Model 8500

Instructions for Use

CE 0123

Rx Only

Instructions for Use / Operator's Manual

https://www.nonin.com/support/8500

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 3 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

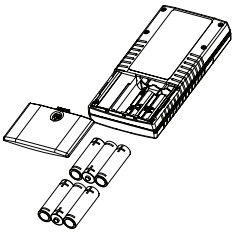
P/N 114855-001-01 11/2022 13700 1st Avenue North, Plymouth, MN 55441-5443 USA nonin.com

Model 8500

Instructions for Use

To set up and use the Nonin Model 8500 handheld pulse oximeter, please follow the simple instructions below.

Install Batteries



The Model 8500 is powered by six AA-size alkaline batteries. Insert the batteries as indicated inside the battery compartment. Proper battery positioning is essential for correct operation.

When batteries are critically low, the digital displays will go blank and the Pulse Quality Indicator will blink amber or red, but not green.

Power On and Off

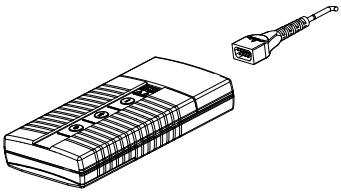
- Turn on the device by pressing the ON (|) button
- Turn off the device by pressing the OFF (Ø) button

The device automatically powers off after 10 minutes of inactivity.

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.

Connect the Sensor



Connect the pulse oximeter sensor with the Nonin logo facing up to the top of the device as shown. Ensure the sensor is firmly plugged in.

Refer to sensor's Instructions for Use for sensor positioning information.

Taking Measurements

Verify the pulse oximeter sensor is properly positioned on the patient. If the Pulse Quality Indicator is blinking red or amber or is blinking erratically, reposition or replace the sensor. The SpO_2 and Pulse Rate readings will display a single dash until a valid pulse signal is detected, which takes about 5 seconds.

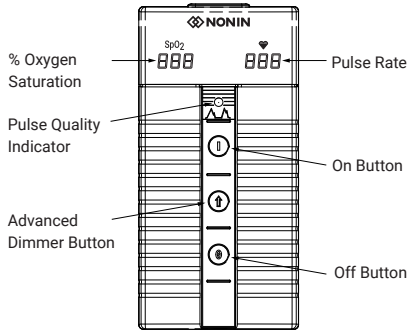


Figure 1: Front View

Care and Maintenance

Clean the device separately from the sensors. For instructions on cleaning sensors, refer to the respective instructions for use.

Clean the device with a soft cloth dampened with isopropyl alcohol or a mild detergent. Do not pour or spray any liquids onto the device, and do not allow any liquid to enter any openings in the device. Allow the device to dry thoroughly before reusing.

Please refer to the Operator's Manual on nonin.com/support/8500 for troubleshooting guidance and more detailed operating instructions.

P/N 114855-001-01 11/2022
13700 1st Avenue North, Plymouth, MN 55441-5443 USA

Model 8500

Instructions for Use

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

Nonin Medical Inc.
13700 1st Avenue North
Plymouth, MN 55441-5443, USA

Nonin B.V.
Doctor Paul Janssenweg 150
5026 RH Tilburg, Netherlands

Have other questions or want to learn more?

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

MIX
From responsible sources
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.

8500 Specifications

*Additional specifications are available in the Operator's Manual that can be located using the QR Code.

- Oxygen saturation measured from 0%-100% SpO_2. With an accuracy typically ± 2 with a maximum of ± 3.
- Pulse rate measured from 18bpm-321bpm. With an accuracy data is typically ± 3 with a maximum of ± 5.

Measurement Wavelengths and Output Power:

- Red: 660 nanometers @ 0.8 mW maximum average
- Infrared: 910 nanometers @ 1.2 mW maximum average

Indications for Use/Intended Use/Intended Purpose

Nonin Model 8500 Handheld Pulse Oximeter is indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate for adult, pediatric, and neonatal patients in hospitals, ambulatory, home, and EMS environments. Model 8500 is intended for continuous monitoring and/or spot-checking of patients when attended by a healthcare professional.

Warnings

- Do not use in an explosive atmosphere or in the presence of flammable anesthetics or gasses.
- Do not use this device in an MR environment.
- This device is not defibrillation proof per IEC 60601-1.
- 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.
- 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.
- Oximeter readings of this device may be affected by the use of an electrosurgical unit (ESU).
- To avoid patient injury, use only with Nonin-branded PureLight® pulse oximeter sensors. These sensors are manufactured to meet the accuracy specifications for Nonin Pulse Oximeters. Using other manufacturers' sensors can result in improper pulse oximeter performance.
- To prevent improper performance and/or patient injury, verify compatibility of the monitor, sensor(s), and accessories before use.
- No modifications to this device are allowed as it may affect device performance.
- Do not use a damaged sensor. If the sensor is damaged in any way, discontinue use immediately and replace the sensor.

Warnings (continued)

- As with all medical equipment, carefully route patient cabling to reduce the possibility of entanglement, strangulation, or injury to the patient.
- 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.
- The use of accessories, sensors, and cables other than those specified in the Parts and Accessories List may result in increased electromagnetic emission and/or decreased immunity of this device.
- This 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.
- Discontinue use of adhesive tape strips if the patient exhibits an allergic reaction to the adhesive material.
- Avoid excessive pressure to the sensor application site as this may cause damage to the skin beneath the sensor.
- The device turns off after approximately 10 minutes when at critically low battery capacity.
- Before changing the batteries, make sure the device is off and the sensor 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

- Before use, carefully read the Instructions for Use provided with the sensors.
- When mounting the monitor to a mobile pole, mounting the monitor higher than 1.5 meters (5 feet) or mounting more than 2 kilograms (4.5 pounds) of equipment onto the pole may result in tipping, damage to the equipment, or injury.
- This device is not an apnea monitor.
- Verify that all visible indicators illuminate during the startup (initialization) sequence. If any indicator is not lit, do not use the device. Contact Nonin Technical Service for assistance.
- The presence of a defibrillator may interfere with the performance of this device.
- This device may not work on all patients. If you are unable to achieve stable readings, discontinue use.
- This device has motion tolerant software that minimizes the likelihood of motion artifact being misinterpreted as good pulse quality. In some circumstances, however, the device may still interpret motion as good pulse quality. Minimize patient motion as much as possible.
- Ear Clip and Reflectance sensors are not recommended for pediatric or neonatal use. The accuracy of these sensors has not been established for pediatric or neonatal use.
- Do not autoclave or immerse the device or sensors in liquid. Do not expose the device or components to excessive moisture or liquids.
- Do not use caustic or abrasive cleaning agents on the device or the sensors.
- The oximeter sensor might not work on cold extremities due to reduced circulation. Warm or rub the finger to increase circulation, or reposition the sensor.
- Always replace the batteries with fully charged batteries. Do not use fully charged and partially charged batteries at the same time as this may cause the batteries to leak.
- Use only Nonin-specified battery types with this device.
- Do not remove any covers other than the battery cover when replacing batteries. There are no user-serviceable parts inside other than the replaceable batteries.
- Follow local, state and national governing ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries.
- Batteries may leak or explode if used or disposed of improperly.
- Remove the batteries if the device will be stored for more than 1 month.
- 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 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.
- 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:
  - Excessive ambient light
  - Excessive motion
  - Electrosurgical interference
  - Blood flow restrictors (arterial catheters, blood pressure - carboxyhemoglobin cuffs, infusion lines, etc.)
  - Moisture in the sensor
  - Improperly applied sensor
  - Incorrect sensor type
  - Inadequate signal
  - 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
- When using the monitor in the home, avoid exposing the monitor to lint and dust.
- When using the monitor around small children and pets, avoid leaving the monitor unattended. Cables pose a risk of injury, including strangulation.
- A functional tester cannot be used to assess the accuracy of a pulse oximeter monitor or sensor.
- All parts and accessories connected to the serial port of this device must be certified according to at least IEC Standard EN 60950, IEC 62368-1, or UL1950 for data-processing equipment.
- This device is a precision electronic instrument and must be repaired by trained Nonin personnel only. 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.
- Any sign or evidence of opening the system, field service by non-Nonin personnel, tampering, or any kind of misuse or abuse of the system, shall void the warranty in its entirety.
- Failure of a network data coupling (serial cable/connectors) will result in loss of data transfer.

Adverse Event Statement

Users and/or patients should report adverse events involve 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.