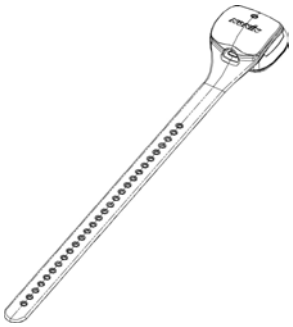
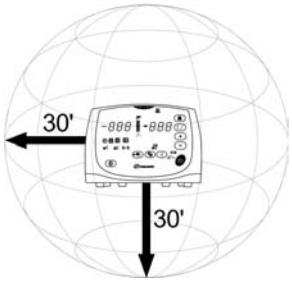
Wrist-Worn Pulse Oximeter Device (POD)



Nonin's Bluetooth®-enabled Wrist-Worn Pulse Oximeter Device (POD) allows SpO_2, pulse rate, and plethysmographic data to be transmitted through a Bluetooth radio to a Bluetooth-enabled device. Nonin's POD includes a class II Bluetooth radio with a range of approximately 30 feet (spherical radius).



Indications for XXX System Use

The NONIN® **XXX** Pulse Oximetry System with Bluetooth® Wireless Technology is indicated for measuring, displaying, and storing functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate of adult, pediatric, infant, and neonatal patients. It is indicated for use in hospitals, medical facilities, ambulatory, subacute, and sleep study environments.

Precautions for Use

- Do not use any part of this system in an MRI environment.
- Explosion Hazard: Do not use this system in an explosive atmosphere or in the presence of flammable anesthetics or gases.
- This system is intended only as an adjunct in patient assessment. It must be used in conjunction with other methods of assessing clinical signs and symptoms.
- Oximeter readings may be affected by the use of an electrosurgical unit (ESU).
- Use only NONIN-manufactured PureLight™ pulse oximeter sensors. These sensors are manufactured to meet the accuracy specifications for NONIN pulse oximeters. Using other manufacturers' sensors can result in improper pulse oximeter performance.
- Do not use a damaged sensor.
- As with all medical equipment, carefully route cables and connections to reduce the possibility of entanglement or strangulation.
- To avoid the risk of confusing or misinterpreting patient data, verify that the patient is paired with the correct display unit. (See "Device Pairing" in the XXX Pulse Oximetry System Operator's Manual.)
- This pulse oximetry system is designed to determine the percentage of arterial oxygen saturation of functional hemoglobin. Significant levels of dysfunctional hemoglobin, such as methemoglobin, might affect the accuracy of the measurement.
- Loss of monitoring can result if any objects hinder the pulse measurement. Ensure that no blood flow restrictors (e.g., blood pressure cuff) hinder pulse measurements.
- This equipment complies with International Standard EN 60601-1-2:2001 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 interference due to close proximity or strength of a source might disrupt the device's performance.
- If any part of this system fails to respond as described, discontinue use until the situation is corrected by qualified personnel.
- This system might misinterpret motion as good pulse quality. Minimize finger motion or change the type of sensor being used.
- 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 device and device components, including batteries. Use only NONIN-approved battery packs, and remove batteries if the system is not used within 30 days.
- Do not fasten the POD too tightly around the patient's wrist. Inaccurate readings and patient discomfort could result.

Declaration of Conformity with FCC Rules for Electromagnetic Compatibility

Nonin Medical, Inc., of 2605 Fernbrook Lane North, Plymouth, Minnesota, 55447, declares under its sole responsibility that the products 4000 and 4100, to which this declaration relates, comply with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Federal Communications Commission (FCC) Notice

This equipment has been tested and found to comply with the limits for a class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy. If not installed and used in accordance with the instructions, it may cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on. The user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the distance between the equipment and the receiver.
- Connect the equipment to an outlet on a circuit different from the outlet where the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for assistance.

- RF Exposure: For body worn operation, to maintain compliance with FCC RF exposure guidelines, use only accessories that contain no metallic components and provide a separation distance of 15mm (0.6 inches) to the body. Use of other accessories may violate FCC RF exposure guidelines and should be avoided.
- The Model 4100 is designed and manufactured not to exceed the emission limits for exposure to radio frequency (RF) energy set by the Federal Communications Commission of the U.S. Government. These limits are part of comprehensive guidelines and establish permitted levels of RF energy for the general population. The guidelines are based on the safety standards previously set by both U.S. and international standards bodies: This EUT has been shown to be capable of compliance for localized specific absorption rate (SAR) for uncontrolled environment/general population exposure limits specified in ANSI/IEEE Std. C95.1-1992 and has been tested in accordance with the measurement procedures specified in FCC/OET Bulletin 65 Supplement C (2001) and IEEE Std. 1528-200X (Draft 6.5, January 2002).
- Ministry of Health (Canada), Safety Code 6: standards include a substantial safety margin designed to ensure the safety of all persons, regardless of age and health. The exposure standard for wireless mobile phones employs a unit of measurement known as the Specific Absorption Rate, or SAR. The SAR limit set by the FCC is 1.6W/kg.

Modifications

The FCC requires the user to be notified that any changes or modifications to this device that are not expressly approved by Nonin Medical, Inc. may void the user's authority to operate the equipment.

Guide to Symbols

Attention: See Instructions for Use or related materials.

Type BF Applied Part (Patient isolation from electrical shock).

UL Mark for Canada and the United States with respect to electric shock, fire, and mechanical hazards only in accordance with UL 2601-1 and CAN/CSA C22.1 No. 601.1.

CE Marking indicating conformance to EC directive No. 93/42/EEC concerning medical devices.

SN **Serial Number.**

Remote Alarms; Not for Continuous Monitoring.

Cut.

Understanding Bluetooth Technology

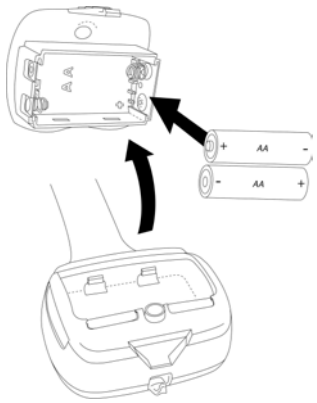
Bluetooth is a technology that enables automatic wireless connections between a variety of electronic communications and computing devices, making it possible to connect any compatible devices without cables or wires. The technology is based on a radio link that offers fast and reliable transmissions of voice, video, and data. Bluetooth uses a license-free, globally available frequency range in the ISM band— intended to ensure communication compatibility worldwide.

The **XXX** Pulse Oximetry System features point-to-point communications, allowing one master device (the display unit) to be connected to one slave device (the POD). Once connected, neither device is detectable by any other Bluetooth-enabled device, which reduces the risk of interference and preserves data integrity.

Important! Before attempting to pair a POD with a different Bluetooth-enabled device, disconnect and reconnect the sensor.

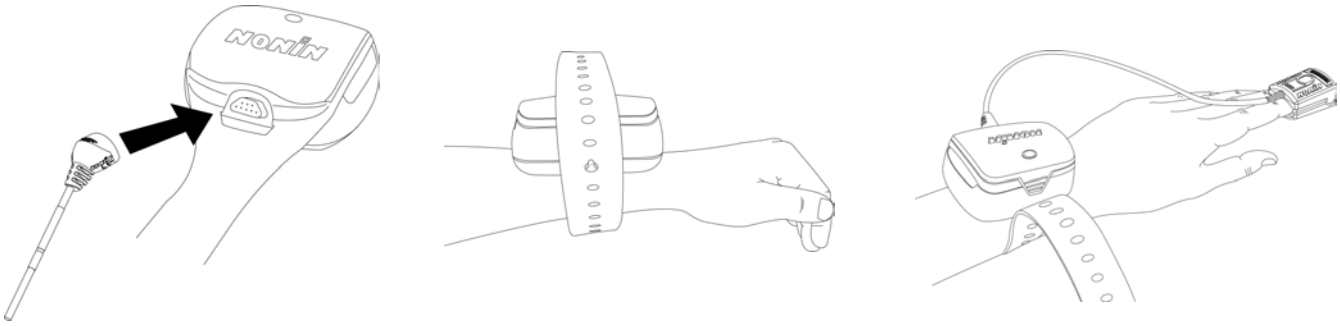
Installing Batteries

The POD requires two AA-size alkaline batteries, which last for approximately 4.5 days when used continuously.



Securing the Wristband and Attaching the Sensor

The POD is automatically activated when a sensor is connected. When the POD's Connection Status indicator flashes green, a connection is established with the display unit. When it flashes amber, no connection is established. The POD's wristband can either be reused or discarded after use, as desired. It may be cut to length to accommodate a variety of patient arm sizes.



Connecting to the POD from a Master Device

The POD can be connected to any compatible Bluetooth-enabled device with supporting software. To create a connection to a compatible device, refer to that device's user instructions.

Important! The POD is a slave device, so users must connect from the master device. The POD *does not* initiate a connection.

SpO_2 Accuracy

Proper sensor placement is critical for good performance. Some factors that may degrade pulse oximeter performance include the following:

- incorrect sensor type
- poor pulse quality
- venous pulsations
- anemia or low hemoglobin concentrations
- cardiovascular dyes
- sensor not at heart level
- excessive ambient light
- excessive motion
- electrosurgical interference
- arterial catheters, blood pressure cuffs, infusion lines, etc.
- moisture in the sensor
- improperly attached sensor

Cleaning Instructions

Clean the POD with a soft cloth dampened with isopropyl alcohol. Do not pour or spray any liquids onto the device, and do not allow any liquids to enter any openings in the device. Allow the unit to dry thoroughly before use.

IMPORTANT! Do not immerse the device in liquid, and do not use caustic or abrasive cleaning agents on the device.

Clean the device separately from its associated sensors. For instructions regarding cleaning pulse oximeter sensors, refer to the appropriate pulse oximeter sensor package inserts.

Specifications

For additional specifications, refer to the **XXX** Pulse Oximetry System Operator's Manual.

Oxygen Saturation Range ($\%SpO_2$)	0% to 100%
Pulse Rate Range	18 to 300 pulses per minute
Accuracy	
Blood Oxygen Saturation ($\%SpO_2$) (± 1 S.D.)[1]	70-100% ±2 digits for adults using Finger Clip Sensor
Pulse Rate	± 3%
Measurement Wavelengths and Output Power	
Red	660 nanometers @ 3 mw nominal
Infrared	910 nanometers @ 3 mw nominal
Internal Power	
Battery	Two 1.5 volt AA batteries
Operating Life	minimum 140 hours of continuous operation with new batteries
Storage Life	10 months
Weight	4.4 ounces with batteries (125 grams)
Antenna Type	Inverted F type antenna
Antenna Gain	+2 dB (typ.), +3 dB (max.)

Warranty

Three years from the date of delivery.

[1]S.D. (Standard Deviation) is a statistical measure; up to 32% of the readings may fall outside these limits.

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