Indications for Use

The Nonin Model X-100 SenSmart modular, universal oximeter system is indicated for use in simultaneously measuring, displaying, monitoring, and recording up to 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 population includes adult, pediatric, infant, and neonate through the use of SenSmart-compatible sensors.

The system is intended for use in hospitals, long-term care, medical facilities, sleep laboratories, subacute environments, and Emergency Medical Services (EMS), including patient transport. 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.

Contraindications

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.

Warnings

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. These sensors are manufactured to meet the accuracy specifications for this device. Using other manufacturers' sensors can result in improper oximeter performance.
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.
Protect from exposure to water or any other liquid, with or without AC power.
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.
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.
This device turns off after approximately 30 minutes when in low battery condition.
If this device is used adjacent to or stacked with other equipment, the device should be observed carefully to verify normal operation.

Warnings (Continued)

The battery pack must be installed at all times while the device is operating—even when operating on AC power. Do NOT use the device without batteries.
The 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.
General operation of this device may be affected by the use of an electrosurgical unit (ESU).

⚠ *Cautions*

The value of 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.
Portable and mobile RF communications equipment can affect medical electrical equipment.
Radios and cell phones or similar devices can affect the equipment and must be kept at least 2 meters (6.5 feet) away from the equipment.
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.

⚠ *Cautions (Continued)*

This device is designed to determine regional hemoglobin oxygen saturation of blood underneath the sensor and the percentage of arterial oxygen saturation of functional hemoglobin. 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
- blood flow restrictors (arterial catheters, blood pressure cuffs, infusion lines
- moisture on the skin
- moisture in the sensor
- improperly applied sensor
- incorrect sensor type
- poor pulse quality
- venous pulsations
- anemia or low hemoglobin concentrations
- cardiogreen and other intravascular dyes, or tissue dyes
- methemoglobin and other dyshemoglobins
- hemoglobinopathies
- carboxyhemoglobin
- performance has not been verified in the presence of elevated carboxyhemoglobin or bilirubin
- non-normocapnic conditions or other conditions that affect blood volume
- artificial nails or fingernail polish

Batteries are a fire hazard if damaged. Do not damage, mishandle, or disassemble.

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

Inspect the sensor application sites at least every 2 to 4 hours to ensure correct sensor alignment and skin integrity. Patient sensitivity to the sensor's adhesive may vary due to medical status or skin condition.

Do not autoclave, sterilize, ~~or~~ immerse, or spray this device ~~in~~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.

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 when the device is on. If the entire memory is filled, portions of the oldest record will be overwritten when a new record begins.

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

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.

When running on battery power, pairing must be initiated within 2 minutes of turning the device on or within 2 minutes of pressing the Bluetooth button. After 2 minutes, the Bluetooth portion of the device turns off to conserve power.

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). Failure to do so could result in inaccurate baseline values for the new patient. Each time the device 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.

The device may not work when circulation is reduced. Warm or rub the finger, or reposition the device.

In some circumstances, the device may interpret motion as good pulse quality. Minimize patient motion as much as possible.

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 1.6W/kg.

Federal Communications Commission (FCC) Notice

This equipment has been tested and found to comply with the limits for a class A 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 "Displays, Indicators, and Controls" on page 7.

Table 1. Symbols

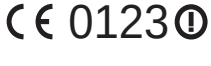
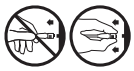
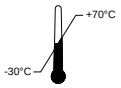
Symbol	Description
	CAUTION!
	Authorized Representative in the European Community.
	Consult instructions for use.
	Follow instructions for use.
	UL Mark for Canada and the United States with respect to electric shock, fire, and mechanical hazards in accordance with: • ANSI/AAMI ES60601-1 (2005, 3rd Ed.), CAN/CSA C22.2 No. 60601-1 (2008, 3rd Ed.), ISO 80601-2-61:2011 • UL 60601-1 and CAN/CSA C22.2 No. 601.1
	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)
	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.
	Technical Service phone numbers

Table 1. Symbols (Continued)

Symbol	Description
	Defibrillation-Proof Type BF Applied Part (patient isolation from electrical shock). (X-100SP)
	Do not discard.
	Do not pull on cable. Retract connector and remove.
	Lot Number
	Non-sterile
	Storage/shipping temperature range of -30 °C to 70 °C (-22 °F to 158 °F).
	Handle with care.
	Keep dry.

Displays, Indicators, and Controls

This chapter describes the displays, indicators, and controls for the Model X-100M.

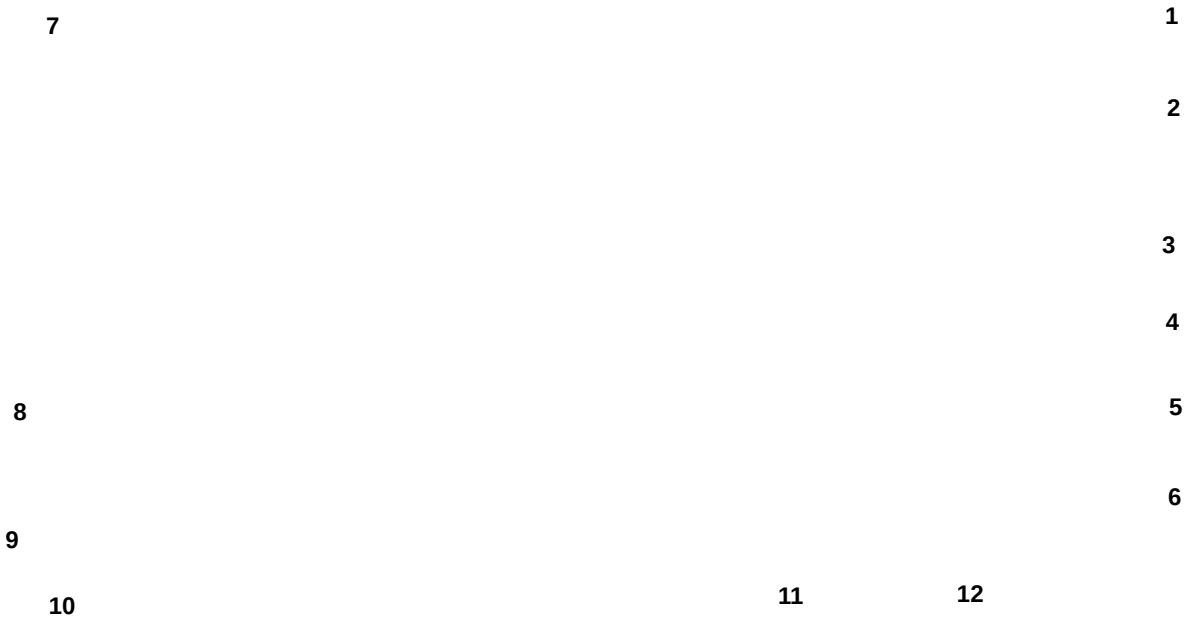


Figure 1. X-100M Front View

Table 2: 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 goes off.
2		**Event Mark Button** 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. Pressing this button for 2 seconds opens the event mark table.

Table 2: X-100M Features

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 30 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 37 for more information. • ***Case*** – allows user to user to start a new case and edit the patient ID. See "Case Menu Screen" on page 41 for more information. • ***System*** – allows user to set system settings. See "System Menu Screen" on page 43 for more information.
4		**Select Button** Pressing Select allows the user to save values when entering labels, settings, 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 readings.

6		**On/Standby Button**
		• ***On*** – Pressing this button once turns on the Model X-100M. Each time the device 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 X-100M 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 2: X-100M Features

No.	Symbol	Description
7		**Navigation Buttons** These buttons are used to navigate between fields and scroll 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**	
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	
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 a X-100H hub or a single 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.	
13	**RS-232 Cable Input** Located on the back of the monitor (shown in figure 21).	

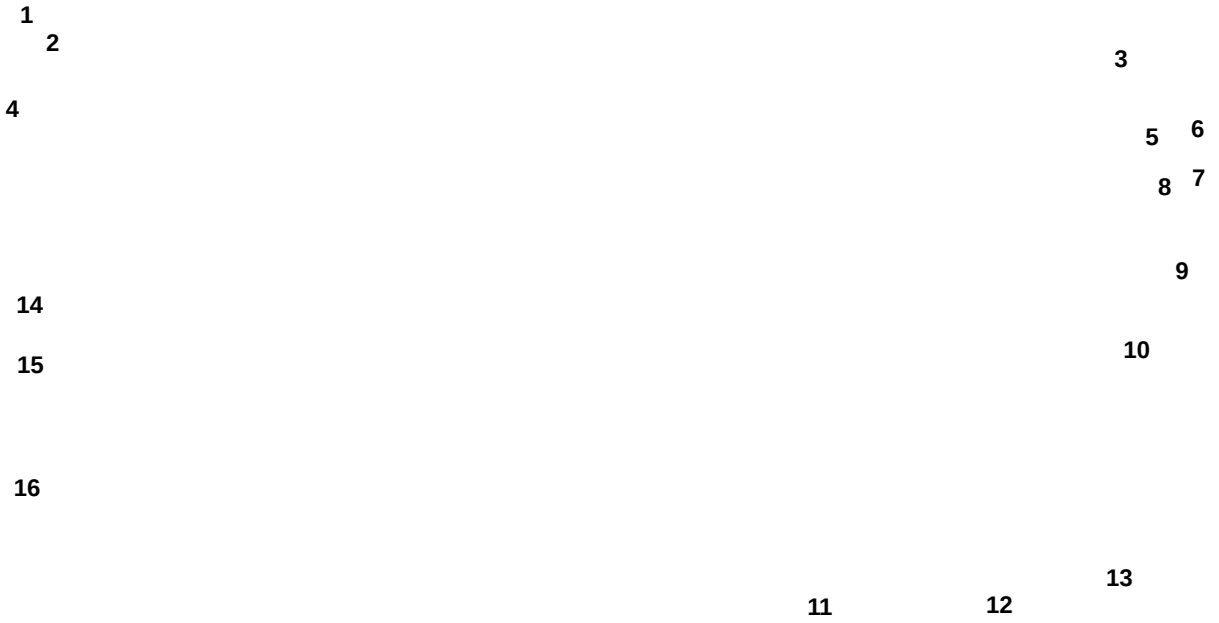


Figure 2. Monitoring Screen (Four-Channel View)

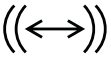
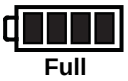
Table 3. X-100M Monitoring Screen Symbols and Indicators

No.	Symbol	Description
1	ex. 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	ex. 30MIN 4HOUR	**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 reading at a specific time on the trendline. The scrolling cursor does not display until the left navigation arrow has been pressed.
4		**Cursor Values** When the scrolling cursor is active, cursor values display on the left side of the monitor screen in a yellow box.
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.

Table 3. X-100M Monitoring Screen Symbols and Indicators (Continued)

No.	Symbol	Description
6	%rSO_2	**Regional Hemoglobin Oxygen Saturation** %rSO_2 displays from 0 to 100% when a monitored channel is setup to measure %rSO_2 or a regional sensor is attached to a signal processor. The device continually displays an rSO_2 trendline for each monitored channel. 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** The baseline value displays below the %rSO_2 value for each monitored channel. When the device 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 Individual Baseline Values" on page 35. • For instructions on setting the baseline values separately or to make finite adjustments to the baseline value, see "Set Individual Baseline Values" on page 35.
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 75% of the patient's baseline.
9	%SpO_2	**Percent Functional Hemoglobin Oxygen Saturation** %SpO_2 data displays from 0 to 100% when a channel is setup to measure %SpO_2 or a pulse oximetry sensor is connected to the system. The background of SpO_2 portion of the channel display flashes red during high priority SpO_2 alarm conditions.
10	PR 	**Pulse Rate and Pulse Rate Bar Graph** Pulse rate data displays below the %SpO_2 display when a channel is setup to measure pulse oximetry. The background of pulse rate portion of the channel display flashes red during high priority pulse rate alarm conditions.

Table 3. X-100M Monitoring Screen Symbols and Indicators (Continued)

No.	Symbol	Description
11		**Sensor Fault** This yellow indicator flashes when a sensor is disconnected, has failed, or is not compatible with the monitor.
12		**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.
13		**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.
14		**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.
15		**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 "Connect/Disconnect Bluetooth" on page 51 for more information.
16	 **Full**  **Empty**	**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 X-100M reaches a low or critical battery condition, a medium priority alarm sounds. To clear the audible alarm, plug in the device. To clear the visible alarm, cycle power.

System Components and Setup

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.

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 oximeter 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-100EC-1, 1-meter extension cable
- X-100EC-2, 2-meter extension cable
- 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.

Before Using the System

- Charge monitor
- Set clock
- Set institution defaults
- Change institution password
- Set up presets

System Configurations

Multiple Channels

X-100M → X-100H → X-100SP (up to 6) → SenSmart-compatible sensor(s)

X-100M → X-100H → X-100EC (up to 6) → X-100SP (up to 6) → SenSmart-compatible sensor(s)

Single Channel

X-100M → X-100SP → SenSmart-compatible sensor

X-100M → X-100EC → X-100SP → SenSmart-compatible sensor

Figure 3. System Components and Setting Up the Monitor

X-100M (Monitor)

The X-100M SenSmart monitor allows the user to view up to six channels of rSO_2 and SpO_2 data. Each channel is color coded to match a signal processor. See table 2 for monitor features and descriptions.

For cleaning instructions, refer to "Care and Maintenance" on page 67.

X-100H (Hub)

The X-100H hub 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 attempt to connect more than one hub in the system.

> ⚠ **CAUTION:** Do not attempt to use an extension cable between the monitor and the hub.

For cleaning instructions, refer to "Care and Maintenance" on page 67.

Figure 4. X-100H – Hub

Table 4. X-100H Features

Number	Description
1	Cable connector
2	Channel port
3	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.
   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 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.

X-100HH (Hub Holster)

The hub fits inside the X-100HH hub holster. The hub holster features a clamp that allows the hub to be attached to hospital bed rails and equipment poles.

Using the Hub Holster

1. Align the hub and hub cable to the hub holster.
2. Push firmly to insert the hub into the hub holster.

To remove the hub from the hub holster, pull the grasp the the front and the back of the hub and pull up. The back of the hub holster has a finger cut out is exposed in the hub holster cut out.

For cleaning instructions, refer to "Care and Maintenance" on page 67.

Figure 5. X-100HH – Hub Holster

Table 5. X-100HH Features

Number	Description
1	
2	
3	

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.

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 an extension cable or without.

The signal processors are color coded:

X-100SP-1, Channel 1, is blue.

X-100SP-2, Channel 2, is orange.

X-100SP-3, Channel 3, is white.

X-100SP-4, Channel 4, is purple.

X-100SP-5, Channel 5, is green.

X-100SP-6, Channel 6, is pink.

Figure 6. X-100SP – Signal Processor

Table 6. X-100SP Features

Number	Description
1	Signal processor cable connector
2	Sensor connection port
3	Sensor lock
4	Cable clip

For cleaning instructions, refer to "Care and Maintenance" on page 67.

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.

Connect/Disconnect a Signal Processor to/from Hub or Monitor

1. To connect:
   a. Align the arrow on the signal processor cable connector with the arrow on one of the hub ports or the monitor connector port.
   b. Push the signal processor cable connector into the port.
   c. The signal processor cable connector will click when it locks into the hub or monitor.
2. To disconnect:
   a. Grasp the ring on the X-100SP signal processor cable connector.
   b. Retract the ring 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.

NOTE: A signal processor can be connected to a hub port, or it can be connected directly to the monitor. When a signal processor is connected directly to the monitor, an extension cable may be used between the monitor and the signal processor.

Connect/Disconnect a Sensor to the Signal Processor

1. To connect:
   a. Flip the clear sensor lock on the signal processor back to expose the sensor connection port.
   b. Insert the sensor connector into the signal processor connection port.
   c. Flip the sensor lock over the sensor connector and click it into place.
2. To disconnect:
   a. Flip the sensor lock back to disengage the sensor lock away from the sensor connector.
   b. Grasp the sensor connector and remove the connector from the signal processor.

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 attempt to use an extension cable between the monitor and the hub.

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

For cleaning instructions, refer to "Care and Maintenance" on page 67.

Figure 7. X-100EC – Extension Cable

Cable Clips

Each extension cable is delivered with 18 cable clips (3 clips of each signal processor color). Cable clips may be attached to each end of the extension cable and the middle.

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. See the specific sensor IFU for instructions on connecting the sensor to the system and applying the sensor to the patient.

Battery

Battery capacity: 7.2 V Li-ion battery pack, 2.4 Ah when charged with the Model X-100M

Operating life (fully charged battery): 3 hours minimum

Storage life: 20-day minimum

Recharge time to 90% capacity: 2.5 hours maximum

> ⚠ **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, or disassemble.

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

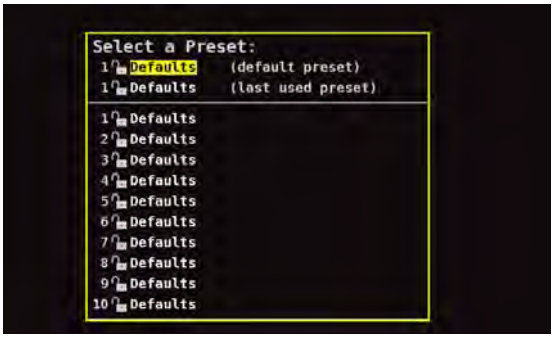
Each time the monitor is turned on, it performs a brief start-up sequence.

1. Press **On/Standby** ⏻.
2. The LCD display lights up and displays the Nonin logo (figure 8, A).
3. An audible tone sounds.
4. If applicable, the message *System clock is not set!* (figure 5,B) briefly displays.
5. Select a Preset screen displays (figure 8, C). This screen allows the user to select a preset. The default preset is selected at start-up. Other choices include the last used preset and the other presets on the monitor.

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

A

B



C

Figure 8. Start-up Screens

Sensor Application

Refer to the sensor Instructions for Use (IFU) 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 or strangulation.

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 the "Baseline" section for more information).
5.

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 25 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 30
- “Presets Menu Screen” on page 37
- “Case Menu Screen” on page 41
- “System Menu Screen” on page 43

NAVIGATION TIPS:

- When viewing the monitoring screen, the right/left navigation buttons scroll through the displayed time. The up/down navigation buttons change the timescale.
- 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 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.
- Preset passwords are set by the user and are 4 numbers in length. Preset passwords can be overridden by the instituion password.

Bluetooth Technology

Bluetooth 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 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 connection from the 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.

Connecting with Bluetooth

The Bluetooth setting is used to connect (pair) the monitor with output devices via Bluetooth.

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 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 pop-up window displays.
5. Note the Bluetooth address on the screen. This address must be chosen at the host computer.

CAUTION: When running on battery power, pairing must be initiated within 2 minutes of turning the device on or within 2 minutes of pressing the Bluetooth button. After 2 minutes, the Bluetooth portion of the device turns off to conserve power.

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

Dymo® 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 is set to Printer, an event summary label prints each time the Event Mark button is pressed. The label (figure 9) provides the following information:

- Event date and time (if date and time are set correctly on the monitor).
- Event mark letter displays along with 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.

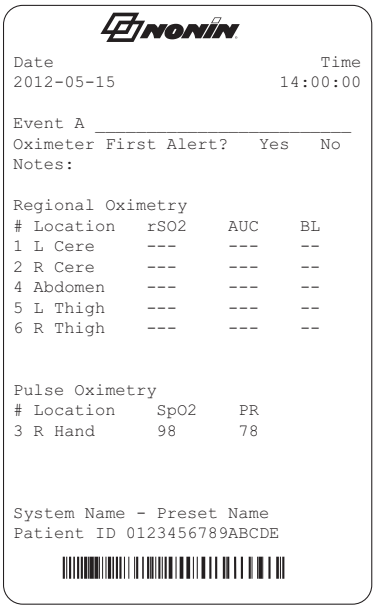


Figure 9: Sample Label from Dymo Printer

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.

Using the Dymo Printer

1. Set the RS-232 port so it outputs to the Dymo 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 RS232.
   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 Event Mark is pressed.

Monitoring Screen

This section contains:

- Description of the monitoring screen features
- Monitoring screen procedures (see “Monitoring Screen – Procedures” on page 29)

Monitoring Screen – Description

Channels

Real-time numeric data displays by channel on the right side for up to four channels. When six 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 and $\%SpO_2$

Figure 10. Monitoring Screen with 4 rSO_2 and 2 SpO_2 Channels Connected (Example)

Event Marks

Event marks are located at the top of the monitoring screen above the timescale (figure 11).

When pressed, the Event Mark button places a mark on the displayed trendline, 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 11. Event Marks, Timescale, and Scrolling Cursor