Instructions for Use—English

Model 8001J Neonatal Flex Sensor and Model 8001JFW Neonatal FlexiWrap® Single Use Sensor Wrap

Indications for Use

Nonin's Model 8001J Neonatal Flex Sensor is designed for extended duration monitoring on the foot of neonates (weighing less than 2 kilograms), where fingertip monitoring is impractical and sensor motion may occur.

The Model 8001JFW Neonatal FlexiWrap Sensor Wrap is designed for use with Nonin's 8001J Neonatal Flex Sensor. The preferred application site for neonates is the outstep of the left foot, directly under the toes. Other sites may not give acceptable results because of inadequate perfusion or inadequate light transmission.

℞ 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 MR environment or in an explosive atmosphere.
- 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.

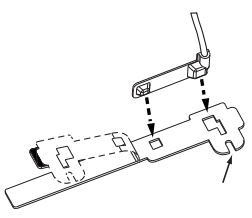
⚠ Cautions:

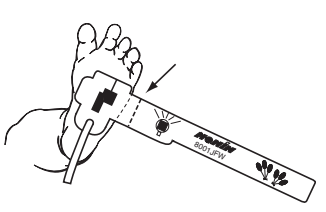
- To prevent improper performance and/or patient injury, verify sensor and pulse oximeter compatibility before use.
- Do not use a damaged sensor. If the sensor is damaged in any way, discontinue use immediately and replace the sensor.
- Discontinue use if the patient exhibits allergic reactions to the 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

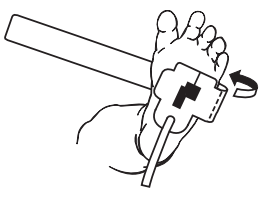
Symbols:

Symbol	Definition
	Follow Instructions for Use
CE 0123	CE Marking indicating conformance to EC Directive No. 93/42/EEC concerning medical devices
	Do Not Reuse (8001JFW FlexiWrap only)
	Use By (8001JFW FlexiWrap only)
	RoHS Compliant (China)
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.

Symbol	Definition
	Storage/shipping temperature range
	Indicates separate collection for waste electrical and electronic equipment (WEEE)
REF	Catalogue number
QTY	Quantity
	Date of manufacture
	Manufacturer
US	Country of manufacture
℞ Only	Medical prescription required
EC REP	Authorized representative in the European Community







Applying the Neonatal FlexiWrap to the 8001J Neonatal Flex Sensor

1. Grasp the blue tab on the Neonatal FlexiWrap. Peel the paper backing halfway, as shown. Fold the unpeeled portion of the FlexiWrap back underneath the paper backing.
2. The Neonatal FlexiWrap has cutouts that match the shape of the Nonin Model 8001J Neonatal Flex Sensor. Carefully line up 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.
3. Align the sensor cable with the notch in the FlexiWrap to stabilize the cable.
4. Remove and discard the paper backing.

Attaching the FlexiWrap and Sensor

1. Carefully position the adhesive side of the FlexiWrap/Sensor assembly on the outstep of the left foot (preferably), directly under the toes. Make sure that the dashed line printed on the FlexiWrap is on the side of the foot. (This positioning helps align the light emitter and light detector correctly.)
2. Wrap the FlexiWrap around the sides of the foot, taking care to ensure that the light detector and light emitter remain aligned and directly opposite each other.
3. If necessary, re-align the sensor cable with the notch in the FlexiWrap.
4. *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 SpO_2 inaccuracies. Proper sensor placement is critical for good performance.*

Cleaning the Reusable Sensor

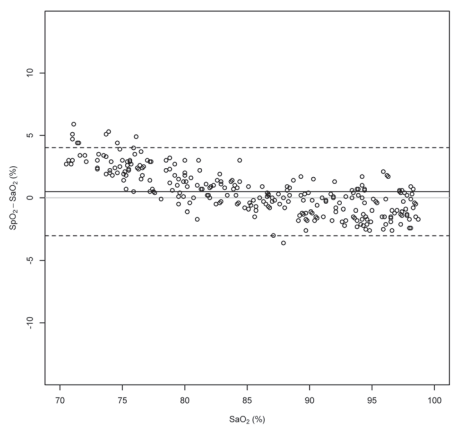
⚠ **Cautions:**

- 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.

1. 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]).
2. Ensure that all tape residue is removed.
3. 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 8001JFW FlexiWrap sensor wrap is not reusable and is intended for *single use only*.



Specifications

SpO_2 Accuracy: [1, 2, 3]

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

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] 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® SpO_2 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 SpO_2 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.
Not made with natural rubber latex.

Warranty

The 8001J 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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