Operator's Manual

Avant® 2120

Pulse Oximeter and Noninvasive Blood Pressure (NIBP) Monitor

CE 0123

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.

Nonin Medical, Inc.
13700 1st Avenue North
Plymouth, MN 55441-5443, 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 0123

EC REP

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

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

7932-001-04

Contents

Contents (Continued)

Figures

Tables

Indications for Use

The Nonin Avant 2120 Pulse Oximeter and NIBP Monitor is a portable device indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate, and blood pressure of adult and pediatric patients in hospitals, medical facilities, and subacute environments. The Avant 2120 is intended for spot-checking and/or continuous monitoring of patients during both motion and no-motion conditions, for patients who are well or poorly perfused. Its functions may be used separately or simultaneously.

The blood pressure monitor is intended for noninvasive monitoring of the blood pressure of adult and pediatric patients in hospitals, medical facilities, and subacute environments. It is intended for attended care and may be used for spot-checking. The device should be used for patients with arm circumferences of 18-44 cm.

Contraindications

Do not use this device in an MR environment.
Do not use this device in an explosive atmosphere.
The pulse oximeter portion of this device is not defibrillation proof per IEC 60601-1.
The blood pressure monitor is not intended for use with neonates.

Warnings

This device is intended only as an adjunct device in patient assessment. It must be used in conjunction with other methods of assessing clinical signs and symptoms.
Inspect the sensor application site at least every 6 to 8 hours to ensure correct sensor alignment and skin integrity. Patient sensitivity to sensors and/or double-backed adhesive strips 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.
This 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.
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.
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.

Warnings (Continued)

A hazard can exist if different presets are used on multiple 2120 monitors in one care area.
As with all medical equipment, carefully route patient cables and connections to reduce the possibility of entanglement, strangulation, or injury to the patient.
This device turns off after approximately 30 minutes when in low battery mode.
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 the device without batteries.
Use this device only with Nonin-specified power supplies.
Do not use this device in or around water or any other liquid, with or without AC power.
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.
To obtain accurate results, and for important safety reasons, the blood pressure cuff must only be placed on the patient's arm.
Use only Nonin-specified blood pressure cuffs and hoses with the device. Using other cuffs might result in inaccurate readings or inability to operate the device.
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.

Cautions

When mounting the monitor to a mobile pole, mounting the monitor higher 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 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.
Portable and mobile RF communications equipment can affect medical electrical equipment.
If this device fails to respond as described, discontinue use until the situation is corrected by qualified technical professionals.

Cautions (Continued)

Do not autoclave or immerse this device in liquid or use caustic or abrasive cleaning agents.
Batteries may leak or explode if used or disposed of improperly.
In some circumstances, the device may interpret motion as good pulse quality. Minimize patient motion as much as possible.
Do not place liquids on top of this device.
Do not immerse this device or sensors in any liquids.
Follow local, state and national governing ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries.
To prevent potential loss of monitoring, do not use ear clip or reflective sensors on pediatric or neonatal patients.
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.
Data is overwritten ONE RECORD AT A TIME so if the entire memory is filled with a single record, portions of that record will be deleted when a new record begins.
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 60950 or UL 1950 for data-processing 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) - 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 ensure proper positioning of tubing/device.
This device's display will go blank after 30 seconds of no readings or poor readings.
Do not place DIP switch 1 in the UP position unless device calibration is intended.
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.
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 symbols that are found on the Avant Model 2120. See section titled Displays, Indicator, and Controls for detailed information about functional symbols.

Table 1: Symbols

Symbol	Description/Function
	Consult Instructions for Use
	Follow Instructions for Use
	Defibrillation-Proof Type BF Applied Part (Patient isolation from electrical shock). ***Applies to NIBP.***
	Type BF Applied Part (Patient isolation from electrical shock). ***Applies to pulse oximeter.***
	UL Mark for Canada and the United States with respect to electric shock, fire, and mechanical hazards only in accordance with UL 60601-1 and CAN/CSA C22.2 No. 601.1.
	CE Marking indicating conformance to EC directive No. 93/42/EEC concerning medical devices.
SN	Serial Number
	Indicates separate collection for electrical and electronic equipment (WEEE).
	Authorized Representative in the European Community.
	Manufacturer
IPX2	Protected against vertically falling water drops when enclosure is tilted up to 15 degrees, per IEC 60529.
%SpO_2	%SpO_2 Display
	Pulse Rate Display
	Signal Output

Displays, Indicators, and Controls

This section describes the displays, indicators, and controls used on the Avant 2120.

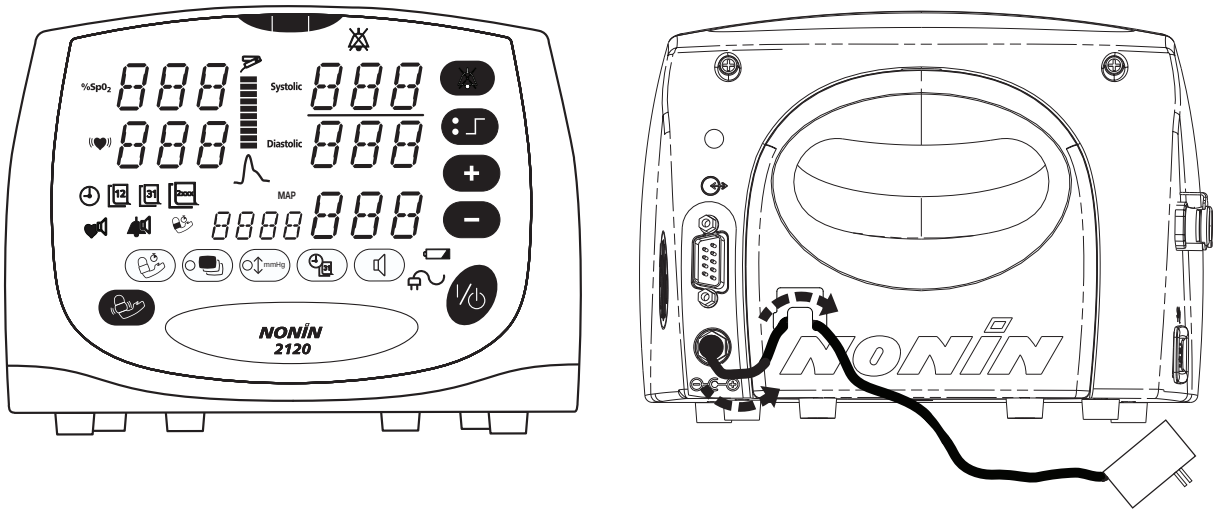


Figure 1: Avant 2120 Front and Back View

Parameter Displays

%SpO_2 Display

Numeric light-emitting diodes (LEDs) on the upper left-hand corner of the device display blood oxygen saturation in percent.

Pulse Rate Display

The pulse rate display is the lower numeric display on the upper left-hand corner of the device (identified by the ((♥)) symbol). This 3-digit LED display shows the pulse rate in beats per minute.

Systolic Pressure Display

The systolic display is a 3-digit LED display near the upper right-hand corner of the device. The Systolic number displayed represents the blood pressure in mmHg during contraction of the ventricles.

Diastolic Pressure Display

The diastolic display is a 3-digit LED display in the middle right-hand side of the device. The Diastolic number displayed represents the blood pressure in mmHg when the ventricles are relaxed.

MAP (Mean Arterial Pressure) Display

The MAP display is a 3-digit LED display near the middle right-hand side of the device. The MAP number displayed is a calculated value in mmHg, based on measurements of systolic and diastolic pressure:

MAP = 2/3 diastolic + 1/3 systolic

NOTE: LED means “light-emitting diode.”

Numeric LEDs

Numeric LEDs appear for SpO_2, Pulse Rate and blood pressure data, and for time and date displays, cuff pressure, volume and NIBP history review.

There are five 3-digit multi color numeric LEDs on the device. They are used for SpO_2, pulse rate, and blood pressure displays.

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

There is also a four-digit, green, numeric LED on the device. It is used primarily to display date and time information, adjust volumes, adjust the auto NIBP cycle time, and set the initial NIBP cuff pressure.

Indicators and Icons

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 / Battery Capacity Bar Graph LED

This 10-segment multi color 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 a low pulse amplitude, the device goes into High Priority Alarm mode.

Green = a good pulse strength

Amber = a marginal pulse strength

Red = a non-discernible pulse strength, high priority alarm.

The Pulse Strength / Battery Capacity Bar Graph LED indicates the battery capacity in 10% increments. Amber represents the depleted capacity of the battery and green indicates the available battery capacity.

Pulse Quality LED

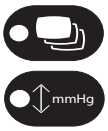
This LED blinks to indicate an inadequate pulse quality. If there is a sustained series of inadequate pulses, the Pulse LED will illuminate solid.

Pulse Volume LED

This amber LED indicates that the device is in Pulse Volume Program mode. When this LED is lit, pulse volume can be adjusted using the Plus (+) and Minus (-) buttons on the front panel. The highest volume is 15, and the lowest volume is 0. The default volume level is 4. The device beeps while pulse volume is being changed, showing the volume progression as it is adjusted.

Auto NIBP Mode LED

This multicolor LED indicates that the device is in Auto NIBP mode when it is lit green. When lit amber, this LED indicates that the device is in Auto NIBP Cycle Time Program mode. The cycle time can be adjusted using the Plus (+) and Minus (-) buttons.



Display Panel LED Indicators

Display panel LED indicators display whether or not the Avant 2120 is functioning in certain modes (NIBP History Display mode or Initial Cuff Pressure Display mode).

Battery LED

This amber LED indicates a marginal battery capacity by blinking in sync with the Main Alarm LED indicator. This LED, when lit solid, indicates that the battery capacity is being displayed. *This LED does not indicate that the* Avant *2120 is running on battery power.*

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 the device without batteries.

AC Power Supply LED

This green LED is displayed when an external power supply is providing power to the device.

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

Alarm Silence LED

This amber LED indicates that the audible alarm is temporarily silenced when it blinks. When lit solid, the Alarm Silence LED indicates that the audible alarm volume is set to zero.

Main Alarm LED

The Main Alarm LED indicates visible alarm conditions. A rapid blinking red main alarm LED indicates high priority; medium priority alarm condition is indicated by a slowly blinking amber main alarm LED.

Alarm Volume LED

This amber LED indicates that the device is in Alarm Volume Program mode. When this button is illuminated, the alarm volume can be adjusted by using the Plus (+) and Minus (-) buttons on the front panel. The highest volume is 15, and lowest volume is 8. The default volume level is 8. If DIP switch 2 is moved to the UP position, then the alarm volume can be adjusted to zero.

Time, Month, Day, and Year LEDs

These amber LEDs indicate that the *Time, Month, Day,* or *Year* displays can be reviewed or adjusted using the Plus (+) and Minus (-) buttons.

Display Panel Buttons

NIBP Button

This button is used to begin or cancel a single blood pressure measurement. While the device is taking a blood pressure reading, pressing any button on the front panel will cancel the action and deflate the cuff.

Auto NIBP Cycle Time Button

This button is used to display the automatic blood pressure measurement cycle time. The Plus (+) and Minus (-) buttons are used to change the cycle time setting. The device can be set to start a blood pressure reading every 1, 2, 3, 5, 10, 15, 30, 45, 60, or 90 minutes after the previous blood pressure reading is complete. The NIBP timer begins after the previous blood pressure measurement is completed.

NIBP History Review Button

This button displays previously measured blood pressure values. The Plus (+) and Minus (-) buttons can be used to scroll through and display stored NIBP readings. By using the NIBP History Review Button, the last 300 readings may be reviewed. Readings are not lost when the device is in Standby mode. Readings from previous sessions are indicated with a blinking time stamp.

Initial Cuff Pressure Button

This button displays the initial cuff inflation pressure (i.e., the amount of pressure to which the cuff initially inflates) when obtaining a reading. The inflation pressure will readjust, based on the patient's previous blood pressure. The initial cuff pressure can be changed using the Plus (+) and Minus (-) buttons. Initial cuff pressure can be set to 120, 140, 160, 180, 200, 220, or 240 mmHg.

ON/STANDBY Button

This button toggles the device between ON and STANDBY modes. Pressing this button once turns on the device. Pressing and holding this button for at least 1 second turns off the device.

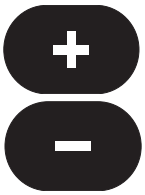
Briefly pressing this button while the device is on displays the battery capacity, in 10% increments. Amber represents the depleted capacity of the battery and green indicates the available capacity. If the ON/STANDBY button is pressed again, the battery capacity display exits. The battery capacity display will exit automatically after four seconds.

Alarm Silence Button

This button toggles the alarm between silenced and audible. Pressing the Alarm Silence button silences all alarms for two minutes. Pressing and holding this button for two seconds clears all NIBP high and medium priority alarms (including any displayed NIBP data).

Limits Button

This button displays the upper and lower limits for alarm indications for SpO_2, heart rate, systolic, diastolic, and MAP measurements. These limits can be adjusted using the Plus (+) and Minus (-) buttons. The upper LED indicates the upper alarm limit is being displayed, and the lower LED indicates the lower alarm limit is being displayed. The limit values are displayed in amber.



Plus and Minus Buttons

The Plus and Minus buttons are used to adjust timing of automatic blood pressure readings, initial cuff pressure, time, date, volume, upper and lower alarm limits, and they are used to scroll through the NIBP history. Pressing this button, when the device is not in program mode, adjusts the intensity of the LED displays.

Time/Date Button

This button displays the time and date. Pressing the button allows the user to set the year, month, day, hour, and minute, with the Plus (+) and Minus (-) buttons. In US mode, pressing the button allows the user to set the year, month, day, hour, and minute with the Plus (+) and Minus (-) buttons. Placing DIP switch 3 in the UP position allows users to view and set the time and date in International mode.

Volume Button

This button displays the pulse volume and alarm volume, identified by the illuminated LED. The pulse and alarm volumes can be adjusted using the Plus (+) and Minus (-) buttons.

Operating the Device

Installing the Batteries

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 the device without batteries.

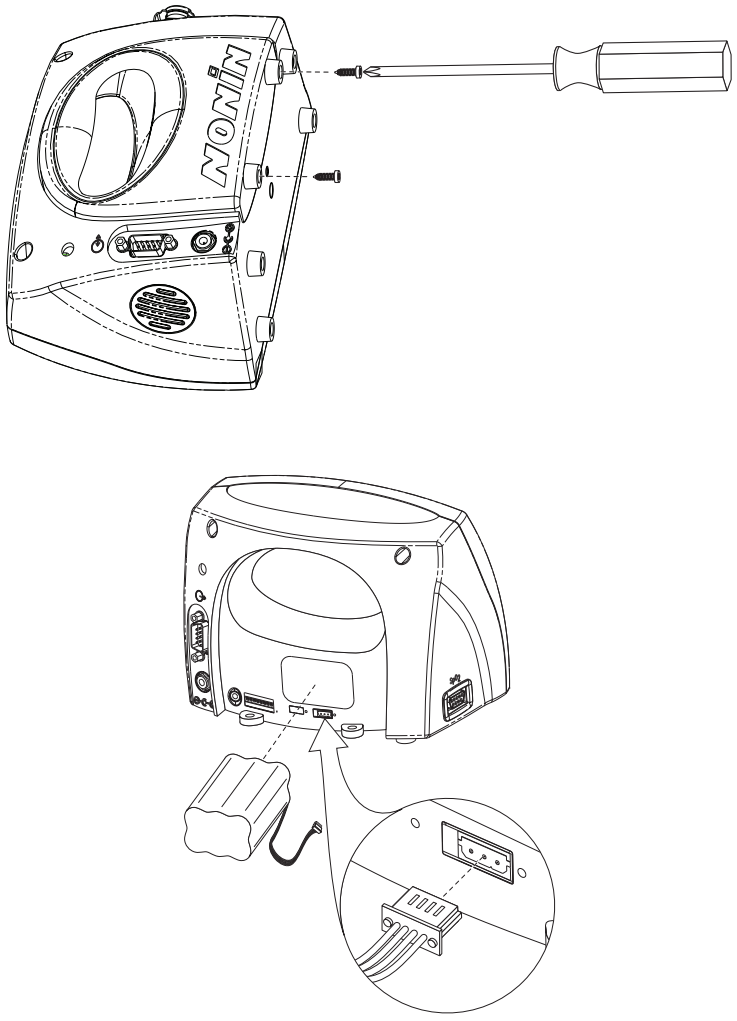


Figure 2: Installing the Batteries

- Remove the back cover by loosening the screws.
- Insert the battery pack as illustrated.
- Reposition the back cover carefully and tighten the screws firmly, do not over-tighten.
- Removing batteries from the device deletes all previous oximetry and NIBP data; it does not delete user-defined alarm limits.

Verifying Operation

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. If any LED is not lit, do not use the device and contact Nonin Technical Service for assistance.

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

1. Ensure the device is on and the sensor is connected to the monitor.
2. Apply the pulse oximeter sensor to the patient.
3. Verify SpO_2 and pulse rate values are displayed, and the pulse strength bar graph LED is activated.

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

Alarm Limit Defaults

During initialization, FAC dFL or USR dFL will appear briefly in the SpO_2 and Pulse Rate displays to indicate which defaults are in use; after initialization, any of the defaults can be modified.

To program user-defined alarm limit and volume defaults, set DIP switch 8 to the UP position. A value for each limit must be programmed before the device will continue to operate.

To return to factory defaults, DIP switch 8 must be set in the DOWN position before entering start-up initialization.

NOTE: The device must be in factory default mode before programming user-defined alarm limit and volume defaults.

NIBP and %SpO_2 Functions

The NIBP and %SpO_2 functions on the Avant 2120 can be used separately or simultaneously.

To take %SpO_2 measurements, ensure that the device is on with a Nonin-branded PureLight sensor connected to the monitor. Apply the sensor, following the Instructions for Use provided with the sensor. SpO_2 and pulse rate measurements will be displayed in the %SpO_2 and Pulse Rate displays.

WARNING: This 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.

Operator Functions

Taking Blood Pressure Measurements

This section describes how to take blood pressure measurements with the Avant 2120.

NIBP Cuff Selection

To obtain accurate readings, the appropriate cuff size must be selected for each patient.

CONTRAINDICATION: The blood pressure monitor is not intended for use with neonates.

WARNING: Use only Nonin-specified blood pressure cuffs and hoses with the device. Using other cuffs might result in inaccurate readings or inability to operate the device.

Small Adult BP Cuff	18-26 cm arm circumference
Standard Adult BP Cuff	26-35 cm arm circumference
Large Adult BP Cuff	32-42 cm arm circumference
Extra Large Adult BP Cuff	35-44 cm arm circumference

NIBP Cuff Placement

Apply the cuff around the bicep of the left or right arm slightly above the elbow, so the inflation bladder is centered over the brachial artery (the inflation bladder is approximately half of the entire length of the cuff). Do not apply the blood pressure cuff to an arm with an IV. The patient's arm should be resting comfortably, at a level that is parallel to his or her heart, with the palm of the hand facing upward.

If a comfortable fit is difficult to obtain, a different cuff size might be required. *Blood pressure cuffs should be applied directly to the patient's skin; applying cuffs over clothing may affect the blood pressure measurements.*

Patients should be in a relaxed position with feet flat on the floor (if sitting). Do not apply the blood pressure cuff to the same arm the pulse oximeter sensor is applied.

WARNING: To obtain accurate results, and for important safety reasons, the blood pressure cuff must only be placed on the patient's arm.

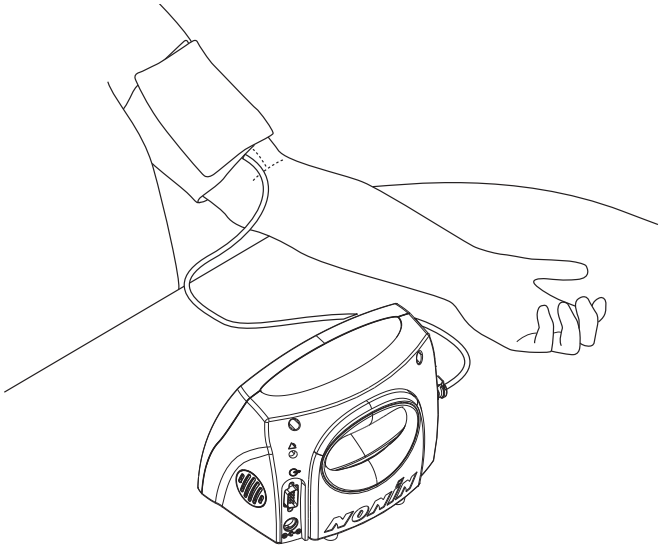


Figure 3: Proper Cuff Placement

Use the following procedure to take blood pressure and/or SpO_2 measurements:

NOTE: If the device is turned on without an oximeter sensor, the oximeter will be disabled and the SpO_2 display will remain blank. Plugging in the oximeter sensor at any time will enable the oximeter.

1. Ensure that the device is on and the start-up sequence is complete.
2. Connect the blood pressure cuff and/or pulse oximeter sensor to the device.
   - Attach the straight or coiled tubing to the monitor; attach the cuff to the tubing as illustrated below.
   - Connect the pulse oximeter sensor as illustrated below, with the Nonin logo facing up.

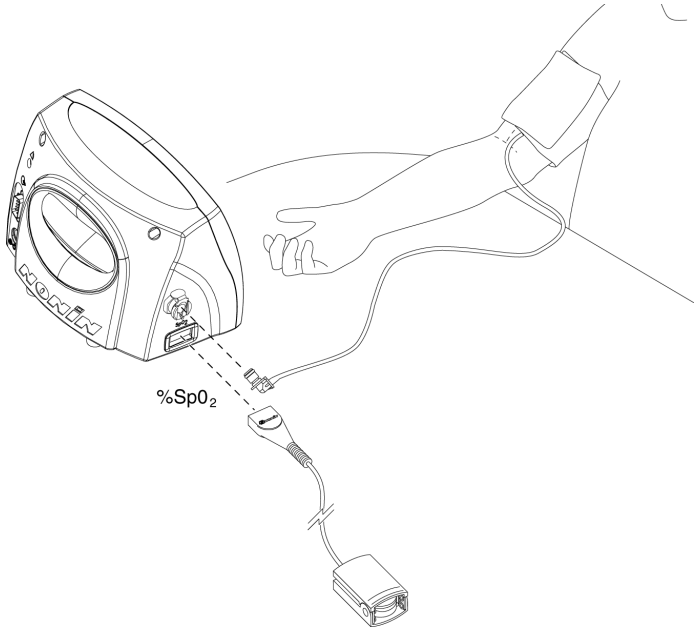


Figure 4: Connecting the Blood Pressure Cuff and Finger Clip Sensor

3. Place the blood pressure cuff around the patient's arm.
4. Apply the finger clip sensor on the patient (see Sensor Instructions for Use for proper placement).
5. Press the NIBP button to begin a single blood pressure measurement. The cuff will begin inflating, and the cuff pressure value will appear in the Time LED display.
6. When the reading is complete, the Systolic, Diastolic, and MAP numeric LEDs will display the results for blood pressure. If pulse rate and SpO_2 readings are not obtained from the oximeter sensor, the pulse rate reading from the NIBP will be displayed.

NOTE: When the finger clip sensor is applied, the %SpO_2 and pulse rate readings are from the Finger Clip sensor, not the blood pressure measurement.

NOTE: If a blood pressure reading must be canceled for any reason, press any button, except the Alarm Silence button, to deflate the cuff.

Automatic and Demand NIBP Measurements

The Auto NIBP Cycle Time button is used to begin or end timed blood pressure measurements and display the Auto NIBP Cycle time, which can be adjusted using the Plus (+) and Minus (-) buttons. Blood pressure readings can be started every 1, 2, 3, 5, 10, 15, 30, 45, 60, or 90 minutes after the previous reading is complete.

When continuous spot-checking of patients is required or to determine fluctuations in blood pressure over periods of time, the Automatic NIBP should be used.

Demand NIBP measurements are single-time measurements taken by pressing the NIBP button on the device.

Calibrating Blood Pressure

Calibration should be performed after every 10,000 inflations or once per year, using the following procedure. Calibration should only be performed by qualified personnel.

Suggested Equipment:

- Mercury Manometer
- Pneumatic T-Adapter
- Pressure Bulb

1. With the device turned off, connect a mercury manometer and pressure bulb to the device using a T-adapter.
2. Using the tip of a screwdriver or other similar device, place DIP switch 1 in the UP position.
3. Turn on the device. A CAL message is displayed in the Systolic display window, verifying that the device is in Calibration mode.
4. Wait for a green "0" to appear in the Diastolic LED display.

5. Verify that the pressure on the manometer is zero, so there is no pressure difference at the pressure transducer and outside the device.
6. Press the NIBP button. A countdown will begin, followed by “250” in the Diastolic display.
7. Using the pressure bulb, apply *exactly* 250 mmHg to the device.
8. Press the NIBP button to calibrate the device at 250 mmHg. The device is now calibrated and will display a `CAL dnE` message.
9. Press the ON/STANDBY button to turn the device off.
10. Return DIP switch 1 to the DOWN position.

NOTE: The pulse oximeter does not require calibration.

Advanced Features

This section describes the advanced features available on the Avant 2120.

Button Combinations

This device offers two advanced features that are available by using multiple button combinations. The device must be in Standby mode before using either of the advanced features.

Button Combination	Feature Name	Function
	Retain Previous User-Defined Volume and Alarm Limits	Allows users to retain the previously set user-defined alarm and volume limits even after shutting down the device. To use this feature, hold the Limits button while pressing the ON/STANDBY button to power the device.
	Clear Oximeter Memory	Allows users to clear the oximeter memory. To use this feature, hold the NIBP History Review button while pressing the ON/STANDBY button to power the device.

NOTE: If the Limits button and NIBP History Review button are both held while pressing the ON/STANDBY button to turn on the device, both of the above advanced features are active.

DIP Switches

The DIP switches are located under the blue battery cover on the rear of the device. A small Phillips screwdriver must be used to remove the battery cover.

The default for all switches is the DOWN position.

Table 2: DIP Switches

Switch	Function
1	UP: Calibration Mode DOWN: Normal Operation (Default)
2	Alarm Disable/Minimum Alarm Volume Definition: *See "Silencing Alarms" for more information*. UP: 0 dB DOWN: 45 dB (Default)

Table 2: DIP Switches (Continued)

Switch	Function
3	UP: International Date Format DOWN: USA Date Format (Default)
4	UP: Real-time data output available via RS232 port DOWN: Print-on-Demand mode activated (Default)
8	UP: User-Defined Alarm Limit and Volume Defaults DOWN: Factory Alarm Limit and Volume Defaults (Default)

CAUTION: Do not place DIP switch 1 in the UP position unless device calibration is intended.

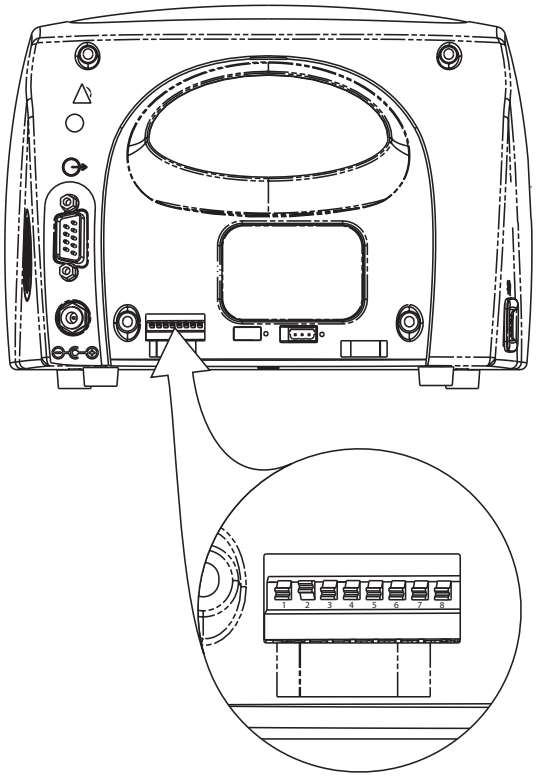


Figure 5: DIP Switches

Quick Reference for Printing

The Avant 2120 features printing capabilities that allow you to print on demand or in real-time. These are controlled by DIP switch 4, which is located under the battery cover at the back of the device.

- When DIP switch 4 is in the UP position, real-time (once per second) data output is available via the RS232 connector port, using a null modem cable.
- When DIP switch 4 is in the DOWN position *(default),* the Print-on-Demand mode is activated, allowing you to print via the RS232 connector port only when desired.

There are three ways to print when the device is in Print-on-Demand mode:

Print-On-Demand	Press	Printout
Normal Mode		Prints displayed data.
History Mode 		Prints displayed history data.
Auto NIBP Mode 		Prints displayed data and automatically prints all new displayed data upon completion of NIBP reading.

NOTES:

- Event markers are not available in Print-On-Demand mode.
- Data must be allowed to finish printing before entering History Review mode.
- When there is invalid NIBP data, “BP=Error” will print in place of “SYS=XXX DIA=XXX MAP=XXX” for all Print-On-Demand formats.
- Valid SpO_2 and heart rate data will continue to be displayed in the event of an NIBP error code.
- Print functions are available only with a 9600 baud serial ASCII printer.
- The device has a Memory Download feature, allowing stored data to be transferred to Nonin’s nVISION data management software for analysis. Printing features are not available during memory download.

Communication

Memory Features

The Avant 2120 can collect and store up to 33.5 hours of SpO_2 and pulse rate information.

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

NOTE: Only SpO_2 and pulse rate data are available for download.

The memory in the device functions as an "endless loop" tape. When the memory fills up, the device begins overwriting 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 is stored. Oxygen saturation values are stored in 1% increments in the range of 0 to 100%.

The stored pulse rate ranges from 18 to 300 pulses per minute. The stored values are in increments of one 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.

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 the device without batteries.

Using nVISION Data Management Software

This device 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 off, attach the null modem cable to the RS-232 connector port of the device and to the back of your computer.
2. With the device still off, press and hold the NIBP History Review button while pressing the ON/STANDBY button. All LEDs will illuminate briefly. "PLy" will appear in the SpO_2 LED display area, and "bAC" will appear in the Systolic display area. This message signals that the device is now in Download mode.
3. The "PLy bAC" message will disappear after a few seconds, indicating that the memory download is complete. Pressing the ON/STANDBY button will exit Download mode.
4. A "CLr no" message will be displayed, and three informational tones will sound.
   - Use the Plus (+) and/or Minus (-) buttons to toggle between "yES" and "no" on the Systolic display window.

5. Press the ON/STANDBY button when the desired Memory Clear selection is made.
   - If selecting "no," pressing the ON/STANDBY button exits Download mode, and normal operation resumes.
   - If selecting "yES," pressing the ON/STANDBY button displays a "dEL" message in the %SpO_2 display window and a "no" message in the Systolic display window. Use the Plus (+) and/or Minus (-) buttons to toggle between "yES" and "no" on the Systolic display window.

NOTE: Selecting yES from the "dEL" window will permanently delete the device's memory.

6. If yES is selected, a "dnE CLr" message appears when patient data is clear. Press the ON/STANDBY button to return to normal operation.
7. For more information about using nVISION, refer to nVISION's online help.

NOTE: Patient oximetry and NIBP data are cleared simultaneously in Download mode.

Real-Time Patient Data Output

The Avant 2120 provides real-time data output capability via the RS232 connector port. A null modem cable must be connected from the device to the receiving computer.

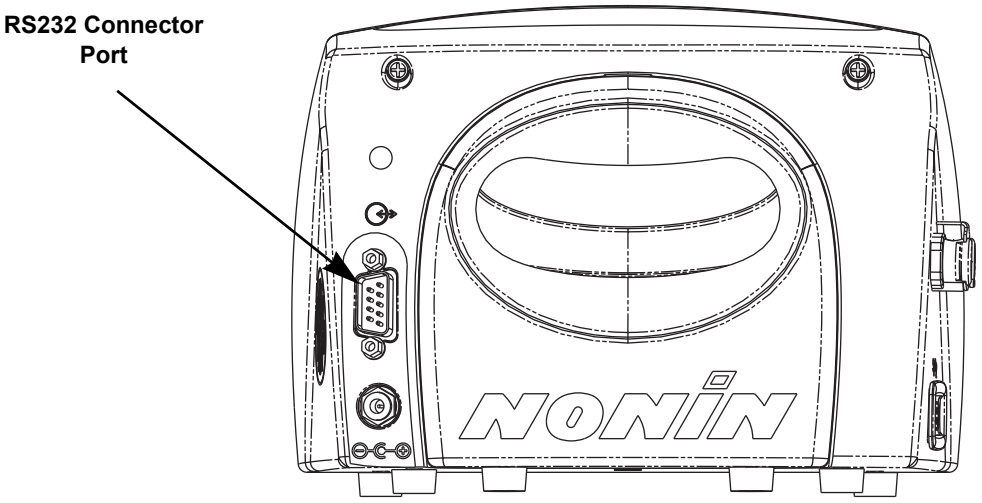


Figure 6: RS232 Connector Port

The 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 output rate is once per second (on separate lines).

Real-time data may be printed or displayed by devices other than the pulse oximeter. Upon start up, a header is sent identifying the format and the time and date; the data format is:

SPO2=XXX HR=YYY

NIBP will be displayed when it is available in the following format:

SPO2=XXX HR=YYY SYS=SSS DIA=DDD MAP=MMM

where XXX is the SpO_2 value, YYY is the heart rate value, SSS is the systolic value, DDD is the diastolic value, and MMM is the MAP value.

When there is no oximeter data, the formats will appear as follows:

SPO2=--- HR=---

SPO2=--- HR=YYY SYS=SSS DIA=DDD MAP=MMM

This device includes an event marker feature. Events are indicated by a single "*" whenever ON/STANDBY is pressed. This feature can be used to mark patient events. The Battery Capacity will be displayed for 4 seconds when marking events. ON/STANDBY may be pressed again to exit sooner.

SPO2=XXX HR=YYY*

SPO2=XXX HR-YYY SYS=SSS DIA=DDD MAP=MMM*

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 NIBP module requires calibration after every 10,000 inflations or once each year; the pulse oximeter module requires no calibration.

Field repair of the device circuitry is not possible. 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” or contact Nonin Technical Service.

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

Cleaning

Clean the Avant 2120 separately from the sensors. For instructions regarding cleaning pulse oximeter sensors, refer to the appropriate pulse oximeter sensor Instructions for Use.

Clean the device with a soft cloth dampened with isopropyl alcohol. 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 reuse.

Cleaning the Blood Pressure Cuff

To clean the reusable blood pressure cuff, wipe the cuff with a soft cloth dampened with isopropyl alcohol. Do not pour or spray any liquids onto the cuff, and allow the cuff to dry thoroughly before reusing it.

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

Alarms and Limits

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.

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

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

Alarms

This device provides high and medium priority audible and visual alarms. It also provides informational tones.

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 a rapidly blinking red 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, a short pause, 2 beeps and a 10-second pause and repeat until the alarm is cleared or silenced.

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 in the MAP area, to identify the error source (see Table 3, Error Codes).

Medium priority alarms are: 3 beeps, a 25-second pause, followed by 3 additional beep, repeated until the alarm is cleared or silenced.

Error Codes

This device includes various error codes to indicate potential problems with the device. The following table describes the error codes present on the Avant 2120.

Table 3: Error Codes

Error Code	Description
CAN	**NIBP Module, User Canceled:** NIBP module was canceled from taking blood pressure reading.
E00	**System Error:** Retry reading. If reading is not possible, turn the device off and on again and retry. Calibration may be required. Call Nonin Technical Service if error persists.
E01	**NIBP Module, Bad Signals:** NIBP module cannot complete reading. Failure could be due to patient's blood pressure falling outside module's range. Check patient, air hose connection, and cuff application.
E02	**NIBP Module, Overpressure:** Overpressure condition occurred.
E03	**NIBP Module, Air Leak:** Check hose and cuff for damage or air leaks.
E04	**NIBP Module, Blockage in Hose:** Check hose for kinks or blockage.
E05	**NIBP Module, Safety Timeout:** Allowed time expired before reading was complete, or system remained in test mode for more than three minutes.
E06	**NIBP Module, Excessive Motion:** Check patient, reduce motion.
E07	**NIBP Module, Transducer Out of Range:** NIBP module pressure transducer may need recalibration.
E10	NIBP Module, Calibration Data Invalid
E11	NIBP Module, ADC Hardware Failure
E13	**NIBP Module, Pressure Calibration Failed:** Module unable to reset pressure calibration data.
E17	Undefined NIBP Error
E19	**NIBP Module, No Communication:** No data from NIBP module.
E31	**Sound Error:** Channel 1 Failure
E32	**Sound Error:** Channel 2 Failure

Table 3: Error Codes (Continued)

Error Code	Description
E33	**Sound Error:** Both Channels Failure
E34	**Sound Error:** Amplifier Failure
E35	**Sound Error:** Channel 1 Failure, Amplifier Failure
E36	**Sound Error:** Channel 2 Failure, Amplifier Failure
E37	**Sound Error:** Channel 1 Failure, Channel 2 Failure, Amplifier Failure
E38	**Sound Error:** Speaker Failure
E39	**Sound Error:** Channel 1 Failure, Speaker Failure
E40	**Sound Error:** Speaker Failure, Channel 2 Failure
E41	**Sound Error:** Channel 1 Failure, Channel 2 Failure, Speaker Failure
E42	**Sound Error:** Speaker Failure, Amplifier Failure
E43	**Sound Error:** Channel 1 Failure, Speaker Failure, Amplifier Failure
E44	**Sound Error:** Speaker Failure, Channel 2 Failure, Amplifier Failure
E45	**Sound Error:** Channel 1 Failure, Channel 2 Failure, Speaker Failure, Amplifier Failure
E51	**Sound Module, Communication Failure:** No SPI communication from sound module to display board microcontroller.
E52	**SCI Communication Error:** SCI communication problem.
E53	**External Memory Failure:** External (patient data) memory failed test.

Watchdog Alarm

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 (press and hold the ON/STANDBY button for one second). If the watchdog alarm does not clear, contact Nonin Technical Service.

Informational Tones

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

Alarm Summary

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

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

If patient readings meet or exceed the upper alarm limit, or if they meet or are below the lower alarm limit, the device will signal a high priority alarm.

Table 4: Alarm Summary

Alarm Description	Adjustment Range	Default
SpO_2 Upper Alarm Limit	Off, 80 to 100 by 1%	Off
SpO_2 Lower Alarm Limit	Off, 50 to 95 by 1%	85%
Pulse Upper Alarm Limit	Off, 75 to 275 by 5 BPM	200 BPM
Pulse Lower Alarm Limit	Off, 30 to 110 by 5 BPM	50 BPM
Systolic Upper Alarm Limit	Off, 75 to 240 by 5 mmHg	200 mmHg
Systolic Lower Alarm Limit	Off, 50 to 150 by 5 mmHg	60 mmHg
Diastolic Upper Alarm Limit	Off, 50 to 180 by 5 mmHg	120 mmHg
Diastolic Lower Alarm Limit	Off, 25 to 125 by 5 mmHg	30 mmHg
MAP Upper Alarm Limit	Off, 70 to 200 by 5 mmHg	150 mmHg
MAP Lower Alarm Limit	Off, 25 to 125 by 5 mmHg	50 mmHg

Setting and Changing Volume and Alarm Limits

NOTE: The alarm limits automatically reset themselves to default values each time the device is turned on. To retain previously adjusted alarm limits, hold the Limits button while turning on the device.

Setting or Changing SpO_2 and/or Pulse Rate Alarm Limits

1. Press the Limits button; the upper amber LED is illuminated on the Limits button. OFF, default value, is displayed in the $\%SpO_2$ display.
2. Use the Plus (+) and Minus (-) buttons to adjust the upper SpO_2 limit to the appropriate value.
3. When the appropriate upper alarm limit is displayed, press the Limits button to set the lower alarm limit. Press the Limits button 10 times to exit this mode; the device will automatically exit this mode after 10 seconds of no activity.

Setting or Changing Systolic, Diastolic, and MAP Alarm Limits

1. Press the Limits button 5 times; the upper amber LED is illuminated on the Limits button, and 200, default value, is displayed in the Systolic display.
2. Use the Plus (+) and Minus (-) buttons to adjust the systolic upper alarm limit to the appropriate value.
3. When the appropriate upper alarm limit is displayed, press the Limits button to set the lower alarm limit. Press the Limits button 6 times to exit this mode; the device will automatically exit this mode after 10 seconds of no activity.

Setting or Changing Alarm and Pulse Volumes

1. Press the Volume button; the Alarm Volume LED illuminates and 08, default value, appears on the display screen.
2. Use the Plus (+) and Minus (-) buttons to adjust the alarm volume to the appropriate level; Alarm Volume range is 08-15.
3. When the appropriate alarm volume is displayed, press one of the following:
   - Volume button **once** to set the Pulse Volume.
   - Volume button **twice** to exit Set/Change Alarm Volume mode.
   - Wait 10 seconds to automatically exit Set/Change Alarm Volume mode.

Silencing Alarms

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

To permanently silence all alarms, DIP switch 2 must be placed in the UP position. This allows the Alarm Volume to be set to zero. *The Alarm Silence LED will remain illuminated when the alarm volume is set to zero.*

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.

Setting and Changing NIBP Settings

Setting or Changing Automatic NIBP Cycle Time

1. Press the Auto NIBP Cycle Time button. The Auto NIBP LED illuminates and OFF, default value, appears on the display screen.
2. Use the Plus (+) and Minus (-) buttons to adjust the automatic NIBP cycle time, in minutes, to the appropriate intervals.
3. When the appropriate cycle time is displayed, either press the Automatic NIBP Cycle Time button once to exit this mode, or simply wait 10 seconds to automatically exit this mode.

Setting or Changing Initial NIBP Cuff Inflation Pressure

1. Press the Initial Cuff Pressure button; the default cuff pressure (typically 160) appears as an LED display.
2. Press the Plus (+) and Minus (-) buttons to adjust the initial NIBP cuff inflation pressure to the appropriate level. Users may select initial pressures of 120, 140, 160, 180, 200, 220, or 240.
3. When the appropriate inflation pressure is displayed, either press the Initial Cuff Pressure button once to exit this mode, or wait 10 seconds to automatically exit this mode.

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) 553 9968, or +31 (0)13 - 79 99 040 (Europe).
- Visit www.nonin.com.

WARNING: 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.

WARNING: 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.

WARNING: Use this device only with Nonin-specified power supplies.

Service, Support and Warranty

> ⚠ **CAUTION:** 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.

The Avant 2120 Pulse Oximeter module performs all computations from internal software stored in microprocessor chips. Thus, there are no critical parts to drift, and no calibration of the pulse oximeter module is required. The Avant 2120 NIBP module should be calibrated after every 10,000 checks or once per year, whichever comes first.

For information about the Avant 2120 and accessories, contact your local sales representative or distributor. For the sales representative or distributor in your area, contact Nonin at (800) 356-8874.

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

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

Warranty

NONIN MEDICAL, INCORPORATED (Nonin) warrants to the purchaser, for a period of one year from the date of purchase, each Avant 2120 battery pack, and for two years from the date of purchase each blood pressure module. Nonin warrants the pulse oximetry module of the Avant 2120 for a period of three years from the date of purchase, and the blood pressure cuff for a period of 90 days from the date of purchase.

Nonin shall repair or replace any Avant 2120 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 2120 delivered to the purchaser that 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 2120 that is found to be within specifications.

Avant 2120 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 2120, field service by non-Nonin personnel, tampering, or any kind of misuse or abuse of the Avant 2120, 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.

Troubleshooting

Problem	Possible Cause	Possible Solution
The device will not activate.	The battery pack is inserted incorrectly.	Check the batteries.
	The batteries are depleted.	Plug in the device to recharge its batteries, or replace the batteries.
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 site.
	The pulse oximeter finger clip sensor is applied incorrectly.	Apply the sensor according to the Instructions for Use provided with the sensor.
	There is possible interference from one of the following sources: • arterial catheter • blood pressure cuff • electrosurgical procedure • infusion line	Reduce or eliminate any interference.
	Circulation is reduced because of 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.
	There is excessive ambient light.	Shield the sensor from the light source.
	The sensor is applied to a polished fingernail or artificial nail.	Apply the sensor to a finger without fingernail polish or an artificial nail.
	The finger is wet.	Dry the finger and the sensor’s inner surfaces.
	The red LED is not illuminated in the finger insertion area.	Contact Nonin’s Technical Service Department.
	Excessive patient motion.	Reduce patient motion.

Problem	Possible Cause	Possible Solution
The Pulse Oximeter Sensor LED appears.	An inadequate pulse signal is detected	Reposition the finger or insert a different finger, and keep the sensor motionless for at least 10 seconds.
		Warm the application site.
	The finger was removed from the sensor.	Reposition the finger or insert a different finger, and keep the sensor motionless for at least 10 seconds.
	The device is not functioning.	Contact Nonin's Technical Service.
An error code appears in the display area.	The device encountered an error.	See "Error Codes Table" or contact Nonin Technical Service.
The NIBP cuff overinflates and detaches from either the device or the hose; blood pressure readings are not displayed.	The cuff is on backward or is positioned incorrectly.	Ensure that the cuff is applied and positioned correctly. See "NIBP Cuff Selection" and "NIBP Cuff Placement" for more information.
	The wrong cuff size was used on the patient.	Ensure that the appropriate cuff size is selected. See "NIBP Cuff Selection" for more information.
The device will not take NIBP readings.	The blood pressure hose is not attached.	Attach the blood pressure hose to the device.
	There is a communication error.	Return the device to Nonin Technical Service for repair or replacement.
The device 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 two minutes, the alarm tones will automatically activate.
	DIP switch 2 is in the On (up) position, and the volume is set to zero.	Adjust the alarm volume, or return DIP switch 2 to the Off (down) position if audible alarms are required.
The device will only operate when it is plugged in.	The battery is not charged or is depleted.	Plug in the AC Power Supply to charge the battery.
	The battery does not charge.	Return the device to Nonin Technical Service for repair or replacement.

If these solutions do not correct the problem, 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 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 5: 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 6: 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 for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	±5% U_T (>95% dip in U_T) for 0.5 cycle ±40% U_T (60% dip in U_T) for 5 cycles ±70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec.	±5% U_T (>95% dip in U_T) for 0.5 cycle ±40% U_T (60% dip in U_T) for 5 cycles ±70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec.	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or battery pack.
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the AC mains voltage before application of the test level.			

Table 7: Guidance and Manufacturer's Declaration—Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance
This device is intended for use in the electromagnetic environment specified below. The customer and/or user of this device should ensure that it is used in such an environment.			
Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.			
			Recommended Separation Distance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V rms	$d = 1.17\sqrt{P}$
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: 
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 8: 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

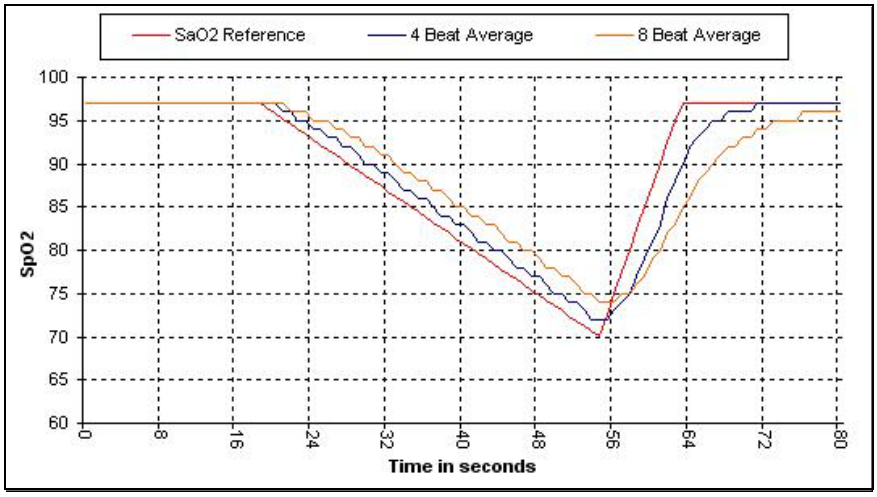
Pulse Rate Values	Response	Latency
Standard/Fast Averaged Pulse Rate	4 beat exponential	2 beats
Extended Averaged Pulse Rate	8 beat exponential	2 beats

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.

NIBP Testing Summary

Clinical evaluation for accuracy of the NIBP module was performed on 93 subjects ranging in age from 3 to 70 years, arm circumference of 16-41 cm, with 3 readings per subject for a total of 279 readings. The evaluation was conducted over a range of pressures 91 - 221 mmHg for systolic and 46-119 mmHg for diastolic.

AAMI SP10, section 4.4.2 and Annex B requires that:

- systolic and diastolic pressures must be evaluated separately
- mean difference must be +/-5 mmHg or less
- standard deviation of 8 mmHg or less

Refer to device specifications for more information.

Specifications

Oxygen Saturation Display Range	0 to 100% SpO_2
Pulse Rate Display Range	18 to 300 beats per minute (BPM)
Displays	
Numeric Displays:	3-digit LEDs, Tricolor (red, green, amber)
Pulse Indicator:	Amber LED
Accuracy - Sensors	Declared accuracy data for compatible sensors can be found in Nonin's Sensor Accuracy document.
Measurement Wavelengths and Output Power*	
Red:	660 nanometers @ 0.8 mW max. average
Infrared:	910 nanometers @ 1.2 mW max. average
Method of Measurement	Oscillometric
Blood Pressure Range	Systolic: 40 mmHg to 260 mmHg Diastolic: 25 mmHg to 200 mmHg MAP = 1/3 Systolic + 2/3 Diastolic
Pressure Transducer Accuracy	±3 mmHg between 0 mmHg and 300 mmHg for operating conditions between 0 °C and 50 °C. (S.D. of 8 mmHg)
Recommended Frequency of Pressure Transducer Calibration	The Pressure Transducer calibration should be verified yearly or every 10,000 readings, whichever comes first.
Pulse Rate Range	Up to 200 pulses per minute (BPM) [displayed if there is no value from the oximeter]
Blood Pressure Altitude	-170 to 12,000 m
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
Power Requirements	
Mains:	100-240 VAC 50-60 Hz
DC Input:	12 VDC 1.5A AC power supply
Internal Power	
Battery:	7.2 volt battery pack (6 cells)
Operating Life:	minimum 5 hours of continuous operation
Storage Life:	18 days
Recharge Time:	4 hours with device off

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

Memory	33.5 hrs (assuming continuous operation)
Alarm Volume Range	55–81 dBA
Informational Tone Volume Range	50–70 dBA
Altitude	
Operating:	Up to 40,000 feet (12,192 m)
Hyperbaric Pressure:	Up to 4 atmospheres
Dimensions	4.5 x 7.5 x 5.4 in. (11.4 x 19.0 x 13.8 cm)
Weight	45.3 oz. (1.28 kG) with batteries
Classifications per IEC 60601-1 / CAN/CSA-C22.2 No. 601.1 / UL60601-1	
Type of Protection:	Class II (when on AC power with MPP30 power supply) Internally powered (on battery power)
Degree of Protection:	Type BF-Applied Part (pulse oximeter). Defibrillation-Proof Type BF Applied Part (NIBP).
Enclosure Degree of Ingress Protection:	IPX2
Mode of Operation	Continuous