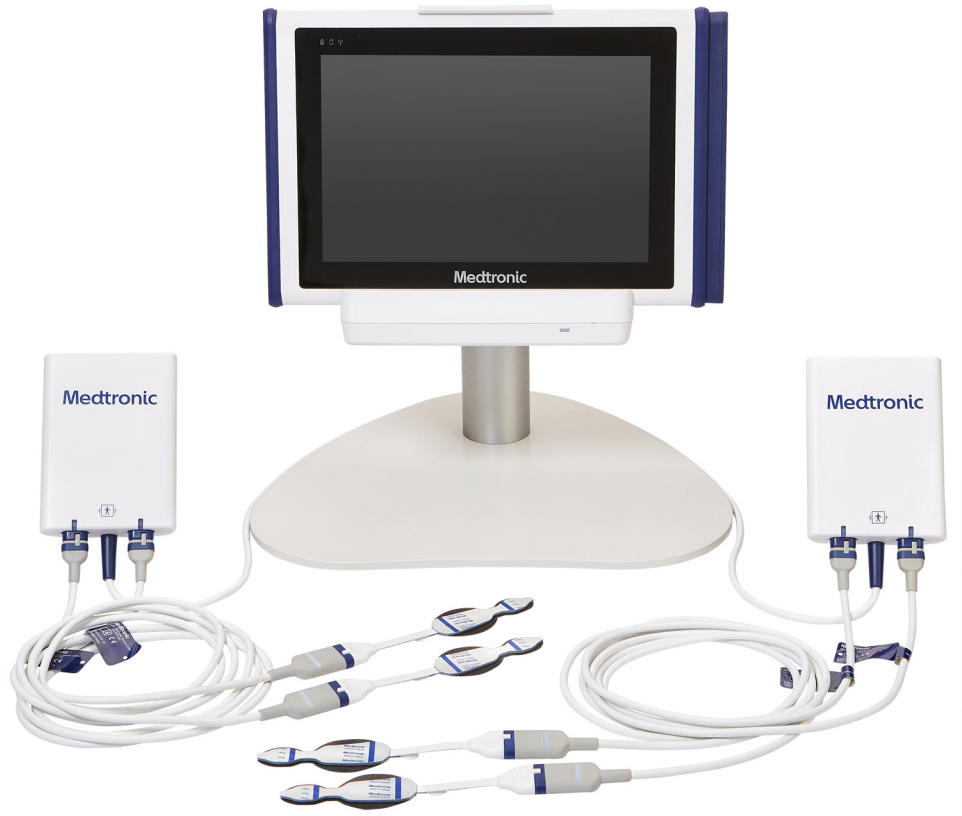
Medtronic

Service Manual

INVOS™

Patient Monitor



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1 Introduction

1.1 Overview

This manual contains information for installing, servicing, and maintaining the INVOS™ patient monitor (the "monitoring system").

This manual applies to the following product:

REF PM7100

1.2 Intended Audience

This manual provides information to authorized technicians for installation, service, and maintenance of the monitoring system. Refer to the monitoring system's operator's manual for operating instructions, specifications, and troubleshooting information.

Before performing installation, service, or maintenance tasks, carefully read this manual and all precautionary information.

1.3 Safety Information

This section contains important safety information for use of the monitoring system.

1.3.1 Safety Symbols

Table 1-1. Safety Symbol Definitions

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

1.3.2 Explosion, Shock, and Toxicity Hazards

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

WARNING:
Explosion hazard — When replacing the battery, do not use the incorrect type. Use only the battery available from Medtronic. See the Accessories/Parts list in the monitoring system's operator's manual.

WARNING:
Shock hazard — Ensure the monitoring system is properly grounded when operating on AC power.

WARNING:
Shock hazard — When connecting the monitoring system to any instrument, verify proper operation before clinical use. Any equipment connected to the data interface

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

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

1.3.3 Patient Monitoring and Safety

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

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

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

WARNING:
An external multi-parameter system will not generate an alarm or error message if remote communication between the multi-parameter system and the monitoring system has been broken. During this period of no remote communication, the monitoring system will continue to monitor, generate alarms, and display status messages. The multi-parameter system operator should not rely on the multi-parameter system for generating alarms.

WARNING:
Choking hazard — The reusable sensor cables (RSCs) include a strain-relief clip that, if detached, may pose a choking hazard.

Caution:
If two sensors are placed in close proximity to each other on a patient, the same preamplifier should be connected to both sensors to avoid poor performance.

1.3.4 Operation

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

WARNING:
If you do not hear a tone at system start-up, discontinue use of the monitoring system and contact Medtronic or a local Medtronic representative.

WARNING:
Explosion hazard — When replacing the battery, do not use the incorrect type. Use only the battery available from Medtronic. See the Accessories/Parts list in the monitoring system's operator's manual.

WARNING:
To ensure proper performance, avoid shock, and prevent device damage or failure, do not expose the monitoring system to extreme moisture, such as direct exposure to rain. Do not immerse in water, solvents, or cleaning solutions, since the monitoring system and connectors are not waterproof.

Caution:
Dispose of the battery in accordance with local guidelines and regulations.

1.3.5 Sensors, Cables, and Other Accessories

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

Caution:
Make sure all connectors are fully engaged and free from moisture. Moisture intrusion may cause poor performance or no readings at all.

1.3.6 Electromagnetic Interference

WARNING:
Electromagnetic emissions from the monitoring system may interfere with other critical devices.

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.

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

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

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

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

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

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. Technical alarms may indicate that the configuration is not appropriate for the monitoring system.

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.

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

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

Caution:
The use of an electrosurgical or electrocautery instrument in the vicinity of the monitoring system may interfere with the signal and cause poor performance or no readings at all.

1.3.7 Cleaning

Caution:
Do not autoclave or gas sterilize any components of the monitoring system.

Caution:
To prevent device damage or failure, do not expose the monitor to isopropyl alcohol.

1.4 Obtaining Technical Assistance

1.4.1 Technical Services

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

Medtronic Technical Services

5870 Stoneridge Drive, Suite 6
Pleasanton, CA 94588 USA

1.800.635.5267 or 1.925.463.4635
or contact a local Medtronic representative

www.medtronic.com

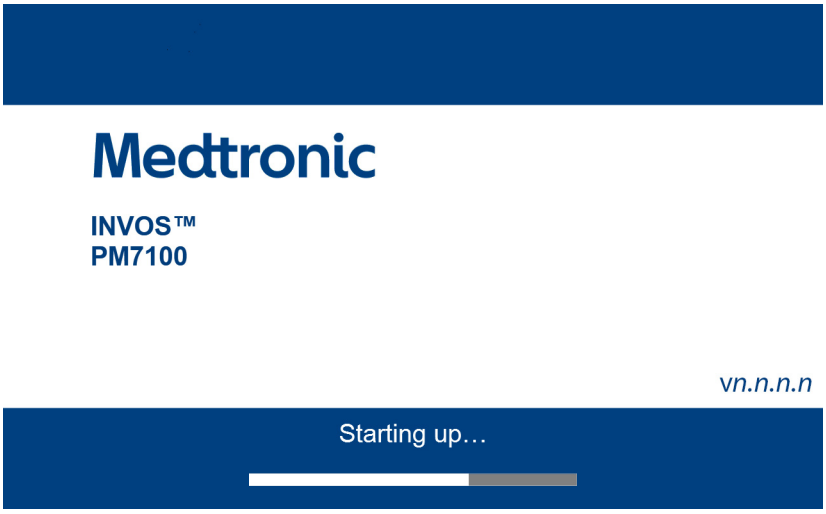
For international contact information, go to:

www.medtronic.com/covidien/en-us/support.html

Select CUSTOMER SERVICE, then select your region.

When calling Medtronic or a local Medtronic representative, have the monitoring system serial numbers and software versions available. Serial numbers are located on the back of the monitor and the preamplifiers. The software version for the monitoring system is displayed on the start-up screen at power-on.

Figure 1-1. Start-up Screen Showing Code Version



In addition, you can view serial numbers and software versions through the monitoring system's service mode. See *Checking Software and Firmware Versions*, page 5-14.

1.4.2 Related Documents

- **INVOS™ Patient Monitor Operator's Manual —** Provides instructions for installing and operating the monitoring system.
- **INVOS™ Adult rSO_2 Sensor Instructions for Use —** Provides important information about sensor selection and use.
- **INVOS™ Reusable Sensor Cable for PM7100 Instructions for Use —** Provides instructions for connecting the monitoring system's reusable sensor cables (RSCs).

Provides instructions for connecting the monitoring system's preamplifiers.

1.5 Warranty Information

To obtain product warranty information, contact Medtronic or a local Medtronic representative. See *Technical Services*, page 1-8.

The information contained in this document is subject to change without notice. Medtronic 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. Medtronic shall not be liable for errors contained herein or for incidental or consequential damages in connection with the furnishing, performance, or use of this material.

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2 Product Overview

2.1 Overview

This chapter contains basic information about the INVOS™ patient monitor (the "monitoring system").

2.2 Product Description

The monitoring system provides continuous, noninvasive indications of changes in regional oxygen saturation of blood (rSO_2) in cerebral and somatic tissues.

The monitoring system consists of:

- A tablet-style monitor that can be operated on AC or battery power
- A VESA™* docking station for the monitor, with USB, Serial (RS-232), and VGA ports
- An AC power supply and cord that attaches to the docking station
- Up to two preamplifiers to accommodate up to four sensors (two per preamplifier)
- Up to four reusable sensor cables (RSCs) to attach sensors to the preamplifiers
- INVOS™ rSO_2 sensors
- Additional accessories as described in the monitoring system's operator's manual

Monitoring system features include:

- User configurable rSO_2 baselines, alarm limits, and AUC thresholds
- Physiological and technical alarm reporting

- User configurable data display (rSO_2, change from baseline, sensor labels, and trend data)
- Alarm silencing
- Event marking
- Visual representations of sensor locations
- Sensor functional state:
  - Sensor off
  - Sensor disconnect
  - Sensor fault
- Case history storage and export
- Real-time data output to external devices such as a Philips multi-parameter system or PC
- VGA, Serial (RS-232), and USB interfaces

2.3 Indications for Use

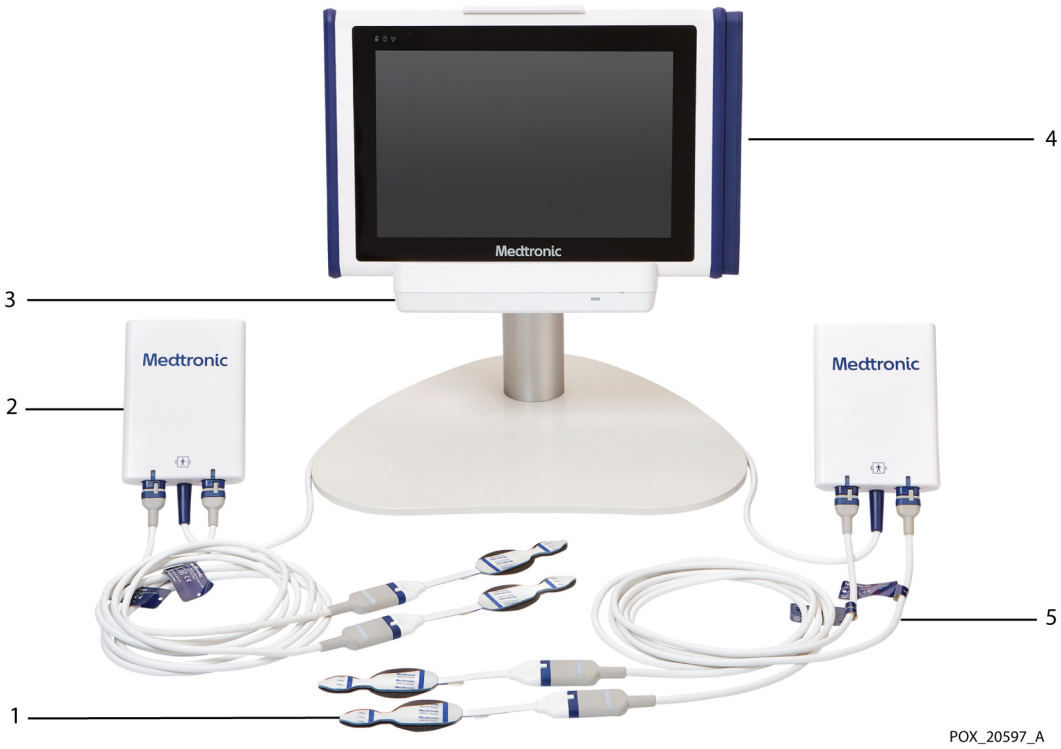
The INVOS™ Patient Monitor, model PM7100, is a noninvasive cerebral/somatic oximetry system intended for use as an adjunct monitor of regional hemoglobin oxygen saturation of blood in the brain or in other tissue beneath the sensor. It is intended for use on individuals greater than 40 kg at risk for reduced-flow or no-flow ischemic states.

2.4 Product Views

2.4.1 Full System

System Component Overview

Figure 2-1. INVOS™ Patient Monitor Components



1	Sensors	4	Monitor
2	Preamplifier	5	Reusable sensor cable (RSC)
3	Docking station		

2.4.2 Monitor Components

Monitor - Front

Figure 2-2. Monitor - Front

1	VESA™*-compliant stand accessory	4	Monitor indicators (power/battery, hard disk activity, wireless)
2	Power cord (connected to bottom of docking station)	5	Monitor
3	Docking station	6	Docking station power indicator (illuminates blue when the docking station is receiving AC power)

Monitor - Left Side

Figure 2-3. Monitor - Left Side

1 Lever for adjusting monitor angle

2 I/O port cover with latch (slide to access ports inside)

3 USB 3.0 port

4 USB 2.0 port

5 Docking station

Monitor - Right Side

Figure 2-4. Monitor - Right Side

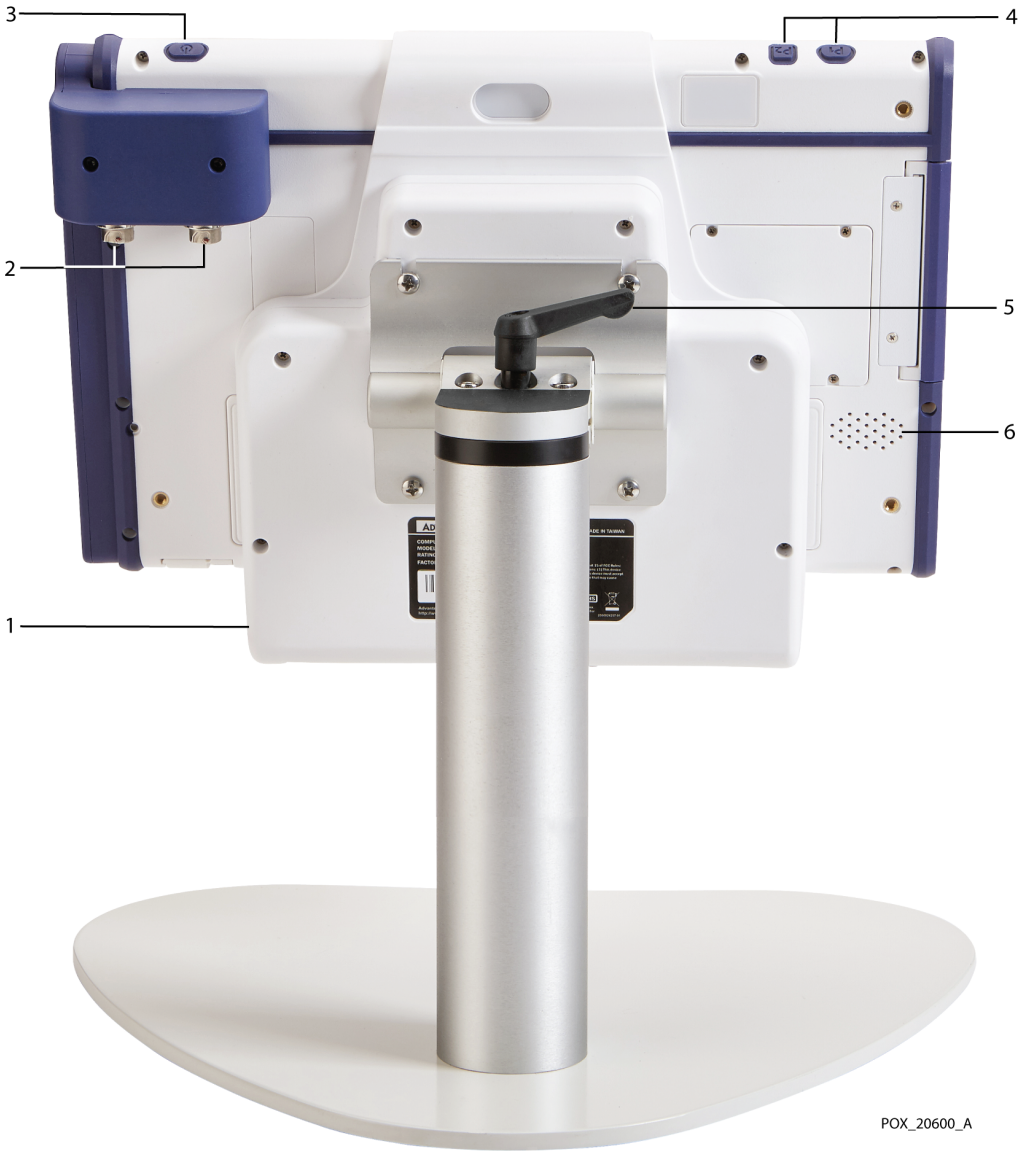
1 Docking station

2 Connector for preamplifier (x2)

3 Lever for adjusting monitor angle

Monitor - Back

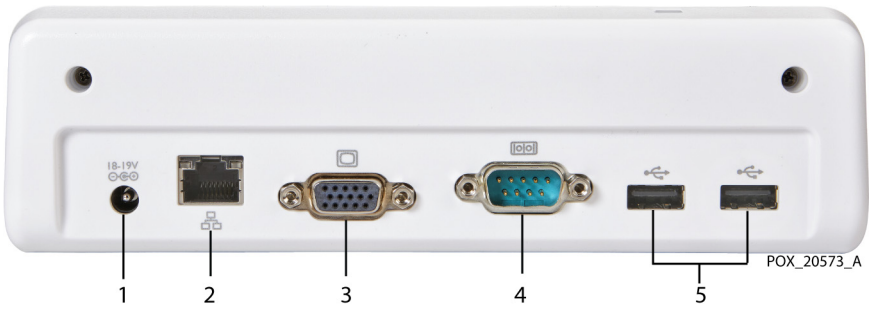
Figure 2-5. Monitor - Back



1	Docking station	4	Programmable buttons (not used)
2	Connectors for preamplifiers	5	Lever for adjusting monitor angle
3	Power button	6	Speaker

Docking Station

Figure 2-6. Docking Station - Bottom View



1 Power input connection (DC in jack)

2 LAN port (not used, disabled)

3 VGA port

4 Serial port (RS-232)

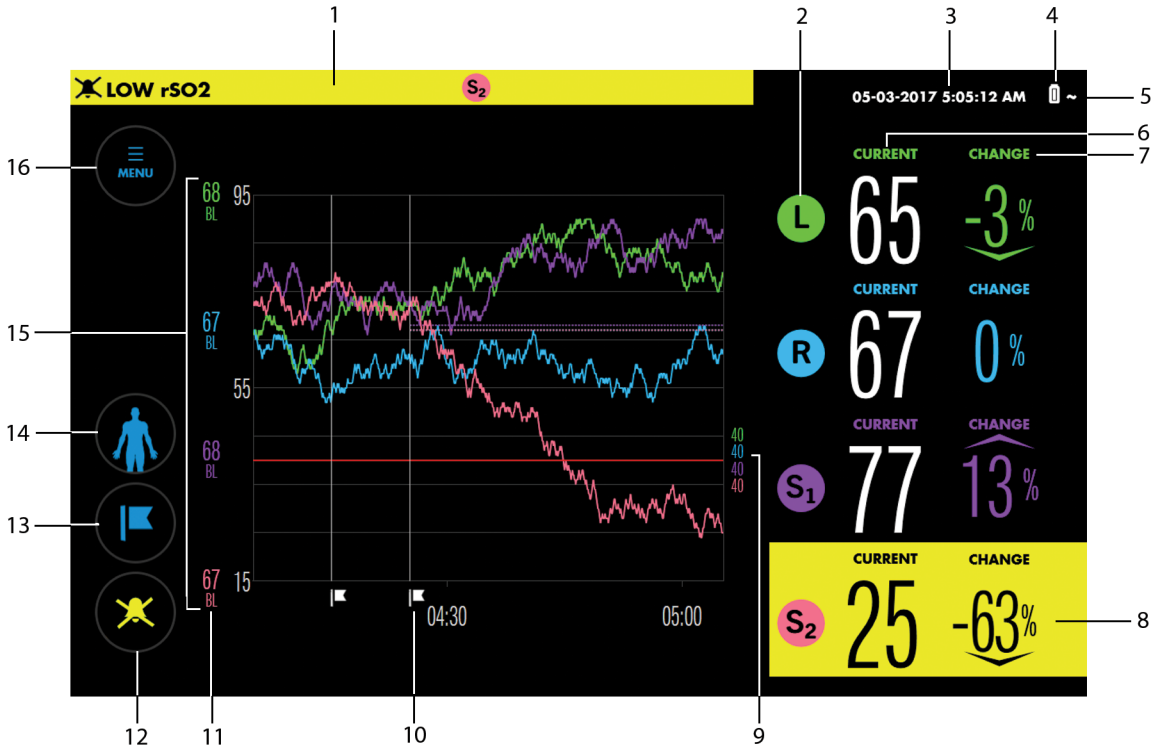
5 USB 2.0 port (x2)

Figure 2-7. Docking Station - Connector for Monitor

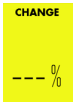
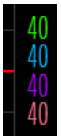
1 Docking station 2 Connector for monitor

Monitoring Screen

Figure 2-8. Sample Monitoring Screen Elements



1		Message area	Provides information about alarm conditions. The background indicates the severity of the condition. If alarm audio is silenced, an alarm audio silenced symbol appears next to the alarm message. See *Alarm Management*, page 4-35. If a "?" appears next to the alarm message, press the "?" for additional information.
N/A	Dismiss	Dismiss button (not shown)	Available in the message area when an alarm is dismissible. See *Dismissing an Alarm*, page 4-43.
2	L	Sensor icons	Each sensor icon has a label indicating its location on the patient. See *Changing the On-Screen Sensor Labels*, page 4-21.
3		Date and time	Current date in MM/DD/YYYY format (by default) and current time in 12-hour HH:MM:SS format (by default). The date and time format can be changed by an authorized technician.

4		Battery status indicator	Indicates the remaining battery capacity: • **Charged battery —** The level in the icon decreases as battery power is used. • **Low battery —** A medium-priority alarm occurs when the monitoring system is operating on battery power and the battery has a charge of <33% remaining. The alarm message BATTERY LOW appears. • **Critically low battery —** A medium-priority alarm occurs when the monitoring system is operating on battery power and the battery has a charge of <5% remaining. The alarm message BATTERY CRITICALLY LOW appears. When no charge remains, the monitoring system automatically shuts down.
5	 	Battery charging indicator AC power indicator	Indicates that the monitoring system is connected to AC power and the battery is charging. When the battery is fully charged and the monitoring system remains connected to AC power, the AC power indicator replaces the battery charging indicator.
6		CURRENT	The most recent rSO_2 reading from each sensor.
7		CHANGE	The percent change between the current rSO_2 reading and the established baseline for each sensor, color-coded to the corresponding sensor icon.
8		Sensor/readings in alarm state	If a sensor alarm or loss of readings occurs, the corresponding sensor is highlighted on the screen. If readings are lost, the CURRENT and CHANGE values are replaced by dashes. Check the message area for information about the condition.
9		Alarm limits	The current alarm limits for each sensor, color-coded to the corresponding sensor icon. A horizontal red line indicates each alarm limit in the trend view graph. See *Setting Alarm Limits*, page 4-38.
10		Event mark	Event marks indicate significant occurrences during monitoring. Event marks can be added to the trend graph at any time during monitoring and are displayed as vertical lines with flags. See *Event Marks*, page 4-44.
11		Baseline values	The current rSO_2 baseline established for each tissue region being monitored, color-coded to the corresponding sensor icon. Dotted lines in the trend view graph also indicate the baseline values, color-coded to the corresponding sensor icon. See *Baselines*, page 4-24.

12		Alarm Audio button	Indicates whether alarm audio is on, silenced, or paused. Press to silence or pause alarm audio or to turn alarm audio back on. When an alarm occurs and alarm audio is silenced or paused, the button's color corresponds to the highest-level alarm. See *Alarm Indicators*, page 4-35, and *Silencing or Pausing Alarms*, page 4-41.
13		MARK EVENT button	Press to add an event mark to the trend graph to indicate a significant occurrence during monitoring. Choose from a customizable list of events. See *Event Marks*, page 4-44.
14		Patient button	While monitoring, press to return to the Set-up screen, reposition on-screen sensors, or assign or modify a patient ID. See *Set Up for Patient Monitoring*, page 4-11, *Repositioning On-Screen Sensors*, page 4-17, and *Assigning or Modifying the Patient ID*, page 4-19.
15		Trend view	The trend view shows the progression of rSO_2 values over the course of a case. Data is color-coded to the corresponding sensor icon. rSO_2 values are presented on the vertical (y) axis. Time is presented on the horizontal (x) axis. See *Trend View Management*, page 4-27.
16		MENU button	Press to access a variety of settings and functions depending on whether or not sensors are connected and monitoring has begun. See *Menu Structure*, page 4-9.

2.5 Product and Carton Label Symbols

Table 2-1. Label Symbol Descriptions

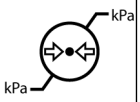
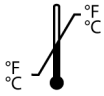
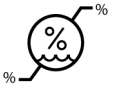
Symbol	Description	Symbol	Description
	Reference code (part number)		Serial number
	Lot number		European Community (EC) authorized representative
	Prescription only US federal law restricts this device to sale by or on the order of a physician		Protection against fluid ingress: Protected against vertically falling water drops when tilted to 15º
	Manufacturer		Date of manufacture
	Fragile		Keep dry
	Must consult instructions for use		Consult instructions for use
	Atmospheric pressure limits (see *Environmental Conditions*, page 11-4)		Temperature limits (see *Environmental Conditions*, page 11-4)
	Humidity limits (see *Environmental Conditions*, page 11-4)		Proper waste disposal for electrical and electronic equipment
	MR unsafe - Do not use during magnetic resonance imaging		Defibrillation-proof type BF applied part
	CSA – Canadian Standards Association certification mark		CE – Conformité Européene authorization mark 0123 – TÜV SÜD Product Service GmbH (notified body)
	Not made with natural rubber latex		Electromagnetic interference may occur in the vicinity of equipment marked with this symbol

Table 2-1. Label Symbol Descriptions (Continued)

Symbol	Description	Symbol	Description
	Quantity included in package (example: 20)		Do not immerse

3 Installation

3.1 Overview

This chapter contains supplementary information for installing the INVOS™ patient monitor (the "monitoring system"). Instructions for performing tasks that require service mode access, as well as instructions for installing the battery are provided. Use these instructions in conjunction with the information in the monitoring system's operator's manual.

3.2 Safety Reminders

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

WARNING:
Shock hazard — Ensure the monitoring system is properly grounded when operating on AC power.

WARNING:
If you do not hear a tone at system start-up, discontinue use of the monitoring system and contact Medtronic or a local Medtronic representative.

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

Caution:
Make sure all connectors are fully engaged and free from moisture. Moisture intrusion may cause poor performance or no readings at all.

3.3 Service Mode Menu Structure

Table 3-1 lists the settings available through the monitoring system's service mode. See *Entering Service Mode*, page 3-8 for instructions for accessing these settings.

Table 3-1. Service Mode Menu Structure

Service Mode 	**SETTINGS Tab**	**SILENCE ALARMS AT STARTUP** - See *Silencing Alarms at Startup*, page 3-9.	
		ALARM REMINDER SIGNAL - See *Turning the Alarm Reminder Signal On/Off*, page 3-10.	
		ALARM AUDIO OFF/PAUSE DURATION - See *Changing Alarm Silence Duration*, page 3-11.	
		LINE FREQUENCY - See *Changing the Line Frequency*, page 3-12.	
		POST DURING SENSOR OFF - For system diagnostics only.	
	DATE/TIME Tab	**Calendar** - See *Changing the Date, Time, and Date/Time Formats*, page 3-13.	
		TIME - See *Changing the Date, Time, and Date/Time Formats*, page 3-13.	
		TIME FORMAT - See *Changing the Date, Time, and Date/Time Formats*, page 3-13.	
		DATE FORMAT - See *Changing the Date, Time, and Date/Time Formats*, page 3-13.	
	DISPLAY Tab	**LANGUAGE** - See *Changing the Language*, page 3-14.	
		ABOUT THIS MONITOR - See *Checking Software and Firmware Versions*, page 5-14.	
	NETWORK Tab	N/A (settings disabled)	
	UTILITIES Tab	**SETTINGS**	**IMPORT SETTINGS FROM USB** - See *Exporting/Importing Settings*, page 3-16.
			EXPORT SETTINGS TO USB - See *Exporting/Importing Settings*, page 3-16.
			RESTORE FACTORY DEFAULTS - See *Restoring Factory Defaults*, page 3-20.
		LOGS	**EXPORT LOGS TO USB** - See *Exporting Logs from the Monitoring System*, page 6-1.
		UPDATES	**IMPORT FIRMWARE FROM USB** - See *Software and Firmware Updates*, page 5-13.
			IMPORT SOFTWARE FROM USB - See *Software and Firmware Updates*, page 5-13.
	COMMUNICATION Tab	**SERIAL PORT** - See *Setting the Serial Port Protocol*, page 3-15.	

3.4 Setup

Refer to the monitoring system's operator's manual for step-by-step setup instructions. As directed in the operator's manual, refer to the following sections to perform tasks that require an authorized technician:

- *Install the Battery*, page 3-3
- *Perform Functional Testing*, page 3-5
- *Set Institutional Defaults*, page 3-5

3.4.1 Install the Battery

The monitoring system's lithium-ion battery is shipped with the monitor, but not installed. Install and fully charge the battery prior to clinical use (see the operator's manual for charging information).

To install the battery:

1. Remove the battery from its packaging.
2. At the back of the monitor, make sure that the battery latch, located above the battery slot, is to the right (*Figure 3-1*).

Figure 3-1. Battery Slot and Latch at Back of Monitor

1 Battery

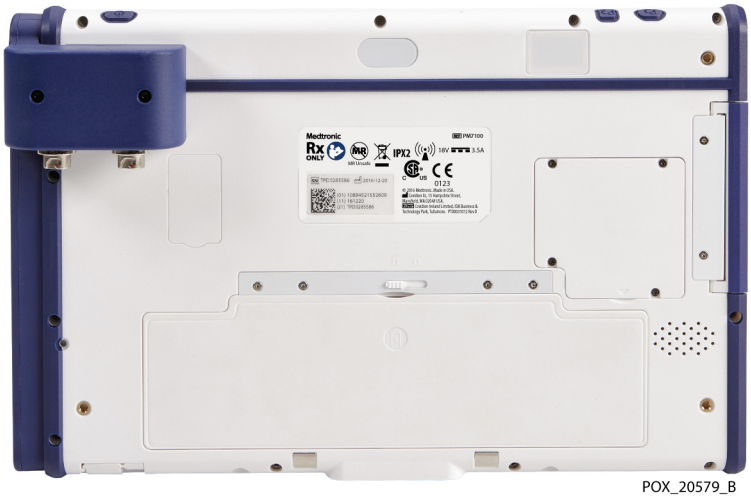
2 Battery slot

3 Battery latch

3. Insert the battery into the slot, bottom edge (with three tabs) first.

4. With the battery completely inserted, slide the battery latch to the left to lock the battery in place (*Figure 3-2*).

Figure 3-2. Battery Installed in Monitor



3.4.2 Perform Functional Testing

Refer to *Functional Testing with the INVOS™ PM7100 Field Test Device*, page 5-5.

3.4.3 Set Institutional Defaults

The following sections provide instructions for setting institutional defaults through the monitoring system's service mode. After setting institutional defaults on a single device, you can export the settings to a USB flash drive and import the settings to additional devices. See *Exporting/Importing Settings*, page 3-16.

- *Institutional Settings - Factory Defaults*, page 3-6
- *Entering Service Mode*, page 3-8
- *Silencing Alarms at Startup*, page 3-9
- *Turning the Alarm Reminder Signal On/Off*, page 3-10
- *Changing Alarm Silence Duration*, page 3-11
- *Changing the Line Frequency*, page 3-12
- *Changing the Date, Time, and Date/Time Formats*, page 3-13
- *Changing the Language*, page 3-14

- *Setting the Serial Port Protocol*, page 3-15
- *Exporting/Importing Settings*, page 3-16
- *Restoring Factory Defaults*, page 3-20

Institutional Settings - Factory Defaults

Table 3-2 describes the institutional settings available through the monitoring system's service mode.

Table 3-2. Institutional Settings

Item	Available settings	Factory default
Silence alarms at startup	YES, NO	NO - Alarms will sound unless the user presses the Alarm Audio button See *Silencing Alarms at Startup*, page 3-9.
Alarm reminder signal	ON, OFF	OFF See *Turning the Alarm Reminder Signal On/Off*, page 3-10.
Alarm audio off/ pause duration	INDEFINITE, 2 MINS	INDEFINITE - When silenced by the user, alarms remain silent until the user unsilences them See *Changing Alarm Silence Duration*, page 3-11.
Line frequency	50 Hz, 60 Hz	60 Hz See *Changing the Line Frequency*, page 3-12.
POST during sensor off	ON, OFF	OFF For system diagnostics only. Do not set to ON when used in a clinical setting.
Date	(Select from calendar)	Coordinated Universal Time (UTC) See *Changing the Date, Time, and Date/Time Formats*, page 3-13.
Date format	DD MM YYYY, YYYY MM DD, MM DD YYYY	MM DD YYYY See *Changing the Date, Time, and Date/Time Formats*, page 3-13.
Time	(Select hh:mm)	N/A See *Changing the Date, Time, and Date/Time Formats*, page 3-13.
Time format	24 hr, 12 hr	12 hr See *Changing the Date, Time, and Date/Time Formats*, page 3-13.

Table 3-2. Institutional Settings (Continued)

Item	Available settings	Factory default
Language	DANISH, DUTCH, ENGLISH, FRENCH, GERMAN, ITALIAN, NORWEGIAN, POLISH, PORTUGUESE, SPANISH, SWEDISH	ENGLISH See *Changing the Language*, page 3-14.
Serial port	OFF, PC LINK 1, PC LINK 2, CLINICAL TEST SETUP, VUE LINK	OFF See *Setting the Serial Port Protocol*, page 3-15.

Operational Defaults - User Changeable

Table 3-3 lists operational default settings that can be changed by the user. Refer to the monitoring system's operator's manual for additional information.

Table 3-3. Operational Defaults

Item	Available settings	Default
Upper alarm limits	OFF, ON	OFF
Lower alarm limits	MANUAL, AUTO	MANUAL
Upper rSO_2 limit	20 - 95	If ON, default is 90
Lower rSO_2 limit	MANUAL: 15 - 90 AUTO: 5 - 30	MANUAL: 40 AUTO: 20
Alarm volume	1 - 10	5
Screen brightness	1 - 10	7
Trend line averaging	ON, OFF	OFF
Trend axis view	TWO AXIS VIEW, ONE AXIS VIEW	ONE AXIS VIEW
Trend time scale (x-axis)	1, 2, 4, 8, 12, 24 hours	1 hour
Sensor placement sequence	4, 3, or 2 sensors	4 sensors
AUC threshold type	FIXED % BELOW BASELINE	FIXED
AUC threshold	FIXED: 30 - 60 % BELOW BASELINE: 0 - 30%	FIXED: 50 % BELOW BASELINE: 25%

Entering Service Mode

To enter service mode:

1. If the monitoring system is powered on, power it off by pressing the Power button on top of the monitor.

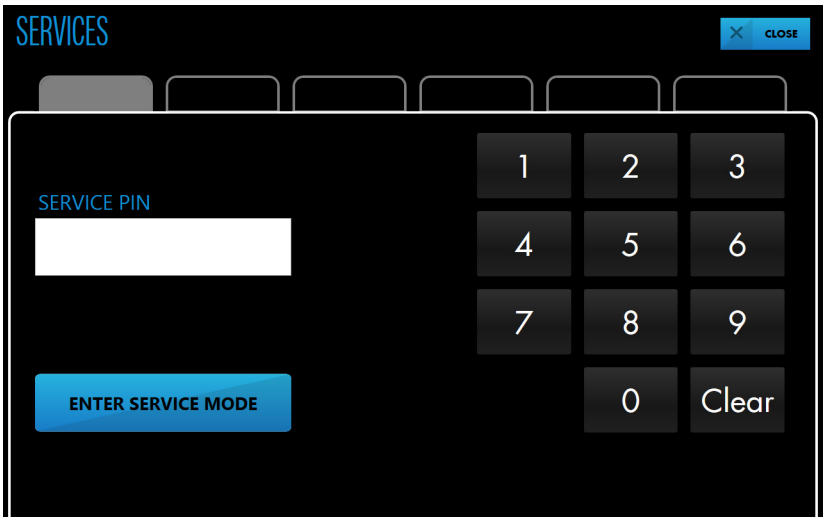
2. Power on the monitoring system. Look for the following screen, which appears during the start-up sequence:

Figure 3-3. Accessing Service Mode

3. Press the service mode icon.

4. At the Services screen, use the on-screen keypad to enter the following PIN: **62907**, then press ENTER SERVICE MODE.

Figure 3-4. Entering the PIN for Service Mode



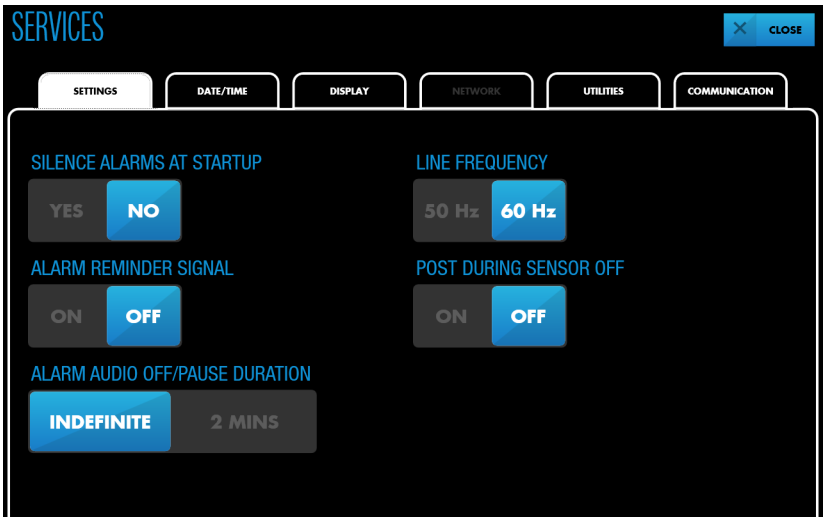
Silencing Alarms at Startup

By default, alarms generate an audible tone that can be silenced or paused by pressing the Alarm Audio button. If desired, you can set the alarm audio so that it is already silenced or paused when the monitoring system is turned on. The user has the option of reactivating alarm audio at any time during a case by pressing the Alarm Audio button. See the monitoring system's operator's manual for additional information.

To turn the alarm audio off or on at startup:

1. Enter service mode as described in *Entering Service Mode*, page 3-8.
2. Press SETTINGS.

Figure 3-5. Service Mode - SETTINGS - SILENCE ALARMS AT STARTUP



3. Press the desired option under SILENCE ALARMS AT STARTUP.

4. If you are finished setting institutional defaults, press CLOSE. The monitoring system exits service mode and restarts.

Turning the Alarm Reminder Signal On/Off

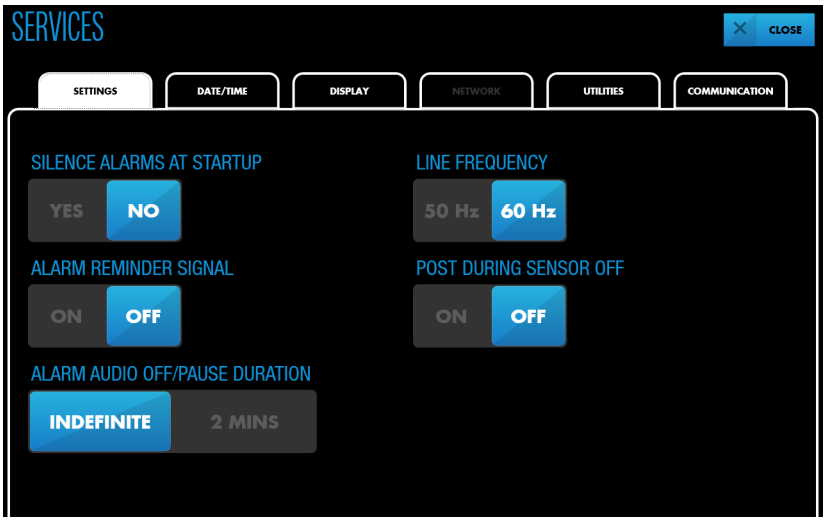
By default, there is no reminder signal when alarms are silenced. If desired, you can turn the reminder signal on. See the monitoring system's operator's manual for additional information.

To turn the alarm reminder signal on or off:

1. Enter service mode as described in *Entering Service Mode*, page 3-8.

2. Press SETTINGS.

Figure 3-6. Service Mode - SETTINGS - ALARM REMINDER SIGNAL



3. Press the desired option under ALARM REMINDER SIGNAL.

4. If you are finished setting institutional defaults, press CLOSE. The monitoring system exits service mode and restarts.

Changing Alarm Silence Duration

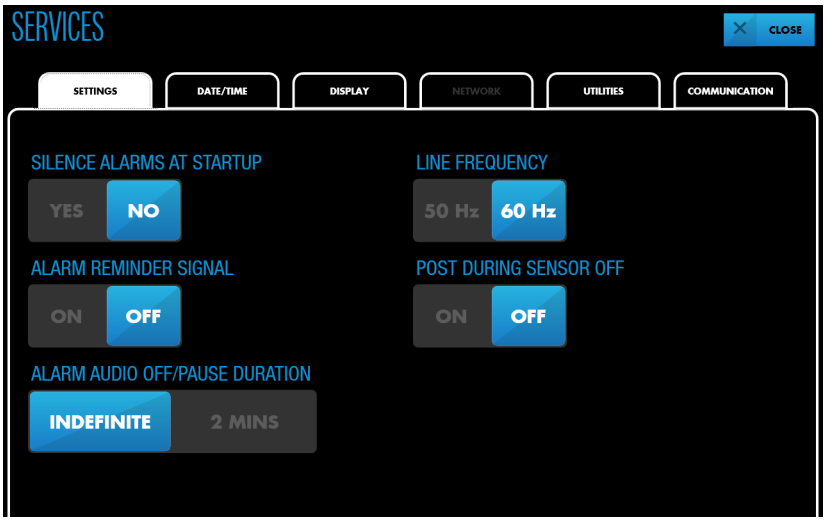
By default, alarm silence duration is indefinite. When the user silences an alarm by pressing the Alarm Audio button, alarm audio remains off until the user presses the Alarm Audio button again. If desired, you can set alarm silence duration to 2 minutes. See the monitoring system's operator's manual for additional information.

To change alarm silence duration:

1. Enter service mode as described in *Entering Service Mode*, page 3-8.

2. Press SETTINGS.

Figure 3-7. Service Mode - SETTINGS - ALARM AUDIO OFF/PAUSE DURATION



3. Press the desired option under ALARM AUDIO OFF/PAUSE DURATION.

4. If you are finished setting institutional defaults, press CLOSE. The monitoring system exits service mode and restarts.

Changing the Line Frequency

If poor signal quality is reported by the monitoring system, it may be the result of a mismatch between the power line frequency and the monitoring system's line frequency setting.

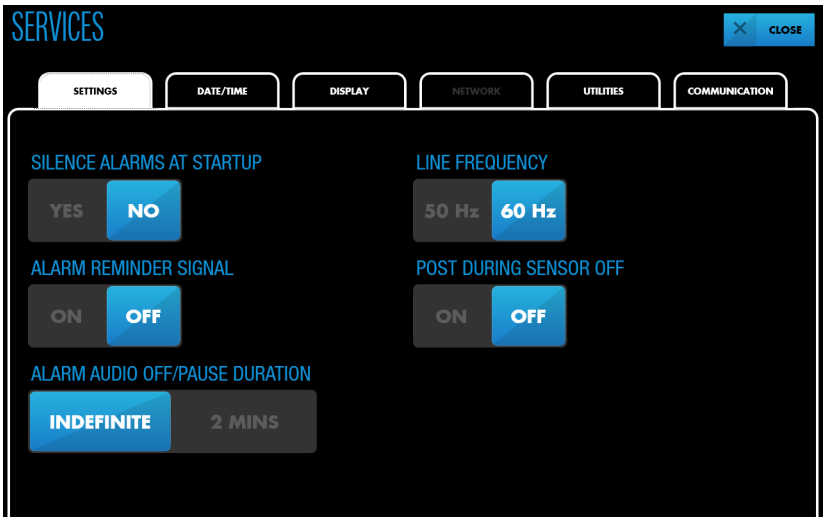
By default the line frequency is 60 Hz. This setting should match the AC power line input to reduce the effects of electrical noise on the monitoring system. If necessary, you can change this setting to 50 Hz.

To change the line frequency:

1. Enter service mode as described in *Entering Service Mode*, page 3-8.

2. Press SETTINGS.

Figure 3-8. Service Mode - SETTINGS - LINE FREQUENCY



3. Press the desired option under LINE FREQUENCY.

4. If you are finished setting institutional defaults, press CLOSE. The monitoring system exits service mode and restarts.

Changing the Date, Time, and Date/Time Formats

The date and time are set at the factory using the MM DD YYYY format for the date and the 12-hour format for the time.

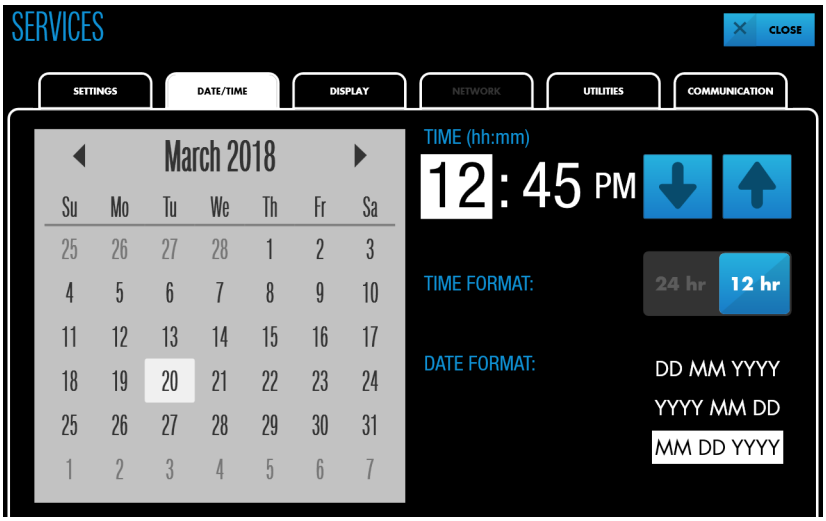
Note:
When the date or time is changed, all trend data and case histories are deleted. Refer to the monitoring system's operator's manual for information about exporting case histories for external storage.

To change the date, time, and date/time formats:

1. Enter service mode as described in *Entering Service Mode*, page 3-8.

2. Press DATE/TIME.

Figure 3-9. Service Mode - DATE/TIME



3. Press the desired format next to DATE FORMAT.
4. Press the desired date in the on-screen calendar.
5. Press the desired format next to TIME FORMAT.
6. Press the hours under TIME, then press the up or down arrow to change.
7. Press the minutes under TIME, then press the up or down arrow to change.
8. If you are finished setting institutional defaults, press CLOSE. The monitoring system exits service mode and restarts.

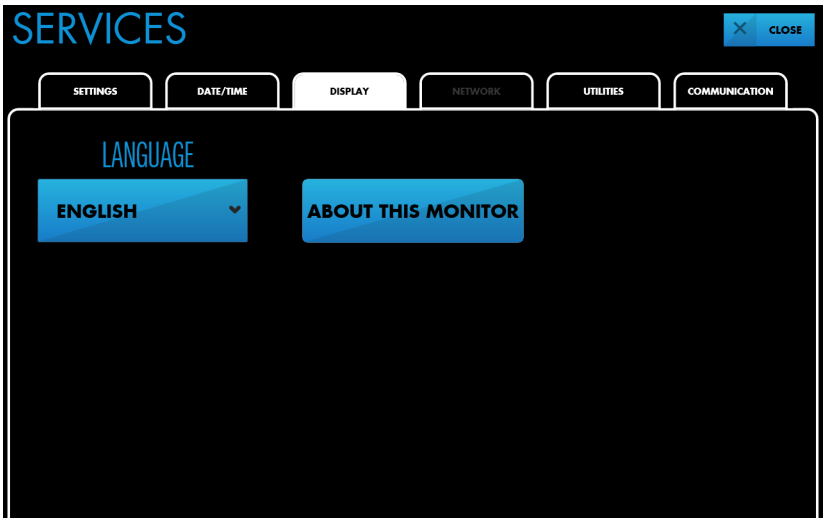
Changing the Language

By default, the screen language is set to English. You can change the language to any of the options listed in *Table 3-2*, page *3-6*.

To change the language:

1. Enter service mode as described in *Entering Service Mode*, page 3-8.
2. Press DISPLAY.

Figure 3-10. Service Mode - DISPLAY - LANGUAGE



3. Scroll through the options in the LANGUAGE menu, and highlight the desired language.
4. If you are finished setting institutional defaults, press CLOSE. The monitoring system exits service mode and restarts.

Setting the Serial Port Protocol

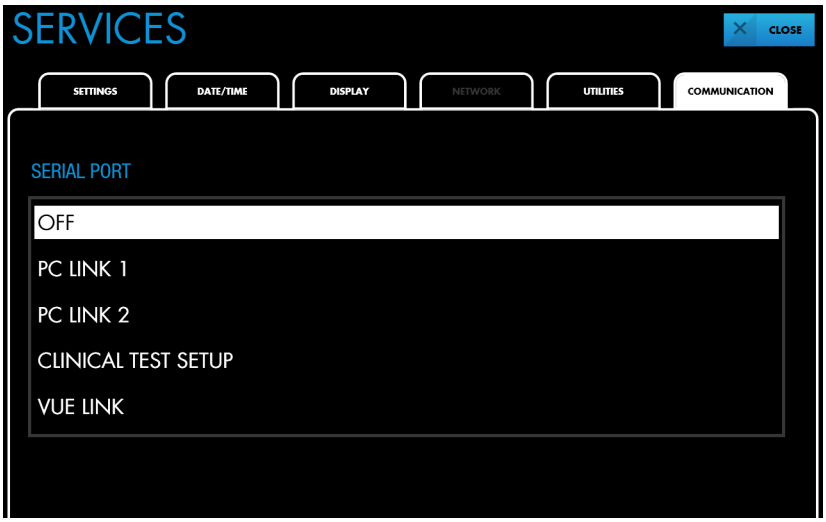
The serial port on the monitoring system's docking station can be used to transmit data to external devices such as a Philips multi-parameter system or a computer. See the monitoring system's operator's manual for additional information and instructions. The available serial port protocols are:

- **OFF —** Use this setting for typical operation (no external data transfer).
- **PC LINK 1, PC LINK 2 —** Use one of these settings when transferring data to a computer.
- **CLINICAL TEST SETUP —** Medtronic use only.
- **VUE LINK —** Use this setting when transferring data to a Philips module in a multi-parameter system.

To set the serial port protocol:

1. Enter service mode as described in *Entering Service Mode*, page 3-8.
2. Press COMMUNICATION.

Figure 3-11. Service Mode - COMMUNICATION - SERIAL PORT



3. Press the desired protocol under SERIAL PORT.

4. If you are finished setting institutional defaults, press CLOSE. The monitoring system exits service mode and restarts.

Exporting/Importing Settings

After setting institutional defaults on a single monitoring system, you can export the settings to a USB flash drive and import the settings to additional monitoring systems.

To export settings from a monitoring system:

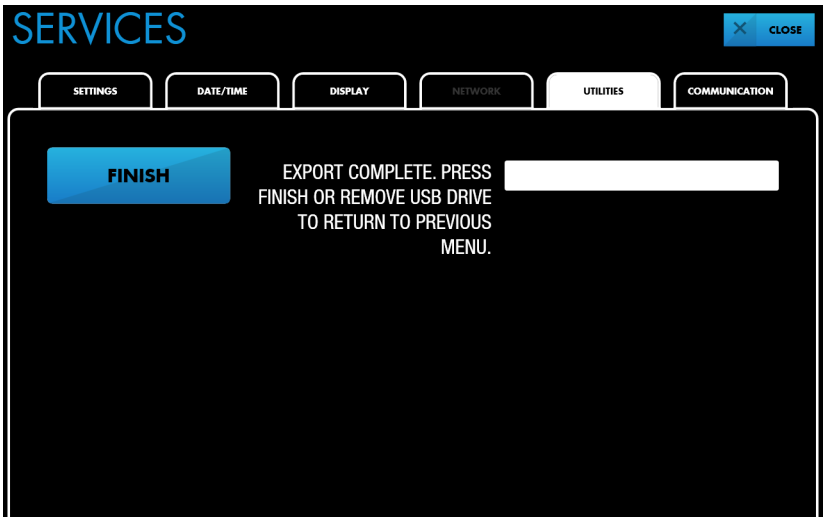
1. As desired, change operational settings that do not require service mode access:
   a. Refer to the monitoring system's operator's manual for the available operational settings.
   b. Power on the monitoring system and set any of these options as desired. Refer to the operator's manual for instructions for setting these options.
   c. Power off the monitoring system when finished.
2. Enter service mode as described in *Entering Service Mode*, page 3-8.
3. Set all institutional defaults as desired following the instructions in *Set Institutional Defaults*, page 3-5.
4. Press CLOSE. The monitoring system exits service mode and restarts.

5. Power off the monitoring system.
6. Re-enter service mode as described in *Entering Service Mode*, page 3-8.
7. Press UTILITIES.

Figure 3-12. Service Mode - UTILITIES - EXPORT SETTINGS TO USB

8. Insert a USB flash drive into a USB port on the monitor or docking station. See Figure 2-3 on page *2-5* and Figure 2-6 on page *2-8*.
9. Press EXPORT SETTINGS TO USB. A progress bar appears during the export. When the screen indicates the export is complete, press FINISH.

Figure 3-13. Exporting Settings to USB - Export Complete

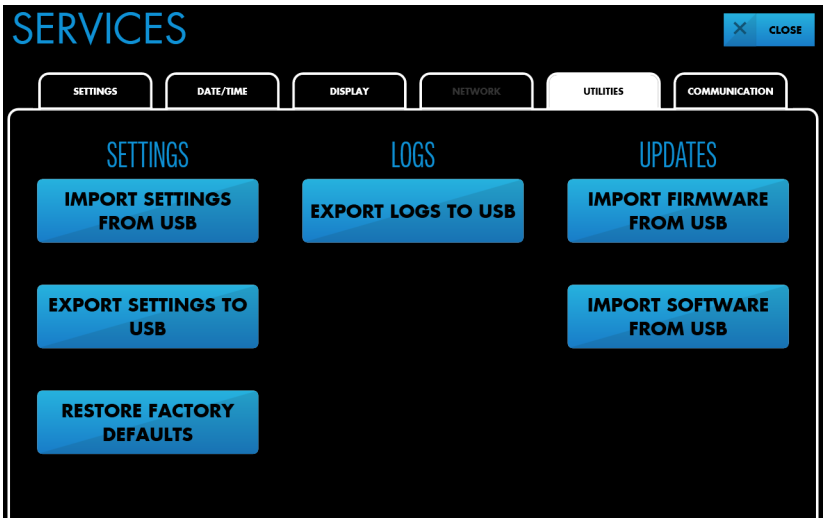


10. Remove the USB flash drive.
11. Press CLOSE. The monitoring system exits service mode and restarts.
12. Power off the monitoring system.

To import settings to a monitoring system:

1. Enter service mode as described in *Entering Service Mode*, page 3-8.
2. Press UTILITIES.

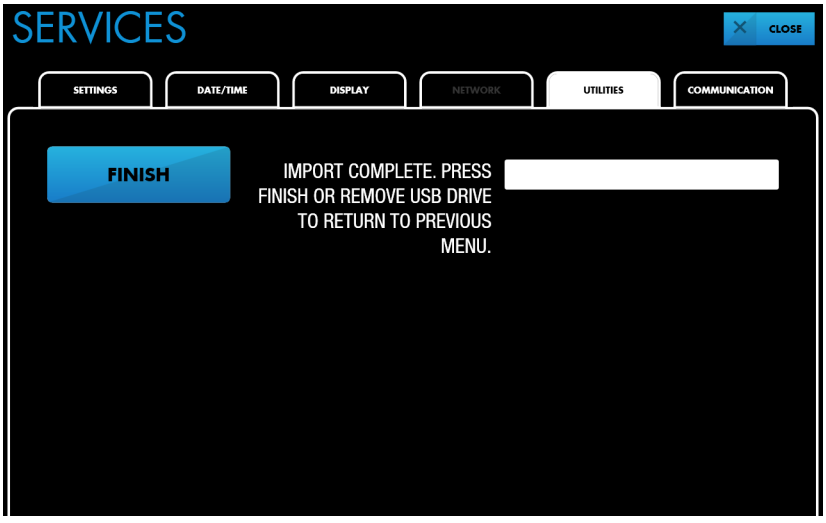
Figure 3-14. Service Mode - UTILITIES - IMPORT SETTINGS FROM USB



3. Insert a USB flash drive into a USB port on the monitor or docking station. See Figure 2-3 on page *2-5* and Figure 2-6 on page *2-8*.

4. Press IMPORT SETTINGS FROM USB. A progress bar appears during the import. When the screen indicates the import is complete, press FINISH.

Figure 3-15. Importing Settings from USB - Import Complete



5. Remove the USB flash drive.

6. Press CLOSE. The monitoring system exits service mode and restarts.

7. Verify that the new settings are in effect before powering off the monitoring system.

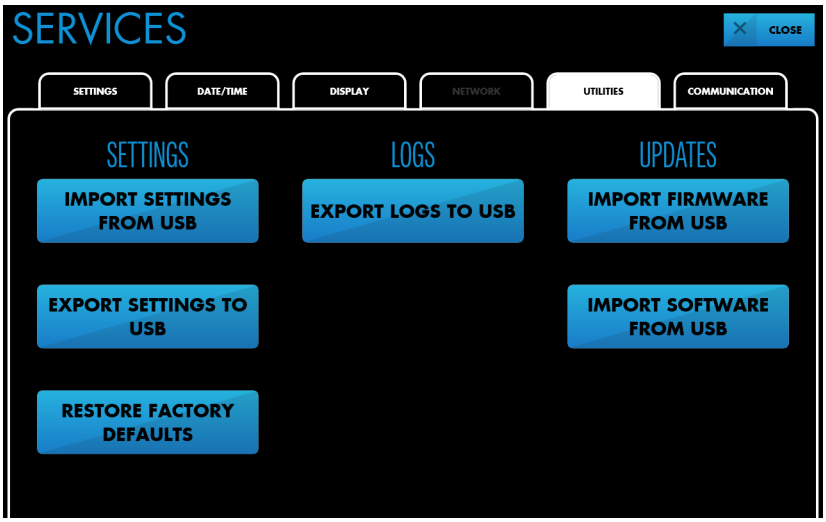
Restoring Factory Defaults

Factory defaults for institutional and operational settings are listed in *Table 3-2* on page *3-6* and *Table 3-3* on page *3-7*.

To restore all factory default settings:

1. Enter service mode as described in *Entering Service Mode*, page 3-8.
2. Press UTILITIES.

Figure 3-16. Service Mode - UTILITIES - RESTORE FACTORY DEFAULTS



3. Press RESTORE FACTORY DEFAULTS.
4. At the confirmation screen, press RESTORE.
5. Press CLOSE. The monitoring system exits service mode and restarts.

4 Performance Considerations - EMI

4.1 Overview

This chapter contains information about optimizing the performance of the INVOS™ patient monitor (the "monitoring system") under conditions of electromagnetic interference (EMI). Refer to the monitoring system's operator's manual for additional performance considerations related to patient conditions and sensor use.

4.2 Safety Reminders

WARNING:
Electromagnetic emissions from the monitoring system may interfere with other critical devices.

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.

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

WARNING:
The monitoring system is intended for use by healthcare professionals only. It may cause radio interference or may disrupt the operation of nearby equipment.

Mitigation for such disruption may require re-orienting or relocating the monitoring system or shielding the location.

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

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

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

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. Technical alarms may indicate that the configuration is not appropriate for the monitoring system.

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.

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

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

Caution:
The use of an electrosurgical or electrocautery instrument in the vicinity of the monitoring system may interfere with the signal and cause poor performance or no readings at all.

4.3 EMI (Electromagnetic Interference)

Because of the proliferation of radio frequency transmitting equipment and other sources of electrical noise in health care environments (for example, electrosurgical units, cellular phones, mobile two-way radios, electrical appliances, and high-definition television), it is possible that high levels of such interference due to close proximity or strength of a source may result in disruption of monitoring system performance. See *Manufacturer's Declaration*, page 4-4.

Disruption may be evidenced by 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 interfering equipment.
- Reorient or relocate the interfering equipment.
- Increase the separation between the interfering equipment and the monitoring system.
- Connect the monitoring system to an outlet on a different circuit from the other device(s).
- Check the line frequency setting for the monitoring system. The setting should match the AC power line input. See *Changing the Line Frequency*, page 3-12.

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. See *Technical Services*, page 1-8.

4.4 Manufacturer's Declaration

4.4.1 Electromagnetic Compatibility (EMC)

The monitoring system is suitable for prescription use only in the specified electromagnetic environments, in accordance with the IEC/EN 60601-1-2:2007 and IEC/EN 60601-1-2:2014 standards. 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 industrial areas and hospitals (CISPR 11 class A). If it is used 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 Guidelines and Compliance

Table 4-1. Electromagnetic Emissions Guidelines and Compliance

Guidance and manufacturer's declaration—electromagnetic emissions		
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**
Radiated emission	CISPR 11/EN 55011, Class A, Group 1	The monitoring system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Conducted emission	CISPR 11/EN 55011, Class A, Group 1	The monitoring system is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power network that supplies buildings used for domestic purposes.
Harmonic emission	IEC/EN 61000-3-2, Class A	
Voltage fluctuations/ flicker emission	IEC/EN 61000-3-3, Section 4	

Electromagnetic Immunity Guidelines and Compliance

Table 4-2. Electromagnetic Immunity Guidelines and Compliance

Guidance and manufacturer's declaration—electromagnetic immunity			
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	± 2kV (100 kHz repetition rate) AC mains ± 1kV (100 kHz repetition rate) input/output >3 m	± 2kV (100 kHz repetition rate) AC mains ± 1kV (100 kHz repetition rate) input/output >3 m	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC/EN 61000-4-5	± 1kV line-line, AC mains ± 2kV line-ground, AC mains	± 1kV line-line, AC mains ± 2kV line-ground, AC mains	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 interruptions, it is recommended that the monitoring system be powered from an uninterruptible power supply or battery.
Power frequency H-field immunity IEC/EN 61000-4-8	50 and 60 Hz, 30 A/m, x-, y-, and z-axes	50 and 60 Hz, 30 A/m, x-, y-, and z-axes	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Recommended Separation Distance Calculations

Table 4-3. Recommended Separation Distance Calculations

Guidance and manufacturer's declaration—electromagnetic immunity			
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 and amateur radio bands between 0.15mHz and 80MHz frequencies	3 Vrms 150 kHz to 80 MHz; 6 Vrms, ISM and amateur radio bands between 0.15mHz and 80MHz frequencies	Portable and mobile RF communications equipment should be used no closer to any part of the monitoring system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ 150 kHz to 80 MHz where *P* is the maximum output power rating of the transmitter in watts (*W*) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (*m*). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 

Table 4-3. Recommended Separation Distance Calculations (Continued)

Guidance and manufacturer's declaration—electromagnetic immunity			
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**
Radiated RF IEC/EN 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m 80 MHz to 2.7 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the monitoring system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.7 GHz where *P* is the maximum output power rating of the transmitter in watts (*W*) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (*m*). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 
RF wireless proximity fields IEC/EN 61000-4-3	See *Table 4-4* on page *4-8*	See *Table 4-4* on page *4-8*	0.3 m
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 4-4. Test Specifications for Enclosure Port Immunity to RF Wireless Communications Equipment

Test frequency (MHz)	Band (MHz)	Service	Modulation	Max. power (W)	Dis-tance (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						

Recommended Separation Distances

Table 4-5. Recommended Separation Distances

Recommended separation distances between portable and mobile RF communications equipment and the monitoring system			
The monitoring system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the monitoring system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the monitoring system as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power (*P*) of transmitter in watts	**Separation distance according to frequency of transmitter in meters**		
	$d = 1.2\sqrt{P}$ **150 kHz to 80 MHz**	$d = 1.2\sqrt{P}$ **80 MHz to 800 MHz**	$d = 2.3\sqrt{P}$ **800 MHz to 2.7 GHz**
0.01	0.12	0.12	0.23
0.10	0.38	0.38	0.73
1.00	1.20	1.20	2.30
10.00	3.80	3.80	7.30
100.00	12.00	12.00	23.00
For transmitters rated at a maximum output power not listed above, the recommended separation distance (*d*) in meters (*m*) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (*W*) according to the transmitter manufacturer. NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

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5 Product Maintenance

5.1 Overview

This chapter describes the maintenance schedule for the INVOS™ patient monitor (the "monitoring system") and provides instructions for performing annual inspections. It also provides information about calibration and service life.

5.2 Safety Reminders

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

WARNING:
Shock hazard — Ensure the monitoring system is properly grounded when operating on AC power.

WARNING:
Explosion hazard — When replacing the battery, do not use the incorrect type. Use only the battery available from Medtronic. See the Accessories/Parts list in the monitoring system's operator's manual.

Caution:
Dispose of the battery in accordance with local guidelines and regulations.

5.3 Maintenance Schedule

In the case of mechanical or functional damage or to schedule regular maintenance and safety checks, contact Medtronic or a local Medtronic representative. See *Obtaining Technical Assistance*, page 1-8.

Medtronic recommends the following checks at the indicated intervals.

Table 5-1. Maintenance Schedule

How often	What to do
Each power-up	Confirm speaker operation. The POST pass tone is an audible confirmation of proper speaker performance. If the speaker does not function, alarm warning sounds will not be audible.
Every 3 months	If the monitoring system is not in use, apply power and charge the battery. For long-term storage, Medtronic recommends removing the battery pack from the monitor.
Annually	Check the INVOS™ system. See *Annual Inspection Procedures*, page 5-3.
Annually	Inspect all safety relevant labels for legibility. Contact Medtronic or a local Medtronic representative, if labels are damaged or illegible.
Annually	Replace the reusable sensor cables (RSCs). See the monitoring system's operator's manual for part number and ordering information.
Every 2 years	Replace the monitor's battery. See the monitoring system's operator's manual for part number and ordering information.
After approximately 25,000 hours of operation	Replace the monitor. See *Service Life*, page 5-13 for more information.

5.4 Annual Inspection Procedures

5.4.1 Mechanical Inspection Points

Inspect the following for damage, dirt, loose connectors, corroded or bent pins, fluid contamination or stains, or damaged cords:

- Power supply and cord
- Reusable sensor cables (RSCs)
- Preamplifiers and cables
- Monitor
- Battery
- Docking station
- Stand

5.4.2 Electrical Inspection Points

Note:
The LAN port on the bottom of the docking station (*Figure 2-6* on page *2-8*) is not used. Do not connect any devices to this port.

Table 5-2. Annual Maintenance - Electrical Inspection Points

Inspection point	Method
Power up/ power down	1. Connect the monitoring system to AC power. 2. Verify that the blue power indicator on the docking station is illuminated (*Figure 2-2* on page *2-4*). 3. Check that the battery status indicator at the top left of the monitor is illuminated (orange = charging; green = fully charged). 4. Press the Power button on top of the monitor. 5. Verify that the POST pass tone sounds and the Set-up screen appears. Refer to the monitoring system's operator's manual. 6. Press the Power button to power off the monitoring system. 7. Verify that the screen goes completely dark. Note that the battery indicator on the monitor and the power indicator on the docking station remain illuminated as long as power is connected.

Table 5-2. Annual Maintenance - Electrical Inspection Points (Continued)

Inspection point	Method
System self-diagnostics	1. Connect the monitoring system to AC power. 2. Press the Power button on top of the monitor. 3. Verify that the POST pass tone sounds and the Set-up screen appears. Refer to the monitoring system's operator's manual.
Battery backup	1. Connect the monitoring system to AC power. 2. Press the Power button on top of the monitor. 3. Note the battery status indicators on the monitor and on the screen (refer to the monitoring system's operator's manual). Charge the battery to full capacity. 4. Disconnect the monitoring system from AC power and verify that the monitoring system continues to run for at least 1 hour. If the battery does not support at least 1 hour of operation, replace the battery. See *Install the Battery*, page 3-3.
VGA port (video output)	1. Connect the monitoring system to AC power. 2. Press the Power button on top of the monitor. 3. Connect an external VGA monitor as described in Displaying Monitoring System Screens on an External Monitor in the operator's manual. 4. Verify that monitoring system screens appear on the external monitor.
Serial port	1. Connect the monitoring system to AC power. 2. Press the Power button on top of the monitor. 3. Refer to Transmitting Monitoring System Data to External Devices via the Serial Port in the operator's manual for instructions for connecting devices. 4. Verify that the data is correctly transmitted.
USB ports	1. Connect the monitoring system to AC power. 2. Press the Power button on top of the monitor. 3. Verify USB functionality by exporting settings to a USB flash drive (see *Exporting/Importing Settings*, page 3-16). 4. Verify that the data has been correctly transmitted. 5. Repeat for all USB ports on the docking station and monitor.
System function	Perform functional testing as described in *Functional Testing with the INVOS™ PM7100 Field Test Device*, page 5-5.

5.4.3 Functional Testing with the INVOS™ PM7100 Field Test Device

Use the INVOS™ PM7100 Field Test Device to test basic monitoring system functions. Do not use any other type of test device with the monitoring system. Do not attach the test device to the monitoring system when the system is in use on a patient.

For information about acquiring and using the INVOS™ PM7100 Field Test Device, contact Technical Services. See *Obtaining Technical Assistance*, page 1-8.

There are two functional test procedures: The 4-channel test is for monitoring systems consisting of two preamplifiers and four reusable sensor cables (RSCs); the 2-channel test is for monitoring systems consisting of one preamplifier and two RSCs. Select the test that matches your configuration:

- *Monitoring System Functional Test for 4-Channel Configuration*, page 5-6
- *Monitoring System Functional Test for 2-Channel Configuration*, page 5-9

Monitoring System Functional Test for 4-Channel Configuration

Note:
This test requires two INVOS™ PM7100 Field Test Devices.

To perform functional testing for a 4-channel configuration:

1. Set up the monitoring system as described in the operator's manual (10139710 Rev A) sections 3.5.1 through 3.5.5.
2. Check that the Sensor L circle is highlighted.
3. Set both channel values on both test devices to 50, but DO NOT connect the RSCs.

Note:
The test devices are battery powered. The LEDs next to the Channel # illuminate when an rSO_2 value is selected. If the LED does not illuminate, check the batteries before proceeding.

4. Identify the RSC with the flashing blue LED and plug it into CH1 of the first test device.
5. Verify that the Sensor L circle indicates the value 50.

Note:
Disregard the CHECK SENSOR alarm on the monitor.

6. Check that the Sensor R circle is highlighted.
7. Identify the RSC with the flashing blue LED and plug it into CH2 of the first test device.
8. Verify that the Sensor R circle indicates the value 50.
9. Check that the Sensor S1 circle is highlighted.
10. Identify the RSC with the flashing blue LED and plug it into CH1 of the second test device.
11. Verify that the Sensor S1 circle indicates the value 50.
12. Check that the Sensor S2 circle is highlighted.
13. Identify the RSC with the flashing blue LED and plug it into CH2 of the second test device.
14. Verify that the Sensor S2 circle indicates the value 50.

15. Select NEW DATA SET.

Note:
Because the monitoring system displays a CHECK SENSOR alarm while running with the test device, data values are not captured and there is no trend line in the trend graph.

16. On both test devices, change the values on all channels to 15.
17. Verify that all channels on the monitor (L, R, S1, S2) indicate an rSO_2 value of 15.
18. Press the down arrow in the message area at the top of the monitoring screen.
19. Verify that there is a LOW rSO2 alarm for all channels (L, R, S1, S2).
20. On both test devices, change the values on all channels to 50.
21. Verify that all channels on the monitor indicate an rSO_2 value of 50.
22. Verify that the LOW rSO2 alarms are dismissed.
23. On both test devices, change the values on all channels to 70.
24. Verify that all channels on the monitor indicate an rSO_2 value of 70.
25. On both test devices, change the values on all channels to 95.
26. Verify that all channels on the monitor indicate an rSO_2 value of 95.
27. If UPPER LIMITS is set to OFF, skip to step 30.
28. If necessary, press the down arrow in the message area to expand the alarm list.
29. Verify that there is a HIGH rSO2 alarm for all channels (L, R, S1, S2).
30. On both test devices, change the values on all channels to 50.
31. Verify that all channels on the monitor indicate an rSO_2 value of 50.
32. Disconnect all RSCs from the test devices.
33. Verify that there is a SENSOR NOT CONNECTED alarm for all channels (L, R, S1, S2).
34. Press Dismiss in the message area.
35. Verify that the monitoring system returns to the sensor Set-up screen.

36. Power off the monitoring system.

37. Turn off all channels on the test devices.

PASS/FAIL Checklist For 4-Channel Configuration Functional Test

Step	Expected result	PASS/FAIL
5	Sensor L Circle indicates a value of 50	
8	Sensor R Circle indicates a value of 50	
11	Sensor S1 Circle indicates a value of 50	
14	Sensor S2 Circle indicates a value of 50	
17	All channels indicate an rSO_2 value of 15	
19	Message area displays LOW rSO2 alarm for all channels	
21	All channels indicate an rSO_2 value of 50	
22	LOW rSO2 alarm was dismissed	
24	All channels indicate an rSO_2 value of 70	
26	All channels indicate an rSO_2 value of 95	
29	Message area displays HIGH rSO2 alarm for all channels (N/A if UPPER LIMITS is set to OFF)	
31	All channels indicate an rSO_2 value of 50	
33	Message area displays SENSOR NOT CONNECTED for all channels	
35	Monitor returns to the sensor Set-up screen	

Monitoring System Functional Test for 2-Channel Configuration

Note:
This test requires one INVOS™ PM7100 Field Test Device.

To perform functional testing for a 2-channel configuration:

1. Set up the monitoring system as described in the operator's manual (10139710 Rev A) sections 3.5.1 through 3.5.5.
2. Check that the Sensor L circle is highlighted.
3. Set both channel values on the test device to 50, but DO NOT connect the RSCs.

Note:
The test device is battery powered. The LEDs next to the Channel # illuminate when an rSO_2 value is selected. If the LED does not illuminate, check the batteries before proceeding.

4. Identify the RSC with the flashing blue LED and plug it into CH1 of the test device.
5. Verify that the Sensor L circle indicates the value 50.

Note:
Disregard the CHECK SENSOR alarm on the monitor.

6. Check that the Sensor R circle is highlighted.
7. Identify the RSC with the flashing blue LED and plug it into CH2 of the test device.
8. Verify that the Sensor R circle indicates the value 50.
9. Select NEW DATA SET.

Note:
Because the monitoring system displays a CHECK SENSOR alarm while running with the test device, data values are not captured and there is no trend line in the trend graph.

10. On the test device, change the values on both channels to 15.
11. Verify that both channels on the monitor (L, R) indicate an rSO_2 value of 15.
12. Press the down arrow in the message area at the top of the monitoring screen.

13. Verify that there is a LOW rSO2 alarm for both channels (L, R).
14. On the test device, change the values on both channels to 50.
15. Verify that both channels on the monitor indicate an rSO_2 value of 50.
16. Verify that the LOW rSO2 alarms are dismissed.
17. On the test device, change the values on both channels to 70.
18. Verify that both channels on the monitor indicate an rSO_2 value of 70.
19. On the test device, change the values on both channels to 95.
20. Verify that both channels on the monitor indicate an rSO_2 value of 95.
21. If UPPER LIMITS is set to OFF, skip to step 24.
22. If necessary, press the down arrow in the message area to expand the alarm list.
23. Verify that there is a HIGH rSO2 alarm for both channels (L, R).
24. On the test device, change the values on both channels to 50.
25. Verify that both channels on the monitor indicate an rSO_2 value of 50.
26. Disconnect the RSCs from the test device.
27. Verify that there is a SENSOR NOT CONNECTED alarm for both channels (L, R).
28. Press Dismiss in the message area.
29. Verify that the monitoring system returns to the sensor Set-up screen.
30. Press the Sensor S1 circle.
31. Check that the Sensor S1 circle is highlighted.
32. Identify the RSC with the flashing blue LED and plug it into CH1 of the test device.
33. Verify that the Sensor S1 circle indicates the value 50.
34. Press the Sensor S2 circle.
35. Check that the Sensor S2 circle is highlighted.
36. Identify the RSC with the flashing blue LED and plug it into CH2 of the test device.

37. Verify that the Sensor S2 circle indicates the value 50.
38. Select NEW DATA SET.
39. On the test device, change the values on both channels to 15.
40. Verify that both channels on the monitor (S1, S2) indicate an rSO_2 value of 15.
41. Press the down arrow in the message area at the top of the monitoring screen.
42. Verify that there is a LOW rSO2 alarm for both channels (S1, S2).
43. On the test device, change the values on both channels to 50.
44. Verify that both channels on the monitor indicate an rSO_2 value of 50.
45. Verify that the LOW rSO2 alarms are dismissed.
46. On the test device, change the values on both channels to 70.
47. Verify that both channels on the monitor indicate an rSO_2 value of 70.
48. On the test device, change the values on both channels to 95.
49. Verify that both channels on the monitor indicate an rSO_2 value of 95.
50. If UPPER LIMITS is set to OFF, skip to step 53.
51. If necessary, press the down arrow in the message area to expand the alarm list.
52. Verify that there is a HIGH rSO2 alarm for both channels (S1, S2).
53. On the test device, change the values on both channels to 50.
54. Verify that both channels on the monitor indicate an rSO_2 value of 50.
55. Disconnect the RSCs from the test device.
56. Verify that there is a SENSOR NOT CONNECTED alarm for both channels (S1, S2).
57. Press Dismiss in the message area.
58. Verify that the monitoring system returns to the sensor Set-up screen.
59. Power off the monitoring system.
60. Turn off both channels on the test device.

PASS/FAIL Checklist For 2-Channel Configuration Functional Test

Step	Expected result	PASS/FAIL
5	Sensor L Circle indicates a value of 50	
8	Sensor R Circle indicates a value of 50	
11	Both channels indicate an rSO_2 value of 15	
13	Message area displays a LOW rSO2 alarm for channels L and R	
15	Both channels indicate an rSO_2 value of 50	
16	LOW rSO2 alarm was dismissed	
18	Both channels indicate an rSO_2 value of 70	
20	Both channels indicate an rSO_2 value of 95	
23	Message area displays a HIGH rSO2 alarm for channels L and R (N/A if UPPER LIMITS is set to OFF)	
25	Both channels indicate an rSO_2 value of 50	
27	Message area displays a SENSOR NOT CONNECTED alarm for channels L and R	
29	Monitor returns to the sensor Set-up screen	
33	Sensor S1 circle indicates a value of 50	
37	Sensor S2 circle indicates a value of 50	
40	Both channels indicate an rSO_2 value of 15	
42	Message area displays a LOW rSO2 alarm for channels S1 and S2	
44	Both channels indicate an rSO_2 value of 50	
45	LOW rSO2 alarm was dismissed	
47	Both channels indicate an rSO_2 value of 70	
49	Both channels indicate an rSO_2 value of 95	
52	Message area displays a HIGH rSO2 alarm for channels S1 and S2 (N/A if UPPER LIMITS is set to OFF)	
54	Both channels indicate an rSO_2 value of 50	
56	Message area displays a SENSOR NOT CONNECTED alarm for channels S1 and S2	
58	Monitor returns to the sensor Set-up screen	

5.5 Service and Calibration

The monitoring system requires no routine service.

The monitoring system requires no calibration.

If service is necessary, contact Technical Services. See *Obtaining Technical Assistance*, page 1-8.

5.6 Service Life

Discontinue use of the monitoring system if the system reports any unrecoverable technical alarms, the monitor is inoperative, or visible damage is present.

Service life of specific components:

- The monitor's battery has a service life of approximately two years.
- The reusable sensor cables have a service life of approximately one year.
- The preamplifiers have a service life of approximately five years.
- The monitor's LCD panel (screen) has a service life of approximately 25,000 hours of operation before the brightness is reduced to approximately 50% of initial brightness. To avoid difficulty reading the screen, Medtronic recommends replacing the monitor at approximately 25,000 hours of operation.

5.7 Software and Firmware Updates

Medtronic may provide platform software or firmware updates periodically. Updates must be performed by Medtronic personnel. To inquire about updates, contact Medtronic or a local Medtronic representative. See *Obtaining Technical Assistance*, page 1-7.

Note:
When the software or firmware is updated, all trend data and case histories are deleted. Refer to the monitoring system's operator's manual for information about exporting case histories for external storage.

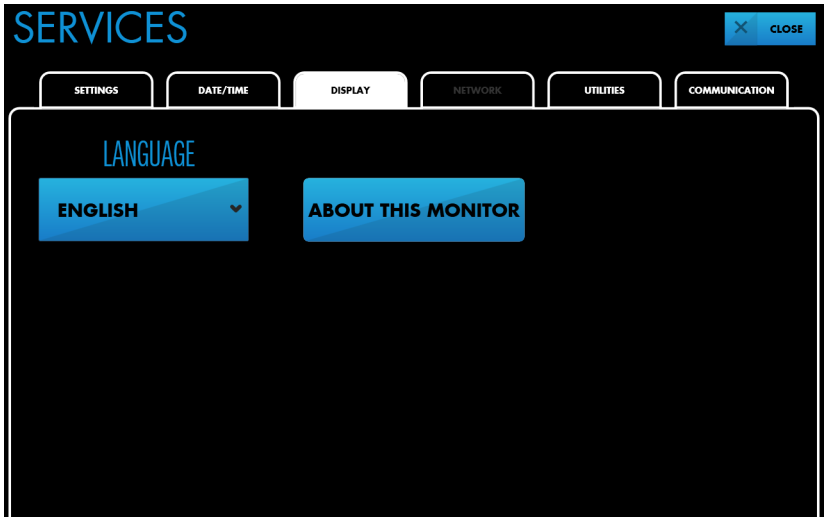
5.7.1 Checking Software and Firmware Versions

After a software or firmware update, check the versions using the following procedure.

To check the current software and firmware versions:

1. Enter service mode as described in *Entering Service Mode*, page 3-8.
2. Press DISPLAY.

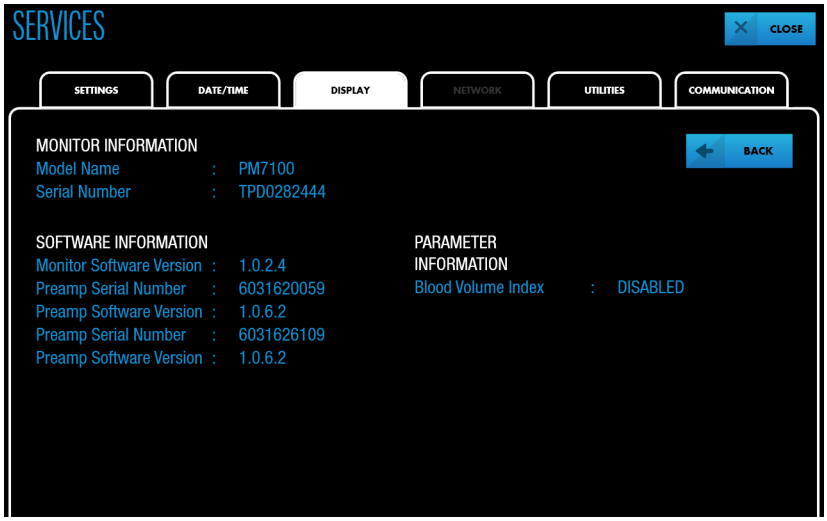
Figure 5-1. Service Mode - DISPLAY - ABOUT THIS MONITOR



3. Press ABOUT THIS MONITOR. Software version information is displayed.

Note:
The firmware version is indicated as "Preamp Software Version." If you are using two preamplifiers, versions are displayed for both preamplifiers.

Figure 5-2. ABOUT THIS MONITOR - System Information



4. Press CLOSE to exit service mode and restart the monitoring system.

5.8 Recycling and Disposal

Caution:
Dispose of the battery in accordance with local guidelines and regulations.

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

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6 Exporting Logs

6.1 Overview

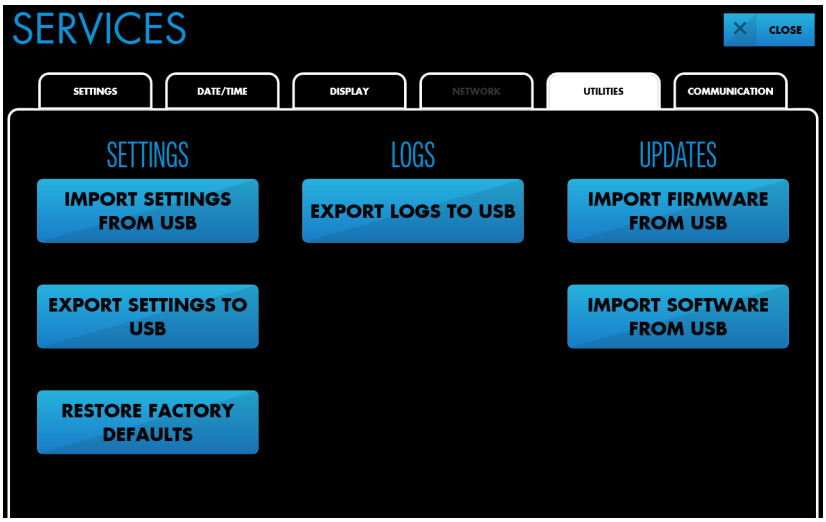
For troubleshooting purposes, you may be asked to export logs from the monitoring system and provide them to Medtronic Technical Services. After exporting logs to a USB flash drive, you can upload them to a computer.

6.2 Exporting Logs from the Monitoring System

To export logs from the monitoring system:

1. Enter service mode as described in *Entering Service Mode*, page 3-8.
2. Press UTILITIES.

Figure 6-1. Service Mode - UTILITIES - EXPORT LOGS TO USB



3. Insert a USB flash drive into the USB port on the monitor or docking station. See Figure 2-3 on page *2-5* and Figure 2-6 on page *2-8*.

4. Press EXPORT LOGS TO USB. A progress bar appears during the export. When the screen indicates the export is complete, press FINISH.

Figure 6-2. Exporting Logs to USB - Export Complete

5. Remove the USB flash drive.

6. Press CLOSE. The monitoring system exits service mode and restarts.

Rx ONLY

CE 0123

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