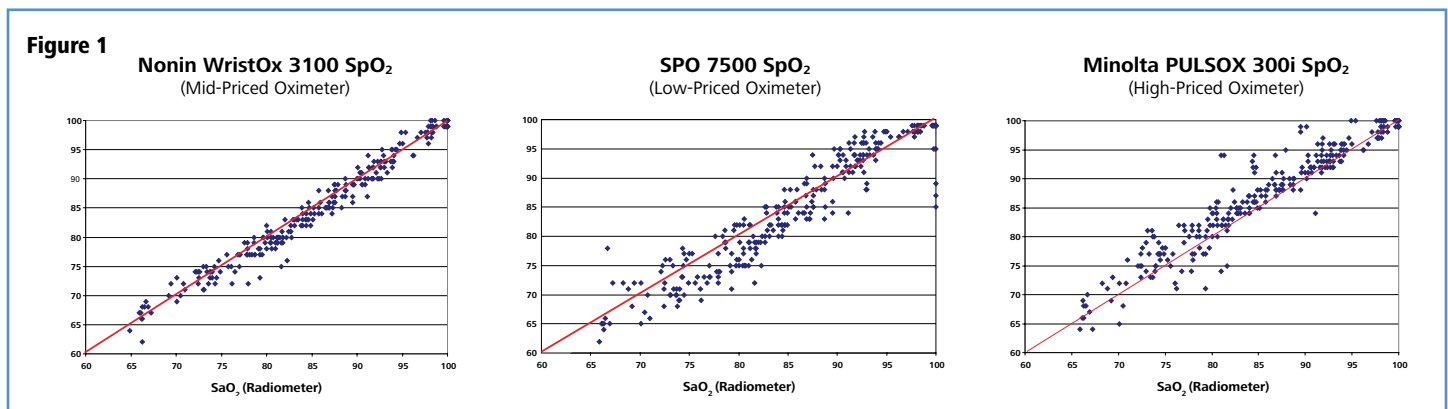


Table 1. Descriptive Statistics for BIAS by Device and Decade

	Number of Samples	Nonin WristOx 3100 (Mid-Priced Oximeter)		SPO 7500 (Low-Priced Oximeter)		Minolta PULSOX 300i (High-Priced Oximeter)	
		Mean (SD)	A_{rms}	Mean (SD)	A_{rms}	Mean (SD)	A_{rms}
All SaO ₂	285	-0.5 (1.6)	1.7	-0.8 (3.3)	3.4	1.5 (2.7)	3.1
SaO ₂ : 90+	111	-0.1 (1.3)	1.3	0.3 (3.2)	3.2	0.7 (1.6)	1.8
SaO ₂ : 80 – 89.9	96	-1.1 (1.5)	1.9	-1.4 (2.9)	3.2	2.3 (3.0)	3.8
SaO ₂ : <80	78	-0.3 (1.8)	1.8	-1.6 (3.5)	3.9	1.5 (3.0)	3.4

Bias (Mean) = Mean Differences Between Oximeter Readings and Co-Oximeter

Bias is the mean of the differences between oximeter readings and the SaO₂ 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 SaO₂ patient 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

Twelve normal subjects underwent an industry standard breath-down protocol of induced hypoxemia at the University of California-San Francisco Hypoxia Research Laboratory. The devices were all worn on the wrists with the pulse oximetry sensors attached to the subjects' fingers. Devices and sensors were rotated between wrists and among the index, middle or ring fingers using a Latin Square design (assuring equal rotation among the three fingers). Inspired gas mixtures were controlled to attain hypoxia plateaus between approximately 70% and 100%. Each plateau was maintained for at least two minutes while pulse oximetry readings and arterial blood samples were acquired simultaneously. Twenty-five samples were obtained from each subject.

The three wrist-worn devices included:

- Nonin WristOx 3100: a mid-priced device with a removable finger clip sensor featuring PureSAT technology.
- A low-priced competing device with an integrated silicone finger probe.
- A high-priced device with a removable finger probe.

Study Methodology Consistent with Real World Application

This study followed a rigorous protocol consistent with US FDA standards for pulse oximetry evaluation, which included the following criteria:

- **Ethnic and gender diversification:** Minimum of 20% non-Caucasian subjects were studied to demonstrate capability to read accurately with different skin tones and finger sizes.
- **Measurement:** Consistently used the same oximeters of each brand across all subjects, with randomized placement on subject fingers to control variability.
- **Data collection:** Used a minimum of 200 data points per device with an even distribution across an oxygen saturation (SpO₂) range from 70-100%. No data points or outliers were excluded from analysis.
- **Independence:** Used an independent lab for recruiting, testing and measuring against gold standard co-oximetry values.

RESULTS

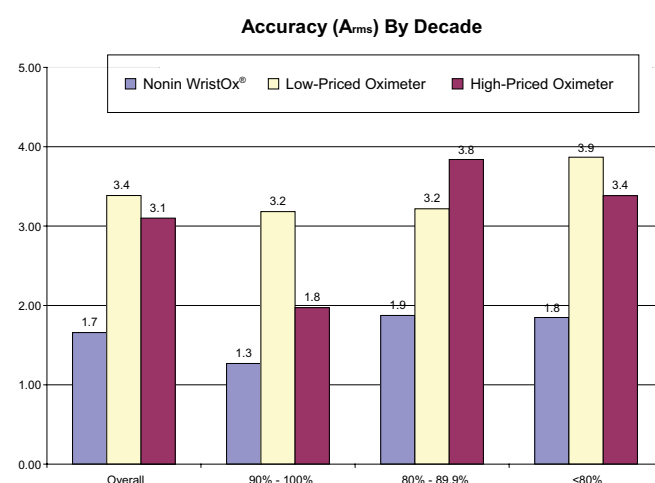
The Nonin WristOx with PureSAT oximetry technology had superior accuracy as noted by the lowest A_{rms} compared to the two competitive devices. Nonin's PureSAT



motion and low perfusion tolerant SpO₂ technology detects the true pulse in challenging conditions such as motion and low perfusion. To determine the most reliable part of the pulse signal, advanced decision algorithms are used for computing SpO₂ saturation that is not affected by typical patient motion or interference. Unlike other technologies, PureSAT's proprietary, next-generation signal processing does not sacrifice accuracy, response time, power, or size in order to achieve motion/low perfusion tolerance.

With PureSAT, the accuracy of Nonin WristOx was consistent throughout the range of oxygenation levels with no signs of deterioration in lower ranges of oxygenation. Conversely, the accuracy of both competitors decreased at values less than 90%. Overall, Nonin WristOx A_{rms} was 1.7, which equates to accuracy within plus or minus two digits (±2) of the observed value while the competitors were only accurate to plus or minus four digits (±4). (Figure 2)

Figure 2



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