SenSmart™
Model X-100
Universal Oximetry (rSO₂/SpO₂) System
In-Service Training
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Introduction

This In-Service Training material is designed to help you become familiar with the SenSmart™ Model X-100 Universal Oximetry (rSO\textsubscript{2}/SpO\textsubscript{2}) System components and functions. It is not intended to replace the SenSmart System Operator’s Manual, which includes warnings, cautions, complete functions of all components, and technical information about the SenSmart System.

The training is designed to:

1) Introduce you to the SenSmart System components and functions,
2) Teach you what actions are needed to make the system function properly, and
3) Provide you the opportunity to demonstrate what you have learned.

Training format conventions in this document you should be aware of:

- *SenSmart System features that perform an action, such as the navigation buttons* Up/Down, Left/Right and Select, *are in bold font.*

- *Menus and options in the display interface that can be selected to configure the SenSmart System are in bold font, such as the Settings, Presets, Case, and System menus, and any option within these menus.*

- *Important notes regarding a specific function are italicized.*

- *Warnings and Cautions for safe operation of the system are in bold font.*
Indications for Use

The SenSmart Model X-100 Universal Oximetry (rSO₂/SpO₂) 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 (SpO₂) and pulse rate or cerebral or somatic hemoglobin oxygen saturation (rSO₂) 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, sub-acute 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 (SpO₂) functionality is suitable for use in both motion and non-motion conditions, including patients who are well or poorly perfused.

**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.

Theory of Operation

**What is rSO₂ and how is it measured?**

- rSO₂ is a representation of oxygen saturation in tissue.
  - rSO₂ correlates to a jugular bulb saturation measurement.
  - rSO₂ has been validated to agree with an assumed 70:30 mix of venous and arterial blood in the tissue capillary bed.

- To measure rSO₂, the SenSmart Universal Oximetry System uses 4 distinct wavelengths of light and 4 light paths to penetrate and determine hemoglobin oxygen saturation of blood in the area under the sensor.

- Nonin’s patented dual light emitter/dual detector architecture allows the sensor to spatially resolve the differences between shallow tissue artifacts and deeper target tissue.

**What is SpO₂ and how is it measured?**

- Pulse oximetry provides a noninvasive method that enables rapid measurement of oxygen saturation of hemoglobin in arterial blood. It can rapidly detect oxygen saturation changes thus providing early warning of dangerous hypoxemia.

- A pulse oximeter shines light composed of two wavelengths—red and infrared—through a part of the body that is relatively translucent and has good arterial pulsed blood flow (e.g., finger, toe, ear lobe).

- The ratio of red to infrared light received by the detector depends on the percentage of oxygenated versus deoxygenated hemoglobin through which the light passes.
System Components

The SenSmart System is a modular oximetry system comprised of the components described in Table 1.

Figure 1. The SenSmart Model X-100 Universal Oximetry (rSO₂/SpO₂) System.

Table 1. SenSmart System components and description.

<table>
<thead>
<tr>
<th>Component</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>X-100M Monitor</td>
<td>Displays up to six channels of rSO₂ and SpO₂ data. Each channel is color coded to match a SenSmart Signal Processor.</td>
</tr>
<tr>
<td>X-100H Hub</td>
<td>The Hub has six ports to provide the connection between the Monitor and up to six Signal Processors. The Hub has a cable 4 meters in length.</td>
</tr>
<tr>
<td>X-100HH Hub Holster (not shown)</td>
<td>The Hub Holster holds the Hub and can be attached to bed rails and equipment poles. (See Figures 4a – 4c, page 5.)</td>
</tr>
</tbody>
</table>
| X-100EC-1 and X-100EC-2 Extension Cable (not shown) | Extension Cables are available in 1- or 2-meter lengths and may be used:  
  1) Between the Hub and a Signal Processor.  
  2) Between the Monitor and a Signal Processor (single channel use only).                                                                 |

- Up to six (6) Signal Processors can be connected to the Hub to provide rSO₂ and/or SpO₂ values.
- Each Signal Processor is programmed to be a specific channel on the Monitor (designated by number and color) and can be connected to any Hub port. For example, X-100SP-1 will display on channel 1 on the Monitor, X-100SP-2 will display on channel 2, and so forth.
- It is important to note that the Hub ports are not designated with a number that aligns with a monitor channel or a signal processor number. Signal Processors can be connected to any Hub port and in any order on the Hub.

**NOTE:** Duplicate Signal Processors (Signal Processors of the same color and number) cannot be used simultaneously and will result in a System Error Message. There can be only one of each number connected at a time, e.g., one X-100SP-1 or one X-100SP-3, etc.
Table 1. SenSmart System components and description (continued).

<table>
<thead>
<tr>
<th>Component</th>
<th>Description</th>
</tr>
</thead>
</table>
| X-100SP Oximetry Signal Processors           | • Cable Clips: Each Signal Processor has 2 pre-attached color-coded clips that match the channel color and are placed at the connector end and in the middle of the cable.  
• Linen Clip: Each Signal Processor has one Linen Clip included in the component package. (Not shown here.) |
| Channels 1 - 6 (continued)                   |                                                                            |
| INT-100 Intermediate Cable                   | • Used between an X-100SP Signal Processor and a compatible sensor.  
• Compatible sensor is 8204CA regional sensor for patients >40 kg. |
| SenSmart Sensors                             | • Available to measure rSO₂ and SpO₂.  
• Sensors are described in more detail in the System Sensors section on page 6. |
| Power supply and cord (not shown)            | Powers the Monitor with AC power and charges the Monitor battery. |
| SenSmart Download Software (CD not shown)    | Data management software.                                                  |

System Setup

This section describes the features of the SenSmart components and how to connect the components to prepare for patient monitoring.

X-100H Hub

- The Hub and cable connects to the port on the front of the Monitor and provides connections for up to six Signal Processors using the Hub ports. See Figure 2.
- The Hub ports are protected from environmental contamination with covers that are opened to connect a Signal Processor. If the Hub port is not being used, the cover should remain closed to eliminate the potential for environmental contamination.

Connect/Disconnect the Hub to the Monitor

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 until it clicks and locks into place as shown in Figure 3.
2. To disconnect:
   a. Grasp the sleeve on the Hub cable connector.
   b. Retract the sleeve to unlock, and pull the Hub cable connector straight back to detach from the Monitor.

X-100HH Hub Holster

The Hub can be placed in the Hub Holster to stabilize the Hub when attaching it to bed linens, a bed rail, or to a pole by using the clamp on the back of the Hub Holster.
1. To place the Hub in to the Hub Holster:
   a. Align the Hub and hub cable to the Hub Holster as shown in Figure 4a. Push firmly into the Hub Holster.
   b. Attach to bed linens, bed rail, or a pole using the clamp as shown in Figure 4b.

2. To remove the Hub from the Hub Holster:
   a. Pull the clip back on the tip of the Hub Holster and pull the Hub out of the Hub Holster as shown in Figure 4c.

X-100SP Signal Processors

- Up to six (6) Signal Processors can be connected to the Hub to provide \( rSO_2 \) and/or \( SpO_2 \) values.

- Each Signal Processor is programmed to be a specific channel on the Monitor (designated by number and color) and can be connected to any Hub port.
  
  - For example, X-100SP-1 will display on channel 1 on the Monitor, X-100SP-2 will display on channel 2, and so forth, regardless of the Hub port the Signal Processor is connected to.

- It is important to note that the Hub ports are not designated with a number that aligns with a monitor channel or a Signal Processor number. Signal Processors can be connected to any Hub port and in any order on the Hub.

**NOTE:** Duplicate Signal Processors (Signal Processors of the same color and number) cannot be used simultaneously and will result in a System Error Message. There can be only one of each number connected at a time, e.g., one X-100SP-1 or one X-100SP-3, etc.

- The Signal Processor has a cable connector on one end to connect to any port on the Hub or directly to the Monitor (for single channel monitoring), and a sensor connection port on the other end with the clear plastic sensor lock to secure the sensor firmly in the Signal Processor. See Figure 5.

- 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 labels. See Table 2 on next page.
### Table 2. SenSmart Signal Processors and channel colors.

<table>
<thead>
<tr>
<th>SenSmart Signal Processor Model</th>
<th>Color</th>
</tr>
</thead>
<tbody>
<tr>
<td>X-100SP-1 (Channel 1)</td>
<td>Blue</td>
</tr>
<tr>
<td>X-100SP-2 (Channel 2)</td>
<td>Orange</td>
</tr>
<tr>
<td>X-100SP-3 (Channel 3)</td>
<td>White</td>
</tr>
<tr>
<td>X-100SP-4 (Channel 4)</td>
<td>Purple</td>
</tr>
<tr>
<td>X-100SP-5 (Channel 5)</td>
<td>Green</td>
</tr>
<tr>
<td>X-100SP-6 (Channel 6)</td>
<td>Pink</td>
</tr>
</tbody>
</table>

### Connect/Disconnect a Signal Processor

A Signal Processor can be connected to *any one* of the Hub channel ports on the Hub or directly into the Monitor connector port (for single channel use).

1. To connect:
   a. Align the arrow on the Signal Processor cable connector with the arrow on the Hub port or the Monitor connector port.
   b. Push the Signal Processor cable connector into the Hub port or Monitor connector port until it clicks and locks into the Hub port or Monitor connector port. See Figure 6a.

2. To disconnect:
   a. Grasp the sleeve on the Signal Processor cable connector.
   b. Retract the sleeve to unlock and pull the Signal Processor connector straight back to detach from the Hub or Monitor as shown in Figure 6b.

### System Sensors

**To connect an Intermediate Cable or Sensor to the Signal Processor**

*NOTE:* The INT-100 Intermediate Cable is required to connect 8204CA (patients >40 kg) sensors to the Signal Processor. The 8004CB, 8004CB-NA sensors (patients <40 kg), and 8100S(X) pulse oximetry soft sensors connect directly to the Signal Processor.
1. To connect:
   a. Flip the clear lock on the Signal Processor back to expose the connection port, align the white arrow on the INT-100 connector or sensor connector with the white arrow on the Signal Processor port, and push until the connector is firmly in place (Figure 7a).
   
   b. Flip the lock over the connector and click into place (Figure 7b).
   
   c. If using an INT-100 Intermediate Cable, connect a compatible sensor to the Intermediate Cable by sliding the sensor lock on the Intermediate Cable away from the sensor connection port.
   
   d. Align the arrows on the sensor connector and the Intermediate Cable. Insert the sensor connector into the Intermediate Cable port.
   
   e. Slide the sensor lock up the cable to the connector 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.
   
   f. rSO₂ values and the trend lines should begin displaying within seconds.

2. To disconnect:
   a. Flip the lock back to disengage the lock from the connector.
   
   b. Grasp the connector and remove it from the Signal Processor.

**NOTE:** Do not discard the INT-100 Intermediate Cable.

## rSO₂ Sensors

Nonin offers sensors to facilitate a wide range of regional oxygen saturation patient monitoring. The following information will assist in sensor selection:

### Table 3. SenSmart rSO₂ Sensors.

<table>
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<tr>
<th>SenSmart rSO₂ Sensor Model</th>
<th>Patient Weight Range</th>
<th>Tissue Sites</th>
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<tr>
<td>8204CA Adult/Pediatric</td>
<td>&gt;40 kg</td>
<td>Cerebral and somatic</td>
</tr>
<tr>
<td>8004CB EQUANOX™ Advance Neonatal/Pediatric</td>
<td>&lt;40 kg</td>
<td>Cerebral and somatic</td>
</tr>
<tr>
<td>8004CB-NA EQUANOX™ Advance Neonatal/Pediatric (non-adhesive)</td>
<td>&lt;40 kg</td>
<td>Cerebral and somatic</td>
</tr>
</tbody>
</table>

## rSO₂ Sensor Application

See the Sensor IFU for complete instructions, cautions and warnings.

1. Signal Processor site(s) and cable pathways:
   a. Select an appropriate site to clip or otherwise stabilize the Signal Processor. The ideal site avoids the patient’s body resting on the Signal Processor or the Signal Processor pulling unnecessarily on the sensor. Ensure the sensor cable and extension cable pathways are clear and unencumbered.
WARNING: As with all medical equipment, carefully route patient cables and connections to reduce the possibility of entanglement or strangulation.

2. Cerebral site:
   a. Select the site(s) on the patient’s forehead lateral of the superior sagittal sinus, superior to the eyebrow and inferior to the hairline (Figure 8).
   b. The area(s) should be free of hair or surface blemishes such as moles or freckles.
   c. Avoid placing the sensor(s) over nevi, sinus cavities, hematomas, or arteriovenous malformations.

3. Somatic site:
   a. Select the site(s) that provides optimal access to desired tissue (Figure 9).

   ![Figure 8. Proper placement of cerebral sensors on adult and neonate/pediatric patients.]

   ![Figure 9. Proper placement of somatic sensors on adult and neonate/pediatric patients.]

   CAUTION: Avoid excessive pressure to the sensor application site(s) as this may cause damage to the skin beneath the sensor.

4. Skin preparation:
   a. Gently cleanse the patient’s skin to remove oils, makeup, or soil that might interfere with adhesive or block light.
   b. Ensure the skin is thoroughly dried.

5. Removal from packaging and pre-check:
   a. Carefully remove the sensor from the plastic pouch.
   b. Check the sensor for any sign of damage in transport.
   c. If signs of damage are found, replace the sensor.

6. Sensor placement:
   a. Remove the protective backing from the sensor pad and gently, but firmly, place the sensor(s) on the desired site(s).
   b. Ensure the sensor surface adheres fully to the skin to prevent light from traveling between emitting or receiving elements or ambient light from entering between the sensor and the skin.

   CAUTION: An improperly placed sensor may result in inaccurate readings.

   NOTE: If these measurements are not clearly identified or alarm conditions are generated, consult the Troubleshooting section on page 31.
WARNING: Use only Nonin-branded SenSmart Signal Processors, sensors, and accessories. The sensors are manufactured to meet the accuracy specifications for this system. Using other manufacturers’ sensors can result in improper oximeter performance.

CAUTION: The sensor is designed for external use only.

CAUTION: Do not apply sensor over open wound, incision, compromised skin, or pre-existing skin condition (e.g., eczema or dermatitis).

CAUTION: Do not use if patient has pre-existing sensitivity to adhesive tapes or adhesives on electrocardiogram (ECG) pads.

SpO₂ Sensors

Nonin offers reusable SpO₂ sensors for a wide range of patients. The following information will help assist in sensor selection.

Table 4. SenSmart Soft SpO₂ Sensors.

<table>
<thead>
<tr>
<th>SenSmart Soft SpO₂ Sensor Size</th>
<th>Digit Height (thickness)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Model 8100SL (Large)</td>
<td>12.5 – 25.5 mm (0.5 – 1.0 in.)</td>
</tr>
<tr>
<td>Model 8100SM (Medium)</td>
<td>10 – 19 mm (0.4 – 0.75 in.)</td>
</tr>
<tr>
<td>Model 8100SS (Small)</td>
<td>7.5 – 12.5 mm (0.3 – 0.5 in.)</td>
</tr>
</tbody>
</table>

Reusable Pulse Oximetry (SpO₂) Sensor Application

1. Use the measurements provided in Table 4 to determine which sensor should be used. Sensor recommendations are based on digit height (thickness), as indicated in the right column.

2. Signal Processor site(s) and cable pathways:
   a. Select an appropriate site to clip or otherwise stabilize the Signal Processor. The ideal site avoids the patient’s body resting on the Signal Processor or the Signal Processor pulling unnecessarily on the sensor. Ensure the sensor cable and extension cable pathways are clear and unencumbered.

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

3. Attaching the sensor:
   a. Insert the selected digit into the sensor as illustrated in Figure 10. The patient’s digit must reach the end of the sensor.
   b. Direct the cable along the patient’s digit, parallel to the arm or leg.
   c. 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.

NOTE: Proper sensor placement is critical for good performance. If the sensor is not positioned properly, light may bypass the tissue and result in SpO₂ inaccuracies.
4. Sensor connections:
   a. Flip the sensor lock on the Signal Processor back to expose the sensor connector port.
   b. Align the white arrow on the sensor connector with the white arrow on the Signal Processor sensor port and push until the sensor is firmly in place.
   c. Flip the Signal Processor sensor lock over the sensor connector and click into place.
   d. SpO₂ and PR values should begin displaying within seconds.

**INT-100 (Intermediate Cable)**

An Intermediate Cable is used between an X-100SP Signal Processor and a compatible sensor. The following sensor is compatible with the intermediate cable:

- 8204CA regional sensor for patients >40 kg

**NOTES:**

- The Intermediate Cable is not an extension cable.
- The 8004CB or 8004CB-NA regional sensors (for patients <40 kg) and 8100S pulse oximetry sensors do not use the Intermediate Cable; they connect directly to the Signal Processor.

For cleaning instructions, refer to “Cleaning the System Components” on page 33.

**X-100EC Extension Cables**

- Extension Cables are available in 1 or 2 meter lengths to increase the distance between the Monitor and the sensor.
- One Extension Cable may be used:
  a. Between the Hub and each Signal Processor.
  b. Between the Monitor and a Signal Processor (single channel use only).

**CAUTION:** Do not use an Extension Cable between the Monitor and the Hub. The System will malfunction.

**CAUTION:** Do not connect multiple Extension Cables between the Monitor and a Signal Processor or between the Hub and each Signal Processor.
1. To connect:
   a. Align the arrow on the Extension Cable connector with the arrow on the Hub port or the Monitor connector port as shown in Figure 11.
   b. Push the Extension Cable connector into the Hub port or Monitor connector port until it clicks and locks into place.
   c. Connect the other end of the Extension Cable to the Signal Processor cable connector.

2. To disconnect:
   a. Grasp the sleeve on the Extension Cable connector.
   b. Retract the sleeve to unlock and pull the Extension Cable connector straight back to detach from the Hub or Monitor.

**System Power On/Off**

1. Plug the power supply into the receptacle located on the bottom of the Monitor, below the indicator light.

2. Connect the power supply to the power cord.

3. Plug the power cord into AC power to operate the Monitor or charge the internal battery.

**NOTE:** *Battery life is dependent on the number of channels being used. See the system Operator’s Manual for specific technical information.*

4. Press the **On/Standby** button to power on the Monitor. Verify that the LCD display lights and displays the Nonin logo, and that an audible tone sounds. If either of these does not occur, contact Nonin Technical Service for assistance.

5. The Monitor will display the opening screen allowing the user to select the default **Preset**, the last used **Preset**, or scroll to select the desired **Preset** (Figure 12).

6. Press **Menu** twice to set the display to the monitoring screen.
Review of the Model X-100 Universal Oximetry (rSO₂/SpO₂) System Setup

To practice making all the connections to the System, please complete the following tasks in the order they presented.

1. Connect the Hub to the Monitor.
2. Securely place the Hub in the Hub Holster.
3. Attach the Hub Holster to the pole using the clamp on the back of the Hub Holster.
4. Connect three (3) Signal Processors to the Hub.
5. Utilizing two (2) INT-100 Intermediate Cables, connect two (2) rSO₂ sensors to Signal Processors and lock into place.
6. Connect one (1) SpO₂ sensor to a Signal Processor and lock into place.
7. Power on the Monitor.
8. Observe the channels that are displaying on the Monitor and list them here.
   a. rSO₂: Channel ________ Color ________
   b. rSO₂: Channel ________ Color ________
   c. SpO₂: Channel ________ Color ________

Congratulations! You are now ready to learn more about how the System functions and displays the patient data.
Monitor Features

This section describes the physical features of the System Monitor that are used to configure and control system functions to assist in patient monitoring. The display features are described in Table 5.

Figure 13. The SenSmart System Monitor features navigation buttons, display, cable port and speakers.

Table 5. SenSmart Monitor display features.

<table>
<thead>
<tr>
<th>Key</th>
<th>Feature</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Navigation Buttons</td>
<td>Up / Down / Left / Right / Select</td>
</tr>
<tr>
<td>B</td>
<td>Graphs</td>
<td>Graphs for each channel with rSO₂ trend lines or SpO₂ plethysmograms</td>
</tr>
<tr>
<td>C</td>
<td>Channel Values</td>
<td>rSO₂ or SpO₂ data for each active channel</td>
</tr>
<tr>
<td>D</td>
<td>Function Control Buttons</td>
<td>Function buttons to control specific system functions</td>
</tr>
<tr>
<td>E</td>
<td>Monitor Connector Port</td>
<td>Insert Hub cable connector, a single Signal Processor or an Extension Cable</td>
</tr>
<tr>
<td>F</td>
<td>AC Power Indicator</td>
<td>LED indicates battery charging (orange) or fully charged (green)</td>
</tr>
<tr>
<td>G</td>
<td>Speaker</td>
<td>For audible alarms</td>
</tr>
</tbody>
</table>
Controls and Navigation

Configuring the System is controlled using the **Navigation** buttons on the left (A) and the **Function** buttons on the right side of the Monitor (B – F). The button functions are described in Table 6.

![Figure 14. The SenSmart System features buttons to navigate all menus and control display functions of the System.](image)

**Table 6.** SenSmart System controls and navigation buttons.

<table>
<thead>
<tr>
<th>Key</th>
<th>Feature</th>
<th>How to Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Navigation Buttons</td>
<td>1. Up ▲/Down ▼ and Left ◄/Right ►: In menus, used to navigate between items.</td>
</tr>
<tr>
<td></td>
<td>Left and Right Select</td>
<td>2. Up ▲/Down ▼: In monitoring screen, change rSO₂ trend line timescale.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3. Left ◄/Right ►: In monitoring screen, scroll back/forward in time in the current case.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4. Select (in center of navigation buttons and between Menu and Baseline buttons):</td>
</tr>
<tr>
<td></td>
<td></td>
<td>a. Select item to edit.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>b. Save entered or changed values.</td>
</tr>
<tr>
<td>B</td>
<td>Alarm Silence</td>
<td>1. Press once to silence audible alarms for 2 minutes.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. Press once to reactivate audible alarms before the 2-minute silence period is over.</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>NOTE:</strong> All silenced audible alarms are automatically reactivated when a new physiological alarm condition occurs.</td>
</tr>
</tbody>
</table>
Table 6 (continued). SenSmart System controls and navigation buttons.

<table>
<thead>
<tr>
<th>Key</th>
<th>Feature</th>
<th>How to Use</th>
</tr>
</thead>
</table>
| C   | Event Mark | 1. Press once to mark an event with an alpha character (A-Z) in 1) memory, 2) on the trend line, and 3) in real-time serial data.  
**NOTE:** It may take up to 4 seconds for the event mark letter to appear.  
**NOTE:** If more than 26 events are marked in a single case, the event marks begin again at A.  
2. Press and hold for 2 seconds to open the Event Mark table which shows the last 10 event marks with date/time and values for each channel. (See Figure 16 on page 17.) |
| D   | Menu | 1. Press to open the Settings screen which contains 4 operating menus:  
   a. Settings – Assign sensor site to channel, select sensor type (rSO$_2$ or SpO$_2$), set limits and graphs, and review presets.  
   b. Presets – Save current settings as a new Preset, select a Preset to use, and edit/delete a Preset.  
   c. Case – Review current patient ID, start a new case, enter new patient ID, and edit current patient ID.  
2. Press Menu to navigate to previous menu.  
3. Press Menu in any menu/item to cancel the entry without saving and navigate to previous menu. |
| E   | Baseline | 1. rSO$_2$ Baseline values can be set by the user for each patient to compare subsequent rSO$_2$ changes relative to this Baseline.  
2. Press Baseline twice to quickly set all baseline(s) to the current rSO$_2$ values from the patient which will show in the channel window. (See Figure 15.) |
| F   | On/Standby | 1. On – Press once to power on the Monitor.  
**NOTE:** Each time the device is turned on, baseline values are cleared, limits are reset to default values, and a new patient case is initiated in data memory.  
2. Cancel – When Monitor is on, press once briefly to return the display to the Monitoring screen from menus.  
3. Standby/off – Press and hold for at least 1 second to power down the Monitor.  
**NOTE:** In Standby/off mode, all device functions are turned off except for:  
   a. The AC power adapter LED is lit whenever the device is plugged in; and,  
   b. Batteries are charging if the device is plugged into AC power outlet. |

WARNING: This device turns off after approximately 30 minutes when in low battery condition.
System Display

The System can display up to six (6) channels of patient data in bright, easy to read numbers, trend lines, and plethysmograms during operation. This section describes the information that is provided in each section of the display.

1. Graph Area
2. Patient Data Channels
3. System Information

Figure 15. The System display featuring 6 channels of patient data. See Table 7 for how to use features.
Table 7 (continued). SenSmart System display information – Graph Area.

<table>
<thead>
<tr>
<th>Feature</th>
<th>Information</th>
</tr>
</thead>
</table>
| Event Mark               | • Indicates events that have been marked in the case by pressing the Event Mark button once.  
• Pressing the Event Mark button for 2 seconds will display the Event Mark Table which shows the last 10 event marks, date/time, and values for each active channel. (See Figure 16.) |
| Timescale of Graphs      | • Can be set to: 7.5 min, 15 min, 30 min, 1 hr, 2 hrs, 4 hrs, 8 hrs, 12 hrs, or 24 hrs.  
• Changed using the Up/Down buttons.                                                                                                           |
| %rSO₂ Axis Scale         | 0 – 100 on each channel graph displayed.                                                                                                    |
| Low Alarm Limit          | Threshold value for rSO₂ set manually or as a percentage below Baseline for each channel and shown for each graph displayed.              |

Figure 16.  
The Event Mark Table displays the last 10 event marks for each channel and the patient data at the time of the Event Mark.
Table 7 (continued). SenSmart System display information – Patient Data Channels.

<table>
<thead>
<tr>
<th>Feature</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>rSO₂ Channels</strong> (Channels 1 – 5 shown here)</td>
<td></td>
</tr>
<tr>
<td><strong>Channel Designation</strong>: For active channels 1 – 6, activated when a Signal Processor is attached.</td>
<td></td>
</tr>
<tr>
<td><strong>Sensor Placement Site</strong>: Indicates user defined sensor placement site set in <strong>Settings</strong> menu.</td>
<td></td>
</tr>
<tr>
<td><strong>Baseline (BL)</strong>: rSO₂ patient Baseline set by user.</td>
<td></td>
</tr>
<tr>
<td><strong>Area Under the Curve (AUC)</strong>: Society for Thoracic Surgery (STS) database reporting value automatically calculated as minutes multiplied by the percent below the set lower alarm limit. See Figure 17 for example of calculation.</td>
<td></td>
</tr>
<tr>
<td><strong>%rSO₂</strong>: Patient rSO₂ value at this sensor site.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Feature</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SpO₂ Channels</strong> (Channel 6 shown here)</td>
<td></td>
</tr>
<tr>
<td><strong>Channel Designation</strong>: For active channels 1 – 6, activated when a Signal Processor is attached.</td>
<td></td>
</tr>
<tr>
<td><strong>SpO₂ amplitude bar graph</strong>: Indicates pulse strength as determined by the oximeter. The height of the bar graph is proportional to the pulse amplitude.</td>
<td></td>
</tr>
<tr>
<td><strong>Sensor Placement Site</strong>: Indicates user defined sensor placement site set in <strong>Settings</strong> menu.</td>
<td></td>
</tr>
<tr>
<td><strong>Pulse Rate (PR)</strong>: Indicates pulse rate in beats per minute.</td>
<td></td>
</tr>
<tr>
<td><strong>%SpO₂</strong>: Patient SpO₂ value at this sensor site.</td>
<td></td>
</tr>
</tbody>
</table>

**Figure 17. AUC example**: Below the reference line (red line) represents a 25% drop from pre-intervention baseline. A low rSO₂ alarm would occur when the rSO₂ value reaches the red line, while the AUC (in yellow) is calculated by the depth and length of the rSO₂ desaturation event below the red line.
### Table 7 (continued). SenSmart System display information – System Information.

<table>
<thead>
<tr>
<th>Feature</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Scrolling Cursor and Values</strong></td>
<td>• When the scrolling cursor is active, cursor oximetry values (rSO₂ or SpO₂) display on the left side of the monitor screen in the Values Chart (yellow box).&lt;br&gt;<strong>NOTE:</strong> Pulse rate values are not displayed in the cursor values.&lt;br&gt;• Use <strong>Left</strong> Navigation button to activate cursor and display rSO₂ channel value chart.&lt;br&gt;• Use <strong>Left/Right</strong> to scroll the timeline to display values.</td>
</tr>
<tr>
<td><strong>Alarm Silence Icon</strong></td>
<td>• This yellow indicator flashes once every 2 seconds when the audible alarm is silenced for 2 minutes.&lt;br&gt;• If the alarm volume is at step 4 or lower (less than 45 decibels), the Alarm Silence indicator is solidly lit.</td>
</tr>
<tr>
<td><strong>Bluetooth® Status</strong></td>
<td>Set by user in <strong>System</strong> menu.&lt;br&gt;• Green – Connected.&lt;br&gt;• White - Enabled (On) but not connected.&lt;br&gt;• Gray - Disabled (Off).</td>
</tr>
<tr>
<td><strong>Battery Indicator</strong></td>
<td>Indicates the approximate percentage of battery life remaining.</td>
</tr>
<tr>
<td><strong>Date / Time</strong></td>
<td>Set by user in <strong>System</strong> menu.</td>
</tr>
</tbody>
</table>
System Configuration Screens and Menus

The System has four (4) operating menus to configure the system for specific needs.

It is important to note that all menus are accessed via the Menu button and are then navigated using the Navigation buttons on the left side of the Monitor.

Settings Menu

In this menu, the user can review and configure the following settings and alarm limits for each channel (1 – 6) using the Navigation buttons to move through the menus and make changes, and the Select button to select fields and save changes.

Table 8. Settings menu options and available settings.

<table>
<thead>
<tr>
<th>Option</th>
<th>Description and Available Settings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensor Site</td>
<td>Select, customize, or clear a Sensor Site name.</td>
</tr>
<tr>
<td>Sensor Type</td>
<td>Select the type of sensor for each channel: rSO₂ or SpO₂. NOTE: This field is automatically defined and disabled (gray) when a compatible sensor is attached to the Signal Processor.</td>
</tr>
<tr>
<td>Baseline (rSO₂ only)</td>
<td>• Set Baseline manually (numerical value).</td>
</tr>
<tr>
<td></td>
<td>• rSO₂ Baseline values can be set by the user for each patient to compare subsequent rSO₂ changes relative to this Baseline.</td>
</tr>
<tr>
<td>%rSO₂ High</td>
<td>Set rSO₂ high alarm manually (numerical value) or turn Off.</td>
</tr>
<tr>
<td></td>
<td>• Set value in the System menu as either %rSO₂ Low (% below BL) or %rSO₂ Low (Absolute).</td>
</tr>
<tr>
<td></td>
<td>• % Below Baseline can be set to Off or -40 to -5. NOTE: The low alarm limit will then be calculated based on the baseline value.</td>
</tr>
<tr>
<td>%rSO₂ Low</td>
<td>• Absolute Low Alarm Limit value can be set to Off or 15 – 90.</td>
</tr>
<tr>
<td>%SpO₂ High</td>
<td>Set value as Off or 80% – 100%.</td>
</tr>
<tr>
<td>%SpO₂ Low</td>
<td>Set value as Off or 50% – 95%.</td>
</tr>
<tr>
<td>PR High</td>
<td>Set value as Off or 75 – 275 BPM.</td>
</tr>
<tr>
<td>PR Low</td>
<td>Set value as Off or 30 – 110 BPM.</td>
</tr>
<tr>
<td>Graph Position</td>
<td>Set location of individual channel trend lines (locations A – F, or Off) or plethysmograms (On or Off).</td>
</tr>
<tr>
<td>Current Preset</td>
<td>The current Preset name is shown here and the settings are displayed in the menu fields. The user can scroll through all Presets using the Left/Right navigation buttons.</td>
</tr>
</tbody>
</table>
Sensor Site

- This setting allows the user to define and show in the channel window the location of the sensor. Using this setting, the user can select, customize, or clear a Sensor Site name.

- Commonly used sensor sites are available in the Category menus to select (Figure 19), or the user can create a Custom location using the Navigation buttons and the alphanumeric keyboard.

To set the Sensor Site for each channel being monitored:

1. Select the Sensor Site field.
2. Select the Category in the pop-up menu, and choose the specific site from the predefined list in the next pop-up menu. See Figure 20.
3. Press Select to save your choice and exit to the Settings menu screen.
4. To create a custom sensor site, choose Custom in the Category pop-up menu.
5. Name the custom sensor site using the alphanumeric keyboard and the Navigation buttons.
6. Select Save when name entry is complete and exit to the Settings menu.

Sensor Type

- When creating a Preset, this setting allows the user to select the type of sensor that will be attached to that channel, either rSO₂ or SpO₂.

- This field is automatically defined and disabled (gray) when a compatible sensor is attached to the Signal Processor.

Baseline (Manual Setting)

- rSO₂ Baseline values can be set by the user for each patient to compare subsequent rSO₂ changes relative to this Baseline.

- Baseline can be set in the Settings menu as a specific value (manually) using the Navigation buttons.
To manually set/change the **Baseline** to a value defined by the user (and not the patient’s current rSO2 value):

1. Select the **Baseline** field.
2. Press **Up/Down** to manually set **Baseline** to the desired value.
3. Press **Select** to save your setting and exit to the **Settings** menu screen.

**CAUTION:** Between patients, turn the SenSmart 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. Each time the device is turned ON or a new case is started, the Monitor clears the baseline values, resets the limits to the default values, clears any activated alarms, and begins a new patient record in data memory.

**Setting High and Low Alarm Limits for rSO2 or SpO2**

1. Connect a sensor to the Signal Processor.
2. Use **Left/Right** and **Up/Down** to move to and **Select** the desired channel and the alarm limit setting (shown in the green rectangle).
3. Press **Up/Down** and **Select** to change and **Save** the setting. See Figure 22 for alarm limit setting options.
4. Repeat as needed for each of the high and low alarm limit settings on all active channels. When complete, press **Menu** twice to return to the monitoring screen, or allow the screen to time out.

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

**Graph Position**

- Data from the sensors can be graphed and shown for each channel on the display.
- Regional oximetry channels will be graphed as a trend line.
- Pulse oximetry channels will be graphed as a plethysmogram.
- The System can display from one to six graphs, showing the rSO2 trend line data or the SpO2 plethysmograms, color-coded to match the channel and Signal Processor colors.
- Multiple rSO2 trend lines (up to six) can be placed on one graph; however, rSO2 trend lines and SpO2 plethysmograms cannot be on the same graph, and multiple SpO2 plethysmograms cannot be on the same graph.

- rSO2 trend lines: select A through F, or Off, trend lines appear in order of channels from A through F.

- SpO2 plethysmograms: select On or Off. Plethysmograms display in order of the channel and below rSO2 trend lines.

- To select and edit graph positions for each channel:
  1. Select the Graph Position setting in the desired channel.
  2. Press Up/Down and Select to change and save the setting.

**Review Current Preset**

- This setting (at the bottom of the Settings menu screen in the middle) shows the current Preset (discussed in the next section Presets Menu) that is displayed in each channel in the Settings menu.

- The user can use this field to scroll through all Presets to review the settings.

- Asterisks appear around the Preset when the active Preset has been modified in the Settings or System menu, but not saved yet.

**NOTE:** The system prompts you to save any modifications to the current Preset before moving to the next Preset to review.

To review all Presets:

1. Select the Preset field and Left/Right to scroll through each Preset and display the settings for that Preset in each channel.

2. Pressing Menu once makes the Preset on the screen the active Preset and pressing Menu again returns to the monitoring screen.
Presets Menu

A **Preset** is a collection of channel-specific, user-defined or default settings, configured in the **Settings** menu and the first six settings in the **System** menu (will be shown in the **System** Menu section), that the user may want to save as a **Preset** and easily recall.

- **In this menu, the user can quickly activate, create, rename, and/or delete the Monitor Presets.**
- **The Monitor can store up to 10 unique Presets as shown in Figure 23.**
- **Presets are either locked or unlocked which determines if they can be edited.**

To save current settings as a **Preset**:

1. First, use the **Settings** and **System** menus to set all limits and settings to the desired values.
2. When settings have been configured, select **Presets**.
3. Highlight “**Save Current Settings as New Preset.**”
4. Press **Select** to display **Presets 1-10** in pop-up menu. See Figure 23.
5. Using **Up/Down**, navigate to the desired **Preset** and **Select** to overwrite.

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

6. Enter **Preset** name (maximum of 11 alphanumeric characters) using the Navigation buttons on the alphanumeric keyboard. See Figure 24.
7. Press **Down** to highlight **Save**, and **Select** to save and activate the **Preset**.
8. The display returns to the monitoring screen.

To activate, delete, rename or lock/unlock a **Preset**:

1. Using **Up/Down**, navigate to the desired option and **Select**. See Figure 25.
2. Select the options in the next screens to confirm your action.
Case Menu

The Case menu screen allows the user to view the Current patient ID, Start a new case and enter a new patient ID, or Edit patient ID on the current case. See Figure 26.

To Open the Case Menu:

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

Case menu screen displays.

To 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 the down navigation arrow to highlight Yes. See Figure 27.
4. Press Select.
5. If the system is set up to enter a patient ID at the start of a new case:
   a. Alphanumeric keyboard screen displays. Enter patient ID (maximum of 15 alphanumeric characters).
   b. After patient ID is entered, “Starting new case...” displays.
   c. Monitor returns to monitoring screen and all baselines from the previous case are cleared.
6. If system is not set up to enter a patient ID at the start of a new case:
   a. “Starting new case...” displays.
   b. Monitor returns to monitoring screen and all baselines from the previous case are cleared.
   c. The case will not have a patient ID.

CAUTION: Between patients, turn the SenSmart 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. Each time the device is turned ON or a new case is started, the Monitor clears the baseline values, resets the limits to the default values, clears any activated alarms, and begins a new patient record in data memory.
System Menu

In the System menu, the user can configure features of the System using the Navigation buttons. See Figure 28.

Table 9. Settings menu options and available settings.

<table>
<thead>
<tr>
<th>Option</th>
<th>Description and Available Settings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brightness*</td>
<td>A slider with 15 adjustable steps; high to low.</td>
</tr>
<tr>
<td>Alarm Volume*</td>
<td>A slider bar with 15 adjustable steps; the lowest step is Off. <strong>NOTE:</strong> If the volume is set at step 4 or lower decibels, the slider turns yellow and the alarm Silence indicator is lit.</td>
</tr>
<tr>
<td>rSO2 Low Alarm Mode*</td>
<td>1. Select % Below Baseline to automatically set low alarm to a set percentage below baseline.</td>
</tr>
<tr>
<td></td>
<td>2. Select Absolute to manually set a low alarm to an absolute value.</td>
</tr>
<tr>
<td>Pulse Tone Volume*</td>
<td>A slider bar with 15 adjustable steps; the lowest step is Off.</td>
</tr>
<tr>
<td>Pulse Tone Source*</td>
<td>Channel designation for pulse tone: Channels 1 – 6.</td>
</tr>
<tr>
<td>Data Output Modes*</td>
<td>Unique once-per-second, real-time data output formats for:</td>
</tr>
<tr>
<td></td>
<td>Bluetooth: Nonin 1 – Nonin 5</td>
</tr>
<tr>
<td></td>
<td>RS-232: Nonin 1 – Nonin 5, Printer</td>
</tr>
<tr>
<td>Clear Memory</td>
<td>Deletes all patient data recordings from Monitor</td>
</tr>
<tr>
<td>Restore Factory Defaults</td>
<td>Discards all Presets and institution settings and restores factory defaults.</td>
</tr>
<tr>
<td>System Information</td>
<td>Hardware and software versions for SenSmart Monitor and attached Signal Processors.</td>
</tr>
<tr>
<td>Date/Time</td>
<td>Set Monitor date YYYY-MM-DD and time HH:MM:SS (See Figure 30).</td>
</tr>
<tr>
<td>Nurse Call Mode</td>
<td>Allows alarm notification at a central monitoring location configured/tested by user. See the System Operator’s Manual for complete instructions for use.</td>
</tr>
<tr>
<td>Bluetooth® Wireless</td>
<td>On/Off and pairing address information. See the SenSmart System Operator’s Manual for complete instructions for use.</td>
</tr>
<tr>
<td>Language</td>
<td>English  Dutch  French  German  Italian  Portuguese  Spanish  Swedish</td>
</tr>
<tr>
<td>Patient ID Request</td>
<td>Determines if patient ID is required to start a new case.</td>
</tr>
<tr>
<td>System Name</td>
<td>Assign system name.</td>
</tr>
<tr>
<td>Default Preset</td>
<td>Assign institution default Preset.</td>
</tr>
<tr>
<td>Institution Default Limits</td>
<td>Institutional defaults for all alarm settings.</td>
</tr>
<tr>
<td>Institution Password</td>
<td>Set 4-digit number to unlock institution-controlled settings; default is 0000.</td>
</tr>
</tbody>
</table>

*These features can be included as a Preset setting.
To select and change the **System** settings:

1. Use the **Navigation** buttons to move to and **Select** the desired feature in the **System** menu.
2. Press **Up/Down** and **Left/Right** to edit settings and **Select** to save the setting.
3. Repeat as needed for each of the settings.
4. When complete, press **Menu** twice to return to the monitoring screen, or allow the screen to time out.

Below are instructions on how to change a few of the **System** settings. See the SenSmart System Operator’s Manual for complete instructions for use.

### To Clear Memory:

1. Select the **System** menu.
2. Select the **Clear Memory** option in the first column.
3. Select **No** or **Yes**.
4. Press **Select** to save your choice and exit to the **System** menu. See Figure 29.

### To set the Date and Time:

1. Select the **System** menu.
2. Select the **Date / Time** option in the second column.
3. Select the field to edit in the pop-up menu.
4. Press **Up/Down** and **Left/Right** to edit the date and time settings.
5. Press **Select** to save field.
6. Use **Up/Down/Right/Left** to move to another field, repeat as needed.
7. Press **Menu** to exit and save your changes. See Figure 30.
Review System Menus

To review what you have learned about the System menus during configuration of the System, please complete the following tasks:

1. In the Settings Menu:
   a. Set the Sensor Site for Channel 1 to Left Cerebral.
   b. Set Channel 1 Sensor Type to rSO2.
   c. Set the Sensor Site for Channel 2 to Right Cerebral.
   d. Set Channel 2 Sensor Type to rSO2.
   e. Set the Sensor Site for Channel 3 to Left Hand Finger.
   f. Set Channel 3 Sensor Type to SpO2.
   g. For Channel 3, set the SpO2 High alarm setting at 100% and the SpO2 Low at 90%.
   h. For Channel 3, set the PR High alarm setting at 150 and the PR Low alarm setting at 50.
   i. Set both rSO2 channels to a rSO2% Low alarm setting of -25.
   j. Set both rSO2 channels to a rSO2% High alarm setting of 90.

2. Verify your new settings in the Settings Menu.

3. Save these new settings as a Preset named TRAINING in the Presets Menu.

4. In the System Menu:
   a. Set the Date/Time to the current date and current time.
   b. Set the Alarm Volume to level 12.

5. In the System Menu:
   a. Set the rSO2 Low Alarm Mode to Absolute.

6. In the Settings Menu:
   a. Set the %rSO2 Low (Abs) in the rSO2 channels to 49.

7. In the Preset Menu:
   a. Save the new settings as a Preset named TRAINING2.
   b. Return to the monitoring screen.

8. Set the rSO2 Baselines to the current rSO2 values at this time.

9. Mark an Event at this time.
   a. Note the Event alpha character that appears
   b. Note the channel 1 rSO2 value at this time
   c. Note the SpO2 value at this time

Congratulations! You will now be able to set up the System and begin patient monitoring.
System Alarm Indicators

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

High Priority Alarms

- High priority alarms require immediate attention to the patient and include high and low rSO2 and SpO2 alarms.

<table>
<thead>
<tr>
<th>Alarm</th>
<th>Visual Indicator</th>
<th>Audible Indicator</th>
</tr>
</thead>
<tbody>
<tr>
<td>rSO2 HIGH Limit (rSO2 ≥ high alarm limit)</td>
<td>• rSO2 channel background flashes RED 2 times per second;</td>
<td>3 beeps, pause, 2 beeps, pause, 3 beeps, pause, 2 beeps, and a 6-second pause.</td>
</tr>
<tr>
<td></td>
<td>• Channel text becomes white.</td>
<td>Cycle repeats until silenced or the alarm condition is cleared.</td>
</tr>
<tr>
<td>rSO2 LOW Limit (rSO2 ≤ low alarm limit)</td>
<td>• rSO2 channel background flashes RED 2 times per second;</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Channel text becomes white.</td>
<td></td>
</tr>
<tr>
<td>SpO2 HIGH Limit (SpO2 ≥ high alarm limit)</td>
<td>• SpO2 portion of channel background flashes RED 2 times per second;</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• SpO2 value becomes white.</td>
<td></td>
</tr>
<tr>
<td>SpO2 LOW Limit (SpO2 ≤ low alarm limit)</td>
<td>• SpO2 portion of channel background flashes RED 2 times per second;</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• SpO2 value becomes white.</td>
<td></td>
</tr>
<tr>
<td>Pulse HIGH Limit – SpO2 channel only (Pulse is ≥ high alarm limit)</td>
<td>• Pulse portion of channel background flashes RED 2 times per second;</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Pulse rate value becomes white.</td>
<td></td>
</tr>
<tr>
<td>Pulse LOW Limit – SpO2 only (Pulse ≤ low alarm limit)</td>
<td>• Pulse portion of channel background flashes RED 2 times per second;</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Pulse rate value becomes white.</td>
<td></td>
</tr>
<tr>
<td>Critical Low Battery</td>
<td>• Battery indicator flashes RED twice every second.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Display will go blank when battery has been completely discharged.</td>
<td></td>
</tr>
<tr>
<td>Low Perfusion – displays when the system detects low perfusion at the SpO2 sensor site.</td>
<td>• Channel background flashes RED 2 times per second.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Channel text becomes white.</td>
<td></td>
</tr>
</tbody>
</table>

WARNING: Ensure all alarm volumes are set appropriately and are audible in all situations. Do not cover or otherwise block any speaker openings.
Medium Priority Alarms

- Medium priority alarms signal potential problems with the equipment or other non-life-threatening situations.
- These alarms will display at the bottom of each channel window on the display to alert the user that there is a potential problem with collecting data from the sensor.
- See the Troubleshooting Guide for actions to take to resolve the alarm condition.

Table 11. SenSmart medium priority alarm indicators and descriptions.

<table>
<thead>
<tr>
<th>Visual Indicator</th>
<th>Alarm</th>
<th>Visual Description</th>
<th>Audible Indicator</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="sensor-fault.png" alt="Sensor Fault" /></td>
<td>Sensor Fault</td>
<td>Flashes YELLOW when a sensor is disconnected, sensor has failed, or is not compatible with the Signal Processor.</td>
<td>3 beeps followed by a 20-second pause.</td>
</tr>
<tr>
<td><img src="poor-signal.png" alt="Poor Signal" /></td>
<td>Poor Signal</td>
<td>Flashes YELLOW when there has been a sustained period of poor patient signals from the sensor.</td>
<td></td>
</tr>
<tr>
<td><img src="signal-processor-communication.png" alt="Signal Processor Communication" /></td>
<td>Signal Processor Communication</td>
<td>Flashes YELLOW when the respective Signal Processor has stopped communicating with the Monitor.</td>
<td>Cycle repeats until silenced or the alarm condition is cleared.</td>
</tr>
</tbody>
</table>
| ![rSO2 Warning](rSO2-warning.png) | rSO2 Warning                 | • rSO2 channel background flashes YELLOW once every 2 seconds when the rSO2 value is within 5 points of the lower alarm limit;  
                                      • Channel text turns gray.                                |                                                        |
| ![Low Battery](low-battery.png) | Low Battery                  | Battery indicator flashes YELLOW once every 2 seconds                               |                                                        |
| ![Error Codes](error-codes.png) | Error Codes                  | Indicated by error code across the screen                                           | Loud, two-tone steadily beeping signal.                 |

Table Data: E + numerical: E01, E02, E03, E04, E06, E08, E09, E10
Troubleshooting

• If you encounter any of the following visual or audible alarms, please review the possible causes and solutions to resolve the problem.

• Save all suspect components for return to Nonin Technical Service for evaluation.

• If these actions do not resolve the problem, please contact Nonin Technical Service at:
  
  USA and Canada  800-356-8874
  Outside USA and Canada  +1 763-553-9968
  Europe  +31 (0)13 79 99 040

Table 12. SenSmart troubleshooting guide.

<table>
<thead>
<tr>
<th>Visual Indicator</th>
<th>Problem / Possible Cause</th>
<th>Possible Solutions</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CHANNEL DOES NOT APPEAR ON MONITOR</td>
<td>Turn the X-100M 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.</td>
</tr>
<tr>
<td></td>
<td>Signal Processor is attached, but the channel does not appear on the Monitor</td>
<td></td>
</tr>
</tbody>
</table>
|                  | DASHES (- - -) APPEAR IN THE rSO2 CHANNEL DISPLAY             | 1. Ensure all connections between components are secure.  
  a. Check the connection between the sensor, Intermediate Cable and the Signal Processor.  
  b. Check the connection between the Signal Processor and the Hub.  
  c. Check the connection between the Hub and the Monitor. |
|                  | Sensor or Signal Processor is disconnected                    | 1. Check sensor application to ensure it is properly adhered to the patient.  
  a. Cover the sensor with your hand and apply very light pressure to see if this eliminates the error. If a value displays again, this is an indication that the sensor is lifting from the skin due to moisture or poor adhesion.  
  2. Ensure the sensor edges are secure.  
  3. Remove the sensor and wipe away the moisture if possible.  
  4. Sensor should be replaced if it does not adhere properly. |
|                  | The signal from the sensor is inadequate                      | 1. Ensure the connection between the Signal Processor and the Monitor.  
  a. If one emitter is not flashing, replace the sensor.  
  b. If both emitters are not flashing, disconnect and reconnect the Signal Processor at the Intermediate Cable and Hub connection. If both emitters continue to not flash, replace the sensor.  
  c. If both emitters are flashing and an alarm symbol is present, replace the sensor.  
  2. If the new sensor does not work, replace the Signal Processor at this time.  
  3. Save all suspect components for return to Nonin Technical Service for evaluation.  
### Table 12. SenSmart troubleshooting guide (continued).

<table>
<thead>
<tr>
<th>Visual Indicator</th>
<th>Problem / Possible Cause</th>
<th>Possible Solutions</th>
</tr>
</thead>
</table>
| **DASHES (- - -) APPEAR IN THE rSO2 CHANNEL DISPLAY** | The Signal Processor is damaged or not functioning properly. Connections may not be secure. | 1. Ensure all connections between components are secure.  
   a. Check the connection between the sensor, Intermediate Cable and the Signal Processor.  
   b. Check the connection between the Signal Processor and the Hub.  
   c. Check the connection between the Hub and the Monitor.  
2. Turn the Monitor off and then back on again.  
3. Contact Nonin Technical Service. |
| **DASHES - - - (<<------>>)** | The SenSmart display is not functioning. | 1. If all channels show dashes, verify secure connections on the Hub to the Signal Processor and to the Monitor.  
2. Contact Nonin Technical Service. |
| **ONE OR MORE CHANNELS DISPLAY MESSAGE “DUPLICATE X-100SP”** | One or more channels display the message “Duplicate X-100SP.” | Verify that duplicate Signal Processors are not attached to the Hub. Remove or replace the duplicate Signal Processor. |
| **AN ERROR CODE APPEARS IN THE DISPLAY AREA** | The SenSmart System encountered an error. | 1. Turn the Monitor off to go through a proper shutdown process.  
2. Turn the Monitor on again.  
3. If the error persists, note the error code and contact Nonin Technical Service. |
| **E01, E02, E03, E04, E06, E08, E09, E10** | The 2-minute Alarm Silence button is activated. | 1. Press **Alarm Silence** to re-engage alarm volume.  
2. After 2 minutes of silence, alarm tones automatically re-engage. |
| **AUDIBLE VOLUME SET TO “0” IN ALARM LIMITS.** | Audible volume set to “0” in alarm limits. | 1. Adjust volume **Up/Down** through **System** menu.  
2. Contact Nonin Technical Service if alarm tones continue to not be audible. |
| **THE UNIT IS IN ALARM MODE, BUT NO AUDIBLE ALARMS CAN BE HEARD** | The unit has no power. | 1. Plug in the AC adapter.  
2. Turn the Monitor on.  
3. If the Monitor does not power on, contact Nonin Technical Service. |
| **SENSMART SYSTEM WILL NOT ACTIVATE** | The battery pack is not charged. | 1. Plug in the SenSmart System AC Adapter to charge the battery pack.  
2. Turn the Monitor on.  
3. If Monitor does not power on, contact Nonin Technical Service. |
| **SENSMART SYSTEM WILL NOT OPERATE ON BATTERIES** | The battery pack is inoperable. | Contact Nonin Technical Service for repair or replacement. |
System Memory

- Data recording in the Monitor functions in an endless loop, meaning that when the memory capacity is reached, as described in Table 13 below, the Monitor begins overwriting the oldest data with new data.
- \( rSO_2 \) and Hbl or SpO_2 and PR is sampled and recorded once every 4 seconds for each channel.
- Patient data can be cleared using the Clear Memory option in the System menu. See Figure 31.

### Table 13. SenSmart System memory.

<table>
<thead>
<tr>
<th>Hours of Memory</th>
<th>Channels in Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>840</td>
<td>2</td>
</tr>
<tr>
<td>420</td>
<td>4</td>
</tr>
<tr>
<td>280</td>
<td>6</td>
</tr>
</tbody>
</table>

System Data Outputs

- The Monitor features 5 different once-per-second, real-time data output formats, Nonin 1 – Nonin 5.
- Data output formats can be selected through the Data Output Modes option in the Systems menu.
- See the SenSmart System Operator's Manual for complete information and instructions for use for all data output formats.

Cleaning the System Components

1. Wipe all components (Monitor, Signal Processor, Intermediate Cable, Hub, Hub Holster, Extension Cable, and SenSmart 8100S(X) Pulse Oximetry Soft Sensors) with a soft cloth dampened with a 90% water/10% bleach 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.

3. SenSmart \( rSO_2 \) sensors are single use and should be discarded after one use.

**CAUTION:** Do not sterilize, autoclave, immerse, spray with liquid, or use caustic or abrasive cleaning agents. Do not use cleaning agents or cleaning products that contain ammonium chloride.
Warranty

Table 14. SenSmart System warranty information.

<table>
<thead>
<tr>
<th>SenSmart Component</th>
<th>Warranty Terms</th>
</tr>
</thead>
<tbody>
<tr>
<td>X-100M Battery Pack</td>
<td>1 year from date of purchase.</td>
</tr>
<tr>
<td>INT-100 Intermediate Cable</td>
<td>1 year from date of purchase.</td>
</tr>
<tr>
<td>X-100M Monitor</td>
<td>3 years from date of purchase.</td>
</tr>
<tr>
<td>X-100H Hub and X-100HH Hub Holster</td>
<td>3 years from date of purchase.</td>
</tr>
<tr>
<td>X-100SP Signal Processor</td>
<td>3 years from date of purchase.</td>
</tr>
<tr>
<td>X-100EC-1 and -2 Extension Cable</td>
<td>3 years from date of purchase.</td>
</tr>
</tbody>
</table>

How to Get Help – Service and Support

Nonin Medical offers extensive technical, clinical, and customer service support for questions or assistance. These include:

- Your Local Account Manager
- Clinical Specialists
- Customer Service
- Technical Service

Customer and Technical Service Contact Information

Ask for Technical Service:

USA and Canada 800-356-8874
Outside USA and Canada +1 763-553-9968
Europe +31 (0)13 79 99 040

Technical Service email:

USA and Canada technicalservice@nonin.com
Europe technicalserviceintl@nonin.com

Contact Nonin Technical Service for a return authorization number (RAN) which is required before returning any product to Nonin. For more information, visit nonin.com/techservices.