Instructions for Use—English

CE 0123

Model 8000Q2 Ear Clip Pulse Oximeter Sensor

Indications for Use

The Nonin Model 8000Q2 Ear Clip Sensor is designed for patients weighing greater than 88 pounds (40 kilograms) where fingertip monitoring is impractical. The recommended application site is the ear lobe.

Note: *Ear clip sensors generally do not perform as well as sensors applied on the fingers.*

Rx Only **CAUTION:** Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner.

Warnings:

- Do not use the device in an MRI environment, in an explosive atmosphere, or on infant or neonatal patients.
- This device is not defibrillation proof per IEC 60601-1.
- 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. Refer to Nonin pulse oximeter operator's manuals for a complete listing of Nonin-branded oximeters, sensors, and accessories.
- Inspect the sensor application site at least every 4 hours to ensure correct sensor alignment and skin integrity. Patient sensitivity to sensors may vary due to medical status or skin condition.
- Avoid excessive pressure to the sensor application site as this may cause damage to the skin beneath the sensor.

⚠ Cautions:

- Do not use a damaged sensor. If the sensor is damaged, discontinue use immediately.
- Do not sterilize, autoclave or immerse in liquid of any kind.
- Do not use caustic or abrasive cleaning agents on the sensor.
- 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 a pulse oximeter monitor or sensor.
- Ear clip sensors are not recommended for pediatric patients less than 88 pounds (40 kilograms) or neonatal use.
- Remove earrings from the patient's ear before applying the ear clip sensor.
- Refer to the pulse oximeter operator's manual for additional warnings and cautions.
- Factors that may degrade pulse oximeter performance include the following:
  - excessive ambient light
  - excessive motion
  - electrosurgical interference
  - moisture in the sensor
  - improperly applied sensor
  - carboxyhemoglobin
  - methemoglobin
  - incorrect sensor type
  - poor pulse quality
  - venous pulsations
  - anemia or low hemoglobin concentrations
  - cardiovascular dyes
  - dysfunctional hemoglobin
  - residue (e.g., dried blood, dirt, grease, oil) in the light path

Symbols:

Symbol	Definition
	Follow Instructions for Use.
	CAUTION!
CE 0123	CE Marking indicating conformance to EC Directive No. 93/42/EEC concerning medical devices
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.
EC REP	Authorized representative in the European Community.
	Indicates separate collection for waste electrical and electronic equipment (WEEE)

Symbol	Definition
	Storage/shipping temperature range
US	Country of manufacture
	Manufacturer
	Date of manufacture
REF	Catalogue number
LOT	Lot number
QTY	Quanity
	RoHS compliant (China)
Rx Only	Medical prescription required

1

Attaching the Ear Clip Sensor

1. Rub the ear lobe vigorously for at least 5 seconds.
2. Apply the ear clip sensor to the lobe of the ear (Figure 1). Ensure that the ear clip sensor is positioned so the light emitter and light detector are completely covered by the earlobe. This ensures that no ambient light bypasses the earlobe, which can cause SpO_2 inaccuracies.

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

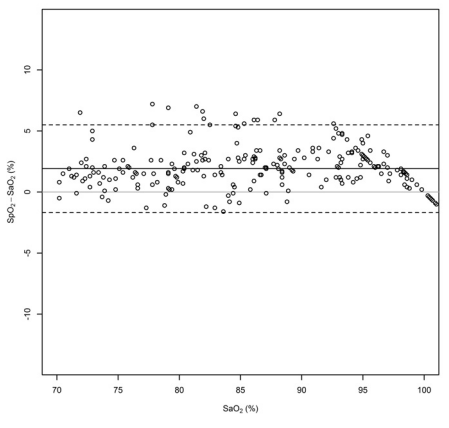
Cleaning the Reusable Sensor

⚠ **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 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 cleaning agents containing ammonium chloride.

1. To clean the sensor, wipe all patient contact surfaces with a soft cloth dampened with mild detergent or 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.*



Specifications

SpO_2 Accuracy[1, 2, 3]:

Range	Oxygen Saturation (A_{rms}*)
70 – 100%	±3
70 – 80%	±3
80 – 90%	±4
90 – 100%	±3

SpO_2 Low Perfusion Accuracy: 70 % to 100 % ±2 digits (A_{rms}*)[1]
Pulse Rate Accuracy: 40 to 240 BPM ±3 digits (A_{rms}*)[1]
Pulse Rate Low Perfusion Accuracy: 40 to 240 BPM ±3 digits (A_{rms}*)[1]
Temperature: [4, 5]
Operating: -20 °C to 50 °C (-4 °F to 122 °F)
Storage/Transportation: -40 °C to 70 °C (-40 °F to 158 °F)
Humidity: [4, 5]
Operating: 10 to 95% non-condensing
Storage/Transportation: 10 to 95% non-condensing

* ±1 A_{rms} encompasses 68% of the population at zero bias.
[1] SpO_2 accuracy was conducted during induced hypoxia study on healthy subjects over the range of 70 % to 100 %.
[2] Accuracy specifications based on Nonin's PureSAT® SpO_2 technology and PureLight® sensor technology.
[3] Additional accuracy and performance information can be found in the sensor accuracy document on the operator's manual CD.
[4] For combined oximeter/sensor specifications, refer to the applicable oximetry system's operator's manual.
[5] Range as tested with Nonin's PureSAT SpO_2 technology.

Measurement Wavelengths and Output Power**

Red: 660 nanometers @ 0.8 mW nominal
Infrared: 910 nanometers @ 1.2 mW nominal

** 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

90 days from the date of delivery.
The sensor's expected service life is 90 days.

Nonin reserves the right to make changes and improvements to these instructions and the product it describes at anytime, without notice or obligation.

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)

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

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