

Nellcor™ Bedside SpO₂ Patient Monitoring System



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Table of Contents

1	Introduction	
1.1	Overview	1-1
1.2	Safety Information	1-1
1.2.1	Safety Symbols	1-1
1.2.2	Warnings	1-2
1.2.3	Cautions	1-4
1.3	Technical Assistance	1-6
1.3.1	Technical Services	1-6
1.3.2	Related Documents	1-6
1.4	Warranty Information	1-7
2	Product Overview	
2.1	Overview	2-1
2.2	Product Description	2-1
2.3	Indications for Use	2-2
2.4	Product Views	2-3
2.4.1	Front Panel and Display Components	2-3
2.4.2	Rear Panel	2-7
2.4.3	Product and Carton Label Symbols	2-8
3	Installation	
3.1	Overview	3-1
3.2	Safety Reminders	3-1
3.3	Unpacking and Inspection	3-2
3.4	Power	3-3
3.4.1	AC Power Connection	3-3
3.4.2	Internal Battery Power	3-4
3.5	Nellcor™ Pulse Oximetry Sensor Connection	3-5
4	Operation	
4.1	Overview	4-1
4.2	Safety Reminders	4-1
4.3	Apply Power to Monitoring System	4-2
4.3.1	Turn On the Monitoring System	4-2
4.3.2	Turn Off the Monitoring System	4-3
4.4	Menu Navigation	4-4
4.5	Choose Patient Settings	4-5

4.5.1	Set Patient Mode (Type)	4-5
4.5.2	Set SpO ₂ and Pulse Rate Alarm Limits	4-5
4.5.3	Set SpO ₂ WAVEFORM	4-9
4.6	Manage Alarms and Alarm Limits	4-10
4.6.1	Audible Alarm Indicators	4-11
4.6.2	Visual Alarm Indicators	4-12
4.7	Set Additional Patient Modes	4-13
4.7.1	Mode (Response Mode)	4-13
4.7.2	Homecare Mode	4-14
4.7.3	Sleep Study Mode	4-15
4.7.4	Standard Mode	4-17
4.8	Select Optional Settings	4-18
4.8.1	Volume	4-18
4.8.2	Brightness	4-19
4.9	Menu Structure and Factory Defaults	4-20
4.10	Maintenance Reminder	4-22
5	Data Management	
5.1	Overview	5-1
5.2	Tabular Trend Data	5-1
5.3	Graphical Trend Data	5-2
5.4	External Data Communication	5-3
5.4.1	Nurse Call Interface	5-3
5.4.2	Trend Data Download	5-5
5.4.3	Firmware Upgrades	5-16
6	Performance Considerations	
6.1	Overview	6-1
6.2	Oximetry Considerations	6-1
6.2.1	Pulse Rates	6-1
6.2.2	Saturation	6-1
6.3	Performance Considerations	6-2
6.3.1	Overview	6-2
6.3.2	Patient Conditions	6-2
6.3.3	Sensor Performance Considerations	6-3
6.3.4	Reducing EMI (Electromagnetic Interference)	6-5
6.4	Obtaining Technical Assistance	6-6

7	Preventive Maintenance	
7.1	Overview	7-1
7.2	Cleaning	7-1
7.3	Recycling and Disposal	7-2
7.4	Battery Maintenance	7-2
7.5	Periodic Safety Checks	7-4
7.6	Service	7-4
8	Troubleshooting	
8.1	Overview	8-1
8.2	General	8-1
8.3	Error Conditions	8-2
8.4	Return	8-4
9	Accessories	
9.1	Overview	9-1
9.2	Nellcor™ Pulse Oximetry Sensors	9-1
9.3	Optional Equipment	9-4
9.4	Biocompatibility Testing	9-4
10	Theory of Operations	
10.1	Overview	10-1
10.2	Theoretical Principles	10-1
10.3	Automatic Calibration	10-2
10.4	Functional versus Fractional Saturation	10-2
10.5	Measured versus Calculated Saturation	10-3
10.6	SatSeconds™ Alarm Management Feature	10-4
10.6.1	First SpO ₂ Event	10-5
10.6.2	Second SpO ₂ Event	10-6
10.6.3	Third SpO ₂ Event	10-7
10.6.4	The SatSeconds™ Safety Net	10-8
11	Product Specifications	
11.1	Overview	11-1
11.2	Physical Characteristics	11-1
11.3	Electrical Requirements	11-2

11.4	Environmental Conditions	11-2
11.5	Tone Definition	11-3
11.6	Performance Specifications	11-4
11.7	Product Compliance	11-7
11.8	Manufacturer’s Declaration and Guidance	11-7
11.8.1	Electromagnetic Compatibility (EMC)	11-7
11.8.2	Sensor and Cable Compliance	11-14
11.8.3	Safety Tests	11-14
11.9	Essential Performance	11-17
A	Clinical Studies	
A.1	Overview	A-1
A.2	Methodology	A-1
A.2.1	Hypoxia Methodology (Accuracy, Low Saturation, and Motion Studies)	A-1
A.2.2	Low Saturation Methodology (Low Saturation Study Only)	A-2
A.2.3	Motion Methodology (Motion Study Only)	A-2
A.3	Results	A-2
A.3.1	Accuracy Results (No Motion)	A-2
A.3.2	Accuracy Results (Low Saturation)	A-23
A.3.3	Accuracy Results (Motion)	A-28
A.4	Conclusion	A-37
A.4.1	No Motion	A-37
A.4.2	Motion	A-37

List of Tables

Table 1-1. Safety Symbol Definitions.....	1-1
Table 2-1. Display Colors.....	2-7
Table 2-2. Symbol Descriptors.....	2-8
Table 3-1. Standard Items.....	3-2
Table 4-1. Alarm Conditions.....	4-10
Table 4-2. Audio Status.....	4-12
Table 4-3. Menu Structure and Factory Defaults.....	4-20
Table 4-4. Service Menu Settings (Password Protected).....	4-21
Table 5-1. Nurse Call Relay Pins States for NORMALLY +.....	5-5
Table 5-2. Nurse Call Relay Pins States for NORMALLY –.....	5-5
Table 5-3. Status Codes.....	5-10
Table 8-1. Common Problems and Resolutions.....	8-2
Table 9-1. Nellcor™ Pulse Oximetry Sensor Models and Patient Sizes.....	9-2
Table 11-1. Transport, Storage, and Operating Condition Ranges.....	11-2
Table 11-2. Tone Definitions.....	11-3
Table 11-3. Trends.....	11-4
Table 11-4. Nellcor™ Sensor Accuracy and Ranges.....	11-5
Table 11-5. Nellcor™ Sensor Operating Ranges and Power Dissipation.....	11-6
Table 11-6. Electromagnetic Emissions Guidelines and Compliance.....	11-9
Table 11-7. Electromagnetic Immunity Guidelines and Compliance.....	11-10
Table 11-8. Recommended Separation Distance Calculations.....	11-11
Table 11-9. Recommended Separation Distances.....	11-12
Table 11-10. Test Specifications for Enclosure Port Immunity to RF Wireless Communications Equipment.....	11-13
Table 11-11. Cables and Sensors.....	11-14
Table 11-12. Earth Leakage and Touch Current.....	11-15
Table 11-13. Patient Leakage Current.....	11-16
Table A-1. SpO2 Accuracy Results (No Motion).....	A-3
Table A-2. Pulse Rate Accuracy Results (No Motion).....	A-4
Table A-3. RMSD of SpO2 per Decade (No Motion).....	A-22
Table A-4. RMSD of SpO2 per Plateau (No Motion).....	A-23
Table A-5. SpO2 Accuracy Results (60 to 80% SaO2).....	A-23
Table A-6. Pulse Rate Accuracy Results (60 to 80% SaO2).....	A-23
Table A-7. RMSD of SpO2 per Decade (Low Saturation).....	A-27
Table A-8. RMSD of SpO2 per Plateau (Low Saturation).....	A-27
Table A-9. SpO2 Accuracy Results During Motion.....	A-28
Table A-10. Pulse Rate Accuracy Results During Motion.....	A-28
Table A-11. Percent Modulation During Motion.....	A-36
Table A-12. RMSD of SpO2 per Decade (Motion).....	A-36
Table A-13. RMSD of SpO2 per Plateau (Motion).....	A-37

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List of Figures

Figure 2-1.	Front and Side Panel Components	2-3
Figure 2-2.	Display Components	2-4
Figure 2-3.	Rear Panel Components.....	2-7
Figure 3-1.	Connecting a Pulse Oximetry Sensor to Interface Cable.....	3-6
Figure 4-1.	Sample Initial Screen	4-3
Figure 4-2.	Save Change Screen	4-5
Figure 4-3.	SpO ₂ QUICK ACCESS Menu	4-7
Figure 4-4.	QUICK ACCESS PR Menu	4-8
Figure 4-5.	ALARM/LIMITS Menu Options.....	4-8
Figure 4-6.	Waveform Display Area Highlighted	4-9
Figure 4-7.	SpO ₂ Waveform Menu	4-9
Figure 4-8.	Response Mode Menu	4-13
Figure 4-9.	Switch to Homecare Mode.....	4-14
Figure 4-10.	Password Entry for Homecare Mode	4-14
Figure 4-11.	Delete or Save Trend Data.....	4-15
Figure 4-12.	Sensor Messages	4-15
Figure 4-13.	Homecare Mode Main Screen with Homecare Icon	4-15
Figure 4-14.	Switch to Sleep Study Mode.....	4-16
Figure 4-15.	“Disabling of Alarms” Message	4-16
Figure 4-16.	Password Entry for Sleep Study Mode	4-16
Figure 4-17.	Sleep Study Mode Main Screen	4-17
Figure 4-18.	Volume Menu Item.....	4-18
Figure 4-19.	Volume Selection.....	4-18
Figure 4-20.	Brightness Menu Item	4-19
Figure 4-21.	Brightness Selection	4-19
Figure 5-1.	Tabular Trend Data Screen.....	5-1
Figure 5-2.	Graphical Trend Data Screen.....	5-2
Figure 5-3.	Nurse Call Interface Pin Layout.....	5-4
Figure 5-4.	Trend Data Download Option.....	5-7
Figure 5-5.	Trend Data Download Status	5-7
Figure 5-6.	Sample Trend Data Printout	5-9
Figure 5-7.	Sample Bridge Driver Installer window	5-11
Figure 5-8.	Sample New Hardware Wizard Screen.....	5-12
Figure 5-9.	Sample Device Manager Button Under Hardware Tab.....	5-13
Figure 5-10.	Sample Hardware List in Device Manager Window	5-14
Figure 5-11.	Sample Initial USB to UART Bridge Properties Window.....	5-15
Figure 5-12.	Sample Baud rate list under Port Settings tab	5-16
Figure 10-1.	Oxyhemoglobin Dissociation Curve	10-3
Figure 10-2.	Series of SpO ₂ Events	10-4
Figure 10-3.	First SpO ₂ Event: No SatSeconds™ Alarm	10-5
Figure 10-4.	Second SpO ₂ Event: No SatSeconds™ Alarm	10-6

Figure 10-5.	Third SpO ₂ Event: Triggers SatSeconds™ Alarm.....	10-7
Figure A-1.	Modified Bland-Altman for SpO ₂ (All Data - No Motion): SaO ₂ vs. (SpO ₂ - SaO ₂)	A-5
Figure A-2.	Modified Bland-Altman for Pulse Rate (All Data - No Motion): ECG HR vs. (Pulse Rate - ECG HR).....	A-6
Figure A-3.	Modified Bland-Altman for SpO ₂ - MAXA Sensor (No Motion): SaO ₂ vs. (SpO ₂ - SaO ₂)	A-7
Figure A-4.	Modified Bland-Altman for SpO ₂ - MAXN Sensor (No Motion): SaO ₂ vs. (SpO ₂ - SaO ₂)	A-8
Figure A-5.	Modified Bland-Altman for SpO ₂ - MAXFAST Sensor (No Motion): SaO ₂ vs. (SpO ₂ - SaO ₂).....	A-9
Figure A-6.	Modified Bland-Altman for SpO ₂ - SC-A Sensor (No Motion): SaO ₂ vs. (SpO ₂ - SaO ₂)	A-10
Figure A-7.	Modified Bland-Altman for SpO ₂ - DS-100A Sensor (No Motion): SaO ₂ vs. (SpO ₂ - SaO ₂).....	A-11
Figure A-8.	Modified Bland-Altman for SpO ₂ - OxiCliq-A Sensor (No Motion): SaO ₂ vs. (SpO ₂ - SaO ₂).....	A-12
Figure A-9.	Modified Bland-Altman for SpO ₂ - D-YSE Sensor (No Motion): SaO ₂ vs. (SpO ₂ - SaO ₂)	A-13
Figure A-10.	Modified Bland-Altman for Pulse Rate - MAXA Sensor (No Motion): ECG HR vs. (Pulse Rate - ECG HR)	A-14
Figure A-11.	Modified Bland-Altman for Pulse Rate - MAXN Sensor (No Motion): ECG HR vs. (Pulse Rate - ECG HR)	A-15
Figure A-12.	Modified Bland-Altman for Pulse Rate - MAXFAST Sensor (No Motion): ECG HR vs. (Pulse Rate - ECG HR)	A-16
Figure A-13.	Modified Bland-Altman for Pulse Rate - SC-A Sensor (No Motion): ECG HR vs. (Pulse Rate - ECG HR)	A-17
Figure A-14.	Modified Bland-Altman for Pulse Rate - DS-100A Sensor (No Motion): ECG HR vs. (Pulse Rate - ECG HR)	A-18
Figure A-15.	Modified Bland-Altman for Pulse Rate - OxiCliq-A Sensor (No Motion): ECG HR vs. (Pulse Rate - ECG HR)	A-19
Figure A-16.	Modified Bland-Altman for Pulse Rate - D-YSE Sensor (No Motion): ECG HR vs. (Pulse Rate - ECG HR)	A-20
Figure A-17.	Correlation Plot for SpO ₂ (All Data - No Motion): SaO ₂ vs. SpO ₂	A-21
Figure A-18.	Correlation Plot for Pulse Rate (All Data - No Motion): ECG HR vs. Pulse Rate	A-22
Figure A-19.	Modified Bland-Altman for SpO ₂ (All Data - Low Saturation): SaO ₂ vs. (SpO ₂ - SaO ₂)	A-24
Figure A-20.	Modified Bland-Altman for Pulse Rate (All Data - Low Saturation): ECG HR vs. (Pulse Rate - ECG HR).....	A-25

Figure A-21.	Correlation Plot for SpO2 (All Data - Low Saturation): SaO ₂ vs. SpO ₂	A-26
Figure A-22.	Correlation Plot for Pulse Rate (All Data - Low Saturation): ECG HR vs. Pulse Rate	A-27
Figure A-23.	Modified Bland-Altman for SpO2 (All Data - Motion): SaO ₂ vs. (SpO ₂ - SaO ₂)	A-29
Figure A-24.	Modified Bland-Altman for Pulse Rate (All Data - Motion): ECG HR vs. (Pulse Rate - ECG HR).....	A-30
Figure A-25.	Modified Bland-Altman for SpO2 - MAXA Sensor (Motion): SaO ₂ vs. (SpO ₂ - SaO ₂)	A-31
Figure A-26.	Modified Bland-Altman for SpO2 - MAXN Sensor (Motion): SaO ₂ vs. (SpO ₂ - SaO ₂)	A-32
Figure A-27.	Modified Bland-Altman for Pulse Rate - MAXA Sensor (Motion): ECG HR vs. (Pulse Rate - ECG HR)	A-33
Figure A-28.	Modified Bland-Altman for Pulse Rate - MAXN Sensor (Motion): ECG HR vs. (Pulse Rate - ECG HR)	A-34
Figure A-29.	Correlation Plot for SpO2 (All Data - Motion): SaO ₂ vs. SpO ₂	A-35
Figure A-30.	Correlation Plot for Pulse Rate (All Data - Motion): ECG HR vs. Pulse Rate	A-35

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1 Introduction

1.1 Overview

This manual contains information for operating the Nellcor™ bedside SpO₂ patient monitoring system.

This manual applies to the following product:

REF PM100N



Note:




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

1.2 Safety Information

This section contains important safety information related to general use of the Nellcor™ bedside SpO₂ Patient monitoring system. Other important safety information appears throughout the manual. The Nellcor™ bedside SpO₂ patient monitoring system will be referred to as the “monitoring system” throughout this manual.

1.2.1 Safety Symbols

Table 1-1. Safety Symbol Definitions

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

1.2.2 Warnings



WARNING:

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



WARNING:

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



WARNING:

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



WARNING:

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



WARNING:

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



WARNING:

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



WARNING:

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



WARNING:

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

**WARNING:**

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

**WARNING:**

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

**WARNING:**

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

**WARNING:**

When the monitoring system is set to Standard Mode, it is intended for use in a hospital or hospital-type environment by trained medical personnel.

**WARNING:**

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

**WARNING:**

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

**WARNING:**

The monitoring system may retain trend data from multiple patients if transferred from one patient to another.

**WARNING:**

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



WARNING:

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



WARNING:

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

1.2.3 Cautions



Caution:

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



Caution:

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




Caution:


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





Caution:


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

-  **Caution:**
For best product performance and measurement accuracy, use only accessories supplied or recommended by Covidien. Use accessories according to the manufacturer's directions for use and institutional standards. Use only accessories that have passed the recommended biocompatibility testing in compliance with ISO 10993-1.

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

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

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

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

1.3 Technical Assistance

1.3.1 Technical Services

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

Covidien Technical Services: Patient Monitoring

15 Hampshire Street

Mansfield, MA 02048 USA

1.800.635.5267, 1.925.463.4635,
or contact a local Covidien representative

www.covidien.com

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

1.3.2 Related Documents

Nellcor™ Bedside SpO₂ Patient Monitoring System Home Use Guide — For caregivers in the home environment. Provides basic information for setup, operation, and cleaning of the monitoring system. Provide this guide to home caregivers and recommend that they use it.

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

Saturation Accuracy Grid — Provides sensor-specific guidance related to desired SpO₂ saturation accuracy measurements. Available online at www.covidien.com.

Nellcor™ Bedside SpO₂ Patient Monitoring System Service Manual — Provides information to qualified service technicians who are servicing the monitoring system.

1.4 **Warranty Information**

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

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2 Product Overview

2.1 Overview



WARNING:

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

This chapter contains basic information about the Nellcor™ bedside SpO₂ patient monitoring system. The monitoring system relies on unique oximetry technology and design to provide hospitals, clinicians, and caregivers accurate, timely data, which includes a number of parameters.

- **Arterial blood oxygen saturation (SpO₂)** — Functional measure of oxygenated hemoglobin relative to the sum of oxyhemoglobin and deoxyhemoglobin
- **Pulse rate (PR)** — Detected heart pulsations in beats per minute
- **Plethysmographic waveform (Pleth)** — A non-normalized waveform that represents relative pulsatile strength
- **Operating status** — State of the monitoring system, including alarm conditions and messages
- **Patient data** — Real-time trend data on the current patient
- **Sensor messages** — Detected real-time information on attached patient sensor

2.2 Product Description

The Nellcor™ bedside SpO₂ patient monitoring system provides continuous, noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO₂) and pulse rate.

2.3 Indications for Use



WARNING:

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

The Nellcor™ Bedside SpO₂ Patient Monitoring System is intended for prescription use only for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO₂) and pulse rate. The Nellcor™ Bedside SpO₂ Patient Monitoring System is intended for use with neonatal, pediatric, and adult patients during both no-motion and motion conditions and for patients who are either well or poorly perfused, in hospitals, hospital-type facilities, intra-hospital transport, or home environments.



Note:

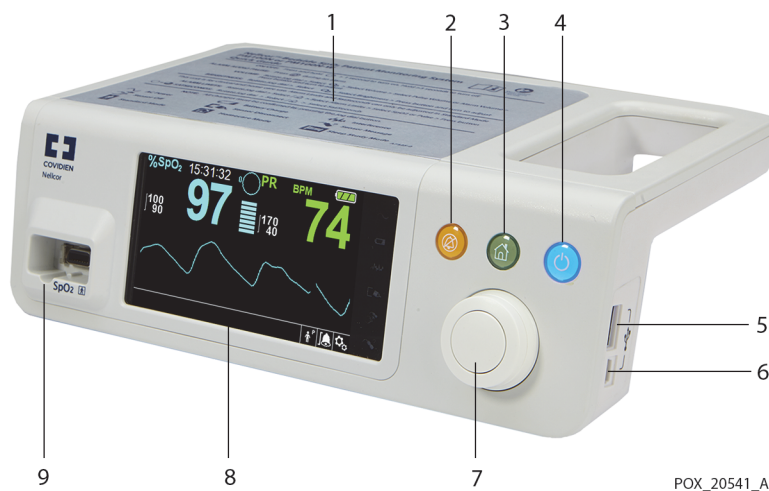
- Hospital use typically covers such areas as general care floors (GCFs), operating rooms, special procedure areas, intensive and critical care areas within the hospital, and in hospital-type facilities.
- Hospital-type facilities include physician office-based facilities, sleep labs, skilled nursing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








2.4 Product Views

2.4.1 Front Panel and Display Components

Front and Side Panels

Figure 2-1. Front and Side Panel Components

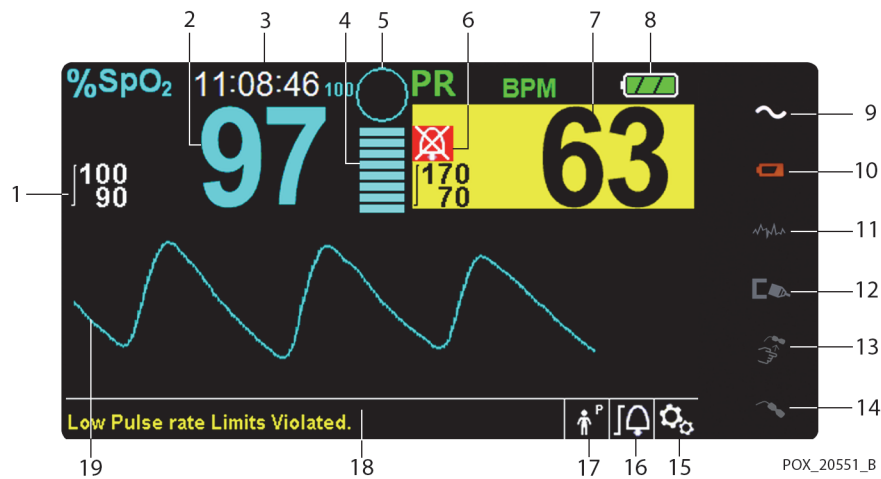







1		Quick Guide	Provides a summary of instructions for operation of the monitoring system.
2		Silence Alarm button	Press to toggle between disabling and re-enabling the audible alarm. Reference <i>Menu Navigation</i> , p. 4-4.
3		Home button	Press to display the OPTIONS Menu or to exit a menu displayed on the screen and go to the main screen. Reference <i>Menu Navigation</i> , p. 4-4.
4		Power On/Off button	Press and hold to turn on or off the monitoring system. Reference <i>Menu Navigation</i> , p. 4-4.
5		USB port (USB A type)	Use for firmware upgrades.
6		USB port (mini USB B type)	Use for trend data downloads.
7		Knob	Use to navigate and control display and monitoring system functions.












- 8 LCD display panel Use to view all graphic and numeric patient information as well as status conditions and warning messages.
- 9 SpO₂ connector Use to connect to the interface cable and SpO₂ sensor.






Display

Figure 2-2. Display Components



- 1  Upper and lower alarm limits Reflects upper and lower SpO₂ and pulse rate alarm limits. An alarm sounds each time patient oxygen saturation or pulse rate values violate these alarm limits.
- 2  SpO₂ real-time value Indicates hemoglobin oxygen saturation levels. Current upper and lower alarm limit settings appear as smaller values to the left of the dynamic SpO₂ value.
- 3  Time Indicates the current time in hours, minutes, and seconds.
- 4  Pulse amplitude (blip bar) Indicates pulse beat and the relative (non-normalized) pulse amplitude. As the detected pulse becomes stronger, more bars light with each pulse.
- 5  SatSeconds™ icon Provides alarm management for mild or brief SpO₂ limit violations. When the SatSeconds™ feature is enabled, the SatSeconds™ icon fills in the clockwise direction as the SatSeconds™ alarm management system detects SpO₂ readings outside of the limits setting. The SatSeconds™ icon empties in the counter-clockwise direction when SpO₂ readings are within limits. When the SatSeconds™ icon reaches full, a medium priority alarm sounds. The adult default setting is 100. Reference [SatSeconds™ Alarm Management Feature](#), p. 10-4.

6		Alarm silenced icon	The yellow icon indicates Alarm Silenced. This indicator also shows the time remaining in the alarm silence period.
		Audio OFF icon	The red icon indicates Audio OFF.
7		Pulse rate real-time value	Displays the pulse rate in beats per minute. Current upper and lower alarm limit settings appear as smaller values to the left of the dynamic pulse rate value.
8	Battery status icon	Displays the battery charge remaining on the internal 5-hour or optional 10-hour battery.	<ul style="list-style-type: none"> <li data-bbox="722 653 1317 737">• Charged Battery — A steady green battery icon indicates the monitoring system is running on internal battery power and the battery is fully charged. <li data-bbox="722 768 1317 936">• Low Battery — A low priority alarm occurs when the remaining battery power is only enough for 15 minutes of operation. The flashing yellow alarm message Low Battery appears. Users cannot silence this alarm while running on battery power. Connect the monitoring system to AC power to stop the alarm. <li data-bbox="722 968 1317 1171">• Critically Low-Battery — A high priority alarm occurs for about five (5) minutes before the monitoring system shuts off. The flashing red alarm message Critically Low-Battery appears. When no charge remains, the monitoring system automatically shuts down. Connect the monitoring system to AC power to avoid any loss of trend data or settings.
			
			
			
9		AC power indicator	Lights continuously when connected to AC power.
10		Battery charge indicator	Lights when the monitoring system is charging the internal 5-hour or optional 10-hour battery.
11		Interference indicator	Lights when the monitoring system detects degraded quality in the incoming signal. Lights intermittently as the monitoring system dynamically adjusts the amount of data required for measuring SpO ₂ and pulse rate. Lights continuously when the monitoring system has extended the amount of data required for measuring SpO ₂ and pulse rate. In this case, fidelity in tracking rapid changes in these values may be reduced. ¹
12		Sensor off indicator	Appears when the sensor is not on the patient.
13		Sensor disconnect indicator	Appears when the sensor is not connected to the monitoring system.

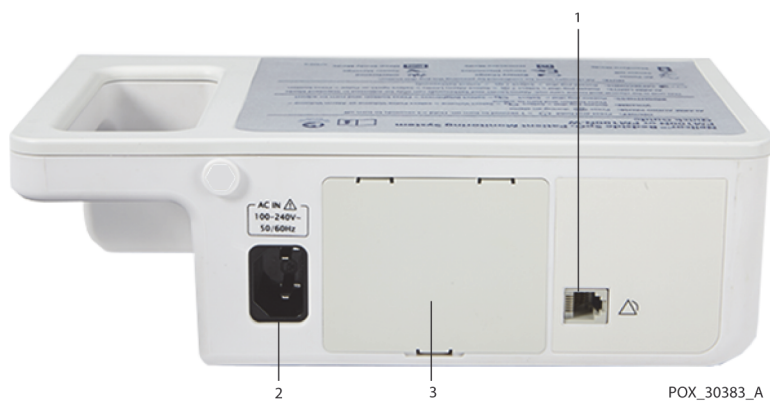
14		Sensor message indicator	Appears when the sensor is invalid.
15		Options menu icon	Select to customize options and features.
16		Alarm limits menu icon	Select to customize audible alarm limits.
17		Patient mode area	<p>Reflects the current patient mode selected.</p> <ul style="list-style-type: none"> • Adult mode — Indicates alarm limits are set to adult limit values. This is the default mode. • Pediatric mode — Indicates alarm limits are set to pediatric limit values. • Neonatal mode — Indicates alarm limits are set to neonate limit values. • Homecare mode — Indicates operating mode for lay users. • Sleep Study mode — Indicates operating mode for sleep study.
18		Informative message area	Contains messages to notify the user of a condition or a request for action.
19		Plethysmographic (pleth) waveform	This non-normalized waveform uses real-time sensor signals, reflecting relative pulsatile strength of incoming signals.

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

Table 2-1. Display Colors

Color	Condition	Function
Cyan numeric	Steady	Value and plethysmographic waveform
Green numeric		Pulse rate value
Black background		General background
Red background	Flashing SpO ₂	High priority alarm condition
Yellow background		Alarm condition
Green font	Steady	Informative message
Yellow font		Low or medium priority message
Red font	Flashing	High priority message
Green, yellow, or red battery icon	Steady	Normal, low, or critically low battery status








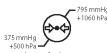











2.4.2 Rear Panel

Figure 2-3. Rear Panel Components

- 1 Nurse call port
- 2 AC power connector
- 3 Battery cover

2.4.3 Product and Carton Label Symbols

Table 2-2. Symbol Descriptors

Symbol	Description	Symbol	Description
	Type BF		Data port
	Class II equipment		Date of manufacture
Rx ONLY	Prescription only device		Keep dry
	Attention, consult accompanying documents		Fragile
	Atmospheric pressure limitations		UL listed
	Humidity limitations		CE Mark
	Temperature limitations		Manufacturer
	This side up		EU representative
	Must consult instructions for use		Proper waste disposal for electrical and electronic equipment
IP22	Protection against fluid ingress		Reference code (part number)
	Serial number		

3 Installation

3.1 Overview

This chapter contains information for the installation and set up of the Nellcor™ bedside SpO₂ patient monitoring system prior to first-time usage.

3.2 Safety Reminders



WARNING:

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



WARNING:

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



WARNING:

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



WARNING:

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



WARNING:

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

**WARNING:**

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

3.3 Unpacking and Inspection

The monitoring system is shipped in a single carton. Examine the carton carefully for evidence of damage. Contact Covidien Technical Services immediately if the carton appears damaged. Do not return all packing material and the monitoring system prior to contacting Covidien. Reference *Technical Services*, p. 1-6.

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

**Note:**

A qualified service technician should verify the performance of the monitoring system following the procedures outlined in the Nellcor™ bedside SpO₂ patient monitoring system *Service Manual* prior to initial installation in a clinical setting.

**Note:**

Contact Covidien Technical Services for pricing and ordering information.

Table 3-1. Standard Items

Item	Quantity
Nellcor™ bedside SpO ₂ patient monitoring system	1
Nellcor™ pulse oximetry interface cable	1
Compact disc (CD) and/or Operator's Manual ¹	1
Lithium-ion battery pack, M-BPL-1 (21) 5 hour	1
AC power cord	1

1. Covidien provides soft copy of monitoring system manuals on a compact disc for easy access and print-on-demand. Order a printed Nellcor™ bedside SpO₂ patient monitoring system *Operator's Manual* at no cost or a printed Nellcor™ bedside SpO₂ patient monitoring system *Service Manual* for a fee from Covidien Technical Services or a local Covidien representative.

3.4 Power

**WARNING:**

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

**Caution:**

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

**Caution:**

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

3.4.1 AC Power Connection

The monitoring system operates on AC power or on a charged internal battery. Prior to connecting to power, perform a safety check of the equipment. Reference [Periodic Safety Checks](#), p. 7-4.

To connect the AC power cable:

1. Ensure the AC outlet is properly grounded and supplies the specified voltage and frequency (100-240 VAC, 50/60 Hz, 45 VA).
2. Connect the female connector end of the AC power cord to the AC power connector on the monitoring system's rear panel.
3. Plug the male connector end of the AC power cord into a properly grounded AC outlet.
4. Ensure the **AC Power Indicator** and **Battery Charge Indicator** light.

**Note:**

Even if the monitoring system is not turned on, the **AC Power Indicator** and **Battery Charge Indicator** light when the AC power cord is connected into a mains outlet. Reference [Troubleshooting](#), p. 8-1, if the battery charging indicator does not light when connected to power.

3.4.2 Internal Battery Power

**WARNING:**

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

**Note:**

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

**Note:**

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

**Note:**

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

**Note:**

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

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

Before using the internal battery, perform a safety check of the equipment. Reference [Periodic Safety Checks](#), p. 7-4.

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

- Operating in Normal mode (Measuring SpO₂ and PR with plethysmograph display)
- Setting for pulse beep indicator is ON (pulse volume: 4 (Default))
- Sleep Study mode is inactive
- Setting for SatSeconds™ is ON
- Experiencing no alarm condition
- Operating at ambient temperature of 25°C (±5°C)



Note:

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



Note:

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



Note:

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

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

To charge the internal battery:

1. Connect the monitoring system to AC power to charge a low or depleted battery. Reference [AC Power Connection](#), p. 3-3.



2. Verify the **AC Power Indicator** and **Battery Charge Indicator** light.

3.5 Nellcor™ Pulse Oximetry Sensor Connection



WARNING:

Incorrect application or use of an SpO₂ sensor can cause tissue damage. Do not wrap the sensor too tightly, apply supplemental tape, or leave a sensor too long on one place. Inspect the sensor site as directed in the *Directions for Use* to ensure skin integrity, correct positioning, and adhesion of the sensor.



WARNING:

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

**WARNING:**

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

**WARNING:**

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

**Caution:**

For best product performance and measurement accuracy, use only accessories supplied or recommended by Covidien. Use accessories according to the *Instructions for Use*. Use only accessories that have passed the recommended biocompatibility testing in compliance with ISO 10993-1.

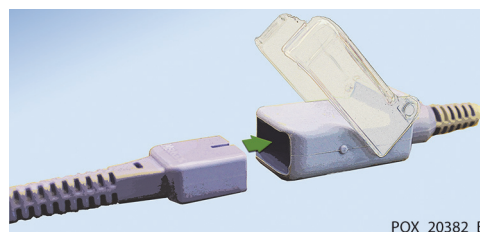
Before connecting a sensor, perform a safety check of the equipment. Reference *Periodic Safety Checks*, p. 7-4. Reference *Nellcor™ Pulse Oximetry Sensors*, p. 9-1, for details regarding sensor selection.

To fully connect a Nellcor™ pulse oximetry sensor:

1. Select an appropriate compatible Nellcor™ pulse oximetry sensor for the patient and desired application. Consider the patient's weight and activity, adequacy of perfusion, availability of sensor sites, need for sterility, and anticipated duration of monitoring.
2. Carefully apply the sensor to the patient after reading the *Instructions for Use* accompanying the sensor. Observe all warnings and cautions in the *Instructions for Use*.
3. Connect the interface cable to the sensor port on the front of the panel and firmly connect the interface cable to the pulse oximetry sensor.

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

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



A **Sensor Message** occurs when the device cannot obtain an SpO₂ level or a pulse rate.



Note:

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



Note:

Reference *Performance Considerations*, p. 6-1.

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4 Operation

4.1 Overview

This chapter identifies methods for viewing and collecting patient oxygen saturation data using the Nellcor™ bedside SpO₂ patient monitoring system. Before operating the monitoring system, thoroughly read this manual.

4.2 Safety Reminders



WARNING:

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



WARNING:

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



WARNING:

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



WARNING:

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



WARNING:

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



Caution:

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



Caution:

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

4.3 Apply Power to Monitoring System

4.3.1 Turn On the Monitoring System



WARNING:

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



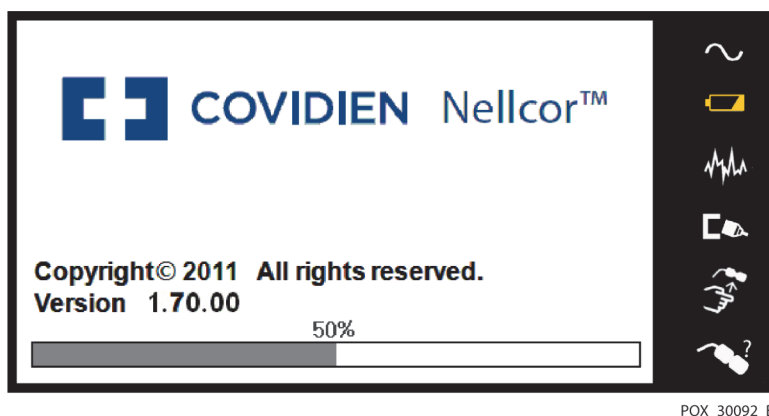
Caution:

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

To power on the monitoring system:

1. Press the **Power On/Off Button** for more than one (1) second.
2. Ensure the software version, the SpO₂ alarm indicator, and the pulse rate alarm indicator light for approximately two (2) seconds.

Figure 4-1. Sample Initial Screen



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

When the monitoring system completes power-on self-test (POST), a POST pass tone sounds. This functions as an audible confirmation of proper speaker performance. If the speaker does not function, the monitoring system emits a continuous audible tone to alert the user that the speaker is not functioning and that the alarm warning sounds will be inaudible.

4. Verify the battery status icon indicates remaining battery power. If the Low Battery alarm occurs, charge the battery by plugging the monitoring system's power cord into a wall outlet.
5. Ensure all monitoring screen elements are properly displayed.

**Note:**

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

**Note:**

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

4.3.2 Turn Off the Monitoring System

After using the monitoring system, turn it off safely.

To turn off the monitoring system:

1. Press the Power On/Off button on the right of the device for approximately one second.

2. Observe the message `System is shutting down` on the screen.

**Note:**

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

4.4 Menu Navigation

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

**Note:**

The three buttons illuminate as long as the monitoring system is powered on.



Power On/Off button: Press and hold this blue button to power on or to power off the monitoring system.



Home button: Press this green button for less than two (2) seconds to display the Options Menu or to exit menu items and return to the main monitoring screen.



Silence Alarm button: Press this orange button for less than two (2) seconds to disable or re-enable audible alarms.



Knob: Turn or press as follows:

Turn the knob to navigate to an item or to increase or decrease a selected value.

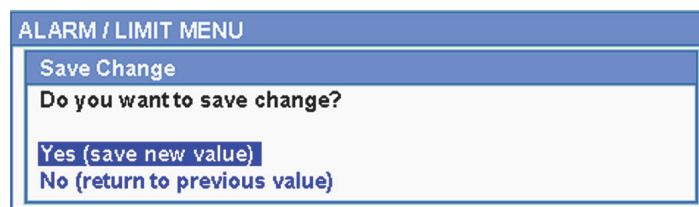


Press the knob to select an item or to confirm a change to a value.

**Note:**

If the Home button is pressed when a change is made but not confirmed, the message shown in [Figure 4-2](#) appears.

Figure 4-2. Save Change Screen



The LCD panel displays easy-to-read numeric values for patient oxygen saturation and pulse rate in cyan and green, respectively. Reference [Table 2-1.](#) on page 2-7.

4.5 Choose Patient Settings

4.5.1 Set Patient Mode (Type)

Select the desired patient mode: Adult, Pediatric or Neonatal.

To set patient mode:



1. Select the Patient Mode icon.

2. Select the correct patient mode (type):



Adult: Use for adults.



Pediatric: Use for children.



Neonatal: Use for newborns.



Note:

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

4.5.2 Set SpO₂ and Pulse Rate Alarm Limits



WARNING:

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

**WARNING:**

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

**WARNING:**

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

Caregivers may choose to adjust SpO₂ and pulse rate (PR) alarm thresholds from default values as necessary. These changes remain in effect until modified again or until a power cycle occurs. Changes to the SpO₂ and pulse rate (PR) alarm thresholds appear in their respective numerical area. In addition, caregivers may choose to use the SatSeconds™ alarm option to manage the frequency of SpO₂ alarm limit violations.



SpO₂ numerical area — Indicates hemoglobin oxygen saturation levels. The display value flashes - - - during loss-of-pulse alarms and flashes the SpO₂ value on a yellow background when saturation is outside the alarm limits. During SpO₂ searches, the monitoring system continues to update the display. Current upper and lower alarm limit settings appear as smaller values to the left of the dynamic SpO₂ value. Reference [Menu Structure and Factory Defaults](#), p. 4-20, for default alarm limit settings.



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



SatSeconds™ circle — SatSeconds™ monitors both degree and duration of desaturation as an index of desaturation severity. Thus, the SatSeconds™ feature helps distinguish clinically significant events from minor and brief desaturations that may result in nuisance alarms. When the SatSeconds™ feature is enabled, the SatSeconds™ icon fills in the clockwise direction as the SatSeconds™ alarm management system detects SpO₂ readings outside of the limits setting. The SatSeconds™ icon empties in the counter-clockwise direction when SpO₂ readings are within limits. When the SatSeconds™ icon

reaches full, a medium priority alarm sounds. by adjusting the setting. The higher the SatSeconds™ value, the less frequent the alarm.

- Available SpO₂ alarm limit thresholds
 - Upper and lower SpO₂ alarm limit thresholds
 - SpO₂ alarm inhibition to disable audible alarms for SpO₂ limit violations
- Pulse Rate alarm limits
 - Upper and lower pulse rate alarm limit thresholds
 - Pulse rate alarm inhibition to disable audible alarms for pulse rate limit violations
- SatSeconds™ alarm management value. Reference [Table 4-3](#) on page 4-20 for possible values.

Set SpO₂ and pulse rate alarm limits and the SatSeconds™ value in two ways:

- Use the QUICK ACCESS Menus
- Use the ALARM/LIMITS Menu

QUICK ACCESS Menus



Note:

Reference *Menu Structure and Factory Defaults*, p. 4-20, for adult, pediatric, and neonate limit options.

Figure 4-3. SpO₂ QUICK ACCESS Menu

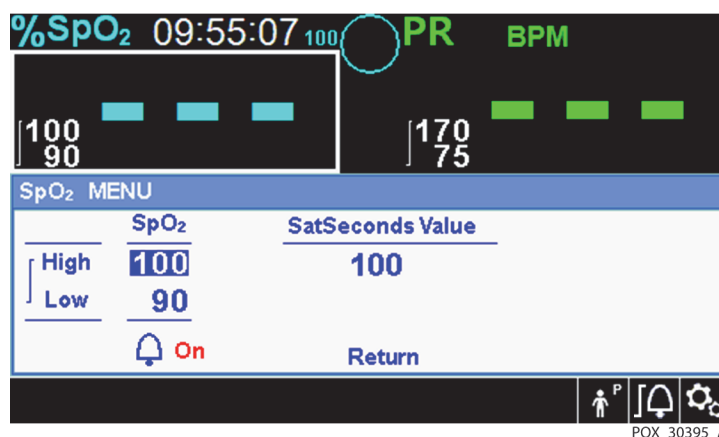
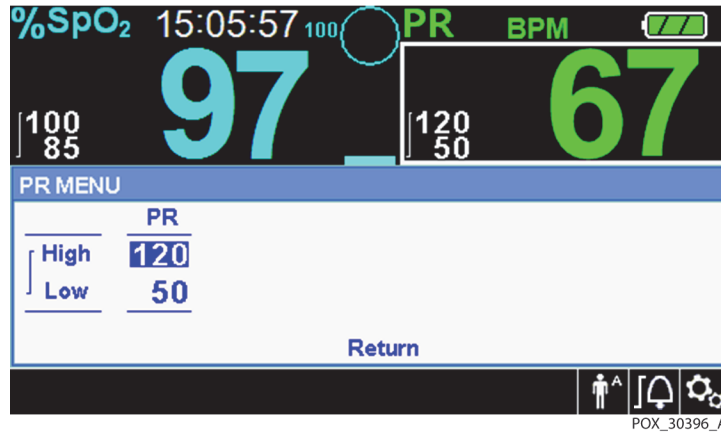


Figure 4-4. QUICK ACCESS PR Menu



To set alarm limits using the QUICK ACCESS menus:

1. Navigate to the SpO₂ or pulse rate (PR) area of the main screen.
A white outline appears around the area.
2. Select the desired area, then make the desired settings.

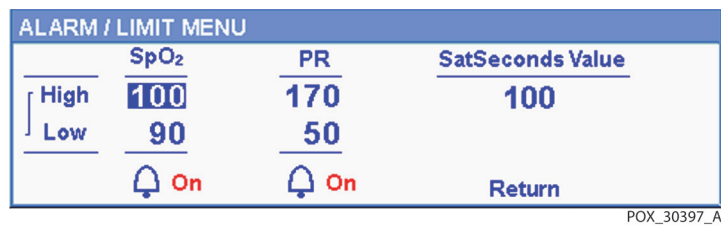
ALARM/LIMITS Menu



Note:

Reference *Menu Structure and Factory Defaults*, p. 4-20, for adult, pediatric, and neonate limit options.

Figure 4-5. ALARM/LIMITS Menu Options



To set alarm limits using the ALARM/LIMITS Menu:



1. Select the ALARM LIMITS Menu.
2. Make the desired settings.

4.5.3 Set SpO₂ WAVEFORM

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

To access the WAVEFORM Menu:



1. Navigate to the waveform display area and select it to display the WAVEFORM Menu.

Figure 4-6. Waveform Display Area Highlighted

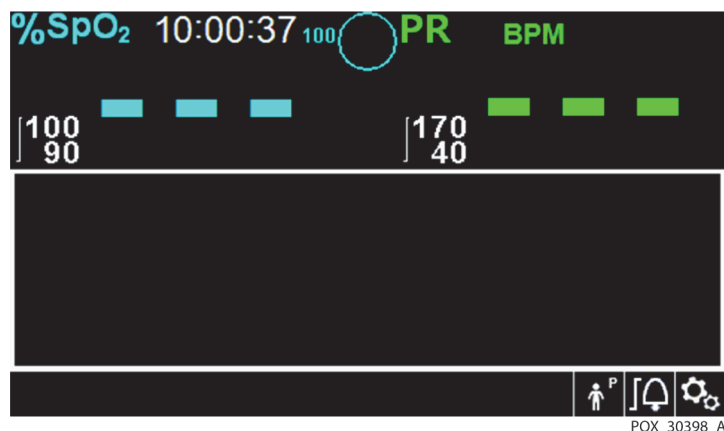
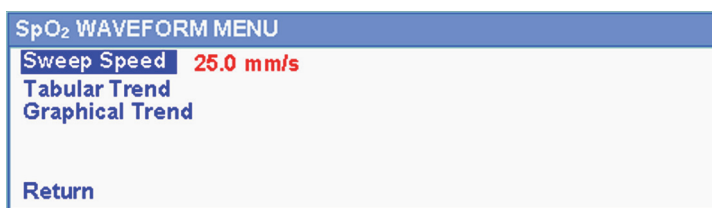


Figure 4-7. SpO₂ Waveform Menu



2. Set the Sweep Speed.

Sweep Speed is the speed at which the SpO₂ waveform trace moves across the screen. The higher the sweep speed value, the more data appears on the screen. Sweep Speed options are 6.25 mm/s, 12.5 mm/s and 25.0 mm/s



Note:

The Tabular Trend and Graphical Trend items on the SpO₂ WAVEFORM Menu are described in *"Data Management"* on page 5-1.

4.6 Manage Alarms and Alarm Limits



WARNING:

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



WARNING:

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



WARNING:

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



WARNING:

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

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

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

Table 4-1. Alarm Conditions

Priority	Rate	Color	Messages
High	Sounds every 4 s	Red Steady message, Fast flashing numeric	SpO ₂ Loss of Pulse
			Critically Low-Battery condition
Medium	Sounds every 8 s	Yellow Steady message, Slow flashing numeric	High Pulse Rate limits violated
			Low Pulse Rate limits violated
			High SpO ₂ limits violated
			Low SpO ₂ limits violated
Low	Sounds every 16 s	Steady yellow	SpO ₂ Cable/Sensor Disconnect
			SpO ₂ Sensor Off
			Low Battery
			Technical System Error: EEE 001

Table 4-1. Alarm Conditions (Continued)

Priority	Rate	Color	Messages
Informative	--	--	SpO ₂ Pulse search
			Patient Movement Detected
			Abnormally shut down last time
			Audio OFF, Alarm Silenced
			Press Home button to Exit

**Note:**

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

**Note:**

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

4.6.1 Audible Alarm Indicators

**WARNING:**

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

**WARNING:**



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

Audible alarm indicators include pitched tones and beeps. Caregivers may choose to silence the audible alarm for the established **Alarm Silence** period of 30, 60, 90 or 120 seconds. Visual alarms continue during this time. The factory default for audible alarm silence period is 60 seconds. To set one of the listed alternate periods as an institutional default, have a qualified service technician set the desired period via the SERVICE Menu.

**Note:**

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

Table 4-2. Audio Status

Alarm Icon	Status
	Alarm Silenced
	Audio OFF

To silence an audible alarm:

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

**Note:**

Press the **Silence Alarm** button to silence audible alarms caused by technical errors. Audible alarms for physiological conditions can be silenced. However, they require appropriate corrective action. Press the **Silence Alarm** button to dismiss an SpO₂ Sensor Off alarm or SpO₂ Cable/Sensor Disconnect alarm.

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

**To silence an audible alarm:**

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



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

**Note:**

To disable limit violation alarms, use the Alarm Limits menus. Reference [ALARM/LIMITS Menu](#), p. 4-8.

4.6.2 Visual Alarm Indicators

Visual alarms appear on the screen in order of highest priority, regardless of any audible alarm status. Reference [Table 4-1.](#) on page 4-10.

4.7 Set Additional Patient Modes

Additional patient modes are available to set the monitoring system to Normal or Fast Response Mode, Homecare Mode, Sleep Study Mode, or Standard Mode.

4.7.1 Mode (Response Mode)

The response mode (Normal or Fast) establishes the rate at which the monitoring system responds to changes in the SpO₂ data. The calculation of pulse rate and the recording of trend data are not affected. The response mode setting does not affect the algorithm's calculation of pulse rate, nor does it influence the recording of trend data which occurs at one-second intervals. The default setting is the Normal Response Mode.

To set response mode:



1. Access the OPTIONS Menu.
2. Select **Change Patient Mode**, then select **Mode**.
3. Select either Normal or Fast mode.
 - **Normal response mode** — Responds to changes in blood oxygen saturation within five (5) to seven (7) seconds.
 - **Fast response mode** — Responds to changes in blood oxygen saturation within two (2) to four (4) seconds. This mode can be particularly helpful for situations that require close monitoring.

Figure 4-8. Response Mode Menu



Note:

When in the Fast Response Mode, the monitoring system may produce more SpO₂ and pulse rate alarms than expected.

4.7.2 Homecare Mode

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



Note:

A four-digit password is required to switch to Homecare Mode.

To set the monitoring system to Homecare Mode:

1. Before switching to Homecare Mode, ensure that the alarm limits and patient type (adult, pediatric, neonate) are appropriate for the home patient.



2. Access the OPTIONS Menu.
3. Select **Change Patient Mode**, then select **Switch to Homecare Mode**.

Figure 4-9. Switch to Homecare Mode



4. Enter the password for Homecare Mode.

Figure 4-10. Password Entry for Homecare Mode



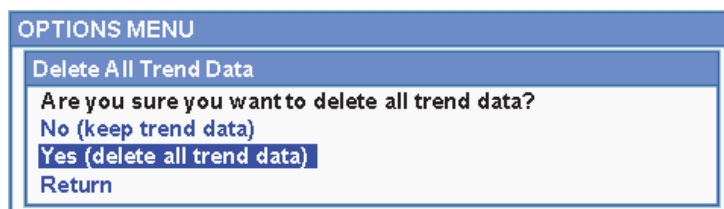
5. Choose whether to keep or delete all trend data.



Note:

It is recommended to delete all trend data when configuring the monitoring system for a different patient.

Figure 4-11. Delete or Save Trend Data



The "Switched to Homecare Mode" message appears.

Until a sensor is connected to the patient and the monitoring system, the following screens appear:

Figure 4-12. Sensor Messages

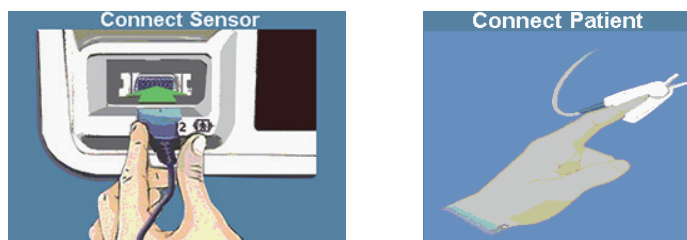
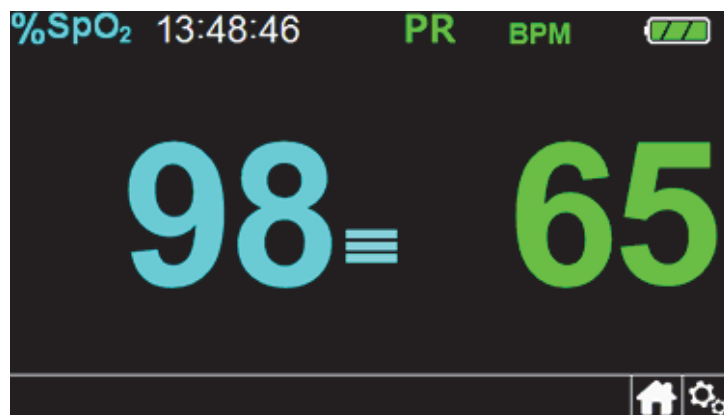


Figure 4-13. Homecare Mode Main Screen with Homecare Icon



4.7.3 Sleep Study Mode

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



Note:

A four-digit password is required to switch to Sleep Study Mode.

To set the monitoring system to Sleep Study Mode:



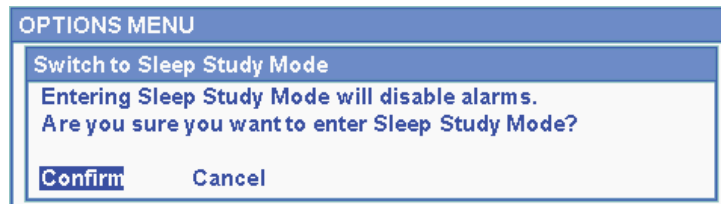
1. Access the OPTIONS Menu.
2. Select **Change Patient Mode**, then select **Switch to Sleep Study Mode**.

Figure 4-14. Switch to Sleep Study Mode



3. Confirm the entry into Sleep Study Mode, or select **Cancel**.

Figure 4-15. "Disabling of Alarms" Message



4. Enter the password for Sleep Study Mode.

Figure 4-16. Password Entry for Sleep Study Mode



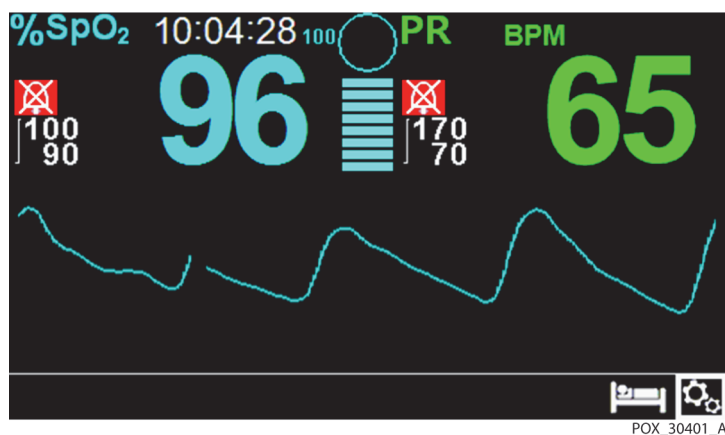
5. When prompted, confirm or cancel the switch to Sleep Study Mode.
6. Choose whether to keep or delete all trend data.

**Note:**

It is recommended to delete all trend data when configuring the monitoring system for a different patient.

The “Switched to Sleep Study Mode” message appears.

Figure 4-17. Sleep Study Mode Main Screen



When the buttons and knob have not been used for 30 seconds, the screen dims.

4.7.4 Standard Mode

Standard Mode is the factory default operating mode. If Homecare Mode or Sleep Study Mode is the current setting, set the monitoring system back to Standard Mode when a clinician will be using it in a hospital or other professional care setting.

**Note:**

A four-digit password is required to switch to Standard Mode.

To set the monitoring system to Standard Mode:


1. Access the OPTIONS Menu.
2. Select **Change Patient Mode**, then select **Switch to Standard Mode**.
3. Enter the password for Standard Mode.
4. When prompted, confirm or cancel the switch to Standard Mode.
5. Choose whether to keep or delete all trend data.



Note:

It is recommended to delete all trend data when configuring the monitoring system for a different patient.

The “Switched to Standard Mode” message appears.

4.8 Select Optional Settings

4.8.1 Volume

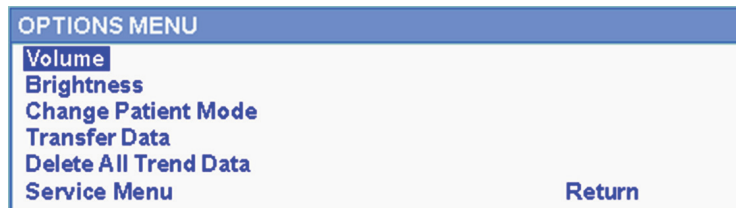
Use this option to adjust volume controls.

To set the desired audible tone volume:



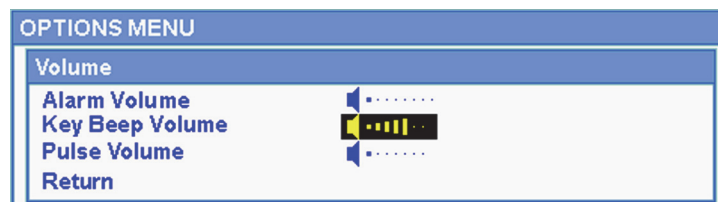
1. Access the OPTIONS Menu.
2. Select **Volume**.

Figure 4-18. Volume Menu Item



3. Select and set the desired volume:
 - **Alarm Volume** controls the volume of alarms.
 - **Key Beep** Volume controls the volume of any button press.
 - **Pulse Volume** controls the volume of the pulse rate tone.

Figure 4-19. Volume Selection



4.8.2 Brightness

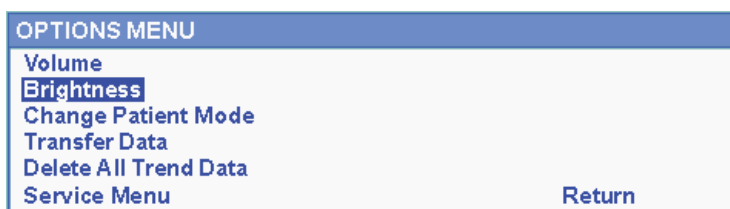
Use this option to adjust the screen brightness.

To set the desired brightness:



1. Access the OPTIONS Menu.
2. Select **Brightness**.

Figure 4-20. Brightness Menu Item



3. Select and set the desired brightness.

Figure 4-21. Brightness Selection



4.9 Menu Structure and Factory Defaults

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



Note:

The ability to change alarm limits is inhibited in Homecare Mode.

Table 4-3. Menu Structure and Factory Defaults

Item	Available Selections	Factory Default		
		Adult	Pediatric	Neonatal
QUICK ACCESS ALARM LIMITS Menus and ALARM/LIMIT Menu				
SpO ₂ Menu	Upper SpO ₂ alarm limit (21-100)	100%		95%
	Lower SpO ₂ alarm limit (20-99)	90%		85%
	Alarm Inhibition for SpO ₂ alarms	Off		
	SatSeconds™ alarm management setting (Off, 10, 25, 50, 100)	Off		
Pulse Rate (PR) Menu	Upper pulse rate alarm limit (30-245) 5 bpm steps	170 bpm		200 bpm
	Lower pulse rate alarm limit (25-240) 5 bpm steps	50 bpm	75 bpm	100 bpm
	Alarm Inhibition for pulse rate alarms	Off		
OPTIONS Menu				
Volume	Alarm Volume (1-8)	5		
	Key Beep Volume (Off, 1-7)	4		
	Pulse Volume (Off, 1-7)	4		
Brightness	Screen brightness (1-8)	4		
Change Patient Mode	Mode—Response Mode (Normal, Fast)	Normal		
	Monitoring Mode (Standard, Homecare, Sleep Study)	Standard Mode		
	Switch to Homecare Mode	--		
	Switch to Sleep Study Mode	--		
Transfer Data	Continuous Transfer, Trend Data Download	By USB		

Table 4-3. Menu Structure and Factory Defaults (Continued)

Item	Available Selections	Factory Default		
		Adult	Pediatric	Neonatal
Delete All Trend Data	No, Yes	No		
Service Menu	(For qualified service technicians only)	--		
PATIENT MODE Menu				
Adult option	Sets Alarm Limits to standard default thresholds for adult patients	Adult		
Pediatric option	Sets Alarm Limits to standard default thresholds for pediatric patients			
Neonate option	Sets Alarm Limits to standard default thresholds for neonate patients			
SpO2 WAVEFORM Menu				
Sweep Speed option	6.25 mm/s, 12.5 mm/s, 25.0 mm/s	25.0 mm/s		
Tabular Trend option	Tabular trend view of trend data (Every 1, 5, 100, or 500 events)	1		
Graphical Trend option	Graphical trend view of trend data (SpO ₂ On/Off; PR On/Off)	SpO ₂ On PR On		

Table 4-4. Service Menu Settings (Password Protected)

Parameter	Ranges/Selection	Factory Default		
		Adult	Pediatric	Neonatal
Power On Settings	Factory Defaults, Last Settings, Institutional Defaults	Factory Defaults		
Alarm Silence Duration	30, 60, 90, 120 s	60 s		
Alarm Disabled Reminder	Off, 3, 10 min	3 min		
Permission to deactivate audible alarm	Yes, No	No		
Language	Chinese, Czech, Danish, Dutch, English, Finnish, French, German, Greek, Hungarian, Italian, Japanese, Korean, Norwegian, Polish, Portuguese, Russian, Slovakian, Spanish, Swedish, Turkish	English		
Date/Time Setting	yy/mm/dd, mm/dd/yy, dd/mm/yy	yy/mm/dd		

Table 4-4. Service Menu Settings (Password Protected) (Continued)

Parameter	Ranges/Selection	Factory Default		
		Adult	Pediatric	Neonatal
Homecare Mode Settings	Minimum Allowed Volume	1		
Communication Settings	Serial Connectivity Settings: ASCII 19200, ASCII 115200, SPDout 19200, SPDout 115200	ASCII, 19200		
	Nurse Call Settings: NORMALLY +, NORMALLY –	NORMALLY +		
Alarm Priorities	Priorities can be set for the following alarms: Sensor Disconnect Alarm, Sensor Off, Sensor Failure, SpO ₂ Low, SpO ₂ High, Pulse Rate Low, Pulse Rate High	High, Medium, or Low; or High or Medium, depending on the alarm		
Password Settings	Passwords can be changed for entry into Homecare Mode and Sleep Study Mode and back to Standard Mode	(Qualified service technicians have the default passwords)		

**Note:**

Only a qualified service technician can access the Service Menu to alter these parameters as described in the *Service Manual*.

4.10 Maintenance Reminder

Schedule regular maintenance and safety checks with a qualified service technician every 24 months. Reference *Periodic Safety Checks*, p. 7-4. In the case of mechanical or functional damage, contact Covidien or a local Covidien representative. Reference *Technical Assistance*, p. 1-6.

5 Data Management

5.1 Overview

This chapter contains information for accessing patient trend data obtained using the Nellcor™ bedside SpO₂ patient monitoring system. Trend data can be viewed anytime patient trend is stored in the monitoring system.

The monitoring system stores up to 96 hours of trend data. When the monitoring system begins measuring vital signs, it saves data every four (4) seconds during normal conditions, and every one (1) second during alarm conditions. It also saves all physiological alarm conditions and errors. Trend data history remains in memory even if the monitoring system is powered off. The monitoring system stores new data over the oldest data when the buffer is full.

The monitoring system can display trend data in tabular and graphical formats.

5.2 Tabular Trend Data

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

To select *Tabular Trend*:



1. Select the waveform area.
2. From the SpO₂ WAVEFORM Menu, select ***Tabular Trend***.

Figure 5-1. Tabular Trend Data Screen

Date / Time	SpO ₂	PR	
2018/09/05 13:47:53	90	60	1
2018/09/05 13:47:49	90	60	5
2018/09/05 13:47:45	90	60	100
2018/09/05 13:47:40	90	60	500

Press Button to Exit Tabular Trend.

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To scroll through *Tabular Trend Data*:

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

**Note:**

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

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

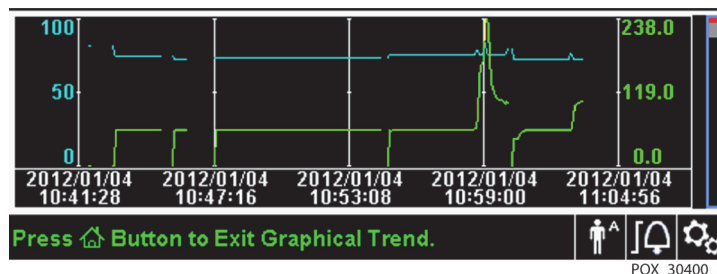
5.3 Graphical Trend Data

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

**To select *Graphical Trend*:**

1. Select the waveform area.
2. From the SpO₂ WAVEFORM Menu, select **Graphical Trend**.

Figure 5-2. Graphical Trend Data Screen

**To scroll through Graphical Trend Data:**

1. Turn the knob to highlight **Scroll**.

2. Press the knob to activate scrolling.
3. Turn the knob to scroll through the trend data.
 - **Clockwise** rotation moves forward to newer data.
 - **Counterclockwise** rotation moves backward to older data.
4. After reviewing trend data, press the **Home** button to exit the graphical trend view.

5.4 External Data Communication



WARNING:

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

5.4.1 Nurse Call Interface



WARNING:

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



WARNING:

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



Caution:

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

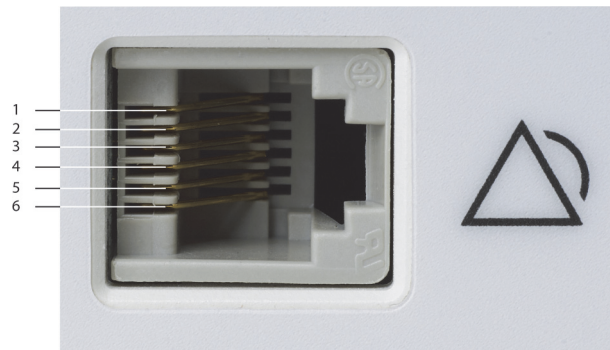


Note:

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

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

Figure 5-3. Nurse Call Interface Pin Layout



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To connect the nurse call cable:

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

To disconnect the nurse call cable:

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

Do not attempt to remove the connector without pressing down on the tab.

2. Gently pull the RJ11 connector out of the nurse call port.

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

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

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

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

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

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

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

Pin 2 is a common lead for both relays.

5.4.2 Trend Data Download



Caution:

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



Caution:

Patient motion, secondary to a variety of external factors, may compromise the presence or accuracy of the displayed values.

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

- Nellcor™ ASCII protocol (ASCII 1)

- ASCII format compatible with several spreadsheet programs (ASCII 2)



Note:

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

System Compatibility Prerequisites

- Windows-based PC
- HyperTerminal or equivalent software

Hardware

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

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



Note:

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

To download trend data

1. Power on the monitoring system.
2. Access the Options Menu.
3. Select the **Trend Data Download** submenu.

Figure 5-4. Trend Data Download Option

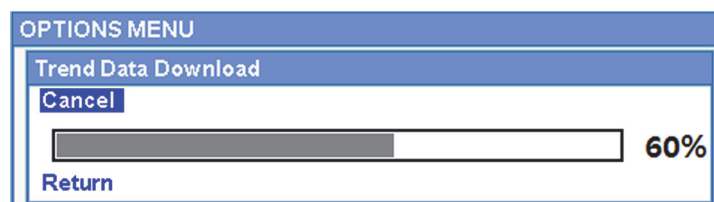


4. Connect a mini-USB cable from the monitoring system to the computer.
 - a. Grasp the mini-USB end of the cable.
 - b. Firmly insert into the bottom mini-USB data port.
 - c. Firmly insert the USB end of the cable into a USB port on the host system.
5. Ensure the computer properly identifies the monitoring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

**Note:**

Users may choose to cancel the download operation at any point in the download process by selecting **Cancel** and then **Return**.

Figure 5-5. Trend Data Download Status



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

9. Wait for the **Output Complete** message to indicate the download is complete.
10. Save patient trend data to the personal computer disk or to an alternate source, depending on institutional requirements.

To launch HyperTerminal

1. Click the **Start** menu in the main task bar.
2. Mouse over the **Programs** submenu, then **Accessories**, then **Communications**, then the **HyperTerminal** option.



Note:

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

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



Note:

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

8. When the Connect To window opens, find the **Connect Using** option and click the down arrow to identify possible modem options.
9. Select the desired COM port.
10. Click the OK button.
11. In the COM Properties window, set the appropriate values.
 - a. Set the baud rate (bits per second) to match the monitoring system. The factory default baud rate is 19200 bits per second (bps).
 - b. Ensure the data bit is set to 8.

- c. Ensure the parity bit is set to none.
 - d. Ensure the stop bit is set to 1.
 - e. Ensure the flow control is set to none.
12. Click the OK button.

**Note:**

To test for trend data download connectivity, proceed with the download by pressing the **Start** option. If no data values appear in HyperTerminal, try a different COM port. select the **File** menu, click **New Connection**, and select a different COM port until data values scroll across the HyperTerminal screen.

To interpret downloaded trend data:

1. Examine trend data on the HyperTerminal screen, in a spreadsheet, or on a printout.

Figure 5-6. Sample Trend Data Printout

1	Covidien	VERSION 1.00.00	TREND	SpO2 Limit: 90-100%	PR Limit: 50-120BPM
		ADULT	100SAT-S		
2	TIME	%SPO2	PR	PA	Status
	11-Feb-26 16:16:40	---	---	---	SD
	11-Feb-26 16:16:44	---	---	---	SO
	11-Feb-26 16:16:48	75	201	127	
	11-Feb-26 16:16:50	75	200	127	
	11-Feb-26 16:16:52	75	200	127	
	11-Feb-26 16:16:56	75	200	127	
	11-Feb-26 16:17:00	75	200	127	
	11-Feb-26 16:17:04	75	201	127	
	11-Feb-26 16:17:08	75	201	129	
	11-Feb-26 16:17:12	75	200	133	
	11-Feb-26 16:17:16	75	200	129	
3	11-Feb-26 16:17:20	75	154	106	PS
	Output Complete				
	4	5	6	7	8

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- | | | |
|---|------------------------------|--|
| 1 | Product column headings | Data source, firmware version, and system settings |
| 2 | Patient data column headings | Lists appropriate time and data headings |
| 3 | Time column | Real-time clock date and time stamp |
| 4 | Output Complete | Message indicating completion of trend data download |
| 5 | %SpO ₂ | Current saturation value |

6	PR	Current pulse rate
7	PA	Current pulse amplitude
8	Status	Operating status of the monitoring system

Table 5-3. Status Codes

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

2. Ensure patient data settings coincide with expected settings. This would include the version of firmware and its CRC code, which should be all zeros; the current method of viewing the data: waveform, trend, or graph; alarm limit settings; patient mode; and SatSeconds™ setting.
3. Scan the time, SpO₂, or PR column until reaching the events of interest.
4. Match the operating status codes to the following table for pertinent system information. Reference *Status Codes*, p. 5-10.

COM port USB Driver Alternatives

- Load the appropriate driver from the product CD or thumb drive into the connected computer. The USB driver will automatically load.
- Contact Technical Services or a local Covidien representative.

**Note:**

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

To install a USB driver from the compact disc

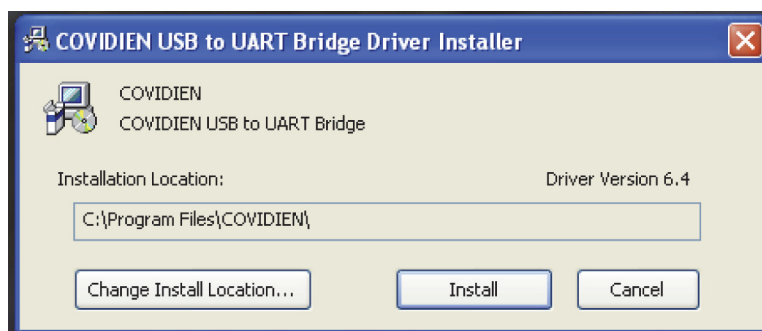
1. Insert the Nellcor™ bedside SpO₂ patient monitoring system compact disc (CD) into the designated personal computer (PC).
2. Copy the COVIDIEN USB to UART Bridge Driver zip file to the PC, installing it in the desired program folder.
3. Right-click on the zipped folder.
4. Select **Extract All**.
5. Open the extracted folder.
6. Launch the Driver Installer executable.

**Note:**

To change the location of the driver, select the desired mapping by clicking **Change Install Location**.

7. Click **Install**.

Figure 5-7. Sample Bridge Driver Installer window



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

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

Figure 5-8. Sample New Hardware Wizard Screen



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



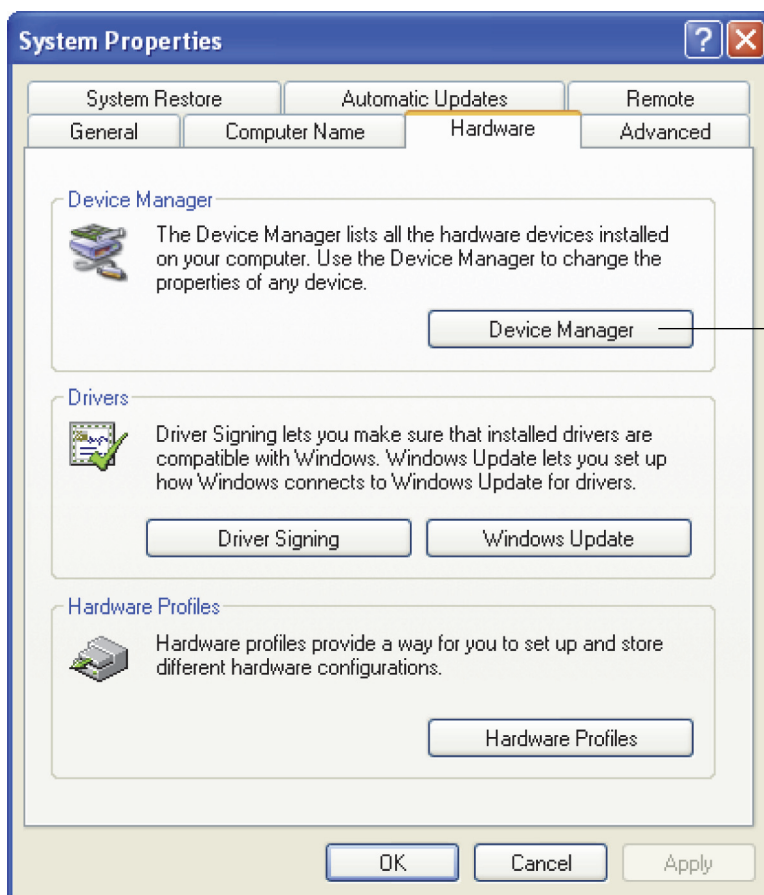
Note:

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

17. Click the OK button to complete the installation in the resulting Success window.

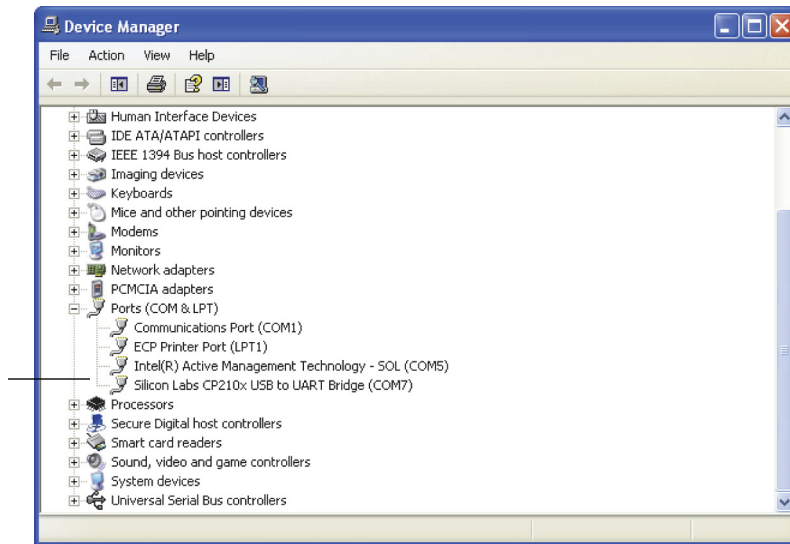
18. Reboot the PC for changes to take effect.
19. From the **Start** menu, click the Settings menu option and select the Control Panel option.
20. Select the System option to open the System Properties window.
21. Click the Hardware tab, then the **Device Manager** button.

Figure 5-9. Sample Device Manager Button Under Hardware Tab



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22. Select the Ports option from the resulting list.

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

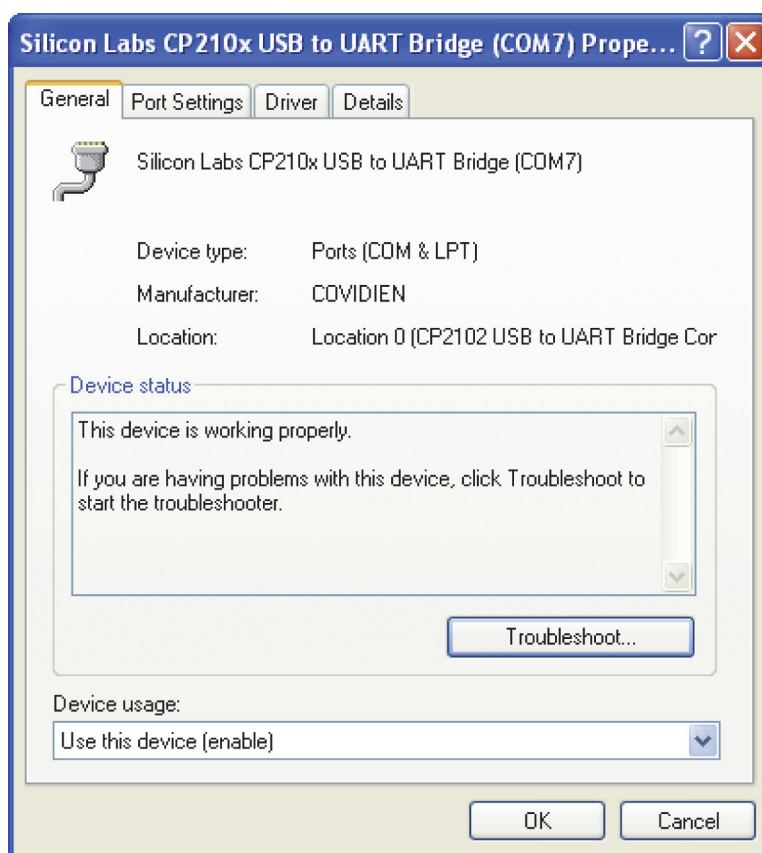
POX_30126_A

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

**Note:**

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

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



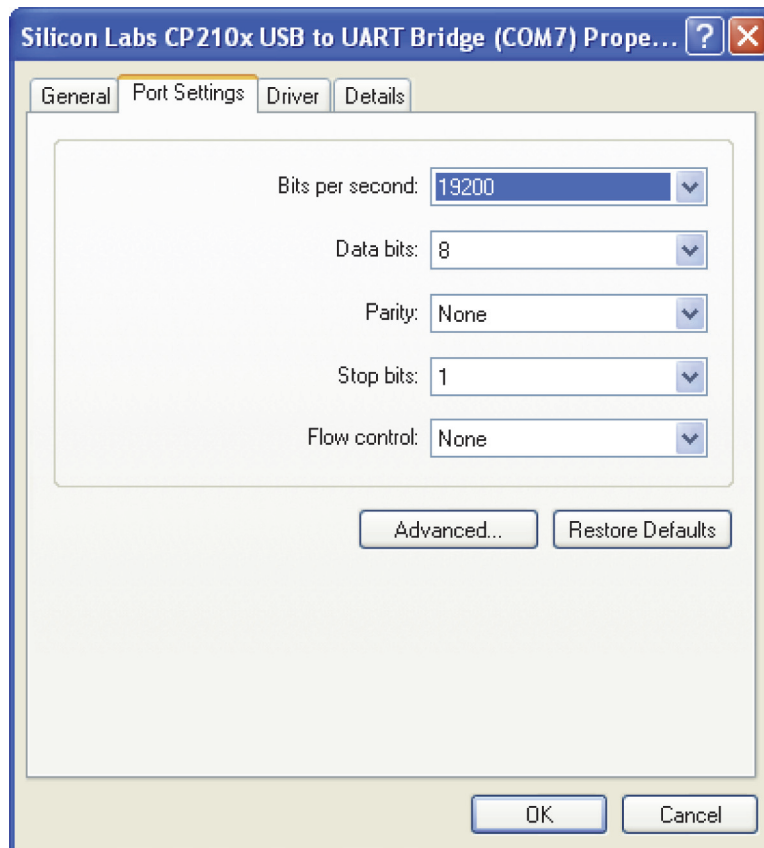
POX_30125_A

24. Click the Port Settings tab.
25. Set the bits per second to one of the following baud rates: 19200 or 115200. The factory default is 19200 bps.



Note:

The monitoring system's baud rate setting must match the baud rate setting for the USB to UART Bridge. Only a qualified service technician can change this setting.

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

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26. Click the OK button to complete the process.
27. Reference [To download trend data](#), p. 5-6, and proceed to step 8, utilizing HyperTerminal to connect to the monitoring system.

5.4.3 Firmware Upgrades

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

6 Performance Considerations

6.1 Overview

This chapter contains information about optimizing the performance of the Nellcor™ bedside SpO₂ patient monitoring system.

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

6.2 Oximetry Considerations



WARNING:

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

6.2.1 Pulse Rates

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

6.2.2 Saturation

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

6.3 Performance Considerations

6.3.1 Overview

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

Verify the performance of the monitoring system by following the procedures outlined in the *SRC-MAX Pulse Oximetry Functional Tester Technical Manual*. Have a qualified service technician perform these procedures prior to initial installation in a clinical setting and every 24 months as part of preventive maintenance. Reference [Service](#), p. 7-4.

6.3.2 Patient Conditions

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

- Anemia — Anemia causes decreased arterial oxygen content. Although 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 sulphemoglobin 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.
 1. Poor peripheral perfusion
 2. Excessive patient movement
 3. Venous pulsations
 4. Dark skin pigment
 5. Intravascular dyes, such as indocyanine green or methylene blue
 6. Externally applied coloring agents (nail polish, dye, pigmented cream)
 7. Defibrillation

6.3.3 Sensor Performance Considerations

**WARNING:**

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

**WARNING:**

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

**WARNING:**

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

**WARNING:**

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

Inaccurate Sensor Measurement Conditions

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

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

Signal Loss

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

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

Recommended Usage

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

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

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

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

If poor perfusion affects performance, consider using the Nellcor™ forehead SpO₂ sensor (MAXFAST).

6.3.4 Reducing EMI (Electromagnetic Interference)



WARNING:

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



WARNING:

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



WARNING:

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



WARNING:

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



Caution:

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

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

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

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

- Increase the separation between the interfering equipment and the monitoring system.
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.

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

6.4 Obtaining Technical Assistance

For technical information and assistance, contact Technical Services or a qualified service technician. Reference *Technical Assistance*, p. 1-6.

7 Preventive Maintenance

7.1 Overview

This chapter describes the steps required to maintain, service, and properly clean the Nellcor™ bedside SpO₂ patient monitoring system.

7.2 Cleaning



WARNING:

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



WARNING:

Remove batteries from the monitoring system before cleaning.

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

- **Surface cleaning** — Periodically surface clean the monitoring system by using a soft cloth dampened with a commercial, nonabrasive cleaner. Lightly wipe the top, bottom, and front surfaces of the monitoring system lightly.

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

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

7.3 Recycling and Disposal

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

7.4 Battery Maintenance



WARNING:

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



WARNING:

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



Caution:

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



Caution:

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



Caution:

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



Caution:

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



Caution:

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



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



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



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



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



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



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



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

Regularly check the battery to ensure optimal performance.

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

7.5 Periodic Safety Checks

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

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

7.6 Service



WARNING:

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



Caution:

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

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

- The monitoring system requires no calibration.
- Have a qualified service technician replace the battery at least every two (2) years.
- If service is necessary, contact Technical Services or a qualified service technician. Reference *Technical Assistance*, p. 1-6.

8 Troubleshooting

8.1 Overview

This chapter describes how to troubleshoot common problems while using the Nellcor™ bedside SpO₂ patient monitoring system.

8.2 General



WARNING:

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



WARNING:

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

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

8.3 Error Conditions

Table 8-1. Common Problems and Resolutions

Problem	Resolution
Battery Charging Indicator not lit	<ul style="list-style-type: none"> Check power cord Check battery Check AC power inlet Check power/ mains outlet
<ul style="list-style-type: none"> Sensor Message SpO₂ Pulse search Patient Movement Detected SpO₂ Sensor Off SpO₂ Cable/Sensor Disconnect SpO₂ Loss of Pulse 	<ul style="list-style-type: none"> Reference <i>Performance Considerations</i>, p. 6-1. Check patient status; keep patient still, check for perfusion Check all connections Reposition sensor Check or change adhesive wrap Choose alternate site Warm site Cover sensor Use forehead, nasal, or ear sensor (adult patient only) Use Nellcor™ adhesive sensor Secure cable Secure with headband (MAXFAST) Remove nail polish Loosen sensor (too tight) Isolate external interference (electrosurgical device, cell phone) Replace the cable and/or sensor Clean site (MAXR)
No response to Power On/Off button press	<ul style="list-style-type: none"> Press the Power On/Off button for more than one (1) second. Ensure the power cord is properly connected to the outlet. Ensure AC indicator blinks. Ensure it does not share the same AC power source with other equipment. If the error continues, contact Technical Services or a qualified service technician.
No response to button press	<ul style="list-style-type: none"> Verify whether the Home button has not been pressed during normal screen. If the error continues, contact Technical Services or a qualified service technician.
Frozen at POST after power on	<ul style="list-style-type: none"> Power cycle by pressing the Power On/Off button. If the error continues, contact Technical Services or a qualified service technician.
System is frozen	<ul style="list-style-type: none"> If the system freezes, it generates beep tone. Press the power button over 15 seconds for force quit the system. If the error continues, contact Technical Services or a qualified service technician.

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

Problem	Resolution
Blank screen	<p>Ensure buttons light. If not, press the Power On/Off button to turn on.</p> <p>Check if AC indicator lights or blinks.</p> <p>Use the same AC power source with other equipment to check for power.</p> <p>If the error continues, contact Technical Services or a qualified service technician.</p>
Screen does not function properly and the power-on beep tones do not sound	<p>Do not use the monitoring system; contact a qualified service technician or Covidien Technical Services.</p>
No sound generation	<p>Verify setting point of volume is not 0 or 1.</p> <p>Verify alarm setup is not set to alarm silenced.</p> <p>If the error continues, contact Technical Services or a qualified service technician.</p>
Abnormally shut down last time message	<p>Check any temporary settings such as alarm limits, response mode, and patient mode, since resets invoke factory or institutional default settings.</p> <p>Press the Power On/Off button to reset system power.</p> <p>If the error continues, contact Technical Services or a qualified service technician.</p>
Date and Time incorrect	<p>Set the time in the Options Menu.</p> <p>Check if date setting format follows locale.</p> <p>If the system displays wrong date and time even after power reset, it means internal battery for power backup is dead.</p> <p>If the error continues, contact Technical Services or a qualified service technician.</p>
System consumes battery power even with AC power connection	<p>Ensure proper connection between power cord and wall socket.</p> <p>Check if AC indicator lights or blinks.</p> <p>Use the same AC power source with other equipment to check for power.</p> <p>Replace the power cord.</p> <p>If the error continues, contact Technical Services or a qualified service technician.</p>
Low Battery / Critically Low-Battery condition	<p>Connect the system to AC power until the internal battery is fully charged.</p> <p>Ensure the system power cord is connected to the wall socket properly.</p> <p>Check if AC indicator lights or blinks.</p> <p>Use the same AC power source with other equipment to check for power.</p> <p>Check the date of manufacture (DOM) of battery.</p> <p>If the error continues, contact Technical Services or a qualified service technician.</p>
Questionable readouts of patient physiological measurements, wrongly tagged or missing patient data	<p>Reference <i>Performance Considerations</i>, p. 6-1.</p> <p>Check patient status.</p> <p>Replace sensor or cable, if necessary.</p> <p>Check all connections and reposition, if necessary.</p> <p>Remove sources of electromagnetic interference.</p> <p>Remove excessive ambient light.</p>

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

Problem	Resolution
Data port does not function properly	Ensure USB cable firmly connected. Disconnect USB cable, reset system power, then reconnect. Ensure baud rate settings for both monitoring system and PC are the same. Check hardware tab in PC 'System Registration Information'; verify normal status. Check COM port. Re-install the bridge driver provided by Covidien.
Experiencing EMI interference	Reference Reducing EMI (Electromagnetic Interference) , p. 6-5.
Technical System Error	Do not use the monitoring system; contact a qualified service technician or Covidien Technical Services.

Reference [Manage Alarms and Alarm Limits](#), p. 4-10, for any issues related to alarm conditions.

8.4 Return

Contact Covidien or a local Covidien representative for shipping instructions, including a Returned Goods Authorization (RGA) number. Reference [Technical Assistance](#), p. 1-6. Unless otherwise instructed by Covidien, it is not necessary to return the sensor or other accessory items with the monitoring system. Pack the monitoring system in its original shipping carton. If the original carton is not available, use a suitable carton with the appropriate packing material to protect it during shipping. Return the monitoring system by any shipping method that provides proof of delivery.

9 Accessories

9.1 Overview

This chapter contains information for selecting the appropriate pulse oximetry sensor for use with the Nellcor™ bedside SpO₂ patient monitoring system.

9.2 Nellcor™ Pulse Oximetry Sensors



WARNING:

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



WARNING:

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



WARNING:

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



WARNING:

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



WARNING:

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



WARNING:

Do not immerse or wet the pulse oximetry sensor.

**Caution:**

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

When selecting a Nellcor™ pulse oximetry sensor, consider the following items: patient's weight and activity level, the adequacy of perfusion, and the available sensor sites, the need for sterility, and the anticipated duration of monitoring. Use the following table for selection or contact Covidien or a local Covidien representative. Reference *Sensor Performance Considerations*, p. 6-3. Use the Nellcor™ pulse oximetry interface cable to connect the pulse oximetry sensor to the monitoring system.

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

Nellcor™ Pulse Oximetry Sensor	SKU	Patient Size
Nellcor™ preemie SpO ₂ sensor, non-adhesive (single-patient use)	SC-PR	<1.5 kg
Nellcor™ neonatal SpO ₂ sensor, non-adhesive (single-patient use)	SC-NEO	1.5 to 5 kg
Nellcor™ adult SpO ₂ sensor, non-adhesive (single-patient use)	SC-A	>40 kg
Nellcor™ adult-neonatal SpO ₂ sensor with wraps (reusable with adhesive)	OXI-A/N	<3 or >40 kg
Nellcor™ pediatric-infant SpO ₂ sensor with wraps (reusable with adhesive)	OXI-P/I	3 to 40 kg
Nellcor™ pediatric SpO ₂ sensor, two piece (sterile, single-use only)	P	10 to 50 kg
Nellcor™ neonatal-adult SpO ₂ sensor, two piece (sterile, single-use only)	N	<3 or >40 kg
Nellcor™ adult SpO ₂ sensor, two piece (sterile, single-use only)	A	> 30 kg
Nellcor™ neonatal-adult SpO ₂ sensor (sterile, single-use only)	MAXN	<3 or >40 kg
Nellcor™ infant SpO ₂ sensor (sterile, single-use only)	MAXI	3 to 20 kg
Nellcor™ pediatric SpO ₂ sensor (sterile, single-use only)	MAXP	10 to 50 kg
Nellcor™ adult SpO ₂ sensor (sterile, single-use only)	MAXA	>30 kg
Nellcor™ adult XL SpO ₂ sensor (sterile, single-use only)	MAXAL	>30 kg
Nellcor™ adult SpO ₂ nasal sensor (sterile, single-use only)	MAXR	>50 kg
Nellcor™ forehead SpO ₂ sensor	MAXFAST	>10 kg

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

Nellcor™ Pulse Oximetry Sensor	SKU	Patient Size
Nellcor™ adult SpO ₂ sensor, reusable (nonsterile)	DS-100A	>40 kg
Nellcor™ SpO ₂ sensor, multi-site reusable (nonsterile)	D-YS	>1 kg
Nellcor™ SpO ₂ ear sensor clip, reusable (nonsterile)	D-YSE	>30 kg
Nellcor™ pediatric SpO ₂ sensor clip, reusable (nonsterile)	D-YSPD	3 to 40 kg
Nellcor™ flexible SpO ₂ sensor (reusable-large)	FLEXMAX	>20 kg
Nellcor™ flexible SpO ₂ sensor (reusable-small)	FLEXMAX-P	>20 kg
Nellcor™ flexible SpO ₂ sensor (reusable-large, home care)	FLEXMAX-HC	>20 kg
Nellcor™ flexible SpO ₂ sensor (reusable-small, home care)	FLEXMAX-P-HC	>20 kg



Note:

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

9.3 Optional Equipment

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

- **Adapter plate** — This adapter plate fits standard, commercially available GCX brackets and securely mounts the monitoring system to a wall bracket or a roll stand. The adapter plate attaches to the bottom of the monitoring system.
- **GCX wall mount arm and channel** — The M-Series wall mount arm attaches to the adapter plate, which attaches to the M-Series arm. The arm slides into the wall mount channel.
- **GCX roll stand** — The GCX roll stand attaches to the adapter plate.

Covidien Technical Services: Patient Monitoring

15 Hampshire Street, Mansfield, MA 02048 USA

1.800.635.5267, 1.925.463.4635

or contact a local Covidien representative

www.covidien.com

9.4 Biocompatibility Testing

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

10 Theory of Operations

10.1 Overview

This chapter explains the theory behind operations of the Nellcor™ bedside SpO₂ patient monitoring system.

10.2 Theoretical Principles

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

Bone, tissue, pigmentation, and venous vessels normally absorb a constant amount of light over time. The arteriolar bed normally pulsates and absorbs variable amounts of light during the pulsations. The ratio of light absorbed is translated into a measurement of functional oxygen saturation (SpO₂).

Ambient conditions, sensor application, and patient conditions can influence the ability of the pulse oximeter to accurately measure SpO₂. Reference *Performance Considerations*, p. 6-1.

Pulse oximetry is based on two principles: oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (measured using spectrophotometry), and the volume of arterial blood in tissue (and hence, light absorption by that blood) changes during the pulse (registered using plethysmography). A monitoring system determines 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.

10.3 Automatic Calibration

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

10.4 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 carboxy-hemoglobin or methemoglobin. In contrast, hemoximeters such as the IL482 report fractional saturation where oxygenated hemoglobin is expressed as a percentage of all measured hemoglobin, including measured dysfunctional hemoglobins. To compare functional saturation measurements to those from a monitoring system that measures fractional saturation, fractional measurements must be converted using the listed equation.

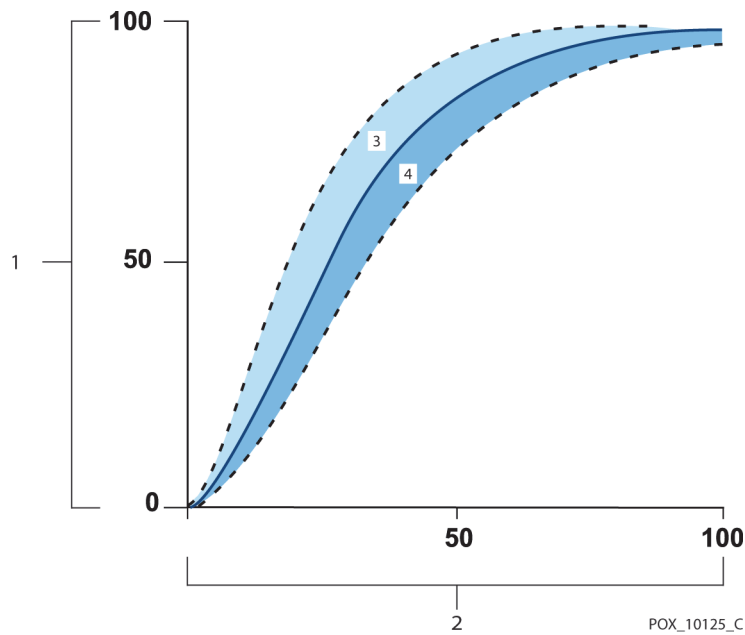
$$\Phi = \frac{\phi}{100 - (\eta + \Lambda)} \times 100$$

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

10.5 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.

Figure 10-1. Oxyhemoglobin Dissociation Curve



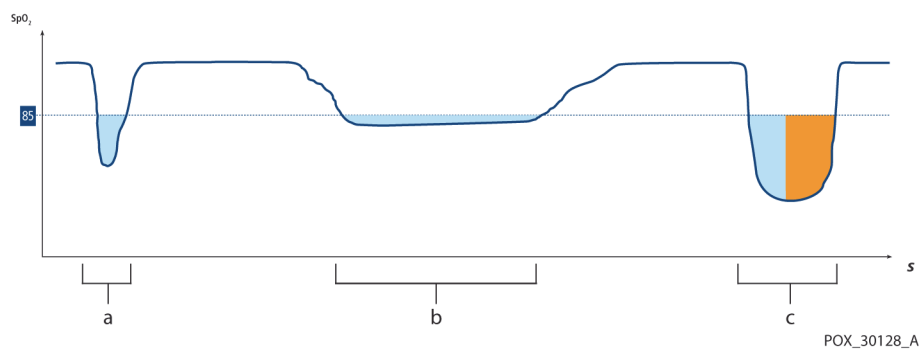
- | | | | |
|---|-----------------------------|---|---|
| 1 | % Saturation Axis | 3 | Increased pH; Decreased temperature, PCO ₂ , and 2,3-DPG |
| 2 | PO ₂ (mmHg) Axis | 4 | Decreased pH; Increased temperature, PCO ₂ , and 2,3-DPG |

10.6 SatSeconds™ Alarm Management Feature

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

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

Figure 10-2. Series of SpO₂ Events



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

10.6.1 First SpO₂ Event

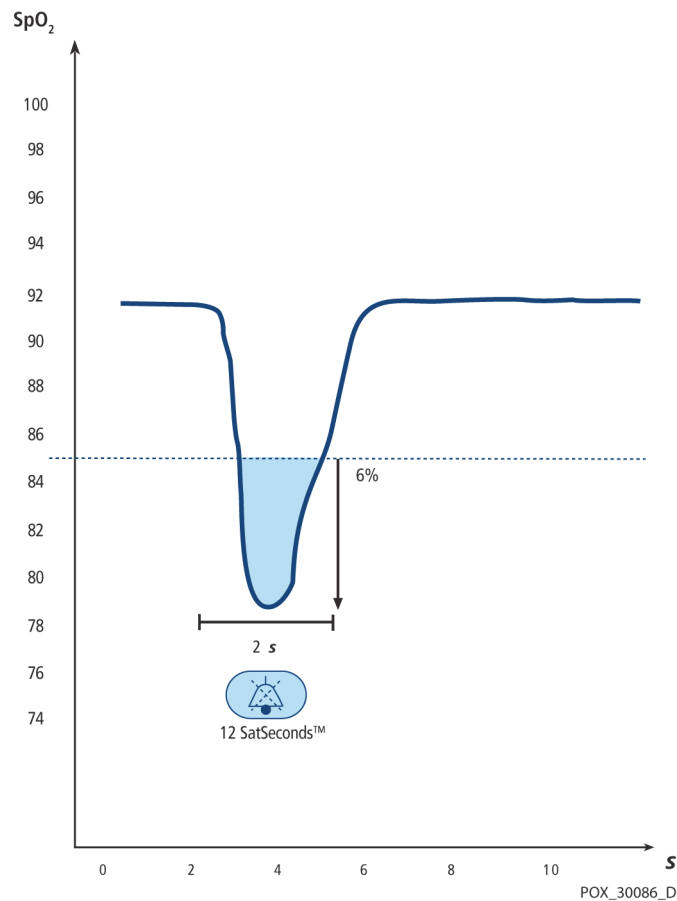
Consider the first event. Suppose the SatSeconds™ alarm limit is set to 25. The patient's SpO₂ drops to 79% and the duration of the event is two (2) seconds before saturation again exceeds the lower alarm threshold of 85%.

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

12 SatSeconds™; no alarm

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

Figure 10-3. First SpO₂ Event: No SatSeconds™ Alarm



10.6.2 Second SpO₂ Event

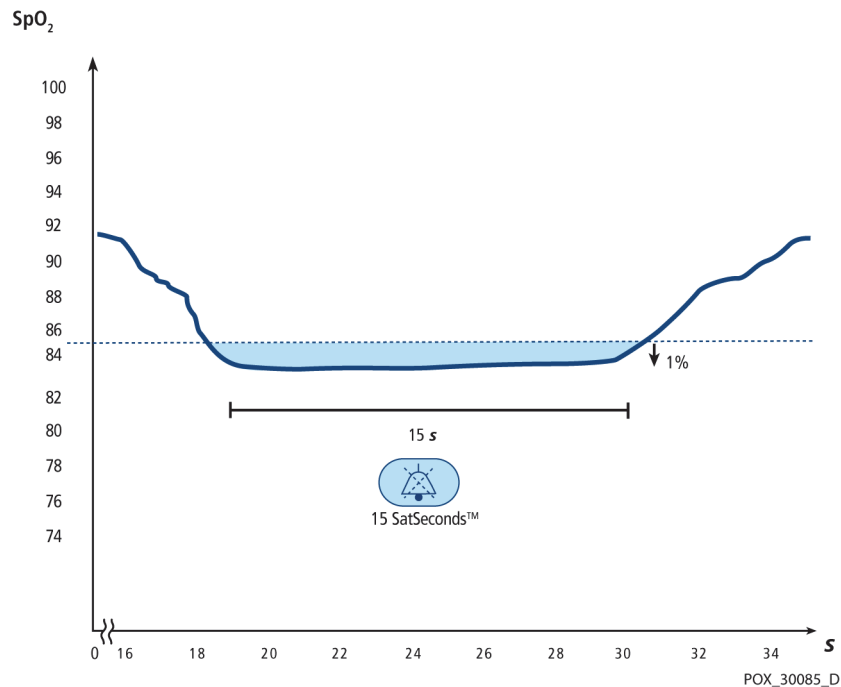
Consider the second event. Suppose the SatSeconds™ alarm limit is still set to 25. The patient's SpO₂ drops to 84% and the duration of the event is 15 seconds before saturation again exceeds the lower alarm threshold of 85%.

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

15 SatSeconds™; no alarm

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

Figure 10-4. Second SpO₂ Event: No SatSeconds™ Alarm



10.6.3 Third SpO₂ Event

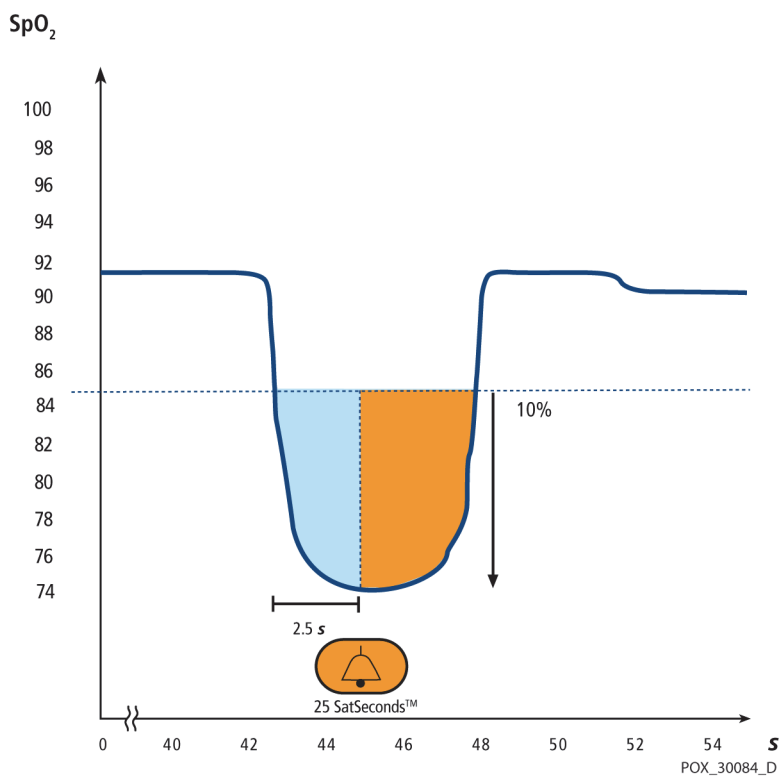
Consider the third event. Suppose the SatSeconds™ alarm limit is still set to 25. During this event, the patient's SpO₂ drops to 75%, which is 10% below the lower alarm threshold of 85%. Since the patient's saturation does not return to a value over the lower alarm threshold within 2.5 seconds, an alarm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

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

25 SatSeconds™; results in an alarm

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

Figure 10-5. Third SpO₂ Event: Triggers SatSeconds™ Alarm



10.6.4 The SatSeconds™ Safety Net

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

11 Product Specifications

11.1 Overview

This chapter contains physical and operational specifications of the Nellcor™ bedside SpO₂ patient monitoring system. Ensure all product requirements are met prior to installation of the monitoring system.

11.2 Physical Characteristics

Enclosure

Weight	1.6 kg (3.5 lbs.) including battery
Dimensions	255 × 82 × 155 mm (10.04 × 3.23 × 6.10 in)

Display

Screen size	109.22 mm (4.3 in), measured diagonally
Screen type	TFT LCD, white LED backlight, viewing cone of 30° and optimal viewing distance of 1 meter
Resolution	480 × 272 pixel

Controls

Dial	Knob
Buttons	Power On/Off, Silence Alarm, Home

Alarms

Categories	Patient status and system status
Priorities	Low, medium and high
Notification	Audible and visual
Setting	Default and individual
Alarm volume level	45 to 80 dB

11.3 Electrical Requirements

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

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

11.4 Environmental Conditions



Note:

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

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

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

11.5 Tone Definition

Table 11-2. Tone Definitions

Tone Category	Description
High Priority Alarm Tone	
Volume level	Adjustable (level 1-8)
Pitch (± 20 Hz)	976 Hz
Effective pulse duration (t_d)	160 msec (IEC 60601-1-8)
Number of pulses in burst	10, interburst interval of 4 sec (IEC 60601-1-8)
Repetitions	Continually
Medium Priority Alarm Tone	
Volume level	Adjustable (level 1-8)
Pitch (± 20 Hz)	697 Hz
Effective pulse duration (t_d)	180 msec (IEC 60601-1-8)
Number of pulses in burst	3, interburst interval of 8 sec (IEC 60601-1-8)
Repetitions	Continually
Low Priority Alarm Tone	
Volume level	Adjustable (level 1-8)
Pitch (± 20 Hz)	488 Hz
Effective pulse duration (t_d)	180 msec (IEC 60601-1-8)
Number of pulses	1, interburst interval of 16 sec (IEC 60601-1-8)
Repetitions	Continually
Alarm Disabled Reminder Tone	
Volume level	Not changeable
Pitch (± 20 Hz)	800 Hz
Pulse width (± 20 msec)	200 msec
Number of pulses	1 pulse per 1 second, 3 min — 10 min interburst
Repetitions	Continually

Table 11-2. Tone Definitions (Continued)

Tone Category	Description
Key Beep	
Volume level	Adjustable (Off, level 1-7), (Invalid key presses are ignored)
Pitch (± 20 Hz)	440 Hz (valid), 168 Hz (invalid)
Pulse width (± 20 msec)	110 msec
Number of pulses	N/A
Repetitions	No repeat
POST Pass Tone	
Volume level	Not changeable
Pitch (± 20 Hz)	780 Hz
Pulse width (± 20 msec)	1500 msec
Number of pulses	N/A
Repetitions	No repeat

11.6 Performance Specifications

Table 11-3. Trends

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

Table 11-4. Nellcor™ Sensor Accuracy and Ranges

Range Type	Range Values
Measurement Ranges	
SpO ₂ saturation range	1% to 100%
Pulse rate range	20 to 250 beats per minute (bpm)
Perfusion range	0.03% to 20%
Display sweep speed	6.25 mm/sec
Accuracy¹	
Saturation	
Adult ^{2,3}	70% to 100% ±2 digits
Adult and Neonate Low Sat ^{2,3,4}	60 to 80% ±3 digits
Neonate ^{4,5}	70 to 100% ±2 digits
Low Perfusion ⁶	70 to 100% ±2 digits
Adult and Neonate with Motion ^{2,7}	70 to 100% ±3 digits
Pulse Rate	
Adult and Neonate ^{2,3,4}	20 to 250 bpm ±3 digits
Low Perfusion ⁶	20 to 250 bpm ±3 digits
Adult and Neonate with Motion ^{2,7}	20 to 250 bpm ±5 digits

¹Saturation accuracy varies by sensor type. Refer to the Sensor Accuracy Grid at www.covidien.com/rms.

²Accuracy 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 (ARMS) range (refer to the Sensor Accuracy Grid for more details).

³Adult specifications are shown for OxiMax™ MAXA and MAXN sensors with the monitoring system.

⁴Neonate specifications are shown for OxiMax™ MAXN sensors with the monitoring system.

⁵Clinical functionality of the MAXN 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.

⁶Specification applies to monitoring system performance. Reading accuracy in the presence of low perfusion (detected IR pulse modulation amplitude 0.03% - 1.5%) was validated using signals supplied by a patient simulator. 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.

⁷Motion performance was validated during a controlled hypoxia blood study over an SaO₂ span of 70% to 98% and a convenience-sample heart rate range of 47-102 bpm. Subjects performed rubbing and tapping movements 1-2 cm in amplitude with aperiodic intervals (randomly changing) with a random variation in frequency between 1-4 Hz. The average percent modulation during quiescent periods was 4.27, during motion 6.91. Motion performance over the entire specified pulse rate range was validated using synthetic signals from a patient simulator that comprised representative cardiac and signal artifact components. Applicability: OxiMax™ MAXA, MAXAL, MAXP, MAXI, and MAXN sensors.

Table 11-5. Nellcor™ Sensor Operating Ranges 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

11.7 Product Compliance

Standards Compliance

EN ISO 80601-2-61: Edition 1.0
 EN IEC 60601-1: Edition 3.1
 EN IEC 60601-1-2: Edition 3.0 and 4.0
 EN IEC 60601-1-6: Edition 3.1
 EN IEC 60601-1-8: Edition 2.1
 EN IEC 60601-1-11: Edition 2.0
 CAN/CSA C22.2 No. 60601-1:14 3rd Edition
 ANSI/AAMI ES 60601-1:2005/(R)2012

Equipment Classifications

Type of Protection against electric shock	Class II (internally powered)
Degree of Protection against electric shock	Type BF - Applied part
Mode of Operation	Continuous
Electromagnetic Compatibility	IEC 60601-1-2:2007 (Ed. 3.0) and IEC 60601-1-2:2014 (Ed. 4.0)
Liquid Ingress	IP22: Protected against finger insertion and water dropped vertically
Degree of Safety	Not suitable for use in the presence of flammable anesthetics

11.8 Manufacturer's Declaration and Guidance

11.8.1 Electromagnetic Compatibility (EMC)



WARNING:

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



WARNING:

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



WARNING:

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



Caution:

For best product performance and measurement accuracy, use only accessories supplied or recommended by Covidien. Use accessories according to the *Instructions for Use*. Use only accessories that have passed the recommended biocompatibility testing in compliance with ISO 10993-1.

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



Note:

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

Electromagnetic Emissions

Table 11-6. Electromagnetic Emissions Guidelines and Compliance

Guidance and Manufacturer's Declaration—Electromagnetic Emissions (IEC/EN 60601-1-2)		
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.		
Emissions Test	Compliance	Electromagnetic Environment Guidance
RF emission CISPR 11	Group 1, Class B	The monitoring system is suitable for use in all establishments.
Harmonic emissions IEC/EN 61000-3-2	Class A	The monitoring system is suitable for use in all establishments.
Voltage fluctuation/ flicker emissions IEC/EN 61000-3-3	Complies	The monitoring system is suitable for use in all establishments.

Electromagnetic Immunity

Table 11-7. Electromagnetic Immunity Guidelines and Compliance

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

Table 11-8. Recommended Separation Distance Calculations


Guidance and Manufacturer's Declaration—Electromagnetic Immunity (IEC/EN 60601-1-2)			
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
Conducted RF IEC/EN 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms ISM bands	3 Vrms 150 kHz to 80 MHz 6 Vrms ISM bands	<p>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.</p> <p>Recommended Separation Distance</p> $d = 1.2\sqrt{P}$
Radiated RF IEC/EN 61000-4-3	20 V/m 80 MHz to 2.5 GHz 10 V/m 80 MHz to 2.7 GHz	20 V/m 80 MHz to 2.5 GHz 10 V/m 80 MHz to 2.7 GHz	$d = 0.2\sqrt{P}$ <p>80 MHz to 800 MHz</p> $d = 0.4\sqrt{P}$ <p>800 MHz to 2.7 GHz</p> <p>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.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			
^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the monitoring system is used exceeds the applicable RF compliance level above, the monitoring system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the monitoring system.			
^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Table 11-9. Recommended Separation Distances

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Monitoring System (IEC/EN 60601-1-2)			
The monitoring system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the monitoring system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the monitoring system as recommended below, according to the maximum output power of the communications equipment.			
Rated Maximum Output Power (<i>P</i>) of Transmitter in Watts	Separation Distance According to Frequency of Transmitter in Meters		
	$d = 1.2\sqrt{P}$ 150 kHz to 80 MHz	$d = 0.2\sqrt{P}$ 80 MHz to 800 MHz	$d = 0.4\sqrt{P}$ 800 MHz to 2.7 GHz
0.01	0.12	0.02	0.04
0.10	0.38	0.06	0.13
1.00	1.20	0.20	0.40
10.00	3.80	0.63	1.26
100.00	12.00	2.00	4.00
For transmitters rated at a maximum output power not listed above, the recommended separation distance (<i>d</i>) in meters (<i>m</i>) can be estimated using the equation applicable to the frequency of the transmitter, where <i>P</i> is the maximum output power rating of the transmitter in watts (<i>W</i>) 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.			

Table 11-10. Test Specifications for Enclosure Port Immunity to RF Wireless Communications Equipment

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

11.8.2 Sensor and Cable Compliance



WARNING:

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

Table 11-11. Cables and Sensors

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

11.8.3 Safety Tests

Ground Integrity

100 milliohms or less

Leakage Current

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

Table 11-12. Earth Leakage and Touch Current

Earth Leakage Current				
Condition	AC Line Polarity	Line Cord	Neutral Line Cord	IEC 60601-1 ANSI/AAMI ES 60601-1
Normal	Normal	Closed	Closed	5 mA
Single Fault		Open	Closed	10 mA
		Closed	Open	
Normal	Reversed	Closed	Closed	5 mA
Single Fault		Open	Closed	10 mA
		Closed	Open	
Touch Current				
Condition	AC Line Polarity	Neutral Line Cord	Power Line Ground	IEC 60601-1 ANSI/AAMI ES 60601-1
Normal	Normal	Closed	Closed	100 μ A
Single Fault		Open	Closed	500 μ A
		Closed	Open	
Normal	Reversed	Closed	Closed	100 μ A
Single Fault		Open	Closed	500 μ A
		Closed	Open	

Table 11-13. Patient Leakage Current

Patient Leakage Current				
Condition	AC Line Polarity	Neutral Line	Power Line Ground Cable	IEC 60601-1 ANSI/AAMI ES 60601-1
Normal	Normal	Closed	Closed	100 μ A
Single Fault		Open	Closed	500 μ A
		Closed	Open	
Normal	Reversed	Closed	Closed	100 μ A
Single Fault		Open	Closed	500 μ A
		Closed	Open	
Patient Leakage Current - Mains on Applied Part				
Condition	AC Line Polarity	Neutral Line	Power Line Ground Cable	IEC 60601-1 ANSI/AAMI ES 60601-1
Single Fault	Normal	Closed	Closed	5000 μ A
	Reversed	Closed	Closed	

11.9 Essential Performance

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

- **SpO₂ and pulse rate accuracy** — Reference Table 11-4, *Nellcor™ Sensor Accuracy and Ranges* on p. 11-5.
- **Audible indicators** — Reference *Manage Alarms and Alarm Limits*, p. 4-10, *Audible Alarm Indicators*, p. 4-11, and *Tone Definition*, p. 11-3.
- **Physiological alarms and priorities** — Reference *Manage Alarms and Alarm Limits*, p. 4-10.
- **Visual indicator of power source** — Reference *Front Panel and Display Components*, p. 2-3 and *Power*, p. 3-3.
- **Backup power source** — Reference *Power*, p. 3-3 and *Internal Battery Power*, p. 3-4.
- **Sensor disconnect/off notification** — Reference *Display*, p. 2-4, *Manage Alarms and Alarm Limits*, p. 4-10, and *Error Conditions*, p. 8-2.
- **Motion, interference, or signal degradation indicator** — Reference *Display*, p. 2-4.

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A Clinical Studies

A.1 Overview

Prospective clinical studies were conducted in accordance with EN ISO 80601-2-61:2011 using a Nellcor™ monitoring system containing identical algorithms and SpO₂ circuitry to the Nellcor™ bedside SpO₂ patient monitoring system. These studies demonstrated the accuracy of pulse oximetry for OxiMax™ sensors used with the Nellcor™ bedside SpO₂ patient monitoring system during both motion and non-motion conditions.

All referenced studies are internal Covidien clinical studies.

A.2 Methodology

A.2.1 Hypoxia Methodology (Accuracy, Low Saturation, and Motion Studies)

The general purpose of invasive controlled desaturation study is to validate the SpO₂ and pulse rate accuracy in comparison to reference-standard measurements of blood SaO₂ by a CO-oximeter and ECG heart rate. This is achieved through paired observations of SpO₂ and SaO₂ values over the SaO₂ accuracy range of 70% to 100% on a group of healthy adult volunteers. The fraction of inspired oxygen (FiO₂) delivered to test subjects is varied to achieve a series of targeted steady-state saturation periods. Arterial blood samples are periodically taken from an indwelling arterial catheter for use in the comparison.

In accordance to EN ISO80601-2-61:2011, desaturation to 70% is conducted in a gradual continuous process targeting multiple saturation plateaus (e.g. 98, 90, 80 and 72%). In these studies, six arterial samples were taken, 20 seconds apart at each plateau, resulting in a total of approximately 24 samples per subject. Each sample was drawn while SpO₂ data were simultaneously collected and marked for direct comparison to CO-oximetry. Similarly, pulse rate from SpO₂ was compared to ECG heart rate.

End tidal CO₂, respiratory rate, respiratory pattern and electrocardiogram were continuously monitored throughout the study.

A.2.2 Low Saturation Methodology (Low Saturation Study Only)

The methodology and purpose of the Low Saturation study is the same as the hypoxia methodology. Reference *Hypoxia Methodology (Accuracy, Low Saturation, and Motion Studies)*, p. A-1. However, the desaturation is to 60% instead of 70%. This lower saturation is obtained by the addition of a new plateau at 60% SaO₂, increasing the range from 70 to 100% to 60 to 100%. This results in approximately 30 arterial samples instead of 24 for this study.

A.2.3 Motion Methodology (Motion Study Only)

Standard motions include tapping and/or rubbing at aperiodic intervals with amplitudes of 1-2 cm and 1-4 Hz with a random variation in frequency to simulate physiological motion. In this study, the subject was instructed to tap with finger tips to maintain consistency of area of effect on the pressure pad and to prevent resting hand on pressure pad between motions so that only qualified taps are recorded by the pressure pad system.

Each plateau (70 to 100%) has both an interval of tapping and rubbing. In this study, the order of tapping and rubbing was alternated between subjects.

Two video cameras were used to capture motion of the subjects. These videos were then reviewed to determine if any data points should be removed if the appropriate amplitudes were not being reached during the blood samples.

A.3 Results

A.3.1 Accuracy Results (No Motion)

The following summary describes the demographic information of the subjects enrolled into the MAXA, MAXN, and MAXFAST Accuracy and Low Saturation study: A total of 11 subjects were analyzed, 5 (45%) males and 6 (55%) females. The mean age of the subjects was 31.8 ± 5.2 years, with a range of 25 to 42 years of age. Two subjects had dark pigmentation (dark olive to extremely dark). Weight ranged from 49 kg to 103.6 kg, and height ranged from 143.5 cm to 192 cm.

The following summary describes the demographic information of the subjects enrolled into the SC-A sensor study: A total of 16 subjects were analyzed. There were 6 (37.5%) males and 10 (62.5%) female subjects enrolled into the study. The mean age of study participants was 31.44 ± 6.7 years, with a range of 24 to 42 years of age. Three subjects had dark pigmentation (dark olive to extremely dark). Weight ranged from 48.7 kg to 96.9 kg, and height ranged from 143.5 cm to 188 cm.

The following summary describes the demographic information of the subjects enrolled into the study for all other sensors (listed in Table A-1): A total of 11 subjects were analyzed. There were 4 (36.4%) males and 7 (63.6%) female subjects enrolled into the study. The mean age of study participants was 30.36 ± 7.85 years, with a range of 22 to 46 years of age. Three subjects had dark pigmentation (dark olive to extremely dark). Weight ranged from 58.4 kg to 114.4 kg, and height ranged from 159 cm to 187 cm.

Accuracy results for both SpO₂ and pulse rate can be found in Table A-1 and Table A-2. A_{RMS} (Accuracy root mean square) is used to describe the accuracy of pulse oximetry, which is affected by both bias and precision. As shown in the tables, both SpO₂ and pulse rate meet the acceptance criteria for all of the listed sensors during non-motion conditions.

Table A-1. SpO₂ Accuracy Results (No Motion)

Sensor	Motion	# of Data Points	A _{RMS} (%)	SpO ₂ Acceptance Criteria 70%-100% (%)	Pass/Fail
MAXA	No	976	1.54	≤ 2.0	Pass
MAXN	No	723	1.41	≤ 2.0	Pass
MAXFAST	No	235	1.42	≤ 2.0	Pass
SC-A	No	659	1.86	≤ 2.0	Pass
DS-100A	No	411	2.16	≤ 3.0	Pass
OxiCliq-A	No	480	1.58	≤ 2.5	Pass
D-YSE	No	458	1.96	≤ 3.5	Pass

Table A-2. Pulse Rate Accuracy Results (No Motion)

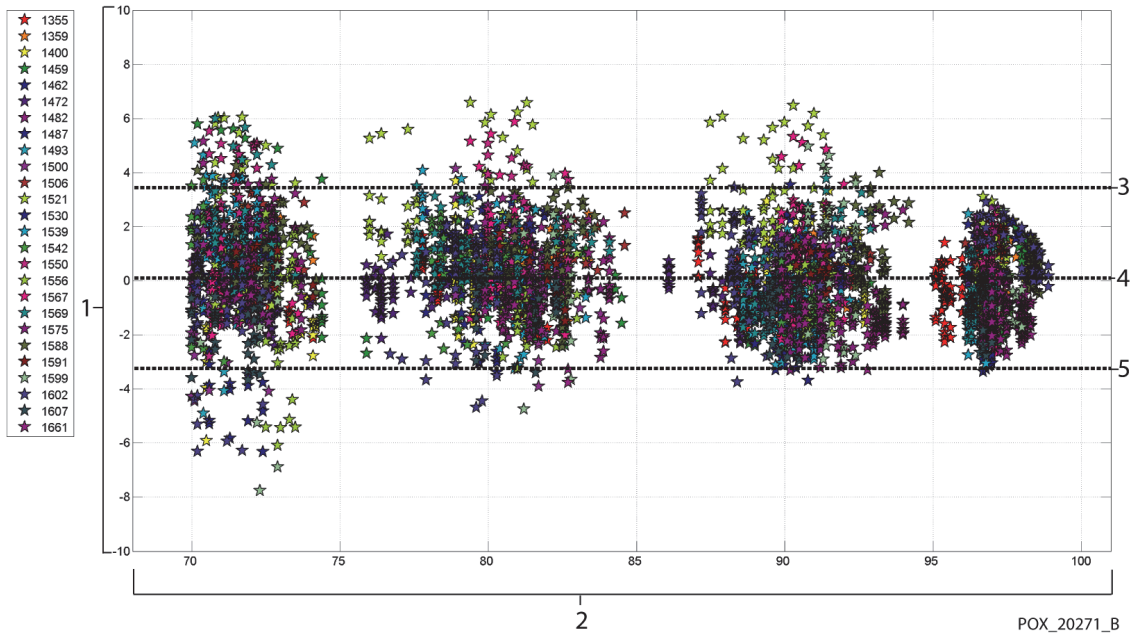
Sensor	Motion	# of Data Points	A _{RMS} (BPM)	Pulse Rate Acceptance Criteria (BPM)	Pass/Fail
MAXA	No	1154	0.76	≤ 3.0	Pass
MAXN	No	874	0.74	≤ 3.0	Pass
MAXFAST	No	281	0.81	≤ 3.0	Pass
SC-A	No	636	2.20	≤ 3.0	Pass
DS-100A	No	444	0.77	≤ 3.0	Pass
OxiCliq-A	No	499	0.79	≤ 3.0	Pass
D-YSE	No	473	0.98	≤ 3.0	Pass

Modified Bland-Altman plots for all the data are presented in Figure A-1 and Figure A-2 for SpO₂ and pulse rate respectively.

**Note:**

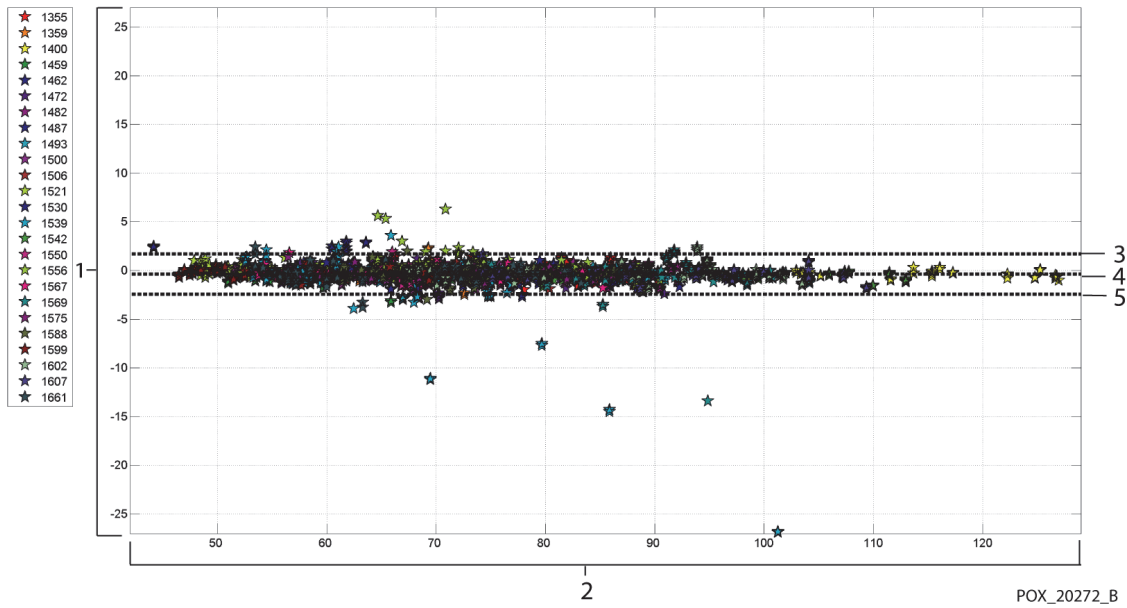
Each individual subject is represented by a unique color on the plots. Subject identification numbers are indicated in the legend to the left of each plot.

Figure A-1. Modified Bland-Altman for SpO₂ (All Data - No Motion): SaO₂ vs. (SpO₂ - SaO₂)



- | | | | |
|---|---|---|---------------|
| 1 | SpO ₂ - SaO ₂ (%) | 3 | Upper 95% LoA |
| 2 | SaO ₂ (%) | 4 | Mean Bias |
| | | 5 | Lower 95% LoA |

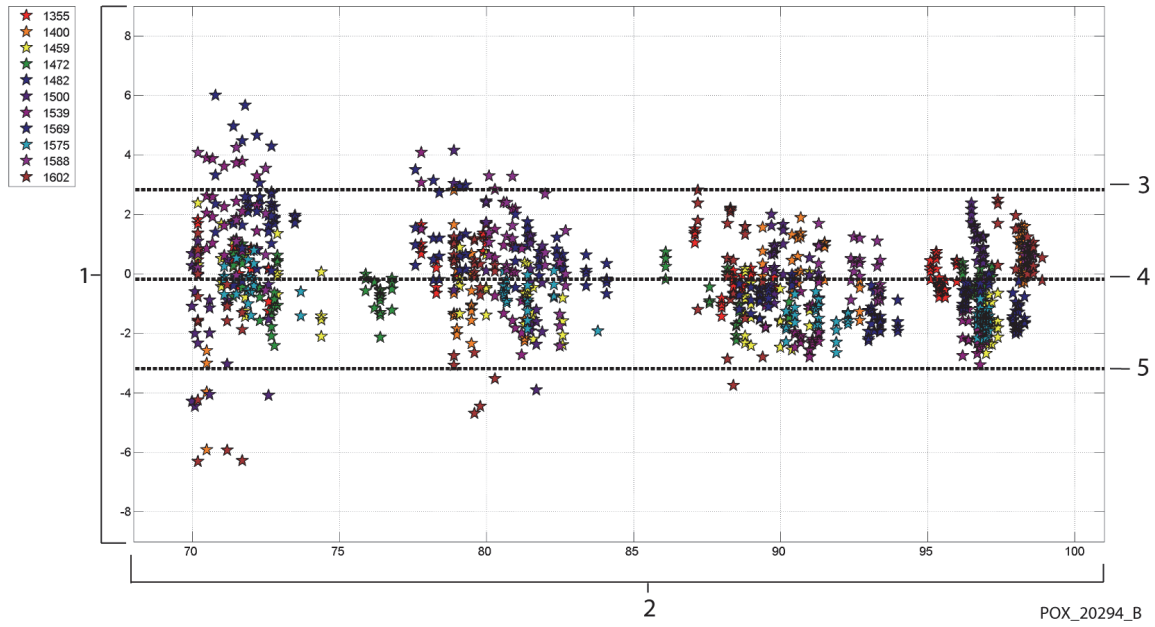
Figure A-2. Modified Bland-Altman for Pulse Rate (All Data - No Motion): ECG HR vs. (Pulse Rate - ECG HR)



- | | | | |
|---|---------------------------|---|---------------|
| 1 | Pulse Rate - ECG HR (BPM) | 3 | Upper 95% LoA |
| 2 | ECG HR (BPM) | 4 | Mean Bias |
| | | 5 | Lower 95% LoA |

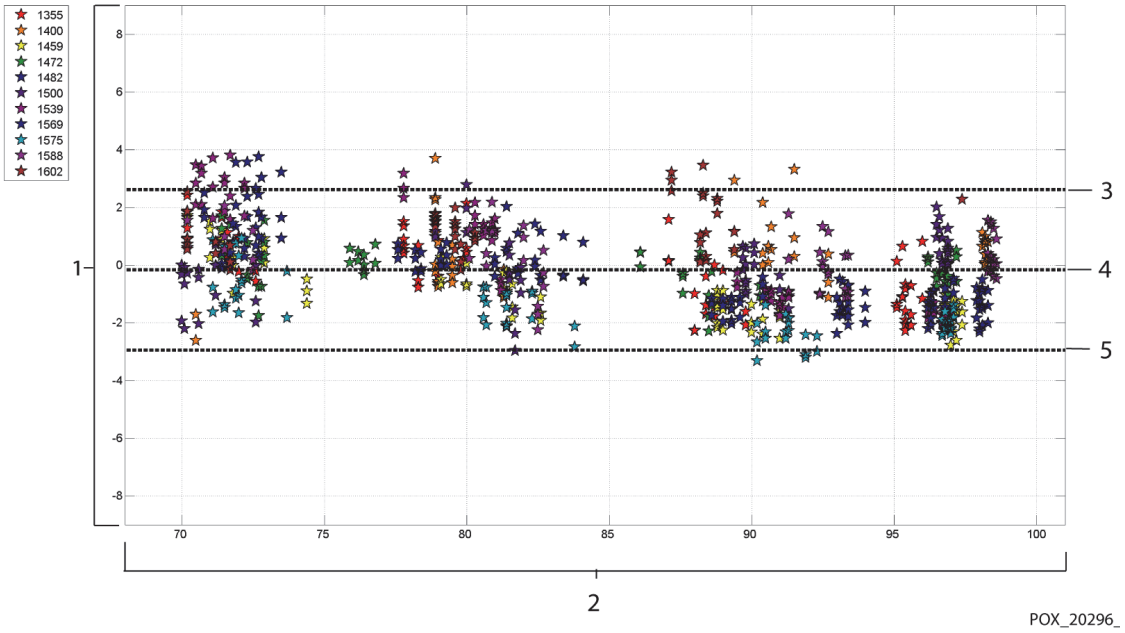
Modified Bland-Altman plots for the SpO₂ data by sensor type are presented in Figure A-3 through Figure A-9.

Figure A-3. Modified Bland-Altman for SpO₂ - MAXA Sensor (No Motion): SaO₂ vs. (SpO₂ - SaO₂)



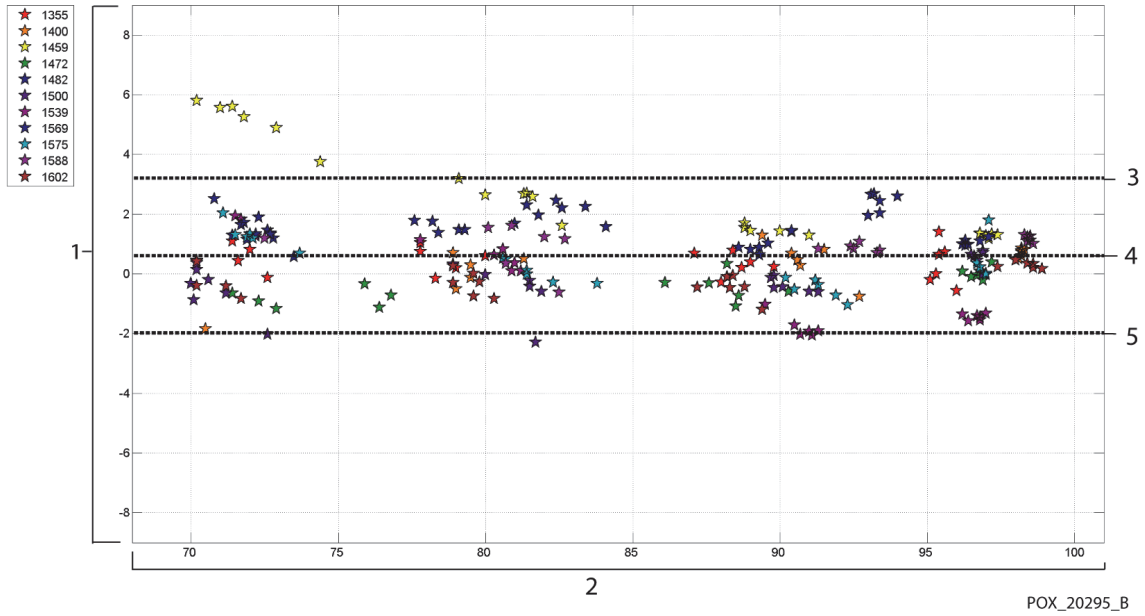
- | | | | |
|---|---|---|---------------|
| 1 | SpO ₂ - SaO ₂ (%) | 3 | Upper 95% LoA |
| 2 | SaO ₂ (%) | 4 | Mean Bias |
| | | 5 | Lower 95% LoA |

Figure A-4. Modified Bland-Altman for SpO₂ - MAXN Sensor (No Motion): SaO₂ vs. (SpO₂ - SaO₂)



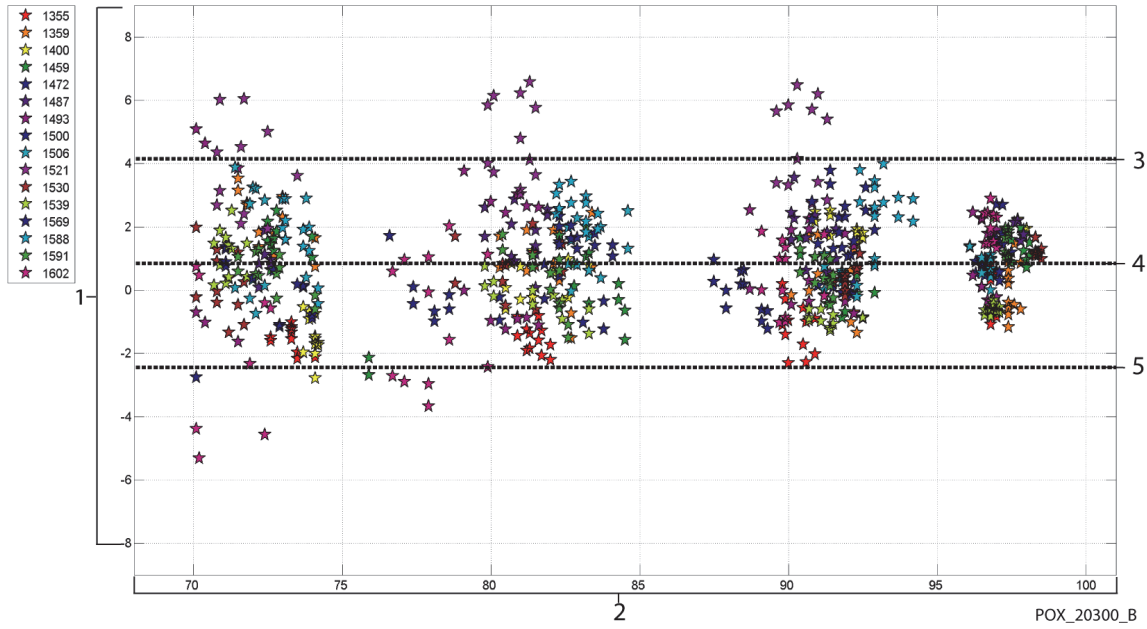
- | | | | |
|---|---|---|---------------|
| 1 | SpO ₂ - SaO ₂ (%) | 3 | Upper 95% LoA |
| 2 | SaO ₂ (%) | 4 | Mean Bias |
| | | 5 | Lower 95% LoA |

Figure A-5. Modified Bland-Altman for SpO₂ - MAXFAST Sensor (No Motion): SaO₂ vs. (SpO₂ - SaO₂)



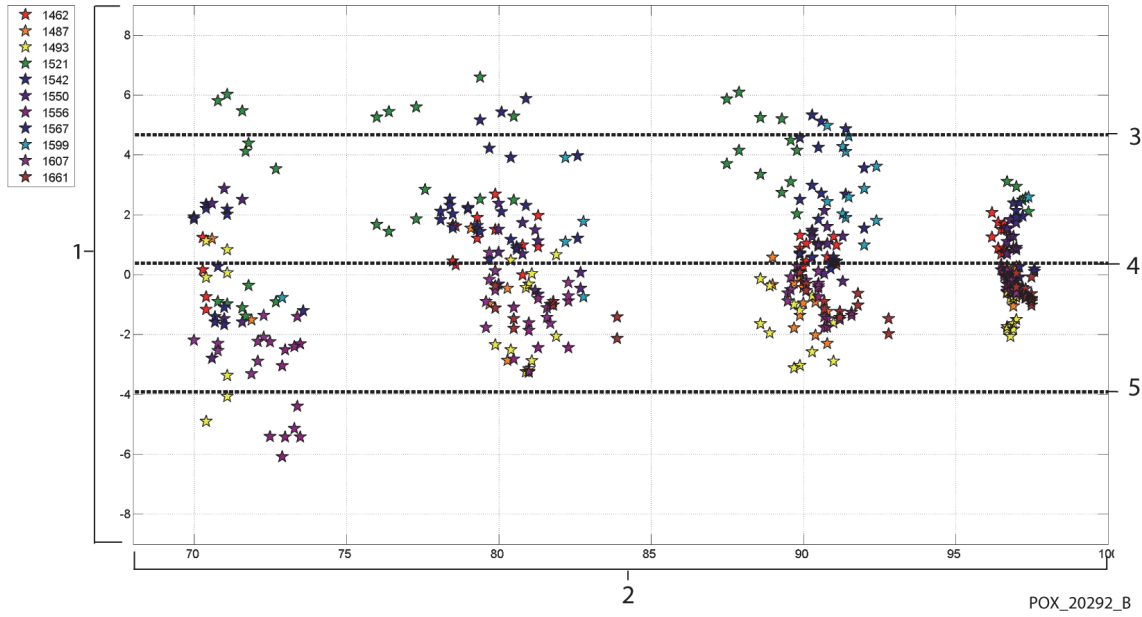
- | | | | |
|---|---|---|---------------|
| 1 | SpO ₂ - SaO ₂ (%) | 3 | Upper 95% LoA |
| 2 | SaO ₂ (%) | 4 | Mean Bias |
| | | 5 | Lower 95% LoA |

Figure A-6. Modified Bland-Altman for SpO₂ - SC-A Sensor (No Motion): SaO₂ vs. (SpO₂ - SaO₂)



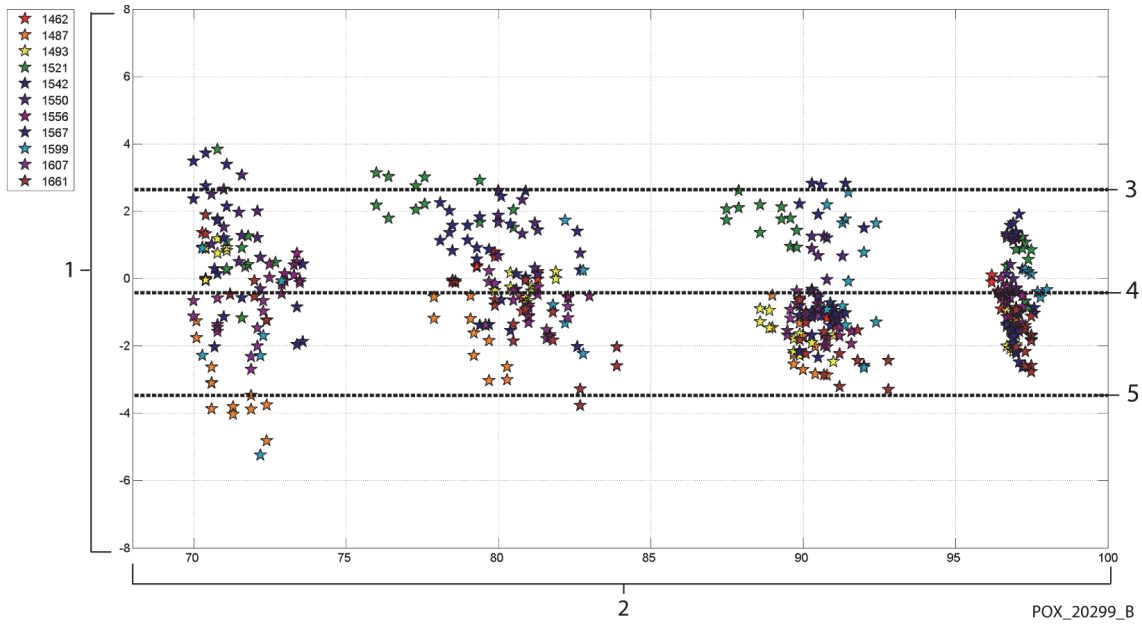
- | | | | |
|---|---|---|---------------|
| 1 | SpO ₂ - SaO ₂ (%) | 3 | Upper 95% LoA |
| 2 | SaO ₂ (%) | 4 | Mean Bias |
| | | 5 | Lower 95% LoA |

Figure A-7. Modified Bland-Altman for SpO₂ - DS-100A Sensor (No Motion): SaO₂ vs. (SpO₂ - SaO₂)



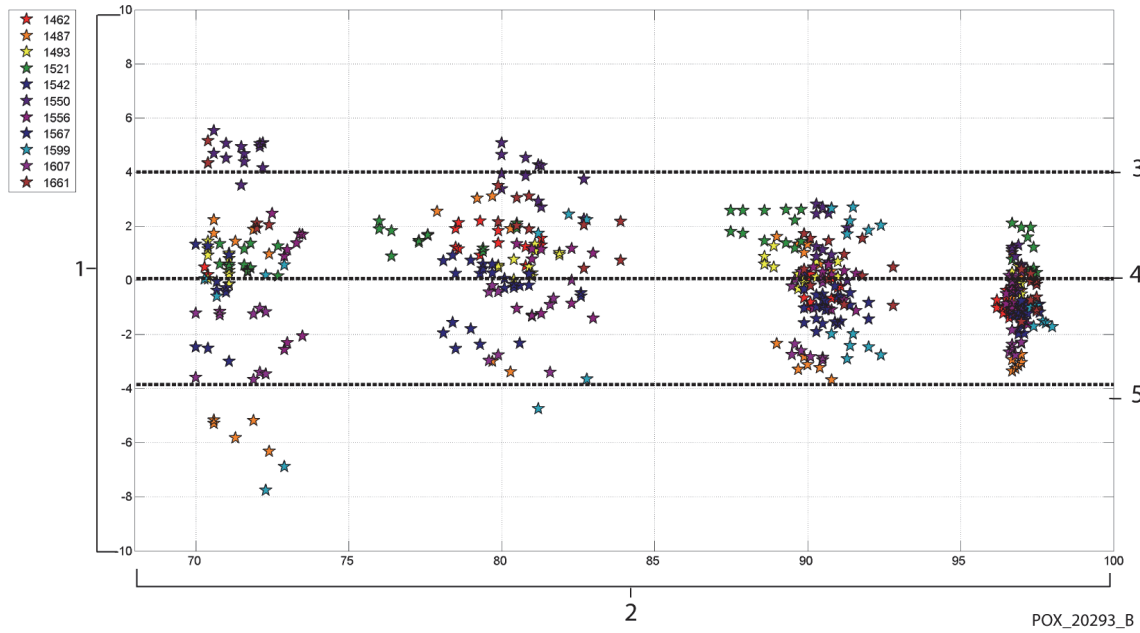
- | | | | |
|---|---|---|---------------|
| 1 | SpO ₂ - SaO ₂ (%) | 3 | Upper 95% LoA |
| 2 | SaO ₂ (%) | 4 | Mean Bias |
| | | 5 | Lower 95% LoA |

Figure A-8. Modified Bland-Altman for SpO₂ - OxiCliq-A Sensor (No Motion): SaO₂ vs. (SpO₂ - SaO₂)



- | | | | |
|---|---|---|---------------|
| 1 | SpO ₂ - SaO ₂ (%) | 3 | Upper 95% LoA |
| 2 | SaO ₂ (%) | 4 | Mean Bias |
| | | 5 | Lower 95% LoA |

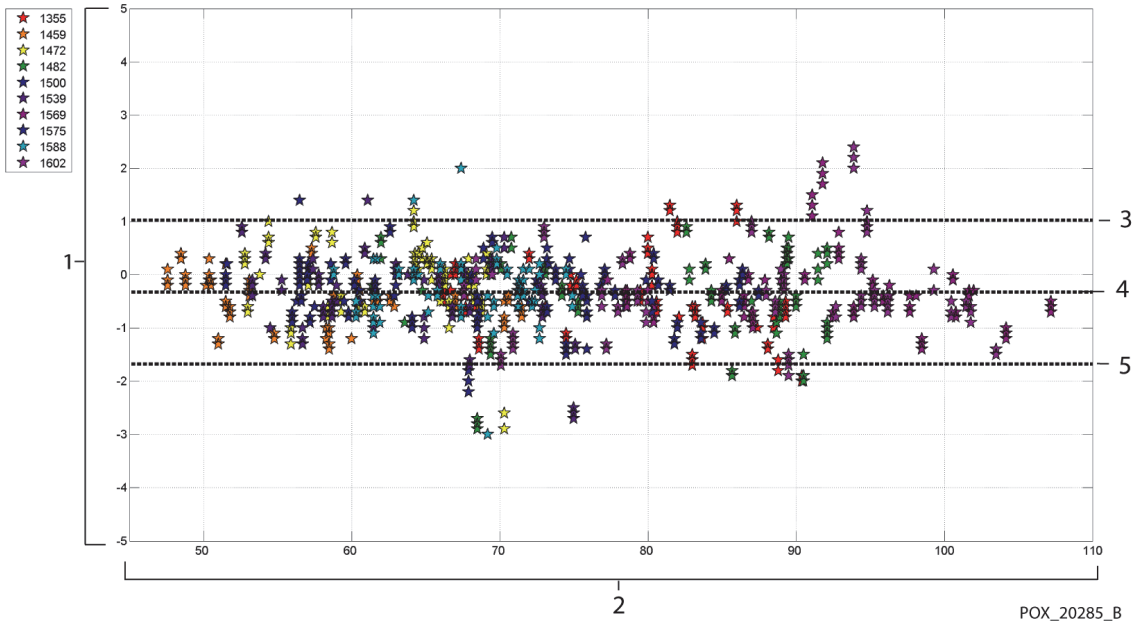
Figure A-9. Modified Bland-Altman for SpO₂ - D-YSE Sensor (No Motion): SaO₂ vs. (SpO₂ - SaO₂)



- | | | | |
|---|---|---|---------------|
| 1 | SpO ₂ - SaO ₂ (%) | 3 | Upper 95% LoA |
| 2 | SaO ₂ (%) | 4 | Mean Bias |
| | | 5 | Lower 95% LoA |

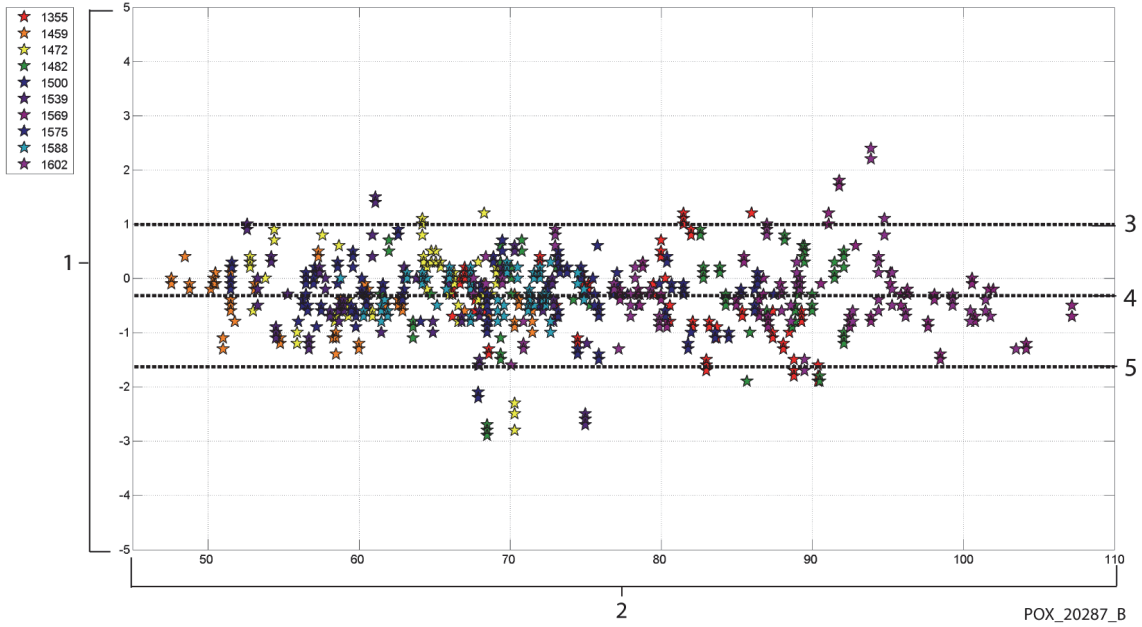
Modified Bland-Altman plots for the pulse rate data by sensor type are presented in Figure A-10 through Figure A-16.

Figure A-10. Modified Bland-Altman for Pulse Rate - MAXA Sensor (No Motion):
ECG HR vs. (Pulse Rate - ECG HR)



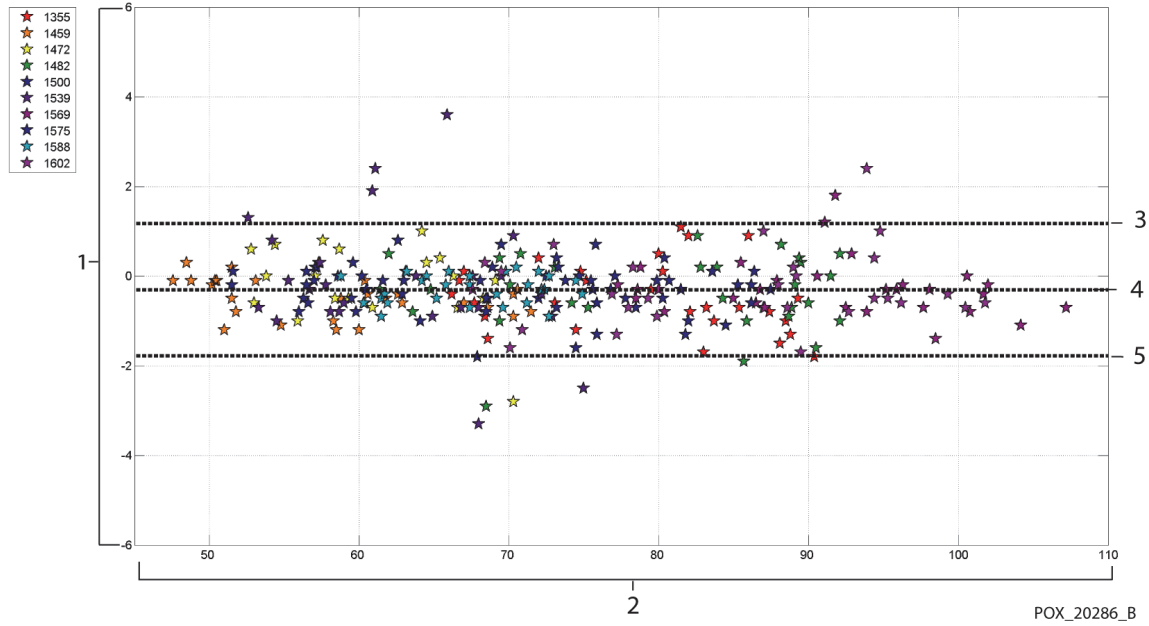
- | | | | |
|---|---------------------------|---|---------------|
| 1 | Pulse Rate - ECG HR (BPM) | 3 | Upper 95% LoA |
| 2 | ECG HR (BPM) | 4 | Mean Bias |
| | | 5 | Lower 95% LoA |

Figure A-11. Modified Bland-Altman for Pulse Rate - MAXN Sensor (No Motion):
ECG HR vs. (Pulse Rate - ECG HR)



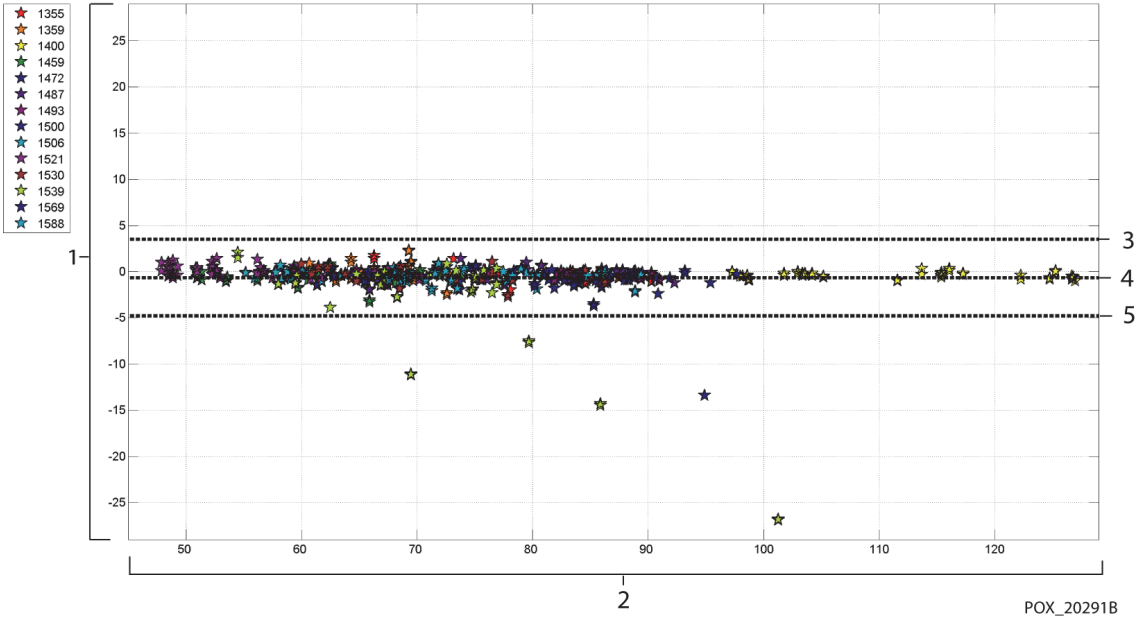
- | | | | |
|---|---------------------------|---|---------------|
| 1 | Pulse Rate - ECG HR (BPM) | 3 | Upper 95% LoA |
| 2 | ECG HR (BPM) | 4 | Mean Bias |
| | | 5 | Lower 95% LoA |

Figure A-12. Modified Bland-Altman for Pulse Rate - MAXFAST Sensor (No Motion):
ECG HR vs. (Pulse Rate - ECG HR)



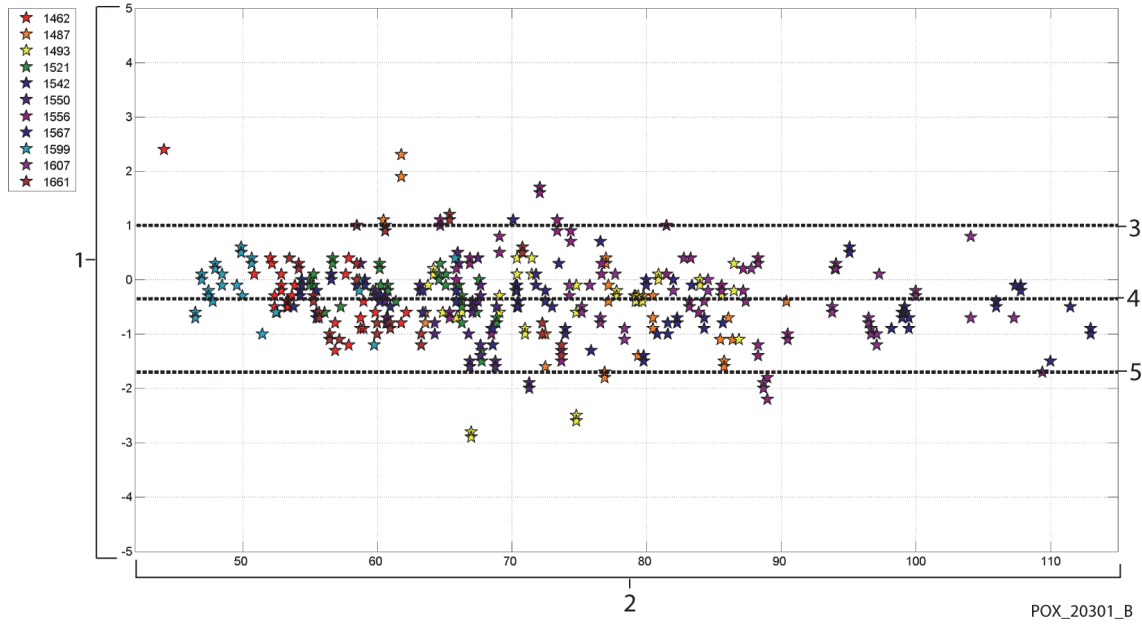
- | | | | |
|---|---------------------------|---|---------------|
| 1 | Pulse Rate - ECG HR (BPM) | 3 | Upper 95% LoA |
| 2 | ECG HR (BPM) | 4 | Mean Bias |
| | | 5 | Lower 95% LoA |

Figure A-13. Modified Bland-Altman for Pulse Rate - SC-A Sensor (No Motion):
ECG HR vs. (Pulse Rate - ECG HR)



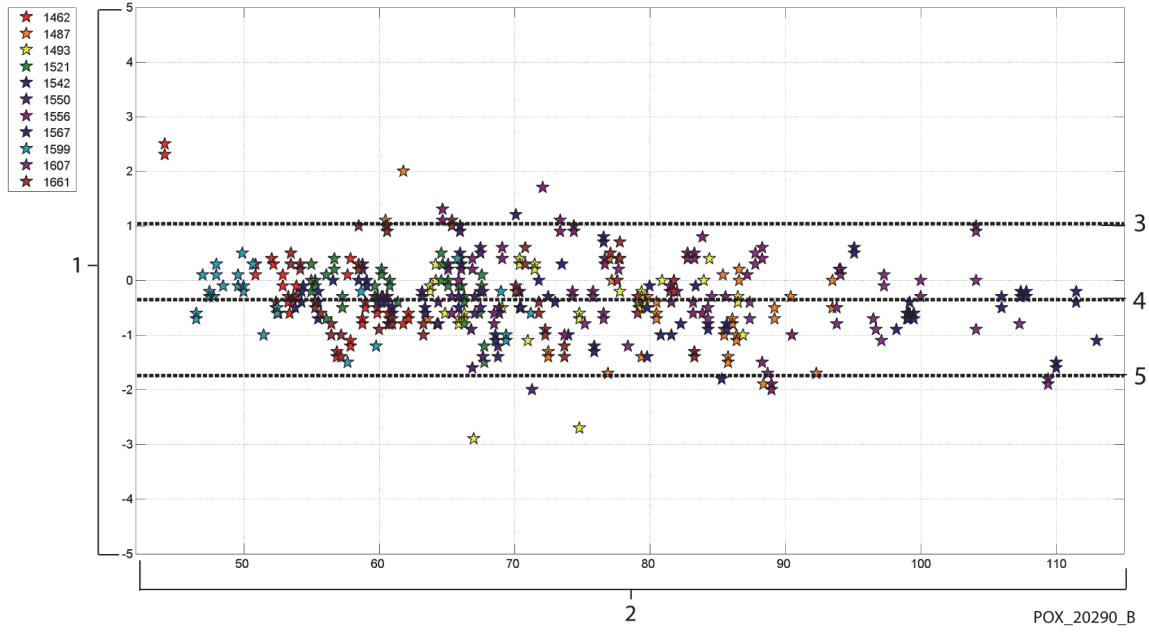
- | | | | |
|---|---------------------------|---|---------------|
| 1 | Pulse Rate - ECG HR (BPM) | 3 | Upper 95% LoA |
| 2 | ECG HR (BPM) | 4 | Mean Bias |
| | | 5 | Lower 95% LoA |

Figure A-14. Modified Bland-Altman for Pulse Rate - DS-100A Sensor (No Motion):
ECG HR vs. (Pulse Rate - ECG HR)



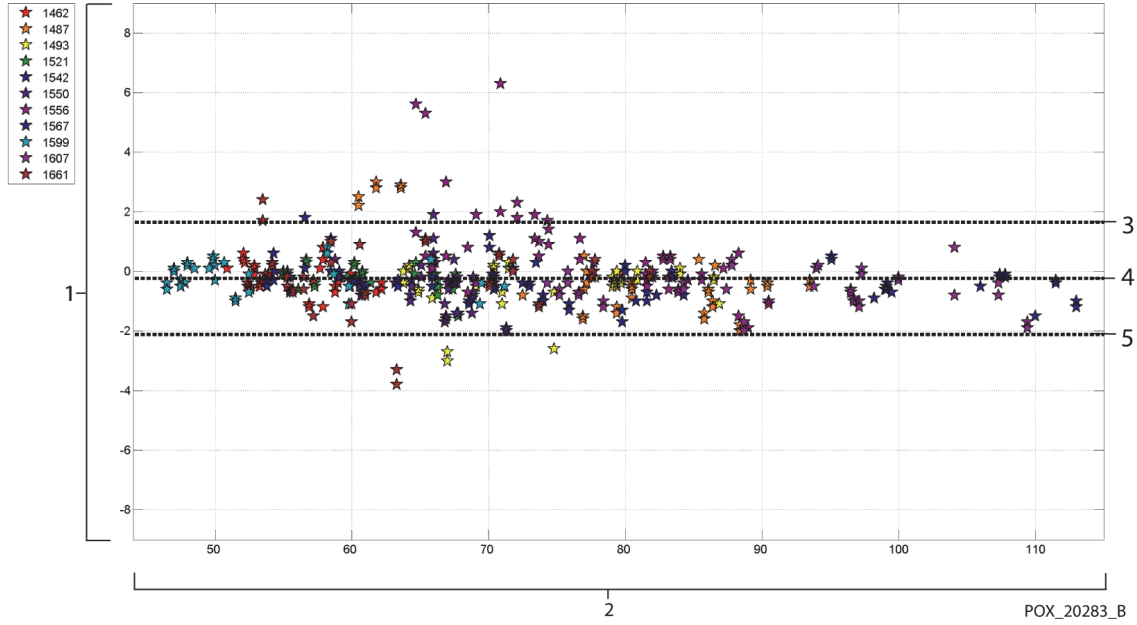
- | | | | |
|---|---------------------------|---|---------------|
| 1 | Pulse Rate - ECG HR (BPM) | 3 | Upper 95% LoA |
| 2 | ECG HR (BPM) | 4 | Mean Bias |
| | | 5 | Lower 95% LoA |

Figure A-15. Modified Bland-Altman for Pulse Rate - OxiCliq-A Sensor (No Motion):
ECG HR vs. (Pulse Rate - ECG HR)



- | | | | |
|---|---------------------------|---|---------------|
| 1 | Pulse Rate - ECG HR (BPM) | 3 | Upper 95% LoA |
| 2 | ECG HR (BPM) | 4 | Mean Bias |
| | | 5 | Lower 95% LoA |

Figure A-16. Modified Bland-Altman for Pulse Rate - D-YSE Sensor (No Motion):
ECG HR vs. (Pulse Rate - ECG HR)



- | | | | |
|---|---------------------------|---|---------------|
| 1 | Pulse Rate - ECG HR (BPM) | 3 | Upper 95% LoA |
| 2 | ECG HR (BPM) | 4 | Mean Bias |
| | | 5 | Lower 95% LoA |

Correlation plots for all the data are presented in Figure A-17 and Figure A-18 for SpO₂ and pulse rate respectively.

Figure A-17. Correlation Plot for SpO₂ (All Data - No Motion): SaO₂ vs. SpO₂

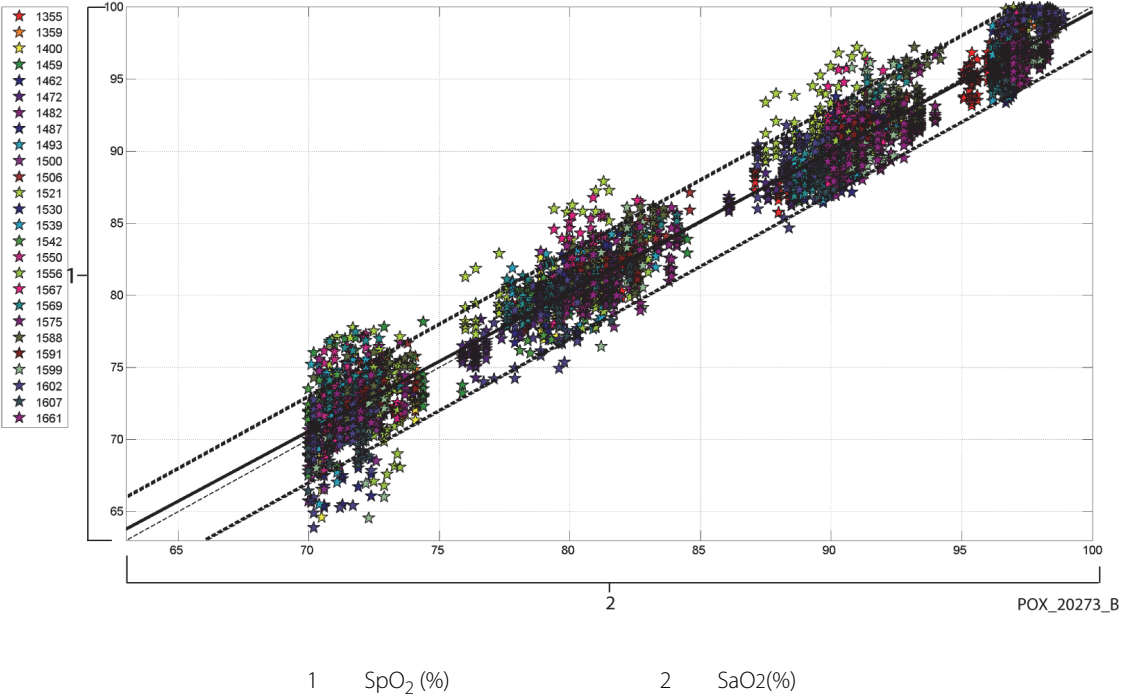
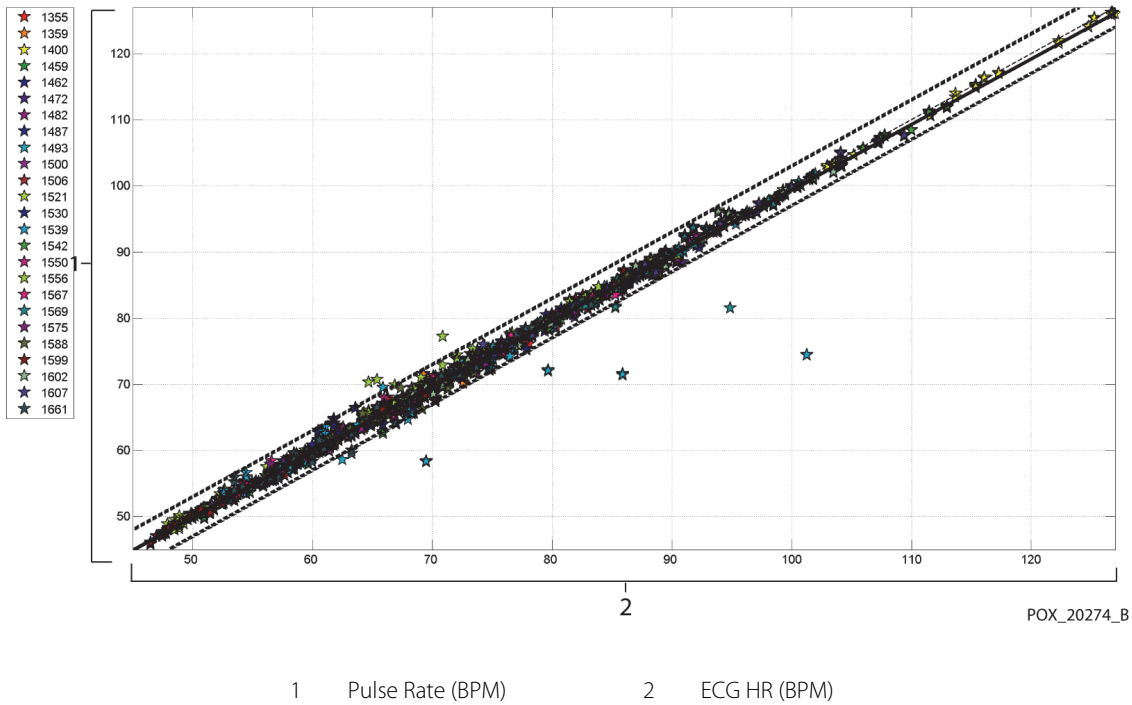


Figure A-18. Correlation Plot for Pulse Rate (All Data - No Motion): ECG HR vs. Pulse Rate



Pulse oximeters have been known to perform better at the higher saturation levels compared to the lower end. Though, when presenting the A_{RMS} , the common methodology is to provide the data across the whole range (70% to 100%). The data below is presented to show each decade, which includes the RMSD (root mean square difference) and N values. RMSD and A_{RMS} are the same. A_{RMS} is used for pooled data across the whole study to represent accuracy of the system, whereas RMSD is used as the general term. There is no acceptance criteria associated with decade levels of hypoxia, thus represented as RMSD. In Table A-3, SpO_2 RMSD is presented per decade.

Table A-3. RMSD of SpO_2 per Decade (No Motion)

SpO_2 Range	100%-90%	89%-80%	79%-70%
N	1693	1037	1212
RMSD (%)	1.46	1.66	2.01

The plateaus that were used during the study were 70 - 76, 76.01 - 85, 85.01 - 94 and >94%, as presented in Table A-4.

Table A-4. RMSD of SpO₂ per Plateau (No Motion)

SpO ₂ Range	Room Air Plateau	90% Plateau	80% Plateau	70% Plateau
N	978	1102	1034	828
RMSD (%)	1.27	1.65	1.69	2.15

A.3.2 Accuracy Results (Low Saturation)

The accuracy results for both SpO₂ and pulse rate can be found in Table A-5 and Table A-6 across a SaO₂ range of 60 to 80%. (Reference *Accuracy Results (No Motion)*, p. A-2, for results for SaO₂ range 70 to 100%.) As shown in the tables, both SpO₂ and pulse rate meet the acceptance criteria for the MAXA, MAXN, and MAXFAST sensors during non-motion conditions.

Table A-5. SpO₂ Accuracy Results (60 to 80% SaO₂)

Sensor	Motion	# of Data Points	A _{RMS} (%)	SpO ₂ Acceptance Criteria 60%-80% (%)	Pass/Fail
MAXA	No	610	2.40	≤ 3.0	Pass
MAXN	No	453	1.92	≤ 3.0	Pass
MAXFAST	No	143	2.41	≤ 3.0	Pass
ALL	No	1206	2.24	≤ 3.0	Pass

Table A-6. Pulse Rate Accuracy Results (60 to 80% SaO₂)

Sensor	Motion	# of Data Points	A _{RMS} (BPM)	Pulse Rate Acceptance Criteria (BPM)	Pass/Fail
MAXA	No	1154	0.76	≤ 3.0	Pass
MAXN	No	874	0.74	≤ 3.0	Pass

Table A-6. Pulse Rate Accuracy Results (60 to 80% SaO₂) (Continued)

Sensor	Motion	# of Data Points	A _{RMS} (BPM)	Pulse Rate Acceptance Criteria (BPM)	Pass/Fail
MAXFAST	No	281	0.81	≤ 3.0	Pass
ALL	No	2309	0.76	≤ 3.0	Pass

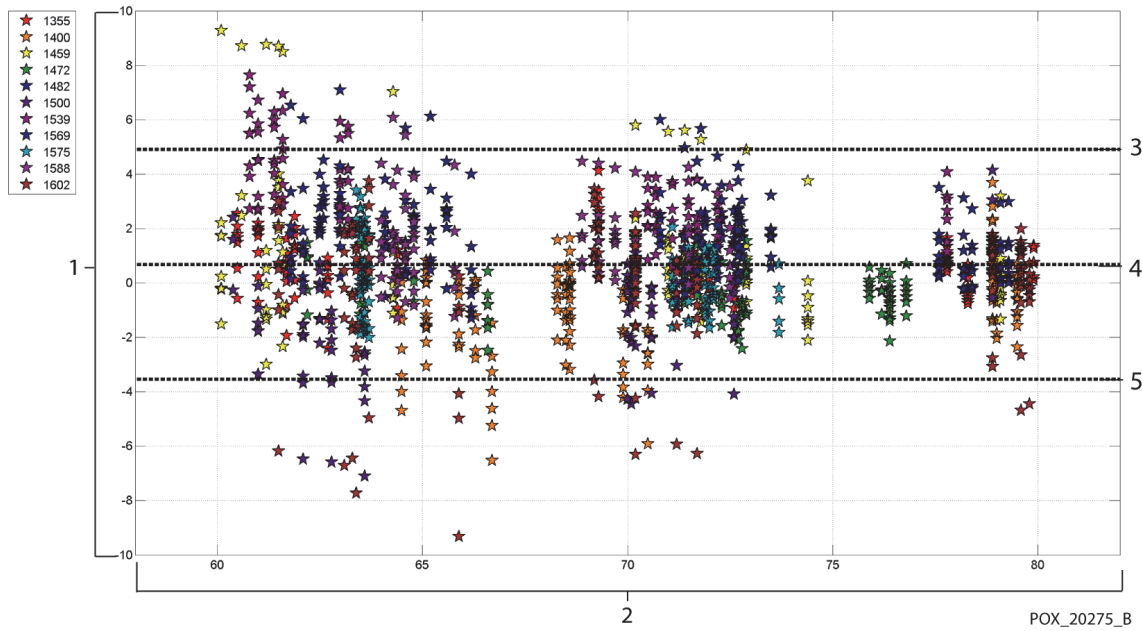
Modified Bland-Altman plots for all the data are presented in Figure A-19 and Figure A-20 for SpO₂ and pulse rate respectively.



Note:

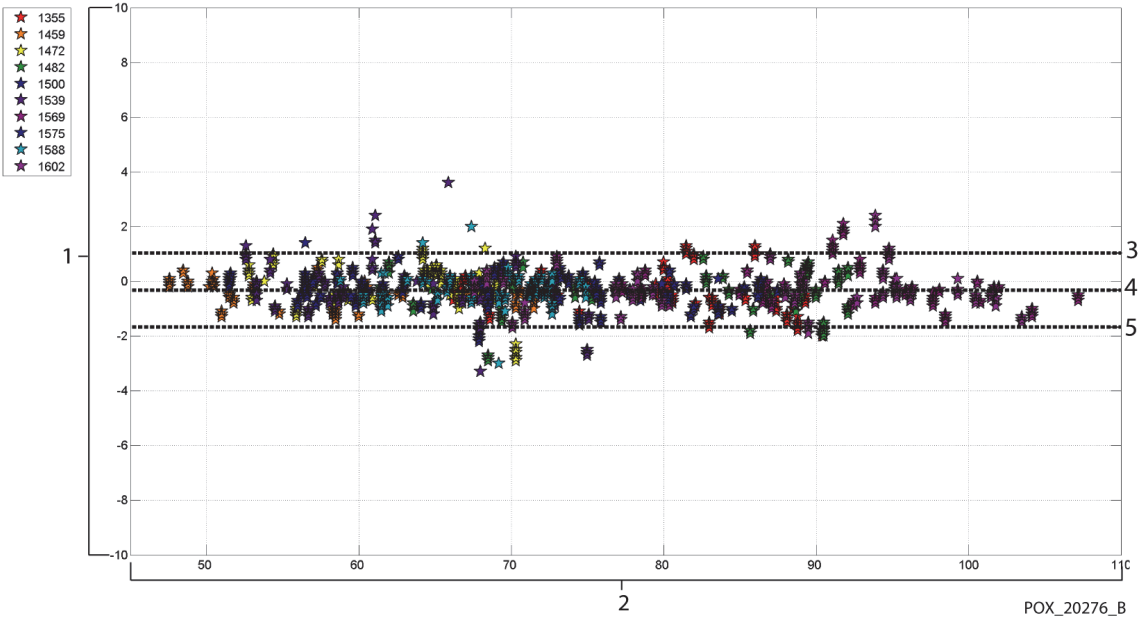
Each individual subject is represented by a unique color on the plots. Subject identification numbers are indicated in the legend to the left of each plot.

Figure A-19. Modified Bland-Altman for SpO₂ (All Data - Low Saturation): SaO₂ vs. (SpO₂ - SaO₂)



- 1 SpO₂ - SaO₂ (%)
- 2 SaO₂ (%)
- 3 Upper 95% LoA
- 4 Mean Bias
- 5 Lower 95% LoA

Figure A-20. Modified Bland-Altman for Pulse Rate (All Data - Low Saturation); ECG HR vs. (Pulse Rate - ECG HR)



- | | | | |
|---|---------------------------|---|---------------|
| 1 | Pulse Rate - ECG HR (BPM) | 3 | Upper 95% LoA |
| 2 | ECG HR (BPM) | 4 | Mean Bias |
| | | 5 | Lower 95% LoA |

Correlation plots for all the data are presented in Figure A-21 and Figure A-22 for SpO₂ and pulse rate respectively.

Figure A-21. Correlation Plot for SpO₂ (All Data - Low Saturation): SaO₂ vs. SpO₂

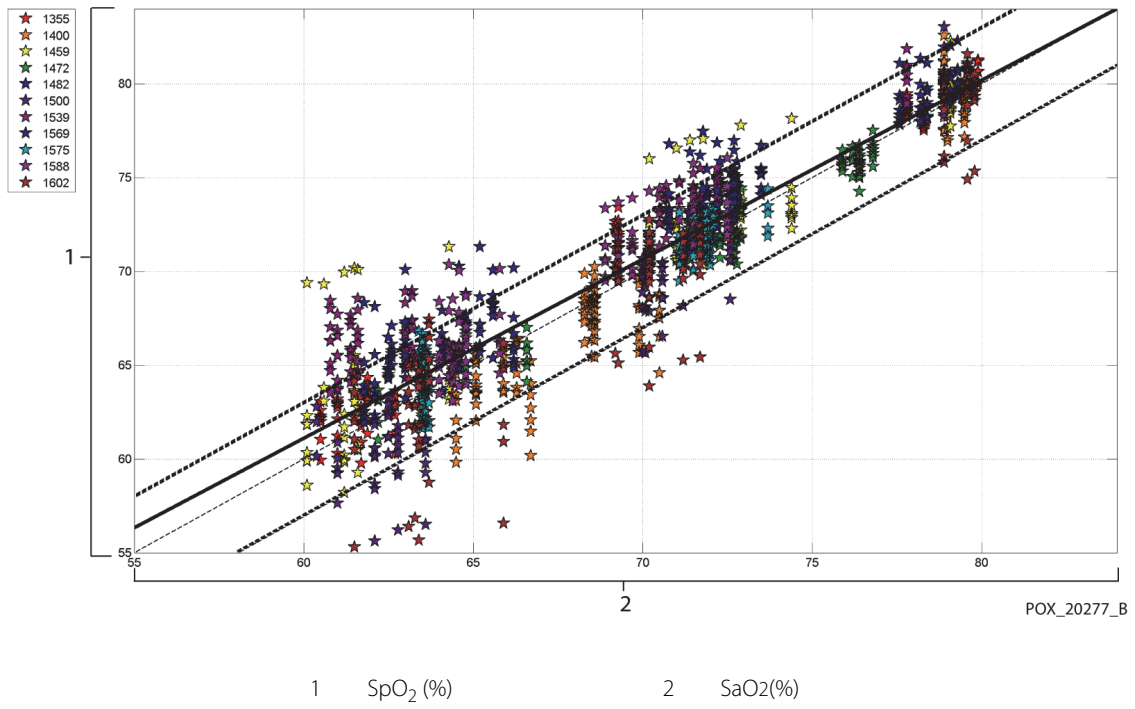
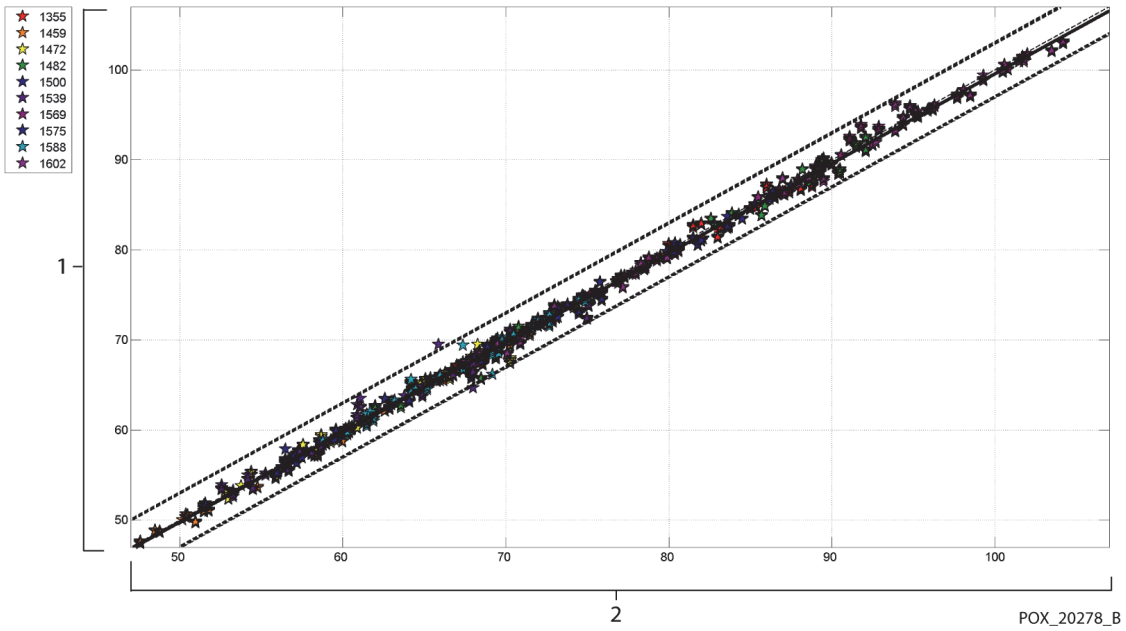


Figure A-22. Correlation Plot for Pulse Rate (All Data - Low Saturation): ECG HR vs. Pulse Rate



1 Pulse Rate (BPM) 2 ECG HR (BPM)

Table A-7. RMSD of SpO₂ per Decade (Low Saturation)

SpO ₂ Range	80%-70%	69%-60%
N	637	569
RMSD (%)	1.73	2.69

Table A-8. RMSD of SpO₂ per Plateau (Low Saturation)

SpO ₂ Range	70% Plateau	60% Plateau
N	506	483
RMSD (%)	1.93	2.79

A.3.3 Accuracy Results (Motion)

The following describes the demographic information of the subjects enrolled into the study: A total of 14 subjects were analyzed, 5 (35.7%) males and 9 (64.3%) female subjects. The mean age was 31.57 ± 6.8 years, with a range of 24 to 42 years of age. Three subjects had dark pigmentation (dark olive to extremely dark). Weight ranged from 48.7 kg to 88.6 kg, and height ranged from 143.5 cm to 185 cm.

The accuracy results for both SpO₂ and pulse rate during motion are presented in Table A-9 and Table A-10. As shown in the tables, both SpO₂ and pulse rate meet the acceptance criteria for both the MAXA and MAXN sensor during motion.

Table A-9. SpO₂ Accuracy Results During Motion

Sensor	Motion	# of Data Points	A _{RMS} (%)	SpO ₂ Acceptance Criteria 70%-100% (%)	Pass/Fail
MAXA	Yes	637	1.70	≤ 3.0	Pass
MAXN	Yes	618	2.76	≤ 3.0	Pass
ALL	Yes	1255	2.28	≤ 3.0	Pass

Table A-10. Pulse Rate Accuracy Results During Motion

Sensor	Motion	# of Data Points	A _{RMS} (BPM)	Pulse Rate Acceptance Criteria (BPM)	Pass/Fail
MAXA	Yes	555	2.58	≤ 5.0	Pass
MAXN	Yes	532	2.88	≤ 5.0	Pass
ALL	Yes	1087	2.73	≤ 5.0	Pass

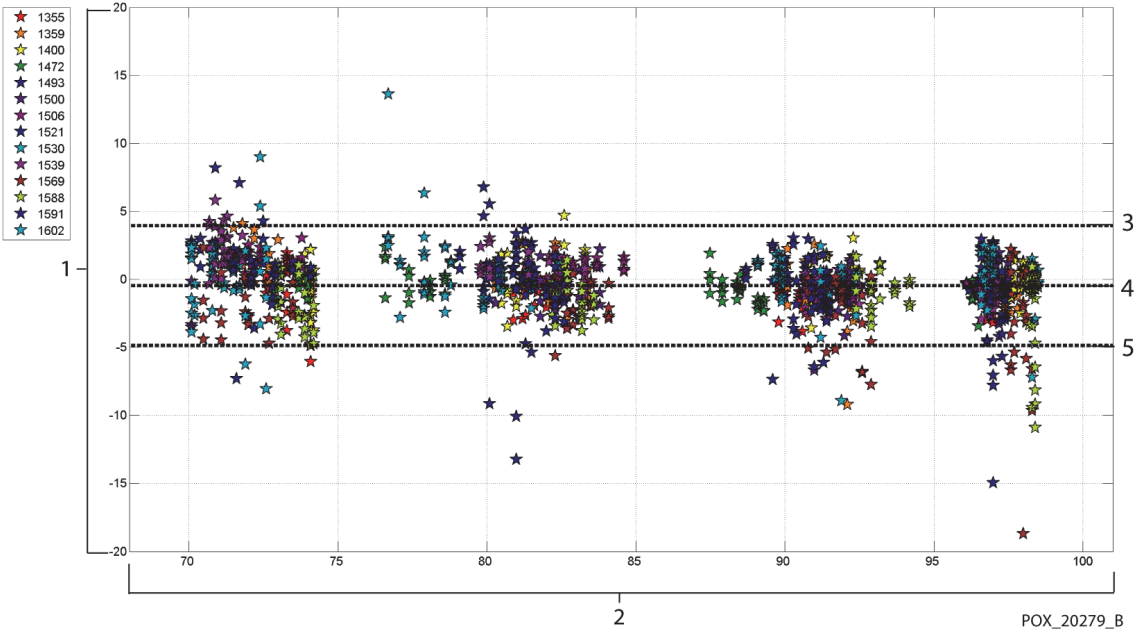
Modified Bland-Altman plots for all the data are presented in Figure A-23 and Figure A-24 for SpO₂ and pulse rate respectively.



Note:

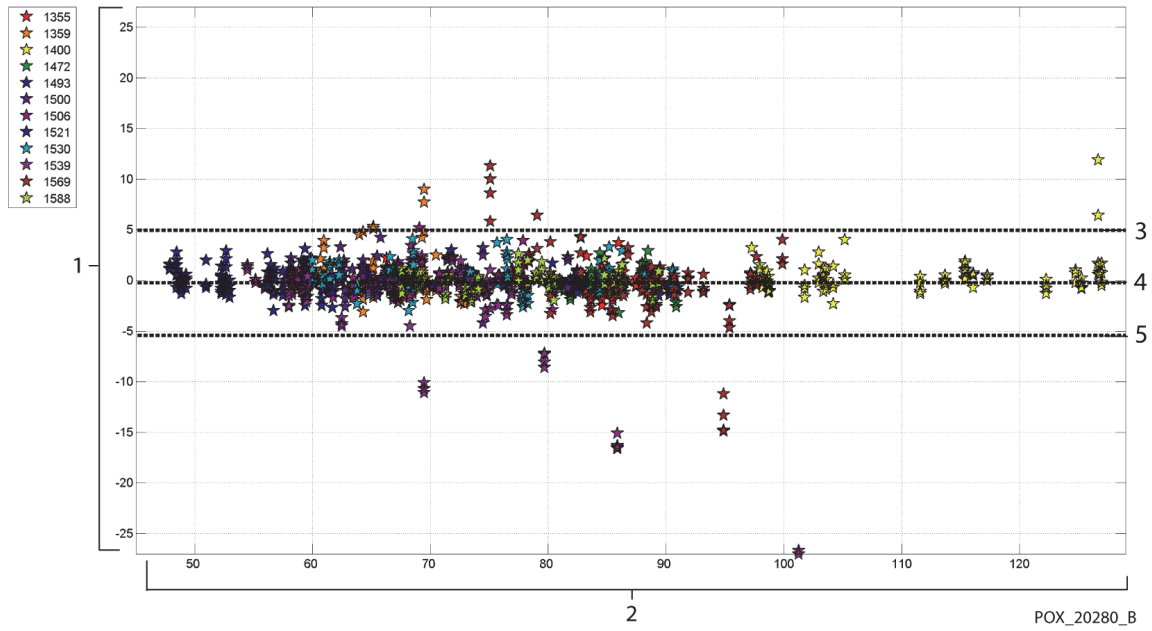
Each individual subject is represented by a unique color on the plots. Subject identification numbers are indicated in the legend to the left of each plot.

Figure A-23. Modified Bland-Altman for SpO₂ (All Data - Motion): SaO₂ vs. (SpO₂ - SaO₂)



- | | | | |
|---|---|---|---------------|
| 1 | SpO ₂ - SaO ₂ (%) | 3 | Upper 95% LoA |
| 2 | SaO ₂ (%) | 4 | Mean Bias |
| | | 5 | Lower 95% LoA |

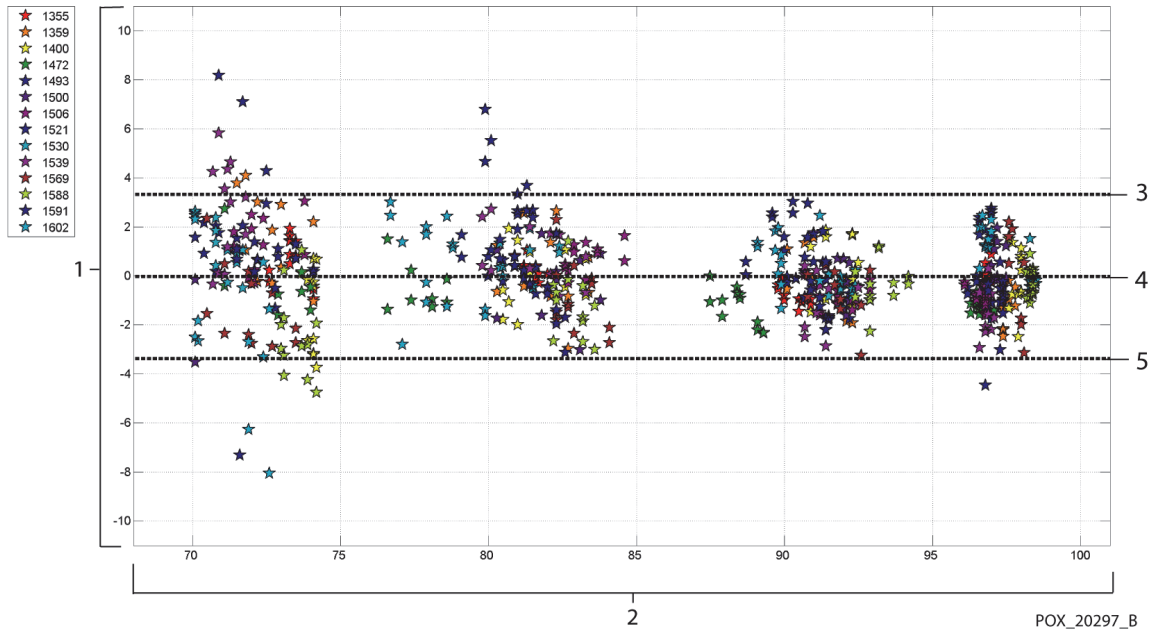
Figure A-24. Modified Bland-Altman for Pulse Rate (All Data - Motion): ECG HR vs. (Pulse Rate - ECG HR)



- | | | | |
|---|---------------------------|---|---------------|
| 1 | Pulse Rate - ECG HR (BPM) | 3 | Upper 95% LoA |
| 2 | ECG HR (BPM) | 4 | Mean Bias |
| | | 5 | Lower 95% LoA |

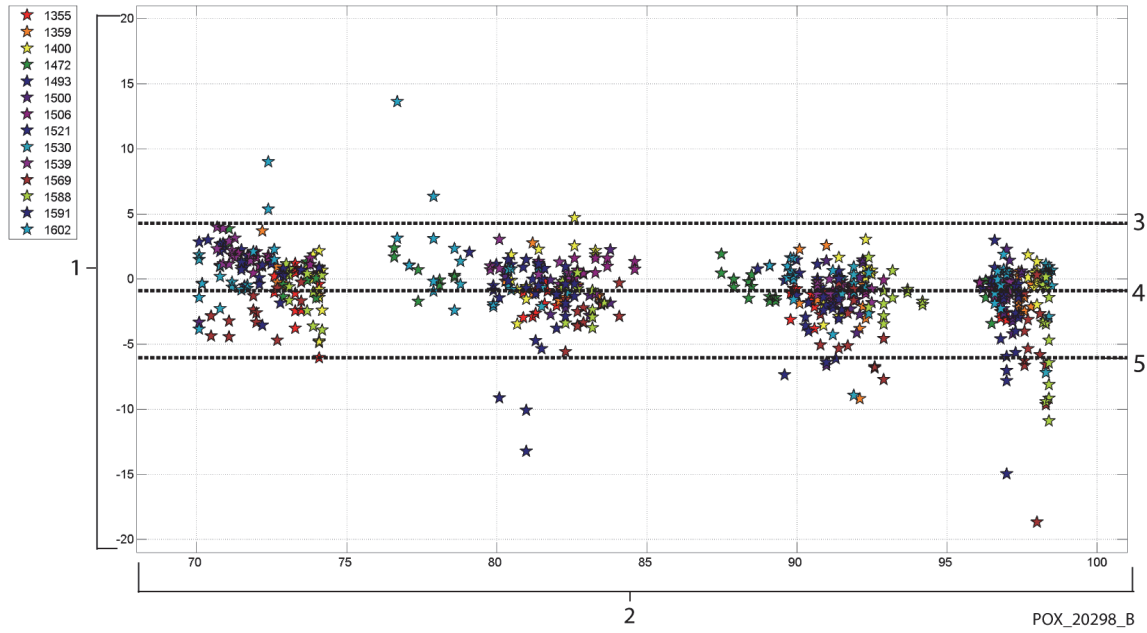
Modified Bland-Altman plots for the SpO₂ data by sensor type are presented in Figure A-25 and Figure A-26.

Figure A-25. Modified Bland-Altman for SpO₂ - MAXA Sensor (Motion): SaO₂ vs. (SpO₂ - SaO₂)



- | | | | |
|---|---|---|---------------|
| 1 | SpO ₂ - SaO ₂ (%) | 3 | Upper 95% LoA |
| 2 | SaO ₂ (%) | 4 | Mean Bias |
| | | 5 | Lower 95% LoA |

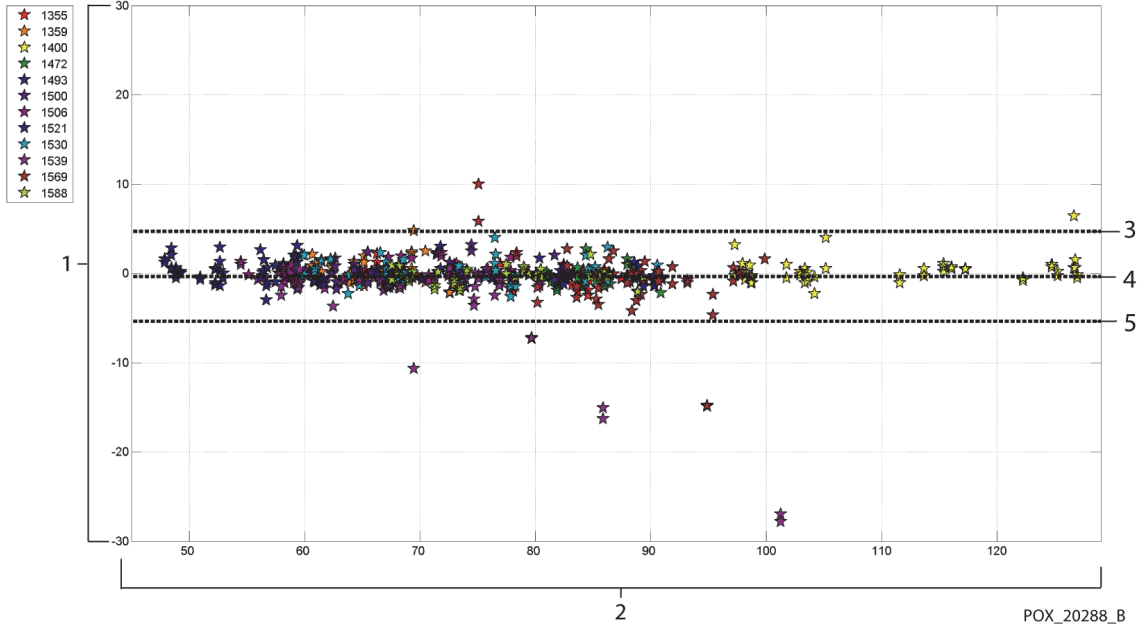
Figure A-26. Modified Bland-Altman for SpO₂ - MAXN Sensor (Motion): SaO₂ vs. (SpO₂ - SaO₂)



- | | | | |
|---|---|---|---------------|
| 1 | SpO ₂ - SaO ₂ (%) | 3 | Upper 95% LoA |
| 2 | SaO ₂ (%) | 4 | Mean Bias |
| | | 5 | Lower 95% LoA |

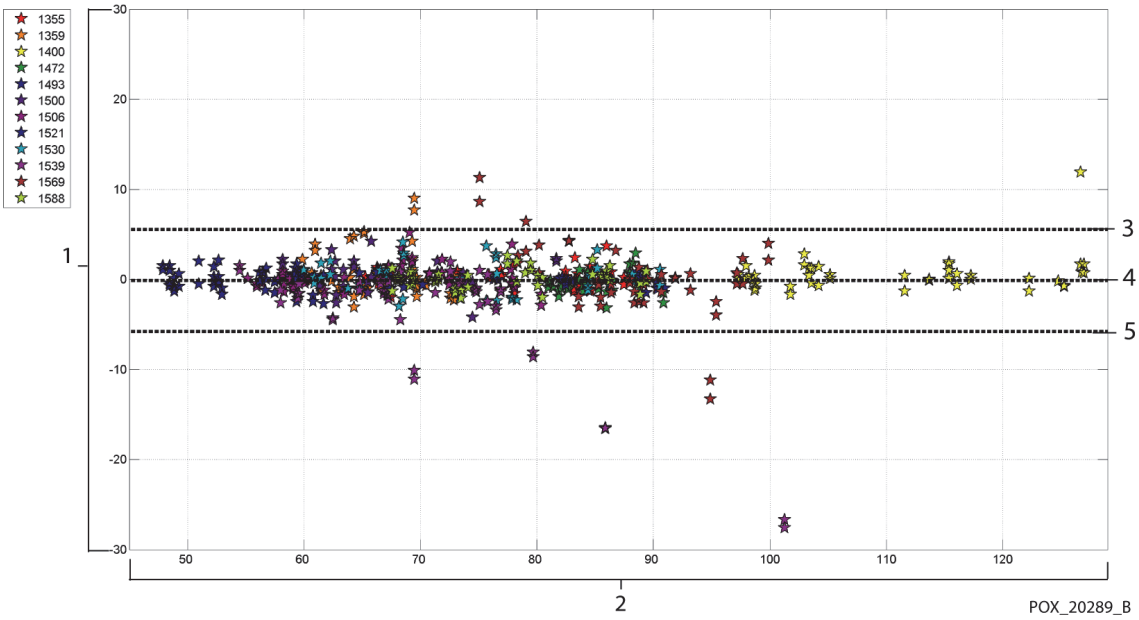
Modified Bland-Altman plots for the pulse rate data by sensor type are presented in Figure A-27 and Figure A-28.

Figure A-27. Modified Bland-Altman for Pulse Rate - MAXA Sensor (Motion):
ECG HR vs. (Pulse Rate - ECG HR)



- | | | | |
|---|---------------------------|---|---------------|
| 1 | Pulse Rate - ECG HR (BPM) | 3 | Upper 95% LoA |
| 2 | ECG HR (BPM) | 4 | Mean Bias |
| | | 5 | Lower 95% LoA |

Figure A-28. Modified Bland-Altman for Pulse Rate - MAXN Sensor (Motion):
ECG HR vs. (Pulse Rate - ECG HR)



- | | | | |
|---|---------------------------|---|---------------|
| 1 | Pulse Rate - ECG HR (BPM) | 3 | Upper 95% LoA |
| 2 | ECG HR (BPM) | 4 | Mean Bias |
| | | 5 | Lower 95% LoA |

Correlation plots for all the data are presented in Figure A-29 and Figure A-30 for SpO₂ and pulse rate respectively.

Figure A-29. Correlation Plot for SpO₂ (All Data - Motion): SaO₂ vs. SpO₂

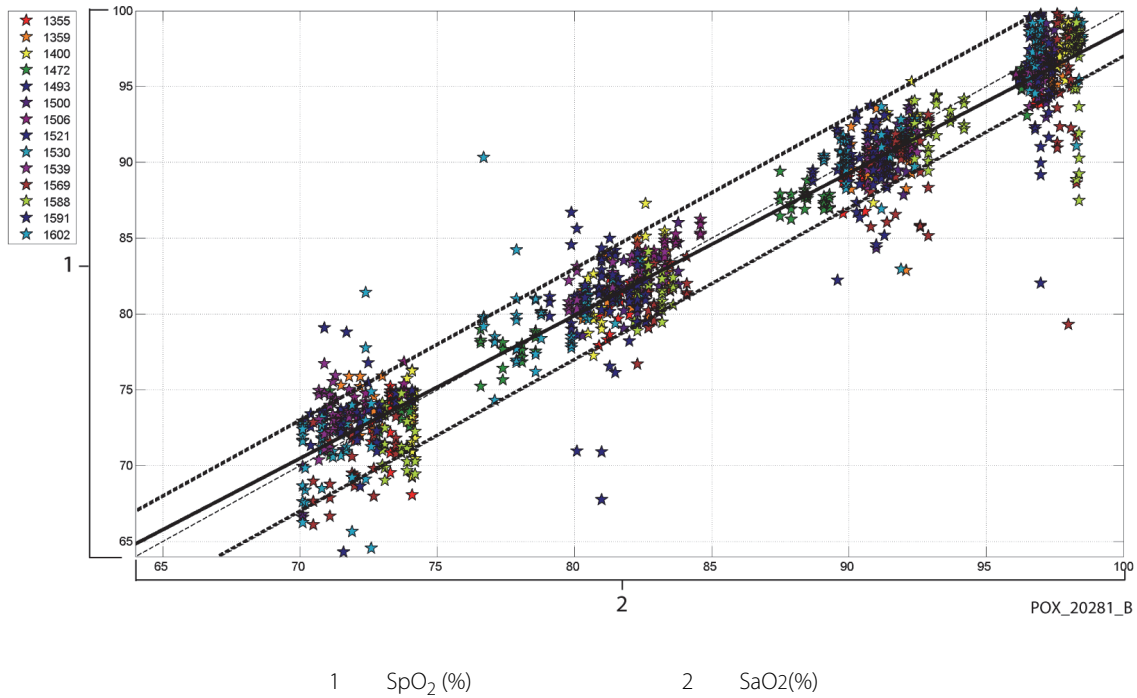
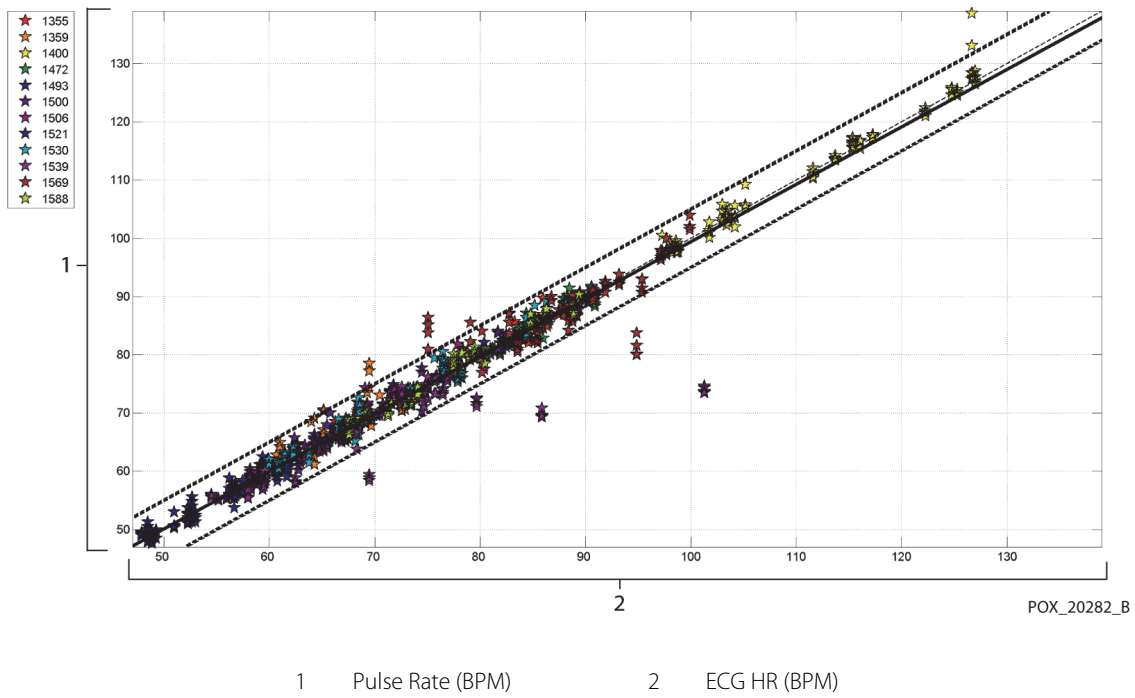


Figure A-30. Correlation Plot for Pulse Rate (All Data - Motion): ECG HR vs. Pulse Rate



The results are presented in Table A-11, showing an increase in percent modulation greater than 2.5-fold during motion.

Table A-11. Percent Modulation During Motion

	Quiescent Periods	Motion Periods	Ratio
Percent Modulation (%)	1.63	4.14	2.54

Pulse oximeters have been known to perform better at the higher saturation levels compared to the lower end. Though, when presenting the A_{RMS} , the common methodology is to provide the data across the whole range (70% to 100%). The data below is presented to show each decade, which includes the RMSD and N values. There is no acceptance criteria associated with decade levels of hypoxia. In Table A-12, SpO₂ RMSD is presented per decade.

Table A-12. RMSD of SpO₂ per Decade (Motion)

SpO₂ Range	100%-90%	89%-80%	79%-70%
N	589	322	344
RMSD (%)	2.36	1.97	2.41

RMSD for each decade are well within the acceptance criteria of 3%. The plateaus that were used during the study were 70 - 76, 76.01 - 85, 85.01 - 94 and >94%, as presented in Table A-13.

Table A-13. RMSD of SpO₂ per Plateau (Motion)

SpO ₂ Range	Room Air Plateau	90% Plateau	80% Plateau	70% Plateau
N	318	330	318	289
RMSD (%)	2.61	1.96	2.19	2.33

A.4 Conclusion

A.4.1 No Motion

The pooled results indicate that the observed SpO₂ A_{RMS} values met the system's specification dependent on the sensor used with the Nellcor™ bedside SpO₂ patient monitoring system during non-motion conditions across the SaO₂ saturation range of 70 to 100%.

The pooled results indicate that for a saturation range of 60-80% for SpO₂, the acceptance criterion was met for the monitoring system when tested with MAXA, MAXN, and MAXFAST sensors.

The pooled results indicate that the observed pulse rate A_{RMS} values met the system's specification of 3 BPM when tested with the Nellcor™ bedside SpO₂ patient monitoring system during non-motion conditions across the SaO₂ saturation range of 60 to 100%.

A.4.2 Motion

The pooled results indicate that the observed SpO₂ A_{RMS} values met the system's specification of 3% when tested with MAXA, MAXN sensors and the Nellcor™ monitoring system for SpO₂ during motion conditions across the SaO₂ saturation range of 70 to 100%.

The pooled results indicate that the observed pulse rate A_{RMS} values met the system's specification of 5 BPM when tested with MAXA, MAXN sensors and the Nellcor™ bedside SpO₂ patient monitoring system during motion conditions across the SaO₂ saturation range of 70 to 100%.

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Index

- A**
 - Accessory
 - Adapter plate 9-4
 - GCX roll stand 9-4
 - GCX vertical wall mount arm 9-4
 - Alarm limits menu icon 2-6
 - Alarm Silenced 4-12
 - Anemia 6-2
- B**
 - Biocompatibility Testing 9-4
 - Button
 - Home 2-3
 - Power 2-3
 - Silence Alarm 2-3
- C**
 - Cables 11-14
 - Calculated Saturation 10-3
 - Calibration 7-4
 - Caution
 - Accessory equipment 1-4
 - Accuracy 1-5
 - Battery disposal 7-4
 - Conductor integrity 1-5
 - Equipment inspection 1-5
 - Excessive environmental conditions 1-4
 - Liquid ingress 1-4
 - Radio frequency energy 1-5
 - Verify proper operation 1-4
 - Cleaning 7-1
 - Clinical studies A-1
 - Colors, Display 2-7
 - Controls 2-3, 2-7
 - Current
 - Earth Leakage and Touch 11-15
 - Patient Leakage 11-16
- D**
 - Dysfunctional Hemoglobins 6-2
- E**
 - Earth Leakage and Touch Current Specifications 11-14
 - Electromagnetic Compatibility (EMC)
 - Electromagnetic Emissions 11-9
 - Electromagnetic Immunity 11-10
 - Electromagnetic Interference 6-5
- F**
 - Feature
 - Nurse call interface 5-3
 - SatSeconds™ alarm management 10-4
 - Trend data download 5-5
 - Fractional Saturation 10-2
 - Front Panel 2-3, 2-4, 11-7
 - Functional Saturation 10-2
- G**
 - Ground Integrity Specification 11-14
- I**
 - Indicator
 - AC power 2-5
 - Battery charge 2-5, 3-3, 3-5
 - Interference 2-5
 - Sensor disconnect 2-5
 - Sensor message 2-6
 - Sensor off 2-5
 - Intended Use 2-2
- M**
 - Measured Saturation 10-3
 - Message, Sensor 3-7
 - Monitoring system
 - Intended use 2-2
 - Product description 2-1
 - Related documents 1-6
 - Warranty 1-7
- N**
 - Nellcor™ pulse oximetry sensor
 - Connection 3-5
 - Disinfection 7-1
 - Performance considerations 6-3
- O**
 - Operating conditions
 - Altitude 11-2
 - Relative humidity 11-2
 - Temperature 11-2
 - Oximetry Considerations
 - Pulse rate 6-1
 - Saturation 6-1
 - Oximetry Overview 10-1
- P**
 - Performance Considerations
 - Electromagnetic interference 6-5
 - Patient conditions 6-2
 - Sensor 6-3
 - Performance Verification 6-1, 6-2
- S**
 - SatSeconds™ alarm management 10-4
 - Saturation
 - Calculated 10-3
 - Fractional 10-2
 - Functional 10-2
 - Measured 10-3
 - Selecting a sensor 9-2
 - Service, Returning your oximeter 8-4

Specifications	
Electrical	11-6
Physical	11-1
Storage	
Altitude	11-2
Relative humidity	11-2
Temperature	11-2
Symbols	
Atmospheric pressure	2-8
Attention	2-8
CE mark	2-8
Data port	2-8
Date of manufacture	2-8
EU representative	2-8
Fragile	2-8
Humidity limitations	2-8
Keep dry	2-8
Manufacturer	2-8
Prescription only	2-8
Temperature limitations	2-8
This side up	2-8
Type BF	2-8
UL listed	2-8
T	
Tabular Trend Data	5-2
Technical Assistance	1-6
Transport	
Altitude	11-2
Relative humidity	11-2
Temperature	11-2
Troubleshooting, Technical Assistance	1-6
W	
Warning	
Broken LCD panel	1-2
Explosion hazard	1-2
High ambient light conditions	1-3
Liquid ingress	1-4
Silencing	1-4

Part No. PT00092862 Rev B (A7429-5) 2018-12


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