

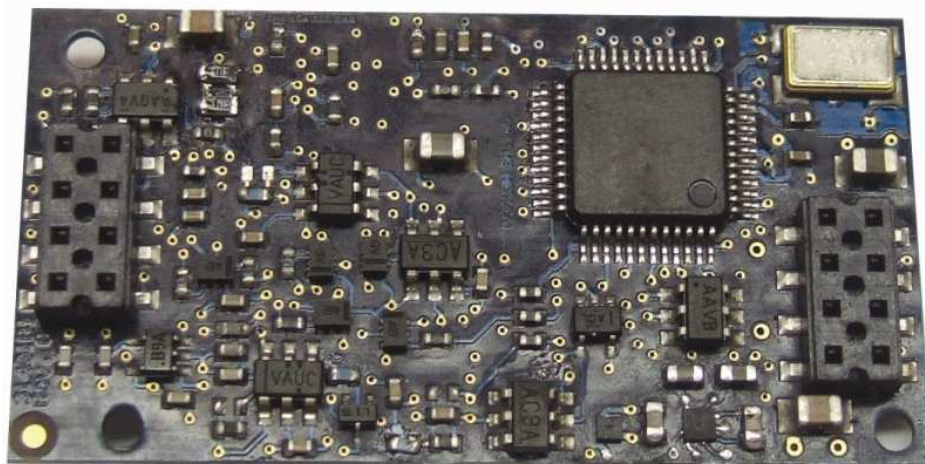
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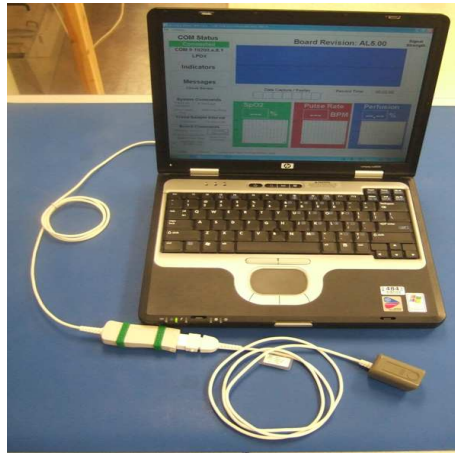
BCI[®] OEM Technologies

**Digital Micro Power Board
SpO₂ Accuracy Validation**



SpO₂ Accuracy Validation Protocol

BCI[®] Digital Micro Power board has been clinically validated using the OxiLink™ III USB connected to a PC running as a Pulse Oximeter in an industry standard breathe-down protocol.



OxiLink™ III with Digital Micro Power Board connected to PC

Validation was conducted in a breathe-down protocol at the Milwaukee VA Hospital, Anesthesia Research Service (Philip Clifford, PhD, Principal Investigator). SpO₂ values that were collected by the OxiLink™ III with the Digital Micro Power board connected to the PC were compared against SaO₂ values from arterial blood samples assayed on a gold-standard Radiometer OSM-3 Co-oximeter. Scientific accuracy was demonstrated by statistically comparing the Digital Micro Power board SpO₂ values to functional SaO₂ values. Volunteers participated in the breathe-down protocols at rest (i.e. no motion) while fully conscious at SaO₂ values ranging from 70-100%.



OSM3 Radiometer Cooximeter (front) and reference blood gas analyzer (rear).

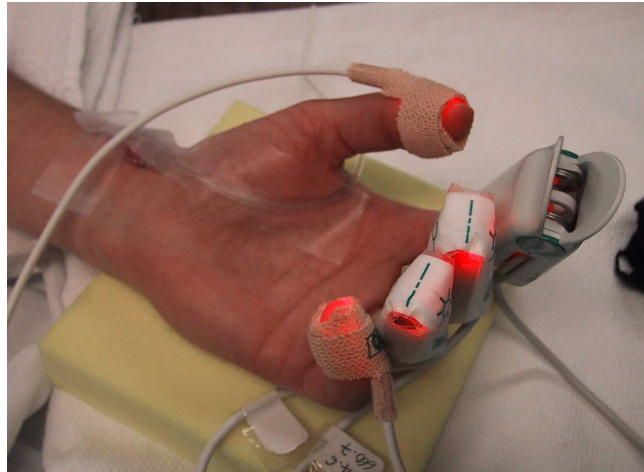
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Volunteers were recruited to the breathe-down protocol based upon Milwaukee VA IRB rules and regulations. Informed consent was obtained from each volunteer prior to study commencement. A radial arterial line was placed into the volunteer's wrist for blood sampling. BCI[®] sensors were placed on the same-side or opposite-side hand as the radial arterial line.



BCI[®] Sensor placed on Fingers

Ambient light covers were placed over the sensors to prevent sensor-to-sensor cross talk.



Black-Felt Ambient Light Covers

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A non-rebreathing system attached to an Oxygen ('O₂') / Nitrogen ('N₂') / Air gas delivery apparatus provided the hypoxic gas mixture to the volunteer, via a facemask held in place by a fabric-elastic head cradle. If the volunteer felt uncomfortable at any time during the protocol, the facemask was simply removed and the subject began breathing room-air again. Seven H-size tanks containing pre-mixed gases were connected to a custom gas manifold, terminating at the facemask through which the volunteer inspired.

Gas tanks were prepared by a certified gas mixing and filling facility, to contain O₂ / N₂ / Air mixtures. Room-air (FiO₂ 0.21) was used to collect room-air SaO₂ values, and to resaturate the volunteers following hypoxic sequences. Pure O₂ was delivered to provide SaO₂ values above those collected at room-air, and to occasionally resaturate volunteers after hypoxic episodes. The inspired gases were varied to provide SaO₂ values from 100% → 70%, as clinically tolerated by each volunteer subject.

The IRB-approved breathe-down protocol allowed 22 blood samples to be drawn per subject. During 22 one to three minute steady-state periods at desired SaO₂ plateaus, a radial arterial blood specimen was withdrawn from the subject and analyzed by CO-oximetry. Generally, a two-step breathe-down method was utilized, which involved the lowering of SaO₂ gradually, desaturating by titrating various FiO₂ gas mixtures, during which blood samples were drawn when SaO₂ plateaus were observed. Functional SpO₂ vs. Functional SaO₂ samples were analyzed from each volunteer subject.



Applying sensors to subject

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BCI[®] Micro Power Board SpO₂ Accuracy Validation

Bland-Altman Statistical Analysis is used to demonstrate accuracy through the calculation of Arms (SpO₂ Accuracy [root mean square]), Bias and Precision values. Arms is calculated using the following equation which is the difference between measured values (SpO_{2i}) and the reference values (S_{Ri}).

$$A_{rms} = \sqrt{\frac{\sum_{i=1}^n (SpO_{2i} - S_{Ri})^2}{n}}$$

The BCI[®] Digital Micro Power board Pulse Oximeter SpO₂ Arms values are compared against the design specification requirements. All data is analyzed using Microsoft Excel Spreadsheet Software. A representative Histogram is shown in the following appendix displaying the number of data points collected at various SaO₂ saturations. Bland-Altman Plots are also shown in following appendix comparing gold standard SaO₂ values on the x-axis to (SaO₂ – SpO₂) values on the y-axis.

What Was Validated

The following BCI[®] Sensor were tested during this SpO₂ accuracy validation with the BCI[®] Digital Micro Power Board.

- BCI[®] 3044 Adult Reusable Finger Sensor
- BCI[®] 1300 Adult Disposable Sensor
- BCI[®] 3178 Pediatric Reusable Finger Sensor

Results Summary

Sensor	Bias	Arms
BCI [®] 3044 Adult Reusable Finger Sensor	-0.31	1.30
BCI [®] 1300 Adult Disposable Sensor	-0.19	1.33
BCI [®] 3178 Pediatric Reusable Finger Sensor	0.03	1.50

The specification for the BCI[®] Digital Micro Power Board SpO₂ Accuracy is to be under ± 2.00 Arms. As seen from the above summary, the sensors that were used in the validation show that the accuracy specifications of the BCI[®] Digital Micro Power Board with the above sensors fall within the required design specifications.

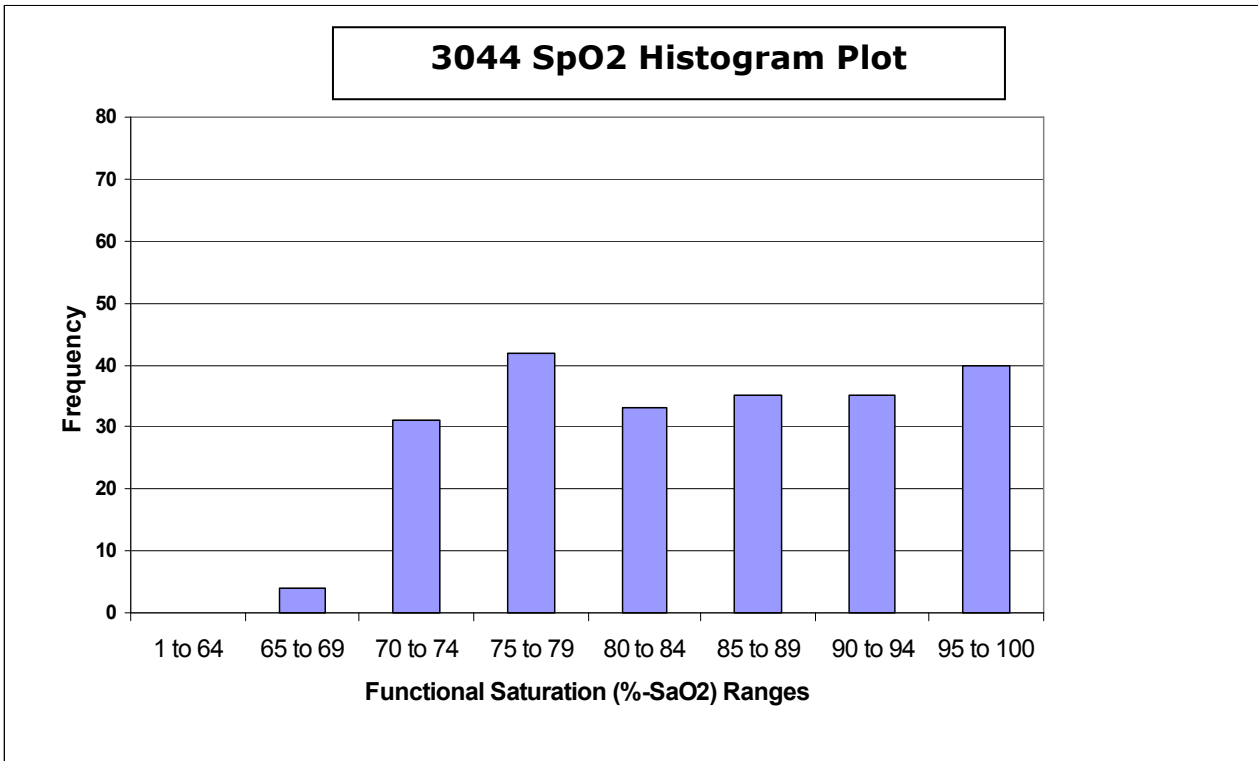
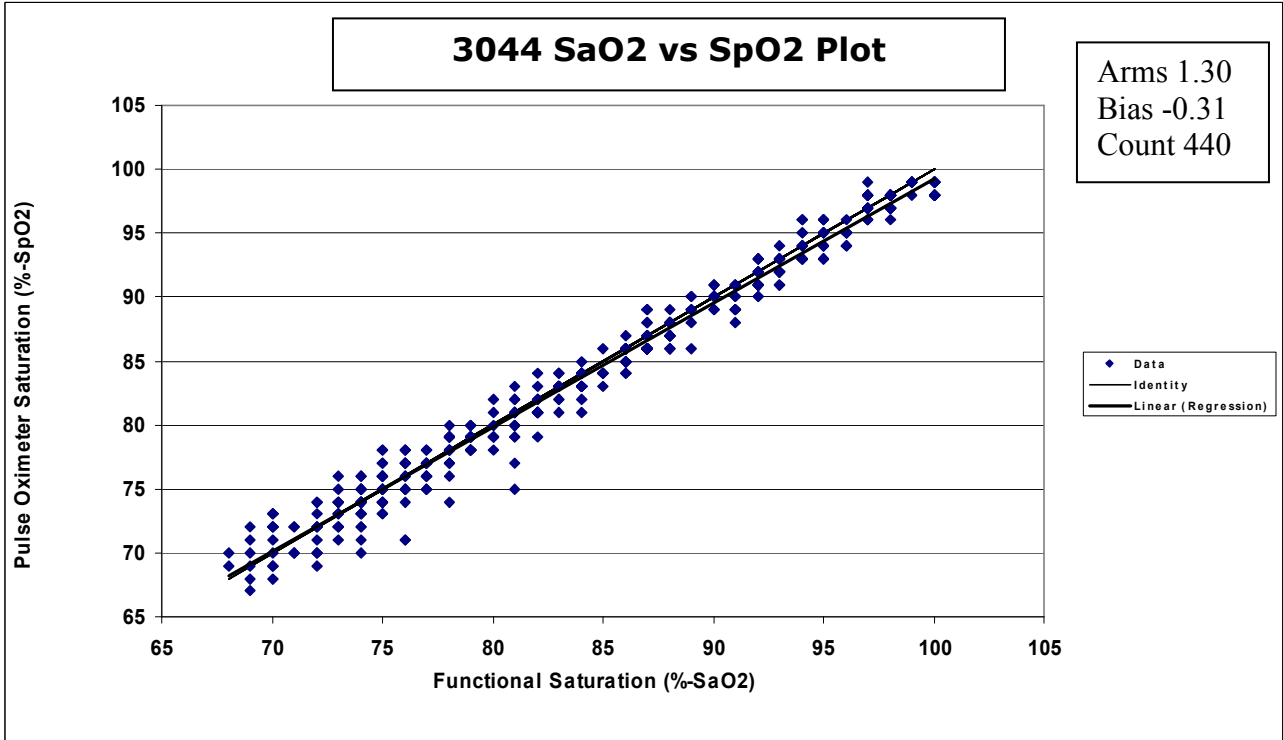
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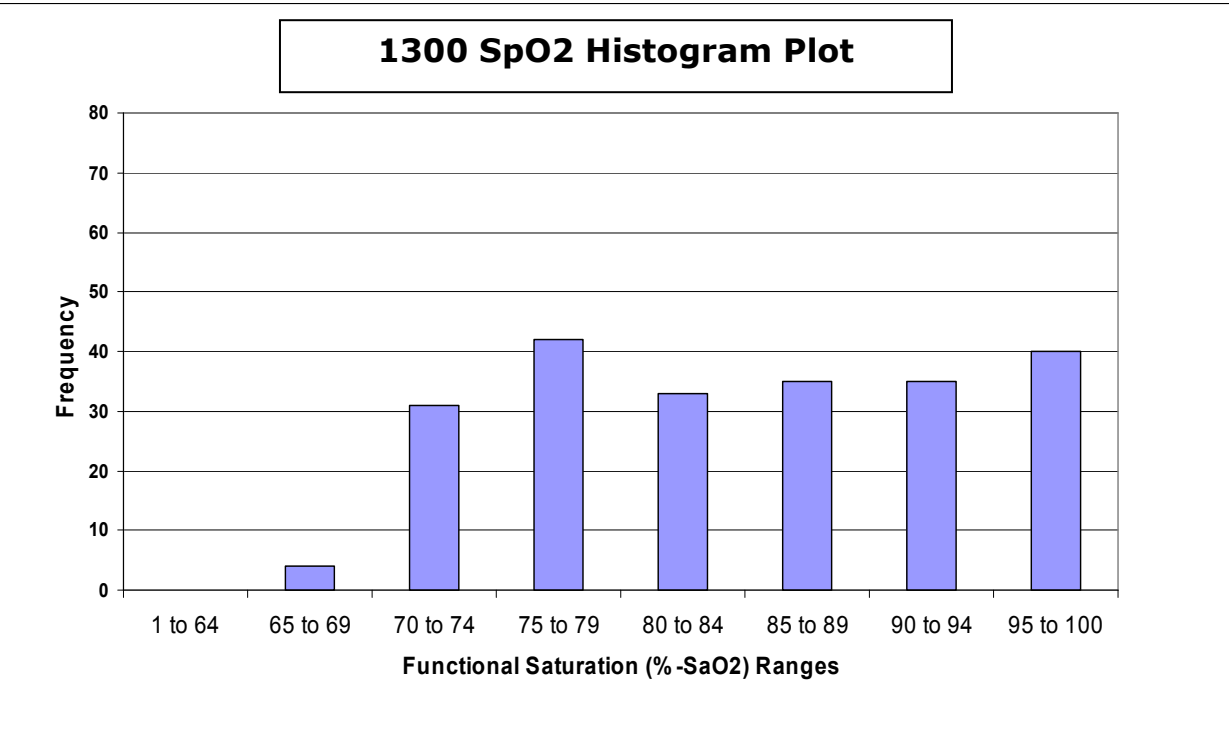
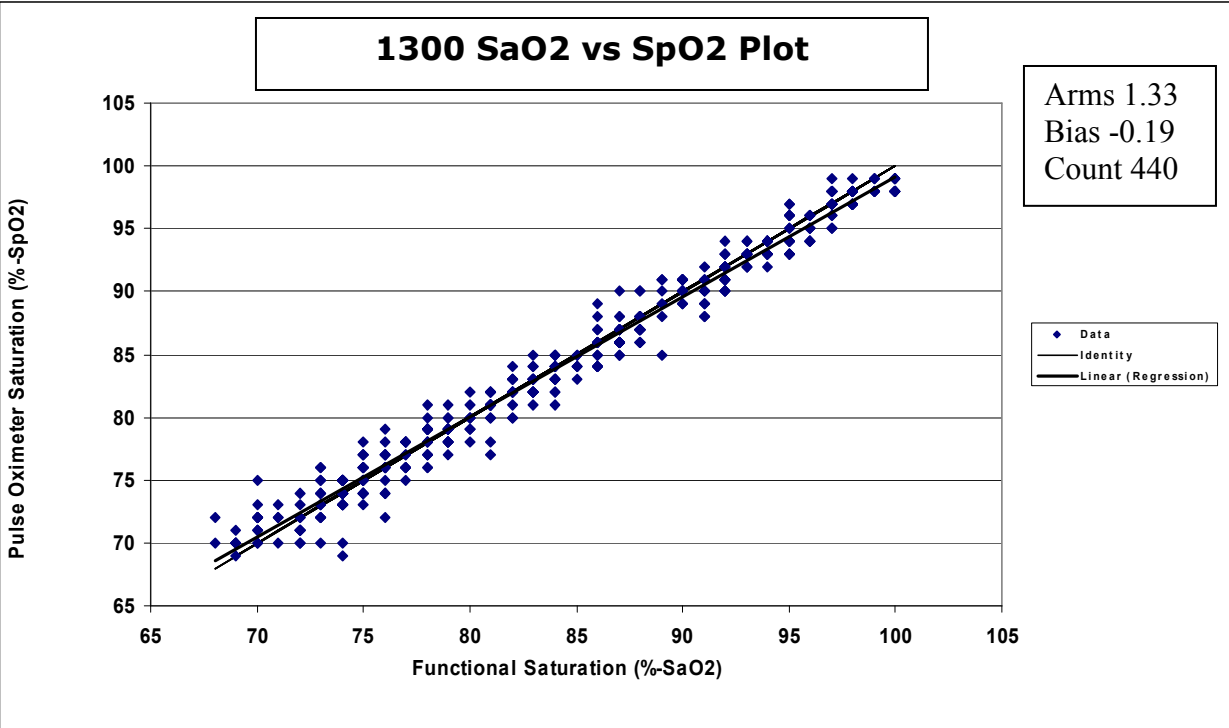
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Smiths Medical Digital Micro Power Board SpO2 Accuracy Validation

Appendix A



Smiths Medical Digital Micro Power Board SpO2 Accuracy Validation



Smiths Medical Digital Micro Power Board SpO2 Accuracy Validation

