NONIN

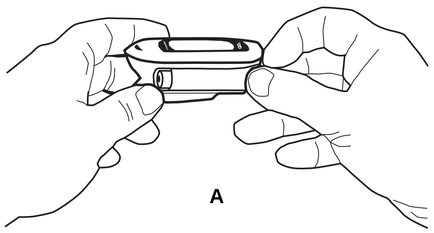
Instructions for Use - English

GO_2 Model 9570 Fingertip Pulse Oximeter

℞ Only

Installing the AAA Battery: Use only alkaline batteries. One 1.5 volt AAA-size (LR03) battery powers the GO_2 for approximately 2400 measurements.

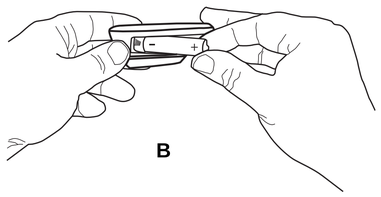
1. Remove the battery door located on the left side of the GO_2 by sliding it towards you.
2. Insert one new 1.5 volt AAA-size battery (**Figure A**). Follow the plus (+) and minus (-) markings for battery direction (as shown inside of the battery compartment).



A

3. Carefully reposition the battery door (**Figure B**).

NOTE: Do not force it into place; it fits only when positioned correctly.

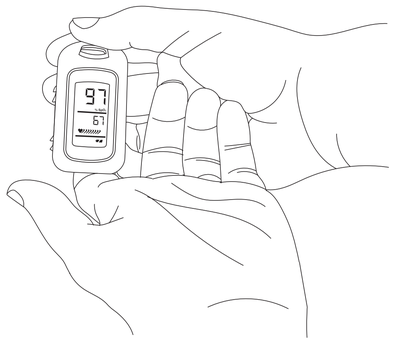


B

When battery is low, the battery indicator symbol on the display will flash. Remove battery if the device will be stored for more than 30 days. Replace low battery as soon as possible.

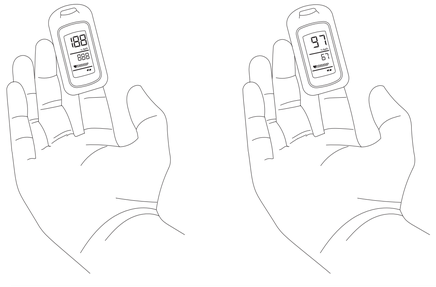
Applying the GO_2 to Your Finger: Hold the GO_2 with the display facing toward you; slide your finger into the opening at the bottom of the device, until the fingertip touches the built-in stop guide (**Figure C**). The index (pointer) finger is recommended.

Have your forearm parallel to the floor when you use the GO_2. Make sure your finger is centered within the finger guide and the GO_2 is at heart or chest level.



C

NOTE: Correct positioning of the device on your finger is critical for accurate measurements. While on the finger, do not press the GO_2 against any surface and do not squeeze or hold it together. The internal spring provides the correct pressure; additional pressure may cause inaccurate readings.



Indications for Use

The GO_2 Model 9570 is intended to measure blood oxygen saturation (**%SpO_2**) (the amount of oxygen in your blood) and pulse rate of both adults and children. It is designed for fingers (not the thumb) between 0.3 and 1.0 inch (0.8 – 2.5 cm) thick. The index finger (pointer finger) is most recommended. Contact your licensed health care professional for your expected oxygen saturation level (to compare with your readings). The GO_2 Model 9570 is intended for Home Health Care only.

Warnings

- Keep the oximeter away from young children. Small items such as the battery door, battery, and lanyard are choking hazards.
- Certain activities may pose a risk of injury, including strangulation, if the lanyard should become wrapped around your neck. Use the lanyard with caution.
- Avoid excessive pressure to the sensor application site as this may cause damage to the skin beneath the sensor.
- Before changing batteries, make sure the device is off and is not applied to a digit.

⚠Cautions

- Do not use the device in an MR environment, in an explosive atmosphere, or on neonatal patients.
- This device is not defibrillation proof per IEC 60601-1.
- Do not use the GO_2 as the only basis for making medical decisions. It is intended only to be used as additional information that you can give to your licensed health care professional.
- The GO_2 might misinterpret excessive movement as good pulse strength. Limit finger movement as much as possible when using the device.
- The GO_2 must be able to measure your pulse properly to give you an accurate reading. Do not put the device on the same hand/arm when using a blood pressure cuff or monitor.
- The GO_2 has no alarms. It will not sound if the amount of oxygen in your blood is low or if your pulse rate is too high or too low.
- Do not sterilze, autoclave, or place the GO_2 in liquid or clean it with agents containing ammonium chloride, or products that are not listed in this instruction. Do not pour or spray any liquids onto the GO_2.
- The GO_2 is not intended for use in institutions.
- Any of the following conditions may reduce the performance of the *GO*:
  - flickering or very bright light;
  - weak pulse quality (low perfusion);
  - low hemoglobin;
  - arterial catheters;
  - nail polish, and/or artificial nails; and
  - any tests recently performed on you that required an injection of intravascular dyes.
- The GO_2 may not work if you have poor circulation. Rub your finger to increase circulation, or place the device on another finger.
- The GO_2 measures oxygen saturation of functional hemoglobin. High levels of dysfunctional hemoglobin (caused by sickle cell anemia, carbon monoxide, etc.) could affect the accuracy of the measurements.
- Batteries can leak or explode if used or disposed of improperly. Remove the battery if the GO_2 will be stored for more than 30 days.
- Do not use the GO_2 in a combustible environment (oxygen enriched environment).
- Do not use the GO_2 outside the specified operating and storage temperature ranges.
- Do not use the GO_2 for more than 30 minutes without relocating the device to another finger.
- The GO_2 needs to be used according to information provided in this instruction.
- Do not tamper with, or hang lanyard from the flexible circuit.
- When using the GO_2 in the home, avoid exposing the GO_2 to lint and dust.
- Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast towers and TV broadcast towers may affect accuracy.
- Use in emergency vehicles with communication systems may affect accuracy.
- Functional tester cannot be used to assess the accuracy of this pulse oximeter.
- Follow local disposal and recycling laws for the GO_2 and its components, including the battery.
- The GO_2 is a precision electronic instrument and must be repaired by Nonin Technical Service. Field repair of the device is not possible. Do not attempt to open the case or repair the electronics. Opening the case may damage the device and void the warranty.

Symbols

Symbol	Definition
	Caution!
	Follow Instructions for Use.
	Type BF Applied Part (patient isolation from electrical shock)
	Temperature Limitation for storage/shipping
	Inadequate signal; the pulse signal is not detected or there is excessive motion.
	Indicates separate collection for electrical and electronic equipment (WEEE)
	Not for continuous monitoring (no alarm for SpO_2)
	Battery orientation
IP32	Protected against vertically falling water drops when enclosure is tilted up to 15 degrees and ingress of solid foreign objects greater than or equal to 2.5 mm (0.1 in.) in diameter per IEC 60529.
SN	Serial Number
℞ Only	Medical prescription required

Display Symbols

Symbol	Description
% SpO_2	The number next to this symbol is the amount of oxygen in your blood (functional oxygen saturation of arterial hemoglobin).
	The number next to this animated symbol is your pulse rate. Pulse rate is the number of times your heart beats per minute.
– – –	Dashes replace the readings when the GO_2 is unable to detect a usable signal.
	Inadequate signal. Steady your hand, reposition finger, warm finger by rubbing, or select a different finger.
	Full capacity
	Half capacity
	Near empty capacity, replace.
	(Flashing) Empty capacity, replace.

Using the Model 9570 GO_2

Activating the Device: The GO_2 automatically turns on when a finger is inserted. When a finger is inserted, the GO_2 performs a brief self test (**Figure D**). Verify that all segments of the LCD (Liquid Crystal Display) appear during the startup sequence. If any part of the screen is not lit, do not use the device; contact Nonin Technical Service for repair or replacement.

Verifying Operation: The GO_2 LCD has an integrated backlight that turns on automatically in low light conditions. This allows the display to be visible in dark spaces.

If the device does not turn on or if it shuts off unexpectedly:

- Verify batteries are correctly inserted.
- The batteries are depleted. Replace batteries.

Continually verify operation. If the problem persists remove the batteries and contact Nonin Technical Service.

The Oxitest^{Plus7} by Datrend Systems, Inc. can be used to verify operation of the pulse oximeter.

Reading Your Results: When you put your finger in the GO_2, you'll notice an LCD display come on (**Figure E**). The numbers you see show:

- the amount of oxygen in your blood, displayed as **%SpO_2**; and
- your Pulse Rate, displayed as a 2 or 3 digit number, measuring the number of times your heart beats per minute.

The Pulse Quality indicator (♥) displays the strength of the pulse rate signal. Bars will display after the ♥, indicating pulse signal strength (♥)))))))); the greater the number of bars indicates a greater pulse quality signal strength.

If you are not getting a pulse rate reading and your pulse quality indicator is weak, warm the finger or reposition to another finger.

While the GO_2 is formulating its reading immediately after activating the device, the inadequate signal indicator (⃠) will appear. The inadequate signal indicator also appears when you remove your finger to indicate the pulse signal is not detected or when there is excessive motion. If this symbol does not turn off while your finger is in the device, reposition your finger or switch to a different finger.

The Battery indicator symbol (▭) shows the battery strength (the less the symbol is filled – the less battery capacity is available – see "Display Symbols" table). Replace the battery when this symbol begins to flash.

Turning Off the Model GO_2 9570: The GO_2 will automatically turn off approximately 10 seconds after the digit is removed, or after a 2-minute period of poor signals.

Care and Maintenance

The GO_2 requires no calibration or periodic maintenance other than battery replacement. The device's expected service life is 2 years.

Wipe the device with a soft cloth dampened with a mild detergent or 10% bleach solution. 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 sterilize, autoclave, or place the GO_2 in liquid or clean it with agents containing ammonium chloride, or products that are not listed in this instruction. Do not pour or spray any liquids onto the GO_2.

Specifications

Oxygen Saturation Display Range: 0% to 100%

Pulse Rate Display Range: 18 to 321 beats per minute (BPM)

Oxygen Saturation Declared Accuracy Range (A_{rms}*): 70% to 100% SpO2 ±2 digits

Low Perfusion Oxygen Saturation Declared Accuracy Range (A_{rms}*): 70% to 100% SpO2 ±2 digits

Pulse Rate Declared Accuracy Range (A_{rms}*): 20 to 250 BPM±3 digits

Low Perfusion Pulse Rate Declared Accuracy Range (A_{rms}*): 40 to 240 BPM ±3 digits

Measurement Wavelengths and Output Power:**
Red: 660 nanometers @ 0.8 mW Max. average
Infrared: 910 nanometers @ 1.2 mW Max. average

Temperature:
Operating: 41 °F to 104 °F (5 °C to 40 °C)
Storage/Transportation: -22 °F to 158 °F (-30 °C to 70 °C)
Time (from storage) for monitor to be ready for its intended use: 7 minutes to warm from -30 °C to 5 °C; 12 minutes to cool from 70 °C to 40 °C

NOTE: Device temperature will not exceed 41 °C as measured during a controlled environment test.

Humidity:
Operating: 10% to 90% relative humidity, non-condensing
Storage/Transportation: 10% to 95% relative humidity, non-condensing

Operating Altitude:
Operating: Up to 4,000 meters / 13,123 feet

Battery Life:
Continuous: Approximately 2,400 spot checks based on ~21 hours of operation using one AAA-size alkaline battery, calculated at 30 seconds per use.
Storage: 6 months minimum

Classifications per ANSI/AAMI ES60601-1 and CAN/CSA-C22.2 No. 60601-1:
Operating: 41 °F to 104 °F (5 °C to 40 °C)
Storage/Transportation: -22 °F to 158 °F (-30 °C to 70 °C)
Enclosure Degree of Ingress Protection: IP32

This equipment complies with International Standard IEC 60601-1-2 for electromagnetic compatibility for medical electrical equipment and/or systems. This standard is designed to provide reasonable protection against harmful interference in a typical installation. However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in health care, home, and many 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.

This product complies with ISO 10993-1, Biographical evaluation of medical devices - Part1: Evaluation and testing.

*±1 A_{rms} represents approximately 68% of measurements.

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

This device is not made with natural latex.

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.

Equipment Response Time

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

SpO2 Values	Average	Latency
Standard/Fast Averages SpO2	4-beat Exponential	2 beats

Pulse Rate Values	Average	Latency
Standard/Fast Averages SpO2	4-beat Exponential	2 beats

Equipment Delays	Delay
Standard/Fast Averages SpO2	1.5 seconds

Example: SpO_2 Exponential Averaging
SpO_2 decreases 0.75% per second; pulse rate = 75 BPM
The response of the 4-beat average is 1.5 seconds.

Testing Summary

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

SpO2 Accuracy Testing: During no-motion conditions at an independent research laboratory, **SpO_2** accuracy testing is conducted during induced hypoxia studies on healthy, male and female, non-smoking, light- to dark-skinned subjects that are 18 years of age and older. The measured arterial hemoglobin saturation value (**SpO_2**) of the sensors is compared to arterial hemoglobin oxygen (**SaO_2**) value, determined from blood samples with a laboratory co-oximeter. The accuracy of the sensors in comparison to the co-oximeter samples measured over the **SpO_2** range of 70 - 100%. Accuracy data is calculated using the root-mean-squared (Arms value) for all subjects, per ISO 80601-2-61 and ISO 9919, Medical Electrical Equipment–Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use.

Low Perfusion Testing: This test uses a **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 and ISO 9919 for heart rate and **SpO_2** at the lowest obtainable pulse amplitude (0.3% modulation).

Warranty

For warranty information go to: **http://www.nonin.com/warranty/**

Manufacturer's Declaration

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

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 environement.		
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.
Electromagnetic Immunity		
Immunity Test	**Compliance**	**Electromagnetic Environment-Guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, relative himidty should be at least 30%.
Power Frequency (50/ 60 Hz) Magnetic Field IEC 61000-4-8	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hosipital environment.
Electromagnetic Immunity		
Immunity Test	**Compliance**	**Electromagnetic Environment-Guidance**
Radiated RF IEC 61000-4-3	10 V/m	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the 9570. Otherwie, degradation of the performance of this equipment could result.
Not Applicable		
IEC 61000-3-2, IEC 61000-3-3, IEC 61000-4-4, IEC 61000-4-5, IEC 61000-4-11, 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.

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