

Service Manual

Nellcor™

Bedside Respiratory Patient Monitoring System



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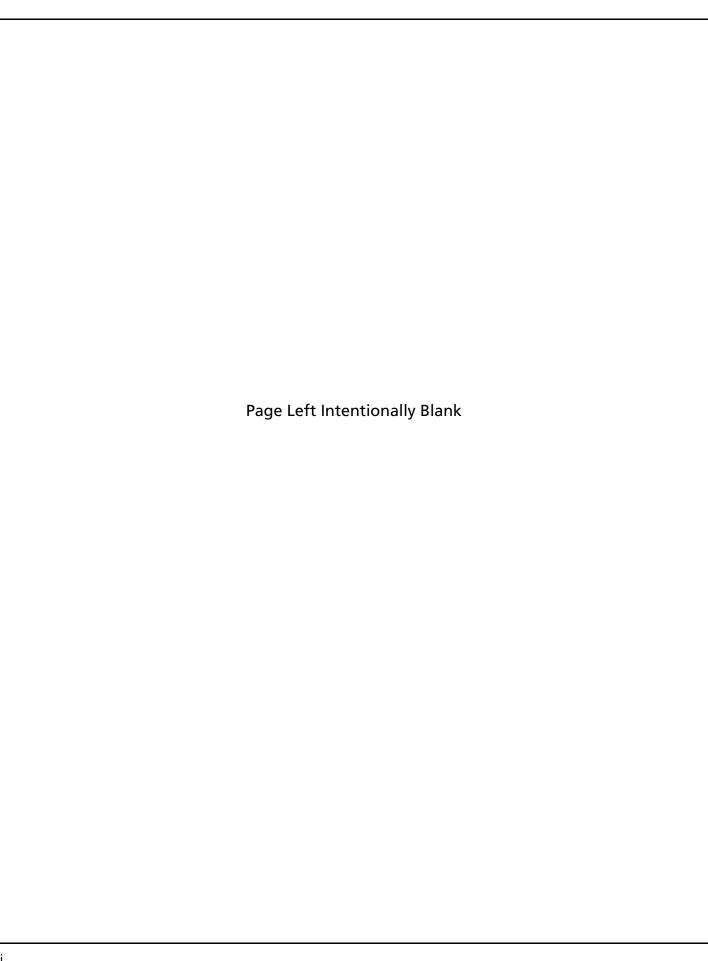
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Service Manual

1 Introduction

1.1 Overview

This manual, for use by qualified personnel only, contains instructions for servicing, testing, and maintaining the Nellcor[™] Bedside Respiratory Patient Monitoring System.

This manual applies to the following products:

REF GR101704

REF GR101704-RR

REF PM1000N

REF PM1000N-RR

1.2 Intended Audience

This manual provides information to professionals acting as trained and qualified service technicians in a hospital or hospital-type setting for maintenance and service or repair of the monitoring system. Refer to the institution for any additional training or skill requirements beyond those identified here for maintenance and repair of the monitoring system. Before servicing, thoroughly read this manual.

1.3 Safety Information

1.3.1 Safety Symbols

Table 1-1. Safety Symbol Definitions

Symbol	Definition	
Λ	WARNING Warnings alert users to potential serious outcomes (death, injury, or adverse events) to the patient, user, or environment.	
•	Caution Cautions alert users to exercise appropriate care for safe and effective use of the product.	
\$	Note Notes provide additional guidelines or information.	

1.3.2 Warnings



WARNING:

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



WARNING:

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



WARNING:

Before attempting to open or disassemble, disconnect the power cord to avoid possible injury.



WARNING:

Use only Covidien-approved internal batteries.



WARNING:

The monitoring system is not defibrillator-proof. It may remain attached to the patient during defibrillation or during use of an electrosurgical unit,

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however, readings may be inaccurate during use in this environment and shortly thereafter.



WARNING:

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



WARNING:

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



WARNING:

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



WARNING:

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



WARNING:

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



WARNING:

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



WARNING:

Do not spray, pour, or spill any liquid on the monitoring system, its accessories, connectors, switches, or openings in the chassis, since this may cause damage to the monitoring system.

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WARNING:

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



WARNING:

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



WARNING:

No user serviceable parts inside.

1.3.3 Cautions



Caution:

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



Caution:

When connecting the monitoring system to any instrument, verify proper operation before clinical use. Both the monitoring system and the instrument connected to it must utilize a grounded outlet. Any equipment connected to the data interface must be certified according to the latest IEC/EN 60950 -1 standard for data-processing equipment, the latest IECEN 60601-1 standard for electromedical equipment, or the latest IEC/EN safety standards relevant to that equipment. All combinations of equipment must be in compliance with Requirements for Medical Electrical Systems IEC Standard 60601-1:2007 and the electromagnetic compatibility IEC/EN Standard 60601-1:2005. Anyone who connects equipment to the data interface is configuring a medical system and, therefore, is responsible for ensuring that the system complies with the Requirements for Medical Electrical Systems IEC/EN Standard 60601-1-1:2007 and the electromagnetic compatibility IEC/ EN Standard 60601-1-2:2007. Accuracy may degrade if it is connected to secondary I/O devices when the equipment is not connected to earth reference.

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Caution:

Observe electrostatic discharge (ESD) precautions prior to opening the chassis or handling any internal components.



Caution:

Observe the required torque for tightening screws. Over-tightening can strip out screw holes, rendering them useless.

1.4 Obtaining Technical Assistance

1.4.1 Technical Services

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

Covidien Technical Services: Patient Monitoring

15 Hampshire Street

Mansfield, MA 02048 USA

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

www.covidien.com

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

To locate the serial number and code versions



- 1. Press MENU.
- 2. Press ABOUT THE MONITOR.
- 3. Locate the serial number under *Monitor Information* and code versions under *Software Information*.

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1.4.2 On-Screen Help

The monitoring system provides users with an on-screen help system for various help topics. Reference *To access on-screen help topics*, p. 6-16.

1.5 Related Documents

Documentation is available online at www.covidien.com. Covidien makes available all appropriate information relevant to servicing monitoring system parts designated as repairable in this manual. For further assistance, contact Covidien.

- Nellcor™ Bedside Respiratory Patient Monitoring System Operator's
 Manual Provides basic information on operating the monitoring system and
 troubleshooting errors or malfunctions. Before using the monitoring system, thoroughly read this manual.
- **Nellcor™ Sensor** *Instructions for Use* Guides sensor selection and usage. Before attaching any of the various Covidien-approved Nellcor™ sensors to the monitoring system, refer to their *Instructions for Use*.
- Nellcor™ Oxygen Saturation Accuracy Specification Grid Provides sensor-specific guidance related to desired SpO₂ saturation accuracy measurements.

1.6 Warranty Information

To obtain information, contact Covidien or a local Covidien representative.

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

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2 Product Specifications

2.1 Overview

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

2.2 Physical Characteristics

Weight 7.5 lbs. (3.4 kg)

Dimensions 10 in. x 6.5 in. x 5 in. (252 mm x 163 mm x 122 mm)

2.3 Electrical Requirements

2.3.1 Power

Power Requirements Rated at 80-263 volts AC (nominal 120-230 VAC), 30 VA

Input Frequency 47/63 Hz

Fuses Slow-blow 1.5 amp, 250 volts, IEC (5 x 20 mm)

Quantity: 2 external

2.3.2 Battery



Note:

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

Type Lithium Ion

Voltage 7.2 Volts DC, 11.6 Ah, 83 Wh

Recharge 8 hours with monitoring system turned off

12 hours with monitoring system turned on

Shelf Life Four months, if monitoring system runs on new, fully-charged battery

After four months storage, units run 33% of stated battery life

Compliance IEC 62133

2.3.3 Rating of Nurse Call Relay

Maximum Input Voltage 30 VAC or VDC (polarity is not important)

Load Current 120 mA continuous (peak 300 mA @ 100 ms)

Minimum Resistance 26.5 ohms to 50.5 ohms (40.5 ohms typical) during alarms

Ground Reference Isolated Ground

Electrical Isolation 1500 Volts

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2.4 Environmental Conditions

2.4.1 Operating

Temperature 5 °C to 40 °C (41 °F to 104 °F)

Altitude -304.8 m to 4,572 m

(-1,000 ft. to 15,000 ft.)

Atmospheric Pressure 105 kPa to 57.2 kPa

(31.0 in. Hg to 16.89 in. Hg)

Relative Humidity 15% to 95% non-condensing

2.4.2 Transport and Storage

	Not in shipping container	In shipping container
Temperature	-20 °C to 60 °C (-4 °F to 140 °F)	-20 °C to 70 °C (-4 °F to 158 °F)
Altitude	-390 m to 5,574 m (-1,2	254 ft. to 18,288 ft.)
Atmospheric Pressure	50 kPa to 106 kPa (14.7	in. Hg to 31.3 in. Hg)
Relative Humidity	15% to 95% no	n-condensing

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2.5 Sensor Accuracy and Ranges

This monitoring system has the capability to detect physiological alarm conditions using SpO₂ accuracy, pulse rate accuracy and alarm limit conditions.

Table 2-1. Nellcor[™] Sensor Accuracy and Ranges

Measurement Range		
SpO ₂	1% to 100%	
Pulse Rate	20 to 250 beats per minute (bpm)	
Perfusion Range	0.03% to 20%	
Accuracy ¹		
Saturation		
Adult ^{2, 3}	70 to 100% ±2 digits	
Adult and Neonate Low Sat ^{2, 3, 4}	60 to 80% ±3 digits	
Neonate ^{4, 5}	70 to 100% ±2 digits	
Low Perfusion ⁶	70 to 100% ±2 digits	
Adult and Neonate with Motion ^{2, 7}	70 to 100% ±3 digits	
Pulse Rate		
Adult and Neonate ^{2, 3, 4}	20 to 250 bpm ±3 digits	
Low Perfusion ⁶	20 to 250 bpm ±3 digits	
Adult and Neonate with Motion ^{2, 7}	48 to 127 bpm ±5 digits	

- Saturation accuracy varies by sensor type. Refer to the Nellcor™ Oxygen Saturation Accuracy Specification Grid at www.covidien.com/rms
- 2. Accuracy specifications were validated using measurements of healthy non-smoking adult volunteers during controlled hypoxia studies spanning the specified saturation ranges. Subjects were recruited from the local population and comprised both men and women ranging in age from 18-50 years old, and spanned a range of skin pigmentations. Pulse oximeter SpO2 readings were compared to SaO2 values of drawn blood samples measured by hemoximetry. All accuracies are expressed as ±1 SD. Because pulse oximeter equipment measurements are statistically distributed, about two-thirds of the measurements can be expected to fall in this accuracy (A_{RMS}) range (refer to the Sensor Accuracy Grid for more details).
- 3. Adult specifications are shown for OXIMAX MAX-A and MAX-N sensors with the NellcorTM Bedside Respiratory Patient Monitoring System.
- 4. Neonate specifications are shown for OXIMAX MAX-N sensors with the Nellcor™ Bedside Respiratory Patient Monitoring System.
- 5. Clinical functionality of the MAX-N sensor has been demonstrated on a population of hospitalized neonate patients. The observed SpO2 accuracy was 2.5% in a study of 42 patients with ages of 1 to 23 days, weight from 750 to 4,100 grams, and 63 observations made spanning a range of 85% to 99% SaO2.
- 6. Specification applies to Nellcor™ Bedside Respiratory Patient Monitoring System oximeter performance. Reading accuracy in the presence of low perfusion (detected IR pulse modulation amplitude 0.03% 1.5%) was validated using signals supplied by a patient simulator. SpO2 and pulse rate values were varied across the monitoring range over a range of weak signal conditions and compared to the known true saturation and pulse rate of the input signals.
- Motion performance was validated during a controlled hypoxia blood study. Subjects performed rubbing and tapping
 movements 1-2 cm in amplitude with aperiodic intervals (randomly changing) with a random variation in frequency between
 1-4 Hz. Applicability: OXIMAX MAX-A, MAX-AL, MAX-P, MAX-I, and MAX-N sensors.

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Table 2-2. Nellcor[™] Sensor Operating Range and Power Dissipation

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			

2.6 Sound Pressure

Table 2-3. Sound Pressure in Decibels

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

2.7 Product Compliance

Equipment Classification IEC/EN 80601-2-61:2011

IEC/EN 60601-1:2005

CAN/CSA C22.2 No. 60601-1:08 ANSI AAMI ES 60601-1:2005

Protection Type Class I (Internally powered)

Degree of Protection Type BF - Applied part

Mode of Operation Continuous

Electromagnetic Compatibility IEC 60601-1-2:2007

Liquid Ingress IPX1: Protected against harmful effects of dripping water

Degree of Safety Not suitable for use in the presence of flammable anesthetics

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2.8 Manufacturer's Declaration and Guidance

2.8.1 Electromagnetic Compatibility (EMC)



WARNING:

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



WARNING:

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

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

Frequency and Bandwidth for Wireless Connection

Table 2-4. Frequency Band, Output Power, and Modulation Type

Frequency Band (MHz)	Output Power (Watts)	Modulation Type
2412 - 2462	0.088	BPSK, CCK, OFDM
5180 - 5240	0.018	OFDM
5260 - 5320	0.018	OFDM
5500 - 5700	0.028	OFDM
5745 - 5825	0.026	OFDM

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Electromagnetic Emissions

Table 2-5. Electromagnetic Emissions Guidelines and Compliance

Guidance and Manufacturer's Declaration—Electromagnetic Emissions (IEC/EN 60601-1-2:2007, Table 1)

The monitoring system is intended for use in the electromagnetic environment specified below. The customer or the user of the monitoring system should assure that it is used in such an environment.

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

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Electromagnetic Immunity

 Table 2-6.
 Electromagnetic Immunity Guidelines and Compliance

Guidance and Manufacturer's Declaration—Electromagnetic Immunity (IEC/EN 60601-1-2:2007, Table 2)

The monitoring system is intended for use in the electromagnetic environment specified below. The customer or the user of the monitoring system should assure that it is used in such an environment.

Immunity Test	IEC/EN 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance	
Electrostatic discharge (ESD) IEC/EN 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floor should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.	
Electric fast transient/burst IEC/EN 61000-4-4	± 2 kV for power supply lines ± 1 kV input/ output lines	± 2 kV for power supply lines ± 1 kV input/ output lines	Mains power quality should be that of a typical commercial and/ or hospital environment.	
Surge IEC/EN 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial and/ or hospital environment.	
Voltage dips, short interruptions and voltage variations on power supply	<5% U _T (>95% dip in U _T) for 0.5 cycle	<5% U _T (>95% dip in U _T) for 0.5 cycle	Mains power quality should be that of a typical commercial and or hospital environment.	
IEC/EN 61000-4-11	40% U _T (60% dip in U _T) for 5 cycles	$40\% \ U_T$ (60% dip in U_T) for 5 cycles	If the user requires continued operation during power mains interruption, it is recommended that the monitoring system be powered from an uninterruptible	
	70% U_T (30% dip in U_T) for 25 cycles	70% U_T (30% dip in U_T) for 25 cycles	power supply or battery.	
	<5% U _T (>95% dip in U _T) for 5 seconds	<5% U _T (>95% dip in U _T) 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.	

Note: U_T is the AC main's voltage prior to application of the test level.

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Table 2-7. Recommended Separation Distance Calculations

Guidance and Manufacturer's Declaration—Electromagnetic Immunity (IEC/EN 60601-1-2:2007, Table 4)

The monitoring system is intended for use in the electromagnetic environment specified below. The customer or the user of the monitoring system should assure that it is used in such an environment.

Immunity Test	IEC/EN 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the monitoring system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF	3 Vrms	3 Vrms	Recommended Separation Distance
IEC/EN 61000-4-6	150 kHz to 80 MHz	150 kHz to 80 MHz	$d = 1.2\sqrt{P}$
Radiated RF	3 V/m	3 V/m	$d = 1.2\sqrt{P}$
IEC/EN 61000-4-3	80 MHz to 2.5 GHz	80 MHz to 2.5 GHz	80 MHz to 800 MHz
			$d = 2.3\sqrt{P}$
			800 MHz to 2.5 GHz
			where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
			Field strengths from fixed RF transmitters, as determined
			by an electromagnetic site survey ^a , should be less than the
			compliance level in each frequency range ^b .
			Interference may occur in the vicinity of equipment marked with the following symbol:
			$((\bullet))$

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

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

^bOver the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

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Table 2-8. Recommended Separation Distances

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Monitoring System (IEC/EN 60601-1-2:2007, Table 6)

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

Rated Maximum	Separation Distance According to Frequency of Transmitter in Meters				
Output Power (P) of Transmitter in Watts	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$		
	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, the recommended separation distance (d) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

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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. Sensor and Cable Length

Item	SKU	Maximum Length			
Sensors					
Nellcor™ Adult SpO2 Sensor, Reusable (Nonsterile)	DS100A	3.0 ft. (0.9 m)			
Nellcor™ Adult XL SpO2 Sensor (Sterile, single-use only)	MAX-AL	3.0 ft. (0.9 m)			
Nellcor™ Forehead SpO2 Sensor (Sterile, single-use only)	MAX-FAST	2.5 ft (0.75 m)			
Nellcor™ Neonatal-Adult SpO2 Sensor (Sterile, single-use only)	MAX-N				
Nellcor™ Infant SpO2 Sensor (Sterile, single-use only)	MAX-I				
Nellcor™ Pediatric SpO2 Sensor (Sterile, single-use only)	MAX-P	1.5 ft. (0.5 m)			
Nellcor™ Adult SpO2 Sensor (Sterile, single-use only)	MAX-A				
Nellcor™ Adult SpO2 Nasal Sensor (Sterile, single-use only)	MAX-R				
Nellcor™ Adult-Neonatal SpO2 Sensor with Wraps (Reusable with adhesive)	OXI-A/N	3.0 ft. (0.9 m)			
Nellcor™ Pediatric-Infant SpO2 Sensor with Wraps (Reusable with adhesive)	OXI-P/I	3.0 11. (0.9 111)			
Nellcor™ Pediatric SpO2 Sensor, Two Piece (Sterile, single-use only)	Р				
Nellcor™ Neonatal-Adult SpO2 Sensor, Two Piece (Sterile, single-use only)	N	OC-3 cable, 3.0 ft. (0.9 m)			
Nellcor™ Adult SpO2 Sensor, Two Piece (Sterile, single-use only)	А				
Nellcor™ SpO2 Sensor, Multisite Reusable (Nonsterile)	D-YS				
Nellcor™ SpO2 Ear Clip, Reusable (Nonsterile)	D-YSE	4.0 ft. (1.2 m)			
Nellcor™ Pediatric SpO2 Clip, Reusable (Nonsterile)	D-YSPD				

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Table 2-9. Sensor and Cable Length (Continued)

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

2.8.2 Ground Integrity

100 milliohms or less

2.8.3 Safety Tests

The following tables describe 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	ANSI/AAMI 60601-1	
Normal	Normal	Closed	Closed	500 μΑ	300 μΑ	
Single Fault		Open	Closed		1000 μΑ	
		Closed	Open			
Normal	Reversed	Closed	Closed	500 μΑ	300 μΑ	
Single Fault		Open	Closed		1000 μΑ	
		Closed	Open			

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 Table 2-10.
 Earth and Enclosure Leakage Current Specifications (Continued)

Enclosure Leakage Current					
Condition	AC Line Polarity	Neutral Line Cord	Power Line Ground	IEC 60601-1 ANSI/AAMI 60601-1	
Normal	Normal	Closed	Closed	100 μΑ	
Single Fault		Open	Closed	500 μΑ	
		Closed	Open		
Normal	Reversed	Closed	Closed	100 μΑ	
Single Fault		Open	Closed	500 μΑ	
		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 60601-1
Normal	Normal	Closed	Closed	100 μΑ
Single Fault		Open	Closed	500 μΑ
		Closed	Open	
Normal	Reversed	Closed	Closed	100 μΑ
Single Fault		Open	Closed	500 μΑ
		Closed	Open	
	Pa	atient Isolation	Risk Current	
Condition	AC Line Polarity	Neutral Line	Power Line Ground Cable	IEC 60601-1 UL 60601-1
Single Fault	Normal	Closed	Closed	5000 μΑ
	Reversed	Closed	Closed	

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3 Theory of Operations

3.1 Overview

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

3.2 Block Diagram

The functional block diagram provides a quick, visual overview of the monitoring system.

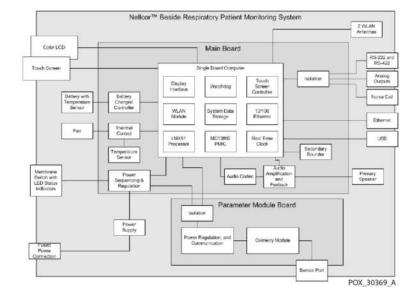


Figure 3-1. Block Diagram

3.3 Theoretical Principles

The monitoring system uses pulse oximetry to measure functional oxygen saturation in the blood. Pulse oximetry works by applying a NellcorTM 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 (SpO₂).

Ambient conditions, sensor application, and patient conditions can influence the ability of the monitoring system to accurately measure SpO₂. Reference *Performance Considerations*, p. 8-1.

Pulse oximetry is based on two principles: oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (measured using spectrophotometry), and the volume of arterial blood in tissue (and hence, light absorption by that blood) changes during the pulse (registered using plethysmography). A monitoring system determines SpO₂ by passing red and infrared light into an arteriolar bed and measuring changes in light absorption during the pulsatile cycle. Red and infrared low voltage, light-emitting diodes (LED) in the sensor serve as light sources; a photo diode serves as the photo detector.

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

The monitoring system uses the pulsatile nature of arterial flow to identify the oxygen saturation of arterial hemoglobin. During systole, a new pulse of arterial blood enters the vascular bed, and blood volume and light absorption increase. During diastole, blood volume and light absorption reach their lowest point. The monitoring system bases its SpO₂ 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.

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3.4 Automatic Calibration

Because light absorption by hemoglobin is wavelength dependent and because the mean wavelength of LEDs varies, a monitoring system must know the mean wavelength of the sensor's red LED to accurately measure SpO₂.

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 SpO₂.

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.

3.5 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 SpO₂ measurements.

Fully evaluating the accuracy of the SpO₂ 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. SpO₂ 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.

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While this will not affect use of the simulator for verifying system functionality, displayed SpO₂ measurement values may differ from the setting of the test device. For a properly functioning monitoring system, this difference will be reproducible over time and from monitoring system to monitoring system within the performance specifications of the test device.

3.6 Unique Technologies

3.6.1 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

n %carboxyhemoglobin

ь fractional saturation

Λ %methemoglobin

3.6.2 Measured versus Calculated Saturation

When calculating saturation from a blood gas partial pressure of oxygen (PO2), the calculated value may differ from the SpO2 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 SpO2.

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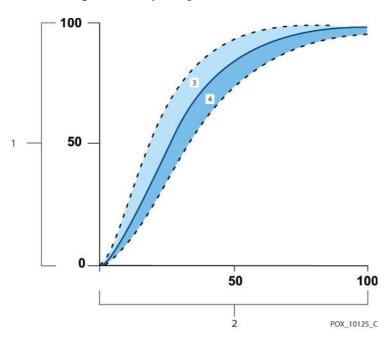


Figure 3-2. Oxyhemoglobin Dissociation Curve

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

3.6.3 Data Update Period, Data Averaging, and Signal Processing

The advanced signal processing of the OxiMax[™] algorithm automatically extends the amount of data required for measuring SpO₂ 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 monitoring system displays the pulse search indicator while continuing to update SpO₂ and pulse rate values every second. If the dynamic averaging time exceeds 25 seconds, a low-priority Extended Update alarm also appears.

As such measurement conditions extend, the amount of data required may continue to increase. If the dynamic averaging time reaches 40 seconds, and/ or 50 seconds for pulse rate, a high priority alarm state results: the monitoring

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system displays the Pulse Timeout alarm and reports a zero saturation indicating a loss-of-pulse condition.

3.7 System Features

3.7.1 Nellcor™ Sensor Technology

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

This unique oximetry architecture enables several new features. When a Nell-cor™ sensor is connected to the monitoring system, the monitoring system reads the information from the sensor memory chip, ensures it is error free, and then loads the sensor data prior to monitoring for new information. As the monitoring system reads sensor information, it sends the sensor model number to the monitoring screen. This process may take a few seconds. The sensor model number disappears after the monitoring system starts tracking the patient's SpO₂ and pulse rate.

Any monitoring system containing OxiMax technology uses calibration data contained in the sensor in calculating the patient's SpO₂. With sensor calibration, the accuracy of many sensors is improved, since the calibration coefficients can be tailored to each sensor.

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

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

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3.7.2 SatSeconds™ Alarm Management Parameter

The monitoring system monitors the percentage of hemoglobin binding sites saturated with oxygen in the blood. With traditional alarm management, upper and lower alarm limits are set to alarm at specific SpO₂ levels. When the SpO₂ level fluctuates near an alarm limit, the alarm sounds each time it violates the alarm threshold. SatSeconds monitors both degree and duration of desaturation as an index of desaturation severity. Thus, the SatSeconds parameter helps distinguish clinically significant events from minor and brief desaturations that may result in nuisance alarms.

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

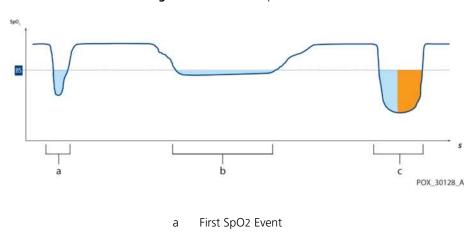


Figure 3-3. Series of SpO₂ Events

b Second SpO2 Event

c Third SpO2 Event

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First SpO₂ Event

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

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

12 SatSeconds; no alarm

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

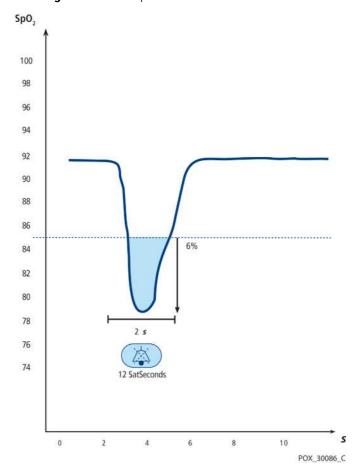


Figure 3-4. First SpO2 Event: No SatSeconds Alarm

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Second SpO₂ Event

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

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

15 SatSeconds; no alarm

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

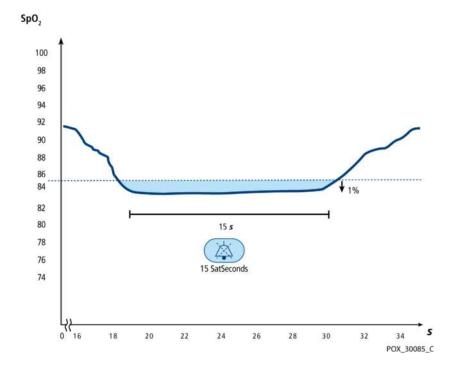


Figure 3-5. Second SpO2 Event: No SatSeconds Alarm

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Third SpO₂ Event

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

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

25 SatSeconds; results in an alarm

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

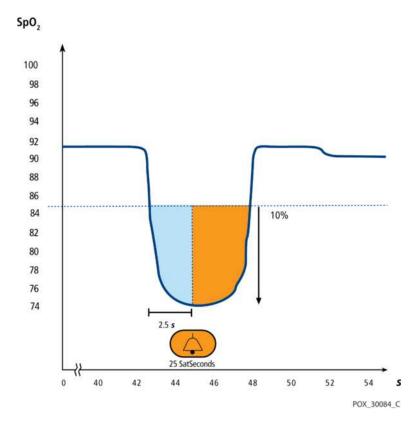


Figure 3-6. Third SpO2 Event: Triggers SatSeconds Alarm

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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.

3.7.3 OxiMax SPD™ Alert Parameter



WARNING:

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



Caution:

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

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

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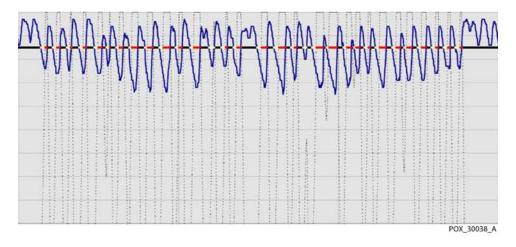


Figure 3-7. Clinically Significant Desaturation Patterns

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

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

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

- The severity of the desaturation event (the depth of the desaturation during the event) and the extent of the following resaturation
- The regularity of the desaturation events (how often the pattern repeats)
- The slope of the desaturation/resaturation trends that form the events

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

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



Note:

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

3.7.4 Pulse Rate Delay Alarm Management Parameter

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

To use Pulse Rate Delay, set the traditional alarm management upper and lower pulse rate alarm limits. Then, set Pulse Rate Delay. The Pulse Rate Delay limit controls the time the pulse rate level crosses either limit before an audible alarm sounds.

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4 Product Overview

4.1 Overview

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

4.2 Product Description

The Nellcor[™] Bedside Respiratory Patient Monitoring System provides continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin SpO₂ and pulse rate.

4.3 Indications for Use

The Nellcor™ Bedside Respiratory Patient Monitoring System is a portable pulse oximeter intended for prescription use only as a continuous non-invasive monitor of arterial oxygen saturation (SpO₂) and pulse rate of adult, pediatric, and neonatal patients during both no motion and motion conditions, and for patients who are well or poorly perfused. The monitoring system is intended for use in hospitals, hospital-type facilities, and during intra-hospital transport. The OxiMax SPD™ Alert (SPD) feature is intended only for facility-use care of adults to detect patterns of desaturation indicative of repetitive reductions in airflow through the upper airway and into the lungs.



Note:

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

Use with any particular patient requires the selection of an appropriate Nell-cor[™] sensor.

Monitoring system users can access trend information, change alarm limits, adjust the internal time clock, select the communications protocol, and choose alternative interface languages.

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

4.4 List of Components

The typical monitoring system carton ships with the following contents.

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

Table 4-1. Typical Packing List

4.5 Synopsis

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

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

If the monitoring system detects an alarm condition, it provides both visual and audible alarms. Reference *Alarms and Error Conditions*, p. 11-4, for alarm conditions.

After monitoring is no complete, remove the recommended sensor from the patient.

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4.6 Product Views

4.6.1 Front Panel

Figure 4-1. Front Panel



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

Service Manual 4-3

4.6.2 Monitoring Screen

Monitoring

3 Alarms Active

View all

Pulse BPM

Pulse

Figure 4-2. Sample Monitoring Screen Elements

1		Monitor status field	Contains patient information in various forms.
2		Alarm status field	Contains prioritized alarms or user prompts.
3		Trend data type button	Contains types of graphed trend data included.
4	MM	Plethysmographic waveform	This non-normalized waveform uses real-time sensor signals, reflecting relative pulsatile strength.
5		Trend data time scale	Contains time period for graphed trend data. Press "-" or "+" to change the time period.
6	64%	Battery fuel gauge	Indicates remaining battery charge and lists percentage of total charge remaining. Fill color indicates acceptable, low, or at a critical state of charge. Lightning bolt indicates monitoring system is connected to AC and charging if not fully charged.
7	FAST	Fast response mode Icon	Indicates algorithm response to SpO2 data changes in two to four seconds.
8		Date and time field	Reflects current date and time.

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9	*	Baby icon (Neonate Mode)	Indicates alarm limits are set to neonate limit values, not set to adult limit values.
10	(A)	Audio alarm paused/ off icon	Yellow alarm silenced icon indicates Alarm Audio Paused or volume set to zero. Red icon indicates Alarm Audio OFF.
11	100	SatSeconds™ icon & limit value	Fills in the clockwise direction with saturation readings outside limits and empties counterclockwise when within SpO2 limits. When completely full, it alarms.
12	100 85	SpO2 upper and lower limits	Displays current upper and lower alarm limit settings to the right of the dynamic SpO2 value.
13	98	Dynamic %SpO2 value	Indicates SpO2 saturation levels. Cyan SpO2 values zero during loss-of-pulse conditions. Updates continue during Pulse Search.
14	$\stackrel{\triangle}{=}$	SPD icon & sensitivity value	Fills from bottom to top as patterns of desaturation in the SpO2 trend become more severe and empties from top to bottom as the patterns become less severe. If the icon fills completely, an alarm sounds.
15	170	Pulse rate (BPM) upper and lower limits	Displays current upper and lower alarm limit settings to the right of the dynamic pulse rate value.
16	76	Pulse rate (BPM) real- time value	Indicates pulse rate in beats per minute . Green pulse rate values zero during loss-of-pulse conditions.
17		Lock bar icon	Provides option of locking out all response to monitoring screen contact except the lock bar.
18	MM	Interference indicator	Lights when incoming signal is inadequate or degraded. Reference <i>Performance Considerations</i> , p. 8-1.
19	Ø	Pulse search indicator	Flashes during pulse search or lights continuously during loss-of- pulse conditions.
20	i	Help information icon	Provides access to on-screen help. Press for descriptions and suggestions.
21	er se	Trend data graph	Contains patient trend data dictated by trend data type and trend data time scale.
22	∷	Menu selection icon	Provides access to menus. Press to alter alarm limits, patient trend data history, screen selections, connectivity settings, as well as audio and visual control.

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Silence alarm icon

Normally a white icon on grey background. Lights continuously as a yellow icon on grey background with silenced audible alarm, and as a disabled grey icon on grey background when audible alarms are disabled. Silence duration (not shown) counts down on screen.

Pulse amplitude (blip bar)

(Not shown in figure.) Indicates pulse beat and the relative (nonnormalized) pulse amplitude in numbers only view. As the detected pulse becomes stronger, more bars light with each pulse.

Pulse beat (heart) icon

(Not shown in figure.) Flashes to indicate each real-time pulse beat.

4.6.3 Rear Panel

Figure 4-3. Rear Panel



- 1 Equipotential terminal (Ground)
- 2 AC power connector
- 3 Fuse drawer

- 4 Carrying handle
- 5 Screw hole for adapter plate (4x)
- 6 Internal battery access
- 7 Parameter module (rear)

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4.7 Labeling Symbology

 Table 4-2.
 Labeling Symbols and Descriptions

Symbol	Description	Symbol	Description
③	Must consult instructions for use	M	Date of manufacture
\triangle	Caution, consult accompanying documents	X	Proper waste disposal for electrical and electronic equipment
♦	Equipotential terminal (ground)	∱	Type BF applied part - Not defibrillator proof
70.50A 250V	Fuse replacement: 1.5 amp	Æ	Federal Communications Commission: Compliance with FCC
IPX1	Protection against fluid ingress	<u>11</u>	This side up
Effective of a final site	Atmospheric pressure limitations	*	Keep dry
A conc	Temperature limitations	ľ	Fragile
	Humidity limitations	MR unsafe	Do not use during magnetic resonance imaging
((•))	Electromagnetic interference may occur in the vicinity of equipment marked with this symbol	REF	Catalog number
EC REP	European Community (EC) authorized representative	® _{∪s}	CSA – Canadian Standards Association certification mark
0123	CE – Conformité Européene authorization mark 0123 – TÜV SÜD Product Service GmbH (notified body)	RX	Prescription only
C	Australian wireless compliance mark	∏i	Consult instructions for use

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4-8 Service Manual

5 Installation

5.1 Overview

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

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

5.2 Safety Reminders



WARNING:

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



WARNING:

Use the test data sheet to ensure the monitoring system passes all safety, performance, and functional tests prior to use in a clinical setting.



WARNING:

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



WARNING:

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



WARNING:

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



WARNING:

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



WARNING:

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



WARNING:

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



WARNING:

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



WARNING:

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



WARNING:

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

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WARNING:

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



Note:

The monitoring system incorporates watchdog timers that reset the monitoring system in the event of software errors. Any temporary limit settings are retained in the event of a watchdog reset.

5.3 Product Setup

The monitoring system receives power either from an AC connection (80-263 VAC) or from a 7.2-volt, 11.6 ampere-hour battery. The monitoring system internal battery can be used to power the monitoring system during transport or when AC power is not available. The monitoring system communicates the transition from AC power to battery power or from battery power to AC power via the AC power or battery indicator on the front panel.

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

5.3.1 Mounting Options and Transport Considerations

Users may choose from a variety of mounting configurations, including adapter plates, wall mounts, and pole mounts. Follow the installation instructions included with the mounting hardware.

Prior to intra-hospital transport, ensure the monitoring system interface is locked to avoid any inadvertent changes.

5.3.2 Connection to an AC Power Source



WARNING:

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

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Caution:

Use only a hospital-grade power cord.



Caution:

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



Caution:

Do not block cooling vents.

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

To connect to an AC power source

- 1. Plug the female connector end of the power cord into the power connector on the rear of the monitoring system. Reference *Rear Panel*, p. 4-6.
- 2. Plug the male connector of the power cord into a properly grounded AC outlet.



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



Note:

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

5.3.3 Battery Insertion



WARNING:

Install only Covidien-approved batteries.

The monitoring system ships with a separate internal battery. The battery must be installed prior to use in a clinical setting. Reference *Battery or Battery Access Door Replacement*, p. 12-7. Insert the battery and test the monitoring system prior to use in a clinical setting. Users should immediately and completely charge the battery prior to clinical use or temporary storage of the battery. Users should also remain vigilant when running on battery power and reconnect to AC power during a low battery state.

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5.3.4 Battery Charge



WARNING:

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



Caution:

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



Note:

Whenever the monitoring system is connected to AC power, the battery is charging.

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

To fully charge the battery

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



Verify the monitoring system is off and the AC Power/Battery Charging indicator lights. On AC power up, check the battery fuel gauge. If the gauge is empty or only partially full, the battery begins charging. The monitoring system operates on AC power while the battery is charging. When the monitoring system is fully charged, the green battery fuel gauge registers 100%. Note that when the monitoring system is connected to AC, a lightning bolt appears in the battery fuel gauge.



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

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system will not produce a low battery alarm for the standard CRITICALLY LOW BATTERY warning duration.

5.3.5 Battery Power Usage



WARNING:

Do not use monitoring system in a depleted battery condition.



Caution:

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

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

- No audible alarms sound
- No analog or serial output devices are attached to the monitoring system, including serial data, analog output, and nurse call output
- 25% monitoring screen brightness setting

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

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

- The monitoring system is running on battery power and the battery capacity remaining reaches 0%.
- The monitoring system has detected an internal temperature above 67 °C or 153 °F.

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5.4 Connection to Nellcor™ Sensors



WARNING:

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

The top of the monitoring system screen indicates the sensor type when connecting a recommended sensor to the monitoring system or when the monitoring system completes POST with an attached sensor.



Note:

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



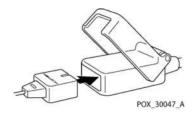
Note:

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

To fully connect a Nellcor™ sensor

- 1. Firmly connect a Nellcor™ interface cable to the monitoring system's sensor port. Reference *Front Panel*, p. 4-3, to identify the port.
- 2. Open the plastic latch at the other end of the interface cable.

Figure 5-1. Sensor Cable insertion into Interface Cable



- 3. Plug the interface cable and recommended sensor together.
- 4. Snap the plastic latch down over the connectors.

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- 5. Apply the recommended sensor to the patient after reading the *Instructions for Use* accompanying the sensor.
- 6. When the monitoring system detects a valid pulse, it enters the monitoring mode and displays real-time patient data.
- 7. Detach the recommended sensor from the patient on completion of monitoring.

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6 Operation

6.1 Overview

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

Perform regular maintenance and safety checks every 24 months. In the case of mechanical or functional damage, contact Covidien or a local Covidien representative.

6.2 Power



WARNING:

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



Caution:

Replace the internal battery every 24 months.



Caution:

Remove and store the internal battery if users expect a significant period of disuse.



Caution:

A normal power cycle or complete discharge of the battery results in a reset of all temporary user settings to factory or institutional default settings.

6.2.1 AC Power



When the user connects the monitoring system to an AC power source, if the internal battery requires charging, the battery condition indicator on the front panel lights until the internal battery reaches complete charge. In addition, when the monitoring system is powered on, the battery fuel gauge on the monitoring screen displays a lightning bolt indicating connection to AC.



If the user powers off the monitoring system while the internal battery is charging, the battery condition indicator remains lit and the internal fan turns on until charging completes. Reference *Connection to an AC Power Source*, p. 5-3.

6.2.2 Battery Power



WARNING:

Do not use monitoring system with a depleted battery or in a low voltage condition.

Battery Status

Reference *Battery Power Usage*, p. 5-6, for details on initial internal battery setup information.

The yellow BATTERY LOW warning flashes and a medium priority alarm sounds when approximately 14% capacity remains on the existing battery charge. The red BATTERY CRITICALLY LOW warning flashes and a high priority alarm sounds when approximately 4% capacity remains on the existing battery charge. The battery will drain completely and the monitoring system will shut down if not connected to AC power during a critically low battery condition. Reference *Battery Power Status*, p. 6-3, for a description of the low and critical battery conditions.

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

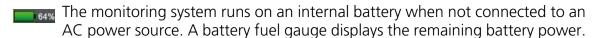
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Battery Fuel Gauge



Caution:

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



When connected to AC power, the battery fuel gauge displays a lightning bolt while charging and at full charge.

Reference *Connection to an AC Power Source*, p. 5-3. Reference *Battery Power Usage*, p. 5-6.



Note:

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



Note:

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

Table 6-1. Battery Power Status¹

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

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

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6.2.3 Power Up

Power Prerequisites



Caution:

If any pixel in the monitoring screen does not light at power up, do not use the monitoring system.



Caution:

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

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

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

Power-on Self-Test (POST)



WARNING:

Use the test data sheet to ensure the monitoring system passes all safety, performance, and functional tests prior to use in a clinical setting.



WARNING:

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



WARNING:

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

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WARNING:

Power-up performance tests verify both power-on self-test (POST) and power-on defaults and alarm range limits.

At power on, the monitoring system performs a power-on self-test (POST), which tests the circuitry and functions, then proceeds to the default monitoring screen. Attach a sensor cable and a recommended sensor and the monitoring system is ready to register and record patient trend data. Reference *Connection to Nellcor*TM *Sensors*, p. 5-7.



Note:

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



Note:

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



Note:

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

To power up the monitoring system

1. Connect the monitoring system to an AC power source.



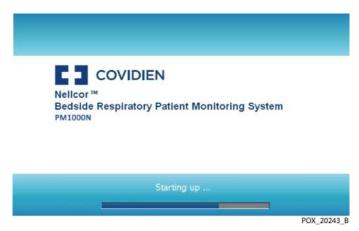
2. Verify the monitoring system is off and the AC Power Indicator lights.



- 3. Turn on the monitoring system by pressing the POWER ON key.
- 4. Within ten seconds, all pixels should illuminate. The monitoring screen should display a corporate logo and the firmware version of the monitoring system.
- 5. Observe the monitoring screen for the POST splash screen, which appears for approximately five (5) seconds.
- 6. Listen for three ascending tones then a one-second beep, indicating proper operation of the speaker and successful completion of power-on self-test.

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Figure 6-1. Sample POST Splash Screen



If the monitoring system detects an internal problem during the POST process, an error tone sounds and the monitoring system displays an error message. Reference *Troubleshooting*, p. 11-1.



Note:

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

6.2.4 System Resets

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

6.2.5 Automatic Shutdown and Power Off

Automatic Shutdown

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

- The monitoring system is running on battery power and the battery capacity remaining reaches 0%.
- The monitoring system has detected an internal temperature above 67 °C or 153 °F.

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Power Off



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

6.3 Nellcor™ Sensor Usage

Reference Connection to Nellcor™ Sensors, p. 5-7, for connecting the proper recommended sensor.

6.3.1 Sensor Detection



WARNING:

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



WARNING:

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



Caution:

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

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

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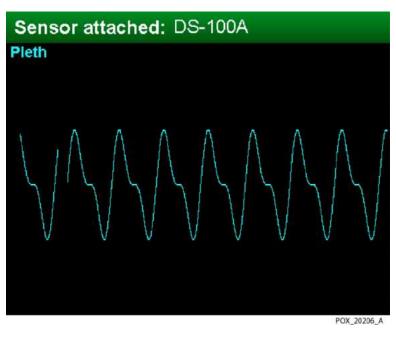


Figure 6-2. Sensor Type Message

The monitoring system displays dashes for %SpO₂ and Pulse Rate while searching for a valid pulse. For optimal performance, allow the monitoring system to search and lock onto a pulse for approximately five to ten seconds.

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

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

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

6.3.2 Sensor Detection Failure

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

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

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6.4 User Interface

6.4.1 Default Monitoring Screen and Trend Data

Users receive monitoring system information via the monitoring screen. This is particularly relevant to real-time and historical patient trend data, which may appear as a plethysmographic waveform, a blip bar, a graph, or saturation and pulse rate values, depending on the accessed monitoring screen. Should the monitoring system detect corrupt trend data, it notifies the caregivers with a TREND DATA LOST message. Users may choose to adjust the monitoring screen layout as needed, and institutions may specify an alternate default. Institutional default settings require changes to the available options in Service Mode by a qualified service technician.



Figure 6-3. Default Monitoring Screen Layout

6.4.2 Status Messages and Alarms in the Monitoring Status Field

Users receive monitoring system information via the monitoring screen. The primary area is the monitoring status field. Background color provides an additional status cue. Reference *Alarm Management and Status Messages*, p. 6-10.

- **User prompts** This status type with a gray background prompts users to perform some action to obtain patient data.
- **Active status** This status type notifies users of the current, active monitoring system state. Green background indicates normal status, cyan background indicates the user has selected the menu option, listing main menu items in grey.

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- Alarm status This status type identifies alarm conditions from highest to lowest priority. If multiple alarms occur while users are choosing menu options, the vertical alarm list of messages appears with the highest priority alarms at the top. If more than three alarms are active, the list collapses into a single VIEW ALL ALARMS line containing the total number of active alarms. Each alarm contains a MORE INFO button. Pressing the MORE INFO button provides a detailed explanation and any corrective action required.
 - a. High priority alarms Alarm message appears on flashing red background. High priority alarms appear first when multiple alarms occur simultaneously.
 - b. **Medium priority alarms** Alarm message appears on flashing yellow background. Medium priority alarms appear after high priority alarms and before low priority alarms.
 - c. **Low priority alarms** Alarm message appears on steady yellow background. Low priority alarms appear after high or medium priority alarms.

6.4.3 Alarm Management and Status Messages

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

The monitoring system comes with factory default alarm limit thresholds for adult-pediatric patients and for neonate patients. Reference *To set institutional defaults*, p. 10-6. Institutions may opt for setting institutional default settings to override the factory defaults. In addition, users may also temporarily change alarm limits. Any temporary changes to alarm limit thresholds revert back to default alarm limit settings after power-off.



Note:

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

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Message Types

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

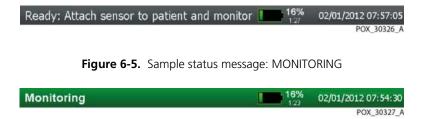


Note:

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

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

Figure 6-4. Sample user prompt message: READY



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

Figure 6-6. High priority alarm: BATTERY CRITICALLY LOW



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

Figure 6-7. Medium priority alarm: SpO2 LOW



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

Figure 6-8. Low priority alarm: SENSOR OFF



To correct a user prompt

- 1. Read the recommended action portion of the message.
- 2. Take the recommended action. The monitoring system triggers off the corrective action and automatically clears the message.
- 3. For multiple messages, press NEXT to view each message in order of priority.

To correct an alarm message

- 1. Press the MORE INFO button for the top, most important alarm message.
- Read the alarm message description.
- 3. Take the recommended action.
- 4. Clear the alarm message by pressing the EXIT or DISMISS ALARM button.

Limit Threshold Violation Indicators

The monitoring system reports real-time patient data. If that data falls outside the alarm limit thresholds, a threshold violation occurs. This triggers an alarm condition, resulting in a visual alarm. Reference *Visual Alarm Management*, p. 6-15. An audible alarm also results, unless a SILENCE ALARM (Audio Paused) or an AUDIO OFF condition exists. Reference *Audible Alarm Management*, p. 6-13.

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

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Figure 6-9. Sample Alarm Limit Violations

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

6.4.4 Audible Alarm Management



WARNING:

Do not silence or disable audible alarms if patient safety could be compromised. Do not dim or disable visual alarms if patient safety could be compromised.

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



Note:

Caregivers may monitor the patient remotely. Reference *Using the Nurse Call Interface*, p. 7-14. For institutions allowing caregivers to turn off all audible alarms and minimize or disable backlight brightness, refrain from reducing both audible and visual alarms unless using a remote monitoring system. When using a remote monitoring system, caregivers should still remain vigilant, periodically assessing patients.

SILENCE ALARM

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

SILENCE ALARM remains available at all times.



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



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

ALARM AUDIO OFF

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



Not active — If Alarm Silence Duration OFF is not active, it does not appear on the monitoring screen. Instead, the SILENCE ALARM icon remains white on a grey background.



Active — If Alarm Silence Duration OFF is active, the AUDIO OFF icon replaces the SILENCE ALARM icon. The AUDIO OFF icon is yellow on a grey background. A red alarm icon above the alarm limits indicates an active ALARM AUDIO OFF status.

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Note:

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



Note:

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

6.4.5 Visual Alarm Management



WARNING:

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

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



Note:

Caregivers may monitor the patient remotely. Reference *Using the Nurse Call Interface*, p. 7-14. For institutions allowing caregivers to turn off all audible alarms and minimize or disable backlight brightness, refrain from reducing both audible and visual alarms unless using a remote monitoring system. When using a remote monitoring system, caregivers should still remain vigilant, periodically assessing patients.



Note:

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

6.4.6 HELP Option

To access on-screen help topics

- \bigcap_{i}
- Press HELP. The appropriate help dialog window appears.
- 2. Review the help dialog box for guidance.
- 3. Press EXIT to return to normal monitoring.

6.5 Service Mode

 Table 6-2. Possible User Interface Settings

Option	Possible Setting	Factory Default			
Display Settings					
Monitor layout view	Pleth, Trend, Blip, Pleth and trend	Pleth			
Main screen trend parameters	SpO2, Pulse, SpO2 and pulse	SpO2 and pulse			
Main screen trend scale	15 or 30 minutes, 1, 2, 4, 8, 12, 24, or 48 hours	1 hour			
Monitoring history trend scale	15 or 30 minutes, 1, 2, 4, 8, 12, 24, or 48 hours	1 hour			
Screen Brightness	0, 25, 50, 75, 100%	75%			
Allow backlight OFF	Yes, No	No			
Wake display on alarm Yes, No		Yes			
Language	Croatian, Czech, Danish, Dutch, English, Estonian, Finnish, French, German, Greek, Hungarian, Italian, Japanese, Lithuanian, Norwegian, Polish, Portu- guese, Romanian, Russian, Serbian, Simplified Chi- nese, Slovak, Slovenian, Spanish, Swedish, Turkish	English			
	Sound Settings				
Alarm Volume		75%			
Button Click Volume	0, 25, 50, 75, 100% (min. 45dB, max > 85dB)	50%			
Pulse Beep Volume		50%			
	Monitoring Settings	•			
Date and time	Time: 24 hour format, Date: and date format	24 hour, MM/DD/YY			
Response mode	Normal, Fast	Normal			
Alarm mode	Adult/Neonate	Adult			

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 Table 6-3. Possible Alarm Management Settings

Option	Possible Setting	Factory Default		
		Adult	Neonate	
	Alarm System		•	
Allow SatSeconds	Yes/No		Yes	
Allow Pulse Rate Delay	Yes/No		Yes	
Allow OxiMax SPD™ Alert (SPD)	Yes/No		Yes	
SPD Audio Alert	Yes, No		Yes	
Allow alarm limits adjustments	Yes/No		Yes	
Allow alarm audio OFF	Yes/No		No	
Allow alarm silence duration OFF	Yes/No		No	
Alarm disabled reminder	Yes/No		Yes	
Silence Alarm	Yes/No, time remaining	No, no time displayed		
ALARM SILENCE Duration	OFF, 30, 60, 90, 120 seconds	120 seconds		
Sensor Alarm Priorities - Sensor Disconnect - Sensor Off - Sensor Failure Note: Each alarm can be set independently.	Low/Medium/High	Low		
	Alarm Limits			
Pulse rate upper alarm limit	Lower limit plus 1 to 250	170 BPM 190 BPM		
Pulse rate lower alarm limit	20 to upper limit minus 1	40 BPM 90 BPM		
SpO2 upper alarm limit	Lower limit plus 1 to 100	100% 95%		
SpO2 lower alarm limit	Upper limit minus 1 to 85	85%		
SatSeconds™ alarm management	OFF, 10, 25, 50, 100	100 OFF		
OxiMax SPD™ Alert (SPD)	OFF, 1, 2, 3	1 Not available		
Pulse rate delay	OFF, 5, 10	OFF		

Table 6-4. Possible Data Interface Settings

Option	Possible Setting	Factory Default
	Wireless LAN: ASCII, SPDOut	
Remote settings	LAN: ASCII, SPDOut	Disconnected
	Disconnected	
Nurse call priority, RS-232	Normally +, normally -	Normally +
	ASCII: 9600 or 19200 baud	
	Clinical: 19200 baud	
Serial connection	SPDout: 19200 or 115200 baud	ASCII, 9600 baud
	Philips: 19200 baud	
	OFF	
WLAN settings	Wi-Fi or Network Connection	None
LAN settings	WITH OF NELWORK CONNECTION	None

Table 6-5. Possible Service Functions

Option	Possible Setting	Factory Default		
Service Options				
Touch screen calibration	Yes, No	No		
Log Access				
View error, event, or software log	Populizas LICD flock deixa			
Export error, event, or software log	Requires USB flash drive			
Clear logs	Requires confirmation of desire to clear logs; not reversible			

All service function menus are accessible when the DOC-10 interface cable is disconnected from the monitoring system. Disconnect the DOC-10 interface cable from the monitoring system or disconnect the sensor from the DOC-10 interface cable.

To access service function menus

- 1. Connect the monitoring system to an AC power source.
- 2. Disconnect any Nellcor™ sensor from the sensor port.

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



4. Touch the monitoring screen at the prompt to enter Service Mode.



Note:

The monitoring system will eventually continue to boot if the user does not touch the monitoring screen at the Service Mode prompt.

Figure 6-10. Prompt to Enter SERVICE MODE



5. Enter 62907 as the service mode password at the prompt, using the onscreen number pad.



- 6. Press ENTER SERVICE MODE.
- 7. Select the desired menu option and any associated submenu options.

6.5.1 Settings Menu

Import and Export Settings

Both import settings and export settings function in the same fashion. Both require a USB flash drive. Reference *To export master institutional defaults*, p. 10-6. Reference *To import master institutional defaults*, p. 10-7.

Alarm System

Reference *To set institutional defaults*, p. 10-6, for modification of alarm system defaults.

Alarm Limits

Use this to set institutional alarm limit thresholds.

- **Set permissions for parameter alarms** Use to set SatSeconds, Pulse Rate Delay, and SPD parameter permissions.
- **Set permissions for alarm limit and audio alarm defaults** Use to set permissions for alarm limit adjustments, alarm audio OFF, setting alarm silence duration, and setting the alarm disabled reminder.
- **Set desired alarm silence duration default** Use to select the desired alarm silence duration default.
- Set desired alarm limit thresholds for adult and neonate mode Use to set SpO2 and pulse rate alarm limit thresholds, as well as SatSeconds, Pulse Rate Delay, and SPD parameter default settings.

To set SatSeconds™, Pulse Rate Delay, and SPD™ Alert parameter defaults

- 1. Access the service function menu. Reference *To access service function menus*, p. 6-18.
- Select SETTINGS.
- 3. Select ALARM SYSTEM.
- 4. Select the appropriate parameter.
 - Select ALLOW SATSECONDS to set the SatSeconds permissions default.
 - b. Select ALLOW PULSE RATE DELAY to set the Pulse Rate Delay permissions default.
 - c. Select ALLOW SPD to set the SPD permissions default.
 - d. Select SPD AUDIO ALERT to set the audio alert default for the SPD parameter.
- Select the desired default.
 - a. Select NO if the institution does not permit caregivers using the parameter.
 - b. Leave it YES if the institution permits caregivers using the parameter.
- 6. Select the desired option.
- 1
- a. Press SAVE CHANGES to retain the change.

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×

b. Press CANCEL to leave the default as it was.

To set alarm limit and audio alarm defaults

- 1. Access the service function menu. Reference *To access service function menus*, p. 6-18.
- 2. Select SETTINGS.
- 3. Select ALARM SYSTEM.
- 4. Select the appropriate parameter.
 - a. Select ALLOW ALARM LIMITS ADJUSTMENTS to set permissions for the adjustment of any alarm limit settings.
 - b. Select ALLOW ALARM AUDIO OFF to set permissions for alarm audio OFF.
 - c. Select ALLOW ALARM SILENCE DURATION OFF to set permissions for the adjustment of the alarm silence duration to OFF.
 - d. Select ALARM DISABLED REMINDER to set permissions for the alarm disabled reminder.
- Select the desired default.
 - a. Select NO if the institution does not permit caregivers using the parameter.
 - b. Leave it YES if the institution permits caregivers using the parameter.
- 6. Select the desired option.



- a. Press SAVE CHANGES to retain the change.
- X

ь. Press CANCEL to leave the default as it was.

To set the alarm silence duration

- 1. Access the service function menu. Reference *To access service function menus*, p. 6-18.
- Select SETTINGS.
- Select ALARM SYSTEM.
- 4. Select ADJUST ALARM SILENCE DURATION to set the alarm silence duration.
- 5. Select the desired default of 30, 60, 90, or 120 seconds or OFF.
- 6. Select the desired option.



- a. Press SAVE CHANGES to retain the change.
- ×
- b. Press CANCEL to leave the default as it was.

To set the alarm limit threshold defaults

- 1. Access the service function menu. Reference *To access service function menus*, p. 6-18.
- 2. Select SETTINGS.
- 3. Select ALARM LIMITS.
- 4. Select the desired mode: ADULT or NEONATE.



Note:

Pulse rate and SpO₂ thresholds are different for adults and neonates. In addition, the SPD alarm management parameter is not available for neonates.

- 5. Select the desired type of limit.
 - a. Select SpO2 and slide bars up or down to set upper and lower alarm limits.
 - b. Select PULSE and slide bars up or down to set upper and lower alarm limits.
 - c. Select SATSECONDS and set to 10, 25, 50, or 100 SatSeconds, or OFF.
 - d. Select SPD and set the sensitivity to 1, 2, or 3, or OFF.
 - e. Select PULSE RATE DELAY to 5 or 10 seconds, or OFF.
- 1
- Press SAVE CHANGES.
- ×
- 7. Press EXIT MENU to return to the Service Main Menu.

Sensor Alarm Priorities

Institutional default alarm priorities can be set for the following sensor alarms:

- Sensor Disconnected
- Sensor Off
- Sensor Failure

By default, these sensor alarms are low priority. They can be configured independently as high, medium, or low.

To set sensor alarm priorities

- 1. Access the service function menu. Reference *To access service function menus*, p. 6-18.
- 2. Select SETTINGS.
- 3. Select ALARM SYSTEM.

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- Select SENSOR ALARM PRIORITIES.
- 5. Select the desired priority (LOW, MEDIUM, or HIGH) for each of the sensor alarms.
- 1
- 6. Press SAVE CHANGES.
- ×
- 7. Press EXIT MENU to return to the Service Main Menu.

Display Settings

Provides means of creating and transferring institutional display settings.

- **Monitoring Layout** Use to set the default monitoring screen layout. The factory default is pleth only.
- Main Screen Trend Parameters Use to set the default trends for the main monitoring screen trend information. Default is SpO₂ and pulse.
- Main Screen Trend Scale Use to set the default trend scale when viewing trend information. Default is one (1) hour.
- **Monitoring History Scale** Use to set the default trend scale when viewing the monitoring history. Default is one (1) hour.
- **Backlight Brightness** Use to set the default backlight brightness. Default is 75% bright.
- Allow Backlight OFF Use to set permission for turning backlight completely
 off. Default is NO.
- Wake Display on Alarm Use to set the default for waking the display during an alarm condition. Default is YES.
- **Language** Use to set the default interface language. Default is English.

To set the default monitoring screen layout

- 1. Access the service function menu. Reference *To access service function menus*, p. 6-18.
- Select SETTINGS.
- Select DISPLAY SETTINGS.
- 4. Select MONITORING LAYOUT.
- 5. Select the desired default.

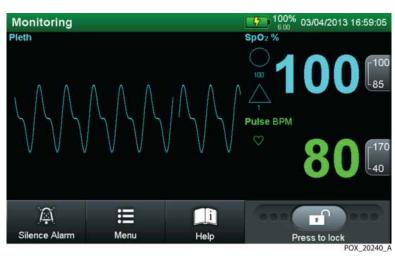


Figure 6-11. Default Monitoring Screen Layout

6. Select the desired option.



- a. Press SAVE CHANGES to retain the change.
- b. Press CANCEL to leave the default as it was.

To set the default main trend parameters

- 1. Access the service function menu. Reference *To access service function menus*, p. 6-18.
- Select SETTINGS.
- 3. Select DISPLAY SETTINGS.
- 4. Select MAIN SCREEN TREND PARAMETERS.
- 5. Select the desired default.
 - a. SpO2 only
 - b. Pulse only
 - c. SpO₂ and pulse
- 6. Select the desired option.



a. Press SAVE CHANGES to retain the change.



b. Press CANCEL to leave the default as it was.

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To set the default main trend scale or monitoring history trend scale

- 1. Access the service function menu. Reference *To access service function menus*, p. 6-18.
- 2 Select SETTINGS.
- 3. Select DISPLAY SETTINGS.
- 4. Select the desired option.
 - a. MAIN SCREEN TREND SCALE
 - b. MONITORING HISTORY TREND SCALE
- 5. Select the desired default.
 - a. Minutes: 15 or 30
 - ы. Hours: 1, 2, 4, 8, 12, 24, or 48
- 6. Select the desired option.



- a. Press SAVE CHANGES to retain the change.
- b. Press CANCEL to leave the default as it was.

To adjust default backlight brightness

- 1. Access the service function menu. Reference *To access service function menus*, p. 6-18.
- 2. Select SETTINGS.
- 3. Select DISPLAY SETTINGS.
- 4. Select BACKLIGHT BRIGHTNESS.
- 5. Adjust to the desired default brightness.



a. Press decrement (-) to decrease the default brightness.



- b. Press increment (+) to increase the default brightness.
- 6. Select the desired option.



- a. Press SAVE CHANGES to retain the change.
- b. Press CANCEL to leave the default as it was.

To set backlight OFF permission

- 1. Access the service function menu. Reference *To access service function menus*, p. 6-18.
- 2. Select SETTINGS.

- Select DISPLAY SETTINGS.
- 4. Select ALLOW BACKLIGHT OFF.
- 5. Select the desired default: YES or NO.
- 6. Select the desired option.
- 1
- a. Press SAVE CHANGES to retain the change.
- ×
- b. Press CANCEL to leave the default as it was.

To set Wake Display default

- 1. Access the service function menu. Reference *To access service function menus*, p. 6-18.
- Select SETTINGS.
- 3. Select DISPLAY SETTINGS.
- 4. Select WAKE DISPLAY ON ALARM.
- 5. Select the desired default: YES or NO.
- 6. Select the desired option.
- 1
- a. Press SAVE CHANGES to retain the change.
- ×
- b. Press CANCEL to leave the default as it was.

To adjust default language

- 1. Access the service function menu. Reference *To access service function menus*, p. 6-18.
- Select SETTINGS.
- 3. Select DISPLAY SETTINGS.
- 4. Select LANGUAGE.
- 5. Select the appropriate language from the list.
- 6. Select the desired option.
- 1
- a. Press SAVE CHANGES to retain the change.
- b. Press CANCEL to leave the default as it was.

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Sound Settings

Reference *Operational Setup*, p. 10-17, to configure alarm, pulse beep, and button click volume.

Connectivity Settings



WARNING:

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

- Remote Settings Use to set default connectivity for remote monitoring applications.
- **Nurse Call Polarity** Use to set default connectivity for nurse call polarity.
- **Serial Connection** Use to set default connectivity for the serial port.
- **WLAN Settings** Use to set default connectivity for WLAN networks.
- **LAN Settings** Use to set default connectivity for LAN networks.

Use the appropriate configuration information to ensure proper connectivity. Any equipment connected to the data port must be certified according to the latest IEC/EN 60950-1 standards. All combinations of equipment must be in compliance with Requirements for Medical Electrical Systems IEC Standard 60601-1: 2007. Anyone who connects equipment to the data output port is configuring a medical system and, therefore, is responsible for ensuring the system complies with the Requirements for Medical Electrical Systems IEC Standard 60601-1: 2007 and the electromagnetic compatibility IEC Standard 60601-1-2: 2007. Accuracy may degrade if it is connected to secondary I/O devices when equipment is not connected to earth reference.

- Connection to a network or data coupling that includes other equipment could result in previously unidentified risks to patients, operators or third parties, so it is the responsibility of the person configuring to identify, analyze, evaluate and control these risks.
- Any subsequent changes to the network or data coupling, such as network or data coupling configuration, connection or disconnection of additional or existing items or equipment, updates or upgrades to items or equipment, might introduce new risks, so requires re-evaluation and analysis.

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

appropriate equipment must be connected to a grounded AC power source.

Configuring any TCP/IP addresses or entering any network keys requires a USB keyboard.

To set default remote or serial connectivity

- 1. Access the service function menu. Reference *To access service function menus*, p. 6-18.
- Select SETTINGS.
- Select CONNECTIVITY SETTINGS.
- 4. Select the desired option.
 - Select REMOTE SETTINGS to set the remote connectivity default.
 - Select SERIAL CONNECTION to set the serial connectivity default.
- 5. Select the desired default. Reference *Input and Output Configuration Options*, p. 7-2, for a complete listing of setting options.
- Select the desired option.
- ×
- Press SAVE CHANGES to retain the change.
- Press CANCEL to leave the default as it was.

To set default WLAN or LAN network connectivity

- Access the service function menu. Reference *To access service function menus*, p. 6-18.
- Select SETTINGS.
- Select CONNECTIVITY SETTINGS.
- Select the desired option.
 - Select WLAN SETTINGS to set the WLAN connectivity default.
 - Select LAN SETTINGS to set the LAN connectivity default.
- Select the desired default. Reference *Input and Output Configuration Options*, p. 7-2, for a complete listing of setting options. Reference Network Configuration, p. 7-9, particularly in reference to the icon table for the configuration interface.
 - Select WI-FI to set a wireless connectivity default, using a USB keyboard to input any TCP/IP address or network key.
 - Select NETWORK CONNECTION to set the LAN connectivity default, using a USB keyboard to input any TCP/IP address or network key.
- Press FINISH to retain the change.

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To set default Nurse Call polarity

- Access the service function menu. Reference *To access service function menus*, p. 6-18.
- Select SETTINGS.
- 3. Select CONNECTIVITY SETTINGS.
- 4. Select NURSE CALL POLARITY.
- 5. Select the desired default: Normally high (+) or normally low (-).
- 6. Select the desired option.



- a. Press SAVE CHANGES to retain the change.
- b. Press CANCEL to leave the default as it was.

Monitoring Settings

- **Alarm Mode** Use to set the default alarm mode to adult settings or neonate settings.
- **Date and Time** Use to set the default display for date and time or after a software update.
- **Response Mode** Use to set the default response mode.

To set alarm mode default

- 1. Access the service function menu. Reference *To access service function menus*, p. 6-18.
- 2. Select SETTINGS.
- 3. Select MONITORING SETTINGS.
- 4. Select ALARM MODE.
- 5. Select the desired default.
 - a. Adult alarm settings
 - ь. Neonate alarm settings
- 6. Select the desired option.



- a. Press SAVE CHANGES to retain the change.
- b. Press CANCEL to leave the default as it was.

To set default date and time

- 1. Access the service function menu. Reference *To access service function menus*, p. 6-18.
- Select SETTINGS.
- 3. Select MONITORING SETTINGS.
- 4. Select DATE AND TIME.
- 5. Adjust to the desired default time in hours, minutes, and seconds.
 - a. Press the desired hour, minute, or second.
 - b. Press decrement (-) to decrease the hour, minute, or second.
 - c. Press increment (+) to increase the hour, minute, or second.
- 6. Adjust to the desired default date by month, day, or year.
 - a. Press the desired month, day, or year.
 - b. Press decrement (-) to decrease the month, day, or year.
 - c. Press increment (+) to increase the month, day, or year.
- 7. Adjust to the desired date format.
 - a. Press DATE FORMAT to display YY/MM/DD.
 - b. Press again to display DD/MM/YY.
 - c. Press again to revert to the default MM/DD/YY.
- 8. Select the desired option.



- a. Press SAVE CHANGES to retain the change.
- b. Press CANCEL to leave the default as it was.

To set default response mode

- 1. Access the service function menu. Reference *To access service function menus*, p. 6-18.
- 2. Select SETTINGS.
- 3. Select MONITORING SETTINGS.
- 4. Select RESPONSE MODE.
- 5. Select the desired default: NORMAL or FAST.
- 6. Select the desired option.

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- 1
- a. Press SAVE CHANGES to retain the change.
- ×
- b Press CANCEL to leave the default as it was.

Restore Factory Defaults

Proceed only if institutional defaults require replacement with the standard factory defaults.

To restore institutional defaults back to factory defaults

- 1. Access the service function menu. Reference *To access service function menus*, p. 6-18.
- 2. Select SETTINGS.
- 3 Select RESTORE FACTORY DEFAULTS.
- 4. Select the desired option.
- ×
- a. Press YES to restore the factory defaults.
- b. Press CANCEL to retain the factory defaults.
 - 5. Select the desired option.
- a. Press BACK to return to the previous submenu.
- b. Press EXIT MENU.

6.5.2 Service Menu

Reference *Monitoring Screen Calibration*, p. 10-44, for monitoring screen calibration instructions. Reference *Software and Firmware Upgrades*, p. 10-45, for software or firmware upgrade instructions.

6.5.3 Logs Menu

Error, event, and software update logs remain in flash until the monitoring system overwrites them and will survive both power cycles and software upgrades. If a user chooses to "clear" a log, the monitoring system renames the current log files, rather than deleting them. Possible scenarios for either file corruption or a partial loss of data in a log would include backdating the monitoring system when it has already recorded data to an existing date or a power interrupt during retrieval of a log.

To view logs

- 1. Access the service function menu. Reference *To access service function menus*, p. 6-18.
- Select LOGS.
- 3. Select the desired option.
 - a. Select VIEW ERROR LOG to review any system errors.
 - b. Select VIEW EVENT LOG to review any historical events.
 - c. Select VIEW SW UPDATE LOG to review the software update log.
- 4. Review the desired information by scrolling or using navigational buttons such as FIRST, PREVIOUS, NEXT, or LAST.
- ★ 5. Press CANCEL.

To export logs

- 1. Access the service function menu. Reference *To access service function menus*, p. 6-18.
- 2. Select LOGS.
- 3. Select the desired option.
 - a. Select EXPORT LOGS to export any system errors and historical events.
 - b. Select EXPORT SW UPDATE LOG to export the software update log.
- 4. Attach a USB flash drive to the USB port.
- 5. Press NEXT.
 - 6. Wait for the export to complete.
- 7. Press FINISH.
 - 8. Select the desired option.
- a. Press BACK to return to the previous submenu.
- b. Press EXIT MENU.

6.5.4 Covidien Service Menu

This is only for Covidien internal personnel. Do not access.

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6.5.5 Parameter Activation Menu

Utilize this menu in conjunction with any upgrades to the parameter module. The upgrade will come with instructions for that particular parameter.

To activate a parameter already installed in the monitoring system

- 1. Access the service function menu. Reference *To access service function menus*, p. 6-18.
- 2 Select PARAMETER ACTIVATION.
- 3. Select the desired parameter.
- 4. Select the desired option.
 - a. Press NEXT, then follow instructions per the activation instructions in the upgrade kit.
- b. Press CANCEL.

X

- 5. If continuing, press NEXT.
- 6. If continuing, press FINISH.
 - 7. Select the desired option.
- a. Press BACK to return to the previous submenu.
- b. Press EXIT MENU.

6.5.6 About Monitor Menu

This screen provides model, serial number, version of software, MAC addresses, and IP addresses, if assigned, for LAN or WLAN connectivity.

To obtain information about the monitoring system

- 1. Access the service function menu. Reference *To access service function menus*, p. 6-18.
- 2. Select ABOUT MONITOR.
- 3. Review data.
- 4. Select the desired option.
- a. Press FINISH to complete the review.
 - ь. Press CANCEL.
 - 5. Select the desired option.



a. Press an alternate menu option.



b. Press EXIT AND RESTART to exit SERVICE MODE.

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7 Trend Data Access

7.1 Overview

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

7.2 Trend Data Management



WARNING:

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

7.2.1 Trend Data Basics

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

Users may view real-time and historical trend data on the monitoring screen. Users may also control the type and amount of visible trend data for a selected span of time. All trend data appears in a graphical format except the Clinical Log which appears in tabular format. The default setting is 1 hour of trend data.

Users may also choose to download trend data in a digital file, print it after downloading, or clear trend data information.

Should the monitoring system detect corrupt trend data, it notifies the caregivers with a TREND DATA LOST message.



Note:

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

7.3 Data Port Connectivity

7.3.1 Overview

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

- 1. **Serial DB-15 data port** This female DB-15 port provides RS-232, RS-422, and differential transmission data connectivity. Use for sending historical trend data to a serial printer for an ASCII print-out.
- 2. **RJ-45 port** This female 100-base-T, wired, ethernet-capable port provides connectivity for digital data output.
- 3. **Serial USB port** This female USB port allows for faster data transfers. Use this port for updating firmware or for digital data output storage.
- 4. **Radio-frequency (RF) antennae** Two radio-frequency antennae broadcast data to a wireless LAN network, should the proper configuration exist.

Mutually Exclusive External Serial		Mutually Exclusive Remote	
ASCII	9600 baud		LAN
ASCII	19200 baud	ASCII	Wireless LAN
Philips	19200 baud		
Clinical	19200 baud		LAN
SPDOut	19200 baud	SPDOut	Wireless LAN
3FDOUL	115200 baud		
OFF		Disconnected	

Table 7-1. Input and Output Configuration Options

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7.3.2 Typical Equipment Used for Connectivity

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

 Table 7-2.
 Sample Equipment Types

Туре	Description		
	Serial connection		
Philips Open Interface 25-pin cable	Wired connection to Philips Vuelink networked platform		
RJ-45 serial cable	RJ-45 to DB-15M adapter; wired connection to hospital network		
DB-15 PC-X cable	DB-15M cable obtains dumps and allows for debug		
	USB connection		
USB flash drive	Any model		
USB keyboard	Any model		
Ethernet connection			
CAT-3 or CAT-4 cable	10base-T connection to network		
Cat 5 cable	100base-T connection to network		

7.3.3 Data Port Configuration Information



WARNING:

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



WARNING:

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



WARNING:

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



Caution:

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

Use the appropriate configuration information to ensure proper connectivity.

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

- Connection to a network or data coupling that includes other equipment could result in previously unidentified risks to patients, operators or third parties, so it is the responsibility of the person configuring to identify, analyze, evaluate and control these risks.
- Any subsequent changes to the network or data coupling, such as network or data coupling configuration, connection or disconnection of additional or existing items or equipment, updates or upgrades to items or equipment, might introduce new risks, so requires re-evaluation and analysis.

Serial DB-15 Requirements



Caution:

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

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Figure 7-1. DB-15 Pin Layout

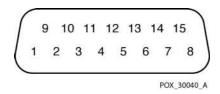


Table 7-3. DB-15 Signal Pinouts

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

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

- **RS-232 Format** Pins 2, 3, and 5 provide RS-232 format data. When building an RS-232 cable, do not add a resistor and keep cable length to a maximum of 25 feet.
- **RS-422 Format** Pins 1 and 4 (TxD+ and TxD-) are the differential transmit data pair. Pins 9 and 12 (RxD+ and RxD-) are the differential receive data pair. They provide RS-422 format data. When building an RS-422 cable, add a resistor (120 ohms, 1/2 watt, 5%) between pin 1 and pin 9 of the cable and keep cable length to a maximum of 4,000 feet. Plug the end of the cable with the resistor added into the monitoring system.

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

- An AMP connector (AMP part number 747538-1)
- A ferrule (AMP part number 1-747579-2)
- Compatible pins (AMP part number 66570-2)

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

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

100base-T RJ-45 Requirements



Caution:

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

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



Note:

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

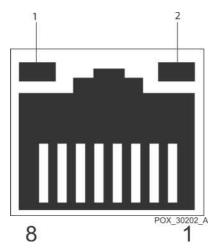


Note:

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

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Figure 7-2. RJ-45 Receptacle



LED 1 Indicates data exchange
 LED 2 Indicates a valid 100base-T TCP/IP link

Figure 7-3. RJ-45 Pin Layout

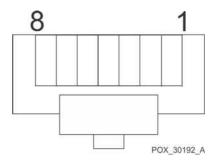


 Table 7-4.
 RJ-45 Signal Pinouts

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

USB Data Port Requirements



Caution:

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

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

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

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

Figure 7-4. USB Pin Layout

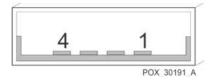


Table 7-5. USB Signal Pinouts

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

To export trend data

- 1. Remove any sensor or interface cable connection to the sensor port.
- Press MENU.
- 3. Press DATA EXPORT.
- 4. Insert a virus-free USB flash drive into the USB port.

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- 5. To include event markers in the exported data, select INCLUDE EVENT MARKERS.
- 6. Press NEXT.
 - 7. **Wait for the prompt** to remove the USB flash drive once the export completes. DO NOT remove the USB flash drive prior to receiving the prompt to do so.



Note:

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

- 8. Remove the USB flash drive.
- 1
- 9. Press FINISH.

Network Configuration

This option provides for both wired and wireless LAN network connectivity. The monitoring system will automatically associate with the first available network, using the appropriate previously established configuration. Configuring a network can only be performed through the Service Menu connectivity options. Reference *Connectivity Settings*, p. 6-27. The wireless configuration supports either ASCII or SPDout options and will both transmit and receive data on an active wireless connection. Users may choose to configure multiple wireless networks.



Note:

By default, the monitoring system is set for 802.11b/g with U.S. regulatory domain settings. If the monitoring system is installed outside the U.S., it must be configured for the appropriate regulatory domain by a Covidien service representative. A service representative may also change the 802.11 frequency band upon customer request to enable 802.11a communications.

Table 7-6. Network Configuration Icons

lcon	Description
0	Radio power, press to turn OFF; default after power cycle is ON
•	Active wireless connection
O	Establishing wireless connection

Table 7-6. Network Configuration Icons (Continued)

lcon	Description
	Delete network configuration
	Secured network
	Types of security supported:
	Open (no security)
	• WEP
	WPA Personal (with TKIP or AES encryption)
	WPA2 Personal (with TKIP or AES encryption)
aitl	Wireless signal strength
•	Network properties

To configure a network connection

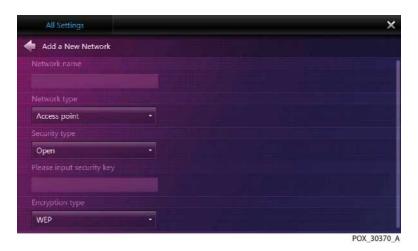
- 1. Establish a wireless LAN or LAN connection. Reference *To set default WLAN or LAN network connectivity*, p. 6-28.
- 2. For detailed configuration options, press the NETWORK PROPERTIES icon.
 - 3. Attach a USB keyboard to enter any alphanumeric information.
 - 4. Detach the USB keyboard.
- 5. Press FINISH.

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To add a new network

- 1. Establish a wireless LAN or LAN connection. Reference *To set default WLAN or LAN network connectivity*, p. 6-28.
- 2. Press ADD A NETWORK.

Figure 7-5. New Network Connection Windows



- 3. Attach a USB keyboard to enter any alphanumeric information.
- 4. Type in the assigned network name.
- 5. Select the network type.
- 6. Select the security type.
- 7. Input the security key.
- 8. Select the encryption type.
- 9. Detach the USB keyboard.
- 10. Close the network connection window by pressing the "X" in the top, right corner.
- 11. Close the control panel window by pressing the "X" in the top, right corner.

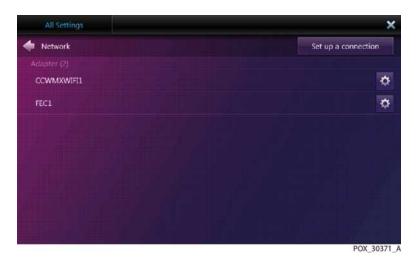
1

12. Press FINISH.

To setup a new network connection

- Establish a wireless LAN or LAN connection. Reference To set default WLAN or LAN network connectivity, p. 6-28.
- 2. Press NETWORK CONNECTION.
- 3. Press SET UP A CONNECTION.

Figure 7-6. New Network Connection Windows



- 4. Press the available, desired option from broadband, dial-up, or VPN.
- 5. Attach a USB keyboard to enter any alphanumeric information.
- 6. Input the assigned user name.
- 7. Input the assigned password.
- 8. Input the appropriate phone number.
- 9. Select or input the connection name.
- 10. Determine whether to remember the user name and password.
- 11. Press CONNECT or OK.
- 12. Detach the USB keyboard.
- 13. Close the network connection window by pressing the "X" in the top, right corner.

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- 14. Ensure the new network connection appears in the list of possible options.
- 15. Close the control panel window by pressing the "X" in the top, right corner.



16. Press FINISH.

To set a static IP address for an established wireless LAN connection

- 1. Access the service function menu. Reference *To access service function menus*, p. 6-18.
- Select SETTINGS.
- 3. Select CONNECTIVITY SETTINGS.
- 4. Select WLAN Settings.



- 5. Press the NETWORK PROPERTIES icon next to the desired network.
- 6. Press "IP properties."
- 7. Press "Static" in the upper, right corner.
- 8. Attach a USB keyboard.
- 9. Input the IP address and subnet mask.
- 10. Press "IP Properties."
- 11. Press "Network Properties."
- 12. Close the window by pressing the "X" in the top, right corner.
- 13. Detach the USB keyboard.



14. Press FINISH.

To set a static IP address for an established LAN connection

- 1. Access the service function menu. Reference *To access service function menus*, p. 6-18.
- Select SETTINGS.
- 3. Select CONNECTIVITY SETTINGS.
- 4. Select LAN Settings.



5. Press the NETWORK PROPERTIES icon next to the desired adapter.



- Disable the Dynamic Host Configuration Protocol by pressing the button next to "Obtain an IP address automatically."
- 7. Attach a USB keyboard.
- 8. Input the IP address and subnet mask.
- 9. Scroll to the bottom of the screen and press OK.
- 10. Close the window by pressing the "X" in the top, right corner.
- 11. Detach the USB keyboard.



12. Press FINISH.

7.3.4 Data Port Communications

To setup data port communication



- 1. While in normal monitoring mode, press MENU.
- 2. Press CONNECTIVITY SETTINGS.
- 3. Select the desired protocol for data exchange.



4. Press SAVE CHANGES to save the selected setting.

7.4 Using the Nurse Call Interface

7.4.1 Nurse Call Feature



WARNING:

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



WARNING:

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

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WARNING:

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

The nurse call feature allows caregivers to remotely monitor patient alarms and works in conjunction with the institution's nurse call system. Reference *DB-15 Pin Layout*, p. 7-5 for port pinouts.

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

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

Pin 11 on the data port is the RS-232 level nurse call signal and pin 5 or 10 is ground. Reference *DB-15 Pin Layout*, p. 7-5. With no alarm condition, the voltage between pins 10 and 11 are -5 VDC to -12 VDC, or +5V DC to +12 VDC, depending on the option chosen (either NORM+ or NORM-). With an audible alarm, the output between pins 5 and 11 will reverse polarity.

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

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

Table 7-7. Nurse Call Relay Pin States

Test the nurse call function prior to using it in any institution and whenever setting up the monitoring system in a location that uses nurse call. Users should periodically confirm not only a firm connection of cables, but also periodically confirm the functionality of the connection. If an attached recommended sensor is not connected to a patient, the screen does not register any data and the monitoring system remains in the Pulse Search Mode for five seconds, then the monitoring system displays three dashes [- - -] in the %SpO₂ and pulse rate area of the screen. One way to test the nurse call function is to

create an alarm condition (for example, SENSOR DISCONNECT) and verify activation of the institution's nurse call system.

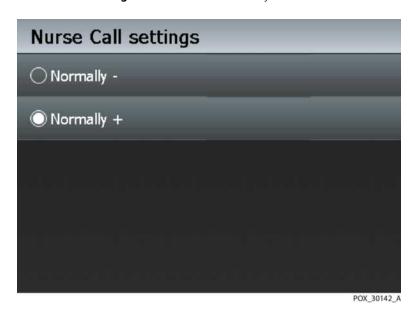
7.4.2 Setting Nurse Call RS-232 Polarity

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

To set nurse call polarity

- ŧ≡
- 1. While in normal monitoring mode, press MENU.
- 2. Press CONNECTIVITY SETTINGS.
- 3. Press NURSE CALL SETTINGS.

Figure 7-7. Nurse Call Polarity Screen



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



5. Press SAVE CHANGES to save the selected setting.

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7.5 Calculating the Analog Voltage Output

The data port provides analog voltage outputs between pins 6, 13, 14, and ground (pin 10), which can be used to calibrate devices such as a chart recorder. The voltage represents a specific measured parameter's current value. The voltage differential varies proportionally from 0.0 to ± 1.0 VDC as the pin's parameter varies over its full range of values. For example, as the current value of SpO₂ varies from 0 to 100%, the voltage from pin 6 to ground (pin 10) varies from 0.0 to ± 1.0 VDC. A voltage of 0.94 volts indicates a current SpO₂ value of 94.

Table 7-8. Analog Pinouts

Pin	Parameter	Parameter Range
6	Saturation	0 - 100%
13	Pulse Rate	0 - 250 bpm
14	Waveform	0 - 254 PAU

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8 Performance Considerations

8.1 Overview

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

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

8.2 Oximetry Considerations

8.2.1 Monitoring System Constraints

- **Pulse Rate** The monitoring system only displays pulse rates between 20 and 250 bpm. Detected pulse rates above 250 bpm appear as 250. Detected pulse rates below 20 appear as a zero (0).
- **Saturation** The monitoring system displays saturation levels between 1% and 100%.

8.2.2 Nellcor™ Sensor Performance Considerations



WARNING:

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



WARNING:

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



WARNING:

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



WARNING:

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

Inaccurate Sensor Measurement Conditions

A variety of conditions can cause inaccurate sensor measurements.

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

Signal Loss

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

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

Recommended Usage

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

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

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

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

If poor perfusion affects performance, consider using the Nellcor[™] forehead SpO₂ sensor (Max-Fast), which provides superior detection in the presence of vasoconstriction. Nellcor[™] forehead SpO₂ sensors work particularly well on supine patients and mechanically ventilated patients. During low perfusion conditions, Nellcor[™] forehead SpO₂ sensors reflect changes to SpO₂ values up to 60 seconds earlier than digit sensors.

8.3 Patient Conditions

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

- **Anemia** Anemia causes decreased arterial oxygen content. Although SpO₂ 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 SpO₂ reading if hemoglobin levels fall below 5 gm/dl.
- **Dysfunctional hemoglobins** Dysfunctional hemoglobins such as carboxyhemoglobin, methemoglobin, and sulfhemoglobin are unable to carry oxygen. SpO2 readings may appear normal; however, a patient may be hypoxic because less hemoglobin is available to carry oxygen. Further assessment beyond pulse oximetry is recommended.
- Additional possible patient conditions may also influence measurements.
 - Poor peripheral perfusion
 - Excessive patient movement

- Venous pulsations
- Dark skin pigment
- Intravascular dyes, such as indocyanine green or methylene blue
- Externally applied coloring agents (nail polish, dye, pigmented cream)
- Defibrillation

8.4 Reducing EMI (Electromagnetic Interference)



WARNING:

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



WARNING:

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



Caution:

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

Because of the proliferation of radio frequency transmitting equipment and other sources of electrical noise in health care environments (for example, electrosurgical units, cellular phones, mobile two-way radios, electrical appliances, and high-definition television), it is possible that high levels of such interference due to close proximity or strength of a source might result in disruption of monitoring system performance. Reference *Electromagnetic Emissions*, p. 2-7.

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

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of use to determine the source of this disruption, and take the listed actions to eliminate the source.

- Turn equipment in the vicinity off and on to isolate the interfering equipment.
- Reorient or relocate the interfering equipment.
- Increase the separation between the interfering equipment and the monitoring system.

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

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9 Product Maintenance

9.1 Overview

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

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

- **Surface cleaning** Use a soft cloth dampened with either a commercial, non-abrasive cleaner or a solution of 70% alcohol in water, lightly wiping the surfaces of the monitoring system.
- **Disinfection** Use a soft cloth saturated with a solution of 10% chlorine bleach in tap water, lightly wiping the surface of the monitoring system.

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

9.3 Periodic Safety Checks

Perform the following checks every 24 months.

- Inspect the monitoring system for mechanical and functional damage or deterioration.
- Inspect the safety relevant labels for legibility. Contact Covidien or a local Covidien representative, if labels are damaged or illegible.
- Inspect the internal fuses for proper value and rating.
- Ensure all user interface items, cables, and accessories function normally.

9.4 Service and Upgrades



WARNING:

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

- The monitoring system generally requires no calibration. In rare instances, the monitoring screen requires re-calibration. Reference *Operational Performance Issues*, p. 11-17.
- Replace the battery at least every 24 months.



Note:

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

9.5 Storage

9.5.1 Monitoring System Transport and Storage

The only true difference between transport and storage with or without the shipping container is in the temperature. It is less tolerant of heat when not in a shipping container. Reference *Transport and Storage*, p. 2-3.

9.5.2 Removed Battery Storage

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

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10 Modification and Testing

10.1 Overview

This chapter provides information on setting institutional defaults, verifying Nellcor™ Bedside Respiratory Patient Monitoring System performance, and accessing service functions.

- User interface customization
 - Display settings Access monitoring layout, trend scale defaults, backlight options, and language settings
 - **Sound settings** Access pulse beep, alarm, and interface volume settings
- Alarm management customization
 - **Monitoring settings** Access response mode or data and time settings
 - Alarm system settings Access settings for SatSeconds, pulse rate delay, SPD Alert, alarm audio off, audio silence duration, alarm disabled reminder, alarm silence duration, and sensor alarm priorities
 - Import and export settings Transfer of default settings from one monitoring system to another
- **Data Interface customization** Access remote monitoring, serial, and wired or wireless settings
- System maintenance
 - Service options Perform touchscreen calibration, software and firmware upgrades
 - **System logs** Access or clear error logs or event logs, and/or upgrade logs
 - **Parameter activation** Access parameter activation or deactivation options

Service functions can be used to select institutional defaults and to access information about the patient or pulse oximeter. Only a trained Covidien Customer Service Technician, qualified service technician, or clinical engineer should access many of the items available through the service functions.

Use the following list as a quick reference for different functions. The Service Menu options provide access to several submenus.

 Table 10-1.
 Possible User Interface Settings

Option	Possible Setting	Factory Default
	Display Settings	
Monitor layout view	Pleth, Trend, Blip, Pleth and trend	Pleth
Main screen trend parameters	SpO2, Pulse, SpO2 and pulse	SpO2 and pulse
Main screen trend scale	15 or 30 minutes, 1, 2, 4, 8, 12, 24, or 48 hours	1 hour
Monitoring history trend scale	15 or 30 minutes, 1, 2, 4, 8, 12, 24, or 48 hours	1 hour
Screen Brightness	0, 25, 50, 75, 100%	75%
Allow backlight OFF	Yes, No	No
Wake display on alarm	Yes, No	Yes
Language	Croatian, Czech, Danish, Dutch, English, Estonian, Finnish, French, German, Greek, Hungarian, Ital- ian, Japanese, Lithuanian, Norwegian, Polish, Por- tuguese, Romanian, Russian, Serbian, Simplified Chinese, Slovak, Slovenian, Spanish, Swedish, Turkish	English
	Sound Settings	
Alarm Volume		75%
Button Click Volume	0, 25, 50, 75, 100% (min. 45dB, max > 85dB)	50%
Pulse Beep Volume		50%
	Monitoring Settings	
Date and time	Time: 24 hour format, Date: and date format	24 hour, MM/DD/YY
Response mode	Normal, Fast	Normal
Alarm mode	Adult, Neonate	Adult

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 Table 10-2.
 Possible Alarm Management Settings

Option	Possible Setting	Factory Default	
		Adult	Neonate
	Alarm System		
Allow SatSeconds	Yes/No		Yes
Allow Pulse Rate Delay	Yes/No	Yes	
Allow OxiMax SPD™ Alert (SPD)	Yes/No	Yes	
SPD Audio Alert	Yes, No	Yes	
Allow alarm limits adjustments	Yes/No	Yes	
Allow alarm audio OFF	Yes/No	No	
Allow alarm silence duration OFF	Yes/No	No	
Alarm disabled reminder	Yes/No	Yes	
Silence Alarm	Yes/No, time remaining	No, no time displayed	
ALARM SILENCE Duration	OFF, 30, 60, 90, 120 seconds	120 seconds	
Sensor Alarm Priorities - Sensor Disconnect - Sensor Off - Sensor Failure Note: Each alarm can be set independently.	Low/Medium/High		Low
	Alarm Limits		
Pulse rate upper alarm limit	Lower limit plus 1 to 250	170 BPM	190 BPM
Pulse rate lower alarm limit	20 to upper limit minus 1	40 BPM	90 BPM
SpO2 upper alarm limit	Lower limit plus 1 to 100	100%	95%
SpO2 lower alarm limit	m limit Upper limit minus 1 to 85 85%		85%
SatSeconds™ alarm management	OFF, 10, 25, 50, 100	100	OFF
OxiMax SPD™ Alert (SPD)	OFF, 1, 2, 3	1	Not available
Pulse rate delay	OFF, 5, 10	OFF	

Table 10-3. Possible Data Interface and Service Settings

Option	Possible Setting	Factory Default
Data Interface Options		
	Wireless LAN: ASCII, SPDOut	
Remote settings	LAN: ASCII, SPDOut	Disconnected
	Disconnected	
Nurse call priority, RS-232	Normally +, normally -	Normally +
	ASCII: 9600 or 19200 baud	
	Clinical: 19200 baud	
Serial connection	SPDout: 19200 or 115200 baud	ASCII, 9600 baud
	Philps: 19200 baud	
	OFF	
Service Options		
Touch screen calibration	Yes, No	No

All service function menus are accessible when the DOC-10 interface cable is disconnected from the monitoring system. Disconnect the DOC-10 interface cable from the monitoring system or disconnect the sensor from the DOC-10 interface cable.

To access service function menus

- 1. Connect the monitoring system to an AC power source.
- 2. Disconnect any Nellcor[™] sensor from the sensor port.



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



4. Touch the monitoring screen at the prompt to enter Service Mode.



Note:

The monitoring system will eventually continue to boot if the user does not touch the monitoring screen at the Service Mode prompt.

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Figure 10-1. Prompt to Enter SERVICE MODE



Enter 62907 as the service mode password at the prompt, using the onscreen number pad.



- 6. Press ENTER SERVICE MODE.
- 7. Select the desired menu option and any associated submenu options.

10.2 Setting Institutional Defaults

Change power-on default values to institutional power-on default values using the monitoring system's service mode.



WARNING:

Audible alarms should not be silenced if patient safety could be compromised.



Note:

Set temporary desired limits during normal operation mode.



Note:

To mirror any institutional default settings from an identical monitoring system, export settings from the master monitoring system. Reference *To export master institutional defaults*, p. 10-6.

To set institutional defaults

- 1. Access the service function menu. Reference *To access service function menus*, p. 10-4.
- Select SETTINGS.
- 3. To mirror any existing institutional defaults, select the IMPORT AND EXPORT SET-TINGS menu.
- 4. Select IMPORT SETTINGS.
- 5. Insert a USB flash drive containing the master institutional default settings.
- 6. Press NEXT.

To export master institutional defaults



Note:

Network settings are not included in the export.

- 1. Access the service function menu. Reference *To access service function menus*, p. 10-4.
- 2. Select SETTINGS.
- 3. Select IMPORT AND EXPORT SETTINGS.
- 4. Select EXPORT SETTINGS.
- 5. Insert a USB flash drive for retaining the master institutional default settings.
- 6. Press NEXT.
 - 7. Remove the USB flash drive at the prompt.
- 8. Press FINISH.
- 9. Press EXIT MENU.
- 10. Press EXIT AND RESTART.
- 11. Press YES.

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To import master institutional defaults



Note:

Settings may only be imported from exports created with the same software version. Do not attempt to import settings from a monitoring system with a different software version.



Note:

Network settings are not affected by the import.

- 1. Access the service function menu. Reference *To access service function menus*, p. 10-4.
- 2. Select SETTINGS.
- 3. Select IMPORT AND EXPORT SETTINGS.
- Select IMPORT SETTINGS.
- 5. Insert a USB flash drive containing the master institutional default settings.
- 6. Press NEXT.
- 7. Press NEXT after ensuring the **ApplicationSettingsFile.xml** option is selected.
 - 8. Remove the USB flash drive at the prompt.
- 9. Press FINISH.
- 10. Press EXIT MENU.
- 11. Press EXIT AND RESTART.
- 12. Press YES.

To restore factory defaults

- 1. Access the service function menu. Reference *To access service function menus*, p. 10-4.
- Select SETTINGS.
- Select RESTORE FACTORY DEFAULTS.
- 4. Press YES.
- 5. Press FINISH.

×

6. Press EXIT MENU.



7. Press EXIT AND RESTART.



8. Press YES.

10.3 Performance Verification



WARNING:

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

10.3.1 Overview

This section discusses the tests used to verify performance following repairs or during routine maintenance. All tests can be performed without removing the monitoring system enclosure. Perform all tests before the battery charge and battery performance checks, then perform both battery checks as the last operation before returning the monitoring system to the caregiver. If the monitoring system fails to perform as specified in any test, make all repairs necessary to correct the problem before returning the monitoring system to the caregiver.

10.3.2 Required Equipment

Table 10-4. Equipment and Descriptions

Equipment	Description
Nellcor™ SRC-MAX functional oximetry tester	Provides monitoring system simulation
Nellcor™ Adult SpO2 Sensor, Reusable	DS-100A
Nellcor™ Adult SpO2 Nasal Sensor	MAX-A
DOC-10 interface cable	Interface cable
Digital multimeter (DMM)	Fluke Model 87 or equivalent
Safety analyzer	Must meet current AAMI ESI & IEC 60601-1 specifications
Stop watch	Manual or electronic

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Table 10-4. Equipment and Descriptions (Continued)

Equipment	Description
9-pin to 15-pin D-connector, pins shorted together	Provides testing for service function menus
Data interface cable	RS-232 cable (optional)
Stylus or very fine, rounded pointer	For monitoring screen calibration

10.4 Safety Testing Standards

The monitoring system safety tests are performed in accordance with and meet the following standards. Also, see Reference *Battery Charge*, p. 10-10.

- IEC 60601-1: 1988 + A1: 1991 + A2: 1995
- EN 60601-1: 1990 + A11: 1993 + A12: 1993 + A13: 1996
- UL 60601-1 1st edition
- CSA C22.2 No. 601.1 M90

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 *Ground Integrity*, p. 2-12, for test values. Reference *Safety Tests*, p. 2-12, 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: "RECONNECT/REPLACE SENSOR".

10.5 Battery Check

Replace batteries every 24 months or when battery charging rapidly depletes.

10.5.1 Battery Power

To check battery power

- 1. Disconnect the monitoring system from AC power.
- 2. Verify the AC Power indicator is not lit.
- 3. Connect the monitoring system to an AC power source.
- 4. Verify the AC Power indicator is lit.
- 5. If the Low Battery indicator is also lit, leave the monitoring system connected to an AC power source to charge the battery.

10.5.2 Battery Charge

Ensure the battery is fully charged by inspecting the Battery Fuel Gauge Indicator, which should be completely full, and check the Low Battery Indicator, which should be off. If the fuel gauge is not completely full, or if the Low Battery Indicator is lit, charge the battery by connecting it to AC power. Reference Connection to an AC Power Source, p. 5-3. Reference Battery Power Usage, p. 5-6.



Note:

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

To check battery charge

- 1. Connect the monitoring system to an AC power source.
- Verify the AC Power indicator is lit.
 - 3. Allow a complete charge of the monitoring system.
- d. Turn on the monitoring system by pressing the POWER ON key.
 - 5. After POST completes, examine the battery fuel gauge for the percentage of charge.

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6. Disconnect the monitoring system from AC power.



7. Verify the AC Power indicator is not lit.

To charge the battery

- 1. Connect the monitoring system to an AC power source.
- 2. Verify the AC Power indicator is lit.
- 3. If the Low Battery indicator is also lit, leave the monitoring system connected to an AC power source to charge the battery.
 - 4. Check the battery charge.

10.6 Performance Tests

The monitoring system automatically sets the Alarm Mode for adult alarm settings at power on. Do not change this selection to neonate alarm settings for any of these tests.



Note:

This section uses factory defaults. If the institution or caregiver using the monitoring system customized the defaults, the monitoring system displays those customized values. Reference *To restore factory defaults*, p. 10-7.

10.6.1 Power-On Defaults and Alarm Ranges

Power-up performance tests verify both power-on self-test (POST) and power-on defaults and alarm range limits. Reference *Power-on Self-Test (POST)*, p. 6-4.



Note:

Power-on defaults are factory settings or defaults set by the institution.



Note:

The descriptions below are based on the default pleth view with SatSeconds and the Saturation Pattern Detection (SPD) feature enabled. The steps for changing an alarm limit are the same for all views.



Note:

When observing or changing alarm limits, a time-out is in effect (approximately ten seconds). If no action is taken within the time-out, the monitoring system automatically returns to the monitoring display.

Testing Alarm Limits

To test upper and lower SpO₂ and Pulse Rate limits

These tests ensure SpO₂ and pulse rate limits extend to either extreme of possible alarm thresholds.



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



- 2. Press MENU.
- 3. Select ALARM LIMITS.
- 4. Test SpO₂ Upper and Lower Alarm Limits.
 - a. Select SpO₂.
 - b. Select the SpO₂ Upper Alarm Limit, which should be set at a value of 100.
 - c. Slide the bar down to a value of 86, using arrow keys as necessary.
- 1
- d. Press SAVE CHANGES.
- e. Repeat steps two through four to view SpO2 Upper and Lower Alarm Limits.
- f. Select SpO₂.
- g. Ensure the selected number for SpO₂ Upper Alarm Limit is set at a value of 86.
- n. Slide the bar down until it will not slide any further. Ensure the selected number for SpO₂ Upper Alarm Limit decreases to a value of 21.
- 1
- i. Press SAVE CHANGES.
- j. Repeat steps two through four to view SpO₂ Upper and Lower Alarm Limits.
- k. Select SpO₂.
- 1. Ensure the selected number for SpO₂ Upper Alarm Limit is set at a value of 21.
- 1
- m. Press SAVE CHANGES.
- n. Repeat steps two through four to view SpO₂ Upper and Lower Alarm Limits.
- o. Select SpO₂.
- p. Select the SpO₂ Lower Alarm Limit, which should be set at a value of 20, since the lower threshold must remain at least one point below the upper threshold.

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- q. Slide the bar up to a value of 85, using arrow keys as necessary.
- r. Press SAVE CHANGES.
 - s. Repeat steps two through four to view SpO2 Upper and Lower Alarm Limits.
 - t. Select SpO₂.

1

- u. Ensure the selected number for SpO₂ Lower Alarm Limit is set at a value of 85.
- v. Slide the bar up until it will not slide any further. Ensure the selected number for SpO₂ Lower Alarm Limit increases to a value of 99.
- w. Press SAVE CHANGES.
 - x. Repeat steps two through four to view SpO₂ Upper and Lower Alarm Limits.
 - y. Select SpO₂.
 - z. Ensure the selected number for SpO₂ Lower Alarm Limit is set at a value of 99.
 - 5. Test Pulse Rate Upper and Lower Alarm Limits.
 - a. Select PULSE RATE.
 - b. Select the Pulse Rate Upper Alarm Limit, which should be set at a value of 170.
 - slide the bar up until it will not slide any further. Ensure the selected number for Pulse Rate Upper Alarm Limit increases to a value of 250 for the Pulse Rate Upper Alarm.
- d. Press SAVE CHANGES.
 - e. Repeat steps two through four to view SpO₂ Upper and Lower Alarm Limits.
 - f. Select PULSE RATE.
 - g. Ensure the selected number for Pulse Rate Upper Alarm Limit is set at a value of 250
 - n. Slide the bar down until it will not slide any further. Ensure the selected number for Pulse Rate Upper Alarm Limit decreases to a value of 21.
- i. Press SAVE CHANGES.
 - Repeat steps two through four to view SpO2 Upper and Lower Alarm Limits.
 - k. Select PULSE RATE.
 - Ensure the selected number for Pulse Rate Upper Alarm Limit is set at a value of 21.
- m. Press SAVE CHANGES.
 - n. Repeat steps two through four to view SpO₂ Upper and Lower Alarm Limits.
 - Select PULSE RATE.

- Select the Pulse Rate Lower Alarm Limit, which should be set at a value of 20, since the lower threshold must remain at least one point below the upper threshold.
- q. Slide the bar up to a value of 85, using arrow keys as necessary.
- 1
- r. Press SAVE CHANGES.
- s. Repeat steps two through four to view SpO₂ Upper and Lower Alarm Limits.
- t. Select PULSE RATE.
- Ensure the selected number for Pulse Rate Lower Alarm Limit is set at a value of 85.
- v. Slide the bar up until it will not slide any further. Ensure the selected number for Pulse Rate Lower Alarm Limit increases to a value of 249.
- 1
- w. Press SAVE CHANGES.
- x. Repeat steps two through four to view SpO₂ Upper and Lower Alarm Limits.
- v. Select PULSE RATE.
- z. Ensure the selected number for Pulse Rate Lower Alarm Limit is set at a value of 249.
- 6. Turn off the monitoring system by pressing the POWER ON key, clearing all changes.
- 7. Turn on the monitoring system by pressing the POWER ON key.
 - . Verify return to factory default limits on the main monitoring screen.
 - a. Verify the SpO₂ Upper Alarm Limit display indicates an alarm limit of 100.
 - b. Verify the SpO₂ Lower Alarm Limit display indicates an alarm limit of 85.
 - c. Verify the Pulse Rate Upper Alarm Limit display indicates an alarm limit of 170.
 - d. Verify the Pulse Rate Lower Alarm Limit display indicates an alarm limit of 40.

To test SatSeconds, SPD, and Pulse Rate Delay

These tests ensure SatSeconds, Saturation Pattern Detection, and Pulse Rate Delay settings allow for all possible setting values.

- φ
- 1. Turn on the monitoring system by pressing the POWER ON key.
- 2. Test the SatSeconds alarm threshold setting.



- a. Press MENU.
- b. Select ALARM LIMITS.
- Select SATSECONDS ALARM SETTINGS.
- d. Ensure the SatSeconds alarm threshold is set to a value of 100.

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- Select the value of 10.
- Press SAVE CHANGES. 1
 - Ensure the SatSeconds alarm threshold is set to a value of 10 under the icon on the main monitoring screen.
 - Test the OxiMax[™] SPD Alert (SPD) sensitivity setting.



- Press ALARM LIMITS.
- Select SPD.
- Ensure the sensitivity is set to a value of 1.
- Select OFF.
- Press SAVE CHANGES.
 - Ensure the SPD sensitivity is set to "OFF" under the icon on the main monitoring screen.
 - Test the Pulse Rate Delay setting.



- Press ALARM LIMITS.
- Select PULSE RATE DELAY.
- Ensure the delay is set to OFF. d.
- Select a delay of 10 seconds.
- Press SAVE CHANGES.
 - Press MENU.
 - Press ALARM LIMITS.
 - Select PULSE RATE DELAY.
 - Ensure the delay is set to 10.
- Turn off the monitoring system by pressing the POWER ON key, clearing all changes. (h
 - Turn on the monitoring system by pressing the POWER ON key.
 - 7. Verify return to factory default limits on the main monitoring screen.
 - Ensure the value under the circle icon is 100.
 - Ensure the value under the triangle icon is 1.
- Press MENU.
 - Press ALARM LIMITS.



















































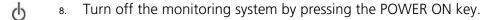








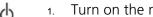
- Select PULSE RATE DELAY.
- Ensure the delay is set to OFF.



Testing Monitoring Settings

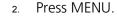
Service technicians may choose to test all monitoring settings in sequence. If so, reserve turning off the monitoring system until the end of the sequence. If not, turn it off after completing the individual test to clear all changes.

To test alarm mode



:=

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



- Press MONITORING SETTINGS.
- Select ALARM MODE.
- Ensure the alarm mode is ADULT ALARM SETTINGS.
- Select NEONATE ALARM SETTINGS.
- 7. Press SAVE CHANGES.
 - Ensure the Baby icon appears on the main monitoring screen between both saturation and pulse rate alarm threshold settings.
- Press YES. 1

To test response mode

Turn on the monitoring system by pressing the POWER ON key. (h



- Press MONITORING SETTINGS.
- 4. Select RESPONSE MODE.
- 5. Ensure the response mode is NORMAL.
- Select FAST.
- 7. Press SAVE CHANGES.

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Ensure the FAST icon appears on the monitoring screen next to %SpO₂.

To test alarm silence duration



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



- 2. Press MENU.
- 3. Press MONITORING SETTINGS.
- 4. Select ALARM SILENCE DURATION.
- 5. Ensure the mode is set to 120 seconds.
- 6. Select 30 seconds.



7. Press SAVE CHANGES.



8. Press SILENCE ALARM.



- 9. Ensure the silenced alarm icon appears above both saturation and pulse rate alarm threshold settings.
- 10. Ensure the silence timer counts down from 0:30 to 0:00.

10.6.2 Operational Setup

Operational Setup procedures confirm settings for and allow configuration of the listed parameters.

- To configure alarms and alarm silence, page 10-17
- To configure alarm volume, page 10-19
- To configure pulse beep volume, page 10-20
- To configure button click volume, page 10-20
- To calibrate analog voltage output, page 10-21

To configure alarms and alarm silence

- 1. Connect the DOC-10 extension cable to the sensor port.
- 2. Connect the Nellcor[™] Adult SpO₂ Sensor (DS-100A) to the interface cable, then to a finger.

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



- 4. Press MENU.
- 5. Select ALARM LIMITS.
- 6. Select SpO₂.
- 7. Slide the SpO₂ Lower Alarm Limit up until it indicates 99. This automatically also sets the SpO₂ Upper Alarm Limit to 100.

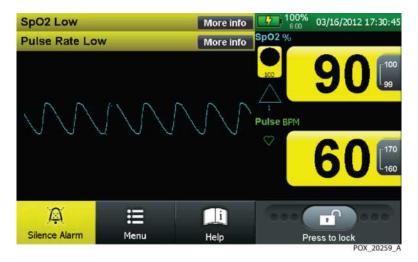


8. Press SAVE CHANGES.



- 9. Press MENU.
- 10. Select ALARM LIMITS.
- 11. Select PULSE RATE.
- 12. Slide the Pulse Rate Lower Alarm Limit up until it indicates 160.
- 13. Confirm the following results:
 - a. The waveform tracks the pulse rate.
 - ь. The Pulse Tone is audible.
 - c. The SpO₂ and pulse alarms are flashing yellow.
 - d. Both audible alarms sound and visual alarms appear, indicating both parameters have violated alarm limits.

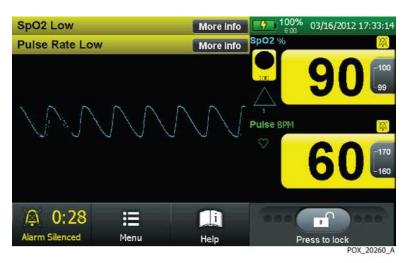
Figure 10-2. Sample: Configuring Alarms



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- 14. Press ALARM SILENCE.
- 15. With the alarm silenced, verify the following:
 - a. Alarm remains silenced for two (2) minutes.
 - b. Alarm Silence indicator lights and time remaining counts down
 - c. SpO₂ and BPM alarms continue to flash yellow
 - d. SpO2 and BPM values are surrounded by yellow
 - e. Pulse tone is audible
 - f. Audible alarm returns in approximately two (2) minutes

Figure 10-3. Sample: Configuring Alarms with Silenced Alarm



To configure alarm volume

Configure the desired volume level of the alarm, from a silent 0% to a loud 100%. The factory default volume level is set to 75%.



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



- Press MENU.
- 3. Select SOUND SETTINGS.
- 4. Select ALARM VOLUME. The monitoring system displays an volume icon with increment and decrement buttons.



Note:

If the alarm duration set to OFF, the display immediately shows AUDIO OFF.

- 5. Adjust the alarm volume setting to an appropriate audio level for the environment in which it is to operate.
- 6. Press SAVE CHANGES.

To configure pulse beep volume

Adjust the pulse tone volume after adjusting the alarm volume. Reference *To configure alarm volume*, p. 10-19.



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



- 2. Press MENU.
- 3. Press SOUND SETTINGS.
- 4. Select PULSE BEEP VOLUME. The monitoring system displays an volume icon with increment and decrement buttons.
- 5. Press decrement (-) until the pulse beep volume setting displays 25%. Verify the volume of the alarm decreases.
- 6. Press increment (+) to increase the pulse beep volume setting to a maximum value of 100%. Verify the volume increases.
 - 7. Adjust the pulse beep volume setting to an appropriate audio level for the environment in which it is to operate.
- 8. Press SAVE CHANGES.

To configure button click volume

Adjust the pulse tone volume after adjusting the alarm volume. Reference *To configure alarm volume*, p. 10-19.



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



- 2. Press MENU.
- 3. Press SOUND SETTINGS.
- 4. Select BUTTON CLICK VOLUME. The monitoring system displays an volume icon with increment and decrement buttons.

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5. Press decrement (-) until the button click volume setting displays OFF. Verify there is no click.



- 6. Press increment (+) to increase the button click volume setting to a maximum value of 100%. Verify the volume increases.
- 7. Adjust the button click volume setting to an appropriate audio level for the environment in which it is to operate.



8. Press SAVE CHANGES.

To calibrate analog voltage output

The monitoring system provides analog outputs for saturation, pulse rate, and the plethysmographic waveform. The output voltage is 0.0 to +1.0 VDC for all three parameters. The voltage decreases as the values for these parameters decrease. If no data for a parameter is available, the output voltage for that parameter is 0.0 VDC.

After the completion of power-on self-test (POST), the monitoring system initiates an automatic three-step calibration signal. The calibration signal begins at 0.0 VDC and holds that point for 60 seconds. It increases to 1.0 VDC and holds that value for 60 seconds. The third part of the calibration signal is a stair step signal. The stair step signal, begins at 0.0 VDC and increases up to 1.0 VDC in 0.1 VDC increments, each held for one (1) second.

Reference Calculating the Analog Voltage Output, p. 7-17.



Note:

If the monitoring system skips an analog calibration step during this process, repeat the calibration after power cycling the monitoring system.



- Connect the negative lead of a voltmeter to pin 10 and the positive lead to pin 6 of the DB-15 data port connector. Reference *DB-15 Pin Layout*, p. 7-5.
- 2. Confirm the output voltage is $+0.0 \pm 0.025$ VDC, verifying the analog SpO₂ function.
- 3. Leave the negative lead connected to pin 10 and verify 0.0 ± 0.025 VDC on pins 13 and 14, verifying BPM and pleth functions.
- 4. Move the positive lead back to pin 6.
- 5. Ensure a full 60 seconds from the beginning of POST has elapsed.

- 6. Confirm the output voltage is $\pm 1.0 \pm 0.025$ VDC, verifying the analog SpO₂ function.
- 7. Leave the negative lead connected to pin 10 and verify 1.0 ± 0.025 VDC on pins 13 and 14, verifying BPM and pleth functions.
- 8. Disconnect the voltmeter.

10.6.3 Overall Performance Check

The following tests provide an overall performance check of the system.

- LED Excitation Test, page 10-22
- Operation with a Live Subject, page 10-23



Note:

Performance check tests require a DOC-10, Nellcor[™] Adult SpO₂ Sensor (MAX-A) and Reusable Nellcor[™] Adult SpO₂ Sensor (DS-100A) sensor.

LED Excitation Test

The LED Excitation Test utilizes normal system components to test circuit operation. Use a Max-A sensor to examine LED intensity control. The test uses the red sensor LED to verify intensity modulation controlled by the LED intensity control circuit.

To test the circuit operation

- 1. Connect a DOC-10 interface cable to the sensor port.
- 2. Connect a Max-A pulse oximetry sensor to the interface cable.
- φ
- 3. Turn on the monitoring system by pressing the POWER ON key.
- 4. Leave the Max-A sensor open with the LEDs and photo detector visible.
- 5. Verify the Max-A optical sensor LED is brightly lit.
- 6. Slowly move the Max-A optical sensor LED in proximity to the photo detector element on the opposing side of the clip, slowly closing the sensor.
- 7. Verify the LED intensity decreases as the LED approaches the optical sensor.
- 8. Open the Max-A sensor and notice the LED intensity increases.

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- 9. Repeat Step 8.
- 10. Verify the intensity continues to decrease. This variation is an indication the microprocessor is in proper control of LED intensity.
- 11. Turn off the monitoring system by pressing the POWER ON key.

Operation with a Live Subject

Patient monitoring involves connecting the DS-100A sensor to a live subject for a qualitative test.

To test using a live subject:

- 1. Ensure the monitoring system is connected to an AC power source.
- 2. Connect a DOC-10 interface cable to the sensor port.
- 3. Connect the DS-100A sensor to the interface cable.
- 4. Attach the sensor to a live subject as recommended in the sensor's *Instructions For Use*.
- 5. Turn on the monitoring system by pressing the POWER ON key.
 - 6. Verify the monitoring system properly identifies the attached sensor. The monitoring system should stabilize on the subject's physiological signal in approximately 15 to 30 seconds.

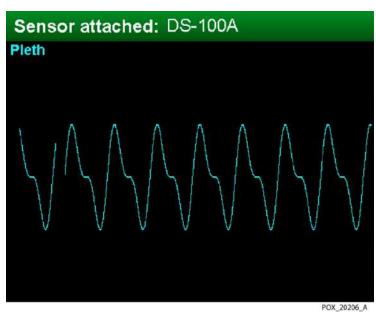


Figure 10-4. Sensor Identification

7. Verify the oxygen saturation and pulse rate values are reasonable for the subject.

10.6.4 Pulse Oximetry Functional Tests

Use the SRC-MAX functional tester to verify the performance of the monitoring system.

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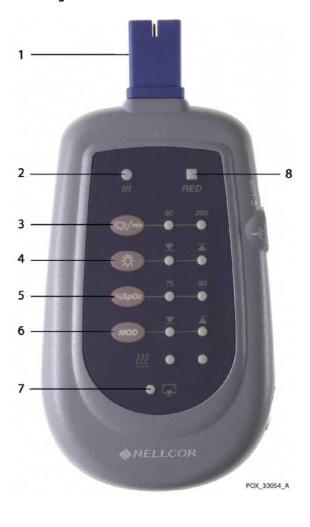


Figure 10-5. SRC-MAX Functional Tester

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

Overview

The SRC-MAX functional tester enables qualified technicians to functionally test Nellcor and OEM OxiMax technology-based pulse oximeters and monitor-

ing systems. The following table provides a brief description of each test. Use the PLETH view for all functional testing.

Once the functional tester is attached to the cable and the unit is turned on, complete all of the tests in sequence, beginning with BPM, then %SpO₂, then Modulation, and finally Light Level.

Tests Descriptions BPM Test The test procedure simulates an Nellcor™ OxiMax sensor attached to a patient indicating a pulse rate of 60 BPM ±3 BPM and 200 BPM ±6 BPM. SpO₂ Test The test procedure simulates a Nellcor™ OxiMax sensor attached to a patient indicating a 75% and 90% blood oxygen saturation ±2 points. Modulation Level Test The test procedure simulates an Nellcor™ OxiMax sensor attached to a patient indicating low pulsatile strength between 0.4% and 0.6%, and high pulsatile strength between 4.5% and 5.5%. The test procedure simulates an Nellcor™ OxiMax sensor attached to a patient Light Level Test indicating low light levels, 750 nAi ±10%, and high light levels, 3,000 nAi ±10%, passing through the patient at the sensor site.

Table 10-5. Functional Tests Options



Note:

The SRC-MAX selectable indicator LEDs may extinguish if there is a delay in proceeding through the above tests. This is normal operation in order to increase the SRC-MAX battery charge.



d

Note:

Pressing a button on the SRC-MAX during the test procedures may be requested, changing 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.

BPM Test

To perform the BPM Test

- 1. Ensure the monitoring system is connected to an AC power source.
- 2. Connect a DOC-10 interface cable to the sensor port.
- 3. Turn on the monitoring system by pressing the POWER ON key.
 - 4. Verify the word PLETH appears at the top left corner of the monitoring screen.

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- 5. Connect the SRC-MAX tester to the interface cable.
- 6. Verify the listed system behaviors.

Sp02 Low

More info

100%
03/16/2012 23:01:44

Sp02 %

75 -100
A

Pulse BPM

Silence Alarm

Menu

Help

Press to lock

POX 20261 A

Figure 10-6. BPM Test: BPM 60 and SpO2 75

- a. Active visual and audio alarms.
- b. Saturation indication between 73 and 77 inclusive, creating an SpO₂ LOW alarm condition.
- c. BPM indication between 57 and 63 inclusive.
- d. 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.



7. Press PULSE RATE.

Verify the 200 BPM LED lights. The monitoring system registers pulse rate increases and stabilizes to a value between 194 to 206 BPM inclusive.



Figure 10-7. BPM Test: BPM 200 and SpO2 75

- a. Active visual and audio alarms.
- b. Saturation indication between 73 and 77 inclusive, creating an SpO₂ LOW alarm condition.
- c. BPM indication between 194 and 206, creating a PULSE RATE HIGH alarm condition.
- Pulse waveform of approximately 1/2-inch P-T-P amplitude. Actual amplitude may vary but references low pulse amplitude/low light patients.



Press PULSE RATE.

- 60 ()
- 10. Verify the 60 BPM LED lights. The monitoring system registers pulse rate decreases and stabilizes to a value between 57 to 63 BPM inclusive.
 - a. Active visual and audio alarms.
 - b. Saturation indication between 73 and 77 inclusive, creating an SpO₂ LOW alarm condition.
 - c. BPM indication between 57 and 63 inclusive.
 - d. 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.

11. Turn off the monitoring system by pressing the POWER ON key.

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SpO₂ Test

To perform the SpO₂ Test

- 1. Ensure the monitoring system is connected to an AC power source.
- 2. Connect a DOC-10 interface cable to the sensor port.
- d) 3. Turn on the monitoring system by pressing the POWER ON key.
 - 4. Verify the word PLETH appears at the top left corner of the monitoring screen.
 - 5. Connect the SRC-MAX tester to the interface cable.
 - 6. Verify the listed system behaviors.

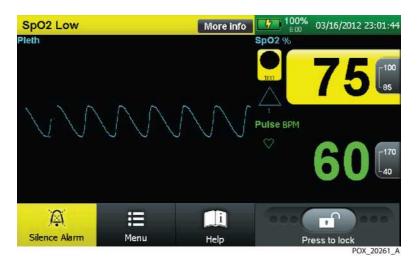


Figure 10-8. SpO2 Test: SpO2 75, BPM 60

- a. Active visual and audio alarms.
- b. Saturation indication between 73 and 77 inclusive, creating an SpO₂ LOW alarm condition.
- c. BPM indication between 57 and 63 inclusive.
- d. 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.



90

Press %SpO₂.

8. Verify the 90% LED lights. The monitoring system registers SpO₂ increases and stabilizes to a value between 88 to 92 inclusive.

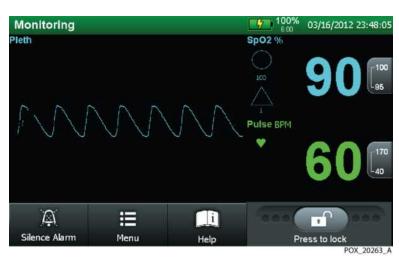


Figure 10-9. SpO2 Test: SpO2 90, BPM 60

- a. No active visual and audio alarms.
- ь Saturation indication between 88 and 92 inclusive.
- c. BPM indication between 57 and 63 inclusive.
- d. Pulse waveform of approximately 1/2-inch P-T-P amplitude. Actual amplitude may vary but references low pulse amplitude/low light patients.



Press %SpO₂.

- 75
- 10. Verify the 75% LED lights. The monitoring system registers SpO₂ decreases and stabilizes to a value between 73 and 77 inclusive.
 - a. Active visual and audio alarms.
 - b. Saturation indication between 73 and 77 inclusive, creating an SpO₂ LOW alarm condition.
 - BPM indication between 57 and 63 inclusive.
 - d. 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.

φ

11. Turn off the monitoring system by pressing the POWER ON key.

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Modulation Level (MOD) Test

To perform the MOD Test

- 1. Ensure the monitoring system is connected to an AC power source.
- 2. Connect a DOC-10 interface cable to the sensor port.
- d) 3. Turn on the monitoring system by pressing the POWER ON key.
 - 4. Verify the word PLETH appears at the top left corner of the monitoring screen.
 - 5. Connect the SRC-MAX tester to the interface cable.
 - 6. Verify the listed system behaviors.

Figure 10-10. MOD Test: BPM 60, SpO2 75, and MOD Low

- Active visual and audio alarms.
- b. Saturation indication between 73 and 77 inclusive, creating an SpO₂ LOW alarm condition.
- c. BPM indication between 57 and 63 inclusive.
- Pulse waveform peak to peak (P-T-P) amplitude of approximately half-inch. Actual amplitude may vary but will be a reference for low pulse amplitude/low light patients.



Press MOD.

Ā

Nerify the MOD increase LED lights. The pulse amplitude waveform initially increases in amplitude and then stabilize at P-T-P amplitude of approximately one-inch.

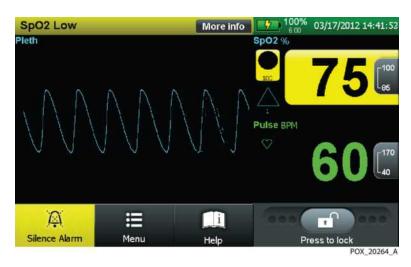


Figure 10-11. MOD Test: BPM 60, SpO2 75, and MOD High

- a. Active visual and audio alarms.
- b. Saturation indication between 73 and 77 inclusive.
- c. BPM indication between 57 and 63 inclusive.
- d. Pulse waveform of approximately one-inch P-T-P amplitude. Actual amplitude may vary but references **high** pulse amplitude/low light patients.



Press PULSE RATE.

200 O 10. Verify the 200 BPM LED lights. The monitoring system registers pulse rate increases and stabilizes to a value between 194 to 206 BPM inclusive.

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Figure 10-12. MOD Test: BPM 200, SpO2 75, and MOD High

- a. Active visual and audio alarms.
- b. Saturation indication between 73 and 77 inclusive, creating an SpO₂ LOW alarm condition.
- c. BPM indication between 194 and 206, creating a PULSE RATE HIGH alarm condition.
- d. Pulse waveform of approximately one-inch P-T-P amplitude. Actual amplitude may vary but references high pulse amplitude/low light patients.



- 1. Press PULSE RATE.
- Verify the 60 BPM LED lights. The monitoring system registers pulse rate decreases
 and stabilizes to a value between 57 to 63 BPM inclusive.
 - a. Active visual and audio alarms.
 - ь. Saturation indication between 73 and 77 inclusive, creating an SpO₂ LOW alarm condition.
 - c. BPM indication between 57 and 63 inclusive.
 - d. Pulse waveform of approximately one-inch peak to peak (P-T-P) amplitude. Actual amplitude may vary but will be a reference for high pulse amplitude/low light patients.



- 13. Press %SpO2.
- Verify the 90% LED lights. The monitoring system registers SpO₂ increases and stabilizes to a value between 88 to 92 inclusive.

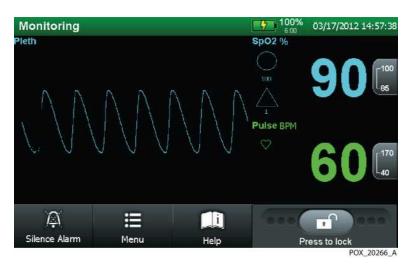


Figure 10-13. MOD Test: BPM 60, SpO2 90, and MOD High

- No active visual and audio alarms.
- b. Saturation indication between 88 and 92 inclusive.
- c. BPM indication between 57 and 63.
- Pulse waveform of approximately one-inch P-T-P amplitude. Actual amplitude may vary but references high pulse amplitude/low light patients.



15. Press %SpO2.

- 75 16. Verify the 75% LED lights. The monitoring system registers SpO₂ decreases and stabilizes to a value between 73 and 77 inclusive.
 - a. Active visual and audio alarms.
 - b. Saturation indication between 73 and 77 inclusive, creating an SpO₂ LOW alarm condition.
 - c. BPM indication between 57 and 63 inclusive.
 - d. Pulse waveform of approximately one-inch peak to peak (P-T-P) amplitude. Actual amplitude may vary but will be a reference for high pulse amplitude/low light patients.



17. Press MOD.



- 18. Verify the MOD decrease LED lights. The pulse amplitude waveform initially decreases in amplitude and then stabilizes at P-T-P amplitude of approximately half-inch.
 - a. Active visual and audio alarms.
 - b. Saturation indication between 73 and 77 inclusive.

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- c. BPM indication between 57 and 63 inclusive.
- d. Pulse waveform of approximately half-inch P-T-P amplitude. Actual amplitude may vary but references low pulse amplitude/low light patients.
- 19. Turn off the monitoring system by pressing the POWER ON key.

Light Level Test

- 1. Ensure the monitoring system is connected to an AC power source.
- 2. Connect a DOC-10 interface cable to the sensor port.
- 3. Turn on the monitoring system by pressing the POWER ON key.
 - 4. Verify the word PLETH appears at the top left corner of the monitoring screen.
 - 5. Connect the SRC-MAX tester to the interface cable.
 - 6. Verify the listed system behaviors.

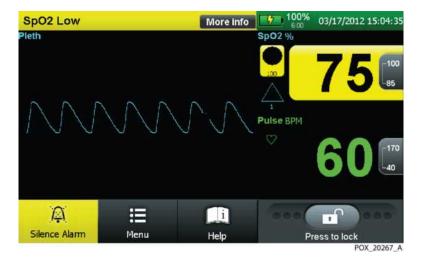


Figure 10-14. LIGHT Test: BPM 60, SpO2 75, MOD low, Light low

- a. Active visual and audio alarms.
- b. Saturation indication between 73 and 77 inclusive, creating an SpO₂ LOW alarm condition.
- BPM indication between 57 and 63 inclusive.

d. Pulse waveform peak to peak (P-T-P) amplitude of approximately half-inch. Actual amplitude may vary but will be a reference for low pulse amplitude/low light patients.



Press LIGHT LEVEL.



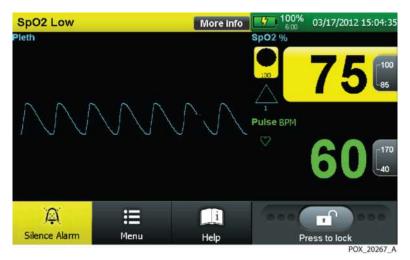
Nerify the increase LED lights. The pulse amplitude waveform initially flatlines and then stabilizes at the same P-T-P amplitude of approximately half-inch.



Note:

Flat-lining is the only indication of a light change at the measurement site. If the monitoring system recovers and displays normally, this is an indication of proper operation with light changes.





- a. Active visual and audio alarms.
- b. Saturation indication between 73 and 77 inclusive.
- c. BPM indication between 57 and 63 inclusive.
- d. Pulse waveform of approximately half-inch P-T-P amplitude. Actual amplitude may vary but references low pulse amplitude/**high** light indications.



Press PULSE RATE.



10. Verify the 200 BPM LED lights. The monitoring system registers pulse rate increases and stabilizes to a value between 194 to 206 BPM inclusive.

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Figure 10-16. LIGHT Test: BPM 200, SpO2 75, MOD low, Light High

- a. Active visual and audio alarms.
- b. Saturation indication between 73 and 77 inclusive, creating an SpO₂ LOW alarm condition.
- c. BPM indication between 194 and 206, creating a PULSE RATE HIGH alarm condition.
- d. Pulse waveform of approximately half-inch P-T-P amplitude. Actual amplitude may vary but references low pulse amplitude/high light indications.



1. Press PULSE RATE.

- Verify the 60 BPM LED lights. The monitoring system registers pulse rate decreases and stabilizes to a value between 57 to 63 BPM inclusive.
 - a. Active visual and audio alarms.
 - b. Saturation indication between 73 and 77 inclusive, creating an SpO₂ LOW alarm condition.
 - c. BPM indication between 57 and 63 inclusive.
 - d. Pulse waveform of approximately half-inch peak to peak (P-T-P) amplitude. Actual amplitude may vary but will be a reference for low modulation/ high light indications.



90

13. Press %SpO2.

14. Verify the 90% LED lights. The monitoring system registers SpO₂ increases and stabilizes to a value between 88 to 92 inclusive.

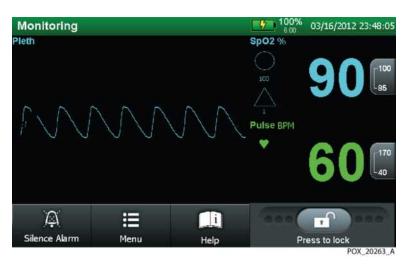


Figure 10-17. LIGHT Test: BPM 60, SpO2 90, MOD low, Light High

- a. No active visual and audio alarms.
- ь Saturation indication between 88 and 92 inclusive.
- c. BPM indication between 57 and 63.
- d. Pulse waveform of approximately half-inch P-T-P amplitude. Actual amplitude may vary but references low pulse amplitude/high light indications.



5. Press %SpO2.

- 75 16. Verify the 75% LED lights. The monitoring system registers SpO₂ decreases and
 - a. Active visual and audio alarms.
 - b. Saturation indication between 73 and 77 inclusive, creating an SpO₂ LOW alarm condition.
 - BPM indication between 57 and 63 inclusive.

stabilizes to a value between 73 and 77 inclusive.

d. Pulse waveform of approximately half-inch peak to peak (P-T-P) amplitude. Actual amplitude may vary but will be a reference for low pulse amplitude/ high light indications.



17. Press MOD.



18. Verify the MOD increase LED lights. The pulse amplitude waveform initially increases in amplitude and then stabilize at P-T-P amplitude of approximately one-inch.

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Figure 10-18. LIGHT Test: BPM 60, SpO2 90, MOD High, Light High

- a. Active visual and audio alarms.
- b Saturation indication between 73 and 77 inclusive.
- c. BPM indication between 57 and 63 inclusive.
- d. Pulse waveform of approximately one-inch P-T-P amplitude. Actual amplitude may vary but references high pulse amplitude/high light indications.



19. Press MOD.



- 20. Verify the MOD decrease LED lights. The pulse amplitude waveform initially decreases in amplitude and then stabilizes at P-T-P amplitude of approximately half-inch.
 - a. Active visual and audio alarms.
 - b. Saturation indication between 73 and 77 inclusive.
 - c. BPM indication between 57 and 63 inclusive.
 - d. Pulse waveform of approximately half-inch P-T-P amplitude. Actual amplitude may vary but references low pulse amplitude/high light patients.



21. Press LIGHT LEVEL.



verify the decrease LED lights. The pulse amplitude waveform initially flatlines and then stabilizes at the same P-T-P amplitude of approximately half-inch.



Note:

Flat-lining is the only indication of a light change at the measurement site. If the monitoring system recovers and displays normally, this is an indication of proper operation with light changes.

- a. Active visual and audio alarms.
- ь. Saturation indication between 73 and 77 inclusive.
- c. BPM indication between 57 and 63 inclusive.
- d. Pulse waveform of approximately half-inch P-T-P amplitude. Actual amplitude may vary but references low modulation/low light indications.
- Turn off the monitoring system by pressing the POWER ON key.

10.6.5 Setting Nurse Call

To set and verify the nurse call function:

- 1. Ensure the monitoring system is connected to an AC power source.
- 2. Connect a DOC-10 interface cable to the sensor port.
- 3. Locate the DB-15 connector on the side of the monitoring system.
- 4. Review the DB-15 pinouts. Reference *DB-15 Pin Layout*, p. 7-5.
- 5. Ensure the audible alarm is set to at least 50%. Reference *To configure alarm volume*, p. 10-19.
- 6. Connect the negative lead of a voltmeter to pin 5 and positive lead to pin 11.
- Connect the SRC-MAX to the DOC-10 interface cable.
- 8. Turn on the monitoring system by pressing the POWER ON key.
 - 9. Verify an output voltage at pins 5 and 11 between +5 to +12 VDC.
 - 10. Press ALARM SILENCE. With the audible alarm silenced, the output voltage at pins 5 and 11 must be between -5 to -12 VDC.
 - 11. Simulate an alarm condition using the RS-232 Nurse Call function.
 - 12. Use a digital voltmeter (DVM) to ensure there is no continuity (1 megohms or greater) between pins 8 and 15 and there is continuity (60 ohms or less) between pins 7 and 15.

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- $_{\mbox{\scriptsize 13.}}$ Change the %SpO2 to 90 on the SRC-MAX.
- 14. Use the DVM to verify continuity between pins 8 and 15 and no continuity between pins 7 and 15, thus verifying the Nurse Call function.

_{10.7} Test Data Sheet Form

Job #				
Model Name	NBRPMS	Serial Number	Software Version	

Table 10-6. Performance and Functional Tests

Item	Res	ults		Remarks	
		Performan	ce Tests		
Battery check	Pass	Fail			
Power up defaults					
Power-on self-test (POST)	Pass	Fail			
Alarms limits	Pass	Fail			
Alarm management: SatSeconds, SPD, and pulse rate delay	Pass	Fail			
Monitoring settings	Pass	Fail			
Operational setup	Pass	Fail			
Nurse call	Pass	Fail			
Monitoring screen calibration	Pass	Fail			
Overall Performance Check					
Sensor LED excitation test	Pass	Fail			
Operation on a live subject	Pass	Fail			
		Functiona	l Tests		
BPM test	Pass	Fail	73-77% 57-63 bpm	73-77% 194-206 bpm	73-77% 57-63 bpm
SpO2 test	Pass	Fail	73-77% 57-63 bpm	88-92% 57-63 bpm	73-77% 57-63 bpm
Modulation test	Pass	Fail			
Light level test	Pass	Fail			
DATE:	TESTS PERF	ORMED BY:			

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 Table 10-7.
 Electrical Safety Tests

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

NC Normal Condition OS Single Fault Condition (Open Line/Neutral)

NCRM Normal Condition Reverse OSRM Single Fault Condition (Open Line/Neutral) Reverse

SFC Single Fault Condition OE Single Fault Condition (Open Earth)

OERM Single Fault Condition (Open Earth) Reverse

10.8 Monitoring Screen Calibration

Only calibrate the monitoring screen if it stops responding appropriately to human touch. If caregivers report problems accessing menu items and the screen is unlocked, consider calibration. Calibration requires a stylus or very fine, rounded tip of a non-marking utensil. Do not use the pointed tip of a pencil or pen.

To calibrate the monitoring screen

- 1. Access the service function menu. Reference *To access service function menus*, p. 10-4.
- 2. Select the SERVICE menu.
- 3. Select the SERVICE option.
- 4. Select TOUCH SCREEN CALIBRATION.
- 5. Press YES.
- 6. Press NEXT.
- + 7. Press and hold stylus in exact center of crosshatch in center of monitoring screen.

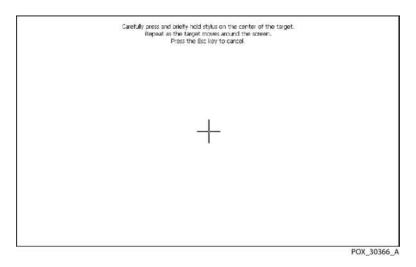


Figure 10-19. Initial Calibration Screen

- + 8. Press and hold stylus in exact center of crosshatch as it moves to each corner of the monitoring screen.
 - 9. Insert a USB keyboard in the USB port.

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- 10. Press the ENTER key on the keyboard.
- 11. Press EXIT MENU.

10.9 Software and Firmware Upgrades

Covidien may provide platform software or firmware updates periodically. Contact Covidien Technical Services to acquire or download the platform software or firmware. Load platform software or firmware onto a virus-free USB flash drive prior to proceeding with an upgrade.

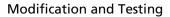


Note:

Upgrades remove all trend data. If desired, export all trend data prior to upgrade. Reference *To export trend data*, p. 7-8.

To upgrade platform software or firmware

- 1. Remove from monitoring.
- 2. Access the service function menu. Reference *To access service function menus*, p. 10-4.
- 3. Select the SERVICE menu.
- 4. Select one of the listed options, depending on the desired upgrade.
 - a. SOFTWARE UPDATE
 - b. FIRMWARE UPDATE
- 5. Insert the USB flash drive containing the upgrade firmly into the USB port.
- Press NEXT, waiting for the upgrade to properly load. This may take time.
- 7. Press FINISH.
 - 8. Remove the USB flash drive.
- 9. Press EXIT MENU.
- 10. Press EXIT AND RESTART.
- 11. Press YES at EXIT PROGRAM prompt.



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11 Troubleshooting

11.1 Overview

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

11.2 System Condition Categories



WARNING:

Use the test data sheet to ensure the monitoring system passes all safety, performance, and functional tests prior to use in a clinical setting.



WARNING:

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



WARNING:

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



WARNING:

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



WARNING:

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

The monitoring system is designed to provide instant feedback to guide caregivers in taking whatever action requires their attention. Alarm conditions appear in order of priority. To access suggestions for resolving the particular message, press the MORE INFO button. If the monitoring system allows the caregiver to dismiss the condition, pressing DISMISS ALARM clears the alarm, but does not clear the condition until the caregiver takes appropriate action.

If the monitoring system detects a condition requiring caregiver intervention, it displays a either a prompt or an error message with a recommended action. Pressing ALARM SILENCE silences any audible tone for a period of up to two (2) minutes. A countdown timer reflects any silence time remaining.

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

Figure 11-1. Ready Prompt



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

Alarm Active

Alarm 1 of 1: Sensor Disconnected

Sensor disconnected. Check all connections. If problem persists, replace cable and/or sensor.

Pulse BPM

Silence Alarm

Dismiss Alarm

Exit

100%
03/04/2013 17:00:25

Sp02 %

Sp02 %

Sp02 %

Sp02 %

Sp02 %

Pulse BPM

Press to lock

POX_20233_A

Figure 11-2. Sensor Disconnected Message and Help Screen

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Figure 11-3. Stacked Alarm/Alerts

- 1 SpO2 LOW Alarm Patient saturation is below the lower SpO2 threshold.
- PULSE RATE LOW Alarm Patient pulse rate is below the lower pulse rate threshold.
- 3 SPD ALERT Alarm Patient is experiencing multiple, sequential occurrences of a desaturation.
- 4 SPD Alert Alarm Icon Appears in the trend data graph each time an SPD Alert alarm occurs.
- 5 SatSeconds Alarm Icon Appears in the trend data graph each time an SatSeconds alarm occurs.

- 6 Silence Alarm Icon Remains yellow until caregiver presses it to silence all alarms.
- 7 SatSeconds Alarm Icon Icon remains black on a yellow background until the error condition clears
- 8 Saturation Value with Alarm Values remain black on a yellow background until the error condition clears.
- 9 SPD Alert Alarm Icon Icon remains black on a yellow background until the error condition clears.
- 10 Pulse Rate Value with Alarm Values remain black on a yellow background until the error condition clears.

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

11.3 User Prompts and Messages

Prompts require a response from or action by the caregiver.

Priority Condition Resolution **Dismiss** Message Connect the interface cable to the Ready: Attach Awaiting patient connection sensor to to begin monitoring sensor port and the appropriate patient and sensor to the interface cable and monitor to the patient. Monitoring Proper connection established, None. patient monitoring in progress

Table 11-1. Common User Prompts and Messages

11.4 Alarms and Error Conditions

This section covers alarms and correctable error conditions. Reference *Non-correctable Failures*, p. 11-19, for non-correctable errors.

11.4.1 Alarms

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



Note:

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

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Alarm Prioritization

Alarms have an assigned priority. Stacked alarms display in order of criticality and priority. Reference *Message Types*, p. 6-11, for details on high, medium, and low priority alarms. Occasionally, the monitoring screen field contains one or more prompts or error messages. Stacked alarms display in order of criticality and priority. High priority messages appear above low priority messages. Alarms of the same priority appear in order of occurrence. If the caregiver does not resolve the issue and clear the condition, the monitoring system may escalate the alarm by increasing the frequency of the alarm.

Table 11-2. Initial Alarm Priority for Errors

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

 Table 11-2.
 Initial Alarm Priority for Errors (Continued)

Priority	Message	Condition	Resolution	Dismiss
Low	SPD Alert	SPD sensitivity value is reached.	The SPD limit has been exceeded.	Yes
High	Pulse Timeout	Sensor connected to a patient AND has detected a pulse in the past, AND now is unable to determine pulse rate value.	Unable to determine pulse rate or oxygen saturation. Check patient immediately. Reposition or replace sensor.	No
Low ¹	Sensor Disconnect- ed	Patient sensor is disconnected from monitor	Sensor disconnected. Check all connections. If problem persists, replace cable and/or sensor.	Yes
Low ¹	Sensor Off	Patient sensor is not attached to patient	Sensor not attached to patient. Reposition or replace sensor.	Yes
Low ¹	Sensor Failure	Bad Sensor, Bad Signal, Sensor Error, Defective Sensor	Defective sensor detected. Replace the sensor.	No
Med	Battery	AC power usage AND battery level critical	Continue charging on AC	Yes
High	Critically Low	Battery power usage AND battery level critical	Connect to AC power	No
Med	Battery Low	Battery power usage AND battery level low	Connect to AC power	Yes
Hlgh	Battery Failure	Battery missing OR battery charger failure	Reference <i>Power Failure Issues</i> , p. 11-11.	No
Low	Trend Data Lost	Corrupt trend data detected at start up	Corrupt trend data detected. Some or all trend data cleared.	Yes
	Data export cancelled	Interruption or cancellation during data export	Retry data export.	Yes
Low	Communi-	Unable to connect to the network	Reference Communication	No
	cation Error	Unable to connect to the wireless network	<i>Issues</i> , p. 11-16.	No
		Unable to establish a connection with the remote system		No
		Communication failure between host and monitor is detected	Unable to connect to the network. Reference <i>Communication Issues</i> , p. 11-16.	No
High	Speaker Failure	Primary speaker failure is detected during operation.	Primary speaker error occurred. Remove from service immediately. Refer- ence <i>Hardware Issues</i> , p. 11- 17.	No

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 Table 11-2.
 Initial Alarm Priority for Errors (Continued)

Priority	Message	Condition	Resolution	Dismiss
High	System Failure	Monitor was reset unexpectedly	Unexpected reset. Settings lost. If problem persists, remove from service. Reference <i>Power Failure Issues</i> , p. 11-11.	Yes
Low	Extended Update	Sensor is connected to a patient and has successfully detected SpO2 and pulse rate during the measurement session, but current conditions are causing the SpO2 and/or pulse rate update period(s) to exceed 25 seconds.	Check patient. Reposition sensor, replace sensor, or assess alternative Nellcor™ sensor if condition persists.	Yes
Low	System Failure	The graphical display of SpO2 or pulse rate data has not been updated for over 30 seconds	Reset the monitoring system. If the problem persists, remove from service and return to a qualified service technician.	No
Low	Equipment Failure	Nurse call output system error	A Nurse Call error occurred. Reference Communication Issues, p. 11-16. Reference Hardware Issues, p. 11-17.	No
		Serial Communications system failure	Serial communication error occurred. Reference <i>Communication Issues</i> , p. 11-16.	Yes
		Analog output system failure	Analog output error occurred. Reference <i>Hard-ware Issues</i> , p. 11-17.	Yes
		Cooling fan failure	A cooling fan failure occurred. Reference <i>Hard-ware Issues</i> , p. 11-17.	Yes
Low	Over Temperature	Thermal control system is above thermal limit	Internal temperature is above thermal limit. The monitor may shut down if the internal temperature continues to increase. Reference <i>Hardware Issues</i> , p. 11-17.	Yes
Low	Clock Set- tings Lost	Invalid date and time value detected during start up	Date and time setting lost. Set the date and time. Reference <i>Hardware Issues</i> , p. 11-17.	Yes

^{1.} The priority for this alarm can be configured to Low, Medium, or High as an institutional setting. The default priority is Low. Reference Sensor Alarm Priorities, p. 6-22.

Sample alarm condition

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

To access an alarm message

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



Figure 11-4. Sample Speaker Failure Message

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

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11.4.2 Correctable error conditions

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

Table 11-3. Common Correctable Problems and Resolutions

	Symptom	Recommended Corrective Action
Pov	wer	Reference <i>Power Failure Issues</i> , p. 11-11.
•	No power, even though attached to AC and/or DC power source	
•	Power membrane switch panel LEDs do not light at appropriate times	
•	Powers down or resets without apparent cause	
•	Battery failure	
Мс	nitoring screen	Reference <i>Monitoring Screen Issues</i> , p. 11-13.
•	Power indicator is ON but monitoring screen is dim	
•	Power indicator is ON but monitoring screen is blank	
•	No response or unexpected response to touch	
•	Pixels do not all light	
•	Screen burn or legibility issue such as cracking, scratches, pen marks, pencil lead, or indents	
Au	dio or visual alarm	Reference <i>Alarm Issues</i> , p. 11-14.
•	Audible alarms do not sound	
•	Audible alarms are faint or too loud	
•	Alarms sound without apparent cause	

 Table 11-3.
 Common Correctable Problems and Resolutions (Continued)

	Symptom	Recommended Corrective Action
Con	nmunication	Reference Communication Issues, p. 11-16.
•	Data ports do not function properly, data transfers incomplete	
•	Communications with external sources are not working	
•	Trend data sent through the data ports is incomplete or garbled	
Оре	erational performance	Reference <i>Operational Performance Issues</i> , p. 11-17.
•	Monitoring screen appears functional, but is not registering patient data	
•	Patient data appears suspect	
•	Intermittent or corrupt patient data	
Har	dware ¹	Reference <i>Hardware Issues</i> , p. 11-17.
•	Over-temperature condition	
•	Patient data appears suspect	
•	Intermittent or corrupt patient data	
•	Nurse call failure	
•	Invalid date during start up	
•	Primary speaker failure	
Sof	tware	Reference System Errors and Software issues, p. 11-
•	System experiences spurious interrupts	19.
•	Patient data appears suspect	
•	Intermittent or corrupt patient data	

^{1.} This excludes any monitoring screen, power, or software issues. Such issues have a dedicated category listed in this table.

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11.5 Power Failure Issues

Power issues may require replacement of hardware, but may also require identifying potential issues in the operating environment. Prior to assuming the problem is with the monitoring system, check the power cable and wall outlet.

Table 11-4. Power Failure Issues

Problem	Resolution	
There is no response when pressing the POWER ON key.	 A fuse may be malfunctioning. Replace the fuse. If operating on battery power, the battery may be missing or discharged. If the battery is discharged, charge the battery. Reference Battery Power, p. 6-2. 	
	If the battery does not charge, replace the battery.	
The monitoring system is not charging the battery even when connected to an AC power source.	 IF the battery is completely depleted and the unit shuts down, it may not charge after connection to AC and the battery charge indicator will not light. Power cycle once and retry charging the battery while connected to AC. Replace the battery. 	
The monitoring system is operating on battery power, even though it is connected to an AC power source.	 Ensure the power cord is properly connected to the monitoring system. Check to see if power is available to other equipment on the same AC circuit. 	
Even though it is connected to an AC power source, the moni- toring system displays the fol- lowing System Error when powered on: "Battery missing or damaged. Contact a quali- fied service technician."	ni-	
The monitoring system is not operating on battery power when it should.	 Charge the battery. Replace the battery. Check the battery interconnect board and power cables and replace as required. 	

Table 11-4. Power Failure Issues (Continued)

Problem	Resolution
Unlit LEDs on the power switch membrane.	Check for power connectivity.
membrane.	Check for cable damage.
	Replace the front chassis.
Powers down or resets without apparent cause	Remove from power and allow to cool down. After it is cool, reconnect to power. If it continues to reset, check the fan. If the fan is functional, remove to a controlled environment and retry. If it still resets or overheats, replace the SBC PCB.
	After confirming it is not a hardware issue, contact Technical Services.
BATTERY MISSING message occurs, even though a battery is present.	The battery charger system is not functioning properly. Replace the battery with a known good battery. If this resolves the problem, replace the defective battery.
	If the problem persists with a known good battery, the battery charger system is not functioning properly. Replace the Main PCB.
	If this does not resolve the issue, return both the battery and the mon- itoring system to Covidien Technical Services.

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11.6 Monitoring Screen Issues

Prior to checking hardware, increase all brightness settings to allow for optimal viewing.

Table 11-5. Monitoring Screen Issues

Problem	Resolution	
Power indicator is ON but monitoring screen is dim.	 Increase the monitoring screen brightness. Check brightness options such as: WAKE ON ALARM and ALLOW BACKLIGHT. 	
One or more display elements do not light during the pow- er-on self-test (POST).	Remove from active service.Reset and power back on.	
Power indicator is ON but monitoring screen is blank.	 Check connectivity between the MAIN PCB and the LCD ASSEMBLY. Replace the MAIN PCB and/or the LCD ASSEMBLY. 	
Monitoring screen is not responsive to touch.	 Ensure the monitoring screen is unlocked. Clean the monitoring screen. Use a firmer touch. The monitoring screen responds after touch slighly deforms the surface. Re-calibrate the touchscreen. Check connectivity between the MAIN PCB and the LCD ASSEMBLY. Replace the MAIN PCB and/or the LCD ASSEMBLY. 	
Monitoring screen is cracked or marred.	Replace the LCD ASSEMBLY.	

11.7 Alarm Issues

Alarm issues may be based on conflicting alarm limit settings or sensor problems.

Table 11-6. Alarm Issues

Problem	Resolution	
Alarms do not sound or do so only faintly.	 Check SOUND SETTINGS for the alarm volume setting. Check SOUND SETTINGS for the pulse beep setting, then determine if it registers a pulse beep, but not an alarm. 	
	 Check speaker wire connectivity to the MAIN PCB. Replace the speaker, then the MAIN PCB. 	
The Pulse Search Indicator is lit for more than 10 seconds (before any measurements take place).	Check the sensor <i>Instructions for Use</i> to confirm appropriate usage and proper application. Check sensor and interface cable connections. Test the sensor on another patient and/or try another sensor or interface cable.	
	 Perfusion may be too low for the monitoring system to track the pulse. Check the patient. Test the monitoring system on someone else. Change the sensor site. Try another type of Nellcor™ sensor. 	
	• Interference may be preventing the monitoring system from tracking the pulse. Keep the patient still, if possible. Verify that the sensor is securely applied and replace it if necessary. Change the sensor site. Electromagnetic interference may be preventing the monitoring system from tracking the pulse. Remove the source of interference and/or try to stabilize the environment.	
	Use a type of sensor that tolerates more patient movement; for example, a Nellcor™ adhesive sensor.	
	The sensor may be too tight, there may be excessive ambient light, or the sensor may be on an extremity with a blood pressure cuff, arterial catheter, or intravascular line. Reposition the sensor as necessary.	

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Table 11-6. Alarm Issues (Continued)

Problem	Resolution	
The Pulse Search indicator illuminates after successful measurements occur.	 Check the status of the patient. Perfusion may be too low for the monitoring system to track the pulse. Test the monitoring system on another patient. Change the sensor site and/or try another type of Nellcor™ sensor. Interference may be preventing the monitoring system from tracking 	
	the pulse. Verify the sensor is securely applied and replace it if necessary. Change the sensor site. Use a type of sensor that tolerates more patient movement; for example, an Nellcor™ adhesive sensor. Electromagnetic interference may be preventing the monitoring system from tracking the pulse. Remove the source of interference and/or try to stabilize the environment.	
	The sensor may be too tight, there may be excessive ambient light, or the sensor may be on an extremity with a blood pressure cuff, arterial catheter, or intravascular line. Reposition the sensor as necessary.	
Alarms only briefly actuate.	Check patient trend data.	
	Examine the patient.	
	Determine if Alarm Audio Off is enabled. If so, an alarm will sound every three (3) minutes.	
	Determine if the SPD alarm is active and alarming.	
	Check the speaker. Reference <i>Hardware Issues</i> , p. 11-17.	

11.8 Communication Issues

Table 11-7. Common Prompts and Error Messages

Problem	Resolution	
Unable to connect to the network.	Review system requirements for compatibility.	
Unable to connect to the wireless network.	Check one port at a time for IP address, cable connection, ca damage. Wireless, ethernet, and serial ports are each mutual	
Unable to establish a connection with the remote system.	exclusive.	
Communication failure between host	 Check to ensure all network connections are properly connected and configured. 	
and monitor is detected.	Replace any suspect cables. Fiber is not always visibly damaged.	
	Contact an IT specialist to review the network connection.	
	Return to a qualified service technician.	
The data relayed over the network is spotty or garbled.	Review system requirements for compatibility.	
sportly of garbied.	Check network settings.	
	Check to ensure all network connections are properly connected and configured.	
	Replace any suspect cables. Fiber is not always visibly damaged.	
	Contact an IT specialist to review the network connection.	
	Replace the Main PCB.	

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11.9 Operational Performance Issues

Table 11-8. Common Operational Performance Issues

Problem	Resolution
Monitoring screen appears functional, but is not registering patient data.	Ensure pulse oximetry sensor and interface cable are both Nellcor™ products.
	Check the for the loss-of-pulse indicator. If lit, ensure Nellcor™ sensor is firmly connected. Reference Nellcor™ Sensor Performance Considerations, p. 8-1.
	Check the monitoring screen for the jagged interference indicator. If lit, ensure Nellcor™ sensor is firmly connected and patient remains still.
Patient data appears suspect.	Check sensor and interface cable connections.
Intermittent or corrupt patient data.	Reset the monitoring system.

11.10 Hardware Issues



WARNING:

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

Table 11-9. Common Prompts and Error Messages

Problem		Resolution
Primary speaker failure is detected during operation.		Remove from service immediately.
operation.	•	Check cabling and connectivity. Replace if needed.
	•	Check the speaker. Replace if needed.
	•	Check the Main PCB. Replace if needed.

 Table 11-9.
 Common Prompts and Error Messages (Continued)

Problem	Resolution
Monitor was reset unexpectedly.	If problem persists, remove from service.
	Check cabling and connectivity. Replace if needed.
	Check fan. The monitoring system may be overheating. Replace if needed.
	Check the Main PCB. Replace if needed.
	Check the SBC PCB. Replace if needed.
	Check the power supply. Replace if needed.
SpO2 or pulse rate data has not been updated for over 30 seconds.	
Nurse call output system error.	Check cabling and connectivity.
Serial Communications system failure.	Reference Communication Issues, p. 11-16.
Analog output system failure.	
Cooling fan failure.	Check fan. Replace if needed.
	Check the Main PCB. Replace if needed.
Thermal control system is above thermal limit.	Power down and allow to cool.
irriit.	Remove any potential sources of heat.
	Check heat and humidity conditions. Reference <i>Environmental Conditions</i> , p. 2-3.
	Move to a controlled environment.
	Check fan. Replace if needed.
	Check the Main PCB. Replace if needed.
Invalid date and time value detected during	Set the date and time.
start up.	Replace the battery, if stored for too long.
	Check the Main PCB. Replace if needed.
BATTERY MISSING message occurs, even though a battery is present.	Reference <i>Power Failure Issues</i> , p. 11-11.

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11.11 System Errors and Software issues

The monitoring system may encounter a software problem, which results in a screen very similar to the initial splash screen during power up. This indicates a serious error. Power cycle the device.

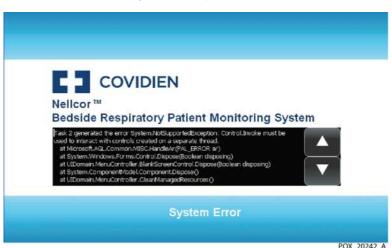


Figure 11-5. System Error

11.12 Non-correctable Failures

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

- The monitoring system sounds a low priority alarm that cannot be silenced except by power cycling the monitoring system.
- Measurements stop.
- All information on the screen vanishes, displaying an error code message.



Note:

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

11.13 Product Return

Contact Covidien or a local Covidien representative for shipping instructions, including a Returned Goods Authorization (RGA) number. Unless otherwise instructed by Covidien, it is not necessary to return the sensor or other accessory items with the monitoring system. Pack the monitoring system in its original shipping carton. If the original carton is not available, use a suitable carton with the appropriate packing material to protect it during shipping.

Return the monitoring system by any shipping method that provides proof of delivery.

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12 Repair

12.1 Overview

This chapter provides trained service technicians with information on how to repair the NellcorTM Bedside Respiratory Patient Monitoring System.

Nellcor™ Bedside Respiratory Patient Monitoring System major component parts include all printed circuit boards (PCBs) and subassemblies.

- Printed circuit boards (PCBs)
- Battery
- Cables
- Chassis enclosures

Obtain part numbers for spare parts by contacting Covidien or accessing http://www.covidien.com/.

12.2 Spare Parts List

Table 12-1. Available Spare Parts

Description	Part Type	Repair Section
Antenna Set (2)	Assembly	Reference <i>p. 12-35</i>
Battery	Item	Reference p. 12-7
Battery Access Door	Item	Reference p. 12-7
Battery Connector (Interconnect) PCB	Assembly	Reference p. 12-28
Battery Cradle, Carrier	Item	Reference <i>p. 12-25</i>
Box, Shipping	Assembly	
Cables, Left	Kit	Reference <i>p. 12-31</i>
Cables, Right	Kit	Reference <i>p. 12-22</i>

 Table 12-1. Available Spare Parts (Continued)

Description	Part Type	Repair Section
Equipotential Ground Lug	Item	
Fan, Cooling	Assembly	Reference <i>p. 12-29</i>
Flex Circuit Cable (J2)	Assembly	Reference <i>p. 12-39</i>
Front Enclosure with Membrane Keypad	Assembly	Reference <i>p. 12-17</i>
Fuse, Line (2)	Item	Reference p. 12-7
Hardware	Kit	
Label, Data: Main Unit	Item	
Label, Data: Parameter Module	Item	
LCD Panel with Overlay	Assembly	Reference <i>p. 12-39</i>
Main PCB	Assembly	Reference <i>p. 12-33</i>
Mounting Plate	Kit	
OEM Module, PCB	Item	Reference <i>p. 12-15</i>
Parameter (Interface) Board with SpO2, PCB	Item	Reference <i>p. 12-15</i>
Parameter Board, PCBA	Assembly	Reference <i>p. 12-15</i>
Parameter Module	Assembly	Reference <i>p. 12-10</i>
Parameter Module Case: Bottom	Item	Reference <i>p. 12-13</i>
Parameter Module Case: Front	Item	Reference <i>p. 12-13</i>
Parameter Module Case: Top	Item	Reference <i>p. 12-13</i>
Power Entry Module (PEM) PCB	Assembly	Reference <i>p. 12-22</i>
Power Supply PCB	Assembly	Reference <i>p. 12-26</i>
Rear Enclosure	Assembly	Reference <i>p. 12-10</i>
Rubber Foot (4)	Kit	Reference p. 12-8
Single Board Computer (SBC) PCB	Assembly	Reference <i>p. 12-37</i>
Speaker	Assembly	Reference <i>p. 12-38</i>

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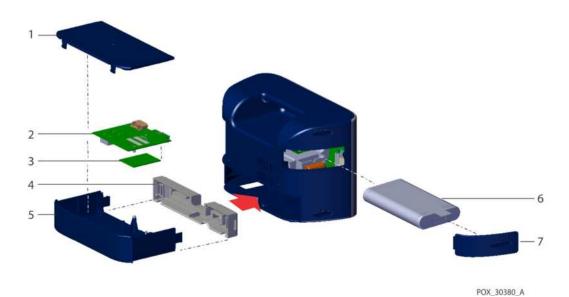


Figure 12-1. Exploded View of Removable Components

- 1 Parameter Module Case: Top
- 2 Parameter (Interface) Board with SpO2
- 3 OEM Module PCB
- 4 Parameter Module Case: Front
- 5 Parameter Module Case: Bottom
- 6 Battery
- 7 Battery Access Door

- 1 Single Board Computer (SBC) PCB
- 2 Main PCB
- 3 Flex Circuit Cable (J2)
- 4 Antenna Set (2)
- 5 Speaker
- 6 Mounting Plate
- 7 LCD Panel with Overlay
- 8 Front Enclosure with Membrane Keypad
- 9 Battery Connector (Interconnect) PCB

- 10 Battery Cradle, Carrier
- 11 Fan, Cooling
- 12 Rear Enclosure
- 13 Power Supply PCB
- 14 Cables, Right
- 15 Power Entry Module (PEM) PCB
- 16 Cables, Left
- 17 Label, Data, Main Unit

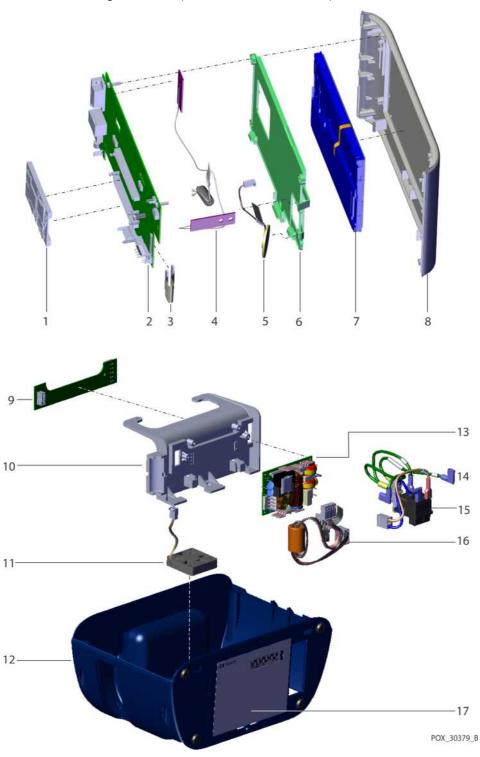


Figure 12-2. Exploded View of Internal Components

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Note:

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

12.3 Repair Prerequisites and Required Equipment



WARNING:

Only qualified service personnel should open the chassis, 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:

Use the test data sheet to ensure the monitoring system passes all safety, performance, and functional tests prior to use in a clinical setting.



WARNING:

Before attempting to open or disassemble, disconnect the power cord to avoid possible injury.



Caution:

Observe electrostatic discharge (ESD) precautions prior to opening the chassis or handling any internal components.



Caution:

Observe the required torque for tightening screws. Over-tightening can strip out screw holes, rendering them useless.



Note:

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

Only a qualified service technician may disassemble the monitoring system to its major component parts. The supported replacement level is to the printed circuit board (PCB) and major subassembly level. After isolating the problem to a suspected PCB, follow the procedures for disassembly, then replace the original suspect PCB with a known good PCB. Verify the symptom disappears and

ensure the monitoring system passes all performance tests. If the symptom persists, swap the known good PCB with the original suspect PCB and continue troubleshooting.

- 1. Collect all tools prior to any disassembly of the monitoring system. Access and repair is not possible without the use of the listed tools.
- 2. Always disconnect the monitoring system from AC power and remove the hospital-grade power cord until completion of any repair.
- 3. Prepare a clean, static-free work surface large enough to accommodate the unit and its subassemblies. A container with cover to retain screws and small parts is also helpful.

Equipment	Description
T-6, T-10, and T-15 torx driver	6-inch or more reach
10mm 1/4" socket	Deep well
Small flat-blade screwdriver	6-inch or more reach
Needle nose pliers or 1/4-inch socket with driver	
Torque driver	Up to 12 inch-pounds rating

Table 12-2. Required Equipment



Note:

The battery charge procedure should be performed before repairs when possible.

12.4 Basic Preventive Maintenance

Replace the battery at least every two years. More frequent battery replacement may be required, depending on usage and environment. Regularly check fuses and replace as needed. The following subsection describes three primary tasks.

- 1. Reference Fuse Removal and Replacement, p. 12-7, for replacing fuses.
- 2. Reference *Battery or Battery Access Door Replacement*, p. 12-7, for battery and battery access door replacement.
- 3. Reference *Rubber Feet Replacement*, p. 12-8, for details regarding replacement of the rubber feet.

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12.4.1 Fuse Removal and Replacement

To remove and replace external fuses

- 1. Remove the fuse drawer from the power entry module.
 - a. Press down on the center tab.
 - ь. Pull outward.
- 2. Remove both 5 x 20-mm, slow blow, 1.5-amp, 250-volt fuses.

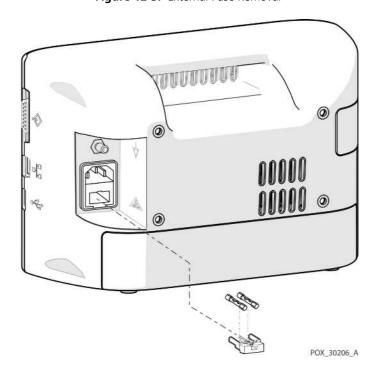


Figure 12-3. External Fuse Removal

- 3. Replace with two (2) new, 5 x 20-mm, slow blow, 1.5-amp, 250-volt fuses.
- 4. Reinsert the fuse drawer until the tab snaps in place.

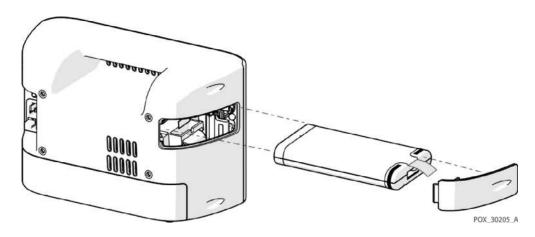
12.4.2 Battery or Battery Access Door Replacement

To remove the battery access door and battery

1. Using the T-15 torx driver, remove and set aside the torx screw from the battery cover.

- 2. Remove and set aside the battery cover.
- 3. Slide out the battery while pulling on the battery tab.

Figure 12-4. Battery Removal



To replace the battery access door and battery

- 1. After removing the old battery, gently slide the new battery into the battery slot, contact side down and facing the slot.
- 2. Replace the battery cover, hooking the tab into the back chassis.
- 3. Place and tighten the T-15 torx battery cover screw to 10 inch-pounds.
- 4. Connect to AC power.
- 5. Press the ON/STANDBY button to power on the monitoring system.
- 6. Verify battery charge and AC power indicators illuminate.
- 7. Allow the battery to fully charge prior to any clinical use.
- 8. Verify unit functionality. Reference *Performance Tests*, p. 10-11.

12.4.3 Rubber Feet Replacement

To remove rubber feet

- 1. Gently rotate the monitoring system, placing so the bottom of the chassis is up.
- 2. Slide the tip of the flat-blade screwdriver under each rubber foot and pry up to remove.

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3. Clean the surface of the bottom of the monitoring system, using one of the standard cleaning solutions described for preventive maintenance, to remove any adhesive residue.

To replace rubber feet

- 1. Ensure the bottom surface of the monitoring system is clean and dry.
- 2. Peel away the protective release liner on the rubber foot to expose the adhesive.
- 3. Gently align the rubber foot to the indented area.
- 4. Press down firmly on the rubber foot to properly seat it.
- 5. Repeat the process for the remaining rubber feet.

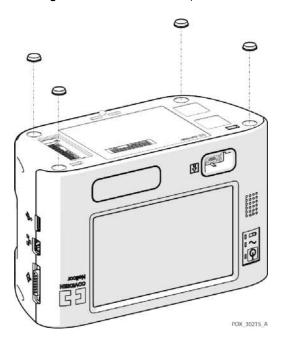


Figure 12-5. Rubber Feet Replacement

- 6. Properly orient and rotate the monitoring system onto its base.
- 7. Reconnect to AC power.
- 8. Turn on the monitoring system by pressing the ON/STANDBY button.

12.5 Chassis Disassembly and Reassembly



WARNING:

Before attempting to open or disassemble, disconnect the power cord to avoid possible injury.



Caution:

Observe ESD (electrostatic discharge) precautions when disassembling and reassembling the monitoring system and when handling any internal components.



Caution:

Ensure the work surface is clean and free of debris.



Note:

The battery charge procedure should be performed before repairs when possible.

Disassembly and reassembly of the chassis requires removal of the parameter module. Prepare a reasonable, static-free work surface for opening and working on both halves. The following section describes three primary tasks.

- 1. Reference *Parameter Module Replacement*, p. 12-10, to remove and then replace the parameter module or its subassemblies.
- 2. Reference *Monitoring System Chassis Disassembly*, p. 12-17, for chassis disassembly.
- 3. Reference *Monitoring System Chassis Reassembly*, p. 12-20, for chassis reassembly.

12.5.1 Parameter Module Replacement

Remove the parameter module prior to performing any internal repair to the monitoring system. The parameter module consists of the parameter module case and the parameter board assembly. The following subsection describes three primary tasks.

- 1. Reference *Parameter Module Replacement*, p. 12-10, to remove and then replace the parameter module assembly.
- 2. Reference *Parameter Module Case Replacements*, p. 12-13, to remove and then replace components of the parameter module case.
- 3. Reference *Parameter Board PCBA Replacements*, p. 12-15, to remove and then replace either the parameter board PCB or the OEM PCB.

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To remove the parameter module

1. Gently rotate the monitoring system, placing so the bottom of the chassis is up.

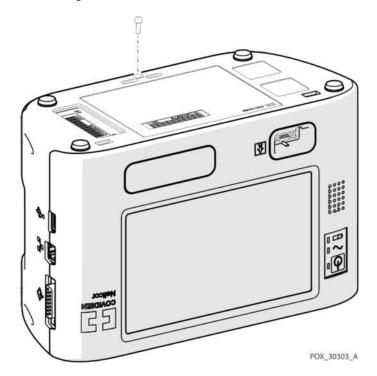


Figure 12-6. Parameter Module Screw Removal

- 2. Remove T-15 screw located between the slots at the rear of the bottom chassis.
- 3. Using a flat-blade screwdriver, release the faceplate tabs on either side by pressing towards the outside and towards the back simultaneously, listening for a click to indicate tab release.

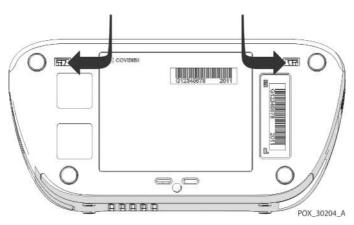


Figure 12-7. Parameter Module Tab Release

4. Gently press inward against the parameter module assembly through the two openings, releasing it from the backplane. Expect minor resistance until it releases.

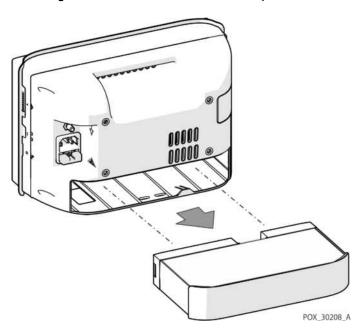


Figure 12-8. Parameter Module Assembly Removal

- 5. Remove and set aside the parameter module assembly.
- 6. Gently rotate the monitoring system to the upright position.

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To replace the parameter module assembly

- 1. Slide the new parameter module assembly into the rear chassis until it snaps into place.
- 2. Connect to AC power.
- 3. Verify unit functionality. Reference *Performance Tests*, p. 10-11.

Parameter Module Case Replacements

The parameter module case consists of three parts: the faceplate, the top cover, and the bottom enclosure.

To remove parameter module case components

- 1. Turn off the monitoring system by pressing the ON/STANDBY button.
- 2. Disconnect from AC power.
- 3. Remove the parameter module. Reference *To remove the parameter module*, p. 12-11.
- 4. Set it face down on a static-free work surface.



Caution:

Ensure the work surface is clean and free of debris.

- 5. Rotate the module so the slot in the side panel is visible.
- 6. Using a flat-blade screwdriver, press inward on the visible faceplate tab by pressing inward, listening for a click to indicate tab release.
- 7. Rotate the module so the slot in the opposite side panel is visible and repeat the process.
- 8. Remove and set aside the faceplate.
- 9. Gently lift outward and upward on the top cover, releasing it from the mating slots in the bottom enclosure.

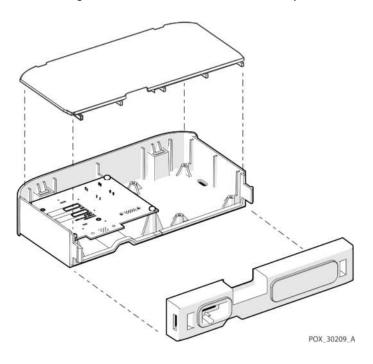


Figure 12-9. Parameter Module Disassembly

- 10. Remove and set aside the top cover.
- 11. Remove and set aside the four parameter interface PCB assembly T-10 torx screws.
- 12. Remove and set aside the parameter interface PCB assembly on a static-free work surface.
- 13. Remove and set aside failing top cover, faceplate, or bottom enclosure in an alternate location.

To replace a parameter module case component

- 1. Select the new parameter module case component: top cover, faceplate, or bottom enclosure, and place with the still-good components on a static-free work surface.
- 2. Rotate the parameter interface PCB assembly so the NELL1SR PCB is facing downward and both connector sockets are facing the front of the bottom enclosure.
- 3. Place on the left-hand bottom enclosure standouts.
- 4. Replace and tighten the four T-10 torx screws to a maximum of 10 inch-pounds.

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- 5. Replace the top cover, ensuring the tabs slip down into the mating slots of the bottom enclosure.
- 6. Replace the faceplate, aligning to the mating tabs of the bottom enclosure and ensuring the lugs of the top cover slip under the faceplate lip.
- 7. Orient and slide the new parameter module into the rear chassis until it snaps into place.
- 8. Replace and tighten the T-15 torx screw to a maximum 10 inch-pounds.
- 9. Connect to AC power.
- 10. Verify unit functionality. Reference *Performance Tests*, p. 10-11.

Parameter Board PCBA Replacements

The parameter board assembly consists of two PCBs: the parameter (interface) board PCB and the oximetry module PCB.

To remove the parameter board assembly

- 1. Turn off the monitoring system by pressing the ON/STANDBY button.
- 2. Disconnect from AC power.
- 3. Remove the parameter module. Reference *To remove the parameter module*, p. 12-11.
- 4. Set it down on a static-free work surface.



Caution:

Ensure the work surface is clean and free of debris.

- 5. Rotate the module so the slot in the side panel is visible.
- 6. Using a flat-blade screwdriver, press inward on the visible faceplate tab by pressing inward, listening for a click to indicate tab release.
- 7. Rotate the module so the slot in the opposite side panel is visible and repeat the process.
- 8. Remove and set aside the faceplate.
- 9. Gently lift outward and upward on the top cover, releasing it from the mating slots in the bottom enclosure.
- 10. Remove and set aside the top cover.

- 11. Remove and set aside the four T-10 torx parameter (interface) board PCB screws.
- 12. Gently rotate the parameter board assembly, laying the assembly flat on a static-free work surface with the oximetry module PCB facing up.
- 13. Remove and set aside the two oximetry module PCB T-10 torx screws.

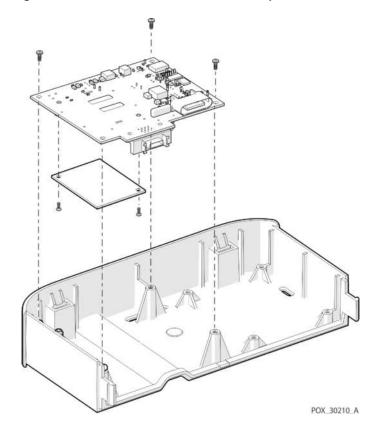


Figure 12-10. Parameter Board PCB and Oximetry Module Removal

- 14. Gently lift upward, removing the oximetry module PCB off the parameter board assembly standoffs, ensuring all pins fully disconnect from both connectors.
- 15. Remove and set aside the failing PCB in an alternate location.

To replace the parameter board assembly

- 1. Obtain the replacement parameter board assembly component: the oximetry module PCB or the parameter board PCB.
- 2. Set with the known good component on a static-free work surface.

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Caution:

Ensure the work surface is clean and free of debris.

- 3. Orient the oximetry module PCB so the 8-pin J5 connector pins mate to the parameter board J9 receptacle and the 10-pin J4 connector pins mate to the parameter board J7 receptacle.
- 4. Press downward on the oximetry module PCB until fully seated on the parameter (interface) board PCB.
- 5. Replace and tighten the two T-10 torx screws to a maximum of 6 inch-pounds.
- 6. Rotate the parameter board assembly so the oximetry module PCB is facing downward and both connector sockets are facing the front of the bottom enclosure.
- 7. Place on the standouts to the left of the bottom enclosure.
- 8. Replace and tighten the four T-10 torx screws to a maximum of 10 inch-pounds.
- 9. Replace the top cover, ensuring the tabs slip down into the mating slots of the bottom enclosure.
- 10. Replace the faceplate, aligning to the mating tabs of the bottom enclosure and ensuring the lugs of the top cover slip under the faceplate lip.
- 11. Replace the parameter module. Reference *To replace the parameter module assembly*, p. 12-13.
- 12. Connect to AC power.
- 13. Verify unit functionality. Reference *Performance Tests*, p. 10-11.

12.5.2 Monitoring System Chassis Disassembly



Caution:

Observe ESD (electrostatic discharge) precautions when disassembling and reassembling the monitoring system and when handling any internal components.



Note:

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

To disassemble the monitoring system chassis

- 1. Turn off by pressing the ON/STANDBY button.
- 2. Disconnect from the AC power source.
- 3. Remove the parameter module. Reference *To remove the parameter module*, p. 12-11.
- 4. Set it face down on a static-free work surface.



Caution:

Ensure the work surface is clean and free of debris.

- 5. Remove the battery. Reference *To remove the battery access door and battery*, p. 12-7.
- 6. Remove and set aside all four T-15 torx screws, one from each corner of the rear chassis.

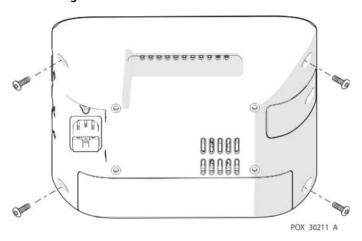


Figure 12-11. Corner Chassis Screws Removal

- 7. Carefully separate front and back chassis cases without stressing the connection harnesses between them.
- 8. Gently set the back chassis on its feet.



Caution:

To avoid stress or damage to the wiring harness, ensure the front chassis is lying flat on the work surface.

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- 9. Ensure both halves remain on a static-free work surface.
- 10. Review the following table for identifying Main PCB connectors. The table identifies cables and connectors beginning on the top, right hand corner of the Main PCB and proceeding clockwise. Some cables are barely visible or require special routing.

Table 12-3. Main PCB Connections

Receptacle	Cable Description	Cable Color
J5	Two-pin speaker cable	Red and black
J7	Five-connector flex cable	Translucent aqua
J15	Main ribbon cable	Gold
J2	Three-pin fan cable	Red, black, and yellow
J22	Four-pin power cable	Red and black
J23	Five-pin battery cable	Black
J21	Spade	Green GND
J10	Six-connector flex cable	Gold
J6	Four-connector flex cable	Gold

- 11. Disconnect the spade connector (GND) from the J21 mating blade on the Main PCB.
- 12. Disconnect the five-pin battery connector from the J23 receptacle on the Main PCB.
- 13. Disconnect the four-pin power connector from the J22 receptacle on the Main PCB.
- 14. Disconnect the three-pin fan connector from the J2 receptacle on the Main PCB.

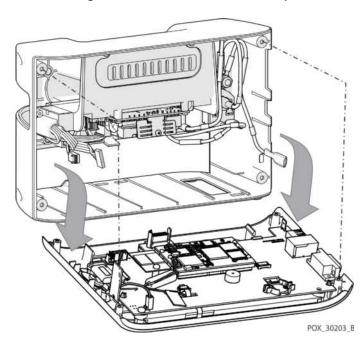


Figure 12-12. Initial Chassis Disassembly

12.5.3 Monitoring System Chassis Reassembly

To reassemble the monitoring system chassis

- 1. Position the front chassis on a static-free work surface, still lying face down, within reach of the back chassis connectors.
- 2. Firmly connect the spade connector (GND) to the J21 mating blade on the Main PCB.
- 3. Firmly connect the five-pin battery connector to the J23 receptacle on the Main PCB.
- 4. Firmly connect the four-pin power connector to the J22 receptacle on the Main PCB.
- 5. Firmly connect the three-pin fan connector to the J2 receptacle on the Main PCB.
- 6. Gently align and place the back chassis onto the front chassis.



Caution:

Do not pinch any wires between the chassis enclosures when reassembling. Before installing the screws, inspect the entire edge of the union for even seating.

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7. Replace and tighten the four T-15 torx screws into the corners of the chassis to a maximum of 10 inch-pounds.



Caution:

Overtightening could strip out the screw holes in the chassis, rendering it unusable.

- 8. Replace the battery. Reference *To replace the battery access door and battery*, p. 12-8.
- 9. Replace the parameter module. Reference *To replace the parameter module assembly*, p. 12-13.
- 10. Connect to AC power.
- 11. Verify unit functionality. Reference *Performance Tests*, p. 10-11.

12.6 Power Components Replacement



WARNING:

Before attempting to open or disassemble, disconnect the power cord to avoid possible injury.



Caution:

Observe ESD (electrostatic discharge) precautions when disassembling and reassembling the monitoring system and when handling any internal components.



Caution:

Ensure the work surface is clean and free of debris.

Power components consist of the battery and three assemblies. The following section describes four primary tasks.

- 1. Reference *Battery or Battery Access Door Replacement*, p. 12-7, for battery details.
- 2. Reference *Power Entry Module (PEM) Replacement*, p. 12-22, for PEM details.
- 3. Reference *Right Power Cable Assembly Replacement*, p. 12-22, for right cable kit details. Reference *Left Power Cable Assembly Replacement*, p. 12-31, for left cable kit details.

4. Reference *Battery Components Replacement*, p. 12-24, for battery cradle, Power Supply PCB, Battery Interconnect PCB, and cooling fan replacement.

12.6.1 Power Entry Module (PEM) Replacement

To remove the power entry module

- 1. Disassemble the monitoring system chassis. Reference *To disassemble the monitoring system chassis*, p. 12-18.
- 2 Move the front chassis off to the side.
- 3. Remove the blue (N), brown (L), and green (GND) power cables connected to the power entry module, noting their current positions.
- 4. Depress tabs on left and right of old power entry module to release from the chassis.



Note:

Technicians may choose to separate the fuse drawer from the power entry module until completing power entry module replacement.

To replace the power entry module

- 1. Properly orient the new power entry module so the single blade is to the top and the dual blades are to the bottom.
- 2. Firmly connect the green (GND) cable to the upper, single blade of the power entry module.
- 3. Firmly connect the blue (N) cable to the left-hand, lower blade and the brown (L) cable to the right-hand, lower blade of the power entry module.
- 4. Slide power entry module into chassis, ensuring no cable pinching occurs, until it snaps into place.
- 5. Reassemble the monitoring system chassis. Reference *To reassemble the monitoring system chassis*, p. 12-20.

12.6.2 Right Power Cable Assembly Replacement

To remove the right power cable assembly

- 1. Disassemble the monitoring system chassis. Reference *To disassemble the monitoring system chassis*, p. 12-18.
- 2. Move the front chassis off to the side.

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- 3. Remove the green (GND) spade connector from the J21 mating blade on the Main PCB.
- 4. Remove the green (GND) spade connector from the E1 mating blade on the power supply PCB.
- 5. Remove the two-pin blue (N) and brown (L) (AC) cable and connector from the 2-pin J1 receptacle on the power supply PCB.

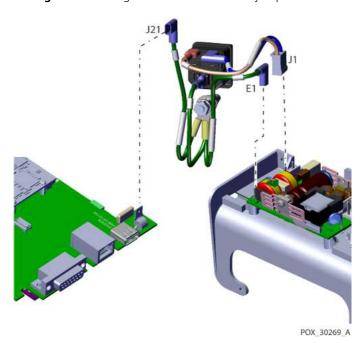


Figure 12-13. Right Power Cable Assembly Replacement

- 6. Remove the blue (N), brown (L), and green (GND) power cables connected to the power entry module, noting their current positions.
- 7. Remove all sets of M6 lug nuts and ground wire cable ring terminals from the equipotential stud using a deep well 10mm socket wrench.

To replace the right power cable assembly

- 1. Properly orient the new right power cable assembly.
- 2. Connect one ground wire cable ring terminals to the equipotential stud.
- 3. Secure in place with a lug nut, tightening to 12 inch-pounds with a deep well 10mm socket wrench.

- 4. Repeat this process for the remaining ground wire cable ring terminal.
- 5. Firmly connect the green (GND) cable to the single prong to the top of the power entry module.
- 6. Firmly connect the blue (N) cable to the left-hand, neutral (N) blade of the power entry module and the brown (L) cable to the right-hand, live (L) blade of the power entry module.
- 7. Firmly connect the green (GND) spade connector to the J21 mating blade on the Main PCB.
- 8. Firmly connect the green (GND) spade connector to the E1 mating blade on the power supply PCB.
- 9. Firmly connect two-pin blue (N) and brown (L) (AC) cable and connector to the 2-pin J1 receptacle on the power supply PCB.
- 10. Reassemble the monitoring system chassis. Reference *To reassemble the monitoring system chassis*, p. 12-20.

12.6.3 Battery Components Replacement

The battery cradle assembly consists of several subassemblies and PCBs. For successful battery cradle replacement, perform the following instructions in order.

To remove and then replace battery components

- 1. Remove the battery. Reference *To remove the battery access door and battery*, p. 12-7.
- 2. Disassemble the chassis. Reference *Monitoring System Chassis Disassembly*, p. 12-17.
- 3. Remove the battery cradle. Reference *Removing the Battery Cradle and Components*, p. 12-25.
- 4. Remove and replace the Power Supply PCB. Reference *Power Supply PCB Replacement*, p. 12-26.
- 5. Remove and replace the Battery Interconnect PCB. Reference *Battery Interconnect PCB Replacement*, p. 12-28.
- 6. Remove and replace the cooling fan. Reference *Cooling Fan Replacement*, p. 12-29.
- 7. Replace the battery cradle. Reference *Replacing the Battery Cradle and Components*, p. 12-26.

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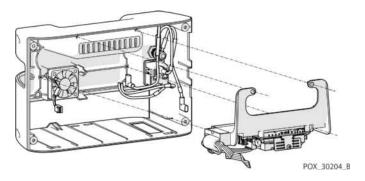
8. Reverse the process for replacement.

Battery Cradle Replacement

Removing the Battery Cradle and Components

- 1. Disassemble the monitoring system chassis. Reference *To disassemble the monitoring system chassis*, p. 12-18.
- 2. Move the front chassis off to the side.
- 3. Remove all four T-10 torx screws, two on top, and two deep underneath, using a long-reach driver.

Figure 12-14. Battery Cradle Removal



4. Lift out the battery cradle, supporting both the battery cradle and still connected wires.



Note:

Cooling fan is still attached by wires, but is free-floating.

5. Set it on a static-free work surface.



Caution:

Ensure the work surface is clean and free of debris.

- 6. Remove the Power Supply PCB. Reference *Power Supply PCB Replacement*, p. 12-26.
- 7. Remove the Battery Interconnect PCB. Reference *Battery Interconnect PCB Replacement*, p. 12-28.

8. Remove the cooling fan. Reference *Cooling Fan Replacement*, p. 12-29.



Note:

Only replace the battery cradle after retaining the three related field replaceable units (FRUs).

Replacing the Battery Cradle and Components



Note:

If replacing ONLY the battery cradle, do not disconnect the J1 and J2 connectors on the power supply PCB. It will still require clipping the wire tie to the ferrite bead.

- 1. Replace the Battery Interconnect PCB. Reference *Battery Interconnect PCB Replacement*, p. 12-28.
- 2. Replace the Power Supply PCB. Reference *Power Supply PCB Replacement*, p. 12-26.
- 3. Replace the cooling fan. Reference *Cooling Fan Replacement*, p. 12-29.
- 4. Gently align and replace the battery cradle.
- 5. Tighten all four T-10 torx screws, two on top, and two deep underneath, using a long-reach driver to 10 inch-pounds.
- 6. Reassemble the monitoring system chassis. Reference *To reassemble the monitoring system chassis*, p. 12-20.

Power Supply PCB Replacement

- 1. Orient the battery cradle to provide access to the power supply.
- 2. Remove the two-pin J1 (AC) and spade E1 (GND) connectors from the power supply PCB.
- 3. Remove the four-pin J2 connector.
- 4. Remove the two T-10 torx screws.
- 5. Slide the power supply PCB outward and upward to release from the battery cradle standoffs and retaining slots.

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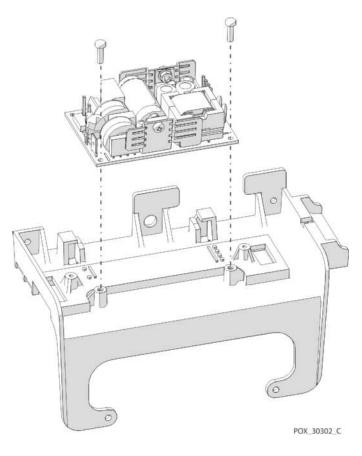


Figure 12-15. Power Supply PCB Removal

- 1. Examine the battery cradle for alignment information. Extruded icons on the battery cradle indicate proper four-pin connector two-pin receptacle orientation.
- 2. Orient the new power supply PCB and slide down into the battery cradle retaining slots and onto the battery cradle standoffs, ensuring the fan cable remains free of the battery cradle.
- 3. Route the fan cable up under the battery cradle so it rests on the appropriate moulded fin nearest the wire-tied cables.
- 4. Replace and tighten both T-10 torx screws to 10 inch-pounds.
- 5. Firmly connect the four-pin J2 connector.
- 6. Firmly connect the two-pin J1 (AC) and spade E1 (GND) connectors to the receptacles on the opposite side of the power supply board.

- 7. Place the fan back down in its enclosure.
- 8. Replace the battery cradle in the back chassis. Reference *Battery Cradle Replacement*, p. 12-25.
- 9. Reassemble the monitoring system chassis. Reference *To reassemble the monitoring system chassis*, p. 12-20.

Battery Interconnect PCB Replacement

To remove the Battery Interconnect PCB

- 1. Follow all previous steps for removing the battery cradle. Reference *Battery Cradle Replacement*, p. 12-25. It is not necessary to remove the power supply PCB.
- 2. Disconnect the five-pin J2 connector from the recess between the power supply PCB and the wire-tied cable assembly with the ferrite bead.
- 3. Rotate the battery cradle to ensure battery interconnect PCB accessibility.
- 4. Remove both T-10 torx screws.
- 5. Lift from the battery cradle.

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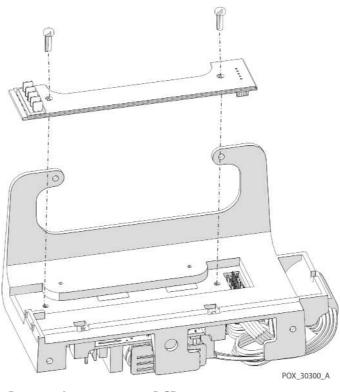


Figure 12-16. Battery Interconnect PCB Removal

To replace the Battery Interconnect PCB

- 1. Place the new battery interconnect PCB on the battery cradle.
- 2. Replace and tighten both T-10 torx screws to 10 inch-pounds.
- 3. Rotate the battery cradle.
- 4. Reconnect the five-pin J2 connector.
- 5. Replace the cooling fan. Reference *Cooling Fan Replacement*, p. 12-29.
- 6. Replace the battery cradle in the back chassis. Reference *Battery Cradle Replacement*, p. 12-25.

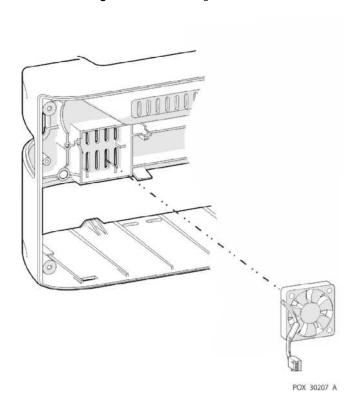
Cooling Fan Replacement

To remove the cooling fan

1. Follow all previous steps for removing the battery cradle. It is not necessary to remove the power supply PCB or battery interconnect PCB.

- 2. Rotate the battery cradle to ensure fan accessibility.
- 3. Clip the wire tie to the wiring harness.
- 4. Remove the fan from its enclosure.

Figure 12-17. Cooling Fan Removal



To replace the cooling fan

- 1. Place the new fan down in its enclosure.
- 2. Replace the battery cradle in the back chassis. Reference *Battery Cradle Replacement*, p. 12-25.
- 3. Wire tie the new cooling fan wire to the wiring harness.

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12.6.4 Left Power Cable Assembly Replacement

To remove the left power cable assembly

- 1. Disassemble the monitoring system chassis. Reference *To disassemble the monitoring system chassis*, p. 12-18.
- 2. Move the front chassis off to the side.
- 3. Identify the proper cables under the battery cradle. They are the cables to the opposite side of the enclosure from the power entry module.
- 4. Remove the five-pin Mini-mate black cable and connector from its J2 receptacle from the power supply PCB.
- 5. Remove the four-pin red and black (DC) cable and connector with ferrite bead from its J2 receptacle on the battery interconnect PCB.

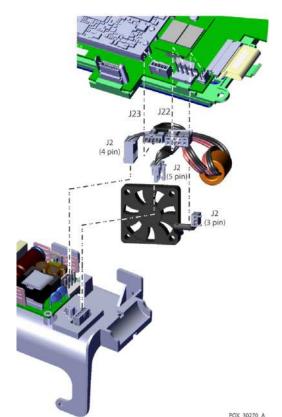


Figure 12-18. Left Power Cable Assembly Replacement

- 6. Remove the cables connected to the five-pin J23 receptacle, the four-pin J22 receptacle, and the three-pin J2 receptacle on the Main PCB.
- 7. Cut the wire tie securing the ferrite bead to the wiring harness.

To replace the left power cable assembly

- 1. Properly orient the new left power cable assembly.
- 2. Tighten a wire tie around the ferrite bead to secure it to the wiring harness.
- 3. Firmly connect the five-pin Mini-mate black cable connector to the J23 beige receptacle on the Main PCB.
- 4. Firmly connect the four-pin red and black (DC) cable and connector to the J22 white receptacle on the Main PCB.
- 5. Firmly connect the three-pin black fan cable and connector to the J2 black receptacle on the Main PCB.
- 6. Firmly connect the five-pin Mini-mate black cable and connector to its J2 white receptacle from the power supply PCB.
- 7. Firmly connect the four-pin red and black (DC) cable and connector to its J2 grey receptacle on the battery interconnect PCB.
- 8. Reassemble the monitoring system chassis. Reference *To reassemble the monitoring system chassis*, p. 12-20.

12.7 Front Panel Components Replacement



WARNING:

Before attempting to open or disassemble, disconnect the power cord to avoid possible injury.



Caution:

Observe ESD (electrostatic discharge) precautions when disassembling and reassembling the monitoring system and when handling any internal components.



Caution:

Ensure the work surface is clean and free of debris.

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Front panel components consist of the Main PCB and LCD PCB assemblies. The following section describes two primary tasks.

- 1. Reference Main PCB Components Replacement, p. 12-33.
- 2. Reference LCD Assembly with Overlay Replacement, p. 12-39.

12.7.1 Main PCB Components Replacement

Main PCB components consist of the Main PCB and four subassemblies. The following subsection describes three primary tasks.

- 1. Reference *Main PCB Replacement*, p. 12-33, for details.
- 2. Reference *Antennae Replacement*, p. 12-35, for details.
- 3. Reference Single Board Computer (SBC) PCB Replacement, p. 12-37, for details.
- 4. Reference *Alarm Speaker Replacement*, p. 12-38, for details.

Main PCB Replacement

To remove the Main PCB

- Disassemble the monitoring system chassis. Reference *Monitoring System Chassis Disassembly*, p. 12-17.
- 2. Move the rear enclosure off to the side, retaining the front panel on a static-free working surface.
- 3. To retain the existing system board SBC PCB, remove it from the Main PCB. Reference *To remove the Single Board Computer (SBC) PCB*, p. 12-37.
- 4. Review the following table for identifying Main PCB connectors. The table identifies cables and connectors. Some cables are barely visible or require special routing.
- 5. Starting from the top left, disconnect the following connectors by disengaging each connector tab or lock, matching cable and connector description and color to ensure accuracy.

Table 12-4. Main PCB Connections

Receptacle	Cable Description	Cable Color	
J10	Six-connector flex cable	Gold	
J6	Four-connector flex cable	Gold	

Receptacle	Cable Description	Cable Color	
J15	Main flex cable	Gold	
J5	Two-pin speaker cable	Red and black	
J7	Five-connector flex cable		
J2	Three-pin fan cable	Red, black, and yellow	
J22	Four-pin power cable	Red and black	

Table 12-4. Main PCB Connections (Continued)

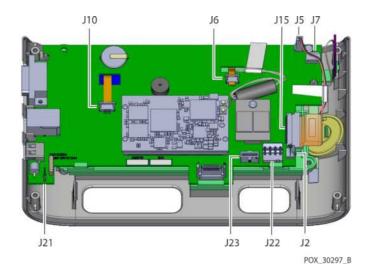
Figure 12-19. Main PCB Connectors

Five-pin battery cable

Spade

Black

Green GND



6. Remove the top two T-15 torx screws.

J23

J21

7. Lift the system board away from the plastic LCD clamp.

To replace the Main PCB

- Mount the SBC PCB on the Main PCB, connecting the golden UFL antennae connectors to the SBC PCB. Reference *To replace the Single Board Computer (SBC) PCB*, p. 12-37.
- 2. Route all four flex cables through their appropriate slots in the Main PCB.

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Note:

All flex cables should be visible above the plastic LCD clamp plate. While the dogleg flex cable appearing in the open square of the plastic LCD clamp plate *could* fit into the CN3 connector on the board below the plastic LCD clamp plate, do not connect it there. Instead, route it through the hole above the J10 ZIF connector.



Note:

The widest flex cable can be ordered separately. Ensure the label printed on the cable, MAIN SIDE J1, connects to the J15 receptacle on the Main PCB.

- 3. Slip the Main PCB back in under the plastic LCD clamp, ensuring all flex cables remain flat and unpinched.
- 4. Replace and tighten the two T-15 torx screws to 10 inch-pounds.
- 5. Firmly connect the J5 speaker connector.
- 6. Reconnect all flex cables into their connectors based on the same method as removal, fully seating all cables and fully engaging all connector tabs.
- 7. Reassemble the monitoring system chassis. Reference *To reassemble the monitoring system chassis*, p. 12-20.

Antennae Replacement

To remove the Antennae PCBs

- 1. Disassemble the monitoring system chassis. Reference *To disassemble the monitoring system chassis*, p. 12-18.
- 2. Remove the Main PCB. Reference *To remove the Main PCB*, p. 12-33.
- 3. Slip right-hand antenna PCB out from the plastic LCD clamp plate.
- 4. Lift plastic LCD clamp plate to remove left-hand antenna PCB.
- 5. Clip wire tie.
- 6. Disconnect both golden UFL antennae connectors from the Single Board Computer (SBC) PCB.

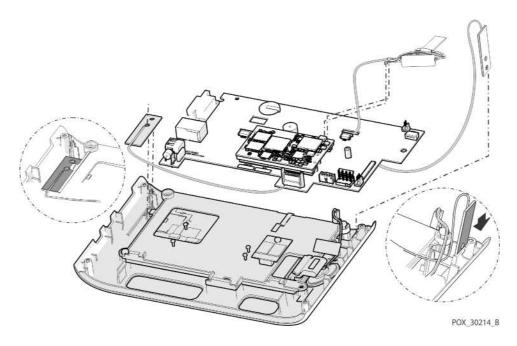


Figure 12-20. Antennae PCB and UFL Connectors Removal

To replace the Antennae PCBs

- 1. Gently thread wires through from the front to the rear of the Main PCB, with the ferrite bead remaining visible and each antenna PCB slipping through the left or right opening on the Main PCB.
- 2. Gently connect both golden UFL antennae connectors onto the SBC PCB.
- 3. Wire tie ferrite bead to the Main PCB, capturing right antenna PCB wire underneath the wire tie, while ensuring the wire remains free under the Main PCB.
- 4. Slide the left-hand antenna PCB under the supporting clip and onto its standouts.
- 5. Slip right-hand antenna PCB back in under the plastic LCD clamp plate.
- 6. Replace the Main PCB. Reference *To replace the Main PCB*, p. 12-34.
- 7. Reassemble the monitoring system chassis. Reference *To reassemble the monitoring system chassis*, p. 12-20.

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Single Board Computer (SBC) PCB Replacement

To remove the Single Board Computer (SBC) PCB

- 1. Disassemble the monitoring system chassis. Reference *Monitoring System Chassis Disassembly*, p. 12-17.
- 2. Move the rear enclosure off to the side, retaining the front panel on a static-free working surface.
- 3. Remove and set aside the four T-6 torx screws.
- 4. Gently disconnect both golden UFL antennae connectors for the antennae from the board.
- 5. Gently remove the SBC board, exerting even pressure on both sides.

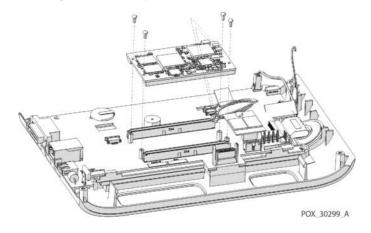


Figure 12-21. Single Board Computer (SBC) Removal

To replace the Single Board Computer (SBC) PCB

- 1. Align the Single Board Computer (SBC) PCB connectors to the staggered connectors on the Main PCB.
- 2. Gently press down to connect the SBC PCB to the Main PCB, ensuring the board is completely seated.
- 3. Reconnect both golden UFL antennae connectors.
- 4. Tighten the four T-6 torx screws to 3 inch-pounds.
- 5. Realign the rear enclosure to the front panel on a static-free working surface.

6. Reassemble the monitoring system chassis. Reference *Monitoring System Chassis Reassembly*, p. 12-20.

Alarm Speaker Replacement



WARNING:

If replacing the speaker because of speaker failure, please contact Covidien Technical Services or your local Covidien (Nellcor) representative.



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.



Note:

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

To remove the alarm speaker

- 1. Disassemble the monitoring system chassis. Reference *Monitoring System Chassis Disassembly*, p. 12-17.
- 2. Move the rear enclosure off to the side, retaining the front panel on a static-free working surface.
- 3. Disconnect the two-pin speaker connector from the J5 white receptacle on the Main PCB.
- 4. Lift the plastic plate clip and gently remove the speaker.

To replace the alarm speaker

- 1. Lift the plastic plate clip and gently replace the speaker.
- 2. Carefully route the speaker wire under the right antennae clip.
- 3. Reconnect the two-pin speaker connector to the J5 white receptacle on the Main PCB.
- 4. Reassemble the monitoring system chassis. Reference *Monitoring System Chassis Reassembly*, p. 12-20.

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12.7.2 LCD Assembly with Overlay 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.

To remove the LCD Assembly

- 1. Disassemble the monitoring system chassis. Reference *Monitoring System Chassis Disassembly*, p. 12-17.
- 2. Move the rear enclosure off to the side, retaining the front panel on a static-free working surface.
- 3. Follow the steps for disconnecting the speaker. Reference *To remove the alarm speaker*, p. 12-38.
- 4. Follow the steps for disconnecting both antennae PCBs. Reference *To remove the Antennae PCBs*, p. 12-35.
- 5. Follow the steps for removing the Main PCB, setting it aside on a static-free working surface. Reference *To remove the Main PCB*, p. 12-33.
- 6. Remove the three T-15 torx screws from the plastic LCD clamp plate.
- 7. Gently lift and set aside the plastic LCD clamp plate, ensuring all flex cables remain free.

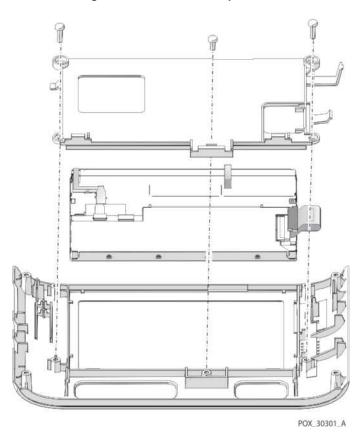


Figure 12-22. LCD Assembly Removal

- 8. Lift out the LCD assembly.
- 9. Remove the display flex cable from the LCD assembly.

To replace the LCD Assembly

- 1. Replace the new LCD assembly, orienting with the two smaller flex cables to the top.
- 2. Thread the large, right-hand flex cable through the plastic LCD clamp plate, ensuring the smaller top flex cable is free above the plastic LCD clamp plate and the dog-leg flex cable threads through the plastic LCD clamp plate cut-away below the battery.
- 3. Tighten the three T-15 torx screws along the sides of the plate to 10 inch-pounds.
- 4. Replace antennae PCBs, ensuring both cables remain unpinched and properly routed. Reference *To replace the Antennae PCBs*, p. 12-36.

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5. Replace the Main PCB, ensuring all wires and cables remain clear. This is particularly critical for the routing of the dog-leg flex cable and remaining flex cables from the LCD display. Reference *To replace the Main PCB*, p. 12-34.



Note:

The widest flex cable can be ordered separately. Ensure the label printed on the cable, J1 DISPLAY SIDE, is visible before connecting to the J1 receptacle on the LCD display.

- 6. Replace the speaker, ensuring the speaker remains under the retaining clip on the plate. Reference *To replace the alarm speaker*, p. 12-38.
- 7. Reassemble the monitoring system chassis. Reference *Monitoring System Chassis Reassembly*, p. 12-20.

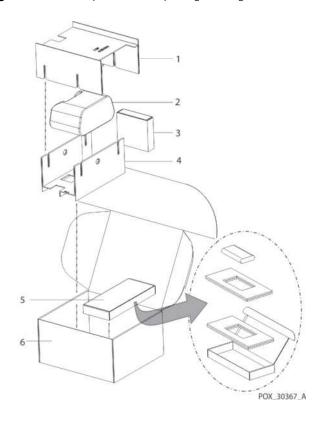
12.8 Return Authorization and Shipment

12.8.1 General Instructions for Return

- Contact Covidien Technical Services or a Covidien Service Center for a Returned Goods Authorization (RGA) number and shipping instructions. Reference Obtaining Technical Assistance, p. 1-5.
- If at all possible, pack in the original carton. If not, follow the directions for an alternate carton.
- Mark the carton and any shipping documents with the RGA number.
- Select a method of shipment which provides tracking and proof of delivery.
- Unless otherwise instructed, do not include any accessories, cables, or sensors.

12.8.2 Repackage in Original Carton

Figure 12-23. Components to Repackage in Original Carton



- 1 Top carton insert
- 2 Plastic-wrapped monitoring system
- 3 Interface cable carton

- 4 Bottom carton insert
- 5 Battery carton
- 6 Monitoring system carton

To repack in the original carton

- 1. Examine the components in the figure.
- 2. Reference Battery or Battery Access Door Replacement, p. 12-7.
- 3. Remove the battery access door and battery.
- 4. Place the battery in a plastic bag.
- 5. Fold the plastic bag around the battery.
- 6. Insert in the original battery carton slot of the battery carton.

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- 7. Close the battery carton, inserting locking tabs into the side slots of the carton
- 8. Place the battery carton flat to the bottom of the monitoring system carton and to the far, right-hand side.
- 9. Replace the monitoring system carton insert butted against the battery carton.
- 10. Replace the battery access door.
- 11. Place the monitoring system in a plastic bag
- 12. Fold the plastic bag around the monitoring system.
- 13. Place face-down in the original monitoring system bottom carton insert.
- 14. Replace the top carton insert, matching the locking tabs of the bottom carton insert.
- 15. Lock the carton flap by folding downwards.
- 16. Completely fill the carton with packing material to ensure nothing will shift during shipment.
- 17. Close the monitoring system carton, inserting locking tabs into the side slots of the carton
- 18. Seal the carton with packing tape.
- 19. Label the carton with shipping address, RGA number, and return address.

12.8.3 Repackage in an Alternate Carton

To repack in an alternate carton

- 1. Locate a corrugated cardboard shipping carton with a minimum bursting strength of 200 pounds per square inch.
- 2. Follow directions for battery removal and packaging.
- 3. Follow the directions for packaging the monitoring system, replacing extra packing material for the carton inserts.
- 4. Follow the directions for sealing and labeling the carton.

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