NONIN®

Operator's Manual

3100

WristOx®

Wrist Oximeter

CE 0123

English

CAUTION! Federal law (USA) restricts this device to sale by or on the order of a physician.

CAUTION! Read this entire manual carefully before using the WristOx.

The information in this manual has been checked carefully and is believed to be accurate. In the interest of continued product development, 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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Guide to Symbols

Detailed information for functional symbols can be found in “Using the WristOx.”

Symbol	Description
	**Attention:** See Instructions for Use or related materials.
	**Type BF Applied Part** (Patient isolation from electrical shock).
	**UL Mark for Canada and the United States** with respect to electric shock, fire, and mechanical hazards only in accordance with UL 60601-1 30EM and CAN/CSA C22.2 No. 601.1.
	**CE Marking** indicating conformance to EC directive No. 93/42/EEC concerning medical devices.
SN	**Serial Number**
	Indicates separate collection for electrical and electronic equipment (WEEE).

Precautions for Use

Read and follow all safety instructions before using the WristOx.

Contraindications

- Do not use the WristOx in a magnetic resonance imaging (MRI) environment.
- Explosion Hazard: Do not use the WristOx in an explosive atmosphere or in the presence of flammable anesthetics or gases.

Warnings

- The WristOx is intended only as an adjunct in patient assessment. It must be used in conjunction with other methods of assessing clinical signs and symptoms.
- General operation of the WristOx might be affected by the presence of an electrosurgical unit (ESU).
- As with all medical equipment, carefully route patient cables and connections to reduce the possibility of patient entanglement or strangulation.
- Use the WristOx only within the specified temperature ranges: +32°F to +122°F (0°C to 50°C) for operating, and 14°F to 122°F (-10°C to +50°C) for storage and transportation.

- Use only NONIN-manufactured 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.
- Discontinue use of adhesive tape strips if the patient exhibits an allergic reaction to the adhesive material.
- Do not stretch the adhesive tape while applying the pulse oximeter sensor.
- Ensure that the wrist band fits comfortably on the patient's arm. Do not over-tighten the wrist band.
- Pulse oximeter readings might be affected while patients are being defibrillated.
- 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 emission and/or decreased immunity of this device.

Cautions

- Federal law (USA) restricts this device to sale by or on the order of a physician.
- Read this entire manual carefully before using the WristOx.
- Before using any sensor, carefully read the Directions for Use.
- Do not, under any circumstances, perform any testing or maintenance on the WristOx while it is being used to monitor a patient.
- Verify that all visible indicators appear during the start-up (initialization) sequence. If any indicator does not appear, do not use the WristOx. Contact NONIN Customer Support for assistance.
- This equipment complies with International Standard EN 60601-1-2:2001 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.

- Portable and mobile RF communications equipment can affect medical electrical equipment.
- If the WristOx fails to respond as described, refer to “Troubleshooting” or discontinue use until the situation has been corrected by qualified personnel.
- Do not remove any covers other than the battery cover when replacing batteries. There are no user-serviceable parts inside.
- Batteries might leak or explode if used or disposed of improperly.
- Follow local governing ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries.
- Do not immerse the WristOx or sensors in water or any other liquids.
- Do not place or pour liquids on top of the WristOx.
- The WristOx is a precision electronic instrument. It must be repaired by trained NONIN personnel only.
- The WristOx is designed to determine the percentage of arterial oxygen saturation of functional hemoglobin. Significant levels of dysfunctional hemoglobin may affect the accuracy of the measurement.

- The WristOx has motion tolerant software that minimizes the likelihood of motion artifact being misinterpreted as good pulse quality. In some circumstances, however, the WristOx may still interpret motion as good pulse quality.
- Check the pulse oximeter sensor application site frequently 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.
- Cardiogreen and other intravascular dyes, depending upon their concentrations, might affect the accuracy of the SpO_2 measurement.
- This device has not been tested for immunity to electromagnetic disturbances.
- Some nail polish colors or artificial nails can reduce light transmission and affect SpO2 accuracy.
- 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.

Unpacking and Inspecting the WristOx

Contact the carrier immediately if the shipping carton for the WristOx is damaged. Confirm that the items listed below are packed with the WristOx:

- Model 3100 Wrist Oximeter
- Two 1.5V Alkaline N-cell Batteries
- WristOx Operator's Manual
- 8000AA-WO Fingerclip Sensor
- 1 Reusable Wristband

Using the WristOx

Indications for Use

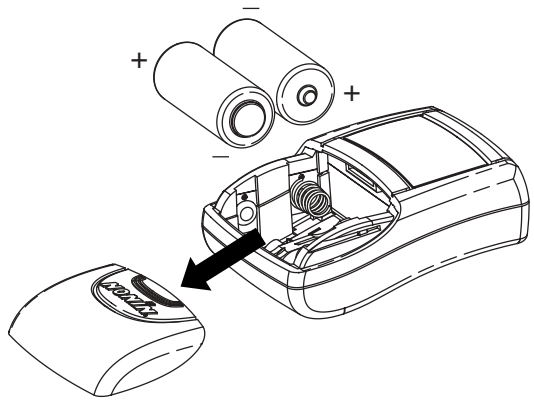
The NONIN® Model 3100 WristOx® pulse oximeter is a small, wrist-worn device indicated for use in measuring, displaying, and storing functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate. It may be used for spot-checking and/or data collection and recording of adult and pediatric patients in hospitals, medical facilities, ambulatory, subacute, and sleep study environments.

WARNING! Do not use the WristOx when alarms are required!

The WristOx comes packaged in Spot Check mode. In Spot Check mode, inserting a finger in the sensor turns on the WristOx automatically, and removing a finger turns off the WristOx automatically. Advanced memory and programming features are only available with NONIN's nVISION® software (version 5.0 or greater). See "Accessing Advanced Features" to learn more about using the WristOx with nVISION software.

Installing the Batteries

1. Use your thumb to loosen the lower front cover of the WristOx, and carefully remove the battery door by sliding it downward.



2. Remove the old batteries and discard or recycle them according to local governing ordinances.
3. Insert two new 1.5V alkaline N-cell batteries. *Correct battery positioning is essential for proper operation.*
4. Carefully re-position the battery door. Do not force the door into place; it fits only when positioned properly.
5. If the WristOx does not turn on when a sensor is plugged into the unit, reinsert the batteries or refer to “Troubleshooting.”

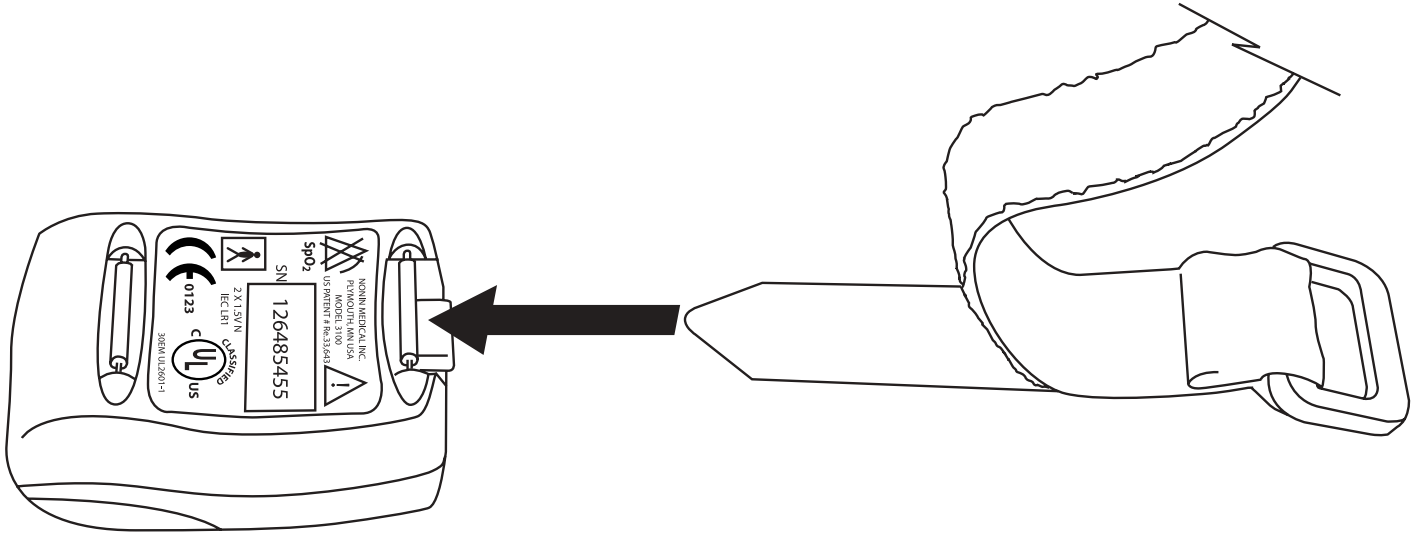
Important Notes about Battery Use

The Battery Indicator will begin to flash approximately 30 minutes before entering critical battery mode. *In critical battery mode, the WristOx no longer monitors or records patient data.* Replace low batteries as soon as possible.

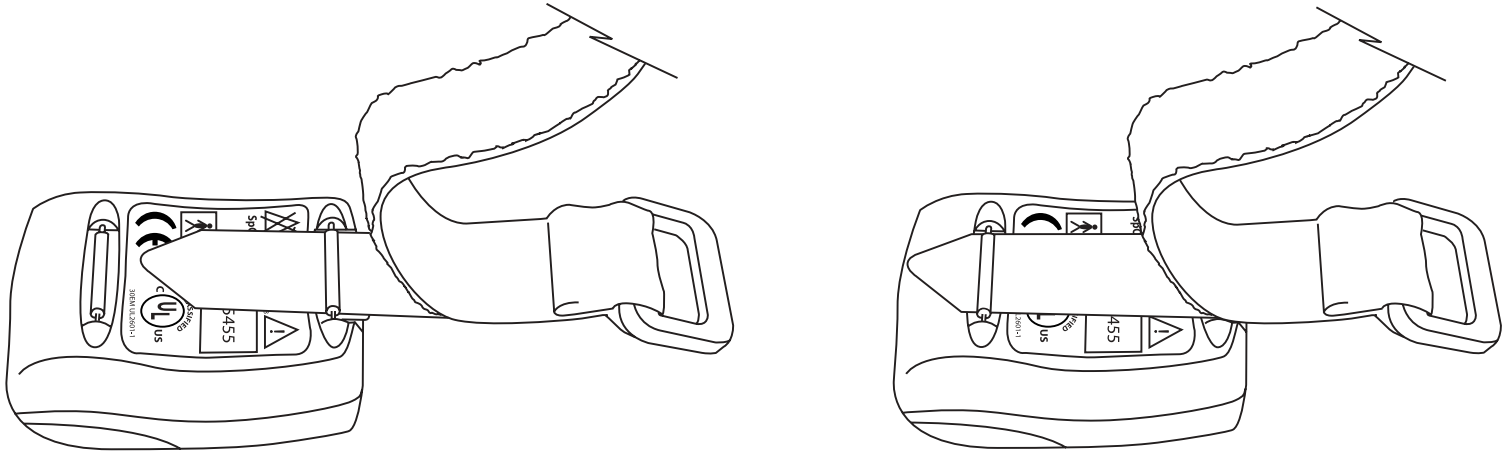
NOTE: The WristOx contains non-volatile memory, so removing or replacing batteries will not affect the data stored in WristOx memory. Stored data will remain in memory until overwritten by newer data or cleared from memory with nVISION software (version 5.0 or greater).

Setting Up the WristOx and Attaching the Sensor

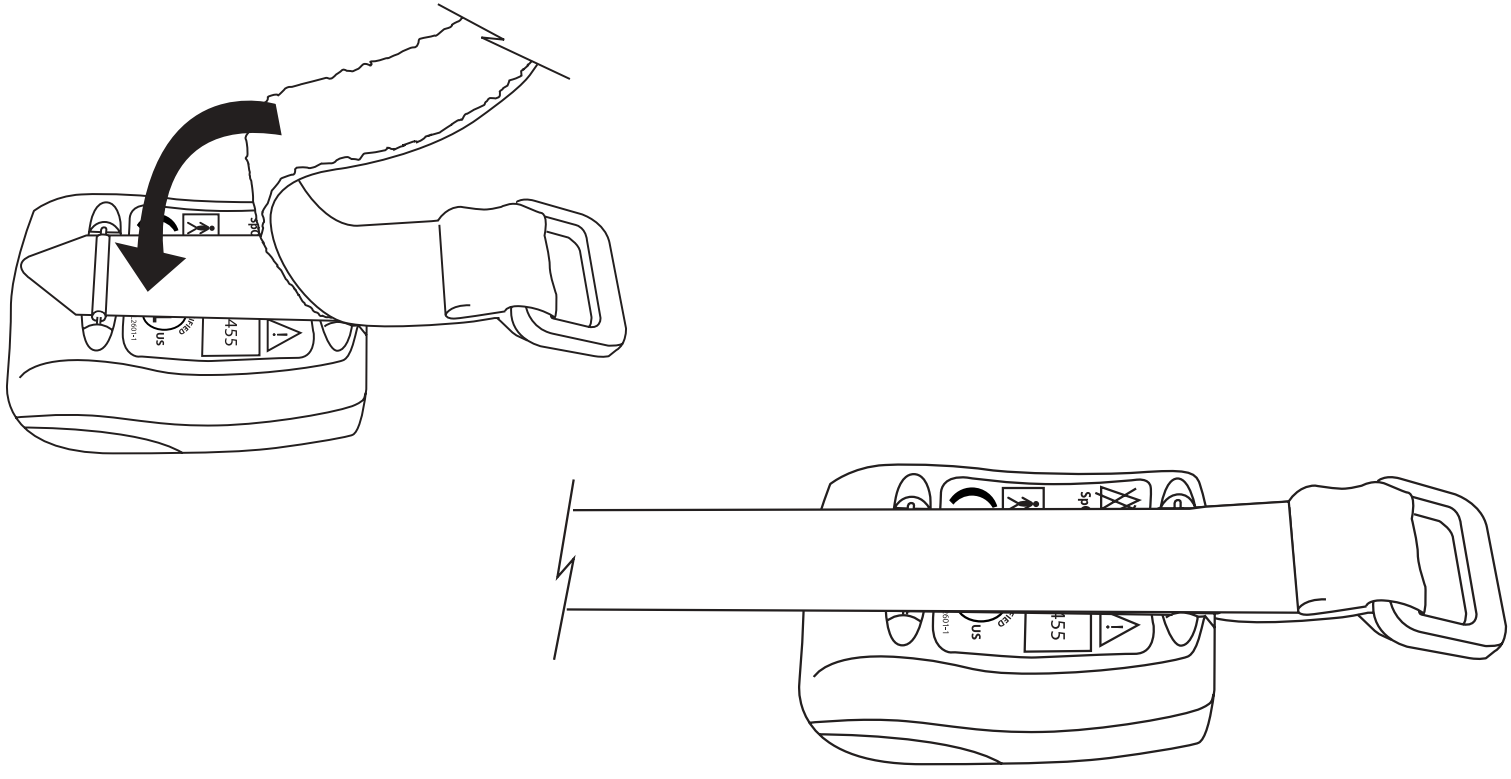
Use the following procedure to thread the wrist strap, attach the sensor, and begin taking %SpO_2 readings.



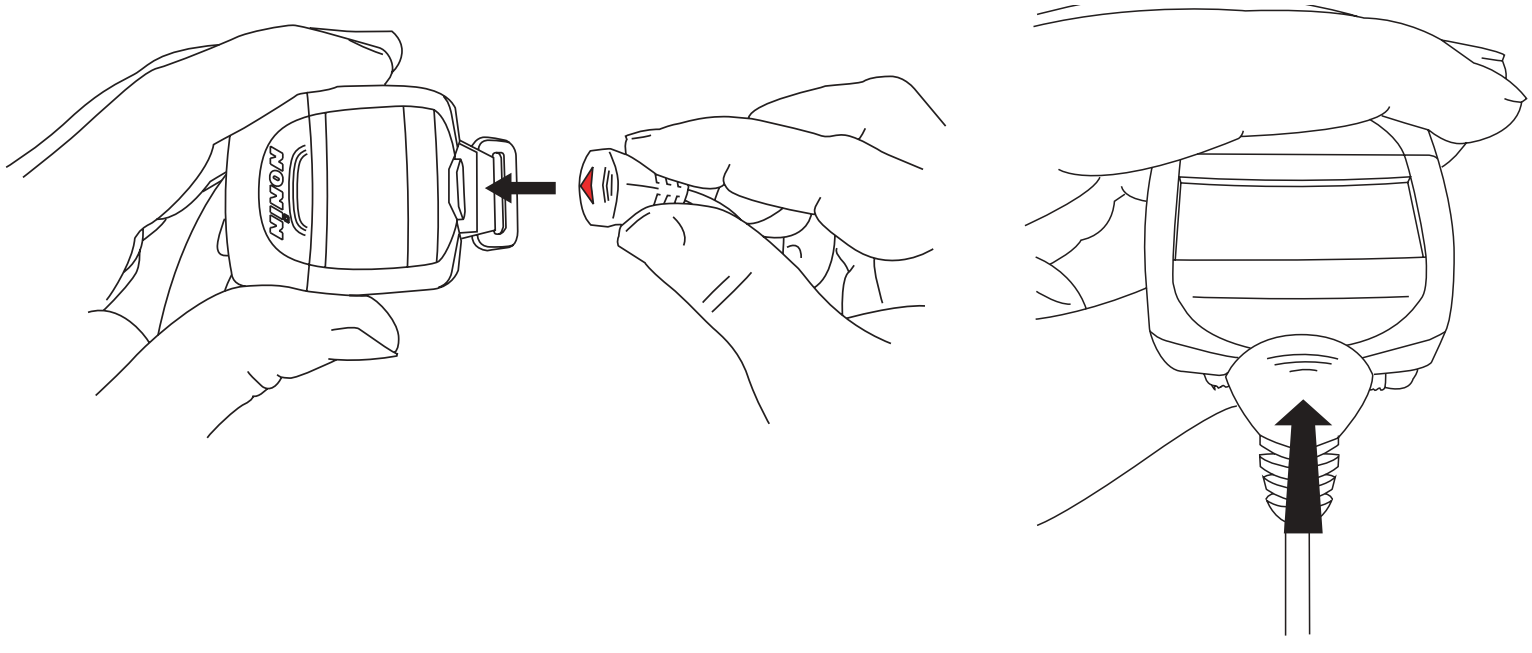
1. Begin threading the short segment of the wrist strap through the spring bars on the rear of the WristOx. As illustrated above, the spring bar near the top of the WristOx should be threaded first.



2. Continue threading the wrist strap until it is pulled securely through both spring bars on the rear of the WristOx.

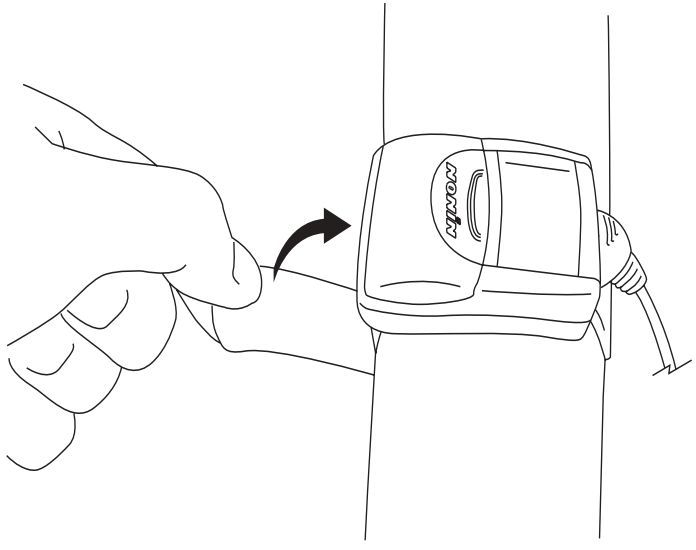


3. Press the long segment of the wrist strap securely against the already-threaded strap. The WristOx is now securely mounted on the wrist strap.



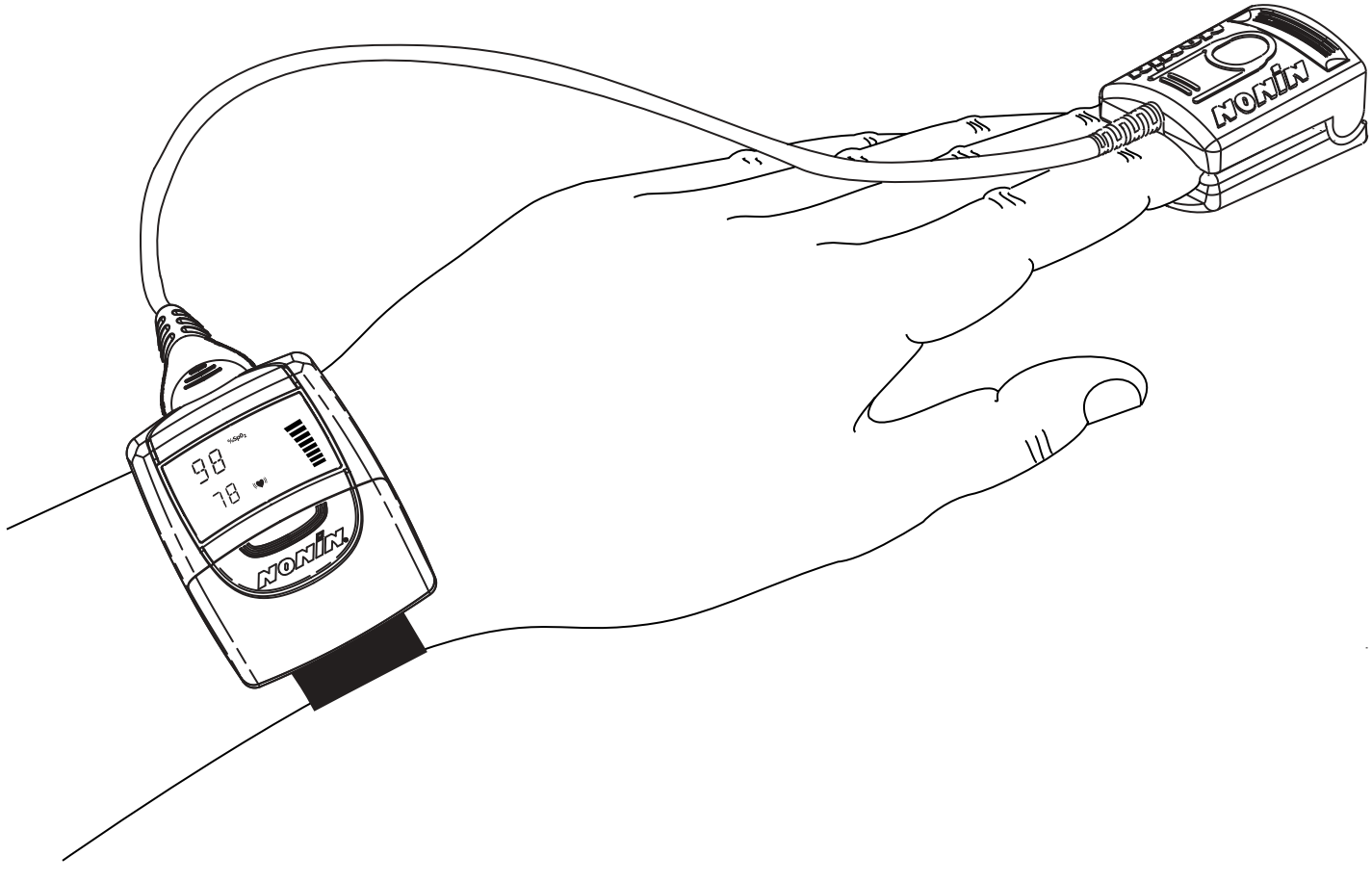
4. Plug the sensor into the connector at the top of the WristOx, ensuring that all indicators appear during the first phase of the startup sequence.

NOTE: When the sensor is completely connected, the red triangle on the sensor connector should not be visible.



5. Apply the wrist band securely and comfortably around the patient's wrist.
6. Place the patient's finger inside the sensor. Refer to the respective sensor instructions for specific information about placement and patient safety.

NOTE: In Spot Check mode (default), the patient finger acts as the ON / OFF switch. See "Accessing Advanced Features" for more information about other modes that are available with the WristOx.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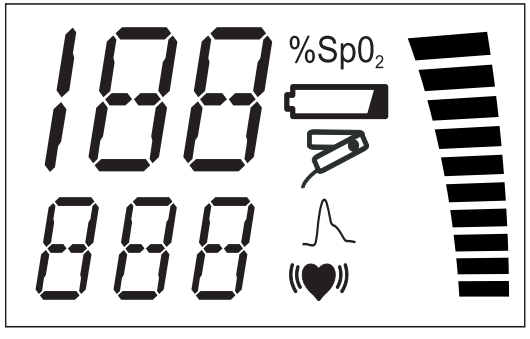
Verifying WristOx Operation

The WristOx performs an automatic startup (initialization) sequence and self-test when a sensor is plugged in. Verify that all indicators display during the first phase of the startup sequence. If any indicator is not displayed, do not use the WristOx. Contact NONIN Customer Support for assistance.



NOTE: If the device cannot track the pulse or finger removal is not detected, the WristOx will shut off automatically after 3 minutes.

System Features

%SpO_2 Display

Numeric indicators on the upper left-hand corner of the WristOx display blood oxygen saturation in percent (indicated by the %SpO_2 icon).

Pulse Rate Display

The pulse rate display is the lower numeric display on the left side of the WristOx (identified by the  symbol). This 3-digit indicator display shows the pulse rate in beats per minute.

Pulse Oximeter Sensor Indicator

The Pulse Oximeter Sensor Indicator indicates when a sensor has become disconnected, has failed, or has not been applied correctly.

Pulse Strength Bargraph Indicator

This 10-segment bargraph indicates pulse strength as determined by the oximeter. The height of the Pulse Strength Bargraph is proportional to the pulse amplitude.

Pulse Quality Indicator

This Indicator blinks to indicate a poor pulse. If there is a sustained series of poor pulses (approximately 10 seconds), the Pulse Quality Indicator will display solid.

Battery Indicator

Any time the WristOx batteries are low or critical, this Indicator blinks, providing early warning to replace them. After critical battery capacity is met, the display turns off and monitoring is stopped.

Numeric Indicators

Numeric Indicators appear after an %SpO_2 or pulse rate reading is complete, providing results of the measurement.

Accessing Advanced Features

To access additional modes of operation and advanced features for the WristOx, nVISION software (version 5.0 or greater) is required. nVISION is a flexible and convenient data management and oximetry screening tool that allows users to record, transfer, analyze, report, and archive patient data. nVISION is compatible with many NONIN pulse oximeter models.

NOTE: Data is stored in the WristOx regardless of which mode the device is in.

Using the WristOx with nVISION Software

The WristOx can be used with nVISION® software (version 5.0 or greater) to set various features and options according to user needs. A WristOx accessory package, which includes nVISION software and a computer cable, is available from NONIN.

The following advanced settings can be programmed in WristOx with nVISION software:

- Date
- ID
- Display Options
- Time
- Patient Data Storage Rate
- Activation Options

In addition, information about device model number, revision, and parameters can be retrieved; patient data can be downloaded and stored; WristOx memory can be cleared; and the WristOx date and time can be synchronized to the date and time of the computer.
Full and Partial Display modes are also programmable with nVISION software. Partial Display mode can be used if visible %SpO_2 and pulse rate data might add to patient anxiety in longer-term studies. In Partial Display mode, %SpO_2 and pulse rate data are not displayed on the WristOx, but the Pulse Strength Bargraph is still visible.

Activation Options

The WristOx features Spot Check mode, Sensor Activation mode, and Programmed mode.

Spot Check Mode

Spot Check mode is the WristOx default activation setting. In Spot Check mode, inserting a finger in the sensor turns ON the WristOx automatically, and removing a finger turns OFF the WristOx automatically. In this mode, the sensor can be left attached (plugged in) to the WristOx.

NOTE: If the device cannot track the pulse or finger removal is not detected, the WristOx will shut off automatically after 3 minutes.

Sensor Activation Mode

Sensor Activation mode can be selected with nVISION software (version 5.0 or greater). In this mode, connecting and disconnecting the sensor from the WristOx functions like an ON / OFF switch (whether or not a finger is in the sensor). In Sensor Activation mode, the WristOx shuts off automatically after 30 minutes of no use or invalid pulse detection.

NOTE: When the WristOx shuts off automatically after 30 minutes, the sensor must be unplugged and then reattached in order to turn on the WristOx.

Programmed Mode

In Programmed mode, the WristOx turns on and off at user-defined intervals that are selected using nVISION software (version 5.0 or greater). Programmed mode allows users to select up to three start and stop times and dates. *The sensor must be connected in order for Programmed mode to function.*

NOTE: In Programmed mode, the WristOx turns on and off ONLY at pre-programmed intervals. The device cannot be used at unprogrammed times until exiting Programmed mode with nVISION software.

Connecting the WristOx to a Computer

To use the WristOx with nVISION software (version 5.0 or greater), a WristOx-compatible computer cable (Model 1000SC-WO) is needed. This cable can be connected to a computer for data downloading and editing with nVISION software. Use the instructions below to connect the WristOx to a computer:

1. Connect the cable to the appropriate COM port on the computer.
2. Plug the cable to the top of the WristOx.
3. Wait until CP appears in the WristOx display. The WristOx is now ready for use with nVISION software.
4. For more information about capturing and saving data, refer to nVISION software's online help.

NOTE: When the cable is connected completely and securely, the red triangle on the cable connector should not be visible.

Memory Features

The WristOx collects and stores up to 33 hours of SpO_2 and pulse rate information with a 4-second data storage rate. When the memory fills up, the unit begins overwriting the oldest data with the new data. Each time the WristOx is turned on, data are automatically collected in memory.

NOTE: Only recording sessions longer than one minute are stored.

Each time the WristOx is turned 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 four seconds (default), or every one or two seconds if programmed using nVISION software (version 5.0 or greater). The oxygen saturation values are stored in 1% increments in the range of 0 to 100%.

NOTE: Storage rates do not affect battery life; however, data storage capacity is reduced when using a 1- or 2-second storage rate.

Using a 2-second storage rate, data storage capacity is reduced to approximately 16 hours.
Using a 1-second storage rate, data storage capacity is reduced to approximately 8 hours.

The stored pulse rate ranges from 18 to 300 pulses per minute. The stored values are in increments of one pulse per minute in the interval from 18 to 200 pulses per minute, and in increments of 2 pulses per minute in the interval from 201 to 300 pulses per minute.

NOTE: Playing back data in memory does not clear any data from memory.

Cleaning and Storing the WristOx

NOTE: Do not immerse the WristOx in liquid, and do not use caustic or abrasive cleaning agents on the WristOx.

Clean the WristOx separately from its associated sensors. For instructions regarding cleaning oximeter sensors, refer to the appropriate sensor package inserts.

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

Store the WristOx within the stated environmental specifications. See “Specifications” for additional information.

Specifications

OXIMETER SPECIFICATIONS

Oxygen Saturation Range (%SpO_2)	0% to 100%
Pulse Rate Range	18 to 300 pulses per minute
Displays	
Numeric Displays	3-digit Indicators
Pulse Indicator	Pulse Strength Bargraph
Accuracy	
Blood Oxygen Saturation (%SpO_2) (± 1 S.D.)[a]	70% to 100% ± 2 digits
Pulse Rate	± 3%
Measurement Wavelengths and Output Power	
Red	660 nanometers @ 3 mw nominal
Infrared	910 nanometers @ 3 mw nominal

Altitude	
Operating Altitude	Up to 40,000 feet
Hyperbaric Pressure	Up to 4 atmospheres
SYSTEM SPECIFICATIONS	
Temperature	
Operating	+32° to +122°F (+0° to +50°C)
Storage/Transportation	14° to +122°F (-10° to +50°C)
Humidity	
Operating	10% to 90% noncondensing
Storage/Transportation	10% to 95% noncondensing
Power Requirements	Two 1.5V alkaline N-cell batteries
Battery Life	
Operating	minimum 24 hours of continuous operation

Storage	9 months
Dimensions (without sensor or strap)	2 in H x 1.75 in W x 0.75 in D (5.08 cm H x 4.445 cm W x 1.905 cm D)
Weight	~0.88 oz. without batteries or wrist strap (~24.95 g without batteries or wrist strap)
Memory	
Type	Nonvolatile
Capacity	33 hours @ 4 sec. data storage rate; 16 hours @ 2 sec. rate; 8 hours @ 1 sec. rate

CLASSIFICATIONS PER IEC 60601-1; CAN/CSA C22.2 NO. 601.1; UL60601-1 30EM

Type of Protection	Internally powered (on battery power)
Degree of Protection	Type BF-Applied Part
Mode of Operation	Continuous

a. S.D. (Standard Deviation) is a statistical measure; up to 32% of the readings may fall outside these limits.

Parts and Accessories

3100CC	WristOx Carrying Case
3100 Manual	Operator's Manual for the WristOx
1000SC-WO	Computer cable
	Pulse Oximeter Reusable Sensors
8000AA-WO	Adult Articulated Finger Clip Sensor
8000J-WO	Adult Flex Sensor
	Other Accessories
nVISION	nVISION® software (5.0 or greater) for Windows® 95/98/00/NT
8000JFW	Adult FlexiWrap Sensor Wrap
3100WB	10" Reusable Wrist Band (elastic VELCRO® material)
3100WBE	5" Reusable Wrist Band Extender for Larger Wrists (elastic VELCRO® material)

For more information about NONIN parts and accessories, contact your distributor, or contact NONIN at (800) 356-8874 (USA and Canada) or (763) 553-9968.

Service and Support

The Model 3100 Wrist Oximeter module performs all computations from internal software stored in microprocessor chips. Thus, there are no critical parts to drift, and no calibration of the pulse oximeter module is required.

For information about the Model 3100 and accessories, contact your local sales representative or distributor. For the sales representative or distributor in your area, contact NONIN at (800) 356-8874. A return authorization number is required before returning any product to NONIN. To obtain this return authorization number, contact NONIN's Customer Support Department at:

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E-mail: mail@nonin.com
Website: www.nonin.com

Warranty

NONIN MEDICAL, INCORPORATED, (NONIN) warrants to the purchaser the pulse oximetry module of the Model 3100 for three years from the date of purchase. NONIN shall repair or replace any Model 3100 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 Model 3100 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. NONIN reserves the right to charge a fee for a warranty repair request on any unit found to be within specifications. The Model 3100 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 Model 3100, field service by non-NONIN personnel, tampering, or any kind of misuse of the Model 3100 shall void the warranty. All non-warranty work shall be done 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.

Troubleshooting

Problem	Possible Cause	Possible Solution
Device won't activate.	Batteries inserted wrong.	Check batteries.
	Batteries are depleted.	Replace batteries and try again.
	Sensor is disconnected.	Re-connect sensor and try again.
	WristOx set in Programmed mode.	Use nVISION software to reset WristOx in Spot Check or Sensor Activation mode.
No %SpO_2 or pulse rate display.	WristOx set in Partial Display mode.	Use nVISION software to reset WristOx in Full Display mode.

Problem	Possible Cause	Possible Solution
No pulse display on bargraph.	Low patient pulse strength.	Reposition or replace finger; keep sensor motionless.
		Remove and re-connect sensor.
	Sensor applied incorrectly.	Refer to sensor instructions to apply sensor correctly.
	Poorly perfused finger.	Reposition or replace finger; keep sensor motionless.
		Warm application site.
	Finger positioned wrong.	Reposition or replace finger; keep sensor motionless.

Problem	Possible Cause	Possible Solution
No pulse display on bargraph, *cont'd*.	Possible interference from: • arterial catheter • blood pressure cuff • electrosurgical procedure • infusion line	Reduce or eliminate interference.
	Reduced circulation from excess pressure on sensor.	Allow hand to rest without squeezing or pressing sensor.
	Excessive ambient light.	Shield sensor from light source.
	Sensor applied to polished or artificial nail.	Apply sensor to finger without fingernail polish or an artificial nail.

Problem	Possible Cause	Possible Solution
No pulse display on bargraph, *cont'd*.	Finger is cold.	Warm the finger.
	Finger is wet.	Dry the finger and inside of sensor.
	Indicator not lit in finger insertion area.	Call NONIN Customer Support.
	Excessive patient motion.	Reduce patient motion.
Pulse Oximeter Sensor indicator appears.	Poor signal detected from finger.	Reposition or replace finger; keep sensor motionless.
		Warm the application site.
	The WristOx needs repair.	Call NONIN Customer Support.

Problem	Possible Cause	Possible Solution
WristOx doesn't record in Programmed mode.	Start and stop times set inconsistently.	Use nVISION software to set start and stop times correctly.
	WristOx date and time settings are incorrect (or lost after removing batteries).	Use nVISION software to set date and time correctly.

If these solutions do not correct the problem, please contact NONIN Customer Support at **(800) 356-8874** (USA and Canada) or **(763) 553-9968.**

Manufacturer's Declaration

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

Table 1: 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 1	This device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
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	

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