EQUANOX™
Cerebral/Somatic Oximetry for Neonatal and Pediatric Patients

The next generation.
For the next generation.
“NIRS [near-infrared spectroscopy] has been shown in multiple prospective observational studies to identify circulatory inadequacy in specific organ systems, such as the brain, kidney, and gut.”¹

“Near-infrared spectroscopy (NIRS), a non-invasive optical technology, can be utilized at the bedside to monitor brain oxygenation to detect tissue hypoxia-ischemia, allowing for early intervention and potential prevention of permanent injury.”²

“Near-infrared spectroscopy monitoring of patients with hypoplastic left heart syndrome awaiting palliation provides noninvasive assessment of oxygen delivery and simplified management, with reduced use of controlled ventilation and inspired gas.”³

Cerebral and somatic oximetry is gaining traction as a way to protect your most vulnerable patients.

Physicians around the world are turning to cerebral/somatic oximetry as a means of identifying circulatory inadequacy in critical organ systems. Now Nonin Medical, a leader in noninvasive medical monitoring, has taken this technology a significant step forward with the introduction of a system designed specifically for neonatal and pediatric patients.
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 EQUANOX Advance Cerebral/Somatic Oximetry System effectively isolates targeted tissue and automatically takes into account the light attenuation changes caused by myelination variation, 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 oximetry systems utilize different-sized sensors or manual entering of patient age and weight in order to function on neonatal/infant/pediatric patients.

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

Infants of the same age can be very different developmentally.

*Patent-pending*
Accuracy calibrated and validated by prospective, multi-center, clinical data on more than 80 neonatal/pediatric patients.

The EQUANOX System with Nonin’s Dynamic Compensation™ algorithm was proven to provide superior results after undergoing stringent analysis in a large clinical setting, providing supporting data for clearance.

Study Description

In a study conducted jointly at Cincinnati Children’s Hospital, Stanford University Medical Center, the Children’s Hospital of Philadelphia and Duke University Medical Center, 86 children, including infants and neonates weighing less than 40 kg were monitored with Nonin’s EQUANOX Advance pediatric sensors during catheterization for congenital heart disease (CHD). The study goal was to calibrate and validate the EQUANOX Advance 8004CB and 8004CB-NA sensors on actual CHD patients. The study achieved the objective of absolute accuracy.

Study Results

“The Nonin EQUANOX Regional Oximeter System with EQUANOX Advance 8004CB [Series] sensor accurately measures the absolute value of cerebral saturation in children over a wide range of oxygenation levels, and may offer advantages in the detection of tissue hypoxia-ischemia in CHD over other devices. ... Age, skin color and hematocrit did not affect these values.”

The results were presented at the 2012 Society of Thoracic Surgeons meeting, followed by a presentation at the 2012 Society of Pediatric Anesthesiologists meeting. Acceptance received by peer-reviewed journal.

In the validation portion of Nonin’s study, 44 subjects between the ages of 4 days and 10 years had simultaneous arterial and jugular bulb samples analyzed by co-oximetry. SavO₂ levels ranged from 45% to 95%. Cerebral oxygen values were taken at the same time with the EQUANOX 8004CB Sensor Series. EQUANOX rSO₂ readings were within 5.9A rms of invasive SavO₂.
Nonin’s exclusive EQUANOX technology reduces inaccuracies caused by light scattering effects from non-target 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 EQUANOX Advance 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:
Nonin’s EQUANOX Advance Sensor

FIGURE 4:
Competitors’ Sensors

Only Nonin EQUANOX uses two emitters and two detectors to provide cerebral cortex measurements that are minimally affected by intervening tissue or surface effects.

Other sensors use one emitter and two detectors (examples include CASMED FORE-SIGHT® and Covidien INVOS®)
“The INVOS demonstrates a relatively short distance between its near and far field detectors compared with the EQUANOX, and consistent with our hypothesis, this appears to be insufficient to appropriately distinguish extracranial from cerebral tissue.”

“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 light path…”

**FIGURE 5:**
Percent Change from the Baseline Regional Cerebral Oxygen Saturation Measurement of FORE-SIGHT, INVOS 5100C-PB, and EQUANOX Classic 7600, After Occlusion of the Head Cuff for 5 Min.

<table>
<thead>
<tr>
<th>Device</th>
<th>Percent Change (%)</th>
<th>Standard Deviation</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>FORE-SIGHT</td>
<td>11.8 ± 5.3</td>
<td></td>
<td>p = 0.0487</td>
</tr>
<tr>
<td>INVOS</td>
<td>16.6 ± 9.6</td>
<td></td>
<td>p = 0.025</td>
</tr>
<tr>
<td>EQUANOX Classic 7600</td>
<td>6.8 ± 6.0</td>
<td></td>
<td>p = 0.0019</td>
</tr>
</tbody>
</table>

P values of interdevice statistical analyses are also shown. Error bars represent the standard deviations.
Finally. Cerebral/somatic oximetry technology designed specifically for neonatal/pediatric patients. (And the clinicians who care for them.)

Until now, neonatal and pediatric cerebral/somatic oximetry technology has been a bit of an oxymoron. Some systems are reduced-size versions of adult technology. The EQUANOX Advance 8004CB Series sensor is different. It has been designed from the ground up as a solution for neonatal/pediatric patients.

A neonatal/pediatric sensor that was not born as an adult.

Some cerebral/somatic oximetry used in the OR, CICU and NICU rely on adult light path spacing housed in smaller sensor “shells.” EQUANOX Advance 8004CB and 8004CB-NA sensors feature light emitter/detector spacing that has been engineered and tested for neonate/infant/pediatric patients. This light path spacing is designed to reach, but not pass through, the vascularized cerebral cortex.

No data entry required.

Some traditional cerebral/somatic oximetry systems require a step for entering patient age and weight to compensate for the variability in pediatric cerebral tissue (e.g., CASMED FORE-SIGHT). But age and weight are rough measures for calculating tissue variance. Nonin’s Dynamic Compensation™ algorithm makes this step unnecessary and provides confidence that the data is patient specific. You simply place the sensor and instantly see the values. The displayed signal refreshes every 1.4 seconds; so, if the tissue saturation is changing, you will see it quickly.

A monitor that is 85% lighter than other models.

Transport and easy positioning of monitoring systems are integral components of caring for neonates, infants and pediatric patients. The EQUANOX monitor is optimized for transport, weighing only two pounds.
EQUANOX Advance Sensors for Patients

< 40 kg

MODEL 8004CB/CB-NA

- For all patients < 40 kg
- Absolute accuracy with Dynamic Compensation™ algorithm
- Depth of measurement ~ 12.5 mm
- Choose adhesive (black) or non-adhesive (blue)

> 40 kg

MODEL 8004CA

- For all patients > 40 kg
- Absolute accuracy
- Depth of measurement ~ 20 mm

The adhesive, size and shape of things to come.

In addition to pediatric-specific light paths and algorithms, the EQUANOX Advance Model 8004CB Series sensor size, shape and adhesive were designed for neonatal and pediatric patients. The sensor is available in highly conformable, adhesive and non-adhesive configurations to accommodate the delicate skin encountered with neonates and infants.

One sensor that accommodates all patients < 40 kg.

To compensate for differences in body weight and size, some traditional oximetry systems for patients < 40 kg require the choice of different sensor sizes. Nonin's Dynamic Compensation allows the EQUANOX system to provide accurate readings with one size of sensor.

Somatic placement — options for clinical flexibility.
Compare cerebral/somatic oximetry systems.
Feature for feature.

<table>
<thead>
<tr>
<th>Channels and Wavelengths</th>
<th>Nonin Medical® Model 7600 Regional Oximetry System</th>
<th>Covidien® INVOS® System</th>
<th>CASMED® FORE-SIGHT® Oximeter System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximum channels</td>
<td>4</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Wavelengths</td>
<td>4</td>
<td>2</td>
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<tr>
<th>Monitor Specifics</th>
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<tbody>
<tr>
<td>Weight</td>
<td>2 lbs. / 900 g</td>
<td>14 lbs. / 6.85 kg</td>
<td>14 lbs. / 6.85 kg</td>
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<tr>
<td>Battery life</td>
<td>3 hours</td>
<td>20 minutes</td>
<td>1.5 hours</td>
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<td>Battery design</td>
<td>Lithium ion</td>
<td>Lead-acid</td>
<td>Lead-acid</td>
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<tr>
<td>Battery re-charge time</td>
<td>2.5 hours</td>
<td>24 hours</td>
<td>16.5 hours</td>
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<tr>
<td>Instant reading</td>
<td>Yes</td>
<td>No (requires signal strength detection)</td>
<td>No (requires setup before sensor reading)</td>
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<tr>
<td>Data entry required for pediatric use</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
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<tr>
<th>Operational Parameters</th>
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<tr>
<td>Display range of rSO₂</td>
<td>0–100%</td>
<td>15–95%</td>
<td>0–99%</td>
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<tr>
<td>Refresh rate</td>
<td>1.4 seconds</td>
<td>5–6 seconds</td>
<td>2 seconds</td>
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<tr>
<th>Sensor Specifics</th>
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<tr>
<td>Cerebral indications</td>
<td>Trending, Absolute</td>
<td>Trending only</td>
<td>Absolute only</td>
</tr>
<tr>
<td>Somatic indications</td>
<td>Yes*</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td>Tolerant to ambient light</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
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<tr>
<td>Number of light paths</td>
<td>4</td>
<td>2</td>
<td>1–2</td>
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<tr>
<th>Warranty Comparison</th>
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<tr>
<td>Monitor warranty</td>
<td>3 years</td>
<td>12 months</td>
<td>12 months</td>
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* For use with the Model 8004CA, CB and CB-NA Sensor only
The EQUANOX Advance Cerebral/Somatic Oximetry System. An unparalleled combination of form and function.

With the EQUANOX Advance Cerebral/Somatic Oximetry System for neonatal/pediatric patients, your clinical team no longer has to make do with yesterday’s engineering. This system offers absolute accuracy—in either cerebral or somatic positions—regardless of body size, skin color, or features. Just as important, it sets new standards in portability, versatility and ease of use.

Non-adhesive sensors

Sensors  MODEL 8004CB/8004CB-NA
• Pliable foam sensors that conform to patient anatomy.
• Adhesive and non-adhesive sensors to accommodate delicate skin.
• Sensors are extremely immune to the effects of ambient light — no need to cover the exposed sensor and surrounding skin with a light-shielding drape.
Monitor MODEL 7600
• Bright, easy-to-read monitor with 69 hours of data memory.
• Intuitive, easy-to-operate user interface — no data entry required.
• Download software included for easy capture and graphing of case data.
• Fast signal acquisition delivers readings within seconds of start-up.
• Light-weight and pole-mountable for easy portability.

Cables
• Thin cables, shielded from ambient electronic signals for use in a variety of settings.
• Cables come from over the head preventing sideways “torquing” on the sensor cable or pressing against skin surfaces with sideways movement of the head.

Overall
• Lightest and thinnest oximeter system available.
• No required scheduled maintenance.
• Battery life of 3 hours with recharge time of 2.5 hours.
• Durable, rugged design withstands the rigors of handling and transport.
• Bluetooth® wireless technology connectivity and serial data output for greater flexibility in patient data reporting.
Evaluate Nonin’s EQUANOX Advance Cerebral/Somatic Oximetry System for Neonatal and Pediatric Patients

Your Terumo Cardiovascular Systems representative can provide more information about the system or can schedule an evaluation. Contact us today!

www.terumo-medical.com/regionaloximetry
800.521.2818
Nonin Medical: A Leader in Innovative, Noninvasive Medical Monitoring

Nonin Medical is a technology-driven company and a global leader in developing high performance, low cost, easy-to-use noninvasive medical monitoring solutions that improve the quality of people’s lives. Nonin invented NIRS-based fingertip pulse oximeters with the Onyx® 9500, so the move to produce accurate, durable, portable NIRS-based cerebral/somatic oximeters and capnographs was a natural one. Today, Nonin’s innovative sensor and signal processing technologies give millions of clinicians confidence that the numerical values they see reflect their patients’ true physiology. Nonin is headquartered in Plymouth, Minnesota, USA. The company sells its products to consumers, clinicians and OEM customers worldwide. For more information, visit www.noninequanox.com.

References

4. Data on File, Nonin Medical, Inc.