COVIDIEN

Operator's Manual

Nellcor™

Bedside SpO_2 Patient Monitoring System

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1 Introduction

1.1 Overview

This manual contains information for operating the Nellcor™ bedside SpO_2 patient monitoring system.

Note:
Before use, carefully read this manual, accessory *Instructions for Use*, and all precautionary information and specifications.

1.2 Safety Information

This section contains important safety information related to general use of the Nellcor™ bedside SpO_2 patient monitoring system. Other important safety information appears throughout the manual. The Nellcor™ bedside SpO_2 patient monitoring system will be referred to as the "monitoring system" throughout this manual.

1.2.1 Safety Symbols

Table 1-1. Safety Symbol Definitions

Symbol	Definition
	**WARNING** **Warnings alert users to potential serious outcomes (death, injury, or adverse events) to the patient, user, or environment.**
	**Caution** **Identifies conditions or practices that could result in damage to the equipment or other property**.
	**Note** Notes provide additional guidelines or information.

1.2.2 Warnings

WARNING:
Explosion hazard — Do not use the monitoring system in the presence of flammable anesthetics.

WARNING:
Explosion hazard — Do not use the battery with other manufacturer's batteries. Do not use different types or models of batteries such as dry batteries, nickel-metal hydride batteries, or Lithium-ion batteries together.

WARNING:
Do not use any monitoring system or pulse oximetry cables, sensors, or connectors that appear damaged.

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

WARNING:
Do not simultaneously touch the patient and the signal input, signal output, or any other connectors.

WARNING:
Do not lift or carry the monitoring system by the pulse oximetry sensor or pulse oximetry interface cable. The cable may disconnect and cause the monitoring system to drop on a patient or cause damage to monitoring system surfaces.

WARNING:
To ensure patient safety, do not place the monitoring system in any location where it might drop on the patient.

WARNING:
The LCD panel contains toxic chemicals. Do not touch broken LCD panels. Physical contact with a broken LCD panel can result in transmission or ingestion of toxic substances.

WARNING:
Always disconnect and remove the monitoring system and sensors during magnetic resonance imaging (MRI) scanning. Attempting to use the monitoring system during an MRI procedure could cause burns or adversely affect the MRI image or the monitoring system's accuracy.

WARNING:
The monitoring system is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.

WARNING:
The values displayed by the monitoring system can be affected by patient conditions, excessive patient movement, sensors, environmental conditions, and nearby external electromagnetic conditions.

WARNING:
The monitoring system is intended for use in a hospital or hospital-type environment by trained medical personnel.

WARNING:
Failure to cover the pulse oximetry sensor site with opaque material in high ambient light conditions may result in inaccurate measurements. Refer to the appropriate sections of this manual for specific safety information.

WARNING:
The monitoring system is not defibrillator-proof. It may remain attached to the patient during defibrillation or during use of an electrosurgical unit; readings may be inaccurate during defibrillation and shortly thereafter.

WARNING:
The monitoring system may retain trend data from multiple patients if transferring the monitoring system from one patient to another.

WARNING:
Any connections between this monitoring system and other devices must comply with applicable medical systems safety standards such as IEC 60601-1. Failure to do so could result in unsafe leakage current and grounding conditions.

WARNING:
Do not silence or decrease the volume of the audible alarm if patient safety could be compromised.

WARNING:
Do not preset different alarm limits for the same or similar equipment within a single area.

1.2.3 Cautions

Caution:
The monitoring system may not operate properly if it is operated or stored at conditions outside the ranges stated in this manual, or if it is subjected to excessive shock or dropping.

Caution:
Do not spray, pour, or spill any liquid on the monitoring system, its accessories, connectors, switches, or openings in the chassis, since this may cause damage to the monitoring system. Never place fluids on the monitoring system. If fluid spills on the monitoring system, remove batteries, wipe dry immediately, and have it serviced to ensure no hazard exists.

Caution:
Accessory equipment connected to the monitoring system's data interface must be certified according to IEC 60950-1 for data-processing equipment. All combinations of equipment must be in compliance with IEC 60601-1 Requirements for Medical Electrical Systems. Anyone who connects additional equipment to the signal input or signal output port configures a medical system and is therefore responsible for ensuring the system complies with the requirements of IEC 60601-1, IEC 60601-1-2:2007, and IEC 60601-1-2:2014.

Caution:
When connecting the monitoring system to any instrument, verify proper operation before clinical use. Both the monitoring system and the instrument connected to it must be connected to a grounded outlet.

Caution:
For best product performance and measurement accuracy, use only accessories supplied or recommended by Covidien. Use accessories according to the manufacturer's instructions for use and institutional standards. Use only accessories that have passed the recommended biocompatibility testing in compliance with ISO10993-1.

Caution:
Where the integrity of the external protective conductor in the installation or its arrangement is in doubt, the monitoring system operates from its battery.

Caution:
This monitoring system generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity.

Caution:
Inspect the monitoring system and all accessories before use to ensure there are no signs of physical damage or improper function. Do not use if damaged.

1.3 Obtaining Technical Assistance

1.3.1 Technical Services

For technical information and assistance, contact Covidien or a local Covidien representative.

Covidien Technical Services: Patient Monitoring

15 Hampshire Street

Mansfield, MA 02048 USA

1.800.635.5267, 1.925.463.4635,
or contact a local Covidien representative

www.covidien.com

When calling Covidien or a local Covidien representative, have the monitoring system serial number available. Provide the firmware version number listed at power-on self-test (POST).

1.3.2 Related Documents

Nellcor™ Bedside SpO_2 Patient Monitoring System Operator's Manual — Provides basic information for operating the monitoring system and troubleshooting errors or malfunctions. Before using the monitoring system, thoroughly read this manual.

Nellcor™ Pulse Oximetry Sensor Instructions for Use — Guides sensor selection and usage. Before attaching any of the various Covidien-approved pulse oximetry sensors to the monitoring system, refer to the individual *Instructions for Use*.

Saturation Accuracy Grid — Provides sensor-specific guidance related to desired SpO_2 saturation accuracy measurements. Available online at www.covidien.com.

Nellcor™ Bedside SpO_2 Patient Monitoring System Service Manual — Provides information to qualified service technicians for use when servicing the monitoring system.

1.4 Warranty Information

The information contained in this document is subject to change without notice. Covidien makes no warranty of any kind with regard to this material, including, but not limited to, the implied warranties or merchantability and fitness for a particular purpose. Covidien shall not be liable for errors contained herein or for incidental or consequential damages in connection with the furnishing, performance, or use of this material.

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2 Product Overview

2.1 Overview

WARNING:
Patient conditions may result in erroneous readings. If the measurements are suspect, verify the reading using another clinically accepted measurement method.

This chapter contains basic information about the Nellcor™ bedside SpO_2 patient monitoring system. The monitoring system relies on unique oximetry technology and design to provide hospitals, clinicians, and caregivers accurate, timely data, which includes a number of parameters.

- **Arterial blood oxygen saturation (SpO_2) —** Functional measure of oxygenated hemoglobin relative to the sum of oxyhemoglobin and deoxyhemoglobin
- **Pulse rate (PR) —** Detected heart pulsations in beats per minute
- **Plethysmographic waveform (Pleth) —** A non-normalized waveform that represents relative pulsatile strength
- **Operating status —** State of the monitoring system, including alarm conditions and messages
- **Patient data —** Real-time trend data on the current patient
- **Sensor messages —** Detected real-time information on attached patient sensor

2.2 Product Description

The Nellcor™ bedside SpO_2 patient monitoring system provides continuous, noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate.

2.3 Indications for Use

WARNING:
The monitoring system is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.

The Nellcor™ Bedside SpO_2 Patient Monitoring System is indicated for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate. The Nellcor™ Bedside SpO_2 Patient Monitoring System is intended for prescription use only with neonatal, pediatric, and adult patients, and for patients who are well or poorly perfused, in hospitals, hospital-type facilities, and intra-hospital transport.

Note:

- Hospital use typically covers such areas as general care floors (GCFs), operating rooms, special procedure areas, intensive and critical care areas within the hospital, and in hospital-type facilities.
- Hospital-type facilities include physician office-based facilities, sleep labs, skilled nursing facilities, surgicenters, and sub-acute centers.
- Intra-hospital transport includes transport of a patient within the hospital or hospital-type facility.

2.4 Product Views

2.4.1 Front Panel and Display Components

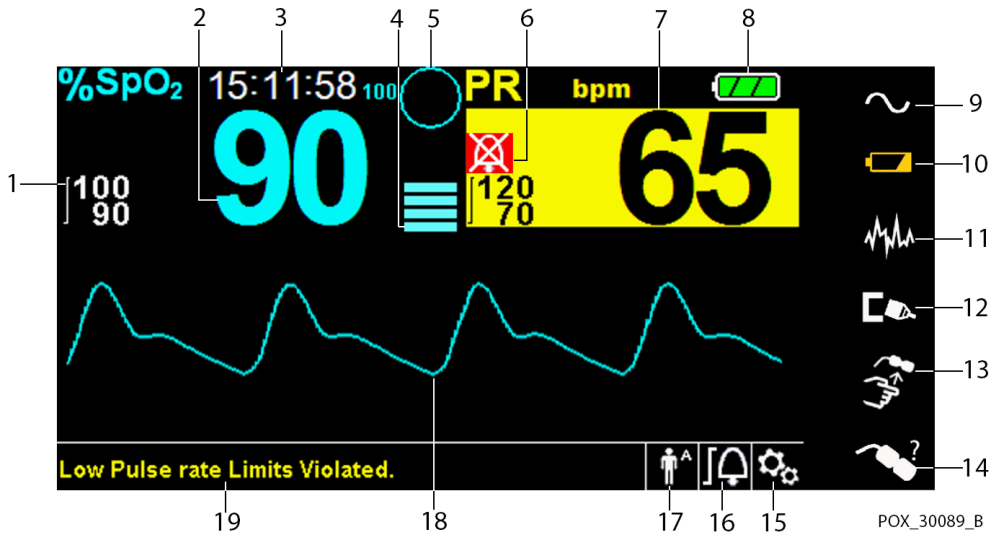
Front and Side Panels

Figure 2-1. Front and Side Panel Components

1		Silence Alarm button	Press to toggle between disabling and re-enabling the audible alarm. Reference *Menu Options Navigation*, p. 4-3.
2		Return button	Press to exit a menu displayed on the screen and go to the main screen. Reference *Menu Options Navigation*, p. 4-3.
3		Power On/Off button	Press and hold to turn on or off the monitoring system, using AC power or Lithium-ion batteries. Reference *Menu Options Navigation*, p. 4-3.
4		USB port (USB A type)	Use USB interface for firmware upgrades.
5		USB port (mini USB B type)	Use mini-USB interface for trend data downloads.
6		Jog dial	Use to navigate and control display and monitoring system functions.
7		LCD display panel	Use to monitor all graphic and numeric patient information as well as status conditions and warning messages.
8		SpO_2 connector	Use to connect to the interface cable and SpO_2 sensor.

Display

Figure 2-2. Display Components



1		Upper and lower alarm limits	Reflects upper and lower SpO_2 and pulse rate alarm limits. An alarm sounds each time patient saturation or pulse rate values violate these alarm limits.
2		SpO_2 real-time value	Indicates hemoglobin oxygen saturation levels. Current upper and lower alarm limit settings appear as smaller values to the left of the dynamic SpO_2 value.
3	**01:04:23**	Time	Indicates the current time in hours, minutes, and seconds.
4		Pulse amplitude (blip bar)	Indicates pulse beat and the relative (non-normalized) pulse amplitude. As the detected pulse becomes stronger, more bars light with each pulse.
5		SatSeconds™ icon	The SatSeconds™ feature provides alarm management for mild or brief SpO_2 limit violations. When the SatSeconds™ feature is enabled, the SatSeconds™ icon fills in the clockwise direction as the SatSeconds™ alarm management system detects SpO_2 readings outside of the limits setting. The SatSeconds™ icon empties in the counterclockwise direction when SpO_2 readings are within limits. When the SatSeconds™ icon reaches full, a medium priority alarm sounds. The adult default setting is 100. Reference *SatSeconds™ Alarm Management Feature*, p. 10-5.
6		Alarm silenced icon	The yellow icon indicates Alarm Silenced. This indicator also shows the time remaining in the alarm silence period.
		Audio OFF icon	The red icon indicates Audio OFF.
7		Pulse rate real-time value	Displays the pulse rate in beats per minute. Current upper and lower alarm limit settings appear as smaller values to the left of the dynamic pulse rate value.

8		Battery status icon	Displays the battery charge remaining on an internal 5- or 10-hour battery. • **Charged Battery —** A steady green battery icon indicates the monitoring system is running on internal battery power and the battery is fully charged. • **Low Battery —** A low priority alarm occurs when the remaining battery power is only enough for 15 minutes of operation. The flashing yellow alarm message `Low Battery` appears. Users cannot silence this alarm while running on battery power. Connect the monitoring system to AC power to stop the alarm. • **Critically Low-Battery —** A high priority alarm occurs for about five (5) minutes before the monitoring system shuts off. The flashing red alarm message `Critically Low-Battery` appears. When no charge remains, the monitoring system automatically shut down. Connect the monitoring system to AC power to avoid any loss of trend data or settings.
9		AC power indicator	Lights continuously when connected to AC power.
10		Battery charge indicator	Lights when the monitoring system is charging an internal 5- or 10-hour battery.
11		Interference indicator	Lights when the monitoring system detects degraded quality in the incoming signal.It is common for it to intermittently light as the monitoring system dynamically adjusts the amount of data required for measuring SpO_2 and pulse rate. When lit continuously, the monitoring system has extended the amount of data required for measuring SpO_2 and pulse rate. In this case, fidelity in tracking rapid changes in these values may be reduced.[1]
12		Sensor disconnect indicator	Appears when the sensor is not connected to the monitoring system.
13		Sensor off indicator	Appears when the sensor is not on the patient.
14		Sensor message indicator	Appears when the sensor is invalid.
15		Options menu area	Visible when users utilize the jog dial to select various menu options for customizing options and features.
16		Alarm limits menu icon	Select to customize audible alarm limits.

17		Patient mode area	Reflects the current patient mode selected. • **Adult mode —** Visible in the patient mode area when the alarm limits are set to adult limit values. This is the default mode. • **Pediatric mode —** Visible in the patient mode area when the alarm limits are set to pediatric limit values. • **Neonatal mode —** Visible in the patient mode area when the alarm limits are set to neonate limit values.
18		Plethysmographic (pleth) waveform	This non-normalized waveform uses real-time sensor signals, reflecting relative pulsatile strength of incoming signals.
19		Informative message area	Contains messages to notify the user of a condition or a request for action.

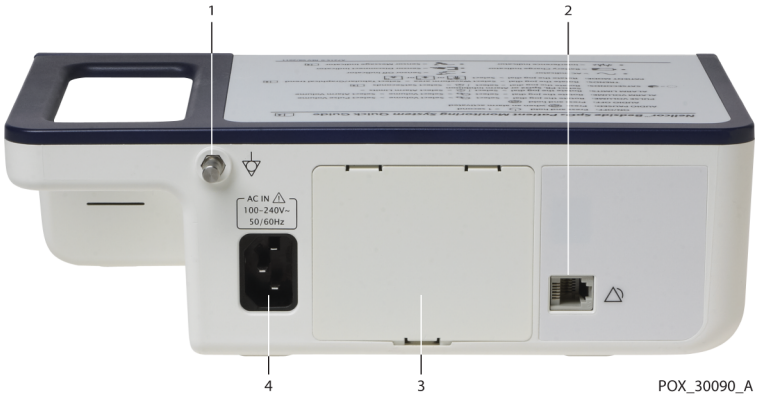
1. Degradation can be caused by ambient light, poor sensor placement, electrical noise, electrosurgical interference, patient activity, or other causes.

Table 2-1. Display Colors

Color	Condition	Function
Cyan numeric	Steady	SpO_2 value and plethysmographic waveform
Yellow numeric		Pulse rate value
Black background		General background
Red background	Flashing	High priority alarm condition
Yellow background		Alarm condition
Green font	Steady	Informative message
Yellow font		Low or medium priority message
Red font	Flashing	High priority message
Green, yellow, or red battery icon	Steady	Normal, low, or critically low battery status

2.4.2 Rear Panel

Figure 2-3. Rear Panel Components



1	Equipotential terminal	3	Battery cover
2	Nurse call port	4	AC power connector

2.4.3 Product and Carton Label Symbols

Table 2-2. Symbol Descriptors

Symbol	Description	Symbol	Description
	Type BF		Data port
	Equipotentiality		Date of manufacture
Rx ONLY	Prescription only device		Keep dry
	Attention, consult accompanying documents		Fragile
375 mmHg +500 hPa / 795 mmHg +1060 hPa	Atmospheric pressure limitations	CLASSIFIED c UL us	UL listed
15% / 95%	Humidity limitations	CE 0123	CE Mark

Table 2-2. Symbol Descriptors (Continued)

Symbol	Description	Symbol	Description
	Temperature limitations		Manufacturer
	This side up	EC REP	EU representative
	Must consult instructions for use		Proper waste disposal for electrical and electronic equipment
IPX2	Protection against fluid ingress		

3 Installation

3.1 Overview

This chapter contains information for the installation and set up of the Nellcor™ bedside SpO_2 patient monitoring system prior to first-time usage.

3.2 Safety Reminders

WARNING:
Ensure the speaker is clear of any obstruction. Failure to do so could result in an inaudible alarm tone.

WARNING:
To ensure accurate performance and prevent device failure, do not expose the monitoring system to extreme moisture, such as direct exposure to rain. Such exposure may cause inaccurate performance or device failure. Reference *Product Specifications*, p. 11-1.

WARNING:
The monitoring system should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, observe the monitoring system to verify normal operation in the desired configuration.

WARNING:
Do not use any monitoring system, pulse oximetry sensor, cables, or connectors that appear damaged.

WARNING:
Use only Nellcor™-approved pulse oximetry sensors and pulse oximetry cables when connecting to the sensor connector. Connecting any other cable or sensor influences the accuracy of sensor data, which may lead to adverse results.

WARNING:
Use only the Nellcor™ pulse oximetry interface cable with the monitoring system. Use of another interface cable will adversely affect performance.

Caution:
Follow local government ordinances and recycling instructions regarding disposal or recycling of device components, including its accessories.

3.3 Unpacking and Inspection

The monitoring system is shipped in a single carton. Examine the carton carefully for evidence of damage. Contact Covidien Technical Services immediately if the carton appears damaged. Do not return all packing material and the monitoring system prior to contacting Covidien. Reference *Technical Services*, p. 1-5.

Note:
A qualified service technician should verify the performance of the monitoring system following the procedures outlined in the Nellcor™ bedside SpO_2 patient monitoring system *Service Manual* prior to initial installation in a clinical setting.

The monitoring system ships with a set of standard items, but may also include a number of optional accessories. Check the shipping carton for all items listed on the packing list.

Note:
Contact Covidien Technical Services for pricing and ordering information.

Table 3-1. Standard Items

Item	Quantity
Nellcor™ bedside SpO_2 patient monitoring system	1
Nellcor™ pulse oximetry interface cable	1
Compact disc (CD) and/or Operator's Manual [1]	1
Lithium-ion battery pack, M-BPL-1 (21) 5 hour	1
AC power cord	1

1. Covidien provides soft copy of monitoring system manuals on a compact disc for easy access and print-on-demand. Order a printed Nellcor™ bedside SpO_2 patient monitoring system *Operator's Manual* at no cost or a printed Nellcor™ bedside SpO_2 patient monitoring system *Service Manual* for a fee from Covidien Technical Services or a local Covidien representative.

3.4 Setup

WARNING:
In the USA, do not connect to an electrical outlet controlled by a wall switch, since this increases the risk of AC power loss to the monitoring system.

Caution:
The monitoring system must be connected to an appropriate power source.

Caution:
If the integrity of the AC power source is in doubt, ensure the monitoring system internal battery is fully charged.

3.4.1 Connecting to Power

The monitoring system operates on AC power or on a charged internal battery. Prior to connecting to power, perform a safety check of the equipment. Reference *Periodic Safety Checks*, p. 7-3.

To connect the AC power cable:

1. Ensure the AC outlet is properly grounded and supplies the specified voltage and frequency (100-240V~ 50-60 Hz).
2. Connect the female connector end of the AC power cord to the AC power connector on the monitoring system's rear panel.
3. Plug the male connector end of the AC power cord into a properly grounded AC outlet.
4. If necessary, connect grounding wire.
   - Connect the grounding wire connector to the rear panel's equipotential terminal.
   - Attach the clip end of the grounding wire to the grounding terminal on the wall.
5. Ensure the ***Battery Charge Indicator*** lights.

Note:
Even if the monitoring system is not turned on, the ***Battery Charge Indicator*** lights when the AC power cord is connected into a mains outlet. Reference *Troubleshooting*, p. 8-1, if the battery charging indicator does not light when connected to power.

To troubleshoot an unlit Battery Charge Indicator:

1. Check the power cord.
2. Check the AC power inlet.

3. Check the power/ mains outlet.
4. Ensure the internal battery is properly installed and charged.
5. Contact a qualified service technician or a local supplier for assistance.

3.4.2 Using the Internal Battery

WARNING:
The amount of time between the low battery alarm and power off becomes shorter as the battery accumulates charge/discharge cycles.

Note:
Remove the battery if the monitoring system is not likely to be used for six (6) months.

Note:
Covidien strongly recommends fully recharging the battery whenever the time between recharges exceeds six (6) months.

Note:
The monitoring system may not operate if the battery charge is critically low.

Note:
Covidien strongly recommends keeping the monitoring system connected to AC power during continuous operation or to recharge the internal battery.

Note:
Recharging the battery over a period of time may shorten the time between the low battery alarm and power off. Have a qualified service technician periodically check the internal battery or replace it if necessary.

The monitoring system has an internal battery that powers the monitoring system when AC power is not available. The monitoring system cannot operate with a fully discharged battery. A lit battery status icon indicates the monitoring system is running on battery power.

Prior to using the internal battery, perform a safety check of the equipment. Reference *Periodic Safety Checks*, p. 7-3.

A new, fully charged optional battery will provide its optimal number of operational hours under these normal conditions:

- Operating in Normal mode (Measuring SpO_2 and PR with plethysmograph display)
- Setting for pulse beep indicator is ON (pulse volume:4 (Default))

- Setting for SatSeconds™ is ON
- Experiencing no alarm condition
- Operating at ambient temperature of 25°C (±5°C)

Note:
Two types of battery are available: the standard 5- hour and optional 10-hour.

Note:
Even if the monitoring system is turned off, the ***Battery Charge Indicator*** remains lit while the battery recharges.

Note:
A full charge of a depleted battery takes more than four (4) hours for a 5-hour battery or eight (8) hours for a 10-hour battery.

Plug the monitoring system into an AC outlet to charge the battery for a minimum of three (3) minutes prior to turning on any monitoring system with a completely discharged battery. When operating on internal battery, the monitoring system battery status icon indicates the battery charge condition.

To charge the internal battery:

1. Connect the monitoring system to AC power to charge a low or depleted battery. Reference *Connecting to Power*, p. 3-3.
2. Verify the ***Battery Charge Indicator*** lights.

3.4.3 Connecting a Nellcor™ Pulse Oximetry Sensor

WARNING:
Incorrect application or use of an SpO_2 sensor can cause tissue damage. Do not wrap the sensor too tightly, apply supplemental tape, or leave a sensor too long on one place. Inspect the sensor site as directed in the *Instructions for Use* to ensure skin integrity, correct positioning, and adhesion of the sensor.

WARNING:
Do not use any other cables to extend the length of the Covidien-approved interface cable. Increasing the length will degrade signal quality and may lead to inaccurate measurements.

WARNING:
Use only the Covidien-approved pulse oximetry sensor and interface cables. Use of another cable can have an adverse effect on performance. Do not attach any cable intended for computer use to the sensor port.

WARNING:
Failure to cover the applied pulse oximetry sensor with opaque material while operating under high ambient light conditions may result in inaccurate measurements.

Caution:
For best product performance and measurement accuracy, use only accessories supplied or recommended by Covidien. Use accessories according to the *Instructions for Use*. Use only accessories that have passed the recommended biocompatibility testing in compliance with ISO10993-1.

Prior to connecting a sensor, perform a safety check of the equipment. Reference *Periodic Safety Checks*, p. 7-3. Reference *Nellcor™ Pulse Oximetry Sensors*, p. 9-1, for details regarding sensor selection.

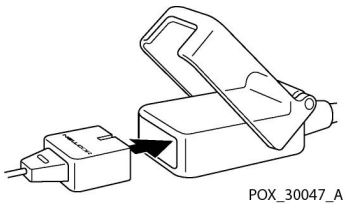
To fully connect a Nellcor™ pulse oximetry sensor:

1. Select an appropriate compatible Nellcor™ pulse oximetry sensor for the patient and desired application. When selecting a sensor, consider the patient's weight and activity, adequacy of perfusion, availability of sensor sites, need for sterility, and anticipated duration of monitoring.

2. Carefully apply the sensor to the patient after reading the *Instructions for Use* accompanying the sensor. Observe all warnings and cautions in the *Instructions for Use*.

3. Connect the interface cable to the sensor port on the front of the panel and firmly connect the interface cable to the pulse oximetry sensor. When the monitoring system detects a valid pulse, it enters monitoring mode and displays real-time patient data.

Figure 3-1. Connecting a Pulse Oximetry Sensor to Interface Cable



A ***Sensor Message*** occurs when the device cannot obtain an SpO_2 level or a pulse rate.

Note:
If the sensor is not connected firmly, the monitoring system could lose signal from patient.

Note:
Physiological conditions, medical procedures, or external agents that may interfere with the monitoring system's ability to detect and display measurements include dysfunctional hemoglobin, arterial dyes, low perfusion, dark pigment, and externally applied coloring agents, such as nail polish, dye, or pigmented cream.

4 Operation

4.1 Overview

This chapter identifies methods for viewing and collecting patient oxygen saturation data using the Nellcor™ bedside SpO_2 patient monitoring system. Before operating the monitoring system, thoroughly read this manual.

4.2 Safety Reminders

WARNING:
The monitoring system is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.

WARNING:
Tissue damage can be caused by incorrect application or use of a pulse oximetry sensor. Do not wrap the pulse oximetry sensor too tightly, apply supplemental tape, or leave it too long on one place. Inspect the pulse oximetry sensor site as directed in the *Instructions for Use* to ensure skin integrity, correct positioning, and adhesion.

WARNING:
Keep patients under close surveillance when monitoring. It is possible, although unlikely, that radiated electromagnetic signals from sources external to the patient and the monitoring system can cause inaccurate measurement readings. Do not rely entirely on the monitoring system's readings for patient assessment. This device has been tested and found to comply with the limits for medical devices related to IEC 60601-1-2: 2007 and IEC 60601-1-2:2014. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

WARNING:
For best product performance and measurement accuracy, use only accessories supplied or recommended by Covidien. Use accessories according to their respective *Instructions for Use*.

WARNING:
Do not use damaged pulse oximetry sensors. Do not use with exposed optical components. Do not immerse completely in water, solvents, or cleaning solutions, since pulse oximetry sensors and connectors are not waterproof. Do not sterilize by irradiation, steam or ethylene oxide. Refer to the cleaning instructions in the *Instructions for Use* for reusable sensors.

Caution:
Do not attach any cable intended for computer use to the sensor port connector.

Caution:
The sensor disconnect error message and associated alarm indicate the pulse oximetry sensor is either disconnected or has faulty wiring. Check the connection and, if necessary, replace it, the pulse oximetry cable, or both.

4.3 User Interface

4.3.1 Turning on the Monitoring System

WARNING:
Ensure the speaker is clear of any obstruction. Failure to do so may result in an inaudible tone.

Caution:
If any indicator or display element does not light, or the speaker does not sound, do not use the monitoring system. Instead, contact a qualified service technician.

Before using the monitoring system in a clinical setting, ensure the monitoring system is working properly and is safe to use.

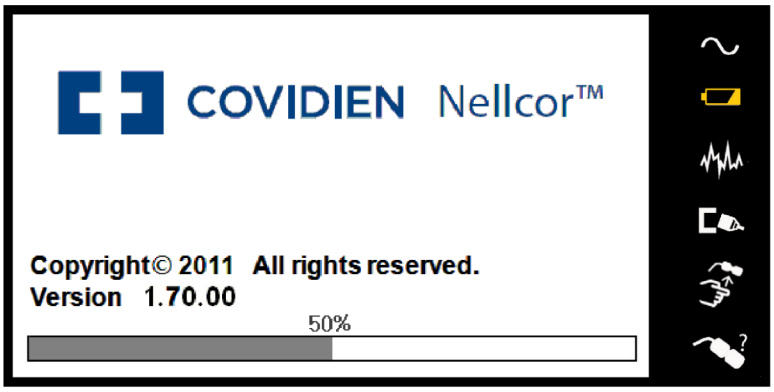
When the monitoring system completes power-on self-test (POST), a POST pass tone sounds. This functions as an audible confirmation of proper speaker performance. If the speaker does not function, the alarm warning sounds remain inaudible.

Note:
Pressing any button should result in either a valid or an invalid tone. If a button press fails to emit a tone, contact a qualified service technician.

To power on the monitoring system:

1. Press the ***Power On/Off Button*** for more than one (1) second.
2. Ensure the software version, the SpO_2 alarm indicator, and the pulse rate alarm indicator light for approximately two (2) seconds.

Figure 4-1. Sample Initial Screen



POX_30092_B

3. Ensure the *POST pass* tone sounds when POST completes.

Note:
Do not use the monitoring system should a repeating, high-pitched alarm tone occur at power on. Instead, please contact Technical Services or a qualified service technician.

4.3.2 Turning off the Monitoring System

After using the monitoring system, turn it off safely.

To turn off the monitoring system:

1. Press the Power On/Off button on the right of the device for approximately one second.
2. Observe the message `System is shutting down` on the screen.

Note:
Press the Power On/Off button for at least 15 seconds to turn off the monitoring system after any situation involving continuous resets or a system lock.

4.4 Menu Options Navigation

Navigating menu options on the monitoring system requires manual manipulation of the three buttons and the jog dial.

Press the desired **interface button**.

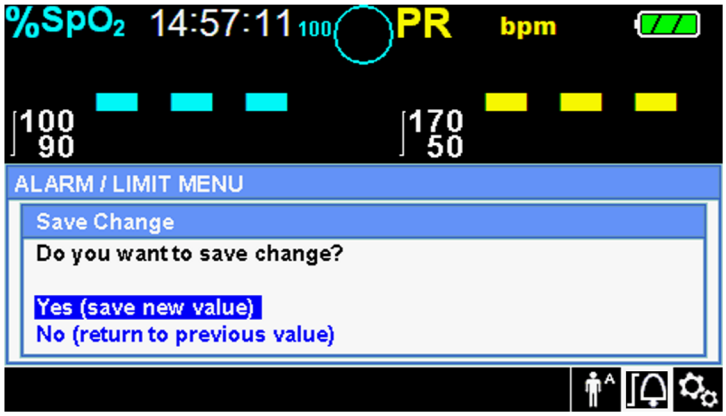
1. **Power On/Off button —** Press and hold this blue button to power on or to power off the monitoring system. This button illuminates at power on and remains lit until power off.
2. **Return button —** Press this green button for less than two (2) seconds to exit menu items and return to the main monitoring screen. This button illuminates at power on and remains lit until power off.

3. **Silence Alarm button —** Press this orange button for less than two (2) seconds to disable or re-enable audible alarms. This button illuminates at power on and remains lit until power off.

Rotate or press the **jog dial** to navigate among various portions of the screen and to select menu items.

Note:
If a user presses and holds the RETURN button while accessing a menu item, but before saving any changes, the monitoring system requires the user to confirm a cancellation of all pending changes. A user prompt appears and the user must either save all pending changes (save new value) or cancel all pending changes (return to previous value) before taking any other action.

Figure 4-2. Save Change Screen



1. **Navigation —** Rotate the jog dial clockwise or counter-clockwise until a colored highlight surrounds the desired area. Any rotation of the jog dial either navigates or changes the desired option setting.

2. **Selection —** Press the jog dial to select that desired area, then continue rotating the jog dial until highlighting the desired menu option, then press again.

The LCD display panel also users with easy-to-read numeric values for patient oxygen saturation and pulse rate in cyan and yellow, respectively. Reference *Table 2-1.* on page 2-6.

4.4.1 Menu Structure

Table 4-1. Menu Structure and Available Options

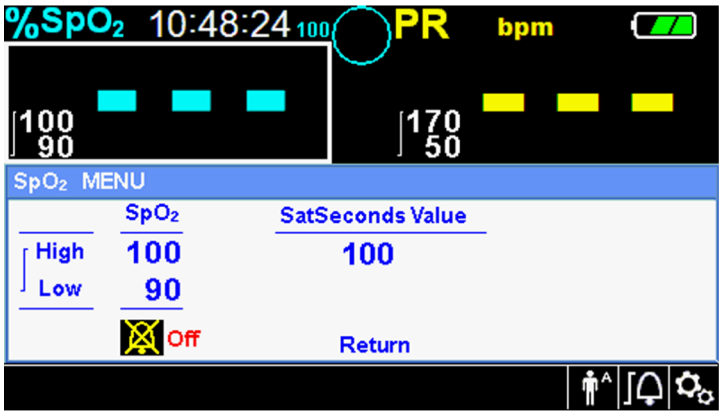
Item	Available selections	Default
QUICK ACCESS ALARM LIMITS menus		
SpO_2 menu	SatSeconds™ alarm management setting (Off, 10, 25, 50, 100) Upper (21-100) SpO_2 alarm limit Lower (20-99) SpO_2 alarm limit Alarm Inhibition for SpO_2 alarms	100 Depends on patient mode. Reference *Table 4-4.* on page 4-17
PULSE RATE (PR) menu	Upper (30-245) pulse rate alarm limit Lower (25-240) pulse rate alarm limit Alarm Inhibition for pulse rate alarms	
OPTIONS menu		
VOLUME	Alarm Volume (1-8)	5
	Key Beep Volume (Off, 1-7)	4
	Pulse Volume (Off, 1-7)	4
MODE (response mode)	Normal, Fast	Normal
TREND DATA DOWNLOAD	Start (Cancel or Return), Return	--
DELETE ALL TREND DATA	No, Yes	--
SERVICE MENU	(For qualified service technicians only)	--
ALARM/LIMITS menu		
SpO_2 LIMITS options	Upper (21-100) SpO_2 alarm limit Lower (20-99) SpO_2 alarm limit Alarm Inhibition for SpO_2 alarms	Depends on patient mode. Reference *Table 4-4.* on page 4-17.
PULSE RATE LIMITS options	Upper (30-245) pulse rate alarm limit Lower (25-240) pulse rate alarm limit Alarm Inhibition for pulse rate alarms	
SATSECONDS option	SatSeconds™ alarm management setting (Off, 10, 25, 50, 100)	100
PATIENT MODE menu		
ADULT option	Sets alarm limits to standard default thresholds for adult patients	Reference *Table 4-4.* on page 4-17.
PEDIATRIC option	Sets alarm limits to standard default thresholds for pediatric patients	
NEONATE option	Sets alarm limits to standard default thresholds for neonate patients	
SpO_2 WAVEFORM menu		
SWEEP SPEED option	6.25 mm/s, 12.5 mm/s, 25.0 mm/s	25.0 mm/s
TABULAR TREND option	Tabular trend view of trend data	--
GRAPHICAL TREND option	Graphical trend view of trend data	

4.4.2 QUICK ACCESS Menus

For quick access to alarm limit settings, use the menu options listed here.

1. **SpO_2 Menu —** Provides access to SpO_2 alarm limit settings, alarm inhibition, and SatSeconds™ alarm management option. Reference *ALARM/LIMITS Menu*, p. 4-10, for basic information. The adult default setting for the SatSeconds™ alarm management option is 100. Other options include OFF, 10, 25, and 50. Reference *SatSeconds™ Alarm Management Feature*, p. 10-5.

Figure 4-3. QUICK ACCESS SpO_2 Menu with Audio Alarm Selected



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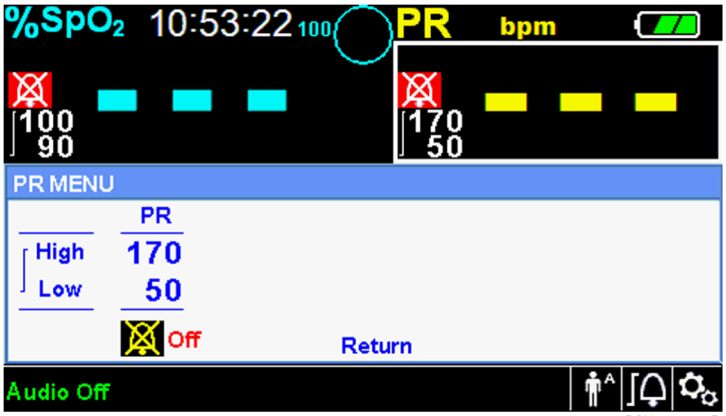
2. **PR Menu —** Provides access to pulse rate (PR) alarm limit settings and alarm inhibition. Reference *ALARM/LIMITS Menu*, p. 4-10.

Figure 4-4. QUICK ACCESS PR Menu with Alarm Audio OFF



POX_30114_D

To select alarm limit settings via Quick Access menus:

1. Rotate the jog dial until the white highlight appears over the SpO_2 or the pulse rate (PR) real-time value field.
2. Press the jog dial.

3. Rotate the jog dial until reaching the desired field.
   - Available SpO_2 alarm limit thresholds
     - SatSeconds™ alarm management values include OFF, 10, 25, 50, 100. The default value is 100. Reference *SatSeconds™ Alarm Management Feature*, p. 10-5.
     - Upper and lower SpO_2 alarm limit thresholds
     - SpO_2 alarm inhibition to disable audible alarms for SpO_2 limit violations
   - Pulse Rate alarm limits
     - Upper and lower pulse rate alarm limit thresholds
     - Pulse rate alarm inhibition to disable audible alarms for pulse rate limit violations
4. Press the jog dial to select the field.
5. Rotate the jog dial to change the field.
6. Exit the menu using either of the listed strategies.
   - Rotate the jog dial to highlight the Return option and press the jog dial.
   - Press the Return button until the LCD returns to its original screen.

4.4.3 OPTIONS Menu

Caregivers may choose from Volume, Mode, or Trend Data menu options.

To access the OPTIONS Menu:

1. Rotate the jog dial to highlight the OPTIONS Menu icon.
2. Press the jog dial to access the OPTIONS Menu.

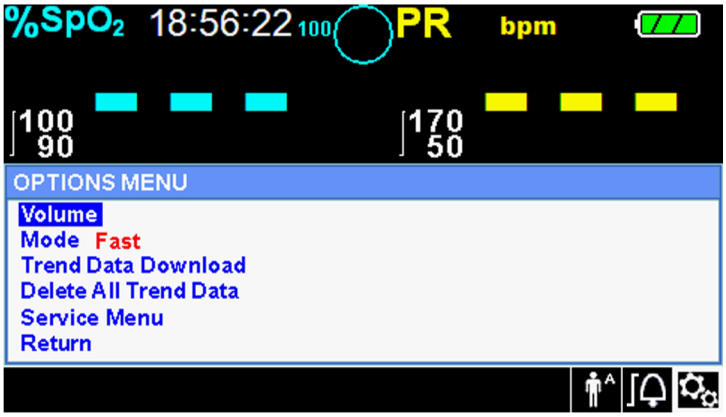
Volume

Access this menu option to adjust volume controls.

To set the desired audible tone volume:

1. Access the OPTIONS Menu.
2. Rotate the jog dial to highlight VOLUME.

Figure 4-5. Volume Selection



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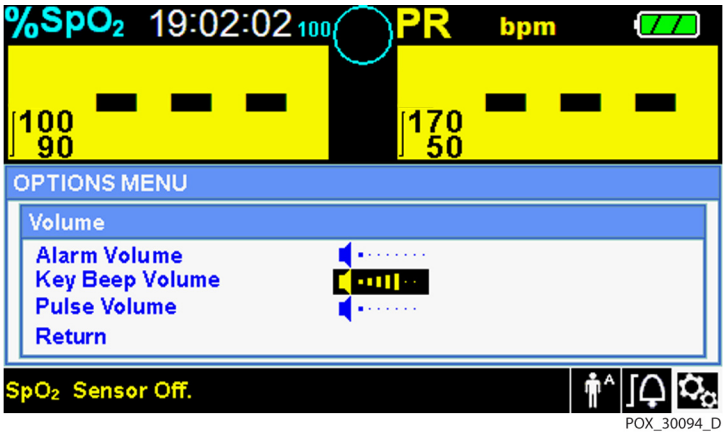
3. Press the jog dial to access Alarm Volume, Key Beep Volume, or Pulse Volume.
   - Alarm Volume controls the volume (1-8) of alarms.
   - Key Beep Volume controls the volume (0ff, 1-7) of any button press.
   - Pulse Volume controls the volume (0ff, 1-7) of the plethysmographic waveform.
4. Rotate the jog dial to select the desired volume level.
5. Press the jog dial to save the desired volume level.

Figure 4-6. Volume Selection



POX_30094_D

Mode (Response Mode)

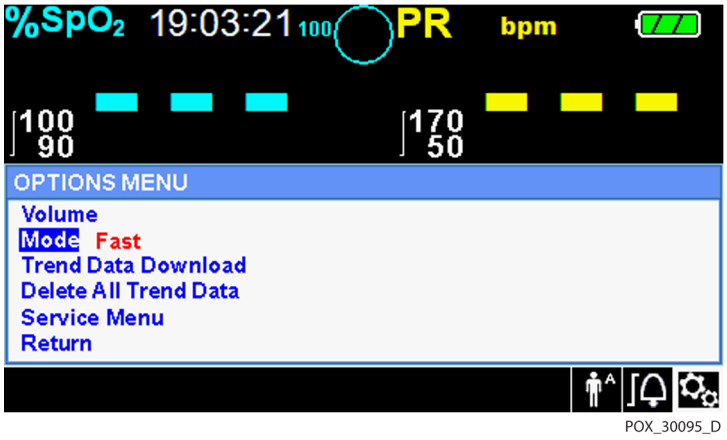
The response mode (Normal or Fast) establishes the rate at which the monitoring system responds to changes in the SpO_2 data.The calculation of pulse rate and the recording of trend data are not affected. The response mode setting does not affect the algorithm's calculation of

pulse rate, nor does it influence the recording of trend data which occurs at one-second intervals. The default setting is the Normal Response Mode.

To set response mode:

1. Access the OPTIONS Menu.
2. Rotate the jog dial to highlight MODE.
3. Press the jog dial to select Normal or Fast response mode.
   - **Normal response mode —** Responds to changes in blood oxygen saturation within five (5) to seven (7) seconds.
   - **Fast response mode —** Responds to changes in blood oxygen saturation within two (2) to four (4) seconds. This mode can be particularly helpful for situations that require close monitoring.

Figure 4-7. Response Mode Menu



Note:
When in the Fast Response Mode, the monitoring system may produce more SpO_2 and pulse rate alarms than expected.

Trend Data Download

Access this menu option to download patient trend data. Reference *Trend Data Download*, p. 5-5.

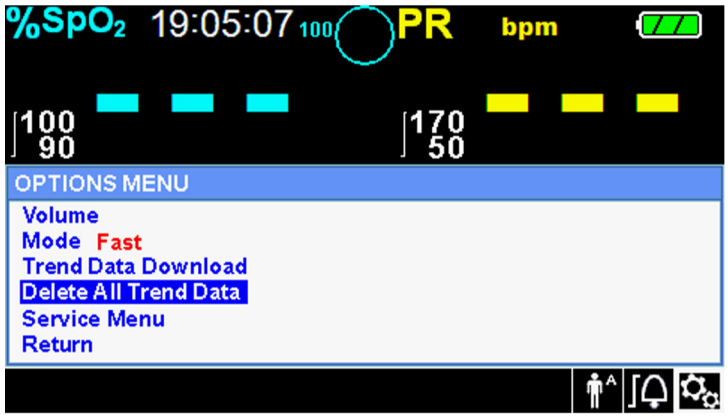
Delete All Trend Data

Access this menu option to delete all patient trend data from memory.

To delete all trend data:

1. Access the OPTIONS Menu.
2. Rotate the jog dial to highlight DELETE ALL TREND DATA.

Figure 4-8. Delete All Trend Data Menu Item



3. At the prompt "Are you sure you want to delete all trend data?" choose one of the following options.

   - Press the jog dial to select NO and keep all trend data.
   - Rotate the jog dial to select YES, then press to delete all trend data.
   - Rotate the jog dial to select RETURN, then press to access the OPTIONS menu.

Service Menu

Only a qualified service technician may change Service Menu settings. A pass code is required for access. Refer to the *Service Manual* for instructions.

4.4.4 ALARM/LIMITS Menu

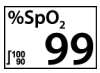
WARNING:
Do not silence the audible alarm or decrease its volume if patient safety could be compromised.

WARNING:
Prior to each use of the monitoring system, check the alarm limits to ensure they are appropriate for the patient being monitored. Ensure alarm limits do not exceed the standard thresholds set by the institution.

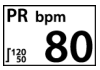
WARNING:
Do not preset different alarm limits for the same or similar equipment within a single area.

Caregivers may choose to adjust SpO_2 and pulse rate (PR) alarm thresholds from default values as necessary. These changes remain in effect until modified again or until a power cycle occurs.

Changes to the SpO_2 and pulse rate (PR) alarm thresholds appear in their respective numerical area. In addition, caregivers may choose to use the SatSeconds™ alarm option to manage the frequency of SpO_2 alarm limit violations by adjusting the SatSeconds™ setting. The higher the value, the less frequent the alarm.



SpO_2 numerical area — Indicates hemoglobin oxygen saturation levels. The display value flashes zeros during loss-of-pulse alarms and flashes the SpO_2 value on a yellow background when saturation is outside the alarm limits. During pulse searches, the monitoring system continues to update the display. Current upper and lower alarm limit settings appear as smaller values to the left of the dynamic SpO_2 value. Reference *Factory Defaults*, p. 4-17, for default alarm limit settings.

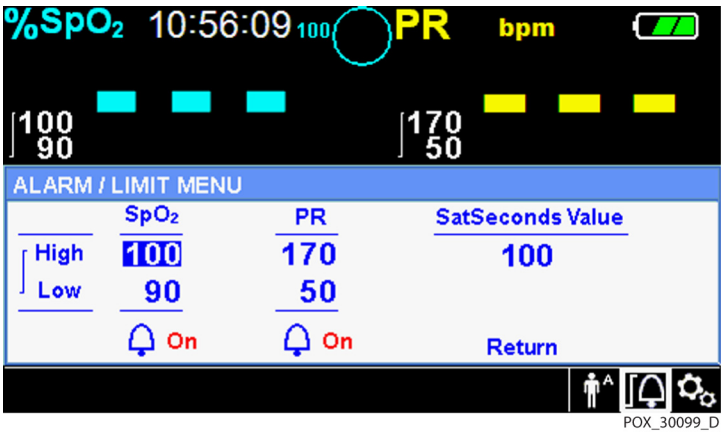


Pulse Rate (PR) numerical area — Displays the pulse rate in beats per minute (bpm). The display value flashes zeros during loss-of-pulse alarms and flashes the pulse rate value on a yellow background when the pulse rate is outside of the alarm limits. During Pulse Search, the monitoring system continues to update the display. Pulse rates outside of the pulse rate range of 20 to 250 bpm are displayed as 0 and 250, respectively. Current upper and lower alarm limit settings appear as smaller values to the left of the dynamic pulse rate value. Reference *Factory Defaults*, p. 4-17, for default alarm limit settings.

To set alarm limits:

1. Rotate the jog dial to highlight the ALARM LIMITS icon.
2. Press the jog dial to display the ALARM/LIMITS Menu.
   - Alarm Limits include pulse rate (PR) and SpO_2 alarm limit ranges.
   - The SatSeconds™ Alarm option provides alarm management of SpO_2 alarm limit violations.
   - The alarm inhibit icon provides caregivers with the option of inhibiting the alarm for SpO_2 and/or pulse rate alarms.
3. Rotate the jog dial to highlight the desired option.
4. Press the jog dial to select the desired option.

Figure 4-9. Alarm/Limits Menu Options



5. Rotate the jog dial to change the desired option value. Reference *Menu Structure*, p. 4-5, for adult, pediatric, and neonate limit options.

   - Available SpO_2 alarm limit thresholds
     - Upper and lower SpO_2 alarm limit thresholds
     - SpO_2 alarm inhibition to disable audible alarms for SpO_2 limit violations
   - Pulse Rate alarm limits
     - Upper and lower pulse rate alarm limit thresholds
     - Pulse rate alarm inhibition to disable audible alarms for pulse rate limit violations
   - SatSeconds™ alarm management values include OFF, 10, 25, 50, 100. The default value is 100. Reference *SatSeconds™ Alarm Management Feature*, p. 10-5.

6. Press the jog dial to save the desired value.

7. Rotate the jog dial to highlight another desired option or to RETURN to the OPTIONS menu.

4.4.5 PATIENT MODE Menu

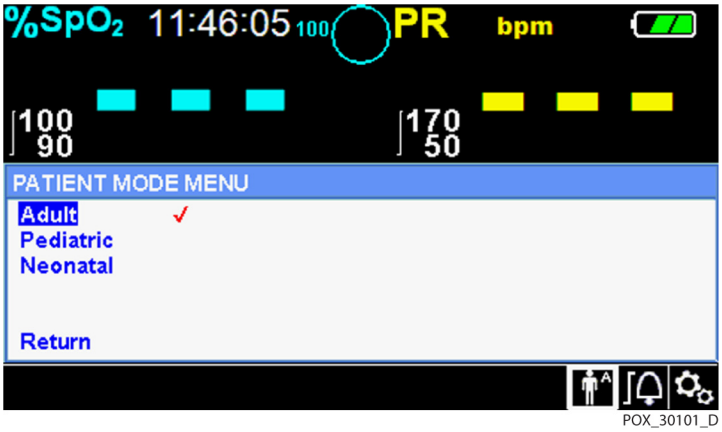
Access this menu option to select the desired PATIENT MODE: Adult, Pediatric or Neonatal.

To set patient mode:

1. Rotate the jog dial to highlight the Patient Mode icon.

2. Press the jog dial to display PATIENT MODE.

Figure 4-10. Patient Mode Menu



3. Rotate the jog dial to highlight the desired mode option: Adult, Pediatric or Neonatal. Use the appropriate patient mode and pulse oximetry sensor based on body weight. Reference the pulse oximetry sensor *Instructions for Use*.

Adult: Use for adults.

Pediatric: Use for children.

Neonatal: Use for newborns.

4. Press the jog dial to save the desired mode.

5. Press the RETURN button to exit PATIENT MODE.

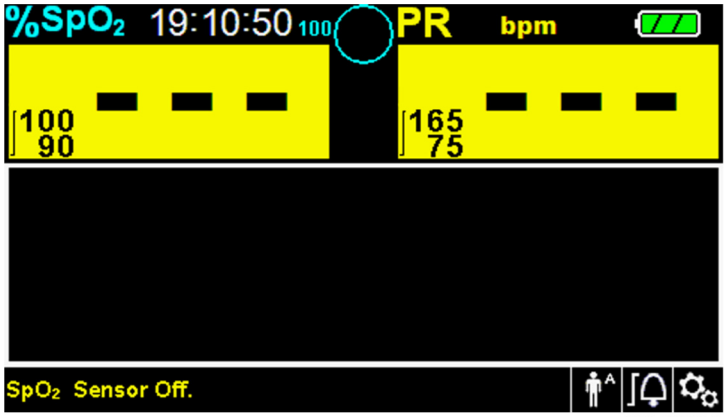
4.4.6 SpO_2 WAVEFORM Menu

Caregivers may choose to set sweep speed of the plethysmographic waveform and opt to view the tabular or graphical trend screen.

To access the WAVEFORM Menu:

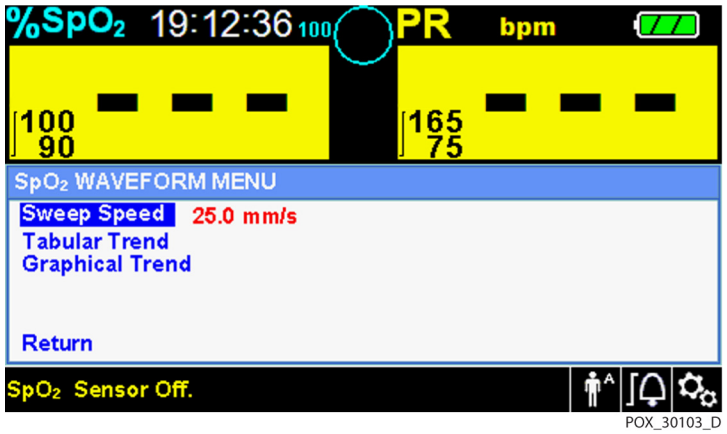
1. Rotate the jog dial to highlight the waveform display area.

Figure 4-11. Highlighting the Waveform Display Area



2. Press the jog dial to display the SpO_2 WAVEFORM Menu.

Figure 4-12. SpO_2 Waveform Menu



- **Sweep Speed —** Access to set the speed at which the SpO_2 waveform trace moves across the screen. The higher the sweep speed value, the more data appears on the screen. Sweep Speed options are 6.25 mm/s, 12.5 mm/s and 25.0 mm/s.
- **Tabular Trend —** Access to display the tabular trend view. Reference *Tabular Trend Data*, p. 5-1.
- **Graphical Trend —** Access to display the graphical trend view. Reference *Graphical Trend Data*, p. 5-2.

4.5 Managing Alarms and Alarm Limits

WARNING:
Setting alarm limits to off or extreme high or low values will reduce alarm efficacy.

WARNING:
Do not silence the audible alarm or decrease its volume if patient safety could be compromised.

WARNING:
Prior to each use of the monitoring system, check the alarm limits to ensure they are appropriate for the patient being monitored. Ensure alarm limits do not exceed the standard thresholds set by the institution.

WARNING:
Ensure the speaker is clear of any obstruction. Failure to do so could result in an inaudible alarm tone.

When the monitoring system detects certain conditions that require user attention, the monitoring system enters an alarm state.

The monitoring system uses both visual and audible indicators to identify high-priority, medium-priority, and low-priority alarms. Audible alarms include pitched tones, beeps, and a buzzing tone. High priority alarms take precedence over medium- and low-priority alarms. Reference *Troubleshooting*, p. 8-1.

Table 4-2. Alarm Conditions

Priority	Rate	Color	Messages
High	Sounds every 4 *s*	Red Steady message, Fast flashing numeric	SpO_2 Loss of Pulse
			Critically Low-Battery condition
Medium	Sounds every 8 s	Yellow Steady message, Slow flashing numeric	High Pulse Rate limits violated
			Low Pulse Rate limits violated
			High SpO_2 limits violated
			Low SpO_2 limits violated
Low	Sounds every 16 s	Steady yellow	SpO_2 Cable/Sensor Disconnect
			SpO_2 Sensor Off
			Low Battery
			Technical System Error: EEE 001
Informative	--	--	SpO_2 Pulse search
			Signal Artifact Detected
			Abnormally shut down last time
			Audio OFF, Alarm Silenced
			Press Return Button to Exit...

Note:
The audible and visual alarms on the monitoring system, used in conjunction with clinical signs and symptoms, are the primary source for notifying medical personnel that a patient alarm condition exists.

Note:
If the monitoring system fails to perform as specified, contact Covidien Technical Services, a qualified service technician, or a local supplier for assistance.

4.5.1 Audible Alarm Indicators

WARNING:
Do not silence the audible alarm or decrease its volume if patient safety could be compromised.

WARNING:
Pressing the Silence Alarm button will silence all audible alarms except "Battery Critically Low."

Audible alarm indicators include pitched tones and beeps. Caregivers may choose to silence the audible alarm for the established ***Alarm Silence*** period of 30, 60, 90 or 120 seconds. Visual alarms continue during this time. The factory default for audible alarm silence period is 60 seconds. To

set one of the listed alternate periods as an institutional default, have a qualified service technician set the desired period via the SERVICE Menu.

Note:
Alarm delays should not exceed 10 seconds other than as specified in this manual.

Table 4-3. Audio Status

Alarm icon	Status
	Alarm Silenced
	Audio OFF

To silence an audible alarm:

1. Press the ***Silence Alarm*** button to immediately silence the alarm tone. The alarm resumes after the ***Alarm Silence*** period, if the alarm condition remains.
2. Take the appropriate corrective action.

Note:
Press the ***Silence Alarm*** button to silence audible alarms caused by technical errors. Audible alarms for physiological conditions can be silenced. However, they require appropriate corrective action. Press the ***Silence Alarm*** button to dismiss an SpO_2 Sensor Off alarm or SpO_2 Cable/Sensor Disconnect alarm.

To re-enable the audio tones during the ***Alarm Silence*** period, press the ***Silence Alarm*** button again.

To silence an audible alarm:

1. Press the ***Silence Alarm*** button.
2. To re-enable, press the ***Silence Alarm*** button again.

If the ***Alarm Silence*** period is enabled, the audible alarm is not active for the specified time interval and the ***Alarm Silenced*** icon appears above the appropriate alarm limit icon. A countdown timer indicates any silence time remaining.

Note:
To disable limit violation alarms, use the Alarm Limits menus. Reference *ALARM/LIMITS Menu*, p. 4-10.

4.5.2 Visual Alarm Indicators

Visual alarms appear on the screen in order of highest priority, regardless of any audible alarm status. Reference *Table 4-2.* on page 4-15.

4.6 Factory Defaults

The monitoring system ships with factory default settings. To set different institutional default settings, contact a qualified service technician.

Table 4-4. Parameter Ranges and Factory Defaults

Parameter	Ranges/selection	Factory default		
		Adult	Pediatric	Neonatal
SpO_2				
$\%SpO_2$ upper alarm limit	21 to 100% (1% steps)	100%		95%
$\%SpO_2$ lower alarm limit	20 to 99% (1% steps)	90%		85%
$\%SpO_2$ limit alarm inhibition	On, Off	Off		
SatSeconds™ alarm	Off, 10, 25, 50, 100	100		
Pulse rate				
Pulse rate upper alarm limit	30 to 245 bpm (5 bpm steps)	170 bpm		200 bpm
Pulse rate lower alarm limit	25 to 240 bpm (5 bpm steps)	50 bpm	75 bpm	100 bpm
PR limit alarm inhibition	On, Off	Off		
Tabular trends				
Scroll	1, 5, 100, 500	1		
Graphical trends				
SpO_2	On, Off	On		
PR	On, Off	On		
Others				
Patient mode	Adult, Pediatric, Neonatal	Adult		
Alarm volume	1, 2, 3, 4, 5, 6, 7, 8	5		
Key beep volume	Off, 1, 2, 3, 4, 5, 6, 7	4		
Pulse volume	Off, 1, 2, 3, 4, 5, 6, 7	4		
Date/time settings[1]	yy/mm/dd, mm/dd/yy, dd/mm/yy	yy/mm/dd		
Alarm silence duration[1]	30, 60, 90, 120 *s*	60 s		
Alarm disabled reminder[1]	OFF, 3, 10 min	3 min		
Mode (response mode)	Normal, Fast	Normal		

Table 4-4. Parameter Ranges and Factory Defaults (Continued)

Parameter	Ranges/selection	Factory default		
		Adult	Pediatric	Neonatal
Trend data download settings[1]	Baud rates: 19200, 38400, 57600, 115200 bps	19200 bps		
	Protocol: ASCII 1, ASCII 2	ASCII 1		
	Nurse call settings: NORMALLY +, NORMALLY –	NORMALLY –		
Sweep speed	6.25, 12.5, 25.0 mm/*s*	25.0 mm/s		
Power on settings[1]	Factory Defaults, Last Settings, Institutional Defaults	Factory Defaults		
Language[1]	Chinese, Czech, Danish, Dutch, English, Finnish, French, German, Greek, Italian, Japanese, Korean, Norwegian, Polish, Portuguese, Russian, Slovakian, Spanish, Swedish, Turkish	English		

1. To alter this parameter, a qualified service technician must access the Service Menu, as described in the *Service Manual*.

4.7 Maintenance Reminder

Schedule regular maintenance and safety checks with a qualified service technician every 24 months. Reference *Periodic Safety Checks*, p. 7-3. In the case of mechanical or functional damage, contact Covidien or a local Covidien representative. Reference *Obtaining Technical Assistance*, p. 1-5.

5 Data Management

5.1 Overview

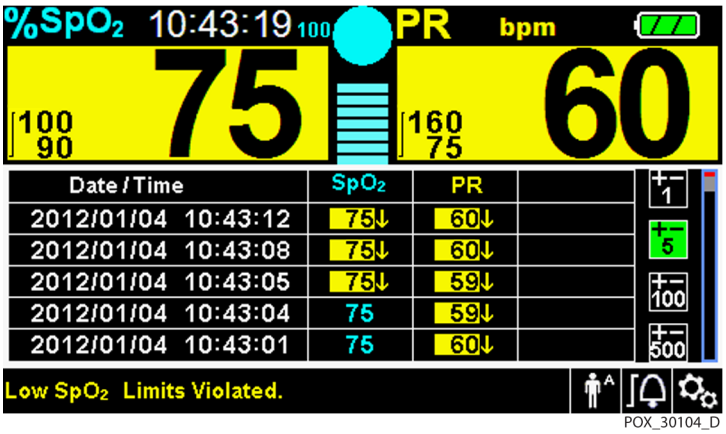
This chapter contains information for accessing patient trend data obtained using the Nellcor™ bedside SpO_2 patient monitoring system. Trend data can be viewed anytime patient trend is stored in the monitoring system.

The monitoring system stores up to 96 hours of trend data. When the monitoring system begins measuring vital signs, it saves data every four (4) seconds. It also saves all physiological alarm conditions and errors. Trend data history remains in memory even if the monitoring system is powered off. The monitoring system stores new data over the oldest data when the buffer is full.

5.2 Tabular Trend Data

The monitoring system presents trend information in tabular format for all monitored parameters when users enable this option. The newest data values appear at the top.

Figure 5-1. Tabular Trend Data Screen



To select *Tabular Trend*:

1. Rotate the jog dial to highlight the waveform area.
2. Press the jog dial to display the SpO_2 WAVEFORM Menu.

3. Select ***Tabular Trend***.

To scroll through *Tabular Trend Data*:

1. Rotate the jog dial to scroll through the trend data.
   - **Clockwise** rotation moves forward to newer data.
   - **Counterclockwise** rotation moves backward to older data.
2. Press the jog dial again to adjust the scroll granularity. Larger values scroll through more data faster.

Note:
To scroll most efficiently, adjust the scroll granularity more than once. For instance, use the +/-500 to scroll quickly to the desired time stamp, then press the jog dial again to reach the +/-1 to scroll through each individual event in that time period.

3. After reviewing trend data, press the RETURN button to exit the tabular trend view.

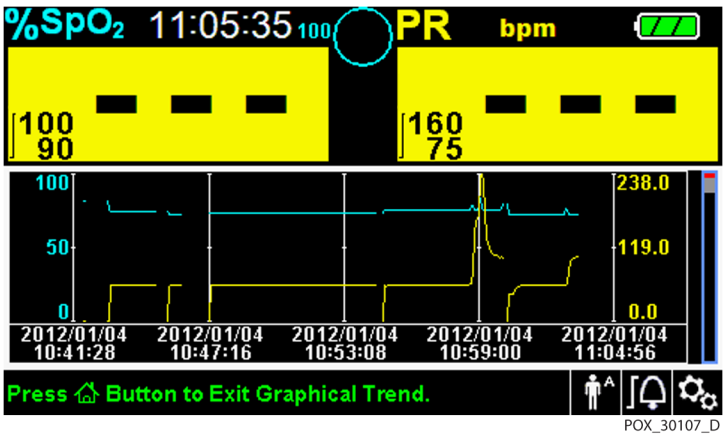
5.3 Graphical Trend Data

The monitoring system presents trend information in a single graph for all monitored parameters when users enable this option. The vertical range of a graphical trend appears as a fixed value. The horizontal range is 24 minutes. The newest data values appear to the right.

To select *Graphical Trend*:

1. Rotate the jog dial to highlight the waveform area.
2. Press the jog dial to display the SpO_2 Waveform Menu.
3. Select ***Graphical Trend***.

Figure 5-2. Graphical Trend Data Screen



To scroll through Graphical Trend Data:

1. Rotate the jog dial to highlight ***Scroll***.
2. Press the jog dial to activate scrolling.
3. Rotate the jog dial to scroll through the trend data.
   - **Clockwise** rotation moves forward to newer data.
   - **Counterclockwise** rotation moves backward to older data.
4. After reviewing trend data, press the RETURN button to exit the graphical trend view.

5.4 External Data Communication

WARNING:
Any connections between this monitoring system and other devices must comply with applicable medical systems safety standards such as IEC 60601-1. Failure to do so may result in unsafe leakage current and grounding conditions.

The monitoring system provides external connectors on the right and rear panels to support data communication.

- **Nurse call interface (RJ11) —** Allows caregivers to remotely monitor patient alarms via the nurse call system of the institution.
- **USB interface —** Enables firmware upgrades. Reference the *Service Manual*.
- **Mini USB interface —** Enables trend data downloads and connection to a personal computer (PC).

5.4.1 Nurse Call Interface

WARNING:
Do not use the nurse call feature as the primary source of alarm notification. The audible and visual alarms of the monitoring system, used in conjunction with clinical signs and symptoms, are the primary sources for notifying medical personnel that an alarm condition exists.

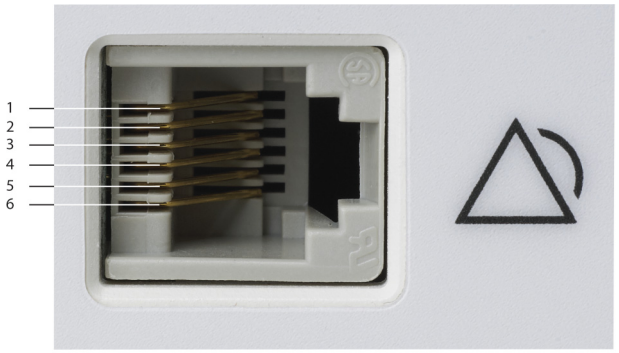
WARNING:
The nurse call feature does not function when monitoring system alarms are silenced.

Caution:
Test the nurse call function prior to use, especially when setting up the monitoring system in a new location. One way to test the nurse call function is to create an alarm condition (for example, sensor disconnect) and verify the nurse call system properly activates.

Note:
Communication (Nurse Call Interface) is limited to inside a single institution.

The nurse call feature of the monitoring system works in conjunction with the nurse call system of the institution when the monitoring system sounds an audible alarm. It is operational regardless of whether the monitoring system uses AC power or battery power, as long as a proper connection between the nurse call port and the host system exists.

Figure 5-3. Nurse Call Interface Pin Layout



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To connect the nurse call cable:

1. Grasp the RJ11 end of the cable.
2. Firmly insert into the nurse call port.
3. Attach the alternate end of the cable into the host system.

To disconnect the nurse call cable:

1. Grasp the RJ11 end of the cable and press down on the plastic tab on the cable's connector.

   Do not attempt to remove the connector without pressing down on the tab.
2. Gently pull the RJ11 connector out of the nurse call port.

The nurse call feature uses a relay closure to signal the nurse station during alarm conditions. The nurse call polarity can be set to NORMALLY + or NORMALLY –. A qualified service technician can set the nurse call polarity using the procedure described in the *Service Manual*.

When the nurse call polarity is set to NORMALLY +, the nurse call relay operation is as follows:

Table 5-1. Nurse Call Relay Pins States for NORMALLY +

	Monitoring system ON		Monitoring system OFF
NORMALLY +	**No alarm or alarm silenced**	**Audible alarm**	
Pin 1 and Pin 2	Open	Closed	Closed
Pin 2 and Pin 3	Closed	Open	Open

When the nurse call polarity is set to NORMALLY –, the nurse call relay operation is as follows:

Table 5-2. Nurse Call Relay Pins States for NORMALLY –

	Monitoring system ON		Monitoring system OFF
NORMALLY –	**No alarm or alarm silenced**	**Audible alarm**	
Pin 1 and Pin 2	Closed	Open	Closed
Pin 2 and Pin 3	Open	Closed	Open

Pin 2 is a common lead for both relays.

5.4.2 Trend Data Download

Caution:
Anyone who connects a PC to the data output port configures a medical system and is therefore responsible for ensuring that the system complies with the requirements of IEC Standard 60601-1-1 and the electromagnetic compatibility IEC Standard 60601-1-2.

Caution:
Signal artifacts, secondary to a variety of external factors, may compromise the presence or accuracy of the displayed values.

Connect the mini-USB port to a PC for downloading trend data. Any PC connected to the data port must be certified according to IEC Standard 60950. All combinations of equipment must be in compliance with IEC Standard 60601-1-1 system requirements. Use either ASCII communication protocol.

- Nellcor™ ASCII protocol (ASCII 1)
- ASCII format compatible with several spreadsheet programs (ASCII 2)

Note:
Users may choose to import patient trend data to a spreadsheet program. To do so, users must export trend data using the ASCII 2 format option. Have a qualified service technician set this option prior to attempting a data download.

System Compatibility Prerequisites

- Windows™* Vista/XP/Server 2003/2000
- Pentium™* 100 MHz CPU
- 256 MB RAM
- HyperTerminal™* or equivalent software

Hardware

- Mini-USB data download cable
- CD, if USB driver required

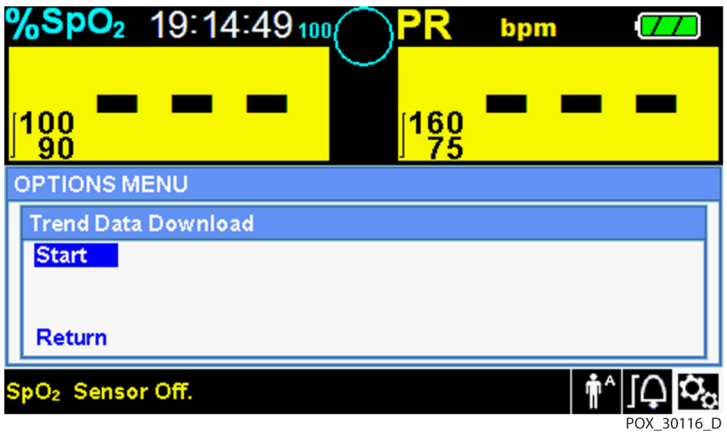
The COM port on the side of the monitoring system provides access to collected trend data. Data transfer relies on existing communication software drivers for USB-based devices already on the computer, so should not require any modification of the drivers used by the USB interface. If, for some reason, the computer does not have the correct USB driver, use the device driver provided on the product CD or from Technical Services. Reference *COM port USB Driver Alternatives*, p. 5-10.

Note:
Any trend data download relies on either factory default settings or institutional default settings established by a qualified service technician prior to usage. This includes baud rate and communication protocol selection.

To download trend data

1. Power on the monitoring system by pressing the button.
2. Rotate the jog dial to highlight the OPTIONS Menu icon.
3. Press the jog dial to access the OPTIONS Menu.
4. Rotate the jog dial to select the TREND DATA DOWNLOAD submenu option.

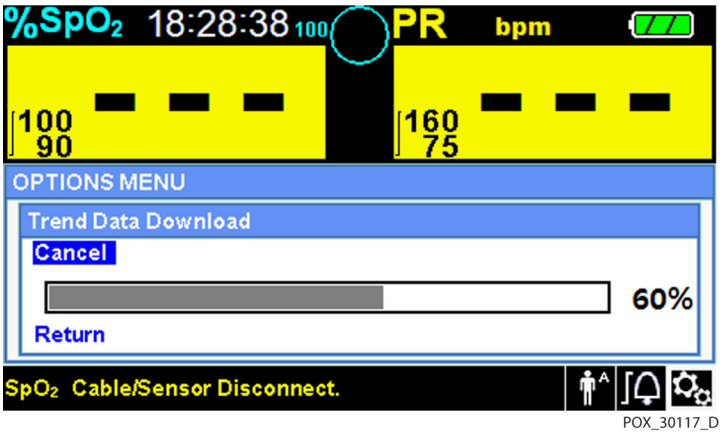
Figure 5-4. Trend Data Download Option



5. Press the jog dial to access the TREND DATA DOWNLOAD Menu.
6. Connect a mini-USB cable from the monitoring system to the computer.
   a. Grasp the mini-USB end of the cable.
   b. Firmly insert into the bottom mini-USB data port.
   c. Firmly insert the USB end of the cable into a USB port on the host system.
7. Ensure the computer properly identifies the monitoring system. If it does not, follow the procedure for loading the appropriate driver. Reference *To install a USB driver from the compact disc*, p. 5-11.
8. Launch HyperTerminal™*. Reference p. 5-8.
9. Press the jog dial again, since the item highlighted is the START option.The status bar indicating total percentage of the download appears and the START option, immediately changes to a CANCEL option.

Note:
Users may choose to cancel the download operation at any point in the download process by selecting CANCEL and then RETURN.

Figure 5-5. Trend Data Download Status



10. Confirm the monitoring system is sending trend data to a personal computer (PC) by observing the computer screen for a scrolling trend data record. If no trend data values appear, check connectivity and ensure the personal computer contains HyperTerminal™* software. If this is all operational, verify patient trend data history exists on the monitoring system. Contact Technical Services or a qualified service technician for assistance.

11. Wait for the OUTPUT COMPLETE message to indicate the download is complete.

12. Save patient trend data to the personal computer disk or to an alternate source, depending on institutional requirements.

To launch HyperTerminal™*:

1. Click the START menu in the main task bar.

2. Mouse over the PROGRAMS submenu, then ACCESSORIES, then COMMUNICATIONS, then the HYPERTERMINAL option.

Note:
If this is the first time the HyperTerminal™* program launches, it will prompt the user to set it as the default Telnet program. Depending on institutional requirements, users may choose YES or NO.

3. Click the HYPERTERMINAL option.

4. When the Connect Description window opens, type in the desired file name in the Name field.

5. Locate the proper icon by scrolling all the way to the far right of the icon field.

6. Select the icon.

7. Click the OK button.

Note:
If the personal computer is not connected via the USB to mini-USB cable to the monitoring system, the proper COM port option will not appear in the list.

8. When the Connect To window opens, find the CONNECT USING option and click the down arrow to identify possible modem options.
9. Select the desired COM port.
10. Click the OK button.
11. In the COM PROPERTIES window, set the appropriate values.
    a. Set the baud rate (bits per second) to match the monitoring system. The factory default baud rate is 19200 bits per second (bps).
    b. Ensure the data bit is set to 8.
    c. Ensure the parity bit is set to none.
    d. Ensure the stop bit is set to 1.
    e. Ensure the flow control is set to none.
12. Click the OK button.

Note:
To test for trend data download connectivity, proceed with the download by pressing the START option. If no data values appear in HyperTerminal™*, try a different COM port, select the FILE menu, click NEW CONNECTION, and select a different COM port until data values scroll across the HyperTerminal™* screen.

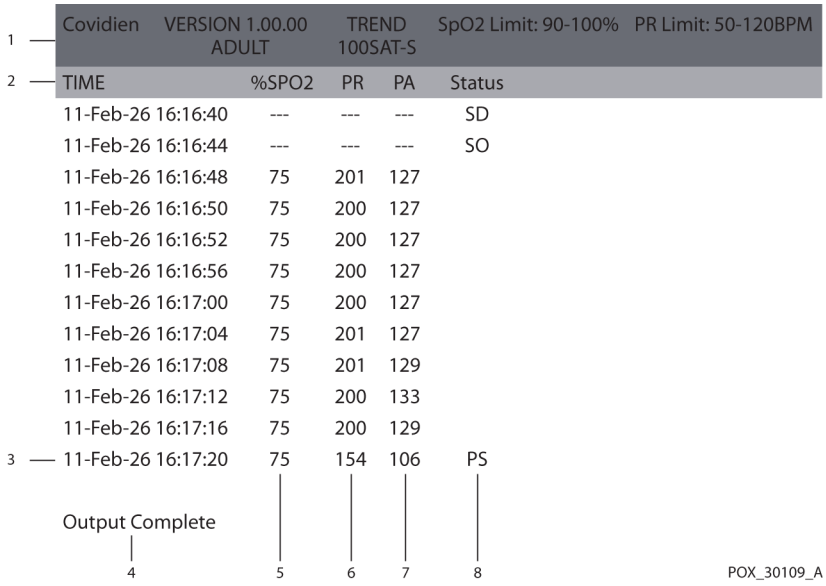
To interpret downloaded trend data:

1. Examine trend data on the HyperTerminal™* screen, in a spreadsheet, or on a printout from the personal computer.

Table 5-3. Operating Status Codes

Code	Definition	Code	Definition
AO	Alarm off	PH	Pulse rate upper limit alarm
AS	Alarm silence	PL	Pulse rate lower limit alarm
BU	Battery in use	PS	Pulse search
LB	Low battery	SD	Sensor disconnect
LM	Loss of pulse with signal artifact	SH	Saturation rate upper limit alarm
LP	Loss of pulse	SL	Saturation rate lower limit alarm
ID	Signal artifact detected	SO	Sensor off
MO	Signal artifact		

Figure 5-6. Sample Trend Data Printout



1	Product column headings	Data source, firmware version, and system settings
2	Patient data column headings	Lists appropriate time and data headings
3	Time column	Real-time clock date and time stamp
4	Output Complete	Message indicating completion of trend data download
5	%SpO_2	Current saturation value
6	PR	Current pulse rate
7	PA	Current pulse ampltitude
8	Status	Operating status of the monitoring system

2. Ensure patient data settings coincide with expected settings. This would include the version of firmware and its CRC code, which should be all zeros; the current method of viewing the data: waveform, trend, or graph; alarm limit settings; patient mode; and SatSeconds™ setting.

3. Scan the time, SpO_2, or PR column until reaching the events of interest.

4. Match the operating status codes to the following table for pertinent system information. Reference *Operating Status Codes*, p. 5-9.

COM port USB Driver Alternatives

- Load the appropriate driver from the product CD into the connected computer.
- Contact Technical Services or a local Covidien representative.

Note:
The following graphics are representative of the screens users may encounter while installing a USB driver from the compact disc. Individual operating system languages may vary.

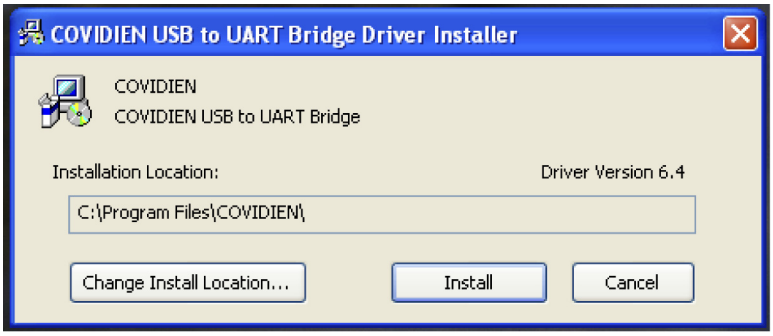
To install a USB driver from the compact disc

1. Insert the Nellcor™ bedside SpO_2 patient monitoring system compact disc (CD) into the designated personal computer (PC).
2. Copy the COVIDIEN USB to UART Bridge Driver zip file to the PC, installing it in the desired program folder.
3. Right-click on the zipped folder.
4. Select EXTRACT ALL.
5. Open the extracted folder.
6. Launch the Driver Installer executable.

Note:
To change the location of the driver, select the desired mapping by clicking CHANGE INSTALL LOCATION.

7. Click INSTALL.

Figure 5-7. Sample Bridge Driver Installer Window



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8. Reboot the PC for changes to take effect.
9. Connect the monitoring system to the PC, firmly engaging the USB end to the PC and the mini-USB to the monitoring system.
10. Allow the PC to sense the new hardware and load the installer, which guides users through the entire setup process. Do not click the CANCEL button.

Figure 5-8. Sample New Hardware Wizard Screen

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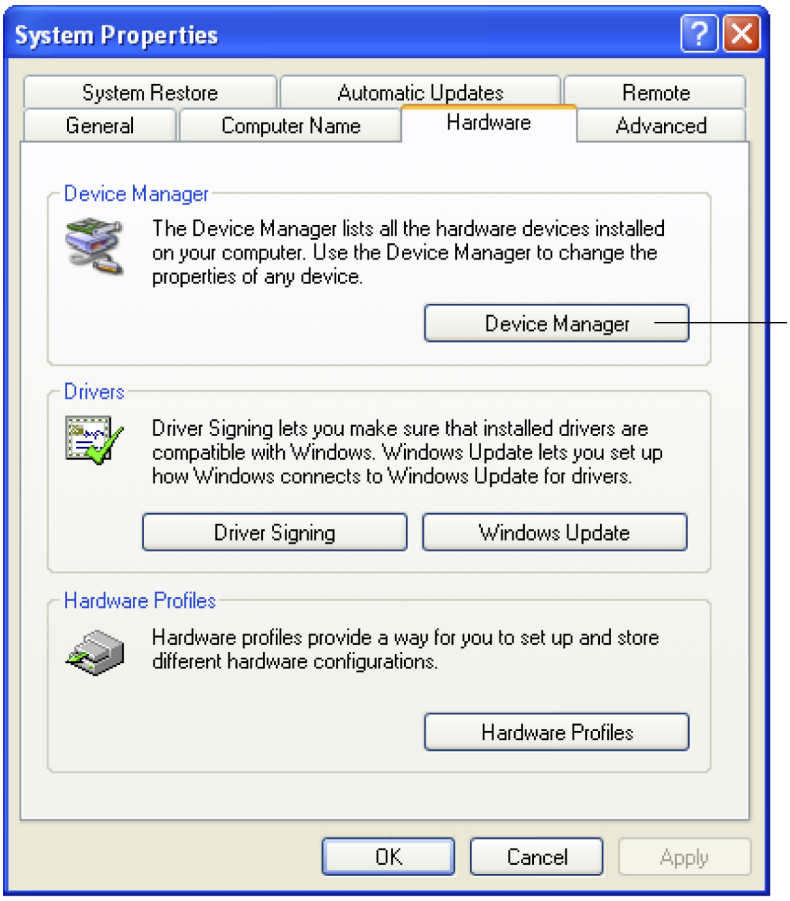
11. At the prompt from the installer, click on the NEXT button to copy the driver to the PC.
12. When the installer provides the end-user license agreement, read it carefully, then click the button for accepting the terms of the license.
13. Click NEXT to formally accept the agreement.
14. Review the Destination Folder mapping. To change the destination, click BROWSE and select the desired mapping.
15. Click NEXT to formally accept the Destination Folder mapping.
16. Click INSTALL in the resulting driver installer window. Do not click the CANCEL button

Note:
If a Windows™* Security window pops up, select the option to install the driver anyway.

17. Click the OK button to complete the installation in the resulting Success window.
18. Reboot the PC for changes to take effect.
19. From the START menu, click the Settings menu option and select the Control Panel option.
20. Select the System option to open the System Properties window.
21. Click the Hardware tab, then the DEVICE MANAGER button.

Figure 5-9. Sample DEVICE MANAGER Button Under Hardware Tab



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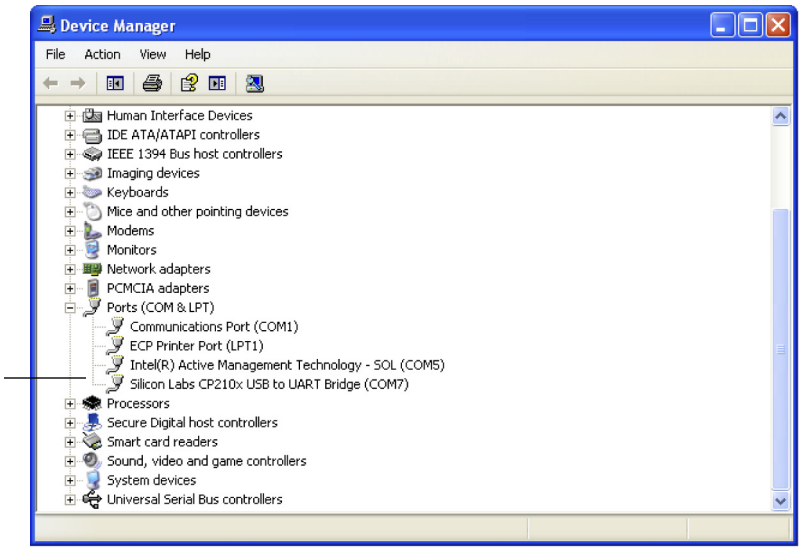
22. Select the Ports option from the resulting list.

Figure 5-10. Sample Hardware List in Device Manager Window

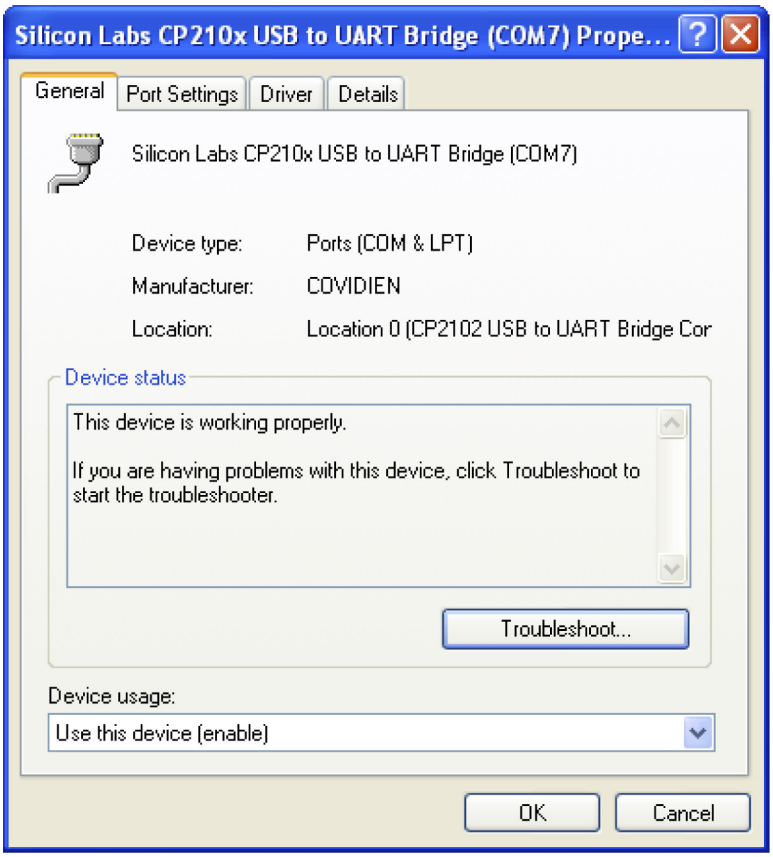


POX_30126_A

23. Double click the Silicon Labs CP210x USB to UART Bridge option.

Note:
The listed COM port should match the HyperTerminal™* COM port designation. Reference *To launch HyperTerminal™*:, p. 5-8.

Figure 5-11. Sample Initial USB to UART Bridge Properties Window

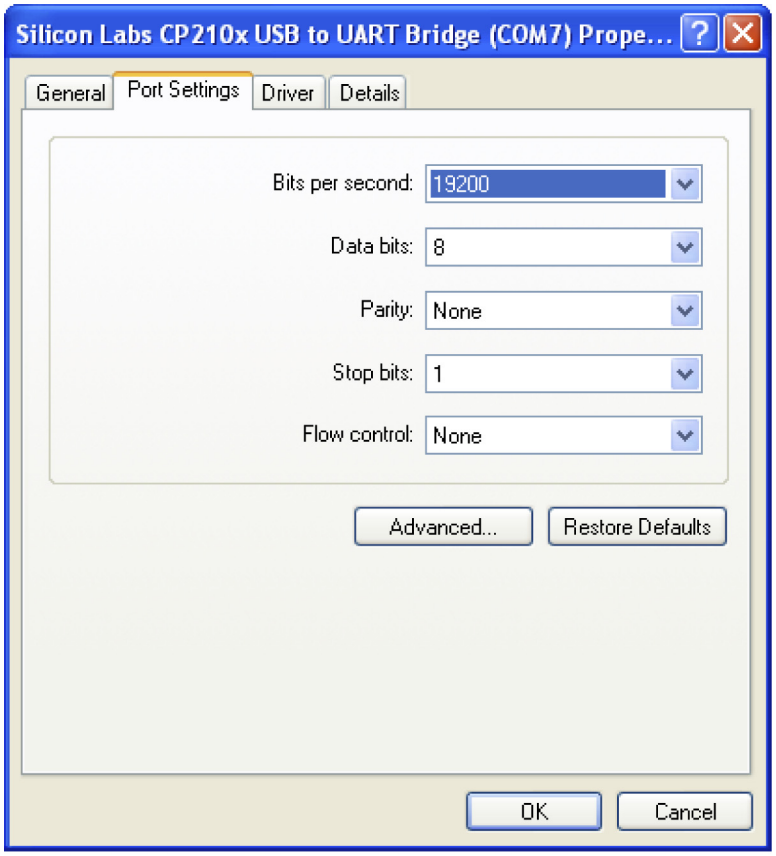


POX_30125_A

24. Click the Port Settings tab.

25. Set the bits per second to one of four possible baud rates: 19200, 38400, 57600, or 115200. The factory default is 19200 bps.

Figure 5-12. Sample Baud Rate List Under Port Settings Tab



POX_30127_A

26. Click the OK button to complete the process.

27. Reference *To download trend data*, p. 5-6, and proceed to step 8, utilizing HyperTerminal™* to connect to the monitoring system.

5.4.3 Firmware Upgrades

Contact a qualified service technician to perform any firmware upgrade to the monitoring system, as described in the *Service Manual*.

6 Performance Considerations

6.1 Overview

This chapter contains information about optimizing the performance of the Nellcor™ bedside SpO_2 patient monitoring system.

Verify the performance of the monitoring system by following the procedures outlined in the *Service Manual*. Have a qualified service technician perform these procedures prior to initial installation in a clinical setting.

6.2 Oximetry Considerations

WARNING:
Pulse oximetry readings and pulse signals can be affected by certain ambient environmental conditions, pulse oximetry sensor application errors, and certain patient conditions.

6.2.1 Pulse Rates

The monitoring system only reports pulse rates between 20 and 250 bpm. Detected pulse rates above 250 bpm appear as 250. Detected pulse rates below 20 appear as a zero (0).

6.2.2 Saturation

The monitoring system reports saturation levels between 1% and 100%.

6.3 Performance Considerations

6.3.1 Overview

This section contains information for optimizing the performance of the monitoring system.

Verify the performance of the monitoring system by following the procedures outlined in the *SRC-MAX Pulse Oximetry Functional Tester Technical Manual*. Have a qualified service technician

perform these procedures prior to initial installation in a clinical setting and every 24 months as part of preventive maintenance. Reference *Service*, p. 7-4.

6.3.2 Patient Conditions

Application issues and certain patient conditions can affect the measurements of the monitoring system and cause the loss of the pulse signal.

- Anemia — Anemia causes decreased arterial oxygen content. Although SpO_2 readings may appear normal, an anemic patient may be hypoxic. Correcting anemia can improve arterial oxygen content. The monitoring system may fail to provide an SpO_2 reading if hemoglobin levels fall below 5 gm/dl.
- Dysfunctional hemoglobins — Dysfunctional hemoglobins such as carboxyhemoglobin, methemoglobin, and sulphemoglobin are unable to carry oxygen. SpO_2 readings may appear normal; however, a patient may be hypoxic because less hemoglobin is available to carry oxygen. Further assessment beyond pulse oximetry is recommended.
- Additional possible patient conditions may also influence measurements.
  - Poor peripheral perfusion
  - Excessive patient activity
  - Venous pulsations
  - Dark skin pigment
  - Intravascular dyes, such as indocyanine green or methylene blue
  - Externally applied coloring agents (nail polish, dye, pigmented cream)
  - Defibrillation

6.3.3 Sensor Performance Considerations

WARNING:
Pulse oximetry readings and pulse signal can be affected by certain ambient conditions, sensor application errors, and certain patient conditions.

WARNING:
Tissue damage can be caused by incorrect application or inappropriate duration of use of a pulse oximetry sensor. Inspect the sensor site as directed in the *Instructions for Use*.

WARNING:
Use only Covidien-approved pulse oximetry sensors and pulse oximetry cables when connecting to the sensor connector. Connecting any other cable or sensor influences the accuracy of sensor data, since this may lead to adverse results.

WARNING:
Failure to cover the pulse oximetry sensor site with opaque material in high ambient light conditions may result in inaccurate measurements.

Inaccurate Sensor Measurement Conditions

A variety of conditions can cause inaccurate Nellcor™ pulse oximetry sensor measurements.

- Incorrect application of the pulse oximetry sensor
- Placement of the pulse oximetry sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line
- Ambient light
- Failure to cover the pulse oximetry sensor site with opaque material in high ambient light conditions
- Excessive patient activity
- Dark skin pigment
- Intravascular dyes or externally applied coloring, such as nail polish or pigmented cream

Signal Loss

Loss-of-pulse signal can occur for several reasons.

- Pulse oximetry sensor applied too tightly
- Inflation of a blood pressure cuff on the same extremity as the attached pulse oximetry sensor
- Arterial occlusion proximal to the pulse oximetry sensor
- Poor peripheral perfusion

Recommended Usage

Select an appropriate Nellcor™ pulse oximetry sensor, apply it as directed, and observe all warnings and cautions presented in the *Instructions for Use* accompanying the sensor. Clean and remove any substances such as nail polish from the application site. Periodically check to ensure that the sensor remains properly positioned on the patient.

High ambient light sources such as surgical lights (especially those with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, and direct sunlight can interfere with

the performance of a Nellcor™ pulse oximetry sensor. To prevent interference from ambient light, ensure that the sensor is properly applied, and cover the sensor site with opaque material.

If patient activity presents a problem, try one or more of the following remedies to correct the problem.

- Verify the Nellcor™ pulse oximetry sensor is properly and securely applied.
- Move the sensor to a less active site.
- Use an adhesive sensor that improves patient skin contact.
- Use a new sensor with fresh adhesive backing.
- Keep the patient still, if possible.

If poor perfusion affects performance, consider using the Nellcor™ forehead SpO_2 sensor (MAX-FAST), which provides superior detection in the presence of vasoconstriction. Nellcor™ forehead SpO_2 sensors work particularly well on supine patients and mechanically ventilated patients. During low perfusion conditions, Nellcor™ forehead SpO_2 sensors reflect changes to SpO_2 values up to 60 seconds earlier than digit sensors.

6.3.4 Reducing EMI (Electromagnetic Interference)

WARNING:
Keep patients under close surveillance when monitoring. It is possible, although unlikely, that radiated electromagnetic signals from sources external to the patient and the monitoring system can cause inaccurate measurement readings.

WARNING:
Any radio frequency transmitting equipment or other nearby sources of electrical noise may result in disruption of the monitoring system.

WARNING:
Large equipment using a switching relay for its power on/off may affect monitoring system operation. Do not operate the monitoring system in such environments.

WARNING:
The monitoring system is designed for use in environments in which the signal can be obscured by electromagnetic interference. During such interference, measurements may seem inappropriate or the monitoring system may not seem to operate correctly.

Caution:
This device has been tested and found to comply with the limits for medical devices related to IEC 60601-1-2:2007 and IEC 60601-1-2:2014. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

Because of the proliferation of radio frequency transmitting equipment and other sources of electrical noise in health care environments (for example, electrosurgical units, cellular phones, mobile two-way radios, electrical appliances, and high-definition television), it is possible that high levels of such interference due to close proximity or strength of a source may result in disruption of monitoring system performance.

Disruption may be evidenced by erratic readings, cessation of operation, or other incorrect functioning. If this occurs, survey the site of use to determine the source of this disruption, then take the appropriate actions to eliminate the source.

- Turn equipment in the vicinity off and on to isolate the offending equipment.
- Reorient or relocate the interfering equipment.
- Increase the separation between the interfering equipment and the monitoring system.
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.

The monitoring system generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with these instructions, may cause harmful interference with other susceptible devices in the vicinity. Contact Technical Services for assistance.

6.4 Obtaining Technical Assistance

For technical information and assistance, contact Technical Services or a qualified service technician. Reference *Obtaining Technical Assistance*, p. 1-5.

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7 Preventive Maintenance

7.1 Overview

This chapter describes the steps required to maintain, service, and properly clean the Nellcor™ bedside SpO_2 patient monitoring system.

7.2 Cleaning

WARNING:
Do not spray, pour, or spill any liquid on the monitoring system, its accessories, connectors, switches, or openings in the chassis.

WARNING:
Remove batteries from the monitoring system before cleaning.

For surface cleaning and disinfection of the monitoring system, follow institutional procedures or the recommended actions below.

- **Surface cleaning —** Surface clean the monitoring system by using a soft cloth dampened with a commercial, nonabrasive cleaner. Lightly wipe the top, bottom, and front surfaces of the monitoring system lightly.
- **Disinfection —** Use a soft cloth saturated with a solution of 10% chlorine bleach in tap water, lightly wiping the surface of the monitoring system.

For sensors, follow cleaning instructions in the instructions for use shipped with those components. Before attempting to clean a Nellcor™ pulse oximetry sensor, read the *Instructions for Use* enclosed with the sensor. Each sensor model has cleaning instructions specific to that sensor. Follow the pulse oximetry sensor cleaning and disinfecting procedures in the particular sensor's *Instructions for Use*.

Avoid spilling liquid on the monitoring system, especially in connector areas, but if a spill occurs, clean and thoroughly dry the monitoring system before reuse. If in doubt about monitoring system safety, refer the monitoring system to a qualified service technician for examination.

7.3 Recycling and Disposal

When the monitoring system, battery, or accessories reach the end of useful life, recycle or dispose of the equipment according to appropriate local and regional regulations.

7.4 Battery Maintenance

WARNING:
Explosion hazard — Do not use the battery with other manufacturer's batteries, different types or models of batteries such as dry batteries, nickel-metal hydride batteries, or Lithium-ion batteries together.

WARNING:
Explosion hazard — Do not connect the battery reversed in positive (+) and negative (-) terminals. Do not charge the battery with polarities reversed.

Caution:
Covidien strongly recommends recharging the battery when it has not been recharged for six (6) or more months.

Caution:
Follow local government ordinances and recycling instructions regarding disposal or recycling of device components, including batteries.

Caution:
Do not short-circuit the battery, as it may generate heat. To avoid short-circuiting, do not let the battery come in contact with metal objects at any time, especially during transport.

Caution:
Do not solder the battery directly. Heat applied during soldering may damage the safety vent in the battery's positive cover.

Caution:
Do not deform the battery by applying pressure. Do not throw, hit, drop, fold or impact the battery.

Caution:
Do not use any chargers not specified by Covidien.

Caution:
Do not mistreat the battery, or use the battery in applications not recommended by Covidien.

Caution:
Keep the battery out of reach of children to avoid any accidents.

Caution:
If there are any problems with the battery, immediately put the monitoring system in a safe place and contact a qualified service technician.

Note:
The service menu displays the number of deep discharge cycles seen by the battery. The monitoring system records a deep discharge cycle when the battery reaches the voltage after a "critically low battery" alarm issues. Reference the *Service Manual*.

Note:
Remove the battery if anticipating long periods of time between use or if storing the monitoring system.

Note:
Storing the monitoring system for a long period without charging the battery may degrade battery capacity. A full charge of a depleted battery takes over four (4) or eight (8) hours, depending on the battery.

Regularly check the battery to ensure optimal performance.

- Charge the lithium-ion battery if the monitoring system has not been used for six (6) months. To charge the battery, connect the monitoring system to AC power.
- Have a qualified service technician replace the monitoring system's lithium-ion battery every two (2) years. Reference the *Service Manual* for battery replacement and general service instructions.

7.5 Periodic Safety Checks

Covidien recommends a qualified service technician perform the following checks every 24 months.

- Inspect the equipment for mechanical and functional damage or deterioration.
- Inspect the safety relevant labels for legibility. Contact Covidien or a local Covidien representative, if labels are damaged or illegible.
- Ensure all user interface keys, cables, and accessories function normally.

7.6 Service

WARNING:
Only a qualified service technician should remove the cover or access any internal components.

Caution:
Dispose of monitoring system in accordance with local requirements and regulations.

The monitoring system requires no routine service other than cleaning, battery maintenance, and service activity mandated by the institution. For more information, reference the *Service Manual*.

- The monitoring system requires no calibration.
- Have a qualified service technician replace the battery at least every two (2) years.
- If service is necessary, contact Technical Services or a qualified service technician. Reference *Obtaining Technical Assistance*, p. 1-5.

8 Troubleshooting

8.1 Overview

This chapter describes how to troubleshoot common problems while using the Nellcor™ bedside SpO_2 patient monitoring system.

8.2 General

WARNING:
Check the patient's vital signs by alternate means should there be any doubt about the accuracy of any measurement. Request a qualified service technician confirm the monitoring system is functioning correctly.

WARNING:
Only a qualified service technician should remove the cover or access any internal components.

If the monitoring system detects an error, it displays an appropriate error code. The *Service Manual* lists all error codes. If an error occurs, check and reseat all power connections and ensure the battery is fully charged. If the error persists, write down the error code and contact Technical Services or a qualified service technician.

8.3 Error Conditions

Table 8-1. Common Problems and Resolutions

Problem	Resolution
Battery Charging Indicator not lit	Check power cord Check battery Check AC power inlet Check power/ mains outlet
Sensor Message SpO_2 Pulse search Signal Artifact Detected SpO_2 Sensor Off SpO_2 Cable/Sensor Disconnect SpO_2 Loss of Pulse	Reference *Performance Considerations*, p. 6-1. Check patient status; keep patient still, check for perfusion Check all connections Reposition sensor Check or change adhesive wrap Choose alternate site Warm site Cover sensor Use forehead, nasal, or ear sensor (adult patient only) Use Nellcor™ adhesive sensor Secure cable Secure with headband (MAX-FAST) Remove nail polish Loosen sensor (too tight) Isolate external interference (electrosurgical device, cell phone) Replace the cable and/or sensor Clean site (MAX-R)
No response to Power On/Off button press	Press the Power On/Off button for more than one (1) second. Ensure the power cord is properly connected to the outlet. Ensure AC indicator blinks. Ensure it does not share the same AC power source with other equipment. If the error continues, contact Technical Services or a qualified service technician.
No response to button press	Verify whether the Return button has not been pressed during normal screen. If the error continues, contact Technical Services or a qualified service technician.
Frozen at POST after power on	Power cycle by pressing the Power On/Off button. If the error continues, contact Technical Services or a qualified service technician.
System is frozen	If the system freezes, it generates beep tone. Press the power button over 15 seconds for force quit the system. If the error continues, contact Technical Services or a qualified service technician.
Blank screen	Ensure buttons light. If not, press the Power On/Off button to turn on. Check if AC indicator lights or blinks. Use the same AC power source with other equipment to check for power. If the error continues, contact Technical Services or a qualified service technician.
Screen does not function properly and the power-on beep tones do not sound	Do not use the monitoring system; contact a qualified service technician or Covidien Technical Services.

Table 8-1. Common Problems and Resolutions (Continued)

Problem	Resolution
No sound generation	Verify setting point of volume is not 0 or 1. Verify alarm setup is not set to alarm silenced. If the error continues, contact Technical Services or a qualified service technician.
Abnormally shut down last time message	Check any temporary settings such as alarm limits, response mode, and patient mode, since resets invoke factory or institutional default settings. Press the Power On/Off button to reset system power. If the error continues, contact Technical Services or a qualified service technician.
Date and Time incorrect	Set the time in the Options Menu. Check if date setting format follows locale. If the system displays wrong date and time even after power reset, it means internal battery for power backup is dead. If the error continues, contact Technical Services or a qualified service technician.
System consumes battery power even with AC power connection	Ensure proper connection between power cord and wall socket. Check if AC indicator lights or blinks. Use the same AC power source with other equipment to check for power. Replace the power cord. If the error continues, contact Technical Services or a qualified service technician.
Low Battery / Critically Low-Battery condition	Connect the system to AC power until the internal battery is fully charged. Ensure the system power cord is connected to the wall socket properly. Check if AC indicator lights or blinks. Use the same AC power source with other equipment to check for power. Check the date of manufacture (DOM) of battery. If the error continues, contact Technical Services or a qualified service technician.
Questionable readouts of patient physiological measurements, wrongly tagged or missing patient data	Reference *Performance Considerations*, p. 6-1. Check patient status. Replace sensor or cable, if necessary. Check all connections and reposition, if necessary. Remove sources of electromagnetic interference. Remove excessive ambient light.
Data port does not function properly	Ensure USB cable firmly connected. Disconnect USB cable, reset system power, then reconnect. Ensure baud rate settings for both monitoring system and PC are the same. Check hardware tab in PC 'System Registration Information'; verify normal status. Check COM port. Re-install the bridge driver provided by Covidien.
Experiencing EMI interference	Reference *Reducing EMI (Electromagnetic Interference)*, p. 6-4.
Technical System Error	Do not use the monitoring system; contact a qualified service technician or Covidien Technical Services.

Reference *Managing Alarms and Alarm Limits*, p. 4-14, for any issues related to alarm conditions.

8.4 Return

Contact Covidien or a local Covidien representative for shipping instructions, including a Returned Goods Authorization (RGA) number. Reference *Obtaining Technical Assistance*, p. 1-5. Unless otherwise instructed by Covidien, it is not necessary to return the sensor or other accessory items with the monitoring system. Pack the monitoring system in its original shipping carton. If the original carton is not available, use a suitable carton with the appropriate packing material to protect it during shipping. Return the monitoring system by any shipping method that provides proof of delivery.

9 Accessories

9.1 Overview

This chapter contains information for selecting the appropriate pulse oximetry sensor for use with the Nellcor™ bedside SpO_2 patient monitoring system.

9.2 Nellcor™ Pulse Oximetry Sensors

WARNING:
Before use, carefully read the pulse oximetry sensor *Instructions for Use*, including all warnings, cautions, and instructions.

WARNING:
Use only Nellcor™-approved pulse oximetry sensors and pulse oximetry cables when connecting to the sensor connector. Connecting any other cable or sensor influences the accuracy of the sensor data, which may lead to adverse results.

WARNING:
Do not use a damaged pulse oximetry sensor or pulse oximetry cable. Do not use a sensor with exposed optical components.

WARNING:
Tissue damage can be caused by incorrect application or duration of use of a pulse oximetry sensor. Inspect the sensor site periodically as directed in the sensor *Instructions for Use*.

WARNING:
Pulse oximetry readings and pulse signal can be affected by certain ambient environmental conditions, sensor application errors, and certain patient conditions.

WARNING:
Do not immerse or wet the pulse oximetry sensor.

Caution:
Nellcor™ adhesive pulse oximetry sensors are intended for single-patient use only. Do not reuse pulse oximetry sensors.

When selecting a Nellcor™ pulse oximetry sensor, consider the following items: patient's weight and activity level, the adequacy of perfusion, and the available sensor sites, the need for sterility, and the anticipated duration of monitoring. Use the following table for selection or contact Covidien or a local Covidien representative. Reference *Sensor Performance Considerations*, p. 6-2. Use the Nellcor™ pulse oximetry interface cable to connect the pulse oximetry sensor to the monitoring system.

Table 9-1. Nellcor™ Pulse Oximetry Sensor Models and Patient Sizes

Nellcor™ pulse oximetry sensor	SKU	Patient size
Nellcor™ preemie SpO_2 sensor, non-adhesive (single-patient use)	SC-PR	<1.5 kg
Nellcor™ neonatal SpO_2 sensor, non-adhesive (single-patient use)	SC-NEO	1.5 to 5 kg
Nellcor™ adult SpO_2 sensor, non-adhesive (single-patient use)	SC-A	>40 kg
Nellcor™ adult-neonatal SpO_2 sensor with wraps (reusable with adhesive)	OXI-A/N	<3 or >40 kg
Nellcor™ pediatric-infant SpO_2 sensor with wraps (reusable with adhesive)	OXI-P/I	3 to 40 kg
Nellcor™ pediatric SpO_2 sensor, two piece (sterile, single-use only)	P	10 to 50 kg
Nellcor™ neonatal-adult SpO_2 sensor, two piece (sterile, single-use only)	N	<3 or >40 kg
Nellcor™ adult SpO_2 sensor, two piece (sterile, single-use only)	A	> 30 kg
Nellcor™ neonatal-adult SpO_2 sensor (sterile, single-use only)	MAX-N	<3 or >40 kg
Nellcor™ infant SpO_2 sensor (sterile, single-use only)	MAX-I	3 to 20 kg
Nellcor™ pediatric SpO_2 sensor (sterile, single-use only)	MAX-P	10 to 50 kg
Nellcor™ adult SpO_2 sensor (sterile, single-use only)	MAX-A	>30 kg
Nellcor™ adult XL SpO_2 sensor (sterile, single-use only)	MAX-AL	>30 kg
Nellcor™ adult SpO_2 nasal sensor (sterile, single-use only)	MAX-R	>50 kg
Nellcor™ forehead SpO_2 sensor	MAX-FAST	>10 kg
Nellcor™ adult SpO_2 sensor, reusable (nonsterile)	DS-100A	>40 kg
Nellcor™ SpO_2 sensor, multisite reusable (nonsterile)	D-YS	>1 kg
Nellcor™ SpO_2 ear clip, reusable (nonsterile)	D-YSE	>30 kg
Nellcor™ pediatric SpO_2 clip, reusable (nonsterile)	D-YSPD	3 to 40 kg

Table 9-1. Nellcor™ Pulse Oximetry Sensor Models and Patient Sizes (Continued)

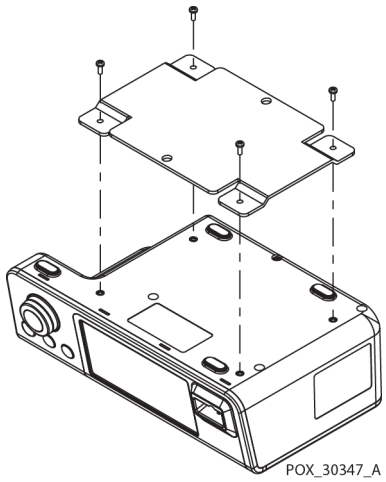
Nellcor™ pulse oximetry sensor	SKU	Patient size
Nellcor™ flexible SpO_2 sensor (reusable, large)	FLEXMAX	>20 kg
Nellcor™ flexible SpO_2 sensor (reusable, small)	FLEXMAX-P	>20 kg
Nellcor™ flexible SpO_2 sensor (reusable, large, home care)	FLEXMAX-HC	>20 kg
Nellcor™ flexible SpO_2 sensor (reusable, small, home care)	FLEXMAX-P-HC	>20 kg

Note:
Physiological conditions, medical procedures, or external agents that may interfere with the monitoring system's ability to detect and display measurements include dysfunctional hemoglobin, arterial dyes, low perfusion, dark pigment, and externally applied coloring agents such as nail polish, dye, or pigmented cream.

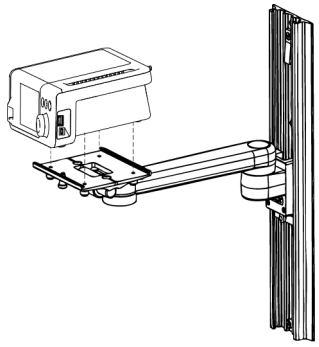
9.3 Optional Equipment

Contact Covidien or a local Covidien representative for more information about optional equipment for use with the monitoring system.

Adapter plate—Fits standard, commercially available GCX brackets and securely mounts the monitoring system to a wall bracket or a roll stand.



GCX wall mount arm and channel—Attaches to the adapter plate, which attaches to the arm.



POX_30345_A

GCX roll stand—Attaches to the adapter plate.

POX_30346_A

Covidien Technical Services: Patient Monitoring

15 Hampshire Street, Mansfield, MA 02048 USA

1.800.635.5267, 1.925.463.4635
or contact a local Covidien representative

www.covidien.com

9.4 Biocompatibility Testing

Biocompatibility testing has been conducted on Nellcor™ pulse oximetry sensors in compliance with ISO 10993-1, Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing. The pulse oximetry sensors have passed the recommended biocompatibility testing and are therefore in compliance with ISO 10993-1.

10 Theory of Operations

10.1 Overview

This chapter explains the theory behind operations of the Nellcor™ bedside SpO_2 patient monitoring system.

10.2 Theoretical Principles

The monitoring system uses pulse oximetry to measure functional oxygen saturation in the blood. Pulse oximetry works by applying a Nellcor™ pulse oximetry sensor to a pulsating arteriolar vascular bed, such as a finger or toe. The sensor contains a dual light source and a photodetector.

Bone, tissue, pigmentation, and venous vessels normally absorb a constant amount of light over time. The arteriolar bed normally pulsates and absorbs variable amounts of light during the pulsations. The ratio of light absorbed is translated into a measurement of functional oxygen saturation (SpO_2).

Ambient conditions, sensor application, and patient conditions can influence the ability of the pulse oximeter to accurately measure SpO_2. Reference *Performance Considerations*, p. 6-1.

Pulse oximetry is based on two principles: oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (measured using spectrophotometry), and the volume of arterial blood in tissue (and hence, light absorption by that blood) changes during the pulse (registered using plethysmography). A monitoring system determines SpO_2 by passing red and infrared light into an arteriolar bed and measuring changes in light absorption during the pulsatile cycle. Red and infrared low-voltage light-emitting diodes (LED) in the sensor serve as light sources; a photo diode serves as the photo detector.

Since oxyhemoglobin and deoxyhemoglobin differ in light absorption, the amount of red and infrared light absorbed by blood is related to hemoglobin oxygen saturation.

The monitoring system uses the pulsatile nature of arterial flow to identify the oxygen saturation of arterial hemoglobin. During systole, a new pulse of arterial blood enters the vascular bed, and blood volume and light absorption increase. During diastole, blood volume and light absorption reach their lowest point. The monitoring system bases its SpO_2 measurements on the difference between maximum and minimum absorption (measurements at systole and

diastole). By doing so, it focuses on light absorption by pulsatile arterial blood, eliminating the effects of nonpulsatile absorbers such as tissue, bone, and venous blood.

10.3 Automatic Calibration

Because light absorption by hemoglobin is wavelength dependent and because the mean wavelength of LEDs varies, a monitoring system must know the mean wavelength of the pulse oximetry sensor's red LED to accurately measure SpO_2.

During monitoring, the monitoring system's software selects coefficients that are appropriate for the wavelength of that individual sensor's red LED; these coefficients are then used to determine SpO_2.

Additionally, to compensate for differences in tissue thickness, the light intensity of the sensor's LEDs is adjusted automatically.

Note:
During certain automatic calibration functions, the monitoring system may briefly display a flat line on the plethysmographic waveform. This is a normal operation and does not require any user intervention.

10.4 Functional Testers and Patient Simulators

Some models of commercially available bench top functional testers and patient simulators can be used to verify the proper functionality of Nellcor™ monitoring systems, sensors, and cables. Reference the individual testing device's operator's manual for the procedures specific to the model of tester used. While such devices may be useful for verifying that the sensor, cabling, and monitoring system are functional, they are incapable of providing the data required to properly evaluate the accuracy of a system's SpO_2 measurements.

Fully evaluating the accuracy of the SpO_2 measurements requires, at a minimum, accommodating the wavelength characteristics of the sensor and reproducing the complex optical interaction of the sensor and the patient's tissue. These capabilities are beyond the scope of known bench top testers. SpO_2 measurement accuracy can only be evaluated in vivo by comparing monitoring system readings with values traceable to SaO_2 measurements obtained from simultaneously sampled arterial blood using a laboratory CO-oximeter.

Many functional testers and patient simulators have been designed to interface with the monitoring system's expected calibration curves and may be suitable for use with monitoring systems and/or sensors. Not all such devices, however, are adapted for use with the OxiMax™ digital calibration system. While this will not affect use of the simulator for verifying system functionality, displayed SpO_2 measurement values may differ from the setting of the test device. For a properly functioning monitoring system, this difference will be reproducible over time and from monitoring system to monitoring system within the performance specifications of the test device.

10.5 Unique Technologies

10.5.1 Functional versus Fractional Saturation

This monitoring system measures functional saturation where oxygenated hemoglobin is expressed as a percentage of the hemoglobin that can transport oxygen. It does not detect significant amounts of dysfunctional hemoglobin, such as carboxyhemoglobin or methemoglobin. In contrast, hemoximeters such as the IL482 report fractional saturation where oxygenated hemoglobin is expressed as a percentage of all measured hemoglobin, including measured dysfunctional hemoglobins. To compare functional saturation measurements to those from a monitoring system that measures fractional saturation, fractional measurements must be converted using the listed equation.

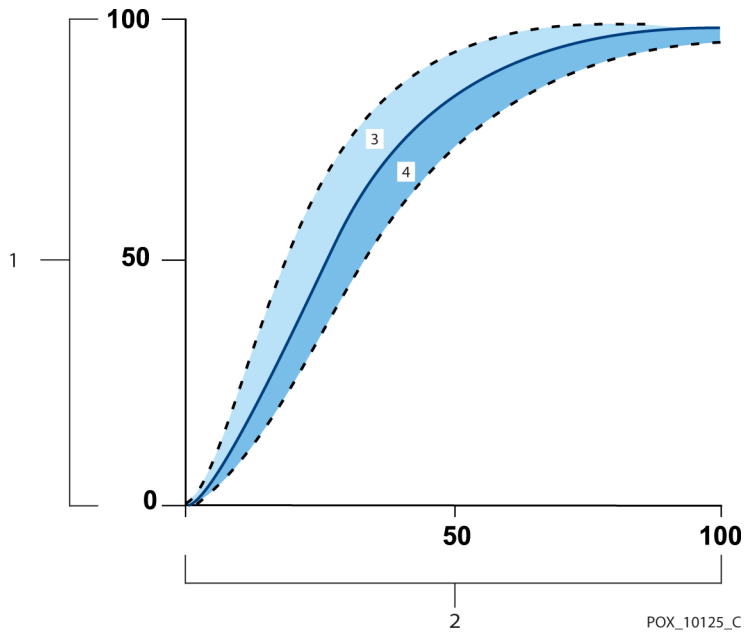
$$\Phi = \frac{\phi}{100 - (\eta + \Lambda)} \times 100$$

Φ	functional saturation	η	%carboxyhemoglobin
ϕ	fractional saturation	Λ	%methemoglobin

10.5.2 Measured versus Calculated Saturation

When calculating saturation from a blood gas partial pressure of oxygen (PO_2), the calculated value may differ from the SpO_2 measurement of a monitoring system. This usually occurs when saturation calculations exclude corrections for the effects of variables such as pH, temperature, the partial pressure of carbon dioxide (PCO_2), and 2,3-DPG, that shift the relationship between PO_2 and SpO_2.

Figure 10-1. Oxyhemoglobin Dissociation Curve



1	% Saturation Axis	3	Increased pH; Decreased temperature, PCO_2, and 2,3-DPG
2	PO_2 (mmHg) Axis	4	Decreased pH; Increased temperature, PCO_2, and 2,3-DPG

10.5.3 Data Update Period, Data Averaging, and Signal Processing

The advanced signal processing of the OxiMax™ algorithm automatically extends the amount of data required for measuring SpO_2 and pulse rate depending on the measurement conditions. The OxiMax™ algorithm automatically extends the dynamic averaging time required beyond seven (7) seconds during degraded or difficult measurement conditions caused by low perfusion, signal artifact, ambient light, electrocautery, other interference, or a combination of these factors, which results in an increase in the dynamic averaging. If the resulting dynamic averaging time exceeds 20 seconds for SpO_2, the algorithm sets the pulse search bit while continuing to update SpO_2 and pulse rate values every second.

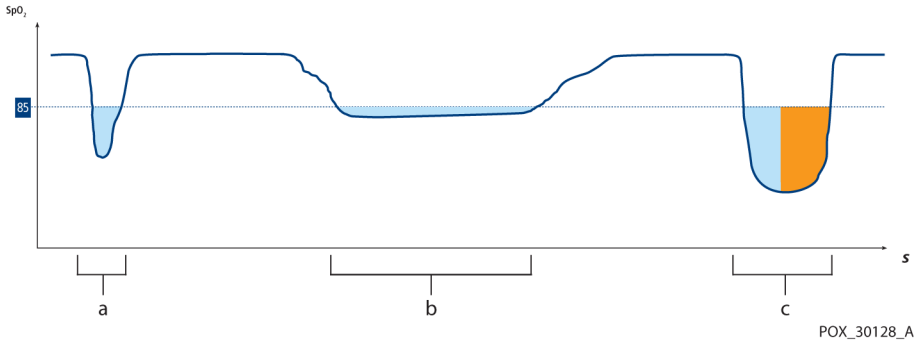
As such measurement conditions extend, the amount of data required may continue to increase. If the dynamic averaging time reaches 40 seconds, and/or 50 seconds for pulse rate, a low priority alarm state results: the algorithm sets the Pulse Timeout bit and the monitoring system reports a zero saturation indicating a loss-of-pulse condition, which should result in an audible alarm.

10.6 SatSeconds™ Alarm Management Feature

The monitoring system monitors the percentage of hemoglobin binding sites saturated with oxygen in the blood. With traditional alarm management, upper and lower alarm limits are set to alarm at specific SpO_2 levels. When the SpO_2 level fluctuates near an alarm limit, the alarm sounds each time it violates the alarm threshold. SatSeconds™ monitors both degree and duration of desaturation as an index of desaturation severity. Thus, the SatSeconds™ feature helps distinguish clinically significant events from minor and brief desaturations that may result in nuisance alarms.

Consider a series of events leading to a violation of the SatSeconds™ alarm limit. An adult patient experiences several minor desaturations, then a clinically significant desaturation.

Figure 10-2. Series of SpO_2 Events



a First SpO_2 Event

b Second SpO_2 Event

c Third SpO_2 Event

10.6.1 First SpO_2 Event

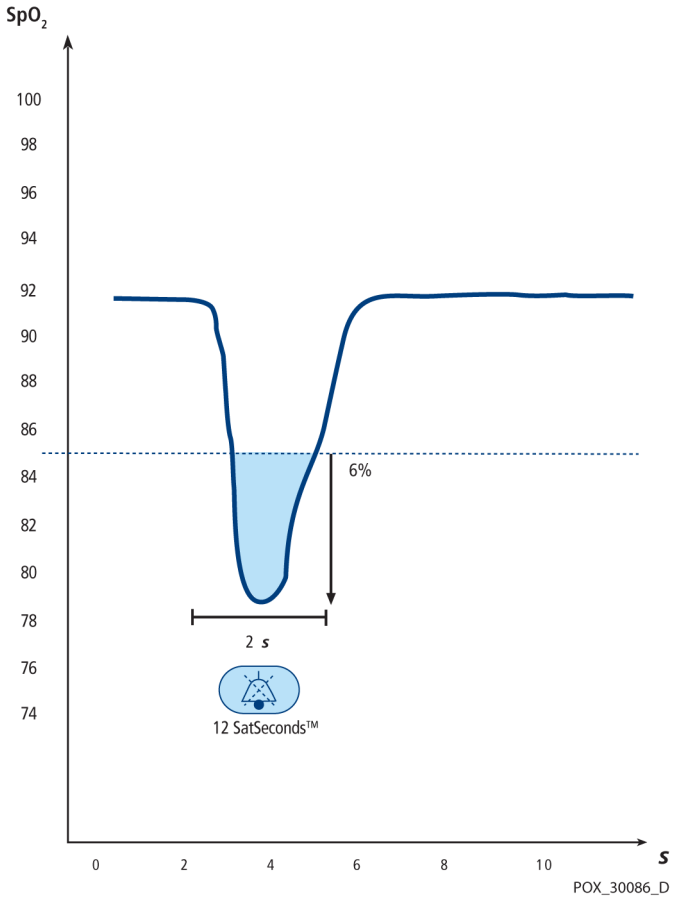
Consider the first event. Suppose the SatSeconds™ alarm limit is set to 25. The patient's SpO_2 drops to 79% and the duration of the event is two (2) seconds before saturation again exceeds the lower alarm threshold of 85%.

6% drop below the lower alarm limit threshold
x 2 second duration below the lower threshold

12 SatSeconds™; no alarm

Because the SatSeconds™ alarm limit is set to 25 and the actual number of SatSeconds™ equals 12, there is no audible alarm.

Figure 10-3. First SpO_2 Event: No SatSeconds™ Alarm



10.6.2 Second SpO_2 Event

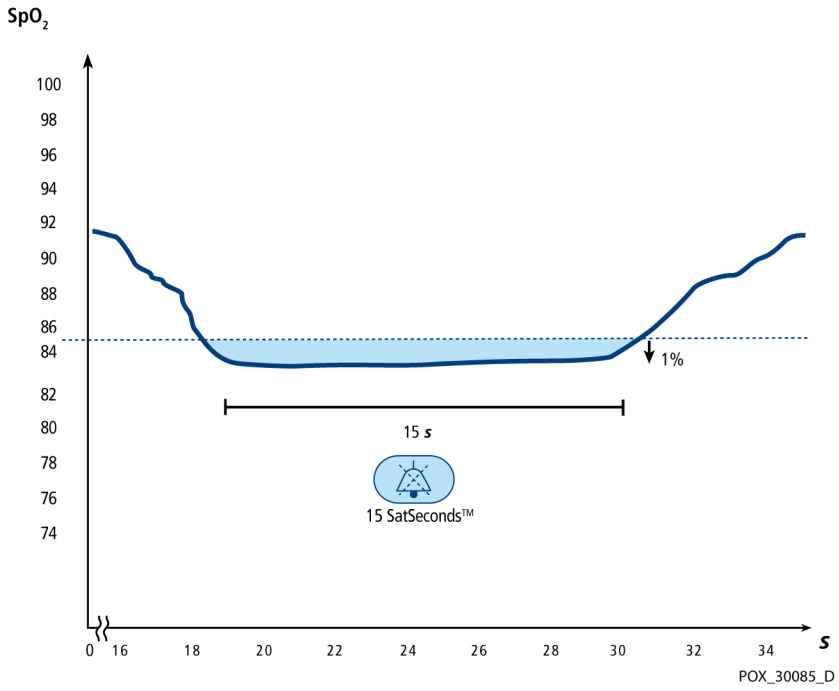
Consider the second event. Suppose the SatSeconds™ alarm limit is still set to 25. The patient's SpO_2 drops to 84% and the duration of the event is 15 seconds before saturation again exceeds the lower alarm threshold of 85%.

1% drop below the lower alarm limit threshold
x15 second duration below the lower threshold

15 SatSeconds™; no alarm

Because the SatSeconds™ alarm limit is set to 25 and the actual number of SatSeconds™ equals 15, there is no audible alarm.

Figure 10-4. Second SpO_2 Event: No SatSeconds™ Alarm



10.6.3 Third SpO_2 Event

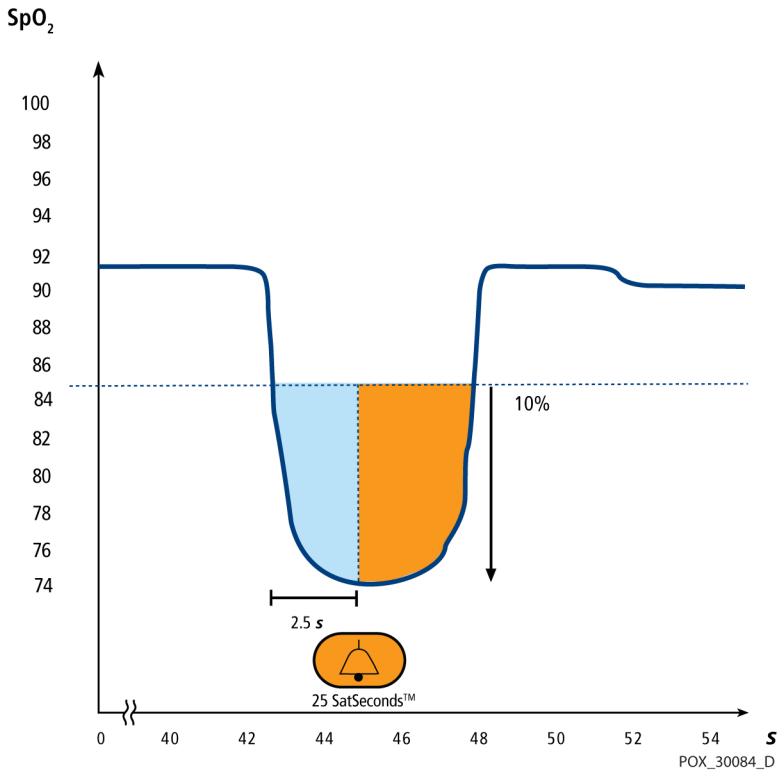
Consider the third event. Suppose the SatSeconds™ alarm limit is still set to 25. During this event, the patient's SpO_2 drops to 75%, which is 10% below the lower alarm threshold of 85%. Since the patient's saturation does not return to a value over the lower alarm threshold within 2.5 seconds, an alarm sounds.

10% drop below the lower alarm limit threshold
x2.5 second duration below the lower threshold

25 SatSeconds™; results in an alarm

At this level of saturation, the event cannot exceed 2.5 seconds without invoking a SatSeconds™ alarm.

Figure 10-5. Third SpO_2 Event: Triggers SatSeconds™ Alarm



10.6.4 The SatSeconds™ Safety Net

The SatSeconds™ "Safety Net" is for patients with saturation levels frequently below the limit, but not staying below the limit long enough for the SatSeconds™ time setting to be reached. When three or more limit violations occur within 60 seconds, an alarm sounds even if the SatSeconds™ time setting has not been reached.

11 Product Specifications

11.1 Overview

This chapter contains physical and operational specifications of the Nellcor™ bedside SpO_2 patient monitoring system. Ensure all product requirements are met prior to installation of the monitoring system.

11.2 Physical Characteristics

Enclosure	
Weight	1.6 kg (3.5 lbs.) including battery
Dimensions	255 × 82 × 165 mm (10.04 x 3.23 x 6.50 in)
Display	
Screen size	109.22 mm (4.3 in), measured diagonally
Screen type	TFT LCD, white LED backlight, viewing cone of 30° and optimal viewing distance of 1 meter
Resolution	480 × 272 pixel
Controls	
Dial	Jog dial control
Buttons	Power On/Off, Silence Alarm, Return
Alarms	
Categories	Patient status and system status
Priorities	Low, medium and high
Notification	Audible and visual
Setting	Default and individual
Alarm volume level	45 to 80 dB

11.3 Electrical

Battery power requirement	AC 100-240VAC, 50/60Hz, 45 VA
Voltage and capacity of Li-Ion, 5 hour[1]	10.8 V/ 2200 mAh
Voltage and capacity of Li-Ion, 10hour[1]	10.8 V/4400 mAh
Compliance	91/157/EEC
Fast-acting fuse	2A 32VAC,/DC
Fast-acting fuse	500 mA 32VAC/50DC

1. New batteries typically provide the stated duration when operating in Normal Response Mode, with pulse beep, the SatSeconds™ feature enabled, with no external communication, no audible alarms, and at 25 °C ± 5°C.

11.4 Environmental Conditions

Note:
The system may not meet its performance specifications if stored or used outside the specified temperature and humidity range.

Table 11-1. Transport, Storage, and Operating Condition Ranges

	Transport and storage	Operating conditions
Temperature	-20 °C to 60 °C, (-4 °F to 140 °F)	5 °C to 40 °C (41 °F to 104 °F)
Altitude	-304 to 6,096 m, (-1,000 to 20,000 ft.)	-170 to 4,877 m, (-557 to 16,000 ft.)
Pressure	50 kPa to 106 kPa, (14.7 in. Hg to 31.3 in. Hg)	58 kPa to 103 kPa, (17.1 in. Hg to 30.4 in. Hg)
Relative humidity	15% to 93% non-condensing	

11.5 Tone Definition

Table 11-2. Tone Definitions

Tone category	Description
High priority alarm tone	
Volume level	Adjustable (level 1-8)
Pitch (± 20Hz)	976 Hz
Pulse width (± 20msec)	150 msec (IEC60601-1-8)
Number of pulses in burst	10, interburst interval of 4 sec (IEC60601-1-8)
Repetitions	Continually
Medium priority alarm tone	
Volume level	Adjustable (level 1-8)
Pitch (± 20Hz)	697 Hz
Pulse width (± 20msec)	150 msec (IEC60601-1-8)
Number of pulses in burst	3, interburst interval of 8 sec (IEC60601-1-8)
Repetitions	Continually
Low priority alarm tone	
Volume level	Adjustable (level 1-8)
Pitch (± 20Hz)	488 Hz
Pulse width (± 20msec)	250 msec (IEC60601-1-8)
Number of pulses	1, interburst interval of 16 sec (IEC60601-1-8)
Repetitions	Continually
Alarm disabled reminder tone	
Volume level	Not changeable
Pitch (± 20Hz)	800 Hz
Pulse width (± 20msec)	200 msec
Number of pulses	1 pulse per 1 second, 3 min ~ 10 min interburst
Repetitions	Continually
Key beep	
Volume level	Adjustable (Off, level 1-7), (Invalid key presses are ignored)
Pitch (± 20Hz)	440 Hz (valid), 168 Hz (invalid)
Pulse width (± 20msec)	110 msec

Table 11-2. Tone Definitions (Continued)

Tone category	Description
Number of pulses	N/A
Repetitions	No repeat
POST pass tone	
Volume level	Not changeable
Pitch (± 20Hz)	813 Hz
Pulse width (± 20msec)	1500 msec
Number of pulses	N/A
Repetitions	No repeat

11.6 Performance Specifications

Table 11-3. Trends

Types	Graphical and tabular
Memory	Saves total 88000 data events Saves date and time, alarm conditions, pulse rate, and SpO_2 measurements
Graphical format	Total 2 graphs A graph for SpO_2 parameters A graph for Pulse Rate parameters
Tabular format	One table for all parameters
Display	5 lists

Table 11-4. Pulse Oximetry Sensor Accuracy and Ranges

Range type	Range values
Measurement ranges	
SpO_2 saturation range	1% to 100%
Pulse rate range	20 to 250 beats per minute (bpm)
Perfusion range	0.03% to 20%
Display sweep speed	6.25 mm/sec, 12.5 mm/sec, 25.0 mm/sec
Measurement accuracy	
Pulse rate accuracy	20 to 250 beats per minute (bpm) ±3 digits
SpO_2 saturation accuracy[1]	70% to 100% ±2 digits, neonates: ±3 digits
Operating range and dissipation	
Red light wavelength	Approximately 660 nm
Infrared light wavelength	Approximately 900 nm
Optical output power	Less than 15 mW
Power dissipation	52.5 mW

1. Monitoring system measurements are statistically distributed; about two-thirds of monitoring system measurements can be expected to fall in this accuracy (ARMS) range. Reference the Clinical Studies section for test results. For a complete listing of SpO_2 accuracy across the full line of available Nellcor™ sensors, contact Covidien, a local Covidien representative, or locate it online at www.covidien.com.

11.7 Sound Pressure

Table 11-5. Sound Pressure in Decibels

Alarm type	Volume setting			
	High (7-8)	**Med high (5-6)**	**Med low (3-4)**	**Low (1-2)**
High priority	83.6-87.4 dB	74.1-77.9 dB	65.6-69.5 dB	57.6-61.1 dB
Medium priority	82.0-84.7 dB	70.2-74.8 dB	64.5-66.9 dB	53.6-57.9 dB
Low priority	77.2-81.7dB	69.5-72.6 dB	60.1-63.8 dB	50.8-56.0 dB

11.8 Product Compliance

Standards compliance	EN ISO 80601-2-61: Edition 1.0 EN IEC 60601-1: Edition 3.1 EN IEC 60601-1-2: Edition 3.0 and 4.0 EN IEC 60601-1-6: Edition 3.1 EN IEC 60601-1-8: Edition 2.1 EN IEC 60601-1-11: Edition 2.0 CAN/CSA C22.2 No. 60601-1:14 3rd Edition ANSI/AAMI ES 60601-1:2005/(R)2012
Equipment classifications	
Type of protection against electric shock	Class I (internally powered)
Degree of protection against electric shock	Type BF - Applied part
Mode of operation	Continuous
Electromagnetic compatibility	IEC 60601-1-2:2007 (Ed. 3.0) and IEC 60601-1-2:2014 (Ed. 4.0)
Liquid ingress	IPX2
Degree of safety	Not suitable for use in the presence of flammable anesthetics

11.9 Manufacturer's Declaration

11.9.1 Electromagnetic Compatibility (EMC)

WARNING:
This monitoring system is intended for use by healthcare professionals only. This monitoring system may cause radio interference or may disrupt the operation of nearby equipment, regardless of whether it is CISPR compliant or not. It may be necessary to take mitigation measures, such as re-orienting or relocating the monitoring system or shielding the location.

WARNING:
The use of accessories, pulse oximetry sensors, and cables other than those specified may result in inaccurate readings of the monitoring system and increased EMI emissions or decreased electromagnetic immunity of the monitoring system.

WARNING:
Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the monitoring system, including cables. Otherwise, degradation of monitoring system performance may result.

Caution:

For best product performance and measurement accuracy, use only accessories supplied or recommended by Covidien. Use accessories according to the *Instructions for Use*. Use only accessories that have passed the recommended biocompatibility testing in compliance with ISO10993-1.

The monitoring system is suitable for prescription use only in the specified electromagnetic environments, in accordance with the IEC 60601-1-2:2007 and IEC 60601-1-2:2014 standard. The monitoring system requires special precautions during installation and operation for electromagnetic compatibility. In particular, the use of nearby mobile or portable communications equipment may influence monitoring system performance.

Note:

The emissions characteristics of this equipment make it suitable for use in a residential environment (for which CISPR 11 class B is normally required). This equipment might not offer adequate protection to radio frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Electromagnetic Emissions

Table 11-6. Electromagnetic Emissions Guidelines

Emissions test	Compliance	Electromagnetic environment guidance
RF emissions CISPR 11	Group 1, Class B	The oximeter is suitable for use in all establishments.
Harmonic emissions IEC/EN 61000-3-2	Class A	The oximeter is suitable for use in all establishments.
Voltage fluctuation/ flicker emissions IEC/EN 61000-3-3	Complies	The oximeter is suitable for use in all establishments.

Electromagnetic Immunity

Note:
These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Table 11-7. Electromagnetic Immunity Guidelines

Immunity test	IEC/EN 60601-1-2 test level	Compliance level	Electromagnetic environment guidance
Electrostatic discharge (ESD) IEC/EN 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floor should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electric fast transient/burst IEC/EN 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 and/or hospital environment.
Surge IEC/EN 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 and/or hospital environment.
Voltage dips and interrupts IEC/EN 61000-4-11	100% reduction for 0.5 cycles (at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°) 100% reduction for 1.0 cycle (at 0°) 30% reduction for 25/30 cycles (at 0°) 100% reduction for 250/300 cycles (at 0°)	100% reduction for 0.5 cycles (at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°) 100% reduction for 1.0 cycle (at 0°) 30% reduction for 25/30 cycles (at 0°) 100% reduction for 250/300 cycles (at 0°)	Mains power quality should be that of a typical commercial and/or hospital environment. If the user requires continued operation during power mains interruption, it is recommended that the monitoring system be powered from an uninterruptible power supply or battery.
Power frequency (50/ 60 Hz) magnetic field IEC/EN 61000-4-8	30 A/m	30 A/m	It may be necessary to position further from the sources of power frequency magnetic fields or to install magnetic shielding.

Table 11-8. Recommended Separation Distances

Immunity test	IEC/EN 60601-1-2 test level	Compliance level	Electromagnetic environment guidance
	Frequency of transmitter		**Equation for separation distance (*d*)**
Conducted RF IEC/EN 61000-4-6	3 Vrms 150 kHz 80 MHz 6 Vrms ISM bands	3 Vrms 150 kHz 80 MHz 6 Vrms ISM bands	$d = 1.2\sqrt{P}$ 150 kHz to 80 MHz
Radiated RF IEC/EN 61000-4-3	20 V/m 80 MHz 2.5 GHz	20 V/m 80 MHz 2.5 GHz	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz
	10 V/m 80 MHz 2.7 GHz	10 V/m 80 MHz 2.7 GHz	$d = 2.3\sqrt{P}$ 800 MHz to 2.7 GHz
Rated maximum output power (*P*) of transmitter in watts	**Separation distance in meters**		
	150 kHz to 80 MHz	**80 MHz to 800 MHz**	**800 MHz to 2.7 GHz**
0.01	0.12	0.12	0.23
0.10	0.38	0.38	0.73
1.00	1.20	1.20	2.30
10.00	3.80	3.80	7.30
100.00	12.00	12.00	23.00

For transmitters rated at a maximum output power not listed above, estimate the separation distance (*d*) using the equation in the corresponding column, where *P* is the maximum output [power rating of the transmitter in watts (*W*)] according to the transmitter manufacturer.

Note:
Portable and mobile RF communications equipment can affect medical electrical equipment. Such RF equipment should be used no closer to any part of the monitoring system, including cables, than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter.

Table 11-9. Test Specifications for Enclosure Port Immunity to RF Wireless Communications Equipment

Test frequency (MHz)	Band (MHz)	Service	Modulation	Max. power (W)	Distance (m)	Immunity test level (V/m)
385	380 to 390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
450	430 to 470	GMRS 460, FRS 460	FM ± 5kHz deviation 1 kHz sine	2	0.3	28
710	704 to 787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9
745						
780						
810	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
870						
930						
1720	1700 to 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28
1845						
1970						
2450	2400 to 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
5240	5100 to 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9
5500						
5785						

11.9.2 Sensor and Cable Compliance

WARNING:
The use of accessories, sensors, and cables other than those specified may result in inaccurate readings of the monitoring system and increased EMI emissions and decreased electromagnetic immunity of the monitoring system.

Table 11-10. Cables and Sensors

Item	Maximum length
Sensors	
Pulse oximetry sensor cable	1.6 ft. (0.5 m)
Cables	
Power cable	10.0 ft. (3.0 m)
Nurse call cable	5.9 ft. (1.8 m)
Pulse oximetry interface cable	10.0 ft. (3.0 m)

11.9.3 Safety Tests

Ground Integrity

100 milliohms or less

Leakage Current

The following tables display the maximum earth and enclosure leakage current allowed, as well as patient leakage.

Table 11-11. Earth Leakage and Touch Current

Earth leakage current				
Condition	**AC line polarity**	**Line cord**	**Neutral line cord**	**IEC 60601-1 ANSI/AAMI ES 60601-1**
Normal	Normal	Closed	Closed	5 mA
Single fault		Open	Closed	10 mA
		Closed	Open	
Normal	Reversed	Closed	Closed	5 mA
Single fault		Open	Closed	10 mA
		Closed	Open	
Touch current				
Condition	**AC line polarity**	**Neutral line cord**	**Power line ground**	**IEC 60601-1 ANSI/AAMI ES 60601-1**
Normal	Normal	Closed	Closed	100 µA
Single fault		Open	Closed	500 µA
		Closed	Open	
Normal	Reversed	Closed	Closed	100 µA
Single fault		Open	Closed	500 µA
		Closed	Open	

Table 11-12. Patient Leakage Current

Patient leakage current				
Condition	**AC line polarity**	**Neutral line**	**Power line ground cable**	**IEC 60601-1 ANSI/AAMI ES 60601-1**
Normal	Normal	Closed	Closed	100 µA
Single fault		Open	Closed	500 µA
		Closed	Open	
Normal	Reversed	Closed	Closed	100 µA
Single fault		Open	Closed	500 µA
		Closed	Open	
Patient leakage current - mains on applied part				
Condition	**AC line polarity**	**Neutral line**	**Power line ground cable**	**IEC 60601-1 ANSI/AAMI ES 60601-1**
Single fault	Normal	Closed	Closed	5000 µA
	Reversed	Closed	Closed	

11.10 Essential Performance

Per IEC 60601-1 and ISO 80601-2-61, the monitoring system's essential performance attributes include:

- **SpO_2 and pulse rate accuracy —** Reference Table 11-4, *Pulse Oximetry Sensor Accuracy and Ranges* on p. 11-5.
- **Audible indicators —** Reference *Managing Alarms and Alarm Limits*, p. 4-14, *Audible Alarm Indicators*, p. 4-15, and *Tone Definition*, p. 11-3.
- **Physiological alarms and priorities —** Reference *Managing Alarms and Alarm Limits*, p. 4-14.
- **Visual indicator of power source —** Reference *Front Panel and Display Components*, p. 2-3 and *Connecting to Power*, p. 3-3.
- **Backup power source —** Reference *Connecting to Power*, p. 3-3 and *Using the Internal Battery*, p. 3-4.
- **Sensor disconnect/off notification —** Reference *Display*, p. 2-4, *Managing Alarms and Alarm Limits*, p. 4-14, and *Error Conditions*, p. 8-2.
- **Motion, interference, or signal degradation indicator —** Reference *Display*, p. 2-4.

A Clinical Studies

A.1 Overview

This appendix contains data from clinical studies conducted for the Nellcor™ sensors used with the Nellcor™ bedside SpO_2 patient monitoring system.

One (1) prospective, controlled hypoxia clinical study was conducted to demonstrate the accuracy of Nellcor™ sensors when used in conjunction with the Nellcor™ bedside SpO_2 patient monitoring system. The study was performed with healthy volunteers at a single clinical laboratory. Accuracy was established by comparison to CO-oximetry.

A.2 Methods

Data from 11 healthy volunteers were included in the analysis. Sensors were rotated on digits and brow to provide a balanced study design. SpO_2 values were continuously recorded from each instrument while inspired oxygen was controlled to produce five steady state plateaus at target saturations of approximately 98, 90, 80, 70 and 60%. Six arterial samples were taken 20 seconds apart at each plateau resulting in a total of approximately 30 samples per subject. Each arterial sample was drawn over two (2) respiratory cycles (approximately 10 seconds) while SpO_2 data were simultaneously collected and marked for direct comparison to CO_2. Each arterial sample was analyzed by at least two of the three IL CO-oximeters and a mean SaO_2 was calculated for each sample. End tidal CO_2, respiratory rate, and respiratory pattern were continuously monitored throughout the study.

A.3 Study Population

Table A-1. Demographic Data

Type	Class	Total
Gender	Male	5
	Female	6
Race	Caucasian	8
	Hispanic	2
	African American	1
	Asian	0
Age	--	19-48
Weight	--	108-250
Skin pigment	Very light	2
	Olive	5
	Dark olive/Medium black	3
	Extremely dark/Blue black	1

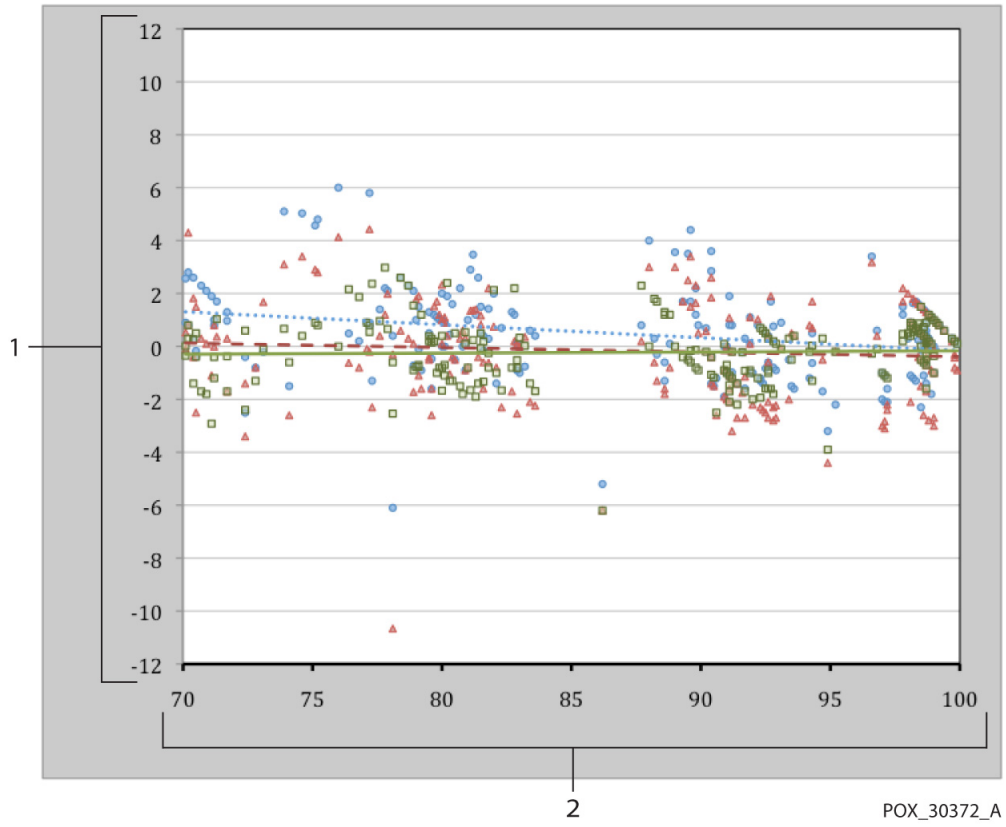
A.4 Study Results

Accuracy was calculated using the root mean square difference (RMSD).

Table A-2. SpO_2 Accuracy for Nellcor™ Sensors vs. CO-oximeters

SpO_2 Decade	MAX-A		MAX-N		MAX-FAST	
	Data points	Arms	Data points	Arms	Data points	Arms
60-70	71	3.05	71	2.89	71	2.22
70-80	55	2.35	55	2.32	55	1.28
80-90	48	1.84	48	1.73	48	1.48
90-100	117	1.23	117	1.68	117	0.98

Figure A-1. Modified Bland-Altman Plot



1	Test sensor; Avg CO-oximeter value 70-100% SpO_2	2	Avg CO-oximeter value 70-100% SpO_2
●	Oximetry board with MAX-A sensor	·····	Trendline of MAX-A sensor
▲	Oximetry board with MAX-N sensor	- - -	Trendline of MAX-N sensor
▫	Oximetry board with MAX-FAST sensor	———	Trendline of MAX-FAST sensor

A.5 Adverse Events or Deviations

The study was conducted as expected with no adverse events and no deviations from the protocol.

A.6 Conclusion

The pooled results indicate that for a saturation range of 60-80% for SpO_2, the acceptance criterion was met for the monitoring system when tested with MAX-A, MAX-N and MAX-FAST sensors. The pooled results indicate that for a saturation range of 70-1 00% for SpO_2, the acceptance criterion was met.

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