Model 3150

Instructions for Use

CE 0123

Rx Only

Instructions for Use / Operator's Manual

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

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

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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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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.

3150 Specifications

*Additional specifications are available in the IFU/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

The Nonin WristOx2®, Model 3150 Pulse Oximeter is a small, wrist-worn device indicated for use in measuring, displaying, and storing functional oxygen saturation of arterial hemoglobin(%SpO2) and pulse rate. It is intended for spot-checking and/or data collection and recording of adult and pediatric patients, during both no motion and motion conditions, and for patients who are well or poorly perfused. The intended use environments are hospitals, medical facilities,ambulatory, subacute, sleep study environments, and mobile units.

Warnings

- Do not use in an explosive atmosphere or in the presence of flammable anesthetics or gases.
- This device is not defibrillation proof per IEC 60601-1.
- This device is intended only as an adjunct device 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 sensors and/or double-backed adhesive strips 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.
- To avoid patient injury, use only 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.
- The USB cable must be unplugged from the device before replacing batteries.
- Before changing the batteries, make sure the device is off and the sensor is not applied to a digit.

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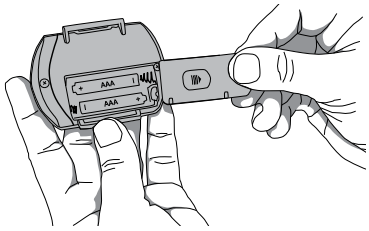
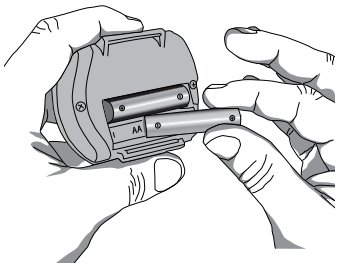
To set up and use the Nonin Model 3150 pulse oximeter, please follow the simple instructions below.

Installing Batteries

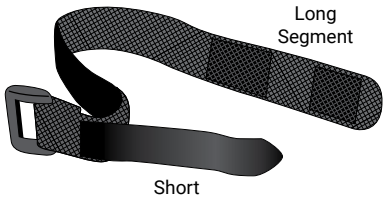
1. Open the battery compartment by sliding the battery door off the back of the device.
2. Insert 2 new AAA batteries. Battery orientation is shown inside the battery compartment.
3. Replace battery door by sliding it back into place.
4. Inserting batteries does not turn the device on. In Spot Check Activation Mode, the device turns on when a finger is inserted in the sensor.

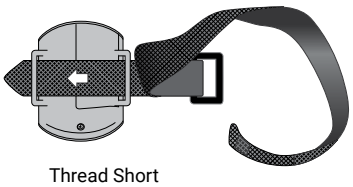


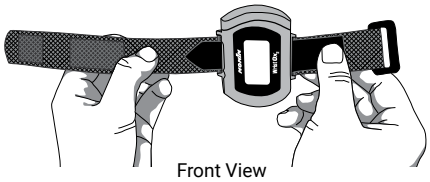


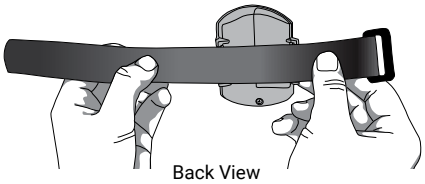
Attaching the Wristband

The WristOx$_2$ Model 3150, is designed to be applied to the patient's wrist using a wristband. There are two wristbands available for the use with the WristOx$_2$ Model 3150 - a multiple use wristband and a single use disposable wristband.



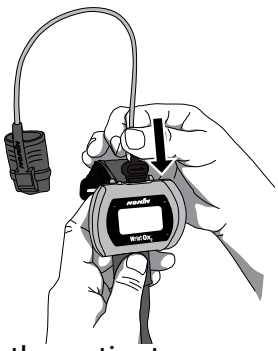






Attaching the Sensor

1. Insert the sensor connector into the sensor port at the top of the device. The Nonin logo on the sensor connector should face the front of the device.
2. Push the connector until it clicks into place.
3. The device is ready to use.



The sensor can be connected to the device before or after applying the device to the patient. Refer to Operator's Manual for applicable sensors and sizing.

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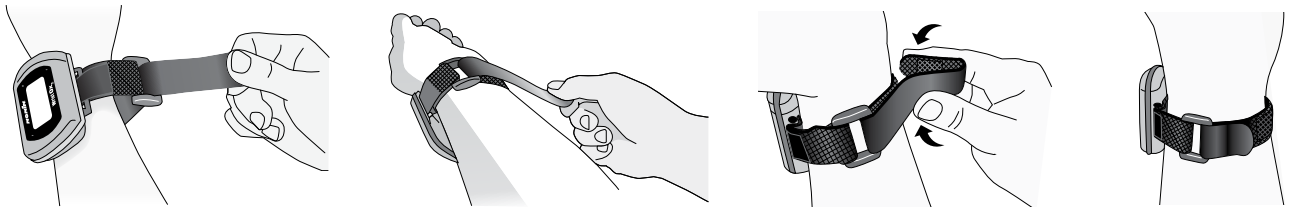
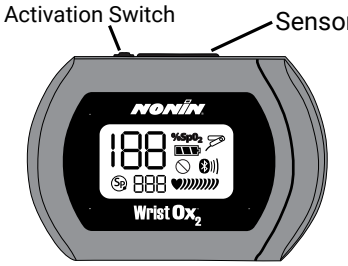
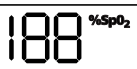
Patient Application

1. Verify the wristband has been attached properly to the device.
2. Place the device on the patient's wrist.
3. If using the multiple use wristband, thread the rounded end of the wristband through the plastic ring. Pull the strap through the plastic ring until the device fits comfortably on the wrist.
4. Fold the wristband back over the plastic ring and attach the fastener to the wristband.



Displays, Controls, and Indicators



%SpO2 Display 	This 3-digit display, located in the upper left corner of the LCD, shows percent blood oxygen saturation (%SpO_2). The range is from 0 to 100 %
Pulse Rate Display 	This 3-digit display, located below the %SpO_2 display, shows the pulse rate in beats per minute (BPM). The range is from 18 to 321 BPM.
Activation Switch	The activation switch is located next to the sensor port at the top of the $WristOx_2$ Model 3150. Pressing the switch will turn on the device.
Sensor Fault Indicator 	This indicator displays if the device determines a sensor fault exists (e.g., sensor disconnect, misalignment, or incompatibility with the device). It also displays when the finger is removed from the sensor.
Pulse Strength Indicator - Full/Partial Display mode  - Memory Volume Display mode 	A pulse strength indicator displays when the device is recording data. The bars on the display depends on the pulse strength as determined by the oximeter. This heart-shaped indicator is followed by up to nine curved bars and displays next to the pulse rate. This indicator consists of up to nine curved bars and displays next to the minutes of stored data.
Poor Pulse Signal Indicator 	This indicator displays when the pulse signal is inadequate or the device does not sense a pulse. It may also display if there is excessive motion at the sensor site.
Battery Indicator 	This indicator shows remaining battery life as either full, half, low, and critical (as shown at left). Replace the batteries when device reaches low state.
Bluetooth Indicator (BLE Model only) 	The Bluetooth indicator is used to show the current condition of the Bluetooth radio.
SmartPoint Indicator 	This indicator displays during the startup sequence.

For more information on the displays, indicators, and controls, please refer to the Operator's Manual.

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Bluetooth Connection (BLE Model only)

Before a Bluetooth collector device can connect and obtain data from the 3150 BLE the devices must be paired. The 3150 BLE will be in pairing mode the first time it is activated following the detection of battery insertion. When in pairing mode the Bluetooth icon on the display will flash once per second. After a connection and successful pairing, the Bluetooth icon will remain solid.

Nonin's WristOx$_2$ Model 3150 BLE, uses a Bluetooth Low Energy radio with a maximum range (spherical radius) of about 60 meters (196 feet). Obstacles and other conditions may affect range and battery life.

Operating Modes

The WristOx$_2$ Model 3150, has two types of mode settings: Activation and Display, which are described below. Activation modes determine how the 3150 turns off and on.

Spot Check Activation Mode is the factory default. Additional modes are available for the 3150, refer to the Operator's Manual for more information.

Memory Features

The WristOx$_2$ Model 3150 measures, collects, and stores up to 1,080 hours of SpO_2 and pulse rate data with a 4-second data collection rate. Data collected at a 1 or 2-second rate reduces memory capacity to 270 or 540 hours, respectively.

When the memory is full, the device overwrites the oldest existing data with the new data. Each time the device is turned on, data are automatically stored in memory. Data collection of less than 1 minute is not retained in memory.

Nonin's nVISION® software allows users to transfer recorded patient data from the device to a PC and then analyze, report, and archive the data. The software is required to access the device's additional modes of operation and advanced features. See Operator's Manual for more information on nVISION®.

Care and Maintenance

Clean the Model 3150 separately from the sensors. Please refer to the sensor's Operator's Manual for information on how to clean the sensors and multiple use wristband.

To clean the Model 3150:

Wipe the device with a soft cloth dampened with a 10% bleach/90% water solution (household bleach [containing less than 10% sodium hypochlorite]). Do not use undiluted bleach or any cleaning solution other than those recommended here, as permanent damage could result. Dry with a soft cloth, or allow to air dry. Clean once per week or more frequently if handled by multiple users.

Error Codes

This device includes error codes that indicate problems with the unit. See "Troubleshooting" section with Operator's Manual for codes and discriptions. If any indicator does not display, do not use the device. Contact Nonin Technical Service for assistance.

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.

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

Warnings (continued)

- 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 listed in the Parts and Accessories List may result in increased electromagnetic emission and/or decreased immunity of this device.
- Do not use the device when alarms are required.
- Do not use a damaged sensor. If the sensor is damaged in any way, discontinue use immediately and replace the sensor.
- This equipment complies with International IEC 60601-1-2 for electromagnetic compatibility (EMC) 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.
- Only use Nonin-branded sensors with a length of 1 meter or less. Accuracy may degrade if sensor cable is over 1 meter in length. Using the sensor cable adapter does not affect accuracy.
- 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

- If this device fails to respond as described, refer to “Troubleshooting” or discontinue use until the situation has been corrected. Contact Nonin Technical Service.
- 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.
- Do not place liquids on top of this device.
- When setting the clock in Programmed Activation Mode using nVISION software, verify all set times and dates are valid.
- Do not place the WristOx2, Model 3150, in liquid or clean it with agents containing ammonium chloride or isopropyl alcohol. Refer to the “Care and Maintenance” section of this operator’s manual.
- Use a detergent that is safe for skin and washable surfaces. Most detergents can be high sudsing, so use sparingly. Wipe with a damp, detergent free cloth to remove residue.
- After cleaning the multiple use wristband, it should only be applied to the same patient; do not apply it to a different patient.
- 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.
- 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 cuffs, infusion lines, etc.)
  - Moisture in the sensor
  - Improperly applied sensor
  - Incorrect sensor type
  - 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
- 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.
- Do not perform any testing or maintenance on this device while it is being used to monitor a patient.
- This device is a precision electronic instrument and must be repaired by Nonin Technical Service. Field repair of this device is not possible. Except to replace batteries, do not attempt to open the case or repair the electronics. Opening the case may damage the device and void the warranty.
- Verify all visible indicators appear during the start-up (initialization) sequence. If any indicator does not appear, do not use the device. Contact Nonin Technical Service for assistance.
- 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.
- To avoid the risk of confusing or misinterpreting patient data when transmitting data via Bluetooth, verify the device is paired with the correct display unit.
- The pulse oximeter may not work when circulation is reduced. Warm or rub the finger or reposition the sensor.
- A functional tester cannot be used to assess the accuracy of a pulse oximeter monitor or sensor.
- Do not fasten the device too tightly around the patient’s wrist. Inaccurate readings and patient discomfort could result.
- If the WristOx2, Model 3150 BLE is being used with wireless communication, use the device within its designated range of approximately 60 meters (spherical radius). Moving outside this range may cause loss of the wireless connection.
- Failure of a network data coupling (serial cable/connectors/wireless connections) will result in loss of data transfer.
- If the time and date settings are lost while in Programmed Activation Mode, the device will revert to Spot Check Activation Mode.
- 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 UL 1950 for data-processing equipment.

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.

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