

Indications for Use

The Nonin[®] Onyx II Model 9550 Finger Pulse Oximeter is a small, lightweight, portable device indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (%SpO₂) and pulse rate of patients who are well or poorly perfused. It is intended for spot-checking of adult and pediatric patients on fingers (other than the thumb) between 0.3 – 1.0 inch (0.8 – 2.5 cm) thick. The device's intended use environments include hospitals, clinics, long-term care facilities, skilled nursing facilities, emergency medical services, and home healthcare services.

Warnings

















- Do not use the device in an MR environment, in an explosive atmosphere, or on infant or neonatal patients.
- This device is not defibrillation proof per IEC 60601-1.
- Inspect the sensor application site at least every 4 hours to ensure correct sensor alignment and skin integrity. Patient sensitivity to the 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 SpO₂ measurement. Verify that nothing is hindering the pulse measurement before relying on the SpO₂ 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).
- The use of accessories other than those specified in these instructions may result in increased electromagnetic emission and/or decreased immunity of this device.
- 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.
- Keep the oximeter away from young children. Small items such as the battery door, battery, and lanyard are choking hazards.
- Certain activities may pose a risk of injury, including strangulation, if lanyard should become wrapped around your neck.
- Before changing batteries, make sure the device is off and is not applied to a digit.
- 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:
 - do not apply 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
 - anemia or low hemoglobin concentrations
 - cardiogreen and other intravascular dyes
 - carboxyhemoglobin
 - methemoglobin
 - dysfunctional hemoglobin
 - artificial nails or fingernail polish
 - residue (e.g., dried blood, dirt, grease, oil) in the light path
- The device may not work when circulation is reduced. Warm or rub the finger, or re-position the device.
- This device's display will go blank after 30 seconds of no readings or poor readings.
- In some circumstances, the device may interpret motion as good pulse quality. Minimize patient motion as much as possible.
- Clean the device before applying it to a patient.
- Do not sterilize, autoclave, or immerse this device in liquid. Do not pour or spray any liquids onto the device.
- Do not use caustic or abrasive cleaning agents, or any cleaning agent containing ammonium chloride.
- This device is a precision electronic instrument and must be repaired by Nonin Technical Service. 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 flexible circuit connects the two halves. Do not twist or pull the flexible circuit or overextend the device's spring. Do not hang the lanyard from the device's flexible circuit.
- A functional tester cannot be used to assess the accuracy of a pulse oximeter monitor or sensor.

- 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 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.
- 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.
- When using the device in the home, avoid exposing the device to lint and dust.

Symbols

Symbol	Definition
	Caution!
	Follow Instructions for Use
	Authorized Representative in the European Community
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)
	Not for Continuous Monitoring (no alarm for SpO ₂)
SN	Serial Number
	Battery Orientation
	UL Mark for Canada and the United States with respect to electric shock, fire, and mechanical hazards only in accordance with UL 60601-1 and CAN/CSA-C22.2 No. 60601-1.
	Indicates separate collection for electrical and electronic equipment (WEEE).
	Non-ionizing electromagnetic radiation. Equipment includes RF transmitters. Interference may occur in the vicinity of equipment marked with this symbol.
IP33	Protected against spraying water and against access to hazardous parts with a tool, per IEC 60529.
	RoHS compliant (China)
	Manufacturer
	Country of manufacture
	Date of manufacture
	Catalogue number
	Quantity
	Storage/shipping temperature range
R_x Only	Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner.

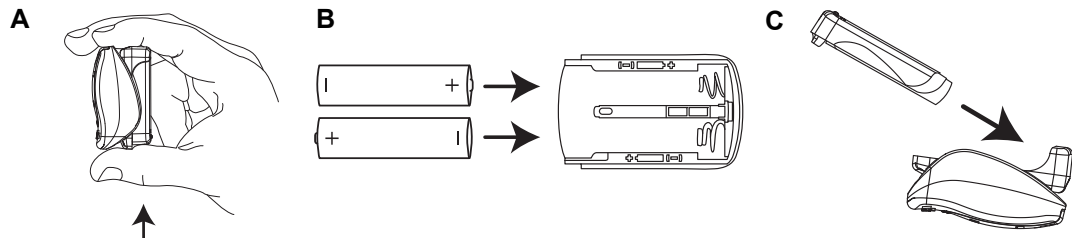
Installing Batteries

Two 1.5 volt AAA-size batteries power the 9550 for about 10,000 spot checks or 63 hours of operation. Nonin recommends using alkaline batteries (included with each new device). When batteries are low, the numeric displays flash once per second. Remove batteries if the device will be stored for more than 30 days. Replace low batteries as soon as possible, using the instructions below.

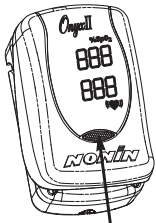
WARNING: Before changing batteries, make sure the device is off and is not applied to a digit.

NOTE: Rechargeable batteries may be used; however, they require more frequent replacement.

1. Hold the 9550 as shown in figure A. To release the device's battery tray, press upward and then pull outward slightly with the thumb.
2. Remove the old batteries from the battery tray. Dispose of the batteries properly.
3. Insert two new 1.5 volt AAA-size batteries. Follow the polarity markings (+ and -) as illustrated in figure B. *Proper positioning of the batteries is essential for operation.*
4. Carefully guide the battery tray back onto the device. Press downward and the push inward slightly to re-secure the battery tray (figure C). *Do not force it into place; it fits only when properly positioned.*
5. Insert your finger into the device to verify operation. See the Activating the Onyx II 9550 and Verifying Operation section for more information.



Activating the Onyx II 9550 and Verifying Operation



Pulse Quality Indicator

The device contains numeric Light-Emitting Diodes (LEDs) that display oxygen saturation and pulse rate. A tricolor LED display (pulse quality indicator, shown at left) provides a visual indication of the pulse signal quality, while blinking at the corresponding pulse rate. This display changes colors to alert you to changes in pulse quality that may affect the readings:

- Green indicates a good pulse signal.
- Yellow indicates a marginal pulse signal.
- Red indicates an inadequate pulse signal.

Activate the 9550 by inserting the patient's finger into the device. The device detects the inserted finger and automatically illuminates the displays. Correct positioning of the device on the finger is critical for accurate measurements.

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.

1. Insert the patient's finger, nail side up, into the 9550 until the fingertip touches the built-in stop guide.
2. Make sure the finger is lying flat (not on its side) and is centered within the device. For best results, keep the 9550 at the patient's heart or chest level.
3. If the device does not turn on, remove the finger and wait a few seconds before reinserting it.

When a finger is inserted, the device performs a brief startup sequence. Verify that all LEDs illuminate during the startup sequence. If any LED is not lit, do not use the 9550; contact Nonin Technical Service for repair or replacement.

After the startup sequence, the device begins sensing the pulse (indicated by the blinking pulse quality indicator). Allow the device to stabilize and observe about 4 seconds of continuous green-colored pulse quality before relying on the displayed values. Continually verify operation. It is common for the displayed values to fluctuate slightly over a period of several seconds. If the pulse quality indicator blinks yellow or red, try another finger.

A minus sign (-) appears in the left-most digit of the %SpO₂ display when the device senses the finger has been removed. The last measured SpO₂ and pulse rate values display for 10 seconds while the device automatically turns off. The device will automatically shut off (to conserve battery life) approximately 10 seconds after the finger is removed, or after a 2-minute period of inadequate pulse signals.

If the 9550 does not turn on or if it shuts off unexpectedly:


- Verify batteries are correctly inserted. **Note:** If batteries are installed backwards, the unit will not function.
- The batteries are depleted. Replace batteries.

If the problem persists, remove the batteries and contact Nonin Technical Service.

The Oxitest^{Plus7} by Datrend Systems, Inc. can be used to verify operation of the pulse oximeter.

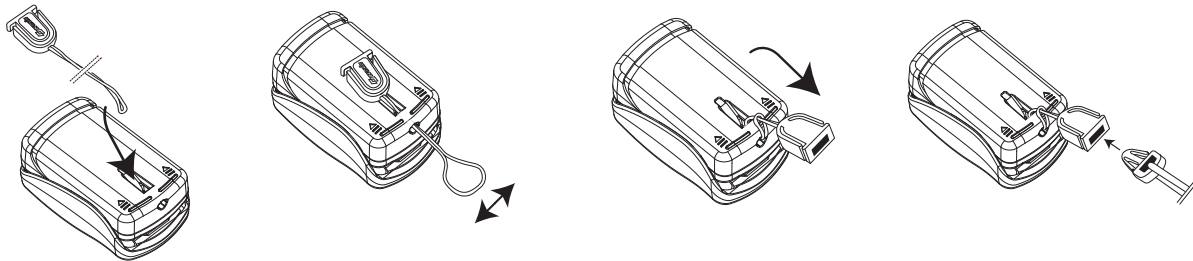
Using the Lanyard and Carrying Case

WARNING: Certain activities may pose a risk of injury, including strangulation, if lanyard should become wrapped around your neck.

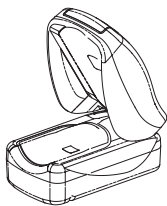
 **CAUTION:** A flexible circuit connects the two halves. Do not twist or pull the flexible circuit or overextend the device's spring. Do not hang the lanyard from the device's flexible circuit.

A lanyard and carrying case are provided for convenience. The device will function with or without the lanyard.

If lanyard use is desired, thread the lanyard as shown below.



Onyx II 9550 Care, Maintenance, and Cleaning



The advanced digital circuitry within the device requires no calibration or periodic maintenance other than battery replacement. The device's expected service life is 5 years. Field repair of the 9550 circuitry is not possible. Do not attempt to open the case or repair the electronics. Opening the case will damage the device and void the warranty. Do not open the 9550 more than 90°, and do not twist or pull on the device when cleaning.

Cleaning the Onyx II 9550

 **CAUTIONS:**

- Clean the device before applying it to a 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 agent containing ammonium chloride.

1. To clean, wipe the surfaces with a soft cloth dampened with a 10% bleach solution (household bleach [5.25% sodium hypochlorite]). Do not use undiluted bleach or any cleaning solution other than those recommended here, as permanent damage could result.
2. Dry with a soft cloth, or allow to air dry. Ensure that all surfaces are completely dry.

Equipment Response Time

If the signal from the sensor is inadequate, the last measured SpO₂ and pulse rate values freeze for 10 seconds and are then replaced with dashes.

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

Equipment Delays	Delay
Display Update Delay	1.5 seconds

Example: SpO₂ Exponential Averaging

SpO₂ decreases 0.75% per second; pulse rate = 75 BPM
 The response of the 4-beat average is 1.5 seconds.

Testing Summary

SpO₂ accuracy and low perfusion testing was conducted by Nonin Medical, Incorporated as described below.

SpO₂ Accuracy Testing

At an independent research laboratory, SpO₂ accuracy testing is conducted during induced hypoxia studies on healthy, male and female, non-smoking, light-to-dark-skinned subjects that are aged 18 years and older. The measured arterial hemoglobin saturation value (SpO₂) of the device is compared to arterial hemoglobin oxygen (SaO₂) 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 SpO₂ 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 SpO₂ Simulator to provide a simulated pulse rate, with adjustable amplitude settings of various SpO₂ levels. The device must maintain accuracy in accordance with ISO 80601-2-61 and ISO 9919 for pulse rate and SpO₂ at the lowest obtainable pulse amplitude (0.3% modulation).

Principles of Operation

Pulse oximetry is a non-invasive method that passes red and infrared light through perfused tissue and detects the fluctuating signals caused by arterial pulses. Well-oxygenated blood is bright red, while poorly oxygenated blood is dark red. The pulse oximeter determines functional oxygen saturation of arterial hemoglobin (SpO₂) from this color difference by measuring the ratio of absorbed red and infrared light as volume fluctuates with each pulse.

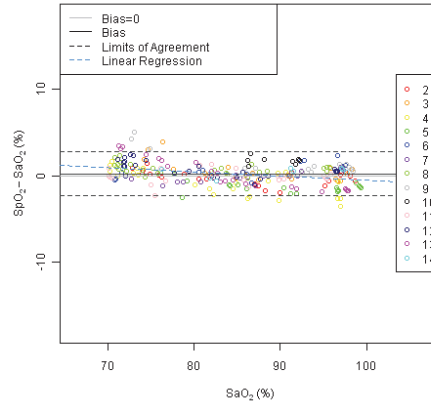
Specifications

Oxygen Saturation Display Range: 0% to 100% SpO₂
Pulse Rate Display Range: 18 to 321 beats per minute (BPM)
Declared Accuracy:

The table below shows A_{rms} values measured using the Onyx II 9550 in a clinical study in non-motion conditions.

Accuracy Summary by Decade

Decade	Oxygen Saturation (A _{rms})
70 – 80%	±2
80 – 90%	±2
90 – 100%	±2
70 – 100%	±2



This graph shows plots of the error (SpO₂ – SaO₂) by SaO₂ using the 9550 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.

SpO₂ Low Perfusion Accuracy (A_{rms}*): 70 to 100% ±2 digits
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 maximum average
Infrared: 910 nanometers @ 1.2 mW maximum 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)
Time (from storage) for monitor to be ready for its intended use: 3 minutes to warm from -40 °C to -5 °C
 5 minutes to cool from 70 °C to 40 °C

Humidity:

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

Altitude:

Operating: Up to 12,192 meters (40,000 feet)
Hyperbaric Pressure: Up to 4 atmospheres

Battery Life:

Operating: Approximately 10,000 spot checks, or 63 hours of continuous operation using new alkaline batteries.
Storage: 48 months

Classifications per ANSI/AAMI ES60601-1 / CAN/CSA-C22.2 No. 60601-1:

Degree of Protection: Type BF-Applied Part
Enclosure Degree of Ingress Protection: IP33
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.

*± 1 A_{rms} represents approximately 68% of measurements at zero bias.

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

Warranty

NONIN MEDICAL, INCORPORATED, (Nonin) warrants to the purchaser, for a period of 4 years from the date of purchase, each Onyx II 9550 exclusive of the batteries, spring, carrying case, lanyard, and lanyard lock.

Nonin shall repair or replace any Onyx II 9550 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. This warranty shall be the sole and exclusive remedy by the purchaser hereunder for any Onyx II 9550 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 Onyx II 9550 found to be within specifications.

Onyx is a precision electronic instrument and must be repaired by trained Nonin personnel only. Any sign or evidence of opening the Onyx II 9550, field service by non-Nonin personnel, tampering, or any kind of misuse of the Onyx II 9550, 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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Military/Safe-to-Fly Information

Nonin Medical's Onyx II 9550 has completed aeromedical test and evaluation by the U.S. Department of Army and has received a "Safe-to-Fly" recommendation from the Department of the Air Force. The Onyx II 9550 carries a NATO Stock Number or National Stock Number (NSN).

For additional information, contact regulatory@nonin.com.

WARNING: 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.

Manufacturer's Declaration

Refer to the following tables for specific information regarding this device's compliance to IEC 60601-1-2.

Essential Performance

Essential performance of the 9550 is defined as SpO₂ 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

<i>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.</i>	
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	
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	30 A/m	
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

<p><i>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), Conducted Immunity (IEC 61000-4-6)</i></p>
<p>NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.</p>