Operator's Manual

Model 7500FO

Digital Pulse Oximeter

CE 0123

English

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

 Consult Instructions for Use.

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

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

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

nonin.com

CE 0123

EC REP

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

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

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Indications for Use

The Nonin® Model 7500FO Digital Pulse Oximeter is a portable, tabletop device indicated for use in simultaneously measuring, displaying, and recording functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate of adult, pediatric and infant patients in an Magnetic Resonance (MR) environment while operating on battery power alone. Testing was performed in MR conditional environments at 1.5T and 3T. It is intended for spot checking and/or continuous monitoring of patients who are well or poorly perfused.

Contraindications

Explosion Hazard: Do not use in an explosive atmosphere or in the presence of flammable anesthetics or gasses.
This device is not defibrillation proof per IEC 60601-1.
The battery charger cannot be used in the MR environment.

Warnings

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.
Inspect the sensor application site at least every 6 to 8 hours to ensure correct sensor alignment and skin integrity. Patient sensitivity to sensors and/or double-backed adhesive strips may vary due to medical status or skin condition.
Avoid excessive pressure to the sensor application site as this may cause damage to the skin beneath the sensor.
Oximeter readings of this device may be affected by the use of an electrosurgical unit (ESU).
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.
Do not use a damaged sensor. If the sensor is damaged in any way, discontinue use immediately and replace the sensor.
Verify all alarm settings and limits during system startup to ensure that they are set as intended.
Do not use this device in or around water or any other liquid, with or without AC power.
As with all medical equipment, carefully route patient cables and connections to reduce the possibility of entanglement, strangulation, or injury to the patient.
Use this device only with power adapters supplied by Nonin Medical.
This device turns off after approximately 30 minutes when in low battery mode.
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.

Warnings (Continued)

The battery pack must be installed at all times while the device is operating—even when operating on AC power. Do NOT use the device without batteries.
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.
To comply with relevant product safety standards, ensure that all alarm volumes are set appropriately and are audible in all situations. Do not cover or otherwise obstruct any speaker openings.
When operating in an MR environment, securely fasten this device to a non-movable pole mount or other large object, and keep it as far from the magnetic field as possible. For magnetic equipment with a magnetic strength of 1.5T or less, the device must be a minimum of 2 meters away from the magnet.
The fiber cable for this device is extremely sensitive and must be handled with caution at all times. Do not use a damaged sensor.
To avoid injury or potential equipment damage, always keep the oximeter, battery charger and metal end of fiber optic cable beyond the distance of magnetic attraction. To ensure safe operation of the 7500FO in the MR environment, the monitor must be located outside the 200 Gauss line of the MR room and must be firmly attached to a fixed object.
When audible alarms cannot be heard due to ambient noise, visible alarms must be used.

Cautions

This equipment complies with IEC 60601-1-2 for electromagnetic compatibility for medical electrical equipment and/or systems. This standard is designed to provide reasonable protection against harmful interference in a typical medical installation. However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in healthcare and other environments, it is possible that high levels of such interference due to close proximity or strength of a source might disrupt the performance of this device. Medical electrical equipment needs special precautions regarding EMC, and all equipment must be installed and put into service according to the EMC information specified in this manual.
Portable and mobile RF communications equipment can affect medical electrical equipment.
When mounting the monitor to a mobile pole, mounting the monitor higher than 1.5 meters (5 feet) or mounting more than 2 kilograms (4.5 pounds) of equipment onto the pole may result in tipping, damage to the equipment, or injury.
If the device does not beep during the initialization sequence, the speaker may not be functioning properly. Discontinue use until the situation is corrected by qualified technical personnel.
Review all limits to ensure they are appropriate for the patient.
Setting alarm limits to extremes can render the alarm system useless.
This device is a precision electronic instrument and must be repaired by qualified technical professionals. 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.
If this device fails to respond as described, discontinue use until the situation is corrected by qualified technical professionals.
The sensor might not work on cold extremities due to reduced circulation. Warm or rub the finger to increase circulation, or reposition the sensor.
Do not gas sterilize or autoclave this device.

Cautions (Continued)

Batteries might leak or explode if used or disposed of improperly.
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.
Do not immerse this device or sensors in any liquids.
Do not use caustic or abrasive cleaning agents on the unit or sensors.
Follow local, state and national governing ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries. Use only Nonin-approved battery packs.
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.
To prevent potential loss of monitoring or inaccurate data, remove any objects that might hinder pulse detection and measurement (e.g., blood pressure cuffs).
Data is written in four-minute intervals—so if the entire memory is filled, portions of the oldest record will be overwritten when a new record begins.
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 - a sensor not at heart level.
A functional tester cannot be used to assess the accuracy of a pulse oximeter monitor or sensor.
All parts and accessories connected to the serial port of this device must be certified according to at least IEC Standard EN 60950 or UL 1950 for data-processing equipment.
Operation of this device below the minimum amplitude of 0.3% modulation may cause inaccurate results.
The two-minute alarm silence is automatically engaged at startup.
Radios and cell phones or similar devices can affect the equipment and must be kept at least 2 meters (6.5 feet) away from equipment.
Failure of a network data coupling (serial cable/connectors/wireless connections) will result in loss of data transfer.

Guide to Symbols

This table describes the symbols that are found on the Model 7500FO. Detailed information about functional symbols can be found in “Operating the Model 7500FO.”

Table 1: Symbols

Symbol	Description
	Caution!
	Consult Instructions for Use.
	Follow Instructions for Use.
	Type BF Applied Part (Patient isolation from electrical shock).
	Magnetic Resonance (MR) Conditional
	Magnetic Resonance (MR) Unsafe
	**UL Mark for Canada and the United States** with respect to electric shock, fire, and mechanical hazards only in accordance with UL 60601-1 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).
	**Authorized Representative** in the European Community.
	Manufacturer
IPX2	Protected against vertically falling water drops when enclosure is tilted up to 15 degrees, per IEC 60529.
%SpO_2	%SpO_2 display.
	Pulse Rate Display.
	Numeric LEDs.
	Alarm Bar LED.

Table 1: Symbols (Continued)

Symbol	Description
	Pulse Quality LED.
	Sensor Alarm LED.
	Pulse Strength Bargraph LED.
	Alarm Silence LED.
	AC Power Adapter LED.
	Low Battery LED.
	ON/STANDBY button.
	Alarm Silence button.
	Limits button.
	Plus button.
	Minus button.
	**Non-ionizing electromagnetic radiation.** Equipment includes RF transmitters; interference may occur in the vicinity of equipment marked with this symbol.

Displays, Indicators and Controls

This section describes the displays, indicators, and controls for the Model 7500FO.

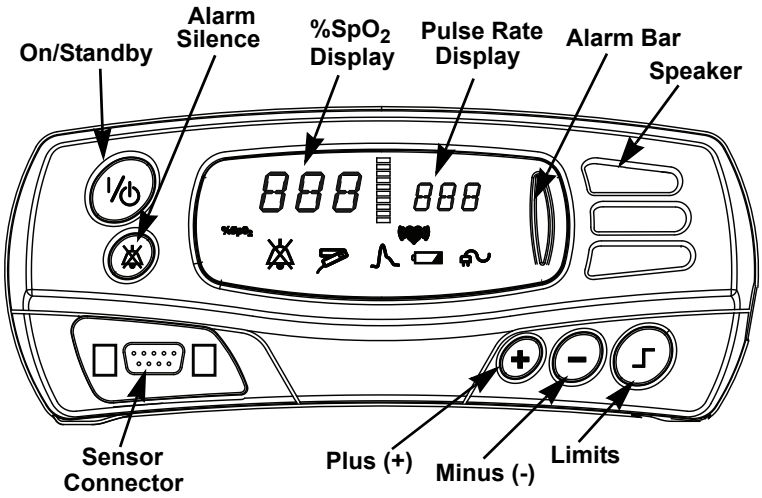


Figure 1: Model 7500FO Front View

%SpO$_2$ Display

The %SpO$_2$ display is located on the left-hand side of the Model 7500FO front panel and is identified by the %SpO$_2$ symbol. This display shows blood oxygen saturation, from 0 to 100 percent. The numeric displays blink during SpO$_2$ alarm conditions. See “Specifications” for sensor accuracy information.

Pulse Rate Display

The pulse rate display is located on the right-hand side of the Model 7500FO front panel and is identified by the (♥) symbol. This display shows the pulse rate in beats per minute, from 18 to 321. The numeric displays blink during pulse rate alarm conditions. See “Specifications” for sensor accuracy information.

NOTE: LED means “light-emitting diode.”

888 *Numeric LEDs*

Green numeric LEDs display %SpO$_2$ and pulse rate values. When setting the device, these LEDs also display values for alarm limits, volume, and date and time settings.

Indicators and Icons

Alarm Bar LED

This LED indicates all alarm conditions. For high priority (patient) alarms, the indicator is displayed in red, blinking fast. For medium priority alarms, the indicator is displayed in amber, blinking slowly.

Pulse Quality LED

This amber LED blinks to indicate an inadequate pulse signal. If there is a sustained period of poor quality signals, this LED will display a steady, constant light.

Sensor Alarm LED

This amber LED indicates when a sensor has become disconnected, has failed, or is not compatible with this monitor.

NOTE: In the 7500FO, the Sensor Alarm LED latches. Sensor must be properly attached to patient and alarm silence button must be toggled to clear LED.

WARNING: Do not use a damaged sensor.

Pulse Strength Bargraph LED

This 8-segment tricolor bargraph indicates pulse strength as determined by the oximeter. The height of the Pulse Strength Bargraph LED is proportional to the pulse signal, and the color is determined by pulse strength:

Green = a good pulse strength

Amber = a marginal pulse strength

Red = a low pulse strength, high priority alarm

Alarm Silence LED

This amber LED indicates that the audible alarm is silenced for two minutes when it blinks. When alarms are active, this LED blinks in time with the alarm bar. If no alarms are active, this LED flashes at the medium priority alarm rate. When lit solid, the Alarm Silence LED indicates that audible alarm volumes are set to less than 45 dB.

AC Power Adapter LED

This green LED is displayed when an external power supply is providing power to the Model 7500FO.

NOTE: When the external power supply is disconnected, the device automatically switches to battery power without loss of functionality.

Low Battery LED

This amber LED indicates a low battery charge when blinking, and a critical battery charge when lit solidly. *This LED does not indicate that the Model 7500FO is running on battery power.*

WARNING: This device turns off after approximately 30 minutes when in low battery mode.

Model 7500FO Front Panel Buttons

ON/STANDBY Button

Pressing this button once turns on the Model 7500FO. Holding this button for at least 1 second shuts down the unit, putting it into Standby mode. In Standby mode, all device functions are shut off, with the following exceptions:

- The AC Power Adapter LED is lit whenever the device is plugged in.
- Batteries are charged whenever the device is plugged in.

Momentarily pressing this button while the unit is on initiates an event marker.

Alarm Silence Button

This button toggles alarms between silenced and audible. Pressing the Alarm Silence button silences the alarm for two minutes. Pressing it again (while alarms are silenced) returns the alarms to their audible mode.

CAUTION: The two-minute alarm silence is automatically engaged at startup.

Limits Button

This button displays the upper and lower limits for alarm indications for SpO_2 and heart rate measurements.

Pressing the Limits button allows users to access advanced menu options, including adjusting alarm settings, alarm volume, and date and time settings. All adjustments can be made using the Plus (+) and Minus (-) buttons.

Plus (+) and Minus (-) Buttons

These buttons adjust values for many Model 7500FO functions. The Plus (+) and Minus (-) buttons are used to adjust time, date, volume and upper and lower alarm limits, except in Patient Security mode.

Operating the Model 7500FO

NOTES:

- Before using the Model 7500FO, please review all contraindications, warnings and cautions.
- Before using the Model 7500FO, the battery must be charged for four (4) hours.
- When the Model 7500FO reaches critical battery, a medium priority alarm will sound. To clear the alarm: charge the battery and turn the device off and back on.

Press the ON/STANDBY button. When the unit is first turned on, the Model 7500FO performs a brief initialization sequence.

CAUTION: If the device does not beep during the initialization sequence, the speaker may not be functioning properly. Discontinue use until the situation is corrected by qualified technical personnel.

Verify that all LEDs illuminate and the unit beeps three times during the first phase of the initialization sequence. If any LED is not lit (except the AC Power Adapter LED), do not use the Model 7500FO. Contact Nonin Technical Service for assistance.

To verify that the Model 7500FO is functioning properly, it is important to monitor SpO_2 and pulse rate readings. Use the following procedure to verify that the sensor is working properly.

1. Ensure that the Model 7500FO is on, with the sensor connected.
2. Apply the pulse oximeter sensor (see sensor instructions for use).
3. Verify that a good SpO_2 reading is displayed, that a pulse rate value appears, and that the pulse strength bargraph LED is active.

WARNING: 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.

WARNING: As with all medical equipment, carefully route patient cables and connections to reduce the possibility of entanglement, strangulation, or injury to the patient.

WARNING: Verify all alarm settings and limits during system startup to ensure that they are set as intended.

Operating Instructions

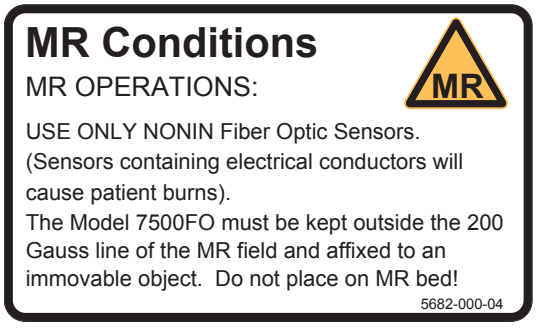
Operating in the MR Environment

When operating the 7500FO in the MR (magnetic resonance) environment, observe the following safety considerations:

Use only Nonin-branded 8000FC or 8000FI Fiber Optic Sensors. **Do not use cables or sensors that contain conductive wires.**

The 7500FO and the connectors for the fiber optic contain ferrous material and **must be kept as far away from the magnet as possible at all times.**

WARNING: To avoid injury or potential equipment damage, always keep the oximeter and metal end of fiber optic cable beyond the distance of magnetic attraction. To ensure safe operation of the 7500FO in the MR environment, the monitor must be located outside the 200 Gauss line of the MR room and must be firmly attached to a fixed object.



Contraindication: The battery charger cannot be used in the MR environment.

When operating the 7500FO in the MR environment, observe the following installation recommendations:

- Install the 7500FO in the MR environment near the observation window or outside the MR environment so the displayed values on the pulse oximeter may be clearly viewed. The 7500FO monitor must also be firmly attached to a fixed object using the mounting hole (1/4-20 thread) on the bottom of the device.
- If interference is suspected to the MR image or to the 7500FO, contact Nonin Technical Service at (800) 356-8874, +1 (763) 553-9968, or +31 (0)13 - 79 99 040 (Europe) for assistance.

When operating the 7500FO inside the MR environment, operate the 7500FO on **battery power only**. Remove the 7500FO from the MR environment to recharge the batteries when the pulse oximeter is not in use.

Operating Modes and Defaults

The Model 7500FO features Setup mode, Factory Defaults, User-Defined Defaults and Patient Security modes.

NOTE: Patient Security mode overrides any default settings.

Setup Mode, Viewing Limits and Setting Time

In Setup mode, users can adjust alarm limits and volumes, set clock and calendar information and clear the device's memory. Pressing the Limits button activates Setup mode, and all adjustments can be made using the Plus (+) or Minus (-) buttons. Setup mode is available when the device is operating, or during the startup/initialization process. Time is set by adjusting each of the last five options in setup mode: year, month, day, hour and minute.

Setup mode is not available in Patient Security mode. In Patient Security mode, pressing the Limits button scrolls through the limits on the displays, allowing the operator to view the current limits. Pressing and holding the Plus (+) button also reviews the limits, regardless of operating mode.

Factory Defaults

In Factory Defaults, all adjustable parameters are set as indicated in the table below. This is the Model 7500FO's default operating setting.

The Model 7500FO is shipped with factory defaults active. To revert to factory default alarm limits from the user-defined default alarm limits, simultaneously press the alarm silence and minus (-) buttons.

NOTE: User-Defined Default values are lost when Factory Defaults are set active.

Table 2: Factory Default Settings

Alarm Limit	Factory Default	Adjustment Options	Increment
SpO_2 High Alarm Limit	Off	Off, 80-100	1%
SpO_2 Low Alarm Limit	85%	Off, 50-95	1%
Pulse Rate High Alarm Limit	200 BPM	Off, 75-275	5 BPM
Pulse Rate Low Alarm Limit	50 BPM	Off, 30-110	5 BPM
Alarm Volume	High	Off, Low, High	N/A

Default alarm and volume settings are automatically selected for every operating session in which the parameters were not recalled or changed within the setup menu.

User-Defined Defaults

In User-Defined Defaults, alarm limit and volume settings must be adjusted. To set the User-Defined Defaults, set the alarm limits, hold the Alarm Silence button and then press the Limits button. This sets the User-Defined Defaults to be the same as the current alarm limits.

The Model 7500FO recalls User-Defined Default settings at startup whenever this option is selected. Once activated, User-Defined Defaults have priority over Factory Defaults.

NOTE: All user-defined default settings are retained even when both external and battery power are lost.

Patient Security Mode

Alarm limits cannot be changed when the Model 7500FO is in Patient Security mode. Patient Security mode prevents accidental changes to critical parameters. The Model 7500FO allows users to lock and unlock alarm limits, volume settings, and time settings through the use of Patient Security mode. Operators will notice several operating differences with Patient Security mode:

- Default and other previous device settings cannot be recalled.
- Clock and calendar data cannot be changed.
- SpO_2 and pulse rate alarm limits and volumes cannot be changed. Pressing the Limits button allows the operator to review the limits.
- Patient memory cannot be cleared.
- To put the device into Standby mode, the ON/STANDBY button must be held for at least 3 seconds.
- Memory playback not available.

Patient Security mode remains active when the device is turned off and then turned back on. Patient Security mode is retained even when both external and battery power are lost.

NOTE: Turn on the device and verify Patient Security mode and settings after initiating Patient Security mode.

When the Patient Security mode is enabled, operators cannot change SpO_2, or Pulse Rate limits or Alarm Volume—though it is still possible to view those settings. In Patient Security mode, operators cannot view or set the time and date.

When the Model 7500FO is turned on in Patient Security mode, "SEC on" is displayed in the display area, and three informational tones sound. The upper alarm limits are then displayed, followed by the lower alarm limits.

NOTE: Patient memory cannot be cleared when this device is in Patient Security mode. In addition, Patient Security mode is not disabled when the unit is turned off.

Viewing and Changing Patient Security Mode

To enter Patient Security mode, press and hold the Alarm Silence button while turning on the device. To exit Patient Security mode, press and hold the Alarm Silence and Limits buttons while turning on the device.

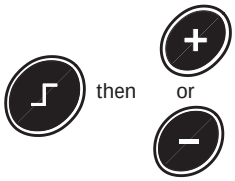
When the device is restarted, the Patient Security mode status is displayed on the Numeric LEDs for 1 second:

- "SEC on" is displayed when Patient Security mode is enabled.
- "SEC OFF" is displayed when Patient Security mode is disabled.

Operator Functions

The Model 7500FO has several easy-to-use basic functions. Most involve pressing only a single button.

Table 3: Basic Functions

Function	Button	Instruction
Turn the Model 7500FO on and off.		Press the ON/STANDBY button to turn on the Model 7500FO. Press and hold the button for at least one second to turn off the Model 7500FO. In Patient Security mode, hold the ON/STANDBY button for three seconds to turn off the Model 7500FO.
Initiate an event marker.		Momentarily press the ON/STANDBY button while the unit is on.
Mute the audible alarms (2 minutes).		Momentarily press the Alarm Silence button.
Change Pulse tone volume.		Momentarily press the Plus (+) button while the unit is in operating mode. Press again to sequence through volume options for pulse tones.
Set alarm limits or alarm volumes, clear memory or set clock.		Momentarily press the Limits button to step through the Limits menu. Use the Plus or Minus buttons to adjust alarm limits or selected volumes as desired. When pressing Limits button, settings will appear in the order shown in Table 4.

CAUTION: Review all limits to ensure they are appropriate for the patient.

CAUTION: Setting alarm limits to extremes can render the alarm system useless.

Table 4: Limits Display Sequence

Parameter	Parameter (SpO_2) Display	Initial Setting (Pulse Rate Display)	Adjustment Range
Recall Alarm Settings	“rCL”	“no”	“yES” or “no”
Low %SpO_2 Alarm Limit	“O2L” [2,3]	“85”	“OFF”, 50 to 95 by 1
Pulse High Alarm Limit	“HH” [2]	“200”	“OFF”, 75 to 275 by 5

Table 4: Limits Display Sequence (Continued)

Parameter	Parameter (SpO_2) Display	Initial Setting (Pulse Rate Display)	Adjustment Range
Pulse Low Alarm Limit	"HL" [2]	"50"	"OFF", 30 to 110 by 5
High %SpO_2 Alarm Limit	"02H" [2]	"OFF"	"OFF", 80 to 100 by 1
Alarm Volume	"adb" [2]	"Hi"	"OFF" or "Lo" or "Hi"
Clear Memory	"CLr" [1]	"no"	"yES" or "no"
Confirm Memory Clear	"dEL" [1]	"no"	"yES" or "no"
Year	"y"	"00"	0 to 99 by 1
Month	"nn"	"00"	0 to 12 by 1
Day	"d"	"00"	1 to 31 by 1
Hour	"h"	"00"	0 to 23 by 1
Minutes	"nn"	"00"	0 to 59 by 1

Notes:

1) Both of these menu options are part of the memory clear command; "dEL" will be displayed only if "yES" was selected as the setting for the "CLr" parameter.

2) These parameters are restored when Recall Alarm Settings is set to "yES." These are also the settings displayed by Review Alarm Settings.

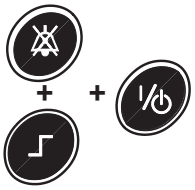
3) The low SpO_2 Alarm limit saved for recall cannot be lower than the current default for that alarm limit. If it is, the default value will be used when alarm limits are restored.

The Model 7500FO features a number of advanced options, which are intentionally more difficult to activate. These functions are recommended only for trained operators and require multiple button presses to prevent accidental activation.

Table 5: Advanced Functions

Function	Button	Instruction
Recall Previous Alarm Limit Settings		Press the Limits button while the unit is on. "rCL" appears, indicating that previous alarm limit settings may be recalled. To recall the settings, press the Plus button and select "yES." Press the Limits button again to confirm.
Memory Playback		Press and hold the Plus (+) button while turning on the Model 7500FO. This functions with the Nonin nVISION® software. Select the Model 7500 option in nVISION software.

Table 5: Advanced Functions (Continued)

Function	Button	Instruction
NOTE: Alarm limits cannot be changed when the Model 7500FO is in Patient Security mode. Patient Security mode prevents accidental changes to critical parameters. The Model 7500FO allows users to lock and unlock alarm limits, volume settings, and time settings.		
Enter Patient Security Mode		To enter Patient Security mode, press and hold the Alarm Silence button while turning on the device.
Exit Patient Security Mode		To exit Patient Security mode, press and hold the Alarm Silence and Limits buttons while turning on the device.
Make Current Alarm Values User-defined Defaults		To set the User-Defined Defaults to the current alarm settings, hold the Alarm Silence button and then press the Limits button.
Revert to Factory Defaults		To revert to the factory defaults, from the User-Defined Defaults alarm limits, hold the alarm Silence button and then press the Minus (-) button. **NOTE:** User-defined default values will be lost when factory defaults are made active.

CAUTION: Review all limits to ensure they are appropriate for the patient.

Care and Maintenance

The advanced digital circuitry within the pulse oximeter of the Model 7500FO requires **no calibration** or periodic maintenance other than battery replacement by qualified technical professionals.

Field repair of the Model 7500FO circuitry is not possible. Do not attempt to open the Model 7500FO case or repair the electronics. Opening the case may damage the Model 7500FO and void the warranty. If the Model 7500FO is not functioning properly, see “Troubleshooting.”

CAUTION: Follow local, state and national governing ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries. Use only Nonin-approved battery packs. Batteries might leak or explode if used or disposed of improperly.

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

Cleaning the Model 7500FO

Clean the Model 7500FO with a soft cloth dampened with isopropyl alcohol, mild detergent, or a 10% bleach (5.25% sodium hypochlorite) with water solution. Do not pour or spray any liquids onto the Model 7500FO, and do not allow any liquid to enter any openings in the device. Allow the unit to dry thoroughly before reusing it.

WARNING: Do not use this device in or around water or any other liquid, with or without AC power.

CAUTION: Do not immerse this device in liquid, and do not use caustic or abrasive cleaning agents on the device. Do not gas sterilize or autoclave this device. Do not place liquids on top of this device.

Clean the Model 7500FO separately from its associated sensors. For instructions regarding cleaning pulse oximeter sensors, refer to the appropriate pulse oximeter sensor package inserts.

Alarms and Limits

The Model 7500FO is equipped with audio and visual alarm indicators to alert the operator to provide immediate patient attention or to abnormal device conditions.

The intended operator's position for correctly perceiving a visual alarm signal and its priority is 1 meter (3.3 feet), per IEC 60601-1-8.

High Priority Alarms

High priority alarms require immediate attention to the patient. They include SpO_2, pulse rate, and low perfusion alarms. On the Model 7500FO, high priority alarms are indicated by a rapidly blinking red Alarm Bar LED when the value is equal to or greater than the alarm limit. In addition, the pulse strength bargraph LED illuminates a red segment to indicate low perfusion.

High priority alarms are sounded as follows: three beeps, pause, two beeps and a 10 second pause.

Medium Priority Alarms

Medium priority alarms signal potential problems with the equipment or other non-life-threatening situations. On the Model 7500FO, medium priority alarms are indicated with a slowly blinking amber Alarm Bar LED.

Medium priority alarms are illuminated amber on the Alarm Bar LED and on the appropriate indicator(s) or numeric displays, sometimes displaying an error code to help the user identify the source of the error.

Medium priority alarms are sounded as three beeps and a 25-second pause.

Watchdog Alarms

Watchdog alarms are loud, two-tone, steadily beeping signals that indicate a hardware or software malfunction. When a watchdog alarm is activated, it can be cleared by shutting down the Model 7500FO. If the watchdog alarm cannot be cleared, remove power and contact your distributor or Nonin Technical Service.

Informational Tones

Informational tones communicate important information. They are typically single beeps or a series of three beeps. Informational tones include the startup/initialization tone and the pulse rate tone (which changes in pitch with SpO_2 values: higher tones for higher SpO_2, and lower tones for lower SpO_2).

Alarm Summary

The Model 7500FO detects both patient and equipment alarms. In general, patient alarms are identified as high priority, while equipment alarms are identified as medium priority. High priority alarms always take priority over medium priority alarms. Alarm indicators remain active for as long as the alarm condition is present.

Patient Alarms

If patient SpO_2 or pulse readings are equal to or above the upper alarm limit, or if they are equal to or below the lower alarm limit, the device will signal a high priority alarm, indicated by numeric LEDs flashing in sync with the red Alarm Bar LED.

Alarm Description	Factory Default	Adjustment Options	Increment
SpO_2 High Alarm Limit	Off	Off, 80-100	1%
SpO_2 Low Alarm Limit	85%	Off, 50-95	1%
Pulse Rate High Alarm Limit	200 BPM	Off, 75-275	5 BPM
Pulse Rate Low Alarm Limit	50 BPM	Off, 30-110	5 BPM
Low Perfusion Alarm	Red segment on Pulse Strength Bargraph indicates low pulse amplitude.		

Equipment Alarms

Alarm Description	Visual Indicator
Low Battery Alarm	Battery LED blinks in sync with Alarm Bar LED. This alarm signifies that the battery has less than 30 minutes of normal operation. When Critical Low Battery is reached, the device's oximetry functions are disabled.
Sensor Alarm	Sensor Alarm LED blinks in sync with Alarm Bar LED. This alarm signifies a sensor fault or disconnect.
Other Equipment Alarms	Error code appears in main display area.

Reviewing and Setting Volume and Alarm Limits

NOTE: Alarm limits reset themselves to default values each time the unit is powered up—unless the unit is in Patient Security mode. In Patient Security mode, alarm limits and volumes cannot be adjusted; they can only be viewed.

WARNING: To comply with relevant product safety standards, ensure that all alarm volumes are set appropriately and are audible in all situations. Do not cover or otherwise obstruct any speaker openings.

Reviewing, Setting, or Changing Volumes and Alarm Limits

1. Ensure that the device is on.
2. Press the Limits button until the limit you want to view or change is displayed.
   - The current limit appears in the %SpO_2 display.
   - The current setting appears in the pulse rate display.
   - Continue to press the Limits button until the limit you want to change is displayed.
3. To change the displayed value, press the Plus (+) or Minus (-) buttons as desired.
4. Continue to press the Limits button until the unit returns to normal operation.

CAUTION: Review all limits to ensure they are appropriate for the patient.

Silencing Alarms

Press the Alarm Silence button to silence alarms for two minutes. The Alarm Silence LED blinks at the medium priority alarm rate while alarms are temporarily silenced. If alarms are silenced during active alarm conditions, the Alarm Silence LED blinks in time with the alarm bar.

The Alarm Silence LED will be lit solidly when the alarm volume is set to less than 45 dB. Audible indicators can be turned off in the Limits menu, by selecting "OFF" in the corresponding Alarm Volume menu option.

Recalling Previous Settings

The digital pulse oximeter includes a feature that allows recall of the operator-adjusted settings in use when the device was last turned off. The following settings are recalled when this feature is activated:

- SpO_2 high and low alarm limits
- Pulse rate high and low alarm limits
- Alarm volume settings

Previous operator-adjusted settings can be recalled by pressing the Limits button while the unit is on. "rCL" appears, indicating that previous alarm limit settings may be recalled. To recall the settings, press the Plus button and select "yES." Press the Limits button again to accept the recall and return to normal operation.

CAUTION: Review all limits to ensure they are appropriate for the patient.

NOTE: The recalled value for the SpO_2 low alarm will not be less than the current default.

Error Codes

This device includes error codes that indicate problems with the unit. Error codes are indicated by "Err" in the %SpO_2 display, and a capital "E" followed by a 2-digit code in the pulse rate display. To correct error conditions, perform the following steps:

1. Turn the unit off and then back on again to remove the error code.
2. If the error persists, disconnect all power, and then reconnect the power and turn the unit back on.

If the error still persists, note the error code and contact Nonin Technical Service at (800) 356-8874 (USA and Canada), +1 (763) 553-9968, or +31 (0)13 - 79 99 040 (Europe).

Memory and Data Output Features

The Model 7500FO provides real-time (serial) patient data output, as well as analog output signals for SpO_2, pulse rate and event markers.

Serial Patient Data Output

This device features real-time data output capabilities. The serial format includes an ASCII header containing model number, time, and date information.

The device provides real-time data output capability via the serial connector port. The 7500 SC cable, available from Nonin, may be used to connect the Model 7500FO to the receiving computer. The information from the Model 7500FO is sent in an ASCII serial format at 9600 baud with 8 data bits, 1 start bit, and 2 stop bits. Each line is terminated by CR/LF.

Data from the device are sent once per second in the following format:

SPO_2=XXX HR=YYY

NOTE: Pressing the ON/STANDBY button will insert a “*” at the end of the corresponding printed line to serve as an event marker.

Pin Number	Pin Assignment
1	Analog Output, SpO_2
2	No Connect
3	Serial Data Output
4	Analog Output, Pulse Rate
5	Ground
6	No Connect
7	Event Marker
8	No Connect
9	5V, 250 mA Accessory Power Supply

Analog Output

The Model 7500FO provides analog output signals for SpO_2, pulse rate, and event markers. Each output level conforms to the specifications shown below:

Output	Specification
SpO_2 Output Analog Range	0 - 1.0 VDC (representing 0-100%) 1.27 VDC (out of track)
Pulse Rate Output Analog Range	0 - 1.0 VDC (representing 0-300 BPM) 1.27 VDC (out of track)
Event Marker	0 VDC or 1.0 VDC nominal (representing an event). Event marker high for SpO_2 less than low alarm limit.
Analog Output Load Current	2 mA maximum
%SpO_2 Analog Output Accuracy	±2%
Pulse Rate Analog Output Accuracy	±5%

Analog Output Calibration

Analog calibration signals that allow external device calibration are provided after initial power up, and continue until the Model 7500FO begins tracking SpO_2 and pulse rate readings. The calibration routine ends when the system begins tracking signals. The calibration signal sequence is as follows:

Time Interval	Analog Signal
30 seconds	1.0 VDC
30 seconds	0.0 VDC
1 second	0.1 VDC
1 second	0.2 VDC
1 second	0.3 VDC
1 second	0.4 VDC
1 second	0.5 VDC
1 second	0.6 VDC
1 second	0.7 VDC
1 second	0.8 VDC
1 second	0.9 VDC
1 second	1.0 VDC
1 second	1.27 VDC
Repeat	

Memory Features

The Model 7500FO can collect and store 70 hours of continuous SpO_2 and pulse rate information.

Data may be played back with data retrieval software (Nonin's nVISION software is recommended). If you wish to create your own software, contact Nonin for the data format.

The memory in the Model 7500FO functions much like an "endless loop" tape. When the memory is full, the unit begins overwriting the oldest data with new data.

CAUTION: Data is written in four-minute intervals—so if the entire memory is filled, portions of the oldest record will be overwritten when a new record begins.

Each time the Model 7500FO is turned on, the current time/date information (if the clock is set properly) is stored in memory, starting a new recording session. Only recording sessions greater than one minute in length are stored in memory.

Patient SpO_2 and pulse rate are sampled every second. Every 4 seconds, the extreme value of the 4-second sample period is stored. Oxygen saturation values are stored in 1% increments in the range of 0 to 100%.

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.

Patient data is retained even when both external and battery power are lost.

Clearing Patient Memory

Patient memory can be cleared using the Model 7500FO's Setup mode. Press the Limits button to enter Setup mode, and use the Limits button again to scroll through the device's options until Memory Clear is displayed. Select "Yes" or "No" using the Plus (+) or Minus (-) buttons to clear patient memory, and then confirm your selection using the Limits button.

Playing Back Memory Data

The Model 7500FO has a Memory Playback feature, allowing stored data to be output through an external serial connection. Playing back the data does not clear the data from memory.

1. With the unit off, connect the serial connector port of the Model 7500FO to the back of your computer using the 7500 SC cable, which is available from Nonin.
2. Press and hold the Plus (+) button while briefly pressing the ON/STANDBY button.
3. Release the Plus (+) button. Playback mode will be shown on the SpO_2 and Pulse Rate displays until memory playback is completed.
4. When Memory Playback is complete, the device will return to normal operation.

NOTES:

- Patient memory cannot be cleared when the Model 7500FO is in Patient Security mode.
- If using nVISION software, select the Model 7500 option for model type.
- The event marker is not stored in the 7500FO memory.

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:

- Use of a multiple-socket outlet with multiple devices results in a Medical Electrical System.
- When using the serial 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 and accessories:

- Contact your distributor or Nonin at (800) 356-8874 (USA and Canada), +1 (763) 553 9968, or +31 (0)13 - 79 99 040 (Europe).
- Visit www.nonin.com.

The following Nonin accessories function with the Model 7500FO. Detailed information regarding specified sensor use (patient population, body/tissue, and application) can be found in the respective sensor instructions.

Model Number	Description
AvantB	Battery Pack
7500FO Manual	Operator's Manual for the Model 7500FO
MPP30M-004	Power supply, 30W, used with a 7600PCS power cord
7600PCS–US	Power cord, North America
7600PCS–UK	Power cord, United Kingdom
7600PCS–EU	Power cord, European Union and South America
7600PCS–AU	Power cord, Australia
Pulse Oximeter Reusable Sensors	
8000FC	Adult Fiber Optic Pulse Oximeter Sensor
8000FI	Infant/Pediatric Fiber Optic Pulse Oximeter Sensor
External Cables	
7500 SC	7500 serial output cable
7500A	7500 analog output cable (unterminated)
Sensor Accessories	
8000FW	Adult Sensor Wrap
8000TW	Infant/Pediatric Sensor Wrap
Other Accessories	
nVISION	nVISION software for Microsoft Windows® operating systems
Avant PC	Pole Mount Clamp

WARNING: 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.

WARNING: 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.

CAUTION: Use the Model 7500FO only with power adapters supplied by Nonin Medical.

Service, Support, and Warranty

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

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

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

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

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

nonin.com

CAUTION: This device is a precision electronic instrument and must be repaired by qualified technical professionals. 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.

Warranty

NONIN MEDICAL, INCORPORATED, (Nonin) warrants to the purchaser, for a period of one year from the date of purchase, each Model 7500FO battery pack. Nonin warrants the pulse oximetry module of the Model 7500FO for a period of three years from the date of purchase. Extended warranties are available on most Nonin pulse oximeter models. Please consult your local Nonin distributor for additional information.

Nonin shall repair or replace any Model 7500FO 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 7500FO delivered to the purchaser which is found to be defective in any manner, whether such remedies be in contract, tort, or by law.

This warranty excludes cost of delivery to and from Nonin. All repaired units shall be received by the purchaser at Nonin's place of business. Nonin reserves the right to charge a fee for a warranty repair request on any Model 7500FO that is found to be within specifications.

The Model 7500FO is a precision electronic instrument and must be repaired by qualified technical professionals. Accordingly, any sign or evidence of opening the Model 7500FO, field service by non-authorized personnel, tampering, or any kind of misuse or abuse of the Model 7500FO, shall void the warranty in its entirety. 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 EXPRESS WARRANTIES SET FORTH IN THIS MANUAL ARE EXCLUSIVE AND NO OTHER WARRANTIES OF ANY KIND, WHETHER STATUTORY, WRITTEN, ORAL, OR IMPLIED, INCLUDING WARRANTIES OF FITNESS FOR A PARTICULAR PURPOSE OR MERCHANTABILITY, SHALL APPLY.

Troubleshooting

Problem	Possible Cause	Possible Solution
Model 7500FO will not activate.	The unit has no power.	Plug in the AC adapter.
Model 7500FO does not beep during initialization sequence.	The speaker may not be functioning properly.	Contact Nonin Technical Service for repair or replacement.
Model 7500FO will not operate on batteries.	The battery pack is not charged.	Plug in the Model 7500FO AC Adapter to charge the battery pack.
	The battery pack is inoperable.	Contact Nonin Technical Service for repair or replacement.
Unable to obtain a green pulse display on the bargraph. **NOTE:** In some instances, patient perfusion may be inadequate for pulse detection.	The patient pulse strength is indiscernible or perfused poorly.	Reposition the finger or insert a different finger, and keep the sensor motionless for at least 10 seconds.
		Warm the patient's finger by rubbing or covering with a blanket.
		Position the sensor at a different site.
	Circulation is reduced because of excess pressure on the sensor (between the sensor and a hard surface) after inserting finger.	Allow the hand to rest comfortably without squeezing or pressing the sensor on a hard surface.
	The finger is cold.	Warm the patient's finger by rubbing or covering with a blanket.
		Position the sensor at a different site.
	The sensor is applied incorrectly.	Apply the sensor correctly.
	There is possible interference from one of the following sources: • arterial catheter • blood pressure cuff • electrosurgical procedure • infusion line	Reduce or eliminate any interference. Make sure that the sensor is not placed on the same arm being used for other patient therapies or diagnostics (e.g., blood pressure cuff).

Problem	Possible Cause	Possible Solution
Unable to obtain a green pulse display on the bargraph, cont'd.	The red LED is not lit in the sensor's finger insertion area.	Ensure the sensor is securely attached to the Model 7500FO.
		Check the sensor for any visible signs of deterioration.
		Contact Nonin Technical Service.
Frequent or steady pulse quality indication.	There is excessive ambient light.	Shield the sensor from the light source.
	The Model 7500FO is applied to a polished or artificial fingernail.	Apply the sensor to a finger without artificial or polished nails.
		Position the sensor at a different site.
	The red LED is not lit in the sensor's finger insertion area.	Ensure the sensor is securely attached to the Model 7500FO.
		Check the sensor for any visible signs of deterioration.
		Contact Nonin Technical Service.
	Excessive patient motion.	Reduce patient motion.
A dash (-) appears in the %SpO_2 display.	An inadequate signal from the finger is being detected.	Reposition finger or insert a different finger, keeping sensor motionless for at least 10 seconds.
		Position sensor at different site.
	The finger was removed from the sensor.	Reinsert the finger and keep the sensor motionless for at least 10 seconds.
	The Model 7500FO is not functioning.	Turn the unit off, check all connections, and retry.
		Contact Nonin Technical Service.

Problem	Possible Cause	Possible Solution
An error code appears in the display area.	The Model 7500FO encountered an error.	Turn the unit off and then back on again to remove the error code. If the error persists, disconnect all power, and then reconnect the power and turn the unit back on. If the error still persists, note the error code and contact Nonin Technical Service.
The unit is in Alarm mode, but no audible alarms can be heard.	The 2-minute Alarm Silence button is activated.	Press the Alarm Silence button to re-engage alarm volume, or wait for two minutes. After two minutes, alarm tones will automatically re-engage.
	Audible volume set to "OFF" in alarm limits.	Adjust volume through setup mode
The Model 7500FO does not record data.	The battery is low.	Recharge the battery.
	The battery is missing.	Contact your distributor or Nonin Technical Service for repair or replacement.

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).

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 serial port of this device must be certified according to at least IEC Standard EN 60950 or UL 1950 for data-processing equipment.

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

Manufacturer's Declaration

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

Table 6: Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment—Guidance
This device is intended for use in the electromagnetic environment specified below. The 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	

Table 7: Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance
This device is intended for use in the electromagnetic environment specified below. The user of this device should ensure that it is used in such an environment.			
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/Burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	±5% U_T (>95% dip in U_T) for 0.5 cycle ±40% U_T (60% dip in U_T) for 5 cycles ±70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec.	±5% U_T (>95% dip in U_T) for 0.5 cycle ±40% U_T (60% dip in U_T) for 5 cycles ±70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec.	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or battery pack.
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the AC mains voltage before application of the test level.			

Table 8: Guidance and Manufacturer's Declaration—Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance
This device is intended for use in the electromagnetic environment specified below. The user of this device should ensure that it is used in such an environment.			
Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.			
			Recommended Separation Distance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	$d = 1.17\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.17\sqrt{P}$ $d = 2.33\sqrt{P}$ where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTES: • At 80 MHz and 800 MHz, the higher frequency range applies. • These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 9: Recommended Separation Distances

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

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

	Separation Distance According to Frequency of Transmitter		
Rated Maximum Output Power of Transmitter W	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	80 MHz to 800 MHz $d = 1.17\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.33\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTES:

- At 80 MHz and 800MHz, the separation distance for the higher frequency range applies.
- 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

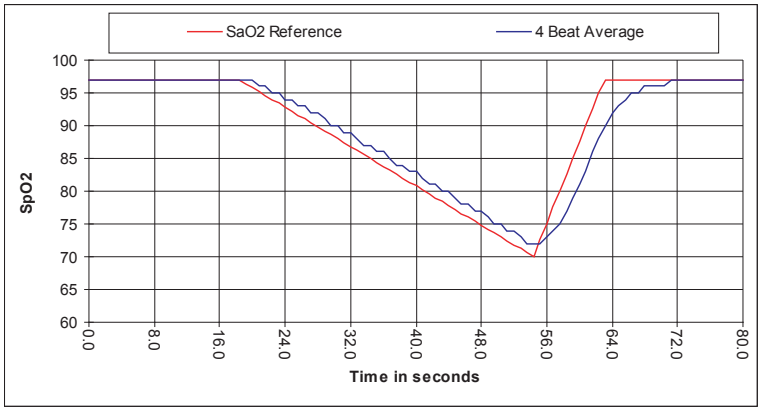
Pulse Rate Values	**Response**	**Latency**
Standard/Fast Averaged Pulse Rate	4 beat exponential	2 beats

Equipment Delays	**Delay**
Display Update Delay	1.5 seconds
Alarm Signal Generation Delay	0 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 were conducted by Nonin Medical, Inc., as described below:

SpO_2 Accuracy Testing

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

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

Oxygen Saturation Display Range:	0 to 100% SpO_2	
Pulse Rate Display Range:	18 to 321 pulses per minute (BPM)	
Displays:		
Pulse Quality:	LED, amber	
Sensor Alarm:	LED, amber	
Pulse Strength Bargraph:	LED, bargraph, tri-color segments	
Alarm Indicator:	LED, bi-color	
Alarm Silenced:	LED, amber	
Numeric Displays:	3-digit, 7-segment LEDs, green	
Low Battery:	LED, amber	
SpO_2 Accuracy (A_{rms})[a]:		
FO Sensor:	70-100% ± 2 digits	
Pulse Rate Accuracy (A_{rms})[a]:		
No Motion:	±3 digits, 18-300 BPM	
Low Perfusion:	±3 digits, 40-240 BPM	
Alarm Volume:	High:	75 dBA
	Low:	64 dBA
Informational Tone Volume:	High:	30 dBA
	Low:	26 dBA
Measurement Wavelengths and Output Power:[b]		
Red:	660 nm @ 0.8 mW maximum average	
Infrared:	910 nm @ 1.2 mW maximum average	
Memory:	70 hours (assuming continuous operation)	
Temperature (Operating):	0 to 40 °C (32 to 104 °F)	
Temperature (Storage/Transportation):	-40 to 70 °C (-40 to 158 °F)	

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

b.) This information is especially useful for clinicians performing photodynamic therapy.

Humidity (Operating):	10 to 90% noncondensing
Humidity (Storage/Transportation):	10 to 95% noncondensing
Altitude (Operating):	Up to 12,000 meters (40,000 feet)
Hyperbaric Pressure:	Up to 4 atmospheres
Power Requirements:	
Mains:	100-240 VAC 50-60 Hz
DC Input:	12 VDC 1.5A AC adapter (in MR use battery operation only)
Internal Power:	
Battery:	7.2 volt NiMH battery pack
Operating Life (fully charged battery):	30 hours minimum
Operating Life (when using 5V, 250 mA accessory power supply [Pin 9]):	10 hours
Storage Life:	27 days minimum
Recharge Rate:	4 hours maximum
Dimensions:	Approximately 219 mm (8.6”) W x 92 mm (3.6”) H x 142 mm (5.6”) D
Weight:	Approximately 900 grams (2 lbs) with battery
Warranty:	3 years
Classification per IEC 60601-1/CAN/CSA-22.2 No. 601.1/UL60601-1:	
Type of Protection:	Internally powered (on battery power).
Degree of Protection:	Type BF-Applied Part
Mode of Operation:	Continuous
Enclosure Degree of Ingress Protection:	IPX2
Analog Outputs:	
SpO_2 Output Range:	0-1 VDC (0-100% SpO_2, 1.27 VDC (no data)
Pulse Rate Output Range:	0-1 VDC (0-300 BPM), 1.27 VDC (no data)
Event Marker:	0 V (no event), 1 V (event occurred)
Accuracy:	±2% (SpO_2), ±5% (Pulse Rate)
Load Current:	2 mA maximum