Instructions for Use—English

℞ Only CE 0123

Model 8006CA Reusable, Regional Oximetry Sensor and Model 8006PI Single Patient Use, Disposable Patient Interface

For use only with Nonin SenSmart™ Oximetry Technology

Indications for Use

The Model 8006CA reusable, non-sterile, regional oximetry 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 and/or the patient interface may be repositioned or replaced with another 8006CA sensor without baseline re-establishment.

Nonin's Model 8006PI single patient use, non-sterile disposable patient interface is designed for use with Nonin's Model 8006CA sensor.

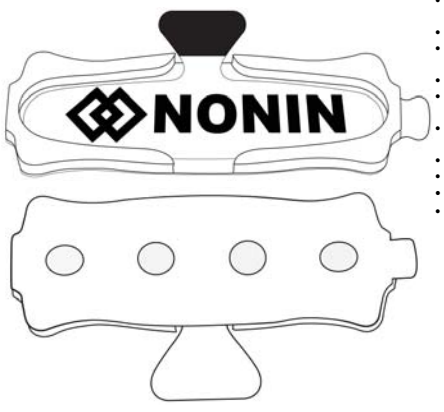
Refer to the oximetry system's operator's manual for all use environments.

Warnings:

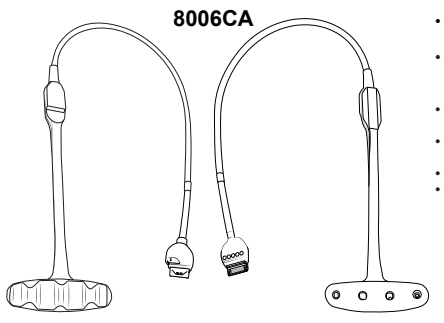
- Do not use the device in an MR environment, in an explosive atmosphere, or in the presence of flammable anesthetic compounds.
- This device is only defibrillation proof per *IEC 60601-1* when used with the Nonin SenSmart technology signal processor.
- Inspect the sensor application site(s) at least every 2 to 4 hours to ensure correct sensor alignment and skin integrity. Patient sensitivity to the 8006CA/8006PI 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 8006CA sensor is only compatible with systems using SenSmart 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.
- The use of sensor and oximeter combinations other than SenSmart technology products have not been tested for accuracy as a system and may affect performance of the system.
- 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 and Back Views
Vues avant et arrière
Vorder- und Rückansicht
Panoramica anteriore e posteriore
Vista frontal y trasera
Vistas frontal e traseira
Voor- en achteraanzicht

8006PI



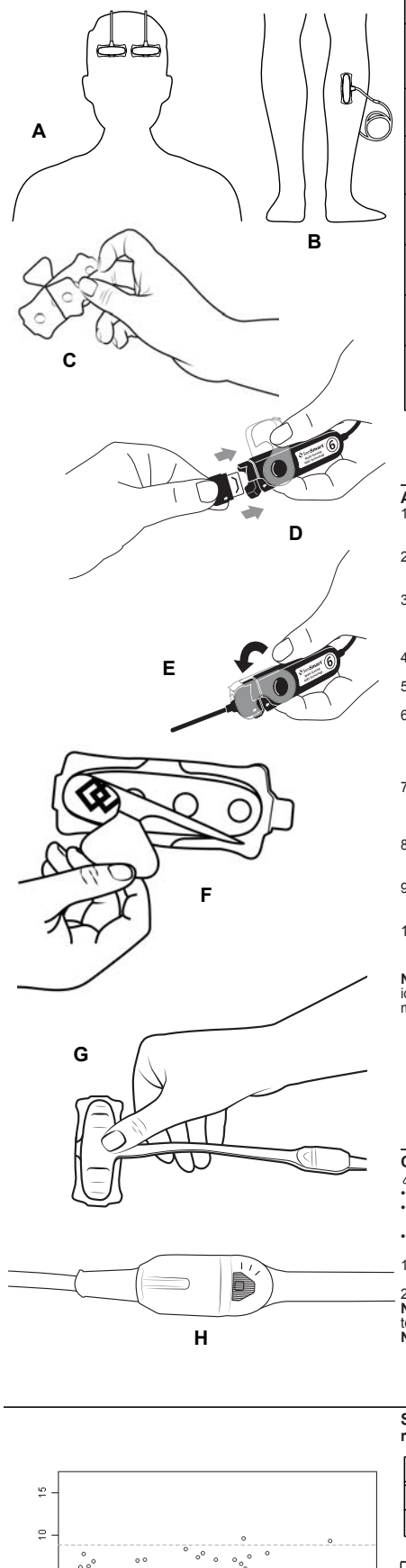
8006CA



⚠ 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.
- Clean the reusable sensor before applying it to a new patient.
- Do not sterilize, autoclave, or immerse the sensor in liquid of any kind. Do not pour or spray any liquids onto the sensor.
- Do not use caustic or abrasive cleaning agents on the sensor. Do not use any cleaning solution other than those recommended here, as permanent damage could result.
- As with all medical equipment, carefully route patient cables and connections to reduce the possibility of entanglement or strangulation.
- The sensor and patient interface are designed for external use over intact skin, outside of the sterile field.
- SenSmart 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.
- Damaging the sensor and patient interface, by cutting, modifying, folding, creasing, or writing on the sensor with anything other than a felt-tip marker, may result in inaccurate readings or loss of 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 8006CA sensor.
- Refer to the oximetry system's operator's manual for additional warnings and cautions.
- Refer to the oximetry system's operator's manual for ingress protection.
- 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 the device 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
  - residue (e.g., dried blood, dirt, grease, oil) in the light path
- Environments with excessive ambient light, such as high intensity operating room lighting, may require an opaque drape placed between the lights and the sensor.
- 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.
- Do not store the 8006PI next to magnets or in areas of magnetic fields where the magnetic field strength is greater than 100 gauss (10mT).
- Refer to package labeling for expiration dating on 8006PI.
- The Model 8006PI is designed for single-patient use and should not be reused. Reuse may cause unreliable readings, and if an 8006PI is used on two patients, there is a risk of cross-contamination.

Sensor and Patient Interface
Capteur et interface patient
Sensor und Patienteninterface
Sensore e interfaccia paziente
Sensor e interfaz para el paciente
Sensor e interface do doente
Sensor en patiëntinterface



Symbols:

Symbol	Definition
	Follow Instructions for Use
	CAUTION!
CE 0123	CE Marking indicating conformance to EC Directive No. 93/42/EEC concerning medical devices
	Do Not Discard (8006CA)
	Do Not Reuse (8006PI)
LOT	Lot Number
EC REP	Authorized Representative in the European Community.
	Type BF Applied Part
	Defibrillation Proof Type BF Applied Part (patient isolation from electrical shock when connected to a signal processor.

Symbol	Definition
	Non-sterile
	Use By (8006PI)
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
US	Country of Manufacturer

Applying the Regional Sensor(s)

1. *Signal Processor and Cable Pathways.* Select an appropriate site to locate the signal processor. The ideal site avoids the patient's body resting on the signal processor or the signal processor pulling unnecessarily on the sensor. Ensure all cable pathways are clear and unencumbered.
2. *Removal from Packaging and Pre-check.* Open the plastic pouch by tearing along the perforation (blue dashes). Carefully remove and check the patient interface for any sign of damage in transport. If signs of damage are found, replace the patient interface.
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. Avoid placing the patient interface(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. *Patient Interface Placement.* Remove the protective backing from the patient interface using tab on side of 8006PI and gently, but firmly, place the patient interface(s) on the desired site(s) (see examples at *Figure C*). Ensure patient interface 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 (*Figure D*). Engage all applicable sensor locks (*Figure E*). **Note:** Consult the system operator's manual for signal processor connection to the hub and monitor. Sensor light at midpoint of cable will turn amber, signaling proper connection to hub.
8. *Mating Sensor to Patient Interface.* Remove protective liner on sensor side of patient interface using blue tab (*Figure F*). Place sensor firmly into interface (*Figure G*). Sensor light will turn green verifying proper mating (*Figure H*).
9. Verify proper operation as described in the system operator's manual. Verify the sensors are connected as required for the desired system configuration and that the displayed data correctly correlates with the sensor application site.
10. *Sensor/Patient Interface Removal.* Remove sensor from patient interface, and dispose of patient interface. Clean sensor according to instructions provided. **Note:** Do not dispose of 8006CA reusable sensor.

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.

Cleaning the Reusable Sensor

⚠ Cautions:

- Clean the reusable sensor before applying it to a new patient.
- Do not sterilize, autoclave or immerse the sensor in liquid of any kind. Do not pour or spray any liquids onto the sensor.
- Do not use caustic or abrasive cleaning agents on the sensor. Do not use any cleaning solution other than those recommended here, as permanent damage could result.

1. To clean the sensor, wipe all surfaces with a soft cloth dampened with a 10% bleach/90% water solution (household bleach [containing less than 10% sodium hypochlorite]).
2. Allow the sensor to dry thoroughly before reusing.

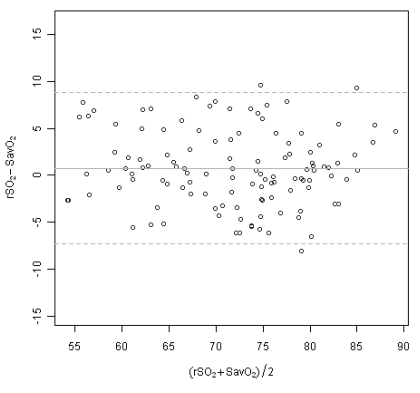
NOTE: To minimize cable deterioration when cleaning the cable, gently wipe away from the plug end towards the sensor end.
NOTE: The 8006PI is not reusable and is intended for single patient use only.

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 male and female, over 18 years of age, healthy, 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)

Device temperature will not exceed 41 °C as measured during a controlled environment test.

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

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

Magnetic Field Strength (8006PI):
Less than 1 gauss (0.1T) at a distance of 12cm.

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.

Warranty
The Model 8006CA sensor is warranted for 6 months from delivery.
The Model 8006PI adhesive properties are guaranteed up to the Use By date.
Nonin reserves the right to make changes and improvements to these Instructions for Use and the product it describes at anytime, without notice or obligation.

Nonin Medical, Inc.
13700 1st Avenue North
Plymouth, MN 55441, USA

nonin.com

Phone: +1 (763) 553-9968
(800) 356-8874 (US and Canada)
+31 (0)13 - 79 99 040 (Europe)

E-mail: info@nonin.com
infointl@nonin.com (Europe)

EC REP
MPS, Medical Product Service GmbH
Borngasse 20
D-35619 Braunfels, Germany

113338-000-03