SenSmart™

**Model X-100 Universal Oximetry System
for Pediatric Patients**

## The first oximetry system to put regional oximetry, pulse oximetry and ease of use at your fingertips.

Introducing Nonin Medical's Dynamic Compensation™*
The first cerebral oximetry algorithm to automatically account for developing neonatal/pediatric brain tissue

The optical properties of brain tissue change significantly during the first few months of life. The SenSmart Universal Oximetry System, combined with EQUANOX™ regional sensor technology, effectively isolates targeted tissue and automatically takes into account the light attenuation changes caused by myelination variation and other developmental changes, providing you with data you can act on.

Figure 1
Myelination development changes the optical properties of the pediatric brain and can vary from patient to patient.
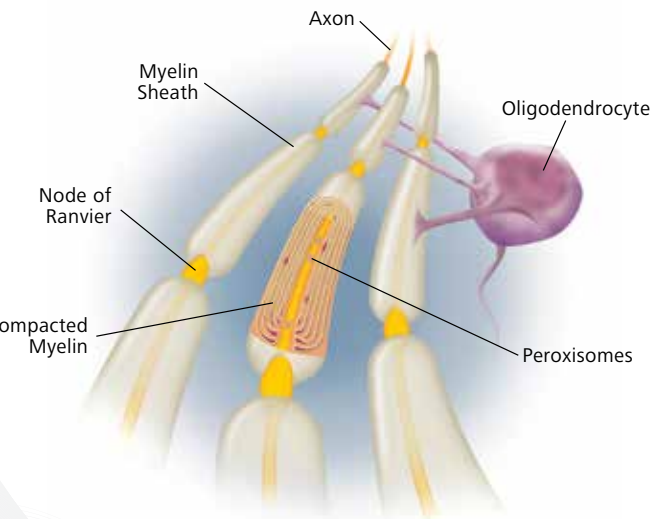
To measure blood oxygen saturation levels, cerebral and somatic oximeters must separate the optical effects of blood from tissue.

Traditional regional oximetry systems utilize different-sized sensors or manual entry of patient age and weight.

No such steps are required with Nonin's Dynamic Compensation algorithm.

Axon
Myelin Sheath
Oligodendrocyte
Node of Ranvier
Compacted Myelin
Peroxisomes

Figure 2
Infants of the same age can be very different developmentally.

Dual emitters. Dual detectors.
A singular NIRS breakthrough in neonatal and pediatric cerebral/somatic oximetry

Nonin's exclusive EQUANOX technology reduces inaccuracies caused by light scattering effects from non-targeted tissue.

Dual emitters/detectors in the EQUANOX Advance sensor create pairs of reflected light paths through surface tissue and through the cerebral cortex, producing measurements that are minimally affected by intervening tissue or surface effects.

Four-wavelength algorithms translate light information into accurate measurements.

The light absorption information collected by the dual emitter/detector architecture is automatically incorporated into Nonin's Dynamic Compensation light processing algorithm, to provide real tissue oxygenation saturation values based on the patient's unique brain development characteristics.

A real-time measurement. A real improvement over trending-only technology.

The SenSmart signal processing data provides the actual percent of oxygenated hemoglobin in the target tissue for display on the monitor. The system's accuracy is not just tied to the amount of "change from specific patient's baseline." This improved accuracy makes it possible to rely on the values, even when no baseline value is available.

Figure 3
EQUANOX rSO_2 Sensor Technology

Light Emitter
Light Detector
Light Detector
Light Emitter
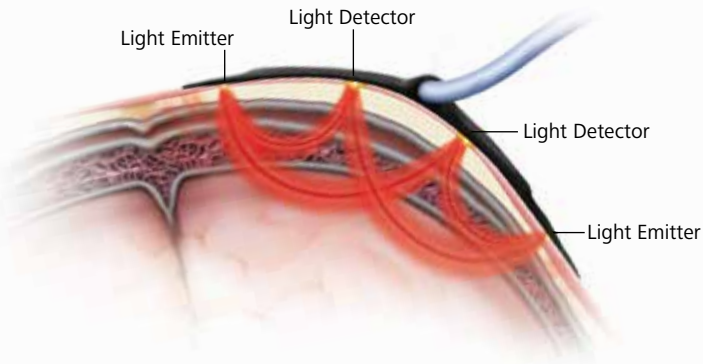
Only Nonin's sensors use two emitters and two detectors to provide cerebral cortex measurements that are minimally affected by intervening tissue or surface effects.[2]

Figure 4
Competitors' rSO_2 Sensor Technology

Light Detector
Light Detector
Light Emitter
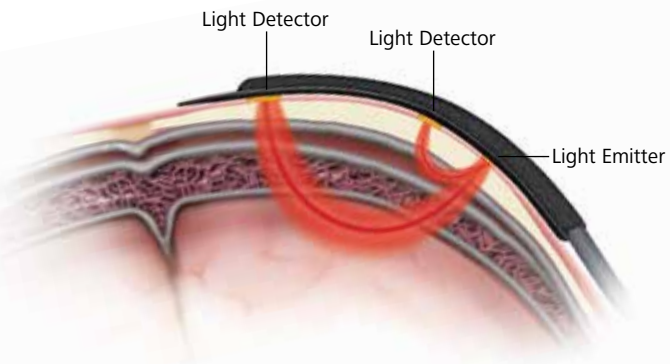
Other sensors use only one emitter and one or two detectors (examples include CASMED FORE-SIGHT® and Covidien INVOS®) and have significantly greater signal contamination from shallow tissue.[2]

Clinically proven accuracy, consistency and reliability

Instant, absolute rSO$_2$ accuracy from EQUANOX technology

Davie SN, Grocott HP[2]

"The EQUANOX contains two light emitters which may provide further accuracy by allowing this device to account for extracranial tissue variation and contamination throughout the entire curvilinear path ..."

"The INVOS demonstrates a relatively short distance between its near and far field detectors ... this appears to be insufficient to appropriately distinguish extracranial from cerebral tissue."[2]

Study Results/Conclusions

The primary objective of this study was to determine which NIRS-derived cerebral oxygen saturation technology best eliminates signal contamination from extracranial tissue.

This study showed in a statistically significant manner that of the three cerebral oximeters, EQUANOX technology had the least interference from extracranial tissue.

Percent change from baseline after occlusion for 5 minutes (%)

p = 0.0487
p = 0.025   p = 0.0019
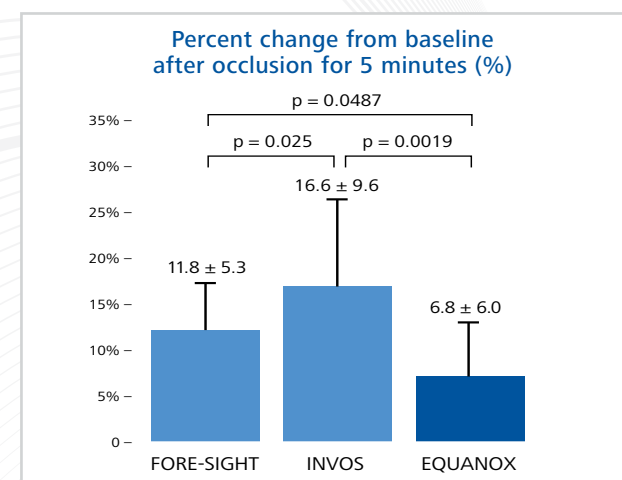11.8 ± 5.3   16.6 ± 9.6   6.8 ± 6.0
FORE-SIGHT   INVOS   EQUANOX

Figure 5
Percent change from the baseline regional cerebral oxygen saturation measurement of FORE-SIGHT, INVOS 5100-PB, and EQUANOX Classic 7600, after occlusion of the head cuff for 5 minutes.[2]

Kreeger R, et al[3]

"Accuracy is improved by using more wavelengths, more source-detector separations ..."

"... dual-emitter/dual-detector sensor and dynamic compensatory algorithms more effectively eliminate scalp and skull contamination to focus on brain tissue and automatically adjust for variations in tissue optical properties to improve accuracy over a wide range of age and physiologic condition."[3]

Study Results/Conclusions

This is the largest published multicenter study to date calibrating and validating an advanced technology NIRS cerebral oximeter for use in children with congenital heart disease.

- This cerebral oximeter accurately measured the absolute value of cerebral saturation in children over a wide range of oxygenation and subject characteristics, offering advantages in assessment of cerebral hypoxia-ischemia in congenital heart disease.
- The accuracy was consistent, even in low saturation, and the researchers did not detect any impact of skin color, age or gender.
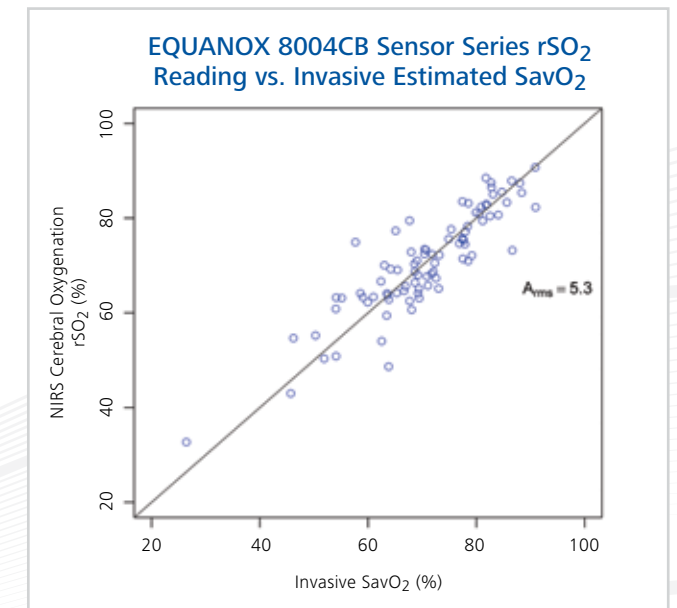

EQUANOX 8004CB Sensor Series rSO$_2$ Reading vs. Invasive Estimated SavO$_2$

NIRS Cerebral Oxygenation rSO$_2$ (%)

A_{rms} = 5.3

Invasive SavO$_2$ (%)

Figure 6
Eighty-six congenital cardiac patients were evaluated, from neonate through pediatrics, with varying skin color and a wide range of SavO$_2$ representative of typical patient physiology. Simultaneous arterial and jugular bulb samples were analyzed by CO-oximetry. Cerebral oxygen values were taken at the same time with the EQUANOX 8004CB sensor series.[3]

Accurate, dependable SpO$_2$ readings from PureSAT® technology

Nonin Pulse Oximetry System with PureSAT technology had excellent accuracy throughout all saturation levels.

Study Results/Conclusions

Twelve healthy subjects underwent a standard breath-down protocol to achieve arterial oxygen saturation between 70% and 100%. SpO$_2$ values were compared to the gold-standard, which is CO-oximetry analysis of arterial blood samples.

Accuracy – a combined measure of error and variability – was excellent with the Nonin oximeter and sensor in all subjects throughout the most challenging environments.
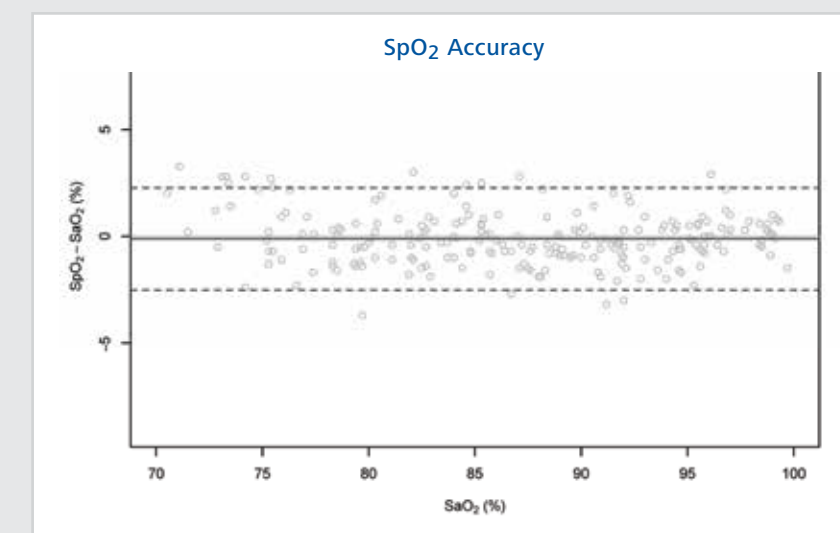

SpO$_2$ Accuracy

SpO$_2$ − SaO$_2$ (%)

SaO$_2$ (%)

Figure 7
Differences between the Nonin PureSAT SpO$_2$ technology and CO-oximeter values. Nonin PureSAT SpO$_2$ technology demonstrated consistent accuracy even at low saturations.[4]

Accuracy you can act on in regional oximetry

Nonin's EQUANOX Advance Model 8004CB sensor represents a major step forward in pediatric patient monitoring because it provides a single-sensor solution designed specifically for pediatric patients. Until now, most pediatric cerebral/somatic oximetry sensors have essentially been trimmed versions of adult sensors.

The sensor features adhesive and non-adhesive versions, a small footprint for space-saving placement, and light path spacing for pediatric-appropriate tissue depth readings. Nonin's patent-pending Dynamic Compensation algorithm automatically calculates accurate, patient-specific values.

And, because the EQUANOX 8004CB provides a single-sensor solution for all patients less than 40 kg, it simplifies protocols and inventory requirements, saving time and money. In addition, there is no need to input patient age and weight.

SENSORS SHOWN ACTUAL SIZE

## Somatic placement — options for clinical flexibility

The SenSmart System's EQUANOX Advance rSO_2 sensors are spatially resolved to calculate accurate, patient-specific values. The rSO_2 display refreshes every 1.5 seconds, so if tissue saturation is changing, you will see it when it happens.

SenSmart EQUANOX rSO_2 Sensors

EQUANOX Advance Model 8004CA (adhesive),
4-wavelength sensor. For patients >40 kg
Depth of measurement ~20 mm

20 mm   20 mm

40 mm

40 mm
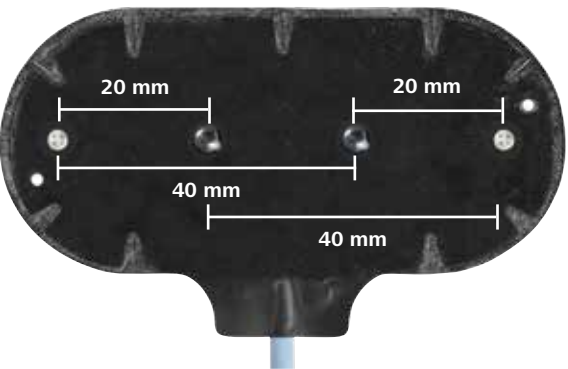
**EQUANOX Advance Model 8004CB (adhesive), and
EQUANOX Advance Model 8004CB-NA (non-adhesive),**
4-wavelength sensors. For patients <40 kg
D...

12.5 mm   12.5 mm

25 mm

25 mm
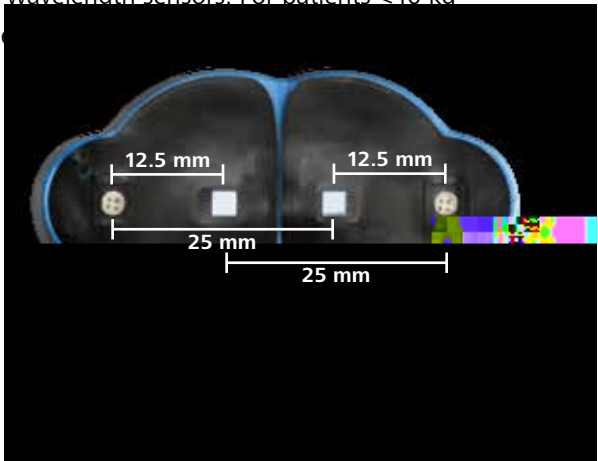
Note: A 3-wavelength trending sensor for patients >40 kg is also available upon request: EQUANOX Classic Plus Model 8003CA

Accuracy you can act on in pulse oximetry

Nonin's clinically proven PureSAT pulse oximetry technology utilizes intelligent pulse-by-pulse filtering to provide precise oximetry measurements when combined with Nonin's reusable soft SpO_2 sensors. Result: Fast, accurate and reliable readings even in patients with low perfusion or in the presence of motion.

SenSmart Soft SpO_2 Sensors

**8100SL
Large Soft Sensor**
Digit thickness:
12.5 to 25.5 mm
(0.5 to 1 in)

**8100SM
Medium Soft Sensor**
Digit thickness:
10 to 19 mm
(0.4 to 0.75 in)

**8100SS
Small Soft Sensor**
Digit thickness:
7.5 to 12.5 mm
(0.3 to 0.5 in)

Monitor

- Color-coded display automatically recognizes and displays signal processor channel number, oximetry type (rSO_2 and/or SpO_2), and lets you select or customize display of sensor site per channel. In multi-sensor situations you can quickly identify which sensor is which channel, so you can focus on the patient, not the monitoring system.
- Intuitive, easy-to-operate user interface includes

Compare oximetry systems
Feature for feature

Nonin Medical
SenSmart™ Model X-100
Universal Oximetry System

Covidien®
INVOS®
rSO$_2$ System

CASMED®
FORE-SIGHT®
rSO$_2$ Oximeter System

Monitor System			
Weight	**900 g / 2 lbs**	6.85 kg / 14 lbs	6.85 kg / 14 lbs
Maximum channels	**6**	4	2
Battery life	**3 hours** (when operating with 2 channels)	20 minutes	1.5 hours
Battery design	**Lithium ion**	Lead-acid	Lead-acid
Battery re-charge time	**2.5 hours**	24 hours	16.5 hours
Instant reading	**Yes**	No*	No†
Signal processor/pre-amp size (Approx.)	**33 cc**	318 cc	121 cc
Operational Parameters			
Display range of rSO$_2$	**0–100%**	15–95%	0–99%
Display range of SpO$_2$	**0–100%**	n/a	n/a
Refresh rate	**1.5 seconds**	5–6 seconds	2 seconds
Data entry required for rSO$_2$ pediatric use	**No**	No	Yes
rSO$_2$ Sensor			
Cerebral indications	**Trending, Absolute**	Trending only	Absolute only
Somatic indications	**Yes**	Yes	Yes
Wavelengths	**3, 4**	2	4
Tolerant of ambient light	**Yes**	No	No
Number of light emitters	**2**	1	1
Number of light paths	**4**	2	1–2
SpO$_2$ Sensor			
SpO$_2$ accuracy	**70-100% ±2 digits‡**	n/a	n/a
SpO$_2$ low perfusion accuracy	**70-100% ±2 digits‡**	n/a	n/a
Pulse rate accuracy	**18-300 BPM ±3 digits‡**	n/a	n/a
Pulse rate low perfusion accuracy	**40-240 BPM ±3 digits‡**	n/a	n/a
Warranty Comparison			
Monitor warranty	**36 months**	12 months	12 months

* Requires signal strength detection
† Requires setup before sensor reading
‡ See Instruction for Use (IFU) for more information on product specifications and testing
Specifications subject to change without notice.

Nonin Medical: Leaders in Noninvasive Medical Monitoring

Nonin Medical is a technology-driven company and a leader in developing high performing, low cost, easy-to-use noninvasive medical monitoring solutions. Nonin took NIRS-based oximetry to a new level of clinical utility when it invented the fingertip pulse oximeter, so the move to provide clinicians with an accurate, versatile, portable regional oximeter was a natural one. Today, Nonin's new SenSmart™ Universal Oximetry System takes clinical utility and convenience to the nth degree, utilizing the same innovative sensing and signal processing technologies that already give millions of clinicians the confidence that the numbers they see reflect their patients' true physiology.

Nonin Medical NIRS-based oximetry advancements include:

1990 — Introduced world's first portable hand-held pulse oximeter
1995 — Introduced world's first fingertip pulse oximeter — the Onyx® 9500
2004 — Introduced world's first pulse oximeter with *Bluetooth*® wireless technology
2009 — Introduced EQUANOX™ regional oximetry system
2011 — Introduced industry-leading accuracy* in the EQUANOX Advance™ adult absolute regional oximetry sensor for cerebral and somatic applications
2011 — Released world's first regional oximetry OEM Solution
2012 — Introduced Nonin's Dynamic Compensation™ algorithm which automatically accounts for pediatric brain tissue development variation when measuring oxygen saturation levels
2013 — Introduced world's first rSO$_2$ /SpO$_2$ universal oximetry system

For more information, visit **sensmart.com**.

* EQUANOX 8004CA sensor

References
1. Tweddell J, Ghanayem N, Hoffman G. Pro: NIRS is "standard care" for postoperative management. S*emin Thoracic Cardiovasc Surg Pediatric Card Surg Annu*. 2010; 13(1):44–50.
2. Davie SN, Grocott HP. Impact of Extracranial Contamination on Regional Cerebral Oxygen Saturation: A Comparison of Three Cerebral Oximetry Technologies. *Anesthesiology*. 2012; 116(4):834–40.
3. Kreeger R, Ramamoorthy C, Nicolson S, et al. Evaluation of a Pediatric Near-Infrared Cerebral Oximeter for Cardiac Disease. *The Annals of Thoracic Surgery.* 2012; 94:1527-33.
4. Nonin Medical, Inc. Data on file.

Leaders in *Nonin*vasive Medical Monitoring