NONIN

Operator's Manual

Model 3150
WristOx$_2$® Pulse Oximeter
BLE and USB

CE 0123

English

Rx Only	**CAUTION: Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner.**
	Follow Instructions for Use.
	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.

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

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

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

Phone: +31 (0)13 - 79 99 040 (Europe)
E-mail: infointl@nonin.com

www.nonin.com

CE 0123

EC	REP

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

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

Nonin, WristOx$_2$, PureLight, nVISION, FlexiWrap, and Flexi-Form are registered trademarks or trademarks of Nonin Medical, Inc. The Bluetooth word mark and logo are owned by the Bluetooth SIG, Inc. and any use of such marks by Nonin Medical, Inc. is under license. Other trademarks and trade names are those of their respective owners.

© 2020 Nonin Medical, Inc.

114415-001-01

Contents

Indications for Use **1**
- Warnings 1
- Cautions 2
- Declaration of Conformity with FCC and Canadian Ministry of Health Rules for Electromagnetic Compatibility 3
- Point-to-Point Communications (BLE Only) 4

Guide to Symbols **5**

Displays, Controls, and Indicators **7**

Introduction **10**
- Unpacking the WristOx$_{2,}$ Model 3150 10
  - Standard Kit (USB or BLE) 10
  - Starter Kit (USB Only) 10
- Batteries 10
- Bluetooth Technology (3150 BLE only) 11

Modes **12**
- Activation Modes 12
  - Spot Check Activation Mode 12
  - Sensor Activation Mode 12
  - Programmed Activation Mode 12
- Display Modes 13
  - Full Display Mode 13
  - Partial Display Mode 13
  - Memory Volume (MVI) Display Mode 13

Using the WristOx$_{2,}$ Model 3150 ..... **15**
- Installing Batteries 15
- Attaching the Wristband 16
  - Wristband Description 16
- Attaching the Sensor 22
- Patient Application 23
- Verifying Operation 28
  - Startup Sequence and Self-Test 28
- Error Codes 29

Troubleshooting **30**

Care and Maintenance **32**
- Cleaning the Device 32
- Cleaning the Sensor 32
- Cleaning the Multiple Use Wristband 32
- Storing 32

Contents (continued)

Memory and Data **33**

nVISION Software **34**

nVISION Settings 34
Accessing nVISION Settings 34
Cable Connection 35
USB Driver Installation (Windows 7) 36
USB Driver Installation (Windows 8) 36
USB Driver Installation (Windows 10) 37
Bluetooth Connection 37
Bluetooth Security 37
Bluetooth Wireless Technology Information 38
Connecting the Device into a Medical System 38

Parts and Accessories **40**

Sensors 40

Service, Support, and Warranty **42**

Service and Support 42
Warranty 42

Technical Information **43**

Manufacturer's Declaration 43
Essential Performance 43
Equipment Response Time 45
Testing Summary 46
SpO_2 Accuracy Testing 46
Pulse Rate Motion Testing 46
Low Perfusion Testing 46
Principles of Operation 46
Specifications 47
Oximeter Specifications 47
System Specifications 47
..... 48
Transmitter 49

Figures

Figure 1. Front Display (Startup Screen) 7
Figure 2. Comparison of Full and Partial Display 13
Figure 3. Memory Volume Display Mode 14
Figure 4. Remove Battery Door 15
Figure 5. Insert Batteries 15
Figure 6. Multiple Use Wristband 17
Figure 7. Thread Short Segment 17
Figure 8. Secure Long Segment 18
Figure 9. Device with Multiple Use Wristband Attached (Front and Back Views) 19
Figure 10. Single Use Wristband 20
Figure 11. Device with Single Use Wristband Attached 21
Figure 12. Attach Sensor 22
Figure 13. Thread and Tighten Wristband 23
Figure 14. Fasten Wristband 24
Figure 15. Using the Rectangle Fastener 24
Figure 16. Using the Square Fastener 25
Figure 17. Attach Single Use Wristband 26
Figure 18. Removal of Single Use Wristband 27
Figure 19. Apply Sensor to Patient 27
Figure 20. nVISION Settings Window 35

Tables

Table 1. Labeling Symbols 5
Table 2. Error Codes 29
Table 3. Electromagnetic Emissions 43
Table 4. Electromagnetic Immunity 44
Table 5. Not Applicable 44

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, 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 (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.

Warnings (Continued)

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 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 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.

Cautions (Continued)

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 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 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 USB 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.

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.

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 WristOx2, 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.

Point-to-Point Communications (BLE Only)

The WristOx2, Model 3150 BLE, features point-to-point communication and allows only one connection at a time. Once the 3150 BLE is in a connection, it will no longer be advertising and therefore is not available for an additional connection.

> ⚠ **CAUTION:** If the WristOx$_2$, 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 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.
	Consult Instructions for Use.
	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 (BLE only).
	Bluetooth® figure mark (BLE only)
	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 in accordance with: • ANSI/AAMI ES60601-1:2005/(R)2012 and CAN/CSA-C22.2 No. 60601-1:14 • ISO 80601-2-61:2017 • IEC 60601-1-11:2015

Table 1: Labeling Symbols (Continued)

Symbol	Description
IP33	Protected against spraying water and against access to hazardous parts with a tool, per IEC 60529.
	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

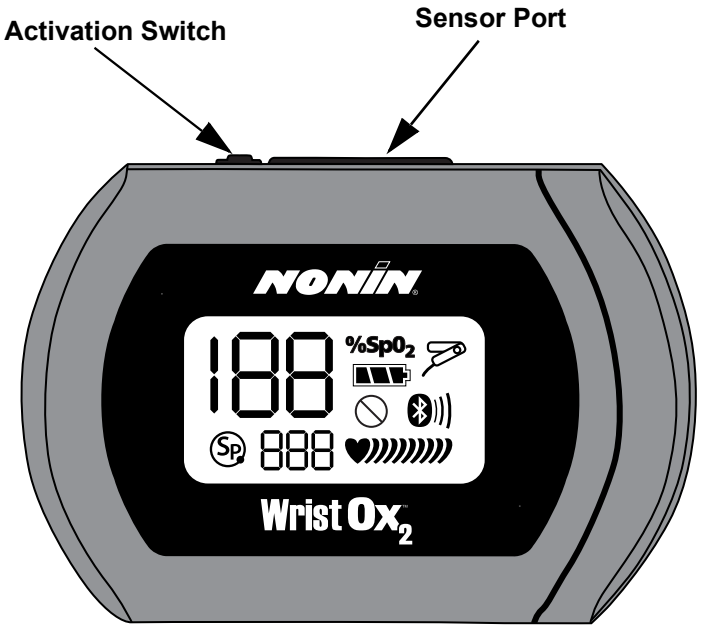


Figure 1: Front Display (Startup Screen)

%SpO_2 Display

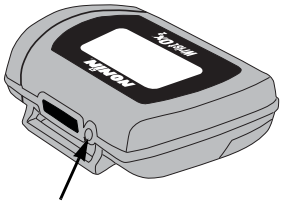
This 3-digit display, located in the upper left corner of the LCD, shows percent blood oxygen saturation (%SpO_2). The range is from 0 to 100 %.

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

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

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 13.

Poor Pulse Signal Indicator

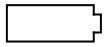
This indicator displays when the pulse signal is inadequate or the device does not sense a pulse. It may also display if there is excessive motion at the sensor site.

Battery Indicator

Full

Half

Low

Critical 

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.

Bluetooth Indicator (BLE Model only)

Bluetooth indicator

Bluetooth indicator with animated bars

The Bluetooth indicator is used to show the following conditions:

- Flashing once per second – The radio is on and is available for a new pairing. (This will occur for up to 2 minutes following battery installation or until a pairing is made).
- Solid On – The Bluetooth radio is on and currently not in a connection.
- Solid on with animated bars - The Bluetooth radio is on and is connected to a collector.

SmartPoint Indicator

This indicator displays during the startup sequence.

Introduction

The WristOx$_2$, Model 3150 pulse oximeter is a small, wrist-worn device that displays, measures, and stores patient SpO_2 and pulse rate data and is capable of transmitting stored data via USB. The 3150 BLE model includes a Bluetooth Low Energy radio with a range (spherical radius) of approximately 60 meters (196 feet).

Advanced memory and programming features are available with Nonin's nVISION® software (version 6.5 or greater). See the "nVISION Software" section to learn more about using the device with nVISION.

NOTE: If using the WristOx$_2$, Model 3150 BLE 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 (USB or BLE)

- 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 (includes operator's manual) – required to use the PC USB interface cable
- Carrying case (3150 USB Only)

Starter Kit (USB Only)

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

- 2 additional wristbands (3 total)
- 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 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 the 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.

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 confirm the device is in the desired activation mode (see "Accessing nVISION Settings" on page 34).

Remove the batteries and disconnect the sensor if the device is to be stored for more than 1 month. Do not store with batteries installed.

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 6.5 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 (January 1st, 2010 at 12:00 a.m.).

Bluetooth Technology (3150 BLE only)

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.

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. See "Specifications" for detailed battery life information.

Modes

The WristOx$_2$, Model 3150, has two types of mode settings: Activation and Display, which are described below.

Activation Modes

Activation modes determine how the 3150 turns off and on. Spot Check Activation Mode is the factory default.

Spot Check Activation Mode

In this activation mode, the 3150 will automatically turn on when a finger is inserted into the sensor. It will turn off 10 seconds after the finger is removed. If the sensor is disconnected, the device turns off immediately.

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 turns off after 3 minutes.

Sensor Activation Mode

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 patient (e.g., disposable or wrap sensor).

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

Programmed Activation Mode

When in Programmed Activation Mode, the user can program the device to turn on for up to three sessions. In between the programmed sessions, the device will turn off. When off, the device will display the next session start time every 30 seconds.

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

A sensor must be connected to the 3150 in order for the 3150 to turn on at the programmed session time.

Between the programmed sessions, pressing the activation switch will turn on the device for three minutes. During this time, the user is able to take and store measurements. After three minutes, the device will turn off.

⚠ **CAUTION:** A device in Programmed Activation Mode reverts to Spot Check Activation Mode if the clock is not set or if the clock settings are lost when replacing the batteries or due to critical battery level.

Display Modes

Full Display Mode is the factory default.

Full Display Mode

Full Display Mode will display SpO_2, pulse rate, the animated pulse strength indicator and battery life on the display (as well as the connection status for the 3150 BLE.)

Partial Display Mode

When using Partial Display Mode, the SpO_2 and the pulse rate readings do not display. The user will only see the battery indicator and the animated pulse strength indicator. See *figure 2* below for display comparison with Full Display Mode.

Full Display **Partial Display**

Figure 2: Comparison of Full and Partial Display

Partial Display Mode is not supported in Spot Check Activation Mode.

Memory Volume (MVI) Display Mode

Memory Volume (MVI) Display Mode is selected using nVISION software (version 6.5 or greater). 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.

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

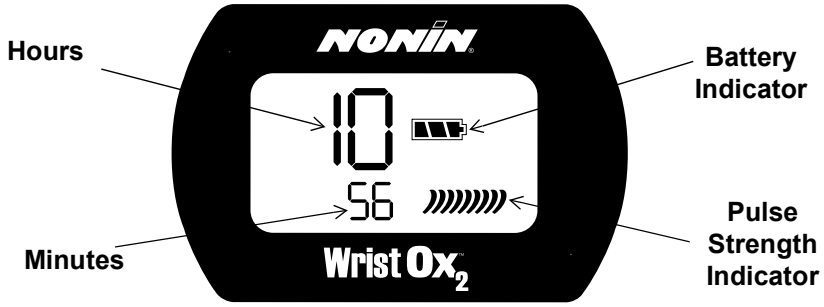


Figure 3: Memory Volume Display Mode

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).

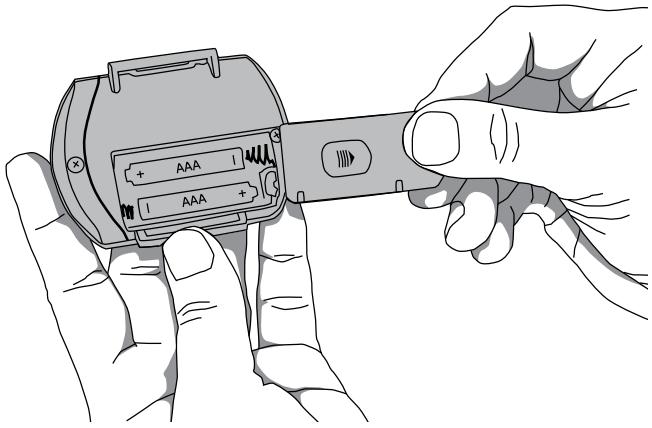


Figure 4: Remove Battery Door

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

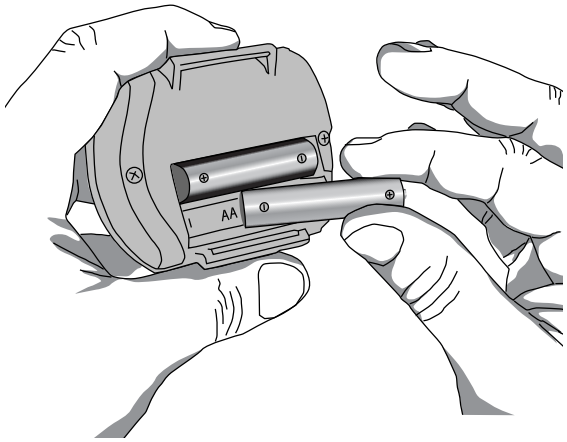


Figure 5: Insert Batteries

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

4. Inserting batteries does not turn the device on. In Spot Check Activation 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 if in Programmed Activation Mode, the device reverts to Spot Check Activation Mode. Use nVISION software to synchronize the clock and confirm the device is in the desired activation mode (see "Accessing nVISION Settings" on page 34).

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

There are two wristbands available for the use with the WristOx2, Model 3150 - a multiple use wristband and a single use disposable wristband.

The multiple use 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 multiple use wristband to the device. Figure 9 shows front and back views of the attached wristband.

Figure 11 demonstrates how to attach the single use wristband to the device.

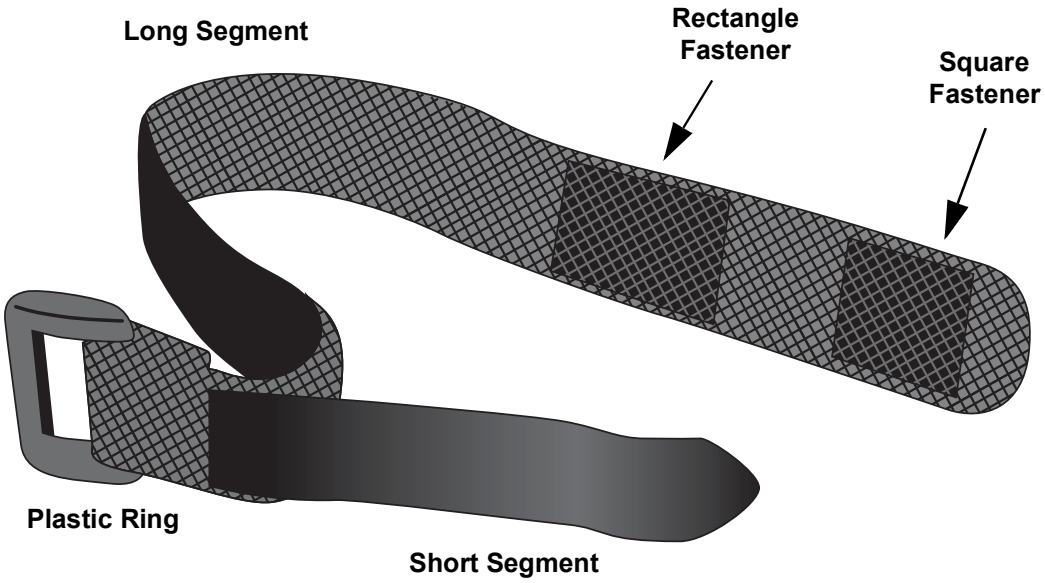


Figure 6: Multiple Use Wristband

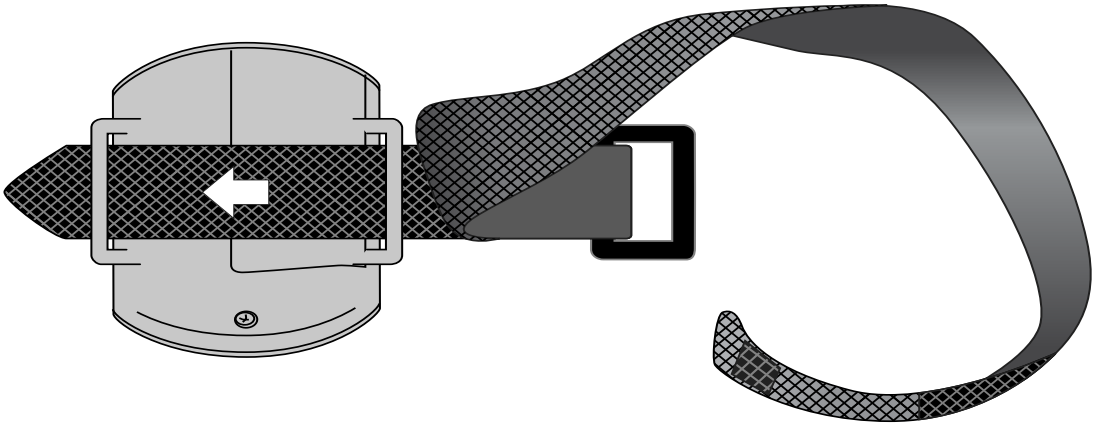


Figure 7: Thread Short Segment

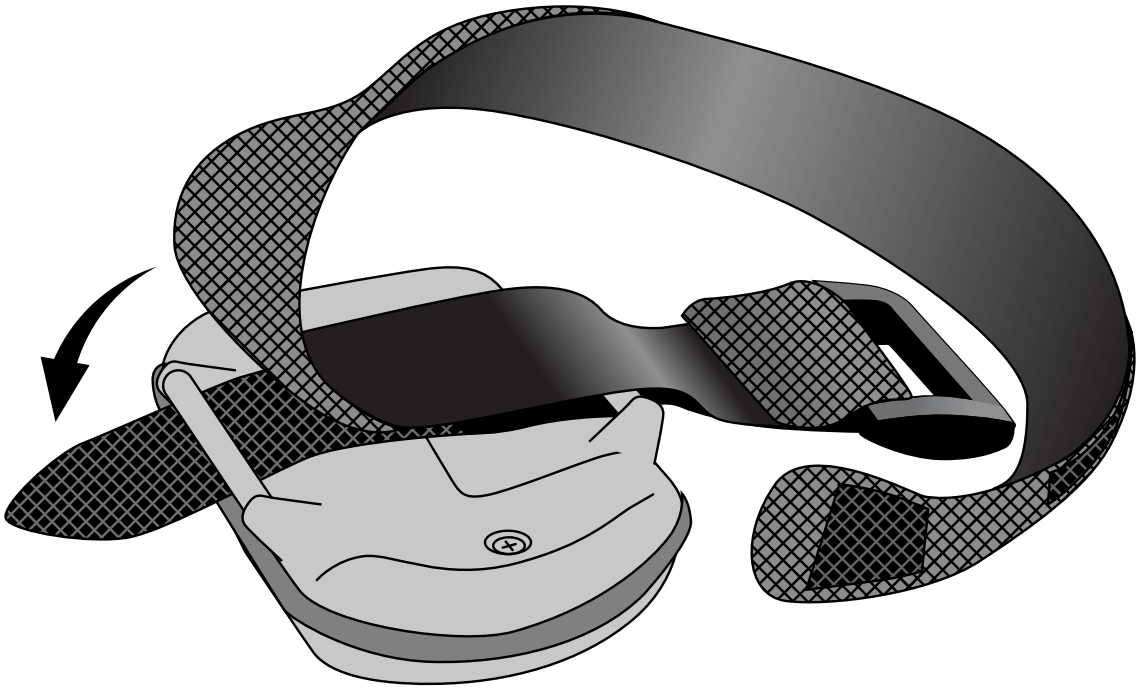


Figure 8: Secure Long Segment

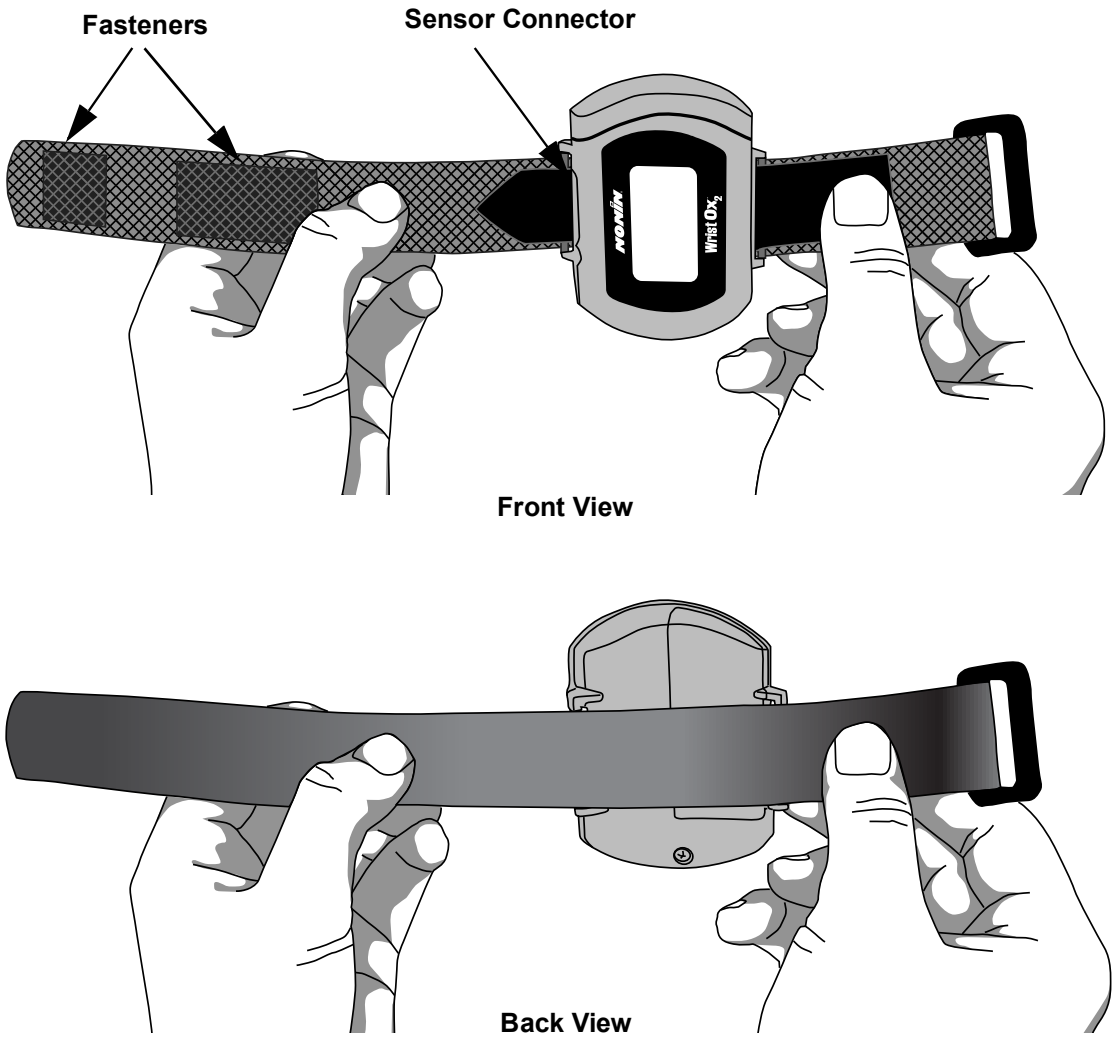


Figure 9: Device with Multiple Use Wristband Attached (Front and Back Views)

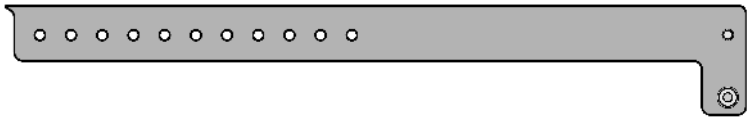


Figure 10: Single Use Wristband

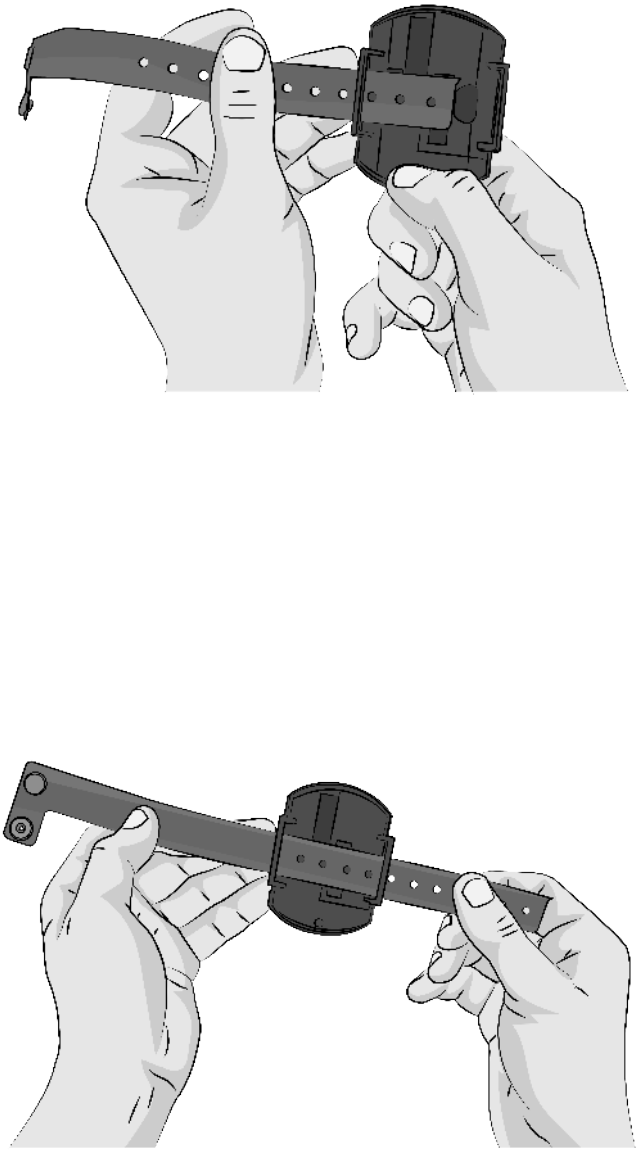


Figure 11: Device with Single Use Wristband Attached

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
- 6000CA-WO2

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

If using 8000R or 8000QR Noninsensor, 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 12). 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.

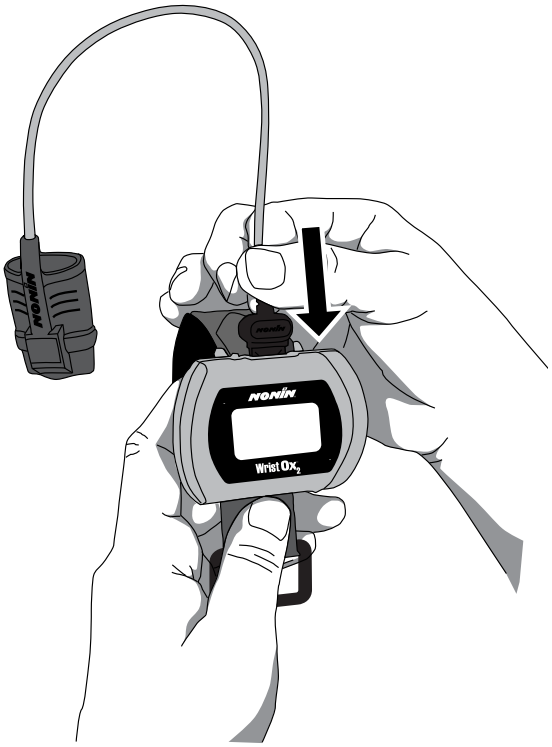


Figure 12: Attach Sensor

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 & 11). If the wristband has not been attached to the device, see "Attaching the Wristband."
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 (figure 13).

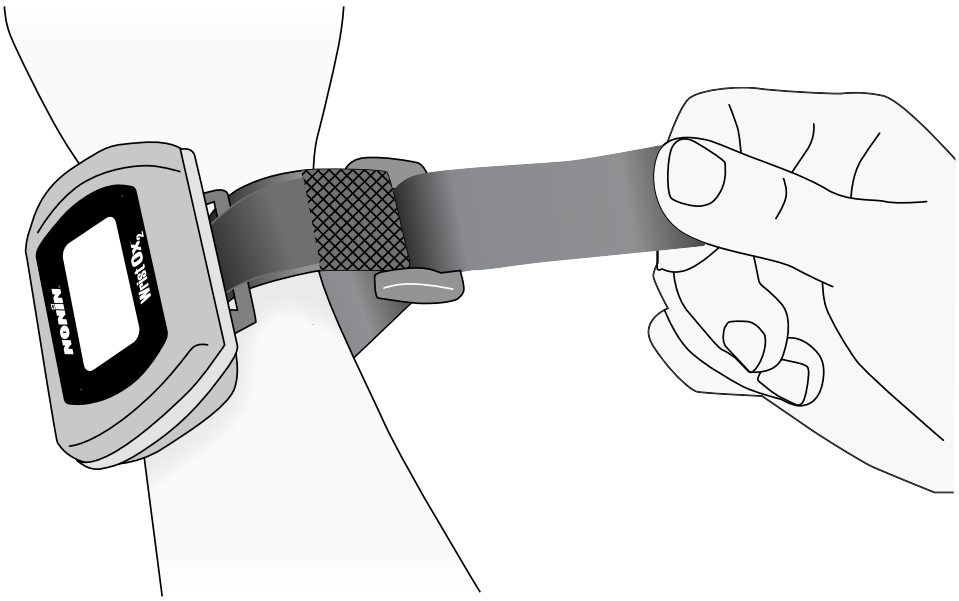


Figure 13: Thread and Tighten Wristband

4. Fold the wristband back over the plastic ring (figure 14) and attach the fastener to the wristband (figure 15 or figure 16). Wrist circumference will determine which fastener is used.
5. If using the single-use wristband, align the fastener button with the appropriate size hole on the opposite side of the wristband, ensuring that the wristband fits comfortably and securely. Once the correct size is found, fold tamper proof fastener button over to close the fastener. Fastener will pop into place when closed (figure 17). Note, once tamper-proof fastener is close, the wristband cannot be readjusted.

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 15).

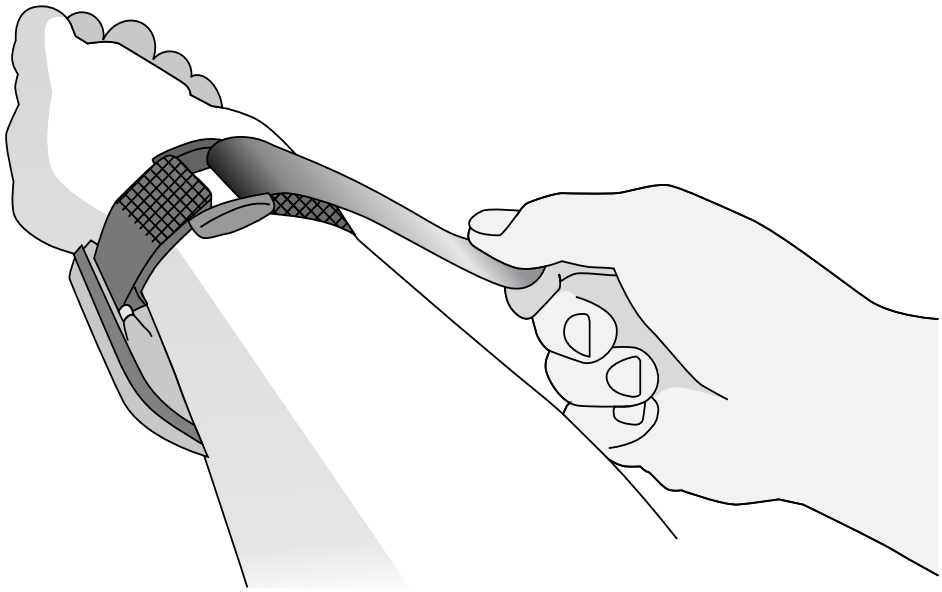


Figure 14: Fasten Wristband

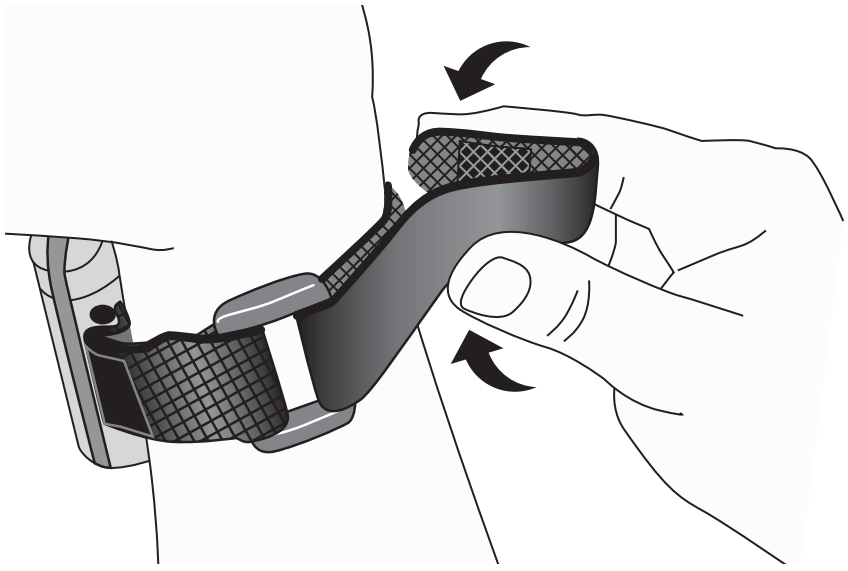


Figure 15: Using the Rectangle Fastener

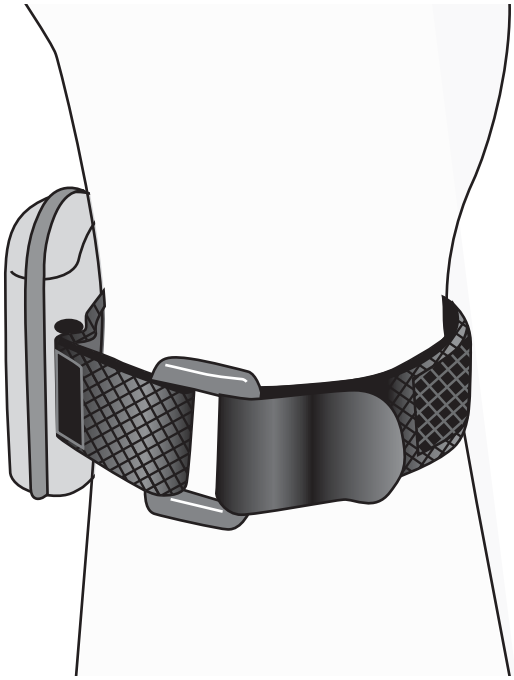


Figure 16: Using the Square Fastener

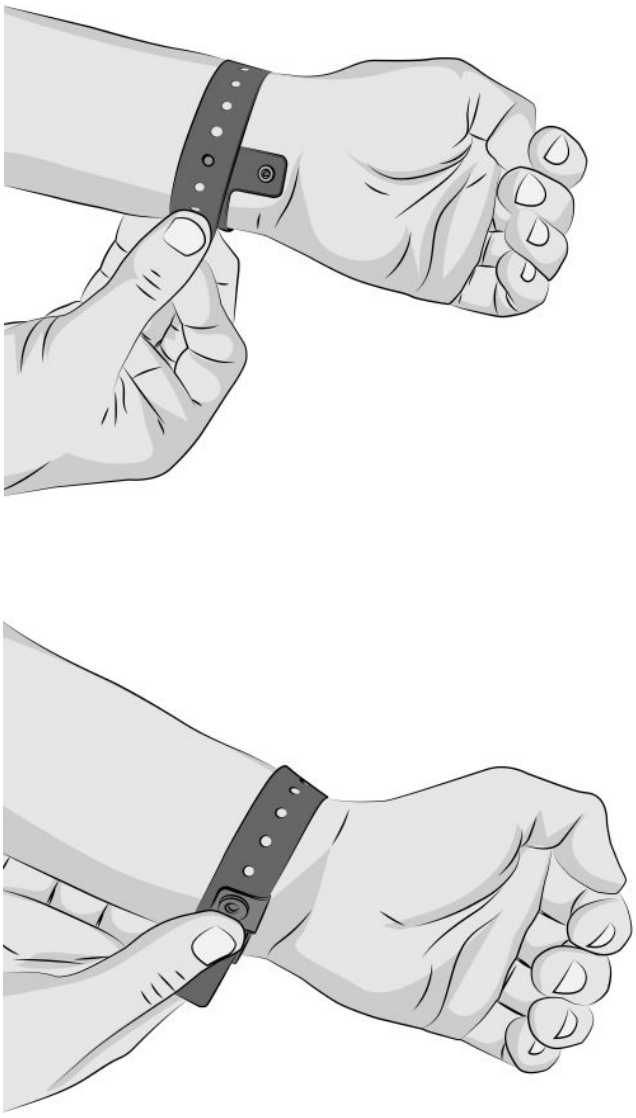


Figure 17: Attach Single Use Wristband

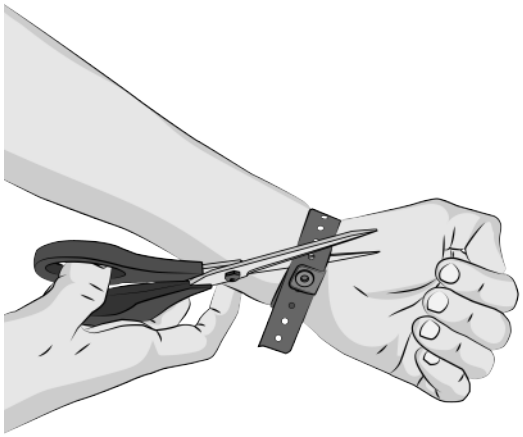


Figure 18: Removal of Single Use Wristband

6. Attach the sensor if it is not already connected (see “Attaching the Sensor”).
7. Apply the sensor to the patient (figure 19). Refer to the sensor Instructions for Use for proper sensor application sites and sensor application cautions and warnings.

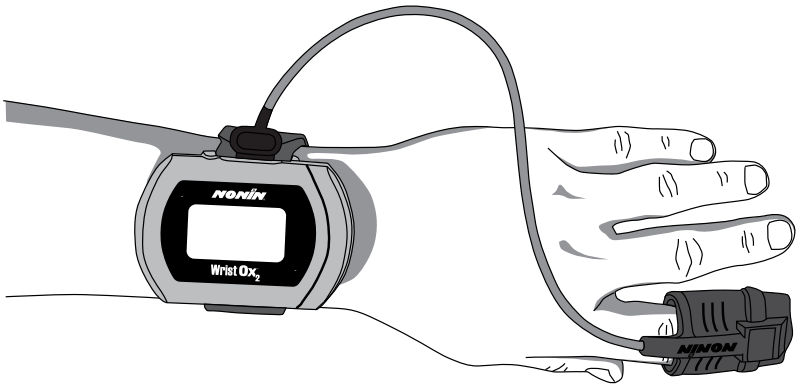


Figure 19: Apply Sensor to Patient

8. When in Spot Check Activation Mode, inserting a finger in the sensor automatically turns the device on. When the finger is removed, the device turns off in approximately 10 seconds.

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

9. If the device does not turn on, verify battery orientation, activation 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 Activation 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 Activation Mode).
- When the activation switch is pressed.

Startup Sequence and Self-Test

1. r and the software revision level:

2. All display icons:

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

NOTE: The Bluetooth indicator and activity bars will not be shown on the 3150 USB.

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 (January 1st, 2010 at 12:00 a.m.).

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.)
06	Radio Communications Error

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 Activation Mode.	Use nVISION software to select Spot Check Activation 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 **displays on LCD.**	Device memory failure.	Contact Nonin Technical Service.
Er 03 **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.
Er 06 **displays on LCD.**	Radio Communications Error	Remove batteries and restart the 3150. 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 Activation 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 60 meters [196 feet] spherical radius).
	3150 BLE is not in pairing mode.	The 3150 will be in pairing mode for 2 minutes the first time it is used following battery installation. Re-insert batteries and attempt to pair within the first 2 minutes the device is running.
%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 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.

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 Multiple Use 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.

Whenever the 3150 is running for more than one minute, the 3150 creates a record of the measurements taken and stores them within non-volatile memory. For each record, the current oximeter time and date are stored to allow quick differentiation of recording sessions. Within these records, patient SpO2 and pulse rate are stored every 4 seconds. The frequency of data storage can be modified from the 4 second default to either 1 or 2 seconds by using nVISION software. The oxygen saturation values are stored in 1% increments in the range of 0 to 100%.

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

nVISION Software

Nonin's nVISION software 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
- Activation modes – Sensor Activation, Spot-Check Activation, or Programmed Activation (see "Activation Modes")
- Device ID – up to 50 alphanumeric characters
- Bluetooth Radio – disable at startup (this setting has no effect on the 3150 USB or 3150 BLE devices.)
- Synchronize device time/date to the PC time/date
- Download and save patient data to a PC
- Clear device memory

Accessing nVISION Settings

1. Connect the device to a PC using the USB interface cable.

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.

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 20). Update or change settings as needed.
7. Click **OK**.

8. For more information, see nVISION Help.

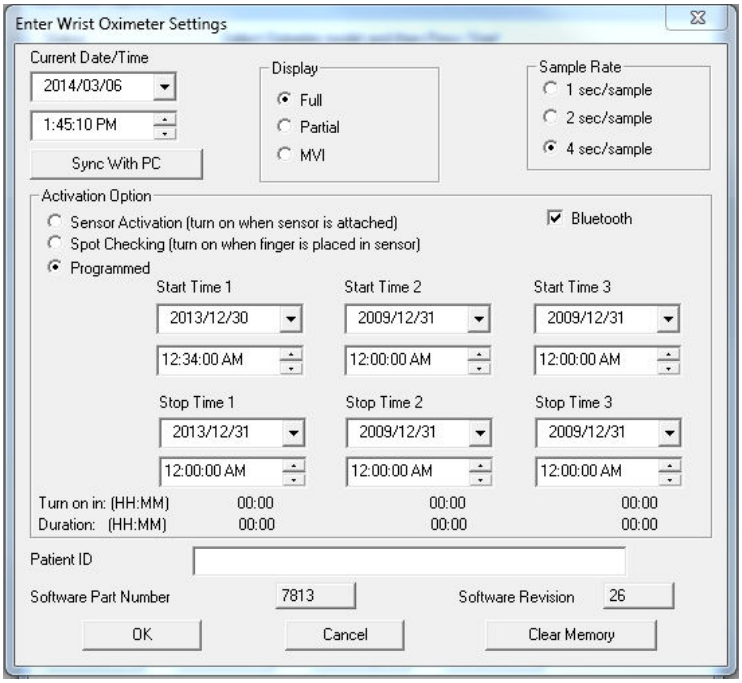


Figure 20: nVISION Settings Window

NOTE: Bluetooth Radio - disable at startup does not have an effect on the 3150 BLE or 3150 USB.

Cable Connection

CAUTION: All parts and accessories connected to the USB 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.

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 the 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

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.

NOTE: Pairing mode is only required when connecting to a Bluetooth collector device for the first time. Subsequent connections will not require battery removal and insertion.

Bluetooth Security

The Bluetooth radio contained in the 3150 BLE is compliant to version 4.2 of the Bluetooth Specification. The radio contained in the 3150 BLE is a Bluetooth single-mode, low-energy radio. The 3150 BLE supports an encryption key size of 128 bits. While the 3150 BLE is in a Bluetooth connection, it will be unavailable for other connections.

Data Integrity:	Adaptive Frequency Hopping 24-bit CRC (cyclic redundancy check) with 32-bit message integrity check
Authentication and Encryption:	Enforced on all data channels (outgoing and incoming)

Encryption Key Size:	128 bits AES (advanced encryption standard)

Bluetooth Wireless Technology Information

Bluetooth Compliance: Version 4.0 single mode low energy
Operating Frequency: 2.4 to 2.4835 GHz
Output Power: TX: +3 dBM
Operating Range: 10 meter radius (line of sight)
Network Topology: Star - bus
Operation: Slave
Model 3230
Antenna Type: Integrated chip type antenna
Modulation Type: Frequency Hopping Spread Spectrum
Data Rate: 1 Mbit/second
Data Latency: 6 ms
Data Integrity: Adaptive Frequency Hopping
24-bit CRC (cyclic redundancy check)
32-bit message integrity check
Data Format: Sends data packets once per second. Includes a second counter that allows the host to detect if packets are missing and the device to retransmit.
Quality of Service: This device uses Bluetooth Smart technology for wireless communications, which allows for reliable communications in electrically noisy environments, and transmits physiological data once per second. If data is lost, the device will transmit data again one second later. If the connection is lost, the device will change the Bluetooth symbol from green to white and become available for a connection in a few seconds.
Bluetooth Profiles Supported: GATT-based proprietary Nonin profile
Authentication and Encryption: Supported
Encryption Key Size: 128 bits AES (advanced encryption standard)
The Bluetooth® word mark and logo are registered trademarks owned by Bluetooth SIG, Inc.

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 6.5 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. Compatible with Model 8000R and 8000Q2 1-meter sensors, see below, contact Nonin or your distributor, or visit www.nonin.com.
3150WB	Wristband

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
6000CA-WO2	Cloth Disposable Sensor
Optional Pulse Oximeter Sensors (use with Interface Cable 3150I)	
Reusable – 1 meter length	
8000Q2	Ear Clip Sensor
8000R	Reflectance Sensor

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 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

www.nonin.com

Warranty

For warranty information please refer to: http://www.nonin.com/warranty

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: All parts and accessories connected to the USB 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.

WARNING: 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.

Manufacturer's Declaration

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

Essential Performance

Essential performance of the 3150 BLE/USB is defined as SpO_2 accuracy and pulse rate accuracy or an indication of abnormal operation. Accuracies may be affected as a result of exposure to electromagnetic disturbances that are outside of the environments listed in the *Indications For Use*. If issues are experienced, move the Nonin system away from the source of electromagnetic disturbances.

Table 3: Electromagnetic Emissions

This device is intended for use in the electromagnetic environment specified in the Indications for Use section. The user of this device should ensure that it is used in such an environment.	
Emissions Test	**Compliance**
RF Emissions CISPR 11	Group 2, Class B

Table 4: Electromagnetic Immunity

Immunity Test	Compliance	
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	
Conducted RF IEC 61000-4-6	150 kHz	3 Vrms
	ISM and Amateur radio bands between 150 kHz to 80 MHz	6 Vrms
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	30 A/m	
Radiated RF IEC 61000-4-3	80 MHz – 2.7 GHz	10 V/m
	380 – 390 MHz	27 V/m
	430 – 470 MHz	28 V/m
	704 – 787 MHz	9 V/m
	800 – 960 MHz	28 V/m
	1.7 – 1.99 GHz	28 V/m
	2.4 – 2.57 GHz	28 V/m
	5.1 – 5.8 GHz	9 V/m

Table 5: Not Applicable

Harmonic Emissions (IEC 61000-3-2), Voltage Flicker Emissions (IEC 61000-3-3), Electrical Fast Transients (IEC 61000-4-4), Surge (IEC 61000-4-5), Voltage dips (IEC 61000-4-11), Conducted Immunity (IEC 61000-4-6)
NOTE: 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

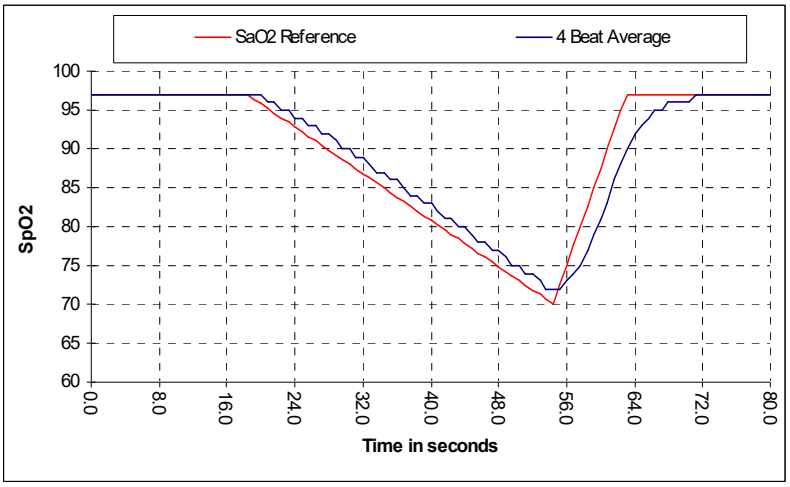
Pulse Rate Values	**Response**	**Latency**
Standard/Fast Averaged Pulse Rate	4 beat exponential	2 beats

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-square (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 (1050 mAh)[c]**
Storage: MVI Display Mode off: MVI Display Mode on:	9 months 25 days	Not specified	Not specified
Operating without Bluetooth Connection, continuous use:	53 hours	36 hours	52 hours
Operating with Bluetooth Connection, continuous use:	44 hours	24 hours	31 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:	Non-volatile		
Capacity:	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:	Internally powered (battery power)		
Degree of Protection:	Type BF-Applied Part		
Mode of Operation:	Continuous		
Enclosure Degree of Ingress Protection:	IP33		
This product complies with ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluation and testing.			

a.Batteries used: Harding Alkaline AAA

b.Batteries used: Energizer (MR03) Ni-MH 700mAh Rechargable Batteries 1.2 VDC

c.Batteries used: Ansmann (HR03) Ni-MH 1050 nMh Rechargable Batteries 1.2 VDC

Transmitter

Bluetooth Compliance	Version 4.2
Operating Frequency	2.4 to 2.4835 GHz
Output Power	3 dBm
Operating Range	60-meter (196-foot) radius indoors
Network Topology	Point-to-Point
Operation	Peripheral, Slave
Antenna Type	Internal
Modulation Type	Frequency Shift Keying Frequency Hopping Spread Spectrum
Band Width	1 MHz