

Nonin Customer Frequently Asked Questions

EQUANOX Advance™ Sensor, Model 8004CA

- **How accurate is the Nonin EQUANOX Advance™ Sensor Technology?**

Accuracy of the Nonin EQUANOX Advance Technology is measured in rSO_2 variability to saturation values in venous and arterial blood under the sensor, in a proportion of 70% venous and 30% arterial. The A_{RMS} relative invasive blood draws is $4.1A_{RMS}$.ⁱ

- **What is the difference between trending and absolute?**

A trending device can be used to assess changes in rSO_2 . For example, a baseline measurement should be established. Changes in rSO_2 from this baseline value during the case reflect underlying change in saturation. rSO_2 reading from only one point in time may not reflect the patient's actual condition. There may be certain patients (outliers) who will read high or low, therefore making decisions based solely on single value may be unwarranted.

An absolute device can be used to measure rSO_2 and assess changes in rSO_2 . Most healthy people fall around 60% of rSO_2 at room air. The rSO_2 value at any point in time accurately reflects the underlying saturation. So, the physician has greater confidence in the accuracy of the measurement and the need for intervention. With both devices, clinical judgment, in addition to the rSO_2 readings, is required to completely determine a patient's condition.

- **What studies support absolute cerebral oximetry?**

Since the field of absolute NIRS regional oximetry is new, research is still progressing. Data on Nonin's EQUANOX Advance absolute technology will become available. However there are two published studies, including a survey article in *Seminars in Cardiothoracic and Vascular Anesthesia* (2008; 12:60), and a more recent article on aortic arch replacement in the *Journal of Thoracic and Cardiovascular Surgery* (epub ahead of print 23 June 2010).

- **How does EQUANOX Advance technology compare to FORE-SIGHT® technology?**


Research has shown that some patients don't read with FORE-SIGHT, while EQUANOX Advance always captures a measurement.^{i,ii}

- **What is the clinical algorithm for absolute cerebral application?**

The algorithm for absolute cerebral application is similar to that of trending, except that without a resting baseline, the physician can intervene with greater confidence if the patient falls or presents below about 60% rSO_2 .ⁱⁱⁱ

- **How do I establish a baseline?**

As with a trending device, the baseline is best established with the patient resting comfortably at room air, prior to administration of medication or therapy that might alter hemoglobin saturation, and after the system stabilizes (about 5-7 seconds). However, it should be noted that according to research on the subject, a resting baseline is not as critical with a NIRS system of absolute accuracy.ⁱⁱⁱ With EQUANOX Advance, normal healthy patients do not fall below the 60% rSO_2 range.ⁱ Patients who present with a resting baseline value below 60% rSO_2 should be assumed to already be in a state of limited oxygen reserve, and the physician should consult other parameters immediately to avoid profound desaturation that might lead to cerebral injury.



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- **Is the 8004CA EQUANOX Advance sensor cleared for somatic use?**
Yes, the Model 8004CA sensor can be used anywhere on the body, but should be limited to tissue areas no deeper than 2 cm below the sensor.
- **How is the somatic value different from cerebral?**
Somatic measurements may be different from cerebral, but the difference will vary with patients and their clinical conditions; e.g., peripheral perfusion, cardio-pulmonary by-pass pressure and flow, and temperature.
- **What clinical research supports somatic application?**
There is an extensive compendium of clinical support for use of NIRS in the somatic position, and that material can be supplied on request.
- **Can the Model 8004CA sensor be used in four-channel mode?**
Yes, since the Model 8004CA sensor is cleared for somatic application, it can be used in four-channel mode using Nonin's four-channel monitor, the Model 7600 Regional Oximeter System.
- **If I am already a Nonin EQUANOX user, do I need to replace my existing equipment?**
Yes, the Model 8004CA sensor has a new connector and operates with a new oximetry pod. Please contact your Nonin Representative or call customer service at either of the following numbers: (800) 356-8874 or Nonin Medical AB at +46 650 401500.
- **Does the warranty change?**
No, the monitor, trunk cable and pods are still warranted for three years, except for the battery in the monitor, which is warranted for one year.
- **How long can I leave the sensor on a patient?**
There is no limit on number of hours a sensor can be left on a patient; the IFU advises that the sensor be checked every 2-4 hours to avoid damage to a patient's skin.
- **Does near-infrared light generated by the LED in EQUANOX sensors burn the skin?**
No, the LEDs do not generate perceptible heat. The instructions for use advise to inspect the sensor application site(s) at least every 2 to 4 hours to ensure correct sensor alignment and skin integrity. Patient sensitivity to the sensor's adhesive may vary due to medical status or skin condition.

Nonin Medical: Innovative Leaders in Noninvasive Physiological Monitoring

Nonin Medical is a technology-driven company and a global leader in developing noninvasive medical monitoring solutions that improve the quality of people's lives and enable them to live their lives to the fullest. We do this by developing low-cost, high-quality, easy-to-use technologies that empower clinicians to make better decisions and individuals to proactively manage their health.

References:

- QATR1587 Calibration and Validation of the Non-Invasive Regional Oximeter System
- QATI1749 Regional Oxygen Saturation (rSO₂) Verification of Repeatability and Comparability of the 8004CA Sensor
- Fischer G; *Sem Cardiothorac Vasc Anesh* 2008; 12:60