



Instructions for Use—English

Model 8008J Infant Flex Sensor and Model 8008JFW Infant FlexiWrap® Single Use Sensor Wrap

Indications for Use

Nonin's Model 8008J Infant Flex Sensor is designed for extended duration monitoring on the large toe or foot of infants and neonates weighing 2 to 20 kilograms, where fingertip monitoring is impractical and sensor motion may occur.

The Nonin Model 8008JFW Infant FlexiWrap is designed for use with the Model 8008J Infant Flex Sensor. The preferred application site for infants is the large toe of the right foot. Other sites may not give acceptable results because of inadequate perfusion or light transmission.

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 MR environment.
- Use only with Nonin pulse oximeters. These pulse oximeters are manufactured to meet the accuracy specifications for Nonin sensors. Using other pulse oximeters may cause improper sensor performance. Refer to Nonin pulse oximeter operator's manuals for a complete listing of compatible 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:

- To prevent improper performance and/or patient injury, verify sensor and pulse oximeter compatibility before use.
- Do not use a damaged sensor. If the sensor is damaged in any way, discontinue use immediately and replace the sensor.
- Discontinue use if the patient exhibits allergic reactions to the adhesive material.
- Do not stretch the adhesive tape while applying the sensor. This may cause inaccurate readings or skin blisters.
- Do not use caustic or abrasive cleaning agents on the sensors.
- Do not autoclave or immerse in liquid of any kind.
- 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.
- 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
 - arterial catheters, blood pressure cuffs, infusion lines, etc.
 - moisture in the sensor
 - improperly applied sensor
 - carboxyhemoglobin
 - methemoglobin
 - artificial nails
 - incorrect sensor type
 - poor pulse quality
 - venous pulsations
 - anemia or low hemoglobin concentrations
 - cardiovascular dyes
 - sensor not at heart level
 - dysfunctional hemoglobin
 - fingernail polish
 - residue (e.g., dried blood, dirt, grease, oil) in the light path

Symbols:

Symbol	Definition	Symbol	Definition
	Follow Instructions for Use		Storage/shipping temperature range
	CE Marking indicating conformance to EC Directive No. 93/42/EEC concerning medical devices		Indicates separate collection for waste electrical and electronic equipment (WEEE)
	Do Not Reuse (8008JFW FlexiWrap only)		Catalogue number
	Use By (8008JFW FlexiWrap only)		Quantity
	RoHS Compliant (China)		Date of manufacture
	Lot Number		Manufacturer
	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.		Country of manufacture
			Medical prescription required
			Authorized representative in the European Community

Applying the Infant FlexiWrap to the 8008J Infant Flex Sensor

- Grasp the blue tab on the Infant FlexiWrap. Peel the paper backing halfway, as shown. Fold the unpeeled portion of the FlexiWrap back underneath the paper backing.
- The Infant FlexiWrap has cutouts that match the shape of the Nonin Model 8008J Infant Flex Sensor. Carefully align the sensor with the cutouts on the adhesive side of the FlexiWrap, using the edge of the FlexiWrap as a guide. Then press the sensor firmly against the FlexiWrap.
- Align the sensor cable with the notch in the FlexiWrap to stabilize the cable.
- Remove and discard the paper backing.

Attaching the FlexiWrap and Sensor

- Place the FlexiWrap/Sensor assembly on the bottom of the large toe of the right foot. If impossible, position the sensor around the foot. (When placing the sensor on the foot, position the sensor as far forward near the toes as is practical. Place the light emitter portion on the top side of the foot, and the detector on the bottom.)
- Note:** Sensor placement on the big toe is preferred, as this placement provides better light transmission than foot placement.
- Use the center line mark (indicated by the black arrow in Figure 1) as a guide for aligning the light emitter and light detector. Ensure that the light detector is centered on the bottom of the toe and the light emitter is located directly opposite on the toe nail.
- Wrap the FlexiWrap around the toe as indicated by the arrow in Figure 2, taking care to ensure that the detector and emitter remain aligned and directly opposite each other.
- Fold the top flap down over the top of the toe, securing the FlexiWrap in place.
- If necessary, re-align the sensor cable with the notch in the FlexiWrap.
- Optional:** For best results, secure the sensor cable independently from the sensor with medical tape. Ensure that the tape securing the cable does not restrict blood flow.

Note: If the sensor is not positioned properly, light might bypass the tissue and result in SpO₂ inaccuracies. Proper sensor placement is critical for good performance.

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.
- To clean the sensor, wipe all patient contact surfaces with a soft cloth dampened with a 10% bleach/90% water solution (household bleach [containing less than 10% sodium hypochlorite]).
 - Ensure that all tape residue is removed.
 - 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.

The 8008JFW FlexiWrap sensor wrap is not reusable and is intended for single use only.

Specifications

SpO₂ Accuracy: 1, 2, 3

Range	Oxygen Saturation (A _{rms} *)
70 – 100%	±3
70 – 80%	±3
80 – 90%	±2
90 – 100%	±2

SpO₂ 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 Additional accuracy and performance information can be found in the sensor accuracy document on the operator's manual CD.

² Accuracy testing was performed under no-motion conditions.

³ Accuracy specifications based on Nonin's PureSAT® SpO₂ technology and PureLight® sensor technology.

⁴ For combined oximeter/sensor specifications, refer to the applicable oximetry system's operator's manual.

⁵ Range as tested with Nonin's PureSAT SpO₂ technology.

Measurement Wavelengths and Output Power**

Red: 660 nanometers @ 3 mW nominal

Infrared: 910 nanometers @ 3 mW nominal

** This information is especially useful for clinicians.

Compliance

This product complies with ISO 10993-1.

Not made from natural rubber latex.

Warranty

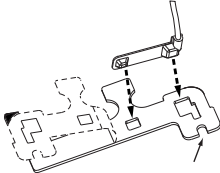
The 8008J is warranted for 90 days from delivery.

The sensor's expected service life is 90 days.

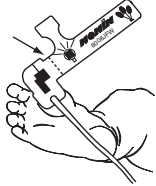
Nonin reserves the right to make changes and improvements to these instructions and the product it describes at anytime, without notice or obligation.



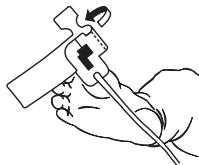
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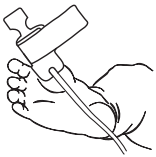
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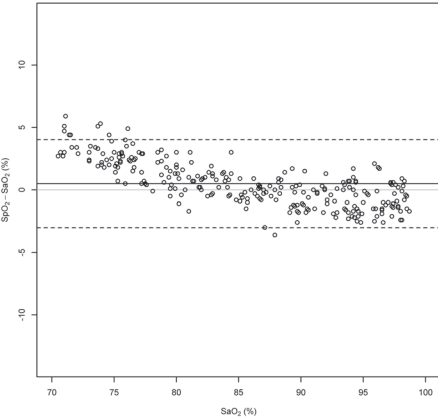
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