

SenSmart™ Model X-100

Universal Oximetry (rSO₂/SpO₂) System

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



Introducing Nonin's SenSmart™ Universal Oximetry (rSO₂/SpO₂) 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 (rSO₂), pulse oximetry (SpO₂) and pulse rate values for real-time decision making.

The SenSmart System lets you use any combination of Nonin SenSmart-compatible rSO₂ sensors and/or SpO₂ 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 rSO₂ and SpO₂

You now have the opportunity to explore what a gradient between rSO₂ and SpO₂ might tell you.

- rSO₂ values allow management of patients at risk for compromised oxygen saturation of the brain or other tissues.
- SpO₂ and pulse rate values can help to proactively identify oxygen delivery issues for early intervention.

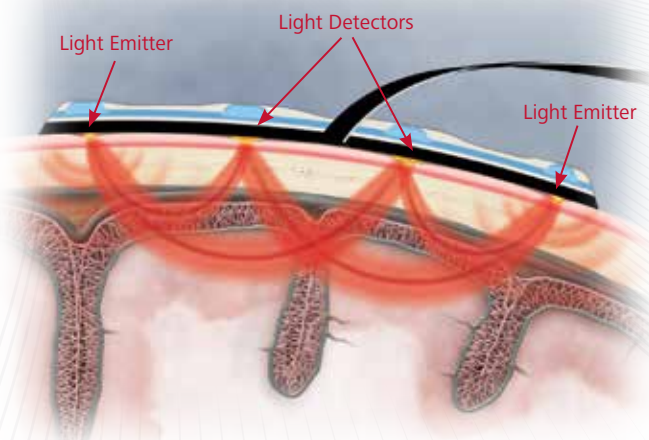


Accuracy you can act on in regional

Only the patented Nonin 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

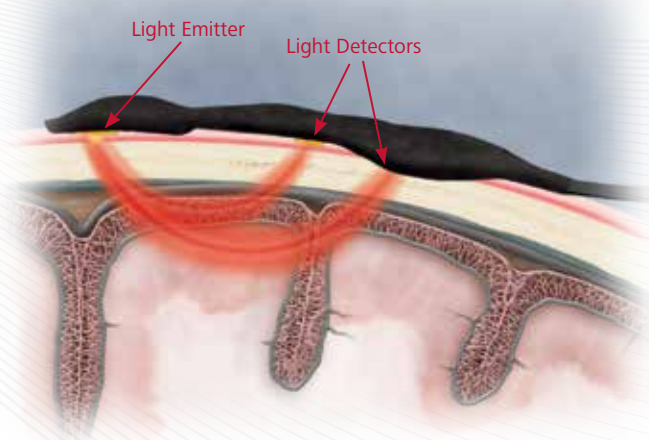
The SenSmart System's rSO₂ sensors provide clinicians with state-of-the-art absolute accuracy that reduces the need to establish a patient baseline and provides values you can act on with confidence.

Nonin rSO₂ Sensor Technology



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' rSO₂ Sensor Technology



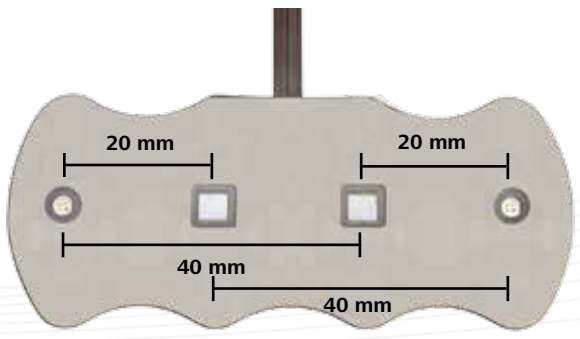
Other sensors use one emitter and two detectors (examples include CASMED FORE-SIGHT® Elite and Covidien INVOS®) and have significantly greater signal contamination from shallow tissue.¹

oximetry

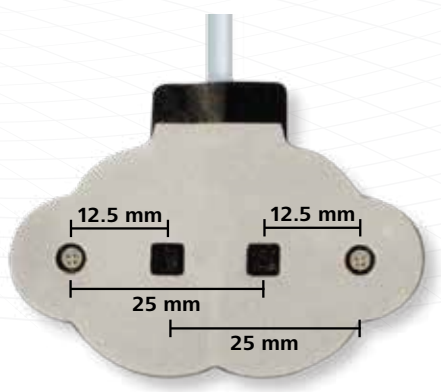
The SenSmart System's rSO₂ sensors are spatially resolved to calculate accurate, patient-specific values. The rSO₂ display refreshes every 1.8 seconds, so if tissue saturation is changing, you will see it when it happens.

SenSmart™ rSO₂ Sensors

Model 8204CA (adhesive)
4-wavelength sensor. For patients >40 kg
Depth of measurement ~20 mm



Model 8004CB (adhesive), and Model 8004CB-NA (non-adhesive)
4-wavelength sensors. For patients <40 kg
Depth of measurement ~12.5 mm



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 SpO₂ Sensors. Result: fast, accurate and reliable readings even in patients with low perfusion or in the presence of motion.

SenSmart™ Soft SpO₂ Sensors

8100SL Large Soft SpO₂ Sensor
Digit thickness:
12.5 to 25.5 mm
(0.5 to 1 in)



8100SM Medium Soft SpO₂ Sensor
Digit thickness:
10 to 19 mm
(0.4 to 0.75 in)



8100SS Small Soft SpO₂ Sensor
Digit thickness:
7.5 to 12.5 mm
(0.3 to 0.5 in)



Clinically proven accuracy, consistency

Instant, absolute rSO₂ accuracy from Nonin SenSmart™ technology

..... MacLeod D, et al²

"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 SenSmart 8204CA sensor provides an accurate assessment of absolute cerebral saturation (4.1A_{rms}).
- The SenSmart 8204CA sensor provides consistent accuracy, even at low saturations which has been shown to be problematic for some NIRS technologies.

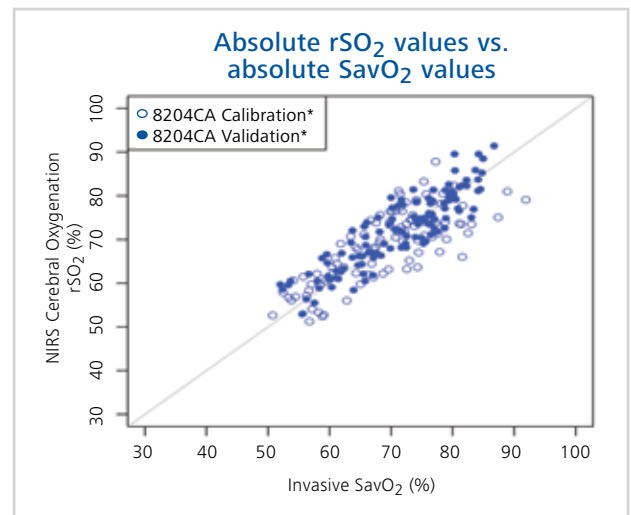


Figure 1
The regional oxygen saturation of brain tissue (rSO₂) values are validated against the gold-standard invasive arterio-venous saturation (SavO₂) values.²

*Given the optical equivalence with its 8004CA predecessor, the same calibration and validation apply.

Accurate, dependable SpO₂ readings from PureSAT technology

Nonin Pulse Oximetry System with PureSAT technology has 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%. SpO₂ 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 HP¹

“The Nonin Regional Oximetry System 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, Nonin’s technology had the least interference from extracranial tissue.

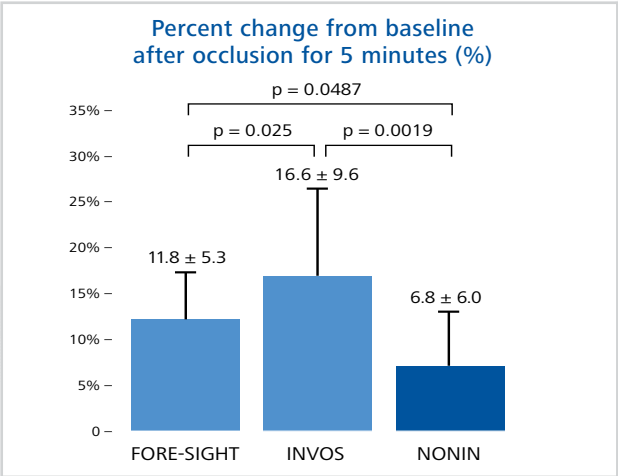


Figure 2
Percent change from the baseline regional cerebral oxygen saturation measurement of FORE-SIGHT, INVOS 5100C, and Nonin’s 3-wavelength sensor (8003CA), after occlusion of the head cuff for 5 minutes.¹

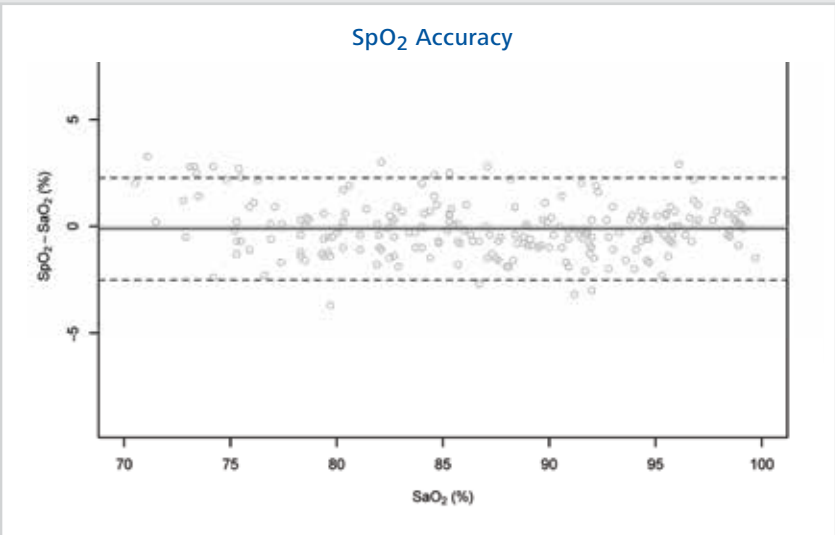


Figure 3
Differences between the Nonin PureSAT SpO₂ technology and CO-oximeter values. Nonin PureSAT SpO₂ technology demonstrated consistent accuracy even at low saturations.³



rSO₂ and SpO₂ sensor solutions designed specifically for your pediatric patients

The SenSmart System is designed for use on neonatal and pediatric patients in cerebral and somatic applications. The SenSmart 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 SpO₂ Sensors produce a high-intensity pure light spectrum that eliminates variations in readings from patient-to-patient and sensor-to-sensor. These reusable SpO₂ 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

..... Kreeger R, et al⁴

"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."⁴

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.

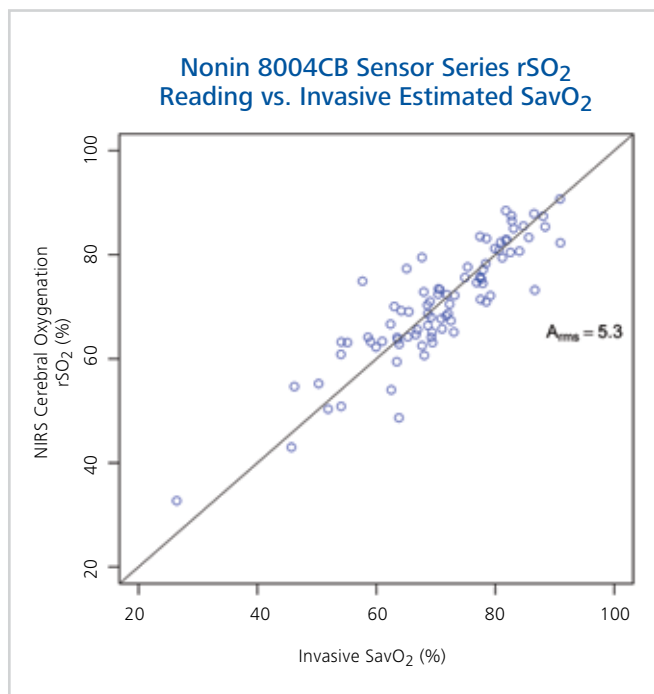


Figure 4
Eighty-six congenital cardiac patients were evaluated, from neonate through pediatrics, with varying skin color and a wide range of SavO₂ representative of typical patient physiology. Simultaneous arterial and jugular bulb samples were analyzed by CO-oximetry. Cerebral oxygen values were taken at the same time with Nonin's 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 rSO₂ and SpO₂ 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.

rSO₂ Sensors

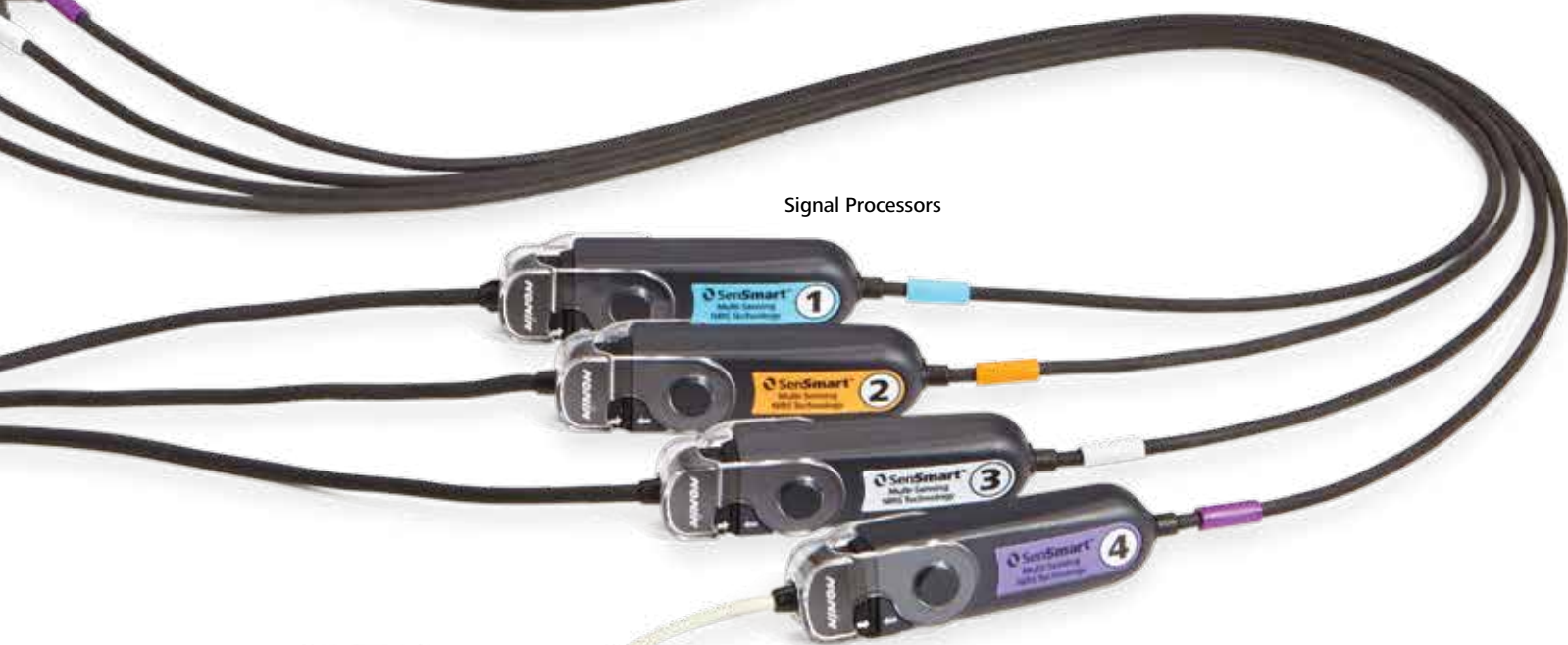
- Flexible sensors conform easily to patient anatomy.
- Adhesive and non-adhesive options for neonate/infant/pediatric patients.
- Center orientation of the rSO₂ sensor connector cable allows for directing cables over the patient's forehead, preventing sideways torquing on the sensor or pressure against 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.
- Highly resistant to interference and signal loss from electrosurgical cutting/coag devices



rSO₂ Sensors



Monitor



Signal Processors



Soft SpO2 Sensor

SpO₂ Sensors

- High-intensity pure light spectrum eliminates variations in readings from patient-to-patient and sensor-to-sensor.
- Fast, accurate SpO₂ readings.
- Reusable with a durable design and comfortable fit for continuous monitoring.
- Form fitted to decrease ambient light interference.
- Available in three patient sizes.

Monitor

- Color-coded display automatically recognizes and displays signal processor channel number, oximetry type (rSO₂ and/or SpO₂), 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 (rSO₂) and plethysmography displays (SpO₂) 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.
- Provides complete connectivity solutions for electronic medical record systems.
- 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 connector cable is shielded from ambient electronic signals; ideal for use in a variety of settings including OR, ICU, Electrophysiology and NICU.



Portable, Pole-Mountable Monitor
(Now with available GCX plate adapter)

Compare oximetry systems

Feature for feature



Nonin Medical
SenSmart™ Model X-100
Universal Oximetry
(rSO₂/SpO₂) System



Covidien®
INVOS®
rSO₂ System



CASMED®
FORE-SIGHT® ELITE†
rSO₂ System

Monitor System			
Weight	900 g / 2 lbs	6.85 kg / 14 lbs	5.9 kg / 13.2 lbs
Maximum channels	6	4	4
Battery life	3 hours (when operating with 2 channels)	20 minutes	30 minutes
Battery design	Lithium ion	Lead-acid	Lead-acid
Battery re-charge time	2.5 hours	24 hours	6 hours
Instant reading	Yes	No*	Yes
Signal processor/pre-amp size (Approx.)	33 cc	318 cc	97 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	1.8 seconds	5–6 seconds	2 seconds
rSO ₂ Sensor			
Cerebral indications	Absolute	Trending only	Absolute
Somatic indications	Yes	Yes	Yes
Wavelengths	4	2	5
Tolerant of ambient light	Yes	No	Unknown
Number of light emitters	2	1	1
Number of light paths	4	2	2
SpO ₂ Sensor			
SpO ₂ accuracy	70-100% ±2 digits‡	n/a	None
SpO ₂ low perfusion accuracy	70-100% ±2 digits‡	n/a	None
Pulse rate accuracy	18-300 BPM ±3 digits‡	n/a	None
Pulse rate low perfusion accuracy	40-240 BPM ±3 digits‡	n/a	None
Warranty Comparison			
Monitor warranty	36 months	12 months	24 months

* Requires signal strength detection

† See Instruction for Use (IFU) for more information on product specifications and testing

‡ 510(k) Summary K123700

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 (rSO₂/SpO₂) 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 (8004CA)
- 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 rSO₂ /SpO₂ universal oximetry system

For more information, visit sensmart.com.

References

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2. MacLeod D, Ikeda, K, Vacchiano C, Lobbstaal 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.

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