COVIDIEN

Operator's Manual

Nellcor™
Bedside Respiratory Patient Monitoring System

Monitoring 96% 01/05/2012 08:36:51

Pleth SpO2 %

97

Trend SpO2 and Pulse 15Min

Pulse BPM

80

Silence Alarm | Menu | Help

Press and hold to lock

COVIDIEN
Nellcor

OxiMax™ Technology

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1 Introduction

1.1 Overview

This manual contains information for collecting patient oxygen saturation data while operating the Nellcor™ Bedside Respiratory Patient Monitoring System.

1.2 Intended Audience

This manual provides information to health-care professionals acting as care-givers in a hospital or hospital-type setting for operation and maintenance of the monitoring system. Refer to the institution for any additional training or skill requirements beyond those identified here for operation and maintenance of the monitoring system. Before operating, thoroughly read this manual.

1.3 Safety Information

This section contains safety information requiring users to exercise appropriate caution while using the monitoring system.

1.3.1 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 **Cautions alert users to exercise appropriate care for safe and effective use of the product.**
	Note Notes provide additional guidelines or information.

1.3.2 Warnings

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

WARNING:
Shock hazard — Use only when connected to a grounded outlet to avoid electric shock.

WARNING:
Use only Covidien-approved internal batteries.

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

WARNING:
Supplemental oxygen will attenuate patterns of desaturation. A patient's respiratory compromise can be proportionally more severe before patterns appear in the saturation trend. Remain vigilant when monitoring a patient on supplemental oxygen.

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

WARNING:
Ensure the monitoring system is clear of any obstructions that prevent awareness of visual or audible alarms. Failure to do so may result in inadvertently missing a visual alarm or an inaudible alarm tone.

WARNING:
Do not use any monitoring system, sensor, cable, or connector that appears damaged. Remove any damaged equipment from service for inspection by a qualified service technician.

WARNING:

Do not lift by the sensor or interface cable. The cable may disconnect, potentially dropping the monitoring system on a patient or damaging surface.

WARNING:

When installing the AC power cord, ensure the cord is carefully positioned to prevent tripping and entanglement.

WARNING:

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.

WARNING:

To ensure accurate performance and prevent device failure, do not subject to extreme moisture, such as direct exposure to rain. Such exposure may cause inaccurate performance or device failure.

WARNING:

The monitoring screen contains toxic chemicals. Do not touch a broken enclosure or monitoring screen. Physical contact with a broken enclosure or monitoring screen can result in transmission or ingestion of toxic substances.

1.3.3 Cautions

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 utilize a grounded outlet. Any equipment connected to the data interface must be certified according to the latest IEC/EN 60950 -1 standard for data-processing equipment, the latest IEC/EN 60601-1 standard for electromedical equipment, or the latest IEC/EN safety standards relevant to that equipment. All combinations of equipment must be in compliance with Requirements for Medical Electrical Systems IEC Standard 60601-1-1:2007. Anyone who connects equipment to the data interface is configuring a medical system and, therefore, is responsible for ensuring the system complies with the Requirements for Medical Electrical Systems IEC/EN

Standard 60601-1-1:2007 and the electromagnetic compatibility IEC/EN Standard 60601-1-2:2007. Accuracy may degrade if it is connected to secondary I/O devices when the equipment is not connected to earth reference.

Caution:
Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.

1.4 Obtaining Technical Assistance

1.4.1 Technical Services

For technical information and assistance, if unable to correct a problem while using the monitoring system, to order parts, or to order an *Operator's* or *Service Manual*, 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 (toll)
or contact a local Covidien representative

www.covidien.com

When calling Covidien or a local Covidien representative, have the serial number, as well as the code versions available.

To locate the serial number and code versions

1. Press MENU.

2. Press ABOUT THE MONITOR.

3. Locate the serial number under *Monitor Information* and code versions under *Software Information*.

1.4.2 On-Screen Help

The monitoring system provides users with an on-screen help system for various help topics. Reference

1.5 Related Documents

Documentation is available online at www.covidien.com.

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

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

- **Saturation Accuracy Grid —** Provides sensor-specific guidance related to desired SpO_2 saturation accuracy measurements.

- **The Nellcor™ Bedside Respiratory Patient Monitoring System *Service Manual* —** Provides information to qualified service technicians for use when modifying, testing, troubleshooting, repairing, and upgrading the monitoring system.

1.6 Warranty Information

To obtain information, 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 (toll)
or contact a local Covidien representative

www.covidien.com

Purchase of this instrument confers no express or implied license under any Covidien patent to use that instrument with any sensor not manufactured or licensed by Covidien llc.

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2 Product Overview

2.1 Overview

This chapter contains basic introductory information for operating the Nellcor™ Bedside Respiratory Patient Monitoring System. The monitoring system relies on unique oximetry technology and design in providing hospitals, clinicians and caregivers accurate, timely data.

2.2 Product Description

The Nellcor™ Bedside Respiratory Patient Monitoring System provides continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin SpO_2 and pulse rate.

2.3 Indications for Use

The Nellcor™ Bedside Respiratory Patient Monitoring System is a portable pulse oximeter intended for prescription use only as a continuous non-invasive monitor of arterial oxygen saturation (SpO_2) and pulse rate of adult, pediatric, and neonatal patients during both no motion and motion conditions and for patients who are well or poorly perfused. The monitoring system is intended for use in hospitals, hospital-type facilities, and during intra-hospital transport. The OxiMax SPD™ Alert (SPD) feature is intended only for facility-use care of adults to detect patterns of desaturation indicative of repetitive reductions in airflow through the upper airway and into the lungs.

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.

Use with any particular patient requires the selection of an appropriate Nellcor™ sensor. Reference *Nellcor™ Sensor Usage*, p. 4-6.

Monitoring system users can access trend information, change alarm limits, adjust the internal time clock, select the communications protocol, and choose alternative interface languages. Reference *User Interface*, p. 4-8.

The monitoring system operates on AC power or on an internal battery.

2.4 List of Components

The typical monitoring system carton ships with the following contents.

Table 2-1. Typical Packing List

Quantity	Item
1	Nellcor™ Bedside Respiratory Patient Monitoring System
1	DOC-10 interface cable
1	*Operator's Manual* (applicable to country of sale) and/or compact disc
1	Hospital-grade power cord (applicable to country of sale)

2.5 Synopsis

Caregivers may use the monitoring system by connecting it to an interface cable and a Nellcor™ sensor, then attaching the recommended sensor to a patient. When the monitoring system detects a valid pulse, it enters monitoring mode and displays patient parameters.

The movement of the blip bar or the plethysmographic waveform and the flashing heart icon are **visual indicators** of real-time data. The pulse beep tone is an **audible indicator** of the real-time patient data.

If the monitoring system detects an alarm condition, it provides both visual and audible alarms. Reference *Visual Alarms*, p. 2-12, for visual alarm condition behaviors. Reference *Audible Alarms and Indicators*, p. 2-13, for audible alarm condition behaviors.

After monitoring is complete, remove the recommended sensor from the patient.

2.6 Product Views

2.6.1 Front Panel

Figure 2-1. Front Panel

POX_30189_B

1	⏻	Power on key	Powers on and off	6	🧍	Type BF	Indicates Type BF applied part
2	∿	AC indicator	Indicates connection to alternating current power source	7	◇	Data port	Houses DB-15 serial connector
3	▭	Battery condition indicator	Indicates battery is charging	8		Ethernet port	Houses RJ-45 ethernet receptacle
4	---	Speaker	Issues audible alarms	9		Universal Serial Bus port	Houses USB connector
5	---	Sensor port	Houses interface cable connector	10	---	Parameter module (front)	Offers monitoring system modular customization

2.6.2 Monitoring Screen

Figure 2-2. Sample Monitoring Screen Elements

1	---	Monitor status field	Contains patient information in various forms.
2	---	Alarm status field	Contains prioritized alarms or user prompts.
3	---	Trend data type button	Contains types of graphed trend data included.
4		Plethysmographic waveform	This non-normalized waveform uses real-time sensor signals, reflecting relative pulsatile strength.
5	---	Trend data time scale button	Contains time period for graphed trend data.
6		Battery fuel gauge	Indicates remaining battery charge and lists percentage of total charge remaining. Fill color indicates acceptable, low, or at a critical state of charge.
7	FAST	Fast response mode Icon	Indicates algorithm response to SpO2 data changes in two to four seconds.
8	---	Date and time field	Reflects current date and time.
9		Audio alarm paused/off icon	Yellow alarm silenced icon indicates Alarm Audio Paused or volume set to zero. Red icon indicates Alarm Audio OFF.
10		SatSeconds™ icon & limit value	Fills in the clockwise direction with saturation readings outside limits and empties counterclockwise when within SpO2 limits. When completely full, it alarms.
11	NEO	Neonate Mode icon	Indicates alarm limits are set to neonate limit values, not set to adult limit values.

12	[100 85]	SpO2 upper and lower limits	Displays current upper and lower alarm limit settings to the right of the dynamic SpO2 value.
13	98	Dynamic %SpO2 value	Indicates SpO2 saturation levels. Cyan SpO2 values zero during loss-of-pulse conditions. Updates continue during Pulse Search.
14	▲	SPD icon & sensitivity value	Fills from bottom to top as patterns of desaturation in the SpO2 trend become more severe and empties from top to bottom as the patterns become less severe. If the icon fills completely, an alarm sounds.
15	[170 40]	Pulse rate (BPM) upper and lower limits	Displays current upper and lower alarm limit settings to the right of the dynamic pulse rate value.
16	76	Pulse rate (BPM) real-time value	Indicates pulse rate in **beats per minute**. Green pulse rate values zero during loss-of-pulse conditions.
17	🔓	Lock bar icon	Provides option of locking out all response to monitoring screen contact except the lock bar.
18		Interference indicator	Lights when incoming signal is inadequate or degraded. Reference *Performance Considerations*, p. 6-1.
19		Pulse search indicator	Flashes during pulse search or lights continuously during loss-of-pulse conditions.
20		Help information icon	Provides access to on-screen help. Press for descriptions and suggestions.
21		Trend data graph	Contains patient trend data dictated by trend data type and trend data time scale.
22		Menu selection icon	Provides access to menus. Press to alter alarm limits, patient trend data history, screen selections, connectivity settings, as well as audio and visual control.
23		Silence alarm icon	Lights continuously as a yellow icon on grey background with silenced audible alarm and as a black icon on yellow background when alarm silence duration is OFF. Silence duration (not shown) counts down on screen.
--		Pulse amplitude (blip bar)	(Not shown in figure.) Indicates pulse beat and the relative (non-normalized) pulse amplitude in numbers only view. As the detected pulse becomes stronger, more bars light with each pulse.
--	♥	Pulse beat (heart) icon	(Not shown in figure.) Flashes to indicate each real-time pulse beat.

2.6.3 Rear Panel

Figure 2-3. Rear Panel

POX_20174_B

1	Equipotential terminal (Ground)	4	Carrying handle
2	AC power connector	5	Screw hole for adapter plate (4x)
3	Fuse drawer	6	Internal battery access
		7	Parameter module (rear)

2.7 Labeling Symbology

Table 2-2. Labeling Symbols and Descriptions

Symbol	Description	Symbol	Description
	Must consult instructions for use		Date of manufacture
	Caution, consult accompanying documents		Proper waste disposal for electrical and electronic equipment
	Equipotential terminal (ground)		Type BF applied part - Not defibrillator proof
	Fuse replacement: 1.5 amp	FC	Federal Communications Commission: Compliance with FCC
IPX1	Protection against fluid ingress		This side up
	Atmospheric pressure limitations		Keep dry
	Temperature limitations		Fragile
	Humidity limitations		

2.8 User Interface

2.8.1 Monitoring Screen Selection

Screen Layout Introduction

Users receive monitoring system information via the monitoring screen. Users may choose to adjust the monitoring screen layout as needed. Reference *Monitoring Screen Layout Options*, p. 4-34. Institutions may specify an alternate default. Institutional default settings require changes to the available options in Service Mode by a qualified service technician.

Select the view that best suits the user, the location, and the situation. Users should ensure optimal visibility and remain within audible range or engage a

remote monitoring system. Reference *Nurse Call Feature*, p. 5-16. The factory default setting is the plethysmographic (pleth) view.

⚠️ **WARNING:**
Ensure the monitoring screen is clear of any obstructions. Failure to do so may reduce effective interpretation of alarms, messages, and user prompts.

🔶 **Caution:**
Verify the movement of the blip bar, plethysmographic waveform, or flashing heart icon before accepting any monitoring system data as a current measurement.

📖 **Note:**
Prior to relocating or transporting the monitoring system, lock the monitoring screen by pressing the icon on the lock bar until it locks. This prevents any unintentional alteration. Once it is safe for further interaction with the monitoring screen, press the icon on the lock bar until it unlocks and proceed. Reference *To lock the monitoring screen*, p. 4-10.

Plethysmographic (Pleth) View

Figure 2-4. Pleth View

POX_30172_B
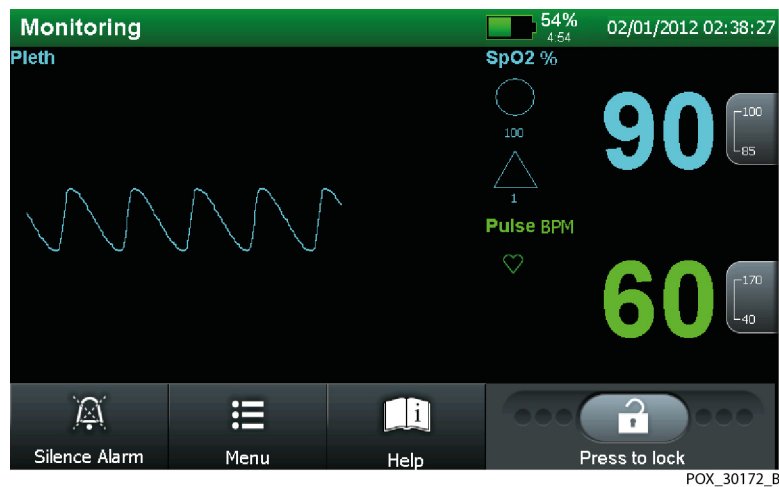
Use this view for visually monitoring the plethysmographic (pleth) waveform. Plethysmographic waveforms with peak to peak amplitudes less than ten pulse amplitude units (PAUs) are associated to one another. Each time the monitor-

ing system detects a pulse, the heart icon in the PR field flashes. Reference *DISPLAY SETTINGS Menu*, p. 4-26.

Trend View

Figure 2-5. Trend View
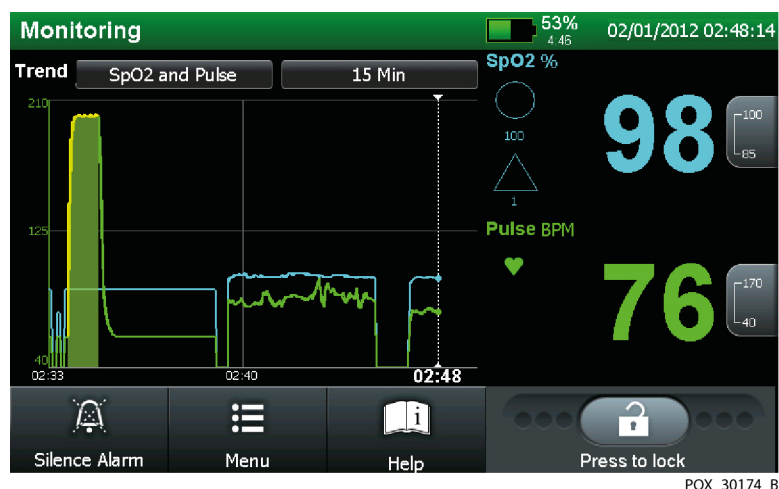
POX_30174_B

Use this view for visually monitoring real-time trends. The trend data plots automatically update as monitoring system calculates each new trend point, where the interval between calculations is based on the time scale selected. The real-time trend monitoring screen includes SpO_2 and/or pulse rate trend data plots, current measured SpO_2 and pulse rates. Each time the monitoring system detects a pulse, the heart icon in the PR field flashes. Reference *DISPLAY SETTINGS Menu*, p. 4-26.

Combined View (Pleth and Trend)

Figure 2-6. Combined Pleth and Trend View

POX_30173_B
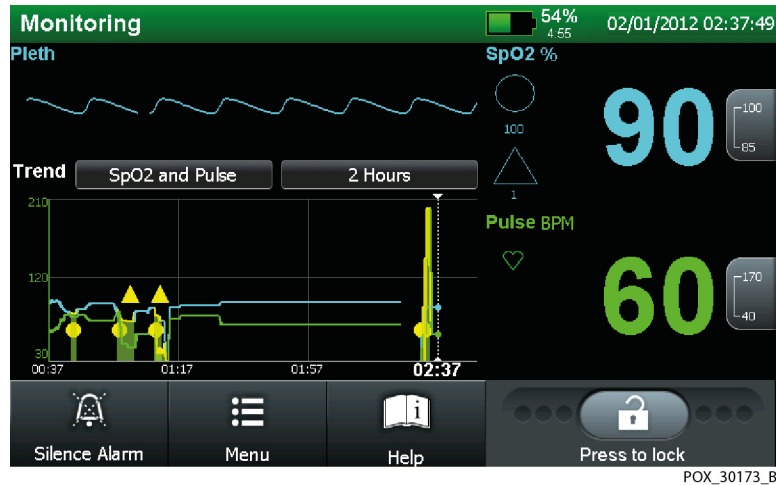
Use this view for simultaneously monitoring both plethysmographic waveform and real-time trends. Reference *Plethysmographic (Pleth) View*, p. 2-8, for details on the pleth portion of the screen. Reference *Trend View*, p. 2-9, for details on the trend portion of the screen. Each time the monitoring system detects a pulse, the heart icon in the PR field flashes. Reference *DISPLAY SETTINGS Menu*, p. 4-26.

Blip (Numbers) View

Figure 2-7. Blip View

POX_30175_B
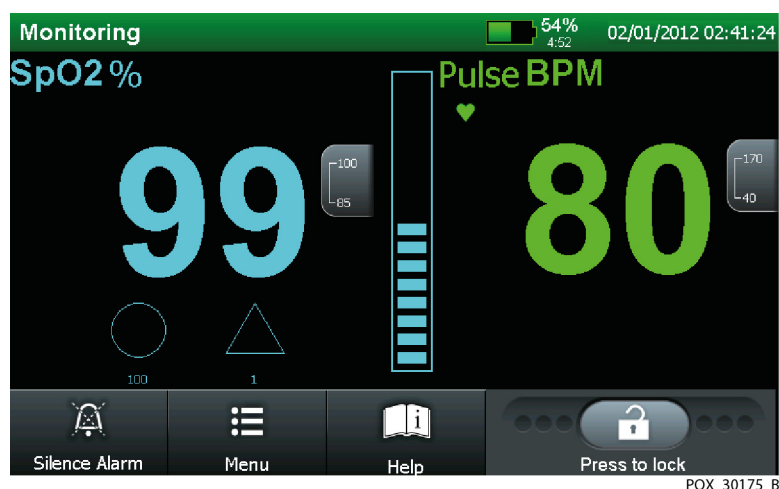
Use this view for visually monitoring the blip bar. The blip view includes a pulse amplitude blip bar, current measured SpO2 and pulse rate, current upper and lower SpO2 and pulse rate limits. Each time the monitoring system detects a pulse, the blip bar moves. Reference *DISPLAY SETTINGS Menu*, p. 4-26.

2.8.2 Monitoring Values

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

The monitoring system continuously assesses the relative strength of the signal while monitoring patient SpO2 and pulse rate. Front panel values reflect the data derived from the patient.

The algorithm automatically extends the amount of data required for measuring SpO2 and pulse rate depending on measurement conditions.

1. **Normal conditions —** During normal measurement conditions, averaging time is six to seven seconds, or approximately three seconds in Fast Mode.

2. **Brief abnormal conditions —** During conditions such as those caused by low perfusion, interference (e.g., external interference like ambient light), or a combination of these, the monitoring system automatically extends the amount of data

required beyond seven seconds. If the resulting dynamic averaging time exceeds 20 seconds, the pulse search indicator lights and remains solid, while SpO2 and pulse rates update every second.

3. **More severe conditions —** As these conditions extend, the required amount of data continues to increase. If the dynamic averaging time reaches 40 seconds, several things occur.

- The pulse search indicator flashes to denote a loss-of-pulse condition.

- SpO2 and pulse rate zero.

- An audible alarm sounds, unless audible alarms are disabled.

2.8.3 Visual Alarms

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

All alarm message elements flash during an alarm condition. Reference *Status Messages and Alarms in the Monitoring Status Field*, p. 4-9.

Table 2-3. Visual Alarm Properties

Category	Color	Frequency
High priority alarm	Red	Fast flash, 1.5 Hz
Medium priority alarm	Yellow	Slow flash, .5 Hz
Low priority alarm	Yellow	Steady

Note:
Caregivers may monitor the patient remotely. Reference *Using the Nurse Call Interface*, p. 5-16. For institutions allowing caregivers to turn off all audible alarms and minimize or disable backlight brightness, refrain from reducing both audible and visual alarms unless using a remote monitoring system. When using a remote monitoring system, caregivers should still remain vigilant, periodically assessing patients.

2.8.4 Audible Alarms and Indicators

⚠ **WARNING:**
Pressing ALARM SILENCE will keep ALL alarms from sounding for the alarm silence duration period.

⚠ **WARNING:**
Should the caregiver silence an SPD alarm, this resets the index that tracks repetitive patterns of desaturation and silences ALL alarms.

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

◆ **Caution:**
If the pulse beep tone does not sound with each pulse, the pulse beep volume is turned off, the speaker is malfunctioning, or the signal is corrupt. Reset the device.

◆ **Caution:**
Should the caregiver fail to clear a primary audible alarm within two (2) minutes, the audible alarm escalates to a more frequent interval.

Audible indicators include pitched tones and beeps. Audible alarms vary, depending on the priority of the alarm. Caregivers may choose to silence alarms by pressing ALARM SILENCE. For any alarm condition still active for more than two (2) minutes, the monitoring system will increase the urgency level of the audible alarm signal by increasing its frequency.

📖 **Note:**
Caregivers may monitor the patient remotely. Reference *Using the Nurse Call Interface*, p. 5-16. For institutions allowing caregivers to turn off all audible alarms and minimize or disable backlight brightness, refrain from reducing both audible and visual alarms unless using a remote monitoring system. When using a remote monitoring system, caregivers should still remain vigilant, periodically assessing patients.

Table 2-4. Audible Indicator Functions

Function	Description
Alarm Silence Reminder	A three tone sequence sounds approximately every three minutes when the alarm silence duration is OFF and alarm silence reminder is ON or when the alarm volume is OFF.
Pulse Beep	A single beep sounds for each detected pulse. The pitch of the pulse beep signal changes with a point-by-point rise or fall in the saturation level.
High Priority Alarm	A high-pitched, fast-pulsing tone indicates PULSE TIMEOUT, BATTERY CRITICAL-LY LOW, or SYSTEM FAILURE.
Medium Priority Alarm	A medium-pitched, pulsing tone indicates a violation of SpO2 or pulse rate limits.
Low Priority Alarm	A low-pitched, slow-pulsing tone at 3.5 second intervals indicates SENSOR DIS-CONNECT, SENSOR OFF, or BATTERY LOW.
SPD™ Alert Alarm	A trio of quick high-, medium-, high-pitched tones at 2.5 second intervals indicates an SPD™ Alert alarm.
Power-On Self-Test Pass	A one-second tone indicates power on and successful completion of power-on self-test.

2.9 Unique Parameters

2.9.1 SatSeconds™ Alarm Management Parameter

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 SpO2 levels. When the SpO2 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 parameter helps distinguish clinically significant events from minor and brief desaturations that may result in nuisance alarms. Reference *SatSeconds™ Alarm Management Parameter*, p. 10-6, for the theory behind how the SatSeconds parameter works. Reference *SatSeconds™Alarm Management Parameter Limits*, p. 4-18, for information on controlling this parameter.

The SatSeconds Safety Net

The SatSeconds "Safety Net" is for patients with saturation levels frequently falling 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.

2.9.2 OxiMax SPD™ Alert Parameter

The OxiMax SPD™ Alert (SPD) parameter detects patterns of desaturation in adults that are indicative of repetitive reductions in airflow through a patient's upper airway into the lungs. Relative reductions in a patient's minute ventilation over a period of time may cause a progressive drop in alveolar partial pressure of oxygen, leading to arterial desaturation. If these decreases in ventilation are repetitive, they generate distinct patterns in the saturation trend. Patterns of repetitive desaturation often develop gradually over time, increasing in severity. Detection of patterns indicates that a patient might be suffering progressively severe decrements in airflow that may increase in acuity if left untreated. Reference *OxiMax SPD™ Alert Parameter*, p. 10-10, for the theory behind how the OxiMax SPD™ Alert parameter works. Reference *OxiMax SPD™ Alert Parameter Limits*, p. 4-20, for information on controlling this parameter.

2.9.3 Pulse Rate Delay Alarm Management Parameter

The monitoring system also monitors pulse rate by determining the number of pleth waves over unit time. With traditional alarm management, upper and lower alarm limits are set for monitoring pulse rate. When pulse rates fluctuate near an alarm limit, alarms trigger with each violation. Pulse Rate Delay allows a period of threshold violation before the pulse rate alarm sounds. Thus, it distinguishes clinically significant events from minor and brief pulse rate limit violations that result in nuisance alarms.

Reference *Pulse Rate Delay Alarm Management Parameter*, p. 10-12, for the theory behind how the Pulse Rate Delay parameter works. Reference *Pulse Rate Delay Alarm Management Parameter Limits*, p. 4-22, for information on controlling this parameter.

2.9.4 Additional Parameters

The monitoring system is modular in design, so users may opt to add additional parameters from Covidien. Each parameter comes with any documentation specific to that parameter as an addendum to this manual.

To order an additional parameter from Covidien

1. Contact Covidien or a local Covidien representative. Reference *Warranty Information*, p. 1-5.

2. Place a purchase order for the desired parameter.

3. Receive the parameter kit.

4. Follow all included instructions after reviewing all enclosed documentation. Instructions may require contacting Covidien again for an activation key and adhering the kit's enclosed adhesive label to each monitoring system receiving the additional parameter.

3 Installation

3.1 Overview

This chapter contains information for the installation and set up of the Nellcor™ Bedside Respiratory Patient Monitoring System, prior to first-time usage by the clinician. Before operating the monitoring system, thoroughly read the *Operator's Manual*.

Inspect the monitoring system for mechanical and functional damage or deterioration prior to every use. Do not use if it appears damaged or does not perform as expected. Have a qualified service technician install and set up the monitoring system after performing functional tests per the *Service Manual*.

3.2 Safety Reminders

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

⚠️ **WARNING:**
Have a qualified service technician perform a safety and functional test prior to use in a clinical setting.

⚠️ **WARNING:**
To ensure patient safety, do not place the monitoring system in any position where it might tip or fall on the patient. Do not allow direct contact with the patient.

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

WARNING:
Disconnect the monitoring system and sensor from the patient during magnetic resonance imaging (MRI) scanning. Objects containing metal can become dangerous projectiles when subjected to the strong magnetic fields created by MRI equipment. Also, induced currents could potentially cause burns.

WARNING:
To ensure accurate performance and prevent device failure, do not subject the monitoring system to extreme moisture, such as direct exposure to rain. Such exposure may cause inaccurate performance or device failure.

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

WARNING:
Use only Covidien-approved sensors and interface cables when connecting to the sensor port. Connecting any other cable or sensor influences the accuracy of sensor data, which may lead to adverse results.

WARNING:
Use only Covidien-approved interface cables with the monitoring system. Use of another interface cable will adversely impact performance. Do not attach any cable intended for computer use to the sensor port.

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:
Ensure the monitoring system is clear of any obstructions that prevent awareness of visual or audible alarms. Failure to do so may result in inadvertently missing a visual alarm or an inaudible alarm tone.

WARNING:
Do not lift the monitoring system by the interface cable or power cord. The cable or cord may disconnect, potentially dropping the monitoring system on a patient or a damaging surface.

Note:
The monitoring system incorporates watchdog timers that reset the monitoring system in the event of software errors. Any temporary limit settings reset to either factory or institutional defaults.

3.3 Product Setup

The monitoring system receives power either from an AC connection (100-240 VAC) or from a 7.2-volt, 11.6 ampere-hour battery. The monitoring system internal battery can be used to power the monitoring system during transport or when AC power is not available. The monitoring system communicates the transition from AC power to battery power or from battery power to AC power via the AC power or battery indicator on the front panel.

A new, fully charged battery provides approximately seven hours of monitoring time under typical conditions.

3.3.1 Mounting Options and Transport Considerations

Users may choose from a variety of mounting configurations, including adapter plates, wall mounts, and pole mounts. Reference *Optional Equipment*, p. 9-4. Follow the installation instructions included with the mounting hardware.

Prior to intra-hospital transport, ensure the monitoring system interface is locked to avoid any inadvertent changes. Reference *To lock the monitoring screen*, p. 4-10.

3.3.2 Connection to an AC Power Source

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

◆ **Caution:**
Use only a hospital-grade power cord.

◆ **Caution:**
Ensure the monitoring system is properly grounded when operating on AC power. If uncertain whether the AC outlet is properly grounded, disconnect the monitoring system from the outlet and use battery power. Contact a qualified electrician to examine the outlet for ground connections.

◆ **Caution:**
Do not block cooling vents.

Ensure the monitoring system remains connected to an AC power source when not in use so a fully charged battery remains available for use at any time.

To connect to an AC power source

1. Plug the female connector end of the power cord into the power connector on the rear of the monitoring system. Reference *Rear Panel*, p. 2-6.

2. Plug the male connector of the power cord into a properly grounded AC outlet.

∼ 3. Verify the monitoring system's AC power indicator lights.

📖 **Note:**
If the AC power indicator does not light, check the power cord, user-accessible fuses, and AC power outlet.

3.3.3 Battery Insertion

⚠ **WARNING:**
Use only Covidien-approved batteries installed by a qualified service technician.

The monitoring system ships with an separate internal battery. The battery must be installed prior to use in a clinical setting. Ensure a qualified service technician inserts the battery and tests the monitoring system prior to use in a clinical setting. Users should immediately, completely charge the battery prior to clinical use or temporary storage of the battery. Users should also remain vigilant when running on battery power and reconnect to AC power during a low battery state.

3.3.4 Battery Charge

⚠ **WARNING:**
Charge only with specified charger, according to instructions. Do not heat above 80° C. Do not open battery, dispose of in fire, or short circuit. It may ignite, explode, leak, or get hot, causing personal injury.

◆ **Caution:**
To fully recharge a low or fully-depleted battery, connect the monitoring system to an AC power outlet. Charge the battery for at least eight hours with the monitoring system turned off or twelve hours with the monitoring system turned on. Have a qualified service technician periodically check the battery; if fewer than four bars light after fully charging the battery, the technician should replace the battery. Recharge the battery at least every three months, allowing the full charge time if it is the first recharge in several weeks.

◆ **Note:**
Whenever the monitoring system is connected to AC power, the battery is charging.

Excessive temperatures will cause battery cell failure. Continued excessive temperatures may trigger the thermal fuse, which permanently shuts down the battery. Should this occur, replace the battery pack.

To fully charge the battery

1. Connect the monitoring system to AC power. The monitoring system will not power up without connection to AC power when the battery charge is below 4%.

~ 2. Verify the monitoring system is off and the AC Power/Battery Charging indicator lights. On AC power up, check the battery fuel gauge. If the gauge is empty or only partially full, the battery begins charging. The monitoring system operates on AC power while the battery is charging. When the monitoring system is fully charged, the green battery fuel gauge registers 100%.

3. Until the battery recharges, the monitoring system displays the message, BATTERY CRITICALLY LOW and supplies the additional information: THE MONITOR'S BATTERY IS CRITICALLY LOW. THE MONITOR MAY SHUT DOWN IF AC POWER IS LOST. DO NOT DISCONNECT MONITOR FROM AC POWER SOURCE. If AC power is lost before the battery is charged past the critically low state, the monitoring system will not produce a low battery alarm for the standard CRITICALLY LOW BATTERY warning duration.

3.3.5 Battery Power Usage

WARNING:
Do not use monitoring system in a depleted battery condition.

Caution:
Should a low battery alarm sound, connect the monitoring system to an AC power source and then silence the alarm by pressing ALARM SILENCE. If the monitoring system is operated on an AC power source with a depleted battery and AC power is subsequently lost, the monitoring system will shut down immediately.

The monitoring system will operate on battery when not connected to AC power. Some usage conditions draw more power from the internal battery than others. Duration of operation depends on the battery charge status. Avoid power-intensive conditions for ideal battery usage. The following list identifies the least power-intensive conditions possible.

- Pulse simulator set for 200 bpm, high light and low modulation

- No audible alarms sound

- No analog or serial output devices are attached to the monitoring system, including serial data, analog output, and nurse call output

- Default monitoring screen brightness setting

Ensure the monitoring system remains connected to an AC power source when not in use so a fully charged battery remains available for use at any time.

When any of the following conditions are present, the monitoring system automatically shuts down.

- The monitoring system is running on battery power and the battery capacity remaining reaches 0%.

- The monitoring system has detected an internal temperature above 67 ℃ or 153 ℉.

3.4 Connection to Nellcor™ Sensors

WARNING:
Use only Covidien-approved sensors and interface cables when connecting to the sensor port. Connecting any other cable or sensor influences the accuracy of sensor data, which may lead to adverse results.

The top of the monitoring system screen indicates the sensor type when connecting a recommended sensor to the monitoring system or when the monitoring system completes POST with an attached sensor. Reference *Selecting a Nellcor™ Sensor*, p. 9-1.

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

Note:
Sensor LED light emissions fall within Class 1 level, according to IEC 60825-1:2001.

To fully connect a Nellcor™ sensor

1. Firmly connect a Nellcor™ interface cable to the monitoring system's sensor port. Reference *Front Panel*, p. 2-3, to identify the port.

2. Open the plastic latch at the other end of the interface cable.

Figure 3-1. Sensor Cable insertion into Interface Cable

POX_30047_A
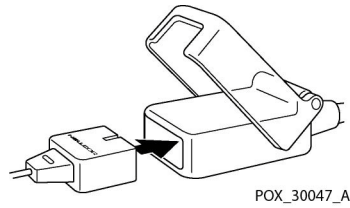
3. Plug the interface cable and recommended sensor together.

4. Snap the plastic latch down over the connectors.

5. When the monitoring system detects a valid pulse, it enters the monitoring mode and displays real-time patient data.

6. Apply the recommended sensor to the patient after reading the *Instructions for Use* accompanying the sensor.

7. Detach the recommended sensor from the patient on completion of monitoring.

4 Operation

4.1 Overview

This chapter identifies methods for collecting patient oxygen saturation data while using the Nellcor™ Bedside Respiratory Patient Monitoring System. It describes menu navigation, power on/off and monitoring screen options, parameter ranges, Nellcor™ sensor attachments, and configuring default settings suitable for the specific care environment.

Schedule regular maintenance and safety checks with a qualified service technician every 24 months. In the case of mechanical or functional damage, contact Covidien or a local Covidien representative.

4.2 Power

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

Caution:
Have a qualified service technician replace the internal battery every 24 months.

Caution:
Have a qualified service technician remove and store the internal battery if users expect a significant period of disuse.

Caution:
Any complete discharge or replacement of the battery, power interrupts, or system processor reset results in a reset of all temporary user settings to factory or institutional default settings. If this occurs, have a qualified service technician reset the institutional defaults, per the *Service Manual*.

4.2.1 AC Power

When the user connects the monitoring system to an AC power source, if the internal battery requires charging, the battery condition indicator lights until the internal battery reaches complete charge. If the user powers off the monitoring system while the internal battery is charging, the battery condition indicator remains lit and the internal fan turns on until charging completes. Reference *Connection to an AC Power Source*, p. 3-4.

4.2.2 Battery Power

Battery Status

⚠ **WARNING:**
Do not use monitoring system with a depleted battery or in a low voltage condition.

Reference *Battery Power Usage*, p. 3-6, for details on initial internal battery setup information.

The yellow BATTERY LOW warning flashes and a medium priority alarm sounds when approximately 14% capacity remains on the existing battery charge. The red BATTERY CRITICALLY LOW warning flashes and a high priority alarm sounds when approximately 4% capacity remains on the existing battery charge. The battery will drain completely and the monitoring system will shut down if not connected to AC power during a critically low battery condition. Reference *Battery Power Status*, p. 4-3, for a description of the low and critical battery conditions.

To cancel a visual or audible battery condition alarm, connect the monitoring system to an AC power source. The low battery warning status remains as long as the battery is in a low voltage condition or until the caregiver presses DISMISS for the low battery alarm message.

Battery Fuel Gauge

⚠ **WARNING:**
Do not use monitoring system with a depleted battery or in a low voltage condition.

◆ **Caution:**

Should a low battery alarm sound, connect the monitoring system to an AC power source and then silence the alarm by pressing ALARM SILENCE. If the monitoring system is operated on an AC power source with a depleted battery and AC power is subsequently lost, the monitoring system will shut down immediately.

The monitoring system runs on an internal battery when not connected to an AC power source. A battery fuel gauge displays the remaining battery power. Reference *Connection to an AC Power Source*, p. 3-4. Reference *Battery Power Usage*, p. 3-6.

📖 **Note:**

The battery is recyclable. Do not dispose of the battery by placing it in the regular trash. Dispose of the battery in accordance with local guidelines and regulations or contact Covidien to arrange for disposal.

📖 **Note:**

As the battery is used and recharged over time, the amount of time between the onset of low battery alarms and the monitoring system shut-off may become shorter.

Table 4-1. Battery Power Status[1]

Message	Color	Power Charge Status
None	Green	**Normal Status —** Indicates 15-100% (approximately 15 minutes to 6 hours) battery capacity remains.
BATTERY LOW	Yellow	**Low Status —** Indicates 5-14% (approximately 15 minutes) battery capacity remains.
BATTERY CRITICALLY LOW	Red	**Critical Status —** Indicates 1-4% (less than 15 minutes) battery capacity remains.

1. The levels listed are based on a new battery. Continued battery charge and discharge eventually reduces capacity. For example, a battery two years old may provide only 75% of the capacity of a new battery.

4.2.3 Power Up

Power Prerequisites

◆ **Caution:**

If any pixel in the monitoring screen does not light at power up, do not use the monitoring system. Instead, contact a qualified service technician, Covidien, or a local Covidien representative.

Caution:

During POST (immediately after power-up), confirm that all pixels in the monitoring screen turn on and the monitoring system speaker sounds a sequence of three ascending tones. After the POST process completes, confirm that a single one-second tone sounds.

Before using the monitoring system in a clinical setting, ensure the monitoring system is safe and working properly. Verify proper working condition at each power up by following the directions for powering up the monitoring system.

To do so, carefully view the splash screen during power on. Verify there are no black gaps on the monitoring screen during power-on self-test (POST) or when every pixel on the screen is completely lit. Should users observe any black gaps or unlit pixels, do not use the monitoring system before having the monitoring system serviced.

Power-on Self-Test (POST)

WARNING:
Have a qualified service technician perform a safety and functional test prior to use in a clinical setting.

WARNING:
Ensure the monitoring system is clear of any obstructions that prevent awareness of visual or audible alarms. Failure to do so may result in inadvertently missing a visual alarm or an inaudible alarm tone.

WARNING:
If the power-on self-test (POST) pass tone does not sound, do not use the monitoring system. Instead, contact Covidien or a local Covidien representative.

WARNING:
Power-up performance tests verify both power-on self-test (POST) and power-on defaults and alarm range limits. Reference *Factory Default Alarm Limit Settings and Parameters*, p. 4-16.

At power on, the monitoring system performs a power-on self-test (POST), which tests the circuitry and functions, then proceeds to the default monitoring screen. Reference *Combination Pleth and Trend View*, p. 4-40. Attach a sensor cable and a recommended sensor and the monitoring system is ready to register and record patient trend data. Reference *Connection to Nellcor™ Sensors*, p. 3-7.

Note:

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

Note:

In addition to serving as the POST pass verification, the POST pass tone also functions as an audible confirmation that the speaker is performing properly. If the speaker does not function, the alarm warning sounds cannot be heard.

Note:

For standard usage, connect sensor cables prior to turning on the monitoring system. Have a qualified service technician perform any functional testing prior to usage.

To power up the monitoring system

1. Connect the monitoring system to an AC power source. The monitoring system can run on battery power, but for performance testing, use an AC power source.

2. Verify the monitoring system is off and the AC Power Indicator lights.

3. Turn on the monitoring system by pressing the POWER ON key.

4. Within ten seconds, all pixels should illuminate. The monitoring screen should display a corporate logo and the firmware version of the monitoring system.

5. Observe the monitoring screen for the POST splash screen, which appears for approximately five (5) seconds.

6. Listen for three ascending tones then a one-second beep, indicating proper operation of the speaker and successful completion of power-on self-test.

Figure 4-1. Sample POST Splash Screen

POX_30133_A
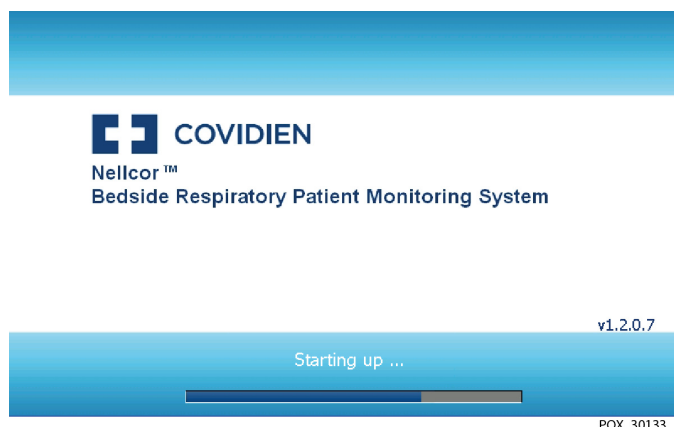
If the monitoring system detects an internal problem during the POST process, an error tone sounds and the monitoring system displays an error message. Reference *Troubleshooting*, p. 8-1.

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

4.2.4 System Resets

If the monitoring system issues a system reset, based on triggering the watchdog timer, all temporary settings will be lost. Neither factory nor institutional default settings are impacted.

4.2.5 Automatic Shutdown and Power Off

Automatic Shutdown

When any of the following conditions are present, the monitoring system automatically shuts down.

- The monitoring system is running on battery power and the battery capacity remaining reaches 0%.

- The monitoring system has detected an internal temperature above 67 °C or 153 °F.

Power Off

To turn off the monitoring system, only hold the POWER ON key long enough for three descending tones to sound. Then the screen darkens and the monitoring system powers off.

4.3 Nellcor™ Sensor Usage

Reference *Selecting a Nellcor™ Sensor*, p. 9-1, for identifying the proper recommended sensor. Consider all possible variables. If in doubt, contact Covidien or a local Covidien representative. Reference *Connection to Nellcor™ Sensors*, p. 3-7, for connecting the proper recommended sensor.

4.3.1 Sensor Detection

⚠ **WARNING:**
Use only Covidien-approved interface cables with the monitoring system. Use of another interface cable will adversely impact performance. Do not attach any cable intended for computer use to the sensor port.

⚠ **WARNING:**
Use only Covidien-approved sensors and interface cables when connecting to the sensor port. Connecting any other cable or sensor influences the accuracy of sensor data, which may lead to adverse results.

◆ **Caution:**
If the pulse beep tone does not sound with each pulse, the pulse beep volume is set to zero, the speaker is malfunctioning, or the signal is corrupt. Reset the device.

A "SENSOR ATTACHED: xxxx" message appears for between four and six seconds when users first connect a recommended sensor. The message identifies the type of sensor connected to the monitoring system. Sensor type determines any action messages in the sensor message(s) function.

Figure 4-2. Sensor Type Message

POX_30194_A
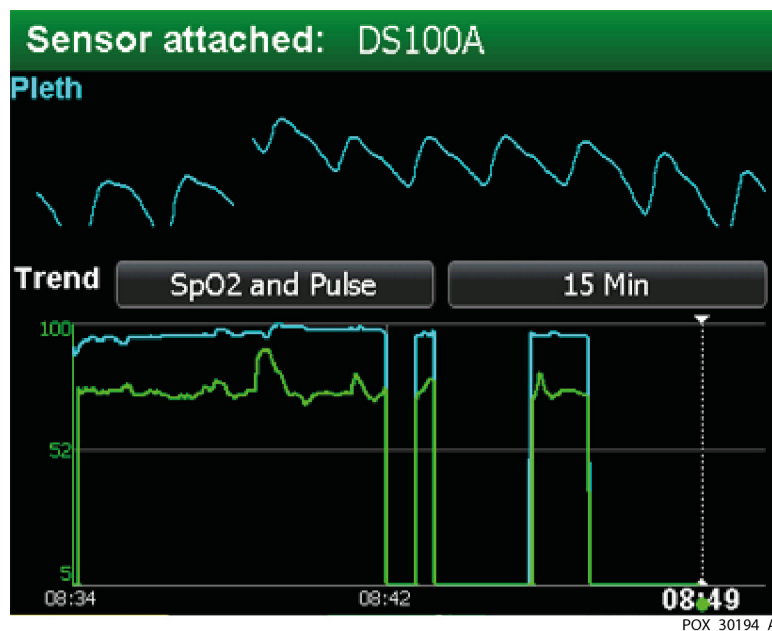
The monitoring system displays dashes for %SpO$_2$ and Pulse Rate while searching for a valid pulse. For optimal performance, allow the monitoring system to search and lock onto a pulse for approximately five to ten seconds.

When the monitoring system detects a valid pulse, it enters monitoring mode and displays patient parameters.

The movement of the blip bar or the plethysmographic waveform and the flashing heart icon are **visual indicators** of real-time data. The pulse beep tone is an **audible indicator** of the real-time patient data.

When users first apply a recommended sensor to a patient, the monitoring system may lose a pulse signal. Upon loss of the pulse signal, the monitoring system posts an alarm.

4.3.2 Sensor Detection Failure

Upon successful completion of the POST process, the monitoring system sounds a one-second tone indicating it has passed POST.

Should the monitoring system fail to detect a recommended sensor, it displays a user prompt indicating it is in the ready state and the caregiver should attach a recommended sensor to both the patient and the monitoring system.

4.4 User Interface

4.4.1 Default Monitoring Screen and Trend Data

Users receive monitoring system information via the monitoring screen. This is particularly relevant to real-time and historical patient trend data, which may appear as a plethysmographic waveform, a blip bar, a graph, or saturation and pulse rate values, depending on the accessed monitoring screen. Reference *Default Monitoring Screen and Trend Data*, p. 4-8, to understand real-time trend data. Reference *MONITORING HISTORY Menu*, p. 4-23, to understand online historical trend-data. Reference *Trend Data Management*, p. 5-1, to better manage both real-time and historical trend data. Should the monitoring system detect corrupt trend data, it notifies the caregivers with a TREND DATA LOST message. Users may choose to adjust the monitoring screen layout as needed, and institutions may specify an alternate default. Institutional default settings require changes to the available options in Service Mode by a qualified service technician. Reference *Monitoring Screen Layout Options*, p. 4-34.

Figure 4-3. Default Monitoring Screen Layout

POX_30172_B
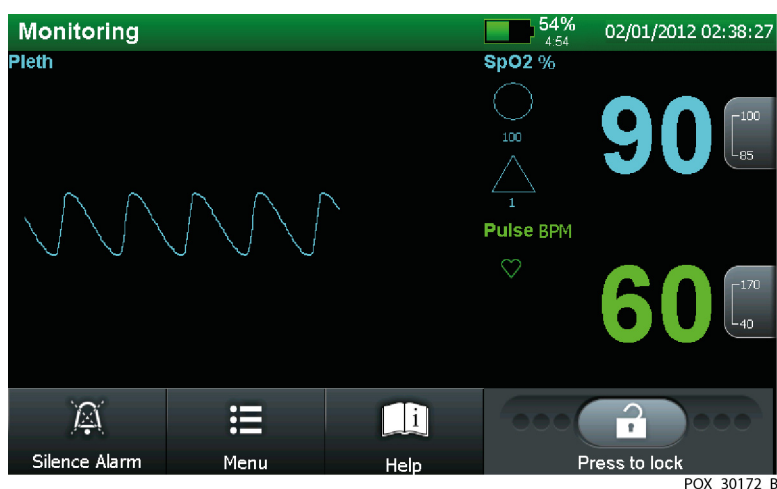
4.4.2 Status Messages and Alarms in the Monitoring Status Field

Users receive monitoring system information via the monitoring screen. The primary area is the monitoring status field. Background color provides an additional status cue. Reference *Alarm Management and Status Messages*, p. 4-43.

• **User prompts —** This status type with a gray background prompts users to perform some action to obtain patient data.

• **Active status —** This status type notifies users of the current, active monitoring system state. Green background indicates normal status, cyan background indicates the user has selected the menu option, listing main menu items in grey.

• **Alarm status —** This status type identifies alarm conditions from highest to lowest priority. If multiple alarms occur while users are choosing menu options, the vertical alarm list of messages appears with the highest priority alarms at the top. If more than three alarms are active, the list collapses into a single VIEW ALL ALARMS line containing the total number of active alarms. Each alarm contains a MORE INFO button. Pressing the MORE INFO button provides a detailed explanation and any corrective action required.

  a. **High priority alarms —** Alarm message appears on flashing red background. High priority alarms appear first when multiple alarms occur simultaneously.

  b. **Medium priority alarms —** Alarm message appears on flashing yellow background. Medium priority alarms appear after high priority alarms and before low priority alarms.

c. **Low priority alarms —** Alarm message appears on steady yellow background. Low priority alarms appear after high or medium priority alarms.

4.4.3 Introduction to Menu Options

Interact with and customize the monitoring system using the monitoring screen buttons. Confirm the monitoring screen is unlocked by checking for the unlocked icon on the lock bar.

To lock the monitoring screen

1. Locate the lock bar at the lower right of the monitoring screen.

2. Press and hold the unlocked icon.

3. Observe the progression of green lights to either side of the unlocked icon until all three on each side light.

4. Ensure the icon now appears as a locked icon.

To unlock the monitoring screen

1. Locate the lock bar at the lower right of the monitoring screen.

2. Press and hold the locked icon.

3. Observe the progression of green lights to either side of the locked icon until all three on each side light.

4. Ensure the icon now appears as an unlocked icon.

Press MENU to access any submenus. Use the scroll bar or adjustment arrows to select or change options. Reference *Menu Option Selection*, p. 4-12.

Table 4-2. Menu icons and primary user interface features

Icons available during standard operation		
🔔	SILENCE ALARM icon	Press to silence ANY current alarms for the alarm silence duration period. After silencing an alarm, press again to reactivate the alarm. To adjust alarm silence duration requires a qualified service technician. Remains available at all times.
☰	MENU icon	Press to access current menu functions, including alarm limits, monitoring history, monitoring screen selections, audio controls, and connectivity settings.
📖	HELP icon	Press to access on-screen help.
🔒	LOCK bar with lock icon	Press until the lock icon appears to prevent access to monitoring system options, with the exception of SILENCE ALARM. Press until the unlocked icon appears to permit access to make desired changes.
Menu items available during menu selection		
✖	CANCEL or EXIT MENU icon	Press to return to the monitoring screen without altering the current selection.
◀	BACK icon	Press BACK to return to the previous menu level without exiting the selected menu area entirely.
🗑	CLEAR HISTORY icon	Press CLEAR HISTORY to delete any stored historical trend data.
✔	SAVE CHANGES icon	Press SAVE CHANGES to retain any selection and return to monitoring.
▲▼	ADJUST UP, DOWN arrows	During menu selection, press to increment up or down. During selection of variable parameters, press to incrementally increase or decrease the specified parameter.
	ADJUST slider bar	During menu selection, slide to scroll up or down to access upper or lower menu options.

4.4.4 Menu Option Selection

Menus and Submenus

The user interface provides for customization. Press MENU to access various menus and submenus, then save any desired changes. Changes occur immediately after users press SAVE CHANGES. Use menu options to change alarm limits, display settings, baud rates, time and date, and trend data views.

ALARM LIMITS Menu	SpO2	Set Upper and Lower SpO2 Alarm Limits
	Pulse Rate (PR)	Set Upper and Lower PR Alarm Limits
	SatSeconds	Set SatSeconds Alarm Limit Threshold
	SPD	Set SPD Sensitivity Setting
	Pulse Rate Delay	Set PR Delay Threshold

MONITORING HISTORY Menu	Use to clear trend data history

SOUND SETTINGS Menu	Alarm Volume	Set - (softer) or + (louder)
	Pulse Beep Volume	Set - (softer) or + (louder) and OFF
	Button Click Volume	Set - (softer) or + (louder) and OFF

DISPLAY SETTINGS Menu	Monitoring Layout	Set Pleth and Trend view
		Set Pleth Only view
		Set Trend Only view
		Set Blip (Numbers Only) view
	Screen Brightness	Set - (less bright) or + (more bright)

MONITORING SETTINGS Menu	Alarm Mode	Adult alarm settings
		Neonate alarm settings
	Response Mode	NORMAL response mode
		FAST response mode
	Time and Date	Time settings (+ or -)
		Date settings (+ or -)
		Date format (DD/MM/YY, MM/DD/YY, or YY/MM/DD)
	Alarm Silence Duration	Set Alarm Silence duration

CONNECTIVITY SETTINGS Menu	Oxinet	Set to WLAN (ASCII or SPDout)
		Set to LAN (ASCII or SPDout)
		Set to serial (ASCII or SPDout)
		Set to disconnected
	Serial Connection	ASCII (9600 or 19200 baud)
		Clinical (19200 baud)
		SPDout (19200 or 115200 baud)
		Philips (19200 baud)
		Off
	Nurse Call	Set to normally - or normally +

DATA EXPORT Menu	Use to export trend history data to alternate sources

ABOUT THE MONITOR Menu	Identify model, software, parameter, and network Information

Factory Defaults and Institutional Defaults

Each monitoring system ships to the customer with settings established at the factory. These are **factory default** settings.

Institutions may choose to modify such settings without losing those changes at power reset or power off. Such **institutional default** settings must be set and tested by a qualified service technician prior to **use in a clinical setting**.

Table 4-3. Factory Default Settings

Option	Adult Defaults	Neonate Defaults
Alarm silence duration	120 Seconds	
Alarm disabled reminder	Yes, every three minutes	
Allow alarm audio OFF	No	
%SpO2 lower alarm limit	85%	
%SpO2 upper alarm limit	100%	95%
SatSeconds	100	**OFF**
SPD sensitivity	1	Always **OFF**
Allow SPD	Yes	No
Pulse rate lower alarm limit	40 BPM	90 BPM
Pulse rate upper alarm limit	170 BPM	190 BPM
Pulse Rate Delay	Off	
Alarm volume	75%	
Pulse beep volume	50%	
Button click volume	50%	
Screen brightness	75%	
Wake display on alarm	Yes	
Monitoring screen layout	Pleth	
Vital sign colors	%SpO2: Cyan, Pulse BPM: Green	
Displayed language	English	
Response mode	Normal	
Trend scale	SpO2 Only, 4 Hours	
Real-time trend scale	1 hour	
Real-time trend display	Dual (SpO2and Pulse)	
Nurse call polarity	Normally high (+)	
Oxinet protocol	Disconnected	
Serial protocol	ASCII, 9600 baud	

Note:

Some values cannot be saved as power-on defaults. Attempts to save such values as default result in an INVALID tone. Users may alter such limits for current patients, but limits return to factory or institutional defaults at power-off.

ALARM LIMITS Menu

WARNING:

Ensure alarm limits are appropriate for the patient being monitored with each use of the monitoring system.

WARNING:

Do not silence or disable audible alarms or decrease the volume of the audible alarm if patient safety could be compromised. Do not dim or disable visual alarms if patient safety could be compromised.

WARNING:

Supplemental oxygen will attenuate patterns of desaturation. A patient's respiratory compromise can be proportionally more severe before patterns appear in the saturation trend. Remain vigilant when monitoring a patient on supplemental oxygen.

WARNING:

Only change the alarm threshold setting levels under the supervision of a qualified clinician.

WARNING:

Do not preset different or inappropriate alarm limits for the same or similar equipment in any single area, since this may compromise patient safety.

WARNING:

Only use the SPD parameter with adult patients. Do not use on neonate patients. In Neonate Mode, the SPD parameter remains OFF.

Caution:

Do not set alarm limits to extreme values that render the monitoring system useless. Ensure alarm limits are appropriate for each patient.

◆ **Caution:**

Use of the SPD parameter does not change the need to set threshold limits appropriate to the patient being monitored.

Select standard monitoring system alarm limits for either adults or neonates. Reference *To set the alarm mode*, p. 4-29, for setting adult or neonate modes. The monitoring system ships with factory default settings. Factory default alarm settings fall into two groups: adult and neonate. The monitoring system automatically uses adult-pediatric alarm limit settings at power-up. Any temporary changes to the ALARM LIMITS menu remain active until power off or power loss greater than 30 seconds. Have a qualified service technician set institutional default settings that differ from factory default settings as described in the *Service Manual*.

◆ **Note:**

The ability to adjust the alarm limit default settings can be enabled or disabled by qualified service personnel as described in the *Service Manual*.

Figure 4-4. ALARM LIMITS Menu Options
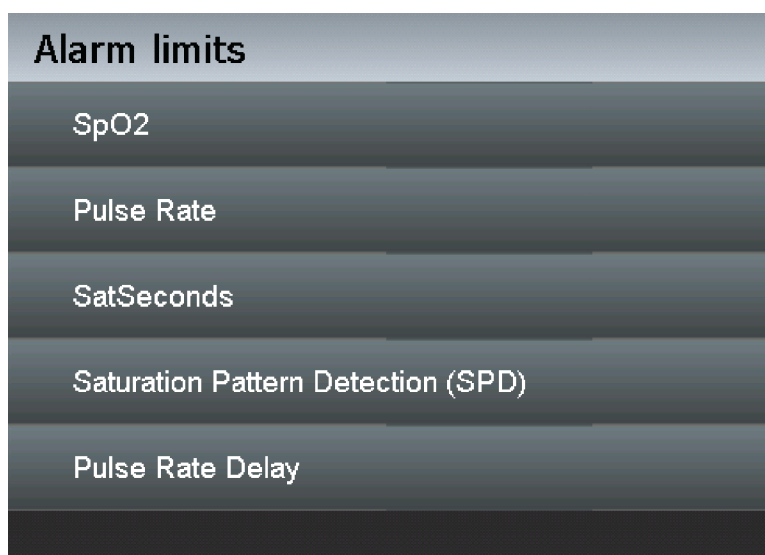
POX_30141_A

Factory Default Alarm Limit Settings and Parameters

⌈ 100
⌊ 85

- **SpO2 Limits —** The adult default upper limit is 100% and the lower limit is 85%. The neonate default upper limit is 95% and the lower limit is 85%. If neonate mode is enabled, the NEO icon will appear between the threshold setting values. An alarm

sounds each time patient saturation violates these alarm limits. Reference *To set temporary SpO2 and pulse rate alarm limit settings*, p. 4-17.

170
40

- **Pulse Rate Limits —** The adult default upper limit is 170 bpm and lower limit is 40 bpm. The neonate default upper limit is 190 bpm and the lower limit is 90 bpm. If neonate mode is enabled, the NEO icon will appear between the threshold setting values. An alarm sounds each time patient pulse rate violates these alarm limits. Reference *To set temporary SpO2 and pulse rate alarm limit settings*, p. 4-17.

- **SatSeconds™ Alarm Management —** The adult default SatSeconds™ value is 100 SatSeconds. The neonate default SatSeconds™ value is OFF. An alarm sounds based on a violation of SatSeconds™ alarm limits. Reference *To set SatSeconds alarm limit*, p. 4-19.

- **Saturation Pattern Detection (SPD) —** The SPD™ Alert parameter is not indicated for use on pediatric patients, but on adult patients only. This option is not available for neonates. The adult default SPD alarm sensitivity is a value of one (1) for most sensitive to patterns of desaturation. Reference *To set OxiMax SPD™ Alert (SPD) sensitivity*, p. 4-21. When the SPD™ Alert parameter is enabled, the SatSeconds™ parameter is automatically enabled with a setting of 100.

- **Pulse Rate Delay parameter —** Use the pulse rate delay parameter to distinguish clinically significant alarms from minor nuisance alarms. The default setting is OFF. Reference *Pulse Rate Delay Alarm Management Parameter Limits*, p. 4-22.

Temporary Alarm Limits

The initial values in the limits screen are the *factory* default settings or are the *institutional* default settings set by qualified service personnel. Reference *Factory Default Settings*, p. 4-14. Any changes to these settings are temporary; settings return to the factory or institutional default values after power cycle.

Note:

Limit changes remain in effect as long as the monitoring system retains power, but return to the factory or institutional default limit settings at power off. Only qualified service personnel may configure and save institutional defaults as described in the *Service Manual*.

To set temporary SpO2 and pulse rate alarm limit settings

1. While in normal monitoring mode, press MENU.

2. Press ALARM LIMITS.

3. Select either SpO2 or PULSE RATE. All lower threshold values must be at least one digit lower than the upper limit threshold, so change lower thresholds first. Default limit settings depend on the selected patient mode.

4. Slide the bar up or down until reaching the desired value.

Figure 4-5. Adjusting Alarm Limit Settings
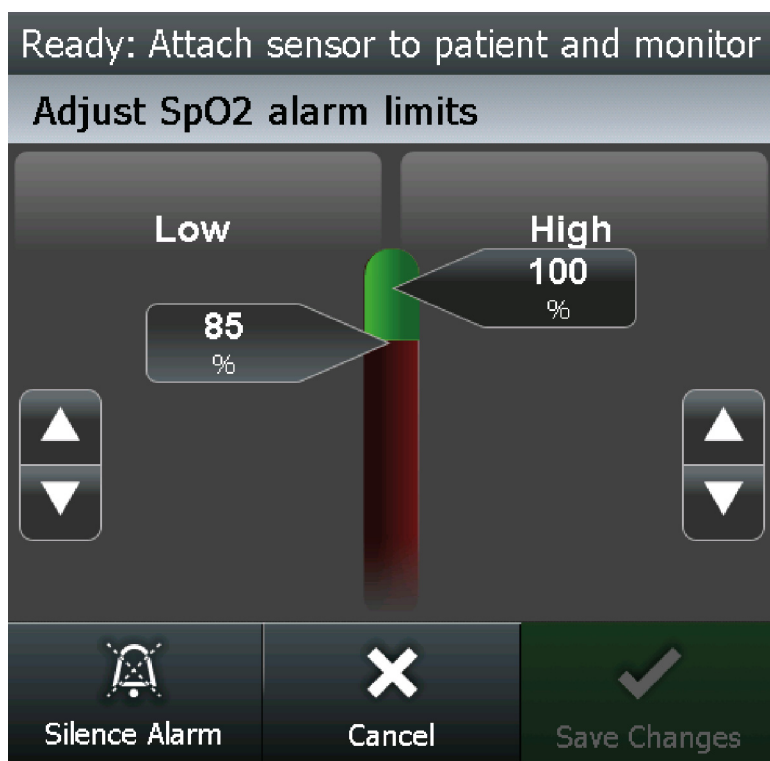
POX_30236_B

5. Press SAVE CHANGES to save the selected setting.

6. Ensure the selected limit value appears in the appropriate limit area.

SatSeconds™Alarm Management Parameter Limits

For mild or brief SpO$_2$ limit violations, use the parameter to reduce nuisance alarms.

-   **SatSeconds icon —** With the parameter enabled, the SatSeconds circle icon fills in the clockwise direction as the alarm management system detects SpO$_2$ readings outside of the limit setting. The circle icon empties in counterclockwise direction when SpO$_2$ readings are within limits. When the icon fills completely, a medium priority alarm sounds.

-   **SatSeconds trend data —** The trend history captures the SatSeconds violation and identifies each SatSeconds alarm activation period. Caregivers should view

the data to examine SatSeconds violations in the trend data history. Reference *Real-time Trend Data*, p. 5-2.

- **SatSeconds alarms —** SatSeconds alarm settings include both audible and visual alarms.

  a. **Audible alarm —** Once an audible alarm occurs, the monitoring system will continue to alarm until the caregiver clears the alarm.

  b. **Visual alarm —** Once a SatSeconds alarm occurs, a medium priority alarm message flashes.

To set SatSeconds alarm limit

1. While in normal monitoring mode, press MENU.

2. Press ALARM LIMITS.

3. Press SATSECONDS.

4. Select the desired limit. The choices are 10, 25, 50, 100 SatSeconds or OFF. The default setting is 100.

Figure 4-6. Setting SatSeconds Alarm Limits
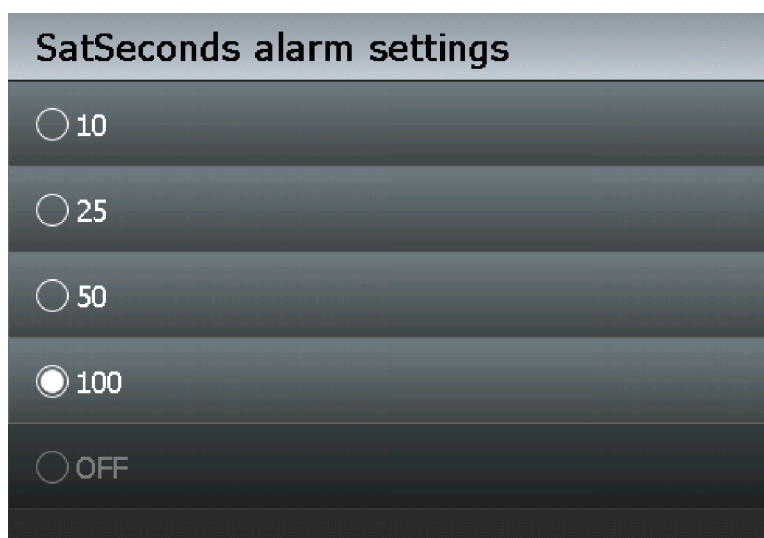
POX_30137_B

5. Press SAVE CHANGES to save the selected setting.

6. Ensure selected limit value underneath the SatSeconds circle icon matches the desired limit just set.

Note:
The ability to adjust SatSeconds default settings can be enabled or disabled by qualified service personnel as described in the *Service Manual*.

Note:
Press HELP to display a SatSeconds alarm help dialogue.

OxiMax SPD™ Alert Parameter Limits

WARNING:
Supplemental oxygen will attenuate patterns of desaturation. A patient's respiratory compromise can be proportionally more severe before patterns appear in the saturation trend. Remain vigilant when monitoring a patient on supplemental oxygen.

WARNING:
Only use the SPD parameter with adult patients. Do not use on neonate patients. In Neonate Mode, the SPD parameter remains OFF.

Reference *OxiMax SPD™ Alert Parameter*, p. 10-10, for specifics on how the SPD parameter works. The SPD parameter can be disabled as an institutional default. The SPD parameter communicates information to the caregiver about patterns of desaturation in a variety of ways.

- **SPD icon —** When the SPD parameter detects patterns of desaturation in the SpO$_2$ trend in adults, caregivers are alerted to these patterns via a visual indicator, and optionally, an audio alarm. The triangle icon for SPD appears on the monitoring system when the parameter is enabled. The triangle fills from bottom to top as patterns become more severe. The triangle empties from top to bottom as the patterns become less severe. When the icon fills completely, an alarm sounds. With SPD enabled, the default setting is ON with the sensitivity set to 1. The parameter can be turned off in the LIMITS menu. Caregivers can select from three alarm sensitivity settings: 1 (most sensitive), 2 (medium sensitivity) or 3 (least sensitive), with 1 resulting in more alarms and 3 resulting in fewer alarms. The rate at which the SPD icon fills depends on the SPD sensitivity setting.

- **SPD trend data —** The trend history captures the SPD patterns and identifies SatSeconds and SPD alarms activation periods. Once patterns exceed the SPD limit, an SPD ALERT alarm message will flash. Caregivers should view the data to examine SatSeconds and SPD patterns in the trend data history. Reference *Real-time Trend Data*, p. 5-2.

- **SPD alarms —** SPD alarm settings include both audible and visual alarms.

a. **Audible alarm —** Once an audible SPD ALERT alarm occurs, the monitoring system will continue to alarm for up to six (6) minutes after the alarm triggers or until the caregiver clears the alarm.

b. **Visual alarm —** Once an SPD ALERT alarm occurs, a low priority SPD ALERT alarm message flashes.

When the indicator reaches capacity, indicating the SPD limit has been reached, an audible alarm sounds and an alarm message flashes. The default setting of one (1) is the most sensitive to desaturation patterns and results in more frequent alarms. For less frequent alarms, use a less sensitive setting of two (2) or three (3).

Note:
To disable audible alarms, contact a qualified service technician.

Note:
Unrecognized repetitive reductions in airflow through the upper airway occur in some clinically significant scenarios. Patients exhibiting sleep apnea symptoms were used in studies to validate the SPD™ Alert parameter. The presence of repetitive reductions in airflow was scored using a standard diagnostic polysomnogram. Study results indicate SPD is a sensitive marker in detecting repetitive reductions in airflow.

Note:
Prior to changing SPD sensitivity settings, clear all alarms.

Note:
Enabling SPD automatically sets the SatSeconds value to 100.

To set OxiMax SPD™ Alert (SPD) sensitivity

The SPD sensitivity setting establishes a threshold for how sensitive the monitoring system is to patterns of desaturation.

1. While in normal monitoring mode, press MENU.

2. Press ALARM LIMITS.

3. Press SPD ALARM SETTINGS.

4. Select the desired sensitivity setting. The choices are 1, 2, 3, or OFF. The default setting is 1. The setting of one (1) is the most sensitive to patterns of desaturation, but may also lead to more alarms. The setting of two (2) is moderately sensitive to

patterns of desaturation. The setting of three (3) is the least sensitive to desaturation patterns, but may result in fewer alarms.

Figure 4-7. Setting SPD Sensitivity
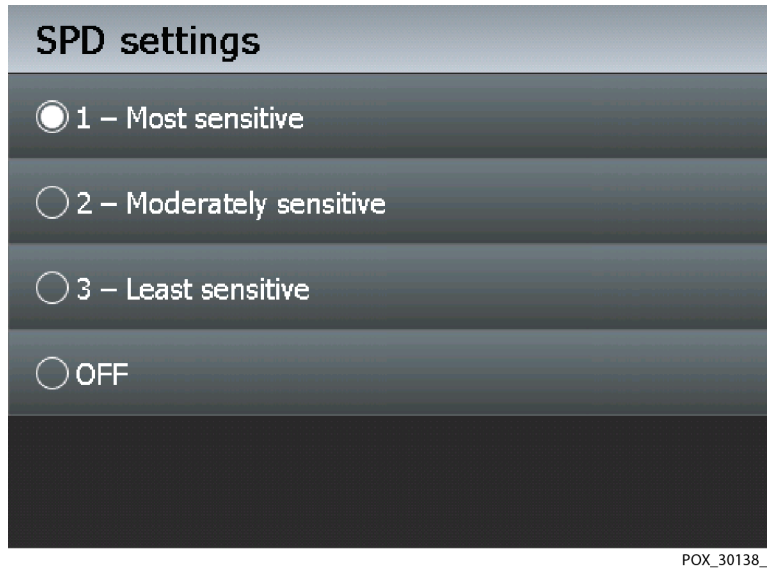
POX_30138_B

5. Press SAVE CHANGES to save the selected setting.

6. Ensure selected sensitivity value underneath the SPD triangle icon matches the desired limit just set.

Note:
Press HELP to display a SPD alarm help dialogue for online assistance.

Pulse Rate Delay Alarm Management Parameter Limits

Reference *Pulse Rate Delay Alarm Management Parameter*, p. 10-12, for specifics on how the pulse rate delay parameter works. To use the Pulse Rate Delay parameter, set the traditional alarm management upper and lower pulse rate alarm limits. Then, set the Pulse Rate Delay. The Pulse Rate Delay limit controls the time the pulse rate level crosses either limit before an audible alarm sounds.

To set pulse rate delay

1. While in normal monitoring mode, press MENU.

2. Press ALARM LIMITS.

3. Press PULSE RATE DELAY.

4. Select the desired delay. The choices are 5, 10, or OFF. The setting of five (5) or ten (10) provides a five or ten second alarm delay, respectively. The default setting is OFF.

Figure 4-8. Setting Pulse Rate Delay

Pulse Rate Delay settings

Pulse Rate Delay

| 5 | 10 | Off |

POX_30177_A
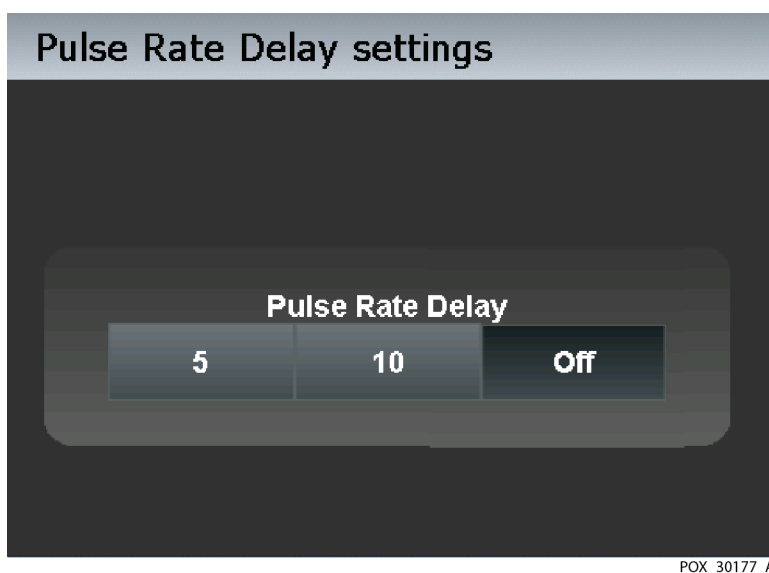
5. Press SAVE CHANGES to save the selected setting.

MONITORING HISTORY Menu

Use this menu to review historical trend data. Should the monitoring system detect corrupt trend data, it notifies the caregivers with a TREND DATA LOST message.

To review historical trend data

1. While in normal monitoring mode, press MENU.

2. Press MONITORING HISTORY.

3. Review the visible trend field.

Figure 4-9. MONITORING HISTORY Screen

POX_30322_B
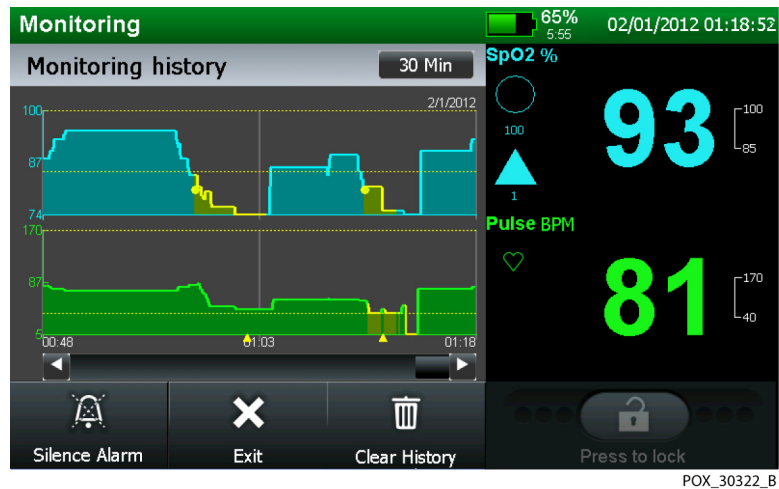
4. Scroll left or right using the arrows or the scroll bar for any additional historical trend data.

5. View specifics for visible trend data by touching the screen at the area of interest. A pop-up appears.

Figure 4-10. Trend data pop-up

POX_30178_B
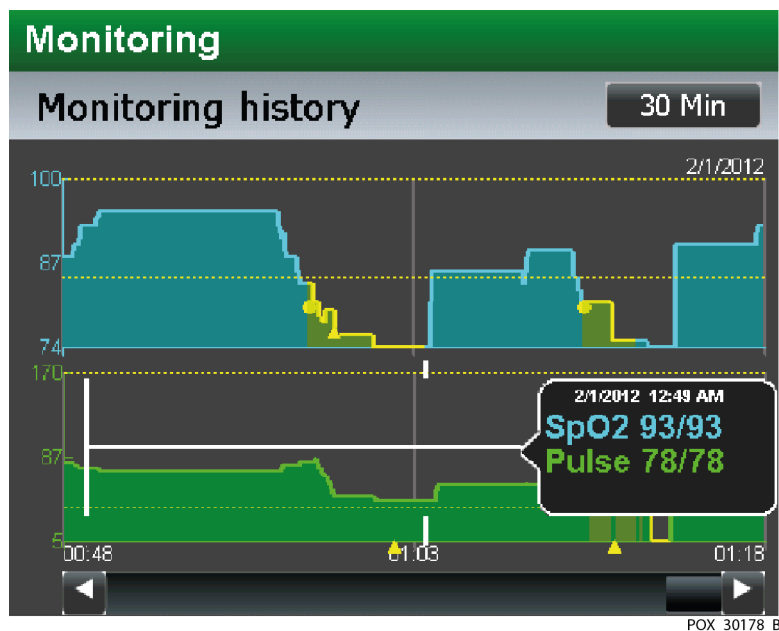
6. Press CLEAR HISTORY to delete the trend data and then confirm or CANCEL to retain historical trend data.

7. Press EXIT to return to normal monitoring.

SOUND SETTINGS Menu

Select volume levels for alarms, pulse beep, and sound effects in increments or decrements of 25 percent.

Note:
Any adjustment of volume levels results in an issued sound not only to indicate the change, but also to indicate functionality of the speaker and audible alarm signal.

Figure 4-11. SOUND SETTINGS Menu Options

Sound settings

Alarm Volume

Pulse Beep Volume

Button click volume
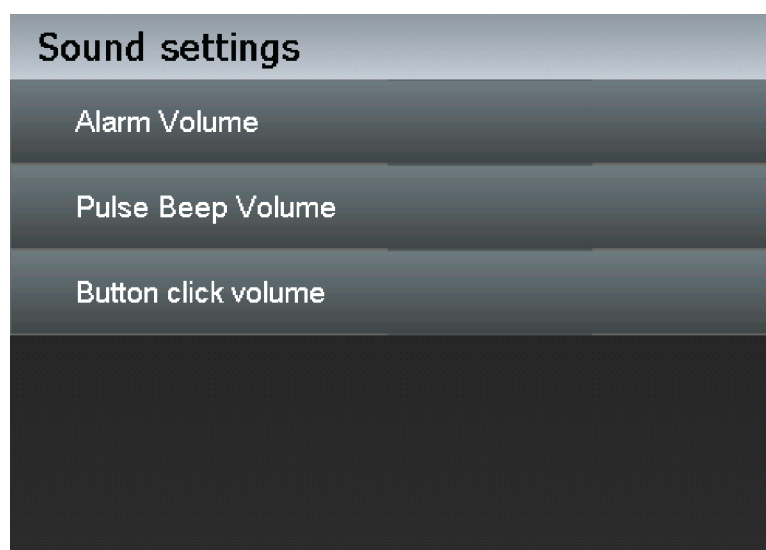
POX_30179_A

- **Alarm volume —** Adjust the volume to the desired level by pressing the minus or plus icon. Save the change to retain the change made. Options for volume settings are 25, 50, 75, and 100 percent. The default setting is 75 percent. Some institutions may allow caregivers to disable audible alarms.

- **Pulse beep volume —** Adjust the volume to the desired level by pressing the minus or plus icon. Save the change to retain the change made. Options for volume settings are OFF, 25, 50, 75, and 100 percent. The default setting is 50 percent.

- **Button click volume —** Adjust the volume to the desired level by pressing the minus or plus icon. Save the change to retain the change made. Options for volume settings are OFF, 25, 50, 75, and 100 percent. The default setting is 50 percent.

DISPLAY SETTINGS Menu

WARNING:

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

Note:

Caregivers may monitor the patient remotely. Reference *Using the Nurse Call Interface*, p. 5-16. For institutions allowing caregivers to turn off all audible alarms and minimize or disable backlight brightness, refrain from reducing both audible and visual alarms unless using a remote monitoring system. When using a remote monitoring system, caregivers should still remain vigilant, periodically assessing patients.

Use this menu to control monitoring system monitoring layout options, and screen brightness options.

Figure 4-12. DISPLAY SETTINGS Menu Options
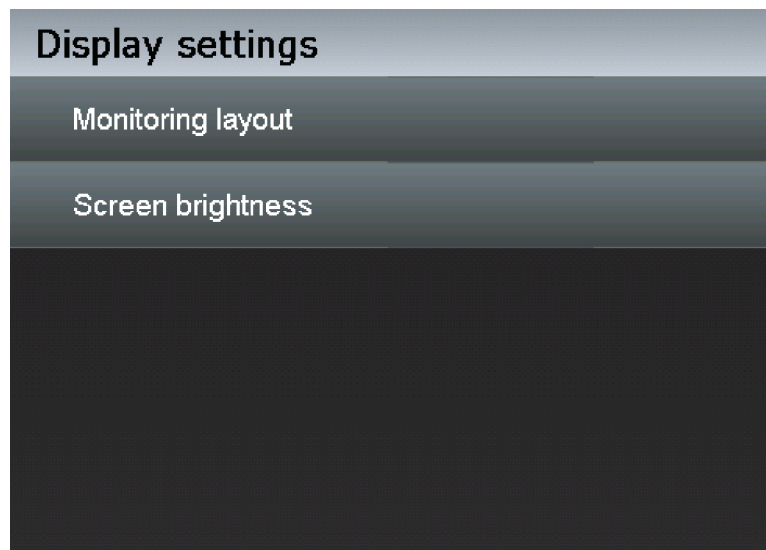
POX_30171_A

- **Monitoring Layout —** Select the desired monitoring screen layout from the available options: Pleth only, Trend only, Pleth and trend, or Blip layouts. The Pleth view is the default.

  a. **PLETH layout —** Access plethysmographic (pleth) waveform display view. Reference *Pleth View*, p. 4-35.

  b. **TREND layout —** Access trend data display view. Reference *Real-Time Trend (Trend) View*, p. 4-36.

  c. **PLETH and TREND layout —** Access a split screen containing both the plethysmographic (pleth) waveform and the trend data simultaneously. Reference *Combination Pleth and Trend View*, p. 4-40.

  d. **NUMBERS ONLY (BLIP) layout —** Access blip bar display view. Reference *Using the Blip (Numbers Only) View*, p. 4-42.

- **Screen brightness —** Adjust the screen brightness of the monitoring system screen to suit each individual situation. This option does not remain after power cycle, but returns to default brightness. Some institutions may allow caregivers to disable visual alarms by turning screen brightness OFF.

To adjust the backlight brightness

1. While in normal monitoring mode, press MENU.

2. Press DISPLAY SETTINGS.

3. Press SCREEN BRIGHTNESS.

4. Increment or decrement to obtain the desired backlight brightness.

Note:
 Any of the following conditions turns on the backlight if the backlight is dimmed:

- Pressing the monitoring screen

- Any alarm, as long as the WAKE DISPLAY ON ALARM is not set to OFF

5. Press SAVE CHANGES to save the selected setting.

MONITORING SETTINGS Menu

Use this menu to set the alarm mode, response mode, or institution time and date.

Figure 4-13. MONITORING SETTINGS Menu Options

POX_30188_B
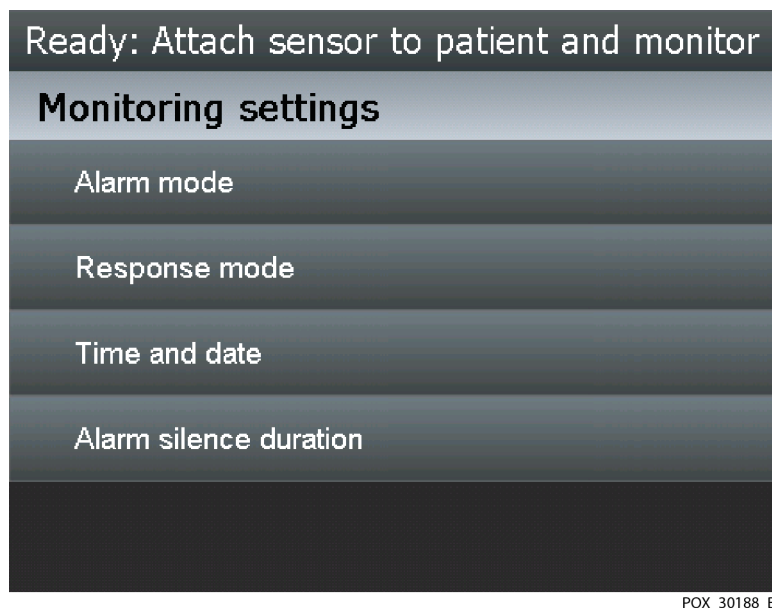
- **Alarm Mode —** Use to set the alarm settings for adults and pediatric patients or for neonates. The default alarm mode is ADULT, which does not have any indicator. Reference *To set the alarm mode*, p. 4-29.

    a. **Adult Alarm Mode —** This alarm mode establishes adult upper and lower default alarm threshold settings.

    b. **Neonate Alarm Mode —** This alarm mode establishes neonate upper and lower default alarm threshold settings. When users select the neonate alarm mode, the NEO indicator appears between the appropriate alarm limit threshold values.

- **Response Mode —** The response mode establishes the rate at which the monitoring system responds to changes in SpO2 saturation levels, but does not affect the calculation of pulse rate or recording of trend data, which occurs at one-second intervals. The response mode, however, may impact SPD alarm behavior. The default response mode is NORMAL. Reference *To set the response mode*, p. 4-30.

    a. **Normal Response Mode —** Responds to changes in blood oxygen saturation in five (5) to seven (7) seconds.

    b. **Fast Response Mode —** Responds to changes in blood oxygen saturation levels in two (2) to four(4) seconds. This can be particularly helpful for situations that require close monitoring. The Fast Response Mode icon in italics appears near the SpO2 value.

> **Note:**
> When in FAST response mode, the monitoring system may produce more SpO$_2$ and pulse rate alarms. Response mode may also impact SPD alarm behavior.

- **Time and Date —** Use to set time, date, and date format. Reference *To set the date and time*, p. 4-30.

- **Alarm Silence Duration —** Use to set total time allocated for silencing an alarm. Reference *To set the alarm silence duration*, p. 4-31.

To set the alarm mode

1. While in normal monitoring mode, press MENU.

2. Press MONITORING SETTINGS.

3. Press ALARM MODE.

4. Select NEONATE ALARM SETTINGS. The default setting is ADULT ALARM SETTINGS.

Figure 4-14. Selecting Adult and Pediatric vs. Neonate Alarm Mode
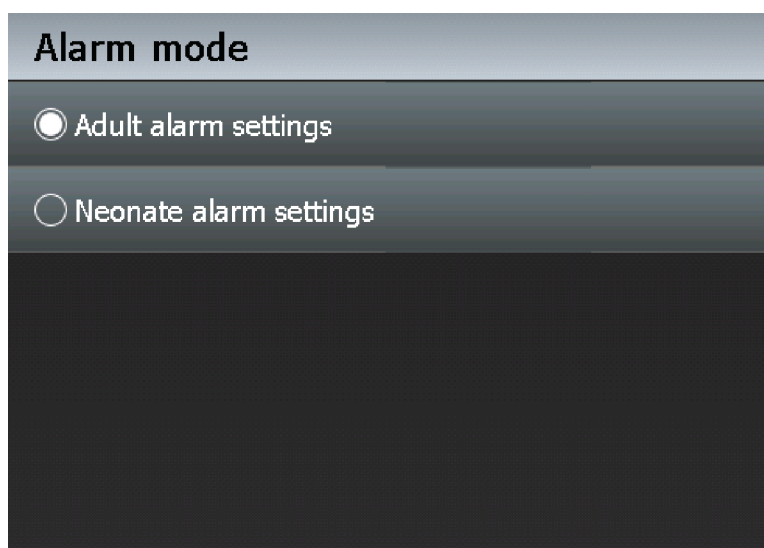
POX_30139_A

5. Press SAVE CHANGES to save the selected setting.

6. Confirm the NEO icon appears between upper and lower alarm limit threshold settings.

7. Use the same procedure to revert back to the ADULT ALARM SETTINGS, selecting that option in step 4 and confirming the NEO icon is no longer visible for step 6.

To set the response mode

1. While in normal monitoring mode, press MENU.

2. Press MONITORING SETTINGS.

3. Press RESPONSE MODE.

Figure 4-15. Response Mode Selection Screen
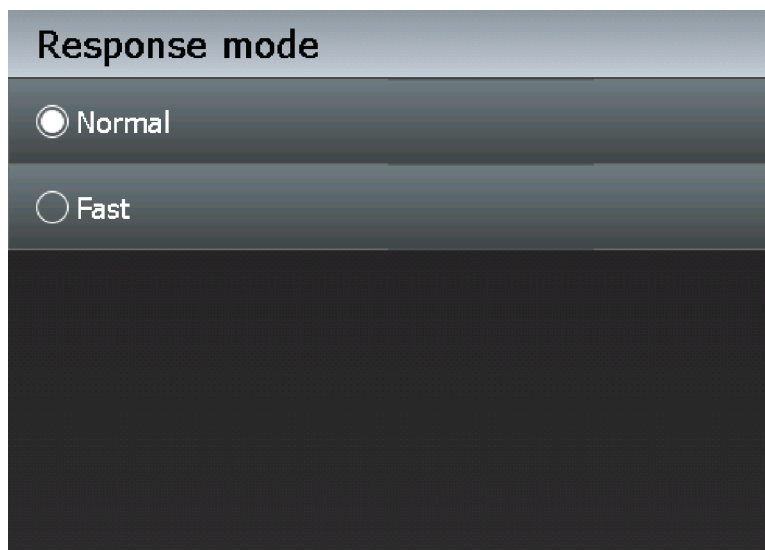
POX_30140_A

4. Select FAST response mode. The default setting is NORMAL response mode.

5. Press SAVE CHANGES to save the selected setting.

6. Ensure the FAST icon appears near the SpO2 value.

7. Use the same procedure to revert back to NORMAL, selecting that option for step 4 and ensuring the FAST icon is no longer visible for step 6.

To set the date and time

1. While in normal monitoring mode, press MENU.

2. Press MONITORING SETTINGS.

3. Press TIME AND DATE.

4. Select the desired field for the time or date.

Figure 4-16. Time and Date Selection Screen

POX_30181_A
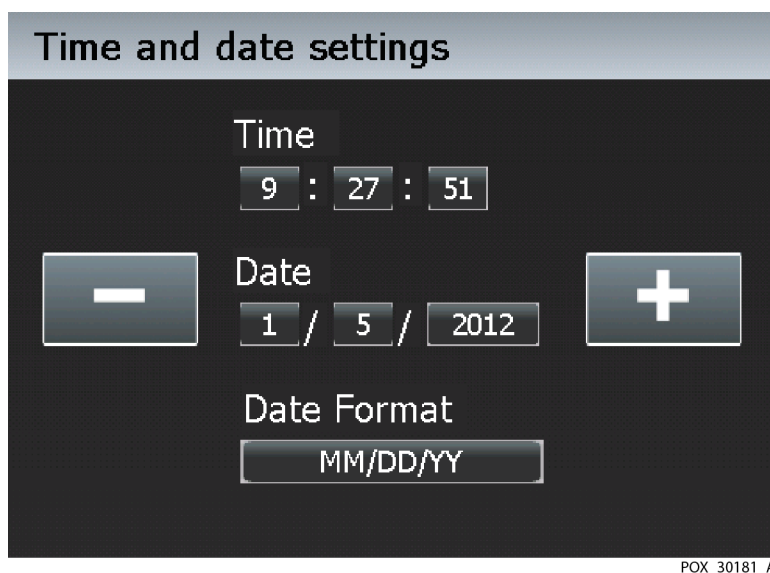
5. Increment or decrement to set the proper values.

6. Select the desired date format by repeatedly pressing the DATE FORMAT field to scroll through the various format options until locating the desired one. Options are the default DD/MM/YY format or the alternate MM/DD/YY or YY/MM/DD formats.

7. Press SAVE CHANGES to save the selected setting.

To set the alarm silence duration

1. While in normal monitoring mode, press MENU.

2. Press MONITORING SETTINGS.

3. Press ALARM SILENCE DURATION.

4. Select the desired number of seconds: 30, 60, 90, 120, or OFF.

Figure 4-17. Alarm Silence Duration Screen

Adjust alarm silence duration

○ 30 Seconds

○ 60 Seconds

○ 90 Seconds

◉ 120 Seconds

○ OFF

POX_30368_A
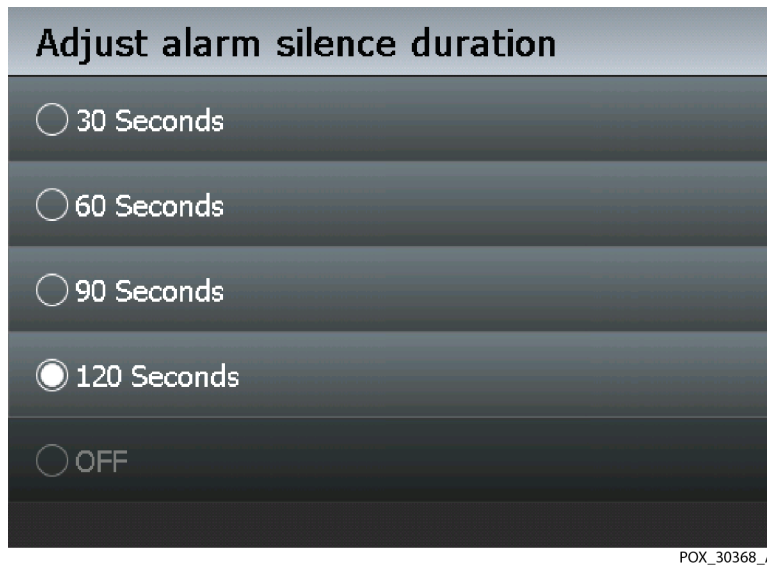
5. Press SAVE CHANGES to save the selected setting.

CONNECTIVITY SETTINGS Menu

Use this menu to select the proper communication protocol for attaching the monitoring system to external devices. The monitoring system provides a bedside monitor communication for interfacing with the listed protocols.

Figure 4-18. CONNECTIVITY SETTINGS Menu Options
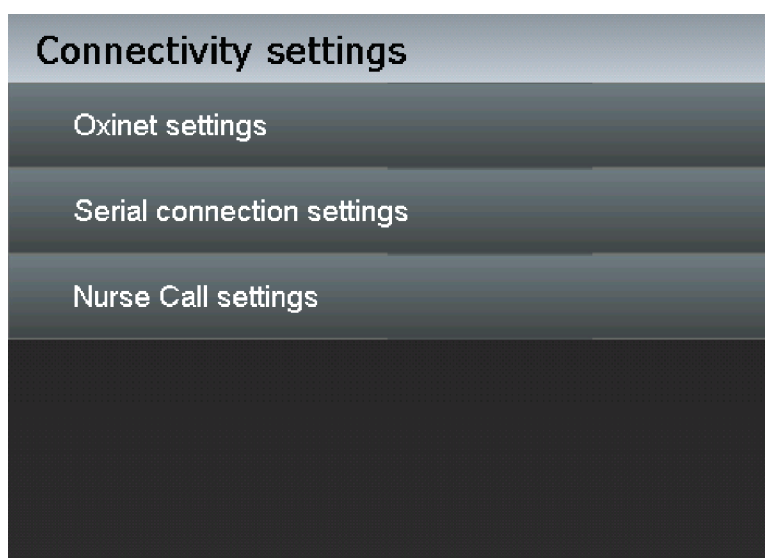
POX_30182_A

- **Oxinet —** Provides flexible connectivity to an Oxinet system. Options include variants for WLAN, LAN, and Serial, as well as Disconnected. Default is DISCONNECTED.

- **Serial —** Provides flexible connectivity to a serial port. Options include ASCII, Clinical, variants for SPDout, Philips, and OFF. Default is ASCII at 9600 baud.

Table 4-4. Serial Connectivity Protocols

Communication Protocol	Baud Rate
ASCII	9600 19200
Clinical	19200
Philips Vuelink	19200
SPDout	19200 115200

- **Nurse Call —** Provides connectivity to a Nurse Call connection. Ensure there is no audible alarm. Then, select either option. The default is normally high (+). Select *Normally* + to set voltage from +5 VDC to +12 VDC. Select *Normally* - to set voltage from -5 VDC to -12 VDC. Voltages switch polarity when the audible alarm sounds.

DATA EXPORT Menu

Use this menu to obtain the trend data history. This requires an external USB flash drive to export trend data. View the trend data file using any number of standard software packages to parse the data, review the data, and compile reports from the data.

ABOUT THE MONITOR Menu

Use this menu to obtain model number and firmware revision level information prior to contacting Covidien or a local Covidien representative.

- **Monitor Information —** This field contains the monitoring system model number and serial number.

- **Software Information —** This field contains the software version and current firmware revision running on the monitoring system.

- **Parameter Information —** This field contains the parameter name and number.

- **Network Information —** This field contains the LAN and WLAN IP addresses.

4.4.5 Monitoring Screen Layout Options

Select the preferred method of viewing real-time data. Reference *Monitoring Screen Selection*, p. 2-7. Selections last until power-cycle or until users manually select another monitoring screen from the monitoring layout options.

Figure 4-19. Monitoring Layout Options
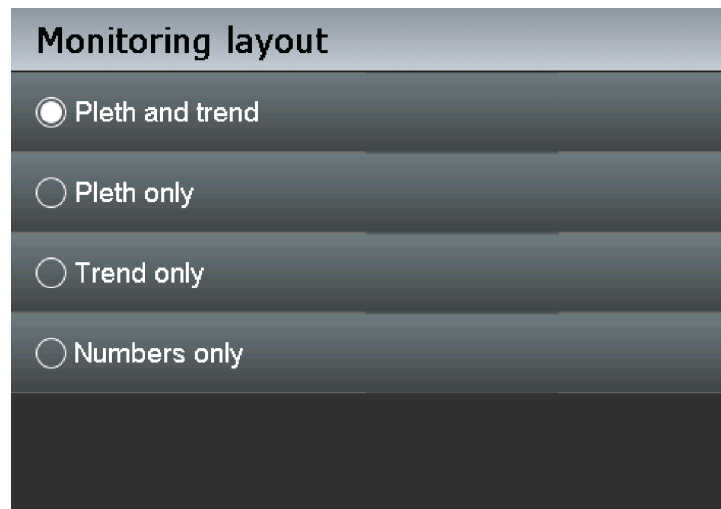
POX_30180_A

Pleth View

Use this monitoring screen for visual monitoring information in waveform. The plethysmographic (pleth) monitoring screen contains a "wiper bar" plethysmographic waveform. Plethysmographic waveforms with peak to peak amplitudes less than ten pulse amplitude units (PAUs) are associated. Reference *Theory of Operations*, p. 10-1, for a description of the pleth waveform. This view also reflects current measured SpO$_2$ and pulse rates and also indicates upper and lower limit settings. When the monitoring system is not attached to AC power, it runs on the internal battery. A battery fuel gauge indicates remaining internal battery charge.

- **SatSeconds™ parameter —** For mild or brief SpO$_2$ limit violations, use the SatSeconds parameter to reduce nuisance alarms. With the SatSeconds parameter enabled, the monitoring screen includes a circle icon and its setting. The SatSeconds alarm limit value appears just below the circle icon. When the SatSeconds parameter is enabled, the circle icon fills in the clockwise direction as the alarm management system detects SpO$_2$ readings outside of the limit setting. The circle icon empties in counterclockwise direction when SpO$_2$ readings are within limits. When the icon fills completely, a medium-priority alarm sounds. Reference *SatSeconds™Alarm Management Parameter Limits*, p. 4-18.

- **SPD parameter —** Use the SPD™ alert (SPD) parameter to detect patterns of desaturation in the SpO$_2$ trend in adults. Using the SPD™ Alert parameter also triggers the SatSeconds parameter. With the SPD parameter enabled, the monitoring screen includes both triangle and circle icons and their settings. The SPD alarm sensitivity value appears just below the triangle icon. When the SPD parameter is enabled, the triangle icon fills from bottom to top as desaturation patterns develop. The triangle icon empties from top to bottom as patterns dissipate. When the icon fills completely, a low-priority alarm sounds. The monitoring system will sound the SPD alarm sooner if the SPD alarm sensitivity is set to the default value of one (1). A less sensitive setting will result in less frequent alarms. Reference *OxiMax SPD™ Alert Parameter Limits*, p. 4-20.

Figure 4-20. Pleth Only View

POX_30172_B
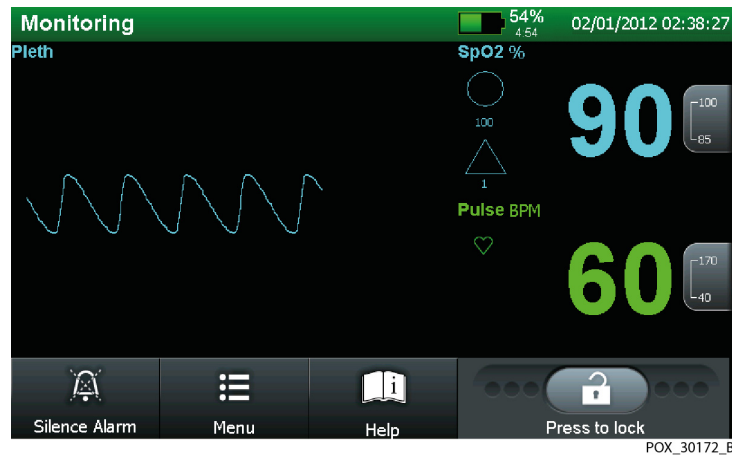
To select the pleth view

1. While in normal monitoring mode, press MENU.

2. Press DISPLAY SETTINGS.

3. Press MONITORING LAYOUT.

4. Select PLETH ONLY.

5. Press SAVE CHANGES to save the selected setting.

Real-Time Trend (Trend) View

Use this monitoring screen for visual monitoring information related to real-time trends. The trend data plots automatically update as the monitoring system calculates each new trend point, where the interval between calculations is based on the time scale selected. The real-time trend monitoring screen includes SpO2 and/or pulse rate trend data plots, current measured SpO2 and pulse rates. It also includes a battery fuel gauge if running on battery power. Each time the monitoring system detects a pulse, the heart icon flashes. Should the monitoring system detect corrupt trend data, it notifies the caregivers with a TREND DATA LOST message.

This view also reflects current measured SpO2 and pulse rates and also indicates upper and lower limit settings. When the monitoring system is not attached to AC power, it runs on the internal battery. A battery fuel gauge indicates remaining internal battery charge.

- **SatSeconds™ parameter —** For mild or brief SpO$_2$ limit violations, use the SatSeconds parameter to reduce nuisance alarms. With the SatSeconds parameter enabled, the monitoring screen includes a circle icon and its setting. The SatSeconds alarm limit value appears just below the circle icon. When the SatSeconds parameter is enabled, the circle icon fills in the clockwise direction as the alarm management system detects SpO$_2$ readings outside of the limit setting. The circle icon empties in counterclockwise direction when SpO$_2$ readings are within limits. When the icon fills completely, a medium-priority alarm sounds. Reference *SatSeconds™Alarm Management Parameter Limits*, p. 4-18.

- **SPD parameter —** Use the SPD™ alert (SPD) parameter to detect patterns of desaturation in the SpO$_2$ trend in adults. Using the SPD™ Alert parameter also triggers the SatSeconds parameter. With the SPD parameter enabled, the monitoring screen includes both triangle and circle icons and their settings. The SPD alarm sensitivity value appears just below the triangle icon. When the SPD parameter is enabled, the triangle icon fills from bottom to top as desaturation patterns develop. The triangle icon empties from top to bottom as patterns dissipate. When the icon fills completely, a low-priority alarm sounds. The monitoring system will sound the SPD alarm sooner if the SPD alarm sensitivity is set to the default value of one (1). A less sensitive setting will result in less frequent alarms. Reference *OxiMax SPD™ Alert Parameter Limits*, p. 4-20.

Isolate oxygenation (SpO$_2$) or pulse trend data or view them both together (SpO$_2$ + Pulse).

Figure 4-21. Real-time Trend Only View

POX_30174_B
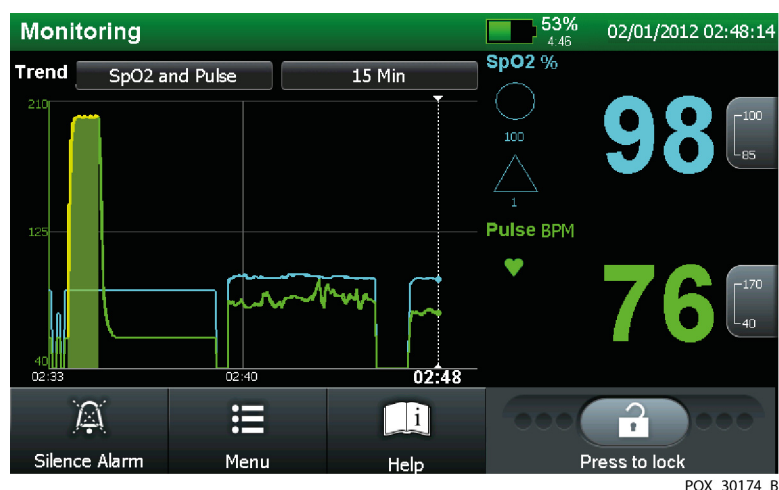
To select the trend view

1. While in normal monitoring mode, press MENU.

2. Press DISPLAY SETTINGS.

3. Press MONITORING LAYOUT.

4. Select the TREND ONLY option.

5. Press SAVE CHANGES to save the selected setting.

To select the type of trend data displayed

1. Follow the steps listed for selecting the trend monitoring screen.

2. Press the trend data time scale button. Reference *Monitoring Screen*, p. 2-4.

3. Select one of the SELECT TRENDS options. The default is to display SpO2 ONLY, but caregivers may choose from SpO2 ONLY, PULSE ONLY, and SpO2 AND PULSE.

Figure 4-22. Select Trends Options
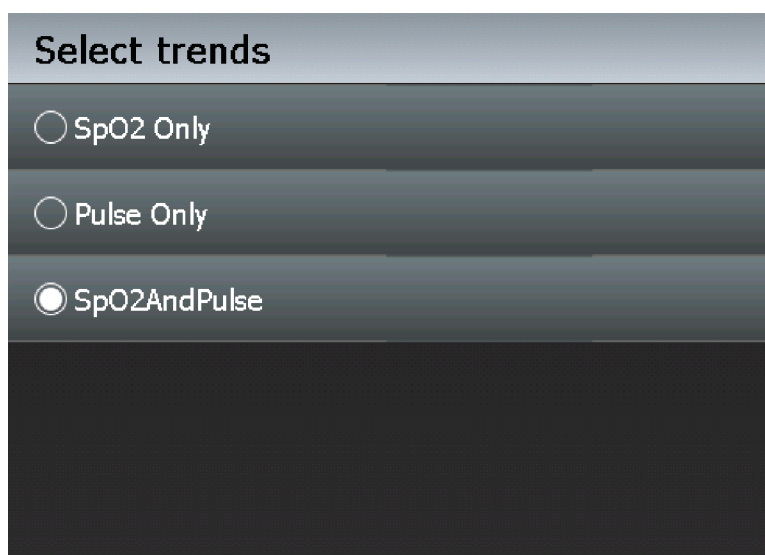
POX_30183_A

- **Dual (SpO2 and pulse) option —** View oxygenation (SpO2) and pulse (PULSE) trend data simultaneously for a specified length of time.

Figure 4-23. Dual (SpO2 and pulse) Trend Data, 15 minute
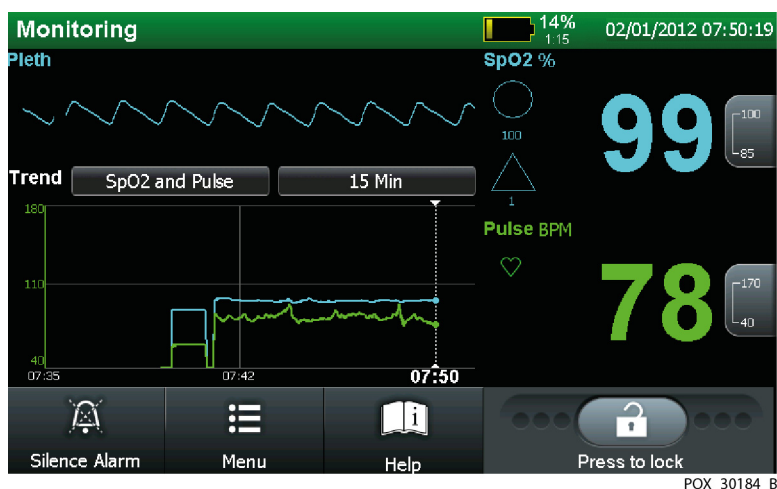
POX_30184_B

- **SpO2 only option —** Isolate oxygenation (SpO2) trend data for a specified length of time. Dashed yellow lines indicate alarm limits.

Figure 4-24. SpO2 Only Trend Data, 30 minute
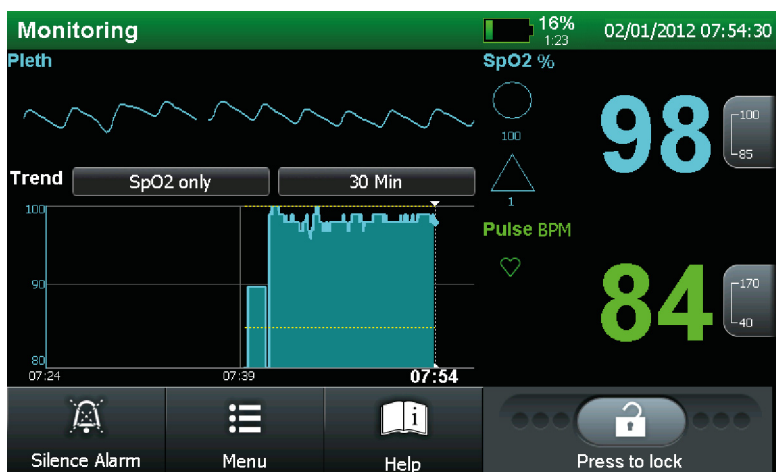
POX_30185_B

- **Pulse rate only option —** Isolate pulse (PR) trend data for a specified length of time. Dashed yellow lines indicate alarm limits.

Figure 4-25. Pulse Only Trend Data, 30 minute
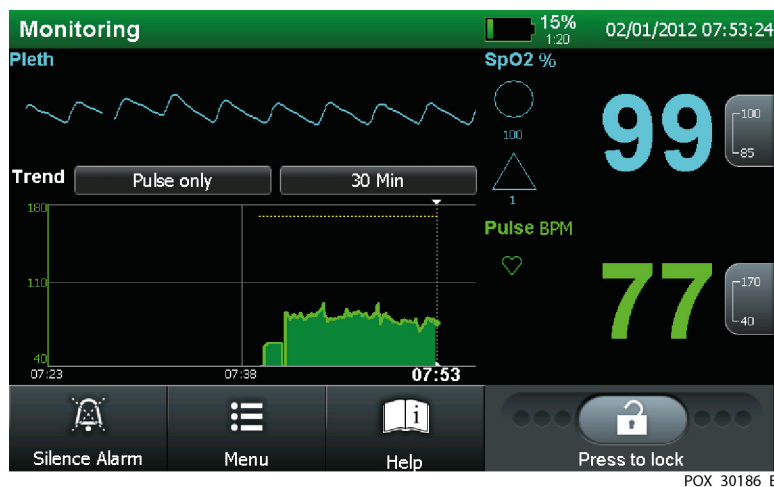
POX_30186_B

To set up the trend time scale

1. Follow the steps listed for selecting the trend monitoring screen.

2. Press the time button to the far right of the trend field.

3. Select the desired trend time scale. The options are 15 minutes, 30 minutes, 1 hour, 2 hours, 4 hours, 8 hours, 12 hours, 24 hours, 36 hours, and 48 hours. The default is 1 hour.

Combination Pleth and Trend View

Use this default monitoring screen for visual monitoring information related to both pleth and real-time trends.

The **pleth** field contains a "wiper bar" plethysmographic waveform. Plethysmographic waveforms with peak to peak amplitudes less than ten pulse amplitude units (PAUs) are associated. Reference *Theory of Operations*, p. 10-1, for a description of the pleth waveform.

The real-time **trend** field can include SpO_2 and/or pulse rate trend data plots, depending on user preference. The default is for viewing both SpO_2 and pulse rate trend data plots.The trend data plots automatically update as the monitoring system calculates each new trend point, where the interval between calculations is based on the time scale selected.

This view also reflects current measured SpO_2 and pulse rates and also indicates upper and lower limit settings. When the monitoring system is not

attached to AC power, it runs on the internal battery. A battery fuel gauge indicates remaining internal battery charge.

- **SatSeconds™ parameter —** For mild or brief SpO2 limit violations, use the SatSeconds parameter to reduce nuisance alarms. With the SatSeconds parameter enabled, the monitoring screen includes a circle icon and its setting. The SatSeconds alarm limit value appears just below the circle icon. When the SatSeconds parameter is enabled, the circle icon fills in the clockwise direction as the alarm management system detects SpO2 readings outside of the limit setting. The circle icon empties in counterclockwise direction when SpO2 readings are within limits. When the icon fills completely, a medium-priority alarm sounds. Reference *SatSeconds™Alarm Management Parameter Limits*, p. 4-18.

- **SPD parameter —** Use the SPD™ alert (SPD) parameter to detect patterns of desaturation in the SpO2 trend in adults. Using the SPD™ Alert parameter also triggers the SatSeconds parameter. With the SPD parameter enabled, the monitoring screen includes both triangle and circle icons and their settings. The SPD alarm sensitivity value appears just below the triangle icon. When the SPD parameter is enabled, the triangle icon fills from bottom to top as desaturation patterns develop. The triangle icon empties from top to bottom as patterns dissipate. When the icon fills completely, a low-priority alarm sounds. The monitoring system will sound the SPD alarm sooner if the SPD alarm sensitivity is set to the default value of one (1). A less sensitive setting will result in less frequent alarms. Reference *OxiMax SPD™ Alert Parameter Limits*, p. 4-20.

Figure 4-26. Combination Pleth and Trend View
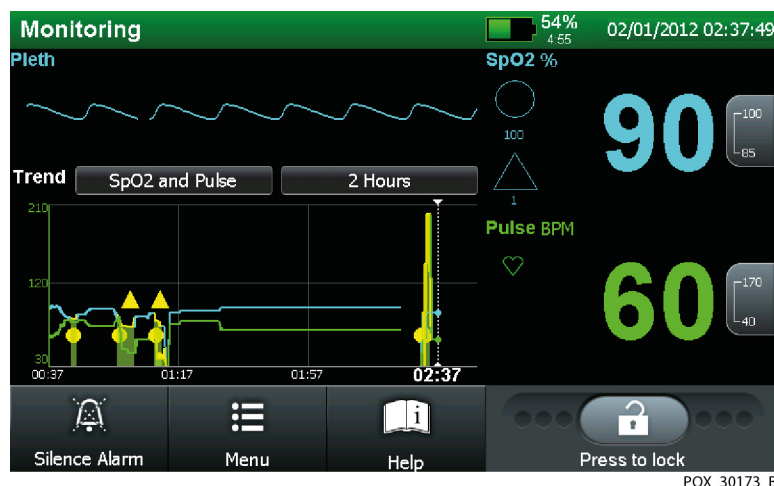
POX_30173_B

To select the pleth and trend view

1. While in normal monitoring mode, press MENU.

2. Press DISPLAY SETTINGS.

3. Press MONITORING LAYOUT.

4. Select the PLETH AND TREND option.

✅ 5. Press SAVE CHANGES to save the selected setting.

Using the Blip (Numbers Only) View

Use this monitoring screen for visual monitoring information in blip bar (numbers only) form. This view also reflects current measured SpO$_2$ and pulse rates and also indicates upper and lower limit settings. When the monitoring system is not attached to AC power, it runs on the internal battery. A battery fuel gauge indicates remaining internal battery charge.

- **SatSeconds™ parameter —** For mild or brief SpO$_2$ limit violations, use the SatSeconds parameter to reduce nuisance alarms. With the SatSeconds parameter enabled, the monitoring screen includes a circle icon and its setting. The SatSeconds alarm limit value appears just below the circle icon. When the SatSeconds parameter is enabled, the circle icon fills in the clockwise direction as the alarm management system detects SpO$_2$ readings outside of the limit setting. The circle icon empties in counterclockwise direction when SpO$_2$ readings are within limits. When the icon fills completely, a medium-priority alarm sounds. Reference *SatSeconds™Alarm Management Parameter Limits*, p. 4-18.

- **SPD parameter —** Use the SPD™ alert (SPD) parameter to detect patterns of desaturation in the SpO$_2$ trend in adults. Using the SPD™ Alert parameter also triggers the SatSeconds parameter. With the SPD parameter enabled, the monitoring screen includes both triangle and circle icons and their settings. The SPD alarm sensitivity value appears just below the triangle icon. When the SPD parameter is enabled, the triangle icon fills from bottom to top as desaturation patterns develop. The triangle icon empties from top to bottom as patterns dissipate. When the icon fills completely, a low-priority alarm sounds. The monitoring system will sound the SPD alarm sooner if the SPD alarm sensitivity is set to the default value of one (1). A less sensitive setting will result in less frequent alarms. Reference *OxiMax SPD™ Alert Parameter Limits*, p. 4-20.

Figure 4-27. Blip (Numbers Only) View

POX_30175_B
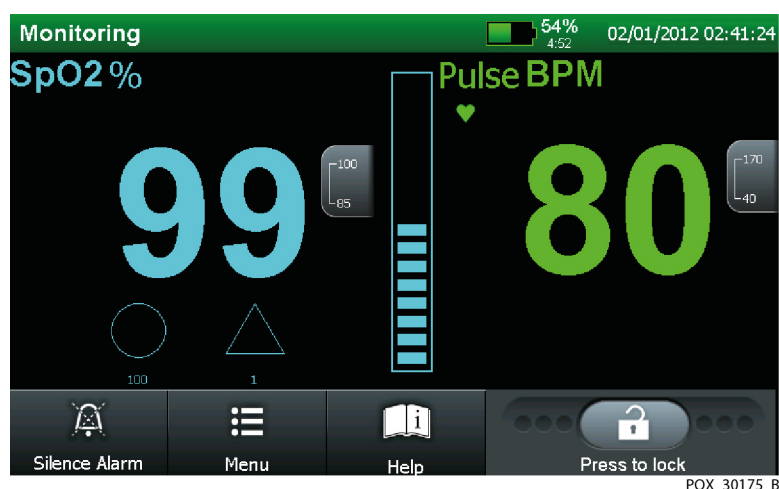
To select the blip (numbers only) view

1. While in normal monitoring mode, press MENU.

2. Press DISPLAY SETTINGS.

3. Press MONITORING LAYOUT.

4. Select the PLETH AND TREND option.

5. Press SAVE CHANGES to save the selected setting.

4.4.6 Alarm Management and Status Messages

The status field at the top of the monitoring screen contains information describing overall monitoring system status and any active alarms. If multiple alarms occur during user interaction with a menu or dialog box, the list of alarm messages collapses to a single line listing the total number of alarms currently active. Cancellation or dismissal of an alarm message requires user intervention, whereas status messages do not. The message identifies the alarm or status. If it is an alarm, it offers users a MORE INFO button, which when pressed, provides detailed data and a means to correct the situation or clear the alarm.

The monitoring system comes with factory default alarm limit thresholds for adult-pediatric patients and for neonate patients. Reference *Factory Default Alarm Limit Settings and Parameters*, p. 4-16. Institutions may opt for setting institutional default settings to override the factory defaults. In addition, users

may also temporarily change alarm limits. Any temporary changes to alarm limit thresholds revert back to default alarm limit settings after power-off. Reference *Temporary Alarm Limits*, p. 4-17.

Note:
There are no delays associated with any alarm conditions that exceed ten (10) seconds unless otherwise specified.

Message Types

Messages begin at the top of the status field and continue to tile downward until reaching three lines.

Note:
Not all high-priority alarms have a DISMISS option. If this is the case, it is a serious error and requires the user to resolve the issue or return the monitoring system to Covidien or a qualified service technician.

- **User prompt or status messages —** User prompts requiring user intervention appear as white text on a grey bar. The READY status message is the most common of this type. Status messages require no user intervention and appear as white text on a green background. The MONITORING status message is the most common of this type.

Figure 4-28. Sample user prompt message: READY

Ready: Attach sensor to patient and monitor 16% 1:27 02/01/2012 07:57:05

POX_30326_A

Figure 4-29. Sample status message: MONITORING

Monitoring 16% 1:23 02/01/2012 07:54:30

POX_30327_A

- **High priority alarm messages —** High priority alarms take precedence over any other alarm messages, so appear first. If more than one high priority alarm occurs within quick succession, alarm messages appear in order of occurrence. High priority alarms appear in a flashing, red bar in the status field.

Figure 4-30. High priority alarm: BATTERY CRITICALLY LOW

Battery Critically Low More info 4% 0:21 02/15/2012 03:11:33

POX_30328_A

- **Medium priority alarm messages —** Medium priority alarms take precedence over low priority alarm messages. If more than one medium priority alarm occurs within quick succession, alarm messages appear in order of occurrence. Medium priority alarms appear in a flashing, yellow bar in the status field.

Figure 4-31. Medium priority alarm: SpO2 LOW

POX_30329_A

- **Low priority alarm messages —** Low priority alarms take precedence over user prompt and status messages. If more than one low priority alarm occurs within quick succession, alarm messages appear in order of occurrence. Low priority alarms appear in a steady, yellow bar in the status field.

Figure 4-32. Low priority alarm: SENSOR OFF

POX_30330_A

To correct a user prompt

1. Read the recommended action portion of the message.

2. Take the recommended action. The monitoring system triggers off the corrective action and automatically clears the message.

3. For multiple messages, press NEXT ALARM to view each alarm in order of priority.

To correct an alarm message

1. Press the MORE INFO button for the top, most important alarm message.

2. Read the alarm message description.

3. Take the recommended action.

4. Clear the alarm message by pressing the CANCEL or DISMISS button.

Limit Threshold Violation Indicators

The monitoring system reports real-time patient data. If that data falls outside the alarm limit thresholds, a threshold violation occurs. This triggers an alarm condition, resulting in a visual alarm. Reference *Visual Alarms*, p. 2-12. An audible alarm also results, unless a SILENCE ALARM (Audio Paused) or an AUDIO OFF condition exists. Reference *Audible Alarm Management*, p. 4-46.

- **SpO2 —** The monitoring system reports real-time blood oxygen saturation that falls within the upper and lower limit thresholds as a cyan value on a black background. If a threshold violation occurs, the value turns black on a yellow background.

- **Pulse (BPM) —** The monitoring system reports real-time pulsations that fall within the upper and lower limit thresholds as a green value on a black background. If a threshold violation occurs, the value turns black on a yellow background.

Figure 4-33. Sample Alarm Limit Violations

POX_30323_A
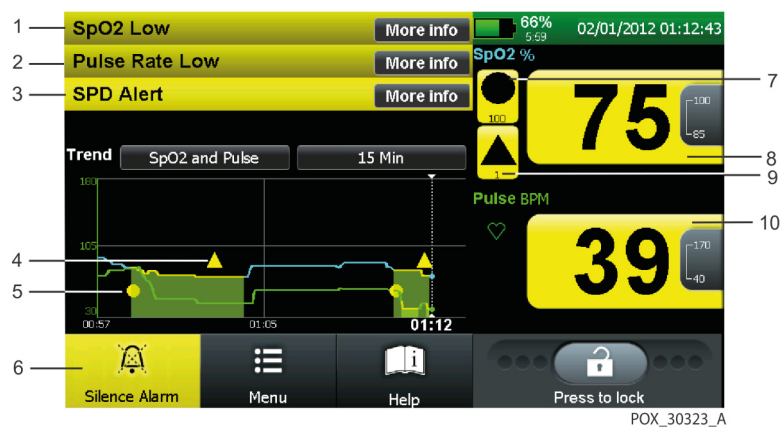
1	Saturation below lower threshold	6	Silence Alarm icon, not active
2	Pulse rate below lower threshold	7	SatSeconds alarm present
3	Patterns of desaturation present	8	Current saturation value, low
4	SPD Alert alarm icon	9	SPD Alert alarm present
5	SatSeconds alarm icon	10	Current pulse rate value, low

4.4.7 Audible Alarm Management

⚠ **WARNING:**
Do not silence or disable audible alarms or decrease the volume of the audible alarm if patient safety could be compromised. Do not dim or disable visual alarms if patient safety could be compromised.

Audible indicators include pitched tones and beeps. Audible alarms vary, depending on the priority of the alarm. Caregivers may choose to silence alarms by pressing ALARM SILENCE. For any alarm condition still active for more than two (2) minutes, the monitoring system will increase the urgency level of the audible alarm signal by increasing its frequency.

Note:

Caregivers may monitor the patient remotely. Reference *Using the Nurse Call Interface*, p. 5-16. For institutions allowing caregivers to turn off all audible alarms and minimize or disable backlight brightness, refrain from reducing both audible and visual alarms unless using a remote monitoring system. When using a remote monitoring system, caregivers should still remain vigilant, periodically assessing patients.

SILENCE ALARM

The factory default setting provides both visual and audible alarms for alarm conditions. Institutions may choose to temporarily silence audible alarms and rely on visual alarms. To do so, caregivers may press the SILENCE ALARM icon. The default duration for SILENCE ALARM is two (2) minutes. To alter this duration, a qualified service technician must set an alternate institutional default setting in the Service Mode.

SILENCE ALARM remains available at all times. Reference *Introduction to Menu Options*, p. 4-10.

- **Not active —** If SILENCE ALARM is not active, the SILENCE ALARM icon remains white on a grey background.

- **Active —** If SILENCE ALARM is active, the SILENCE ALARM icon turns yellow on a grey background and posts the time remaining. A yellow alarm icon above the alarm limits indicates an active SILENCE ALARM status.

ALARM AUDIO OFF

The factory default setting provides both visual and audible alarms for alarm conditions. Institutions may choose to turn off audible alarms and rely on visual alarms. To allow caregivers to turn off audible alarms, a qualified service technician must alter this alarm system setting in Service Mode.

- **Not active —** If ALARM AUDIO OFF is not active, it does not appear on the monitoring screen. Instead, the SILENCE ALARM icon remains white on a grey background.
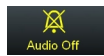
- **Active —** If ALARM AUDIO OFF is active, the AUDIO OFF icon replaces the SILENCE ALARM icon. The AUDIO OFF icon is yellow on a grey background and posts the time remaining. A red alarm icon above the alarm limits indicates an active ALARM AUDIO OFF status.

Note:

Caregivers may turn off audio SPD alerts in addition to ALARM AUDIO OFF. This also requires access to the Service Mode by a qualified service technician.

Note:

For institutions preferring visual alarms only, yet allowing caregivers to minimize or disable backlight brightness, it may prove useful to have a qualified service technician verify the WAKE DISPLAY ON ALARM option remains enabled.

4.4.8 Visual Alarm Management

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 factory default setting provides both visual and audible alarms for alarm conditions. Institutions may choose to allow caregivers to turn off or dim the backlight, thus also dimming visual alarms. The factory default is to enable the WAKE DISPLAY ON ALARM option. The monitoring system then returns to full brightness during an alarm condition. Reference *DISPLAY SETTINGS Menu*, p. 4-26.

Note:

Caregivers may monitor the patient remotely. Reference *Using the Nurse Call Interface*, p. 5-16. For institutions allowing caregivers to turn off all audible alarms and minimize or disable visual alarms or backlight brightness, refrain from reducing both audible and visual alarms unless using a remote monitoring system. When using a remote monitoring system, caregivers should still remain vigilant, periodically assessing patients.

Note:

For institutions preferring visual alarms only, yet allowing caregivers to minimize or disable backlight brightness, have a qualified service technician verify the WAKE DISPLAY ON ALARM option remains enabled.

4.4.9 HELP Option

To access on-screen help topics

1. Press HELP. The appropriate help dialog window appears.

2. Review the help dialog box for guidance.

3. Press EXIT to return to normal monitoring.

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5 Trend Data Access

5.1 Overview

This chapter contains information for accessing patient trend data obtained with the Nellcor™ Bedside Respiratory Patient Monitoring System. Trend data can be viewed anytime patient trends exist.

5.2 Trend Data Management

⚠ **WARNING:**
In the case of a monitoring system failure, reset the monitoring system and ensure it is functioning correctly prior to usage.

5.2.1 Trend Data Basics

The monitoring system stores trend data readings in memory every second, whether monitoring a patient or not, and retains this information even during total loss of power. It can store up to 48 hours of trend data, which is available for download when desired.

Users may view real-time and historical trend data on the monitoring screen. Users may also control the type and amount of visible trend data for a selected span of time. All trend data appear in a graphical format except the 20 and 40 second trends, which appear in tabular format. The default setting is 15 minutes of trend data.

Users may also choose to download trend data in a digital file, print it directly to a printer or PC, or clear trend data information.

The monitoring system stores trend data readings in memory every second, whether monitoring a patient or not. It can store up to 48 hours of trend data, which is available for download when desired. Reference *Real-time Trend Data*, p. 5-2. Reference *Historical Trend Data*, p. 5-7. Should the monitoring system detect corrupt trend data, it notifies the caregivers with a TREND DATA LOST message.

Note:
Trend memory always contains the most recent 48 hours of data, with newly collected data overwriting the oldest data on a rolling basis. The monitoring system continues to record data points as long as it is powered on, with "blank" data points collected if no recommended sensor is connected to the monitoring system or patient. "Blank" data overwrites older patient data if the memory is full. To save old patient data, turn the monitoring system off when not monitoring a patient and download the trend memory before it fills up and overwrites the old data with new data (or "blank" data).

5.2.2 Real-time Trend Data

Users may view the trend monitoring screen at any time. Reference *Real-Time Trend (Trend) View*, p. 4-36. Users may choose to view on-screen trend data in a tabular or graphical format. Users may also choose to view streaming trend data remotely.

- **Graphical views —** Provide access to between 15 minutes and 48 hours of continuous trend data.

- **Tabular views —** Provide access to 20 or 40 seconds of continuous trend data.

- **Streaming real-time trending —** Provides real-time access to trend data via a data port. Reference *Data Port Connectivity*, p. 5-9.

The default one-hour SpO2 and Pulse trend view provides 60 minutes of trend information. The most recent data readings are to the far right side of the graph. The numbers below each graph indicate the recording time as a vertical dotted line on the monitoring screen. Reference *Real-time Trend Data*, p. 5-2.

On-screen trend views provide patient information for each event, as well as any relevant alarm status information in the form of a status code in the far right column.

Table 5-1. On-Screen Status Code Definitions

Code	Definition
PT	Pulse Timeout
SD	Sensor Disconnect
SF	Sensor Failure
SO	Sensor Off
SPD	SPD Alert

Graphical Trend View

The graphical trend view provides users with data from 15 minutes to 48 hours of continuous trend data.

Figure 5-1. Graphical Trend Data Monitoring History Components

POX_30348_A
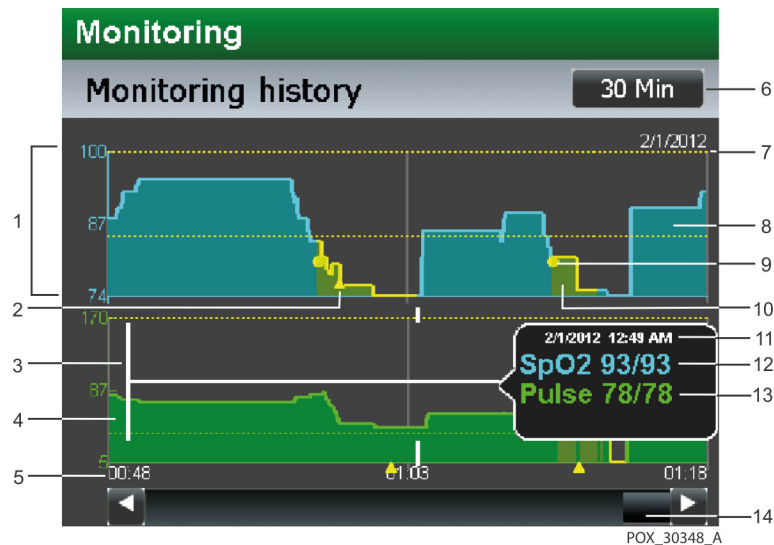
1	Graph y-axis contains signal amplitude values
2	Yellow triangle icon for period of SPD alert
3	White vertical line to indicate current time
4	Green pulse trend data for specified time scale
5	Graph x-axis contains time divisions, depending on specified time scale
6	Trend scale button for adjusting time scale to view more or less data
7	Dashed horizontal yellow lines for upper and lower thresholds
8	Cyan SpO2 trend data for specified time scale
9	Yellow circle icon for period of SatSeconds alarm
10	Yellow fill for period of limit threshold violation
11	Pop-up date and time stamp for identified moment
12	Pop-up SpO2 high and low reading for identified moment
13	Pop-up pulse high and low reading for identified moment
14	Scroll bar for access to additional trend data

Tabular Trend View

The tabular trend view provides users with data from 20 to 40 seconds of continuous trend data in a tabular format.

Figure 5-2. Tabular trend data components
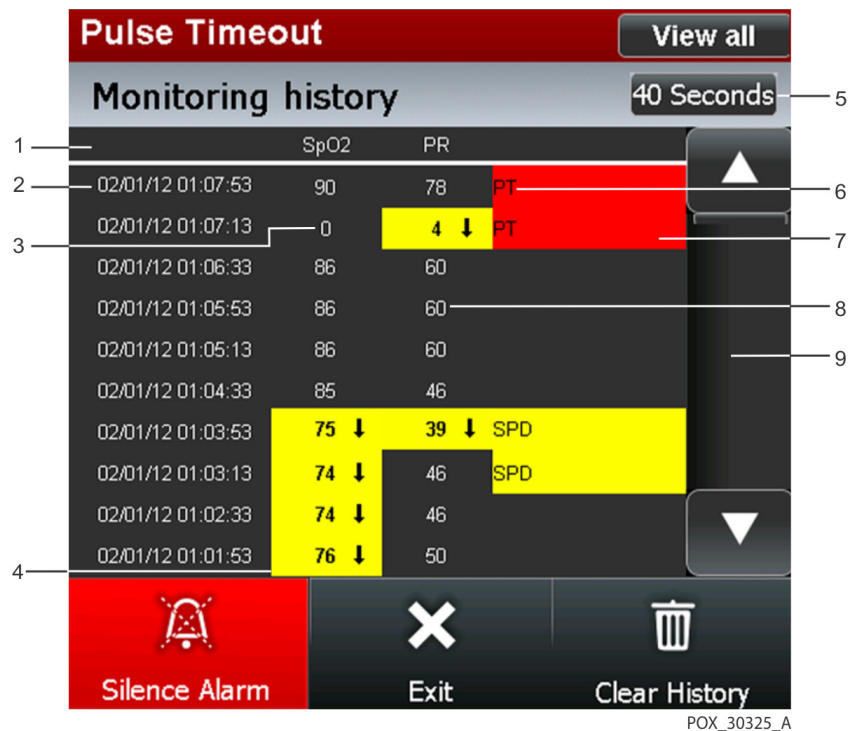
POX_30325_A

1   Column heading(s)
2   Time and date stamp
3   Zero indicates missing trend data
4   Yellow highlight, indicating an upper or lower limit threshold violation
5   Trend scale button for adjusting time scale to select 20 or 40 second view
6   Status code, indicating an alarm condition
7   Red highlight, indicating a high priority alarm
8   Trend data
9   Vertical scroll bar for access to additional trend data

Streaming Real-Time Trending

Real-time data is continuously sent to the DB-15 data port for streaming to a host system or serial printer. Obtain patient data through the DB-15 data port by connecting the monitoring system data port to a host system or serial printer. During data transmission to a host system or serial printer, a new line of data appears every second. Column headings appear or print after every 25 lines, or if one of the values in the column heading changes. Readings appear at one-second intervals.

Figure 5-3. Sample Real-Time Data Output

POX_30331_A

1	Data Source	7	Column Headings
2	Time Stamp	8	Response Mode
3	Firmware Version	9	Data Column Headings
4	Alarm Mode	10	Patient Data
5	SatSeconds Alarm Limit Setting	11	Operating Status
6	Alarm Limits		

- **Data Source —** The model number of the monitoring system.

- **Firmware Version —** The next data field shows the firmware level and a firmware verification number (CRC: XXXX). Neither of these numbers should change during normal operation.

Note:
The firmware revision may change if a qualified service provider upgrades the monitoring system.

- **Alarm Mode —** The first field of the second line identifies the ADULT or NEONATE alarm mode.

- **Column Headings —** Every 25th line of the data output consists of a column heading. A column heading appears whenever the value within a column heading changes. The example above shows three distinct column heading sets. Starting at the top row, there are 25 lines before the second row of column headings print. The third row of column headings in the above figure appear when the operator changes the SpO2 lower alarm limit from 85 percent to 80 percent.

- **Alarm Limits —** The last data field in the top line indicates the upper and the lower alarm limits for SpO2 and for the pulse rate (PR limit). In the example, the lower alarm limit for SpO2 is 85% and the upper alarm limit is 100%. Pulse Rate alarm limits are 40 and 170 BPM. The SatSeconds alarm limit (100SAT-S) indicates the SatSeconds alarm setting. In this example, the SatSeconds alarm is set to 100.

- **Response Mode —** The second field of the second line identifies the SatSeconds alarm limit and SpO2 response (NORMAL or FAST) mode. The response mode may impact the SPD alarm behavior.

- **Data Column Headings —** Actual column headings are in the last row of the column heading line.

  a. **Patient data —** Presented in the chart from left to right.

    - Time the patient data was recorded

    - Current %SpO2 value

    - Current Pulse Rate (BPM)

    - Current Pulse Amplitude (PA)

    - Operating status of the monitoring system

  a. **Time —** The Time column shows the value of the real-time clock.

  b. **Trend Data —** Parameter values appear directly beneath the heading for each parameter. In this example, the %SpO2 is 100 and the pulse rate is 190

beats per minute. The "*" next to the 190 indicates that 190 beats per minute is outside of the alarm limits, indicated in the top row, for pulse rate. If no data for a parameter is available, three dashes [- - -] appear. PA represents the pulse amplitude value, in which the number can range from 0 to 254. There are no alarm parameters for this value. It can be used for trending information as an indication of a change in pulse volume, relative pulse strength, or circulation.

c. **Operating Status —** The Status column indicates alarm conditions and operating status of the monitoring system. In this example, "PH" (Pulse High) indicates the pulse rate upper alarm limit has been exceeded. As many as four codes can appear at one time in the Status column.

Table 5-2. Status Code Definitions

Code	Definition
AO	Alarm Off
AS	Alarm Silence
BU	Battery in Use
LB	Low Battery
LM	Loss of Pulse with Patient Motion
LP	Loss of Pulse
ID	Patient Motion Detected
MO	Patient Motion
PH	Pulse Rate Upper Limit Alarm
PL	Pulse Rate Lower Limit Alarm
PS	Pulse Search
SH	Saturation Upper Limit Alarm
SL	Saturation Lower Limit Alarm

5.2.3 Historical Trend Data

Obtaining historical trend data output requires connectivity to either the RJ-45 port or the USB port. Reference *Data Port Connectivity*, p. 5-9.

Historical Trend Data Output

Obtain historical trend data and export it to a digital file, then parse that data into a spreadsheet or document. Reference *To export trend data*, p. 5-15.

Figure 5-4. Sample Historical Data Export

Time Stamp	SpO2 Max	SpO2 Min	SpO2 LL	SpO2 UL	Pulse Max	Pulse Min	Pulse LL	Pulse UL	RR Max	RR Min	RR LL	RR UL	SatSec Min	SatSec Max	SatSec Limit	SPD Max	SPD Min	SPD Limit	Alarms	%Mod Max	%Mod Min	Interval	First Sample
1/17/2012 11:49	0	0	85	100	0	0	40	170	0	0	8	28	0	0	0	0	0	0	0	0	0	1	255
1/17/2012 11:49	0	0	85	100	0	0	40	170	0	0	8	28	0	0	0	0	0	0	0	0	0	1	0
1/17/2012 11:50	0	0	85	100	0	0	40	170	0	0	8	28	0	0	0	0	0	0	1024	0	0	1	0
1/17/2012 11:50	0	0	85	100	0	0	40	170	0	0	8	28	0	0	0	0	0	0	1024	0.4	0.4	2	0
1/17/2012 11:50	0	0	85	100	0	0	40	170	0	0	8	28	0	0	0	0	0	0	1024	1.1	1.1	1	0
1/17/2012 11:50	0	0	85	100	0	0	40	170	0	0	8	28	0	0	0	0	0	0	1024	25.5	25.5	1	0
1/17/2012 11:50	0	0	85	100	0	0	40	170	0	0	8	28	0	0	0	0	0	0	1024	25.5	25.5	1	0
1/17/2012 11:50	0	0	85	100	0	0	40	170	0	0	8	28	0	0	0	0	0	0	1024	25.5	25.5	1	0
1/17/2012 11:50	0	0	85	100	0	0	40	170	0	0	8	28	0	0	0	0	0	0	1024	25.5	25.5	1	0
1/17/2012 11:50	0	0	85	100	0	0	40	170	0	0	8	28	0	0	0	0	0	0	1024	18.1	18.1	1	0
1/17/2012 11:50	0	0	85	100	0	0	40	170	0	0	8	28	0	0	0	0	0	0	1024	12.9	12.9	1	0
1/17/2012 11:50	0	0	85	100	0	0	40	170	0	0	8	28	0	0	0	0	0	0	1024	5.9	5.9	1	0
1/17/2012 11:50	0	0	85	100	0	0	40	170	0	0	8	28	0	0	0	0	0	0	1024	3.2	3.2	1	0
1/17/2012 11:50	0	0	85	100	0	0	40	170	0	0	8	28	0	0	0	0	0	0	1024	2.6	2.6	1	0
1/17/2012 11:50	0	0	85	100	0	0	40	170	0	0	8	28	0	0	0	0	0	0	1024	2.7	2.7	1	0
1/17/2012 11:50	0	0	85	100	0	0	40	170	0	0	8	28	0	0	0	0	0	0	1024	2.8	2.8	1	0
1/17/2012 11:50	0	0	85	100	0	0	40	170	0	0	8	28	0	0	0	0	0	0	0	2.9	2.9	1	0
1/17/2012 11:51	82	82	85	100	0	0	40	170	0	0	8	28	18	18	0	0	0	0	16	3	3	1	0
1/17/2012 11:51	81	81	85	100	0	0	40	170	0	0	8	28	21	21	0	0	0	0	16	5.4	5.4	1	0
1/17/2012 11:51	79	79	85	100	0	0	40	170	0	0	8	28	25	25	0	0	0	0	16	11.1	11.1	1	0
1/17/2012 11:51	79	79	85	100	0	0	40	170	0	0	8	28	31	31	0	0	0	0	16	11	11	1	0
1/17/2012 11:51	80	80	85	100	0	0	40	170	0	0	8	28	37	37	0	0	0	0	16	7.9	7.9	1	0
1/17/2012 11:52	80	80	85	100	0	0	40	170	0	0	8	28	42	42	0	0	0	0	16	23.6	23.6	1	0
1/17/2012 11:52	80	80	85	100	0	0	40	170	0	0	8	28	47	47	0	0	0	0	16	23.6	23.6	1	0
1/17/2012 11:52	80	80	85	100	0	0	40	170	0	0	8	28	52	52	0	0	0	0	16	25.5	25.5	1	0
1/17/2012 11:52	80	80	85	100	0	0	40	170	0	0	8	28	57	57	0	0	0	0	16	25.5	25.5	1	0
1/17/2012 11:52	80	80	85	100	0	0	40	170	0	0	8	28	62	62	0	0	0	0	16	24.9	24.9	1	0
1/17/2012 11:52	80	80	85	100	0	0	40	170	0	0	8	28	67	67	0	0	0	0	16	24.9	24.9	1	0
1/17/2012 11:52	81	81	85	100	0	0	40	170	0	0	8	28	72	72	0	0	0	0	16	24.9	24.9	1	0
1/17/2012 11:52	0	0	85	100	0	0	40	170	0	0	8	28	76	76	0	0	0	0	1040	25.5	25.5	1	0
1/17/2012 11:52	0	0	85	100	0	0	40	170	0	0	8	28	0	0	0	0	0	0	1040	2.3	2.3	1	0
1/17/2012 11:52	0	0	85	100	0	0	40	170	0	0	8	28	0	0	0	0	0	0	2064	2	2	1	0
1/17/2012 11:52	0	0	85	100	0	0	40	170	0	0	8	28	0	0	0	0	0	0	2064	1.7	1.7	1	0

POX_30332_A

1	Time Stamp	4	Alarm type
2	Measurement minimum/maximum	5	Pulsatile strength minimum/maximum
3	Upper and lower alarm limits	6	Sample interval (period in seconds)

Historical Trend Data Erasure

To clear trend data

1. While in normal monitoring mode, press MENU.

2. Press MONITORING HISTORY.

3. Choose an action.

- • Press CLEAR HISTORY, then confirm the action by selecting YES.

- • Press EXIT MENU to return to normal monitoring mode.

- • Press HELP for online assistance.

Note:

All the trend data clears after confirming the CLEAR HISTORY request.

5.3 Data Port Connectivity

5.3.1 Overview

The monitoring system contains three different data ports and two antennae. Each data port has a different intended use.

- • **Serial DB-15 data port —** This female DB-15 port provides RS-232, RS-422, and differential transmission data connectivity. Use for sending historical trend data to a serial printer for an ASCII print-out.

- • **RJ-45 port —** This female 100-base-T, wired, ethernet-capable port provides connectivity for digital data output.

- • **Serial USB port —** This female USB port allows for faster data transfers. Use this port for updating firmware or for digital data output storage.

- • **Radio-frequency (RF) antennae —** Two radio-frequency antennae broadcast data to a wireless LAN network, should the proper configuration exist.

Table 5-3. Input and Output Configuration Options

Mutually Exclusive External Serial		Mutually Exclusive Oxinet III	
ASCII	9600 baud	ASCII	Serial
	19200 baud		LAN
Philips	19200 baud		Wireless LAN
Clinical	19200 baud	SPDout	Serial
SPDout	19200 baud		LAN
	115200 baud		Wireless LAN
OFF	---	Disconnected	

5.3.2 Typical Equipment Used for Connectivity

The following list contains only a small sample of potential equipment used to interface with the monitoring system.

Table 5-4. Sample Equipment Types

Type	Description
Serial connection	
Philips Open Interface 25-pin cable	Wired connection to Philips Vuelink networked platform
RJ-45 serial cable	RJ-45 to DB-15M adapter; wired connection to hospital network
DB-15 PC-X cable	DB-15M cable obtains dumps and allows for debug
USB connection	
USB flash drive	Any model
USB keyboard	Any model
Ethernet connection	
CAT-3 or CAT-4 cable	10base-T connection to network such as Perle or IOLAN + 16rack/422 (10/100)
CAT-5 cable	100base-T connection to network such as Perle or IOLAN + 16rack/422 (10/100)

5.3.3 Data Port Configuration Information

WARNING:
If the serial port, analog outputs, or nurse call lines are shorted, remote communication may be lost.

WARNING:
A loose connection to a monitoring system data port may result in bad or missing data.

WARNING:
Only use Covidien-approved hardware or remote monitoring software for data port connectivity.

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 utilize a grounded outlet. Any equipment connected to the data port must be certified according to the latest IEC/EN 60950-1 standards for data-processing equipment, the latest IEC/EN safety standards for electromedical equipment, the latest IEC/EN 60601-1 standard for electromedical equipment, or the latest IEC/EN safety standards relevant to that equipment. All combinations of equipment must be in compliance with Requirements for Medical Electrical Systems IEC Standard 60601-1: 2007. Anyone who connects equipment to the data interface is configuring a medical system and, therefore, is responsible for ensuring the system complies with the Requirements for Medical Electrical Systems IEC Standard 60601-1-1: 2007 and the electromagnetic compatibility IEC Standard 60601-1-2: 2007. Accuracy may degrade if it is connected to secondary I/O devices when equipment is not connected to earth reference.

Use the appropriate configuration information to ensure proper connectivity.

When connecting the to any other equipment, ensure that equipment is virus-free. When connecting the monitoring system to equipment to obtain specific patient trend data, verify proper operation of the monitoring system prior to use with a patient. The monitoring system and any appropriate equipment must be connected to a grounded AC power source.

- Connection to a network or data coupling that includes other equipment could result in previously unidentified risks to patients, operators or third parties, so it is the responsibility of the person configuring to identify, analyze, evaluate and control these risks.

- Any subsequent changes to the network or data coupling, such as network or data coupling configuration, connection or disconnection of additional or existing items or equipment, updates or upgrades to items or equipment, might introduce new risks, so requires re-evaluation and analysis.

Serial DB-15 Requirements

Caution:
Do not create sharp bends in the cable, as this may tear or break the shielding.

Figure 5-5. DB-15 Pin Layout

POX_30040_A
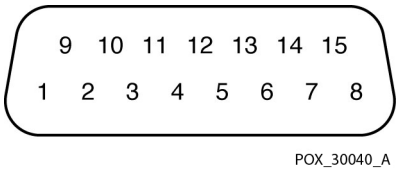
Table 5-5. DB-15 Signal Pinouts

Pin	Signal Name	Description	Pin	Signal Name	Description
1	RxD+	RS-422 [+] input	9	RxD-	RS-422 [-] input
2	RxD_RS232	RS-232 input	10	IGND	Signal Ground, isolated from earth ground
3	TxD_RS-232	RS-232 output	11	NC_232	Nurse call signal, RS-232-level-output
4	TxD+	RS-422 [+] output	12	TxD-	RS-422 [-] output
5	IGND	Signal Ground, isolated from earth ground	13	AN_PULSE	Analog pulse rate output
6	AN_SpO2	Analog saturation output	14	AN_PLETH	Analog pleth waveform output
7	NC_NO	Nurse call relay closure, normally open	15	F_NC_COM	Nurse call relay closure, common return, fused
8	NC_NC	Nurse call relay closure, normally closed			

The pin layout illustrates the pins viewed from the top to the bottom of the D-shell. The conductive shell connects to earth ground when connected to external equipment.

- **RS-232 Format —** Pins 2, 3, and 5 provide RS-232 format data. When building an RS-232 cable, do not add a resistor and keep cable length to a maximum of 25 feet.

- **RS-422 Format —** Pins 1 and 4 (TxD+ and TxD-) are the differential transmit data pair. Pins 9 and 12 (RxD+ and RxD-) are the differential receive data pair. They provide RS-422 format data. When building an RS-422 cable, add a resistor (120 ohms, 1/2 watt, 5%) between pin 1 and pin 9 of the cable and keep cable length to a maximum of 4,000 feet. Plug the end of the cable with the resistor added into the monitoring system.

To save specific patient data, firmly connect and properly secure the appropriate cable from the data port to a host system or serial printer. Connect the data port to a serial printer or host system by using a cable terminated with the following devices.

- An AMP connector (AMP part number 747538-1)

- A ferrule (AMP part number 1-747579-2)

- Compatible pins (AMP part number 66570-2)

The cable should not exceed 25 feet (7.6 meters) in length using RS-232 protocol or 4,000 feet (1219.2 meters) in length using RS-422 protocol. The external ITE (Information Technology Equipment) device must be certified to the latest IEC/EN Standard 60950-1 standards. The cable used must have a braided shield that provides 100% coverage. The shield must have a 360-degree connection to the metal shell on the DB-15 connector and to the connector on the equipment.

No hardware flow control is used. However, support exists for XON/XOFF flow control in ASCII mode.

100base-T RJ-45 Requirements

Caution:
Do not create sharp bends in the cable. Bend radius cannot exceed one inch.

To save specific patient data, firmly connect and properly secure the appropriate cable from the data receptacle to a receiving device capable of 100base-T communication. Connect to the data receptacle via an RJ-45 jack properly attached to a CAT-5 or better cable. The cable should not exceed 100 meters in length. The external ITE (Information Technology Equipment) device must be certified to the latest IEC/EN Standard 60950-1 and IEE 802.3 standards.

Note:
The monitoring system also supports 10base-T with a CAT-3 or CAT-4 connection.

Note:
The pin layout illustrates the pins viewed from left to right on the RJ-45 jack, beginning with pin 8. The tab snap-fits to the receptacle and requires pressure to release it. The data lines are shielded twisted pair (STP) with an additional drain wire to reduce crosstalk or noise.

Figure 5-6. RJ-45 Receptacle
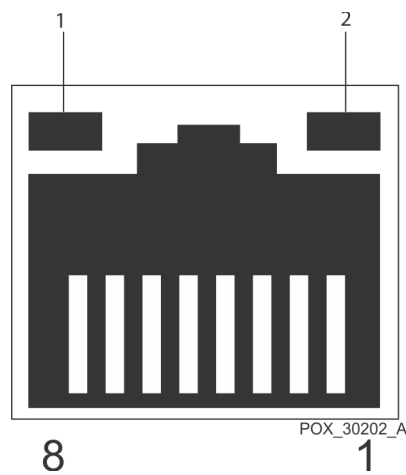
1	LED 1	Indicates data exchange
2	LED 2	Indicates a valid 100base-T TCP/IP link

Figure 5-7. RJ-45 Pin Layout
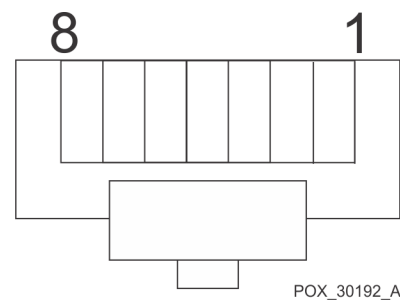
Table 5-6. RJ-45 Signal Pinouts

Pin	Signal Name	Description	Pin	Signal Name	Description
1	TX_D1+	[+] output	5	Not used	N/A
2	TX_D1-	[-] output	6	RX_D2-	[-] input
3	RX_D2+	[+] input	7	Not used	N/A
4	Not used	N/A	8	Not used	N/A

USB Data Port Requirements

Caution:
This is a client-only connection. Only insert a USB flash drive or USB keyboard to this port. Do not attach any other device.

Use only a USB flash drive or USB keyboard when connecting to the USB data port. Transfer of trend data to an external drive is a data export function from the monitoring system to the external drive.

This port can also function as a tool for software and firmware upgrades. Contact Covidien or a qualified service technician for upgrade support.

The pin layout illustrates the pins viewed from the left to the right of the USB connector, beginning with pin 4. The data lines are shielded twisted pair (STP) to reduce crosstalk or noise. Maximum length is 5.0 meters or 16.4 feet.

Figure 5-8. USB Pin Layout

POX_30191_A
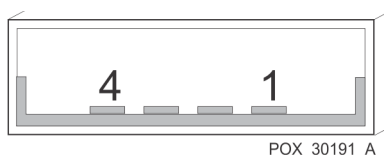
Table 5-7. USB Signal Pinouts

Pin	Signal Name	Description	Pin	Signal Name	Description
1	USB Vcc	Power, red	3	USB Data +	[-] data, green
2	USB Data -	[+] data, white	4	GND	Signal ground, black

To export trend data

1. Remove any sensor or interface cable connection to the sensor port.

2. Insert a virus-free USB flash drive into the USB port.

3. Press DATA EXPORT.

4. Press NEXT.

5. **Wait for the prompt** to remove the USB flash drive once the export completes. DO NOT remove the USB flash drive prior to receiving the prompt to do so.

Note:
Any cancellation of the trend data export results in an alarm.

6. Remove the USB flash drive.

7. Press FINISH.

Wireless Requirements

This option provides for both wireless LAN and LAN network connectivity. The wireless configuration supports either ASCII or SPDout options and will both transmit and receive data on an active wireless connection. Caregivers may choose from multiple wireless networks. The monitoring system will automatically associate with the first available network, using the appropriate previously established configuration. Configuring a network can only be performed by a qualified service technician.

5.3.4 Data Port Communications

To setup data port communication

1. While in normal monitoring mode, press MENU.

2. Press CONNECTIVITY SETTINGS.

3. Select the desired protocol for data exchange.

4. Press SAVE CHANGES to save the selected setting.

5.4 Using the Nurse Call Interface

5.4.1 Nurse Call Feature

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 of the monitoring system is operational when the monitoring system is powered by AC power or battery power. However, the nurse call feature does not function when monitoring system alarms are silenced.

⚠ **WARNING:**

A loose connection to the monitoring system data port may result in bad or missing data.

The nurse call feature allows caregivers to remotely monitor patient alarms and works in conjunction with the institution's nurse call system. Reference *DB-15 Pin Layout*, p. 5-12 for port pinouts.

The monitoring system provides two different types of nurse call interfaces: an RS-232 level and relay closure. Both the RS-232 and relay-based level nurse call function operate when the monitoring system is operating either on AC power or on battery power.

When enabled, audible alarms signal the remote location. If the audible alarm has been turned off or silenced, the nurse call function is also disabled.

Table 5-8. Nurse Call Relay Pin States

Pin	No Alarm or Alarm Silenced	Audible Alarm	Monitoring System Off
7 NO	Open	Closed	Closed
8 NC	Closed	Open	Open

Pin 11 on the data port is the RS-232 level nurse call signal and pin 5 or 10 is ground. Reference *DB-15 Pin Layout*, p. 5-12. With no alarm condition, the voltage between pins 10 and 11 are -5 VDC to -12 VDC, or +5V DC to +12 VDC, depending on the option chosen (either NORM+ or NORM-). With an audible alarm, the output between pins 5 and 11 will reverse polarity.

Pins 7 and 15 provide a relay that closes when an alarm is sounding on the monitoring system. Pins 8 and 15 provide a relay that opens when an alarm is sounding. Pin 15 is common, pin 7 is normally open, and pin 8 is normally closed. Reference *Rating of Nurse Call Relay*, p. 11-2.

Test the nurse call function prior to using it in any institution and whenever setting up the monitoring system in a location that uses nurse call. Users should periodically confirm not only a firm connection of cables, but also periodically confirm the functionality of the connection. If an attached recommended sensor is not connected to a patient, the screen does not register any data and the monitoring system remains in the Pulse Search Mode for five seconds, then the monitoring system displays three dashes [- - -] in the %SpO$_2$ and pulse rate area of the screen. One way to test the nurse call function is to create an alarm condition (for example, SENSOR DISCONNECT) and verify activation of the institution's nurse call system.

5.4.2 Setting Nurse Call RS-232 Polarity

The nurse call polarity can be set to a positive signal or a negative signal during an alarm condition.

To set nurse call polarity

1. While in normal monitoring mode, press MENU.

2. Press CONNECTIVITY SETTINGS.

3. Press NURSE CALL SETTINGS.

Figure 5-9. Nurse Call Polarity Screen

POX_30142_A
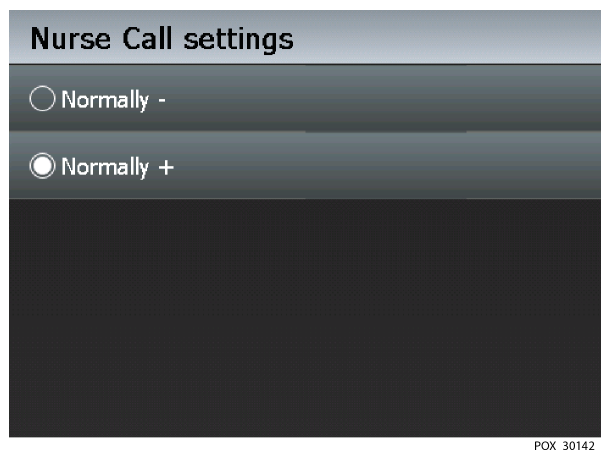
4. Press NORM + for a normally high OR press NORM - for a normally low setting.

5. Press SAVE CHANGES to save the selected setting.

6 Performance Considerations

6.1 Overview

This chapter contains information for assisting users to optimize the performance of the Nellcor™ Bedside Respiratory Patient Monitoring System.

Prior to initial installation in a clinical setting, have a qualified service technician verify the performance of the monitoring system per the *Service Manual*.

6.2 Oximetry Considerations

6.2.1 Monitoring System Constraints

⚠ **WARNING:**
Do not utilize for measurements outside the display levels listed for the monitoring system while monitoring patients.

- **Pulse Rate —** The monitoring system only displays 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).

- **Saturation —** The monitoring system displays saturation levels between 1% and 100%.

6.2.2 Nellcor™ Sensor Performance Considerations

⚠ **WARNING:**
Incorrect application or inappropriate duration of use of a sensor can cause tissue damage. Inspect the sensor site as directed in the *Instructions for Use*.

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

> ⚠ **WARNING:**
> **Use only Covidien-approved sensors and interface cables when connecting to the sensor port. Connecting any other cable or sensor influences the accuracy of sensor data, which may lead to adverse results.**

> ⚠ **WARNING:**
> **Failure to cover the sensor site with opaque material when operating under high ambient light conditions may result in inaccurate measurements. Pulse oximetry readings and pulse signals can be affected by certain environmental conditions, sensor application errors, and certain patient conditions.**

Inaccurate Sensor Measurement Conditions

A variety of conditions can cause inaccurate sensor measurements.

- Incorrect application of the recommended sensor

- Placement of the recommended sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line

- Ambient light

- Failure to cover the sensor site with opaque material when operating under high ambient light conditions

- Excessive patient motion

- 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.

- Recommended sensor applied too tightly

- Inflation of a blood pressure cuff on the same extremity as the attached sensor

- Arterial occlusion proximal to the recommended sensor

- Poor peripheral perfusion

Recommended Usage

Select an appropriate recommended 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 recommended 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 recommended sensor. To prevent interference from ambient light, ensure the recommended sensor is properly applied, and cover the sensor with opaque material.

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

- Verify the recommended 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 (MAXFAST), 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 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 sulfhemoglobin 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 motion

    - Venous pulsations

    - Dark skin pigment

    - Intravascular dyes, such as indocyanine green or methylene blue

    - Externally applied coloring agents (nail polish, dye, pigmented cream)

    - Defibrillation

6.4 Reducing EMI (Electromagnetic Interference)

WARNING:
EMI disruption can cause erratic readings, cessation of operation, or other incorrect functioning.

WARNING:
The monitoring system is intended for use by healthcare professionals only. It may cause radio interference or may disrupt the operation of nearby equipment. Mitigation for such disruption may require re-orienting or relocating the monitoring system or shielding the location.

Caution:
This device has been tested and found to comply with the limits for medical devices related to IEC 60601-1-2: 2007. 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 might result in disruption of monitoring system performance. Reference *Electromagnetic Emissions*, p. 11-6.

The monitoring system is designed for use in environments in which electromagnetic interference might obscure the client's pulse. During such interference, measurements may seem inappropriate or the monitoring system may not seem to operate correctly. EMI disruption can cause erratic readings, cessation of operation, or other incorrect functioning. If this occurs, survey the site of use to determine the source of this disruption, and take the listed actions to eliminate the source.

- Turn equipment in the vicinity off and on to isolate the interfering equipment.

- Reorient or relocate the interfering equipment.

- Increase the separation between the interfering equipment and the monitoring system.

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

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7 Product Maintenance

7.1 Overview

This chapter describes the steps required to maintain, service, and properly clean the Nellcor™ Bedside Respiratory 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.

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

- **Surface cleaning —** Use a soft cloth dampened with either a commercial, non-abrasive cleaner or a solution of 70% alcohol in water, lightly wiping the surfaces of the monitoring system.

- **Disinfection —** Use a soft cloth saturated with a solution of 10% chlorine bleach in tap water, lightly wiping the surface of the monitoring system.

Before attempting to clean a Nellcor™ sensor, read the *Instructions for Use* enclosed with the sensor. Each sensor model has cleaning instructions specific to that sensor. Follow the sensor cleaning and disinfecting procedures in the particular sensor's *Instructions for Use*.

7.3 Periodic Safety Checks

Perform the following checks every 24 months.

- Inspect the monitoring system 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.

- Inspect the internal fuses for proper value and rating.

- Ensure all user interface items, cables, and accessories function normally.

7.4 Service and Upgrades

WARNING:
Only qualified service personnel should remove the monitoring system cover. There are no user-serviceable parts inside. Users may not modify any components of the monitoring system.

To service or upgrade the monitoring system, contact Technical Services or a local Covidien representative for a referral to a qualified service technician. Reference *Obtaining Technical Assistance*, p. 1-4.

- The monitoring system generally requires no calibration. In rare instances, the monitoring screen requires re-calibration. Reference *Operational Performance Issues*, p. 8-13.

- Have a qualified service technician replace the battery at least every 24 months.

Note:
The battery is recyclable. Do not dispose of the battery by placing it in the regular trash. Dispose of the battery in accordance with local guidelines and regulations or contact Covidien to arrange for disposal.

7.5 Storage

7.5.1 Monitoring System Transport and Storage

The only true difference between transport and storage with or without the shipping container is in the temperature. It is less tolerant of heat when not in a shipping container. Reference *Transport and Storage*, p. 11-3.

7.5.2 Removed Battery Storage

Optimum storage for a removed battery is room temperature. Elevated temperatures will reduce storage life. Newly ordered batteries ship with 30 - 50% remaining capacity to give at least six (6) months shelf life at room temperature. Recharge the battery if storing for a longer period than six (6) months.

8 Troubleshooting

8.1 Overview

This chapter describes how to troubleshoot common problems while using the Nellcor™ Bedside Respiratory Patient Monitoring System. This chapter includes information about the on-screen help function, error code messages, and how to obtain technical help and support.

8.2 System Condition Categories

⚠️ **WARNING:**
Have a qualified service technician perform a safety and functional test prior to use in a clinical setting.

⚠️ **WARNING:**
In the case of a monitoring system failure, reset the monitoring system and ensure it is functioning correctly prior to usage.

⚠️ **WARNING:**
Only qualified service personnel should remove the monitoring system cover. There are no user-serviceable parts inside. Users may not modify any components of the monitoring system.

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

⚠️ **WARNING:**
If uncertain about the accuracy of any measurement, check the patient's vital signs by alternate means. Ensure the monitoring system is functioning correctly.

The monitoring system is designed to provide instant feedback to guide care-givers in taking whatever action requires their attention. Alarm conditions appear in order of priority. To access suggestions for resolving the particular

message, press the MORE INFO button. If the monitoring system allows the caregiver to dismiss the condition, pressing DISMISS clears the alarm, but does not clear the condition until the caregiver takes appropriate action.

If the monitoring system detects a condition requiring caregiver intervention, it displays a either a prompt or an error message with a recommended action.

Note:
Pressing ALARM SILENCE silences any audible tone for a period of up to two (2) minutes. A countdown timer reflects any silence time remaining.

- **Prompts —** Prompts require a response. For example, the READY: ATTACH SENSOR TO PATIENT AND MONITOR prompt reminds users to connect both an interface cable and sensor to the monitoring system and to the patient.

Figure 8-1. Ready Prompt

Ready: Attach sensor to patient and monitor | 16% 1:27 | 02/01/2012 07:57:05

POX_30326_A

- **Alarms and Error condition messages —** When the monitoring system detects an error condition, it displays the alarm message, suggests corrective action, and sounds an alarm. It continues monitoring the patient. For example, the SENSOR DISCONNECTED error message leaves any action to the discretion of the user, but the PULSE RATE LOW error message requires immediate caregiver intervention.

Figure 8-2. Sensor Disconnected Message and Help Screen

POX_30333_A
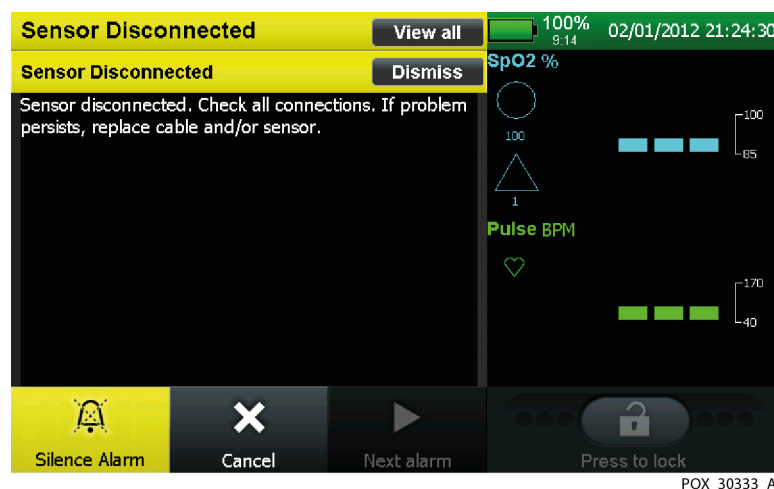
Figure 8-3. Stacked Alarm/Alerts

POX_30323_A

1   **SpO2 LOW Alarm** — Patient saturation is below the lower SpO2 threshold.

2   **PULSE RATE LOW Alarm** — Patient pulse rate is below the lower pulse rate threshold.

3   **SPD ALERT Alarm** — Patient is experiencing multiple, sequential occurrences of a desaturation.

4   **SPD Alert Alarm Icon** — Appears in the trend data graph each time an SPD Alert alarm occurs.

5   **SatSeconds Alarm Icon** — Appears in the trend data graph each time an SatSeconds alarm occurs.

6   **Silence Alarm Icon** — Remains yellow until caregiver presses it to silence all alarms.

7   **SatSeconds Alarm Icon** — Icon remains black on a yellow background until the error condition clears.

8   **Saturation Value with Alarm** — Values remain black on a yellow background until the error condition clears.

9   **SPD Alert Alarm Icon** — Icon remains black on a yellow background until the error condition clears.

10   **Pulse Rate Value with Alarm** — Values remain black on a yellow background until the error condition clears.

Messages remain on the screen until the condition clears. Users may dismiss some messages. Most high-priority messages require user intervention or service to clear the condition.

8.3 User Prompts and Messages

Prompts require a response from or action by the caregiver. Messages provide the caregiver with useful information.

Table 8-1. Common User Prompts and Messages

Priority	Message	Condition	Resolution	Dismiss
---	Ready: Attach sensor to patient and monitor	Awaiting patient connection to begin monitoring	Connect the interface cable to the sensor port and the appropriate sensor to the interface cable and to the patient. Reference *Selecting a Nellcor™ Sensor*, p. 9-1.	---
---	Monitoring	Proper connection established, patient monitoring in progress	None.	---

8.4 Alarms and Error Conditions

This section covers alarms and correctable error conditions. Reference *Non-correctable Failures*, p. 8-15, for non-correctable errors.

8.4.1 Alarms

The status field at the top of the monitoring screen contains information describing overall monitoring system status and any active alarms. If multiple alarms occur during user interaction with a menu or dialog box, the list of alarm messages collapses to a single line listing the total number of alarms currently active. Cancellation or dismissal of an alarm message requires user intervention, whereas status messages do not. The message identifies the alarm or status. If it is an alarm, it offers users a MORE INFO button, which when pressed, provides detailed data and a means to correct the situation or clear the alarm. Press DISMISS to clear the alarm if that is an option. If it is not an option, take the recommended action. If that does not clear the alarm, reset it. If a reset does not clear the alarm, return it for service.

Note:

Not all high-priority alarms have a DISMISS option. These are serious errors and require the user to resolve the issue or return the monitoring system to Covidien or a qualified service technician.

Alarm Prioritization

Alarms have an assigned priority. Stacked alarms display in order of criticality and priority. Reference *Message Types*, p. 4-44, for details on high, medium, and low priority alarms. Occasionally, the monitoring screen field contains one or more prompts or error messages. Stacked alarms display in order of criticality and priority. High priority messages appear above low priority messages. Alarms of the same priority appear in order of occurrence. If the caregiver does not resolve the issue and clear the condition, the monitoring system may escalate the alarm by increasing the frequency of the alarm.

Table 8-2. Initial Alarm Priority for Errors

Priority	Message	Condition	Resolution	Dismiss
Med.	Pulse Rate Low	1. If Pulse Rate Delay is enabled and not set to OFF, patient pulse rate violates the lower pulse rate limit threshold and exceeds the Pulse Rate Delay limit 2. If Pulse Rate Delay is disabled or set to OFF, patient pulse rate violates the lower pulse rate limit threshold	Pulse rate is below the alarm limit. Check patient immediately.	No
Med.	Pulse Rate High	1. If Pulse Rate Delay is enabled and not set to OFF, patient pulse rate violates the upper pulse rate limit threshold and exceeds the Pulse Rate Delay limit 2. If Pulse Rate Delay is disabled or set to OFF, patient pulse rate violates the upper pulse rate limit threshold	Pulse rate is above the alarm limit. Check patient immediately.	No
Med.	SpO2 Low	1. If the SatSeconds alarm is enabled and not set to OFF, patient SpO2 violates the lower SpO2 limit threshold AND exceeds the SatSeconds limit 2. If the SatSeconds alarm is disabled or set to OFF, patient SpO2 value violates the lower SpO2 limit threshold	SpO2 is below the alarm limit. Check patient immediately.	No

Table 8-2. Initial Alarm Priority for Errors (Continued)

Priority	Message	Condition	Resolution	Dismiss
Med.	SpO2 High	1. If the SatSeconds alarm is enabled and not set to OFF, patient SpO2 violates the upper SpO2 limit threshold AND exceeds the SatSeconds limit 2. If the SatSeconds alarm is disabled or set to OFF, patient SpO2 value violates the upper SpO2 limit threshold	SpO2 is above the alarm limit. Check patient immediately.	No
Low	SPD Alert	SPD sensitivity value is reached.	The SPD limit has been exceeded. Check patient.	Yes
High	Pulse Timeout	Sensor connected to a patient AND has detected a pulse in the past, AND now is unable to determine pulse rate value.	Unable to determine pulse rate or oxygen saturation. Check patient immediately. Reposition or replace sensor.	No
Low	Sensor Disconnected	Patient sensor is disconnected from monitor	Sensor disconnected. Check all connections. If problem persists, replace cable and/or sensor.	Yes
Low	Sensor Off	Patient sensor is not attached to patient	Sensor not attached to patient. Reposition or replace sensor.	Yes
Low	Sensor Failure	Bad Sensor, Bad Signal, Sensor Error, Defective Sensor	Defective sensor detected. Replace the sensor.	No
Med	Battery Critically Low	AC power usage AND battery level critical	Continue charging on AC	Yes
High	Battery Critically Low	Battery power usage AND battery level critical	Connect to AC power	No
Med	Battery Low	Battery power usage AND battery level low	Connect to AC power	Yes
High	Battery Failure	Battery missing OR battery charger failure	Return to a qualified service technician.	No
Low	Trend Data Lost	Corrupt trend data detected at start up	Corrupt trend data detected. Some or all trend data cleared.	Yes
	Data export cancelled	Interruption or cancellation during data export.	Retry data export.	Yes
Low	Communication Error	Unable to connect to the network	Unable to connect to the network. Return to a qualified service technician.	No
		Unable to connect to the wireless network	Unable to connect to wireless network. Corrupt trend data detected. Old trend data cleared.	No

Table 8-2. Initial Alarm Priority for Errors (Continued)

Priority	Message	Condition	Resolution	Dismiss
Low	Communi-cation Error	Unable to establish a connection with the Oxinet system	Cannot establish a connection with Oxinet system. Return to a qualified service technician.	No
		Communication failure between host and monitor is detected	Unable to connect to the net-work. Return to a qualified service technician.	No
High	Speaker Failure	Primary speaker failure is detected during operation.	Primary speaker error occurred. Remove from service immediately. Return to a qualified service tech-nician.	No
High	System Failure	Monitor was reset unexpectedly	Unexpected reset. Settings lost. If problem persists, remove from service. Return to a qualified service technician.	Yes
Low	System Failure	SpO2 or pulse rate data has not been updated for over 30 seconds	No update to SpO2 or pulse rate data in more than 30 seconds.	No
Low	Equip-ment Failure	Nurse call output system error	A Nurse Call error occurred. Return to a qualified service tech-nician.	No
		Serial Communications system failure	Serial communication error occurred. Return to a qualified service technician.	Yes
		Analog output system failure	Analog output error occurred. Return to a qualified service tech-nician.	Yes
		Cooling fan failure	A cooling fan failure occurred. Return to a qualified service tech-nician.	Yes
Low	Over Tem-perature	Thermal control system is above thermal limit	Internal temperature is above thermal limit. The monitor may shut down if the internal tem-perature continues to increase. Return to a qualified service tech-nician.	Yes
Low	Clock Set-tings Lost	Invalid date and time value detected during start up	Date and time setting lost. Set the date and time. Return to a quali-fied service technician.	Yes

Sample alarm condition

The monitoring system may detect a failure of the primary speaker and sound a high-pitched piezo tone. A primary speaker failure alarm appears.

To access an alarm message

1. Press MORE INFO or VIEW ALL to continue, depending on which is available. A description of the error and any recommended action appears. This particular alarm cannot be cleared.

Figure 8-4. Sample Speaker Failure Message
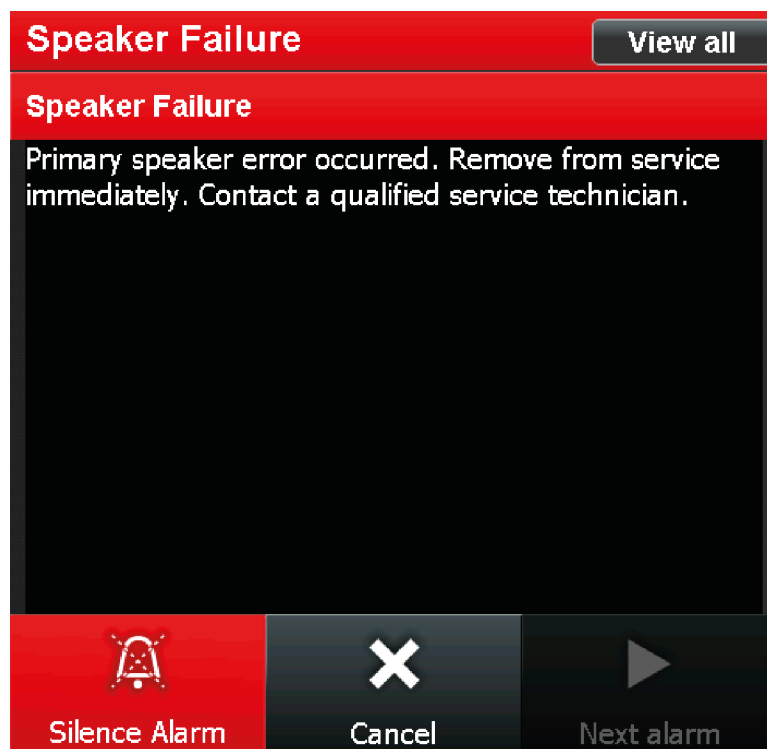
POX_30146_B

2. Press ALARM SILENCE to silence the high-pitched piezo tone. This provides the caregiver two (2) minutes to resolve the issue.

3. Take the recommended action to resolve the issue.

8.4.2 Correctable error conditions

When an error code other than a correctable error appears, turn the monitoring system off and back on again. If the error code reappears, record it and notify service personnel. When this occurs, the monitoring system will stop monitoring the patient until the caregiver takes corrective action and clears the error condition.

Table 8-3. Common Correctable Problems and Resolutions

Symptom	Recommended Corrective Action
Power • No power, even though attached to AC and/or DC power source • Power membrane switch panel LEDs do not light at appropriate times • Powers down or resets without apparent cause	Reference *Power Failure Issues*, p. 8-11.
Monitoring screen • Power indicator is ON but monitoring screen is dim • Power indicator is ON but monitoring screen is blank • No response or unexpected response to touch • Pixels do not all light • Screen burn or legibility issue such as cracking, scratches, pen marks, pencil lead, or indents	Reference *Monitoring Screen Issues*, p. 8-11.
Audio or visual alarm • Audible alarms do not sound • Audible alarms are faint or too loud • Alarms sound without apparent cause	Reference *Alarm Issues*, p. 8-12.

Table 8-3. Common Correctable Problems and Resolutions (Continued)

Symptom	Recommended Corrective Action
Communication • Data ports do not function properly, data transfers incomplete • Communications with external sources are not working • Trend data sent through the data ports is incomplete or garbled	Reference *Communication Issues*, p. 8-13.
Operational performance • Monitoring screen appears functional, but is not registering patient data • Patient data appears suspect • Intermittent or corrupt patient data	Reference *Operational Performance Issues*, p. 8-13.
Hardware • Over-temperature condition • Patient data appears suspect • Intermittent or corrupt patient data • Primary speaker failure • Battery failure	Reference *Hardware Issues*, p. 8-13.
Software • System experiences spurious interrupts • Patient data appears suspect • Intermittent or corrupt patient data	Reference *System Errors and Software issues*, p. 8-14.

8.5 Power Failure Issues

Table 8-4. Power Failure Issues

Problem	Resolution
There is no response when pressing the POWER ON key.	A fuse may be malfunctioning. Notify a qualified service technician to check and, if necessary, replace the fuse. If operating on battery power, the battery may be missing or discharged. If the battery is discharged, charge the battery. Reference *Battery Power*, p. 4-2. If the battery does not charge, notify a service personnel to replace the battery.
The monitoring system is operating on battery power, even though it is connected to an AC power source.	Ensure the power cord is properly connected to the monitoring system. Check to see if power is available to other equipment on the same AC circuit.

8.6 Monitoring Screen Issues

Table 8-5. Monitoring Screen Issues

Problem	Resolution
Power indicator is ON but monitoring screen is dim.	Increase the monitoring screen brightness. Reference *To adjust the backlight brightness*, p. 4-27.
One or more display elements do not light during the power-on self-test (POST).	Do not use the monitoring system. Return the monitoring system to a qualified service technician. Reset and power back on.
Power indicator is ON but monitoring screen is blank.	Return to a qualified service technician.
Monitoring screen is not responsive to touch.	Ensure the monitoring screen is unlocked. Clean the monitoring screen. Use a firmer touch. The monitoring screen responds after touch slightly deforms the surface. Have a qualified service technician re-calibrate the touchscreen. Return to a qualified service technician.
Monitoring screen is cracked or marred.	Return to a qualified service technician.

8.7 Alarm Issues

Table 8-6. Alarm Issues

Problem	Resolution
The Pulse Search Indicator is lit for more than 10 seconds (before any measurements take place).	Check the sensor *Instructions for Use* to confirm appropriate usage and proper application. Check sensor and interface cable connections. Test the sensor on another patient and/or try another sensor or interface cable.
	Perfusion may be too low for the monitoring system to track the pulse. Check the patient. Test the monitoring system on someone else. Change the sensor site. Try another type of Nellcor™ sensor.
	Interference may be preventing the monitoring system from tracking the pulse. Keep the patient still, if possible. Verify that the sensor is securely applied and replace it if necessary. Change the sensor site. Electromagnetic interference may be preventing the monitoring system from tracking the pulse. Remove the source of interference and/or try to stabilize the environment.
	Use a type of sensor that tolerates more patient motion; for example, a Nellcor™ adhesive sensor.
	The sensor may be too tight, there may be excessive ambient light, or the sensor may be on an extremity with a blood pressure cuff, arterial catheter, or intravascular line. Reposition the sensor as necessary.
The Pulse Search indicator illuminates after successful measurements occur.	Check the status of the patient.
	Perfusion may be too low for the monitoring system to track the pulse. Test the monitoring system on another patient. Change the sensor site and/or try another type of Nellcor™ sensor.
	Interference may be preventing the monitoring system from tracking the pulse. Verify the sensor is securely applied and replace it if necessary. Change the sensor site. Use a type of sensor that tolerates more patient motion; for example, an Nellcor™ adhesive sensor. Electromagnetic interference may be preventing the monitoring system from tracking the pulse. Remove the source of interference and/or try to stabilize the environment.
	The sensor may be too tight, there may be excessive ambient light, or the sensor may be on an extremity with a blood pressure cuff, arterial catheter, or intravascular line. Reposition the sensor as necessary.
Alarms only briefly actuate.	Check patient trend data. Examine the patient. Determine if Alarm Audio Off is enabled. If so, an alarm will sound every three (3) minutes.

8.8 Communication Issues

Table 8-7. Common Prompts and Error Messages

Problem	Resolution
Unable to connect to the network.	Review system requirements for compatibility. Check one port at a time for IP address, cable connection, cable damage. Wireless, ethernet, and serial ports are each mutually exclusive. Try serial first, then add. Check to ensure all network connections are properly connected and configured. Replace any suspect cables. Fiber is not always visibly damaged. Contact an IT specialist to review the network connection. Return to a qualified service technician.
Unable to connect to the wireless network.	
Unable to establish a connection with the Oxinet system.	
Communication failure between host and monitor is detected.	

8.9 Operational Performance Issues

Table 8-8. Common Operational Performance Issues

Problem	Resolution
Monitoring screen appears functional, but is not registering patient data.	Ensure pulse oximetry sensor and interface cable are both Nellcor™ products. Check the monitoring screen for the jagged interference indicator. If lit, ensure Nellcor™ sensor is firmly connected and patient remains still. Check the for the loss-of-pulse indicator. If lit, ensure Nellcor™ sensor is firmly connected. Reference *Nellcor™ Sensor Performance Considerations*, p. 6-1.
Patient data appears suspect.	Reset the monitoring system. Check sensor and interface cable connections.
Intermittent or corrupt patient data.	Reset the monitoring system. Check sensor and interface cable connections.

8.10 Hardware Issues

WARNING:
If an monitoring system reports a primary speaker failure, do not use the monitoring system longer than necessary to ensure patient safety. Contact Covidien or a local Covidien representative.

Table 8-9. Common Prompts and Error Messages

Problem	Resolution
Primary speaker failure is detected during operation.	Remove from service immediately. Return to a qualified service technician.
Monitor was reset unexpectedly.	If problem persists, remove from service. Return to a qualified service technician.
SpO2 or pulse rate data has not been updated for over 30 seconds.	Return to a qualified service technician.
Nurse call output system error.	
Serial Communications system failure.	
Analog output system failure.	
Cooling fan failure.	
Thermal control system is above thermal limit.	Power down and allow to cool. Remove any potential sources of heat. Check heat and humidity conditions. Reference *Environmental Conditions*, p. 11-2. Move to a controlled environment. Return to a qualified service technician.
Invalid date and time value detected during start up.	Set the date and time. Replace the battery, if stored for too long. Return to a qualified service technician.

8.11 System Errors and Software issues

The monitoring system may encounter a software problem, which results in a screen very similar to the initial splash screen during power up. This indicates a serious error. Reset the device. If the error occurs again, return to a qualified service technician.

Figure 8-5. Sample System Error Screen

POX_30352_A
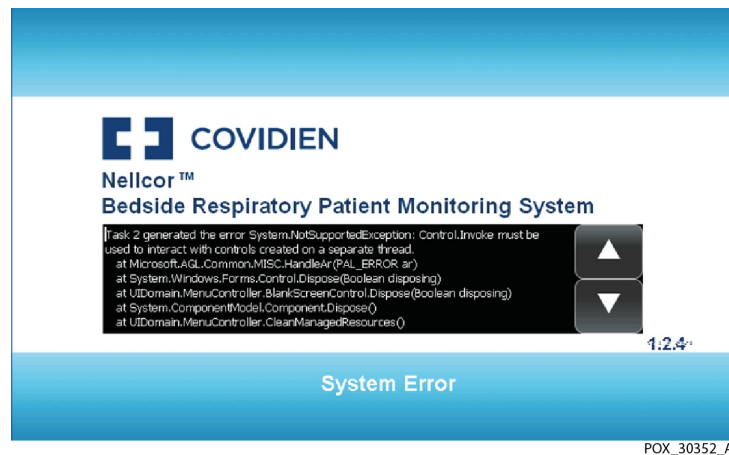
8.12 Non-correctable Failures

Contact Covidien or a local Covidien representative should the monitoring system detect a non-correctable failure. When a non-correctable error occurs, several events also occur.

- The monitoring system sounds a low priority alarm that cannot be silenced except by power cycling the monitoring system.

- Measurements stop.

- All information on the screen vanishes, displaying an error code message.

Note:
Cycling the power may clear the non-correctable error. If it does not, return to a qualified service technician.

8.13 Product Return

Contact Covidien or a local Covidien representative for shipping instructions, including a Returned Goods Authorization (RGA) number. 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.

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9 Accessories

9.1 Overview

This chapter contains information for selecting the appropriate sensor for connection to the appropriate interface cable and identifies optional equipment for use with the Nellcor™ Bedside Respiratory Patient Monitoring System. Refer to the Covidien web site to obtain current part numbers for all related items.

9.2 Nellcor™ Sensors

9.2.1 Selecting a Nellcor™ Sensor

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

⚠️ **WARNING:**
Use only Covidien-approved sensors and interface cables when connecting to the sensor port. Connecting any other cable or sensor influences the accuracy of sensor data, which may lead to adverse results.

⚠️ **WARNING:**
Do not use any monitoring system, sensor, cable, or connector that appears damaged. Remove any damaged equipment from service for inspection by a qualified service technician.

⚠️ **WARNING:**
Do not use a damaged sensor or interface cable. Do not use a sensor with exposed optical components.

⚠️ **WARNING:**
Shock hazard — Do not immerse or wet the sensor.

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

WARNING:
Incorrect application or duration of use of a sensor can cause tissue damage. Inspect the sensor site periodically as directed in the sensor *Instructions for Use*.

WARNING:
Do not lift by the sensor or interface cable. The cable may disconnect, potentially dropping the monitoring system on a patient or damaging surface.

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

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

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

Caution:
Adhesive sensors are intended for single-patient use only. Do not transfer a sensor from one patient to a second patient.

Caution:
Single-patient use sensors are intended for single-patient use only. Do not transfer an adhesive sensor from one patient to a second patient.

When selecting a Nellcor™ sensor, consider the 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 recommended

sensor's *Instructions for Use* to guide sensor selection or contact Covidien or a local Covidien representative. Reference *Nellcor™ Sensor Performance Considerations*, p. 6-1.

The Nellcor™ interface cable connects the monitoring system with the Nellcor™ sensor. Do not attach any cable to the sensor port that is intended for computer use. Use only Covidien-approved sensors and interface cables when connecting to the sensor port.

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

Nellcor™ Sensor	SKU	Patient Size
Nellcor™ Preemie SpO2 Sensor, non-adhesive (Single-patient use)	SC-PR	<1.5 kg
Nellcor™ Neonatal SpO2 Sensor, non-adhesive (Single-patient use)	SC-NEO	1.5 to 5 kg
Nellcor™ Adult SpO2 Sensor, non-adhesive (Single-patient use)	SC-A	>40 kg
Nellcor™ Adult-Neonatal SpO2 Sensor with Wraps (Reusable with adhesive)	OXI-A/N	<3 or >40 kg
Nellcor™ Pediatric-Infant SpO2 Sensor with Wraps (Reusable with adhesive)	OXI-P/I	3 to 40 kg
Nellcor™ Pediatric SpO2 Sensor, Two Piece (Sterile, single-use only)	P	10 to 50 kg
Nellcor™ Neonatal-Adult SpO2 Sensor, Two Piece (Sterile, single-use only)	N	<3 or >40 kg
Nellcor™ Adult SpO2 Sensor, Two Piece (Sterile, single-use only)	A	> 30 kg
Nellcor™ Neonatal-Adult SpO2 Sensor (Sterile, single-use only)	MAXN	<3 or >40 kg
Nellcor™ Infant SpO2 Sensor (Sterile, single-use only)	MAXI	3 to 20 kg
Nellcor™ Pediatric SpO2 Sensor (Sterile, single-use only)	MAXP	10 to 50 kg
Nellcor™ Adult SpO2 Sensor (Sterile, single-use only)	MAXA	>30 kg
Nellcor™ Adult XL SpO2 Sensor (Sterile, single-use only)	MAXAL	>30 kg
Nellcor™ Adult SpO2 Nasal Sensor (Sterile, single-use only)	MAXR	>50 kg
Nellcor™ Forehead SpO2 Sensor (Sterile, single-use only)	MAXFAST	≥10 kg
Nellcor™ Adult SpO2 Sensor, Reusable (Nonsterile)	DS100A	>40 kg
Nellcor™ SpO2 Sensor, Multi-site Reusable (Nonsterile)	D-YS	>1 kg
• Nellcor™ SpO2 Ear Clip, Reusable (Nonsterile)	D-YSE	>30 kg
• Nellcor™ Pediatric SpO2 Sensor Clip, Reusable (Nonsterile)	D-YSPD	3 to 40 kg

Contact Covidien or a local Covidien representative for a *Sensor Accuracy Grid* listing all of the Nellcor™ sensors used with the monitoring system. Covidien retains a soft copy at www.covidien.com.

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

9.2.2 Nellcor™ Sensor Features

Nellcor™ sensor features are different for sensors at a different revision level and by sensor type (adhesive, recycled, and reusable). The revision level of an sensor is located on the sensor plug.

9.2.3 Biocompatibility Testing

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

9.3 Optional Equipment

Several mounting configurations are offered with the monitoring system. Contact Covidien or a local Covidien representative for more information.

Covidien Technical Services: Patient Monitoring

15 Hampshire Street

Mansfield, MA 02048 USA

1.800.635.5267, 1.925.463.4635 (toll)
or contact a local Covidien representative

www.covidien.com

10 Theory of Operations

10.1 Overview

This chapter explains the theory behind operations of the Nellcor™ Bedside Respiratory 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™ 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 monitoring system 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 arte-

rial 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 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 Covidien 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 SaO2 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 SpO2 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.

$$\Phi = \frac{\phi}{100 - (\eta + \Lambda)} \times 100$$
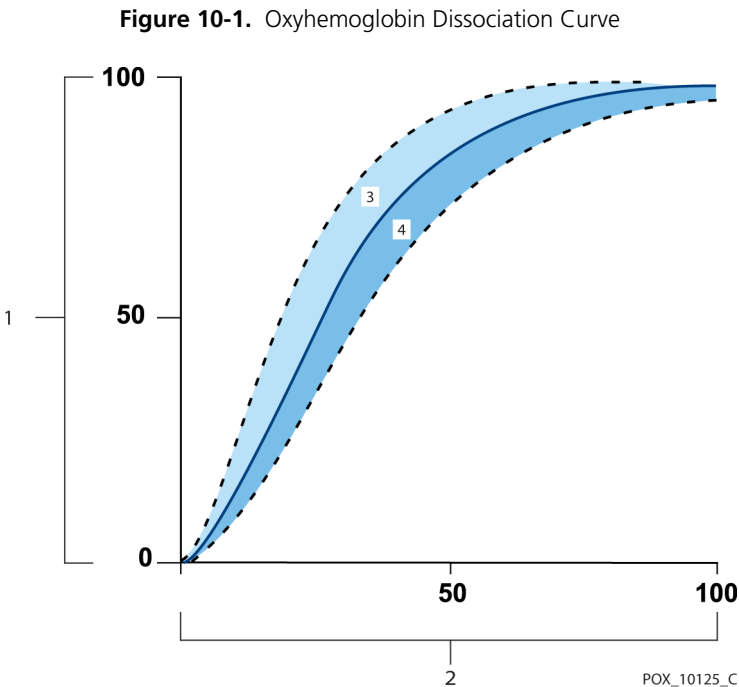
Φ	functional saturation	η	%carboxyhemoglobin
ϕ	fractional saturation	Λ	%methemoglobin

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, PCO2, and 2,3-DPG
2	PO2 (mmHg) Axis	4	Decreased pH; Increased temperature, PCO2, 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, patient motion, 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 System Features

10.6.1 Nellcor™ Sensor Technology

Use Nellcor™ sensors, which are specifically designed for use with the monitoring system. Identify Nellcor™ sensors by the Nellcor™ logo on the plug. All Nellcor™ sensors contain a memory chip carrying information about the sensor which the monitoring system needs for correct operation, including the sensor's calibration data, model type, troubleshooting codes, and error detection data.

This unique oximetry architecture enables several new features. When a Nellcor™ sensor is connected to the monitoring system, the monitoring system reads the information from the sensor memory chip, ensures it is error free, and then loads the sensor data prior to monitoring for new information. As the monitoring system reads sensor information, it sends the sensor model number to the monitoring screen. This process may take a few seconds. The sensor model number disappears after the monitoring system starts tracking the patient's SpO_2 and pulse rate.

Any monitoring system containing OxiMax technology uses calibration data contained in the sensor in calculating the patient's SpO_2. With sensor calibration, the accuracy of many sensors is improved, since the calibration coefficients can be tailored to each sensor.

Contact Covidien or a local Covidien representative for a *Sensor Accuracy Grid* listing all of the sensors used with the monitoring system. Covidien retains a soft copy at www.covidien.com.

The monitoring system uses the information in the sensor, tailoring messages to better help the clinician troubleshoot client or data issues. The sensor automatically identifies its sensor type to the monitoring system when attached.

10.6.2 SatSeconds™ Alarm Management Parameter

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 parameter 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 SpO2 Events

POX_30128_A
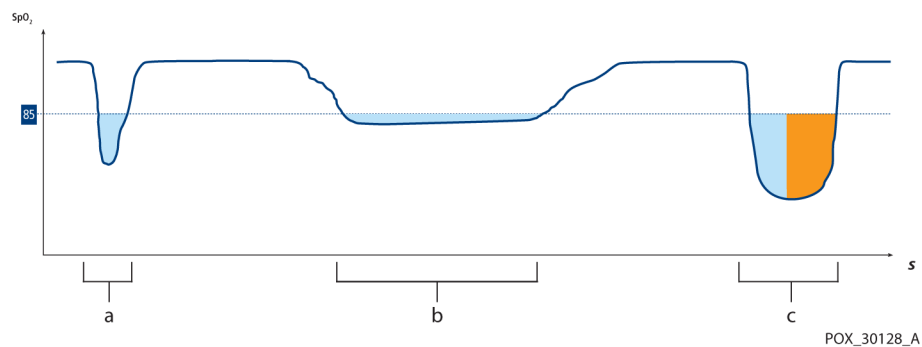
a	First SpO2 Event
b	Second SpO2 Event
c	Third SpO2 Event

First SpO₂ Event

Consider the first event. Suppose the SatSeconds alarm limit is set to 25. The patient's SpO₂ drops to 79% and the duration of the event is two (2) seconds before saturation again exceeds the lower alarm threshold of 85%.
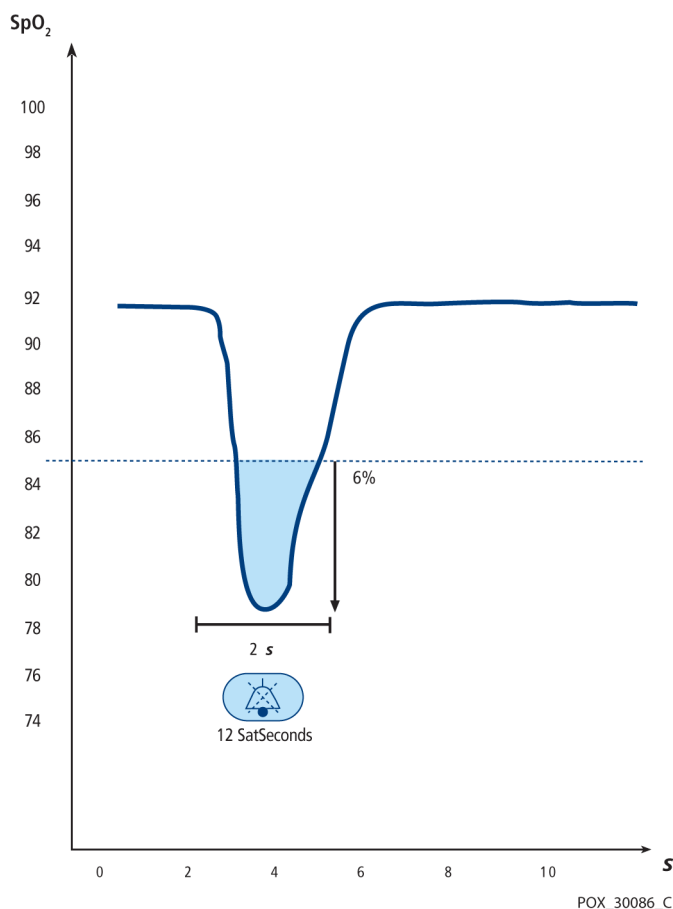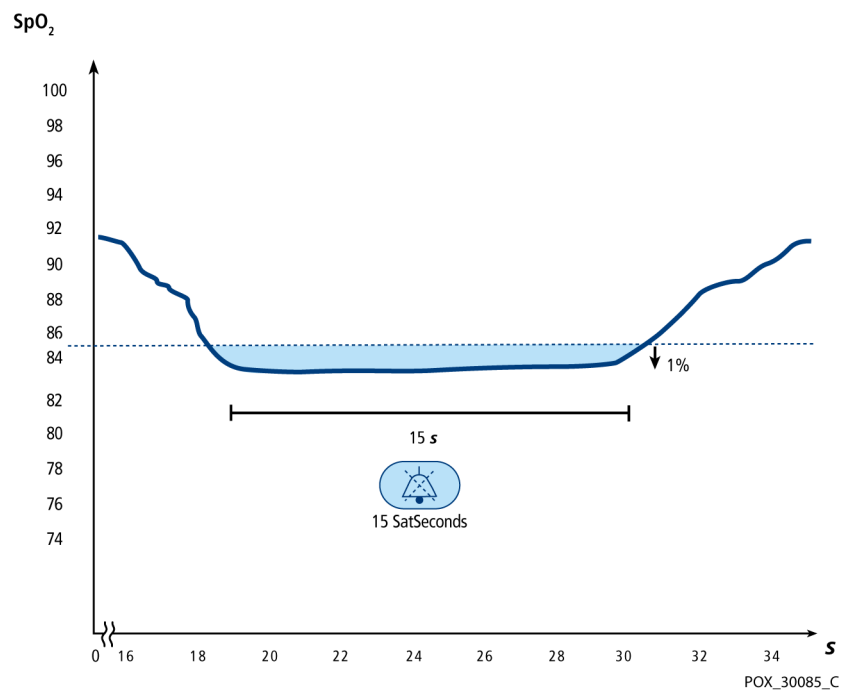
> 6% drop below the lower alarm limit threshold
> x 2 second duration below the lower threshold
> _____
> **12 SatSeconds**; no alarm

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 SpO2 Event: No SatSeconds Alarm

Second SpO₂ Event

Consider the second event. Suppose the SatSeconds alarm limit is still set to 25. The patient's SpO₂ 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 SpO2 Event: No SatSeconds Alarm

Third SpO2 Event

Consider the third event. Suppose the SatSeconds alarm limit is still set to 25. During this event, the patient's SpO2 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.
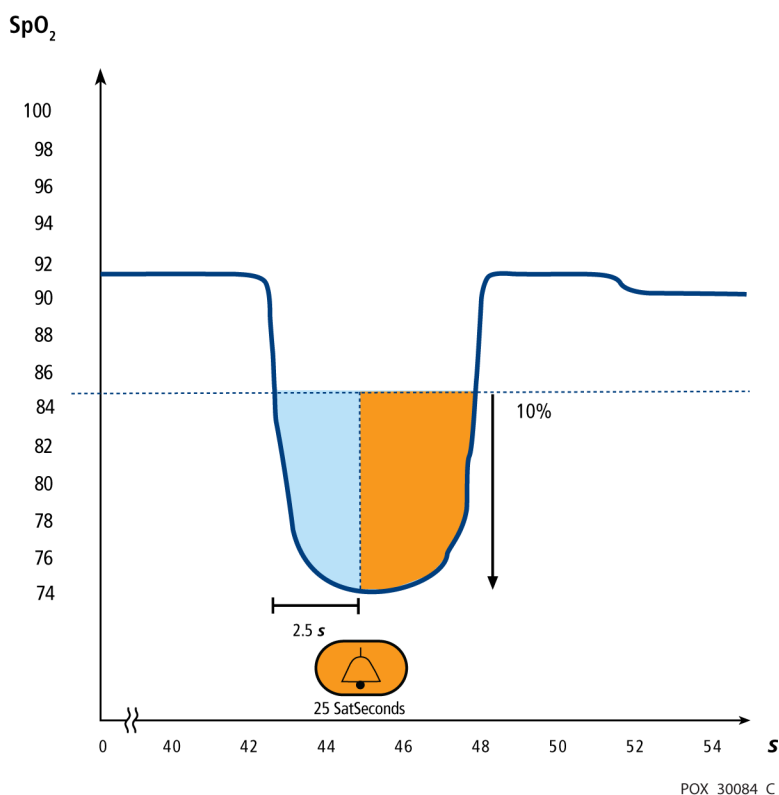
10% drop below the lower alarm limit threshold
x2.5 second duration below the lower threshold
_____

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 SpO2 Event: Triggers SatSeconds Alarm

POX_30084_C

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.
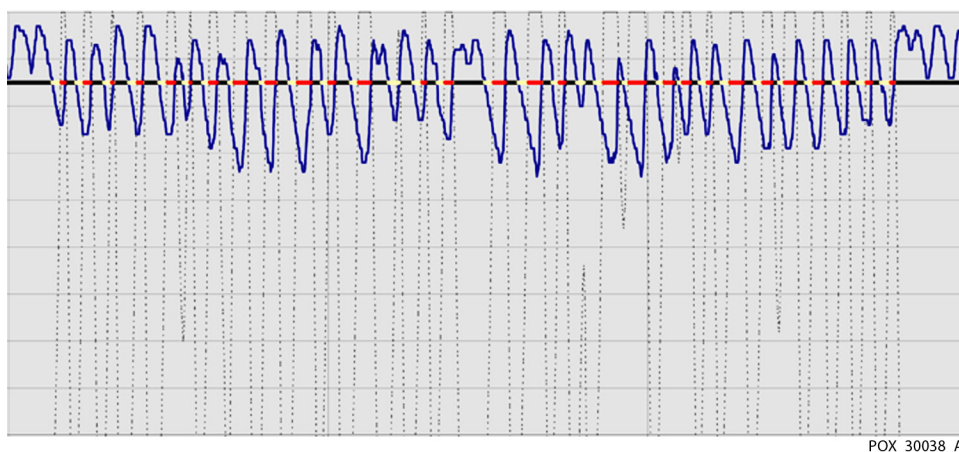
10.6.3 OxiMax SPD™ Alert Parameter

WARNING:
Supplemental oxygen will attenuate patterns of desaturation. A patient's respiratory compromise can be proportionally more severe before patterns appear in the saturation trend. Remain vigilant when monitoring a patient on supplemental oxygen.

Caution:
Do not modify any other alarm settings while using the SPD parameter.

The OxiMax SPD™ Alert (SPD) method of detecting patterns of desaturation in adults is a function of the software within the monitoring system, which detects repetitive occurrences of desaturation followed by resaturation. These patterns are indicative of repetitive reductions in airflow through the upper airway and into the lungs. With the SPD parameter enabled, the default value for SatSeconds alarms is 100.

Figure 10-6. Clinically Significant Desaturation Patterns

POX_30038_A

The SPD parameter detects patterns of desaturation in adults that are indicative of repetitive reductions in airflow through a patient's upper airway into the lungs. Relative reductions in a patient's minute ventilation over a period of time may cause a progressive drop in alveolar partial pressure of oxygen, leading to arterial desaturation. If these decreases in ventilation are repetitive, they generate distinct patterns in the saturation trend. Patterns of repetitive desaturation often develop gradually over time, increasing in severity. Detection of patterns indicates that a patient might be suffering progressively severe decrements in airflow that may increase in acuity if left untreated.

Patterns of desaturation are multiple, sequential occurrences of a desaturation followed by a resaturation. The SPD parameter qualifies patterns of desaturation resulting from such repetitive reductions in airflow based on specific characteristics.

The SPD parameter qualifies these patterns of desaturation over a period of six (6) minutes. Depending on the sensitivity setting for SPD, patterns that persist may result in an SPD alarm, alerting the caregiver to the condition.

- The severity of the desaturation event (the depth of the desaturation during the event) and the extent of the following resaturation

- The regularity of the desaturation events (how often the pattern repeats)

- The slope of the desaturation/resaturation trends that form the events

The SPD parameter communicates information to the caregiver about these patterns of desaturation in a variety of ways with icons and alarms and in trend data.

When the indicator reaches capacity, indicating the SPD limit has been reached, an audible alarm sounds and an alarm message flashes. The default setting of one (1) is the most sensitive to desaturation patterns and results in more frequent alarms. For less frequent alarms, use a less sensitive setting of two (2) or three (3).

Note:
Unrecognized repetitive reductions in airflow through the upper airway occur in some clinically significant scenarios. Patients exhibiting sleep apnea symptoms were used in studies to validate the SPD™ Alert parameter. The presence of repetitive reductions in airflow was scored using a standard diagnostic polysomnogram. Study results indicate SPD is a sensitive marker in detecting repetitive reductions in airflow.

10.6.4 Pulse Rate Delay Alarm Management Parameter

The monitoring system also monitors pulse rate by determining the number of pleth waves over unit time. With traditional alarm management, upper and lower alarm limits are set for monitoring pulse rate. When pulse rates fluctuate near an alarm limit, alarms trigger with each violation. Pulse Rate Delay allows a period of threshold violation before the pulse rate alarm sounds. Thus, it distinguishes clinically significant events from minor and brief pulse rate limit violations that result in nuisance alarms.

To use Pulse Rate Delay, set the traditional alarm management upper and lower pulse rate alarm limits. Then, set Pulse Rate Delay. The Pulse Rate Delay limit controls the time the pulse rate level crosses either limit before an audible alarm sounds. Reference *Pulse Rate Delay Alarm Management Parameter Limits*, p. 4-22.

11 Product Specifications

11.1 Overview

This chapter contains physical and operational specifications of the Nellcor™ Bedside Respiratory Patient Monitoring System. Ensure all product requirements are met prior to installation.

11.2 Physical Characteristics

Weight	7.5 lbs. (3.4 kg)
Dimensions	10 in. x 6.5 in. x 5 in. (252 mm x 163 mm x 122 mm)

11.3 Electrical Requirements

11.3.1 Power

Power Requirements	Rated at 100 to 240 volts AC (nominal 120-230 VAC), 30 VA
Input Frequency	50/60 Hz
Fuses	Slow-blow 1.5 amp, 250 volts, IEC (5 x 20 mm) Quantity: 2 external

11.3.2 Battery

Note:
The battery provides approximately seven hours of battery life when new and fully-charged with no alarms, no serial data, no analog output, no nurse call output, with backlight on while using a pulse simulator set for 200 bpm, high light and low modulation.

Type	Lithium Ion
Voltage	7.2 Volts DC, 11.6 Ah, 83 Wh
Recharge	8 hours with monitoring system turned off 12 hours with monitoring system turned on
Shelf Life	Four months, if monitoring system runs on new, fully-charged battery After four months storage, units run 33% of stated battery life
Compliance	91/157/EEC

11.3.3 Rating of Nurse Call Relay

Maximum Input Voltage	30 VAC or VDC (polarity is not important)
Load Current	120 mA continuous (peak 300 mA @ 100 ms)
Minimum Resistance	26.5 ohms to 50.5 ohms (40.5 ohms typical) during alarms
Ground Reference	Isolated Ground
Electrical Isolation	1500 Volts

11.4 Environmental Conditions

11.4.1 Operating

Temperature	5 °C to 40 °C (41 °F to 104 °F)
Altitude	-390 m to 3,012 m (-1,254 ft. to 9,882 ft.)
Atmospheric Pressure	70 kPa to 106 kPa (20.6 in. Hg to 31.3 in. Hg)
Relative Humidity	15% to 95% non-condensing

11.4.2 Transport and Storage

	Not in shipping container	In shipping container
Temperature	-20 ℃ to 60 ℃ (-4 ℉ to 140 ℉)	-20 ℃ to 70 ℃ (-4 ℉ to 158 ℉)
Altitude	-390 m to 5,574 m (-1,254 ft. to 18,288 ft.)	
Atmospheric Pressure	50 kPa to 106 kPa (14.7 in. Hg to 31.3 in. Hg)	
Relative Humidity	15% to 95% non-condensing	

11.5 Essential Performance

This monitoring system has the capability to detect physiological alarm conditions using SpO$_2$ accuracy, pulse rate accuracy and alarm limit conditions.

Table 11-1. Nellcor™ Sensor Ranges

Type	Values
Measurement Ranges	
SpO2 saturation range	1% to 100%
Pulse rate range	20 to 250 beats per minute (bpm)
Perfusion range	0.03% to 20%
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

Table 11-2. Pulse Oximetry Sensor Accuracy

Saturation[1]	
Adult[2,3]	70% to 100% ±2 digits
Adult and neonate Low Sat[2,3,4]	60% to 80% ±3 digits
Neonate[4,5]	70% to 100% ±2 digits
Low perfusion[6]	70% to 100% ±2 digits
Adult and neonate with motion[2,7]	70% to 100% ±3 digits
Pulse Rate	
Adult and neonate[2,3,4]	20 to 250 beats per minute (bpm) ±3 digits
Low perfusion[6]	20 to 250 beats per minute (bpm) ±3 digits
Adult and neonate with motion[2,7]	20 to 250 beats per minute (bpm) ±5 digits

1. Saturation accuracy varies by sensor type. Refer to the *Sensor Accuracy Grid* at www.covidien.com/rms.
2. Accuracy specifications were validated using measurements of healthy non-smoking adult volunteers during controlled hypoxia studies spanning the specified saturation ranges. Subjects were recruited from the local population and comprised both men and women ranging in age from 18-50 years old, and spanned a range of skin pigmentations. Pulse oximeter SpO_2 readings were compared to SaO_2 values of drawn blood samples measured by hemoximetry. All accuracies are expressed at ±1 SD. Because pulse oximeter equipment measurements are statistically distributed, about two-thirds of the measurements can be expected to fall in this accuracy (ARMS) range (refer to the *Sensor Accuracy Grid* for more details).
3. Adult specifications are shown for OXIMAX MAXA and MAXN sensors with the N-600x.
4. Neonate specifications are shown for OXIMAX MAXN sensors with the N-600x.
5. Clinical functionality of the MAXN sensor has been demonstrated on a population of hospitalized neonate patients. The observed SpO_2 accuracy was 2.5% in a study of 42 patients with ages of 1 to 23 days, weight from 750 to 4,100 grams, and 63 observations made spanning a range of 85% to 99% SaO_2.
6. Specification applies to the N-600x pulse oximeter performance. Reading accuracy in the presence of low perfusion (detected IR pulse modulation amplitude 0.03% - 1.5%) was validated using signals supplied by a patient simulator. SpO_2 and pulse rate values were varied across the monitoring range over a range of weak signal conditions and compared to the known true saturation and pulse rate of the input signals.
7. Motion performance was validated during a controlled hypoxia blood study over an SaO_2 span of 70% to 98% and a convenience sample heart rate range of 47-102 bpm. Subjects performed rubbing and tapping movements 1-2 cm in amplitude with aperiodic intervals (randomly changing) with a random variation in frequency between 1-4 Hz. The average percent modulation during quiescent periods was 4.27, during motion 6.91. Motion performance over the entire specified pulse rate range was validated using synthetic signals from a patient simulator that comprised representative cardiac and signal artifact components. Applicability: OXIMAX MAXA, MAXAL, MAXP, MAXI, and MAXN sensors.

11.6 Sound Pressure

Table 11-3. Sound Pressure in Decibels

Alarm Type	Volume Setting			
	High	Med High	Med Low	Low
High Priority	88.1 dB	85.5 dB	80.6 dB	71.5 dB
Medium Priority	78.3 dB	75.4 dB	70.2 dB	61.2 dB
Low Priority	74.4 dB	71.1 dB	66.4 dB	57.6 dB
SPD Alarm (Low Priority)	74.4 dB	70.7 dB	65.7 dB	57.5 dB

11.7 Product Compliance

Equipment Classification	IEC/EN 80601-2-61:2011
	IEC/EN 60601-1:2005
	CAN/CSA C22.2 No. 60601-1:08
	ANSI AAMI ES 60601-1:2005
Protection Type	Class I (Internally powered)
Degree of Protection	Type BF - Applied part
Mode of Operation	Continuous
Electromagnetic Compatibility	IEC 60601-1-2:2007
Liquid Ingress	IPX1: Protected against harmful effects of dripping water
Degree of Safety	Not suitable for use in the presence of flammable anesthetics

11.8 Manufacturer's Declaration and Guidance

11.8.1 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, sensors, and cables other than those specified may result in inaccurate readings of the monitoring system and increased EMI emissions of the monitoring system.

The monitoring system is suitable for prescription use only in the specified electromagnetic environments, in accordance with the IEC 60601-1-2:2007 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.

Frequency and Bandwidth for Wireless Connection

- 2.40 to 2.50 GHz (Low Band)

- 4.90 to 5.85 GHz (High Band)

Electromagnetic Emissions

Table 11-4. Electromagnetic Emissions Compliance and Guidance, All Systems

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF emission CISPR 11 EN 55011	Group 1, Class A	Not intended for use in a residential environment. If used in a domestic environment, may not offer adequate protection to radio-frequency communication services. The user may be required to take mitigation measures, such as relocating or re-orienting the equipment.
Harmonic emissions IEC/EN 61000-3-2	Class A	N/A
Voltage fluctuation/ flicker emissions IEC/EN 61000-3-3	Complies	**N/A**

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 11-5. Electromagnetic Immunity Compliance and Guidance, All Systems

Immunity Test	IEC/EN 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) IEC/EN 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 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 input/output lines	± 2 kV for power supply lines ± 1 kV 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, short interruptions and voltage variations on power supply IEC/EN 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle	<5% UT (>95% dip in UT) for 0.5 cycle	Mains power quality should be that of a typical commercial and/or hospital environment. If the user requires continued operation during power mains interruption, power from an uninterruptible power supply, or battery. **Note:** UT is the AC main's voltage prior to application of the test level.
	40% UT (60% dip in UT) for 5 cycles	40% UT (60% dip in UT) for 5 cycles	
	70% UT (30% dip in UT) for 25 cycles	70% UT (30% dip in UT) for 25 cycles	
	<5% UT (>95% dip in UT) for 5 seconds	<5% UT (>95% dip in UT) for 5 seconds	
Power frequency (50/60 Hz) magnetic field IEC/EN 61000-4-8	3 A/m	3 A/m	It may be necessary to position further from the sources of power frequency magnetic fields or to install magnetic shielding.

Table 11-6. Electromagnetic Immunity Compliance and Guidance, Not Life-Supporting Equipment

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	3 Vrms 150 kHz 80 MHz	$d = 1.2\sqrt{P}$ 150 kHz to 80 MHz
Radiated RF IEC/EN 61000-4-3	3 V/m 80 MHz 800 MHz	3 V/m 80 MHz 800 MHz	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz
	3 V/m 800 MHz 2.5 GHz	3 V/m 800 MHz 2.5 GHz	$d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz

Table 11-7. Recommended Separation Distance, Not Life-Supporting

Rated Maximum Output Power (P) of Transmitter in Watts	Separation Distance in Meters		
	$d = 1.2\sqrt{P}$ **150 kHz to 80 MHz**	$d = 1.2\sqrt{P}$ **80 MHz to 800 MHz**	$d = 2.3\sqrt{P}$ **800 MHz to 2.5 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.

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 emission of the monitoring system.

Table 11-8. Sensor Lengths

Item	SKU	Maximum Length
Nellcor™ Adult SpO2 Sensor, Reusable (Nonsterile)	DS100A	3.0 ft. (0.9 m)
Nellcor™ Adult XL SpO2 Sensor (Sterile, single-use only)	MAXAL	3.0 ft. (0.9 m)
Nellcor™ Forehead SpO2 Sensor (Sterile, single-use only)	MAXFAST	2.5 ft (0.75 m)
Nellcor™ Neonatal-Adult SpO2 Sensor (Sterile, single-use only)	MAXN	1.5 ft. (0.5 m)
Nellcor™ Infant SpO2 Sensor (Sterile, single-use only)	MAXI	
Nellcor™ Pediatric SpO2 Sensor (Sterile, single-use only)	MAXP	
Nellcor™ Adult SpO2 Sensor (Sterile, single-use only)	MAXA	
Nellcor™ Adult SpO2 Nasal Sensor (Sterile, single-use only)	MAXR	
Nellcor™ Adult-Neonatal SpO2 Sensor with Wraps (Reusable with adhesive)	OXI-A/N	3.0 ft. (0.9 m)
Nellcor™ Pediatric-Infant SpO2 Sensor with Wraps (Reusable with adhesive)	OXI-P/I	
Nellcor™ Pediatric SpO2 Sensor, Two Piece (Sterile, single-use only)	P	OC-3 cable, 3.0 ft. (0.9 m)
Nellcor™ Neonatal-Adult SpO2 Sensor, Two Piece (Sterile, single-use only)	N	
Nellcor™ Adult SpO2 Sensor, Two Piece (Sterile, single-use only)	A	
Nellcor™ SpO2 Sensor, Multi-site Reusable (Nonsterile)	D-YS	4.0 ft. (1.2 m)
• Nellcor™ SpO2 Ear Clip, Reusable (Nonsterile)	D-YSE	
• Nellcor™ Pediatric SpO2 Sensor Clip, Reusable (Nonsterile)	D-YSPD	

Table 11-9. Cable Lengths

Item	SKU	Maximum Length
Power cord		9.84 ft. (3 m)
DOC-10 interface cable (only compatible interface cable)		10.0 ft. (3 m)
Firmware download cable, RS-232 serial, 15 to 9 pin "D"	----	10.0 ft. (3 m)
Non-terminated cable, RS-232 analog, 15 pin "D"		3.3 ft. (1 m)
Printer cable, RS-232, 15 to 9 pin "D"		10.0 ft. (3 m)
Philips interface cable	M1943 NL	3.3 ft. (1 m)
Oxinet™ III hardwire cable	----	10.0 ft. (3 m)
Oxinet™ III data cable		

11.8.2 Ground Integrity

100 milliohms or less

11.8.3 Safety Tests

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

Table 11-10. Earth and Enclosure Leakage Current Specifications

Earth Leakage Current					
Condition	AC Line Polarity	Line Cord	Neutral Line Cord	IEC 60601-1	ANSI/AAMI 60601-1
Normal	Normal	Closed	Closed	500 µA	300 µA
Single Fault		Open	Closed		1000 µA
		Closed	Open		
Normal	Reversed	Closed	Closed	500 µA	300 µA
Single Fault		Open	Closed		1000 µA
		Closed	Open		

Table 11-10. Earth and Enclosure Leakage Current Specifications (Continued)

Enclosure Leakage Current				
Condition	**AC Line Polarity**	**Neutral Line Cord**	**Power Line Ground**	**IEC 60601-1 ANSI/AAMI 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 11-11. Patient Applied and Patient Isolation Risk Current

Patient Applied Risk Current				
Condition	**AC Line Polarity**	**Neutral Line**	**Power Line Ground Cable**	**IEC 60601-1 ANSI/AAMI 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 Isolation Risk Current				
Condition	**AC Line Polarity**	**Neutral Line**	**Power Line Ground Cable**	**IEC 60601-1 UL 60601-1**
Single Fault	Normal	Closed	Closed	5000 µA
	Reversed	Closed	Closed	

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A Clinical Studies

A.1 Overview

This appendix contains data from clinical studies conducted for Nellcor™ sensors used with the Nellcor™ Bedside Respiratory 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 Respiratory 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. SpO2 Accuracy for Nellcor™ Sensors vs. CO-oximeters

SpO2 Decade	MAXA		MAXN		MAXFAST	
	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
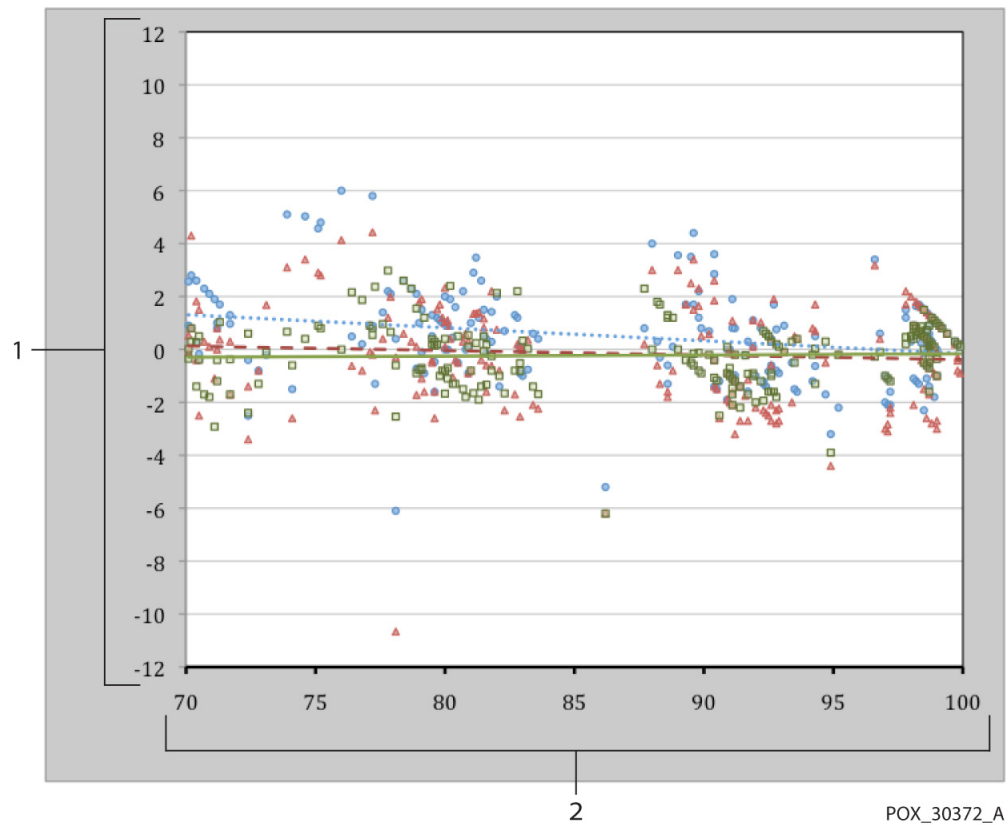
1	Test Sensor; Avg CO-oximeter value 70-100% SpO2	2	Avg CO-oximeter value 70-100% SpO2
●	Oximetry board with MAXA sensor	··········	Trendline of MAXA sensor
▲	Oximetry board with MAXN sensor	– – –	Trendline of MAXN sensor
▫	Oximetry board with MAXFAST sensor	——	Trendline of MAXFAST sensor

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 MAXA, MAXN and MAXFAST sensors. The pooled results indicate that for a saturation range of 70-100% for SpO_2, the acceptance criterion was met.

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