INVOS™
Patient Monitor

Operator's Manual
## Symbols

| **REF** | Reference code (part number) |
| **SN** | Serial number |
| **LOT** | Lot number |
| **EC REP** | European Community (EC) authorised representative |
| **Rx ONLY** | Prescription only. US federal law restricts this device to sale by or on the order of a doctor. |
| **IPX2** | Protection against fluid ingress: Protected against vertically falling water drops when tilted to 15° |
| **Mount** | Manufacturer |
| **Date** | Date of manufacture |
| **Fragile** | Fragile |
| **Keep** | Keep it in a dry area |
| **Must consult** | Must consult instructions for use |
| **Consult** | Consult instructions for use |
| **Atmospheric pressure limits** | Atmospheric pressure limits (see Environmental Conditions, page 112) |
| **Temperature limits** | Temperature limits (see Environmental Conditions, page 112) |
| **Humidity limits** | Humidity limits (see Environmental Conditions, page 112) |
| **Proper waste disposal for electrical and electronic equipment** | Proper waste disposal for electrical and electronic equipment |
| **MR unsafe – Do not use during magnetic resonance imaging** | MR unsafe – Do not use during magnetic resonance imaging |
| **Defibrillation-proof type BF applied part** | Defibrillation-proof type BF applied part |
| **CSA – Canadian Standards Association certification mark** | CSA – Canadian Standards Association certification mark |
| **Not made with natural rubber latex** | Not made with natural rubber latex |
| **MR safe – Safe for use during magnetic resonance imaging** | Electromagnetic interference may occur in the vicinity of equipment marked with this symbol |
| **Quantity included in package (example: 20)** | 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 healthcare 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 anaesthetics.
Warning: Explosion hazard – When replacing the battery, do not use the incorrect type. Use only the battery provided by Medtronic. See Accessories/Parts List, page 107.
Warning: Shock hazard – Ensure that 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 that 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 be poor 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 that 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 that there are no signs of physical damage or improper function. Do not use damaged cables on the patient.

**Warning:** If you do not hear a tone at system startup, 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 provided by 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 that 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, poor 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-orientating 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-sterilise 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  
001.800.635.5267 or 001.925.463.4635  
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 startup screen at power-on.

---

**Figure 1. Startup Screen Showing Code Version**

---

**Medtronic**  
**INVOS™**  
**PM7100**

Starting up...  

vn.n.n.n
Note: An authorised 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 rSO₂ 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 authorised 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’).
- Product Description, page 13
- Indications for Use, page 14
- Product Views, page 14

2.2. Product Description
The monitoring system provides continuous, non-invasive indications of changes in regional oxygen saturation of blood (rSO₂) 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 amplifier)
- Up to four reusable sensor cables (RSCs) to attach sensors to the preamplifiers
- INVOS™ rSO₂ sensors
- Additional accessories as described in Chapter 9, Accessories, page 107

Monitoring system features include:
- User configurable rSO₂ baselines (page 52), alarm limits (page 62) and AUC thresholds (page 70)
- Physiological and technical alarm reporting (page 99)
- User configurable data display (rSO₂, 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 non-invasive cerebral/somatic oximetry system intended for use as an adjunct monitor of regional haemoglobin 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

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 (CC 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**

<table>
<thead>
<tr>
<th></th>
<th>Element</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Message area</td>
<td>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.</td>
</tr>
<tr>
<td>N/A</td>
<td>Dismiss button (not shown)</td>
<td>Available in the message area when an alarm is dismissable. See Dismiss an Alarm, page 65.</td>
</tr>
<tr>
<td>2</td>
<td>Sensor icons</td>
<td>Each sensor icon has a label indicating its location on the patient. See Changing the On-Screen Sensor Labels, page 50.</td>
</tr>
<tr>
<td>3</td>
<td>Date and time</td>
<td>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 authorised technician.</td>
</tr>
<tr>
<td>4</td>
<td>Battery status indicator</td>
<td>Indicates the remaining battery capacity:</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Charged battery</strong> – The level in the icon decreases as battery power is used.</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Low battery</strong> – A medium-priority alarm occurs when the monitoring system is operating on battery power and the battery has a charge of &lt;33% remaining. The alarm message BATTERY LOW appears.</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Critically low battery</strong> – A medium-priority alarm occurs when the monitoring system is operating on battery power and the battery has a charge of &lt;5% remaining. The alarm message BATTERY CRITICALLY LOW appears. When no charge remains, the monitoring system automatically shuts down.</td>
</tr>
<tr>
<td>5</td>
<td>Battery charging indicator</td>
<td>Indicates that the monitoring system is connected to AC power and the battery is charging.</td>
</tr>
</tbody>
</table>
### Operator’s Manual

<table>
<thead>
<tr>
<th>6</th>
<th>AC power indicator</th>
<th>When the battery is fully charged and the monitoring system remains connected to AC power, the AC power indicator replaces the battery charging indicator.</th>
</tr>
</thead>
<tbody>
<tr>
<td>7</td>
<td>CURRENT</td>
<td>The most recent rSO₂ reading from each sensor.</td>
</tr>
<tr>
<td>8</td>
<td>CHANGE</td>
<td>The percent change between the current rSO₂ reading and the established baseline for each sensor, colour-coded to the corresponding sensor icon.</td>
</tr>
<tr>
<td>9</td>
<td>Sensor/readings in alarm state</td>
<td>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.</td>
</tr>
<tr>
<td>10</td>
<td>Alarm limits</td>
<td>The current alarm limits for each sensor, colour-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.</td>
</tr>
<tr>
<td>11</td>
<td>Event mark</td>
<td>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.</td>
</tr>
<tr>
<td>12</td>
<td>Baseline values</td>
<td>The current rSO₂ baseline established for each tissue region being monitored, colour-coded to the corresponding sensor icon. Dotted lines in the trend view graph also indicate the baseline values, colour-coded to the corresponding sensor icon. See Baselines, page 52.</td>
</tr>
<tr>
<td>13</td>
<td>Alarm Audio button</td>
<td>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 colour corresponds to the highest-level alarm. See Alarm Indicators, page 60 and Silencing or Pausing Alarms, page 64.</td>
</tr>
<tr>
<td>14</td>
<td>MARK EVENT button</td>
<td>Press to add an event mark to the trend graph to indicate a significant occurrence during monitoring. Choose from a customisable list of events. See Event Marks, page 66.</td>
</tr>
<tr>
<td>15</td>
<td>Patient button</td>
<td>While monitoring, press to return to the Setup screen, reposition on-screen sensors or assign or modify a patient ID. See Setup for Patient Monitoring, page 42, Repositioning On-Screen Sensors, page 47 and Assigning or Modifying the Patient ID, page 49.</td>
</tr>
<tr>
<td>16</td>
<td>Trend view</td>
<td>The trend view shows the progression of rSO₂ values over the course of a case. Data is colour-coded to the corresponding sensor icon. rSO₂ values are presented on the vertical (y) axis. Time is presented on the horizontal (x) axis. See Trend View Management, page 55.</td>
</tr>
<tr>
<td>17</td>
<td>MENU button</td>
<td>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.</td>
</tr>
</tbody>
</table>
3. Installation

3.1. Overview
This chapter contains information for the installation and setup of the INVOS™ patient monitor (the ‘monitoring system’) prior to first-time use.

• Safety Reminders, page 23
• Unpacking and Inspection, page 23
• Power Options, page 24
• Setup, page 27

3.2. Safety Reminders
Warning: Inspect the monitoring system and all accessories before use to ensure that there are no signs of physical damage or improper function. Do not use damaged cables on the patient.
Warning: Shock hazard – Ensure that the monitoring system is properly grounded when operating on AC power.
Warning: If you do not hear a tone at system startup, 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 that 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>
<thead>
<tr>
<th>Item</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient monitor</td>
<td>1</td>
</tr>
<tr>
<td>Lithium-ion battery</td>
<td>1</td>
</tr>
<tr>
<td>Patient monitor stand</td>
<td>1</td>
</tr>
</tbody>
</table>
Table 1. Monitoring System – Standard Shipped Items (continued)

<table>
<thead>
<tr>
<th>Item</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>VESA™* docking station</td>
<td>1</td>
</tr>
<tr>
<td>Preamplifiers</td>
<td>1 or 2</td>
</tr>
<tr>
<td>Reusable sensor cables (RSCs)</td>
<td>2 or 4</td>
</tr>
<tr>
<td>INVOS™ adult rSO₂ sensors</td>
<td>Box of 5, 10 or 20</td>
</tr>
<tr>
<td>AC power supply</td>
<td>1</td>
</tr>
<tr>
<td>Power cord</td>
<td>1</td>
</tr>
<tr>
<td>Operator's manual (on USB flash drive)*</td>
<td>1</td>
</tr>
</tbody>
</table>

* 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 that 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](POX_20075_A)

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).
AC power to the monitoring system is indicated as follows:

Table 2. AC Power Indicators

<table>
<thead>
<tr>
<th>Status</th>
<th>Monitor LED</th>
<th>Screen icon</th>
</tr>
</thead>
<tbody>
<tr>
<td>AC connected (battery charging)</td>
<td><img src="image1.png" alt="Monitor LED Icon" /></td>
<td><img src="image2.png" alt="Screen Icon" /></td>
</tr>
<tr>
<td>AC connected (battery fully charged)</td>
<td><img src="image1.png" alt="Monitor LED Icon" /></td>
<td><img src="image2.png" alt="Screen Icon" /></td>
</tr>
<tr>
<td>AC not connected</td>
<td><img src="image1.png" alt="Monitor LED Icon" /></td>
<td><img src="image2.png" alt="Screen Icon" /></td>
</tr>
</tbody>
</table>

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.
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>
<thead>
<tr>
<th>Battery status</th>
<th>Screen icon</th>
<th>Audible alarm</th>
<th>Message</th>
</tr>
</thead>
<tbody>
<tr>
<td>Charged</td>
<td>📅</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>(33%–100% remaining)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low</td>
<td>📅</td>
<td>Medium priority</td>
<td>BATTERY LOW</td>
</tr>
<tr>
<td>(&lt;33% remaining)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Critically Low</td>
<td>📅</td>
<td>Medium priority</td>
<td>BATTERY CRITICALLY LOW</td>
</tr>
<tr>
<td>(&lt;5% remaining)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Malfunctioning</td>
<td>📅ometrics</td>
<td>Low priority – no audible alarm</td>
<td>BATTERY FAILURE</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### 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 two 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).
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 that 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 amplifier cable connector with the red marking on the monitor input connection (**Figure 16**).
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.
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 startup, 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.
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.

![Battery Indicators]

Charging

Fully charged

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

![Power Button]

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 Setup screen appears (Figure 20).
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.

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 authorised 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

<table>
<thead>
<tr>
<th>Item</th>
<th>Available settings</th>
<th>Factory default</th>
</tr>
</thead>
<tbody>
<tr>
<td>Silence alarms at startup</td>
<td>YES, NO</td>
<td>NO – Alarms will sound unless the user presses the Alarm Audio button</td>
</tr>
<tr>
<td>Alarm audio off/pause duration</td>
<td>INDEFINITE, 2 MINS</td>
<td>INDEFINITE – When silenced by the user, alarms remain silent until the user unsilences them</td>
</tr>
<tr>
<td>Alarm reminder signal</td>
<td>ON, OFF</td>
<td>OFF</td>
</tr>
<tr>
<td>Line frequency</td>
<td>50 Hz, 60 Hz</td>
<td>60 Hz</td>
</tr>
<tr>
<td>POST during sensor off</td>
<td>ON, OFF</td>
<td>OFF For system diagnostics only. Do not set to ON when used in a clinical setting.</td>
</tr>
<tr>
<td>Date</td>
<td>(Select from calendar)</td>
<td>Coordinated Universal Time (UTC)</td>
</tr>
<tr>
<td>Date format</td>
<td>DD MM YYYY, YYYY MM DD, MM DD YYYY</td>
<td>MM DD YYYY</td>
</tr>
<tr>
<td>Time</td>
<td>(Select hh:mm)</td>
<td>N/A</td>
</tr>
<tr>
<td>Time format</td>
<td>24 hr, 12 hr</td>
<td>12 hr</td>
</tr>
<tr>
<td>Language</td>
<td>DANISH, DUTCH, ENGLISH, FRENCH, GERMAN, GREEK, HUNGARIAN, ITALIAN, NORWEGIAN, POLISH, PORTUGUESE, ROMANIAN, RUSSIAN, SLOVAK, SPANISH, SWEDISH</td>
<td>ENGLISH</td>
</tr>
<tr>
<td>Serial port</td>
<td>OFF, PC LINK 1, PC LINK 2, CLINICAL TEST SETUP, VUE LINK</td>
<td>OFF</td>
</tr>
</tbody>
</table>

#### 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).
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 that 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 socket access and power cord position** – Ensure that the power socket 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 rSO₂ 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.

• Safety Reminders, page 37
• Quick Start, page 39
• Operational Defaults, page 40
• Menu Structure, page 41
• Monitoring System Memory, page 42
• Setup for Patient Monitoring, page 42
• Optional SetUp Tasks, page 46
• Baselines, page 52
• Trend View Management, page 55
• Alarm Management, page 60
• Event Marks, page 66
• Area Under the Curve (AUC), page 70
• Finish Monitoring, page 72
• Case Histories, page 73

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 that there are no signs of physical damage or improper function. Do not use damaged cables on the patient.

**Warning:** Explosion hazard – Do not use the monitoring system in the presence of flammable anaesthetics.

**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 that 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 startup, 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, poor 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-orientating 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 that 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 that 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 **Setup for Patient Monitoring, page 42**.

**Table 5. Quick Start Steps**

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
<th>Additional Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Make sure that all components of the monitoring system are present: Monitor, docking station, power supply, power cord, preamplifier(s), reusable sensor cables (RSCs), INVOS™ rSO₂ sensors</td>
<td>See <strong>Setup for Patient Monitoring, page 42</strong></td>
</tr>
<tr>
<td>2</td>
<td>Attach up to four INVOS™ rSO₂ sensors to the patient</td>
<td>See the Instructions for Use provided with the sensors</td>
</tr>
<tr>
<td>3</td>
<td>Power on the monitoring system</td>
<td>See <strong>Setup for Patient Monitoring, page 42</strong></td>
</tr>
<tr>
<td>4</td>
<td>Optionally, change the sensor placement sequence</td>
<td>See <strong>Changing the Sensor Placement Sequence, page 46</strong></td>
</tr>
<tr>
<td>5</td>
<td>Connect the sensors to the RSCs, following the onscreen prompts, and verify the sensor locations</td>
<td>See <strong>Setup for Patient Monitoring, page 42</strong></td>
</tr>
<tr>
<td>6</td>
<td>Secure all cables to avoid patient skin injury or entanglement</td>
<td>See <strong>Setup for Patient Monitoring, page 42</strong></td>
</tr>
<tr>
<td>7</td>
<td>Optionally, enter a patient ID</td>
<td>See <strong>Assigning or Modifying the Patient ID, page 49</strong></td>
</tr>
</tbody>
</table>
| 8    | Begin monitoring:  
  - For a new case, press NEW DATA SET  
  - To continue a case, press APPEND OLD DATA | See **Setup 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)

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
<th>See:</th>
</tr>
</thead>
</table>
| 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 authorised access, as indicated.

Table 6. Operational Defaults

<table>
<thead>
<tr>
<th>Item</th>
<th>Available settings</th>
<th>Default</th>
<th>See:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upper alarm limits</td>
<td>OFF, ON</td>
<td>OFF</td>
<td>Setting Alarm Limits, page 62</td>
</tr>
<tr>
<td>Lower alarm limits</td>
<td>MANUAL, AUTO</td>
<td>MANUAL</td>
<td>Setting Alarm Limits, page 62</td>
</tr>
<tr>
<td>Upper rSO₂ limit</td>
<td>20–95</td>
<td>If ON, default is 90</td>
<td>Setting Alarm Limits, page 62</td>
</tr>
</tbody>
</table>
| Lower rSO₂ limit         | MANUAL: 15–90  
    AUTO: 5–30    | MANUAL: 40  
    AUTO: 20    | 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 authorised 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 authorised technician. |
| Alarm reminder signal    | ON, OFF            | OFF – No reminder when alarms are silenced This setting may be changed by an authorised technician. |
| Line frequency           | 50 Hz, 60 Hz       | 60 Hz  | Setting Alarm Limits, page 62 |
| Alarm volume             | 1–10               | 5       | Changing the Alarm Volume, page 63 |
| Screen brightness        | 1–10               | 7       | Changing the Screen Brightness, page 51 |
| Time format              | 24 hr, 12 hr       | 12 hr  | Setting Alarm Limits, page 62 |

This setting may be changed by an authorised technician.
Table 6. Operational Defaults (continued)

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

4.5. Menu Structure

Table 7. Menu Structure

<table>
<thead>
<tr>
<th>MENU</th>
<th>ALARM LIMITS</th>
<th>UPPER LIMITS</th>
<th>LOWER LIMITS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>SETTINGS</td>
<td>GENERAL</td>
<td>SCREEN BRIGHTNESS</td>
</tr>
<tr>
<td></td>
<td></td>
<td>SENSOR PLACEMENT SEQUENCE</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>ALARMS</td>
<td>ALARM VOLUME</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TRENDS</td>
<td>TREND LINE AVERAGING</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EVENTS</td>
<td>TWO AXIS VIEW/ONE AXIS VIEW</td>
</tr>
<tr>
<td></td>
<td>CASE HISTORIES a</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>SET BASELINES b</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>AREA UNDER CURVE 2</td>
<td>RESET AUC</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>THRESHOLD</td>
<td></td>
</tr>
</tbody>
</table>

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 that 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 setup 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

<table>
<thead>
<tr>
<th>When this situation occurs…</th>
<th>Perform this action…</th>
</tr>
</thead>
<tbody>
<tr>
<td>You have started monitoring a patient but notice that you have the sensor locations swapped.</td>
<td>Navigate to the sensor Setup 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.</td>
</tr>
<tr>
<td>Sensors need to be disconnected from the monitoring system during a case (for example, to reroute the cables).</td>
<td>Disconnect and reconnect the affected sensors. The monitoring system automatically assigns the sensors back to the proper locations.</td>
</tr>
<tr>
<td>The monitoring system is powered off and back on during a case.</td>
<td>No action is necessary. The monitoring system automatically assigns sensors to the proper location and resumes monitoring.</td>
</tr>
<tr>
<td>A case has ended.</td>
<td>Unplug and discard all sensors that were used during the case. Dismiss the ‘Sensor Not Connected’ alarm. The monitoring system returns to the Setup screen.</td>
</tr>
</tbody>
</table>

4.7. Setup 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 that you have reviewed the information in Safety Reminders, page 37 before monitoring a patient.
To set up the monitoring system:

1. Make sure that 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™ rSO₂ sensors** – Before use, carefully read the sensor Instructions for Use, including all warnings, cautions and instructions.

2. Determine the sites that you will monitor on the patient. Select the correct type of INVOS™ rSO₂ 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:
   - Make sure that the monitoring system’s power supply is plugged into the docking station and a properly grounded hospital mains socket (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.
   - 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).
   - 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 Setup screen appears (Figure 23).
4. Optionally, you can set the sensor sequence for the number of sensors that 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 rSO₂ 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 Setup screen. However, trends are not tracked, and physiological alarms are disabled. Do not attempt to monitor the patient from the Setup 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**

![Monitoring Screen](image)

**Note:** If necessary, you can return to the Setup screen while monitoring by pressing the Patient button:

![Patient Button](image)


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.


13. Optionally, check the list of available event markers and change it if necessary. See Changing the Event List, page 69.


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 SetUp 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:
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 Setup 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.
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

4. At the Setup 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 Setup 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.
2. Press the patient icon. A keyboard appears.

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 labelled as follows on screen:
You can change the sensor labels to any alphabetic value (A–Z) or S₁–S₄.

**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 that you want to change. A sensor label menu appears.

   **Figure 34. Sensor Label Menu**

   ![](image)

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 that 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 Setup 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 rSO₂ 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, it indicates the values and times that they were taken (Figure 38).

Figure 37. SET BASELINES – No 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 rSO₂ 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 rSO₂ 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, colour-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.

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

- About the Trend View, page 55
- Changing the Trend View – Two Graphs or One Graph, page 56
- Turning Trend Line Averaging On/Off, page 57
- Zooming the Trend View, page 58
- Reviewing Data that has Scrolled Off the Trend View, page 58
- Viewing Previous rSO2 Values on the Trend Graph, page 59

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 rSO₂ values over the course of a case. It provides a visual reference for on-going rSO₂ 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. rSO₂ scale (y-axis)
2. Current baselines (colour-coded to sensor labels)
3. Trend line (colour-coded to sensor labels)
4. Alarm limits (colour-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.
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 rSO₂ values. Viewing a rolling average can be useful in situations where there is frequent and wide variability in rSO₂ values. The averaged data is displayed as a bold line superimposed over the real-time rSO₂ values in the graph. The trend line is the same colour as the real-time values for each sensor. The numerical rSO₂ values and percent change from baseline continue to be displayed in real time.

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, 2.5–5 cm (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.
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\textsubscript{2} Values on the Trend Graph

While monitoring a patient, you can view rSO\textsubscript{2} values that were recorded earlier in the case. Values appear in a pop-up corresponding to the point of interest (Figure 47).

To view previous rSO\textsubscript{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 that they were recorded.
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 colour 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\textsubscript{2} value crosses an alarm threshold, the background of the affected rSO\textsubscript{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. rSO₂ reading in alarm state

Table 9. Alarm Audio Button States

<table>
<thead>
<tr>
<th>Alarm Audio button</th>
<th>Alarm audio on, silenced or paused</th>
<th>Alarm status</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Bell Icon]</td>
<td>On</td>
<td>Alarm of any status or no alarms</td>
</tr>
<tr>
<td>![Silenced Icon]</td>
<td>Silenced</td>
<td>No alarms</td>
</tr>
<tr>
<td>![Paused Icon]</td>
<td>Paused (2 minutes)</td>
<td>No alarms</td>
</tr>
<tr>
<td>![Low-Medium Icon]</td>
<td>Low- or medium-priority alarm</td>
<td>Low- or medium-priority alarm</td>
</tr>
</tbody>
</table>

Table 10 summarises the monitoring system’s alarm indicators.
Table 10. Audible and Visual Alarm Indicators

<table>
<thead>
<tr>
<th>Priority</th>
<th>Audible tone(^a)</th>
<th>Visual indication(^b)</th>
<th>Example messages(^c)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medium</td>
<td>3 pulse burst</td>
<td>Message area: Flashing yellow bar with text message</td>
<td>BATTERY LOW LOW RSO2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Battery icon: For battery alarm, flashing yellow; otherwise, no change</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>rSO(_2) readings area: Yellow flashing background on affected reading for sensor alarms (dashes appear if readings are lost)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Alarm Audio button: Yellow if alarms silenced or paused</td>
<td></td>
</tr>
<tr>
<td>Low</td>
<td>2 pulse burst</td>
<td>Message area: Yellow bar with text message (not flashing)</td>
<td>TREND DATA LOST</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Battery icon: No change</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>rSO(_2) readings area: No change</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Alarm Audio button: Yellow if alarms silenced or paused</td>
<td></td>
</tr>
</tbody>
</table>

\(^a\) 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 that 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

<table>
<thead>
<tr>
<th>Alarm limits item</th>
<th>Available settings</th>
<th>Default</th>
</tr>
</thead>
<tbody>
<tr>
<td>UPPER LIMITS</td>
<td>OFF – No alarm sounds for high rSO(_2) values</td>
<td>OFF</td>
</tr>
<tr>
<td></td>
<td>ON – Specify a high rSO(_2) value that will generate an alarm</td>
<td></td>
</tr>
<tr>
<td>Upper limit range (when ON)</td>
<td>20 to 95</td>
<td>90</td>
</tr>
<tr>
<td>LOWER LIMITS</td>
<td>MANUAL – Specify a low rSO(_2) value that will generate an alarm</td>
<td>MANUAL</td>
</tr>
<tr>
<td></td>
<td>AUTO – Specify a percentage below baseline that will generate an alarm</td>
<td></td>
</tr>
<tr>
<td>Lower limit range when set to MANUAL</td>
<td>15 to 90</td>
<td>40</td>
</tr>
<tr>
<td>Lower limit range when set to AUTO</td>
<td>-30% to -5%</td>
<td>-20%</td>
</tr>
</tbody>
</table>

**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).
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.
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 colour 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.

![Image of alarm audio button]

The button changes to the following:

![Image of alarm button with bell icon]

**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.

![Image of countdown timer]

The pause option, which must be set by an authorised 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 authorised 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

   ![Dismissable Alarm](image)

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

- About Event Marks, page 66
- Marking Events, page 67
- Viewing an Event Mark Label, page 67
- Renaming an Event, page 68
- Changing the Event List, page 69

4.12.1. About Event Marks

Use event marks to indicate significant occurrences during monitoring. Choose from a list of events that is customisable 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.
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 that 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.
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 that 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 that 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.
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 tick box 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)

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 by 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 three 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

- About Case Histories, page 73
- Viewing Case Histories, page 73
- Exporting Case Histories, page 75
- Deleting Case Histories, page 76

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 offline.

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 occurs 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 tick box 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 tick box next to one or more cases to be deleted.
5. Press the Delete button.

The message ‘Delete the selected cases?’ will appear. Press OK to delete.
6. When complete, the following message will appear: ‘Successfully deleted (n) cases’.
7. Press FINISH.
8. Confirm that 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.

• Safety Reminders, page 77
• Displaying Monitoring System Screens on an External Monitor, page 77
• Downloading Case Histories to a USB Drive, page 78
• Transmitting Monitoring System Data to External Devices via the Serial Port, page 78
• Data Formats, page 82

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 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 that 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 be poor 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.
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 (IVO) Module, page 79. Contact Medtronic Technical Services for information about compatibility with other commercial devices. See Technical Services, page 10.
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.

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-
The 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 rSO₂ 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

<table>
<thead>
<tr>
<th>System</th>
<th>Hardware requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Philips VueLink™ System</td>
<td>• Philips VOI B module (Philips VueLink™ P/N M1032A #A05)</td>
</tr>
<tr>
<td></td>
<td>• Philips VOI/RS-232 Interface Cable (Philips VueLink™ P/N M1032 #K6B)</td>
</tr>
<tr>
<td></td>
<td>• VueLink™ adaptor cable, DB25F to DB9F (Medtronic P/N VLI)</td>
</tr>
<tr>
<td>Philips IntelliBridge™ System</td>
<td>• Philips IntelliBridge™ module (EC10)</td>
</tr>
<tr>
<td></td>
<td>• Philips Ethernet Cable</td>
</tr>
<tr>
<td></td>
<td>• Philips IntelliBridge™ ECS Open Interface RS232 Cable</td>
</tr>
</tbody>
</table>

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 that 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™ adaptor 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 Setup 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 that 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 Setup 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 1 and 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 Setup 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.

<table>
<thead>
<tr>
<th>Column:</th>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
<th>E</th>
<th>F</th>
<th>G</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description:</td>
<td>Version</td>
<td>Date</td>
<td>Time</td>
<td>Ch 1 rSO₂</td>
<td>Event</td>
<td>Status</td>
<td>Rsvd</td>
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<tr>
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<tr>
<td>Description (continued):</td>
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<td>Rsvd</td>
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</tbody>
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<tr>
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</table>

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<tr>
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<td>Rsvd</td>
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<table>
<thead>
<tr>
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</tr>
</thead>
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</table>

Table 14. Case History Downloads – Data Fields

<table>
<thead>
<tr>
<th>Field</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Version</td>
<td>&lt;major&gt;.&lt;minor&gt;.&lt;patch&gt;.&lt;build&gt;/&lt;event list version&gt;/&lt;output format version&gt; Example: 1.2.34.56/1/1 (For Medtronic use only)</td>
</tr>
<tr>
<td>Date</td>
<td>Date of the reading Format: MM/DD/YY</td>
</tr>
<tr>
<td>Time</td>
<td>Time of the reading Format: HH:MM:SS (24-hour format)</td>
</tr>
<tr>
<td>Ch n rSO₂</td>
<td>rSO₂ reading for channel n (Integer) Range: 15 to 95 0 = Channel not active</td>
</tr>
<tr>
<td>Event</td>
<td>Current event. (Integer) Range: 0 to 160, 252 to 254 See Event Codes for Data Downloads, page 85 for descriptions. 0 = No event</td>
</tr>
<tr>
<td>Status</td>
<td>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.</td>
</tr>
<tr>
<td>Rsvd (Reserved)</td>
<td>Zero, to maintain backwards compatibility. Format: 0</td>
</tr>
</tbody>
</table>

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

<table>
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<tr>
<th>Column:</th>
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<th>C</th>
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<td>Status</td>
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<td>AUC</td>
<td>UAL</td>
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<td>A</td>
<td>B</td>
<td>Rsvd</td>
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<td>Y</td>
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<td>Event</td>
<td>Status</td>
<td>Baseline</td>
<td>AUC</td>
<td>UAL</td>
<td>LAL</td>
<td>A</td>
<td>B</td>
<td>Rsvd</td>
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<td>Status</td>
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<td>Event</td>
<td>Status</td>
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<td>AUC</td>
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<td>AE</td>
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<td></td>
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<td></td>
</tr>
<tr>
<td>Description (continued):</td>
<td>Ch 1 sensor ID</td>
<td>Ch 2 sensor ID</td>
<td>Ch 3 sensor ID</td>
<td>Ch 4 sensor ID</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Column (continued):</td>
<td>Terminating character</td>
<td>Terminating character</td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

### 5.6.2.2. Data Format 2 - PC LINK 2

<table>
<thead>
<tr>
<th>Column:</th>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
<th>E</th>
<th>F</th>
<th>G</th>
<th>H</th>
<th>I</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description:</td>
<td>Date</td>
<td>Time</td>
<td>rSO₂</td>
<td>Event</td>
<td>Status</td>
<td>A</td>
<td>B</td>
<td>C</td>
<td>Rsvd</td>
</tr>
<tr>
<td>Column (continued):</td>
<td>J</td>
<td>K</td>
<td>L</td>
<td>M</td>
<td>N</td>
<td>O</td>
<td>P</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Description (continued):</td>
<td>rSO₂</td>
<td>Event</td>
<td>Status</td>
<td>A</td>
<td>B</td>
<td>C</td>
<td>Rsvd</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Column (continued):</td>
<td>Q</td>
<td>R</td>
<td>S</td>
<td>T</td>
<td>U</td>
<td>V</td>
<td>W</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Description (continued):</td>
<td>rSO₂</td>
<td>Event</td>
<td>Status</td>
<td>A</td>
<td>B</td>
<td>C</td>
<td>Rsvd</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Column (continued):</td>
<td>X</td>
<td>Y</td>
<td>Z</td>
<td>AA</td>
<td>AB</td>
<td>AC</td>
<td>AD</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Description (continued):</td>
<td>rSO₂</td>
<td>Event</td>
<td>Status</td>
<td>A</td>
<td>B</td>
<td>C</td>
<td>Rsvd</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Column (continued):</td>
<td>AE</td>
<td>AF</td>
<td>AG</td>
<td>AH</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Description (continued):</td>
<td>Ch 1 sensor ID</td>
<td>Ch 2 sensor ID</td>
<td>Ch 3 sensor ID</td>
<td>Ch 4 sensor ID</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Column (continued):</td>
<td>Terminating character</td>
<td>Terminating character</td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

Description (continued):

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>0x0A</td>
<td>0x0D</td>
</tr>
</tbody>
</table>
Table 15. Case Data Downloads (PC LINK 1 and PC LINK 2) - Data Fields

<table>
<thead>
<tr>
<th>Field</th>
<th>Included in PC LINK 1 format</th>
<th>Included in PC LINK 2 format</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Version</td>
<td>✓</td>
<td></td>
<td><code>&lt;major&gt;.&lt;minor&gt;.&lt;patch&gt;.&lt;build&gt;/[event list version]/[output format version]</code></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Example: 1.2.34.56/1/1</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>(For Medtronic use only)</td>
</tr>
<tr>
<td>Date</td>
<td>✓</td>
<td>✓</td>
<td>Date of the reading</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Format: MM/DD/YY</td>
</tr>
<tr>
<td>Time</td>
<td>✓</td>
<td>✓</td>
<td>Time of the reading</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Format: HH:MM:SS (24-hour format)</td>
</tr>
<tr>
<td>Ch label</td>
<td>✓</td>
<td></td>
<td>Range: A to Z, S1 to S4</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>0 = Channel not active</td>
</tr>
<tr>
<td>rSO₂</td>
<td>✓</td>
<td>✓</td>
<td>Current rSO₂ reading for channel. (integer)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Range: 15 to 95</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>0 = Channel not active</td>
</tr>
<tr>
<td>Event</td>
<td>✓</td>
<td>✓</td>
<td>An event that was marked between the last transmission and this transmission.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>(Integer)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Range: 0 to 160, 252 to 254</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>See Event Codes for Data Downloads, page 85 for descriptions.</td>
</tr>
<tr>
<td>Status</td>
<td>✓</td>
<td>✓</td>
<td>Current active status. (integer)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Range: 0 to 21</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>See Status Codes for Data Downloads, page 88 for descriptions.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>0 = No status</td>
</tr>
<tr>
<td>Baseline</td>
<td>✓</td>
<td></td>
<td>Current baseline value. (integer)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Range: 15 to 95</td>
</tr>
<tr>
<td>AUC</td>
<td>✓</td>
<td></td>
<td>Area Under the Curve. (integer)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Range: 0 to 9999</td>
</tr>
<tr>
<td>UAL</td>
<td>✓</td>
<td></td>
<td>Upper Alarm Limit. (integer)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Range: 20 to 95</td>
</tr>
<tr>
<td>LAL</td>
<td>✓</td>
<td></td>
<td>Lower Alarm Limit. (integer)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Range: 15 to 90</td>
</tr>
<tr>
<td>A</td>
<td>✓</td>
<td>✓</td>
<td>Zero, to maintain backwards compatibility.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Format: 0.0000</td>
</tr>
<tr>
<td>B</td>
<td>✓</td>
<td>✓</td>
<td>Zero, to maintain backwards compatibility.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Format: 0.0000</td>
</tr>
<tr>
<td>C</td>
<td></td>
<td>✓</td>
<td>Zero, to maintain backwards compatibility.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Format: 0</td>
</tr>
<tr>
<td>Rsvd (Reserved)</td>
<td>✓</td>
<td>✓</td>
<td>Zero, to maintain backwards compatibility.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Format: 0</td>
</tr>
<tr>
<td>Channel ID</td>
<td>✓</td>
<td>✓</td>
<td>String (14 characters) – if a sensor is connected.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>0 = No sensor connected</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Event code</th>
<th>Description</th>
<th>Event code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Miscellaneous</td>
<td>21</td>
<td>Afterload Reduction</td>
</tr>
<tr>
<td>2</td>
<td>Set Baseline</td>
<td>22</td>
<td>Blood Transfusion</td>
</tr>
<tr>
<td>3</td>
<td>Induction</td>
<td>23</td>
<td>Cardioversion</td>
</tr>
<tr>
<td>4</td>
<td>Sternotomy</td>
<td>24</td>
<td>Cell Saver Blood</td>
</tr>
<tr>
<td>5</td>
<td>Cannulate</td>
<td>25</td>
<td>Cerebral Perfusion On</td>
</tr>
<tr>
<td>6</td>
<td>On CPB</td>
<td>26</td>
<td>ECLS On</td>
</tr>
<tr>
<td>7</td>
<td>Cross Clamp On</td>
<td>27</td>
<td>FFP/Platelets</td>
</tr>
<tr>
<td>8</td>
<td>Cooling</td>
<td>28</td>
<td>Fluid/Volume Expander</td>
</tr>
<tr>
<td>9</td>
<td>Cardioplegia</td>
<td>29</td>
<td>Haemoconcentrate/MUF</td>
</tr>
<tr>
<td>10</td>
<td>Warming</td>
<td>30</td>
<td>Inotrope</td>
</tr>
<tr>
<td>11</td>
<td>Cross Clamp Off</td>
<td>31</td>
<td>Increase Anaesthetic</td>
</tr>
<tr>
<td>12</td>
<td>Off CPB</td>
<td>32</td>
<td>Increase CO₂</td>
</tr>
<tr>
<td>13</td>
<td>Skin Closure</td>
<td>33</td>
<td>Increase FiO₂</td>
</tr>
<tr>
<td>14</td>
<td>Arrhythmia</td>
<td>34</td>
<td>Increase Pump Flow</td>
</tr>
<tr>
<td>15</td>
<td>Circulatory Arrest</td>
<td>35</td>
<td>Paced</td>
</tr>
<tr>
<td>16</td>
<td>Hypocapnia</td>
<td>36</td>
<td>Reposition Cannula</td>
</tr>
<tr>
<td>17</td>
<td>Hypotension</td>
<td>37</td>
<td>Reposition Clamp</td>
</tr>
<tr>
<td>18</td>
<td>One Lung Ventilation</td>
<td>38</td>
<td>Reposition Head</td>
</tr>
<tr>
<td>19</td>
<td>Pump Flow Down</td>
<td>39</td>
<td>Reposition Heart</td>
</tr>
<tr>
<td>20</td>
<td>Reduced Venous Return</td>
<td>40</td>
<td>Vasopressor</td>
</tr>
</tbody>
</table>

### Table 17. Data Downloads - Event Codes 41 to 80

<table>
<thead>
<tr>
<th>Event code</th>
<th>Description</th>
<th>Event code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>41</td>
<td>Miscellaneous</td>
<td>61</td>
<td>Blood Transfusion</td>
</tr>
<tr>
<td>42</td>
<td>Set Baseline</td>
<td>62</td>
<td>Chest Closed</td>
</tr>
<tr>
<td>43</td>
<td>Enteral Feeding</td>
<td>63</td>
<td>Dialysis/CRRT</td>
</tr>
<tr>
<td>44</td>
<td>Extubated</td>
<td>64</td>
<td>Diuretic</td>
</tr>
<tr>
<td>45</td>
<td>Intubated</td>
<td>65</td>
<td>ECLS On</td>
</tr>
<tr>
<td>46</td>
<td>Reposition Patient</td>
<td>66</td>
<td>ECLS Circuit Change</td>
</tr>
<tr>
<td>47</td>
<td>Sensor Change</td>
<td>67</td>
<td>ECLS Off</td>
</tr>
<tr>
<td>48</td>
<td>Apnoea</td>
<td>68</td>
<td>ET Tube Suctioned</td>
</tr>
<tr>
<td>49</td>
<td>Arrhythmia</td>
<td>69</td>
<td>Fluid Bolus</td>
</tr>
<tr>
<td>50</td>
<td>Bradycardia</td>
<td>70</td>
<td>FFP/Platelets</td>
</tr>
<tr>
<td>51</td>
<td>Cardiac Arrest</td>
<td>71</td>
<td>Hi Frequency Vent</td>
</tr>
<tr>
<td>52</td>
<td>ICP Changes</td>
<td>72</td>
<td>Hypothermia</td>
</tr>
<tr>
<td>53</td>
<td>LOC Changes</td>
<td>73</td>
<td>Inotrope</td>
</tr>
<tr>
<td>54</td>
<td>Painful Procedure</td>
<td>74</td>
<td>Nitric Oxide</td>
</tr>
<tr>
<td>55</td>
<td>Seizure Activity</td>
<td>75</td>
<td>Paralytic</td>
</tr>
<tr>
<td>56</td>
<td>Tamponade</td>
<td>76</td>
<td>PDA Ligated</td>
</tr>
</tbody>
</table>
### Table 17. Data Downloads - Event Codes 41 to 80 (continued)

<table>
<thead>
<tr>
<th>Event code</th>
<th>Description</th>
<th>Event code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>57</td>
<td>Afterload Reduction</td>
<td>77</td>
<td>Prostaglandin</td>
</tr>
<tr>
<td>58</td>
<td>Anti-Arrhythmic</td>
<td>78</td>
<td>Sedation</td>
</tr>
<tr>
<td>59</td>
<td>Anti-Epileptic</td>
<td>79</td>
<td>Vasopressor</td>
</tr>
<tr>
<td>60</td>
<td>Anti-Pyretic</td>
<td>80</td>
<td>Ventilator Change</td>
</tr>
</tbody>
</table>

### Table 18. Data Downloads - Event Codes 81 to 120

<table>
<thead>
<tr>
<th>Event code</th>
<th>Description</th>
<th>Event code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>81</td>
<td>Miscellaneous</td>
<td>101</td>
<td>Balloon Inflated</td>
</tr>
<tr>
<td>82</td>
<td>Set Baseline</td>
<td>102</td>
<td>Balloon Deflated</td>
</tr>
<tr>
<td>83</td>
<td>Intubated</td>
<td>103</td>
<td>Blood Transfusion</td>
</tr>
<tr>
<td>84</td>
<td>Incision</td>
<td>104</td>
<td>EPD Deployed</td>
</tr>
<tr>
<td>85</td>
<td>Heparin Given</td>
<td>105</td>
<td>Fogarty Catheter In</td>
</tr>
<tr>
<td>86</td>
<td>Cannulate</td>
<td>106</td>
<td>FFP/Platelets</td>
</tr>
<tr>
<td>87</td>
<td>Clamp On Vessel</td>
<td>107</td>
<td>Haemostasis Device In</td>
</tr>
<tr>
<td>88</td>
<td>Suturing Vessel/Graft</td>
<td>108</td>
<td>IAB Catheter In/On</td>
</tr>
<tr>
<td>89</td>
<td>Clamp Off Vessel</td>
<td>109</td>
<td>IAB Catheter Out/Off</td>
</tr>
<tr>
<td>90</td>
<td>Decannulate</td>
<td>110</td>
<td>Increase Anaesthetic</td>
</tr>
<tr>
<td>91</td>
<td>Extubulated</td>
<td>111</td>
<td>Increase etCO₂</td>
</tr>
<tr>
<td>92</td>
<td>Arrhythmia</td>
<td>112</td>
<td>Increase FiO₂</td>
</tr>
<tr>
<td>93</td>
<td>Blood Loss</td>
<td>113</td>
<td>Shunt Flushed</td>
</tr>
<tr>
<td>94</td>
<td>Contrast Dye Injected</td>
<td>114</td>
<td>Shunt Open</td>
</tr>
<tr>
<td>95</td>
<td>Dissection</td>
<td>115</td>
<td>Shunt Repositioned</td>
</tr>
<tr>
<td>96</td>
<td>EEG Change</td>
<td>116</td>
<td>Stent Deployed</td>
</tr>
<tr>
<td>97</td>
<td>Hypotension</td>
<td>117</td>
<td>Thrombus Removed</td>
</tr>
<tr>
<td>98</td>
<td>Hypocapnia</td>
<td>118</td>
<td>Vasopressor</td>
</tr>
<tr>
<td>99</td>
<td>Shunt Clamped</td>
<td>119</td>
<td>Vasodilator</td>
</tr>
<tr>
<td>100</td>
<td>Thrombus Suspected</td>
<td>120</td>
<td>Vessel Repaired</td>
</tr>
</tbody>
</table>

### Table 19. Data Downloads - Event Codes 121 to 254

<table>
<thead>
<tr>
<th>Event code</th>
<th>Description</th>
<th>Event code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>121</td>
<td>Miscellaneous</td>
<td>141</td>
<td>Seizure</td>
</tr>
<tr>
<td>122</td>
<td>Set Baseline</td>
<td>142</td>
<td>Anti-Arrhythmic</td>
</tr>
<tr>
<td>123</td>
<td>Physical Assessment</td>
<td>143</td>
<td>Anti-Epileptic</td>
</tr>
<tr>
<td>124</td>
<td>Reposition Patient</td>
<td>144</td>
<td>Blood Trans/Platelets</td>
</tr>
<tr>
<td>125</td>
<td>Heel Stick/Lab Draw</td>
<td>145</td>
<td>Cooling Cap On-Off</td>
</tr>
<tr>
<td>126</td>
<td>Suction ET Tube</td>
<td>146</td>
<td>Dialysis/CRRT</td>
</tr>
<tr>
<td>127</td>
<td>Weigh Patient</td>
<td>147</td>
<td>ECLS On</td>
</tr>
<tr>
<td>128</td>
<td>Enteral Feeding</td>
<td>148</td>
<td>ECLS Circuit Change</td>
</tr>
</tbody>
</table>
Table 19. Data Downloads - Event Codes 121 to 254 (continued)

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

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

<table>
<thead>
<tr>
<th>Status code</th>
<th>Status message</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>SENSOR NOT CONNECTED</td>
</tr>
<tr>
<td>2</td>
<td>CHECK SENSOR</td>
</tr>
<tr>
<td>3</td>
<td>POOR SIGNAL QUALITY</td>
</tr>
<tr>
<td>4</td>
<td>SYSTEM SIGNAL OK</td>
</tr>
<tr>
<td>5</td>
<td>HIGH rSO2</td>
</tr>
<tr>
<td>6</td>
<td>LOW rSO2</td>
</tr>
<tr>
<td>11</td>
<td>PREAMP NOT CONNECTED</td>
</tr>
<tr>
<td>17</td>
<td>REPLACE SENSOR</td>
</tr>
<tr>
<td>19</td>
<td>INTERFERENCE DETECTED</td>
</tr>
<tr>
<td>21</td>
<td>AUTO BASELINE SET</td>
</tr>
</tbody>
</table>

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 optimising the performance of the INVOS™ patient monitor (the ‘monitoring system’).

- Safety Reminders, page 91
- Patient Conditions, page 91
- Sensor Use Considerations, page 91
- EMI (Electromagnetic Interference), page 92

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
- Carboxyhaemoglobin or other dyshaemoglobins
- Haemoglobinopathies
- Conjugated hyperbilirubinaemia (direct)
- Myoglobin (Mb), haemoglobin from muscular tissue, in the blood
- Dark skin pigment
-Externally applied colouring agents (dye, pigmented cream)

6.4. Sensor Use Considerations
Select an appropriate INVOS™ rSO₂ 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, poor 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-orientating 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 healthcare environments (for example, electrosurgical units, mobile 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.
- Re-orientate or relocate the interfering equipment.
- Increase the separation between the interfering equipment and the monitoring system.
- Connect the monitoring system to a socket on a different circuit from the other device(s).
- Have an authorised 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.

- Safety Reminders, page 95
- Cleaning the Monitoring System, page 95
- Maintenance Schedule, page 96
- Service and Calibration, page 97
- Service Life, page 97
- Software and Firmware Updates, page 97
- Recycling and Disposal, page 97

7.2. Safety Reminders

Warning: Inspect the monitoring system and all accessories before use to ensure that there are no signs of physical damage or improper function. Do not use damaged cables on the patient.

Warning: Explosion hazard – When replacing the battery, do not use the incorrect type. Use only the battery provided by 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-sterilise 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-sterilise 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>
<thead>
<tr>
<th>How often</th>
<th>What to do</th>
</tr>
</thead>
<tbody>
<tr>
<td>Each power-up</td>
<td>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.</td>
</tr>
<tr>
<td>Every 3 months</td>
<td>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.</td>
</tr>
<tr>
<td>Annually</td>
<td>Check the INVOS™ system. The monitoring system's service manual provides annual inspection procedures to be followed by an authorised technician.</td>
</tr>
<tr>
<td>Annually</td>
<td>Inspect all safety relevant labels for legibility. Contact Medtronic or a local Medtronic representative, if labels are damaged or illegible.</td>
</tr>
<tr>
<td>Annually</td>
<td>Replace the reusable sensor cables (RSCs). See Accessories/Parts List, page 107 for part number and ordering information.</td>
</tr>
<tr>
<td>Every 2 years</td>
<td>Replace the monitor's battery. See Accessories/Parts List, page 107 for part number and ordering information.</td>
</tr>
<tr>
<td>After approximately 25,000 hours of operation</td>
<td>Replace the monitor. See Service Life, page 97 for more information.</td>
</tr>
</tbody>
</table>
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.

- Alarm Messages, page 99
- Error Conditions, page 102
- Product Return, page 105

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 non-latching except the following:

SYSTEM FAILURE

<table>
<thead>
<tr>
<th>Alarm</th>
<th>Condition</th>
<th>Priority</th>
<th>Audio/visual</th>
<th>Dismissible</th>
<th>Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td>BATTERY CRITICALLY LOW</td>
<td>System is using battery power AND battery level is Critical (&lt;5% charge remaining).</td>
<td>Medium</td>
<td>Audio and visual</td>
<td>No</td>
<td>Immediately connect to AC power. If the battery does not charge, contact Medtronic or a local Medtronic representative.</td>
</tr>
<tr>
<td>BATTERY FAILURE</td>
<td>Battery is malfunctioning.</td>
<td>Low</td>
<td>Visual only</td>
<td>No</td>
<td>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.</td>
</tr>
<tr>
<td>BATTERY LOW</td>
<td>System is using battery power AND battery level is Low (&lt;33% charge remaining).</td>
<td>Medium</td>
<td>Audio and visual</td>
<td>Yes</td>
<td>Connect to AC power as soon as possible. If the battery does not charge, contact Medtronic or a local Medtronic representative.</td>
</tr>
</tbody>
</table>
Table 22. Alarm Conditions (continued)

<table>
<thead>
<tr>
<th>Alarm</th>
<th>Condition</th>
<th>Priority</th>
<th>Audio/visual</th>
<th>Dismissible</th>
<th>Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td>CHECK SENSOR</td>
<td>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 haematomas, arteriovenous malformations, broken skin, thick fatty deposits, hair, bony protuberances or areas contaminated with residue.</td>
<td>Medium</td>
<td>Audio and visual</td>
<td>No</td>
<td>Make sure that 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 socket. Have an authorised 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 that 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.</td>
</tr>
<tr>
<td>HIGH RSO2</td>
<td>Upper rSO₂ alarm limit is exceeded.</td>
<td>Medium</td>
<td>Audio and visual</td>
<td>No</td>
<td>Immediately check the patient.</td>
</tr>
<tr>
<td>INTERFERENCE DETECTED</td>
<td>Interference on a sensor channel is corrupting the rSO₂ data.</td>
<td>Medium</td>
<td>Audio and visual</td>
<td>No</td>
<td>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 authorised 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.</td>
</tr>
<tr>
<td>LOW RSO2</td>
<td>Lower rSO₂ alarm limit is exceeded.</td>
<td>Medium</td>
<td>Audio and visual</td>
<td>No</td>
<td>Immediately check the patient.</td>
</tr>
<tr>
<td>Alarm</td>
<td>Condition</td>
<td>Priority</td>
<td>Audio/visual</td>
<td>Dismissible</td>
<td>Resolution</td>
</tr>
<tr>
<td>---------------------</td>
<td>---------------------------------------------------------------------------</td>
<td>----------</td>
<td>--------------</td>
<td>-------------</td>
<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>POOR SIGNAL QUALITY</strong></td>
<td>Poor signal quality is detected on a sensor channel. rSO₂ 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 haematomas, arteriovenous malformations, broken skin, thick fatty deposits, hair, bony protuberances or areas contaminated with residue. OR Defective sensor. OR Defective RSC.</td>
<td>Medium</td>
<td>Audio and visual</td>
<td>No</td>
<td>Identify any possible sources of interference, and take the actions recommended in EMI (Electromagnetic Interference), page 92. Try another hospital-grade electrical socket. Under high ambient light conditions, loosely cover the sensor with opaque material. Have an authorised 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 that 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.</td>
</tr>
<tr>
<td><strong>PREAMP FAILURE</strong></td>
<td>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.</td>
<td>Medium</td>
<td>Audio and visual</td>
<td>No</td>
<td>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.</td>
</tr>
<tr>
<td><strong>PREAMP NOT CONNECTED</strong></td>
<td>Preamplifier becomes disconnected from the monitor during use.</td>
<td>Medium</td>
<td>Audio and visual</td>
<td>Yes</td>
<td>Make sure that the preamplifier connector is locked into the monitor. See Connect the Preamplifier(s), page 29. Normal operation will resume when the preamplifier is reconnected.</td>
</tr>
</tbody>
</table>
Table 22. Alarm Conditions (continued)

<table>
<thead>
<tr>
<th>Alarm</th>
<th>Condition</th>
<th>Priority</th>
<th>Audio/visual</th>
<th>Dismis-ible</th>
<th>Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td>REPLACE SENSOR</td>
<td>Sensor incompatible OR Invalid calibration data OR Bad sensor OR Open/short condition OR Unable to access sensor memory</td>
<td>Medium</td>
<td>Audio and visual</td>
<td>No</td>
<td>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.</td>
</tr>
<tr>
<td>SENSOR NOT CONNECTED</td>
<td>Sensor is disconnected from the RSC. OR RSC is disconnected from the preamplifier.</td>
<td>Medium</td>
<td>Audio and visual</td>
<td>Yes</td>
<td>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.</td>
</tr>
<tr>
<td>SYSTEM FAILURE</td>
<td>Monitoring system was reset unexpectedly. Note: All settings may be lost.</td>
<td>Medium</td>
<td>Audio^ and visual</td>
<td>Yes</td>
<td>Power the monitoring system off and back on. If the problem persists, contact Medtronic or a local Medtronic representative.</td>
</tr>
<tr>
<td>TREND DATA LOST</td>
<td>Software was upgraded. OR Time setting was changed. OR Corrupt trend data was detected at start up.</td>
<td>Low</td>
<td>Audio and visual</td>
<td>Yes</td>
<td>If the problem persists, contact Medtronic or a local Medtronic representative.</td>
</tr>
</tbody>
</table>

^ 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

<table>
<thead>
<tr>
<th>Problem</th>
<th>Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td>No AC power to monitoring system when plugged in and powered on</td>
<td>• Make sure that the monitoring system’s power supply is plugged into a hospital-grade power socket.</td>
</tr>
<tr>
<td>(runs on battery power only)</td>
<td>• 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.</td>
</tr>
<tr>
<td></td>
<td>• Check that the AC indicator on the docking station is illuminated. See Apply Power, page 31.</td>
</tr>
<tr>
<td></td>
<td>• Make sure that the monitor is completely seated in the docking station. See Insert the Monitor into the Docking Station, page 28.</td>
</tr>
<tr>
<td></td>
<td>• If the problem persists, contact Medtronic or a local Medtronic representative.</td>
</tr>
<tr>
<td>Does not power up when power button is pressed</td>
<td>• Press the power button for more than 3 seconds.</td>
</tr>
<tr>
<td></td>
<td>• If operating on AC power, refer to the resolutions above.</td>
</tr>
<tr>
<td></td>
<td>• If operating on battery power, make sure that the battery latch is in the locked position. See Install the Battery, page 27.</td>
</tr>
<tr>
<td></td>
<td>• If operating on battery power, the battery may be discharged. Connect to AC power to charge the battery. See Apply Power, page 31.</td>
</tr>
<tr>
<td>System indicates a preamplifier has been disconnected when it is still</td>
<td>• Check the preamplifier connection to the monitor. See Connect the Preamplifier(s), page 29.</td>
</tr>
<tr>
<td>physically connected</td>
<td>• Try a different preamplifier.</td>
</tr>
<tr>
<td>Error message: PREAMP NOT CONNECTED</td>
<td>• Contact Medtronic or a local Medtronic representative.</td>
</tr>
<tr>
<td>System does not recognise and gives no indication a preamplifier has</td>
<td>• Check the preamplifier connection to the monitor. See Connect the Preamplifier(s), page 29.</td>
</tr>
<tr>
<td>been connected after it has been physically connected</td>
<td>• Try a different preamplifier.</td>
</tr>
<tr>
<td></td>
<td>• Contact Medtronic or a local Medtronic representative.</td>
</tr>
<tr>
<td>Does not power off when power button is pressed</td>
<td>If the monitoring system does not power off within approximately 30 seconds after pressing the Power button, press and hold the Power button for at least 10 seconds to power off the monitoring system.</td>
</tr>
<tr>
<td>Electrical noise on AC power line causing poor signal quality</td>
<td>Have an authorised 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.</td>
</tr>
<tr>
<td>Multiple, consecutive sensor alarms</td>
<td>If sensor alarms continue to occur after you have performed the recommended corrections for the alarms (see Table 22, page 99), replace the following:</td>
</tr>
<tr>
<td></td>
<td>• RSCs</td>
</tr>
<tr>
<td></td>
<td>• Preamplifiers</td>
</tr>
<tr>
<td>Displayed rSO\textsubscript{2} value is 0 with sensor properly applied</td>
<td>Replace the sensor.</td>
</tr>
<tr>
<td>to a patient according to the sensor Instructions for Use</td>
<td></td>
</tr>
<tr>
<td>Frequent battery alarms</td>
<td>Replace the battery. See Install the Battery, page 27.</td>
</tr>
<tr>
<td>Touch screen is unresponsive</td>
<td>• Power the monitoring system off and back on.</td>
</tr>
<tr>
<td></td>
<td>• If the problem persists, contact Medtronic or a local Medtronic representative.</td>
</tr>
</tbody>
</table>
### Table 23. Error Conditions and Resolutions (continued)

<table>
<thead>
<tr>
<th>Problem</th>
<th>Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td>System errors are non-recoverable technical issues resulting in a non-</td>
<td>• Power the monitoring system off and back on.</td>
</tr>
<tr>
<td>responsive system. These include:</td>
<td>• If the problem persists, contact Medtronic or a local Medtronic</td>
</tr>
<tr>
<td>• Sensor is connected to a patient, but the rSO$_2$ data display has not</td>
<td>representative.</td>
</tr>
<tr>
<td>been updated for over 30 seconds.</td>
<td></td>
</tr>
<tr>
<td>• The system may indicate that settings are corrupted.</td>
<td></td>
</tr>
<tr>
<td>Error message: SYSTEM ERROR</td>
<td></td>
</tr>
<tr>
<td>A USB error occurs during any of the following situations:</td>
<td>• Follow the resolution indicated in the error message.</td>
</tr>
<tr>
<td>• Exporting case histories</td>
<td>• If a USB flash drive is present but isn’t recognised by the</td>
</tr>
<tr>
<td>• Exporting logs</td>
<td>system, make sure that the drive has been formatted. If necessary,</td>
</tr>
<tr>
<td>• Exporting or importing system settings</td>
<td>you can format the drive on a computer running Microsoft Windows</td>
</tr>
<tr>
<td>• Importing firmware or software</td>
<td>.NET.</td>
</tr>
<tr>
<td>Possible error messages include:</td>
<td></td>
</tr>
<tr>
<td>• USB DRIVE NOT FOUND. INSERT USB DRIVE AND TRY AGAIN.</td>
<td></td>
</tr>
<tr>
<td>• USB DRIVE ERROR. CHECK USB DRIVE AND TRY AGAIN.</td>
<td></td>
</tr>
<tr>
<td>• MULTIPLE USB DRIVES FOUND. REMOVE EXTRA USB DRIVES AND TRY AGAIN.</td>
<td></td>
</tr>
<tr>
<td>• INSUFFICIENT STORAGE SPACE. INSERT NEW USB DRIVE AND TRY AGAIN.</td>
<td></td>
</tr>
<tr>
<td>• NO FIRMWARE UPDATE FOUND. CHECK USB DRIVE AND TRY AGAIN.</td>
<td></td>
</tr>
<tr>
<td>• NO SOFTWARE UPDATE FOUND. CHECK USB DRIVE AND TRY AGAIN.</td>
<td></td>
</tr>
</tbody>
</table>
Table 23. Error Conditions and Resolutions (continued)

<table>
<thead>
<tr>
<th>Problem</th>
<th>Resolution</th>
</tr>
</thead>
</table>
| 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 that it is completely seated at both connections.  
  • Verify that the power cord is fully plugged in to 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 that it is completely seated at both connections.  
  • Verify that the power cord is fully plugged in to the monitor’s docking station.  
  • Have an authorised 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 Setup 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 Authorisation (RGA) number. See Obtaining Technical Assistance, page 10. Pack the monitoring system in its original delivery carton. If the original carton is not available, use a suitable carton with the appropriate packing material to protect it during delivery. 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 rSO₂ 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

<table>
<thead>
<tr>
<th>Part number</th>
<th>Item</th>
</tr>
</thead>
<tbody>
<tr>
<td>PMSENS71-A</td>
<td>INVOS™ adult rSO₂ sensor</td>
</tr>
<tr>
<td>PMAC71DOC</td>
<td>INVOS™ docking station</td>
</tr>
<tr>
<td>PMAC71STAND</td>
<td>INVOS™ patient monitor stand</td>
</tr>
<tr>
<td>PMAC71RSC</td>
<td>INVOS™ reusable sensor cable for PM7100</td>
</tr>
<tr>
<td>PMAC71BAT</td>
<td>INVOS™ PM7100 battery</td>
</tr>
<tr>
<td>PMAC71PS</td>
<td>INVOS™ PM7100 power supply</td>
</tr>
<tr>
<td>VLI</td>
<td>INVOS™ rSO₂ interface cable (VueLink™ adaptor cable, DB25F to DB9F)</td>
</tr>
</tbody>
</table>
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 colour 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-coloured haemoglobin molecules within red blood cells have the highest light absorption of the wavelengths used, and the exact shade of red of each haemoglobin molecule indicates the amount of oxygen that it is carrying.

The type and quantity of absorption data returned to the detectors reflects relative amounts of deoxyhaemoglobin and total haemoglobin, from which a regional oxygen saturation (rSO₂) 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’).

- Physical Characteristics, page 111
- Electrical, page 112
- Battery, page 112
- Environmental Conditions, page 112
- Alarm Audio and Visual Characteristics, page 113
- Sensor Operating Range, page 114
- Equipment Classifications, page 114
- Biocompatibility Testing, page 114
- Manufacturer’s Declaration, page 114
- Essential Performance, page 119

11.2. Physical Characteristics

<table>
<thead>
<tr>
<th>Monitor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dimensions</td>
</tr>
<tr>
<td>Weight</td>
</tr>
<tr>
<td>Screen size</td>
</tr>
<tr>
<td>Screen type</td>
</tr>
<tr>
<td>Resolution</td>
</tr>
<tr>
<td>Visibility</td>
</tr>
<tr>
<td>Buttons</td>
</tr>
<tr>
<td>Power</td>
</tr>
<tr>
<td>Ports</td>
</tr>
<tr>
<td>Indicators</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Docking Station</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type</td>
</tr>
<tr>
<td>Dimensions</td>
</tr>
<tr>
<td>Indicator</td>
</tr>
</tbody>
</table>
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 C22.2 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

<table>
<thead>
<tr>
<th></th>
<th>Transport and storage</th>
<th>Operating conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature</td>
<td>-20ºC to 45ºC (-4ºF to 113ºF)</td>
<td>10ºC to 35ºC (50ºF to 95ºF)</td>
</tr>
<tr>
<td>Altitude</td>
<td>-500 m to 6100 m (-1640 ft to 20013 ft)</td>
<td>-500 m to 4000 m (-1640 ft to 13123 ft)</td>
</tr>
<tr>
<td>Atmospheric pressure</td>
<td>1075 hPa to 465 hPa (32 in. Hg to 14 in. Hg)</td>
<td>1075 hPa to 616 hPa (32 in. Hg to 18 in. Hg)</td>
</tr>
<tr>
<td>Relative humidity</td>
<td>10% to 95% non-condensing</td>
<td>15% to 95% non-condensing</td>
</tr>
</tbody>
</table>

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

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

Table 27. Average Alarm Sound Pressure Levels

<table>
<thead>
<tr>
<th>Alarm</th>
<th>Volume = 1</th>
<th>Volume = 5 (default)</th>
<th>Volume = 10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medium priority</td>
<td>21 dB</td>
<td>33 dB</td>
<td>38 dB</td>
</tr>
<tr>
<td>Low priority</td>
<td>19 dB</td>
<td>29 dB</td>
<td>35 dB</td>
</tr>
</tbody>
</table>
11.6.2. Alarm Visual Characteristics

Table 28. Alarm Visual Characteristics

<table>
<thead>
<tr>
<th>Alarm</th>
<th>Colour</th>
<th>Flashing frequency(^a) (Hz)</th>
<th>Duty cycle</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medium priority</td>
<td>Yellow</td>
<td>0.5</td>
<td>50%</td>
</tr>
<tr>
<td>Low priority</td>
<td>Yellow</td>
<td>None</td>
<td>100%</td>
</tr>
</tbody>
</table>

\(^a\) Alarm visual flashing alternates between the original colour (brightness = 100%) and a darker shade of the same colour (brightness = 70%).

11.6.3. POST Pass Tone

Table 29. POST Pass Tone Characteristics

<table>
<thead>
<tr>
<th>POST pass tone</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Volume level</td>
<td>Not changeable</td>
</tr>
<tr>
<td>Number of pulses</td>
<td>N/A</td>
</tr>
<tr>
<td>Repetitions</td>
<td>No repeat</td>
</tr>
</tbody>
</table>

11.7. Sensor Operating Range

Table 30. INVOS™ Adult rSO\(_2\) Sensor Operating Range

<table>
<thead>
<tr>
<th>Operating range</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Four-wavelength LEDs</td>
<td>Approximately 700 nm to 900 nm</td>
</tr>
</tbody>
</table>

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 |
| Ingress protection | IPX2 |
| Degree of safety | Not suitable for use in the presence of flammable anaesthetics |

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, poor 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-orientating 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-orientating the equipment.
### 11.10.1.1. Electromagnetic Emissions Guidelines and Compliance

<table>
<thead>
<tr>
<th>Emissions test</th>
<th>Compliance</th>
<th>Electromagnetic environment guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radiated emission</td>
<td>CISPR 11/EN 55011, Class A, Group 1</td>
<td>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.</td>
</tr>
<tr>
<td>Conducted emission</td>
<td>CISPR 11/EN 55011, Class A, Group 1</td>
<td>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.</td>
</tr>
<tr>
<td>Harmonic emission</td>
<td>IEC/EN 61000-3-2, Class A</td>
<td></td>
</tr>
<tr>
<td>Voltage fluctuations/flicker emission</td>
<td>IEC/EN 61000-3-3, Section 4</td>
<td></td>
</tr>
</tbody>
</table>

### 11.10.1.2. Electromagnetic Immunity Guidelines and Compliance

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC/EN 60601-1-2 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD)</td>
<td>IEC/EN 61000-4-2</td>
<td>±8 kV contact ±15 kV air</td>
<td>Floor should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.</td>
</tr>
<tr>
<td>Electric fast transient/burst</td>
<td>IEC/EN 61000-4-4</td>
<td>± 2kV (100 kHz repetition rate) AC mains ± 1kV (100 kHz repetition rate) input/output &gt; 3 m</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Surge</td>
<td>IEC/EN 61000-4-5</td>
<td>± 1kV line-line, AC mains ± 2kV line-ground, AC mains</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Voltage dips and interrupts</td>
<td>IEC/EN 61000-4-11</td>
<td>100% reduction for 0.5 cycles (at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°) 100% reduction for 1.0 cycle (at 0°) 100% reduction for 2.0 cycles (at 0°) 100% reduction for 25/30 cycles (at 0°) 100% reduction for 250/300 cycles (at 0°)</td>
<td>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.</td>
</tr>
<tr>
<td>Power frequency H-field immunity</td>
<td>IEC/EN 61000-4-8</td>
<td>50 and 60 Hz, 30 A/m, x-, y-, and z-axes</td>
<td>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</td>
</tr>
</tbody>
</table>
11.10.1.3. Recommended Separation Distance Calculations

Table 33. Recommended Separation Distance Calculations

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC/EN 60601-1-2 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment guidance</th>
</tr>
</thead>
</table>
| Conducted RF  | IEC/EN 61000-4-6 3 Vrms     | 150 kHz to 80 MHz; 6 Vrms, ISM and amateur radio bands between 0.15 MHz and 80 MHz 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 metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. 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 | 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 metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: |
Table 33. Recommended Separation Distance Calculations (continued)

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC/EN 60601-1-2 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF wireless proximity fields</td>
<td>See Table 34, page 118</td>
<td>See Table 34, page 118</td>
<td>0.3 m</td>
</tr>
</tbody>
</table>

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.

Table 34. Test Specifications for Enclosure Port Immunity to RF Wireless Communications Equipment

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

Table 35. Recommended Separation Distances

<table>
<thead>
<tr>
<th>Rated maximum output power (P) of transmitter in watts</th>
<th>Separation distance according to frequency of transmitter in metres</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>( d = 1.2 \sqrt{P} )</td>
</tr>
<tr>
<td></td>
<td>150 kHz to 80 MHz</td>
</tr>
<tr>
<td></td>
<td>80 MHz to 800 MHz</td>
</tr>
<tr>
<td></td>
<td>800 MHz to 2.7 GHz</td>
</tr>
<tr>
<td>0.01</td>
<td>0.12</td>
</tr>
<tr>
<td>0.10</td>
<td>0.38</td>
</tr>
<tr>
<td>1.00</td>
<td>1.20</td>
</tr>
<tr>
<td>10.00</td>
<td>3.80</td>
</tr>
<tr>
<td>100.00</td>
<td>12.00</td>
</tr>
</tbody>
</table>

For transmitters rated at a maximum output power not listed above, the recommended separation distance \( (d) \) in metres \( (m) \) 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 \( \geq 20\% \) 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 (rSO₂) from the system to blood sample analysis in 20 volunteers (hypoxia study). No adverse events attributable to the system were reported during the study.

- Hypoxia Study, page 121
- Interventional Studies, page 123
- Validation Studies, page 124

A.2. Hypoxia Study

The hypoxia study compared the rSO₂ as reported by the system to the ‘field’ saturation (fSO₂) calculated from arterial and jugular venous blood oxygen saturation measurements at five levels of oxygen saturation and two levels of inspired CO₂. Based on the assumption that cerebral tissue contains arterial and venous blood in a 1:3 ratio, fSO₂ was calculated as:

\[
\text{fSO}_2 = (0.25 \times \text{SarterialO}_2) + (0.75 \times \text{Sjugular veinO}_2)
\]

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 O₂ saturation (74% to 100%). This sequence was performed twice at two different CO₂ levels (4–7 mmHg increase) intended to raise cerebral blood flow and evaluate the ability of the system to reject non-cerebral data.
A.2.2. Results

Figure 70. Accuracy rSO2 and fSO2, 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 rSO2 and fSO2, 20 Subjects

<table>
<thead>
<tr>
<th></th>
<th>Individual subjects (N=20)</th>
<th>Range</th>
<th>Pooled (N=189) data points</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accuracy Bias (%) a</td>
<td>2.56</td>
<td>-6.47 to +11.78</td>
<td>2.51</td>
</tr>
<tr>
<td>Error (SD) (%) a</td>
<td>2.08</td>
<td>0.85 to 4.22</td>
<td>5.23</td>
</tr>
<tr>
<td>RMSD a</td>
<td>5.11</td>
<td>2.15 to 12.03</td>
<td>5.79</td>
</tr>
<tr>
<td>Correlation ($R^2$) a</td>
<td>0.946</td>
<td>0.823 to 0.990</td>
<td>0.729</td>
</tr>
</tbody>
</table>

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 4 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

<table>
<thead>
<tr>
<th></th>
<th>Pooled (N=179) data points</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trend Bias (%)</td>
<td>0.26</td>
</tr>
<tr>
<td>Error (SD) (%)</td>
<td>2.90</td>
</tr>
<tr>
<td>Correlation (R(^2))</td>
<td>0.958</td>
</tr>
</tbody>
</table>

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.


A.4. Validation Studies

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

