

SenSmart™

Model X-100
Universal Oximetry System

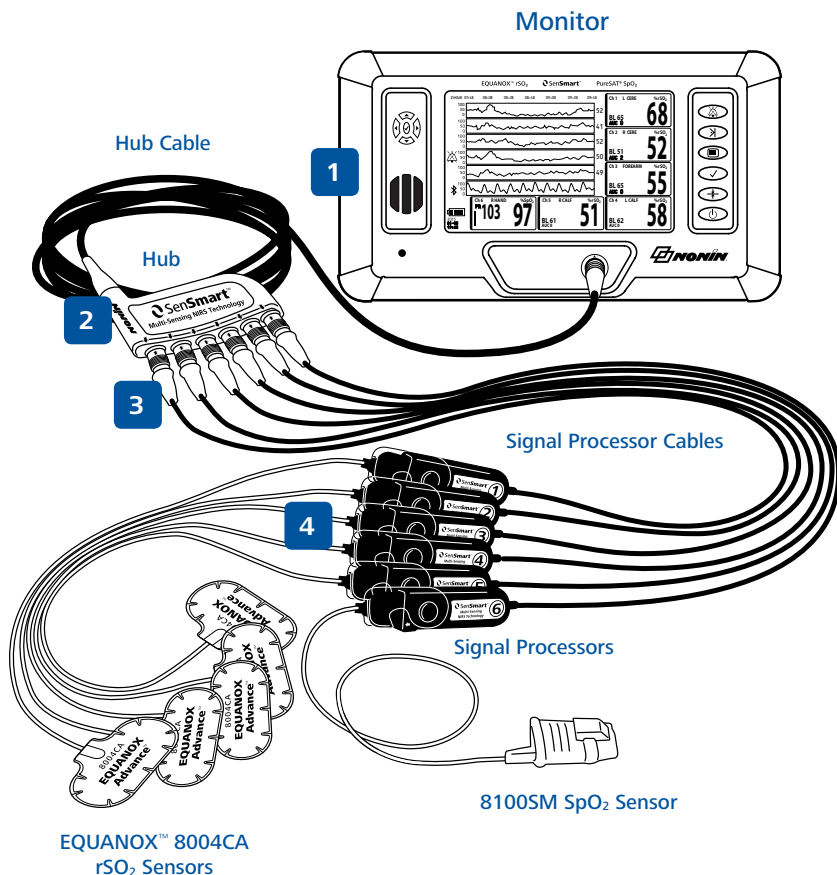
Quick Start Guide



SenSmart™ System Components



Refer to the SenSmart™ Model X-100 Universal Oximetry System Operator's Manual for complete instructions for use to fully understand the device, its operation, and the potential risks to user and patient.



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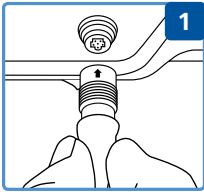
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Monitor Setup

MONITOR SETUP:

1. Connect the X-100 SenSmart components as shown here. Up to six channels of rSO₂ and SpO₂ monitoring can be utilized.
2. Press the **On/Standby** button to power on the Monitor. The Monitor will display the opening screen allowing the user to select a Preset.
3. Select a Preset. Verify the alarm limits are correct.
4. Press **Menu** to set the display to the monitoring screen.

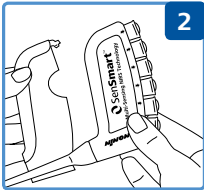


To connect the Hub Cable to the Monitor port:

- Align the arrow on the Hub Cable connector with the small triangle on the Monitor connector port.
- Push connector straight into the port to click and lock into place.

To disconnect:

- Grasp the sleeve on the Hub Cable connector, retract the sleeve to unlock, and pull the connector straight back to detach.

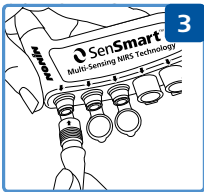


To place the Hub into the Hub Holster

- Align the Hub and Hub Cable to the Hub Holster, push firmly into the Hub Holster; clip to liners or pole.

To remove:

- Pull the clip back on the tip of the Hub Holster and pull out of holster.
- If not being used, the hub port covers should remain closed to eliminate the potential for environmental contamination.

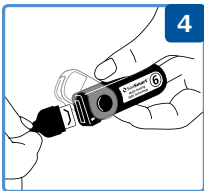


To connect a Signal Processor to the Hub:

- Align the arrow on the Signal Processor cable connector with the arrow on the Hub port or the Monitor connector port and push until it clicks and locks into port.

To disconnect:

- Grasp the sleeve on the Signal Processor cable connector, retract to unlock and pull the Signal Processor connector straight back.

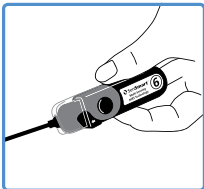


To connect a Sensor to the Signal Processor:

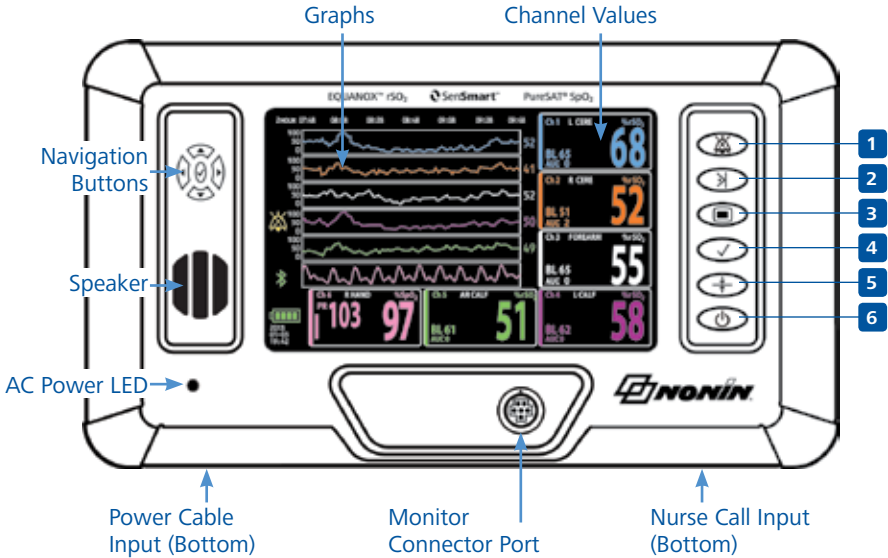
- Flip the clear sensor lock on the Signal Processor back to expose the sensor port, align the white arrow on the Sensor connector with the white arrow on the Signal Processor port and push until the Sensor is firmly in place.
- Flip the Sensor lock over the Sensor connector and click into place.

To disconnect:

- Flip the sensor lock back to disengage the lock from the Sensor. Pull the Sensor connector to remove from the Signal Processor.



Monitor Features and Patient Monitoring



- 1 **ALARM SILENCE:** Press once to silence audible alarms for 2 minutes, press once to reactivate.
- 2 **EVENT MARK:** Press once to mark an event; press and hold for 2 seconds to open Event Mark table.
- 3 **MENU:** Press to open Settings menu. Allows access to System menu which changes device settings.
- 4 **SELECT:** Select item to edit using navigation buttons; press Select to save changed values.
- 5 **BASELINE:** Press twice to quickly set all baseline(s) to the current rSO₂ values.
- 6 **ON:** Press once to power on.
STANDBY (OFF): Press and hold for at least 1 second to power off.

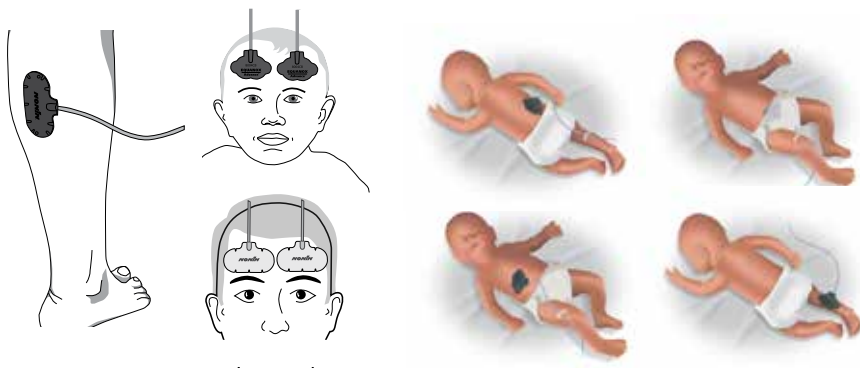
SenSmart Signal Processor Model	Color Channel
X-100SP-1 – Channel 1	Blue
X-100SP-2 – Channel 2	Orange
X-100SP-3 – Channel 3	White
X-100SP-4 – Channel 4	Purple
X-100SP-5 – Channel 5	Green
X-100SP-6 – Channel 6	Pink

The measurement from the Signal Processor will display on the Monitor screen in the same color and channel location as shown on the Signal Processor label.



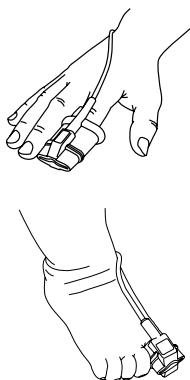
WARNING! Refer to the sensor IFU for complete instructions for use, including potential risks to patient and user.

EQUANOX™ Cerebral/Somatic Sensor Application



- 1. Cerebral Site.** Select the site(s) on the patient's forehead lateral of the superior sagittal sinus, superior to the eyebrow and inferior to the hairline (see cerebral examples above). The area(s) should be free of hair or surface blemishes such as moles or freckles. Avoid placing the sensor(s) over nevi, sinus cavities, hematomas, or arteriovenous malformations.
- 2. Somatic Site(s).** Select the site(s) that provides optimal access to desired tissue.
- 3. Skin Preparation.** Gently cleanse the patient's skin to remove oils, makeup, or soil that might interfere with adhesive or block light. Ensure the skin is thoroughly dried.
- 4. Sensor Placement.** Remove the protective backing from the sensor pad and gently, but firmly, place the sensor(s) on the desired site(s) (see examples above). Ensure sensor surface adheres to the skin to prevent emitted light from traveling along the surface between emitters/detectors, or ambient light from entering.

8100SS, 8100SM and 8100SL Reusable Pulse Oximeter Sensor Application



- 1.** Insert the selected digit into the sensor as shown. The patient's digit must reach the end of the sensor.
- 2.** Direct the cable along the patient's digit, parallel to the arm or leg.
- 3.** Secure the sensor cable with medical tape so the cable does not become caught on nearby equipment. Ensure that the tape securing the cable does not restrict blood flow or pull the sensor out of position.

System Configuration – Screens and Menus



The System has four (4) operating menus to configure system settings accessed via the **Menu** button and navigated using the **Navigation** buttons on the left side of the Monitor.

Up ▲ / Down ▼ and **Left ◀ / Right ▶**: In menus, used to navigate between items.

Select ✓ to Select item to edit and Save entered or changed values.

Monitoring Screen Navigation:

Up ▲ / Down ▼: Change rSO₂ trend line timescale.

Left ◀ / Right ▶: Scroll back/forward in time in the current case.

Settings	Presets	Case	System			
Sensor Site	1 L CELL	2 Blank	3 Blank	4 Blank	5 Blank	6 Blank
Sensor Type	rSO ₂	rSO ₂	rSO ₂	SpO ₂	rSO ₂	rSO ₂
Baseline	72	47	66		off	off
rSO ₂ High	off	off	off		off	off
rSO ₂ Low (r BL)	-25	-25	-25		-25	-25
Map ₂ High			off			
Map ₂ Low			03			
PR High			200			
PR Low			50			
Brach Position	A	B	C	Ea	E	F

SENSOR SITE: To select, customize, or clear a **Sensor Site** name.

rSO₂ BASELINE: To set manually as a specific value.

1. Select the **Baseline** field.
2. Press **Up/Down** to manually set **Baseline** value, and press **Select** to save and exit to **Settings** menu.

SET HIGH/LOW ALARM LIMITS

1. Connect a sensor to the Signal Processor.

2. Press **Left/Right** and **Up/Down** to move to and **Select** the desired channel and the alarm limit setting; press **Select** to save the setting.

GRAPH POSITION

1. Set location of individual channel trend lines (locations **A – F**, or **Off**) or plethysmograms (**On** or **Off**).

Settings	Presets	Case	System
Save Current Settings as New Preset			
Save User Presets:			
1 % Defaults	6 % Defaults		
2 % Defaults	7 % Defaults		
3 % Defaults	8 % Defaults		
4 % Defaults	9 % Defaults		
5 % Defaults	10 % Defaults		

PRESETS: To activate, create, or rename a **Preset**:

1. Use **Settings** and **System** menus to set all limits and settings to desired values.
2. Select **Presets**.
3. Highlight "**Save Current Settings as New Preset.**"
4. Press **Select** to display **Presets 1-10** in pop-up menu.
5. Press **Up/Down** to navigate to desired **Preset** and **Select** to overwrite.

NOTE: If the **Preset** is locked, the message "**Cannot overwrite locked preset!**" displays.

6. Enter **Preset** name (maximum of 11 alphanumeric characters) using the alphanumeric keyboard.
7. Highlight **Save**, and **Select** to save and activate **Preset**.

System Configuration – Screens and Menus



START NEW CASE and PATIENT ID:

1. Highlight **“Start new case”** and press **Select**; **“Start new case?”** pop-up displays with **No** highlighted.
 2. Highlight **Yes** and press **Select**.
 3. If system is set up to enter a patient ID at the start of a new case: Enter ID using alphanumeric keyboard and press **Select**.
 4. Monitor returns to monitoring screen and all baselines from the previous case are cleared.
5. If system is not set up to enter a patient ID at the start of a new case: **“Starting new case...”** displays.
6. Monitor returns to monitoring screen and all baselines from the previous case are cleared. The case will not have a patient ID.



All System settings can be changed and saved in this menu.

PRESET SYSTEM SETTINGS:

These System settings can be included in a **PRESET** by changing the settings before creating the **PRESET**: Brightness, Alarm Volume, rSO₂ Low Alarm Mode, Pulse Tone Volume and Source, and Data Output Modes.

CLEAR MEMORY:

Deletes all patient data recordings from Monitor.

High and Medium Priority Alarms






The System has audible and visual alarm indicators to alert the user when immediate patient attention may be required or an equipment alarm occurs.



WARNING! Ensure all alarm volumes are set appropriately and are audible in all situations. Do not cover or otherwise block any speaker opening.

HIGH PRIORITY ALARMS: Require immediate attention and include high and low rSO₂ alarms.

MEDIUM PRIORITY ALARMS: Signal potential problems with the equipment or other non-life-threatening situations.

HIGH Priority Alarm	Visual Indicator	Audible Indicator
rSO ₂ Limit (rSO ₂ ≥ high alarm limit OR rSO ₂ ≤ low alarm limit)	rSO ₂ background flashes in RED at 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.
SpO ₂ Limit (SpO ₂ ≥ high alarm limit OR SpO ₂ ≤ low alarm limit)	SpO ₂ portion of channel background flashes RED 2 times per second; SpO ₂ value becomes white.	
Pulse Limit – SpO ₂ channel only (Pulse is ≥ high alarm limit OR pulse ≤ low alarm limit)	Pulse portion of channel background flashes RED 2 times per second; Pulse rate value becomes white.	
Critical Low Battery	Battery indicator  flashes RED twice every second.	
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.	
MEDIUM Priority 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 when the rSO ₂ value is within 5 points of the lower alarm limit. Channel text turns 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 when a sensor is disconnected, sensor has failed, or is not compatible with the Monitor. ACTION: Check sensor site and connection. Replace sensor if necessary.	
Poor Signal	 Poor Signal indicator flashes YELLOW once every 2 seconds when there has been a sustained period of poor patient signals from the sensor. ACTION: Check the sensor site and reposition or replace the sensor if necessary.	
Signal Processor Communication Error	 Communication Lost indicator flashes YELLOW once every 2 seconds and <i>X-100SP not connected</i> displays when the respective Signal Processor has stopped communicating with the monitor. ACTION: Check the signal processor connections or replace the signal processor to correct the issue.	
Error Codes (E01, E02, E03, E04, E06, E08)	Indicated by error code across the screen. ACTION: Contact Nonin Technical Service at 1-800-356-8874, +1 (763) 553-9968 or +31 (0)13-79 99 040 .	