Instructions for Use – English

NoninConnect™ Model 3230
Bluetooth® Smart Pulse Oximeter

CE 0123

Installing AAA Batteries

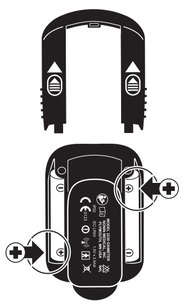
WARNING: Before changing batteries, make sure the device is off and is not applied to a digit.

1. Hold the 3230 so you see the back of the device and the arrows on the battery door point away from you.

2. Place your thumbs on the ovals.

3. Slide the battery door away from you and off the 3230.

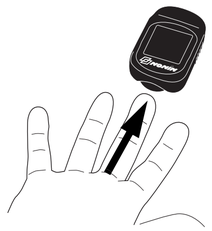
4. If applicable, remove the old batteries from the 3230. Properly dispose of the batteries.
5. Insert two new 1.5 volt AAA-size batteries. Carefully match the polarity markings (+ and -). The 3230 will not work if the batteries are inserted the wrong way.



6. Carefully slide the battery door back onto the device.

Turning On the NoninConnect Model 3230

1. Insert a digit into the Model 3230 until it touches the built-in stop.



NOTE: Make sure the finger is lying flat (not on its side) and is centered within the device. For best results, keep the device at heart or chest level.

2. If the CorrectCheck screen (see Display Symbols table) displays, slide finger further into device. Correct positioning of the finger is critical for accurate measurements.
3. The 3230 begins sensing the pulse and displaying readings.

4. View about 4 seconds of readings before relying on the displayed values. It is common for the displayed values to vary slightly over a period of several seconds.

NOTE: While on the finger, do not press the device against any surface and do not squeeze or hold it together. The internal spring provides the correct pressure; additional pressure may cause inaccurate readings.

Indications for Use

The NoninConnect Model 3230 Finger Pulse Oximeter is a small, lightweight, portable device indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (%SpO_2) and pulse rate of patients who are well or poorly perfused. It is intended for spot-checking of adult and pediatric patients with digits between 0.8 – 2.5 cm (0.3 – 1.0 inch) thick.

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

NOTE: Use Environment—Home healthcare environments under the supervision of qualified medical professionals. Users include current/potential users of pulse oximetry in the home and caregivers/potential caregivers of such a user.

Contraindications

Do not use the device in an MR environment, in an explosive atmosphere, or on neonatal patients.
- This device is not defibrillation proof per IEC 60601-1.

Warnings

- Use the Model 3230 within its designated range (approximately 10 m/32 ft, spherical radius, line of sight when connected to a *Bluetooth* Smart Ready device). Moving outside this range may cause missing, lost, and/or inaccurate data.
- Inspect the sensor application site at least every 6 to 8 hours to ensure correct sensor alignment and skin integrity. Patient sensitivity to sensor 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.
- This device is intended only as an adjunct in patient assessment. It must be used in conjunction with other methods of assessing clinical signs and symptoms.
- The device must be able to measure the pulse properly to obtain an accurate SpO_2 measurement. Verify that nothing is hindering the pulse measurement before relying on the SpO_2 measurement.
- Operation of this device below the minimum amplitude of 0.3% modulation may cause inaccurate results.
- General operation of the device may be affected by the use of an electrosurgical unit (ESU).
- Keep the oximeter away from young children. Small items such as the battery door and battery are choking hazards.
- Before changing batteries, make sure the device is off and is not applied to a digit.

Cautions

- This device has no audible alarms and is intended only for spot-checking.
- This device is designed to determine the percentage of arterial oxygen saturation of functional hemoglobin. Factors that may degrade pulse oximeter performance or affect the accuracy of the measurement include the following:
  - applying the pulse oximeter on the same arm as a blood pressure cuff, arterial catheter or infusion line(s) (IVs)
  - excessive light, such as sunlight or direct home lighting
  - excessive motion
  - moisture in the device
  - improperly applied device
  - finger is outside recommended size range
  - poor pulse quality
  - venous pulsations
  - cardiogreen and other intravascular dyes
  - anemia or low hemoglobin concentrations
  - carboxyhemoglobin
  - methemoglobin
  - dysfunctional hemoglobin
  - artificial nails or fingernail polish
- The device may not work when circulation is reduced. Warm or rub the finger, or re-position the device.
- The device is designed to be attached only to a digit.
- This device's display will shut off after 30 seconds of no readings or poor readings.
- In some circumstances, the device will interpret motion as good pulse quality. Minimize patient motion as much as possible.
- Clean the device before applying it to a new patient.
- Do not sterilize, autoclave, or immerse this device in liquid. Do not pour or spray any liquids into the device.
- Do not use caustic or abrasive cleaning agents, or any cleaning products containing ammonium chloride or isopropyl alcohol.
- Do not use cleaning solutions other than those recommended here, as permanent damage could result.
- This device is a precision electronic instrument and must be repaired by qualified technical professionals. Field repair of the device is not possible. Do not attempt to open the case or repair the electronics. Opening the case may damage the device and void the warranty.
- This equipment complies with IEC 60601-1-2 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 health care 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 including CT, diathermy, RFID, and electronic article security systems can affect medical electrical equipment.
- Batteries may leak or explode if used or disposed of improperly. Remove batteries if the device will be stored for more than 30 days. Do not use different types of batteries at the same time. Do not mix fully charged and partially charged batteries at the same time. These actions may cause the batteries to leak.
- Follow local, state, and national governing ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries.
- 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
⚠	Caution!
	Follow Instructions for Use.
	Consult Instructions for Use.
	MR unsafe
	Type BF Applied Part (patient isolation from electrical shock)
C UL US	UL Mark for Canada and the United States with respect to electric shock, fire, and mechanical hazards only in accordance with IEC 60601-1, UL 60601-1 and CAN/CSA-C22.2 No. 601.1.
CE 0123	CE Marking indicating conformance to EC Directive No. 93/42/EEC concerning medical devices.
	Radio Equipment Class Identifier
	Non-ionizing electromagnetic radiation. Equipment includes RF transmitters. Interference may occur in the vicinity of equipment marked with this symbol.

Symbol	Definition
	Not for continuous monitoring (no alarm for SpO_2)
	Battery orientation
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 (0.1 in.) in diameter per IEC 60529.
SN	Serial Number
BDA	*Bluetooth* Device Address
	Storage/shipping temperature range of -40 °C to 70 °C (-40 °F to 158 °F)
	Handle with care
	Keep dry
	Indoor use (France only)
℞ Only	Medical prescription required
	Manufacturer

Symbol	Definition
	Indicates separate collection for electrical and electronic equipment (WEEE)

Symbol	Definition
EC REP	Authorized Representative in the European Community
REF	Catalogue number

NOTE: Where applicable, an additional label bearing your country radio communications license information will appear on the side of your device. This is not a serial number or device identifier.

Display Symbols

Symbol	Description
	Nonin's CorrectCheck™ senses that the finger has not been correctly inserted. If you see this symbol, slide finger further into device.
% SpO_2	The number next to this symbol is the amount of oxygen in your blood (functional oxygen saturation of arterial hemoglobin).
	The number next to this animated symbol is your pulse rate. Pulse rate is the number of times your heart beats per minute.
– – –	Dashes replace the readings when the 3230 is unable to detect a usable signal.
	White symbol – Radio is on. **Green symbol** – 3230 is connected. **Flashing white symbol** – Connection error. The radio will reset.
	Poor signal. Steady your hand, reposition finger, warm finger by rubbing, or select a different finger.
	Low battery. Replace batteries.
	Critical battery. Flashing indicator on full screen. The device will not work until the batteries are replaced.

Using the NoninConnect Model 3230

Installing AAA Batteries

Use only alkaline batteries. When batteries are low, displays. Replace low batteries as soon as possible. See the "Installing AAA Batteries" instructions and figures at left.

Turning On the NoninConnect Model 3230

See the "Turning on the NoninConnect Model 3230" instructions and figures at left.

Connection via *Bluetooth* Wireless Technology

When the Model 3230 is placed on the finger and turns on, it is ready for a *Bluetooth* wireless connection. The 3230 stays in this mode until it is shut off. The symbol is white when the *Bluetooth* radio is on, green when the 3230 is connected, and flashes white when there is a communication error.

The *Bluetooth* symbol is useful for the product installer.

Due to the wide variety of wireless environments, the *Bluetooth* connection between the 3230 and the host device must be tested before using the 3230's *Bluetooth* capabilities.

Turning Off the NoninConnect Model 3230

The Model 3230 will automatically turn off approximately 10 seconds after the digit is removed, or after a 2-minute period of poor signals.

Cleaning the NoninConnect Model 3230

⚠ **CAUTIONS:**
- Clean the device before applying it to a new patient.
- Do not sterilize, autoclave, or immerse this device in liquid. Do not pour or spray any liquids into the device.
- Do not use caustic or abrasive cleaning agents, or any cleaning products containing ammonium chloride or isopropyl alcohol.
- Do not use cleaning solutions other than those recommended here, as permanent damage could result.

1. To clean, wipe the device's surfaces with a soft cloth dampened with one of the following:
   - A 10% bleach solution (household bleach [5.25% sodium hypochlorite]).
   - Warm, soapy water (hand dishwashing detergent – see note below), and then rinse the cleaned surfaces with a soft cloth dampened with water (home use only).
2. Dry with a soft cloth, or allow to air dry. Ensure that all surfaces are completely dry.

NOTE: The hand dishwashing detergent that was tested includes these ingredients: Sodium Lauryl Sulfate, Sodium Laureth Sulfate, Lauramine Oxide, Sodium Chloride, PPG-26, PEG-8 Propylheptyl Ether, and Phenoxyethanol.

Warranty

NONIN MEDICAL, INCORPORATED, (Nonin) warrants to the purchaser, for a period of 2 years from the date of purchase, each Model 3230 exclusive of the batteries and spring. The device's expected service life is 5 years.

Nonin shall repair or replace any 3230 found to be defective in accordance with this warranty, free of charge, for which Nonin has been notified by the purchaser by serial number that there is a defect, provided notification occurs within the applicable warranty period. If unable to repair, Nonin shall replace with a 3230 or a comparable device. This warranty shall be the sole and exclusive remedy by the purchaser hereunder for any 3230 delivered to the purchaser which is found to be defective in any manner whether such remedies be in contract, tort or by law.

This warranty excludes cost of delivery to and from Nonin. All repaired units shall be received by the purchaser at Nonin's place of business. Nonin reserves the right to charge a fee for a warranty repair request on any 3230 found to be within specifications.

Model 3230 is a precision electronic instrument and must be repaired by trained Nonin personnel only. Any sign or evidence of opening the 3230, field service by non-Nonin personnel, tampering, or any kind of misuse of the 3230, shall void the warranty. All non-warranty work shall be done at Nonin's standard rates and charges in effect at the time of delivery to Nonin.

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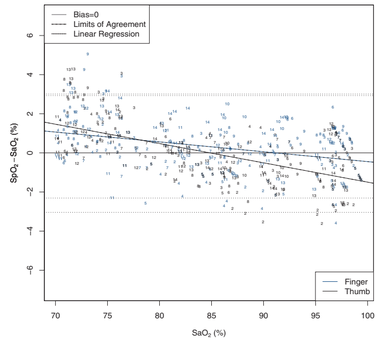
Specifications

Oxygen Saturation Display Range: 0% to 100% SpO_2
Pulse Rate Display Range: 18 to 321 beats per minute (BPM)
Declared Accuracy*: The table below shows A_{rms} values measured using the Model 3230 in a clinical study.

NOTE: If your national regulatory authority recognizes accuracy in motion, please contact regulatory@nonin.com for accuracy data.

Accuracy Summary – Finger and Thumb

Range	Specified Oxygen Saturation (A_{rms})	Finger Oxygen Saturation (A_{rms})	Thumb Oxygen Saturation (A_{rms})	Low Perfusion Oxygen Saturation (A_{rms})
70 – 100%	± 2	± 1.31	± 1.56	± 2
70 – 80%	± 2	± 1.65	± 1.91	± 2
80 – 90%	± 2	± 1.05	± 1.21	± 2
90 – 100%	± 2	± 1.18	± 1.49	± 2



This graph shows plots of the error ($SpO_2 – SaO_2$) by SaO_2 using the 3230 with a linear regression fit and upper 95% and lower 95% limits of agreement. Each sample data point is identified by subject from a clinical study in non-motion conditions.

Pulse Rate Declared Accuracy Range (A_{rms})*: 20 to 250 BPM ±3 digits
Low Perfusion Pulse Rate Declared Accuracy Range (A_{rms})*: 40 to 240 BPM ±3 digits
Measurement Wavelengths and Output Power:**
Red. 660 nanometers @ 0.8 mW max. average
Infrared. 910 nanometers @ 1.2 mW max. average
Temperature:
Operating. -5 °C to 40 °C / 23 °F to 104 °F
Storage/Transportation. -40 °C to 70 °C / -40 °F to 158 °F
Humidity:
Operating. 10% to 95% non-condensing
Storage/Transportation. 10% to 95% non-condensing
Altitude:
Operating. Up to 10,000 meters / 32,808 feet
Hyperbaric Pressure. Up to 4 atmospheres
Battery Life:
Operating. Approximately 2,200 spot checks (25 sec. per spot-check), within 10 meters/32 feet of collector with streaming data
Storage. 1 month, with batteries installed. **CAUTION:** Remove batteries if the device will be stored for more than 30 days.

* ±1 A_{rms} represents approximately 68% of measurements.
** This information is especially useful for clinicians performing photodynamic therapy.

Bluetooth Wireless Technology Information

Bluetooth Compliance: Version 4.0 single mode low energy
Operating Frequency: 2.4 to 2.4835 GHz
Output Power: TX: +3 dBM
Operating Range: 10 meter radius (line of sight)
Network Topology: Star - bus
Operation: Slave
Model 3230
Antenna Type: Integrated chip type antenna
Modulation Type: Frequency Hopping Spread Spectrum
Data Rate: 1 Mbit/second
Data Latency: 6 ms
Data Integrity: Adaptive Frequency Hopping
24-bit CRC (cyclic redundancy check)
32-bit message integrity check
Data Format: Sends data packets once per second. Includes a second counter that allows the host to detect if packets are missing and the device to retransmit.
Quality of Service: This device uses *Bluetooth* Smart technology for wireless communications, which allows for reliable communications in electrically noisy environments, and transmits physiological data once per second. If data is lost, the device will transmit data again one second later. If the connection is lost, the device will change the *Bluetooth* symbol from green to white and become available for a connection in a few seconds.
Bluetooth Profiles Supported: GATT-based proprietary Nonin profile
Authentication and Encryption: Supported
Encryption Key Size: 128 bits AES (advanced encryption standard)

Bluetooth Security

The *Bluetooth* radio contained in the 3230 is a *Bluetooth* Smart single-mode, low-energy radio. It supports a GATT-based, proprietary Nonin profile to transmit current readings from the patient. Data is not stored by the 3230 to be transferred at a later time. The 3230 supports an encryption key size of 128 bits. While the 3230 is in a *Bluetooth* connection, it will be unavailable for other connections. Apart from the standard *Bluetooth* security measures, Nonin has implemented a non-standard security measure to the 3230 that, if used, will restrict the transfer of data to only devices with a specified organizationally unique identifier (OUI).

For additional technical information, please see the insert, "NoninConnect Model 3230 Technical Description."

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