COVIDIEN

Operator's Manual

Nellcor™

Portable SpO_2 Patient Monitoring System

Table of Contents

List of Tables

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List of Figures

1 Introduction

1.1 Overview

This manual contains information for operating the Nellcor™ Portable SpO_2 Patient Monitoring System. Before operating the monitoring system, thoroughly read this manual.

This manual applies to the following product:

REF PM10N

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

1.2 Safety Information

This section contains important safety information related to general use of the Nellcor™ Portable SpO_2 Patient Monitoring System. Other important safety information appears throughout the manual. The Nellcor™ Portable SpO_2 Patient Monitoring System is referred to as the "monitoring system" throughout this manual.

1.2.1 Safety Symbols

Table 1-1. Safety Symbol Definitions

Symbol	Definition
	**WARNING** **Alerts users to potential serious outcomes (death, injury, or adverse events) to the patient, user, or environment.**

Table 1-1. Safety Symbol Definitions

Symbol	Definition
	**Caution** **Identifies conditions or practices that could result in damage to the equipment or other property**.
	**Note** Provides additional guidelines or information.

1.2.2 Explosion, Shock, and Toxicity Hazards

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

WARNING:
Shock hazard—Do not pour or spill liquids onto the monitoring system.

WARNING:
Shock hazard—Firmly close the battery cover to prevent moisture from entering the monitoring system.

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

1.2.3 Patient Monitoring and Safety

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

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

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

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

1.2.4 Monitoring System Operation and Service

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

WARNING:
To ensure accurate performance and prevent device failure, do not expose the monitoring system to extreme moisture, such as direct exposure to rain. Such exposure may cause inaccurate performance or device failure. Do not immerse in water, solvents, or cleaning solutions, since the monitoring system and pulse oximetry sensors and connectors are not waterproof.

WARNING:
Do not sterilize the monitoring system by irradiation, steam, or ethylene oxide.

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:
The only user-serviceable parts inside the monitoring system are the four AA batteries. While users can open the battery cover to change the batteries, only qualified service personnel should remove the cover or access internal components for any other reason. Users should 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 casing, since this may cause damage to the monitoring system. Never place fluids on the monitoring system. If fluid spills on the monitoring system, remove batteries, wipe all components dry immediately, and have the monitoring system serviced to ensure no hazard exists.

WARNING:
Do not damage the batteries by applying pressure. Do not throw, hit, or drop or impact the batteries.

WARNING:
Keep the monitoring system and batteries out of reach of children to avoid any accidents.

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

1.2.5 Monitoring System Readings

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

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

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

1.2.6 Sensors, Cables, and Other Accessories

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

WARNING:
Use only the Covidien-approved pulse oximetry sensors, interface cables, and accessories. Use of other sensors, cables, and accessories can result in inaccurate readings and increased monitoring system emissions.

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

WARNING:
To prevent damage, avoid undue bending of the sensor cable.

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

1.2.7 Electromagnetic Interference

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

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

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

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.

Caution:
This monitoring system generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. If interference is suspected, move pulse oximetry cables away from the susceptible device.

Caution:
Be aware of possible interference from sources of electromagnetic interference, such as cellular phones, radio transmitters, motors, telephones, lamps, electrosurgical units, defibrillators, and other medical devices. If pulse oximetry readings are not as expected for the patient's condition, remove the sources of possible interference.

1.2.8 Connections with Other Equipment

Caution:
Accessory equipment connected to the monitoring system's data interface must be certified according to IEC Standard 60950-1 for data-processing equipment. All combinations of equipment must be in compliance with IEC Standard 60601-1:2005 Requirements for Medical Electrical Systems. Anyone who connects additional equipment to the signal input or signal output port configures a medical system and is therefore responsible for ensuring the system complies with the requirements of IEC Standard 60601-1:2005 and IEC Standard 60601-1-2:2007.

Caution:
When connecting the monitoring system to any instrument, verify proper operation before clinical use.

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

1.2.9 Monitoring System Storage, Transport, and Disposal

Caution:
Remove the batteries from the monitoring system before placing it in storage or when not using it for a long period.

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

Caution:
Follow local government ordinances and recycling instructions regarding disposal or recycling of the monitoring system and its components, including batteries and accessories.

1.3 Obtaining Technical Assistance

1.3.1 Technical Services

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

Covidien Technical Services: Patient Monitoring

15 Hampshire Street

Mansfield, MA 02048 USA

1.800.635.5267, 1.925.463.4635,
or contact a local Covidien representative

www.covidien.com

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

1.3.2 Related Documents

Nellcor™ Portable SpO_2 Patient Monitoring System Home Use Guide — Provides basic information for operating the monitoring system, handling alarms, and troubleshooting errors or malfunctions. This manual is directed to home caregivers.

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

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

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

1.4 Revision History

The documentation part number and revision number indicate its current edition. The revision number changes when Covidien prints a new edition. Minor corrections and updates incorporated at reprint do not cause a change in the revision number. Extensive changes may require a new document part number.

1.5 Warranty Information

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

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2 Product Overview

2.1 Overview

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

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

2.2 Product Description

The Nellcor™ Portable SpO_2 Patient Monitoring System provides continuous, noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate.

2.3 Intended Use

WARNING:
The monitoring system is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms. Do not make any clinical judgments based on this monitoring system's measurements only.

The Nellcor™ Portable SpO_2 Patient Monitoring System is indicated for prescription use only for spot-check or continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate. It is intended for use with neonatal, pediatric, and adult patients during both no-motion and motion conditions, and for patients who are either well or poorly perfused, in hospitals, hospital-type facilities, and in mobile and home environments.

Note:

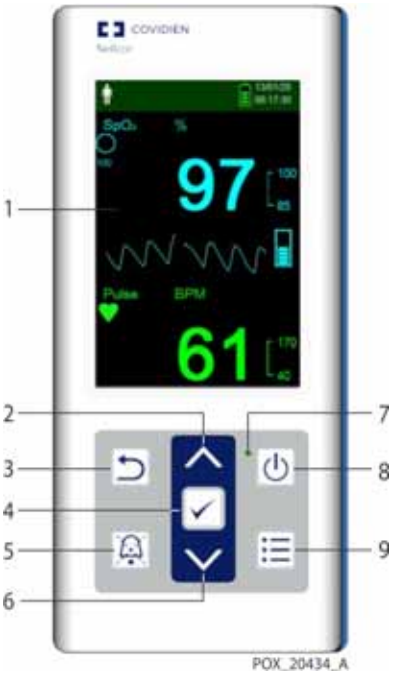
- Hospital use typically covers such areas as general care floors (GCFs), operating rooms, special procedure areas, intensive and critical care areas within the hospital, and in hospital-type facilities.
- Hospital-type facilities include physician office-based facilities, sleep labs, skilled nursing facilities, surgicenters, and sub-acute centers.
- Hospital transport and mobile environments include transport of a patient within the hospital or hospital-type facility, or transport between facilities or between a facility and a home environment.
- Home environment includes any environment other than a professional healthcare facility or clinical laboratory where a device may be used.

2.4 Product Views

2.4.1 Front Panel and Display Components

Front Panel

Figure 2-1. Front Panel Components



1		LCD panel (“display” or “screen”)	Use to monitor all graphic and numeric patient information as well as status conditions and warning messages. Reference *Figure 2-2.* on page 2-5.
2		Up button	Press to increase value (such as bpm, alarm volume, or brightness) and to scroll up.
3		Return button	Press to exit a menu on the display and go to monitoring screen.

4		OK button	Press to select the desired menu or setting. In the Monitoring History view, press to select granularity.
5		Audio Paused button	Press to toggle between disabling and re-enabling the audible alarm. Press to pause a high- or medium-priority alarm or to cancel a low-priority alarm.
6		Down button	Press to decrease value (such as bpm, alarm volume, or brightness) and to scroll down.
7		Power-on indicator	Is lit green when power is on.
8		Power On/Off button	Press and hold to turn on or off the monitoring system.
9		Menu button	Press to access menu or to return to the monitoring screen.

Display

Figure 2-2. Display Components

1		Patient Type and Patient Mode area	Reflects the current patient type selected. • **Adult/Pediatric type —** Appears when the alarm limits are set to adult and pediatric limit values. (Default)
			• **Neonatal type —** Appears when the alarm limits are set to neonate limit values.
			Or indicates that the monitoring system is in **Sleep Study Mode**.
2		SpO2 real-time value	Indicates hemoglobin oxygen saturation levels. Current upper and lower alarm limit settings appear as smaller values to the right of the dynamic SpO2 value.

3		Battery status icon	Displays the remaining battery capacity. • **Battery Good —** Battery power good. Four green bars appear when battery is fully charged. The number of green bars decreases as battery power is used. • **Low Battery —** A low priority alarm occurs when the remaining battery power is only enough for 15 minutes of operation. The flashing yellow alarm message `Low Battery` appears. Users cannot pause this alarm. Replace the battery to stop the alarm. • **Critically Low-Battery —** A high priority alarm occurs for about five (5) minutes before the monitoring system shuts off. The flashing red alarm message `Critically Low-Battery` appears. When no charge remains, the monitoring system automatically shuts down. Replace the battery.
4		Date/Time	Indicates the current date in day/month/year format and the current time in hours:minutes:seconds format. The date format can be changed in the Service Menu (pass code required).
5		SpO2 upper and lower alarm limits	Reflects upper and lower SpO2 alarm limits. An alarm sounds each time the patient's saturation value violates these alarm limits.
6		Pulse amplitude (blip bar)	Indicates pulse beat and the relative (non-normalized) pulse amplitude. As the detected pulse becomes stronger, more bars light with each pulse.
7		Pulse rate (BPM) upper and lower alarm limits	Reflects upper and lower pulse rate alarm limits. An alarm sounds each time the patient's pulse rate violates these alarm limits.
8		Pulse rate real-time value	Displays the pulse rate in beats per minute. Current upper and lower alarm limit settings appear as smaller values to the right of the dynamic pulse rate value.
9		Pulse beat (heart) icon	Flashes to indicate each real-time pulse beat. (Standard Mode only.)
10		Pulse rate icon	Indicates the pulse rate area of the display.
11		Plethysmographic (pleth) waveform	This non-normalized waveform uses real-time sensor signals, reflecting relative pulsatile strength of incoming signals.

12		SatSeconds™ icon	The SatSeconds™ feature provides alarm management for mild or brief SpO2 limit violations. When the SatSeconds™ feature is enabled, the SatSeconds icon fills in the clockwise direction as the SatSeconds alarm management system detects SpO2 readings outside of the limits setting. The SatSeconds icon empties in the counterclockwise direction when SpO2 readings are within limits. When the SatSeconds icon reaches full, a medium priority alarm sounds. The adult default setting is 100. Reference *Using the SatSeconds™ Alarm Management System*, p. 4-14.
13		SpO2 icon	Indicates the SpO2 area of the display.
--		Interference indicator	(Not shown in figure.) Lights when the monitoring system detects degraded quality in the incoming signal. It is common for it to intermittently light as the monitoring system dynamically adjusts the amount of data required for measuring SpO2 and pulse rate. When lit continuously, the monitoring system has extended the amount of data required for measuring SpO2 and pulse rate. In this case, fidelity in tracking rapid changes in these values may be reduced.[1]
--		Audio Paused indicator	(Not shown in figure.) Visible in the alarm limits area when the audible alarm is paused. When the Audio Paused button is pressed, the alarm is not audible for 30, 60, 90, 120 (default) seconds....., and the indicator displays the time countdown.
--		Sensor off indicator	(Not shown in figure.) Appears when the sensor is not on the patient.
--		Sensor disconnect indicator	(Not shown in figure.) Appears when the sensor is not connected to the monitoring system.
--		Sensor message indicator	(Not shown in figure) Appears when the sensor is invalid.
17		Informative message area (example shown)	Contains messages to notify the user of a condition or a request for action. The background color indicates the severity of the condition. Reference *Table 2-1.*

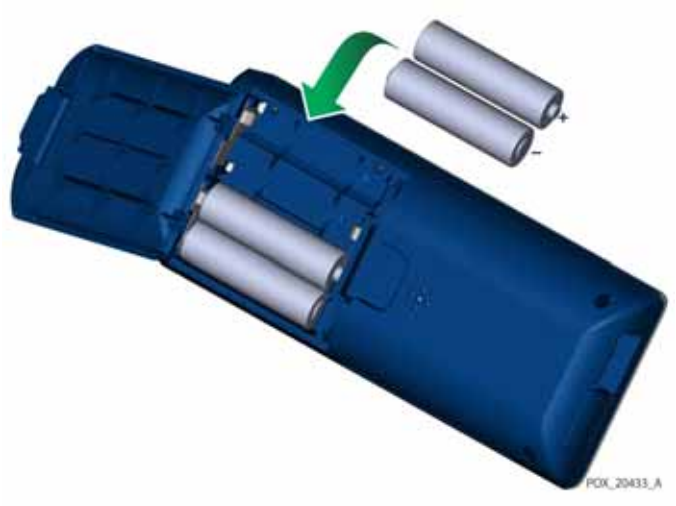
1. Degradation can be caused by ambient light, poor sensor placement, electrical noise, electrosurgical interference, patient movement, or other causes.

Table 2-1. Display Colors

Example	Description	Condition	Function
	Cyan numeric	Steady	SpO_2 value and plethysmographic waveform
	Green numeric		Pulse rate value
	Red background	Flashing	High priority alarm condition
	Yellow background		Alarm condition
	Yellow icon	Steady	Alarm condition (corresponds with yellow background containing a text-based message)
	Green, yellow, or red battery icon	Steady	Normal, low, or critically low battery status

2.4.2 Rear Panel

Figure 2-3. Rear Panel Components



2.4.3 Product and Carton Label Symbols

Table 2-2. Symbol Descriptors

Symbol	Description	Symbol	Description
	Type BF	SN	Serial number
Rx ONLY	Prescription only device		Date of manufacture
	Atmospheric pressure limitations		Keep dry
	Humidity limitations		Fragile
	Temperature limitations		UL listed

Table 2-2. Symbol Descriptors

Symbol	Description	Symbol	Description
	Must consult instructions for use		CE Mark
	Lithium battery		Manufacturer
	Reference code (part number)		EU representative
IP22	Protected against foreign objects and moisture		Consult instructions for use
	Chinese RoHS		Proper waste disposal for electrical and electronic equipment
	Flammable		

3 Installation

3.1 Overview

This chapter contains information for the installation and set up of the Nellcor™ Portable SpO_2 Patient Monitoring System prior to first-time usage.

3.2 Unpacking and Inspection

The monitoring system is shipped in a single carton. Examine the carton carefully for evidence of damage. Contact Covidien Technical Services immediately if the carton appears damaged. Do not return all packing material and the monitoring system prior to contacting Covidien. Reference *Technical Services*, p. 1-8.

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

Table 3-1. Standard Items

Item	Quantity
Nellcor™ Portable SpO2 Patient Monitoring System	1
Compact Disc (CD) and/or Operator's Manual and Home Use Guide[1]	1
Type AA lithium battery	4

1. Covidien provides electronic copy of monitoring system manuals on a compact disc for easy access and print-on-demand. Order a printed Nellcor™ Portable SpO2 Patient Monitoring System *Operator's Manual* or Home Use Guide at no cost or a printed Nellcor™ Portable SpO2 Patient Monitoring System *Service Manual* for a fee from Covidien Technical Services or a local Covidien representative.

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

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

3.3 Setup

3.3.1 Using the Batteries

WARNING:
Explosion hazard — Use only AA size batteries. Do not use a combination of different battery types at the same time. For example, do not use dry batteries and nickel-metal hydride batteries or Lithium-ion batteries together.

WARNING:
Do not operate the monitoring system with the battery cover open or removed.

The monitoring system is powered by four AA batteries.

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

New lithium batteries will provide 20 hours of monitoring operation under the following conditions:

- Monitoring the patient (Measuring SpO_2 and PR with blip bar and plethysmograph display)
- Setting for pulse beep tone is 25%
- Experiencing no alarm condition
- Display backlight is set to 25% brightness
- Ambient temperature is 25°C

To check battery power

1. Turn on the monitoring system.
2. Ensure the POST pass tone sounds when POST completes. Reference *Power On the Monitoring System*, p. 4-1 for details about the POST process.

3. Verify the Battery Status icon indicates remaining battery power. Reference *Figure 2-1.* on page 2-3 for battery status indicators.

4. If the Low Battery alarm occurs, replace the batteries. Reference *Figure 2-3.* on page 2-9.

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

Note:
Remove the batteries if the monitoring system will not be used for a period of time.

Note:
Periodically check the batteries for corrosion. Remove the batteries from the monitoring system before storage.

3.3.2 Connecting a Nellcor™ Pulse Oximetry Sensor

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

To connect a Nellcor™ pulse oximetry sensor

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

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

3. Open the sensor port cover.

Figure 3-1. Sensor Port Cover

4. If using a DEC-4 interface cable (optional), connect it to the sensor port. Otherwise, connect the sensor's cable to the port.

Figure 3-2. Interface Cable (DEC-4) or Sensor Cable Connection

5. If using a DEC-4 interface cable (optional), firmly connect the interface cable to the pulse oximetry sensor.

Figure 3-3. Interface Cable (Optional) Connection to Sensor

6. Attach the sensor to the patient.

When the monitoring system detects a valid pulse, it enters monitoring mode and displays real-time patient data. Reference *Figure 2-1.* on page 2-3.

A ***Sensor Message*** appears when the device cannot obtain an SpO_2 level or a pulse rate. Reference *Figure 2-2.* on page 2-5 ("Informative message area").

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

Note:
Physiological conditions, medical procedures, or external agents that may interfere with the monitoring system's ability to detect and display measurements include dysfunctional hemoglobin, arterial dyes, low perfusion, dark pigment, and externally applied coloring agents, such as nail polish, dye, or pigmented cream. Reference *Performance Considerations*, p. 6-1.

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4 Operation

4.1 Overview

This chapter identifies methods for viewing and collecting patient oxygen saturation data using the Nellcor™ Portable SpO_2 Patient Monitoring System.

4.2 Operation Basics

4.2.1 Power On the Monitoring System

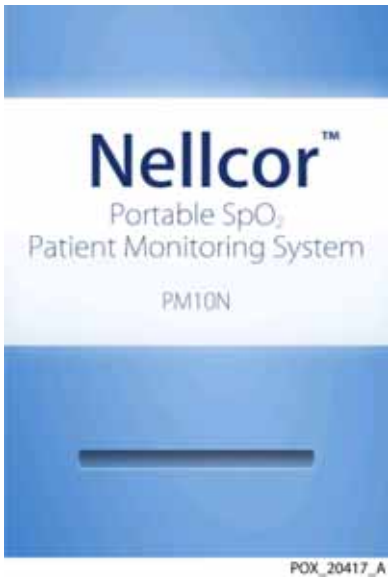
WARNING:
If any indicator or display element does not light, or the speaker does not sound, do not use the monitoring system. Instead, contact a qualified service technician.

To power on the monitoring system

1. Press the ***Power On/Off Button*** for approximately one second.

   While the monitoring system performs power-on self-test (POST), a progress bar appears at the bottom of the display.

Figure 4-1. Example Initial Screen



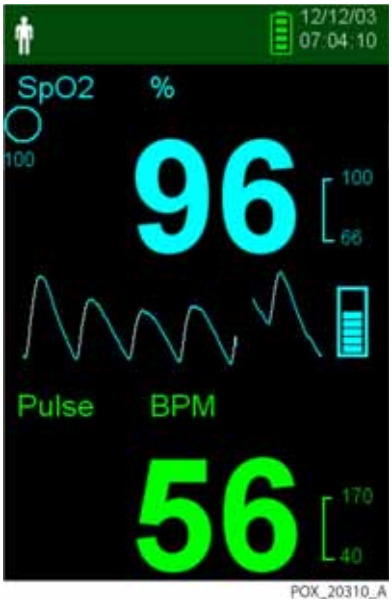
2. Ensure the *POST pass* tone sounds when POST completes.

   The POST pass tone functions as an audible confirmation of proper speaker performance. If the speaker does not function, the alarm warning sounds remain inaudible.

   Once POST is complete, the monitoring screen appears. If a sensor is connected to the patient, SpO2 and pulse readings are displayed, as shown in *Figure 4-2 on page 4-3*.

3. Ensure all monitoring screen elements are properly displayed.

Figure 4-2. Main Monitoring Screen



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

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

4.2.2 Power Off the Monitoring System

After using the monitoring system, turn it off safely.

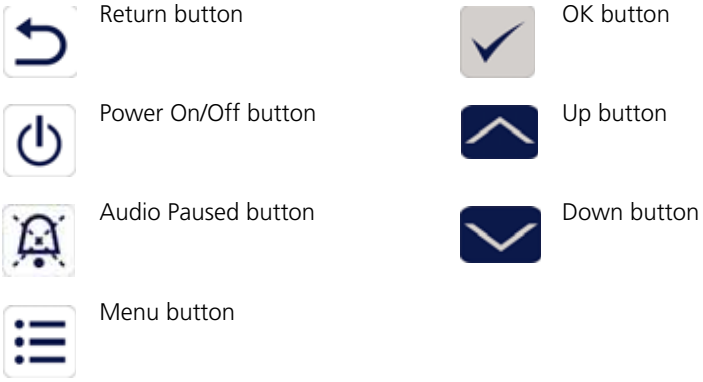
To turn off the monitoring system

1. Press the Power On/Off button for approximately 1 second.
2. Observe that the monitoring system's screen goes dark with nothing displayed.

Note:
After any situation involving continuous resets or a system lock, press the Power On/Off button for at least 10 seconds to turn off the monitoring system.

4.2.3 Navigate the Menus

Access the following buttons from the front panel of the monitoring system:



Unless the Key Beep volume is set to 0 (default), a beep is audible whenever a button is pressed. Invalid button presses are ignored. Reference *Product Views*, p. 2-3 for more information about the buttons and the items that appear on the display.

4.3 Menu Structure and Factory Defaults

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

Table 4-1. Menu Structure and Available Options

Item	Available Selections	Factory Defaults	
		Adult/ Pediatric	Neonate
Alarm Limits			
Audio Pause	30, 60, 90, 120 *s*	120 s	
High %SpO2	21-100% (1% steps)	100%	95%
Low %SpO2	20-99% (1% steps)	85%	
High Pulse Rate	21-250 bpm (1 bpm steps)	170 bpm	190 bpm
Low Pulse Rate	20-249 bpm (1 bpm steps)	40 bpm	90 bpm
SatSeconds Limit	Off, 10, 25, 50, 100	100	Off

Table 4-1. Menu Structure and Available Options (Continued)

Item	Available Selections	Factory Defaults	
		Adult/ Pediatric	Neonate
Device Settings			
Sound Settings			
Alarm Volume	0%, 25%, 50%, 75%, 100%		
	Standard Mode	75%	
	Homecare Mode	75%	
	Sleep Study Mode	0%	
Pulse Beep Volume	0%, 25%, 50%, 75%, 100%		
	Standard Mode	0%	
	Homecare Mode	0%	
	Sleep Study Mode	0%	
Key Beep Volume	0%, 25%, 50%, 75%, 100%		
	Standard Mode	25%	
	Homecare Mode	25%	
	Sleep Study Mode	0%	
Brightness Setting	0%, 25%, 50%, 75%, 100%		
	Standard Mode	25%	
	Homecare Mode	25%	
	Sleep Study Mode	0%	
	Screen Save Mode (Service Menu)	25%	
Monitoring History			
View Spot Data	Saved spot readings	N/A	
View Continuous Data	Intervals of 1, 5, 100, and 500	100	
Clear Monitoring History	No, Yes	Yes	
Transfer Data			
Spot Data	By USB	By USB	
Continuous Data	By USB		

Table 4-1. Menu Structure and Available Options (Continued)

Item	Available Selections	Factory Defaults	
		Adult/ Pediatric	Neonate
Change Patient Mode			
Patient Mode	Adult, Neonate	Adult	
Response Mode	Normal, Fast	Normal	
Homecare Mode	Confirm (after entering pass code), Cancel	Confirm	
Sleep Study Mode	Confirm (after entering pass code), Cancel	Confirm	
Service Menu			
(For qualified service technicians only.)			

4.4 Patient Monitoring

WARNING:
Unless the monitoring history is cleared before the monitoring system is attached to a new patient, the monitoring system will retain trend data from multiple patients.

Follow the instructions in this section to perform basic patient monitoring functions.

4.4.1 Set Patient Mode

Caution:
When the monitoring system is set to standard mode, it is intended for use in a hospital or hospital-type environment by trained medical personnel. Reference *Additional Patient Modes*, p. 4-16 for information about other operating modes.

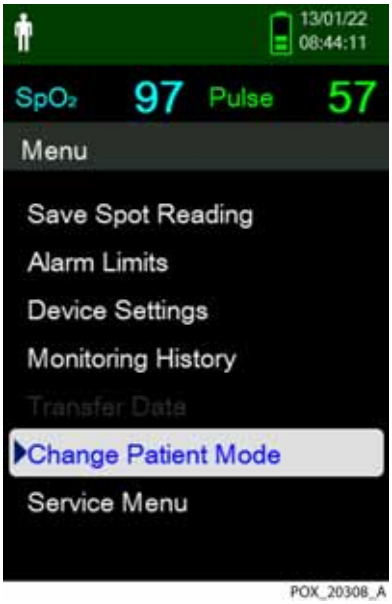
Select the patient mode, either Adult or Neonate.

To select the patient mode

1. Press the Menu button.

2. Scroll to Change Patient Mode and press the OK button.

Figure 4-3. Patient Mode Menu



3. Select the appropriate patient mode and pulse oximetry sensor based on body weight. Reference the pulse oximetry sensor *Directions for Use*.

Adult — For adult and pediatric patients

Neonatal — For newborns

4. Press the OK button to confirm the selection of patient mode.

5. Press the Menu or RETURN button to go back to the monitoring screen.

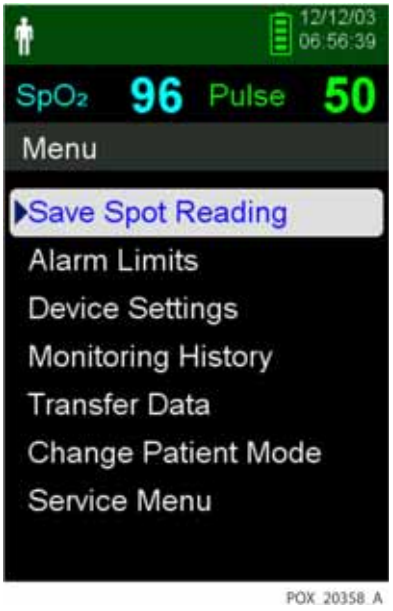
4.4.2 Save a Spot Reading

The Save Spot Reading function saves a point in time of the patient's data.

To save a spot reading

1. Press the Menu button.

Figure 4-4. Save Spot Reading



2. If it is not already selected, scroll to Save Spot Reading.
3. Press the OK button to select this item.

   The message "Spot Reading Saved" appears.
4. Reference *Monitoring History*, p. 5-1 to view the saved spot readings.

4.5 Alarms and Alarm Limits Management

4.5.1 Alarm Indicators

The monitoring system enters an alarm state when a condition occurs that requires user attention. Reference *Troubleshooting*, p. 8-1.

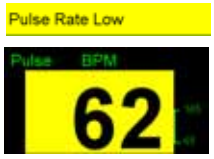
As described in *Table 4-2 on page 4-9*, the monitoring system uses both visual and audible indicators to identify high-priority, medium-priority, and low-priority alarms. High priority alarms take precedence over medium- and low-priority alarms.

Visual alarms appear on the screen in order of highest priority, regardless of any audible alarm status.

Sensor Disconnect, Sensor Off, and Sensor Failure alarms, which by default are low-priority alarms, can be set as medium- or high-priority alarms in the Service Menu (pass code required).

Note:
Visual and audible alarm indicators are turned off when the monitoring system is set to Sleep Study Mode.

Table 4-2. Alarm Conditions

	Audible	Visual		
Priority	**Rate**	**Description**	**Example**	**Messages**
High	Triple beep, sounds every 4 s	Top of screen: Flashing red bar with text message Pulse area: Flashing red background with dashed line		Loss of Pulse Battery Critically Low
Medium	Triple beep, sounds every 8 s	Top of screen: Flashing yellow bar with text message SpO2 and Pulse areas: Flashing yellow back-ground on numeric value		Pulse Rate High Pulse Rate Low SpO2 High SpO2 Low
Low	Single beep, sounds every 16 s	Top of screen: Steady yellow bar with text message SpO2 and Pulse areas: Steady yellow with dashed line		Sensor Disconnected[1] Sensor Off (Patient)[1] Sensor Failure[1] Low Battery Pulse search[2]
Informative	--	--		Interference Alarm audio paused

1. Can be set as a low-, medium-, or high-priority alarm through the Service Menu. A pass code is required to access the Service Menu.
2. Visual alarm only.

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

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

4.5.2 Pausing an Audible Alarm

WARNING:
If patient safety could be compromised, do not pause the audible alarm or decrease its volume.

WARNING:
To avoid compromising patient safety, do not cover or obstruct the holes for the speaker.

Audible alarm indicators include pitched tones, beeps, and a buzzing sound. Audible alarms can be paused for 30, 60, 90, or 120 seconds. Visual alarms continue during any ***Audio Paused*** period.

The factory default pause period for an audible alarm is 120 seconds. To set one of the alternate periods as an institutional default, a qualified service technician must access the Service Menu.

To pause an audible alarm

1. Press the ***Audio Paused*** button to immediately pause the alarm tone.

   Note the following:

- When the ***Audio Paused*** period is enabled, the audible alarm is not active for the specified time interval and the ***Audio Paused*** icon appears above the appropriate alarm limit icon.
- If the audible alarm is caused by a technical error, pressing the Alarm ***Audio Paused*** button cancels the alarm.
- If another alarm occurs during the ***Audio Paused*** period, the monitoring system re-enables all audio tones.

- After the ***Audio Paused*** period, the audible alarm resumes if the alarm condition remains.

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

3. Take the appropriate corrective action.

Note:
Audible alarms for battery failure and physiological alarms cannot be canceled without appropriate corrective action.

4.5.3 Adjusting Alarm Limits

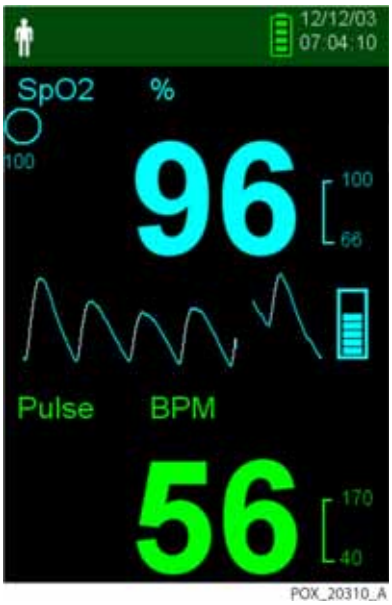
WARNING:
Check alarm limits to ensure they are appropriate for the patient being monitored with each use. Ensure alarm limits do not exceed the standard thresholds set by the institution.

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

As necessary, caregivers can adjust SpO_2 and pulse rate (PR) alarm thresholds from default values. These changes remain in effect until modified again or until a power cycle occurs. Changes to the SpO_2 and pulse rate (PR) alarm thresholds appear in their respective numerical area on the monitoring screen.

In addition, caregivers can use the SatSeconds™ alarm option to manage the frequency of SpO_2 alarm limit violations by adjusting the SatSeconds™ setting. The higher the value, the less frequent the alarm.

Figure 4-5. Main Monitoring Screen



SpO₂ %

SpO2 numerical area — Indicates hemoglobin oxygen saturation levels. The display value flashes zeros during loss-of-pulse alarms and flashes the SpO2 value on a yellow background when saturation is outside the alarm limits. During SpO2 searches, the monitoring system continues to update the display. Current upper and lower alarm limit settings appear as smaller values to the right of the dynamic SpO2 value. Reference *Menu Structure and Factory Defaults*, p. 4-4, for default alarm limit settings.

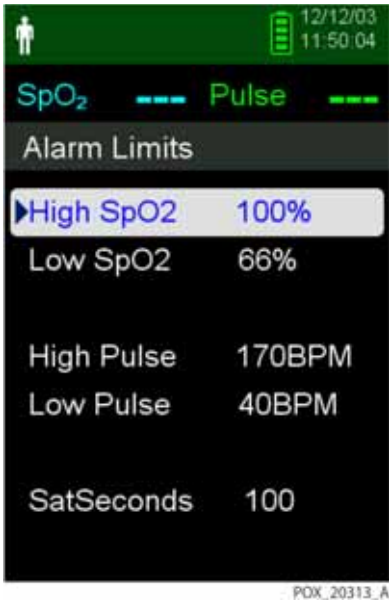
Pulse BPM

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

To set alarm limits

1. Press the Menu button.
2. Press the Down button and OK button to select the Alarm Limits menu.

Figure 4-6. Alarm Limits Menu

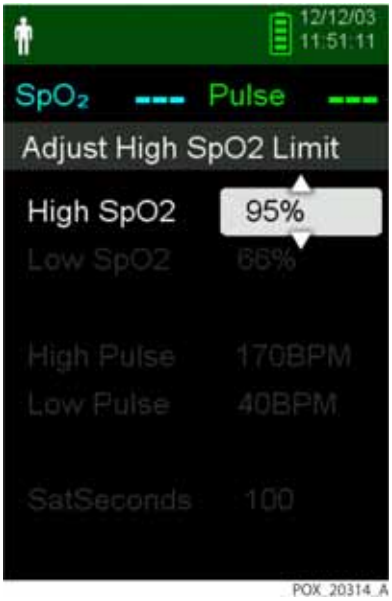


Alarm settings include:

- Pulse rate (PR) and SpO_2 alarm limit ranges.
- SatSeconds™ Alarm option, which provides alarm management of SpO_2 alarm limit violations.

3. Press the Up button or Down button to highlight the desired option.
4. Press the OK button to select the desired option. For example, *Figure 4-7* shows the High SpO_2 setting selected.

Figure 4-7. High SpO2 Setting



5. Press the up button or down button to change the value. Reference *Menu Structure and Factory Defaults*, p. 4-4, for adult and neonate limit options.

6. Press the OK button to save the desired value.

7. Press the up button or down button to highlight another option or press the Return button to return to the Main Menu.

4.5.4 Using the SatSeconds™ Alarm Management System

The SatSeconds feature monitors both *degree* and *duration* of desaturation as an index of desaturation severity. Use the appropriate SatSeconds setting—Off, 10, 25, 50, or 100—to distinguish clinically significant events from minor and brief desaturations that may result in nuisance alarms.

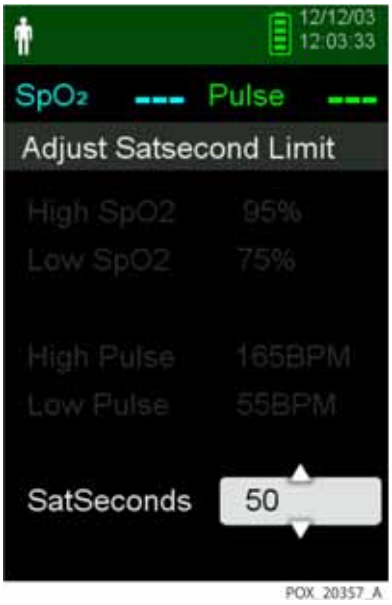
The SatSeconds alarm management system calculates the duration of the event multiplied by the number of percentage points that saturation falls outside of the saturation alarm threshold. With SatSeconds, an alarm is triggered only when the SatSeconds value is reached.

For more information about SatSeconds, reference Reference *SatSeconds™ Alarm Management Parameter*, p. 10-6.

To set SatSeconds

1. Press the Menu button.
2. Press the Down button to highlight the Alarm Limits menu item and press OK to select it.
3. On the Alarm Limits Menu, press the Down button to highlight SatSeconds.
4. Press the Down arrow to change SatSeconds to 50, 25, 10, or off (the default value is 100).
5. Press OK to select the value.

Figure 4-8. SatSeconds Setting



4.6 Additional Patient Modes

In addition to setting the patient mode to Adult or Neonate, patient mode settings include Response Mode, Homecare Mode, and Sleep Study Mode. These are described in the following sections.

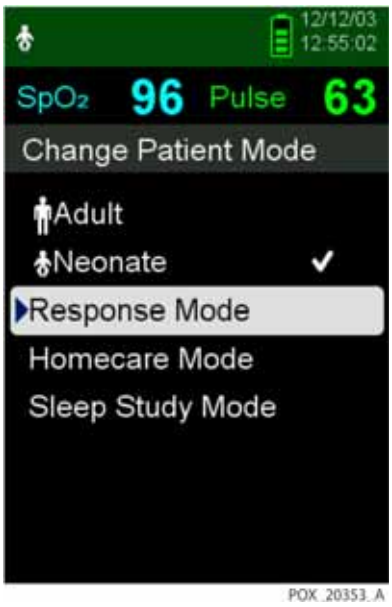
4.6.1 Set Response Mode

Response Mode establishes the rate at which the monitoring system responds to changes in SpO_2 readings.

To set Response Mode

1. Access the Change Patient Mode menu.
2. Press the Up or Down button to highlight the Response Mode menu, then press the OK button to select the Response Mode menu.

Figure 4-9. Response Mode Menu



3. Press the Up or Down button to highlight Normal or Fast, then press the OK button to confirm the selection.

   - **Normal —** Responds to changes in blood oxygen saturation within five (5) to seven (7) seconds.

- **Fast —** Responds to changes in blood oxygen saturation within two (2) to four (4) seconds. This mode can be particularly helpful for situations that require close monitoring.

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

Note:
The Monitoring Speed setting does not affect the calculation of pulse rate or the recording of trend data. Recording occurs at one-second intervals.

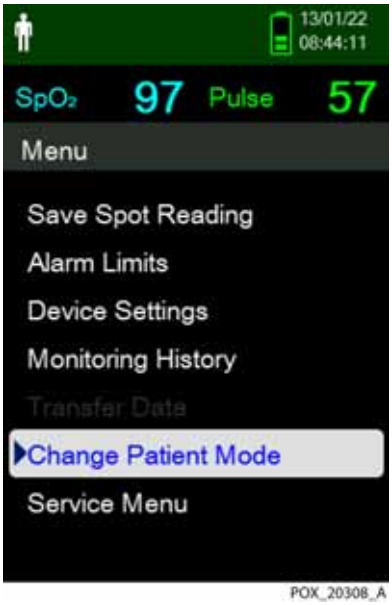
4.6.2 Set Homecare Mode

Set the monitoring system to Homecare Mode when a lay person will be using the monitoring system outside of a hospital or other professional care setting. Homecare Mode provides limited functionality to simplify operation.

To set Homecare Mode

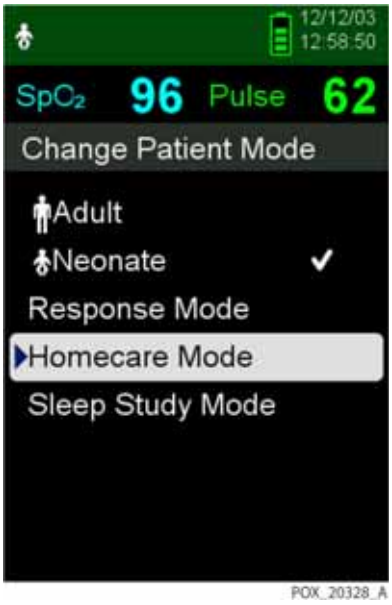
1. Access the Change Patient Mode menu.

Figure 4-10. Patient Mode Menu Item



2. Press the Up or Down button to highlight the Homecare Mode menu, then press the OK button to select the Homecare Mode menu item.

Figure 4-11. Homecare Mode Menu Item



3. Enter the four-digit pass code for Homecare Mode.

   Use the Up and Down Arrows to change the value for each digit, then press the OK button to select the value.

Figure 4-12. Pass Code Entry for Homecare Mode

4. After entering the four-digit pass code, select Confirm to enter Homecare Mode.
5. When prompted to clear or keep monitoring history, select Yes or No.

Figure 4-13. Prompt to Delete or Keep Monitoring History

The monitoring system is now operating in Homecare Mode.

Figure 4-14. Homecare Mode Monitoring Screen

6. To return to Standard Mode, access the Patient Mode menu again, and enter the pass code for Standard Mode.

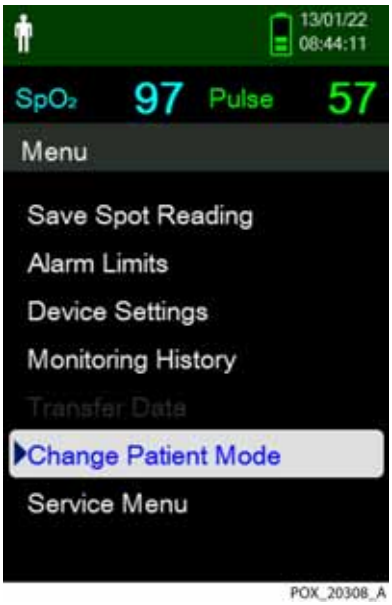
4.6.3 Set Sleep Study Mode

Set the monitoring system to Sleep Study Mode when a sleep study will be performed on a patient. In Sleep Study Mode, alarms are silenced and the screen is dimmed.

To set Sleep Study Mode

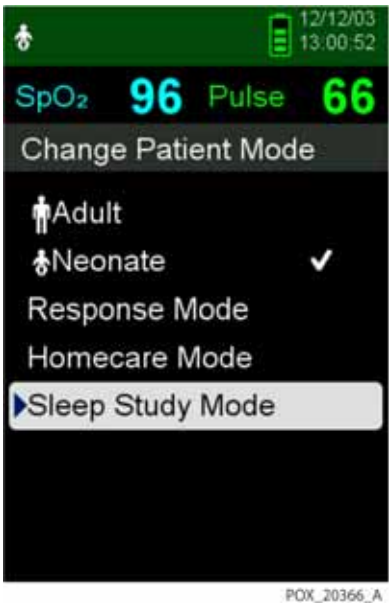
1. Access the Change Patient Mode menu.

Figure 4-15. Patient Mode Menu Item



2. Press the Up or Down button to highlight the Sleep Study Mode menu, then press the OK button to select the Sleep Study Mode menu item.

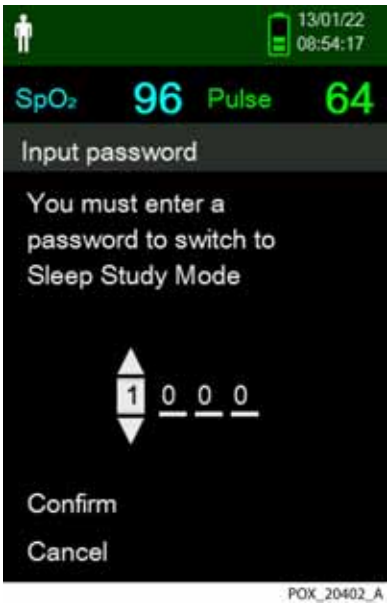
Figure 4-16. Sleep Study Mode Menu Item



3. Enter the four-digit pass code for Sleep Study Mode.

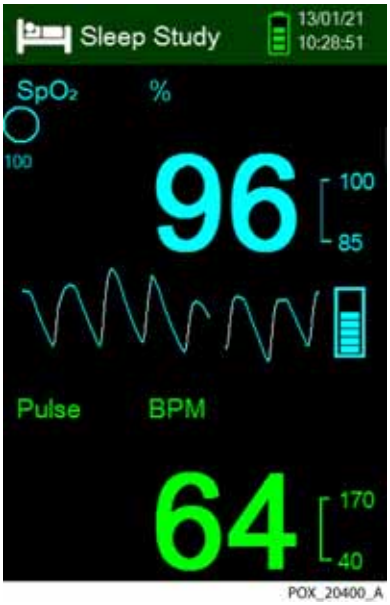
   Use the Up and Down Arrows to change the value for each digit, then press the OK button to select the value.

Figure 4-17. Pass Code Entry for Sleep Mode



4. After entering the four-digit pass code, select Confirm to enter Sleep Study Mode.

Figure 4-18. Sleep Study Mode



When the buttons have not been pressed for three minutes, the screen dims.

5. To brighten the screen again, press any button.

6. To return to Standard Mode, access the Patient Mode menu again, and enter the password for Standard Mode.

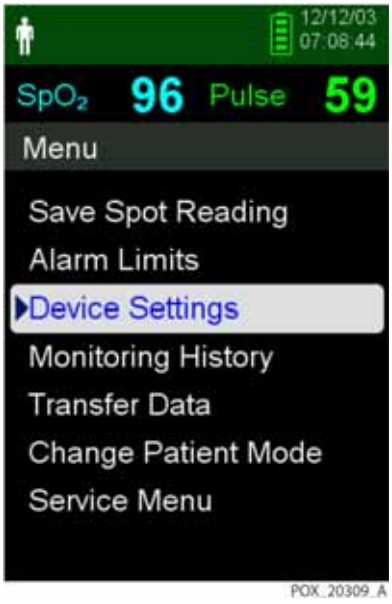
4.7 Adjust Brightness and Volume

Access the Device Settings menu to adjust the monitoring system's brightness and volume.

To access the Device Settings menu

1. Press the Menu button.
2. Press the up button or down button to highlight the Device Settings menu and then press the OK button to select the Device Settings menu.

Figure 4-19. Device Settings Menu

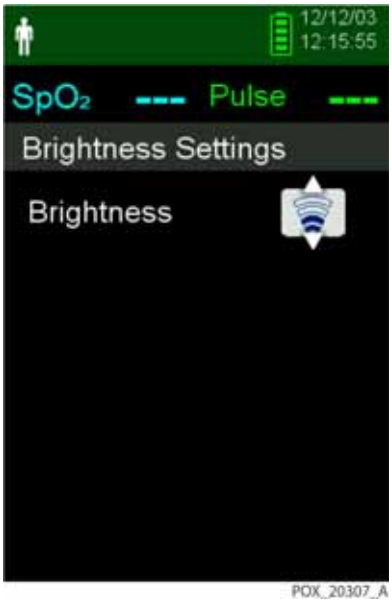


4.7.1 Adjust Brightness

To adjust the brightness of the screen

1. In the Device Settings menu, press the up button or down button to highlight the Brightness Setting menu item and then press the OK button to select the Brightness Setting menu.

Figure 4-20. Brightness Setting Menu



- Press the down button to decrease the brightness.
- Press the up button to increase the brightness.

2. Press the OK button to save the desired brightness.

4.7.2 Adjust Volume

To set the desired audible tone volume

1. Press the Menu button.
2. Press the down button to highlight the Device Settings menu and then press the OK button to select the Device Settings menu.
3. Select the Sound Settings menu.

Figure 4-21. Sound Settings Menu

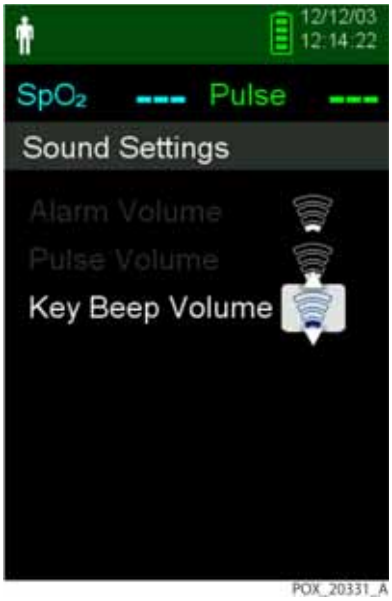
4. Press the OK button to select Alarm Volume. Press the down arrow and OK button to highlight and select Pulse Volume or Key Beep Volume.

   - Alarm volume controls the volume of alarms. The lowest possible alarm setting is governed by the Permission to Mute Alarm setting in the Service Menu. Ask a technician to enable this option.

   - Pulse volume controls the volume of the blip bar and plethysmographic waveform.

   - Key Beep volume controls the volume of any button press.

Figure 4-22. Example Volume Setting



5. Adjust to the desired volume level.
   - Press the down button to decrease the volume level.
   - Press the up button to increase the volume level.
6. Press the OK button to save the desired volume level.

4.7.3 Screen Saver

If Screen Saver is enabled through the Service Menu (pass code required), the screen will turn off after 10 minutes of no button presses. To turn the screen back on, press any button on the monitoring system's front panel.

4.8 Service Menu

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

4.9 Maintenance Reminder

Schedule regular maintenance and safety checks with a qualified service technician every 24 months. Reference *Periodic Safety Checks*, p. 7-3. In the case of mechanical or functional damage, contact Covidien or a local Covidien representative. Reference *Obtaining Technical Assistance*, p. 1-8.

5 Data Management

5.1 Overview

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

The monitoring system stores up to 80 hours of trend data. When the monitoring system begins measuring vital signs, it saves data every one (1) second. It also saves all physiological alarm conditions and errors. Trend data history remains in memory even if the monitoring system is powered off. The monitoring system stores new data over the oldest data when the buffer is full.

The monitoring system displays trend data in tabular and graphical formats.

5.2 Monitoring History

The monitoring system presents trend information in tabular format. The newest data values appear at the top.

To review monitoring history

1. Press the Menu button.
2. Press the Up or Down button to highlight the Monitoring History menu, then press the OK button to select the menu.

Figure 5-1. Monitoring History Menu

3. From the Monitoring History menu, select View Spot Data or View Continuous Data.

Figure 5-2. Monitoring History Screen

The View Spot Data screen displays only the readings that were saved using the Save Spot Reading item from the main menu.

If the list of readings is longer than one screen, a scroll bar displays on the right edge of the screen.

4. Use the Down Arrow to scroll through the list.

   The Continuous Data screen allows for adjustment of the interval of the display readings.

5. While viewing Continuous Data, adjust the interval of the displayed readings by pressing OK to display every 1, 5, 100, or 500 data points. The default interval is 100.

Figure 5-3. Continuous Data Screen (Interval 100) and Scroll Bar

The Status column of the history table will be blank if no errors were present when the data point was recorded. Status codes are listed in *Table 5-1*

.

Table 5-1. Monitoring Status Codes

Status Code	Description
LM	Loss of pulse, patient motion
LP	Loss of pulse
CB	Critically low battery
LB	Low battery
SO	Sensor off
SD	Sensor disconnect
AO	Alarm off
AS	Alarm paused
MO	Signal interference, patient motion
PS	Pulse search

5.3 External Data Communication

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

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

Caution:
Connect the monitoring system to a medical grade PC that is on an isolated AC circuit.

Note:
Reference the manuals for Oxinet III or VitalSync for operation information and recommendations for the placement of the monitoring system relative to the distributed alarm system.

The monitoring system supports trend data downloads by mini-USB connection to a PC.

5.3.1 Monitoring History (Trend Data) Download

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

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

Caution:
If the monitoring system does not contain its own isolation barrier, connect it to a medical grade PC that is on an isolated AC circuit.

To download monitoring history (trend data), connect by mini-USB port to a PC using HyperTerminal or other data transmission and analysis tools. Any PC connected to the data port must be certified according to IEC Standard 60950. All combinations of equipment must be in compliance with IEC Standard 60601-1-1 system requirements. Use either ASCII communication protocol:

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

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

System Compatibility Prerequisites

- Windows-based PC
- HyperTerminal or equivalent software installed on PC

Hardware

- Mini-USB data download cable
- CD or thumb drive, if USB driver required

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

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

To download trend data using HyperTerminal

1. Ensure that a service technician has configured the monitoring system's Serial Connectivity Settings appropriately.
2. Connect the monitoring system's mini-USB port to the computer.
3. Execute HyperTerminal.

Note:
If this is the first time the HyperTerminal program launches, it will prompt the user to set it as the default Telnet program. Depending on institutional requirements, choose Yes or No.

4. Set the appropriate values for HyperTerminal's port settings:
    a. Set the baud rate (bits per second) to match the monitoring system's baud rate.
    b. Ensure the data bit is set to 8.

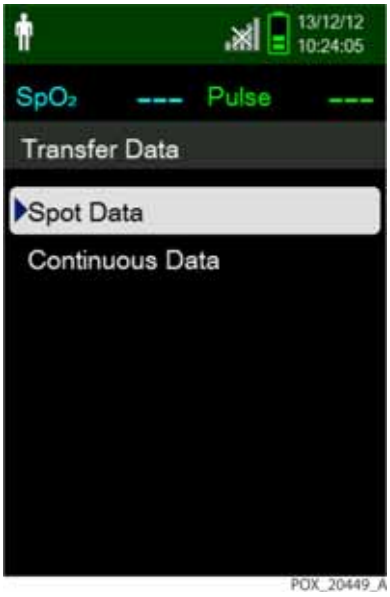
c. Ensure the parity bit is set to none.

d. Ensure the stop bit is set to 1.

e. Ensure the flow control is set to off.

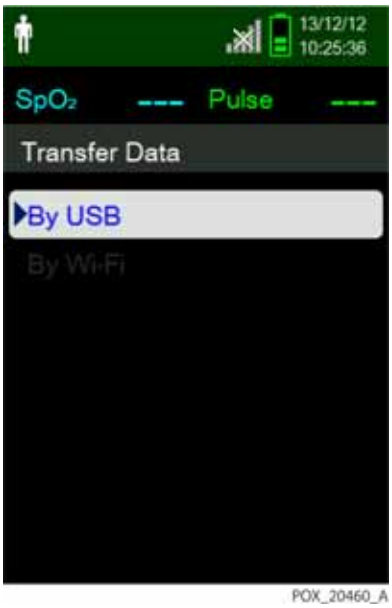
5. From the monitoring system's Transfer Data menu, select Spot Data or Continuous Data.

Figure 5-4. Transfer Data Type



6. Select By USB.

Figure 5-5. Transfer Data by USB



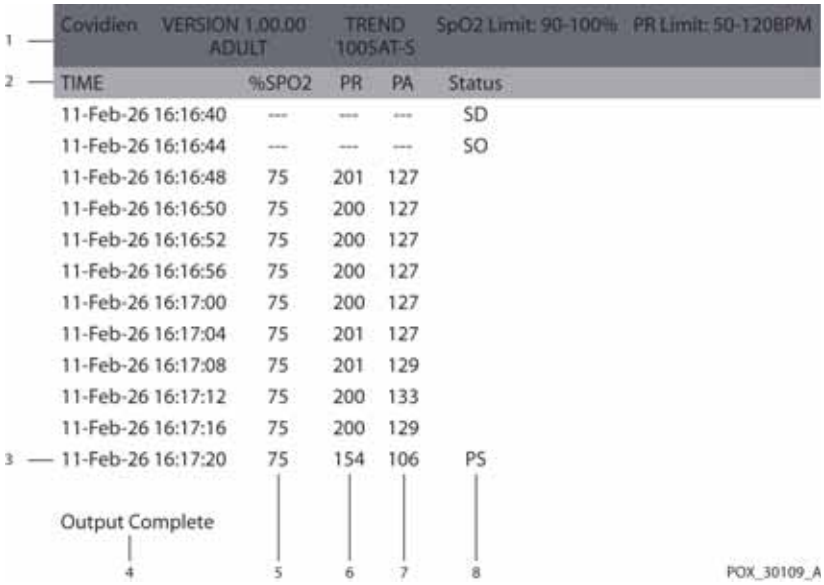
The data is transferred, and a progress bar is displayed. If desired, select Cancel to abort the transmission.

The Output Complete message is displayed when the transmission is complete.

To interpret downloaded trend data

1. Examine trend data on the HyperTerminal screen, in a spreadsheet, or on a print-out from the personal computer.

Figure 5-6. Sample Trend Data Printout



1	Product column headings	Data source, firmware version, and system settings
2	Patient data column headings	Lists appropriate time and data headings
3	Time column	Real-time clock date and time stamp
4	Output Complete	Message indicating completion of trend data download
5	%SpO2	Current saturation value
6	PR	Current pulse rate
7	PA	Current pulse ampltitude
8	Status	Operating status of the monitoring system

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

3. Scan the time, SpO2, or PR column until reaching the events of interest.

4. Reference *Table 5-1.* on page 5-4 for descriptions of the operating status codes.

COM port USB Driver Alternatives

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

To install a USB driver from the compact disc

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

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

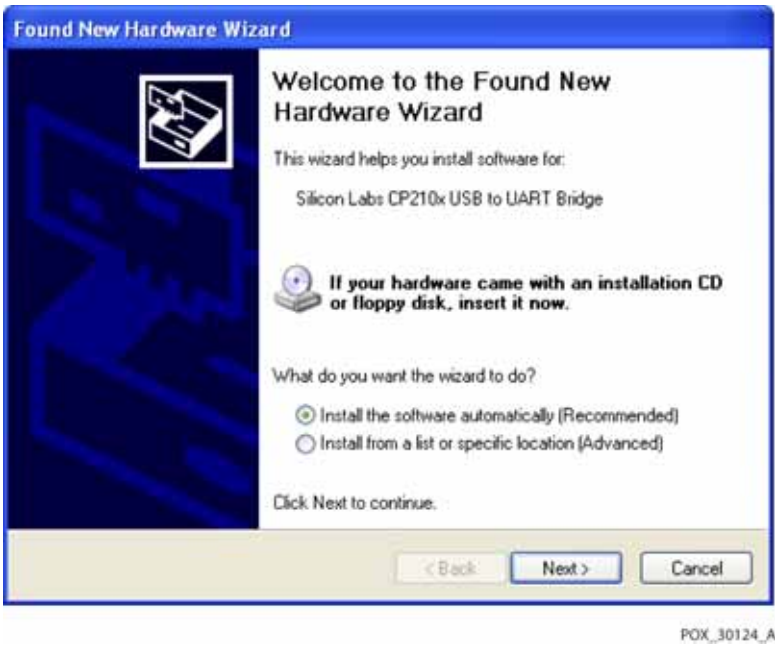
7. Click INSTALL.

Figure 5-7. Bridge Driver Installer window

8. Reboot the PC for changes to take effect.
9. Connect the monitoring system to the PC, firmly engaging the USB end to the PC and the mini-USB to the monitoring system.

10. Allow the PC to sense the new hardware and load the InstallShield Wizard, which guides users through the entire setup process. Do not click the CANCEL button.

Figure 5-8. New Hardware Wizard Screen



11. At the prompt from the InstallShield Wizard, click on the NEXT button to copy the driver to the PC.

12. When the InstallShield Wizard provides the end-user license agreement, read it carefully, then click the button for accepting the terms of the license.

13. Click NEXT to formally accept the agreement.

14. Review the Destination Folder mapping. To change the destination, click BROWSE and select the desired mapping.

15. Click NEXT to formally accept the Destination Folder mapping.

16. Click INSTALL in the resulting driver installer window. Do not click the CANCEL button.

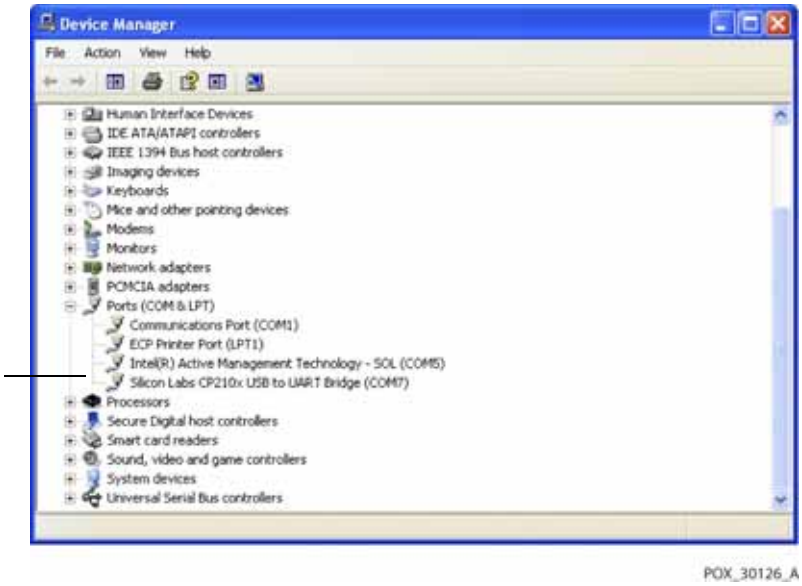
Note:
If Windows Security pops up, select the option to install the driver anyway.

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

Figure 5-9. Device Manager Button Under Hardware Tab

22. Select the Ports option from the resulting list.

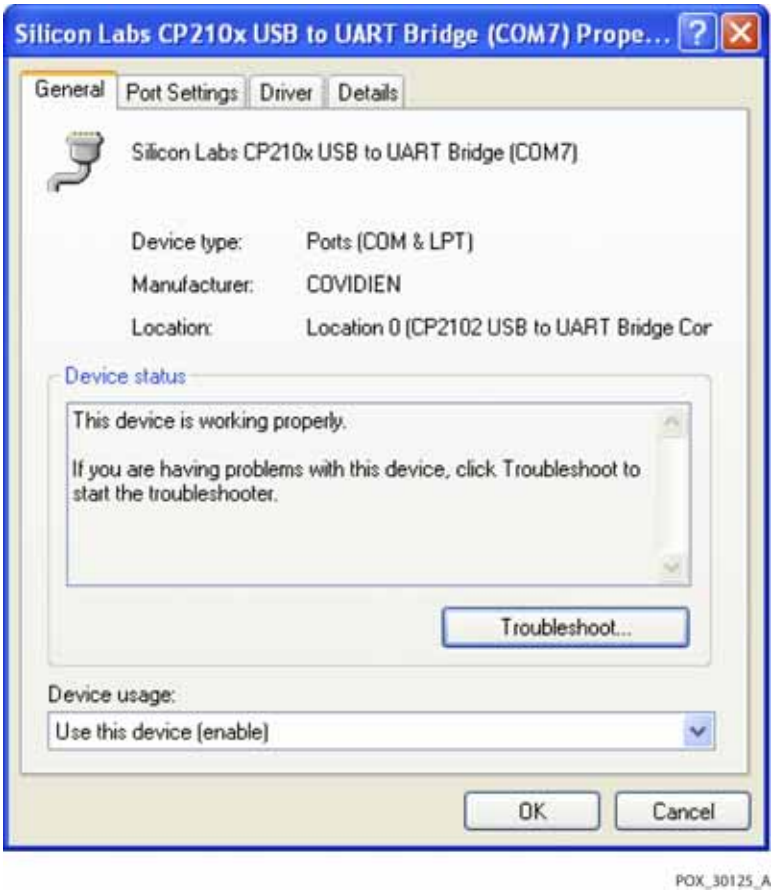
Figure 5-10. Hardware list in Device Manager window



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

Note:
The listed COM port should match the HyperTerminal COM port designation. Reference *To download trend data using HyperTerminal*, p. 5-6.

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



24. Click the Port Settings tab.

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

Figure 5-12. Baud rate list under Port Settings tab

26. Click the OK button to complete the process.

27. Reference *To download trend data using HyperTerminal*, p. 5-6.

5.3.2 Firmware Upgrades

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

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6 Performance Considerations

6.1 Overview

This chapter contains information about optimizing the performance of the Nellcor™ Portable SpO_2 Patient Monitoring System.

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

6.2 Oximetry Considerations

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

6.2.1 Pulse Rates

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

6.2.2 Saturation

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

6.3 Performance Considerations

6.3.1 Overview

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

Verify the performance of the monitoring system by following the procedures outlined in the *SRC-MAX Pulse Oximetry Functional Tester Technical Manual*. Have a qualified service technician perform these procedures prior to initial installation in a clinical setting and every 24 months as part of preventive maintenance. Reference *Service*, p. 7-3.

6.3.2 Patient Conditions

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

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

6.3.3 Sensor Performance Considerations

WARNING:
To ensure accurate measurements in bright ambient light, cover the pulse oximetry sensor site with opaque material.

Inaccurate Sensor Measurement Conditions

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

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

Signal Loss

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

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

Recommended Usage

Select an appropriate Nellcor™ pulse oximetry sensor, apply it as directed, and observe all warnings and cautions presented in the *Instructions for Use* accompanying the sensor. Clean and remove any substances such as nail polish from

the application site. Periodically check to ensure that the sensor remains properly positioned on the patient.

High ambient light sources such as surgical lights (especially those with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, and direct sunlight can interfere with the performance of a Nellcor™ pulse oximetry sensor. To prevent interference from ambient light, ensure that the sensor is properly applied, and cover the sensor site with opaque material.

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

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

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

6.3.4 Reducing EMI (Electromagnetic Interference)

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

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

- Turn equipment in the vicinity off and on to isolate the offending equipment.
- Reorient or relocate the interfering equipment.

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

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

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7 Preventive Maintenance

7.1 Overview

This chapter describes the steps required to maintain, service, and properly clean the Nellcor™ Portable SpO_2 Patient Monitoring System.

7.2 Cleaning

WARNING:
Remove batteries from the monitoring system before cleaning.

WARNING:
For reusable sensors, refer to the cleaning instructions in the *Instructions for Use* for each sensor. Reference *Product Specifications*, p. 11-1.

The monitoring system may be surface-cleaned by using a soft cloth dampened with either a commercial, nonabrasive cleaner or one of the solutions listed below. Lightly wipe all surfaces of the monitoring system.

- Quaternary ammonium compounds
- Quaternary ammonium compounds in combination with polyhexanide
- Alcohols, such as 70% isopropyl
- Glucoprotamin
- 10% chlorine bleach solution
- PDI Sani-System

Figure 7-1. Monitoring System Cleaning

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

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

7.3 Recycling and Disposal

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

7.4 Battery Maintenance

Note:
Use the monitoring system's battery indicator as a guide to the amount of battery power remaining. Reference *Figure 2-2.* on page 2-5.

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

7.5 Periodic Safety Checks

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

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

7.6 Service

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

- The monitoring system requires no calibration.
- Have a qualified service technician replace the battery at least every two (2) years.
- If service is necessary, contact Technical Services or a qualified service technician. Reference *Obtaining Technical Assistance*, p. 1-8.

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8 Troubleshooting

8.1 Overview

This chapter describes how to troubleshoot common problems while using the Nellcor™ Portable SpO_2 Patient Monitoring System.

8.2 General

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

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

If the monitoring system detects an error, it displays an appropriate error code. The *Service Manual* lists all error codes. If an error occurs, check and reseat the batteries. If the Low Battery alarm occurs, replace the batteries. If the error persists, write down the error code and contact Technical Services or a qualified service technician.

8.3 Error Conditions

Table 8-1. Common Problems and Resolutions

Problem	Resolution
Sensor Message Pulse search Interference Sensor Off of patient SpO2 Cable/Sensor Disconnect Loss of Pulse	Reference *Performance Considerations*, p. 6-1. Check patient status; keep patient still, check for perfusion Check all connections Reposition sensor Check or change adhesive wrap Choose alternate site Warm site Cover sensor Use forehead, nasal, or ear sensor (adult patient only) Use Nellcor™ adhesive sensor Secure cable Secure with headband (MAX-FAST) Remove nail polish Loosen sensor (too tight) Isolate external interference (electrosurgical device, cell phone) Replace the cable and/or sensor Clean site (MAX-R)
No response to Power On/Off button press	Press the Power On/Off button for more than one (1) second. Replace the batteries with new lithium batteries. If the error continues, contact Technical Services or a qualified service technician.
No response to button press	Verify whether the Return button has not been pressed during normal screen. If the error continues, contact Technical Services or a qualified service technician.
Frozen at POST after power on	Power cycle by pressing the Power On/Off button for at least 10 seconds. If the error continues, contact Technical Services or a qualified service technician.
System is frozen	If the system freezes, it generates beep tone. Press the power button for approximately 10 seconds to force the monitoring system to shut down. If the error continues, contact Technical Services or a qualified service technician.

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

Problem	Resolution
Blank screen	Ensure the Power On indicator is lit. If not, press the Power On/Off button briefly to check if the monitoring system is in Sleep Mode. The screen will light if in Sleep Mode. If not in Sleep Mode, press the Power On/Off button for approximately 1 second to turn on the monitoring system. If the monitoring system does not turn on, power cycle by pressing the Power On/Off button for at least 10 seconds. If the monitoring system does not turn on, replace the batteries with new lithium batteries. If the error continues, contact Technical Services or a qualified service technician.
Screen does not function properly and the power-on beep tones do not sound	Do not use the monitoring system; contact a qualified service technician or Covidien Technical Services.
No sound generation	Verify the volume setting is loud enough to hear. Verify the monitoring system is not in Sleep Mode. Verify the alarm audio is not paused. Verify the monitoring system is not set to Permission to Mute Alarms (accessible from Service Menu; pass code required). If the error continues, contact Technical Services or a qualified service technician.
Abnormally shut down last time message	Check any temporary settings such as alarm limits, response mode, and patient mode, since resets invoke factory or institutional default settings. Press the Power On/Off button to reset system power. If the error continues, contact Technical Services or a qualified service technician.
Date and Time incorrect	Set the date and time from the Service Menu (pass code required). Power cycle the monitoring system. If the system displays the wrong date and time even after a power cycle, contact Technical Services or a qualified service technician.
Low Battery / Critically Low-Battery condition	Immediately replace the batteries with new lithium batteries. If the error continues, contact Technical Services or a qualified service technician.

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

Problem	Resolution
Questionable readouts of patient physiological measurements, wrongly tagged or missing patient data	Reference *Performance Considerations*, p. 6-1. Check patient status. Replace sensor or cable, if necessary. Check all connections and reposition, if necessary. Remove sources of electromagnetic interference. Remove excessive ambient light.
Data port does not function properly	Ensure the USB cable is firmly connected. Disconnect the USB cable, reset system power, then reconnect. Ensure baud rate settings for both monitoring system and PC are the same. Check hardware tab in PC 'System Registration Information'; verify normal status. Transmit the data to confirm accurate transmission. Check COM port. Re-install the bridge driver provided by Covidien.
Experiencing EMI interference	Reference *Reducing EMI (Electromagnetic Interference)*, p. 6-4.
Technical System Error	Do not use the monitoring system; contact a qualified service technician or Covidien Technical Services.

Reference *Alarms and Alarm Limits Management*, p. 4-8, for any issues related to alarm conditions.

8.4 Return

Contact Covidien or a local Covidien representative for shipping instructions, including a Returned Goods Authorization (RGA) number. Reference *Obtaining Technical Assistance*, p. 1-8. Unless otherwise instructed by Covidien, it is not necessary to return the sensor or other accessory items with the monitoring system. Pack the monitoring system in its original shipping carton. If the original carton is not available, use a suitable carton with the appropriate packing material to protect it during shipping. Return the monitoring system by any shipping method that provides proof of delivery.

9 Accessories

9.1 Overview

This chapter contains information for selecting the appropriate pulse oximetry sensor and other accessories for use with the Nellcor™ Portable SpO_2 Patient Monitoring System.

9.2 Nellcor™ Pulse Oximetry Sensors

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 *Sensor Performance Considerations*, p. 6-3.

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™ Forehead SpO2 Sensor (Sterile, single-use only)	MAX-FAST	>10 kg (22 lbs)
Nellcor™ Adult SpO2 Sensor, Reusable (Nonsterile)	DS-100A	>40 kg (88 lbs)
Nellcor™ Adult SpO2 Sensor (Sterile, single-use only)	MAX-A	>30 kg (66 lbs)
Nellcor™ Adult XL SpO2 Sensor (Sterile, single-use only)	MAX-AL	>30 kg (66 lbs)
Nellcor™ Neonatal-Adult SpO2 Sensor (Sterile, single-use only)	MAX-N	<3 or >40 kg (<6.6 lbs or >88 lbs)
Nellcor™ Pediatric SpO2 Sensor (Sterile, single-use only)	MAX-P	10 to 50 kg (22 to 110 lbs)

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

Nellcor™ Sensor	SKU	Patient Size
Nellcor™ Infant SpO2 Sensor (Sterile, single-use only)	MAX-I	3 to 20 kg (6.6 to 44 lbs)
Nellcor™ Adult SpO2 Nasal Sensor (Sterile, single-use only)	MAX-R	>50 kg (110 lbs)
Nellcor™ Adult-Neonatal SpO2 Sensor with Wraps (Reusable with adhesive)	OXI-A/N	<3 or >40 kg (<6.6 lbs or >88 lbs)
Nellcor™ Pediatric-Infant SpO2 Sensor with Wraps (Reusable with adhesive)	OXI-P/I	3 to 40 kg (6.6 lbs to 88 lbs)
Nellcor™ Pediatric SpO2 Sensor, Two Piece (Sterile, single-use only)	P	10 to 50 kg (22 to 110 lbs)
Nellcor™ Neonatal-Adult SpO2 Sensor, Two Piece (Sterile, single-use only)	N	<3 or >40 kg (<6.6 lbs or >88 lbs)
Nellcor™ Infant SpO2 Sensor, Two Piece (Sterile, single-use only)	I	3 to 20 kg (6.6 to 44 lbs)
Nellcor™ Adult SpO2 Sensor, Two Piece (Sterile, single-use only)	A	> 30 kg (>66 lbs)
Nellcor™ SpO2 Sensor, Multisite Reusable (Nonsterile)	D-YS	>1 kg (>2.2 lbs)
Nellcor™ SpO2 Ear Clip, Reusable (Nonsterile)	D-YSE	>30 kg (>66 lbs)
Nellcor™ Pediatric SpO2 Clip, Reusable (Nonsterile)	D-YSPD	3 to 40 kg (6.6 to 88 lbs)
Nellcor™ Preemie SpO2 Sensor, non-adhesive (Single-patient use)	SC-PR	<1.5 kg (3.3 lbs)
Nellcor™ Neonatal SpO2 Sensor, non-adhesive (Single-patient use)	SC-NEO	1.5 to 5 kg (3.3 to 11 lbs)
Nellcor™ Adult SpO2 Sensor, non-adhesive (Single-patient use)	SC-A	>40 kg (>88 lbs)

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

Note:
Physiological conditions such as excessive patient movement, 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.

9.2.1 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 a sensor is located on the sensor plug.

9.2.2 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

The following optional items are available for the monitoring system.

Figure 9-1. Standard Protective Covers

Figure 9-2. Transport Protective Cover

WARNING:
To avoid possible shock when using the monitoring system during patient transport, place it in a transport protective cover. It is made of heavier material than the standard protective cover and has a stand for easy viewing of the monitoring screen.

Figure 9-3. Carrying Case

Figure 9-4. Extension Cable (DEC-4)

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10 Theory of Operations

10.1 Overview

This chapter explains the theory behind operations of the Nellcor™ Portable SpO_2 Patient Monitoring System.

10.2 Theoretical Principles

The monitoring system uses pulse oximetry to measure functional oxygen saturation in the blood. Pulse oximetry works by applying a Nellcor™ 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.

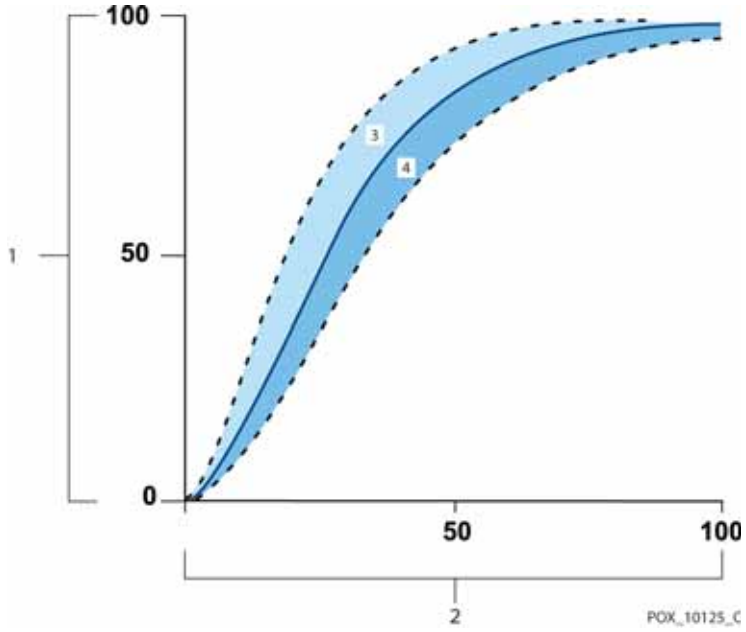
$$\Phi = \frac{\phi}{100 - (\eta + \Lambda)} \times 100$$

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

10.5.3 Data Update Period, Data Averaging, and Signal Processing

The advanced signal processing of the OxiMax™ algorithm automatically extends the amount of data required for measuring SpO_2 and pulse rate depending on the measurement conditions. The OxiMax™ algorithm automatically extends the dynamic averaging time required beyond seven (7) seconds during degraded or difficult measurement conditions caused by low perfusion, signal artifact, ambient light, electrocautery, other interference, or a combination of these factors, which

results in an increase in the dynamic averaging. If the resulting dynamic averaging time exceeds 25 seconds for SpO2, the monitoring system displays a low priority (visual only) alarm while continuing to update SpO2 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 high priority alarm state results: the monitoring system displays a Pulse Timeout alarm and reports a zero saturation indicating a loss-of-pulse condition.

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 SpO2 and pulse rate.

Any monitoring system containing OxiMax technology uses calibration data contained in the sensor in calculating the patient's SpO2. 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 Nellcor™ *Oxygen Saturation Accuracy Specification Grid* listing all of the sensors used with the monitoring system. Covidien retains a soft copy at www.covidien.com.

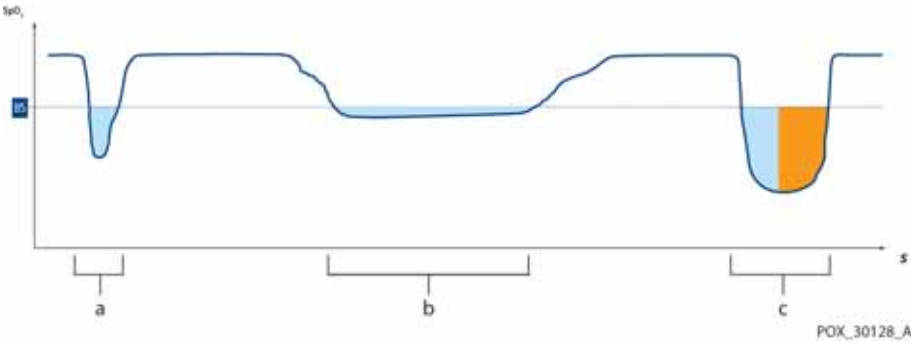
The monitoring system uses the information in the sensor, tailoring messages to better help the clinician troubleshoot client or data issues. The sensor automatically identifies its sensor type to the monitoring system when attached.

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 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.

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



a First SpO2 Event

b Second SpO2 Event

c Third SpO2 Event

First SpO2 Event

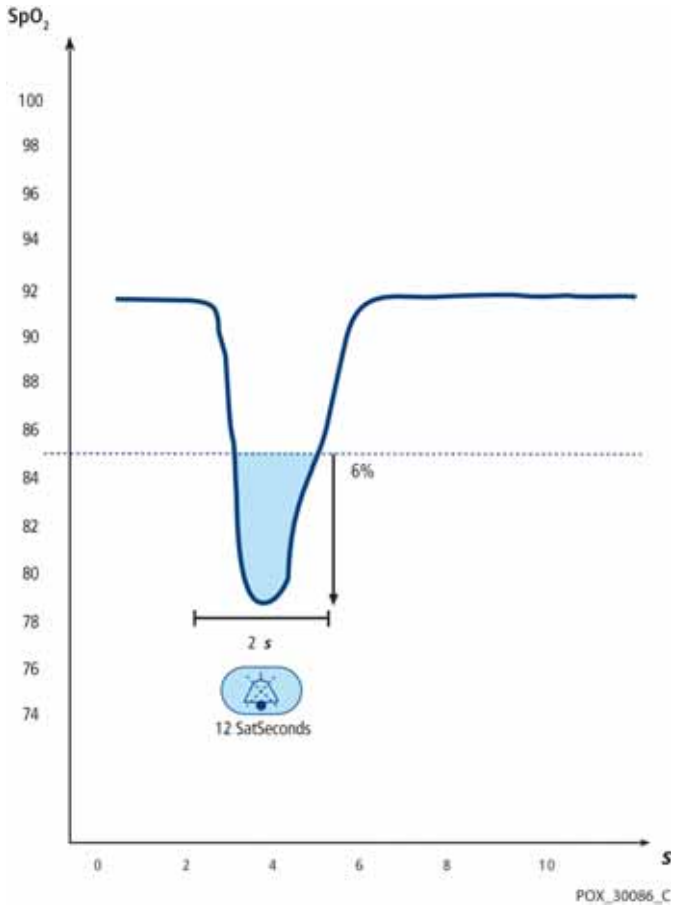
Consider the first event. Suppose the SatSeconds alarm limit is set to 25. The patient's SpO2 drops to 79% and the duration of the event is two (2) seconds before saturation again exceeds the lower alarm threshold of 85%.

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

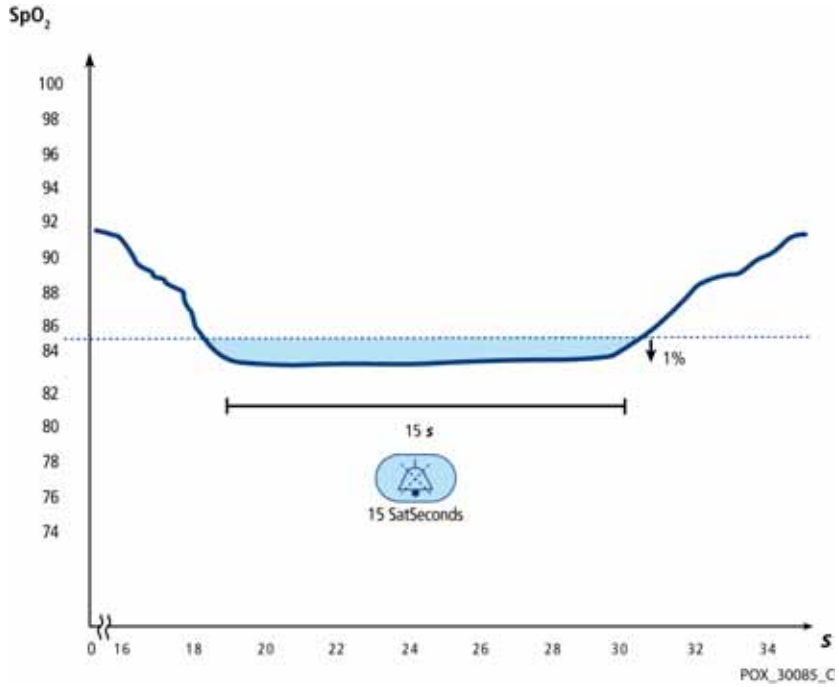
Consider the second event. Suppose the SatSeconds alarm limit is still set to 25. The patient's SpO2 drops to 84% and the duration of the event is 15 seconds before saturation again exceeds the lower alarm threshold of 85%.

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

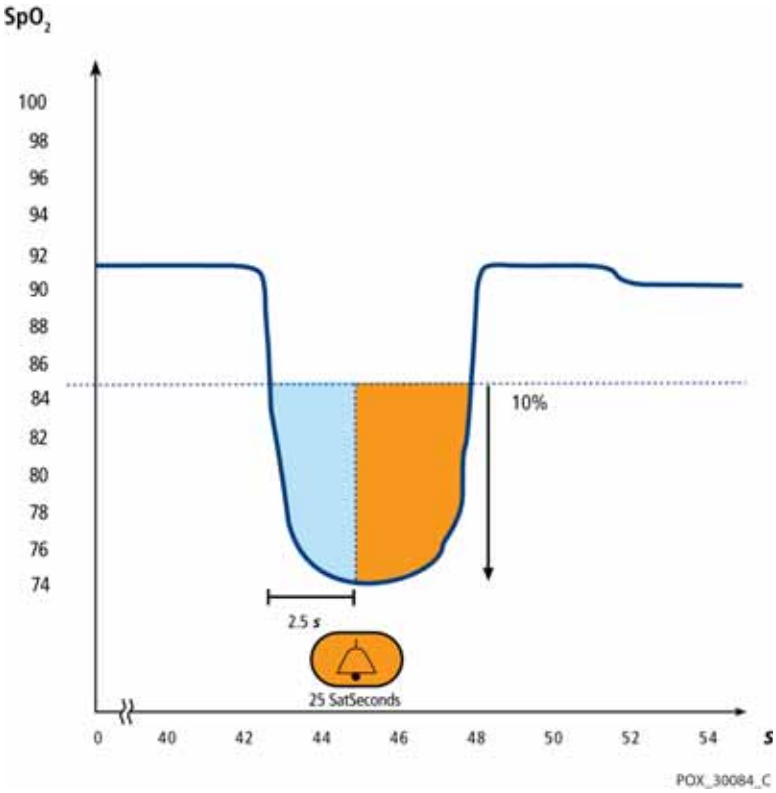
Consider the third event. Suppose the SatSeconds alarm limit is still set to 25. During this event, the patient's SpO2 drops to 75%, which is 10% below the lower alarm threshold of 85%. Since the patient's saturation does not return to a value over the lower alarm threshold within 2.5 seconds, an alarm 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



The SatSeconds Safety Net

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

11 Product Specifications

11.1 Overview

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

11.2 Physical Characteristics

Enclosure	
Weight	274 g (0.604 lbs), including four batteries
Dimensions	70 mm W x 156 mm H x 32 mm D (2.76 in W x 6.14 in H x 1.26 in D)
Display	
Screen size	88.9 mm (3.5 in), measured diagonally
Screen type	TFT LCD, white LED backlight, viewing cone of 60° and optimal viewing distance of 1 meter
Resolution	320 x 480 pixels
Controls	
Buttons	Power On/Off, Alarm Audio Paused, Menu, Directional (Up, Down), Enter/selection, Back/Return
Alarms	
Categories	Patient status and system status
Priorities	Low, medium, and high
Notification	Audible and visual
Setting	Default, Institutional, and Last Setting
Alarm volume level	45 to 80 dB

Alarm system delay	Less than 10 s

11.3 Electrical

Battery	Four new lithium batteries with 3,000 mAh will typically provide 20 hours of monitoring with no external communication, no audible alarm sound, display backlight set to 25% brightness, and at an ambient temperature of 25° C.
Type	Lithium AA
Voltage	1.5V x 4
Accuracy, Real-Time Clock	< 52 s per month (typically)

11.4 Environmental Conditions

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

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

	Transport and Storage	Operating Conditions
Temperature	-20 °C to 70 °C, (-4 °F to 158 °F)	5 °C to 40 °C (41 °F to 104 °F)
Altitude	-390 to 5,574 m, (106 kPa to 52 kPa)	
Relative humidity	15% to 95% non-condensing	

11.5 Tone Definition

Table 11-2. Tone Definitions

Tone Category	Description
High Priority Alarm Tone	
Volume level	Adjustable (level 1-4)
Pitch (± 20Hz)	540 Hz
Pulse width (± 20msec)	175 msec (IEC60601-1-8)
Number of pulses in burst	10, interburst interval of 4 sec (IEC60601-1-8)
Repetitions	Continually
Medium Priority Alarm Tone	
Volume level	Adjustable (level 1-4)
Pitch (± 20Hz)	470 Hz
Pulse width (± 20msec)	175 msec (IEC60601-1-8)
Number of pulses in burst	3, interburst interval of 8 sec (IEC60601-1-8)
Repetitions	Continually
Low Priority Alarm Tone	
Volume level	Adjustable (level 1-4)
Pitch (± 20Hz)	380 Hz
Pulse width (± 20msec)	175 msec (IEC60601-1-8)
Number of pulses	1, interburst interval of 16 sec (IEC60601-1-8)
Repetitions	Continually
Alarm Reminder Tone	
Volume level	Not changeable
Pitch (± 20Hz)	700 Hz
Pulse width (± 20msec)	150 msec
Number of pulses	1 pulse per 1 second, 3 min ~ 10 min interburst
Repetitions	Continually

Table 11-2. Tone Definitions (Continued)

Tone Category	Description
Key Beep	
Volume level	Adjustable (level 0-4), (Invalid key presses are ignored)
Pitch (± 20Hz)	1,200 Hz
Pulse width (± 20msec)	20 msec
Number of pulses	N/A
Repetitions	No repeat
POST Pass Tone	
Volume level	Not changeable
Pitch (± 20Hz)	600 Hz
Pulse width (± 20msec)	500 msec
Number of pulses	N/A
Repetitions	No repeat

11.6 Sensor Accuracy and Ranges

Table 11-3. Trends

Types	Tabular
Memory	Saves total 80 hours data events Saves date and time, alarm conditions, pulse rate, and SpO2 measurements
Tabular Format	One table for all parameters

Table 11-4. Pulse Oximetry Sensor Accuracy and Ranges

Range Type	Range 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%
Display sweep speed	6.25 mm/sec
Measurement Accuracy[1]	
Saturation	
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 bpm ±3 digits
Low Perfusion[6]	20 to 250 bpm ±3 digits
Adult and Neonate with Motion[2, 7]	20 to 250 bpm ±5 digits
Operating Range and Dissipation	
Red Light Wavelength	Approximately 660 nm
Infrared Light Wavelength	Approximately 900 nm
Optical Output Power	Less than 15 mW
Power Dissipation	52.5 mW

[1]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 as ±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* MAX-A and MAX-N sensors with the monitoring system.

[4]Neonate specifications are shown for *OxiMax* MAX-N sensors with the monitoring system.

[5]Clinical functionality of the MAX-N 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 monitoring system 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* MAX-A, MAX-AL, MAX-P, MAX-I, and MAX-N sensors.

11.7 Sound Pressure

Table 11-5. Sound Pressure in Decibels

Alarm Type	Volume 4	Volume 3	Volume 2	Volume 1
High Priority	78.0 ±3 dB	69.0 ±3 dB	60.0 ±3 dB	50.0 ±3 dB
Medium Priority	74.0 ±3 dB	66.0 ±3 dB	57.0 ±3 dB	48.0 ±3 dB
Low Priority	70.0 ±3dB	61.5 ±3 dB	53.0 ±3 dB	45.0 ±3 dB

11.8 Product Compliance

Standards Compliance

IEC 60601-1:2005+A1:2012, EN 60601-1:2006/AC:2010
IEC 60601-1:1998 + A1:1991 +A2:1995, EN 60601-1:1990 +A11:1993 +A12:1993 +A13:1996
IEC 60601-1-2:2007, EN60601-1-2:2007
IEC 60601-1-6:2010, EN 60601-1-6:2010 +A1:2013
IEC 60601-1-8:2006, EN 60601-1-8:2006 +A1:2012
IEC 60601-1-11:2010, EN 60601-1-11:2010
ISO 9919:2005, EN ISO 9919:2009
ISO 80601-2-61:2011, EN ISO 80601-2-61:2011
CAN/CSA C22.2 No. 601.1 M90
UL 60601-1: 1st edition

Equipment Classifications

Type of Protection against electric shock	Class I (internally powered)
Degree of Protection against electric shock	Type BF - Applied part
Mode of Operation	Continuous
Electromagnetic Compatibility	IEC 60601-1-2:2007
Ingress Protection	IP22: Protected against foreign objects and moisture, without protective cover IP34: Protected against foreign objects and moisture, with protective cover
Degree of Safety	Not suitable for use in the presence of flammable anesthetics

11.9 Manufacturer's Declaration

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

Caution:
When operating medical electrical equipment, special precautions related to electromagnetic compatibility (EMC) are required. Install the monitoring system according to the EMC information included in this manual.

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

11.9.1 Electromagnetic Compatibility (EMC)

The monitoring system is suitable for prescription use only in the electromagnetic environments specified in the standard. Use the monitoring system in accordance with the electromagnetic environments described.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. Any changes or modifications to this equipment not expressly approved by Covidien may cause harmful radio frequency interference and void your authority to operate this equipment.

Electromagnetic Emissions

Table 11-6. Electromagnetic Emissions Guidelines and Compliance

Guidance and Manufacturer's Declaration—Electromagnetic Emissions (IEC/EN 60601-1-2:2007, Table 1)		
The monitoring system is intended for use in the electromagnetic environment specified below. The customer or the user of the monitoring system should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment Guidance**
RF emissions CISPR 11	Group 1, Class B	The monitoring system is suitable for use in all establishments.
Harmonic emissions IEC/EN 61000-3-2	Not applicable	Not applicable because of battery-only operation.
Voltage fluctuation/ flicker emissions IEC/EN 61000-3-3	Not applicable	Not applicable because of battery-only operation.

Electromagnetic Immunity

Table 11-7. Electromagnetic Immunity Guidelines and Compliance

Guidance and Manufacturer's Declaration—Electromagnetic Immunity (IEC/EN 60601-1-2:2007, Table 2)			
The monitoring system is intended for use in the electromagnetic environment specified below. The customer or the user of the monitoring system should assure that it is used in such an environment.			
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	± 1kV for input/ output lines	± 1kV for input/ output lines	Not applicable because of battery-only operation.
Surge IEC/EN 61000-4-5	Not applicable	Not applicable	Not applicable because of battery-only operation.
Voltage dips, short interruptions and voltage variations on power supply IEC/EN 61000-4-11	Not applicable	Not applicable	Not applicable because of battery-only operation.
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 11-8. Recommended Separation Distance Calculations

Guidance and Manufacturer's Declaration—Electromagnetic Immunity (IEC/EN 60601-1-2:2007, Table 4)			
The monitoring system is intended for use in the electromagnetic environment specified below. The customer or the user of the monitoring system should assure that it is used in such an environment.			
Immunity Test	**IEC/EN 60601-1-2 Test Level**	**Compliance Level**	**Electromagnetic Environment Guidance**
Conducted RF IEC/EN 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the monitoring system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended Separation Distance $d = 1.2\sqrt{P}$
Radiated RF IEC/EN 61000-4-3	20 V/m 80 MHz to 800 MHz	20 V/m 80 MHz to 800 MHz	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz
	20 V/m 800 MHz to 2.5 GHz	20 V/m 800 MHz to 2.5 GHz	$d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where *P* is the maximum output power rating of the transmitter in watts (*W*) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (*m*). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			
[a]Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the monitoring system is used exceeds the applicable RF compliance level above, the monitoring system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the monitoring system. [b]Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Table 11-9. Recommended Separation Distances

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Monitoring System (IEC/EN 60601-1-2:2007, Table 6)			
The monitoring system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the monitoring system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the monitoring system as recommended below, according to the maximum output power of the communications equipment.			
Rated Maximum Output Power (*P*) of Transmitter in Watts	**Separation Distance According to Frequency of Transmitter 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, the recommended separation distance (*d*) in meters (*m*) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (*W*) according to the transmitter manufacturer. NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

11.9.2 Sensor and Cable Compliance

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

Table 11-10. Sensor and Cable Length

Item	SKU	Maximum Length
Sensors		
Nellcor™ Adult SpO2 Sensor, Reusable (Nonsterile)	DS100A	3.0 ft. (0.9 m)
Nellcor™ Adult XL SpO2 Sensor (Sterile, single-use only)	MAX-AL	3.0 ft. (0.9 m)
Nellcor™ Forehead SpO2 Sensor (Sterile, single-use only)	MAX-FAST	2.5 ft (0.75 m)
Nellcor™ Neonatal-Adult SpO2 Sensor (Sterile, single-use only)	MAX-N	1.5 ft. (0.5 m)
Nellcor™ Infant SpO2 Sensor (Sterile, single-use only)	MAX-I	
Nellcor™ Pediatric SpO2 Sensor (Sterile, single-use only)	MAX-P	
Nellcor™ Adult SpO2 Sensor (Sterile, single-use only)	MAX-A	
Nellcor™ Adult SpO2 Nasal Sensor (Sterile, single-use only)	MAX-R	
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, Multisite Reusable (Nonsterile)	D-YS	4.0 ft. (1.2 m)
Nellcor™ SpO2 Ear Clip, Reusable (Nonsterile)	D-YSE	
Nellcor™ Pediatric SpO2 Clip, Reusable (Nonsterile)	D-YSPD	
Cables		
DEC-4 interface cable (only compatible interface cable)		4.0 ft. (1.2 m)

11.9.3 Safety Tests

Leakage Current

The following tables indicate the maximum enclosure and patient leakage current allowed.

Table 11-11. Enclosure Leakage Current Specification

Enclosure Leakage Current	
Test Condition	**Allowable Leakage Current (Microamps)**
Normal Condition (NC)	100

Table 11-12. Patient Leakage Current Values

Enclosure Leakage Current	
Test Condition	**Allowable Leakage Current (Microamps)**
Normal Condition (NC)	100

11.10 Essential Performance

Per IEC 60601-1-2:2007 and ISO 80601-2-61:2011, the monitoring system's essential performance attributes include:

- **SpO_2 and pulse rate accuracy —** Reference *Sensor Accuracy and Ranges*, p. 11-4.
- **Audible indicators —** Reference *Alarm Indicators*, p. 4-8.
- **Physiological alarms and priorities —** Reference *Alarm Indicators*, p. 4-8.
- **Visual indicator of power source —** Reference *Figure 2-2.* on page 2-5.
- **Backup power source —** Not applicable.
- **Sensor disconnect/off notification —** Reference *Figure 2-2.* on page 2-5. Reference *Alarm Indicators*, p. 4-8.
- **Motion, interference, or signal degradation indicator —** Reference *Figure 2-2.* on page 2-5. Reference *Alarm Indicators*, p. 4-8.

A Clinical Studies

A.1 Overview

This appendix contains data from clinical studies conducted for the Nellcor™ sensors used with the Nellcor™ Portable SpO_2 Patient Monitoring System.

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

A.2 Methods

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

A.3 Study Population

Table A-1. Demographic Data

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

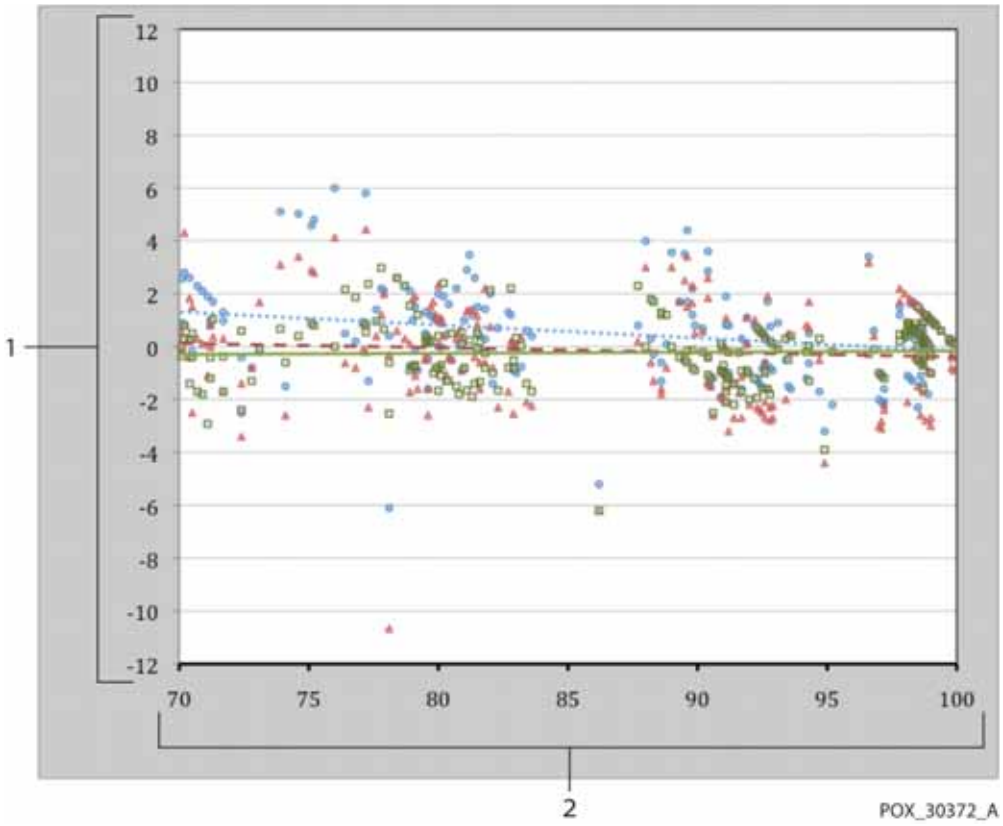
A.4 Study Results

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

Table A-2. SpO2 Accuracy for Nellcor™ Sensors vs. CO-oximeters

SpO2 Decade	MAX-A		MAX-N		MAX-FAST	
	Data Points	Arms	Data Points	Arms	Data Points	Arms
60-70	71	3.05	71	2.89	71	2.22
70-80	55	2.35	55	2.32	55	1.28
80-90	48	1.84	48	1.73	48	1.48
90-100	117	1.23	117	1.68	117	0.98

Figure A-1. Modified Bland-Altman Plot



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

A.5 Adverse Events or Deviations

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

A.6 Conclusion

The pooled results indicate that for a saturation range of 60-80% for SpO_2, the acceptance criterion was met for the monitoring system when tested with MAX-A, MAX-N and MAX-FAST sensors. The pooled results indicate that for a saturation range of 70-100% for SpO_2, the acceptance criterion was met.

Index

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Rx ONLY

CE 0123

Covidien llc
15 Hampshire Street, Mansfield, MA 02048 USA.
EC REP Covidien Ireland Limited, IDA Business & Technology Park, Tullamore.

www.covidien.com [T] 1.800.NELLCOR