Operator's Manual

Model 9843

Handheld Pulse Oximeter and Carbon Dioxide (CO_2) Detector

CE 0123

English

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

 Consult Instructions for Use.

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

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

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Indications for Use

The Nonin® Model 9843 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 9843 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.

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 9843 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 9843 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).

Warnings (Continued)

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 in the Parts and Accessories List may result in increased electromagnetic emission and/or decreased immunity of this device.
To avoid patient injury, 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.
To prevent improper performance and/or patient injury, verify compatibility of the monitor, sensor(s), and accessories before use.
No modifications to this device are allowed as it may affect device performance.
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.
As with all medical equipment, carefully route patient cabling to reduce the possibility of entanglement, strangulation, or injury to the patient.
Discontinue use of adhesive tape strips if the patient exhibits an allergic reaction to the adhesive material.
Avoid excessive pressure to the sensor application site as this may cause damage to the skin beneath the sensor.
Do not reuse the Model 9840AAT Airway Adapter Tube.
If the airway adapter tube or airway adapter tube packaging appears or 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.
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 9843 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 9843 CO_2 detector with a humidifier or nebulizer in the breathing circuit, as the fine mist may cause erroneous readings.
The device turns off after approximately 10 minutes when at critically low battery capacity.
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.
Before changing the batteries, make sure the device is off and the sensor is not attached to a digit.

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. 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.
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.
When mounting the monitor to a mobile pole, mounting the monitor higher than 1.5 meters (5 feet) or mounting more than 2 kilograms (4.5 pounds) of equipment onto the pole may results in tipping, damage to the equipment, or injury.
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.
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.

Cautions (Continued)

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.
This equipment complies with IEC 60601-1-2 for electromagnetic compatibility for medical electrical equipment and/or systems. This standard is designed to provide reasonable protection against harmful interference in a typical medical installation. However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in healthcare and other environments, it is possible that high levels of such interference due to close proximity or strength of a source might disrupt the performance of this device. Medical electrical equipment needs special precautions regarding EMC, and all equipment must be installed and put into service according to the EMC information specified.
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.
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.
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.
Radios and cell phones or similar devices can affect the equipment and must be kept at least 2 meters (6.5 feet) away from equipment.
Failure of a network data coupling (serial cable/connectors/wireless connections) will result in loss of data transfer.

Guide to Symbols

This table describes the symbols that are found on the Model 9843 and in this manual.

Table 1 : Symbols

Symbol	Description
	Consult Instructions for Use.
	Follow 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).
	CE Marking indicating conformance to EC Directive No. 93/42/EEC concerning medical devices.
	Authorized Representative in the European Community.
	Manufacturer
Front Panel Buttons	
	ON/Standby
	Advance/Beep Volume Control
	Set-up/Event Marker
Display Indicators	
SpO_2	%SpO_2 Display
	Battery Indicator
	Pulse Rate Display
	Pulse Quality Indicator
ΔCO_2	Change in CO_2 Concentration
	No Alarms

A General Description

Nonin 9843 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 9843 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.

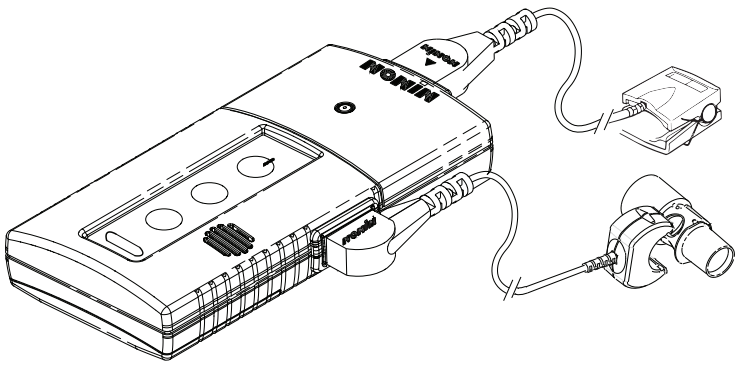


Figure 1: Model 9843 Pulse Oximeter and Carbon Dioxide Detector

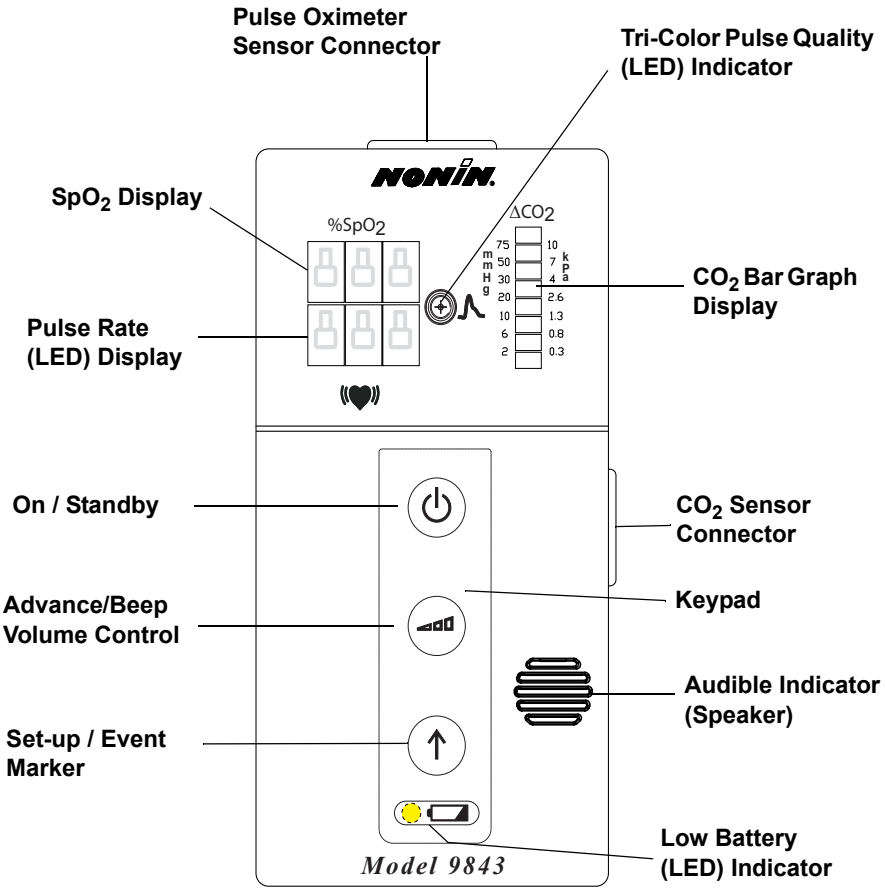


Figure 2: Model 9843 Controls and Indicators

About Pulse Oximetry

9843 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.

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
- 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.

Carbon Dioxide Detector

9843 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:

- the no breath indicator blinks and
- the lowest CO_2 bar graph segment will be illuminated, and CO_2 readings will be displayed with the next breath detected.

Unpacking the Model 9843

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

- 1 Model 9843 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

9843 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
- no patient data displayed

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

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 "Choosing Settings - Calender Setting" on page 15.

Replacing Batteries

WARNING: Before changing the batteries, make sure the device is off and the sensor is not attached to a digit.

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.

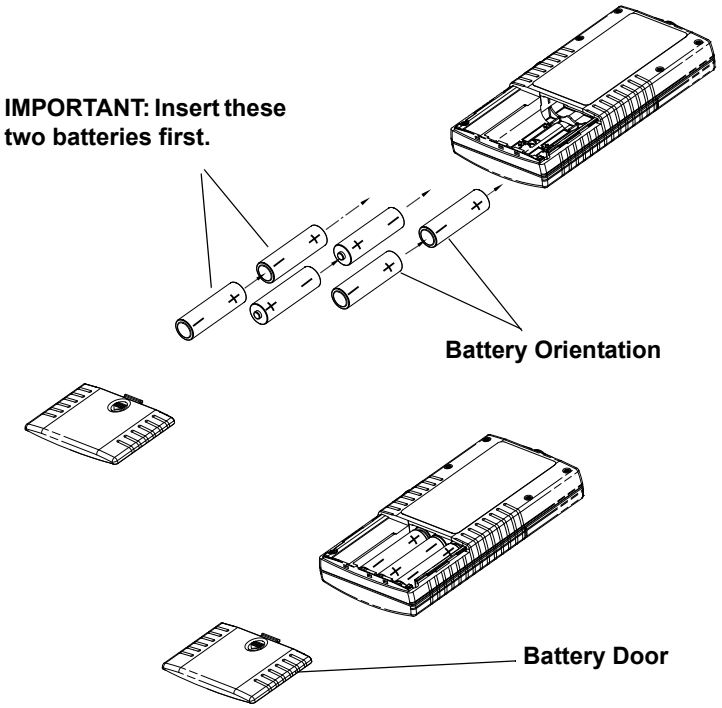


Figure 3: Replacing Batteries - Model 9843, example only

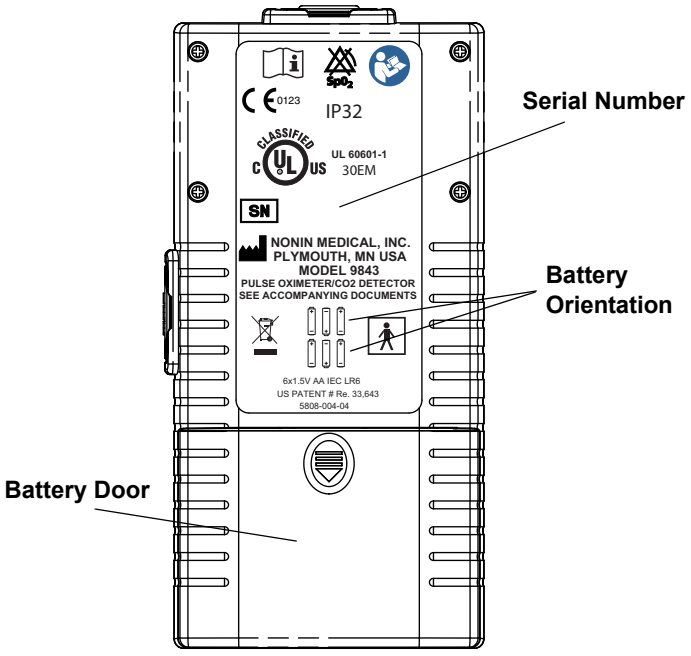


Figure 4: Rear View - Model 9843, example only

When batteries are critically low, the digital displays will go blank, and the Pulse Quality display will blink yellow or red, but not green. After 10 minutes at critically low battery capacity, the pulse oximeter will shut off automatically.

WARNING: The device turns off after approximately 10 minutes when at critically low battery capacity.

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 9843 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 Setting" on page 15 for additional information.
- The memory of the 9843 may be erased when the batteries are removed.
- Replacing batteries may erase the clock settings of the 9843.
- 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/Clock settings (starting on page 15) for more information.
  - 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 the 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. 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 9843 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 below. Verify the sensor is securely connected.

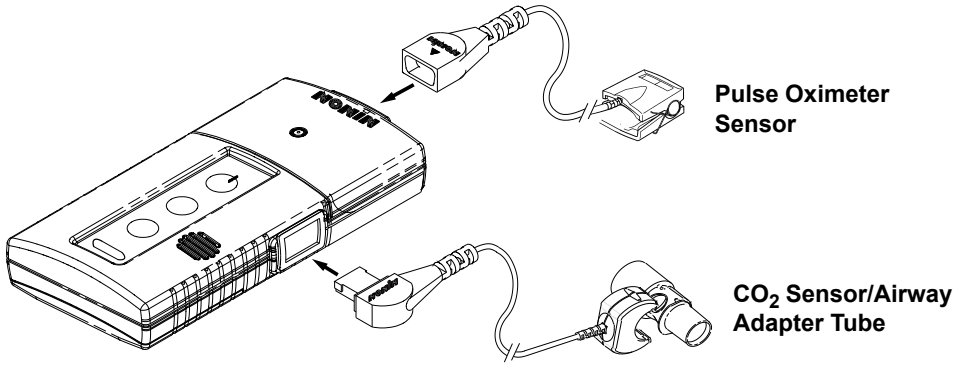


Figure 5: Connecting Sensors to the Model 9843

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 above. 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. To conserve battery life, the device automatically enters standby after 10 minutes of inactivity. Inactivity is indicated by dashes on the displays and may result from an improperly connected or positioned sensor, or from an inadequate patient pulse signal.

Startup Self-Test

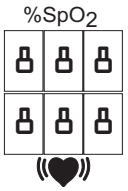
When the device is turned on, the device will cycle through a startup/initialization sequence before displaying valid data. During startup, always check for any missing indicators or LED display segments. If any indicator is not functioning, do not use the device. Contact Nonin Technical Service for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

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

- The audible breath beeps three times.
- The low battery indicator will display for approximately 2 seconds, unless the batteries are low.

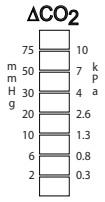
- The pulse quality indicator will blink red, then green. The device will enter standby if no pulse oximeter sensor is connected.

- 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. # (approximately 1 second each).
4. Any sensor connection 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 the year ("y" and 2 digits for the current year).

The CO_2 bar graph sequence is:



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

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 and
- 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).

Setup

All functions of the 9843 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.

NOTE: After 10 minutes of no SpO_2 or breath detection, the device will automatically revert to standby mode.

Setup Mode

Setup mode is used to set the calendar, and the internal time-of-day clock. In setup mode, the set-up/event marker 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, press and hold the set-up/event marker button.
2. Release the set-up/event marker button when "88 88" is displayed on the SpO_2 and pulse rate displays. Three brief beeps will sound, and "y" along with 2 digits (for current year) will appear in the SpO_2 and pulse rate displays.

NOTE: You may exit setup mode at any point and save your current changes (without stepping through the remainder of the setup mode menu options). Complete the desired selections, then turn off the 9843.

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, the year (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 set-up/event marker button to store the value and advance the SpO_2 display to the next sequential parameter as listed in Table 2.
3. Continue this process until all parameters are set.

When the setting sequence has been completed, the 9843:

a. exits the setup mode, and

b. begins normal operation.

The settings can be easily checked, since the first value displayed for each parameter represents the current setting.

Table 2 : Calendar and Clock Mode Parameters

Parameter	Appears in SpO_2 Display	Pulse Rate (♥) Display Range of Values	Default Value
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

Choosing Settings

Calendar Setting

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 setting.

Clock Setting

1. After the calendar setting 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:
   a. exit the setup mode, and
   b. begin normal operation.

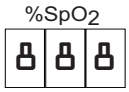
Visible Indicators

Refer to Figure 2 on page 6 for a detailed illustration of the 9843 controls and indicators.

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

SpO_2 Display

The SpO_2 display is the upper numeric display. This 3-digit light-emitting diode (LED) display shows the current oxygen satura6tion percentage.



Pulse Rate Display

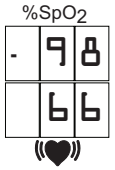
The pulse rate display is the lower numeric display. This 3-digit LED display shows pulse rate in pulses per minute.

Dashes in the SpO_2 and Pulse Rate Displays

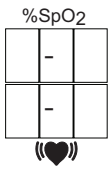
A pulse oximeter sensor fault will occur if the 9843 pulse oximeter detects:

- 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.



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



Blinking SpO_2 and Pulse Rate Displays

When the SpO_2 or pulse rate limits are met or exceeded, the numerical values of the corresponding parameter will blink.

Pulse Quality Indicator

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

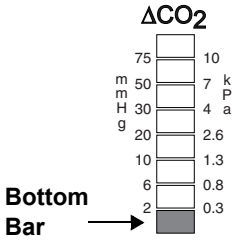
The pulse quality indicator blinks once for each pulse while measuring oxygen saturation. The pulse quality indicator changes color to indicate changes in the pulse waveform signal that may affect the SpO_2 data.

The pulse quality indicator may blink one of three colors:

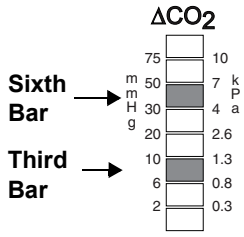
- **Green** indicates that the pulse waveform signal is of good quality and the SpO_2 and pulse rate data are accurate.
- **Yellow** indicates that the pulse waveform amplitude is marginal or that the pulse oximeter has detected artifact. Although the SpO_2 and pulse rate data may be acceptable, corrective 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. After approximately 20 seconds, the values are replaced with dashes indicating that SpO_2 and pulse rate measurements are not possible.

CO_2 Bar Graph

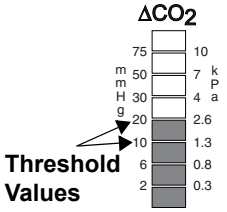
The CO_2 bar graph will remain blank until the CO_2 sensor is plugged in. When an airway adapter tube is connected to the CO_2 sensor and an adequate signal is detected, the bottom bar is initially illuminated. The bars will be illuminated to indicate the change in CO_2 level as the patient exhales and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



If a CO_2 sensor fault exists, the third and sixth bars of the CO_2 bar graph will be illuminated. When the CO_2 sensor fault is corrected, the CO_2 bar graph will return to normal operation.



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 $\geq$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 is lit.

When batteries are critically low:

- the 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 9843.

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

Audible Indicators

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

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 “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 9843 is turned on, the audible breath beep will default to the medium sound volume setting. During normal operation, pressing the set-up/event marker button cycles the audible breath beep sound volume between low, medium, high, and off. A “volume” beep will sound and advance to the next volume level each time the set-up/event marker button is pressed.

CO_2 Sensor Indicator

CO_2 sensor fault may be caused by the following:

- 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 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 17.) The visible CO_2 sensor indicators will stop when the condition is corrected.

Carbon Dioxide (CO_2) Sensor and Airway Adapter Tube

WARNING: Do not use the Model 9843 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 9843. 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.

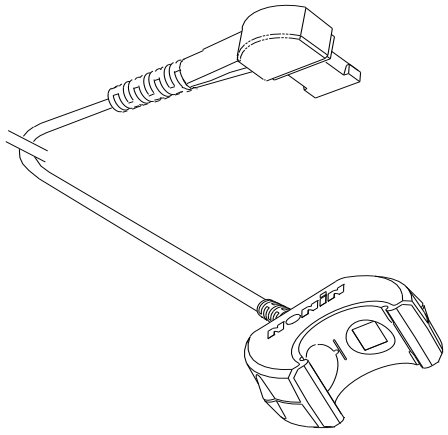


Figure 6: Model 9840SA Carbon Dioxide Sensor

Airway Adapter Tube

WARNING: Do not use the Model 9843 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), which 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 below) 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.

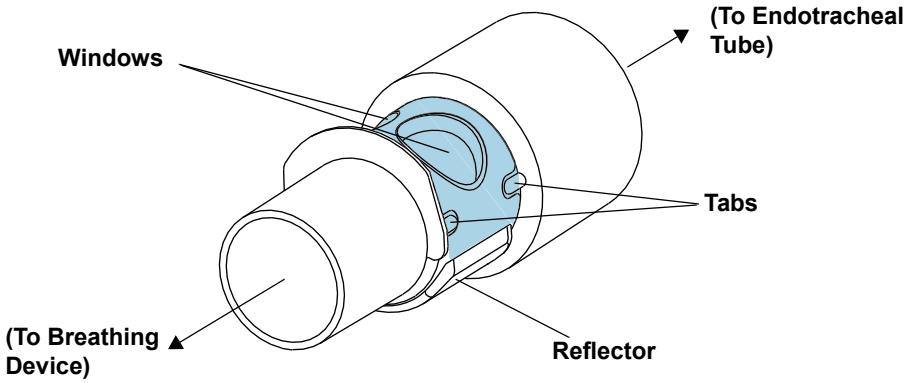


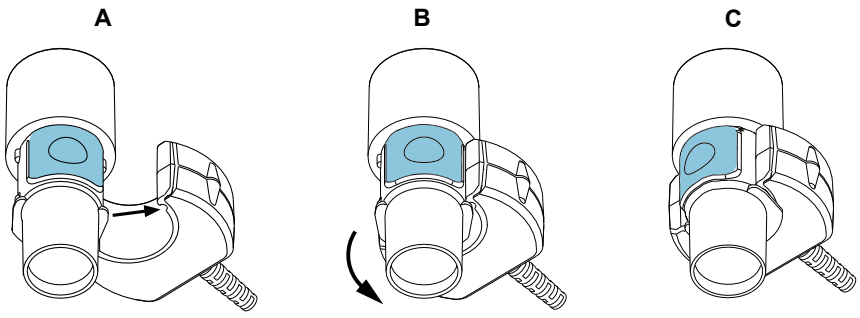
Figure 7: Model 9840AAT Airway Adapter Tube

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 8-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.

2. Join the tabs on one side of the airway adapter tube onto either side of the CO_2 sensor (Figure 8-A), then rotate the airway adapter tube (Figure 8-B) and push firmly to set the other pair of tabs. You should hear a clicking sound as the pieces are connected together (Figure 8-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.

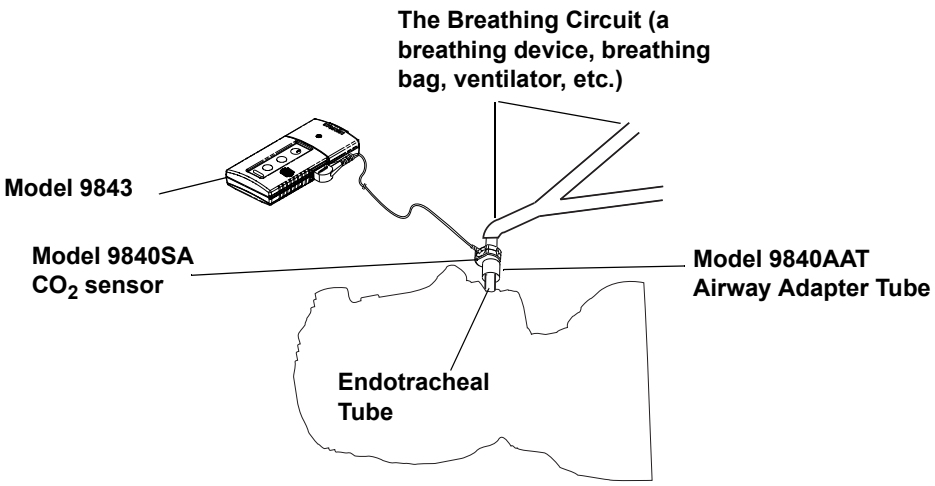


Figure 9: The Airway Adapter Tube and the Breathing Circuit

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 9843 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 9843 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.

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

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 9843 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 1 minute in length are kept in memory for later printing.

Memory Playback Mode

1. With the unit off, press and hold the set-up/event marker button while pressing and then releasing the on/standby button.
2. Release the set-up/event marker button when "888 888" is displayed on the SpO_2 and pulse rate displays. Three brief beeps will sound and the year will 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 zeros and the start times for that file will then not match up.

Communications

Real-Time Serial Output

The 9843 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.

Table 3 : 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 6 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.

Connecting the Device into a Medical System

Incorporating the device into a medical system requires the integrator to identify, analyze, and evaluate the risks to patient, operators, and third parties. Subsequent changes to the medical system after device integration could introduce new risks and will require additional analysis. Changes to the medical system that must be evaluated include:

- Changing the system configuration
- Adding devices to or disconnecting devices from the system
- Updating or upgrading equipment connected to the system

Issues resulting from user-initiated system changes may include corruption or loss of data.

NOTES:

- When using the serial port to connect the device to other equipment, follow each device's cleaning instructions.
- Verify all equipment connected to the device is suitable for the patient's environment.

CAUTION: Failure of a network data coupling (serial cable/connectors/wireless connections) will result in loss of data transfer.

Service, Support and Warranty

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

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 9843 requires no periodic maintenance or calibration. Nonin does not recommend field repair of the Model 9843.

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

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

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

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

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

nonin.com

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 9843 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 9843 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 9843 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 9843 delivered to the purchaser which is found to be defective in any manner whether such remedies be in contract, tort or by law.

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

The Model 9843 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 9843, field service by non-Nonin personnel, tampering, or any kind of misuse or abuse of the Model 9843, 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.

Parts and Accessories

For more information about Nonin parts and accessories:

- See the Parts and Accessories List on the Operator's Manual CD.
- Contact your distributor or Nonin at (800) 356-8874 (USA and Canada), +1 (763) 553 9968, or +31 (0)13 - 79 99 040 (Europe).
- Visit www.nonin.com

Detailed information regarding specific sensor use (patient population, body/tissue, and application) can be found in the respective sensor Instructions for Use.

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

WARNING: To avoid patient injury, 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 Battery Low indicator is steadily lit or flashing.	The battery level is low or critically low.	Replace all six batteries of the 9843.
	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.
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.

Problem	Possible Cause	Possible Solution
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.
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 comfortable 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.

If these solutions do not correct the problem with your device, please contact Nonin Technical Service at (800) 356-8874 (USA and Canada), +1 (763) 553-9968, or +31 (0)13 - 79 99 040 (Europe).

Technical Information

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

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

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

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

Manufacturer's Declaration

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

Table 4 : 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 5 : 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 6 : 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 7 : Recommended Separation Distances

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

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

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

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

NOTES:

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

Equipment Response Time

If the signal from the sensor is inadequate, the last measured SpO_2 and pulse rate values freeze for 10 seconds and are then replaced with dashes.

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

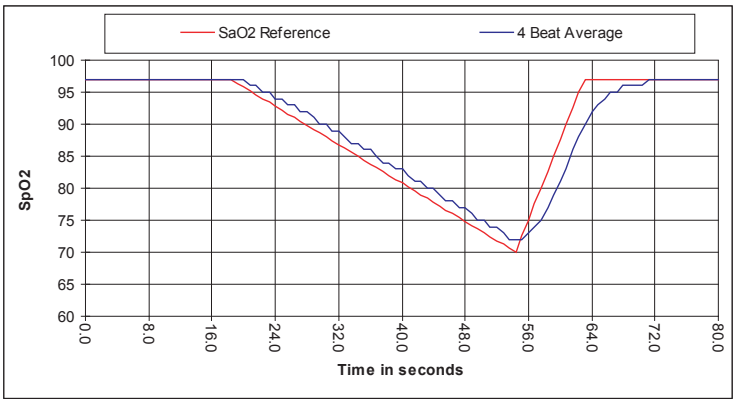
Pulse Rate Values	Response	Latency
Standard/Fast Averaged Pulse Rate	4 beat exponential	2 beats

Equipment Delays	Delay
Display Update Delay	1.5 seconds

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 - 100%. Accuracy data is calculated using the root-mean-squared (A_{rms} value) for all subjects, per ISO 80601-2-61, Medical Electrical Equipment—Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use.

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 80601-2-61 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 80601-2-61 for heart rate and SpO_2 at the lowest obtainable pulse amplitude (0.3% modulation).

Principles of Operation

Pulse oximetry is a non-invasive method that passes red and infrared light through perfused tissue and detects the fluctuating signals caused by arterial pulses. Well-oxygenated blood is bright red, while poorly oxygenated blood is dark red. The pulse oximeter determines functional oxygen saturation of arterial hemoglobin (SpO_2) from this color difference by measuring the ratio of absorbed red and infrared light as volume fluctuates with each pulse.

Specifications

Oxygen Saturation Display Range	0% to 100% SpO_2
Pulse Rate Display Range	18 to 321 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
Accuracy – Sensors	Declared accuracy data for compatible sensors can be found in Nonin's Sensor Accuracy document.
ΔCO_2 Accuracy of Bar Graph Thresholds (A_{rms})*	±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, red
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):	-40 °C to +70 °C (-40 °F to +158 °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.

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

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

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 / UL 60601-1	
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 device is not made with natural rubber latex.