Comparative Accuracy Testing of Nonin PureSAT® Signal Processing Technology

Summary

A study comparing the Nonin Pulse Oximeter Signal Processing Technology to two leading pulse oximeter manufacturers was conducted at the UCSF Hypoxia Research lab in November of 2003. SpO_2 accuracy data was obtained for the Nonin Xpod® pulse oximeter, and the latest models of two leading pulse oximeter manufacturers. Results of the testing showed that Nonin demonstrated the best overall accuracy in terms of Root Mean Squared (RMS). For both male and female subjects with low perfusion index values, the Nonin product was again more accurate. In the lower saturation ranges, the Nonin product had the smallest standard deviation, and showed less variability from the co-oximeter results than the other two products tested.

About the Study

The study involved rapid arterial oxygen desaturation in healthy consenting volunteers at the UCSF – Hypoxia Research Laboratory. The study consisted of eight male and two female non-smoking subjects between the ages of 20 and 30, with skin tones ranging from light to dark. Each subject was placed in a semi-supine position and allowed to breathe through a mouthpiece while the nose was blocked by a nose-clip. Subject hands were kept warm with heating pads. Arterial catheters were placed in the left radial artery under local anesthesia. Hypoxia was induced to several levels of oxyhemoglobin saturation (between 65–100%) by having subjects breathe mixtures of nitrogen, room air, and carbon dioxide, with each level held at a stable plateau for approximately two minutes. Inspired O_2 concentration was adjusted breath-by-breath using a computed saturation based on end-tidal PO_2 and PCO_2, as sampled by a mass spectrometer. The level of oxyhemoglobin saturation was maintained at each plateau to allow pulse oximeter readings to stabilize. Two blood draws were taken in a one-minute period at each plateau. The blood draws were analyzed by a Radiometer OSM-3 multi-wavelength co-oximeter and the SaO_2 co-oximeter readings were recorded. After two cycles with several levels of desaturation, a total of 18 to 20 SaO_2 readings plus two control (room air) SaO_2 readings were obtained for each subject. SpO_2 and Pulse Rate (PR) Data were collected from the oximeters at a rate of once per second.

Systems Tested

The system labeled #1 is the Nonin Xpod oximeter, which was tested using the Nonin 8000AA clip reusable sensor. Systems labeled as #2 and #3 were tabletop oximeters from two leading manufacturers. Sensors used for testing were the respective proprietary reusable clip sensors, and all oximeters were tested using their default settings.

Results

A total of 201 sample blood draws in the range of 65% to 100% SaO_2, were used to compare the SpO_2 values from three oximeter systems with the co-oximeter SaO_2 value. Of the 201 samples, 161 were from a male population and 40 from a female population.

- 10 were below 70% SaO_2
- 71 were between 70% and 80% SaO_2
- 71 were between 80% and 90% SaO_2
- 49 were between 90% to 100% SaO_2

The SpO_2 value is determined by calculating the average of three readings starting from the end of each blood draw. The mean difference, standard deviation difference, and accuracy in terms of RMS were computed based on 201 comparisons between the SpO_2 and SaO_2.

The RMS = $\sqrt{MEAN^2 + S.D.^2}$.

As indicated in Table 1, the overall results of this study show the Nonin product to be the most accurate product based on RMS.

Accuracy – 65% to 100% SaO_2:

	Xpod	#2	#3
Mean Diff	-1.03	1.07	1.54
StDev diff	1.57	2.42	1.82
RMS	**1.88**	**2.65**	**2.39**
n samples	201	201	201

Table 1

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Accuracy in ranges of SaO_2:

The accuracy in terms of RMS is computed for six different saturations levels. The results are summarized in Chart 1 and Table 2. The Nonin Xpod was superior in accuracy in four out of six ranges of SpO_2 values.

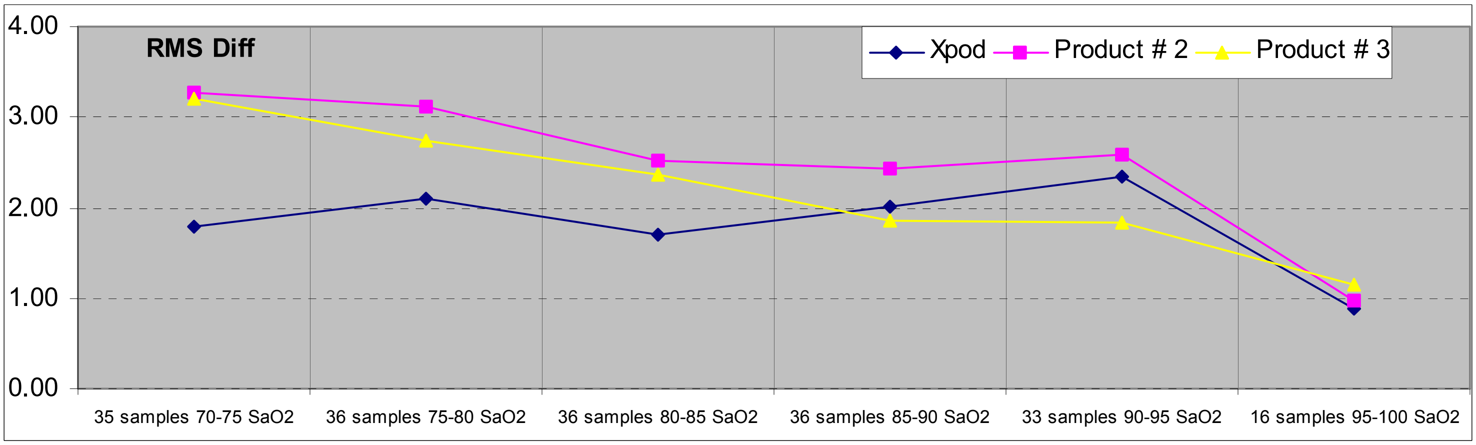

Chart 1

RMS	Xpod	#2	#3
35 samples 70-75 SaO2	1.78	3.28	3.21
36 samples 75-80 SaO2	2.11	3.12	2.74
36 samples 80-85 SaO2	1.70	2.52	2.37
36 samples 85-90 SaO2	2.01	2.44	1.85
33 samples 90-95 SaO2	2.34	2.58	1.83
16 samples 95-100 SaO2	0.87	0.98	1.15

Table 2

Accuracy with Low Perfusion Index

The accuracy was further evaluated on the subjects having the lowest perfusion index as indicated by product #2's perfusion index value. From the table below, the female subjects (#s 2 and 8) and two of the male subjects (#s 6 and 7) had the lowest perfusion index values, yet the Nonin system had the highest degree of accuracy as compared to the other two products.

In this study, the Nonin system was more accurate on both the male and female subjects having the lowest perfusion index values.

			Xpod	**Product #2**	**Product #3**	Product #2
subject	Sex	samples	**Accuracy (RMS)**	**Accuracy (RMS)**	**Accuracy (RMS)**	Perf Index %
1	M	20	**2.09**	**0.57**	**1.08**	8.58
2	F	20	**1.40**	**1.95**	**1.75**	0.79
3	M	19	**1.38**	**1.19**	**2.81**	4.99
4	M	22	**1.66**	**0.45**	**1.68**	4.99
5	M	22	**2.41**	**1.81**	**1.01**	6.68
6	M	14	**0.61**	**2.86**	**3.1**	2.85
7	M	20	**1.75**	**6.54**	**4.35**	1.3
8	F	20	**1.31**	**3.00**	**2.56**	0.81
9	M	22	**2.68**	**1.46**	**1.61**	3.61
10	M	22	**1.73**	**1.10**	**2.25**	3.76

Table 3

SpO_2 Correlation with SaO_2

The following page shows results of the correlation of the SpO_2 data with the SaO_2 "gold standard" of co-oximetry. In appendix A, charts 2-4 demonstrate the extremely tight correlation for the entire 100-70% range with the Nonin Xpod. The Nonin technology consistently reported values closer to those of the co-oximeter than either product #2 or product #3.

SpO_2 Variability of Standard Deviation Within SpO_2 ranges

Charts 5-10 of Appendix A illustrate that in the normal range of 95-100% the products were consistent with each other. However, in the ranges from 90% SpO_2 and below, where a patient may require an intervention, the Nonin Xpod outperformed the other two systems. Overall, the Xpod had the greatest agreement with the co-oximeter SaO_2 values.

Appendix A Charts 2-4 show plots of the SaO_2 vs. SpO_2 for each of the three systems.

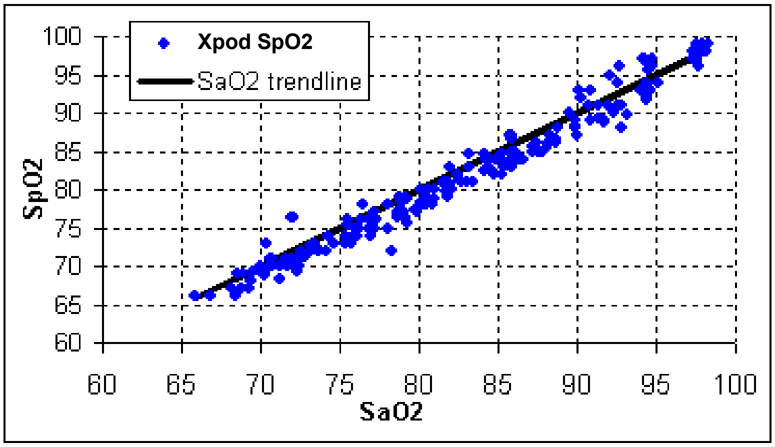

Chart 2

Xpod	
201	samples
-1.03	mean diff
1.57	stdev diff
1.88	**RMS**

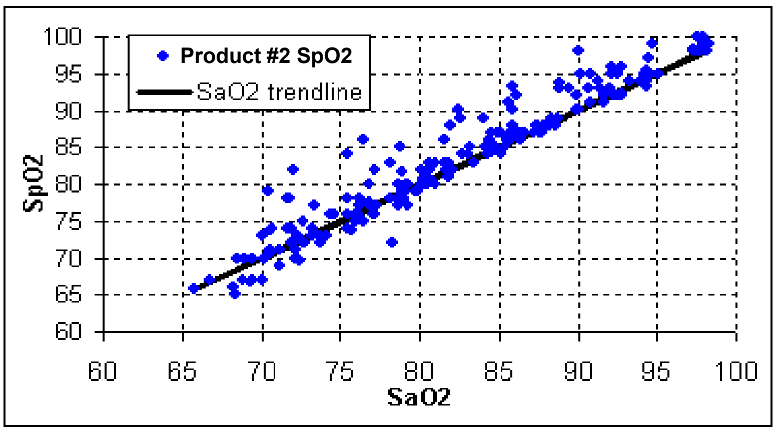

Chart 3

Product #2	
201	samples
1.07	mean diff
2.42	stdev diff
2.65	**RMS**

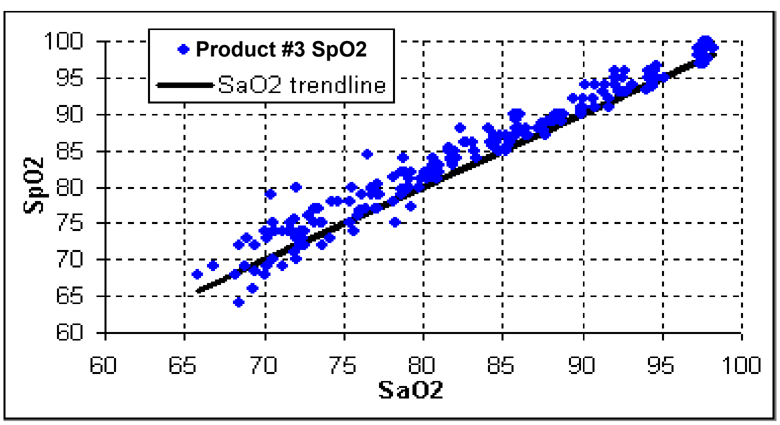

Chart 4

Product #3	
201	samples
1.54	mean diff
1.82	stdev diff
2.39	**RMS**

Appendix A (cont) Charts 5–10 show the mean difference from SpO_2–SaO_2 and ±Standard Deviation for six different saturation levels

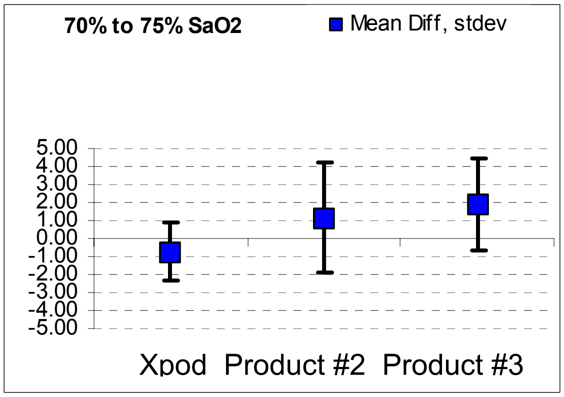

Chart 5

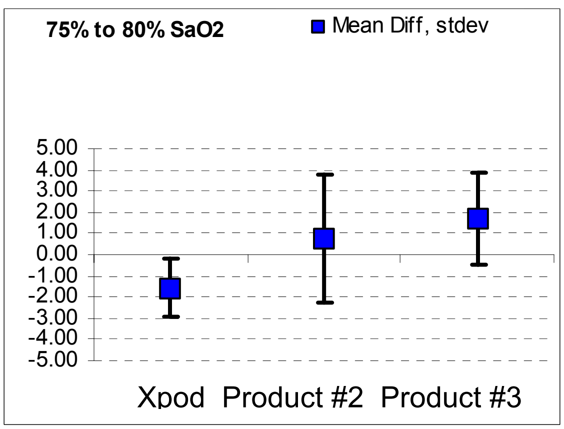

Chart 6

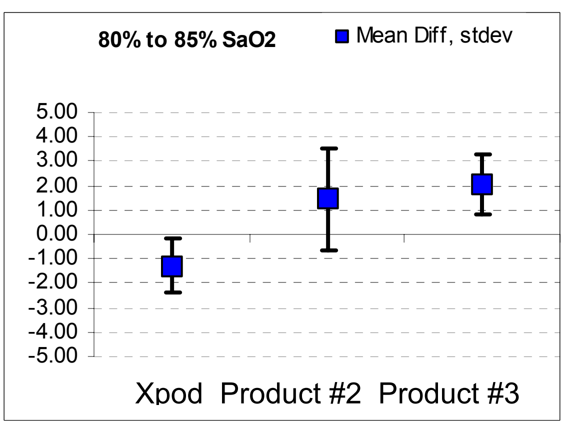

Chart 7

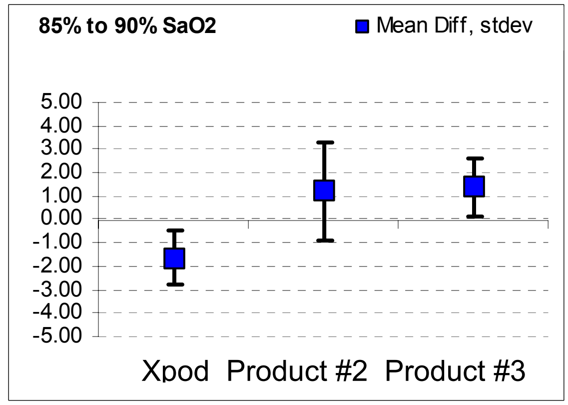

Chart 8

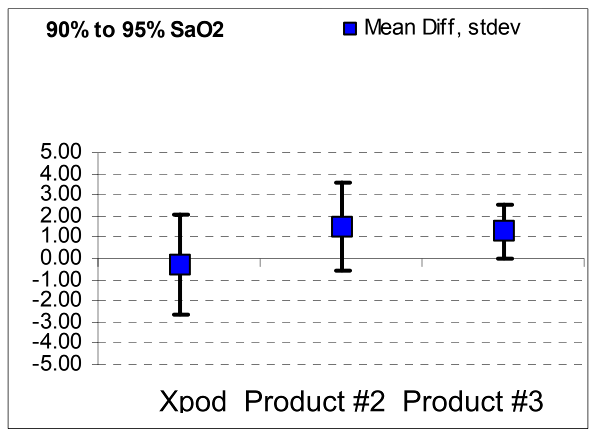

Chart 9

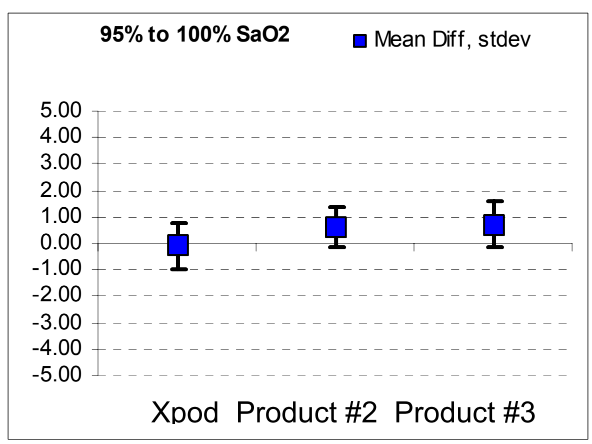

Chart 10

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