

Instructions for Use

Onyx[®] 9500 Finger Pulse Oximeter



Indications for Use

The Nonin[®] Onyx Model 9500 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.

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

Contraindications

- Do not use this device in an MRI environment, in an explosive atmosphere, or on infant or neonatal patients.
- This device is not defibrillation proof per IEC 60601-1:1990 clause 17h.

Warnings

- 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.
- Certain activities may pose a risk of injury, including strangulation, if the lanyard should become wrapped around your neck. Use the lanyard with caution.
- Keep the oximeter away from young children. Small items such as the battery door, battery, and lanyard are choking hazards.

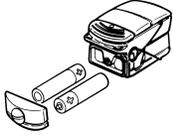
Cautions

- This device is designed to determine the percentage of arterial oxygen saturation of functional hemoglobin. Significant levels of dysfunctional hemoglobin may affect measurement accuracy.
- This device has no audible alarms and is intended only for spot-checking.
- 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.
- Fluctuating or very bright light, moisture, blood pressure cuffs, infusion lines, venous pulsations, insufficient pulse signals, anemia, arterial catheters, nail polish, and/or artificial nails may degrade the device's performance.
- 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.
- Cardiovascular and other intravascular dyes may affect the accuracy of the SpO₂ measurement.
- Do not sterilize, autoclave or immerse this device in liquid. Do not use caustic or abrasive cleaning agents or any cleaning products containing ammonium chloride.
- 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/strain relief.
- A functional tester cannot be used to assess the accuracy of a pulse oximeter monitor or sensor.
- This equipment complies with IEC 60601-1-2:2001 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 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.
- 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 of Symbol
	Consult Instructions for Use
	Follow Instructions for Use
	Caution
	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)
	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 IEC 60601-1, UL 60601-1 and CAN/CSA C22.2 No. 601.1
	Lot Number
	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.
	Authorized Representative in the European Community.
	Protected against vertically falling water drops when enclosure is tilted up to 15 degrees, per IEC 60529.
	RoHS Compliant (China)

Installing Batteries



Two 1.5 volt AAA-size batteries power the Onyx for about 1,600 spot checks or 18 hours of continuous operation. Nonin recommends using alkaline batteries (included with each new Onyx). When batteries are low, the numeric displays flash once per second. Replace low batteries as soon as possible.

NOTES:

- Remove batteries if device will be stored for more than 30 days.
- Rechargeable batteries may be used; however, they require more frequent replacement.

1. Loosen the screw at the end of the Onyx using a coin or a standard flat screwdriver.
2. Remove the battery door and the old batteries, disposing of the batteries properly.
3. Insert two new 1.5 volt AAA-size batteries. Follow the polarity markings (+ and -) as illustrated. *Proper positioning of the batteries is essential for Onyx operation.*
4. Carefully reposition the battery door. Do not force it into place; it fits only when properly positioned.
5. Tighten the screw firmly, but do not overtighten. Insert your finger in the Onyx to verify operation.

Activating the Onyx and Verifying Operation



The Onyx contains numeric LEDs that display oxygen saturation and pulse rate. A tricolor LED display 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, and *red* indicates an inadequate pulse signal.

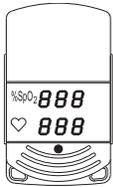
Activate the Onyx by inserting the patient's finger into the unit. The Onyx detects the inserted finger and automatically illuminates the displays. Correct positioning of the Onyx's light emitter and photodetector on the finger is critical for accurate measurements. All emitted light must pass through the fingertip.

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

1. Insert the patient's finger, nail side up, into the Onyx 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 Onyx. For best results, keep the Onyx at the patient's heart or chest level.
3. If the Onyx does not turn on, remove the finger and wait a few seconds before reinserting it.

When a finger is inserted, the Onyx performs a brief startup sequence. Verify that all LEDs illuminate during the first phase of the startup sequence. If any LED is not lit, do not use the Onyx; contact Nonin Customer Support for repair or replacement. After the startup sequence, the Onyx begins sensing the pulse (indicated by the blinking pulse quality display). Allow the Onyx to stabilize, observing about 10 seconds of continuous green-colored pulse quality before relying on the displayed values. It is common for the displayed values to fluctuate slightly over a period of several seconds. If the pulse quality display blinks yellow or red, try another finger.

A minus sign (-) appears in the left-most digit of the %SpO₂ display when the Onyx senses that the finger has been removed. The last measured SpO₂ and pulse rate values freeze for 10 seconds, and then the displays go blank. The Onyx 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.



Using the Lanyard



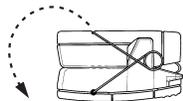
A lanyard is provided for convenience. The Onyx will function with or without the lanyard.

1. If lanyard use is desired, thread the ends of the lanyard through the lanyard holes as shown at left.
2. Push in the lanyard lock button. Slide the lock onto the lanyard to the desired length.
3. Release the lock button to secure its position.
4. Reverse this procedure to remove the lanyard.

Note: The lanyard must cross over the top of the Onyx (as illustrated) to permit full opening of the device.

Onyx Care, Maintenance, and Cleaning

The advanced digital circuitry within the Onyx requires no calibration or periodic maintenance other than battery replacement. Field repair of the Onyx circuitry is not possible. Do not attempt to open the Onyx case or repair the electronics. Opening the case will damage the Onyx and void the warranty.

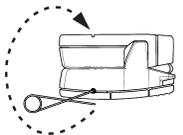


Disengaging and Removing the Spring

1. Turn the Onyx over with the back cover facing up.
2. Disengage the spring by gently pulling it up and lifting it out of the retaining groove. Next, rotate the spring forward (as indicated by the dashed arrow), bringing it past the finger cavity.
3. *(When replacing spring):* Remove the spring by carefully pulling the ends from the pivot holes on either side.

Replacing the Spring

1. Insert the ends of the new spring into the pivot holes on both sides of the Onyx. Make sure that the spring is positioned as indicated in the illustration.
2. Rotate the spring up and past the finger cavity (as indicated by the dashed arrow).
3. Seat the spring into the retaining groove.



Cleaning the Onyx's Inner Surfaces

1. Disengage the spring. (See "Disengaging and Removing the Spring.") It is unnecessary to remove the spring.
2. Wipe the surfaces with a soft cloth dampened with a mild detergent; see **CAUTION** below. Do not use any cleaning solution other than those recommended here, as permanent damage could result.
3. Dry with a soft cloth, or allow to air dry.

⚠ Caution

Do not sterilize, autoclave or immerse this device in liquid. Do not use caustic or abrasive cleaning agents or any cleaning products containing ammonium chloride.

4. Ensure that all surfaces are completely dry, and re-engage the spring. (See "Replacing the Spring.")
5. Clean once per week or more frequently if handled by multiple users.



Replacing the Gripping Insert

A gripping insert is adhered to the upper inner surface of the Onyx to provide a secure fit to the finger. Replace the gripping insert if it becomes torn or damaged, or if it begins to peel off. The Onyx will function without the gripping insert; however, Nonin recommends using the insert during normal operation. Contact your local distributor for replacement springs and gripping inserts.

1. Disengage the spring. (See instructions above.) It is unnecessary to completely remove the spring.
2. Carefully peel the old gripping insert away from the surface.
3. Remove any residual adhesive with a soft cloth dampened with isopropyl alcohol.
4. Peel the backing paper off the new gripping insert, uncovering the adhesive back.
5. Position the new insert (with the adhesive side toward the Onyx) and gently press it into place.
6. Re-engage the spring. (See "Replacing the Spring.")

Testing Summary

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

SpO₂ Accuracy Testing

SpO₂ accuracy testing is conducted during induced hypoxia studies on healthy, non-smoking, light-to-dark-skinned subjects in an independent research laboratory. The measured arterial hemoglobin saturation value (SpO₂) of the sensors is compared to arterial hemoglobin oxygen (SaO₂) value, determined from blood samples with a laboratory co-oximeter. The accuracy of the sensors 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 9919:2005, 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 module must maintain accuracy in accordance with ISO 9919:2005 for pulse rate and SpO₂ at the lowest obtainable pulse amplitude (0.3% modulation).

Specifications

Oxygen Saturation Display Range:	0% to 100% SpO ₂
Pulse Rate Display Range:	18 to 321 beats per minute (BPM)
Oxygen Saturation Declared Accuracy Range (A_{rms}*):	70% to 100% SpO ₂ ±2 digits
Low Perfusion Oxygen Saturation Declared Accuracy Range (A_{rms}*):	70-100% SpO ₂ ±2 digits
Pulse Rate Declared Accuracy Range (A_{rms}*):	20-250 BPM ±3 digits
Low Perfusion Pulse Rate Declared Accuracy Range (A_{rms}*):	40-240 BPM ±3 digits
Measurement Wavelengths and Output Power**:	
<i>Red:</i>	660 nanometers @ 0.8 mW maximum average
<i>Infrared:</i>	910 nanometers @ 1.2 mW maximum average
Temperature (Operating):	32 °F to 104 °F / 0 °C to 40 °C
<i>Temperature (Storage/Transportation):</i>	-22 °F to 158 °F / -30 °C to 70 °C
Humidity (Operating):	10% to 90% non-condensing
<i>Humidity (Storage/Transportation):</i>	10% to 95% non-condensing
Altitude (Operating):	Up to 40,000 feet / 12,192 meters
<i>(Hyperbaric Pressure):</i>	Up to 4 atmospheres
Battery Life (Continuous):	Approximately 1,600 spot checks based on ~18 hours of operation using two AAA-size alkaline batteries, calculated at 40 seconds per spot check. 9 months typical, using two AAA-size alkaline batteries
<i>Battery Life (Storage):</i>	
Classifications per IEC 60601-1 / CAN/CSA-C22.2 No. 601.1 / UL 60601-1:	
<i>Degree of Protection:</i>	Type BF-Applied Part
<i>Enclosure Degree of Ingress Protection:</i>	IPX2
<i>Mode of Operation:</i>	Continuous

This product complies with ISO 10993-1.

*± 1 Arms represents approximately 68% of measurements.

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

Warranty

NONIN MEDICAL, INCORPORATED, (Nonin) warrants to the purchaser, for a period of two years from the date of purchase, each Onyx exclusive of the batteries, spring, carrying case, lanyard, and lanyard lock. Nonin shall repair or replace any Onyx 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 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 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, field service by non-Nonin personnel, tampering, or any kind of misuse of the Onyx, 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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Manufacturer's Declaration

Refer to the following tables for specific information regarding this device's compliance to IEC 60601-1-2:2001.

Table 1: Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment—Guidance
<i>This device is intended for use in the electromagnetic environment specified below. The customer and/or user of this device should ensure that it is used in such an environment.</i>		
RF Emissions CISPR 11	Group 1	This device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	This device is suitable for use in all establishments, including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	N/A	
Voltage Fluctuations/Flicker Emissions IEC 61000-3-3	N/A	

Table 2: Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance
<i>This device is intended for use in the electromagnetic environment specified below. The customer and/or user of this device should ensure that it is used in such an environment.</i>			
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, relative humidity should be at least 30%.
Electrical Fast Transient/Burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	±5% U_T (>95% dip in U_T) for 0.5 cycle ±40% U_T (60% dip in U_T) for 5 cycles ±70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec.	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the AC mains voltage before application of the test level.			

Table 3: Guidance and Manufacturer's Declaration—Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance
<p><i>This device is intended for use in the electromagnetic environment specified below. The customer and/or user of this device should ensure that it is used in such an environment.</i></p>			
<p>Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p>			
<p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>3 Vrms 150 kHz to 80 MHz</p> <p>3 V/m 80 MHz to 2.5 GHz</p>	<p>N/A</p> <p>[3] V/m</p>	<p>Recommended Separation Distance</p> $d = 1.17\sqrt{P}$ <p>80 MHz to 800 MHz $d = 1.17\sqrt{P}$ 800 MHz to 2.5 GHz $d = 2.33\sqrt{P}$</p> <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey^a, should be less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

- a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.
- b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [3] V/m.

NOTES:

- At 80 MHz and 800 MHz, the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Table 4: Recommended Separation Distances

The following table details the recommended separation distances between portable and mobile RF communications equipment and this device.

Rated Maximum Output Power of Transmitter W	Separation Distance According to Frequency of Transmitter		
	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	80 MHz to 800 MHz $d = 1.17\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.33\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTES:

- At 80 MHz and 800 MHz, the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.