NONIN

Operator's Manual

Model X-100

SenSmart™

Universal Oximetry System

CE 0123

English

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

Follow Instructions for Use.

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

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Indications for Use/Intended Use/Intended Purpose

Nonin's SenSmart™ Model X-100 Universal Oximetry System is a modular system and is indicated for use in simultaneously measuring, displaying, monitoring, and recording up to six (6) channels of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate or cerebral or somatic hemoglobin oxygen saturation (rSO_2) of blood underneath the sensor. Patient populations include adult, pediatric, infant, and neonate through the use of SenSmart-compatible sensors.

The SenSmart system is intended for use in hospitals, long-term care, medical facilities, sleep laboratories and subacute environments. The X-100 SenSmart system may be used for spot-checking and continuous monitoring with patient alarms. The SenSmart pulse oximetry (SpO_2) functionality is suitable for use in both motion and non-motion conditions, including patients who are well or poorly perfused.

Clinical Benefits

Nonin pulse oximeters allow for the management of patients' medical conditions by providing fast, accurate, real-time, noninvasive oxygen meas order to meet patients' medical needs.

Residual Risk

The residual risks are covered by Warnings & Cautions.

Warnings

Do not use this device in an MR environment.
Explosion Hazard: Do not use in an explosive atmosphere or in the presence of flammable anesthetics or gases.
This system is not intended to be used simultaneously on multiple patients.
Refer to the applicable sensor instructions for use for additional contraindications, warnings, and cautions.
This device is intended only as an adjunct device in patient assessment. It should not be used as the sole basis for diagnosis or therapy decisions. It must be used in conjunction with other methods of assessing clinical signs and symptoms.
Use only Nonin-branded SenSmart oximeter signal processors, sensors, and accessories, otherwise patient injury can result. These sensors are manufactured to meet the accuracy specifications for this device. Using other manufacturers' sensors can result in improper oximeter performance.
Inspect the sensor application sites in accordance with the sensor instructions for use to ensure correct sensor alignment and skin integrity. Patient sensitivity to the sensor may vary due to medical status or skin condition.
Avoid excessive pressure to the sensor application site(s) as this may cause damage to the skin beneath the sensor.
Always inspect the device before use. Do not use a damaged device or sensor. Before using any sensor, carefully read the sensor instructions for use, which contains sensor application information for each sensor.
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.
Verify all alarm settings and limits during system startup to ensure that they are set as intended.
Protect from exposure to water or any other liquid, with or without AC power.

Warnings (Continued)

Use the device only with Nonin-specified power supplies.
As with all medical equipment, carefully route patient cables and connections to reduce the possibility of entanglement, strangulation, or tripping.
For remote monitoring, use the X-100M monitor only within its designated range (approximately 100 meters (300 feet) spherical radius from monitor to remote location). Moving outside this range may cause missing or lost data at the remote monitoring location.
Memory is cleared if error code E06 appears on the display screen.
The device presets are deleted if error code E09 appears on the display screen.
The device configuration is deleted if error code E10 appears on the display screen.
This device turns off after approximately 30 minutes when in low battery alarm condition.
If this device is used adjacent to or stacked with other equipment, the device should be observed carefully to verify normal operation.
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 the battery pack installed.
The use of signal processors, sensors, accessories, and cables other than those listed in the Parts and Accessories List may result in increased electromagnetic emission and/or decreased immunity of this device.
The device's Nurse Call and Bluetooth features should not be used as the primary source of alarm notification.
The user must verify the device Bluetooth pairing to ensure the correct patient is remotely monitored.
Ensure all alarm volumes are set appropriately and are audible in all situations. Do not cover or otherwise block any speaker openings.
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 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 for SpO_2.
Readings of this device may be affected by the use of an electrosurgical unit (ESU). Keep electrosurgical/ electrocautery instruments away from the sensors and signal processors, as they may cause damage or result in erroneous readings.
When defibrillation voltages are applied to the patient, the X-100M monitor may recover to a menu screen. The X-100M will return to the monitoring screen after the menu screen times out (2 minutes) or with operator interaction (press Menu button).
It is the user's responsibility to implement the interface between the nurse call system and the Model X-100M, and to adequately test the interface between the Model X-100M and the nurse call system to ensure operation. The X-100M monitor has not been evaluated with specific nurse call systems.
A hazard can exist if different presets are used on multiple X-100M monitors in one care area.
Portable RF communications equipment such as cell phones or radios (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the medical electrical system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
Refer to the applicable sensor instructions for use for additional contraindications, warnings, and cautions.

⚠ *Cautions*

The value of rSO_2 data from the system has not been demonstrated in specific disease states, under conditions of hemoglobinopathies or clinical conditions that may affect blood volume, or under hypocapnic and hypercapnic conditions.

When using this device in an operating room, it must remain outside the sterile field.

When mounting the monitor to a mobile pole, mounting the monitor higher than 1.5 meters or mounting more than 2 kilograms of equipment onto the pole may result in tipping, damage to the equipment, or injury.

This equipment complies with IEC 60601-1-2 for electromagnetic compatibility (EMC) 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.

Exposure to Radio Frequency Radiation. The radiated output power of the display device is far below FCC radio frequency exposure limits. Nevertheless, the device must be used in such a way that the potential for human contact during normal operation is minimized. To avoid the possibility of exceeding FCC radio frequency exposure limits, remain at least 20 cm (8 in.) away from the display unit's internal antenna during normal operation. The monitor has been tested and meets allowed limits for exposure.

This device is designed to determine regional hemoglobin oxygen saturation of blood underneath the sensor when used with SenSmart regional oximetry sensors. Factors that may degrade performance or affect the accuracy of the measurement include the following:

- excessive ambient light or direct sunlight
- excessive motion
- electrosurgical interference
- metal plate or other foreign object in sensor path
- moisture on skin
- improperly applied sensor
- placement over bony prominence
- incorrect sensor type
- skin barriers used between sensor and patient skin
- anemia or low hemoglobin concentrations
- cardiogreen or other intravascular or tissue dyes
- carboxyhemoglobin and other dyshemoglobins
- hemoglobinopathies
- billirubinemia and/or icterus (jaundice)
- non-normocapnic conditions or other conditions that affect blood volume

This device is designed to determine the percentage of arterial oxygen saturation of functional hemoglobin when used with SenSmart pulse oximetry sensors. Factors that may degrade pulse oximeter performance include the following:

- excessive ambient light
- excessive motion
- electrosurgical interference
- moisture in the sensor
- improperly applied sensor
- carboxyhemoglobin
- methemoglobin
- blood flow restrictors (arterial catheters, blood pressure cuffs, infusion lines, etc.)
- incorrect sensor type
- poor pulse quality
- venous pulsations
- anemia or low hemoglobin concentrations
- cardiovascular dyes
- dysfunctional hemoglobin
- artificial nails or fingernail polish
- residue (e.g., dried blood, dirt, grease, oil) in the light path

Batteries are a fire hazard if damaged. Do not damage, mishandle, disassemble, service, or replace with non-specified components.

Do not charge Li-Ion batteries at a temperature of 0 °C (32 °F) or less as this may result in significantly reduced battery life.

Do not apply sensor over open wound, incision, or compromised skin. Inspect the sensor site(s) prior to applying the sensor(s).

Do not autoclave, sterilize, immerse, or spray this device with liquid or use caustic or abrasive cleaning agents. Do not use cleaning agents or cleaning products that contain ammonium chloride.

Follow local, state and national governing ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries. Use only Nonin-approved battery packs.

⚠ *Cautions (Continued)*

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 written continuously to memory when the device is on. If the entire memory is filled, portions of the oldest record will be overwritten when new data is written.
Setting alarm limits to extremes can render the alarm system useless.
A preset cannot be saved with %rSO_2 or %SpO_2 low alarm limit settings that are lower than the institution default settings. %rSO_2 and %SpO_2 low alarm limits that are lower than the institution defaults will be replaced in the preset with the institution default setting(s).
A 2-minute alarm silence is automatically engaged at startup.
A functional tester cannot be used to assess the accuracy of the oximeter monitor or sensor.
If this device fails to respond as described, discontinue use until the situation is corrected by qualified technical professionals.
Between patients, turn the X-100M monitor off (Standby mode) or start a new case (Case Menu). Failure to do so could result in inaccurate baseline values for the new patient. When the device is turned on or a new case is started, the monitor clears the baseline values, resets the limits to the default values, and begins a new patient record in data memory.
For SpO_2 monitoring, 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 during SpO_2 monitoring. Minimize patient motion as much as possible.
Do not connect more than one hub in the system. The system will not function.
Do not use an extension cable between the monitor and the hub. The system will not function.
Duplicate signal processors cannot be used simultaneously and will result in an error message.
Do not connect multiple extension cables between the monitor and a signal processor or between the hub and a signal processor.
Do not simultaneously touch the accessible connector pins and the patient.
The device has been designed for use within the specified ranges. Use outside of these ranges has not been tested and may result in improper oximeter performance.
All parts and accessories connected to the serial port of this device must be certified according to at least IEC Standard EN 60950, IEC 62368-1, or UL 1950 for data processing equipment.
Failure of a network data coupling (serial cable/connectors/wireless connections) will result in loss of data transfer.
Refer to the applicable sensor instructions for use for additional contraindications, warnings, and cautions.
Before first use and before storing this monitor, fully charge battery.
If not in continuous use, fully charge battery at six-month intervals.

Declaration of Conformity with FCC and Canadian Ministry of Health Rules for Electromagnetic Compatibility

- Nonin Medical, Inc., of 13700 1st Avenue North, Plymouth, Minnesota, 55441, declares under its sole responsibility that the Model X-100M, to which this declaration relates, comply with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.
- Ministry of Health (Canada), Safety Code 6: standards include a substantial safety margin designed to ensure the safety of all persons, regardless of age and health. The exposure standard for wireless mobile phones employs a unit of measurement known as the Specific Absorption Rate, or SAR. The SAR limit set by the FCC is 1.6 W/kg.

Federal Communications Commission (FCC) Notice

This equipment has been tested and found to comply with the limits for a class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy. If not installed and used in accordance with the instructions, it may cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on. The user is encouraged to try to correct the interference by one or more of the following measures: (1) Reorient or relocate the receiving antenna, (2) Increase the distance between the equipment and the receiver, (3) Connect the equipment to an outlet on a circuit different from the outlet where the receiver is connected, or (4) Consult the dealer or an experienced radio/TV technician for assistance.

The Model X-100M is designed and manufactured not to exceed the emission limits for exposure to radio frequency (RF) energy set by the Federal Communications Commission of the U.S. Government. These limits are part of comprehensive guidelines and establish permitted levels of RF energy for the general population. The guidelines are based on the safety standards previously set by both U.S. and international standards bodies. This EUT has been shown to be capable of compliance for localized specific absorption rate (SAR) for uncontrolled environment/general population exposure limits specified in ANSI/IEEE Std. C95.1-2005.

The FCC requires the user to be notified that any changes or modifications to this device that are not expressly approved by Nonin Medical, Inc. may void the user's authority to operate the equipment.

NOTE: No modifications to this device are allowed that in any way affect or alter its antenna or antenna configuration.

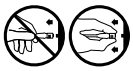
Guide to Symbols

This chapter describes the symbols that are found on the Model X-100 system components and packaging. Detailed information about functional symbols can be found in "System Components and Set Up" on page 12.

Table 1. Labeling and Packaging Symbols

Symbol	Description
	CAUTION!
	Consult instructions for use.
	Follow instructions for use.
	UL Mark for Canada and the United States with respect to electric shock, fire, and mechanical hazards in accordance with: • ANSI/AAMI ES60601-1 (2005, 3rd Ed.), CAN/CSA C22.2 No. 60601-1 (2008, 3rd Ed.), ISO 80601-2-61:2011, IEC 60601-1-8:2006 • UL 60601-1 and CAN/CSA C22.2 No. 601.1
CE 0123	CE Marking indicating conformance to all applicable directives, including EC Directive No. 93/42/EEC concerning medical devices.
	Class II, double insulated
SN	Serial number
IP32	Protected against vertically falling water drops when enclosure is tilted up to 15 degrees and ingress of solid foreign objects greater than or equal to 2.5 mm in diameter, per IEC 60529.
	Direct current
	Type BF Applied Part (X-100M, X-100H)
	Indicates separate collection for waste electrical and electronic equipment (WEEE).
	Non-ionizing electromagnetic radiation. Equipment includes RF transmitters. Interference may occur in the vicinity of equipment marked with this symbol.
	Defibrillation-Proof Type BF Applied Part (patient isolation from electrical shock). (X-100SP)

Table 1. Labeling and Packaging Symbols (Continued)

Symbol	Description
	Do not discard.
	Do not pull on cable. Retract connector and remove.
	Medical prescription required.
	Magnetic Resonance (MR) Unsafe
	Authorized Representative in the European Community
	Authorized Representative in Switzerland

See www.nonin.com/symbols for additional symbols.

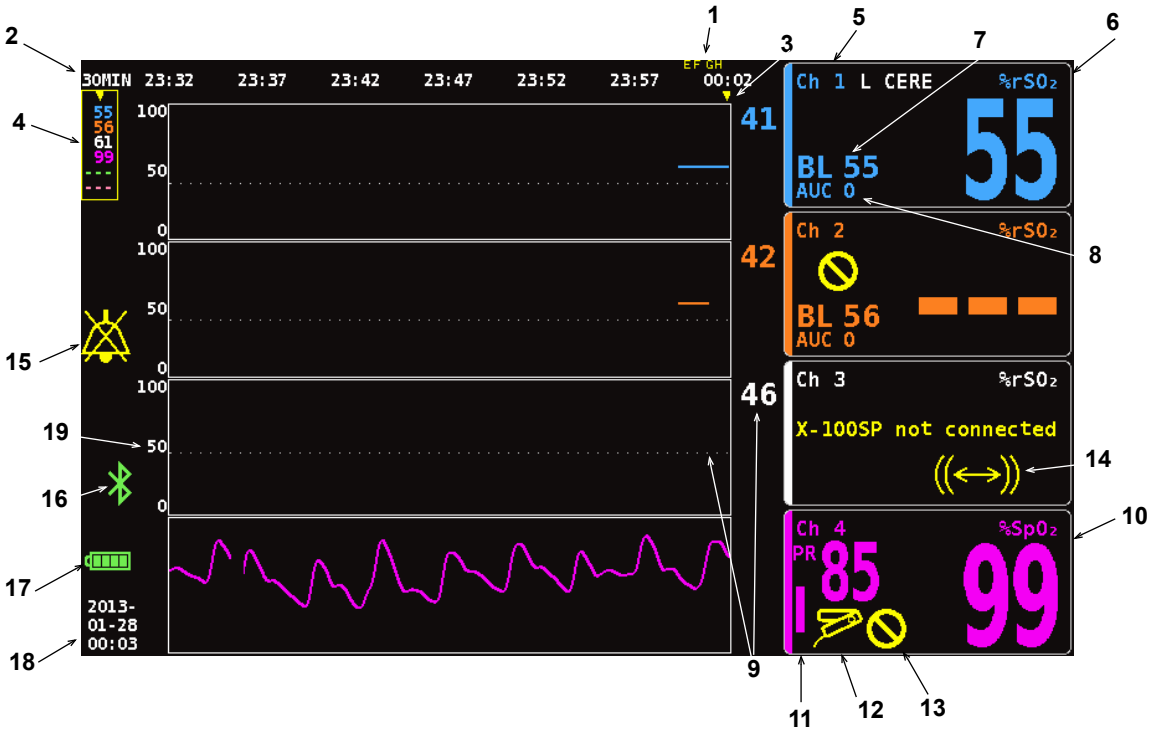


Figure 1. Monitoring Screen Symbols (Four-Channel View)

Table 2. X-100M Monitoring Screen Symbols and Indicators

No.	Symbol	Description
1	example: A B	**Event Marks** Located at the top of the monitoring screen, event marks (A, B, C, D, etc.) display when the Event Mark button is pressed.
2	example: 30MIN	**Timescale** Located below the event marks, the timescale shows the amount of data time displaying on the screen.
3	▼	**Scrolling Cursor** Located below the timescale, the yellow scrolling cursor allows the user to view a channel's rSO_2 or SpO_2 reading at a specific time on the trendline. The scrolling cursor does not display until the Left navigation button has been pressed.
4		**Cursor Values** When the scrolling cursor is active, cursor oximetry (rSO_2 or SpO_2) values display on the left side of the monitor screen in a yellow box. **NOTE:** Pulse rate values are not displayed in the cursor values.

Table 2. X-100M Monitoring Screen Symbols and Indicators (Continued)

No.	Symbol	Description
5	Ch	**Channel** Located at the top of each channel, this indicator shows the channel's number (e.g., Ch 1, Ch 2, etc.). If set, the sensor site name displays to the right of the channel indicator.
6	$\%rSO_2$ or $\%rSO_2$-T	**Regional Hemoglobin Oxygen Saturation** **NOTE:** $\%rSO_2$ displays when an absolute regional sensor is attached to a signal processor. $\%rSO_2$-T displays when a trending regional sensor is attached to a signal processor. $\%rSO_2$ displays from 0 to 100% when a signal processor receives an adequate signal from an attached regional sensor. The channel background display flashes: • ***Yellow*** during medium priority alarm conditions (equipment alarms and rSO_2 values that are 5% or less above the rSO_2 low alarm limit). • ***Red*** during high priority rSO_2 alarm conditions (set by the high and low rSO_2 alarm limits).
7	BL	**Baseline** When the monitor is turned on, the BL display shows dashes until the user sets the baseline values. The user must set the baselines for each new patient. • For instructions on setting the baseline values to the current rSO_2 values, see "Set All rSO_2 Channel Baselines to Current $\%rSO_2$ Values" on page 31. • For instructions on setting the baseline values separately or to make finite adjustments to the baseline value, see "Set Individual Baseline Values" on page 37.
8	AUC	**Area Under the Curve** (cumulative saturation below low alarm limit) For each channel, the rSO_2 values below the low alarm limit are integrated together and displayed as the cumulative saturation below low alarm limit, also known as AUC (Area Under the Curve). The value is expressed in units of % minutes (%Min). When a baseline value is changed, the AUC recalculates from the beginning of the current record. The AUC will not calculate if a channel's $\%rSO_2$ Low setting is OFF. **NOTE:** In order for the AUC display to match the Society of Thoracic Surgeons (STS) database definition, the low alarm limit value for each channel must be set to 25% below the patient's baseline.

Table 2. X-100M Monitoring Screen Symbols and Indicators (Continued)

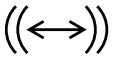
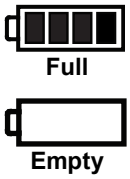
No.	Symbol	Description
9	example: 46	**Low Alarm Limit** The low alarm limit is determined by the %rSO_2 Low setting and displays as the following: • ***Numeric value*** – This value displays to the right of a trendline graph. The color of the value matches the color of the associated channel. • ***White, dotted line*** – This line only displays in a graph when the graph shows a single rSO_2 trendline. The dotted line does not display when multiple trendlines are set to display in one graph. **NOTE:** A low alarm limit does not display on the monitoring screen if the channel's %rSO_2 Low setting is OFF.
10	%SpO_2	**Percent Functional Hemoglobin Oxygen Saturation** %SpO_2 data displays from 0 to 100% when a signal processor receives an adequate signal from an attached pulse oximetry sensor. The background of the SpO_2 portion of the channel display flashes red during high priority SpO_2 alarm conditions (set by the high and low SpO_2 alarm limits) and low perfusion alarm conditions.
11	PR 	**Pulse Rate and Pulse Rate Bar Graph** Pulse rate data displays along with the %SpO_2 display when a channel is set up to measure pulse oximetry. The bar graph indicates pulse strength as determined by the oximeter. The height of the bar graph is proportional to the pulse amplitude. The background of the pulse rate portion of the channel display flashes red during high priority pulse rate alarm conditions (set by the high and low pulse rate alarm limits) and low perfusion alarm conditions.
12		**Sensor Fault** This yellow indicator flashes when a sensor is disconnected, has failed, has not received any usable data in the last 90 seconds, or is not compatible with the monitor.
13		**Poor Signal** This yellow indicator flashes when there has been a sustained period of poor patient signals from the sensor. Check the sensor site and reposition or replace the sensor if necessary.
14		**Signal Processor Communication Error** This yellow indicator flashes and the message *X-100SP not connected* displays when the respective signal processor has stopped communicating with the display. Check the signal processor connections or replace the signal processor to correct the issue. If the message appears in each channel, check the hub's connection to the monitor.

Table 2. X-100M Monitoring Screen Symbols and Indicators (Continued)

No.	Symbol	Description
15		**Alarm Silence** This yellow indicator flashes once every 2 seconds when the audible alarm is silenced for 2 minutes. If the alarm volume is at step 4 or lower (less than 45 decibels), the Alarm Silence indicator is solidly lit.
16		**Bluetooth** The Bluetooth indicator is green when Bluetooth is connected to a host, white when it is enabled but not connected, and gray when it is disabled. See "Enable/Disable Bluetooth Radio" on page 55 for more information.
17		**Battery** The battery indicator shows the approximate percentage of battery life remaining. When AC power is connected, the battery indicator fills up repeatedly to indicate the battery is charging. The indicator stops filling when the battery is fully charged. • ***Low*** – battery indicator flashes yellow • ***Critical*** – battery indicator flashes red **NOTE:** When the monitor reaches a low or critical battery condition, an audible alarm sounds. To clear the alarm, connect the monitor to the AC power adapter.
18	example: 2013 09-25 14:27	**Date and Time** The date and time display in 24-hour clock format. To set the date and/or time, see "Set the Date and Time" on page 54.
19		**rSO_2 Axis Scale** Fixed scale with a range from 0 to 100%.

System Components and Set Up

NOTES:
- Before using the SenSmart system, please review all contraindications, warnings, and cautions.
- Before using the Model X-100M for the first time, the battery should be charged for 4 hours.
- Additional, but recommended, set-up tasks include: setting the clock, setting the institution defaults, changing the institution password, and setting up presets.

Carefully remove the monitor and accessories from the shipping carton. Save the packaging materials in case the monitor or accessories must be returned. Compare the packing list with the accessories received to make sure the shipment is complete.

The standard system configuration includes these non-sterile components:

- X-100M, SenSmart universal oximetry monitor
- X-100H, hub
- X-100HH, hub holster
- X-100SP-1 and X-100SP-2, oximetry signal processors for channels 1 and 2 (a garment clip is shipped with each signal processor)
- X-100EC1, 1-meter extension cable, quantity 2
- INT-100, intermediate cable, quantity 2
- Operator's manual/parts and accessories list (CD)
- Power supply and cord
- SenSmart download software (CD)

For a list of compatible sensors and other accessories, see the Parts and Accessories List on the operator's manual CD.

System Configurations

Multiple Channels

When using the X-100H hub, up to six signal processors can be connected to the hub. If needed, an extension cable may be used between the hub and a signal processor.

- The example in figure 2 shows a system set up using regional sensors for patients weighing ≥ 40 kg. The 8204CA sensor connects to the X-100SP signal processor via the INT-100 intermediate cable. The 8100S(X) pulse oximetry sensor connects directly to the signal processor.
- The example in figure 3 shows a system set up using regional sensors for patients weighing ≤ 40 kg. These sensors (8004CB, 8004CB-NA) connect directly to the X-100SP signal processor. The 8100S(X) pulse oximetry sensor connects directly to the signal processor.
- The example in figure 4 shows a system set up using regional sensors for patients weighing ≥ 40 kg. These sensors (8003CA, 8004CA) connect directly to the X-100SP signal processor. The 8100S(X) pulse oximetry sensor connects directly to the signal processor.

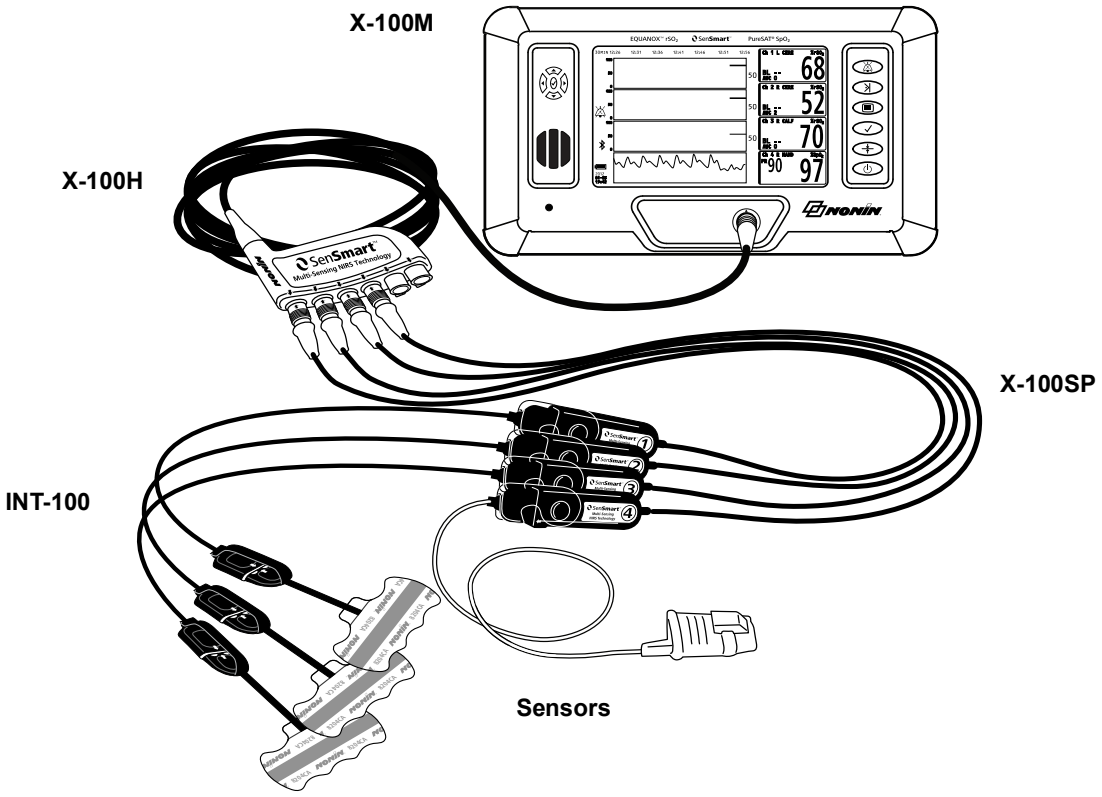


Figure 2. System Set Up (≥40 kg Sensors, INT-100, 4 Channels Connected)

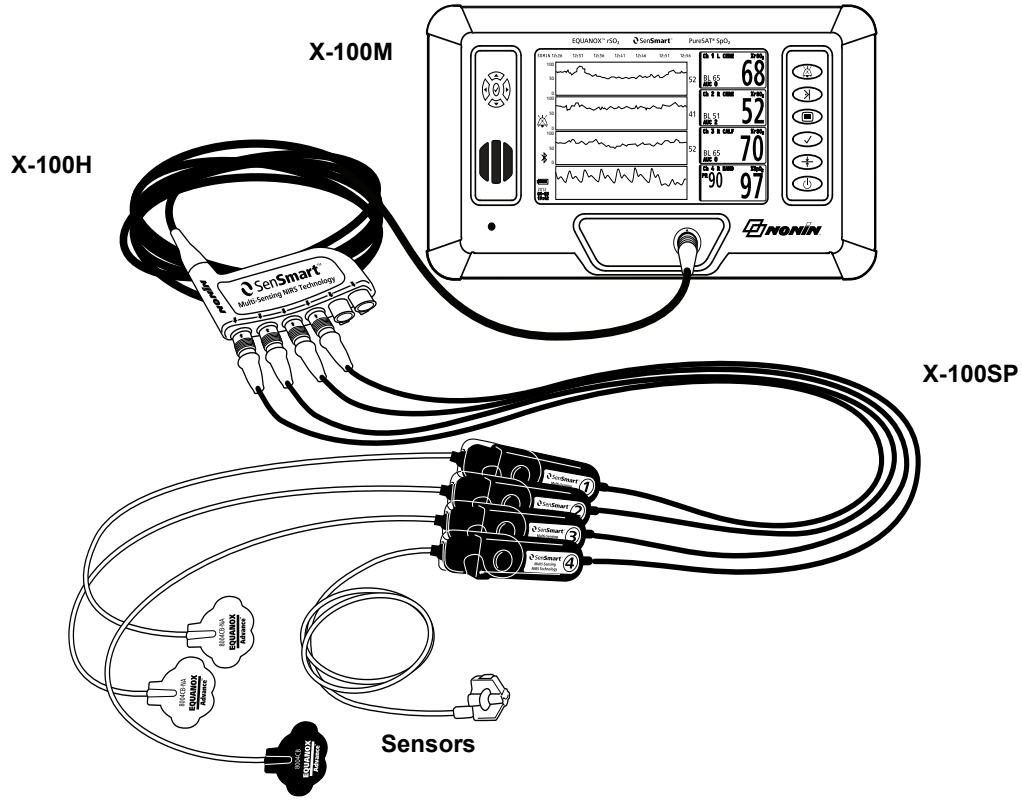


Figure 3. System Set Up (≤40 kg Sensors, 4 Channels Connected)

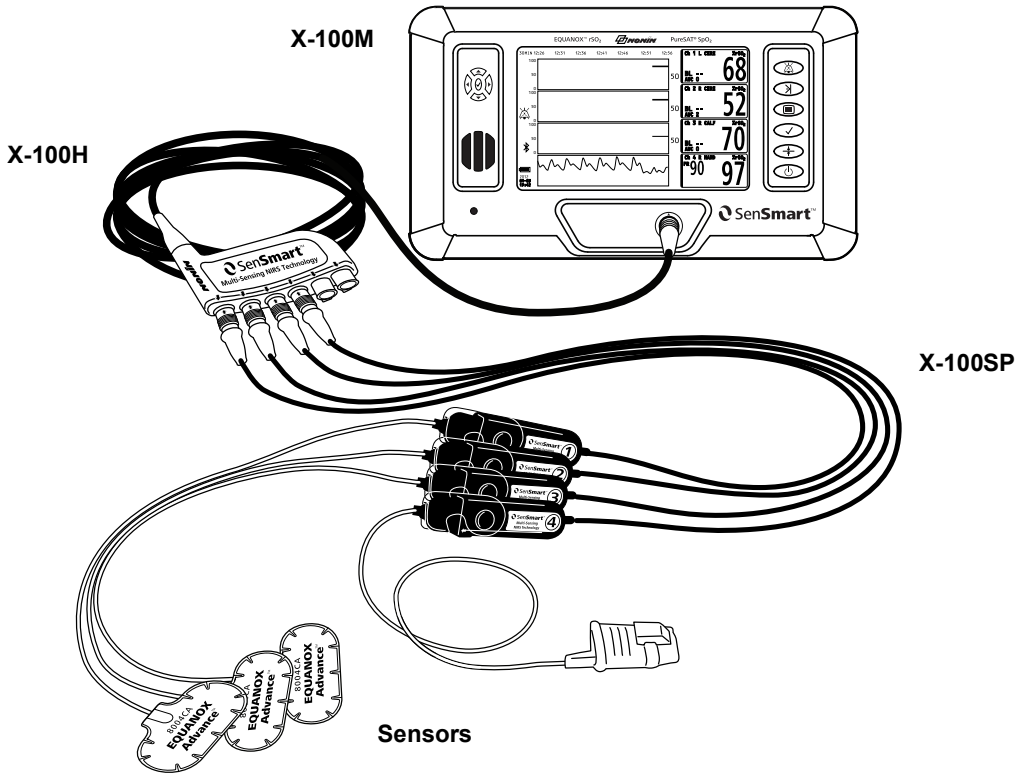


Figure 4. System Set Up (≥40 kg Sensors, 4 Channels Connected)

Single Channel

When using a single channel (figure 5), the signal processor can be connected directly to the monitor. If needed, an extension cable can be used between the monitor and the signal processor.

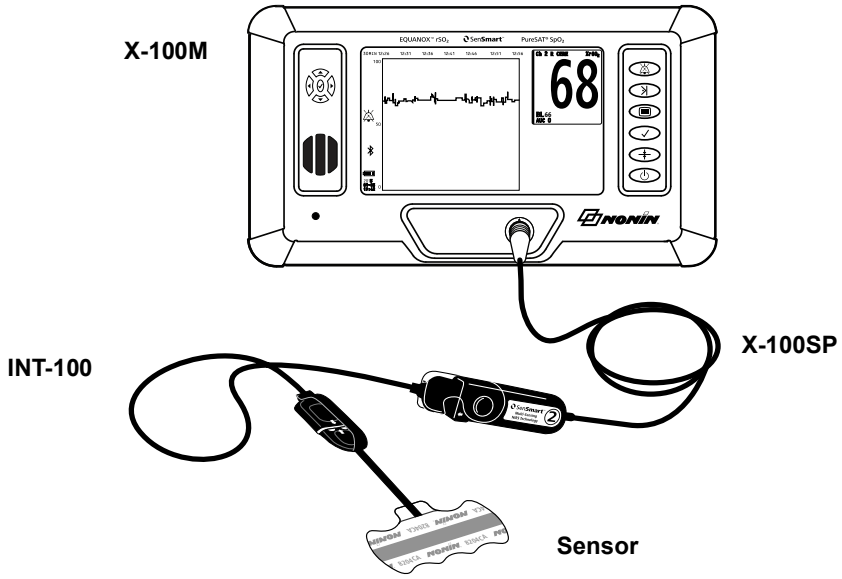


Figure 5. System Set Up (≥40 kg Sensor, INT-100, Single Channel)

X-100M (Monitor)

The X-100M monitor (figure 6) allows the user to view up to six channels of rSO_2 and SpO_2 data. Each channel is color coded and numbered to match a signal processor. See table 3 for monitor features and descriptions.

For cleaning instructions, refer to "Care and Maintenance" on page 74.

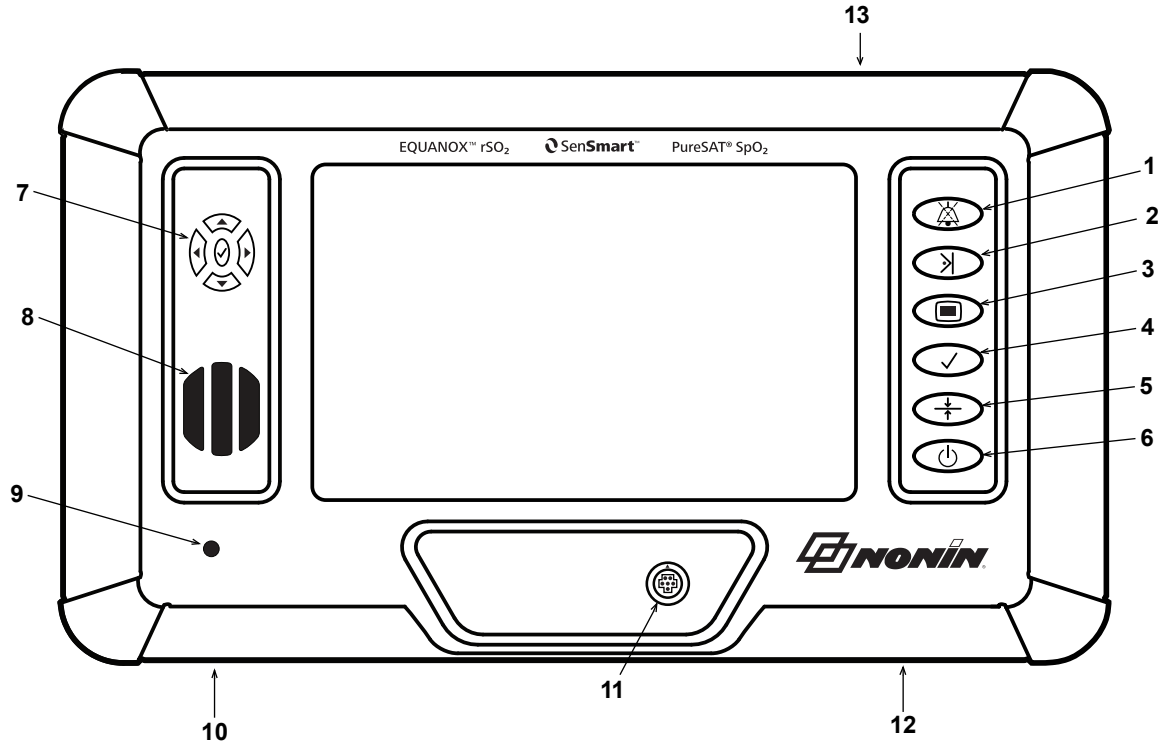
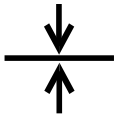


Figure 6. X-100M Front View

Table 3. X-100M Features

No.	Symbol	Description
1		**Alarm Silence Button** Press **Alarm Silence** to silence alarms for 2 minutes. Audible alarms may be reactivated before the 2 minute silence period is over by pressing Alarm Silence again. All silenced audible alarms are automatically reactivated when a new physiological alarm condition occurs.
2		**Event Mark Button** Momentarily pressing this button marks an event in memory and on the trendline. Events are denoted by increasing alphabetic letters. If more than 26 events are marked, the event marks begin at A again. **NOTE:** It may take up to 4 seconds for the event mark to appear on the display. Pressing this button for 2 seconds opens the event mark table. Momentarily pressing the button closes the event mark table.

Table 3. X-100M Features (Continued)

No.	Symbol	Description
3		**Menu Button** Pressing this button opens the Settings menu and allows access to the Presets, Case, and System menus: • ***Settings*** – allows users to assign a sensor site name to a channel, select sensor type (rSO_2 or SpO_2), set limits and graphs, and review presets. See "Settings Menu Screen" on page 32 for more information. • ***Presets*** – allows user to save current settings as a new preset, select a preset to use, and delete a preset. See "Presets Menu Screen" on page 39 for more information. • ***Case*** – allows user to start a new case and edit the patient ID. See "Case Menu Screen" on page 43 for more information. • ***System*** – allows user to set system settings. See "System Menu Screen" on page 45 for more information.
4		**Select Button** Pressing Select allows the user to save values when entering labels, settings, and parameters. The monitor has two Select buttons: • Right side of the monitor (between Menu and Baseline) • Center of the navigation buttons
5		**Baseline Button** This button is used to quickly set the baseline(s). Pressing this button twice sets the baselines for all connected rSO_2 channels to the patient's current readings.

6		**On/Standby Button**
		• ***On*** – Pressing this button once turns on the monitor. Each time the monitor is turned on, the monitor clears the baseline values, resets the limits to the default values, and begins a new patient record in data memory.
		• ***Cancel*** – While operating the monitor, momentarily pressing this button returns the display to the monitoring screen.
		• ***Standby (off)*** – When the monitor is on, pressing this button for at least 1 second shuts down the monitor, putting it into Standby mode. In Standby mode, all device functions are shut off, with the following exceptions:
		  • The AC power adapter LED is lit whenever the device is plugged in.
		  • Batteries are charged whenever the device is plugged in.

Table 3. X-100M Features (Continued)

No.	Symbol	Description
7		**Navigation Buttons** These buttons are used to navigate between fields, scroll, and change the timescale. ▲ (**Up**) and ▼ (**Down**): In menus, used to navigate between items. On the monitoring screen, used to change the rSO_2 trendline timescale. ▶ (**Right**): In menus, used to navigate between items. On the monitoring screen, used to scroll forward in time in the current case. ◀ (**Left**): In menus, used to navigate between items. In the monitoring screen, used to scroll back in time in the current case. ✓ (**Select**): See Select button description (#4) in this table.
8	**Speaker** **WARNING: Do not cover or otherwise block any speaker openings.**	
9	**AC Power Adapter LED** This light-emitting diode (LED) indicator is lit when an external power supply provides power to the device. • ***Yellow*** – battery pack is charging • ***Green*** – battery pack is fully charged **NOTE:** When the external power supply is disconnected, the device automatically switches to battery power without loss of functionality.	
10	**Power Adapter Input** Located on the bottom of the monitor below the AC power adapter LED, this input connects the external power supply to the monitor.	
11	**Monitor Connector Port** Located on the front of the monitor, this port allows an X-100H hub or a single X-100SP signal processor to connect to the monitor.	
12	**Nurse Call Input** Located on the bottom of the monitor below the On/Standby button, this input connects a nurse call cable to the monitor. **WARNING: It is the user's responsibility to implement the interface between the Nurse Call system and the Model X-100M, and to adequately test the interface between the Model X-100M and the Nurse Call system to ensure operation. The X-100M monitor has not been evaluated with specific nurse call systems.**	
13	**RS-232 Cable Input** Located on the back of the monitor (shown in figure 30). **CAUTION:** All parts and accessories connected to the serial port of this device must be certified according to at least IEC Standard EN 60950, IEC 62368-1, or UL 1950 for data processing equipment.	

X-100H (Hub)

The X-100H hub (figure 7) connects to the connector port on the front of the monitor. The hub provides connections for up to six X-100SP signal processors via the hub ports. Each hub port has a protective port cover.

> **CAUTION:** Do not connect more than one hub in the system. The system will not function.

> **CAUTION:** Do not use an extension cable between the monitor and the hub. The system will not function.

For cleaning instructions, refer to "Care and Maintenance" on page 74.

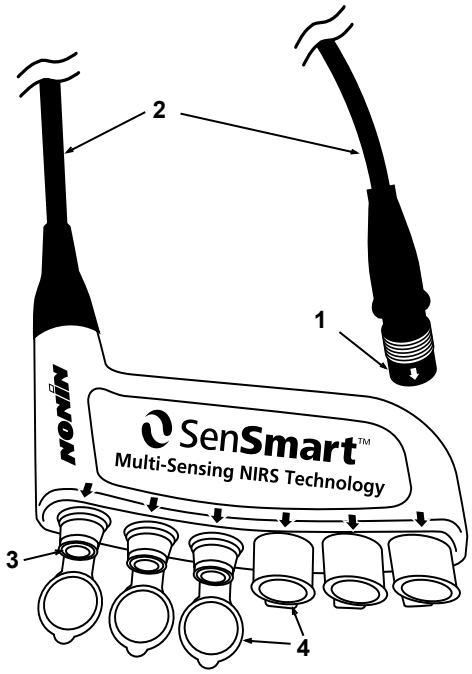


Figure 7. X-100H – Hub

Table 4. X-100H Features

No.	Description
1	Cable connector
2	4-meter (13-foot) cable
3	Port
4	Port cover

Connect/Disconnect the Hub

1. To connect:
   a. Align the arrow on the hub cable connector with the small triangle on the monitor connector port (figure 8).
   b. Push the hub cable connector straight into the port. The hub cable connector will click when it locks into the monitor connector port.
2. To disconnect:
   a. Grasp the retractable sleeve (figure 8-1) on the hub cable connector.
   b. Retract the sleeve and pull the hub cable connector straight back. The hub will unlock and detach from the monitor.

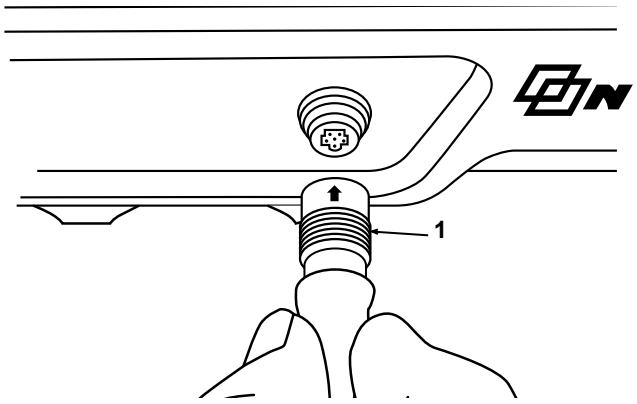


Figure 8. Connect Hub or Signal Processor to Monitor

X-100HH (Hub Holster)

The hub fits inside the X-100HH hub holster (figure 9). The hub holster clamp allows the hub to be attached to bed rails, equipment poles, and linen.

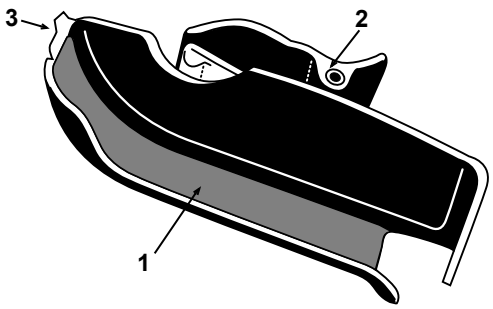


Figure 9. X-100HH – Hub Holster

Using the Hub Holster

1. To insert the hub:
   a. Align the hub and hub cable to the hub holster (figure 10).
   b. Push firmly to insert the hub into the hub holster.
2. To remove the hub:
   a. Pull the clip (figure 9-3) back on the tip of the hub holster.
   b. Pull the hub out of the hub holster. The back of the hub holster has a cutout, which allows the user to grasp the hub when removing it from the holster.

Table 5. X-100HH Features

No.	Description
1	Holster
2	Clamp
3	Clip

For cleaning instructions, refer to "Care and Maintenance" on page 74.

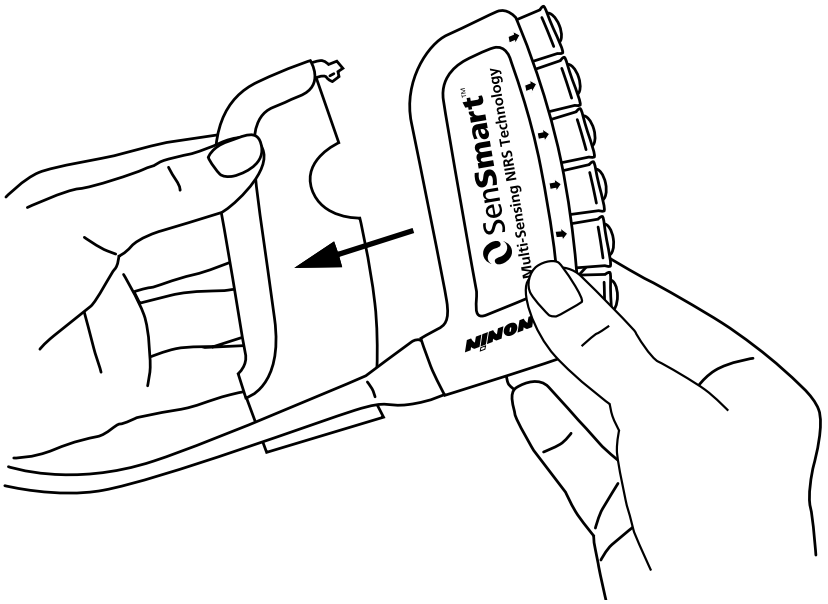


Figure 10. Insert Hub into Hub Holster

X-100SP (Signal Processor)

Up to six signal processors can be connected to the hub. Each signal processor is programmed to be a specific channel on the monitor, so a signal processor may be connected to any hub port.

> ⚠ **CAUTION:** Duplicate signal processors cannot be used simultaneously and will result in an error message.

A single signal processor may be connected directly to the monitor with or without an extension cable.

The signal processors are color coded:

- X-100SP-1, Channel 1: blue
- X-100SP-2, Channel 2: orange
- X-100SP-3, Channel 3: white
- X-100SP-4, Channel 4: purple
- X-100SP-5, Channel 5: green
- X-100SP-6, Channel 6: pink

For cleaning instructions, refer to "Care and Maintenance" on page 74.

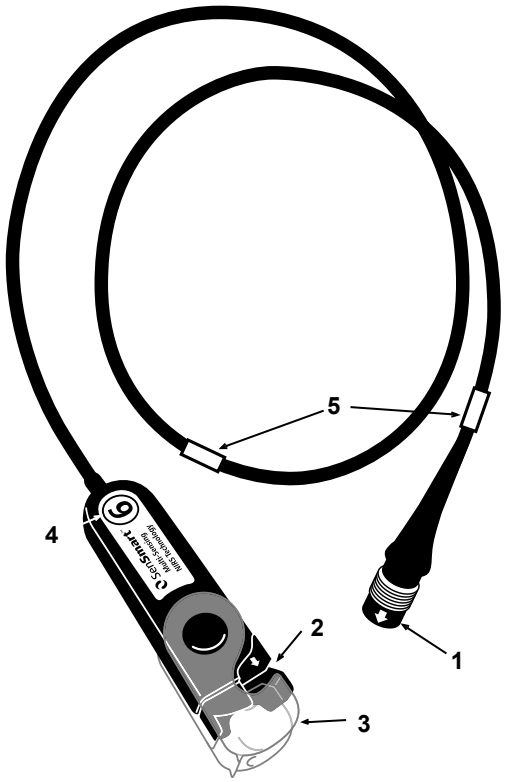


Figure 11. X-100SP – Signal Processor

Table 6. X-100SP Features

No.	Description
1	Signal processor cable connector
2	Port (for sensor or INT-100)
3	Lock (for sensor or INT-100)
4	Channel number
5	Cable clips

Connect a Signal Processor to Hub or Monitor

1. Align the arrow on the signal processor cable connector with the arrow on one of the hub ports or the monitor connector port.
2. Push the signal processor cable connector straight into the port.
3. The signal processor cable connector will click when it locks into the hub or monitor.

NOTE: An extension cable may be used between the hub and the signal processor, or between the monitor and the signal processor.

Disconnect a Signal Processor from Hub or Monitor

1. Grasp the retractable sleeve on the X-100SP signal processor cable connector.
2. Retract the sleeve and pull the X-100SP connector straight back. The X-100SP will unlock and detach from the hub or monitor.

NOTE: When removing the signal processor from the hub or the monitor, do not pull on the signal processor cable.

Connect/Disconnect an INT-100 Intermediate Cable to the Signal Processor

NOTE: The INT-100 is used to connect the 8204CA (patients ≥40 kg) sensor to the signal processor.

1. To connect:
   a. Flip the clear lock on the signal processor back to expose the connection port.
   b. Align the arrows on the INT-100 connector and the signal processor (figure 12-A). Insert the INT-100 connector into the signal processor connection port.
   c. Flip the lock over the connector and click it into place (figure 12-B).
   d. Connect a compatible sensor to the INT-100.
2. To disconnect:
   a. Flip the clear lock on the signal processor back to disengage the lock from the connector.
   b. Grasp the connector and remove it from the signal processor.

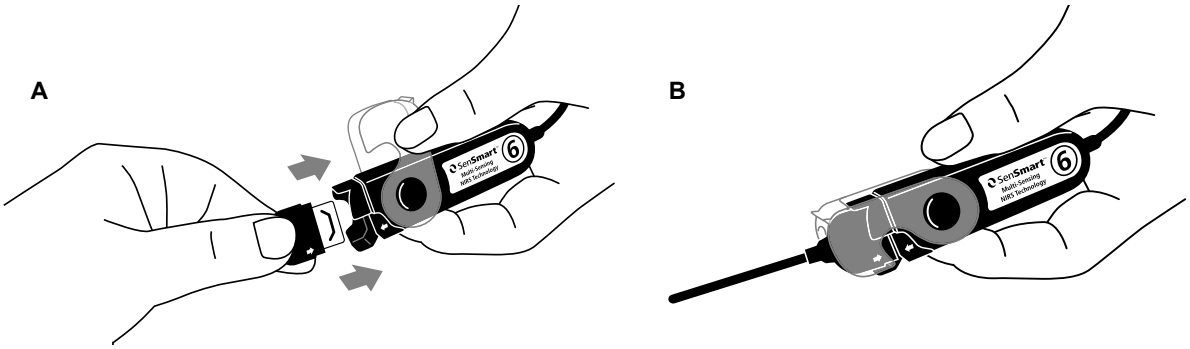


Figure 12. Connect Intermediate Cable or Sensor to Signal Processor

Connect/Disconnect a Sensor to the Signal Processor

NOTE: The following sensors connect directly to the signal processor: 8003CA (patients ≥40 kg), 8004CA (patients ≥40 kg), 8004CB (patients ≤40 kg), 8004CB-NA (patients ≤40 kg), and the 8100S(X) pulse oximetry soft sensors.

1. To connect:
   a. Flip the clear lock on the signal processor back to expose the connection port.
   b. Align the arrows on the sensor connector and the signal processor (figure 12-A). Insert the sensor connector into the signal processor connection port.
   c. Flip the lock over the sensor connector and click it into place (figure 12-B).
2. To disconnect:
   a. Flip the clear lock on the signal processor back to disengage the lock from the connector.
   b. Grasp the connector and remove it from the signal processor.

Replacing the Lock on the Signal Processor

NOTE: Replacement locks may be ordered if the lock is lost or damaged.

1. Align the lock hinge with the connector end of the signal processor (figure 13-A).
2. Gently spread the lock hinge so it fits over the end of the signal processor.
3. Click the lock into place (figure 13-B).

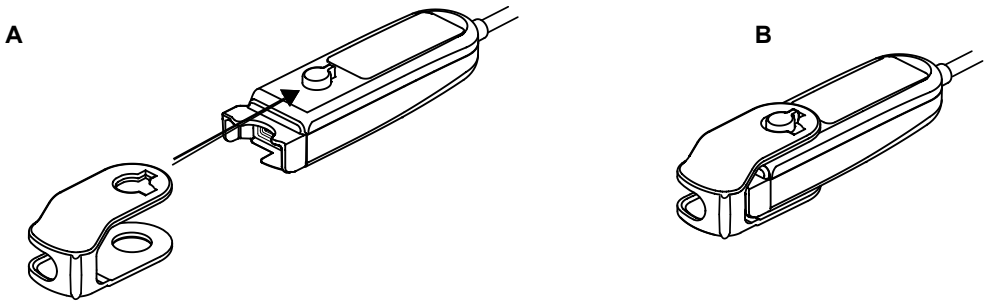


Figure 13. Signal Processor Lock Replacement

Cable Clips

The signal processor is delivered with 2 pre-attached, color-coded clips that match the color of the channel (e.g., X-100SP-1 has two blue clips attached to the cable). One cable clip is attached at the connector end and another cable clip is attached in the middle of the cable.

INT-100 (Intermediate Cable)

An intermediate cable (figure 14) is used between an X-100SP signal processor and a compatible sensor. The following sensors are compatible with the INT-100 intermediate cable:

- 8204CA regional sensor for patients ≥40 kg

NOTES:
- The INT-100 is not an extension cable.
- The 8003CA and 8004CA regional sensors (for patients ≥40 kg); 8004CB and 8004CB-NA regional sensors (for patients ≤40 kg); and 8100S(X) pulse oximetry sensors do not use the INT-100; these sensors connect directly to the signal processor.
- Do not discard the INT-100 intermediate cable.

For cleaning instructions, refer to "Care and Maintenance" on page 74.

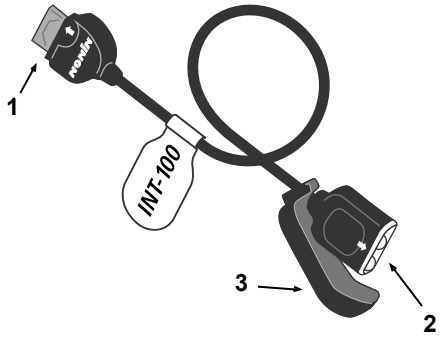


Figure 14. INT-100 – Intermediate Cable

Table 7. INT-100 Features

No.	Description
1	Connector (to signal processor)
2	Port (for sensor)
3	Sensor lock

Connect/Disconnect a Sensor to the Intermediate Cable

NOTE: The INT-100 is used to connect the 8204CA (patients ≥40 kg) sensor to the signal processor.

1. To connect:
   a. Slide the sensor lock on the INT-100 away from the port.
   b. Align the arrows on the sensor connector and the INT-100 (figure 15-A). Insert the sensor connector into the INT-100 port.
   c. Slide the sensor lock to the port. Secure the sensor lock so it covers the sides of the port and the sensor connector. The sensor cable fits into the notch on the sensor lock (figure 15-B).

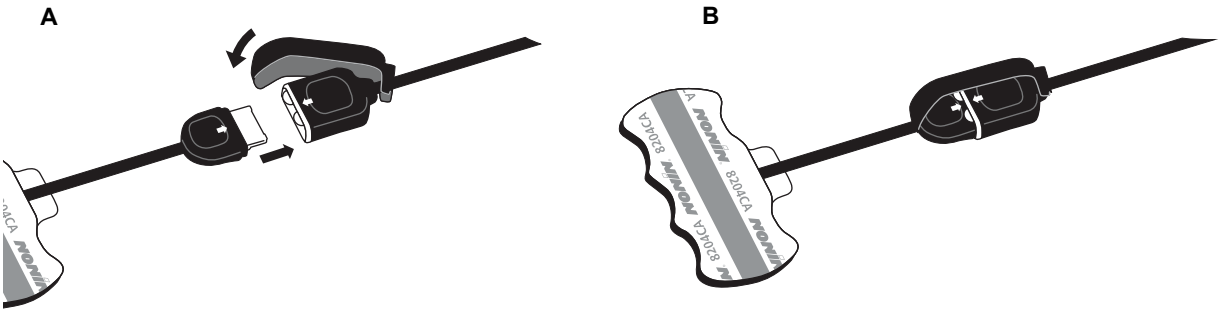


Figure 15. Connect Sensor to Intermediate Cable

2. To disconnect:
   a. Disengage the sensor lock from the joined sensor and cable and slide it away from the INT-100 port.
   b. Grasp the sensor connector and remove it from the INT-100 port.

X-100EC (Extension Cable)

Extension cables are available in 1- or 2-meter lengths. An extension cable may be used:

- Between the hub and a signal processor.
- Between the monitor and a signal processor.

> ⚠ **CAUTION:** Do not use an extension cable between the monitor and the hub. The system will not function.

> ⚠ **CAUTION:** Do not connect multiple extension cables between the monitor and a signal processor or between the hub and a signal processor.

For cleaning instructions, refer to "Care and Maintenance" on page 74.

Figure 16. X-100EC – Extension Cable

rSO$_2$ and SpO$_2$ Sensors

See the Parts and Accessories List on the operator's manual CD for a complete list of compatible sensors. Detailed information regarding specific sensor use (e.g., patient population, body/tissue, application, connecting the sensor to the system) can be found in the respective sensor instructions for use.

Battery

⚠ **CAUTION:** Before first use and before storing this monitor, fully charge battery.

⚠ **CAUTION:** If not continuous use, fully charge battery at six-month intervals.

For more information, see the Internal Power section of the "Specifications" on page 86.

⚠ **CAUTIONS:**

- Follow local, state and national governing ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries.
- Use only Nonin-approved battery packs.
- Batteries are a fire hazard if damaged. Do not damage, mishandle, disassemble, service, or replace with non-specified components.
- Do not charge Li-Ion batteries at a temperature of 0 °C (32 °F) or less as this may result in significantly reduced battery life.

For optimal performance, the battery should be replaced once per year to limit the amount of Li build up if the battery is charged in a cold environment.

System Operation

> **CAUTION:** Between patients, turn the X-100M monitor off (Standby mode) or start a new case (Case Menu). Failure to do so could result in inaccurate baseline values for the new patient. When the device is turned on or a new case is started, the monitor clears the baseline values, resets the limits to the default values, and begins a new patient record in data memory.

Start-up Sequence

Each time the monitor is turned on, it performs a brief start-up sequence.

1. Press **On/Standby**.
2. The LCD display lights up and displays the Nonin logo (figure 17).
3. An audible tone sounds.

Verify each of the above items occur on initialization. If any do not occur, contact Nonin Technical Service for assistance.

Figure 17. Start-up Screen

Following the start-up sequence, the monitor displays the Select a Preset screen (figure 18). However, depending on the system configuration, the monitor may first display one or both of the following screens:

- If the clock is not set, the message *System clock is not set!* will briefly display.
- If the system is set up to require entry of a patient ID, the Enter patient ID screen displays. If a patient ID is not needed, allow the screen to time out (2 minutes) or press Menu to advance to the Select a Preset screen.

Once the Select a Preset screen (figure 18) displays, the user can select a preset. The default preset is highlighted at start-up. Other choices include the last used preset and the other presets on the monitor.

Once a preset is selected, the Settings Menu screen displays so the limits can be reviewed. If the connected system configuration does not match the selected preset, the message *Verify sensor type and limits!* displays before the monitor displays the Settings Menu screen.

Figure 18. Select a Preset Screen

> **WARNING: A hazard can exist if different presets are used on multiple X-100M monitors in one care area.**

Sensor Application

Refer to the sensor instructions for use for proper sensor application sites and sensor application cautions and warnings.

WARNING: This device is intended only as an adjunct device in patient assessment. It should not be used as the sole basis for diagnosis or therapy decisions. It must be used in conjunction with other methods of assessing clinical signs and symptoms.

WARNING: As with all medical equipment, carefully route patient cables and connections to reduce the possibility of entanglement, strangulation, or tripping.

Monitoring a Patient

After setting up the monitor and applying the sensor(s) to the patient:

1. Press **On/Standby** to turn on the monitor.
2. Verify active preset or select a new preset.
3. Verify the alarm limits in the preset are appropriate.
4. If using rSO_2 sensors, establish a baseline rSO_2 value(s) and set the patient's baseline (see "Baseline (rSO_2 channels only)" on page 33 for more information).

⚠ **CAUTION:** Between patients, turn the X-100M monitor off (Standby mode) or start a new case (Case Menu). Failure to do so could result in inaccurate baseline values for the new patient. When the device is turned on or a new case is started, the monitor clears the baseline values, resets the limits to the default values, and begins a new patient record in data memory.

Operating Screens and Menus

The X-100M monitoring screen can be configured to display up to six channels of rSO_2 and SpO_2 data, along with rSO_2 trendlines and SpO_2 plethysmograms. See “Monitoring Screen” on page 28 for more information.

The operating menus display when the Menu button is pressed. The Settings Menu screen opens and additional menu tabs for Presets, Case, and System display across the top of the screen. In this manual, each operating menu has its own section, which contains a description of the menu and procedures. See the following for more information:

- “Settings Menu Screen” on page 32
- “Presets Menu Screen” on page 39
- “Case Menu Screen” on page 43
- “System Menu Screen” on page 45

NAVIGATION TIPS:

- When viewing the monitoring screen, the **Right**/**Left** navigation buttons scroll through the current case. The **Up/Down** navigation buttons change the trendline timescale.
- When scrolling through a case, quickly return to the current time by pressing **Menu** twice or momentarily pressing **On/Standby**.
- Menu screens time out and return to the monitoring screen after 2 minutes.
- When a menu tab is active, the box around the tab is yellow and the text is highlighted. When a field on a menu screen is active, the box around the tab is yellow and the tab text is white.
- When in a menu or submenu, pressing **Menu** once backs the highlighted field up one level.
- When on a main menu (i.e., Settings, Presets, Case, System) screen, pressing **Menu** once activates the tab at the top of screen. Pressing **Menu** twice returns the user to the monitoring screen.
- When a settings name is highlighted in yellow, the field is active. When a field has small yellow arrows around it, the field can be modified.
- When in a pop-up menu, pressing **Menu** once cancels the pop-up.
- When in a menu, momentarily pressing **On/Standby** returns the display to the monitoring screen.
- Passwords for presets are set by the user and are 4 numbers in length. Preset passwords can be overridden by the institution password.

Monitoring Screen

This section contains:

- Description of the monitoring screen features
- Monitoring screen procedures (see page 31)

Monitoring Screen – Description

Channels

When up to four channels are monitoring, real-time numeric data displays by channel on the right side of the screen. When more than four channels are monitoring, the channels display on the right side and along the bottom of the screen.

rSO_2 Channels

rSO_2 channels display the channel number, the sensor site name (if set), $\%rSO_2$, BL, and AUC.

SpO_2 Channels

SpO_2 channels display the channel number, the sensor site name (if set), pulse rate, pulse amplitude bar graph, and $\%SpO_2$.

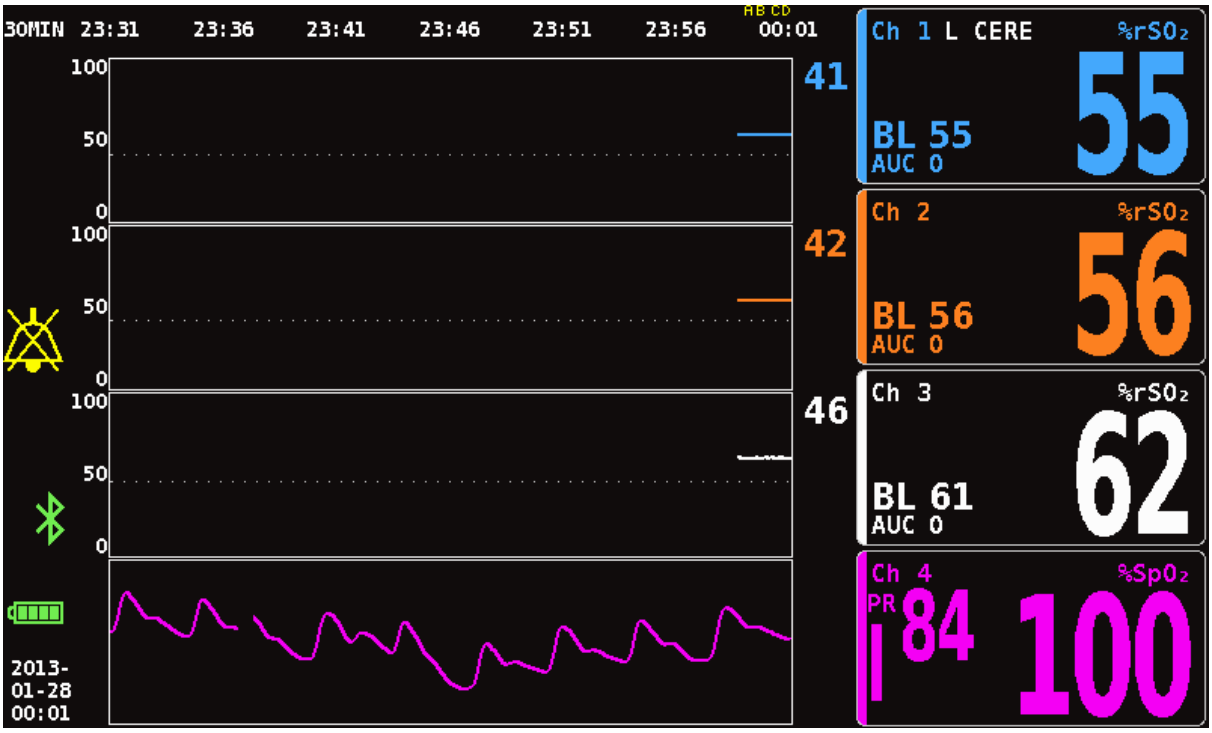


Figure 19. Monitoring Screen with Four Channels Connected (3 rSO_2 and 1 SpO_2)

Event Marks

Event marks are located at the top of the monitoring screen above the timescale (figure 20).

When pressed, the Event Mark button places a mark above the displayed graphs, in the memory, and in the real-time serial data output. Events are marked with increasing alphabetic letters. When Z is reached, the letters start over at A.

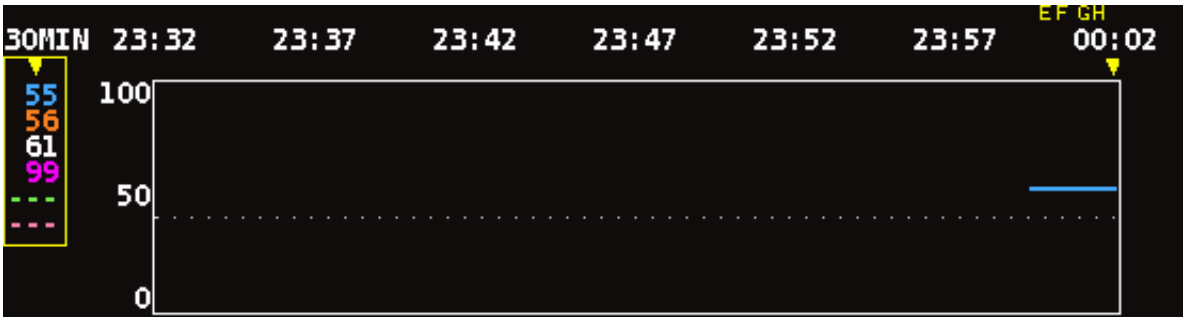


Figure 20. Event Marks, Timescale, and Scrolling Cursor

Event Mark Table

The event mark table (figure 21) shows the last 10 event marks, along with the date and time the event was marked, the event mark letter, and the readings for each connected channel.

The event mark table screen automatically closes after 2 minutes. To quickly exit the event mark table, momentarily press **Event Mark**, **Menu**, **Select**, or **On/Standby**.

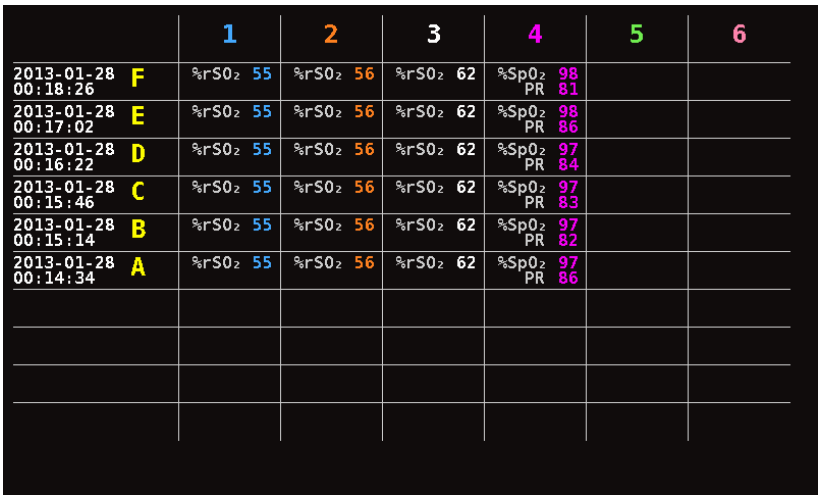


Figure 21. Event Mark Table

Timescale

The timescale is located in the upper left corner of the monitoring screen and is the duration of data that will display on the screen (figure 20). The default timescale is 30 minutes. Using the Up and Down navigation buttons, the range can be set so the monitoring screen shows as few as 7.5 minutes of data or up to 24 hours of data. The timescale uses a 24-hour clock.

Scrolling Cursor and Cursor Values

The scrolling cursor and the cursor values display when the Left navigation button is pressed. The scrolling cursor displays directly below the timescale and moves back and forth across the top of the channel graph display area (figure 20). Use the Left and Right navigation buttons to move the cursor.

While scrolling, patient readings (rSO_2 and SpO_2) display on the left side of the monitoring screen as a list of cursor values.

NOTE: Pulse rate values are not displayed in the cursor values.

To quickly exit scrolling mode and return to the current time in the case, press **Menu** twice or momentarily press **On/Standby**.

Graphs

The user may choose to have each connected channel display a graph on the monitoring screen, for a total of up to six graphs. Graphs may also be shut off. Graph height will vary depending on how many graphs are set to display on the monitoring screen. rSO_2 channels display trendlines and SpO_2 channels display plethysmograms.

rSO_2 Trendlines

The color-coded trendlines (figure 22-A) can be displayed individually or can be combined so multiple trendlines appear in a single graph. The channel's color-coded low alarm limit value displays to the right of each trendline graph when turned on.

The default setting has each channel displaying as a separate graph.

SpO_2 Plethysmograms

Each color-coded plethysmogram (figure 22-B) displays as a separate graph. The plethysmogram is normalized and the scale is automatically determined by how many graphs are set up to display on the monitoring screen. The plethysmogram timescale is approximately 14 mm/s, and it cannot be modified.

The default setting is On.

NOTE: When displayed, the color-coded plethysmograms are automatically located below the rSO_2 trendlines and may not be located next to their channel number. To keep an SpO_2 channel box near its plethysmogram, connect the SpO_2 sensor to a signal processor that has a higher channel number than any of the connected rSO_2 sensors.

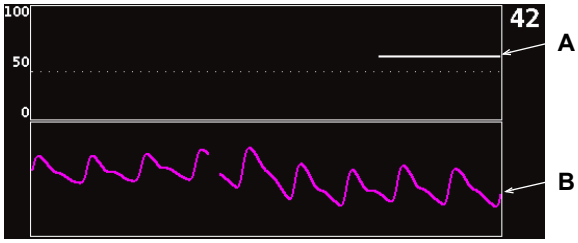


Figure 22. Graphs

Monitoring Screen – Procedures

Set All rSO_2 Channel Baselines to Current $\%rSO_2$ Values

1. (OPTIONAL STEP) Press **Event Mark** to mark an event. Record the letter of the event in the hospital records.
2. While in the monitoring screen, press **Baseline**. “Update baselines for rSO_2 channels” screen displays with the patient’s baseline values.
3. Press **Baseline** or **Select**.
4. rSO_2 channel baseline values are set to the current baseline readings and the display returns to the monitoring screen.

Mark an Event

1. While monitoring, momentarily press **Event Mark**.
2. The event mark letter appears on the screen and is stored in memory.

NOTE: It may take up to 4 seconds for the event mark to appear on the display.

View the Event Mark Table

1. While monitoring, press **Event Mark** for approximately 2 seconds.
2. The event mark table (figure 21) displays on the monitor.
3. The event mark table screen automatically closes after 2 minutes. To quickly exit the event mark table, momentarily press **Event Mark**, **Menu**, **Select**, or **On/Standby**.

Change the Timescale

While monitoring, press **Up**/**Down** to change the timescale to the desired setting.

Available settings are:

- 7.5 minutes
- 15 minutes
- 30 minutes (default)
- 1 hour
- 2 hours
- 4 hours
- 8 hours
- 12 hours
- 24 hours

Scroll Through the Timescale

1. While monitoring, press **Left** to display the cursor above the graph(s).
2. When the scrolling cursor displays, the color-coded cursor values display on the left side of the monitoring screen below the timescale rate.
3. To quickly exit scrolling mode and return to the current time in the case, press **Menu** twice or momentarily press **On/Standby**.

Graph Set-up

Graphs are set up on the Settings Menu screen. See “Graph Position” on page 35 or “Set Graph Position(s)” on page 38 for more information.

Settings Menu Screen

This section contains:

- Description of the Settings Menu
- Settings Menu procedures (see page 36)

Settings Menu – Description

The Settings screen allows the user to configure the system for specific use case needs. From the Settings screen, the user can review and configure the following settings and alarm limits.

- Sensor site
- Sensor type
- Baseline
- $\%rSO_2$ high
- $\%rSO_2$ low (% BL) **or** $\%rSO_2$ low (Abs)
- $\%SpO_2$ high
- $\%SpO_2$ low
- PR high
- PR low
- Graph position
- Preset #:

Settings	Presets		Case		System	
	1	2	3	4	5	6
Sensor Site	L CERE	blank	blank	blank	blank	blank
Sensor Type	%rSO2	%rSO2	%rSO2	%SpO2	%rSO2	%rSO2
Baseline	72	47	66		Off	Off
%rSO2 High	Off	Off	Off		Off	Off
%rSO2 Low (% BL)	-25	-25	-25		-25	-25
%SpO2 High				Off		
%SpO2 Low				85		
PR High				200		
PR Low				50		
Graph Position	A	B	C	On	E	F
◄ *Preset 1: Defaults* ►						

Figure 23. Settings Menu Screen

Sensor Site

The sensor site setting allows the user to select, customize, or clear a sensor site name. Table 8 lists the pre-defined, commonly-used sensor site names.

Table 8. Commonly-Used Sensor Site Names

Head	Arms	Torso	Legs	Leg Compartments
L Cere (Left Cerebral)	L Delt (Left Deltoid)	Abdomen (Abdominal)	L Thigh (Left Thigh)	LAC (Left Anterior Calf)
R Cere (Right Cerebral)	R Delt (Right Deltoid)	L Flank (Left Flank)	R Thigh (Right Thigh)	LLC (Left Lateral Calf)
L Ear (Left Ear)	L Fore (Left Forearm)	R Flank (Right Flank)	L Calf (Left Calf)	LDP (Left Deep Posterior)
R Ear (Right Ear)	R Fore (Right Forearm)	Up R Abd (Upper Right Abdomen)	R Calf (Right Calf)	LP (Left Posterior)
FH (Forehead)	L Then (Left Thenar)		L Foot (Left Foot)	RAC (Right Anterior Calf)
	R Then (Right Thenar)		R Foot (Right Foot)	RLC (Right Lateral Calf)
	L Hand (Left Hand Finger)		L Toe (Left Foot Toe)	RDP (Right Deep Posterior)
	R Hand (Right Hand Finger)		R Toe (Right Foot Toe)	RP (Right Posterior)

Sensor Type

When creating a preset, this setting allows the user to select the type of sensor that will be attached to that channel. The sensor type options are rSO_2 or SpO_2. This field is disabled when a compatible sensor is attached.

Baseline (rSO_2 channels only)

If the patient's baseline values have not been set by the user, the BL display shows dashes. When starting a new case and the rSO_2 Low Alarm Mode is set to "% below Baseline," the rSO_2 low alarm limit values are the institution's or preset's default %rSO_2 Low (Abs) value. Once the user sets the baseline, the rSO_2 low alarm limit will become a percentage of the baseline.

The rSO_2 baseline values need to be set by the user for each patient so that subsequent rSO_2 changes are measured relative to this baseline. As soon as rSO_2 values appear on the monitoring screen, the device begins plotting trend data on the screen. At this point, if the patient condition is stable, a baseline value should be set for each rSO_2 channel in use. For example, in surgical patients, the baseline should be set prior to induction.

Baselines may be set to the current rSO_2 values displayed on the monitor or be set to specific values.

⚠ **CAUTION:** Between patients, turn the X-100M monitor off (Standby mode) or start a new case (Case Menu). Failure to do so could result in inaccurate baseline values for the new patient. When the device is turned On or a new case is started, the monitor clears the baseline values, resets the limits to the default values, and begins a new patient record in data memory.

Alarm Limits

Most alarm limits can be set and saved in a preset according to the options listed in table 9. The exceptions are the "%rSO_2 Low" and "%SpO_2 Low" alarm limits, which cannot be saved in a preset with a value lower than the institution default settings. See the "%rSO_2 Low" and "%SpO_2 Low" sections below for more information.

NOTE: The institution default limits are populated with factory default values until changed by the institution.

Table 9. Alarm Limit Settings

Alarm Limit	Factory Defaults	Adjustment Options	Adjustment Increments
%rSO_2 High	Off	Off, 20% to 95%	1%
%rSO_2 Low*			
%rSO_2 Low (% BL) % below baseline	Baseline - 25% (Baseline minus 25%)	Off, - 40% to - 5% (minus 40% to minus 5%)	1%
or			
%rSO_2 Low (Abs) Absolute	50%	Off, 15% to 90%	1%
%SpO_2 High	Off	Off, 80% to 100%	1%
%SpO_2 Low	85%	Off, 50% to 95%	1%
Pulse High	200 BPM	Off, 75 to 275 BPM	5 BPM
Pulse Low	50 BPM	Off, 30 to 110 BPM	5 BPM

* Depending on how the rSO_2 Low Alarm Mode is set on the System Menu screen, this setting will be either "%rSO_2 Low (% BL)" or "%rSO_2 Low (Abs)."

CAUTION: A preset cannot be saved with %rSO_2 or %SpO_2 low alarm limit settings that are lower than the institution default settings. %rSO_2 and %SpO_2 low alarm limits that are lower than the institution defaults will be replaced in the preset with the institution default setting(s).

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

NOTE: The AUC will not calculate if the "%rSO_2 Low (% BL)" setting or "%rSO_2 Low (Abs)" setting is OFF.

%rSO_2 Low

When a case begins, the rSO_2 low alarm limit will be the "%rSO_2 Low" value in the selected preset. During the case, the rSO_2 low alarm limit can be modified; however, the "%rSO_2 Low" setting is restricted by the device's defaults when saving a preset. The rSO_2 low alarm limit cannot be saved with a value lower than the institution default setting.

Anytime the low alarm limit is modified, the AUC recalculates from the beginning of the current record.

The rSO_2 low alarm limit displays as a value to the right of a trendline graph on the monitoring screen. When a graph shows a single rSO_2 trendline, the low alarm limit also displays as a white, dotted line in the graph.

A low alarm limit value does not display on the monitoring screen if the channel's "%rSO_2 Low" setting is OFF.

Depending on how the rSO_2 Low Alarm Mode is set on the System Menu screen, this setting will be either "%rSO_2 Low (% BL)" or "%rSO_2 Low (Abs)."

%rSO_2 Low (% BL) (default): When using the "%rSO_2 Low (% BL)" setting, the low alarm limit is set to a percentage between -40% to -5%. The low alarm limit calculation is the set baseline minus the selected percentage. The factory default is the baseline value minus 25% of the baseline value (see table 9).

Example: if the BL is 60, then the low alarm limit is 45 (60 minus 25% = 45).

%rSO_2 Low (Abs): When using the "%rSO_2 Low (Abs)" setting, the low alarm limit is set to a specific value between 15% to 90%. The factory default setting is 50%.

%SpO_2 Low

When a case begins, the SpO_2 low alarm limit will be the "%SpO_2 Low" value in the selected preset. During the case, the SpO_2 low alarm limit can be modified; however, the "%SpO_2 Low" setting is restricted by the device's defaults when saving a preset. The SpO_2 low alarm limit cannot be saved with a value lower than the institution default setting.

Graph Position

This setting determines the location of individual channel trendlines or plethysmograms.

TIPS:

- The trendlines and plethysmograms are color-coded and match the signal processor channel colors
- A graph may not align with its respective channel on the monitoring screen.
- Multiple rSO_2 trendlines can be placed on one graph.
- rSO_2 trendlines and SpO_2 plethysmograms cannot be on the same graph.
- rSO_2 graphs display at the top of the monitoring screen in the order they are set (A – F).
- Each SpO_2 plethysmogram is a separate graph. SpO_2 graphs display below rSO_2 graphs and are ordered based on channel number.

Preset #:

The setting allows the user to quickly access and review the monitor's presets.

Asterisks appear around the preset name when the active preset has been modified on the Settings Menu screen or the System Menu screen. To save these changes for future use, save the preset (see "Presets Menu – Procedures" on page 40).

Settings Menu – Procedures

Open the Settings Menu

1. Press **Menu**. Settings Menu screen displays.

Assign a Pre-Defined Sensor Site Name

1. While in the Settings Menu screen, use the navigation buttons to move to and highlight the desired channel's "Sensor Site" setting.
2. Press **Select**. Pop-up menu displays.
3. Use the navigation buttons to move to and highlight the desired sensor site category.
4. Press **Select**. Pop-up submenu displays.
5. Use the navigation buttons to move to and highlight the desired sensor site name.
6. Press **Select** to save. Display returns to the Settings menu. The abbreviated sensor site name displays below the channel number.
7. Change additional settings, press **Menu** twice to return to monitoring screen, or allow the screen to time out.

Customize a Sensor Site Name

1. While in the Settings Menu screen, use the navigation buttons to move to and highlight the desired channel's "Sensor Site" setting.
2. Press **Select**. Pop-up menu displays.
3. Use the navigation buttons to move to and highlight "Custom."
4. Press **Select.** Alphanumeric keyboard screen displays.
5. Enter sensor site name (maximum of 8 characters):
   a. Use the navigation buttons to move to and highlight the desired character.
   b. Press **Select**.
   c. Repeat steps a and b as needed to enter the name.
6. Press **Down** until "Save" is highlighted.
7. Press **Select**. Display returns to the Settings Menu screen. The custom sensor site name displays below the channel number.
8. Change additional settings, press **Menu** twice to return to monitoring screen, or allow the screen to time out.

Clear a Sensor Site Name

1. While in the Settings Menu screen, use the navigation buttons to move to and highlight the desired channel's "Sensor Site" setting.
2. Press **Select**. Pop-up menu displays.
3. Use the navigation buttons to move to and highlight "Clear."
4. Press **Select**. Display returns to the Settings Menu screen. The sensor site field displays "blank" below the channel number.
5. Change additional settings, press **Menu** twice to return to monitoring screen, or allow the screen to time out.

Set Sensor Type

NOTE: Sensor type is automatically set and cannot be manually changed when a Nonin SenSmart-compatible rSO_2 or SpO_2 sensor is attached to the signal processor.

1. While in the Settings Menu screen, use the navigation buttons to move to and highlight the desired channel's "Sensor Type" setting.
2. Press **Select**. Small arrows display above and below the setting.
3. Press the **Up/Down** navigation buttons to change the setting.
4. Press **Select** to set the sensor type. When the sensor type is set, the Settings Menu screen activates the settings for that sensor type:

   rSO_2 settings:

   - Baseline
   - $\%rSO_2$ high
   - $\%rSO_2$ low (% BL) **or** $\%rSO_2$ low (Abs)

   SpO_2 settings:

   - $\%SpO_2$ high
   - $\%SpO_2$ low
   - PR high
   - PR low

5. Change additional settings, press **Menu** twice to return to monitoring screen, or allow the screen to time out.

Set Individual Baseline Values

1. (OPTIONAL STEP) While monitoring, press **Event Mark** to mark an event. Record the letter of the event in the hospital records.
2. Press **Menu**. Settings Menu screen displays.
3. Use the navigation buttons to move to and highlight the desired channel's "Baseline" setting.
4. Press **Select**. Small arrows display above and below the setting.
5. Press the **Up/Down** navigation buttons to change the setting.
6. Press **Select** to set the baseline value.
7. Repeat as needed for each rSO_2 channel.
8. Change additional settings, press **Menu** twice to return to monitoring screen, or allow the screen to time out.

NOTE: Alarm limits reset to currently active default values each time the unit is powered up.

Set Alarm Limits

1. Follow steps 1 – 4 of the "Set Sensor Type" on page 37 or connect a Nonin SenSmart-compatible sensor to the signal processor.
2. Use the navigation buttons to move to and highlight the desired channel's alarm limit setting.
3. Press **Select**. Small arrows display above and below the setting.
4. Press the **Up/Down** navigation buttons to change the setting. See table 9 for alarm limit setting options.
5. Press **Select** to set the limit.
6. Repeat as needed for each of the high and low alarm limit settings.
7. Change additional settings, press **Menu** twice to return to monitoring screen, or allow the screen to time out.

Set Graph Position(s)

1. While in the Settings Menu screen, use the navigation buttons to move to and highlight a channel's "Graph Position" setting.
2. Press **Select**. Small arrows display above and below the setting.
3. Press the **Up/Down** navigation buttons to change the setting.
   - rSO_2 channels can be set to a letter from A to F, or Off. Up to six rSO_2 channel trendlines can display in one graph.
   - SpO_2 channels can be set to On or Off.
4. Press **Select** to set the graph position.
5. Change additional settings, press **Menu** twice to return to monitoring screen, or allow the screen to time out.

Review/Select a Preset

1. While in the Settings Menu screen, press **Down** to move to and highlight the "Preset" field at the bottom of the Settings Menu screen.
2. Use the **Right/Left** navigation buttons to scroll through the presets and review the settings for each preset.
3. To select a preset, stop scrolling through the presets. The preset on the screen becomes the active preset.
4. Press **Menu** twice to return to the monitoring screen.

Presets Menu Screen

This section contains:

- Description of the Presets Menu
- Presets Menu procedures (see page 40)

TIPS:

- All channel-specific settings on the Settings Menu screen can be saved in a preset.
- Six of the System Menu settings will be saved in a preset: Brightness, Alarm Volume, rSO_2 Low Alarm Mode, Pulse Tone Volume, Pulse Tone Source, and Data Output Modes.

Presets Menu – Description

A preset is a collection of channel and system settings that can be saved and recalled. The Presets Menu screen allows the user to save the current settings as a preset, activate a saved preset, and delete, rename, lock, or unlock a preset.

The monitor can save up to 10 presets. The 10 presets are initially designated as default presets and are set to the factory default settings. If the institution default limits have been set, the default presets use those settings.

One preset can be designated as the institution default preset. When the monitor is turned on, the institution default preset is applied to the new case. The user may use this preset or activate another preset.

When a preset is deleted, the name reverts to “Defaults” and the settings revert to the factory default values, or the institution defaults if they have been set.

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

WARNING: A hazard can exist if different presets are used on multiple X-100M monitors in one care area.

NOTE: Presets are retained even when both external and battery power are lost.

NOTE: If the user changes the settings in an active preset and then wants to save the new settings as the preset, see "Save Current Settings as a Preset" on page 40.

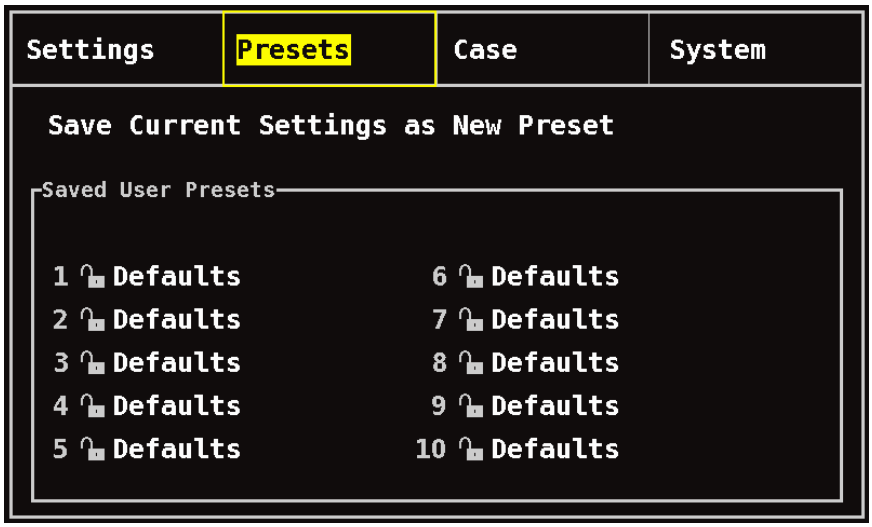


Figure 24. Presets Menu Screen

Presets Menu – Procedures

Open the Presets Menu

1. Press **Menu**.
2. Press **Right** once to highlight the Presets tab. Presets Menu screen displays.

Activate a Preset

1. While in the Presets Menu screen, use the navigation buttons to move to and highlight the desired preset.
2. Press **Select**. Pop-up menu displays with “Use This Preset” highlighted.
3. Press **Select**. Preset activates and display returns to the Settings screen.
4. Change additional settings, press **Menu** to return to monitoring screen, or allow the screen to time out.

Save Current Settings as a Preset

> ⚠ **CAUTION:** A preset cannot be saved with %rSO_2 or %SpO_2 low alarm limit settings that are lower than the institution default settings. %rSO_2 and %SpO_2 low alarm limits that are lower than the institution defaults will be replaced in the preset with the institution default setting(s).

1. Using the Settings and System menus, set all parameters and settings to the desired values.
2. Use the navigation buttons to move to and highlight the Presets tab.
3. While in the Presets Menu screen, use the navigation buttons to move to and highlight “Save Current Settings as New Preset.”
4. Press **Select**. Pop-up menu displays.

5. Using the **Up/Down** navigation buttons, select a preset to overwrite.

NOTE: If the preset is locked, the message *Cannot overwrite locked preset!* displays. To unlock the preset, see “Lock/Unlock a Preset” on page 42.

6. Press **Select**. Preset name box displays along with alphanumeric keyboard screen. If updating an existing preset, continue to step 8.
7. Enter Preset name (maximum of 11 alphanumeric characters):
   a. Use the navigation buttons to move to and highlight the desired character.
   b. Press **Select**.
   c. Repeat steps a and b as needed to enter the name.
8. Press **Down** until “Save” is highlighted.
9. Press **Select** to save. Preset activates and the display returns to the monitoring screen.

Delete a Preset

1. While in the Presets Menu screen, use the navigation buttons to move to and highlight the desired preset.
2. Press **Select**. Pop-up menu displays. If needed, unlock the preset (see “Lock/Unlock a Preset” on page 42).
3. Press **Down** once to highlight “Delete.”
4. Press **Select**. “Delete selected preset?” pop-up displays with “No” highlighted.
   - To cancel deletion, press **Select**.
   - To delete preset, press **Down** to highlight “Yes,” and then press **Select**. The preset name reverts to “Defaults” and the preset values become the institution defaults.
5. Press **Menu** twice to return to the monitoring screen.

Rename a Preset

1. While in the Presets Menu screen, use the navigation buttons to move to and highlight the desired preset.
2. Press **Select**. Pop-up menu displays. If needed, unlock the preset (see “Lock/Unlock a Preset” on page 42).
3. Press **Down** twice to highlight “Rename.”
4. Press **Select**. Alphanumeric keyboard screen displays
5. Enter Preset name (maximum of 11 alphanumeric characters):
   a. Use the navigation buttons to move to and highlight the desired character.
   b. Press **Select**.
   c. Repeat steps a and b as needed to enter the name.
6. Press **Down** until “Save” is highlighted.
7. Press **Select**. Display returns to the Presets Menu screen.
8. Press **Menu** twice to return to the monitoring screen.

Lock/Unlock a Preset

NOTE: An unlocked preset displays an open lock symbol next to the preset name, and a locked preset displays a closed lock symbol next to the preset name.

1. While in the Presets Menu screen, use the navigation buttons to move to and highlight the desired preset.
2. Press **Select**. Pop-up menu displays.
   - To unlock a preset, press **Down** to highlight “Unlock.”
   - To lock a preset, press **Down** to highlight “Lock.”
3. Press **Select**.
4. Enter a preset password. This is a user-specific password, which can be overridden by the institution password.
5. Display returns to the Presets Menu screen.
6. Press **Menu** twice to return to the monitoring screen.

Case Menu Screen

This section contains:

- Description of the Case Menu
- Case Menu procedures (see page 43)

Case Menu – Description

The Case menu screen (figure 25) allows the user to view the current patient's ID (identification), start a new case, or edit a patient's ID.

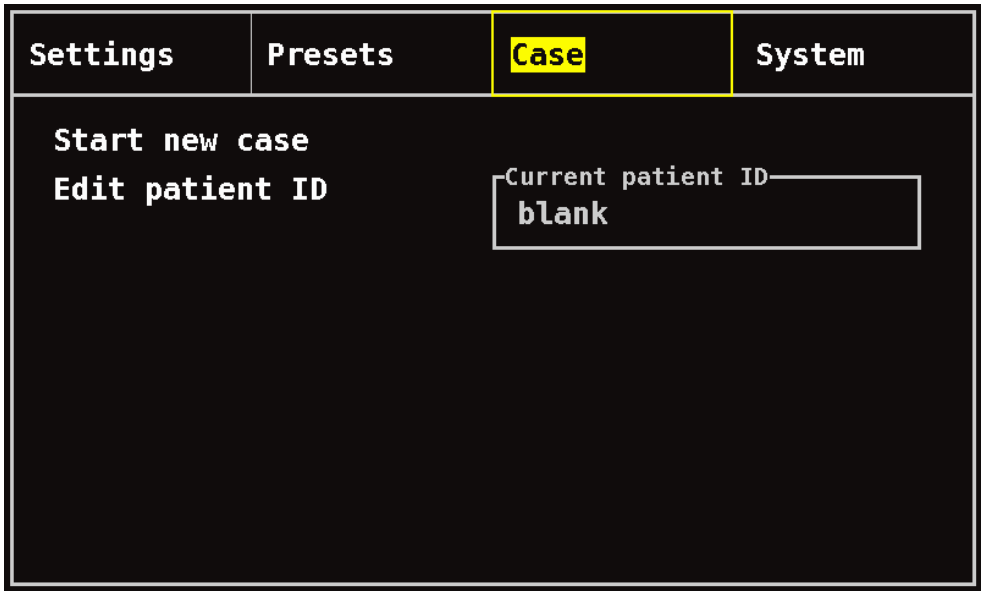


Figure 25. Case Menu Screen

Start New Case

This setting allows the user to begin a new case using the current preset. When a new case is started, the baselines are cleared and a new record starts in memory.

Edit Patient ID

This setting allows the user to edit an existing patient ID or add a patient ID to a case. Patient IDs may be a maximum of 15 alphanumeric characters.

Case Menu – Procedures

Open the Case Menu

1. Press **Menu**.
2. Press **Right** twice to highlight the Case tab. Case Menu screen displays.

Start a New Case

1. While in the Case Menu screen, use the navigation buttons to move to and highlight “Start new case.”
2. Press **Select**. “Start new case?” pop-up displays with “No” highlighted.
3. Press **Down** to highlight “Yes.”
4. Press **Select**.
   - If system is set up to require the entry of a patient ID at the start of a new case (see “Patient ID Request” for more information):
     - Alphanumeric keyboard screen displays. Follow steps 3 – 5 in the next procedure, “Edit a Patient ID.”
     - After patient ID is entered, “Starting new case...” displays. Monitor returns to monitoring screen and all baselines from the previous case are cleared.
   - If system is not set up to require entry of a patient ID at the start of a new case:
     - “Starting new case...” displays. Monitor returns to monitoring screen and all baselines from the previous case are cleared.
     - The case will not have a patient ID. To enter a patient ID, see the next procedure, “Edit a Patient ID.”

Edit a Patient ID

1. While in the Case Menu screen, use the navigation buttons to move to and highlight “Edit patient ID.”
2. Press **Select**. Alphanumeric keyboard screen displays.
3. Enter the Patient ID (maximum of 15 alphanumeric characters).
   a. Use the navigation buttons to move to and highlight the desired character.
   b. Press **Select**.
   c. Repeat steps a and b as needed to enter the name.
4. Press **Down** until “Save” is highlighted.
5. Press **Select** to save. Current patient ID displays on the Case Menu screen.
6. Press **Menu** twice to return to the monitoring screen, or allow the screen to time out.

System Menu Screen

This section contains:

- Description of the System Menu
- System Menu procedures (see page 51)

System Menu – Description

The System Menu screen (figure 26) allows the user to access the following settings:

- Brightness*
- Alarm volume*
- rSO_2 low alarm mode*
- Pulse tone volume*
- Pulse tone source*
- Data output modes*

- Clear memory
- Restore factory defaults
- System information
- Date / time
- Nurse call mode
- Bluetooth
- Language
- Patient ID request
- System name
- Default preset
- Institution default limits
- Institution password

* These settings can be included as a preset parameter.

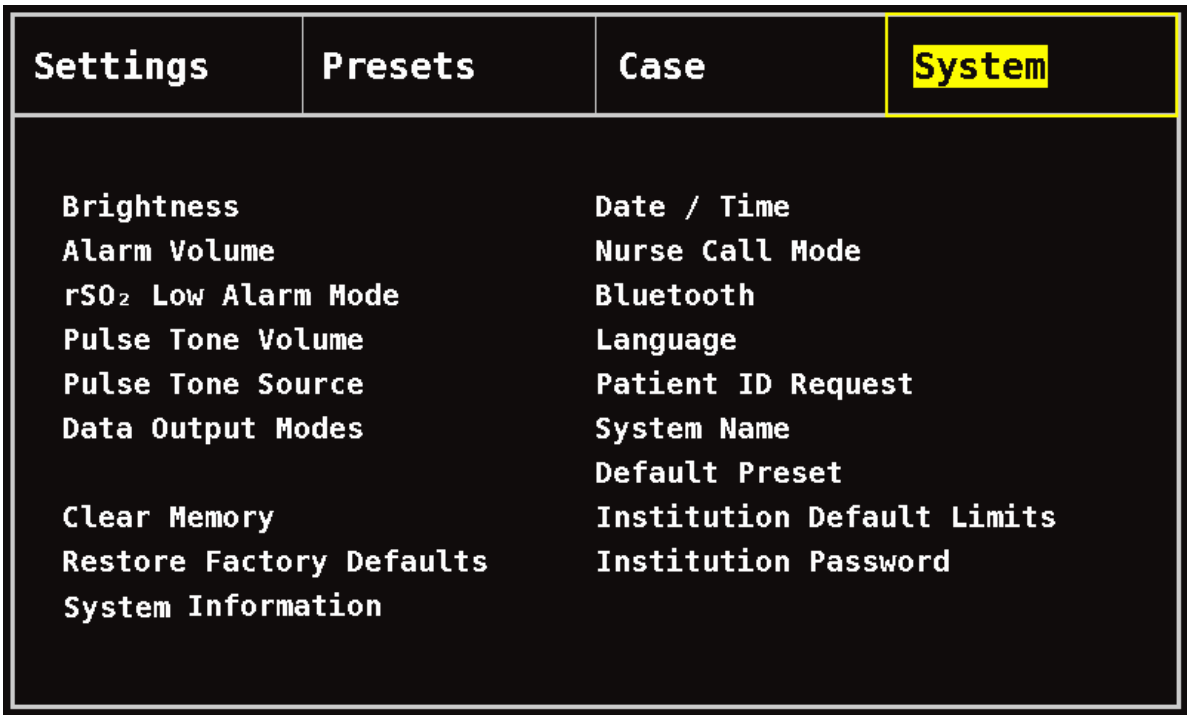


Figure 26. System Menu Screen

Brightness

This setting determines the display screen brightness. The brightness slider has 15 steps. The default brightness is maximum brightness (15). This setting can be saved as a preset parameter.

Alarm Volume

This setting determines the volume of audible alarms. The alarm volume slider has 15 steps. The default alarm volume is maximum volume (15). This setting can be saved as a preset parameter.

If the alarm volume is at step 5 or higher, the slider is green. If the alarm volume is at step 4 or lower (less than 45 decibels), the slider is yellow, and the yellow Alarm Silence indicator is lit solidly on the monitoring screen.

rSO_2 Low Alarm Mode

This setting determines how the low alarm limit will be calculated. This setting can be set to either “% Below Baseline” or “Absolute.” Default is “% Below Baseline.”

Once set, either %rSO_2 Low (% BL) or %rSO_2 Low (Abs) will display on the Settings Menu screen. See page 34 for more information about rSO_2 low alarm limits.

This setting can be saved as a preset parameter.

% Below Baseline

To have the rSO_2 low alarm limit value automatically calculated as a percentage below the baseline, set the rSO_2 Low Alarm Mode to “% Below Baseline” (default). The factory default is the baseline value minus 25% of the baseline value (table 9 on page 34).

Example: if the BL is 60, then the low alarm limit is 45 (60 minus 25% = 45).

When starting a new case and the rSO_2 Low Alarm Mode is set to “% Below Baseline,” the rSO_2 low alarm limit values are the institution’s or preset’s default %rSO_2 Low (Abs) value. Once the user sets the baseline, the rSO_2 low alarm limit will become a percentage of the baseline.

Absolute

To have the %rSO_2 low alarm limit be a specific value, set the rSO_2 Low Alarm Mode to “Absolute.”

When starting a new case and the rSO_2 Low Alarm Mode is set to “Absolute,” the rSO_2 low alarm limit values are the selected preset’s %rSO_2 Low (Abs) values.

Pulse Tone Volume

This setting determines the volume of the pulse beep. The pulse tone volume slider has 15 steps. The default pulse tone volume is off (0). This setting can be saved as a preset parameter.

Pulse Tone Source

This setting determines which SpO_2 channel will provide the pulse tone. Only one SpO_2 channel can be set as the pulse tone source. This setting can be saved as a preset parameter.

Data Output Modes

This device features 5 different once-per-second, real-time data output formats (Nonin 1, Nonin 2, Nonin 3, Nonin 4, Nonin 5). In addition, the RS-232 port outputs data for the optional Dymo printer (Printer).

This setting can be saved as a preset parameter.

NOTE: Bluetooth and the RS-232 port have separate selection options and may use different data output formats.

For more information on data formats, see "Memory and Data Output Features" on page 61.

Clear Memory

This setting deletes patient data recordings from the monitor. This setting does not delete presets from the monitor.

Restore Factory Defaults

This setting discards all presets, institution defaults, and other user settings and returns the monitor to the factory default alarm limit settings (table 10).

Table 10. Factory Default Alarm Limit Settings

Alarm Limit Setting	Factory Default
rSO_2 High	Off
rSO_2 Low (% BL) % below baseline	Baseline - 25% (Baseline minus 25%)
rSO_2 Low (Abs) Absolute	50%
SpO_2 High	Off
SpO_2 Low	85%
Pulse High	200 BPM
Pulse Low	50 BPM

System Information

This pop-up window provides system information for the monitor and any attached signal processors. If calling Nonin’s Technical Service department, the service representative may request this information.

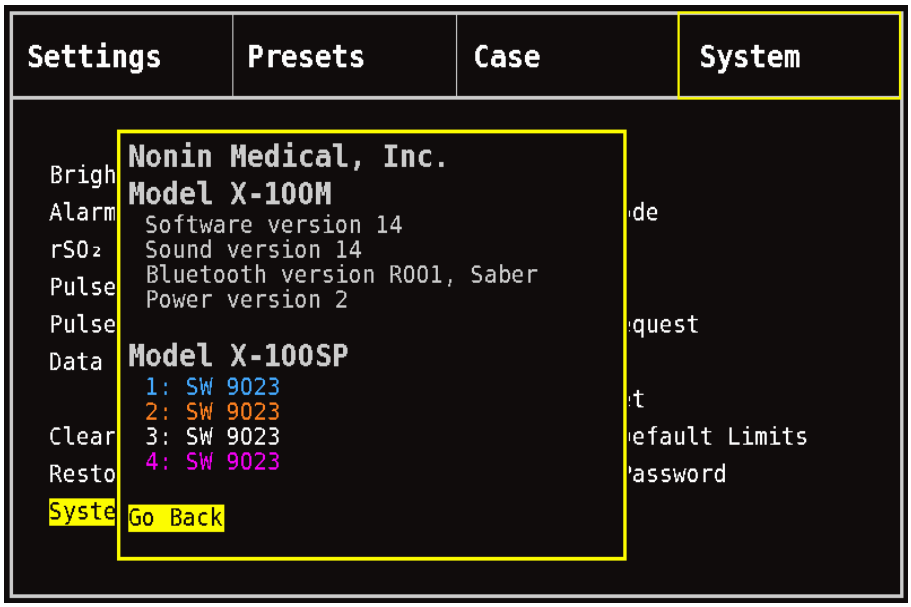


Figure 27. System Information Pop-up

Date / Time

This setting allows the user to set the monitor's date and time (24-hour clock).

Nurse Call Mode

This setting allows alarm notification at a central monitoring location. Nurse call functions on AC or battery power. The facility determines the alarm condition as audible, visual, or both. The nurse call options are:

- ***Normally open, continuous*** (default setting) – The nurse call contact is normally open, but closes during alarm conditions. The nurse call contact changes state for the duration of an alarm condition and only reverts to the original non-alarm state when the alarm condition is cleared.
- ***Normally open, momentary*** – The nurse call contact is normally open, but closes during alarm conditions. The nurse call contact temporarily changes state at the onset of an alarm condition and repeats the 1 second change each minute for the duration of the alarm condition.
- ***Normally closed, continuous*** – The nurse call contact is normally closed, but opens during alarm conditions. The nurse call contact changes state for the duration of an alarm condition and only reverts to the original non-alarm state when the alarm condition is cleared.
- ***Normally closed, momentary*** – The nurse call contact is normally closed, but opens during alarm conditions. The nurse call contact temporarily changes state at the onset of an alarm condition and repeats the 1 second change each minute for the duration of the alarm condition.

NOTE: The Nurse Call feature overrides silenced alarms.

WARNING: It is the user's responsibility to implement the interface between the Nurse Call system and the Model X-100M, and to adequately test the interface between the Model X-100M and the Nurse Call system to ensure operation. The X-100M monitor has not been evaluated with specific nurse call systems.

WARNING: The device Nurse Call and Bluetooth features should not be used as the primary source of alarm notification.

Bluetooth

This pop-up window provides the user with the information needed to pair the Model X-100M to a Bluetooth master device and the option to turn off the Bluetooth radio.

For more information on Bluetooth technology, see page 62.

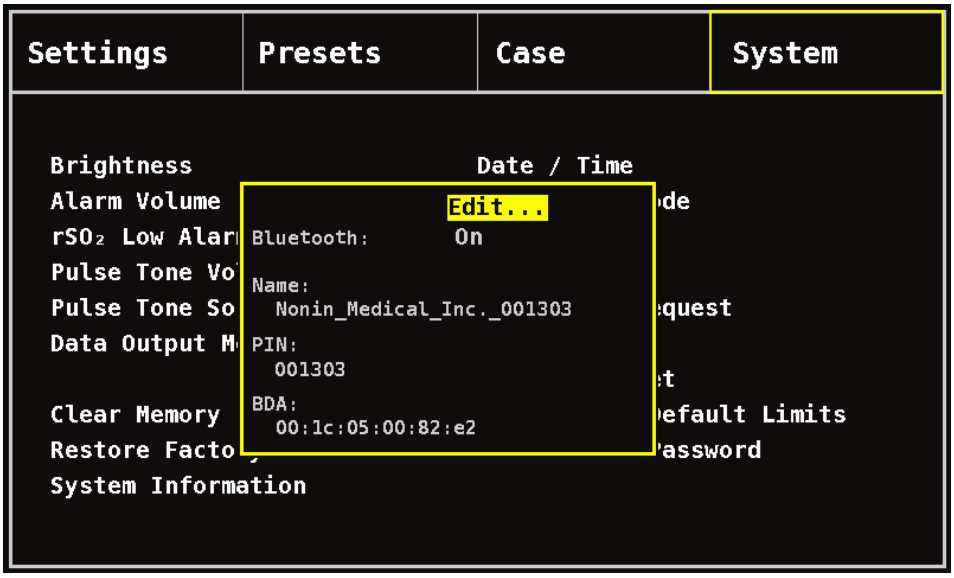


Figure 28. Bluetooth Information Pop-up

Language

This feature allows the user to change the language displayed on the monitor. The available languages are:

- English
- German (Deutsch)
- Spanish (Español)
- French (Français)
- Italian (Italiano)
- Dutch (Nederlands)
- Swedish (Svenska)
- Portuguese (Português)

Patient ID Request

This setting determines whether or not the user will be asked to enter patient identification (ID) when a new case is started. If set to “At Start of New Case,” the Enter Patient ID screen will display when the monitor is turned on and when “Start a new case” is selected on the Case Menu screen.

System Name

This setting allows the user to assign a name to the system. The default name is X-100.

Default Preset

This setting allows the user to select one of the presets to be the default preset. Once the preset has been selected as the default preset, it automatically locks. When the monitor is turned on, the default preset is shown on the “Select a Preset” start-up screen. The default preset will be the active preset unless another preset is selected.

Institution Default Limits

NOTE: The institution default limits are populated with factory default values until changed by the institution.

This setting allows the user to establish institution default high and low limits for %rSO_2, %SpO_2, and pulse rate. When the institutional default limits are set, these values become the default values in any default presets.

After updating the institutional defaults, the message *Presets with SpO_2 or rSO_2 low alarm limits lower than the new institution limits have been updated to the new limits* displays. The institution low alarm limit defaults take precedent over any low alarm limits saved in a preset if the low alarm limits violate the institutional low alarm limits.

⚠ **CAUTION:** A preset cannot be saved with %rSO_2 or %SpO_2 low alarm limit settings that are lower than the institution default settings. %rSO_2 and %SpO_2 low alarm limits that are lower than the institution defaults will be replaced in the preset with the institution default setting(s).

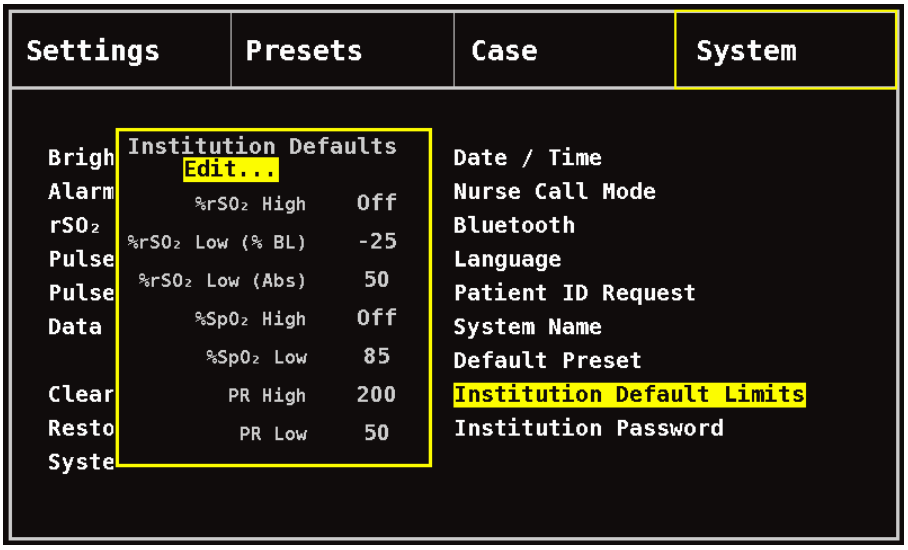


Figure 29. Institution Defaults Pop-up

Institution Password

The default institution password is 0000. The institution password may be set to any four-digit number and is used to unlock parameter settings on the System Menu screen. The institution password can be used to unlock saved presets.

System Menu – Procedures

Open the System Menu

1. Press **Menu**.
2. Press **Right** three times to highlight the System tab. System Menu screen displays.

Adjust the Display Brightness

1. While in the System Menu screen, use the navigation buttons to move to and highlight “Brightness.”
2. Press **Select**. Brightness slider displays.
3. Press the **Up/Down** navigation buttons to adjust the setting.
4. Press **Select** to save the setting. Display returns to System Menu screen.
5. Change additional settings, press **Menu** twice to return to monitoring screen, or allow the screen to time out.

Adjust the Alarm Volume

1. While in the System Menu screen, use the navigation buttons to move to and highlight "Alarm Volume."
2. Press **Select**. Alarm volume slider displays.
3. Press the **Up/Down** navigation buttons to adjust the setting.
   - ***Green slider*** – volume is above 45 decibels (steps 5 – 15).
   - ***Yellow slider*** – volume is below 45 decibels and the alarm silence indicator displays on the monitor (steps 0 – 4).
4. Press **Select** to save the setting. Display returns to System Menu screen.
5. Change additional settings, press **Menu** twice to return to monitoring screen, or allow the screen to time out.

WARNING: Ensure all alarm volumes are set appropriately and are audible in all situations. Keep speaker openings clear of all obstructions.

Set the rSO_2 Low Alarm Mode

1. While in the System Menu screen, use the navigation buttons to move to and highlight "rSO_2 Low Alarm Mode."
2. Press **Select**. Pop-up menu displays.
3. Press the **Up/Down** navigation buttons to change the setting.
   - % Below Baseline
   - Absolute
4. Press **Select** to save the setting. Display returns to System Menu screen.
5. Change additional settings, press **Menu** twice to return to monitoring screen, or allow the screen to time out.

Adjust the Pulse Tone Volume

1. While in the System Menu screen, use the navigation buttons to move to and highlight "Pulse Tone Volume."
2. Press **Select**. Pulse tone volume slider displays. Default volume is off.
3. Press the **Up/Down** navigation buttons to change the setting.
4. Press **Select** to save the setting. Display returns to System Menu screen.
5. Change additional settings, press **Menu** twice to return to monitoring screen, or allow the screen to time out.

Select a Pulse Tone Source

NOTE: When setting a channel as the pulse beep source, verify the pulse tone volume has been adjusted so it is audible.

1. While in the System Menu screen, use the navigation buttons to move to and highlight “Pulse Tone Source.”
2. Press **Select**. Pulse tone source pop-up window displays.
3. Press the **Up/Down** navigation buttons to change the setting.
4. Press **Select** to save the setting. Display returns to System Menu screen.
5. Change additional settings, press **Menu** twice to return to monitoring screen, or allow the screen to time out.

Set Bluetooth and/or RS-232 Data Output Formats

1. While in the System Menu screen, use the navigation buttons to move to and highlight “Data Output Modes.”
2. Press **Select**. Pop-up window displays with Bluetooth setting highlighted. If not using Bluetooth, proceed to step 3.
   a. Press **Select**. Small arrows display above and below the setting.
   b. Press **Up/Down** to select a Bluetooth data output format.
   c. Press **Select** to save the setting. Continue with RS-232 output mode, or skip to step 4 if RS-232 is not needed.
3. Press **Down** to highlight RS-232 setting.
   a. Press **Select**. Small arrows display above and below the setting.
   b. Press **Up/Down** to select a RS-232 data output format.
   c. Press **Select** to save the setting.
4. Press **Menu** to close the pop-up and return to the System Menu screen.
5. Change additional settings, press **Menu** twice to return to monitoring screen, or allow the screen to time out.

Clear the Memory

1. While in the System Menu screen, use the navigation buttons to move to and highlight “Clear Memory.”
2. Press **Select**. “Clear ALL patient data recordings?” pop-up displays with “No” highlighted.
   - To cancel, press **Select**.
   - To clear memory, press **Down** to highlight “Yes,” and then press **Select**.
3. *Memory cleared!* message displays. Display returns to the System Menu screen.
4. Change additional settings, press **Menu** twice to return to monitoring screen, or allow the screen to time out.

Restore Factory Defaults

1. While in the System Menu screen, use the navigation buttons to move to and highlight “Restore Factory Defaults.”
2. Press **Select**. “Discard ALL presets and settings?” pop-up displays with “No” highlighted.
   - To cancel, press **Select**.
   - To restore factory defaults, press **Down** to highlight “Yes,” and then press **Select**.
3. Enter the institution password.
4. *Factory defaults restored!* message displays. Display returns to monitoring screen.

NOTE: Institution-specific defaults are lost when factory defaults are restored.

Review System Information

1. While in the System Menu screen, use the navigation buttons to move to and highlight “System Information.”
2. Press **Select**. System information pop-up window displays (figure 27).
3. To close the window, press **Menu** or **Select**. Display returns to System Menu screen.
4. Press **Menu** twice to return to the monitoring screen.

Set the Date and Time

NOTE: To save the date and time, **Menu** must be pressed.

1. While in the System Menu screen, use the navigation buttons to move to and highlight “Date / Time.”
2. Press **Select**. Pop-up window displays.
   a. To move between fields, use the navigation buttons.
   b. To update a field, press **Select** (small arrows display above and below the setting) and then press **Up/Down** to change the setting. To close a field, press **Select** or **Menu**.
   c. Repeat as needed for each date/time field.
3. When finished, press **Menu** to save the date and time, close the pop-up, and return to the System Menu screen.
4. Change additional settings, press **Menu** twice to return to monitoring screen, or allow the screen to time out.

Set-up Nurse Call

1. While in the System Menu screen, use the navigation buttons to move to and highlight “Nurse Call Mode.”
2. Press **Select** to review current setting. Pop-up window displays setting along with “Edit...” highlighted.
   - To change the setting, press **Select** and continue with step 3.
   - To cancel, press **Menu**. Display returns to System Menu screen.
3. Enter the institution password. Pop-up menu displays.
4. Press the **Up/Down** navigation buttons to change the setting.

5. Press **Select** to save. Display returns to System Menu screen.
6. Change additional settings, press **Menu** twice to return to monitoring screen, or allow the screen to time out.

Enable/Disable Bluetooth Radio

1. While in the System Menu screen, use the navigation buttons to move to and highlight “Bluetooth.”
2. Press **Select**. Bluetooth information pop-up window (figure 28) displays with “Edit...” highlighted.
3. To change the setting, press **Select**.
4. Enter the institutional password.
5. Press **Select**. Small arrows display above and below the setting.
6. Press the **Up**/**Down** navigation buttons to change the setting.
7. Press **Select** to save. If turning Bluetooth on, the message *Please wait...* displays while the Bluetooth radio is enabled. Bluetooth information pop-up window displays.
8. Press **Menu** to return to the System Menu screen.
9. Change additional settings, press **Menu** twice to return to monitoring screen, or allow the screen to time out.

Change Language

1. While in the System Menu screen, use the navigation buttons to move to and highlight “Language.”
2. Press **Select**. Pop-up menu displays.
3. Press the **Up/Down** navigation buttons to change the setting.
4. Press **Select** to save. Display returns to System Menu screen.
5. Change additional settings, press **Menu** twice to return to monitoring screen, or allow the screen to time out.

Set Patient ID Request

1. While in the System Menu screen, use the navigation buttons to move to and highlight “Patient ID Request.”
2. Press **Select** to review current setting. Pop-up window displays settings along with “Edit...” highlighted.
   - To change the setting, press **Select** and continue with step 3.
   - To cancel, press **Menu**. Display returns to System Menu screen.
3. Enter the institution password. Pop-up menu displays.
4. Press the **Up/Down** navigation buttons to change the setting.
5. Press **Select** to save. Display returns to System Menu screen.
6. Change additional settings, press **Menu** twice to return to monitoring screen, or allow the screen to time out.

Assign System Name

1. While in the System Menu screen, use the navigation buttons to move to and highlight “System Name.”
2. Press **Select** to review current setting. Pop-up window displays setting along with “Edit...” highlighted.
   - To change the setting, press **Select** and continue with step 3.
   - To cancel, press **Menu**. Display returns to System Menu screen.
3. Enter the institution password. Alphanumeric keyboard screen displays.
4. Enter the System Name (maximum of 15 alphanumeric characters).
   a. If needed, delete existing system name.
   b. Use the navigation buttons to move to and highlight the desired character.
   c. Press **Selec**t.
   d. Repeat steps b and c as needed to enter the name.
5. Press **Down** until “Save” is highlighted.
6. Press **Select** to save. Display returns to System Menu screen.
7. Change additional settings, press **Menu** twice to return to monitoring screen, or allow the screen to time out.

Select Default Preset

1. While in the System Menu screen, use the navigation buttons to move to and highlight “Default Preset.”
2. Press **Select** to review current setting. Pop-up window displays setting along with “Edit...” highlighted.
   - To change the setting, press **Select** and continue with step 3.
   - To cancel, press **Menu**. Display returns to System Menu screen.
3. Enter the institution password. “Select default preset” pop-up displays.
4. Current default preset is highlighted. Press the **Up/Down** navigation buttons to move to and highlight the desired preset.
5. Press **Select** to save. Display returns to System Menu screen. The selected default setting will be the active setting the next time the monitor is turned on.
6. Change additional settings, press **Menu** twice to return to monitoring screen, or allow the screen to time out.

Set Institution Default Limits

1. While in the System Menu screen, use the navigation buttons to move to and highlight “Institution Default Limits.”
2. Press **Select** to review current settings. Pop-up window displays settings along with “Edit...” highlighted.
   - To change the setting, press **Select** and continue with step 3.
   - To cancel, press **Menu**. Display returns to System Menu screen.
3. Enter the institution password.
4. “Institution Defaults” pop-up displays (figure 29). The following institution default limits may be set:
   - %rSO_2 High
   - %rSO_2 Low (% BL)
   - %rSO_2 Low (Abs)
   - %SpO_2 High
   - %SpO_2 Low
   - PR High
   - PR Low
5. Press the **Up**/**Down** navigation buttons to move to and highlight a setting.
6. Press **Select**. Small arrows display above and below the setting.
7. Press **Up/Down** navigation buttons to change the setting.
8. Press **Select** to set.
9. Repeat steps 5 – 8 until all desired institution defaults are set.
10. Press **Menu**. Monitor displays the following message: *Institution Defaults Changed. Presets with SpO_2 and rSO_2 low alarm limits lower than the new institution limits have been updated to the new limits.* Display returns to System Menu screen.
11. Change additional settings, press **Menu** twice to return to monitoring screen, or allow the screen to time out.

Change the Institution Password

1. While in the System Menu screen, use the navigation buttons to move to and highlight “Institution Password.”
2. Press **Select** and follow the on-screen instructions:
   a. Enter current institution password.
   b. Enter new institution password.
   c. Enter new password again to confirm change.
      - If confirmation is successful, monitor displays *New password saved!* and returns to System Menu screen.
      - If password change is not successful, monitor displays *Confirmation failed* and returns to System Menu screen.
3. Change additional settings, press **Menu** twice to return to monitoring screen, or allow the screen to time out.

Alarms

The Model X-100M has audible and visual alarm indicators to alert the operator in case immediate patient attention is required or an equipment alarm occurs.

The intended operator's position for correctly perceiving a visual alarm signal and its priority is 1 meter (3.3 feet).

High Priority Alarms

High priority alarms require immediate attention to the patient.

Table 11. High Priority Alarms

Alarm	Visual Indicator	Audible Indicator
rSO_2 High Limit – displays when rSO_2 is equal to or above high alarm limit	Channel background flashes RED 2 times per second. Channel text becomes white.	3 beeps, pause, 2 beeps, pause, 3 beeps, pause, 2 beeps, and a 6-second pause. This cycle repeats until silenced or the alarm condition is cleared.
rSO_2 Low Limit – displays when rSO_2 is equal to or below low alarm limit	Channel background flashes RED 2 times per second. Channel text becomes white.	
SpO_2 High Limit – displays when SpO_2 is equal to or above high alarm limit	SpO_2 portion of channel background flashes RED 2 times per second. SpO_2 value becomes white.	
SpO_2 Low Limit – displays when SpO_2 is equal to or below low alarm limit	SpO_2 portion of channel background flashes RED 2 times per second. SpO_2 value becomes white.	
Pulse High Limit – displays when pulse is equal to or greater than the Pulse High alarm limit	Pulse rate portion of channel background flashes RED 2 times per second. Pulse rate value becomes white.	
Pulse Low Limit – displays when pulse is equal to or less than the Pulse Low alarm limit	Pulse rate portion of channel background flashes RED 2 times per second. Pulse rate value becomes white.	
Low Perfusion – displays when the system detects low perfusion at the SpO_2 sensor site.	Channel background flashes RED 2 times per second. Channel text becomes white.	
Critical Low Battery	Battery indicator ▭ flashes RED 2 times per second.	

Medium Priority Alarms

Medium priority alarms signal potential problems with the equipment or other non-life-threatening situations. On the Model X-100M, the medium priority alarms are as follows:

Table 12. Medium Priority Alarms

Alarm	Visual Indicator	Audible Indicator
rSO_2 Warning (rSO_2 5% or less above low rSO_2 alarm limit)	rSO_2 background flashes YELLOW once every 2 seconds. Channel text becomes gray.	3 beeps followed by a 20-second pause. This cycle repeats until silenced or the alarm condition is cleared.
Low Battery	Battery indicator flashes YELLOW once every 2 seconds.	
Sensor Fault	Sensor fault indicator flashes YELLOW once every 2 seconds.	
Signal Processor Communication Error	Communication lost indicator flashes YELLOW once every 2 seconds and *X-100SP not connected* displays.	
Poor Signal	Poor Signal indicator flashes YELLOW once every 2 seconds.	

Silencing Alarms

Press **Alarm Silence** to silence alarms for 2 minutes. Audible alarms may be reactivated before the 2-minute silence period is over by pressing Alarm Silence again. All silenced audible alarms are automatically reactivated when a new physiological alarm condition occurs.

- The Alarm Silence indicator blinks while alarms are temporarily silenced.
- The Alarm Silence indicator is lit solidly when the alarm volume slider is yellow (step 4 or lower [less than 45 decibels]).
- Audible indicators can be turned off in the Alarm Volume setting on the System Menu screen.

Error Codes

This device includes error codes that indicate problems with the unit. When an error occurs, the device emits a loud, two-tone, steadily beeping signal and an error code displays on the monitor screen. Error codes are indicated by the letter “E” and a two-letter code (table 13).

To correct error conditions, perform these steps:

1. Turn the unit off and then back on again to remove the error code.
2. If the error persists, 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).

Table 13. Error Codes

Error	Visual Indicator
Stuck Key	E01
Sound Module Fault	E02
Sound Module Communications Fault	E03
Signal Processor Overcurrent	E04
Memory Alarm **WARNING: Memory is cleared if error code E06 appears on the display screen.**	E06
Battery Fault (fails precondition)	E08
Corrupt Preset **WARNING: The device presets are deleted if error code E09 appears on the display screen.**	E09
Corrupt Device Configuration **WARNING: The device configuration is deleted if error code E10 appears on the display screen.**	E10

Memory and Data Output Features

Memory

The Model X-100M monitor can collect and store:

- 840 hours of data when 2 channels are in use.
- 420 hours of data when 4 channels are in use.
- 280 hours of data when 6 channels are in use.

The memory in the Model X-100M functions much like an “endless loop” tape. When the memory is full, the unit begins overwriting the oldest data with new data.

> ⚠ **CAUTION:** Data is written continuously to memory when the device is on. If the entire memory is filled, portions of the oldest record will be overwritten when new data is written.

Each time the Model X-100M is turned on, the current time/date information (if the clock is set properly) is stored in memory and a new recording session starts.

Oximetry data for each channel (rSO_2 or SpO_2 and pulse rate) is sampled and recorded in memory once every 4 seconds. Oxygen saturation values are stored in 1% increments in the range of 0 to 100%. Pulse rate values are stored in 1 BPM increments in the range of 18 – 300 BPM.

Patient data is retained even when power is lost.

To clear patient memory, refer to "Clear the Memory" on page 53.

Patient Data Output

The Model X-100M provides real-time patient data output. The device may be connected to a PC via a Bluetooth connection or using the RS-232 serial data port on the back of the X-100M monitor (figure 30).

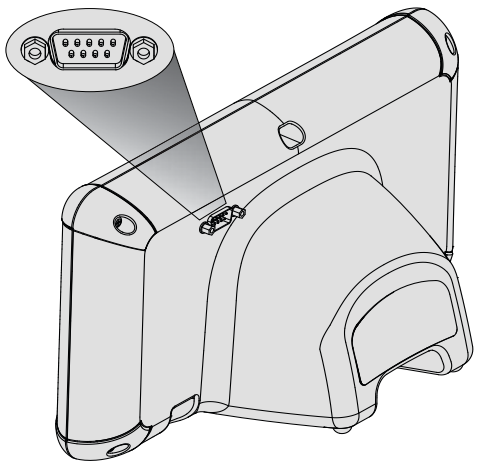


Figure 30. RS-232 Serial Data Port

NOTE: Use only a null modem serial cable to connect the Model X-100M to a PC.

NOTE: Verify Bluetooth status as follows: Bluetooth symbol is green when Bluetooth is connected to a host, white when it is enabled but not connected, and gray when it is disabled.

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

Bluetooth Technology

Bluetooth technology allows wireless connections between electronic communications and computing devices. The technology is based on a radio link that offers fast and reliable data transmissions. Bluetooth technology uses a license-free, globally available frequency range in the ISM band—intended to ensure communication compatibility worldwide.

Nonin's use of Bluetooth wireless technology allows oxygen saturation information to be transmitted through a Bluetooth radio to a compatible Bluetooth-enabled device. Nonin's wireless system removes the need for a physical connection from the X-100M monitor to a remote monitor location, giving increased ability to move the monitor freely. Nonin's X-100M monitor uses an automatically switchable class I/class II Bluetooth radio with a maximum range of about 100 meters (328 feet) (spherical radius).

The Model X-100M features point-to-point communications, allowing one master device (the remote monitor) to be paired to one slave device (the X-100M monitor). Once connected, the X-100M monitor will not connect with any other Bluetooth-enabled device.

Bluetooth Connection

The Bluetooth setting is used to connect (pair) the monitor with output devices via Bluetooth. Before a Bluetooth master device can connect with the X-100M (slave device), the devices must be paired. The X-100M will connect when the master device initiates a connection.

On the X-100M monitor, the Bluetooth symbol is green when Bluetooth is connected to a host, white when it is enabled but not connected, and gray when it is disabled.

Determine the Bluetooth Address and PIN for the Monitor

1. Press **Menu**.
2. Press **Right** three times to highlight the System tab. System Menu screen displays.
3. Use the navigation buttons to move to and highlight "Bluetooth."
4. Press **Select**. Bluetooth information pop-up window displays.
5. Note the Bluetooth Address and PIN on the screen. These numbers are used when pairing the device to the host system. Refer to the host system's operator's manual for additional information.

WARNING: The user must verify the device Bluetooth pairing to ensure the correct patient is remotely monitored.

NOTE: If the Bluetooth radio in the X-100M monitor needs to be disconnected from the host device, there are three ways to disconnect it: 1) use the host device, 2) disable the monitor's Bluetooth radio (see "Enable/Disable Bluetooth Radio" on page 55"), or 3) cycle power on the monitor.

Bluetooth Security

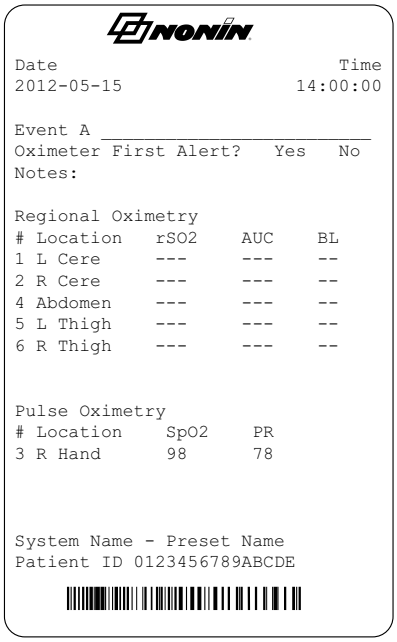
The Bluetooth radio contained in the X-100M monitor is compliant to version 2.0 of the Bluetooth Specification. It supports the Serial Port Protocol (SPP) with security mode 2 (service level enforced). The supported encryption key size is up to 128 bits and encryption is enforced on all outgoing and incoming data channels. While the X-100M monitor is in a Bluetooth connection, it will be unavailable for other connections. If the Bluetooth connection is unused, it is recommended that the Bluetooth radio be disabled to provide additional security from unintended connections.

RS-232 Connection to Printer

The optional Dymo LabelWriter® SE450 printer connects to the monitor via the RS-232 port. When the printer is connected and the RS-232 port data output mode is set to Printer, an event summary label prints each time the Event Mark button is pressed. The label (figure 31) provides the following information:

- Event date and time (if date and time are set correctly on the monitor).
- Event mark letter and space to write a patient summary for the event.
- Ability to track if oximeter provided first alert of event.
- Space to write notes.
- Regional and pulse oximetry parameters, by channel, at the time of the event (rSO_2, AUC, BL, SpO_2, and PR).
- System and preset name.
- Patient ID and bar code.

The label size is 2 5/16 x 4 inches (59 x 101 mm). Refill rolls (Dymo 30256, or compatible) are available at office supply stores.


NONIN

Date Time
2012-05-15 14:00:00

Event A _____
Oximeter First Alert? Yes No
Notes:

Regional Oximetry

#	Location	rSO2	AUC	BL
1	L Cere	---	---	--
2	R Cere	---	---	--
4	Abdomen	---	---	--
5	L Thigh	---	---	--
6	R Thigh	---	---	--

Pulse Oximetry

#	Location	SpO2	PR
3	R Hand	98	78

System Name - Preset Name
Patient ID 0123456789ABCDE

Figure 31. Sample Label from Dymo Printer

Using the Dymo Printer

1. Set the RS-232 port so it outputs to the printer.
   a. Press **Menu**.
   b. Press **Right** three times to highlight the System tab. System Menu screen displays.
   c. Use the navigation buttons to move to and highlight "Data Output Modes."
   d. Press **Select**. Pop-up window displays with Bluetooth settings highlighted.
   e. Press **Down** to highlight RS-232 settings.

f. Press **Select**. Small arrows display above and below the setting.
g. Press **Up/Down** to select “Printer.”
h. Press **Select** to save the setting.
i. Press **Menu** to close the pop-up and return to the System Menu screen.
j. Press **Menu** to return to the monitoring screen.

2. Connect the printer cable to the RS-232 port.
3. When monitoring a patient, an event summary label prints each time the Event Mark button is pressed.

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.

Data Output Formats

This device features 5 once-per-second, real-time data output formats (Nonin 1 – Nonin 5). Each data format includes an ASCII header containing model number, time, and date information. In addition, the RS-232 port outputs data through the Dymo printer (Printer).

Formats are selected from the System Menu screen (see "Set Bluetooth and/or RS-232 Data Output Formats" on page 53). Under the Data Output Modes setting, the Bluetooth and RS-232 ports have separate selection options and may use different data output formats.

NOTE: When using SenSmart download software with the monitor, the port used to download data (either Bluetooth or RS-232) must be set to Nonin 1 or Nonin 5 before connecting to the SenSmart software.

Nonin 1

NOTE: This format is not compatible with all of the X-100M's features.

Baud Rate	57,600
Delimiter	See format in table 13
Line Terminator	CR [0x0D] LF [0x0A]
CRC	CRC-16 CCITT (XMODEM)

Data from the device are sent once per second in the following format:

Ch1=XXX Ch2=XXX Ch3=XXX Ch4=XXX 1234&$*|
yyyy-mm-ddThh:mm:ss|rSO2=xxx,xxx,xxx,xxx|HbI=xx.x,xx.x,xx.x,xx.x|
AUC=xxxx,xxxx,xxxx,xxxx|REF=xxx,xxx,xxx,xxx|HI_LIM=xxx,xxx,xxx,xxx|
LOW_LIM=xxx,xxx,xxx,xxx|ALM=xxx,xxx,xxx,xxx|SIG_QUAL_ALM=x,x,x,x|
POD_COMM_ALM=x,x,x,x|SNS_FLT=x,x,x,x\LCD_FLT=x\
LOW_BATT=x\CRIT_BATT=x\BATT_FLT=x\STK_KEY=x\SND_FLT=x\
SND_ERR=x\EXT_MEM_ERR=x\CKSUM=xxxx<CR><LF>

NOTE: The 1234&$* order shall be preserved in all alarm conditions.

Table 14. Nonin 1 Data Output Format

Parameter	Value	Following Delimiter
Ch1=XXX	Channel 1 regional oximeter value. Leading zeros blank; --- if no value available.	space
Ch2=XXX	Channel 2 regional oximeter value. Leading zeros blank; --- if no value available.	space
Ch3=XXX	Channel 3 regional oximeter value. Leading zeros blank; --- if no value available.	space
Ch4=XXX	Channel 4 regional oximeter value. Leading zeros blank; --- if no value available.	space
1234	Patient alarm indication for channel 1,2,3,4. Appears only if a channel's patient alarm is active. If not active, number does not appear (e.g., 14 means channel 1 and 4 patient alarms are active).	none
&	Appears if an equipment alarm is active.	none
$	Appears if the critical battery state is detected.	none
*	Appears if the event is marked.	|
yyyy-mm-ddThh:mm:ss	International date and time format: year, month, day, hour, minutes, seconds.	|

Table 14. Nonin 1 Data Output Format (Continued)

Parameter	Value	Following Delimiter
rSO2=xxx,xxx,xxx,xxx	Regional oximetry values for channels 1,2,3,4 in %. Leading zeros blank; --- if no value available.	|
HbI=xx.x,xx.x,xx.x,xx.x	Hemoglobin index values for channels 1,2,3,4 in grams per deciliter. Leading zeros blank; --.- if no value available.	|
AUC=xxxx,xxxx,xxxx,xxxx	Area under curve for channels 1,2,3,4. Leading zeros blank.	|
REF=xxx,xxx,xxx,xxx	Reference (low alarm limit) line values for channels 1,2,3,4. Used to calculate AUC. Leading zeros blank.	|
HI_LIM=xxx,xxx,xxx,xxx	High limit alarm setting for channels 1,2,3,4. Leading zeros blank. “OFF” if no limit set.	|
LOW_LIM=xxx,xxx,xxx,xxx	Low limit alarm setting for channels 1,2,3,4. Leading zeros blank. “OFF” if no limit set.	|
ALM=xxx,xxx,xxx,xxx	Active alarm indication for channels 1,2,3,4. Valid values: HI, MAR (marginal), LOW, OFF.	|
SIG_QUAL_ALM=x,x,x,x	Signal quality alarm indication for channels 1,2,3,4. 0 = no active alarm. 1 = active alarm.	|
POD_COMM_ALM=x,x,x,x	Pod communication alarm indication for channels 1,2,3,4. 0 = no active alarm. 1 = active alarm.	|
SNS_FLT=x,x,x,x	Sensor fault indication for channels 1,2,3,4. 0 = no active alarm. 1 = active alarm.	\
LCD_FLT=x	Display fault indicator. 0 = no fault active. 1 = fault active.	\
LOW_BATT=x	Low battery indicator. 0 = no low battery state. 1 = low battery state.	\
CRIT_BATT=x	Critical battery indicator. 0 = no critical battery state. 1 = critical battery state.	\

Table 14. Nonin 1 Data Output Format (Continued)

Parameter	Value	Following Delimiter
BATT_FLT=x	Battery fault indicator. 0 = no battery fault. 1 = battery fault active.	\
STK_KEY=x	Stuck key fault indicator. 0 = no stuck key fault active. 1 = stuck key fault active.	\
SND_FLT=x	Sound fault indicator. 0 = no sound fault active. 1 = sound fault active.	\
SND_ERR=x	Sound error indicator. 0 = no sound error active. 1 = sound error active.	\
EXT_MEM_ERR=x	External memory error indicator. 0 = no external memory error active. 1 = external memory error active.	\
CKSUM=xxxx	CRC-16 CCITT (XMODEM)[1] of all parameters and values beginning with the “C” of “Ch1” and ending with “CKSUM=”. Leading zeros if appropriate.	<CR><LF>

[1] CRC-16 CCITT (XMODEM) Algorithm

Algorithm Details:

- Initial value: 0
- Polynomial: $x^{16} + x^{12} + x^5 + 1$ [0x1021]
- XOR out: 0
- Reflection: none

Test

- Run algorithm against the string of ASCII characters “123456789”
- Result should be 0x31C3

Nonin 2

NOTE: This format is not compatible with all of the X-100M's features.

Baud Rate	9,600
Delimiter	Comma [0x2C]
Line Terminator	CR [0x0D] LF [0x0A]
CRC	N/A

Column 1	Column 2	Column 3	Column 4
Current value of Channel 1	Current value of Channel 2	Average of Channel 1 and Channel 2	0

Missing data is output as -1.

Nonin 3

NOTE: This format is not compatible with all of the X-100M's features.

Baud Rate	9,600
Delimiter	One or more consecutive spaces [0x20]
Line Terminator	LF [0x0A] CR [0x0D]
CRC	N/A

Version	Date	Time	Channel Name	rSO_2	Event	Status	Baseline	AUC	UAL	LAL	A	B	C
99.99.99/1/1	mm/dd/yy	hh/mm/ss	These columns repeat per channel										

Continues with:

Sensor ID 1	Sensor ID 2	Sensor ID 3	Sensor ID 4
s/n	s/n	s/n	s/n

Version is 99.99.99/1/1.

Date: month, day, year

Time: hour, minutes, seconds

Channel names:

L = Channel 1
R = Channel 2
S1 = Channel 3
S2 = Channel 4

rSO_2 readings for missing data outputs as 0.

Event: 0 = no event; 1 = miscellaneous event.

Status values:

1 = Pod connected with no sensor (sensor fault)
2 = Excessive light indication (used for poor signal quality)
4 = Good signal quality, valid rSO_2 readings occurring
5 = rSO_2 high alarm
6 = rSO_2 low alarm
7 = Pod became connected to the system
9 = Critical battery alarm
11 = Pod is not connected to the system

Baseline and AUC are the current values.

UAL is the upper alarm limit. 0 = OFF.

LAL is the lower alarm limit. 0 = OFF.

A, B, C are 0.

Sensor ID is the sensor image number.

Nonin 4

NOTE: This format is not compatible with all of the X-100M's features.

Baud Rate	9,600
Delimiter	One or more consecutive spaces [0x20]
Line Terminator	LF [0x0A] CR [0x0D]
CRC	N/A

Date	**Time**	**rSO_2**	**Event**	**Status**	**A**	**B**	**C**	**D**	**Sensor ID 1**	**Sensor ID 2**	**Sensor ID 3**	**Sensor ID 4**
mm/dd/yy	hh/mm/ss	These columns repeat per channel							s/n	s/n	s/n	s/n

Date: month, day, year

Time: hour, minutes, seconds

rSO_2 readings for missing data outputs as 0.

Event: 0 = no event; 1 = miscellaneous event

Status values:

1 = Pod connected with no sensor (sensor fault)
2 = Excessive light indication (used for poor signal quality)
4 = Good signal quality, valid rSO_2 readings occurring
5 = rSO_2 high alarm
6 = rSO_2 low alarm
7 = Pod became connected to the system
9 = Critical battery alarm
11 = Pod is not connected to the system

A, B, C, and D are 0.

Sensor ID is the sensor image number.

Nonin 5

This data format was designed to be extensible. Future enhancements to the Model X-100M may be included in the data output. As these enhancements become available, new column labels may be added at any position within the data format.

Baud Rate	57,600
Delimiter	Comma [0x2C]
Line Terminator	CR [0x0D] LF [0x0A]
CRC	CRC-16 CCITT (XMODEM)

Date	Time	System Name	Preset Name	Channel Data Columns	Event	Error Code	CRC16
yyyy-mm-dd	hh:mm:ss			The data columns for each connected channel vary depending on the type of sensor connected.		EXX	

Date: year, month, day

Time: hour, minutes, seconds

System name is the name assigned to the system.

Preset name is the name of the preset in use.

Channel data columns: see below for regional oximeter columns, pulse oximeter columns, and unrecognized oximeter columns.

Event: 0 = no event; 1 = miscellaneous event.

Error_Code: See table 13 in the Error Codes section for error code information.

CRC16 is CRC-16 CCITT[1].

[1] CRC-16 CCITT (XMODEM) Algorithm

Algorithm Details:
- Initial value: 0
- Polynomial: $x^{16} + x^{12} + x^5 + 1$ [0x1021]
- XOR out: 0
- Reflection: none

Test
- Run algorithm against the string of ASCII characters “123456789”
- Result should be 0x31C3

Regional Oximeter Columns

When a regional sensor is attached to the signal processor, the channel data columns are the following:

Channel	Name	rSO_2	HbI	AUC	BL	UAL_rSO_2	LAL_rSO_2	Status

Channel is the channel number.

Name is the sensor site name.

rSO_2, HbI, AUC and BL are the current values. Blank if data is missing [dashes on display].

UAL is the current upper alarm limit value.

LAL is the current lower alarm limit value.

Status is defined by the following and are active high:

Bit 7	Bit 6	Bit 5	Bit 4	Bit 3	Bit 2	Bit 1	Bit 0
Measurement Accuracy: 0 = Absolute 1 = Trending	Low Alarm: 0 = Auto 1 = Manual	rSO_2 High	rSO_2 Low	rSO_2 Marginal	Sensor Fault	Pod Comm. Lost	Signal Quality

Pulse Oximeter Columns

When a pulse oximetry sensor is attached to the signal processor, the channel data columns are the following

Channel	Name	SpO_2	PR	UAL_SpO_2	LAL_SpO_2	UAL_PR	LAL_PR	Status

Channel is the channel number.

Name is the sensor site name.

SpO_2, PR are the current values. Blank if data is missing [dashes on display].

UAL is the current upper alarm limit value.

LAL is the current lower alarm limit value.

Status is defined by the following and are active high:

Bit 7	Bit 6	Bit 5	Bit 4	Bit 3	Bit 2	Bit 1	Bit 0
Low Perfusion	PR High	PR Low	SpO_2 High	SpO_2 Low	Sensor Fault	Pod Comm. Lost	Signal Quality

Unrecognized Oximeter Columns

When there is no sensor attached to the signal processor, the channel data columns are the following

Channel	Name	Status

Channel is the channel number.

Name is the sensor site name.

Status is defined by the following and are active high:

Bit 7	Bit 6	Bit 5	Bit 4	Bit 3	Bit 2	Bit 1	Bit 0
Unused	Unused	Unused	Unused	Unused	Unrecognized Sensor	Pod Comm. Lost	Unused

Printer

This data output format was designed to work with the Dymo LabelWriter SE450 Label Printer. See "RS-232 Connection to Printer" on page 63 for more information.

SenSmart Download Software

The SenSmart oximetry system has comprehensive data management capability. Confidential patient data is extracted from the system via Bluetooth or the RS-232 serial port using the SenSmart Download Software. During memory download, *TX* displays on the left side of the monitoring screen along with a percentage that shows the download progression.

Each data record in the SenSmart system is identified by date and time. On a host computer, files are identified by the date and time, extracted, and stored as either raw data or as a .pdf. The files comply with standards defined in the STS National Adult Cardiac Surgery Database.

For instructions on using the data management feature, please see the SenSmart Download Software User Guide, which is found on the SenSmart Download Software CD included with the system.

System Requirements

- Operating system: Windows® 7 (32 and 64 bit), Windows 8 (32 and 64 bit), Windows 10 (32 and 64 bit)
- Bluetooth communication device or RS-232 serial port
- 1024 x 768 monitor resolution
- CD/DVD drive
- 50 MB free space on hard drive

Installing SenSmart Download Software

Nonin's SenSmart patient data management software works with Microsoft Windows operating systems. It allows users to transfer recorded patient data from the device to a PC and then analyze, report, and archive the data.

To install the software:

1. Insert the CD into the computer's CD/DVD drive.
2. Installation should start automatically. If it does not start automatically, initiate installation by:
   - Windows 7 operating systems: From the Start menu, place the cursor in the Search box and type **D:\setup.exe** (where D is the letter of the CD/DVD drive).
   - Windows 8 operating systems: Right click on the Start screen to display the App bar. Click or tap **All apps** on the App bar, and then click or tap **Computer**. Double-click or double-tap the CD/DVD icon or the folder with the installation set-up. Double-click or double-tap **setup.exe**.
   - Windows 10 operating systems: Open **File Explorer**. Browse to the CD/DVD drive. Double-click **Setup.exe**.
3. Follow the on-screen instructions until the software install completes.
4. For help using the SenSmart Download Software, open the software and then go to Help > User Guide.

Care and Maintenance

The advanced digital circuitry within the Model X-100 system components requires no calibration or periodic maintenance other than battery replacement in the X-100M monitor by qualified technical professionals.

Field repair of the Model X-100 system components is not possible. Do not attempt to open the case of any of the system components or repair the electronics. Opening the case may damage the component and void the warranty. If the device or system is not functioning properly, see "Troubleshooting" on page 76.

The Oxitest^{Plus7} (software rev. 2.5 or greater) by Datrend Systems, Inc. can be used to verify operation of the pulse oximeter.

CAUTIONS:

- Follow local, state and national governing ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries.
- Use only Nonin-approved battery packs.
- Batteries are a fire hazard if damaged. Do not damage, mishandle, disassemble, service, or replace with non-specified components.
- Do not charge Li-Ion batteries at a temperature of 0 °C (32 °F) or less as this may result in significantly reduced battery life.

Cleaning Instructions

The following cleaning instructions apply to the X-100M monitor, X-100SP signal processor, X-100H hub, X-100HH hub holster, X-100EC extension cable, and INT-100 intermediate cable.

1. Wipe the component with a soft cloth dampened with a 10% bleach/90% water solution (household bleach [containing less than 10% sodium hypochlorite]). Do not use undiluted bleach or any cleaning solution other than those recommended here, as permanent damage could result.
2. Dry with a soft cloth or allow to air dry.

WARNING: Protect from exposure to water or any other liquid, with or without AC power.

CAUTION: Do not place the device in liquid or clean it with agents containing ammonium chloride, isopropyl alcohol, or products that are not listed in this operator's manual.

Parts and Accessories

For more information about Nonin parts and accessories:

- See the Part 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

WARNING: Use the Model X-100M only with power adapters supplied by Nonin Medical.

WARNING: The use of signal processors, sensors, accessories, and cables other than those listed in the Parts and Accessories List may result in increased electromagnetic emission and/or decreased immunity of this device.

WARNING: Use only Nonin-branded oximeter sensors. These sensors are manufactured to meet the accuracy specifications for Nonin oximeters. Using other manufacturers' sensors can result in improper oximeter performance.

Troubleshooting

Problem	Possible Cause	Possible Solution
Monitor will not activate.	The unit has no power	Plug in the AC power adapter.
Monitor will not operate on battery power.	The battery pack is not charged.	Plug in the Model X-100M AC power adapter to charge the battery pack.
	The battery pack is inoperable.	Contact Nonin Technical Service for repair or replacement.
Monitor displays the message *Verify sensor types and limits!*	The sensor types connected to the monitor do not match the preset selected for the case.	Verify the sensors connected are correct for the case. Verify the alarm limits in the preset.
Signal processor is attached, but the channel does not appear on the display.	The signal processor is damaged.	Turn the monitor off and then back on again. If the signal processor still does not display, go to the System Menu, and then the System Information pop-up. If the channel is not in the list of attached sensors, the signal processor is not communicating to the display device. Contact Nonin Technical Service.
One or more channels display the message *Duplicate X-100SP*.	Duplicate signal processors are attached to the hub.	Verify that duplicate signal processors are not attached to the hub. Remove or replace the duplicate signal processor.
Dashes (---) appear in a %rSO_2 or %SpO_2 display.	Sensor or signal processor is disconnected.	Check the connections between the sensor, the intermediate cable, and the signal processor and between the hub and the monitor. Ensure all connections are secure.
	The Model X-100M display is not functioning.	Contact Nonin Technical Service.
	The signal from the sensor is inadequate.	rSO_2: Reposition sensor. Position sensor at different site. SpO_2: Reposition the sensor or apply the sensor to a different digit, and keep the sensor motionless for at least 10 seconds. Warm the sensor application site.

Problem	Possible Cause	Possible Solution
Dashes (---) appear in a %rSO$_2$ display.	The sensor is damaged.	Remove the sensor from the patient and observe the sensor emitters while the system is on. If both emitters do not flash red, replace the sensor. Ensure both emitters flash red on new sensor.
Dashes (---) appear in a %SpO$_2$ display.	The digit was removed from the sensor.	Reapply the sensor or apply the sensor to a different digit.
Unable to obtain a pulse rate display.	The patient pulse strength is low.	Reposition the sensor or apply the sensor to a different digit, and keep the sensor motionless for at least 10 seconds. Warm the sensor application site.
	Circulation is reduced due to excess pressure on the sensor (between the sensor and a hard surface) after inserting the digit.	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 digit without fingernail polish or an artificial nail.
	Excessive patient motion.	Reduce patient motion.
An error code appears in the display area.	The monitor encountered an error.	Turn the monitor off and then back on again to remove the error code. If the error persists, note the error code and contact Nonin Technical Service.

Problem	Possible Cause	Possible Solution
The monitor is in alarm mode, but no audible alarms can be heard.	The 2-minute Alarm Silence button is activated.	Press Alarm Silence to re-engage alarm volume, or wait 2 minutes. After 2 minutes, alarm tones automatically re-engage.
	Audible volume is turned down.	Adjust volume through the System Menu screen.
Sensor LED is not lit.	Signal processor initialization error.	Disconnect the signal processor. Wait 5 seconds and reconnect signal processor. If problem continues, contact Nonin Technical Service.
Bluetooth symbol is yellow.	Fault within the Bluetooth module.	Contact Nonin Technical Service.

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 - 45 87 130 (Europe).

Service, Support, and Warranty

Service and Support

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 55441-5443 USA

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

Nonin Medical B.V.
Doctor Paul Janssenweg 150
5026 RH Tilburg, Netherlands

+31 (0)13 - 45 87 130 (Europe)
E-mail: technicalserviceintl@nonin.com

nonin.com

WARNING: 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.

Warranty

NONIN MEDICAL, INCORPORATED, (Nonin) warrants to the purchaser, for a period of 1 year from the date of purchase, each Model X-100M battery pack and INT-100 intermediate cable. Nonin warrants the X-100M monitor, X-100SP signal processors, X-100H hub, X-100HH hub holster, and X-100EC extension cables for a period of 1 year from the date of purchase. Extended warranties are available on most Nonin oximeter models. Please consult your local Nonin distributor for additional information.

Nonin shall repair or replace any X-100M monitor, X-100SP signal processor, X-100H hub, X-100HH hub holster, X-100EC extension cable, or INT-100 intermediate cable found to be defective in accordance with this warranty, free of charge, for which Nonin has been notified by the purchaser by serial number that there is a defect, provided said notification occurs within the applicable warranty period. This warranty shall be the sole and exclusive remedy by the purchaser hereunder for any Model X-100 system component delivered to the purchaser which is found to be defective in any manner, whether such remedies be in contract, tort, or by law.

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

The Model X-100 oximetry system is a precision electronic instrument and must be repaired by qualified technical professionals. Accordingly, any sign or evidence of opening the device, field service by non-authorized personnel, tampering, or any kind of misuse or abuse of the device, 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, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing.

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

WARNING: Portable RF communications equipment such as cell phones or radios (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the ME system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Manufacturer's Declaration

Essential Performance

Essential Performance of the SenSmart X-100 Oximetry System includes SpO2 Accuracy, Pulse Rate Accuracy, rSO2 Accuracy, and Limit Alarm Conditions or generation of a Technical Alarm Condition. Accuracies or alarms may be affected as a result of exposure to electromagnetic disturbances that are outside of the environments listed in the Indications For Use. If issues are experienced, move Nonin system away from the source of electromagnetic disturbances.

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

Table 15. Electromagnetic Emissions

Emissions Test	Compliance
This device is intended for use in the electromagnetic environment specified in the Indications For Use.	
RF Emissions CISPR 11	Group 2
RF Emissions CISPR 11	Class B
Harmonic Emissions IEC 61000-3-2	Class A
Voltage Fluctuations/Flicker Emissions IEC 61000-3-3	Within limits of IEC 61000-3-3

Table 16. Electromagnetic Immunity

Immunity Test	Compliance Level	
This device is intended for use in the electromagnetic environment specified in the Indications For Use.		
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	
Electrical Fast Transient/Burst IEC 61000-4-4	±2 kV for power supply lines ±2 kV for input/output lines	
Surge IEC 61000-4-5	±0.5kV, ±1kV, ±2kV for Line-to-Ground ±0.5kV, ±1kV for Line-to-Line	
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	0% UT for 0.5 Cycles at 50 Hz at 0, 45, 90, 135, 180, 225, and 315° Phase 0% UT for 1 Cycle at 50 at 0°Phase 70% UT for 25 Cycles at 50 Hz at 0°Phase 0% UT for 250 cycles at 50 Hz at 0°Phase	
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	30 A/m	
Conducted RF IEC 61000-4-6	150 kHz to 80 MHz	3 Vrms
	ISM and Amateur radio bands between 150 kHz to 80 MHz	6 Vrms
Radiated RF IEC 61000-4-3	80 MHz – 2.7 GHz	10 V/m
	380 – 390 MHz	27 V/m
	430 – 470 MHz	28 V/m
	704 – 787 MHz	9 V/m
	800 – 960 MHz	28 V/m
	1.7 – 1.99 GHz	28 V/m
	2.4 – 2.57 GHz	28 V/m
	5.1 – 5.8 GHz	9 V/m
Note: U_T is the AC mains voltage before application of the test level.		

Equipment Response Time

If the signal from the sensor is inadequate, the last measured values freeze for 20 seconds and are then replaced with dashes.

SpO_2 Values	Response	Latency
Fast Averaged SpO_2	3 second or faster exponential time constant	2 beats

Pulse Rate Values	Response	Latency
Fast Averaged Pulse Rate	3 second or faster exponential time constant	2 beats

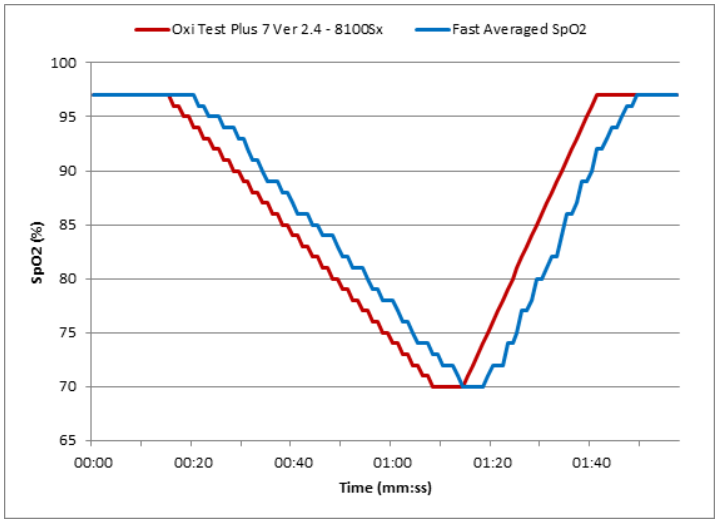
Equipment Delays	Delay
Display Update Delay	1.5 – 2.5 seconds*
Alarm Signal Generation Delay	0 seconds

* In all configurations, the display update delay is typically less than 2 seconds.

Example – SpO_2 Exponential Averaging

SpO_2 decreases 1.0% every 2 seconds (5% over 10 seconds)

Pulse Rate = 75 BPM



Specific to this example:

- The response of the SpO_2 average is 6 seconds.

Testing Summary

rSO_2 Principles of Operation

Model X-100SP signal processor uses calculations based on the Beer-Lambert law or Beer's law, to determine regional oxygenation. The Beer-Lambert law relates the absorption of light to the properties of the material through which the light is traveling. The law states that there is a logarithmic relationship between the concentration of compounds and the transmission of light through it. By utilizing wavelengths of light that are absorbed by the compounds to be measured, the concentration of the compounds can be determined. For regional oximetry, the compounds of interest are hemoglobin, deoxygenated hemoglobin, and tissue.

The oximetry sensors use a proprietary, patented arrangement of light emitters (LEDs) and light detectors (photodiodes). This arrangement effectively provides a "deep tissue" absorption measurement focused on the cerebrum. The absorption measurement is largely unaffected by surface or near-surface features, irregularities, or substances.

SpO_2 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 the volume fluctuates with each pulse.

rSO_2 Accuracy Testing

rSO_2 accuracy testing was conducted by Nonin Medical, Inc., as described below:

8003CA/8004CA/8204CA

At an independent research laboratory, rSO_2 accuracy testing was conducted during induced hypoxia studies on healthy, non-smoking, light- to dark-skinned subjects that were 18 years of age and older. The measured regional hemoglobin saturation value (rSO_2) of the sensors was compared to arterial/venous hemoglobin oxygen ($SavO_2$) value, determined from venous and arterial blood samples. The model used for blood in the brain was 70% venous and 30% arterial, which is applicable under normocapnic conditions. The venous blood was drawn from the right jugular bulb. The accuracy of the sensors in comparison to the blood gas analyzer samples measured over the rSO_2 range of 45 – 100%. Accuracy data was calculated using the root-mean-squared (A_{rms} value) for all subjects, per ISO 80601-2-61, Medical Electrical Equipment—Particular requirements for basic safety and essential performance of pulse oximeter equipment.

8004CB/8004CB-NA

rSO_2 accuracy testing was conducted in cardiac catheterization laboratories on sick, male and female, pediatric patients ranging in age from 4 days to 10 years with light- to dark-skin. The measured regional hemoglobin saturation value (rSO_2) of the sensors is compared to arterial/venous hemoglobin oxygen ($SavO_2$) value, determined from venous and arterial blood samples. The model used for blood in the brain was 70% venous and 30% arterial. The venous blood was drawn from the right jugular bulb. The accuracy of the sensors in comparison to the blood gas analyzer samples measured over the rSO_2 range of 45 – 95%. Accuracy data was calculated using the root-mean-squared (A_{rms} value) for all subjects, per ISO 80601-2-61, Medical Electrical Equipment—Particular requirements for basic safety and essential performance of pulse oximeter equipment.

SpO_2 Accuracy Testing

During motion and no-motion conditions at an independent research laboratory, SpO_2 accuracy testing was conducted during induced hypoxia studies on healthy, male and female, non-smoking, light- to dark-skinned subjects that were 18 years of age and older. The measured arterial hemoglobin saturation value (SpO_2) of the sensors was 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 was calculated using the root-mean-squared (A_{rms} value) for all subjects, per ISO 80601-2-61, Medical Electrical Equipment—Particular requirements for basic safety and essential performance of pulse oximeter equipment.

Pulse Rate Accuracy Testing (Motion and Non-motion)

This test measured pulse rate oximeter accuracy with and without 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 Accuracy 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 pulse rate and SpO_2 at the lowest obtainable pulse amplitude (0.3% modulation).

Specifications

CAUTION: The device has been designed for use within the specified ranges. Use outside of these ranges has not been tested and may result in improper oximeter performance.

Oxygen Saturation Display Ranges:	
	rSO_2: 0 to 100%
	SpO_2: 0 to 100%
Pulse Rate Display Range:	18 to 300 beats per minute (BPM)
Sensor Accuracy:	For declared accuracy data for compatible sensors, refer to the sensor Instructions for Use (IFU). Sensor IFUs are included on the operator's manual CD.
Measurement Wavelengths and Output Power [a]:	Refer to sensor IFU for details. Sensor IFUs are included on the operator's manual CD.
Alarm Volume (at 1 m):	15: 75 dBA 8: 61 dBA
Informational Tone Volume (at 1 m):	67 dBA
Memory:	840 hours (operating with 2 channels) 420 hours (operating with 4 channels) 280 hours (operating with 6 channels)
Temperature (X-100M, X-100SP, X-100H, INT-100):	
Operating:	0 ºC to 40 ºC (32 ºF to 104 ºF)
Storage/Transportation:	-30 ºC to 70 ºC (-22 ºF to 158 ºF)
Humidity (X-100M, X-100SP, X-100H, INT-100):	
Operating:	15% to 93% noncondensing
Storage/Transportation:	Up to 93% noncondensing
Altitude (X-100M, X-100SP, X-100H, INT-100):	
Operating:	0 to 4,000 meters (13,124 feet)
Power Requirements (Mains):	100 – 240 VAC 50 – 60 Hz
Internal Power:	
Battery:	7.4 volt Li-ion battery pack, 3.8 Ah when charged
Operating Life (fully charged battery and screen at default brightness):	6 hours minimum (operating with 1 channel) 3 hours minimum (operating with 2 channels) 2 hours minimum (operating with 4 channels) 1 hour minimum (operating with 6 channels)
Storage Life:	20 days minimum
Recharge Time to 90% Capacity:	2.5 hours maximum

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

Dimensions:	
X-100M:	305 mm W x 180 mm H x 130 mm D (12.0 in. W x 7.2 in. H x 5.0 in. D)
X-100H:	105 mm W x 66 mm H x 22 mm D with 4.0 m cable (4.14 in. W x 2.6 in. H x 0.86 in. D with 13.1 ft cable)
X-100SP:	21.4 mm H x 21.7 mm W x 72.7 mm L (including strain relief) with 0.75 m cable (0.84 in. H x 0.85 in. W x 3.1 in. L (including strain relief) with 2.5 ft cable)
INT-100:	Approximately 40.6 cm (16 in.)
Weight:	
X-100M:	Approximately 900 grams (2 pounds)
X-100H:	243 grams (8.6 ounces)
X-100SP:	40 grams (1.4 ounces)
INT-100:	Approximately 19 grams (0.67 ounces)
Warranty:	
X-100M, X-100SP, X-100H, X-100HH, X-100EC:	1 year
X-100M Battery Pack, INT-100:	1 year
Classification per IEC 60601-1 / CAN/CSA-C22.2 No. 601.1 / UL60601-1:	
Type of Protection:	Internally powered (on battery power). Class II with AC adapter.
Degree of Protection:	Defibrillation Proof Type BF Applied Part
Mode of Operation:	Continuous
Enclosure Degree of Ingress Protection:	
X-100M, X-100H, X-100SP:	IP32

Transmitter

Bluetooth Compliance:	Version 2.0
Operating Frequency:	2.4 to 2.4835 GHz
Output Power:	< 20 dBm
Operating Range:	100-meter (328-feet) radius indoors (line of sight when connected to a class I device)
Network Topology:	Star
Operation:	Bluetooth Slave
Antenna Type:	Internal
Modulation Type:	Gaussian Frequency Shift Keying
Band Width:	1 MHz
Bluetooth Profiles Supported:	Serial Port Profile (SPP)
Security Mode:	Mode 2 (service level enforced security)
Authentication and Encryption:	Enforced on all data channels (outgoing and incoming)
Encryption Key Size:	Up to 128 bits

External Monitor Installation Instructions

Philips Monitors

The Model X-100 SenSmart universal oximetry system communicates with the Philips Patient Monitoring System using an Interface Module and a cable (figures 32 and 34). See the appropriate “Setting up the Connection” section for detailed steps.

Components

- Nonin Model X-100 oximetry system
- Philips IntelliVue™ Patient Monitoring System (MP40/50/60/70/90, MX600/700/800, running software revisions H.0 and above)

VueLink Components

- Philips M1032A#A05 VueLink Interface Module Auxiliary Plus (Type B) with Digital Open Interface Driver (Philips P/N M1032-60605)
- VueLink Open Interface Cable with 9-Pin Connector (Philips P/N M1032-61699)
- Philips M1032A VueLink Module Handbook (Philips P/N M1032-9000D)

IntelliBridge Components

- IntelliBridge EC10 Interface Module (Philips P/N 865115 #A01), running the IB-ED101-A.2 Open Interface Device Driver
- IntelliBridge EC5 ID Module (Philips P/N 865114 #104)
- Patch cable, CAT5 or better, straight wired
- Philips Instructions for Use and Service Information for Devices Using the IntelliBridge Open Interface (Philips P/N 4534 642 15921)

Connection Specifications

Baud Rate (X-100M Communication to Interface Module): 19200

Word Length: 8 Bit

Start Bit: 1

Stop Bit: 1

Parity: None

Connecting the X-100M Monitor to the Philips Monitor

Once the connection between the X-100M monitor and the Philips monitor is established, the X-100M monitor transfers patient numerics (rSO_2 and AUC), as well as patient and equipment alarms, to the Philips monitor. A Philips monitor with a VueLink Interface Module can display up to 6 numerics at a time. A Philips monitor with an IntelliBridge EC10 Interface Module can display up to 8 numerics at a time.

The connection procedure only needs to be completed once. When complete, the X-100M and Philips monitor should communicate even after disconnecting/reconnecting the X-100M or after cycling power.

NOTES:
- The Open Interface Protocol is unidirectional. The Philips monitor can display data received from the X-100M monitor, but cannot remotely control the X-100M.
- Due to the specific features of the Open Interface Protocol, the data transmission from the X-100M to a Philips monitor may be delayed by several seconds.

X-100M Configuration

The X-100M monitor is a plug and play device. It does not require any configuration to be used with the Philips monitor. The monitor detects the connection and begins communicating automatically.

NOTE: If the X-100M monitor's display language is changed during operation, the language displayed on the Philips monitor will not update until the X-100M monitor is powered off and then on again.

Philips Interface Module Installation and Configuration

A Philips-authorized technician installs the Interface Module. During installation, the technician activates the module so it will operate with any external device that supports the Open Interface.

NOTE: The instructions below refer to the Philips IntelliVue MP50 patient monitor. The procedure to set up the connection may vary slightly for other Philips IntelliVue models.

Setting Up the Connection – VueLink

To connect the X-100M monitor to a Philips monitor:

1. Switch the Philips monitor OFF.
2. Verify the VueLink Interface Module has been inserted in the module rack of the Philips monitor (done by a Philips authorized technician).
3. Connect the VueLink connection cable to the VueLink Interface Module (see figure 32).
4. Connect the VueLink connection cable to the RS-232 serial data port on the back of the X-100M monitor. Use the screws to secure the cable to the serial data port.

NOTE: RS-232 extension cables should not be used.

5. Turn on the X-100M monitor.
6. Turn on the Philips monitor. Ensure the Open Interface LED on the VueLink Interface Module is lit. This indicates the module has correctly been identified and configured by the Philips monitor (contact a Philips authorized technician if the VueLink Interface Module has not been configured).
7. Communication between the X-100M and Philips monitor should be established within approximately 45 seconds. Once established, MPM (multi-parameter mode) displays on the left side of the X-100M monitor (figure 33).

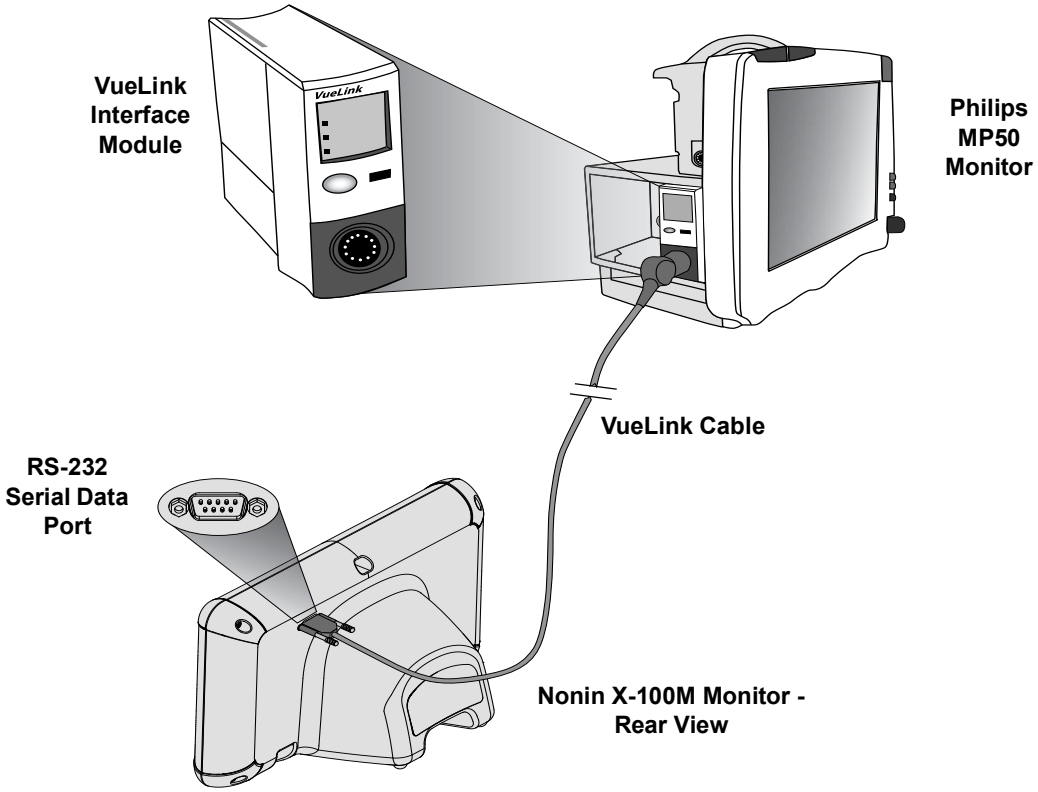


Figure 32. X-100M Connection to Philips Monitor with VueLink

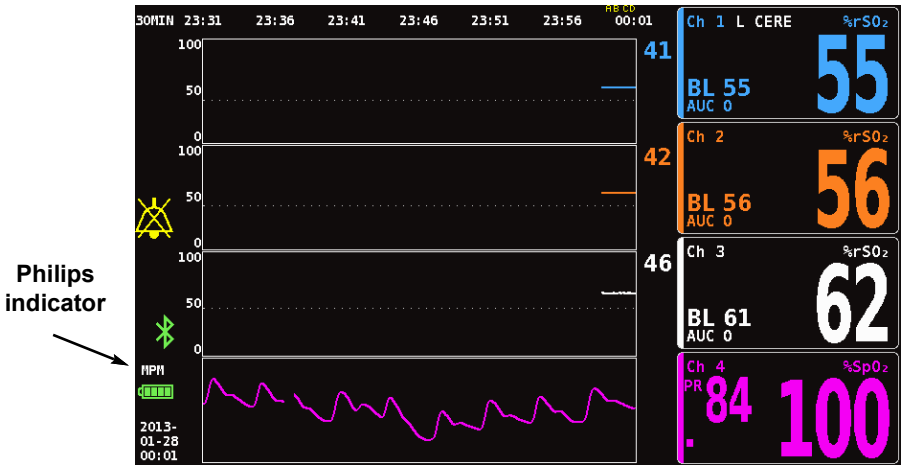


Figure 33. Philips Indicator on Model X-100M Display

Setting Up the Connection – IntelliBridge

To connect the X-100M monitor to a Philips monitor:

1. Switch the Philips monitor OFF.
2. Verify the EC10 Interface Module has been inserted in the module rack of the Philips monitor (done by a Philips-authorized technician).
3. Connect the IntelliBridge patch cable to the EC10 Interface Module (see figure 34).
4. Connect the patch cable to the IntelliBridge EC5 ID module.
5. Connect the EC5 module to the RS-232 serial data port on the back of the X-100M monitor. Use the screws to secure the module to the serial data port.

NOTE: RS-232 extension cables should not be used.

6. Turn on the X-100M monitor.
7. Turn on the Philips monitor. Ensure the Open Interface LED on the Interface Module is lit. This indicates the module has correctly been identified and configured by the Philips monitor (contact a Philips-authorized technician if the Interface Module has not been configured).
8. Communication between the X-100M and Philips monitor should be established within approximately 45 seconds. Once established, MPM (multi-parameter mode) displays on the left side of the X-100M monitor (figure 33).

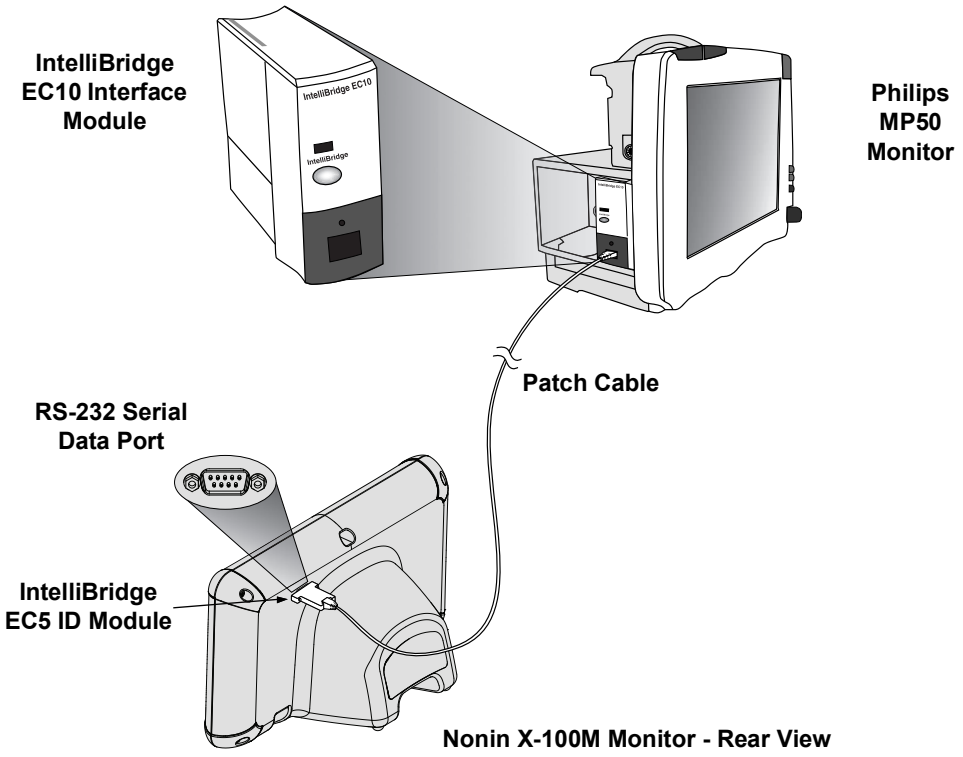


Figure 34. X-100M Connection to Philips Monitor with IntelliBridge

Philips Monitor Display Configuration

The numerics transmitted from Nonin's X-100M monitor to the Philips monitor will vary depending on which type of Philips interface module is used.

VueLink Interface Module – Nonin's X-100M rSO_2 and AUC real-time numeric data are transmitted to the Philips monitor through the VueLink Interface Module. Up to 12 numerics are transmitted at a time, and up to 6 of the patient numerics can be displayed on the Philips monitor.

IntelliBridge EC10 Interface Module – Nonin's X-100M rSO_2 and AUC real-time numeric data are transmitted to the Philips monitor through the EC10 Interface Module. Up to 12 numerics are transmitted at a time, and up to 8 of the patient numerics can be displayed on the Philips monitor.

The default numerics are rSO_2 for channels 1 through 6. The rSO_2 data trendlines for channels 1 through 4 are available on Philips IntelliVue MP40 to IntelliVue MP90 monitors running rev. H.0 and above.

NOTE: A Philips monitor may accommodate several interface modules at once. They are identified as AUXILIARY PLUS 1, AUXILIARY PLUS 2, etc. Be sure to select the proper identifier.

Setup Philips Monitor with VueLink Interface Module to Display X-100M Numerics

1. Connect the X-100M monitor to the Philips monitor (see the "Setting up the Connection" section).
2. Verify the X-100M and Philips monitors are on.
3. On the Philips monitor, enter Configuration Mode by selecting **Main Setup** key.
4. Select **Operating Modes**.
5. Select **Config**.
6. Enter the 5-digit Configuration Password and press **Enter**. The password can be found in the Philips Configuration Guide.
7. Philips monitor enters Config Mode.
8. Select **Main Setup**.
9. Select **Measurements**.
10. Select **NONIN X-100M** (see note below). Setup NONIN X-100M window opens.

NOTE: If communications between the X-100M and Philips monitor have not been established, VueLink X (where X is the VueLink module number) will appear in the Measurements menu instead of NONIN X-100M. Select VueLink X.

NOTE: After NONIN X-100M is selected, the Philips monitor pauses while VueLink re-synchronizes with the X-100M. Wait for values to appear.

11. Select a **Numeric #** to update.
    a. Drop down list, which show the available and in-use numerics, displays to right of the numerics. **NOTE:** The X-100M channel number appears at the end of the numeric (e.g., AUC 1, rSO_2-3).
    b. Select available Numeric. If a numeric is in use, it is grayed out.

c. Repeat as needed until up to 6 numerics have been assigned.

12. User may also setup Device Alarms (options include Accepted or Ignored) and Default Color. The X-100M numerics will display in the color chosen.
13. When setup is complete, select **Store to Module** to save settings to the VueLink module. Other options include Restore from Module and Recall Mod. Def. (Module Defaults).
14. In the Please Confirm task bar, user is asked to select Confirm to store new settings. Select **Confirm**.
15. Philips monitor stores active values as user defaults.
16. Close Setup NONIN X-100M window.
17. Close Measurements window.
18. Close Main Setup window.
19. To place a numeric on the Philips monitor:
    a. Select the appropriate screen configuration for the Philips monitor (see Philips IntelliVue Patient Monitor Instructions for Use [Philips P/N M8000-9001K] for screen configuration information).
    b. Using either the touch screen or the Navigation Point knob, select a numeric location on the Philips monitor. White box displays on monitor.
    c. Select the white box to open the Change Numeric window.

NOTE: If the Change Numeric window does not open, that location is not available for X-100M numerics.

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    d. Scroll up to see the 6 numerics.
    e. Choose a numeric to display on the Philips monitor.
    f. Repeat until up to 6 numerics display.
20. Exit Config Mode by shutting off the Philips monitor.
21. Turn the Philips monitor back on. Monitor is ready to use.

Setup Philips Monitor with IntelliBridge Interface Module to Display X-100M Numerics

1. Connect the X-100M monitor to the Philips monitor (see the “Setting up the Connection” section).
2. Verify the X-100M and Philips monitors are on.
3. On the Philips monitor, enter Configuration Mode by selecting **Main Setup** key.
4. Select **Operating Modes**.
5. Select **Config**.
6. Enter the 5-digit Configuration Password and press **Enter**. The password can be found in the Philips Configuration Guide.
7. Philips monitor enters Config Mode.
8. Select **Main Setup**.
9. Select **Measurements**.
10. Select **Auxiliary Device** (see note below). Setup Auxiliary Device window opens.

NOTE: After Auxiliary Device is selected, the Philips monitor pauses while the interface module re-synchronizes with the X-100M. Wait for values to appear.

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11. Select **Device Driver**.

12. Select **Setup Numerics**.
    a. Drop down list, which shows the in-use numerics, displays to right of the numerics. **NOTE:** The X-100M channel number appears at the end of the numeric (e.g., AUC 1, rSO_2-3).
    b. Numerics can be added or deleted. To add, select **Add**. Drop down list of numerics displays. Select available Numeric. If a numeric is in use, it is grayed out.
    c. Repeat as needed until up to 8 numerics have been assigned.
    d. Close Setup Numerics window.
13. In Setup Auxiliary Device window, select Open Interface.
    a. Device Alarms: Options include Accepted or Ignored.
    b. Default Color: The X-100M numerics will display in the color chosen.
14. Close Setup Auxiliary Device window.
15. Close Measurements window.
16. Close Main Setup window.
17. To place a numeric on the Philips monitor:
    a. Select the appropriate screen configuration for the Philips monitor (see Philips IntelliVue Patient Monitor Instructions for Use [Philips P/N M8000-9001K] for screen configuration information).
    b. Using either the touch screen or the Navigation Point knob, select a numeric location on the Philips monitor. White box displays on monitor.
    c. Select the white box to open the Change Numeric window.

NOTE: If the Change Numeric window does not open, that location is not available for X-100M numerics.

    d. Scroll up or down to see the 8 numerics.
    e. Choose a numeric to display on the Philips monitor.
    f. Repeat until up to 8 numerics display.
18. Exit Config Mode by shutting off the Philips monitor.
19. Turn the Philips monitor back on. Monitor is ready to use.

Alerts

The Open Interface Protocol recognizes two types of alerts: patient alarms and equipment alarms (also known as inops or inoperable conditions).

Only one alert message text of each alert type can be displayed at the Philips monitor at the same time. Therefore, a priority is assigned to each alarm and inop. All other functions related to alerts (e.g., flashing value, value removed from the display) of two or more active alerts may occur simultaneously.

NOTES:
- By default, alerts are deactivated. Activation requires access to the configuration mode of the monitor and can only be done by technical staff.
- The interface module does not allow the Philips monitor to generate audible signals at the bedside for alarms and inops generated by the X-100M monitor.

Patient Alarms

The Open Interface Protocol defines two types of patient alarms:

- **Red alarms:** Indicate potentially life-threatening situations that require an immediate response.
- **Yellow alarms:** Indicate less critical situations. A response is required, but is of less critical importance.

Alarm Messages

On Philips IntelliVue patient monitors, red alarm messages may display in the upper right corner of the monitor screen. Yellow alarm messages may display at the top of the monitor screen in the middle. For more information on Philips monitor alarm messages, see the specific monitor's documentation.

Alarm Indicators

The Philips IntelliVue patient monitor may have alarm indicators at the top, left side of the monitor. For more information on Philips monitor alarm indicators, see the specific monitor's documentation.

Table 17. Philips Monitor Patient Alarms

X-100M Alarm	Alarm Priority	Effect on Philips Display
rSO_2 Limit Low	Red	Numeric flashes. ***rSO_2 LOW** displays. Alarm indicator flashes red.
rSO_2 Limit High	Red	Numeric flashes. ***rSO_2 HIGH** displays. Alarm indicator flashes red.
rSO_2 Low Limit Warning	Yellow	Numeric flashes. ****rSO_2 LOW WARN** displays. Alarm indicator flashes yellow.

NOTE: For more information on X-100M alarms, see the "Alarms" chapter.

Equipment Alarms

The Philips monitor displays equipment alarms as “inops” or “inoperatives.” Each inop carries information either on the validity of all related measurements (general inop) or on the validity of a specific numeric. Depending on this information, the numeric may display differently on the Philips IntelliVue monitor (e.g., it may blink or be replaced with “-?-”).

On the Philips IntelliVue patient monitor, inop messages may display in the upper left corner of the monitor screen. Inop messages are blue. For more information on Philips monitor equipment alarms, see the specific monitor’s documentation.

Table 18. Philips Monitor Equipment Alarms

X-100M Alarm (Medium Priority)	Effect on Philips Display
Pod Communication Error	Numeric data disappears. **rSO_2 SP COMM ERR** displays.
Sensor Fault	Numeric data disappears. **rSO_2 SENSOR FAULT** displays.
Sensor Alarm (Signal Quality Alarm)	**?** displays next to numeric label. **rSO_2 SENSOR ALARM** displays.
Sensor Alarm (rSO_2 Data Unavailable)	Numeric data disappears. **rSO_2 UNAVAILABLE** displays.
Low Battery	**SENSMART LOW BATT** displays.
Critical Battery	**SENSMART CRIT BATT** displays.
Error Codes	Numeric data disappears. **SENSMART ERROR** displays.