NONIN

# Operator's Manual

# Model 7800

## ECG/$SpO_2$/Respiration Monitor

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.


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CE 0123

EC REP

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




6528-001-03

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# Indications for Use

The NONIN Model 7800 ECG/$SpO_2$/Respiration Monitor is a portable ECG and oximetry monitor with impedance respiration. It continuously and non-invasively monitors and displays functional oxygen saturation of arterial hemoglobin ($SpO_2$), pulse rate, respiration rate, plethysmogram, respiration, and ECG waveforms. The device may be used in the hospital or clinical environment. The device will provide fast, reliable measurements on patients ranging from infant to adult when using the appropriate NONIN-branded accessories. The monitor is not intended to be an apnea monitor. It was not designed or validated for use as an apnea monitor. The monitor is not intended for neonatal use. Nonin's use of Bluetooth wireless technology allows $SpO_2$, pulse rate, heart rate, and respiration information to be transmitted through a Bluetooth radio to a compatible Bluetooth-enabled device.

## *Contraindications*

- Do not use this device in an MR environment.
- Explosion Hazard: Do not use in an explosive atmosphere or in the presence of flammable anesthetics or gasses.

## *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.
- The use of this equipment is restricted to one patient at a time.
- Readings of this device may be affected by the use of an electrosurgical unit (ESU).
- Using accessories, sensors, and cables other than those listed in this manual is not recommended for the following reasons:
  - • Results may include increased electromagnetic emission and/or decreased immunity of this device.
  - • NONIN-branded PureLight® sensors are manufactured to meet the accuracy specifications for Nonin pulse oximeters.
  - • Using other manufacturers' sensors can result in improper pulse oximeter performance.
  - • Using only NONIN-specified ECG cables and accessories provides defibrillation protection. These cables have internal resistance to limit the defibrillation voltage to which the operator is exposed.

## Warnings (Cont'd)

- Always inspect the device before use. Do not use a damaged device, lead(s), electrode(s), cable(s), or sensor. Before using any sensor, carefully read the sensor Instructions for Use, which contains sensor application information for each sensor.
- Do not use this device in or around water or any other liquid, with or without AC power.
- Use the Model 7800 only with power adapters supplied by Nonin Medical.
- As with all medical equipment, carefully route patient cables and connections to reduce the possibility of entanglement or strangulation.
- Use the Model 7800 Monitor only within its designated range (approximately 300 feet / 100 meters - spherical radius - from the 7800 monitor to remote location). Moving outside this range may cause missing, lost, and/or inaccurate data at the remote monitoring location.
- Pacemaker Patients - Rate meters may continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias. Do not rely entirely upon rate meter alarms. Keep pacemaker patients under close surveillance. See this manual for disclosure of the pacemaker pulse rejection capability of this instrument.
- This device turns off after approximately 30 minutes when in low battery condition.
- 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.
- Conductive parts of electrodes and associated conductors for applied parts (including the neutral electrode) should not contact other conductive parts, including earth.
- 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.
- 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 block any speaker openings.

## *Warnings (Cont'd)*

- 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.
- The device Nurse Call and Bluetooth features should not be used as the primary source of alarm notification.
- The user must verify the device Bluetooth pairing to ensure the correct patient is remotely monitored.

## *Cautions*

- This equipment complies with IEC 60601-1-2:2001 for electromagnetic compatibility (EMC) for medical electrical equipment and/or systems. This standard is designed to provide reasonable protection against harmful interference in a typical medical installation. However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in healthcare and other environments, it is possible that high levels of such interference due to close proximity or strength of a source might disrupt the performance of this device. Medical electrical equipment needs special precautions regarding EMC, and all equipment must be installed and put into service according to the EMC information specified in this manual.
- Although this device meets the patient leakage current limits of IEC 60601-1 and AAMI ES1, summation of leakage current due to the interconnection of several devices by coupling and/or a multiple portable socket-outlet may exceed these limits.
- When using this device, it is recommended that the caregiver be trained in cardiopulmonary resuscitation.
- Portable and mobile RF communications equipment can affect medical electrical equipment.
- Radios and cell phones or similar devices can affect the equipment and must be kept **at least 2 meters** away from the equipment.
- If this device fails to respond as described, discontinue use until the situation is corrected by qualified technical professionals.

## ⚠ Cautions (Cont'd)

- 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.
- Battery pack might leak or explode if used or disposed of improperly or if leads are cut.
- 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.
- Inspect the sensor and ECG electrode application sites at least every six to eight hours to ensure correct sensor alignment and skin integrity. Patient sensitivity to sensors and/or adhesive-backed strips may vary due to medical status or skin condition.
- Do not autoclave, sterilize, or immerse this device in liquid or use caustic or abrasive cleaning agents. Do not use cleaning agents or cleaning products that contain ammonium chloride.
- 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.
- Use only NONIN-specified Silver/Silver Chloride electrodes. Other electrode types may cause large offset potentials due to electrode polarization, slowing recovery time after application of defibrillator pulses, among other issues. Use of "squeeze bulb" type electrodes is not recommended. Do not use electrodes of dissimilar materials.
- To prevent potential loss of monitoring, do not use ear clip or reflective sensors on pediatric or infant patients.
- 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.

## ⚠ *Cautions (Cont'd)*

- Data is written continuously, when the device is on—so if the entire memory is filled, portions of the oldest record will be overwritten when a new record begins.

- To prevent potential loss of monitoring or inaccurate data, remove any objects that might hinder pulse detection and measurement (e.g., blood pressure cuffs).

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.

*Caution: Exposure to Radio Frequency Radiation.* The radiated output power of the display device is far below FCC radio frequency exposure limits. Nevertheless, the device must be used in such a way that the potential for human contact during normal operation is minimized. To avoid the possibility of exceeding FCC radio frequency exposure limits, remain at least 20 cm (8 inches) away from the display unit's internal antenna during normal operation. The monitor has been tested and meets allowed limits for exposure.

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

A 2-minute alarm silence is automatically engaged at startup.

| ⚠ Cautions (Cont'd) |
| --- |
| A functional tester cannot be used to assess the accuracy of a pulse oximeter monitor or sensor. |
| Operation of this device below the minimum amplitude of 0.3% modulation may cause inaccurate results. |
| Pairing must be initiated by the host within 2 minutes of turning the device on or within 2 minutes of pressing the Bluetooth button when running on internal battery power. After 2 minutes the Bluetooth portion of the device turns off to conserve power. |

## Declaration of Conformity with FCC and Canadian Ministry of Health Rules for Electromagnetic Compatibility

- Nonin Medical, Inc., of 13700 1st Avenue North, Plymouth, Minnesota, 55441, declares under its sole responsibility that the Model 7800, to which this declaration relates, comply with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.
- Ministry of Health (Canada), Safety Code 6: standards include a substantial safety margin designed to ensure the safety of all persons, regardless of age and health. The exposure standard for wireless mobile phones employs a unit of measurement known as the Specific Absorption Rate, or SAR. The SAR limit set by the FCC is 1.6W/kg.

## Federal Communications Commission (FCC) Notice

This equipment has been tested and found to comply with the limits for a class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy. If not installed and used in accordance with the instructions, it may cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on. The user is encouraged to try to correct the interference by one or more of the following measures: (1) Reorient or

relocate the receiving antenna, (2) Increase the distance between the equipment and the receiver, (3) Connect the equipment to an outlet on a circuit different from the outlet where the receiver is connected, or (4) Consult the dealer or an experienced radio/TV technician for assistance.

The Model 7800 is designed and manufactured not to exceed the emission limits for exposure to radio frequency (RF) energy set by the Federal Communications Commission of the U.S. Government. These limits are part of comprehensive guidelines and establish permitted levels of RF energy for the general population. The guidelines are based on the safety standards previously set by both U.S. and international standards bodies. This EUT has been shown to be capable of compliance for localized specific absorption rate (SAR) for uncontrolled environment/ general population exposure limits specified in ANSI/IEEE Std. C95.1-1992 and has been tested in accordance with the measurement procedures specified in FCC/OET Bulletin 65 Supplement C (2001) and IEEE Std. 1528-200X (Draft 6.5, January 2002).

RF Exposure: For body worn operation, to maintain compliance with FCC RF exposure guidelines, use only accessories that contain no metallic components and provide a separation distance of 15mm (0.6 inches) to the body. Use of other accessories may violate FCC RF exposure guidelines and should be avoided.

The FCC requires the user to be notified that any changes or modifications to this device that are not expressly approved by Nonin Medical, Inc. may void the user's authority to operate the equipment.

**NOTE:** No modifications to this device are allowed that in any way affect or alter its antenna or antenna configuration.

# Guide to Symbols

This table describes the symbols that are found on the Model 7800. Detailed information about functional symbols can be found in “Using the Model 7800 ECG/$SpO_2$/Respiration Monitor”.

**Table 1: Labeling Icons**

| Symbol | Description |
|---|---|
|  | **Caution!** |
|  | Consult instructions for use. |
|  | Defibrillation-Proof Type BF Applied Part (Patient isolation from electrical shock). |
|  | Defibrillation-Proof Type CF Applied Part (Patient isolation from electrical shock). |
|  | AC Power Adapter LED |
|  | Class II equipment |
|  | Non-ionizing electromagnetic radiation. Equipment includes RF transmitters; interference may occur in the vicinity of equipment marked with this symbol. |
| CE 0123 | 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). |
| EC REP | Authorized Representative in the European Community. |
| LOT | Lot Number |

**Table 1: Labeling Icons**

| Symbol | Description |
|---|---|
|  | Storage/shipping temperature range of -30°C to +70°C. |
| IP33 | Protected against spraying water and against access to hazardous parts with a tool, per IEC 60529. |

**Table 2: Display Icons**

| Symbol | Description |
|---|---|
| $\%SpO_2$ | $\%SpO_2$ |
|  | Factory Defaults |
|  | Nurse Call Alarm |
|  | Adjustable Upper Limit |
|  | Adjustable Lower Limit |
|  | User-Defined Defaults |
|  | Patient Security mode |
|  | Pulse Rate (from Plethysmogram) |
|  | Heart Rate from ECG |
|  | Respiration |

**Table 2: Display Icons**

| Symbol | Description |
|---|---|
|  | No Breath |
|  | Pulse Quality |
|  | Sensor Alarm |
|  | Pulse Strength Bar Graph |
|  | Alarm Silence |
|  | Low Battery |

**Table 3: Button Icons**

| Symbol | Description |
|---|---|
|  | ON/STANDBY |
|  | Alarm Silence |

**Table 4: Soft Button Icons**

| Symbol | Description |
|---|---|
|  | Limits Menu |
|  | Menu |
|  | Date/Time |
|  | Bluetooth Wireless Technology |
|  | Plus |
|  | Minus |
|  | Enter (Next) |
|  | Save |

# How Supplied

**NOTES:**
- Before using the Model 7800, please review all contraindications, warnings, and cautions.
- Before using the Model 7800, the battery must be charged for 4 hours.

## *Setting Up the Model 7800 Monitor*

### Unpacking the Monitor and Checking the Shipment

Carefully remove the monitor and accessories from the shipping carton. Save the packaging materials in case the monitor or accessories must be returned. Compare the packing list with the accessories received to make sure the shipment is complete.

The monitor includes the following components:

- Model 7800 ECG/$SpO_2$/Respiration Monitor
- ECG cable
- One set of ECG leads
- Package of three ECG electrodes
- 8000AA finger-clip sensor
- Operator's Manual
- Universal Battery Charger (Power Supply)

**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 or strangulation.**

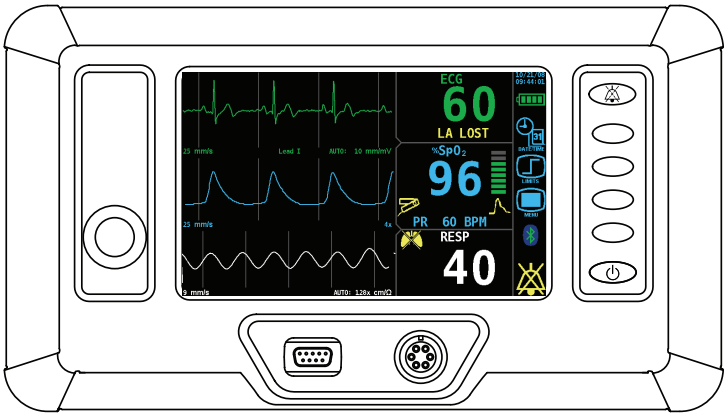



**Figure 1: Model 7800 ECG/$SpO_2$/Respiration Monitor**

## *General Information about Bluetooth Wireless Technology*

Bluetooth is a technology that enables automatic wireless connections between a variety of electronic communications and computing devices, making it possible to connect any compatible devices without cables or wires. The technology is based on a radio link that offers fast and reliable transmissions of voice, video, and data. Bluetooth uses a license-free, globally available frequency range in the ISM band—intended to ensure communication compatibility worldwide.

Nonin's use of Bluetooth wireless technology allows $SpO_2$, pulse rate, heart rate, and respiration information to be transmitted through a Bluetooth radio to a compatible Bluetooth-enabled device. Nonin's system removes the connection from the monitor to a remote monitor location, giving patients increased ability to move freely—without being hindered by cables. Nonin's Model 7800 monitor uses an automatically switchable class I/class II Bluetooth radio with a range of about 100 meters (spherical radius).

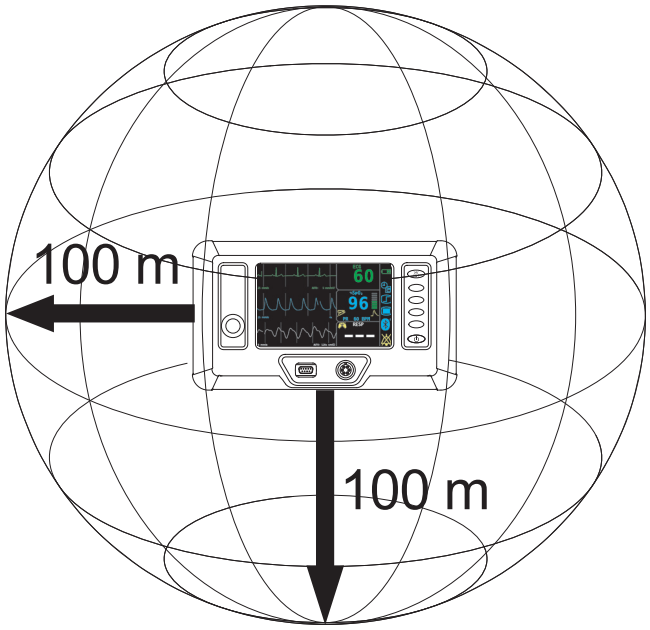



**Figure 2: 7800 Bluetooth Range**

## Point-to-Point Communications

The Model 7800 features point-to-point communications, allowing one master device (the remote monitor) to be paired to one slave device (the 7800 monitor). Once connected, the 7800 monitor is not detectable by any other Bluetooth-enabled device, which reduces the risk of interference and preserves data integrity.

# Displays, Indicators, and Controls

This section describes the displays, indicators, and controls for the Model 7800.

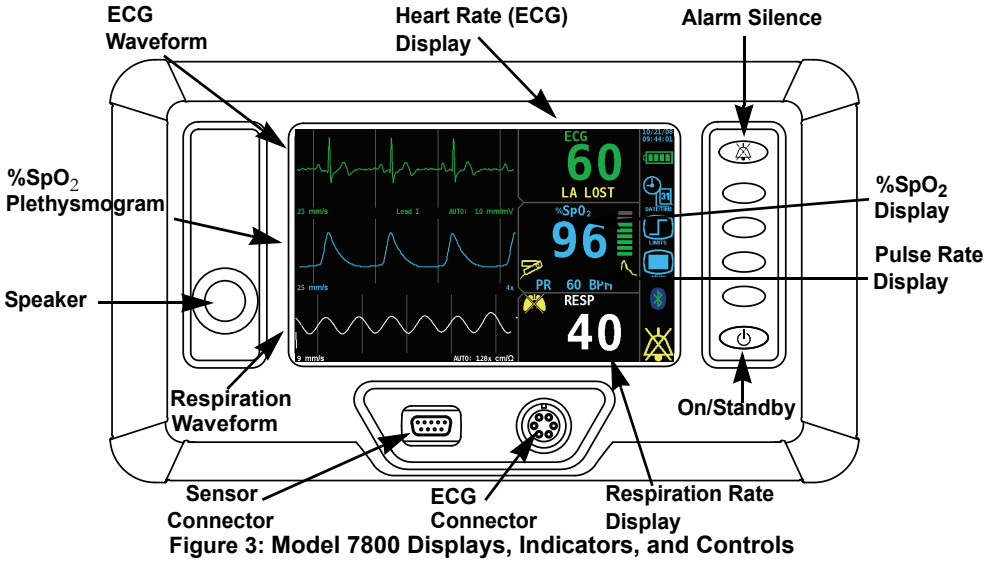



**Figure 3: Model 7800 Displays, Indicators, and Controls**

## *Displays*

### %$SpO_2$ Display

The %$SpO_2$ display is located on the right center side of the 7800 Monitor front panel (example shown: 96%) and is identified by "%$SpO_2$". This display shows %$SpO_2$ blood oxygen saturation, from 0 to 100 percent. The numeric display is highlighted in RED and blinks during $SpO_2$ alarm conditions. See "Specifications" for sensor accuracy information. The device continually displays a pulse Plethysmogram; the waveforms can be turned off using the Settings Menu.

### Pulse Rate Display

The pulse rate display is located on the right-hand side (just below the $SpO_2$ parameter) of the 7800 Monitor front panel and is identified by "PR". This display shows the pulse rate in beats per minute (BPM), from 18 to 321. The numeric display is highlighted in RED and blinks during alarm conditions. The pulse rate measurement is determined by the $SpO_2$ sensor. See "Specifications" for sensor accuracy information.

## ECG Heart Rate Display

The ECG Heart Rate display is located on the upper right-hand side of the 7800 Monitor front panel. The monitor continuously measures and displays a heart rate from the ECG and an ECG waveform. The monitor may be set to beep with each heart beat. The volume of the heart beat beep is adjustable. ECG alarm limits are also adjustable. In the event a signal from one of the ECG leads is lost a “LEAD LOST” message will appear on the front panel display (in YELLOW). If more than one lead is lost, the Model 7800 will no longer attempt measurement or display of ECG.

## Respiration Rate Display

The respiration rate display is located on the lower right-hand side of the 7800 Monitor front panel. Impedance pneumography measurement through the ECG leads measures the respiration of the patient, including respiration rate and no breath monitoring. The respiration waveform is displayed in units of centimeters per ohm. The numeric display is highlighted in RED and blinks during respiration alarm condition.

# *Indicators*

## Pulse Quality Indicator

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

## Sensor Alarm Indicator

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

**WARNING: Always inspect the device before use. Do not use a damaged device, lead(s), electrode(s), cable(s), or sensor. Before using any sensor, carefully read the sensor Instructions for Use, which contains sensor application information for each sensor.**

## Pulse Strength Bar Graph Indicator

This eight-segment tricolor bar graph indicates pulse strength as determined by the oximeter. The height of the Pulse Strength Bar Graph indicator is proportional to the pulse signal, and the color is determined by pulse strength:

**Green** = a good pulse strength
**Yellow** = a marginal pulse strength
**Red** = a low pulse strength, high priority alarm

## Alarm Silence Indicator

This yellow icon indicates that the audible alarm is silenced for 2 minutes when it blinks. This indicator flashes at the medium priority alarm rate. When lit solid, the Alarm Silence indicator indicates that audible alarm volumes are set to less than 45 dB.

## AC Power Adapter LED

This LED is displayed when an external power supply is providing power to the Model 7800. It is YELLOW when the battery pack is being charged and GREEN when the battery pack is fully charged.

## Battery Indicator

The battery indicator shows the approximate percentage of battery life remaining when the AC power is not connected. When AC power is connected, the battery indicator will fill up repeatedly to indicate the battery pack is charging. The indicator stops filling when the battery pack is fully charged. When the battery icon flashes yellow, it indicates a low battery condition - only 30 minutes of battery life remain. When the icon is solid red, it indicates a critical battery condition.

**WARNING: This device turns off after approximately 30 minutes when the battery is low.**

**NOTE:** *Critical Battery Condition.* When the Model 7800 reaches a critical battery condition, a medium priority alarm will sound, To clear the alarm, charge the battery. Also, during critical battery the display blanks unless there was an alarm active when the device went into critical battery. When that is the case, the display(s) that had the alarm condition(s) show(s) dashes in critical battery mode.

# Controls

## *Model 7800 Front Panel Buttons*

### ON/STANDBY Button

Pressing this button once turns on the Model 7800. Holding this button for at least 1 second (3 seconds in Patient Security mode) shuts down the Model 7800, 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.

### Alarm Silence Button

This button toggles alarms between silenced and audible. Pressing the Alarm Silence button silences the alarm for 2 minutes. Pressing it again (while alarms are silenced) returns the alarms to their audible mode.

**CAUTION:** A 2-minute alarm silence is automatically engaged at startup.

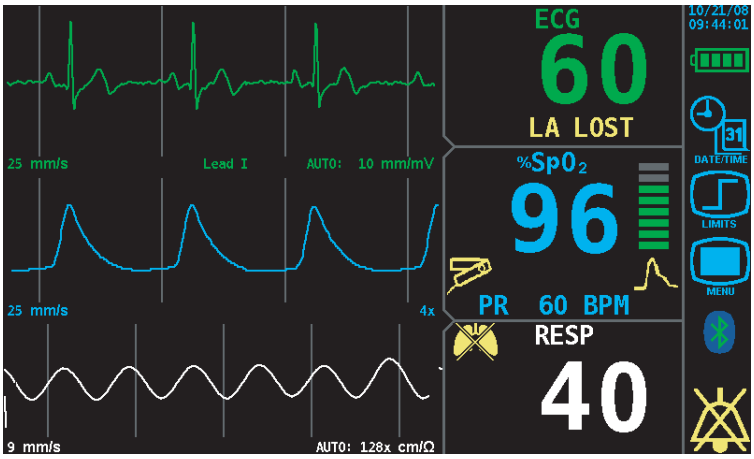



**Figure 4: Model 7800 Main Menu Screen**


## Date/Time Button

This button displays the date and the time. Year, month, day, hour and minute can be set using the Plus (+) and Minus (-) buttons.

## Limits Button

This button allows the user to display or change the upper and lower limits for alarm indications for $SpO_2$, pulse rate, respiration rate, no breath, and heart rate measurements. All adjustments can be made using the Plus and Minus buttons.

## Menu Button

This button displays menu options.
Pressing the Menu button allows users to access advanced menu options, including selecting the monitored ECG lead, adjusting alarm volume, waveform display, memory clear, brightness and ECG vertical scale. All adjustments can be made using the Plus (+) and Minus (-) buttons.

## Bluetooth Wireless Technology Button

The Bluetooth button activates the internal Bluetooth module for pairing with host devices. It also displays pairing information for the device. The Bluetooth icon is green when the Model 7800 is paired to a host, white when it is powered on but not paired, gray when it is not powered on, and red when there is a fault with the Bluetooth module (eg. it is disconnected).

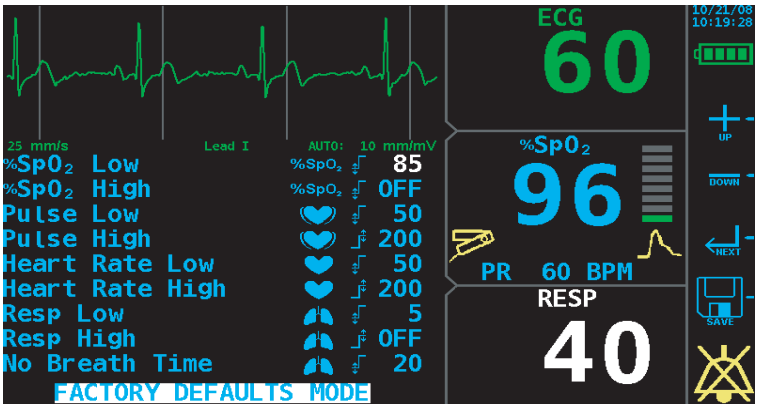



**Figure 5: Model 7800 Limits Menu Screen**

## Plus (+) and Minus (-) Buttons

These buttons adjust values in the menus for many Model 7800 functions. The Plus (+) and Minus (-) buttons are used to adjust time, date, volume and upper and lower alarm limits, except in Patient Security mode.

## Save Button

Press this button to exit a menu. It saves the changed settings within each menu while the device is on. If the device is turned off and back on, the active default settings (User-Defined Defaults, Factory Defaults, or Patient Security mode) are used for limits and settings.

## Enter Button

This button is used to move to the next option.

# Using the Model 7800 ECG/$SpO_2$/Respiration Monitor

## *Verifying System Operation*

Press the **ON/STANDBY** button. Each time the unit is turned on, the Model 7800 performs a brief initialization sequence:

- The LCD display lights up and displays the Nonin logo, allowing the operator to verify operation.
- An audible information tone sounds.
- Software revisions for all microcontrollers display on the LCD.
- The Default alarm limits display on the LCD.
- If the unit is in patient security mode, “Patient Security Mode” displays on the LCD.

Verify each of the above items occur during initialization. If any do not occur, contact Nonin Customer Support for assistance.

> **CAUTION:** Radios and cell phones or similar devices can affect the equipment and must be kept **at least 2 meters** away from the equipment.

## *Device Pairing*

The Bluetooth Information screen is used to pair the display device with input or output devices via Bluetooth. Devices could include real time data output to a computer system or Bluetooth hub, memory download to a computer system, or memory download to a Bluetooth enabled cell phone for relay via a cell phone connection.

To enter the Bluetooth Pairing Mode, press the **Bluetooth** soft button on the lower right side of the front panel display while viewing the main menu screen. The $SpO_2$, heart rate, pulse rate, and respiration rate numbers will remain on the screen, but the plethysmograph and respiration waveforms are replaced by a settings menu. The device Bluetooth information is displayed on the LCD.

### *How to Determine the Bluetooth Information for this Device*

1. Press the **Bluetooth** button.
2. Note the Bluetooth address that appears on the screen. This address must be selected on at the host computer to pair the host to this monitor via Bluetooth.
3. This is accomplished by opening a software program (like nVISION) and connecting to the paired communications port to download from memory.

4. The Bluetooth icon is green when the Model 7800 is paired to a host, white when it is powered on but not paired, gray when it is not powered on, and red if there is a fault with the Bluetooth module (e.g. it is disconnected).

**CAUTION:** Pairing must be initiated by the host within 2 minutes of turning the device on or within 2 minutes of pressing the Bluetooth button when running on internal battery power. After 2 minutes the Bluetooth portion of the device turns off to conserve power.

**WARNING: The user must verify the device Bluetooth pairing to ensure the correct patient is remotely monitored.**

# Operating Modes and Defaults

The Model 7800 features Limits mode, Menu mode, Date/Time mode, Factory Defaults, User-Defined Defaults and Patient Security modes.

**NOTE:** Patient Security Mode overrides any default settings.

## *Limits Mode, Viewing and Setting Limits*

In Limits mode, users can adjust alarm limits.

Pressing the Limits button activates the Limits mode, and all adjustments can be made using the blue colored Soft buttons -- see Plus (+), Minus (-), Enter and Save buttons. Limits mode is available when the device is operating.

In operating mode, the user may review the limits by pressing the Limits button.

Limits cannot be changed when the device is in Patient Security mode. In Patient Security mode, pressing the Limits button displays the limits allowing the operator to view the current limits.

**NOTE:** Alarm limits cannot be changed when the Model 7800 is in Patient Security mode. Patient Security mode prevents accidental changes to critical parameters.

## *Reviewing and Setting Alarm Limits*

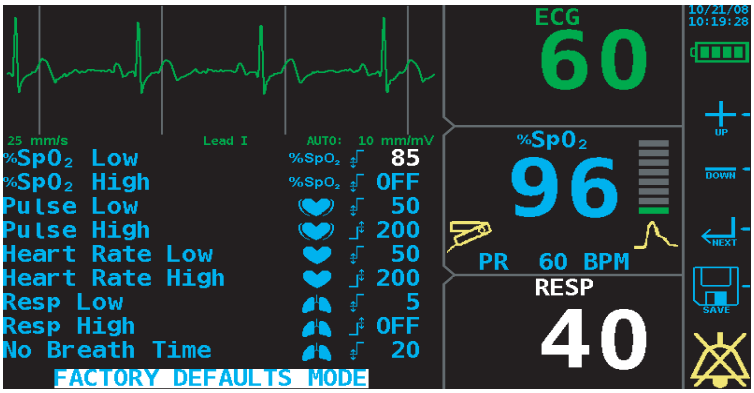



**Figure 6: Model 7800 Limits Screen**

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

## Reviewing, Setting, or Changing Alarm Limits

*How to Set Limits*

1. Press the **Limits** button.
2. Use the **Enter** button to step through the limits to the setting you would like to change.
3. Adjust each limit setting with the **Plus** (+) and **Minus** (-) buttons.
4. Use the **Enter** button to step through the limits to the next setting you would like to change.
5. Repeat steps 3 and 4 as needed.
6. When all limits have been set appropriately, press the **Save** button to save the settings and return to the monitoring screen.

# *Date/Time Mode*

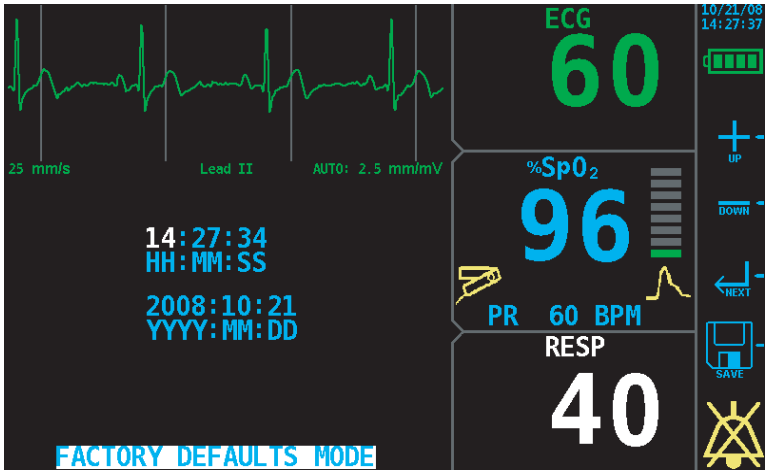



**Figure 7: Model 7800 Date/Time Mode Screen**

In Date/Time mode, users can set the internal clock and/or calendar to the device.

*How to Set the Clock*

1. Press the **Date/Time** button.
2. Use the **Enter** button ↵ to step through the time and date settings to the setting you would like to change.
3. Adjust each date and time setting with the **Plus** (+) and **Minus** (-) buttons.
4. Use the **Enter** button ↵ to step through the time and date settings to the next setting you would like to change.
5. Repeat steps 3 and 4 as needed.
6. When the date and time have been set appropriately, press the **Save** button to save the settings and return to the monitoring screen.

## *Menu Mode*

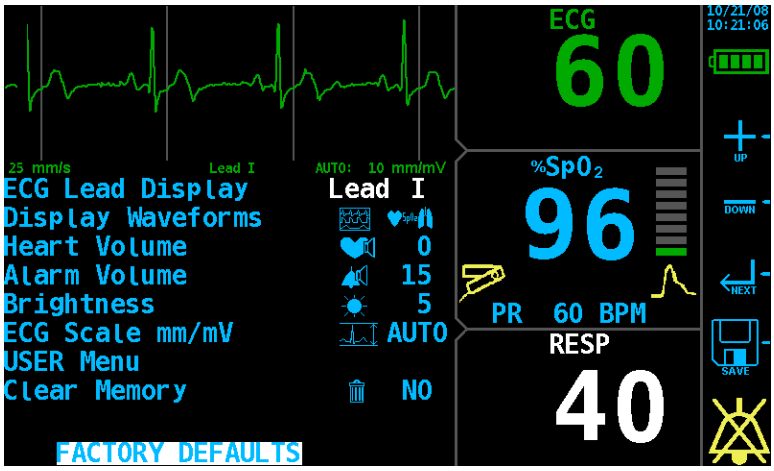



**Figure 8: Model 7800 Menu Mode Screen**

*How to Change ECG Lead*

1. Press the **Menu** button.
2. Press the **Enter** button ↵ to move through the settings and select "ECG Lead".
3. Press the **Plus** (+) button to change the lead to the desired setting.
4. When all settings have been set appropriately, press the **Save** button to save the settings and return to the monitoring screen.

### *How to Change Waveform Selection*

1. Press the **Menu** button.
2. Press the **Enter** button ↵ to move through the settings and select "Display Waveforms".
3. Press the **Plus** (+) button to change the waveform to the desired setting.
4. When all settings have been set appropriately, press the **Save** button to save the settings and return to the monitoring screen to begin viewing waveforms.

### *How to Change Heart Volume*

1. Press the **Menu** button.
2. Press the **Enter** button ↵ to move through the settings and select "Heart Volume".
3. Press the **Plus** (+) button to change the heart volume to the desired setting.
4. When all settings have been set appropriately, press the **Save** button to save the settings and return to the monitoring screen.

### *To Change Alarm Volume*

1. Press the **Menu** button.
2. Press the **Enter** button ↵ to move through the settings and select "Alarm Volume"
3. Press the **Plus** button (+) to change the alarm volume to the desired setting.
4. When all settings have been set appropriately, press the **Save** button to save the settings and return to the monitoring screen.

**WARNING: To comply with relevant product safety standards, ensure that all alarm volumes are set appropriately and are audible in all situations. Keep speaker openings clear of all obstructions.**

### *How to Change Screen Brightness*

1. Press the **Menu** button.
2. Press the **Enter** button to move through the settings and select "Brightness".
3. Press the **Plus** (+) button to change the brightness to the desired setting.
4. When all settings have been set appropriately, press the **Save** button to save the settings and return to the monitoring screen.

### *How to Change the ECG Vertical Scale*

1. Press the **Menu** button.
2. Press the **Enter** button to move through the settings and select "ECG Scale mm / mV".
3. Press the **Plus** (+) button to change the ECG scale to the desired setting.
4. When all settings have been set appropriately, press the **Save** button to save the settings and return to the monitoring screen.

### *How to Change the Memory Clear Setting*

1. Press the **Menu** button to enter Menu mode, and use the **Enter** button to scroll through the device's options and select **Clear Memory**.
2. Select "Yes" using the **Plus** (+) or **Minus** (-) buttons to clear patient memory, and then confirm your selection by pressing the **Save** button.
3. The device will ask again to confirm your deletion. Select "Yes" again, then press the **Save** button to delete.
4. The device will clear the memory and confirm, by displaying a "Now Clearing Memory" message.

**NOTE:** Patient memory cannot be cleared when the Model 7800 is in Patient Security mode.

### *How to Enter User Menu Mode*

Utilize the User Menu to select Nurse Call settings and current defaults (factory or user-defined defaults or Patient Security mode).

1. Press the **Menu** button.
2. Press the **Enter** button ↵ to move through the settings and select "User Menu".
3. Press the **Plus** (+) and **Minus** (-) buttons at the same time to enter the User Menu mode.
4. Use the **Plus**, **Minus**, and **Enter** buttons to change User Menu settings. When all settings have been set appropriately, press the **Save** button to save the settings and return to the monitoring screen.

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

# User Menu Mode Options

## *Factory Defaults*

In Factory Defaults, all adjustable parameters are set as indicated in the table below. These are the Model 7800's default operating settings.

The Model 7800 is shipped with factory defaults active.

**NOTE:** User-Defined Default values are lost when the user sets Factory Defaults to active.

**Table 5: Factory Defaults**

| Alarm Limit | Factory Default | Adjustment Options | Increment |
|---|---|---|---|
| $SpO_2$ High | Off | Off, 80-100 | 1% |
| $SpO_2$ Low | 85% | Off, 50 - 95 | 1% |
| Pulse High | 200 BPM | Off, 75 - 275 | 5 BPM |
| Pulse Low | 50 BPM | Off, 30 - 110 | 5 BPM |
| Heart Rate High | 200 BPM | Off, 75 - 275 | 5 BPM |
| Heart Rate Low | 50 BPM | Off, 30 - 110 | 5 BPM |
| Respiration High | Off | Off, 20 – 150 | 5 breath/min |
| Respiration Low | 5 breath/min | Off, 4 – 25 | 1 breath/min |
| No Breath | 20 seconds | Off 10 – 40 seconds | 1 second |

Default alarm and volume settings are automatically selected by the device every time the device is turned on.

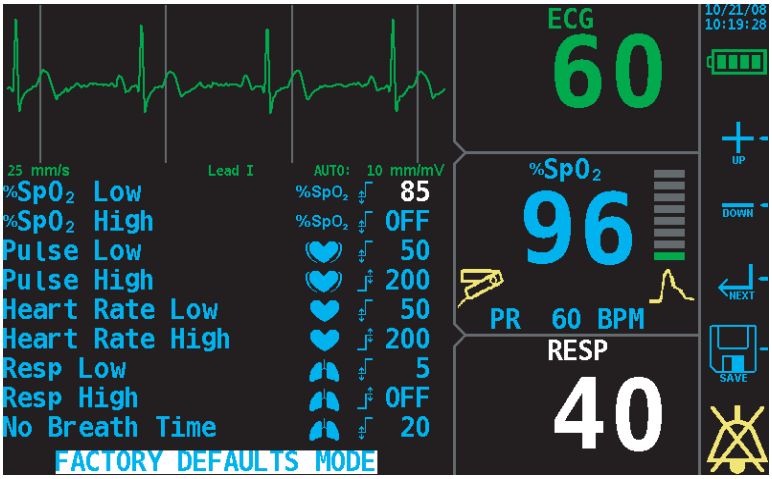



**Figure 9: Model 7800 Factory Defaults Screen**

*How to Restore Factory Defaults*

1. Press the **Menu** button.
2. Press the **Enter** button to move through the settings and select "USER Menu".
3. Press the **Plus** (+) and **Minus** (-) buttons at the same time to enter the user menu.
4. In the user menu, press the **Enter** button to move through the settings and select "Operating Mode".
5. Press the **Plus** (+) button to change the option to the Factory Default option, denoted by "FAC".
6. Press the **Save** button to restore the factory defaults and return to the monitoring screen.

## *User-Defined Defaults*

In User-Defined Defaults, default alarm limit and volume settings may be set to any value. When User-Defined Defaults are active, these settings will override the Factory Defaults on each power-on. User-Defined Defaults consist of monitored ECG lead, all alarm limits, alarm volume, heart volume, ECG scale, display waveforms and brightness.

### *How to Set User-Defined Defaults*

1. Adjust settings to desired User-Defined Default values using the limits and menu modes as usual.
2. Press the **Menu** button.
3. Press the **Enter** button ↵ to move through the settings and select "USER menu"
4. Press the **Plus** (+) and **Minus** (-) buttons at the same time to enter the user menu.
5. In the user menu, press the **Enter** button ↵ to move through the settings and **select** "Operating Mode".
6. Press the **Plus** (+) button to change the option to the User Default option, denoted by "USER".
7. Press the **Save** button to set the current settings as the User-Defined Defaults and return to the monitoring screen.

The Model 7800 recalls User-Defined Default settings at startup whenever this option is selected. Once activated, User-Defined Defaults have priority over Factory Defaults.

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

**NOTE:** All User-Defined Default settings are retained even when both external power and battery power are lost.

## Patient Security Mode

Alarm limits cannot be changed when the Model 7800 is in Patient Security mode. Patient Security mode prevents accidental changes to critical parameters. The Model 7800 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:

- Default settings cannot be changed.
- Clock and calendar data cannot be changed.
- $SpO_2$, ECG, respiration and pulse rate alarm limits and volumes cannot be changed. However, 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.

**NOTE:** Enter the Limits Menu and verify Patient Security mode and settings after initiating Patient Security mode.

When the Model 7800 is turned on in Patient Security mode, “Patient Security Mode” is displayed along with the alarm limits.

**NOTE:** Patient memory cannot be cleared when the Model 7800 is in Patient Security mode. In addition, Patient Security mode is not disabled when the unit is turned off or if power is lost.

## Viewing and Changing Patient Security Mode

*How to Set Patient Security Mode*

1. Adjust setting to desired Patient Security mode values using the limits and menu modes as usual.
2. Press the **Menu** button.
3. Press the **Enter** button to move through the settings and select “User Menu”.
4. Press the **Plus** (+) and **Minus** (-) buttons at the same time to enter the user menu.
5. In the user menu, select “Operating Mode”.
6. Press the **Plus** (+) button to change the option to the Patient Security mode option, denoted by “PSM”.
7. Press the **Save** button to set the current settings as the Patient Security mode settings and return to the monitoring screen.

## Nurse Call Feature

The Model 7800 Nurse Call feature allows alarm notification at a central monitoring location. This feature functions on AC or battery power. The facility determines the alarm condition as audible, visual, or both.

**NOTES:**

- When patients are not continuously monitored by an operator it is recommended that the alarm condition be monitored remotely via the Nurse Call output. It is also recommended that the audible alarm volume be set to the maximum setting.
- The Nurse Call feature overrides silenced alarms.
- It is the user facility's responsibility to implement the interface between the Nurse Call system and the Model 7800, and to adequately test the interface between the Model 7800 and the Nurse Call system to ensure operation.

**WARNING: The device Nurse Call and Bluetooth features should not be used as the primary source of alarm notification.**

*How to Set Up Nurse Call Feature:*

1. Press the **Menu** button. 
2. Press the **Enter** button ↵ to move through the settings and select User Menu.
3. Press the **Plus** (+) button and **Minus** (-) button simultaneously.
4. Press the **Enter** button ↵ to move through the settings and select Nurse Call. The Nurse Call feature can be setup multiple ways to meet the Nurse Call system requirements of your facility. See symbols below.

**Table 6: Nurse Call Setup Options**

| Symbol | Description |
|---|---|
|  | Signifies that the Nurse Call contact is normally open and the nurse call contact is closed during alarm conditions. |
|  | Signifies that the Nurse Call contact is normally closed and the Nurse Call contact is open during alarm conditions. |
|  | Signifies a momentary nurse call signal. The Nurse Call contact temporarily changes state at the onset of an alarm condition. |
|  | Signifies a continuous Nurse Call signal. The Nurse Call contact continuously changes state during alarm condition. It only reverts to the original non-alarm state when the alarm condition is cleared. |

# Alarms and Limits

The Model 7800 is equipped with audio and visual alarm indicators to alert the operator in case immediate patient attention is required or abnormal device conditions occur.

## *High Priority Alarms*

High priority alarms require immediate attention to the patient. They include $SpO_2$, ECG, respiration, pulse rate, and low perfusion alarms. On the Model 7800, high priority alarms are indicated as follows:

**Table 7: High Priority Alarms**

| ALARM | VISUAL INDICATORS | AUDIBLE INDICATOR |
|---|---|---|
| Respiration Rate Limit | Respiration background flashes in RED at 2 Hz. | Sounded as follows: three beeps, pause, two beeps and a 10 second pause. |
| No Breath | Respiration background flashes in RED, No Breath icon flashes at 2 Hz. | Sounded as follows: three beeps, pause, two beeps and a 10 second pause. |
| $SpO_2$ Limit | $SpO_2$ background flashes in RED at 2 Hz. | Sounded as follows: three beeps, pause, two beeps and a 10 second pause. |
| Pulse Rate Limit | Pulse rate background flashes in RED at 2 Hz. | Sounded as follows: three beeps, pause, two beeps and a 10 second pause. |
| Heart Rate Limit | Heart rate background flashes in RED at 2 Hz. | Sounded as follows: three beeps, pause, two beeps and a 10 second pause. |
| Low Perfusion | $SpO_2$ background flashes in RED at 2 Hz. | 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. They include low battery, critical battery, $SpO_2$ sensor fault, ECG lead lost, and system faults. Medium priority alarms are illuminated in yellow color. If a system fault occurs, an error code will be displayed to help the user identify the source of the error. On the Model 7800, medium priority alarms are indicated as follows:

**Table 8: Medium Priority Alarms**

| ALARM | VISUAL INDICATORS | AUDIBLE INDICATOR |
|---|---|---|
| Low Battery | Battery indicator flashes in YELLOW at 0.5 Hz. | Sounded as three beeps followed by a 25 second pause. |
| Critical Battery | Battery indicator lights solid RED, parameters with alarms flash dashes. | Sounded as three beeps followed by a 25 second pause. |
| $SpO_2$ Sensor Fault | Sensor fault indicator lights solid. | Sounded as three beeps follows by a 25 second pause. |
| ECG Lead Lost | LEAD LOST text message lights up and flashes (see NOTE). | Sounded as three beeps follows by a 25 second pause. |
| System Faults | Error Code is displayed. | Sounded as three beeps follows by a 25 second pause. |

**NOTE:** For ECG Lead Lost messages, the message may read “RA LOST”, “LA LOST”, “LL LOST”, or “ML LOST”. The RA lead is the right arm lead, LA is the left arm lead, LL is the left leg lead, and ML is multiple leads. Check the attachment of the electrode, leadwire, and cables for the lead causing the alarm. The alarm will reset automatically when the lead is reattached.

## 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 turning off the Model 7800. If the watchdog alarm cannot be cleared, remove power and contact your distributor or NONIN Technical Service Support.

## 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 heart rate tone (which changes in pitch with $SpO_2$ values: higher tones for higher $SpO_2$, and lower tones for lower $SpO_2$).

### *Silencing Alarms*

Press the **Alarm Silence** button to silence alarms for 2 minutes. Audible alarms may be reactivated before the 2 minute silence period is over by pressing the alarm silence button again.

The Alarm Silence LED blinks at the medium priority alarm rate while alarms are temporarily silenced.

*The Alarm Silence LED will be lit solidly when the alarm volume is set to less than 45 dB. This corresponds to alarm volume settings of less than 4.* Audible indicators can be turned off in the Limits menu, by selecting “Off” in the corresponding Alarm Volume menu option.

## Error Codes

This device includes error codes that indicate problems with the unit. Error codes are indicated by the word “Error” on the LCD and a two digit error code. 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 - turn the unit off and back on.

If the error still persists, the device will automatically stop operation. Note the error code and contact NONIN Customer Support at (800) 356-8874 (USA and Canada) or +1 (763) 553-9968

**Table 9: Error Codes**

| ERROR | VISUAL INDICATORS | Effects on Operation |
|---|---|---|
| Stuck button | Display error code E01 | Stop operation. Contact NONIN Customer Support. |
| Sound Module Fault | Display error code E02 | Stop operation. Contact NONIN Customer Support. |
| Sound Module Communications | Display error code E03 | Stop operation. Contact NONIN Customer Support. |
| Oximeter Module Communications | Display error code E04 | Stop operation. Contact NONIN Customer Support. |
| Display Module Fault | Display error code E05 | Stop operation. Contact NONIN Customer Support. |
| External Flash Memory Alarm | Display error code E06 | Stop operation. Contact NONIN Customer Support. |
| LCD Display Alarm | Display error code E07 | Stop operation. Contact NONIN Customer Support. |

# ECG

ECG is a continuous waveform of a patient's cardiac electrical activity. The ECG waveform is displayed in the top waveform area of the Model 7800 monitor. The quality of an ECG signal is directly affected by electrode site skin preparation, electrode patch quality and ECG lead placement. If artifact is present on the ECG waveform, then the alarm processing and quality of the monitoring function may be affected. The presence of artifact can prevent the monitor from establishing an accurate ECG reference waveform, increasing the difficulty experienced in assessing the ECG rhythm.

The ECG time scale is fixed at 25 mm/s, matching the sweep time of permanent printed ECG records. The vertical scale may be set to 2.5, 5, 10 or 20 mm/mV or to Autoscale, meaning the device automatically adjusts the waveform scale to best fit the waveform space. 10 mm/mV matches the scale of permanent printed ECG records.

The Model 7800 measures ECG through 3-leadwires. The device also measures lead to lead impedance to determine if any of the three leadwires have been lost. If one leadwire is lost, the Model 7800 displays an ECG lead alarm (a LEAD LOST message will appear), but will continue heart rate measurement and ECG waveform display with the two remaining leads. If two leads are lost, the Model 7800 will no longer attempt measurement or display of ECG. The LEAD LOST messages are as follows:

- "RA LOST" when the right arm lead is lost;
- "LA LOST" when the left arm lead is lost;
- "LL LOST" when the left leg lead is lost; or
- "ML LOST" when multiple leads are lost.

## Pacemaker Pulse Detection

The Model 7800 displays the ECG signal in the presence of pacemaker pulses without distortion and also shows a representation of pacemaker pulses as a vertical green line on the ECG waveform.

## Setting Up ECG Monitoring

The ECG waveform can be turned on or off in the Limits menu. *The numeric heart rate remains displayed at all times.*

1. Press the **Limits** button.
2. Press the **Enter** button to move through the settings and select "Display Waveforms".
3. Note the three icons highlighted in white:

for ECG,

$SpO_2$ for $SpO_2$, and

for respiration.

4. Press the **Plus** button (+) to alter this setting.

The settings allow any individual waveform or any combination thereof.

5. To turn the ECG waveform off, press the **Plus** button (+) until the ECG icon disappears from the option.
   Ensure that the $SpO_2$ $SpO_2$ and respiration icons are lit for parameters that are intended to remain active.
6. When all settings have been set appropriately, press the **Save** button to save the settings and return to the monitoring screen.

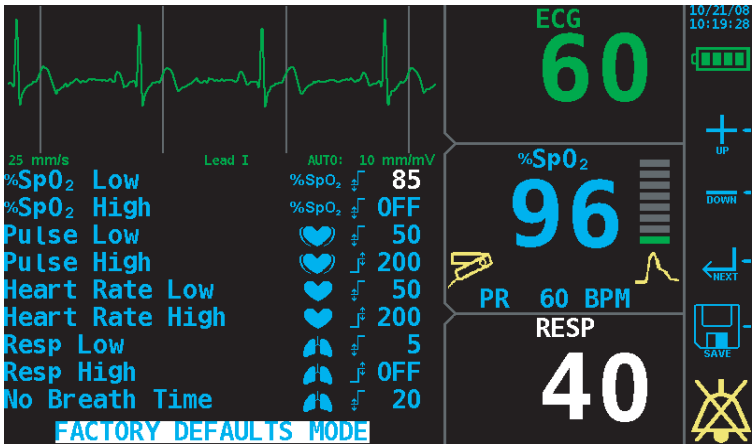



**Figure 10: Model 7800 Limits Menu Screen**

## *Setting ECG Limits*

1. Press the **Limits** button.
2. Use the **Enter** button ↵ to step through the limits to the Heart Rate settings.
3. Adjust each Heart Rate limit setting with the **Plus** (+) and **Minus** (-) buttons.
4. Use the **Enter** button ↵ to step through the limits to the next setting you would like to change.
5. Repeat steps 3 and 4 as needed.
6. When all limits have been set appropriately, press the **Save** button to save the settings and return to the monitoring screen.

## *Electrode Attachment*

### Skin Preparation

Proper skin preparation is essential in obtaining an accurate ECG reading. Electrode sites should be clean and dry and should provide a smooth flat surface. Incidental electrical activity and inaccurate readings may arise from incorrect skin preparation.

The following procedure is recommended for secure electrode patch application:

1. When necessary, shave chest hair from the electrode application sites in a circular area with a diameter of 2 - 4 inches.
2. Use an alcohol pad to clean the electrode site. (Take care not to damage skin.) Allow the skin to dry before placing the electrode patch on the skin.

### Electrode Patch Location

**WARNING: Conductive parts of electrodes and associated conductors for applied parts (including the neutral electrode) should not contact other conductive parts, including earth.**

⚠ **CAUTION:** Use only NONIN-specified Silver/Silver Chloride electrodes. Other electrode types may cause large offset potentials due to electrode polarization, slowing recovery time after application of defibrillator pulses, among other issues. Use of “squeeze bulb” type electrodes is not recommended. Do not use electrodes of dissimilar materials.

1. Peel the backing off of the electrode patch only when it is ready for use to prevent evaporation of the contact gel. Inspect the contact gel surface for moistness. If the gel is not moist, discard the electrode patch. Dry electrode patches are not conductive.

**NOTE:** When using the snap type electrode wires, attach the electrode patch to the leadwire before placing patch on the patient.

2. Attach the electrode patch to the skin at the prepared site. Smooth the electrode patch down in a circular motion to ensure proper skin contact. When using hard gel electrodes, it is recommended that during application, the center of the electrode should be slightly pressed onto the skin to ensure direct contact. Consult the electrode patch manufacturer's instructions for specific use.

3. Secure the leadwires to the patient according to hospital practice.

**WARNING: The use of this equipment is restricted to one patient at a time.**

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

**NOTES:**
- Store electrode patches at room temperature and open just prior to use.
- Avoid using more than one type of electrode on a patient because of potential variations in electrical resistance and galvanic effect.
- Avoid placing the electrode directly over bone.
- Refer to the electrode manufacturer's Instructions for Use for additional information.

**CAUTION:** Inspect the sensor and ECG electrode application sites 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.

## Connecting the ECG Cable to the 7800 Monitor

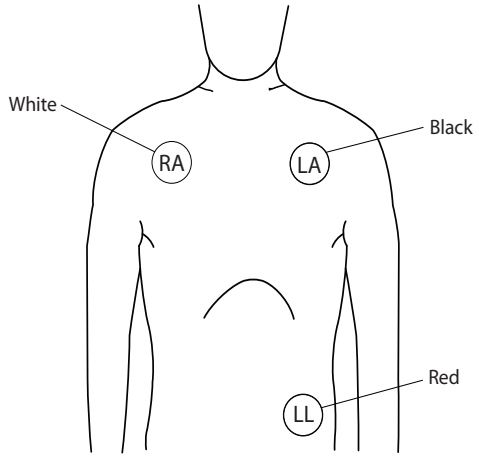



**Figure 11: Attach the electrodes to the patient**

**ECG 3 - Lead Electrode Identification**

| ELECTRODE LABEL | LOCATION | COLOR |
|---|---|---|
| RA | Right Arm | White |
| LA | Left Arm | Black |
| LL | Left Leg | Red |

Connect the ECG leads to the electrodes, then connect the leads to the ECG cable. Ensure the leads are in the correct position. The ECG leads and patient cable connector are color-coded according to the AAMI EC13 standard for ECG leads.

ECG and respiration monitoring begins as soon as the patient is connected to the monitor.

**NOTE:** If measurements are not shown, check the patient attachment and leads to make sure they are applied correctly.

Position the three new, disposable ECG electrodes in the standard configuration shown in Figure 8 (Figure 9 for pacemaker patients) for 3-lead monitoring.

- Place the RA (white) electrode under the patient's right clavicle, at the mid-clavicular line within the rib cage frame.
- Place the LA (black) electrode under the patient's left clavicle, at the mid-clavicular line within the rib cage frame.
- Place the LL (red) electrode on the patient's lower left abdomen within the rib cage frame.

*Method for determining a valid ECG pulse:* A heart beat is detected when the slope, amplitude, and width of an ECG pulse all exceed their respective thresholds.

**NOTE:** Line isolation monitor transients may resemble cardiac waveforms and inhibit heart rate alarms. Use only NONIN-approved accessories and place electrodes as described in this manual to mitigate these effects.

## Monitoring a Pacemaker Patient

The recommended lead placement for monitoring a pacemaker patient is as follows:

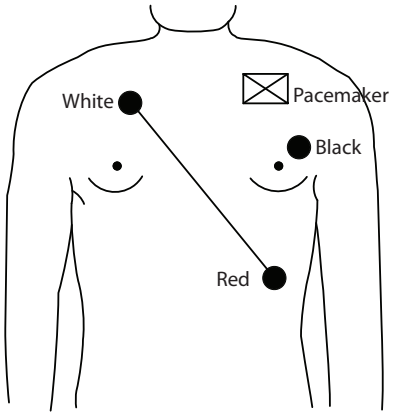



**Figure 12: 3-Wire Lead Placement for a Pacemaker Patient (AHA)**

A patient with a pacemaker usually requires a different electrode patch placement configuration than a non-pacemaker patient.

Do not place an ECG electrode directly over the pacemaker generator. Place the electrode patches 3 - 5 inches away from the pacemaker generator area. *Example:* If the pacemaker generator is located in the left subclavian area, relocate the LA (black) electrode closer in towards the center of the chest.

**NOTE:** When any amplifier in the ECG signal chain is overloaded or saturated, it is denoted by the ECG trace being shown at the extreme top of the ECG window. An alarm message that says “AMP SAT” also appears. When this occurs, the amplifier should recover within seconds and the ECG trace will return. If it does not return, ensure the electrodes are not dissimilar materials and reconnect the patient leads.

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

# Oximetry (%$SpO_2$)

Oximetry is the measurement of functional oxygen saturation of arterial hemoglobin (%$SpO_2$).

The lungs transfer oxygen from the air into the bloodstream. This oxygenated (arterial) blood is then pumped by the heart to all organ systems. The arterial oxygen blood level can be measured by drawing blood from an artery (arterial blood gas measurement). This accurately measures the oxygen and carbon dioxide (waste gas metabolism) and levels of each in the blood.

A pulse oximeter, usually attached to the finger, shines two separate light beams into the blood circulating in the small vessels, i.e., capillaries. Oxygen in the blood absorbs light from each of the beams. The absorbed light ratios are used to calculate the oxygen saturation as a percentage. Pulse rate is also derived from absorbed light ratios. Oxygen saturation measures how much oxygen the blood is carrying compared with its full capacity.

Apply the sensor according to the sensor Instructions for Use.

**NOTE:** Alarm limits reset to currently active default values each time the unit is powered up.

**CAUTION:** Inspect the sensor and ECG electrode application sites at least every 6 to 8 hours to ensure correct sensor alignment and skin integrity. Patient sensitivity to sensors and/or adhesive-backed strips may vary due to medical status or skin condition.

**WARNING: To comply with relevant product safety standards, ensure that all alarm volumes are set appropriately and are audible in all situations. Keep speaker openings clear of all obstructions.**

## *Setting Up $SpO_2$ Monitoring*

The $SpO_2$ waveform can be turned on or off in the Limits menu.

**NOTE:** If the device is turned on without an oximeter sensor plugged in, the oximeter will be disabled and the $SpO_2$ display will remain blank. Plugging in the oximeter sensor at any time will enable the oximeter.

1. Press the **Menu** button.
2. Press the **Enter** button to move through the settings and select "Display Waveforms".
3. Note the three icons highlighted in white:

for ECG,

$SpO_2$ for $SpO_2$, and

for respiration.

4. Press the **Plus** button (+) to alter this setting. The settings allow any individual waveform or any combination thereof.
5. To turn the Oximetry ($SpO_2$) waveform off, press the **Plus** button (+) until the $SpO_2$ icon disappears. Ensure that all other icons are lit for waveforms that are intended to remain active.
6. When all settings have been set appropriately, press the **Save** button to save the settings and return to the monitoring screen.

## *Setting Oximetry Limits*

1. Press the **Limits** button.
2. Use the **Enter** button ↵ to step through the limits to the Oximetry limits ($SpO_2$ high and low, pulse rate high and low).
3. Adjust each Oximetry limit setting with the **Plus** (+) and **Minus** (-) buttons.
4. Use the **Enter** button ↵ to step through the limits to the next setting you would like to change.
5. Repeat steps 3 and 4 as needed.
6. When all limits have been set appropriately, press the **Save** button to save the settings and return to the monitoring screen.

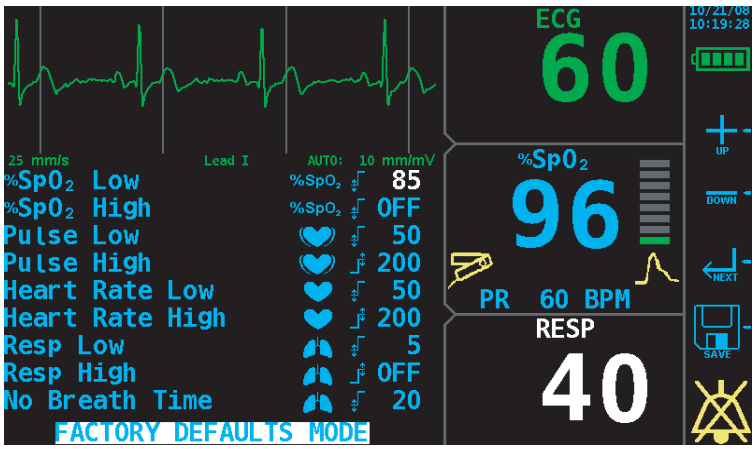



**Figure 13: Model 7800 Limits Menu Screen.**

**WARNING: The use of this equipment is restricted to one patient at a time.**

# Respiration

Respiration is detected by measuring the impedance across the chest. When respiration is monitored, a small AC current is passed through ECG lead I (RA -> LA). The device will continue to monitor respiration even when any single lead is lost.

**WARNING: This monitor is not for apnea detection. The monitor has not been tested or validated for use in apnea detection.**

**WARNING: To comply with relevant product safety standards, ensure that all alarm volumes are set appropriately and are audible in all situations. Keep speaker openings clear of obstructions at all times.**

**NOTE:** Alarm limits reset themselves to currently active default values each time the unit is powered up.

## *Setting Up Respiration Monitoring*

The Respiration waveform can be turned on or off in the Limits menu.

1. Press the **Limits** button.
2. Press the **Enter** button to move through the settings and select "Display Waveforms".
3. Note the three icons highlighted in white:

for ECG,

$SpO_2$ for $SpO_2$, and

for respiration.

4. Press the **Plus** (+) button to alter this setting. The settings allow for individual monitoring parameters or any combination thereof.
5. To turn the respiration waveform off, press the **Plus** (+) button until the respiration icon disappears from the option. Ensure that all other icons are lit for waveforms that are intended to remain active.
6. When all settings have been set appropriately, press the **Save** button to save the settings and return to the monitoring screen.

## *Setting Respiration Limits*

1. Press the **Limits** button.
2. Use the **Enter** button ↵ to step through the limits to the Respiration limits (Respiration rate high and low, no breath).
3. Adjust each respiration limit setting with the **Plus** (+) and **Minus** (-) buttons.
4. Use the **Enter** button ↵ to step through the limits to the next setting you would like to change.
5. Repeat steps 3 and 4 as needed.
6. When all limits have been set appropriately, press the **Save** button to save the settings and return to the monitoring screen.

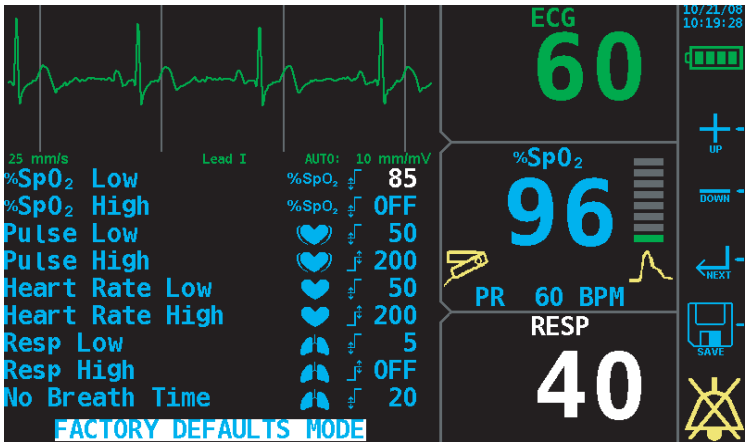



**Figure 14: Model 7800 Limits Menu Screen.**

# Memory and Data Output Features

The Model 7800 provides real-time (Bluetooth) patient data output for $SpO_2$, pulse rate, respiration and event markers.

**NOTE:** Verify your Bluetooth status as follows: The Bluetooth icon is green when the Model 7800 is paired to a host, white when it powered on but not paired, gray when it is not powered on, and red if there is a fault with the Bluetooth module (e.g. it is disconnected).

## *Bluetooth Patient Data Output*

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

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

SPO2=XXX PR=YYY HR=ZZZ Resp=JJJ SPHR&$*

where XXX is the $SpO_2$ value or '---' if no value is available

YYY is the pulse rate from the plethysmogram or '---' if no value is available

ZZZ is the heart rate from the electrocardiogram or '---' if no value is available

JJJ is the respiration rate or '---' if no value is available

Leading zeroes are blanked with ASCII spaces

S indicates an $SpO_2$ alarm is active, and does not appear if no $SpO_2$ alarm is active

P indicates a pulse rate alarm is active, and does not appear if no pulse rate alarm is active

H indicates a heart rate alarm is active, and does not appear if no heart rate alarm is active

R indicates a respiration rate alarm is active, and does not appear if no respiration rate alarm is active

& only appears if an equipment alarm is active

$ only appears if the battery has reached a critical charge state

* indicates that a pacemaker pulse has been detected since the last real time data output, and does not appear if no pacemaker pulse has been detected.

The SPHR&$* order is preserved in all alarm combinations.

## *Memory Features*

The Model 7800 collects and stores up to 48 hours of continuous $SpO_2$, pulse rate, heart rate, and respiration rate information. It also stores up to 10 minutes of continuous ECG waveform data.

Data may be viewed or played back with NONIN's nVISION® data retrieval software. If you wish to create your own software, contact NONIN for the data format.

**NOTE:** See nVISION instructions for additional information.

The memory in the Model 7800 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 continuously when the device is on—so if the entire memory is filled, portions of the oldest record will be overwritten when a new record begins.

Each time the Model 7800 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 1 minute in length are stored in memory.

Patient $SpO_2$, pulse rate, heart rate, and respiration 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 a range of 0 to 100%.

The stored pulse rate and heart rate ranges are from 18 to 300 pulses per minute. The stored values are in increments of 1 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.

The stored respiration rate range is from 3 to 150 breaths per minute.

Patient data is retained even when power is lost.

## Clearing Patient Memory

Patient memory can be cleared using the Model 7800's Menu mode:

1. Press the **Menu** button to enter Menu mode, and use the **Enter** button again to scroll through the device's options and select "**Clear Memory**".
2. Select "Yes" using the **Plus** (+) or **Minus** (-) buttons to clear patient memory, and then confirm your selection by pressing the **Save** button.
3. The device will ask again to confirm your deletion. **Select** "Yes" again, then press the **Save** button to delete.
4. The device will clear the memory and confirm by displaying a "Now clearing memory" message.

**NOTE:** Patient memory cannot be cleared when the Model 7800 is in Patient Security mode.

## Playing Back Memory Data

The Model 7800 has a Memory Playback feature, allowing stored data to be output through the Bluetooth connection. Playing back the data does not clear the data from memory. A playback request must originate from the host computer using a program such as nVISION.

1. With the unit on, select the 7800 option in nVISION.
2. Press the **Start** button and confirm to begin playback. When all memory has been played back the device will enter operating mode.
3. Stop Playback before completion by pressing the **On/Standby** button on the Model 7800.

# Care and Maintenance

The advanced digital circuitry within the Model 7800 requires **no calibration** or periodic maintenance other than battery replacement by qualified technical professionals.

Field repair of the Model 7800 is not possible. Do not attempt to open the Model 7800 case or repair the electronics. Opening the case may damage the Model 7800 and void the warranty. If the Model 7800 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, or if the leads are cut.

## *Cleaning the Model 7800*

Clean the Model 7800 after each patient use 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 7800, and do not allow any liquid to enter any openings in the device. Allow the device 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 7800 separately from its associated sensors and ECG leads. For instructions regarding cleaning pulse oximeter sensors and ECG leads, refer to the appropriate accessory package inserts.

# Parts and Accessories

The following NONIN accessories function with the Model 7800. Detailed information regarding specified sensor use (patient population, body/ tissue, and application) can be found in the respective sensor instructions (packed with each sensor)..

| Model Number | Description |
|---|---|
| 7800B | Li-ION Battery Pack |
| 7800PS | Power supply, 25W |
| 7800 Manual | Operator's Manual for the Model 7800 |
| Pulse Oximeter Reusable Sensors | |
| 8000AA-1 | Adult Articulated Finger Clip Sensor (1 meter) |
| 8000AA-2 | Adult Articulated Finger Clip Sensor (2 meters) |
| 8000AA-3 | Adult Articulated Finger Clip Sensor (3 meters) |
| 8000AP-1 | Pediatric Finger Clip Sensor (1 meter) |
| 8000AP-3 | Pediatric Finger Clip Sensor (3 meters) |
| 8000J | Adult Flex Sensor (1 meter) |
| 8000J-3 | Adult Flex Sensor (3 meters) |
| 8008J | Infant Flex Sensor |
| 8000Q2 | Ear Clip Sensor |
| 8000R | Reflectance Sensor |
| 8000SL | Reusable Pulse Oximeter Sensor (Large) |
| 8000SM | Reusable Pulse Oximeter Sensor (Medium) |
| 8000SS | Reusable Pulse Oximeter Sensor (Small) |
| Pulse Oximeter Disposable Sensors | |
| 6000A | Disposable Pulse Oximeter Sensor (Adult) |
| 6000P | Disposable Pulse Oximeter Sensor (Pediatric) |
| 6000I | Disposable Pulse Oximeter Sensor (Infant) |
| 7000A | Adult Finger Flexi-Form II Sensor, 10 per box |
| 7000P | Pediatric Finger Flexi-Form II Sensor, 10 per box |
| 7000I | Infant Toe Flexi-Form II Sensor, 10 per box |
| 7000D | Flexi-Form II Sensor Assortment Pack, 10 per box |

* Contact your distributor or Nonin for options.

| Model Number | Description |
|---|---|
| External Cables | |
| UNI-RA-0 | 7.25” 90-degree patient cable |
| UNI-EXT-X | Patient Extension Cable (select 1, 3, 6, or 9 meters) |
| | Pkg Assy, ECG Trunk Cable |
| Sensor Accessories | |
| 8000JFW | Adult FlexiWrap Sensor Wrap |
| 8008JFW | Infant FlexiWrap Sensor Wrap |
| 8000H | Reflectance Sensor Holder System |
| 8000S | Patient Simulator |
| | Pkg Assy, ECG Lead Wires (package of 3) |
| | ECG electrodes (package of 3) |
| Other Accessories | |
| nVISION | nVISION 6.1 (or greater) software for Microsoft Windows 95/ 98/2000/NT 4.0/XP/Vista operating systems |
| 7800NC | Nurse Call Cable |
| Avant RS | Rolling Stand; available in standard or deluxe |
| 7800C | Carrying Case, 7800 |
| Avant PC | Pole Mount Clamp |

For more information about NONIN parts and accessories, contact your distributor, or contact NONIN at (800) 356-8874 (USA and Canada) or (763) 553-9968. This information is also available on NONIN’s website: www.nonin.com.

**WARNING: Use the Model 7800 only with power adapters supplied by Nonin Medical.**

**WARNING: Using accessories, sensors, and cables other than those listed in this manual is not recommended for the following reasons:**
**• Results may include increased electromagnetic emission and/or decreased immunity of this device.**
**• NONIN-branded PureLight® sensors are manufactured to meet the accuracy specifications for NONIN pulse oximeters.**
**• Using other manufacturers’ sensors can result in improper pulse oximeter performance.**
**• Using only NONIN-specified ECG cables and accessories provides defibrillation protection. These cables have internal resistance to limit the defibrillation voltage to which the operator is exposed.**

# Troubleshooting

| Problem | Possible Cause | Possible Solution |
|---|---|---|
| Model 7800 will not activate. | The unit has no power. | Plug in the AC adapter. |
| Model 7800 will not operate on batteries. | The battery pack is not charged. | Plug in the Model 7800 AC Adapter to charge the battery pack. |
| | The battery pack is inoperable. | Contact NONIN Customer Support for repair or replacement. |
| Unable to obtain a green pulse display on the bargraph. | 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 ten seconds. |
| | | Warm the patient's finger by rubbing or covering with a blanket. |
| | | Position the sensor at a different site. |
| **NOTE:** In some instances, patient perfusion may be inadequate for pulse detection. | 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. |

| Problem | Possible Cause | Possible Solution |
|---|---|---|
| Unable to obtain a green pulse display on the bargraph, cont'd. | The sensor is applied incorrectly. | Apply the sensor correctly. |
| | There is possible interference from one of the following sources:<br>• arterial catheter<br>• blood pressure cuff<br>• electrosurgical procedure<br>• 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). |
| | The red LED is not lit in the sensor's finger insertion area. | Ensure the sensor is securely attached to the Model 7800. |
| | | Check the sensor for any visible signs of deterioration. |
| | | Contact NONIN Customer Support. |
| Frequent or steady pulse quality indication. | There is excessive ambient light. | Shield the sensor from the light source. |
| | The Model 7800 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 7800. |
| | | Check the sensor for any visible signs of deterioration. |
| | | Contact NONIN Customer Support. |
| | Excessive patient motion. | Reduce patient motion. |

| Problem | Possible Cause | Possible Solution |
|---|---|---|
| ECG waveform is noisy or heart rate from ECG is erratic. | Poor electrode connection. | Remove electrodes, clean electrodes site with alcohol, allow to dry, place new electrodes. |
| RA, LA, LL, or ML lead lost alarm. | Poor electrode connection. | Remove electrodes, clean electrodes site with alcohol, allow to dry, place new electrodes. |
| | Damaged lead wire. | Inspect and replace affected lead wire. |
| | Damaged trunk cable. | Inspect and replace trunk cable. |
| Dashes (---) appear 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 7800 is not functioning. | Turn the unit off, check all connections, and try again. |
| | | Contact NONIN Customer Support. |
| Sensor alarm icon is lit. | A non-Nonin $SpO_2$ sensor is being used. | Sensor is faulty. Replace the sensor with a Nonin sensor. |
| An error code appears in the display area. | The Model 7800 encountered an error. | Turn the unit off and then back on again to remove the error code.<br>If the error persists, disconnect all power, and then reconnect the power and turn the unit back on.<br>If the error still persists, note the error code and contact Nonin Customer Support. |
| 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 2 minutes. After 2 minutes, alarm tones will automatically re-engage. |
| | Audible volume set to “Off” in alarm limits. | Adjust volume through setup mode |

If these solutions do not correct the problem, please contact NONIN Customer Support at **(800) 356-8874** (USA and Canada) or **+1 (763) 553-9968**.

# Service, Support, and Warranty

A return authorization number (RAN) is required before returning any product to NONIN. To obtain this return authorization number, contact NONIN Customer Support:

**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: mail@nonin.com
www.nonin.com

**WARNING: 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 7800 battery pack. NONIN warrants the ECG, pulse oximetry, and respiration modules of the Model 7800 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 7800 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 7800 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 7800 that is found to be within specifications.

The Model 7800 is a precision electronic instrument and must be repaired by qualified technical professionals. Accordingly, any sign or evidence of opening the Model 7800, field service by non-authorized personnel, tampering, or any kind of misuse or abuse of the Model 7800, 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.

# Technical Information

**NOTE:** This product complies with ISO 10993, 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:** Portable and mobile RF communications equipment can affect medical electrical equipment. |
| **CAUTION:** Radios and cell phones or similar devices can affect the equipment and must be kept **at least 2 meters** away from the equipment . |

## *Manufacturer's Declaration*

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

**Table 1: Electromagnetic Emissions**

| Emissions Test | Compliance | Electromagnetic Environment—Guidance |
|---|---|---|
| *This device is intended for use in the electromagnetic environment specified below. The user of this device should ensure that it is used in such an environment.* | | |
| RF Emissions CISPR 11 | Group 2 | This device must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected. |
| 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 2: 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<br>±8 kV air | ±6 kV contact<br>±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<br>±1 kV for input/output lines | ±2 kV for power supply lines<br>±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<br>±2 kV common mode | ±1 kV differential mode<br>±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<br>±40% $U_T$ (60% dip in $U_T$) for 5 cycles<br>±70% $U_T$ (30% dip in $U_T$) for 25 cycles<br><5% $U_T$ (>95% dip in $U_T$) for 5 sec. | ±5% $U_T$ (>95% dip in $U_T$) for 0.5 cycle<br>±40% $U_T$ (60% dip in $U_T$) for 5 cycles<br>±70% $U_T$ (30% dip in $U_T$) for 25 cycles<br><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 3: 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 | $d = 1.17\sqrt{P}$ 80 MHz to 800 MHz |
| Radiated RF IEC 61000-4-3 | 3 V/m 80 MHz to 2.5 GHz | 3 V/m | $d = 1.17\sqrt{P}$ 800 MHz to 2.5 GHz<br>$d = 2.33\sqrt{P}$<br>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).<br>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]<br>Interference may occur in the vicinity of equipment marked with the following symbol:  |
| **NOTES:**<br>• At 80 MHz and 800 MHz, the higher frequency range applies.<br>• 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 4: 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 800 MHz, 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.

- This device provides protection against patient burns from Electrosurgery Units in accordance with AAMI EC13 and IEC 60601-2-49 when used with cables and accessories listed in this manual.
- This device applies an electrical signal to the patient to measure respiration. The parameters of this signal are: 70 kHz square wave, 0.5 V peak to peak amplitude, 200 microamperes maximum peak current.
- This device provides operator protection from external defibrillators when used with cables and accessories listed in this manual. Operators must remain clear of ECG cables and leadwires when defibrillators are used on the patient.
- This device provides pacemaker pulse detection in accordance with AAMI EC13.

- Pacemaker Patients - Rate meters may continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias. Do not rely entirely upon rate meter alarms. Keep pacemaker patients under close surveillance. See this manual for disclosure of the pacemaker pulse rejection capability of this instrument.
- In accordance with AAMI/EC13, section 5.1.2.1C, maximum T-wave amplitude for which the heart rate measurement is within +/- 10% of the input rate (or +/- 5 BPM): 0.4 mV.

# Equipment Response Time

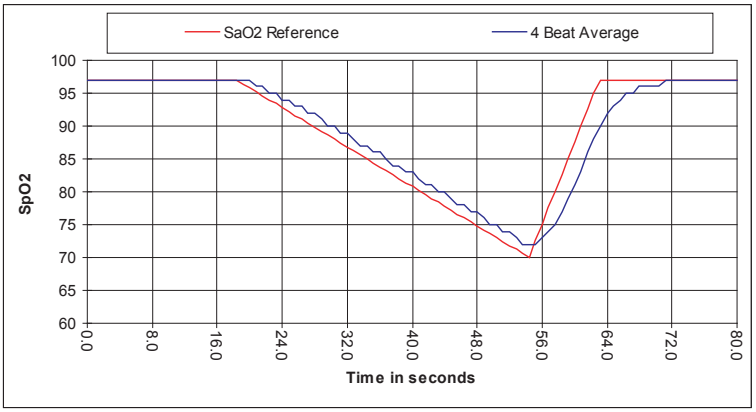
| $SpO_2$ Values | Response | Latency |
|---|---|---|
| Standard/Fast Averaged $SpO_2$ | 4 beat exponential | 2 beats |

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

*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.

*How the heart rate is calculated and the type of averaging used:*

An exponential average of the time between heart beat detections is inverted to calculate the heart rate. The weight of the exponential average varies with the current heart rate and corresponds to a number of heart beats. If the heart rate is less than 112 bpm, the weight is 4, For heart rates between 112 bpm and 225 bpm, the weight is 8 and for heart rates above 225, the weight is 16. Before being averaged, the time between heart beat detections is slew limited and spike filtered.

## Testing Summary

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

### $SpO_2$ Accuracy Testing

$SpO_2$ accuracy testing is conducted during induced hypoxia studies on healthy, non-smoking, light- to dark-skinned subjects during motion and no-motion conditions in an independent research laboratory. 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 9919:2005, Medical Electrical Equipment—Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use.

### Pulse Rate Motion Testing

This test measures pulse rate oximeter accuracy with motion artifact simulation introduced by a pulse oximeter tester. This test determines whether the oximeter meets the criteria of ISO 9919:2005 for pulse rate during simulated movement, tremor, and spike motions.

### Low Perfusion Testing

This test uses an $SpO_2$ Simulator to provide a simulated pulse rate, with adjustable amplitude settings at various $SpO_2$ levels for the oximeter to read. The oximeter must maintain accuracy in accordance with ISO 9919:2005 for heart rate and $SpO_2$ at the lowest obtainable pulse amplitude (0.3% modulation).

## Specifications

| | | |
|---|---|---|
| **Oxygen Saturation Display Range:** | 0 % to 100 % $SpO_2$ | |
| **Pulse Rate Display Range** | 18 to 321 beats per minute (BPM) | |
| **$SpO_2$ Accuracy ($A_{rms}$)[a]:** | 70 % to 100 % | |
| **NO MOTION** | | **Adults/ Pediatrics** |
| Reusable: | Finger Clip: | ±2 digits |
| | Flex: | ±2 digits |
| | Soft Sensor: | ±2 digits |
| | Reflectance: | ±2 digits |
| | Ear Clip Sensor[b]: | ±4 digits |
| Disposable: | 6000 Series: | ±2 digits |
| | 7000 Series: | ±3 digits |
| **Pulse Rate Accuracy ($A_{rms}$)[a]:** | 18 to 300 BPM (no motion)<br>40 to 240 BPM (motion)<br>40 to 240 BPM (low perfusion) | |
| **NO MOTION** | | **Adults/ Pediatrics** |
| Reusable: | Finger Clip: | ±3 digits |
| | Flex: | ±3 digits |
| | Soft Sensor: | ±3 digits |
| | Reflectance: | ±3 digits |
| Disposable: | 6000 Series: | ±3 digits |
| | 7000 Series: | ±3 digits |
| **LOW PERFUSION** | | |
| Reusable: | Finger Clip: | ±3 digits |
| | Flex: | ±3 digits |
| | Soft Sensor: | ±3 digits |
| | Reflectance: | ±3 digits |
| Disposable: | 6000 Series: | ±3 digits |
| | 7000 Series: | ±3 digits |

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

b.) Ear Clip Sensor for use on Adults only.

**Respiration**

| | |
|---|---|
| Respiration Measurement Rate: | 4 to 150 breaths per minute |
| Respiration Accuracy: | ± 2 breaths/min or ± 5%, whichever is greater |
| Respiration Sensitivity: | 0.4 ohm delta |

**ECG**

| | |
|---|---|
| Heart Rate Display Range: | 18 to 321 BPM |
| Heart Rate Accuracy: | ± 10% or ± 5 BPM, whichever is greater |
| ECG Sensitivity: | 0.5 mV |

*AAMI EC13:2002/(R) 2007 Disclosures:*

Heart Rate Meter accuracy and response to irregular rhythm from section 4.1.2.1e:

| | |
|---|---|
| Figure 3a: | 40 BPM |
| Figure 3b: | 30 BPM |
| Figure 3c: | 60 to 120 BPM |
| Figure 3d: | 55 to 90 BPM |

Maximum response time for heart rate meter to change in heart rate from section 4.1.2.1f:

| | |
|---|---|
| 80 BPM to 120 BPM: | Average - 6 seconds; Range - 4 to 7 seconds |
| 80 BPM to 40 BPM: | Average - 13 seconds; Range - 11 to 15 sec's |

Maximum time to alarm for tachycardia from section 4.1.2.1g:

| | |
|---|---|
| 1 X Figure 4a: | 5 seconds |
| 2 X Figure 4a: | 3 seconds |
| 0.5 X Figure 4a: | 7 seconds |
| 1 X Figure 4b: | 3 seconds |
| 2 X Figure 4b: | 3 seconds |
| 0.5 X Figure 4b: | 4 seconds |

Heart rate measured by the monitor in the presence of pacemaker pulses without overshoot from section 4.1.4.1:

| Without atrial pulse: | With atrial pulse: |
|---|---|
| Figure 5a: --- BPM | Figure 5a: --- BPM |
| Figure 5b: 60 BPM | Figure 5b: 60 BPM |
| Figure 5c: 30 BPM | Figure 5c: 30 BPM |

Heart rate measured by the monitor in the presence of pacemaker pulses with overshoot from section 4.1.4.2:

| Without atrial pulse: | With atrial pulse: |
|---|---|
| Figure 5a: --- BPM | Figure 5a: --- BPM |
| Figure 5b: 60 BPM | Figure 5b: 60 BPM for overshoot amplitude less than ±0.75 mV |
| Figure 5c: 30 BPM | Figure 5c: 30 BPM for overshoot amplitude less than ±0.75 mV |

Minimum input slew rate causing 50% of pulses in figure 5d to trigger the device pacer pulse detector:

1.4 Volts/second

| | | |
|---|---|---|
| **Display Update Rate:** | | |
| Heart: | 1.5 seconds | |
| Respiration Rate: | 1.5 seconds | |
| Pulse Rate: | 1.5 seconds | |
| SpO2: | 1.5 seconds | |
| **Alarm Volume:** | High: | 75dBA |
| | Low: | 64dBA |
| **Informational Tone Volume:** | High: | 67dBA |
| | Low: | 55dBA |
| **Measurement Wavelengths and Output Power:**[c] | | |
| Red: | 660 nm @ 0.8 mW maximum average power | |
| Infrared: | 910 nm @ 1.2 mW maximum average power | |
| **Memory** | 48 hours (assuming continuous operation) | |
| **Temperature (Operating):** | -5 ºC to +45 ºC (+23 ºF to +113 ºF) | |
| Temperature (Storage/Transportation): | -30 ºC to +70 ºC (-22 ºF to +158 ºF) | |
| **Humidity (Operating):** | 10 % to 90 % noncondensing | |
| Humidity (Storage/Transportation): | 10 % to 95 % noncondensing | |
| **Power Requirements (Mains)** | 100-240 VAC 50-60 Hz | |
| **Internal Power** | | |
| Battery: | 7.2 volt Li-ion battery pack | |
| Operating Life (fully charged battery): | 4 hours minimum | |
| Storage Life: | 20 days minimum | |
| Recharge Time: | 3 hours | |
| **Dimensions** | Approximately 305 mm (12.0”) W x 180 mm (7.2”) H x 130 mm (5.0”) D | |
| **Weight** | Approximately 900 grams (2 lbs) | |
| **Warranty** | 3 years | |
| **Classification per IEC 60601-1 / CAN/CSA-C22.2 No. 601.1 / UL60601-1:** | | |
| Type of Protection: | Internally powered (on battery power) | |
| Degree of Protection: | Type BF-Applied Part ($SpO_2$) | |
| | Type CF Applied Part (ECG) | |
| Mode of Operation: | Continuous | |
| **Enclosure Degree of Ingress Protection:** IP32 | | |

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

| TRANSMITTER | |
|---|---|
| **Bluetooth Compliance** | Version 2.0 |
| **Operating Frequency** | 2.4 to 2.4835 GHz |
| **Output Power** | < 20 dBm |
| **Operating Range** | 100-meter radius indoors (line of sight when connected to a class I device) |
| **Network Topology** | Star |
| **Operation** | Bluetooth Slave |
| **Antenna Type** | Internal |
| **Modulation Type:** | Gaussian Frequency Shift Keying |
| **Band Width** | 1 MHz |