Instructions for Use—English

Model 8000J, 8000J-WO, and 8000J-WO2 Reusable Adult Flex Pulse Oximeter Sensor and Model 8000JFW FlexiWrap® Single Use Sensor Wrap

Indications for Use

Nonin's Model 8000J, 8000J-WO and 8000J-WO2 Adult Flex Sensors are designed for continuous monitoring of adult and pediatric patients (weighing more than 20 kilograms) in which sensor motion might occur.

Nonin's Model 8000JFW Adult FlexiWrap adhesive wrap is designed for applying Nonin's Model 8000J, 8000J-WO and 8000J-WO2 Adult Flex Sensors.

Warnings:

- 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 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:

- Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner.
- 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.
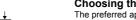- Do not use caustic or abrasive cleaning agents on the sensors.
- Do not autoclave or immerse in liquid of any kind.
- Follow local governing ordinances and recycling instructions regarding disposal or recycling of the sensor and any components.
- A functional tester cannot be used to assess the accuracy 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 of Symbol
(icon)	Follow Instructions for Use
C E 0123	CE Marking indicating conformance to EC Directive No. 93/42/EEC concerning medical devices
⊗	Do Not Reuse (8000JFW FlexiWrap only)
(hourglass)	Use By (8000JFW 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.
(WEEE icon)	Indicates separate collection for waste electrical and electronic equipment (WEEE)
(thermometer)	Storage/shipping temperature range

Choosing the Sensor Application Site

The preferred application site for adults is the index finger. However, other fingers or toes may be used where the tissue thickness is between 5 and 21 millimeters (dimension "A" in Figure 1). Other sites may not give acceptable results because of inadequate light transmission or perfusion.

Attaching the Adult Flex Sensor and FlexiWrap

1. Grasp the blue tab on the FlexiWrap, and peel away the paper backing just far enough to apply the Flex Sensor (see Figure A).
2. Place the FlexiWrap, printed side down, onto a table or other hard, smooth surface.
3. Position the Flex Sensor into the cutouts on the adhesive side of the FlexiWrap (see Figure B).
4. Press the sensor firmly onto the adhesive, and fully remove the paper backing.
5. Position the tip of the finger between the notches on the FlexiWrap (see Figure C).
6. Wrap the side flaps of the FlexiWrap around the sides of the finger.
7. Pull the FlexiWrap with the sensor over the tip of the finger, and adhere the wrap to the top and side of the finger (see Figure D).
8. Wrap the long flap of the FlexiWrap around the entire finger. Do not wrap too tightly and restrict blood flow (see Figure E).
9. Optional: For best results, secure the sensor cable independently from the sensor with medical grade tape, preferably around the base of the finger. Make sure that the tape 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.

Note: The 8000J-WO2 sensor is compatible with the WristOx₂, Model 3150. It is also compatible with Nonin's Model 3100 and 4100 oximeters when used with the 3150WI adapter.

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 8000JFW FlexiWrap sensor wrap is not reusable and is intended for *single use only.*

Accuracy

70 to 100% ±3 digits (A$_{rms}$*). Additional accuracy and performance information can be found in the sensor accuracy document on the operator's manual CD.

* A$_{rms}$ encompasses 68% of the population.

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 8000J, 8000J-WO and 8000J-WO2 Adult Flex Sensors are warranted for 90 days from delivery.