COVIDIEN

Service Manual

Nellcor™

Bedside SpO_2 Patient Monitoring System

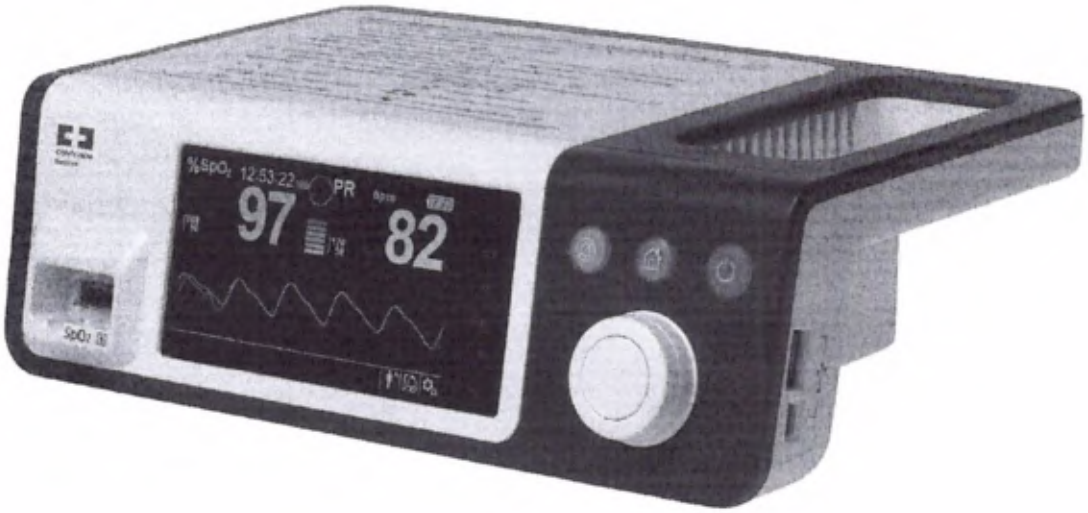

Table of Contents

List of Figures

List of Tables

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1 Introduction

1.1 Overview

This manual contains information for servicing the Nellcor™ Bedside SpO_2 Patient Monitoring System.

Note:
Before use, carefully read this manual, the *Operator's Manual*, accessory *Directions for Use*, and all precautionary information and specifications.

1.2 Safety Information

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

1.2.1 Safety Symbols

Table 1-1. Safety Symbol Definitions

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

1.2.2 Warnings Regarding Electric Shock and Explosion Hazards

WARNING:
To prevent possible electric shock or explosion, do not service the monitoring system in a flammable environment or in an excessively moist environment.

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

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

1.2.3 Warnings Regarding Service Procedures

WARNING:
To avoid possible injury, do not attempt to service the monitoring system if there are any signs of burning or smoking coming from the monitoring system.

WARNING:
Before attempting to service the monitoring system, disconnect it from the patient to avoid possible injury to the patient.

WARNING:
Before attempting to open or disassemble the monitoring system, disconnect the power cord from the monitoring system to avoid possible injury.

WARNING:
Ensure that conductive portions of the electrodes, leads, and cable do not come into contact with any other conductive parts.

WARNING:
High voltage is generated by the LCD backlight driver. Exercise caution when operating the monitoring system with covers open.

WARNING:
During the safety test, AC power voltage will be present on the applied part terminals. Exercise caution to avoid electrical shock hazard.

WARNING:
Extreme care must be taken in modifying default or other settings to ensure they are appropriate to the intended use.

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

WARNING:
Make sure to complete all performance and safety tests outlined in *Chapter 10, Modification and Testing* before placing the monitoring system into operation after repair or maintenance. Failure to perform all tests could result in erroneous monitoring system readings.

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

WARNING:
To ensure accurate performance and prevent device failure, do not expose the monitoring system to extreme moisture, such as direct exposure to rain. Such exposure may cause inaccurate performance or device failure. Reference *Chapter 2, Product Specifications*.

1.2.4 Patient-Related Warnings

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

WARNING:
Carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.

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

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, potentially harming a patient or damaging the monitoring system.

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

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

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

WARNING:
The measured values of the monitoring system can be affected by patient conditions, motion, sensors, environmental conditions, and nearby electromagnetic external conditions.

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

WARNING:
Failure to cover the pulse oximetry sensor site with opaque material in high ambient light conditions may result in inaccurate measurements. Pulse oximetry readings and pulse signals can be affected by certain environmental conditions, pulse oximetry sensor application errors, and certain patient conditions. Refer to the appropriate sections of this manual for specific safety information.

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

WARNING:
If transferring the monitoring system from one patient to another, it may retain trend data from previous patients.

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

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

1.2.5 Cautions

Caution:
Observe ESD (electrostatic discharge) precautions when working within the unit and/or when disassembling and reassembling the monitoring system and when handling any components.

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

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

Caution:
Do not immerse the monitoring system or its accessories in liquid or clean with caustic or abrasive cleaners.

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. Both the monitoring system and the instrument connected to it must be connected to a grounded outlet.

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

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

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

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 with other devices in the vicinity.

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

Caution:
When reassembling the monitoring system, over-tightening screws could strip the screw holes in the cases, rendering them unusable.

Caution:
Ferrite cores are used for electromagnetic compatibility. Please do not remove ferrite cores while disassembling or reassembling; otherwise the monitoring system can be affected by electromagnetic interference and cause inaccurate data to be displayed or stored.

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. The serial number label is located on the bottom of the monitoring system. Provide the firmware version number displayed during the power-on self-test (POST).

1.3.2 Related Documents

Nellcor™ Bedside SpO_2 Patient Monitoring System Operator's Manual — Provides basic information for operating the monitoring system and troubleshooting errors or malfunctions.

Nellcor™ Pulse Oximetry Sensor Directions 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 *Directions for Use*.

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

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 Specifications

2.1 Overview

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

2.2 Physical Characteristics

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

2.3 Electrical

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

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

2.4 Environmental Conditions

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

Table 2-1. Transport, Storage, and Operating Condition Ranges

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

2.5 Tone Definition

Table 2-2. Tone Definitions

Tone Category	Description
High Priority Alarm Tone	
Volume level	Adjustable (level 1-8)
Pitch (± 20Hz)	976 Hz
Pulse width (± 20msec)	150 msec (IEC60601-1-8)
Number of pulses in burst	10, interburst interval of 4 sec (IEC60601-1-8)
Repetitions	Continually
Medium Priority Alarm Tone	
Volume level	Adjustable (level 1-8)
Pitch (± 20Hz)	697 Hz
Pulse width (± 20msec)	150 msec (IEC60601-1-8)
Number of pulses in burst	3, interburst interval of 8 sec (IEC60601-1-8)
Repetitions	Continually
Low Priority Alarm Tone	
Volume level	Adjustable (level 1-8)
Pitch (± 20Hz)	488 Hz
Pulse width (± 20msec)	250 msec (IEC60601-1-8)
Number of pulses	1, interburst interval of 16 sec (IEC60601-1-8)
Repetitions	Continually
Alarm Reminder Tone	
Volume level	Not changeable
Pitch (± 20Hz)	800 Hz
Pulse width (± 20msec)	200 msec
Number of pulses	1 pulse per 1 second, 3 min ~ 10 min interburst
Repetitions	Continually

Table 2-2. Tone Definitions (Continued)

Tone Category	Description
Key Beep	
Volume level	Adjustable (Off, level 1-7), (Invalid key presses are ignored)
Pitch (± 20Hz)	440 Hz (valid), 168 Hz (invalid)
Pulse width (± 20msec)	110 msec
Number of pulses	N/A
Repetitions	No repeat
POST Pass Tone	
Volume level	Not changeable
Pitch (± 20Hz)	813 Hz
Pulse width (± 20msec)	1500 msec
Number of pulses	N/A
Repetitions	No repeat

2.6 Performance Specifications

Table 2-3. Trends

Types	Graphical and Tabular
Memory	Saves total 88000 data events Saves date and time, alarm conditions, pulse rate, and SpO2 measurements
Graphical Format	Total 2 graphs A graph for SpO2 parameters A graph for Pulse Rate parameters
Tabular Format	One table for all parameters
Display	5 lists

Table 2-4. 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, 12.5 mm/sec, 25.0 mm/sec
Measurement Accuracy	
Pulse rate accuracy	20 to 250 beats per minute (bpm) ±3 digits
SpO2 saturation accuracy[1]	70% to 100% ±2 digits, neonates: ±3 digits
Operating Range and Dissipation	
Red Light Wavelength	Approximately 660 nm
Infrared Light Wavelength	Approximately 900 nm
Optical Output Power	Less than 15 mW
Power Dissipation	52.5 mW

1. Monitoring system measurements are statistically distributed; about two-thirds of monitoring system measurements can be expected to fall in this accuracy (ARMS) range. Reference the Clinical Studies section for test results. For a complete listing of SpO2 accuracy across the full line of available Nellcor™ sensors, contact Covidien, a local Covidien representative, or locate it online at www.covidien.com.

2.7 Sound Pressure

Table 2-5. Sound Pressure in Decibels

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

2.8 Product Compliance

Standards Compliance	EN ISO 9919:2009, EN ISO 80601-2-61:2011 EN IEC 60601-1:2005 EN IEC 60601-1-2:2nd edition EN IEC 60601-1:1998 + A1:1991 + A2:1995 EN 60601-1:1990 + A11:1993 + A12:1993 + A13:1996 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
Liquid Ingress	IPX2
Degree of Safety	Not suitable for use in the presence of flammable anesthetics

2.9 Manufacturer's Declaration

2.9.1 Electromagnetic Compatibility (EMC)

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

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

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

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.

Electromagnetic Emissions

Table 2-6. Electromagnetic Emissions Guidelines

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

Electromagnetic Immunity

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

Table 2-7. Electromagnetic Immunity Guidelines

Immunity Test	IEC/EN 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) IEC/EN 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floor should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electric fast transient/burst IEC/EN 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	± 2 kV for power supply lines ± 1 kV for input/ output lines	Mains power quality should be that of a typical commercial and/ or hospital environment.

Table 2-7. Electromagnetic Immunity Guidelines (Continued)

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

Table 2-8. Recommended Separation Distances

Immunity Test	IEC/EN 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
	Frequency of Transmitter		**Equation for Separation Distance (*d*)**
Conducted RF IEC/EN 61000-4-6	3 Vrms 150 kHz 80 MHz	3 Vrms 150 kHz 80 MHz	$d = 1.2\sqrt{P}$ 150 kHz to 80 MHz
Radiated RF IEC/EN 61000-4-3	3 V/m 80 MHz 800 MHz	3 V/m 80 MHz 800 MHz	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz
	3 V/m 800 MHz 2.5 GHz	3 V/m 800 MHz 2.5 GHz	$d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz

Table 2-8. Recommended Separation Distances

Immunity Test	IEC/EN 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
Rated Maximum Output Power (*P*) of Transmitter in Watts	Separation Distance in Meters		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
0.01	0.12	0.12	0.23
0.10	0.38	0.38	0.73
1.00	1.20	1.20	2.30
10.00	3.80	3.80	7.30
100.00	12.00	12.00	23.00

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

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

2.9.2 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 2-9. Cables and Sensors

Item	Maximum Length
Sensors	
Pulse oximetry sensor cable	1.6 ft. (0.5 m)
Cables	
Power cable	10 ft. (3 m)
Nurse call cable	5.9 ft. (1.8 m)
Pulse oximetry interface cable	10.0 ft. (3.0 m)

2.9.3 Safety Tests

Ground Integrity

100 milliohms or less

Leakage Current

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

Table 2-10. Earth and Enclosure Leakage Current Specifications

Earth Leakage Current					
Condition	**AC Line Polarity**	**Line Cord**	**Neutral Line Cord**	**IEC 60601-1**	**IEC 60601-1 ANSI/AAMI ES 60601-1: 2005**
Normal	Normal	Closed	Closed	500 µA	300 µA
Single Fault		Open	Closed	1000 µA	
		Closed	Open		
Normal	Reversed	Closed	Closed	500 µA	300 µA
Single Fault		Open	Closed	1000 µA	
		Closed	Open		
Enclosure Leakage Current					
Condition	**AC Line Polarity**	**Neutral Line Cord**	**Power Line Ground**	**IEC 60601-1 ANSI/AAMI ES 60601-1: 2005**	
Normal	Normal	Closed	Closed	100 µA	
Single Fault		Open	Closed	500 µA	
		Closed	Open		
Normal	Reversed	Closed	Closed	100 µA	
Single Fault		Open	Closed	500 µA	
		Closed	Open		

Table 2-11. Patient Applied and Patient Isolation Risk Current

Patient Applied Risk Current				
Condition	**AC Line Polarity**	**Neutral Line**	**Power Line Ground Cable**	**IEC 60601-1 ANSI/AAMI ES 60601-1: 2005**
Normal	Normal	Closed	Closed	100 µA
Single Fault		Open	Closed	500 µA
		Closed	Open	
Normal	Reversed	Closed	Closed	100 µA
Single Fault		Open	Closed	500 µA
		Closed	Open	
Patient Isolation Risk Current				
Condition	**AC Line Polarity**	**Neutral Line**	**Power Line Ground Cable**	**IEC 60601-1 ANSI/AAMI ES 60601-1: 2005**
Single Fault	Normal	Closed	Closed	5000 µA
	Reversed	Closed	Closed	

3 Theory of Operations

3.1 Overview

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

3.2 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 pulse oximeter to accurately measure SpO_2. Reference *Performance Considerations*, p. 105.

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.

3.3 Automatic Calibration

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

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

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

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

3.4 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 SpO_2 measurement values may differ from the setting of the test device. For a properly functioning monitoring system, this difference will be reproducible over time and from monitoring system to monitoring system within the performance specifications of the test device.

3.5 Unique Technologies

3.5.1 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.

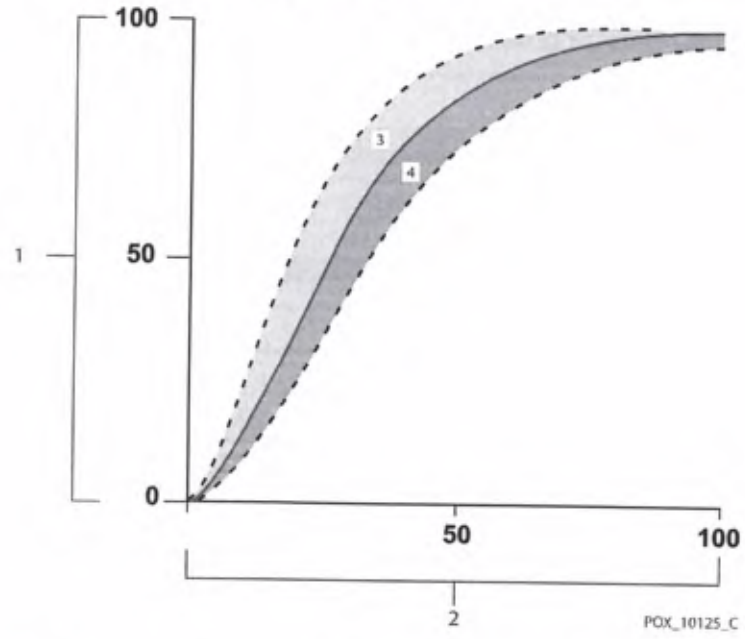
$$\Phi = \frac{\phi}{100 - (\eta + \Lambda)} \times 100$$

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

3.5.2 Measured versus Calculated Saturation

When calculating saturation from a blood gas partial pressure of oxygen (PO2), 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 (PCO2), and 2,3-DPG, that shift the relationship between PO2 and SpO_2.

Figure 3-1. Oxyhemoglobin Dissociation Curve



3.5.3

1 % Saturation Axis
2 PO2 (mmHg) Axis
3 Increased pH; Decreased temperature, PCO2, and 2,3-DPG
4 Decreased pH; Increased temperature, PCO2, and 2,3-DPG

3.5.4 Data Update Period, Data Averaging, and Signal Processing

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

results in an increase in the dynamic averaging. If the resulting dynamic averaging time exceeds 20 seconds for SpO2, the algorithm sets the pulse search bit while continuing to update SpO2 and pulse rate values every second.

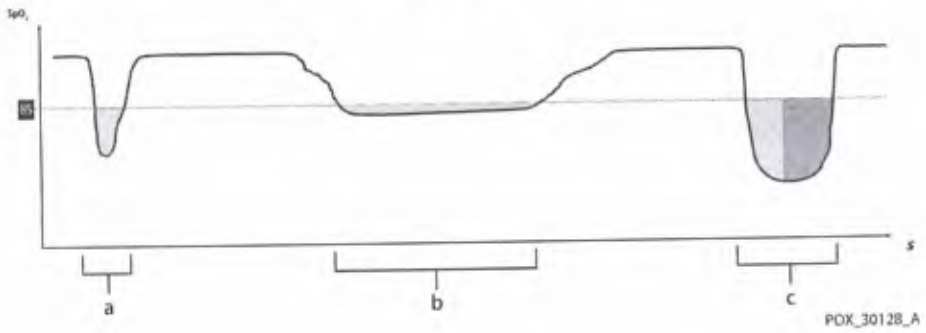
As such measurement conditions extend, the amount of data required may continue to increase. If the dynamic averaging time reaches 40 seconds, and/or 50 seconds for pulse rate, a low priority alarm state results: the algorithm sets the Pulse Timeout bit and the monitoring system reports a zero saturation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

3.6 SatSeconds™ Alarm Management Feature

The monitoring system monitors the percentage of hemoglobin binding sites saturated with oxygen in the blood. With traditional alarm management, upper and lower alarm limits are set to alarm at specific 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 feature helps distinguish clinically significant events from minor and brief desaturations that may result in nuisance alarms.

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

Figure 3-2. Series of SpO2 Events



a First SpO2 Event

b Second SpO2 Event

c Third SpO2 Event

3.6.1 First SpO_2 Event

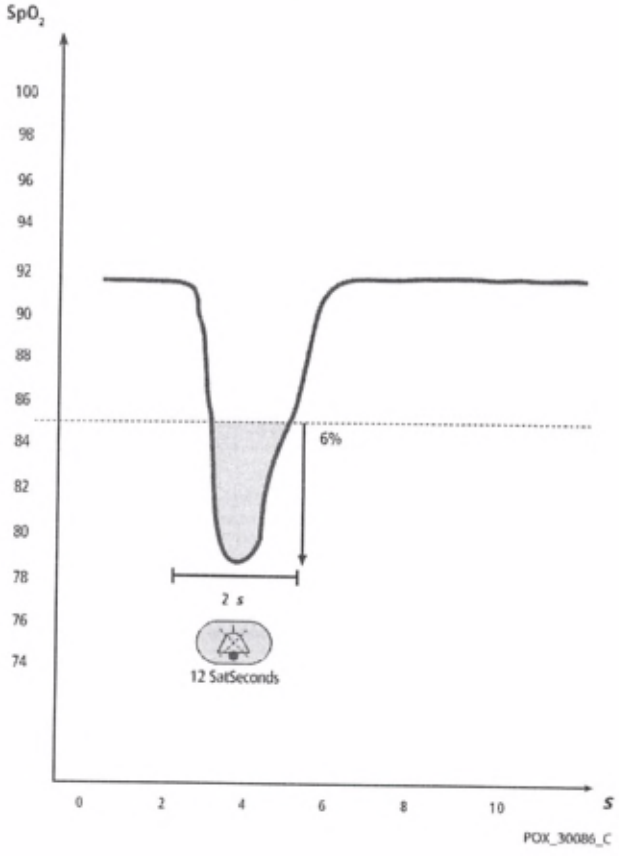
Consider the first event. Suppose the SatSeconds alarm limit is set to 25. The patient's SpO2 drops to 79% and the duration of the event is two (2) seconds before saturation again exceeds the lower alarm threshold of 85%.

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 3-3. First SpO2 Event: No SatSeconds Alarm



3.6.2 Second SpO_2 Event

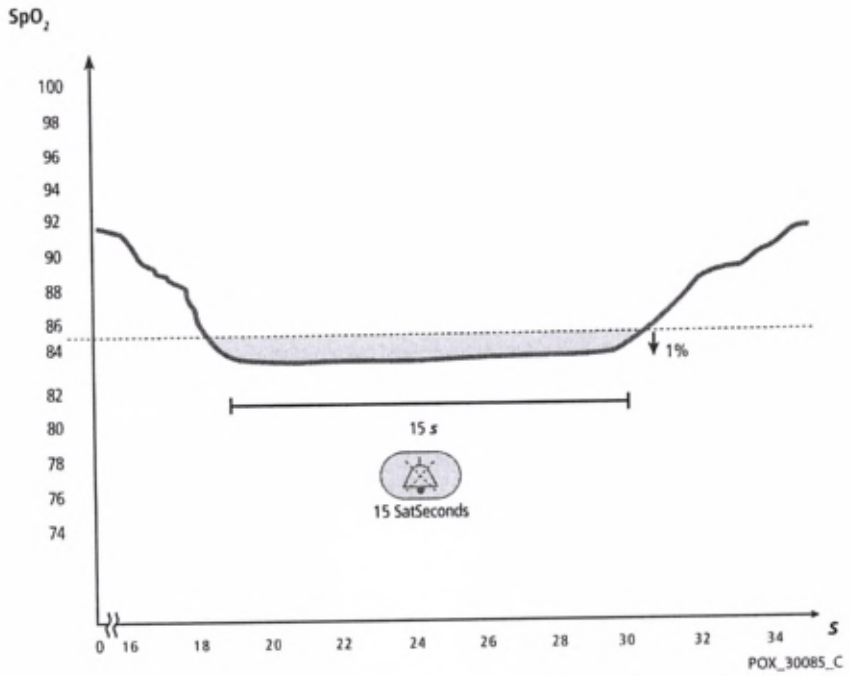
Consider the second event. Suppose the SatSeconds alarm limit is still set to 25. The patient's SpO_2 drops to 84% and the duration of the event is 15 seconds before saturation again exceeds the lower alarm threshold of 85%.

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

15 SatSeconds; no alarm

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

Figure 3-4. Second SpO2 Event: No SatSeconds Alarm



3.6.3 Third SpO_2 Event

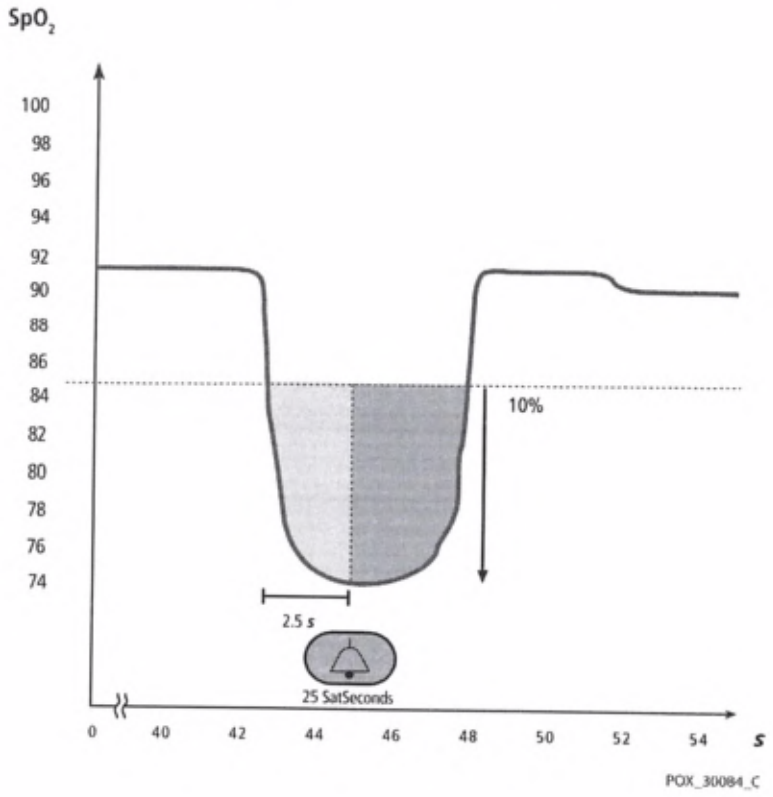
Consider the third event. Suppose the SatSeconds alarm limit is still set to 25. During this event, the patient's SpO_2 drops to 75%, which is 10% below the lower alarm threshold of 85%. Since the patient's saturation does not return to a value over the lower alarm threshold within 2.5 seconds, an alarm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

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

25 SatSeconds; results in an alarm

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

Figure 3-5. Third SpO2 Event: Triggers SatSeconds Alarm



3.6.4 The SatSeconds Safety Net

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

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4 Product Overview

4.1 Overview

This chapter contains basic information about the Nellcor™ Bedside SpO_2 Patient Monitoring System.

4.2 Product Description

The Nellcor™ Bedside SpO_2 Patient Monitoring System provides continuous, noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate. For more information, reference the *Operator's Manual*.

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

4.3 Indications for Use

The Nellcor™ Bedside SpO_2 Patient Monitoring System is intended for prescription use only with adult, pediatric, and neonatal patients who are well or poorly perfused in hospitals, hospital-type facilities, and during intra-hospital transport.

Note:
Hospital use typically covers such areas as general care floors (GCFs), operating rooms, special procedure areas, intensive and critical care areas within the hospital, and in hospital-type facilities.

Hospital-type facilities include physician office-based facilities, sleep labs, skilled nursing facilities, surgicenters, and sub-acute centers.

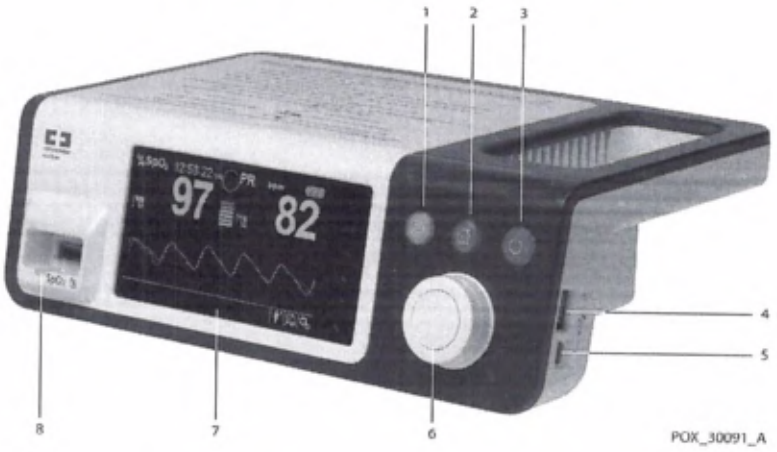
Note:
Intra-hospital transport includes transport of a patient within the hospital or hospital-type facility.

4.4 Product Views

4.4.1 Front Panel and Display Components

Front and Side Panels

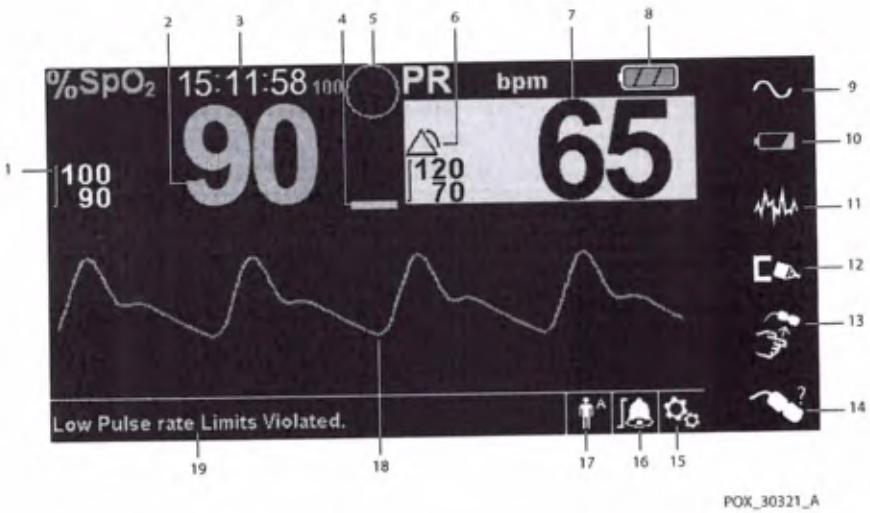
Figure 4-1. Front and Side Panel Components



1	Audio Paused button	Toggles between disabling and enabling the audible alarm.
2	Return button	Exits a menu displayed on the screen and goes to the main screen.
3	Power On/Off button	Turns the monitoring system on or off.
4	USB port (USB A type)	Provides interface for firmware upgrades.
5	USB port (mini USB B type)	Provides interface for trend data downloads.
6	Jog dial	Offers control of display and monitoring system functions.
7	LCD	Reports all graphic and numeric patient information as well as status conditions and warning messages.
8	SpO2 connector	Provides a connection to the extension cable and SpO2 sensor.

Display

Figure 4-2. Display Components



1	100 90	Upper and lower alarm limits	Reflects upper and lower SpO2 and pulse rate alarm limits. An alarm sounds each time SpO2 saturation or pulse rate values violate these alarm limits.
2	%SpO2 99	SpO2 real-time value	Indicates hemoglobin oxygen saturation levels. Current upper and lower alarm limit settings appear as smaller values to the left of the dynamic SpO2 value.
3	01:04:23	Time	Indicates the current time in hours, minutes, and seconds. Uses a 24-hour clock.
4		Pulse amplitude (blip bar)	Indicates pulse beat and the relative (non-normalized) pulse amplitude. As the detected pulse becomes stronger, more bars light with each pulse.
5	100	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 *SatSeconds™ Alarm Management Feature*, p. 37.
6		Alarm active icon	Appears, along with an alarm message, when patient values violate an alarm limit threshold. Audible and visual alarms occur.

7		Pulse rate real-time value	Displays the pulse rate in beats per minute. Current upper and lower alarm limit settings appear as smaller values to the left of the dynamic pulse rate value.
8		Battery status icon	Displays the battery charge remaining on the internal battery. • **Charged Battery** — A steady green battery icon indicates the monitoring system is running on internal battery power and the battery is fully charged. • **Low Battery** — A low priority alarm occurs when the remaining battery power is only sufficient for 15 minutes of operation. The flashing yellow alarm message `Low Battery` appears. Users cannot pause this alarm while running on battery power. Connect the monitoring system to AC power to stop the alarm. • **Critically Low-Battery** — A high priority alarm occurs for about five (5) minutes before the monitoring system shuts off. The flashing red alarm message `Critically Low-Battery` appears. When no charge remains, the monitoring system automatically shuts down. Connect the monitoring system to AC power to avoid any loss of trend data or settings.
9		AC power indicator	Lights continuously when connected to AC power.
10		Battery charge indicator	Lights when the monitoring system is charging the internal battery.
11		Interference indicator	Lights when the monitoring system detects degraded quality in the incoming signal. It is common for it to intermittently light as the monitoring system dynamically adjusts the amount of data required for measuring 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]
12		Sensor off indicator	Appears when the sensor is not on the patient.
13		Sensor disconnect indicator	Appears when the sensor is not connected to the monitoring system.
14		Sensor message indicator	Appears when the sensor is invalid.

15		Options menu area	Visible when users utilize the jog dial to select various menu options for customizing options and features.
16	 	Alarm limits menu area	Indicates the current audible alarm status. • Audio Paused • Audio Off
17	  	Patient mode area	Indicates the current patient mode selected. • Adult mode (default) • Pediatric mode • Neonatal mode
18		Plethysmographic (pleth) waveform	Non-normalized waveform using real-time sensor signals to reflect relative pulsatile strength and quality of incoming signals.
19		Informative message area	Contains messages to notify the user of a condition or a request for action.

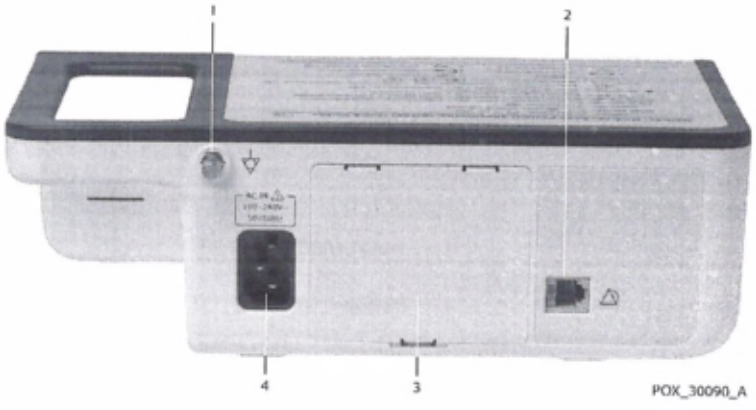
1. Degradation can be caused by ambient light, poor sensor placement, electrical noise, electrosurgical interference, patient activity, or other causes.

Table 4-1. Display Colors

Color	Condition	Function
Cyan numeric	Steady	SpO2 value and plethysmographic waveform
Yellow numeric		Pulse rate value
Black background		General background
Red background	Flashing	High priority alarm condition
Yellow background		Alarm condition
Green font	Steady	Informative message
Yellow font		Low or medium priority message
Red font	Flashing	High priority message
Green, yellow, or red battery icon	Steady	Normal, low, or critically low battery status

4.4.2 Rear Panel

Figure 4-3. Rear Panel Components



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

5 Installation

5.1 Overview

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

5.2 Safety Reminders

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

WARNING:
To ensure accurate performance and prevent device failure, do not expose the monitoring system to extreme moisture, such as direct exposure to rain. Such exposure may cause inaccurate performance or device failure. Reference *Product Specifications*, p. 21.

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

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

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

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

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

5.3 Unpacking and Inspection

The monitoring system is shipped in a single carton. Examine the carton carefully for evidence of damage. Contact Covidien Technical Services immediately if the carton appears damaged. Do not return the monitoring system prior to contacting Covidien. Reference *Technical Services*, p. 18.

Note:
Verify the performance of the monitoring system following the procedures outlined in this manual prior to initial installation in a clinical setting.

5.3.1 List of Components

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

Note:
Contact Covidien Technical Services for pricing and ordering information. Reference *Technical Services*, p. 18.

Table 5-1. Standard Items

Item	Quantity
Nellcor™ Bedside SpO2 Patient Monitoring System	1
Nellcor™ pulse oximetry interface cable, 10 ft (3m)	1
Compact Disc (CD) and/or Operator's Manual [1]	1
Lithium-ion battery pack, 5-hour[2]	1
AC power cord, hospital grade, 10 ft (3 m)	1

1. Covidien provides electronic copies of monitoring system manuals on a compact disc for easy access and print-on-demand. Order a printed *Nellcor™ Bedside SpO2 Patient Monitoring System Operator's Manual* or a printed *Nellcor™ Bedside SpO2 Patient Monitoring System Service Manual* at no cost from Covidien Technical Services or a local Covidien representative.
2. An optional 10-hour battery is available from Covidien.

5.4 Setup

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

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

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

5.4.1 Internal Battery Installation

The monitoring system operates on AC power or on a charged internal battery. The monitoring system cannot operate with a fully discharged battery, nor does it operate on AC power unless the battery is also installed.

Reference *Battery Replacement*, p. 173 for instructions for installing or replacing the internal battery.

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

Note:
If the monitoring system's battery is completely discharged, plug the monitoring system into an AC outlet for a minimum of three (3) minutes before turning it on.

5.4.2 Connecting to Power

Prior to connecting to power, install the internal battery and perform a safety check of the equipment. Reference *Periodic Safety Checks*, p. 113.

To connect the AC power cable:

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

Note:
Even if the monitoring system is not turned on, the ***Battery Charge Indicator*** lights when the AC power cord is connected into a mains outlet. Reference *Chapter 11, Troubleshooting*, if the battery charging indicator does not light when connected to AC power.

5.4.3 Using the Internal Battery

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

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

The monitoring system has an internal 5-hour (or optional 10-hour) battery that powers the monitoring system when AC power is not available. The monitoring system cannot operate with a fully discharged battery, nor does it operate on AC power unless the battery is also installed. A lit battery status icon indicates the monitoring system is running on battery power. Reference *Figure 4-2.* on page 45.

Prior to using the internal battery, charge it fully and perform a safety check of the equipment. Reference *Periodic Safety Checks*, p. 113.

To charge the internal battery:

1. Connect the monitoring system to AC power. Reference *Connecting to Power*, p. 52.
2. Verify the ***Battery Charge Indicator*** lights. Reference *Figure 4-2.* on page 45.
3. Allow the battery to charge for the required amount of time before disconnecting the monitoring system from AC power.

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

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

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

- Operating in Normal mode (measuring SpO_2 and PR with plethysmograph display)
- Setting for pulse beep indicator is ON (pulse volume: 4 (Default))
- Setting for SatSeconds is ON
- Operating at ambient temperature of 25°C (±5°C)
- Experiencing no alarm condition

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

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

Note:
Even when the monitoring system is connected to AC power, the battery must be installed, or the monitoring system will not power on. The monitoring system may not operate if the battery charge is critically low.

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

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

5.4.4 Connecting a Nellcor™ Pulse Oximetry Sensor

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

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

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

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

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.

Prior to connecting a sensor, perform a safety check of the equipment. Reference *Periodic Safety Checks*, p. 113. Reference the *Operator's Manual* for details regarding sensor selection.

To fully connect a Nellcor™ pulse oximetry sensor:

1. Select a compatible Nellcor™ pulse oximetry sensor appropriate 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 carefully reading the *Directions for Use* accompanying the sensor. Observe all warnings and cautions in the *Directions for Use*.

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

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

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

6 Operation

6.1 Overview

This chapter provides an overview to the operation of the Nellcor™ Bedside SpO_2 Patient Monitoring System, including instructions for turning the monitoring system on and off and accessing the menus. Reference the appropriate chapters of this manual for additional information about service-related monitoring system functions.

6.2 Safety Reminders

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

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

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

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

6.3 User Interface

6.3.1 Turning on the Monitoring System

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

Caution:
If any indicator or display element does not light, or the speaker does not sound, do not use the monitoring system. Reference *Troubleshooting*, p. 157 to determine the source of the problem.

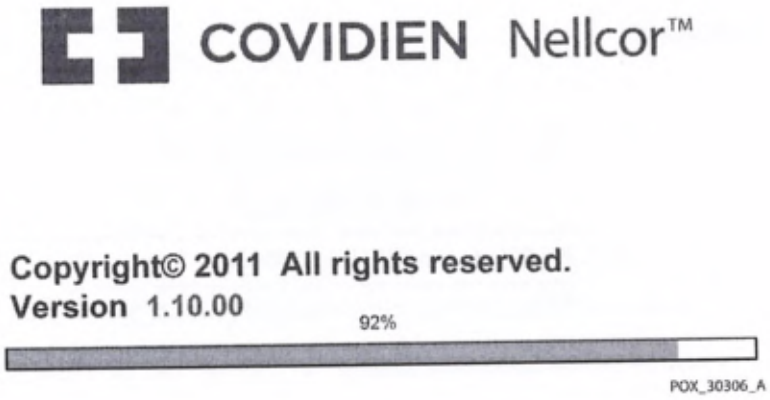
When the monitoring system completes power-on self-test (POST), a POST pass tone sounds. This functions as an audible confirmation of proper speaker performance. If the speaker does not function, the alarm warning sounds remain inaudible.

Note:
Pressing any button should result in either a valid or an invalid tone. Reference *Troubleshooting*, p. 157 if a button press fails to emit a tone.

To turn on the monitoring system:

1. Press and hold the ***Power On/Off*** button.
2. Ensure the POST screen, status indicators, and control buttons light for several seconds.

Figure 6-1. Example Initial Screen



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

Note:
Do not use the monitoring system should a repeating, high-pitched alarm tone occur at power-on. Reference *Troubleshooting*, p. 157.

6.3.2 Turning off the Monitoring System

After using the monitoring system, turn it off safely.

To turn off the monitoring system:

1. Press and hold the ***Power On/Off*** button.
2. Observe the message `System is shutting down` on the screen.

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

6.4 Menu Options Navigation

6.4.1 Menu Structure

Table 6-1. Menu Structure and Available Options

Item	Available Selections	Default
QUICK ACCESS ALARM LIMITS Menus		
SpO2 Menu	SatSeconds™ alarm management setting (Off, 10, 25, 50, 100) Upper (21-100) SpO2 alarm limit Lower (20-99) SpO2 alarm limit Alarm Inhibition for SpO2 alarms	100 Depends on patient mode. Reference *Table 6-6.* on page 80
PULSE RATE (PR) Menu	Upper (30-245) pulse rate alarm limit Lower (25-240) pulse rate alarm limit Alarm Inhibition for pulse rate alarms	
OPTIONS Menu		
VOLUME option	Alarm Volume (1-8)	5
	Key Beep Volume (Off, 1-7)	4
	Pulse Volume (Off, 1-7)	4
MODE option (Response Mode)	Normal, Fast	Normal
TREND DATA DOWNLOAD option	Start (Cancel or Return), Return	--
TREND CLEAR option	Yes, No	--
SERVICE MENU option	Power On Settings, Alarm Audio Paused, Alarm Audio Reminder, Language, Date/Time Settings, System Information, System Test, Trend Data Download Settings	--
ALARM LIMITS Menu		
SpO2 LIMITS options	Upper (21-100) SpO2 alarm limit Lower (20-99) SpO2 alarm limit Alarm Inhibition for SpO2 alarms	Depends on patient mode. Reference *Table 6-6.* on page 80.
PULSE RATE LIMITS options	Upper (30-245) pulse rate alarm limit Lower (25-240) pulse rate alarm limit Alarm Inhibition for pulse rate alarms	
SATSECONDS option	SatSeconds™ alarm management setting (Off, 10, 25, 50, 100)	100

Table 6-1. Menu Structure and Available Options (Continued)

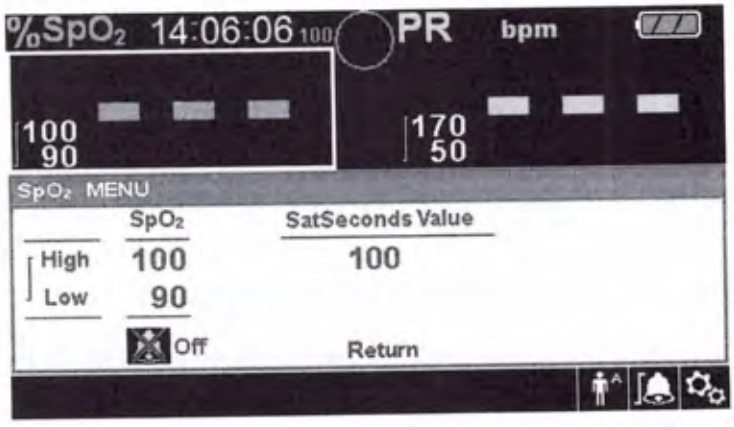
Item	Available Selections	Default
PATIENT MODE Menu		
ADULT option	Default Alarm Limits threshold setting for adult patients	Reference *Table 6-6.* on page 80.
PEDIATRIC option	Default Alarm Limits threshold setting for pediatric patients	
NEONATE option	Default Alarm Limits threshold setting for neonate patients	
SpO2 WAVEFORM Menu		
SWEEP SPEED option	6.25 mm/s, 12.5 mm/s, 25.0 mm/s	25.0 mm/s
TABULAR TREND option	Tabular trend view of trend data	--
GRAPHICAL TREND option	Graphical trend view of trend data	

6.4.2 QUICK ACCESS Menus

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

1. **SpO2 Menu —** Provides access to SpO2 alarm limit settings, alarm inhibition, and SatSeconds alarm management option. The adult default setting is 100. Other options include OFF, 10, 25, and 50. Reference *ALARM LIMITS Menu*, p. 72, for basic information. Reference *SatSeconds™ Alarm Management Feature*, p. 37. for a more thorough explanation of how the SatSeconds option works.

Figure 6-2. QUICK ACCESS SpO2 Menu



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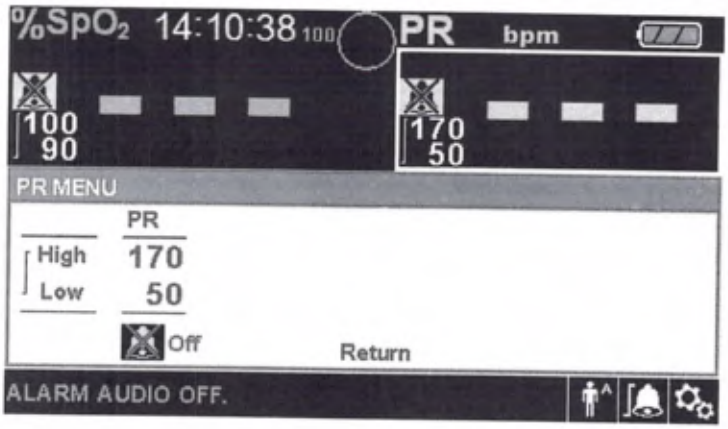
2. **PR Menu —** Provides access to pulse rate (PR) alarm limit settings and alarm inhibition. Reference *ALARM LIMITS Menu*, p. 72.

Figure 6-3. QUICK ACCESS PR Menu



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To select alarm limit settings via Quick Access menus:

1. Rotate the jog dial until the white highlight appears over the SpO2 or the pulse rate (PR) real-time value field.
2. Press the jog dial.
3. Rotate the jog dial to reach the desired field.
   - Available SpO2 alarm limit thresholds
     - SatSeconds™ alarm management values include OFF, 10, 25, 50, 100. The default value is 100. Reference *SatSeconds™ Alarm Management Feature*, p. 37.
     - Upper and lower SpO2 alarm limit thresholds
     - SpO2 alarm inhibition to disable audible alarms for SpO2 limit violations
   - Pulse Rate alarm limits
     - Upper and lower pulse rate alarm limit thresholds
     - Pulse rate alarm inhibition to disable audible alarms for pulse rate limit violations
4. Press the jog dial to select the field.
5. Rotate the jog dial to change the field.
6. Exit the menu using one of the following methods.

- Rotate the jog dial to highlight the Return option and press the jog dial.
- Press the ***Return*** button until the LCD returns to its original screen.

6.4.3 OPTIONS Menu

From the OPTIONS Menu, caregivers can select Volume, Mode, Trend Data Download, or Delete All Trend Data. The SERVICE Menu, accessible only by entering a pass code from Covidien Technical Services, is also available from the OPTIONS Menu.

To access the OPTIONS Menu:

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

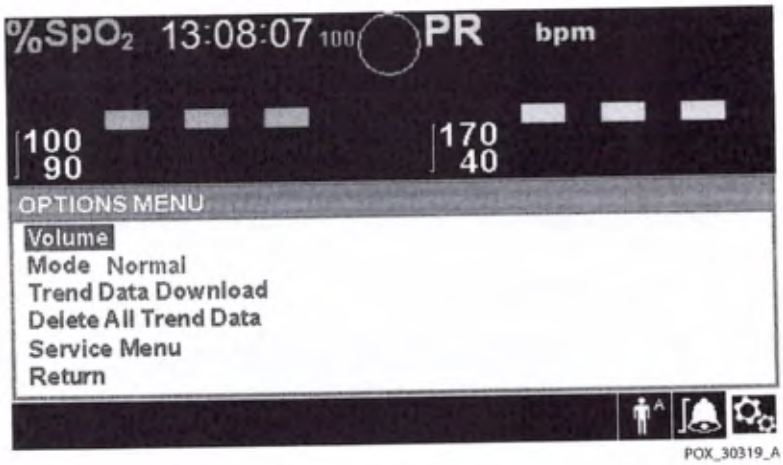
Volume

Access this menu option to adjust volume controls.

To set the desired audible tone volume:

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

Figure 6-4. Volume Menu Item

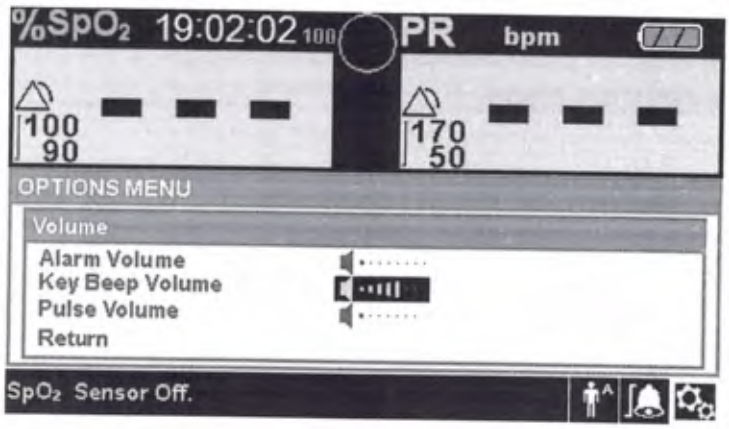


3. Press the jog dial to access Alarm Volume, Key Beep Volume, or Pulse Volume.
   - Alarm Volume controls the volume (1-8) of alarms.

- Key Beep Volume controls the volume (Off, 1-7) of any button press.
- Pulse Volume controls the volume (Off, 1-7) of the plethysmographic waveform.

4. Rotate the jog dial to select the desired volume level.
5. Press the jog dial to save the desired volume level.

Figure 6-5. Volume Selection



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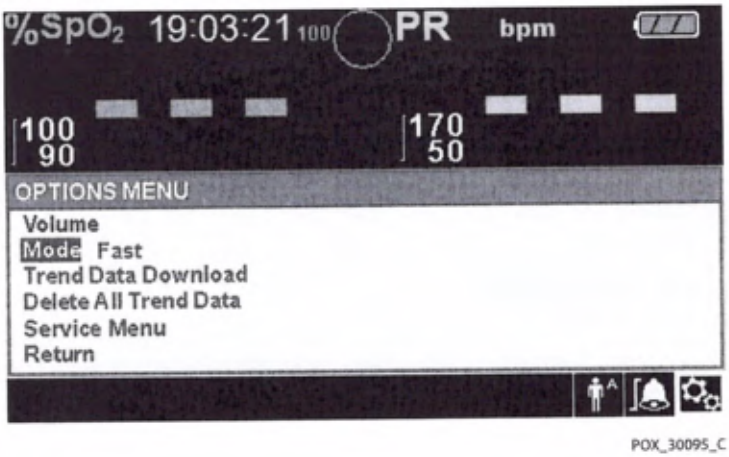
Mode (Response Mode)

The response mode (Normal or Fast) establishes the frequency at which the monitoring system calculates, records, and displays SpO_2 data.The response mode setting does not affect the algorithm's calculation of pulse rate, nor does it influence the recording of trend data, which occurs at one-second intervals. The default setting is the Normal Response Mode.

To set response mode:

1. Access the OPTIONS Menu.
2. Rotate the jog dial to highlight MODE.
3. Press the jog dial to select Normal or Fast response mode.
   - Select **Normal** response mode for a five (5) to seven (7) second calculation of SpO_2 under interference-free conditions.
   - Select **Fast** response mode for a two (2) to four (4) second calculation of SpO_2 under interference-free conditions. This mode can be particularly helpful for situations that require close monitoring.

Figure 6-6. Response Mode Menu



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

Trend Data Download

Access this menu option to download patient trend data. Reference *Trend Data Download*, p. 89.

Delete All Trend Data

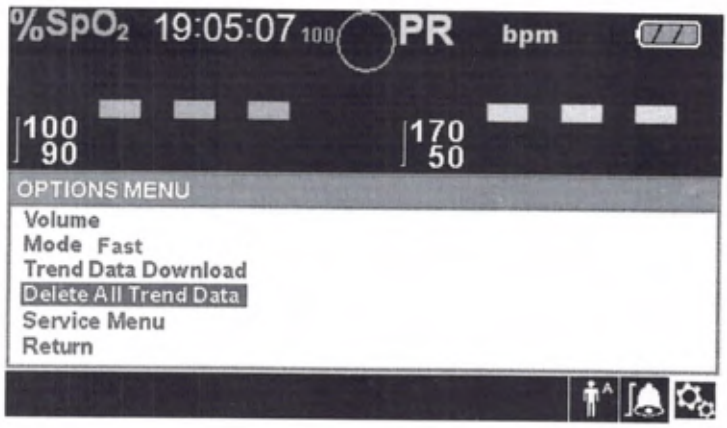
Access this menu option to clear trend data.

Caution:
Once trend data is deleted, it cannot be retrieved.

To clear trend data:

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

Figure 6-7. Delete All Trend Data Menu Item



3. Press the jog dial to select YES or RETURN to access the OPTIONS menu.

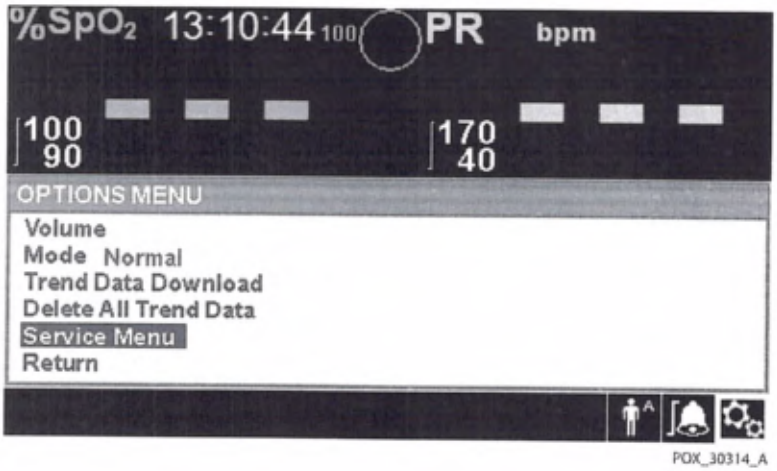
6.4.4 Service Menu

Note:
Do not share the SERVICE Menu access code with anyone who should not be making service-related adjustments to the monitoring system.

To access the SERVICE Menu:

1. Access the OPTIONS Menu.

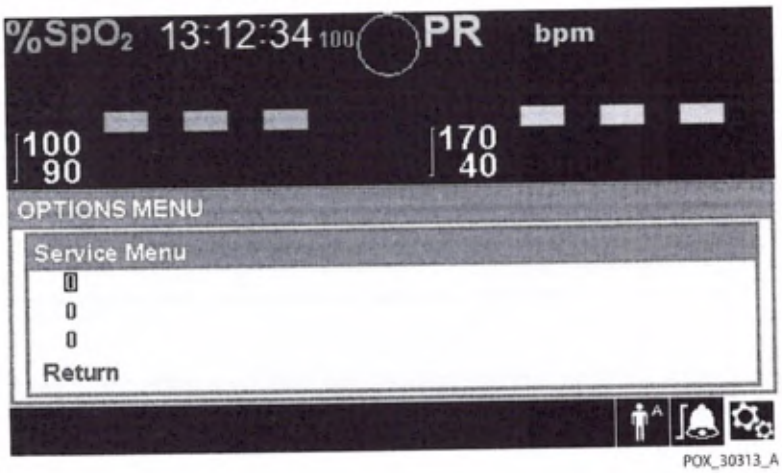
Figure 6-8. Service Menu Item



2. Rotate the jog dial to highlight SERVICE MENU and press the jog dial.

   The access code screen appears. The first digit of the access code is highlighted, and the value of all digits is 0.

Figure 6-9. Service Menu Access



3. The access code is 402. Enter it as follows:

   a. Press the jog dial to select the highlighted digit (this will be the first digit when the access code screen first appears).

   b. Rotate the jog dial to 4 and press the jog dial to select that value.

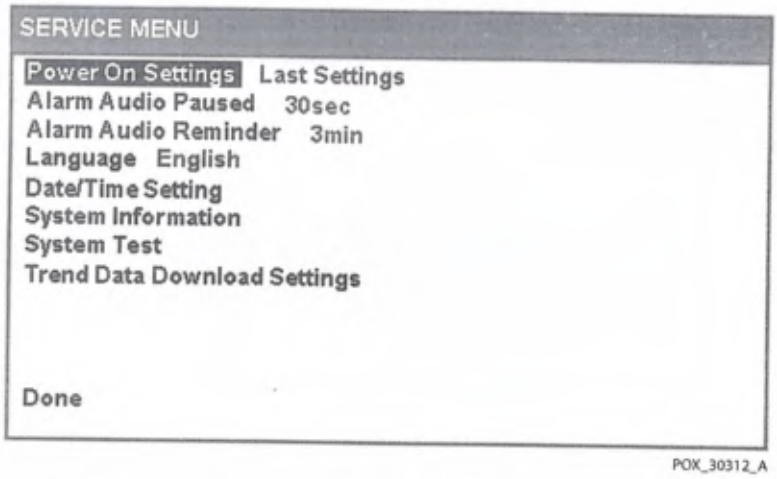
   c. Rotate the jog dial to the next digit.

   d. Repeat steps a through c to set the correct values for the remaining digits.

Note:
The access code is set at the factory and cannot be changed.

Once the access code is entered correctly, the SERVICE Menu appears.

Figure 6-10. Service Menu



4. From the SERVICE Menu, access the desired task by rotating and pressing the jog dial. Reference *Table 6-2.* on page 68 and the sections that follow the table for information about each task.
5. When all changes are complete, select DONE from the bottom of the screen.
6. Wait for the monitoring system to turn off. Then, turn it on again.

Note:
When DONE is selected, the power-on settings in effect for the next power-on session depend on the POWER ON SETTINGS selection. Reference *Power On Settings*, p. 70.

Table 6-2. Service Menu Options

Level 1 Menu	Level 2 Menu	Level 3 Menu
Power On Settings	Factory Defaults, Last Settings, Institutional Defaults	
Alarm Audio Paused	30, 60, 90, 120 sec	
Alarm Audio Reminder	Off, 3, 10 min	
Language	Korean, Chinese, English, French, German, Italian, Japanese, Portuguese, Danish, Dutch, Finnish, Greek, Norwegian, Polish, Russian, Spanish, Swedish, Turkish, Czech, Slovakian	

Table 6-2. Service Menu Options

Level 1 Menu	Level 2 Menu	Level 3 Menu
Date/Time Setting	Year, Month, Day, Hour, Minute, Second (Date Format: yy/mm/dd)	
System Information	Monitor On Time (hh:mm)	
	System Software Version (n.nn.nn)	
	SpO2 (version on NELL1SR board)	
System Test	Switch/LED Test	Exit Test
	LCD Test	Press jog dial button to exit test
	Alarm Audible Test	Exit Test
	Tone Audible Test	Exit Test
	Buzzer Test	Exit Test
Trend Data Download Settings	Baud Rates	19200
		38400
		57600
		115200
	Protocol	ASCII 1
		ASCII 2
Done	Changes are saved and monitoring system is powered off.	

Power On Settings

Use the Power On Settings option to save current or institutional settings, or to revert to factory default settings.

To use the Power On Settings option:

1. Highlight the POWER ON SETTINGS option and press the jog dial to select.
2. Highlight one of three options and press the jog dial to select.
   - **Factory Defaults —** The factory settings become the power-on defaults the next time the monitoring system is powered on.
   - **Last Settings —** The settings made during this power-on session become the power-on defaults the next time the monitoring system is powered on.
   - **Institutional Defaults —** The settings made during this power-on session are saved as institutional defaults. Any changes made during this or any subsequent power-on session will revert back to the saved institutional defaults when the monitoring system is powered off.
3. Rotate the jog dial to highlight Return and press the jog dial to return to the main SERVICE Menu.

Alarm Audio Paused

Use the ALARM AUDIO PAUSED option to select the time interval for which the audible alarm is temporarily silenced.

Alarm Audio Reminder

Use the ALARM AUDIO REMINDER TONE option to select the amount of time that elapses after alarms are silenced before the reminder tone sounds. If Off is selected, the reminder tone is disabled.

Language

Use the LANGUAGE option to select the language for all the text shown on the display. This setting takes effect during the next power-on.

Date/Time Setting

Access this menu option to set the date and time. Reference *Date and Time*, p. 120.

System Information

Use the SYSTEM INFORMATION option to display the following:

Table 6-3. System Information

Item	Description
Monitor On Time	Displays the number of hours and minutes that the monitoring system has been operational.
System Software Version	Displays the revision level of the system software. The revision level is also shown on the LCD as part of the copyright screen.
SpO2	Displays each module or board version.

System Test

Use the SYSTEM TEST options to verify correct operation of the switch/LED, LCD, audible alarm, audible tone, and buzzer. Select a test by rotating and pressing the jog dial. Once selected, each test is performed automatically. To stop a test, press the jog dial again.

Trend Data Download Settings

Use the TREND DATA DOWNLOAD SETTING to set the baud rate (19200, 38400, 57600, or 115200) and protocol (ASCII 1 or 2) that will be used when trend data are downloaded. Reference *Trend Data Download*, p. 89.

Done

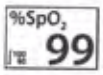
Select Done when changes are complete. The monitoring system is powered off, and any changes made will be in effect the next time the monitoring system is powered on.

6.4.5 ALARM LIMITS Menu

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

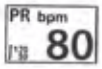
WARNING:
Check alarm limits with each use to ensure they are appropriate for the patient being monitored. Ensure alarm limits do not exceed the standard thresholds set by the institution.

Caregivers may choose to adjust SpO_2 and pulse rate (PR) alarm thresholds from default values as necessary. These changes remain in effect until modified again or until a power cycle occurs. Changes to the SpO_2 and pulse rate (PR) alarm thresholds appear in their respective numerical area. In addition, caregivers may choose to use the SatSeconds™ alarm option to manage the frequency of SpO_2 alarm limit violations by adjusting the SatSeconds™ setting. The higher the value, the less frequent the alarm.



SpO_2 numerical area — Indicates hemoglobin oxygen saturation levels. The display value flashes zeros during loss-of-pulse alarms and flashes the SpO_2 value on a yellow background when saturation is outside the alarm limits. During pulse searches, the monitoring system continues to update the display.

Current upper and lower alarm limit settings appear as smaller values to the left of the dynamic SpO_2 value. Reference *Factory Defaults*, p. 80, for default alarm limit settings.



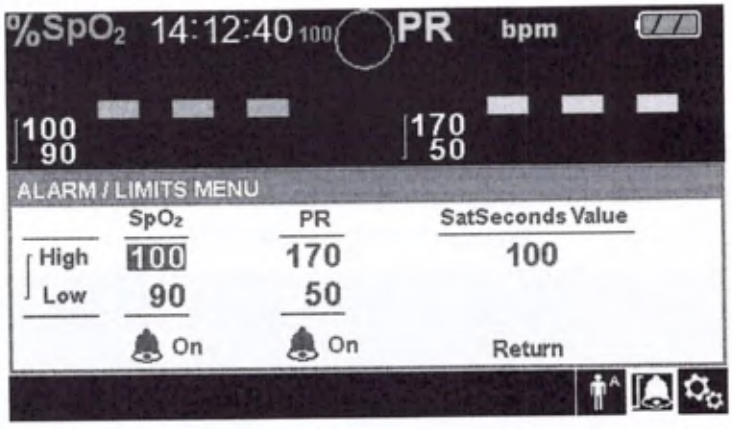
Pulse Rate (PR) numerical area — Displays the pulse rate in beats per minute (bpm). The display value flashes zeros during loss-of-pulse alarms and flashes the pulse rate value on a yellow background when the pulse rate is outside of the alarm limits. During Pulse Search, the monitoring system continues to update the display. Pulse rates outside of the pulse rate range of 20 to 250 bpm are displayed as 0 and 250, respectively.

Current upper and lower alarm limit settings appear as smaller values to the left of the dynamic pulse rate value. Reference *Factory Defaults*, p. 80, for default alarm limit settings.

To set alarm limits:

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

Figure 6-11. Alarm Limits Selection



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5. Rotate the jog dial to change the desired option value. Reference *Menu Structure*, p. 60, for adult, pediatric, and neonate limit options.
   - Available SpO_2 alarm limit thresholds
     - Upper and lower SpO_2 alarm limit thresholds
     - SpO_2 alarm inhibition to disable audible alarms for SpO_2 limit violations

- Pulse Rate alarm limits
  - Upper and lower pulse rate alarm limit thresholds
  - Pulse rate alarm inhibition to disable audible alarms for pulse rate limit violations
- SatSeconds™ alarm management values include OFF, 10, 25, 50, 100. The default value is 100. Reference *SatSeconds™ Alarm Management Feature*, p. 37.

6. Press the jog dial to save the desired value.
7. Rotate the jog dial to highlight the desired option or to RETURN to the OPTIONS menu.

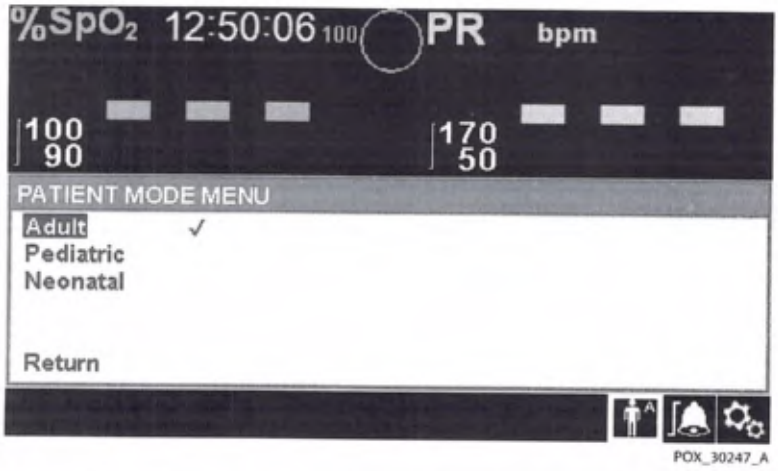
6.4.6 PATIENT MODE Menu

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

To set patient mode:

1. Rotate the jog dial to highlight the Patient Mode icon.
2. Press the jog dial to display PATIENT MODE.

Figure 6-12. Patient Mode Menu



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

Adult: Use for adults.

Pediatric: Use for children.

Neonatal: Use for newborns.

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

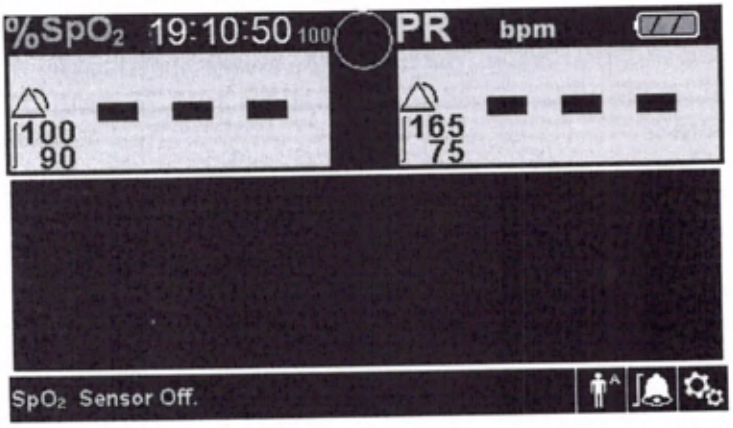
6.4.7 SpO_2 WAVEFORM Menu

Access this menu to set sweep speed of the plethysmographic waveform and opt to view the tabular or graphical trend screen.

To access the WAVEFORM Menu:

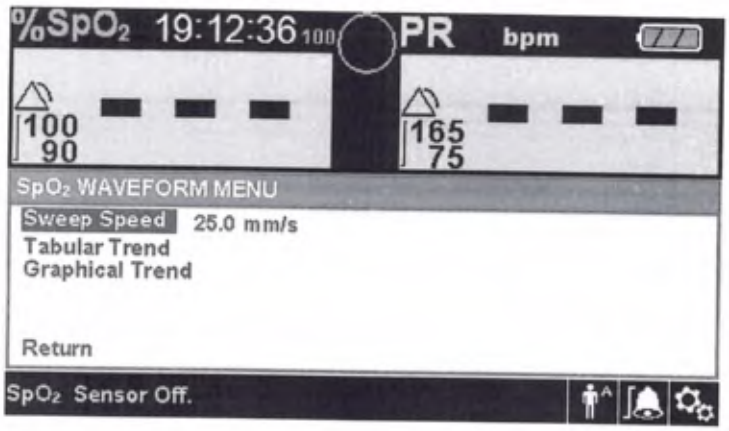
1. Rotate the jog dial to highlight the waveform display area.

Figure 6-13. Highlighting the Waveform Display Area



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

Figure 6-14. SpO2 Waveform Menu



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- **Sweep Speed —** Access to set the speed at which the SpO2 waveform trace moves across the screen. The higher the sweep speed value, the more data appear on the screen. Sweep Speed options are 6.25 mm/s, 12.5 mm/s and 25.0 mm/s.
- **Tabular Trend —** Access to display the tabular trend view. Reference *Tabular Trend Data*, p. 85.
- **Graphical Trend —** Access to display the graphical trend view. Reference *Graphical Trend Data*, p. 86.

6.5 Managing Alarms and Alarm Limits

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

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

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

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

The monitoring system uses both visual and audible indicators to identify high-priority, medium-priority, and low-priority alarms. Audible alarms include pitched tones, beeps, and a buzzing tone. High priority alarms take precedence over medium- and low-priority alarms. Reference *Troubleshooting*, p. 157.

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 or a local supplier for assistance.

6.5.1 Audible Alarm Indicators

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

Audible alarm indicators include pitched tones and beeps. Caregivers may choose to pause alarms for a selectable period of time.

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

Caregivers may choose to pause the audible alarm for the established ***Alarm Audio Paused*** period of 30, 60, 90 or 120 seconds. Visual alarms continue during this time. The factory default for audible alarm silence period is 60 seconds. To set one of the listed alternate periods as an institutional default, set the desired period via the SERVICE Menu.

Table 6-4. Audio Status

Alarm Icon	Status
	Alarm active
	Audio paused
	Audio off

To pause an audible alarm:

1. Press and hold the ***Audio Paused*** button for at least two (2) seconds.
2. To cancel, press and hold the ***Audio Paused*** button for two (2) seconds.

If ***Alarm Audio Paused*** is set, the audible alarm is not active for the specified time interval and the ***Audio Paused*** icon appears.

To re-enable the audio tones while the alarm audio is paused, press the ***Audio Paused*** button again.

If another alarm occurs while the alarm audio is paused, the monitoring system re-enables all audio tones.

Note:
Press the ***Audio Paused*** button to cancel audible alarms caused by technical errors. Audible alarms for battery failure and physiological conditions cannot be canceled without appropriate corrective action.

Note:
To disable limit violation alarms, use the Alarm Limits menus. Reference *ALARM LIMITS Menu*, p. 72.

6.5.2 Visual Alarm Indicators

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

Table 6-5. Alarm Conditions

Priority	Rate	Color	Messages
High	Sounds every 4 *s*	Red Steady message, Fast flashing numeric	SpO2 Loss of Pulse
			Critically Low-Battery condition
Medium	Sounds every 8 s	Yellow Steady message, Slow flashing numeric	High Pulse Rate limits violated
			Low Pulse Rate limits violated
			High SpO2 limits violated
			Low SpO2 limits violated
Low	Sounds every 16 s	Steady yellow	SpO2 Cable/Sensor Disconnect
			SpO2 Sensor Off
			Low Battery
			Technical System Error: EEE 001
Informative	--	--	SpO2 Pulse search
			Signal Artifact Detected
			Abnormally shut down last time
			Alarm audio OFF, Alarm audio paused
			Press Return Button to Exit...

6.6 Factory Defaults

Factory default settings are divided into adult, pediatric and neonatal. Patient mode is preset to Adult mode. Alarm limits are automatically changed to the default settings for each patient mode as the mode is changed to Adult, Pediatric or Neonatal.

Table 6-6. Parameter Ranges and Factory Defaults

Parameter	Ranges/Selection	Factory Default		
		Adult	Pediatric	Neonatal
SpO2				
%SpO2 Upper Alarm Limit	21 to 100% (1% steps)	100%		95%
%SpO2 Lower Alarm Limit	20 to 99% (1% steps)	90%		85%
%SpO2 Limit Alarm Inhibition	On, Off	Off		
SatSeconds™ Alarm	Off, 10, 25, 50, 100	100		
Pulse Rate				
Pulse Rate Upper Alarm Limit	30 to 245 bpm (5 bpm steps)	170 bpm		200 bpm
Pulse Rate Lower Alarm Limit	25 to 240 bpm (5 bpm steps)	50 bpm	75 bpm	100 bpm
PR Limit Alarm Inhibition	On, Off	Off		
Tabular Trends				
Scroll	1, 5, 100, 500	1		
Graphical Trends				
SpO2	On, Off	On		
PR	On, Off	On		
Others				
Patient Mode	Adult, Pediatric, Neonatal	Adult		
Alarm Volume	1, 2, 3, 4, 5, 6, 7, 8	5		
Key Beep Volume	Off, 1, 2, 3, 4, 5, 6, 7	4		
Pulse Volume	Off, 1, 2, 3, 4, 5, 6, 7	4		
Alarm Audio Paused[1]	30, 60,90, 120 s	60 s		
Alarm Audio Reminder[1]	OFF, 3, 10 min	3 min		

Table 6-6. Parameter Ranges and Factory Defaults (Continued)

Parameter	Ranges/Selection	Factory Default		
		Adult	Pediatric	Neonatal
Date/Time Setting	yy/mm/dd, mm/dd/yy, dd/mm/yy	yy/mm/dd		
Mode (Response Mode)	Normal, Fast	Normal		
Trend Data Download Settings[1]	Baud Rates: 19200, 38400, 57600, 115200 bps	19200 bps		
	Protocol: ASCII 1, ASCII 2	ASCII 1		
Sweep Speed	6.25, 12.5, 25.0 mm/s	25.0 mm/s		
Power On Settings[1]	Factory Defaults, Last Settings, Institutional Defaults	Last Settings		
Language[1]	Chinese (Simplified), Czech, Danish, Dutch, English, Finnish, French, German, Greek, Italian, Japanese, Korean, Norwegian, Polish, Portuguese (Brazilian), Russian, Slovakian, Spanish, Swedish, Turkish	English		

1. Settings for this parameter are accessible from the Service Menu. Reference *Service Menu*, p. 66.

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7 Data Management

7.1 Overview

This chapter contains information for accessing and downloading patient trend data, using the nurse call function, and upgrading firmware for the Nellcor™ Bedside SpO_2 Patient Monitoring System.

- **Accessing and downloading patient trend data —** Trend data can be viewed anytime it is stored in the monitoring system. Trend data can also be downloaded to a PC. The monitoring system stores up to 96 hours of trend data. When the monitoring system begins measuring vital signs, it saves data every four (4) seconds. It also saves all physiological alarm conditions and errors. Trend data history remains in memory even if the monitoring system is powered off. The monitoring system stores new data over the oldest data when the buffer is full.
- **Connecting to a nurse call system —** The monitoring system can be connected to a nurse call system for centralized alarm notification.
- **Upgrading the monitoring system's firmware —** Occasionally, Covidien will provide upgrades to the firmware for the monitoring system, which must be loaded via the USB port.

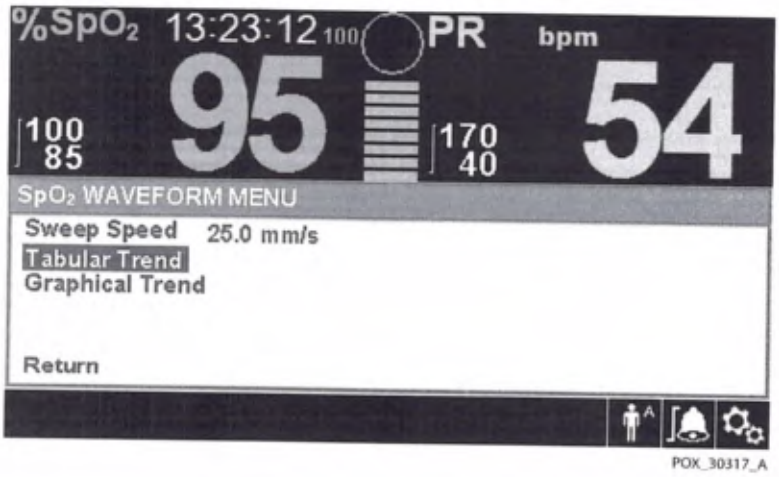
7.2 Trend Data

Trend data is available for viewing in tabular or graphical format. Trend data in tabular format can also be saved to an external device.

WARNING:
Replacing the coin cell battery for the Main board resets the monitoring system's date and time settings. Integrity of existing patient data will be questionable. Reset the date and time after replacing this battery with a known good battery.

Note:
Trend data can be saved to an external device via the USB port. Reference *Trend Data Download*, p. 89

Figure 7-1. SpO2 Waveform Menu



The Waveform Menu contains the following options:

- **Sweep Speed** — Use to set the waveform speed (6.25 mm/s, 12.5 mm/s or 25.0 mm/s).
- **Tabular Trend** — Use to view the trend in tabular form.
- **Graphical Trend** — Use to view the trend in graphical form.

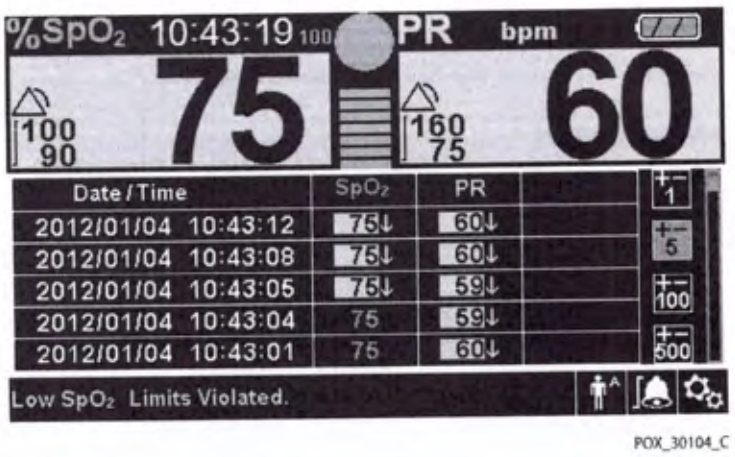
7.2.1 Tabular Trend Data

When the TABULAR TREND DATA option is enabled, the monitoring system presents trend information in tabular format for all monitored parameters. The newest data values appear at the top.

To select *Tabular Trend*:

1. Rotate the jog dial to highlight the waveform area.
2. Press the jog dial to display the SpO2 WAVEFORM Menu.
3. Select ***Tabular Trend***.

Figure 7-2. Tabular Trend Data Screen



To scroll through *Tabular Trend Data*:

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

Note:
To scroll most efficiently, adjust the scroll granularity more than once. For instance, use the +/-500 value to scroll quickly to the desired time stamp, then

press the jog dial again to reach the +/-1 value to scroll through each individual event in that time period.

4. After reviewing trend data, press the Return button to exit scrolling.

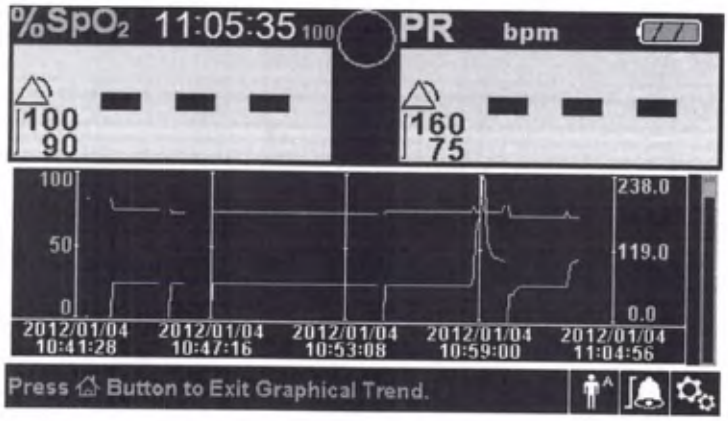
7.2.2 Graphical Trend Data

When the GRAPHICAL TREND DATA option is enabled, the monitoring system presents trend information in a single graph for all monitored parameters. The vertical range of a graphical trend appears as a fixed value. The horizontal range is 24 minutes. The newest data values appear to the right.

To select *Graphical Trend*:

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

Figure 7-3. Graphical Trend Data Screen



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To scroll through Graphical Trend Data:

1. Rotate the jog dial to scroll through the trend data.
2. After reviewing trend data, press the Return button to exit scrolling.

7.3 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. Failure to do so may result in unsafe leakage current and grounding conditions.

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

- **Nurse call interface (RJ11)** — Allows caregivers to remotely monitor patient alarms via the nurse call system of the institution.
- **USB interface** — Enables firmware upgrades. Reference *Firmware Upgrade*, p. 101.
- **Mini USB interface** — Enables trend data downloads and connection to a personal computer (PC).

7.3.1 Nurse Call Interface

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

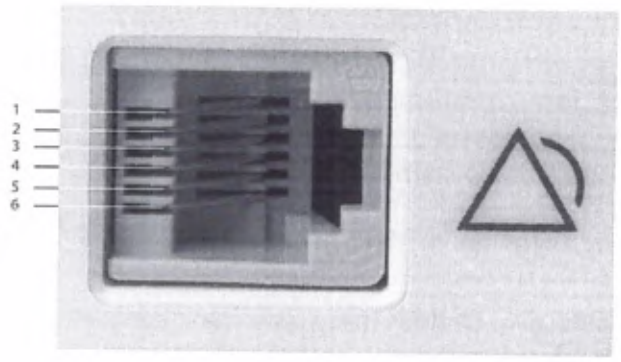
WARNING:
The nurse call feature does not function with *Audio Paused*.

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

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

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

Figure 7-4. Nurse Call Interface Pin Layout



1 Nurse call normally closed

2 Nurse call common lead

3 Nurse call normally open

The nurse call feature utilizes a relay closure to signal the nurse station during alarm conditions. Pins 2 and 3 provide a relay that closes during alarm conditions. Pins 1 and 2 provide a relay that opens during alarm conditions. Pin 2 is a common lead for both relays.

To connect the nurse call cable:

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

7.3.2 Trend Data Download

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

WARNING:
Replacing the coin cell battery for the Main board resets the monitoring system's date and time settings. Integrity of existing patient data will be questionable. Reset the date and time after replacing this battery with a known good battery.

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.

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

ASCII 1 — Nellcor™ ASCII protocol

ASCII 2 — ASCII format compatible with several spreadsheet programs

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

System Compatibility Prerequisites

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

Hardware

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

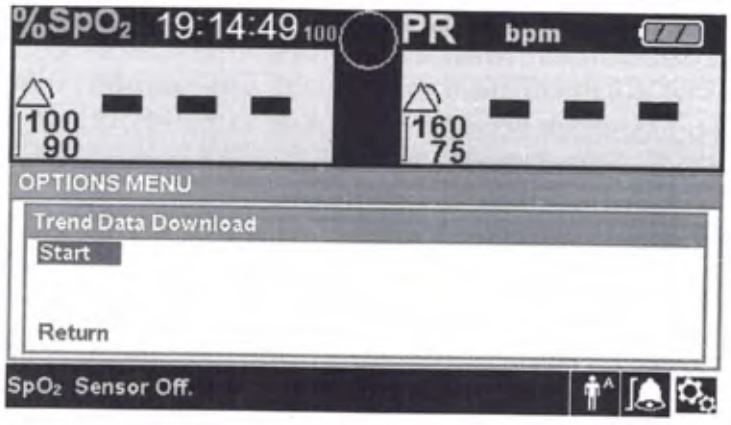
The COM port on the side of the monitoring system provides access to collected trend data. Data transfer relies on existing communication software drivers for USB-based devices already on the computer, so should not require any modification of the drivers used by the USB interface. If, for some reason, the computer does not have the correct USB driver, use the device driver provided on the product CD or from Technical Services. Reference *COM port USB Driver Alternatives*, p. 95.

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

To download trend data:

1. Install the device driver provided on the product CD onto the computer to be used for downloading trend data.
2. Power on the monitoring system.
3. Use the jog dial to select the OPTIONS Menu.
4. Select the TREND DATA DOWNLOAD submenu option.

Figure 7-5. Trend Data Download Option

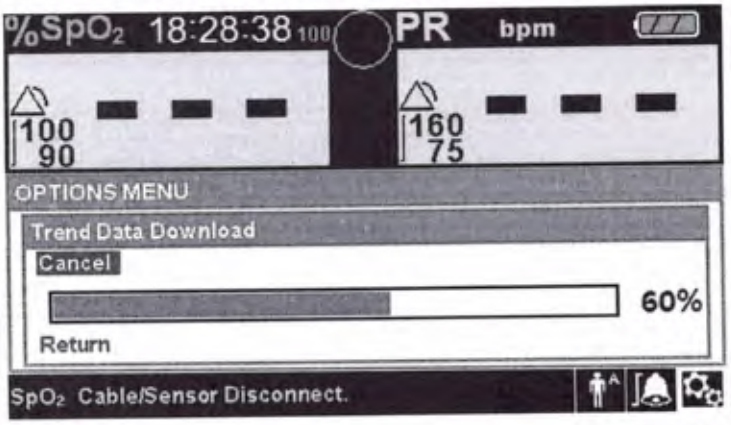


POX_30116_C

5. Connect a mini-USB cable from the monitoring system to the computer.
   a. Grasp the mini-USB end of the cable.
   b. Firmly insert into the bottom mini-USB data port.
   c. Firmly insert the USB end of the cable into a USB port on the computer.
6. Ensure the computer properly identifies the monitoring system. If it does not, follow the procedure for loading the appropriate driver. Reference *To install a USB driver from the compact disc:*, p. 95.
7. Launch HyperTerminal. Reference p. 92.
8. Press the jog dial again, since the item highlighted is the START option.The status bar indicating total percentage of the download appears and the START option, immediately changes to a CANCEL option.

Note:
Cancel the download operation at any point in the download process by selecting CANCEL and then RETURN.

Figure 7-6. Trend Data Download Status



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

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

To launch HyperTerminal:

1. Click the START menu in the main task bar.
2. Mouse over the PROGRAMS submenu, then ACCESSORIES, then COMMUNICATIONS, then the HYPERTERMINAL option.

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

3. Click the HYPERTERMINAL option.
4. When the Connect Description window opens, type in the desired file name in the Name field.
5. Locate the proper icon by scrolling all the way to the far right of the icon field.

6. Select the phone icon.
7. Click the OK button.

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

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

d. Ensure the stop bit is set to 1.

e. Ensure the flow control is set to none.

12. Click the OK button.

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

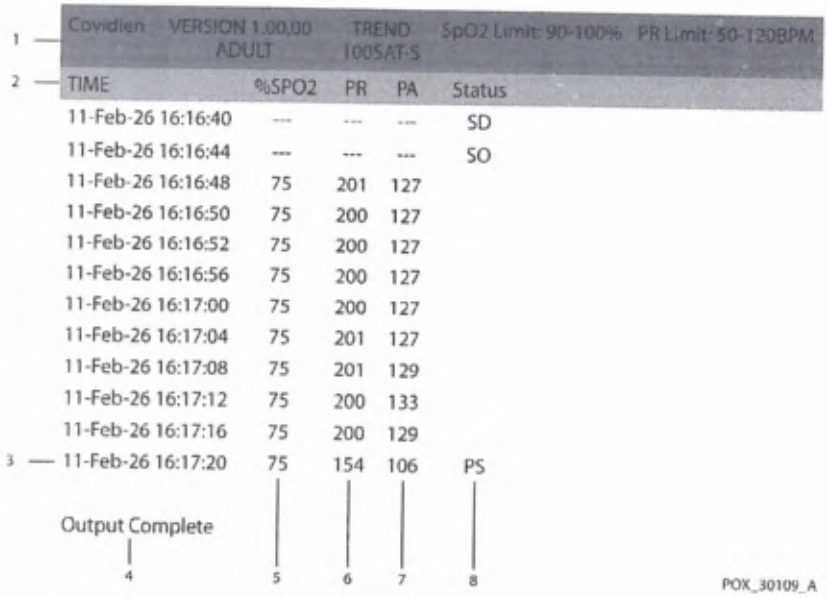
To interpret downloaded trend data:

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

Table 7-1. Operating Status Codes

Code	Definition	Code	Definition
MO	Signal artifact	SD	Sensor disconnect
PS	Pulse search	SO	Sensor off

Figure 7-7. 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, SpO_2, or PR column until reaching the events of interest.

4. Match the operating status codes to *Table 7-1 on page 93* for pertinent system information.

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 7-8. Bridge Driver Installer window

POX_30122_A

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 7-9. New Hardware Wizard Screen

POX_30124_A

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.

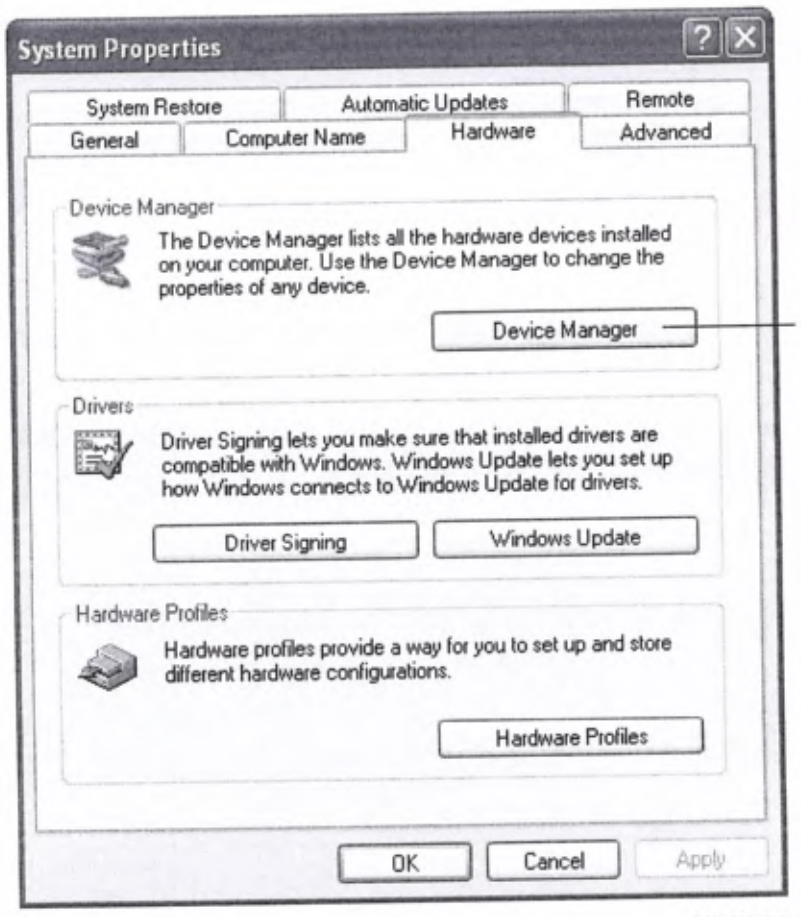
15. Click NEXT to formally accept the Destination Folder mapping.

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.

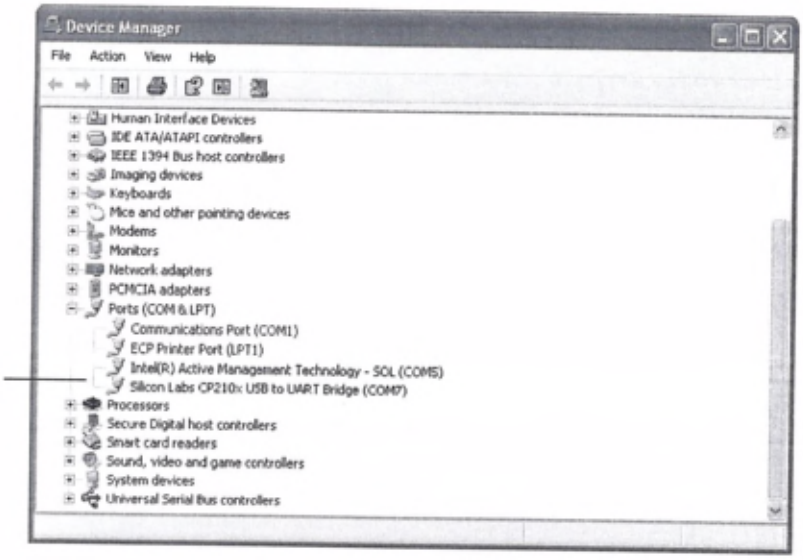
17. Click OK to complete the installation in the resulting Success window.
18. Reboot the PC for changes to take effect.
19. From the START menu, click the Settings menu option and select the Control Panel option.
20. Select the System option to open the System Properties window.
21. Click the Hardware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

Figure 7-10. DEVICE MANAGER Button Under Hardware Tab



22. Select the Ports option from the resulting list.

Figure 7-11. Hardware list in Device Manager window

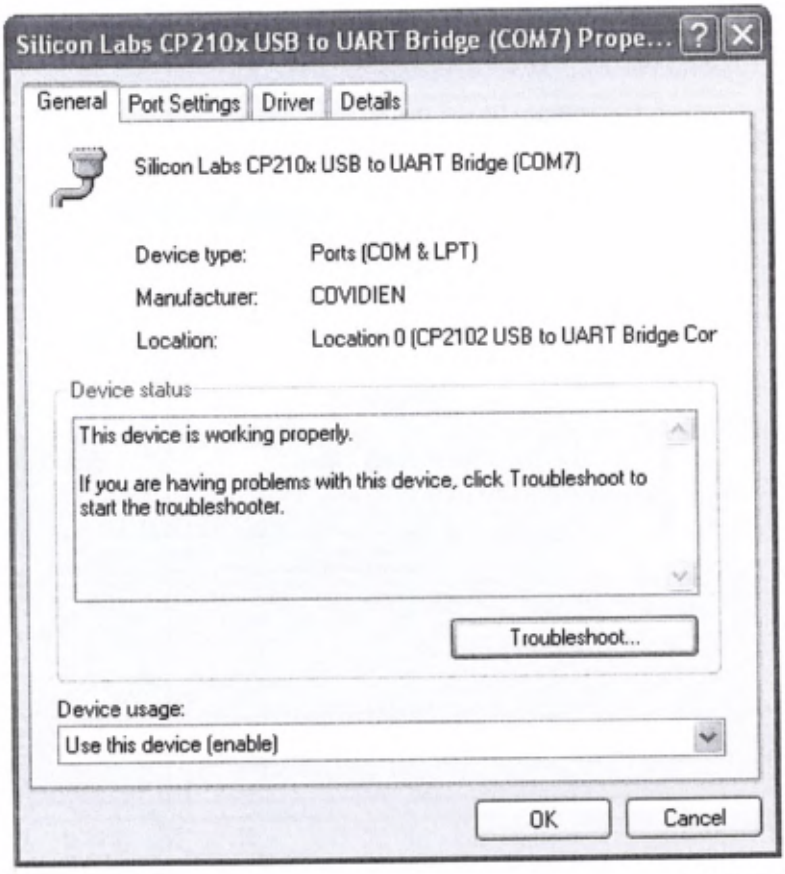


POX_30126_A

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

Note:
The listed COM port should match the HyperTerminal COM port designation.
Reference *To launch HyperTerminal:*, p. 92.

Figure 7-12. Sample Initial USB to UART Bridge Properties Window

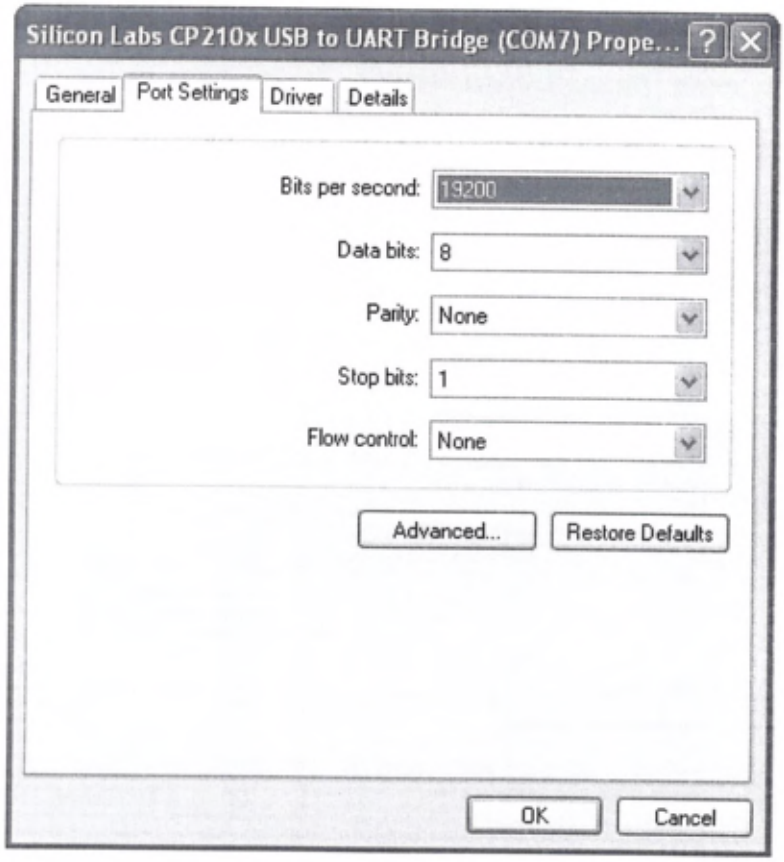


POX_30125_A

24. Click the Port Settings tab.

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

Figure 7-13. Baud rate list under Port Settings tab



26. Click the OK button to complete the process.

27. Reference *To download trend data:*, p. 90, and proceed to step 8, utilizing HyperTerminal to connect to the monitoring system.

7.4 Firmware Upgrade

This section describes how to upgrade the firmware for the monitoring system. Firmware updates occur periodically, and the monitoring system should be kept up to date to ensure proper operation. Reference *Firmware Download Errors*, p. 164 if errors occur during firmware upgrade.

Caution:
To help prevent the loss of power during the upgrade, make sure to use AC power rather than battery power. Before starting the upgrade, fully charge the battery so that if a power failure occurs, the monitoring system can continue the upgrade on battery power.

Note:
The firmware is downloaded via USB A-type port.

To upgrade firmware

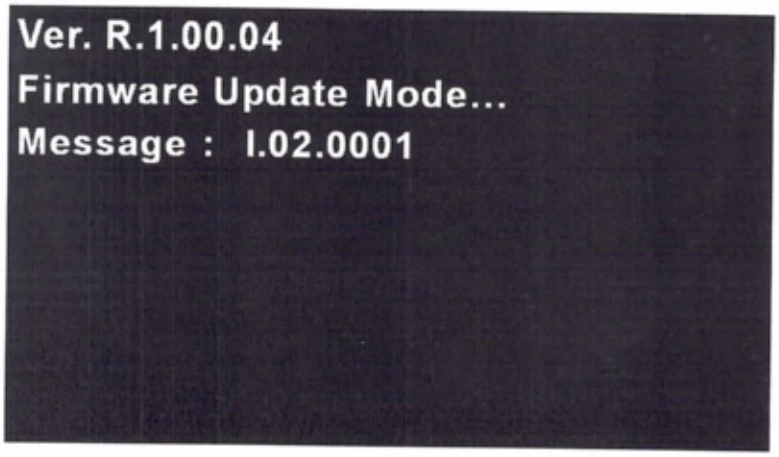
1. Obtain the new version of firmware from Covidien Technical Services. Reference *Technical Services*, p. 18. Place the firmware on a USB drive.

Note:
Ensure the name of the folder in the root directory is Update. Verify this folder contains the new firmware file (in the format NBSPMS_Main_*date_version*.bin), as well as the files Section.muf, Update.muf, and Ver.muf.

2. Power off the monitoring system.
3. Connect the AC power cord to the monitoring system and to the power source.
4. Press the ***Power On/Off*** and ***Return*** buttons simultaneously until the monitoring system powers on.

   The monitoring system powers on in Firmware Update Mode as shown in *Figure 7-14 on page 102*.

Figure 7-14. Firmware Update Mode

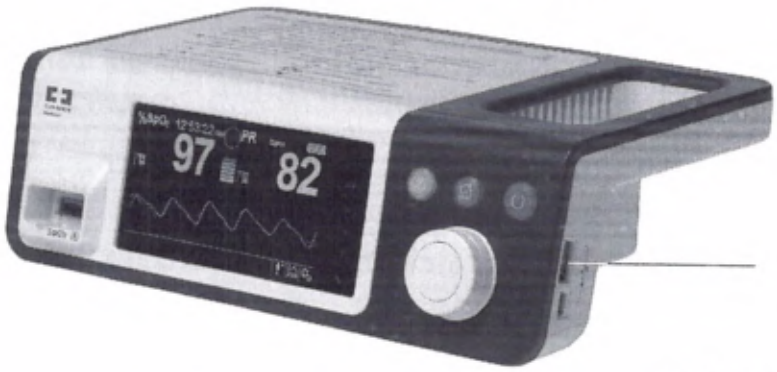


POX_30298_A

5. Connect the USB drive containing the new firmware files to the USB port on the right side of the monitoring system.

   Once the USB drive is installed, the upgrade procedure begins automatically.

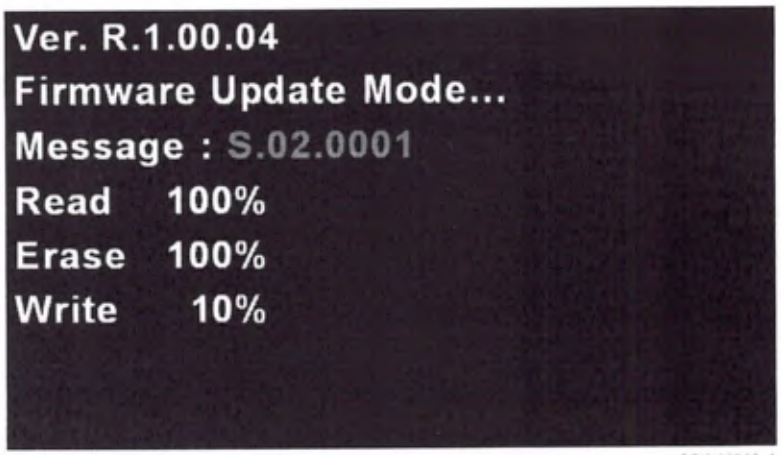
Figure 7-15. USB Port for Firmware Upgrade



POX_30320_A

6. Verify the update process is executed in Read, Erase, and Write order.

Figure 7-16. Firmware Upgrade Read, Erase, Write Messages



POX_30266_A

7. Verify the "Creating memory check sector...Wait" message changes to "Creating memory check sector...Done" and the "Update Complete. Restart." message displays.

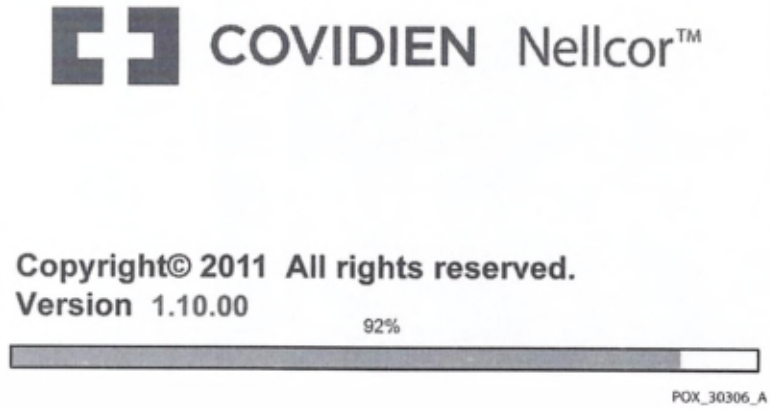
Figure 7-17. Firmware Upgrade Restart Message

POX_30268_A

8. Remove the USB drive from the USB port.

9. Press and hold the ***Power On/Off*** button to turn power off.
10. Press and hold the ***Power On/Off*** button again to turn the power on
11. Verify the upgrade is complete by checking the POST screen and firmware version.

Figure 7-18. POST Screen and Firmware Version



Note:
The monitoring system's previous settings are not modified during the upgrade. Reference *Power On Settings*, p. 70.

8 Performance Considerations

8.1 Overview

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

Verify the performance of the monitoring system by following the procedures outlined in *Chapter 10, Modification and Testing, on page 115*. Perform these procedures prior to initial installation in a clinical setting.

8.2 Oximetry Considerations

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

8.2.1 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).

8.2.2 Saturation

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

8.3 Performance Considerations

8.3.1 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*. Perform these procedures prior to initial installation in a clinical setting and every 24 months as part of preventive maintenance. Reference *Chapter 9, Preventive Maintenance*.

8.3.2 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 activity
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

8.3.3 Sensor Performance Considerations

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

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

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

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

Inaccurate Sensor Measurement Conditions

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

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

Signal Loss

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

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

Recommended Usage

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

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

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

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

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

8.3.4 Reducing EMI (Electromagnetic Interference)

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

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

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

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

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

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

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

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

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

8.4 Obtaining Technical Assistance

For technical information and assistance, contact Technical Services. Reference *Technical Services*, p. 18.

9 Preventive Maintenance

9.1 Overview

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

9.2 Cleaning

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

WARNING:
Remove the Lithium-ion battery from the monitoring system before cleaning.

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

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

For sensors, follow cleaning instructions in the directions for use shipped with those components. Before attempting to clean a Nellcor™ pulse oximetry sensor, read the *Directions 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 *Directions 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, perform the safety tests outlined in *Safety Tests*, p. 148.

9.3 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.

9.4 Battery Maintenance

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

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

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

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

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

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

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

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

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

Caution:
If there are any problems with the battery, immediately remove it from the monitoring system. Reference *Battery Replacement*, p. 173.

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

Note:
Storing the monitoring system for a long period without charging the battery may degrade battery capacity. To fully charge a depleted battery takes over four (4) hours for a 5-hour battery and eight (8) hours for a 10-hour battery.

Regularly check the battery to ensure optimal performance.

- Charge the lithium-ion battery if the monitoring system has not been used for six (6) months. To charge the battery, connect the monitoring system to AC power.
- With regular use, replace the monitoring system's lithium-ion battery every two (2) years. Reference *Battery Replacement*, p. 173.

9.5 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.

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10 Modification and Testing

10.1 Overview

This chapter provides information to trained service technicians on verifying Nellcor™ Bedside SpO_2 Patient Monitoring System performance following repairs or during preventive maintenance. When performing tests, follow these guidelines:

- All tests can be performed without removing the covers from the monitoring system.
- All tests except the battery charge and battery discharge tests must be performed as the last operation before the monitoring system is returned to the user.
- If the monitoring system fails to perform as specified in any test, repairs must be made to correct the problem before the monitoring system is returned to the user.

WARNING:
Only qualified service personnel should open the monitoring system housing, remove and replace parts, or make adjustments. If your medical facility does not have a qualified service technician, please contact Covidien Technical Services or your local Covidien representative.

Note:
Many of the tests outlined in this chapter require access to the monitoring system's SERVICE Menu. Reference *Service Menu*, p. 66.

10.2 Required Equipment

Table 10-1. Required Test Equipment

Equipment	Description/Use
Digital multimeter (DMM)	Voltage testing/nurse call port
SpO2 sensor (durable)	DS-100A Durasensor™ Adult Finger Clip Sensor
SpO2 extension cable	DOC-10
SpO2 simulator	Nellcor model SRC-MAX
Safety analyzer	Must meet current AAMI ESI:1993 & IEC 60601-1:1988 + A1:1991 + A2:1995 specifications (e.g., Fluke QA-90 or equivalent)
Stop watch	Manual or electronic/For alarm audio paused and alarm reminder intervals

Note:
Contact Covidien Technical Services for pricing and ordering information of the required equipment. Reference *Technical Services*, p. 18.

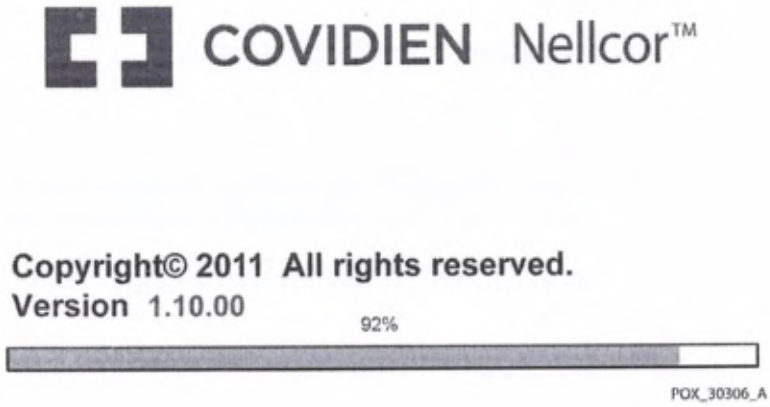
10.3 System Performance Tests

10.3.1 Power-On Self-Test (POST)

To check the power-on self-test (POST):

1. Connect the monitoring system to the AC power source and verify that the AC Indicator and Battery Charge Indicator are lit.
2. With the monitoring system off, press and hold the ***Power On/Off*** button. Verify that the monitoring system performs the following sequence:
   a. Three tones sound, and a status bar appears at the bottom of the LCD.
   b. The POST screen, status indicators, and control buttons light for several seconds.
   c. When POST completes successfully, one pass tone sounds, and the monitoring system displays the main monitoring screen.

Figure 10-1. Power-on Self-test Sequence



Note:
POST takes approximately 13 seconds to complete.

Note:
If an error occurs during POST, the monitoring system displays an error message. Reference *Chapter 11, Troubleshooting*.

10.3.2 Power

To check power:

1. Connect the monitoring system to the AC power source.
2. Verify the Battery Charge Indicator is lit.
3. Press and hold the ***Power On/Off*** button.
4. Verify the monitoring system is turned on and operating normally, then disconnect the power cord.
5. Verify the Battery Status Icon appears on the display and that the Battery Charge Indicator is off.
6. Press and hold the ***Power On/Off*** button for more than 2 seconds and verify that the monitoring system turns off.

10.3.3 Battery Charge

To verify battery charge:

1. Connect the monitoring system to the AC power source.
2. Verify the Battery Charge Indicator is lit.
3. Charge the battery until the Battery Charge Indicator changes to green, which will take approximately 4 hours for a 5-hour battery and 8 hours for a 10-hour battery.
4. To check for a full charge, perform the battery discharge procedure. Reference *Battery Discharge*, p. 118.

Note:
The battery may require a complete charge/discharge cycle to restore its normal capacity, depending on previous usage.

10.3.4 Battery Discharge

To verify battery discharge:

1. When the battery is fully charged, disconnect the power cord from the monitoring system.
2. Turn on the monitoring system by pressing the ***Power On/Off*** button.
3. Verify the Battery Status Icon appears at the top of the screen after power-on self-test is completed. The bar in the Battery Status Icon should be filled, indicating that the battery is charged.
4. Connect the SpO2 simulator (SRC-MAX) to the monitoring system via the SpO2 extension cable.
5. Set the SpO2 simulator as follows: SpO2 of 90% and pulse rate of 60bpm.
6. With the battery fully charged, verify the monitoring system can be operated for 5 hours for a 5-hour battery or 10 hours for a 10-hour battery.

   The monitoring system must operate for at least 15 minutes after the Low Battery message appears before the monitoring system powers down due to the low battery condition.
7. Verify that a low priority alarm occurs and the Low Battery message appears for a minimum of 15 minutes before battery fully discharges.

8. Allow the monitoring system to operate until it automatically powers down due to the low battery condition. Verify that a high priority alarm occurs and the Critically Low Battery message is displayed about 5 minutes before the monitoring system automatically shuts down.

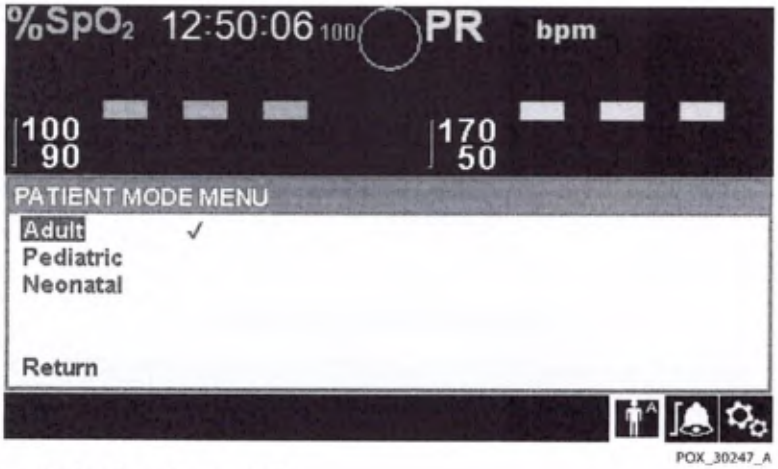
9. If the monitoring system passes this test, immediately recharge the battery.

10.3.5 Patient Modes

To verify that patient modes can be selected:

1. Select the PATIENT MODE Menu.

Figure 10-2. PATIENT MODE Menu



2. Select the desired patient mode.

   A check mark appears next to the selected patient mode.

3. Rotate the jog dial to each patient mode and select it while verifying that the correct PATIENT MODE icon appears at the bottom right of the display.

   Table 10-2 on page 120 lists the patient modes and their icons. The icon for the current patient mode setting appears in the lower right of the monitoring system's display.

Table 10-2. Patient Modes

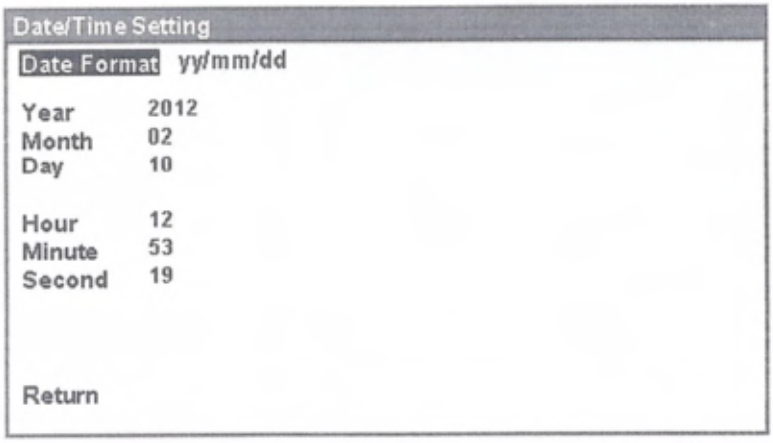
Icon	Patient Mode
	Adult
	Pediatric
	Neonatal

10.3.6 Date and Time

To verify the date and time are accurate:

1. Use the jog dial to select the OPTIONS icon.
2. From the OPTIONS Menu, use the jog dial to select the SERVICE Menu.
3. Select DATE/TIME.

Figure 10-3. DATE/TIME Settings



4. Use the jog dial to scroll through the Date Format options. The options allow for changes in the date format (yy/mm/dd, mm/dd/yy, dd/mm/yy).
5. Set the desired year, month, day, hour or minute.

6. Select the RETURN option.
7. Verify on the monitoring screen that the date and time are correct.

Note:
The time format is 24 hours only.

10.4 Operational and Functional Tests

10.4.1 General Operation Tests

To perform general operation tests:

1. Set the monitoring system to Factory Defaults, which removes Institutional Default settings. Reference *Factory Defaults*, p. 80.
2. Use a durable, adult finger sensor as specified in *Table 10-1 on page 116*.

LED Excitation Test

The LED excitation test uses normal system components to test circuit operation. The test uses the red sensor LED to verify intensity modulation controlled by the LED intensity control circuit. Use an adult finger sensor to examine LED intensity control.

Figure 10-4. Sensor Port

To test the circuit operation:

1. Connect the monitoring system to an AC power source.
2. Connect a DOC-10 pulse oximetry cable to the sensor port.
3. Connect the adult finger sensor to the DOC-10 cable.
4. Press and hold the ***Power On/Off*** button to turn the monitoring system on.
5. Pinch the ends of the finger sensor to open the sensor to its widest point.
6. After the monitoring system completes POST, verify the finger sensor LED is brightly lit.
7. Allow the sensor clip to close slowly.
8. Verify the LED intensity decreases as the LED approaches the optical sensor.
9. Open the sensor again and notice the LED intensity increases.
10. Repeat step *7* and verify the intensity continues to decrease. This variation is an indication the microprocessor is in proper control of LED intensity.
11. Leave the monitoring system on for the next test.

Operation with a Live Subject

Use the same finger sensor used in the *LED Excitation Test*, p. 121, to perform the following test with a live subject.

To test using a live subject:

1. Attach the finger sensor to a live subject as recommended in the OxiMax pulse oximetry sensor's directions for use.
2. If not already done, press and hold the ***Power On/Off*** button to turn the monitoring system on and verify the monitoring system is operating.
3. The monitoring system should stabilize on the subject's physiological signal in about 15 to 30 seconds. Verify the oxygen saturation and pulse rate values are reasonable for the subject.

Alarms and Alarm Paused

Access these settings from the SERVICE Menu by using the access code 402. Reference *Service Menu*, p. 66, for more information about accessing the SERVICE Menu.

To adjust the audio (alarms and alarm paused) options:

1. Connect the DOC-10 pulse oximetry cable to the monitoring system Sensor Port.

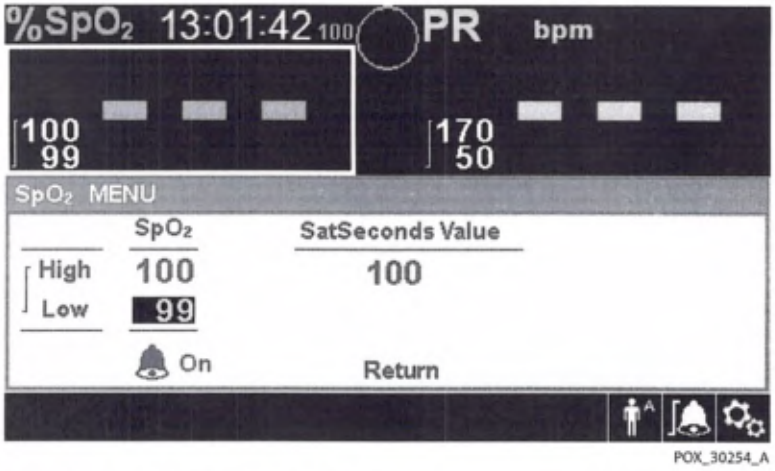
Figure 10-5. Sensor Port

2. Connect the OxiMax DS-100A sensor to the DOC-10 cable, then to a finger.
3. Press and hold the ***Power On/Off*** button to turn the monitoring system on.

ALARM AUDIO PAUSED

1. Verify the %SpO2 and PR indicate the SpO2 and pulse rate.
2. Select the ALARM LIMITS Menu.
3. Select the %SpO2 Lower Alarm Limit.
4. Change the %SpO2 Lower Alarm Limit to 99.

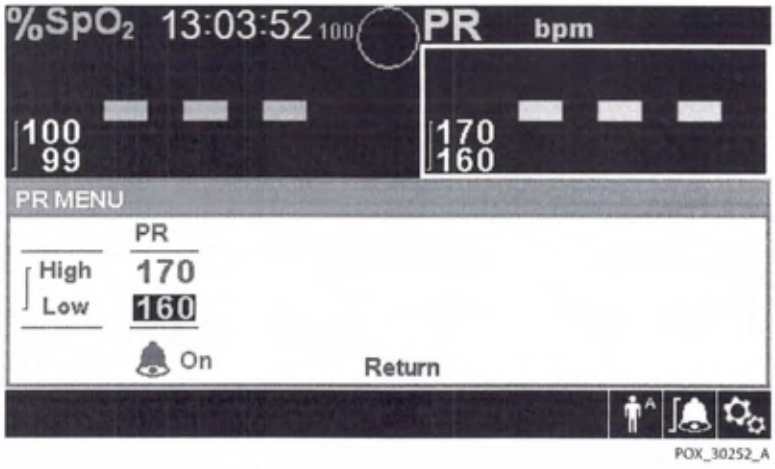
Figure 10-6. %SpO2 Lower Alarm Limit of 99



5. Select the Pulse Rate (PR) Lower Alarm Limit.

6. Change the Pulse Rate Lower Alarm Limit to 160.

Figure 10-7. Pulse Rate Lower Alarm Limit of 160



7. Confirm the following results:

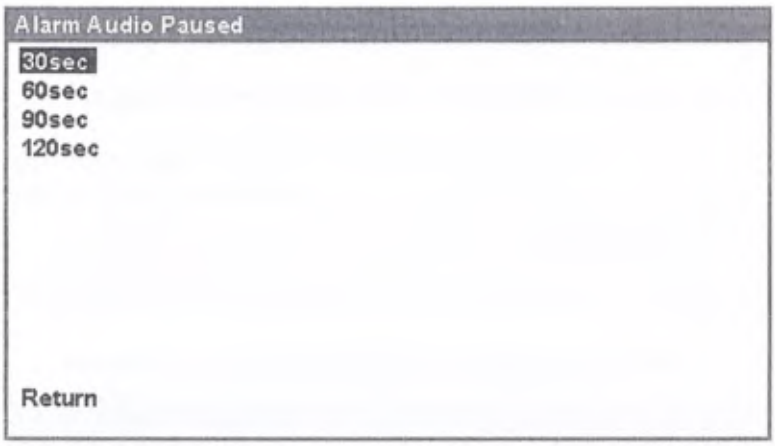
   - The waveform tracks the pulse rate.
   - The Pulse Tone is audible.
   - Once the SatSeconds clock has run to completion, the SpO2 and pulse rate values have flashing yellow highlights behind them.

Note:
Depending on the live subject, an alarm might not be triggered using the Lower SpO2 Limit of 99.

- The Audible Alarm sounds, and the following messages alternately appear in the lower left corner of the display: Low Pulse Rate Limits Violated and Lower SpO2 Limits Violated.

8. Access the SERVICE Menu and set the ALARM AUDIO PAUSED interval to 30sec.

Figure 10-8. ALARM AUDIO PAUSED Setting of 30 Seconds



9. Select Power On Settings from the SERVICE Menu.
10. Select Last Settings from the Power On Settings Menu to save the changes.
11. Select Done to exit the SERVICE Menu.

    A message appears indicating that the settings will be saved and that the monitoring system must be turned off.

12. Turn the monitoring system off and back on and wait for the alarm to sound.
13. Press the ***Audio Paused*** button to immediately pause the alarm tone.
14. With the alarm paused, verify the following:

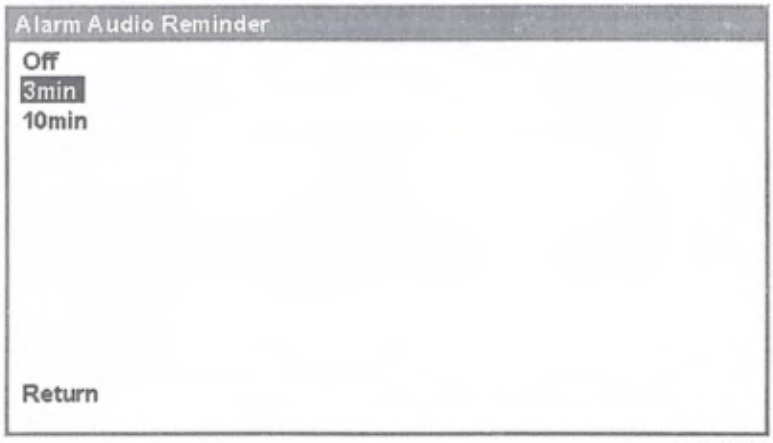
    - Alarm remains silent for 30 seconds and then returns
    - Alarm Silence indicators light, and the Alarm Audio Paused messages appears in the lower left corner of the display

- %SpO2 and PR displays continue to flash
- Pulse tone is audible

ALARM AUDIO REMINDER

1. Use the same values for %SpO2 and PR Lower Alarm Limit as described in *"ALARM AUDIO PAUSED" on page 123*.
2. Confirm the following results:
   - The waveform tracks the pulse rate.
   - The Pulse Tone is audible.
   - The SpO2 and pulse rate values are highlighted by flashing yellow boxes.
   - The Audible Alarm sounds, and the following messages alternately appear in the lower left corner of the display: Low Pulse Rate Limits Violated and Lower SpO2 Limits Violated.
3. In the SERVICE Menu, set the ALARM AUDIO REMINDER interval to 3min.

Figure 10-9. ALARM AUDIO REMINDER Setting of 3 Minutes



4. Select Power On Settings from the SERVICE Menu.
5. Select Last Settings from the Power On Settings Menu to save the changes.
6. Select Done to exit the SERVICE Menu.

   A message appears indicating that the settings will be saved and that the monitoring system must be turned off.

7. Turn the monitoring system off and back on and wait for an alarm condition to be triggered.
8. In the ALARM LIMITS Menu, turn off both the SpO2 and pulse rate alarms.
9. Verify the following:
   - Alarm audio is silent.
   - SpO2 and pulse rate values are highlighted by flashing yellow boxes, and the alarm silence indicators appear.
   - The ALARM AUDIO OFF message appears in the lower left of the display.
   - Pulse tone is audible.
   - After 3 minutes, the ALARM AUDIO REMINDER tone sounds.

Alarm Volume Control

After testing the ALARM AUDIO PAUSED and ALARM AUDIO REMINDER settings, perform the following alarm volume test procedure.

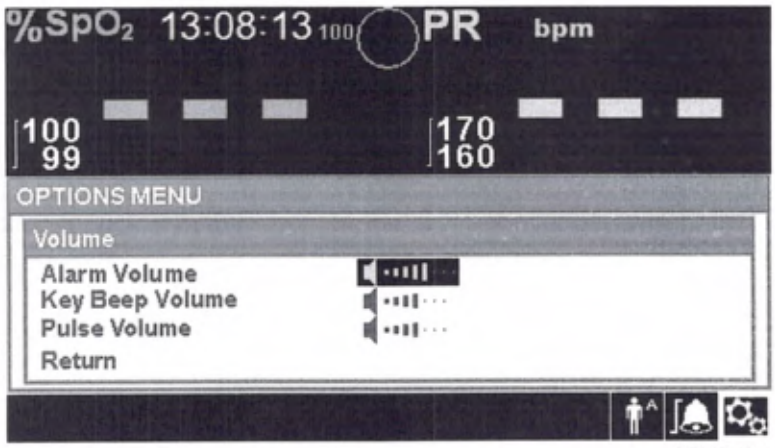
Note:
Turn the alarm audio back on for both SpO2 and pulse rate before performing this procedure.

To test the alarm volume:

1. Press and hold the ***Power On/Off*** button to turn the monitoring system off.
2. Connect the DOC-10 pulse oximetry cable to the monitoring system Sensor Port.
3. Connect the OxiMax DS-100A sensor to the DOC-10 cable, then to a finger.
4. Press and hold the ***Power On/Off*** button to turn the monitoring system on.
5. From the OPTIONS Menu, select Volume, then Alarm Volume.

   The Alarm Volume setting is displayed as dots, where 8 dots represent the highest volume and 1 dot represents the lowest volume. The default setting is 5.

Figure 10-10. ALARM VOLUME Default Setting of 5



6. Trigger an alarm by setting the thresholds to values such as those set in *"Alarms and Alarm Paused" on page 123* and verify that the alarm tone sounds.

7. Select Alarm Volume settings of 1, 5, and 8 and verify that the alarm audio is lowest at 1 and highest at 8.

Key Beep Volume Control

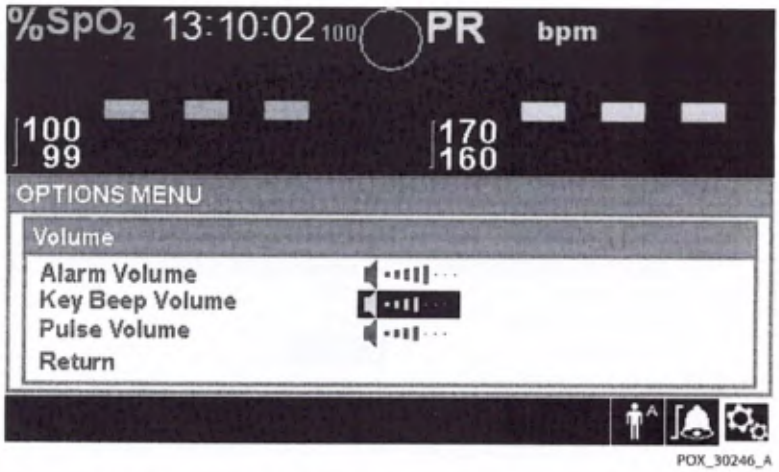
A beep sounds each time a selection is made using the jog dial.

To set the key beep volume:

1. From the OPTIONS Menu, select Volume, then Key Beep Volume.

   The Key Beep Volume setting is displayed as dots, where 7 dots represent the highest volume and 1 dot represents the lowest volume. The default setting is 4.

Figure 10-11. KEY BEEP VOLUME Default Setting of 4



2. Select Key Beep Volume settings of 1, 4, and 7 and verify that the key beeps are lowest at 1 and highest at 7.

Pulse Volume Control

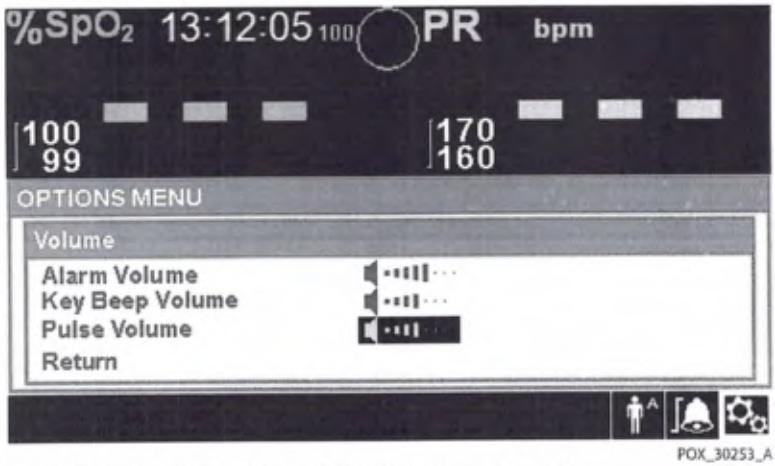
A pulse tone sounds with each detected heart beat.

To set the pulse volume:

1. Press and hold the ***Power On/Off*** button to turn the monitoring system off.
2. Connect the DOC-10 pulse oximetry cable to the monitoring system Sensor Port.
3. Connect the OxiMax DS-100A sensor to the DOC-10 cable, then to a finger.
4. Press and hold the ***Power On/Off*** button to turn the monitoring system on.
5. From the OPTIONS Menu, select Volume, then Pulse Volume.

   The Pulse Volume setting is displayed as dots, where 7 dots represent the highest volume and 1 dot represents the lowest volume. The default setting is 4.

Figure 10-12. PULSE VOLUME Default Setting of 4



6. Verify that with each heart beat the pulse tone sounds.

7. Select Pulse Volume settings of 1, 4, and 7and verify that the pulse audio volume is lowest at 1 and highest at 8.

10.4.2 Functional Tests

To perform functional tests:

1. Read *SRC-MAX Overview*, p. 131 to become familiar with the pulse oximetry functional tester (Nellcor model SRC-MAX).

2. Use the waveform view for all functional testing. Reference *Figure 4-2.* on page 45.

Note:
For the waveform tests, the display will show a pulse waveform of approximately 1/2-inch peak to peak (P-T-P) amplitude. Actual amplitude may vary but will be a reference for low pulse amplitude/low light patients.

3. Once the SRC-MAX is attached to the DOC-10 cable and the SRC-MAX and monitoring system are turned on, complete all of the tests in sequence, beginning with BPM (PR), then %SpO2, then Modulation, and finally Light Level.

SRC-MAX Overview

WARNING:
The SRC-MAX is a functional tester that verifies operation of the monitoring system. It cannot be used to assess the accuracy of the monitoring system's %SpO2 and pulse rate readings.

The SRC-MAX functional tester enables qualified technicians to functionally test Nellcor OxiMax technology-based monitoring systems and OEM OxiMax technology-based monitoring systems. Figure 10-3 provides a brief description of each test.

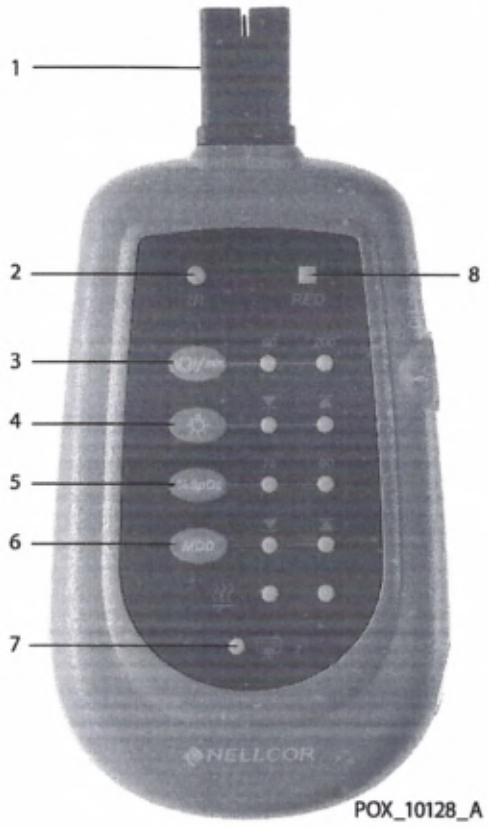
Table 10-3. Functional Tests with SRC-MAX

Tests	Descriptions
BPM Test	The test procedure simulates an OxiMax pulse oximetry sensor attached to a patient indicating a pulse rate of 60 BPM and 200 BPM.
%SpO2 Test	The test procedure simulates an OxiMax pulse oximetry sensor attached to a patient indicating a 75% blood oxygen saturation and 90% blood oxygen saturation.
Modulation Level Test	The test procedure simulates an OxiMax pulse oximetry sensor attached to a patient indicating low and high pulse strength.
Light Level Test	The test procedure simulates an OxiMax pulse oximetry sensor attached to a patient indicating low and high light level passing through the patient at the sensor site.

Note:
The SRC-MAX selectable indicator LEDs may extinguish if there is a delay in proceeding through the above tests. This is normal operation to conserve battery power.

Note:
Pressing a button on the SRC-MAX during the test procedures may be requested to change a certain parameter. If the SRC-MAX LEDs are not lit, press the button twice. Pressing the button once causes the indicators to relight and pressing twice initiates the change.

Figure 10-13. SRC-MAX OxiMax Oximetry Tester

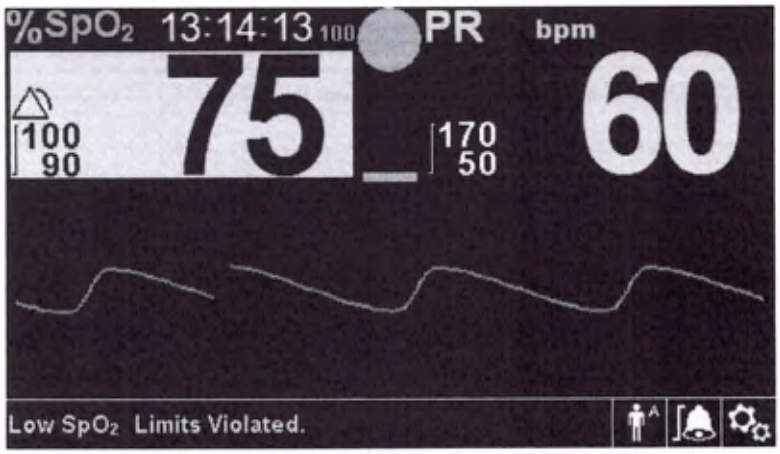


1	DOC-10 Cable Connector	5	%SpO2 Select Button
2	Infrared LED Drive Indicator	6	% Modulation Select Button
3	Pulse Rate Selection Button	7	Battery Low Indicator
4	Light Level Selection Button	8	Red LED Drive Indicator

BPM (PR) Test

1. With the monitoring system turned off, connect the DOC-10 pulse oximetry cable to the sensor port.
2. Connect the SRC-MAX tester to the other end of the DOC-10 cable.
3. Turn on the monitoring system by pressing and holding the ***Power On/Off*** button. Wait for the monitoring system to complete POST.

Figure 10-14. SRC-MAX Tester-Generated Waveform



POX_30262_B

4. Verify the following:

   a. Audio alarm is active.

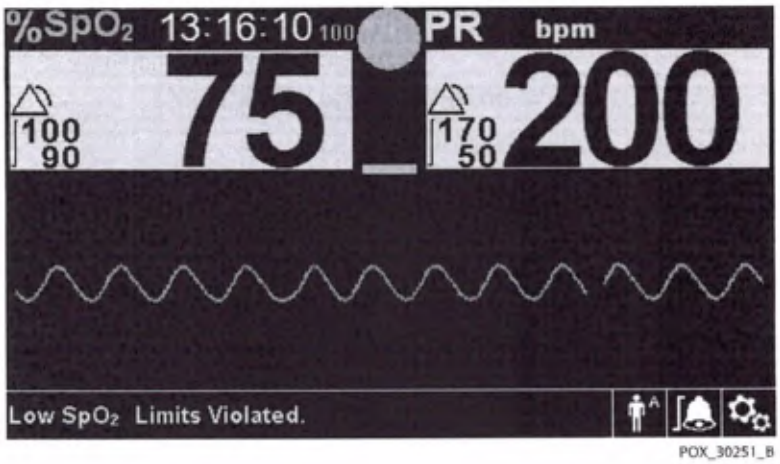
   b. Flashing %SpO2 indication in the range of 73 to 77.

   c. BPM indication in the range of 57 to 63.

   d. Pulse waveform of approximately 1/2-inch peak to peak (P-T-P) amplitude.

5. Press the SRC-MAX PULSE RATE selection button. The SRC-MAX PULSE RATE 200 LED lights. The monitoring system registers that the BPM increases and stabilizes to a value in the range of 197 to 203 BPM.

Figure 10-15. SRC-MAX Increase to 200 BPM



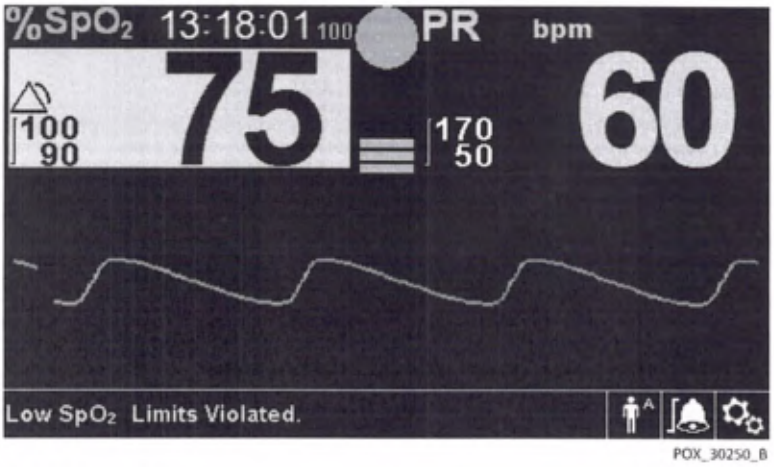
POX_30251_B

Verify the following:

a. Active audio alarm.
b. Flashing %SpO2 indication in the range of 73 to 77.
c. Flashing BPM indication in the range of 197 to 203.
d. Pulse waveform of approximately 1/2-inch P-T-P amplitude.

6. Press the SRC-MAX PULSE RATE selection button. The SRC-MAX PULSE RATE 60 LED lights. The pulse oximeter registers that the BPM decreases and stabilizes to a value in the range of 57 to 63 BPM.

Figure 10-16. SRC-MAX Decrease to 60 BPM



Verify the following:

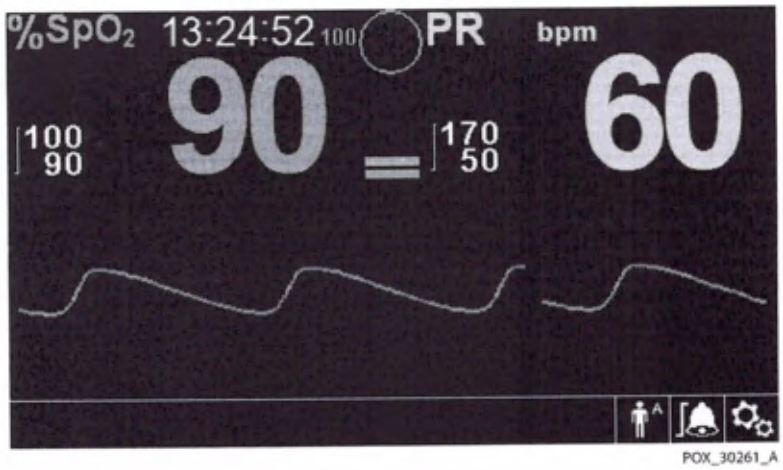
a. Active audio alarm.
b. Flashing %SpO2 indication in the range of 73 to 77.
c. BPM indication in the range of 57 to 63.
d. Pulse waveform of approximately 1/2-inch P-T-P amplitude.

SpO2 Test

%SpO2

1. Press the SRC-MAX %SpO2 selection button. The SRC-MAX %SpO2 90 LED lights. The monitoring system displays three dashes [- - -] until the %SpO2 stabilizes at a value in the range of 88 to 92.

Figure 10-17. SRC-MAX %SpO2 Increase to 90



Verify the following:

a. No audio alarm.

b. %SpO2 indication in the range of 88 to 92.

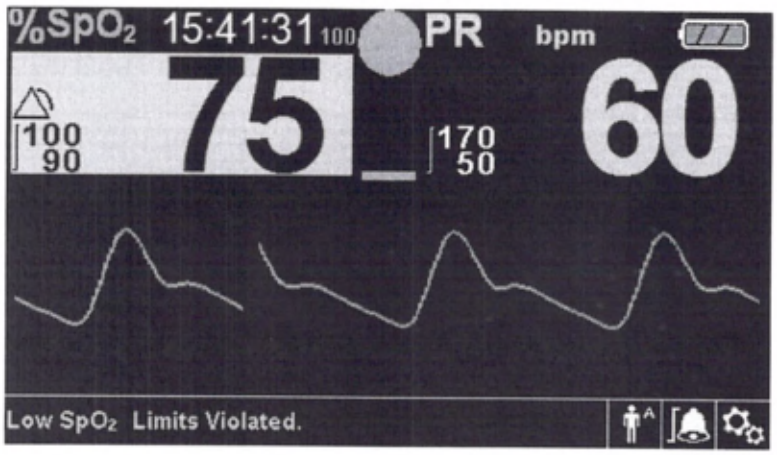
c. BPM indication in the range of 57 to 63.

d. Pulse waveform of approximately 1/2-inch P-T-P amplitude.

%SpO2

2. Press the SRC-MAX %SpO2 selection button. The SRC-MAX %SpO2 75 LED lights. The monitoring system displays three dashes [- - -] until the %SpO2 stabilizes at a value in the range of 73 to 77.

Figure 10-18. SRC-MAX %SpO2 Decrease to 75



Verify the following:

a. Active audio alarm.
b. Flashing %SpO2 indication in the range of 73 to 77.
c. BPM indication in the range of 57 to 63.
d. Pulse waveform of approximately 1/2-inch P-T-P amplitude.

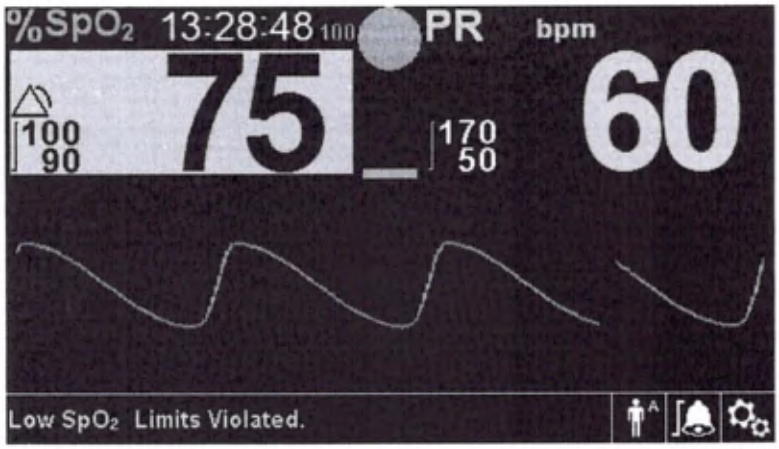
Modulation Level Test

MOD

1. Press the SRC-MAX MODULATION selection button.

   The SRC-MAX MODULATION LED lights. The pulse amplitude waveform increases in amplitude and then stabilizes at a P-T-P amplitude of approximately 1 inch.

Figure 10-19. SRC-MAX High Modulation



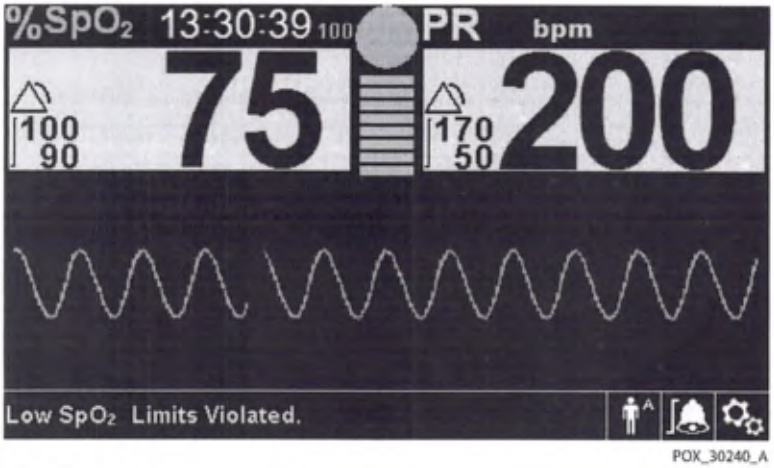
Verify the following:

a. Active audio alarm.
b. Flashing %SpO2 indication in the range of 73 to 77.
c. BPM indication in the range of 57 to 63.
d. Pulse waveform of approximately 1-inch P-T-P amplitude.

♡/min

2. Press the SRC-MAX PULSE RATE selection button. The SRC-MAX PULSE RATE 200 LED lights. The pulse oximeter registers that the BPM increases and stabilizes to a value in the range of 197 to 203.

Figure 10-20. 200 BPM with High Modulation



Verify the following:

a. Active audio alarm.

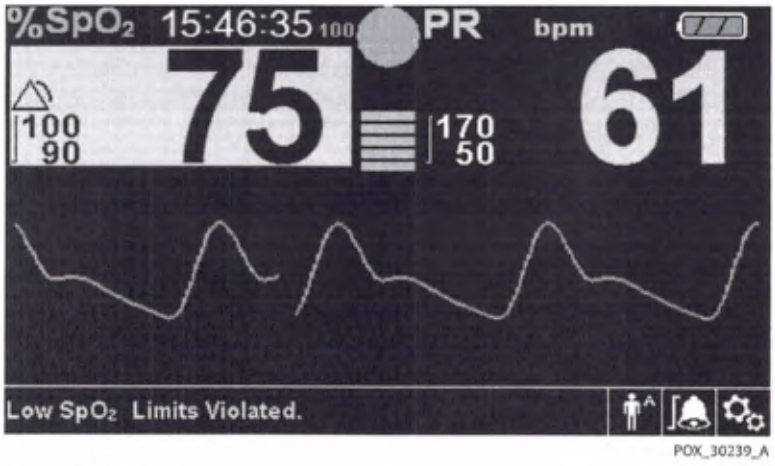
b. Flashing %SpO2 indication in the range of 73 to 77.

c. Flashing BPM indication in the range of 197 to 203.

d. Pulse waveform of approximately 1-inch P-T-P amplitude.

3. Press the SRC-MAX PULSE RATE selection button. The SRC-MAX PULSE RATE 60 LED lights. The monitoring system registers that the pulse rate decreases and stabilizes at a value in the range of 57 to 63.

Figure 10-21. 60 BPM with High Modulation



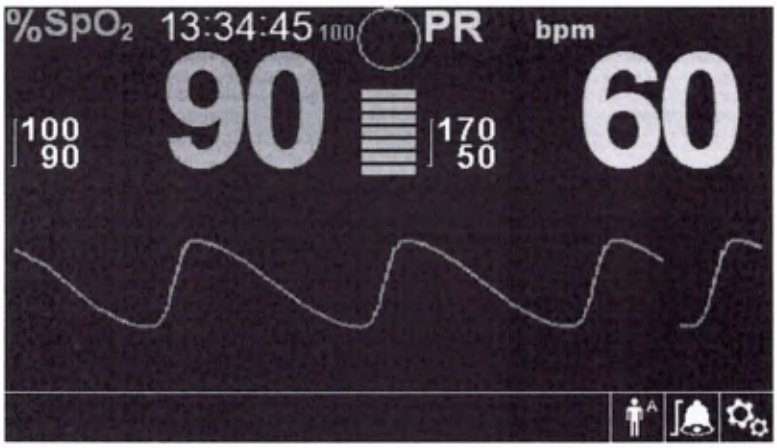
Verify the following:

a. Active audio alarm.
b. Flashing %SpO2 indication in the range of 73 to 77.
c. BPM indication in the range of 57 to 63.
d. Pulse waveform of approximately 1-inch P-T-P amplitude.

%SpO2

4. Press the SRC-MAX %SpO2 selection button. The SRC-MAX %SpO2 90 LED lights. The monitoring system displays three dashes [- - -] until the %SpO2 stabilizes to a value in the range of 88 to 92.

Figure 10-22. %SpO2 of 90 with High Modulation



POX_30259_A

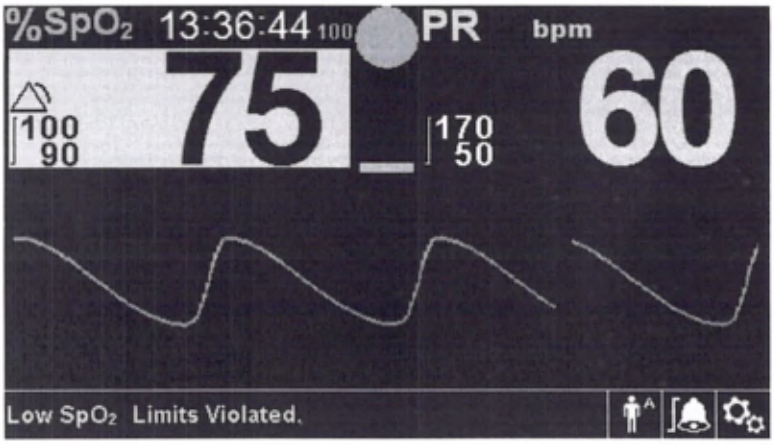
Verify the following:

a. No active audio alarm.
b. %SpO2 indication in the range of 88 to 92.
c. BPM indication in the range of 57 to 63.
d. Pulse waveform of approximately 1-inch P-T-P amplitude.

%SpO2

5. Press the SRC-MAX %SpO2 selection button. The SRC-MAX %SpO2 75 LED lights. The pulse oximeter displays three dashes [- - -] until the %SpO2 stabilizes to a value in the range of 73 to 77.

Figure 10-23. %SpO2 of 75 with High Modulation



Verify the following:

a. Active audio alarm.

b. Flashing %SpO2 indication in the range of 73 to 77.

c. BPM indication in the range of 57 to 63.

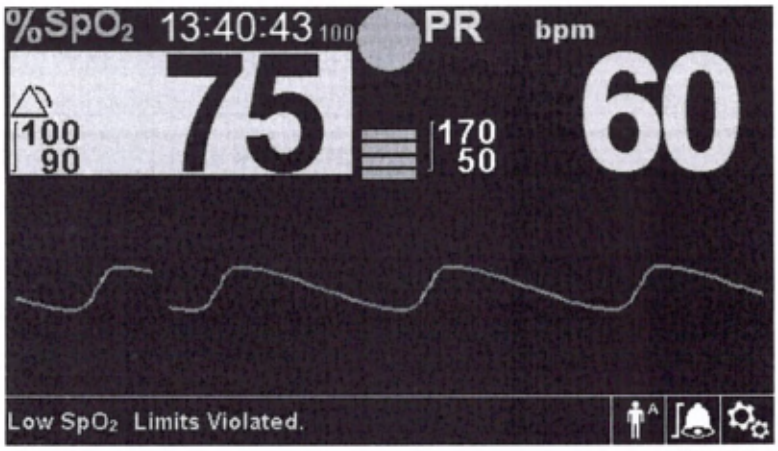
d. Pulse waveform of approximately 1-inch P-T-P amplitude.

MOD

6. Press the SRC-MAX MODULATION selection button. The SRC-MAX MODULATION LED lights. The pulse amplitude waveform decreases in amplitude and the stabilizes at a P-T-P amplitude of approximately 1/2 inch.

Note:
The readings may drop out temporarily.

Figure 10-24. %SpO2 of 75 with Low Modulation



POX_30257_B

Verify the following:

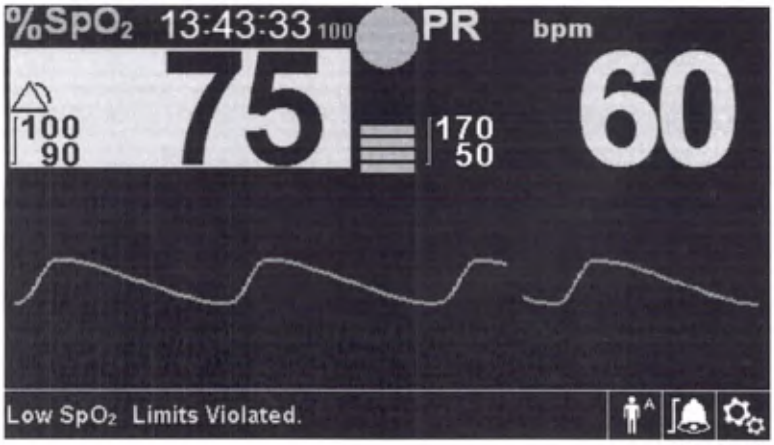
a. Active audio alarm.
b. Flashing %SpO2 indication in the range of 73 to 77.
c. BPM indication in the range of 57 to 63.
d. Pulse waveform of approximately 1/2-inch P-T-P amplitude.

Light Level Test

1. Press the SRC-MAX LIGHT LEVEL selection button. The SRC-MAX LIGHT LEVEL LED lights. The waveform amplitude initially flatlines and then stabilizes at the previous amplitude.

Note:
Flat-lining is the only indication of a light change at the measurement site. For the monitoring system to recover and display normally is an indication of proper operation with light changes.

Figure 10-25. High Light Condition

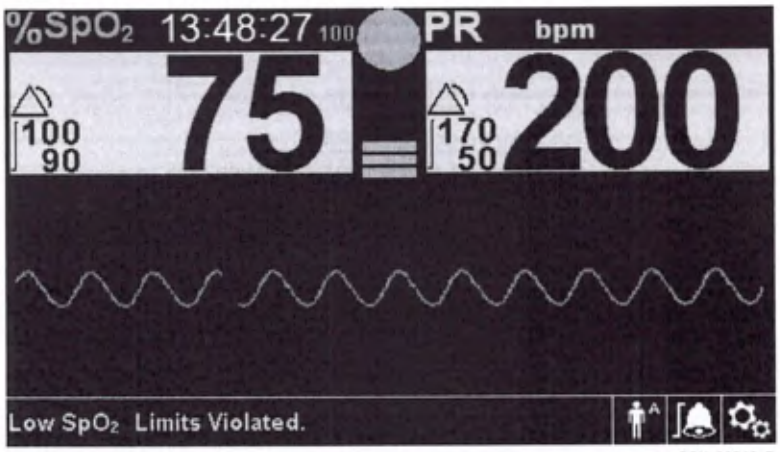


Verify the following:

a. Active audio alarm.
b. Flashing %SpO2 indication in the range of 73 to 77.
c. BPM indication in the range of 57 to 63.
d. Pulse waveform of approximately 1/2-inch P-T-P amplitude.

2. Press the SRC-MAX PULSE RATE selection button. The SRC-MAX PULSE RATE 200 LED lights. The monitoring system registers that the BPM increases and then stabilizes at a value in the range of 197 to 203.

Figure 10-26. 200 BPM with High Light Condition



Verify the following:

a. Active audio alarm.

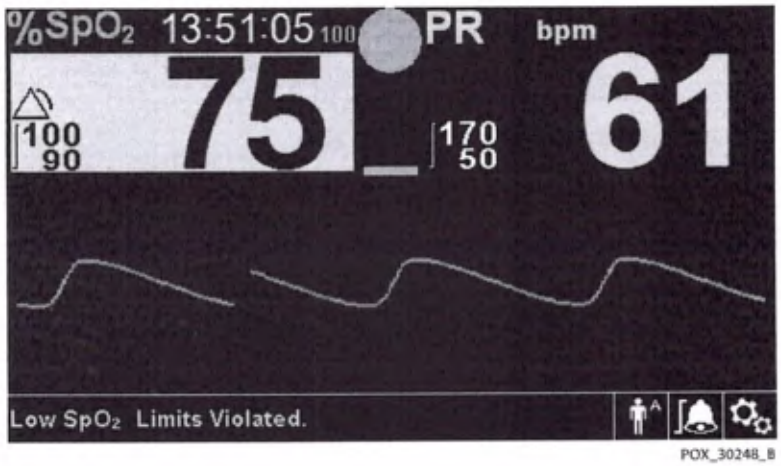
b. Flashing %SpO2 indication in the range of 73 to 77.

c. Flashing BPM indication in the range of 197 to 203.

d. Pulse waveform of approximately 1/2-inch P-T-P amplitude.

3. Press the SRC-MAX PULSE RATE selection button. The SRC-MAX PULSE RATE 60 LED lights. The monitoring system registers that the pulse rate decreases and then stabilizes at a value in the range of 57 to 63.

Figure 10-27. 60 BPM with High Light Condition



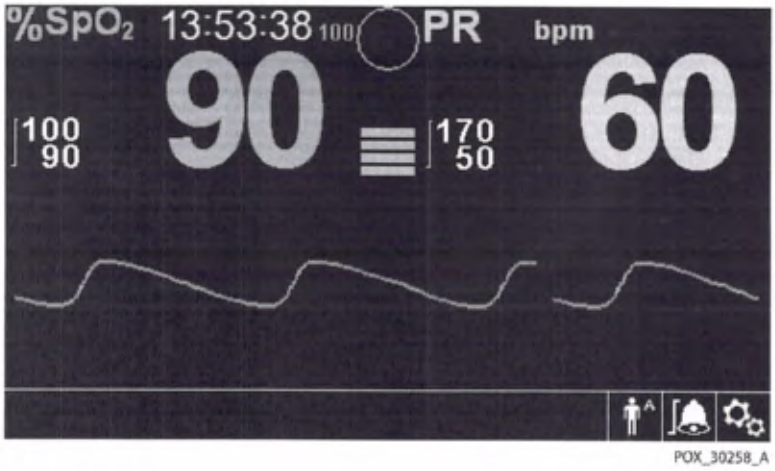
Verify the following:

a. Active audio alarm.
b. Flashing %SpO2 indication in the range of 73 to 77.
c. BPM indication in the range of 57 to 63.
d. Pulse waveform of approximately 1/2-inch P-T-P amplitude.

%SpO2

4. Press the SRC-MAX %SpO2 selection button. The SRC-MAX %SpO2 90 LED lights. The monitoring system displays three dashes [- - -] until the %SpO2 stabilizes to a value in the range of 88 to 92.

Figure 10-28. %SpO2 of 90 with High Light Condition



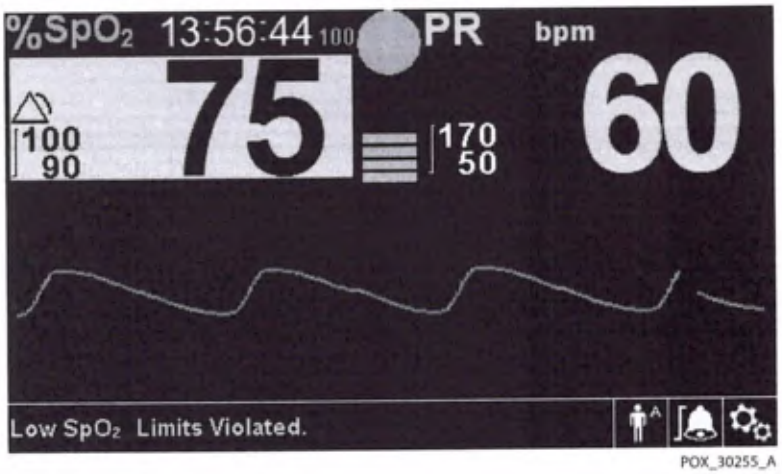
Verify the following:

a. No audio alarm.
b. %SpO2 indication in the range of 88 to 92.
c. BPM indication in the range of 57 to 63.
d. Pulse waveform of approximately 1/2-inch P-T-P amplitude.

%SpO2

5. Press the SRC-MAX %SpO2 selection button. The SRC-MAX %SpO2 75 LED lights. The monitoring system displays three dashes [- - -] until the %SpO2 stabilizes to a value in the range of 73 to 77.

Figure 10-29. %SpO2 of 75 with High Light Condition



Verify the following:

a. Active audio alarm.

b. Flashing %SpO2 indication in the range of 73 to 77.

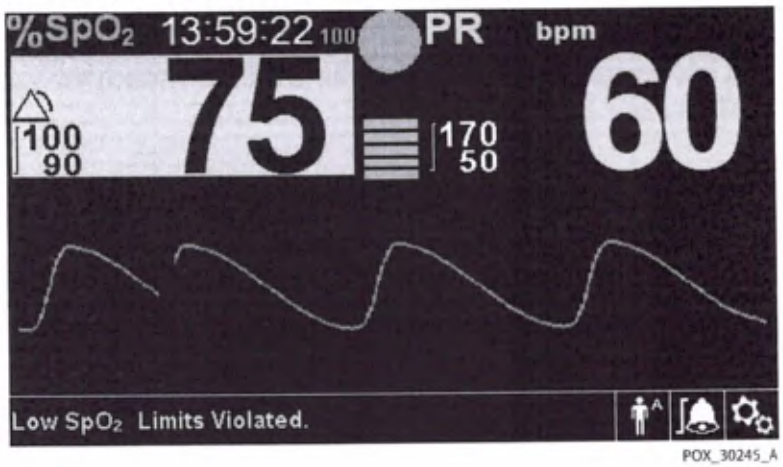
c. BPM indication in the range of 57 to 63.

d. Pulse waveform of approximately 1/2-inch P-T-P amplitude.

MOD

6. Press the SRC-MAX MODULATION selection button. The SRC-MAX MODULATION LED lights. The monitoring system's pulse waveform increases in amplitude and then stabilizes at a P-T-P amplitude of approximately 1 inch.

Figure 10-30. High Modulation and High Light Condition



Verify the following:

a. Active audio alarm.
b. Flashing %SpO2 indication in the range of 73 to 77.
c. BPM indication in the range of 57 to 63.
d. Pulse waveform of approximately 1-inch P-T-P amplitude.

7. Reset the POWER ON SETTINGS to Factory Defaults. Doing so removes any saved settings and clears the Last Setting option.
8. Turn off the monitoring system.

10.4.3 Testing Nurse Call

Test the nurse call port using two procedures:

- Resistance test
- Nurse call system connection

To test the resistance of the nurse call port:

1. Use a digital multimeter to test the resistance between pins 2 and 3 and between pins 1 and 2 when the monitoring system is in the following states:
   - Powered off
   - Powered on with no alarm
   - Powered on with an alarm
2. Verify that the resistance (ohm) readings for each state match the values shown in *Table 10-4 on page 147*.

Figure 10-31. Nurse Call Connector

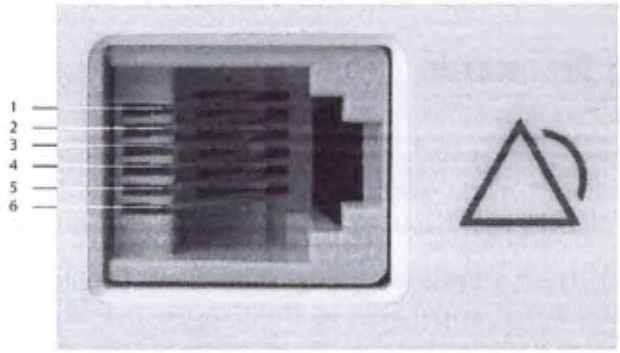


Table 10-4. Nurse Call Output Resistance

State of Monitoring System	Between Pins 2 and 3	Between Pins 1 and 2
Off	Open	0.4 ohm
On without alarm	Open	0.4 ohm
On with alarm	0.4 ohm	Open

To test the connection of the nurse call port to the nurse call system:

1. Using an RJ11 cable, connect the nurse call port to the nurse call system.
2. Ensure the audible alarm is not turned off.
3. Connect the SRC-MAX tester to the monitoring system.
4. Turn on the monitoring system and wait for POST.
5. Verify the %SpO2 of 75 alarm condition on the monitoring system and at the nurses' station.
6. Disconnect the SRC-MAX from the monitoring system and connect a DOC-10 cable and finger sensor in place of the SRC-MAX.
7. Connect the finger sensor to the finger of a live subject and wait several seconds for the SpO2 and pulse rate readings to stabilize.
8. Disconnect the sensor from the live subject's finger.
9. Verify the SpO2 Sensor Off message on the monitoring system's display. Verify the alarm at the nurses' station.

10.5 Safety Tests

10.5.1 Safety Testing Standards

The monitoring system safety tests are performed in accordance with and meet the standards listed in *Product Compliance*, p. 26. Each set of safety tests described in the following sections also list standards when appropriate.

Applicable tests for these standards are listed below. Technicians must be familiar with the standards applicable to their respective institution and country. Test equipment and its application must comply with the applicable standards; reference the following sections for test values.

Note:
For testing the patient applied risk current, the leakage test lead from the test equipment must be connected to the Sensor Port through the DOC-10 pulse oximetry cable using a male 9-pin "D" type connector with all pins shorted together.

During these tests, the monitoring system displays the following message: SpO2 Sensor Off.

10.5.2 Protective Earth Continuity

This test checks the integrity of the power cord ground wire from the AC plug to the monitoring system's chassis ground. The current used for this test is less than or equal to 4 Volts RMS, 50 to 60 Hz, and 25 Amperes.

To test protective earth continuity:

1. Connect the monitoring system AC power plug to the analyzer as recommended by the analyzer operating instructions.
2. Connect the analyzer resistance input lead to the equipotential terminal (ground lug) on the rear of the instrument. Verify that the analyzer indicates 100 milliohms or less.

10.5.3 Electrical Leakage

Earth Leakage Current

This test is in compliance with IEC60601-1 earth leakage current. The applied voltage for IEC60601-1 is +/-10% of nominal AC voltage, whichever is worst, (e.g. if the nominal AC voltage is 240Vac, the applied voltage should be 264Vac), 50 to 60 Hz. All measurements shall be made with the power button in both "On" and "Off" positions.

To test earth leakage current:

1. Connect the monitoring system AC plug to the electrical safety analyzer as recommended by the analyzer operating instructions.
2. Perform the test as recommended by the analyzer operating instructions.

Table 10-5. Earth Leakage Current Values

Test Condition	Allowable Leakage Current (Microamps)
Normal Condition (NC)	500
Single Fault Condition, Open Supply (SFC OS)	1000
Normal Condition Reverse Mains/Lines Voltage (NCRM)	500
Single Fault Condition, Open Supply, Reverse Mains/Lines Voltage (SFC OSRM)	1000

Enclosure Leakage Current

This test is in compliance with IEC60601-1 enclosure leakage current. This test is for ungrounded enclosure current, measured between enclosure parts and earth. The applied voltage for IEC60601-1 is 110% of nominal AC voltage, (e.g. if the nominal AC voltage is 240Vac, the applied voltage should be 264Vac), 50 to 60 Hz.

To test enclosure leakage current:

1. Connect the monitoring system AC plug to the electrical safety analyzer as recommended by the analyzer operating instructions.
2. Place a 200cm^2 foil in contact with the monitoring system's case, making sure the foil is not in contact with any metal parts of the enclosure that may be grounded.

3. Measure the leakage current between the foil and earth. The analyzer leakage current indication must not exceed the values listed in *Table 10-6*.

Table 10-6. Enclosure Leakage Current Values

Test Condition	Allowable Leakage Current (Microamps)
Normal Condition (NC)	100
Single Fault Condition, Open Supply (SFC OS)	500
Single Fault Condition, Open Earth (SFC OE)	500
Normal Condition Reverse Mains/Lines Voltage (NCRM)	100
Single Fault Condition, Open Supply, Reverse Mains/Lines Voltage (SFC OSRM)	500
Single Fault Condition, Open Earth, Reverse Mains/Lines Voltage (SFC OERM)	500

Patient Leakage Current

This test measures patient leakage current in accordance with IEC60601-1, clause 19, for Class I, Type BF equipment. Patient leakage current in this test is measured from any individual patient connection to earth (power ground).

To test patient leakage current:

1. Configure the electrical safety analyzer as recommended by the analyzer operating instructions.
2. Connect the monitoring system's AC power cord to the analyzer as recommended by the analyzer operating instructions.
3. Connect the test cable between the SpO2 sensor on the monitoring system and the appropriate input connector on the analyzer.
4. Turn on the monitoring system.
5. Perform the patient leakage current test as recommended by the analyzer operating instructions.

Note:
Patient leakage current is measured under various conditions of the AC power and protective earth conductor. For each condition, the measured leakage current must not exceed that indicated in *Table 10-7 on page 151*.

Note:
This test requires a test cable for each patient connector. Test cables for SpO2 can be configured by wrapping each sensor end individually with aluminum foil filled with conductive gel (only enough gel to ensure conductivity). Attach a wire to the foil that is connected to a test lead from the electrical safety analyzer.

Table 10-7. Patient Leakage Current Values

Test Condition	Allowable Leakage Current (Microamps)
Normal Condition (NC)	10
Single Fault Condition, Open Supply (SFC OS)	50
Single Fault Condition, Open Earth (SFC OE)	50
Normal Condition Reverse Mains/Lines Voltage (NCRM)	10
Single Fault Condition, Open Supply, Reverse Mains/Lines Voltage (SFC OSRM)	50
Single Fault Condition, Open Earth, Reverse Mains/Lines Voltage (SFC OERM)	50

Patient Leakage Current—Mains Voltage on the Applied Part

WARNING:
AC power voltage will be present on the applied part terminals during this test. Exercise caution to avoid electrical shock hazard.

WARNING:
Do not touch the patient leads clips or the simulator parts connected to patient leads during this test, as an electrical shock will occur.

This test measures patient leakage current in accordance with IEC60601-1, clause 19, for Class I, type BF equipment. In this test, 110% of mains voltage is applied between each patient connection and earth (power ground). Patient leakage current is then measured from any individual patient connection to earth.

Note:
Keep the patient test cable length as short as possible during the leakage test.

Note:
This test requires the same test cables for each patient connector as described in *Patient Leakage Current*, p. 150.

To test patient leakage current with mains voltage on the applied part:

1. Configure the electrical safety analyzer as recommended by analyzer operating instructions.
2. Connect the monitoring system's AC power cord to the analyzer as recommended by the analyzer operating instructions.
3. Connect the test cable between the SpO2 sensor on the monitoring system and the appropriate input connector on the analyzer.
4. Turn on the monitoring system.
5. Perform the test as recommended by the analyzer operating instructions.

Note:
Patient leakage current is measured with normal and reverse mains polarity. For each condition, the measured leakage current must not exceed that indicated in *Table 10-8*.

Table 10-8. Patient Leakage Current Values—Applied Part

Test Condition	Allowable Leakage Current (Microamps)
Normal Polarity (Single Fault Condition)	50
Reverse Polarity (Single Fault Condition, Reverse Mains/Lines Voltage)	50

10.5.4 Verification Check Sheets

Model Name		Serial Number		Software Version	

Performance, Operation, and Functional Test Results

Item	Results	Remarks	
Performance Tests			
Power-on self-test (POST)	Pass / Fail		
Power	Pass / Fail		
Battery charge	Pass / Fail		
Battery discharge (this test is optional)	Pass / Fail		
Patient modes	Pass / Fail		
Date and time	Pass / Fail		
General operation tests			
LED excitation	Pass / Fail		
Operation with a live subject	Pass / Fail		
Alarms and alarm paused	Pass / Fail		
Alarm volume control	Pass / Fail		
Key beep volume control	Pass / Fail		
Pulse volume control	Pass / Fail		
Functional tests			
SpO_2 90 +/- 2%	Pass / Fail	Value:	%
SpO_2 75 +/- 2%	Pass / Fail	Value:	%
Pulse rate 200 +/- 3 bpm (high priority alarm condition)	Pass / Fail	Value:	bpm
Pulse rate 60 +/- 3 bpm	Pass / Fail	Value:	bpm

Modulation level	Pass / Fail	
Light level	Pass / Fail	
Nurse call	Pass / Fail	
TESTS PERFORMED BY:	SIGNATURE and DATE:	

Safety Test Results

Safety Test			
Test Conditions	Limit (µA)	Results	Remarks
Earth leakage current (NC)	500	Pass / Fail	Value: µA
Earth leakage current (SFC OS)	1000	Pass / Fail	Value: µA
Earth leakage current (NCRM)	500	Pass / Fail	Value: µA
Earth leakage current (SFC OSRM)	1000	Pass / Fail	Value: µA
Enclosure leakage current (NC)	100	Pass / Fail	Value: µA
Enclosure leakage current (OS)	500	Pass / Fail	Value: µA
Enclosure leakage current (SFC OE)	500	Pass / Fail	Value: µA
Enclosure leakage current (NCRM)	100	Pass / Fail	Value: µA
Enclosure leakage current (SFC OSRM)	500	Pass / Fail	Value: µA
Enclosure leakage current (SFC OERM)	500	Pass / Fail	Value: µA
Patient leakage current (NC)	10	Pass / Fail	Value: µA
Patient leakage current (SFC OS)	50	Pass / Fail	Value: µA
Patient leakage current (SFC OE)	50	Pass / Fail	Value: µA
Patient leakage current (NCRM)	10	Pass / Fail	Value: µA
Patient leakage current (SFC OSRM)	50	Pass / Fail	Value: µA
Patient leakage current (SFC OERM)	50	Pass / Fail	Value: µA
Mains voltage on applied part (SFC)	5000	Pass / Fail	Value: µA
Mains voltage on applied part (SFCRM)	5000	Pass / Fail	Value: µA
TESTS PERFORMED BY:		SIGNATURE and DATE:	

NC	Normal Condition
NCRM	Normal Condition Reverse
SFC	Single Fault Condition
OS	Single Fault Condition (Open Line/Neutral)
OSRM	Single Fault Condition (Open Line/Neutral) Reverse
OE	Single Fault Condition (Open Earth)
OERM	Single Fault Condition (Open Earth) Reverse

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11 Troubleshooting

11.1 Overview

This chapter describes how to troubleshoot common problems that may occur while using the Nellcor™ Bedside SpO_2 Patient Monitoring System.

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

11.2 Troubleshooting Guide

Potential problems with the monitoring system are separated into categories and listed in *Table 11-1 on page 158*.

General guidelines for troubleshooting:

- Taking the recommended actions discussed in this section will correct the majority of problems that might be encountered. When the recommended action is to replace a part, reference *Chapter 12, Repair*.
- Problems not covered in this section can be resolved by calling Covidien Technical Services. Reference *Technical Services*, p. 18.
- If Technical Service recommends returning the monitoring system for repair, reference *Return*, p. 167, for packing instructions.

11.2.1 Error Conditions by Category

Table 11-1. Error Conditions and Resolutions

Error Condition by Category	Cause or Checkpoint	Corrective Action
Power		
With battery power only: Monitoring system does not turn on when ***Power On/Off*** button is pressed	Monitoring system's ***Power On/Off*** button must be held for 2 seconds	Press and hold the ***Power On/Off*** button .
	Battery is not properly seated	Check battery installation.
	Battery is depleted or defective	Recharge the 5-hour battery for 4 hours. Recharge the 10-hour battery for 8 hours. If problem persists, replace the battery.
With AC power: Monitoring system does not turn on when ***Power On/Off*** button is pressed	AC power cord is connected, but no battery is installed	Install the battery. To operate the monitoring system, battery must be installed even if AC power cord is connected.
With battery installed and monitoring system connected to AC power: No response to ***Power On/Off*** button press	Monitoring system's ***Power On/Off*** button must be held for 2 seconds	Press and hold the ***Power On/Off*** button.
	Failed Power Supply board	Ensure AC indicator is lit. If not, replace Power Supply board.
	AC power interference	Ensure monitoring system does not share the same AC power source with other equipment.
Battery Charge Indicator not lit	AC power cord is disconnected	Connect AC power cord to outlet. Verify good power/mains outlet. Check AC power inlet.
	Battery is missing or defective	Check battery installation. If problem persists, replace battery.
	Failed charger	Replace the Charger board. Replace the Power Supply board. Replace the Main board.

Table 11-1. Error Conditions and Resolutions (Continued)

Error Condition by Category	Cause or Checkpoint	Corrective Action
Low battery/critically low battery condition	Monitoring system has been run on battery power for the life of the battery	Recharge the 5-hour battery for 4 hours. Recharge the 10-hour battery for 8 hours. If problem persists, replace the battery.
	Battery is not recharging	Ensure proper connection at both ends of power cord: (1) between power cord and wall socket; (2) between power cord and monitoring system.
		Verify good power source.
		Verify AC indicator illuminates.
		If problem persists, replace the battery.
Battery status not indicated correctly with batter operation	Battery is defective	Check battery installation. If problem persists, replace the battery.
	Main CPU or sub-CPU failure	Replace the Main board.
Monitoring system consumes battery power even with AC power connection	AC power cord not properly seated	Ensure proper connection at both ends of power cord: (1) between power cord and wall socket; (2) between power cord and monitoring system.
	Faulty power source	Verify good power source.
	Faulty power cord	Replace the power cord.
	Charger board or Power Supply board malfunction	Verify AC indicator illuminates. If it does not, replace the Charger board. If problem persists, replace the Power Supply board.
Monitoring System Malfunction		
Monitoring system is frozen	Reset needed	Press and hold the ***Power On/Off*** button for 15 seconds to force the system to turn off. Turn the monitoring system on again.
	Main board malfunction	If problem persists, replace the Main board.
Monitoring system message:	Monitoring system opened and harnesses disconnected.	Press and hold the ***Power On/Off*** button to turn monitoring system off. Repeat this action to turn it back on. Verify normal POST.
Abnormally shut down last time	Depleted battery.	
	Battery disconnected while monitoring system was powered on.	

Table 11-1. Error Conditions and Resolutions (Continued)

Error Condition by Category	Cause or Checkpoint	Corrective Action
Display		
Blank display after normal POST	LCD cable is disconnected. LCD is damaged.	Reconnect LCD cable. Replace LCD.
Display does not function properly or looks distorted	Electromagnetic interference. LCD cable disconnected or improperly connected. Main board is malfunctioning.	Isolate sources of electromagnetic interference (electrosurgical device, cell phone). Reconnect or reseat cable. Replace Main board.
LCD is visibly cracked or broken		Replace LCD.
Sound		
No sound during POST	Speaker harness is loose or disconnected. Speaker is malfunctioning. Main board is malfunctioning.	Reseat speaker harness in Main board. Ensure connector on Main board is firmly seated. Note: This connector can slide off the Main board. If problem persists, replace speaker. Replace Main board.
Buzzer sounds during POST, EEE910 indicated on LCD	CPU is malfunctioning.	Disconnect speaker and retry POST. If monitoring system emits a buzzing sound: (1) reseat speaker harness in Main board; (2) ensure connector on Main board is firmly seated (Note: This connector can slide off the Main board); (3) ensure both speaker wires are still attached to speaker. If one or both speaker wires have become detached from speaker, replace speaker. If problem persists, replace Main board.
Audio alarm cannot be paused	Main board is malfunctioning.	Replace Main board.
Audio alarm does not pause for the time specified in the institutional default settings	Institutional defaults not set correctly. Audio Paused button activator on Main board is malfunctioning.	Reset institutional defaults. Replace Main board.

Table 11-1. Error Conditions and Resolutions (Continued)

Error Condition by Category	Cause or Checkpoint	Corrective Action
Buttons and Jog Dial		
No response when control buttons are pressed	Possible misplacement of buttons	If buttons were replaced, ensure each of the 3 buttons is in its proper location in the front bezel.
	Button activators on Main board are malfunctioning.	Replace Main board.
Monitoring system does not respond to jog dial operation	Jog dial is malfunctioning	Replace Main board.
	Encoder on Main board is malfunctioning	
SpO2 / Sensor		
Sensor Messages: SpO2 Pulse Search SpO2 Sensor Off SpO2 Cable/Sensor Disconnect Signal Artifact Detected	Sensor could be: Disconnected from cable or monitoring system Detached from patient Unable to get reliable readings because of substances on patient's skin or nails, or because of excessive patient motion	Reference *Figure 4-2.* on page 45. Check all connections. Reposition sensor. Secure cable. Remove items of interference (electrosurgical device, cell phone, nail polish, cream). Replace the cable and/or sensor.
Patient Data / USB Data Port		
USB data port does not function properly	USB cable not firmly connected	Ensure USB cable firmly connected. Disconnect USB cable, reset system power, then reconnect.
	Covidien bridge driver corrupted.	Re-install the bridge driver provided by Covidien.
	Mismatched baud rates between monitoring system and PC	Ensure baud rate settings for both monitoring system and PC are the same.
	Mismatched COM port between PC and HyperTerminal	Ensure same COM port is selected on PC and HyperTerminal.
	USB port damaged	Ensure no physical damage to USB port. If damaged, replace Main board.

Table 11-1. Error Conditions and Resolutions (Continued)

Error Condition by Category	Cause or Checkpoint	Corrective Action
Questionable readouts of patient physiological measurements; wrongly tagged or missing patient data	Sensor not attached correctly	Check all connections and reposition if necessary.
	Faulty sensor	Replace sensor or cable, if necessary.
	Electromagnetic interference	Remove sources of electromagnetic interference (electrosurgical device, cell phone).
	Ambient light interfering with proper sensing	Remove excessive ambient light.
	Coin cell battery was removed from Main board	Delete trend data. Set date and time in SERVICE Menu. Reference *Date/Time Setting*, p. 71. Verify date format follows locale. Replace coin cell battery with known good battery and reset date and time. **WARNING**: Replacing the coin cell battery for the Main board resets the monitoring system's date and time settings. Integrity of existing patient data will be questionable. Reset the date and time after replacing this battery with a known good battery
Date and time incorrect on LCD and in trend data download	Date and time not set correctly during installation.	Set date and time in SERVICE Menu. Verify date format follows locale.
	Coin cell battery depleted or removed and replaced.	If date and time reset unexpectedly, replace coin cell battery with known good battery and reset date and time.
	Coin cell battery tab in Main board does not provide firm contact.	If problems persist, verify the coin cell battery is snug against the tab on the Main board. If not, replace the Main board. **WARNING**: If the monitoring system's date and time have been reset or were not set correctly on installation, integrity of existing patient data will be questionable. Delete existing data immediately after replacing the battery and setting the date and time.

Table 11-1. Error Conditions and Resolutions (Continued)

Error Condition by Category	Cause or Checkpoint	Corrective Action
Firmware download error or technical system error		
Error code starting with E appears on display	Firmware is not loading correctly. Monitoring system is malfunctioning.	Reference *Table 11-2.* on page 164. Reference *Table 11-3.* on page 165. If error persists, do not use monitoring system; record error code, then contact Covidien Technical Services.

Note:
Reference *Managing Alarms and Alarm Limits*, p. 76, for any issues related to alarm conditions.

11.2.2 Firmware Download Errors

If an error code appears during firmware download, take the action specified in *Table 11-2*.

Note:
If the alarm message still appears, take the monitoring system out of service and contact Covidien Technical Services for advice on remedial action. Reference *Technical Services*, p. 18.

Table 11-2. Firmware Download Error Codes

Code	Description	Action
E.00.0001	USB not recognized.	Verify USB connection and integrity.
E.00.0002	Section.muf file corrupt or not found.	Verify USB connection and integrity.
E.00.0003	Ver.muf file corrupt or not found.	Verify USB connection and integrity.
E.00.0004	Update.muf file corrupt or not found.	Verify USB connection and integrity.
E.00.0005	Binary file corrupt or not found.	Verify USB connection and integrity.
E.01.0003	Boot download failed.	Try downloading again.
E.02.0003	Main download failed.	Try downloading again.
E.01.0005	Burn boot failed.	Try downloading again.
E.02.0005	Burn main failed.	Try downloading again.
E.01.0007	Boot data between SDRAM and FLASH do not match.	Try downloading again. If problem persists, contact Covidien Technical Services.
E.02.0007	Main data between SDRAM and FLASH do not match.	Try downloading again.

11.2.3 Technical Alarm Conditions

When the monitoring system detects an error condition, an error code is displayed on the LCD.

Table 11-3 provides a complete list of error codes and problem identification. If an error code occurs, turn the monitoring system off and then on again.

Note:
If the alarm message still appears, record the error code, take the monitoring system out of service, and contact Covidien Technical Services for advice on remedial action. Reference *Technical Services*, p. 18.

Table 11-3. Technical Error Codes

Code	Technical Error Condition
EEE001	SpO2 module RAM error
EEE002	SpO2 module ROM/code integrity error
EEE003	SpO2 module bad CRC in communications
EEE004	SpO2 module bad communication message
EEE005	SpO2 module communication error; incorrect value
EEE006	SpO2 module calibration (offset) failure
EEE009	SpO2 module syntax communication error
EEE010	SpO2 module sensor error
EEE012	SpO2 module other hardware problem
EEE017	SpO2 module indicator that sensor appears defective
EEE050	SpO2 module intermittent error
EEE051	SpO2 module digital communication error
EEE255	SpO2 module invalid jumper selection
EEE256	SpO2 module beginning of packet missing
EEE257	SpO2 module packet start (SID) missing
EEE258	SpO2 module packet length error
EEE259	SpO2 module message length error
EEE260	SpO2 module packet contains unsupported key

Table 11-3. Technical Error Codes (Continued)

Code	Technical Error Condition
EEE261	SpO2 module packet CRC error
EEE262	SpO2 module end of packet missing
EEE263	SpO2 module packet contains undefined key
EEE264	SpO2 module corrupted variable
EEE265	SpO2 module memory overflow
EEE266	SpO2 module bad pointer
EEE267	SpO2 module parameter value out of range
EEE268	SpO2 module reset detected
EEE269	SpO2 module unexpected value
EEE270	SpO2 module time out
EEE271	SpO2 module not ready/not initialized
EEE272	SpO2 module double fault
EEE273	SpO2 module data out of range error
EEE274	SpO2 module incompatible digital sensor
EEE275	SpO2 module incorrect registration number
EEE276	SpO2 module sensor read failure
EEE277	SpO2 module sensor signature verification failure
EEE281	SpO2 module overflow/underflow
EEE282	SpO2 module sensor activation failure
EEE283	SpO2 module sensor write failure
EEE284	SpO2 module both HW and SW ECG triggers received
EEE285	SpO2 module host attempted read or close of sensor trend before successful open
EEE286	SpO2 module host attempted redundant open of sensor trend
EEE287	SpO2 module sensor trend data unavailable for reading by host
EEE288	SpO2 module no more sensor trend data available for reading by host
EEE289	SpO2 module sensor private label/host sensor key incompatible
EEE804	SpO2 module communication error

Table 11-3. Technical Error Codes (Continued)

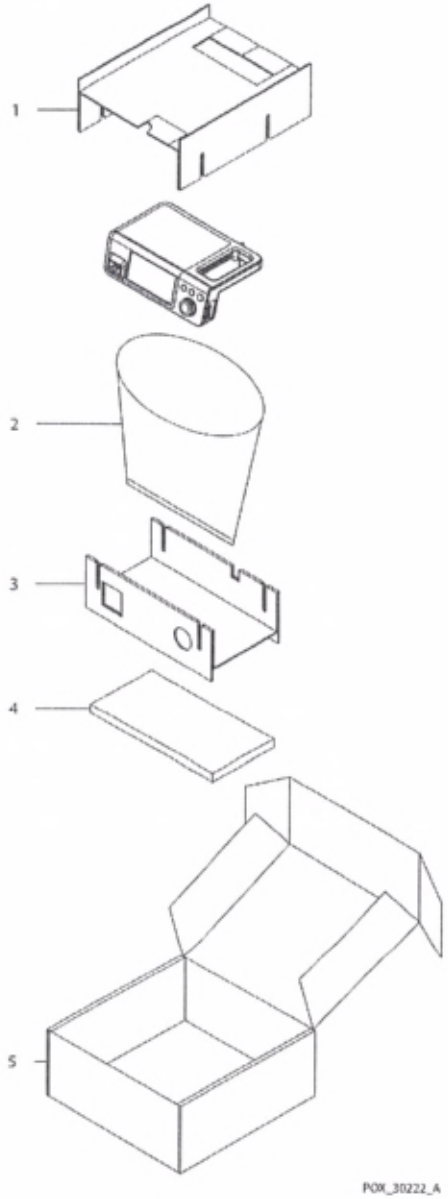
Code	Technical Error Condition
EEE901	Setting value mismatch error between host and NELL1SR
EEE902	Checksum error
EEE903	RAM error
EEE905	SUB CPU communication error
EEE907	RTC error
EEE910	Sound error

11.3 Return

Contact Covidien or a local Covidien representative for shipping instructions, including a Returned Goods Authorization (RGA) number. Reference *Obtaining Technical Assistance*, p. 18. Unless otherwise instructed by Covidien, it is not necessary to return sensors or other accessory items with the monitoring system.

Pack the monitoring system in its original shipping carton, as shown in *Figure 11-1 on page 168*. If the original carton is not available, use a suitable carton with the appropriate packing material to protect the monitoring system during shipping. Return the monitoring system by any shipping method that provides proof of delivery.

Figure 11-1. Return Packaging



1	Product box — inner, upper	4	Product box — inner, lower guide
2	Roll bag	5	Product box — outer
3	Product box — inner, lower		

12 Repair

12.1 Overview

This chapter provides trained service technicians with information about how to repair the Nellcor™ Bedside SpO_2 Patient Monitoring System.

WARNING:
To avoid possible injury, do not attempt to service the monitoring system if there are any signs of burning or smoking coming from the monitoring system.

WARNING:
To prevent possible electric shock or explosion, do not service the monitoring system in a flammable environment or in an excessively moist environment.

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

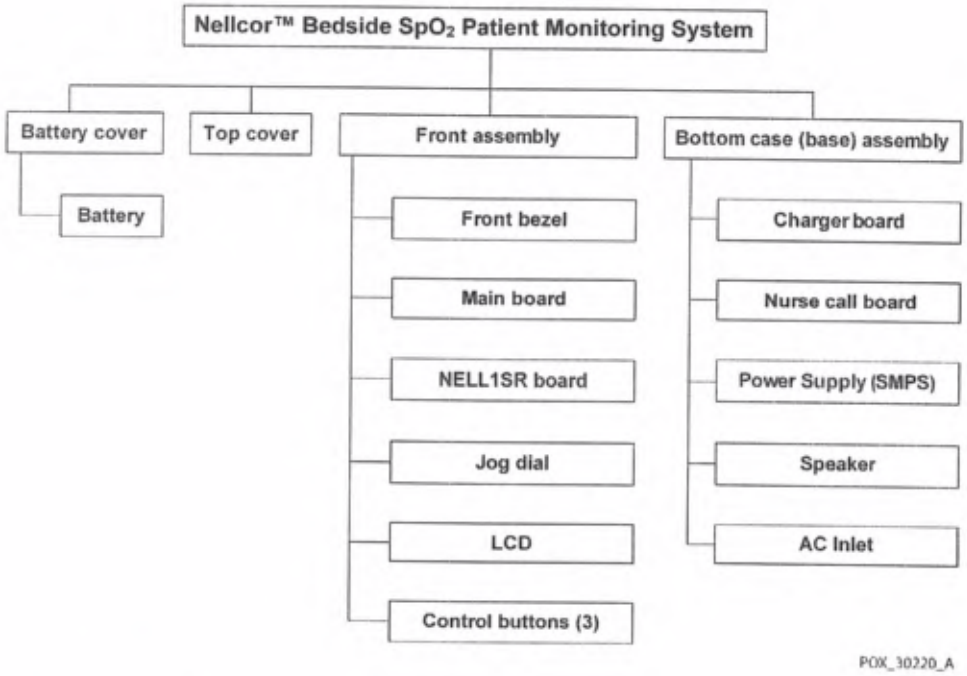
WARNING:
Before attempting to open or disassemble the monitoring system, disconnect the power cord from the monitoring system to avoid possible injury.

Bedside SpO_2 Patient Monitoring System major component parts include all printed circuit boards ("boards") and subassemblies.

- Printed circuit boards ("boards")
- Battery
- Cables ("harnesses")
- Chassis enclosures

Note:
Some spare parts come with an enclosed business reply card. After receiving the spare parts, please complete and return the business reply card.

Figure 12-1. Disassembly Sequence



12.2 Ordering Spare Parts

Covidien Technical Services provides technical assistance and replacement parts. Contact Covidien or your local Covidien representative to obtain replacement parts. Reference *Technical Services*, p. 18 for contact information.

When ordering parts, refer to them by the part names and part numbers, as shown in *Figure 12-2 on page 171* and listed in *Table 12-1 on page 172*. A listing of the spare parts and accessories for the monitoring system is also available on the Internet at:

http://www.covidien.com

An electronic, printable copy of this manual is also available at this Internet site.

Figure 12-2 shows an exploded view of the monitoring system. Reference *Table 12-1 on page 172* for descriptions and part numbers for each spare part.

Figure 12-2. Exploded View

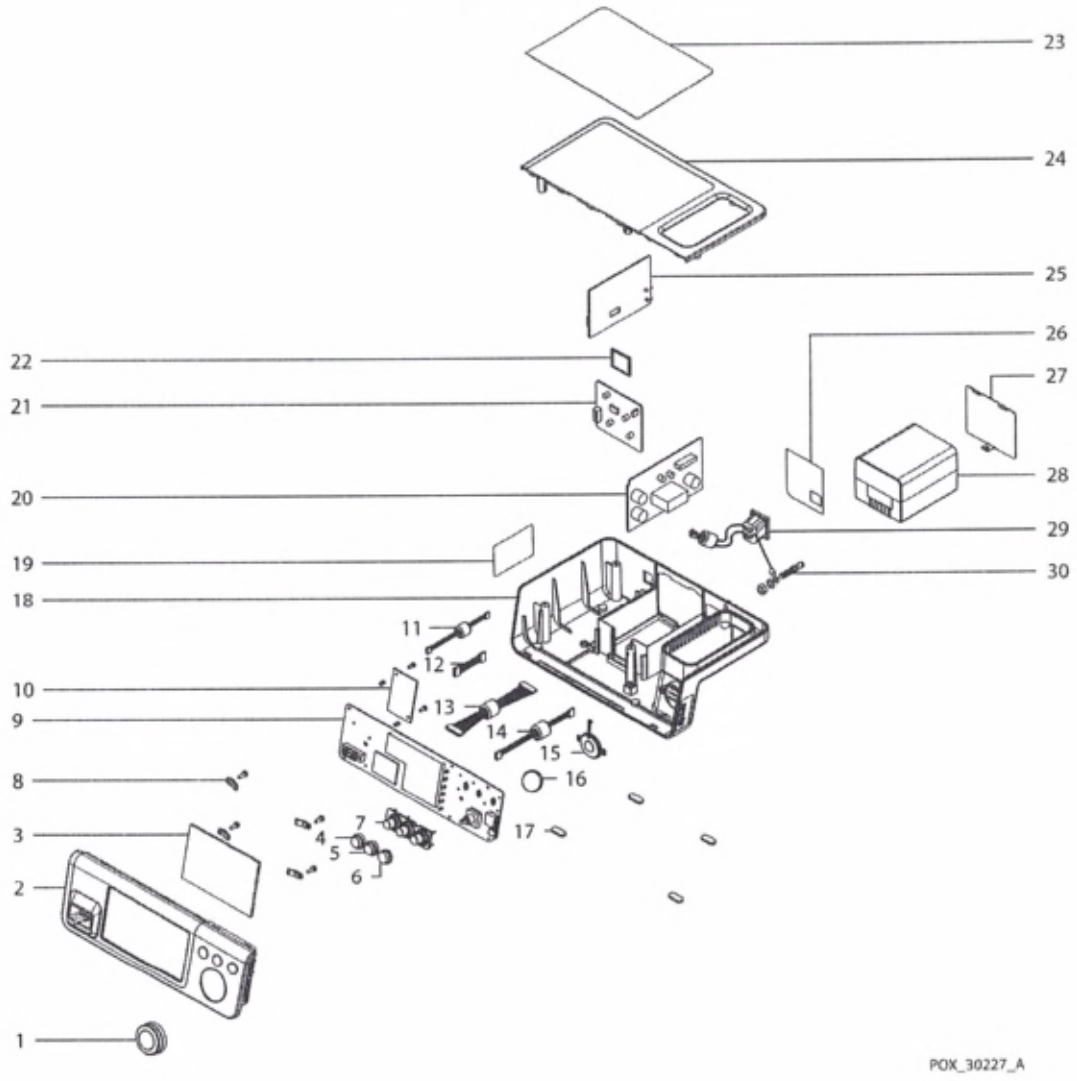


Table 12-1. Spare Parts List by Callout Number

Item	Description	Part Number
1	Jog dial	10087930
2	Front bezel	10091173
3	LCD	10006131
4	Alarm Paused button	10091174
5	Return button	
6	Power On/Off button	
7	Gasket for control buttons	
8	Tabs and screws for LCD (4 each)	10091175
9	Main board	10006082
10	NELL1SR board	SPNELL1SR
11	SpO2 harness (SpO2 to Main board harness)	10006174
12	Nurse Call harness (Nurse Call board to Charger board harness)	10006173
13	Main harness (Charger board to Main board harness)	10006087
14	DC Power harness (Power Supply board to Main board harness)	10006086
15	Speaker and harness subassembly (with 2 screws)	10006114
16	Coin cell battery	10084222
17	Rubber foot (4)	10091179
18	Bottom case (base)	10006092
19	Product description label	10006175
20	Power Supply board	10006115
21	Charger board	10006085
22	Charger board cover/plastic plate	10006103
23	Quick guide	10005988 (English)
24	Top cover	10006130
25	Nurse Call board	10006084
26	Nurse Call port label	10006177
27	Battery cover (with 1 screw)	10091176

Table 12-1. Spare Parts List by Callout Number (Continued)

Item	Description	Part Number
28	Battery (5- or 10-hour)	10005948 (5-hour) 10005949 (10-hour)
29	AC inlet	10006089
30	Equipotential terminal (ground pin)	10006113
—	Hardware kit (2 of each screw type and two standoffs for NELL1SR board)	10091178
—	USB cable for firmware upgrades (3.3 ft; 1.0 m)	10091181

12.3 Required Tools

Collect the following tools before disassembling or replacing the battery for the monitoring system:

- #1 and #2 Phillips-head screwdrivers
- Small flat-blade screwdriver
- Needle nose pliers or 5mm socket with driver
- 10mm open-ended or box wrench
- Adjustable torque wrench, measuring below 6 kgf-cm with 0.5 kgf-cm resolution

12.4 Battery Replacement

The monitoring system comes with a Covidien-approved 5-hour battery. A 10-hour battery can be ordered separately.

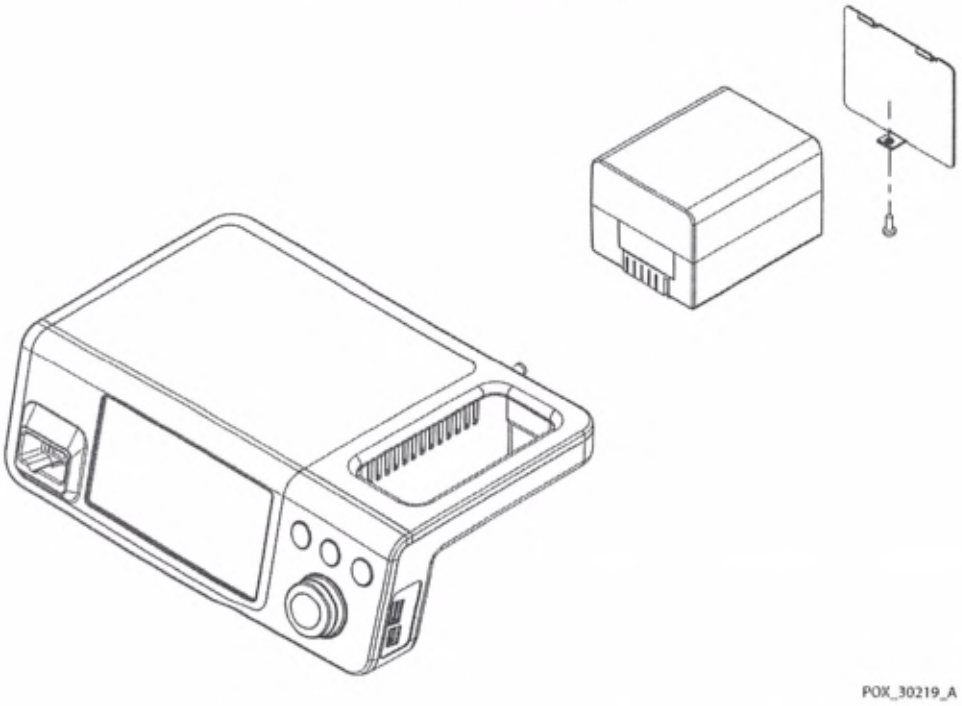
- Five-hour battery: 10005948
- Ten-hour battery: 10005949

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

12.4.1 Removing the Battery

1. Turn the monitoring system off and disconnect it from the AC outlet.
2. Lay the monitoring system on its top side, so that the bottom of the monitoring system is facing up.
3. Using the #2 Phillips screwdriver, remove the screw that holds the battery cover in place. Reference *Figure 12-3*.

Figure 12-3. Battery Replacement



4. If necessary, use the flat blade screwdriver to gently unfasten the battery cover tab.
5. Push the battery's locking tab downward and slide the battery out of its compartment.

12.4.2 Replacing the Battery

Caution:
Use only Covidien-approved batteries.

1. Slide the battery into the battery compartment.

Note:
The battery can only be inserted one way. It takes very little effort to insert the battery the correct way.

2. Insert the two tabs of the battery cover into their slots.
3. Tilt the other edge of the battery cover toward the monitoring system until the single tab is inserted into its slot and the battery cover is flush with the monitoring system.
4. Using the small Phillips screwdriver, replace the battery cover screw. Tighten to 4.0 ±1.0 kgf-cm.
5. Return the monitoring system to its upright position.
6. Connect the monitoring system to AC power.
7. Leave the monitoring system powered off and charge the battery for the specified amount of time for each battery type:
   - Five-hour battery: 4 hours
   - Ten-hour battery: 8 hours

Note:
The charge times are approximations; actual charge time may take longer.

8. Disconnect the monitoring system from AC power.
9. Using just the battery, power on the monitoring system to verify proper operation.

12.5 Disassembly and Reassembly

WARNING:
Only qualified service personnel should open the monitoring system housing, remove and replace components, or make adjustments. If your medical facility does not have a qualified service technician, please contact Covidien Technical Services or your local Covidien representative.

WARNING:
Before attempting to open or disassemble the monitoring system, disconnect the power cord to avoid possible injury.

WARNING:
No user serviceable parts inside.

Caution:
Observe ESD (electrostatic discharge) precautions when working within the monitoring system.

Note:
The battery charge procedure should be performed before monitoring system repairs when possible.

The supported replacement level for the monitoring system is to the printed circuit board ("board") and major subassembly level. After isolating the problem to a suspected board, follow the procedures in *Top Cover Replacement*, p. 177, then replace the faulty board with a known good board. Verify the symptom disappears and ensure the monitoring system passes all performance tests. If the symptom persists, swap the replacement board with the suspected malfunctioning board (the original board installed when you started troubleshooting) and continue troubleshooting.

12.5.1 Top Cover Replacement

Caution:
Observe ESD (electrostatic discharge) precautions when disassembling and reassembling the monitoring system and when handling any of its components.

Caution:
Ensure the work surface is clean and free of debris.

Note:
The battery charge procedure should be performed before monitoring system repairs when possible.

Removing the Top Cover

1. Turn the monitoring system off and disconnect it from the AC outlet.
2. Set the monitoring system upside down on a static-free work surface.
3. Using the #2 Phillips screwdriver, remove the seven screws from the base. Set aside the screws for use during reassembly.

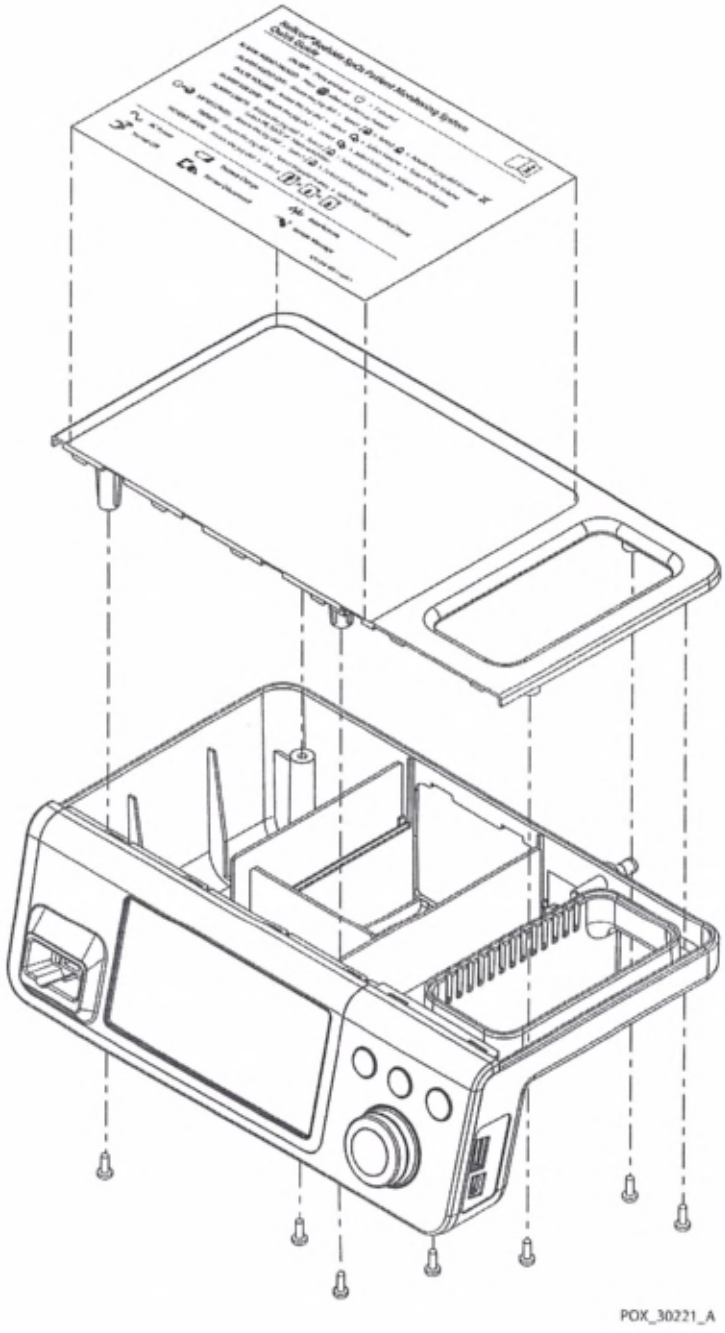
Caution:
The screw for the battery cover is shorter than the rest. Separate it from the other screws.

4. Remove the battery by completing steps *4* and *5* on *page 174*.
5. Carefully set the monitoring system right-side up, grasping the top and bottom halves to prevent premature separation.
6. Pull the monitoring system's top cover straight upward off of the base.

Note:
If necessary, insert the tip of the small flatblade screwdriver between the top cover and base on the handle side of the monitoring system to gently pry the top cover from the base.

7. Place the two halves of the pulse oximeter on the static-free work surface.

Figure 12-4. Top Cover Replacement



Replacing the Top Cover

Caution:
Do not pinch any wires between the covers when reassembling the monitoring system. Before installing the screws, inspect the entire edge of the union for even seating.

Caution:
Overtightening could strip out the screw holes in the top cover, rendering it unusable.

1. Place the monitoring system's top enclosure over the bottom case, being careful to align the front bezel correctly.
2. Grasp both halves, gently turning the monitoring system upside-down.
3. Replace six of the screws (not including the battery cover screw) in the base and tighten each one to 4.0 ±1.0 kgf-cm.
4. Replace the battery by following steps *1* through *5* on *page 175*.

Caution:
The screw for the battery cover is shorter than the rest. Be sure to put the shorter screw in the battery cover location.

5. If installing a new top cover, the quick guide is included in the package with the new cover. Remove the adhesive backing from the quick guide, orient it so the text is readable from the front of the monitoring system, and firmly press on the surface of the quick guide to adhere it to the top cover. Reference *Figure 12-4.* on page 178.

12.5.2 Front Bezel Replacement

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

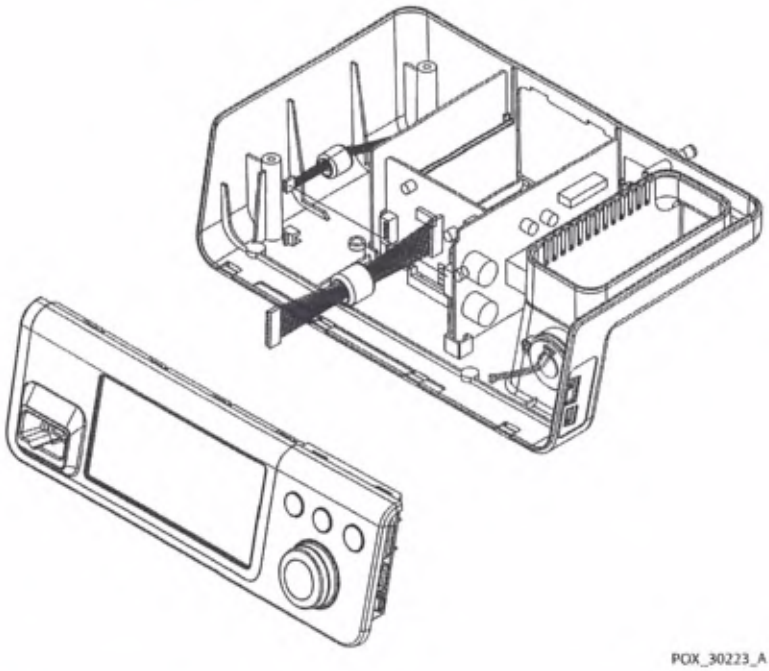
Removing the Front Bezel

1. Turn the monitoring system off and disconnect it from the AC outlet.
2. Complete the steps outlined in *Removing the Top Cover*, p. 177.
3. Unseat the harness from the J4 connector on the Main board (the board attached to the front bezel).

Caution:
Remove all connectors carefully to avoid damage to the connectors, wires, and board.

4. Angle the top of the front bezel outward to disconnect the other two harnesses from the Main board (the connectors from the Charger board and speaker).
5. Remove the front bezel from the base.

Figure 12-5. Front Bezel Replacement



Replacing the Front Bezel

1. If replacing the Main board, complete steps *3* through *8* in *Removing the Main Board*, p. 183 and steps *1* through *9* in *Replacing the Main Board*, p. 185.
2. Hold the front bezel at an angle to the front of the monitoring system's base.
3. Connect the speaker harness to the J1 connector and the Charger board harness to the J2 connector on the Main board.
4. Tilt the top of the front bezel toward the monitoring system base until the cover snaps into place.
5. Connect the Nurse Call board harness to the J4 connector on the Main board.

Caution:
Ensure that all connectors are aligned properly and fully seated.

6. Hold the front bezel in place while replacing the top cover as described in *Replacing the Top Cover*, p. 179.

12.5.3 NELL1SR Board Replacement

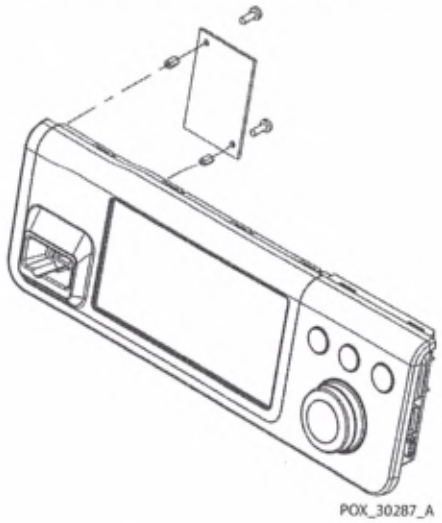
Removing the NELL1SR Board

1. Complete the steps outlined in *Removing the Top Cover*, p. 177.
2. Complete the steps outlined in *Removing the Front Bezel*, p. 180.
3. Lay the front bezel face down on an anti-static work surface.
4. Using the #2 Phillips screwdriver, remove the two screws that secure the NELL1SR board to the standoffs in the Main board.
5. Lift the NELL1SR board straight up from the main board.

Caution:
When removing the NELL1SR board from the Main board, avoid bending the connector pins.

6. If replacing the two standoffs for the NELL1SR board, use a 5mm socket or needle-nose pliers to unscrew the standoffs from the Main board.

Figure 12-6. NELL1SR Board Replacement



Replacing the NELL1SR Board

1. If replacing the two standoffs for the NELL1SR board, screw the new standoffs into the appropriate holes in the Main board. Tighten the standoffs to 4.0 ±1.0 kgf-cm.
2. Align the connectors on the NELL1SR board with the connectors on the Main board as follows:
   - Align the NELL1SR J4 connector (the one with the guide tabs) with the SJ3 connector on the Main board.
   - Align the NELL1SR J5 connector with the unlabeled connector on the Main board.

   Press the board down to seat the connectors.

Caution:
The NELL1SR board can only be installed one way. Ensure that the pins for each connector are properly aligned.

3. Using the #2 Phillips screwdriver, insert the two screws into the NELL1SR board and the standoffs in the Main board. Tighten each screw to 4.0 ±1.0 kgf-cm.
4. Replace the front bezel as described in *Replacing the Front Bezel,* p. 181.
5. Replace the top cover as described in *Replacing the Top Cover,* p. 179.

12.5.4 Main Board Replacement

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

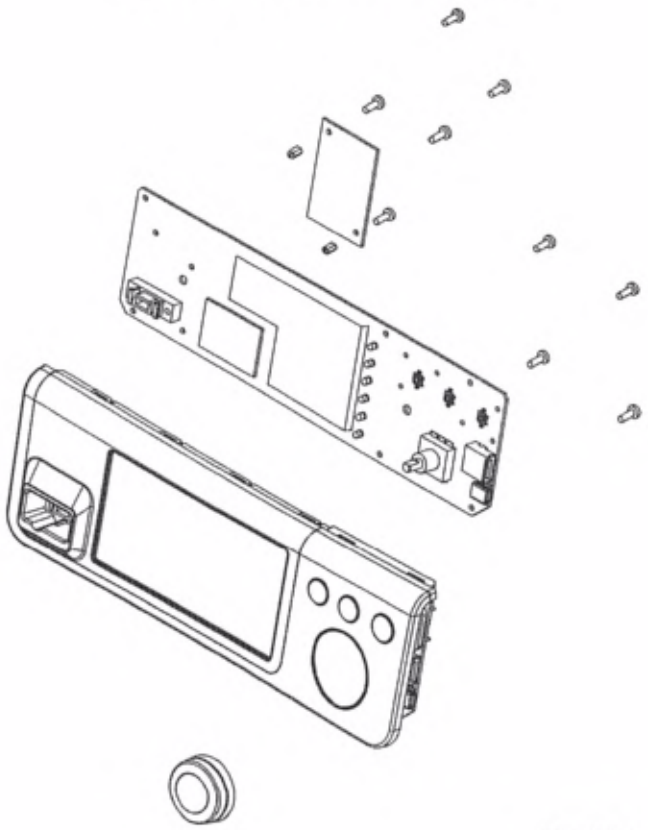
Removing the Main Board

1. Turn the monitoring system off and disconnect it from the AC power source.
2. Complete the steps outlined in *Removing the NELL1SR Board*, p. 182.
3. Remove the jog dial from the front bezel by pulling it straight out.

4. Lay the front bezel face down on an anti-static work surface.

5. Using the #1 Phillips screwdriver, remove the seven screws holding the Main board to the front bezel. Reference *Figure 12-7*.

Figure 12-7. Main Board Replacement



6. With the bottom of the front bezel toward the front edge of the work surface, carefully tilt the top edge of the Main board upward.

Caution:
Do not lift the Main board away from the front bezel with the ribbon cable still attached, or the ribbon cable or connector could be damaged.

7. Release the locking tab on the ribbon cable's connector by lifting the tab straight up.

8. Lift the Main board away from the top cover.

Replacing the Main Board

1. Lay the front bezel face-down with its bottom edge toward the front edge of the work surface.
2. Place the bottom edge of the Main board against the work surface or against the bottom edge of the front bezel.
3. While holding the Main board upright, insert the ribbon cable into its connector. Ensure that the cable is completely inserted into the connector, and press down on the connector tab to lock it.
4. Gently tug on the ribbon cable to ensure it is locked in place.
5. Rotate the Main board until it is laying on top of the front bezel.
6. Align the screw holes in the Main board with the screw holes in the front bezel.
7. Using the #1 Phillips screwdriver, insert the seven screws into the Main board. Tighten each screw to 2.0 ±0.5 kgf-cm).
8. Complete the steps outlined in *Replacing the NELL1SR Board*, p. 183.
9. Replace the jog dial on the front bezel.

12.5.5 Coin Cell Battery Replacement

The coin cell battery is located on the Main board.

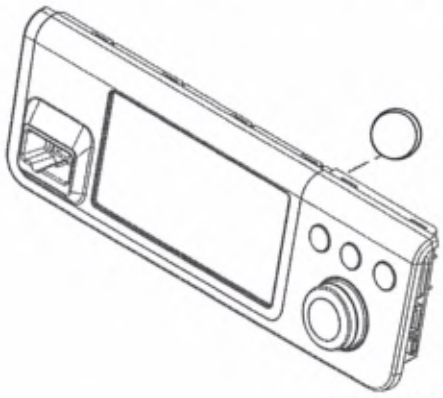
WARNING:
Replacing the coin cell battery for the Main board resets the monitoring system's date and time settings. Integrity of existing patient data will be questionable. Reset the date and time after replacing this battery with a known good battery.

Removing the Coin Cell Battery

1. Complete the steps outlined in *Removing the Top Cover*, p. 177.
2. Complete the steps outlined in *Removing the Front Bezel*, p. 180.
3. Place the front bezel face down on an anti-static work surface.

4. Using a small, flatblade screwdriver, press the locking tab the holds the battery in place away from the battery until the battery is free.

Figure 12-8. Cell Battery Replacement



Replacing the Coin Cell Battery

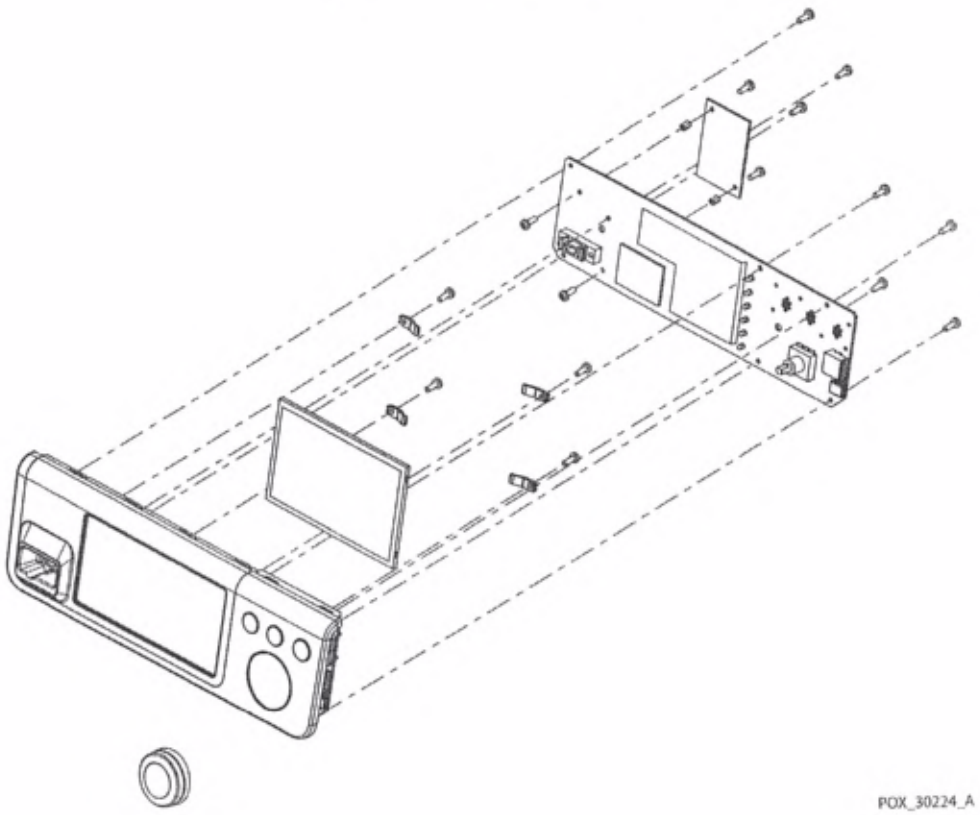
1. Position the new battery with the positive side facing up. The positive side has printing and a plus sign (+) stamped into it.
2. Press the battery into place on the Main board until the locking tab clicks.
3. Complete the steps outlined in *Replacing the Front Bezel*, p. 181.
4. Complete the steps outlined in *Replacing the Top Cover*, p. 179.

12.5.6 LCD Replacement

Removing the LCD

1. Turn the monitoring system off and disconnect it from the AC power source.
2. Complete the steps outlined in *Removing the Top Cover*, p. 177.
3. Complete the steps outlined in *Removing the Front Bezel*, p. 180.
4. Complete the steps outlined in *Removing the Main Board*, p. 183.
5. Remove the four screws and plastic tabs that hold the LCD in place.
6. Lift the LCD away from the front bezel.

Figure 12-9. LCD Replacement



Replacing the LCD

1. Place the new LCD on the inside of the window on the front bezel. Ensure the LCD is oriented so that its ribbon cable is at the bottom of the front bezel.
2. Place the four tabs and screws that hold the LCD onto the front bezel. Tighten each screw to 2.0 ±0.5 kgf-cm.
3. Complete the steps outlined in *Replacing the Main Board*, p. 185.
4. Complete the steps outlined in *Replacing the Front Bezel*, p. 181.
5. Complete the steps outlined in *Replacing the Top Cover*, p. 179.

Replacing the AC Inlet

To replace the AC inlet:

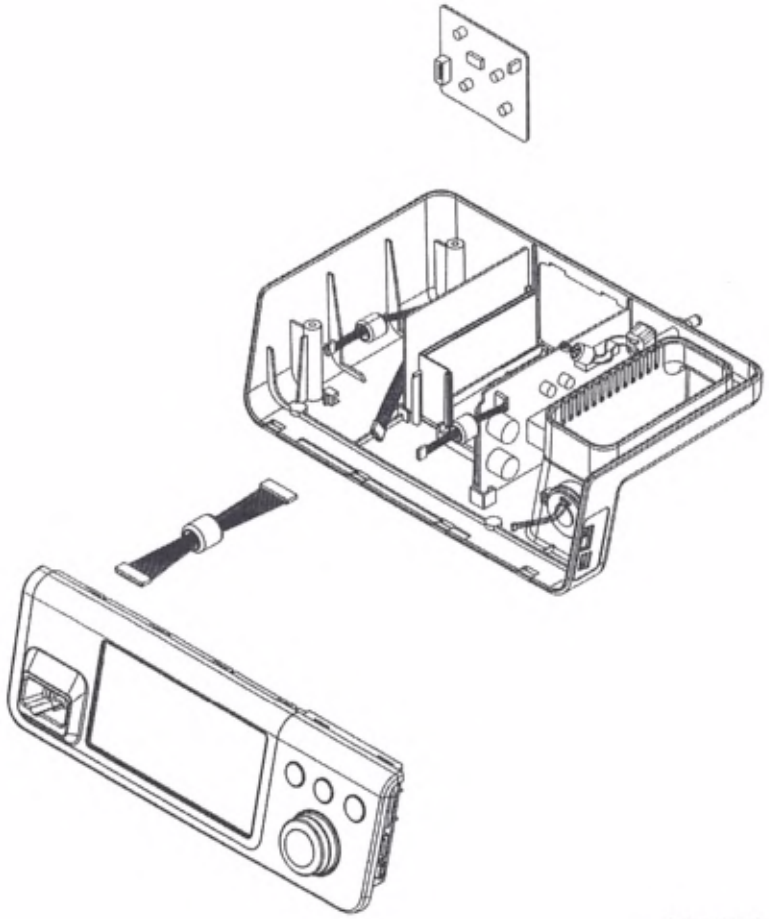
1. Slide the new AC inlet into its slots in the base of the monitoring system.
2. Place the grounding wire onto the equipotential terminal. Replace the nut on the equipotential terminal.
3. Complete the steps outlined in *Replacing the Power Supply Board*, p. 190.

12.5.10 Charger Board Replacement

Removing the Charger Board

1. Turn the monitoring system off and disconnect it from the AC power source.
2. Complete the steps outlined in *Removing the Top Cover*, p. 177.
3. Complete the steps outlined in *Removing the Front Bezel*, p. 180.
4. Disconnect the harness from the J4 connector on the Charger board (from the Nurse Call board).
5. Lift the wires for the harness connecting the Charger board to the Power Supply board up and out of the notch in the Power Supply board.
6. Disconnect the harness from the J1 connector on the Charger board.
7. Remove the small, square plastic plate behind the Charger board by sliding it upward.
8. Lift the Charger board out of the monitoring system's base.

Figure 12-13. Charger Board Replacement



Replacing the Charger Board

1. Place the Charger board into its slots in the base of the monitoring system, ensuring that the battery contacts on the back of the board are toward the bottom of the monitoring system and facing the battery compartment.
2. Slide the small, square plastic plate into place behind the Charger board. The wider side of this plate should be facing the battery.
3. Connect the harness from the Nurse Call board to the J4 connector on the Charger board.

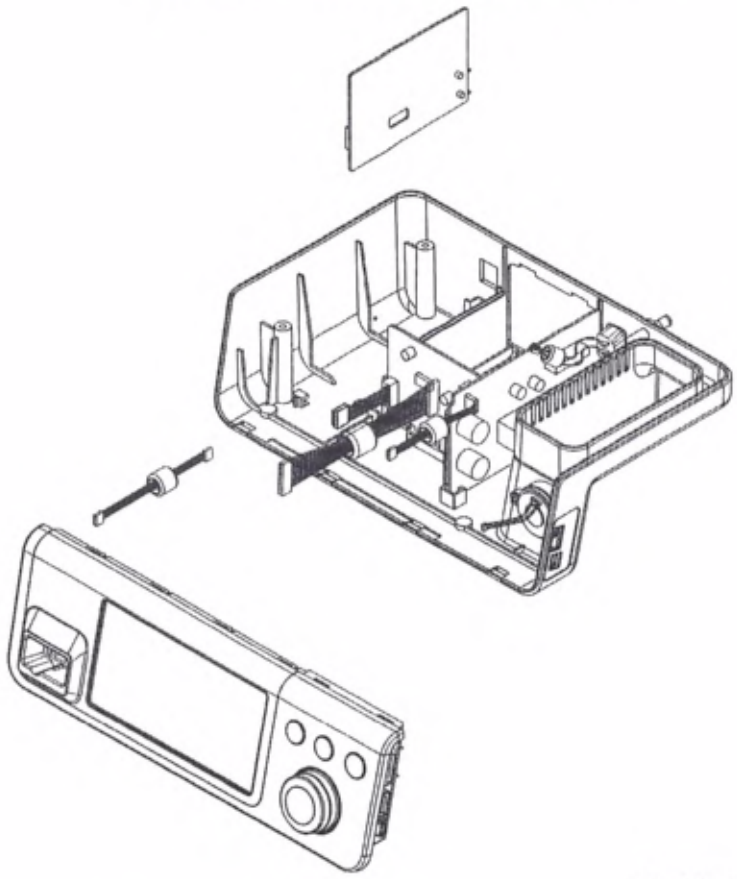
4. Connect the harness from the Power Supply board to the J1 connector on the Charger board. Slide the harness wires into the cutout in the top of the Power Supply board.
5. Complete the steps outlined in *Replacing the Front Bezel*, p. 181.
6. Complete the steps outlined in *Replacing the Top Cover*, p. 179.

12.5.11 Nurse Call Board Replacement

Removing the Nurse Call Board

1. Turn the monitoring system off and disconnect it from the AC power source.
2. Complete the steps outlined in *Removing the Top Cover*, p. 177.
3. Complete the steps outlined in *Removing the Front Bezel*, p. 180.
4. Disconnect the harness from the J1 connector on the Nurse Call board.
5. Disconnect the harness from the J3 connector in the Nurse Call board.
6. Slide the Nurse Call board slightly forward and angle the top front corner or the board upward. Take these steps to ensure that the RJ11 port disengages from the port hole in the back of the monitoring system's base. Slide the Nurse Call board up and out of the base.

Figure 12-14. Nurse Call Board Replacement



Replacing the Nurse Call Board

1. Slide the new Nurse Call board into its slots in the base of the monitoring system, ensuring that the RJ11 port is properly placed in the cutout in the back of the base.
2. Connect the harness from the Main board to the J1 connector on the Nurse Call board.
3. Connect the harness from the Charger board to the J3 connector on the Nurse Call board.
4. Complete the steps outlined in *Replacing the Front Bezel*, p. 181.
5. Complete the steps outlined in *Replacing the Top Cover*, p. 179.

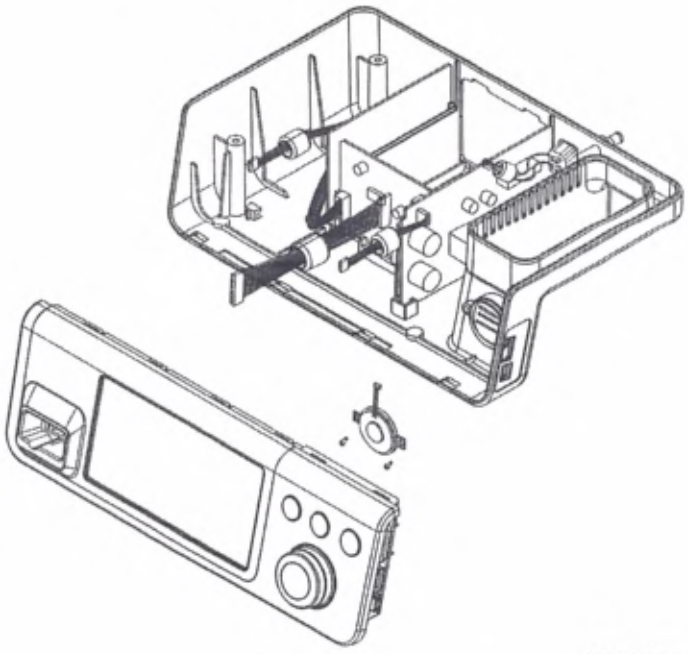
12.5.12 Alarm Speaker Replacement

WARNING:
If the speaker needs replacing because of a speaker failure, please contact Covidien Technical Services or your local Covidien representative.

Removing the Alarm Speaker

1. Turn the monitoring system off and disconnect it from the AC power source.
2. Complete the steps outlined in *Removing the Top Cover*, p. 177.
3. Complete the steps outlined in *Removing the Front Bezel*, p. 180.
4. Use the #2 Phillips screwdriver to remove the two screws that attach the speaker to the base of the monitoring system.
5. Lift the speaker out of the base.

Figure 12-15. Alarm Speaker Replacement



POX_30293_A

Note:
Contact Covidien Technical Services to discuss the return or disposal of the original speaker assembly.

Replacing the Alarm Speaker

WARNING:
Do not allow other metal objects to come into contact with the speaker; permanent damage may occur.

Caution:
Handle the speaker ONLY by the edges of the metal ring to avoid damage.

Caution:
Install the speaker with its wires toward the top of the monitoring system; otherwise, the wires might get pinched between the front bezel and the base.

1. Handling just the edges of the metal ring of the speaker, hold the speaker in place on the speaker molding in the base of the monitoring system.
2. Use the #2 Phillips screwdriver to insert the two screws that hold the speaker in place. Tighten each screw to 4.0 ±1.0 kgf-cm.
3. Complete the steps outlined in *Replacing the Front Bezel*, p. 181.
4. Complete the steps outlined in *Replacing the Top Cover*, p. 179.

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Index