Instructions for Use—English

CE 0123

Model 8000SX, 8000SX-WO, 8000SX-WO2 Reusable Soft Pulse Oximeter Sensors

Indications for Use

Nonin's Model 8000SX-Series Reusable Soft Sensors are indicated for non-invasive spot-checking and/or continuous monitoring of adult and pediatric patients who are well or poorly perfused. It is intended for use in environments including operating room, surgical recovery, critical care, emergency room, long-term care, home use, and mobile environments.

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

Contraindications:

- Do not use the device in an MR environment or in an explosive atmosphere.
- This device is not defibrillation proof per IEC 60601-1 clause 17h.

Warnings:

- 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 6 to 8 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.

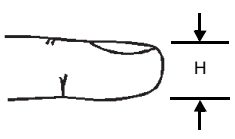
⚠ Cautions:

- 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.
- As with all medical equipment, carefully route patient cables and connections to reduce the possibility of entanglement or strangulation.
- 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
  - blood flow restrictors (arterial catheters, blood pressure cuffs, infusion lines, etc.)
  - incorrect sensor type
  - poor pulse quality
  - venous pulsations
  - anemia or low hemoglobin concentrations
  - cardiovascular dyes
  - dysfunctional hemoglobin
  - artificial nails or fingernail polish
  - residue (e.g., dried blood, dirt, grease, oil) in the light path

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
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.
	Storage/shipping temperature range (if applicable)
	Storage/shipping humidity range (if applicable)
℞ Only	Medical prescription required

Choosing the Appropriate Sensor

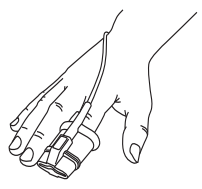


Use the measurements provided below to determine which sensor should be used. Sensor recommendations are based on digit height (thickness), as indicated at left.

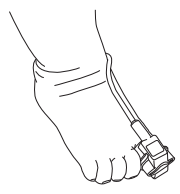
- For heights between 0.5 and 1.0 in. (12.5 – 25.5 mm), use the Model 8000SL (Large).
- For heights between 0.4 and 0.75 inches (10 – 19 mm), use the Model 8000SM (Medium).
- For heights between 0.3 and 0.5 inches (7.5 – 12.5 mm), use the Model 8000SS (Small).

Attaching the Sensor

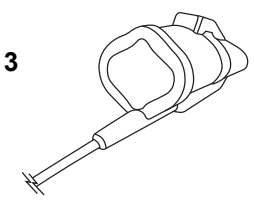
1



2



3



1. Insert the selected digit (refer to the sizing recommendations above) into the sensor as illustrated in Figures 1 and 2. The patient's digit must reach the end of the sensor.
2. Direct the cable along the patient's finger/toe, parallel to the arm/leg. *(Optional: Secure the sensor cable as needed.)*
3. Connect the sensor cable to the pulse oximeter or to the patient cable.
4. Verify proper operation as described in the pulse oximeter operator's manual.

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.*

Note: *The 8000SX-WO2 sensor is compatible with the WristOx$_2$, Model 3150. It is also compatible with Nonin's Model 3100 and 4100 oximeters when used with the 3150WI adapter.*

Cleaning the Sensors

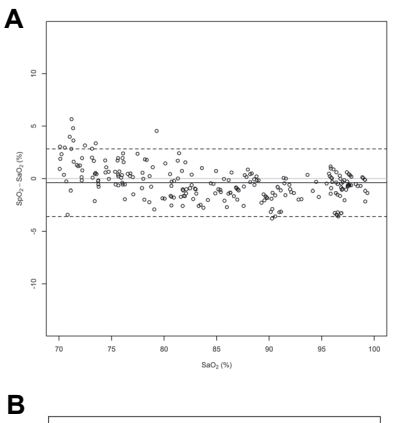
⚠ Cautions:

- 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. Use of these chemicals may shorten the life of the product.

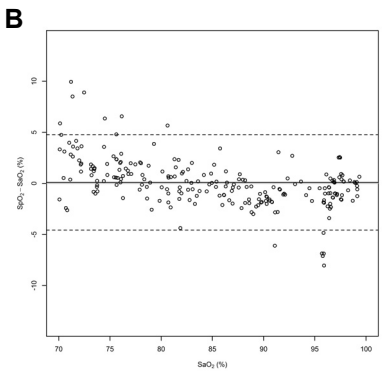
1. To clean the sensor, wipe all patient contact surfaces with a soft cloth dampened with a mild detergent or a 10% bleach/90% water solution (household bleach [containing less than 10% sodium hypochlorite]). *Reference sensor in Figure 3.*
2. Allow the sensor to dry thoroughly before reusing.

Note: *To minimize cable deterioration when cleaning the cable, gently wipe away from the plug end towards the sensor end.*

A



B



Specifications

SpO_2 Accuracy (Adults/Peds)[1, 2]:

Range	Oxygen Saturation (A_{rms}*) (figure A)	Motion Oxygen Saturation (A_{rms}*) (figure B)
70 – 100%	±2	±3
70 – 80%	±2	±3
80 – 90%	±2	±2
90 – 100%	±2	±2

SpO_2 Low Perfusion Accuracy: 70% to 100% ±2 digits (A_{rms}*)[1]

Pulse Rate Accuracy: 18 to 300 BPM ±3 digits (A_{rms}*)[1]

Pulse Rate Low Perfusion Accuracy: 40 to 240 BPM ±3 digits (A_{rms}*)[1]

Temperature: [3, 4]

Operating:	0 °C to 40 °C (32 °F to 104 °F)
Storage/Transportation:	-40 °C to 70 °C (-40 °F to 158 °F)

Humidity: [3, 4]

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

* ±1 A_{rms} encompasses 68% of the population.
[1] Additional accuracy and performance information can be found in the sensor accuracy document on the operator's manual CD.
[2] Accuracy specifications based on Nonin's PureSAT® SpO_2 technology and PureLight® sensor technology.
[3] For combined oximeter/sensor specifications, refer to the applicable oximetry system's operator's manual.
[4] 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

2 years from the date of delivery.
The device's expected service life is 2 years.

Nonin reserves the right to make changes and improvements to this Instructions for Use and the product it describes at anytime, without notice or obligation.

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