Operator's Manual

Model X-100

SenSmart™

Universal Oximetry System

CE 0123 ⓘ

English

R͟x 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

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, 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.
Refer to the applicable sensor instructions for use for additional contraindications, warnings, and cautions.

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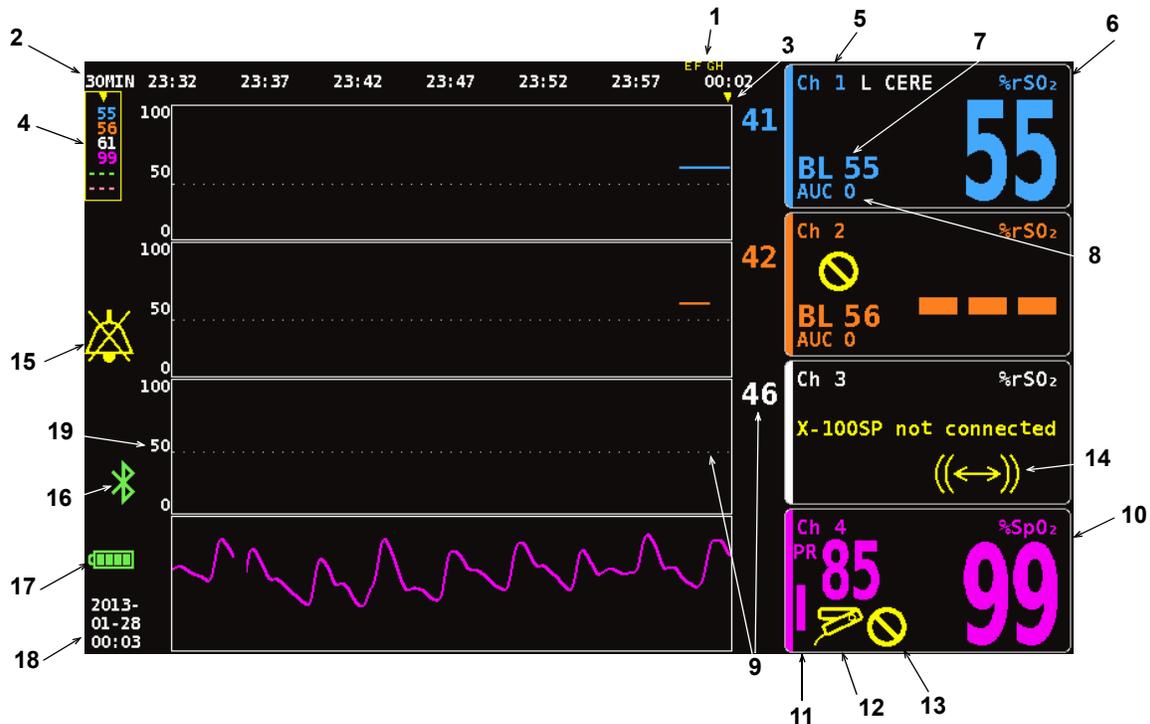
Figure 1. Monitoring Screen Symbols (Four-Channel View)

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	▼ 97 65 --- --- ---	**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 rSO2 Channel Baselines to Current %rSO2 Values" on page 28. • For instructions on setting the baseline values separately or to make finite adjustments to the baseline value, see "Set Individual Baseline Values" on page 34.
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 52 for more information.
17	**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 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 51.
19	100 50 0	**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-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.

System Configurations

Multiple Channels

When using the X-100H hub (figure 2), 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.

Single Channel

When using a single channel (figure 3), 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.