NONIN®

Operator's Manual

2500A PalmSAT®

Pulse Oximeter
with Alarms

CE 0123

English

About the Manual

There are many precautions for use throughout this manual. Read them carefully; they are important to the use of the product.

The information in this manual has been carefully checked and is believed to be accurate. In the interest of ongoing 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.

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

CAUTION! Read this entire manual carefully before using the 2500A PalmSAT Pulse Oximeter with Alarms.

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

Guide to Symbols

This table describes the symbols that are found on the Model 2500A.

Regulatory Symbols

	**Attention:** See Instructions for Use or related materials.
	**Type BF Applied Part** (Patient isolation from electrical shock).
	**UL Mark for Canada and the United States** with respect to electric shock, fire, and mechanical hazards only in accordance with UL 60601-1 and CAN/CSA C22.2 No. 601.1.
	**CE Marking** indicating conformance to EC directive No. 93/42/EEC concerning medical devices.
SN	**Serial Number** (located under the back cover).
IPX2	Protected against vertically falling water drops when enclosure is tilted up to 15 degrees per IEC 60529.
	Indicates separate collection for electrical and electronic equipment (WEEE).

Precautions for Use

Indications for Use

The NONIN® Model 2500A PalmSAT® Pulse Oximeter with Alarms is indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate for adult, pediatric, and neonatal patients. The 2500A is intended for continuous monitoring and/or spot-checking of patients during both motion and no-motion conditions, and for patients who are well or poorly perfused.

Contraindications

- Do not use the 2500A PalmSAT in an MRI environment.
- Explosion Hazard: Do not use the 2500A in an explosive atmosphere.

Warnings

- The 2500A is intended only as an adjunct in patient assessment. It must be used in conjunction with other methods of assessing clinical signs and symptoms.
- Use only NONIN-manufactured pulse oximeter sensors. These sensors are manufactured to meet the accuracy specifications for NONIN Pulse Oximeters. Using other manufacturers' sensors may cause improper pulse oximeter performance.
- As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.
- Discontinue use of adhesive tape strips if the patient exhibits an allergic reaction to the adhesive material.
- Do not stretch the adhesive tape while applying the pulse oximeter sensor. This may cause inaccurate readings or skin blisters.
- General operation of the 2500A may be affected by the use of an electrosurgical unit (ESU).
- Because operating environments vary, use caution to ensure that all audible alarms and indicators can be heard. Users must determine the acceptable audible distance of all alarms.
- Do not place the 2500A in an environment where its speaker opening may become blocked; alarms may become muffled or inaudible.
- Turning off the 2500A's alarm volume creates a situation that is not compliant with relevant safety standards. The alarm silence indicator is lit solid when the alarm volume is turned off or set below 45 dBA.
- Do not use a damaged sensor.

(Continued)Warnings

- When a system fault occurs, the patient will no longer be monitored.
- At critically low battery capacity, the patient will no longer be monitored.
- Blood flow restrictors (e.g., blood pressure cuffs) may hinder pulse measurements. Remove any objects that may hinder the performance of the pulse oximeter.
- 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

- Federal law (USA) restricts this device to sale by or on the order of a physician.
- Read this entire manual carefully before using the 2500A.
- Before use, carefully read the package insert provided with the sensors.
- Inspect the sensor application site at least every 6 to 8 hours to ensure correct sensor alignment and skin integrity. Patient sensitivity to sensors may vary due to medical status or skin condition.
- The 2500A is not an apnea monitor.
- Verify that all visible indicators illuminate and that an audible indicator sounds during the startup (initialization) sequence. If any indicator is not lit or the audible indicator does not sound, do not use the 2500A. Contact NONIN Customer Support for assistance.
- The presence of a defibrillator may interfere with the performance of this device.
- Some nail polish colors (particularly dark shades) or artificial nails may reduce light transmission and affect SpO_2 accuracy. Remove any nail polish or artificial nails before using the 2500A.
- The 2500A may not work on all patients. If you are unable to achieve stable readings, discontinue use.
- The 2500A has motion tolerant software that minimizes the likelihood of motion artifact being misinterpreted as good pulse quality. In some circumstances, however, the 2500A may still interpret motion as good pulse quality. Minimize patient motion as much as possible.
- The 2500A is designed 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.

Cautions (Continued)

- Cardiogreen and other intravascular dyes, depending on the concentration, may affect the accuracy of the SpO_2 measurement.
- Ear Clip and Reflectance sensors are not recommended for pediatric or neonatal use. The accuracy of these sensors has not been established for pediatric or neonatal use.
- Do not immerse the 2500A or NONIN sensors in liquid, and do not expose the device or components to excessive moisture or liquids.
- Do not use caustic or abrasive cleaning agents on the 2500A or the sensors.
- The oximeter sensor might not work on cold extremities due to reduced circulation. Warm or rub the finger to increase circulation, or reposition the sensor.
- The 2500A is a precision electronic instrument and must be repaired by trained NONIN personnel only.
- Replace the batteries as soon as possible after a low battery indication. Always replace the batteries with fully-charged batteries.
- Use only NONIN-specified battery types with this device.
- Do not mix fully charged and partially charged batteries at the same time. This may cause the batteries to leak.
- Do not remove any covers other than the battery cover when replacing batteries. There are no user-serviceable parts inside other than the replaceable batteries.
- Follow local governing ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries.
- Batteries may leak or explode if used or disposed of improperly.
- Remove the batteries if the 2500A will be stored for more than 1 month.
- 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.
- 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.
- Portable and mobile RF communications equipment can affect medical electrical equipment.

Manufacturer's Declaration

Refer to the following tables 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	

Table 2: Electromagnetic Immunity

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

NOTE: U_T is the AC mains voltage before application of the test level.

Table 3: Guidance and Manufacturer's Declaration—Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance
This device is intended for use in the electromagnetic environment specified below. The customer and/or user of this device should ensure that it is used in such an environment.			
Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.			
			Recommended Separation Distance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	[3] V	$d = 1.17\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	[3] V/m	$d = 1.17\sqrt{P}$ 80 MHz to 800MHz $d = 2.33\sqrt{P}$ 800MHz to 2.5 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

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

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

Table 4: Recommended Separation Distances

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

This device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. Customers or users of this device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the device as recommended below, according to maximum output power of the communications equipment.			
	Separation Distance According to Frequency of Transmitter		
Rated Maximum Output Power of Transmitter W	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	80 MHz to 800 MHz $d = 1.17\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.33\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23

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

NOTE: At 80 MHz and 800MHz, the separation distance for the higher frequency range applies.

NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Introduction

Indications for Use

The NONIN® Model 2500A PalmSAT® Pulse Oximeter with Alarms (Figure 1) is indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate for adult, pediatric, and neonatal patients. The 2500A is intended for continuous monitoring and/or spot-checking of patients during both motion and no-motion conditions, and for patients who are well or poorly perfused.

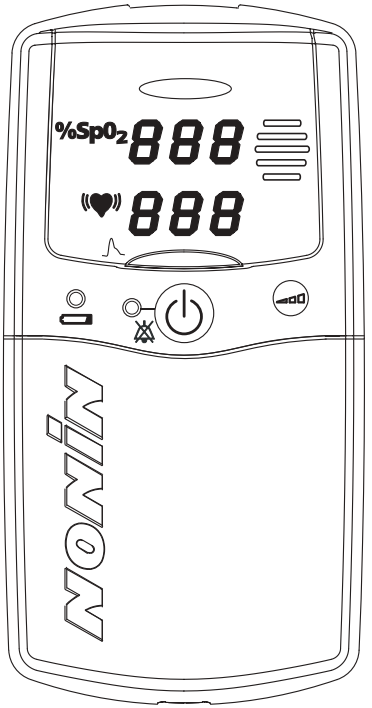

Figure 1. The Model 2500A Pulse Oximeter with Alarms.

General Description

The 2500A PalmSAT is a digital handheld pulse oximeter that displays numerical values for blood oxygen saturation (%SpO_2) and pulse rate. It provides audible and visual alarms for both medium and high priority conditions.

The 2500A will typically operate for 60 hours continuously between alkaline battery replacements, or for 40 hours with the Model 2500B Rechargeable NiMH (Nickel Metal Hydride) Battery Pack (optional). The 2500A requires no routine calibration or maintenance other than replacement of alkaline batteries or recharging the optional battery pack. (Refer to the Model 2500C Operator's Manual.)

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

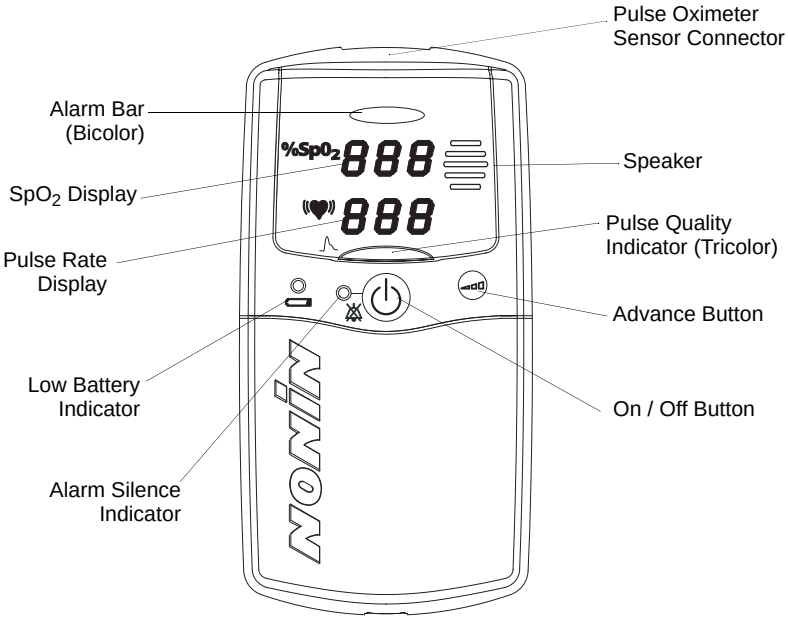

Figure 2. 2500A displays, indicators, and buttons.

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

The 2500A Pulse Oximeter may be used with a variety of NONIN pulse oximeter sensors.

A sensor disconnect or malfunction is indicated by a lack of good pulse quality blinking and/or a dash to the left of the SpO_2 value on the LED display. When adequate pulse signals are not received, the SpO_2 and/or pulse rate numerical values will be replaced by dashes. Low and critically low battery conditions will be indicated by the Low Battery indicator.

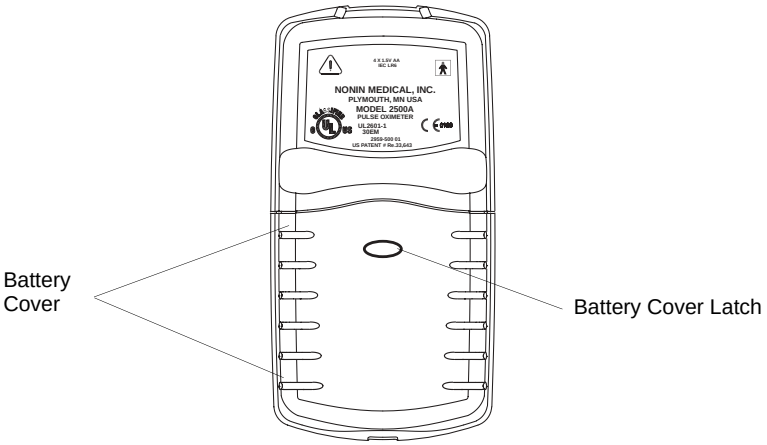

Figure 3. Rear view of the 2500A.

Unpacking the 2500A

The 2500A complete system includes the following items:

1 2500A Pulse Oximeter

1 Model 2500A Operator's Manual on CD

1 NONIN Pulse Oximeter Sensor

4 AA-Size Alkaline Batteries

Confirm that the items listed are packed with the 2500A system. If any item on this list is missing or damaged, contact your distributor. Contact the carrier immediately if the shipping carton is damaged.

Basic Operation

Installing and Using the Batteries

The 2500A can be powered by 4 AA-size alkaline batteries, or by the optional Rechargeable NiMH Battery Pack, Model 2500B.

CAUTION! Use only NONIN-specified battery types with this device.

Low and critically low battery capacity is indicated with a flashing Low Battery indicator and a medium priority alarm. When batteries are critically low, the digital displays will go blank, and the Pulse Quality indicator will blink yellow or red, but not green. Any SpO_2 or pulse rate alarms in effect when critically low battery capacity is reached will be latched, and flashing dashes will appear on the corresponding display. After 10 minutes at critically low battery capacity, the pulse oximeter will shut off automatically.

CAUTION! Replace the batteries as soon as possible after a low battery indication. Always replace the batteries with fully-charged batteries.

WARNING! At critically low battery capacity, the patient will no longer be monitored.

1. Press the battery cover latch, and remove the battery cover on the bottom of the 2500A.
2. Insert four new AA-size alkaline batteries or a Rechargeable NiMH Battery Pack. Be sure to insert the batteries in the correct position, as indicated by the polarity markings (+ and -) inside the battery compartment. *Proper battery positioning is essential for correct operation.*
3. Replace the battery cover and turn on the 2500A. If the unit does not turn on, see "Troubleshooting."

NOTE: Clock/calendar settings, recallable alarm settings, and stored data (including date and time stamp) are retained for approximately 2 minutes after batteries are removed. Replace batteries within 2 minutes to avoid losing the settings.

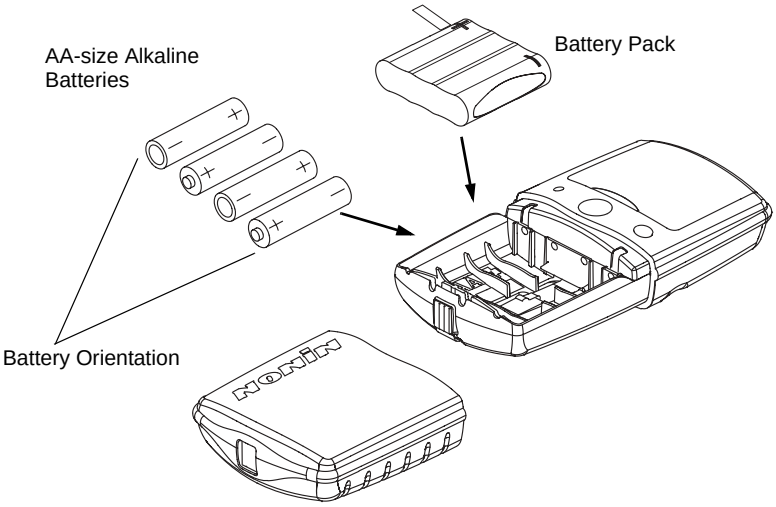

Figure 4. Installing batteries in the 2500A.

Important Notes about Battery Use

Four AA alkaline batteries provide the 2500A with approximately 60 hours of continuous operation, while the Rechargeable NiMH Battery Pack provides the 2500A with approximately 40 hours of continuous operation.

Clock / calendar settings can significantly affect battery storage life. Batteries drain during storage, but they drain much more quickly when the unit's clock / calendar functions are set. Refer to "Clock and Calendar Settings" for more information.

With AA Batteries

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

With Rechargeable NiMH Battery Pack

- If the clock / calendar is *not* set when the unit is stored, the Rechargeable NiMH Battery Pack will need recharging at least every 2 months *if the unit has not been used.*
- If the clock / calendar *is set* when the unit is stored, the Rechargeable NiMH Battery Pack will need recharging at least every 3 weeks *if the unit has not been used.*
- Using the oximeter will shorten the required recharging time.

Recharging Batteries (NiMH Battery Pack Only)

- Completely recharging the NiMH battery pack requires approximately 90 minutes when the unit is completely discharged.
- The expected useful life of the Rechargeable NiMH battery pack is 500 charge / discharge cycles, or approximately 10 years, whichever is first. The battery pack must be charged at least once each year to maintain optimal battery life.
- AA alkaline batteries cannot be recharged in the charging stand.

Connecting the Sensor

Connect the pulse oximeter sensor (with the NONIN logo facing up) to the top of the 2500A as shown below. Ensure that the sensor is firmly plugged in. Refer to “Specifications” or to the specific sensor package insert for pulse oximeter sensor positioning information.

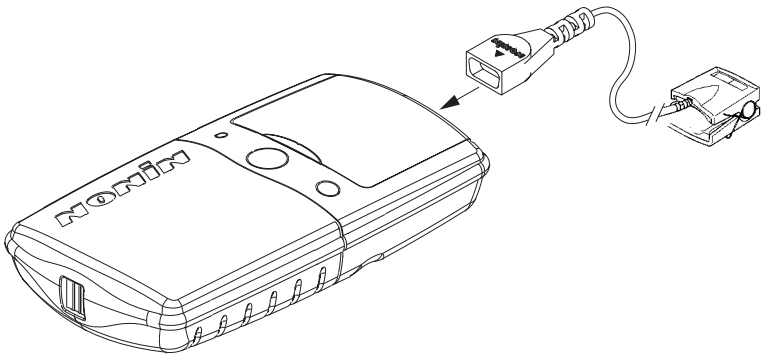

Figure 5. Connecting a sensor to the 2500A.

Power On/Off

- **Turn on** the 2500A by pressing and releasing the On/Off button on the front of the unit.
- **Turn off** the 2500A by pressing and holding the On/Off button for about 2 seconds.

Power On Self-Test

When the 2500A is turned on for normal operation, the unit will cycle through a startup/initialization sequence before displaying valid data. During startup, always check for any missing indicators or LED display segments and ensure that the audible indicator sounds. If any indicator is not functioning, do not use the 2500A. Contact NONIN Customer Support for repair or replacement.

During its normal startup sequence, the 2500A will cycle as follows:

- "888 888" appears briefly in the SpO_2 and pulse rate displays.
- the yellow Low Battery and Alarm Silence indicators turn on steadily for a few seconds.
- the Pulse Quality indicator turns red for 1 second, then green for 1 second, then shuts off, while the Alarm Bar turns red for 1 second, then amber for 1 second.
- the clock time currently set in the memory (in hours and minutes, 04 41 for example) appears briefly in the displays.
- the software revision number (the letter "r" followed by a 3-digit number, r018 for example) appears briefly in the displays.
- three audible beeps sound.
- - - (two dashes) appear in the displays until a valid pulse signal is detected.

NOTE: The two-minute alarm silence feature is automatically enabled immediately after the startup sequence.

NOTE: This startup sequence varies slightly when entering setup mode at power on.

Monitoring

Verify that the pulse oximeter sensor is properly positioned on the patient. Ensure that the pulse oximeter is sensing adequate pulse quality by:

- verifying that the Pulse Quality indicator is blinking green *and*
- verifying that the pulse rate and SpO_2 displays are displaying readings *and*
- verifying that blinking of the Pulse Quality indicator is in time with the pulse rate for at least 10 seconds

If the Pulse Quality indicator is blinking red or yellow or is blinking erratically, reposition the sensor or try a different sensor.

If the sensor is not properly positioned, or no sensor is attached to the pulse oximeter after startup (a few seconds after powering on), both the SpO_2 and pulse rate displays will display a single dash until a valid pulse signal is detected.

Cleaning the Pulse Oximeter

Clean the 2500A Pulse Oximeter separately from the sensors. For instructions on cleaning pulse oximeter sensors, refer to the respective pulse oximeter sensor package inserts.

CAUTION! Do not immerse the 2500A in liquid, and do not use caustic or abrasive cleaning agents on the 2500A.

Clean the 2500A with a soft cloth dampened with isopropyl alcohol. Do not pour or spray any liquids onto the 2500A, and do not allow any liquid to enter any openings in the device. Allow the 2500A to dry thoroughly before reusing.

Detailed Operation

All functions of the 2500A are controlled by the **On/Off** ⏻ and **Advance** ⇨ buttons found on the front of the unit.

Powering the 2500A

- Turn on the 2500A by pressing and releasing the **On/Off** button on the front of the unit.
- Turn off the unit by pressing and holding the **On/Off** button for about 2 seconds.

To conserve battery life, the 2500A automatically powers off after 10 minutes of inactivity. Inactivity is indicated by dashes on the displays and may result from an improperly connected or positioned sensor, or from an inadequate patient pulse signal.

Displays and Indicators

SpO_2 Display

The SpO_2 display is the upper numeric display (identified by the $\%SpO_2$ symbol). This 3-digit light-emitting diode (LED) display shows the current oxygen saturation percentage. This display flashes for SpO_2 alarms.

Pulse Rate Display

The pulse rate display is the lower numeric display (identified by the symbol). This 3-digit LED display shows the pulse rate in pulses per minute. This display flashes for Pulse Rate alarms.

Pulse Quality Indicator

The pulse quality indicator (identified by the symbol), is a tricolor LED that blinks once for each detected pulse. The pulse quality indicator changes color to indicate changes in the pulse waveform signal that may affect the SpO_2 data. It may blink green, yellow, or red.

- **Green** indicates a good pulse strength
- **Yellow** indicates a marginal pulse strength. To improve signal quality, reposition the sensor, try a different sensor type, eliminate patient movement, or improve the site's circulation.
- **Red** indicates an inadequate pulse strength. While the pulse quality indicator is red, SpO_2 and pulse rate values are not updated. After about 20 seconds, the values are replaced with dashes, indicating that readings are not possible.

Low Battery Indicator

Low and critically low battery capacity is indicated with a flashing Low Battery indicator and a medium priority alarm. When batteries are critically low, the digital displays will go blank, and the Pulse Quality indicator will blink yellow or red, but not green. Any SpO_2 or pulse rate alarms in effect when critically low battery capacity is reached will be latched, and flashing dashes will appear on the corresponding display. After 10 minutes at critically low battery capacity, the pulse oximeter will shut off automatically.

Sensor Fault Indicator

If the 2500A determines that a sensor fault exists (a sensor disconnect or failure) or if a pulse oximeter sensor signal is no longer detected, a dash (-) appears in the left-most digit of the SpO_2 display. The readings that are displayed will freeze for 10 seconds if the pulse oximeter sensor fault or the inadequate signal continues. A sensor fault is a medium priority alarm.

If the sensor fault or the inadequate signal is not corrected, the frozen readings and the left-most dash will be replaced by dashes in the middle digit of both the SpO_2 and the pulse rate displays, 10 seconds after the first dash appeared.

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

Alarm Bar

The Alarm Bar flashes amber or red, indicating medium or high priority alarms, respectively. This indicator is located near the top of the 2500A

Alarm Silence Indicator

The Alarm Silence indicator (identified by the  symbol) is located to the left of the On/Off button. Whenever the Alarm Silence indicator is flashing, all audible alarms are temporarily silenced. If the alarm volume is set to “off,” the Alarm Silence indicator is lit solidly.

Pulse Rate Tone

When the pulse rate tone is active, a beep sounds for each detected pulse. This beep changes in pitch with SpO_2 values. The default volume is OFF. During normal operation, the volume can be changed (off, low, or high) by momentarily pressing the advance button.

Setup Mode

Setup mode is used to adjust alarm, memory clear, and memory playback functions, as well as to set the calendar and clock. In Setup mode, the **Advance** and **On/Off** buttons are used to make all selections.

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

Entering Setup Mode

1. With the unit off, press and hold the **Advance** button while pressing and then releasing the **On/Off** button.
2. Release the advance button when 888 888 is displayed on the SpO_2 and pulse rate displays. The clock time currently set in the memory, 04 41 for example, appears briefly in the displays, and then rCl no appears.

Making Selections in Setup Mode

1. When entering Setup mode, rCL no is displayed. (This indicates that Recall Alarms is the setting being adjusted, and that the default value is "no." See Table 1.) Press and release the **Advance** button to change the value for this setting (or press and hold the Advance button to scroll quickly through the range of adjustable values).
2. When the desired value appears, press and release the **On/Off** button to store the value and advance to the next adjustable parameter, as listed in Table 1.
3. Continue this process until all settings are chosen.

   When the setting sequence is complete, the 2500A exits Setup mode, automatically displays the alarm settings in effect, and is then ready to begin normal operation.

Table 1. Adjustable Parameters and Settings

Setting	Appears in SpO_2 Display:	Range of Values Appears in Pulse Rate Display:	Default Value
Recall Alarm Settings*	rcl	yes or no	no
SpO2 Low Alarm	O2L	50-95, Off	85
Heart Rate High Alarm	HH	75-275, Off	200
Heart Rate Low Alarm	HL	30-110, Off	50
SpO2 High Alarm	O2H	80-100, Off	Off
Audible Alarms	Adb	Hi, Lo, Off	Hi
Memory Clear**	Clr	yes or no	no
Delete (confirm clear)	del	yes or no	no
Year	y	00 - 99	04
Month	nn	00 - 12	00
Day	d	01 - 31	00
Hour	h	00 - 23	00
Minute	nn	00 - 59	00
(Not used)[a]	Prn	00-15	00

[a] Prn settings 00 to 15 are not used at this time. Setting these values will not affect the operation of the 2500A.

***NOTE: Choosing "yes" for rcl (Recall Alarm Settings) will recall previous alarm settings and exit setup mode.**

****NOTE: Choosing "yes" for both the CLr and dEL settings (the memory clear function) will clear the memory and exit setup mode.**

Alarm Functions

This section describes the alarm functions of the Model 2500A.

High and Medium Priority Alarms

The 2500A features audible and visual alarms that indicate both high and medium priority alarm conditions. In general, high priority alarms are patient-specific. They are indicated by a flashing red alarm bar and a high priority audible alarm signal. High priority alarms are sounded as follows: “beep, beep, beep,” (short pause), “beep, beep” (10-second pause).

Medium priority alarms are generally equipment-specific, and are indicated by a flashing amber alarm bar and a medium priority audible alarm signal. Medium priority alarms are sounded as follows: “beep, beep, beep,” (25-second pause), “beep, beep, beep.”

Refer to the table below for detailed information about alarm conditions, activation criteria, and priorities.

Condition	Alarm Activation Criteria	Priority
SpO_2 High	Activates when displayed SpO2 is equal to or greater than the SpO2 High alarm limit	High
SpO_2 Low	Activates when displayed SpO2 is equal to or less than the SpO2 Low alarm limit	High
Pulse Rate High	Activates when the displayed pulse rate is equal to or greater than the Pulse Rate High alarm limit	High
Pulse Rate Low	Activates when the displayed pulse rate is equal to or less than the Pulse Rate Low alarm limit	High
Low Perfusion	Activates when the Pulse Quality Indicator indicates red (inadequate) perfusion	High
Low Battery	Activates when estimated battery capacity is low.	Medium
Critically Low Battery	Activates when estimated battery capacity is critically low and does not allow a reliable measurement	Medium
Sensor Fault	Activates when the Sensor Fault Indicator indicates a sensor alarm or sensor disconnect	Medium

Adjusting Alarm Settings

Users may adjust the alarm limits for upper and lower SpO_2 and Pulse Rate alarms and alarm volume as shown below.

Alarm Limit	Default	Adjustment Options	Increments
SpO_2 High	Off	Off, 80-100	1%
SpO_2 Low	85%	Off, 50-95	1%
Pulse Rate High	200 BPM	Off, 75-275	5 BPM
Pulse Rate Low	50 BPM	Off, 30-110	5 BPM
Alarm Volume	Hi	Off, Lo, Hi	N/A

Adjusting alarm settings is only possible when the device is in Setup mode. For every power on in which alarm settings have not been recalled or adjusted in Setup mode, the default alarm settings remain in effect.

Recalling Previous Alarm Settings

The most recently adjusted alarm limits and volume may be recalled each time the 2500A is started up. These alarm settings are retained and available for recall for approximately 2 minutes after batteries are removed. Batteries must be replaced within 2 minutes to avoid losing the settings.

1. With the unit off, press and hold the **Advance** button while pressing and then releasing the **On/Off** button.

   This enters Setup mode and displays rCL no*—indicating that Recall Alarms is the parameter being adjusted, and that the default value is "no."*

2. Press and release the **Advance** button.

   This changes the Recall Alarms value to Yes*—indicating that previously-adjusted alarm settings will be recalled.*

3. Press and release the **On/Off** button to select Yes and recall all previously-adjusted alarm and volume settings.

   All recalled settings are individually flashed on the 2500A's display screen before the unit begins normal operation.

NOTE: Setup mode exits automatically after Recall Alarm Settings is selected.

Reviewing Alarm Settings

At any time during normal operation, alarm limits and volume settings can be reviewed by pressing and holding the **Advance** button for one second. All settings are then individually flashed on the 2500A's display screen.

NOTE: To stop the alarm review early and return to normal operation, press the Advance button momentarily.

Silencing Audible Alarms

Audible alarms are automatically silenced for the first 2 minutes of normal operation. Momentarily press the **On/Off** button to temporarily silence audible alarms (2 minute silence) during normal operation. Press the **On/Off** button again to cancel the temporary alarm silence.

System Fault Alarms

If the 2500A determines that a system fault exists, an error message (e.g., Err E01) appears in the SpO_2 and Pulse Rate displays, along with medium priority alarm indicators. A system fault has also occurred if the displays and indicators are blank but a continuous audible alarm is sounding. Attempt to clear the error by turning the device off and on. If the problem persists, contact Nonin Customer Support.

WARNING! When a system fault occurs, the patient will no longer be monitored.

Memory Functions

Each time the 2500A is turned on (except during Setup mode), data are automatically collected in memory. The 2500A can collect and store up to 72 hours of SpO_2 and pulse rate information.

NOTE: Only recording sessions longer than 1 minute are stored in memory. Memory will clear approximately 2 minutes after removing the batteries. Replace batteries immediately to avoid losing stored data.

NONIN's nVISION® data management software is available for use with Microsoft® Windows® 95/98/2000/NT 4.0 operating systems. Refer to "Accessories."

The memory in the 2500A functions as an "endless loop." When the memory fills up, the unit begins overwriting the oldest data with the newest.

Each time the 2500A is turned on, the current time/date information (if the clock is set properly) is stored in memory to allow quick differentiation of recording sessions. Patient SpO_2 and pulse rate are sampled and stored every 4 seconds.

Oxygen saturation values are stored in 1% increments in the range of 0 to 100%.

The stored pulse rate ranges from 18 to 300 pulses per minute. The stored values are in increments of 1 pulse per minute in the interval from 18 to 200 pulses per minute, and increments of 2 pulses per minute in the interval from 201 to 300 pulses per minute.

During the printing of the data, the last data recorded are the first data printed. For example, the last 4 minutes of data recorded would be the first 4 minutes of printout.

NOTE: Playing back the data in memory does not clear the data from memory.

Playing Back the Data Stored in 2500A Memory

1. With the unit off, press and hold the **Advance** button while pressing and then releasing the **On/Off** button .

2. Release the advance button when 888 888 is displayed on the SpO_2 and pulse rate displays. The clock time currently set in the memory (04 41 for example) appears briefly in the displays, and then rCL no appears.

3. Data will be automatically played back from the memory. Data are played back at a rate of 20 minutes of collected data per second. A 72-hour recording session (the maximum memory saved) is played back in approximately 3.5 minutes.

4. After all data are played back, the 2500A should be shut off before collecting new patient data. The patient information is held in memory as long as the batteries are sufficiently charged, so if the memory must be cleared, use the memory clear function.

Clearing the Memory

The Memory Clear function allows you to delete all data currently stored in memory.

Choosing Memory Clear Settings

1. Enter Setup mode, and scroll through the settings until `Clr` is displayed.

2. `Clr` may be set to `no` or `yes`.

   If `no` is entered in response to `Clr` (indicating that you do not want to clear the memory), the setup mode will continue directly to the calendar and clock settings. (Refer to "Clock and Calendar Settings.")

   If `yes` is entered in response to `Clr`, then `del` will next appear in the SpO_2 display, again with a choice of `no` or `yes`. This prompting gives you a second opportunity to avoid clearing the memory.

   Make the `Clr` selection. Use the Advance button to scroll through the values. Use the On/Off button to accept a value and move to the next setting.

3. `del` may be set to `no` or `yes`.

   If `no` is entered in response to `del` (indicating that you do not want to clear the memory), the setup mode will continue directly to the calendar and clock settings. (Refer to "Choosing Calendar and Clock Settings.")

   If `yes` is entered in response to `del`, (confirming that you do want to clear the memory), then `dne Clr` will briefly appear in the displays indicating that the memory is cleared. After the alarm settings are reviewed, the 2500A will exit setup mode and is ready to begin normal operation.

   Make the `del` selection.Use the Advance button to scroll through the values. Use the On/Off button to accept a value and move to the next setting.

Choosing Calendar and Clock Settings

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

1. After selecting no in the memory clear settings, y will appear in the SpO_2 display indicating the calendar year setting.
2. Make the year, month, day, hour, and minute selections. Use the Advance button to scroll through the values. Use the On/Off button to accept a value and move to the next setting.
3. After selecting the minutes, Prn will appear in the SpO_2 display. However, the Prn setting is not used at this time.
4. Press and release the On/Off button to exit setup mode.

   When the setting sequence is complete, the 2500A exits Setup mode, automatically displays the alarm settings in effect, and is then ready to begin normal operation.

Communications

Serial Output

The 2500A provides real-time data output capability via the pulse oximeter sensor connector (a 9-pin Sub-D connector). The pulse oximeter sensor connector pin assignments are listed in Table 2.

Table 2. Pulse Oximeter Sensor Connector Pin Assignments

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	Sensor Type
7	Cable Shield (Ground)
8	Ground
9	Detector Cathode, +5 V

The information from the 2500A in the real-time mode is sent in an ASCII serial format at 9600 baud with 9 data bits, 1 start bit, and 1 stop bit. The data are output at a rate of once per second.

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

Real-time data may be printed or displayed by devices other than the pulse oximeter. On power up a header is sent identifying the format and the time and date. Thereafter, the data are sent once per second by the 2500A in the following format:

SPO2=XXX HR=YYY

where “XXX” represents the SpO_2 value, and “YYY” represents the pulse rate. The SpO_2 and pulse rate will be displayed as “---” if there are no data available for the data reading.

Specifications

Oxygen Saturation Range (SpO_2) 0 to 100%

Pulse Rate Range 18 to 300 Pulses Per Minute

Accuracy

Saturation Accuracy (±1 S.D.)* 70-100%

	Adults, Pediatrics	Neonates
No Motion Finger Clip Flex, Flexi-Form II, 8000R 8000Q	 ±2 digits ±3 digits ±4 digits	 ±3 digits ±4 digits
Motion Finger Clip	±3 digits	±4 digits
Low Perfusion Finger Clip, Flex, Flexi-Form II	±3 digits	±4 digits

Pulse Rate Accuracy 18 to 300 beats/min. (no motion)
40 to 240 beats/min. (motion)
40 to 240 beats/min. (low perfusion)

	Adults, Pediatrics	Neonates
No Motion Finger Clip, Flex, Flexi- Form II, 8000R, 8000Q	±3 digits	±3 digits
Motion Finger Clip	±5 digits	±5 digits
Low Perfusion Finger Clip, Flex, Flexi-Form II	±3 digits	±3 digits

Finger Clip Sensors: 8000AA-1, 8000AA-3, 8000AP-1, 8000AP-3
Flex Sensors: 8000J-1, 8000J-3, 8008J, 8001J
Flexi-Form II Sensors: 7000A, 7000P, 7000I, 7000N

Measurement Wavelengths and Output Power

Red	660 nanometers @ 3 mw nominal
Infrared	910 nanometers @ 3 mw nominal

Indicators

Pulse Quality Indicator	LED, tricolor
Numeric Displays	3-digit 7-segment LEDs, red
Low Battery Indicator	Dedicated icon, yellow
Alarm Bar	LED, bicolor
Alarm Silence Indicator	LED, yellow

Temperature

Operating	-20 to +50°C (-4 to +122°F)
Storage/Transportation	-30 to +50°C (-22 to +122°F)

Humidity	
Operating	10 to 90% noncondensing
Storage/Transportation	10 to 95% noncondensing
Altitude	
Operating Altitude	Up to 12,000 meters (40,000 feet)
Hyperbaric Pressure	Up to 4 atmospheres
Power Requirements	Four 1.5V AA-size alkaline batteries (60 hours typical operation) or NiMH rechargeable battery pack (40 hours typical operation)
Dimensions	13.8 cm H x 7.0 cm W x 3.2 cm D (5.4 in H x 2.8 in W x 1.3 in D)
Weight	213 g (7.5 oz) (with alkaline batteries) 233 g (8.2 oz) (with NiMH rechargeable battery pack)
Classifications per IEC 60601-1 / CSA601.1 / UL60601-1	
Type of Protection	Internally powered (on battery power)
Degree of Protection	Type BF-Applied Part
Mode of Operation	Continuous
Enclosure Degree of Ingress Protection	IPX2

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

Service

CAUTION! The 2500A is a precision electronic instrument and must be repaired by trained NONIN personnel only. Any sign or evidence of opening the system, field service by non-NONIN personnel, tampering, or any kind of misuse or abuse of the system, shall void the warranty in its entirety.

The advanced digital circuitry within the 2500A requires no periodic maintenance or calibration. *Nonin does not recommend field repair of the 2500A*. The circuit board in the 2500A is a multi-layer board using very narrow traces. 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 2500A must be tested to ensure correct operation.

For additional technical information, contact NONIN's Customer Support department at:

Nonin Medical, Inc.	(800) 356-8874 (USA and Canada)
13700 1st Avenue North	(763) 553-9968
Plymouth, Minnesota 55441-5443 USA	Fax (763) 553-7807
	E-mail: info@nonin.com
	www.nonin.com

All non-warranty work shall be done according to NONIN standard rates and charges in effect at the time of delivery to NONIN. All repairs include a complete retest of the 2500A 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 2500A Pulse Oximeter 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 2500A 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 2500A delivered to the purchaser which is found to be defective in any manner whether such remedies be in contract, tort or by law.

This warranty excludes cost of delivery to and from NONIN. All repaired units shall be received by the purchaser at NONIN's place of business. For any 2500A sent to NONIN for warranty repair which is found to be within specification, the purchaser agrees to pay $100.00 (US dollars).

The 2500A is a precision electronic instrument and must be repaired by knowledgeable and specially trained NONIN personnel only. Accordingly, any sign or evidence of opening the 2500A, field service by non-NONIN personnel, tampering, or any kind of misuse or abuse of the 2500A, 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 2500A:

Model Number	Description
2500B	Rechargeable NiMH Battery Pack
2500C	Charger Stand
300PS-NA	Charger Stand Power Supply - North America/Japan
300PS-UNIV	Charger Stand Power Supply - Universal
Contact your distributor or NONIN for options	Charger Stand Power Cord - Universal
2500CC	Carrying Case (Blue)
2500A-INS	Operator's Manual for the 2500A
2500C-INS	Operator's Manual for the Model 2500C Charger Stand
	Pulse Oximeter Reusable Sensors
8000AA-1	Adult Articulated Finger Clip Sensor (1 meter)
8000AA-3	Adult Articulated Finger Clip Sensor (3 meter)
8000AP-1	Pediatric Finger Clip Sensor (1 meter)
8000AP-3	Pediatric Finger Clip Sensor (3 meters)
8000J-1	Adult Flex Sensor (1 meter)
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

Model Number	Description
	Other Accessories
nVISION	nVISION® Software for Microsoft Windows 95/98/2000/ NT 4.0 operating systems
8000JFW	Adult FlexiWrap Sensor Wrap
8008JFW	Infant FlexiWrap Sensor Wrap
8001JFW	Neonatal FlexiWrap Sensor Wrap
8000H	Reflectance Sensor Holder System
UNI-RA-0	7.5” 90-degree patient cable
UNI EXT	Patient Extension Cable
8000S	Patient Simulator
1000MC	Memory Cable (for use between the 2500A and a PC running Microsoft Windows 95/98 operating systems)

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

Problem	Possible Cause	Possible Solution
The 2500A won't turn on.	The batteries are dead.	Replace all 4 batteries.
	The batteries are installed incorrectly.	Verify correct battery orientations. Refer to Figure 4: Installing batteries in the 2500A.
	A metal contact in the battery compartment is missing or damaged.	Contact NONIN Customer Support.
A dash appears in the left digit of the SpO_2 display.	A sensor fault exists. The sensor may have become dislodged from the 2500A or from the patient.	Verify that the sensor is correctly connected to the 2500A and the patient; try a new sensor if the condition persists.
The middle digits display dashes in both the SpO_2 and pulse rate displays.	No signal is detected because the sensor is not plugged in.	Verify the sensor connections.
	A sensor failure.	Replace the sensor.
The displayed pulse rate does not correlate to the pulse rate displayed on the ECG monitor.	Excessive motion at the sensor site may be prohibiting the 2500A from acquiring a consistent pulse signal.	Eliminate or reduce the cause of the motion artifact **or** reposition the sensor to a new sensor site where motion is not present.
	The patient may have an arrhythmia resulting in some heart beats that do not yield a pulse quality signal at the sensor site.	Examine the patient: the condition may persist even though both monitors are functioning properly if the patient's arrhythmia persists.
	A non-NONIN sensor is being used.	Replace the sensor with a NONIN sensor.
	The ECG monitor may not be functioning properly.	Examine the patient: replace the ECG monitor **or** refer to the operator's manual for the ECG monitor.
An erratic pulse rate display and/or a yellow pulse quality indicator during the concurrent use of electrosurgical equipment (ESU).	The ESU may be interfering with the pulse oximeter performance.	Examine the patient: move the 2500A, cables, and sensors as far away from the ESU as possible **or** refer to the ESU operator's manual.
The pulse quality indicator is blinking yellow with each pulse.	The quality of the pulse signal at the sensor site is marginal.	Examine the patient: reposition the sensor **or** select an alternate sensor site.

Problem	Possible Cause	Possible Solution
You are unable to obtain a green blinking pulse quality display.	Low patient pulse strength; **or** the sensor site is poorly perfused; **or** the sensor is not correctly positioned.	Reposition the sensor on the patient.
	The sensor is attached too tightly, or tape or other items are restricting the pulse quality at the sensor site.	Reapply the sensor, select an alternate sensor site, or remove the restrictive material from the sensor site.
	Circulation is reduced due to excess pressure between the sensor and a hard surface.	Allow the sensor and finger, foot, etc., to rest comfortably on the surface.
	Excessive ambient light.	Reduce the ambient light.
	Excessive patient motion.	Reduce the patient motion.
	The sensor is applied to a polished finger or toe nail.	Remove the nail polish.
	Interference from: • arterial catheter • blood pressure cuff • electrosurgical procedure • infusion line	Reduce or eliminate the interference.
The pulse quality indicator is blinking red and the SpO_2 and/or pulse rate displays show dashes.	An inadequate signal at the sensor site.	Examine the patient: reposition the sensor **or** select an alternate sensor site.
	Excessive motion at the sensor site may be prohibiting the 2500A from acquiring a consistent pulse signal.	Eliminate or reduce the cause of the motion artifact or reposition the sensor to a sensor site where motion is not present.
	A sensor failure.	Replace the sensor.
Segments of the SpO_2 or pulse rate displays are missing.	Defective LED displays.	Displayed values may not be reliable; discontinue use of the 2500A.
Err E01, E02, E03, ***or*** **E04** ***is displayed.***	There is a system fault that must be corrected.	Turn the device off and on. If the problem persists, contact Nonin Customer Support.
Disruption in the 2500A performance.	Electromagnetic interference (EMI).	Remove the 2500A from the EMI environment.

Problem	Possible Cause	Possible Solution
Displays and indicators are off, but a continuous audible alarm is sounding.	There is a system fault that must be corrected.	Turn the device off and on. If the problem persists or the device does not turn on, replace or recharge the batteries. If the problem still persists, contact NONIN Customer Support.

If these solutions do not correct the problem with your 2500A, please contact NONIN Customer Support at (800) 356-8874 (USA and Canada) or (763) 553-9968.