Instructions for Use—English

℞ Only CE 0123

Model 8004CA Single-Patient Use, Non-Sterile, Disposable Regional Oximetry Sensor with EQUANOX™ Technology

Indications for Use

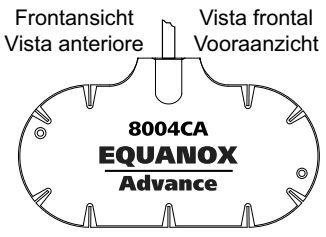
The Model 8004CA single-patient use, non-sterile, disposable sensor is intended for use as an absolute real-time adjunct monitor of regional hemoglobin oxygen saturation (rSO_2) of blood underneath the sensor of adult and pediatric patients weighing ≥ 88 pounds (40 kilograms). The sensor may be repositioned or replaced with another 8004CA sensor without baseline re-establishment.

Refer to the oximetry system's operator's manual for all use environments.

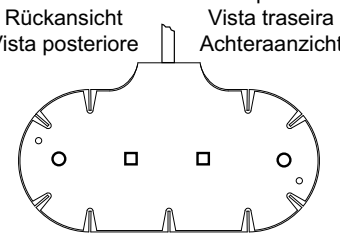
Warnings:

- Do not use the device in an MR environment, in an explosive atmosphere, or in the presence of flammable anesthetic compounds.
- This device is only defibrillation proof per IEC 60601-1 when used with the X-100SP signal processor or 7600PA oximetry pod.
- 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 may vary due to medical status or skin condition.
- Avoid excessive pressure to the sensor application site(s) as this may cause damage to the skin beneath the sensor.
- The use of sensor and oximeter combinations other than Nonin-branded products have not been tested for accuracy as a system and may affect performance of the system.
- The 8004CA sensor is only compatible with systems using EQUANOX technology. Refer to the Parts and Accessories List on the system operator's manual CD for a complete listing of Nonin-branded sensors, parts, and accessories. Patient injury can result from the use of non-compatible combinations.
- This device is intended only as an adjunct device in patient assessment. It should not be used as the sole basis for diagnosis or therapy decisions. It must be used in conjunction with other methods of assessing clinical signs and symptoms.

Front view
Vue avant
Frontansicht
Vista anteriore
Vista frontal
Vista frontal
Vooraanzicht



Back view
Vue arrière
Rückansicht
Vista posteriore
Vista posterior
Vista traseira
Achteraanzicht



Sensor Front and Back Views
Vue avant et arrière du capteur
Front- und Rückansicht des Sensor
Viste anteriore e posteriore del sensore
Vistas frontal y posterior del sensor
Vistas frontal e traseira do sensor
Voor- en achteraanzicht

⚠ Cautions:

- Do not use a damaged sensor. If the sensor is damaged, discontinue use immediately.
- Ensure all pulse oximeter sensors are kept a minimum of 6 cm (2.7 in.) away from all regional oximeter sensors.
- As with all medical equipment, carefully route patient cables and connections to reduce the possibility of entanglement or strangulation.
- The Model 8004CA is designed for single-patient use and should not be reused. Reuse may cause unreliable readings and, if a disposable sensor is used on two patients, there is a risk of cross-contamination.
- Do not clean, sterilize, autoclave, or immerse in liquid of any kind.
- The sensor is designed for external use over intact skin, outside of the sterile field.
- EQUANOX interrogates a small volume of tissue in areas such as the frontal cerebral cortex and is not necessarily reflective of simultaneous saturation values in other tissue areas.
- In order to avoid erroneous readings, ensure all cable connections are correct and secure.
- Cutting or modifying the sensor may result in inaccurate readings.
- Follow local governing ordinances and recycling instructions regarding disposal or recycling of the sensor and any components.
- A functional tester cannot be used to assess the accuracy of the 8004CA sensor.
- Refer to the system operator's manual for additional warnings and cautions.
- This device is designed to determine regional hemoglobin oxygen saturation of blood underneath the sensor. Factors that may degrade performance or affect the accuracy of the measurement include the following:
  - excessive ambient light or direct sunlight
  - excessive motion
  - electrosurgical interference
  - metal plate or other foreign object in sensor path
  - moisture on skin
  - improperly applied sensor
  - placement over bony prominence
  - incorrect sensor type
  - skin barriers used between sensor and patient skin
  - anemia or low hemoglobin concentrations
  - cardiogreen or other intravascular or tissue dyes
  - carboxyhemoglobin and other dyshemoglobins
  - hemoglobinopathies
  - billirubinemia and/or icterus (jaundice)
  - non-normocapnic conditions or other conditions that affect blood volume
- The value of data from the system has not been demonstrated in specific disease states, under conditions of hemoglobinopathies, in clinical conditions that may affect blood volume, or under hypocapnic and hypercapnic conditions.
- Avoid adjacent placement of non-Nonin branded NIRS sensors to prevent loss of monitoring or erroneous readings.

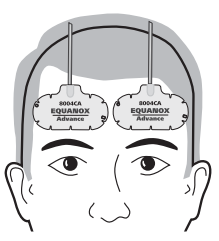
Symbols:

Symbol	Definition of Symbol
	Follow Instructions for Use
	CAUTION!
CE 0123	CE Marking indicating conformance to EC Directive No. 93/42/EEC concerning medical devices
	Do Not Reuse
LOT	Lot Number
IP32	Protected against vertically falling water drops when enclosure is tilted up to 15 degrees and ingress of solid foreign objects greater than or equal to 2.5 mm in diameter per IEC 60529.
	Type BF Applied Part
	Defibrillation Proof Type BF Applied Part (patient isolation from electrical shock when connected to a signal processor or pod)

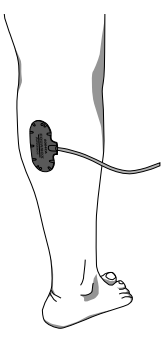
Symbol	Definition of Symbol
	RoHS Compliant (China)
NON STERILE	Non-sterile
EC REP	Authorized Representative in the European Community.
	Use By
SN	Serial number
REF	Catalogue number
QTY	Quantity
	Indicates separate collection for waste electrical and electronic equipment (WEEE)
	Storage/shipping temperature range
℞ Only	Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner.
	Manufacturer

Sensor Site Examples
Exemples de site de capteur
Beispiele für Anlegestellen
Esempi di posizioni del sensore
Ejemplos de sitios del sensor
Exemplos do local do sensor
Voorbeelden sensorlocaties

A



B

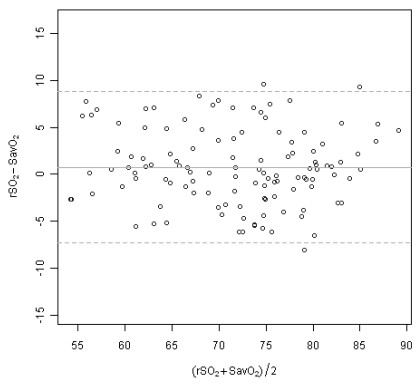


Applying the Regional Sensor(s)

1. *Signal Processor or Pod Site(s) and Cable Pathways.* Select an appropriate site to locate the signal processor or oximetry pod. The ideal site avoids the patient's body resting on the signal processor or pod or the signal processor or pod pulling unnecessarily on the sensor. Ensure all cable pathways are clear and unencumbered.
2. *Removal from Packaging and Pre-check.* Carefully remove the sensor from the plastic pouch and uncoil the sensor cable. Check the sensor for any sign of damage in transport. If signs of damage are found, replace the sensor.
3. *Cerebral Site.* Select the site(s) on the patient's forehead lateral of the superior sagital sinus, superior to the eyebrow and inferior to the hairline (see example in figure A). The area(s) should be free of hair or surface blemishes such as moles or freckles. Avoid placing the sensor(s) over nevi, sinus cavities, hematomas, or arteriovenous malformations.
4. *Somatic Site(s).* Select the site(s) that provides optimal access to desired tissue (see example in figure B).
5. *Skin Preparation.* Gently cleanse the patient's skin with isopropyl alcohol to remove oils, makeup, or soil that might interfere with adhesive or block light. Ensure the skin is thoroughly dried.
6. *Sensor Placement.* Remove the protective backing from the sensor pad and gently, but firmly, place the sensor(s) on the desired site(s) (see examples at left). Ensure sensor surface adheres to the skin to prevent light from traveling between emitting or receiving elements or ambient light from entering. **Note:** An improperly placed sensor may result in inaccurate readings.
7. *Sensor Connections.* Firmly insert the sensor connector into the signal processor or pod. If applicable, engage the sensor lock on the signal processor. **Note:** Consult the system operator's manual for signal processor connection to the hub and monitor or pod connection to the trunk cable and monitor.
8. Verify proper operation as described in the system operator's manual. Verify the sensors are connected as needed for the desired system configuration and that the displayed data correctly correlates with the sensor application site.

Note: rSO_2 values and trend lines should begin within seconds. If these measurements are not clearly identified or alarm conditions are generated, consult the Troubleshooting section of the system operator's manual.

Specifications



rSO_2 Accuracy (A_{rms}*): 50% to 100% rSO_2

Accuracy	Right	Left	Both	Hypercapnia	Hypocapnia
Absolute	4.1	3.8	3.9	5.1	3.3
Trend	1.9	3.0	2.5	3.4	3.8

Range	95% Limits of Agreement (rSO_2)
50 – 100%	(-7.34, 8.75)

rSO_2 accuracy testing was conducted during induced hypoxia studies on healthy, non-smoking, light- to dark-skinned subjects in an independent research laboratory. The measured regional hemoglobin saturation value (rSO_2) of the sensors was compared to arterial/venous hemoglobin oxygen ($SavO_2$) value, determined from venous and arterial blood samples. The model used for blood in the brain was 70% venous and 30% arterial, which is applicable under normocapnic conditions. The venous blood was drawn from the right jugular bulb. The accuracy of the sensors in comparison to the blood gas analyzer samples measured over the rSO_2 range of 45–100%. Accuracy data was calculated using the root-mean-squared (A_{rms} value) for all subjects, per ISO 80601-2-61:2011, Medical Electrical Equipment—Particular requirements for basic safety and essential performance of pulse oximeter equipment.

Inter/Intra Sensor Repeatability Accuracy: ±2 digits (A_{rms}*)

Temperature:

Operating:	-5 °C to 40 °C (23 °F to 104 °F)
Storage/Transportation:	-30 °C to 70 °C (-22 °F to 158 °F)

Humidity:

Operating:	10 % to 90 % non-condensing
Storage/Transportation:	10 % to 95 % non-condensing

* ±1 A_{rms} encompasses 68% of the population.

Measurement Wavelengths and Output Power**

730 nanometers @ 3.0 mW maximum average power
760 nanometers @ 4.5 mW maximum average power
810 nanometers @ 3.2 mW maximum average power
880 nanometers @ 4.5 mW maximum average power

** This information is especially useful for clinicians performing photodynamic therapy.

Compliance

This product complies with ISO 10993-1.

Sensor adhesive properties are guaranteed up to the Use By date.

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