

# SpO<sub>2</sub> Accuracy of PureSAT<sup>®</sup> Signal Processing Technology – The ONYX<sup>®</sup> II

## Summary

A study comparing the accuracy of NONIN PureSAT<sup>®</sup> Signal Processing Technology to the gold standard of co-oximetry was conducted in January of 2005 at the University of California at San Francisco (UCSF) Hypoxia Research Laboratory. The ONYX<sup>®</sup> II pulse oximeter was used for all testing. Data was obtained from human subjects by using an induced hypoxia protocol that recorded saturation levels between 64% and 100% SpO<sub>2</sub>. Results of the testing showed outstanding correlation of the new ONYX II SpO<sub>2</sub> data as compared to the co-oximeter. Accuracy was calculated to be 1.31 A<sub>rms</sub>. ONYX II specifications are labeled as ± 2 (%SpO<sub>2</sub> A<sub>rms</sub>) 70-100%. Accuracy below 70% is not specified.

## About the Study

The study was conducted using the lab's standard protocol of rapid desaturation in healthy, non-smoking, consenting adult subjects at the University of California at San Francisco (UCSF) Hypoxia Research Laboratory. A pool of seven males and five females with skin tones ranging from light to dark were included in the study. Each subject was placed in a semi-supine position and allowed to breathe through a mouthpiece while the nose was blocked with a nose clip. Hypoxia was induced by having subjects breathe mixtures of nitrogen, room air and carbon dioxide, with each desaturation level held at a stable plateau. Each experiment consisted of two runs of five plateaus of oxyhemoglobin saturation between 64% and 100%. The level of oxyhemoglobin saturation was maintained at each plateau until the pulse oximeter readings stabilized and arterial blood samples were obtained. Two blood draws from an arterial cannula were taken sequentially during a stable plateau and analyzed by co-oximeter, the "gold standard" for measuring oxygen saturation. The Radiometer OSM-3 multi-wavelength co-oximeter was used for this study. Inspired O<sub>2</sub> concentration was adjusted breath-by-breath using a computed saturation based on end-tidal PO<sub>2</sub> and PCO<sub>2</sub> as sampled by a mass spectrometer. SpO<sub>2</sub> and pulse rate data were recorded every second using a laptop computer.

## Analysis and Definitions

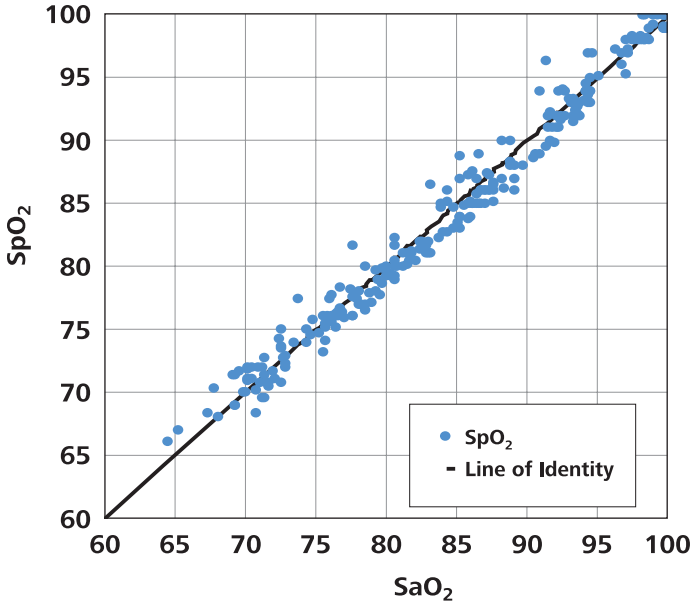
The measurement of accuracy is presented as the A<sub>rms</sub> value, and was calculated according to the requirements of the ISO 9919:2005(E) Clause 50 Accuracy of operating data.

**A<sub>rms</sub>** – Accuracy of the pulse oximeter is stated in terms of the root-mean-square (rms) difference between measured SpO<sub>2</sub> values and co-oximetry (SaO<sub>2</sub>) reference values. The A<sub>rms</sub> calculation incorporates error due to the bias and imprecision (standard deviation). This is the current method generally accepted by the Food and Drug Administration and other regulatory authorities for the representation of accuracy data.

**N(n)** – The number of samples used to calculate the mean bias, standard deviation and A<sub>rms</sub> value.

## Results

### SpO<sub>2</sub> Accuracy

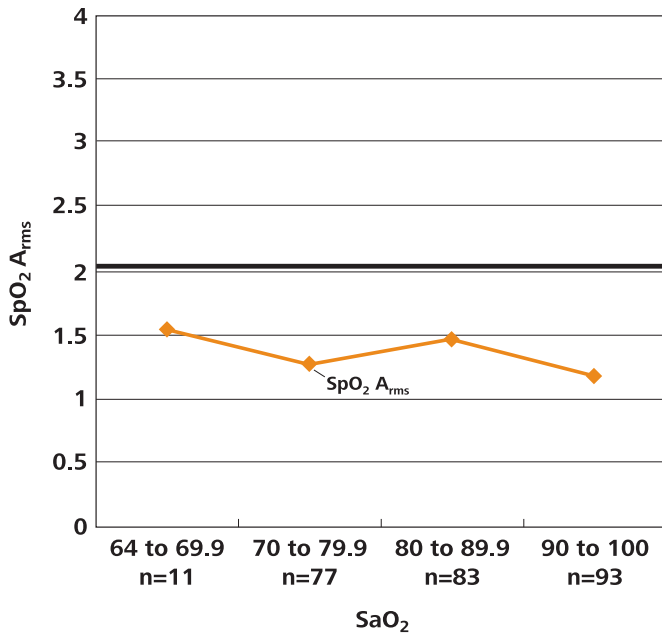


<b>NONIN ONYX II*</b>	
253	Samples (70-100% SaO <sub>2</sub> range)
<b>1.31</b>	<b>%SpO<sub>2</sub> A<sub>rms</sub> (70-100% SaO<sub>2</sub> range)</b>

The blue dots are the SpO<sub>2</sub> values of the ONYX II pulse oximeter plotted against the SaO<sub>2</sub> value of the co-oximeter. Note how tightly the data points align with the dark line, representing a consistent and tight correlation of the ONYX II to the “gold standard” of co-oximetry.

\*Accuracy specified as ±2 (%SpO<sub>2</sub> A<sub>rms</sub>) 70-100%. Accuracy below 70% is not specified.

### SpO<sub>2</sub> Accuracy



<b>NONIN ONYX II**</b>		
<b>%SpO<sub>2</sub> A<sub>rms</sub> = Pulse Oximeter Accuracy</b>		
<b>%SaO<sub>2</sub></b>	<b>%SpO<sub>2</sub> A<sub>rms</sub></b>	<b>Samples</b>
90 to 100	1.18	93
80 to 89.9	1.46	83
70 to 79.9	1.27	77
64 to 69.9	1.54	11

The accuracy of the ONYX II is plotted to show consistency in performance regardless of saturation level. The ONYX II ensures consistent accuracy across the range.

\*\*Results from clinical study on adult human subjects using induced hypoxia protocol. Accuracy below 70% is not specified.