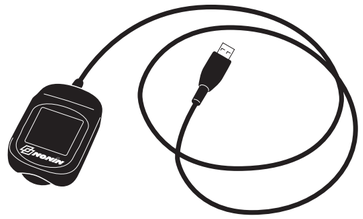
NONIN

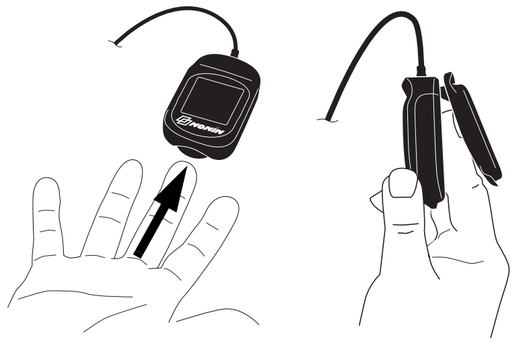
CE 0123 *Instructions for Use – English*

Model 3231 Pulse Oximeter



Turning On the 3231

1. Connect the 3231's USB connector to the computer's USB port.
2. Insert a digit into the Model 3231 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.

3. If the CorrectCheck screen (see Display Symbols table) displays, slide finger further into device. Correct positioning of the finger is critical for accurate measurements.
4. The 3231 begins sensing the pulse and displaying readings.

5. Allow the oximeter values to stabilize before taking the reading. Factors that may affect stabilization include, but are not limited to, cold fingers, low perfusion, and excessive motion or tremors.

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 Nonin® Model 3231 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.

Warnings

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.
- 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).
- This device should not be used adjacent to other equipment. If adjacent use is necessary, the device should be observed carefully to verify normal operation.
- Carefully route cables and connections to reduce the possibility of entanglement or strangulation.
- All parts and accessories connected to the USB connector of the device must be certified according to at least IEC 60950 or UL 1950 for data-processing equipment.
- Portable RF communications equipment such as cell phones or radios (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the ME system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result

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 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.
- A functional tester cannot be used to assess the accuracy of a pulse oximeter monitor.
- 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.
- 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
	Caution!
EC REP	Authorized Representative in the European Community
	Follow Instructions for Use
CE 0123	CE Marking indicating conformance to all applicable directives, including EC Directive No. 93/42/EEC concerning medical devices.
	MR unsafe
REF	Catalogue Number
SN	Serial Number
QTY	Quantity
	Manufacturer
	Date of Manufacture
	Type BF Applied Part (patient isolation from electrical shock)
	Indicates separate collection for electrical and electronic equipment (WEEE)
	Not for continuous monitoring (no alarm for SpO_2)
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.
	Storage/shipping temperature range of -40 °C to 70 °C (-40 °F to 158 °F)
	Handle with care
	Keep dry
℞ Only	Medical prescription required

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 3231 is unable to detect a usable signal.
	Poor signal. Steady your hand, reposition finger, warm finger by rubbing, or select a different finger.

Using the Model 3231

Turning On the 3231

See the "Turning on the 3231" instructions and figures at left.

Turning Off the 3231

The Model 3231 will automatically turn off approximately 10 seconds after the digit is removed, after 30 seconds of poor signals, or after a 2-minute period with no readings.

Cleaning the 3231

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.

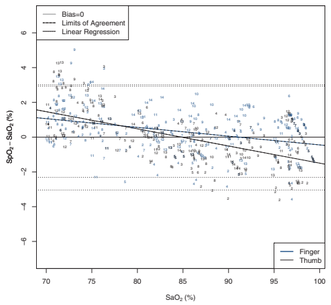
Specifications

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 3231 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 3231 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

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9281-001-05
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Nonin and CorrectCheck are trademarks of Nonin Medical, Inc.
U.S. Patents 5,490,523; 5,792,052; other patents pending.

Device temperature will not exceed 41 °C as measured during a controlled environment test.

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

Altitude:
Operating: Up to 4,000 meters / 16,404 feet
Hyperbaric Pressure: Up to 4 atmospheres

Weight: < 72 g / 2.5 oz., including cable and connector

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

Classifications per IEC 60601-1 / CAN/CSA-C22.2 No. 601.1/ UL 60601-1:
Degree of Protection: Type BF-Applied Part
Enclosure Degree of Ingress Protection: IP32
Mode of Operation: Continuous

This product complies with ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluation and testing.
This device is not made with natural rubber latex.
This product complies with RoHS.
This product complies with REACH.

USB Technology Information

USB Compliance: Specification Release 2.0 Compliant
USB Modes: Single
USB Speed: Full
Power Source: USB Bus
Data Rate: 12 Mbit/second
Data Latency: Less than 1 ms
Data Format: Sends data packets once per second. Includes a second counter that allows the host to detect if packets are missing from the data stream.
Quality of Service: This device uses USB technology for wired communications. To provide error detection, the USB standard uses a checksum called a cyclic redundancy check (CRC) on all data packets. If a corrupted packet is received, the packet will be re-transmitted. Testing has been completed to show that the 3231 has passed the USB-IF Full Speed Device Compliance Testing, including device framework testing, electrical testing, and interoperability testing. The 3231 transmits physiological data once per second. If data is lost, the device will transmit data again one second later.
Security: The 3231 USB interface is wired and is therefore secure from unintended data interception.

Connectivity

The 3231 uses USB technology for wired communications and as a power source. Failure of the USB connection could result in loss of transmitted data and power to the device.

Connection of the 3231 into a Medical System

Incorporating the 3231 into a medical system requires the integrator to identify, analyze, and evaluate the risks to patient, operators, and third parties. Subsequent changes to the medical system after 3231 integration could introduce new risks and will require additional analysis. Changes to the medical system that must be evaluated include:

- Changing the system configuration
- Adding devices to or disconnecting devices from the system
- Updating or upgrading equipment connected to the system

Issues resulting from user-initiated system changes may include corruption of data, loss of data, or loss of power to the 3231.

Warranty

NONIN MEDICAL, INCORPORATED, (Nonin) warrants to the purchaser, for a period of 1 year from the date of purchase, each Model 3231 exclusive of spring.

Nonin shall repair or replace any 3231 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 3231 or a comparable device. This warranty shall be the sole and exclusive remedy by the purchaser hereunder for any 3231 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 3231 found to be within specifications.

Model 3231 is a precision electronic instrument and must be repaired by trained Nonin personnel only. Any sign or evidence of opening the 3231, field service by non-Nonin personnel, tampering, or any kind of misuse of the 3231, 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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Equipment Response Time

SpO_2 Values	Average	Latency
Standard/Fast Averages SpO_2	4 beat exponential	2 beats

Pulse Rate Values	Response	Latency
Standard/Fast Averages Pulse Rate	4 beat exponential	2 beats

Example: SpO_2 Exponential Averaging

SpO_2 decreases 0.75% per second; pulse rate = 75 BPM
The response of the 4-beat average is 1.5 seconds.

Testing Summary

SpO_2 accuracy and low perfusion testing was conducted by Nonin Medical, Inc. as described below.

SpO_2 Accuracy Testing

At an independent research laboratory, SpO_2 accuracy testing is conducted during induced hypoxia studies on healthy, male and female, non-smoking, light-to-dark-skinned subjects that are 18 years of age and older. The measured arterial hemoglobin saturation value (SpO_2) of the device is compared to arterial hemoglobin oxygen (SaO_2) value, determined from blood samples with a laboratory co-oximeter. The accuracy of the device is in comparison to the co-oximeter samples measured over the SpO_2 range of 70 – 100%. Accuracy data is calculated using the root-mean-squared (A_{rms} value) for all subjects, per ISO 80601-2-61 and ISO 9919, Standard Specification for Pulse Oximeters for Accuracy.

Low Perfusion Testing

This test uses an SpO_2 simulator to provide a simulated pulse rate, with adjustable amplitude settings of various SpO_2 levels. The device must maintain accuracy in accordance with ISO 80601-2-61 and ISO 9919 for pulse rate and SpO_2 at the lowest obtainable pulse amplitude (0.3% modulation).

Performance in Motion

Motion artifact simulation introduced by a pulse oximeter tester determines whether the oximeter meets the criteria of ISO 80601-2-61 and ISO 9919 for pulse rate during simulated movement, tremor, and spike motions.

Contact regulatory@nonin.com for more information regarding motion testing.

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Manufacturer's Declaration

Refer to the following tables for specific information regarding this device's compliance to 60601-1-2. Component compliance level is determined by system compliance level.

Essential Performance

Essential performance of the 3231 is defined as SpO_2 accuracy and pulse rate accuracy or an indication of abnormal operation. Accuracies may be affected as a result of exposure to electromagnetic disturbances that are outside of the environments listed in the *Indications For Use*. If issues are experienced, move the Nonin system away from the source of electromagnetic disturbances.

Table 1: Electromagnetic Emissions

This device is intended for use in the electromagnetic environment specified in the Indications for Use section. The user of this device should ensure that it is used in such an environment.	
Emissions Test	**Compliance**
RF Emissions CISPR 11	Group 1, Class B

Table 2: Electromagnetic Immunity

Immunity Test	Compliance	
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	
Conducted RF IEC 61000-4-6	150 kHz	3 Vrms
	ISM and Amateur radio bands between 150 kHz to 80 MHz	6 Vrms
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	30 A/m	

Table 2: Electromagnetic Immunity (Continued)

Immunity Test	Compliance	
Radiated RF IEC 61000-4-3	80 MHz – 2.7 GHz	10 V/m
	380 – 390 MHz	27 V/m
	430 – 470 MHz	28 V/m
	704 – 787 MHz	9 V/m
	800 – 960 MHz	28 V/m
	1.7 – 1.99 GHz	28 V/m
	2.4 – 2.57 GHz	28 V/m
	5.1 – 5.8 GHz	9 V/m

Table 3: Not Applicable

Harmonic Emissions (IEC 61000-3-2), Voltage Flicker Emissions (IEC 61000-3-3), Electrical Fast Transients (IEC 61000-4-4), Surge (IEC 61000-4-5), Voltage dips (IEC 61000-4-11)
NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.