NONIN

Operator's Manual

Model 9847

Handheld Pulse Oximeter and Carbon Dioxide (CO_2) Detector

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

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Contents

Indications for Use

The NONIN® Model 9847 Pulse Oximeter and Carbon Dioxide Detector is indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate, and approximate carbon dioxide (CO_2) changes in the airway of intubated patients. These functions may be used separately or simultaneously.

Pulse Oximeter Intended Use

The pulse oximeter is intended to be used for noninvasively monitoring oxygen saturation and pulse rate for adult, pediatric, and neonatal patients in hospital, ambulatory, and Emergency Medical Services (EMS) environments. The pulse oximeter may be used for spot checking and/or continuous monitoring when attended by a healthcare professional.

Carbon Dioxide Detector Intended Use

The CO_2 detector is a mainstream device intended to be used for semi-quantitative detection of CO_2 levels in intubated patients during patient transport, and for short-term hospital use (e.g. emergency rooms or crash carts), and where gaseous anesthetic is not present. The CO_2 detector may be used to initially confirm proper placement of the endotracheal tube and to provide continued confirmation of correct endotracheal tube placement and patient respiration status. The CO_2 detector is not intended for prolonged CO_2 monitoring. The CO_2 detector is not intended for long-term monitoring of end-tidal CO_2. The CO_2 detector is not intended for use in patients younger than 3 years old and weighing less than 10 kg (22 lb).

Contraindications

Do not use this device in an MR environment.

Do not use the Model 9847 CO_2 detector for patients younger than 3 years old and weighing less than 10 kg (22 lb) due to the dead space introduced by the airway adapter tube.

This device is not defibrillation proof per IEC 60601-1:1988 + A2:1995 clause 17h.

Warnings

Explosion Hazard: Do not use in an explosive atmosphere or in the presence of flammable anesthetics or gasses.

This device is intended only as an adjunct in patient assessment. It must be used in conjunction with other methods of assessing clinical signs and symptoms.

Do not use the Model 9847 CO_2 detector during mouth-to-tube ventilation. The presence of CO_2 in the exhaled breath from the person performing resuscitation will cause inaccurate readings.

The Model 9847 CO_2 detector cannot distinguish between oropharyngeal tube placement and endotracheal tube placement if the airway is patent. Standard clinical assessment must be used.

Oximeter readings of this device may be affected by the use of an electrosurgical unit (ESU).

Do not use a damaged sensor. If the sensor is damaged in any way, discontinue use immediately and replace the sensor.

This device should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device should be observed carefully to verify normal operation.

The use of accessories, sensors, and cables other than those specified may result in increased emission and/or decreased immunity of this device.

Use only with NONIN-branded PureLight® pulse oximeter sensors. These sensors are manufactured to meet the accuracy specifications for NONIN Pulse Oximeters. Using other manufacturers' sensors can result in improper pulse oximeter performance.

Check the pulse oximeter sensor application site every 6 to 8 hours to determine the circulation, positioning, and skin sensitivity of the patient. Each patient's sensitivity to NONIN sensors may vary depending on their medical status or the condition of their skin.

Warnings (Continued)

As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.

Discontinue use of adhesive tape strips if the patient exhibits an allergic reaction to the adhesive material.

Do not stretch the adhesive tape while applying the pulse oximeter sensor. This may cause inaccurate readings or skin blisters.

Do not reuse the Model 9840AAT Airway Adapter Tube. Cleaning the interior will damage the anti-fog coating and cause inaccurate readings.

If the airway adapter tube packaging appears to be damaged or open, discard it and replace it with a new one.

The Model 9840AAT Airway Adapter Tube will increase dead space by approximately 6 cubic centimeters (0.4 cubic inches); this may adversely affect ventilation for patients with small tidal volumes.

If the Model 9847 CO_2 detector results are inconclusive, the correct anatomic location of the endotracheal tube must be confirmed by other methods.

Do not use the Model 9847 CO_2 detector with a humidifier or nebulizer in the breathing circuit, as the fine mist may cause erroneous readings.

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.

This device must be able to measure the pulse properly to obtain an accurate SpO_2 measurement. Verify that nothing is hindering the pulse measurement before relying on the SpO_2 measurement.

Operation of this device below the minimum amplitude of 0.3% modulation may cause inaccurate results.

Cautions

Before use, carefully read the Instructions for Use provided with sensors and airway adapters.

This device is a precision electronic instrument and must be repaired by trained NONIN personnel only.

Any sign or evidence of opening the system, field service by non-NONIN personnel, tampering, or any kind of misuse or abuse of the system, shall void the warranty in its entirety.

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

This device is not an apnea monitor.

Verify that all visible indicators illuminate during the startup (initialization) sequence. If any indicator is not lit, do not use the device. Contact NONIN Technical Service for assistance.

The presence of a defibrillator may interfere with the performance of this device.

This device may not work on all patients. If you are unable to achieve stable readings, discontinue use.

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. Minimize patient motion as much as possible.

Ear Clip and Reflectance sensors are not recommended for pediatric or neonatal use. The accuracy of these sensors has not been established for pediatric or neonatal use.

Do not autoclave or immerse the device or sensors in liquid. Do not expose the device or components to excessive moisture or liquids.

Do not use caustic or abrasive cleaning agents on the device or the sensors.

Cautions (Continued)

The oximeter sensor might not work on cold extremities due to reduced circulation. Warm or rub the finger to increase circulation, or reposition the sensor.

The device is not designed to retain data in memory once the batteries are removed. Memory will clear 60 seconds after removing the batteries. Replacing the batteries before 60 seconds have elapsed most likely will result in corrupt data. Always replace the batteries with fully charged batteries. Do not use fully charged and partially charged batteries at the same time as this may cause the batteries to leak.

Use only NONIN-specified battery types with this device.

Do not use different types of batteries at the same time. Do not mix fully charged and partially charged batteries at the same time. These actions may cause the batteries to leak.

Do not remove any covers other than the battery cover when replacing batteries. There are no user-serviceable parts inside other than the replaceable batteries.

Batteries may leak or explode if used or disposed of improperly.

Remove the batteries if the device will be stored for more than 1 month.

Follow local, state and national governing ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries.

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.

All parts and accessories connected to the serial port of this device must be certified according to at least IEC 60950 or UL1950 for data-processing equipment.

Cautions (Continued)

This equipment complies with IEC 60601-1-2:2007 for electromagnetic compatibility for medical electrical equipment and/or systems. This standard is designed to provide reasonable protection against harmful interference in a typical medical installation. However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in healthcare and other environments, it is possible that high levels of such interference due to close proximity or strength of a source might disrupt the performance of this device. Medical electrical equipment needs special precautions regarding EMC, and all equipment must be installed and put into service according to the EMC information specified.

Do not use the airway adapter tube if the airway adapter tube is below 5° C (41° F). An airway adapter tube that is below 5° C (41° F) may frost, causing a false reading. Warm the airway adapter tube to above 5° C (41° F) by putting it in a warm place (for example, in your hands or in a vehicle) prior to use.

An airway adapter that is between 5° C (41° F) and 10° C (50° F) may cause inaccurate reading due to fogging of optical surfaces. It is recommended that the airway adapter tube be warmed to above 10° C (50° F) before use.

Cautions (Continued)

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
- inadequate signal
- venous pulsations
- anemia or low hemoglobin concentrations
- cardiogreen and other intravascular dyes
- carboxyhemoglobin
- methemoglobin
- dysfunctional hemoglobin
- artificial nails or fingernail polish.

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

A functional tester cannot be used to assess the accuracy of a pulse oximeter monitor or sensor.

Remove earrings from the patient's ear before applying the Ear Clip sensor.

Water or other liquid between the airway adapter tube and the CO_2 sensor may cause erroneous readings.

Ensure that all connections to the airway adapter tube are tight and leak-free, and that the airway adapter tube is properly attached to the CO_2 sensor.

Ensure that this device, the airway adapter tube, and the sensors have stabilized at the specified environmental operating conditions before use.

Cautions (Continued)

Gastric distention with air prior to intubation may introduce CO_2 into stomach and esophagus and yield false results. Observe six breaths before interpreting results.

This device's CO_2 detector must not be used with gaseous anesthetics.

Do not block the audible indicator speaker holes. Blocking the speakers will significantly reduce the sound volume.

Verify that the audible alarms can be heard over the ambient noise of the operating environment.

Guide to Symbols

This table describes the symbols that are found on the Model 9847.

Table 1: Symbols

	Consult Instructions for Use.
	Type BF Applied Part (Patient isolation from electrical shock).
	**UL Mark for Canada and the United States** with respect to electric shock, fire, and mechanical hazards only in accordance with UL 60601-1 and CAN/CSA C22.2 No. 601.1.
SN	**Serial Number** (located on the back cover).
IP32	Protected against vertically falling water drops when enclosure is tilted up to 15 degrees and ingress of solid foreign objects greater than or equal to 2.5 mm (0.1 in) in diameter per IEC 60529.
	Indicates separate collection for electrical and electronic equipment (WEEE).
Front Panel Buttons	
	ON/Standby
	Advance/Breath Beep Volume Control
	Alarm Limit Review
	Audible Alarm Disable
Display Indicators	
SpO_2	%SpO_2 Display
	Battery Indicator
	Pulse Rate Display
	Pulse Quality Indicator
Δ CO_2	Change in CO_2 Concentration
No Breath	Absence of CO_2 Detection

General Description

NONIN Model 9847 Pulse Oximeter and Carbon Dioxide Detector is a hand-held, battery-operated, noninvasive monitoring device that has visible and/or audible indicators for tracking patient and equipment status. The 9847 will typically operate for 90 hours continuously between battery replacements when used for pulse oximetry alone, or for 20 hours continuously when used for both CO_2 detection and pulse oximetry.

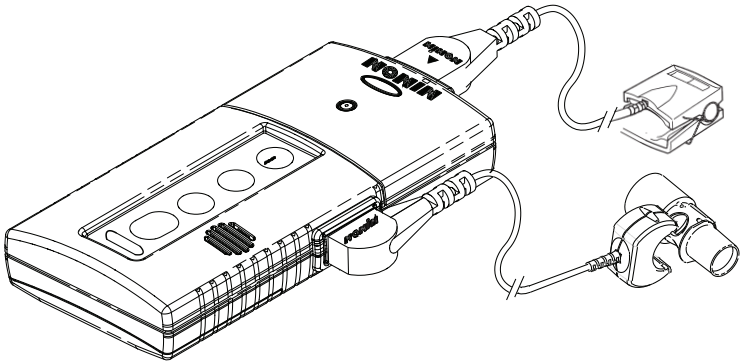


Figure 1: Model 9847 Pulse Oximeter and Carbon Dioxide Detector with alarms.

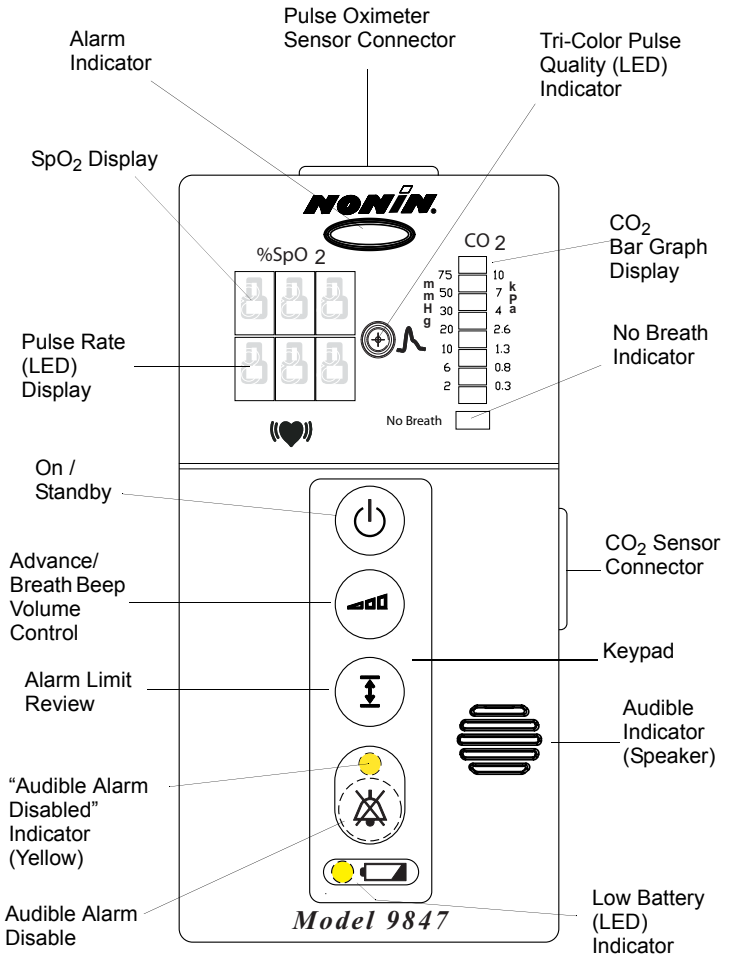


Figure 2: Model 9847 Controls and Indicators

Audible Alarms and Informational Tones

Model 9847 uses audible alarms and informational tones (along with visible indicators) to alert healthcare providers to several patient and equipment conditions. A high priority (patient) alarm alerts the healthcare provider of a patient's absence of breath, high or low oxygen saturation,

pulse rate, or inadequate pulse quality signal. A medium priority (equipment) alarm indicates the batteries have reached critically low capacity, or that a sensor alarm condition is occurring. An informational tone (a beep) indicates a non-alarm event (a breath).

The audible alarms can be silenced or temporarily disabled using the audible alarm disable button.

About Pulse Oximetry

Model 9847 determines functional oxygen saturation of arterial hemoglobin (SpO_2) by measuring the absorption of red and infrared light passed through perfused tissue. Changes in absorption caused by pulsation of blood in the vascular bed are used to determine arterial saturation and pulse rate.

Oxygen saturation and pulse rate values are indicated on light-emitting diode (LED) digital displays. On each detected pulse, the pulse quality indicator blinks. Patient pulse quality signals are graded as good, marginal, or inadequate and are indicated as such by the pulse quality indicator blinking green, yellow, or red respectively. This simple method gives the user a pulse-by-pulse visual indication of waveform signal quality without requiring the user to perform complex waveform analysis during critical patient care situations.

If an inadequate pulse is detected, the pulse quality indicator will blink red and a high priority patient audible alarm will sound.

If the SpO_2 or the pulse rate meets or exceeds user-defined alarm limits, the corresponding numerical value will blink on the SpO_2 or pulse rate displays and a high priority patient audible alarm will sound.

If the pulse oximeter sensor is disconnected, malfunctions, or an adequate signal is not detected:

- a dash appears in the leftmost position of the SpO_2 display,
- the displayed SpO_2 and pulse rate values will freeze for 10 seconds, and
- a medium priority equipment alarm will sound (unless the audible alarms are disabled or unless overridden by a high priority patient alarm).
- 10 seconds after the first dash appears, the SpO_2 and pulse rate values will be replaced by dashes, if the condition is not corrected, and
- dashes will blink if there was a patient alarm in process.

Carbon Dioxide Detector

Model 9847 determines approximate CO_2 changes in the airway of intubated patients by measuring the absorption of mid-infrared light passed through the airway adapter tube. The approximate CO_2 concentration change is indicated by an 8-segment LED bar graph display. The CO_2 detector relies on the assumption that the inhaled air contains minimal amounts of CO_2.

Breaths are indicated when the CO_2 level increases by approximately 5 mmHg during exhalation. A detected breath is indicated on the CO_2 bar graph and by an audible breath beep.

When no breath is detected:

- a high priority patient audible alarm sounds,
- the no breath indicator blinks,
- the lowest CO_2 bar graph segment will be illuminated, and CO_2 readings will be displayed with the next breath detected.

Medium priority (equipment) alarms occur when:

- the CO_2 sensor is unplugged,
- the airway adapter tube is removed from the CO_2 sensor,
- the light path is blocked, or
- a CO_2 sensor failure occurs.

A high priority (patient) alarm overrides a medium priority alarm. If the audible alarms are disabled, the third and sixth bars will be solidly illuminated.

Unpacking the Model 9847

Contact the carrier immediately if the shipping carton is damaged. Carefully unpack the device and its accessories. Nonin's standard package configuration consists of the following items:

- 1 Model 9847 Pulse Oximeter and CO_2 Indicator
- 1 Operator's Manual (on CD)
- 1 Model 8000AA-1 Adult Articulated Finger Clip Sensor
- 1 Model 9840SA Carbon Dioxide Sensor
- 3 Model 9840AAT Airway Adapter Tubes
- 6 AA-Size Alkaline Batteries

If any item on this list is missing or damaged, contact your distributor.

Installing and Using the Batteries

Model 9847 is powered by six AA size alkaline batteries. Approximate battery capacity:

- Pulse Oximeter (SpO_2) only: 90 hours
- CO_2 and Pulse Oximeter: 20 hours.
- CO_2 only: 24 hours.

Low battery indicator illuminates when the battery capacity is low. The batteries should be replaced as soon as possible.

Critical battery capacity is indicated by:

- low battery indicator blinks
- medium priority (equipment) alarm

To avoid loss of monitoring, batteries must be replaced immediately.

NOTE: Audible high priority patient alarms override medium priority alarms.

If the batteries are critically low when the device is turned on, setup mode will be disabled and the displays will be blank. Replace the batteries before continuing.

⚠	**CAUTION:** Use only NONIN-specified battery types with this device.

NOTE: To conserve battery life disconnect the CO_2 sensor not in use.

NOTE: Setting the month to “00” disables the calender and clock functions and helps conserve battery life. Refer to “Calender Settings” on page 28 for additional information.

Replacing Batteries

1. Slide open and remove the battery door on the bottom of the device.
2. Remove **all six** batteries.
3. Replace all six batteries with new AA size batteries as illustrated below with the proper battery orientation noted on the back of the device.

⚠	**CAUTION:** The device is not designed to retain data in memory once the batteries are removed. Memory will clear 60 seconds after removing the batteries. Replacing the batteries before 60 seconds have elapsed most likely will result in corrupt data. Always replace the batteries with fully charged batteries. Do not use fully charged and partially charged batteries at the same time as this may cause batteries to leak.

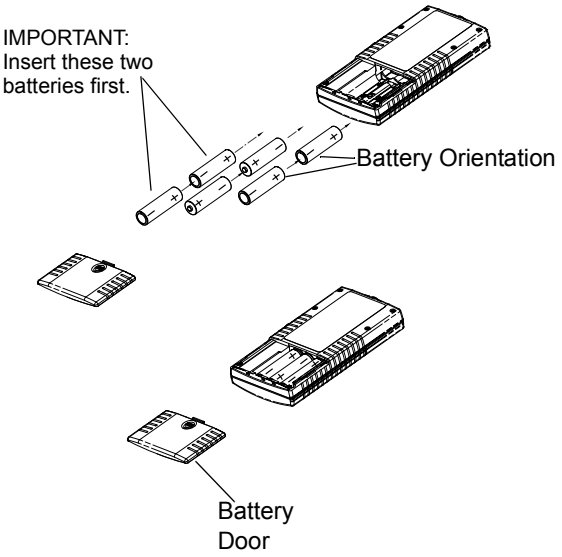


Figure 3: Replacing Batteries - Model 9847, example only.

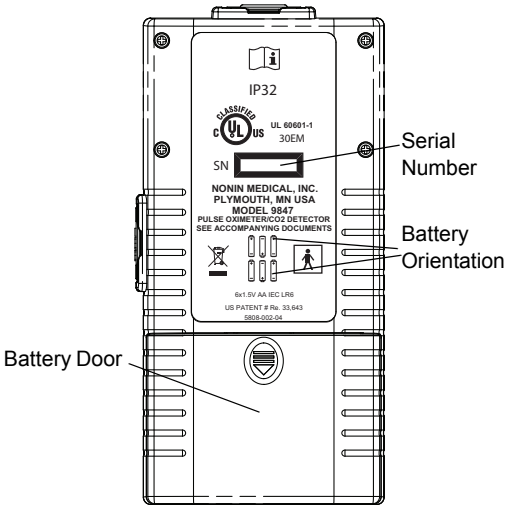


Figure 4: Rear View - Model 9847, example only.

When batteries are critically low, the digital displays will go blank, and the Pulse Quality display will blink yellow or red, but not green.

⚠	**CAUTION:** Replace the batteries as soon as possible after a low battery indication. Always replace the batteries with fully charged batteries. Do not use fully charged and partially charged batteries at the same time. This may cause the batteries to leak.

⚠	**CAUTION:** Remove the batteries if the device will be stored for more than 1 month.

Important Notes about Battery Use

- To conserve battery life, NONIN recommends disconnecting the CO_2 sensor from the Model 9847 when CO_2 detection is not in use. The flashing lamp in the CO_2 sensor consumes a significant amount of energy.
- Setting the month to “00” disables the calendar and clock functions and helps conserve battery life. Refer to “Calendar Settings” on page 28 for additional information.
- The memory of the Model 9847 may be erased when the batteries are removed.
- Replacing batteries may erase the clock settings of the Model 9847.
- Six AA alkaline batteries provide the device with approximately 90 hours of continuous operation.
- **Calendar/clock/ settings can affect battery storage life.** Batteries drain during storage, but they drain more quickly when the unit’s calendar/clock functions are set. Refer to “Calendar Settings” and “Clock Setting” (starting on page 28) for more information.

With AA Batteries

- If the calendar/clock is not set when the unit is stored, alkaline batteries will need replacement in 10-12 months if the unit has not been used.
- If the calendar/clock is set when the unit is stored and if the unit has not been used, alkaline batteries will require replacement in about 6 weeks.

Displays and Indicators

SpO_2 Display

The SpO_2 display is identified by the SpO_2 symbol. This 3-digit light-emitting diode (LED) display shows the current oxygen saturation percentage.

Pulse Rate Display

The Pulse Rate display is identified by the  symbol. This 3-digit LED display shows the pulse rate in pulses per minute.

Pulse Quality Indicator

The Pulse Quality Indicator display, identified by the  symbol, is a tricolor LED that blinks once for each detected pulse. The color of the Pulse Quality indicator changes with the pulse strength signal, as described below.

- **Green** indicates a good pulse strength signal.
- **Yellow** indicates a marginal pulse strength signal. To improve signal quality, reposition the sensor, try a different sensor type, reduce patient movement, or improve the site's circulation.
- **Red** indicates an inadequate pulse strength signal. While the Pulse Quality display is red, SpO_2 and pulse rate values are not updated. After about 10 seconds, the values are replaced with dashes, indicating that readings are not possible.

Low Battery Indicator 

When battery level is low, the low battery indicator is lit. When the batteries reach critically low level, the display will be blank and the low battery indicator will blink.

Sensor Fault or Inadequate Signal Display

If the device determines that a sensor fault or inadequate signal condition exists (a sensor disconnect, failure, misalignment or incompatibility with the monitor) or if a pulse oximeter sensor signal is no longer detected, a dash (-) appears in the leftmost position of the $\%SpO_2$ display and the alarm indicator blinks yellow. The readings that are displayed will freeze for 10 seconds if the pulse oximeter sensor fault or the inadequate signal continues.

If the sensor fault or the inadequate signal is not corrected, the frozen readings and the dash in the leftmost position will be replaced by dashes in the middle of both the %SpO_2 and the Pulse Rate displays.

When the sensor fault or the inadequate signal is corrected, the %SpO_2 and pulse rate displays will return to normal operation.

Using the 9847 Pulse Oximeter

Connecting the Sensors

Pulse Oximeter Sensor

Attach the sensor (with the NONIN logo facing up) to the device as shown in Figure 5. Verify the sensor is securely connected.

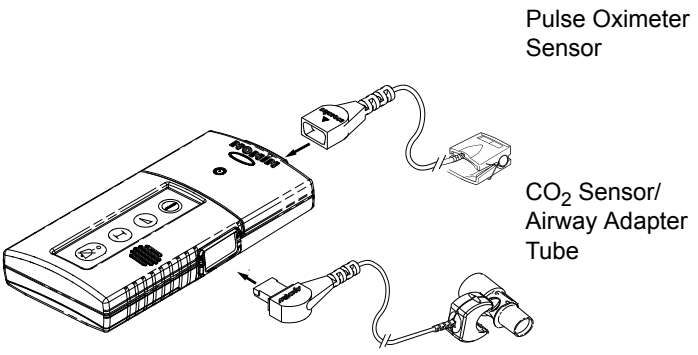


Figure 5: Connecting Sensors to the Model 9847

Carbon Dioxide Sensor and Airway Adapter Tube

Connect the CO_2 sensor (with the NONIN logo facing up) to the side of the device as shown in Figure 5. Verify the sensor is securely attached. Refer to “Carbon Dioxide Sensor” for more information.

Turn On/Standby

Turn on (or off) the device by pressing the ON/Standby (⏻) button.

Startup Self-Test

When the device is turned on, the device will cycle through a startup/ initialization sequence before displaying valid data. During startup, always check for any missing indicators or LED display segments. If any indicator is not functioning, do not use the device. Contact NONIN Technical Service for repair or replacement.

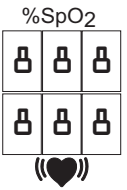
During its normal startup sequence, the device will cycle as follows:

- The audible breath beeps three times.
- The No Breath indicator will display for approximately 2 seconds.

- The low battery indicator will display for approximately 2 seconds, unless the batteries are low.

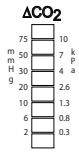
- The pulse quality indicator will blink red, then green. The device will enter standby if no pulse oximeter sensor is connected.

- The %SpO_2 and pulse rate displays will sequence as follows.



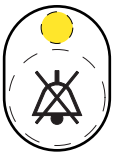
  1. "888 888".
  2. The current time (if set) or "00 00" if the time is not set.
  3. Display 3 software revision numbers; oximetry/ display software rev #, then CO_2 memory software rev #, then sound module software rev. # approx 1 second each.
  4. Any sensor connections issues:
     - if a sensor is not connected the display will revert to blank, or
     - if a sensor is connected but is not detecting an adequate signal, a single dash (-) will appear in the middle position of both displays, or
     - if entering setup mode, the device will display "Alr" and "dFt".

The CO_2 bar graph sequence is:



- each segment illuminates once,
- remains blank (until CO_2 sensor is connected to the device), or
- only the bottom segment illuminates when ready for use if CO_2 sensor is connected to the device.

- The yellow audible alarm disabled indicator is lit until initialization is complete and a CO_2 or pulse oximeter sensor is connected.



NOTE: The audible alarm disabled indication cannot be turned off until a sensor is plugged in.

NOTE: When Model 9847 is turned on and the alarms are disabled, the yellow audible alarm disabled indicator will remain illuminated.

Pulse Oximeter Startup

Apply the pulse oximeter sensor to the patient as directed in the sensor Instructions for Use. Verify operation by:

- the pulse quality indicator is blinking green,
- the pulse rate and SpO_2 ($\%SpO_2$) displays are showing values, and
- the pulse quality indicator blinking is correlated to the pulse rate for at least 10 seconds.

If the pulse quality indicator LED is blinking red or yellow or is blinking inconsistently, reposition the sensor or replace the sensor.

Carbon Dioxide Detector

Verify:

- that the airway adapter tube is properly attached to the CO_2 sensor,
- the CO_2 sensor is properly connected to the device,
- the lower bar of the CO_2 display is lit,
- the CO_2 sensor light is blinking, and
- the CO_2 bar graph segments indicate change in CO_2 level.

Attach the CO_2 sensor/airway adapter tube to the patient's endotracheal tube. The CO_2 detector will reflect values and breath beeps for each breath (if the breath beep sound volume is not turned off).

Medium priority (equipment) alarm will occur (if the alarms are not disabled), when:

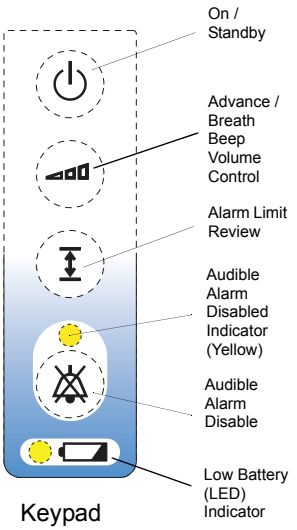
- the CO_2 sensor is disconnected,
- the airway adapter tube is removed from the CO_2 sensor,
- the light path is blocked, or
- a CO_2 sensor failure occurs.

High priority patient alarms override medium priority (equipment). The third and sixth segments of the CO_2 bar graph will be illuminated, indicating a CO_2 sensor fault.

Setup

All functions of the Model 9847 are controlled by buttons found on the keypad on the front of the device.

Press the On/Standby button to turn the device on or to enter Standby mode.



Keypad

Setup Mode

Setup mode is used to control the audible and visible patient alarm limits, the breath beep pitch, the calendar, and the internal time-of-day clock. In setup mode, the alarm limit review button is used to make the menu selections, and the advance button is used to change the value.

Entering Setup Mode

1. With the unit in Standby mode, press and hold the alarm limit review button while pressing and then releasing the On/Standby button.
2. Release the alarm limit review button when "888 888" is displayed on the %SpO_2 and pulse rate displays. Three brief beeps will sound, and "Alr" and the "dFt" will appear in the %SpO_2 and pulse rate displays.

NOTE: Entering setup mode with audible alarms disabled:
1. Press and hold the alarm limit review and audible alarm disable buttons while pressing and releasing the On/Standby button;
2. Release the alarm limit review and audible alarm disable buttons; and the display will appear as described in #2 above; the audible alarm limit indicator will illuminate steadily.

NOTE: You may exit setup mode at any point and save your current patient alarm limit changes (without stepping through the remainder of the setup mode menu options). Complete the desired selections, then turn off the 9847. Next, enter setup mode again and choose "rcl" (recall stored limits) from the alarm mode settings.

NOTE: Setting the month to "00" disables the calendar and clock functions and helps conserve battery life.

NOTE: Setup mode will be disabled if the batteries are critically low at power on.

Making Selections in Setup Mode

1. Upon entering setup mode, "Alr" (the first parameter) will appear in the %SpO_2 display. Press the advance button (or press and hold to quickly scroll) to increment the number (the menu value) on the pulse rate display. The menu starts at the current value stored in memory for the parameter designated in the %SpO_2 display and will cycle through the range of values listed in Table 2.
2. When the value appears in the pulse rate display, press the alarm limit review button to store the value and advance the %SpO_2 display to the next sequential parameter (no breath delay time, alarm limit, etc.) as listed in Table 2.
3. Continue this process until all parameters are set.

   When the setting sequence has been completed, the Model 9847:

   1. exits the setup mode,
   2. briefly displays "rcl Alr" (recall alarm settings), followed by the alarm limit settings, and
   3. begins normal operation.

Disabling the Audible Alarms

The audible alarms can be temporarily disabled, or they can be disabled at power on or when entering setup mode using the audible alarm disable button.

When the audible alarms are disabled, informational beeps will continue to sound at the set loudness level, and the visible alarm indicators will remain enabled.

Temporarily Disabling the Audible Alarms (Maximum Two Minutes)

With the unit on, press and then release the audible alarm disable button. The “audible alarm disabled” indicator will blink. The audible alarms will be disabled for two minutes (unless overridden by an audible critical battery alarm). The audible alarms can be re-enabled by pressing the audible alarm disable button again before the two minute period has expired.

Disabling the Audible Alarms During Power On

1. With the unit in Standby, press and hold the audible alarm disable button while pressing and then releasing the on/standby button.
2. Release the audible alarm disable button when “ ” is displayed on the %SpO_2 and pulse rate displays. After the power on self-test, the “audible alarm disabled” indicator will illuminate steadily. The patient alarms will be set at the default limits. The audible alarms can be re-enabled by pressing the audible alarm disable button again.

Table 2: Patient Alarm Limit, Breath Beep Pitch, Printer, Calendar, and Clock Mode Parameters

Parameter	Appears in SpO_2 Display:	Pulse Rate ♥ Display Range of Values	Default Value
Alarm Mode (dFt =default limits; rcl = recall stored limits; co2 = only no breath and the sensor alarms)	Alr	dFt, rcl, co2	dFt
No Breath Delay (seconds)	nbd	15 to 60 by 5, OFF	20
Oxygen Saturation Low Limit (%)	O2L	50 to 95 by 1, OFF	85
Pulse Rate Low Limit (beats/minute)	H L	30 to 110 by 5, OFF	50
Pulse Rate High Limit (beats/minute)	H H	75 to 275 by 5, OFF	200
Oxygen Saturation High Limit (%)	O2H [a]	80 to 100 by 1, OFF	OFF
Breath Beep Pitch (fixed or variable)	FPt	ON or OFF	OFF (fixed pitch off)
Year	y	00 - 99	09
Month	nn	00 - 12	00
Day	d	01 - 31	00
Hours	h	00 - 23	00
Minutes	nn	00 - 59	00

a. The default setting for "O2H" is "OFF" (disabled). Any of the other patient alarm limit parameters can be individually disabled by setting to "OFF".

Alarm Mode Setting

NOTE: The Advance button sets your selection. The Alarm Limits button moves you to the next setting.

1. Upon entering setup mode, "Alr" will appear in the SpO_2 display indicating alarm mode. The alarm mode may be set to "dFt", "rcl", or "co2".

   Choosing "dFt" (default alarm limits) will set up the system-defined (default) patient alarm limit settings.

   Choosing "rcl" (recall stored limits) will set up the last stored patient alarm limit settings of the Model 9847.

   Choosing "co2" (no breath alarm limits and sensor alarms) will disable the oxygen saturation high and low and the pulse rate high and low settings temporarily by setting them to "OFF". Only the no breath alarm and the sensor alarms will be enabled, along with the breath beep pitch mode selection. Setup mode will skip over the other patient alarm settings ("co2" alarm mode first goes to "nbd", then to "FPt", etc.).
2. When the alarm mode setting has been selected, setup mode continues to the no breath delay time setting.

No Breath Delay Time Setting

1. Upon entering the no breath delay time setup, "nbd" will appear in the SpO_2 display. The no breath delay time may be set from 15 to 60 (seconds) in increments of 5, or to "OFF". Make the no breath delay time setting selection.
2. When the no breath delay time has been selected, setup mode continues to the SpO_2 low alarm limit setting, described in the next section ("co2" alarm mode next goes to "FPt", then to "y", etc.).

SpO_2 Low Alarm Limit Setting

1. Upon entering the SpO_2 low alarm limit, "O2L" will appear in the SpO_2 display. The SpO_2 low alarm limit may be set from 50 to 95 (%) in increments of 1, or to "OFF". Make the SpO_2 low alarm limit selection.
2. When the SpO_2 low alarm limit setting has been selected, setup mode continues to the pulse rate alarm limit settings. (Refer to "Choosing Pulse Rate Alarm Limit Settings".)

NOTE: See page 26 for Table 2 - Default settings.

Pulse Rate Alarm Limit Settings

1. Upon entering the pulse rate low alarm limit, "H L" will appear in the SpO_2 display. The pulse rate low alarm limit may be set from 30 to 110 (beats per minute) in increments of 5, or to "OFF".
2. After selecting the pulse rate low alarm limit, the SpO_2 display will show "H H" indicating the setup mode for the pulse rate high alarm limit. The pulse rate high alarm limit may be set from 75 to 275 (beats per minute) in increments of 5, or to "OFF".
3. When the desired pulse rate high alarm limit setting has been selected, setup mode continues to the SpO_2 high alarm limit.

SpO_2 High Alarm Limit Settings

1. Upon entering the SpO_2 high alarm limit, "O2H" will appear in the SpO_2 display. The SpO_2 high alarm limit may be set from 80 to 100 (%) in increments of 1, or to "OFF".
2. When the SpO_2 high alarm limit setting has been selected, setup mode continues to the breath beep pitch settings.

Settings

Breath Beep Pitch

Upon entering the breath beep pitch, "FPt" will appear in the SpO_2 display. The breath beep pitch defaults to "variable pitch" (fixed pitch off). Refer to "Audible Breath Beep" on page 37 for additional information. The breath beep pitch selection may be toggled between "ON" or "OFF".

Calendar Settings

NOTE: Setting the month to "00" disables the calendar and clock functions. The calendar and clock functions are used to time stamp real-time data for memory. Unless you intend to use real-time data output or memory playback options, skip this section.

1. After the calendar setting has been selected in the setup mode, "y" will appear in the SpO_2 display indicating the calendar setup mode for the year. The year may be set to "00" through "99".
2. After selecting the year, the display will show "nn" indicating the setup mode for the month. The month may be set to "00" through "12".
3. After selecting the month, the display will show "d" indicating the setup mode for the day of the month. The day may be set to "01" through "31". After selecting the day, the setup mode continues to the clock settings.

Clock Setting

1. After the calendar settings have been selected in the setup mode, "h" will appear in the SpO_2 display indicating clock setup mode for the hour. The hour may be set to "00" through "23".
2. After selecting the hour, the SpO_2 display will show "nn" indicating the setup mode for the minutes. The minutes may be set to "00" through "59".
3. After selecting the minutes, the device will:
   1. exit the setup mode,
   2. briefly display "rcl Alr" (recall alarm settings) and then the current alarm limit settings, and
   3. begin normal operation.

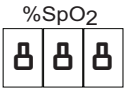
Indicators

Refer to Figure 2 on page 11 for a detailed illustration of the Model 9847 controls and indicators.

Visible Indicators

SpO_2 Display

The SpO_2 display is the upper numeric display. This 3-digit light-emitting diode (LED) display shows the current oxygen saturation percentage.



Pulse Rate Display ( )

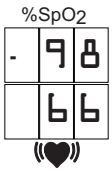
The pulse rate display is the lower numeric display. This 3-digit LED display shows pulse rate in pulses per minute.

SpO_2 and Pulse Rate Displays (-)

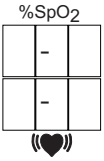
A pulse oximeter sensor fault will occur if the Model 9847 pulse oximeter detects:

- a pulse oximeter sensor disconnect,
- a pulse oximeter sensor dislodgment, or
- a pulse oximeter sensor failure.

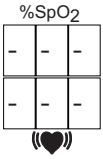
If a pulse oximeter sensor fault occurs or a sensor signal is no longer detected, a medium priority equipment alarm is started. A dash (-) appears in the left digit of the SpO_2 display. The readings that are displayed will freeze for 10 seconds if the sensor fault or inadequate signal continues. (Also during this medium priority alarm, an audible indicator will occur.)



If the sensor fault or inadequate signal is not corrected, dashes will be displayed in the middle digit of both the SpO_2 and pulse rate displays 10 seconds after the first dash appears. The corresponding dash(es) will blink if there was a prior high priority patient alarm. When the sensor fault or inadequate signal is corrected, the SpO_2 and pulse rate displays will return to normal operation.



When the SpO_2 or pulse rate alarm limits are met or exceeded, a high priority patient alarm condition exists. The corresponding numbers on the display will blink.



When the SpO_2 or pulse rate alarm limits are met or exceeded, a high priority patient alarm condition exists and the numerical values of the corresponding parameter will blink. (Also during these high priority alarms, an audible alarm indication will occur.)

If latched for a pulse oximeter medium priority equipment alarm (a sensor fault or inadequate signal), a single blinking dash will be displayed in the corresponding middle digit of the SpO_2 or the pulse rate display.

The visible and audible indicators will stop when the condition is cleared.

Alarm Limit Review

When the alarm limit review button is pressed and held, the patient alarm limits in effect for no breath delay time (in seconds), SpO_2, and pulse rate, as well as the breath beep pitch setting will display in sequence for approximately 2 seconds in the order and format shown in Table 3 on the next page. If the button is released, the review mode is exited and normal operation is resumed.

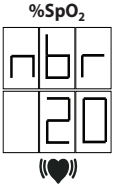


Table 3: Alarm Limits Displayed During an Alarm Limit Review

Parameter	Appears in SpO_2 Display	Alarm Limits (Default Values Are Shown)
No Breath Delay (seconds)	nbd	20
Oxygen Saturation Low Limit (%)	O2L	85
Pulse Rate Low Limit (beats/minute)	H L	50
Pulse Rate High Limit (beats/minute)	H H	200
Oxygen Saturation High Limit (%)	O2H	OFF
Breath Beep Pitch (fixed or variable)	FPt	OFF (fixed pitch off)

During the alarm limit review only the SpO_2 and pulse rate displays will be affected. The current SpO_2 and pulse rate measurements will be displayed after completing the limit review. If a critical battery state exists, the alarm limit review sequence will not appear.

NOTE: Pressing and holding the alarm limit review button can be used to review alarm limits and to activate an event marker.

Pulse Quality Indicator

CAUTION: The device may misinterpret motion artifact as good pulse quality.

The pulse quality indicator blinks once for each pulse while measuring oxygen saturation. The pulse quality indicator changes color to indicate changes in the pulse waveform signal that may affect the SpO_2 data.

The pulse quality indicator may blink one of three colors:

- **Green** indicates that the pulse waveform signal is of good quality and the SpO_2 and pulse rate data are accurate.
- **Yellow** indicates that the pulse waveform amplitude is marginal or that the pulse oximeter has detected artifact. Although the SpO_2 and pulse rate data may be acceptable, corrective measures should be considered if the indicator continues to blink yellow frequently. To improve the signal quality, try repositioning the sensor, try a different sensor type, eliminate patient movement, or improve circulation at the site by massaging the area.

- **Red** indicates that the pulse waveform amplitude is inadequate. During red pulse quality, SpO_2 and pulse rate values are not updated. A high priority patient alarm occurs. After approximately 20 seconds, the values are replaced with dashes indicating that SpO_2 and pulse rate measurements are not possible. (Also during this high priority patient alarm, the high priority audible pulse quality alarm sounds if the audible alarms are not disabled.)

No Breath Indicator

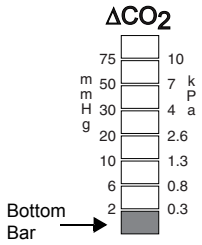
The visible no breath indicator is a high priority patient visible alarm that flashes when a breath has not been detected for a period of time exceeding the set no breath delay time (measured in seconds). During this alarm, the high priority audible no breath alarm sounds if the audible alarms are not disabled. (See “Audible No Breath Alarm” on page 39 for additional information.)

If a CO_2 sensor alarm occurs, existing visible and audible absence of breath indicators will latch. In most cases, however, during “fixed pitch” breath beep mode, when the airway adapter tube is unsnapped from the CO_2 sensor, the visible and audible absence of breath indicators will stop.

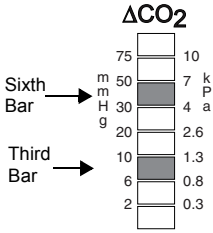
When a breath is again detected, the visible and audible no breath indicators will stop. The no breath delay timer is first started when the CO_2 sensor is plugged into the Model 9847 and the system is not in setup mode (when the lower bar is illuminated on the CO_2 display).

CO_2 Bar Graph

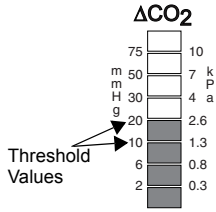
The CO_2 bar graph will remain blank until the CO_2 sensor is plugged in. When an airway adapter tube is connected to the CO_2 sensor and an adequate signal is detected, the bottom bar is initially illuminated. The bars will be illuminated to indicate the change in CO_2 level as the patient exhales and inhales through the airway adapter tube.



The 3rd and 6th bars of the CO_2 bar graph will be illuminated if a medium priority (equipment) alarm is started. (See page 36 for additional alarm information.)



CO_2 values are displayed as a range between two threshold values. The threshold values are located between each CO_2 bar. The values (displayed in both mmHg and kPa) are an approximate measurement of the change in CO_2 level in the airway adapter tube. For example, if four bars are illuminated, the detected CO_2 level change lies within the range ≥10 mmHg and <20 mmHg (the threshold values).



NOTE: Because the CO_2 detector is a semi-quantitative device, the rising and falling CO_2 bar graph should NOT be interpreted as a CO_2 waveform.

Low Battery Indicator ( )

The low battery indicator steadily illuminates when the battery level is marginal. The batteries should then be replaced as soon as possible.

When the battery level is low:

- the low battery indicator blinks,
- a medium priority equipment audible alarm is started (unless an audible high priority patient alarm is in progress),

- if the respective alarms are not “latched” (continuing), the SpO_2, pulse rate, and CO_2 bar graph will be blank,
- if not “latched”, the pulse quality indicator will blink yellow or red but not green, and
- an existing visible high priority patient alarm will “latch” (continue):
    - a latched no breath alarm will blink the no breath indicator,
    - a latched high or low SpO_2 or pulse rate alarm will display three dashes blinking in the corresponding numeric display, and
    - a latched pulse quality alarm will blink red.

When batteries are critically low:

- low battery indicator blinks,
- set-up mode is disabled,
- displays are blank (no patient data), and
- batteries must be replaced.

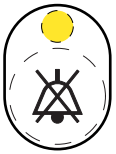
The device will not monitor a patient once the batteries reach a critically low level. The batteries must then be replaced before further use of the Model 9847.

NOTE: Removing batteries may delete memory and all user defined settings, including calendar and clock.

Audible Alarm Disabled Indicator

If the device is turned on with the audible alarms permanently disabled, the yellow “audible alarm disabled” indicator will be steadily illuminated. If the audible alarms are temporarily disabled, the “audible alarm disabled” indicator will blink.

Audible Alarm Disabled Indicator (Yellow)



After the Model 9847 is turned on (and after exiting the setup mode, if applicable) and until a pulse oximeter or CO_2 sensor is plugged in for the first time, the “audible alarm disabled” indicator will blink (or will remain steadily illuminated if the audible alarms are “permanently” disabled).

This “audible alarm disabled” indication cannot be turned off until a sensor is plugged in. (This is the only illuminated indicator until a sensor is detected, and provides an “on” indication to the user.) If the audible alarms are not disabled, a 2-minute “temporarily disabled” timer starts the first time a sensor is plugged in after power on. See “Disabling the Audible Alarms” on page 23 for additional information.

Audible Indicators

⚠	**CAUTION:** Do not block the audible indicator speaker holes. Blocking the speakers will significantly reduce the sound volume.

⚠	**CAUTION:** Verify that the audible alarms can be heard over the ambient noise of the operating environment.

Audible Indicators include medium priority equipment and high priority patient alarms, and informational tones (breath beeps). For information on disabling the audible alarms, see “Disabling the Audible Alarms” on page 23.

Audible and Visible Indicator Functions During Alarm Conditions

Table 4 on page 36 summarizes the audible and visible indications that occur during the equipment and patient alarm conditions.

Table 4: Audible and Visible Indicator Functions During Alarm Conditions

Note: These rules assume that the audible alarms have not been temporarily or permanently disabled using the “audible alarm disabled” switch.

Alarm Condition	Audible Indication	Visible Indication
Low battery level	None	Low battery indicator steadily illuminated
Battery level critically low	Medium priority alarm[a], unless audible high priority patient alarm is latched	• Battery indicator blinking • Latched prior high priority patient alarm • All other visible indicators off (the Model 9847 is unavailable for use)
SpO_2 high or low	High priority patient alarm	SpO_2 numeric display blinking; if latched for critical battery state, will display blinking dashes in all 3 LEDs
Pulse rate high or low	High priority patient alarm	Pulse rate numeric display blinking; if latched for critical battery state, will display blinking dashes in all 3 LEDs
Inadequate pulse quality	High priority patient alarm	Pulse quality indicator blinking red as it normally does in inadequate pulse quality situations; can be latched for critical battery state
No breath (no breath detected during set delay time interval measured in seconds)	High priority patient alarm	• No breath indicator flashing • CO_2 bar graph remains active • CO_2 bar graph blank (disabled) during critical battery state
Pulse oximeter sensor disconnect, dislodgment, or pulse oximeter sensor failure	Medium priority alarm until valid signal again detected, unless audible high priority patient alarm is latched	• Display “dash” sign in leftmost SpO_2 digit and freeze numeric displays for 10 seconds • Display dashes in middle digit of SpO_2 and pulse rate displays 10 seconds after first dash • Corresponding dashes will blink if prior high priority pulse oximeter patient alarms are latched
CO_2 sensor reduced signal due to: • CO_2 sensor disconnection or • Malfunction or • Blocked light path or • Airway adapter tube removed from the CO_2 sensor	Medium priority alarm until valid signal again detected, unless audible high priority patient alarm is latched	• Third and sixth bars of CO_2 display steadily illuminated • Latched prior no breath indicator blinking

a. Note that if a critical battery condition occurs while the audible alarms are disabled, the audible alarms will become re-enabled. A medium priority alarm will sound unless there is a high priority alarm condition in effect.

Audible Breath Beep

When the detected CO_2 increases (during exhalation) by approximately 5 mmHg, a breath is detected and the audible breath beep will sound. One beep is sounded for each breath detected. The breath beeps will only sound during the quiet part of an alarm burst sequence.

The “variable pitch” (fixed pitch “off”) breath beep is the default setting at setup. During variable pitch breath beeps, the tone of the breath beeps is indexed to the number of bars illuminated on the CO_2 bar graph. The more bars lit, the higher the pitch. In variable pitch mode, breath beeps will sound at inspiration (on the falling edge of the CO_2 waveform).

However, if desired the “fixed pitch” breath beep (fixed pitch “on”) can be selected at setup. The “fixed pitch” breath beep has a pitch higher than the highest bar graph-indexed pitch. In fixed pitch mode, breath beeps will sound during exhalation (on the rising edge of the CO_2 waveform). During power on initialization and when changing the breath beep sound volume, beeps will sound as fixed pitch.

Each time the Model 9847 is turned on, the audible breath beep will default to the medium sound volume setting. During normal operation, pressing the advance switch cycles the audible breath beep sound volume between low, medium, high, and off. A “volume” beep will sound each time the advance switch is pressed to indicate the current setting, unless an audible alarm is in progress.

NOTE: The advance switch will not alter the volume of the medium and high priority audible alarms.

Audible Critically Low Battery Alarm

The audible critically low battery alarm is a medium priority equipment alarm indicating that the batteries have reached a critically low level and must be replaced immediately. The Model 9847 will not monitor patients after the batteries reach a critical power level. Also during this medium priority alarm, the visible low battery indicator blinks.

If a high priority patient alarm condition exists before reaching critically low battery level, the audible and visible alarms will “latch”. A “latched” patient alarm condition will sound a high priority patient audible alarm. A high priority patient visible alarm indicator that is “latched” for a critically low battery will either blink (for no breath or pulse quality) or will display three blinking dashes (for SpO_2 or pulse rate).

⚠	**CAUTION:** The critically low battery state overrides the audible alarm disable switch. If a critically low battery condition occurs and the audible alarms are either temporarily or permanently disabled, the audible alarms will become re-enabled. A medium priority alarm will sound unless there is a high priority alarm condition in effect. The “audible alarm disabled” indicator will not be illuminated.

The audible critically low battery alarm cannot be disabled by the alarm disable switch.

Audible SpO_2 High or Low Alarm

The audible SpO_2 alarm is a high priority patient alarm that sounds (if the audible alarms are not disabled) when the SpO_2 high or low alarm limits are reached or exceeded. (Also during this high priority alarm, a visible alarm indication will occur. See “SpO_2 and Pulse Rate Displays” on page 29 for more information.) The audible and visible indicators will stop when the condition is cleared.

Audible Pulse Rate High or Low Alarm

The audible pulse rate alarm is a high priority patient alarm that sounds (if the audible alarms are not disabled) when the pulse rate high or low alarm limits are matched or exceeded. (Also during this high priority alarm, a visible alarm indication will occur. See “SpO_2 and Pulse Rate Displays” on page 29 for more information.) The audible and visible indicators will stop when the condition is cleared.

Audible Pulse Quality Alarm

The audible pulse quality alarm is a high priority patient alarm that sounds (if the audible alarms are not disabled) when the pulse signals that are detected are of inadequate pulse quality. (During this high priority alarm, the pulse quality indicator will blink red as it normally does in inadequate pulse quality situations, and can be latched (will continue) for the critical battery state. See “Pulse Quality Indicator” on page 31 for additional information.) The audible and visible indicators will stop when the condition is cleared.

Audible No Breath Alarm

The audible no breath alarm is a high priority patient alarm that sounds (if the audible alarms are not disabled) when a breath has not been detected for a period of time exceeding the set no breath delay time (measured in seconds). (Also during this high priority alarm, the visible no breath indicator blinks.)

If a CO_2 sensor alarm occurs, existing audible and visible no breath indicators will latch (continue). In most cases, however, during “fixed pitch” breath beep mode, when the airway adapter tube is disconnected from the CO_2 sensor, the audible and visible no breath (apnea) indicators will stop.

When a breath is again detected, the audible and visible no breath indicators will stop. The no breath delay timer is first started when the CO_2 sensor is connected into the Model 9847 and the system is not in setup mode (that is, when the lower bar is illuminated on the CO_2 bar graph).

Audible Pulse Oximeter Sensor Alarm

The pulse oximeter sensor alarm is a medium priority equipment audible alarm that sounds when the pulse oximeter sensor is either disconnected, dislodged, or a pulse oximeter sensor failure occurs. (Also during this medium priority alarm, visible indicators will occur.) The audible and visible pulse oximeter sensor alarm indicators will stop when the condition is corrected.

Audible CO_2 Sensor Alarm

The CO_2 sensor alarm is a medium priority equipment audible alarm. Conditions that may cause the audible equipment alarm include:

- the CO_2 sensor is unplugged,
- the airway adapter tube is removed from the CO_2 sensor,
- the light path is blocked, or
- a CO_2 sensor failure occurs.

Also during this medium priority alarm, a visible indication occurs (a CO_2 sensor fault) where the third and sixth bars on the CO_2 bar graph will be steadily illuminated (see “CO_2 Bar Graph” on page 33). The audible and visible CO_2 sensor alarm indicators will stop when the condition is corrected.

Description of Alarm Sounds

The pitch of the alarm sounds is the same as a “volume” beep (the tone heard when changing the breath beep sound volume). The high priority (patient) audible alarm will sound at high volume and the medium priority (equipment) audible alarm will sound at medium volume.

NOTE: Audible alarm volumes are fixed. The audible alarms can be disabled, but their volumes are not user-adjustable.

The sound sequence for the high priority alarm consists of 3 short beeps, a delay, and then 2 more beeps within a 1 second period; then an identical pattern after a 1 second delay. This sound sequence then repeats every 10 seconds until the high priority patient alarm condition is cleared.

The sound sequence for the medium priority alarm consists of 3 medium long beeps within a 1 second period. This sound sequence will repeat every 25 seconds until the medium priority equipment alarm condition is cleared.

Audible Indicator Sound Control Priorities

Only one audible alarm or informational tone may sound at a time. However, more than one type of alarm condition may occur at the same time. (For example, a critical battery condition could begin while a no breath condition is occurring). Therefore, the Model 9847 software uses a set of “rules” to determine the priority of these sounds. These sound control rules are described in Table 5 on the next page.

Table 5: Audible Indicator Sound Control Priorities

NOTE: These priorities assume that the audible alarms have not been temporarily or "permanently" disabled using the "audible alarm disabled" button.

Condition	Sound Control Priorities
Low Battery Level	Normal sound operation; steadily illuminated low battery indicator only.
• Critically Low Battery Level or • Pulse Oximeter Sensor Alarm or • CO_2 Sensor Alarm (medium priority equipment alarm)	Medium priority audible alarm unless a prior high priority patient alarm is "latched". When "latched" it will sound a high priority patient alarm. If a critically low battery condition occurs and the audible alarms are either temporarily or permanently disabled, the audible alarms will become re-enabled. A medium priority alarm will sound unless there is a high priority alarm condition in effect. The medium priority sound cycle will not be restarted should a new equipment alarm condition occur; the existing sound will be maintained.
• SpO_2 high or low or • Pulse rate high or low or • Inadequate pulse quality or • No breath (high priority patient alarm)	The onset of a high priority patient alarm condition will cause the initiation of the high priority patient alarm. If a medium priority equipment alarm condition occurs after the onset of a patient alarm condition, the patient alarm state will be latched and will not be overridden by the equipment alarm. When the patient alarm condition is cleared and there is an equipment alarm in effect, then the medium priority sound will be started.
Audible alarms re-enabled via Audible Alarm Disable Button or ending of 2-minute disable	When the audible alarms are re-enabled, and at least one alarm condition exists, the sound cycle for the highest priority alarm condition in effect at that time will be started. Note: The critically low battery state overrides the audible alarm disable. If a critically low battery condition occurs and the audible alarms are either temporarily or permanently disabled, the audible alarms will become re-enabled. A medium priority alarm will sound unless there is a high priority alarm condition in effect.
Breath beep	Informational beeps will occur only during the "quiet" part of any alarm sound in progress. (Or the beep volume can be set to "OFF".)

Carbon Dioxide (CO_2) Sensor and Airway Adapter Tube

CONTRAINDICATION: Do not use the Model 9847 CO_2 detector for patients younger than 3 years old and weighing less than 10 kg (22 lb) due to the dead space introduced by the airway adapter tube.

WARNING: Do not use a damaged sensor.

⚠ **CAUTION:** Before use, carefully read the instruction insert provided with the sensors.

⚠ **CAUTION:** Water or other liquid between the airway adapter tube and the CO_2 sensor may cause erroneous readings.

⚠ **CAUTION:** Ensure that all connections to the airway adapter tube are tight and leak-free, and that the airway adapter tube is properly attached to the CO_2 sensor.

Carbon Dioxide Sensor

The Model 9840SA CO_2 Sensor is a crescent-shaped device containing light emitting and detecting elements (Figure 6) on the end of a cable that connects to the Model 9847. The CO_2 sensor is connected on to the Model 9840AAT Airway Adapter Tube, which in turn is connected between the endotracheal tube and the breathing circuit of intubated patients.

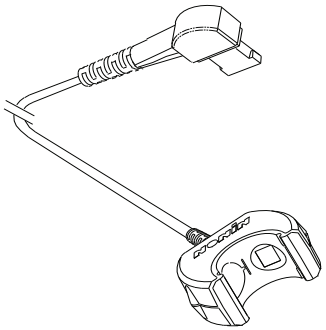


Figure 6: Model 9840SA Carbon Dioxide Sensor

Airway Adapter Tube

CONTRAINDICATION: Do not use the Model 9847 CO_2 detector for patients younger than 3 years old and weighing less than 10 kg (22 lb) due to the dead space introduced by the airway adapter tube.

WARNING: Do not reuse the Model 9840AAT Airway Adapter Tube.

WARNING: If the airway adapter tube becomes contaminated or damaged, discard it and replace it with a new one. Cleaning the interior will damage the anti-fog coating and cause inaccurate readings.

WARNING: Do not use the airway adapter tube if the airway adapter tube is below 5° C. An airway adapter tube that is below 5° C may frost, causing a false reading. Warm the airway adapter tube to above 5° C by putting it in a warm place (for example in your hands or in a vehicle) before use.

WARNING: The Model 9840AAT Airway Adapter Tube will increase dead space by approximately 6 cubic centimeters (0.4 cubic inches); this may adversely affect ventilation for patients with small tidal volumes.

⚠ **CAUTION:** An airway adapter tube that is between 5° C and 10° C may cause inaccurate readings due to fogging of optical surfaces. It is recommended that the airway adapter tube be warmed to above 10°C before use.

The Model 9840AAT Airway Adapter Tube (Figure 7) is a single-use only, disposable adapter designed to be placed between the endotracheal tube and the breathing circuit of intubated patients. The airway adapter tube connects to the CO_2 sensor so that the two devices do not move relative to each other (you may notice the connection by feel or sound).

The CO_2 detector will not function properly unless the light emitting and detecting elements of the CO_2 sensor are properly aligned with the windows in the airway adapter tube.

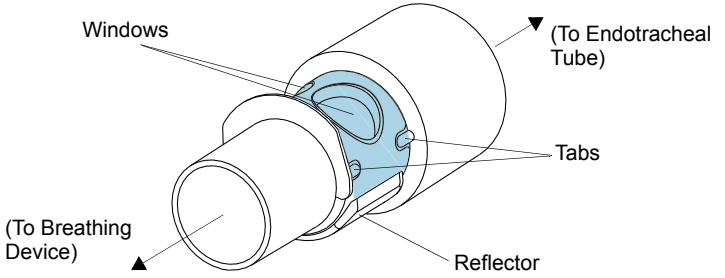


Figure 7: Model 9840AAT Airway Adapter Tube

Attaching the Airway Adapter Tube to the Carbon Dioxide Sensor

1. While grasping the large end of the airway adapter tube, place the clear windows of the tube toward the CO_2 sensor (Figure A). The reflector should face away from the CO_2 sensor.

NOTE: It is possible to force the airway adapter tube and the CO_2 sensor into an improper alignment and connection. However, the CO_2 detector will not function properly unless these pieces are correctly attached to each other.

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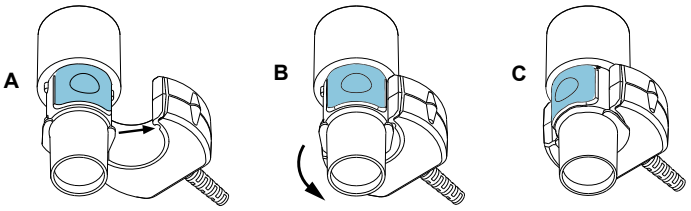
2. Join the tabs on one side of the airway adapter tube onto either side of the CO_2 sensor (Figure A), then rotate the airway adapter tube (Figure B) and push firmly to set the other pair of tabs. You should hear a clicking sound as the pieces are connected together (Figure C).



(Note: The ends of the airway adapter tube can be placed in either direction relative to the CO_2 sensor.)

Figure 8: Connecting the Airway Adapter Tube to the CO_2 Sensor

3. Ensure that the airway adapter tube and the CO_2 sensor are firmly attached to each other. Gently tug on the assembly to make sure the pieces are tightly connected.

NOTE: Both sides of the airway adapter tube must be connected onto the CO_2 sensor. If only one side of the airway adapter tube is attached to the CO_2 sensor, the pieces will come apart.

The airway adapter tube attaches between the endotracheal tube of the patient and the breathing circuit. See Figure 9 for an illustration of the configuration.

NOTE: Not all tapered connectors are compatible with the airway adapter tube. Ensure that all connections are secure.

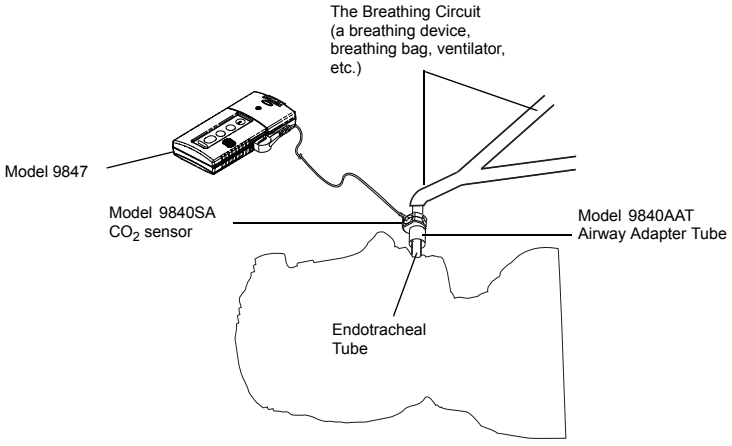


Figure 9: The Airway Adapter Tube and the Breathing Circuit

Care and Maintenance

Wipe the device with a soft cloth dampened with a mild detergent or 10% bleach solution. Do not use undiluted bleach or any cleaning solution other than those recommended here, as permanent damage could result. Dry with a soft cloth, or allow to air dry.

Clean the device separately from the sensors. For instructions on cleaning pulse oximeter sensors, refer to the respective sensor instructions for use.

⚠	**CAUTION:** Do not place the Model 9847 in liquid or clean it with agents containing ammonium chloride, isopropyl alcohol, or products that are not listed in this User's Guide.

Maintenance

The 9847 requires no routine calibration or maintenance, other than battery replacement.

⚠	**CAUTION:** Do not use caustic or abrasive cleaning agents on the device or the sensors.

⚠	**CAUTION:** Do not autoclave or immerse the device or sensors in liquid. Do not expose the device or components to excessive moisture or liquids.

Cleaning the CO_2 Sensor

⚠	**CAUTION:** Do not immerse the CO_2 sensor in liquid, and do not use caustic or abrasive cleaning agents on the CO_2 sensor.

The CO_2 sensor is protected against splashing water.

Cleaning the CO_2 Sensor

Clean the Model 9840SA CO_2 Sensor with a soft cloth dampened with isopropyl alcohol. Do not pour or spray any liquids onto the Model 9840SA CO_2 Sensor. Allow the Model 9840SA CO_2 Sensor to dry thoroughly before reusing.

Returning the CO_2 Sensor for Service

If the Model 9840SA CO_2 Sensor must be returned to NONIN for service, the product should be free of any contaminants, and sterilization may be required. Contact NONIN's Customer Support department for shipping instructions.

Memory Functions

Memory

The Model 9847 can collect and store up to 24 hours of SpO_2 and pulse rate information.

Nonin offers nVISION® Data Management Software for Oximetry Screening, for use with a personal computer. nVISION is an easy to use Windows®-based program for pulse oximetry data retrieval, analysis, report generation, and data storage.

The solid-state memory in the device functions much like an endless loop. When the memory fills up, the unit begins overwriting the oldest locations with the latest data.

Each time the device is turned on, the current time/date information (if the clock is set properly) is stored in memory to allow quick differentiation of recording sessions. Patient SpO_2 and pulse rate are sampled and stored every four seconds. The oxygen saturation values are stored in 1% increments in the range of 0 to 100%. The stored pulse rate ranges from 18 to 300 pulses per minute. The stored values have increments of 1 pulse per minute from 18 to 200 pulses per minute, and increments of 2 pulses per minute from 201 to 300 pulses per minute.

NOTE: CO_2 detector data is not stored in memory.

During data retrieval, the last data recorded is the first displayed. For example, the last four minutes of data recorded are the first four minutes displayed.

Recording Sessions
Each time the device is turned on (except while setting the clock) data is automatically collected.

NOTE: Only recording sessions greater than one minute in length are kept in memory for later printing.

Memory Playback Mode

1. With the unit off, press and hold the alarm limit review button while pressing and then releasing the on/standby button.
2. Release the alarm limit review button when "888 888" is displayed on the SpO_2 and pulse rate displays. Three brief beeps will sound and "Alr" and "dFt" appear in the SpO_2 and pulse rate displays.
3. Data will be automatically played back from the memory.

NOTE: The keypad sequence for starting memory playback is identical to the sequence used for entering setup mode.

Data are played back at a rate of 20 minutes of collected data per second. A 24-hour recording session (the maximum memory saved) is played back in approximately 1 minute. After all data are played back the device should be shut off before collecting new patient data. The patient information is held in memory as long as the batteries are good, so if the memory must be cleared, remove the batteries for a period of 60 seconds or longer. Playing back the data in memory does not clear any data from the memory.

The size of this file will depend on the amount of data saved in the memory. The most recent data are played back first. The memory data format is in binary. Bad data is represented by FF (hexadecimal) or 255 (decimal). If the memory “wrapped around” (the recording time exceeded 24 hours) and the final (i.e., the oldest) file of data has been truncated, the final start time will be represented by zeroes and the start times for that file will then not match up.

Communications

Real-Time Serial Output

The 9847 provides real-time data output capability via the pulse oximeter sensor connector (a 9-pin Sub-D connector). The sensor connector pin assignments are listed below.

Pulse Oximeter Sensor Connector Pin Assignments

Pin Number	Assignment
1	Sensor Detect
2	IR Drive
3	Red Drive
4	Serial Data Output
5	Signal
6	Sensor Type
7	Ground
8	NC
9	Sensor Bias

Real-time data can also be transmitted to another device through the serial data infrared link (Sensor Connector) at the top of the device. Refer to Figure 2 on page 11 for the location of the Sensor Connector.

The information from the device in the real-time mode is sent in an ASCII serial format at 9600 baud with 9 data bits, 1 start bit, and 1 stop bit. The data are output at a rate of once per second.

NOTE: The 9th data bit is used for parity in memory playback mode. In real-time mode, it is always set to the mark condition. Therefore the real-time data may be read as 8 data bits, no parity.

Real-time data may be printed or displayed by compatible devices. On power up a header is sent identifying the format and the time and date. Thereafter, the data are sent once per second by the device in the following format:

HH:MM:SS SPO2=XXX HR=YYY

NOTE: Marked events will display as an asterisk (*) at the end of the line.

where “HH” represents the hour the real-time clock is set to, “MM” represents the minutes, “SS” represents the seconds, “XXX” represents the SpO_2 value, and “YYY” represents the pulse rate. The SpO_2 and pulse rate will be displayed as “---” if there are no data available for the data reading.

If a breath was detected in the previous interval a “B” will be appended to the data line and will be printed by some devices.

Service, Support and Warranty

⚠	**CAUTION:** This device is a precision electronic instrument and must be repaired by trained NONIN personnel only.

⚠	**CAUTION:** Any sign or evidence of opening the system, field service by non-NONIN personnel, tampering, or any kind of misuse or abuse of the system, shall void the warranty in its entirety.

The advanced digital circuitry within the Model 9847 requires no periodic maintenance or calibration. NONIN does not recommend field repair of the Model 9847.

For additional technical information, contact NONIN's Technical Service department at:

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

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

All non-warranty work shall be done according to NONIN standard rates and charges in effect at the time of delivery to NONIN. All repairs include a complete retest of the Model 9847 using factory test fixtures.

Warranty

NONIN MEDICAL, INCORPORATED, (NONIN) warrants to the purchaser, for a period of three years from the date of purchase, each Model 9847 Pulse Oximeter and CO_2 Detector exclusive of sensors, cables, and batteries. (Refer to the individual package inserts for specific warranty information for sensors, cables, and other accessories.) NONIN shall repair or replace any Model 9847 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 9847 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. For any Model 9847 sent to NONIN for warranty repair which is found to be within specification, the purchaser agrees to pay $100.00 (US dollars).

The Model 9847 is a precision electronic instrument and must be repaired by knowledgeable and specially trained NONIN personnel only. Accordingly, any sign or evidence of opening the Model 9847, field service by non-NONIN personnel, tampering, or any kind of misuse or abuse of the Model 9847, 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.

Accessories

The following NONIN accessories function with Model 9847. Detailed information regarding specific sensor use (patient population, body/tissue, and application) can be found in the respective sensor Instructions for Use.

Model Number	Description
Carbon Dioxide Sensor Assembly	
9840AAT	Airway Adapter Tube, 12 per box
9840SA	Carbon Dioxide Sensor
Pulse Oximeter Reusable Sensors	
8000AA-1	Adult Articulated Finger Clip Sensor (1 meter)
8000AA-3	Adult Articulated Finger Clip Sensor (3 meter)
8000AP	Pediatric Finger Clip Sensor
8000J	Adult Flex Sensor
8000JFW	FlexiWrap® Single Use Sensor Wrap
8008J	Infant Flex Sensor
8008JFW	Infant FlexiWrap® Single Use Sensor Wrap
8001J	Neonatal Flex Sensor
8001JFW	Neonatal FlexiWrap® Single Use Sensor Wrap
8000Q2	Ear Clip Sensor
8000R	Reflectance Sensor
8000H	Reflectance Sensor Holder System
8000SL	Soft Sensor (Large)
8000SM	Soft Sensor (Medium)
8000SS	Soft Sensor (Small)
Pulse Oximeter Disposable Sensors	
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
7000N	Neonatal Foot Flexi-Form II Sensor, 10 per box
7000D	Flexi-Form Sensor Assortment Pack, 10 per box

Model Number	Description
6000A	Adult Disposable Sensors
6000P	Pediatric Disposable Sensors
6000I	Infant Disposable Sensors
6000N	Neonatal Disposable Sensors
Other Accessories	
nVISION	nVISION® Software for Microsoft Windows 95/98/2000/ NT 4.0/XP/Vista operating systems
8000S	Patient Simulator
8500I	Patient Extension Cable
HH-CC	Carrying Case
8500MB	Mounting Bracket
8500MB-PMS	Mounting Bracket (w/Pole Mount System - includes Pole Mount side bracket and Pole Mount clamp)
8500RB	Rubber Bumper
8500TS	Table Top Stand
PC	Pole Mount clamp
1000MC	Memory Cable (for use between Model 9847 and a PC running Microsoft Windows 95/98/2000/NT 4.0/XP/Vista operating systems)
UNI-EXT-1	Extension Cable - 3 feet/1 meter
UNI-EXT-3	Extension Cable - 10 feet/3 meters
UNI-EXT-6	Extension Cable - 20 feet/6 meters
UNI-EXT-9	Extension Cable - 30 feet/9 meters
1000RTC	Serial Cable, Memory or Real-Time

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.

WARNING: The use of accessories, sensors, and cables other than those specified may result in increased emission and/or decreased immunity of this device.

WARNING: Use only with NONIN-branded PureLight® pulse oximeter sensors. These sensors are manufactured to meet the accuracy specifications for NONIN Pulse Oximeters. Using other manufacturers' sensors can result in improper pulse oximeter performance.

Troubleshooting

Problem	Possible Cause	Possible Solution
The device won't turn on.	The batteries are depleted.	Replace all 6 batteries.
	The batteries are installed incorrectly.	Verify battery orientation, illustrated inside the battery compartment or on the device label.
The Low Battery indicator is steadily lit or flashing.	The battery level is low or critically low.	Replace all six batteries of the Model 9847.
	An incorrect battery installation.	Verify correct battery orientation.
A dash appears in the leftmost position of the SpO_2 display.	A SpO_2 sensor fault exists (disconnect, failure, misalignment, or incompatibility with the monitor).	Verify that the sensor is correctly connected to the device and the patient; replace sensor if the condition persists.
	A non-compatible SpO_2 sensor is being used.	Replace the sensor with a NONIN-branded Purelight sensor.
The middle digits display dashes in both the SpO_2 and pulse rate displays.	No SpO_2 signal is detected.	Verify the sensor connection.
	A sensor failure.	Replace the sensor with a NONIN-branded Purelight sensor.

Problem	Possible Cause	Possible Solution
The displayed pulse rate does not correlate to the pulse rate displayed on the ECG monitor when used together.	Excessive motion at the sensor site may be prohibiting the device from detecting a consistent pulse signal.	Eliminate or reduce the cause of the motion **or** reposition the sensor to a new sensor site.
	The patient may have an arrhythmia resulting in some heart beats that do not detect a pulse quality signal at the sensor site.	Assess the patient.
	A non-compatible sensor is being used.	Replace the sensor with a NONIN-branded Purelight sensor.
	The ECG monitor may not be functioning properly.	Assess the patient.
An inconsistent Pulse Rate or a yellow Pulse Quality display during the use with electrosurgical unit (ESU).	The ESU may be interfering with the pulse oximeter performance.	Assess the patient. Move the device, cables, and sensors as far away from the ESU as possible.
The Pulse Quality LED is blinking yellow with each pulse.	The quality of the pulse signal at the sensor site is inadequate.	Assess the patient. Reposition sensor **or** select an alternate sensor site.

Problem	Possible Cause	Possible Solution
Pulse Quality LED does not blink green.	Inadequate pulse signal **or** the sensor site is poorly perfused **or** the sensor is not correctly positioned.	Reposition the sensor.
	The sensor is restricting blood circulation at the sensor site.	Remove the restriction to increase blood circulation at the sensor site **or** relocate the sensor.
	Circulation is reduced due to excess pressure between the sensor and a hard surface.	Allow the sensor and the application site to rest comfortably on the surface.
	Excessive ambient light.	Reduce ambient light.
	Excessive patient motion.	Reduce patient motion.
	The patient is wearing nail polish or artificial nails.	Remove nail polish or artificial nails.
	Performance degradation from: • arterial catheter • blood pressure cuff • infusion line.	Reduce or eliminate the source.

Problem	Possible Cause	Possible Solution
The Pulse Quality display is blinking red and the SpO_2 and/or Pulse Rate displays are dashes.	Inadequate pulse signal at sensor site.	Assess the patient. Reposition sensor **or** select an alternate sensor site.
	Inadequate pulse signal due to excessive motion.	Reduce patient motion. Reposition **or** relocate the sensor.
	SpO_2 Sensor failure.	Replace the SpO_2 sensor.
Numeric display segments are missing.	Defective LEDs.	Discontinue use of the device.
The lower CO_2 bar is not illuminated.	The CO_2 sensor is not plugged in.	Plug the CO_2 sensor in.
Only the third and sixth CO_2 bars are illuminated.	The CO_2 sensor has become disconnected.	Reconnect the CO_2 sensor.
	The airway adapter tube is not connected to the CO_2 sensor.	Verify that the airway adapter tube is connected, with windows toward the sensor.
	The light path is blocked.	Replace the airway adapter tube.
	The CO_2 sensor lamp is burned out.	Replace the CO_2 sensor.
Degradation of device performance.	Electromagnetic interference (EMI).	Remove the device from the EMI environment.

Note: If these solutions do not correct the problem with your device, please contact NONIN Technical Service at (800) 356-8874 (USA and Canada) or (763) 553-9968.

Technical Information

NOTE: This product complies with ISO 10993-1, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing.

⚠	**CAUTION:** A functional tester cannot be used to assess the accuracy of a pulse oximeter monitor or sensor.

⚠	**CAUTION:** All parts and accessories connected to the serial port of this device must be certified according to at least IEC Standard EN 60950 or UL 1950 for data-processing equipment.

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

Manufacturer's Declaration

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

Table 6: Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment—Guidance
This device is intended for use in the electromagnetic environment specified below. *The user of this device should ensure that it is used in such an environment.*		
RF Emissions CISPR 11	Group 1	This device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	This device is suitable for use in all establishments, including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	N/A	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	N/A	

Table 7: Electromagnetic Immunity

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

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

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance
This device is intended for use in the electromagnetic environment specified below. *The user of this device should ensure that it is used in such an environment.*			
Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.			
			Recommended Separation Distance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	$d = 1.17\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 1.0 GHz	3 V/m	$d = 1.17\sqrt{P}$ $d = 2.33\sqrt{P}$
	3 V/m 1.0 GHz to 2.5 GHz	3 V/m[a] 0.5 V/md[b]	where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[c], should be less than the compliance level in each frequency range.[d] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTES: • At 80 MHz and 800 MHz, the higher frequency range applies. • These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

a. SpO_2 and HR operate as intended.

b. Breath detection is affected at fields greater than specified level.

c. 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.

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

Table 9: Recommended Separation Distances

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

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

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

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

NOTES:

- At 80 MHz and 800MHz, the separation distance for the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Equipment Response Time

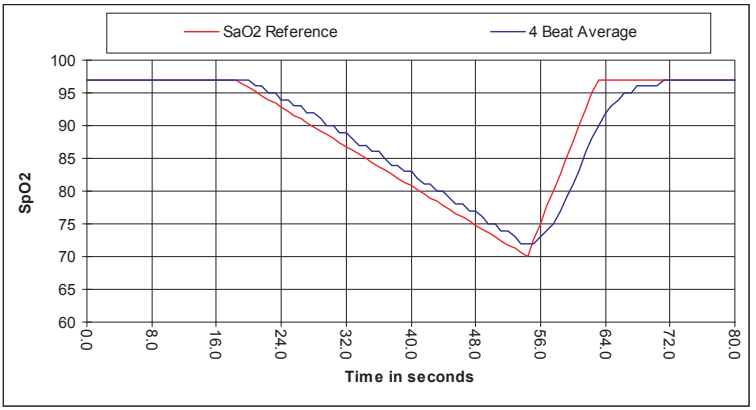
SpO_2 Values	Average	Latency
Standard/Fast Averaged SpO_2	4 beat exponential	2 beats

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

Example - SpO_2 Exponential Averaging

SpO_2 decreases 0.75% per second (7.5% over 10 seconds)

Pulse Rate = 75 BPM



Specific to this example:

- The response of the 4-beat average is 1.5 seconds.

Testing Summary

SpO_2 accuracy, and low perfusion testing was 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% to 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)	
CO_2 Range	0 to >75mmHg	
CO_2 Response Time	250 ms	
Respiration Rate Range	1 to 60 breaths per minute	
Breath Detection Threshold	5 mmHg	
Saturation Declared Accuracy (A_{rms})*	70% to 100%	70% to 95%
No Motion	**Adults / Pediatrics**	**Infants / Neonates**
Finger Clip:	±2 digits	N/A
Flex, Flexi-Form II:	±3 digits	±4 digits
8000R:	±3 digits	N/A
8000Q2:	±4 digits	N/A
8000SX:	±3 digits	±4 digits
Disposables:	±3 digits	±4 digits
Motion		
Finger Clip:	±3 digits	N/A
Low Perfusion		
Finger Clip:	±3 digits	N/A
Flex:	±3 digits	±4 digits
Pulse Rate Declared Accuracy (A_{rms})*	18 to 300 BPM	
No Motion	**Adults / Pediatrics**	**Infants / Neonates**
Finger Clip:	±3 digits	N/A
Flex:	±3 digits	±3 digits
8000R:	±3 digits	N/A
Motion		
Finger Clip:	±5 digits	N/A
Low Perfusion		
Finger Clip:	±3 digits	N/A
Finger Clip, Flex, Flexi-Form II:	±3 digits	N/A

Sensor Families:

Finger Clip Sensors: 8000AA-1, 8000AA-3, 8000AP-1, 8000AP-3
Flex Sensors: 8000J-1, 8000J-3, 8008J, 8001J
Ear Clip Sensors: 8000Q2
Reflectance Sensors: 8000R
Disposable Sensors: 7000A, 7000P, 7000I, 7000N, 7000D, 6000A, 6000P, 6000I, 6000N

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

Δ CO_2 Accuracy of Bar Graph Thresholds	±25% of reading (typical)
Measurement Wavelengths and Output Power**	
Red:	660 nanometers @ 0.8 mW max. avg.
Infrared:	910 nanometers @ 1.2 mW max. avg.
Indicators	
Pulse Quality Indicator:	LED, tricolor
Numeric Displays:	3-digit, 7-segment LEDs, tricolor
CO_2 Bar Graph:	8-segment bar graph, red
Low Battery Indicator:	Dedicated icon, yellow
No Breath Indicator:	Dedicated icon, red
“Audible Alarm Disabled” Indicator:	Dedicated icon, yellow
Audible Indicator:	Miniature speaker
Temperature (Operating)	
Pulse Oximeter:	-20° C to +50°C (-4° F to +122° F)
CO_2 Detector:	0° C to +50°C (32° F to +122° F)
Temperature (Storage/Transportation):	-30° C to +50° C (-22° F to +122° F)
Humidity (Operating)	10% to 95% noncondensing
Humidity (Storage/Transportation):	10% to 95% noncondensing
Altitude (Operating)	Up to 3,000 meters (10,000 feet)
Altitude (Hyperbaric Pressure):	Up to 4 atmospheres
Power Requirements	Six 1.5V AA-size alkaline batteries. 90 hours - Pulse Oximeter only. 20 hours - CO_2 and Pulse Oximeter. 24 hours - CO_2 only.
Dimensions	8 cm W x 15 cm H x 2.5 cm D (3 in W x 6 in H x 1 in D)
Weight	310 g (11 oz) (with alkaline batteries)
Classifications 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
Mode of Operation:	Continuous
Enclosure Degree of Ingress Protection	IP32

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