NONIN

MODEL
9570

GO2™

User Guide

Live life on the GO!

Table of Contents

ENGLISH

Introduction

Thank you for buying the ***GO$_2$*** Model 9570 Fingertip Pulse Oximeter. This small, portable device will give you important information about your oxygen saturation (the amount of oxygen in your blood) and pulse *rate at your fingertip!* The Model 9570 is easy to use and needs no routine maintenance except battery replacement. This User Guide explains how to use and care for your ***GO$_2$*** Model 9570.

Contents of Package

- ***GO$_2$*** Model 9570
- One AAA Alkaline Battery
- User Guide
- Quick Guide

Symbols

*The following symbols are associated with your **GO$_2$** Model 9570.*	
Symbol	**Definition of Symbol**
	Consult Instructions for Use
	Follow Instructions for Use
	**Caution!**
	CE Marking: conformance to EC Directive No. 93/42/EEC for medical devices
	Type BF Applied Part (patient isolation from electrical shock)
	Not for Continuous Monitoring (no alarm for **SpO$_2$**)
	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 80601-2-61:2011 and IEC 60601-1-11:2015

Symbol	Definition of Symbol
	Battery
	Indicates separate collection for electrical and electronic equipment (WEEE).
IP33	Protected against spraying water and against access to hazardous parts with a tool, per IEC 60529.
SN	Serial Number
	Sensor disconnect; the pulse signal is not detected or there is excessive motion.
EC REP	Authorized Representative in the European Community.
	Temperature Limitation for storage/shipping.
	Keep dry.
R_x only	Medical prescription required.

Intended Use

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.*

Contraindications

- Do not use the ***GO$_2$*** in a magnetic resonance (MR) environment.
- This device is not defibrillation proof per IEC 60601-1.

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 ***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 place the ***GO$_2$*** in liquid or clean it with agents containing ammonium chloride, isopropyl alcohol, or products that are not listed in this User's Guide.
- The ***GO$_2$*** is not intended for use in institutions.

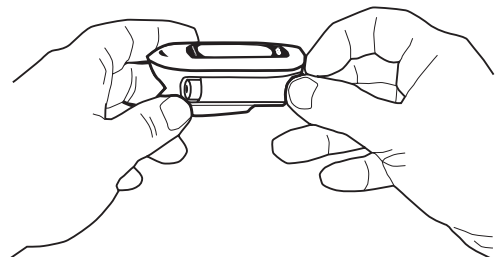
- Any of the following conditions may reduce the performance of the ***GO$_2$***:
  - flickering or very bright light;
  - weak pulse quality (low perfusion);
  - low hemoglobin;
  - arterial catheters;
  - nail polish, and/or artificial nails; and
  - any tests recently performed on you that required 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 the User Guide.
- 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.

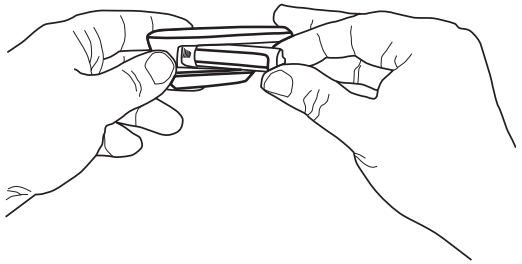
Installing the Battery

One 1.5 volt AAA-size (LR03) battery powers the ***GO$_2$*** for approximately 2400 measurements. Nonin recommends using alkaline batteries (one is included with each new ***GO$_2$***). ***NOTE:*** You may use rechargeable batteries; however, they may require more frequent replacement.

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. Follow the plus (+) and minus (-) markings for battery direction (as shown inside of the battery compartment).



3. Carefully reposition the battery door. ***NOTE:*** Do not force it into place; it fits only when positioned correctly.

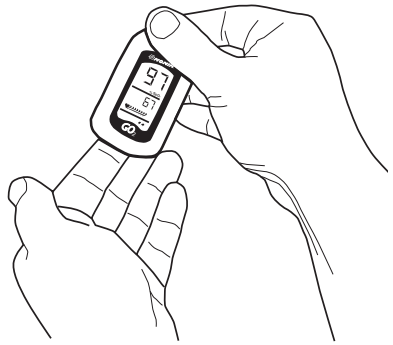


When battery is low, the battery indicator symbol on the display will flash. Remove battery if the device will be stored for more than 30 days. Replace low battery as soon as possible.

Applying the GO_2 Model 9570 to Your Finger

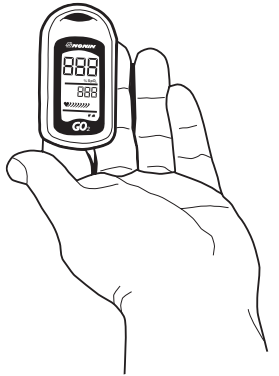
Hold the GO_2 with the display facing toward you; slide your finger into the opening at the bottom of the device, as shown at right, until the fingertip touches the built-in stop guide. The index (pointer) finger is recommended.

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.



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.

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, as shown at right. Verify that all segments of the LCD (Liquid Crystal Display) appear during the startup sequence.

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 ***GO$_2$*** does not turn on or if it shuts off unexpectedly, remove the ***GO$_2$*** from your finger, remove the battery, and see the Troubleshooting section. Continually verify operation.

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. 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 sensor disconnect indicator (⃠) will appear. The sensor disconnect 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 chart below). Replace the battery when this symbol begins to flash.

= full capacity

= half capacity

= near empty, replace

(flashing) = empty, replace

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 place the ***GO$_2$*** in liquid or clean it with agents containing ammonium chloride, isopropyl alcohol, or products that are not listed in this User's Guide.

Troubleshooting

Problems	Possible Cause	Possible Solution
Display lockup	Display does not appear to change (you should see a change to the pulse indicator if the device is on the finger).	***Reposition*** *finger or change fingers.* ***Remove*** *and replace battery.* *If the problem persists,* ***contact*** *Nonin Technical Service.*
Display blank	Finger not properly inserted.	***Reposition*** *finger to activate the device.*

Troubleshooting

Problems	Possible Cause	Possible Solution
Display blank	Battery.	***Verify*** *battery is correctly inserted.* ***Note:*** *If battery is installed backwards, the unit will not function.* *Dead battery. Replace battery.* *If the problem persists,* ***remove*** *the battery and* ***contact*** *Nonin Technical Service.*
	Device may be too cold to operate.	*Allow device to sit at room temperature for at least 10 minutes.*
Missing segments on LCD display.	Faulty display.	***Contact*** *Nonin Technical Service.*

Troubleshooting

Problems	Possible Cause	Possible Solution
No readings	Low pulse quality (no reading).	*If the ⃠ indicator is visible and the pulse quality bar graph does not show more than 2 bars, try the following:* *1. Reposition finger.* *2. Warm finger by rubbing.* *3. Select a different finger.* *For more information, please see Reading Your Results.*

Parts and Accessories

GO2CC *Black neoprene carrying case with belt loop*

GO2L *Black 20" lanyard*

GO2R *Clip on retractable holder*

WARNING: Certain activities may pose a risk of injury, including strangulation, if the lanyard should become wrapped around your neck. Use the lanyard with caution.

For more information about Nonin parts and accessories, contact your distributor, or contact Nonin at (877) 577-2635 (USA and Canada), +1 (763) 553-9968, or +31 (0)13 - 79 99 040 (Europe).

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% SpO_2 ±2 digits
Low Perfusion Oxygen Saturation Declared Accuracy Range (A_{rms}*)	70% to 100% SpO_2 ±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

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

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
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	Up to 13,123 feet /4,000 meters
Battery Life (Continuous)	Approximately 2400 spot checks based on ~21 hours of operation using one AAA-size alkaline battery, calculated at 30 seconds per use.
Battery Life (Storage)	6 months minimum

This device is not made with natural rubber latex.

Classifications per ANSI/AAMI ES60601-1 and CAN/CSA-C22.2 No. 60601-1

Degree of Protection	Type BF-Applied Part
Enclosure Degree of Ingress Protection	IP33
Mode of Operation	Continuous

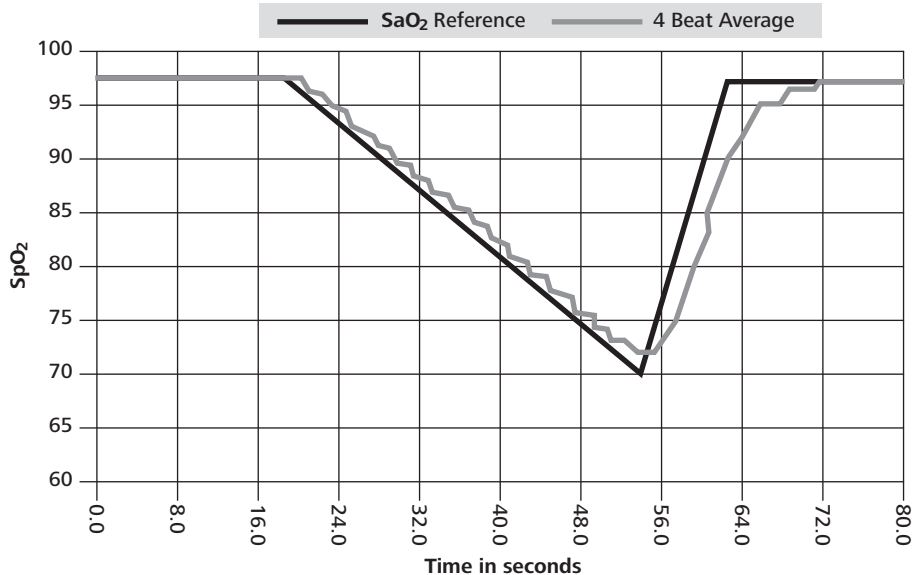
This equipment complies with International Standard IEC 60601-1-2 for electromagnetic compatibility for medical electrical equipment and/or systems. This standard is designed to provide reasonable protection against harmful interference in a typical installation. However, because of the proliferation 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, Biological evaluation of medical devices – Part 1: Evaluation and testing.

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



Specific to this example: 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:

SpO_2 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 (A_{rms} 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

Nonin warrants to the purchaser, for 2 years from the date of purchase, each ***GO$_2$*** Model 9570 exclusive of the battery. Nonin will repair or replace any ***GO$_2$*** Model 9570 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 notification occurs within the applicable warranty period. Nonin reserves the right to replace the device with a suitable alternative.

This warranty excludes cost of delivery to and from Nonin. Nonin reserves the right to charge a fee for a warranty repair request on any ***GO$_2$*** Model 9570 found to be within specifications. ***GO$_2$*** Model 9570 is a precision electronic instrument and must be repaired by Nonin Technical Service. Any sign or evidence of opening the ***GO$_2$*** Model 9570, field service by non-Nonin personnel, tampering, or any kind of misuse of the ***GO$_2$*** Model 9570, shall void the warranty. The ***GO$_2$*** Model 9570 is warranted for Home Health Care Use Only. All non-warranty work shall be done at Nonin's standard rates and charges in effect at the time of delivery to Nonin.

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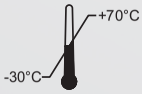
EC REP

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

6963-101-07

Please take a moment to find and record the 9-digit serial number found on the back of your ***GO$_2$*** Model 9570. You'll need this number if you have to contact Nonin with technical service issues or if you have any questions regarding the use or performance of your pulse oximeter. Nonin's technical service department can be reached at (877) 577-2635 (USA and Canada), +1 (763) 553-9968, or +31 (0)13 - 79 99 040 (Europe).

My Serial Number: _____



CE 0123

EC REP

MPS, Medical Product Service GmbH
Borngasse 20
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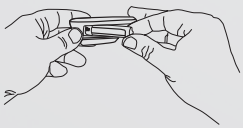
1.



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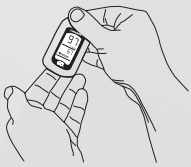

Warning: *Keep away from small children; this device contains small parts that may pose a choking hazard.*

www.go2nonin.com

℞ only

Live life on the GO!