Model 9550
Instructions for Use

CE 0123

Rx Only

Instructions for Use / Operator's Manual

https://www.nonin.com/support/9550

ENG – Translations of the IFU can be found using this QR code.

FRE – Les traductions de cette notice d'utilisation peuvent être retrouvées à l'aide de ce code QR.

GER – Übersetzungen dieses Handbuchs können über diesen QR-Code abgerufen werden.

ITL – Utilizzando questo codice QR, è possibile trovare le traduzioni delle Istruzioni per l'uso.

SPA – Las traducciones de este manual se pueden encontrar utilizando este código QR.

POR – Pode aceder às traduções das instruções de utilização através deste código QR.

DUT – Vertalingen van de handleiding zijn te vinden met behulp van deze QR-code.

GRK – Με τη χρήση αυτού του κωδικού QR μπορείτε να βρείτε μεταφράσεις των οδηγιών χρήσης (IFU).

DAN – Scan denne QR-kode for at finde oversættelser af denne brugsvejledning.

SWE – Översättningar av den här guiden kan hittas med denna QR-kod.

FIN – Käyttöohjeen käännökset löytyvät tällä QR-koodilla.

POL – Tłumaczenia tego przewodnika można znaleźć za pomocą tego kodu QR.

NOR – Oversettelser av denne bruksanvisningen kan finnes ved å bruke denne QR-koden.

Warranty

The device warranty is 4 years.

nonin.com/warranty

Symbol Glossary

nonin.com/symbols

Compliance

This product complies with ISO 10993.
Not made from natural rubber latex.

For summary of safety and clinical data see above QR code.

EC REP MPS, Medical Product Service GmbH
Borngasse 20
D-35619 Braunfels, Germany

CH REP MedEnvoy Switzerland
Gotthardstrasse 28, 6302 Zug
Switzerland

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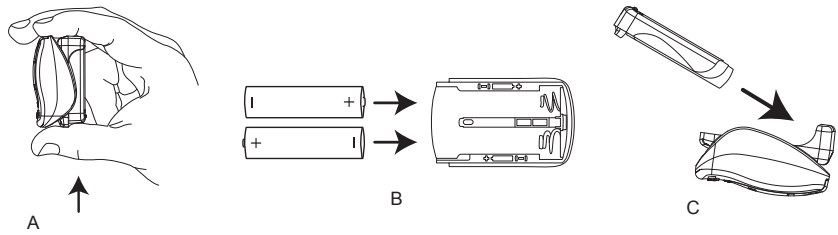
Clinical Benefits
Nonin pulse oximeters allow for the management of patients' medical conditions by providing fast, accurate, real-time, noninvasive oxygen measurement in order to meet patients' medical needs.

To use the Onyx® II 9550 fingertip pulse oximeter, please follow the simple instructions below.

1. Insert two AAA batteries. Follow the polarity markings (+ and -) as illustrated in the figure below.



2. Insert patient's finger, nail side up, into the 9550 until the fingertip touches the built-in stop guide. Ensure the finger is lying flat and is centered within the device.
3. The device detects the inserted finger and automatically illuminates the display. The display changes colors to alert you of 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

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

- Remove the finger and wait a few seconds before reinserting.
- Verify batteries are correctly inserted.
- If it still does not turn on, the batteries are depleted and must be replaced.

Specifications
Additional specifications available in the Operator's Manual that can be located using the QR Code.
- Oxygen saturation measured from 0%-100% SpO_2
- Pulse rate measured from 18bpm-321bpm
- 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).

Measurement Wavelengths and Output Power:
- Red: 660 nanometers @ 0.8 mW maximum average
- Infrared: 910 nanometers @ 1.2 mW maximum average

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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 onto the device.
- Do not use caustic or abrasive cleaning agents, or any cleaning agent containing ammonium chloride or isopropyl alcohol.

1. Wipe surfaces with a soft cloth dampened with mild detergent or 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 solutions are complete dry.

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.

Thank you for trusting Nonin with your patients' healthcare needs. We sincerely appreciate your business. Please read your Operator's Manual carefully and direct any further questions to a Nonin Technical Service representative. If you would like to order products or check the status of a current order, please contact Customer Service.

Contact Customer Service or Technical Service

Toll Free: 800.356.8874 (U.S. and Canada only)
Phone: +1 763.553.9968
Email: customerservice@nonin.com

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Doctor Paul Janssenweg 150
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Have other questions or want to learn more?

Visit **nonin.com** to read more about our history, product offerings, and more.

MIX
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FSC® FPO FPO

Nonin is committed to sustainable practices. This paper is made with FSC-certified materials, printed with soy ink, and is 100% recyclable.

Indications for Use/Intended Use/Intended Purpose

The Nonin® Onyx II 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 digits (fingers, thumb, toes) that are 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.

CAUTION: Regulatory authorities outside the U.S. recognize the use of this device in motion conditions.

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 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).
- 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 motion
  - Excessive light, such as sunlight or direct home lighting
  - 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.
- 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.

Adverse Event Statement

Users and/or patients should report adverse events involving their Nonin device to Nonin Medical, Inc. and the competent authority of the EU Member State in which the user and/or patient is established, if applicable.

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