Operator's Manual

PalmSAT®
Model 2500A VET

Veterinary Pulse Oximeter with Alarms

CE

English

Follow Instructions for Use.

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

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

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

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

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

nonin.com

CE

EC REP

MPS, Medical Product Service GmbH
Borngasse 20
D-35619 Braunfels, Germany

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

7678-001-06

Contents

Contents (Continued)

Figures

Tables

Indications for Use

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

CONTRAINDICATION: Do not use in an explosive atmosphere or in the presence of flammable anesthetics or gasses.

Warnings

Do not use this device in an MR environment.
This device is not defibrillation proof per IEC 60601-1.
The Model 2500A VET is intended for VETERINARY USE ONLY.
This device is intended only as an adjunct in animal assessment. It must be used in conjunction with other methods of assessing clinical signs and symptoms.
Inspect the sensor application site at least every 4 hours to ensure correct sensor alignment and tissue integrity. Animal sensitivity to sensors and/or double-backed adhesive strips may vary due to medical status or skin condition.
Oximeter readings of this device may be affected by the use of an electrosurgical unit (ESU).
Do not use a damaged sensor. If the sensor is damaged in any way, discontinue use immediately and replace the sensor.
Verify all alarm settings and limits during system startup to ensure that they are set as intended.
A hazard can exist if different presets are used on multiple 2500A VET monitors in one care area.
As with all medical equipment, carefully route cabling to reduce the possibility of animal entanglement, strangulation, or injury.
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.
To prevent improper performance and/or injury to the animal, verify compatibility of the monitor, sensor(s), and accessories before use.
No modifications to this device are allowed as it may affect device performance.
Discontinue use of adhesive tape strips if the animal exhibits an allergic reaction to the adhesive material.
Avoid excessive pressure to the sensor application site as this may cause damage to the skin beneath the sensor.
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 this device in an environment where its speaker opening may become blocked; alarms may become muffled or inaudible.
Turning off the 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.
When a system fault occurs, the animal will no longer be monitored.
To comply with relevant product safety standards, ensure that all alarm volumes are set appropriately and are audible in all situations. Do not cover or otherwise hinder any speaker openings.
The device turns off after approximately 10 minutes when at critically low battery capacity.

Warnings (Continued)

In the event the sensor becomes dislodged from the animal, audible and visual alarms are activated, requiring that a veterinary professional investigate the reason for the alarm status. The veterinary professional must investigate animal status and sensor attachment after every sensor alarm indication. It is possible when the sensor is dislodged from the animal (under certain conditions of light and vibration of the sensor) for the pulse oximeter to display normal physiological values.
Verify all alarm settings and limits during system startup to ensure that they are set as intended.
Before changing the batteries, make sure the device is off and the sensor is not applied to the animal.

Cautions

Before use, carefully read the package insert provided with the sensors.
This device 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 device. Contact Nonin Technical Service for assistance.
Review all limits to ensure they are appropriate for the animal.
Setting alarm limits to extremes can render the alarm system useless.
The presence of a defibrillator may interfere with the performance of this device.
This device may not work on all animals. If you are unable to achieve stable readings, discontinue use.
Inadequate perfusion, thick fur, foreign matter that blocks light, or an improperly applied sensor can result in erratic and inaccurate oxygen saturation and/or pulse rate measurement. Follow the instructions outlined in “Monitoring.” If proper operation cannot be verified, remove the sensor from the animal and DO NOT use the oximeter on the animal.
This device has motion tolerant software that minimizes the likelihood of motion artifact being misinterpreted as good pulse quality. In some circumstances, however, the device may still interpret motion as good pulse quality. Minimize animal motion as much as possible.
Do not place the Model 2500A VET in liquid or clean it with agents containing ammonium chloride, isopropyl alcohol, or products that are not listed in this operator’s manual.
Do not autoclave or immerse the device or sensors in liquid. Do not expose the device or components to excessive moisture or liquids.
Do not use caustic or abrasive cleaning agents on the device or the sensors.
The oximeter sensor might not work on cold extremities due to reduced circulation. Warm or rub the sensor site to increase circulation, or reposition the sensor.
Sensor sites must be checked periodically to determine circulation, sensor positioning, and tissue sensitivity.
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 use 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, state, and national 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.

Cautions (Continued)

Remove the batteries if the device will be stored for more than 1 month.
This equipment complies with IEC 60601-1-2 for electromagnetic compatibility for medical electrical equipment and/or systems. This standard is designed to provide reasonable protection against harmful interference in a typical medical installation. However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in healthcare and other environments, it is possible that high levels of such interference due to close proximity or strength of a source might disrupt the performance of this device. Medical electrical equipment needs special precautions regarding EMC, and all equipment must be installed and put into service according to the EMC information specified.
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.
This device's display will go blank after 10 seconds of inadequate signals. The data update period is every 1.5 seconds.
Portable and mobile RF communications equipment can affect medical electrical equipment.
This device is designed to determine the percentage of arterial oxygen saturation of functional hemoglobin. Factors that may degrade pulse oximeter performance or affect the accuracy of the measurement include the following: - excessive ambient light - excessive motion - electrosurgical interference - blood flow restrictors (arterial catheters, blood pressure cuffs, infusion lines, etc.) - moisture in the sensor (for non-lingual applications) - improperly applied sensor - incorrect sensor type - inadequate signal - venous pulsations - anemia or low hemoglobin concentrations - cardiogreen and other intravascular dyes - carboxyhemoglobin - methemoglobin - dysfunctional hemoglobin - residue (e.g., dried blood, dirt, grease, oil) in the light path
A functional tester cannot be used to assess the accuracy of a pulse oximeter monitor or sensor.
All parts and accessories connected to the serial port of this device must be certified according to at least IEC Standard EN 60950, IEC 62368-1, or UL1950 for data-processing equipment.
This device is a precision electronic instrument and must be repaired by trained Nonin personnel only. Field repair of the device is not possible. Do not attempt to open the case or repair the electronics. Opening the case may damage the device and void the warranty.
Any sign or evidence of opening the system, field service by non-Nonin personnel, tampering, or any kind of misuse or abuse of the system, shall void the warranty in its entirety.
Replace batteries within 30 seconds to avoid losing settings (date, time, and data stored in memory) or corrupting data.
Use only the Nonin-branded Model 2000SL, 2000T, or 2000SA veterinary sensors for monitoring. These sensors are manufactured to meet the calibration requirements for the Nonin Model 2500A VET pulse oximeter. The oximeter is calibrated for adult human hemoglobin measured at the finger tip. Although animal hemoglobin has similar optical characteristics, other types of hemoglobin or alternate sensor locations may affect the calibration.
Certain pharmacologic agents used to sedate or anesthetize animals may have cardiovascular effects that can adversely affect the performance of the pulse oximeter by reducing the perfusion to the sensor site. Examples of commonly used agents that may have this type of effect on certain animal species are Detomidine HCl and Xylazine HCl.
There is a wide range of variability between animal species and their respective differences in anatomy, physiology, and responses to veterinary pharmacological agents. Therefore, the veterinary professional will need to use discretion when selecting sensors and/or sensor sites that are appropriate for the animal species and the monitoring conditions.
When attaching the pulse oximeter sensor, make sure to secure the sensor in a manner that will not restrict perfusion. An improperly applied sensor could inhibit proper function of the pulse oximeter and cause discomfort or localized ischemia to the animal.
Failure of a network data coupling (serial cable/connectors) will result in loss of data transfer.

Guide to Symbols

This table describes the symbols that are found on the Model 2500A VET system or packaging. Detailed information about functional symbols can be found in “Displays, Indicators, and Controls.”

Table 1: Symbols

Symbol	Description
	CAUTION!
	Consult Instructions for Use.
	Follow Instructions for Use.
	Type BF Applied Part (patient isolation from electrical shock).
	UL Mark for Canada and the United States with respect to electric shock, fire, and mechanical hazards only in accordance with: • ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10) and CAN/CSA-C22.2 No. 60601-1 (2008) • ISO 80601-2-61:2011, IEC 60601-1-8: 2006+A1:2012
	CE Marking indicating conformance to EC directive No. 93/42/EEC concerning medical devices.
SN	Serial Number (located under the back cover).
IP32	Protected against vertically falling water drops when enclosure is tilted up to 15 degrees and ingress of solid foreign objects greater than or equal to 2.5 mm (0.1 in.) in diameter per IEC 60529.
	Indicates separate collection for electrical and electronic equipment (WEEE).
	Authorized Representative in the European Community.
	Manufacturer
	Catalogue Number
	Quantity
	Date of Manufacture
	Country of Manufacture

Table 1: Symbols (Continued)

Symbol	Description
	Storage/Shipping Temperature Range
	RoHS Compliant (China)
Display Symbols	
%SpO$_2$	%SpO$_2$ Display
	Pulse Rate Display
	Pulse Quality LED
	Low Battery LED
	Alarm Silence LED
Front Panel Buttons	
	On/Off
	Advance

Displays, Indicators, and Controls

This chapter describes the displays, indicators, and controls (figure 1) for the Model 2500A VET.

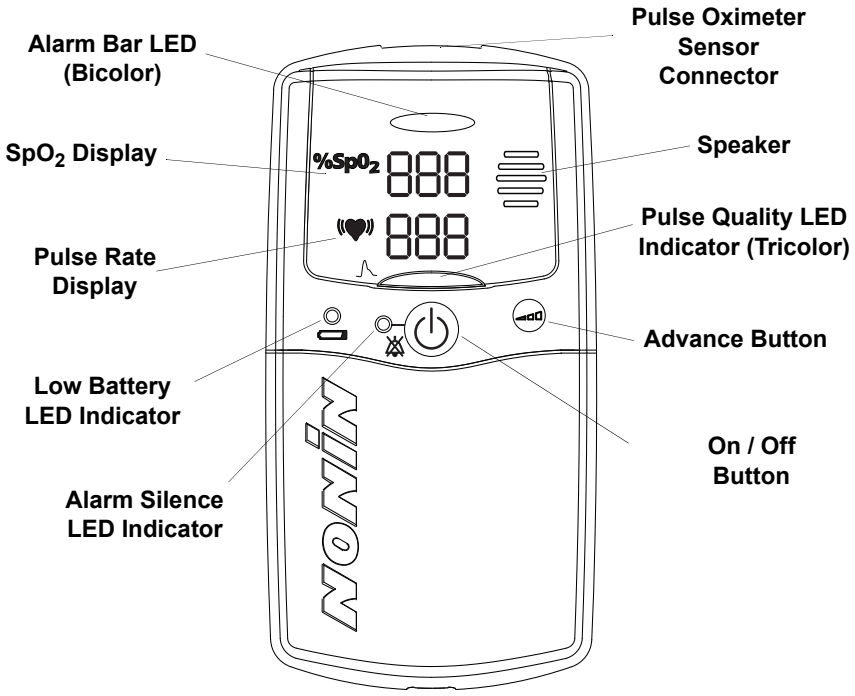


Figure 1: Model 2500A VET - Front View

Displays

%SpO_2 SpO_2 Display

The upper 3-digit light-emitting diode (LED) display shows the current oxygen saturation percentage. This display flashes during SpO_2 alarms.

This display also indicates if a pulse oximeter sensor fault or inadequate signal condition exists. If one exists, a dash (-) appears in the leftmost position of the SpO_2 display and the readings freeze. After 10 seconds, a dash appears in the middle position of the SpO_2 display.

Pulse Rate Display

The lower 3-digit LED display shows the pulse rate in beats per minute. This display flashes during pulse rate alarms.

During a pulse oximeter sensor fault or inadequate signal condition, the pulse rate display freezes for 10 seconds and then a dash appears in the middle position of the display.

Indicators

Pulse Quality LED Indicator

Located above the On/Off button, this tricolor indicator blinks once for each detected pulse and changes color with the pulse strength signal:

- **Green** indicates a good pulse strength.
- **Amber** indicates a marginal pulse strength. To improve signal quality, reposition the sensor, try a different sensor type, eliminate animal movement, or improve the site's circulation.
- **Red** indicates an inadequate pulse strength. When the Pulse Quality indicator is red, SpO_2 and pulse rate values are not updated. After 10 seconds, the values are replaced with dashes, indicating that readings are not possible.

Low Battery LED Indicator

This amber indicator flashes to indicate a low or critically low battery. It is a medium priority alarm.

When batteries are critically low, the digital displays go blank and the Pulse Quality indicator blinks amber or red. Any SpO_2 or pulse rate alarms in effect when critically low battery capacity is reached are latched, and flashing dashes appear on the corresponding display. After 10 minutes at critically low battery capacity, the pulse oximeter automatically shuts off.

Alarm Silence LED Indicator

Located left of the On/Off button, this amber indicator blinks when all audible alarms are temporarily silenced. If the alarm volume is set to OFF, the Alarm Silence indicator is solidly lit.

Alarm Bar LED Indicator

Located near the top of the device, this indicator flashes:

- **Amber** during medium priority alarms
- **Red** during high priority alarms

Audible Indicators

The pulse rate tone beeps 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 by momentarily pressing the Advance button.

Audible alarms also sound for high and medium priority alarms. See "Alarms" for more information.

Controls

On/Off Button

This button turns the device on and off.

During Setup mode, this button selects the value of a setting and advances to the next setting.

Advance Button

During normal operation, this button allows the user to adjust the volume or review settings.

During Setup mode, this button is used to scroll through the values for a setting.

Introduction

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

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.

Oxygen saturation and pulse rate values are displayed by light-emitting diode (LED) digital displays. On each detected pulse, the Pulse Quality indicator blinks. Pulse quality signals are graded as good (green), marginal (amber), or inadequate (red) and are indicated as such by the Pulse Quality indicator. 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 Model 2500A VET pulse oximeter may be used with a variety of Nonin-branded veterinary oximeter sensors.

A sensor disconnect or malfunction is indicated by a red blinking Pulse Quality indicator 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 are replaced by dashes.

The device requires no routine calibration or maintenance other than replacing batteries or recharging the battery pack. This device typically operates for 60 hours continuously between alkaline battery replacements, or for 40 hours with the Model 2500B Rechargeable NiMH (Nickel Metal Hydride) Battery Pack.

Unpacking the Model 2500A VET

The Model 2500A VET complete system includes:

- 1 Model 2500A VET Pulse Oximeter
- 1 Model 2500A VET Operator’s Manual on CD
- 1 Nonin Small Lingual Clip Pulse Oximeter Sensor
- 4 AA-Size Alkaline Batteries

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

Batteries

CAUTION: Use only Nonin-specified battery types with this device.

CAUTION: Do not use fully charged and partially charged batteries at the same time. This may cause the batteries to leak.

The Model 2500A VET can be powered by either 4 AA-size alkaline batteries or the optional Model 2500B Rechargeable NiMH (Nickel Metal Hydride) Battery Pack.

Commercially available rechargeable AA batteries can be used in the Model 2500A VET, but are not recommended by Nonin.

Operating Life:

- Alkaline batteries - 60 hours, continuous
- Rechargeable NiMH battery pack - 40 hours, continuous

Storage Life:

- Alkaline batteries:
  - If calendar/clock is set, approximately 6 weeks.
  - If calendar/clock is not set, approximately 10 -12 months.
- Rechargeable NiMH battery pack:
  - If calendar/clock is set, approximately 3 weeks.
  - If calendar/clock is not set, approximately 2 months.

Recharge Time Using Model 2500C Charger Stand:

- Rechargeable NiMH battery pack - 180 minutes

Low and Critically Low Battery

Low and critically low battery capacity is indicated with a flashing Low Battery indicator and a medium priority alarm.

When the batteries are low, the Low Battery indicator flashes and battery capacity allows for less than 30 minutes of normal operation.

When batteries are critically low, the Low Battery indicator flashes, the digital displays go blank, and the Pulse Quality indicator blinks amber or red, but not green. Any SpO_2 or pulse rate alarms in effect when critically low battery capacity is reached are latched, and flashing dashes appear on the corresponding display. After 10 minutes at critically low battery capacity, the pulse oximeter shuts off automatically.

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

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

Installing Batteries

WARNING: Before changing the batteries, make sure the device is off and the sensor is not applied to the animal.

1. Press the battery cover latch (figure 2), and slide off the battery cover from the bottom of the unit.
2. Insert 4 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 (figure 3).
3. Replace the battery cover and turn on the device. If the unit does not turn on, see "Troubleshooting."

⚠ **CAUTION:** Replace batteries within 30 seconds to avoid losing settings (date, time, and data stored in memory) or corrupting data.

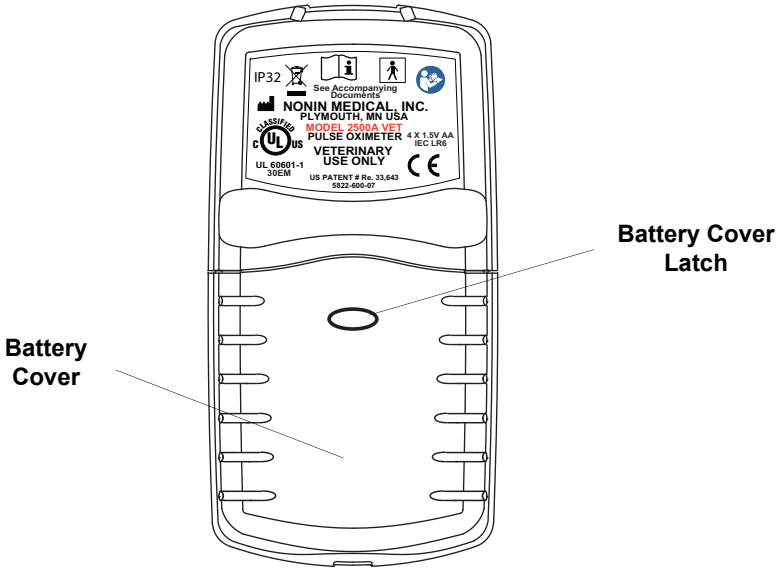


Figure 2: Model 2500A VET - Rear View

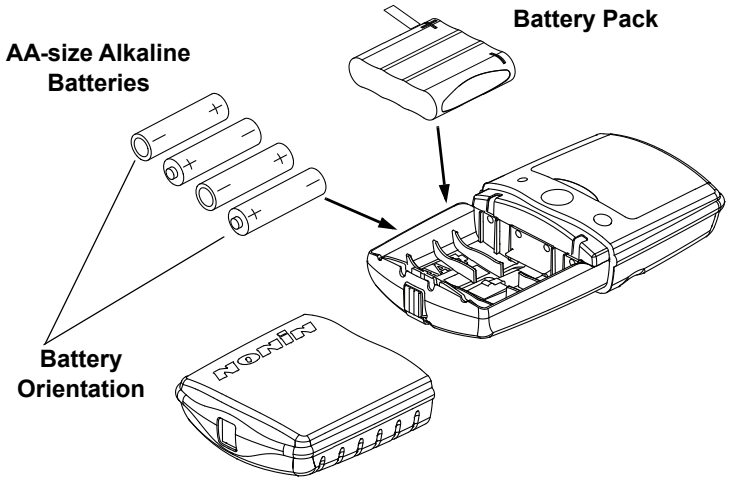


Figure 3: Installing Batteries

Important Notes about Battery Use

Four AA alkaline batteries provide the device with approximately 60 hours of continuous operation. The rechargeable NiMH battery pack provides 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 clock/calendar functions are set. Refer to “Clock and Calendar Settings” for more information.

When Using AA Batteries

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

When Using the Rechargeable NiMH Battery Pack

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

Recharging Batteries (NiMH Battery Pack Only)

- When the unit is completely discharged, it takes approximately 180 minutes to recharge the NiMH battery pack with the Model 2500C Charger Stand.
- The expected useful life of the rechargeable NiMH battery pack is 500 charge/discharge cycles, or approximately 2 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.

Using the 2500A VET Pulse Oximeter

Connecting the Sensor

Connect the pulse oximeter sensor (with the Nonin logo facing up) to the top of the device (figure 4). Ensure the sensor is firmly plugged in.

Refer to “Sensor Placement” or to the specific sensor package insert for pulse oximeter sensor positioning information.

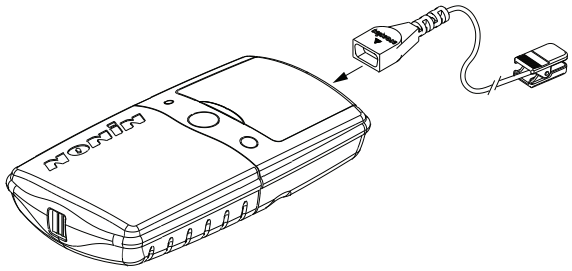


Figure 4: Connecting the Sensor

Power On/Off

- To turn ON, press and release **On/Off** ⏻.
- To turn OFF, press and hold **On/Off** for approximately 2 seconds.

To conserve battery life, the device 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 animal pulse signal.

Power On Self-Test

When the Model 2500A VET is turned on for normal operation, the unit cycles through a startup/initialization sequence before displaying valid data. During startup, always check for missing indicators or LED display segments and ensure the audible indicator sounds. If any indicator does not function, do not use the device. Contact Nonin Technical Service for repair or replacement.

During its normal startup sequence, the device cycles as follows:

1. 888 888 appears briefly in the SpO_2 and pulse rate displays.
2. Pulse Quality and Alarm Bar indicators flash red for 1 second.
3. Low Battery and Alarm Silence indicators turn on steadily for a few seconds.
4. The Pulse Quality indicator flashes green and the Alarm Bar flashes amber for 1 second.
5. Clock time in hours and minutes (as currently set in the memory) briefly appears in the SpO_2 and pulse rate displays (e.g., 04 41).
6. Software revision numbers display for approximately 1 second each in the following order:
   - Main revision (“A” + 3 digits)
   - Memory revision (“nn” (for m) + 3 digits)
   - Sound revision (“S” + 3 digits)

7. Three beeps sound.
8. A dash (-) appears in the center digit of the SpO_2 and pulse rate displays until a valid pulse signal is detected.

NOTES:

- The 2-minute alarm silence feature is automatically enabled immediately after the startup sequence.
- This startup sequence varies slightly when entering Setup mode at power on.

Monitoring

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

1. Pulse Quality indicator blinks green.
2. Pulse rate and SpO_2 displays show readings.
3. Pulse Quality indicator blinks in time with the pulse rate for at least 10 seconds.

If the Pulse Quality indicator blinks red or amber or blinks erratically, reposition or replace the sensor.

If the sensor is not properly positioned, or a sensor is not 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.

Veterinary Sensors

The Model 2500A VET pulse oximeter features sensors ideal for a variety of veterinary applications. Each sensor is designed for a specific site application and specific animal size. The sensors include:

- Small Lingual Clip (2000SL) – Recommended for spot checks or short-term continuous monitoring. For most small animals, the sensor performs best when used on the tongue.
- Small Animal Flex Sensor (2000SA) – Suitable for use on the toe of a dog and on the paw or at the base of the tail on very small animals (e.g., rats).
- Transflectance Sensor (2000T) – Suitable for placement on the underside, base of the tail (near the anal orifice) of a dog.

Nonin's veterinary sensors are reusable. Clean them with a mild detergent. Allow enough time for the sensor to dry thoroughly before reusing.

⚠ **CAUTION:** Use only the Nonin-branded Model 2000SL, 2000T, or 2000SA veterinary sensors for monitoring. These sensors are manufactured to meet the calibration requirements for the Nonin Model 2500A VET pulse oximeter. The oximeter is calibrated for adult human hemoglobin measured at the finger tip. Although animal hemoglobin has similar optical characteristics, other types of hemoglobin or alternate sensor locations may affect the calibration.

CAUTION: This device is designed to determine the percentage of arterial oxygen saturation of functional hemoglobin. Factors that may degrade pulse oximeter performance or affect the accuracy of the measurement include the following:

- excessive ambient light
- excessive motion
- electrosurgical interference
- blood flow restrictors (arterial catheters, blood pressure cuffs, infusion lines, etc.)
- moisture in the sensor (for non-lingual applications)
- improperly applied sensor
- incorrect sensor type
- inadequate signal
- venous pulsations
- anemia or low hemoglobin concentrations
- cardiogreen and other intravascular dyes
- carboxyhemoglobin
- methemoglobin
- dysfunctional hemoglobin
- residue (e.g., dried blood, dirt, grease, oil) in the light path

CAUTION: Sensor sites must be checked periodically to determine circulation, sensor positioning, and tissue sensitivity.

NOTE: The Model 2000SL Small Lingual Clip, 2000T Transflectance, and 2000SA Small Animal Flex sensors differ only in the configuration of the attachment housing. These sensor configurations enable pulse oximetry measurement with the sensor positioned on the tongue (primary), toe (alternate), or at the base of the tail (alternate).

Sensor Placement

Model 2000SL Small Lingual Clip Application

The recommended application site for the small lingual clip is on the tongue of a small animal (dog, cat, etc.) (figure 5).

Position the tongue clip so it is fully onto the tongue. If the clip is only partially on the tongue, the sensor light may bypass the edge of the tongue, resulting in SpO_2 measurement error.

CAUTION: Inadequate perfusion, thick fur, foreign matter that blocks light, or an improperly applied sensor can result in erratic and inaccurate oxygen saturation and/or pulse rate measurement. Follow the instructions outlined in “Monitoring.” If proper operation cannot be verified, remove the sensor from the animal and DO NOT use the oximeter on the animal.

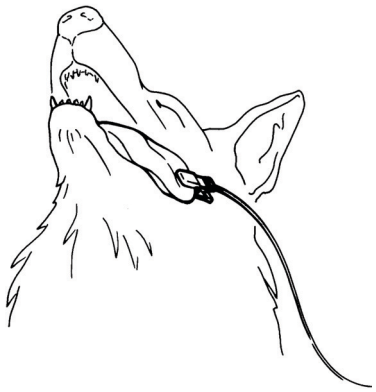


Figure 5: Small Lingual Clip Placement

Model 2000SA Small Animal Flex Sensor Application

The small animal flex sensor is suitable for use on the toe of a dog or the base of the tail on very small animals such as rats.

Shave the site completely before sensor application. Position the light emitter and light detector of the sensor so that the sensor light is directed through the tail or toe.

NOTE: Mispositioning might allow sensor light to bypass the toe or tail resulting in SpO_2 measurement error. Secure the sensor with tape, ensuring that the tape does not restrict perfusion.

Model 2000T Transflectance Sensor Application

The transflectance sensor is designed for placement on the underside, base of the tail (near the anal orifice) of a dog.

Shave the site completely before sensor application. Position the light emitter and light detector of the sensor against the underside of the tail at the base near the anal orifice. Secure the sensor with tape, ensuring that the tape does not restrict perfusion.

Detailed Operation

All functions of the Model 2500A VET are controlled by the **On/Off** ⏻ and **Advance** ◿▭▯ buttons located on the front of the unit.

Setup Mode

Setup mode is used to adjust alarm limits, clear the memory, and adjust calendar and clock settings. In Setup mode, the **Advance** and **On/Off** buttons are used to make all selections.

Entering Setup Mode

1. With the unit off, press and hold **Advance** ◿▭▯ while pressing and then releasing **On/Off** ⏻.
2. Release **Advance** when 888 888 appears in the SpO_2 and pulse rate displays.
3. The clock time currently set in the memory (e.g., 04 41) appears briefly in the SpO_2 and pulse rate displays.
4. rCL no appears in the SpO_2 and pulse rate displays.

Adjusting Settings in Setup Mode

1. Enter Setup mode as above. See table 2 for the device's adjustable settings and the order in which they display on the device.
2. The SpO_2 and pulse rate displays show the first setting that can be changed and its value (rCL no).
   a. To skip a setting, press **On/Off** ⏻.
   b. To change a setting, press and release **Advance** ◿▭▯ to step through the range of values, or press and hold **Advance** to scroll through the values.
3. When the desired value appears, press and release **On/Off** to store the value and advance to the next setting.
4. Continue this process until all settings are chosen.
5. When the setting sequence is complete, the device exits Setup mode, automatically displays the alarm settings in effect, and begins normal operation.

Table 2: Adjustable Parameters and Settings

Setting	SpO_2 Display	Pulse Rate Display Range of Values	Default Value
Recall Alarm[1]	rCL	No, Yes	No
SpO_2 Low Alarm	02L	50 - 95 Off	85
Pulse Rate High Alarm	H H	125 to 425 by 25 50 to 100 by 5 Off	200

Table 2: Adjustable Parameters and Settings (Continued)

Setting	SpO_2 Display	Pulse Rate Display Range of Values	Default Value
Pulse Rate Low Alarm	H L	20 to 200 by 5 Off	50
SpO_2 High Alarm	02H	80 - 100 Off	Off
Audible Alarms	Adb	Hi, Lo, Off	Hi
Memory Clear[2]	CLr	No, Yes	No
Delete (confirm clear)	dEL	No, Yes	No
Year	y	00 - 99	10
Month	nn	00 - 12	00
Day	d	01 - 31	00
Hour	h	00 - 23	00
Minute	nn	00 - 59	00

Notes:

1. Choosing “Yes” for rCL (Recall Alarm) recalls previous alarm and volume settings and exits Setup mode.
2. Choosing “Yes” for both CLr and dEL (Memory Clear and Delete) clears the memory and exits Setup mode.

Alarm Settings

WARNING: To comply with relevant product safety standards, ensure that all alarm volumes are set appropriately and are audible in all situations. Do not cover or otherwise hinder any speaker openings.

WARNING: Verify all alarm setting and limits during system startup to ensure that they are set as intended.

CAUTION: Review all limits to ensure they are appropriate for the animal.

CAUTION: Setting alarm limits to extremes can render the alarm system useless.

Users may adjust the alarm limits for upper and lower SpO_2 and pulse rate alarms and alarm volume as in table 3. Adjusting alarm settings is only possible when the device is in Setup mode (see “Adjusting Settings in Setup Mode”). When alarm settings have not been recalled or adjusted in Setup mode, the default alarm settings remain in effect.

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

Table 3: Alarm Limits and Volume Settings

Alarm Limit	Default	Adjustment Options	Increments
SpO_2 High (02H)	Off	Off, 80 - 100	1%
SpO_2 Low (02L)	85%	Off, 50 - 95	1%
Pulse Rate High (H H)	200 BPM	Off 50 - 100 125 - 425	 5 BPM 25 BPM
Pulse Rate Low (H L)	50 BPM	Off, 20 - 200	5 BPM
Alarm Volume (Adb)	Hi	Off, Lo, Hi	N/A

Recalling Alarm Settings

The 2500A VET retains most user settings when the device is turned off. However, if SpO_2 Low (02L) is set below 85% and/or the Alarm Volume (Adb) is OFF, these settings revert to their default values when the device is turned on.

The user may recall the Alarm Volume--OFF setting by using Setup mode to turn on the device and selecting rCL yES. SpO_2 returns to the default if it is set below 85% even when the device is turned on with Setup mode.

Alarm settings are retained and available for recall for approximately 30 seconds after removing batteries.

> ⚠ **CAUTION:** Replace batteries within 30 seconds to avoid losing settings (date, time, and data stored in memory) or corrupting data.

NOTE: If set below 85%, the SpO_2 Low Alarm setting defaults to 85% every time the unit is powered off. The SpO_2 Low setting cannot be recalled by turning on the device in Setup mode.

1. Enter Setup mode. Device displays Recall Alarm (rCL). Default value is no.
2. Press **Advance** to change value to Yes.
3. Press **On/Off** ⏻ to accept and recall the previously-adjusted alarm and volume settings.
4. Device exits Setup mode, automatically displays the alarm settings in effect, and begins normal operation.

NOTE: Setup mode exits automatically after the Recall Alarms setting is selected.

Reviewing Alarm Settings

At any time during normal operation, alarm limits and volume settings can be reviewed.

1. Press and hold **Advance** for 1 second.
2. All settings individually flash on the display screen.

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

Silencing Audible Alarms

Audible alarms are automatically silenced for the first 2 minutes of normal operation and can be temporarily silenced during normal operation.

1. Momentarily press **On/Off** ⏻ to temporarily silence audible alarms (2 minute silence) during normal operation.
2. Alarm Silence indicator blinks when alarms are temporarily silenced.
3. Press **On/Off** again to cancel the temporary alarm silence.

Clearing the Memory

The Memory Clear function deletes the data currently stored in the device's memory.

NOTE: If "no" is selected for either CLr or dEL, Setup mode continues to the calendar and clock settings.

1. Enter Setup mode, and scroll through the settings until Memory Clear (CLr) appears in the SpO_2 display. Default value is No.
2. Press **Advance** to change value to Yes.
3. Press **On/Off** ⏻ to accept and move to the next setting (dEL). Default value is No.
4. Press **Advance** to change value to yES.
5. Press **On/Off** to accept and clear the device memory.
6. dnE CLr briefly appears in the SpO_2 and pulse rate displays to show the memory has cleared.
7. Device exits Setup mode, automatically displays the alarm settings in effect, and begins normal operation.

Calendar and Clock Settings

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

1. Enter Setup mode and scroll through the settings until the calendar year setting (y) appears in the SpO_2 display.
2. Press **Advance** to scroll through the values.
3. Press **On/Off** ⏻ to accept a value and move to the next setting. After year, select month (nn), day (d), hour (h), and minute (nn).
4. After selecting the last desired setting, press and release **On/Off**.
5. Device exits Setup mode, automatically displays the alarm settings in effect, and begins normal operation.

Care and Maintenance

Wipe the device with a soft cloth dampened with a mild detergent or 10% bleach solution. Do not use undiluted bleach or any cleaning solution other than those recommended here, as permanent damage could result. Dry with a soft cloth, or allow to air dry.

Clean after each use or as needed.

Clean the device separately from the sensors. For instructions on cleaning pulse oximeter sensors, refer to the respective sensor instructions for use.

> ⚠ **CAUTION:** Do not place the Model 2500A VET in liquid or clean it with agents containing ammonium chloride, isopropyl alcohol, or products that are not listed in this operator's manual.

> ⚠ **CAUTION:** Do not autoclave or immerse the device or sensors in liquid. Do not expose the device or components to excessive moisture or liquids.

> ⚠ **CAUTION:** Do not use caustic or abrasive cleaning agents on the device or the sensors.

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

Alarms

This section describes the alarm functions of the Model 2500A VET. The device features audible and visual alarms that indicate both high and medium priority alarm conditions.

WARNING: In the event the sensor becomes dislodged from the animal, audible and visual alarms are activated, requiring that a veterinary professional investigate the reason for the alarm status. The veterinary professional must investigate animal status and sensor attachment after every sensor alarm indication. It is possible when the sensor is dislodged from the animal (under certain conditions of light and vibration of the sensor) for the pulse oximeter to display normal physiological values.

High Priority Alarms

High priority alarms (table 4) are animal-specific and are indicated by a flashing red Alarm Bar and a high priority audible alarm.

High priority alarms sound as 3 beeps, a pause, 2 beeps, and a 10-second pause. This cycle repeats until silenced.

Table 4: High Priority Alarms

Condition	Visible Indicators
SpO_2 high or low	SpO_2 display flashes in sync with the Alarm Bar. If in critically low battery state, 3 dashes are inserted in the display and flash in sync with the Alarm Bar.
Pulse rate high or low	Pulse rate display flashes in sync with the Alarm Bar. If in critically low battery state, 3 dashes are inserted in the display and flash in sync with the Alarm Bar.
Pulse waveform amplitude is inadequate	Pulse Quality indicator blinks red, and SpO_2 and pulse rate displays show dashes in 10 seconds.

Medium Priority Alarms

Medium priority alarms (table 5) are generally equipment-specific, and are indicated by a flashing amber Alarm Bar and a medium priority audible alarm signal.

Medium priority alarms sound as 3 beeps followed by a 25-second pause. This cycle repeats until silenced.

Table 5: Medium Priority Alarms

Condition	Visible Indicators
Inadequate signal (i.e., sensor dislodgement, unusable signal)	Pulse Quality indicator blinks, dash (-) appears in leftmost digit of SpO_2 display, then SpO_2 and pulse rate displays freeze for 10 seconds, and then dash appears in middle digit of SpO_2 and pulse rate displays.
Sensor fault I (i.e., sensor disconnect, bad cable, Nonin incompatible sensor)	Pulse Quality indicator is not lit, dash (-) appears in leftmost digit of SpO_2 display, then SpO_2 and pulse rate displays freeze for 10 seconds, and then dash appears in middle digits of SpO_2 and pulse rate displays.
SpO_2 or pulse rate data not adequate for more than 20 seconds	Dash (-) displays in middle digit of SpO_2 and pulse rate displays (i.e., out-of-track indication).
Pulse rate data not updated for more than 30 seconds	Dashes display in pulse rate display.
Battery low	Low Battery indicator flashes.
Battery critical	Low Battery indicator flashes; SpO_2 and pulse rate displays are blank; and latched Pulse Quality indicator is red or amber, but not green.
Sound module or system failure detected	Display error code.

System Fault Alarms

If the device 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.

1. Attempt to clear the error by turning the device off and on.
2. If the problem persists, contact Nonin Technical Service.

WARNING: When a system fault occurs, the animal will no longer be monitored.

Memory Functions

Data Collection

Each time the Model 2500A VET is turned on (except during Setup mode), data are automatically collected in memory. The device 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 30 seconds after removing the batteries. Replace batteries immediately to avoid losing stored data.

The memory in the device functions as an “endless loop.” When the memory fills up, the unit begins overwriting the oldest data with the newest.

Each time the device is turned on, the current time/date information (if the clock is set correctly) is stored in memory to allow quick differentiation of recording sessions. 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 2500A VET memory stores pulse rates from 18 to 450 beats per minute. The stored values are in increments of 1 pulse 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.

Memory Playback

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

1. Connect the 2500A VET to a computer with the Memory Cable (1000MC), Real-Time Cable (1000RTC), or USB Interface Adapter (1000USB/1000USB-C).
2. Enter Setup mode (see “Entering Setup Mode”).
3. When `rCL no` appears in the SpO_2 and pulse rate displays do not press any buttons.
4. After 8 seconds, data automatically plays back from the memory at a rate of 20 minutes of data per second. A 72-hour recording session (the maximum memory saved) is played back in approximately 3.5 minutes.
5. After all data are played back, the device should be shut off before collecting new animal data.

Animal information is held in memory as long as the batteries are sufficiently charged. If the memory must be cleared, see “Clearing the Memory.”

Communications

Serial Output

The Model 2500A VET 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 6.

Table 6: Pulse Oximeter Sensor Connector Pin Assignments

Pin Number	Assignment
1	1-Wire®
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	No Connection
9	Detector Cathode, +5 V

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

NOTE: The 9th data bit is used for 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 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 display as “---” if there are no data available for the data reading.

Connecting the Device into a Medical System

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

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

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

NOTES:

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

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

Service, Support, and Warranty

Service and Support

> **CAUTION:** This device is a precision electronic instrument and must be repaired by trained Nonin personnel only. Field repair of the device is not possible. Do not attempt to open the case or repair the electronics. Opening the case may damage the device and void the warranty.

> **CAUTION:** Any sign or evidence of opening the system, field service by non-Nonin personnel, tampering, or any kind of misuse or abuse of the system, shall void the warranty in its entirety.

The advanced digital circuitry within the Model 2500A VET requires no periodic maintenance or calibration. Nonin does not recommend field repair of the Model 2500A VET. The circuit board in the Model 2500A VET 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 Model 2500A VET must be tested to ensure correct operation.

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

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

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

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

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

nonin.com

All non-warranty work shall be done according to Nonin standard rates and charges in effect at the time of delivery to Nonin. All repairs include a complete retest of the Model 2500A VET using factory test fixtures.

Warranty

NONIN MEDICAL, INCORPORATED, (Nonin) warrants to the purchaser, for a period of 3 years from the date of purchase, each Model 2500A VET 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 Model 2500A VET found to be defective in accordance with this warranty, free of charge, for which Nonin has been notified by the purchaser by serial number that there is a defect, provided said notification occurs within the applicable warranty period. This warranty shall be the sole and exclusive remedy by the purchaser hereunder for any Model 2500A VET delivered to the purchaser which is found to be defective in any manner whether such remedies be in contract, tort or by law.

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

The Model 2500A VET is a precision electronic instrument and must be repaired by knowledgeable and specially trained Nonin personnel only. Accordingly, any sign or evidence of opening the Model 2500A VET, field service by non-Nonin personnel, tampering, or any kind of misuse or abuse of the Model 2500A VET, 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 Model 2500A VET. Detailed information regarding specified sensor use (animal population, body/tissue, and application) can be found in the respective sensor instructions.

Model Number	Description
2500B	Rechargeable NiMH Battery Pack
2500C	Charger Stand
MPP30M-002	Power supply, 30W, used with a 7600PCS power cord
7600PCS-US	Power cord, North America
7600PCS-UK	Power cord, United Kingdom
7600PCS-EU	Power cord, European Union and South America
7600PCS-AU	Power cord, Australia
7600PCS-JP	Power cord, Japan
2500CC	Carrying Case (Blue)
2500A VET-INS	Operator's Manual for the Model 2500A VET
2500C-INS	Operator's Manual for the Model 2500C Charger Stand
Pulse Oximeter Reusable Sensors	
2000SL	Small Lingual Clip Sensor
2000SA	Small Animal Flex Sensor
2000T	Transflectance Sensor
Other Accessories	
UNI-RA-0	7.5" 90-degree patient cable
UNI-EXT-1	Extension Cable, 1 meter (3 feet)
UNI-EXT-3	Extension Cable, 3 meter (10 feet)
UNI-EXT-6	Extension Cable, 6 meter (20 feet)
UNI-EXT-9	Extension Cable, 9 meter (30 feet)
1000MC	Memory Cable (for use between the Model 2500A VET and a PC running Microsoft Windows operating systems)
1000RTC	Real Time Cable (for use between the Model 2500A VET and a PC running Microsoft Windows operating systems)
1000USB	USB Interface Adapter
1000USB-C	USB Interface Adapter (Continua™)

For more information about Nonin parts and accessories contact your distributor, or contact Nonin at (800) 356-8874 (USA and Canada), +1 (763) 553-9968, or +31 (0)13 - 79 99 040 (Europe).

WARNING: The use of accessories, sensors, cables, and power supplies other than those specified may result in increased emission and/or decreased immunity of this device.

⚠ **CAUTION:** Use only the Nonin-branded Model 2000SL, 2000T, or 2000SA veterinary sensors for monitoring. These sensors are manufactured to meet the calibration requirements for the Nonin Model 2500A VET pulse oximeter. The oximeter is calibrated for adult human hemoglobin measured at the finger tip. Although animal hemoglobin has similar optical characteristics, other types of hemoglobin or alternate sensor locations may affect the calibration.

Troubleshooting

Problem	Possible Cause	Possible Solution
The device will not turn on.	Batteries are depleted.	Replace all 4 batteries.
	Batteries are installed incorrectly.	Verify correct battery orientations. Refer to Figure 3: Installing Batteries.
	Metal contact in battery compartment is missing or damaged.	Contact Nonin Technical Service.
A dash appears in the left digit of the SpO_2 display.	Sensor fault exists. Sensor may have become dislodged from the device or from the animal.	Verify sensor is correctly connected to the device and the animal. Replace sensor if condition persists.
Dashes appear in the middle digits for both the SpO_2 and pulse rate displays.	No signal is detected because sensor is not plugged in.	Verify sensor connections.
	Sensor failure.	Replace sensor.
The displayed pulse rate does not correlate to the pulse rate displayed on the ECG monitor.	Excessive motion at sensor site may be prohibiting device 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.
	Animal may have an arrhythmia resulting in some heart beats that do not yield a pulse quality signal at the sensor site.	Examine animal. Condition may persist, even though both monitors are functioning properly, if the animal's arrhythmia persists.
	Non-specified sensor is being used.	Replace sensor with a Nonin-branded sensor.
	ECG monitor may not be functioning properly.	Examine animal. Replace ECG monitor or refer to ECG monitor operator's manual.
An erratic pulse rate display and/or an amber Pulse Quality indicator during the concurrent use of electrosurgical equipment (ESU).	ESU may be interfering with pulse oximeter performance.	Examine animal. Move the device, cables, and sensors as far away from the ESU as possible or refer to the ESU operator's manual.
Pulse Quality indicator blinks amber with each pulse.	Quality of pulse signal at sensor site is marginal.	Examine animal. Reposition sensor or select an alternate sensor site.

Problem	Possible Cause	Possible Solution
Unable to obtain a green blinking Pulse Quality indicator.	Low animal pulse strength, sensor site is poorly perfused, or sensor is not correctly positioned.	Reposition sensor on the animal.
	Sensor is attached too tightly, or tape or other items are restricting pulse quality at sensor site.	Reapply sensor, select an alternate sensor site, or remove restrictive material from the sensor site.
	Circulation is reduced due to excess pressure between the sensor and a hard surface.	Allow sensor and sensor site to rest comfortably on the surface.
	Excessive ambient light.	Reduce ambient light.
	Excessive animal motion.	Reduce animal motion.
	Interference from: • arterial catheter • blood pressure cuff • electrosurgical procedure • infusion line	Reduce or eliminate interference.
Pulse Quality indicator blinks red and the SpO_2 and/or pulse rate displays show dashes.	Inadequate signal at the sensor site.	Examine animal. Reposition sensor or select an alternate sensor site.
	Excessive motion at the sensor site may be prohibiting the device 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 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 device.
`Err E01`, `E02`, `E03`, **or** `E04` **displays.**	There is a system fault that must be corrected.	Turn the device off and on. If the problem persists, contact Nonin Technical Service.
Disruption in the device performance.	Electromagnetic interference (EMI).	Remove the device from the EMI environment.
Displays and indicators are off, but a continuous audible alarm is sounding.	There is a system fault that must be corrected.	Turn device off and on. If problem persists or device does not turn on, replace or recharge the batteries. If the problem persists, contact Nonin Technical Service.

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

Technical Information

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

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

CAUTION: All parts and accessories connected to the serial port of this device must be certified according to at least IEC Standard EN 60950, IEC 62368-1, or UL 1950 for data-processing equipment.

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

Manufacturer's Declaration

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

Table 7: Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment—Guidance
This device is intended for use in the electromagnetic environment specified below. The user of this device should ensure that it is used in such an environment.		
RF Emissions CISPR 11	Group 1	This device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	This device is suitable for use in all establishments, including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	N/A	
Voltage Fluctuations/Flicker Emissions IEC 61000-3-3	N/A	

Table 8: Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance
This device is intended for use in the electromagnetic environment specified below. The user of this device should ensure that it is used in such an environment.			
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 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	30 A/m	30 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 9: Guidance and Manufacturer's Declaration— Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance
This device is intended for use in the electromagnetic environment specified below. The user of this device should ensure that it is used in such an environment.			
Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.			
			Recommended Separation Distance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	$d = 1.17\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.17\sqrt{P}$ $d = 2.33\sqrt{P}$
Radiated RF per ISO 9919 clause 36 and ISO 80601-2-61 clause 202.6.2.3	20 V/m 80 MHz to 2.7 GHz	20 V/m	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: 
NOTES: • At 80 MHz and 800 MHz, the higher frequency range applies. • These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

a. 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.

Table 10: Recommended Separation Distances

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

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

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

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

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

Equipment Response Time

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

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

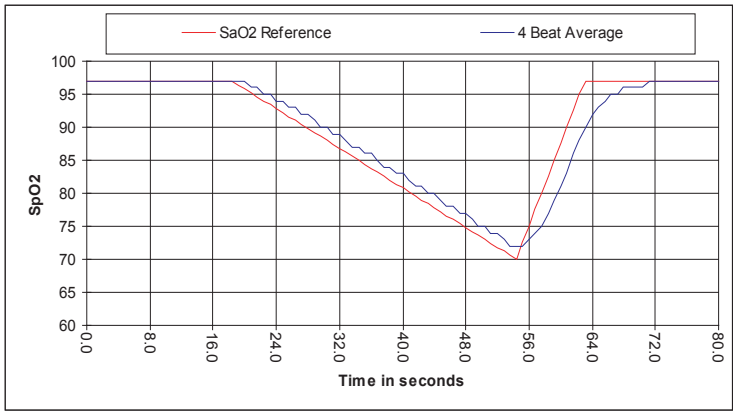
Pulse Rate Values	**Response**	**Latency**
Standard/Fast Averaged Pulse Rate	4 beat exponential	2 beats

Equipment Delays	**Delay**
Display Update Delay	1.5 seconds
Alarm Signal Generation Delay	0 seconds

Example - SpO_2 Exponential Averaging

SpO_2 decreases 0.75% per second (7.5% over 10 seconds)

Pulse Rate = 75 BPM



Specific to this example:

- The response of the 4-beat average is 1.5 seconds.

Testing Summary

SpO_2 accuracy, and low perfusion testing were conducted by Nonin Medical, Inc., as described below:

SpO_2 Accuracy Testing

During motion and no-motion conditions at an independent research laboratory, SpO_2 accuracy testing is conducted during induced hypoxia studies on healthy, male and female, non-smoking, light- to dark-skinned human subjects that are 18 years of age and older. The measured arterial hemoglobin saturation value (SpO_2) of the sensors is compared to arterial hemoglobin oxygen (SaO_2) value, determined from blood samples with a laboratory co-oximeter. The accuracy of the sensors in comparison to the co-oximeter samples measured over the SpO_2 range of 70 - 100%. Accuracy data is calculated using the root-mean-squared (A_{rms} value) for all subjects, per ISO 80601-2-61 Medical Electrical Equipment—Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use.

Pulse Rate Motion Testing

This test measures pulse rate oximeter accuracy with motion artifact simulation introduced by a pulse oximeter tester. This test determines whether the oximeter meets the criteria of ISO 80601-2-61 for pulse rate during simulated movement, tremor, and spike motions.

Low Perfusion Testing

This test uses an SpO_2 Simulator to provide a simulated pulse rate, with adjustable amplitude settings at various SpO_2 levels for the oximeter to read. The oximeter must maintain accuracy in accordance with ISO 80601-2-61 for heart rate and SpO_2 at the lowest obtainable pulse amplitude (0.3% modulation).

Principles of Operation

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

Specifications

Oxygen Saturation Display Range	0 to 100% SpO_2
Pulse Rate Display Range	18 to 450 beats per minute (BPM)
Saturation Declared Accuracy (A_{rms})*	70 - 100% ±3 digits for the Model 2000SL, 2000SA, and 2000T sensors. Below 70% is not specified for all sensors.
Pulse Rate Declared Accuracy	±3% ±3 digits
Alarm Volume:	High: 70 dBA Low: 55 dBA
Informational Tone Volume:	High: 65 dBA Low: 45 dBA
Measurement Wavelengths and Output Power**	
Red:	660 nanometers @ 0.8 mW maximum average
Infrared:	910 nanometers @ 1.2 mW maximum average
Indicators:	
Pulse Quality:	LED, tricolor
Numeric Displays:	3-digit 7-segment LEDs, red
Low Battery:	LED, amber
Alarm Bar:	LED, bicolor
Alarm Silence:	LED, amber
Temperature (Operating):	-20 to +50 °C (-4 to +122 °F)
Temperature (Storage/Transportation):	-40 to +70 °C (-40 to +158 °F)
Humidity (Operating):	10 to 95% noncondensing
Humidity (Storage/Transportation):	10 to 95% noncondensing
Altitude (Operating):	Up to 4,000 meters (13,123 feet)
Altitude (Hyperbaric Pressure):	Up to 4 atmospheres
Power Requirements:	Four 1.5V AA-size alkaline batteries (60 hours typical operation) NiMH rechargeable battery pack (40 hours typical operation)

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

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

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 ANSI/AAMI ES60601-1 and CAN/CSA-C22.2 No. 60601-1:	
Type of Protection:	Internally powered (on battery power)
Degree of Protection:	Type BF-Applied Part
Mode of Operation:	Continuous
Enclosure Degree of Ingress Protection:	IP32

This device is not made with natural rubber latex.