Model 2500

Instructions for Use

CE 0123

℞ Only

Instructions for Use / Operator's Manual

https://www.nonin.com/support/2500

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 114856-001-01 11/2022 13700 1st Avenue North, Plymouth, MN 55441-5443 USA nonin.com

Nonin Model 2500 PalmSAT® Pulse Oximeter and Model 2500A PalmSAT® Pulse Oximeter with Alarms

Indications for Use/Intended Use/Intended Purpose

The Nonin® Model 2500 PalmSAT® Pulse Oximeter and Model 2500A PalmSAT® Pulse Oximeter with Alarms are indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate for adult, pediatric, and neonatal patients. These devices are intended for continuous monitoring and/or spot- checking of patients during both motion and no-motion conditions, and for patients who are well or poorly perfused.

Warnings

- Do not use this device in an MR environment.
- **Explosion Hazard:** Do not use in an explosive atmosphere or in the presence of flammable anesthetics or gasses.
- 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.
- Oximeter readings of this device may be affected by the use of an electrosurgical unit (ESU).
- Inspect the sensor application site at least every 6 to 8 hours to ensure correct sensor alignment and skin integrity. Patient sensitivity to sensors and/or double-backed adhesive strips may vary due to medical status or skin condition.
- 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.
- As with all medical equipment, carefully route patient cabling to reduce the possibility of patient 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, cables, and power supplies 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.
- When a system fault occurs, the patient will no longer be monitored.
- To comply with relevant product safety standards, ensure that all alarm volumes are set appropriately and are audible in all situations. Do not cover or otherwise hinder any speaker openings.
- The device turns off after approximately 10 minutes when at low battery capacity.
- Before changing the batteries, make sure the device is off and the sensor is not attached 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.

Warnings – only for the Model 2500A PalmSAT Pulse Oximeter with Alarms

- Verify all alarm settings and limits during system startup to ensure that they are set as intended.
- A hazard can exist if different presets are used on multiple 2500A monitors in one care area.
- Because operating environments vary, use caution to ensure that all audible alarms and indicators can be heard. Users must determine the acceptable audible distance of all alarms.
- Do not place this device in an environment where its speaker opening may become blocked; alarms may become muffled or inaudible.
- Turning off the alarm volume creates a situation that is not compliant with relevant safety standards. The alarm silence indicator is lit solid when the alarm volume is turned off or set below 45 dBA.

Cautions

- Before use, carefully read the package insert provided with the sensors.
- This device is not an apnea monitor.
- Verify that all visible indicators illuminate and that an audible indicator sounds during the startup (initialization) sequence. If any indicator is not lit or the audible indicator does not sound, do not use the device. Contact Nonin Technical Service for assistance.
- Review all limits to ensure they are appropriate for the patient.
- 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.
- Replace the batteries as soon as possible after a low-battery indication. Always replace the batteries with fully charged batteries.
- Use only Nonin-specified battery types with this device.
- Do not use fully charged and partially charged batteries at the same time. This may cause the batteries to leak.
- 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.

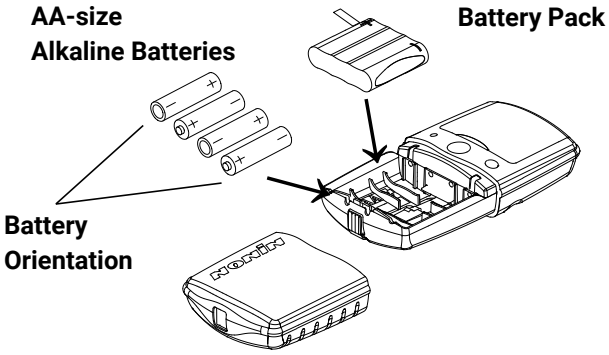
Model 2500
Instructions for Use

To use the Nonin Model 2500 (Model 2500A with alarms) PalmSAT® pulse oximeter, please follow the simple instructions below.

Install Batteries or Use Rechargeable Battery Pack

Ensure device is turned off and sensor is not applied to a digit.

1. Press the battery cover latch and remove the battery cover on the bottom of the unit
2. Insert four new AA-size alkaline batteries or a rechargeable NiMH battery pack*, as indicated by the polarity markings (+ and -) inside the battery compartment
3. Replace the battery cover and turn on the device



* Model 2500B Rechargable NiMH Battery Pack included with Model 2500C Charger Stand. 2500C Charger Stand will only work with the NiMH Battery Pack not with alkaline batteries.

Power On and Off

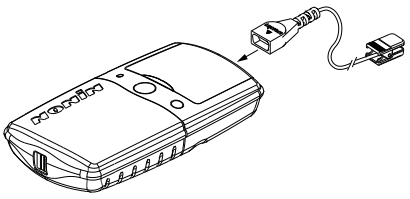
- Turn on the device by pressing and releasing the ⏻ button on the front of the unit
- Turn off the device by pressing and holding the ⏻ button for approximately two seconds

The device automatically powers off after 10 minutes of inactivity. Change battery when low battery indicator light appears. AA-sized batteries should provide 60 hours of continuous use while the rechargeable NiMH pack will provide 40 hours of continuous use.

Charging the Battery Pack Using the Charger Stand–Only Applicable to 2500C (sold separately)

To use, place a PalmSAT Pulse Oximeter containing a rechargeable battery pack into the charger stand. Next, connect the charger power supply to the charger, then plug the power supply into an appropriate AC power source (wall outlet). The battery pack will be fully charged in approximately 180 minutes.

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 the Operator's Manual or the specific sensor package insert for pulse oximeter sensor positioning information.

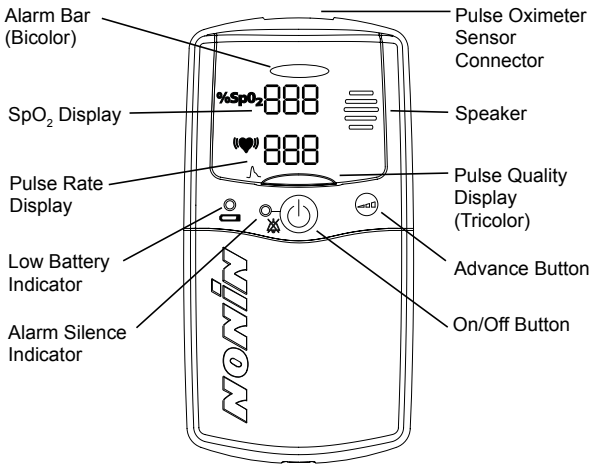
P/N 114856-001-01 11/2022
13700 1st Avenue North, Plymouth, MN 55441-5443 USA

Model 2500
Instructions for Use

Taking Measurements

Verify the pulse oximeter sensor is properly positioned on the patient. If the Pulse Quality display is blinking red or amber or is blinking erratically, reposition, or replace the sensor.

If the sensor is not properly positioned, or no sensor is attached to the pulse oximeter after startup (a few seconds after powering on), both the SpO_2 and Pulse Rate displays will display a single dash until a valid pulse signal is detected.



Alarm Functions – Only Applicable to 2500A

High-priority alarms are patient-specific and are indicated by a flashing red alarm bar and a high priority audible alarm signal. Medium-priority alarms are equipment-specific and are indicated by a flashing amber alarm bar and a medium priority audible alarm signal. These alarm cycles repeat until silenced. Silence alarms by pressing the On/Off button twice.

Users may adjust alarm settings when the device is in Setup mode.

For additional information on adjusting alarm settings, please reference the Operator's Manual.

Memory Functions

Each time the Model 2500 is turned on (except during Setup mode), data are automatically collected in memory. The device can collect and store up to 72 hours of SpO_2 and pulse rate information. Refer to the Operator's Manual.

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.

Care and Maintenance

Cleaning the pulse oximeter

- Clean the device separately from the sensors. For instructions on cleaning sensors, refer to the respective sensor Instructions for Use.
- Clean the device with a soft cloth dampened with isopropyl alcohol. 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.

Cleaning the charger stand – only applicable to 2500C (sold separately)

Unplug the power supply from the AC power outlet. Clean the product with a soft cloth dampened with isopropyl alcohol. Do not pour or spray any liquids onto the product, and do not allow any liquid to enter any openings in the product. Allow the product to dry thoroughly before reusing.

Please refer to the Operator's Manual on nonin.com/support/2500 for troubleshooting guidance and more detailed operating instructions.

P/N 114856-001-01 11/2022
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Model 2500

Instructions for Use

2500/2500A 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
- 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

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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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.

Cautions (continued)

- 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's display will go blank after 10 seconds of inadequate signals. The data update period is every 1.5 seconds.
- 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
  - A sensor not at heart level
- 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 60950 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.
- Replace batteries within 30 seconds to avoid losing settings (date, time, and patient data stored in memory) or corrupting data.
- Radios and cell phones or similar devices can affect the equipment and must be kept at least 2 meters (6.5 feet) away from equipment.
- Failure of a network data coupling (serial cable/connectors/wireless connections) will result in loss of data transfer.

Cautions – only for the Model 2500A PalmSAT Pulse Oximeter with Alarms

- Setting alarm limits to extremes can render the alarm system useless.

Nonin Model 2500C Charger Stand

Indications for Use/Intended Use/Intended Purpose

The Nonin Model 2500C Charger Stand is intended for use with the PalmSAT Models 2500 and 2500A Pulse Oximeters and the Model 2500B Rechargeable NiMH (Nickel Metal Hydride) Battery Pack.

Warnings

- Do not use this product in an MR environment.
- Do not use this product in an explosive atmosphere.
- This product is not defibrillation proof per IEC 60601-1.
- As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement, strangulation, or injury to the patient.
- This product should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the product should be observed carefully to verify normal operation.
- The use of accessories, sensors, cables, and power supplies other than those listed in the Parts and Accessories List may result in increased electromagnetic emission and/or decreased immunity of this product.
- 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.
- 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 equipment complies with International Standard 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 product. 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.
- Do not connect this product to an AC outlet controlled by a wall switch. If the switch is accidentally turned off before the battery pack is recharged, the pulse oximeter may not function.
- Grounding reliability can only be achieved when the equipment is connected to an equivalent receptacle marked "Hospital Only" or "Hospital Grade".
- This product contains sensitive electronic components and must be repaired by trained Nonin personnel only.
- Do not immerse this product in liquid.
- Do not place liquids on top of this product.
- Do not use caustic or abrasive cleaning agents on this product.
- Do not remove any covers from the product. There are no user-serviceable parts inside the unit.
- Do not attempt to charge disposable batteries. Disposable batteries may leak or explode if used improperly.
- Follow local, state and national governing ordinances and recycling instructions regarding disposal or recycling of the product and product components, including batteries. Use only Nonin-approved battery packs.
- 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 product contains WEEE materials; please contact your distributor regarding take-back or recycling of the product. If you are unsure how to reach your distributor, please call Nonin for your distributor's contact information.

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.