Technology

What are we measuring?

We measure regional tissue oxygen saturation (rSO\textsubscript{2}), the percent of oxygenated blood within a targeted tissue bed under our sensor.

How do we measure rSO\textsubscript{2}?

We use three or four wavelengths of light (depending on the sensor) to measure both oxygenated and deoxygenated hemoglobin, adjusting for potential confounding effects of light scatter and other extraneous chromophores (light absorbing substances) in the tissue bed.

Different spacing of the light emitting diodes/detectors creates different light path depths which allow us to isolate the signal from deep tissue beds while eliminating the impact of signal from the shallow, superficial tissues (referred to as Spatial Resolution). In addition, we further enhance this target tissue focus through a patent-protected, dual light emitter design which doubles the number of light paths analyzed by our algorithm.

Finally, our proprietary algorithm combines the information from all wavelengths and light paths in fractions of a second and converts it to a percent oxygenated hemoglobin value for the targeted deep tissue. The measurement is completely independent of pulsatile flow.

Why do 3 or 4 wavelengths work better than 2?

Two-wavelength NIRS configurations allow a very basic assessment of the hemoglobin oxygen saturation status under the sensor but are documented and claimed to only provide an accurate trend in that saturation status. With only two wavelengths, the ability to adjust for scatter, other tissue chromophores, and individual subject variability is limited. A third wavelength allows a more robust measurement algorithm, and accuracy significantly improves as a result.

Adding a fourth wavelength increases accuracy beyond trending levels to “absolute” levels where you are confidently reporting the actual percent of oxygenated hemoglobin in the targeted tissue. The fourth wavelength also allows the algorithm to do the best job of removing inter-subject variability.

What is the difference between absolute, trending, and “real-time” accuracy?

Absolute and trending accuracy refer to the methodology of how accuracy is assessed in testing. Absolute accuracy is when \textit{individual samples} are compared to a “gold standard.” In trending accuracy a series of samples are compared to a “gold standard” and the accuracy refers to how the changes in a \textit{series of samples} “trend” with the gold standard. In regional oximetry the device is normally compared to jugular bulb and arterial blood samples as measured by a co-oximeter (the “gold standard”). Signal processing capable of absolute accuracy generally has half of the plus/minus variation from “truth” exhibited by signal processing only capable of trending accuracy.

There is no scientific basis for the term “real-time” as applied to accuracy. While Covidien refers to its INVOS technology as having “real-time accuracy”, they have not released or published any accuracy studies to define or support this statement. The term “Real-time accuracy” does not appear in the FDA 510(k) clearance for this device.\textsuperscript{1}
I use cerebral oximetry as a trending monitor. Why is absolute accuracy important?

The significantly greater accuracy of an absolute monitor helps eliminate the non-physiologic fluctuations, lost or no readings, and unusual readings frequently seen on your most difficult patients. Absolute regional oximetry accuracy gives you the confidence that your second-to-second readings are accurate, thereby helping you avoid the potential to over-treat or under-treat your patient. 1-3

EQUANOX sensors have two light emitters. Do I only need to use a single sensor?

The sensor still interrogates only the tissue beneath the sensor. Since physiologic differences can result in unequal left and right perfusion it is best to monitor bilaterally with two sensors.

I already utilize a brain monitor (e.g., BIS or Sedline). Why do I need to use regional oximetry?

The Bispectral Index (BIS) and Sedline monitors measure EEG waves and through algorithmic calculation display a number related to depth of anesthesia. Regional oximetry assesses the supply and demand of oxygen in tissues being monitored. The two sets of information provided by these technologies are very different.

What is your update speed? Why is this important?

The Nonin EQUANOX updates measurements every 1.4 seconds. Our competitors update every 2 seconds (CASMED) or 6 seconds (INVOS). Our rapid update speed is important for noting desaturation events quickly and responding quickly. Within our 1.4 second data update, our algorithm recalculates rSO$_2$ 26 times.

What are your data output capabilities?

The Nonin 7600 features real-time data output via Bluetooth® connectivity or RS232 port. Data from the device are sent once per second. Data output includes all measured regional oximetry parameters and alarms, as well as all alarm settings. Data transfer can occur in one of five available data output formats for compatibility with legacy regional oximetry systems. All data output occurs in ASCII format. 4-5

Can the Nonin EQUANOX 7600 system interface with electronic medical records systems?

The EQUANOX Model 7600 can populate EMR data fields via a Capsule™ interface into:

- Epic Systems EpicCare
- Cerner Millennium®
- Dräger Medical Systems and Siemens Innovian® Critical Care
- GE Healthcare (via Aware and Carescape® gateways in compatibility mode)
- McKesson Anesthesia Care (MAC)
- MEDITECH ClientServer & MAGIC (through Forward Advantage, MEDITECH’s approved third party implementer)
- SAFERSleep®

In addition, Cerner has created a driver for interfacing the EQUANOX System into its EMR. The driver number is Cerner 61032.
Can the Nonin EQUANOX Model 7600 System interface with patient monitoring systems such as Philips and GE?

The EQUANOX Model 7600 will also interface to the Philips IntelliVue MX50-90 series patient monitors via the Philips VueLink or Philips IntelliBridge modules. At this time the VueLink and IntelliBridge modules allow display of key data values.

At this time there is no released interface to GE Monitoring systems. We suggest facilities contact GE directly to request interface of the EQUANOX System to their GE monitoring system, such as through their Unity interface module.

Are EQUANOX Sensors latex free?

Yes. All components of the EQUANOX System and sensors are “not made with natural rubber,” in accordance with the language used per FDA guidance documents. A letterhead statement to this effect is available upon request.

How many times can adhesive sensors be removed and re-applied?

A sensor may be removed and reapplied several times before the adhesive does not allow proper application without additional assistance such as tape or a wrap. Of course, the patient skin condition variability can greatly affect the adhesive’s reapplication effectiveness.

How long are the sensors good for once I apply them to the patient?

There is no specific limit to the length of time a sensor can be used before needing replacement. We recommend that the sensor application site be inspected 15 minutes after application and every 2-4 hours thereafter to ensure correct sensor alignment and skin integrity. The practice of inspecting and changing sensor position and placement should be conducted in accordance with your institution’s standard of care.

Some hospitals think that regional oximetry is too expensive. What studies have been published that document cost savings?

There are several studies that have documented cost savings for hospitals as a result of utilizing regional oximetry in certain areas.

Monitoring Patients

What alarm settings are used for cerebral oximetry?

Most literature describes the use of regional oximetry for a cerebral application. The bulk of this evidence recommends the establishment of a pre-intervention baseline, with alarms set 20-25% below this baseline, or an absolute value of 50.

When using a four-wavelength, absolute accuracy sensor (Model 8004CA) capturing the patient’s pre-induction baseline is not a necessity to achieve parameter accuracy, but is still clinically useful since;

1) baseline settings are needed to auto-set low alarm limits,
2) beginning oxygen saturations can vary between patients, and
3) published literature demonstrates that in cardiac surgery, low baselines can be associated with poor outcome.
Can I just set a single alarm limit for everybody?

The EQUANOX Model 7600 regional oximetry system allows a configuration that defaults to a single alarm value independent of a pre-intervention baseline value.

I have a patient with unusual baseline values (low). What can cause that?

Physiological reasons for low baseline values in an adult patient include conditions causing poor cardiac output such as valve disease or heart failure. Other physiological causes can include carotid disease and cerebral vascular accidents as well as physiological malformations causing reduced perfusion to the monitored tissue. Unusually low, and not necessarily valid, baselines are often reported by users of the competitive 2-wavelength system.13

I have a patient with unusual baseline values. Should I treat based upon what I am seeing?

Regional saturation monitors remain an adjunct monitor of regional hemoglobin oxygen saturation of tissue under the sensor. Readings should be used in conjunction with other methods of assessing a patient’s clinical condition including experienced clinical judgment.4

References:

1. Somanetics 5100C 510(k) market clearance K082327; United Stated Food and Drug Administration; April 3rd, 2009
4. Model 7600 Operators Manual, part no. 7839-001-02_7600
5. Model 7600 Interface Guide, part no. 8060-000-002
6. Model 8004CA Sensor Information for Use, part no. 7727-001-04
7. Model 8004CB Sensor Series Information for Use, part nos. 8924-001-01 and 8924-101-01