Operator's Manual

Models 8500A & 8500MA
Hand-held Pulse Oximeters
With Alarms

English

About the Manual

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.

Trademarks

References

References to **"**NONIN" in this manual shall imply NONIN Medical, Inc.

References to "8500A" in this manual shall imply Models 8500A and 8500MA.

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Guide to Symbols

Symbol	Definition Of Symbol
	ATTENTION: Consult Accompanying Documents
	Type BF Applied Part (patient isolation from electric shock)
	UL Mark for Canada and the United States with respect to electric shock, fire, and mechanical hazards only in accordance with UL 60601-1 30EM and CAN/CSA C22.2 No. 601.1
	CE Marking indicating conformance to EC directive No. 93/42//EEC concerning medical devices
	Indicates separate collection for electrical and electronic equipment (WEEE).

Precautions for Use

Contraindication

- Do not operate in an explosive atmosphere.
- Do not operate the NONIN 8500A in an MRI environment.

Warning

- The 8500A is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.
- The audible alarm of the 8500A 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 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 the application site **frequently** to determine the circulation and skin sensitivity of the patient and the positioning of the sensor. Each patient's sensitivity to NONIN sensors might vary depending upon medical status or skin condition.
- 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.

Caution

- Federal law (USA) restricts this device to sale by or on the order of a physician.
- Read this manual carefully before use of the 8500A.
- Carefully read the instructional insert provided with the sensor before use.
- The 8500A is intended for spot checking or continuous monitoring by an attending health care professional.
- The 8500A must be able to measure the pulse properly to obtain accurate SpO_2 measurement. Verify that nothing is hindering the pulse measurement before relying on the SpO_2 measurement.
- Fingernail polish may reduce light transmission and thereby affect SpO_2 accuracy.
- The 8500A may not work on all patients. If you are unable to achieve stable readings, discontinue use.
- 8500A Pulse Oximeters are sensitive and must be repaired by knowledgeable and specially trained personnel only.
- The 8500A may interpret motion artifact of sufficient amplitude and regularity as good perfusion (green).
- The NONIN 8500A Hand Held Pulse Oximeter 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 SpO_2 measurement.
- Do not use different types of batteries at the same time. Do not mix fully charged and partially charged cells at the same time. These actions may cause the batteries to leak.
- Do not immerse the 8500A or NONIN sensors in liquid to clean.
- Do not use caustic or abrasive cleaning agents.
- 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.
- Do not remove any covers other than the battery cover when battery replacement is necessary. There are no user serviceable parts inside other than the replaceable batteries.
- Alkaline batteries may leak or explode if used or disposed of improperly.
- 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.
- This device has not been tested for immunity to electromagnetic disturbances.
- Portable and mobile RF communications equipment can affect medical electrical equipment.
- 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**
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.		
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 8500A is damaged. Carefully unpack the instrument and its accessories. Confirm that the items listed below are packed with the 8500A Hand Held Pulse Oximeter. The 8500A/8500MA shipment includes:

- 8500A or 8500MA Hand Held Pulse Oximeter
- Operator's Manual for Models 8500A and 8500MA
- Six AA batteries
- 8000K2 Sensor (Adult Finger Clip) or 8000AA 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's Customer Support department at (800) 356-8874.

Introduction

A. Indications For Use

The 8500A Hand Held Pulse Oximeter is intended to be used for monitoring oxygen saturation and pulse rate for adult, pediatric, and neonatal patients in hospital, ambulatory, home, and EMS environments. The 8500A may be used for spot checking and/or continuous monitoring when attended by a healthcare professional. The variety of individual sensors available must be checked frequently to ensure proper circulation and application.

B. General

The 8500A Hand Held Pulse Oximeter is small and light weight. The 8500A has audible and visual alarms for tracking patient status. It typically will operate for 100 hours continuously between battery replacements. **The 8500A requires no routine calibration or maintenance.**

The 8500A determines arterial oxyhemoglobin saturation (%SpO_2) 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 LED flashes. Patient perfusion signals are graded as good, marginal or inadequate and are indicated as such by the LED flashing green, yellow, or red. 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 a dash to the upper left of the SpO_2 value on the LED display. Ultimately, if adequate perfusion pulses are not received, the SpO_2 and Pulse Rate (♥) numerical values will be replaced by dashes. When the batteries are low, the digital displays will blink.

The 8500 Pulse Oximeter may be used with all NONIN pulse oximeter sensors (except fiber optic) enabling proper operation for nearly every patient.

NOTE: Nonin sensors do not contain natural rubber latex. Natural rubber latex has been found to cause allergic reactions in some individuals.

Operating Instructions

A. Batteries

Caution:

- Do not remove any covers other than the battery cover when battery replacement is necessary. There are no user serviceable parts inside other than the replaceable batteries.
- Alkaline batteries may leak or explode if used or disposed of improperly.
- Do not use different types of batteries at the same time. In addition, do not mix fully charged and partially charged cells at the same time. These actions may cause the batteries to leak.

The 8500A Hand Held Pulse Oximeter is powered by 6 AA Alkaline cells that will typically provide 100 hours of continuous operation. **The 8500A indicates when the batteries are low by flashing the digital displays once each second.** When the displays begin flashing, the batteries should be replaced as soon as possible. Replace the batteries by removing the battery door on the back of the 8500A. Be sure to follow the polarity markings on the rear label of the pulse oximeter when installing new batteries. Refer to Figure I for an illustration of battery replacement.

Rechargeable Nickel Cadmium batteries may be used in the 8500A if desired. Since NiCad batteries have less than half the capacity of alkaline batteries, the batteries will have to be recharged more often than every 100 hours.

NOTE: *Replacing batteries erases the clock settings of the 8500A. The memory of the 8500MA will also be erased when the batteries are replaced. These settings should be reset after the batteries are replaced.*

NOTE: *Batteries should be removed if the 8500A is going to be stored for more than 30 days. Batteries may leak if left in the device for a long period of time.*

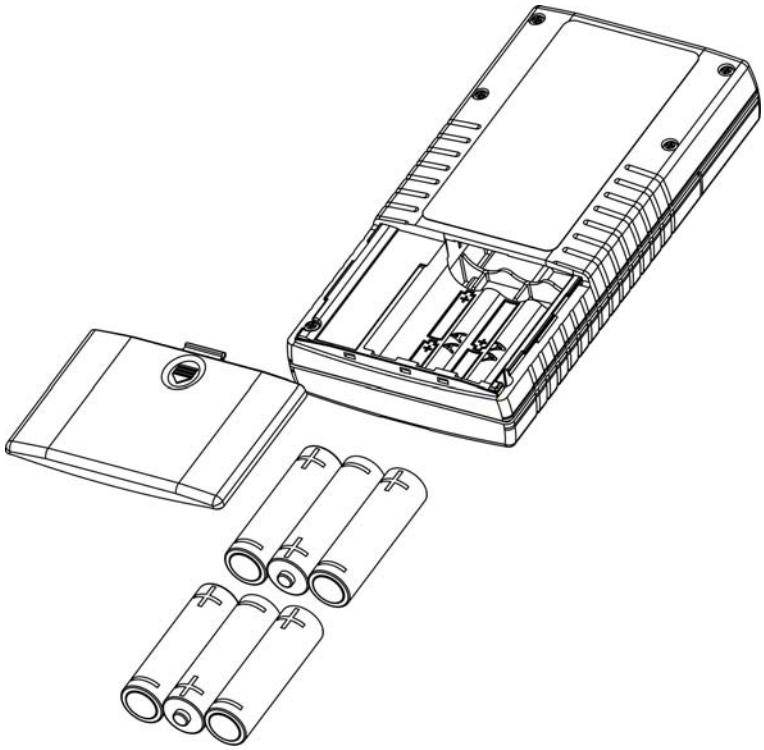

Figure I: Replacing Batteries in the 8500A

B. General

The 8500A Hand Held Pulse Oximeter is portable and is intended for attended patient monitoring by trained personnel. It displays numerical values for oxygen saturation and pulse rate.

1. Connect Sensors

Connect the sensor to its 9-pin mating jack on the top of the 8500A as shown in Figure II. If additional cable length is necessary, connect the Model 8500I Patient Cable between the sensor and the 8500A Hand Held Pulse Oximeter. Position the appropriate sensor on the patient.

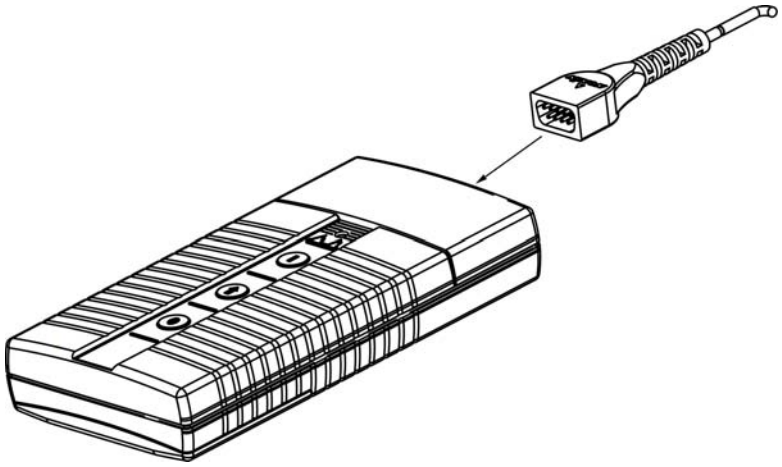

Figure II: Connecting Sensors to the 8500A

2. Turn on the Pulse Oximeter

Turn on the 8500A Hand Held Pulse Oximeter by pressing the "|" switch on the front of the pulse oximeter. Refer to Figure III.

When the 8500A is powered on, the SpO_2 and ♥ displays will cycle through the following sequence before displaying valid data values:

- "888 888"
- current time
- software revision number
- "- -"

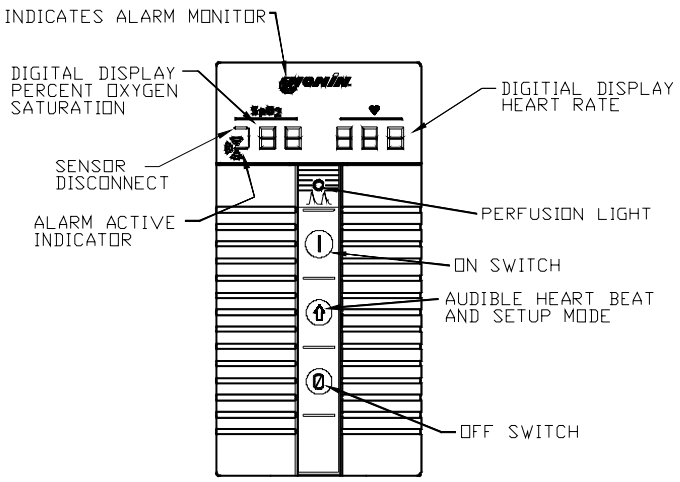

Figure III: Front View of the 8500A

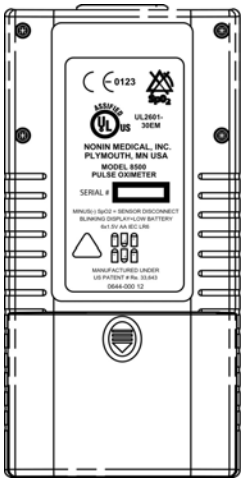

Figure IV: Rear View of the 8500A

3. Verify Operation

Caution:

- The 8500A must be able to measure the pulse properly to obtain accurate SpO_2 measurement. Verify that nothing is hindering the pulse measurement before relying on the SpO_2 measurement.

Verify that the sensor is properly positioned. Ensure the system is sensing adequate perfusion by observing that the  indicator is blinking green, and the blinking is correlated 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.

If the alarm is not disabled, the Alarm Active Indicator will flicker for the first 2 minutes of operation. This indicates that the alarm is enabled, but the audible alarm is temporarily disabled when powered on. During this time, the "|" switch may be pressed to enable the audible alarm. After the 2 minute power on period is completed or the "|" switch has been pressed, the Alarm Active Indicator will be continuously illuminated and the audible alarm will be enabled.

If the alarm is disabled, the Alarm Active Indicator will not illuminate, and pressing the "|" switch will not affect the operation of the 8500A.

4. Cleaning the Pulse Oximeter

Caution:

- Do not immerse the 8500A in liquid to clean.
- Do not use caustic or abrasive cleaning agents.

The 8500A Hand Held Pulse Oximeter may be cleaned with a mild detergent and a soft cloth or with an isopropyl alcohol wipe. Allow enough time for the 8500A to dry thoroughly before reusing.

Features

A. Controls

All functions of the 8500A are controlled by switches found on the front of the unit. Refer to Figure III for an illustration of these switches.

1. Power

Pressing the ON switch ("|") causes power to be applied to all internal circuitry. Pressing the OFF switch ("∅") causes power to be removed from the displays and puts the oximetry circuitry into a low power standby mode.

In order to conserve battery life, the 8500A will automatically power off after 10 minutes of inactivity. Inactivity is indicated by dashes on the displays and is caused by:

- no sensor connected to the pulse oximeter
- patient pulse too low
- sensor not attached to a patient

Each time a reading is displayed, the 10 minute timer is restarted.

The "|" switch has additional alarm, printer, clock, and calendar mode setting functions when used in conjunction with the "⇧" switch.

2. Setup Mode

Setup mode is used to control the alarms, internal time-of-day clock and calendar, and the external real-time printer (purchased separately). The setup mode is initiated by holding the "⇧" switch when the unit is turned on by pressing the "|" switch. In setup mode, the "|" switch and the "⇧" switch are used to make the selections.

Advance to the next sequential mode by pressing the "|" switch. Each time the "⇧" switch is pressed, the number on the ♥ display will increment. It starts with the current value stored in memory for the parameter designated in the SpO_2 display. When the correct value appears in the ♥ display, pressing the "|" switch will advance the SpO_2 display to the next sequential parameter as listed in Table I. 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 8500A exits the setup mode and begins normal operation.

Parameter	Appears in ♥ Display	Range of Values	Default Value
Alarm mode	AIr	dFt, rcl, □ (OFF)	ON
High SpO_2 limit	O2H	0 (OFF), 80 - 100	OFF
Low SpO_2 limit	O2L	0 (OFF), 50 - 95	80%
High Pulse Rate limit	H H	0 (OFF), 75 - 275 [1]	200 BPM
Low Pulse Rate limit	H L	0 (OFF), 30 - 110	50 BPM
Printer	Prn	00 - 15	00
Year	Y	00 - 99	94
Month	M M	00 - 12	00
Day	d	01 - 31	01
Hours	h	00 - 23	00
Minutes	M M	00 - 59	00

Table I: Alarm, Printer, Calendar, and Clock Mode Parameters

[1] The high pulse rate limit value increments by 5, while all other parameters are incremented in steps of 1.

a. Alarm Settings

Once setup mode is initiated, " AIr " will appear in the SpO_2 display indicating the alarm settings. There are three options for the alarm settings: default (" dFt "), recall (" rcl "), or OFF (" □ "). These options appear in the ♥ display. Refer to Figure V for a flow chart of setting the alarms. When the alarm setting sequence has been completed, the 8500A continues to the printer settings.

NOTE: *When the 8500A is powered on, it resets to the default alarm settings unless the user specifies to recall parameters in the Setup mode each time the unit is powered on.*

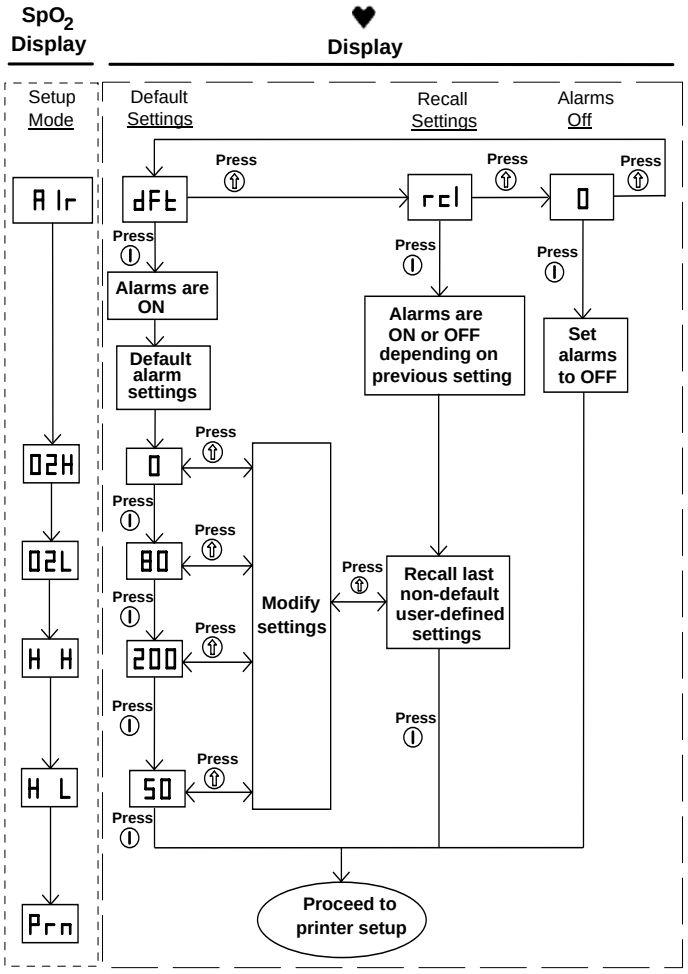

Figure V: Flow Chart for Setting Alarms

b. Printer Settings

* ***NOTE:*** *The 8500P prints out real-time data only. Data stored in the 8500MA can not be downloaded to the 8500P.*

After the alarm settings have been determined in the setup mode, "Prn" will appear in the SpO_2 display indicating print setup mode. There are 16 options for the printer mode: 00 through 15. Each printer mode is explained in Table II. The modes determine how often data is written out to the printer and the format of data written to the printer. Refer to Figure VI for a flow chart of setting the printer mode. When the printer setting sequence has been completed, the 8500A continues to the calendar settings (refer to Calendar Settings section).

WARNING: The use of the 8500P may result in increased emission and/or decreased immunity of this device.

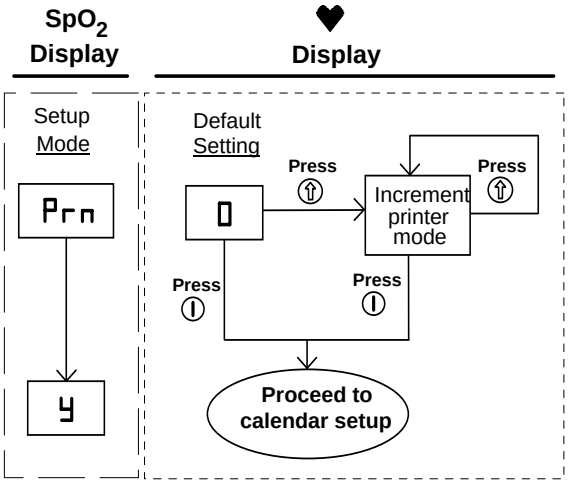

Figure VI: Flow Chart for Setting Printer Mode

Printer Mode	Seconds per data point	Minimum SpO_2 printed?*	Touch print capability?**
00	10	No	Yes
01	30	No	Yes
02	120	No	Yes
03	10	Yes	Yes
04	30	Yes	Yes
05	120	Yes	Yes
15	---	No	Yes

***** For modes where the minimum SpO_2 data is written, there are two lines of data written for each data output. The first line contains the minimum value for SpO_2 since the last printout, and the second line contains the current data values.

****** The touch print mode enables the user to print out data at any time. This is activated by pressing the "|" switch.

Table II: 8500P Printer Modes

* ***NOTE:*** *Printer modes 06 - 14 are not used at this time. They are reserved for future development.*

c. Calendar Settings

After the printer setting has been determined in the setup mode, "Y" will appear in the SpO_2 display indicating calendar setup mode for the year. The year may be set to "00" through "99". After selecting the year, the display will show "M M" indicating the setup mode for the month. The month may be set to "00" through "12". 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". Refer to Figure VII for a flow chart of setting the calendar. When the calendar setting sequence has been completed, the 8500A continues to the clock settings (refer to Clock Settings section).

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

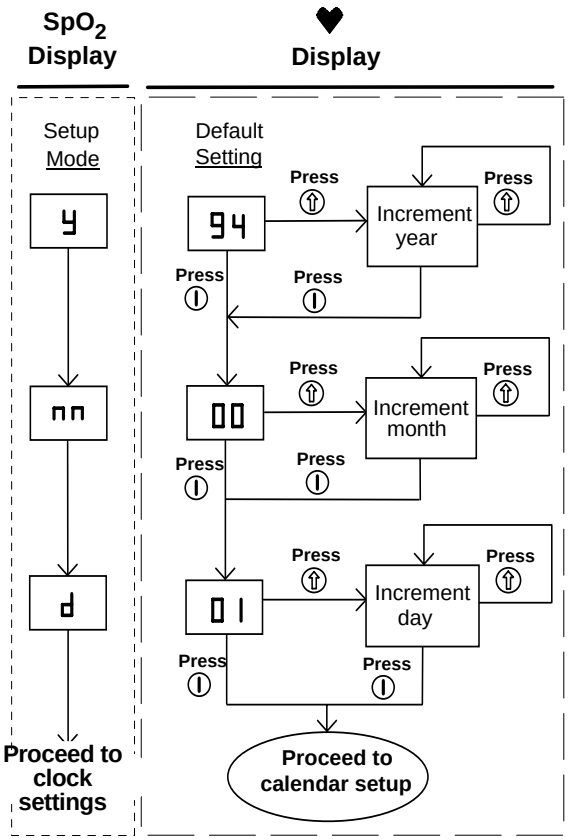

Figure VII: Flow Chart for Setting Calendar

d. Clock Settings

After the calendar settings have been determined in the setup mode, "⊢" will appear in the SpO_2 display indicating clock setup mode for the hour. The hour may be set to "00" through "23". After selecting the hour, the display will show "⊓ ⊓" indicating the setup mode for the minutes. The minutes may be set to "00" through "59". After selecting the minutes, the display will flash the settings for the alarms and will then return to normal operation. Refer to Figure VIII for a flow chart of setting the clock.

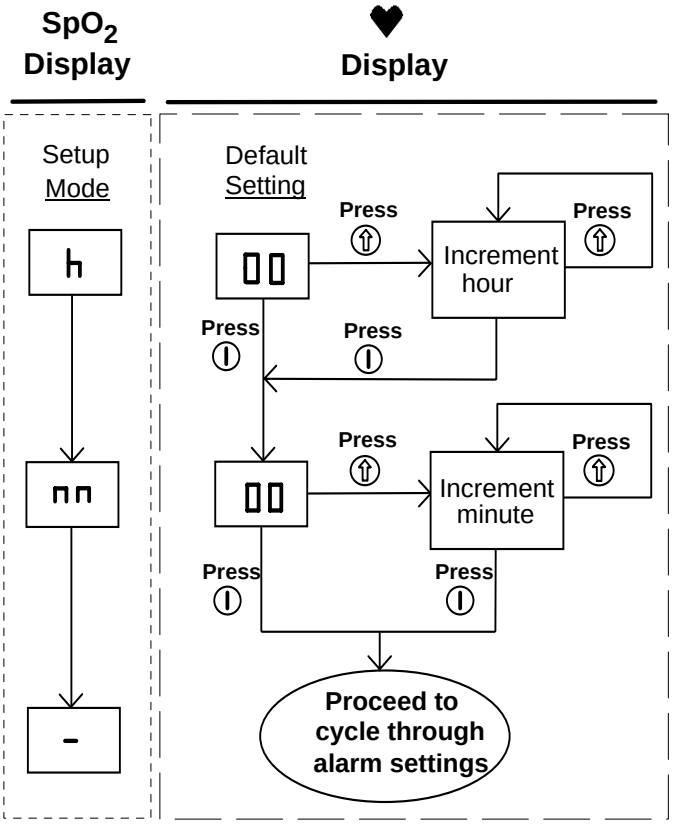

Figure VIII: Flow Chart for Setting Clock

3. Alarms Indicated On Demand

The set points of the adjustable alarms may be displayed upon demand at any time during operation of the 8500A oximeter, either when SpO_2 and Pulse Rate values are being displayed, or when the unit is out-of-track. Press the "|" switch while holding the "⇧" switch depressed. This will cause the current settings of the four alarms - SpO_2 high limit, SpO_2 low limit, pulse rate high limit, and pulse rate low limit - to be displayed in the same format and order as during clock set. Each alarm set point is displayed for approximately three seconds. If the alarms are OFF, then " □ " will be displayed for settings.

B. Displays

1. Visual Indicators

a. SpO_2 Display

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

b. ♥ (Pulse Rate) Display

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

c.  (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 SpO_2 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, SpO_2 and pulse rate values are not updated. After approximately twenty seconds, the values are replaced with dashes indicating SpO_2 measurement is not possible.
- **Yellow** indicates the pulse waveform amplitude is marginal or the pulse oximeter has detected artifact. Although SpO_2 data is acceptable, corrective measures should be considered to improve sensor placement, change sensor type, or reduce patient movement.
- **Green** indicates the pulse waveform signal is of good quality and SpO_2 data is accurate.

Caution:

- The 8500A may interpret motion artifact of sufficient amplitude and regularity as good perfusion (green).

d. Flashing or Flickering Displays

♥ Display

If the patient's pulse rate is equal to or goes beyond the set limits for pulse rate, the ♥ display flickers until the alarm condition concludes.

SpO_2 Display

If the patient's SpO_2 is equal to or goes beyond the set limits for SpO_2, the SpO_2 display flickers until the alarm condition concludes.

♥ and SpO_2 Display

If both the SpO_2 and ♥ displays flicker, the pulse rate and SpO_2 values are both equal to or go beyond their set limits.

If both the SpO_2 and ♥ displays flash at once per second, the batteries are low and need to be replaced. Replace all six batteries. Refer to Figure I: Replacing batteries in the 8500A.

NOTE: *Inaccurate SpO_2 and/or pulse rate measurement may result if the 8500A is operated in a low battery condition.*

e. (Alarm Active) Indicator

- The Alarm Active Indicator continuously illuminated indicates audible alarms are **enabled**. (See Figure IX)
- The Alarm Active Indicator not illuminated indicates audible alarms are **disabled**. (See Figure IX)
- The Alarm Active Indicator flickers when the audible alarms are **temporarily disabled**.

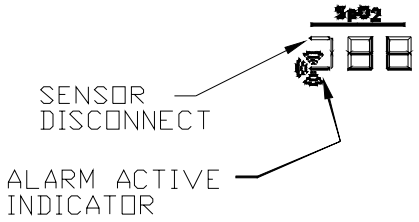

Figure IX: Sensor Disconnect and Alarm Active Indicators

f. Dash in SpO_2 Display

If the 8500A determines that a sensor fault exists (sensor disconnect, sensor failure, or sensor dislodgment), a dash (**-**) appears in the upper left-most digit of the SpO_2 display (refer to Figure IX). The readings that are displayed remain unchanged while the sensor fault exists. If the sensor fault is not corrected, a dash will be displayed in both the SpO_2 and ♥ displays 10 seconds after the sensor disconnect indicator appears.

2. Audible Indicators

Caution:

- The audible alarm of the 8500A 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.

a. Audible Alarm

- During operation, pressing the "|" switch disables audible alarms for 2 minutes (includes during power up).
- Pressing the "|" switch during the 2-minute disabled period immediately enables the audible alarm.
- When enabled, the audible alarm sounds once per second for all patient alarms: high SpO_2, low SpO_2, high heart rate, low heart rate, and low perfusion.
- When enabled, the audible alarm sounds steadily for equipment alarms: sensor alarm and low battery.

b. Audible Heart Beat

- During operation, pressing the "⇧" switch toggles the audible heart beat status ON or OFF.
- When enabled, the 8500A will sound once for each heart beat detected.
- The audible heart beat is disabled when batteries are installed.
- Each time the 8500A is turned on, the audible heart beat will default to the previously selected mode (audible heart beat ON or OFF).

C. Printer/Serial Output

Both the 8500A and 8500MA Pulse Oximeters provide output capability to a custom printer via the 9-pin Sub-D connector. This connector serves as a sensor input connector as well as a printer interconnect device. The 9-pin Sub-D connector pin assignments are listed in Table III.

Pin Number	Assignment
1	Battery Voltage
2	Infrared Anode, Red Cathode
3	Infrared Cathode, Red Anode
4	Serial Data, TTL Levels
5	Detector Anode
6	Logic Level
7	Cable Shield
8	Coaxial Shield
9	Detector Cathode, +5 V

Table III: Printer/Sensor Interface Assignments

The information from the 8500A 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:*** *The 9th data bit is used for parity in memory playback mode. In real-time mode, it is always set to the mark condition. Therefore the real-time data may be read as 8 data bits, no parity.*

The data printed by the 8500P printer is in the following format:

HH:MM:SS SPO_2=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 SpO_2 value, and "YYY" represents the pulse rate. The SpO_2 and pulse rate will be displayed as "---" if there is no data available for the data reading.

WARNING: The use of the 8500P may result in increased emission and/or decreased immunity of this device.

D. Memory Option (8500MA Only)

The memory option is identified by the "M" in the model number (i.e. 8500MA as opposed to the 8500A). This model number is located just above the serial number on the back of the unit. The 8500MA Hand Held Pulse Oximeter can collect and store up to eighteen hours of SpO_2 and pulse rate information. An infrared optical link or 8500YC cable transfers the data to the 8586 Printer Interface unit where it can be printed on an Epson®-compatible graphics printer (parallel version).

The solid-state memory in the 8500MA functions much like the "endless loop" tapes that are used in some telephone answering machines. When the memory fills up, the unit begins overwriting the oldest locations with the latest data.

Each time the 8500MA 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 SpO_2 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 the printing of the data, 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.

1. Recording Sessions

Each time the 8500MA is turned on (except while setting the clock) data is automatically collected.

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

2. Memory Output Mode

To output the data stored in the memory of the 8500MA, start with the unit OFF and then:

1) Hold the "⇧" switch while pressing the "|" switch;
2) Release the "⇧" and "|" switches when "888 888" is displayed in the SpO_2 and ♥ LEDs;
3) Observe "Prn dFt" will be displayed in the SpO_2 and ♥ LEDs;
4) Data is automatically transferred from the memory.

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 8500M should be shut off prior to collecting new patient data. The patient information is held in memory as long as the batteries are good, so if the memory has to be cleared, remove the batteries for a period of 60 seconds or longer. Outputting the memory does not clear any data from the memory.

NOTE: *The memory is cleared each time the batteries are changed.*

The format of the data transferred is given in Table IV. The size of this file will depend on the amount of data saved in the 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. the oldest) file of data has been truncated, the final start time will be represented by zeroes and the start times for that file will then not match up.

E. Cleaning the Sensors

Caution:

- Do not immerse the sensors in liquid to clean.
- Do not use caustic or abrasive cleaning agents.

Carefully clean the NONIN reusable sensors with an isopropyl alcohol wipe and ensure that all tape residue is removed. Allow enough time for the sensor to dry thoroughly before reusing. The sensors may be sterilized using ethylene oxide (EtO) (cold cycle).

F. Sensor Compatibility

Caution:

- Use only NONIN manufactured sensors. These sensors are manufactured to meet the calibration requirements for NONIN Pulse Oximeters.

The 8500A is compatible with all NONIN manufactured sensors (except the Fiber Optic sensors).

Specifications

1. Oxygen Saturation Range (SpO_2)	0 to 100%
2. Pulse Rate Range	18 to 300 Pulses Per Minute
3. Displays	
Patient Indicator	Perfusion LED
Digital Displays	3-digit 7-segment LEDs
4. Measurement Wavelengths	
Red	660 nanometers
Infrared	910 nanometers
5. Accuracy	
SpO_2 (± 1 Standard Deviation)♦	70 - 100% ± 2 digits for adults using the Finger Clip Sensors
	70 - 95% ± 3 digits for neonates using infant or neonatal sensors
	70 - 100% ± 3 digits for adults using Flex or Reflectance Sensors
	70 - 100% ± 4 digits using Ear Clip Sensor
	Below 70% is not specified for all sensors
Pulse Rate	± 3% ± 1 digits
6. Alarm Ranges	
High SpO_2 limit	80 – 100 %, OFF default: OFF
Low SpO_2 limit	50 – 95 %, OFF default: 80 %
High pulse rate limit	75 – 275 BPM, OFF (increments of 5) default: 200 BPM
Low pulse rate limit	30 – 100 BPM, OFF default: 50 BPM
7. Alarm Volume	70 dbA at 1 ft. (30 cm)
8. Temperature	
Operating	-20 to +50 °C
Non-operating	-30 to +50 °C
9. Humidity	
Operating	10 to 90% non-condensing
Non-operating	10 to 95% non-condensing
10. Power Requirements	6 AA alkaline batteries; 100 hours typical operation
11. Dimensions	3" wide x 6" high x 1" deep 8 cm x 15 cm x 2 cm
12. Weight	10 oz. (280 g) with batteries

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

Service

Caution:

- 8500A 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 8500A Hand Held Pulse Oximeter requires no periodic maintenance or calibration other than battery replacement.

NONIN does not recommend field repair of the 8500A Hand Held Pulse Oximeter. The circuit board in the 8500A 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.

NOTE: *All repair work on the 8500A Hand Held Pulse Oximeter should be done by trained NONIN personnel. For NONIN Customer Support contact:*

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

+1 (763) 553-9968
(800) 356-8874 (USA and Canada only)
FAX: +1 (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 purchase, each system exclusive of sensors, cables, and batteries. (Refer to the individual package inserts for specific warranty information for sensors, cables, and other accessories.) NONIN shall repair or replace any 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 or accessories 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. NONIN reserves the right to charge a fee for a warranty repair request on any device that is found to be within specifications.

These are precision electronic instruments and must be repaired by knowledgeable and specially trained NONIN personnel only. Accordingly, any evidence of opening the system, field service by non-NONIN personnel, tampering, or any kind of system misuse or abuse 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 8500A and 8500MA Hand Held Pulse Oximeter:

Model	Description
	Pulse Oximeter Reusable Sensors
8000AA-1	Adult Articulated Finger Clip Sensor (1 meter)
8000AA-2	Adult Articulated Finger Clip Sensor (2 meters)
8000AA-3	Adult Articulated Finger Clip Sensor (3 meters)
8000AP	Pediatric Finger Clip Sensor (1 meter)
8000AP-3	Pediatric Finger Clip Sensor (3 meters)
8000J	Adult Flex Sensor
8000J-3	Adult Flex Sensor (3 meters)
8008J	Infant Flex Sensor
8001J	Neonatal Flex Sensor
8000Q	Ear Clip Sensor
8000R	Reflectance Sensor
	Pulse Oximeter Disposable Sensors
7000A	Adult Finger Flexi-Form® II Sensor, 10 per box
7000P	Pediatric Finger Flexi-Form® II Sensor, 10 per box
7000I	Infant Toe Flexi-Form® II Sensor, 10 per box
7000N	Neonatal Foot Flexi-Form® II Sensor, 10 per box
7000D	Flexi-Form® Sensor Assortment Pack, 10 per box
	Accessories
8000JFW	Adult FlexiWrap, 8000JFW, bag of 25
8001JFW	Neonatal FlexiWrap, 8001JFW, bag of 25
8008JFW	Infant FlexiWrap, 8008JFW, bag of 25
8000H	Reflectance Sensor Holder System
8000S	Patient Simulator
UNI-EXT-1	Extension Cable (3 feet/1 meter)
UNI-EXT-3	Extension Cable (10 feet/3 meters)
UNI-EXT-6	Extension Cable (20 feet/6 meters)
UNI-EXT-9	Extension Cable (30 feet/9 meters)
UNI-RA-0	Right Angle Connector (6 inches/0.15 meters)
UNI-RA-3	Right Angle Connector (10 feet/3 meters)
NiMHBC-NA	Nickel metal hydride battery charger with 12 AA NiMH batteries
NiMHBC-UNIV	Nickel metal hydride battery charger with 12 AA NiMH batteries
NiMHB	1800 mAH NiMH, 6 AA batteries for use with NiMHBC-NA and -UNIV
HHCC	Handheld carrying case, 8500/9840, black, holds 8500/9840 monitor, sensor, and airway adapter tubes
8500P	Attachable printer—8500/9840-series (Real-time pulse oximetry data)
8500PAP	Thermal Printer Paper (package of 20 rolls)
8500PCC	Carrying case for 8500, 8500P, and accessories (blue)
8500TS	Tabletop stand
8500CC-B	Carrying Case – Black
8500MB	Mounting Bracket (Wall or Pole Mount System)
1000MC	Memory Transfer Cable (for use with PC)
1000RTC	Serial cable, memory or real-time (may be used for real-time interface to a PC; however, this application is not supported by nVISION software).
8500RB	Rubber Bumper
nVISION	nVISION Data Management Software for oximetry screening (CD-ROM)

For more information about NONIN parts and accessories contact your distributor, or contact NONIN at (800) 356-8874 (USA and Canada) or (763) 553-9968.

Troubleshooting Guide

Symptom	Possible Cause	Possible Solution
8500A will not power up	Batteries are completely depleted	Replace all six batteries of the 8500A
	Incorrect battery installation	Verify battery sequence. Refer to Figure I: Replacing Batteries in the 8500A
Numeric displays are blinking at once per second	Battery voltage is low	Replace all six batteries of the 8500A
	Incorrect battery installation	Verify battery sequence. Refer to Figure I: Replacing Batteries in the 8500A
	SpO_2 or pulse rate alarm condition exists	***Examine the patient:*** Patient may need medical attention
Dash appears in upper left of SpO_2 display	Sensor fault exists. Sensor may have become dislodged from 8500A or from the patient	Verify sensor is connected to the 8500A and the patient correctly; Try a new sensor if condition persists
Displayed pulse rate does not correlate to pulse rate displayed on ECG monitor	Excessive motion at sensor site may be prohibiting the 8500A from acquiring a consistent pulse signal	Eliminate or reduce cause of motion artifact or 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 or refer to operator's manual for ECG monitor
Erratic ♥ display and/or yellow perfusion LED 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 or 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 or select alternate sensor site
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: • arterial catheter • blood pressure cuff • electrosurgical procedure • infusion line	Reduce or eliminate interference

Troubleshooting Guide (Continued)

Symptom	Possible Cause	Possible Solution
Segments of SpO_2 or ♥ display are missing	Defective LED displays	Displayed values may not be reliable; discontinue use of 8500A
Perfusion LED is blinking red and SpO_2 and ♥ displays show dashes	Inadequate perfusion signal at sensor site	***Examine the patient:*** reposition sensor or select alternate sensor site
	Excessive motion at sensor site may be prohibiting 8500A from acquiring a consistent pulse signal	Eliminate or reduce cause of motion artifact or reposition sensor to sensor site where motion is not present
Alarm going continuously but SpO_2 and pulse rate are within alarm limits	Internal circuitry watchdog failed	Reset 8500A by turning the unit OFF, wait a few seconds, and turn the unit ON
Printer not printing out after changing Prn mode	Printer mode did not get updated internally	Reset pulse oximeter by turning it off and then on

If any of these solutions do not correct the problem with your 8500A, please contact NONIN Customer Support at (800) 356-8874.