SenSmart™

Model X-100 Universal Oximetry System

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

EQUANOX™ rSO₂   SenSmart   PureSAT® SpO₂

SenSmart™
Multi-Sensing
NIRS Technology
1

NONIN

Introducing the SenSmart™ Universal Oximetry System: Where advanced clinical utility meets unprecedented ease of use

One test drive with the world's first universal oximetry system and you know the future is in your hands. With an innovative design that pairs simple with smart, Nonin Medical's SenSmart™ Model X-100 Universal Oximetry System is a new technology platform that, **for the first time, delivers both pulse and regional oximetry measurements today, and is designed to accommodate many more parameters in the future**. This is just one of many reasons to re-evaluate your options in regional tissue and pulse oximetry.

More insight from multiple oxygen saturation data points.

Now, one system provides a side-by-side view of regional oximetry (rSO_2), pulse oximetry (SpO_2) and pulse rate values for real-time decision making.

The SenSmart System lets you use any combination of Nonin SenSmart-compatible rSO_2 sensors and/or SpO_2 sensors with any Nonin SenSmart signal processor to monitor up to six sites on a patient.

What's more, SenSmart's universal signal processors are considerably smaller, lighter and less intrusive than anything you have used before. Plus, they automatically recognize and display all of your oximetry values on the SenSmart monitor.

Today: Side-by-side view of rSO_2 and SpO_2

You now have the opportunity to explore what a gradient between rSO_2 and SpO_2 might tell you.

- rSO_2 values allow management of patients at risk for compromised oxygen saturation of the brain or other tissues.
- SpO_2 and pulse rate values can help to proactively identify oxygen delivery issues for early intervention.

Accuracy you can act on in regional

Only the patented EQUANOX™ regional oximetry sensors use dual emitters and dual detectors to provide accurate cerebral and somatic tissue oxygen values. Other sensors use only one emitter and one or two detectors. Along with advanced, patent-protected algorithms, these dual emitters and dual detectors create pairs of light paths through surface tissue and through the cerebral cortex, producing measurements that are proven to be the industry's least affected by intervening tissue or surface effects.[1]
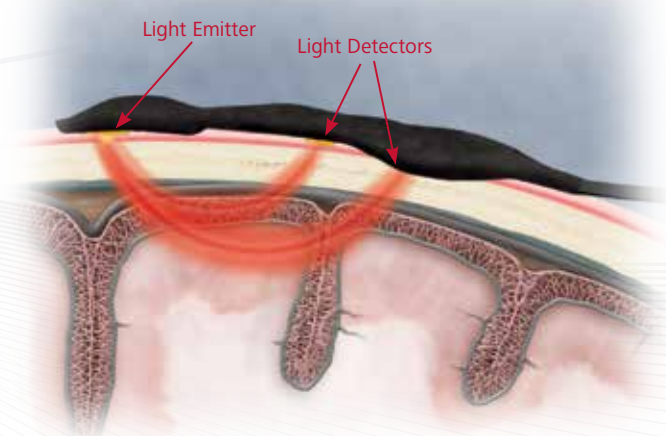
The SenSmart System's EQUANOX Advance rSO_2 sensors provide clinicians with state-of-the-art absolute accuracy that reduces the need to establish a patient baseline and provides values you can act on with confidence.

EQUANOX rSO_2 Sensor Technology

Light Emitter

Light Detectors

Light Emitter
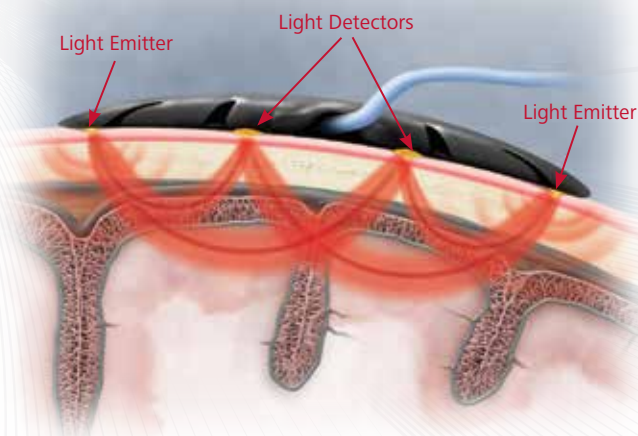
Only Nonin's sensors use two emitters and two detectors to provide cerebral cortex measurements that are minimally affected by intervening tissue or surface effects.[1]

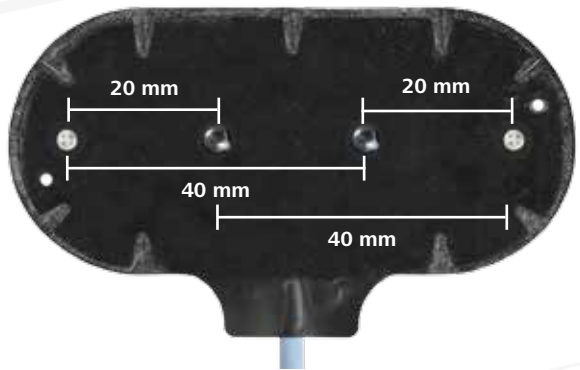## Competitors' rSO_2 Sensor Technology

Light Emitter

Light Detectors

Other sensors use one emitter and two detectors (examples include CASMED FORE-SIGHT® and Covidien INVOS®) and have significantly greater signal contamination from shallow tissue.[1]
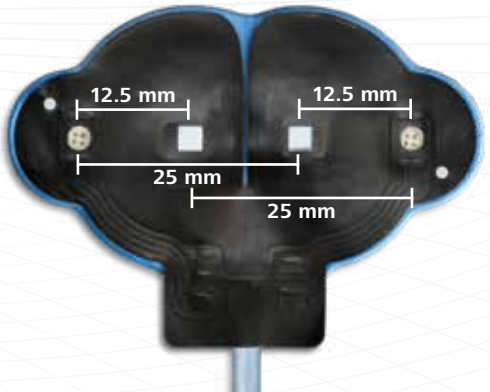
oximetry

Accuracy you can act on in pulse oximetry

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.

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 EQUANOX rSO$_2$ Sensors

EQUANOX Advance Model 8004CA (adhesive), 4-wavelength sensor. For patients >40 kg

SenSmart Soft SpO$_2$ Sensors

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

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

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)

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

Clinically proven accuracy, consistency

Instant, absolute rSO$_2$ accuracy from EQUANOX™ technology

·············· **MacLeod D, et al**[2] ···········

"Inaccuracy resulting from individual variations in light scattering may be decreased or eliminated through the use of additional wavelengths and/or improved algorithms."

"… Absolute accuracy offers distinct advantages over trend monitors."[2]

Study Results/Conclusions

This is the only peer-reviewed study that validates the accuracy of *absolute* versus *trending* cerebral oximetry in adults.

- Illustrates that not all NIRS technologies are equivalent; wavelengths and algorithms can impact accuracy and performance.
- The EQUANOX 8004CA sensor provides an accurate assessment of absolute cerebral saturation (4.1A$_{RMS}$).
- The EQUANOX 8004CA sensor provides consistent accuracy, even at low saturations which has been shown to be problematic for some NIRS technologies.
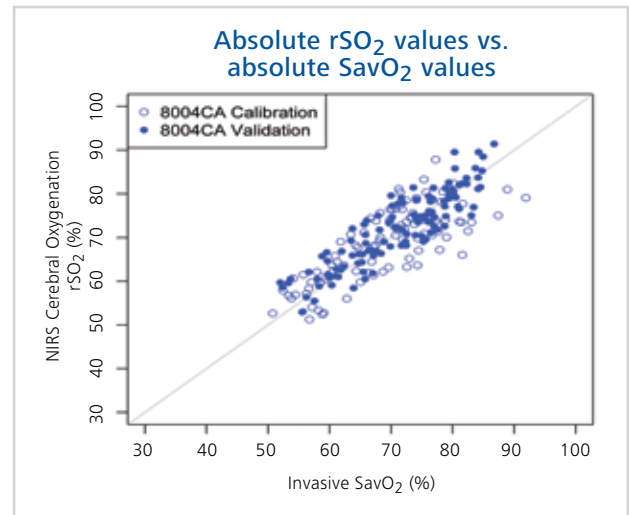

Absolute rSO$_2$ values vs. absolute SavO$_2$ values

○ 8004CA Calibration
● 8004CA Validation

NIRS Cerebral Oxygenation rSO$_2$ (%)

Invasive SavO$_2$ (%)

Figure 1
The regional oxygen saturation of brain tissue (rSO$_2$) values are validated against the gold-standard invasive arterio-venous saturation (SavO$_2$) values.[2]

Accurate, dependable SpO$_2$ readings from PureSAT technology

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

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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.

and reliability

•• **Davie SN, Grocott HP**[1] ••

"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."[1]

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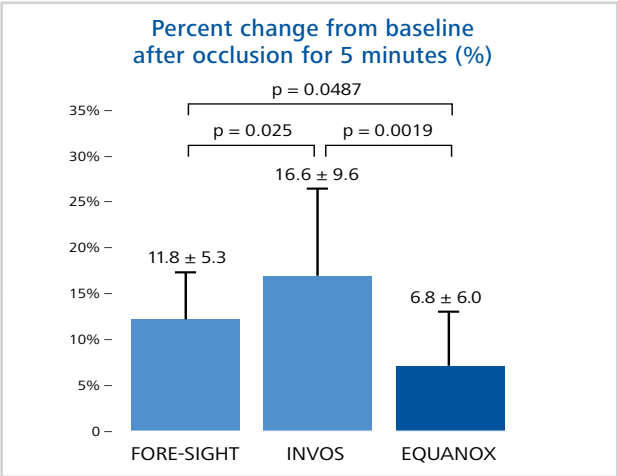
Percent change from baseline after occlusion for 5 minutes (%)

$p = 0.0487$
$p = 0.025$ $p = 0.0019$

16.6 ± 9.6
11.8 ± 5.3
6.8 ± 6.0

FORE-SIGHT   INVOS   EQUANOX

Figure 2
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.[1]
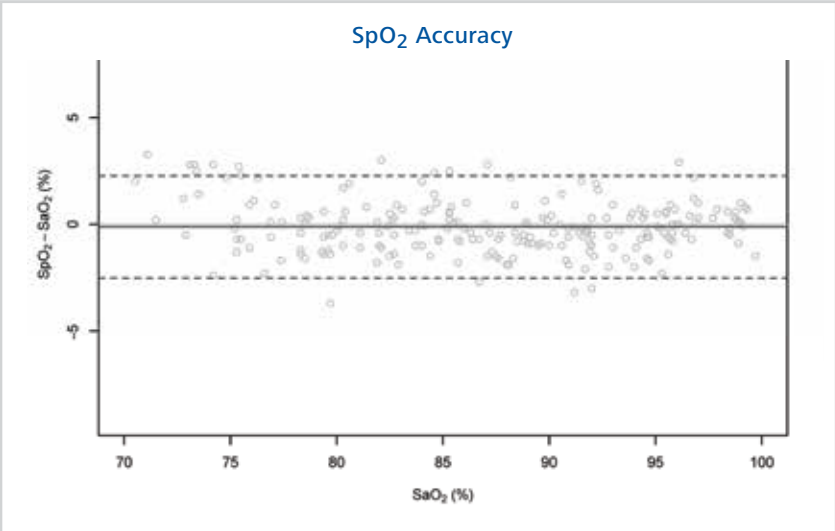
SpO_2 Accuracy

$SpO_2 - SaO_2$ (%)

SaO_2 (%)

Figure 3
Differences between the Nonin PureSAT SpO_2 technology and CO-oximeter values. Nonin PureSAT SpO_2 technology demonstrated consistent accuracy even at low saturations.[3]

rSO$_2$ and SpO$_2$ sensor solutions designed specifically for your pediatric patients

The SenSmart System, with EQUANOX Advance regional oximetry sensors, is designed for use on neonatal and pediatric patients in cerebral and somatic applications. The EQUANOX sensors feature Nonin Medical's proprietary Dynamic Compensation™ algorithm which automatically takes into account the light attenuation changes caused by myelination variation in developing neonatal/pediatric brain tissue to calculate accurate, patient-specific values.

Nonin's soft SpO$_2$ sensors produce a high-intensity pure light spectrum that eliminates variations in readings from patient-to-patient and sensor-to-sensor. These reusable SpO$_2$ sensors are available in a variety of sizes down to a digit thickness of 7.5 mm (0.3 inches).

Clinically proven accuracy for pediatric patients

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.
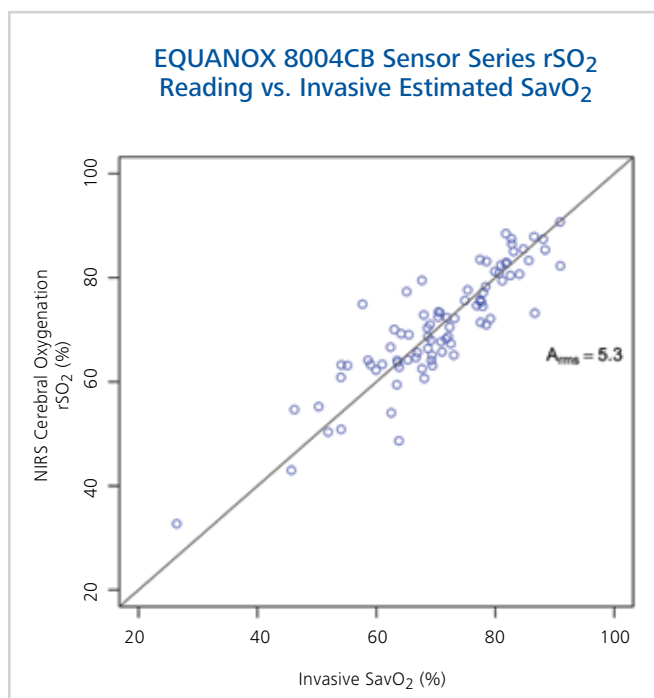

EQUANOX 8004CB Sensor Series rSO_2 Reading vs. Invasive Estimated $SavO_2$

$A_{rms} = 5.3$

NIRS Cerebral Oxygenation rSO_2 (%)

Invasive $SavO_2$ (%)

Figure 4

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.[4]

Unprecedented ease of use
The beauty of working smarter rather than harder

From a portable monitor to smaller signal processors to interchangeable rSO_2 and SpO_2 sensors, the SenSmart System brings new possibilities that support your decision-making process today, and provides a platform for adding more parameters in the future.

Hub

Signal Processors

- Smaller (33 cc) and less bulky (40 g/1.4 oz) signal processors are easy to work around, easy to move around and will not get in your way. Ideal for use in a variety of settings including neonatal incubators and minimum space-on-bed situations.
- Fast start-up and fast signal acquisition deliver readings within seconds. Turn the system on and start monitoring.

- Easy to use, the color-coded and numbered universal signal processors connect to any of the six hub ports. Channels will display properly without any need to connect to the hub in any certain order.
- Sensor-lock eliminates disconnections.

rSO_2 Sensors

- Flexible sensors conform easily to patient anatomy.
- Adhesive and non-adhesive options for neonate/infant/pediatric patients.
- Center orientation of the rSO_2 sensor cables allows for directing cables over the patient's forehead, preventing sideways torquing on the sensor cable or pressure against skin surfaces with sideways movement of the head.
- Immune to the effects of ambient light; no need to cover the exposed sensor and surrounding skin with a light-shielding drape.
- Skin color or pigmentation has not been shown to affect the accuracy of the readings.

rSO_2 Sensors

Monitor
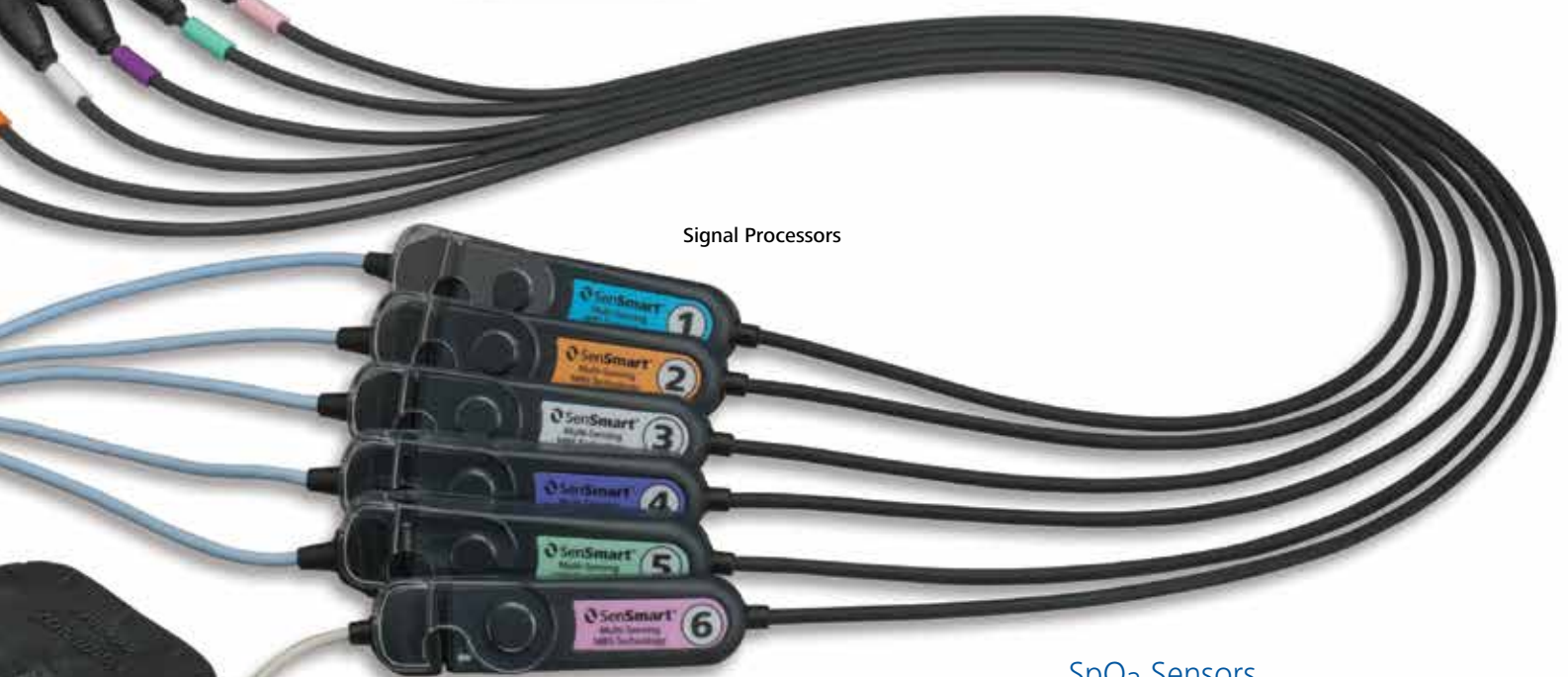
Signal Processors

SpO$_2$ Sensors

- High-intensity pure light spectrum eliminates variations in readings from patient-to-patient and sensor-to-sensor.
- Fast, accurate SpO$_2$ readings.
- Reusable with a durable design and comfortable fit for continuous monitoring.
- Form fitted to decrease ambient light interference.
- Available in three patient sizes.

SpO$_2$ Sensor

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 optional patient I.D. capability, as well as the ability to scroll back in the case and/or instantly retrieve a table of event values recorded.
- Weight advantage: 900 g (2 lbs) versus the 6.85 kg (14 lbs) of other regional oximetry systems currently on the market.
- Up to 10 customizable presets allow quick start, even when departments or individual clinicians have unique preferences. A major advancement for clinicians dissatisfied with "one-configuration-fits-all."

- Easy-to-read, configurable trend lines (rSO_2) and plethysmography displays (SpO_2) for a quick visual reference.
- Data transport to electronic medical record (EMR) systems via the hospital's interface engines.
- Long battery life (three hours when operating with two channels) makes it suitable for easy transport in and outside of the hospital.
- Up to 840 hours of data memory and SenSmart™ Download Software for case analysis, record keeping or research. State-of-the-art *Bluetooth*® wireless connectivity allows you to download cases without a connecting cable.
- Designed to work with the Philips® IntelliBridge® interface and Philips IntelliVue® patient monitors to provide parameter and trend line display.
- Display can operate in eight different languages.

Cables

- 4-meter hub cables allow flexibility in system placement; plus 1- or 2-meter signal processor extension cables increase range when needed.
- Thin, durable sensor cables shielded from ambient electronic signals; ideal for use in a variety of settings including OR, ICU, Electrophysiology and NICU.

Portable, Pole-Mountable Monitor

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	**CASMED®** FORE-SIGHT® ELITE * Absolute Tissue Oximeter
Monitor System				
Weight	**900 g / 2 lbs**	6.85 kg / 14 lbs	6.85 kg / 14 lbs	5.9 kg / 13.2 lbs
Maximum channels	**6**	4	2	4
Battery life	**3 hours** (when operating with 2 channels)	20 minutes	1.5 hours	30 minutes
Battery design	**Lithium ion**	Lead-acid	Lead-acid	Lead-acid
Battery re-charge time	**2.5 hours**	24 hours	16.5 hours	6 hours
Instant reading	**Yes**	No*	No†	Yes
Signal processor/pre-amp size (Approx.)	**33 cc**	318 cc	121 cc	97 cc
Operational Parameters				
Display range of rSO_2	**0–100%**	15–95%	0–99%	0–99%
Display range of SpO_2	**0–100%**	n/a	n/a	n/a
Refresh rate	**1.5 seconds**	5–6 seconds	2 seconds	2 seconds
rSO_2 Sensor				
Cerebral indications	**Trending, Absolute**	Trending only	Absolute only	Absolute only
Somatic indications	**Yes**	Yes	Yes	Yes
Wavelengths	**3, 4**	2	4	5
Tolerant of ambient light	**Yes**	No	No	Unknown
Number of light emitters	**2**	1	1	1
Number of light paths	**4**	2	1–2	2
SpO_2 Sensor				
SpO_2 accuracy	**70-100% ±2 digits‡**	n/a	n/a	None
SpO_2 low perfusion accuracy	**70-100% ±2 digits‡**	n/a	n/a	None
Pulse rate accuracy	**18-300 BPM ±3 digits‡**	n/a	n/a	None
Pulse rate low perfusion accuracy	**40-240 BPM ±3 digits‡**	n/a	n/a	None
Warranty Comparison				
Monitor warranty	**36 months**	12 months	12 months	24 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.

✳ 510(k) Summary K123700

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. 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.
2. MacLeod D, Ikeda, K, Vacchiano C, Lobbestael A, Wahr J, Shaw A. Development and Validation of a Cerebral Oximeter Capable of Absolute Accuracy. *Journal of Cardiothoracic and Vascular Anesthesia*, December 2012; 26(6):1007-1014.
3. Nonin Medical, Inc. Data on file.
4. 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.

Leaders in *Nonin*vasive Medical Monitoring