Medtronic

INVOS™

Patient Monitor

Operator's Manual

Rx ONLY CE 0123

Symbols

REF	Reference code (part number)
SN	Serial number
LOT	Lot number
EC REP	European Community (EC) authorized representative
Rx ONLY	Prescription only. US federal law restricts this device to sale by or on the order of a physician.
IPX2	Protection against fluid ingress: Protected against vertically falling water drops when tilted to 15°
	Manufacturer
	Date of manufacture
	Fragile
	Keep dry
	Must consult instructions for use
	Consult instructions for use
	Atmospheric pressure limits (see Environmental Conditions, page 112)
	Temperature limits (see Environmental Conditions, page 112)
	Humidity limits (see Environmental Conditions, page 112)
	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 0123	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
	Quantity included in package (example: 20)

	Do not immerse

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1. Introduction

1.1. Overview

This manual contains information for operating the INVOS™ patient monitor (the "monitoring system").

This manual applies to the following product: PM7100

- Intended Audience, page 7
- Safety Information, page 7
- Obtaining Technical Assistance, page 10
- Warranty Information, page 11

1.2. Intended Audience

This manual provides information to health-care professionals in a hospital setting for operation and maintenance of the monitoring system. Refer to the institution for any additional training or skill requirements beyond those identified here for operation and maintenance of the monitoring system.

Before operating the monitoring system, carefully read this manual, the Instructions for Use for the accessories, and all precautionary information and specifications.

1.3. Safety Information

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

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

1.3.1. 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 Accessories/Parts List, page 107.

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.

1.3.2. Patient Monitoring and Safety

Warning: The monitoring system should not be used as the sole basis for diagnosis or therapy. It is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.

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

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.

1.3.3. 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: Monitoring system readings can be affected by certain patient conditions. Refer to Patient Conditions, page 91.

Warning: Explosion hazard — When replacing the battery, do not use the incorrect type. Use only the battery available from Medtronic. See Accessories/Parts List, page 107.

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.

1.3.4. 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.

Warning: Failure to cover the sensor site with opaque material when operating under high ambient light conditions may result in poor performance.

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

1.3.5. 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.

1.3.6. 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

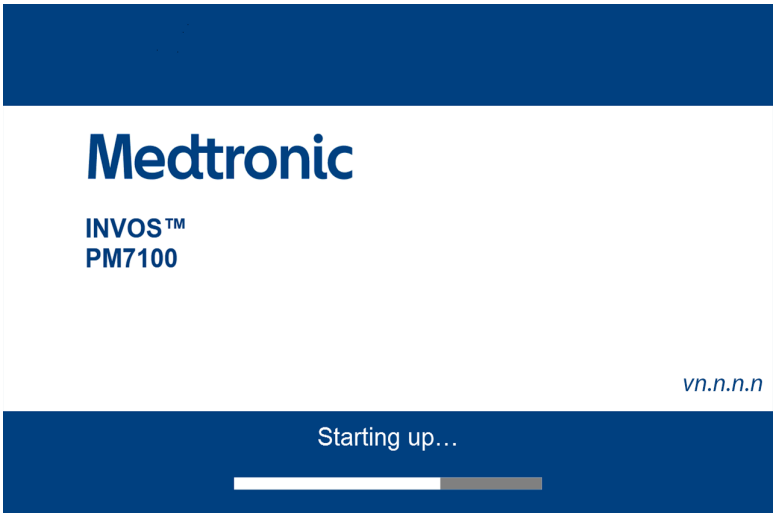
1.800.635.5267 or 1.925.463.4635

or contact a local Medtronic representative

www.medtronic.com

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. Start-up Screen Showing Code Version



Note: An authorized technician can view serial numbers and software versions through the monitoring system's service mode. Refer to the monitoring system's service manual.

1.4.2. Related Documents

- **INVOS™ Adult rSO_2 Sensor Instructions for Use** — Provides important information about sensor selection and use.
- **INVOS™ Preamplifier Instructions for Use** — Provides instructions for connecting the monitoring system's preamplifiers.
- **INVOS™ Patient Monitor Service Manual** — Provides information to authorized technicians for use when servicing the monitoring system.

1.5. Warranty Information

To obtain product warranty information, contact Medtronic or a local Medtronic representative. See Technical Services, page 10.

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.

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 Chapter 9, Accessories, page 107

Monitoring system features include:

- User configurable rSO_2 baselines (page 52), alarm limits (page 62), and AUC thresholds (page 70)
- Physiological and technical alarm reporting (page 99)
- User configurable data display (rSO_2, change from baseline, sensor labels, and trend data) (Figure 9, page 20)
- Alarm silencing (page 64)
- Event marking (page 66)
- Visual representations of sensor locations (page 47)
- Sensor functional state (page 99):
  - Sensor off
  - Sensor disconnect
  - Sensor fault
- Case history storage and export (page 73)

- Real-time data output to external devices such as a Philips multi-parameter system or PC (page 78)
- VGA, Serial (RS-232), and USB interfaces (Figure 4, page 16 and Figure 7, page 19)

2.3. Indications for Use

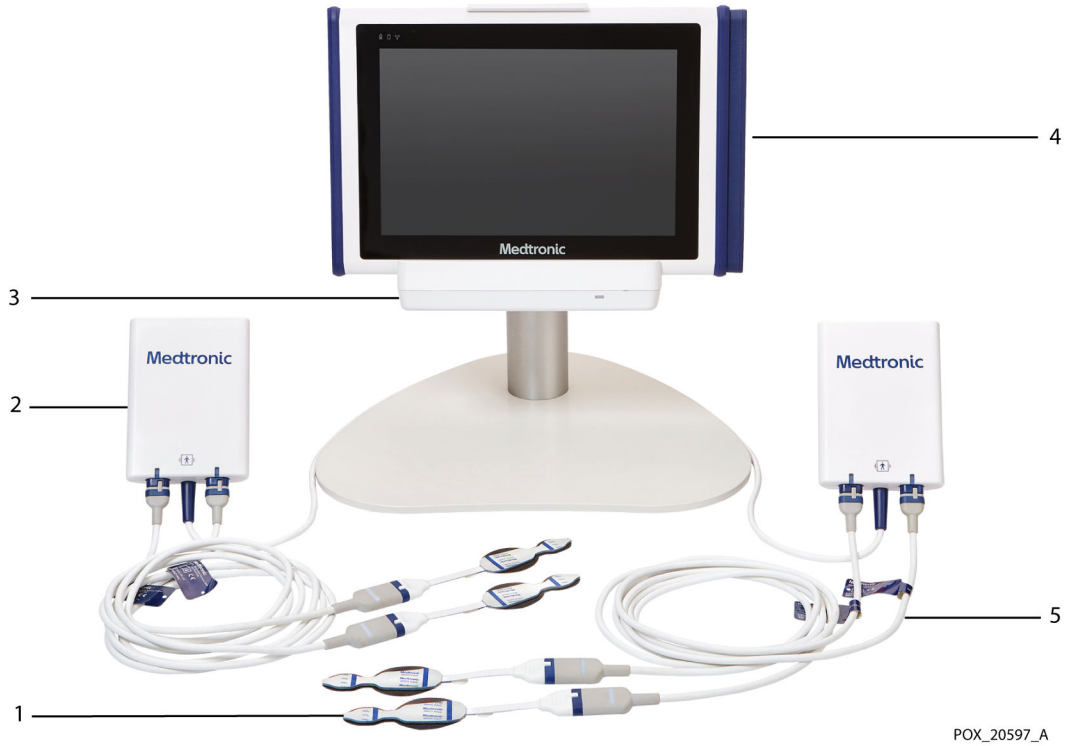
The INVOS™ Patient Monitor, model PM7100, is a noninvasive cerebral/somatic oximetry system intended for use as an adjunct monitor of regional hemoglobin oxygen saturation of blood in the brain or in other tissue beneath the sensor. It is intended for use on individuals greater than 40 kg at risk for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

2.4. Product Views

2.4.1. Full System

2.4.1.1. System Component Overview

Figure 2. INVOS™ Patient Monitor Components



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

2.4.2. Monitor Components

2.4.2.1. Monitor - Front

Figure 3. Monitor - Front

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

2.4.2.2. Monitor - Left Side

Figure 4. 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

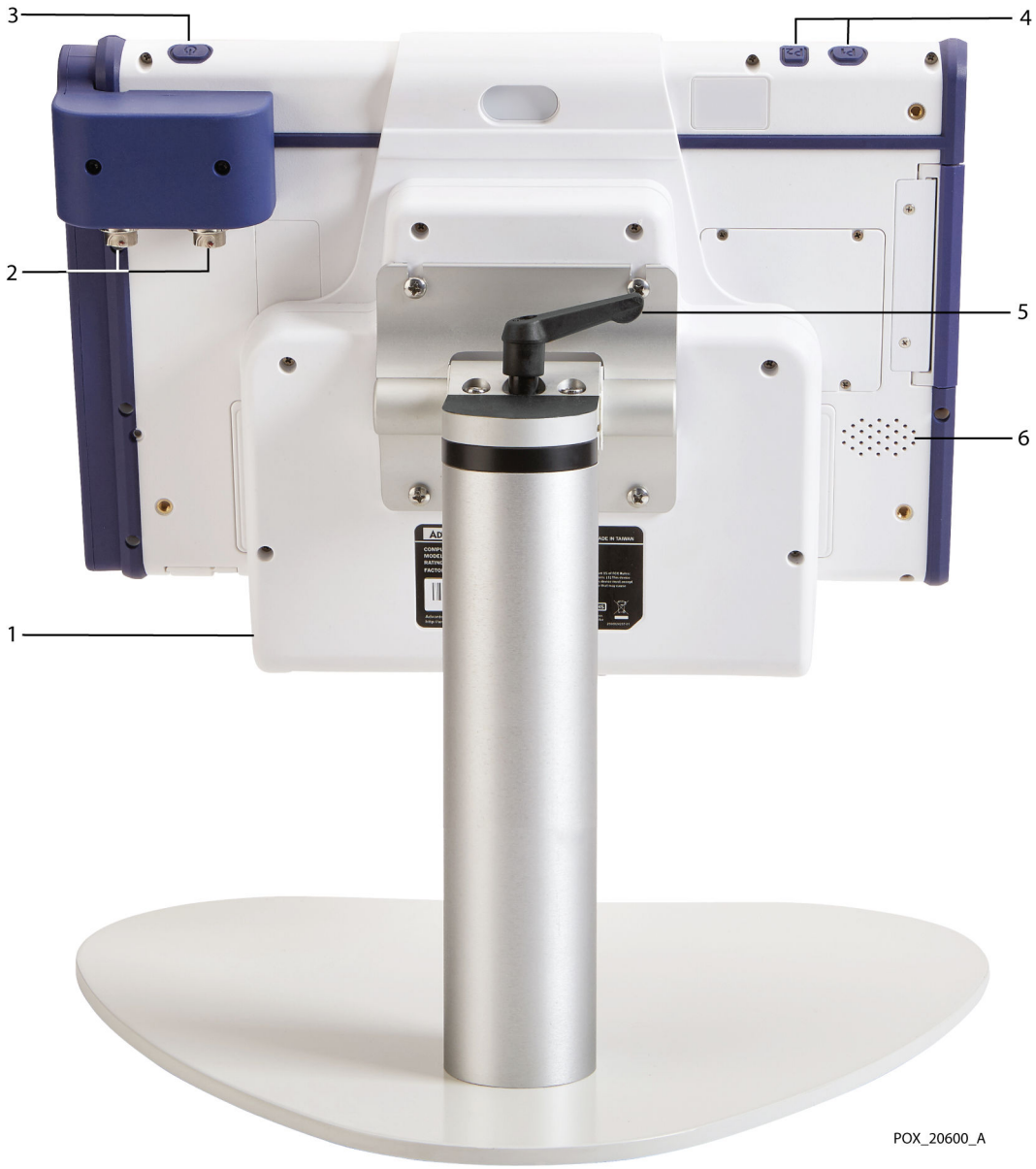
2.4.2.3. Monitor - Right Side

Figure 5. Monitor - Right Side

1. Docking station
2. Connector for preamplifier (x2)
3. Lever for adjusting monitor angle

2.4.2.4. Monitor - Back

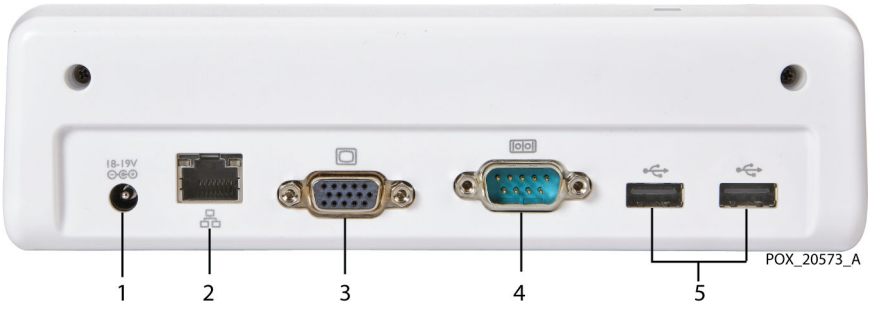
Figure 6. Monitor - Back



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

2.4.2.5. Docking Station

Figure 7. Docking Station - Bottom View



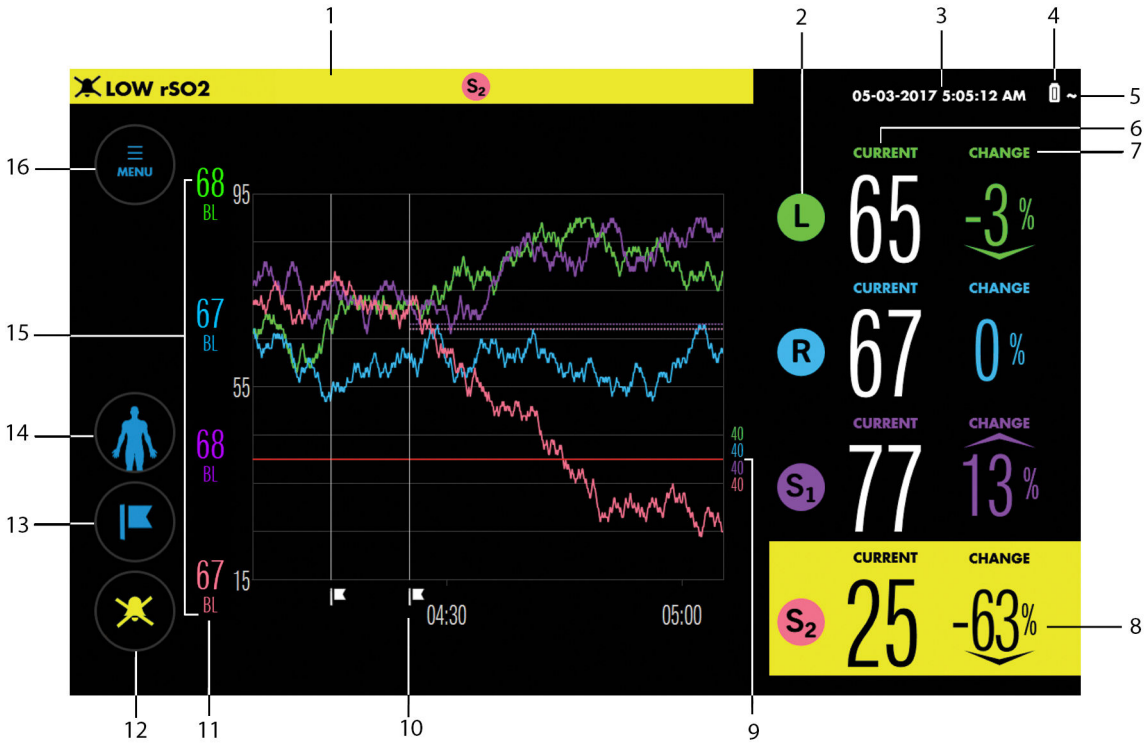
1. Power input connection (DC in jack)
2. LAN port (not used, disabled)
3. VGA port
4. Serial port (RS-232)
5. USB 2.0 port (x2)

Figure 8. Docking Station - Connector for Monitor

1. Docking station
2. Connector for monitor

2.4.2.6. Monitoring Screen

Figure 9. 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 60. 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 65.
2	L	Sensor icons	Each sensor icon has a label indicating its location on the patient. See Changing the On-Screen Sensor Labels, page 50.
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	Indicates that the monitoring system is connected to AC power and the battery is charging.

(continued)

		AC power indicator	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 62.
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 66.
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 52.
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 60 and Silencing or Pausing Alarms, page 64.
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 66.
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 42, Repositioning On-Screen Sensors, page 47, and Assigning or Modifying the Patient ID, page 49.
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 55.
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 41.

3. Installation

3.1. Overview

This chapter contains information for the installation and set up of the INVOS™ patient monitor (the "monitoring system") prior to first-time use.

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. Unpacking and Inspection

The monitoring system ships in multiple cartons. Upon receipt of the monitoring system, examine the cartons for evidence of damage. Contact Medtronic Technical Services immediately if a carton appears damaged. See Technical Services, page 10.

Standard items shipped are listed in Table 1. Quantities of some items may vary based on customer requirements. Check all items for any sign of damage.

If you need to return the monitoring system for any reason, contact Medtronic Technical Services. See Technical Services, page 10.

Note: Save the cartons and packing material for any future transport.

Table 1. Monitoring System - Standard Shipped Items

Item	Quantity
Patient monitor	1
Lithium-ion battery	1
Patient monitor stand	1
VESA™* docking station	1

Table 1. Monitoring System - Standard Shipped Items (continued)

Item	Quantity
Preamplifiers	1 or 2
Reusable sensor cables (RSCs)	2 or 4
INVOS™ adult rSO_2 sensors	Box of 5, 10, or 20
AC power supply	1
Power cord	1
Operator's manual (on USB flash drive)[a]	1

a The manual may be printed from the included USB drive. Order a printed Operator's Manual or Service Manual from Medtronic Technical Services or your local Medtronic representative. See Technical Services, page 10.

3.4. Power Options

The monitoring system operates on AC power or on a rechargeable internal battery. Medtronic recommends operating the monitoring system on AC power whenever possible. Use battery power only when necessary, such as while moving the patient within the facility or during AC power interruptions.

3.4.1. AC Power

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

The power input connection for the monitoring system is at the bottom of the docking station. Always use the provided AC power cord and power supply.

Figure 10. Power Input Connection at Bottom of Docking Station

When the power supply is connected to the AC outlet and the docking station, the power indicator on the docking station illuminates blue (Figure 11).

Figure 11. Docking Station Power Indicator

AC power to the monitoring system is indicated as follows:

Table 2. AC Power Indicators

Status	Monitor LED	Screen icon
AC connected (battery charging)		
AC connected (battery fully charged)		
AC not connected		One of the following, depending on battery charge level. See Table 3, page 26. 

3.4.2. Battery Power

Note: Whenever the monitoring system is connected to AC power, the battery will charge as needed.

The monitoring system includes a rechargeable lithium-ion battery located in the back of the monitor.

Figure 12. Battery Location at Back of Monitor

Medtronic strongly recommends using AC power during continuous operation. Use battery power only when necessary, such as during transport within a facility. If the monitoring system is operating on battery power, alarms are generated if the battery reaches low or critical levels. When the battery is depleted, the monitoring system shuts down immediately.

3.4.2.1. Battery Status Indicators

If using the monitoring system on battery power, be sure to frequently check the battery status (Table 3).

Table 3. Battery Status Indicators - Monitoring System Operating on Battery Power

Battery status	Screen icon	Audible alarm	Message
Charged (33% - 100% remaining)		N/A	N/A
Low (<33% remaining)		Medium priority	BATTERY LOW
Critically Low (<5% remaining)		Medium priority	BATTERY CRITICALLY LOW
Malfunctioning		Low priority - no audible alarm	BATTERY FAILURE

3.4.2.2. Battery Life

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

For maximum battery reliability, replace the battery on a regular basis. Medtronic recommends replacing the battery once every 2 years. If the battery will not sustain monitoring for more than approximately 1 hour when fully charged, replace the battery immediately.

Contact Medtronic or a local Medtronic representative for information about obtaining replacement batteries. See Technical Services, page 10.

3.5. Setup

Use the following instructions to prepare the monitoring system for first use. See Chapter 4, Operation, page 37 for additional steps to be performed by the clinician when monitoring a patient.

- Install the Battery, page 27
- Insert the Monitor into the Docking Station, page 28
- Connect the Preamplifier(s), page 29
- Connect the Reusable Sensor Cables (RSCs), page 30
- Apply Power, page 31
- Set Institutional Defaults, page 33
- Power Off the Monitoring System, page 34
- Position the Monitoring System in the Clinical Setting, page 34

3.5.1. 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 Apply Power, page 31 for charging information).

To install the battery:

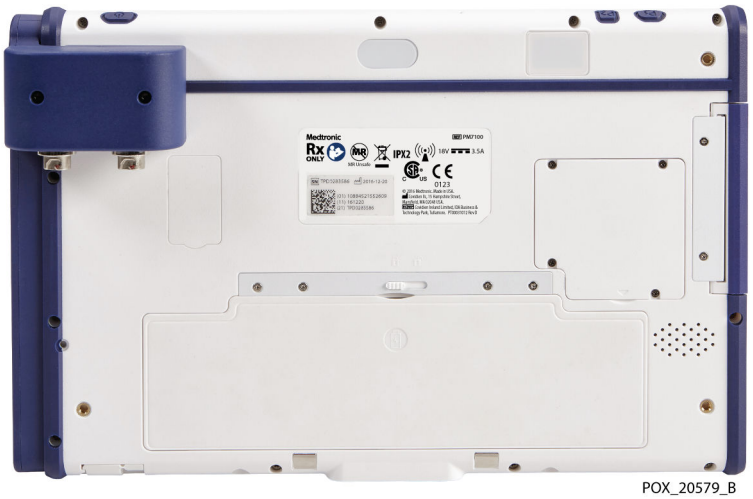
1. Remove the battery from its packaging.
2. At the back of the monitor, make sure that the battery latch, located above the battery slot, is to the right (Figure 13).

Figure 13. 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 14).

Figure 14. Battery Installed in Monitor



3.5.2. Insert the Monitor into the Docking Station

The docking station is intended to hold the monitor during typical use of the monitoring system. You can mount the docking station on the provided stand or on other VESA™*-

compatible equipment capable of supporting at least 5.1 lb (2.3 kg) (VESA™* FDMI MIS-D, 75).

Monitor stand use: If you intend to use the monitor stand, attach the docking station to the stand using the provided hardware. Refer to the instructions provided with the monitor stand.

To insert the monitor into the docking station:

1. Align the connector at the bottom of the monitor with the connector in the docking station (Figure 15).
2. Press the monitor down into the docking station until the connectors engage. Pegs and guide holes in the docking station and monitor ensure proper alignment.
3. Press the monitor back into the clip at the top of the docking station until it fully engages.

Figure 15. Monitor Mounted in Docking Station

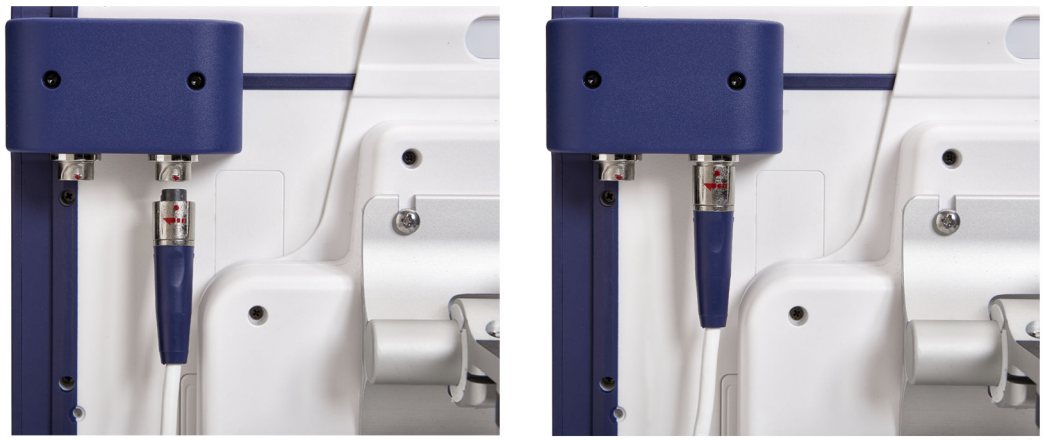
3.5.3. Connect the Preamplifier(s)

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

To connect the preamplifier(s) to the monitor:

1. Align the red dot on the preamplifier cable connector with the red marking on the monitor input connection (Figure 16).

Figure 16. Connecting the Preamplifier Cable



POX_20581_A

2. Insert the cable connector directly upward into the connection until the locking sleeve rotates and clicks into place.
3. Repeat steps if using a second preamplifier.

Note: To disconnect a preamplifier cable from the monitor, grasp the locking sleeve and rotate it in the direction indicated by the arrow while pulling downward.

3.5.4. Connect the Reusable Sensor Cables (RSCs)

Each preamplifier allows connection of up to two sensors via reusable sensor cables (RSCs). Using two preamplifiers, the monitoring system can accommodate up to four RSCs and four sensors.

To connect the RSCs:

1. Align the RSC's male connector with the connection slot on the preamplifier. The connector and slot are keyed to guide insertion.
2. Press firmly until the connector snaps into place. Ensure that the clip on the connector engages completely with the connection slot.

Figure 17. Connecting the RSC to the Preamplifier

3. Repeat these steps for each RSC to be used.
4. Coil and secure the RSC cabling to avoid tangling.

3.5.5. Apply 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.

Before applying power, refer to Power Options, page 24 to understand the requirements for using AC power and battery power.

To power on the monitoring system:

1. Ensure that the AC outlet is properly grounded and supplies the specified voltage and frequency. See Electrical, page 112 for voltage and frequency specifications.
2. Connect the power supply to the power input connection on the bottom of the docking station.

Figure 18. Power Input Connection at Bottom of Docking Station

3. Connect the AC power cord to the power supply and the AC outlet. Verify that the blue power indicator on the docking station is illuminated (Figure 11, page 25).

   The battery indicator at the top left of the monitor indicates the charge status. The battery will charge as necessary when the monitoring system is connected to AC power.

    Charging

    Fully charged

4. Press the Power button on top of the monitor.

Figure 19. Power Button on Top of Monitor

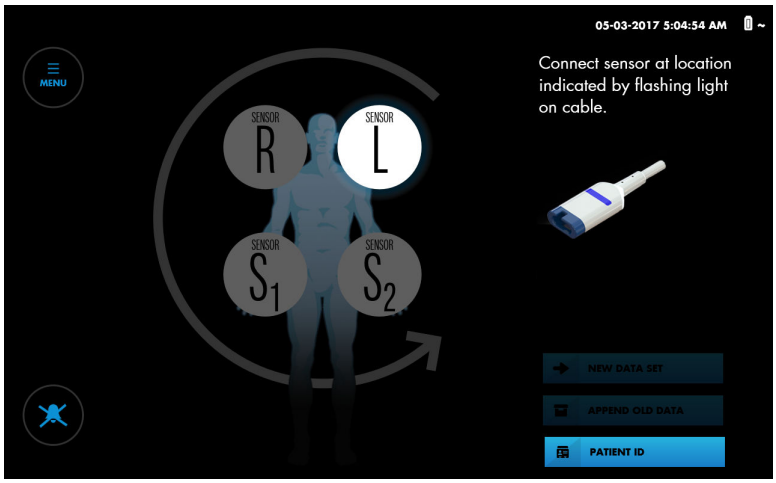
   While the monitoring system performs its power-on self-test (POST), a progress bar appears at the bottom of the screen.

5. Ensure that the POST pass tone sounds when POST completes. See POST Pass Tone, page 114 for tone specifications.

   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.

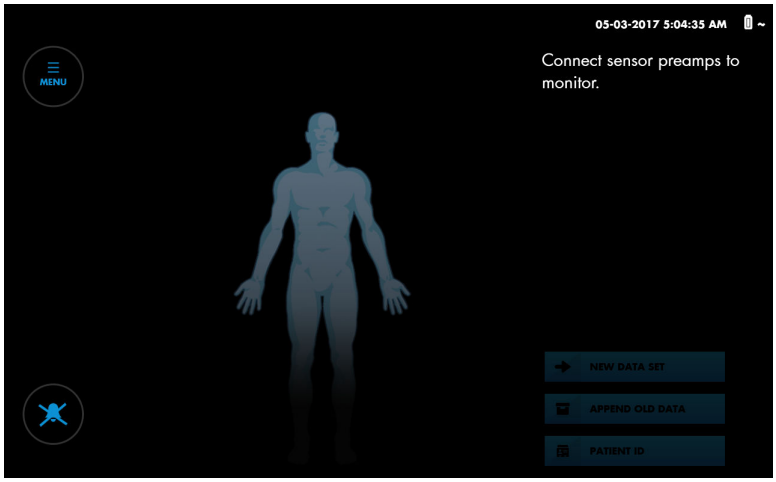
   Once POST is complete, the Set-up screen appears (Figure 20).

Figure 20. Set-Up Screen - Preamplifier(s) Connected



Note: If no preamplifiers are connected to the monitoring system, the screen prompts you to connect them (Figure 21). See Connect the Preamplifier(s), page 29.

Figure 21. Set-Up Screen - No Preamplifier(s) Connected



Note: Make sure that the battery is fully charged prior to clinical use. Table 2, page 25 describes the charging status indicators.

3.5.6. Set Institutional Defaults

Table 4 describes the institutional settings available for the monitoring system. Institutional defaults must be set by an authorized technician. Refer to the monitoring system's service manual. Refer to Table 6, page 40 for information about additional options that can be set or changed by the clinician.

Table 4. 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
Alarm audio off/pause duration	INDEFINITE, 2 MINS	INDEFINITE - When silenced by the user, alarms remain silent until the user unsilences them
Alarm reminder signal	ON, OFF	OFF
Line frequency	50 Hz, 60 Hz	60 Hz
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)
Date format	DD MM YYYY, YYYY MM DD, MM DD YYYY	MM DD YYYY
Time	(Select hh:mm)	N/A
Time format	24 hr, 12 hr	12 hr
Language	DANISH, DUTCH, ENGLISH, FRENCH, GERMAN, GREEK, HUNGARIAN, ITALIAN, NORWEGIAN, POLISH, PORTUGUESE, ROMANIAN, RUSSIAN, SLOVAK, SPANISH, SWEDISH	ENGLISH
Serial port	OFF, PC LINK 1, PC LINK 2, CLINICAL TEST SETUP, VUE LINK	OFF

3.5.7. Power Off the Monitoring System

To power off the monitoring system:

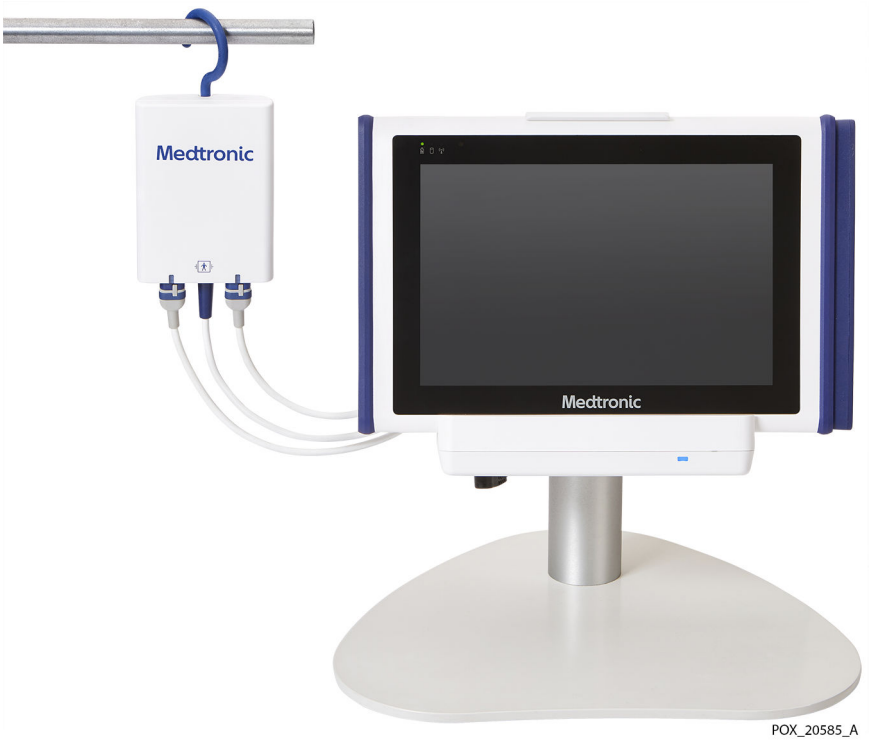
1. Press the Power button on top of the monitor.
2. Observe that the screen goes completely dark. The battery indicator on the monitor and the power indicator on the docking station remain illuminated as long as power is connected.

3.5.8. Position the Monitoring System in the Clinical Setting

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

Users may choose from a variety of mounting configurations, including the provided monitor stand or other VESA™*-compatible mounting options capable of supporting at least 5.1 lb (2.3 kg) (VESA™* FDMI MIS-D, 75). In addition, the preamplifiers have a fold-away swivel hook for attachment to rails or poles (Figure 22).

Figure 22. Monitoring System on Stand with Preamplifier Hung on Rail



Be sure to consider the following when positioning the monitoring system:

- **Docking station use** — The docking station is intended to hold the monitor during typical use and provides the power connection for the monitoring system. Make sure the docking station is accessible at all times. See Insert the Monitor into the Docking Station, page 28.
- **Monitor stand use** — When using the monitor stand, place the stand on a sturdy flat surface. Use the lever on the back of the stand to adjust the angle of the monitor for best visibility.
- **Power outlet access and power cord position** — Ensure that the power outlet used for the monitoring system is easily accessible.
- **Cable routing** — Position the monitoring system for ease of access to all cabling. You can use the fold-away hooks on the preamplifiers to hang them from rails or poles. Ensure that cables are routed so that there is no risk of patient entanglement or strangulation.
- **Monitor access and visibility** — Ensure that the operator can easily access and view the monitor while monitoring. Choose a location that allows visual communication of rSO_2 values and alarms. See Physical Characteristics, page 111 for visibility specifications.

4. Operation

4.1. Overview

This chapter explains how to use the INVOS™ patient monitor (the “monitoring system”) to view and collect patient regional oxygen saturation (rSO_2) data.

This chapter assumes that the monitoring system has been installed at the location of use and tested by the institution. See Installation, Chapter 3, Installation, page 23 for full installation instructions.

4.2. Safety Reminders

Warning: The monitoring system should not be used as the sole basis for diagnosis or therapy. It is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.

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

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

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: 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: Monitoring system readings can be affected by certain patient conditions. Refer to Patient Conditions, page 91.

Warning: Failure to cover the sensor site with opaque material when operating under high ambient light conditions may result in poor performance.

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: 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.

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

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.

Refer to Safety Information, page 7 for additional warnings and cautions regarding use of the monitoring system.

4.3. Quick Start

If you are familiar with operating the monitoring system, follow the steps in Table 5 to set up the device and monitor a patient. Be sure you have reviewed the information in Safety Reminders, page 37 before monitoring a patient.

If you are not familiar with operating the monitoring system, carefully read all instructions in this chapter, beginning with Set Up for Patient Monitoring, page 42.

Table 5. Quick Start Steps

1	**Make sure all components of the monitoring system are present:** Monitor, docking station, power supply, power cord, preamplifier(s), reusable sensor cables (RSCs), INVOS™ rSO_2 sensors	See Set Up for Patient Monitoring, page 42
2	**Attach up to four INVOS™ rSO_2 sensors to the patient**	See the Instructions for Use provided with the sensors
3	**Power on the monitoring system**	See Set Up for Patient Monitoring, page 42
4	**Optionally, change the sensor placement sequence**	See Changing the Sensor Placement Sequence, page 46
5	**Connect the sensors to the RSCs, following the onscreen prompts, and verify the sensor locations**	See Set Up for Patient Monitoring, page 42
6	**Secure all cables to avoid patient skin injury or entanglement**	See Set Up for Patient Monitoring, page 42
7	**Optionally, enter a patient ID**	See Assigning or Modifying the Patient ID, page 49
8	**Begin monitoring:** • For a new case, press NEW DATA SET • To continue a case, press APPEND OLD DATA	See Set Up for Patient Monitoring, page 42
9	**Set baselines** Press MENU, SET BASELINES	See Baselines, page 52
10	**Set or change alarm limits, as desired** Press MENU, ALARM LIMITS	See Setting Alarm Limits, page 62
11	**Optionally, change the trend view:** • Number of graphs • Trend-line averaging • Time scale	See Trend View Management, page 55
12	**Optionally, change the on-screen sensor labels**	See Changing the On-Screen Sensor Labels, page 50
13	**Optionally, check and modify the list of event markers**	See Changing the Event List, page 69
14	**Optionally, change Area Under the Curve (AUC) thresholds**	See Changing the AUC Threshold, page 71
15	**Optionally, adjust the screen brightness**	See Changing the Screen Brightness, page 51
16	**Optionally, adjust the alarm volume**	See Changing the Alarm Volume, page 63

Table 5. Quick Start Steps (continued)

17	**Respond to alarms, as necessary:** • Alarm indicators • Alarm message lookup • Silence or pause alarms • Dismiss alarms	See: • Alarm Indicators, page 60 • Alarm Messages, page 99 • Silencing or Pausing Alarms, page 64 • Dismissing an Alarm, page 65
18	**Mark events, as desired**	See Event Marks, page 66
19	**Finish monitoring**	See Finish Monitoring, page 72

4.4. Operational Defaults

The following table lists default settings for the monitoring system. Some of these settings can be changed by the user, while others require authorized access, as indicated.

Table 6. Operational Defaults

Item	Available settings	Default
Upper alarm limits	OFF, ON	OFF See Setting Alarm Limits, page 62
Lower alarm limits	MANUAL, AUTO	MANUAL See Setting Alarm Limits, page 62
Upper rSO_2 limit	20 - 95	If ON, default is 90 See Setting Alarm Limits, page 62
Lower rSO_2 limit	MANUAL: 15 - 90 AUTO: 5 - 30	MANUAL: 40 AUTO: 20 See Setting Alarm Limits, page 62
Silence alarms at startup	YES, NO	NO - Alarm audio is on by default, but alarm audio may be silenced or paused by the user. See Silencing or Pausing Alarms, page 64. This setting may be changed by an authorized technician.
Alarm audio off/ pause duration	INDEFINITE, 2 MINS	INDEFINITE - When silenced, alarms remain silent until the user unsilences them. See Alarm Silence Duration, page 65. This setting may be changed by an authorized technician.
Alarm reminder signal	ON, OFF	OFF - No reminder when alarms are silenced This setting may be changed by an authorized technician.
Line frequency	50 Hz, 60 Hz	60 Hz This setting may be changed by an authorized technician.
Alarm volume	1 - 10	5 See Changing the Alarm Volume, page 63
Screen brightness	1 - 10	7 See Changing the Screen Brightness, page 51
Time format	24 hr, 12 hr	12 hr This setting may be changed by an authorized technician.

Table 6. Operational Defaults (continued)

Item	Available settings	Default
Date format	DD MM YYYY, YYYY MM DD, MM DD YYY	MM DD YYYY This setting may be changed by an authorized technician.
Language	Danish, Dutch, English, French, German, Greek, Hungarian, Italian, Norwegian, Polish, Portuguese, Romanian, Russian, Slovak, Spanish, Swedish	English This setting may be changed by an authorized technician.
Trend line averaging	ON, OFF	OFF See Turning Trend Line Averaging On/Off, page 57
Trend axis view	TWO AXIS VIEW, ONE AXIS VIEW	ONE AXIS VIEW See Changing the Trend View - Two Graphs or One Graph, page 56
Trend time scale (x-axis)	1, 2, 4, 8, 12, 24 hours	1 hour See Zooming the Trend View, page 58
Sensor placement sequence	4, 3, or 2 sensors	4 sensors See Changing the Sensor Placement Sequence, page 46
AUC threshold type	FIXED, % BELOW BASELINE	FIXED See Changing the AUC Threshold, page 71
AUC threshold	FIXED: 30 - 60 % BELOW BASELINE: 0 - 30%	FIXED: 50 % BELOW BASELINE: 25% See Changing the AUC Threshold, page 71
Serial port	OFF, PC LINK 1, PC LINK 2, CLINICAL TEST SETUP, VUE LINK	OFF This setting may be changed by an authorized technician.

4.5. Menu Structure

Table 7. Menu Structure

MENU			
	**ALARM LIMITS**	UPPER LIMITS	
		LOWER LIMITS	
	SETTINGS	GENERAL	SCREEN BRIGHTNESS
			SENSOR PLACEMENT SEQUENCE
		ALARMS	ALARM VOLUME
		TRENDS	TREND LINE AVERAGING
			TWO AXIS VIEW/ONE AXIS VIEW
		EVENTS	
	CASE HISTORIES [a]		
	SET BASELINES [b]		
	AREA UNDER CURVE [2]	RESET AUC	
		THRESHOLD	

[a] Available only when no sensors are connected to the monitoring system.
[b] Available only when monitoring has begun.

4.6. Monitoring System Memory

The monitoring system stores the following information about the current case in memory:

- Case ID
- Current baselines (value and time baselines were obtained)
- Current sensor positions:
    - The monitoring system remembers the last sensors that were connected, the locations they were assigned (for example, left cerebral), and their last baseline values.
    - The monitoring system also remembers the last reusable sensor cable (RSC) and preamplifier port assignments (for example, which RSC and preamplifier the left cerebral sensor was connected to).
    - The previously used sensor location overrides the last RSC/preamplifier port assignment. For example, if you plug what was the right cerebral sensor into what was the left cerebral RSC/preamplifier port, it will show up on screen as the right cerebral sensor.

Because the monitoring system retains this information for an ongoing case, you can disconnect sensors from the system and reconnect the same sensors without having to reassign sensor locations or perform the sensor set-up routine.

Table 8 describes some common situations, the actions you should perform, and how the system reacts.

Table 8. System Memory - Common Situations and Recommended Actions

When this situation occurs...	Perform this action...
You have started monitoring a patient but notice that you have the sensor locations swapped.	Navigate to the sensor Set-up screen (see Repositioning On-Screen Sensors, page 47), drag and drop the sensors to the correct locations on the screen, confirm the new locations, then press APPEND OLD DATA to resume monitoring.
Sensors need to be disconnected from the monitoring system during a case (for example, to reroute the cables).	Disconnect and reconnect the affected sensors. The monitoring system automatically assigns the sensors back to the proper locations.
The monitoring system is powered off and back on during a case.	No action is necessary. The monitoring system automatically assigns sensors to the proper location and resumes monitoring.
A case has ended.	Unplug and discard all sensors that were used during the case. Dismiss the “Sensor Not Connected” alarm. The monitoring system returns to the Set-up screen.

4.7. Set Up for Patient Monitoring

The following steps assume you are ready to begin monitoring a patient in a surgical setting or other hospital environment. Be sure you have reviewed the information in Safety Reminders, page 37 before monitoring a patient.

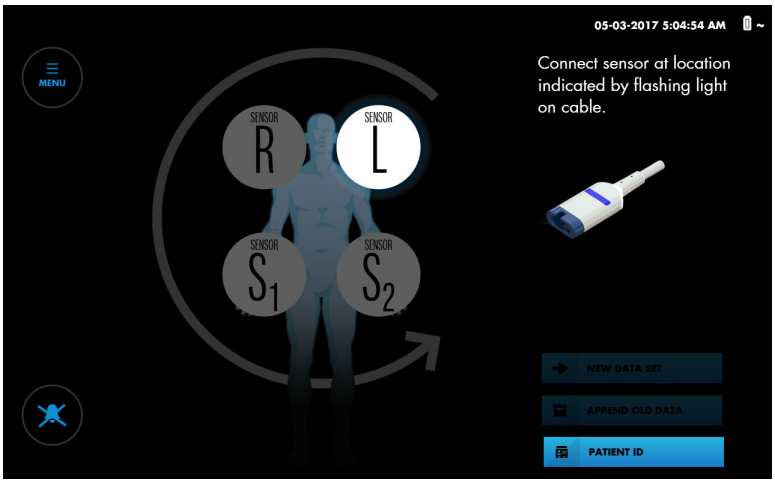
To set up the monitoring system:

1. Make sure all components of the monitoring system are present:
   - **Monitor**
   - **Docking station** - Recommended for extended monitoring.
   - **Power supply and power cord** - AC power is recommended for extended monitoring. You can use battery power briefly, if necessary, such as when transporting a patient between locations within a hospital.
   - **Preamplifiers** - Use one or two preamplifiers, depending on the number of sites to be monitored. Each preamplifier accommodates two sensors. If no preamplifiers are connected, see Connect the Preamplifier(s), page 29 for instructions.
   - **Reusable sensor cables (RSCs)** - Use one RSC per sensor, up to two per preamplifier. If no RSCs are connected, see Connect the Reusable Sensor Cables (RSCs), page 30, for instructions.
   - **INVOS™ rSO_2 sensors** - Before use, carefully read the sensor Instructions for Use, including all warnings, cautions, and instructions.
2. Determine the sites you will monitor on the patient. Select the correct type of INVOS™ rSO_2 sensor for your patient; do not mix sensor types. Attach up to four sensors to the patient. Refer to the Instructions for Use provided with the sensors for application instructions.
3. Power on the monitoring system:
   a. Make sure that the monitoring system's power supply is plugged into the docking station and a properly grounded hospital mains outlet (see AC Power, page 24). You may operate the monitoring system briefly on battery power if necessary, but AC power is recommended for extended monitoring. See Power Options, page 24 for additional information about powering the monitoring system.
   b. Press the Power button on top of the monitor (see Apply Power, page 31). If operating on battery power, check the battery status indicator on the screen to determine whether the battery needs charging (see Table 3, page 26).
   c. Ensure that the POST pass tone sounds when POST completes. See POST Pass Tone, page 114 for tone specifications.

      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.

      Once POST is complete, the Set-up screen appears (Figure 23).

Figure 23. Set-Up Screen - Prompt for Sensor Connection



4. Optionally, you can set the sensor sequence for the number of sensors you are using. If you are using fewer than four sensors, you can set the number to three or two for onscreen representations. See Changing the Sensor Placement Sequence, page 46.
5. Connect the RSCs to the sensors that have been applied to the patient:

   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.

   a. Note the highlighted sensor location on screen (Figure 23). Locate the corresponding sensor applied to the patient.
   b. Look for the flashing blue light on the preamplifier and at the end of the corresponding RSC.
   c. Align the sensor's male connector with the connection slot on the RSC. The connector and slot are keyed to guide insertion.
   d. Press firmly until the connector snaps into place. The monitoring system indicates proper connection by displaying an rSO_2 reading at the corresponding sensor location. If the sensor was previously used on the monitoring system, the last baseline obtained on the sensor is also displayed.
   e. Look for the next highlighted sensor location on screen and the next flashing blue light on the preamplifier and RSC. Connect the next sensor to the corresponding RSC.
   f. Repeat these steps for each sensor applied to the patient.
   g. Verify the placement of all sensors by briefly pressing each on-screen sensor location and noting the blue flashing light on the RSC cable. Make sure that the onscreen location matches the sensor location on the patient. If the location does not match, you can reposition the on-screen sensors rather than disconnecting the RSCs. See Repositioning On-Screen Sensors, page 47.

   Note: As you connect the RSCs to sensors applied to the patient, readings are displayed on the Set-up screen. However, trends are not tracked and physiological alarms are disabled. Do not attempt to monitor the patient from the Set-up screen.
6. Check the location of all cables connected to the monitoring system. Make sure that the patient is not lying on any cables or connectors. To prevent entanglement and prolonged contact with patient skin, you can secure the RSCs with the strain-

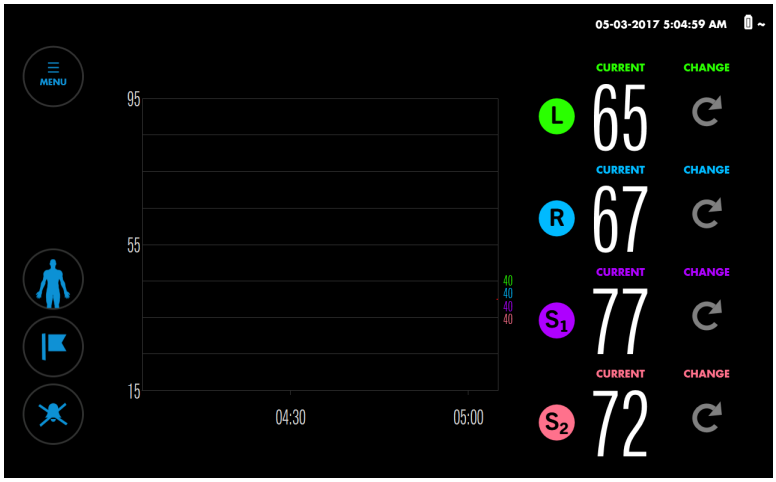
relief clips attached to the cables. Do not place the RSCs, preamplifiers, or cables connecting the preamplifiers to the monitor in contact with the patient.

7. Optionally, enter a patient ID. See Assigning or Modifying the Patient ID, page 49.
8. Begin monitoring by starting a new case or continuing an existing case:
   - For a new case, press NEW DATA SET.
   - To continue a case, press APPEND OLD DATA.

     Note: You can only append to the most recent case. If the append button is greyed out, the append feature is disabled.

   The monitoring screen appears (Figure 24).

Figure 24. Monitoring Screen - New Case - No Baselines Set



Note: If necessary, you can return to the Set-up screen while monitoring by pressing the Patient button:

9. Set baselines. See Baselines, page 52.
10. Set or change alarm limits, as desired. See Setting Alarm Limits, page 62.
11. Optionally, change the trend view. You can view all sensor readings on one graph or two, use trend line averaging, and change the time scale. See Trend View Management, page 55.
12. Optionally, change the on-screen sensor labels. See Changing the On-Screen Sensor Labels, page 50.
13. Optionally, check the list of available event markers and change it if necessary. See Changing the Event List, page 69.
14. Optionally, change the Area Under the Curve (AUC) threshold. See Changing the AUC Threshold, page 71.
15. Optionally, adjust the screen brightness. See Changing the Screen Brightness, page 51.
16. Optionally, adjust the alarm volume. See Changing the Alarm Volume, page 63.

17. As you monitor the patient, you may need to perform the following tasks:
    - Respond to alarms - See Alarm Indicators, page 60, Alarm Messages, page 99, Silencing or Pausing Alarms, page 64, and Dismissing an Alarm, page 65.
    - Mark clinically significant events - See Event Marks, page 66.

    Note: In the event of defibrillation, the monitoring system will recover operation without intervention within 30 seconds after the defibrillation voltage is removed.
18. When the monitoring session is complete, follow the steps in Finish Monitoring, page 72.

4.8. Optional Set-Up Tasks

- Changing the Sensor Placement Sequence, page 46
- Repositioning On-Screen Sensors, page 47
- Assigning or Modifying the Patient ID, page 49
- Changing the On-Screen Sensor Labels, page 50
- Changing the Screen Brightness, page 51

4.8.1. Changing the Sensor Placement Sequence

By default, the monitoring system assumes that you will use two cerebral sensors and two somatic sensors per case. You are prompted to connect the sensors in the following order:

Figure 26. Default Sensor Placement Sequence

If you monitor a different combination of sites, you can change the prompts to one of the following sequences:

Figure 27. Optional Sensor Placement Sequences

To change the sensor placement sequence:

1. Press MENU.

2. Press SETTINGS.
3. Press GENERAL.
4. Under SENSOR PLACEMENT SEQUENCE, press the desired sequence.
5. Press CLOSE.

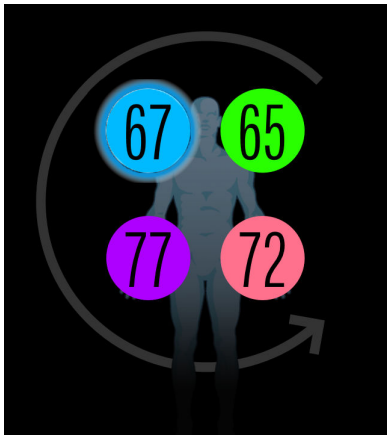
4.8.2. Repositioning On-Screen Sensors

If the on-screen sensor representation does not correspond to sensor placement on the patient, you can reposition the on-screen sensors before or during monitoring.

To reposition the on-screen sensors before monitoring:

1. At the Set-up screen, briefly press an on-screen sensor icon to determine the corresponding sensor's location on the patient. The on-screen sensor icon is highlighted. The blue LEDs on the RSC and preamplifier flash to indicate the corresponding sensor.

Figure 28. Highlighting an On-Screen Sensor

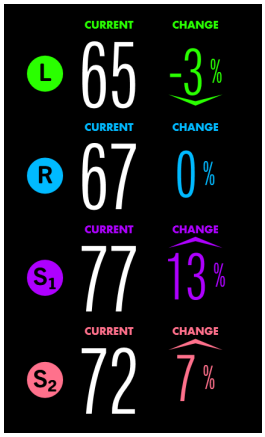


2. Drag the on-screen sensor to a new position and release.
3. Confirm the new position by touching each highlighted on-screen sensor.

To reposition the on-screen sensors while monitoring:

1. At the monitoring screen, briefly press a sensor icon next to the CURRENT values to determine the corresponding sensor's location on the patient. The blue LEDs on the RSC and preamplifier flash to indicate the corresponding sensor.

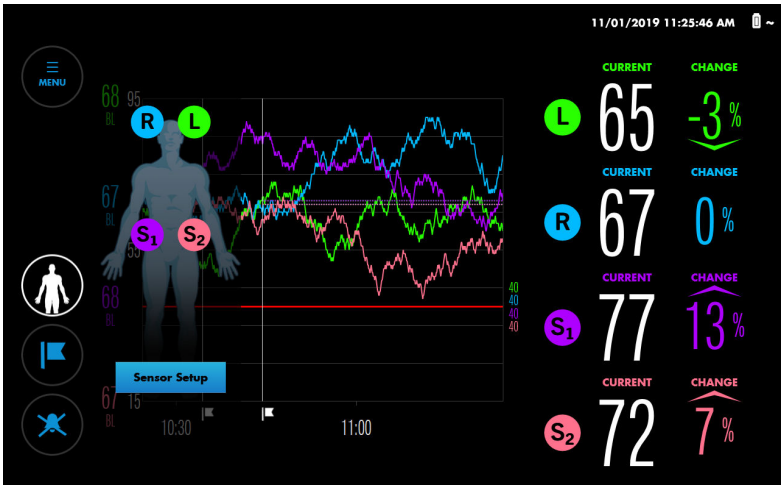
Figure 29. Sensor Icons Next to CURRENT Values (Press to Locate Sensor on Patient)



2. Press the Patient button.

The patient icon appears.

Figure 30. Patient Icon



3. Press Sensor Set-up.
4. At the Set-up screen, drag the on-screen sensor to a new position and release.
5. Confirm the new position by touching each highlighted on-screen sensor.
6. Press APPEND OLD DATA to resume monitoring. Note that there will be a brief gap in the data on the trend graph.

4.8.3. Assigning or Modifying the Patient ID

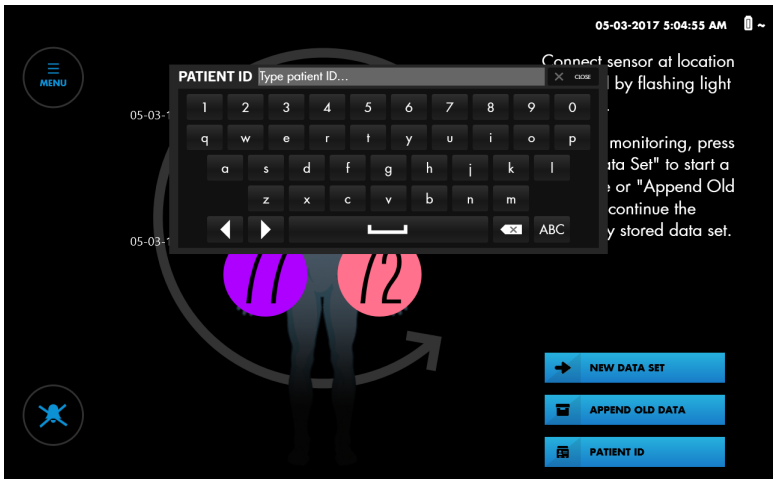
By default, cases are identified by date and start/end time, but do not have patient IDs assigned. As an option, you can assign an alphanumeric patient ID to a case before or during monitoring. You can also modify a patient ID at any time while monitoring.

Note: Follow institutional protocols for assigning patient IDs. Avoid using patient-sensitive information in IDs.

To assign a patient ID before monitoring:

1. Set up the monitoring system as described in Set Up for Patient Monitoring, page 42, but do not begin monitoring.
2. Press PATIENT ID. A keyboard appears.

Figure 31. Entering a Patient ID Before Monitoring



3. Type the patient ID.
4. Press CLOSE to dismiss the keyboard.
5. Begin the case by pressing NEW DATA SET.

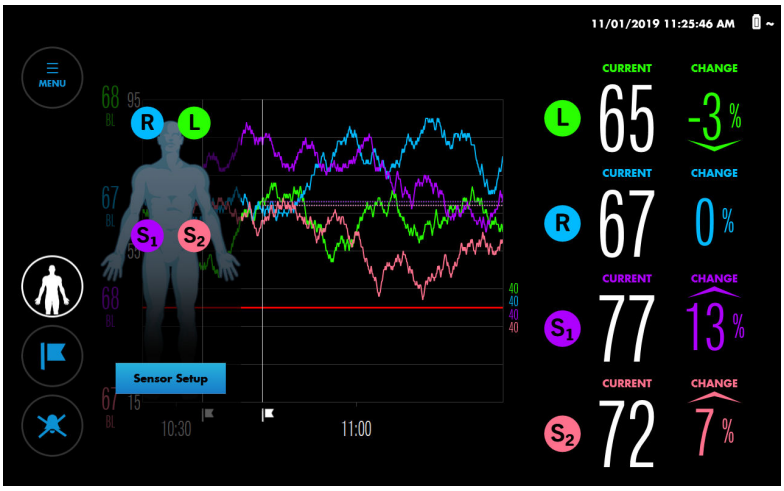
To assign or modify a patient ID while monitoring:

1. After monitoring begins, press the Patient button.

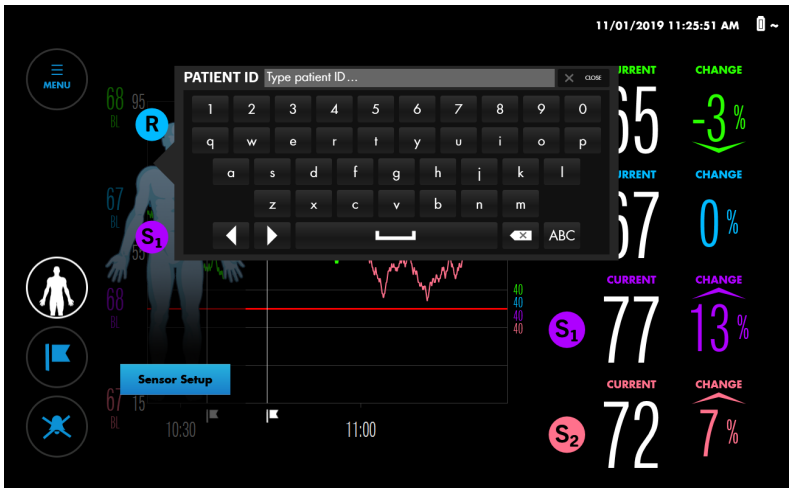
   The patient icon appears.

Figure 32. Patient Icon



2. Press the patient icon. A keyboard appears.

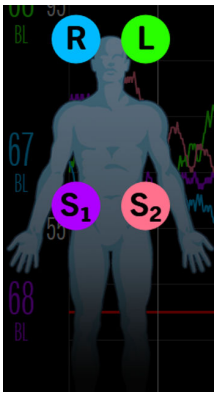
Figure 33. Entering a Patient ID During Monitoring



3. Type the patient ID, or modify the existing ID.
4. Press CLOSE to dismiss the keyboard.
5. Press the Patient button to dismiss the patient icon.

4.8.4. Changing the On-Screen Sensor Labels

By default, sensors are labeled as follows on screen:



L	Left cerebral sensor
R	Right cerebral sensor
S_1	Right somatic sensor
S_2	Left somatic sensor

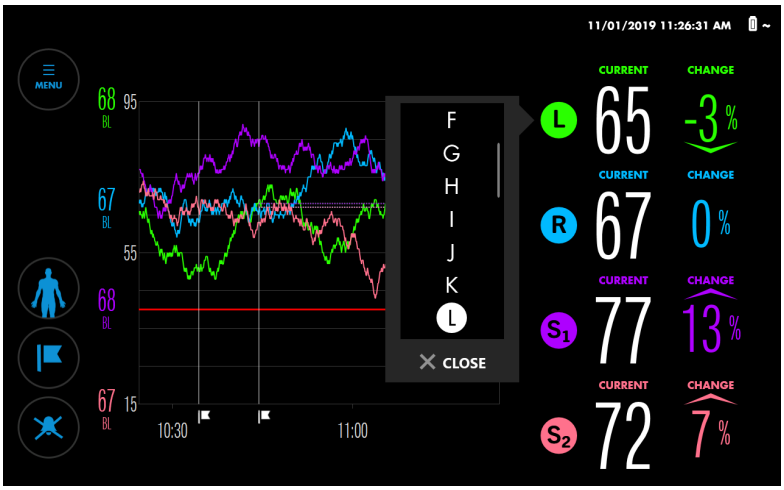
You can change the sensor labels to any alphabetic value (A - Z) or S_1 - S_4.

Note: You can verify the location of a sensor by briefly pressing the sensor label next to the CURRENT value on the monitoring screen. The blue LEDs on the RSC light to indicate the corresponding sensor.

To change a sensor label:

1. After monitoring begins, press and hold the sensor label you want to change. A sensor label menu appears.

Figure 34. Sensor Label Menu



2. Scroll through the choices by pressing anywhere within the list and dragging up or down. When you see the choice you want, press it to highlight it. Note that duplicate labels are not permitted.
3. Press CLOSE.
4. Verify that the sensor label has changed.

4.8.5. Changing the Screen Brightness

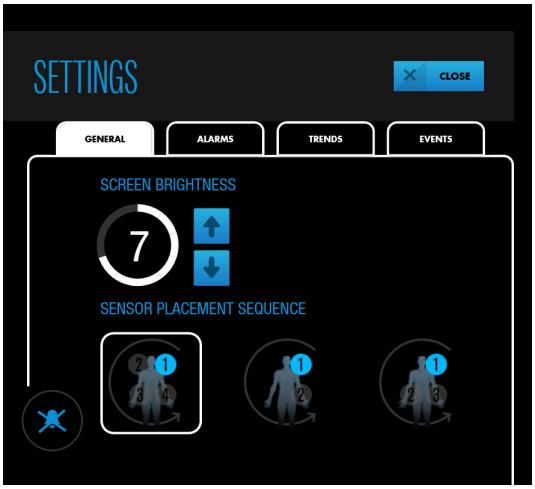
By default, the screen brightness is set to 7 with a range of 1 to 10.

To change the screen brightness:

1. Press MENU.

2. Press SETTINGS.
3. Press GENERAL.

Figure 35. SETTINGS - GENERAL - SCREEN BRIGHTNESS



4. Press an arrow key to increase or decrease the screen brightness.
5. Press CLOSE.

4.9. Baselines

The monitoring system requires an rSO_2 baseline for each tissue region being monitored so that changes from the baseline can be reported. Changes in rSO_2 values of >20% from baseline are considered clinically significant and cause for concern and possible interventions.

When measured rSO_2 values are below or above specific limits, the monitoring system issues an alarm. You can use the monitoring system's default alarm limits or set custom limits, as described in Setting Alarm Limits, page 62.

It is recommended that you obtain baselines while the patient is stable and awake (for example, prior to surgical induction). You can set baselines for all sensors at once or for individual sensors. If necessary, you can retake baselines at any time during monitoring.

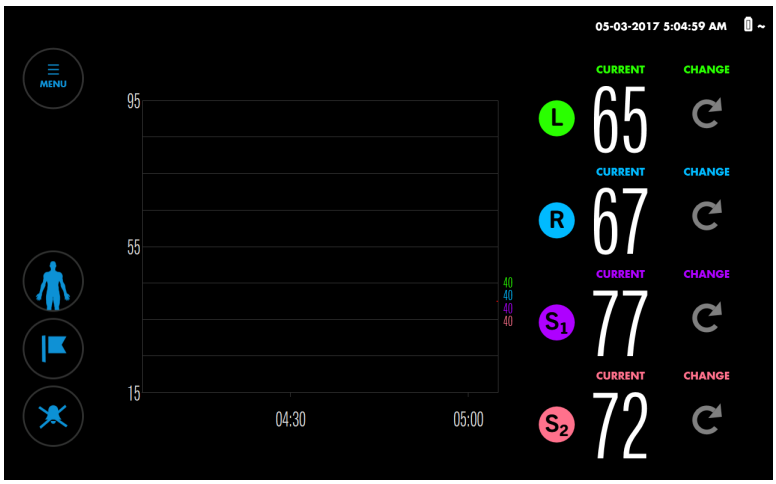
Automatic Baselines: If you do not actively set baselines, the monitoring system automatically sets them approximately five minutes after monitoring begins. You can use these automatic baselines, or retake the baselines. Be aware that sudden large changes in a patient's saturation values during the initiation of monitoring can result in unrepresentative automatically calculated baseline values. If you use automatic baselines, be sure to check the values to make sure they are appropriate. Manually retake the baselines, if necessary.

Note: If you reposition or replace a sensor during monitoring, be sure to retake the baseline for that sensor to ensure a valid representation of rSO_2 at that location.

To set or retake baselines:

1. Set up the monitoring system and begin monitoring as described in Set Up for Patient Monitoring, page 42. While baselines have not yet been set, the monitoring system displays rotating arrows for the CHANGE values next to the CURRENT rSO_2 readings.

Figure 36. Monitoring Screen - New Data Set - No Baselines Set



2. Press MENU.

3. Press SET BASELINES. The SET BASELINES screen either indicates that no baselines have been set (no value next to “BL” as in Figure 37), or, if automatic baselines have taken effect, indicates the values and times they were taken (Figure 38).

Figure 37. SET BASELINES - No Baselines Previously Set

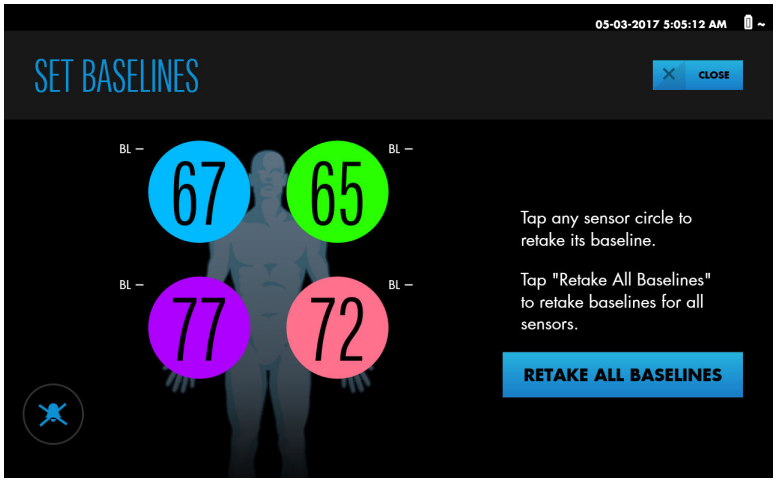
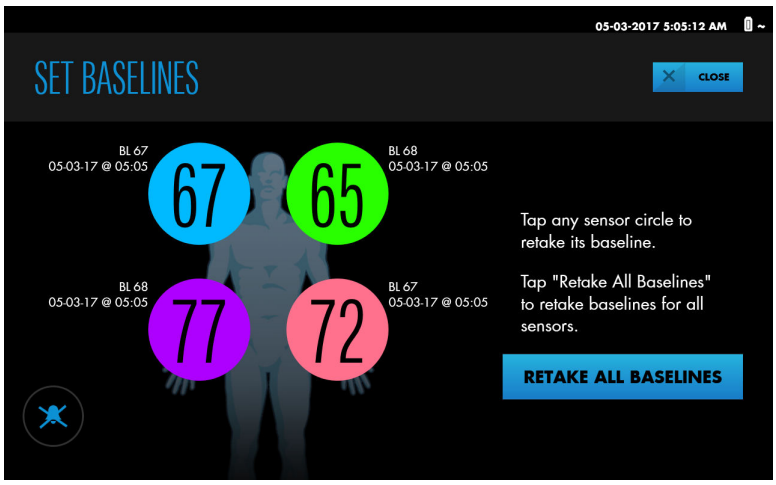


Figure 38. SET BASELINES - Baselines Previously Set

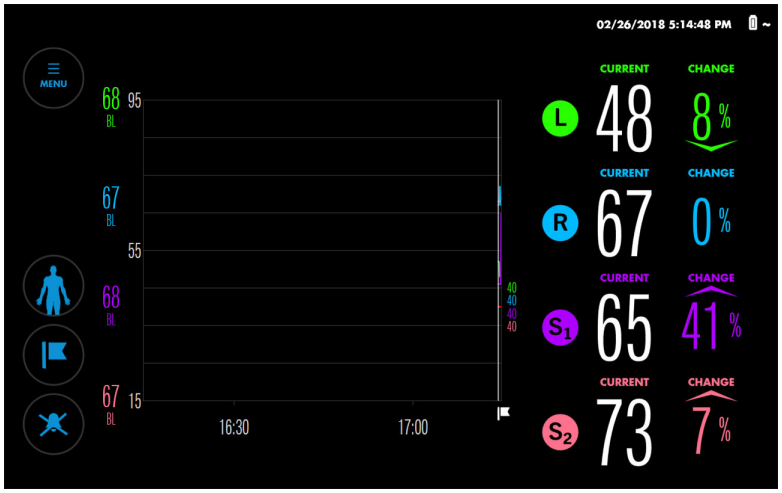


4. Set baselines for an individual sensor or all sensors at once:
    - Individual sensor - Press the on-screen circle representing the sensor. The baseline is set to the current rSO_2 reading at that sensor site. The new baseline value is displayed with the date and time it was taken.
    - All sensors - Press RETAKE ALL BASELINES. The baselines are set to the current rSO_2 readings at all sensor sites. The new baseline values are displayed with the date and time they were taken.
5. Press CLOSE.

The baseline values are indicated to the left of the trend graph, color-coded to the corresponding sensor label. An event marker in the trend graph indicates the point at which the baselines were taken.

The CHANGE values reflect the difference between the baselines and the CURRENT readings.

Figure 39. Monitoring Screen with Baselines Set



Note: If you disconnect and re-connect the same sensor while monitoring, the baseline for that sensor is maintained. If you replace a sensor with a new sensor while monitoring, the baseline calculated with the previous sensor is applied to the new sensor. If the monitoring

system is powered off and back on while monitoring, baselines are maintained for all sensors connected to the system.

4.10. Trend View Management

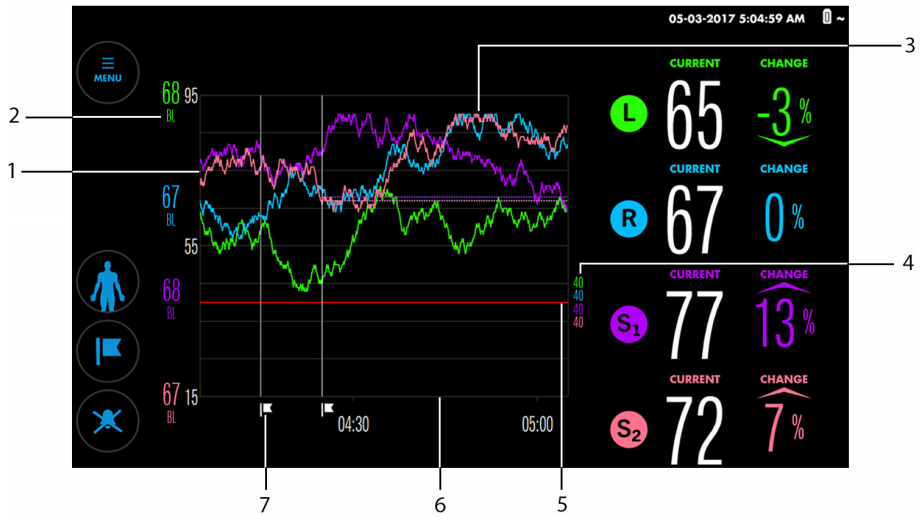
4.10.1. About the Trend View

"Trend view" refers to the data graph on the monitoring screen.

The trend view shows the progression of rSO_2 values over the course of a case. It provides a visual reference for on-going rSO_2 readings in relationship to baseline values and alarm limits, as well as a means to reference significant clinical events during the case.

The trend view is stored in the monitoring system's memory and can be reviewed at a later time. See Case Histories, page 73.

Figure 40. Trend View

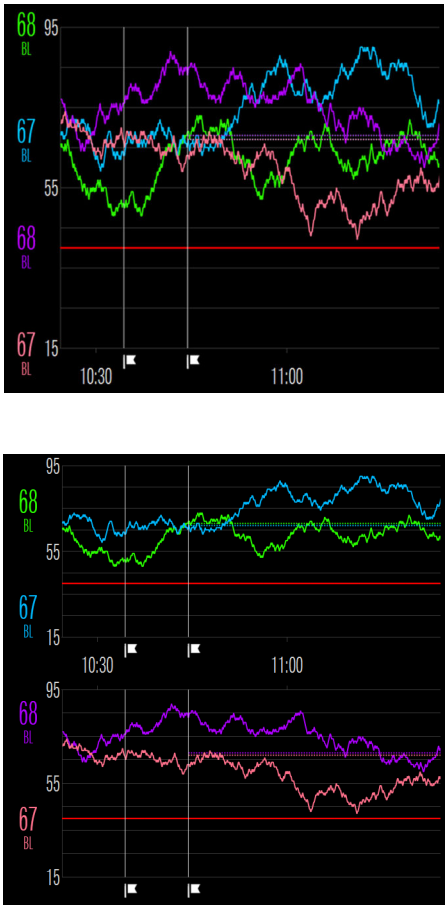


1. rSO_2 scale (y-axis)
2. Current baselines (color-coded to sensor labels)
3. Trend line (color-coded to sensor labels)
4. Alarm limits (color-coded to sensor labels)
5. Alarm limit line
6. Time scale (x-axis)
7. Event mark

4.10.2. Changing the Trend View - Two Graphs or One Graph

By default, the monitoring system displays all trends on one graph (Figure 41, top). If desired, you can display trends on two graphs - one for cerebral sensors, one for somatic sensors (Figure 41, bottom).

Figure 41. Trend View - One Graph (Top, Default) and Two Graphs (Bottom)



To change the trend view (two graphs vs. one graph):

1. Press MENU.

2. Press SETTINGS.
3. Press TRENDS.

Figure 43. SETTINGS - TRENDS - TWO AXIS VIEW vs. ONE AXIS VIEW

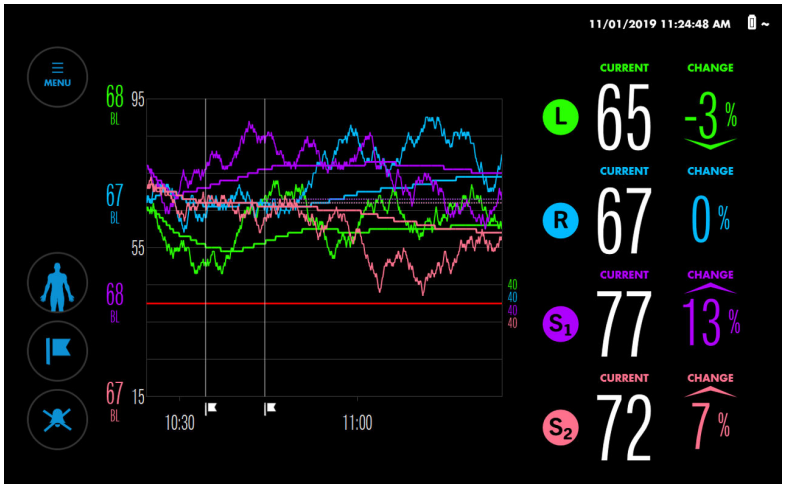
4. Press TWO AXIS VIEW or ONE AXIS VIEW, as desired. Your choice is highlighted by a white square.
5. Press CLOSE.

Note: The trend view setting remains in effect across power cycles.

4.10.3. Turning Trend Line Averaging On/Off

Trend line averaging provides a 60-minute rolling average of rSO_2 values. Viewing a rolling average can be useful in situations where there is frequent and wide variability in rSO_2 values. The averaged data is displayed as a bold line superimposed over the real-time rSO_2 values in the graph. The trend line is the same color as the real-time values for each sensor. The numerical rSO_2 values and percent change from baseline continue to be displayed in real-time.

Figure 44. Trend Line Averaging



By default, trend line averaging is off.

To turn trend line averaging on/off:

1. Press MENU.

2. Press SETTINGS.
3. Press TRENDS.

Figure 45. SETTINGS - TRENDS - TREND LINE AVERAGING

4. Press ON or OFF next to TREND LINE AVERAGING, as desired.
5. Press CLOSE.

Note: The trend line averaging setting remains in effect across power cycles.

4.10.4. Zooming the Trend View

By default, the trend view shows 1 hour of data at a time. You can zoom the trend view to see different time intervals. Available intervals are 1, 2, 4, 8, 12, and 24 hours.

Note that only the horizontal axis (time) zooms, not the vertical axis (rSO_2 values).

To zoom the trend view:

1. To zoom out and see a longer time range, place two fingers within the trend graph, 1- 2 inches apart horizontally, and slide together.
2. To zoom in and see a shorter time range, place two fingers within the trend graph, side-by-side horizontally, and slide apart.

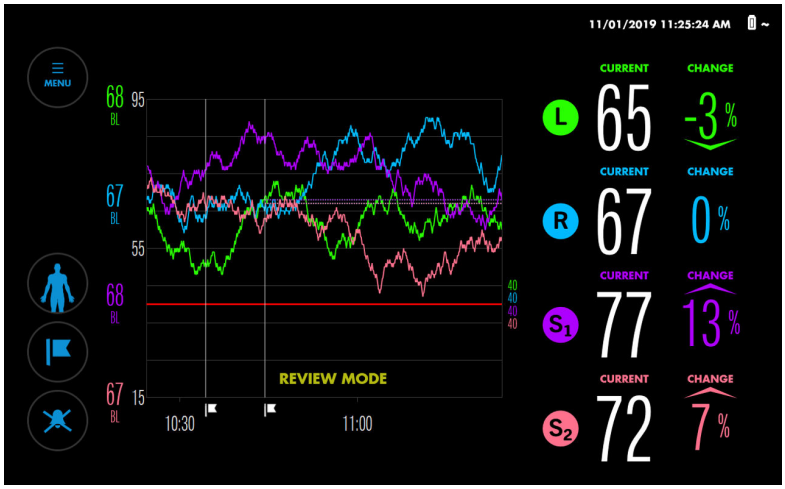
Note: The zoom setting remains in effect across power cycles.

4.10.5. Reviewing Data that has Scrolled Off the Trend View

During extended monitoring, trend data scrolls off the trend view to the left. You can review this trend data while monitoring by swiping the trend view to the right.

Current rSO_2 values are still displayed while you review older trends, but current trends are not displayed until you swipe the trend view back to the left. As an indication that current trends are not shown, “REVIEW MODE” appears on the trend view.

Figure 46. Trend View Review Mode



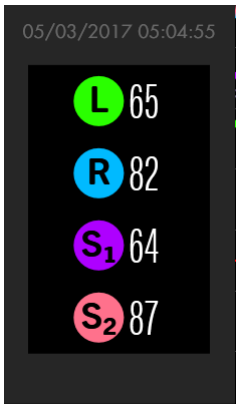
To review data that has scrolled off the trend view:

1. Briefly touch within the trend graph and swipe to the right. The data shifts back in time as indicated by the time scale. The message "REVIEW MODE" appears.
2. Repeat swipes until the data you want to view appears. Note that the amount of shift corresponds to the length of the swipe.
3. To return to current trend data, swipe to the left until the message "REVIEW MODE" no longer appears.

4.10.6. Viewing Previous rSO_2 Values on the Trend Graph

While monitoring a patient, you can view rSO_2 values that were recorded earlier in the case. Values appear in a pop-up corresponding to the point of interest (Figure 47).

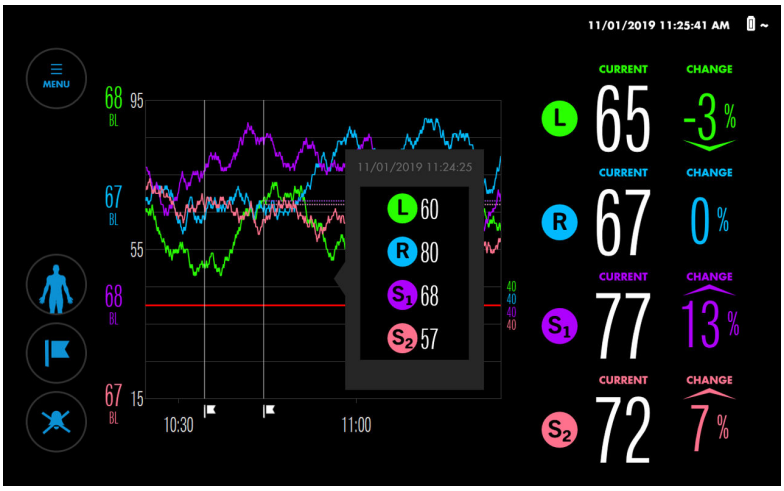
Figure 47. Trend Graph Pop-Up



To view previous rSO_2 values on the trend graph:

1. Press and hold the point of interest on the trend graph. The values at that point appear in a pop-up that indicates the time they were recorded.

Figure 48. Monitoring Screen - Trend Graph Pop-Up



2. Slide your finger in either direction on the graph to see values at different times.
3. Release when finished viewing values.

4.11. Alarm Management

- Alarm Indicators, page 60
- Setting Alarm Limits, page 62
- Changing the Alarm Volume, page 63
- Silencing or Pausing Alarms, page 64
- Dismissing an Alarm, page 65

Note: Refer to Table 22, page 99 for a complete list of alarm messages, priorities, and resolutions.

4.11.1. Alarm Indicators

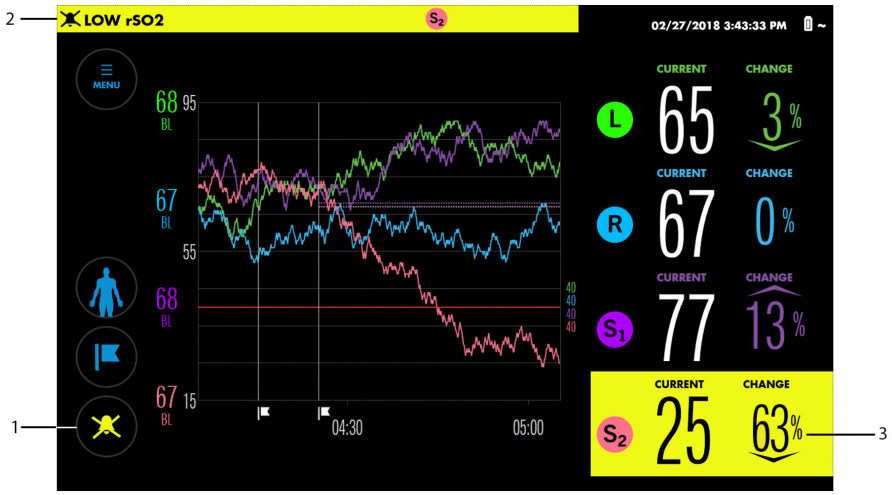
The monitoring system uses audio and visual indicators to identify alarms.

The message area at the top of the monitoring screen indicates active alarms (Figure 49). If multiple alarms occur, the message area shows the color of the highest priority alarm and indicates the total number of alarms currently active. By pressing the arrow in the message area, you can expand the list and view all active alarms.

When an rSO_2 value crosses an alarm threshold, the background of the affected rSO_2 reading flashes yellow.

The Alarm Audio button indicates alarm audio status. When alarms are silenced or paused, the Alarm Audio button also indicates alarm status (Table 9).

Figure 49. Visual Alarm Indicators



1. Alarm Audio button
2. Message area
3. rSO_2 reading in alarm state

Table 9. Alarm Audio Button States

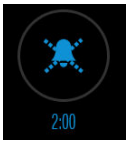
Alarm Audio button	Alarm audio on, silenced, or paused	Alarm status
	On	Alarm of any status or no alarms
	Silenced	No alarms
		Low- or medium-priority alarm
	Paused (2 minutes)	No alarms
		Low- or medium-priority alarm

Table 10 summarizes the monitoring system's alarm indicators.

Table 10. Audible and Visual Alarm Indicators

Priority	Audible tone[a]	Visual indication[b]	Example messages[c]
Medium	3 pulse burst	Message area: Flashing yellow bar with text message Battery icon: For battery alarm, flashing yellow; otherwise, no change rSO_2 readings area: Yellow flashing background on affected reading for sensor alarms (dashes appear if readings are lost) Alarm Audio button: Yellow if alarms silenced or paused	BATTERY LOW LOW RSO2
Low	2 pulse burst	Message area: Yellow bar with text message (not flashing) Battery icon: No change rSO_2 readings area: No change Alarm Audio button: Yellow if alarms silenced or paused	TREND DATA LOST

a By default, alarm audio is on, but may be silenced or paused by the user. See Silencing or Pausing Alarms, page 64. See Table 26, page 113 for alarm tone specifications.
b See Table 28, page 114 for alarm visual specifications.
c See Table 22, page 99 for a complete list of alarm messages.

4.11.2. Setting Alarm Limits

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

The monitoring system provides default alarm limit settings, as listed in Table 11.

You can change the alarm limits before or after setting baselines, or you can use the existing alarm limits. Alarm limits are retained across power cycles, so check the current settings to determine if they are appropriate for the patient.

Table 11. Alarm Limits Settings

Alarm limits item	Available settings	Default
UPPER LIMITS	OFF - No alarm sounds for high rSO_2 values ON - Specify a high rSO_2 value that will generate an alarm	OFF
Upper limit range (when ON)	20 to 95	90
LOWER LIMITS	MANUAL - Specify a low rSO_2 value that will generate an alarm AUTO - Specify a percentage below baseline that will generate an alarm	MANUAL
Lower limit range when set to MANUAL	15 to 90	40
Lower limit range when set to AUTO	-30% to -5%	-20%

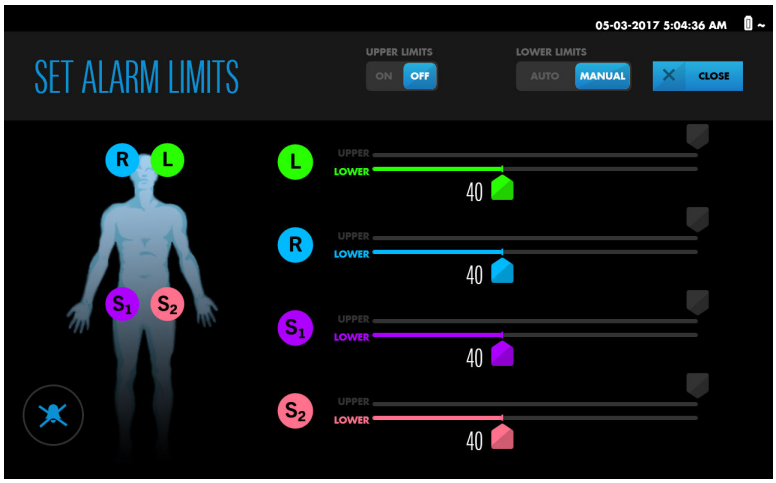
Note: Upper and lower alarm limits for each sensor are not allowed to cross.

To set alarm limits:

1. Press MENU.

2. Press ALARM LIMITS. The SET ALARM LIMITS screen shows the most recent limits set (or the defaults if limits have not previously been set).

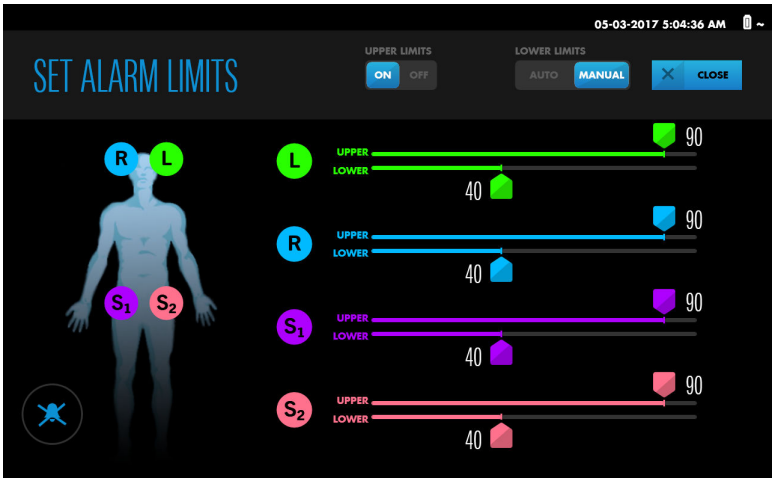
Figure 50. SET ALARM LIMITS - Default Settings



Note: Four sensors are shown even if fewer are in use.

3. To set upper alarm limits:
   a. Press ON for UPPER LIMITS. A second scale appears for each sensor.

Figure 51. SET ALARM LIMITS - Upper Limits On



   b. Next to a sensor, press and hold the slider for the UPPER limit, drag it to the desired value, and release. You can set different values for each sensor.
4. To set lower alarm limits:
   a. Press MANUAL or AUTO for LOWER LIMITS, as desired.
   b. Next to a sensor, press and hold the slider for the LOWER limit, drag it to the desired value, and release. You can set different values for each sensor.
5. Press CLOSE. The new alarm limits take effect immediately.

Note: Alarm limit settings remain in effect across power cycles.

4.11.3. Changing the Alarm Volume

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

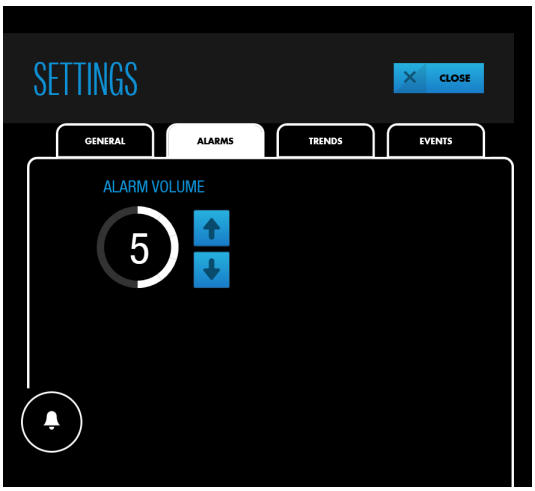
When alarm audio is on, the default alarm volume is set to 5 with a range of 1 to 10. See Table 26, page 113 for alarm tone specifications.

To change the alarm volume:

1. Press MENU.

2. Press SETTINGS.
3. Press ALARMS.

Figure 52. SETTINGS - ALARMS - ALARM VOLUME



4. Press an arrow key to increase or decrease the alarm volume.
5. Press CLOSE.

Note: The alarm volume setting remains in effect across power cycles.

4.11.4. Silencing or Pausing Alarms

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

Depending on your institutional default, alarm audio may be on or off when you start a case. When alarm audio is on, you can silence or pause the audio.

A white Alarm Audio button indicates alarm audio is on.

You can silence or pause alarms by pressing the button. The button changes to indicate whether alarms are silenced or paused (see Table 9, page 61). Whether an alarm is silenced or paused depends on institutional default settings (see Alarm Silence Duration, page 65).

If an alarm condition occurs when alarm audio is silenced or paused, the Alarm Audio button changes color to match the current highest-priority alarm condition (see Table 9, page 61).

If alarms are silenced or paused, you can turn alarm audio back on by pressing the Alarm Audio button.

The button changes to the following:

Note: When alarms are silenced or paused, the following alarms are not silenced:

- BATTERY CRITICALLY LOW (while monitoring system is operating on battery power)
- SYSTEM FAILURE (under certain circumstances)

Note: After a power cycle, the last setting used (alarm audio on or silenced) is retained.

4.11.4.1. Alarm Silence Duration

Pressing the Alarm Audio button either silences alarms or pauses them temporarily, depending on institutional defaults. The factory default is permanent silence of alarms.

The pause option, which must be set by an authorized technician, is 2 minutes. If the pause option is implemented, a countdown timer appears below the Alarm Audio button when the button is pressed to pause an alarm. After 2 minutes, alarm audio resumes.

4.11.4.2. Alarm Reminder Signal

By default, there is no reminder signal to indicate that alarms are silenced or paused. Alarm silence reminders may be turned on by an authorized technician. See Alarm Audio and Visual Characteristics, page 113 for alarm reminder signal specifications.

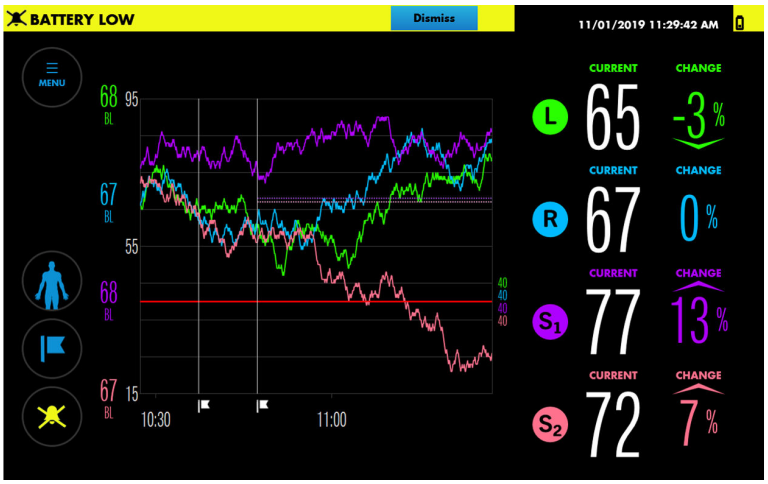
4.11.5. Dismissing an Alarm

Some alarms, such as BATTERY LOW and SENSOR NOT CONNECTED, can be dismissed without resolving the situation. Others, such as LOW RSO2 and CHECK SENSOR, clear only when the condition is resolved. Table 22, page 99 indicates which alarms are dismissible and which are not.

To dismiss an alarm:

1. Note whether the DISMISS button is available in the alarm message area and whether there are multiple alarms occurring. When there are multiple alarms, the DISMISS button applies only to dismissible alarms.

Figure 56. Dismissible Alarm



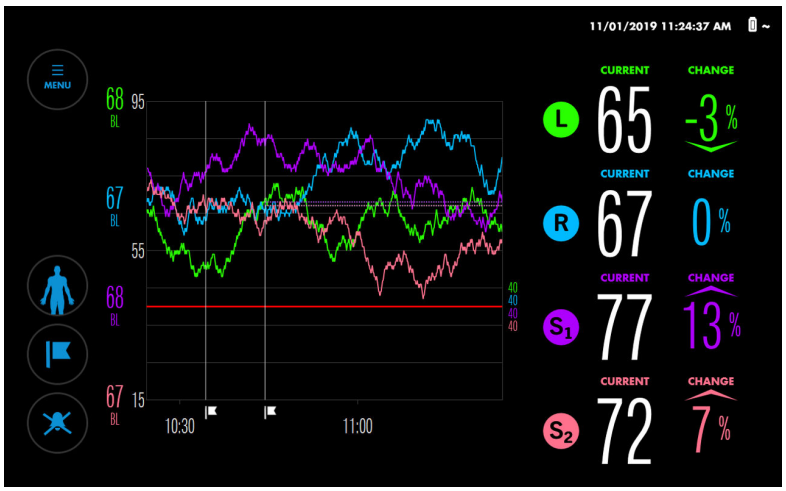
2. If there are multiple alarms, press the down arrow to view all current alarms and determine which are appropriate to be dismissed.
3. Press DISMISS next to the appropriate alarm. Dismissible alarms can only be dismissed individually.

4.12. Event Marks

4.12.1. About Event Marks

Use event marks to indicate significant occurrences during monitoring. Choose from a list of events that is customizable for specific cases. Event marks are displayed on the trend graph as vertical lines with flags and stored in memory for case history review. Note that when baselines are set (either automatically or manually), an event mark is automatically added to the trend graph.

Figure 58. Events Marked in Trend View



4.12.2. Marking Events

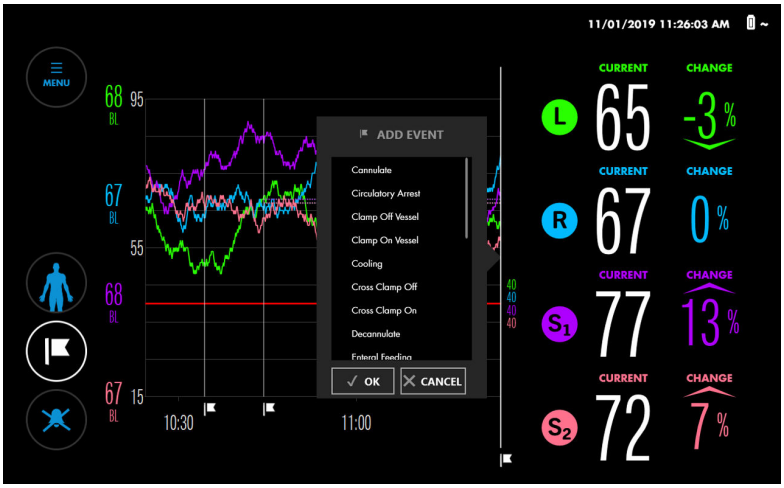
To mark an event:

1. While monitoring, press MARK EVENT.

   The ADD EVENT menu lists the available events.

Figure 59. ADD EVENT Menu



2. Scroll through the list by pressing anywhere within the list and dragging up or down. When you see the event you want, press it to highlight it. (If you don't see the event you want, see Changing the Event List, page 69.)
3. Press OK. The event mark appears on the trend graph.

4.12.3. Viewing an Event Mark Label

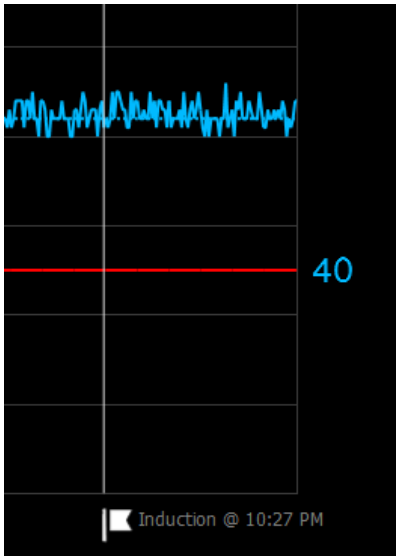
Event mark labels indicate the event name and the time the event was recorded. You can view event mark labels while monitoring or reviewing a case history.

To view an event mark label:

At the trend graph, press the flag below an event mark line.

The event name and time appear for approximately 5 seconds.

Figure 60. Event Mark Label



4.12.4. Renaming an Event

If an event is mis-named, you can change it at any time while monitoring or reviewing a case history.

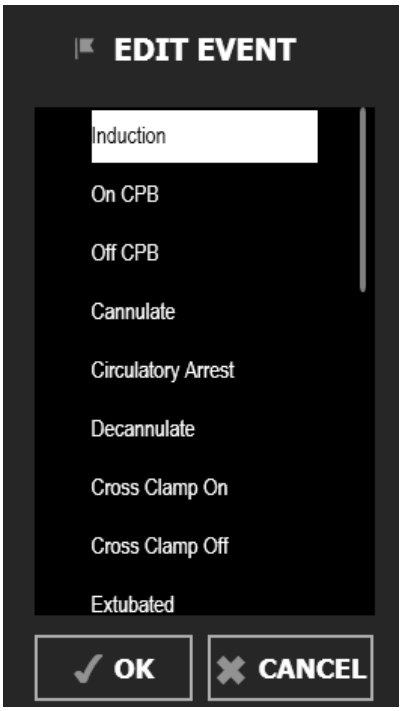
To rename an event:

1. At the trend graph, press the flag below an event mark line.

2. When the event mark label appears, release the flag and press the label or the flag again. The EDIT EVENT menu appears.

Figure 61. EDIT EVENT Menu



3. Scroll through the list by pressing anywhere within the list and dragging up or down. When you see the event you want, press it to highlight it. (If you don't see the event you want, see Changing the Event List, page 69.)
4. Press OK.
5. Press the flag below the event mark line to verify the change.

4.12.5. Changing the Event List

A default list of common events is provided. You can change the list before or during a case.

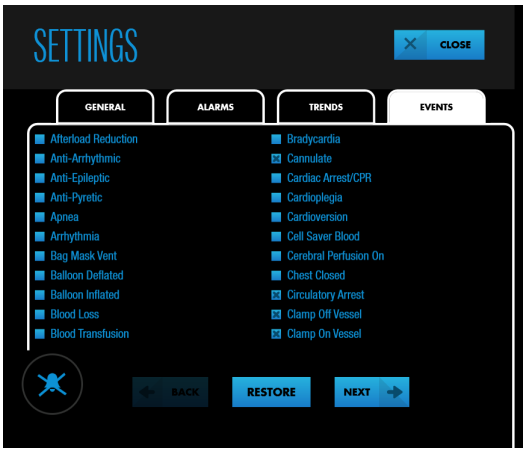
Note: Be aware that changes to the list are retained across power cycles, so the list you see may reflect a previous case. Make sure that the list of events is appropriate for your patient.

To change the event list:

1. Press MENU.

2. Press SETTINGS.
3. Press EVENTS. One of several screens of available events appears. An X next to an event indicates that it currently appears in the ADD EVENT and EDIT EVENT menus.

Figure 62. SETTINGS - EVENTS (Screen 1)



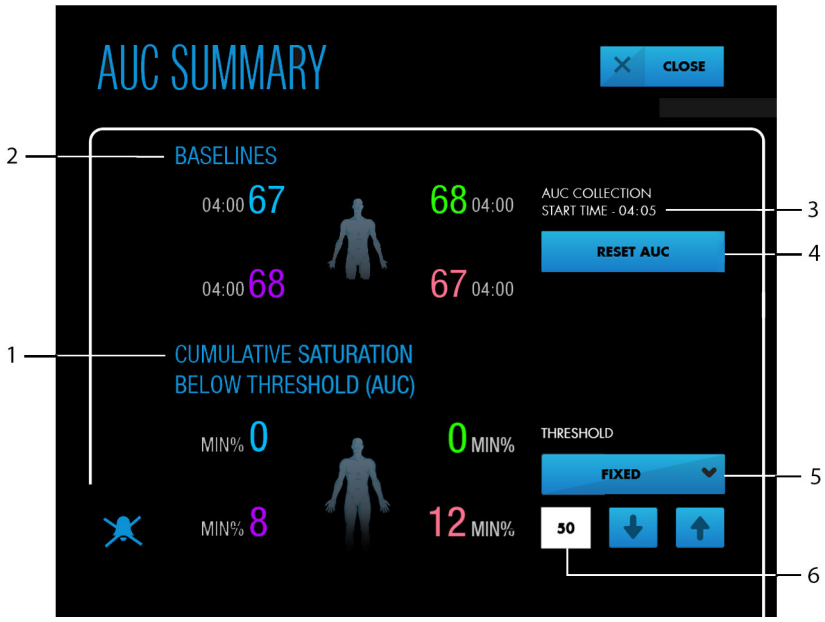
4. Press NEXT or BACK to view all of the available events in alphabetical order.
5. To select or de-select an individual event, press the checkbox next to the event or the event itself. If necessary, you can restore the list to its default values by pressing RESTORE.
6. Press CLOSE.

4.13. Area Under the Curve (AUC)

- About Area Under the Curve (AUC), page 71
- Changing the AUC Threshold, page 71
- Resetting AUC Collection, page 72

4.13.1. About Area Under the Curve (AUC)

Figure 63. AUC SUMMARY Screen



1. Current AUC totals
2. Current baselines
3. AUC start time
4. RESET AUC (press to restart collection)
5. Current AUC threshold type (press to change)
6. Current AUC threshold (press arrow keys to change)

AUC (Area Under the Curve), also referred to as cumulative saturation below threshold, quantifies the depth and duration of desaturation below a specific value.

AUC was originally a metric in The STS (Society of Thoracic Surgeons) Adult Cardiac Surgery Database and Congenital Heart Surgery Database. High AUC calculated from a threshold of 25% below baseline rSO_2 has been found to correlate with increased morbidity.

By default, the monitoring system uses a threshold of 50 for AUC calculations. If desired, you can change the AUC threshold to any value between 30 and 60, or you can specify a percentage below baseline from 0% to 30%.

The monitoring system automatically calculates AUC by multiplying the difference between the threshold and the current rSO_2 values times the duration that rSO_2 is below the threshold. Units are minute-%. Values are accumulated throughout the case. The AUC threshold applies to all sensors being monitored.

Note: If you retake baselines at any point while monitoring, the monitoring system does not reset AUC data collection to zero. If desired, you can reset AUC data collection as described in Resetting AUC Collection, page 72.

4.13.2. Changing the AUC Threshold

By default, rSO_2 values must fall below a fixed threshold of 50 to be included in AUC totals. You can change this threshold any time after monitoring begins.

Note: Be aware that changes to the AUC threshold are retained across power cycles, so the current setting may reflect a previous case. Check the setting to make sure that it is appropriate for your patient.

To change the AUC threshold:

1. After monitoring begins, press MENU.

2. Press AREA UNDER CURVE.
3. At the AUC SUMMARY screen, the type of threshold currently in use is indicated (see Figure 63, page 71):
   - FIXED, or
   - % BELOW BASELINE

   Press to toggle between the two choices.
4. Adjust the value for the threshold by pressing the arrow buttons. The ranges are:
   - FIXED: 30 - 60
   - % BELOW BASELINE: 0% - 30%
5. Press CLOSE.

4.13.3. Resetting AUC Collection

You can reset AUC data collection to zero at any point while monitoring. AUC data collection restarts at the time of reset.

To reset AUC Collection:

1. After monitoring begins, press MENU.

2. Press AREA UNDER CURVE.
3. At the AUC SUMMARY screen, press RESET AUC (see Figure 63, page 71).
4. Press CLOSE.

4.14. Finish Monitoring

To finish monitoring a patient:

1. Power off the monitoring system by pressing the power button on top of the monitor for approximately 3 seconds.
2. Disconnect the RSCs from the sensors, and unclip the RSC strain-relief clips, if used. You can leave the RSCs connected to the preamplifier(s).
3. Carefully remove the sensors from the patient. Dispose of the sensors according to institution procedures for single-use devices.

4. Clean the monitoring system as required by your institution. See Cleaning the Monitoring System, page 95.

4.15. Case Histories

4.15.1. About Case Histories

While not actively monitoring a patient, you can view case histories stored on the monitoring system. You can also export case histories to a USB flash drive and review or store them off-line.

The monitoring system automatically records trend data every 5 seconds and stores up to 30 days (720 hours) of data in any combination of cases. When storage capacity is reached, the monitoring system overwrites the oldest data to make room for new data.

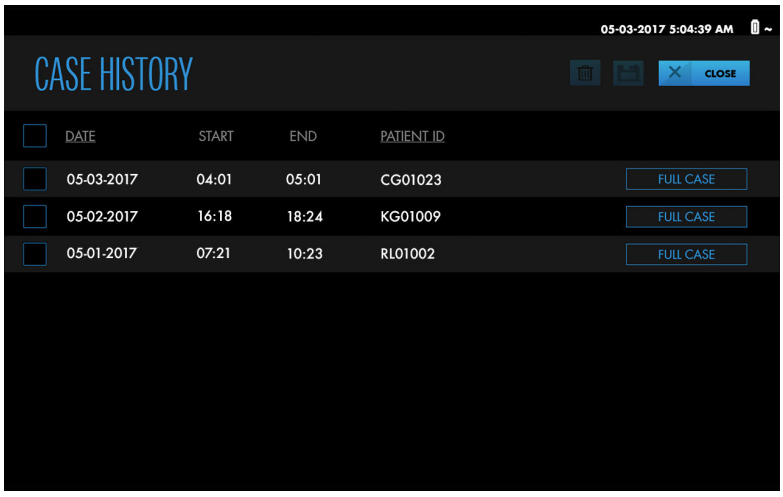
4.15.2. Viewing Case Histories

To view a case history:

1. Make sure that the monitoring system is powered on but that no sensors are connected.
2. Press MENU.

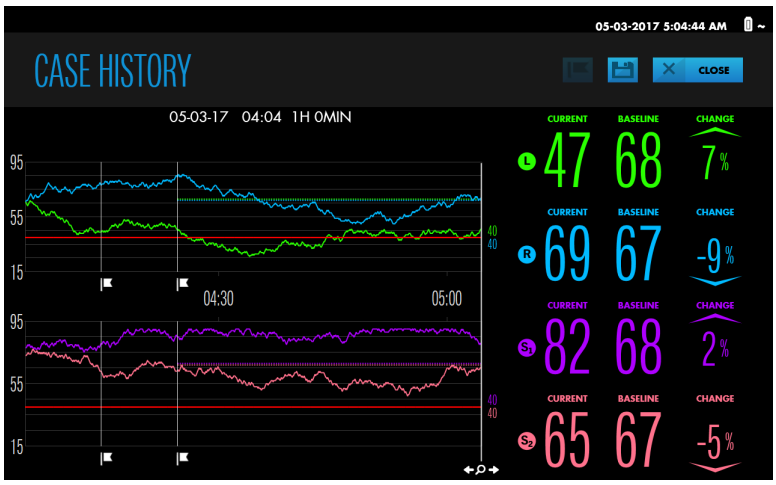
3. Press CASE HISTORIES. The CASE HISTORY list appears.

Figure 64. CASE HISTORY List



4. Locate a case using the following methods:
    - Sort the list by pressing DATE or PATIENT ID. Press your choice again to reverse the sort order.
    - Scroll through the cases by pressing anywhere within the list and dragging up or down.
5. Press FULL CASE next to the case you want to view. The trend data for the case is displayed.

Figure 65. Case History Example



6. View items in the case history as follows:
    - Zoom the trend graph. See Zooming the Trend View, page 58.
    - Press the trend graph at any location to see the readings at that point in the case. The vertical line with the magnifier moves to that point. Slide your finger along the graph to move the vertical line left or right to see additional values. If an alarm occurred at any point, the alarm message is displayed and the sensor reading is highlighted, if applicable.
    - Scroll backward and forward in time by briefly touching within the trend graph and swiping to the right or left. The shift is indicated by the time scale. Repeat swipes until the data you want to view appears. Note that the amount of shift corresponds to the length of the swipe.
    - View an event mark label by pressing the flag below the vertical event line. See Viewing an Event Mark Label, page 67.

      
    - Change an event mark label, if necessary, as described in Renaming an Event, page 68.
    - Add a new event mark by pressing the trend graph at the location of the event, then pressing the Add Event button at the top of the screen. Select an event as described in Marking Events, page 67.

- Export the case history, if desired. See Exporting Case Histories, page 75.

7. Press CLOSE to exit the case history view.
8. Press CLOSE to exit the CASE HISTORY list.

4.15.3. Exporting Case Histories

Using a USB flash drive, you can export individual or multiple cases from the case history list, or you can export the case that you are viewing. After exporting cases, you can upload them to a computer. See Downloading Case Histories to a USB Drive, page 78 for information about data format, file names, and working with the data.

Note: Medtronic recommends incorporating appropriate security measures for any external devices receiving patient data from the monitoring system.

To export one or more case histories from the case history list:

1. Make sure that the monitoring system is powered on but that no sensors are connected.
2. Press MENU.

3. Press CASE HISTORIES. The case history list appears.
4. Press the checkbox next to one or more cases to export.
5. Insert a USB flash drive into a USB port on the monitor or docking station. See Figure 4, page 16 and Figure 7, page 19.
6. Press the Export button.

A progress bar appears. Do not remove the USB drive while the export is taking place.

7. When the export is complete, press FINISH or remove the USB drive.
8. Press CLOSE to exit the case history list.
9. If you have not already done so, remove the USB drive.

To export a case history that you are viewing:

1. Follow the steps in Viewing Case Histories, page 73, but do not close the case history view.
2. Insert a USB flash drive into a USB port on the monitor or docking station. See Figure 4, page 16 and Figure 7, page 19.
3. Press the Export button.

A progress bar appears. Do not remove the USB drive while the export is taking place.

4. When the export is complete, press FINISH or remove the USB drive to return to the case history list.

5. Press CLOSE to exit the case history list.
6. If you have not already done so, remove the USB drive.

4.15.4. Deleting Case Histories

Note: Exporting case histories, as described in the previous section, does not delete them from the monitoring system. This section explains how to delete case histories.

To delete one or more case histories from the case history list:

1. Make sure that the monitoring system is powered on and that no sensors are connected.
2. Press MENU.

3. Press CASE HISTORIES. The case history list appears.
4. Press the checkbox next to one or more cases to be deleted.
5. Press the Delete button.

The message “Delete the selected cases?” appears. Press OK to delete.

6. When complete, the following message appears: “Successfully deleted (n) cases.”
7. Press FINISH.
8. Confirm the cases have been removed from the case history list.

Note: If you delete the most recent case, the append feature (continuing a case) is disabled.

5. Data Management

5.1. Overview

This chapter explains how to display INVOS™ patient monitor screens on an external monitor, download case data for storage and analysis on a computer, and transmit real-time data to external devices such as a Philips multi-parameter system.

5.2. Safety Reminders

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 dataprocessing 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: 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.

5.3. Displaying Monitoring System Screens on an External Monitor

To display monitoring system screens on an external monitor, use the VGA port on the docking station (Figure 66). Using a VGA cable no longer than 50 feet (15.24 m), connect the cable between the VGA port and the external monitor.

Figure 66. VGA Port on Docking Station

5.4. Downloading Case Histories to a USB Drive

Using a USB flash drive, you can download case histories from the monitoring system for storage or later analysis on a computer. See Exporting Case Histories, page 75 for instructions. Downloaded case history data can be graphed using a commercial spreadsheet program. See Case Histories Downloaded via USB, page 82 for case history data format and file name information.

Use any of the USB ports on the monitor or docking station to download case histories. The monitor has one USB 2.0 and one USB 3.0 port (see Figure 4, page 16). The docking station has two USB 2.0 ports (see Figure 7, page 19). Do not connect any device other than a USB flash drive to the monitoring system's USB ports.

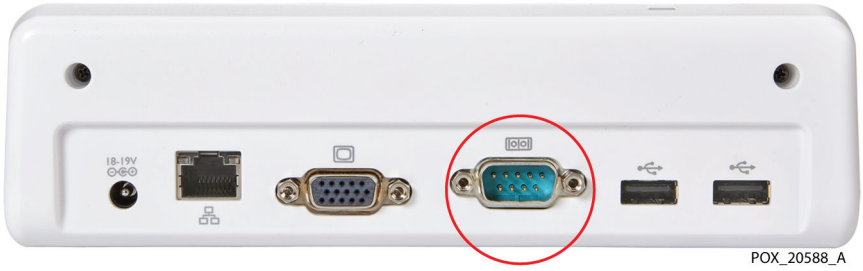
Note: Medtronic recommends incorporating appropriate security measures for any external devices receiving patient data from the monitoring system.

5.5. Transmitting Monitoring System Data to External Devices via the Serial Port

To transmit monitoring system data to devices such as a Philips IVOI module or a computer, use the serial port on the docking station (Figure 67). As described in the following sections, real-time data can be transmitted for display on a Philips multi-parameter system or similar systems. Data can also be transmitted during a case to a computer for storage and later analysis.

Note: The monitoring system will also interface with multi-parameter systems that accept the Philips VOI B module specified in Transmitting Real-Time Data to a Philips IntelliBridge™* and VueLink™* Open Interface (IVOI) Module, page 79. Contact Medtronic Technical Services for information about compatibility with other commercial devices. See Technical Services, page 10.

Figure 67. Serial Port on Docking Station



5.5.1. Serial Port Specifications

The monitoring system's serial port uses the following protocol:

- Baud: 19200 for VUE LINK format; 9600 for PC LINK 1 and PC LINK 2 formats
- No parity
- 8 data bits
- 1 stop bit
- Flow control: hardware

Pin-outs for the serial port are shown in Figure 68 and described in Table 12.

Figure 68. Serial Port Pin-Outs

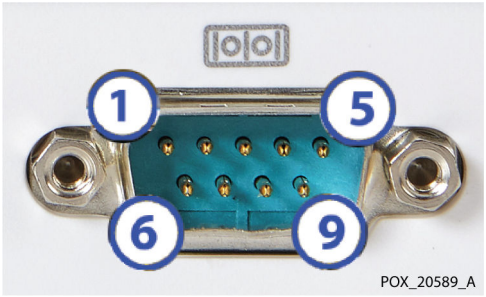


Table 12. Serial Port Pin-Out Descriptions

Pin #	Signal name	Pin #	Signal name
1	Data carrier detect	6	Data set ready
2	Receive data	7	Request to send
3	Transmit data	8	Clear to send
4	Data terminal ready	9	Ring indicator
5	Ground		

5.5.2. Transmitting Real-Time Data to a Philips IntelliBridge™* and VueLink™* Open Interface (IVOI) Module

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.

The following instructions explain how to transmit real-time data to a Philips IVOI module for display on a Philips multi-parameter system. The data transmitted includes rSO_2 values, alarms, and status messages.

Hardware requirements for communicating with a Philips VueLink™* module or Philips IntelliBridge™* EC10 module are described in Table 13.

Table 13. Hardware Requirements for Philips VueLink™* and IntelliBridge™* Communication

System	Hardware requirements
Philips VueLink™* System	• Philips VOI B module (Philips VueLink™* P/N M1032A #A05) • Philips VOI/RS-232 Interface Cable (Philips VueLink™* P/N M1032 #K6B) • VueLink™* adapter cable, DB25F to DB9F (Medtronic P/N VLI)
Philips IntelliBridge™* System	• Philips IntelliBridge™* module (EC10) • Philips Ethernet Cable • Philips IntelliBridge™* EC5 Open Interface RS232 Cable

To set up communication with a Philips VueLink™* module:

1. Slide the Philips VOI B module into any of the open slots in the multi-parameter system, making sure it locks into place.
2. Connect the VOI/RS-232 Interface Cable to the VOI B module.
3. Connect the VOI/RS-232 Interface Cable via the VueLink™* adapter cable to the serial port on the monitoring system docking station (Figure 67, page 79).
4. Tighten all screw locks at each connector junction.
5. Ensure that the Philips monitor and VOI B module are properly configured per Philips instructions.
6. Power on the monitoring system and set the serial port protocol to VUE LINK, as described in the monitoring system's service manual. After the monitoring system restarts, it begins communicating with the Philips monitor.
7. Begin a case as described in Set Up for Patient Monitoring, page 42.

To set up communication with a Philips IntelliBridge™* module:

1. Insert the Philips IntelliBridge™* EC10 module into any of the open slots in the multi-parameter system, making sure it locks into place.
2. Connect the Ethernet cable to the IntelliBridge™* EC10 module.
3. Connect the other end of Ethernet cable to the IntelliBridge™* EC5 ID module.
4. Using the IntelliBridge™* EC5 Open Interface RS232 cable, connect the IntelliBridge™* EC5 ID module to the serial port on the monitoring system docking station (Figure 67, page 79).
5. Tighten all screw locks at each connector junction.
6. Ensure that the Philips monitor and IntelliBridge™* module are properly configured per Philips instructions.

7. Power on the monitoring system and set the serial port protocol to VUE LINK, as described in the monitoring system's service manual. After the monitoring system restarts, it begins communicating with the Philips monitor.
8. Begin a case as described in Set Up for Patient Monitoring, page 42.

5.5.3. Transmitting Case Data to a Computer

The following instructions explain how to transmit case data to a computer using a null modem cable and a terminal emulation program such as Tera Term™* or HyperTerminal™* programs.

Data is transmitted approximately once every second as the case progresses. Data can be transmitted in two formats: PC LINK 1and PC LINK 2. Instructions for selecting a format are provided in the monitoring system's service manual. See Case Data Downloaded via Serial Port, page 83 for descriptions of the formats.

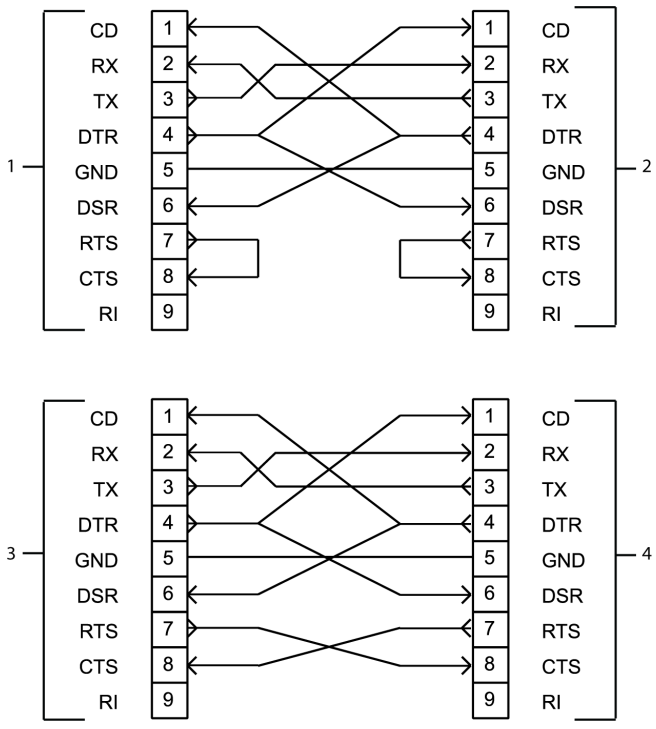
5.5.3.1. Null Modem Cable Requirements

A 9-pin to 9-pin null modem cable is required for transmitting case data to a computer via the serial port.

The null modem cable must be no longer than 50 feet (15.24 m).

Refer to Figure 69 for acceptable 9-pin to 9-pin wiring configurations.

Figure 69. Null Modem Cable Diagram for Connection to Serial Port (Two Options)



1. Monitoring System Serial Port (Option 1)
2. Computer (PC) COM Port (Option 1)
3. Monitoring System Serial Port (Option 2)
4. Computer (PC) COM Port (Option 2)

5.5.3.2. Using a Terminal Emulation Program to Transmit Case Data to a Computer

The following procedure presents general steps for transmitting case data to a computer using a terminal emulation program and a null modem cable. Steps will vary among programs. Refer to the terminal emulation program's instructions for specific steps.

To use a terminal emulation program to transmit data:

1. Connect the null modem cable to the serial port on the monitoring system docking station (Figure 67, page 79) and to a COM port on the computer.
2. Power on the monitoring system and set the serial port protocol to PC LINK 1 or PC LINK 2, as described in the monitoring system's service manual.
3. Set up the terminal emulation program (one-time set-up):
   a. Power on the computer.
   b. Open the terminal emulation program.
   c. Set the inputs for the COM port:
      - Bits per second: 9600 baud
      - Data bits: 8
      - Parity: None
      - Stop bits: 1
      - Flow control: hardware
4. Begin a case as described in Set Up for Patient Monitoring, page 42.
5. When you are ready to transmit data from the monitoring system, open the terminal emulation program.
6. In the terminal emulation program, begin the transfer and text capture. Specify a file name and directory to save the file.
7. When monitoring is complete, end the transfer, disconnect, and close the terminal emulation program.

5.6. Data Formats

5.6.1. Case Histories Downloaded via USB

Downloaded case history data can be accessed and graphed on a computer using a commercial spreadsheet program.

5.6.1.1. File Name - Case History Downloads

Case histories downloaded to a USB flash drive are stored in individual files named as follows (if not assigned a custom name):

CaseID__MonitorSerialNumber.H3

CaseID is the date and time the case started (YYYYMMDD_HHMM in 24-hour format). For example, 20171023_0841.

An example file name is:

5.6.1.2. Data Format - Case History Downloads

Downloaded case history data is stored in ASCII format as a single line as shown below. Each field is separated by two space characters. Data is transmitted on a per channel basis (Channel 1 through Channel 4). See Table 14, page 83 for field descriptions.

Column:	**A**	**B**	**C**	**D**	**E**	**F**	**G**
Description:	Version	Date	Time	Ch 1 rSO_2	Event	Status	Rsvd
Column (continued):				**H**	**I**	**J**	**K**
Description (continued):				Ch 2 rSO_2	Event	Status	Rsvd
Column (continued):				**L**	**M**	**N**	**O**
Description (continued):				Ch 3 rSO_2	Event	Status	Rsvd
Column (continued):				**P**	**Q**	**R**	**S**
Description (continued):				Ch 4 rSO_2	Event	Status	Rsvd
Column (continued):				**Terminating character**			
Description (continued):				0x0A			

Table 14. Case History Downloads - Data Fields

Field	Description
Version	*<major>.<minor>.<patch>.<build>/[event list version]/[output format version]* Example: 1.2.34.56/1/1 (For Medtronic use only)
Date	Date of the reading Format: MM/DD/YY
Time	Time of the reading Format: HH:MM:SS (24-hour format)
Ch *n* rSO_2	rSO_2 reading for channel *n*. (Integer) Range: 15 to 95 0 = Channel not active
Event	Current event. (Integer) Range: 0 to 160, 252 to 254 See Event Codes for Data Downloads, page 85 for descriptions. 0 = No event
Status	Current status. (Integer) Range: 0 to 19 See Status Codes for Data Downloads, page 88 for descriptions. 0 = No status **Note:** Status 21 is not stored in the export file.
Rsvd (Reserved)	Zero, to maintain backwards compatibility. Format: 0

5.6.2. Case Data Downloaded via Serial Port

During a case, data is transmitted in ASCII text-based streams in either of two user selectable formats: PC LINK 1 and PC LINK 2.

Data is transmitted as a single line of text, approximately once per second, as shown below. Each field is separated by two space characters. Data is transmitted on a per channel basis (Channel 1 through Channel 4). If a particular channel is not active, a zero is sent for all the fields corresponding to that channel. See Table 15, page 85 for field descriptions.

Case data can be accessed and graphed on a computer using a commercial spreadsheet program.

5.6.2.1. Data Format 1 - PC LINK 1

Column:	A	B	C	D	E	F	G	H	I	J	K	L	M	N
Description:	Version	Date	Time	Ch label	rSO_2	Event	Status	Baseline	AUC	UAL	LAL	A	B	Rsvd
Column (continued):				O	P	Q	R	S	T	U	V	W	X	Y
Description (continued):				Ch label	rSO_2	Event	Status	Baseline	AUC	UAL	LAL	A	B	Rsvd
Column (continued):				Z	AA	AB	AC	AD	AE	AF	AG	AH	AI	AJ
Description (continued):				Ch label	rSO_2	Event	Status	Baseline	AUC	UAL	LAL	A	B	Rsvd
Column (continued):				AK	AL	AM	AN	AO	AP	AQ	AR	AS	AT	AU
Description (continued):				Ch label	rSO_2	Event	Status	Baseline	AUC	UAL	LAL	A	B	Rsvd

Column (continued):	AV	AW	AX	AY
Description (continued):	Ch 1 sensor ID	Ch 2 sensor ID	Ch 3 sensor ID	Ch 4 sensor ID
Column (continued):	Terminating character		Terminating character	
Description (continued):	0x0A		0x0D	

5.6.2.2. Data Format 2 - PC LINK 2

Column:	A	B	C	D	E	F	G	H	I
Description:	Date	Time	rSO_2	Event	Status	A	B	C	Rsvd
Column (continued):			J	K	L	M	N	O	P
Description (continued):			rSO_2	Event	Status	A	B	C	Rsvd
Column (continued):			Q	R	S	T	U	V	W
Description (continued):			rSO_2	Event	Status	A	B	C	Rsvd
Column (continued):			X	Y	Z	AA	AB	AC	AD
Description (continued):			rSO_2	Event	Status	A	B	C	Rsvd

Column (continued):	AE	AF	AG	AH
Description (continued):	Ch 1 sensor ID	Ch 2 sensor ID	Ch 3 sensor ID	Ch 4 sensor ID
Column (continued):	Terminating character		Terminating character	
Description (continued):	0x0A		0x0D	

Table 15. Case Data Downloads (PC LINK 1 and PC LINK 2) - Data Fields

Field	Included in PC LINK 1 format	Included in PC LINK 2 format	Description
Version	✓		**<major>.<minor>.<patch>.<build>/[event list version]/ [output format version]** Example: 1.2.34.56/1/1 (For Medtronic use only)
Date	✓	✓	Date of the reading Format: MM/DD/YY
Time	✓	✓	Time of the reading Format: HH:MM:SS (24-hour format)
Ch label	✓		Range: A to Z, S1 to S4 0 = Channel not active
rSO_2	✓	✓	Current rSO_2 reading for channel. (Integer) Range: 15 to 95 0 = Channel not active
Event	✓	✓	An event that was marked between the last transmission and this transmission. (Integer) Range: 0 to 160, 252 to 254 See Event Codes for Data Downloads, page 85 for descriptions. 0 = No event
Status	✓	✓	Current active status. (Integer) Range: 0 to 21 See Status Codes for Data Downloads, page 88 for descriptions. 0 = No status
Baseline	✓		Current baseline value. (Integer) Range: 15 to 95
AUC	✓		Area Under the Curve. (Integer) Range: 0 to 9999
UAL	✓		Upper Alarm Limit. (Integer) Range: 20 to 95
LAL	✓		Lower Alarm Limit. (Integer) Range: 15 to 90
A	✓	✓	Zero, to maintain backwards compatibility. Format: 0.0000
B	✓	✓	Zero, to maintain backwards compatibility. Format: 0.0000
C		✓	Zero, to maintain backwards compatibility. Format: 0
Rsvd (Reserved)	✓	✓	Zero, to maintain backwards compatibility. Format: 0
Channel **n** sensor ID	✓	✓	String (14 characters) - if a sensor is connected. 0 = No sensor connected

5.6.3. Event Codes for Data Downloads

The following event codes apply to case histories downloaded from the monitoring system via USB and case data transmitted via the monitoring system's serial port.

Table 16. Data Downloads - Event Codes 1 to 40

Event code	Description	Event code	Description
1	Miscellaneous	21	Afterload Reduction
2	Set Baseline	22	Blood Transfusion
3	Induction	23	Cardioversion
4	Sternotomy	24	Cell Saver Blood
5	Cannulate	25	Cerebral Perfusion On
6	On CPB	26	ECLS On
7	Cross Clamp On	27	FFP/Platelets
8	Cooling	28	Fluid/Volume Expander
9	Cardioplegia	29	Hemoconcentrate/MUF
10	Warming	30	Inotrope
11	Cross Clamp Off	31	Increase Anesthetic
12	Off CPB	32	Increase CO_2
13	Skin Closure	33	Increase FiO_2
14	Arrhythmia	34	Increase Pump Flow
15	Circulatory Arrest	35	Paced
16	Hypocapnia	36	Reposition Cannula
17	Hypotension	37	Reposition Clamp
18	One Lung Ventilation	38	Reposition Head
19	Pump Flow Down	39	Reposition Heart
20	Reduced Venous Return	40	Vasopressor

Table 17. Data Downloads - Event Codes 41 to 80

Event code	Description	Event code	Description
41	Miscellaneous	61	Blood Transfusion
42	Set Baseline	62	Chest Closed
43	Enteral Feeding	63	Dialysis/CRRT
44	Extubated	64	Diuretic
45	Intubated	65	ECLS On
46	Reposition Patient	66	ECLS Circuit Change
47	Sensor Change	67	ECLS Off
48	Apnea	68	ET Tube Suctioned
49	Arrhythmia	69	Fluid Bolus
50	Bradycardia	70	FFP/Platelets
51	Cardiac Arrest	71	Hi Frequency Vent
52	ICP Changes	72	Hypothermia
53	LOC Changes	73	Inotrope
54	Painful Procedure	74	Nitric Oxide
55	Seizure Activity	75	Paralytic
56	Tamponade	76	PDA Ligated

Table 17. Data Downloads - Event Codes 41 to 80 (continued)

Event code	Description	Event code	Description
57	Afterload Reduction	77	Prostaglandin
58	Anti-Arrhythmic	78	Sedation
59	Anti-Epileptic	79	Vasopressor
60	Anti-Pyretic	80	Ventilator Change

Table 18. Data Downloads - Event Codes 81 to 120

Event code	Description	Event code	Description
81	Miscellaneous	101	Balloon Inflated
82	Set Baseline	102	Balloon Deflated
83	Intubated	103	Blood Transfusion
84	Incision	104	EPD Deployed
85	Heparin Given	105	Fogarty Catheter In
86	Cannulate	106	FFP/Platelets
87	Clamp On Vessel	107	Hemostasis Device In
88	Suturing Vessel/Graft	108	IAB Catheter In/On
89	Clamp Off Vessel	109	IAB Catheter Out/Off
90	Decannulate	110	Increase Anesthetic
91	Extubated	111	Increase etCO_2
92	Arrhythmia	112	Increase FiO_2
93	Blood Loss	113	Shunt Flushed
94	Contrast Dye Injected	114	Shunt Open
95	Dissection	115	Shunt Repositioned
96	EEG Change	116	Stent Deployed
97	Hypotension	117	Thrombus Removed
98	Hypocapnia	118	Vasopressor
99	Shunt Clamped	119	Vasodilator
100	Thrombus Suspected	120	Vessel Repaired

Table 19. Data Downloads - Event Codes 121 to 254

Event code	Description	Event code	Description
121	Miscellaneous	141	Seizure
122	Set Baseline	142	Anti-Arrhythmic
123	Physical Assessment	143	Anti-Epileptic
124	Reposition Patient	144	Blood Trans/Platelets
125	Heel Stick/Lab Draw	145	Cooling Cap On-Off
126	Suction ET Tube	146	Dialysis/CRRT
127	Weigh Patient	147	ECLS On
128	Enteral Feeding	148	ECLS Circuit Change

Table 19. Data Downloads - Event Codes 121 to 254 (continued)

Event code	Description	Event code	Description
129	Extubated-Intubated	149	ECLS Off
130	Vent Change	150	Fluid Bolus
131	Conventional Vent	151	Fem Art CutDwn
132	Hi Frequency Vent	152	Hypothermia
133	Bag Mask Vent	153	Nitric Oxide On-Off
134	Hand Bag Vent	154	NG Tube In-Out
135	Sensor Change	155	Paralytic
136	Apnea/Bradycardia	156	Prostaglandin
137	Arrhythmia	157	OR Procedure Bedside
138	Cardiac Arrest/CPR	158	Sedation
139	ICP Changes	159	Vasopressor
140	LOC Changes	160	Whole Body Cooling
		252	Begin Post Op
		253	First Alert
		254	Somatic First Alert

5.6.4. Status Codes for Data Downloads

The following status codes apply to case histories downloaded from the monitoring system via USB and case data transmitted via the monitoring system's serial port.

Table 20. Data Downloads - Status Codes

Status code	Status message
1	SENSOR NOT CONNECTED
2	CHECK SENSOR
3	POOR SIGNAL QUALITY
4	SYSTEM SIGNAL OK
5	HIGH rSO2
6	LOW rSO2
11	PREAMP NOT CONNECTED
17	REPLACE SENSOR
19	INTERFERENCE DETECTED
21	AUTO BASELINE SET

Note: The following alarms are not reported in downloaded data:

- BATTERY CRITICALLY LOW
- BATTERY FAILURE
- BATTERY LOW
- PREAMP FAILURE
- SYSTEM FAILURE

- TREND DATA LOST

6. Performance Considerations

6.1. Overview

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

6.2. Safety Reminders

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: Monitoring system readings can be affected by certain patient conditions. Refer to Patient Conditions, page 91.

6.3. Patient Conditions

Certain patient conditions can cause poor performance of the monitoring system:

- Cardiogreen, indigo carmine, methylene blue, or other intravascular dyes
- Carboxyhemoglobin or other dyshemoglobins
- Hemoglobinopathies
- Conjugated hyperbilirubinemia (direct)
- Myoglobin (Mb), hemoglobin from muscular tissue, in the blood
- Dark skin pigment
- Externally applied coloring agents (dye, pigmented cream)

6.4. Sensor Use Considerations

Select an appropriate INVOS™ rSO_2 sensor, apply it as directed, and observe all warnings and cautions in the Instructions for Use accompanying the sensor.

A variety of sensor use situations can cause poor measurement performance, including incorrect site selection, patient preparation, and sensor placement. Refer to the sensor Instructions for Use for detailed information.

6.5. EMI (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.

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 114.

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).
- Have an authorized technician check the line frequency setting for the monitoring system. The setting should match the AC power line input. Refer to the monitoring system's service manual.

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 Obtaining Technical Assistance, page 10.

7. Product Maintenance

7.1. Overview

This chapter describes the steps required to properly clean the INVOS™ patient monitor (the "monitoring system"). It also provides information about periodic safety checks, service, software and firmware upgrades, and component disposal.

7.2. 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: Explosion hazard — When replacing the battery, do not use the incorrect type. Use only the battery available from Medtronic. See Accessories/Parts List, page 107.

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: 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.

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

7.3. Cleaning the Monitoring System

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: 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.

7.3.1. Materials

- Lint-free cloths
- Water
- Sodium hypochlorite (8.25% household bleach diluted 1:500 with tap water)
- Quaternary ammonium germicidal detergent (PDI Sani-Cloth™* AF3)
- Phenolic germicidal detergent (Lysol™* concentrate diluted 1:100 with tap water)
- CaviCide™* disinfectant (Metrex CaviWipes™*)

7.3.2. Procedure

Note: Follow recommended cleaning procedures for your institution.

To clean the monitoring system:

1. Power off the monitoring system and disconnect AC power.
2. Clean the outside surface of all monitoring system components with a cloth dampened with a cleaning agent or a pre-moistened wipe.
3. Clean the faceplate and screen. Do not use acetone or abrasives.
4. Allow the monitoring system to completely dry before reconnecting AC power or returning to use.

7.4. 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 10.

Medtronic recommends the following checks at the indicated intervals.

Table 21. 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. See Apply Power, page 31.
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. The monitoring system's service manual provides annual inspection procedures to be followed by an authorized technician.
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 Accessories/Parts List, page 107 for part number and ordering information.
Every 2 years	Replace the monitor's battery. See Accessories/Parts List, page 107 for part number and ordering information.
After approximately 25,000 hours of operation	Replace the monitor. See Service Life, page 97 for more information.

7.5. Service and Calibration

The monitoring system requires no routine service other than cleaning.

The monitoring system requires no calibration.

If service is necessary, contact Technical Services. See Obtaining Technical Assistance, page 10.

7.6. 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.

7.7. 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 10.

7.8. 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.

8. Alarms and Troubleshooting

8.1. Overview

This chapter describes alarms generated by the INVOS™ patient monitor (the "monitoring system") and explains how to troubleshoot other errors that might occur.

8.2. Alarm Messages

Technical vs. Physiological Alarms - All monitoring system alarms are technical except the following which are physiological:

LOW RSO2

HIGH RSO2

Non-Latching vs. Latching Alarms - The monitoring system terminates non-latching alarms within five seconds after the alarm condition no longer exists. Latching alarms must be acknowledged by the user. All monitoring system alarms are nonlatching except the following:

SYSTEM FAILURE

Table 22. Alarm Conditions

Alarm	Condition	Priority	Audio/visual	Dismissible	Resolution
BATTERY CRITICALLY LOW	System is using battery power AND battery level is Critical (<5% charge remaining).	Medium	Audio[a] and visual	No	Immediately connect to AC power. If the battery does not charge, contact Medtronic or a local Medtronic representative.
BATTERY FAILURE	Battery is malfunctioning.	Low	Visual only	No	Make sure that the battery is present and that the latch is in the locked position. Try removing and reinstalling the battery. See Install the Battery, page 27. If the battery is in place and locked, discontinue use of the monitor.
BATTERY LOW	System is using battery power AND battery level is Low (<33% charge remaining).	Medium	Audio and visual	Yes	Connect to AC power as soon as possible. If the battery does not charge, contact Medtronic or a local Medtronic representative.

Table 22. Alarm Conditions (continued)

Alarm	Condition	Priority	Audio/visual	Dismissible	Resolution
CHECK SENSOR	Sensor is not attached to patient. OR Excessive light is detected on a sensor channel. OR Electrical interference. OR Moisture in connector. OR Sensor applied over nevi, sinus cavities, the superior sagittal sinus, subdural or epidural hematomas, arteriovenous malformations, broken skin, thick fatty deposits, hair, bony protuberances, or areas contaminated with residue.	Medium	Audio and visual	No	Make sure the sensor is securely adhered to the patient. If necessary, replace the sensor. Under high ambient light conditions, loosely cover the sensor with opaque material. Identify any possible sources of interference, and take the actions recommended in EMI (Electromagnetic Interference), page 92. Try another hospital-grade electrical outlet. Have an authorized technician check the line frequency setting for the monitoring system. The setting should match the AC power line input. Refer to the monitoring system's service manual. Ensure sensor and RSC connectors are moisture-free. Check sensor site. Refer to the sensor Instructions for Use for site selection information. If the problem persists, contact Medtronic or a local Medtronic representative.
HIGH RSO2	Upper rSO_2 alarm limit is exceeded.	Medium	Audio and visual	No	Immediately check the patient.
INTERFERENCE DETECTED	Interference on a sensor channel is corrupting the rSO_2 data.	Medium	Audio and visual	No	Move or turn off the source of interference. Normal operation will resume when the excessive noise stops. See EMI (Electromagnetic Interference), page 92. Have an authorized technician check the line frequency setting for the monitoring system. The setting should match the AC power line input. Refer to the monitoring system's service manual.
LOW RSO2	Lower rSO_2 alarm limit is exceeded.	Medium	Audio and visual	No	Immediately check the patient.

Table 22. Alarm Conditions (continued)

Alarm	Condition	Priority	Audio/visual	Dismissible	Resolution
POOR SIGNAL QUALITY	Poor signal quality is detected on a sensor channel. rSO_2 values will not be displayed due to: Electrical interference. OR Incorrect line frequency setting. OR Moisture in connector. OR Sensor applied over nevi, sinus cavities, the superior sagittal sinus, subdural or epidural hematomas, arteriovenous malformations, broken skin, thick fatty deposits, hair, bony protuberances, or areas contaminated with residue. OR Defective sensor. OR Defective RSC.	Medium	Audio and visual	No	Identify any possible sources of interference, and take the actions recommended in EMI (Electromagnetic Interference), page 92. Try another hospital-grade electrical outlet. Under high ambient light conditions, loosely cover the sensor with opaque material. Have an authorized technician check the line frequency setting for the monitoring system. The setting should match the AC power line input. Refer to the monitoring system's service manual. Ensure sensor and RSC connectors are moisture-free. Check sensor site. Refer to the sensor Instructions for Use for site selection information. Replace sensor. Replace RSC. If the problem persists, contact Medtronic or a local Medtronic representative.
PREAMP FAILURE	Preamplifier is not communicating with the system as expected. OR Preamplifier is generating unrecoverable errors. OR Preamplifier version is incompatible with the monitor. PM7100 preamplifiers with version 1.2.0.0 or greater are only compatible with PM7100 monitors that are version 1.2.0.0 or greater.	Medium	Audio[a] and visual	No	If you are using two preamplifiers, determine which preamplifier is generating the alarm by touching each sensor label on the monitoring screen and noting whether the corresponding LED on the preamplifier flashes. If an LED does not flash on a preamplifier, disconnect the preamplifier cable from the monitor and reconnect it. See Connect the Preamplifier(s), page 29. If the problem persists, replace the preamplifier. Contact Medtronic or a local Medtronic representative.
PREAMP NOT CONNECTED	Preamplifier becomes disconnected from the monitor during use.	Medium	Audio and visual	Yes	Make sure the preamplifier connector is locked into the monitor. See Connect the Preamplifier(s), page 29. Normal operation will resume when the preamplifier is reconnected.

Table 22. Alarm Conditions (continued)

Alarm	Condition	Priority	Audio/visual	Dismissible	Resolution
REPLACE SENSOR	Sensor incompatible OR Invalid calibration data OR Bad sensor OR Open/short condition OR Unable to access sensor memory	Medium	Audio and visual	No	Make sure that all sensors match and are compatible with the monitoring system. See the Instructions for Use provided with the sensors. Replace the sensor(s) if necessary. Replace the RSC(s) if necessary.
SENSOR NOT CONNECTED	Sensor is disconnected from the RSC. OR RSC is disconnected from the preamplifier.	Medium	Audio and visual	Yes	Check the connection between the sensor and RSC and between the RSC and preamplifier. If the problem persists, replace the RSC and/or the sensor.
SYSTEM FAILURE	Monitoring system was reset unexpectedly. Note: All settings may be lost.	Medium	Audio[a] and visual	Yes	Power the monitoring system off and back on. If the problem persists, contact Medtronic or a local Medtronic representative.
TREND DATA LOST	Software was upgraded. OR Time setting was changed. OR Corrupt trend data was detected at start up.	Low	Audio and visual	Yes	If the problem persists, contact Medtronic or a local Medtronic representative.

[a] Sounds even when alarms are silenced or paused.

8.3. Error Conditions

If resolutions don't work, contact Technical Services (Obtaining Technical Assistance, page 10).

Table 23. Error Conditions and Resolutions

Problem	Resolution
No AC power to monitoring system when plugged in and powered on (runs on battery power only)	• Make sure that the monitoring system's power supply is plugged into a hospital-grade power outlet. • Make sure that the power cord is securely connected to the power supply and that the power supply is securely connected to the docking station. • Check that the AC indicator on the docking station is illuminated. See Apply Power, page 31. • Make sure that the monitor is completely seated in the docking station. See Insert the Monitor into the Docking Station, page 28. • If the problem persists, contact Medtronic or a local Medtronic representative.
Does not power up when power button is pressed	• Press the power button for more than 3 seconds. • If operating on AC power, refer to the resolutions above. • If operating on battery power, make sure that the battery latch is in the locked position. See Install the Battery, page 27. • If operating on battery power, the battery may be discharged. Connect to AC power to charge the battery. See Apply Power, page 31.
System indicates a preamplifier has been disconnected when it is still physically connected Error message: PREAMP NOT CONNECTED	• Check the preamplifier connection to the monitor. See Connect the Preamplifier(s), page 29. • Try a different preamplifier. • Contact Medtronic or a local Medtronic representative.
System does not recognize and gives no indication a preamplifier has been connected after it has been physically connected	• Check the preamplifier connection to the monitor. See Connect the Preamplifier(s), page 29. • Try a different preamplifier. • Contact Medtronic or a local Medtronic representative.
Does not power off when power button is pressed	If the monitoring system does not power off within approximately 30 seconds after you press the Power button, press and hold the Power button for at least 10 seconds to power off the monitoring system.
Electrical noise on AC power line causing poor signal quality	Have an authorized technician check the line frequency setting for the monitoring system. The setting should match the AC power line input. Refer to the monitoring system's service manual.
Multiple, consecutive sensor alarms	If sensor alarms continue to occur after you have performed the recommended corrections for the alarms (see Table 22, page 99), replace the following: • RSCs • Preamplifiers
Displayed rSO_2 value is 0 with sensor properly applied to a patient according to the sensor Instructions for Use	Replace the sensor.
Frequent battery alarms	Replace the battery. See Install the Battery, page 27.
Touch screen is unresponsive	• Power the monitoring system off and back on. • If the problem persists, contact Medtronic or a local Medtronic representative.

Table 23. Error Conditions and Resolutions (continued)

Problem	Resolution
System errors are non-recoverable technical issues resulting in a non-responsive system. These include: • Sensor is connected to a patient, but the rSO_2 data display has not been updated for over 30 seconds. • The system may indicate that settings are corrupted. Error message: SYSTEM ERROR	• Power the monitoring system off and back on. • If the problem persists, contact Medtronic or a local Medtronic representative.
A USB error occurs during any of the following situations: • Exporting case histories • Exporting logs • Exporting or importing system settings • Importing firmware or software Possible error messages include: • USB DRIVE NOT FOUND. INSERT USB DRIVE AND TRY AGAIN. • USB DRIVE ERROR. CHECK USB DRIVE AND TRY AGAIN. • MULTIPLE USB DRIVES FOUND. REMOVE EXTRA USB DRIVES AND TRY AGAIN. • INSUFFICIENT STORAGE SPACE. INSERT NEW USB DRIVE AND TRY AGAIN. • NO FIRMWARE UPDATE FOUND. CHECK USB DRIVE AND TRY AGAIN. • NO SOFTWARE UPDATE FOUND. CHECK USB DRIVE AND TRY AGAIN.	• Follow the resolution indicated in the error message. • If a USB flash drive is present but isn't recognized by the system, make sure that the drive has been formatted. If necessary, you can format the drive on a computer running Microsoft Windows ™*.

Table 23. Error Conditions and Resolutions (continued)

Problem	Resolution
Unable to consistently display monitoring system screens to an external monitor	• Make sure that the monitor is completely seated in the docking station. See Insert the Monitor into the Docking Station, page 28. • Disconnect the VGA cable from the docking station and external monitor. Reconnect the cable, making sure it is completely seated at both connections. • Verify that the power cord is fully plugged into the monitor's docking station. • Verify that the external monitor is connected to power. • Verify that the VGA cable meets the requirements described in Displaying Monitoring System Screens on an External Monitor, page 77. • Power the monitoring system off and back on.
No data received or data scrambled during serial port transmissions	• Make sure that the monitor is completely seated in the docking station. See Insert the Monitor into the Docking Station, page 28. • Disconnect the serial cable from the docking station and external device. Reconnect the cable, making sure it is completely seated at both connections. • Verify that the power cord is fully plugged into the monitor's docking station. • Have an authorized technician check the serial port format for the monitoring system. The format must be set correctly for the type of transmission. Refer to the monitoring system's service manual. • If transmitting data, verify that the serial cable meets the requirements described in Serial Port Specifications, page 79 and Null Modem Cable Requirements, page 81. • If using a terminal emulation program to receive data from the monitor, verify that the terminal emulation program settings are correct. See Transmitting Case Data to a Computer, page 81. • Make sure that the system is monitoring (the monitoring screen is displayed). The monitoring system does not transmit data when the Set-up screen is displayed. • Power the monitoring system off and back on.

8.4. Product Return

Contact Medtronic or a local Medtronic representative for shipping instructions, including a Returned Goods Authorization (RGA) number. See Obtaining Technical Assistance, page 10. 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 rSO_2 sensor and other accessories for use with the INVOS™ patient monitor (the "monitoring system").

- Safety Reminder, page 107
- Accessories/Parts List, page 107

9.2. Safety Reminder

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.

9.3. Accessories/Parts List

Contact Medtronic or a local Medtronic representative to order accessories. See Technical Services, page 10.

Table 24. Monitoring System Accessory Part Numbers

Part number	Item
PMSENS71-A	INVOS™ adult rSO_2 sensor
PMAC71DOC	INVOS™ docking station
PMAC71STAND	INVOS™ patient monitor stand
PMAC71RSC	INVOS™ reusable sensor cable for PM7100
PMAC71BAT	INVOS™ PM7100 battery
PMAC71PS	INVOS™ PM7100 power supply
VLI	INVOS™ rSO_2 interface cable (VueLink™* adapter cable, DB25F to DB9F)

10. Theory of Operations

10.1. Overview

This chapter explains the theory behind operations of the INVOS™ patient monitor (the "monitoring system").

10.2. Theoretical Principles

The INVOS™ system "reflects the color of life." The near-infrared wavelengths generated by the INVOS™ system's light-emitting diodes (LEDs) pass through scalp and bone tissue beneath the sensor. Once in vivo they are either absorbed or scattered back up to the sensor's shallow and deep detectors. Other than variations in the thickness and composition of the tissue layers, somatic and cerebral measurements are quite similar.

Red-colored hemoglobin molecules within red blood cells have the highest light absorption of the wavelengths used, and the exact shade of red of each hemoglobin molecule indicates the amount of oxygen it is carrying.

The type and quantity of absorption data returned to the detectors reflects relative amounts of deoxyhemoglobin and total hemoglobin, from which a regional oxygen saturation (rSO_2) value unique to the specific area under the sensor is calculated.

Values are measured continuously, with screen updates provided to clinicians every second.

11. Product Specifications

11.1. Overview

This chapter contains physical and operational specifications for the INVOS™ patient monitor (the "monitoring system").

11.2. Physical Characteristics

Monitor	
Dimensions	20 x 30.75 x 5.1 cm (7.87 x 12.1 x 2 in.)
Weight	1270 g (2.8 lb)
Screen size	25.7 cm (10.1 in.), measured diagonally
Screen type	TFT LCD, projected capacitive multi-touch
Resolution	1280 x 800 pixels
Visibility	Visual communication of parameter values and alarms is visible by an operator with 20/20 vision (corrected as necessary) from a distance of 1 meter when the monitor is placed in an environment with ambient light in the range of 100 to 1500 lux and the operator's position is anywhere on or within the base of a cone subtended by an angle of 30° normal to the center of the plane of display of the monitor. Visual communication of parameter alarm priority is visible under the same conditions from 4 meters.
Buttons	Power on/off
Power	AC power adapter, Li-ion battery
Ports	USB 3.0, USB 2.0, DC In, docking port
Indicators	Power/battery, hard disk activity, wireless
Docking Station	
Type	VESA™*
Dimensions	22.47 x 20 x 5.64 cm (8.85 x 7.87 x 2.22 in.)
Indicator	Power

(continued)

Ports	DC In, USB 2.0 (x2), serial (RS-232), and VGA ports
Stand	
Dimensions	24.3 x 31.1 x 26.8 cm (9.58 x 12.25 x 10.57 in.)
Preamplifier	
Dimensions	12.8 x 8.7 x 2.8 cm (5.04 x 3.43 x 1.1 in.) with hook folded down
Weight	294 g (0.65 lb)
Indicators	Reusable sensor cable (RSC) connection prompt
Preamplifier cable length	428.4 cm (14 ft) (approximate)
Preamplifier cable connector	Amphenol 8-pin
Reusable sensor cable (RSC)	
Length	162 cm (5.3 ft) (approximate)
Indicators	Sensor connection prompt
Power cable	
Length	International: 2.5 m US: 10 ft

11.3. Electrical

Power	100 VAC to 240 VAC ±10%
Input frequency	50 Hz to 60 Hz

11.4. Battery

Type	Lithium-ion
Voltage	11.1 VDC
Capacity	31.7 Whrs (11.1V 2860mAh)
Operating time	1 hour under normal monitoring conditions
Recharge	24 hours
Compliance	IEC 62133:2012, EN 62133: 2013 UL2054 2nd Edition, UL 60950-1 2nd Edition CAN/CSA C22.22 No. 60950-1-07 2nd Edition UN 38.3 Rev 5, Amd 1 PSE

11.5. Environmental Conditions

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

Table 25. Transport, Storage, and Operating Condition Ranges

	Transport and storage	Operating conditions
Temperature	-20ºC to 45ºC (-4ºF to 113ºF)	10ºC to 35ºC (50ºF to 95ºF)
Altitude	-500 m to 6100 m (-1640 ft to 20013 ft)	-500 m to 4000 m (-1640 ft to 13123 ft)
Atmospheric pressure	1075 hPa to 465 hPa (32 in. Hg to 14 in. Hg)	1075 hPa to 616 hPa (32 in. Hg to 18 in. Hg)
Relative humidity	10% to 95% noncondensing	15% to 95% noncondensing

11.6. Alarm Audio and Visual Characteristics

Alarms	
Categories	Physiological (patient status) and technical (system status)
Priorities	Medium and low
Notifications	Audible and visual
Alarm volume level	Adjustable 1 to 10 15 to 45 dB
Alarm system delay	None
Alarm reminder signal	Once every 3 minutes ±10 seconds Three pulses in burst

11.6.1. Alarm Audio Characteristics

Table 26. Alarm Audio Characteristics

Sound	Number of pulses in burst	Pitch (Hz)	Effective pulse duration (ms)	Rise/fall time (ms)	Inter-pulse spacing (ms)	Number of harmonic components
Medium priority alarm	3	525	144.9	Rise: 19.2 Fall: 12	Between pulse 1 and 2: 188.1 Between pulse 2 and 3: 188.1	> 4
Low priority alarm	2	Pulse 1: 660 Pulse 2: 525	186.9	Rise: 19.2 Fall: 12	Between pulse 1 and 2: 188.1	> 4

Table 27. Average Alarm Sound Pressure Levels

Alarm	Volume = 1	Volume = 5 (default)	Volume = 10
Medium priority	21 dB	33 dB	38 dB
Low priority	19 dB	29 dB	35 dB

11.6.2. Alarm Visual Characteristics

Table 28. Alarm Visual Characteristics

Alarm	Color	Flashing frequency[a] (Hz)	Duty cycle
Medium priority	Yellow	0.5	50%
Low priority	Yellow	None	100%

[a] Alarm visual flashing alternates between the original color (brightness = 100%) and a darker shade of the same color (brightness = 70%).

11.6.3. POST Pass Tone

Table 29. POST Pass Tone Characteristics

POST pass tone	
Volume level	Not changeable
Number of pulses	N/A
Repetitions	No repeat

11.7. Sensor Operating Range

Table 30. INVOS™ Adult rSO_2 Sensor Operating Range

Operating range	
Four-wavelength LEDs	Approximately 700 nm to 900 nm

11.8. Equipment Classifications

Type of protection against electric shock	Class I and internally powered
Degree of protection against electric shock	Defibrillation-proof type BF applied part
Mode of operation	Continuous
Electromagnetic compatibility	IEC 60601-1-2:2007 and IEC 60601-1-2:2014
Ingress protection	IPX2
Degree of safety	Not suitable for use in the presence of flammable anesthetics

11.9. Biocompatibility Testing

Biocompatibility testing has been conducted on INVOS™ sensors in compliance with ISO 10993-1:2009, Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing. INVOS™ sensors have passed the recommended biocompatibility testing and are therefore in compliance with ISO 10993-1:2009.

11.10. Manufacturer's Declaration

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.

11.10.1. 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.

11.10.1.1. Electromagnetic Emissions Guidelines and Compliance

Table 31. 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	

11.10.1.2. Electromagnetic Immunity Guidelines and Compliance

Table 32. 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.

11.10.1.3. Recommended Separation Distance Calculations

Table 33. 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: 
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: 

Table 33. 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**
RF wireless proximity fields IEC/EN 61000-4-3	See Table 34, page 118	See Table 34, page 118	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 34. 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 ±5 kHz 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						

11.10.1.4. Recommended Separation Distances

Table 35. 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.			

11.11. Essential Performance

Per EN 60601-1, essential performance for the INVOS™ patient monitor includes the detection and reporting of changes in rSO_2 values of ≥ 20% from baseline.

Appendix A. Clinical Studies

A.1. Overview

This appendix provides information on clinical studies using the INVOS™ regional saturation patient monitoring system. A reference bibliography containing additional clinical studies is available on Medtronic's website (www.medtronic.com) or by contacting Medtronic or a local Medtronic representative. See Technical Services, page 10.

An adult volunteer study was performed comparing the regional oxygen saturation (rSO_2) from the system to blood sample analysis in 20 volunteers (hypoxia study). No adverse events attributable to the system were reported during the study.

A.2. Hypoxia Study

The hypoxia study compared the rSO_2 as reported by the system to the "field" saturation (fSO_2) calculated from arterial and jugular venous blood oxygen saturation measurements at five levels of oxygen saturation and two levels of inspired CO_2. Based on the assumption that cerebral tissue contains arterial and venous blood in a 1:3 ratio, fSO_2 was calculated as:

$fSO_2 = (0.25 \text{ X } \text{SarterialO}_2) + (0.75 \text{ X } \text{Sjugular veinO}_2)$

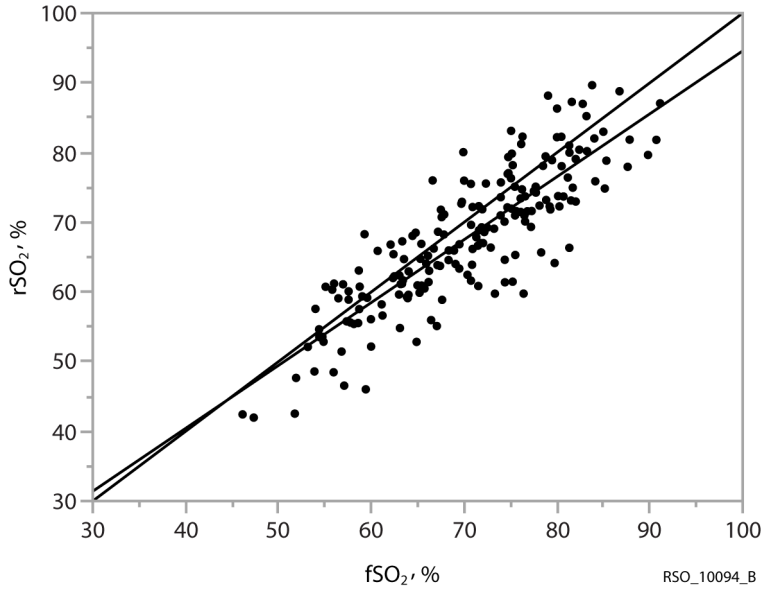
The 20 volunteers included: 19 with light and 1 with dark skin; 12 males and 8 females; age 20 to 36 years, with a median of 25 years. One data point was excluded from analysis due to delays in blood sampling caused by catheter problems.

A.2.1. Methods

Blood samples were obtained from the right internal jugular bulb and the radial artery. A SomaSensor™ sensor was placed on the right forehead. Subjects breathed controlled gas mixtures in a predefined sequence of 4- and 5- minute intervals to attain five levels of arterial O_2 saturation (74% to 100%). This sequence was performed twice at two different CO_2 levels (4- 7 mmHg increase) intended to raise cerebral blood flow and evaluate the ability of the system to reject noncerebral data.

A.2.2. Results

Figure 70. Accuracy rSO_2 and fSO_2, 20 Subjects



Accuracy 96 and 97 data; last 20 subjects; 189 data points. y=0.9026x+4.3235; R^2=0.729; bias=2.51; standard deviation=5.23.

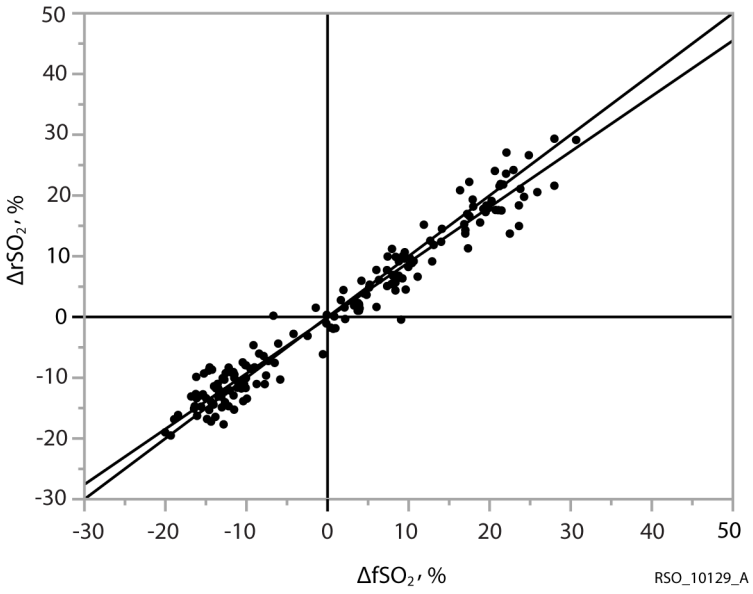
Table 36. Performance Characteristics: Accuracy Bias, Error (SD), RMSD, and Correlation (R^2) for rSO_2 and fSO_2, 20 Subjects

	Individual subjects (N=20) mean	Range	Pooled (N=189) data points
Accuracy Bias (%)[a]	2.56	–6.47 to +11.78	2.51
Error (SD) (%)[a]	2.08	0.85 to 4.22	5.23
RMSD[a]	5.11	2.15 to 12.03	5.79
Correlation (R^2)[a]	0.946	0.823 to 0.990	0.729
[a] Less subject 206			

One subject had a bias value of 37.2%, which corresponded with a very low signal quality index number (SQI=1). The remaining 41 subjects had SQIs that started at 10 and remained greater than four throughout the study.

Subject 206's absolute bias data was excluded from the analysis due to the low signal quality, but the trend data was left in as trending is not dependent on SQI.

Figure 71. Trend rSO_2 and fSO_2, 20 Subjects



Trend 96 and 97 data; last 20 subjects; 179 data points. y=0.9133x–0.1755; R^2=0.958; bias=0.26; standard deviation=2.9.

Table 37. Trend Bias, Error (SD), and Correlation (R^2) for ΔrSO_2 and ΔfSO_2, 20 subjects

	Pooled (N=179) data points
Trend Bias (%)	0.26
Error (SD) (%)	2.90
Correlation (R^2)	0.958

A.3. Interventional Studies

In controlled studies of carotid endarterectomy (references 1-3), changes in the rSO_2 of 12-20 points (absolute) or 20% to 30% (relative) correlated with changes in the patient's neurological status. In these studies, as well as in other interventional studies of general and cardiac surgery patients (references 4-10), rSO_2 values less than 50 were associated with higher probabilities of a poor outcome.

1. Cho H, Nemoto EM, Yonas H, Balzer J: Cerebral monitoring by oximetry And Somatosensory Evoked Potentials (SSEP) during Carotid Endarterectomy. J Neurosurg, 89:533-38, 1998.
2. Roberts KW, Crnkowic AP, Linneman LJ: Near infrared spectroscopy detects critical cerebral hypoxia during carotid endarterectomy in awake patients. Anesthesiology 1998;89(3A):A934.
3. Samra S, Dy E, Welch K, Dorje P, Zelenock G, Stanley J: Evaluation of a cerebral oximeter as a monitor of cerebral ischemia during carotid endarterectomy. Anesthesiology 2000;93:964-70.
4. Murkin JM, Adams SJ, Novick RJ, Quantz M, Bainbridge D, Iglesias I, Cleland A, Schaefer B, Irwin B, Fox S. Monitoring brain oxygen saturation during coronary

bypass surgery: a randomized, prospective study. Anesth Analg. 2007 Jan;104(1):51-8.

5. Casati A, Fanelli G, Pietropaoli P, Proietti R, Tufano R, Montanini S. Monitoring cerebral oxygen saturation in elderly patients undergoing general abdominal surgery: a prospective cohort study. Eur J Anaesthesiol. 2006 Jul 7;:1-7 [Epub ahead of print].
6. Casati A, Fanelli G, Pietropaoli P, Proietti R, Tufano R, Danelli G, Fierro G, De Cosmo G, Servillo G. Continuous monitoring of cerebral oxygen saturation in elderly patients undergoing major abdominal surgery minimizes brain exposure to potential hypoxia. Anesth Analg. 2005 Sep;101(3):740-7.
7. Edmonds HL Jr, Ganzel BL, Austin EH 3rd. Cerebral oximetry for cardiac and vascular surgery. Semin Cardiothorac Vasc Anesth. 2004;8:147-66.
8. Goldman S, Sutter F, Ferdinand F, Trace C. Optimizing intraoperative cerebral oxygen delivery using noninvasive cerebral oximetry decreases the incidence of stroke for cardiac surgical patients. Heart Surgery Forum 2004;7(5):#2004-1062.
9. Murkin JM, Iglesias I, Bainbridge D, Adams S, Schaefer B, Irwin B, Fox S. Monitoring cerebral oxygen saturation significantly decreases major organ morbidity in CABG patients: A randomized blinded study. The Heart Surgery Forum 2004;7(6):515.
10. Yao FSF, Tseng CCA, Ho CYA, Levin SK, Illner P. Cerebral oxygen desaturation is associated with early postoperative neuropsychological dysfunction in patients undergoing cardiac surgery. J Cardiothorac Vasc Anesth 2004;18(5):552-558.

A.4. Validation Studies

Validation studies for the system include, but are not limited to, the following references:

1. Kim MB, Ward DS, Cartwright CR, Kolano J, Chlebowski S, Henson LC. Estimation of jugular venous O_2 saturation from cerebral oximetry or arterial O_2 saturation during isocapnic hypoxia. J Clin Monit Comput. 2000;16(3):191-9.
2. Kolb JC, Ainslie PN, Ide K, Poulin MJ. Effects of five consecutive nocturnal hypoxic exposures on the cerebrovascular responses to acute hypoxia and hypercapnia in humans. J Appl Physiol. 2004 May;96(5):1745-54. Epub 2004 Jan 16.

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