



Operator's Manual

**Models 8600 & 8600M
Pulse Oximeters**

CAUTION! Federal law (USA) restricts this device to sale by or on the order of a physician.

CAUTION! Read this manual carefully before using the 8600.

The information in this manual has been carefully checked and is believed to be accurate. In the interest of continued product development, 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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Nonin is a registered trademark of Nonin Medical, Inc.
References to "8600" in this manual shall imply Models 8600 and 8600M.

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Authorized EC Representative:
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Guide to Symbols



ATTENTION: Consult Accompanying Documents



CE Marking indicating conformance to EC directive No. 93/42/EEC concerning medical devices



UL Mark for Canada and the United States with respect to electric shock, fire, and mechanical hazards only in accordance with UL 2601-1 and CAN/CSA C22.2 No. 601.1.

Precautions For Use

Contraindications

- Do not operate the 8600 in an explosive atmosphere.
- Do not operate the 8600 in an MRI environment.
- Do not use the 8600 for home healthcare. The 8600 alarms can easily be turned off, and the alarm settings can easily be modified.

Warnings

- The 8600 is intended as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.
- Do not set the alarm volume too low to be heard. Doing so could compromise patient safety.
- The audible alarm of the 8600 is for the convenience of the attendant near the patient. It is not intended to call an attendant from another room or from a distance. The user must determine the audible distance based on the operating environment.
- The use of supplemental oxygen with premature infants has been associated with an increased incidence of retinopathy of prematurity and bronchopulmonary dysplasia. The SpO₂ high alarm setting must be chosen with regard to accepted clinical standards.
- Use only NONIN manufactured sensors. These sensors are manufactured to meet the calibration requirements for NONIN pulse oximeters. Use of other manufacturer's sensors may cause improper pulse oximeter performance.
- Check application site **frequently** to determine 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.
- Use of NONIN double-backed adhesive strips or the Hydrogel tape strips should be discontinued if the patient exhibits allergic reactions to the adhesive material.
- Do not stretch the adhesive tape while applying the sensors. This may cause inaccurate readings or skin blisters.
- 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 listed in this manual may result in increased emission and/or decreased immunity of this device.

Cautions

- This equipment complies with International Standard EN 60601-1-2:2001 for electromagnetic compatibility for medical electrical equipment and/or systems. This standard is designed to provide reasonable protection against harmful interference in a typical medical installation. However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in healthcare and other environments, it is possible that high levels of such interference due to close proximity or strength of a source might disrupt the performance of this device. Medical electrical equipment needs special precautions regarding EMC, and all equipment must be installed and put into service according to the EMC information specified in this manual.
- Portable and mobile RF communications equipment can affect medical electrical equipment.
- Federal law (USA) restricts this device to sale by or on the order of a physician.
- Carefully read this manual and the instructional insert provided with the sensor before use of the 8600.
- Ear Clip and Reflectance sensors are not recommended for pediatric or neonatal use. The accuracy of the sensors has not been established for pediatric or neonatal use.
- Remove earrings from the patient's ear before applying the Ear Clip Sensor.
- The 8600 must be able to measure the pulse properly to obtain accurate SpO₂ measurement. Verify that nothing is hindering the pulse measurement before relying on the SpO₂ measurement.
- Inaccurate SpO₂ and/or pulse rate measurement may result if the 8600 is operated in a low battery condition
- Fingernail polish may reduce light transmission and thereby affect SpO₂ accuracy.
- The 8600 may not work on all patients. If you are unable to achieve stable readings, discontinue use.
- The 8600 may interpret motion artifact of sufficient amplitude and regularity as good perfusion (green).
- The 8600 is calibrated to determine the percentage of arterial oxygen saturation of functional hemoglobin. Significant levels of dysfunctional hemoglobin such as carboxyhemoglobin or methemoglobin may affect the accuracy of the measurement.
- Cardiogreen and other intravascular dyes, depending on the concentration, may affect the accuracy of the SpO₂ measurement.
- Do not immerse the 8600 or NONIN sensors in liquid to clean.
- Do not use caustic or abrasive cleaning agents on the 8600 or NONIN sensors.
- This device has not been tested for immunity to electromagnetic disturbances.
- The 8600 is sensitive and must be repaired by knowledgeable and specially trained personnel only.

Manufacturer's Declaration

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

Table 1: Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment— Guidance
<p><i>This device is intended for use in the electromagnetic environment specified below. The customer and/or user of this device should ensure that it is used in such an environment.</i></p>		
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	

Unpacking Your Pulse Oximeter

Contact the carrier immediately if the shipping carton for the 8600 is damaged. Carefully unpack the pulse oximeter and its accessories. Confirm that the items listed below are packed with the 8600 Pulse Oximeter. The 8600/8600M shipment includes:

- 8600 or 8600M Pulse Oximeter
- A/C Battery Charger
- Operator's Manual for Models 8600 and 8600M
- 8800I Patient Interface Cable
- 8000AA-1 Sensor (Adult Articulated Finger Clip)

If any item on this list is missing or damaged, do not use the pulse oximeter. Contact your local distributor or, if you do not know your local distributor, contact NONIN at (800) 356-8874 or (763) 553-9968.

Introduction



Indications For Use

The 8600 Pulse Oximeter is intended to be used to monitor oxygen saturation and pulse rate for adult, pediatric, and neonatal patients in hospital, ambulatory, and EMS environments.

General

The 8600 Pulse Oximeter is small, light weight, and is intended to be portable. It has audible and visual alarms for monitoring patient status. The 8600 may be connected to A/C power or run from its internal battery. It typically operates for 30 hours on a fully charged battery. **The 8600 requires no routine calibration or maintenance.**

The 8600 determines arterial oxyhemoglobin saturation (SpO₂) by measuring the absorption of red and infrared light passed through 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 are displayed on light emitting diode (LED) digital displays. On each detected pulse, the perfusion () indicator flashes. Patient perfusion signals are graded as good, marginal, or inadequate and are indicated by the  indicator flashing 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.





Sensor disconnect or malfunction is indicated by lack of good perfusion flashes and/or the red **SENSOR** indicator on the front panel illuminating. Ultimately, if adequate perfusion pulses are not received, the SpO₂ and pulse rate numerical values will be replaced by dashes.

The 8600 Pulse Oximeter has been approved by the U.S. Air Force for use in the U.S.A.F. aeromedical evacuation environment when operating on its internal battery or with the NONIN Model 7708 A/C Battery Charger.

Operating Instructions

Battery Charging

If portable operation is not necessary, continuously charging with the proper battery charger is recommended. The battery charger plugs into the back of the 8600 where it is marked "BATTERY CHARGER". Refer to Figure II for illustration. This will assure a fully charged battery should portable operation be required.

The battery charger requires 15 hours to recharge a completely depleted battery pack. While the battery charger is connected to AC power, the green  indicator will be illuminated, and the pulse oximeter may be operated during this time if the red  indicator is not illuminated when the unit is turned on. If the red  indicator is illuminated when the unit is turned on, the battery must charge until the red  is no longer illuminated before it may be used.

The battery pack in the 8600 will typically power the unit for 30 hours with a full charge without needing to be charged.

The 8600 indicates when the battery is low by illuminating the  indicator in red.

NOTE: The Nonin Model 7708 Battery Charger must be used in place of other NONIN battery chargers to meet U.S. Air Force requirements for the U.S.A.F. aeromedical evacuation environment


Connecting the Cable and Sensors

Connect the patient interface cable (Model 8800I) to the 8-pin female latching connector on the front of the 8600 shown in Figure I. Connect the sensor to the patient interface cable. Position the appropriate sensor on the patient. If additional cable length is necessary, connect the Model 8604X-10, -20, or -30 Extension Cable or the Model 8500I Patient Extension Cable between the sensor and the 8800I.

Turning On The Pulse Oximeter

Turn on the 8600 by pressing the " I " power switch on the front of the pulse oximeter. Refer to Figure I.

When the 8600 is turned on, the displays will cycle through the following sequence before displaying valid data:

- "888 888" (8600) or "888 888" (8600M)
- current time in hours and minutes saved in memory
- software revision number
- " ■ ■ "
- SELF TEST indicator illuminates
- SENSOR indicator illuminates
-  indicator illuminates

NOTE: If this sequence does not complete properly, do not use the pulse oximeter. Contact Nonin Customer Support.

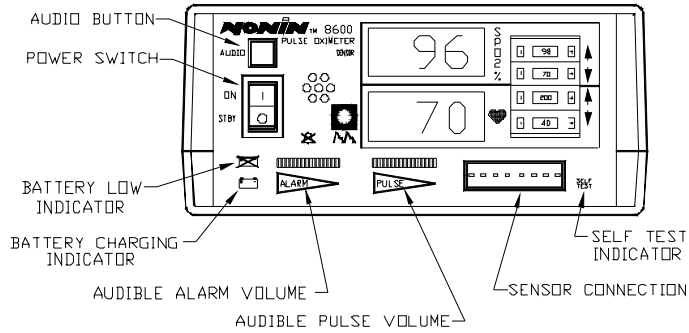


Figure 1: Front View of the 8600

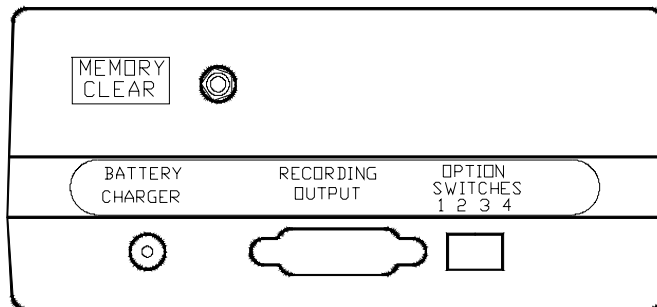


Figure 2: Rear View of the 8600

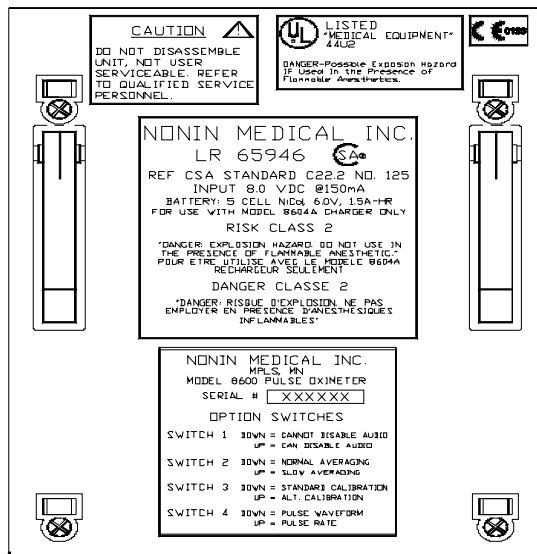






Figure 3: Labels on the 8600

Verifying Operation

CAUTION! The 8600 must be able to measure the pulse properly to obtain accurate SpO₂ measurement. Verify that nothing is hindering the pulse measurement before relying on the SpO₂ measurement.

Verify that the sensor is properly positioned. Ensure the system is sensing adequate perfusion by observing that the  indicator is blinking green and correlates to the pulse rate for 10 seconds. Should the perfusion light be red or yellow or flashing erratically, reposition the sensor or try a different sensor.

For the first 2 minutes of operation, the  indicator will flash to indicate the audible alarm is temporarily disabled during power on. During the first two minutes, the audible alarm may be enabled by pressing the **AUDIO** button. If the audible alarm is not permanently disabled, the  indicator will not be illuminated after the first 2 minutes of operation and the audible alarm will be enabled.

If the alarm is permanently disabled, the  indicator will illuminate continuously, and pressing the **AUDIO** button will not have no effect on the audible alarm.

Cleaning the Pulse Oximeter

CAUTION! Do not immerse the 8600 in liquid, and do not use caustic or abrasive cleaning agents.

The 8600 Pulse Oximeter may be cleaned with a mild detergent and a soft cloth or with an isopropyl alcohol wipe. Allow enough time for the 8600 to dry thoroughly before reusing.

Features

Controls

All functions of the 8600 are controlled by switches found on the front and rear of the unit. Refer to Figures I and II for illustrations of these switches.

Power Switch

Pressing the power switch ON (" I ") causes power to be applied to all internal circuitry. Pressing the power switch to STBY (" O ") causes power to be removed from the displays and puts the pulse oximetry circuitry into a low power standby mode.

AUDIO Button

The **AUDIO** button has 4 different functions, which are described below.

Function	Activation Instructions
<i>Audible Alarm Enable/Disable</i>	Momentary press during normal operation
<i>Calibrate Recorders</i>	Hold for more than 5 seconds during normal operation
<i>Memory Playback (8600M only)</i>	Hold for less than 2 seconds during power up
<i>Real-time Setup Mode</i>	Hold for more than 2 seconds during power up

Audible Alarm Enable/Disable

Momentarily pressing the **AUDIO** button disables the audible alarm for 2 minutes. Pressing this button again will override the 2 minute period, re-enabling the audible alarm.

NOTE: Pressing this button has no effect if the audible alarm has been permanently disabled.

Calibrate Recorders

When using a strip-chart recorder for outputting data, calibration between the recorder and the 8600 may be necessary. To do this during normal operation, hold the **AUDIO** button for more than 5 seconds to activate the recording output calibrate sequence. You can select the calibration sequence with Option Switch 3.

NOTE: Calibration signals are sent via the SpO2 and pulse rate lines; not the serial output line.

Standard Calibration:

The value sent for the SpO2 will alternate from 0% (for 5 seconds) to 100% (for 6 seconds) to 50% (for 5 seconds) and then repeat. The value sent out for the pulse rate will alternate from 0 BPM to 125 BPM to 250 BPM and then repeat. To end calibration sequence, release the **AUDIO** button, and the 8600 will return to normal operation.

Alternate Calibration:

The value sent for the SpO2 will step through at 5% intervals when actuated by the user by pressing the **AUDIO** button beginning at 0% through 100% and then repeat. The value sent out for the pulse rate will remain at 60 BPM. To end calibration sequence, hold the **AUDIO** button for 5 seconds, and the 8600 will return to normal operation.

Memory Playback (8600M Only)

To place the 8600M in playback mode, hold the **AUDIO** button while turning on the unit and release within 2 seconds. Memory playback is automatically initiated. While data is being played back, the SpO₂ display will show the hour of data being played back, and the ♥ display will show the minutes as they count down. Data is output as last data in is first data out.

NOTE: Memory playback does not clear the memory of the 8600. Data may be played back multiple times if desired.

Real-Time Setup Mode

To set up the real-time settings, hold the **AUDIO** button for more than 2 seconds on power on. “P r n” will appear in the upper LED display, indicating print setup mode. The 8600 automatically advances to the clock setting mode. Pressing the **AUDIO** button increments the number in the lower LED display. It starts with the current value stored in memory for that particular parameter. When the correct value appears in the lower display, release the **AUDIO** button and wait for the 8600 to advance to the next parameter, as listed in the table below. This process is continued until all parameters are set. The settings can be easily checked, since the first value displayed for each parameter represents the current setting. When the setting sequence has been completed, the 8600 exits the setup mode and begins normal operation.

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

NOTE: Clock parameters are not stored until all 5 parameter settings have been entered and the 8600 has automatically exited the clock setting mode and returned to normal operation.

Sequence	Appears in SpO ₂ Display	Range of Values	
		From	To
Printer	P r n	00	15
Year	y	00	99
Month	nn	00	12
Day	d	01	31
Hours	h	00	23
Minutes	nn	00	59

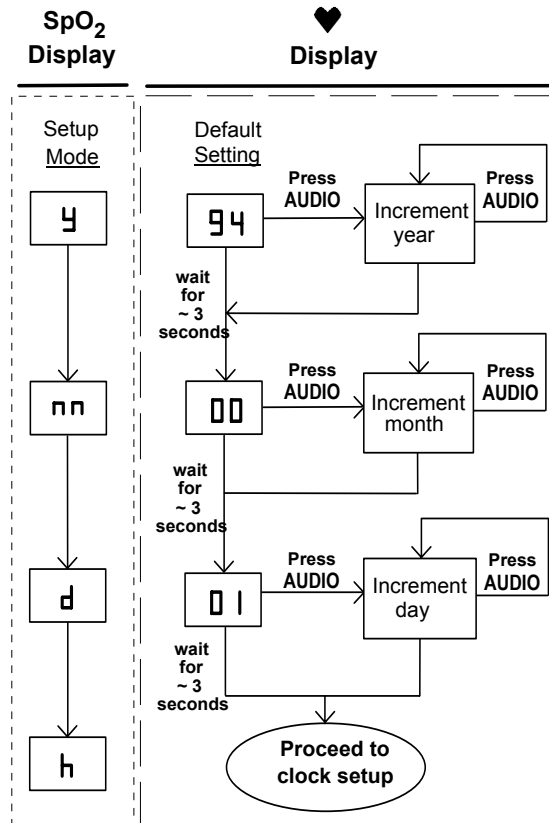
Printer Settings

Prn will appear in the SpO₂ display indicating print setup mode. This option is not available at this time. Release the **AUDIO** button and wait for approximately 3 seconds for the 8600 to automatically advance to the calendar settings (refer to the next section).

NOTE: There are 16 settings available for future expansion of the printer settings. Setting for the printer for any one of these values will have no effect on the 8600.

Calendar Settings

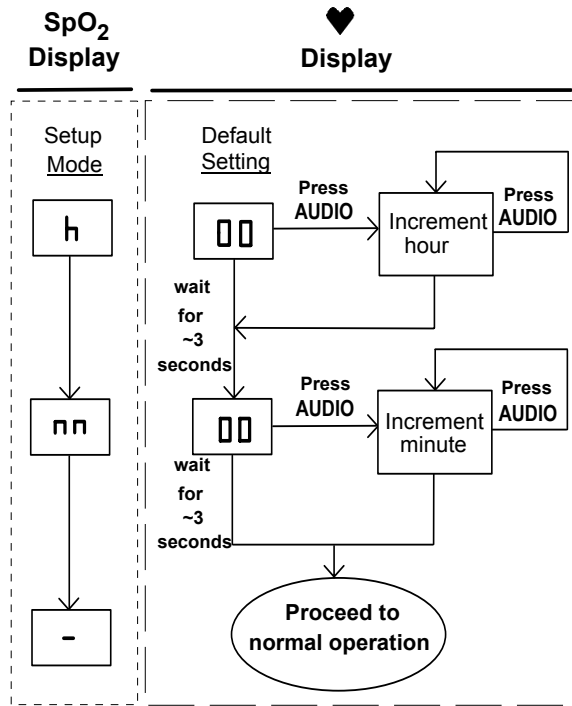
After the printer setting has been displayed in the setup mode, **y** will appear in the SpO₂ display, indicating calendar setup mode for the year. Press the **AUDIO** button momentarily to advance through the values. The year may be set to **00** through **99**. After selecting the year, wait for approximately 3 seconds for the display to show **nn** indicating the setup mode for the month. The month may be set to **00** through **12** using the **AUDIO** button. 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**. When the calendar setting sequence has been completed, the 8600 continues to the clock settings (refer to next section).



Flow Chart for Setting Calendar

- Clock Settings

After the calendar settings have been determined in the real-time setup mode, **h** will appear in the SpO₂ display, indicating the hour. The time is set in a 24-hour format. The hour may be set to **00** through **23**. After selecting the hour, the display will show **nn** indicating the minutes. The minutes may be set to **00** through **59**. After selecting the minutes, the display will return to normal operation.



Flow Chart for Setting Clock

Patient Alarm Limits

Set the patient alarm condition switches located on the front of the 8600 to the attending physician's recommendations. These values may be changed at any time and will take effect immediately.

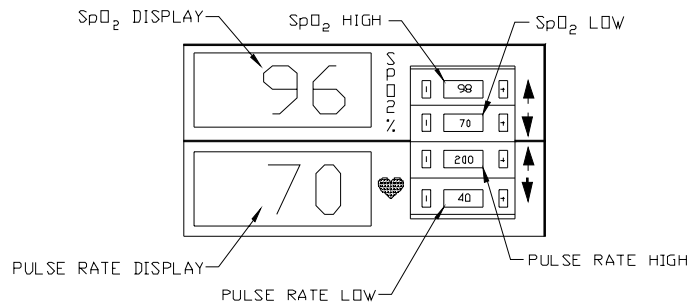




Figure 4: Patient Alarm Display

Patient Alarm	Alarm Values
SpO₂ High	85, 90, 92, 94, 95, 96, 97, 98, 99, OFF
SpO₂ Low	55, 60, 65, 70, 75, 80, 85, 86, 87, 88, 89, 90, 91, 92, 95, OFF
Pulse Rate High	75, 100, 125, 150, 175, 200, 225, 250, 275, OFF
Pulse Rate Low	30, 40, 50, 60, 70, 80, 90, 100, 110, OFF


SpO₂ High Limit



CAUTION! The use of supplemental oxygen with pre-mature infants has been associated with an increased incidence of retinopathy of pre-maturity and bronchopulmonary dysplasia. The SpO₂ high alarm setting must be chosen with regard to accepted clinical standards.

The button labeled with the  next to the SpO₂% display sets the high SpO₂ alarm limit. The available values for the SpO₂ high alarm are provided in the preceding table. An alarm condition exists if the SpO₂ level is at or above the chosen SpO₂ high limit level



- Press the  button to the left of the number to decrease value.
- Press the  button to the right of the number to increase value.



SpO₂ Low Limit

The button labeled with the  next to the SpO₂% display sets the low SpO₂ alarm limit. The available values for the SpO₂ low alarm are provided in the preceding table. An alarm condition exists if the SpO₂ level is at or below the chosen SpO₂ low limit level



- Press the  button to the left of the number to decrease value.
- Press the  button to the right of the number to increase value.



Pulse Rate High Limit

The button labeled with the  next to the  display sets the high pulse rate alarm limit. The available values for the pulse rate high alarm are provided in the preceding table.


- Press the  button to the left of the number to decrease value.
- Press the  button to the right of the number to increase value.

Pulse Rate Low Limit


The button labeled with the  next to the  display sets the low pulse rate alarm limit. The available values for the pulse rate low alarm are provided in the preceding table.

- Press the  button to the left of the number to decrease value.
- Press the  button to the right of the number to increase value.

Pulse Volume

The 8600 may be set such that it will emit a short tone for each pulse detected. Turn the pulse volume control, marked with the  symbol, until an audible pulse is heard with each beat. The tone will change pitch as the SpO₂ level changes. The pitch is lower in frequency with lower SpO₂ levels. A noticeably higher pitched tone is heard if the unit loses track of the pulse signal.

Alarm Volume

Adjust the alarm volume intensity by rotating the thumbwheel volume control on the front of the 8600 marked with the  symbol. The OFF position is only effective when option switch 1 is in the up position. The option switches are located on the rear of the 8600.

NOTE: **Nonin does not recommend disabling the audible alarm when monitoring in critical situations.**

To generate an alarm for test purposes, momentarily disconnect the patient cable assembly from the monitor. Press the latches and pull the connector out. This will generate a sensor alarm. The **SENSOR** indicator will illuminate. The audible alarm will sound provided the alarm volume control is not disabled, and option switch 1 is not in the up position, and the two minute audible disable period is not active.

Option Switches

Refer to Figure 2 for the location of the option switches.

Option Switch 1

This switch controls the audible alarm OFF capabilities.

- down: *Audible Alarm May Not Be Disabled*
Prevents audible alarm from being permanently disabled by the user
- up: *Audible Alarm May Be Disabled*
Allows the audible alarm to be permanently disabled by the user via the alarm volume dial turned to OFF

Option Switch 2

This switch controls the rate of averaging of the pulse rate and SpO₂ data.

- down: *Fast Response Mode*
Pulse rate has an 8-beat averaging and the SpO₂ has a 4-beat exponential average
- up: *Slow Response Mode*
Pulse rate has an 16-beat averaging and the SpO₂ has a 8-beat exponential average

Option Switch 3

Option switch 3 controls the analog output sequence for calibration of strip chart recorders.

NOTE: This switch has no effect if you are not using the analog communications (strip chart recorders).

- down: *Standard Calibration Sequence*
Output analog values step from 0% to 100% to 50%
- up: *Alternate Calibration Sequence*
Output analog values step from 0% to 100% in increments of 5%, and then to 127% for out-of-range

Option Switch 4

Option switch 4 controls the analog output format to pin 13 of the output connector.

- down: *Analog Pulse Waveform:*
Output analog (0 - 1 VDC) waveform for the pulse rate
- up: *Analog Pulse Rate:*
Output analog (0 - 1 VDC) value for pulse rate in the range of 0 to 250 pulses per minute

MEMORY

CLEAR Button (8600M Only)

The data within the internal memory is retained until it is cleared or overwritten by new data. To clear the internal memory the pulse oximeter is first placed in the "memory output mode." Once the Memory Output Mode is entered, the memory is cleared by pressing and holding the **MEMORY CLEAR** button located on the rear of the monitor for a minimum of 5 seconds. This will cause the 8600M to count quickly through all its memory locations, clearing each one.

NOTE: Pressing the **MEMORY CLEAR button during normal operation will not clear the memory.**

Visual Indicators


SpO₂ Display

The upper digital display is a 3-digit light emitting diode (LED) digital display that displays oxygen saturation percentage.

♥ (Pulse Rate) Display

The lower digital display is a 3-digit LED digital display that displays pulse rate in pulses per minute.



⚡ (Perfusion) Indicator



The perfusion indicator (identified by the waveform symbol ) will flash once for each pulse while measuring oxygen saturation. The perfusion indicator changes color to indicate changes in the pulse waveform signal that may affect the SpO₂ data.

The perfusion indicator may blink one of three colors: green, yellow, or red:

- **Red** indicates the pulse amplitude is too small. During red perfusion, SpO₂ and pulse rate values are not updated. After twenty seconds, the values are replaced with dashes indicating SpO₂ measurement is not possible.
- **Yellow** indicates the pulse waveform amplitude is marginal or the pulse oximeter has detected artifact. Although SpO₂ data is acceptable, corrective measures should be considered to improve sensor placement, change sensor type, or reduce patient movement. After 90 seconds of yellow perfusion, the 8600 will go into sensor alarm mode.
- **Green** indicates the pulse waveform signal is of good quality and SpO₂ data is accurate.

⊗ (Audible Alarm Inactive) Indicator

- The  indicator continuously illuminated indicates audible alarms are **permanently disabled**.
- The  indicator flashes at once a second when the audible alarms are **temporarily disabled**.

This indicator is a yellow  indicator that flashes when the audible alarm is temporarily disabled. The  indicator will illuminate continuously if the audible alarm has been permanently disabled via option switch 1 and the alarm volume OFF.

SENSOR Indicator

The **SENSOR** indicator continuously illuminated indicates there is a sensor alarm. This is caused by the system determining that the sensor is disconnected, damaged, or dislodged. When a sensor fault is found, the red **SENSOR** indicator illuminates and the audible alarm sounds continuously until the condition terminates.

If a sensor alarm condition persists for 10 seconds or longer the displays will show dashes (---). From the beginning of the sensor alarm condition up to the time that the displays go into the dash mode, the numerical values will freeze on the last valid values. The displays display new, valid data after three discernible pulses have been found.



SELF TEST Indicator

The self test function is active whenever the unit is powered on. If a self test fault is found, the **SELF TEST** indicator illuminates and the audible alarm sounds continuously. This condition can only be cleared by turning the 8600 to STBY (**O**) and then back ON (**I**). This alarm cannot be shut off with the alarm volume control or by pressing the **AUDIO** button.

NOTE: If this condition cannot be cleared, do not use the pulse oximeter. Contact Nonin Customer Support at (800) 356-8874 or (763) 553-9968.


(Low Battery) Indicator

CAUTION! Inaccurate SpO₂ and/or pulse rate measurement may result if the 8600 is operated in a low battery condition.

The  indicator will illuminate in red if the battery voltage becomes low and the battery needs to be recharged. Fully charged batteries will typically power the 8600 for 30 hours. Charging depleted batteries will require 15 hours to fully recharge, but the pulse oximeter may be used if only partially recharged as long as the  indicator is not illuminated.

NOTE: Setting the month to “00” disables the clock function and helps conserve battery life.

(Battery Charging) Indicator

When the  indicator is illuminated in green, the 8600 is connected to AC power and the battery is charging. To recharge a fully depleted battery, the 8600 must be connected to AC power for 15 hours.

If the  indicator is not illuminated, the 8600 is operating from the battery (AC power is not connected).

Flashing Displays

♥ Display

If the patient's pulse rate is equal to or goes beyond the set limits, the ♥ display flashes at once per second until alarm condition concludes.

SpO₂ Display

If the patient's SpO₂ is equal to or goes beyond the set limits, the SpO₂ display flashes at once per second until alarm condition concludes.


♥ and SpO₂ Display

If both the SpO₂ and ♥ displays flash at once per second, both the pulse rate and SpO₂ values are equal to or go beyond the set limits.

Audible Indicators

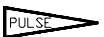
CAUTION! The audible alarm of the 8600 is for the convenience of the attendant near the patient. It is not intended to call an attendant from another room or from a distance. The user must determine the audible distance based on the operating environment.

Audible Alarm

- During normal operation, rotating the  dial counter-clockwise until it clicks will turn the audible alarm OFF if option switch 1 is in the up position. If option switch 1 is in the down position, turning the audible alarm OFF will have no effect.
- During normal operation, pressing the **AUDIO** button disables the audible alarm for 2 minutes.
- Pressing the **AUDIO** button during the 2-minute disabled period immediately enables the audible alarm.
- The audible alarm sounds once per second for all patient alarms.
- The audible alarm sounds steadily for a sensor alarm.

The audible alarm is adjustable from OFF to 80 db(A).

Audible Pulse Tone

- During normal operation, rotating the  dial counter-clockwise until it clicks will turn the audible pulse tone OFF.
- When enabled, the 8600 will sound a tick once for each heart beat.
- The tone varies in pitch with the SpO₂ level. As the SpO₂ level decreases, the pitch of the pulse tone decreases. If the 8600 loses the pulse, the audible pulse tone will beep at a much higher pitch.

The audible pulse tone volume may be varied from OFF to 70 db(A).

Communications

The 8600 may communicate in two forms: serial and analog communications. It may be connected to three different devices, as listed in the table below.

COMMUNICATION LINK	Strip Chart Recorder	8586PI Printer Interface	PC (nVISION* Software)
Analog - Real-time - Memory Output	X		
Serial - Real-time - Memory Output		X	X


Communications Links


Real-Time Data Output

Both the 8600 and 8600M Pulse Oximeters provide real-time output capability to a custom printer via the 15-pin Sub-D connector labeled as “RECORDING OUTPUT” on the rear of the 8600 (refer to Figure 2).

The information from the 8600/8600M 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 is output at a rate of once per second.

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

During data output, the  indicator displays the status of the data transfer.

 indicator	Flashing	solid	flickering
green	real-time data transfer	memory data transfer	printing memory data
yellow	waiting for data	data in memory	scrolling
red	real-time error	memory error	printing error

Status Indicator During Data Transfer

Real-time data is printed in the following format:

HH:MM:SS SPO2=XXX HR=YYY

where “HH” represents the hour the real-time clock is set to, “MM” represents the minutes, “SS” represents the seconds, “XXX” represents the SpO₂ value, and “YYY” represents the heart rate. The SpO₂ and heart rate will be displayed as “---” if there is no data available for the data reading.

NOTE: Pressing the **AUDIO** button during real-time printing will force a line to be printed (touch print).

Memory Option (8600M Only)

The 8600M pulse oximeter can collect and store up to 18 hours of SpO₂ and pulse rate information. This information may be output via the 15-pin sub-D connector labeled as “RECORDING OUTPUT” on the rear of the 8600 (refer to Figure 2).

The solid-state memory in the 8600M 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 8600M is powered up, the current time/date information (if the clock is set properly) is stored in memory to allow quick differentiation of recording sessions. Patient SpO₂ and pulse rate are sampled and stored every four seconds. The stored resolution of the oxygen saturation is in 1% increments in the range of 0 to 100%. The stored pulse rate ranges from 18 to 300 BPM. The stored values have a resolution of 1 BPM from 18 to 200 and a resolution of 2 BPM from 201 to 300.

During data printing, the last data recorded is the first data printed. For example, the last four minutes of data recorded would be the first four minutes of printout.

Recording Sessions

Each time the 8600M is turned on, data is automatically collected. Only recording sessions longer than one minute are kept in memory for later printing.

Memory Output Mode

To output the data stored in the memory of the 8600M, start with the unit OFF and then:

- 1) Hold the **AUDIO** button while pressing the "I" switch;
- 2) Release the **AUDIO** button when **888 888** is displayed in the SpO₂ and ♥ LEDs;
- 3) Observe that the hour and minute of the output data will be displayed in the SpO₂ and ♥ LEDs;
- 4) Data is automatically transferred from the memory;
- 5) When data is done being output, **dnE 000** is displayed;
- 6) Restart the 8600M.

Data is transferred at a rate of 20 minutes of collected data per second. An 18-hour recording session (the maximum memory saved) is transferred in approximately 1 minute. After all the data is transferred, the 8600M should be shut off before collecting new patient data. Outputting the memory does not clear any data from the memory. The patient information is held in memory until overwritten by new data, unless you clear the memory by pressing the **MEMORY CLEAR** button for at least 5 seconds while the 8600M is in memory output mode.

File sizes depend on the amount of data saved in memory. The most recent data is transferred 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 18 hours) and the final (i.e. oldest) data file has been truncated, the final start time will be represented by zeroes and the start times for that file will then not match.

NOTE: If the memory has not been cleared, the 8600M may be downloaded multiple times with the same data.

Specifications

1. Oxygen Saturation Range (SpO₂)	0 to 100%
2. Pulse Rate Range	18 to 300 pulses per minute
3. Displays	
Digital Displays	3-digit 7-segment LEDs
Patient Indicator	Perfusion indicator
Equipment Indicators	Sensor, Self Test, Battery Low, Battery Charging, and Audible Alarm Disabled indicators
4. Measurement Wavelengths	
Red	660 nanometers
Infrared	910 nanometers
5. Accuracy	
SpO₂ (±1 Standard Deviation)*	70 - 95% ±3 digits for neonates using infant or neonatal sensors 70 - 100% ±2 digits for adults using the Finger Clip Sensor 70 - 100% ±3 digits for adults using Flex or Reflectance Sensors 70 - 100% ±4 digits using Ear Clip Sensor 50 - 70% ±3 digits for adults using Flex or Finger Clip Sensors Below 50% is not specified for all sensors
Pulse Rate	±3% ±1 digit
6. Alarm Ranges	
High SpO₂ limit	85%, 90%, 92%, 94%, 95%, 96%, 97%, 98%, 99%, OFF
Low SpO₂ limit	55%, 60%, 65%, 70%, 75%, 80%, 85%, 86%, 87%, 88%, 89%, 90%, 91%, 92%, 95%, OFF
High pulse rate limit	75BPM, 100BPM, 125BPM, 150BPM, 175BPM, 200BPM, 225BPM, 250BPM, 275BPM, OFF
Low pulse rate limit	30BPM, 40BPM, 50BPM, 60BPM, 70BPM, 80BPM, 90BPM, 100BPM, 110BPM, OFF
7. Alarm Volume	50 to 80 dbA at 1 ft. (30 cm)
8. Temperature	
Operating	0°C to +45°C (+32°F to +113°F)
Non-operating	-20°C to +45°C (-4°F to +113°F)
9. Humidity	
Operating	10 to 90% non-condensing
Non-operating	10 to 95% non-condensing
10. Battery Charger	
Model 8604A	120 VAC / 60 Hz
Model 8604A-50	220 VAC / 50 Hz
Model 7708	110 VAC / 50 - 400 Hz (meets U.S.A.F. aeromedical requirements)
11. Batteries	5-cell rechargeable Ni-Cad battery pack 30 hours minimum operation 15 hours to fully recharge
12. Degree of Protection	Type BF Applied Part
13. Dimensions	5.8" wide x 2.7" high x 7.5" deep 14.7 cm x 6.9 cm x 19 cm
14. Weight	2 lbs (0.75 kg)

* Standard Deviation is a statistical measure; up to 32% of the readings may fall outside these limits.

Service

CAUTION! 8600 Pulse Oximeters are sensitive and must be repaired by knowledgeable and specially trained 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

The solid state circuitry within the 8600 Pulse Oximeter requires no periodic maintenance or calibration. The internal battery pack will provide maintenance-free operation for up to 5 years and may be replaced by NONIN if necessary.

NONIN does not recommend field repair of the 8600 Pulse Oximeter. If opening the case is necessary, special precautions are required. To prevent damage, remove the four screws on the bottom of the 8600 using a screwdriver. Next, remove the four rubber feet. While gently pulling on the back of the cover, use a flat blade screwdriver to release the plastic catches. Failure to release the plastic catches when opening the case will damage the case.

The circuit board in the 8600 is a multi-layer board using traces 0.01" wide. Due to the very small trace size, extreme care must be used when replacing components to prevent permanent non-repairable damage to the circuit board. Most components are surface-mounted and require special hot air jet soldering and desoldering equipment. After any repairs are made, the pulse oximeter must be tested to ensure correct operation.

All repair work on the 8600 pulse oximeter must be done by trained NONIN personnel. For Customer Support contact:

NONIN Medical, Inc.
2605 Fernbrook Lane North
Plymouth, MN 55447-4755 USA

(763) 553-9968
(800) 356-8874 (USA and Canada only)
FAX: (763) 553-7807

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 pulse oximeter using factory test fixtures.

Warranty

NONIN MEDICAL, INCORPORATED, (NONIN) warrants to the purchaser, for a period of three years from the date of delivery, each system exclusive of sensors, cables, and battery charger. NONIN shall repair all systems 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 systems delivered to the purchaser which are 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 system sent to NONIN for warranty repair which is found to be within specification, the purchaser agrees to pay \$100.00.

These systems are sensitive and must be repaired by knowledgeable and specially trained personnel only. Accordingly, 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.

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 the 8600 Pulse Oximeter:

7708	Battery Charger 110 V / 50-400 Hz (U.S.A.F. Approved)
8000A	Battery Charger 220 V / 50 Hz (European Turret)
8000H	Reflectance Sensor Holder
8000S	Simulator
8000T	Sensor Attachment Tape, clear, 100 per box
8000TH	Hydrogel Tape Strips, 25 per bag
8100-50	Battery Charger 100 V / 50 Hz
8500I	Patient Cable - 3 feet/1 meter
8600CC	Carrying Case - Black
8600PMS	Pole Mount System (must be factory installed)
8600SB	Pole Mount Side Bracket (must be factory installed)
8604A	Battery Charger 120 V / 60 Hz
8604A-50	Battery Charger 220 V / 50 Hz (European Shuko Plug)
8800I	Patient Interface Cable - 9 feet/3 meters

Reusable Sensors

8000AA	Adult Articulated Finger Clip Sensor
8000AP	Pediatric Finger Clip Sensor
8000J	Adult Flex Sensor
8000Q	Ear Clip Sensor
8000R	Reflectance Sensor
8001J	Neonatal Flex Sensor
8008J	Infant Flex Sensor

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

For more information about Nonin parts and accessories contact your local distributor, or call NONIN at (800) 356-8874 or (763) 553-9968, and ask for your local distributor's name and phone number.

Troubleshooting Guide

Symptom	Possible Cause	Possible Solution
Numeric displays are blinking at once per second	SpO ₂ or pulse rate alarm condition exists	Examine the patient: patient may need medical attention
Displayed pulse rate does not correlate to pulse rate displayed on ECG monitor	Excessive motion at sensor site may be prohibiting the 8600 from acquiring a consistent pulse signal	Eliminate or reduce cause of motion artifact <u>or</u> reposition sensor to new sensor site where motion is not present
	Patient may have an arrhythmia resulting in some heart beats that do not yield a perfusion signal at sensor sight	Examine the patient: condition may persist even though both monitors are functioning properly if patient's arrhythmia persists
	Non-NONIN sensor is being used	Replace sensor with a NONIN sensor
	ECG monitor may not be functioning properly	Examine the patient: replace ECG monitor <u>or</u> refer to operator's manual for ECG monitor
Erratic ♥ display and/or yellow perfusion indicator during concurrent use of electrosurgical equipment (ESU)	ESU may be interfering with oximeter performance	Examine the patient: move oximeter, cables, and sensor as far away from ESU as possible <u>or</u> refer to the ESU operator's manual
Perfusion is blinking yellow with each pulse	Perfusion signal at sensor site is marginal	Examine the patient: reposition sensor <u>or</u> select alternate sensor site
Segments of SpO ₂ or ♥ display are missing	Defective LED displays	Displayed values may not be reliable; discontinue use of 8600
Perfusion indicator is blinking red and SpO ₂ and ♥ displays show dashes	Inadequate perfusion signal at sensor site	Examine the patient: reposition sensor <u>or</u> select alternate sensor site
	Excessive motion at sensor site may be prohibiting 8600 from acquiring a consistent pulse signal	Eliminate or reduce cause of motion artifact or reposition sensor to sensor site where motion is not present
Unable to obtain green perfusion	Low patient pulse strength	Reposition sensor on patient
	Sensor site poorly perfused	
	Sensor not correctly positioned	
	Sensor attached too tightly or tape or other items are restricting perfusion at sensor site	Reapply sensor, select alternate sensor site, or remove restrictive material from sensor site
	Circulation reduced due to excess pressure between the sensor and a hard surface	Allow sensor and finger to rest comfortably on surface
	Excessive ambient light	Reduce ambient light
	Excessive patient motion	Reduce patient motion
	Sensor applied to a polished fingernail	Remove fingernail polish
Interference from:	Reduce or eliminate interference	
• arterial catheter		
• blood pressure cuff		
• electro-surgical procedure		
• infusion line		
Alarm going continuously but SpO ₂ and pulse rate are within alarm limits	Internal circuitry watchdog failed	Reset 8600 by turning the unit OFF, wait a few seconds, and turn the unit ON

If any of these solutions do not correct the problem with your 8600, please contact NONIN Customer Support at (800) 356-8874 or (763) 553-9968.