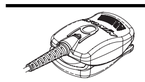
NONIN

CE 0123 ⚠ *Instructions for Use—English*

IPOD® Integrated Pulse Oximetry Device



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

Indications for Use

The Nonin IPOD® Integrated Pulse Oximetry Device is designed to measure pulse rate and oxygen saturation in adult patients. The sensor is designed for use on the fingers of patients weighing more than 30 kilograms, where the finger tissue is between 5 and 21 millimeters.

Contraindications

- Do not use the device in an MR environment, in an explosive atmosphere, or on infant or neonatal patients.

Warnings

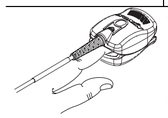
- As with all medical equipment, consult your host device manufacturer's instructions for correct product integration, environmental and electrical safety requirements.
- Carefully route patient cables and connections to reduce the possibility of patient entanglement or strangulation.
- This device should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device should be observed carefully to verify normal operation.
- Operation of this device below the minimum amplitude of 0.3% modulation may cause inaccurate results.

⚠ Cautions

- Do not use a damaged device. If the device is damaged, discontinue use immediately.
- Inspect the sensor application site at least every four hours to ensure correct sensor alignment and skin integrity. Patient sensitivity to sensors may vary due to medical status or skin condition.
- Do not sterilize, autoclave, or immerse in liquid of any kind.
- Do not use caustic or abrasive cleaning agents on the device. Do not use cleaning agents containing ammonium chloride.
- A functional tester cannot be used to assess the accuracy of this device.
- Refer to the host device manufacturer's operator's manual for additional warnings. and cautions.
- Factors that may degrade pulse oximeter performance include the following: • Fluctuating or excessive ambient light • Excessive motion • Electrosurgical interference • Moisture in the sensor • Improperly applied sensor • Carboxyhemoglobin • Methemoglobin • Incorrect Sensor type • Poor pulse quality • Venous pulsations • Dysfunctional hemoglobin • Nail polish or artificial nails • Cardiogreen / other Intravascular dyes • Anemia or low hemoglobin concentrations
- This device is designed to determine the percentage of arterial oxygen saturation of functional hemoglobin. Significant levels of dysfunctional hemoglobin may affect measurement accuracy.
- Attaching the IPOD sensor to the same side as blood pressure cuffs, infusion lines, or arterial catheters may affect the device's performance.
- The device may not work when circulation is reduced. Warm or rub the finger, or re-position the device.
- In some circumstances, the device may interpret motion as good pulse quality. Minimize patient motion as much as possible.
- A flexible circuit connects the two halves. Do not twist or pull the flexible circuit or overextend the device's spring.
- This equipment complies with International Standard EN 60601-1-2:2004 for electromagnetic compatibility for medical electrical equipment and/or systems. This standard is designed to provide reasonable protection against harmful interference in a typical medical installation. However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in healthcare and other environments, it is possible that high levels of such interference due to close proximity or strength of a source might disrupt the performance of this device. Medical electrical equipment needs special precautions regarding EMC, and all equipment must be installed and put into service according to the EMC information specified in this manual.
- Portable and mobile RF communications equipment can affect medical electrical equipment.
- Follow local, state and national governing ordinances and recycling instructions regarding disposal or recycling of the device and device components.
- In compliance with the European Directive on Waste Electrical and Electronic Equipment (WEEE) 2002/96/EC, do not dispose of this product as unsorted municipal waste. This device contains WEEE materials; please contact your distributor regarding take-back or recycling of the device. If you are unsure how to reach your distributor, please call NONIN® for your distributor's contact information.

Symbols:

Symbol	Definition of Symbol
	Consult Instructions for Use
⚠	CAUTION!
CE 0123	CE Marking indicating conformance to EC Directive No. 93/42/EEC concerning medical devices
	Type BF Applied Part (patient isolation from electrical shock)
SN	Serial number
	Non-ionizing electromagnetic radiation. Interference may occur in the vicinity of equipment marked with symbol.
	Indicates separate collection for electrical and electronic equipment (WEEE)
EC REP	Authorized Representative in the European Union
IP32	Enclosure degree of ingress protection

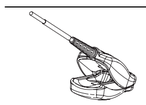


Attaching the IPOD

1. Insert a finger (preferably the index, middle, or ring finger) into the IPOD until the end of the finger reaches the finger stop. Keep the fingernail facing the sensor top, and ensure that long fingernails do not interfere with proper sensor position.
2. For best results when using the device for short-term continuous monitoring, secure the device cable with medical tape, preferably around the base of the finger. Make sure that the tape securing the cable does not restrict blood flow.

Note: *The IPOD does not contain natural rubber latex.*
Note: *The thumb is not recommended for use with the IPOD.*
Note: *Proper sensor placement is critical for good performance.*

⚠ **Caution:** Attaching the IPOD sensor to the same side as blood pressure cuffs, infusion lines or arterial catheters may affect the device's performance.



Cleaning the IPOD

To clean the IPOD, wipe all patient contact surfaces with a soft cloth dampened with a mild detergent or isopropyl alcohol. Do not pour or spray any liquids onto the device. Allow it to dry thoroughly before reuse.

Note: *Do not open the IPOD more than 90°, or it may be damaged; do not twist or pull on the device when cleaning. The illustration at the left shows the appropriate opening of the case for cleaning.*

⚠ **Cautions:** •Unplug the IPOD from the host device before cleaning.•Do not sterilize, autoclave, or immerse the IPOD in liquid of any kind.•Do not use caustic or abrasive cleaning agents on the device; do not use cleaning agents containing ammonium chloride.•Clean the IPOD after each patient use.

Specifications

SpO_2 Accuracy

70 - 100% ±2 digits (A_{rms}*).

Pulse Rate Accuracy

18 to 300 BPM ±3 digits (A_{rms}*).

Temperature

Operating: -5° to +50° C (23° F to 122° F)
Storage/Transportation:-40° to +70° C (-40° F to 158° F)

Humidity

Operating:10 to 95% non-condensing
Storage/Transportation:10 to 95% non-condensing

If the IPOD is transferred from a storage or transport environment outside the operating environment conditions described above, a minimum of one (1) hour is required for the device to stabilize prior to use.

* ±1 A_{rms} encompasses 68% of the population.

Measurement Wavelengths and Output Power**

Red: 660 nanometers @ 0.8 mw nominal
Infrared: 910 nanometers @ 1.2 mw nominal

** This is especially useful for clinicians performing photodynamic therapy.

Compliance

This product complies with ISO 10993-1.

Manufacturer's Declaration

Refer to the host manufacturer's operator's manual or the IPOD technical specification document for specific information regarding this device's compliance to IEC Standard 60601-1-2.

Warranty

The IPOD sensor and cable component (top half) come with a one-year warranty from the delivery date. The IPOD oximeter component (bottom half) comes with a three-year warranty from the delivery date.

The information in this instruction insert has been carefully checked and is believed to be accurate. In the interest of continued product development, NONIN reserves the right to make changes and improvements to this insert and the product it describes at any time, without notice or obligation.

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