Invivo

Essential MRI Patient Monitor

(Model 865353)

Instructions for Use

989803173791 Rev 0.6

English

989803173791

Manufacturer

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Equipment Classification

EQUIPMENT CLASSIFICATION (according to IEC 60601-1)	
According to the type of protection against electrical shock	Class I equipment
According to the degree of protection against electrical shock:	Type CF (defibrillator-proof) equipment
According to the degree of protection against harmful ingress of water:	IPX2 (enclosed equipment tilted 15 degrees with protection against dripping liquid).
According to the methods of sterilization or disinfection:	Non-sterilizable. Use of liquid surface disinfectants only.
According to the mode of operation:	Continuous operation
Equipment not suitable for use in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide.	

NOTE

Laws in the United States restrict this device to sale by or on the order of a physician.

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The documentation part number and revision indicate the current edition. The printing date changes when a new revision is printed. (Minor corrections and updates which are incorporated at reprint do not cause the date to change.) The document revision letter changes when extensive technical changes are incorporated.

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Appendix B: Warranty

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Chapter 1: Important Information

Information regarding the safety, accessories, installation, and operation of a fully equipped Essential MRI Patient Monitor (Model 865353) is included in this manual. For additional information about your accessories, please consult the documentation that accompanies the accessory.

This product will perform in conformity with the description contained in this manual and accompanying labeling when assembled, operated, maintained, and repaired in accordance with the instructions provided.

This device must be checked periodically. A malfunctioning device must not be used. Parts that are broken, missing, plainly worn, distorted, or contaminated must be replaced immediately. Refer the device to qualified service personnel for repair or replacement. This device or any of its parts must not be repaired other than in accordance with written instructions provided by the manufacturer. The device shall not be altered without written approval of Invivo. The user has the sole responsibility for any malfunction which results from improper use, faulty maintenance, improper repair, damage or alteration by anyone other than Invivo or Invivo-authorized service personnel.

Intended Audience

The Essential MRI Patient Monitor (Model 865353) is intended for use by healthcare professionals trained in the use of the equipment and vital signs monitoring.

Warnings

Before using the Essential MRI Patient Monitor (Model 865353), read the warnings here and those in the Safety section below. The warnings and notes below refer to the Essential MRI Patient Monitor (Model 865353) in its entirety.

WARNINGS

- **Thoroughly read and understand these Instructions for Use prior to use.**
- **Shock hazard exists if the system is operated without covers.**
- **Use only supplied power cords and connect only to properly grounded AC outlets to avoid electrical shock.**

WARNINGS

- **Patient motion or position of the accessories may affect measurement accuracy. Always consult a physician for interpretation of measurements provided by the system.**
- **Perform operational verification prior to use. If the system fails to function properly, remove it from use and contact Invivo Technical Support personnel.**
- **Screen all patients for metallic wires, implants, stents, etc. prior to MR procedures. These electrical conductors will react with the MR environment or with the Invivo accessory (if applied directly over the conductor), thus increasing the risk of heating.**

NOTE

The Essential MRI Patient Monitor (Model 865353) is not intended for use on a patient being transported outside a healthcare facility.

Conventions

The Essential MRI Patient Monitor (Model 865353) uses certain conventions throughout the interface to make it easy for you to learn and use. This accompanying user information also uses document conventions to assist you in finding and understanding information.

System Conventions

These conventions are used in the system:

- Operational control is accomplished through the display panel.
- When control or menu items are provided on the display panel, touching that control or item will activate or open it.
- To protect against accidental changes of irreplaceable data, a confirm/cancel prompt is associated with certain menu options. When a prompt is displayed, you must confirm or cancel this action; otherwise, a delay of approximately 30 seconds without selection will be equivalent to selecting cancel.

Document Conventions

- All procedures are numbered, while any sub-procedures are lettered. Complete the steps in the sequence presented to ensure success. Procedures are indicated by the following table:

Step	Action
1	
2	
3	

- Bulleted lists indicate general information about a particular function or procedure, and do not imply a sequential procedure.
- Messages regarding a condition in the device are given within quotation marks (“”) spelled and punctuated as they appear in the system, unless included as information in a table.
- Control names, buttons and menu items or titles are spelled and punctuated as they appear in the system.
- Symbols appear as they appear on the system.
- *Select* means to touch or tap lightly with a finger (or stylus) within the boundaries of a control item on the display panel.
- The left side of the system is on your left as you stand in front of the system, facing it. The front of the system is nearest you as you operate it.
- The front of the module is nearest you as you operate it.

Warnings

WARNING

Warnings provide information you should know to avoid injuring yourself, patients or personnel.

Cautions

CAUTION

Cautions provide information you should know to avoid damaging the equipment and software.

Notes

NOTE

Notes provide additional information regarding system usage.

Accessories

Available accessories are listed in the tables below. Only use recommended Invivo patient sensors, grips, etc, as other brands may compromise the safety and accuracy of the system.

SpO_2

Description	Part Number
Quick Connect SpO_2 Clip, Adult	989803166531
Quick Connect SpO_2 Clip, Pediatric	989803166541
Quick Connect SpO_2 Grip, Adult, 20/box	989803166551
Quick Connect SpO_2 Grip, Infant, 20/box	989803166571
Quick Connect SpO_2 Grip, Neonatal, 20/box	989803166581
Quick Connect SpO_2 Grip, Pediatric, 20/box	989803166561
Quick Connect SpO_2 Grip, Starter Pack	989803167111
Quick Connect SpO_2 Sensor, MRI	989803161991
Wireless SpO_2 Module (Expression)	989803163111
Wireless SpO_2 Module (Precess - Blue version)	989803172431

Power

Description	Part Number
Main Battery	989803171671
Module Battery	9065
Power Adapter	989803171691
Power Cord, Brazil 250V	989803173901
Power Cord, European 220-230V	453564177501
Power Cord, United Kingdom 220-240V	989803174171
Power Cord, US 110V	989803168211
Power Cord, Universal 220V	AS18A

Miscellaneous

Description	Part Number
Carry Case	989803171711
Mount Adapter	989803171681
Roll Stand	989803173761
Universal Holder Pole Kit (for use with Roll Stand)	989803174281
Information for Use Manual, Chinese, Simplified	989803174041
Information for Use Manual, Chinese, Traditional	989803174081
Information for Use Manual, Czech	989803173911
Information for Use Manual, Dutch	989803173921
Information for Use Manual, English	989803173791
Information for Use Manual, Finnish	989803173931
Information for Use Manual, French	989803173941
Information for Use Manual, German	989803173951
Information for Use Manual, Greek	989803173961
Information for Use Manual, Hungarian	989803173971
Information for Use Manual, Italian	989803173981
Information for Use Manual, Japanese	989803173991
Information for Use Manual, Norwegian	989803174001
Information for Use Manual, Polish	989803174011
Information for Use Manual, Portuguese	989803174021
Information for Use Manual, Russian	989803174031
Information for Use Manual, Slovak	989803174051
Information for Use Manual, Spanish	989803174061
Information for Use Manual, Swedish	989803174071
Information for Use Manual, Turkish	989803174091
Service Manual	989803173771

Safety

Electromagnetic Compatibility (EMC)

The system is intended for use in the electromagnetic environment specified below. Given the system's electromagnetic emissions and immunity characteristics, the customer or the user should assure that the system is used within such an environment.

Radios

Frequency Range: 2402 to 2482 MHz.

Modulation Type: GMSK.

Monitor EIRP: 4.2 dBm (peak).

WSpO_2 EIRP: 0 dBm (peak)

EMC WARNINGS

- **Operation of the system outside the specifications indicated in Appendix A may cause inaccurate results.**
- **The use of portable and mobile radio-frequency (RF) communications equipment can affect the operation of this device.**
- **The use of accessories and components other than those specified in the Accessories list accompanying these instructions for use (with the exception of items sold by Invivo for the equipment or system as replacement parts for internal components) will result in increased emissions or decreased immunity of the equipment or system.**
- **The system should not be used adjacent to or stacked with other equipment (except other Invivo equipment, as detailed in this document) and that if adjacent or stacked use is necessary, the equipment or system must be observed to verify normal operation in the configuration in which it will be used.**
- **The system needs to be installed and put into service according to the EMC information provided below. Portable and mobile RF communications equipment can affect medical electrical equipment. The system may be interfered with by other equipment with CISPR emission requirements.**

EMC Emissions

Electromagnetic emissions is the ability of a product, a device, or a system to introduce intolerable electromagnetic disturbances into the use environment.

<table>
<tr><th colspan="3">Guidance and Manufacturer's Declaration –
Electromagnetic Emissions</th></tr>
<tr><th>Emissions Test</th><th>Compliance</th><th>Electromagnetic Environment - Guidance</th></tr>
<tr><td colspan="3">The Essential MRI Patient Monitor (Model 865353) is intended for use in the electromagnetic environment specified below. The customer or the user of the Essential MRI Patient Monitor (Model 865353) should assure that it is used in such an environment.</td></tr>
<tr><td>RF Emissions
CISPR 11</td><td>Group 1</td><td>The system uses RF energy only for its internal functions. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF Emissions
CISPR 11</td><td>Class A</td><td rowspan="3">The system is suitable for use in all establishments, other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic Emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage Fluctuations/flicker emissions
IEC 61000-3-3</td><td>Complies</td></tr>
</table>

EMC Immunity

Electromagnetic immunity is the ability of a product, a device, or a system to function satisfactorily in the presence of electromagnetic interference.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
The Essential MRI Patient Monitor (Model 865353) is intended for use in the electromagnetic environment specified below. The customer or the user of the Essential MRI Patient Monitor (Model 865353) should assure that it is used in such an environment.			
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 KHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	V1 = 3 Vrms E1 = 3 V/m	Portable and mobile RF communications equipment should not be used closer to any part of the system (including cabling) than the recommended separation distance, as calculated by the equation applicable to the frequency of the transmitter. Recommended separation distance: d = (3.5/V1) $\sqrt{P}$ d = (3.5/E1) $\sqrt{P}$ (80 MHz to 800 MHz) d = (7/E1) $\sqrt{P}$ (800 MHz to 2.5 GHz) Where P is the maximum transmitter output power rating in watts (W), according to its manufacturer, and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with this symbol: 

NOTES

- *At 80 MHz and 800 MHz, the higher frequency range applies.*
- *These guidelines may not apply in all situations, as electromagnetic propagation is affected by absorption and reflection from structures, objects and people.*

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

[b] Over the frequency range 150 KHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended Separation Distances

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

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the System

Rated Maximum Output Power of Transmitter (W)	**Separation Distance According to Frequency of Transmitter (m)**		
	150 KHz to 80 MHz $d = (3.5/V1)\sqrt{P}$	**80 MHz to 800 MHz** $d = (3.5/E1)\sqrt{P}$	**800 MHz to 2.5 GHz** $d = (7/E1)\sqrt{P}$
The Essential MRI Patient Monitor (Model 865353) is intended for use in the electromagnetic environment specified below. The customer or the user of the Essential MRI Patient Monitor (Model 865353) should assure that it is used in such an environment.			
0.01	0.117	0.117	0.233
0.1	0.369	0.369	0.738
1	1.167	1.167	2.333
10	3.689	3.689	7.379
100	11.667	11.667	23.333

For transmitters rated at a minimum output power not listed above, the recommended separation distance (d) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to its manufacturer.

NOTES

- *At 80 MHz and 800 MHz, the higher frequency range applies.*
- *These guidelines may not apply in all situations, as electromagnetic propagation is affected by absorption and reflection from structures, objects and people.*

Battery Disposal

The system uses lithium batteries that are subject to strict disposal regulations for user and environmental safety.

CAUTIONS

- Store batteries in a dry place, between 0°C to 40°C.
- Never heat or throw a battery into fire. Heating the battery will damage the safety circuitry, which can cause rupture or ignition of the battery.
- Never disassemble the battery. The batteries contain hazardous material that must be recycled or disposed of properly. (Refer to the disposal guidelines below.)

Disposing of Batteries in Europe

The European Community (EC) has issued two directives regarding battery disposal: 91/157/EEC and 93/86/EEC. Each member country implements these independently. Thus, in each country the manufacturers, importers, and users are responsible for the proper disposal or recycling of batteries. Confirm proper disposal requirements with your healthcare facility or distributor.

Disposing of Batteries in the United States

Lithium batteries are neither specifically listed nor exempted from the Federal Environmental Protection Agency (EPA) hazardous waste regulations, as conveyed by the Resources Conservation and Recovery Act (RCRA). The only metal of possible concern in the battery is the lithium metal, which is not listed or characterized as a toxic hazardous waste. A significant amount of spent cells and batteries that are untreated and not fully discharged are considered as reactive hazardous waste. Thus, hazardous waste of spent cells and batteries can be disposed after they are first neutralized through an approved secondary treatment prior to disposal (as required by U.S. Land Ban Restriction of the Hazardous and Solid Waste Amendments of 1984). Disposal of spent batteries must be performed by an authorized, professional disposal company, which has the knowledge in the requirements of the Federal, the State and the Local authorities regarding hazardous materials, transportation, and waste disposal. Confirm proper disposal requirements with your healthcare facility, distributor, and/or local EPA office.

List of Symbols

The following symbols are used on the system, packing materials, and in this document:

	Attention, consult accompanying documents		MR Conditional: Use in the MR environment is restricted to certain conditions of use to ensure patient and operator safety.
	Non-ionizing radiation		Not MR safe
	Power on / off	$\%SpO_2$	Percent oxygen pulse saturation
REF	Product part number		Earth ground
	Alternating current		Antenna
	Direct current		Device conforms to the Medical Device Directive
SN	Product serial number		Warning Shock Hazard
	Warning / Caution	 YYYY-MM	Date of manufacture

	Defibrillator-Proof type CF equipment (IEC 60601-1) protection against shock		Attention: Electrostatic safety device, observe precautions
	Potential restrictions for equipment including radios may apply within one or more European (EU) member states.		Dangerous voltage
	Type CF applied part		Patient
	Main battery gauge		Module battery gauge
	No Battery Communications		No (Module) Communications
	Energy Star rated product		Green Seal product
	Do not adjust without referring to service manual		Radio network (wireless modules)
	Network A		Network 1
	Network B		Network 2

	Network C		Network 3
	Network D		Network 4
	Network E		Network 5
	Device conforms to the R&TTE Directive (Radio & Telecommunications Terminal Equipment)		Canadian Standards Association (CSA) Safety Mark for the United States and Canada
	Federal Communications Commission		Dispose of the battery in accordance with your country's requirements
	Dispose of electrical equipment in accordance with your country's requirements		Indoor, dry location use only
	Device conforms to the Electrical Appliance and Materials Law of Japan		External power supply international efficiency mark, level 4
	Underwriters Laboratories Recognized Component Mark, compliance in Canada and U.S.A.		

Unpacking the System

Remove the contents from the shipping container(s). Carefully examine all items for signs of damage that may have occurred during shipment. Also, check all items against the packing list and the purchase request.

To report shipping damage or to resolve any issues or concerns with your order, contact Invivo Customer Service. (Save all packing materials and related shipping documents, as these will be required to process a damage claim with the carrier.)

CAUTION

The Essential MRI Patient Monitor (Model 865353) must be used and stored according to the environmental specifications in Appendix A. Failure to follow these specifications may affect system accuracy.

Examining the Contents

The system includes these items:

- Monitor and battery
- Power adapter (not MR safe)
- Power cord
- IFU manual
- Wireless SpO_2 module, battery and accessories (optional)

Accessories

Optional accessories are available to protect, carry and mount the system.

CAUTION

When using the accessories make sure that the view of the display panel is not obstructed.

Carry Case

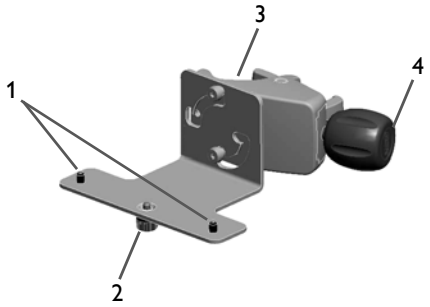
The carry case (REF 989803171711) offers convenient protected storage for the monitor, even during operation. A large clear window allows visual and operational access to the display panel, while side and rear pockets offer storage for modules and accessories.

CAUTIONS

- Do not place magnetic items inside the carry case, as they could be inadvertently brought into the MRI system room.
- Ensure that the alarm tone is audible when operating the monitor using the carry case.
- Use caution when operating the monitor using the carry case, as the alarm light will not be visible.

Mount Adapter

The mount adapter (REF 989803171681) is a secure solution when attaching the monitor to a pole or rail.



1	Pins
2	Thumbscrew
3	Clamp
4	Knob

To install the monitor onto the mount adapter, follow the steps below:

Step	Action
1	Align the pins (Item 1) of the mount adapter to the locator holes in the base of the monitor. 
2	Insert the Thumbscrew (Item 2) into the base of the monitor then tighten to secure the monitor to the mount. 
3	With the monitor in the desired location, place the clamp (Item 3) around a pole or rail then securely tighten the knob (Item 4).
4	If needed, pivot the mount horizontally or vertically to orient the monitor for viewing.
5	If needed, loosen the knob (Item 4) slightly to readjust the monitor for the optimum viewing angle then retighten the knob. This completes the procedure.

Roll Stand

The roll stand (REF 989803173761) offers a wheeled mobility solution when transporting the monitor (mount adapter option also required). And, for convenient storage of the module and accessories, the Universal Holder Pole Kit (REF 989803174281) is available.

Chapter 2: Getting Started

The Essential MRI Patient Monitor (Model 865353) is intended for use by health care professionals monitoring pulse oximetry and pulse rate in an MRI system room and in close proximity to the scanner magnet. Additionally, this monitoring is provided before, during and after active scanning in the MRI environment.

The system combines wireless communications, radio frequency shielding, digital signal processing and adaptable mounting technologies to provide accurate, continuous and reliable patient monitoring performance in the dynamic MRI environment.

The Essential MRI Patient Monitor (Model 865353) can be configured, accessed and adjusted for the unique vital needs, conditions and situations of a wide spectrum of patients from neonate to adult, specifically:

- Critically ill patients
- Intervention procedures
- Intraoperative procedures
- Patient transport within the MR environment

NOTE

The system is suitable for use in the presence of electrosurgery.

System Components

The components that comprise a working Essential MRI Patient Monitor (Model 865353) system include the monitor and a WSpO_2 module with attachments.

CAUTION

To minimize the chance of image artifacts, none of the monitoring components should be placed within the MRI Field of View.

Battery Operation

The Essential MRI Patient Monitor (Model 865353) operates from rechargeable batteries that provide approximately 8 hours of continuous power. Visual indications of the charged capacity of the batteries is constantly reported, while alarms provide alerts when low power conditions are detected.

Using Batteries Safely

The batteries in this system are non-magnetic and can be handled safely in the MR system room.

WARNING

Do not use or take the power adapter inside the MR system room. The device is magnetic and will be pulled into the MR system. The device is intended for use with the main battery and the module battery only when outside the MR system room.

Batteries have life cycles. When the equipment operating time provided by battery power becomes much shorter than usual, the battery life is at an end. Immediately remove a battery that has an expired life cycle and replace it with a new Invivo specified battery; refer to *Battery Disposal* in Chapter 1 when discarding a battery. To ensure the safety of operators and patients, observe the following warnings and cautions.

WARNING

Stop using any battery that exhibits abnormal heat, odor, color, deformation, or other condition. If a battery is punctured or if battery liquid leaks onto your skin or clothing, immediately wash the area and clothing with fresh water. If battery liquid gets into your eyes, do not rub your eyes; immediately flush your eyes with clean water and consult a physician.

CAUTIONS

- If the battery contacts become dirty, wipe them clean with a dry cloth before use.
- Keep metal objects away from the battery contacts.

Main Battery

The main battery fits the contour of the monitor and latches into the battery compartment.

CAUTION

Never force the battery into the battery compartment as damage to the battery and/or the monitor could occur.

Installing the main battery

To install the main battery follow these steps:

Step	Action
1	Place the cover over the DC inlet on the main battery. 
2	Lower the main battery into the battery compartment then pivot it into place, as shown below. 
3	Slide the locking tab to the left until latched. 

Removing the main battery

To remove the main battery follow these steps:

Step	Action
1	Slide the locking tab on the main battery to the right. 
2	Lift the main battery out of the battery compartment. 

Module Battery

The module battery latches into the wireless module.

Installing the module battery

To install the module battery, slide the battery in between the slots on the module until both locking tabs latch.

Removing the module battery

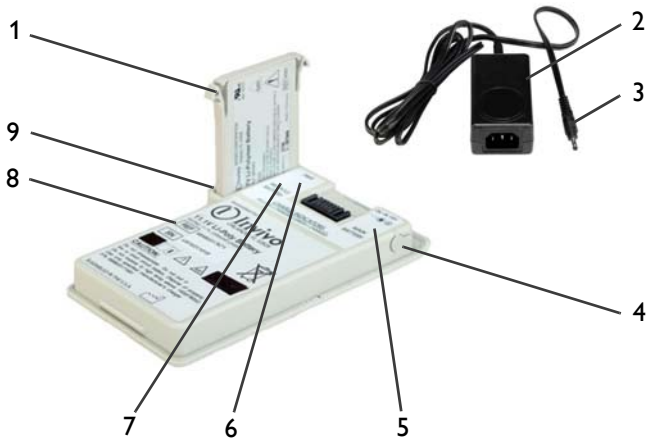
To remove the module battery, press both locking tabs and then slide the battery out of the module.

Charging Batteries

The intelligent charger, an integral part of the main battery assembly, simultaneously charges the main and module batteries, while the external power adapter supplies the appropriate DC input.

NOTE

Before initial use, place the main battery on the charger for at least 5 seconds, as the battery is shipped in a hibernating, partially charged, condition.



1	Module battery
2	Power adapter (AC cord not shown)
3	DC plug
4	DC inlet (with cover)
5	Main battery charge indicator
6	Power indicator
7	Module battery charge indicator
8	Main battery
9	Charging bay

WARNING

Do not use or take the power adapter inside the MR system room. The device is magnetic and will be pulled into the MR system. The device is intended for use with the main battery and the module battery only when outside the MR system room.

To charge batteries follow these steps:

Step	Action
1	Press the power switch for at least 1 second to turn off the monitor. 
2	Remove the main battery; see *Removing the main battery*, above.
3	Remove the module battery; see *Removing the module battery*, above.
4	Insert the module battery into the charging bay on the main battery. (The charging bay is keyed for proper battery insertion; do not force the battery.) 
5	Remove the cover from the DC inlet on the main battery. 
6	Connect the AC cord to the AC inlet on the power adapter.
7	Connect the AC cord to an AC outlet located outside of the MR system room.

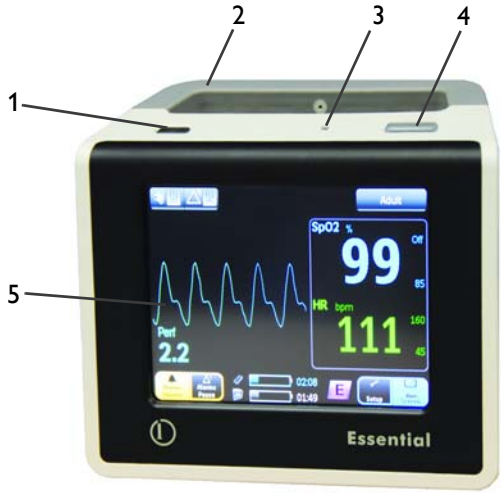
8	Connect the power adapter to the DC inlet. Observe the power (PWR) indicator and verify that power is applied: • Green = DC power is connected. • None = No power is connected or an error was detected. (Ensure that the power adapter is properly connected to the AC outlet.) 
9	Allow both batteries to fully charge, as indicated by the charge indicators: • Green = Charging complete • Yellow = Battery charging • None = No battery is installed or an error was detected. 
10	Disconnect the power adapter from the DC inlet.
11	Remove the module battery from the charging bay.
12	Insert the module battery into the module; see *Installing the module battery*, above.
13	Insert the main battery into the monitor; see *Installing the main battery*, above. This completes the procedure.

Monitor Overview

The monitor is an integrated device that houses communication, display, processing and power technologies (including the transceivers and antennas). The monitor has the following user features:

CAUTION

When using the monitor, ensure that your view of the display panel remains unobstructed.



1	Power switch
2	Handle
3	Speaker
4	Alarm light
5	Display panel

1. Power switch (⏻) - Controls power to the monitor, where pressing the switch for more than 0.5 seconds turns power on, and pressing the switch for more than 1 second turns power off.

NOTE

If communications have not been detected for 15 minutes, the monitor will automatically turn off.

2. Handle - Provides portability and houses the antennas.

3. Speaker - Provides audible prompts and alarm indications, at a maximum volume of up to 85 dB; see *Sound Menu* in Chapter 3 for details.

4. Alarm light - Provides a 360 degree visual alert for alarm conditions, glowing yellow or red, depending upon the condition detected; see *Managing Alarms* in Chapter 4 for details.

5. Display panel - Provides visual information and is the all-touch interface for operation, control and setup of the monitor.

Wireless SpO_2 Module Overview

The wireless pulse oximetry ($WSpO_2$) module provides the patient's readings, as detected signals are converted then transmitted for processing and display. The module has the following user features:

1	Network selection button
2	Sensor connector
3	Status indicator
4	Network icons

1. Network selection button - Selects the network setting of the module.

2. Sensor connector - Connects the module to the SpO_2 Quick Connect sensor.

3. Status indicator - Indicates the power and communication conditions of the module:

Status indicator		**Meaning**	
Color	**State**	**Power**	**Communication**
None	Not applicable	The battery is not installed or it lacks sufficient charge to power the module.	Not applicable
Green	Flashing	Battery power good	Not communicating
Green	Solid	Battery power good	Good communications
Red	Flashing	Low battery condition (less that 45 minutes remain)	Not communicating
Red	Solid	Low battery condition (less that 45 minutes remain)	Good communications

4. Network icons - Indicate the wireless network designated for module communications, where the illuminated icon denotes the current network.

Assigning the Module Network

The module communicates through a bidirectional 2.4 GHz spread-spectrum link, which is automatically established upon monitor power-up. The wireless network can be changed as needed to comply with the requirements of your operating environment, but should always

match the setting assigned to the monitor; see *Network Menu* in Chapter 3 for monitor setup details.

The wireless network for the module is indicated by its illuminated icon, while the currently assigned network for the monitor is indicated by the network button on the display panel.

CAUTION

For system communications, the monitor and module must have the same network setting.

Changing the Module Network Setting

The wireless network for the module is changed via its network selection button, located beneath the overlay, in the front upper left corner of the device. (A slight bump can be felt when you pass a finger over the button.)

When selecting a network for the module, place the module on a flat steady surface, or hold it as shown in the illustration, and use your thumb to press the network selection button.

Before starting the procedure, take note of these conventions that are used to explain the process:

- In the procedure below, the following symbols are used to convey the state of the network icon on a wireless module.

Icon illuminated

Icon flashing

- In the procedure below, the following illustrations are used to convey actions concerning the use of the network selection button:

Press the button

Release the button

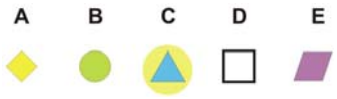
Press and hold the button

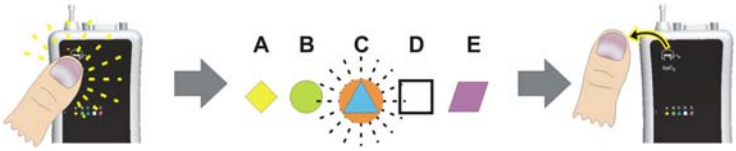
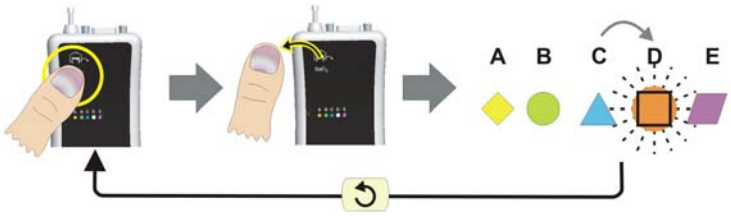
Repeat as desired

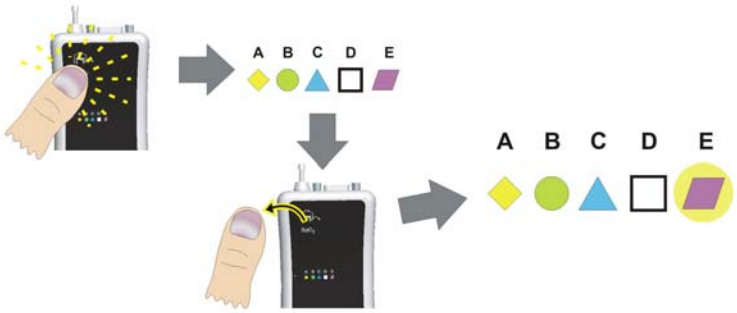
NOTE

Any part of the above sequence not completed will cause the module to revert to the network previously set 30 seconds after the network selection button was last released.

To assign the wireless module to the monitor's network follow these steps:

Step	Action
1	Identify the network setting of the monitor, as indicated by the **network button**. 
2	Remove the module battery from the module; see *Module Battery*, above.
3	Install the module battery. The network icons will flash briefly and then the current network icon will illuminate (for example, Network C in the illustration below).  ***NOTE*** *Depending upon your module, the network icons may have letter or numeric designators; and, though these examples show letter designators, the process is the same for numeric designators.*

Step	Action
4	Set the network of the module to the same network as the monitor (see Step 1). Enter the network change mode. After the current network icon has been illuminated (and within 15 seconds from module power-up) press and hold the network selection button until the current network icon begins flashing rapidly. Then release the network selection button.  ***NOTE*** *If the network change sequence is not started within 15 seconds after the module has been turned on, a network change will not be allowed. You must cycle module power and restart the sequence.*
5	Changing the network, press the button again until the icon stops flashing, then release the button. When you do this, the next network icon in the sequence will blink rapidly. (In other words, if the module was originally using network “C,” now the “D” icon will be flashing.) Repeat this sequence of pressing and releasing the button until the icon of the network you prefer is rapidly flashing. If you pass the desired network, simply continue pressing and releasing the button until the desired network is flashing again. 

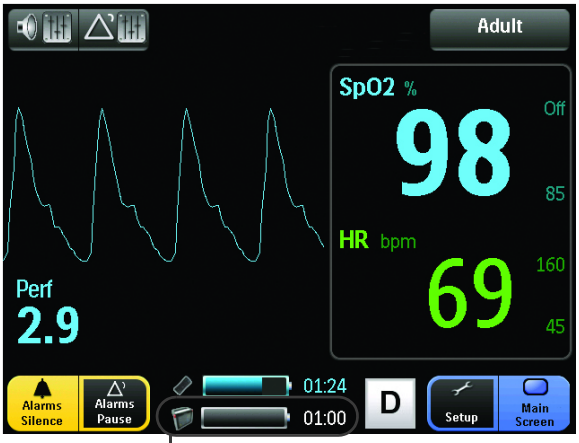
Step	Action
6	When you reach the desired network, press and hold the button for approximately 5 seconds to lock and save the new network. The selected network's icon will turn off while the button is depressed. Then it will illuminate (not blink) when the new network setting is saved. Once illuminated, release the button. The module will begin using the selected network.  **WARNING** **If the message box, "WARNING! Multiple wireless modules detected on network" is displayed, a module network setting conflict has been detected by the monitor. Before proceeding, for proper function, ensure that only one SpO_2 module per network has been assigned and is being used.**

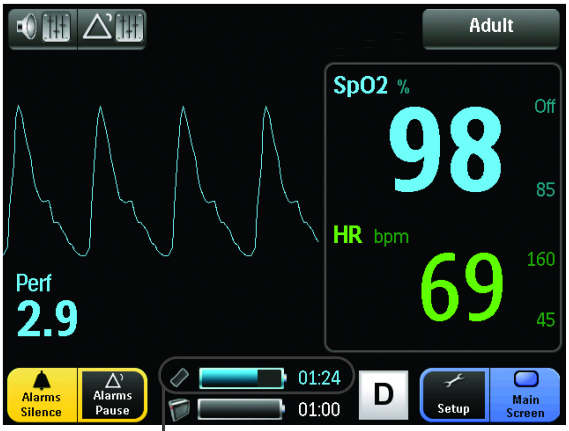
Initial System Power-Up

To apply power to the system follow these steps:

Step	Action
1	Ensure that the main battery is installed in the monitor; see *Main Battery*, above.
2	Ensure that the module battery is installed the module; see *Module Battery*, above.

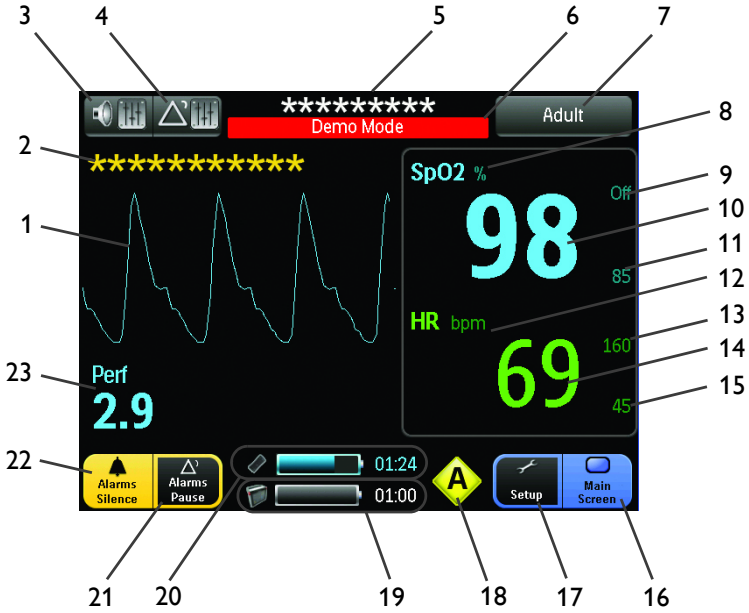
Step	Action
3	Press the power switch for at least 0.5 seconds to turn on the monitor. 
4	The first time the monitor is turned on, set the display language for the system: ***NOTE*** *It can take up to 30 seconds until the boot-up process has finished and the monitor becomes ready.* • In the Language menu, select a display language by touching a corresponding Language button; see *Navigating the Menu Groups and Controls* in Chapter 3 for details.  Language buttons (If not set initially, the Language menu will continue to appear at subsequent power-ups until a display language is selected.)

Step	Action
5	Ensure sufficient monitor power by checking the main battery indicators, where: • Gray gauge and time= Battery power OK, time remaining field indicates approximate remaining charge in hours and minutes. • Flashing yellow gauge and time = Low battery power (45 minutes or less power remaining). • No Battery Communications symbol  = No communications between the monitor and the main battery.  Main battery indicators

Step	Action
6	Ensure sufficient module power and communications with the monitor by checking the module battery indicators, where: • Blue gauge and time = Battery power OK (time remaining field indicates approximate remaining charge in hours and minutes) and good communications. • Flashing yellow battery gauge and time = Low battery power (45 minutes or less power remaining). • No Comm symbol  = No communications between the monitor and the module.  Module battery indicators
7	Verify proper operation of the SpO_2 parameter; see Chapter 4.

Display Panel Overview

The display panel provides the following functions and information:



1	SpO_2 waveform
2	SpO_2 message area
3	Speaker button
4	Alarms button
5	Informational message area
6	Demo Mode indicator
7	Patient category button
8	SpO_2 parameter identifier (in percent)
9	SpO_2 high alarm limit indicator
10	SpO_2 vital sign numeric
11	SpO_2 low alarm limit indicator
12	Heart rate (HR) parameter identifier (in beats per minute)
13	Heart rate high alarm limit indicator
14	Heart rate vital sign numeric
15	Heart rate low alarm limit indicator
16	Main Screen button
17	Setup button
18	Network button (dependent upon the network selection)
19	Main battery indicators
20	Module battery indicators
21	Alarms Pause button
22	Alarms Silence button
23	Perfusion index value

NOTE

Display update period is typically 1 second, up to a maximum of 30 seconds.

1. SpO_2 waveform - Provides the plethysmographic waveform, fixed across the screen and updated with an erase bar, where a red waveform indicates an alarm condition; see *Waveform and Vital Sign Information* in Chapter 4 for details.

2. SpO_2 message area - Displays SpO_2 related messages. For a listing, see *System Messages* in Chapter 4 for details.

3. Speaker button - Sets the volume for alarm tone, touch and pulse tones; see *Sound Menu* in Chapter 3 for details.

4. Alarms button - Sets the high and low alarm limits for SpO_2 and heart rate alarms; see *Setup Menu* in Chapter 3 for details.

5. Informational message area - Displays alarm messages when the Alarms Pause button or the Alarms Silence button is selected. For a listing, see *System Messages* in Chapter 4 for details.

6. Demo Mode indicator - Indicates that the monitor is operating in demonstration mode; see *Service Menu* in Chapter 3 for details.

7. Patient category button - Indicates and allows changes to the patient category; see *Patient Menu* in Chapter 3 for details.

8. Parameter identifier - Indicates the SpO_2 parameter and unit of measurement.

9. SpO_2 high alarm limit indicator - Indicates and allows changes to the high limit setting for the SpO_2 alarm; see *Alarm Limits Menu* in Chapter 3 for details.

10. SpO_2 vital sign numeric - Indicates the SpO_2 vital sign of the patient (given as a percentage) and allows changes to the SpO_2 alarm limits; see *Waveform and Vital Sign Information* in Chapter 4 for details.

NOTE

Normal response time of the numerics is approximately 10 seconds; however, in case of artifact or poor signal conditions, the update period can be longer.

11. SpO_2 low alarm limit indicator - Indicates and allows changes to the low limit setting for the SpO_2 alarm; see *Alarm Limits Menu* in Chapter 3 for details.

12. Parameter identifier - Indicates the heart rate parameter and unit of measurement.

13. Heart rate high alarm limit indicator - Indicates and allows changes to the high limit setting for the heart rate alarm; see *Alarm Limits Menu* in Chapter 3 for details.

14. Heart rate vital sign numeric - Indicates the heart rate vital sign of the patient (given in beats per minute) and allows changes to the heart rate alarm limits; see *Waveform and Vital Sign Information* in Chapter 4 for details for details.

NOTE

Normal response time of the numerics is approximately 10 seconds; however, in case of artifact or poor signal conditions, the update period can be longer.

15. Heart rate low alarm limit indicator - Indicates and allows changes to the low limit setting for the heart rate alarm; see *Alarm Limits Menu* in Chapter 3 for details.

16. Main Screen button - Closes any open menus, returns the display to the normal operating view, and can lock the screen; see *Locking and Unlocking the Screen* in Chapter 3 for details.

17. Setup button - Opens the Setup menu; see *Setup Menu* in Chapter 3 for details.

18. Network button - Opens the network setup menu; see *Network Menu* in Chapter 3 for details.

19. Main battery indicators:

- Displays the remaining main battery power as a gauge  and a time remaining counter (formatted in hours:minutes). When less than forty-five (45) minutes remain, the time will flash in yellow and an alarm will be declared; see *Managing Alarms* in Chapter 4 for details.
- Flashes the No Battery Communications symbol  if communications are not established, or have been lost, between the monitor and the main battery.

20. Module battery indicators:

- Displays the remaining module battery power as a gauge  and a time remaining counter (formatted in hours:minutes). When less than forty-five (45) minutes remain, the time will flash in yellow and an alarm will be declared; see *Managing Alarms* in Chapter 4 for details.
- Flashes the No Comm symbol  if communications are not established, or have been lost, between the monitor and the module; also see *No Data Available Indication* in Chapter 4 for details.

21. Alarms Pause button - Allows you to temporarily deactivate alarm functions, where during deactivation a 2 minute timer, flashing in red, will countdown in the informational message area; see *Managing Alarms* in Chapter 4 for details.

22. Alarms Silence button - Allows you to mute the alarm sound and turn off the alarm light during an alarm (though indications will continue to appear in the informational message area, and the alarming numeric will continue to flash). A new alarm will cause reactivation of alarm functions. When selected, the “Alarms Silenced” message, flashing in red, will be displayed in the informational message area; see *Managing Alarms* in Chapter 4 for details.

23. Perf - Is the perfusion index, a numeric value for the portion of the measured signal caused by arterial pulsation; see *Waveform and Vital Sign Information* in Chapter 4 for details.

Chapter 3: Preparation for Use

The Essential MRI Patient Monitor (Model 865353) provides the flexibility needed to perform standard SpO_2 monitoring, while allowing you to customize operations to fit your needs.

WARNING

Always verify proper communications between the module and monitor prior to patient use.

CAUTIONS

- Avoid the use of cellular phones or other radio-frequency transmitters in the proximity of an operating system.
- A minor but noticeable degradation in the wireless SpO_2 radio communications will occur in the presence of high-powered radios.

Using the Monitor

Observe all warnings and cautions when using the Essential MRI Patient Monitor (Model 865353).

WARNING

Keep the Essential display out of the MR system bore and avoid contact with the patient's bare skin while the MRI scan is running. The device is electronic and susceptible to excessive heating from the MRI scan RF only if placed inside the bore of the MR system during that scan. Failure to do so may result in patient injury.

WARNING

Do not use or take the power adapter inside the MR system room. The device is magnetic and will be pulled into the MR system. The device is intended for use with the main battery and the module battery only when outside the MR system room.

System Parameters

The Essential MRI Patient Monitor (Model 865353) facilitates processing and display of the plethysmographic waveform, and the associated numeric values and alarms for the oxygen saturation of arterial blood and the derived heart rate. All patient information is provided on the display panel.

Navigating the Menu Groups and Controls

The menu groups and controls for the Essential MRI Patient Monitor (Model 865353) are accessed and navigated by touching the active areas on the touch screen.

Touching an active button or indicator with your finger or a passive object (such as a stylus) will cause the system to produce a touch tone and open that menu or select that option, setting or value. (Note that simultaneously touching two or more areas of the screen may produce unpredictable results.)

To guard against accidental changes, a locking feature allows you to protect the monitor settings.

CAUTION

Never use sharp objects on the display panel or apply unnecessary pressure to the display panel, as action can result in screen damage or failure.

Controlling Menu Changes

Depending upon the menu, these buttons control changes made to the options and settings:

NOTE

If a menu is open, delaying selection of an option for longer than 30 seconds closes the menu.

- **Confirm and Close button**  **:** Touch to save changes and close the menu.
- **Close button**  **:** Touch to discard changes that require confirmation and close the menu. (Or touch another button.)

- **Main Screen button** 

: Touch to close an open menu (and save any changes - except those that require confirmation) and return to the normal operating view.

Locking and Unlocking the Screen

The touch screen can be locked to protect against accidental changes to the setup or alarm controls, while allowing monitoring functions to continue. When locked, the touch screen functions will be inaccessible, as denoted by the "Screen Locked" message which will appear for about 2.5 seconds after a button or indicator is touched. To restore operation to a locked screen, press and hold the Unlock Screen button for about 3 seconds. Locking and unlocking methods are described below.

NOTE

The Main Screen button is dynamic, changing to reflect the current state of the display where "Main Screen" indicates an unlocked condition and "Unlock Screen" indicates a locked condition.

To lock the screen:

Touch the **Main Screen button for about 3 seconds**.

Main Screen button

To unlock the screen:

Touch the **Unlock Screen button for about 3 seconds**.

Patient Menu

The Patient menu allows you to select the patient category.

Determining the appropriate patient category

Each safety agency recognizes that the patient category descriptions can be arbitrary and that the following patient factors are more accurate in determining the appropriate method of patient monitoring and treatment:

- Weight
- Body size
- Limb circumference
- Physiological development
- Neurological development
- Neuromuscular coordination

CAUTION

There may be occasions when a particular patient category is not suitable for its apparent categorization based only on age. In these cases, a clinical decision shall be made to use another patient category or measurement technique. The clinical decision shall be based on all of the factors listed in *Determining the appropriate patient category* (above) to ensure the best possible and most timely measurement acquisitions.

NOTES

- *The patient category button is dynamic, changing to reflect the current patient category.*
- *Alarm limit default settings are applied whenever the patient category is changed, and previously changed alarm settings for a certain patient category will be lost; see* Alarm Limits Menu *(below) for details.*

To enter the Patient menu:

Touch the **Patient category button**.

The following options are available:

- **Adult:** Allows you to set the monitoring functions for adult patients.
- **Pediatric:** Allows you to set the monitoring functions for pediatric patients.
- **Neonatal:** Allows you to set the monitoring functions for neonatal patients.

Setup Menu

The Setup menu options configure the alarm limits, adjust the brightness of the display panel and access the service functions.

To enter the Setup menu:

Touch the **Setup button**.

The following options are available:

- **Alarm Limits:** Allows you to access the Alarm Limits menu (see below).
- **Brightness:** Allows you to set the desired intensity of the display, where:
  - 3 (Brightest)
  - 2 (Bright)
  - 1 (Normal)

NOTE

Brightness options higher than the Normal setting will reduce battery run time.

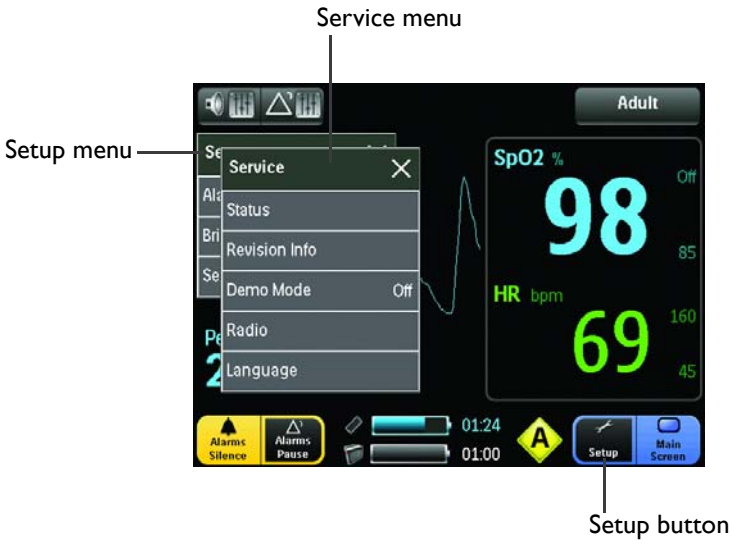
- **Service:** Allows you to access the Service menu (see below).

Service Menu

The Service menu allows you to examine the status of the hardware and software revision levels, and to set the language displayed by the monitor. Other options remain reserved for use by qualified service providers, as noted below.

To enter the Service menu:

Touch the **Setup button** and then **Service**.



The following options are available:

- **Status:** Allows you to check the Real Time Clock, and to display the communication status of the module and the main battery.

- **Revision Info:** Allows you to examine the firmware and software level of the boot loader, application and power programs.

- **Demo Mode:** Allows system operations to be simulated; see the service manual for details.

NOTE

The correct password is required for access: 12151.

WARNING

The Essential MRI Patient Monitor (Model 865353) is equipped with a simulation mode that displays computer generated data for training purposes. As a safety feature, a "Demo Mode" message is displayed while in simulation mode. Do not attach a patient to the system when in simulation mode and do not activate simulation mode when a patient is connected to the system. The system will not monitor patients while in the simulation mode. Failure to properly monitor the patient will result. To exit simulation mode, turn off Demo Mode using the menu, or power off the monitor, or remove the battery.

- **Radio:** Allows a service provider to change the radio and to test radio power; see the service manual for details.

NOTE

The correct password is required for access.

- **Language:** Allows you to set the language used to display menus, messages and interface items, where the following options are available:
  - **English**
  - **Espanol**
  - **Deutsch**
  - **Francais**
  - **Nederlands**
  - **Dansk**
  - **Svenska**
  - **Italiano**
  - **Norsk**
  - **Portugues**

Network Menu

The Network menu allows you to set the network used by the monitor to communicate with the $WSpO_2$ module. For proper communications, the monitor and module must be linked on the same network. For ease of identification, network selection buttons have unique shapes, designators and colors. (To change the module's network setting, see *Assigning the Module Network* in Chapter 2.)

WARNING

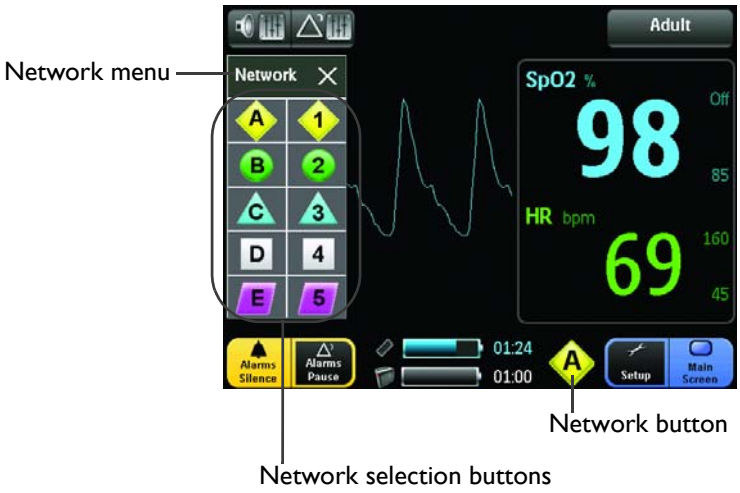
If the message box, "WARNING! MULTIPLE WIRELESS MODULES DETECTED ON NETWORK" is displayed, recheck the desired configuration of the module and monitor. In environments where multiple systems are being used, you must be aware of each system's network setting. Operating multiple systems on the same network (or with an incorrect network setting) will interfere with communications, and incorrect patient vital signs information may be obtained and displayed as a result. Before proceeding, you must resolve the conflicting assignments.

NOTE

The network button is dynamic, changing to reflect the current network setting.

To enter the Network menu:

Touch the **Network button**.



The following options are available by pressing the associated **Network selection button**:

- **(Network 1):** Allows you to set system communications for wireless network 1 (compatibility with a Precess MRI Patient Monitor and module, Model 3160 - Blue version).
- **(Network 2):** Allows you to set system communications for wireless network 2 (compatibility with a Precess MRI Patient Monitor and module, Model 3160 - Blue version).

- **(Network 3):** Allows you to set system communications for wireless network 3 (compatibility with a Precess MRI Patient Monitor and module, Model 3160 - Blue version).
- **(Network 4):** Allows you to set system communications for wireless network 4 (compatibility with a Precess MRI Patient Monitor and module, Model 3160 - Blue version).
- **(Network 5):** Allows you to set system communications for wireless network 5 (compatibility with a Precess MRI Patient Monitor and module, Model 3160 - Blue version).
- **(Network A):** Allows you to set system communications for wireless network A (compatibility with an Expression MRI Patient Monitor and module, Model 865214).
- **(Network B):** Allows you to set system communications for wireless network B (compatibility with an Expression MRI Patient Monitor and module, Model 865214).
- **(Network C):** Allows you to set system communications for wireless network C (compatibility with an Expression MRI Patient Monitor and module, Model 865214).
- **(Network D):** Allows you to set system communications for wireless network D (compatibility with an Expression MRI Patient Monitor and module, Model 865214).
- **(Network E):** Allows you to set system communications for wireless network E (compatibility with an Expression MRI Patient Monitor and module, Model 865214).

Alarm Limits Menu

The Alarm Limits menu allows you to set limits for the SpO_2 and HR (heart rate) alarms, and to control the presence of these settings on the display. During patient monitoring when a vital sign has violated an alarm limit, a high priority alarm is declared; see *Managing Alarms* in Chapter 4 for details.

WARNINGS

- **Always respond promptly to any alarm condition.**
- **Setting the alarm limits to extreme values can render the alarm monitoring useless. A potential hazard can exist if different alarm monitoring settings are used for the same or similar equipment in any single patient care unit.**
- **Alarms generated by the Essential MRI Patient Monitor (Model 865353) will not synchronize with other patient monitoring systems.**
- **Alarm limits can be set to a wide range of values, including Off. It is the responsibility of the operator of the system to ensure that alarm limit values appropriate for each patient are established and set.**

NOTES

- *The system automatically prevents crossover of the low and high alarm limit settings.*
- *Alarm limit setting changes are saved when power is turned off or when changing the battery.*
- *When the patient category is changed, factory default alarm limit settings are used.*

To enter the Alarm Limits menu:

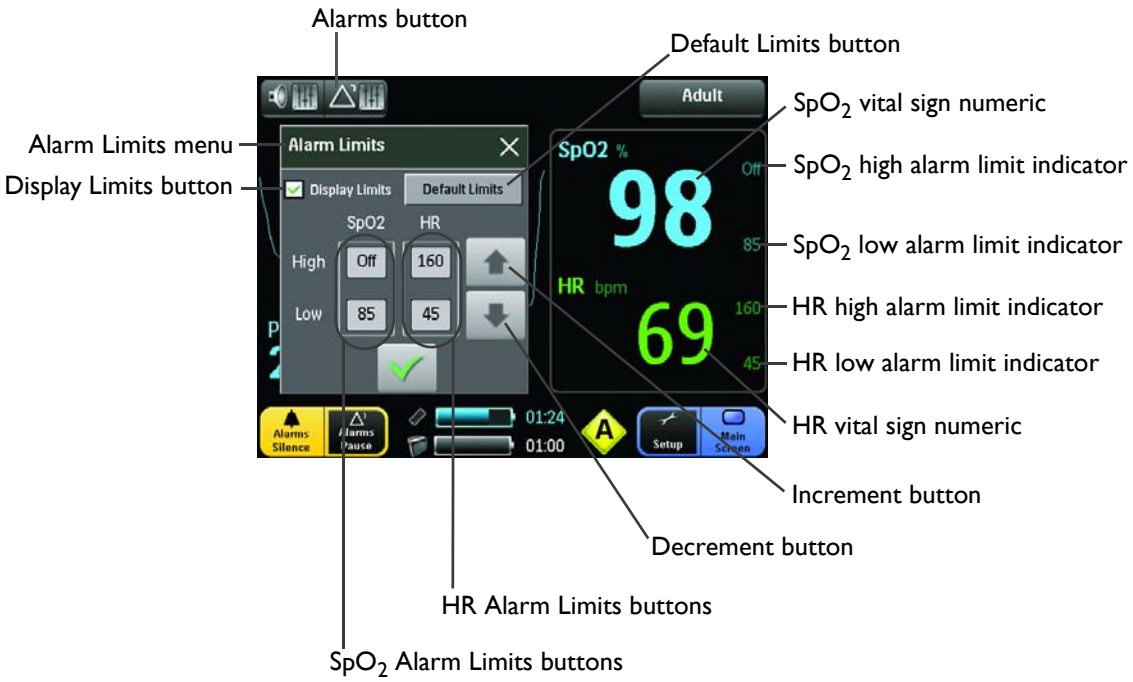
- Touch the **Alarms button**.

  Alarm Limits can also be accessed by:

  – Touching the **SpO_2** or **HR vital sign numeric**,

  – Touching a specific **alarm limit indicator** (for direct access to that setting), or

  – Touching the **Setup button** and then **Alarm Limits**.



The following options are available:

- **SpO2 Alarm Limits buttons:** Indicates the current setting and allows you to set the limits for the SpO2 alarm, adjusted by touching the button (High or Low) followed by the increment or decrement button.

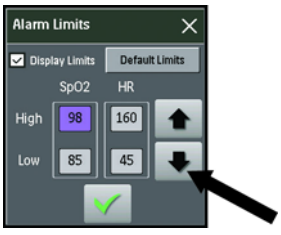
- **HR Alarm Limits buttons:** Indicates the current setting and allows you to set the limits for the HR (heart rate) alarm, adjusted by touching the button (High or Low) followed by the increment or decrement button.
- **Decrement button:** Allows you to decrease an Alarm Limits setting, where touching it once decreases the count by one and holding it decreases the count continuously.
- **Increment button:** Allows you to increase an Alarm Limits setting, where touching it once increases the count by one and holding it increases the count continuously.
- **Default Limits button:** Allows you to automatically change the low and high alarm limits for both parameters to the default settings (see the tables below).
- **Display Limits button:** Allows you to control the presence of the high and low alarm limit indicators for SpO_2 and HR, where a checked box displays the indicators.
- **SpO2 vital sign numeric:** Indicates the SpO_2 vital sign of the patient (given as a percentage) and allows you to change to the SpO_2 alarm limits, where touching it opens the Alarm Limits menu.
- **HR vital sign numeric:** Indicates the heart rate vital sign of the patient (given in beats per minute) and allows you to change to the heart rate alarm limits, where touching it opens the Alarm Limits menu.
- **SpO2 high alarm limit indicator:** Indicates and allows direct changes to the high limit setting for the SpO2 alarm, where touching it opens the Alarm Limits menu.
- **SpO2 low alarm limit indicator:** Indicates and allows direct changes to the low limit setting for the SpO2 alarm, where touching it opens the Alarm Limits menu.
- **HR high alarm limit indicator:** Indicates and allows direct changes to the high limit setting for the heart rate alarm, where touching it opens the Alarm Limits menu.
- **HR low alarm limit indicator:** Indicates and allows direct changes to the low limit setting for the heart rate alarm, where touching it opens the Alarm Limits menu.

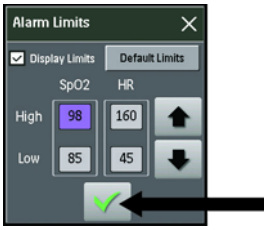
Neonatal Alarm Limits							
Vital Sign Parameter	Unit	Low Limit			High Limit		
		MIN	MAX	Default	MIN	MAX	Default
SpO_2	Percent	50	99	90	70	99	Off
HR	BPM	30	249	90	60	249	210

Pediatric Alarm Limits							
Vital Sign Parameter	Unit	Low Limit			High Limit		
		MIN	MAX	Default	MIN	MAX	Default
SpO_2	Percent	50	99	90	70	99	Off
HR	BPM	30	249	75	60	249	160

Adult Alarm Limits							
Vital Sign Parameter	Unit	Low Limit			High Limit		
		MIN	MAX	Default	MIN	MAX	Default
SpO_2	Percent	50	99	85	70	99	Off
HR	BPM	30	249	45	60	249	160

To change an alarm setting, follow the steps below:

Step	Action
1	If a change in the patient category is needed, touch the Patient category button then make that change; otherwise, proceed to Step 2.
2	Touch the Alarms button .
3	Touch the high or the low Alarm Limits button for the parameter. (The touch tone will sound and the button will be highlighted.) *The example below follows a SpO_2 high alarm limit change.* 
4	Touch the decrement or the increment button until the desired setting is reached, as displayed in the highlighted Alarm Limits button. *For example, the decrement button was touched twice, resulting in a high alarm limit of 98.* 
5	Repeat Steps 2 and 3 to adjust additional alarm limits.

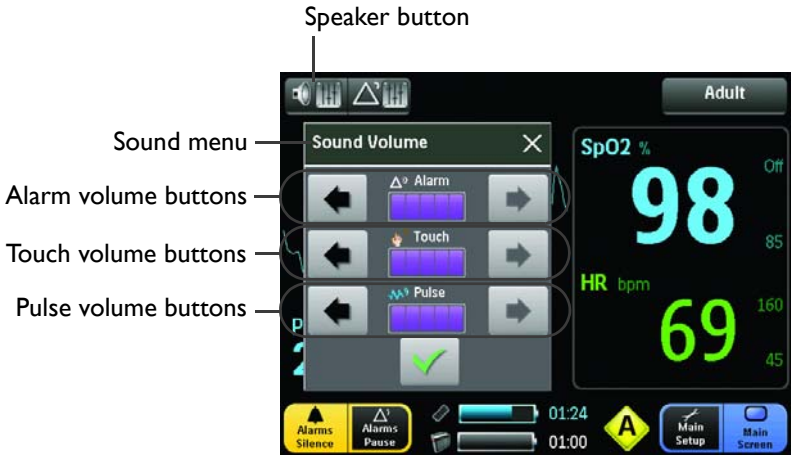
6	Touch the confirm and close button to save your changes. 
7	If Display Limits are enabled, the alarm setting(s) will be indicated by the high and low alarm limit indicators. (This completes the procedure.)

Sound Menu

The Sound Menu allows you to adjust the volume level of the alarm, touch and pulse tones produced by the monitor.

To enter the Sound menu:

Touch the **Speaker button**.



The following options are available:

- **Alarm volume buttons:** Sets the volume (range is 1 – 5) of the tone generated during an alarm condition, where touching the decrement button (left) lowers the volume or touching the increment (right) button increases the volume.

WARNING

Adjustable for suitability to various clinical environments, the alarm volume can be turned low but never completely off. Always ensure that the alarm volume setting is appropriate for each patient. When you use the system, always verify that the alarm tone can be heard above the ambient noise level. Be sure the minimum alarm volume setting is still audible during MRI scanning because in some environments a particular setting is barely audible. Do not rely exclusively on the audible alarm system for patent monitoring. Adjustment of the alarm volume to a low level during patient monitoring may result in patient danger. Remember the most reliable method of patient monitoring combines close personal surveillance with correct operation of monitoring equipment.

- **Touch volume buttons:** Sets the volume (range is 0 – 5) of the tone generated when an active area of the display panel is touched, where touching the decrement button (left) lowers the volume or touching the increment (right) button increases the volume.
- **Pulse volume buttons:** Sets the volume (range is 0 – 5) of the tone generated when a pulse is detected, where touching the decrement button (left) lowers the volume or touching the increment (right) button increases the volume.

Chapter 4: Monitoring SpO_2

The pulse oximetry feature uses a motion-tolerant signal processing algorithm based on Fourier Artifact Suppression Technology (FAST) to provide oxygenated hemoglobin measurements and a pulse rate, specifically:

- **Oxygen saturation of arterial blood (SpO_2):** The percentage of oxygenated hemoglobin in relation to the sum of oxyhemoglobin and deoxyhemoglobin (functional arterial oxygen saturation).
- **Plethysmographic waveform:** A visual indication of the patient's pulsatile blood flow.
- **Heart rate:** The number of detected pulsations per minute.
- **Perfusion index value:** A numeric value for the pulsatile portion of the measured signal caused by arterial pulsation.

SpO_2 Sensor and Wireless SpO_2 Module

The SpO_2 sensor and wireless SpO_2 ($WSpO_2$) module may be used in the MR system bore, although the module must not be placed within the MRI field of view (FOV). Invivo-specified fiber optic SpO_2 sensors and the $WSpO_2$ module are designed for use in the MR environment. Use only the specified fiber optic SpO_2 sensors; see *Accessories* in Chapter 1 for a listing.

WARNING

Connecting SpO_2 sensors other than those specified by Invivo into the $WSpO_2$ module can cause inaccurate SpO_2 readings or damage the module.

CAUTIONS

- If dropped, the $WSpO_2$ module must be verified for correct operation before use.
- Guard against the accidental ingress of liquid into the module, as measurements made by the device can be adversely affected.

Connecting the Sensor and Attachments to the $WSpO_2$ Module

Verify the SpO_2 sensor and $WSpO_2$ module status as follows:

Step	Action
1	Press the power switch for about 0.5 seconds. After the monitor is on, check the main battery indicators to ensure sufficient power.  ***NOTE*** *Use Alarms Pause to temporarily disable the alarm functions.*
2	Connect a SpO_2 sensor to the module.
3	Connect the attachment (clip or grip) to the SpO_2 sensor.
4	Check the status indicator on the module to verify sufficient power and good communications for monitoring: • Solid green = Good battery power and good communications • Flashing green = Good battery power but no communications • Solid red = Low battery power and good communications • Flashing red = Low battery power but no communications
5	Proceed to *Applying and Positioning the SpO2 Sensor*, below.

1	$WSpO_2$ module
2	SpO_2 sensor
3	SpO_2 attachment (clips or grips)

Patient Preparation

To prepare a patient for MRI SpO_2 monitoring, follow the instructions below.

Applying and Positioning the SpO_2 Sensor

Apply the $WSpO_2$ attachment to the patient as follows:

Step	Action
1	Follow the Instructions for Use provided with the SpO_2 sensor, adhering to all warnings and cautions, and choose an application site.
2	If present, remove any colored nail polish from the application site.
3	Apply the attachment to the patient. The application site should match the size of the attachment used, so that the sensor does not fall off the site or apply excessive pressure to the site (see the Warnings, below).
4	Ensure the sensor is not placed within the MRI Field of View (FOV).
5	Check that the light emitter and the photodetector are directly opposite each other, as the light must pass through the patient's tissue to the photodetector for proper operation.
6	Proceed to *Measuring SpO2*, below.

WARNINGS

- **GENERAL SENSOR FIT: If a sensor is too loose, it might compromise the optimal alignment or dislocate. If the sensor is too tight (for example, if the application site is too large or becomes large due to edema), excessive pressure may be applied resulting in venous congestion distal from the application site, which could lead to interstitial edema, hypoxemia, tissue malnutrition, and inaccurate measurements. Skin irritations may occur as a result of the sensor being attached to one location for too long. Periodically inspect the sensor application site and change the application site at least every four hours. Exercise care when using tape to secure the sensor, as the stretch memory properties of most tapes can apply unintended pressure to the sensor site easily.**
- **EXTREMITIES TO AVOID: Avoid placing the sensor on extremities with an arterial catheter, intravascular venous infusion line, or inflated blood pressure cuff. Failure to do so may result in inaccurate readings or false alarm indications.**

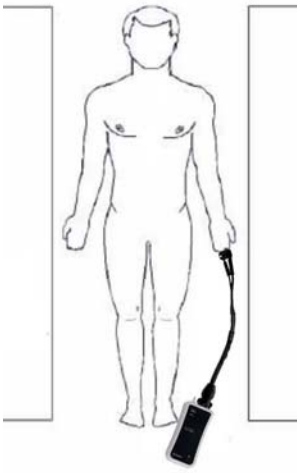
NOTE

At system power-up, if the monitor has communication with the module but the module attachment is not connected to the patient, no alarm will be declared.

Positioning the $WSpO_2$ Module

The selected site, sensor position, attachment connection, and ambient environment all impact performance and operation during SpO_2 monitoring. To ensure best possible results from the $WSpO_2$ module during harsh scan sequences (with peripheral nerve stimulation [PNS] levels above 80 percent), observe the following general placement rules:

- Place the $WSpO_2$ module on or near the patient, as close as possible to the bore iso-center (considering the scan to be performed), but keep the wireless module outside the FOV.
- Place the $WSpO_2$ module as close as possible to the bore opening. (If the module can be placed outside the bore, positioning at the iso-center is not necessary.)
- Place the $WSpO_2$ module on a cushioned surface to minimize the MR vibrations.



WARNING

If the $WSpO_2$ module is incorrectly positioned when used within the MR system room, the following factors can cause SpO_2 waveform distortion and numeric inaccuracies:

- **Fast magnetic field changes, usually found but not limited to scan sequences using PNS levels above 80 percent;**
- **Severe vibrations induced by scan sequences using PNS levels above 80 percent;**
- **The distance from the MR bore opening; and,**
- **The distance from the bore iso-center in the x, y, or z directions.**

Measuring SpO_2

To display functional SpO_2 values, follow the instructions below:

Step	Action
1	Select the patient category (Adult, Pediatric, or Neonatal).
2	During measurement, ensure that the application site: • has a pulsatile flow, ideally with a perfusion index value above 1.0; and, • has not changed in thickness (for example, due to edema) causing an improper sensor fit.

NOTE

A pulse oximeter should be considered an early warning device. As a trend towards patient deoxygenation is indicated, blood samples must be analyzed by a laboratory co-oximeter to understand the patient's condition completely.

Waveform and Vital Sign Information

The waveform and vital sign numeric data provides important physiological information, as detailed in the table below.

Item Number	Explanation
1	The SpO_2 (pleth) pulsatile waveform, updated from left to right across the display panel. If the pulse is above a minimum level, the amplitude of the waveform will automatically be adjusted for proper viewing. If you need an indication of change in pulse volume, use the perfusion index value described in item 4.
2	The SpO_2 numeric is the patient's arterial oxygen saturation reading, given as a percentage. Also, if Displayed Limits are set to on, the SpO_2 alarm settings are shown in the high and low alarm limit indicators. ***NOTE*** *Averaging time is fixed and may be overridden by Expression or Precess workflow.*
3	The HR numeric is the patient's heart rate, as derived from the SpO_2 measurement, given in beats per minute. Also, if Displayed Limits are set to on, the HR alarm settings are shown in the high and low alarm limit indicators.

No Data Available Indication

Under certain conditions, the vital sign numerics and/or the perfusion index value may be displayed as 3 dashes (---), which means no data is currently available for the parameter(s). This can happen for any of the following reasons:

- The parameter is in a start-up state;
- The SpO_2 sensor is not applied to the patient;
- There is no communication with the module; or
- The measurement is distorted, the pulse too weak or the signal inadequate in any respect.

NOTES

- *If the system was just turned on or if the probe was just applied, give the monitor a moment to lock onto the wireless signal.*
- *If this condition persists, ensure that the network setting is the same for the module and the monitor, and that the communication between the devices is good.*

Assessing Suspicious SpO_2 Readings

With newer algorithms, such as FAST-SpO_2, the calculation of SpO_2 is not directly linked to the correct detection of each pulse. When the pulse rate is very low or a strong arrhythmia is present, the SpO_2 / plethysmography pulse rate may differ from the heart rate calculated via an ECG. This does not indicate an inaccurate SpO_2 value. If you doubt the measured SpO_2, use the plethysmography wave and perfusion index value to assess the signal quality.

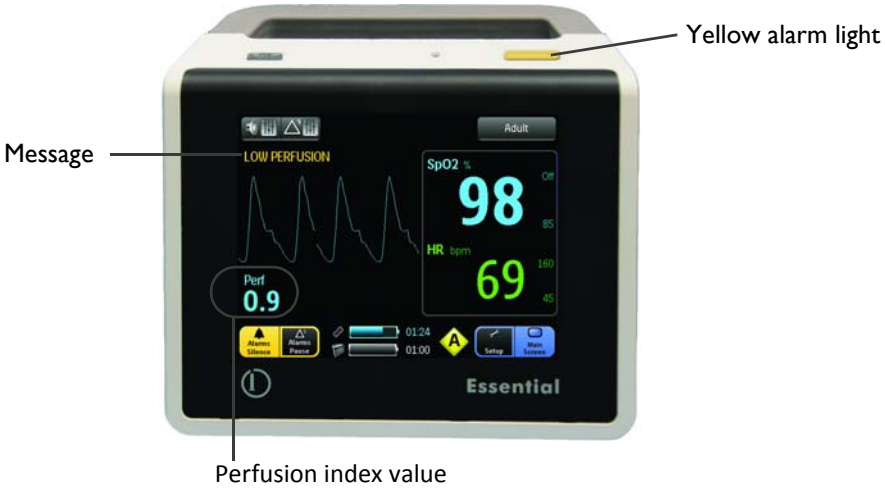
WARNINGS

- **Always shield the SpO_2 sensor from extraneous incidental light sources (for example, cover the sensor with opaque material), as such light can cause erroneous SpO_2 readings or pulse detection errors.**
- **SpO_2 monitoring requires the detection of valid pulses to correctly determine SpO_2 and heart rate values. Any of the following items can lead to inaccuracies of the SpO_2 readings and/or prolonged measurement time: Ambient light (including photodynamic therapy), physical movement (patient and imposed motion), arrhythmias and/or erratic heart beats, diagnostic testing, low perfusion, electromagnetic interference, electrosurgical units, dysfunctional hemoglobin, intravascular dyes, presence of dyes or pigments at the application site, and inappropriate positioning of the pulse oximeter probe. If questionable readings are obtained, check the patient's vital signs by alternate means before administering medication.**
- **Sensor movement, ambient light (especially strobe lights or flashing lights), or electromagnetic interference can give unexpected intermittent readings when the sensor is not attached to a patient. Bandage and grip sensor designs are particularly sensitive to minimal sensor movement that might occur when the sensor is dangling, not attached to the patient. Unapplied sensors may cause readings to be displayed on the monitor. To avoid misdiagnosis, verify sensor is applied to patient correctly.**

Perfusion Index Value

The perfusion index value is an indication of the pulsatile portion of the SpO_2 signal caused by the patient's arterial blood flow. This value can be used as a quality indicator of the SpO_2 measurement from the module. The table below provides general guidelines regarding this index value, as well as the corrective actions needed when a "Low Perfusion" alarm is generated,

Perfusion Index Value	Meaning
Above 1.0	Optimal – high quality readings
0.3 to 1.0	Acceptable – good quality readings
Below 0.3	Marginal – the position of the attachment should be adjusted or another site should be used for measurement.



Managing Alarms

Access to every parameter alarm is provided by the Alarms button (see *Alarm Limits Menu* in Chapter 3 for details). Alarm limits may be turned on, adjusted (manually or automatically) or turned off using the Alarm Limits menu. The system gives visual alarm signals (on the display panel and by the alarm light) and audible signals.

Alarm Types, Priorities and Indications

The Essential MRI Patient Monitor (Model 865353) assigns different priorities and indications when reporting alarms. Alarms are assigned a high or medium priority status by the system according to the type of violation: physiological or technical.

NOTES

- *High priority alarms sound levels range from at least 53dB (a minimum volume setting) to 84dB (maximum volume setting) in 1m distance.*
- *Medium priority alarms sound levels range from at least 49dB (a minimum volume setting) to 71dB (maximum volume setting) in 1m distance.*
- *The delay time of making visual and audible alarms available from the alarming equipment to the remote equipment at the signal output port is less than 1 second. In the case of artifact or poor signal conditions, update time of SpO_2 and HR numerics can take as long as 30 seconds. Alarm limit violations are reported as a high priority alarm within 1 second.*

Physiological Alarm Violations

Physiological alarms receive the highest priority reporting status. A physiological alarm is violated when a patient parameter (SpO_2 or heart rate) exceeds the high or low setting of the corresponding alarm limit. The reaction of the system to a physiological alarm depends upon the settings described below and generally as follows:

a. The alarm light flashes red (see illustration below).

b. If SpO_2 related, a red waveform is displayed.

c. The numeric of the violated parameter flashes red.

d. The high priority alarm tone sounds--at a high pitch--5 pulse tones followed by a 1 second delay then 5 pulse tones, repeating every 5 seconds.

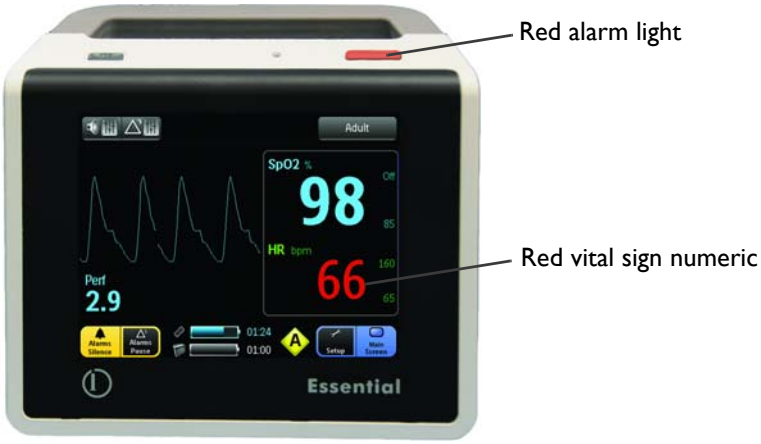
e. The numeric continues to flash while the parameter violates its alarm limit, even after the alarm tone has been muted by touching the Alarms Silence button.

f. If the numeric exceeds the highest value that can be displayed, OVR will be indicated in the parameter numeric.

g. The numeric stops flashing after the parameter returns to within its alarm limits.

h. The displayed numeric of the violated parameter flashes and the audible alarm, once silenced, will not sound again until the alarm condition has been corrected and re-violated. Only a second different parameter alarm will cause the alarm sound and alarm light to reactivate.

Example, visual physiological alarm indicators:



Physiological alarm testing can be performed using a patient SpO_2 simulator to exceed an individual alarm limit. Alarm testing can also be performed using the monitor's Demo mode where an individual parameter alarm limit can be adjusted--a high limit set below the simulated numeric or a low limit set above the simulated numeric (except SpO_2)--to trigger a physiological alarm. If a problem with the alarm tone or message system is suspected, this system must be referred to an Invivo-authorized service personnel for evaluation.

Technical Alarm Violations

Technical alarms receive a medium priority reporting status. A technical alarm is violated when a change in system status or a problem with the hardware or the measurement is detected (for example - a low battery, a communications failure, or a SpO2 inoperative condition).

NOTES

- *At system power-up, if the monitor does not have communication with the module, a medium priority alarm will be declared.*
- *At module power-up, if communication with the module battery is lost, a medium priority alarm will be declared.*
- *If the system loses communication with the main battery, a medium priority alarm will be declared.*

The reaction of the system to a technical alarm depends upon specific system operations and generally as follows:

a. The alarm light flashes yellow (see illustration below).

b. The medium priority alarm tone sounds--at a low pitch--3 pulse tones followed by a 10 second delay, repeating.

c. Messages are displayed in yellow (except for low battery or communications failure conditions) to identify the cause of the alarm; see *System Messages*, below, for the listing.

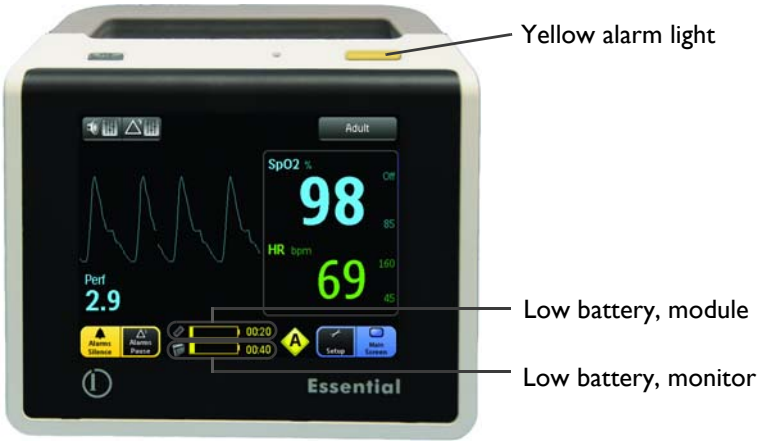
d. If a low battery condition exists, the corresponding battery indicator and time remaining counter will flash in yellow.

e. If a communications failure exists, the corresponding symbol will flash in yellow (the No Comm symbol  for monitor to module communications, or the No Battery Communication symbol  for monitor to main battery communications).

f. The alarm condition stops after the problem is corrected or the system status returns to a normal condition.

g. The message flashes and the audible alarm, once silenced, will not sound again until the alarm condition has been corrected and re-violated. Only a second different parameter alarm will cause the alarm sound and alarm light to reactivate.

Example, visual technical alarm indicators:

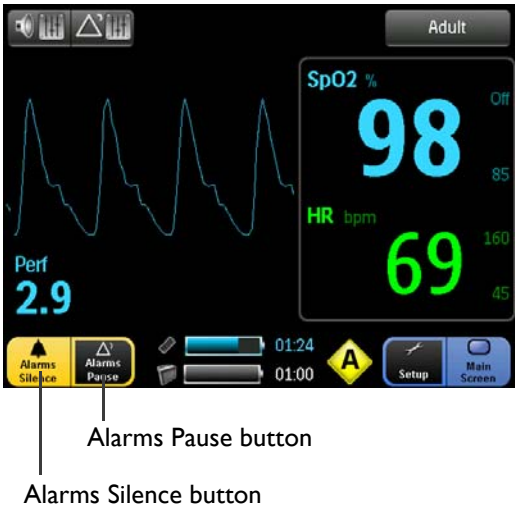


Alarm Controls

Alarms can be controlled using the Alarms Silence button or the Alarms Pause button.

WARNINGS

- **When alarm indicators (light, message, or sound) are generated, always confirm alarm conditions with clinical observation of the patient before administering interventions. Failure to do so may result in inappropriate intervention.**
- **Once the numeric has exceeded the alarm limit, the delay to announcing the alarm condition is less than 1 second, and the total alarm delay is less than 1 second.**



- **Alarms Silence button:** Allows you to mute the alarm tone and turn off the alarm light during an alarm condition (although alarm indications will continue to be displayed). When

selected, the “Alarms Silenced” message, flashing in red, will be displayed in the informational message area. A new alarm condition will cause reactivation of the sound and light functions.

WARNING

An active silenced alarm may not be accompanied by an “ALARMS SILENCED” message if Alarms Pause has been activated, or if a subsequent additional alarm has occurred and was self-corrected.

- **Alarms Pause button:** Allows you to temporarily deactivate the alarm functions (helpful, for example, when prepping a patient for monitoring). When selected, the “Alarms Paused” message and a 2 minute countdown timer, flashing in red, will be displayed in the informational message area.

NOTE

Alarm functions are restored when the countdown timer reaches zero (0) or when the Alarms Pause button is touched during the countdown.

System Messages

The following table lists messages that can be displayed by the system during operation, and provides meanings, probable causes and recommended actions (if needed) for problem resolutions. If the message persists after performing the recommended action(s), contact Invivo Technical Support or Invivo-authorized service personnel for assistance.

Message	Meaning	Probable Cause	Recommended Action
Alarms Paused	Alarms are paused until the countdown timer reaches zero.	The Alarms Pause button was touched.	No action required. Normal alarm monitoring function will resume upon expiration of the countdown (or immediately if Alarms Pause is touched again.)
Alarms Silenced	Alarms have been silenced.	The Alarms Silence button was touched.	Touch the Alarms Pause button twice to return normal alarm monitoring functions.
Bad Probe	The system has detected a hardware failure in the sensor.	The SpO_2 sensor is defective.	Try another SpO_2 sensor.
Erratic	Erratic measurements are being produced by the system.	The SpO_2 sensor is not properly applied to the patient, is not properly positioned, or the probe is faulty.	• Check the alignment of the probe. • Try using a different probe.

Message	Meaning	Probable Cause	Recommended Action
HW FAIL	SpO_2 hardware failure.	A hardware or other fatal error has occurred inside the wireless module or the monitor.	Try another $WSpO_2$ module. If the failure persists, immediately remove the system from service and contact Invivo for repair, as the system must not be used on any patient requiring SpO_2 measurement.
INTRFERNCE	The signal quality of the light channels is inadequate for accurate saturation calculation.	The probe light source may not be aligned with the light receiver, or the probe may be poorly positioned.	• Check the alignment of the probe. • Try a different limb or site. • Try using a different probe.
LOW PERFUSION	The perfusion measured is low enough to cause possible inaccuracies in the reported saturation value.	The tissue at the site may be too opaque and/or thick.	If the sensor is positioned on a finger, check the fingernail for nail polish, or long or artificial fingernails. Remove fingernail polish completely. For artificial nails, try another location (for example, a toe).
NO PROBE	The $WSpO_2$ module detects that no probe is connected.	The SpO_2 probe is not connected (or is not properly connected) to the module.	Check the connection of the probe to the $WSpO_2$ module. If connection appears sound, try another probe.
NON-PULSAT	Non-pulsatile condition.	Check the condition of the patient. The patient's pulse is too weak for the system to report reliable SpO_2 saturation and pulse measurements.	• Check the probe position and alignment on the patient, then re-position or re-apply as necessary. • Try a different limb or site.
NOISE	Patient motion or electrical interference is being experienced by the SpO_2 system.	Excessive patient motion or electrical noise.	• Check for patient motion, especially at the monitored site. • Ensure that the probe is positioned so that the sensors are not exposed to excessive levels of ambient light.
PROBE OFF	The system detects that the probe is not applied to the patient.	The SpO_2 sensor is not properly applied to the patient.	Check probe position and alignment on the patient, then reposition or reapply it as necessary.
PULSE?	The SpO_2-derived pulse rate is outside the detectable range.	The probe may not be applied optimally or the tissue at the applied site may too opaque.	• Check the alignment of the probe. • Try a different limb or site.

Message	Meaning	Probable Cause	Recommended Action
SEARCHING	The system is searching for a good pulse.	The probe was just applied to the patient, or the probe has shifted position since being applied.	If the probe was just applied, give the system time (usually less than 20 seconds) to lock onto a good pulse; otherwise, check the probe position and re-position.
WRONG PROBE	The system has detected that an incorrect probe is connected to the module.	The probe connected to the module is wrong.	Attach the correct SpO_2 sensor to the module.

Chapter 5: Workflow

The Essential MRI Patient Monitor (Model 865353) can be used in conjunction with the Expression MRI Patient Monitor (Model 865214) and the Precess MRI Patient Monitor (Model 3160 - Blue version) to provide seamless patient monitoring from induction to scanning to recovery.

Expression MRI Patient Monitor
(Model 865214)

Precess MRI Patient Monitor
(Model 3160 - Blue version)

When using the Essential with these other Invivo MRI monitors, observe the following warnings and notes.

WARNINGS

- **Alarm limit settings do not transfer between monitoring systems and may be different, so always ensure correct alarm limit settings when using multiple monitoring systems.**
- **All SpO_2 modules must be on different networks; otherwise, interference, or wrong patient or alternating pickup between patients can occur.**

NOTES

- *The Essential MRI Patient Monitor (Model 865353) is not compatible with the original Precess $WSpO_2$ module.*
- *The numerics and waveform are generated by the $WSpO_2$ module, and therefore are identical regardless of the monitoring system used.*

NOTES

- *To establish patient monitoring, the Essential must be communicating on the same network as the module and attached to the patient.*
- *Monitor settings (for example, patient category, alarm limits, etc.) do not transfer between monitoring systems, and alarm behavior remains linked to the alarm limit settings and the detected numerics.*

Workflow Management

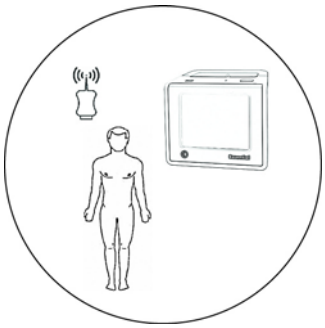
The following diagrams illustrate typical and alternate workflow objectives when using the Essential as a standalone device or when using it together with compatible Invivo MRI monitors.

NOTE

The network settings and groupings used below are given as examples only; your selections may differ. However, the network conventions (A-E or 1-5) as well as the grouping of the settings (network A versus B, 1 versus 2, etc) should be observed.

Workflow when using the Essential as a standalone monitor with one $WSpO_2$ module:

- A patient, an MR induction room, an MR system room and an MR recovery room.
  - The Essential and the WSpO2 module are set to network A or network 1, depending upon the module type (Expression or Precess - Blue version).

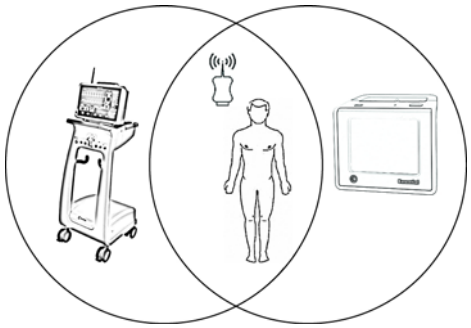


Step	Action
1	Prep the patient in the MR induction room.
2	Turn on the Essential and the $WSpO_2$ module. Both are set to network A (or 1).
3	Verify sufficient power and good communications.
4	Apply the SpO_2 sensor to the patient.

5	Set the patient category and verify pulsatile flow.
6	Transport the patient with the Essential into the MR system room.
7	Scan the patient, monitoring SpO_2 with the Essential through the control room window.
8	Transport the patient with the Essential and the $WSpO_2$ module into the MR recovery room.
9	Transition the patient into the MR recovery room to bedside monitoring, if needed, then take the Essential and the $WSpO_2$ module into the MR induction room for the next patient.

Workflow when using the Essential with an Expression (or a Precess - Blue version) system and one $WSpO_2$ module:

- A patient, an MR induction room, an MR system room with an Expression (or a Precess) and an MR recovery room.
  - The Essential, the Expression and the WSpO2 module are set to network A (or if using a Precess - Blue version, network 1).

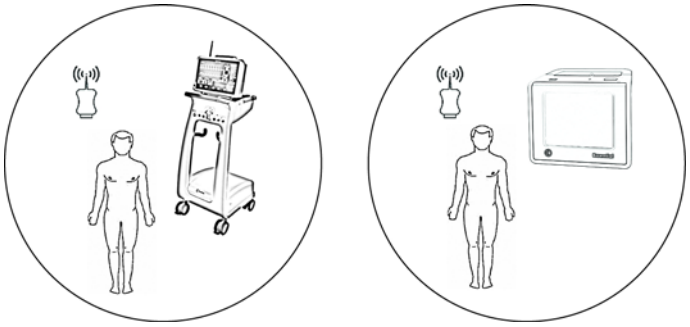


Step	Action
1	Prep the patient in the MR induction room.
2	Turn on the Essential and the $WSpO_2$ module. Both are set to network A (or 1 if using a Precess).
3	Verify sufficient power and good communications.
4	Apply the SpO_2 sensor to the patient.
5	Set the patient category and verify pulsatile flow.
6	Transport the patient with the Essential into the MR system room for scanning, where the Expression is set to network A (or if using a Precess, network 1).

7	In the MR system room, connect the patient to the additional vital signs measurements then adjust the alarm limits, patient category, and other settings as needed on the Expression (or Precess). As soon as the $WSpO_2$ module is within range, the Expression [or Precess] will begin monitoring SpO_2 automatically and you can turn off the Essential.
8	Scan the patient, using the Expression (or Precess) in the control room.
9	Turn on the Essential to monitor SpO_2. (The Essential will now begin to monitor SpO_2 automatically.)
10	In order to transport the patient to the MR recovery room, disconnect the patient from all vital sign measurements except SpO_2 provided by Expression (or Precess).
11	Transport the patient with the Essential and the $WSpO_2$ module into the MR recovery room.
12	If needed, transition the patient in the MR recovery room to bedside monitoring. Take the Essential and the $WSpO_2$ module into the MR induction room for the next patient.

Workflow when using the Essential with an Expression (or a Precess - Blue version) system and two $WSpO_2$ modules:

- Two patients simultaneously, an MR induction room, an MR room with an Expression (or a Precess) and an MR recovery room.
  - The Expression and a $WSpO_2$ module are set to network A (or for Precess, network 1).
  - The Essential and a $WSpO_2$ module are set to network B (or for Precess, network 2).

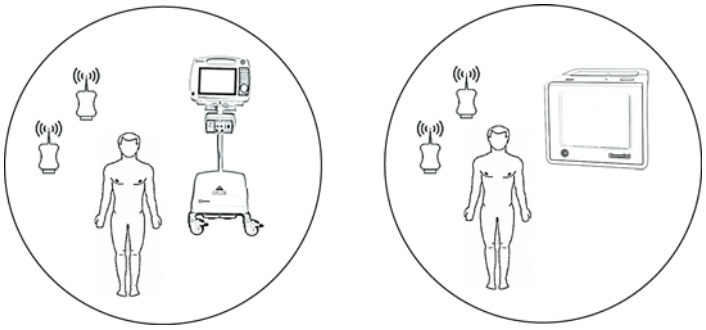


Step	Action
1	One (current) patient is in the MR system room, where an Expression and $WSpO_2$ module are set to network A (or if using a Precess, network 1).
2	Prep the second (new) patient in the MR induction room.

3	Turn on the Essential and the $WSpO_2$ module. Both are set to network B (or if using a Precess, network 2).
4	Verify sufficient power and good communications.
5	Apply the SpO_2 sensor to the new patient.
6	Set the patient category and verify pulsatile flow.
7	When the scan of the current patient has finished, transport the new patient with the Essential and the $WSpO_2$ module into the MR system room.
8	From the current patient in the MR system room, disconnect the sensor from the SpO_2 Quick Connect attachment (grip). ***NOTE*** *Press the Alarms Silence key to temporarily disable the alarm functions.*
9	From the new patient in the MR system room, disconnect the sensor from the SpO_2 Quick Connect attachment (grip). ***NOTE*** *Touch the Alarms Pause button to temporarily disable the alarm functions.*
10	In the MR system room, connect the new patient to the additional vital measurements on the Expression, still on network A (or the Precess, still on network 1).
11	Transport the current patient with the Essential and the $WSpO_2$ module, still on network B (or for the Precess still on network 2) into the MR recovery room.
12	If needed, transition the current patient in the MR recovery room to bedside monitoring. Take the Essential and the $WSpO_2$ module into the MR induction room for the next patient.
13	Scan new the patient, using the Expression DCU (or the Precess CRD) in the control room.

Workflow when using the Essential with a Precess (Blue version) system, two $WSpO_2$ modules and two ECG modules:

- Two patients simultaneously, an MR induction room, an MR room with a Precess and an MR recovery room.
  - The Precess, a $WSpO_2$ module and an ECG module are set to network 1.
  - The Essential, a $WSpO_2$ module and an ECG module are set to network 2.



Step	Action
1	One (current) patient is in the MR system room, where a Precess, a $WSpO_2$ module and a ECG module are set to network 1.
2	Prep the second (new) patient in the MR induction room.
3	Turn on the Essential, the $WSpO_2$ module and the ECG module. All are set to network 2.
4	Verify sufficient power and good communications. (The ECG module cannot not be checked at this point.)
5	Apply the SpO_2 sensor and the ECG leads to the new patient.
6	Set the patient category and verify pulsatile flow.
7	When the scan of the current patient has finished, transport the new patient with the Essential, the $WSpO_2$ module and the ECG module into the MR system room.
8	In the MR system room, on the Precess display panel, press the MONITOR SETUP key. Turn the control knob to NETWORK, press the knob and select Network 2. ***NOTE*** *Press the Alarms Silence key to temporarily disable the alarm functions.*
9	In the MR system room, connect the new patient to the additional vital measurements on the Precess. Verify sufficient power and good communications for the modules.

10	In the control room, on the Precess CRD display panel, press the MONITOR SETUP key. Turn the control knob to NETWORK, press the knob and select Network 2.
11	On the Essential display panel, press the Network button then select Network 1. ***NOTE*** *Touch the Alarms Pause button to temporarily disable the alarm functions.*
12	Verify sufficient power and good communications for the $WSpO_2$ module. (The ECG module will not be used and cannot not be checked at this point.)
13	Transport the current patient with the Essential, the $WSpO_2$ module and the ECG module into the MR recovery room.
14	If needed, transition the current patient in the MR recovery room to bedside monitoring. Take the Essential the $WSpO_2$ module and the ECG module into the MR induction room for the next patient.
15	Scan new the patient, using the Precess CRD in the control room.

Chapter 6: Maintenance and Repair

Methods to keep the Essential MRI Patient Monitor (Model 865353) clean and in proper working condition are discussed here.

Maintenance

Cleaning

Use only the Invivo approved substances and methods listed in this section to clean or disinfect the Essential MRI Patient Monitor (Model 865353). Warranty does not cover damage caused by using unapproved substances or methods.

Invivo makes no claims regarding the efficacy of the listed chemicals or methods as a means for controlling infection. Consult your facility's Infection Control Officer or Epidemiologist. For comprehensive details on cleaning agents and their efficacy refer to "*Guidelines for Prevention of Transmission of Human Immunodeficiency Virus and Hepatitis B Virus to Health Care and Public-Safety Workers*" issued by the U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, February 1989. Also refer to any policies that apply within your facility and country.

Cleaning the System

The Essential MRI Patient Monitor (Model 865353) cannot be sterilized. Always turn off the system to perform cleaning. Do not immerse any part of the system in any fluid or attempt to clean it with liquid cleaning agents. Remove dirt and dust from the monitor and the wireless module by wiping them with a lint-free cloth, moistened with warm water (40°C/104°F maximum). Gently wipe all surfaces to be cleaned briefly (30 seconds to 1 minute) as needed to ensure proper cleaning. Stains can be removed by scrubbing briskly with the moistened cloth.

If disinfection is required, use only the dilute solutions of any of the following recommended liquid surface disinfectants:

- CaviWipes
- Alcohol (70%)
- Antibacterial Soap (0.1% Triclosan)

WARNING

To avoid damage to the connector, do not remove the battery before performing any cleaning or maintenance. And, to avoid an electrical hazard, never immerse any part of the system in any cleaning agent or attempt to clean it with liquid cleaning agents.

CAUTIONS

- Avoid ammonia-based, phenol-based, and acetone-based cleaners. They will damage the system surfaces.
- If the system becomes accidentally wet during use, discontinue operation until all affected components have been cleaned and permitted to dry completely. Contact Invivo Technical Support if additional information is required.

Cleaning the Accessories

Any reusable patient accessories must be cleaned after each use. Disposable patient accessories must be discarded and replaced with new items. The accessories cannot be sterilized.

WARNING

Single-use devices, as indicated on the device packaging, should be disposed of after use and must never be reused.

CAUTION

Never immerse an accessory in any cleaning fluid.

To clean reusable accessories (such as SpO_2 sensors and grips), complete the following steps:

Step	Action
1	Remove the accessory from use.
2	Remove dirt and dust from the accessory using a lint-free cloth, moistened with warm water (40°C/104°F maximum) gently wiping all surfaces to be cleaned briefly (30 seconds to 1 minute) as needed to ensure proper cleansing. Stains can be removed from the accessory by scrubbing briskly with the moistened cloth.
3	Inspect the accessory for any cracks, holes, tears, cuts, etc. that could affect operation and replace as necessary.
4	If disinfection is required, use only the recommended liquid surface disinfectants, unless otherwise specified in the accessory's instructions for use. Recommended surface disinfectants include dilute solutions of any of the following: • CaviWipes • Alcohol (70%) • Antibacterial Soap (0.1% Triclosan)

CAUTION

Disinfect the accessory as determined by your facility's policy.

Repair

All repairs on products under warranty must be performed by Invivo personnel or an authorized Invivo Service and Repair Center. Unauthorized repairs will void the warranty.

WARNING

A shock hazard exists if the system is operated without covers.

If the Essential MRI Patient Monitor (Model 865353) fails to function properly or requires maintenance, contact Technical Support:

In the United States:

1-877-INVIVO1

-or-

1-877-468-4861

Internationally, please contact your Key Market. For a current listing, go to www.invivocorp.com

CAUTIONS

- No repair should ever be undertaken or attempted by anyone not having a thorough knowledge of the repair of Invivo patient monitoring systems. Only replace damaged parts with components manufactured or sold by Invivo (Philips). Contact the Technical Service and Repair Center for technical assistance and service.
- This product, or any of its parts, must not be repaired other than in accordance with written instructions provided by Invivo (Philips), or altered without prior written approval. Changes and modifications to the radio and its components not expressly approved by Invivo (Philips) can void your authority to operate this equipment under Federal Communications Commission's rules.
- The user of this product shall have the sole responsibility for any malfunction which results from improper use, faulty maintenance, improper repair, damage, or alteration by anyone other than Invivo (Philips) or its authorized service personnel.

NOTE

Dispose of the system and parts thereof according to local regulations.

Appendix A: Specifications

General	
Patient Safety	
Conforms to UL STD 60601-1. Certified to CAN/CSA STD C22.2 No. 601.1	
According to degree of protection against harmful ingress of water: IPX 2 (equipment is protected from vertically dripping liquid)	
This equipment complies to the following international industry standards for safety and performance: • IEC 60601-1, *General Requirements for Safety of Medical Electrical Equipment* • IEC 60601-1-2, *General Requirements for Safety - Electromagnetic Compatibility* • IEC 60601-1-4, *General Requirements for Safety of Programmable Electrical Medical Systems* • IEC 60601-1-8, *General Requirements, Tests and Guidance for Alarm Systems in Medical Electrical Equipment and Medical Electrical Systems* • ISO 9919, *Particular Requirements for the Basic Safety and Essential Performance of Pulse Oximeter Equipment for Medical use* Where appropriate, the equipment complies to worldwide standards for safety and performance of each system feature, when considering the indications for use within the MR environment.	
Power Requirements	
Operating Voltage	Battery only
Battery	
Type	Lithium polymer
Operation Time	**Monitor:** Approximate operation time is 8 hours. **Module:** Approximate operation time is 8 hours.
Charge Time	**Monitor:** Time required to recharge a fully discharged battery is approximately 8 hours. **Module:** Time required to recharge a fully discharged battery is approximately 6 hours.
Environment	
Operating Temperature	10°C to 40°C (50°F to 104°F)
Storage Temperature	**Batteries:** 0°C to 40°C (32°F to 104°F) **System:** -25°C to 70°C (-13 to 158°F) When storing beyond the temperature ranges specified, remove the designated component and store it appropriately.
Relative Humidity	15 to 90%, non-condensing
Transport Temperature	-25°C to 70°C (-13 to 158°F)

Dimensions and Weights (Note: all measurements made including handle)	
Height	**Monitor:** 6.1 inches (155 mm) **Wireless SpO_2 Module:** 5.5 inches (13.9 cm)
Width	**Monitor:** 6.9 inches (175 mm) **Wireless SpO_2 Module:** 2.5 inches (6.4 cm)
Depth	**Monitor:** 3.7 inches (94 mm) **Wireless SpO_2 Module:** 0.91 inches (2.3 cm)
Weight	**Monitor:** 3.3 lbs (1.5 Kg) **Wireless SpO_2 Module:** 5.2 oz (147 gm)
Display (LCD)	
Type	640 x 480 pixels, color VGA Liquid Crystal Display with 5-Wire touch screen
Screen Size	5.7 inches (14.5 cm)
Sweep Speed	25 mm/second gives 2.7 seconds of display
Waveform Display Mode	Fixed Trace, Moving Erase Bar

Displayed Parameters	
Alarms	High and low limit selectable
Heart Rate	Derived from SpO_2
Pulse Oximeter	Heart rate, pulse waveform, percent saturation, and perfusion index

Pulse Oximeter	
Pitch of pulse tone is modulated by saturation value.	
Saturation Range	0 to 100%
Saturation Accuracy	±3% at 70 to 100% (The specified accuracy is the root-mean square (RMS) difference between the measured values and the reference values)
Pulse Range	30 to 250 bpm
Pulse Accuracy	±2% or 1 bpm, whichever is greater
Wavelength Range	500 to 1000 nm: Information about the wavelength range can be especially useful to clinicians (for instance, when photodynamic therapy is performed.
Emitted Light Energy	<15mW: Information about the wavelength range can be especially useful to clinicians (for instance, when photodynamic therapy is performed.
Pulse Oximeter Calibration Range	70% - 100%

Alarm Limits	
SpO_2 Alarm Limits	Low: 50 to 99 or Off High: 70 to 99 or Off
Heart Rate Alarm Limits	Low: 30 to 249 or Off High: 60 to 249 or Off

Note:

Measurement validation: *SpO_2 accuracy has been validated in human studies against arterial blood sample reference measured with a CO-oximeter. In a controlled desaturation study, healthy adult volunteers with saturation levels between 70% and 100% SaO_2 were studied. The population characteristics for those studies were:*

- *about 50% female and 50% male subjects*
- *age range: 19-27*
- *skin tone: from light to black*

A functional tester cannot be used to assess the accuracy of a pulse oximeter monitor; however, it can be used to demonstrate that a particular pulse oximeter monitor reproduces a calibration curve that has been independently demonstrated to fulfill a particular accuracy specification.

SpO_2 measurements are statistically distributed; therefore, in accordance to ISO 9919:2005, it is possible that only two-thirds of the measurements will fall within ±3 percent of the value measured by the CO-Oximeter

Power Adapter

Power Requirements	
Input Voltage (to AC inlet)	Universal AC; 100 to 240VAC @ 50 to 60Hz.
Input Power	0.4 amps, without power factor correction.
DC Connector	15 VDC
Environment	
Location	Console room (Outside the MR system room)
Operating Temperature	10°C to 40°C (50°F to 104°F)
Storage Temperature	-25° to 70°C (-13°F to 158°F)
Relative Humidity	15% to 90%, non-condensing

Appendix B: Warranty

Warranty Statement

Invivo warrants this product, other than its expendable parts, to be free from defects in materials and workmanship for a period of twelve (12) months from the date of original delivery to the buyer or to buyer's order, provided that same is properly operated under conditions of normal use, and that periodic maintenance and service is performed. This same warranty is made for a period of thirty (30) days on expendable parts. This warranty shall become null and void if the system has been repaired by someone other than Invivo or if the product has been subject to misuse, accident, negligence or abuse.

Invivo's sole obligation under this warranty is limited to repairing a system which has been reported to Invivo's Technical Service Center during normal business hours and shipped transportation prepaid. Invivo shall not be liable for any damages including but not limited to incidental damages, consequential damages or special damages.

This warranty is in lieu of any other warranties, guarantees or conditions, including merchantability or fitness for a particular purpose. The remedies under this warranty are exclusive and Invivo assumes nor authorizes anyone to assume for it any other obligation in connection with the sale or repair of its products.

Appendix C: Regulatory Information

European Union

Declaration of Conformity

To obtain a copy of the Declaration of Conformity to the European Union Medical Device Directive (93/42/EEC) and Radio & Telecommunications Terminal Equipment Directive (1995/5/EC), contact the Regulatory Affairs Department of Invivo:

407-275-3220

1-800-331-3220 (Toll-free)

Internationally, please contact your Invivo sales representative.

Authorized Representative

The Authorized Representative for the European Union (as required by the Medical Device Directive, 93/42/EEC) is as follows:

Philips Medical Systems Boblingen
GmbH, Hewlett-Packard-Str. 2
71034, Boblingen Germany

Appendix D: Guidelines and References

Guidelines for the Prevention of Excessive Heating And Burns Associated with Magnetic Resonance Procedures

In general, magnetic resonance (MR) imaging is considered to be a relatively safe diagnostic modality. However, the use of radiofrequency coils, physiologic monitors, electronically-activated devices, and external accessories or objects made from conductive materials has caused excessive heating, resulting in burn injuries to patients undergoing MR procedures. Heating of implants and similar devices may also occur in association with MR procedures, but this tends be problematic primarily for objects made from conductive materials that have elongated shapes such as leads, guidewires, and certain types of catheters (e.g., catheters with thermistors or other conducting components).

Notably, more than 30 incidents of excessive heating have been reported in patients undergoing MR procedures in the United States that were unrelated to equipment problems or the presence of conductive external or internal implants or materials [review of data files from U.S. Food and Drug Administration, Center for Devices and Radiological Health, Manufacturer and User Facility Device Experience Database, MAUDE, http://www.fda.gov/cdrh/maude.html and U.S. Food and Drug Administration, Center for Devices and Radiological Health, Medical Device Report, (http://www.fda.gov/CDRH/mdrfile.html)]. These incidents included first, second, and third degree burns that were experienced by patients. In many of these cases, the reports indicated that the limbs or other body parts of the patients were in direct contact with body radiofrequency (RF) coils or other RF transmit coils of the MR systems or there were skin-to-skin contact points suspected to be responsible for these injuries.

MR systems require the use of RF pulses to create the MR signal. This RF energy is transmitted readily through free space from the transmit RF coil to the patient. When conducting materials are placed within the RF field, the result may be a concentration of electrical currents sufficient to cause excessive heating and tissue damage. The nature of high frequency electromagnetic fields is such that the energy can be transmitted across open space and through insulators. Therefore, only devices with carefully designed current paths can be made safe for use during MR procedures. Simply insulating conductive material (e.g., wire or lead) or separating it from the patient may not be sufficient to prevent excessive heating or burns from occurring.

Furthermore, certain geometrical shapes exhibit the phenomenon of “resonance” which increases their propensity to concentrate RF currents. At the operating frequencies of present day MR systems, conducting loops of tens of centimeters in size may create problems and, therefore, must be avoided, unless high impedance is used to limit RF current. Importantly, even loops that include small gaps separated by insulation may still conduct current.

To prevent patients from experiencing excessive heating and possible burns in association with MR procedures, the following guidelines are recommended:

1. Prepare the patient for the MR procedure by ensuring that there are no unnecessary metallic objects contacting the patient's skin (e.g., metallic drug delivery patches, jewelry, necklaces, bracelets, key chains, etc.).

2. Prepare the patient for the MR procedure by using insulation material (i.e., appropriate padding) to prevent skin-to-skin contact points and the formation of “closed-loops” from touching body parts.

3. Insulating material (minimum recommended thickness, 1-cm) should be placed between the patient's skin and transmit RF coil that is used for the MR procedure (alternatively, the RF coil itself should be padded). For example, position the patient so that there is no direct contact between the patient's skin and the body RF coil of the MR system. This may be accomplished by having the patient place his/her arms over his/her head or by using elbow pads or foam padding between the patient's tissue and the body RF coil of the MR system. This is especially important for those MR examinations that use the body coil or other large RF coils for transmission of RF energy.

4. Use only electrically conductive devices, equipment, accessories (e.g., leads, electrodes, etc.), and materials that have been thoroughly tested and determined to be safe and compatible for MR procedures.

5. Carefully follow specific MR safety criteria and recommendations for implants made from electrically-conductive materials (e.g., bone fusion stimulators, neurostimulation systems, etc.).

6. Before using electrical equipment, check the integrity of the insulation and/or housing of all components including surface RF coils, monitoring leads, cables, and wires. Preventive maintenance should be practiced routinely for such equipment.

7. Remove all non-essential electrically conductive materials from the MR system (i.e., unused surface RF coils, leads, cables, wires, etc.).

8. Keep electrically conductive materials that must remain in the MR system from directly contacting the patient by placing thermal and/or electrical insulation between the conductive material and the patient.

9. Keep electrically conductive materials that must remain within the body RF coil or other transmit RF coil of the MR system from forming conductive loops. Note: The patient's tissue is conductive and, therefore, may be involved in the formation of a conductive loop, which can be circular, U-shaped, or S-shaped.

10. Position electrically conductive materials to prevent “cross points”. For example, a cross point is the point where a cable crosses another cable, where a cable loops across itself, or where a cable touches the patient or sides of the transmit RF coil more than once. Notably, even the close proximity of conductive materials with each other should be avoided because some cables and RF coils can capacitively-couple (without any contact or crossover) when placed close together.

11. Position electrically conductive materials to exit down the center of the MR system (i.e., not along the side of the MR system or close to the body RF coil or other transmit RF coil).

12. Do not position electrically conductive materials across an external metallic prosthesis (e.g., external fixation device, cervical fixation device, etc.) or similar device that is in direct contact with the patient.

13. Allow only properly trained individuals to operate devices (e.g., monitoring equipment) in the MR environment.

14. Follow all manufacturer instructions for the proper operation and maintenance of physiologic monitoring or other similar electronic equipment intended for use during MR procedures.

15. Electrical devices that do not appear to be operating properly during the MR procedure should be removed from the patient immediately.

16. Closely monitor the patient during the MR procedure. If the patient reports sensations of heating or other unusual sensation, discontinue the MR procedure immediately and perform a thorough assessment of the situation.

17. RF surface coil decoupling failures can cause localized RF power deposition levels to reach excessive levels. The MR system operator will recognize such a failure as a set of concentric semicircles in the tissue on the associated MR image or as an unusual amount of image non-uniformity related to the position of the RF coil.

The adoption of these guidelines will help to ensure that patient safety is maintained, especially as more conductive materials and electronically-activated devices are used in association with MR procedures.

References

Bashein G, Syrory G. Burns associated with pulse oximetry during magnetic resonance imaging. Anesthesiology 1991;75:382-3.

Brown TR, Goldstein B, Little J. Severe burns resulting from magnetic resonance imaging with cardiopulmonary monitoring. Risks and relevant safety precautions. Am J Phys Med Rehabil 1993;72:166-7.

Chou C-K, McDougall JA, Chan KW. Absence of radiofrequency heating from auditory implants during magnetic resonance imaging. Bioelectromagnetics 1997;44:367-372.

Dempsey MF, Condon B. Thermal injuries associated with MRI. Clin Radiol 2001;56:457-65.

Dempsey MF, Condon B, Hadley DM. Investigation of the factors responsible for burns during MRI. J Magn Reson Imaging 2001;13:627-631.

ECRI, Health Devices Alert. A new MRI complication? Health Devices Alert. May 27, pp. 1, 1988.

ECRI. Thermal injuries and patient monitoring during MRI studies. Health Devices Alert. 1991;20: 362-363.

Finelli DA, Rezai AR, Ruggieri PM, Tkach JA, Nyenhuis JA, Hrdlicka G, Sharan A, Gonzalez-Martinez J, Stypulkowski PH, Shellock FG. MR imaging-related heating of deep brain stimulation electrodes: In vitro study. Am J Neuroradiol 2002;23:1795-1802.

Hall SC, Stevenson GW, Suresh S. Burn associated with temperature monitoring during magnetic resonance imaging. Anesthesiology 1992;76:152.

Heinz W, Frohlich E, Stork T. Burns following magnetic resonance tomography study. (German) Z Gastroenterol 1999;37:31-2.

http://www.MRIsafety.com

International Electrotechnical Commission (IEC), Medical Electrical Equipment, Particular requirements for the safety of magnetic resonance equipment for medical diagnosis, International Standard IEC 60601-2-33, 2002.

Jones S, Jaffe W, Alvi R. Burns associated with electrocardiographic monitoring during magnetic resonance imaging. Burns 1996;22:420-1.

Kanal E, Shellock FG. Burns associated with clinical MR examinations. Radiology 1990;175: 585.

Kanal E, Shellock FG. Policies, guidelines, and recommendations for MR imaging safety and patient management. J Magn Reson Imaging 1992;2:247-248.

Knopp MV, Essig M, Debus J, Zabel HJ, van Kaick G. Unusual burns of the lower extremities caused by a closed conducting loop in a patient at MR imaging. Radiology 1996;200:572-5.

Knopp MV, Metzner R, Brix G, van Kaick G. Safety considerations to avoid current-induced skin burns in MRI procedures. (German) Radiologe 199838:759-63.

Nakamura T, Fukuda K, Hayakawa K, Aoki I, Matsumoto K, Sekine T, Ueda H, Shimizu Y. Mechanism of burn injury during magnetic resonance imaging (MRI)-simple loops can induce heat injury. Front Med Biol Eng 2001;11:117-29

Nyenhuis JA, Kildishev AV, Foster KS, Graber G, Athey W. Heating near implanted medical devices by the MRI RF-magnetic field. IEEE Trans Magn 1999;35:4133-4135.

Rezai AR, Finelli D, Nyenhuis JA, Hrdlick G, Tkach J, Ruggieri P, Stypulkowski PH, Sharan A, Shellock FG. Neurostimulator for deep brain stimulation: Ex vivo evaluation of MRI-related heating at 1.5-Tesla. Journal of Magnetic Resonance Imaging 2002;15:241-250.

Schaefer DJ. Safety Aspects of radio-frequency power deposition in magnetic resonance. MRI Clinics of North America 1998;6:775-789.

Schaefer DJ, Felmlee JP. Radio-frequency safety in MR examinations, Special Cross-Specialty Categorical Course in Diagnostic Radiology: Practical MR Safety Considerations for Physicians, Physicists, and Technologists, Syllabus, 87th Scientific of the Radiological Society of North America, Chicago, pp 111-123, 2001.

Shellock FG. Magnetic Resonance Procedures: Health Effects and Safety. CRC Press, LLC, Boca Raton, FL, 2001.

Shellock FG. MR safety update 2002: Implants and devices. Journal of Magnetic Resonance Imaging 2002;16:485-496.

Shellock FG. Radiofrequency-induced heating during MR procedures: A review. Journal of Magnetic Resonance Imaging 2000;12: 30-36.

Shellock FG. Reference Manual for Magnetic Resonance Safety: 2003 Edition, Amirsys, Inc., 2003.

Shellock FG, Slimp G. Severe burn of the finger caused by using a pulse oximeter during MRI. American Journal of Roentgenology 1989;153:1105.

Shellock FG, Hatfield M, Simon BJ, Block S, Wamboldt J, Starewicz PM, Punchard WFB. Implantable spinal fusion stimulator: assessment of MRI safety. Journal of Magnetic Resonance Imaging 2000;12:214-223.

Smith CD, Nyenhuis JA, Kildishev AV. Health effects of induced electrical fields: implications for metallic implants. In: Shellock FG, ed. Magnetic resonance procedure: health effects and safety. Boca Raton, FL: CRC Press, 2001; 393-414.

U.S. Food and Drug Administration, Center for Devices and Radiological Health (CDRH), Medical Device Report (MDR) (http://www.fda.gov/CDRH/mdrfile.html). The files contain information from CDRH's device experience reports on devices which may have malfunctioned or caused a death or serious injury. The files contain reports received under both the mandatory Medical Device Reporting Program (MDR) from 1984 - 1996, and the voluntary reports up to June 1993. The database currently contains over 600,000 reports.

U.S. Food and Drug Administration, Center for Devices and Radiological Health (CDRH), Manufacturer and User Facility Device Experience Database, MAUDE, (http://www.fda.gov/cdrh/maude.html). MAUDE data represents reports of adverse events involving medical devices. The data consists of all voluntary reports since June, 1993, user facility reports since 1991, distributor reports since 1993, and manufacturer reports since August, 1996.

Notes

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