Set Institution Default Limits

1. While in the System Menu screen, use the navigation buttons to move to and highlight "Institution Default Limits."
2. Press **Select** to review current settings. Pop-up window displays settings along with "Edit..." highlighted.
   - To change the setting, press **Select** and continue with step 5.
   - To cancel, press **Menu**. Display returns to System Menu screen.
3. Enter the institution password.
4. "Institution Defaults" pop-up displays (figure 20). The following institution default limits may be set on this screen:
   - %rSO_2 High
   - %rSO_2 Low (% BL)
   - %rSO_2 Low (Abs)
   - %SpO_2 High
   - %SpO_2 Low
   - PR High
   - PR Low
5. Press the **up**/**down** navigation buttons to move to and highlight a setting.
6. Press **Select**. Small arrows display above and below the setting.
7. Press **up/down** navigation buttons to change the setting.
8. Press **Select** to set.
9. Repeat steps 7 – 9 until all desired institution defaults are set.
10. Press **Menu**. Monitor displays the following message: *Institution Defaults Changed. Presets with low SpO_2 and rSO_2 alarm limits lower than the new institution limits have been updated wtih the new limits.* Display returns to System Menu screen.
11. Change additional settings, press **Menu** twice to return to monitoring screen, or allow the screen to time out.

Change the Institution Password

1. While in the System Menu screen, use the navigation buttons to move to and highlight "Institution Password."
2. Press **Select** and follow the on-screen instructions:
   a. Enter current institution password.
   b. Enter new institution password.
   c. Enter new password again to confirm change.
      - If confirmation is successful, monitor displays *New password saved!* and returns to System Menu screen.
      - If password change is not successful, monitor displays *Confirmation failed* and returns to System Menu screen.
3. Change additional settings, press **Menu** twice to return to monitoring screen, or allow the screen to time out.

Alarms

The Model X-100M has audio and visual alarm indicators to alert the operator in case immediate patient attention is required or an equipment alarm occurs.

High Priority Alarms

High priority alarms require immediate attention to the patient. They include high and low rSO_2 alarms.

Table 10. High Priority Alarms

Alarm	Visual Indicator	Audible Indicator
rSO_2 High Limit – displays when rSO_2 is equal to or above high alarm limit	Channel background flashes RED 2 times per second. Channel text becomes white.	3 beeps, pause, 2 beeps, and a 10-second pause. This cycle repeats until silenced.
rSO_2 Low Limit – displays when rSO_2 is equal to or below low alarm limit	Channel background flashes RED 2 times per second. Channel text becomes white.	
SpO_2 High Limit – displays when SpO_2 is equal to or above high alarm limit	SpO_2 portion of channel background flashes RED 2 times per second and SpO_2 value becomes white.	
SpO_2 Low Limit – displays when SpO_2 is equal to or below low alarm limit	SpO_2 portion of channel background flashes RED 2 times per second and SpO_2 value becomes white.	
Pulse High Limit (SpO_2 only) – displays when pulse is equal to or greater than the Pulse High alarm limit	Pulse rate portion of channel background flashes RED 2 times per second and pulse rate value becomes white.	
Pulse Low Limit (SpO_2 only) – displays when pulse is equal to or less than the Pulse Low alarm limit	Pulse rate portion of channel background flashes RED 2 times per secondand pulse rate value becomes white.	
Critical Low Battery	Battery indicator ▭ flashes RED once every 2 seconds, parameters with alarms show dashes.	

Medium Priority Alarms

Medium priority alarms signal potential problems with the equipment or other non-life-threatening situations. They include rSO_2 warning, low battery, critical low battery, and sensor fault. On the Model X-100M, the medium priority alarms are as follows:

Table 11. Medium Priority Alarms

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. Channel text becomes gray.	3 beeps followed by a 25-second pause. This cycle repeats until silenced.
Low Battery	Battery indicator flashes YELLOW once every 2 seconds.	
Sensor Fault	Sensor fault indicator flashes YELLOW once every 2 seconds.	
Signal Processor Communication Error	Communication lost indicator flashes YELLOW once every 2 seconds and *X-100SP not connected* displays.	
Poor Signal	Poor Signal indicator flashes YELLOW once every 2 seconds.	

Silencing Alarms

Press **Alarm Silence** to silence alarms for 2 minutes. Audible alarms may be reactivated before the 2-minute silence period is over by pressing Alarm Silence again. All silenced audible alarms are automatically reactivated when a new physiological alarm goes off.

- The Alarm Silence indicator blinks while alarms are temporarily silenced.
- The Alarm Silence indicator is lit solidly when the alarm volume slider is yellow (step 4 or lower [less than 45 decibels]). Audible indicators can be turned off in the Alarm Volume menu option on the System Menu screen.

Error Codes

This device includes error codes that indicate problems with the unit. When an error occurs, the device emits a loud, two-tone, steadily beeping signal and an error code displays on the monitor screen. Error codes are indicated by the letter “E” and a two-letter code (table 9).

To correct error conditions, perform these steps:

1. Turn the unit off and then back on again to remove the error code.
2. If the error persists, note the error code and contact Nonin Technical Service at (800) 356-8874 (USA and Canada), +1 (763) 553-9968, or +46 650 401500 (Europe).

Table 12. Error Codes

Error	Visual Indicator
Stuck Key	E01
Sound Module Fault	E02
Sound Module Communications Fault	E03
Oximeter Communications Fault	E04
Memory Alarm **WARNING: Memory is cleared if error E06 appears on the display screen.**	E06
Critical Battery	E08

Memory and Data Output Features

The Model X-100M provides real-time patient data output. The device may be connected to a PC via a Bluetooth connection or using the RS-232 serial data port on the back of the X-100M monitor (figure 21).

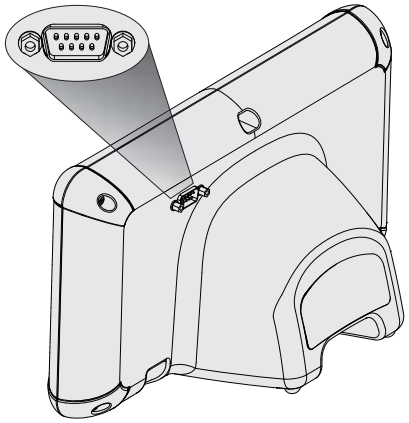

Figure 21. RS-232 Serial Data Port

NOTE: Use only a null modem serial cable to connect the Model X-100M to a PC.

NOTE: Verify Bluetooth status as follows: Bluetooth symbol is green when Bluetooth is connected to a host, white when it is enabled but not connected, and gray when it is disabled.

Patient Data Output

This device features 5 different once-per-second, real-time data output formats (Nonin 1 – Nonin 5). Each data format includes an ASCII header containing model number, time, and date information. In addition, the RS-232 port outputs data through the Dymo printer (Printer).

Formats are selected from the System Menu screen (see "Set Bluetooth and/or RS-232 Data Output Formats" on page 49). Under the Data Output Modes setting, the Bluetooth and RS-232 ports have separate selection options and may use different data output formats.

When using SenSmart download software with the monitor, the port used to download data (either Bluetooth or RS-232) must be set to Nonin 1 before connecting to the SenSmart software.

Nonin 1

Baud Rate	57,600
Delimiter	See format in table 13
Line Terminator	CR [0x0D] LF [0x0A]
CRC	CRC-16 CCITT (XMODEM)

Data from the device are sent once per second in the following format:

Ch1=XXX Ch2=XXX Ch3=XXX Ch4=XXX 1234&$*|
yyyy-mm-ddThh:mm:ss|rSO2=xxx,xxx,xxx,xxx|HbI=xx.x,xx.x,xx.x,xx.x|
AUC=xxxx,xxxx,xxxx,xxxx|REF=xxx,xxx,xxx,xxx|HI_LIM=xxx,xxx,xxx,xxx|
LOW_LIM=xxx,xxx,xxx,xxx|ALM=xxx,xxx,xxx,xxx|SIG_QUAL_ALM=x,x,x,x|
POD_COMM_ALM=x,x,x,x|SNS_FLT=x,x,x,x\LCD_FLT=x\
LOW_BATT=x\CRIT_BATT=x\BATT_FLT=x\STK_KEY=x\SND_FLT=x\
SND_ERR=x\EXT_MEM_ERR=x\CKSUM=xxxx<CR><LF>

NOTE: The 1234&$* order shall be preserved in all alarm conditions.

Table 13: Nonin 1 Data Output Format

Parameter	Value	Following Delimiter
Ch1=XXX	Channel 1 regional oximeter value. Leading zeros blank; --- if no value available.	space
Ch2=XXX	Channel 2 regional oximeter value. Leading zeros blank; --- if no value available.	space
Ch3=XXX	Channel 3 regional oximeter value. Leading zeros blank; --- if no value available.	space
Ch4=XXX	Channel 4 regional oximeter value. Leading zeros blank; --- if no value available.	space
1234	Patient alarm indication for channel 1,2,3,4. Appears only if a channel's patient alarm is active. If not active, number does not appear (e.g., 14 means channel 1 and 4 patient alarms are active).	none
&	Appears if an equipment alarm is active.	none
$	Appears if the critical battery state is detected.	none
*	Appears if the event is marked.	|
yyyy-mm-ddThh:mm:ss	International date and time format: year, month, day, hour, minutes, seconds.	|
rSO2=xxx,xxx,xxx,xxx	Regional oximetry values for channels 1,2,3,4 in %. Leading zeros blank; --- if no value available.	|

Table 13: Nonin 1 Data Output Format (Continued)

Parameter	Value	Following Delimiter
HbI=xx.x,xx.x,xx.x,xx.x	Hemoglobin index values for channels 1,2,3,4 in grams per deciliter. Leading zeros blank; --.- if no value available.	|
AUC=xxxx,xxxx,xxxx,xxxx	Area under curve for channels 1,2,3,4. Leading zeros blank.	|
REF=xxx,xxx,xxx,xxx	Reference (low alarm limit) line values for channels 1,2,3,4. Used to calculate AUC. Leading zeros blank.	|
HI_LIM=xxx,xxx,xxx,xxx	High limit alarm setting for channels 1,2,3,4. Leading zeros blank. “OFF” if no limit set.	|
LOW_LIM=xxx,xxx,xxx,xxx	Low limit alarm setting for channels 1,2,3,4. Leading zeros blank. “OFF” if no limit set.	|
ALM=xxx,xxx,xxx,xxx	Active alarm indication for channels 1,2,3,4. Valid values: HI, MAR (marginal), LOW, OFF.	|
SIG_QUAL_ALM=x,x,x,x	Signal quality alarm indication for channels 1,2,3,4. 0 = no active alarm. 1 = active alarm.	|
POD_COMM_ALM=x,x,x,x	Pod communication alarm indication for channels 1,2,3,4. 0 = no active alarm. 1 = active alarm.	|
SNS_FLT=x,x,x,x	Sensor fault indication for channels 1,2,3,4. 0 = no active alarm. 1 = active alarm.	\
LCD_FLT=x	Display fault indicator. 0 = no fault active. 1 = fault active.	\
LOW_BATT=x	Low battery indicator. 0 = no low battery state. 1 = low battery state.	\
CRIT_BATT=x	Critical battery indicator. 0 = no critical battery state. 1 = critical battery state.	\
BATT_FLT=x	Battery fault indicator. 0 = no battery fault. 1 = battery fault active.	\

Table 13: Nonin 1 Data Output Format (Continued)

Parameter	Value	Following Delimiter
STK_KEY=x	Stuck key fault indicator. 0 = no stuck key fault active. 1 = stuck key fault active.	\
SND_FLT=x	Sound fault indicator. 0 = no sound fault active. 1 = sound fault active.	\
SND_ERR=x	Sound error indicator. 0 = no sound error active. 1 = sound error active.	\
EXT_MEM_ERR=x	External memory error indicator. 0 = no external memory error active. 1 = external memory error active.	\
CKSUM=xxxx	CRC-16 CCITT (XMODEM)[1] of all parameters and values beginning with the “C” of “Ch1” and ending with “CKSUM=”. Leading zeros if appropriate.	<CR><LF>

[1] CRC-16 CCITT (XMODEM) Algorithm

Algorithm Details:

- Initial value: 0
- Polynomial: $x^{16} + x^{12} + x^5 + 1$ [0x1021]
- XOR out: 0
- Reflection: none

Test

- Run algorithm against the string of ASCII characters “123456789”
- Result should be 0x31C3

Nonin 2

Baud Rate	9,600
Delimiter	Comma [0x2C]
Line Terminator	CR [0x0D] LF [0x0A]
CRC	N/A

Column 1	Column 2	Column 3	Column 4
Current value of Channel 1	Current value of Channel 2	Average of Channel 1 and Channel 2	0

Missing data is output as -1.

Nonin 3

Baud Rate	9,600
Delimiter	One or more consecutive spaces [0x20]
Line Terminator	LF [0x0A] CR [0x0D]
CRC	N/A

Version	Date	Time	Channel Name	rSO_2	Event	Status	Baseline	AUC	UAL	LAL	A	B	C
99.99.99/1/1	mm/dd/yy	hh/mm/ss	These columns repeat per channel										

Continues with:

Sensor ID 1	Sensor ID 2	Sensor ID 3	Sensor ID 4
s/n	s/n	s/n	s/n

Version is 99.99.99/1/1.

Date: month, day, year

Time: hour, minutes, seconds

Channel names:

L = Channel 1
R = Channel 2
S1 = Channel 3
S2 = Channel 4

rSO_2 readings for missing data outputs as 0.

Event: 0 = no event; 1 = miscellaneous event.

Status values:

1 = Pod connected with no sensor (sensor fault)
2 = Excessive light indication (used for poor signal quality)
4 = Good signal quality, valid rSO_2 readings occurring
5 = rSO_2 high alarm
6 = rSO_2 low alarm
7 = Pod became connected to the system
9 = Critical battery alarm
11 = Pod is not connected to the system

Baseline and AUC are the current values.

UAL is the upper alarm limit. 0 = OFF.

LAL is the lower alarm limit. 0 = OFF.

A, B, C are 0.

Sensor ID is the sensor image number.

Nonin 4

Baud Rate	9,600
Delimiter	One or more consecutive spaces [0x20]
Line Terminator	LF [0x0A] CR [0x0D]
CRC	N/A

Date	**Time**	**rSO_2**	**Event**	**Status**	**A**	**B**	**C**	**D**	**Sensor ID 1**	**Sensor ID 2**	**Sensor ID 3**	**Sensor ID 4**
mm/dd/yy	hh/mm/ss	These columns repeat per channel							s/n	s/n	s/n	s/n

Date: month, day, year

Time: hour, minutes, seconds

rSO_2 readings for missing data outputs as 0.

Event: 0 = no event; 1 = miscellaneous event

Status values:

1 = Pod connected with no sensor (sensor fault)
2 = Excessive light indication (used for poor signal quality)
4 = Good signal quality, valid rSO_2 readings occurring
5 = rSO_2 high alarm
6 = rSO_2 low alarm
7 = Pod became connected to the system
9 = Critical battery alarm
11 = Pod is not connected to the system

A, B, C, and D are 0.

Sensor ID is the sensor image number.

Nonin 5

This data format was designed to be extensible. Future enhancements to the Model X-100M may be included in the data output. As these enhancements become available, new column labels may be added at any position within the data format.

Baud Rate	57,600
Delimiter	Comma [0x2C]
Line Terminator	CR [0x0D] LF [0x0A]
CRC	CRC-16 CCITT (XMODEM)

Date	Time	Channel	rSO_2	HbI	AUC	BL	UAL	LAL	Status	Event	Error_Code	CRC16
yyyy-mm-dd	hh:mm:ss	These columns repeat per channel									EXX	

Date: year, month, day

Time: hour, minutes, seconds

Channel is the channel number.

rSO2, HbI, AUC and BL are the current values. Blank if data is missing [dashes on display].

UAL is the current upper alarm limit value.

LAL is the current lower alarm limit value.

Status is defined by the following and are active high:

Bit 7	Bit 6	Bit 5	Bit 4	Bit 3	Bit 2	Bit 1	Bit 0
Unused	Low Alarm: 0 = Auto 1 = Manual	rSO_2 High	rSO_2 Low	rSO_2 Marginal	Sensor Fault	Pod Comm. Lost	Signal Quality

Event: 0 = no event; 1 = miscellaneous event.

Error_Code: See table 12 in the Error Codes section for error code information.

CRC16 is CRC-16 CCITT[1].

[1] CRC-16 CCITT (XMODEM) Algorithm

Algorithm Details:

- Initial value: 0
- Polynomial: $x^{16} + x^{12} + x^5 + 1$ [0x1021]
- XOR out: 0
- Reflection: none

Test

- Run algorithm against the string of ASCII characters “123456789”
- Result should be 0x31C3

Printer

This setting was designed to work with the Dymo LabelWriter SE450 Label Printer. See "Dymo® Printer" on page 23 for more information.

Memory Features

The Model X-100M monitor can collect and store:

- 840 hours of data when 2 channels are in use.
- 420 hours of data when 4 channels are in use.
- 280 hours of data when 6 channels are in use.

The memory in the Model X-100M functions much like an “endless loop” tape. When the memory is full, the unit begins overwriting the oldest data with new data.

> ⚠ **CAUTION:** Data is written continuously when the device is on. If the entire memory is filled, portions of the oldest record will be overwritten when a new record begins.

Each time the Model X-100M is turned on, the current time/date information (if the clock is set properly) is stored in memory, starting a new recording session. Only recording sessions greater than 1 minute in length are stored in memory.

rSO_2 is sampled and recorded in memory once every 4 seconds. Oxygen saturation values are stored in 1% increments in the range of 0 to 100%.

Patient data is retained even when power is lost.

To clear patient memory, refer to "Clear the Memory" on page 50

SenSmart Download Software

The SenSmart oximetry system has comprehensive data management capability. Confidential patient data is extracted from the system via Bluetooth or the RS-232 serial port using the SensSmart Download Software. During memory download, *Sending Memory...* displays on the monitor.

Each data record in the SenSmart system is identified by date and time. On a host computer, files are identified by this data, extracted, and stored as either raw data or as a .pdf. The files comply with standards defined in the STS National Adult Cardiac Surgery Database.

For instructions on using the data management feature, please see the SenSmart Download Software User Guide, which is found on the SenSmart download software CD included with the device.

Installing SenSmart Download Software

Nonin's SensSmart patient data management software works with Microsoft Windows® XP/ Vista/7/8 operating systems. It allows users to transfer recorded patient data from the device to a PC and then analyze, report, and archive the data.

To install the software:

1. Insert the CD into the computer's CD/DVD drive.
2. Installation should start automatically. If it does not start automatically, initiate installation by:
   - Windows XP operating systems: From the Start menu, choose **Run**.
   - Other Windows operating systems: From the Start menu, place the cursor in the Search box and type **D:\setup.exe** (where D is the letter of the CD/DVD drive).
3. Follow the on-screen instructions until the software install completes.-
4. For help using the SenSmart Download Software, go to Help > User Guide.

Bluetooth Connection

NOTE: Etched onto the device is the word "pin" followed by a 6-digit number. This is the device's unique identification number, also known as the Bluetooth Passkey or PIN Code. This number is used when pairing the device to the host system. Refer to the host system's operator's manual for additional information

Before a Bluetooth master device can connect with the X-100M (slave device), the devices must be paired. Once paired, the X-100M will automatically connect with the last paired master device when turned on or activated.

Care and Maintenance

The advanced digital circuitry within the Model X-100M requires no calibration or periodic maintenance other than battery replacement by qualified technical professionals.

Field repair of the Model X-100M is not possible. Do not attempt to open the Model X-100M case or repair the electronics. Opening the case may damage the Model X-100M and void the warranty. If the device is not functioning properly, see “"Troubleshooting" on page 69.

CAUTIONS:

- Follow local, state and national governing ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries.
- Use only Nonin-approved battery packs.
- Batteries are a fire hazard if damaged. Do not damage, mishandle, or disassemble.

Cleaning the Monitor, Signal Processor, and Hub

1. Wipe the component with a soft cloth dampened with a mild detergent or a 10% bleach solution (household bleach [5.25% 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.

WARNING: Protect from exposure to water or any other liquid, with or without AC power.

CAUTION: Do not place the device in liquid or clean it with agents containing ammonium chloride, isopropyl alcohol, or products that are not listed in this operator’s manual.

Parts and Accessories

For more information about Nonin parts and accessories:

- See the Part and Accessories List on the operator's manual CD.
- Contact your distributor or Nonin at (800) 356-8874 (USA and Canada), +1 (763) 533-9968, or +46 650 401500 (Europe).
- Visit www.nonin.com

WARNING: Use the Model X-100M only with power adapters supplied by Nonin Medical.

WARNING: The use of signal processors, sensors, accessories, and cables other than those listed in the Parts and Accessories List may result in increased electromagnetic emission and/or decreased immunity of this device.

WARNING: Use only Nonin-branded oximeter sensors. These sensors are manufactured to meet the accuracy specifications for Nonin oximeters. Using other manufacturers' sensors can result in improper oximeter performance.

Troubleshooting

Problem	Possible Cause	Possible Solution
Monitor will not activate.	The unit has no power	Plug in the AC adapter.
Monitor will not operate on battery power.	The battery pack is not charged.	Plug in the Model X-100M AC adapter to charge the battery pack.
	The battery pack is inoperable.	Contact Nonin Technical Service for repair or replacement.
Signal processor is attached, but the channel does not appear on the display.	The signal processor is damaged.	Turn the X-100M off and then back on again. If the signal processor does still 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.
One or more channels display the message "Unrecognized packet."	Duplicate signal processors are attached to the hub.	Verify that duplicate signal processors are not attached to the hub. Remove or replace the duplicate signal processor.
Dashes (---) appear in an rSO_2 or SpO_2 display.	Sensor or signal processor is disconnected.	Check the connections between the sensor and the signal processor and between the hub and the X-100M monitor. Ensure all connections are secure.
	The Model X-100M display is not functioning.	Contact Nonin Technical Service.
	The signal from the sensor is inadequate.	rSO_2: Reposition sensor. Position sensor at different site. SpO_2: Reposition the sensor or apply the sensor to a different digit, and keep the sensor motionless for at least 10 seconds. Warm the sensor application site.
Dashes (---) appear in an rSO_2 display.	The sensor is damaged.	Remove the sensor from the patient and observe the sensor emitters while the system is on. If both emitters do not flash red, replace the sensor. Ensure both emitters flash red on new sensor.

Problem	Possible Cause	Possible Solution
Dashes (---) appear in an %SpO_2 display.	The digit was removed from the sensor.	
Unable to obtain a pulse rate display.	The patient pulse strength is low.	Reposition the sensor or apply the sensor to a different digit, and keep the sensor motionless for at least 10 seconds. Warm the sensor application site.
	Circulation is reduced due to excess pressure on the sensor (between the sensor and a hard surface) after inserting the digit.	Identify the source of the pressure. Allow the hand to rest comfortably without squeezing or pressing the sensor on a hard surface.
	The sensor is applied incorrectly.	Apply the sensor according to the Instructions for Use provided with the sensor.
	Possible interference from one of the following sources: • arterial catheter • blood pressure cuff • electrosurgical procedure • infusion line	Reduce or eliminate any interference.
	The red LED is not illuminated in the finger insertion area.	Contact Nonin Technical Service.
	There is excessive ambient light.	Shield the sensor from the light source.
	The sensor is applied to a polished or artificial fingernail.	Apply the sensor to a digit without fingernail polish or an artificial nail.
	Excessive patient motion.	Reduce patient motion.
An error code appears in the display area.	The monitor encountered an error.	Turn the monitor off and then back on again to remove the error code. If the error persists, note the error code and contact Nonin Technical Service.
The monitor is in alarm mode, but no audible alarms can be heard.	The 2-minute Alarm Silence button is activated.	Press Alarm Silence to re-engage alarm volume, or wait 2 minutes. After 2 minutes, alarm tones automatically re-engage.
	Audible volume is turned down.	Adjust volume through the System Menu screen.

Problem	Possible Cause	Possible Solution
Sensor LED is not lit.	Signal processor initialization error.	Disconnect the signal processor. Wait 5 seconds and reconnect signal processor. If problem continues, contact Nonin Technical Service.
Bluetooth symbol is yellow.	Fault within the Bluetooth module.	Contact Nonin Technical Service.

If these solutions do not correct the problem, please contact Nonin Technical Service at (800) 356-8874 (USA and Canada), +1 (763) 553-9968, or +46 650 401500 (Europe).

Service, Support, and Warranty

Service and Support

A return authorization number is required before returning any product to Nonin. To obtain this return authorization number, contact Nonin Technical Service:

Nonin Medical, Inc.
13700 1st Avenue North
Plymouth, Minnesota 55441-5443 USA

(800) 356-8874 (USA and Canada)
+1 (763) 553-9968 (outside USA and Canada)
Fax: +1 (763) 553-7807
E-mail: technicalservice@nonin.com

Nonin Medical AB
Fibervägen 2
82450 Hudiksvall, Sweden

+46 650 401500 (Europe)
Fax: +46 650 401514
E-mail: serviceintl@nonin.se

www.nonin.com

WARNING: This device is a precision electronic instrument and must be repaired by qualified technical professionals. Field repair of the device is not possible. Do not attempt to open the case or repair the electronics. Opening the case may damage the device and void the warranty.

Warranty

NONIN MEDICAL, INCORPORATED, (Nonin) warrants to the purchaser, for a period of 1 year from the date of purchase, each Model X-100M battery pack. Nonin warrants the X-100M monitor, X-100SP signal processors, X-100H hub, X-100HH hub holster, and X-100EC extension cables for a period of 3 years from the date of purchase. Extended warranties are available on most Nonin oximeter models. Please consult your local Nonin distributor for additional information.

Nonin shall repair or replace any Model X-100M or signal processor found to be defective in accordance with this warranty, free of charge, for which Nonin has been notified by the purchaser by serial number that there is a defect, provided said notification occurs within the applicable warranty period. This warranty shall be the sole and exclusive remedy by the purchaser hereunder for any Model X-100M or signal processor delivered to the purchaser which is found to be defective in any manner, whether such remedies be in contract, tort, or by law.

This warranty excludes cost of delivery to and from Nonin. All repaired units shall be received by the purchaser at Nonin's place of business. Nonin reserves the right to charge a fee for a warranty repair request on any device that is found to be within specifications.

The Model X-100M is a precision electronic instrument and must be repaired by qualified technical professionals. Accordingly, any sign or evidence of opening the device, field service by non-authorized personnel, tampering, or any kind of misuse or abuse of the device, shall void the warranty in its entirety. All non-warranty work shall be done according to Nonin standard rates and charges in effect at the time of delivery to Nonin.

DISCLAIMER/EXCLUSIVITY OF WARRANTY:

THE EXPRESS WARRANTIES SET FORTH IN THIS MANUAL ARE EXCLUSIVE AND NO OTHER WARRANTIES OF ANY KIND, WHETHER STATUTORY, WRITTEN, ORAL, OR IMPLIED, INCLUDING WARRANTIES OF FITNESS FOR A PARTICULAR PURPOSE OR MERCHANTABILITY, SHALL APPLY.

Technical Information

NOTE: This product complies with ISO 10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing.

⚠	**CAUTION:** A functional tester cannot be used to assess the accuracy of the oximeter monitor or sensor.
⚠	**CAUTION:** Portable and mobile RF communications equipment can affect medical electrical equipment.
⚠	**CAUTION:** Radios and cell phones or similar devices can affect the equipment and must be kept at least 2 meters (6.5 feet) away from the equipment.

Manufacturer's Declaration

Refer to the following table for specific information regarding this device's compliance to IEC 60601-1-2.

Table 14. Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment—Guidance
This device is intended for use in the electromagnetic environment specified below. The user of this device should ensure that it is used in such an environment.		
RF Emissions CISPR 11	Group 2	This device must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF Emissions CISPR 11	Class A	This device is suitable for use in all establishments, other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	N/A	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	N/A	

Table 15. Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance
This device is intended for use in the electromagnetic environment specified below. The user of this device should ensure that it is used in such an environment.			
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/Burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	±5% U_T (>95% dip in U_T) for 0.5 cycle ±40% U_T (60% dip in U_T) for 5 cycles ±70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec.	±5% U_T (>95% dip in U_T) for 0.5 cycle ±40% U_T (60% dip in U_T) for 5 cycles ±70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec.	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or battery pack.
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the AC mains voltage before application of the test level.			

Table 16. Guidance and Manufacturer's Declaration—Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance
This device is intended for use in the electromagnetic environment specified below. The user of this device should ensure that it is used in such an environment.			
Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.			
			Recommended Separation Distance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	$d = 1.17\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.17\sqrt{P}$ 80 MHz to 800 MHz $d = 2.33\sqrt{P}$ 800 MHz to 2.5 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTES: • At 80 MHz and 800 MHz, the higher frequency range applies. • These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [3]V/m.

Table 17. Recommended Separation Distances

This table details the recommended separation distances between portable and mobile RF communications equipment and this device.

This device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. Users of this device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the device as recommended below, according to maximum output power of the communications equipment.

	Separation Distance According to Frequency of Transmitter		
Rated Maximum Output Power of Transmitter W	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	80 MHz to800 MHz $d = 1.17\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.33\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTES:

- At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Testing Summary

Principles of Operation

Model X-100SA signal processor uses calculations based on the Beer-Lambert law or Beer's law, to determine regional oxygenation. The Beer-Lambert law relates the absorption of light to the properties of the material through which the light is traveling. The law states that there is a logarithmic relationship between the concentration of compounds and the transmission of light through it. By utilizing wavelengths of light that are absorbed by the compounds to be measured, the concentration of the compounds can be determined. For regional oximetry, the compounds of interest are hemoglobin, deoxygenated hemoglobin, and tissue.

The oximetry sensors use a proprietary, patented arrangement of light emitters (LEDs) and light detectors (photodiodes). This arrangement effectively provides a "deep tissue" absorption measurement focused on the cerebrum. The absorption measurement is largely unaffected by surface or near-surface features, irregularities, or substances.

rSO_2 Accuracy Testing

rSO_2 accuracy testing was conducted by Nonin Medical, Inc., as described below:

rSO_2 accuracy testing is conducted during induced hypoxia studies on healthy, non-smoking, light- to dark-skinned subjects in an independent research laboratory. The measured regional hemoglobin saturation value (rSO_2) of the sensors is compared to arterial/venous hemoglobin oxygen ($SavO_2$) value, determined from venous and arterial blood samples. The model used for blood in the brain is 70% venous and 30% arterial, which is applicable under normocapnic conditions. The venous blood was drawn from the right jugular bulb. The accuracy of the sensors in comparison to the blood gas analyzer samples measured over the rSO_2 range of 45–100%. Accuracy data is calculated using the root-mean-squared (A_{rms} value) for all subjects, per ISO 9919:2005, Medical Electrical Equipment—Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use.

SpO_2 Accuracy Testing

SpO_2 accuracy testing is conducted during induced hypoxia studies on healthy, non-smoking, light- to dark-skinned subjects during motion and no-motion conditions in an independent research laboratory. The measured arterial hemoglobin saturation value (SpO_2) of the sensors is compared to arterial hemoglobin oxygen (SaO_2) value, determined from blood samples with a laboratory co-oximeter. The accuracy of the sensors in comparison to the co-oximeter samples measured over the SpO_2 range of 70 - 100%. Accuracy data is calculated using the root-mean-squared (A_{rms} value) for all subjects, per ISO 9919:2005, Medical Electrical Equipment—Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use.

Pulse Rate Motion Testing

This test measures pulse rate oximeter accuracy with motion artifact simulation introduced by a pulse oximeter tester. This test determines whether the oximeter meets the criteria of ISO 9919:2005 for pulse rate during simulated movement, tremor, and spike motions.

Low Perfusion Testing

This test uses an SpO_2 Simulator to provide a simulated pulse rate, with adjustable amplitude settings at various SpO_2 levels for the oximeter to read. The oximeter must maintain accuracy in accordance with ISO 9919:2005 for heart rate and SpO_2 at the lowest obtainable pulse amplitude (0.3% modulation).