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FORE-SIGHT
Clinical Summary

# Testing a new NIRS method to measure regional mesenteric tissue oxygen saturation in preterm infants that compensates for meconium and transitional stool interference.

Said M, Niforatos N, Rais-Bahrami K. *J Neonatal Perinatal Med.* 2012; 5(1): 9-16.

## Introduction

NIRS is becoming more popular to measure abdominal oxygenation; however few data exist outside of cerebral validations. One reason for the increasing demand is the desire to measure bowel ischemia as a potential precursor to NEC (necrotizing enterocolitis) occurring in 7-10% of preterm babies less than 1500g. Traditional NIRS algorithms have shown wide variability when used on newborns' abdomens, often displaying the lowest saturation possible. Laboratory data has shown meconium interferes with NIRS measurement and gives false values. The aim of this study is to understand the limitations in traditional NIRS monitoring and test a prototype stool-compensating algorithm to start determining accurate abdominal tissue oxygen saturation ($StO_2$).

## Methods

Twenty-three neonates [26-34 weeks GA (gestational age), 740-1930 g] with prematurity and respiratory distress syndrome were enrolled. The subjects were monitored for cerebral and abdominal $StO_2$ using small FORE-SIGHT sensors (CASMED, Branford, CT), along with $SpO_2$. The level of interference with the traditional algorithm was broadly quantified into four categories: low, moderate, high, and very high. A new stool-compensating algorithm was then tested to see if this interference could be compensated for and if the new abdominal $StO_2$ correlated with cerebral $StO_2$ and $SpO_2$.

## Results

Considerable abdominal $StO_2$ variability was seen in patients, with higher interference in patients at younger gestational age. Patients passing meconium stools (n=9) had a greater frequency of high interference while patients passing transitional stools (n=14) had occasions with high interference. When using the traditional algorithm, all meconium subjects and 64% of transitional stool subjects had abdominal $StO_2$ of 0% at some time point. When using the new algorithm, no patient had $StO_2$ lower than 21%.

Since patients had mostly healthy GI (gastrointestinal) tracts, abdominal $StO_2$ was expected to have some correlation with both cerebral $StO_2$ and $SpO_2$. The correlation with cerebral $StO_2$ and $SpO_2$ increased approximately 3-fold in meconium subjects and 2-fold in transitional stool subjects when applying the new stool-compensating algorithm over the traditional algorithm.

## Authors' Discussion and Conclusions

While most of the abdominal $StO_2$ measurements were taken over the subject's GI tract, a spot check of $StO_2$ over subjects' liver and flank areas revealed there was still stool interference, which was lower than GI, but more pronounced in younger GA subjects. This interference would likely be more problematic in sensors with a 40 mm optode separation.

Traditional NIRS algorithms may not perform well when used on the abdomen of neonates. The effects of an unknown chromophore in both meconium and transitional stools need to be resolved to accurately measure abdominal $StO_2$. This new algorithm shows promise and may be able to help establish a normal range for abdominal $StO_2$ in neonates.

**NOTE:** This summary was created by CAS Medical Systems Inc. Any views expressed above are those of CASMED and do not necessarily reflect those of the authors or publications referenced.

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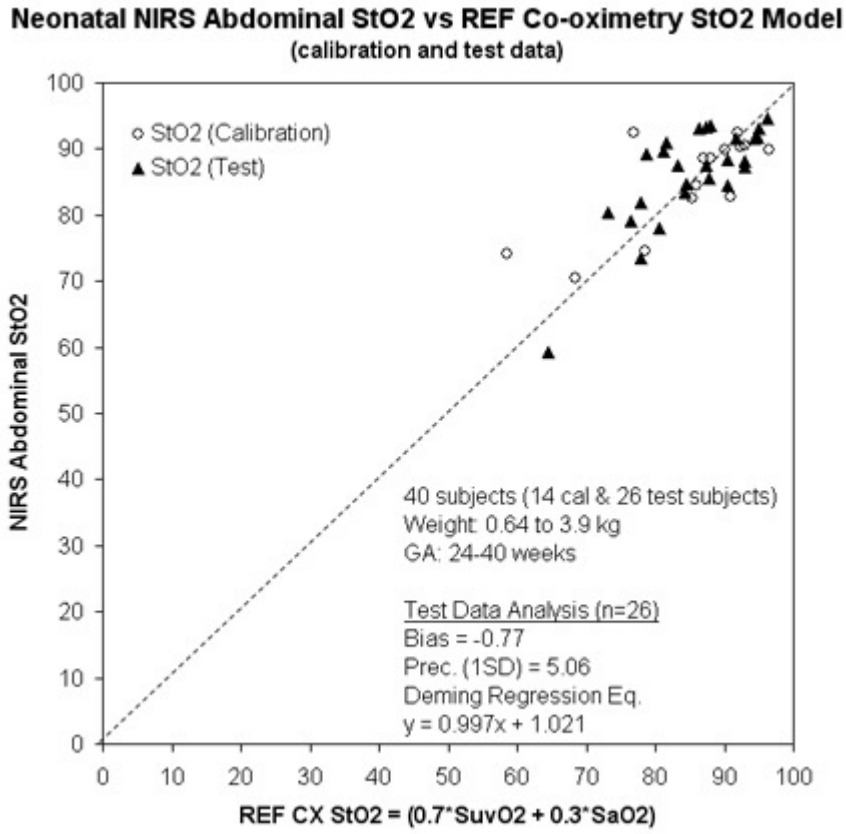
**[1534.582] NIRS Abdominal Somatic Tissue Oxygen Saturation Validation Model for Neonates ≤ 4kg**

***Mariam M. Said, Nickie Niforatos, Khodayar Rais-Bahrami. Neonatology, Children's National Medical Center, Washington, DC; The George Washington University School of Medicine, Washington, DC.***

BACKGROUND: Near infrared spectroscopy (NIRS) is used in the measurement of cerebral and somatic tissue oxygenation ($StO_2$). Traditional NIRS algorithms have been primarily designed in the measurement of cerebral StO2, however, no formal validation studies exist for measurement of somatic $StO_2$.
OBJECTIVE: In this study, we present a method to validate a novel stool compensating somatic NIRS algorithm to measure abdominal tissue oxygen saturation ($StO_2$) in neonates ≤ 4 kg, using weighted umbilical venous and arterial oxygen saturation as a reference model.
DESIGN/METHODS: With parental agreement we enrolled neonates with an umbilical venous catheter (UVC) positioned in the inferior vena cava (IVC) to validate a NIRS tissue oximeter (FORE-SIGHT®, CAS Medical Systems, Branford, CT USA) to measure abdominal $StO_2$. A sensor was placed over left & right flank, liver, and intestine in three positions (infraumbilical, RLQ, LLQ) for a period of 2 minutes each. The $StO_2$ measurements from the six abdominal positions were averaged together to determine a composite abdominal $StO_2$, which better reflects global IVC blood. The composite abdominal $StO_2$ value from each subject was compared with co-oximetry measured oxygen saturation obtained from UVC ($SuvO_2$) and pulse oximetry ($SaO_2$) to determine a Reference co-oximetry $StO_2$ value from the equation ($0.7*SuvO_2 + 0.3*SaO_2$).
RESULTS: Data was obtained from 40 subjects weighing 0.64-3.9 kg, 1-13 days old, and GA of 24-40 weeks. Figure 1 illustrates a scatterplot of the composite NIRS abdominal StO2 vs Reference $StO_2$ with both monitor calibration data (n=14) and test data (n=26). The test data showed an overall bias ± precision (1sd) of -0.77 ± 5.06%. For the test data, the concordance correlation coefficient (CCC) was 0.789 demonstrating strong correlation.




CONCLUSIONS: This validation model demonstrates that the FORE-SIGHT new somatic algorithm, which compensates for the optical properties of stools, can be applied to abdominal tissue in order to yield accurate measures of abdominal $StO_2$.

E-PAS2012:1534.582

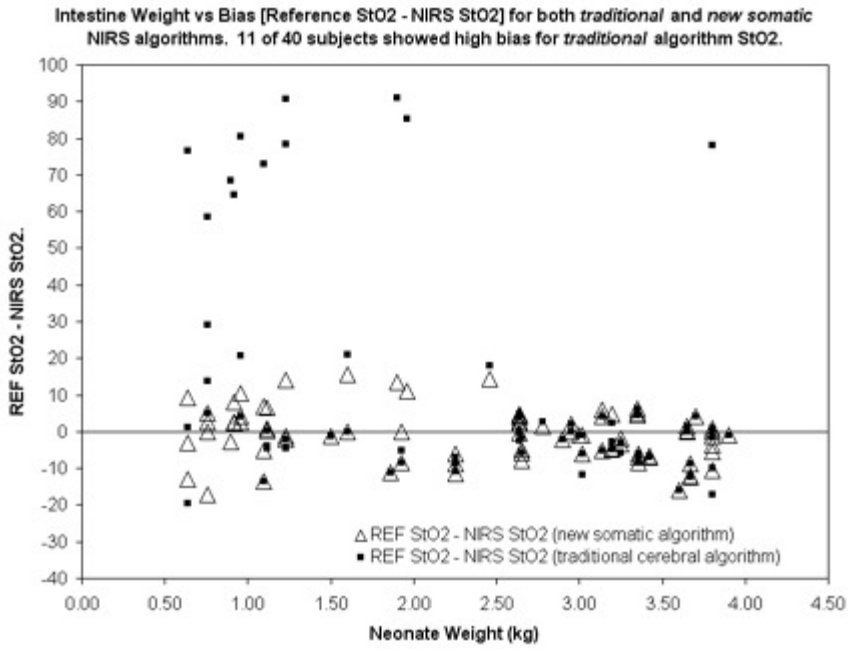
**Session:** Poster Session: Neonatology - General (1:00 PM - 4:00 PM)
**Date/Time:** Saturday, April 28, 2012 - 1:00 PM
**Room:** Exhibit Halls A/B - Hynes Convention Center
**Board:** 582
**Course Code:** 1534

Close Window

**[1534.581] Comparison of NIRS Traditional Vs Stool Compensating Somatic Algorithms When Measuring Abdominal Tissue Oxygen Saturation on Neonates ≤ 4kg**

***Mariam M. Said, Nickie Niforatos, Khodayar Rais-Bahrami. Children's National Medical Center, Washington, DC; The George Washington University School of Medicine, Washington, DC.***

BACKGROUND: Near-infrared spectroscopy (NIRS) has been used to measure cerebral and somatic tissue oxygen saturation ($StO_2$), however, traditional NIRS algorithms have been primarily designed in the measurement of cerebral $StO_2$.
OBJECTIVE: In this study, we compared a novel stool compensating somatic NIRS algorithm vs a traditional NIRS algorithm to measure abdominal $StO_2$ in neonates ≤ 4 kg, using weighted umbilical venous and arterial oxygen saturation as a reference.
DESIGN/METHODS: With parental agreement we enrolled neonates with an umbilical venous catheter (UVC) in this prospective study using a NIRS oximeter (FORE-SIGHT®, CAS Medical Systems, Branford, CT USA). NIRS $StO_2$ values from both algorithms were compared with co-oximetry measured oxygen saturation obtained from UVC ($SuvO_2$) and pulse oximetry ($SaO_2$) to determine a Reference $StO_2$ value from the equation ($0.7*SuvO_2 + 0.3*SaO_2$). A sensor was placed over left & right flank, liver, and intestine in three positions (infraumbilical, RLQ, LLQ) for a period of 2 minutes each.
RESULTS: Data was obtained from 40 subjects weighing 0.64-3.9 kg, 1-13 days old, and GA of 24-40 weeks. Figure 1 illustrates the difference between the Reference $StO_2$ and NIRS $StO_2$ measured over the intestine as a function of subject weight. The *new somatic* algorithm $StO_2$ correlated more closely with the Reference $StO_2$, as compared with the *traditional* algorithm $StO_2$, which showed a high bias for 11/40 subjects, indicating stool interference. Additionally, smaller subjects (lower BW & GA) tended to have lower *traditional* algorithm $StO_2$ values when compared to Reference $StO_2$. Among organ systems, the intestine had the highest degree of stool interference, followed by the liver, and least interference in the flank measurements.




CONCLUSIONS: Data from this study suggest that the FORE-SIGHT new somatic algorithm, which compensates for the optical properties of stool, can be applied to abdominal tissue in order to yield accurate measures of abdominal $StO_2$.

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# Method for Validating Abdominal NIRS with Presence of Meconium in Neonates < 4kg

*Paul B. Benni PhD[1], Robert J. Kopotic PhDh[1], Mariam M. Said MD[2], Nickie Niforatos MD[2], Khodayar Rais-Bahrami MD[2]*

[1]CAS Medical Systems, Branford, CT; [2]Children's National Medical Center and The George Washington University School of Medicine, Washington, D.C.

## BACKGROUND

Typically, near-infrared spectroscopy (NIRS) has been used to measure cerebral tissue oxygen saturation ($SctO_2$), where the means of validation is a composite of jugular bulb and arterial blood CO-oximetry specimens. Similar comparison rigor of somatic NIRS data to blood oximetry has not occurred to date.

## OBJECTIVE

In this study, we present methodology for validating abdominal tissue NIRS ($SctO_2$) in neonates <4 kg, using weighted functional oxygen saturation from umbilical venous blood and arterial oximetry as the reference. $StO_2$ values from over the left and right flank, liver, and intestine in three positions were evaluated by site as well as in aggregate against measures blood oxygen values. Additionally, we assessed the effects of a known source of abdominal NIRS interference, meconium and transitional stool.

## DESIGN/METHODS

With parental consent, neonates having an umbilical venous catheter positioned in the inferior vena cava (IVC) and pulse oximetry were studied with a NIRS tissue oximeter (FORE-SIGHT®, CAS Medical Systems, Branford, CT USA). NIRS sensors were placed over the left and right flank, as well as the liver, and three intestinal positions (infraumbilical, right lower-quadrant and left lower-quadrant), for a period of 2 minutes each. Abdominal $StO_2$ values derived with and without a meconium compensating algorithm (new somatic and traditional, respectively) were compared with simultaneous 70% venous weighted plus 30% arterial weighted oxygen saturation blood values. Functional oxygen saturation by CO-oximetry of umbilical venous blood ($SuvO_2$) and arterial blood oxygen saturation ($SaO_2$) by pulse oximetry were the source of reference $StO_2$ value: REF $StO_2$ = 0.7*$SuvO_2$ + 0.3*$SaO_2$.

## RESULTS

Data were obtained from 40 subjects weighing 0.64-3.9 kg, 1-13 days old, and GA of 24-40 weeks. Figure 1 illustrates a scatterplot of the composite NIRS abdominal $StO_2$ vs. REF $StO_2$ with both monitor calibration data (n=14) and test data (n=26). The test data showed an overall bias ± precision (1sd) of -0.77 ± 5.06%. For the test data, the concordance correlation coefficient (CCC) was 0.789 demonstrating strong correlation. Figure 2 illustrates the difference between the REF $StO_2$ and NIRS $StO_2$ measured over the intestine as a function of subject weight. The new somatic algorithm $StO_2$ correlated more closely with the REF $StO_2$, as compared with the traditional algorithm $StO_2$, which showed a high bias for 11/40 subjects, indicating stool interference. Additionally, smaller subjects (lower birth weight and gestational age) tended to have lower traditional algorithm $StO_2$ values when compared to REF $StO_2$. Among organ systems, the intestine had the highest degree of stool interference, followed by the liver and both flank measurements (Figures 3-8).

## CONCLUSION

This validation model demonstrates that the FORE-SIGHT absolute tissue oximeter can yield accurate abdominal $StO_2$ values. Data from this study suggest that the FORE-SIGHT new somatic algorithm, which compensates for the optical properties of stool, when applied to abdominal tissue yields greater accuracy performance for abdominal $StO_2$ values.

## REFERENCES

1. Fenik JC, Rais-Bahrami K. Neonatal cerebral oximetry monitoring during ECMO cannulation. *J Perinatol* 29(5):376-81.
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Figure 1

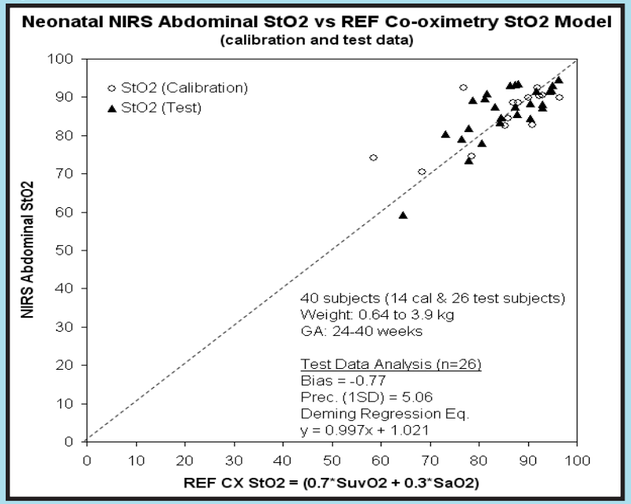



Figure 2

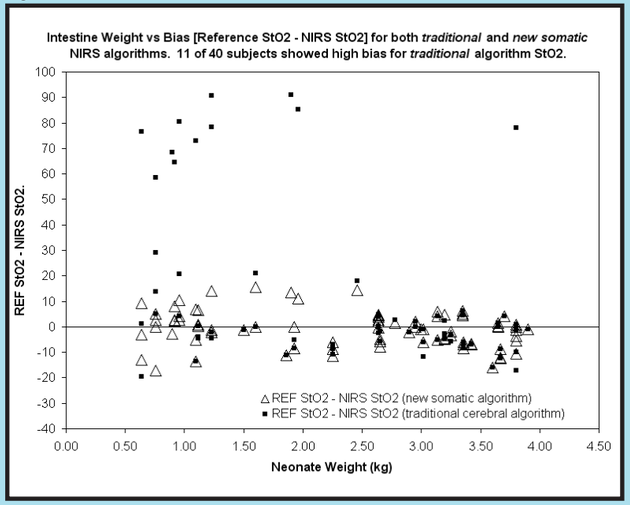



Figure 3

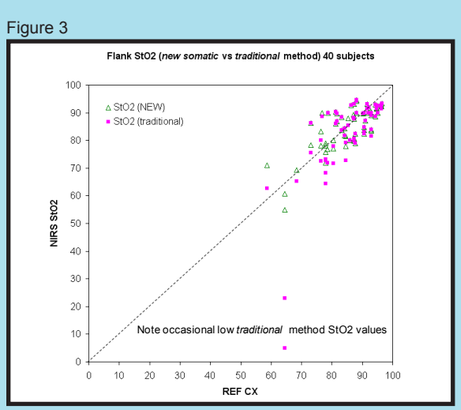



Figure 4

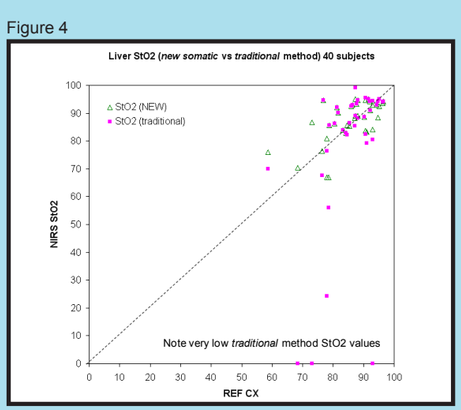



Figure 5

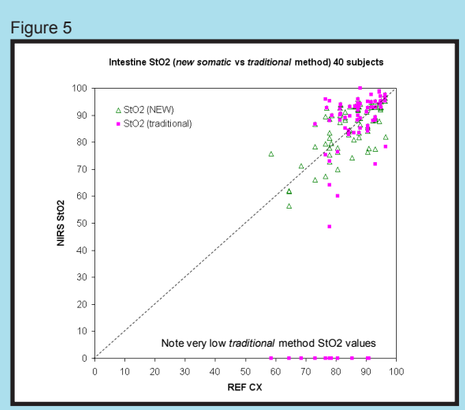



Figure 6

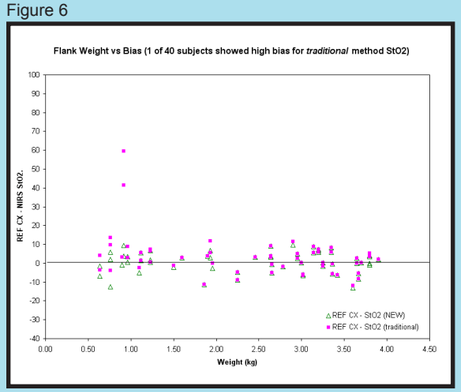



Figure 7

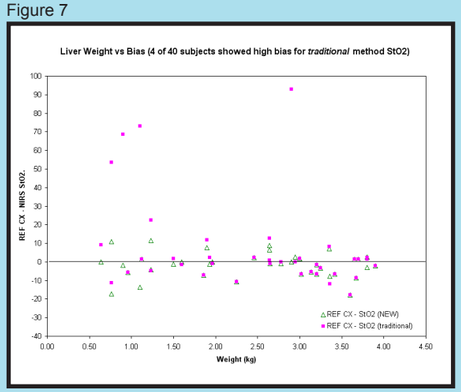
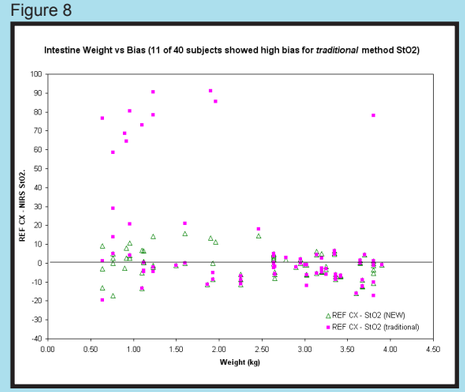



Figure 8



FORE-SIGHT®
Absolute Tissue Oximetry

# Direct Accuracy Performance Comparison of Cerebral Oximeter Devices

CASMED, Branford, CT

Highlighting data reported in: Bickler PE, Feiner JR, Eilers H, Rollins M. Performance of 5 cerebral oximeters during hypoxia in healthy volunteers. Proceedings of the 2011 Annual Meeting of the American Society of Anesthesiologists; Abstract LBT07.

**Background** Reported accuracy values of various cerebral oximeters are difficult to compare without identical patient cohorts and testing methodology.

**Objective** The purpose of this study is to measure the accuracy of commercially available cerebral oximeter monitors tested on identical subjects to eliminate selection bias and ensure uniform data analysis.

**Methods** Controlled oxygen desaturation sequences were performed on 23 healthy volunteer subjects of mixed gender and ethnicity. Values reported by four cerebral oxygenation monitors were compared against simultaneous invasive weighted CO-oximetry jugular bulb and arterial oxygen saturation reference measurements.

**Results** Precision for the cerebral oximeters tested ranged from 3.90% to 9.72% (1SD) and $A_{rms}$ accuracy from 4.26% to 9.69%.

**Conclusions** Performance among the tested monitors varied considerably. The FORE-SIGHT Oximeter demonstrated the greatest precision and accuracy.

## Introduction

An imbalance between cerebral oxygen supply and demand can lead to cerebral hypoxic/ischemic injury and has been reported across a wide spectrum of disorders. Lower levels of cerebral oxygenation have been associated with increased cognitive dysfunction, a higher incidence of major organ morbidity, worse outcomes, and extended hospital length of stay.[1] Difficulties in detecting cerebral ischemia as it occurs may cause missed opportunities to prevent or minimize permanent ischemic brain and other organ injury.[2]

Measurements of cerebral oxygenation are useful in assessing the balance between cerebral metabolic supply and demand. Direct invasive methods of measurement such as jugular venous oximetry and brain tissue oxygen tension are expensive and less than ideal. In contrast, cerebral oximetry with near infrared spectroscopy (NIRS) offers a noninvasive, continuous and easy to use measurement of cerebral tissue oxygen saturation and continues to gain acceptance as a crucial monitoring tool in critical care environments.[3]

Cerebral oximetry has been available as a monitoring device for over a decade. Recent refinements to NIRS technology have resulted in more reliable oximeters with increased accuracy performance.[4] Currently, at least three manufacturers have FDA clearance to market NIRS based cerebral oximeters in the United States, but direct comparisons of accuracy among these monitors has been difficult. Some studies have been published where a single monitor brand has been compared to an invasive standard to determine accuracy.[5,6] Individual studies, however, provide limited guidance for clinicians to compare the accuracy of devices due to the possibility of patient selection bias or variability in methodologies. Until now, only one published study compared two branded monitors against a mixed venous and arterial reference standard within the same patient cohort.[4] While head-to-head comparisons in clinical settings have been reported,[7] objective evaluation of the accuracy of the devices without an invasive standard is difficult.

To provide a direct comparison of accuracy performance among commercially available cerebral oximeter monitors without selection bias, this comparative study evaluated the precision of four commercially available cerebral oximeters on the same subjects. Results are also compared with previously published studies conducted with similar reference methods to determine consistency.

## Devices

Simultaneous measurements from four commercially available near-infrared spectroscopy (NIRS) cerebral oximeters: FORE-SIGHT® (CAS Medical Systems, Branford, CT, USA), INVOS® 5100C (Covidien, Boulder, CO, USA), EQUANOX™ Model 7600 (Nonin Medical, Plymouth, MN, USA) with both EQUANOX Advance™ and EQUANOX Classic™ sensors, and NIRO®-200NX (Hamamatsu Photonics, Hamamatsu City, Japan) on adult volunteers. The reported cerebral oxygenation values (variously identified as $SctO_2$, $rSO_2$, and TOI) were compared against the commonly recognized invasive standard of weighted CO-oximetry jugular bulb and arterial oxygen saturation values during episodes of deliberate oxygen desaturation. All of these monitors have FDA clearance with the exception of the NIRO-200NX which has only CE Mark.

## Methods

Healthy adult volunteers were enrolled in this IRB-approved volunteer study after obtaining written informed consent at the Hypoxia Research Laboratory at the University of California, San Francisco. Sensors from different manufacturers were randomly placed on alternating right or left sides of each subject's forehead for each hypoxia run.[a] An internal jugular vein catheter was placed at the position of the subject's superior jugular bulb and an arterial catheter was placed in the subject's radial artery. During the study period, all

[a] This Configuration minimized systematic inter-device interference across the study.

subjects remained in a semi-Fowler's position to ease breathing. Before affixing a mouthpiece and noseclip, and with subjects breathing room air, an initial blood sample was withdrawn from the two catheters. Subjects then breathed gas mixtures through the mouthpiece and were instructed to breathe two to three times deeper and faster than normal to speed alveolar gas equilibration. Inspired $CO_2$ was adjusted to maintain an end-tidal $CO_2$ value of 40 ±2 mmHg. Inspired oxygen was adjusted to target $SpO_2$ plateaus in approximately equal increments from 98% down to approximately 68%. Subjects were then given pure oxygen to return to normal state.

Blood samples (1.5 -2.0 ml) from the jugular bulb and radial artery catheters were simultaneously withdrawn during the target plateaus into heparinized syringes. The cerebral oximetry values reported by each monitor were recorded synchronously on a laptop every two seconds and averaged in ten-second moving windows. Readings from each monitor were identified at the moment of each blood draw. Each blood sample was analyzed for functional oximetry in an OSM3 Hemoximeter (Radiometer Medical ApS, Brønshøj, Denmark) for either radial ($SaO_2$) or jugular ($SjvO_2$) data. The subjects underwent three induced hypoxia sessions with 7 to 8 blood samples collected each run. Weighted CO-oximeter reference values were calculated based on the manufacturer's claims:

**For FORE-SIGHT, EQUANOX, and NIRO:**
**$CX(70:30) = [0.70 \times SjvO_2] + [0.30 \times SaO_2]$**
**For INVOS:**
**$CX(75:25) = [0.75 \times SjvO_2] + [0.25 \times SaO_2]$**

Composite precision (±1SD), bias (mean of [CX – oximeter] error value), and $A_{rms}$ (root-mean-square difference between the displayed cerebral oximeter readings and CX)[8] values were determined for each monitor including all subjects. Data from this study were then compared to previously published studies based upon similar testing methods on adult volunteers with monitor values measured against weighted CO-oximeter values.

## Results

Accuracy data from 23 patients (14 Male / 9 Female; 13 White / 3 Hispanic White / 3 Asian / 2 Black / 2 Multiracial; 20-40 years; 54.5 - 97.7 kg) comprising 175-180 data points for each monitor are reported (Table 1, Figures 1-5). Data from an additional two subjects were excluded from the analysis: on one subject all monitors failed to provide a value and in another both the INVOS monitor and EQUANOX monitor with Advance sensors failed to read continuously. In those events where a monitor failed to provide a value, corrective actions such as checking cable connections, replacing hardware, or turning off the opposing sensor were taken, but were unsuccessful in obtaining a measurement from the monitor.

Reference CX values were calculated based upon blood draws when the subjects were breathing room air prior to the hypoxia run and were separated into decade increments and compared with the corresponding cerebral oximeter values (Figure 6-10).

## Discussion

This study represents the first detailed comparative performance analysis of cerebral oximeters using an invasive reference standard and a common cohort, testing methodology, and data analysis. Large differences were observed in the precision of commercially available monitors in healthy adult volunteers undergoing induced hypoxia events with precisions ranging from ±3.90% to ±9.72% (1SD). The FORE-SIGHT Oximeter monitor measured cerebral oxygenation with the greatest precision (3.90%) and $A_{rms}$ accuracy (4.26%). Data from this study is consistent with several earlier validation studies. Two reports of the FORE-SIGHT Oximeter demonstrated similar precisions of 3.70%[5] and 3.12%[4], respectively. Furthermore, one of those studies also included a comparison to an INVOS monitor and measured an INVOS precision of 9.62%[4], consistent with the precision of 9.69% reported in this study. The current results, however, do not agree with another INVOS reported volunteer hypoxia study showing a precision of 5.0%.[9]

The EQUANOX Classic sensor has FDA clearance as a trending sensor, but absolute accuracy data published earlier indicated a $A_{rms}$ of 8.3%[10], similar to the $A_{rms}$ of 8.47% determined in this study. In contrast with a previous study where EQUANOX Advance sensors reported an $A_{rms}$ value of 4.10%[6], this investigation measured an $A_{rms}$ accuracy for those sensors of 6.86%. No standard deviation was available in the previous study.

The variations in measured accuracy across investigations highlight the difficulty of comparing performance across studies employing different subjects and methodology. This study controlled experimental and analysis conditions to ensure traceability of truly comparative data.

Room air measurement values are important because they often are used as a baseline for determining treatment interventions based upon decrements or trends in that value.[11] The FORE-SIGHT Oximeter reported all room air values (Figure 6) in the expected range for healthy adults of 60% to 80%, with a distribution mirroring the reference values. Other manufacturer's oximeters reported a wide variety of subject room air saturation values ranging from less than 40% to greater than 80%. Large variability in baseline room air values may undermine treatment confidence when intervention at fixed oxygenation levels (e.g., 60%[1]) are prescribed or when the values are used to stratify risk for cardiac patients prior to on-pump surgery.[11]

## Clinical Implications

Clinicians should be aware of the limitations of certain cerebral oximeters as accuracy varies considerably among brands. Advancements in NIRS technology as found in the FORE-SIGHT Oximeter provide improved accuracy affording clinicians increased confidence to intervene appropriately in the care of their patients.

| | FORE-SIGHT | INVOS | NIRO-200NX | EQUANOX Classic | EQUANOX Advance |
|---|---|---|---|---|---|
| **Prec (±1SD)** | 3.90 | 9.72 | 9.64 | 8.12 | 6.27 |
| **Bias** | -1.73 | -0.05 | 1.23 | -2.48 | -2.84 |
| **$A_{rms}$** | 4.26 | 9.69 | 9.68 | 8.47 | 6.86 |

**Table 1:** Precision, Bias, and $A_{rms}$ of different manufacturer's device. Bias is presented as [Reference CX - Measured Value].

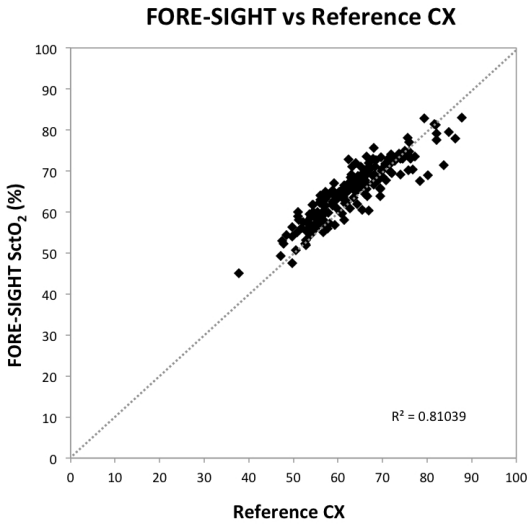



**Fig 1:** Scatter Plot Graph Comparing FORE-SIGHT with Reference CX

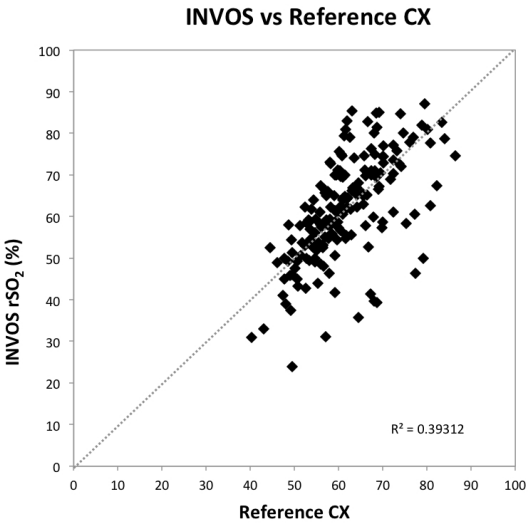



**Fig 2:** Scatter Plot Graph Comparing INVOS with Reference CX

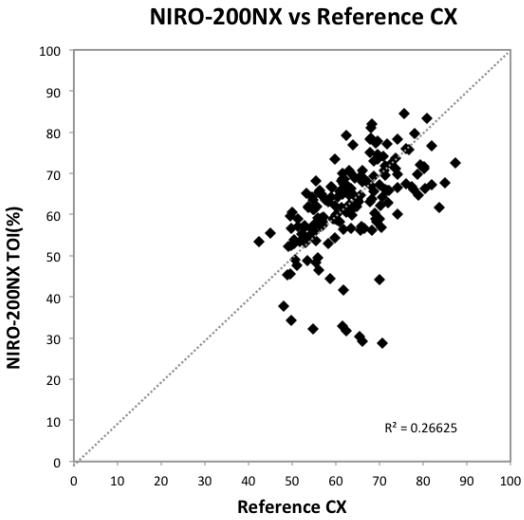



**Fig 3:** Scatter Plot Graph Comparing NIRO-200NX with Reference CX

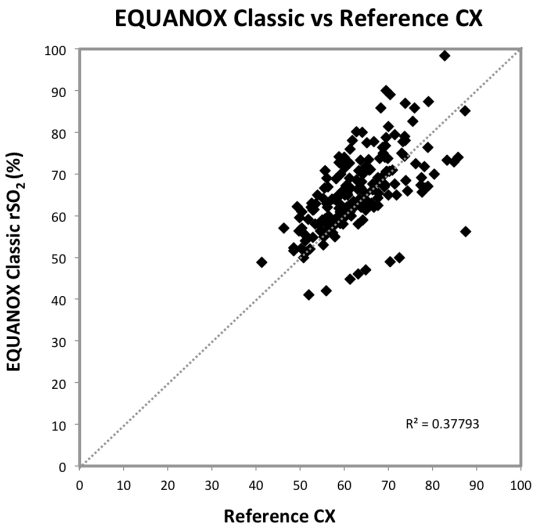



**Fig 4:** Scatter Plot Graph Comparing EQUANOX Classic with Reference CX

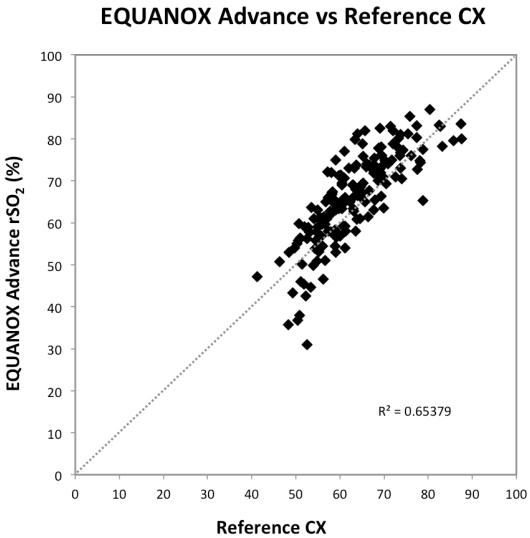



**Fig 5:** Scatter Plot Graph Comparing EQUANOX Advance with Reference CX

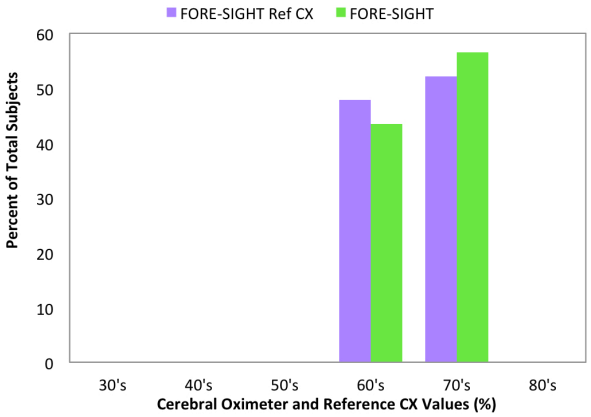



**Fig 6:** FORE-SIGHT room air values compared to Reference CX values

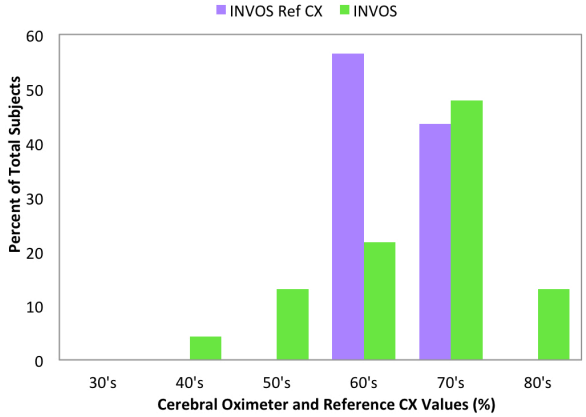



**Fig 7:** INVOS room air values compared to Reference CX values

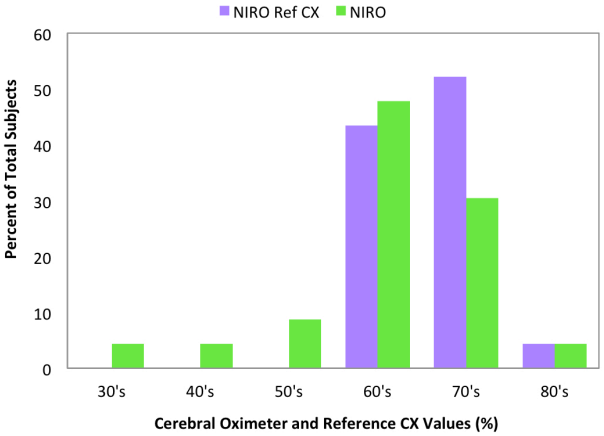



**Fig 8:** NIRO-200NX room air values compared to Reference CX values

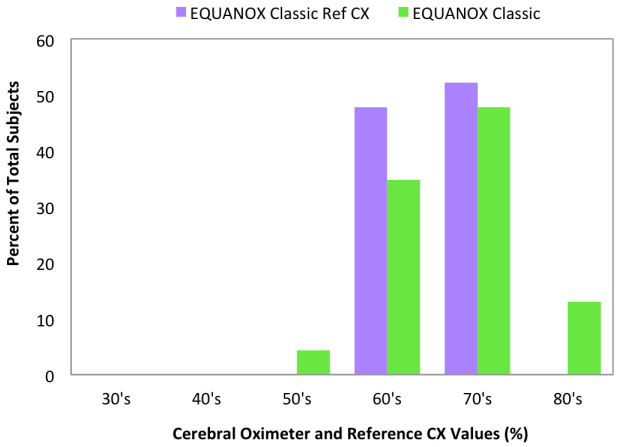



**Fig 9:** EQUANOX Classic room air values compared to Reference CX values

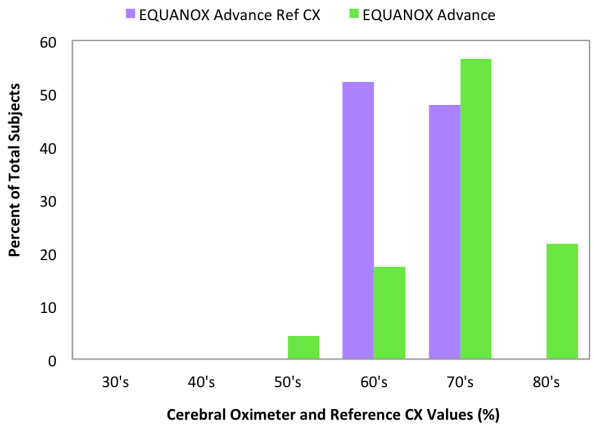



**Fig 10:** EQUANOX Advance room air values compared to Reference CX values

## *References*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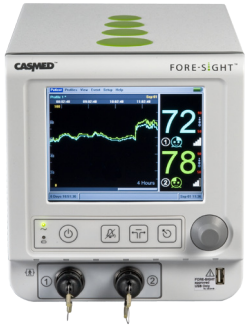
# FORE-SIGHT®

Absolute Tissue Oximetry

## ABSOLUTE ACCURACY: IMPROVING THE PRECISION OF PATIENT CARE




FORE-SIGHT provides clinicians with "Best-in-Class" accuracy. Independent studies from leading academic institutions have demonstrated the superiority and consistent accuracy of FORE-SIGHT Absolute Tissue Oximetry compared to other commercially available devices (see table below).

### *Physicians and Clinicians expect:*

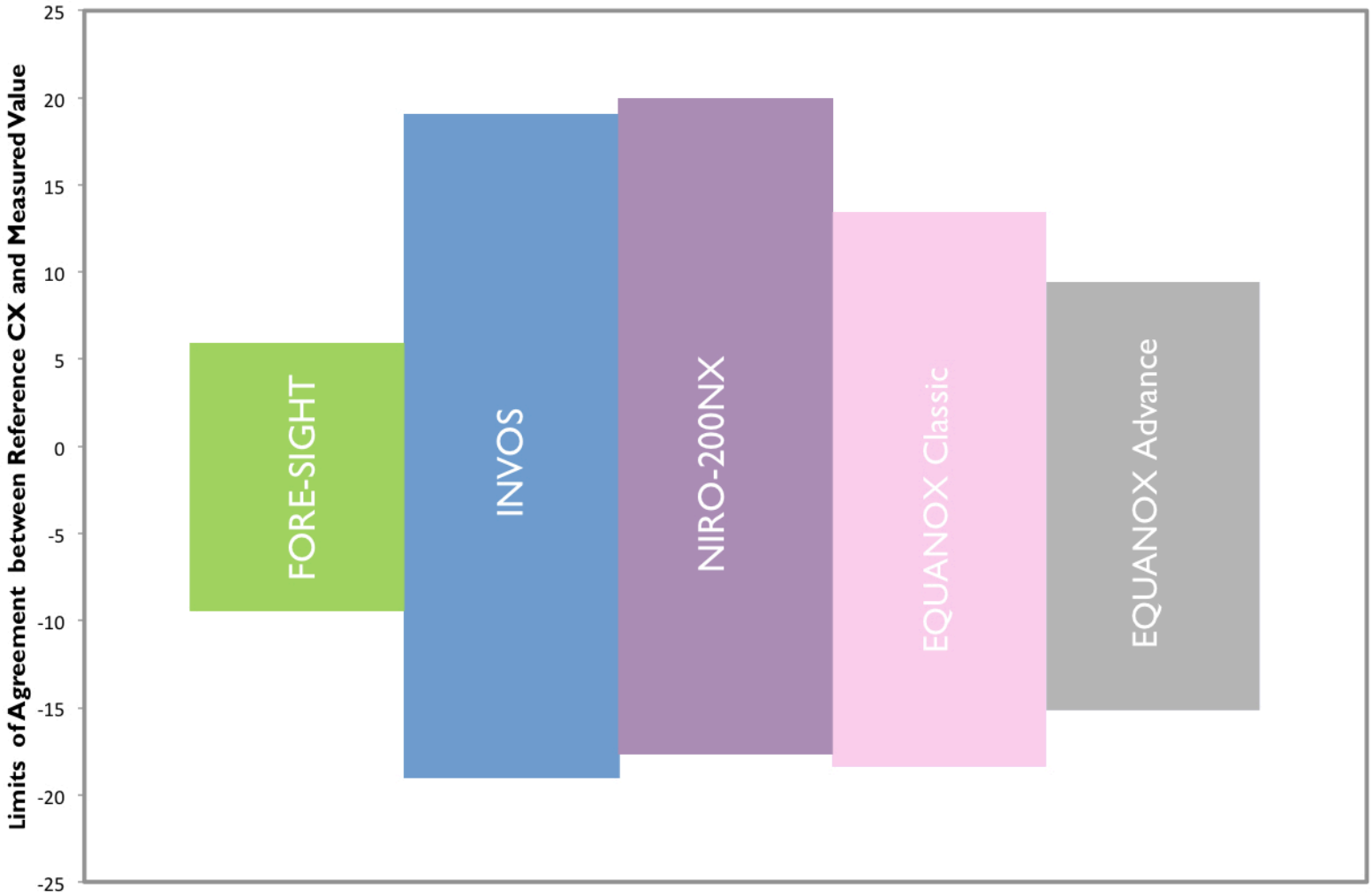
- **PRECISION** from FORE-SIGHT's consistent performance has been repeatedly validated in a diverse patient population
- **CONFIDENCE** from FORE-SIGHT's unsurpassed accuracy may lead to effective clinical interventions and to better outcomes

| Abstract | | | FORE-SIGHT CASMED | | | INVOS COVIDIEN | | | NIRO-200NX HAMAMATSU | | | EQUANOX Classic NONIN | | | EQUANOX Advance NONIN | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Year | Presented at | Title, Lead Author, Institution | SD | Bias | $A_{rms}$ | SD | Bias | $A_{rms}$ | SD | Bias | $A_{rms}$ | SD | Bias | $A_{rms}$ | SD | Bias | $A_{rms}$ |
| 2006 | IARS | Validation of the CAS adult cerebral oximeter during hypoxia in healthy volunteers. MacLeod et al. Duke University Medical Center | **±3.70**[1] | 0.18 | * | * | * | * | * | * | * | * | * | * | * | * | * |
| 2009 | ASA | Absolute and trending accuracy of FORE-SIGHT and INVOS cerebral oximeters in healthy volunteers. MacLeod et al. Duke University Medical Center | **±3.12** | 1.59 | * | **±9.62** | 2.00 | * | * | * | * | * | * | * | * | * | * |
| 2011 | IARS | Nonin Equanox 8004CA Advance cerebral oximeter sensor provides valid assessment of true tissue oxygen saturation. MacLeod et al. Duke University Medical Center | * | * | * | * | * | * | * | * | * | * | * | * | * | * | 4.10 |
| 2011 | ASA | Performance of 5 cerebral oximeters during hypoxia in healthy volunteers. Bickler et al. University of California at San Francisco | **±3.90** | 1.73 | 4.26 | **±9.72** | 0.05 | 9.69 | **±9.64** | -1.23 | 9.68 | **±8.12** | 2.48 | 8.47[2] | **±6.27** | 2.84 | 6.86 |

*Not stated in the Abstract
1) FORE-SIGHT published specification
2) EQUANOX Classic published Arms=8.3
3) Bias is presented as [Measured value - Reference CX]

FORE-SIGHT's accuracy performance provides clinicians with greater confidence to choose when to intervene. This increased precision over conventional NIRS devices could minimize the risk of under- or over-treating a patient. Over-treatment can be harmful and increases the cost of care, while under-treatment can also be harmful as opportunities to intervene are missed. FORE-SIGHT Absolute Tissue Oximetry assists physicians and clinicians in tailoring care for each patient, potentially increasing the probability of a better patient outcome.

## Accuracy Testing of Commercially Available Cerebral Oximeters
## Bland-Altman 95% Confidence Interval for Limits of Agreement




The graphic is based on data collected from 23 healthy adult volunteers breathing controlled gas mixtures with weighted CO-oximetry blood data as reference. Data reprinted in Bickler PE, Feiner JR, Eilers H, Rollins M. Performance of 5 cerebral oximeters during hypoxia in healthy volunteers. Proceedings of the 2011 Annual Meeting of the American Society of Anesthesiologists; Abstract LBT07.

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