



Operator's Manual

Models 8600FO and 8600FOM Pulse Oximeters



English

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 8600FO.

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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References to “NONIN” in this manual shall imply NONIN Medical, Inc. References to “8600FO” in this manual shall imply Models 8600FO and 8600FOM. Nonin is a registered trademark of Nonin Medical, Inc.

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Guide to Symbols



ATTENTION: Consult accompanying documents.



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 60601-1 30EM and CAN/CSA C22.2 No. 601.1



Indicates separate collection for electrical and electronic equipment (WEEE).

Precautions for Use

Contraindications

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

Warnings

- The 8600FO is intended as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.
- The pulse oximeter and the cable connector contain ferrous material and must be kept away from magnets at all times. To avoid injury or potential equipment damage, always keep the oximeter, battery charger, and metal end of fiber optic cable beyond the distance of magnetic attraction.
- Do not operate the 8600FO in the MRI environment while connected to A/C power. The battery charger contains a large amount of ferrous material; remove the unit from the MRI environment to recharge.
- Because the printer, printer interface, and other recording devices contain ferrous materials, do not use in the MRI environment. The 8600FOM will store patient data in memory for printing at a later time away from the MRI environment.
- Do not set the alarm volume too low to be heard. Doing so could compromise patient safety.
- The audible alarm of the 8600FO 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.
- Use only NONIN manufactured fiber optic 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 the positioning of the sensor and the circulation and skin sensitivity of the patient. Each patient's sensitivity to NONIN sensors may vary depending on medical status or skin condition.
- Discontinue use of NONIN double-backed adhesive or tape strips if the patient exhibits allergic reactions to the adhesive material.
- Do not stretch 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 specified 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 8600FO.
- Use only NONIN 8600FO compatible accessories.
- The fiber optic cable contains **glass** fibers. Care must be taken when handling the cable. Do not bend sharply, step on, pull, drop, or stretch the fiber optic cable.
- Measurements may be affected in the presence of magnetic resonance imaging (MRI) and computed tomography (CT) devices. It is the facility's responsibility to verify performance prior to installing equipment in these environments.
- The 8600FO 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 8600FO is operated in a low battery condition
- Fingernail polish may reduce light transmission and thereby affect SpO₂ accuracy.
- The 8600FO may not work on all patients. If you are unable to achieve stable readings, discontinue use.
- The 8600FO may interpret motion artifact of sufficient amplitude and regularity as good perfusion (green).
- The 8600FO 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 8600FO or NONIN sensors in liquid to clean.
- Do not use caustic or abrasive cleaning agents on the 8600FO or NONIN sensors.
- This device has not been tested for immunity to electromagnetic disturbances.
- The 8600FO is sensitive and must be repaired by knowledgeable and specially trained personnel only.
- 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.

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

Confirm that the items listed below are packed with the 8600FO Pulse Oximeter. The 8600FO/8600FOM shipment includes the following:

- 8600FO or 8600FOM Pulse Oximeter with Pole Mount System
- A/C Battery Charger
- Operator's Manual for Models 8600FO and 8600FOM

NOTE: *A fiber optic sensor is NOT included with the pulse oximeter. The sensor must be ordered separately.*

Contact the carrier immediately if the shipping carton for the 8600FO is damaged. If any item on this list is missing or damaged, do not use the pulse oximeter. Contact your local distributor, or contact NONIN at (800) 356-8874 or (763) 553-9968.

Introduction

Indications For Use



The 8600FO Pulse Oximeter is intended to monitor oxygen saturation and pulse rate for adult, pediatric, and infant patients in magnetic resonance imaging (MRI) and computed tomography (CT) environments.

General

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

The 8600FO 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. Its primary application is monitoring patients where the following characteristics are desired:

- very high electrical isolation between the patient and the pulse oximeter electronics, especially in the radio frequency range;
- no electrically conductive material present in the pulse oximeter sensor or cable at or near attachment locations on the patient.

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.

Operating Instructions

Operating in the MRI Environment

When operating the 8600FO in the MRI (magnetic resonance imaging) environment, observe the following safety considerations:

- Use only NONIN 8000FC or 8000FI Fiber Optic Sensors. Do not use standard cables or sensors that contain conductive wires.
- While setting up the patient for an MRI, check the patient's baseline oxygen saturation and pulse rate for comparison with scan readings.
- The 8600FO and the connectors for the fiber optic contain ferrous material and *must be kept an appropriate distance away from the magnet at all times.*

WARNING! To avoid injury or potential equipment damage, always keep the oximeter, battery charger, and metal end of fiber optic cable beyond the distance of magnetic attraction. (For magnetic equipment with a magnetic strength of 1.5T or less, place the 8600FO at least two meters away from the magnet.)

- If the 8600FO is used in an MRI environment, it must be securely fastened to a non-movable pole mount or other large non-movable object, and it must be kept as far from the magnetic field as possible.





When operating the 8600FO in the MRI environment, observe the following installation recommendations:

- Install the 8600FO in the MRI environment near the observation window or outside the MRI environment so the displayed values on the pulse oximeter may be clearly viewed. Mounting the 8600FO on a pole is recommended.
- If operating the 8600FO inside the MRI environment, *operate the 8600FO on battery power only.* Remove the 8600FO from the MRI environment to recharge the batteries when the pulse oximeter is not in use.
- If interference is suspected to the MRI image or to the 8600FO, contact NONIN's Customer Support at (800) 356-8874 or (763) 553-9968 for assistance.


Battery Charging

WARNING! Do not operate the 8600FO in an MRI environment while connected to A/C power; the battery charger has a large amount of ferrous material. Remove the unit from the MRI environment to recharge the battery.

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

The battery charger requires 15 hours to recharge a completely depleted battery pack. While the battery charger is connected to A/C 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 8600FO will typically power the unit for 30 hours with a full charge before requiring a recharge.

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


Connecting The Sensors

Connect the fiber optic cable to the 9-pin sub-D connector on the front of the 8600FO, and carefully position the appropriate sensor on the patient.

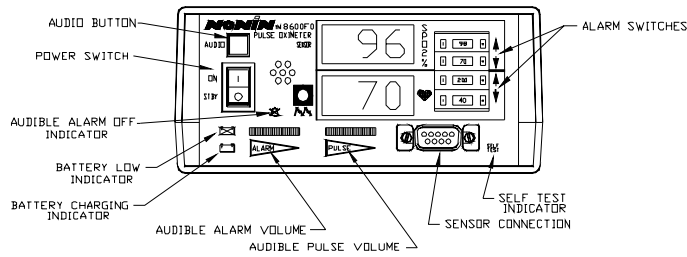
Turning On the Pulse Oximeter

Turn on the 8600FO by pressing the " I " power switch on the front of the pulse oximeter.

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

- "888 888" (8600FO) or "888 888" (8600FOM)
- 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. Call NONIN Customer Support at (800) 356-8874 or (763) 553-9968.*






Front View of the 8600FO

Verifying Operation

CAUTION! The 8600FO must be able to measure the pulse properly to obtain accurate SpO₂ measurements. 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 8600FO in liquid, and do not use caustic or abrasive cleaning agents.

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

Features

Controls

All functions of the 8600FO are controlled by switches found on the front and rear of the unit.

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, described below.

Function	Activation Option
Audible Alarm Enable/Disable	Momentary press during normal operation
Calibrate Recorders	Press for more than 5 seconds during normal operation
Memory Playback (8600FOM only)	Press for less than 2 seconds during power up
Real-time Setup Mode	Press for more than 2 seconds during power up

AUDIO Button Functions

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 8600FO may be necessary. To do this, press the **AUDIO** button continuously for more than 5 seconds during normal operation to activate the recording output calibrate sequence. The user can select the calibration sequence per Option Switch 3.

NOTE: *The 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 8600FO 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, press the **AUDIO** button for 5 seconds, and the 8600FO will return to normal operation.

Memory Playback (8600FOM Only)

To place the 8600FOM in playback mode, hold down 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 8600FO. Data may be played back multiple times if desired.*

Real-Time Setup Mode

To setup the real-time settings, hold down, 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 8600FO 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 8600FO to advance to the next parameter. 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 8600FO 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 8600FO 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, Calendar, and Clock Parameters

- **Printer Settings**

P r n 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 8600FO 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 the printer for any one of these values will have no effect on the 8600FO.*

- **Calendar Settings**

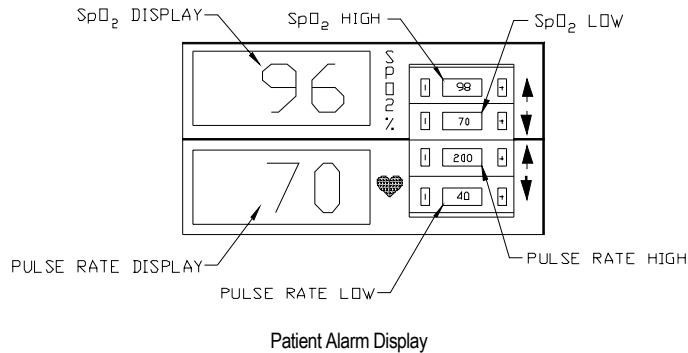
After the printer setting has been displayed in the setup mode, **y** will appear in the SpO2 display, indicating calendar setup mode for the year. Press the **AUDIO** button momentarily to advance through the values. The year may be set to 00 through 99. After selecting the year, wait for approximately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

- **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.

Patient Alarm Limits

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



<i>Patient Alarm</i>	<i>Alarm Values</i>
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

Patient Alarm Values

SpO₂ High Limit

CAUTION! 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.

The button labeled with the Δ next to the SpO₂% display sets the high SpO₂ alarm limit. An alarm condition exists if the SpO₂ level is at or above the chosen SpO₂ high limit level

- Press the \square button to the left of the number to decrease value.
- Press the \square 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.

- Press the \square button to the left of the number to decrease value.
- Press the \square 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.


- 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.

- 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 8600FO may be set such that it will emit a short tone on 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 8600FO 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 8600FO.

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

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 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 (8600FOM 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." After 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 8600FOM to count quickly through all its memory locations, clearing each one.

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

Visual Indicators


SpO₂ Display

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

♥ (Pulse Rate) Display

The lower digital display is a 3-digit LED digital display that indicates 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 8600FO will go into sensor alarm mode.
- *Green* indicates the pulse waveform signal is of good quality and SpO₂ data is accurate.

CAUTION! The 8600FO might misinterpret motion artifact as good perfusion.

(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 is 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 8600FO 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 might result if the 8600FO 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 8600FO 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 8600FO is connected to A/C power and the battery is charging. To recharge a fully depleted battery, the 8600FO must be connected to A/C power for 15 hours.

If the  indicator is not illuminated, the 8600FO is operating from the battery (A/C 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

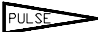
CAUTION! The audible alarm of the 8600FO is for the convenience of the attendant near the patient. It is not intended to call an attendant from another room or from a distance. The user must determine the audible distance based on the operating environment.

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 8600FO 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 8600FO 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

WARNING! Because the printer, printer interface, and other recording devices contain ferrous materials, do not use in the MRI environment. The 8600FOM will store patient data in memory for printing at a later time away from the MRI environment.

The 8600FO may communicate in two forms: serial and analog communications. It may be connected to three different devices. Real-time data may be output to all listed devices from a 8600FO or 8600FOM, and stored memory data may be output to all listed devices from a 8600FOM.

COMMUNICATION LINK	Strip Chart Recorder	PC (nVISION Software)
Analog - Real-time - Memory Output	X	
Serial - Real-time - Memory Output		X

Communications Links

 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 Output

Both the 8600FO and 8600FOM 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 8600FO.

The information from the 8600FO/8600FOM 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. The data printed out for real-time is in the following format:

HH:MM:SS SPO2=XXX HR=YYY

where "HH" represents the hour, "MM" represents the minutes, "SS" represents the seconds, "XXX" represents the SpO₂ value, and "YYY" represents the heart rate. The SpO₂ and pulse 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 (8600FOM Only)

The 8600FOM 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 8600FO.

The solid-state memory in the 8600FOM functions as an endless loop. When the memory fills up, the unit begins overwriting the oldest data with the newest.

Each time the 8600FOM 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. During data output, the  indicator displays the status of the data transfer.

Recording Sessions

Each time the 8600FOM is turned on, data is automatically collected.

NOTE: *Only recording sessions longer than one minute are stored in memory.*

Memory Output Mode

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

- 1) Press 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 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 8600FOM.

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 8600FOM 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 it is overwritten by new data unless you clear the memory by pressing the **MEMORY CLEAR** button for a minimum of 5 seconds while the 8600FOM is in the Memory Output Mode.

NOTE: *If the memory has not been cleared, the 8600FOM 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	925 nanometers
5. Accuracy	
SpO₂ (±1 Standard Deviation) ♦	<ul style="list-style-type: none"> • 70 - 100% ±3 digits for Adult/Pediatric Fiber Optic and Infant/Pediatric Fiber Optic Sensors • Below 70% 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	0 to 80 dB(A) at 24" (60 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 8000A	230 VAC / 50 Hz
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! 8600FO Pulse Oximeters are sensitive and must be repaired by trained Nonin personnel only. Any sign or evidence of opening the system, field service by non-Nonin personnel, tampering, or any kind of misuse or abuse of the system, shall void the warranty in its entirety.

The solid state circuitry within the 8600FO 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 8600FO Pulse Oximeter. If opening the case is necessary, contact NONIN Customer Support for assistance (see below for phone numbers).

The circuit board in the 8600FO 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 8600FO Pulse Oximeter should be done by trained NONIN personnel. For NONIN Customer Support contact:

Nonin Medical, Inc.
13700 1st Avenue North
Plymouth, MN 55441 - 5443 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 WARRANTIES IN THIS MANUAL ARE EXCLUSIVE, AND NO OTHER WARRANTIES OF ANY KIND, WHETHER STATUTORY, WRITTEN, ORAL, OR IMPLIED, SHALL APPLY.

Accessories

The following NONIN accessories function with the 8600FO Pulse Oximeter:

<u>Model</u>	<u>Description</u>
<i>Accessories</i>	
8000A	Battery Charger 230 V / 50 Hz (European Turret)
8000FW	Sensor Wrap, Finger (package of 2)
8000TW	Sensor Wrap, Toe (package of 2)
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
8600CC	Carrying Case - Black
8604A	Battery Charger 120 V / 60 Hz
nVISION	NVISION® software for Microsoft Windows 95/98/2000/NT 4.0 operating systems
<i>Sensors</i>	
8000FC-20	Adult/Pediatric Fiber Optic Sensor (20 feet/6 meters)
8000FC-30	Adult/Pediatric Fiber Optic Sensor (30 feet/9 meters)
8000FI-20	Infant/Pediatric Fiber Optic Sensor (20 feet/6 meters)
8000FI-30	Infant/Pediatric Fiber Optic Sensor (30 feet/9 meters)

For more information about NONIN parts and accessories, visit Nonin's website at www.nonin.com, or contact your local distributor. If you do not have your local distributor information, call NONIN at **(800) 356-8874** or **(763) 553-9968**, and ask for your local distributor's name and phone number.

Troubleshooting

Symptom	Possible Cause	Possible Solution
Numeric displays are blinking at once per second	SpO2 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 8600FO 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 ESU	ESU may be interfering with oximeter performance	<i>Examine the patient:</i> 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	<i>Examine the patient:</i> reposition sensor <u>or</u> select alternate sensor site
Segments of SpO2 or ♥ display are missing	Defective LED displays	Displayed values may not be reliable; discontinue use of 8600FO
Perfusion indicator is blinking red and SpO2 and ♥ displays show dashes	Inadequate perfusion signal at sensor site	<i>Examine the patient:</i> reposition sensor <u>or</u> select alternate sensor site
	Excessive motion at sensor site may be prohibiting 8600FO from acquiring a consistent pulse signal	Eliminate or reduce cause of motion artifact <u>or</u> 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 SpO2 and pulse rate are within alarm limits	Internal circuitry watchdog failed	Reset 8600FO 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 8600FO, please contact NONIN Customer Support at (800) 356-8874 or (763) 553-9968.