Operator's Manual

Model 3150
WristOx$_2$® Pulse Oximeter

CE 0123

English

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

Consult Instructions for Use.

Nonin® reserves the right to make changes and improvements to this manual and the products it describes at any time, without notice or obligation.

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EC REP

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References to “Nonin” in this manual imply Nonin Medical, Inc.

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Indications for Use

The Nonin WristOx$_2$®, Model 3150 Pulse Oximeter is a small, wrist-worn device indicated for use in measuring, displaying, and storing functional oxygen saturation of arterial hemoglobin (%SpO$_2$) 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, and sleep study environments, and mobile units.

Warnings

Do not use this device in a Magnetic Resonance (MR) environment 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.
Check the pulse oximeter sensor application site every 4 hours to determine the positioning of the sensor and the circulation and skin sensitivity of the patient. Patient sensitivity varies depending on medical status or skin condition.
Avoid excessive pressure to the sensor application site as this may cause damage to the skin beneath the sensor.
Carefully route patient cables and connections to reduce the possibility of patient entanglement, strangulation, or injury to the patient.
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.
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 this manual 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 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.

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 Mode using nVISION software, verify all set times and dates are valid.
Do not place the WristOx$_2$, 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 single-patient 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.
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.
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.

Cautions (Continued)

A functional tester cannot be used to assess the accuracy of the oximeter or sensor.
Do not fasten the device too tightly around the patient's wrist. Inaccurate readings and patient discomfort could result.
If the WristOx$_2$, Model 3150 is being used with wireless communication, use the device within its designated range of approximately 100 meters (spherical radius). Moving outside this range may cause missing or lost data.
Failure of a network data coupling (serial cable/connectors/wireless connections) will result in loss of data transfer.

Declaration of Conformity with FCC and Canadian Ministry of Health Rules for Electromagnetic Compatibility

- Nonin Medical, Inc., of 13700 1st Avenue North, Plymouth, Minnesota, 55441, declares under its sole responsibility that Model 3150, WristOx$_2$ Pulse Oximeter, to which this declaration relates, complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.
- Ministry of Health (Canada), Safety Code 6: standards include a substantial safety margin designed to ensure the safety of all persons, regardless of age and health. The exposure standard for wireless mobile phones employs a unit of measurement known as the Specific Absorption Rate, or SAR. The SAR limit set by the FCC is 1.6 W/kg.

NCC

警語低功率電波輻射性電機管理辦法第十二條經型式認證合格之低功率射頻電機，非經許可，公司、商號或使用者均不得擅自變更頻率、加大功率或變更原設計之特性及功能。第十四條低功率射頻電機之使用不得影響飛航安全及干擾合法通信；經發現有干擾現象時，應立即停用，並改善至無干擾時方得繼續使用。前項合法通信，指依電信規定作業之無線電信。低功率射頻電機須忍受合法通信或工業、科學及醫療用電波輻射性電機設備之干擾

在 5.25-5.35 秭赫頻帶口操作之無線資訊傳輸設備，限於室口使用。

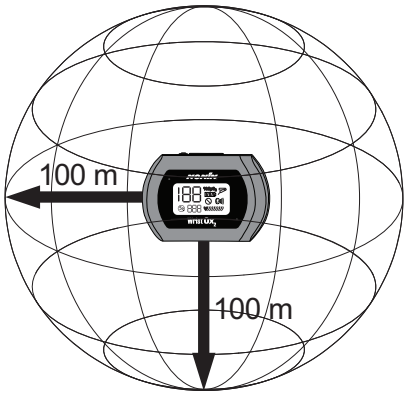
Federal Communications Commission (FCC) Notice

This device has been tested and found to comply with the limits for a class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This device generates, uses, and can radiate radio frequency energy. If not installed and used in accordance with the instructions, it may cause harmful interference to radio or television reception, which can be determined by turning the device off and on. The user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the distance between the device and the receiver.

- Connect the device to an outlet on a circuit different from the outlet where the receiver is connected
- Consult the dealer or an experienced radio/TV technician for assistance.
- RF Exposure: For body worn operation, to maintain compliance with FCC RF exposure guidelines, use only accessories that contain no metallic components. Use of other accessories may violate FCC RF exposure guidelines and should be avoided.
- The WristOx$_2$, Model 3150, is designed and manufactured not to exceed the emission limits for exposure to radio frequency (RF) energy set by the United States FCC. These limits are part of comprehensive guidelines and establish permitted levels of RF energy for the general population. The guidelines are based on the safety standards previously set by both U.S. and international standards bodies. This device has been shown to be compliant for localized specific absorption rate (SAR) for uncontrolled environment/general population exposure limits specified in ANSI/IEEE Std. C95.1-2005.
- The FCC requires the user to be notified that any changes or modifications to this device that are not expressly approved by Nonin Medical, Inc. may void the user's authority to operate the device.

Nonin's use of Bluetooth wireless technology allows SpO_2, pulse rate, and plethysmographic data to be transmitted through a Bluetooth radio to a compatible Bluetooth-enabled device. Nonin's system removes the connection from the sensor cable to the display device, giving patients increased ability to move freely—without being hindered by cables. Nonin's patient module uses a Bluetooth radio with a range of about 100 meters (328 feet) (spherical radius).



Point-to-Point Communications

The WristOx$_2$, Model 3150, features point-to-point communications, allowing one master device (the display device) to be paired to one slave device (the patient module). Once connected, neither device is detectable by any other Bluetooth-enabled device, which reduces the risk of interference and preserves data integrity.

CAUTION: If the WristOx$_2$, Model 3150 is being used with wireless communication, use the device within its designated range of approximately 100 meters (spherical radius). Moving outside this range may cause missing or lost data.

Guide to Symbols

This chapter describes the symbols that are found in this manual and on the WristOx$_2$, Model 3150. Detailed information about display symbols can be found in “Displays, Controls, and Indicators.”

Table 1: Labeling Symbols

Symbol	Description
	Caution!
	Follow Instructions for Use.
EC REP	Authorized Representative in the European Community.
CE 0123	CE Marking indicating conformance to EC directive No. 93/42/EEC concerning medical devices.
	Type BF-Applied Part (patient isolation from electrical shock)
	No alarms
	Indicates separate collection for electrical and electronic equipment (WEEE).
	Continua Certified™ signifies that this product has been tested and proven to be interoperable with other products that carry the Continua Certified symbol.
	Bluetooth® figure mark
	Non-ionizing electromagnetic radiation. Equipment includes RF transmitters. Interference may occur in the vicinity of equipment marked with this symbol.
	UL Mark for Canada and the United States with respect to electric shock, fire, and mechanical hazards only in accordance with: • ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10) and CAN/CSA-C22.2 No. 60601-1 (2008) • ISO 80601-2-61:2011
IP33	Protected against spraying water and against access to hazardous parts with a tool, per IEC 60529.

Table 1: Labeling Symbols (Continued)

Symbol	Description
	Manufacturer
	Serial Number
	Catalogue Number
	Quantity
	Date of Manufacture
	Country of Manufacture
	Storage/shipping Temperature Range
	RoHS Compliant (China)
	Medical prescription required

Displays, Controls, and Indicators

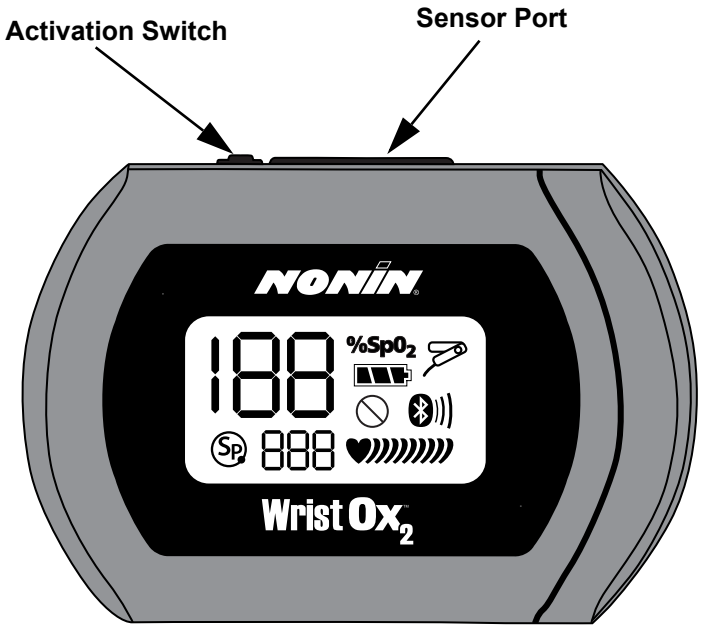


Figure 1: Front Display (Startup Screen)

%SpO_2 Display

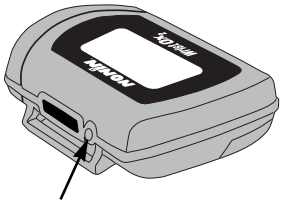
This 3-digit display, located in the upper left corner of the LCD, shows percent blood oxygen saturation (%SpO_2). The range is from 0 to 100 %.

This display also shows the month, year, and hour (24-hour clock format) during startup.

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.

This display also shows the day and minute during startup.



Activation Switch

This switch is located next to the sensor port.

Pressing this switch activates the Bluetooth radio for 3 minutes.

It can also be used to turn the device on when it is in Standby mode. See “Activation Switch” section for more information.

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

A pulse strength indicator displays when the device is recording data. The number bars on the display depends on the pulse strength as determined by the oximeter.

Full and Partial Display Mode

Full and Partial Display Mode – This heart-shaped indicator is followed by up to nine curved bars and displays next to the pulse rate.

Memory Volume Display Mode

Memory Volume (MVI) Display Mode – This indicator consists of up to nine curved bars and displays next to the minutes of stored data. For more information, see “Memory Volume (MVI) Display Mode” on page 14.

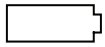
Poor Pulse Signal Indicator

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.

Full 

Half 

Low 

Critical 

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.

When the battery reaches critical state:

- All indicators clear from the display except for the blinking critical battery indicator.
- The current session closes.
- The Bluetooth radio shuts down.
- The clock settings are lost.
- The device reverts to Spot Check mode.

Bluetooth indicator

Bluetooth Indicator

This indicator displays when the Bluetooth radio is on. It appears as either the Bluetooth logo or the Bluetooth logo with animated bars.

This indicator displays for the first 2 minutes the device is on. If a master device does not connect to the device in those 2 minutes, the Bluetooth radio shuts down and the icon no longer displays.

Bluetooth indicator with animated bars

When the device is connected to a master device, the indicator displays with animated bars.

If the Bluetooth radio is on when the device enters Standby mode or connects to the USB interface cable, the Bluetooth indicator appears on the LCD while the Bluetooth radio shuts down. It will be the only indicator on the LCD and will display for up to 10 seconds.

SmartPoint Indicator

This indicator displays during the startup sequence.

Introduction

The Bluetooth-enabled WristOx$_2$, Model 3150, is a small, wrist-worn device that displays, measures, and stores patient SpO_2 and pulse rate data. The device includes a Bluetooth radio with a range (spherical radius) of approximately 100 meters (328 feet).

The device ships ready to use in Spot Check turn on mode. In Spot Check turn on mode, inserting a finger in the sensor automatically turns the device on. Approximately 10 seconds after the finger is removed, the device enters Standby mode.

Advanced memory and programming features are available with Nonin's nVISION® software (version 6.3 or greater). See the "nVISION Software" section to learn more about using the device with nVISION.

NOTE: If using the WristOx$_2$, Model 3150 with 3rd party software, please disregard nVISION information.

Unpacking the WristOx$_2$, Model 3150

The WristOx$_2$, Model 3150, standard or starter kit includes the items listed below. Once the shipping carton is unpacked, verify these items were received. Contact the carrier immediately if the shipping carton is damaged.

Standard Kit

- Model 3150, WristOx$_2$ Pulse Oximeter
- Model 8000SM-WO2, reusable soft sensor
- 1 wristband
- 2 AAA (1.5 volt) alkaline batteries
- Operator's manual (CD)
- USB driver software (on operator's manual CD) – required to use the PC USB interface cable

Starter Kit

A starter kit is required to configure the device and download data to a PC. The starter kit consists of the standard kit, plus:

- 3 wristbands
- nVISION SpO_2 data management software (CD)
- Model 3150SC, PC USB interface cable

Batteries

The device uses 2 AAA batteries.

With new alkaline batteries, battery life is approximately 53 hours (minimum) when not connected to a Bluetooth device. When connected to a Bluetooth device, battery life will vary depending on class of operation. See "Specifications" for detailed battery life information.

The battery indicator shows one of four states: full, half, low, and critical. Replace the batteries when device reaches low state. A low battery has a minimum of 10 minutes before it reaches critical state. Actual battery life depends on Bluetooth radio use. In critical battery mode:

- The battery indicator blinks.
- The device no longer monitors or records patient data.
- The clock settings are lost.
- The device reverts to Spot Check mode.

When batteries are removed in low battery mode, the device maintains the time and date for up to 30 seconds. After battery replacement, check the device's screen during startup to ensure date and time are set. Use nVISION software to synchronize the clock and change the operation mode (see "Accessing nVISION Settings" on page 29).

Remove the batteries and disconnect the sensor if the device is to be stored for more than 1 month. In storage, battery life is approximately 9 months.

NOTES:

- This device contains non-volatile memory. Removing or replacing batteries does not affect the data stored in memory. Stored data remains in memory until overwritten by newer data or cleared from memory with nVISION software (version 6.3 or greater).
- If batteries are replaced while recording data, the session will terminate and some data from the session may not be saved. The terminated session will be time stamped with the current date/time the next time the device turns on.
- To avoid potential battery cell damage for all battery types, remove batteries from the device when the critical battery indicator displays. Leaving rechargeable batteries in the device during critical battery will decrease battery life.
- If clock settings are lost, the date and time restarts at 01:01:10:00:00.

Bluetooth Technology

Bluetooth technology allows wireless connections between electronic communications and computing devices. The technology is based on a radio link that offers fast and reliable data transmissions. Bluetooth uses a license-free, globally available frequency range in the ISM band—intended to ensure communication compatibility worldwide.

Nonin's use of Bluetooth wireless technology allows SpO_2 and pulse rate data to be transmitted through a Bluetooth radio to a compatible Bluetooth-enabled device. Nonin's wireless system removes the cable connection from the device, giving patients increased ability to move freely.

To make efficient use of battery life, Nonin's WristOx$_2$, Model 3150, uses an automatically switchable Class 1/Class 2 Bluetooth radio with a maximum range (spherical radius) of about 100 meters (328 feet). Obstacles and other conditions may affect range, and class of operation and connection mode will impact battery life. See "Specifications" for detailed battery life information.

Operation Modes

The WristOx$_2$, Model 3150, has three states: Cable, Standby, and On.

Cable (USB)

The device is in Cable mode when it is connected to a PC using the USB interface cable. While in Cable mode, the device does not collect or save data and the Bluetooth radio is off.

NOTE: To save battery life, the Model 3150 will automatically shut off after 60 minutes when it is connected to a PC using the USB interface cable.

Standby

When the device is in Standby mode, the screen is blank and the device appears to be off. In Standby, it is ready for a signal that will turn the device on (e.g., pressing activation switch, inserting finger in sensor [Spot Check mode], connecting sensor [Sensor Activation mode], or programmed start time [Programmed mode]). While in Standby mode, the device does not collect or save data and the Bluetooth radio is off.

On

When the device is on, it can collect and save data. The device features three turn on modes:

- Spot Check mode
- Sensor Activation mode
- Programmed mode

The device is delivered in Spot Check mode. nVISION software (version 6.3 or greater) is needed to access the device settings and change Spot Check mode to Sensor Activation or Programmed mode (see “nVISION Software”). nVISION software (version 6.4 or greater) is needed to access memory volume (MVI) display mode.

The device recalls the active settings when the device is shut off and turned on again.

Spot Check Mode

Spot Check mode is the default turn on operation mode.

The device automatically turns on when a finger is inserted into the sensor. It enters Standby mode 10 seconds after the finger is removed. If the sensor is disconnected, the device enters Standby mode immediately.

In this mode, the sensor can be left connected to the device.

NOTE: If the device determines that a sensor fault exists (a sensor failure, misalignment, or incompatibility with the device) or if a pulse oximeter sensor signal cannot be detected, the device enters Standby mode after 3 minutes.

Sensor Activation Mode

Sensor Activation mode may be selected through nVISION software. In this mode, the device turns on when the activation switch is pressed or when the sensor is disconnected and reconnected. This mode is useful when using a sensor that is not easily removed from the sensor site (e.g., disposable or wrap sensor).

NOTE: The sensor does not need to be applied to a finger to turn the device on.

If the sensor is not used for at least 10 minutes or if an inadequate pulse signal is detected, the device automatically enters Standby mode. To turn the device on again, press the activation switch or disconnect and reconnect the sensor.

This mode allows for Full or Partial display (see figure 2 for display comparison). When using Partial display, the SpO_2 and pulse rate readings do not display. The user will only see the battery indicator and the animated pulse strength indicator.

Full Display **Partial Display**

Figure 2: Comparison of Full and Partial Display

Programmed Mode

Programmed mode may be selected and setup through nVISION software. With the software, the user can program the device to start and stop for up to three sessions. Once programmed, the next start time displays on the LCD every 30 seconds in HH:MM format.

CAUTION: When setting the clock in Programmed Mode using nVISION software, verify all set times and dates are valid.

A sensor must be connected for Programmed mode to function.

If the programmed device is in Standby mode and the activation switch is pressed, the user activates the Bluetooth radio and the device for 3 minutes. During this time, the user is able to take and store measurements. After 3 minutes, the device returns to Standby mode.

This mode allows for Full or Partial display (see figure 2 above for display comparison). When using Partial display, the SpO_2 and pulse rate readings do not display. The user will only see the battery indicator and the animated pulse strength indicator.

NOTE: A programmed device reverts to Spot Check mode if the clock is not set or if the clock settings are lost when replacing the batteries.

Memory Volume (MVI) Display Mode

NOTE: When the device is in Memory Volume display mode, the $\%SpO_2$ and pulse rate readings do not display on the screen.

MVI display mode is selected using nVISION software (version 6.4 or greater) or it can be enabled using an OEM command (refer to the Model 3150 OEM Specification and Technical Information for details). MVI display mode functions with all operating modes (spot check, sensor activation, and programmed).

Memory Volume display mode is used to quickly see how many hours and minutes of valid data are stored in the device's memory.

In Memory Volume display mode, the display screen (figure 3) only shows:

- The volume of data (in hours and minutes) stored in memory
  - hours: display range of 0 – 199
  - minutes: display range of 0 – 59
- The battery indicator
- The pulse strength indicator

When the animated pulse strength indicator displays, the device is recording data. The number next to the indicator are the minutes of stored data, not the pulse rate.

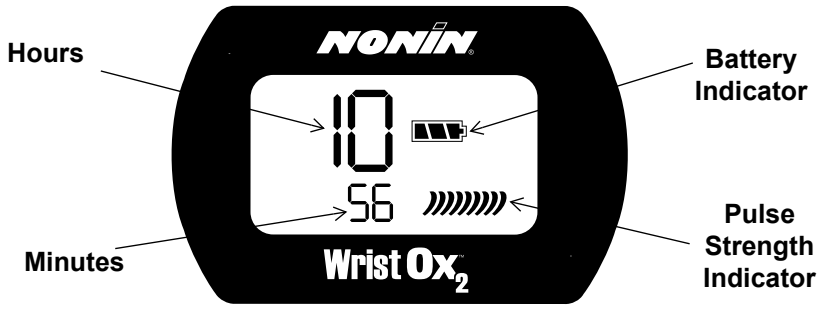


Figure 3: Memory Volume Display Mode

The example in figure 3 shows a device with 10 hours and 56 minutes of stored data.

Using the WristOx$_2$, Model 3150

WARNING: Do not use the device when alarms are required.

WARNING: The USB cable must be unplugged from the device before replacing batteries.

Installing Batteries

WARNING: Before changing the batteries, make sure the device is off and the sensor is not applied to a digit.

1. Open the battery compartment by sliding the battery door off the back of the device (figure 4).

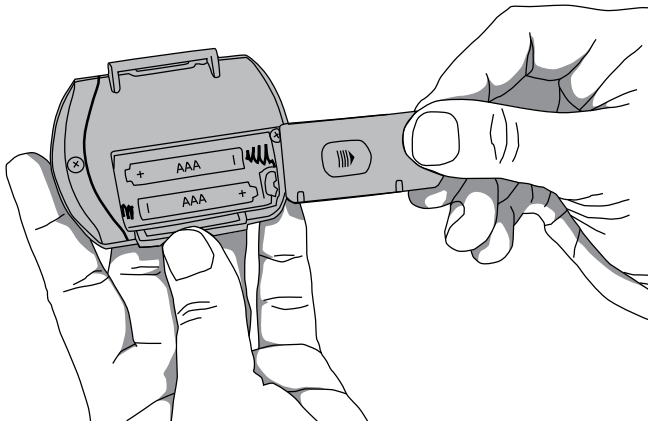


Figure 4: Remove Battery Door

2. Insert 2 new AAA batteries (figure 5). Battery orientation is shown inside the battery compartment.

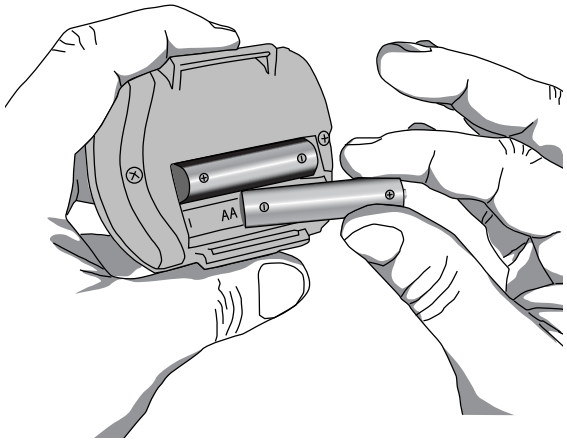


Figure 5: Insert Batteries

3. Replace battery door by sliding it back into place.

4. Inserting batteries does not turn the device on. In Spot Check mode, the device turns on when a finger is inserted in the sensor.

NOTE: When batteries are removed in low battery mode, the device maintains the time and date for up to 30 seconds. After battery replacement, check the device's screen during startup to ensure date and time are set. If the battery level is at or below the critical level, clock settings are lost and the device reverts to Spot Check mode. Use nVISION software to synchronize the clock and change the operation mode (see "Accessing nVISION Settings" on page 29).

Attaching the Wristband

The WristOx$_{2,}$ Model 3150, is designed to be applied to the patient's wrist using a wristband.

This section contains instructions for attaching the wristband to the device. See the "Patient Application" section for instructions on how to apply the device to the patient.

Wristband Description

The adjustable wristband has a long segment, a short segment, and a plastic ring (figure 6). The wristband uses hook and loop fasteners to secure the wristband to the device and to the patient.

The long segment has two fasteners to accommodate a wide range of wrist sizes.

Figures 7 and 8 demonstrate how to attach the wristband to the device. Figure 9 shows front and back views of the attached wristband.

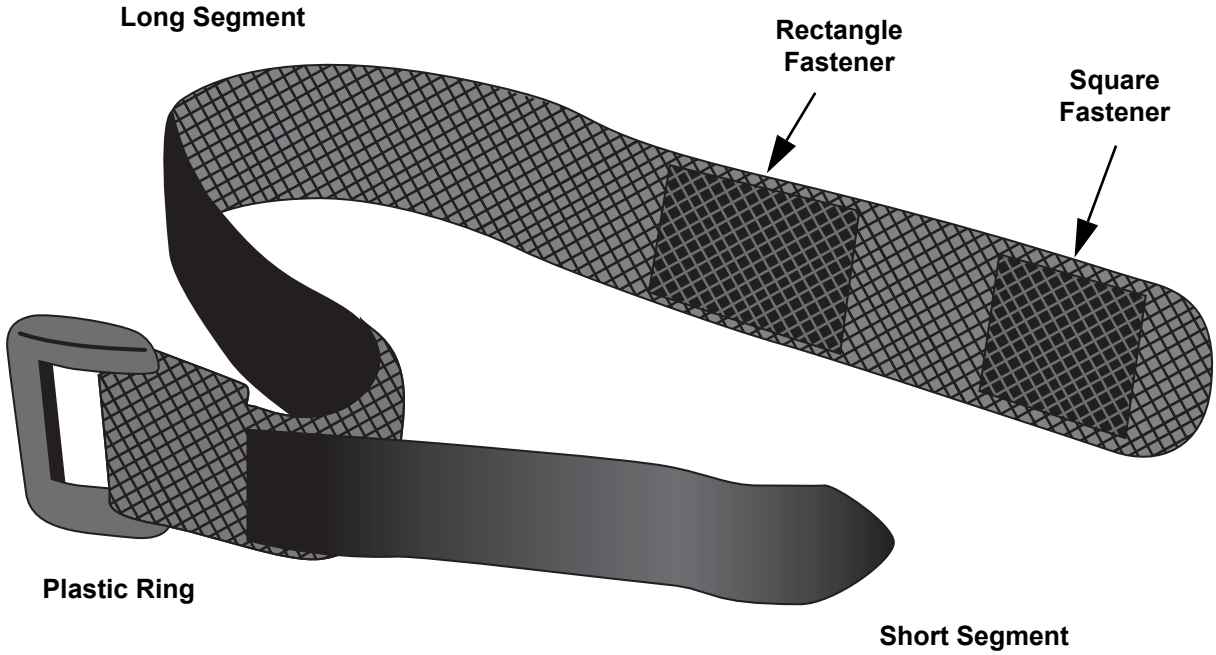


Figure 6: Wristband

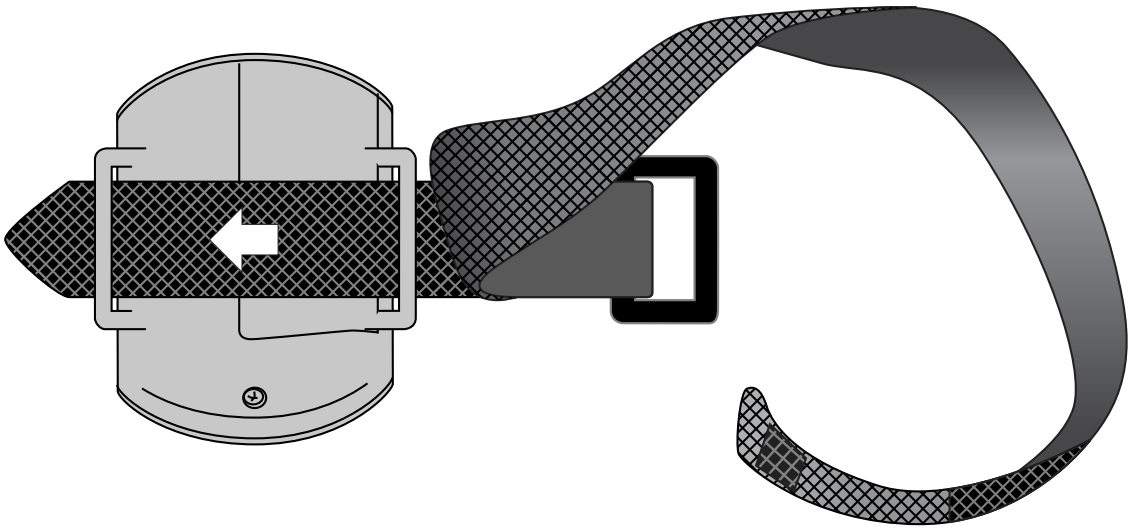


Figure 7: Thread Short Segment

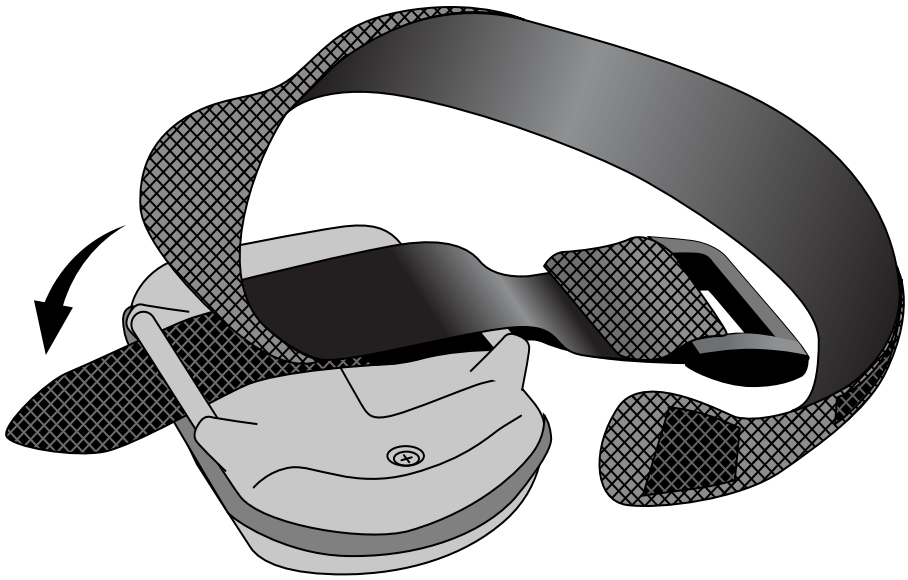


Figure 8: Secure Long Segment

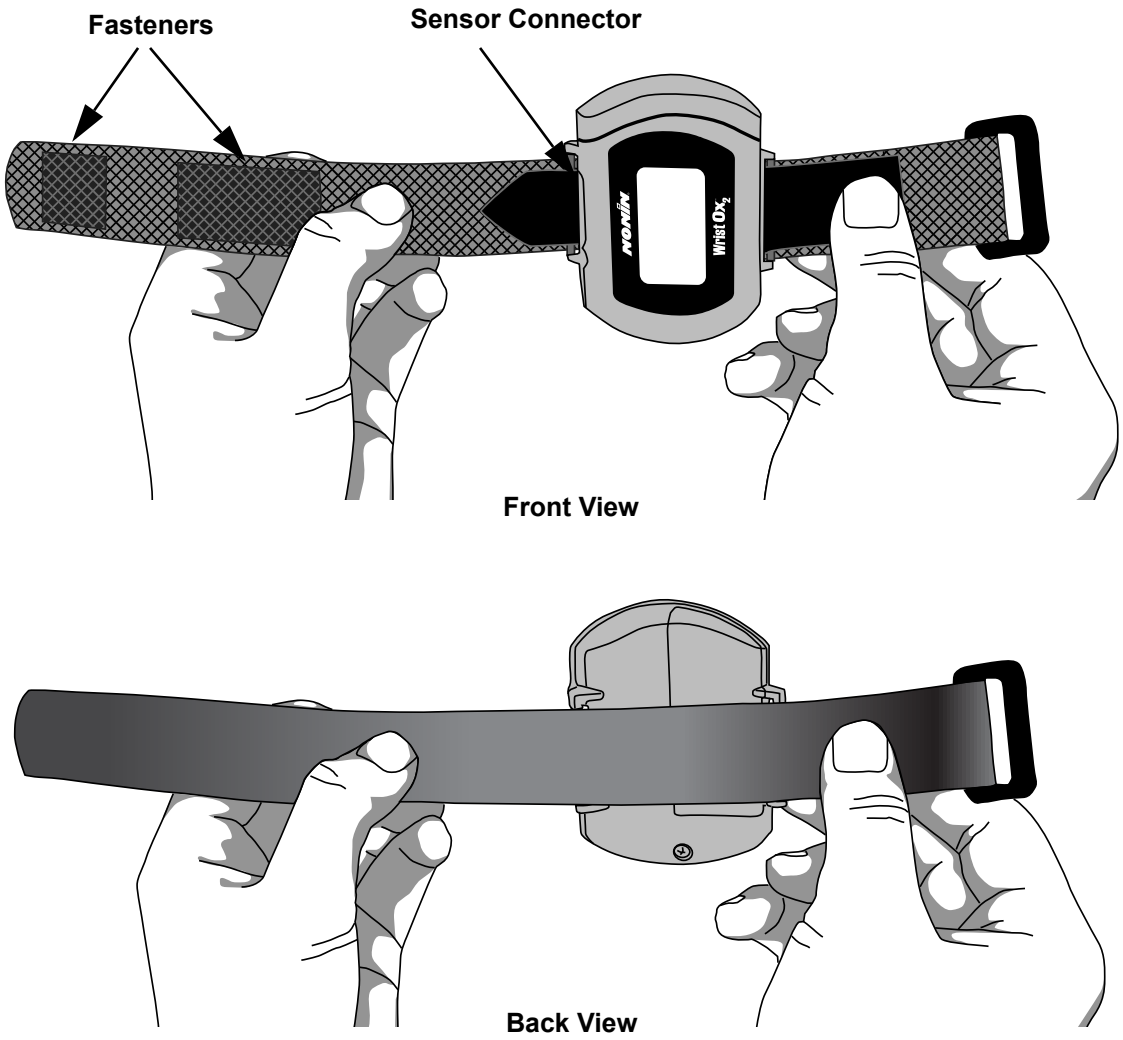


Figure 9: Device with Wristband Attached (Front and Back Views)

Attaching the Sensor

The sensor can be connected to the device before or after applying the device to the patient.

The following steps apply to these Nonin sensors:

- 8000SS-WO2, 8000SM-WO2, 8000SL-WO2
- 8000AA-WO2
- 8000J-WO2

NOTE: Refer to the sensor Instructions for Use for appropriate sensor sizing.

If using another Nonin-branded sensor, use sensor adapter cable 3150I (see “Parts and Accessories”).

WARNING: 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.

1. Insert the sensor connector into the sensor port at the top of the device (figure 10). 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.

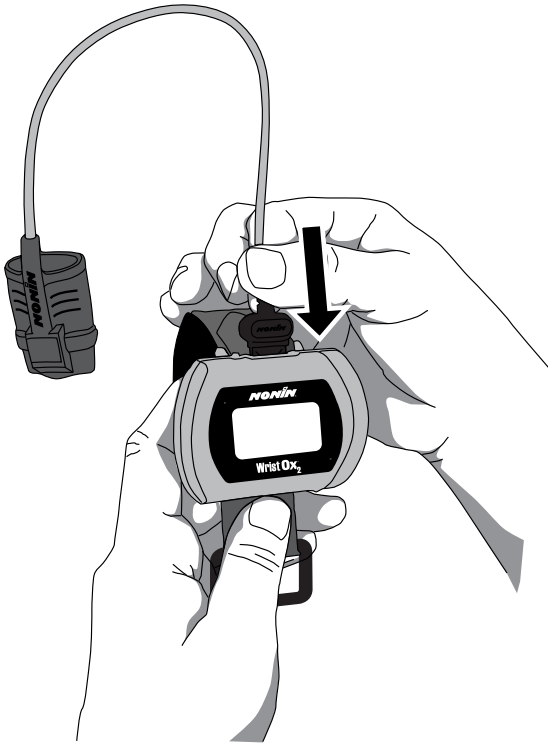


Figure 10: Attach Sensor

Patient Application

The WristOx$_{2,}$ Model 3150, is usually worn on the back of a patient's wrist.

NOTE: The wristband can be used to secure the device to an alternate location (e.g., the upper arm or a bed rail).

NOTE: Ensure the wristband fits comfortably on the patient's arm. Do not over-tighten the wrist band.

1. Verify the wristband has been attached properly to the device (figure 9). If the wristband has not been attached to the device, see "Attaching the Wristband."
2. Place the device on the patient's wrist.
3. 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 (figure 11).

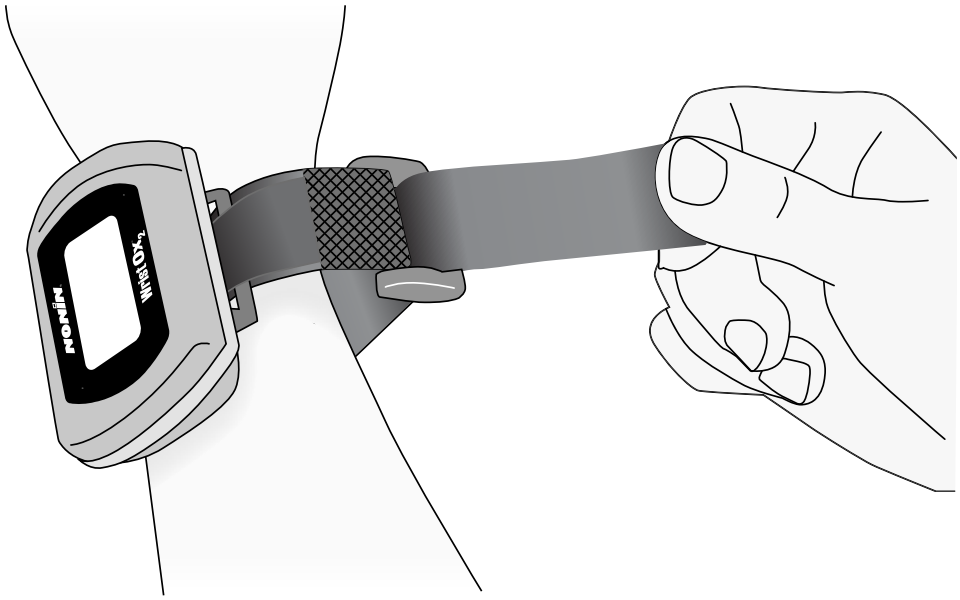


Figure 11: Thread and Tighten Wristband

4. Fold the wristband back over the plastic ring (figure 12) and attach the fastener to the wristband (figure 13 or figure 14). Wrist circumference will determine which fastener is used.

NOTE: When using the rectangle fastener, the end of the wristband can be shortened. To do so, fold the end of the wristband so the square fastener attaches onto the wristband (figure 13).

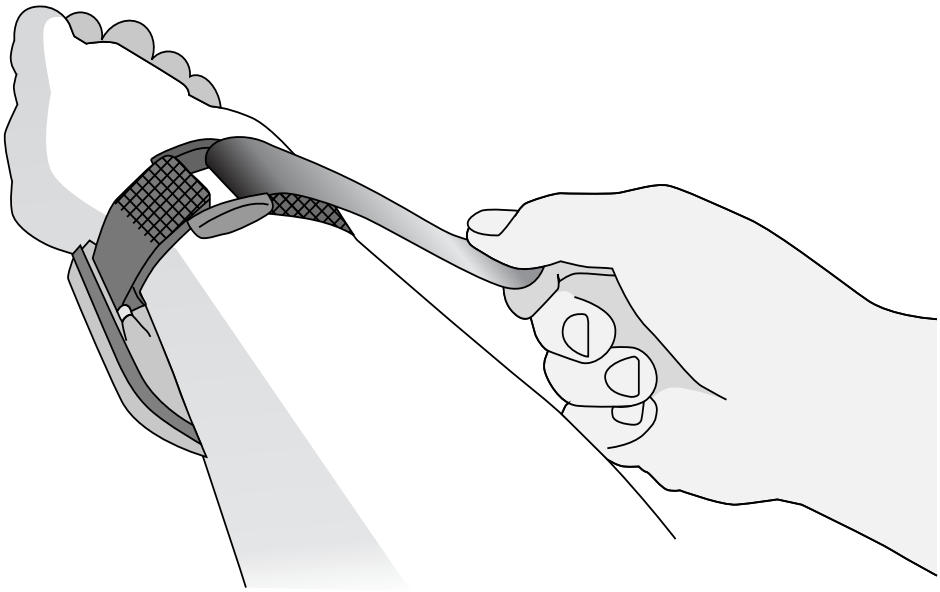


Figure 12: Fasten Wristband

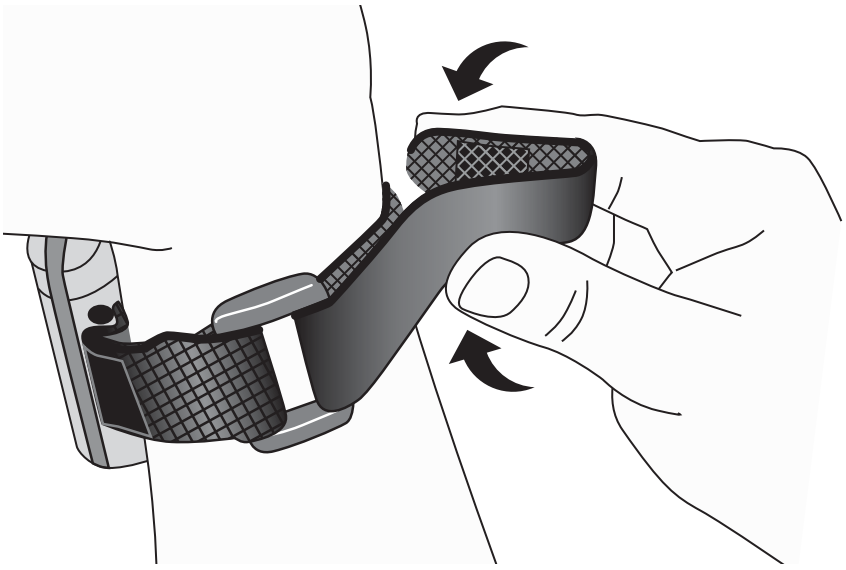


Figure 13: Using the Rectangle Fastener

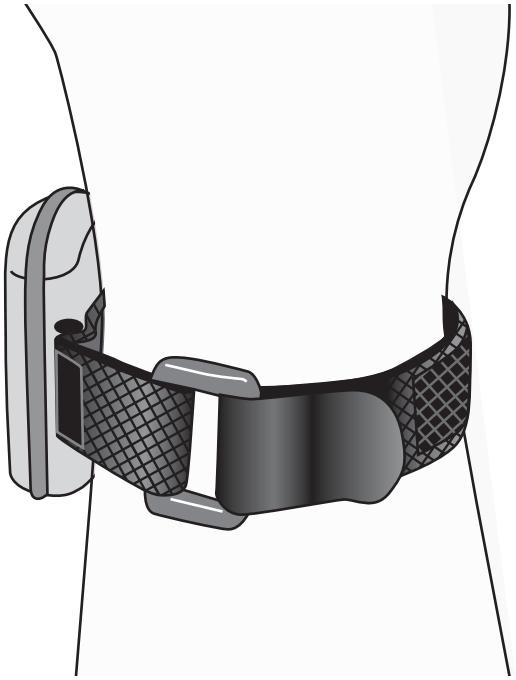


Figure 14: Using the Square Fastener

5. Attach the sensor if it is not already connected (see “Attaching the Sensor”).
6. Apply the sensor to the patient (figure 15). Refer to the sensor Instructions for Use for proper sensor application sites and sensor application cautions and warnings.

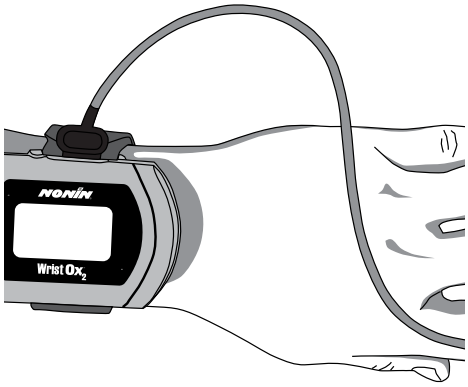


Figure 15: Apply Sensor to Patient

7. When in Spot Check mode, inserting a finger in the sensor automatically turns the device on. When the finger is removed, the device enters Standby mode in approximately 10 seconds.

NOTE: Depending on the sensor and ambient light conditions, it may take up to 3 minutes for the device to enter Standby mode.

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8. If the device does not turn on, verify battery orientation, operation mode, and sensor connection. Refer to “Troubleshooting” for additional information.

Verifying Operation

When the WristOx$_2$, Model 3150, first turns on, it performs a startup sequence and self-test. It occurs:

- When a sensor is applied to a patient (Spot Check mode).
- When a sensor is attached to the device (Sensor Activation mode).
- At a programmed start time when a sensor is attached to the device (Programmed mode).
- After the activation switch is pressed while the device is in Standby mode.
- After the device disconnects from nVISION (Bluetooth connection only).

Verify all indicators display during the startup sequence. Indicators appear in the following order for 1 second each.

Startup Sequence and Self-Test

1. r and the software revision level:

2. All display icons:

3. Date/time using 24-hour clock format (MM:DD:YY:HH:MM) (example shows 23 April 2010 at 5:57 p.m.):

Month and Day
(MM:DD)

Year
(YY)

Hour and Minutes
(HH:MM)

If the time is not set, the device displays 01:01:10:00:00.

If any indicator does not display, do not use the device. Contact Nonin Technical Service for assistance.

Activation Switch

The activation switch is located next to the sensor port at the top of the WristOx$_{2,}$ Model 3150. It is primarily used to:

- Activate the Bluetooth radio when the device is either on or in Standby.
- Activate the device when it is in Sensor Activation mode so the user does not need to disconnect and reconnect the sensor.

It will also activate the device when it is in Spot Check and Programmed modes.

Activate Bluetooth Radio

When the device's Bluetooth radio is on, a master device can connect to it. If a connection is not made, the Bluetooth radio shuts down.

Pressing the activation switch turns the Bluetooth radio on for 3 minutes. The device will remain on until the Bluetooth radio shuts down. For example, if in Sensor Activation mode, unplugging the sensor will not put the device in Standby.

Activate Device

When in Sensor Activation mode, the device enters Standby mode after 10 minutes without a signal. Pressing the activation switch allows the user to turn the device on without disconnecting and reconnecting the sensor.

Error Codes

This device includes error codes that indicate problems with the unit. When an error occurs, the device displays the letters "Er" and a two-digit code (table 2).

Table 2: Error Codes

Error Code	Description
01	Configuration sector error
02	Patient data pointer error
03	Main memory pointer error (Device memory is intact; however, the most recent session may be missing from the device.)
04	Data format 13 stored packet pointer error
05	Main data format 13 pointer error (Device memory is intact; however, the most recent stored measurement may be missing from the device.)

Some error codes may be corrected by the user. See "Troubleshooting" for more information.

Troubleshooting

Problem	Possible Cause	Possible Solution
Device will not activate.	Batteries inserted wrong.	Check batteries.
	Batteries are depleted.	Replace batteries.
	Sensor is disconnected.	Reconnect sensor.
	Device is in Sensor Activation mode and has timed out.	Press the activation switch.
		Disconnect and then reconnect the sensor.
	Device is in Programmed mode.	Use nVISION software to select Spot Check or Sensor Activation mode.
%SpO_2 and pulse rate do not display.	Device set in Partial Display mode.	Use nVISION software to select Full Display mode. Reconnect sensor.
Poor pulse signal ⃠ indicator displays.	Excessive patient motion.	Reduce patient motion.
Poor pulse signal ⃠ indicator displays and pulse strength ♥))) indicator shows two bars or less.	Inadequate pulse signal.	Reposition or replace sensor, or place sensor on a different finger.
		Remove and reconnect sensor.
	Hands are cold.	Warm sensor application site.
No pulse display on pulse strength bar graph indicator.	Sensor applied incorrectly.	Refer to sensor Instructions for Use for proper sensor application.
	Device needs repair.	Contact Nonin Technical Service.
	Possible interference from blood flow restrictors (arterial catheters, blood pressure cuffs, infusion lines, etc.).	Reduce or eliminate restriction.
	Reduced circulation due to excess pressure from sensor.	Check sensor alignment, reposition sensor, verify correct sensor size.
	Excessive ambient light.	Shield sensor from light source. Check sensor alignment.
	Sensor applied to polished or artificial nail.	Remove fingernail polish or an artificial nail.
	Sensor Light-Emitting Diode (LED) is not lit.	Contact Nonin Technical Service.

Problem	Possible Cause	Possible Solution
Er 01 displays on LCD.	Device configuration memory failure.	Device reverts to default settings (Spot-Check mode, 4-second sample rate). Use nVISION software to change settings. If error code continues, contact Nonin Technical Service.
Er 02 or 04 displays on LCD.	Device memory failure.	Contact Nonin Technical Service.
Er 03 or 05 displays on LCD.	Device failure. Device memory intact, but device may have lost most recent session or stored data.	If error code continues, contact Nonin Technical Service.
Dashes continually display on LCD.	Sensor malfunction.	Replace sensor with a Nonin-branded sensor.
Device does not record in Programmed mode.	Data collection start and stop times are set incorrectly.	Use nVISION software to program correct start and stop times.
	Clock settings are lost after replacing batteries.	Use nVISION software to reset clock.
Devices will not pair.	Device is out of range.	Verify device is in range while being paired (approximately 100 meters [328 feet] spherical radius).
	Bluetooth radio has timed out.	Press activation switch to turn on Bluetooth radio.
%SpO_2 indicator and the heart in the pulse strength indicator do not display.	Device has been set to Memory Volume (MVI) display mode.	Use nVISION software to configure the device to full or partial display mode.

If these solutions do not correct the problem, please contact Nonin Technical Service at (800) 356-8874 (USA and Canada), + 1 (763) 553-9968, or +31 (0)13 - 79 99 040 (Europe).

Care and Maintenance

The device requires no calibration or maintenance other than battery replacement. The device's expected service life is 5 years.

Cleaning the Device

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.

CAUTION: Do not place the WristOx$_2$, Model 3150, in liquid or clean it with agents containing ammonium chloride or isopropyl alcohol.

Cleaning the Sensor

Refer to the sensor Instructions for Use for cleaning information.

Cleaning the Wristband

The wristband is designed for single-patient use. If it needs to be cleaned, hand wash with a mild detergent (see note) in cool water (30 °C/86 °F). Allow to air dry.

Do not machine wash or dry. The wristband will shrink if placed in a dryer.

NOTES:
- Mild detergents, such as hand and dish washing liquid detergents, dissolve dirt and grease. To clean washable surfaces, use in a solution of warm water.
- Replace the wristband if the hook and loop fastener no longer secures the wristband to the device or to the patient.

CAUTION: 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.

CAUTION: After cleaning the single-patient use wristband, it should only be applied to the same patient; do not apply it to a different patient.

Storing

Store the device within the stated environmental specifications. See "Specifications" for additional information.

Remove the batteries and disconnect the sensor if it is to be stored for more than 1 month.

Memory and Data

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.

Each time the device turns on, the current oximeter time and date (if the clock is set properly) are stored in memory to allow quick differentiation of recording sessions. Patient SpO_2 and pulse rate are stored every 4 seconds (default), or every 1 or 2 seconds if programmed using nVISION software. The oxygen saturation values are stored in 1% increments in the range of 0 to 100%.

This device contains non-volatile memory. Removing or replacing batteries does not affect the data stored in memory. Stored data remains in memory until overwritten by newer data or cleared from memory with nVISION software.

NOTE: Downloading data in memory does not clear memory. To clear memory, see “nVISION Settings.”

nVISION Software

Nonin's nVISION software (version 6.3 or greater) works with Microsoft Windows® operating systems. It 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.

nVISION Settings

The following WristOx$_2$, Model 3150, settings are programmed using nVISION:

- Date and time – 24-hour clock format
- Display options – allows clinicians to choose the best display option for each patient:
  - Full display shows %SpO$_2$ and pulse rate data
  - Partial display shows pulse strength indicator, but not %SpO$_2$ and pulse rate data
  - MVI (memory volume) display shows pulse strength indicator and volume (hours and minutes) of data stored in memory. %SpO$_2$ and pulse rate readings do not display on the screen.
- Patient data storage (sample) rate – 1, 2, or 4 seconds
- Operation Modes – Sensor Activation, Spot-Checking, and Programmed (see "Activation Options")
- Patient ID – up to 50 alphanumeric characters
- Bluetooth Radio – disable at startup
- Synchronize device time/date to the PC time/date
- Download and save patient data to a PC
- Clear device memory

To access nVISION settings, connect the device to a PC using either the PC USB interface cable or a Bluetooth connection.

Accessing nVISION Settings

1. Connect the device to a PC using the USB interface cable (see "Cable Connection") or Bluetooth (see "Bluetooth Connection").

NOTE: If using Windows 2000, the WristOx$_2$, Model 3150 will only connect to a PC with a Bluetooth connection. Windows 2000 does not function with the USB interface cable.

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2. Open nVISION.
3. Click the **Data Capture** icon, or select **New Data Capture** from the File drop down menu.
4. Select **3150** from the list of oximeters.
5. Click **Settings**.
6. "Enter Wrist Oximeter Settings" window opens (figure 16). Update or change settings as needed.
7. Click **OK**.

8. For more information, see nVISION Help.

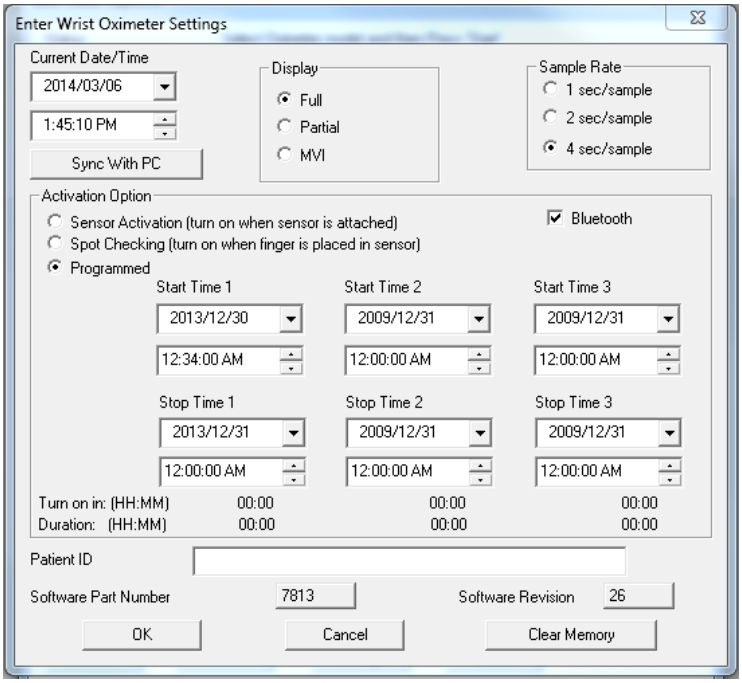


Figure 16: nVISION Settings Window

Cable Connection

NOTE: To save battery life, the Model 3150 will automatically shut off after 60 minutes when it is connected to a PC using the USB interface cable.

To connect the device to a PC, use the PC USB interface cable found in the starter kit. Once connected to a PC, the device settings may be accessed and data can be downloaded using nVISION software.

The USB driver software for the cable needs to be installed before the device can connect to the PC. The software is located in the USB Driver folder on the Operator's Manual CD.

1. Install USB driver if needed. See appropriate "USB Driver Installation" section for more information.
2. Connect the cable to the USB port on the PC.
3. Connect the cable to the device's sensor port.
4. When the device is ready to use with nVISION, these indicators display on the LCD:
   - CP
   - Battery indicator

5. For more information about nVISION, refer to nVISION Help.

NOTE: Disconnect the USB interface cable from the device when the data transfer or device configuration is complete. Leaving the cable connected will reduce battery life.

USB Driver Installation (Windows 7)

1. The USB driver software is on the Model 3150 Operator's Manual CD. Insert the CD into the PC's CD/DVD drive.
2. Connect the Model 31501SC USB cable to the sensor port on the Model 3150 and a USB port on the PC.
3. Open the Device Manager by clicking **Start / Control Panel / System** and then selecting Device Manager.
4. Expand **Other devices**.
5. Right click **Model 3150** and select **Update Driver Software...**
6. Update Driver Software - Model 3150 window opens. Choose **Browse my computer for driver software**.
7. Browse to the USB Driver folder on the Operator's Manual CD and click **OK**.
8. Click **Next**.
9. In the Windows Security pop-up window, select **Install this driver software anyway**.
10. Driver software installs. When Windows has successfully updated the driver software, click **Close**.
11. In the Device Manager window, look up the communications (comm or COM) port for the device. Expand **Ports (COM & LPT)**. One port should say "Nonin Model 3150 (COM#)." Make a note of the COM#. It is needed to set up the Model 3150 with nVISION software.

USB Driver Installation (Windows 8)

1. The USB driver software is on the Model 3150 Operator's Manual CD. Insert the CD into the PC's CD/DVD drive.
2. Connect the Model 3150SC USB cable to the sensor port on the Model 3150 and a USB port on the PC.
3. Open the Device Manager by right clicking in the bottom left corner of the screen and then click **Device Manager**. Device Manager window opens.
4. If needed, expand **Other devices**.
5. Right click **Model 3150** and select **Update Driver Software...**
6. Update Driver Software - Model 3150 window opens. Choose **Browse my computer for driver software**.
7. Browse to the USB Driver folder on the Operator's Manual CD and click **Next**. Verify that "Include subfolders" is checked.
8. In the Windows Security pop-up window, check "Always trust software from Nonin Medical, Inc." and then click **Install**.
9. Driver software installs. When Windows has successfully updated the driver software, click **Close**.
10. In the Device Manager window, look up the communications (comm or COM) port for the device. Expand **Ports (COM & LPT)**. One port should say "Nonin Model 3150 (COM#)." Make a note of the COM#. It is needed to set up the Model 3150 with nVISION software.

USB Driver Installation (Windows 10)

1. The USB driver software is on the Model 3150 Operator's Manual CD. Insert the CD into the PC's CD/DVD drive.
2. Connect the Model 3150SC USB cable to the sensor port on the Model 3150 and a USB port on the PC.
3. Type **Device Manager** in the taskbar's search box, then select Device Manager from the list of results. Device Manager window opens.
4. If needed, expand **Other devices**.
5. Right click **Model 3150** and select **Update Driver Software...**
6. Update Driver Software - Model 3150 window opens. Choose **Browse my computer for driver software**.
7. Browse to the USB Driver folder on the Operator's Manual CD and click **Next**. Verify that "Include subfolders" is checked. **NOTE:** If the Windows Security pop-up window displays, check "Always trust software from Nonin Medical, Inc." and then click **Install**.
8. Driver software installs. When Windows has successfully updated the driver software, click **Close**.
9. In the Device Manager window, look up the communications (comm or COM) port for the device. Expand **Ports (COM & LPT)**. One port should say "Nonin Model 3150 (COM#)." Make a note of the COM#. It is needed to set up the Model 3150 with nVISION software.

Bluetooth Connection

NOTE: Etched onto the device is the word "pin" followed by a 6-digit number. This is the device's unique identification number, also known as the Bluetooth Passkey or PIN Code. This number is used when pairing the device to the host system. Refer to the host system's operator's manual for additional information.

Before a Bluetooth master device can connect with the WristOx$_2$, Model 3150 (slave device), the devices must be paired. Once paired, the WristOx$_2$, Model 3150, will automatically connect with the last paired master device when turned on or activated.

1. To connect the WristOx$_2$, Model 3150, to a PC or another device using Bluetooth, see Nonin's online Bluetooth Connection Tutorial:

   http://www.nonin.com/training/products/3150/bluetooth_connection_tutorial/

2. When nVISION connects to the WristOx$_2$, Model 3150, the device stops recording patient data and the following indicators display on the LCD:
   - CP
   - Battery indicator
   - Bluetooth icon with animated bars

3. For more information about nVISION, refer to nVISION Help.

Bluetooth Security

The Bluetooth radio contained in the 3150 is compliant to version 2.0 of the Bluetooth Specification. It supports the Serial Port Protocol (SPP) and the Health Device Profile (HDP) with security mode 2 (service level enforced). The supported encryption key size is up to 128 bits and encryption is enforced on all outgoing and incoming data channels. While the 3150 is in a Bluetooth connection, it will be unavailable for other connections.

Bluetooth Profiles Supported:	Serial Port Profile (SPP), Health Device Profile (HDP)
Security Mode:	Mode 2 (service-level enforced security)
Authentication and Encryption:	Enforced on all data channels (outgoing and incoming)
Encryption Key Size:	Up to 128 bits

Connecting the Device into a Medical System

Incorporating the device into a medical system requires the integrator to identify, analyze, and evaluate the risks to patient, operators, and third parties. Subsequent changes to the medical system after device integration could introduce new risks and will require additional analysis. Changes to the medical system that must be evaluated include:

- Changing the system configuration
- Adding devices to or disconnecting devices from the system
- Updating or upgrading equipment connected to the system

Issues resulting from user-initiated system changes may include corruption or loss of data.

NOTES:
- When using the sensor port to connect the device to other equipment, follow each device's cleaning instructions.
- Verify all equipment connected to the device is suitable for the patient's environment.

CAUTION: Failure of a network data coupling (serial cable/connectors/wireless connections) will result in loss of data transfer.

Parts and Accessories

For more information about Nonin parts, accessories, and sensors, contact your distributor, or contact Nonin at (800) 356-8874 (USA and Canada), +1 (763) 553-9968, or +31 (0)13 - 79 99 040 (Europe). This information is also available on Nonin's website: www.nonin.com.

Model Number	Description
3100CC	Carrying Case
3150 Manual	CD with Operator's Manual and USB Driver Software
3150SC	PC USB Interface Cable
nVISION	nVISION Software (version 6.3 or greater). Used with Microsoft Windows operating systems.
3150I	Sensor Interface Cable. Used to connect 1-meter, 9-pin connector sensors to the WristOx$_2$, Model 3150. For compatible 1-meter sensors, see below, contact Nonin or your distributor, or visit www.nonin.com.
3150WB	Wristband
3100WBE	Wristband Extender, 5 in. (13 cm)

Sensors

WARNING: 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.

Model Number	Description
Reusable Pulse Oximeter Sensors – 12 inch (0.3 meter) length	
8000AA-WO2	Adult Articulated Finger Clip Sensor
8000J-WO2	Adult Flex Sensor
8000SS-WO2	Soft Sensor Small
8000SM-WO2	Soft Sensor Medium
8000SL-WO2	Soft Sensor Large

Model Number	Description
Optional Pulse Oximeter Sensors (use with Interface Cable 3150I)	
Reusable – 1 meter length	
8000AA	Adult Articulated Finger Clip Sensor
8000AP	Pediatric Finger Clip Sensor
8000Q2	Ear Clip Sensor
8000R	Reflectance Sensor
8000H	Reflectance Sensor Holder
8000SS	Soft Sensor (small)
8000SM	Soft Sensor (medium)
8000SL	Soft Sensor (large)
8000J / 8000JFW	Adult Flex Reusable Sensor / FlexiWrap® Single-Use Sensor Wrap
Disposable – 1 meter length	
6000 Series	Disposable Sensors
6000CA	Adult
6000CP	Pediatric
7000 Series	Flexi-Form® III Single-Patient Use Sensors
7000A	Adult
7000P	Pediatric
6500MA	Adult/Pediatric
6500SA	Adult/Pediatric

Service, Support, and Warranty

Service and Support

For information about the device and accessories, contact your local sales representative or distributor. For the sales representative or distributor in your area, contact Nonin.

A return authorization number is required before returning any product to Nonin. To obtain this return authorization number, contact Nonin's Technical Service Department at:

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

(800) 356-8874 (USA and Canada)
+ 1 (763) 553-9968
Fax: + 1 (763) 553-7807
E-mail: technicalservice@nonin.com

Nonin Medical B.V.
Prins Hendriklaan 26
1075 BD Amsterdam, Netherlands

+31 (0)13 - 79 99 040 (Europe)
Fax: +31 (0)13 - 79 99 042
E-mail: technicalserviceintl@nonin.com

nonin.com

Warranty

NONIN MEDICAL, INCORPORATED, (Nonin) warrants to the purchaser the Model 3150, WristOx$_2$ Pulse Oximeter for 3 years from the date of purchase. Nonin shall repair or replace any WristOx$_2$, Model 3150, 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 said notification occurs within the applicable warranty period. This warranty shall be the sole and exclusive remedy by the purchaser hereunder for any WristOx$_2$, Model 3150, delivered to the purchaser that 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 unit found to be within specifications.

The WristOx$_2$, Model 3150, is a precision electronic instrument and must be repaired by knowledgeable and specially trained Nonin personnel only. Accordingly, any sign or evidence of opening the WristOx$_2$, Model 3150, field service by non-Nonin personnel, tampering, or any kind of misuse of the WristOx$_2$, Model 3150, shall void the warranty.

All non-warranty work shall be performed according to Nonin standard rates and charges in effect at the time of delivery to Nonin.

DISCLAIMER/EXCLUSIVITY OF WARRANTY:

THE WARRANTIES IN THIS MANUAL ARE EXCLUSIVE, AND NO OTHER WARRANTIES OF ANY KIND, WHETHER STATUTORY, WRITTEN, ORAL, OR IMPLIED, SHALL APPLY.

Technical Information

NOTE: This product complies with ISO 10993-1, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing.

CAUTION: A functional tester cannot be used to assess the accuracy of a pulse oximeter monitor or sensor.

CAUTION: Portable and mobile RF communications equipment can affect medical electrical equipment.

Manufacturer's Declaration

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

Table 3: Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment—Guidance
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.		
RF Emissions CISPR 11	Group 2	This device must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
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 4: Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance
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.			
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 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 seconds	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	30 A/m	30 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 5: Guidance and Manufacturer's Declaration—Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance
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.			
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.			
			Recommended Separation Distance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = 1.17\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m 3 V/m	80 MHz to 800 MHz $d = 1.17\sqrt{P}$ 800 MHz to 2.7 GHz $d = 2.33\sqrt{P}$ 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). 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] Interference may occur in the vicinity of equipment marked with the symbol: 
NOTES: 1. At 80 MHz and 800 MHz, the higher frequency range applies. 2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

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.

Table 6: Recommended Separation Distances

This table details the recommended separation distances between portable and mobile RF communications equipment and this device

This device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. Users of this device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the device as recommended below, according to maximum output power of the communications equipment.

	Separation Distance According to Frequency of Transmitter		
Rated Maximum Output Power of Transmitter W	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	80 MHz to 800 MHz $d = 1.17\sqrt{P}$	800 MHz to 2.7 GHz $d = 2.33\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.73
1	1.2	1.2	2.3
10	3.7	3.7	7.3
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:

1. At 80 MHz and 800 MHz, the higher frequency range applies.

2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Equipment Response Time

If the signal from the sensor is inadequate, the last measured SpO_2 and pulse rate values freeze for 10 seconds and are then replaced with dashes.

SpO_2 Values	**Average**	**Latency**
Standard/Fast Averaged SpO_2	4 beat exponential	2 beats

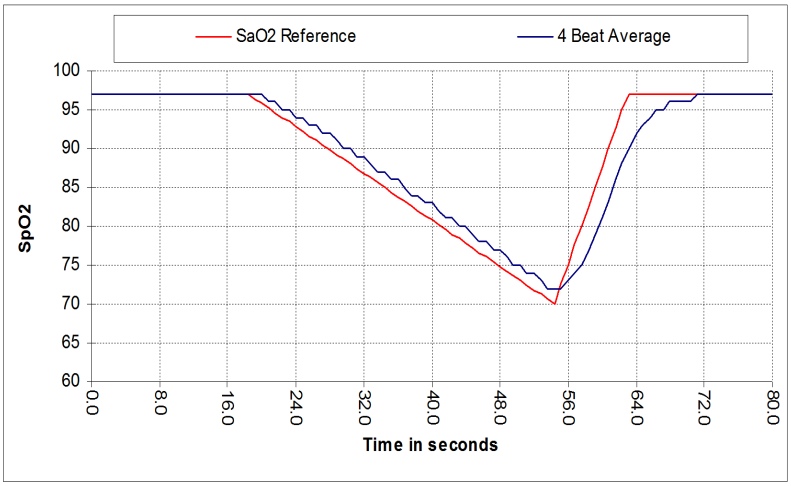
Pulse Rate Values	**Response**	**Latency**
Standard/Fast Averaged Pulse Rate	4 beat exponential	2 beats

Equipment Delays	**Delay**
Display Update Delay	1.5 seconds

Example - SpO_2 Exponential Averaging

SpO_2 decreases 0.75% per second (7.5% over 10 seconds)

Pulse Rate = 75 BPM



Specific to this example:

- The response of the 4-beat average is 1.5 seconds.

Testing Summary

SpO_2 accuracy and low perfusion testing was conducted by Nonin Medical, Inc., as described below.

SpO_2 Accuracy Testing

During motion and no-motion conditions at an independent research laboratory, SpO_2 accuracy testing is conducted during induced hypoxia studies on healthy, male and female, non-smoking, light- to dark-skinned subjects that are 18 years of age and older. The measured arterial hemoglobin saturation value (SpO_2) of the sensors is compared to arterial hemoglobin oxygen (SaO_2) value, determined from blood samples with a laboratory co-oximeter. The accuracy of the sensors in comparison to the co-oximeter samples measured over the SpO_2 range of 70 – 100%. Accuracy data is calculated using the root-mean-squared (A_{rms} value) for all subjects, per ISO 80601-2-61, Medical Electrical Equipment—Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use.

Pulse Rate Motion Testing

This test measures pulse rate oximeter accuracy with motion artifact simulation introduced by a pulse oximeter tester. This test determines whether the oximeter meets the criteria of ISO 80601-2-61 for pulse rate during simulated movement, tremor, and spike motions.

Low Perfusion Testing

This test uses an SpO_2 Simulator to provide a simulated pulse rate, with adjustable amplitude settings at various SpO_2 levels for the oximeter to read. The oximeter must maintain accuracy in accordance with ISO 80601-2-61 for heart rate and SpO_2 at the lowest obtainable pulse amplitude (0.3% modulation).

Principles of Operation

Pulse oximetry is a non-invasive method that passes red and infrared light through perfused tissue and detects the fluctuating signals caused by arterial pulses. Well-oxygenated blood is bright red, while poorly oxygenated blood is dark red. The pulse oximeter determines functional oxygen saturation of arterial hemoglobin (SpO_2) from this color difference by measuring the ratio of absorbed red and infrared light as volume fluctuates with each pulse.

Specifications

Oximeter Specifications

Oxygen Saturation Display Range:	0 to 100 % SpO_2
Pulse Rate Display Range:	18 to 321 beats per minute (BPM)
Displays:	
Numeric:	3-digit LCD
Pulse Strength:	Pulse Strength Bar Graph
Accuracy – Sensors:	Declared accuracy data for compatible sensors can be found in Nonin's Sensor Accuracy document.
Measurement Wavelengths and Output Power[a]:	
Red:	660 nanometers @ 0.8 mW max. avg.
Infrared:	910 nanometers @ 1.2 mW max. avg.

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

System Specifications

Temperature:	
Operating:	-5 °C to 40 °C (23 °F to 104 °F)
Storage/Transportation:	-40 °C to 70 °C (40 °F to 158 °F)
Time (from storage) for monitor to be ready for its intended use:	10 minutes to warm from -40 °C to -5 °C 10 minutes to cool from 70 °C to 40 °C
Device temperature will not exceed 41°C as measured during a controlled environment test.	
Humidity:	
Operating:	10 % to 95 % noncondensing
Storage/Transportation:	10 % to 95 % noncondensing
Operating Altitude:	Up to 4,000 meters (13,123 feet)
Operating Hyperbaric Pressure:	Up to 4 atmospheres

Power Requirements:	Two AAA (1.5V) batteries		
Battery Life (expected minimum): **NOTE:** Based on testing new and fully-charged batteries. See footnotes for brands used. Refer to battery manufacturers' operator's manuals for instructions for use.	**Alkaline AAA[a]**	**Rechargeable AAA (700 mAh)[b]**	**Rechargeable AAA (1100 mAh)[c]**
Storage: MVI display mode off: MVI display mode on:	9 months 25 days	Not specified	Not specified
Operating without Bluetooth, continuous use:	53 hours	36 hours	55 hours
Operating at 100 m (Bluetooth Class 1[d]), continuous use:	19 hours	15 hours	24 hours
Operating at 10 m (Bluetooth Class 2), continuous use:	21 hours	16 hours	24 hours
Dimensions (without sensor or wristband):	51 mm x 73 mm x 19 mm (H x W x D) (2.0 in. x 2.9 in. x 0.75 in.)		
Weight (with batteries and wristband):	70.0 g (2.5 oz)		
Memory: Type: Capacity:	 Non-volatile up to 1,080 hours (4 sec. data storage rate) up to 540 hours (2 sec. data storage rate) up to 270 hours (1 sec. data storage rate)		
Classification per ANSI/AAMI ES60601-1 and CAN/CSA-C22.2 No. 60601-1: Type of Protection: Degree of Protection: Mode of Operation: Enclosure Degree of Ingress Protection: This product complies with ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluation and testing.	 Internally powered (battery power) Type BF-Applied Part Continuous IP33		

a.Batteries used: Harding Model LR03 Alkaline AAA

b.Batteries used: Energizer Recharge® Power Plus Model NH12BP NiMH AAA
Charger used: Energizer Model CH15MN2

c.Batteries used: Ansmann Model 5035232 NiMH AAA
Charger used: Ansmann PL 8 Model AN12510

d. When operating with Bluetooth, typical battery life may vary depending on proximity to host connection and configuration of host-to-device communications. Times provided are minimum times for common configurations.

Transmitter

Bluetooth Compliance:	Version 2.0
Operating Frequency:	2.4 to 2.4835 GHz
Output Power:	< 20 dBm
Operating Range:	100-meter (328-foot) radius indoors
Network Topology:	Point-to-Point
Operation:	Slave
Antenna Type:	Internal
Modulation Type:	Frequency Shift Keying Frequency Hopping Spread Spectrum
Band Width:	1 MHz