NONIN

Operator's Manual

Avant® 9700

Digital Pulse Oximeter

English

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner.

 Consult 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.

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

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Indications for Use

The Nonin® Avant® 9700 Digital Pulse Oximeter is a portable, tabletop device indicated for use in simultaneously measuring, displaying, and recording functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate of adult, pediatric, infant, and neonatal patients in hospitals, medical facilities, home care, sleep laboratories, and subacute environments. The Avant 9700 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.

Warnings

Do not use this device in an MR environment.
This device is not defibrillation proof per IEC 60601-1.
Do not use this device in an explosive atmosphere.
This device is intended only as an adjunct in patient assessment. It must be used in conjunction with other methods of assessing clinical signs and symptoms.
The device must be able to measure the pulse properly to obtain an accurate SpO_2 measurement. Verify that nothing is hindering the pulse measurement before relying on the SpO_2 measurement.
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.
Avoid excessive pressure to the sensor application site as this may cause damage to the skin beneath the sensor.
Operation of this device below the minimum amplitude of 0.3% modulation may cause inaccurate results.
General operation of this device may be affected by the use of an electrosurgical unit (ESU).
The use of accessories other than those specified in the Parts and Accessories List may result in increased electromagnetic emission and/or decreased immunity of this device.
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 avoid patient injury, use only Nonin-branded PureLight® pulse oximeter sensors. These sensors are manufactured to meet the accuracy specifications for Nonin pulse oximeters. Using other manufacturers' sensors can result in improper pulse oximeter performance.
To prevent improper performance and/or patient injury, verify compatibility of the monitor, sensor(s), and accessories before use.
No modifications to this device are allowed as it may affect device performance.
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 9700 monitors in one care area.
Do not use the device in or around water or any other liquid when the AC power supply is used.
As with all medical equipment, carefully route patient cables and connections to reduce the possibility of entanglement, strangulation, or injury to the patient.

Warnings (Continued)

Use the device only with Nonin-specified power supplies.
The device's Nurse Call feature should not be used as the primary source of alarm notification.
All parts and accessories connected to the serial port of the device must be certified according to at least IEC 60950 or UL 1950 for data-processing equipment.
The battery pack must be installed at all times while the device is operating, even when operating on AC power. The audible alarms and memory will not function if batteries are removed from the device.
To comply with relevant product safety standards, ensure that all alarm volumes are set appropriately and are audible in all situations.
The serial port cover must be installed at all times unless serial cable is attached.

Cautions

When mounting the monitor to a mobile pole, mounting the monitor more than 1.5 meters (5 feet) or mounting more than 2 kilograms (4.4 pounds) of equipment onto the pole may result in tipping, damage to the equipment, or injury.
Review all limits to ensure they are appropriate for the patient.
Setting alarm limits to extremes can render the alarm system useless.
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) - moisture in the sensor - improperly applied sensor - incorrect sensor type - poor pulse quality - venous pulsations - anemia or low hemoglobin concentrations - cardiogreen and other intravascular dyes - carboxyhemoglobin - methemoglobin - dysfunctional hemoglobin - artificial nails or fingernail polish.
The device may not work when circulation is reduced. Warm or rub the finger, or reposition the device.
In some circumstances, the device may interpret motion as good pulse quality. Minimize patient motion as much as possible.
Do not autoclave or immerse this device in liquid or use caustic or abrasive cleaning agents.
A functional tester cannot be used to assess the accuracy of a pulse oximeter monitor or sensor.
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 this manual.

Cautions (Continued)

Portable and mobile RF communications equipment can affect medical electrical equipment.
Follow local, state and national governing ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries.
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.
If the device fails to respond as described, discontinue use until the situation is corrected by qualified personnel.
This device is a precision electronic instrument and must be repaired by qualified technical professionals. 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.
To prevent potential loss of monitoring, do not use ear clip or reflective sensors on pediatric or neonatal patients.
This product complies with ISO 10993.
Radios and cell phones or similar devices can affect the equipment and must be kept at least 2 meters (6.5 feet) away from equipment.
Failure of a network data coupling (serial cable/connectors/wireless connections) will result in loss of data transfer.

Guide to Symbols

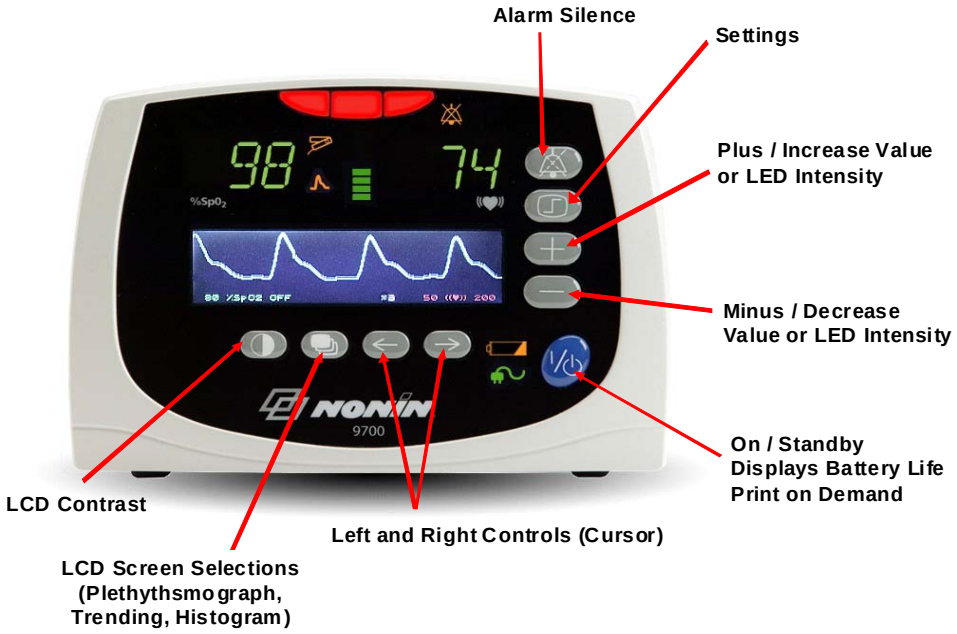
This table describes the Nonin symbols located on the Avant 9700. See Section titled Displays, Indicators and Controls for detailed information about functional symbols.

Table 1: Symbols

Symbol	Description
	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 UL 60601-1 30EM and CAN/CSA C22.2 No. 601.1.
SN	**Serial Number** (located under the back cover).
	**Signal Output** (located on back of device).
	Indicates separate collection for electrical and electronic equipment (WEEE).
	**Alarm Call** (located on back of device).
	Manufacturer
IP22	Protected against vertically falling water drops when enclosure is tilted up to 15 degrees and against access to hazardous parts with a finger per IEC 60529.
$\%SpO_2$	$\%SpO_2$ Display
	Pulse Rate Display

Displays, Indicators, and Controls

This section describes the displays, indicators, and controls for the Avant 9700.



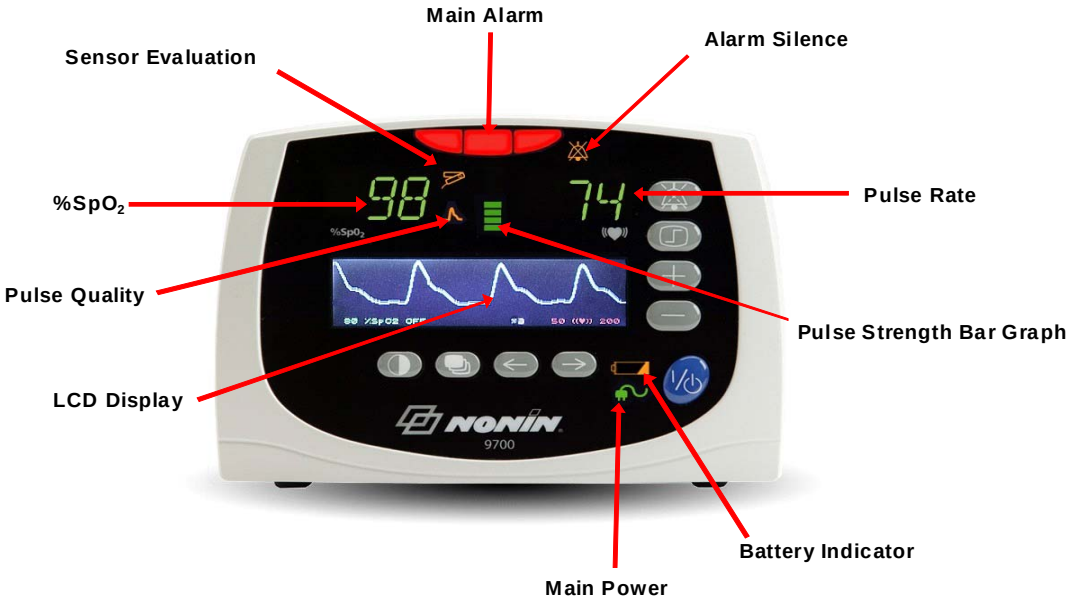


Figure 1: Displays, Indicators, and Controls

%SpO_2 Display

The %SpO_2 Display is located on the front panel of the Avant 9700 and is identified by the **%SpO_2** symbol. This display shows blood oxygen saturation, from 0 to 100 percent. The numeric LEDs blink during SpO_2 alarm conditions.

NOTE: LED means “light-emitting diode.”

Pulse Rate Display

The Pulse Rate Display, located on the front panel of the Avant 9700, is identified by the symbol. This display shows the pulse rate in beats per minute, from 18 to 300. The numeric display blinks during pulse rate alarm conditions.

Numeric LEDs

Green numeric LEDs display %SpO_2 and pulse rate values. When setting the device, the LEDs also display values for alarm limits, volume, and date and time settings.

Red, rapidly blinking LEDs indicate a High Priority patient alarm. Values are displayed in amber when reviewing or changing limits.

Indicators and Icons

Main Alarm LED

Red, rapidly blinking LEDs indicate a High Priority patient alarm. Amber slowly blinking LEDs indicate a medium priority (equipment) alarm.

Pulse Quality LED

This LED blinks to indicate an inadequate pulse signal. If there is a sustained period of inadequate pulse signals, this LED will illuminate solid.

Pulse Oximeter Sensor LED

The Pulse Oximeter Sensor LED indicates when a sensor has become disconnected, has failed, is misplaced or is not compatible with this monitor.

Pulse Strength Bar Graph LED

This 8-segment tricolor bar graph indicates pulse strength as determined by the oximeter. The bar graph changes color based upon the strength of the pulse. The color and height of the Pulse Strength Bar Graph is proportional to the pulse amplitude. For low pulse amplitude, the device goes into High Priority Alarm mode:

Green = a good pulse strength

Amber = a marginal pulse strength

Red = an inadequate pulse strength, high priority alarm

The Pulse Strength Bar Graph LED also indicates the battery capacity in 12% increments in green. Amber represents the depleted capacity of the battery and green indicates the available battery capacity.

Alarm Silence LED

This amber LED indicates that the audible alarm is silenced for 2 minutes when it blinks. When lit solid, the Alarm Silence LED indicates that the audible alarm volume is set to less than 45 dB.

AC Power Supply LED

This green LED is displayed when an external power supply is providing power to the Avant 9700. Any time this LED is displayed, the battery is charging.

NOTE: When the external power supply is disconnected, the device automatically switches to battery power without loss of functionality.

Battery LED

This amber LED indicates marginal battery capacity when blinking. When solidly lit, the LED indicates that the battery pack is not installed. *This LED does not indicate that the device is running on battery power.* New battery packs must complete one charge/discharge/recharge cycle before the Battery LED displays the actual capacity.

WARNING: The battery pack must be installed at all times while the device is operating—even when operating on AC power. The audible alarms and memory will not function if batteries are removed from the device. DO NOT use this device without batteries.

LCD Indicators and Icons

Pulse Volume

This icon indicates that the pulse volume can be reviewed or adjusted using the Plus (+) and Minus (-) buttons.

Alarm Volume

This icon indicates that the alarm volume can be reviewed or adjusted using the Plus (+) and Minus (-) buttons.

Recall Settings

Selecting “Yes” for the Recall Settings icon allows users to retrieve the previous parameter settings.

Patient Security Mode

This icon can be advanced between NO *(default)* and YES to lock and unlock the Avant 9700’s alarms. Selecting YES activates Patient Security mode, locking all alarms to prevent accidental activation or adjustment. The Plus (+) and Minus (-) buttons must be pressed and held for 3 seconds to advance between NO and YES.

Date and Time

This icon indicates that the *Month, Day, Year*, *Hour*, or *Minute* displays can be reviewed or adjusted using the Plus (+) and Minus (-) buttons.

Display Intensity

This icon indicates that the LED display intensity can be adjusted using the Plus (+) and Minus (-) buttons.

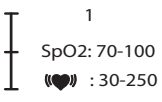
Backlight

This icon can be advanced between ON *(default)* and MOM (momentary) to adjust the display LCD’s backlight.

Data Output

This icon can be advanced between  and  to adjust the output mode of external printing devices:

-  is used for print-on-demand output
-  is used for real-time (once-per-second) output



Trend Waveform Display Selection

This icon can be advanced between modes 1, 2, and 3 to select data display ranges. See “Trend Waveform View” for more information.

Front Panel Buttons

ON/STANDBY

- Press Once: Turns the device on
- Hold 1 second: Turns the device off
- Hold 5 seconds: Turns the device off when in Patient Security mode
- Press momentarily while the unit is on:
  - Indicates the battery capacity in green, in 12% increments for 3 seconds
  - Initiates Print-on-demand feature
  - Records event marker

Alarm Silence

- Engages the 2-minute alarm silence automatically at start-up
- Changes the alarm from silenced to audible
- Silences the alarm for 2 minutes
- Cancels audible and visual alarms, when in Locked Alarms mode, if the alarm condition is no longer present.

Settings

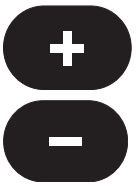
Pressing this button advances the operator through the displays, such as alarm limits and volumes for SpO_2 and heart rate. At each display, the operator has the option of adjusting the limits, as necessary.

LCD Intensity

This button adjusts the intensity (brightness) of the 16-color LCD display. Holding the button or pressing it multiple times adjusts the LCD intensity.

LCD Screens

The LCD display screen button allows the operator to alternate among Plethysmographic Waveform, Trend Waveform, and Trend Histogram view.

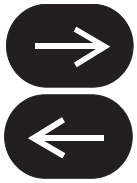


Plus Button and Minus Button

The Plus (+) and Minus (-) buttons are used to adjust time, date, volume, and upper and lower alarm limits.

When the Avant 9700 is in Plethysmographic Waveform View, and the device is not in program mode, pressing either button adjusts the intensity of the front panel LED Display.

In Trend Waveform view, the Plus (+) and Minus (-) buttons can be used to focus on specific displayed data.



Left Control and Right Control

These buttons are used to advance through either factory default or user-defined limits, on the LCD display. In Trend Waveform view, these buttons can also be used to advance through saved data.

Installing the Batteries and Serial Port Cover

WARNING: The battery pack must be installed at all times while the device is operating—even when operating on AC power. The audible alarms and memory will not function if batteries are removed from the device. Do not use this device without batteries.

NOTE: New battery packs must be fully charged before use; minimum recharge time is 4 hours.

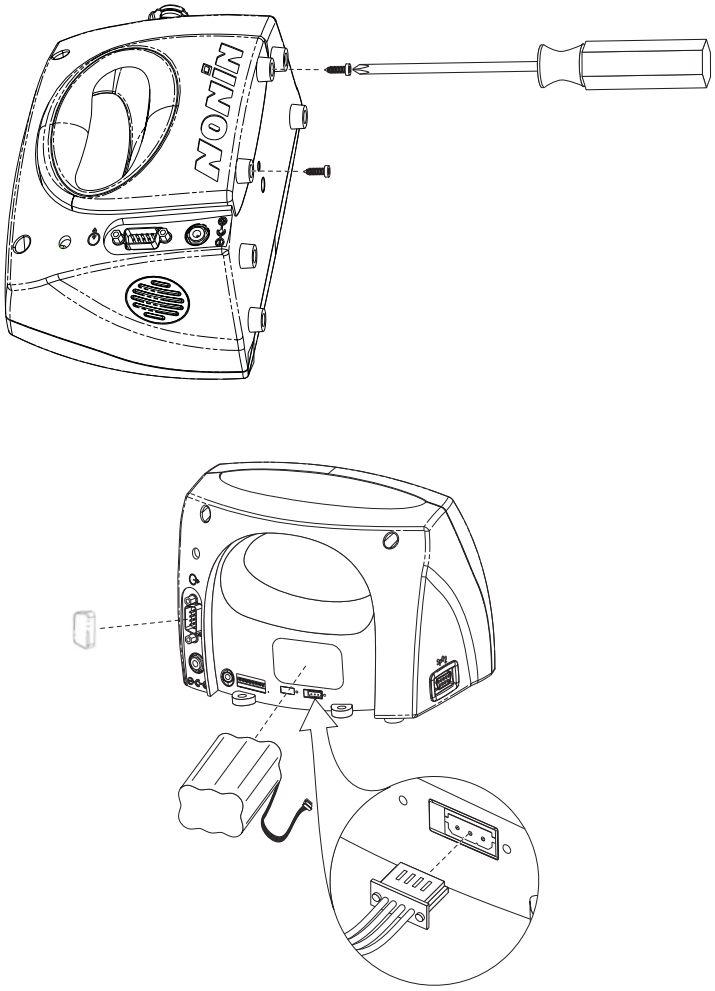


Figure 2: Installing the Batteries and Serial Port Cover

NOTES:

- Contact Nonin to purchase or replace battery packs.
- Reposition the back cover carefully, and tighten the screws firmly. Do not over-tighten.
- The serial port cover must be installed at all times unless serial cable is attached.

Operating the Avant 9700

Press the ON/STANDBY button to perform the start-up (initialization) sequence. Verify that all LEDs, except the AC Power Supply LED, are illuminated and the unit beeps three times during the start-up sequence. Contact Nonin Technical Service for assistance.

Use the following procedure to verify that the pulse oximeter sensor is functioning properly.

1. Ensure that the Avant 9700 is on, and the sensor is connected to the monitor.
2. Apply the pulse oximeter sensor to the patient.
3. Verify that SpO_2 and pulse rate values are displayed, and the pulse strength bar graph LED is activated.
4. Verify the plethysmographic waveform is displayed on the LCD screen.

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

Factory Default

In Factory Default, all adjustable alarm and volume parameters are set at their default values. Factory Default settings are in the table below:

Table 2: Factory Default Settings

Description	Default
SpO_2 Upper Alarm Limit	Off
SpO2 Lower Alarm Limit	85%
Pulse Upper Alarm Limit	200 BPM
Pulse Lower Alarm Limit	50 BPM

Factory default is indicated by option switch 4 in the DOWN position. Refer to Options Switches Section.

User-Defined Defaults

User-Defined Defaults (option switch 4 in the UP position), alarm limits and volume settings can be adjusted. To set user-defined defaults, enter limit settings for SpO_2 and pulse rate alarms, alarm volume and pulse rate volume. The device will not return to operating mode until all user-defined default limits are set. The programmed limits are the defaults until the device is turned off. To return to Factory Defaults, turn the device off, move Option Switch 4 to the Down position and turn the device on.

Operator Functions

Basic Functions

The Avant 9700 basic functions are described in the table below.

Table 3: Basic Functions

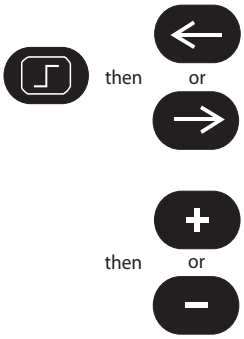
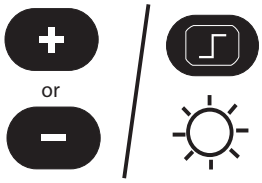
Function	Button	Instruction
Turns device on and off		Using the ON/STANDBY button: • **Press** once (turns the device on) • **Hold** 1 second (turns the device off) • **Hold** 5 seconds (turns the device off when in Patient Security mode)
Battery capacity		Briefly **press** the ON/STANDBY button while the device is on to display battery capacity.
View or set alarms, volumes, time/date, and other parameters.		**Press** the Settings button to enter the menu. (There are two screens within the menu. The Settings button advances the operator to the second screen.) • The Left and Right Control buttons advance through limits on each screen. • The Plus and Minus buttons adjust the highlighted limits up and down.
Change the LCD display screen.		**Press** the LCD Screens button to advance through Plethysmographic Waveform, Trend Waveform, and Trend Histogram views.
Adjust the display intensity (brightness).		**Press** the Plus or Minus button with the device in Plethysmographic Waveform view to change display intensity. Display intensity can also be adjusted by **pressing** the Settings button and advancing to the Display Brightness icon. **NOTE:** When option switch 6 is in the DOWN position, display intensity will automatically be reduced when converting from AC to battery power.
Print-on-Demand		**Press** the ON/STANDBY button while the device is on.

Table 3: Basic Functions (Continued)

Function	Button	Instruction
Record an event marker.		**Press** the ON/STANDBY button while the device is on.
Silence audible alarms		**Press** the Alarm Silence button.
Cancel locked alarms		**Press** the Alarm Silence button.
Display intensity (brightness)		**Hold** the LCD intensity button until the appropriate brightness is displayed.

NOTE: When option switch 6 is in the DOWN position, the display intensity is automatically reduced when changing between AC and battery power.

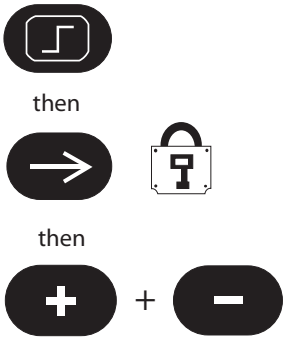
User-Defined Defaults

User-Defined Default functions are restricted to trained users, and they require multiple button presses in order to prevent accidental activation.

Table 4: User-Defined Defaults

Function	Button	Instruction
Recall Previous User-Defined Settings		**Press** and **hold** the Settings button while turning on the Avant 9700. **NOTE:** Previous user-defined settings can also be recalled within the Parameter Adjustment menu, which is accessed by **pressing** the Settings button.
Play back and/or clear patient data		**Press** and **hold** the LCD Screens button while turning on the Avant 9700. Follow the display prompts after the PLy bAC message clears.

Table 4: User-Defined Defaults (Continued)

Function	Button	Instruction
Enter Patient Security Mode		• After entering the Parameter Adjustment menu via the Settings button, use the Right Control button to scroll to the Patient Security Mode icon. • When the Patient Security Mode icon is highlighted, **press** and **hold** the Plus and Minus buttons simultaneously for 3 seconds. • To deactivate Patient Security mode, **highlight** the Patient Security Mode icon and **press** and **hold** the Plus and Minus buttons simultaneously for 3 seconds.

Option Switches

The Avant 9700 contains eight option switches located under the back cover (See “Installing the Batteries” for instructions on removing the back cover). **The device is supplied with all option switches in the DOWN position.**

Table 5: Option Switches

Switch	Function
Switch 1	Alarm Disable **Up**—Alarm volume may be disabled **Down**—Alarm volume cannot be set to zero (disabled)
Switch 2	Normal / Slow SpO_2 Averaging **Up**—Slow Averaging (8 beat exponential average) **Down**—Normal Averaging (4 beat exponential average)
Switch 3	Alarm Unlocked / Locked **Up**—Alarms Locked **Down**—Alarms Unlocked
Switch 4	Factory / User-Defined Defaults **Up**—User-Defined Defaults for Alarm Limits and Volume Settings **Down**—Factory Defaults for Alarm Limits and Volume Settings

Table 5: Option Switches (Continued)

Switch	Function
Switch 5	US / International Date Format **Up**—International Date Format **Down**—US Date Format
Switch 6	Power Saving During Battery Use (Dims Display) **Up**—Power Saving Disabled **Down**—Power Saving Enabled
Switch 7	Nurse Call Output **Up**—Continuous **Down**—One second audible alarm at 60 second intervals
Switch 8	Serial Data Output **Up**—Fast SpO_2 and pulse rate output **Down**—SpO_2 and pulse rate output, as determined by the position of option switch 2

LCD Display Views

Plethysmographic Waveform View

The default view is the Plethysmographic Waveform. Approximately 3.4 seconds of data are displayed on the LCD screen; new data is always displayed from the left edge of the screen. Alarm limits and vertical scaling are shown at the bottom of the LCD display. (Vertical scaling is a value. Shown with x1, x2, x4, x8, or x16 identifying the vertical scaling of the waveform.)

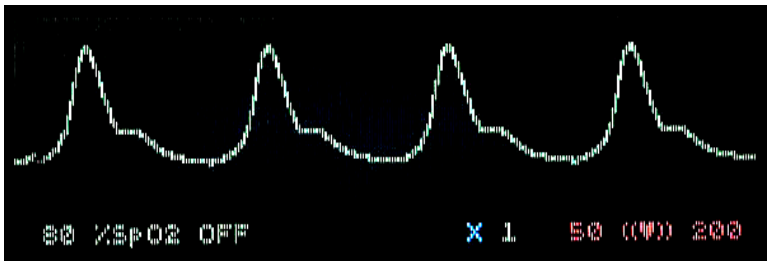


Figure 3: Plethysmographic Waveform

Trend Waveform View

Trend Waveform allows viewing of the last 24 hours of patient SpO_2 and Pulse Rate data stored in nonvolatile patient memory. The SpO_2 displayed in green and Pulse Rate waveform displayed in red, appear on the same LCD screen.

The Left and Right Control buttons are used to move the cursor, located at the bottom of the LCD display, to any point on the trend waveform display. The length of time, the Time, Date, SpO_2 and Pulse Rate data for the current cursor position appear at the top of the LCD display in light blue numeric text.

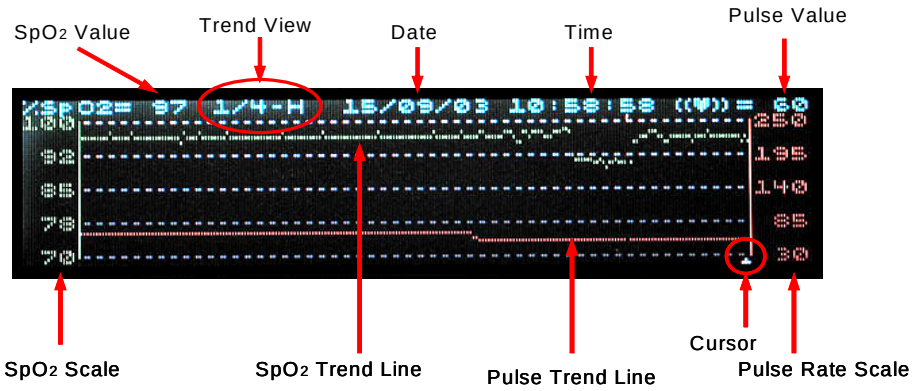


Figure 4: Trend Waveform

The Plus and Minus buttons are used to scale (focus) specific displayed data.

Trend view time: 15 minutes (1/4 hour) of data (at maximum scale)

24 hours of data (at minimum scale)

If multiple data are displayed at a single point when the LCD is at minimum scale, only the lowest SpO_2 and Pulse Rate values are displayed in text at the top of the LCD.

When the oximeter does not have data for any given period, the values are shown as SpO2 = --- or HR = ---. When this occurs, the waveform for that period is not visible.

NOTE: Gaps in data collection are identified with a white vertical line.

In Trend Waveform view, specific records may be selected by positioning the cursor and pressing the LCD Screens button. One of three pre-defined SpO_2 and Pulse Rate ranges selected during setup can be displayed. Those ranges are as follows:

Mode	%SpO_2	Heart Rate
1 (default)	70-100%	30-250 BPM
2	80-95%	50-200 BPM
3	85-100%	80-250 BPM

Trend Histogram View

Trend Histogram allows users to view up to the last 24 hours of stored data for any selected record. To select a record, position the cursor to the specific record in Trend Waveform view, and press the LCD Screens button.

The starting and ending time and date for the selected record are displayed. The Trend Histogram includes columns with fixed values for SpO_2 and Pulse Rate data. (SpO_2 data appears in the left column, and Pulse Rate data appears in the right column.)

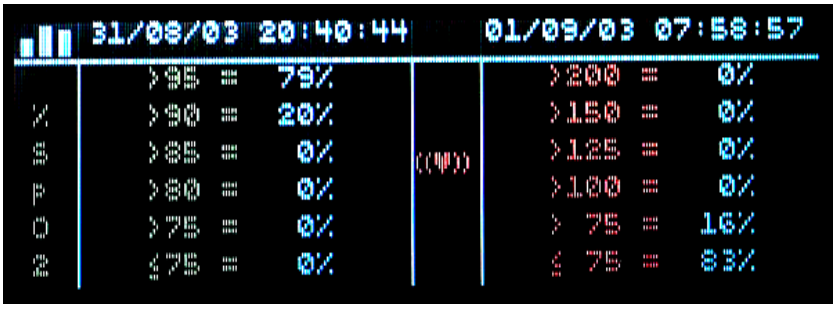


Figure 5: Trend Histogram

Data summaries are displayed in table format. For example, if the first row of the SpO_2 column (>95) displays “85%”, this means that 85% of the data collected, the patient’s SpO_2 was greater than 95. Data summaries may total less than 100% if there are periods in the data collection with no SpO_2 and Pulse Rate data.

In some instances, data may be identified with a *1, *2, or *3 in the lower right-hand corner of the LCD display screen. The identifiers are described in the following table.

Identifier	Meaning
*1	Record length is greater than 24 hours; trend histogram represents only most recent 24 hours.
*2	Trend histogram record was selected when zoomed out. Verify date and time of record to ensure that desired record is being displayed.
*3	Condition *1 and *2 have both occurred for this record.

Nurse Call Feature

The Avant 9700 features a nurse call circuit that can be connected to a facility nurse call system, allowing alarm conditions to be recognized at a central monitoring location and on the device. Two switches located on the back of the device under the back cover allow users to activate the Nurse Call feature.

Option switch 7 allows users to select the duration output of a signal. In the DOWN position, a one-second signal is output and repeated every 60 seconds when an audible alarm starts and will continue every 60 seconds until the alarm is silenced. In the UP position, the nurse call signal is active during the entire duration of an audible alarm.

NOTE: The Nurse Call feature overrides silenced alarms.

The Nurse Call Circuit Switch, located near the option switch, allows users to select NO (Normally Open—the left position) or NC (Normally Closed—the right position). The hospital's nurse call system configuration will determine whether the Nurse Call Circuit Switch on the device must be placed in the Normally Open (NO) or Normally Closed (NC).

	Electrical State of Nurse Call Output		
Nurse Call Switch Position	**Nurse Call Not Active**	**Nurse Call Active**	**Standby Mode**
Right	Open	Closed	Closed
Left	Closed	Open	Open

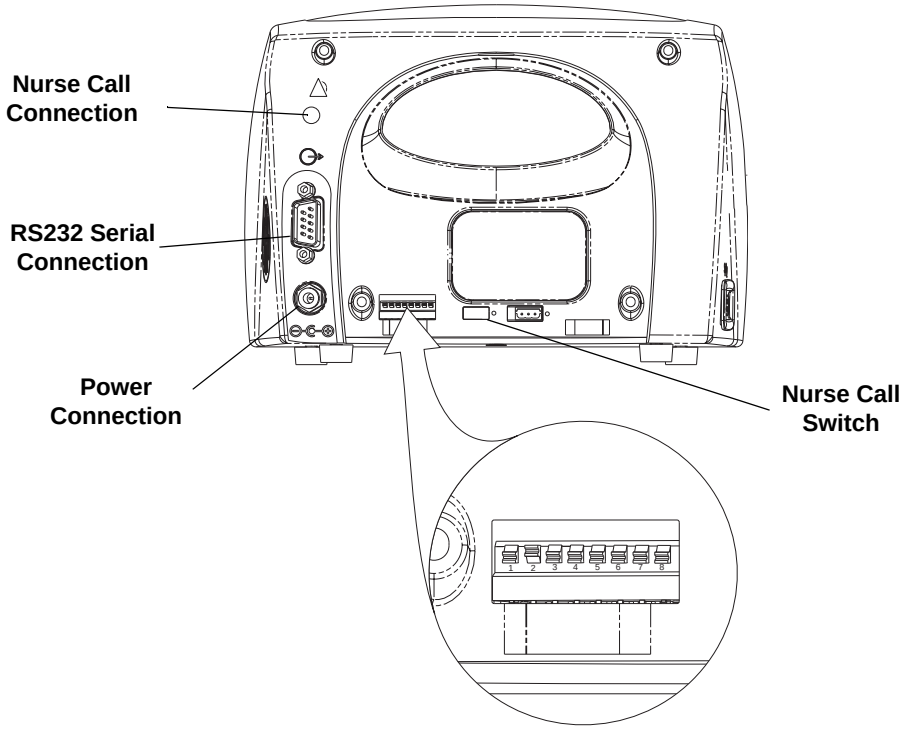


Figure 6: Monitor Rear View

NOTE: It is the user's responsibility to implement the interface between the Nurse Call system and the Avant 9700, and to adequately test the interface between the Avant 9700 and the Nurse Call system to ensure operation.

Alarms and Limits

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

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

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.

High Priority Alarms

High priority alarms require immediate attention to the patient. High priority alarms are indicated with rapidly blinking red LEDs in sync with the Main Alarm LED, when alarm limits are met or exceeded. Low perfusion is indicated by a red segment on the Pulse Strength Bar Graph LED.

High priority alarms are: 3 beeps, pause, 2 beeps and a 10-second pause. This sequence repeats until the alarm is cleared or silenced. The following table describes the default settings, adjustment ranges and intervals.

Table 6: High Priority Alarms

High Priority Alarm Description	Default	Adjustment Options	Adjustment Interval
SpO_2 Upper Alarm Limit	Off	Off, 80 to 100	1% SpO_2
SpO_2 Lower Alarm Limit	85%	Off, 50 to 95	1% SpO_2
Pulse Upper Alarm Limit	200 BPM	Off, 75 to 275	5 BPM
Pulse Lower Alarm Limit	50 BPM	Off, 30 to 110	5 BPM
Low Perfusion Alarm Red segment on Pulse Strength Bar Graph indicates low patient perfusion.			

Medium Priority Alarms

Medium priority alarms signal potential problems with the equipment or other non-life-threatening situations. Medium priority alarms are indicated with slowly blinking amber displays on the Main alarm LED and the appropriate indicators or numeric displays. An error code may display to identify the error source. See table in Error Code Section.

Medium priority alarms are: 3 beeps and a 25-second pause. This sequence repeats until the alarm is cleared or silenced. The following table describes alarm conditions and visual indicators.

Table 7: Medium Priority Alarms

Alarm Condition	Visual Indicator
Low Battery Alarm	Battery LED blinks in sync with Main Alarm LED.
Sensor Alarm	Pulse Oximeter Sensor LED blinks in sync with Main Alarm LED
Other Equipment Alarms	Amber error code appears in main display area.

Watchdog Alarms

Watchdog alarms are loud, two-tone, steadily beeping signals that indicate a hardware or software malfunction. When a watchdog alarm is activated, it can be cleared by shutting down the device. If the watchdog alarm does not clear, remove the battery and contact your distributor or Nonin Technical Service.

Informational Tones

Informational tones are at startup/initialization (speaker verification) and the pulse rate tone (which changes in pitch with SpO_2 values). They are typically single “beeps” or a series of 3 “beeps.”

Reviewing, Setting and Changing Alarm Limits

NOTE: Alarm limits reset themselves to default values each time the device is turned on, unless the device is in Patient Security mode. In Patient Security mode, alarm limits and volumes cannot be adjusted; they can only be viewed.

SpO_2 and/or Pulse Alarm Limits

1. Press the Settings button to access menus; the Left and Right Control buttons allow the operator to advance to specific limits
2. The limits can be adjusted by using the Plus (+) or Minus (-) buttons until the appropriate limits are displayed.

NOTE: The upper and lower SpO_2 and pulse rate alarm limits are always displayed at the bottom of the LCD display when the Avant 9700 is in Plethysmographic Waveform view.

Silencing Alarms

To silence alarms for 2 minutes, press the Alarm Silence button.

To permanently silence all alarms, Option Switch 1 must be placed in the UP position. This allows the Alarm Volume to be set to zero. The Alarm Silence LED will remain lit when the alarm volume is set less than 45dB.

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.

Recalling Previous Settings

The Avant 9700 allows the operator to recall settings in use when the device was turned off:

- SpO_2 high and low alarm limits
- Pulse rate high and low alarm limits
- Alarm volume settings
- Informational tone volume settings

Previous user-defined settings can be recalled by either:

- Press the Settings button to enter the menu.
- Press the Plus (+) button to advance to the Recall Setting icon.

Or

- By pressing and holding both the Settings and ON/STANDBY buttons when turning on the device.

Locked and Unlocked Alarms

The Avant 9700 allows users to switch between Locked or Unlocked Alarms with Option Switch 3, located under the back cover. Unlocked alarms (Option Switch 3 in the DOWN position) is the default.

When the device is in Unlocked Alarms, the Main Alarm LED and the exceeded alarm value will flash, and the audible alarm will sound until the alarm condition is no longer present.

In Locked Alarms, the audible and visual alarm will continue to signal, until the alarm is cleared or silenced, by pressing the Alarm Silence button.

NOTE: High Priority (Patient Alarms) may be locked or unlocked; Medium Priority (Equipment Alarms) are always unlocked.

Patient Security Mode

When the Patient Security mode is enabled, users cannot change SpO_2 or Pulse Rate limits but it is still possible to view limits. In Patient Security mode, users cannot view or set the alarm volume, pulse volume, time and date, or serial output rate.

NOTES:

- Patient memory cannot be cleared when the device is in Patient Security mode.
- Patient Security mode is not disabled when the device is turned off
- Patient Security retains limits when the device is turned off.

Viewing and Changing Patient Security Mode

To access Patient Security Mode:

1. Press Settings button to enter the menu.
2. Press the Right Control button until the Patient Security mode icon is highlighted.
3. Press and hold the Plus (+) and Minus (-) buttons simultaneously for 3 seconds until "yES" appears next to the padlock icon in the display.

The padlock icon appears at the bottom of the LCD display while the device is in Patient Security mode.

NOTE: Alarm limits cannot be changed when the device is in Patient Security mode. Patient Security mode prevents accidental changes to critical limits.

To exit Patient Security mode:

1. Highlight the padlock with the Left Control button.
2. Simultaneously press and hold the Plus (+) and Minus (-) buttons.
3. "NO" appears next to the padlock, confirming you have exited Patient Security mode.

Error Codes

This device includes error codes that indicate error conditions. The following table describes the error codes for the Avant 9700.

Table 8: Error Codes

Error Code	Description
E01	Stuck Button (Holding button down more than 30 seconds)
E02	Sound Module Fault
E03	Sound Module Communications
E04	Oximeter Module Communications

Table 8: Error Codes (Continued)

Error Code	Description
E05	Display Module Fault
E06	External Flash Memory Alarm (Memory Non-functional)
E07	LCD Display Alarm
E08	ISR Alarm
E09	External Flash Memory Alarm (Patient Data Storage/Retrieval)
E10	External Flash Memory Alarm (Settings Data)

To correct error conditions, perform the following steps or see “Clearing Error Codes 06, 08, or 10” section:

1. Turn the device off and then back on again to remove the error code.
2. If the error continues, disconnect all power (AC and battery), and then reconnect the power and turn the device back on.
3. If the error is not cleared, note the error code and contact Nonin Technical Service at (800) 356-8874 (USA and Canada), +1 (763) 553-9968, or +31 (0)13 - 79 99 040 (Europe).

Clearing Error Codes 06, 08, or 10

Error codes 06, 08, and 10 cannot be cleared by turning the device off and then back on again. To clear these codes, follow the steps below. Please read through the instructions before beginning.

1. Press and hold the Plus (+) and Minus (-) buttons at the same time while momentarily pressing the ON/STANDBY button.
2. Continue holding Plus and Minus until the numerical display shows 888 888. Release Plus and Minus.
3. Before the revision level (r) displays, press and hold the Alarm Silence button.
4. Continue holding Alarm Silence until dnE CLr displays. Release Alarm Silence button.
5. To use the device, turn it off and then on again using the ON/STANDBY button. If error has not cleared, contact Nonin Technical Service.

Memory and Data Output Features

Memory Features

Model 9700 collects and stores a minimum of 115 hours of SpO_2 and pulse rate data.

Data may be downloaded with Nonin's nVISION® data management software.

The memory in the device functions as an "endless loop" tape. When the memory fills up, the device overwrites the oldest data with the new data.

Each time the device is turned on, the current time/date information (if the clock is set properly) is stored in memory, starting a new data collection. Only data collections greater than one minute in length are stored in memory.

Patient SpO_2 and pulse rate are sampled every 2 seconds. Every 4 seconds, the high and low values of the 4-second sample period are stored. Oxygen saturation values are stored in 1% increments in a range of 0 to 100%.

The stored pulse rate ranges from 18 to 300 pulses per minute (BPM). The stored values are in increments of 1 pulse per minute in a range of 18 to 200 pulses per minute, and in increments of 2 pulses per minute in a range of 201 to 300 pulses per minute (BPM).

WARNING: The battery pack must be installed at all times while the device is operating—even when operating on AC power. Do NOT use the device without batteries. The audible alarms and memory will not function if batteries are removed from the device.

Using nVISION Data Management Software

The Avant 9700 has a Memory Download feature allowing stored data to be transferred to Nonin's nVISION data management software for analysis. When downloading data, use the following procedure:

1. With the device turned off, attach the null modem cable to the RS232 connector port of the device and to the back of your computer.
2. With the device turned off, simultaneously press and hold the LCD Screens button and the ON/STANDBY button. All LEDs will illuminate briefly. PLy bAC will appear in the SpO_2 and Pulse Rate display areas. This message indicates the device is now in Download mode.
3. The PLy bAC message will disappear after a few seconds, indicating memory download is complete; larger files might take several minutes. Pressing the ON/STANDBY button will exit Download mode.
4. A CLr no message will be displayed, and 3 beeps will sound.
5. Memory CLear (OPTIONAL):
   - Simultaneously press and hold the ON/STANDBY button and the Plus (+) button to select CLr yES.
   - Press the ON/STANDBY button for the next prompt.

- Use the Plus (+) and/or Minus (-) buttons to select dEL yES if desired.
- Press the ON/STANDBY button for the next prompt.
- dnE CLr confirms that the memory is clear.

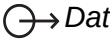
6. Press the ON/STANDBY button to return to normal operation.
7. For more information about using nVISION, refer to nVISION's online help.

NOTES:

- Patient memory cannot be cleared when the Avant 9700 is in Patient Security mode.
- Selecting yES from the dEL window will permanently delete the device's memory.

Serial Patient Data Outputs

The Avant 9700 features real-time and print-on-demand options. All reports include a header with the model number, time, and date information.


Data Output icon


Print-On-Demand indicator


Real-time indicator

Real-time data output is provided by connecting a null modem cable to the RS232 connector port and the receiving computer. Data is sent in an ASCII serial format at 9600 baud with 8 data bits, 1 start bit, and 2 stop bits; each line is terminated by CR/LF.

Print-On-Demand Output

Avant 9700 allows Print-on Demand if the system is connected to a printer. This operation is performed by pressing the ON/STANDBY button, as needed. The device features a Print-On-Demand option, allowing users to output data each time the ON/STANDBY button is pressed.

When the Avant 9700 is in Trend Histogram view, all data from the recording selected on the trend display are output, including the start time of the record, the record's SpO_2 histogram data, the record's pulse rate histogram data, and the record's ending time. In any other display view, time, date, SpO_2 and pulse rate data are output. In addition, space is provided to include patient and physician information.

Real-Time Patient Data Output

Data output is sent once per second in one of the following formats:

- If option switch 8 is in the UP position, the data will be displayed as follows:

  SPO_2=XXX HR=YYY F

  where XXX and YYY are the SpO_2 and pulse rate values and F signifies "output: fast".

- If option switch 8 is in the DOWN position, the data will be displayed as follows:

  SPO_2=XXX HR=YYY

  where XXX and YYY are the SpO_2 and pulse rate values as selected by option switch 2.

NOTES:

- To insert an event marker, press the ON/STANDBY button.
- The serial output rate is automatically returned to its previous setting upon device startup.

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:

- Use of a multiple-socket outlet with multiple devices results in a Medical Electrical System.
- 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/wireless connections) will result in loss of data transfer.

Care and Maintenance

The Avant 9700 requires no calibration or periodic maintenance other than battery replacement. The device's expected service life is 5 years.

Do not attempt to open the case or repair the electronics. Opening the case will damage the device and void the warranty. If the device is not functioning properly, see "Troubleshooting."

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

Cleaning the Model 9700

Clean the Avant 9700 with a soft cloth dampened with a mild detergent or a 10% bleach/90% water solution (household bleach [containing less than 10% sodium hypochlorite]). Do not pour or spray any liquids onto the device, and do not allow any liquid to enter any openings in the device. Allow the device to dry thoroughly before reusing it.

CAUTION: Do not autoclave or immerse this device in liquid or use caustic or abrasive cleaning agents.

Refer to the pulse oximeter sensor Instructions for Use for cleaning information.

Parts and Accessories

For more information about Nonin parts and accessories:

- See the Parts and Accessories List on the Operator’s Manual CD.
- Contact your distributor or Nonin at (800) 356-8874 (USA and Canada), +1 (763) 533-9968, or +31 (0)13 - 79 99 040 (Europe).
- Visit www.nonin.com.

Troubleshooting

Problem	Possible Cause	Possible Solution
Device will not activate.	The device has no power.	Plug in the AC power supply.
	The battery pack is connected incorrectly.	Check the battery pack connector orientation.
	The battery pack is not charged.	Plug in the device AC power supply to charge the battery pack. New battery packs must complete one charge/ discharge/recharge cycle before the Battery LED displays the actual capacity.
	The battery pack will not charge.	Contact Nonin Technical Service for repair or replacement.
Unable to obtain a green pulse display on the bar graph.	The patient pulse strength is low.	Reposition the sensor or apply the sensor to a different finger, and keep the sensor motionless for at least 10 seconds; warm the sensor application area.
	Circulation is reduced due to excess pressure on the sensor (between the sensor and a hard surface) after inserting finger.	Identify the source of the pressure. Allow the hand to rest comfortably without squeezing or pressing the sensor on a hard surface.
	The sensor is applied incorrectly.	Apply the sensor according to the Instructions for Use provided with the sensor.
	Possible interference from one of the following sources: • arterial catheter • blood pressure cuff • electrosurgical procedure • infusion line	Reduce or eliminate any interference.
	The red LED is not illuminated in the finger insertion area.	Contact Nonin Technical Service.
	There is excessive ambient light.	Shield the sensor from the light source.
	The sensor is applied to a polished or artificial fingernail.	Apply the sensor to a finger without fingernail polish or an artificial nail.
	Excessive patient motion.	Reduce patient motion.

Problem	Possible Cause	Possible Solution
A dash (-) appears in the %SpO_2 display.	An inadequate signal from the finger is being detected.	Reposition the sensor or apply the sensor to a different finger, and keep the sensor motionless for at least 10 seconds. Warm the sensor application site.
	The finger was removed from the sensor.	Reposition the sensor or apply the sensor to a different finger, and keep the sensor motionless for at least 10 seconds. Warm the sensor application site.
	The device is not functioning.	Contact Nonin Technical Service.
An error code appears in the display area.	The device encountered an error.	See Error Codes table, “Clearing Error Codes 06, 08, or 10” section, or contact Nonin Technical Service.
The unit is in Alarm mode, but no audible alarms can be heard.	The 2-minute Alarm Silence button is activated.	Press the Alarm Silence button to activate alarm volume, or wait for 2 minutes; and alarm tones will automatically activate.
	Option switch 1 is in the UP position, and the unit’s volume is set to zero.	Adjust the alarm volume, or return option switch 1 to the DOWN position if audible alarms are required.
The device does not record data.	The battery is low.	Recharge the battery.
	The battery is missing.	Contact your distributor or Nonin Technical Service.

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

Service, Support, and Warranty

A return authorization number is required before returning any product to Nonin. To obtain this return authorization number, contact Nonin Technical Service:

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

(800) 356-8874 (USA and Canada)
+1 (763) 553-9968 (outside USA & Canada)
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

Warranty

NONIN MEDICAL, INCORPORATED, (Nonin) warrants to the purchaser, for a period of one year from the date of purchase, each Avant 9700 battery pack. Nonin warrants the pulse oximetry module of the Avant 9700 for a period of three years from the date of purchase. Extended warranties are available on most Nonin pulse oximeter models. Please consult your local Nonin distributor for additional information.

Nonin shall repair or replace any Avant 9700 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 Avant 9700 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 devices 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 Avant 9700 that is found to be within specifications.

The Avant 9700 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 Avant 9700, field service by non-Nonin personnel, tampering, or any kind of misuse or abuse of the Avant 9700, 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.

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 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 compliance to IEC 60601-1-2 for this device.

Table 9: Electromagnetic Emission

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 61000-3-3	N/A	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	N/A	

Table 10: 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, 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 ±1 kV	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 ±2 kV	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.
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 11: 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 Vrms	$d = 1.17\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.17\sqrt{P}$ $d = 2.33\sqrt{P}$ 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.

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.

Table 12: 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 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
Extended Averaged SpO_2	8 beat exponential	2 beats

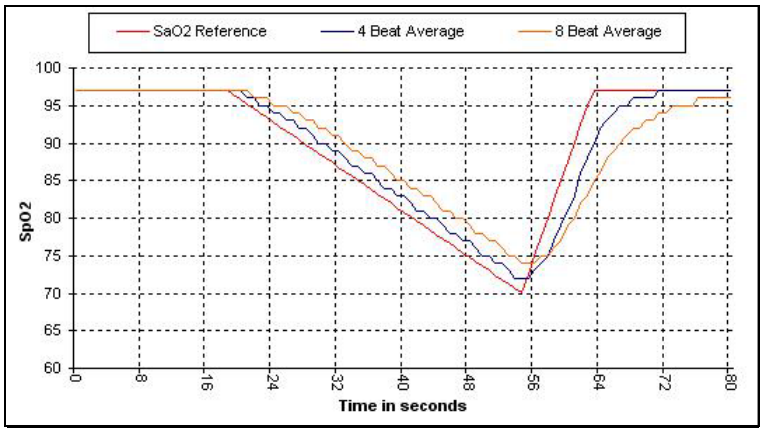
Pulse Rate Values	Response	Latency
Standard/Fast Averaged Pulse Rate	4 beat exponential	2 beats
Extended Averaged Pulse Rate	8 beat exponential	2 beats

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.
- The response of the 8-beat average is 3 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 in 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 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

Oximeter

Oxygen Saturation Display Range:	0 to 100% SpO_2
Pulse Rate Display Range:	18 to 300 pulses per minute (BPM)
Displays:	
Numeric Displays:	3-digit LEDs, Tricolor (red, green, amber)
Pulse Strength Bar Graph LED:	Tri-color LED segments
Accuracy – Sensors:	Declared accuracy data for compatible sensors can be found in Nonin's Sensor Accuracy document.

System

Measurement Wavelengths and Output Power*:	
Red:	660 nanometers @ 0.8 mW max. avg.
Infrared:	910 nanometers @ 1.2 mW max. avg.
Alarm Volume Range:	52–82 dBA
Informational Tone Volume Range:	50–70 dBA
Temperature:	
Operating:	32 °F to 122 °F (0 °C to 50 °C)
Storage/Transportation:	-40 °F to 158 °F (-40 °C to 70 °C)
Humidity:	
Operating:	10 % to 90 % noncondensing
Storage/Transportation:	10 % to 95 % noncondensing
Altitude (Operating):	Up to 12,000 meters (40,000 feet)
Power Requirements:	7.2 volt battery pack (6 cells) or 12 VDC 1.5A AC Power Supply
Battery Life:	
Operating:	Minimum 12 hours of continuous operation with a fully charged battery pack
Storage:	27 days
Battery Recharge Time:	4 hours
Dimensions:	5.5" H x 7.25" W x 4.5" D
Weight:	2.2 lbs
Memory:	115 hours minimum

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

Classifications per IEC 60601-1 / CAN/CSA-C22.2 No. 601.1 / UL60601-1	
Type of Protection:	Class II (on AC power with MPP30 power supply). Internally powered (on battery power)
Degree of Protection:	Type BF-Applied Part
Enclosure Degree of Ingress Protection:	IP22
Mode of Operation:	Continuous

Nurse Call

Voltage	30 VAC or DC (non-polarized), maximum
Current	100mA continuous (maximum)
Output Impedance	30 ohms (maximum)
Ground Reference	Isolated ground
Electrical Isolation	1500 VDC
Output	Normally Open or Normally Closed; switch selectable
Output Connector Type	0.141” phone jack
Serial Port Pin-out	
PIN #	**RS-232 FUNCTION**
1	Device Carrier Detect
2	Received Data
3	Transmitted Data
4	Data Terminal Ready
5	Signal Ground
6	Data Set Ready
7	Request to Send
8	Clear to Send
9	Ring Indicator