Instructions for Use—English

Model 6000CI/7000I
Infant Disposable Single-Patient Use Pulse Oximeter Sensor

⚠ Cautions:

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

Indications for Use

Nonin's Models 6000CI and 7000I Single-Patient Use Disposable Pulse Oximeter Sensors are indicated for non-invasive spot-checking and/or continuous monitoring of infant patients who are well or poorly perfused, weighing greater than 4 pounds (2 kilograms). It is intended for use in environments including operating room, surgical recovery, critical care, emergency room, long-term care, home use and mobile environments.

Contraindications:

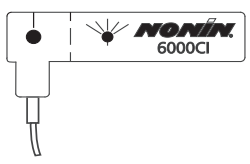
- Do not use the device in an MR environment or in an explosive atmosphere.
- This device is not defibrillation proof per IEC 60601-1:1990 clause 17h.

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
  - fingernail polish



Emitter
Émetteur
Emitter
Dispositivo di emissione
Emisor
Emissor
Lichtbron

Detector
Détecteur
Detektor
Rivelatore
Detector
Detector
Detector

Center Line
Ligne centrale
Mittellinie
Linea mediale
Línea central
Linha Central
Middellijn

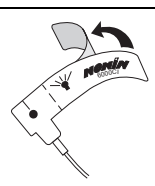
Symbols:

Symbol	Definition of Symbol
	Follow Instructions for Use
CE 0123	CE Marking indicating conformance to EC Directive No. 93/42/EEC concerning medical devices.
	CAUTION!
	Do Not Reuse
EC REP	Authorized Representative in the European Community
	Manufacturer
LOT	Lot Number
	Use By
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.
	Indicates separate collection for waste electrical and electronic equipment (WEEE)
	Storage/shipping temperature range

Choosing the Sensor Application Site

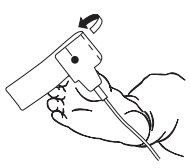
The preferred application site for infants is the large toe. Other sites may not give acceptable results because of inadequate light transmission or perfusion.

A

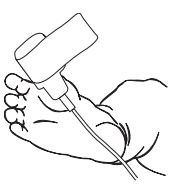


B

C



D



E

Attaching the Infant Disposable Sensor:

1. Carefully peel away and discard the adhesive backing (figure A).
2. Place the sensor light detector on the bottom of the large toe as shown in figure B.
3. Wrap the tape around the toe (figures C, D, and E). When wrapping the tape, ensure the light detector is centered on the bottom of the toe and the light emitter is on the toe nail, directly opposite the light detector. The center line may be used as an alignment guide and should be on the side of the toe.
4. For best results, use medical tape to secure the sensor cable independently from the sensor (figure E). Ensure the tape securing the cable does not restrict blood flow.

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.*

Specifications

SpO_2 Accuracy: 70 % to 100 % ±2 digits (A_{rms}*)[1, 2, 3]

SpO_2 Low Perfusion Accuracy: 70 % to 100 % ±2 digits (A_{rms}*)[3]

Pulse Rate Accuracy: 18 to 321 BPM ±2 digits (A_{rms}*)[3]

Pulse Rate Low Perfusion Accuracy: 40 to 240 BPM ±2 digits (A_{rms}*)[3]

* ±1 Arms encompasses 68 % of the population.
[1]SpO2 accuracy was conducted during induced hypoxia study on healthy subjects over the range of 70 % to 100 %.
[2]Accuracy specifications based on testing with Models 2500/2500A and 9600.
[3]Additional accuracy and performance information can be found in the pulse oximeter operator's manual.

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 with natural rubber latex.

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