Instructions for Use—English

CE 0123

Model 8000FI Infant/Pediatric Fiber Optic Pulse Oximeter Sensor

⚠ Caution:
- Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner.

Intended Use

The Nonin Model 8000FI Infant/Pediatric Fiber Optic Sensor is intended for use with Nonin's Fiber Optic Pulse Oximeters, for spot-checking or continuous monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate in a Magnetic Resonance (MR) environment.

Note: *Because the fiber optic sensors and cables contain no conductive components, they can safely be placed on the patient's toe while inside an MR (magnetic resonance) environment.*

Contraindication:

- Do not use this device on neonatal patients.

Warnings:

- Do not use a damaged sensor.
- As with all medical equipment, carefully route patient cables and connections to reduce the possibility of entanglement or strangulation.
- The fiber cable for the sensor is extremely sensitive and must be handled with caution at all times.
- The connector that attaches to the monitor must be kept outside the 200 Gauss line of the MR field and firmly secured to the monitor.

⚠ Cautions:
- The sensor might not work on cold extremities due to reduced circulation. Warm or rub the toe to increase circulation, or reposition the sensor.
- Do not sterilize, autoclave, or immerse this device in any liquid.
- Do not use caustic or abrasive cleaning agents or any cleaning products containing ammonium chloride on this device.
- Inspect the sensor application site at least every 6 to 8 hours to ensure correct sensor alignment and skin integrity. Patient sensitivity to sensors and/or adhesive strips may vary due to medical status or skin condition.
- Follow local, state and national governing ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries. Use only Nonin-approved battery packs.
- In compliance with the European Directive on Waste Electrical and Electronic Equipment (WEEE) 2002/96EC, do not dispose of this product as unsorted municipal waste. This device contains WEEE materials; please contact your distributor regarding take-back or recycling of the device. If you are unsure how to reach your distributor, please call Nonin for your distributors contact information.
- A functional tester cannot be used to assess the accuracy of a pulse oximeter sensor.
- This device is designed to determine the percentage of arterial oxygen saturation of functional hemoglobin. Factors that may degrade pulse oximeter performance or affect the accuracy of the measurement include the following:
  - excessive ambient light
  - excessive motion
  - electrosurgical interference
  - blood flow restrictors (arterial catheters, blood pressure cuffs, infusion lines, etc.)
  - moisture in the sensor
  - improperly applied sensor
  - incorrect sensor type
  - poor pulse quality
  - venous pulsations
  - anemia or low hemoglobin concentrations
  - cardiogreen and other intravascular dyes
  - carboxyhemoglobin
  - methemoglobin
  - dysfunctional hemoglobin
  - artificial nails or nail polish
  - a sensor not at heart level

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
LOT	Lot Number
MR	MR Conditional Symbol
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.

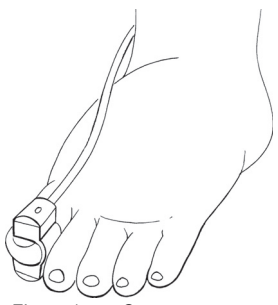

Figure 1 Sensor
Figure 1 Capteur
Abbildung 1 Sensore
Figura 1 Sensore
Figura 1 Sensor
Figura 1 Sensor
Afbeelding 1 Sensor

Attaching the Model 8000FI Infant/Pediatric Fiber Optic Sensor:

1. Before applying the sensor, remove nail polish, as it may unnecessarily reduce light transmission.
2. Place the sensor strap between the large toe and the second toe (Figure 1). Vertically align the emitter bundle directly opposite the detector bundle. Avoid any configuration that would allow emitted light to bypass the toe.
3. Overwrap the sensor and foot with Nonin Model 8000TW Sensor Wrap. To ensure excessive ambient light does not affect sensor performance, other wraps or tapes are not recommended.
4. Secure the cable to the ankle with adhesive tape, relieving strain on the sensor from the cable. Ensure that the tape securing the cable does not restrict blood flow.

Note: *If the sensor is not positioned properly, light may bypass the tissue and result in SpO_2 inaccuracies. Proper sensor application is critical for optimal performance.*

Note: *Use care when applying or removing the 8000TW sensor wrap to, and removing it from, the Model 8000FI sensor. The sheathing material protecting the glass fibers (located in the area between the dotted lines in Figure 2) is fragile and can easily be damaged.*

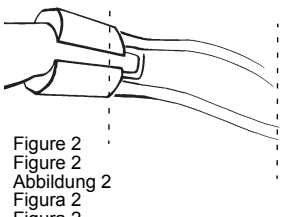

Figure 2
Figure 2
Abbildung 2
Figura 2
Figura 2
Figura 2
Afbeelding 2

Verifying Operation

Allow at least 1 minute for the system to stabilize after the sensor has been properly applied and the patient is at rest. After stabilization, verify that the system is operating properly by:
- Ensuring that the sensor is applied to the toe as described above.
- Observing the Pulse Strength Bar Graph is blinking green at a rate and rhythm corresponding to the patient's pulse for at least 3 minutes.
- Observing that the SpO_2 and pulse rate displays are stable and displaying values expected for the patient.

If the following are observed, reposition the sensor or move the sensor to a different toe, following steps 1 – 4 of Applying the Sensor.
- The Pulse Strength Bar Graph is blinking yellow or red.
- The Pulse Strength Bar Graph, pulse rate display, or SpO_2 display are functioning inconsistently.

If unable to verify operation, do not use the pulse oximeter. Contact Nonin for assistance.

Cleaning the Reusable Sensor

⚠ Cautions:
- Clean the sensor before applying it to a new patient.
- Unplug the sensor from the pulse oximeter before cleaning.
- Do not sterilize, autoclave, or immerse the sensors in liquid of any kind. Do not pour or spray any liquids into the sensor.
- Do not use caustic or abrasive cleaning agentson the sensors. Do not use cleaning agents containing ammonium chloride.

1. Clean the sensor with a soft cloth dampened with a mild detergent or a 10% bleach/90% water solution (household bleach [containing less than 10% sodium hypochlorite]). Ensure that all tape residue is removed.
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.*

Accuracy

SpO_2: 70 to 100% ±2 digits (A_{rms}*). Additional accuracy and performance information can be found in the respective pulse oximeter manual.
Pulse Rate Accuracy: ±3 digits (BPM)
*±1 A_{rms} represents approximately 68% of measurements.

Measurement Wavelengths and Output Power**

Red:	660 nanometers @ 0.8 mW maximum average
Infrared:	910 nanometers @ 1.2 mW maximum average

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

Compliance

This product complies with ISO 10993-1.
Not made with natural rubber latex.

Warranty

The 8000FI is warranted for 90 days from delivery.

Nonin Medical, Inc.
13700 1st Avenue North
Plymouth, MN 55441-5443 USA

nonin.com

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

Fax: +1 (763) 553-7807
+31 (0)13 - 79 99 042 (Europe)

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

Authorized EC Representative:
MPS, Medical Product Service GmbH
Borngasse 20
D-35619 Braunfels, Germany

1447-001-09