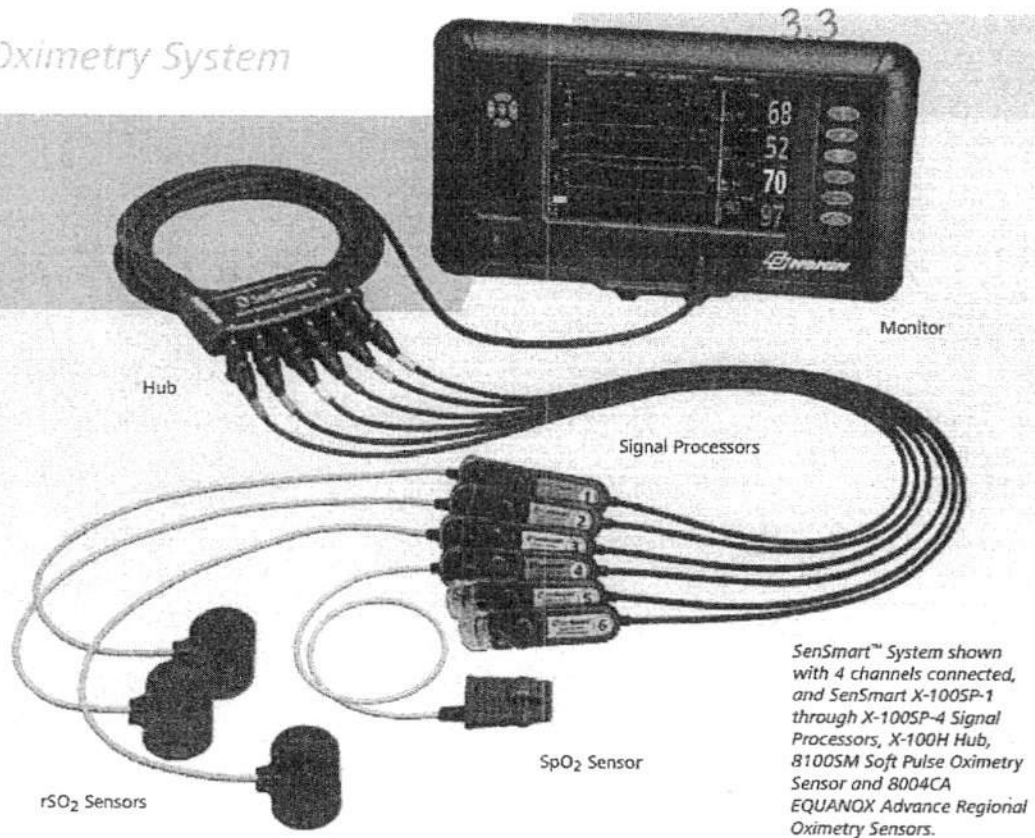


1, 2, 3

# SenSmart™ Model X-100

Universal Oximetry System



SenSmart™ System shown with 4 channels connected, and SenSmart X-100SP-1 through X-100SP-4 Signal Processors, X-100H Hub, 8100SM Soft Pulse Oximetry Sensor and 8004CA EQUANOX Advance Regional Oximetry Sensors.

The first oximetry system to put regional oximetry, pulse oximetry and ease of use at your fingertips.

An innovative design that pairs simple with smart, Nonin Medical's **SenSmart Model X-100 Universal Oximetry System** is the first system to deliver both pulse and regional oximetry measurements today, and is designed to accommodate more parameters in the future.

3.2 The portable SenSmart System provides multiple rSO<sub>2</sub> and SpO<sub>2</sub> values on the same screen for real-time decision making.

# SenSmart™ Model X-100 Universal Oximetry System

## Product Highlights

- Highly Accurate** – The SenSmart System's EQUANOX Advance 8004CA rSO<sub>2</sub> Sensor provides clinicians with state-of-the-art accuracy. Nonin's reusable SpO<sub>2</sub> Soft Sensors provide fast, accurate and reliable readings even in patients with low perfusion or in the presence of motion.
- Versatile** – The ability to use any combination of Nonin SenSmart-compatible rSO<sub>2</sub> sensors and/or SpO<sub>2</sub> sensors to monitor up to six sites on a patient.
- Easy to Use** – The smaller, lighter and less-intrusive SenSmart Universal Signal Processors automatically recognize and display all of your oximetry values on the SenSmart Monitor.
- Convenient** – The portable, easy-to-operate SenSmart Monitor offers Bluetooth wireless connectivity and comes with case download software.



## Data Management

The SenSmart™ Download Software enables the easy transfer of a patient file as a PDF or CSV file.



## SenSmart™ Model X-100 System Components

|   |   |
|---|---|
| <b>SenSmart Standard System Configuration</b><br>System Configuration with US power plug<br>System Configuration with UK power plug<br>System Configuration with EU power plug<br>System Configuration with AU power plug | SenSmart 8100SS Soft Pulse Oximetry Sensor (small)<br>SenSmart 8100SM Soft Pulse Oximetry Sensor (medium)<br>SenSmart 8100SL Soft Pulse Oximetry Sensor (large) |
| <b>SenSmart X-100M Monitor<sup>1</sup></b>  | SenSmart 8004CA EQUANOX Advance Adult/Pediatric Regional Oximetry Sensor (absolute) (20 pack)   |
| <b>SenSmart X-100SP-1 Signal Processor Channel 1<sup>1</sup></b>  | SenSmart 8003CA EQUANOX Classic Plus Adult/Pediatric Regional Oximetry Sensor (trending) (20 pack)  |
| <b>SenSmart X-100SP-2 Signal Processor Channel 2<sup>1</sup></b>  | SenSmart 8004CB EQUANOX Advance Neonatal/Pediatric Regional Oximetry Sensor (adhesive) (20 pack)  |
| <b>SenSmart X-100SP-3 Signal Processor Channel 3</b>  | SenSmart 8004CB-NA EQUANOX Advance Neonatal/Pediatric Regional Oximetry Sensor (non-adhesive) (20 pack)   |
| <b>SenSmart X-100SP-4 Signal Processor Channel 4</b>  | SenSmart X-100CC Carrying Case  |
| <b>SenSmart X-100SP-5 Signal Processor Channel 5</b>  | Pole Mount Clamp  |
| <b>SenSmart X-100SP-6 Signal Processor Channel 6</b>  | SenSmart MPP30M Power Supply <sup>1</sup>   |
| <b>SenSmart X-100H Hub<sup>1</sup></b>  | SenSmart Download Software <sup>1</sup>   |
| <b>SenSmart X-100HH Hub Holster<sup>1</sup></b>   |   |
| <b>SenSmart X-100EC-1 Extension Cable (1 m)<sup>1*</sup></b>  |   |
| <b>SenSmart X-100EC-2 Extension Cable (2 m)</b>   |   |

<sup>1</sup>Indicates component is included in the Standard System Configuration.  
<sup>\*</sup>Standard System Configuration includes two cables.

## 4. Specifications

**Oxygen Saturation Display Ranges:** rSO<sub>2</sub>: 0 to 100%, SpO<sub>2</sub>: 0 to 100%  
**Pulse Rate Display Range:** 18 to 300 beats per minute (BPM)  
**Sensor Accuracy:** For declared accuracy data for compatible sensors, refer to the sensor Instructions for Use (IFU). Sensor IFUs are included on the operator's manual CD.

**Memory:**  
 840 hours (operating with 2 channels)  
 420 hours (operating with 4 channels)  
 280 hours (operating with 6 channels)  
**Temperature:** Operating: 0 °C to 40 °C (32 °F to 104 °F)  
 Storage/Transportation: -30 °C to 70 °C (-22 °F to 158 °F)  
**Humidity:** Operating: 15% to 93% noncondensing.  
 Storage/Transportation: Up to 93% noncondensing

**4.3 Altitude:** Operating: 0 to 4,000 meters (13,124 feet)

**Power Requirements (Mains):** 100–240 VAC 50–60 Hz  
**Internal Power:** 3.4, 4.12  
 Battery: 7.2 volt Li-ion battery pack; 2.4 Ah when charged

**Operating Life (fully charged battery and screen at default brightness):**

3 hours minimum (operating with 2 channels)  
 1 hour minimum (operating with 6 channels)  
**4.12**

**Charged Storage Life:** 20 days minimum  
**Recharge Time to 90% Capacity:** 2.5 hours maximum  
**4.12**

### Dimensions:

X-100M: 305 mm W x 180 mm H x 130 mm D (12.0 in W x 7.2 in H x 5.0 in D)  
 X-100H: 105 mm W x 66 mm H x 22 mm D with 4.0 m cable (4.14 in. W x 2.6 in H x 0.86 in D with 13.1 ft cable)  
 X-100SP: 21.4 mm H x 21.7 mm W x 72.7 mm L (including strain relief) with 0.75 m cable (0.84 in H x 0.85 in W x 3.1 in L including strain relief) with 2.5 ft cable)

### Weight:

X-100M: Approximately 900 grams (2 pounds)  
 X-100H: 243 grams (8.6 ounces)  
 X-100SP: 40 grams (1.4 ounces)  
**4.15**

**Warranty:** X-100M, X-100SP, X-100H, X-100HH, X-100EC: 3 years; X-100M Battery Pack: 1 year  
**Classification per IEC 60601-1 / CAN/CSA-C22.2 No. 601.1 / UL60601-1:** 3.5

Type of Protection: Internally powered (on battery power) Class II with AC adapter  
 Degree of Protection: X-100SP: Defibrillation Proof Type BF Applied Part  
 X-100M: Type BF Applied Part

Mode of Operation: Continuous

**Enclosure Degree of Ingress Protection:** X-100M, X-100H, X-100SP: IP32

### Transmitter

**4.10 Bluetooth Compliance:** Version 2.0  
 Operating Frequency: 2.4 to 2.4835 GHz  
 Output Power: < 20 dBm  
 Operating Range: 100 meter (328 feet)  
 radius indoors (line of sight when connected to a class I device)  
 Network Topology: Star  
 Operation: Bluetooth Slave  
 Antenna Type: Internal

Modulation Type: Gaussian  
 Frequency Shift Keying  
 Bandwidth: 1 MHz  
 Bluetooth Profiles Supported:  
 Serial Port Profile (SP2)  
 Security Mode: Mode 2  
 (service level enforced security)  
 Authentication and Encryption:  
 Enforced on all data channels  
 (outgoing and incoming)  
 Encryption Key Size: Up to 128 bits

Specifications are subject to change without notice.

## Authorized Distributors



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 PIN 40361-001-01

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|  |  |
|--|--|
| <b>Internal Power:</b>   |  |
| Battery:   | 7.2 volt Li-ion battery pack, 2.4 Ah when charged  |
| Operating Life (fully charged battery and screen at default brightness):         | 6 hours minimum (operating with 1 channel)<br>3 hours minimum (operating with 2 channels)<br>2 hours minimum (operating with 4 channels)<br>1 hour minimum (operating with 6 channels) |
| Storage Life:  | 20 days minimum  |
| Recharge Time to 90% Capacity:   | 2.5 hours maximum  |
| <b>Dimensions:</b>   |  |
| X-100M:  | 305 mm W x 180 mm H x 130 mm D<br>(12.0 in. W x 7.2 in. H x 5.0 in. D)   |
| X-100H:  | 105 mm W x 66 mm H x 22 mm D with 4.0 m cable<br>(4.14 in. W x 2.6 in. H x 0.86 in. D with 13.1 ft cable)  |
| X-100SP:   | 21.4 mm H x 21.7 mm W x 72.7 mm L (including strain relief) with 0.75 m cable<br>(0.84 in. H x 0.85 in. W x 3.1 in. L (including strain relief) with 2.5 ft cable)                     |
| <b>Weight:</b>   |  |
| X-100M:  | Approximately 900 grams (2 pounds)   |
| X-100H:  | 243 grams (8.6 ounces)   |
| X-100SP:   | 40 grams (1.4 ounces)  |
| <b>Warranty:</b>   |  |
| X-100M, X-100SP, X-100H, X-100HH,  | 3 years  |
| X-100EC:   |  |
| X-100M Battery Pack:   | 1 year   |
| <b>Classification per IEC 60601-1 / CAN/CSA-C22.2 No. 601.1 / UL60601-1: 3.5</b> |  |
| Type of Protection:  | Internally powered (on battery power).<br>Class II with AC adapter.  |
| Degree of Protection:  | Defibrillation Proof Type BF Applied Part  |
| Mode of Operation:   | Continuous   |
| <b>Enclosure Degree of Ingress Protection:</b>                                   |  |
| X-100M, X-100H, X-100SP:   | IP32   |



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## X-100SP (Signal Processor)

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

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

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

The signal processors are color coded:

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

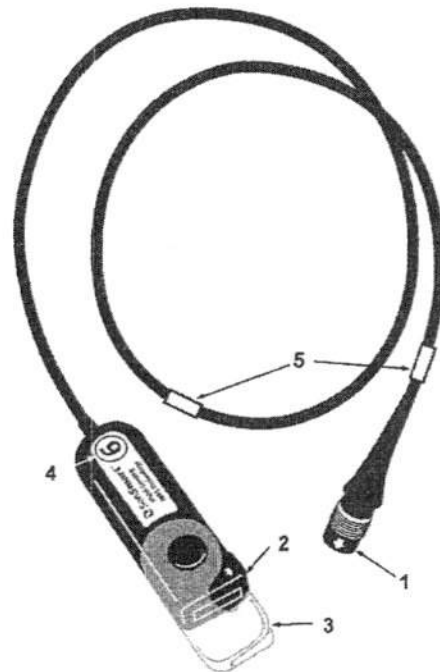


Figure 9. X-100SP – Signal Processor

Table 6. X-100SP Features

| No. | Description                      |
|-----|----------------------------------|
| 1   | Signal processor cable connector |
| 2   | Sensor connection port           |
| 3   | Sensor lock                      |
| 4   | Channel number                   |
| 5   | Cable clips                      |

For cleaning instructions, refer to "Care and Maintenance" on page 71.

### Connect a Signal Processor to Hub or Monitor

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

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

### Disconnect a Signal Processor from Hub or Monitor

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

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

4.4



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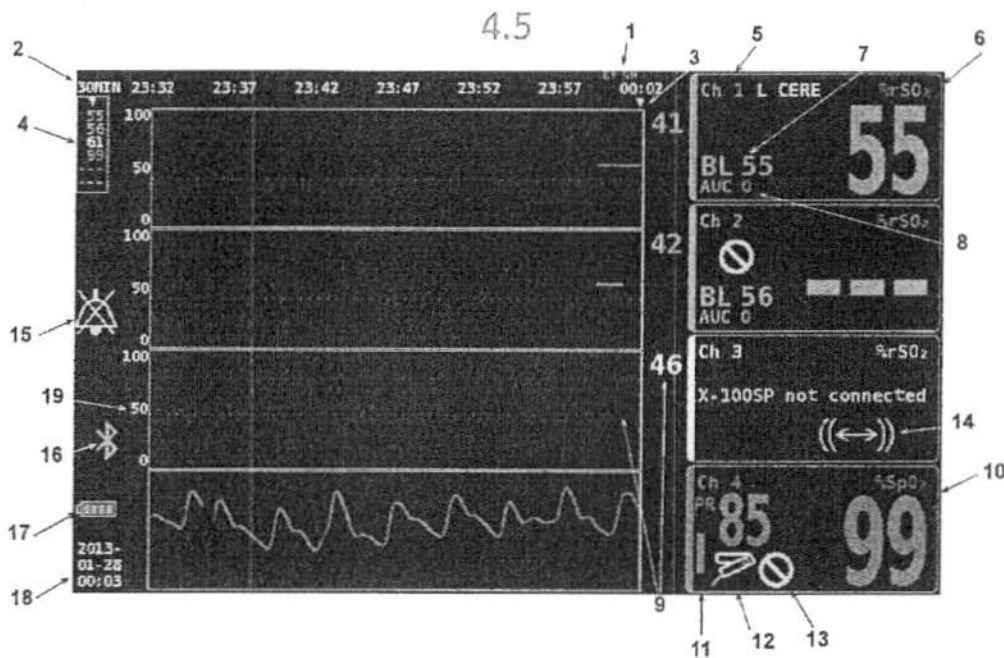


Figure 1. Monitoring Screen Symbols (Four-Channel View)

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

| No. | Symbol            | Description   |
|-----|-------------------|---|
| 1   | example:<br>A B   | <b>Event Marks 4.14</b><br>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:<br>30MIN | <b>Timescale</b><br>Located below the event marks, the timescale shows the amount of data time displaying on the screen.  |
| 3   |                   | <b>Scrolling Cursor</b><br>Located below the timescale, the yellow scrolling cursor allows the user to view a channel's rSO <sub>2</sub> or SpO <sub>2</sub> reading at a specific time on the trendline.<br>The scrolling cursor does not display until the Left navigation button has been pressed. |
| 4   |                   | <b>Cursor Values</b><br>When the scrolling cursor is active, cursor oximetry (rSO <sub>2</sub> or SpO <sub>2</sub> ) values display on the left side of the monitor screen in a yellow box.<br><b>NOTE:</b> 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  | <p><b>Channel</b></p> <p>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.</p>  |
| 6   | %rSO <sub>2</sub><br>or<br>%rSO <sub>2</sub> -T | <p><b>Regional Hemoglobin Oxygen Saturation</b></p> <p><b>NOTE:</b> %rSO<sub>2</sub> displays when an absolute regional sensor is attached to a signal processor. %rSO<sub>2</sub>-T displays when a trending regional sensor is attached to a signal processor.</p> <p>%rSO<sub>2</sub> displays from 0 to 100% when a signal processor receives an adequate signal from an attached regional sensor.</p> <p>The channel background display flashes:</p> <ul style="list-style-type: none"> <li>• <b>Yellow</b> during medium priority alarm conditions (equipment alarms and rSO<sub>2</sub> values that are 5% or less above the rSO<sub>2</sub> low alarm limit).</li> <li>• <b>Red</b> during high priority rSO<sub>2</sub> alarm conditions (set by the high and low rSO<sub>2</sub> alarm limits).</li> </ul> |
| 7   | BL4.7   | <p><b>Baseline</b></p> <p>When the monitor is turned on, the BL display shows dashes until the user sets the baseline values.</p> <p>The user must set the baselines for each new patient.</p> <ul style="list-style-type: none"> <li>• For instructions on setting the baseline values to the current rSO<sub>2</sub> values, see "Set All rSO<sub>2</sub> Channel Baselines to Current %rSO<sub>2</sub> Values" on page 28.</li> <li>• 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.</li> </ul>   |
| 8   | AUC4.8  | <p><b>Area Under the Curve</b> (cumulative saturation below low alarm limit)</p> <p>For each channel, the rSO<sub>2</sub> 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.</p> <p>The AUC will not calculate if a channel's %rSO<sub>2</sub> Low setting is OFF.</p> <p><b>NOTE:</b> 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.</p>   |



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

| No. | Symbol   | Description   |
|-----|--|---|
| 9   | example:<br><br>46<br><br>.....  | <p><b>Low Alarm Limit 4.8</b></p> <p>The low alarm limit is determined by the %rSO<sub>2</sub> Low setting and displays as the following:</p> <ul style="list-style-type: none"> <li>• <b>Numeric value</b> – This value displays to the right of a trendline graph. The color of the value matches the color of the associated channel.</li> <li>• <b>White, dotted line</b> – This line only displays in a graph when the graph shows a single rSO<sub>2</sub> trendline. The dotted line does not display when multiple trendlines are set to display in one graph.</li> </ul> <p><b>NOTE:</b> A low alarm limit does not display on the monitoring screen if the channel's %rSO<sub>2</sub> Low setting is OFF.</p> |
| 10  | %SpO <sub>2</sub>  | <p><b>Percent Functional Hemoglobin Oxygen Saturation</b></p> <p>%SpO<sub>2</sub> data displays from 0 to 100% when a signal processor receives an adequate signal from an attached pulse oximetry sensor.</p> <p>The background of the SpO<sub>2</sub> portion of the channel display flashes red during high priority SpO<sub>2</sub> alarm conditions (set by the high and low SpO<sub>2</sub> alarm limits) and low perfusion alarm conditions.</p>   |
| 11  | PR<br> | <p><b>Pulse Rate and Pulse Rate Bar Graph</b></p> <p>Pulse rate data displays along with the %SpO<sub>2</sub> 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.</p> <p>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.</p>   |
| 12  |       | <p><b>Sensor Fault</b></p> <p>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.</p>  |
| 13  |       | <p><b>Poor Signal</b></p> <p>This yellow indicator flashes when there has been a sustained period of poor patient signals from the sensor.</p> <p>Check the sensor site and reposition or replace the sensor if necessary.</p>  |
| 14  |       | <p><b>Signal Processor Communication Error</b></p> <p>This yellow indicator flashes and the message <i>X-100SP not connected</i> displays when the respective signal processor has stopped communicating with the display.</p> <p>Check the signal processor connections or replace the signal processor to correct the issue.</p> <p>If the message appears in each channel, check the hub's connection to the monitor.</p>  |

## Alarm Limits 4.6

Most alarm limits can be set and saved in a preset according to the options listed in table 8. The exceptions are the "%rSO<sub>2</sub> Low" and "%SpO<sub>2</sub> Low" alarm limits, which cannot be saved in a preset with a value lower than the institution default settings. See the "%rSO<sub>2</sub> Low" and "%SpO<sub>2</sub> Low" sections below for more information.

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

Table 8. Alarm Limit Settings

| Alarm Limit                                      | Factory Defaults                       | Adjustment Options                            | Adjustment Increments |
|--|--|---|-----------------------|
| %rSO <sub>2</sub> High                           | Off                                    | Off, 20% to 95%                               | 1%                    |
| %rSO <sub>2</sub> Low*                           |  |   |                       |
| %rSO <sub>2</sub> Low (% BL)<br>% below baseline | Baseline - 25%<br>(Baseline minus 25%) | Off, - 40% to - 5%<br>(minus 40% to minus 5%) | 1%                    |
| <b>or</b>  |  |   |                       |
| %rSO <sub>2</sub> Low (Abs) Absolute             | 50%                                    | Off, 15% to 90%                               | 1%                    |
| %SpO <sub>2</sub> High                           | Off                                    | Off, 80% to 100%                              | 1%                    |
| %SpO <sub>2</sub> Low                            | 85%                                    | Off, 50% to 95%                               | 1%                    |
| Pulse High                                       | 200 BPM                                | Off, 75 to 275 BPM                            | 5 BPM                 |
| Pulse Low  | 50 BPM                                 | Off, 30 to 110 BPM                            | 5 BPM                 |

\* Depending on how the rSO<sub>2</sub> Low Alarm Mode is set on the System Menu screen, this setting will be either "%rSO<sub>2</sub> Low (% BL)" or "%rSO<sub>2</sub> Low (Abs)."

**CAUTION:** A preset cannot be saved with %rSO<sub>2</sub> or %SpO<sub>2</sub> low alarm limit settings that are lower than the institution default settings. %rSO<sub>2</sub> and %SpO<sub>2</sub> low alarm limits that are lower than the institution defaults will be replaced in the preset with the institution default setting(s).

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

**NOTE:** The AUC will not calculate if the "%rSO<sub>2</sub> Low (% BL)" setting or "%rSO<sub>2</sub> Low (Abs)" setting is OFF.

### %rSO<sub>2</sub> Low

When a case begins, the rSO<sub>2</sub> low alarm limit will be the "%rSO<sub>2</sub> Low" value in the selected preset. During the case, the rSO<sub>2</sub> low alarm limit can be modified; however, the "%rSO<sub>2</sub> Low" setting is restricted by the device's defaults when saving a preset. The rSO<sub>2</sub> low alarm limit cannot be saved with a value lower than the institution default setting.



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Cerebral and Tissue Oximetry Technology  
Reliable Measurements  
in Real Time

**Count on Nonin.**



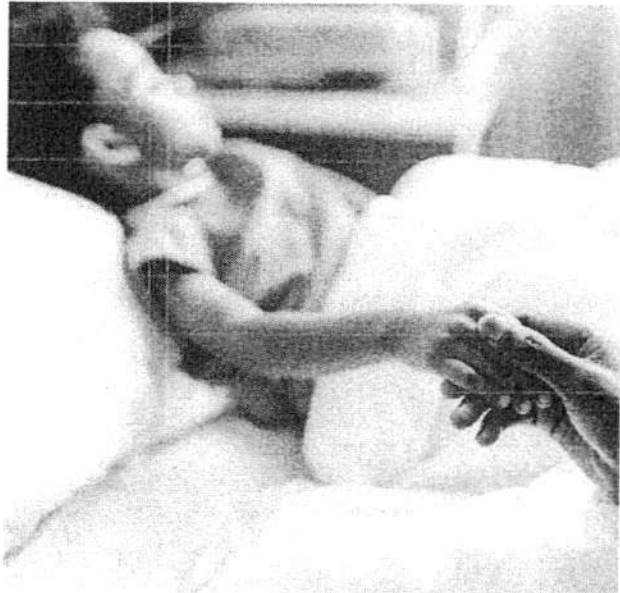
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# Unreliable Measurements Undermine Confidence

Medical professionals need to make important care decisions quickly. Knowing the oxygen saturation levels in a patient's brain or other tissue can make a critical difference.

Cerebral and tissue oximetry (rSO<sub>2</sub> or regional oximetry), lets clinicians noninvasively monitor patients at risk for compromised oxygenation. It can be used to:

- Monitor brain oxygen levels while patients are under general anesthesia
- Monitor tissue oxygen levels on a limb, especially when a femoral artery is used for access
- Monitor brain oxygen levels during CPR



Reliable rSO<sub>2</sub> values can be difficult to measure with confidence. Factors from extraneous tissue to ambient light to skin pigmentation can affect readings. Nonin regional oximetry technologies help overcome these complications to consistently deliver measurements clinicians can trust.

## Reliable Monitoring Solutions Work Whenever and Wherever You Need Them

Built on the foundation of proven SenSmart technology, Nonin cerebral and tissue oximetry systems provide responsive monitoring of adult, pediatric, and neonate patients who are at risk for compromised oxygen saturation to the brain or other tissues. Nonin solutions give clinicians the information they need to inform treatment decisions in multiple care environments.

Undetected desaturations can compromise care and negatively impact patient outcomes\*

\* Mohandas BS, Jagadeesh AM, Vikram SB. Impact of monitoring cerebral oxygen saturation on the outcome of patients undergoing open heart surgery. Ann Card Anaesth. 2013 Apr-Jun;16(2):102-5.



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# Advanced Technology for Proven Performance

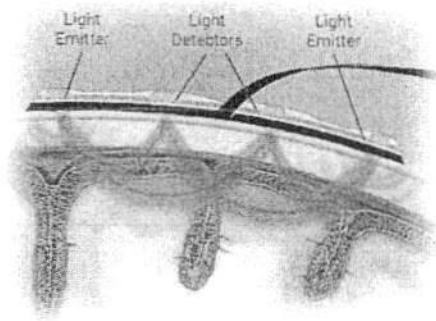
## 3.1

Oximetry equipment uses **near-infrared spectroscopy** to measure blood oxygenation levels in the brain and other tissues. Those measurements can be affected by factors such as extraneous tissue, ambient light, variations in skin pigmentation, and the presence of myelin (in the case of infants and neonates). Sensors with only one emitter are more vulnerable to errors as a result of these factors.

### Dual Emitter, Dual Detector Architecture

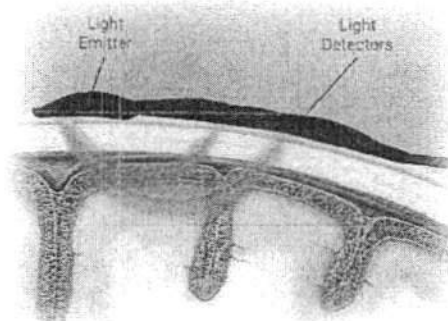
Nonin technology uses two emitters and two detectors in each sensor, plus patented algorithms, to create light paths through surface tissue and the cerebral cortex. This minimizes interference from extraneous tissue, variations in skin pigmentation, and ambient light. The resulting measurements are proven to be the industry's least affected by intervening tissue or surface effects.<sup>1</sup>

#### Nonin rSO<sub>2</sub> Sensor Technology



With two emitters and two detectors, Nonin delivers deep tissue readings with minimal signal contamination.

#### Competitors' rSO<sub>2</sub> Sensor Technology



Competitors who use one emitter and two detectors experience more interference.

### Sampling Rates and Display Update Speed

Nonin regional oximeters track changes in blood oxygen saturation levels and display results within two seconds. This provides fast, accurate information to help clinicians make quick and confident treatment decisions.

Reliable measurements help medical professionals provide responsive care

UPDATES WITHIN  
**2**  
SECONDS

<sup>1</sup> Davie SN, Greccott HP. Impact of Extracranial Contamination on Regional Cerebral Oxygen Saturation: A Comparison of Three Cerebral Oximetry Technologies. *Anesthesiology*. 2012; 116(4):834-40.

 **NONIN**



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