



Model 8000AP Pediatric Finger Clip Pulse Oximeter Sensor

Indications for Use

The Nonin Model 8000AP Pediatric Finger Clip Sensor is designed for spot checking or short-term continuous monitoring of pediatric patients where little sensor motion is expected.

Contraindications:

- This product is contraindicated for use in the presence of Magnetic Resonance Imaging (MRI) devices.

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.

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, do not use, or discontinue use immediately.
- 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.
- 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 probe.
- 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
 - ingernail polish
 - residue (e.g., dried blood, dirt, grease, oil) in the light path

Symbols:

Symbol	Definition of Symbol
	Follow Instructions for Use
	CAUTION!
	CE Marking indicating conformance to EC Directive No. 93/42/EEC concerning medical devices
	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.

Choosing the Appropriate Sensor

The 8000AP sensor is designed for use on the fingers of patients weighing between 8 and 30 kilograms, where the finger tissue thickness is between 5 and 13 millimeters (dimension "H" in Figure A). If excessive sensor motion is occurring, use the Model 8008J Infant Flex Sensor.

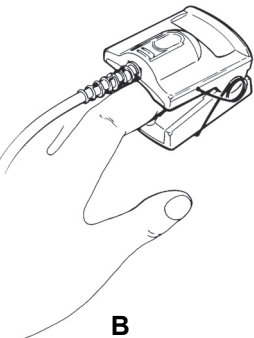


Attaching the Pediatric Finger Clip Sensor

- Insert a finger (preferably the index, middle, or ring finger) into the Pediatric Finger Clip Sensor (Figure B) until the end of the finger reaches the finger stop. Keep the finger nail facing the sensor top (as shown in Figure B). Ensure that long fingernails do not interfere with proper finger position.
- For the best results when using the sensor for short-term continuous monitoring, secure the sensor cable independently from the sensor with medical tape, preferably around the base of the finger. Make sure that the tape securing the cable does not restrict the blood flow.

The thumb is not recommended for use with the Pediatric Finger Clip Sensor.

Note: Proper sensor placement is critical for good performance. If the sensor is not positioned properly, light may bypass the tissue and result in SpO₂ 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 sensors in liquid of any kind. Do not spray any liquids into the sensor. Do not sterilize with ETO.
- Do not use caustic or abrasive cleaning agents on the sensors. Do not use cleaning agents containing ammonium chloride or isopropyl alcohol.

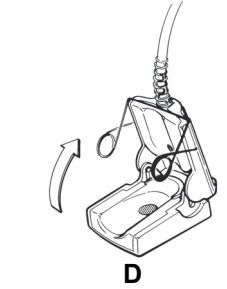
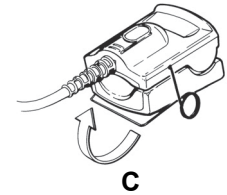
- To aid in cleaning the sensor, remove the spring from the slot on the bottom of the sensor (Figure C), and then rotate the spring forward as shown in Figure D.

Note: The spring **must** be disengaged from the bottom slot before opening the sensor 90°, or the spring will be damaged.

- 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]). Ensure that all tape residue is removed.

- Allow the sensor to dry thoroughly before reusing.
- Reverse the steps shown in Figures C and D to reattach the sensor spring.

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



SpO₂ Accuracy

70 – 100% ±2 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.
Not made with natural rubber latex.

Warranty

1 year from the date of delivery.