Expression Model MR400
MRI Patient Monitoring System

Instructions for Use

453665113081 Revision A

English

PHILIPS

INVIVO, a division of Philips Medical Systems
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Orlando FL 32826, USA

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Illustrations are representative depictions.

Some features are optional and may not be present on your device.

For use in the United States only.

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1: Introduction

1.1 Intended Use

The Expression Model MR400 MRI Patient Monitoring System is intended for use by healthcare professionals to monitor vital signs of patients undergoing MRI procedures and to provide signals for the synchronization of the MRI scanner.

1.2 Indications for Use

The Expression MR400 MRI Patient Monitoring System is intended to monitor vital signs for patients undergoing MRI procedures and to provide signals for synchronization for the MRI scanner.

The Expression MR400 MRI Patient Monitoring System is intended for use by healthcare professionals.

The Expression MR400 MRI Patient Monitoring System provides monitoring for the following vital sign parameters: ECG, pulse oximetry (SpO2), non-invasive blood pressure (NIBP), and optionally, invasive blood pressure (IBP), carbon dioxide (CO2) and respiration rate, anesthetic agents, nitrous oxide (N2O), oxygen (O2), and/or temperature.

1.3 Contraindication

This device is contraindicated for patients with metallic wires, implants, stents, et cetera. Screen all patients for metallic wires, implants, stents, et cetera prior to MR procedures. These electrical conductors will react with the MR environment or with the accessory (if applied directly over the conductor), thus increasing the risk of heating.

1.4 Basic Safety and Essential Performance

The Expression MR400 MRI Patient Monitoring System (MR400) complies with basic safety and essential performance as specified in IEC 60601-1.

1.5 Performance Characteristics

The MR400 system is designed to operate in MRI environments ranging from 1.5 to 3.0 Tesla (except the Battery charger for the Wireless Module batteries). The system enables clinicians to monitor patient vital signs during MRI procedures where the

radio frequency power does not exceed 4 W/kg peak (0.4 W/kg average). The system is compatible with MRI system operation.

1.6 Clinical Benefits

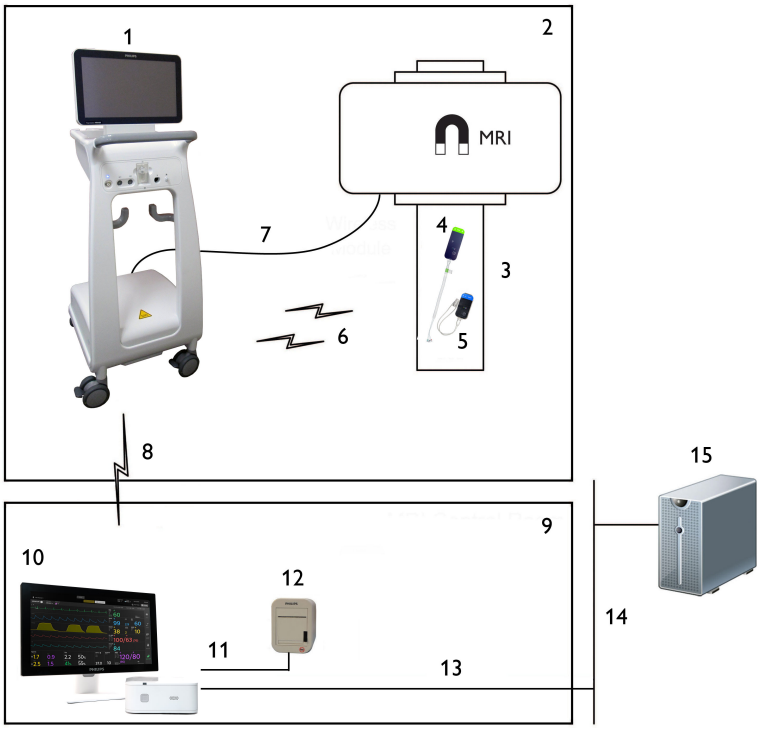
Through its intended use, the MR400:

- Simplifies care and improves the clinical management of patients
- Supports a diagnosis to be made by a trained healthcare professional

1.7 Use Model

The MR400 is for clinicians and MRI technicians to monitor a single patient in the MR area of hospitals before, during, and after MR imaging procedures.

This figure describes the MR400 use model, including optional components.



Part	Description
1	MR400 cart
2	MRI system
3	Patient table
4	ECG module
5	SpO2 module
6	Wireless connection between: • MR400 and SpO2 module • MR400 and ECG module • SpO2 module and MRI scanner for triggering and synchronization • ECG module and MRI scanner for triggering and synchronization

7	Wired connection between the MR400 and MRI scanner for triggering and synchronization
8	Wireless connection between the MR400 and remote monitor
9	MR control, induction, or recovery room
10	Remote monitor
11	USB cable connection: remote monitor to printer
12	Printer
13	Ethernet cable connection: remote monitor to hospital network
14	Hospital network
15	Hospital information system or Philips Patient Information Center iX (PIC iX)

1.8 Authorized Service Provider

An authorized service provider (Service) is a person or organization whom Philips has authorized to service the MR400 cart, accessories, and components. For more information, contact your local Philips representative.

1.9 Training Requirements

Before using the MR400 system, ensure you meet the following criteria:

- You read the contents of this document and understand it.
- You agree to comply with all warning and caution statements in this document.
- You agree to follow all requirements, procedures, and instructions given in this document.
- You complete training on the use of the MR400 system according to local regulations.

For training, go to the Philips Learning Center at www.philips.com/learn. Service personnel require extra training. For more information about training, contact your local Philips representative or Service.

1.10 Privacy

Patient data is present only when the MR400 system includes a remote monitor. When using a remote monitor, the patient name and patient ID appear on the Information bar. The MR400 system stores patient data in non-encrypted RAM. The system deletes data when you discharge a patient or turn off the system. For information about patient data on the remote monitor, including how to remove patient data from view on the MR400 system, see the remote monitor's instructions for use.

Screen captures may contain patient data. Screen captures that contain patient data may be saved to a USB flash drive, presenting a risk of unsecured data transfer. Restrict use of such drives to authorized personnel.

Trend records on the screen and printed do not contain patient data.

Patient reports do contain patient data. When you discharge a patient, you can print a patient report. This report is titled *System Data Report*. See the remote monitor's instructions for use.

1.11 Data Security

The MR400 system is designed to minimize vulnerabilities. The MR400 system includes several security features.

To view the *Manufacturer Disclosure Statement for Medical Device Security* and the *Software Bill of Materials*, go to www.philips.com/security.

Communication security:

- Data is transmitted between the MR400 patient monitor and remote monitor through a 2.4-GHz spread-spectrum radio using a proprietary protocol.
- Data is encrypted (FIPS 140-2, Level 1) when communicating with the MR Patient Care Portal 5000 remote monitor.
- Data is unencrypted when communicating with the IP5 remote monitor, except patient data. The system uses a custom encryption method to encrypt patient data.
- Data transmitted between the ECG and SpO2 modules and the MR400 is not authenticated or encrypted.
- Data interfaces are designed to minimize vulnerability.
- When the MR400 communicates with the IP5, ECG, and SpO2 modules, a skilled attacker within range may be able to eavesdrop on communications, gain unauthorized access, and compromise information.
- Data scrambling, automatic frequency hopping, and encrypting patient identifiers reduce the risk of eavesdropping and other wireless attacks.
- To prevent replay attacks, the MR400 and the MR Patient Care Portal 5000 exchange security tokens.

Communication between devices	Encryption	Authentication
MR400 and IP5	Patient data: proprietary encryption method All other data: no encryption	None
MR400 and Portal 5000	FIPS 140-2, Level 1	Token exchange
MR400 and modules	No encryption	None

Other security features are as follows:

- Operating system services that are not required are disabled.
- Secure shell access is disabled.
- JTAG test access ports are disabled.
- Software updates require permission from the MR400 administrator. To allow updates, select **Setup** > **Monitor** > **Administrative Settings** > **Admin Controls** > **Enable Program Update**.
- U-Boot interruption timer is disabled.

- Files used to upgrade software on the MR400 are encrypted (FIPS 140-2, Level 2).
- The service log records system status, usage, setting changes, and alarm limit changes.
- Removable storage devices are supported only to transfer system update files, save and restore user profiles, save service logs, and save screen captures.
- User profile files are encrypted.

1.12 Safety

This section lists general warnings and cautions required to minimize the risk of injury or device damage. Additional, topic-specific warnings and cautions may appear within a topic.

For safety in the MR environment, follow the instructions for use (IFU) that accompany the MRI system. Follow MR safety labeling for all implants in patients and clinicians.

1.12.1 Warning Statements

A warning alerts you to a potential serious outcome, adverse event, or safety hazard. Failure to observe warnings may result in death or serious injury to the user or patient.

The following warnings are general warnings. More warnings appear throughout this book.

WARNINGS

- The MR400 system is an electrical device. Minimize the risk of injury or damage to the system. When operating the MR400 system, follow all requirements, procedures, and instructions given in this document. Do not use the MR400 if you do not understand the contents of this document.
- Do not use the MR400 for a purpose other than its intended use.
- When operating and storing the MR400 system, adhere to the environmental specifications listed in "A.1 Environmental Specifications" on page 191.
- Do not store ferrous materials on the MR400 cart.
- To minimize the risk of patient injury, operator injury, degraded performance, increased electromagnetic emissions, or decreased electromagnetic immunity, use only compatible accessories. Compatible accessories are in "2.3 Accessory List" on page 14. Do not use incompatible accessories. Verify compatibility before use.
- Do not reuse disposable (single-use) accessories. Reusing a disposable accessory can result in the spread of patient infection, degradation of monitoring performance, or inaccurate measurements.
- Inspect the MR400 cart, accessories, and their packages for damage. Do not use a damaged cart or accessory.
- Use all vital signs together when assessing the patient's health. If you see questionable data, check the patient's vital signs by alternate means.

- High-frequency electrosurgical equipment may interfere with patient data collection. Data may be inaccurate or missing for less than 10 seconds and then return to normal.
- High-frequency electrosurgical overloads may damage the MR400 system.
- During defibrillation, waveforms may be distorted for less than 5 seconds and then return to normal.
- Properly ground defibrillators and high-frequency electrosurgical equipment. Otherwise, they can be a safety hazard, interfering with MR400 data.
- Prevent patient heating and burns:
  - Do not allow accessories to form a loop: a circle, a U-shape, or an S-shape.
  - Do not allow cables and modules to touch the patient's bare skin.
  - Multiple electrical conductors (examples include metal wires, implants, and stents) in the bore may act as an antenna for RF energy and may cause patient burns.
  - When operating the MRI system at SAR levels of 4 W/kg or greater, ensure that the patient is conscious and has normal thermoregulatory capabilities.
  - Screen all patients for cardiac implants before MR procedures. MR unsafe cardiac implants have the potential of being electrical conductors when used in the MR environment with the ECG accessory if the ECG accessory is placed over the implant, and this may increase the risk of heating and patient burns. When used with MR conditional cardiac implants, the labeling of the MR conditional implant and the MR400 must be followed to ensure patient safety.
  - Prevent high levels of radio frequency energy.
  - Monitor the patient for reports of heating during the MRI procedure.
  - High-frequency electrosurgical equipment may cause patient burns.
- Use only 1 remote monitor per MR400 system.
- Routinely inspect accessories to ensure you attach and position accessories correctly.
- Contact support if you experience any problems with the MR400.
- During monitoring, ensure that the patient remains still.
- Do not use the MR400 on a patient being transported outside of the healthcare facility.
- Do not modify the MR400 cart, accessories, and safety features.
- Clean and disinfect the cart and reusable accessories as instructed in this book.
- Perform operational verification of the entire system before use and while monitoring a patient.
- Placing objects within the field of view of the bore may result in a potential serious outcome, adverse event, or safety hazard.

1.12.2 Caution Statements

A caution statement indicates that special care is necessary for the safe and effective use of the product. Failure to observe caution statements may have the following results:

- Minor or moderate injury to the user or patient
- Damage to the product or other property
- Remote risk of more serious injury

CAUTION

- You have the sole responsibility for any malfunction that results from improper use, improper maintenance, improper repair, damage, or alteration by anyone other than Philips or a Philips-authorized service provider.
- If you drop any part of the MR400 system, verify the device operation before use.
- If the cart becomes lodged in the bore due to magnetic pull force, do not use the display panel or guide handles to remove the cart from the magnet.
- Do not apply excessive force to the display panel.
- When using a defibrillator, do not introduce discharges of 360 joules or more, repeated 5 times over 5 minutes.
- Follow all EMC and ESD requirements in "A.16 Electromagnetic Compatibility (EMC)" on page 211.
- Proximity to high-powered radios may degrade wireless performance.
- Store batteries in a dry place, between 0°C to 40°C (32°F to 104°F). Do not expose the battery to temperatures above 60°C (140°F).

1.12.3 Reporting Serious Incidents

Any serious incident that has occurred in relation to this device should be reported to Philips and the competent authority of the Member State in which the user and/or patient is established.

1.12.4 Prescription Use Only

United States federal law restricts this device to sale by or on the order of a physician.

2: System Overview

2.1 About the MR400 System Components

Before use, familiarize yourself with the MR400 and its components. A complete MR400 system consists of the following components:

- MR400 cart
- ECG module
- SpO2 module
- Batteries and other accessories. See "2.3 Accessory List" on page 14.
- Optional: remote monitor and printer

The MR400 system is a MR-conditional device. It shall meet its full function and performance specifications when positioned in the MR environment of a 1.5T or 3T magnet, up to the 5000 gauss line, at RF power levels not exceeding 4W/kg SAR, and 7.2 µT B1rms in all orientations.

The cart can operate on A/C or battery power. The ECG and SpO2 modules run on battery power. See "5: System Power" on page 47.

The modules and cart communicate through a 2.4-GHz radio channel. The cart sends signals to the modules, controlling how the modules collect data. The modules send the patient's physiologic data to the cart. The cart receives the data, processes it, and shows it on the screen. See "4: System Communications" on page 41.

The cart communicates with a remote monitor outside the MR environment. The remote monitor displays information from the cart. The remote monitor may communicate with a hospital information system or Philips Patient Information Center iX (PIC iX). You can use the remote monitor to control and configure some parts of the MR400 system. See the remote monitor's instructions for use and "4.5 Remote Monitor Communication" on page 44.

You can also use modules to perform gating. See "17: Gating Feature" on page 179.

In this chapter:

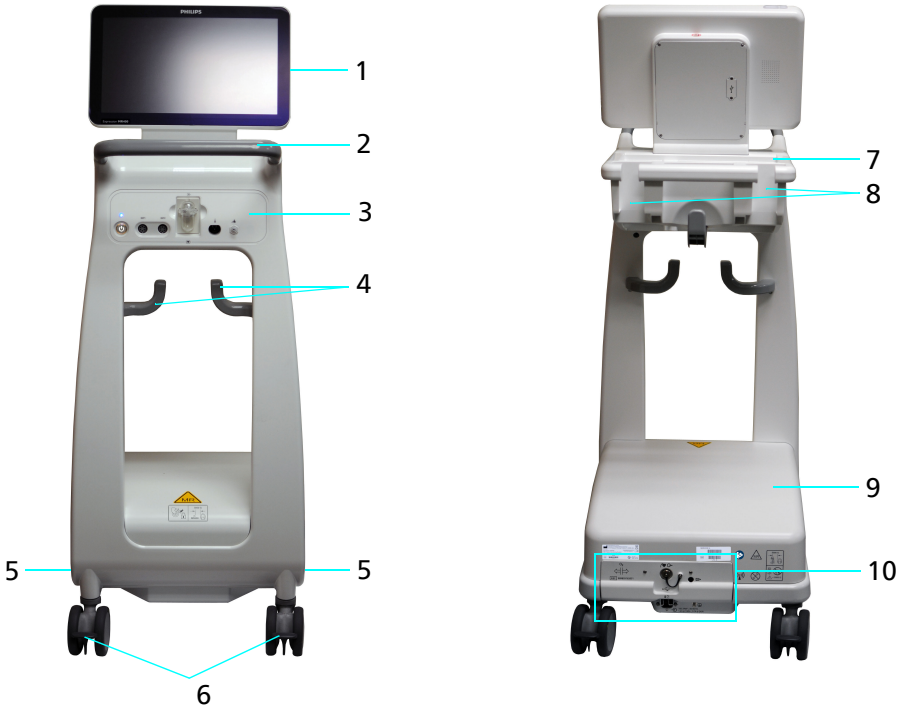
- "2.2 Hardware Overview" on page 10 (and subsections) describes the MR400 system hardware.
- "2.3 Accessory List" on page 14 contains the accessories that are compatible with the MR400 system.
- "2.4 Software Overview" on page 17 (and subsections) describes the MR400 system software.

2.2 Hardware Overview

This section describes the parts of the cart, ECG module, and SpO2 module.

2.2.1 Parts of the Cart

The following image shows the parts of the cart.



Cart front Cart rear

Part	Description
1	Display panel See "2.2.2 Parts of the Display Panel" on page 11.
2	Handle
3	Patient connection panel See "2.2.3 Parts of the Patient Connection Panel" on page 11.
4	Accessory storage hooks
5	Battery compartments See "2.2.4.3 Battery Compartments" on page 13.
6	Locking wheels
7	Accessory storage basket
8	Module holders
9	Cart base
10	Rear panel See "2.2.4.1 Parts of the Rear Panel" on page 12.

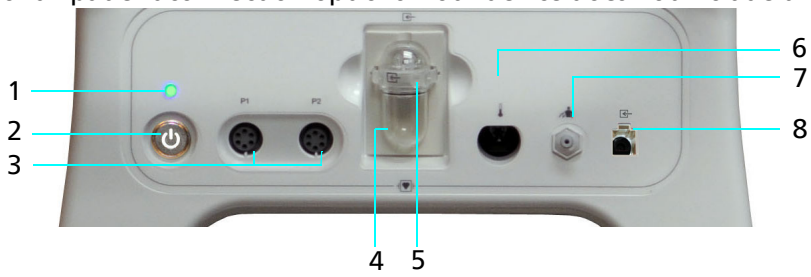
2.2.2 Parts of the Display Panel

The following image shows the parts of the display panel.

Part	Description
1	Touchscreen
2	Alarm lights
3	Speaker
4	Universal Serial Bus (USB), port/plug

2.2.3 Parts of the Patient Connection Panel

The following image shows the parts of the patient connection panel. The image is a composite of all patient connection options. Your device does not include them all.



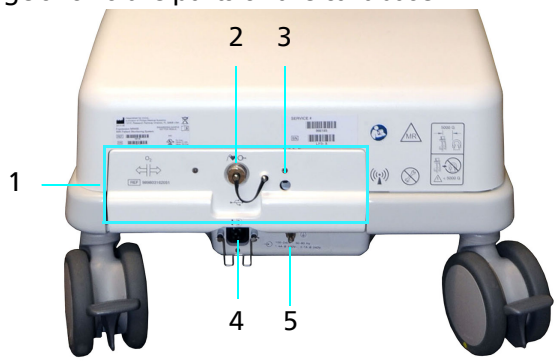
Part	Description	Symbol
1	Power light	None
2	Power button (standby switch)	
3	Invasive pressure ports (optional)	P1, P2
4	Water trap (optional)	
5	Anesthesia and gas sample port (optional)	
6	Temperature port (optional)	
7	Noninvasive pressure port	
8	CO_2 sample port (optional)	

2.2.4 Parts of the Cart Base

The cart base includes the rear panel, service panel, and battery compartments.

2.2.4.1 Parts of the Rear Panel

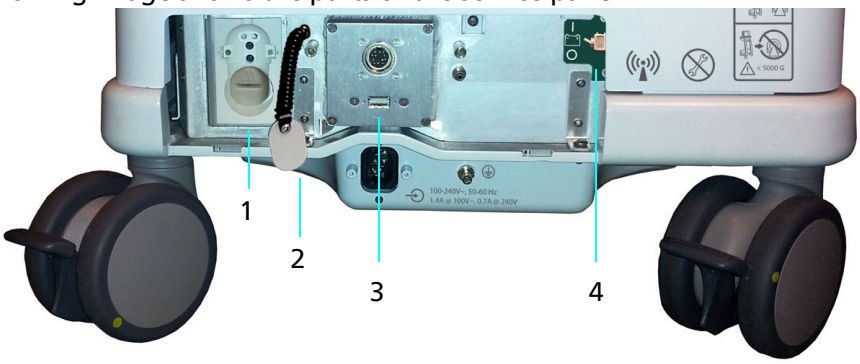
The following image shows the parts of the cart base.



Part	Description
1	Service panel door See "2.2.4.2 Parts of the Service Panel" on page 12.
2	Gating connector
3	Waste gas port
4	Power cord connector and retainer clip
5	Ground lug (Service only)

2.2.4.2 Parts of the Service Panel

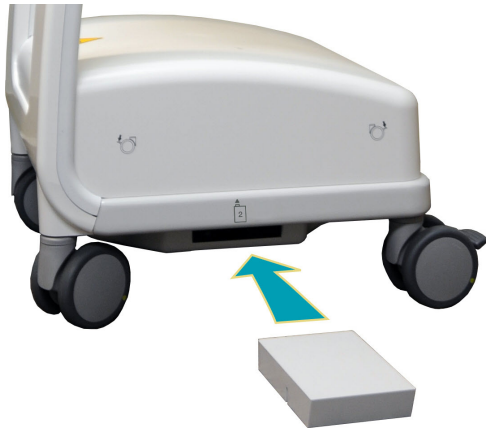
The following image shows the parts of the service panel.



Part	Description
1	Oxygen sensor
2	Oxygen sensor tool
3	Universal Serial Bus (USB), port/plug
4	Reserve battery switch

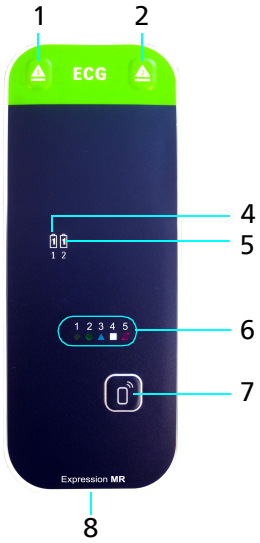
2.2.4.3 Battery Compartments

Each side of the cart base contains one battery compartment. The following image shows one side. The other side is identical.



2.2.5 Parts of the ECG Module

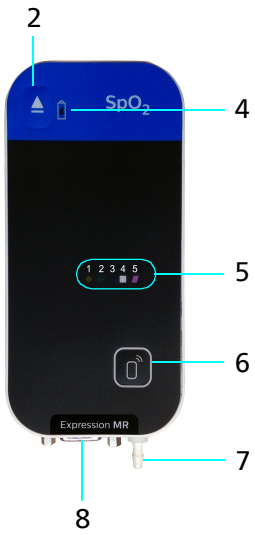
The following images show the parts of the ECG module.



Part	Description
1	Eject button, battery 1
2	Eject button, battery 2
3	Batteries with alignment arrows
4	Charge indicator, battery 1
5	Charge indicator, battery 2
6	Channel indicators
7	Channel selection button
8	ECG lead cable connector

2.2.6 Parts of the SpO2 Module

The following images show the parts of the SpO2 module.



Part	Description
1	Battery alignment arrow
2	Battery eject button
3	Battery compartment
4	Battery charge indicator
5	Channel indicators
6	Channel selection button
7	Pneumatic respiration port (Use only for respiration gating.)
8	SpO2 sensor connector

2.3 Accessory List

To prevent adverse performance or injuries, use the MR400 only with the following compatible accessories. The lists include the accessory's catalog number (REF). Ensure you read any IFU that accompanies an accessory. Ensure that MR400 software is at the latest revision.

The following accessories are compatible with the Expression Model MR400 MRI Patient Monitoring System (REF 866185). Some accessories may not be available in all countries. Some accessories are not compatible with all device options. Contact your local Philips representative or Service.

ECG Monitoring Accessories

Accessory	REF
Gel, ECG/EEG, Skin Prep, Tube, 3-Pack	989803152291
Single Patch ECG Electrodes (25)	989803179031
Multiple Patch ECG Electrodes (25)	989803179041
Neonatal ECG Electrodes (25)	989803179051
Wide ECG 3.0 Cable AAMI	989803193721
Standard ECG 3.0 Cable AAMI	989803193731

Accessory	REF
Neonatal ECG 3.0 Cable AAMI	989803193741
Wide ECG 3.0 Cable IEC	989803193751
Standard ECG 3.0 Cable IEC	989803193761
Neonatal ECG 3.0 Cable IEC	989803193771
Wireless ECG 3.0 Module (1-5)	989803192761
Wireless ECG 3.0 Module (6-10)	989803194341

SpO2 Monitoring Accessories

Accessory	REF
Wireless SpO2 3.0 Module (1-5)	989803192771
Wireless SpO2 3.0 Module (6-10)	989803194331
SpO2 Sensor	989803161991
Reusable clips	
Adult SpO2 Clip	989803166531
Pediatric SpO2 Clip	989803166541

Accessory	REF
Single-use grips	
Adult SpO2 Grips (20)	989803166551
Pediatric SpO2 Grips (20)	989803166561
Infant SpO2 Grips (20)	989803166571
Neonatal SpO2 Grips (20)	989803166581
SpO2 Grip Starter Kit (20 piece)	989803167111

Noninvasive Pressure Accessories

Accessory	REF
Single-use noninvasive blood pressure cuffs	
Infant NBP Cuffs (10)	989803182511
Pediatric NBP Cuffs (10)	989803182521
Small Adult NBP Cuffs (10)	989803182531
Adult NBP Cuffs (10)	989803182541
Adult-Long NBP Cuffs (10)	989803182551
Large Adult NBP Cuffs (10)	989803182561
Large Adult-Long NBP Cuffs (10)	989803182571
Thigh NBP Cuffs (10)	989803182581
Neonatal Size 1 NBP Cuffs (10)	989803183171
Neonatal Size 2 NBP Cuffs (10)	989803183181
Neonatal Size 3 NBP Cuffs (10)	989803183191
Neonatal Size 4 NBP Cuffs (10)	989803183201
Infant Size 5 NBP Cuffs (10)	989803183211

Accessory	REF
Reusable noninvasive blood pressure cuffs	
Infant NBP Cuff	989803182611
Pediatric NBP Cuff	989803182621
Small Adult NBP Cuff	989803182631
Adult NBP Cuff	989803182641
Large Adult NBP Cuff	989803182661
Noninvasive blood pressure hoses	
Adult Pressure Interconnect Hose	989803183221
Neonatal Pressure Interconnect Hose	989803183231

CO_2 Monitoring Accessories (for models that monitor only CO_2)

Accessory	REF
LoFlo Sample Line, Adult Cannula, Box 20	989803183241
LoFlo Sample Line, Ped. Cannula, Box 20	989803183251
LoFlo Sample Line, Neo. Cannula, Box 20	989803183261

Accessory	REF
LoFlo Line, Adu Dvd Cannula, Box 20	989803183271
LoFlo Line, Ped Dvd Cannula, Box 20	989803183281
LoFlo Line, Adu Airway Adpt, Box 20	989803183291

Anesthesia Monitoring Accessories

Accessory	REF
Anesthetic Oxygen (O2) Sensor	989803162051
KIT,DISPOSABLE WATER TRAP,3160	989803152671 or 94012
$etCO_2$ Sampling Cannulas	
CANNULA, DISP, ADULT	989803152561 or 9012
CANNULA, DISP, PED	989803152571 or 9013
CANNULA, DISP, INFANT	989803152581 or 9014
CANNULA, DISP, INT INFANT	989803152591 or 9015

Accessory	REF
KIT,SAMPLE,AGENTS,3160	989803152661 or 94018

Divided Cannulas Simultaneous oxygen delivery and $etCO_2$ sampling	
CANNULA, DISP, ADULT	989803152601 or 9016
CANNULA,DISP,PED,(DIVIDED)	989803152631 or 9016C
CANNULA,DISP,INFANT,(DIVIDED)	989803152611 or 9016A
CANNULA,DISP,INT INF,(DIVIDED)	989803152621 or 9016B

Invasive Pressure Accessories

Accessory	REF
Expression MR IBP Transducer Cable, 5 ft	989803194601
Expression MR IBP DPT Kit, A/P, Box 20	989803194631

Accessory	REF
Expression MR IBP DPT Kit, I/N, Box 20	989803194641

Temperature Monitoring Accessories

Accessory	REF
Temperature Sensor (Esophageal/Rectal/ Axillary, Direct Mode)	989803194511

Accessory	REF
FlexTEMP System, Jacket	989803178181

Batteries and Power Accessories

Accessory	REF
Battery, Module (Gen 3)	989803191341
Battery, MRI, 14.8 V, 5.08 AH, UL	989803169491
Module Charger	989803191031
European Line Cord	453564177501
North American Line Cord	989803168211
Brazilian Power Cord, 3 Meter	989803173901
UK Line Cord, 3 Meter	989803174171

Accessory	REF
Power Cord, AUS/NZL, 3 Meter	989803181291
Power Cord, S Africa, 3 Meter	989803181321
Power Cord, Danish, 3 Meter	989803181331
Power Cord, Israeli, 3 Meter	989803181341
Power Cord, Argentina, 3 Meter	989803181351
Power Cord, Swiss, 3 Meter	989803181361
Cord, Jumper, 25 Feet	989803168221

Remote Monitors

Accessory	REF
MR Patient Care Portal 5000 Requires revision 02.00.00.00 software. If the Portal 5000 revision is lower, then it requires an upgrade.	866162

Accessory	REF
Advanced Communications Option	989803176521
Expression Information Portal (IP5)	865471

Other Documents

Accessory	REF
MR400 Quick Reference Guide	453665129121

Accessory	REF
Expression Model MR400 MRI Patient Monitoring System Service Manual Release 2.0	453665111181

Gating Accessories

Accessory	REF
UNIVERSAL GATING INTERFACE	989803195521

Accessory	REF
Other gating components	See your MRI system instructions for use.

2.4 Software Overview

This section and subsections describe the MR400 software. Additional information about the software appears throughout this instructions for use.

2.4.1 Software Conventions

Touchscreen operation:

- To select an item, touch the item on the touchscreen. Selectable elements may look like buttons or words.
- To open a menu, select the associated parameter label or quick access button.
- To work with individual alarm limits, select the alarm limit.
- Do not touch multiple parts of the main screen simultaneously.
- To close most dialog boxes, select ☒
- To accept and save changes in some dialog boxes, select ✓

System time-out:

The MR400 may automatically close open menus and windows as follows:

- Most menus and dialog boxes: the MR400 automatically closes the control after 30 or 60 seconds of inactivity. The system does not save the changes.
- Some service and system-related messages, menus, and windows: the MR400 does not automatically close these controls due to inactivity.

Dashes:

When a parameter is turned on but no data is present, 3 dashes (**---**) appear on the screen. Possible causes are as follows:

- The MR400 or an accessory is starting up.
- Distorted measurement values or inadequate data.
- Data can no longer be produced, which may generate an alarm.
- Hardware is inoperable, which generates an alarm.

Values that are outside the MR400 measurement range:

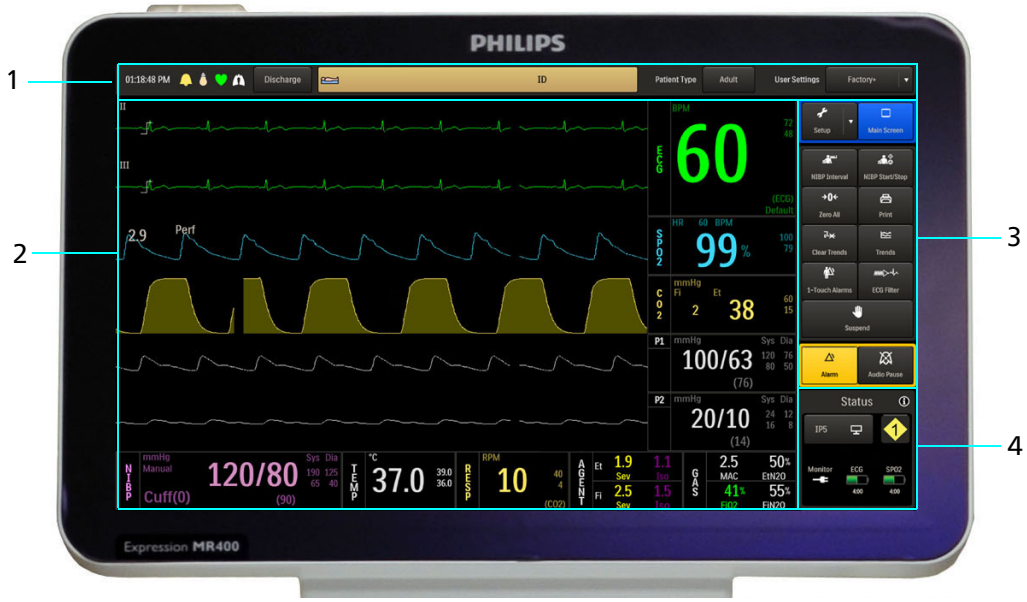
When a patient's physiologic data is outside the measurement range, an alarm occurs and values are replaced with text as follows:

- OVR: the value is higher than the MR400 measures.
- UND: the value is lower than the MR400 measures.

See "7.10 Alarms List" on page 78.

2.4.2 Parts of the Main Screen

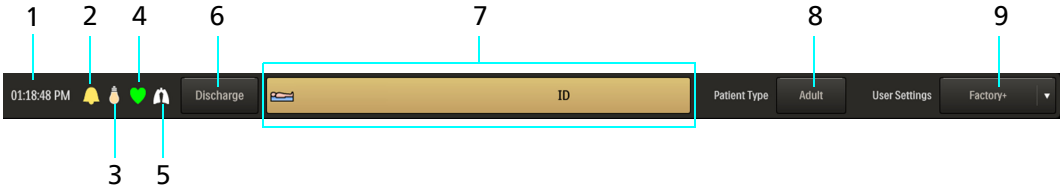
The following image shows the parts of the main screen.



Part	Description
1	Information bar
2	Patient monitoring pane
3	Quick access buttons
4	Status pane

2.4.3 Information Bar

The Information bar provides general use, vital sign detection, and patient information.

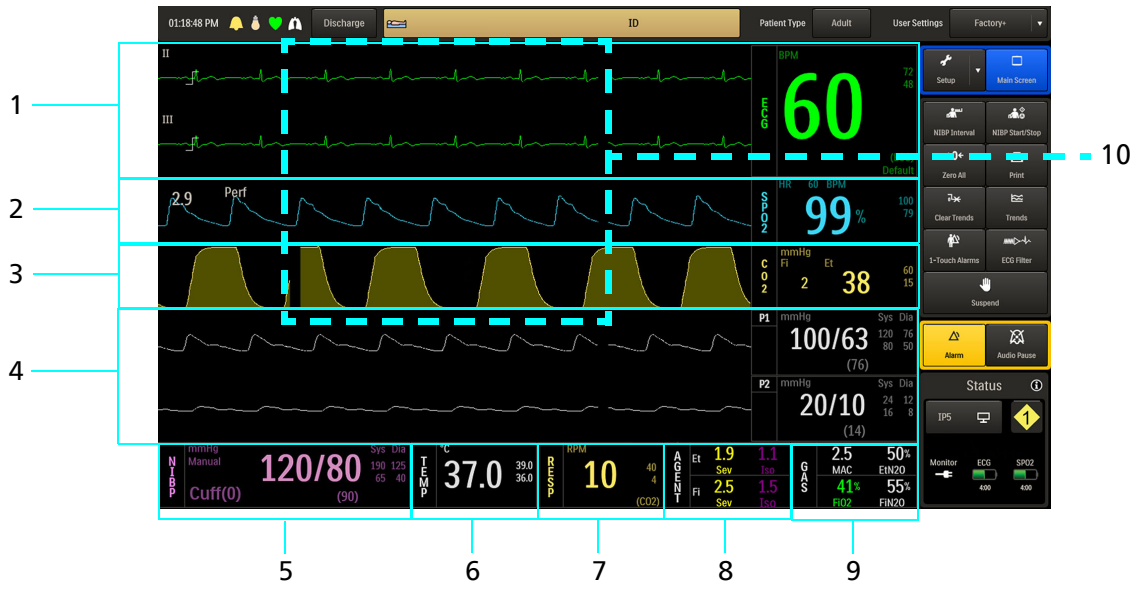


Part	Description	More information
1	Current time Select to show the date.	"2.4.8.4 Set Time & Date Menu" on page 27
2	Alarm sound indicator	"7.3.6 Audio Indicators" on page 63
3	Alarm light indicator	Shows whether alarm lights are **Continuous**, **Temporary**, or **Off**. See "7.3.1 Light Indicators" on page 61.

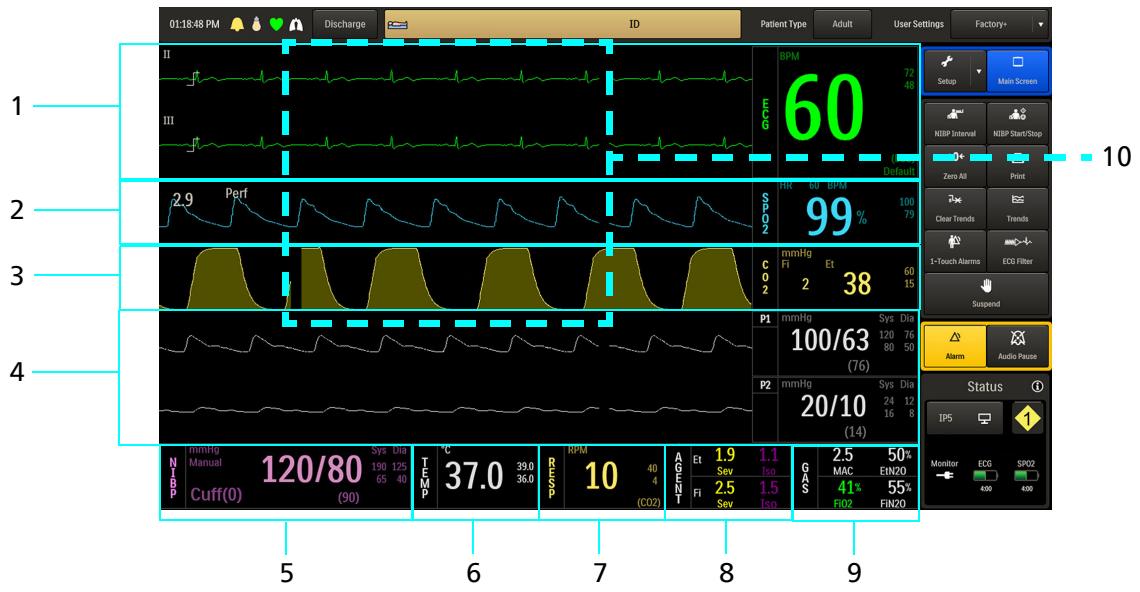
Part	Description	More information
4	Heartbeat indicator	The heartbeat indicator shows the patient's heartbeat and includes a sound. See "2.4.8.3 Sound Adjust Menu" on page 26.
5	Breath indicator	This indicator appears when the system detects a patient breath.
6	**Discharge** button	Select to discharge a patient. This button is disabled when communicating with a remote monitor that is configured to communicate with a Philips Patient Information Center iX (PIC iX). See the remote monitor's instructions for use.
7	Patient data (requires remote monitor)	See the remote monitor's instructions for use.
8	**Patient Type**	"6.2 Selecting the Patient Type" on page 56
9	**User Settings**	Select to change the user settings profile. "2.4.8.1 Edit User Settings Menu" on page 25.

2.4.4 Patient Monitoring Pane

The following image describes the patient monitoring pane.



Part	Description	More information
1	ECG waveforms and numerics (**ECG 1** and **ECG 2**)	"8.4 About the ECG Waveforms and Numerics" on page 88

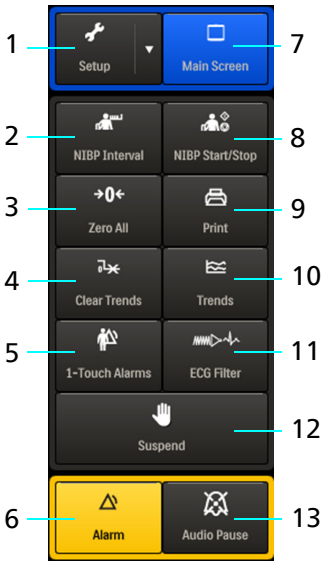


Part	Description	More information
2	SpO2 waveform (pulsatile waveform) and numerics	"9.4 About the SpO2 Waveform and Numerics" on page 106
3	CO2 waveform and numerics	"11.3 About the CO_2 Waveform and Numerics, and RESP Numerics" on page 126
4	Invasive pressure waveforms and numerics (**P1** and **P2**)	"12.2 About the Invasive Pressure Waveforms and Numerics" on page 140
5	NIBP numerics	"10.3 About the NIBP Numerics" on page 116
6	Temperature (**Temp**) numerics	"13.2 About the Temperature Numerics" on page 147
7	Respiration (**RESP**) numerics	"11.3 About the CO_2 Waveform and Numerics, and RESP Numerics" on page 126
8	Anesthetic agent (**Agents**) numerics	"11.4 About the Anesthetic Agent Numerics" on page 128
9	Gas numerics	"11.5 About the Gas Numerics" on page 128
10	System message area	"7.3 Alarm and System Message Priorities and Indicators" on page 59

2.4.5 Quick Access Buttons

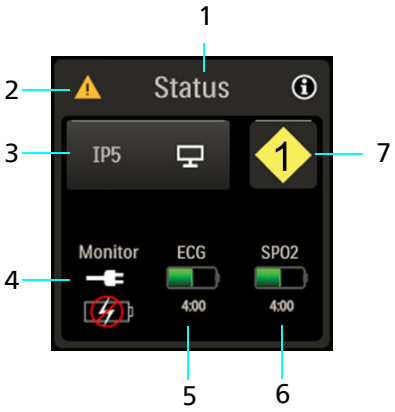
Use the Quick Access buttons to perform actions while monitoring a patient and to set up the MR400.

Part	Description
1	**Setup** Open the Monitor Setup, Printer, and Alarms menus. See "2.4.7 Setup Menu" on page 24.
2	**NIBP Interval** Set the frequency of automatic noninvasive pressure measurement. See "10.10 Setting the Automatic Measurement Interval" on page 122.
3	**Zero All** Calibrate both invasive pressure channels simultaneously. See "12.6 Zeroing Invasive Pressure" on page 142.
4	**Clear Trends** Clear trend data. See "14.1 About Trends" on page 155.
5	**1-Touch Alarms** Set most alarm limits simultaneously, based on current vital sign measurements. See "7.5 Setting Alarms and Alarm Limits" on page 67.
6	**Alarm** Acknowledge an active alarm. Audio and light indicators stop. All other visual indicators continue until the alarm condition resolves. See "7.6 Responding to an Alarm or System Message" on page 72.
7	**Main Screen** Return to the main screen.
8	**NIBP Start/Stop** Start or stop a noninvasive pressure measurement. See "10.11 Starting and Stopping Noninvasive Pressure Measurement" on page 122.
9	**Print** Print waveforms and shows printer status. See "14.2 Printing" on page 157.
10	**Trends** Set up trends and view historical data. See "14.1 About Trends" on page 155.
11	**ECG Filter** Change the ECG filter. See "8.15.3 Filter Mode" on page 103.
12	**Suspend** Suspend the system. Do not suspend the system during monitoring. See "7.3.7 About Quick Access Buttons and Alarm Behavior" on page 64.
13	**Audio Pause** Pause alarm audio for 2 minutes. See "7.6 Responding to an Alarm or System Message" on page 72.

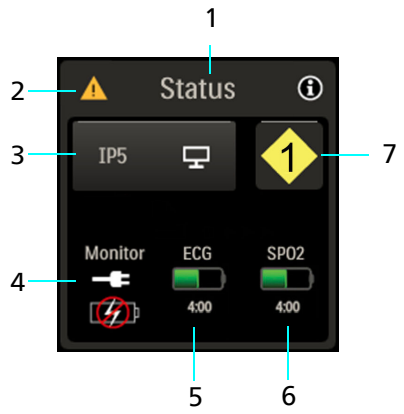


2.4.6 Status Pane

Use the **Status** pane to change the cart channel, control remote monitor communication, and see communication and power status. Status changes appear within 2 seconds.



Part		Description
1	Status	Select to open the **Status Information Panel**, a dialog box that contains additional information about the items shown in the **Status** pane, and the remote monitor's printer.
2	Warning symbol	Appears when an issue requires attention. Open the **Status Information Panel** immediately to view the system message. See "2.4.6.1 Status Information Panel" on page 23.
3	Remote connect button	View the remote monitor's communication status. Select to manage communication with a remote monitor. See "4.5.2 Managing Remote Monitor Communication" on page 46. • Connected: • Disconnected: • Radio off:
4	Monitor power	View cart power type and status, including estimated remaining battery time. • A/C power: • Battery power: • Battery power, low battery: • MR400 main and reserve batteries are not installed: • MR400 cannot charge the batteries due to magnetic field interference:
5	ECG module	Shows communication and power status, including estimated battery time. • Disconnected: • Battery status: • Battery low:
6	SpO2 module	

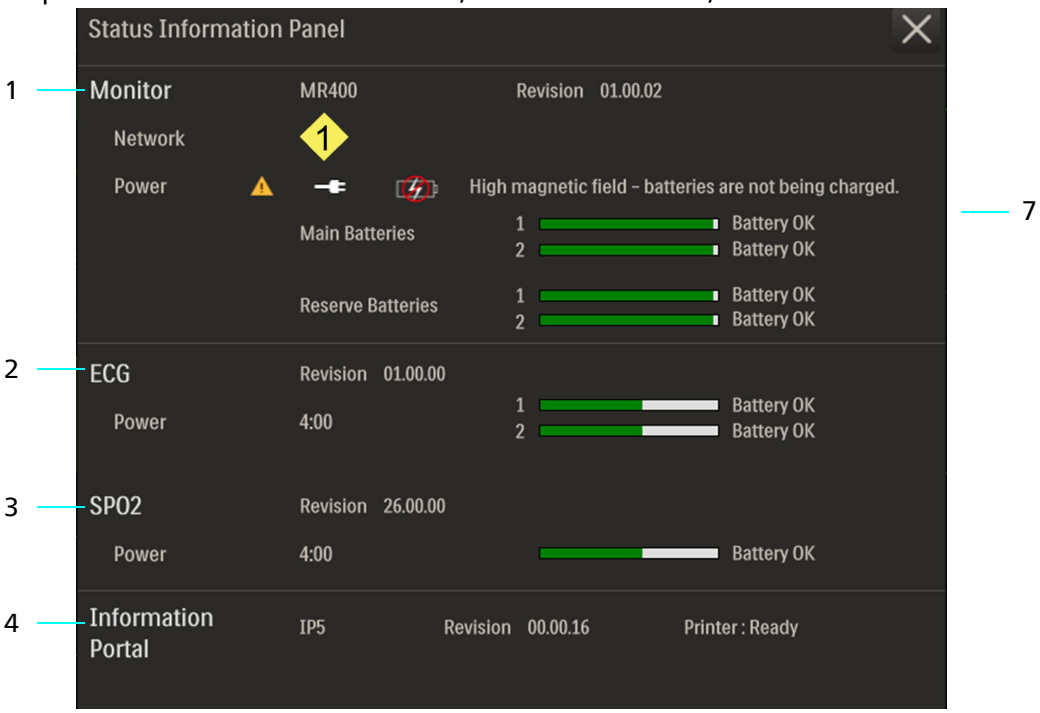


Part		Description
7	Channel icon	View the cart channel. Select to open the channel menu and change the channel.

2.4.6.1 Status Information Panel

Use the **Status Information Panel** to view power and communication details, including system messages.

To open the **Status Information Panel**, on the main screen, select **Status**.



Part	Description
The warning symbol indicates a condition that requires your attention.	
1	View the MR400 cart's software revision, cart channel, and cart battery status.

Part	Description
2	View the ECG module's software revision, battery status, and remaining battery time (estimate).
3	View the SpO2 module's software revision, battery status, and remaining battery time (estimate).
4	View the remote monitor's software revision and printer status.

2.4.7 Setup Menu

To open the setup menu, select **Setup.**

Command	For more information, see
Monitor	"2.4.8 Monitor Setup Menu" on page 24.
Printer	"14.2 Printing" on page 157.
Alarms	"7.4 Alarms Menu" on page 64.

2.4.8 Monitor Setup Menu

To change MR400 settings, select **Setup** > **Monitor**.

Control name	Description	For more information, see
Edit User Settings	Create, delete, backup, and restore user settings files.	"2.4.8.1 Edit User Settings Menu" on page 25.
Parameters	Control monitoring parameters and how they appear.	"2.4.8.2 Parameters Menu" on page 26.
Sound Adjust	Control system sounds.	"2.4.8.3 Sound Adjust Menu" on page 26.
Set Time & Date	Set the time and date and how they appear.	"2.4.8.4 Set Time & Date Menu" on page 27.
Sweep Speed	Adjust all waveform sweep speeds except CO_2.	"2.4.8.5 Sweep Speed Menu" on page 28.
Resp Speed	Adjust the CO_2 waveform sweep speed.	"2.4.8.6 Resp Speed Menu" on page 28.
System Settings	Change the system language and units of measure for invasive and noninvasive blood pressure and CO_2.	"2.4.8.7 System Settings Menu" on page 28.
Service (Bio-Med)	• View software and firmware revisions. • Adjust the screen brightness. • Perform a noninvasive pressure leak test. • Calibrate the CO_2 and O_2 sensors and test the CO_2 system accuracy.	"2.4.8.8 Service (Bio-Med)" on page 29.
Administrative Settings	• Manage passwords. • Configure parameters. • Access service utilities. • View license information.	"2.4.8.9 Administrative Settings Menu" on page 31.

2.4.8.1 Edit User Settings Menu

To manage user settings files (profiles), select **Setup** > **Monitor** > **Edit User Settings**.
For more information, see "2.4.9 About User Settings" on page 32.

Control name	Description
List of user-created profile names	A list of the profiles that you created appears at the top of this menu. Select a profile to modify.  To edit the profile name: Type a new name in the text box. To delete the profile: Select **Delete Settings**. To set the selected profile as the default when the system starts: Select **Set To Default.** To overwrite the profile with the current MR400 settings: Select **Capture Settings.** To save your changes: Select **Save & Close.**
Factory	The settings in this profile are the factory default settings. Select this profile to be the default when the system starts.
Add New	Select to capture the current MR400 settings and save them as a new profile. To save the current group of user settings as a profile: 1. Enter a profile name (20-character maximum). 2. If you want this profile to be the default when the system starts, select **Set To Default.** 3. Select **Save & Close.** 4. The MR400 saves the current settings as a profile.
Backup/Restore Settings	Save a copy of the profiles to a USB flash drive. You can use the profiles on a different MR400 system or as a backup copy. See "16.10 User Settings Backup and Restore" on page 175.

2.4.8.2 Parameters Menu

Use the **Parameters** menu to select which vital signs and data to monitor. Parameter availability depends on your system configuration.

To turn waveforms and numerics off or on, select **Setup** > **Monitor** > **Parameters**, locate the parameter, and then select **Off** or **On.**

Control name	Factory default	Monitored data	Data location
ECG	**On**	ECG and heart rate, depending on the heart rate source You can change the source of the heart rate that appears in the ECG numerics.	**ECG 1** and **ECG 2** waveforms and **ECG** numerics
NIBP	**On**	Noninvasive blood pressure	**NIBP** numerics
P1	**Off**	Invasive pressure from the P1 port on the patient connection panel	**P1** waveform and numerics
P2	**Off**	Invasive pressure from the P2 port on the patient connection panel	**P2** waveform and numerics
SpO2	**On**	Pulse oximetry and heart rate	**SpO2** waveform and numerics
CO2	**Off**	CO_2 and CO_2-derived respiration rate	**CO2** waveform and numerics
RESP	**Off**	Pneumatic respiration rate When **CO2** is selected as the source in the **RESP** menu, this control is disabled.	**RESP** numerics
TEMP	**Off**	Temperature	**TEMP** numerics
AGENT	**Off**	Anesthetic agents and gases When the **AGENT** control is on, the MR400 automatically turns on the **CO2** control.	**AGENT** and **Gas** numerics

2.4.8.3 Sound Adjust Menu

Use the **Sound Adjust** menu to control MR400 system sounds.

To control system sounds, select **Setup** > **Monitor** > **Sound Adjust**.

Control name	Description	Options
Alarms	Turn alarm sounds on or off. This control is identical to the **Alarm Sound** control in the **Alarms** menu (**Setup** > **Alarms**).	• **Off**: No alarms sound. Visual alarm indicators continue to appear. • **On** (factory default)

Control name	Description	Options
HR Tone Source	Turn the heartbeat indicator and heart rate sound on or off and select the source. The heartbeat indicator appears on the Information bar. 💚 This control is identical to the **HR Tone Source** control in both the **ECG** and **SpO2** menus.	• **Off** (factory default): no visual indicator or sound • **QRS**: Heart rate source is QRS detection from the ECG vital sign. • **SpO2**: Heart rate source is the SpO2 vital sign. Higher values produce a higher pitch. Lower values produce a lower pitch.
Alarm Volume*	Set the alarm volume.	**1** (softest) through **10** (loudest). The factory default is **4**.
Pulse Volume*	Set the heartbeat volume.	**1** (softest) through **10** (loudest). The factory default is **4**.
Click Tone	Turn click tones on or off.	• **Off**: Silent click tones • **On** (factory default): The MR400 beeps when you touch the screen.
Click Volume*	Set the click tone volume.	**1** (softest) through **10** (loudest). The factory default is **4**.
***When adjusting volume, **Real Tones Disabled** appears and the system plays the sound at the volume you selected. Ensure that the volume is loud enough. Select ✓ to save your changes.		

2.4.8.4 Set Time & Date Menu

Use the Set Time & Date menu to set the system time and date, and to select the time and date appearance in the system. See *"2.4.3 Information Bar" on page 18*.

To control the system time and date, select **Setup** > **Monitor** > **Set Time & Date**.

To save and accept changes, select ✓

To cancel, select ✗.

Control name	Description	
Remote Time Sync	Synchronize the time and date to a remote monitor.	
Time Format	Select one of the following:	
	• **12 Hr**	12-hour clock Example: 09:00:00 PM
	• **24 Hr**	24-hour clock Example: 21:00:00
Date Format	Select one of the following:	
	• **Month/Day/Year**	Example: 06/23/2031
	• **Day/Month/Year**	Example: 23/06/2031
	• **Month Day, Year**	Example: June 23, 2031

Control name	Description
Second	Use + and - to increase or decrease these system time and date elements.
Minute	
Hour	
Day	
Month	
Year	

2.4.8.5 Sweep Speed Menu

Use the Sweep Speed menu to select the sweep speed for all waveforms except CO_2.

To control the sweep speed of ECG, SpO2, and invasive pressure waveforms, select **Setup** > **Monitor** > **Sweep Speed**.

Select **50 mm/s** or **25 mm/s** (factory default).

2.4.8.6 Resp Speed Menu

Use the Resp Speed menu to select the sweep speed for the CO_2 waveform.

To control the sweep speed of the CO_2 waveform, select **Setup** > **Monitor** > **Resp Speed**.

Select one of the following speeds:

- **25 mm/s**
- **12.5 mm/s** (factory default)
- **6.25 mm/s**
- **3.125 mm/s**

2.4.8.7 System Settings Menu

Use the System Settings menu to select the system language and units of measure for invasive pressure and CO_2.

To adjust these settings, select **Setup** > **Monitor** > **System Settings**.

Control name	Description	Options
Language	Change the system language.	• **English** (factory default) • **Deutsch** • **Español** • **Français** • **Português (BR)** • **Italiano** • **Dansk** • **Svenska** • **Norsk** • **Nederlands**
Pressure Units	Change the unit of measure for invasive and noninvasive blood pressure.	• **mmHg** (factory default) • **kPa**
Gas Units	Change the unit of measure for CO_2.	• **mmHg** (factory default) • **kPa**

2.4.8.8 Service (Bio-Med)

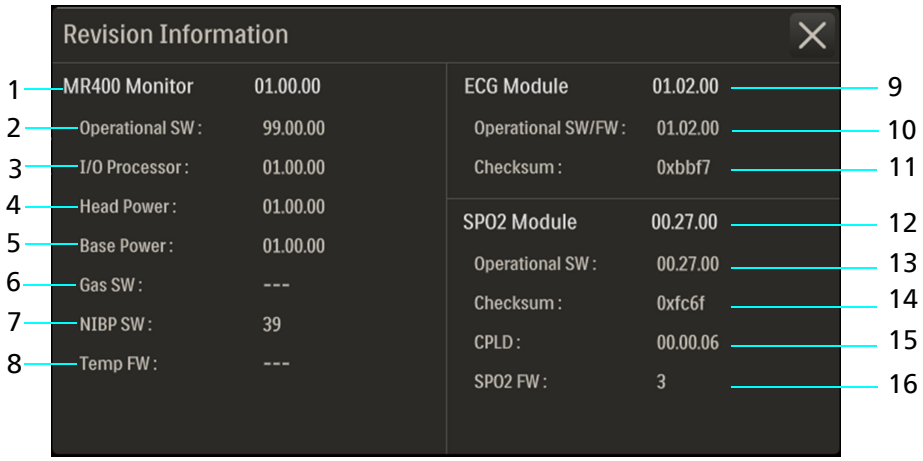
This menu contains several service functions.

To access service functions, select **Setup** > **Monitor** > **Service (Bio-Med)**.

Control name	Description	Options
Revision Information	Select to see MR400 system software and firmware revisions.	For more information, see "2.4.8.8.1 Revision Information" on page 30.
Backlight Brightness	Change the screen brightness.	**1** (dimmest) through **8** (brightest). The factory default is **6**.
NIBP Leak Test	Test the noninvasive pressure system for leaks.	To conduct the test, follow the system prompts.
Gas Cal	Calibrate the CO_2 and O_2 sensors and test CO_2 accuracy.	• **Zero Cal** • **O2 Cal** • **CO2 Accuracy Check** For more information, see "2.4.8.8.2 Gas Cal" on page 30.

2.4.8.8.1 Revision Information

To view system component revisions, select **Setup** > **Monitor** > **Service (Bio-Med)** > **Revision Information**.



Part	Name	Description
1	**MR400 Monitor**	MR400 monitor revision, this is the high-level system revision number
2	**Operational SW**	MR400 software revision
3	**I/O Processor**	Input/output processor software revision
4	**Head Power**	Power manager microcontroller, top-board software revision
5	**Base Power**	Power manager microcontroller, bottom-board software revision
6	**Gas SW**	Gas system software revision
7	**NIBP SW**	Noninvasive pressure software revision
8	**Temp FW**	Temperature system firmware revision
9	**ECG Module**	ECG module revision
10	**Operational SW/ FW**	ECG module software and firmware revision
11	**Checksum**	ECG module binary image checksum
12	**SPO2 Module**	SpO2 module revision
13	**Operational SW**	SpO2 module software revision
14	**Checksum**	SpO2 module binary image checksum
15	**CPLD**	SpO2 module component revision
16	**SPO2 FW**	SpO2 module firmware revision

2.4.8.8.2 Gas Cal

To access gas sensor calibration and test functions, select:
Setup > **Monitor** > **Service (Bio-Med)** > **Gas Cal**.

Control name	Description	Options
Zero Cal	Calibrate the CO_2 sensor.	For more information, see "11.11 Zeroing CO_2" on page 133.

Control name	Description	Options
O2 Cal	Calibrate the O_2 sensor.	Select to begin calibration. Follow the instructions on the screen.
CO2 Accuracy Check	Test the CO_2 system accuracy.	For more information, see the MR400 service manual (453665111181).

2.4.8.9 Administrative Settings Menu

The Administrative Settings menu contains password controls, system configuration, service utilities, and license information. Typically, only service personnel access these features. This menu requires a password to access. Do not adjust these settings while you monitor a patient.

To access **Administrative Settings**, select **Setup** > **Monitor** > **Administrative Settings**. Enter your password at the prompt.

Control name	Options	Description
Admin Controls	**Change Password**	Select to change the MR400 password. Follow the instructions on the screen then select **Apply**. When you access **Administrative Settings** 60 days after the last password change, the MR400 prompts you to change the password. The factory-default password is: *administrator* To reset the password, see "16.6 Performing a Cold Start Reset (Default Initialization)" on page 171.
	Enable Program Update	Turn on to allow a technician to upgrade MR400 software. The factory default is **Off**.
System Config	**ECG 1**	For Philips use only. Do not change these settings.
	ECG 2	
	NIBP	
	P1	
	P2	
	SpO2	
	Gas Bench	
	RESP	
	Temperature	
	ECG Notch Filter	

Control name	Options	Description
Service Utilities	**Simulation Mode**	**WARNING** Do not use simulation mode when monitoring a patient. When you turn **Simulation** on, the MR400 discharges any active case, displays fictional patient data, and shows the **Simulation** message in the system message area. Controls: • **Off** (factory default): Stop simulation mode. • **On**: Start simulation mode. Do not use when monitoring a patient.
	Diagnostics **Allow Screen Capture**	For more information, see the MR400 service manual (453665111181).
	Backup Screen Captures	Moves screen capture files from the MR400 to a USB flash drive. This action deletes the files from the MR400. To backup screen captures, select **Backup Screen Captures**, insert a USB flash drive, then select **Move**.
	ECG Tests **NIBP Tests**	For more information, see the MR400 service manual (453665111181).
	Gas Cal	Identical to the menu found in **Service (Bio-Med)**. See "2.4.8.8.2 Gas Cal" on page 30.
	Service Information **Write Service Log**	For more information, see the MR400 service manual (453665111181).
	Remote Support **Test Facility**	Reserved for engineering use only. Do not change these settings.
License Information	• **GPL2** • **PSFL2** • **LGPL2-IQtSE** • **Apache2** • **PubDomain**	Select to view open-source software licenses.

2.4.9 About User Settings

WARNING

Ensure that the IP5 user settings match the MR400 user settings, including the default profile. See "4.5 Remote Monitor Communication" on page 44.

CAUTION

Ensure that the MR400 settings are appropriate for the patient. Settings may have been changed since they were last stored, synchronized, or recalled. See "2.4.9.1 Settings that Are Saved" on page 33.

You can customize a group of MR400 settings and then save them to a profile with a unique name. When you want to change settings quickly, you can select a profile to change all user settings at once.

You can save the profiles to a USB flash drive to load onto a different MR400 or to keep as a backup. See "16.10 User Settings Backup and Restore" on page 175.

The following rules apply:

- You can save a maximum of 10 profiles.
- The Expression Information Portal (IP5) remote monitor has separate user settings files. To see how the IP5 and MR400 resolve differences between the profiles, see "4.5 Remote Monitor Communication" on page 44.
- The MR Patient Care Portal 5000 remote monitor does not have separate user settings files.
- You cannot create or edit a profile in which all alarm limits are off.
- You can select one profile to be the default. Default profile settings are applied when the system starts.

To learn about creating, editing, and deleting user profiles, see "2.4.8.1 Edit User Settings Menu" on page 25.

2.4.9.1 Settings that Are Saved

When you create or edit a profile, the following settings are saved:

- Patient Type
- Parameters that are turned on or off (Setup > Monitor > Parameters)
- The following sound settings: (Setup > Monitor > Sound Adjust)
  - HR Tone Source
  - Alarm Volume
  - Pulse Volume
  - Click Tone
  - Click Volume
- Setup > Monitor > Sweep Speed
- Setup > Monitor > Resp Speed
- Setup > Monitor > System Settings > Gas Units
- Setup > Monitor > Service (Bio-Med) > Backlight Brightness
- All alarm settings except turning Alarm Sound on or off.
- All printer settings
- The following trends settings:
  - Trend Arrows
  - Arrow Period
- All settings in the following menus:
  - ECG
  - SpO2
  - CO2
  - P1
  - P2
  - NIBP
  - Temp
  - RESP

2.4.9.2 Settings that are Not Saved

The following settings are not saved to a profile:

- Remote monitor communication settings
- Alarm sound on or off
- All time and date settings
- System language and pressure units
- The data interval for trends
- 1-Touch Alarms percentages

2.4.9.3 Selecting a User Settings Profile

To select a user settings profile:

On the Information bar, select **User Settings** and then select the profile you want to use. An asterisk (*) indicates the default profile.

2.4.9.4 Change Indicator on the User Settings Button

On the Information bar, on the **User Settings** button, a plus sign (+) appears to indicate when settings change.

Settings can be changed by a device user or when the MR400 and a remote monitor synchronize settings.

To remove the indicator, save the changes to the profile. Always confirm that all settings are appropriate for the patient’s safety. To learn about creating, editing, and deleting user profiles, see "2.4.8.1 Edit User Settings Menu" on page 25.

3: Initial Setup

3.1 Initial Setup Process Overview

If you find any problem at any time during initial setup, contact Service. To set up the MR400 system for the first time, follow these steps:

Step	Action	Reference
1	Unpack the device and accessories	"3.2 Unpacking the MR400 System" on page 35
2	Set up the hardware	"3.3 Hardware Setup" on page 36
3	Set up the software	"3.4 Software Setup" on page 37

3.2 Unpacking the MR400 System

When unpacking the device and accessories, save accessory packing materials and accompanying documents, including shipping documents. Dispose of the remaining materials according to local regulations.

Ensure you are outside the MR environment. Follow the instructions printed on the containers. Remove all packing materials from the devices.

Be gentle when unpacking so you do not damage delicate materials. Be especially careful when handling cables, which may contain glass fibers.

3.2.1 Package Contents

Package contents vary according to the items that you purchased. The package includes a packing list.

Primary package:

- Expression Model MR400 MRI Patient Monitoring System
- 2 main batteries
- Expression Model MR400 MRI Patient Monitoring System Instructions for Use
- Quick Reference Guide (included in English-localized shipments only)
- Power (Line) Cord

Accessory package:

- Wireless ECG 3.0 Module
- Wireless SpO2 3.0 Module
- Module battery charger
- Module batteries
- Additional accessories according to the packing list

3.2.2 Examining the Package Contents

After removing the contents from the shipping containers, check the packing list and purchase request to ensure that all items are present. Then carefully examine all items for signs of damage, including loose or missing hardware.

To report shipping damage or any concerns with your order, contact your local Philips representative or Service.

3.3 Hardware Setup

To set up the hardware, you need the following items:

- A #1 standard screwdriver
- A #2 Phillips screwdriver
- MR400 cart
- ECG and SpO2 modules
- All accessories
- Remote monitor

3.3.1 Cart Setup

To set up the MR400 cart, follow these steps.

Step	Action	Reference
1	Verify that you are outside the MR environment.	
2	Read the electromagnetic guidance and ensure that the setup location meets requirements.	"A.16 Electromagnetic Compatibility (EMC)" on page 211
3	Familiarize yourself with the parts of the cart.	"2.2 Hardware Overview" on page 10
4	Insert the main batteries.	"5.2.2.2 Inserting and Removing Main Batteries" on page 49
5	Turn on the reserve batteries.	"5.2.2.1 Turning Reserve Batteries On and Off" on page 49
6	Connect the power cable.	"5.2.2.3 Connecting and Disconnecting A/C Power" on page 50
7	Turn on the monitor. Ensure that the power indicator is blue or green. If it is red, contact Service.	"5.2.3 Turning the Cart On and Off (System Startup)" on page 51 "5.5.1 Power Light Indicators" on page 52
8	Confirm that AC power is connected.	"2.4.6 Status Pane" on page 22
9	In the **Status** pane, select **Status**. In the **Status Information Panel**, verify that the **Main Batteries** and the **Reserve Batteries** are **Charging**. If the batteries are not charging, contact Service.	"2.4.6.1 Status Information Panel" on page 23
10	Turn off the monitor. Allow the batteries to charge at least 12 hours.	

Step	Action	Reference
11	Remove all protective tape from the monitor.	
12	Connect the ground lug (equipotential bonding connection) to a ground conductor or to a potential equalization conductor.	

3.3.2 Accessories Setup

To set up the MR400 accessories, follow these steps.

Step	Action	Reference
1	Verify that you are outside the MR environment.	
2	Plug in the module battery charger and charge the module batteries at least 4 hours.	Module battery charger's instructions for use
3	Attach an ECG cable to the ECG module.	"8.8 Attaching the ECG Cable to the Module and Electrodes" on page 93
4	Store the ECG module in a module holder.	"3.6 Storing Modules and Accessories" on page 39
5	Attach the SpO2 sensor to the SpO2 module.	"3.5 Attaching the SpO2 Sensor to the SpO2 Module" on page 38
6	Store the SpO2 module in a module holder.	"3.6 Storing Modules and Accessories" on page 39
7	Connect a noninvasive pressure hose to the cart. Attach a cuff to the hose. Hang the cuff and hose on an accessory storage hook.	"10.8 Connecting the Cuff and Hose to the MR400" on page 120
8	Loosely loop the temperature sensor and then hang it on an accessory storage hook.	"3.6 Storing Modules and Accessories" on page 39
9	Store small accessories such as electrodes, clips, and grips in the accessory storage basket.	"3.6 Storing Modules and Accessories" on page 39
10	After the module batteries are charged, insert the batteries into the modules and verify battery status.	"5.3 About Module Power" on page 51
11	Set up the remote monitor.	See the remote monitor's instructions for use.

3.4 Software Setup

Software setup requires all batteries to be fully charged as instructed in the previous section.

To set up the MR400 software, follow these steps.

Step	Action	Reference
1	If you are in the MR environment, position the cart and lock the wheels.	"6.3 Moving and Positioning the Cart" on page 57
2	Turn on the monitor.	"5.2.3 Turning the Cart On and Off (System Startup)" on page 51

Step	Action	Reference
3	Familiarize yourself with the parts of the screen.	"2.4 Software Overview" on page 17
4	Select the vital sign data that you want to appear on the main screen.	To turn vital signs off or on, select **Setup** > **Monitor** > **Parameters**, locate the parameter, and then select **Off** or **On**.
5	Set the system time and date.	"2.4.8.4 Set Time & Date Menu" on page 27
6	Select the system language, pressure unit of measure, and gas unit of measure.	"2.4.8.7 System Settings Menu" on page 28
7	Configure system sounds.	"2.4.8.3 Sound Adjust Menu" on page 26
8	Configure the alarm light.	"7.5 Setting Alarms and Alarm Limits" on page 67
9	Select the cart channel for communication. If you set up multiple MR400 systems, set each cart to a different channel.	"4.4.1 Setting the Cart's Channel" on page 42
10	Set the modules to the same channel as the cart and verify communication.	"4.4.2 Setting the Modules' Channels" on page 43
11	Set the remote monitor to the same channel as the cart and verify communication.	See the remote monitor's instructions for use. See "4.5 Remote Monitor Communication" on page 44.
12	Create at least one basic user settings profile that represents a typical patient or scan type. Set it to be the default. Create other profiles as necessary.	"2.4.8.1 Edit User Settings Menu" on page 25. "7.5 Setting Alarms and Alarm Limits" on page 67.
13	If you set up multiple MR400 systems, save the user profiles so you can apply the settings to the other systems.	"16.10 User Settings Backup and Restore" on page 175
14	Read the section on security. Understand your responsibility to keep the system secure.	"3.8 Security" on page 39
15	Change the administrator password.	"3.8.1 Administrator Password" on page 39

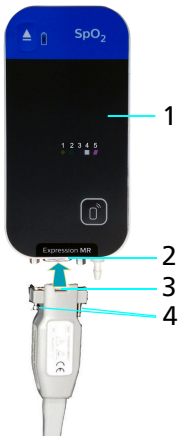
3.5 Attaching the SpO2 Sensor to the SpO2 Module

Requirements:

- A #1 standard screwdriver
- SpO2 sensor
- SpO2 module

To attach the SpO2 sensor, follow these steps.

Insert the SpO2 sensor connector into the DB-9 connector on the SpO2 module. Tighten both screws. Do not overtighten the screws.



Definition	
1	SpO2 module
2	DB-9 connector
3	SpO2 sensor connector
4	Screws

3.6 Storing Modules and Accessories

Accessories	Storage Instructions
ECG Module	Slide the ECG module into a module holder. Clip the cable to itself so it does not touch the floor. You cannot turn off a module. When a module contains a battery, the module is on and draining power. Remove the batteries and store them in the charger.
SpO2 Module	Slide the SpO2 module into a module holder and allow the SpO2 sensor to hang down. Remove the battery and store it in the charger.
Temperature Sensor	Loosely loop the temperature sensor and then hang it on an accessory storage hook.
Cuffs, electrodes, and other small accessories	Store cuffs, electrodes, and other small accessories in the accessory storage basket.
Sample lines and hoses	Hang sample lines and hoses on the accessory storage hooks.

3.7 Setting Up Multiple MR400 Systems

When you set up more than one MR400 system, the following rules apply:

- Each system must communicate on a separate channel. Ensure that each part of a system communicates on the same channel.
- Confirm that data is consistent across all parts of the system (cart, modules, remote monitor).

3.8 Security

To ensure MR400 system security, the following rules apply:

- Restrict MR400 system access to authorized users.
- Position the monitor so patient information is visible only to authorized users.
- Store the MR400 system in a secure location when not in use.
- If unexpected behavior occurs on any part of the MR400 system, contact your local Philips representative or Service. It may be necessary to reinstall the software on the device.
- Change the administrator password as instructed in the next section.

3.8.1 Administrator Password

Access to the **Administrative Settings** menu requires an administrator password. Keep this password secure and restricted.

The password is encrypted and saved on the MR400 system, even when the power is off.

The administrator password is 8 to 14 characters in length and must contain at least 3 of the following character types:

- Uppercase
- Lowercase
- Number
- Special characters such as: % & #

Passwords expire after 60 days. When you access the **Administrative Settings** menu with an expired password, the MR400 automatically prompts you to change the password.

To change the password, follow these steps.

Step	Action
1	Select **Setup** > **Monitor** > **Administrative Settings**.
2	If this is the initial setup or if you reset the MR400, enter the default password: *administrator* Otherwise, enter the current password.
3	Select **Setup** > **Monitor** > **Administrative Settings** > **Admin Controls** > **Change Password**.
4	Follow the instructions on the screen then select **Apply**.

To reset the password to the default password, see "16.6 Performing a Cold Start Reset (Default Initialization)" on page 171.

4: System Communications

4.1 About MR400 System Communications

The MR400 system uses radio channels to transmit data between the parts of the system.

Each MR400 system communicates on one of 10 radio channels. You may have up to 10 different systems. Each system must communicate on a different channel.

Each part of a system (the cart, the ECG module, the SpO2 module, and the remote monitor) must communicate on the same channel.

For information about communication with a hospital information system or Philips Patient Information Center iX (PIC iX), see the remote monitor's instructions for use.

4.2 Communications Safety

WARNINGS

- When multiple MR400 systems are present, ensure that each part of a system communicates on the same channel. Ensure that each system communicates on a different channel.
- Do not accidentally change the channel on the cart, modules, or remote monitor.

CAUTION

High-powered radios near the MR400 may interfere with MR400 system communications. Move the equipment or change the system channel.

Note—If the MR400 system interferes with other equipment's wireless communication, change the system's channel to a channel that does not interfere.

4.3 Communications Setup Process Overview

To set up system communications, follow these steps:

Step	Action	Reference
1	Turn on the MR400 cart.	"5.2.3 Turning the Cart On and Off (System Startup)" on page 51

Step	Action	Reference
2	Select a channel on the cart.	"4.4.1 Setting the Cart's Channel" on page 42
3	Set the ECG module's channel to the same number as the cart.	"4.4.2 Setting the Modules' Channels" on page 43
4	Set the SpO2 module's channel to the same number as the cart.	"4.4.2 Setting the Modules' Channels" on page 43
5	Turn on the remote monitor.	See the remote monitor's instructions for use.
6	Set the remote monitor's channel to the same number as the cart.	See the remote monitor's instructions for use.
7	On the MR400, in the **Status** pane, select the remote connect button then select a remote type.	"4.5.2 Managing Remote Monitor Communication" on page 46

4.4 SpO2 and ECG Module Communication

WARNING

Do not connect more than one ECG module to a single MR400 cart. Do not connect more than one SpO2 module to a single MR400 cart.

The modules and MR400 communicate through a 2.4-GHz radio frequency. The cart automatically establishes communication with the modules, approximately 30 seconds after module battery installation. The modules must be in the same room as the cart. They may be up to 9.1 m (30 feet) away from the cart. Both modules must communicate on the same channel as the cart.

4.4.1 Setting the Cart's Channel

The following table describes the MR400 cart channel icons and the channels that they represent.

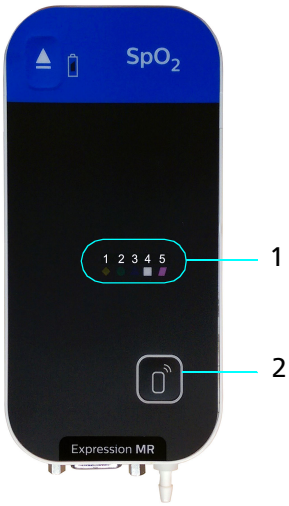
Channel 1 (factory default)		Channel 6
Channel 2		Channel 7
Channel 3		Channel 8
Channel 4		Channel 9
Channel 5		Channel 10

To set the MR400 cart channel, follow these steps.

Step	Action
1	Look at the modules to see which channels are available: • Channels 1 through 5 • Channels 6 through 10
2	In the **Status** pane, select the channel icon.
3	In the channel menu, select a channel as follows: • If the modules use channels 1 through 5, then select a channel from 1 through 5. • If the modules use channels 6 through 10, then select a channel from 6 through 10. If you want to set up multiple MR400 systems, set each cart to a different channel.
4	After you change the channel, wait 5 seconds before you turn off the cart.

4.4.2 Setting the Modules' Channels

Channel indicators and the channel button appear on the front of the modules. 5 channels appear, based on the channel group you selected when you purchased the MR400. The image shows channel group 1-5.



1 Channel indicators
2 Channel button

On the ECG and SpO2 modules, the channel indicators behave as follows:

- The light is on and steady when the module and cart are communicating on that channel.
- The light flashes when the channel is selected but the module and cart are not communicating.

The following table describes the modules' channel indicators and the channels that they represent. Only one channel group appears on a module.

Channel Group 1-5		**Channel Group 6-10**	
Channel Indicator	**Channel**	**Channel Indicator**	**Channel**
	Channel 1		Channel 6
	Channel 2		Channel 7
	Channel 3		Channel 8

Channel Group 1-5		Channel Group 6-10	
Channel Indicator	**Channel**	**Channel Indicator**	**Channel**
	Channel 4		Channel 9
	Channel 5 (factory default)		Channel 10 (factory default)

To change the module channel, follow these steps.

Step	Action
1	Eject the module battery or batteries.
2	On the cart, in the **Status** pane, check the MR400 cart channel number.
3	Insert a battery into the module.
4	Within 10 seconds, press and hold the channel button until the channel indicator light blinks rapidly.
5	Press and release the channel button to cycle through the channels until you get to the same channel as the cart.
6	Hold the channel button for 5 seconds and then release it.
7	Verify that the module and cart are communicating: • Is the indicator light on and steady? • Does channel on the cart (in the **Status** pane) match the channel on the module? If not, then repeat this process. If you continue to have problems, contact Service.

4.5 Remote Monitor Communication

A remote monitor is a device that you can use to monitor a patient's vital signs and control the MR400 system from outside the MR environment. It also features printing capabilities and HL7 data output.

Compatible remote monitors are

- Expression Information Portal (Model IP5)
- MR Patient Care Portal 5000

The MR400 connects to the remote monitor through a radio transceiver. To connect the remote monitor to a hospital information system, or to the PIC iX, see the remote monitor' instructions for use.

4.5.1 Remote Monitor Synchronization

When an MR400 system includes a remote monitor, the devices synchronize settings as shown in the following table.

Device state	Action	How settings are applied
MR400 cart is on and the startup process is complete	You turn on the remote monitor within communication range of the cart.	The cart applies the settings to the remote monitor.
MR400 cart is on and the startup process is complete	The remote monitor starts out of communication range. Then you move the remote monitor and the cart to be within range.	The cart applies the settings to the remote monitor.
Remote monitor is on and the startup process is complete	You turn on the cart within communication range of the remote monitor.	The remote monitor applies the settings to the cart.

4.5.1.1 Synchronization Effects

When the system detects different patient data on the MR400 and remote monitor, the **Patient Selection** dialog box appears. To resolve the conflict, select which patient data to use. When the remote monitor is communicating with a PIC iX, this dialog box does not appear. The MR400 automatically uses the patient data from the PIC iX.

When the systems synchronize, settings from the remote monitor may override user profile settings on the cart. A plus sign (+) appears on the user profile button to show you that the system changed the settings.

4.5.1.2 Synchronized Settings

The system synchronizes the following settings and actions. All other settings and actions remain local to the cart or to the remote monitor.

- Patient Type
- Whether parameters are on or off
- Alarm limits, but not 1-Touch Alarms percentages
- HR Tone Source
- Pressure Units
- Gas Units
- All printer settings
- All trends settings except whether trend arrows are on or off and the trend data interval
- All settings in the ECG menu
- All settings in the SPO2 menu except Perfusion Index
- All settings in the CO2 menu
- All settings in the P1 and P2 menus except Format
- All settings in the RESP menu
- All settings in the TEMP menu

- All settings in the NIBP menu except Format
- Simulation
- Suspend (See "6.4 Suspending the System Between Patients" on page 58.)

4.5.2 Managing Remote Monitor Communication

To manage communications between the MR400 and remote monitor, follow these steps.

Step	Action
1	Turn on the MR400 and the remote monitor.
2	Check the channel on the MR400 and the remote monitor to ensure they are on the same channel. To set the cart's channel, see "4.4.1 Setting the Cart's Channel" on page 42. To set the remote monitor's channel, see the remote monitor's instructions for use.
3	On the MR400, in the **Status** pane, select the remote connect button. 
4	On the **Select Remote Type** dialog box, select one of the following: • **IP5**: Connects to the IP5 remote monitor. • **Portal 5000** (factory default): Connects to the Portal 5000 remote monitor. • **Stop Remote Communication**: Stops communication with the remote monitor.
5	On the remote connect button, confirm the connection status: • Connected:  • Disconnected:  • Radio off: 

5: System Power

The MR400 system includes several power sources. The cart can run on A/C or battery power. The modules run on battery power.

5.1 Power Safety

WARNINGS

- When the high-priority, low battery alarm occurs, connect to A/C power immediately or replace the module batteries.
- The MR400 has dangerous electrical voltages. Removing covers or cables could lead to serious or fatal injury. Only authorized Service providers may remove covers or cables.
- The MR400 cannot charge its batteries when positioned closer than the 5,000-gauss line. Follow the instructions in "6.3 Moving and Positioning the Cart" on page 57.
- Periodically check batteries. Replace any battery that exhibits abnormal heat, odor, color, deformation, puncture, or other damage. Follow your facility's policies for battery safety.

CAUTION

- Never heat a battery. Never throw a battery onto a fire.

Do not force batteries into a battery compartment.

5.2 About Cart Power

The cart can run on A/C or battery power. The cart contains 2 types of batteries:

- Main batteries: removable batteries
- Reserve batteries: internal batteries that you cannot remove. You can turn them on and off with a switch in the service panel.

When you connect the cart to A/C power, the cart behaves as follows:

- Automatically operates on A/C power.
- Charges the installed main batteries.
- Charges reserve batteries when the internal battery switch is on.

Priority	Power Source	Adequate Power Indicators	Low Power Indicators	No Power Functionality
1	A/C	The **Status** pane **Monitor** icon is  .	Not applicable	The cart changes the power source to the main batteries. The cart continues to function.
2	Main batteries	The **Status** pane **Monitor** icon is  and the estimated remaining battery time appears.	**System Low Battery** appears in the **Status Information Panel**. The **Status** pane **Monitor** icon is  and the estimated remaining battery time appears.	The cart changes the power source to the reserve batteries. The cart continues to function.
3	Reserve batteries	**Reserve Batteries In Use** appears in the **Status Information Panel**.	**System Low Battery** or **Very Low** appears in the **Status Information Panel**.	The cart stops functioning and turns off.

If you position the cart too close to the magnet, the cart cannot charge the batteries due to magnetic field interference. The **Status** pane **Monitor** icon is  .

Move the cart further away from the magnet. See "6.3 Moving and Positioning the Cart" on page 57.

5.2.1 Loss of All Power

When the cart loses all power (A/C power, main batteries, and reserve batteries), the following information is lost:

- Settings that you did not save to a profile
- Patient name and ID
- Trend data, after 10 minutes of power loss

During an A/C power outage, to prevent loss of power, keep the main batteries inserted and the reserve batteries turned on.

5.2.2 Adding and Removing Cart Power

To add power to the cart, turn on the reserve batteries, insert the main batteries, and then connect A/C power.

To remove all power from the cart, turn off the reserve batteries, remove the main batteries, and then disconnect A/C power.

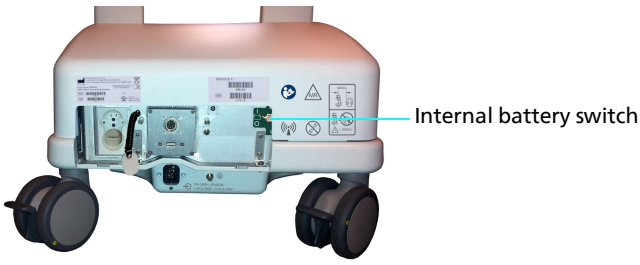
See the following sections:

- "5.2.2.1 Turning Reserve Batteries On and Off" on page 49.
- "5.2.2.2 Inserting and Removing Main Batteries" on page 49.
- "5.2.2.3 Connecting and Disconnecting A/C Power" on page 50.

5.2.2.1 Turning Reserve Batteries On and Off

Only Service may access the reserve batteries. You can use the internal battery switch to turn reserve batteries on and off.

To turn the reserve batteries on and off, follow these steps.

Step	Action
1	Remove the service panel door. See "16.5 Accessing the Service Panel" on page 171.
2	 • To turn on the reserve batteries, point the switch to the | symbol. • To turn off the reserve batteries, point the switch to the O symbol.
3	Replace the service panel door and shield cap.

5.2.2.2 Inserting and Removing Main Batteries

WARNING

Main and reserve cart batteries contain ferrous materials. Do not insert or remove the main batteries when closer than the 1,000 gauss (0.1 T) field line, measured from the center line of the MR bore to the MR400. The batteries will be attracted to the magnetic field, possibly causing patient or user injury.

To insert the main batteries, follow these steps.

Step	Action
1	Ensure that the cart is not closer to the magnet than the 1,000-gauss field line. Ensure that the wheels are locked.
2	Slide the battery into the battery compartment until it latches into place.
3	Repeat on the other side of the cart to insert the second battery.

To remove the main batteries, follow these steps.

Step	Action
1	Ensure that the cart is not closer to the magnet than the 1,000-gauss field line. Ensure that the wheels are locked.
2	Press the battery eject button to remove the battery.
3	Repeat on the other side of the cart to remove the second battery.

5.2.2.3 Connecting and Disconnecting A/C Power

WARNING

Use only a compatible power cord to connect to properly grounded A/C outlets. See "2.3 Accessory List" on page 14.

To connect A/C power, follow these steps.

Step	Action
1	Ensure that the cart is not closer to the magnet than the 5,000-gauss field line. Always lock the wheels.
2	At the rear panel, raise the cord retainer clip.
3	Insert the power cord into the power cord connector then lower the cord retainer clip.
4	If the power cord is too short to reach the wall outlet, add the power cord extension (REF 989803168221). Route the power cord to prevent a tripping hazard.
5	Plug the power cord into the wall outlet.

To disconnect A/C power, follow these steps.

Step	Action
1	At the rear panel, raise the cord retainer clip to remove the power cord.
2	Remove the power cord from the wall outlet.

5.2.3 Turning the Cart On and Off (System Startup)

WARNING

Ensure that the system completes the following startup process before you use the system.

When you turn on the cart, the MR400 system performs the following startup and verification activities:

- The MR400 plays the high-priority alarm audio. A notification flag instructs you to **Check Alarm Volume** to ensure that alarms are loud enough. To adjust the alarm volume, see "7.5 Setting Alarms and Alarm Limits" on page 67.
- If a default user profile exists, the system applies those settings.
- The MR400 pauses alarm audio and lights for 120 seconds. A system message includes a timer that counts down until the system is ready.
- If the MR400 is near a remote monitor, the system synchronizes settings according to the rules stated in "4.5.1 Remote Monitor Synchronization" on page 45.

The MR400 reaches an operational state within 60 seconds after you turn it on and then attains full measurement accuracy as follows:

- MR400 systems that include the anesthesia option: approximately 10 minutes
- All other MR400 systems: approximately 2 minutes

When the **CO2 Warming Up** system message disappears, the MR400 is ready for use.

To turn on the cart: hold the power button in for approximately 2 seconds.

To turn off the cart: hold the power button in for approximately 2 seconds.

5.3 About Module Power

The ECG and SpO2 modules run on battery power. Modules turn on automatically when you insert a battery. Modules turn off automatically when you remove the batteries. Modules do not include a power switch.

The ECG module contains 2 batteries, but needs only one to operate. The module uses one battery until its power runs out. Then the module uses the other battery. You can replace the drained battery without interrupting operation.

WARNING

Check batteries before inserting and removing. If you notice anything unusual (such as abnormal heat, odor, color, or other damage) then discard the battery immediately according to local regulations.

5.3.1 Inserting and Removing Module Batteries

To insert a battery, align the indicators on the battery and on the module. Insert the battery into the battery bay.

Ensure that the channel is set to the same number as the cart.

To remove a battery, press the eject button.

5.4 Charging Module Batteries

To charge module batteries, see the battery charger's instructions for use.

5.5 Power Indicators

Power status appears on the cart, modules, in the main screen, and on the cart batteries.

5.5.1 Power Light Indicators

The power light on the cart above the power button shows the cart's power status as described in the following table:

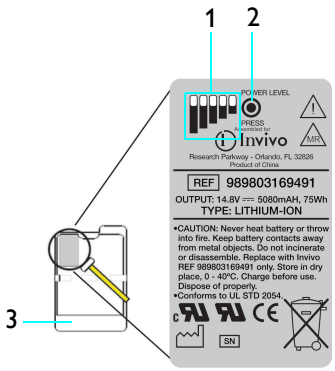
Power Light Condition		Meaning	
Color	**State**	**Power Source**	**Power Button**
None	Off	None	Off
Green	Steady	• A/C power when the cart is plugged in • Battery power when the cart is not plugged in	On
Red	Steady	Power fault. Contact technical support	N/A
Blue	Blinking	The cart is charging its batteries.	Off
Blue	Steady	Batteries at full charge	Off

5.5.2 Main Battery Indicators

To see the main battery charge when the battery is in the cart, select **Status** to open the **Status Information Panel**. See "2.4.6.1 Status Information Panel" on page 23.

To see the main battery charge on an ejected battery, press the power level button on the battery,

Description	
1	Charge indicator
2	Power level button
3	Main battery



5.5.3 Module Battery Indicators

Both modules include a battery charge indicator on the front of the module. The indicator's color shows the battery power level when the battery is in the module

Color	Status
None	No battery or no charge
Red	Low charge
Green	Sufficient charge

The main screen of the cart shows the estimated battery time in the **Status** pane. Select **Status** to open the **Status Information Panel** for more details. See "2.4.6.1 Status Information Panel" on page 23.

6: Monitoring a Patient

6.1 Patient Monitoring Process Overview

If you find any problem at any time when monitoring a patient, discontinue monitoring and contact Service.

This overview lists typical steps required to monitor a patient.

Step	Action	Instruction and Reference
1	Inspect the MR400 cart and accessories for damage. Do not use a damaged cart or accessory. If you see damage, contact Service.	
2	Select the vital sign data to appear on the main screen.	Select **Setup** > **Monitor** > **Parameters**, locate the parameter, and then select **Off** or **On**. See "2.4.8.2 Parameters Menu" on page 26.
3	Connect accessories to the MR400 for each parameter that you want to monitor.	See the following chapters: • "4: System Communications" on page 41 • "8: Monitoring ECG" on page 87 • "9: Monitoring SpO2" on page 105 • "11: Monitoring Gases and Respiration Rate" on page 125 • "12: Monitoring Invasive Pressure" on page 139 • "13: Monitoring Temperature" on page 147 • "10: Monitoring Noninvasive Pressure" on page 115
4	Admit the patient from the remote monitor (optional).	See the remote monitor's instructions for use.
5	Select a patient type or select a profile. If you select a profile, confirm that the patient type is correct.	On the Information bar, select **Patient Type** and then select a type. See "6.2 Selecting the Patient Type" on page 56. On the Information bar, select **User Settings** and then select a profile. See "2.4.9.3 Selecting a User Settings Profile" on page 34.
6	Confirm that alarm settings are appropriate for the patient. Adjust alarm limits if necessary.	See "7.5 Setting Alarms and Alarm Limits" on page 67.
7	Check the **Status** pane to ensure that the cart, modules, and remote monitor are communicating properly. Ensure that the cart and monitoring accessories are communicating properly. No technical alarms should occur.	See the following chapters: • "4: System Communications" on page 41 • "7: Alarms" on page 59
8	Confirm the information on the monitor against the patient's condition before treating the patient.	

Step	Action	Instruction and Reference
9	If you prepped the patient outside of the MR environment, move the cart and patient into the MR environment.	See "6.3 Moving and Positioning the Cart" on page 57.
10	Connect the MR400 to the gas scavenging system.	See "11.8 Connecting to the Gas Scavenging System" on page 131.
11	Calibrate the invasive pressure transducer, when present.	See "12.6 Zeroing Invasive Pressure" on page 142.
12	Scan the patient.	See your magnet's instructions for use.
13	If you admitted the patient from a remote monitor that is not connected to a PIC iX, then discharge the patient. On the Information bar, select **Discharge**.	
14	Clean and disinfect the cart and accessories. Dispose of single-use accessories.	See "15: Cleaning and Disinfection" on page 161.

6.2 Selecting the Patient Type

Standards agencies define patient types differently. Patient type descriptions can be arbitrary. Use your clinical judgment and the following factors when you select the patient type:

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

The MR400 includes 3 patient types:

- **Adult** (factory default)
- **Pediatric**
- **Neo**

When you change the patient type, the MR400 automatically adjusts the following:

- Noninvasive cuff inflation pressure
- Pulse sensitivity
- Alarms: alarm limits, limit ranges, measurement ranges, and other values related to alarms.
- Parameter data, durations, ranges, settings, and algorithms
- Sample flow rate

When you change the patient type, the MR400 instructs you to change the noninvasive blood pressure cuff.

To select the patient type, on the Information bar, select **Patient Type** and then select a type.

6.3 Moving and Positioning the Cart

WARNINGS

- To prevent operator or patient injury, position the cart up to the 5,000-gauss line. Do not position the cart any closer to the magnet. Always lock the cart's wheels.
- Main and reserve cart batteries contain ferrous materials. Do not insert or remove the batteries when closer than the 1,000 gauss (0.1 T) field line, as measured from the center line of the MR bore to the MR400. The batteries will be attracted to the magnetic field, possibly causing patient or user injury.
- Do not stack the cart with other equipment.
- Do not place the cart next to other equipment.

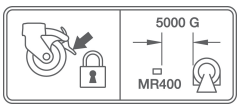
CAUTION

- Determining the 5,000-gauss line location may be difficult. If you see system abnormalities or malfunctions, move the cart further away from the magnet.

Follow these cart placement guidelines:

- Place the MR400 cart so you can see the screen and alarm light from your position at all times. You can tilt the display panel to reduce glare. The visual alarms must be legible at 1 meter (assuming a visual acuity of 20/20 and with no line of sight obstructions).
- Do not block access to the cart with other equipment. Do not block access to the A/C power outlet. Route the power cord to prevent a tripping hazard.
- When you are in the magnet room, you may position the cart up to the 5,000-gauss line, but no closer to the magnet. Use a gauss meter to locate the 5,000-gauss line.
- If you position the cart too close to the magnet, the MR400 cannot charge the batteries due to magnetic field interference.
- Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
- If you are inserting or removing a battery, the cart must be no closer than the 1,000 gauss (0.1 T) field line. See "5.2.2.2 Inserting and Removing Main Batteries" on page 49.

To move the cart, follow these steps.

Step	Action
1	Lift each wheel lock to unlock the wheels.
2	Use the cart handle or cart base to move the cart. Do not use the accessory hooks or display panel to move the cart. If the magnet pulls the cart, pull the cart base to move the cart. Do not use the cart handle to move the cart.
3	Press down each wheel lock to lock the cart's wheels. 

6.4 Suspending the System Between Patients

WARNING

Do not suspend the system while you monitor a patient. Do not suspend the system to respond to an alarm.

You can suspend the system when you are not monitoring a patient. For example, when you disconnect one patient and connect another patient.

When you suspend the system, the MR400 behaves as follows:

- Continues to show patient data on the screen
- Displays **Suspended** in the system message area
- Suspends automatic noninvasive pressure measurement
- Uses default inflation pressures for manual noninvasive pressure measurement
- Disables alarm audio and lights. All other alarm indicators continue normally.

When the MR400 system includes a remote monitor, **Suspend** is synchronized between the remote monitor and the MR400 cart. When you select **Suspend** at either the cart or the remote monitor, both devices are suspended.

To suspend the system, select the **Suspend** button.

To resume monitoring while the system is suspended, select **Suspend** a second time. To resume automatic noninvasive pressure measurement, select **NIBP Start/Stop**.

7: Alarms

7.1 About Alarms

The MR400 generates alarms to alert you when a potential or actual hazardous situation exists that requires your attention.

Physiological alarms (patient alarms) and technical alarms alert you to a patient or device issue. The MR400 prioritizes each alarm based on the risk of harm to the patient.

The cart does not send alarm signals to the remote monitor, hospital information system, or the PIC iX. The cart sends patient data to the remote monitor, which generates alarms. For information about the remote monitor, see the remote monitor's instructions for use.

7.2 Alarm Safety

WARNINGS

- To prevent a delay in patient treatment, respond to alarms immediately.
- Adjust alarm settings appropriately for the patient.
- Visual alarm indicators occur immediately. Audio alarm indicators may be delayed by 4 seconds.
- Invasive pressure alarm delays are as follows:
  - Transducer disconnect: 6 seconds
  - Pressure disconnect: 6 seconds
  - High and low pressure: 10 seconds

CAUTION

Setting the alarm limits to extreme values can render alarm monitoring useless. Adjust alarm settings appropriately for the patient.

7.3 Alarm and System Message Priorities and Indicators

Alarms can be high, medium, or low priority. Alarms include both audio (beeps) and visual indicators (lights, flags, and messages). System messages appear in the system message area or in the Status Information Panel. They do not include audio indicators.

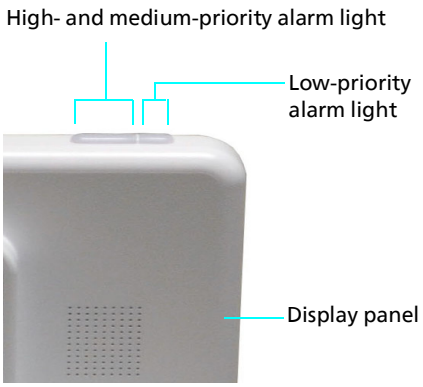
The following table lists the alarm levels and shows the types of indicators:

Alarm Priority	Indicators	Meaning
Critical Failure	• All vital sign monitoring stops. • The critical-failure audio indicator beeps repeatedly. • The power light is red. • The display turns off.	A catastrophic failure has occurred. Contact Service.
High	• The alarm light is red and blinking rapidly. • The alarm flag is red. • The vital sign values are red and blinking. • High-priority audio indicator: – High pitch – 10 pulses per burst – 5 seconds between bursts	Take action immediately.
Medium	• The alarm light is yellow and blinking moderately. • The alarm flag is yellow. • The vital sign values are yellow and blinking. • Medium-priority audio indicator: – Medium pitch – 3 pulses per burst – 7 seconds between bursts	Take action promptly.
Low	• The alarm light is blue and shines steadily. • The alarm flag is blue. • Low-priority audio indicator: – Low pitch – 2 pulses per burst – 15 seconds between bursts Another indicator appears below the ECG value to indicate that a lead failed. See "7.10.5 Low-Priority Technical Alarms" on page 80.	Action may be required.
System messages	• A white flag indicator appears. • A plain text message appears in the system message area or **Status Information Panel**. • Sometimes, a warning symbol appears in the **Status** pane. The symbol indicates that a system message appears in the **Status Information Panel**. Select **Status** to view the system message. • No alarm lights or audio indicators occur.	Action may be required.

7.3.1 Light Indicators

The display panel has 2 alarm lights:

- High-priority alarms: The high- and medium-priority light is red and blinks rapidly.
- Medium-priority alarms: The high- and medium-priority light is yellow and blinks moderately.
- Low-priority alarms: The low-priority light is blue and shines steadily.



When a high-priority alarm condition overrides a medium-priority alarm condition, the light changes from yellow to red.

You can control alarm light behavior as follows:

Action	Instruction	Information bar symbol
Turn off alarm lights permanently.	Select **Setup** > **Alarms** > **Alarm Light** > **Off**.	
Alarm lights turn on, stay on for 25 seconds, and then turn off.	Select **Setup** > **Alarms** > **Alarm Light** > **Temporary**. When the MR400 detects a new alarm condition, the lights turn on again. Except when you pause alarm audio, the lights stay off until audio pause ends (maximum of 120 seconds). A system message shows the pause timer.	
Alarm lights turn on and stay on until you acknowledge the alarm.	Select **Setup** > **Alarms** > **Alarm Light** > **Continuous**.	
Acknowledge an alarm event.	Select the **Alarm** quick access button to deactivate audio and the alarm light. All other visual indicators continue until the alarm condition resolves. The **Audio Off** system message appears.	No change to symbol
Pause the alarm light for 120 seconds.	Select the **Audio Pause** quick access button.	No change to symbol
Resume the alarm light after pausing.	During the pause, select **Audio Pause** again.	No change to symbol

7.3.2 Flag Indicators

Flag indicators may appear next to numerics or in the System Message area. Multiple flags may appear simultaneously.

When you pause or turn off audio and lights, flags continue to occur.

Flag colors are as follows:

Flag color	Meaning
Red	High-priority alarm
Yellow	Medium-priority alarm
Blue	Low-priority alarm
White	System message

7.3.3 System Message Indicators

System messages appear in the center of the system message area or in the Status Information Panel.

System messages may or may not appear with other types of indicators. System messages are associated with technical alarm conditions, such as system status, pausing alarm audio and lights, and shutting down the system.

When you pause or turn off audio and lights, system messages continue to occur.

7.3.4 Vital Sign Numeric Indicators

During a patient alarm condition, vital sign numbers appear as follows:

- High-priority alarm
  The numbers flash red and white at 1.5 Hz with a 50% duty cycle. When the value is higher than the MR400 can measure, then OVR appears. When the value is lower than the MR400 can measure, then UND appears.
- Medium-priority alarm
  The numbers flash yellow and white at 0.75 Hz with a 50% duty cycle. When the value is higher than the MR400 can measure, then OVR appears. When the value is lower than the MR400 can measure, then UND appears.
- Low-priority alarm: no change to numbers.
- System message: no change to numbers.

When you pause or turn off audio and lights, numeric indicators continue to occur.

Higher-priority indicators override lower-priority indicators.

Another numeric indicator appears below the ECG values, during the **Lead Fail** alarm condition. See "7.10.5 Low-Priority Technical Alarms" on page 80.

7.3.5 Status Pane Indicator

A warning symbol appears on the main screen in the **Status** pane. This symbol indicates that a system message related to power or the printer appears in the **Status Information Panel**.

When you pause or turn off audio and lights, status pane indicators continue to occur.

7.3.6 Audio Indicators

WARNINGS

- To prevent patient injury, set the alarm volume appropriately for each patient and verify that you can hear the alarms above ambient noise, particularly during a scan.
- When you select the **Audio Pause** quick access button, the MR400 pauses alarm audio for 120 seconds.

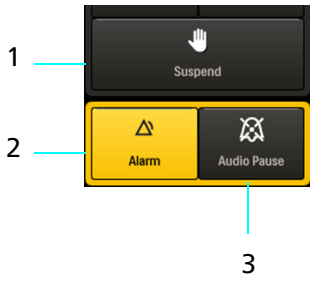
Audio indicators differ depending on the alarm type. The table in "7.3 Alarm and System Message Priorities and Indicators" on page 59 lists the audio indicator for each alarm type.

Audio indicators also occur during the startup procedure and when recalling user settings so you can check the alarm volume. The highest-priority indicator overrides lower-priority indicators.

Action	Instruction	Information bar symbol
Turn off all alarm audio indicators permanently.	Select **Setup** > **Alarms** > **Alarm Sound** > **Off**.	
Turn on all alarm audio indicators.	Select **Setup** > **Alarms** > **Alarm Sound** > **On**.	
Acknowledge an alarm event.	Select the **Alarm** quick access button to deactivate audio and the alarm light. All other visual indicators continue until the alarm condition resolves. The **Audio Off** system message appears.	
Pause alarm audio for 120 seconds.	Select the **Audio Pause** quick access button to pause both audio and the alarm light for 120 seconds.	
Resume alarm audio after pausing audio.	During the pause, select **Audio Pause** again.	
Change the alarm audio volume.	To change alarm audio volume follow these steps: 1. Select **Setup** > **Monitor** > **Sound Adjust** > **Alarm Volume** and then select an alarm volume from **1** (low) to **10** (high). 2. Listen as the MR400 plays the alarm briefly to check the volume. 3. Select the check to save and exit.	No change

7.3.7 About Quick Access Buttons and Alarm Behavior

The following image shows the quick access buttons that affect alarm indicators. To respond to an alarm, see "7.6 Responding to an Alarm or System Message" on page 72.



Part	Description
1	The **Suspend** button suspends the system, which disables alarm audio and lights. Never select the **Suspend** button to respond to an alarm. Do not suspend the system while you monitor a patient. See "6.4 Suspending the System Between Patients" on page 58.
2	The **Alarm** button acknowledges the alarm. Audio and light indicators stop. All other visual indicators continue until the alarm condition resolves.
3	The **Audio Pause** button pauses alarm audio and the alarm light for 120 seconds. All other visual indicators continue until the alarm condition resolves.

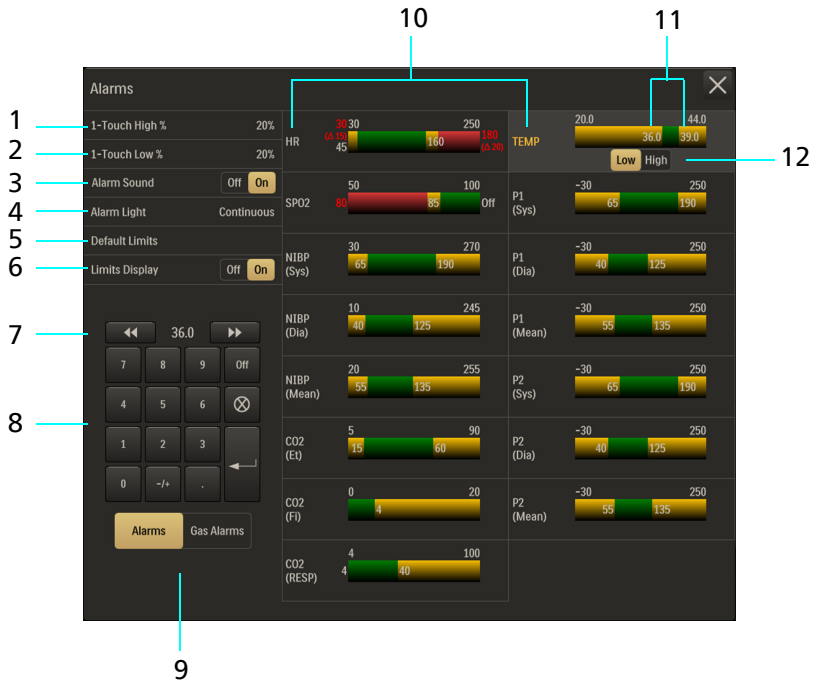
7.4 Alarms Menu

Use the **Alarms** menu to do the following:

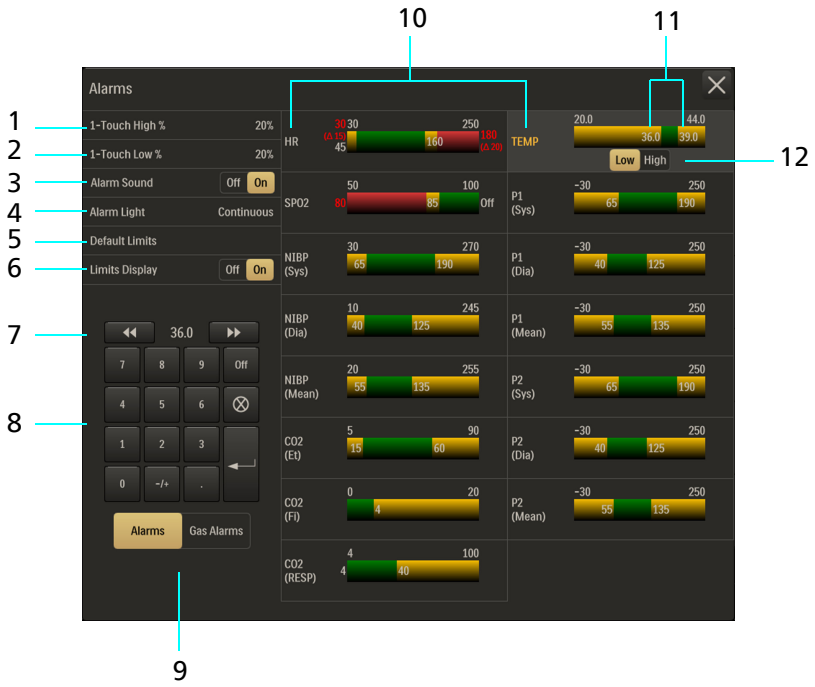
- Set **1-Touch Alarms** percentages.
- Control alarm audio.
- Control alarm lights.
- Restore factory-default alarm settings.
- Show or hide alarm limits in the main screen.
- Set alarm limits for patient alarms.

To open the **Alarms** menu, in the main screen, select **Setup** > **Alarms.**

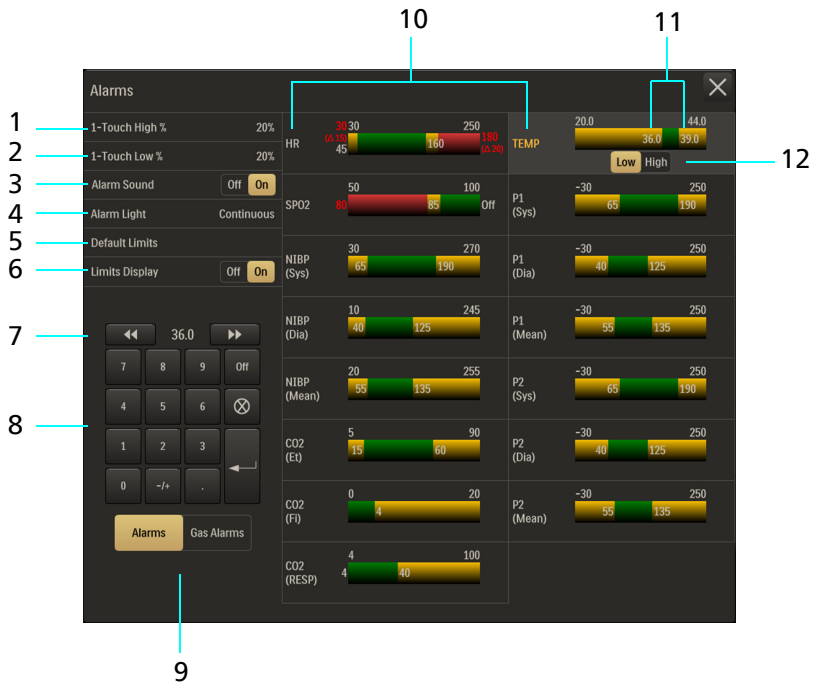
The parts of the **Alarms** menu are as follows:



Part	Control name	Options	Description
1	**1-Touch High %**	• **5%** • **10%** • **15%** • **20%** (factory default) • **30%**	Select to configure the percentages used when selecting **1-Touch Alarms**. See "7.5.1 Selecting 1-Touch Alarms and Setting Limits" on page 68.
2	**1-Touch Low %**		
3	**Alarm Sound**	• **Off** • **On** (factory default)	Turn alarm audio off or on. When **Alarm Sound** is off, audio indicators never occur. This control is identical to the **Alarms** control in the **Monitor Setup** menu (**Setup** > **Monitor** > **Sound Adjust** > **Alarms**). You cannot set the alarm volume in the **Alarms** menu. To set the alarm volume, see "7.5 Setting Alarms and Alarm Limits" on page 67.
4	**Alarm Light**	• **Off** • **Temporary** • **Continuous** (factory default)	Select to configure the alarm light. See "7.5 Setting Alarms and Alarm Limits" on page 67.
5	**Default Limits**	None	Select to restore all alarm limits to the factory-default settings. See "7.9 Measurement Range and Over/Under Values" on page 76.



Part	Control name	Options	Description
6	**Limits Display**	• **Off** • **On** (factory default)	Select **On** for alarm limits to appear in the main screen next to the vital sign values. When you turn off this control, you cannot select the alarm limits on the main screen to adjust the limits. You must open this **Alarms** menu.
7	Decrease button		Select to decrease or increase an alarm limit value
	Increase button		
8	Keypad	**Off**	Select to turn off the alarm limit.
		Numeric values	Enter an alarm limit value.
		Clear 	Select to clear the value.
		Enter 	Select to save the value.
9	Alarm type buttons	• **Alarms** • **Gas Alarms**	Switch between standard alarms and gas alarms.
10	Alarm limit labels	None	Shows the type of alarm. Requires you to turn on the parameter.



Part	Control name	Options	Description
11	Alarm limit values	Variable	Shows the current alarm limits. • Green: values within this range do not trigger an alarm. • Yellow: a value in the yellow range triggers a medium-priority patient alarm • Red: a value in the red range triggers a high-priority patient alarm.
12	Alarm limit type	• **Low** • **High** • **Δ ExtrBrady** • **Δ ExtrTachy** • **Desat**	Select to set individual alarm limits and values. Button availability depends on the type of alarm.

7.5 Setting Alarms and Alarm Limits

You can control alarms related to a patient's vital sign measurements, such as heart rate or oxygen saturation.

You cannot adjust MR400 system function alarms, such as alarms related to power or system status.

When a patient's vital sign data is outside the alarm limit range, an alarm alerts you to the change in the patient's condition.

You can adjust patient vital sign alarms and limits 3 ways:

- Simultaneously set all alarms to a percentage of the patient's baseline vital signs (**1-Touch Alarms**). See "7.5.1 Selecting 1-Touch Alarms and Setting Limits" on page 68.

- View and adjust all alarms in one screen. In the main screen, select **Setup > Alarms.** See "7.5.2 Setting Individual Alarm Limits" on page 69.
- Set one parameter's alarm limits: In the main screen, select the alarm limit. See "7.5.2 Setting Individual Alarm Limits" on page 69.

7.5.1 Selecting 1-Touch Alarms and Setting Limits

WARNING

1-Touch Alarms may cause the low SpO2 limit to be inappropriately low for the patient. After you set the 1-Touch Alarms percentage, confirm the low SpO2 limit is appropriate for the patient.

The MR400 calculates **1-Touch Alarms** limits as a percentage of the patient's vital sign value. You can set the percentage for the high limit and low limit.

If a calculated limit falls outside acceptable limit ranges, the MR400 adjusts the calculated limit so it is acceptable.

For example, a patient's oxygen saturation is 99%. When the **1-Touch High %** limit is 20%, the MR400 adjusts the upper limit from 119% to 100%, the maximum allowed. When using **1-Touch Alarms**, ensure that the limits are appropriate for each patient. For a list of alarm limit ranges, see "7.8 Alarm Limit Ranges and Factory-Default Values" on page 73.

1-Touch Alarms do not include the following alarm settings:

- **Extreme Brady**
- **Extreme Tachy**
- **Desat**
- **Apnea**

To set the 1-Touch Alarms high and low percentages, follow these steps.

Step	Action
1	Select **Setup** > **Alarms** > **1-Touch High %** and then select a percentage**.**
2	Select **1-Touch Low %** and then select a percentage**.**
3	Verify that the alarm limits are appropriate for the patient.

To select **1-Touch Alarms,** in the main screen, select the **1-Touch Alarms** button. Confirm that each alarm limit is appropriate for the patient. To adjust a limit, see "7.5.2 Setting Individual Alarm Limits" on page 69.

1-Touch Alarms percentages work differently on remote monitors. See the remote monitor's instructions for use.

7.5.2 Setting Individual Alarm Limits

This section contains procedures to set individual alarm limits.

7.5.2.1 Setting Heart Rate Alarm Limits

Heart rate alarms include the following 4 types of settings.

Setting	Description
Δ ExtrBrady	Sets the amount that the heart rate can decrease below the low heart rate limit. In this example, the **Δ ExtrBrady** value is 15. The low heart rate limit is 45. When the patient's heart rate decreases below 30 (15 below 45), the **Extreme Brady** alarm occurs.
Low	Sets the low heart rate alarm limit. In this example, the **Low** limit is 45. When the patient's heart rate decreases below 45, the low heart rate alarm occurs.
High	Sets the high heart rate alarm limit. In this example, the **High** limit is 160. When the patient's heart rate exceeds 160, the high heart rate alarm occurs.
Δ ExtrTachy	Sets the amount that the heart rate can increase above the high heart rate limit. In this example, the **Δ ExtrTachy** value is 20. When the heart rate exceeds 180 (20 above 160), the **Extreme Tachy** alarm occurs.

To set heart rate alarm limits, follow these steps.

Step	Action
1	In the main screen, select the heart rate alarm limit. Alternatively, in the main screen, select **Setup** > **Alarms.** In the **Alarms** window, select **Alarms** and then select **HR**.
2	Select **Low** or **High**. Use the increase or decrease buttons to set the limit. Or, use the keypad to enter a value, then select the Enter button.
3	If you do not want to set extreme heart rate alarms, skip this step. To set the extreme heart rate alarm, select **Δ ExtrBrady** or **Δ ExtrTachy**. Use the increase or decrease buttons to set the value. Or, use the keypad to enter a value, or select **Off**, then select Enter.
4	Verify that the alarm limits are appropriate for the patient.

7.5.2.2 Setting SpO2 Alarm Limits

SpO2 alarms include the following types of settings.

Setting	Description
Desat	When the patient's SpO2 remains below this value for the time that you selected to be the Desat Time, the desaturation alarm occurs. In this example, the Desat value is 80 and the Desat Time is 10 seconds. When the patient's SpO2 remains below 80% for 10 seconds, the Desat alarm occurs. The desaturation alarm value must be 2 or more below the low alarm limit. The MR400 automatically adjusts or restricts SpO2 alarm limits based on the Desat value. Ensure that the alarm limits are appropriate for the patient.
Low	Sets the low SpO2 alarm limit. In this example, the **Low** limit is 85. When the patient's SpO2 decreases below 85%, the low SpO2 alarm occurs.
High	Sets the high SpO2 alarm limit. In this example, the **High** limit is off.

To set individual alarm limits, follow these steps.

Step	Action
1	If you are not setting the **Desat** alarm, go to step 5. If you are setting the **Desat** alarm, go to the next step.
2	In the main screen, select the **SpO2** label.
3	In the **SpO2** menu, select **Desat** > **On**.
4	In the **SpO2** menu, select **Desat Time** and then select the time that must pass before a desaturation alarm occurs.
5	In the main screen, select the SpO2 alarm limit.
6	Select **Desat**, **Low**, or **High**. Use the increase or decrease buttons to set the value. Or, use the keypad to enter a value, or select **Off**, then select Enter.
7	Verify that the alarm limits are appropriate for the patient.

7.5.2.3 Setting the Apnea Alarm Limit

The apnea alarm limit is the time that the system waits for a patient breath before triggering the apnea alarm. The apnea alarm must be on.

Although the MR400 measures respiration rate through pneumatic devices, that value is for gating purposes only. You cannot set an apnea alarm for the respiration rate from a pneumatic device.

When you connect a pneumatic device, and change the source of the **RESP** value to **BEL**, then the apnea alarm controls appear in the **CO2** menu. Otherwise, the apnea alarm controls appear in the **RESP** menu.

To set the CO_2 apnea alarm limit when you connect a pneumatic device, follow these steps.

Step	Action
1	Select the **RESP** label. Then select **Source** > **BEL**.
2	Select the **CO2** label. Verify that **Apnea** is on or select **On**.
3	Select **Apnea Time** and then select the time limit, from 20 to 40 seconds.
4	Verify that the alarm limit is appropriate for the patient.

To set the CO_2 apnea limit when a pneumatic device is not connected, follow these steps.

Step	Action
1	Select the **RESP** label. Then select **Source** > **CO2**.
2	Verify that **Apnea** is on or select **On**.
3	Select **Apnea Time** and then select the time limit, from 20 to 40 seconds.
4	Verify that the alarm limit is appropriate for the patient.

7.5.2.4 Setting All Other Alarm Limits

To set individual alarm limits:, follow these steps.

Step	Action
1	In the main screen, select the alarm limit that you want to change. Alternatively, in the main screen, select **Setup** > **Alarms.** In the **Alarms** window, select **Alarms** or **Gas Alarms** and then select the alarm limit label that you want to change.
2	Select **Low** or **High**. Use the increase or decrease buttons to set the value. Or use the keypad to enter a value, then select Enter.
3	Verify that the alarm limit is appropriate for the patient.

7.5.3 Showing and Hiding Alarm Limits

You can show or hide the alarm limits that appear on the main screen next to the vital sign values.

When you hide the alarm limits, you cannot select the alarm limit to change an individual alarm. You must open the **Alarms** menu (**Setup** > **Alarms**).

To show the alarm limits, select **Setup** > **Alarms** > **Limits Display** > **On**.

To hide the alarm limits, select **Setup** > **Alarms** > **Limits Display** > **Off**.

7.5.4 Alarm Limits and User Settings

When you save user settings to a profile, another clinician can change the alarm limits and save their changes to the profile. Verify that alarm limits are appropriate for the patient.

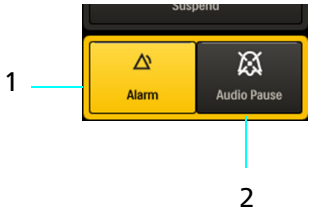
7.6 Responding to an Alarm or System Message

WARNING

Do not suspend the system while you monitor a patient. Do not suspend the system to respond to an alarm.

When responding to an alarm, visually monitor the patient at all times. Alarms persist until the alarm condition resolves. A clinician must assess each alarm to determine the risk to the patient's health.

To respond to an alarm or system message, follow these steps.

Step	Action
1	Patient safety is the first priority. When an alarm occurs: • Use clinical judgment and use all vital signs together to assess the patient's health. • Visually monitor the patient at all times. • If you see questionable data, check the patient vital signs by alternate means.
2	To acknowledge the alarm, select the **Alarm** quick access button (1). To pause alarm audio for 120 seconds, select the **Audio Pause** quick access button (2). To end a pause, select **Audio Pause** again. 
3	Determine the alarm trigger. See the "7.10 Alarms List" on page 78.

7.6.1 Troubleshooting Technical Alarms and System Messages

Check the following items and functions to resolve the alarm or system message trigger.

Check the patient for movement.

Accessories:
- Ensure you selected the correct accessories.
- Ensure you connected the accessories correctly.
- Reconnect accessories.
- Reposition accessories.
- Clear accessory obstructions or occlusions.
- Replace the accessories.

Power:
- Replace or charge batteries.
- Remove and restore power to the cart.

Environmental conditions, such as temperature, humidity, and gauss limit:
- Change the temperature of the room
- Move the cart

System communications:
- Ensure you did not change the channel on either module.
- Ensure you did not change the channel on the cart.

7.7 Alarms and Remote Monitors

When the system includes a remote monitor, the MR400 does not send alarm signals to the remote monitor. The MR400 sends patient data to the remote monitor, which may generate an alarm signal based on the data and based on remote monitor settings.

Acknowledging or pausing alarms at the cart has no impact on alarms at the remote monitor. Acknowledging or pausing alarms at the remote monitor has no impact on alarms at the cart.

When a remote monitor transmits alarm signals to a Philips Patient Information Center iX (PIC iX), a distributed information system is formed. The remote monitor does not transmit alarm signals to the hospital information system.

For more information, including system-wide alarm delays, see the remote monitor's instructions for use.

7.8 Alarm Limit Ranges and Factory-Default Values

You can set the patient alarm limits. When patient data exceeds the limits, an alarm occurs.

The following tables list the alarm limit ranges and factory-default alarm settings.

To restore all alarm limits to the factory-default settings, select **Setup** > **Alarms** > **Default Limits**.

Patient Alarm Limits and Factory-Default Values
All alarm limits may be turned off.
When the unit of measure is kPa, allow ± 0.1 kPa to account for conversion rounding.

Alarm	Unit	Patient Type	Low Limit	Default Low Limit	High Limit	Default High Limit
Heart rate	BPM	Adult	30-250	45	60-250	160
	BPM	Pediatric	30-250	75	60-250	160
	BPM	Neo	30-250	90	60-250	210
Extreme Brady	%	All	0-50	Δ15	None	Δ15
Extreme Tachy	Δ%	All	None	20	0-50	20
SpO2	Percent	Adult	50-100	85	70-100	100
	Percent	Pediatric	50-100	90	70-100	100
	Percent	Neo	50-100	90	70-100	100
Desat	Percent	All	50	80	98	80
CO2(Et)	mmHg kPa	Adult	5-60 0.7-8.0	15 2.0	5-76 0.7-10.1	60 8.0
	mmHg kPa	Pediatric	5-60 0.7-8.0	15 2.0	5-76 0.7-10.1	60 8.0
	mmHg kPa	Neo	5-60 0.7-8.0	30 4.0	5-76 0.7-10.1	45 6.0
CO2 (Fi)	mmHg kPa	All	None	None	0-20 0-2.7	4 0.5
CO2 (RESP)	RPM	Adult	4-40	4	20-100	40
	RPM	Pediatric	4-40	4	20-100	40
	RPM	Neo	4-40	30	20-100	70
Apnea	Seconds	All	20	20	40	20
P1 and P2 Systolic	mmHg kPa	Adult	-30-250 -4.0-33.3	65 8.7	-30-250 -4.0-33.3	190 25.3
	mmHg kPa	Pediatric	-30-250 -4.0-33.3	70 9.3	-30-250 -4.0-33.3	120 16.0
	mmHg kPa	Neo	-30-250 -4.0-33.3	70 9.3	-30-250 -4.0-33.3	100 13.3
P1 and P2 Mean	mmHg kPa	Adult	-30-250 -4.0-33.3	55 7.3	-30-250 -4.0-33.3	135 18.0
	mmHg kPa	Pediatric	-30-250 -4.0-33.3	50 6.7	-30-250 -4.0-33.3	90 12.0
	mmHg kPa	Neo	-30-250 -4.0-33.3	40 5.3	-30-250 -4.0-33.3	90 12.0

Patient Alarm Limits and Factory-Default Values
All alarm limits may be turned off.
When the unit of measure is kPa, allow ± 0.1 kPa to account for conversion rounding.

Alarm	Unit	Patient Type	Low Limit	Default Low Limit	High Limit	Default High Limit
P1 and P2 Diastolic	mmHg kPa	Adult	-30-250 -4.0-33.3	40 5.3	-30-250 -4.0-33.3	125 16.7
	mmHg kPa	Pediatric	-30-250 -4.0-33.3	40 5.3	-30-250 -4.0-33.3	70 9.3
	mmHg kPa	Neo	-30-250 -4.0-33.3	35 4.7	-30-250 -4.0-33.3	50 6.7
Temperature	°C °F	All	20.0-44.0 68.0-111.2	36.0 96.8	20.0-44.0 68.0-111.2	39.0 102.2
NIBP Systolic	mmHg kPa	Adult	30-270 4.0-36.0	65 8.7	30-270 4.0-36.0	190 25.3
	mmHg kPa	Pediatric	30-180 4.0-24.0	70 9.3	30-180 4.0-24.0	120 16.0
	mmHg kPa	Neo	30-130 4.0-17.3	70 9.3	30-130 4.0-17.3	100 13.3
NIBP Mean	mmHg kPa	Adult	20-255 2.7-34.0	55 7.3	20-255 2.7-34.0	135 18.0
	mmHg kPa	Pediatric	20-160 2.7-21.3	50 6.7	20-160 2.7-21.3	90 12.0
	mmHg kPa	Neo	20-120 2.7-16.0	40 5.3	20-120 2.7-16.0	90 12.0
NIBP Diastolic	mmHg kPa	Adult	10-245 1.3-32.7	40 5.3	10-245 1.3-32.7	125 16.7
	mmHg kPa	Pediatric	10-150 1.3-20.0	40 5.3	10-150 1.3-20.0	70 9.3
	mmHg kPa	Neo	10-100 1.3-13.3	35 4.7	10-100 1.3-13.3	50 6.7

Anesthetic Gas and Oxygen Alarm Limits and Factory-Default Values
Limits are the same for all patient types
All alarm limits can be off except FiN_2O and FiO_2.

Breath Phase and Gas	Unit	Low and High Alarm Limit Range	Factory-default Limit	Required Separation Between the Low and High Limit
Des (Et), Expired Desflurane	Vol.%	0.1-18.0	18.0	
Des (Fi), Inspired Desflurane	Vol.%	0.1-18.0	18.0	0.1
Enf (Et) Expired Enflurane	Vol.%	0.1-5.0	5.0	0.1
Enf (Fi) Inspired Enflurane	Vol.%	0.1-5.0	5.0	0.1

Anesthetic Gas and Oxygen Alarm Limits and Factory-Default Values Limits are the same for all patient types All alarm limits can be off except FiN_2O and FiO_2.				
Breath Phase and Gas	**Unit**	**Low and High Alarm Limit Range**	**Factory-default Limit**	**Required Separation Between the Low and High Limit**
Hal (Et) Expired Halothane	Vol.%	0.1-5.0	5.0	0.1
Hal (Fi) Inspired Halothane	Vol.%	0.1-5.0	5.0	0.1
ISO (Et) Expired Isoflurane	Vol.%	0.1-5.0	5.0	0.1
ISO (Fi) Inspired Isoflurane	Vol.%	0.1-5.0	5.0	0.1
SEV (Et) Expired Sevoflurane	Vol.%	0.1-8.0	8.0	0.1
SEV (Fi) Inspired Sevoflurane	Vol.%	0.1-8.0	8.0	0.1
N2O (Fi) Inspired Nitrous Oxide	%	Low limit range: none High limit range: 0.0-80	Low limit: none High limit: 80	1
O2 (Fi) Inspired Oxygen	%	Low limit range: 18-100 High limit range: 20-100	Low limit: 18 High limit: 99	2

7.9 Measurement Range and Over/Under Values

When a patient's vital sign value is greater than the MR400 can measure, then it flashes **OVR** (over).

When a patient's vital sign value is lower than the MR400 can measure, then it flashes **UND** (under).

The following table lists the range of values that the MR400 can measure and the value at which an **OVR** or **UND** alarm occurs.

Vital Sign or Parameter	Value	Units	Patient Type	Measurement Range		OVR/UND Values	
				Low	High	Under	Over
ECG	Heart Rate	BPM	Adult	30	250	30	250
ECG	Heart Rate	BPM	Ped	30	300	30	300
ECG	Heart Rate	BPM	Neo	30	300	30	300
SpO2	Heart Rate	BPM	All	30	250	30	250
SpO2	Saturation	%	All	1	100	none	none
Invasive Pressure	Systolic	mmHg	Adult	-30	250	-30	250
Invasive Pressure	Mean	mmHg	Ped	-30	250	-30	250
Invasive Pressure	Diastolic	mmHg	Neo	-30	250	-30	250
Invasive Pressure	Pulse Rate	BPM	All	30	250	30	250
NIBP	Systolic	mmHg	Adult	30	270	30	270
NIBP	Systolic	mmHg	Ped	30	180	30	180

Vital Sign or Parameter	Value	Units	Patient Type	Measurement Range		OVR/UND Values	
				Low	High	Under	Over
NIBP	Systolic	mmHg	Neo	30	130	30	130
NIBP	Mean	mmHg	Adult	20	255	20	255
NIBP	Mean	mmHg	Ped	20	160	20	160
NIBP	Mean	mmHg	Neo	20	120	20	120
NIBP	Diastolic	mmHg	Adult	10	245	10	245
NIBP	Diastolic	mmHg	Ped	10	150	10	150
NIBP	Diastolic	mmHg	Neo	10	100	10	100
Temperature	Temperature	°C	All	20	44	20.0	44.0
CO2 (LoFlo option)	CO2 (Et)	mmHg	All	0	76	none	150
CO2 (LoFlo option)	CO2 (Fi)	mmHg	All	3	50	none	50
CO2 (LoFlo option)	Resp. Rate	RPM	All	4	100	none	150
CO2 (AGENT option)	CO2 (Et)	mmHg	All	0	80	none	80
CO2 (AGENT option)	CO2 (Fi)	mmHg	All	0	80	none	80
CO2 (AGENT option)	Resp. Rate	RPM	All	2	100	none	N/A
AGENT*	Desflurane (Et & Fi)	vol%	All	Primary/ ISO: 0.15 Secondary/ ISO: 0.3	Primary/ISO: 0.4 Secondary/ ISO: 0.5	none	18.0
AGENT*	Enflurane (Et & Fi)	vol%	All	Primary/ ISO: 0.15 Secondary/ ISO: 0.3	Primary/ISO: 0.4 Secondary/ ISO: 0.5	none	5.0
AGENT*	Halothane (Et & Fi)	vol%	All	Primary/ ISO: 0.15 Secondary/ ISO: 0.3	Primary/ISO: 0.5 Secondary/ ISO: 0.6	none	5.0
AGENT*	Isoflurane (Et & Fi)	vol%	All	Primary/ ISO: 0.15 Secondary/ ISO: 0.3	Primary/ISO: 0.4 Secondary/ ISO: 0.5	none	5.0
AGENT*	Sevoflurane (Et & Fi)	vol%	All	Primary/ ISO: 0.15 Secondary/ ISO: 0.3	Primary/ISO: 0.4 Secondary/ ISO: 0.5	none	8.0
AGENT	N2O (Et)	%	All	0	100	none	none
AGENT	N2O (Fi)	%	All	0	100	none	none
AGENT	O2 (Fi)	%	All	0	100	none	none
Secondary pneumatic respiration	Resp. Rate	RPM	All	0	60	none	150

7.10 Alarms List

This section lists all patient alarms and technical alarms. The alarms are listed from high priority to low priority, followed by system messages.

7.10.1 High-Priority Patient Alarms

High-priority patient-alarm indicators:

- Alarm light: red and blinking rapidly.
- Alarm flag: red, positioned next to the numeric that is the source of the alarm.
- Vital sign value: red and blinking.
- High-priority audio indicator.

Alarm text	Alarm trigger
Apnea	The time between patient breaths exceeds the apnea time setting.
Desat	The MR400 detects a desaturation event.
Extreme Brady	A heart rate value violates the Extreme Bradycardia alarm setting.
Extreme Tachy	A heart rate value violates the Extreme Tachycardia alarm setting.
OVR replaces the heart rate value	A heart rate value is greater than the MR400 can measure.
UND replaces the heart rate value	A heart rate value is lower than the MR400 can measure.
Low O2	The MR400 measures oxygen at less than 18 percent.

7.10.2 High-Priority Technical Alarms

High-priority technical alarm indicators:

- Alarm light: red and blinking rapidly.
- Alarm flag: red, positioned in the system message area, or next to the numeric that is the source of the alarm.
- High-priority alarm audio.
- Alarms related to batteries: warning symbol in the status pane
- Alarms related to batteries: message in the **Status Information Panel**.
- Alarms related to batteries: low battery symbol in the **Status** pane 

Alarm text	Alarm trigger
All Alarms Are Off	The alarm limit settings (or the associated vital sign) for the following parameters are turned off: • Heart Rate • SpO2 Saturation • NIBP Systolic, Diastolic, and Mean • Invasive Pressure (P1 and P2) Systolic, Diastolic, and Mean • TEMP • CO2 RESP • $etCO_2$ This alarm excludes anesthesia and gas alarm limits.
Deflation Timeout	The noninvasive blood pressure cuff does not deflate within 80 seconds (neonatal patient type) or 150 seconds (adult and pediatric patient types)

Alarm text	Alarm trigger
No text  This symbol appears in the **Status** pane	The battery charge level is low. This symbol appears in the **Status** pane to indicate which battery is low (**Monitor**, **ECG**, or **SpO2**). Open the **Status Information Panel** to view descriptive text.

7.10.3 Medium-Priority Patient Alarms

Medium-priority patient-alarm indicators:

- Alarm light: yellow and blinking moderately.
- Alarm flag: yellow, positioned next to the numeric that is the source of the alarm.
- Vital sign value: yellow and blinking.
  - When the value is higher than the MR400 can measure, then **OVR** appears.
  - When the value is lower than the MR400 can measure, then **UND** appears.
- Medium-priority audio indicator.

Alarm text	Alarm trigger
High	A vital sign value is greater than the high alarm limit.
Low	A vital sign value is lower than the low alarm limit.
Vital sign value flashes **OVR**	A vital sign value is greater than the MR400 can measure. (All vital signs except ECG. ECG **OVR** is a high-priority patient alarm.)
Vital sign value flashes **UND**	A vital sign value is lower than the MR400 can measure. (All vital signs except ECG. ECG **UND** is a high-priority patient alarm.)

7.10.4 Medium-Priority Technical Alarms

Medium-priority technical alarm indicators:

- Alarm light: yellow and blinking moderately.
- Alarm flag: yellow, positioned next to the numeric that is the source of the alarm.
- Vital sign value: yellow and blinking. 3 dashes (**---**) indicate missing data.
- Medium-priority audio indicator.

Alarm text	Alarm trigger
No text The vital sign numeric shows only dashes (**---**)	Vital sign data is unavailable. The data is missing.
Catheter Disconnected	The invasive pressure catheter cannot be detected.
Multiple Agents	• The MR400 detects more than one anesthetic gas in a breath phase with ≥ 3 MAC. This alarm is low-priority when MAC is <3. • Anesthetic gases in the inspired and end-tidal breath phases are pure but differ from one another. • You change from one anesthetic agent to another. • Some hydrocarbons (for example, acetone or methane) trigger this alarm.
Transducer Faulty	The MR400 detects a problem with the invasive-pressure transducer.
Transducer Not Present	The MR400 cannot detect the invasive-pressure transducer.

7.10.5 Low-Priority Technical Alarms

Low-priority technical alarm indicators:

- Alarm light: blue and shines steadily.
- Alarm flag: blue, positioned next to the numeric that is the source of the alarm.
- Low-priority audio indicator.

Alarm text	Alarm trigger
Bad Probe	The SpO2 sensor is defective.
Cal Error	The MR400 detects a temperature sensor calibration error.
Check CO2 Sampling Line	The MR400 detects reduced flow in the CO_2 system.
Check for CO2 Occlusion	Sample line flow is less than 40 ml/min or the water trap may be full of fluid.
Check Probe	The temperature sensor connection is bad, has a sharp bend, or is damaged.
CO2 Low Flow	Sample line flow is 10 percent less than the sample flow for the patient type: • Adult: ≤ 180 ml/min • Pediatric: ≤ 180 ml/min • Neo: ≤ 135 ml/min
CO2 Out of Range	The CO_2 value is greater than the upper CO_2 limit.
CO2 Sensor Faulty	The MR400 detects an error with the CO_2 sensor.
CO2 Sensor Over Temp	The CO_2 sensor temperature is too high.
CO2 Warming Up	The CO_2 module is warming to operating temperature, which requires approximately 2 minutes.
CO2 Zero Required	Calibrate the CO_2 module. See "11.11 Zeroing CO_2" on page 133.
Communication Error	The MR400 detects an internal noninvasive pressure error. Stop using noninvasive pressure and contact Service.
Erratic	The SpO2 clip or grip may be improperly positioned. Or, the SpO2 sensor may be faulty.
Expired Probe	The MR400 detects an issue with the temperature sensor.
Hardware Error	The MR400 detects an accessory hardware failure, typically because the data update period exceeded 30 seconds.
Inflation Timeout	The MR400 cannot inflate the noninvasive blood pressure cuff within the time limit.
Interference	The SpO2 clip or grip may require repositioning or replacement. • Check the clip or grip position on the patient. • Try a different limb or site. • Ensure that the SpO2 module is outside of the bore. • Reposition the SpO2 module. • Replace the clip or grip.

Alarm text	Alarm trigger
Lead Fail	The MR400 detects a problem with an ECG lead or electrode. This alarm includes a unique notification type. The **Lead Fail** indicator that appears below the heart rate to indicate which lead wire, lead clip, or electrode is causing the problem. This indicator uses AAMI abbreviations only. • **LL** = left leg (IEC cable: F) • **LA** = left arm (IEC cable: L) • **RA** = right arm (IEC cable: R) • **LL LA RA** = all leads or right leg (IEC cable: N)
Lead Saturation	The ECG input signal is too large to process.
Low Perfusion	SpO2 accuracy may be compromised due to low perfusion.
Magnetic Field Too High	The gauss limit is exceeded. If you position the cart too close to the magnet, the cart cannot charge the batteries due to magnetic field interference. Move the cart further away from the magnet. See "6.3 Moving and Positioning the Cart" on page 57.
Measurement Failed	The noninvasive pressure measurement failed.
Measurement Timeout	The noninvasive pressure measurement took too long.
Module Not Calibrated	Noninvasive pressure is not calibrated.
Motor Speed Error	The MR400 is too close to the MR magnet.
Multiple Agents	• The MR400 detects more than one anesthetic gas in a breath phase with <3 MAC. This alarm is high-priority when MAC is ≥ 3. • Anesthetic gases in the inspired and end-tidal breath phases are pure but differ from one another. • You changed one anesthetic agent to another. • Some hydrocarbons (for example, acetone or methane) trigger this alarm.
No Probe	The temperature sensor or SpO2 sensor is not connected to the MR400 properly.
Noise	The SpO2 system has excessive noise.
Non-Pulsat	The pulse is too weak.
O2 Sensor Fail	O2 sensor has failed or expired. Replace the O2 sensor.
O2 Sensor Not Present	Possible O2 sensor failure.
Occlusion	The sample line is occluded.
Occlusion at Start	When the MR400 starts, it detects an occluded sample line.
Over Pressure	The noninvasive pressure is too high for the patient type.
Performing CO2 Zero	This message appears during CO_2 sensor calibration.
Persistent CO2 Occlusion	The MR400 detects reduced CO_2 flow longer than 2 minutes.
Pressure Correction	The MR400 detects an error in the noninvasive pressure system.
Probe Off	An SpO2 accessory is incorrectly positioned.
Pulse?	Pulse data is questionable.
Residual Pressure	Residual pressure remains in the noninvasive pressure system. Reconnect the noninvasive pressure accessories.
Searching	The MR400 is searching for SpO2 data, which may require 20 seconds.

Alarm text	Alarm trigger
Wrong Probe	The temperature sensor or SpO2 sensor connected to the MR400 is not the proper type.

7.10.6 System Messages

System messages appear in the system message area or in the flag areas.

Message text	Message trigger
Alarm Light Paused Message in the system message area	The alarm light is paused (and alarm sound is off).
Audio and Alarm Light Paused Message in the system message area	The alarm audio and alarm light are paused.
Audio Off Message in the system message area	Alarm audio is silenced.
Audio Paused Message in the system message area	Alarm audio is paused (and alarm light is off).
CAUTION **Magnet field too strong.** **Move monitor away from magnet.** Message in the system message area	The MR400 is too close to the magnet.
CO2 Zero in seconds Notification flag in the CO2 flag area	This message includes a timer that counts down from 120 seconds. This timer lets you know the time until the next automatic zero.
Change NIBP Cuff Notification flag in the NIBP flag area	The **Patient Type** was changed so the noninvasive blood pressure cuff should be changed.
Check Alarm Volume Message in the system message area	This notification appears when you turn on the cart or when you load user settings from a flash drive. Listen as the MR400 plays sample alarm audio. Ensure that the volume is high enough to alert you to an alarm.
ECG Test Signal Notification flag in the ECG flag area	ECG test signal is on.
Overscale Notification flag in the ECG flag area	Displayed within 10 seconds of detection, where the size of the ECG waveform is too large and the tops of the ECG waveforms are clipped (that is, cut off). Reduce the size using the Scale setting. See "8.15.1 Scale" on page 103.
Real Tones Disabled Message in the system message area	When you adjust the alarm audio volume, alarm audio is suspended while the MR400 plays sample audio. To remove the flag, close the **Alarm Volume** menu.

Message text	Message trigger
Shutting Down Message in the system message area	The system is turning off.
Simulation Message in the system message area	The system is running a simulation. This message remains until you stop the simulation. See "2.4.8.9 Administrative Settings Menu" on page 31
Suspended Message in the system message area	The system suspended. This message remains until you resume monitoring. See "7.3.7 About Quick Access Buttons and Alarm Behavior" on page 64.
Updating Message in the system message area	The system is recalling a user settings file or is changing the channel.
WARNING **Internal Battery Switch is turned off. Please turn on the switch and press "OK" to use internal batteries.** Message in the system message area	The internal battery switch is off. See "5.2.2.1 Turning Reserve Batteries On and Off" on page 49.

7.10.7 Status Information Panel Messages

Status Information Panel messages may include a warning symbol in the status pane.

Message Text, Location, Indication	Message trigger
Battery OK Message in the Status Information Panel	No battery issues exist. No action required.
Cannot Charge Warning symbol in the Status pane and message in the Status Information Panel	The MR400 cannot charge the battery safely. Replace the battery. If the issue persists, contact Service.
Charging Message in the Status Information Panel	The MR400 is charging the battery. No action required.
Charging Inhibited Warning symbol in the Status pane and message in the Status Information Panel	The power supply temperature is too high. The power supply cannot charge batteries until the power supply temperature is acceptable.
Communication Fail Warning symbol in the Status pane and plain text message in the Status Information Panel	There is an issue with the battery in one of the main slots. Replace the battery. If the issue persists, contact Service.

Message Text, Location, Indication	Message trigger
High magnetic field - Batteries are not being charged. Warning symbol in the Status pane and message in the Status Information Panel	The cart is within the 5,000-gauss line. Move the cart further away from the magnet.
No Battery Message in the Status Information Panel	The MR400 does not detect a battery in one of the main battery slots.
Over Temperature Warning symbol in the Status pane and message in the Status Information Panel	The battery is too hot to operate. Replace the battery. If the issue persists, contact Service.
Overcharged Warning symbol in the Status pane and message in the Status Information Panel	The MR400 charged the battery over its maximum voltage. Replace battery. If the issue persists, contact Service.
Printer Door Open Warning symbol in the Status pane and message in the Status Information Panel	The printer door is open. Close the printer door.
Printer Hardware Error Warning symbol in the Status pane and message in the Status Information Panel	The MR400 detects a problem with the connected printer.
Printer Not Connected Warning symbol in the Status pane and message in the Status Information Panel	The MR400 detects a problem with the connected printer. See the remote monitor
Printer Option Not Installed Message in the Status Information Panel	The printer connected to the remote monitor has an issue.
Printer Paper Out Warning symbol in the Status pane and message in the Status Information Panel	The printer is out of paper. Load a roll of paper.
Printer Ready Message in the Status Information Panel	The printer is ready to print. No action required.
Reserve Batteries In Use Warning symbol in the Status pane and message in the Status Information Panel	The cart's main batteries are drained. The cart is using the reserve batteries. Insert charged batteries or plug the cart in to charge all batteries.
Slow Charging Warning symbol in the Status pane and message in the Status Information Panel	The cart is operating on A/C power. The cart battery charge level is low and is charging slowly.

Message Text, Location, Indication	Message trigger
System Low Battery Warning symbol in the Status pane and message in the Status Information Panel	The cart's combined main and reserve battery power is too low. Insert charged batteries or plug the cart in to charge all batteries.
Very Low Warning symbol in the Status pane and message in the Status Information Panel	The cart is operating on battery power only and there is no usable power remaining. Plug the cart in or replace the battery.

8: Monitoring ECG

8.1 About Monitoring ECG

ECG monitoring in the MR environment is different from other environments. Some of the key differences are as follows:

- The MRI scanner generates electromagnetic fields that interfere with ECG signals. Cable and electrode placement are different in the MR environment.
- The magnetohydrodynamic effect (MHD) can impact a patient's blood flow. In some patients, the impact is significant. When you move a patient into the bore, you may see an immediate T-Wave or ST segment elevation. You must determine whether the elevation is due to a change in the patient's condition changed or due to the MHD effect.
- The MR environment presents a risk of radio frequency heating, which may injure a patient. Accessories may form a loop, which increases the risk of heating. A loop can be circular, U-shaped, or S-shaped. A loop may include an implant. Although the MR400 ECG accessories are designed to minimize the risk of heating, you must adhere to placement instructions and monitor the patient for heating. See "8.11 Positioning the ECG Cable and ECG Module" on page 98.

8.2 ECG Safety

WARNINGS

- Arrhythmias, erratic heartbeats, operation of electrical stimulators, pacemakers, and patient motion can result in inaccurate heart rate readings. If questionable readings are obtained, check the patient's vital signs via SpO2.
- Rate meters may continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias. Do not rely entirely upon heart rate meter alarms. Keep pacemaker patients under close surveillance. Heart rate meters may continue to count pacemaker pulses during occurrences of cardiac arrest or some arrhythmias when ECG is the heart rate source.
- During cardiac arrest or other arrhythmias, when ECG is the heart rate source, the MR400 may show inaccurate heart rate data. During these events, change the heart rate source to SpO2. Check the patient. Verify the heart rate by an alternate source.

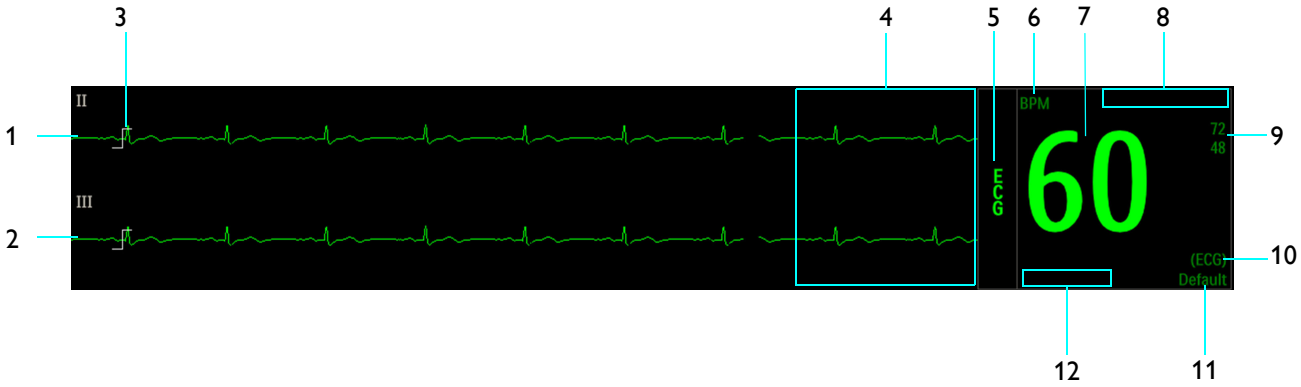
8.3 Monitoring ECG for Patients with Pacemakers

Heart rate meters may continue to count pacemaker pulses during occurrences of cardiac arrest or some arrhythmias when ECG is the heart rate source. When

monitoring patients who have MR-conditional pacemakers or electrical stimulators, use SpO2 as the heart rate source to prevent inaccurate measurements.

8.4 About the ECG Waveforms and Numerics

The following image shows the parts of the ECG waveforms and numerics



Part		Description
1 2	ECG waveforms	1 or 2 ECG waveforms appear here (**ECG 1** and **ECG 2**). The **ECG 1** waveform and label is based on the **Trace A Lead** setting. The **ECG 2** label and waveform is based on the **Trace B Lead** setting. See "8.15 ECG Menu" on page 101.
3	Scale indicator	Shows 1-mV signal amplitude on the waveform. Ideally, the waveform is twice the size of this scale. Minimally, the waveform is equal to this scale.
4	Flag and trend area	Alarm flags and trend arrows appear here. See "7: Alarms" on page 59 and "14: Trends and Printing" on page 155.
5	**ECG** label	Select this label to open the **ECG** menu. See "8.15 ECG Menu" on page 101.
6	Unit of measure	Shows the unit of measure: **BPM** (beats per minute).
7	Heart rate value	Shows the heart rate value. • **---** replaces the value when the MR400 can no longer measure data • **OVR** replaces the value when the value is higher than the MR400 can measure. • **UND** replaces the value when the value is lower than the MR400 can measure. To change the heart rate source, see "8.15.2 Heart Rate Source" on page 103.
8	Control indication	**Magnet Control** appears when the MRI system is controlling lead settings, gradient artifact filtering, and T-Wave Suppression. **Magnet Filter** appears when the MRI system is filtering ECG data and controlling lead settings, gradient artifact filtering, and T-Wave Suppression.
9	Upper and lower alarm limits	Shows the upper and lower limits of the heart rate alarm. Select to change the heart rate alarm limits. See "7: Alarms" on page 59.
10	Heart rate source	Shows the source used to measure the heart rate. See "8.15.2 Heart Rate Source" on page 103.
11	Filter mode	Shows the active ECG filtering mode. See "8.15.3 Filter Mode" on page 103.

Part		Description
12	Electrode fault indication	Shows electrode fault indicators when the MR400 detects a disconnected ECG lead or bad electrode. See "7.10.5 Low-Priority Technical Alarms" on page 80.

8.5 Monitoring ECG Process Overview

Step	Action	More Information
1	Turn on the ECG parameter. Select **Setup** > **Monitor** > **Parameters** > **ECG** > **On**.	"2.4.8.2 Parameters Menu" on page 26
2	Select a patient type or select a profile. If you select a profile, confirm that the patient type is correct.	On the Information bar, select **Patient Type** and then select a type. See "6.2 Selecting the Patient Type" on page 56. On the Information bar, select **User Settings** and then select a profile. See "2.4.9.3 Selecting a User Settings Profile" on page 34.
3	Confirm that alarm settings are appropriate for the patient. Adjust alarm limits if necessary.	"7.5 Setting Alarms and Alarm Limits" on page 67
4	Select a cable and electrodes.	"8.7 Selecting the ECG Cable and Electrodes Pair" on page 92
5	Attach the cable to the ECG module and electrodes.	"8.11 Positioning the ECG Cable and ECG Module" on page 98
6	Identify where to place the electrodes to the patient.	"8.9 Identifying the Electrodes Placement Site" on page 94
7	Prep the patient and place the electrodes.	"8.10 Placing the Electrodes on the Patient" on page 97
8	Position the patient, the lead cable, and the ECG module for scanning.	"8.11 Positioning the ECG Cable and ECG Module" on page 98
9	Evaluate the ECG waveform. Optimize system settings and positioning.	"8.12 Optimizing ECG Data" on page 99
10	Move the patient and the cart into the magnet room.	"6.3 Moving and Positioning the Cart" on page 57
11	Slide the patient into the bore, and reevaluate the waveform. Resolve any issues.	"8.12 Optimizing ECG Data" on page 99
12	Conduct the scan.	"8.13 Monitoring ECG During the Scan" on page 100
13	Discontinue monitoring.	"8.14 To Discontinue Monitoring ECG" on page 101

8.6 ECG Monitoring Requirements

Monitoring ECG requires the following:

- ECG monitoring is on. See "2.4.8.2 Parameters Menu" on page 26.
- A powered ECG module that is communicating on the same channel as the MR400 cart. See "5.3 About Module Power" on page 51 and "4.4 SpO2 and ECG Module Communication" on page 42.
- An ECG cable and electrodes pair according to "8.7 Selecting the ECG Cable and Electrodes Pair" on page 92.
- ECG skin prep gel. See "2.3 Accessory List" on page 14.

8.6.1 About the ECG Module

The ECG module receives and processes signals from the ECG cable. Then the module transmits the signals to the cart.

The ECG module is reusable (multi-patient, multi-use). Clean and disinfect it before use and between patients.

8.6.1.1 ECG Module Intended Use and Indications for Use

Intended use	The Wireless ECG 3.0 Module's use enables the Intended Use of the connected compatible MRI Patient Monitoring System. The MRI Patient Monitoring System is intended to monitor vital signs for patients undergoing MRI procedures and to provide signals for synchronization for the MRI scanner. The MRI Patient Monitoring System is intended for use by healthcare professionals. The MRI Patient Monitoring System provides monitoring for the following vital sign parameter: Electrocardiograph (ECG).
Indications for use	The Wireless ECG 3.0 Module is indicated for use with the ECG cable and the ECG electrode when continuous electrocardiograph (ECG) monitoring or cardiac gating is required during MRI procedures.

8.6.2 About the ECG Cable

The ECG cable transmits electrical signals from the electrodes to the module. The cable is reusable (multi-patient, multi-use). Clean and disinfect it before use and between patients.

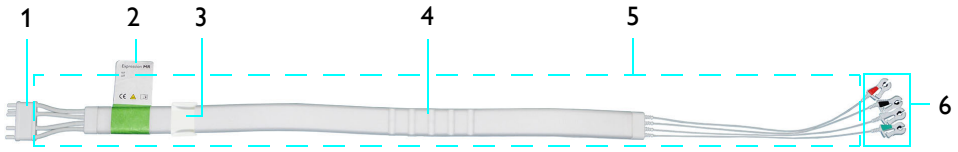
Never apply excessive force to the wires. When storing the cable, do not let it touch the ground.

WARNING

Do not use the cable clip while monitoring a patient.

CAUTION

ECG cable lead wires are delicate. To prevent damage, use the lead clips to attach and remove the lead wires.



Description	
1	Connector
2	Cable label
3	Cable clip
4	Cable trunk with foam insulator
5	Lead wires
6	Lead clips

8.6.2.1 ECG Cables Intended Use and Indications for Use

Intended use	The ECG Cable's use enables the Intended Use of the connected compatible MRI Patient Monitoring System. The MRI Patient Monitoring System is intended to monitor vital signs for patients undergoing MRI procedures and to provide signals for synchronization for the MRI scanner. The MRI Patient Monitoring System is intended for use by healthcare professionals. The MRI Patient Monitoring System provides monitoring for the following vital sign parameter: Electrocardiograph (ECG).
Indications for use	The ECG cables are indicated for use with the ECG electrodes and the wireless ECG module when continuous electrocardiograph (ECG) monitoring or cardiac gating is required during MRI procedures.

8.6.3 About the ECG Electrodes

ECG electrodes are conductive pads that attach to a patient. They transmit electrical signals from the patient to the cable. Different electrodes are available to meet each patient requirement: multiple patches, single patch, and neonatal.

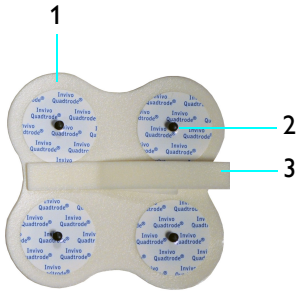
The electrodes are single use. Do not reuse.

CAUTION

Use electrodes immediately after you open the package.

The components of an electrode patch are:

Description	
1	Foam insulator
2	Electrode contact
3	Lead retainer (Single Patch ECG Electrodes only)



8.6.3.1 ECG Electrodes Intended Use and Indications for Use

Intended use	The ECG Electrode's use enables the Intended Use of the connected compatible MRI Patient Monitoring System. The MRI Patient Monitoring System is intended to monitor vital signs for patients undergoing MRI procedures and to provide signals for synchronization for the MRI scanner. The MRI Patient Monitoring System is intended for use by healthcare professionals. The MRI Patient Monitoring System provides monitoring for the following vital sign parameter: Electrocardiograph (ECG).
Indications for use	The ECG electrodes are indicated for use with the ECG cable and wireless ECG module when continuous electrocardiograph (ECG) monitoring or cardiac gating is required during MRI procedures.

8.7 Selecting the ECG Cable and Electrodes Pair

Select a cable and electrodes pair as follows.

If the patient weight is 10 kg (22 lb) or less, then pair a neonatal cable with neonatal electrodes.

Description	Reference number	Electrodes image
Neonatal ECG 3.0 Cable AAMI Neonatal ECG 3.0 Cable IEC Neonatal ECG Electrodes	989803193741 989803193771 989803179051	

If the patient weight is 10 kg (22 pounds) or more, then pair a standard cable with single-patch electrodes.

Description	Reference number	Electrodes image
Standard ECG 3.0 Cable AAMI Standard ECG 3.0 Cable IEC Single Patch ECG Electrodes	989803193731 989803193761 989803179031	

If the patient weight is 10 kg (22 pounds) or more and single-patch electrode placement is difficult, then pair a wide cable with multiple-patch electrodes.

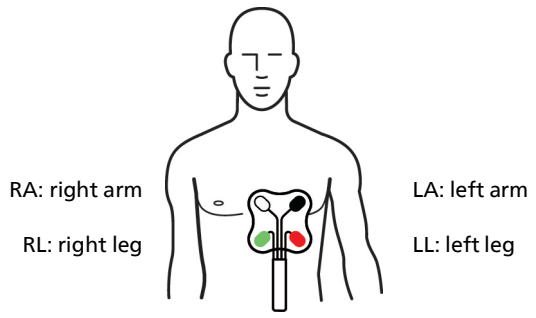
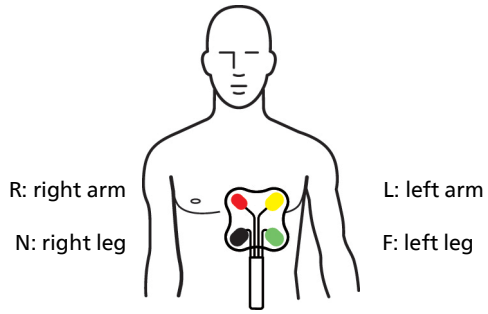
Description	Reference number	Electrodes image
Wide ECG 3.0 Cable AAMI Wide ECG 3.0 Cable IEC Multiple Patch ECG Electrodes	989803193721 989803193751 989803179041	

8.8 Attaching the ECG Cable to the Module and Electrodes

AAMI (Association for the Advancement of Medical Instrumentation) and IEC (International Electrotechnical Commission) cable labels and colors are different from each other.

Lead clips on the cables reference electrode contacts. In the MR environment, you place electrodes close to the heart. See the reference images in "8.9 Identifying the Electrodes Placement Site" on page 94.

To help you attach the lead clips correctly, the following images show where to place the clips on the electrodes.

AAMI Cable Connections	IEC Cable Connections
	

To attach the cable to the module and to the electrode contacts, follow these steps.

Step	Action
1	Inspect the cable and module. Do not use a damaged accessory.
2	Gently insert the connector of the ECG lead cable into the cable port on the ECG module. 
3	Inspect the electrodes and their package. • If the package is damaged or expired, discard the electrodes. • If the electrodes are damaged or dried out, discard the electrodes.
4	Squeeze the clips to attach them to the electrode contacts. When present, secure the lead wires with the lead retainer clip.

8.9 Identifying the Electrodes Placement Site

Electrode placement in the MR environment is different from placement outside the MR environment. Placing electrodes over the heart is important for optimal ECG performance. Do not place the electrodes on the patient's limbs.

Placement differs based on patient type:

- Adult and pediatric patients: align the top 2 electrodes with the fourth intercostal space.
- Infant and neonatal patients: center electrodes over the sternum and the fourth intercostal space.

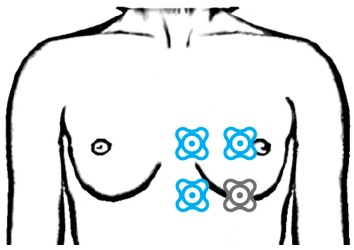
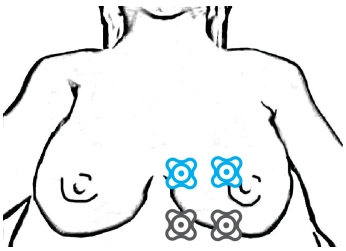
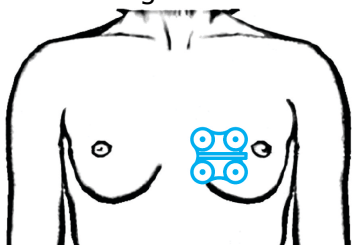
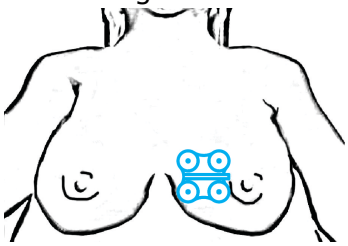
Changing electrode placement can affect the ECG signal as follows:

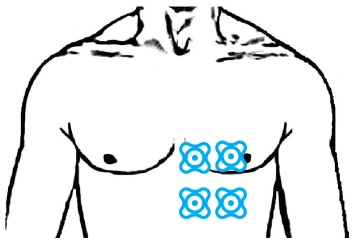
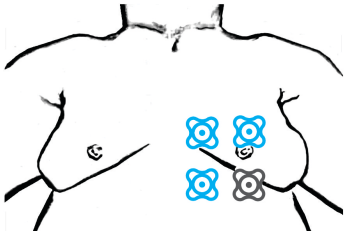
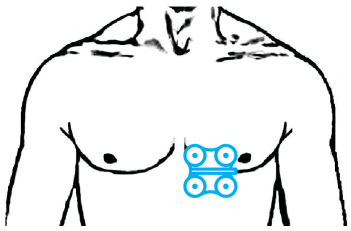
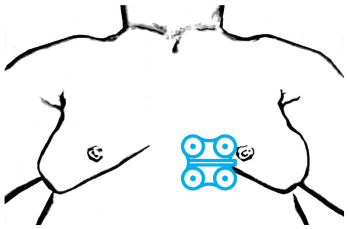
- Above the fourth intercostal space:
  - Increases T-wave amplitude
  - Increases the susceptibility to static field (B0) effects.
- Below the fourth intercostal space:
  - Decreases T-wave amplitude
  - Increases the distance from the electrode to the aorta
  - Decreases susceptibility to static field (B0) effects
  - Increases the ECG waveform amplitude
- Proximity to the sternum:
  - Closer to the sternum: increases the ECG waveform amplitude and respiration noise.
  - Farther from the sternum: decreases the ECG waveform amplitude and respiration noise.

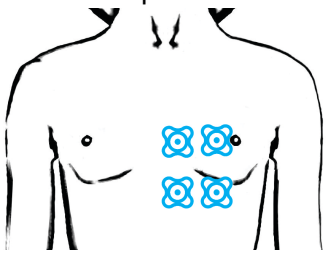
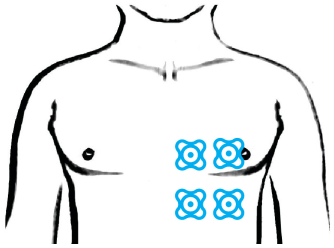
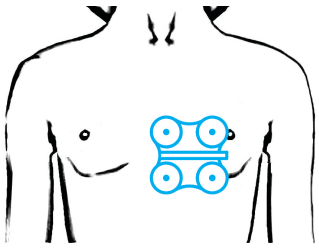
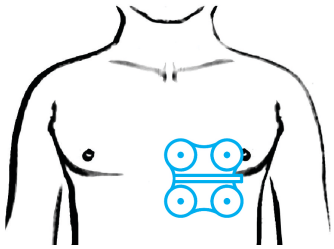
When using multiple-patch electrodes, keep the electrodes close together to prevent excessive noise.

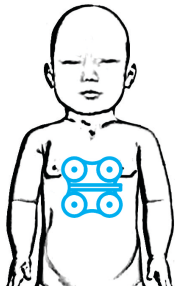
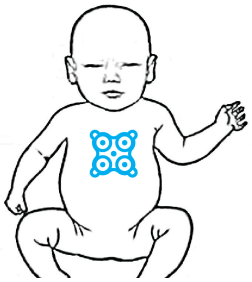
The following images show electrode placement according to patient type, including the preferred electrode type and location for different patient body sizes.

Gray images show placement against the ribcage under the breast.

Adult Female: Average Weight	**Adult Female: Overweight**
Multiple Patch Preferred 	Multiple Patch Preferred 
Single Patch 	Single Patch 

Adult Male: Average Weight	Adult Male: Overweight
Multiple Patch 	Multiple Patch Preferred 
Single Patch Preferred 	Single Patch 

Pediatric female	Pediatric male
Multiple Patch 	Multiple Patch 
Single Patch Preferred 	Single Patch Preferred 

Infants and Neonates	
Single Patch	Neonatal
	

8.10 Placing the Electrodes on the Patient

WARNING

Ensure that the electrodes and cables do not contact other conductive parts, including grounded conductive parts.

CAUTION

Use electrodes immediately after you open the package.

Proper site preparation and placement are critical for optimal ECG performance. If skin contact is poor, discard the electrodes and repeat the process.

Do not use isopropyl alcohol to prepare the skin.

To prepare the electrode site on a patient, follow these steps.

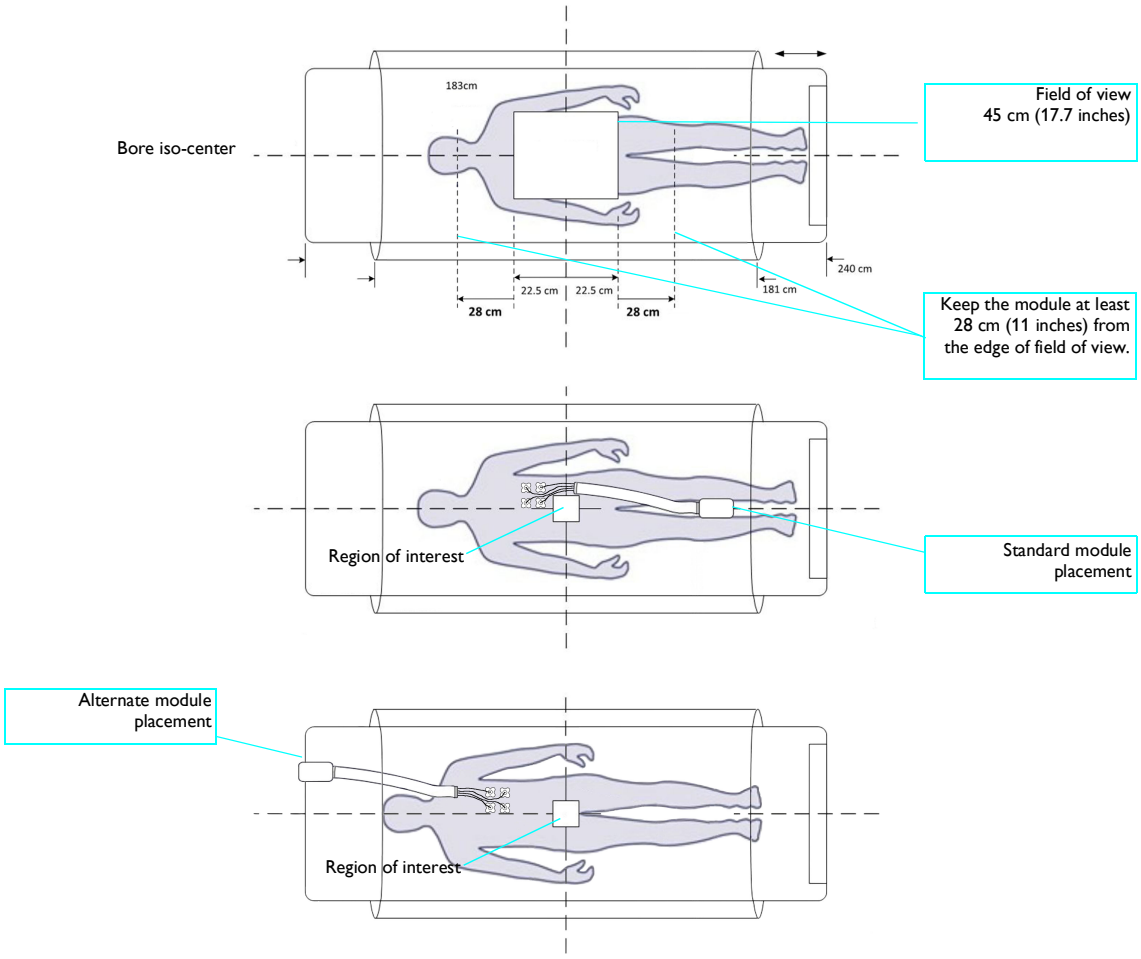
Step	Action
1	Inspect the electrodes. Do not use a damaged accessory.
2	Select the placement site, according to "8.9 Identifying the Electrodes Placement Site" on page 94.
3	Remove any hair present at the placement site.
4	Apply ECG Skin Prep Gel (REF 989803152291) to a gauze pad.
5	Briskly rub the area with the gauze pad (the skin may turn pink).
6	Remove excess gel with a clean gauze pad.

Step	Action
7	Place the electrodes on the patient.
8	Check the lead wires. Ensure that the wires do not cross or form loops.

8.11 Positioning the ECG Cable and ECG Module

You can place the ECG module and lead cable in the MR system bore. The module must remain 28 cm (11 in) out of the field of view.

The following figure shows 2 options for module placement:



To position the ECG module and cable, follow these steps.

Step	Action
1	Arrange the cable and lead wires in a straight line. Any loop (circular, U-shaped, S-shaped) may cause heating, which may harm the patient.
2	Ensure that the cables do not touch the bore. Contact with the bore may cause heating, which may harm the patient.

Step	Action
3	Ensure that the cables do not touch bare skin. To minimize vibrations, cushion the module.
4	Position the module outside the bore when possible. If you must place the module inside the bore, place it near (or on) the patient and 28 cm (11 inches) outside the field of view. Ensure that module is within 9.1 m (30 feet) of the MR400, in the same MRI room or in the same shielded room, and is set to the same channel as the cart.

8.12 Optimizing ECG Data

Before moving the patient into the bore, check the ECG signal.

Check the waveform amplitude. At minimum, the QRS complex should be the same height as the scale indicator (1 mV). Ideally, the QRS complex would be twice the size of the scale indicator.

Each patient may react to the magnet differently, which can result in a noisy waveform. When assessing a patient, use all vital signs together. If you see questionable data, check the patient's vital signs by alternate methods.

Electrode placement, scan type, slice angle, and slice thickness may all affect ECG performance.

The following table lists possible ECG troubleshooting methods:

Issue	**Suggested solutions**	**See section**
The QRS complex is too small, indicating a weak signal	• Replace the electrodes. Ensure you follow the process. • Change the **Trace A Lead** or **Trace B Lead** setting. The lead view setting can change the signal amplitude.	"8.15 ECG Menu" on page 101 "8.10 Placing the Electrodes on the Patient" on page 97
Gradient artifacts increase during a scan	• Change the filter settings. • Change the **Trace A Lead** or **Trace B Lead** setting.	"8.15.3 Filter Mode" on page 103 "8.15 ECG Menu" on page 101
Incorrect cables or electrodes	Ensure you use the correct cable and electrodes pair.	"8.7 Selecting the ECG Cable and Electrodes Pair" on page 92
Damaged ECG cable leads	Inspect the cable and leads to ensure they are not damaged.	"8.8 Attaching the ECG Cable to the Module and Electrodes" on page 93
Expired or dry electrodes	Ensure that the electrodes are not expired or dry.	
Improper electrode placement	Ensure that you place the electrodes according to the diagrams.	"8.9 Identifying the Electrodes Placement Site" on page 94
Excessive distance between electrodes		
Alcohol-based products	Do not use alcohol-based products to prepare the patient.	"8.10 Placing the Electrodes on the Patient" on page 97

Issue	Suggested solutions	See section
Incorrect ECG cable and electrode connection	Ensure that you connect the cable and electrodes correctly.	"8.8 Attaching the ECG Cable to the Module and Electrodes" on page 93
The ECG module is inside the field of view	Move the module outside the field of view.	"8.11 Positioning the ECG Cable and ECG Module" on page 98
MR vibrations affect the ECG module	Place the module on a cushioned surface.	
The module is too far from the iso-center	Move the module closer to the iso-center.	
The cable is too close to a coil	Route the cable so it is further away from the coil.	
The module or cable is inside a coil	Reposition the module and cable to be outside of the coil.	
The MR400 is inside the 5,000-gauss line	Move the MR400 outside the 5,000-gauss line.	"6.3 Moving and Positioning the Cart" on page 57
You set the filter mode to **Monitor**	Do not use the **Monitor** filter during active MRI sequences.	"8.15.3 Filter Mode" on page 103
Magnet settings result in poor ECG data	Change the magnet's settings. Settings that may impact the ECG signal: • Echo Time (TE) • Repetition Time (TR) • Inversion Time (TI) • Image plane orientation • Fat suppression • Peripheral nerve stimulation level (PNS) • Gradient strength level	See the magnet's instructions for use.
Despite troubleshooting, the ECG signal is poor	Use **SpO2** for the heart rate source. To change the heart rate source: 1. Select the **ECG** label. 2. In the **ECG** menu, select **HR Source**, and then select **SpO2**.	"8.15.2 Heart Rate Source" on page 103

8.13 Monitoring ECG During the Scan

WARNING

Limit SAR levels and scan times when using the cable or electrode to prevent burns.

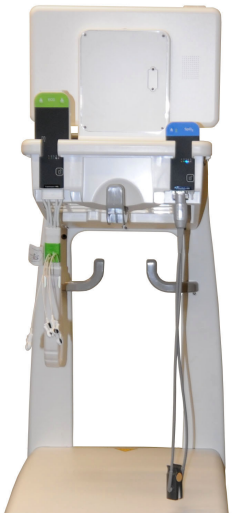
During the scan, perform the following actions.

- Check the patient to ensure that heating does not occur.
- Ensure the module and cable are positioned correctly.
- Observe the ECG waveform and adjust as necessary. See "8.12 Optimizing ECG Data" on page 99
- Respond promptly to alarms and system messages. See "7.10 Alarms List" on page 78.

- If you drop the ECG module or module battery, see "16.8 Testing a Dropped Module" on page 173.

8.14 To Discontinue Monitoring ECG

After scanning is complete, clean and disinfect reusable accessories and the cart. Store reusable accessories on the cart.



1. Disconnect the electrodes from the patient.
2. Remove any batteries from the module. Store batteries in the battery charger (optional).
3. Clean and disinfect the cart, module, and cable. See "15: Cleaning and Disinfection" on page 161.
4. Use the lead clips to remove the electrodes. Discard the electrodes according to local regulations.
5. Loop the cable and secure it to the cable clip to keep the cable off the floor.
6. Slide the module (with the cable attached) into the module holder on the cart.

8.15 ECG Menu

Use the ECG menu to control ECG monitoring functions.

To open the **ECG** menu, select the **ECG** label.

The **ECG** menu contains the following controls:

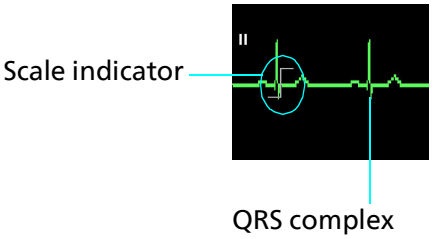
Control name	Options	Description
Trace A Lead **Trace B Lead**	• **Off** (Trace B factory default) • **I** • **II** (Trace A factory default) • **III** • **AVL** • **AVR** • **AVF**	Select the waveform that you want the MR400 to show in the main screen. -and- Select the leads that the MR400 uses to create the waveform. **Trace A Lead** sets the ECG 1 waveform. **Trace B Lead** sets the ECG 2 waveform.
Scale	• **Auto** • **1x** • **5x** • **10x** (factory default) • **15x** • **20x** • **25x** • **30x** • **40x**	Select the size of the waveform. This setting does not change the signal strength or signal analysis. See "8.15.1 Scale" on page 103.

Control name	Options	Description
Gating Source	• **ECG** (factory default) • **Pulse**	Select the gating source. See "17: Gating Feature" on page 179.
HR Source	• **Auto** • **ECG** (factory default) • **ABP** • **SpO2**	Select the heart rate source. See "8.15.2 Heart Rate Source" on page 103.
HR Tone Source	• **Off** (factory default) • **QRS** • **SpO2**	Turn off the heart rate tone or select the source. This control is identical to **HR Tone Source** in the **Monitor Setup** > **Sound Adjust** menu and in the **SpO2** menu. When **SpO2** is the source, the pitch rises and falls to match changes in oxygenation.
Filter Mode	• **Monitor** • **Default** (factory default) • **Advanced 1** • **Advanced 2**	See "8.15.3 Filter Mode" on page 103.
Extreme HR	• **Off** • **On** (factory default)	Turn on Extreme Bradycardia and Extreme Tachycardia alarms. See "7.5 Setting Alarms and Alarm Limits" on page 67.
Pediatric ECG	• **Off** (factory default) • **On**	The MR400 adds pediatric algorithms. When you select the **Patient Type**, the MR400 changes this setting automatically as follows: • **Adult**: Automatically turned off. You can change the setting. • **Pediatric**: Automatically turned on. You can change the setting. • **Neo**: Automatically turned on. You cannot change the setting.
T-Wave Suppression	• **Off** (factory default) • **On**	Turn on to reduce T-wave amplitude when the T-wave is large due to the magnetohydrodynamic effect (MHD), which can prevent gating. When the **Filter Mode** is **Monitor**, this control is disabled. When **Magnet Control** is **Auto**, this control is disabled because the magnet filters the signal.
Magnet Control	• **Auto** (factory default) • **Disabled**	The MRI system can control lead settings, gradient artifact filtering, and T-Wave Suppression. See the gating instructions in the MRI system instructions for use.

8.15.1 Scale

The **Scale** setting changes the size of the waveform on the screen. It does not change the signal strength or signal analysis.

Typically, the **Auto** setting is sufficient for typical scans.



If the setting results in a waveform with distorted or clipped peaks, the **Overscale** flag appears. Decrease the scale.

If the monitored heart rate falls below 40 BPM and the scale is above 10mm/mV, the scale defaults to 10mm/mV.

To select the scale, select the **ECG** label. In the **Scale** list, select the scale.

8.15.2 Heart Rate Source

Selects the source of the heart rate that appears in the **ECG** and **SpO2** numerics. **HR Source** in the **ECG** menu is identical to **HR Source** in the **SpO2**, **P1** and **P2** menus.

The following options are available:

- **Auto**
  The MR400 selects the first source that reports valid patient data and has the highest priority. If a source does not produce valid data for 10 seconds, the MR400 selects the next highest source.
  - **ECG** (highest priority)
  - **P1** (requires ABP label)
  - **P2** (requires ABP label)
  - **SpO2** (lowest priority)
- **ECG** sets ECG as the source.
- **ABP** sets the invasive pressure channel labeled ABP as the source. The MR400 may prompt you to turn on invasive pressure and set the pressure waveform label to **ABP**. See "12.9 Invasive Pressure Menus" on page 144.
- **SpO2** sets SpO2 as the source.

Note—Heart rate meters may continue to count pacemaker pulses during occurrences of cardiac arrest or some arrhythmias when ECG is the heart rate source. When monitoring patients who have MR-conditional pacemakers or electrical stimulators, use SpO2 as the heart rate source to prevent inaccurate measurements.

8.15.3 Filter Mode

WARNING

Filters may remove pacemaker pulses. Use SpO2 as the heart rate source when you monitor a patient with a pacemaker.

Use **Filter Mode** to change how the MR400 filters ECG signals. **Filter Mode** is disabled when **Magnet Control** or **Magnet Filter** appears. For simple sequences that do not require cardiac gating, start with the default filter. Change this setting if gradient artifacts appear.

- **Monitor:**
  Filters based on AAMI and IEC specifications. Use when preparing the patient. Do not use during a scan.
- **Default**
  Optimized for most scans on 1.5T and 3.0T MR systems.
- **Advanced 1**
  Filters gradients for more challenging scans.
- **Advanced 2**
  A different type of gradient filter. Try Advanced 1, then Advanced 2.

To select the **Filter Mode** in the **ECG** menu, select the **ECG** label > **Filter Mode** and then select the filter mode.

To select the **Filter Mode** in the main screen, select the **ECG Filter** quick access button and then select the filter mode.

9: Monitoring SpO2

9.1 About Monitoring SpO2

The MR400 provides the following information:

- Functional peripheral oxygen saturation (SpO2)
- Pulsatile waveform
- Heart rate
- Perfusion index value

9.2 SpO2 Monitoring Safety

WARNINGS

- The following may cause inaccurate SpO2 values and prolonged measurement time:
  - Dysfunctional hemoglobins (such as carboxyhemoglobin or methemoglobin)
  - Arterial catheters
  - Intravascular venous infusion lines and significant levels of intravascular dyes
  - Inflated noninvasive blood pressure cuffs
  - Ambient light
  - Physical movement
  - Arrhythmias and erratic heartbeats
  - Diagnostic testing
  - Electromagnetic interference
  - Electrosurgical units
  - Presence of dyes or pigments at the application site
  - Incorrect clip, grip, or sensor position
  - Inadequate perfusion
- While monitoring SpO2, routinely check the patient for heating. Routinely inspect the clip or grip for proper positioning.
- Cover the clip or grip to shield it from ambient light.

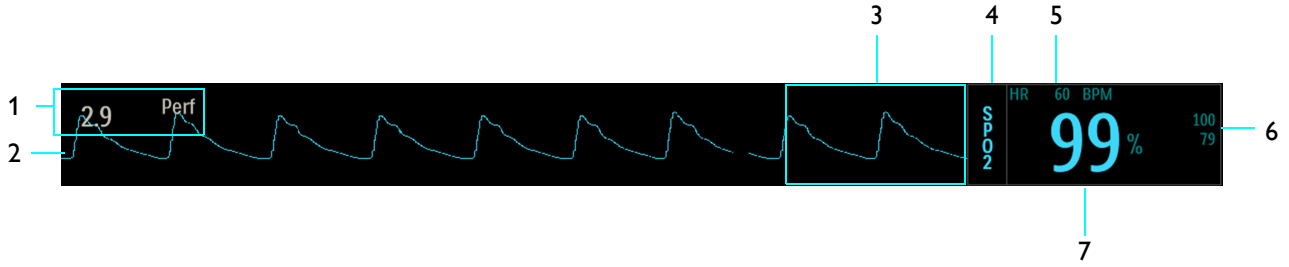
9.3 SpO2 Accuracy

When monitoring SpO2, the clip or grip location and environmental conditions impact the performance and operation of the parameter.

SpO2 monitoring requires the detection of valid pulses to determine SpO2 and heart rate values. If you see questionable readings, check the patient's vital signs by alternate means. See "9.2 SpO2 Monitoring Safety" on page 105.

9.4 About the SpO2 Waveform and Numerics

The following image shows the parts of the SpO2 waveform and numerics.



Part		Description
1	Perfusion index	Shows the pulse strength.
2	Pulse waveform	Shows the pulsatile waveform, or plethysmograph.
3	Flag and trend area	Alarm flags appear here. See "7: Alarms" on page 59. Trend indicators appear here. See "14: Trends and Printing" on page 155.
4	SpO2 label	Select this label to open the **SpO2** menu. See "9.13 SpO2 Menu" on page 113.
5	Heart rate	Shows the heart rate value and unit of measure. This value matches the ECG numeric when ECG is on. • **---** replaces the value when the MR400 can no longer measure data • **OVR** replaces the value when the value is higher than the MR400 can measure. • **UND** replaces the value when the value is lower than the MR400 can measure. To change the heart rate source, see "8.15.2 Heart Rate Source" on page 103.
6	Upper and lower alarm limits	Shows the upper and lower limits of the SpO2 alarm. Select to change the SpO2 alarm limits. See "7: Alarms" on page 59.
7	SpO2 value	Shows the arterial oxygen saturation percentage

9.4.1 Perfusion Index Value

When enabled, the perfusion index value is an indication of the pulsatile portion of the SpO2 signal caused by the patient's arterial blood flow. If you need an indication of change in pulse volume, use the perfusion index value. You can also use this value to check the quality of the SpO2 data from the module.

Perfusion Index Value	Meaning
Above 1.0	Optimal: high-quality readings
0.3 to 1.0	Acceptable: good-quality readings
Below 0.3	Marginal: poor-quality readings Tissue at the attachment site may be opaque, thick, or cold. • Adjust the attachment position or use another site. • Check for long, artificial, or polished nails. Remove any nail polish or reposition the attachment. • Try another attachment site, such as a toe. • Try rubbing or warming the limb to stimulate circulation.

9.5 Monitoring SpO2 Process Overview

Step	Action	More Information
1	Turn on the SpO2 parameter. Select **Setup** > **Monitor** > **Parameters** > **SpO2** > **On**.	"2.4.8.2 Parameters Menu" on page 26
2	Select a patient type or select a profile. If you select a profile, confirm that the patient type is correct.	On the Information bar, select **Patient Type** and then select a type. See "6.2 Selecting the Patient Type" on page 56. On the Information bar, select **User Settings** and then select a profile. See "2.4.9.3 Selecting a User Settings Profile" on page 34.
3	Confirm that alarm settings are appropriate for the patient. Adjust alarm limits if necessary.	"7.5 Setting Alarms and Alarm Limits" on page 67
4	Select a clip or grip.	"9.7 Selecting the SpO2 Clip or Grip" on page 110
5	Attach the sensor to the clip or grip.	"3.5 Attaching the SpO2 Sensor to the SpO2 Module" on page 38
6	Place the clip or grip.	"9.9 Placing the Clip or Grip" on page 110
7	Position the patient, the sensor, and the SpO2 module for scanning.	"9.10 Positioning the SpO2 Module and Sensor" on page 111 "6.3 Moving and Positioning the Cart" on page 57
8	Conduct the scan.	"9.11 Monitoring SpO2 During the Scan" on page 112
9	Clean, disinfect, and store reusable accessories and the cart.	"9.12 To Discontinue Monitoring SpO2" on page 112

9.6 SpO2 Monitoring Requirements

Monitoring SpO2 requires the following:

- SpO2 monitoring is on. See "2.4.8.2 Parameters Menu" on page 26.
- A powered SpO2 module that is communicating on the same channel as the MR400 cart. See "5.3 About Module Power" on page 51 and "4.4 SpO2 and ECG Module Communication" on page 42.
- SpO2 sensor that is connected to the module. See "3.5 Attaching the SpO2 Sensor to the SpO2 Module" on page 38.
- SpO2 clip or grip "9.7 Selecting the SpO2 Clip or Grip" on page 110.
- All reusable accessories are cleaned and disinfected before use.

9.6.1 About the SpO2 Module

The SpO2 module receives signals from the SpO2 sensor, processes the signals, and transmits the signals to the cart.

The SpO2 module is reusable (multi-patient, multi-use). Clean and disinfect it before use and between patients.

9.6.1.1 SpO2 Module Intended Use and Indications for Use

Intended use	The Wireless SpO2 3.0 Module's use enables the Intended Use of the connected compatible MRI Patient Monitoring System. The MRI Patient Monitoring System is intended to monitor vital signs for patients undergoing MRI procedures and to provide signals for synchronization for the MRI scanner. The MRI Patient Monitoring System is intended for use by healthcare professionals. The MRI Patient Monitoring System provides monitoring for the following vital sign parameter: oxygen saturation of arterial hemoglobin (SpO2).
Indications for use	The Wireless SpO2 3.0 Modules are indicated for use with the SpO2 sensor and the SpO2 clips and grips when continuous noninvasive arterial oxygen saturation monitoring, pulse rate monitoring, or pulse triggering is required during MRI procedures.

9.6.2 About the SpO2 Sensor

The SpO2 sensor sends light from a light-emitting sensor tip, through a patient's appendage, to a receiver sensor tip. The sensor gathers blood flow and oxygen saturation data and sends the data to the SpO2 module.

The sensor contains fiber-optic material, which can break. To prevent damage, handle the sensor with care. Never bend the sensor into a radius of less than 15 mm (0.6 inches).

The sensor is reusable (multi-patient, multi-use). Clean and disinfect it before use and between patients.

9.6.2.1 SpO2 Sensor Intended Use and Indications for Use

Intended use	The SpO2 Sensor use enables the Intended Use of the connected compatible MRI Patient Monitoring System. The MRI Patient Monitoring System is intended to monitor vital signs for patients undergoing MRI procedures and to provide signals for synchronization for the MRI scanner. The MRI Patient Monitoring System is intended for use by healthcare professionals. The MRI Patient Monitoring System provides monitoring for the following vital sign parameter: oxygen saturation of arterial hemoglobin (SpO2).
Indications for use	The SpO2 Sensor is indicated for use with the SpO2 Clips and Grip and the wireless SpO2 module when continuous noninvasive arterial oxygen saturation monitoring, pulse rate monitoring, or pulse triggering is required during MRI procedures.

9.6.3 About the SpO2 Clips and Grips

The SpO2 clips hold the sensor heads close to the patient's skin.

The clips are reusable (multi-patient, multi-use). Clean and disinfect them before use and between patients.

The SpO2 grips hold the sensor heads close to the patient's skin.

The grips are single use. Do not reuse.

9.6.3.1 SpO2 Clips and Grips Intended Use and Indications for Use

Intended use	The SpO2 clips and grips use enables the Intended Use of the connected compatible MRI Patient Monitoring System. The MRI Patient Monitoring System is intended to monitor vital signs for patients undergoing MRI procedures and to provide signals for synchronization for the MRI scanner. The MRI Patient Monitoring System is intended for use by healthcare professionals. The MRI Patient Monitoring System provides monitoring for the following vital sign parameter: oxygen saturation of arterial hemoglobin (SpO2).
Indications for use	The SpO2 clips and grips are indicated for use with the SpO2 sensor and the wireless SpO2 module when continuous noninvasive arterial oxygen saturation monitoring, pulse rate monitoring, or pulse triggering is required during MRI procedures.

9.7 Selecting the SpO2 Clip or Grip

When selecting a clip or grip, consider how it fits on the patient's appendage.

- The clip or grip should fit snug against the patient's skin to block ambient light.
- The sensor tips should be on opposite sides of the appendage.
- The clip or grip should not be so tight that it prevents circulation.

Description	Part number	Patient weight	Body part
Adult SpO2 Grips (20)	989803166551	Over 40 kg	Finger or toe
Pediatric SpO2 Grips (20)	989803166561	10 to 50 kg	Finger or toe
Infant SpO2 Grips (20)	989803166571	5 to 15 kg	Finger or toe
Neonatal SpO2 Grips (20)	989803166581	1 to 5 kg	Foot, hand, or wrist
Adult SpO2 Clip	989803166531	Over 40 kg	Finger
Pediatric SpO2 Clip	989803166541	10 to 50 kg	Finger

9.8 Connecting the Clip or Grip to the Sensor

To connect a clip or grip to the SpO2 sensor, snap the sensor tips into the connectors on the clip or grip.

9.9 Placing the Clip or Grip

WARNINGS

- Do not place the clip, grip, or sensor on an extremity that contains an arterial catheter, intravenous infusion line, or noninvasive blood pressure cuff. Otherwise, measurements may be inaccurate.
- To reduce the risk of a pressure injury, ensure that the clip or grip is not so tight that it prevents circulation.

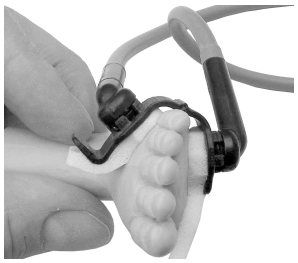
To place a clip, follow these steps.

Step	Action
1	Inspect the module, sensor, and clip. Do not use a damaged accessory.
2	If present, remove any colored nail polish from the application site.
3	Open the clip then slide it over the digit.
4	Ensure that the digit is centered, the light source is on the nail bed, and the sensor tips are on opposite sides.
5	Ensure that the clip is secure and circulation is sufficient.
6	Cover the clip to shield it from ambient light.
7	Verify that the perfusion index is higher than 0.3.

To place an adult, pediatric, or infant grip, follow these steps.

Step	Action
1	Inspect the module, sensor, and grip. Do not use a damaged accessory.
2	If present, remove any colored nail polish from the application site.
3	Remove the adhesive liners.
4	Wrap the grip around the digit. Ensure that the digit is centered, the light source is on the nail bed, and the sensor tips are on opposite sides.
5	Press to adhere the grip.
6	Ensure that the grip is secure and circulation is sufficient.
7	Cover the grip to shield it from ambient light.
8	Verify that the perfusion index is higher than 0.3.

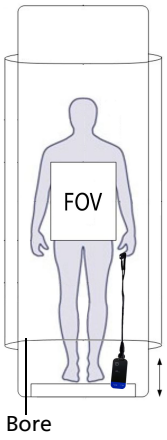
To place a neonatal grip, follow these steps.

Step	Action
1	Inspect the module, sensor, and grip. Do not use a damaged accessory.
2	Remove the adhesive liners.
3	Place the hinge on the outside of the hand, wrist, or foot. Avoid the fingers and toes.
4	Wrap the grip around the appendage so it is centered and the sensor tips are on opposite sides, if possible. Keep the angle between the sensor tips less than 45°. 
5	Press to adhere the grip.
6	Ensure that the grip is secure and circulation is sufficient.
7	Cover the grip to shield it from ambient light.
8	Verify that the perfusion index is higher than 0.3.

9.10 Positioning the SpO2 Module and Sensor

To ensure the best performance, specific positioning considerations are required when using the SpO2 module in the MR magnet room, including during aggressive scan sequences with peripheral nerve stimulation levels above 80 percent.

To position the SpO2 module and sensor, follow these steps.



Step	Action
1	Ensure that the SpO2 module is within 9.1 m (30 feet) of the MR400, in the same MRI room or in the same shielded room, and is set to the same channel as the cart.
2	Select the **Patient Type**. See "6.2 Selecting the Patient Type" on page 56.
3	Place the SpO2 module outside of the bore.
4	Swivel each sensor tip to keep the sensor as straight as possible. Ensure that the sensor does not form a circle, U, or S.
5	Verify that the perfusion index is higher than 0.3. To improve the perfusion index: • Cushion the module • Cover the sensor to block ambient light • Reposition the sensor clip or grip

9.11 Monitoring SpO2 During the Scan

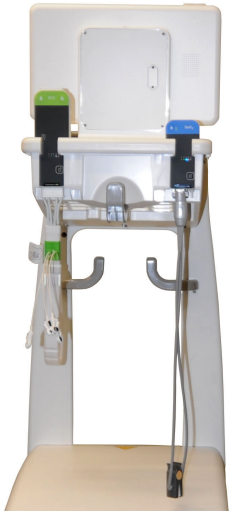
During the scan, perform the following actions.

- Check the patient to ensure that heating does not occur.
- Ensure the module, cable, and clip or grip are positioned correctly.
- Check the patient's circulation.
- Respond promptly to alarms and system messages. See "7.10 Alarms List" on page 78.
- Check the SpO2 numeric and waveform to verify that the SpO2 module is operating correctly and communicating.

9.12 To Discontinue Monitoring SpO2

After scanning is complete, clean and disinfect reusable accessories and the cart. Store reusable accessories on the cart.

1. Remove the SpO2 clip or grip from the patient.
2. Remove any batteries from the module. Store batteries in the battery charger.
3. Clean and disinfect the clip (if used), sensor, and module. See "15: Cleaning and Disinfection" on page 161.
4. Discard the grip (if used).
5. Slide the SpO2 module into a module holder on the cart and allow the SpO2 sensor to drape downward.
6. Store the clips in the accessory basket.



9.13 SpO2 Menu

Use the SpO2 menu to control the waveform, saturation averages, gating, heart rate source and tone, and desaturation alarms.

To open the **SpO2** menu, select the **SpO2** label.

The **SpO2** menu contains the following controls:

Control name	Options	Description
Size	• **10%** • **20%** • **40%** • **60%** • **80%** • **100%** (factory default)	Select the size of the waveform. This setting does not change the signal strength or signal analysis.
Averaging Time	• **5 Sec** • **10 Sec** (factory default) • **15 Sec**	Select the span of time the MR400 uses to calculate the saturation average (more time equals more data.)
Perfusion Index	• **Off** • **On** (factory default)	Show or hide the perfusion index
Gating Source	• **ECG** (factory default) • **Pulse**	Select the gating source. See "17: Gating Feature" on page 179.
HR Source	• **Auto** • **ECG** (factory default) • **ABP** • **SpO2**	Select the heart rate source. See "8.15.2 Heart Rate Source" on page 103.
HR Tone Source	• **Off:** (factory default) no visual indicator or sound • **QRS:** Heart rate source is QRS detection from the ECG vital sign. • **SpO2:** Heart rate source is the SpO2 vital sign. Higher values produce a higher pitch. Lower values produce a lower pitch.	Turn the heartbeat indicator and heart rate sound on or off and select the source. The heartbeat indicator appears on the Information bar. 💚 This control is identical to **HR Tone Source** in the **Monitor Setup > Sound Adjust** menu and in the **SpO2** menu.
Desat	• **Off** • **On** (factory default)	Turn the desaturation alarm off or on. **Desat** alerts you when a patient's oxygen saturation remains below the limit that you select for an amount of time that you select (**Desat Time**). Do not turn off the desaturation alarm when communicating with the Portal 5000 remote monitor. If you do, the alarm turns back on automatically. See "7: Alarms" on page 59.

Control name	Options	Description
Desat Time	• **0 Sec** • **5 Sec** • **10 Sec** • **15 Sec** • **20 Sec** (factory default) • **25 Sec** • **30 Sec**	Set the time the patient's oxygen saturation can remain below the **Desat** limit before the **Desat** alarm occurs. See "7: Alarms" on page 59.

10: Monitoring Noninvasive Pressure

10.1 About Monitoring Noninvasive Pressure

The MR400 measures and displays systolic, diastolic, and mean arterial pressures, using the oscillometric method. The MR400 inflates a noninvasive blood pressure cuff (cuff) on the patient's arm or leg.

The following may affect pressure measurement:

- Measurement site
- Patient position
- Exercise
- Patient physiological condition
- Environmental conditions outside the ranges described in "A.1 Environmental Specifications" on page 191.

10.2 Noninvasive Pressure Safety

WARNING

When you change the patient type, the MR400 resets cuff inflation rate and pressure (up to 180 mmHg). To prevent patient injury, select the correct patient type. See "10.6 Selecting the Patient Type" on page 119.

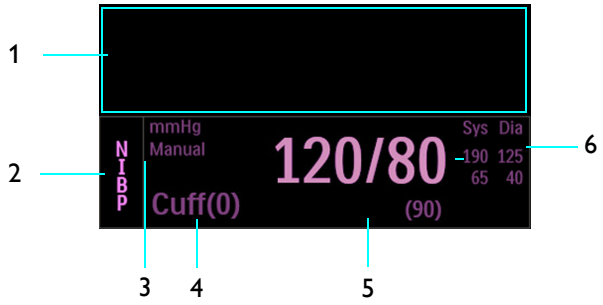
NIBP function is suitable for use in the presence of electrosurgery, in accordance with IEC 80601-2-30, clause 201.7.9.2.101. Adhere to the following warnings:

WARNINGS

- High-frequency electrosurgical equipment may interfere with patient data collection. Data may be inaccurate or missing for less than 10 seconds and then return to normal.
- High-frequency electrosurgical overloads may damage the MR400 system.
- Properly ground defibrillators and high-frequency electrosurgical equipment. Otherwise, they can be a safety hazard, interfering with MR400 data.
- High-frequency electrosurgical equipment may cause patient burns.

10.3 About the NIBP Numerics

The following image shows the parts of the noninvasive pressure numerics:



Part		Description
1	Flag and trend area	Alarm flags and trend arrows appear here. See "7: Alarms" on page 59 and "14: Trends and Printing" on page 155.
2	**NIBP** label	Select this label to open the **NIBP** menu. See "10.15 NIBP Menu" on page 123.
3	• **mmHg** or **kPa** • Manual or automatic measurement indicator	• Shows the unit of measure. • Shows whether the measurement type is manual (**Manual**) or shows the time until the next automatic pressure measurement (**Next:**).
4	Current cuff pressure or elapsed time	During a measurement, this field shows the cuff pressure. Otherwise, this field counts the time since the last automatic measurement (**Et:**).
5	Measurement values	Shows the recent pressure measurement. • **---** replaces the value when the MR400 can no longer measure data. • **OVR** replaces the value when the value is higher than the MR400 can measure. • **UND** replaces the value when the value is lower than the MR400 can measure. Systolic, diastolic, and mean always appear. To select which numbers are bigger, see "10.15 NIBP Menu" on page 123.
6	Upper and lower alarm limits	Shows the upper and lower limits of the alarms. Select to change the alarm limits. See "7: Alarms" on page 59.

10.4 Monitoring Noninvasive Pressure Process Overview

Step	Action	More Information
1	Turn on the NIBP parameter. Select **Setup** > **Monitor** > **Parameters** > **NIBP** > **On**.	"2.4.8.2 Parameters Menu" on page 26

Step	Action	More Information
2	Select a patient type or select a profile. If you select a profile, confirm that the patient type is correct.	On the Information bar, select **Patient Type** and then select a type. See "6.2 Selecting the Patient Type" on page 56. On the Information bar, select **User Settings** and then select a profile. See "2.4.9.3 Selecting a User Settings Profile" on page 34.
3	Confirm that alarm settings are appropriate for the patient. Adjust alarm limits if necessary.	"7.5 Setting Alarms and Alarm Limits" on page 67
4	Select a cuff and pressure interconnect hose.	"10.7 Selecting Noninvasive Pressure Accessories" on page 119
5	Connect the cuff and hose to the MR400.	"10.8 Connecting the Cuff and Hose to the MR400" on page 120
6	If you want automatic measurement, select a measurement interval (optional).	"10.15 NIBP Menu" on page 123
7	Place the cuff on the patient.	"10.9 Positioning the Patient and Cuff" on page 121
8	Start measurement.	"10.11 Starting and Stopping Noninvasive Pressure Measurement" on page 122
9	Discontinue monitoring.	"10.14 To Discontinue Monitoring Noninvasive Pressure" on page 123

10.5 Noninvasive Pressure Monitoring Requirements

Monitoring noninvasive pressure requires the following:

- Noninvasive pressure monitoring is on. See "2.4.8.2 Parameters Menu" on page 26.
- Noninvasive blood pressure cuff. See "10.7.1 Selecting the Cuff" on page 119.
- Pressure interconnect hose. See "10.7.2 Selecting the Pressure Interconnect Hose" on page 120.

10.5.1 About the Cuffs

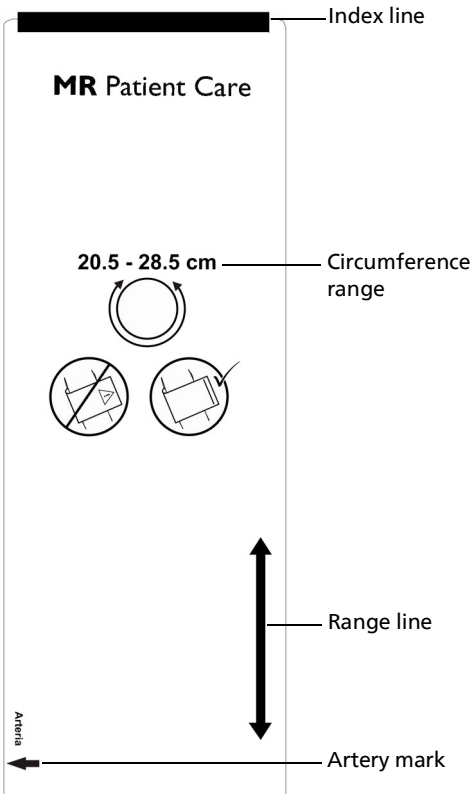
Cuff labels include the circumference range. Select a cuff that fits the circumference of the patient's limb. See "10.7.1 Selecting the Cuff" on page 119.

When wrapped around the patient's limb, place the index line within the range line. See "10.9 Positioning the Patient and Cuff" on page 121.

Do not reuse single-use cuffs.

Clean and disinfect reusable cuffs (multi-patient, multi-use) before use and between patients. See "15.6 SpO2 Clips, ECG Cables, and Reusable NBP Accessories" on page 164.

The cuff connects to the pressure interconnect hose, which connects to the cart.



10.5.1.1 Cuffs Intended Use and Indications for Use

Intended use	The NIBP cuff use enables the Intended Use of the connected compatible MRI Patient Monitoring System. The MRI Patient Monitoring System is intended to monitor vital signs for patients undergoing MRI procedures and to provide signals for synchronization for the MRI scanner. The MRI Patient Monitoring System is intended for use by healthcare professionals. The MRI Patient Monitoring System provides monitoring for the following vital sign parameter: non-invasive blood pressure.
Indications for use	The NIBP cuffs are indicated for use when non-invasive blood pressure monitoring of systolic, diastolic, and mean arterial pressures is required during MRI procedures.

10.5.2 About the Pressure Interconnect Hoses

Sizes: adult and neonatal.

The pressure interconnect hose connects the cuff to the cart.

The hose is reusable (multi-patient, multi-use). Clean and disinfect it before use and between patients. See "15.6 SpO2 Clips, ECG Cables, and Reusable NBP Accessories" on page 164.

10.6 Selecting the Patient Type

WARNING

Select the correct patient type. Do not select the adult patient type when monitoring a neonatal patient.

When you change the patient type, the MR400 behaves as follows:

- Turns off automatic measurement.
- Shows a notification flag to remind you to change the cuff.
- Resets the initial cuff inflation pressure and rate.
- Resets noninvasive pressure limits.

For a new patient, for the first noninvasive pressure measurement, the MR400 uses the following pressure and duration, based on patient type:

Patient Type	Initial Inflation Pressure	Maximum Measurement Duration
Adult	165 ± 15 mmHg	180 seconds
Pediatric	130 ± 15 mmHg	180 seconds
Neo	100 ± 15 mmHg	90 seconds

The MR400 adjusts subsequent measurements on the same patient based on the previous results.

To select the patient type, on the Information bar, select **Patient Type,** and then select one of the following patient types:

- **Adult**
- **Pediatric**
- **Neo**

10.7 Selecting Noninvasive Pressure Accessories

10.7.1 Selecting the Cuff

The following table lists compatible cuffs and their circumference ranges. Select a cuff that fits the patient's limb.

Cuff Circumference Range	Description	Catalog number
3.1 to 5.7 cm (1.2 to 2.2 inches)	Neonatal Size 1 NBP Cuffs (10)	989803183171

Cuff Circumference Range	Description	Catalog number
4.3 to 8.0 cm (1.7 to 3.1 inches)	Neonatal Size 2 NBP Cuffs (10)	989803183181
5.8 to 10.9 cm (2.3 to 4.3 inches)	Neonatal Size 3 NBP Cuffs (10)	989803183191
7.1 to 13.1 cm (2.8 to 5.2 inches)	Neonatal Size 4 NBP Cuffs (10)	989803183201
10.0 to 15.0 cm (3.9 to 5.9 inches)	Infant Size 5 NBP Cuffs (10)	989803183211
	Infant NBP Cuff	989803182611
	Infant NBP Cuffs (10)	989803182511
14.0 to 21.5 cm (5.5 to 8.4 inches)	Pediatric NBP Cuff	989803182621
	Pediatric NBP Cuffs (10)	989803182521
20.5 to 28.5 cm (8.0 to 11.2 inches)	Small Adult NBP Cuff	989803182631
	Small Adult NBP Cuffs (10)	989803182531
27.5 to 36.0 cm (10.8 to 14.0 inches)	Adult NBP Cuff	989803182641
	Adult NBP Cuffs (10)	989803182541
	Adult-Long NBP Cuffs (10)	989803182551
35.0 to 45.0 cm (13.8 to 17.8 inches)	Large Adult NBP Cuffs (10)	989803182561
	Large Adult-Long NBP Cuffs (10)	989803182571
44.0 to 56.0 cm (17.3 to 22 inches)	Thigh NBP Cuffs (10)	989803182581

10.7.2 Selecting the Pressure Interconnect Hose

Select the appropriate size pressure interconnect hose. Neonatal cuffs connect to the neonatal hose. All other cuffs connect to the adult hose.

10.8 Connecting the Cuff and Hose to the MR400

To connect the cuff and hose to the MR400 cart, follow these steps.

Step	Action
1	Inspect the cuff and hose for damage. Do not use a damaged accessory. Dispose damaged accessories according to local regulations.
2	Connect the interconnect hose to the NIBP port. Insert the hose connector then turn it clockwise. 

Step	Action
3	Connect the interconnect hose to a cuff. Insert the hose connector and then turn it clockwise.
4	Ensure that the hoses are not kinked.

10.9 Positioning the Patient and Cuff

WARNINGS

- To prevent patient injury, do not place noninvasive pressure cuffs on limbs where any of the following are present:
  - Intravenous infusion line
  - Arterial catheter
  - Wounds
  - Intravascular access is required
  - Intravascular therapy is required
  - Arteriovenous (AV) shunt
  - History of lymphectomy or history of mastectomy on that side of the body
- Keep the pressure interconnect hose 6 cm outside the field of view to prevent image artifacts.

Step	Action
1	Select a limb that does not contain an intravenous infusion line or arterial catheter.
2	When possible, ensure that the patient is: • Seated • Legs uncrossed • Feet flat on the floor • Back and arms supported • Silent, still, and has relaxed for 5 minutes
3	Position the cuff as follows: • Place the artery mark over the artery. • Place the middle of the cuff at the level of the right atrium. • Ensure that the range line is within the index line.
4	Keep the pressure interconnect hose 6 cm (2.4 inches) outside the field of view.
5	After the patient and cuff are positioned, wait 5 minutes before the first reading.

10.10 Setting the Automatic Measurement Interval

For automatic pressure measurement, turn **Auto Mode** on. Then set a measurement interval.

Step	Action
1	Select **NIBP** > **Auto Mode** > **On**.
2	Select the **NIBP Interval** Quick Access button and then select the interval time. If the **NIBP** parameter is off, then a dialog box asks you if you want to turn it on. Alternatively, select **NIBP** > **Interval** and then select the interval time.

10.11 Starting and Stopping Noninvasive Pressure Measurement

Automatic measurement:

In the main screen, select the **NIBP Start/Stop** Quick Access button to start automatic measurement.

Manual measurement:

In the main screen, select the **NIBP Start/Stop** Quick Access button. Repeat each time you want to measure pressure.

To stop a manual or automatic pressure measurement, select the **NIBP Start/Stop** Quick Access button.

10.12 Optimizing Noninvasive Pressure Data

In patients with low pulse amplitude, you may try one of the following:

- Change the patient type.
- Change the cuff size or placement.
- Turn off automatic measurement.

10.13 Monitoring Noninvasive Pressure During the Scan

WARNINGS

- When monitoring noninvasive pressure, check the following:
  - Check the tubing. Ensure it is not kinked, compressed, restricted, or otherwise interfering with the patient's blood flow.
  - Ensure that no leak is present.
  - Ensure you connected and positioned the accessories correctly.
  - Check the patient for circulation impairment. Frequent or prolonged measurement may injure the patient.

- Patient movement may cause inaccurate data or prolonged measurement.
- Check the patient to ensure that heating does not occur.

- Be aware that inflating or deflating the cuff frequently may cause purpura, ischemia, and neuropathy.
- Confirm unexpected data against other vital sign measurements.
- Respond promptly to alarms and system messages. See "7.10 Alarms List" on page 78.

10.14 To Discontinue Monitoring Noninvasive Pressure

After scanning is complete, clean, disinfect, and store reusable accessories and the cart:

1. Remove the cuff from the patient. Keep the hose and cuff attached.
2. Clean and disinfect the cart, hose, and reusable cuff, if used. See "15: Cleaning and Disinfection" on page 161.
3. Discard the single-use cuff, if used.
4. Store the reusable cuff and hose in the accessory basket.

10.15 NIBP Menu

Use the **NIBP** menu to set an automatic measurement interval, turn on automatic measurement, and select a format for the values.

To open the **NIBP** menu, select the **NIBP** label.

The **NIBP** menu contains the following controls:

Control name	Options	Description
Interval	• **1 Min** • **2 Min** • **3 Min** (factory default) • **5 Min** • **10 Min** • **15 Min** • **20 Min** • **30 Min**	Select the automatic measurement interval. (Requires **Auto Mode** to be on.) This setting is identical to the **NIBP Interval** Quick Access button.
Auto Mode	• **Off** (factory default) • **On**	Select to turn automatic measurement on or off. When you change the patient type, the MR400 turns **Auto Mode** off.
Format	• **Sys/Dia** (factory default) • **Mean**	Select the values that you want to appear bigger. All 3 values always appear.

10.16 Changing the Noninvasive Pressure Unit of Measure

When you use a remote monitor and you change the unit of measure, the unit changes immediately. The numeric values do not reflect the new unit for 2 seconds. Do not print for 2 seconds.

To change the unit of measure, follow these steps.

Step	Action
1	In the main screen, select **Setup** > **Monitor** > **System Settings** > **Pressure Units**.
2	Select the unit: • **mmHg** (factory default) • **kPa**

10.17 Calibrating Noninvasive Pressure

Calibrate the noninvasive pressure system yearly. For more information, see the MR400 service manual (453665111181).

11: Monitoring Gases and Respiration Rate

11.1 About Gas and Respiration Rate Monitoring

The MR400 measures $FiCO_2$ (fractional inspired carbon dioxide), $etCO_2$ (end-tidal carbon dioxide), and respiration rate.

If your system includes anesthesia monitoring, then the MR400 also measures anesthetic gases, oxygen, and nitrous oxide.

Values appear in 4 locations in the main screen:

- Capnography waveform and numerics: See "11.3 About the CO_2 Waveform and Numerics, and RESP Numerics" on page 126.
- Respiration rate numerics: See "11.3 About the CO_2 Waveform and Numerics, and RESP Numerics" on page 126.
- Anesthesia gas numerics: See "11.4 About the Anesthetic Agent Numerics" on page 128.
- Gas numerics: See "11.5 About the Gas Numerics" on page 128.

11.2 Gas and Respiration Monitoring Safety

WARNINGS

- Check all parts of the patient circuit and sample line. Ensure that all parts are unobstructed and undamaged. Ensure that no leak is present.
- Alcohol in the patient's breath may change anesthetic gas data.
- A risk of patient cross-infection exists when sampled gas is returned to the cart.
- Gases and vapors in the sample line or in the room may change anesthetic gas data.
- Allow the system to warm up before use. Wait 2 minutes after you turn on the CO2 parameter and 10 minutes after you turn on the AGENT parameter.
- The MR400 may not detect apnea safely or effectively, particularly for neonatal and preterm infant patients.
- Ensure the patient's breath matches the CO2 waveform.
- Ensure that the cannula remains positioned according to the cannula's instructions for use.

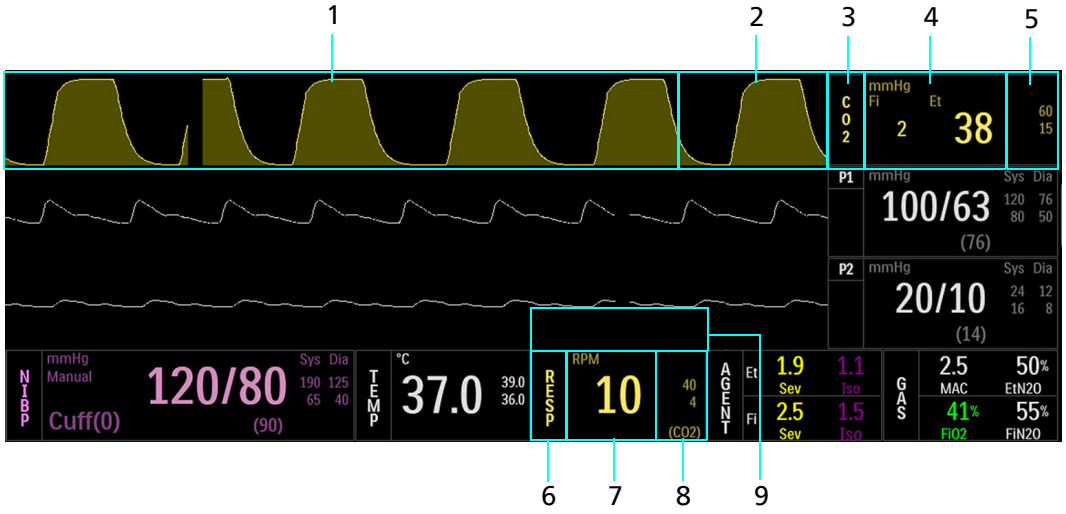
CAUTION

- Verify the CO2 flow rate accuracy by direct measurement using a calibrated flow meter every 12 months. An internal leak may result in condensation within the system. If a leak is suspected or if condensation is observed, discontinue use and

contact technical support. See the annual service requirements that are listed in the MR400 service manual (453665111181).

11.3 About the CO_2 Waveform and Numerics, and RESP Numerics

The following image shows the parts of the capnography waveform and associated numerics:

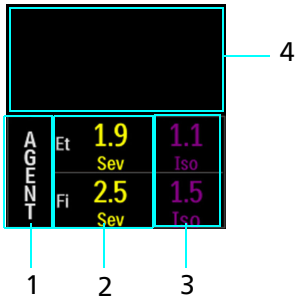


Part		Description
1	**CO2** waveform	Shows the patient's **CO2** values as a waveform.
2	Flag and trend area	**CO2** alarm flags appear here. See "7: Alarms" on page 59. **CO2** trend indicators appear here. See "14: Trends and Printing" on page 155.
3	**CO2** label	Select this label to open the **CO2** menu. See "11.15 CO2 Menu" on page 135.

Part		Description
4	• $FiCO_2$ • $etCO_2$ • CO_2 unit of measure • Respiration rate (when you add a pneumatic respiration rate sensor and change the source of the RESP value at the bottom of the window)	Shows the $FiCO_2$ and $etCO_2$ values and the measurement units. • **---** replaces the value when the MR400 can no longer measure data • **OVR** replaces the value when the value is higher than the MR400 can measure. • **UND** replaces the value when the value is lower than the MR400 can measure. To change the unit of measure, select **Setup** > **Monitor** > **System Settings** > **Gas Units.** See "2.4.8.7 System Settings Menu" on page 28. When a respiration rate appears here, use this respiration data to monitor the patient's respiration. Do not use the data that appears next to the RESP label. The 2 respiration rates may be different. The data source indicator appears as follows: • **(CO2)**: the source of the respiration rate is the sample line. • **(Bel)**: the source of the respiration rate is the pneumatic device.
5	**CO2** upper and lower alarm limits	Shows the upper and lower limits of the $FiCO_2$ and $etCO_2$ alarms. Select to change the alarm limits. See "7: Alarms" on page 59.
6	**RESP** label	Select this label to open the **RESP** menu. See "11.16 RESP Menu" on page 136.
7	Respiration rate	Shows the respiration rate from the sample line or from a secondary pneumatic device. Do not use the secondary pneumatic device data to monitor the patient. • **---** replaces the value when the MR400 can no longer measure data • **OVR** replaces the value when the value is higher than the MR400 can measure. • **UND** replaces the value when the value is lower than the MR400 can measure. If you want to use a secondary pneumatic device, see the MRI system instructions for use. If you want to change which respiration rate appears here, see "11.16 RESP Menu" on page 136.
8	• Respiration rate upper and lower alarm limits • Data source indicator	Shows the upper and lower limits of the CO2 (RESP) alarm. Select to change the alarm limits. The data source indicator appears as follows: • **(CO2)**: the source of the respiration rate is the sample line. • **(Bel)**: the source of the respiration rate is the pneumatic device.
9	Trend area	**CO2** trend indicators appear here. See "14: Trends and Printing" on page 155.

11.4 About the Anesthetic Agent Numerics

The following image shows the parts of the anesthetic agent numerics.



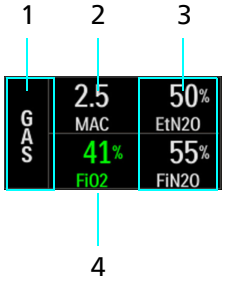
Part		Description
1	**AGENT** label	Select to open the MAC window.
2	Primary anesthetic agent	Shows information about the primary anesthetic agent: • Gas type • End-tidal concentration: volume percent • Fractional inspired concentration: volume percent
3	Secondary anesthetic agent	Shows information about the secondary anesthetic agent: • Gas type • End-tidal concentration: volume percent • Fractional inspired concentration: volume percent
4	Alarm flag area	Alarm flags appear here. See "7: Alarms" on page 59.

Gas abbreviations and colors are:

Anesthetic gas	Abbreviation	Color
Desflurane	**Des**	Light blue
Enflurane	**Enf**	Orange
Halothane	**Hal**	Pink
Isoflurane	**Iso**	Purple
Sevoflurane	**Sev**	Yellow

11.5 About the Gas Numerics

The following image shows the parts of the gas numerics.



Part		Description
1	**Gas** label	Select to open the MAC window.
2	**MAC**	Shows the total MAC (see "11.17 MAC Window" on page 137)

Part		Description
3	**N2O**	Shows the EtN_2O and FiN_2O percentage.
4	**FiO2**	Shows the FiO_2 percentage.

11.6 Monitoring Respiration Process Overview

Step	Action	More Information
1	Connect the MR400 to the gas scavenging system.	"11.8 Connecting to the Gas Scavenging System" on page 131
2	Turn on parameters. Select **Setup** > **Monitor** > **Parameters**. Select the parameter, and then select **On**. Parameter availability depends on the purchased system.	"2.4.8.2 Parameters Menu" on page 26
3	Wait 2 minutes after you turn on the **CO2** parameter and 10 minutes after you turn on the **AGENT** parameter.	
4	Select a patient type or select a profile. If you select a profile, confirm that the patient type is correct.	On the Information bar, select **Patient Type** and then select a type. See "6.2 Selecting the Patient Type" on page 56. On the Information bar, select **User Settings** and then select a profile. See "2.4.9.3 Selecting a User Settings Profile" on page 34.
5	Confirm that alarm settings are appropriate for the patient. Adjust alarm limits if necessary.	"7.5 Setting Alarms and Alarm Limits" on page 67
6	Select a sample line.	"11.9 Selecting a Sample Line" on page 131
7	Attach the sample line to the cart and to the patient.	"11.10 Attaching the Sample Line" on page 132
8	Scan the patient.	"11.12 Monitoring CO_2 and Gases During the Scan" on page 134
9	Discontinue monitoring.	"11.13 To Discontinue Monitoring CO_2 and Gases" on page 134

11.7 Respiration Monitoring Requirements

Requirement	Reference
Sample line appropriate for your system.	See "2.3 Accessory List" on page 14.
You connected the MR400 to the gas scavenging system.	See "2.2.4.1 Parts of the Rear Panel" on page 12.

Requirement	Reference
You turned on the **CO2** or **AGENT** (only when monitoring anesthesia, oxygen, or nitrous oxide) parameter.	See "2.4.8.2 Parameters Menu" on page 26.
The **CO2 Warming Up** system message is not active. If it is active, wait 2 minutes (10 minutes when monitoring anesthesia).	See "7.10.5 Low-Priority Technical Alarms" on page 80.
Calibrated oxygen sensor (when monitoring oxygen).	See "16.9 Replacing the Oxygen Sensor" on page 174.
Water trap (when monitoring anesthesia)	See "11.14 Replacing the Water Trap" on page 134

11.7.1 About the Sample Line

The sample line sends a sample of the patient's breath to the cart for capnography and gas analysis. A divided sample line also delivers oxygen. See the sample line's instructions for use. Sample lines are single use. Do not reuse. Do not clean or disinfect the sample line.

11.7.1.1 Agent Sample Line Intended Use and Indications for Use

Intended use	The Agent Sample Line use enables the Intended Use of the connected compatible MRI Patient Monitoring System. The MRI Patient Monitoring System is intended to monitor vital signs for patients undergoing MRI procedures and to provide signals for synchronization for the MRI scanner. The MRI Patient Monitoring System is intended for use by healthcare professionals. The MRI Patient Monitoring System provides monitoring for the following vital sign parameter: AGENTS.
Indications for use	The Agent Sample Line is indicated for use when monitoring the level of anesthetic agent gases, oxygen (O_2), carbon dioxide (CO_2), and nitrous oxide (N_2O) concentrations is required during MRI procedures.

11.7.2 About the Oxygen Sensor

The oxygen sensor measures the concentration of oxygen in the patient's breath. For installation and calibration instructions, see "16.9 Replacing the Oxygen Sensor" on page 174. Your system may not include an oxygen sensor.

11.7.3 About the Water Trap

The water trap protects the cart from humidity, secretions, bacterial contamination, and dust. See the water trap's instructions for use. To replace, see "11.14 Replacing the Water Trap" on page 134. Your system may not include a water trap.

11.8 Connecting to the Gas Scavenging System

WARNING

Do not block the waste gas port.

CAUTION

Inspect the line to the gas scavenging system for deterioration. If you see deterioration, replace the line.

Use standard waste gas tubing that meets the following diameter requirements:

- 3.175 mm (0.125 inch) outer diameter
- 1.6 mm (0.063 inch) inner diameter

Connect the waste gas tube from the waste gas port to the gas scavenging system. Route the tubing so it is not a tripping hazard.

11.9 Selecting a Sample Line

Select the accessories that are appropriate for the patient's condition and the type of MR400 system.

When the cart includes anesthesia monitoring, the sample line connects to the water trap. Otherwise, the sample line connects to the CO2 sample port. See "2.3 Accessory List" on page 14.

Sample line type	Use
Sample line with cannula	$etCO_2$ sampling
Divided sample line with cannula	$etCO_2$ sampling and oxygen delivery
Sample line with airway adapter	Patient circuit connection for $etCO_2$ sampling (connects to systems that do not include a water trap)
Sample line with Luer connector at each end	Patient circuit connection for $etCO_2$ sampling (connects to systems that include a water trap)

11.10 Attaching the Sample Line

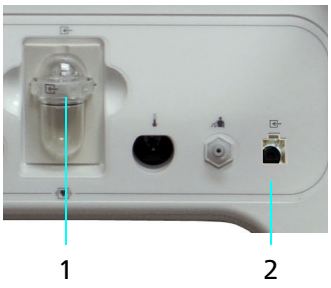
WARNINGS

- Check sample lines and circuits. Ensure they are positioned properly.
- Leaks in the sampling or breathing system may cause inaccurate data.

CAUTION

- To prevent damage to the devices, do not over-tighten any connections.
- Check the sample lines. Ensure they are connected correctly.

To attach the sample line to the patient and to the cart, follow these steps.

Step	Action
1	Inspect the sample line. Do not use damaged accessories.
2	If your system includes anesthesia monitoring, connect the sample line to the water trap (1). Turn clockwise to tighten the connector. Otherwise, connect the sample line to the CO_2 sample port (2). 
3	If your system includes anesthesia monitoring, let the MR400 sample room air for at least one minute. Check the FiO_2 value. If it is approximately 21 percent, then go to the next step. If the FiO_2 is not 21 percent, then replace the oxygen sensor. See "16.9 Replacing the Oxygen Sensor" on page 174. If the issue persists, contact Service.
4	Pinch the sample line for 5 seconds and verify that the **Check for CO2 Occlusion** alarm occurs. If the alarm does not occur, then check all connections for leaks and retest. If the issue persists, contact Service.
5	Connect to a patient circuit: • Circuit with a sample port: connect the sample line to the sample port on the circuit. Turn clockwise to tighten the connector. • Airway adapter: place the adapter at the proximal end of the patient circuit. • Cannula: connect the cannula to the patient's nose. See the cannula's instructions for use.
6	If the patient requires oxygen, connect the oxygen line from the divided cannula to the oxygen source.

11.11 Zeroing CO_2

WARNINGS

- To prevent inaccurate data, zero the MR400 in a well-ventilated area.
- Manually zero the MR400 only after the capnography system has warmed up. Allow 10 minutes after connecting CO_2 accessories to the cart and turning on the CO2 or AGENT parameter.
- The MR400 suspends automatic calibration under the following conditions:
  - During a high- or medium-priority gas alarm.
  - When the Apnea alarm occurs, the MR400 suspends calibration. 5 minutes after the alarm is resolved, the MR400 resumes automatic calibration.
  - When CO_2 respiration rate data is lost for 30 seconds, the MR400 suspends calibration. 5 minutes after the respiration rate returns, the MR400 resumes automatic calibration.

11.11.1 Automatic Zero

When you monitor anesthesia, the MR400 may calibrate (zero) the system automatically.

When the zero procedure will require more than 30 seconds, then a notification flag appears that counts down the time until the zero. The message is: **CO2 Zero in** <timer> **seconds**.

The message changes to **Performing CO2 Zero** when the MR400 zeros the system.

The MR400 may automatically zero in situations such as the following:

- You change anesthesia gases.
- You change a high gas concentration to low or turn off the gas. When the concentration changes by 200 percent, the MR400 calibrates the capnography system and attains full accuracy within 30 seconds.
- Approximately every 4 hours
- When the system temperature changes by more than 1°C (1.8°F).

The MR400 suspends automatic calibration under the following conditions:

- During a high- or medium-priority gas alarm.
- When the Apnea alarm occurs, the MR400 suspends calibration. 5 minutes after the alarm is resolved, the MR400 resumes automatic calibration.
- When CO_2 respiration rate data is lost for 30 seconds, the MR400 suspends calibration. 5 minutes after the respiration rate has returned, the MR400 resumes automatic calibration.

11.11.2 Manual Zero

After you turn on monitoring, allow the system 10 minutes to warm up before you manually zero.

To calibrate the capnography system, select the **CO2** label then select **Zero Cal**.

11.12 Monitoring CO_2 and Gases During the Scan

During the scan:

- Respond promptly to alarms and system messages. See "7.10 Alarms List" on page 78.
- If you see questionable values, check the patient connections, tubing and connections to the cart, the anesthesia device, and the vaporizer before adjusting gas delivery.
- Anesthetic agent measurements appear within 22 seconds of detection.
- Check the sample line for secretions. If secretions appear, replace the line.

11.13 To Discontinue Monitoring CO_2 and Gases

WARNING

Cannulas, sample lines, and airway adapters are single-use accessories. Discard according to local regulations for infectious waste. See "16.15 Disposing the MR400" on page 177.

WARNING

Inspect the water trap after each patient. Discard the water trap when it becomes filled. Do not attempt to clean or reuse the water trap. Discard according to local regulations for infectious waste.

To increase the life of the filter and pump, turn off the CO2 parameter. See "2.4.8.2 Parameters Menu" on page 26.

To remove the sample line from the CO2 port, press down on the locking tab and pull the connector from the port. Discard the sample line as infectious waste.

To remove the sample line from the water trap, turn the connector counterclockwise and remove it. Discard the sample line as infectious waste.

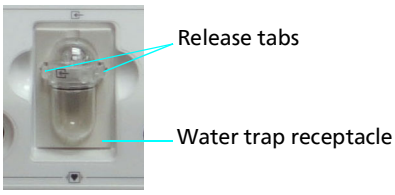
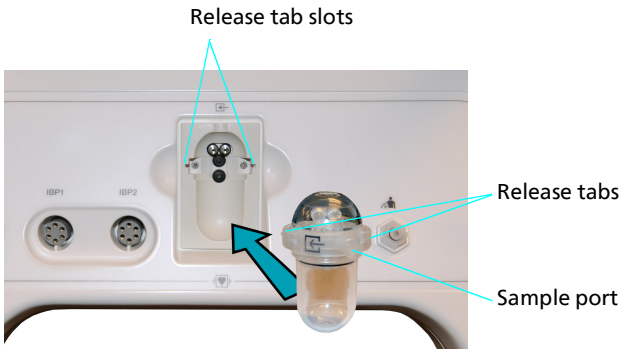
Inspect the water trap. If it is full, replace it. See "11.14 Replacing the Water Trap" on page 134.

11.14 Replacing the Water Trap

WARNING

Discard the water trap when it becomes filled. Do not attempt to clean or reuse the water trap. Accidental fluid ingress into the cart can affect gas measurements.

To replace the water trap, follow these steps.

Step	Action
1	If a sample line is connected, then remove the line from the sample port on the water trap.
2	Squeeze the release tabs and then pull the water trap from the receptacle. Dispose of the water trap according to local regulations for infectious waste. 
3	Position the new water trap so that the sample port is facing toward you. Insert the release tabs into the release tab slots. Confirm that you hear 2 clicks. 
4	Attach the sample line to the sample port.

11.15 CO2 Menu

Use the CO2 menu to control the waveform, control the Apnea alarm, and calibrate the capnography system.

To open the **CO2** menu, select the **CO2** label.

The **CO2** menu contains the following controls:

Control name	Options	Description
Size	• **40 mmHg** (factory default) • **60 mmHg** • **80 mmHg**	Select the size of the waveform. This setting does not change the signal strength or signal analysis.
Grids	• **Off** (factory default) • **On**	Turns a waveform scale off or on.

Control name	Options	Description
Zero Cal	**None**	Select to calibrate the capnography system manually. See "11.11 Zeroing CO_2" on page 133.
Apnea	• **Off** • **On** (factory default)	Turns the Apnea alarm off or on. This control appears here when you add a pneumatic device to the MR400 and the respiration source is **BEL.** Otherwise, this control appears in the **RESP** menu. See "11.16 RESP Menu" on page 136.
Apnea Time	• **20 Sec** (factory default) • **25 Sec** • **30 Sec** • **35 Sec** • **40 Sec**	Sets the time between breaths before triggering the Apnea alarm. This control appears here when you add a pneumatic device to the MR400 and the respiration source is **BEL.** Otherwise, this control appears in the **RESP** menu. See "11.16 RESP Menu" on page 136.

11.16 RESP Menu

Use the RESP menu to select the type of respiration rate values that appear and control the Apnea alarm when a pneumatic device is not in use.

To open the **RESP** menu, select the **RESP** label.

The **RESP** menu contains the following controls:

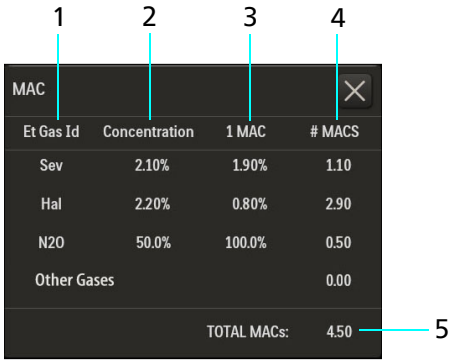
Control name	Options	Description
Source	• **CO2** (factory default) • **BEL**	Select **CO2** to view the **CO2** respiration rate next to the **RESP** label. Select **BEL** to view the **CO2** respiration rate next to the **CO2** label and the pneumatic respiration rate next to the **RESP** label. Do not use the pneumatic respiration rate to monitor the patient's respiration rate. Use the respiration data that appears next to the **CO2** label. The respiration rate values may be different.
Apnea	• **Off** • **On** (factory default)	Turn the Apnea alarm off or on. This control appears here when the respiration source is **CO2.** Otherwise, this control appears in the **CO2** menu. See "11.15 CO2 Menu" on page 135.

Control name	Options	Description
Apnea Time	• **20 Sec** (factory default) • **25 Sec** • **30 Sec** • **35 Sec** • **40 Sec**	Sets the time between breaths before triggering the Apnea alarm. This control appears here when the respiration source is **CO2.** Otherwise, this control appears in the **CO2** menu. See "11.15 CO2 Menu" on page 135.

11.17 MAC Window

The MAC window shows the concentration of the expired gases that contribute to the MAC (minimum alveolar concentration) value.

To open the **MAC** window, select the **AGENT** or the **Gas** label.



Part		Description
1	**Et Gas Id**	End-tidal gas
2	**Concentration**	Concentration percentage
3	**1 MAC**	Shows the MAC at which 50 percent of patients do not move in response to a noxious stimulus, such as skin incision.

Gas	1 MAC Value
Des (Desflurane)	6.00 volume%
Enf (Enflurane)	1.70 volume%
Hal (Halothane)	0.77 volume%
Iso (Isoflurane)	1.15 volume%
Sev (Sevoflurane)	2.10 volume%
N2O (Nitrous oxide)	105 percent

4	**# MACS**	Shows the amount that each gas contributes to the total MAC value. The calculation is **# MACS** = C/M • C = the current concentration of the given gas • M = the 1 MAC value for the given gas

Part		Description
5	**TOTAL MACs:**	Shows the total MAC value. The calculation is: TOTAL MAC = EtN2O/1MACN2O + EtA1/1MA1 + EtA2/2MA2 • EtN2O = nitrous oxide end-tidal value • 1MACN2O = nitrous oxide 1 MAC value • EtA1 = primary agent gas concentration • EtA2 = secondary agent gas concentration • 1MA1 = primary agent gas, 1 MAC value • 2MA2 = secondary agent gas, 2 MAC value

12: Monitoring Invasive Pressure

When your MR400 system includes the option to monitor invasive pressure, the system can monitor data from 2 separate ports (P1 or P2).

12.1 Invasive Pressure Safety

WARNINGS

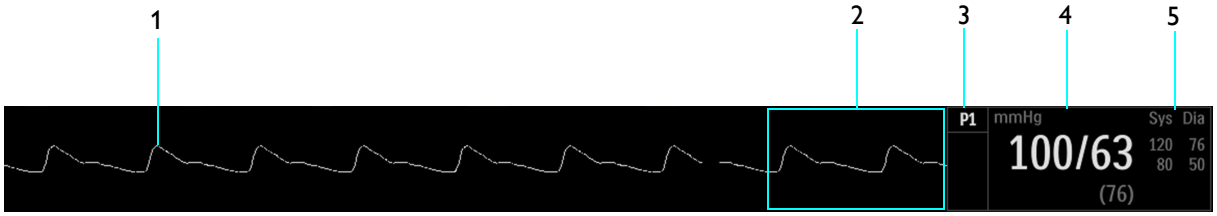
- Intra-aortic balloon pumps cause inaccurate invasive pressure data. If you see questionable data, check the patient vital signs by alternate means.
- Non-physiological data in pulsatile waveforms leads to inaccurate pressure measurement.
- When connecting invasive pressure accessories, do not introduce air into the invasive pressure system. Flush the lines to remove air. Do not create a vacuum when you remove air from the lines.
- Do not attach the pressure transducer directly to the patient.
- Do not place the transducer and cable within the 5,000-gauss line. Follow the transducer labeling.
- When using high-frequency electrosurgical equipment, invasive pressure transducers may heat up. Do not touch the transducer or allow the patient to touch the transducer.

CAUTION

Do not exceed the maximum pressure specifications for a transducer. Do not create a vacuum when you remove air from the lines. Consult the transducer's instructions for use.

12.2 About the Invasive Pressure Waveforms and Numerics

The following image shows the parts of the invasive pressure waveform and numerics. Both P1 and P2 waveforms and numerics have the same parts.



Part		Description
1	Invasive pressure waveform	Shows changes in pressure over time.
2	Flag and trend area	Alarm flags and trend indicators appear here. See "7: Alarms" on page 59 and "14: Trends and Printing" on page 155.
3	**P1** or **P2** label	Select this label to open the **P1** or **P2** menu. This space includes the label that you set to identify the type of pressure measurement.
4	Invasive pressure	Shows the pressure and unit of measure. • **---** replaces the value when the MR400 can no longer measure data • **OVR** replaces the value when the value is higher than the MR400 can measure. • **UND** replaces the value when the value is lower than the MR400 can measure.
5	Upper and lower alarm limits	Shows the upper and lower limits of the alarms. Select to change the alarm limits. See "7: Alarms" on page 59.

12.3 Monitoring Invasive Pressure Process Overview

Step	Action	More Information
1	Turn on the invasive pressure port that you want to use. Select **Setup** > **Monitor** > **Parameters** > **P1** or **P2** > **On**.	"2.4.8.2 Parameters Menu" on page 26
2	Select a patient type or select a profile. If you select a profile, confirm that the patient type is correct.	On the Information bar, select **Patient Type** and then select a type. See "6.2 Selecting the Patient Type" on page 56. On the Information bar, select **User Settings** and then select a profile. See "2.4.9.3 Selecting a User Settings Profile" on page 34.
3	Confirm that alarm settings are appropriate for the patient. Adjust alarm limits if necessary.	"7.5 Setting Alarms and Alarm Limits" on page 67
4	Connect the invasive pressure cable to the MR400.	"12.5 Connecting the Invasive Pressure Cable to the MR400" on page 141

Step	Action	More Information
5	Connect the invasive pressure accessories to the cable and to the patient.	See the accessories' instructions for use.
6	Zero one or both transducers.	"12.6 Zeroing Invasive Pressure" on page 142
7	Scan the patient. If you move the patient during the scan, recalibrate the transducers.	"12.7 Monitoring Invasive Pressure During the Scan" on page 143
8	Discontinue monitoring.	"12.8 To Discontinue Monitoring Invasive Pressure" on page 143

12.4 Selecting the Invasive Pressure Accessories

Use the transducer cable to connect the transducer to the MR400.

Transducers are single use.

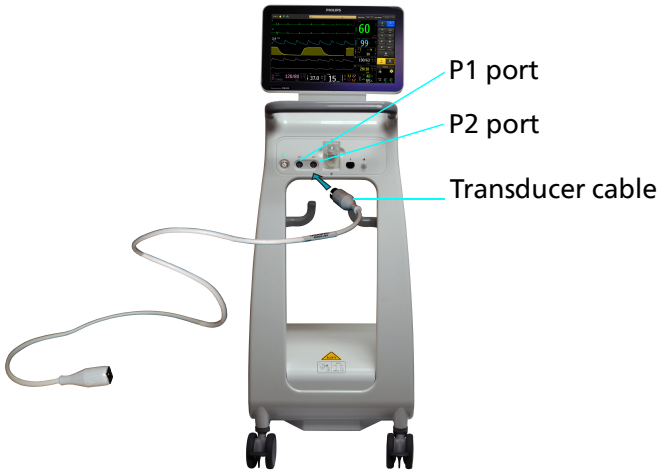
The following pressure transducer kits are compatible with the MR400 system. Consult the transducer's instructions for use:

- 989803194641, Expression MR IBP DPT Kit, I/N, Box 20
- 989803194631, Expression MR IBP DPT Kit, A/P, Box 20

12.5 Connecting the Invasive Pressure Cable to the MR400

Inspect the transducer cable for damage. Do not use a damaged accessory.

Connect the transducer cable to the P1 or the P2 port on the patient connection panel.



12.6 Zeroing Invasive Pressure

WARNINGS

- If you zero invasive pressure and then move the transducer, invasive pressure data will be inaccurate.
- After zeroing invasive pressure, inspect the IV line for air. Remove air from the line.

Zero invasive pressure according to the following criteria:

- When you use a new transducer or tubing
- Daily
- When the transducer is in the final setup position just before scanning
- When you reconnect the transducer cable to the monitor
- When you move or turn a patient
- When you think the pressure data is incorrect
- According to your facility policies

To zero invasive pressure, follow these steps.

Step	Action
1	Turn the zero reference stopcock off to the patient. Remove the yellow non-vented cap from the side port, which opens the zero reference stopcock to air. Alternatively, attach a catheter to the distal end of the transducer and prime it. Purge all air from the catheter. Open the stopcock to the catheter. The catheter tip is now the system air-fluid interface. If you want to zero 2 transducers, repeat this step for the second transducer.
2	Place the air-fluid interface at or near the right atrial (mid-axillary) level. If you want to zero 2 transducers, repeat this step for the second transducer.
3	Place the transducer in the horizontal plane that it will maintain during pressure measurement. If you want to zero 2 transducers, repeat this step for the second transducer.
4	To zero both transducers, select the **Zero All** Quick Access button. Otherwise, select the **P1** or **P2** label and then select **Zero Set**.

Step	Action
5	After zeroing, turn off the zero reference stopcock to the side port and replace the yellow cap. If zeroing fails: • Verify that you comply with the transducer's instructions for use and try again. • Attach a different transducer or cable. • Contact Service.
6	Inspect the IV line for air. Remove air from the line. Consult the transducer's instructions for use.

12.6.1 Zero Set Dialog Box

The following messages may appear in the **Zero Set** dialog box when you zero invasive pressure:

Message	Description
Done	Zeroing is successful
Not Zeroed	Zeroing failed
Err: Unstable	Pressure is unstable
Zero Cal Err (Hi)	Pressure offset is too high
Zero Cal Err (Lo)	Pressure offset is too low
Zeroing All Pressure Channels	Zeroing is in process for both pressure channels
Zeroing Pressure Channel	Zeroing is in process for a single pressure channel

12.7 Monitoring Invasive Pressure During the Scan

During the scan, perform the following actions:

- Check the patient to ensure that heating does not occur.
- Respond promptly to alarms and system messages. See "7.10 Alarms List" on page 78.

12.8 To Discontinue Monitoring Invasive Pressure

Disconnect the accessories.

Clean and disinfect the cable. Follow the accessory's instructions for use.

Discard the transducer according to local regulations. See "16.15 Disposing the MR400" on page 177.

12.9 Invasive Pressure Menus

Use the invasive pressure menus to zero the transducer or modify information that appears in the main screen.

To open the invasive pressure menus, select the **P1** or **P2** label.

The invasive pressure menu contains the following controls:

Control name	Options	Description
Zero Set	None	Calibrate one or two pressure transducers. See "12.6 Zeroing Invasive Pressure" on page 142.
Set Label	• **None** (factory default) • **ABP** (arterial blood pressure) • **PAP** (pulmonary artery pressure) • **CVP** (central venous pressure) • **LAP** (left atrial pressure) • **ICP** (intracranial pressure)	Assign a label to the pressure data. Assigning a label may change the waveform size and data. See "12.9.1 Default Waveform Size Based on Label and Patient Type" on page 145.
Size	• **40 mmHg** • **75 mmHg** • **100 mmHg** • **150 mmHg** (factory default) • **200 mmHg** • **250 mmHg**	Select the size of the waveform. This setting does not change the signal strength or signal analysis. See "12.9.1 Default Waveform Size Based on Label and Patient Type" on page 145
HR Source	• **Auto** • **ECG** (factory default) • **ABP** • **SpO2**	Select the heart rate source. See "8.15.2 Heart Rate Source" on page 103.
Grids	• **Off** (factory default) • **On**	Turn waveform grids off or on. Turn on grids for a faster response.
Grids Size	• **40 mmHg** • **75 mmHg** • **100 mmHg** • **150 mmHg** (factory default) • **200 mmHg** • **250 mmHg**	Change the waveform grid size (amplitude) when **Grids** are **On**.
Format (disabled when the label is **CVP** or **ICP**)	• **Sys/Dia** (factory default) • **Mean**	Control the numeric data format. The format depends on the label that you set. • **ABP** (arterial blood pressure) • **PAP** (pulmonary artery pressure) • **CVP** (central venous pressure) • **LAP** (left atrial pressure) • **ICP** (intracranial pressure)

12.9.1 Default Waveform Size Based on Label and Patient Type

When grids are off, the MR400 changes the waveform size automatically, based on patient type and the label that you select. To select a label, see "12.9 Invasive Pressure Menus" on page 144.

Patient Type	Label Name/Automatic Size Setting (mmHg)					
	None	**ABP**	**PAP**	**CVP**	**LAP**	**ICP**
Adult	150	150	40	40	40	40
Pediatric	150	150	40	40	40	40
Neonatal	100	100	40	40	40	40

13: Monitoring Temperature

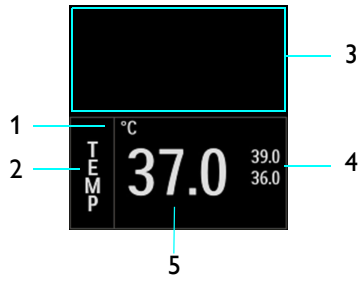
13.1 About Monitoring Temperature

Use the direct mode temperature sensor to monitor a patient.

During MRI procedures, a large amount of radio frequency energy is present, which may cause a patient's body temperature to increase.

13.2 About the Temperature Numerics

The following image shows the parts of the temperature numerics.



Part		Description
1	Temperature unit of measure	Shows the temperature measurement units. To change the unit, see "13.11 Temperature Menu" on page 153.
2	**TEMP** label	Select this label to open the **TEMP** menu. See "13.11 Temperature Menu" on page 153.
3	Flag and trend area	Alarm flags appear here. See "7: Alarms" on page 59. Trend indicators appear here. See "14: Trends and Printing" on page 155.
4	Upper and lower alarm limits	Shows the upper and lower limits of the temperature alarms. Select to change the alarm limits. See "7: Alarms" on page 59.
5	Temperature	Shows the patient's temperature. • **---** replaces the value when the MR400 can no longer measure data • **OVR** replaces the value when the value is higher than the MR400 can measure. • **UND** replaces the value when the value is lower than the MR400 can measure.

13.3 Monitoring Temperature Process Overview

Step	Action	Reference
1	Connect the temperature sensor to the MR400.	"13.6 Connecting the Temperature Sensor to the MR400" on page 150
2	Turn on the temperature parameter. Select **Setup** > **Monitor** > **Parameters** > **TEMP** > **On**.	"2.4.8.2 Parameters Menu" on page 26
3	Select a patient type or select a profile. If you select a profile, confirm that the patient type is correct.	On the Information bar, select **Patient Type** and then select a type. See "6.2 Selecting the Patient Type" on page 56. On the Information bar, select **User Settings** and then select a profile. See "2.4.9.3 Selecting a User Settings Profile" on page 34.
4	Confirm that alarm settings are appropriate for the patient. Adjust alarm limits if necessary.	"7.5 Setting Alarms and Alarm Limits" on page 67
5	Place the sensor in a jacket. • Required for internal temperature monitoring. • Optional for surface temperature monitoring.	"13.7 Placing the Temperature Sensor in a Jacket" on page 150
6	Place the sensor.	"13.8 Monitoring Rectal or Esophageal Temperature" on page 151 "13.9 Monitoring Axillary Temperature" on page 152
7	Scan the patient.	
8	Discontinue monitoring.	"13.10 To Discontinue Monitoring Temperature" on page 152

13.4 Temperature Monitoring Requirements

Monitoring temperature requires the following:

- Temperature monitoring is on. See "2.4.8.2 Parameters Menu" on page 26.
- Temperature sensor
- Temperature sensor jacket: required for internal measurement and recommended for surface measurement
- Water-based lubricant

13.4.1 About the Temperature Sensor

CAUTION

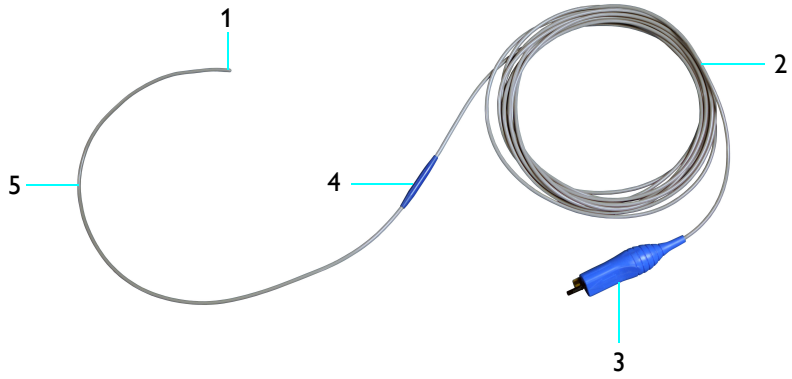
- The temperature sensor is not sterile.
- Do not pull on the temperature sensor cable or use excessive force to connect and disconnect the sensor. Hold the sensor by the connector.

The temperature sensor measures the internal and surface temperature of adult, pediatric, and neonatal patients. The thermometer is direct mode.

The cable contains fiber-optic material. Handle with care.

The temperature sensor is reusable (multi-patient, multi-use). Clean and disinfect it before use and between patients.

Parts of the temperature sensor are as follows.



Part	Description
1	Sensor tip Only the sensor tip measures temperature.
2	Cable
3	Connector
4	Jacket retainer
5	Patient segment Temperature is not measured anywhere along the patient segment.

13.4.2 About the Temperature Sensor Jacket

CAUTION

A temperature sensor jacket is required when monitoring rectal or esophageal temperature.

Temperature sensor jackets are sterile, polyurethane covers that protect the temperature sensor from contamination. The jackets are single use. Do not reuse.

13.5 Selecting the Site

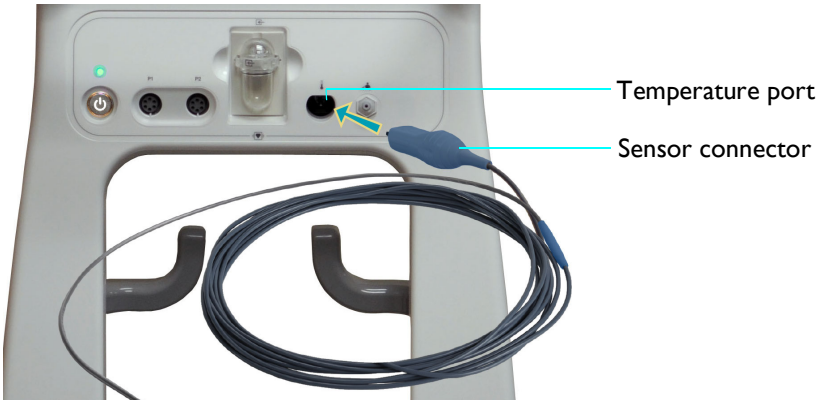
CAUTION

Do not place the temperature sensor near an open wound.

Select a measurement site:

- Internal: rectal or esophageal
- Surface: axillary, under the armpit

13.6 Connecting the Temperature Sensor to the MR400



To connect the temperature sensor, follow these steps.

Step	Action
1	Inspect the sensor. Do not use a damaged accessory.
2	Hold the sensor by the connector. Insert it into the temperature port.
3	Clean and disinfect the sensor. See "15: Cleaning and Disinfection" on page 161.

13.7 Placing the Temperature Sensor in a Jacket

WARNING

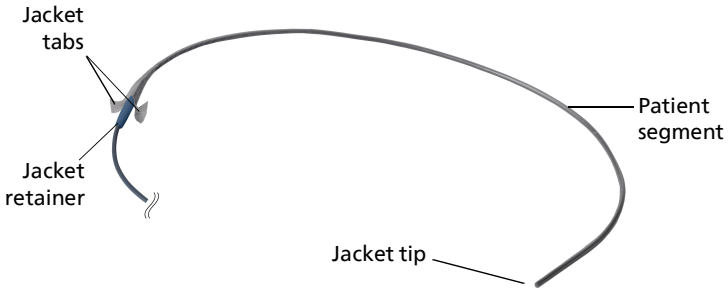
Inspect the jacket package. If the package is damaged, discard the jacket.

CAUTION

Use the jacket immediately after opening its package.

To place the temperature sensor in a jacket, follow these steps.

Step	Action
1	Inspect the jacket package. If the package is damaged, discard the jacket.

Step	Action
2	Open the package enough to expose the jacket tabs.
3	Holding the jacket tabs, pull the jacket up to the jacket retainer. Do not allow excess space at the jacket tip. 

13.8 Monitoring Rectal or Esophageal Temperature

CAUTION

- Before monitoring, wait 2 minutes for the temperature to stabilize.
- After 4 hours of monitoring, check the application site frequently to prevent a pressure wound.
- Do not insert the sensor past the patient segment.
- If you reposition the sensor, use a new jacket.

To monitor rectal or esophageal temperature, follow these steps.

Step	Action
1	Ensure that a jacket is on the sensor (see "13.7 Placing the Temperature Sensor in a Jacket" on page 150).
2	Peel the jacket package open and remove the jacketed sensor. Maintain sterility.
3	Apply a water-based lubricant to the jacket.
4	Insert the sensor tip into the patient's rectum or esophagus. Do not insert the sensor beyond the patient segment of the sensor.
5	Wait 2 minutes for the temperature to stabilize.
6	Scan the patient. • Check the patient to ensure that heating does not occur. • Ensure the sensor and jacket are positioned correctly. • Respond promptly to alarms and system messages. See "7.10 Alarms List" on page 78.

13.9 Monitoring Axillary Temperature

CAUTION

- Before monitoring, wait 2 minutes for the temperature to stabilize.
- After 4 hours of monitoring, check the application site frequently to prevent a pressure wound.
- Do not insert the sensor past the patient segment.
- If you reposition the sensor, use a new jacket.

To monitor axillary temperature, follow these steps.

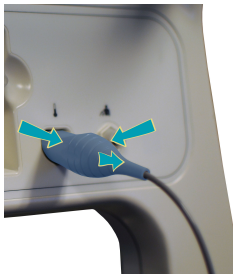
Step	Action
1	If you want to protect the sensor from contamination, see "13.7 Placing the Temperature Sensor in a Jacket" on page 150.
2	Thoroughly clean and dry the patient's underarm.
3	Position the sensor tip under the patient's arm.
4	Wait 2 minutes for the temperature to stabilize.
5	Scan the patient. • Check the patient to ensure that heating does not occur. • Ensure the sensor and jacket are positioned correctly. • Respond promptly to alarms and system messages. See "7.10 Alarms List" on page 78.

13.10 To Discontinue Monitoring Temperature

CAUTION

Ensure you remove the entire sensor jacket.

After the scan is complete, perform the following actions:



1. Remove the sensor and any jacket from the patient.
2. Remove the jacket and discard according to your facility's biohazard policies. See "16.15 Disposing the MR400" on page 177.
3. Clean and disinfect the sensor. See "15: Cleaning and Disinfection" on page 161.
4. Carefully disconnect the sensor. Do not yank the cable.
5. Loosely loop the temperature sensor and then hang it on an accessory storage hook.

13.11 Temperature Menu

Use the **TEMP** menu to change the temperature unit of measure.

Select the **TEMP** label > **Units** and then select **°C** (factory default) or **°F**.

14: Trends and Printing

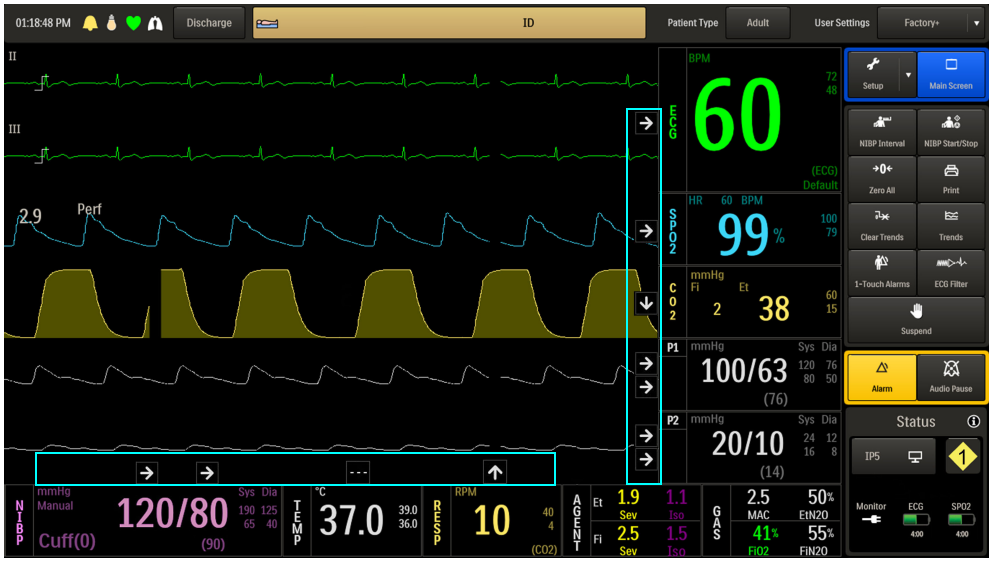
14.1 About Trends

The MR400 collects, averages, and compares data continuously. It refreshes trend data at 1-minute intervals, except noninvasive pressure. The MR400 refreshes noninvasive pressure data after each reading. Trend indicators may not represent the patient's current condition. Trend data appears in the Trends table.

The MR400 shows trend indicators next to related vital sign values, except for anesthesia agents and gases.

The MR400 stores up to 12 hours of trend data. The MR400 deletes trend data when you discharge a patient, clear all trends, or remove all power from the cart for 10 minutes.

The following image shows the main screen with trend indicators:

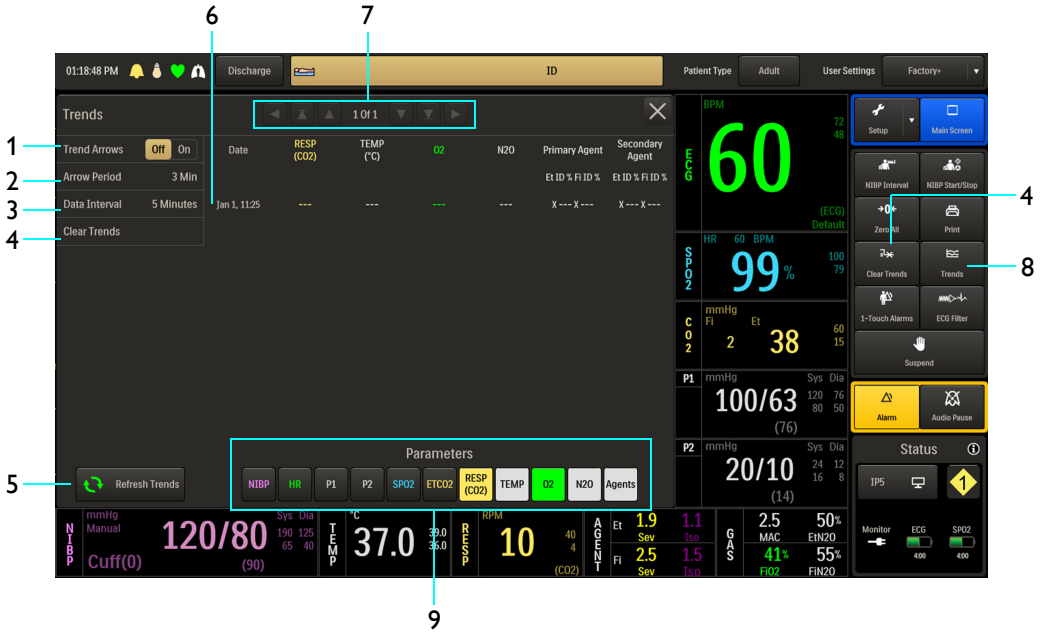


14.1.1 Trends Menu

Use the **Trends** menu to control trends, view trended data, and print trended data.

To open the **Trends** menu, in the main screen, select the **Trends** quick access button.

The following image shows the parts of the **Trends** menu.



Part		Description
1	**Trend Arrows** • **Off** • **On** (factory default)	Turn trend arrows off or on.
2	**Arrow Period**	Select the frequency of trend arrow changes. The factory default is 3 minutes.
3	**Data Interval**	Select the frequency of trend data readings. To match the automatic noninvasive pressure interval, select **Auto NIBP**. The factory default is 5 minutes.
4	**Clear Trends**	Manually delete all trend data.
5	**Refresh Trends** button	Refresh the data.
6	Trend record	View trend data.
7	Navigation buttons	Use these buttons to navigate through the trend records: Scroll one column to the left. View the oldest record. View the previous page of records. View the next page of records. View the newest record. Scroll one column to the right.
8	**Trends** button	Select to view the **Trends** table and menu.
9	**Parameters**	Select the parameter that you want to see in the trends window.

14.1.2 Trend Indicators

Types of trend indicators are as follows:

Indicator	Description
	Values are increasing
	Values are decreasing
	Values are stable
	• Data is unavailable • A value is higher than the MR400 measures. • A value is lower than the MR400 measures. • MR400 is suspended

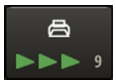
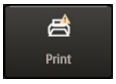
14.2 Printing

When the MR400 system includes a remote monitor connected to a printer, you can print waveforms, trends, and patient reports on a strip chart.

- To set up a printer, see the remote monitor's instructions for use.
- To set up waveform printing, see "14.2.2.2 Waveform Printing Setup" on page 158.
- To set up trend and patient report printing, see the remote monitor's instructions for use.

14.2.1 Printer Status

The **Print** button shows the printer status. Before printing, ensure that the printer is ready to print.

Symbol	Status
	Ready to print.
	The printer is printing. A counter shows the time remaining in seconds.
	The printer is unavailable to print. See the remote monitor's instructions for use.
	Printer error In the **Status** pane, select **Status** to open the **Status Information Panel** and see more information. See "2.4.7 Setup Menu" on page 24.

14.2.2 Printing Waveforms

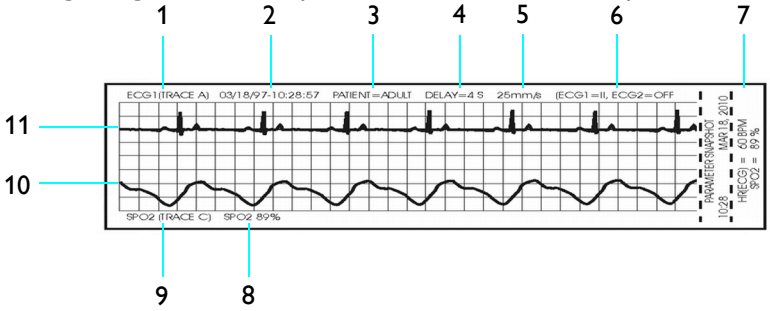
When printing waveforms, titled *Parameter Snapshot*, the MR400 prints 30 seconds of patient data and then automatically stops printing.

To print a *Parameter Snapshot,* in the main screen, press the **Print** button.

To stop printing, in the main screen, press the **Print** button a second time.

14.2.2.1 Parts of a Printed Waveform

The following image shows the parts of the *Parameter Snapshot*:



Part	Description
1	**Trace 1** measurement label
2	Date and time (formatted as MM/DD/YY-HH:MM:SS)
3	**Patient Type**
4	**Trace Delay**
5	Trace speed
6	**Trace 1** parameter information
7	Parameter values at time of printing
8	**Trace 2** parameter information
9	**Trace 2** measurement label
10	**Trace 2** waveform
11	**Trace 1** waveform

14.2.2.2 Waveform Printing Setup

Use the **Printer Setup** menu to manage printing waveforms.

To open the **Printer Setup** menu, press the **Setup** key and then the **Printer** key.

The **Printer Setup** menu contains the following controls:

Control name	Description
Trace 1	Select a waveform to print: • **ECG 1** (factory default) • **ECG 2** • **P1** • **P2** • **SpO2** • **RESP (CO2)**
Trace 2	Select a second waveform to print: • **Off** (factory default) • **ECG 1** • **ECG 2** • **P1** • **P2** • **SpO2** • **RESP (CO2)**
Trace Delay	Select the time to delay sending trace data to the printer: • **0 Sec** • **4 Sec** (factory default) • **8 Sec** • **16 Sec**

15: Cleaning and Disinfection

15.1 Overview

Clean and disinfect the cart and reusable accessories before use and between patients.

Keep the MR400 and accessories free of dust, dirt and pathogens. After cleaning and disinfection, always check the equipment carefully. Stop using equipment that shows signs of deterioration or damage. Observe the following general precautions when cleaning:

- Always dilute the cleaning substance according to the manufacturer's instructions or use lowest possible concentration.
- Never allow liquid to enter the equipment.
- Never immerse any part of the equipment in liquid.
- Never pour liquid onto the equipment.
- Never use abrasive material to wipe the equipment.

Note—For answers to questions regarding infection control, call us at (800) 722-9377 (inside the USA) or contact your local/regional support center (outside the USA).

Clean using a lint-free cloth, moistened with warm water (40°C / 104°F maximum) and mild soap, a diluted non-caustic detergent or alcohol-based cleaning agent. Never use strong solvents such as acetone or trichloroethylene. Stains can be removed by scrubbing briskly with a moistened cloth. If disinfection is required, clean the equipment before disinfecting it.

Never use corrosive or solvent disinfectants or sterilizing agents. If you are not sure about the properties of a disinfectant or sterilizing agent, do not use it.

The recommended types of disinfecting agents are listed in the following table. Philips 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.

Product Name	Product Type
Cavicide Disinfectant: CaviWipes	Towelette
Sani-Cloth Germicidal Wipes*	Towelette
Sklar Disinfectant*	Towelette

* Any product residue should be removed by wiping the surface.

Those parts of the product that are suitable for such treatment, including accessories and connecting cables, can be disinfected by gently wiping the surfaces with a cloth dampened with a suitable agent for a brief period (30 seconds to 1 minute) or as directed by the substance manufacturer. Never use corrosive or solvent disinfectants or sterilizing agents. If you are not sure about the properties of a disinfectant or sterilizing agent, do not use it.

Device type:	To clean and disinfect:
• Power cords • Universal gating interfaces	Follow your facility's policies for MRI surface housekeeping.
• Reusable invasive pressure accessories • Remote monitor and remote monitor accessories • Battery chargers	Follow the accessory's instructions for use.
• Enameled parts and aluminum surfaces	See "15.3 Cleaning Enameled Parts and Aluminum Surfaces" on page 163.
• Main batteries • Module batteries	See "15.4 Cleaning Batteries" on page 163.
• Touchscreen	See "15.5 Cleaning the Touchscreen" on page 163.
• SpO_2 clips • ECG cables • Noninvasive pressure cuffs and hoses	See "15.6 SpO2 Clips, ECG Cables, and Reusable NBP Accessories" on page 164.
• SpO2 sensors • Temperature sensors	See "15.7 SpO2 and Temperature Sensors" on page 165.
• MR400 cart • ECG module • SpO2 module	See "15.8 MR400 Cart and Modules" on page 166.

15.2 Cleaning and Disinfection Safety

WARNINGS

- Do not use flammable or potentially explosive disinfecting sprays.
- Before cleaning and disinfection, remove the module batteries and remove all power from the cart. See"5.3.1 Inserting and Removing Module Batteries" on page 52 and "5.2.2 Adding and Removing Cart Power" on page 48.
- The MR400 cart is not protected against liquid ingress. See "A.2 IP Ratings" on page 192. Do not pour liquid onto the MR400 and accessories. Prevent liquid from entering the MR400 and accessories. If the MR400 cart or any accessory becomes wet, discontinue use. Clean and dry the affected parts before use. Liquid ingress presents risks of device damage and user injury.

CAUTION

Do not submerge, soak, or immerse the device, modules, and accessories in liquid. Do not allow liquid or soil to enter the device. Do not clean by automated process. Do not disconnect the accessories during cleaning, except the temperature sensor.

15.3 Cleaning Enameled Parts and Aluminum Surfaces

Do not use corrosive cleaning agents, solvents, abrasive detergents, or abrasive polishes. If you are not sure about the properties of a cleaning agent, do not use it.

Enameled parts and aluminum surfaces are as follows

Requirements:
- Cloth dampened with a mild detergent
- Dry, woolen cloth

Step	Action
1	Inspect the enameled parts and aluminum surfaces. If they are damaged, contact Service. Otherwise, go to the next step.
2	Remove all power from the cart. See "5.2.2 Adding and Removing Cart Power" on page 48.
3	Wipe the enameled parts and aluminum surfaces with a cloth dampened with a mild detergent. Continue wiping until the parts are visibly clean.
4	Rub the enameled parts and aluminum surfaces clean with a dry, woolen cloth.
5	Inspect the enameled parts and aluminum surfaces. If liquid has entered the device, if it is damaged or broken, or if soil remains visible, contact Service.

15.4 Cleaning Batteries

Remove the battery from the cart or module. Wipe it with a dry, lint-free cloth.

15.5 Cleaning the Touchscreen

Requirement:
- Soft, non-woven cloth dampened with an 80% diluted alcohol mixture.

Step	Action
1	Inspect the touchscreen. If it is damaged, contact Service. Otherwise, go to the next step.
2	Wipe the touchscreen gently with a soft, non-woven cloth dampened with an 80% diluted alcohol mixture.
3	Inspect the touchscreen. If liquid has entered the device, if it is damaged or broken, or if soil remains visible, contact Service.

15.6 SpO2 Clips, ECG Cables, and Reusable NBP Accessories

This section applies to all reusable SpO_2 clips, ECG cables, and NBP cuffs and hoses. Clean and disinfect these accessories before use and between patients.

CAUTION

- Do not submerge, soak or immerse the device in liquid, and do not allow liquid or soil to enter the device or you may damage the device. Do not disconnect the accessory.
- Clean and disinfect SpO_2 clips, ECG cables, and reusable NBP cuffs and hoses according to this procedure. Otherwise, exposure to hazardous chemicals may cause a skin reaction, and improper disinfection may cause infection.

Requirements:

- Enzymatic detergent cleaning solution prepared according to the manufacturer's instructions
- Deionized water
- 70% isopropyl alcohol
- Lint-free cloths
- Soft-bristle brush or cotton swabs

Step	Action
1	Inspect the accessory. If it is damaged or broken, discard it. Otherwise, go to the next step.
2	Do not disconnect the accessory from any other part of the system. Use a lint-free cloth dampened (not dripping) with deionized water to remove excess soil.
3	Dampen another lint-free cloth with the prepared enzymatic cleaning solution.
4	Gently clean the accessory. Ensure you remove all visible soil.
5	Repeat steps 3 and 4, using a swab or brush to access crevices or small areas.

Step	Action
6	Use a clean, lint-free cloth or swab, dampened (not dripping) with deionized water to remove any excessive detergent residue.
7	Inspect for cleanliness. Repeat steps 3 through 6 until the surfaces are visibly clean.
8	Allow to dry completely.
9	Use a lint-free cloth to wipe the alcohol onto the accessory, thoroughly wetting the surfaces.
10	Keep wet 12 minutes.
11	Allow to air dry.
12	Inspect the accessory. If liquid has entered the accessory, if it is damaged or broken, or if soil remains visible, discard it.

15.7 SpO2 and Temperature Sensors

This section applies to SpO_2 sensors and temperature sensors. Clean and disinfect these accessories before use and between patients. Do not immerse or autoclave these accessories.

Requirements:

- Alcohol
- CaviWipes disinfectant towelettes

Step	Action
1	Remove the accessory from use.
2	Inspect the accessory. If it is damaged or broken, discard it. Otherwise, go to the next step.
3	Remove all visible debris from the accessory using soap and water.
4	Clean the accessory by thoroughly wiping it using CaviWipes disinfectant towelettes. Discard the used towelettes (refer to your facility's biohazard procedure for disposal).
5	Disinfect the accessory by thoroughly wiping it using CaviWipes disinfectant towelettes. Discard the used towelettes (refer to your facility's biohazard procedure for disposal).
6	Allow the accessory to dry. (No rinsing is required.)

Step	Action
7	Check the accessory for any residual debris. If any debris is present, repeat steps 3 through 6 then examine the item again before proceeding. *Note*—Adhesive residue may accumulate on the SpO2 sensor. Carefully remove any residue with alcohol to keep the glass fiber ends clean.
8	Check the accessory for damage (cracks, holes, tears, cuts, et cetera) and discard the accessory if damage is found.

15.8 MR400 Cart and Modules

Clean and disinfect the MR400 cart and the ECG and SpO2 modules before use and between patients.

Requirements:

- Soap
- 80% diluted alcohol mixture
- Soft, non-woven cloths
- CaviWipes disinfectant towelettes

Step	Action
1	Inspect the cart and modules. If any part is damaged or broken, discontinue use and contact Service. Otherwise, go to the next step.
2	Remove all power from the cart. See "5.2.2 Adding and Removing Cart Power" on page 48.
3	Remove all batteries from the modules. "5.3.1 Inserting and Removing Module Batteries" on page 52.
4	Clean the touch screen by wiping it gently using a soft non-woven cloth with 80% diluted alcohol mixture.
5	Remove all visible debris from the cart and modules using soap and water.
6	Clean the cart and modules by thoroughly wiping the devices using CaviWipes disinfectant towelettes. Follow the CaviWipes instructions for use.
7	Discard the used towelettes (refer to your facility's biohazard procedure for disposal).
8	Clean the cart and modules by thoroughly wiping the devices using CaviWipes disinfectant towelettes. Follow the CaviWipes instructions for use.
9	Discard the used towelettes (refer to your facility's biohazard procedure for disposal).

Step	Action
10	Allow the cart and the wireless modules to dry. (No rinsing is required.)
11	Check the cart and the wireless modules for any residual debris. If any debris is present, repeat steps 4 through 10 then re-examine the cart and wireless modules before proceeding.
12	Check the cart and wireless modules for damaged, loose or missing hardware. Contact technical support if necessary.

16: Maintenance

16.1 Service Life

The expected service life of the cart is 7 years from the date of manufacture. The date of manufacture appears on the device identification label on the rear of the device. MR400 system accessories, listed in the "2.3 Accessory List" on page 14, are excluded from the expected service life determination.

The expected service life is the time during which the device is expected to maintain basic safety and essential performance, when the user follows the routine maintenance instructions in this instructions for use. Expected service life is not synonymous with warranty period and does not imply any coverage beyond the stated limits of the warranty.

16.2 Device Lifetime

Device lifetime is considered to end once the device shows signs of damage such as the following.

- Cracks, holes, tears, gouges, cuts, and so on.
- Cracks or other signs of damage to the connector, including bent or damaged pins.
- Soil that you cannot remove by following the cleaning instructions.

16.3 Cart and Accessory Maintenance Requirements

WARNING

Follow these maintenance requirements. Do not use the MR400 if you do not follow this schedule. Do not use the MR400 if you suspect any part of the system is defective or was not properly maintained.

The MR400 and accessories require maintenance by trained healthcare professionals. For training information, see "1.9 Training Requirements" on page 3.

Do not service or maintain any part of the MR400 system while in use with a patient.

Maintenance activities are as follows:

Frequency	Maintenance Requirement
Every 8 hours of use	Recharge the module batteries. See "2.4.6 Status Pane" on page 22 for charge levels. See the battery charger's instructions for use for recharging instructions.
Daily	Clean, disinfect, and inspect the cart and reusable accessories for damage. Do not use a damaged cart or accessories. Do not clean single-use accessories. See "15: Cleaning and Disinfection" on page 161.
Daily	Test the alarms. See "16.7 Testing Alarms" on page 172.
Every 12 months	• Replace the main batteries. • Replace the reserve batteries. Contact Service.
Every 12 months	Replace the module batteries.
Every 12 months	Annual service requirements that are listed in the MR400 service manual (453665111181). Contact Service.
When you see the following system messages: • O2 Sensor Not Present • O2 Sensor Fail	Replace the oxygen sensor. See "16.9 Replacing the Oxygen Sensor" on page 174.
• When you update software • When the touchscreen behaves erratically	Calibrate the touchscreen. See "16.12 Calibrating the Touchscreen" on page 177.
As needed	If you drop a module, see "16.8 Testing a Dropped Module" on page 173.
As needed	Update software. See "16.11 Updating Software" on page 176.
As needed	Testing and other activities to be performed only by Service. See the MR400 service manual (453665111181).

16.4 Contacting Service

USA: Call Philips Service at 1-800-722-9377.

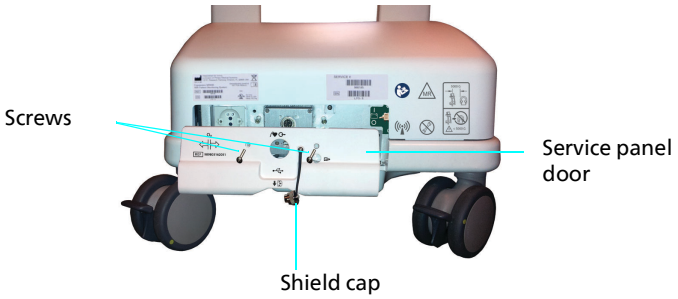
All other countries: Contact your local Philips representative or authorized service provider (Service).

Authorized service providers require extra training and qualification.

16.5 Accessing the Service Panel

Requirement: A #2 Phillips screwdriver

To access the service panel, follow these steps.

Step	Action
1	Turn off the MR400.
2	Remove the gating cable or remove the shield cap from the gating connector. 
3	Remove the screws. Then remove the service panel door.

To close the service panel door, follow these steps.

Step	Action
1	Replace the door. Tighten the 2 screws.
2	Replace the shield cap.

16.6 Performing a Cold Start Reset (Default Initialization)

The MR400 is equipped with a cold start reset feature for use in the unlikely event that the system enters a state where it does not fully start up or shuts down during the startup process or shortly thereafter.

Performing a cold start reset will remove all stored user settings data in an attempt to correct this problem, which may be due to data that have been corrupted or that are incompatible with the installed software. If experiencing a startup problem, perform the following procedure.

Note—This procedure deletes all stored user settings data and restores the factory default values to the settings used by the MR400.

Step	Action
1	Turn off the MR400.
2	Press and hold the power button. Hold the power button until the Philips MR400 start-up screen disappears. Then release the power button.
3	Allow the system to complete the start-up sequence. All stored user settings have been automatically deleted. If the MR400 starts up successfully, the problem was most likely due to corrupt or incompatible user settings.
4	If the system start-up is successful, this completes the procedure, otherwise, go to step 5. To determine if the start up is successful, check to see if all profiles (user settings) are deleted. Or check the Admin password is reset to the default password. A cold start deletes all stored user settings and resets the Admin password to the default password.
5	If the MR400 still does not start up successfully, return to step 1 and attempt the procedure one more time.
6	If the MR400 still does not start up successfully, contact technical support for assistance.

16.7 Testing Alarms

Requirements:

- The system is not suspended.
- The system is not in simulation mode.
- Sound is on. (Select **Alarms** > **Alarm Sound** > **On**).
- The SpO2 lower alarm limit is set to a value (not turned off).
- The SpO2 module batteries are charged.
- The SpO2 module is communicating with the cart.
- The SpO2 module is within 9.1 m (30 feet) of the MR400, in the same MRI room or in the same shielded room.

To verify the alarm functions, follow these steps.

Step	Action
1	Place the adult SpO2 clip on your finger and wait for an SpO2 value to appear in the main screen.
2	Remove your finger from the clip.

Step	Action
3	Verify the following: • **Non-Pulsat** or **Probe Off** notification flag appears. • The SpO2 waveform is flat. • The SpO2 value flashes yellow. • You hear the medium-priority audio indicator.
4	If you suspect a problem with any part of the alarm system, stop using the MR400 immediately. Contact Service.

16.8 Testing a Dropped Module

CAUTION

If you drop any part of the MR400 system, verify the device operation before use.

If you drop the ECG or SpO2 module, perform the following procedure before monitoring ECG or SpO2.

To verify the basic functions of a dropped wireless module, follow these steps.

Step	Action
1	Examine the module and battery for signs of damage such as cracks or damaged connectors: • If you do not see visual signs of damage, go to the next step. • If you see damage, replace the module, the battery, or both. Follow your facility's policies for battery safety.
2	Ensure that the module contains a fully charged battery (2 batteries in the ECG module). • If the battery and channel indicators are illuminated, go to the next step. • If the battery and channel indicators are NOT illuminated, replace the module.
3	Ensure that the module is • Within 9.1 m (30 feet) of the MR400 • In the same magnet room, or in the same shielded room • Set to the same channel used by the cart.
4	In the MR400 main screen, check the status pane: • If the module's battery time and communication channel appear, go to the next step. • If the status pane shows that the module is disconnected or if battery time does not appear, replace the module.
5	Proceed to use the dropped module. If the module and cart cannot communicate or if alarms or system messages such as **Lead Fail** or **No Probe** occur, then replace the module.

16.9 Replacing the Oxygen Sensor

WARNING

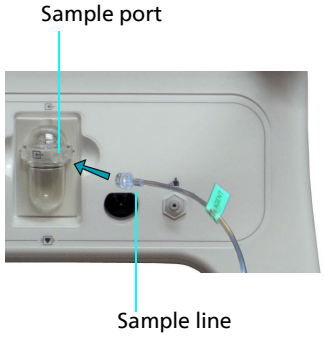
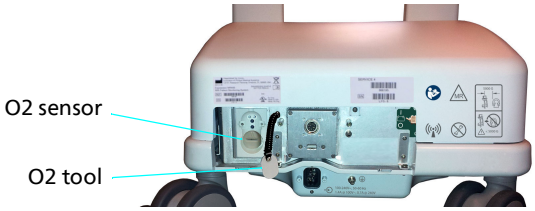
Disconnect the sample line from the sample port or water trap before replacing the oxygen sensor.

The oxygen sensor expiration date appears on the sensor package and the sensor label. Plan accordingly.

The MR400 shows the following oxygen sensor messages to let you know to replace the sensor:

- **O2 Sensor Not Present**: the sensor is missing or malfunctioning.
- **O2 Sensor Fail**: the sensor is missing, malfunctioning, or drained.

To replace the O_2 sensor, follow these steps.

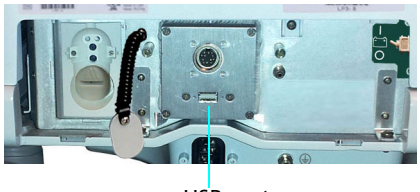
Step	Action
1	Turn off the MR400.
2	At the patient connection panel, disconnect the sample line from the sample port. Turn the Luer connector counterclockwise. 
3	Use a #2 Phillips screwdriver to remove the service panel door. See "16.5 Accessing the Service Panel" on page 171.
4	Locate the sensor tool and the O_2 sensor port. 
5	Use the sensor tool to turn the sensor counterclockwise and remove it. 
6	Insert a new sensor then use the sensor tool to turn the sensor clockwise to replace.
7	Replace the service panel door and tighten the 2 screws.

Step	Action
8	At the patient connection panel, connect a sample line to the sample port on the water trap.
9	Turn on the MR400.
10	Turn on the **Agents** parameter and wait until **CO2 Warming Up** no longer appears.
11	Calibrate the O2 sensor: a. In the main screen, select **Monitor**. b. In the **Monitor Setup** menu, select **Service (Bio-Med)** > **Gas Cal** > **O2 Cal**. c. When prompted: **Flow Room Air For 10 Seconds Do you wish to continue?**, select **Yes** to proceed.

16.10 User Settings Backup and Restore

Use a flash drive to back up user settings. You can restore the settings when you reset the cart. You can also use **Restore** as a way to copy settings from one MR400 cart to a different MR400 cart, which is useful when you are setting up several systems.

To backup and restore user settings, follow these steps.

Step	Action
1	Create the user profiles. See "2.4.8.1 Edit User Settings Menu" on page 25 for details.
2	Use a #2 Phillips screwdriver to remove the service panel door. See "16.5 Accessing the Service Panel" on page 171.
3	Insert the USB flash drive (REF 453564562231) into the USB port.  USB port
4	In the main screen, select **Setup** > **Monitor** > **Edit User Settings** > **Backup/Restore Settings**.
5	On the Backup/Restore Settings dialog box: • If you want to save profiles to the flash drive, select **Backup**. • If you want to load profiles from the flash drive, select **Restore**.
6	Follow the instructions on the screen. Do not remove the USB flash drive.
7	When the system notifies you that the process is complete, remove the USB flash drive.
8	Replace the service panel door and shield cap.

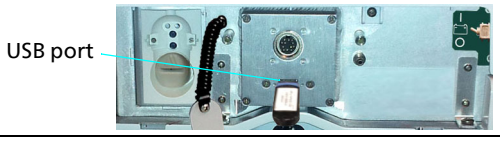
16.11 Updating Software

CAUTION

Contact Service before you update software.

Ensure the cart, modules, and remote monitor hardware and software revisions are compatible with the software update. Ensure that all other necessary program or hardware updates are complete. Ensure that the software is validated. If you have questions, contact Service.

To update software in the MR400, follow these steps.

Step	Action
1	Back up the user settings to a flash drive. See "16.10 User Settings Backup and Restore" on page 175.
2	Use a #2 Phillips screwdriver to remove the service panel door. See "16.5 Accessing the Service Panel" on page 171.
3	Connect A/C power to the cart and insert at least one fully charged battery.
4	Turn on the cart and allow the system to initialize. If the cart does not initialize, contact Service. A recovery may be required.
5	Select **Setup** > **Monitor** > **Administrative Settings**. Enter your password at the prompt.
6	Select **Admin Controls** > **Enable Program Update** > **On**.
7	Insert the flash drive that contains the update into the USB port. 
8	On the **Program Update** dialog box, select **Yes**. This dialog box lists part numbers and revisions. It also shows update status. While the software updates, do not remove the flash drive and do not turn off the MR400.
9	When instructed, remove the flash drive and restart the MR400.
10	To verify the installation, select **Setup** > **Monitor** > **Service (Bio-Med)** > **Revision Information**. Confirm that the revision is correct.
11	Restore the user settings. See "16.10 User Settings Backup and Restore" on page 175.
12	Replace the service panel door and shield cap.

16.12 Calibrating the Touchscreen

Calibrate the touchscreen under the following circumstances:

- You install new operating software
- The touchscreen response is inaccurate
- The touchscreen does not accept input

To calibrate the touchscreen, follow these steps.

Step	Action
1	Ensure that screen captures are disabled. Select **Setup** > **Monitor** > **Administrative Settings** > **Service Utilities** > **Allow Screen Capture** > **Off**.
2	Briefly press and then release the power button 3 times within 6 seconds.
3	When prompted, press and release the power button again to confirm you want to calibrate the touchscreen.
4	Turn off the cart then turn it back on.
5	Use your index finger or a stylus to touch the center of the cross hair each time it moves to a new location. If calibration does not resolve touchscreen issues, try again or contact Service.

16.13 Repair

Do not attempt to repair the MR400 system. Only Service may repair the system. Consult the MR400 service manual (453665111181).

16.14 Passing the Product on to another User

Philips supports recycling and sustainability. For more information, go to:

https://www.philips.com/a-w/about/environmental-social-governance/environmental/circular-economy/recycle

If you want to pass this product to another user, contact Service.

16.15 Disposing the MR400

WARNING

Do not dispose any part of the MR400 system in industrial or domestic waste.

Dispose of the MR400 and accessories according to local regulations, particularly those related to infectious, electrical, and hazardous waste. Ensure you remove all

personal health information and reset the password. See "16.6 Performing a Cold Start Reset (Default Initialization)" on page 171.

Philips supports customers in recovering reusable parts, recycling useful materials, and safe and effective disposal.

For guidance, contact your local Philips representative or Service.

17: Gating Feature

17.1 About Gating

For MRI systems that can accept wireless gating signals through a wireless triggering unit, see the gating instructions in the MRI system instructions for use.

For performance characteristics of the gating connector on the cart, see the MR400 service manual (453665111181).

The Universal Gating Interface (UGI) connects the MR400 system to an MRI system's ECG leads. The MR400 modules communicate data with the cart. The cart communicates with the MRI system through the UGI. The Universal Gating Interface does not support respiratory gating.

For information about the control indication, see "8.4 About the ECG Waveforms and Numerics" on page 88.

For information about disabling magnet control, see "8.15 ECG Menu" on page 101.

17.2 About the Universal Gating Interface

Intended use	The Universal Gating Interface use enables the Intended Use of the connected compatible MRI Patient Monitoring System. The MRI Patient Monitoring System is intended to monitor vital signs for patients undergoing MRI procedures and to provide signals for synchronization for the MRI scanner. The MRI Patient Monitoring System is intended for use by healthcare professionals. The MRI Patient Monitoring System provides monitoring for the following vital sign parameter: ECG or SpO2.
Indications for use	The Universal Gating Interface, which connects the patient monitor to the MRI system, is indicated for use when low latency MRI triggering and synchronization is needed during MRI procedures based on the measured cardiac physiology signal.

17.3 Universal Gating Interface Setup

Requirement	Reference
MRI system that is set up for gating	MRI system's instructions for use
Universal Gating Interface	"2.3 Accessory List" on page 14
For ECG gating, complete all procedures to monitor ECG.	"8.5 Monitoring ECG Process Overview" on page 89 "8.6 ECG Monitoring Requirements" on page 90
For peripheral pulse gating, complete all procedures to monitor SpO2.	"9.5 Monitoring SpO2 Process Overview" on page 107 "9.6 SpO2 Monitoring Requirements" on page 107

WARNING

Do not place the Universal Gating Interface on the MR patient table during imaging.

Cardiac gating data can come from 2 sources, depending on whether you want to gate on cardiac data (ECG module) or peripheral pulse data (SpO2 module). For patients with pacemakers, you must use peripheral pulse data for cardiac gating.

Step	Action
1	Connect the Universal Gating Interface to the gating connector on the base of the MR400 cart.
2	Connect the magnet's ECG leads to the Universal Gating Interface. Ensure you match the labeling on the interface.
3	Select the **ECG** label. On the **ECG** menu, select **HR Source** and then select one of the following: • **SpO2:** To gate on peripheral pulse data. (Use with pacemakers.) • **ECG**: To gate on cardiac data. (Do not use with pacemakers.)
4	Select the **ECG** label. On the **ECG** menu, select **Gating Source** and then select either: • **ECG** • **Pulse**

18: Symbols Glossary

18.1 Explanation of Symbols

The symbols in this chapter may appear on the Expression Model MR400 MRI Patient Monitoring System, the accessories, or the packing material.

The MR400 system devices, packages, and instructions are compliant with United States 21CFR801.437.

18.2 Symbols on Devices and Packages

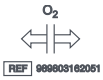
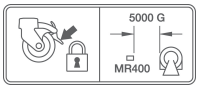
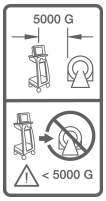
The symbols in this table may appear on devices and packages.

Symbol	Description
Common symbols on devices and packages	
	Manufacturer ISO 7000-3082 ISO 15223-1 5.1.1
	Catalog Number ISO 7000-2493 ISO 15223-1 5.1.6
 YYYY-MM-DD YYYY-MM	Country of Manufacture with 2-letter country code per ISO 3166-1. IEC 60417-6049 ISO 15223-1 5.1.11 Date of Manufacture appears below or next to the country of manufacture Date of Manufacture IEC 60417-6049 ISO 15223-1 5.1.11 YYYY = year MM = month DD = date
	Prescription Only US FDA 21 CFR 801.109(b)(1)
	Refer to instruction manual/booklet ISO 7010-M002
	Caution ISO 7000-0434A ISO 15223-1 5.4.4
	CE Marking EU Directive 93/42/EEC Conformity to EU Directive 93/42/EEC with Notified Body Number

Symbol	Description
CE	CE Marking Indicates conformity to applicable EU regulations.
MD	Medical Device Symbol ISO 15223-1 5.7.7
MR	MR Conditional ASTM F2503-20
MR	MR Safe ASTM F2503-20
SN	Serial Number ISO 7000-2498 ISO 15223-1 5.1.7
LOT	Batch Code ISO 7000-2492, ISO 15223-1 5.1.5
SERVICE #	Service Number Manufacturer's service part number
UDI	UDI Identifier ISO 15223-1 5.7.10
www.philips.com/IFU	Electronic instructions for use ISO 7000-1641, ISO 15223-1 5.4.3
	WEEE wheeled bin Waste Electrical and Electronic Equipment (WEEE) Directive Annex IX
	Defibrillation-proof type CF applied part IEC 60417-5336
	Non-Ionizing Radiation IEC 60417-5140
IP21	Ingress Protection IEC 60529 section 4 Solid particles: > 12.5 mm (0.49 in) particles (fingers or similar objects) Liquid ingress: vertically dripping water
IP20	Ingress Protection IEC 60529 section 4 Solid particles: no protection Liquid ingress: vertically dripping water when tilted at 15°
IP57	Ingress Protection IEC 60529 section 4 Solid particles: dust protected Liquid ingress: immersion, up to 1 meter (3 ft 3 in) depth
R	Ministry of Internal Affairs and Communications (MIC) Japanese Radio Law Certification: Article 38-24-1 of the Radio Law (Law No. 131 of 1950)
CLASSIFIED c UL us	UL classification marks for Canada and the United States
FC	FCC Logo
	Temperature limit ISO 7000-0632 ISO 15223-1 5.3.7

Symbol	Description
	Humidity limitation ISO 7000-2620 ISO 15223-1 5.3.8
	Atmospheric pressure limitation ISO 7000-2621 ISO 15223-1 5.3.9
	Packaging unit by count ISO 7000-2794 A number in the box shows the number of items in the package.
	Philips Shield
PHILIPS	Philips wordmark
UK CA 0168	UK CA Mark
UK RP	UK Responsible Person
	Fragile, handle with care ISO 15223-1, 5.3.1 Indicates a medical device that can be broken or damaged if not handled carefully
	Keep dry ISO 15223-1, 5.3.4 Indicates a medical device that needs to be protected from moisture.
	This way up ISO 780, 13 This is the correct upright position of the distribution package for transport and/or storage.
	Use by date ISO 7000-2607 ISO 15223-1 5.1.4
	Do not re-use ISO 7000-1051 ISO 15223-1 5.4.2
	Mass ISO 7000-1321A To indicate mass. To identify a function related to mass.
	Person, general; Patient, normal IEC 60417-5390: Person, general; patient, normal To indicate a reference to a person or human body. On medical equipment this graphical symbol is used to indicate a reference to a normal patient. When accompanied by the mass symbol: patient mass
	Baby IEC 60417-5667: Baby To identify equipment, connections on equipment or operating modes which are dedicated for babies, for example on medical equipment. When accompanied by the mass symbol: infant patient mass
CH REP Philips AG Seestrasse 87 CH-8810 Horgen	Authorized Representative in Switzerland

Symbol	Description
	China ROHS
	China ROHS EFUP 50 Chinese Ministry of Industry and Information Technology Indicates that any overlimit restricted substances in the device shall not leach or leak into the environment within a period of 50 years from the date of manufacture.
	Sterilized using irradiation ISO 7000-2502 ISO 15223-1 5.2.4
	Non-Sterile ISO 7000-2609 ISO 15223-1 5.2.7
AGENT	To identify the sample line to be used for anesthetic agents.
	Do not stack ISO 7000-2402 To indicate that the items shall not be vertically stacked, either because of the nature of the transport packaging or because of the nature of the items themselves.
	Keep away from sunlight ISO 15223-1, 5.3.2 Indicates a medical device that needs protection from light sources.
	Equipotentiality IEC 60417-5021 Indicates the terminals which, when connected together, bring the various parts of an equipment or of a system to the same potential, not necessarily being the earth (ground) potential, e.g. for local bonding.
	Importer ISO 7000-3725 To indicate the entity importing the medical device into the locale.
	Assortment ISO 7000-2791 To identify that the package includes an assortment of types or sizes.
	Contains or presence of ISO 7000-2725 Indicates that the equipment contains the identified product or substance. "XXX" is replaced by the substance that is contained or present. For example: LATEX, DEHP
	Distributor ISO 15223-1, 5.1.9 Indicates the entity distributing the medical device into the locale.
Symbols on the MR400 cart	
	Power button (standby switch)
P1, P2	Invasive pressure ports 1 and 2
	Input
	Input
	Temperature input

Symbol	Description
	Noninvasive blood pressure (NIBP) input
	Universal Serial Bus (USB), port/plug
	Cardiac Gating Outport
	Output
	Power Port
	Anesthetic Oxygen
	No pushing
	Cart Lock & MR400 Positioning
	MR400 Positioning
Symbols on modules	
	ECG module: Battery ejection indicators for battery 1 and battery 2
	ECG module: Battery charge indicators for battery 1 and battery 2
	SpO2 module: Battery ejection and charge indicators
	Channel indicator and channel selection button For modules with channels 1 through 5
	Channel indicators for modules with channels 6 through 10
	Battery alignment arrow

Symbol	Description
Symbols on SpO2 Clips and Grips	
A	Adult
P	Pediatric
I	Infant
N	Neonatal
Symbols on Noninvasive Blood Pressure Cuffs	
	Patient Limb Circumference (cm)
	Improper application of cuff Wrong side out
	Proper application of cuff Correct side out
	Indication of positioning
	Index and range indicator line

18.3 Software Symbols

18.3.1 Information Bar Symbols

Symbol	Description	Symbol	Description
	IEC 60417-5013: Bell Alarm audio is on.		The alarm lights are off.
	IEC 60417-5576: Bell cancel Indicates one of the following: • Alarm audio is off. • You acknowledged an alarm event.		The alarm lights are temporary.
	IEC 60417-5576-2: Bell, cancel temporary Indicates one of the following: • You paused alarm audio • You paused alarm audio and lights		Heartbeat indicator
	The alarm lights are continuous.		Breath indicator

18.3.2 Quick Access Button Symbols

Symbol	Description	Symbol	Description
	Setup		Main Screen
	NIBP Interval		NIBP Start/Stop
	Zero All		Ready to print.
	Clear Trends		Printer unavailable
	1-Touch Alarms		Printer error
	Suspend		Trends
	Audio Pause		ECG Filter
	IEC 60417-5307: Alarm, general		

18.3.3 Status Pane Symbols

Symbol	Description	Symbol	Description
	General Warning ISO 7010-W001 Indicates a general warning is associated with the equipment		Channel 1

Symbol	Description	Symbol	Description
	Information button	2	Channel 2
	IP5 button	3	Channel 3
	Remote monitor button	4	Channel 4
	Information Portal 5000 button	5	Channel 5
	Connecting	6	Channel 6
	Stop remote monitor communication	7	Channel 7
	A/C power	8	Channel 8
	No battery	9	Channel 9
	Low battery	10	Channel 10
	Charging battery		
	Battery not charging		

18.3.4 Navigation Symbols

Symbol	Description	Symbol	Description
	Close		Accept and save changes
	Decrease a value		Clear
	Increase a value		Enter

18.3.5 Trends Symbols

Symbol	Description	Symbol	Description
---	No trend data		Values are trending downwards
	Values are stable over time		Values are trending upwards
	Scroll one column to the left		Scroll one column to the right
	View the previous page of records		View the next page of records
	View the oldest record		View the newest record

Appendix A: Specifications

A.1 Environmental Specifications

WARNING

To prevent inaccurate data, patient injury, and operator injury, adhere to the following environmental specifications when operating the MR400 system.

CAUTION

Store the cart batteries in a dry place between 0 to 40°C (32 to 104°F). Do not expose the cart batteries to temperatures above 60°C (140°F).

The MR400 system and accessories are to be stored, transported, and operated under the following environmental conditions.

Device	Operating temperature	Storage and transport temperature	Operating humidity non-condensing	Storage and transport humidity non-condensing	Operating pressure	Storage and transport pressure
Cart with touchscreen	50 to 95°F 10 to 35°C	-4 to 122°F -20 to 50°C	15 to 80%	5 to 80%	708 hPa to 1,020 hPa	570 hPa to 1,020 hPa
ECG modules	50 to 95°F 10 to 35°C	-4 to 140°F -20 to 60°C	15 to 80%	5 to 80%	708 hPa to 1,020 hPa	570 hPa to 1,020 hPa
SpO2 modules	50 to 95°F 10 to 35°C	-4 to 140°F -20 to 60°C	15 to 80%	5 to 80%	708 hPa to 1,020 hPa	570 hPa to 1,020 hPa
Cart batteries	See label	32 to 104°F 0 to 40°C	See label	Dry place	See label	See label
ECG module batteries	50 to 95°F 10 to 35°C	-4 to 140°F -20 to 60°C	15 to 90%	15 to 90%	708 hPa to 1,020 hPa	962 hPa to 1,064 hPa
Power cords	50 to 95°F 10 to 35°C	-4 to 140°F -20 to 60°C	15 to 80%	5 to 80%	708 hPa to 1,020 hPa	570 hPa to 1,020 hPa
Battery chargers	50 to 95°F 10 to 35°C	-4 to 140°F -20 to 60°C	15 to 80%	5 to 80%	708 hPa to 1,020 hPa	570 hPa to 1,020 hPa
Noninvasive blood pressure cuffs and hoses	50 to 95°F 10 to 35°C	-4 to 140°F -20 to 60°C	10 to 80%	5 to 80%	708 hPa to 1,020 hPa	570 hPa to 1,020 hPa
ECG electrodes	50 to 95°F 10 to 35°C	50 to 90°F 10 to 32°C	15 to 80%	5 to 80%	708 hPa to 1,020 hPa	570 hPa to 1,020 hPa
ECG skin prep gel	No environmental protective measures are necessary. To maintain product quality, store at room temperature with the lid closed.					

Device	Operating temperature	Storage and transport temperature	Operating humidity non-condensing	Storage and transport humidity non-condensing	Operating pressure	Storage and transport pressure
ECG cables	50 to 95°F 10 to 35°C	-4 to 140°F -20 to 60°C	15 to 80%	5 to 80%	708 hPa to 1,020 hPa	570 hPa to 1,020 hPa
SpO2 clips	50 to 95°F 10 to 35°C	-4 to 140°F -20 to 60°C	15 to 80%	5 to 80%	708 hPa to 1,020 hPa	570 hPa to 1,020 hPa
SpO2 grips	50 to 95°F 10 to 35°C	-4 to 140°F -20 to 60°C	15 to 80%	5 to 80%	708 hPa to 1,020 hPa	570 hPa to 1,020 hPa
SpO2 sensor	50 to 95°F 10 to 35°C	-4 to 140°F -20 to 60°C	15 to 80%	5 to 80%	708 hPa to 1,020 hPa	570 hPa to 1,020 hPa
CO2 cannulas	50 to 95°F 10 to 35°C	-4 to 140°F -20 to 60°C	15 to 80%	5 to 80%	708 hPa to 1,020 hPa	570 hPa to 1,020 hPa
CO2 sample lines	50 to 95°F 10 to 35°C	-4 to 122°F -20 to 50°C	15 to 80%	5 to 80%	708 hPa to 1,020 hPa	570 hPa to 1,020
CO2 adapters	50 to 95°F 10 to 35°C	-4 to 140°F -20 to 60°C	15 to 80%	5 to 80%	708 hPa to 1,020 hPa	570 hPa to 1,020 hPa
Invasive pressure transducers and cables	50 to 95°F 10 to 35°C	5 to 140°F -15 to 60°C	15 to 85%	5 to 80%	708 hPa to 1,020 hPa	570 hPa to 1,020 hPa
Temperature sensor	50 to 95°F 10 to 35°C	-4 to 140°F -20 to 60°C	15 to 80%	5 to 80%	708 hPa to 1,020 hPa	570 hPa to 1,020 hPa
Temperature sensor lubricant	50 to 95°F 10 to 35°C	-4 to 140°F -20 to 60°C	15 to 80%	5 to 80%	708 hPa to 1,020 hPa	570 hPa to 1,020 hPa
Temperature sensor jackets	50 to 95°F 10 to 35°C	-4 to 140°F -20 to 60°C	15 to 80%	5 to 80%	708 hPa to 1,020 hPa	570 hPa to 1,020 hPa
Anesthesia cannula	50 to 95°F 10 to 35°C	See label	15 to 80%	5 to 80%	708 hPa to 1,020 hPa	570 hPa to 1,020 hPa
Anesthesia sample lines	50 to 95°F 10 to 35°C	-4 to 122°F -20 to 50°C	15 to 80%	5 to 80%	708 hPa to 1,020 hPa	570 hPa to 1,020 hPa
Oxygen sensor	59 to 95°F 5 to 35°C	Transport -40 to 122°F -40 to 50°C Storage 41 to 77°F 5 to 25°C	15 to 80%	5 to 80%	Not available	
Water trap	50 to 95°F 10 to 35°C	-4 to 140°F -20 to 60°C	15 to 80%	5 to 80%	Not available	
Universal gating interfaces	64 to 75°F 18 to 24°C	-4 to 122°F -20 to 50°C	15 to 80%	5 to 80%	708 hPa to 1,020 hPa	570 hPa to 1,020 hPa
MR Patient Care Portal 5000	59 to 95°F 15 to 35°C	14 to 140°F -10 to 60°C	10 to 80%	5 to 80%	Not available	

A.2 IP Ratings

Devices rated IP20: protected against access to hazardous parts, the ingress of solid foreign objects greater than 12.5 mm (0.5 inch), and not protected from liquid ingress.

- Cart with touchscreen:

Devices rated IP21: protected against access to hazardous parts, the ingress of solid foreign objects greater than 12.5 mm (0.5 inch), and vertically dripping liquid.

- ECG and SpO2 modules
- SpO2 sensor

Device rated IP57: protected against access to hazardous parts, the ingress of dust, and temporary immersion in liquid.

- Temperature sensor

A.3 General Specifications

MRI System Range	1.5 and 3.0 Tesla, 5000 gauss, at RF power levels not exceeding 4W/kg SAR and 7.2 µT B1rms in all orientations
Pressure Compensation	Automatic barometric pressure compensation
Mode of operation	Continuous operation
Defibrillator Protection	Type CF (defibrillation-proof) equipment Defibrillator protection up to 5 KVDC
Attenuation	110 dB, conducted

A.4 Displayed Information

Time	Battery-backed quartz crystal clock
Alarms	High and low limits selectable for patient parameters No algorithms were used to determine the manufacturer configured alarm presets
ECG	ECG waveform scale, displayed leads (2)
Heart Rate	Automatic mode selects the vital sign to provide the heart rate according to vital sign source availability and priority. If no source available (if no vital sign meets the criteria), then the heart rate source will be displayed as None and no heart rate will be produced. Manual mode selection to provide the heart rate is also available.
Pulse Oximeter	Pulse rate, pulse waveform (normalized), percent saturation
Trends	Heart rate, respiration rate, P1 and/or P2(systolic, diastolic, mean), NIBP (systolic, diastolic, mean), EtCO2, O2, N2O, SpO2, and Agents
CO2	End-tidal and fractional inspired
NIBP	Pressures (systolic, mean, diastolic) and status
Respiration Rate	Respiration rate derived from pneumatic respiration port or CO2
N2O	End-tidal and fractional inspired
O2	Fractional inspired
AGENT	Automatic identification of primary and secondary agents (Desflurane, Isoflurane, Enflurane, Halothane or Sevoflurane) displaying both end-tidal (Et) and fractional inspired (Fi) concentrations.

Temperature	Body temperature (°C or °F)

A.5 Power Specifications

Operating Voltage Range	100 to 240 VAC, ± 10 percent
Power Frequency Range	50 to 60 Hz, single phase
Power Current	1.4 A @ 100 VAC/0.7 A @ 240 VAC
Battery Capacity	Cart: 75 Wh per battery (300-Wh capacity with 4 batteries installed) Modules: 3 Wh Wh per battery
Operation Time on Battery Power	Values assume new and fully charged batteries. Cart: Minimum 6 hours, depending on enabled parameters and settings. Modules: Approximately 8 hours
Battery Charge Time	Main and reserve cart batteries: To recharge a fully discharged battery is approximately 12 hours with the MR400 turned off. Battery charge time to 90 percent of capacity is approximately 6 hours. Module: To recharge a fully discharged battery is approximately 4 hours. Battery charge time to 90 percent of capacity is less than 4 hours.
Minimum Battery Voltage (For normal operation)	Cart: 14.4 V Module: 3.7 V

A.6 Alarm Specifications

Alarm volume	45 to 86 dB, typical
Alarm audio, priority indication	• High priority: 960 Hz/10 pulses per sound burst/5-second pause between bursts • Medium priority: 720 Hz/3 pulses per sound burst/7-second pause between bursts • Low priority: 480 Hz/2 pulses per sound burst/15-second pause between bursts
Alarm light	• High priority: Red/Flashing/1.5 Hz, 50% duty cycle • Medium priority: Yellow/Flashing/0.75 Hz, 50% duty cycle • Low priority: Blue/Steady
Alarm visibility	Legible at 1 meter (assuming a visual acuity of 20/20 and with no line of sight obstructions)

A.7 ECG Specifications

ECG Amplifier	Protected against defibrillator and electrosurgery potentials Lead Fail: Passive, sensing signal imbalance ECG Input Impedance: > 2.5 MΩ, single-ended (according to IEC 60601-2-27, 50.102.3) Electrode Contact Impedance: ≤ 20 K ohms @ 10 Hz
Heart rate resolution	1 beat per minute
Heart rate range	30 to 250 beats per minute (adult) 30 to 300 beats per minute (pediatric)
Heart rate accuracy	± 2 percent or ± 1 beat per minute, whichever is greater, in the absence of MRI gradients
Sensitivity (monitor filter mode)	Adult patient type: > 200 µV Neonate/Pediatric patient type: > 100 µV
QRS Duration	Adult patient type: 70 to 120 ms Neonate/Pediatric patient type: 40 to 120 ms
Bandwidth (monitor filter mode)	0.5 to 40 Hz
Baseline Offset	Automatically removed
Tall T-Wave Rejection Capability for Heart Rate Indication	2 mV with a 1-mV QRS amplitude (Monitor mode)
Leads-off Sensing	Detection by DC current waveform of < 100 nA
Square Wave Test Signal	60 beats per minute ± 1, 1 mV ± 10 percent
Heart Rate (HR) Averaging Method	Fifteen-point median filter employed. Heart rate average is determined by looking at 15 data points and then taking the mean average of the middle 3 readings. Update rate of the display is 2 Hz.
Time to Alarm for Tachycardia B1 - Ventricular Tachycardia 1 mVpp, 206 beats per minute B2 - Ventricular Tachycardia 2 mVpp, 195 beats per minute	Measurements were made with the MR400 outside of the MR environment. The Filter Mode was Monitor. Time-to-alarm may be affected by MRI gradient artifacts. Gain 0.5; Average: 11.9 seconds (The monitoring system may temporarily exit the alarm condition during the arrhythmia waveform duration.) Gain 1.0; Average: 9.4 seconds Gain 2.0; Average: 9.3 seconds Gain 0.5; Average: 9.0 seconds Gain 1.0; Average: 8.7 seconds Gain 2.0; Average: 8.1 seconds

Response Time of Heart Rate Meter to Change in Heart Rate	Heart rate change from 80 to 120 beats per minute: 9.1-seconds average Heart rate change from 80 to 40 beats per minute: 10.2-seconds average
Heart Rate Meter Accuracy and Response to Irregular Rhythm	The MR400 was outside of the MR environment and the Filter Mode was Monitor. Accuracy may be affected by MRI gradient artifacts. A1: Ventricular bigeminy: Adult mode: 40 beats per minute Neonatal mode: 40 beats per minute A2: Slow alternating ventricular bigeminy: Adult mode: 30 beats per minute Neonatal mode: 57 to 61 beats per minute A3: Rapid alternating ventricular bigeminy: Adult mode: 118 to 124 beats per minute Neonatal mode: 60 beats per minute A4: Bidirectional systoles: Adult mode: 60 to 80 beats per minute Neonatal mode: 80 to 90 beats per minute

A.8 Respiration Specifications

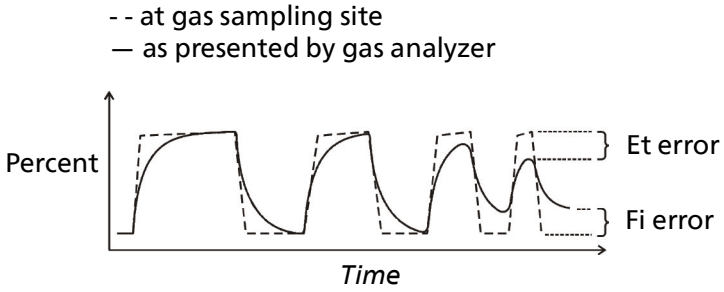
Respiration specifications depend on the cart's monitoring options.

For carts that monitor only carbon dioxide, see "A.8.2 CO2 (LoFlo Option)" on page 197.

For carts that monitor anesthetic agents and other gases, see "A.8.3 Anesthetic Agents and Gases" on page 200.

A.8.1 Breath Rate Distortion

The effect of rise time distortion to the gas curve becomes apparent when the breathing rate increases so that the time for a full inspiratory or expiratory event gets shorter. In those situations, due to the effect of the rise time, the gas curve does not reach the true end-tidal (or first inspired value) and the end-tidal gas value may then be underestimated. Correspondingly, the first inspired value may be overestimated. Below is an exaggerated illustration of the effect.



The breath rate limit for accurately resolved end-tidal gas values (at an I:E ratio of 1:1) may be found in the following sections: "A.8.2 CO2 (LoFlo Option)" on page 197 and "A.8.3 Anesthetic Agents and Gases" on page 200. The effect of other I:E ratios may be calculated by determining the length of the shortest inspiratory/expiratory event that can be resolved accurately:

$$t_{resolved} = 60 / (2 \times BR_{limit}(1:1))$$

$$BR_{limit}(I:E) = 60 / ((I + E) \times t_{resolved})$$

The difference in these results when compared to the rise time's specification is that rise time's specification only tests 10–90% performance. This specification is for (0 + accuracy) to (100 -accuracy) percent and more difficult to meet. The ability to properly resolve end-tidal values can be measured by using the set-up described in ISO 80601-2- 55. In short, the method consists of sampling gas from two different sources connected to an electrically controlled pneumatic valve to permit rapid switching between the two sources. During the test, the valve is set to switch gas source at a number of frequencies (simulating the range of specified breath rates) and for each frequency the end-tidal value presented by the gas analyzer is noted. From a diagram of end-tidal value over frequency, the frequency at which the gas analyzer is no longer able to resolve end-tidal values according to specification is identified. This ability to properly resolve end-tidal values is listed in the specification.

A.8.2 CO2 (LoFlo Option)

Applies to carts that monitor only carbon dioxide.

Side stream, non-dispersive infrared absorption technique, includes multiple filtration and microprocessor logic control of sample handling and calibration. Method for determining end-tidal CO2 measurement: Measures peak of the end-tidal CO2 waveform every 20 seconds.	
Output	CO2 waveform, etCO2, and FiCO2 measurement numeric values, and respiration rate
Initialization Time	Waveform displayed in less than 20 seconds, at an ambient temperature of 25°C (77°F). Full specifications attained within 2 minutes
Zero Calibration Interval	Automatic or user requested

CO2 Unit of Measure	Millimeters of mercury (mmHg) or kilopascals* (kPa)
CO2 Resolution	1 mmHg (0.1 kPa)
Flow Rate	50 mL/minute ± 10 mL/minute
Data Sample Rate	100 Hz
End-tidal CO2 (etCO2) Measurement Range (In which the CO2 accuracy specification is met)	0 to 76 mmHg (0 to 10.1 kPa) for respiration rates ranging from 4 to 60 rpm, inclusive
Fractional inspired CO2 (FiCO2) Measurement Range	3 to 50 mmHg (0.4 to 6.7 kPa) Method: Lowest reading of the CO2 waveform in the previous 20 seconds
CO2 Accuracy (All measurements at gas temp of 25°C)	± 4 mmHg (± 0.5 kPa) or ± 12 percent, whichever is greater, after the specified warm-up period There is a degradation in measurement accuracy outside of the rated range for an inspiratory/expiratory time ratio of 4 to 60 respirations per minute
CO2 Stability Short Term Drift Long Term Drift	 Not to exceed 0.8 mmHg (0.1 kPa) over a 4-hour period Accuracy specification maintained over a 120-hour period
Respiration Accuracy	± 1 breath or ± 3 percent, whichever is greater
Respiration Resolution	1 breath per minute
Respiration Rate Range (In which the respiration accuracy specification is met)	4 to 100 rpm, inclusive
A simulator was used to simulate breathing rates and calibrated gas was flowed through the simulator and into the system, and effects on accuracy were recorded to determine the rated respiration rate range and the corresponding effects of end-tidal gas reading accuracy as a function of respiratory rate.	
Accessory usage	Functional without changing accessories for a minimum of 6 hours
System response and rise times (As measured from the patient gas input of the complete pneumatic circuit, including tubing, from 10 to 90 percent of the measured CO2 levels)	
Airway Adapter	System response: 10.89 seconds Rise time: 0.94 seconds
CO2 Cannula	System response: 12.44 seconds Rise time: 1.12 seconds
Divided Cannula	System response: 16.17 seconds Rise time: 2.01 seconds

Anesthetic Agent Effects (MAC Levels)	Anesthetic Agent Sensitivity[A] (uncompensated): Accuracy specification will be maintained for halogenated anesthetic agents present at accepted MAC (Minimum Alveolar Concentration) clinical levels Anesthetic Agent Sensitivity (compensated): Testing at agent levels defined by accepted regulatory standards (80601-2-55)
Compensations (Automatic CO2 ambient pressure compensation 523 to 760 mmHg [69.7 to 101.3 kPa])	For end-tidal O_2 balance gas (N_2, N_2O, O, He) and anesthetic agents[B] Uses gas compensation information to correct the raw carbon dioxide value
Cross-sensitivity Compensation Error (Additional worst case error when compensation for O_2, N_2O, anesthetic agents, or helium is correctly selected for the actual fractional gas constituents present.)	0 to 40 mmHg: ± 1 mmHg (0 to 5.3 kPa: ± 0.1 kPa) 41 to 70 mmHg: ± 2.5 mmHg (5.5 to 9.3 kPa: ± 0.3 kPa) 71 to 100 mmHg: ± 4 mmHg (9.5 to 13.3 kPa: ± 0.5 kPa) 101 to 150 mmHg: ± 5 mmHg (13.5 to 20 kPa: ± 0.6 kPa)
Quantitative effects of gas sample humidity or condensate**: **With appropriate compensations applied	0 to 40 mmHg: ± 2 mmHg (0 to 5.3 kPa: ± 0.2 kPa) 41 to 70 mmHg: ± 5 percent (5.5 to 9.3 kPa: ± 5 percent) 71 to 100 mmHg: ± 8 percent (9.5 to 13.3 kPa: ± 8 percent) 101 to 150 mmHg: ± 10 percent (13.5 to 20 kPa: ± 10 percent)
There are no known adverse effects on stated performance due to cyclical pressure of up to 10 kPa (100 cmH2O).	
Calibration Interval	Calibration verification must be performed at 1-year intervals.

*For kilopascals (kPa), allow ± 1 least significant digit to accommodate round-off error for calculated values.

A.

Gas or Vapor	Halothane	Enflurane	Isoflurane	Desflurane	Sevoflurane	N2O
MAC Level, % vol fraction	0.77	1.70	1.15	6.00	2.10	105

(From ISO 80601-2-55. FDA recommended for a healthy 40-year old male.)

B.

Measured Gas	Quantitative Effects of Gas or Vapor											
	N2O	HAL	ENF	ISO	SEVO	Xenon	Helium	DES	Ethanol	Isopropanol	Acetone	Methane
Carbon Dioxide	NE @ 60%	NE @ 4%	NE @ 5%	NE @ 5%	NE @ 5%	ME1 @ 80%	NE @ 50%	ME2 @ 15%	NE @ 0.1%	NE @ 0.1%	NE @ 0.1%	NE @ 1%
No Effect (NE)												
Minimal Effect 1 (ME1) = Negatively bias Carbon Dioxide values by up to an additional 5 mmHg at 38 mmHg												
Minimal Effect 2 (ME2) = Concentrations greater than 5% will positively bias Carbon Dioxide values by up to an additional 3 mmHg at 38 mmHg												

Measured	Quantitative Effects of Gas or Vapor
***Metered dose inhaler propellants: Unspecified	

A.8.3 Anesthetic Agents and Gases

Applies to carts that monitor carbon dioxide, anesthetic gases, oxygen, and nitrous oxide:

Side Stream, non-dispersive infrared (NDIR) absorption technique, including water trap filtration system and microprocessor logic control of sample handling and calibration	
Simultaneously measured gases	Any 2 of the following (inspired or expired), while also measuring carbon dioxide, nitrous oxide, and oxygen: • Halothane • Isoflurane • Sevoflurane • Desflurane • Enflurane
Measurement range after maximum warm-up period	Halothane: 0 to 5.0 Vol.% Isoflurane: 0 to 5.0 Vol.% Sevoflurane: 0 to 8.0 Vol.% Desflurane: 0 to 18.0 Vol.% Enflurane: 0 to 5.0 Vol.% Carbon Dioxide: 0 to 10.0 Vol.% Nitrous Oxide: 0 to 100 Vol.%

Accuracy after maximum warm-up period (includes stability and drift)	
Halothane:	±0.15 Vol.% at 0 to 1.00 Vol% ±0.20 Vol% at 1.00 to 5.00 Vol% Unspecified > 5.00
Isoflurane:	±0.15 Vol.% at 0 to 1.00 Vol% ±0.20 Vol% at 1.00 to 5.00 Vol% Unspecified > 5.00
Sevoflurane:	±0.15 Vol.% at 0 to 1.00 Vol% ±0.20 Vol% at 1.00 to 5.00 Vol% ±0.40 Vol% at 5.00 to 8.00 Vol% Unspecified > 8.00
Desflurane:	±0.15 Vol% at 0 to 1.00 Vol% ±0.20 Vol% at 1.00 to 5.00 Vol% ±0.40 Vol% at 5.00 to 10.00 Vol% ±0.60 Vol% at 10.00 to 15.00 Vol% ±1.0 Vol% at 15.00 to 18.00 Vol% Unspecified > 18.00
Enflurane:	±0.15 Vol.% at 0 to 1.00 Vol% ±0.20 Vol% at 1.00 to 5.00 Vol% Unspecified > 5.00
Carbon Dioxide:	±0.10 Vol% at 0 to 1.00 Vol% ±0.20 Vol% at 1.00 to 5.00 Vol% ±0.30 Vol% at 5.00 to 7.00 Vol% ±0.50 Vol% at 7.00 to 10.00 Vol% Unspecified > 10.00
Nitrous Oxide:	±2.00 Vol% at 0 to 20 Vol% ±3.00 Vol% at 20.0 to 100 Vol%
Interference Gas	CO2: N2O, O2, Any Agent = 0.1% ABS inaccuracy allowance for each N2O: CO2, O2, Any Agent = 0.1% ABS inaccuracy allowance for each Agents: CO2 = 0% ABS inaccuracy allowance N2O, O2, 2nd Agent = 0.1% ABS inaccuracy allowance for each
Flow Rate (fixed)	200 ± 20 ml/min (Adult, Pediatric) 150 ± 15 ml/min (Neonate)
Maximum specified interval for intervention of water (hours at specified minimum sample flow rate)	AGENT mode: Adult and pediatric is 17 hours @ 200 ml/min, 37°C, 100% RH Neonate is 17 hours @ 120 ml/min, 37°C, 100% RH CO2 mode: 8 hours @ 50 mL/min ± 10 ml/min

System Response and rise times (As measured from patient gas input of the complete pneumatic circuit, including tubing, from 10 to 90 percent of measured levels)	
Cannula, Adult	
Halothane:	System response: 11.56 seconds Rise time: 5.77 seconds
Enflurane:	System response: 7.55 seconds Rise time: 1.75 seconds
Isoflurane:	System response: 6.71 seconds Rise time: 0.88 seconds
Sevoflurane:	System response: 6.45 seconds Rise time: 0.62 seconds
Desflurane:	System response: 6.63 seconds Rise time: 0.57 seconds
Oxygen:	System response: 6.99 seconds Rise time: 1.02 seconds
Nitrous oxide:	System response: 6.28 seconds Rise time: 0.25 seconds
Carbon Dioxide:	System response: 6.62 seconds Rise time: 0.61 seconds
Cannula, Infant	
Halothane:	System response: 15.95 seconds Rise time: 8.63 seconds
Enflurane:	System response: 11.98 seconds Rise time: 4.75 seconds
Isoflurane:	System response: 9.26 seconds Rise time: 1.70 seconds
Sevoflurane:	System response: 6.48 seconds Rise time: 0.62 seconds
Desflurane:	System response: 6.47 seconds Rise time: 0.61 seconds
Oxygen:	System response: 8.61 seconds Rise time: 1.13 seconds
Nitrous oxide:	System response: 7.95 seconds Rise time: 0.72 seconds
Carbon Dioxide:	System response: 6.51 seconds Rise time: 0.48 seconds

Divided Cannula, Adult	
Halothane:	System response: 20.81 seconds Rise time: 14.18 seconds
Enflurane:	System response: 13.83 seconds Rise time: 7.11 seconds
Isoflurane:	System response: 10.99 seconds Rise time: 3.91 seconds
Sevoflurane:	System response: 7.48 seconds Rise time: 0.78 seconds
Desflurane:	System response: 7.38 seconds Rise time: 0.64 seconds
Oxygen:	System response: 8.02 seconds Rise time: 1.07 seconds
Nitrous oxide:	System response: 7.16 seconds Rise time: 0.51 seconds
Carbon Dioxide:	System response: 7.57 seconds Rise time: 0.64 seconds
Divided Cannula, Infant	
Halothane:	System response: 9.98 seconds Rise time: 3.95 seconds
Enflurane:	System response: 7.32 seconds Rise time: 1.37 seconds
Isoflurane:	System response: 6.75 seconds Rise time: 0.89 seconds
Sevoflurane:	System response: 5.45 seconds Rise time: 0.67 seconds
Desflurane:	System response: 6.25 seconds Rise time: 0.60 seconds
Oxygen:	System response: 7.25 seconds Rise time: 0.84 seconds
Nitrous oxide:	System response: 6.51 seconds Rise time: 0.39 seconds
Carbon Dioxide:	System response: 5.49 seconds Rise time: 0.49 seconds
Data Sample Rate	25 Hz
Full Accuracy Respiration Rate (Range permitting specified gas accuracy)	2 to 60 rpm There is a degradation in measurement accuracy outside of the rated range for an inspiratory/expiratory time ratio of 2 to 60 respirations per minute

A simulator was used to simulate breathing rates and calibrated gas was flowed through the simulator and into the system, and effects on accuracy were recorded to determine the rated respiration rate range and the corresponding effects of end-tidal gas reading accuracy as a function of respiratory rate.	
End-tidal gas readings, calculation method	etCO2 concentration readings are identified by using the highest value of the temporal CO2 curve. Corresponding readings of N2O and anesthetic agents are taken at the same point in time. End-tidal O2 concentration readings are identified by the O2 mean value during the respiratory phase as identified by the temporal CO2 curve. Once correctly identified, the lowest O2 concentration reading during the phase will be presented as end-tidal O2.
Total Respiration Range	2 to 100 rpm, accuracy is unspecified from 60 to 100 rpm
Relevant Interference	0.5-mmHg equivalent with 37.5°C saturated with H2O (0.1% relative max)
Display Resolution	0.1 percent volume
Maximum Warm-up Time	10 minutes, ISO accuracy achieved in < 45 seconds of activation
Auto ID Threshold (full accuracy mode)	Primary Agent ID: 0.15% Secondary Agent ID: 0.3%
Detection threshold for a single halogenated anaesthetic gas in a gas mixture	0.15%
Detection threshold for multiple halogenated anaesthetic gases in a gas mixture	Primary gas: 0.15% Secondary gas: 0.3%
Multiple Agents Alarm Threshold	0.3% (0.5% during ISO accuracy mode) or 5%REL (10% for Isoflurane) of primary agent if primary agent > 10% (For Hal, add 0.1% ABS to threshold values)
CO2 Ambient Pressure Compensation Range	500 mmHg to 900 mmHg
Pressure Compensation	Unaffected by cyclical pressures of up to 10 kPa as, apart from the described automatic pressure compensation, the pump automatically regulates flow so that not only gas readings but also gas sample flow is unaffected
Calibration Interval	Calibration verification must be performed yearly.
O2	
Resolution	1 percent
Range	0 to 100 percent
Signal Output (at constant temperature and pressure)	10 mV ±1.5 mV @ 20°C / 20.95% O2
Maximum Response Time (21% to 100% step change through patient sampling line as seen in WPU gas monitor window)	Adult/Pediatric < 7.3 seconds Neonate: < 8.2 seconds
Accuracy (includes stability and drift), full scale*	±1% at 0 to 40% ±2% at 40 to 60% ±3% at 60 to 80% ±4% at 80 to 100%
*Gas measurement performance requirements are met after the maximum warm-up period.	
Offset	±1 percent

O2 Interfering Gas Effects:	
N2O	< 0.3 vol% at 80 vol% N2O
CO2	< 0.3 vol% at 5 vol% CO2
Halothane	< 0.3 vol% at 5 vol% Halothane
Enflurane	< 0.3 vol% at 5 vol% Enflurane
Isoflurane	< 0.3 vol% at 5 vol% Isoflurane
Desflurane	< 0.3 vol% at 18 vol% Desflurane
Sevoflurane	< 0.3 vol% at 8 vol% Sevoflurane
Acetone	< 0.3 vol% at 1 vol% Acetone
Ethanol	< 0.3 vol% at 0.1 vol% Ethanol
Helium	< 0.3 vol% at 80 vol% Helium
Methane	< 0.3 vol% at 0.1 vol% Methane
Nitric Oxide	< 0.3 vol% at 50 ppm Nitric Oxide
Oxygen Sensor, Operating Temperature	15 to 35°C (59 to 95°F)
Oxygen Sensor, Expected Operating Life	Use by the date printed on the sensor and its package
CO2	
Resolution	1 mmHg (0.1 kPa)
Range	0 to 76 mmHg (0 to 10.1 kPa)

A.9 Temperature Sensor Specifications

With or without a jacket, the following specifications apply:

Operating mode	Direct mode
Units	Celsius (°C) or Fahrenheit (°F)
Output range	20.0°C to 44.0°C (68.0°F to 111.2°F)
Resolution	0.1
Accuracy	±0.5°C (±0.9°F)
Bend radius	15 mm (0.6 inches)
Response time	The measuring time to obtain a steady-state reading within the manufacturer's accuracy specifications is within 15 seconds.
Numeric display update time	2 seconds
Sensor type	Fiber optic, reusable when used with single-use jackets
Application sites	Axillary, esophageal, rectal

A.10 Pulse Oximeter and Pulse Oximeter Accessories Specifications

The pulse oximetry feature of the MR400 uses a motion-tolerant signal processing algorithm based on Fourier Artifact Suppression Technology (FAST) and is calibrated to display oxygenated hemoglobin measurements, a visual pulse indication, and a pulse rate.	
Pulse tone pitch	Modulated by the saturation value

Saturation range	1 to 100 percent
Saturation value resolution	1 percent
Saturation value accuracy	± 3 percent at 70 to 100 percent Pulse oximeter calibration range 70 to 100 percent
Pulse rate accuracy	± 2 percent or ± 1 beat per minute, whichever is greater
Pulse rate range	30 to 250 beats per minute
Pulse rate resolution	1 beat per minute
Data update period	5, 10, or 15 seconds, according to the SpO2 Averaging Time setting
Data update period during alarm	4 seconds plus the SpO2 Averaging Time setting 9, 14, or 19 seconds, maximum (according to the SpO2 Averaging Time setting)
Wavelength Range	500 to 1,000 nm
Emitted Light Energy	< 15 mW
Measurement validation	SpO2 accuracy 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 to 100 percent SpO2 were studied. The population characteristics for those studies were: • about 50% female and 50% male subjects • 19 to 27 years of age • light to black skin tones Reference method for the computation of pulse rate accuracy made using an electronic pulse simulator. A functional tester cannot be used for accuracy assessment of a pulse oximeter monitor. However, it can demonstrate that a pulse oximeter monitor reproduces a calibration curve that has been independently demonstrated to fulfill a particular accuracy specification. SpO2 measurements are statistically distributed. In accordance to 80601-2-61, it is possible that only two-thirds of the measurements fall within ± 3 percent of the value measured by the CO-Oximeter.
Typical SpO2 clip and grip application time	1 hour
Maximum SpO2 clip and grip application time	16 hours

A.11 Noninvasive Pressure Specifications

Pneumatic Systems	
Cuff Inflation Pressure	Initial inflation pressures
Adult:	165 mmHg (22kPa) ± 15 mmHg (2 kPa)
Pediatric:	130 mmHg (17.3 kPa) ± 15 mmHg (2 kPa)
Neonate:	100 mmHg (13.3 kPa) ± 15 mmHg (2 kPa)
	Subsequent inflation pressures are determined by last noninvasive pressure measurement
Overpressure Protection Automatic cuff pressure release when inflation pressure exceeds:	
Adult:	300 mmHg (40 kPa)
Pediatric:	300 mmHg (40 kPa)
Neonate:	150 mmHg (20 kPa)
Systolic Measurement Range	
Adult:	30 to 270 mmHg (4.0 to 36 kPa)
Pediatric:	30 to 180 mmHg (4.0 to 24 kPa)
Neonate:	30 to 130 mmHg (4.0 to 17.3 kPa)
Mean Measurement Range	
Adult:	20 to 255 mmHg (2.7 to 34 kPa)
Pediatric:	20 to 160 mmHg (2.7 to 21.3 kPa)
Neonate:	20 to 120 mmHg (2.7 to 16 kPa)
Diastolic Measurement Range	
Adult:	10 to 245 mmHg (1.3 to 32.7 kPa)
Pediatric:	10 to 150 mmHg (1.3 to 20 kPa)
Neonate:	10 to 100 mmHg (1.3 to 13.3 kPa)
Accuracy	
Pressure Measurement Accuracy	Maximum mean error ± 5 mmHg (± 0.6 kPa) with a standard deviation of less than 8 mmHg (1 kPa)
Pressure Measurement Resolution	1 mmHg (0.1 kPa)
Pressure Transducer Range	0 to 300 mmHg (0 to 40 kPa)
Modes	
Manual	Immediate upon operator command
Automatic	Determinations automatically made with selectable intervals of 1, 2, 3, 5, 10, 15, 20, and 30 minutes

Notes

The effectiveness of noninvasive pressure has not been established in the presence of any dysrhythmias included in the exclusion criteria.

The noninvasive pressure clinical study was performed on adult and pediatric patients with the following attributes:

- Gender: 61% male, 39% female.
- No patients less than 29 days of age.
- Patients with limb circumferences ranged from 10.5 cm to 39 cm, with a distribution of 46 percent below 25 cm and 7 percent above 35 cm.
- The arterial systolic pressure ranges from 58 mmHg to 211 mmHg, with an average of 115 mmHg and with a distribution of 32.7 percent below 100 mmHg and 2.4 percent above 180 mmHg. The arterial diastolic pressure ranges from 34 mmHg to 131 mmHg, with an average of 65 mmHg and with a distribution of 42.3 percent below 60 mmHg and 3.9 percent above 100 mmHg.
- Patients with any sign of arterial disease were excluded.
- Patients with a heart beat greater than 180 beat per minute were excluded.
- The radial artery was acceptable as a reference site for all patients but one which used the femoral artery.
- The effectiveness was not validated on pregnant, including preeclamptic, patient populations.

The noninvasive pressure clinical study was performed on neonatal patients with the following attributes:

- No specified gender.
- All patients 28 days or less if born at term (37 gestation or more). Otherwise, up to 44 gestational weeks.
- Patients with limb circumferences ranged from 5.75 35 cm to 13 cm with an average of 7.9 cm.
- The arterial systolic pressure ranged from 42 mmHg to 89 mmHg, with an average of 57 mmHg. The arterial diastolic pressure ranged from 20 mmHg to 62 mmHg, with an average of 34 mmHg.

Arterial reference sites included the umbilical, femoral, brachial, and radial artery.

A.12 Invasive Pressure Specifications

Pressure Amplifier	
Isolation Voltage	5 KVDC
Measurement Range	-30 to 250 mmHg
Sensitivity	5 µV/V/mmHg
Gain Accuracy	±0.5 percent
Bandwidth	0 to 10 Hz (-3 dB)
Transducer Offset Range	± 300 mmHg
Transducer	
Operating Pressure	-50 to 300 mmHg
Overpressure Limits	-400 to 5,000 mmHg
Sensitivity	5 µV/V/mmHg ±1 @ 6 Vdc and 22°C (71.6°F)
Zero Offset	< ±25 mmHg
Zero Drift	< ±2 mmHg in 8 hours
Input Impedance	300 to 350 ohms

Output Impedance	300 ohms ± 30 ohms
Warm-up Time	2 minutes
Automatic Zero	
Range	+300 mmHg
Zero Accuracy	±1.0 mmHg
Response Time	1 second, notifies operator when done
Pressure Waveform Display	
Number of Channels	0, 1 or 2
ABP, PAP, and LAP	Numeric display of systolic, mean, and diastolic pressures
CVP and ICP	Numeric display of mean pressure only
Pressure Scale Ranges (User Selectable)	0 to 250 mmHg 0 to 200 mmHg 0 to 150 mmHg 0 to 100 mmHg 0 to 75 mmHg 0 to 45 mmHg
Pulse Rate Requires **HR Source** and pressure waveform label set to **ABP**	
Range	30 to 250 beats per minute
Accuracy	±2 percent of full scale
Resolution	1 beat per minute
Alarm Delay	
Transducer disconnect	6 seconds
Pressure disconnect	6 seconds
High and low pressure	10 seconds
Transducer adapter cable compatibility Invasive pressure input mates with an Amphenol connector (MS-3106A 145-6P). With this connector and the following connection information, transducer adapter cables may be fabricated or ordered from various manufacturers.	
Connector Pin	Signal Name
A	- Signal
B	+ Excitation
C	+ Signal
D	- Excitation
E	Shield

A.13 Pneumatic Respiration Specifications

Respiration rate measurement range	0 to 60 breaths per minute
Respiration rate resolution	1 breath per minute
Respiration rate accuracy	±1 breath per minute

A.14 Third-Party Software

U-Boot (open source)	Bootstrap loader
Linux (open source)	Operating system
GNU C and Standard Libraries (open source)	Compiler, linker, and libraries
Busybox (open source)	Linux shell and utilities
Qt (open source)	Graphics engine and GUI framework
SQLite	Relational database
OpenSSL	Secure communication

A.15 Radios

INDUSTRY CANADA STATEMENT

This device complies with Industry Canada license-exempt RSS standards. Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

FCC COMPLIANCE STATEMENT

WARNING

Changes or modifications not expressly approved could void your authority to use this equipment.

If the MR400 receives interference from or causes interference in other wireless devices in the vicinity, change the radio channel on which the MR400 is operating. If interference persists, the radio can be disabled, ceasing all wireless communications with the remote monitor until enabled at the operator.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Transmitter	Function	Frequency (MHz)	Occupied Bandwidth	Modulation	Effective Radiated Power
nRF2401	SpO2/ECG data	2401-2482	1 MHz	GFSK	< 2.5 mW
WIT2410NF	Remote Comm	2401-2471	750 kHz	FHSS	100 mW

Frequency ranges for communications between devices included in the MR400 system:

Devices	Maximum Power Level	Measured Power Level in dBm	Frequency Range in MHz	Measured Duty Cycle	Modulation Type
Remote monitor to MR400	19.92 dBm	19.92	2402-2470	09.12%	GFSK
MR400 to remote monitor	19.65 dBm	19.65	2402-2470	35.16%	GFSK
MR400 to ECG Module	6 (4 dBm+2 dBi)	2.19	2435-2472	30.40%	GFSK
MR400 to SpO2 Module	6 (4 dBm+2 dBi)	1.16	2425-2471	30.30%	GFSK
ECG Module to MR400	5.1 (4 dBm+1.1 dBi)	0.70	2435-2480	14.20%	GFSK
SpO2 Module to MR400	5.6 (4 dBm+1.6 dBi)	4.10	2425-2479	03.33%	GFSK

As detailed in the table below, the radio channels utilized for MR400 to wireless module communications are provided at the following primary frequencies in MHz (secondary is 8 MHz higher).

Radio Channel	ECG Module	SpO2 Module
1	2469	2457
2	2436	2459
3	2437	2456
4	2440	2460
5	2435	2470
6	2472	2439
7	2455	2434
8	2454	2425
9	2458	2438
10	2453	2471

A.16 Electromagnetic Compatibility (EMC)

This Philips product complies with relevant international and national law and standards on EMC (electromagnetic compatibility) for this type of product when used as intended. Such laws and standards define both the permissible electromagnetic emission levels from product and its required immunity to electromagnetic interference from external sources.

Other electronic products exceeding the limits defined in such EMC standards could, under unusual circumstances, affect the operation of the product.

Medical electrical products need special precautions regarding EMC, and must be installed and put into service according this EMC information.

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
The Expression Model MR400 MRI Patient Monitoring System is intended for use in the electromagnetic environment specified below. The following information is mandated by IEC 60601-1-2, the international standard for the electromagnetic compatibility (EMC) of medical electrical equipment.		
Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions, CISPR 11	Group 1	The Expression Model MR400 MRI Patient Monitoring 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.
RF Emissions, CISPR 11	Class A	The Expression Model MR400 MRI Patient Monitoring 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.
Harmonic Emissions, IEC 61000-3-2	Class A	
Voltage Fluctuations/ Flicker Emissions, IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The Expression Model MR400 MRI Patient Monitoring System is intended for use in the electromagnetic environment specified below. The customer or the user of the Expression Model MR400 MRI Patient Monitoring System should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2, 4, 8, 15 kV air	± 8 kV contact ± 8kV air for the IBP P1 and P2 ports (per IEC 60601-2-34:2011, 201.2) ± 15kV air for all other ports and enclosures	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 0.5, 1, 2 kV 100 kHz repetition frequency for power supply lines ± 1 kV 100 kHz repetition frequency for input/output lines	± 2 kV 100 kHz repetition frequency for power supply lines ± 1 kV 100 kHz repetition frequency for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.

Surge IEC 61000-4-5	± 0.5, 1 kV Line to line ± 0.5, 1, 2 kV Line to ground	± 1 kV Line to line ± 2 kV Line to ground	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, IEC 61000-4-11	0% *U*t; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% *U*t; 1 cycle and 70% *U*t; 25/30 cycles Single phase at 0°	0% *U*t; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% *U*t; 1 cycle and 70% *U*t; 25/30 cycles Single phase at 0°	Mains power quality should be that of a typical commercial or hospital environment. If the user of the MR400 requires continued operation during AC power interruptions, power from an uninterruptible power supply or battery is recommended. Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage interruptions IEC 61000-4-11	0% *U*t; 250/300 cycle	0% *U*t; 250/300 cycle	
Power frequency magnetic fields IEC 61000-4-8	30 A/m 50 or 60 Hz	30 A/m 50 or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
*U*t *is the AC mains voltage prior to application of the test level.*			

Guidance and Manufacturer's Declaration - Electromagnetic Immunity		
Immunity Test	EN/IEC 60601 Test Level	Compliance Level
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 0.15 MHz to 80 MHz 6 Vrms in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz 3 V/m 80 MHz-2.7 GHz 80% AM at 1 kHz	V1 = 3 Vrms E1 = 3 V/m
At 80 MHz and 800 MHz, the higher frequency range applies. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.		

Test specifications for enclosure port immunity to RF wireless communications equipment						
Test frequency (MHz)	Band[a] (MHz)	Service[a]	Modulation[b]	Maximum Power (w)	Distance (m)	Immunity Test Level (V/M)
385	330 -390	TETRA 400	Pulse modulation[b] 10 Hz	1.8	0.3	27
450	430 - 470	GMRS 460, FRS 460	FM[c] ±5 kHz deviation 1 kHz sine	2	0.3	28
710 745 780	704 - 787	LTE Band 13, 17	Pulse modulation[b] 217 Hz	0.2	0.3	9
810 870 930	800 - 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation[b] 18 Hz	2	0.3	28
1 720 1 845 1 970	1 700 - 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation[b] 217 Hz	2	0.3	28
2 450	2 400 - 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation[b] 217 Hz	2	0.3	28
5 240 5 500 5 785	5 100 - 5 800	WLAN 802.11 a/n	Pulse modulation[b] 217 Hz	0.2	0.3	9
If necessary to achieve the Immunity Test Level, the distance between the transmitting antenna and the equipment or system may be reduced to 1 m. The 1-m test distance is permitted by IEC 61000-4-3.						
[a] - For some services, only the uplink frequencies are included. [b] - The carrier shall be modified using a 50% duty cycle square wave signal. [c] - As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worse case.						

Mains terminal disturbance voltage limits for class A group 1 equipment measured on a test site		
Frequency Range (MHz)	**Quasi-peak dB(µV)**	**Average dB(µV)**
0.15 - 0.50	79	66
0.50 - 5	73	60
5 - 30	73	60
At the transition frequency, the more stringent limit shall apply.		
Limits only apply to low voltage a.c.mains input ports. For class A equipment intended to be connected solely to isolated neutral or high impedance earthed (IT) industrial power distribution networks (see IEC 60364-1), the limits defined for group 2 equipment with rated input power > 75 kVa in Table c can be applied.		

Electromagnetic radiation disturbance limits for class A group 1 equipment measured on a test site		
Frequency Range (MHz)	Quasi-peak dB(µV/m)	
	10 m measuring distance rated input power	3 m measuring distance[a] rated input power
30 - 230	40	50
230 - 1000	47	57
On a test site, class A equipment can be measured at a nominal distance of 3 m, 10 m, or 30 m. A measuring distance less than 10 m is allowed only for equipment which complies with the definition given in 3.10. In case of measurements at a separation distance of 30 m, an inverse proportionality factor of 20 dB per decade shall be used to normalize the measured data to the specified distance for determining compliance. At the transition frequency, the more stringent limit shall apply.		
[a] - The limits specified for the 3-m separation distance apply only to small equipment meeting the size criterion defined in 3.10.		

Philips healthcare website: www.philips.com/healthcare

Philips IFU website: www.philips.com/IFU

INVIVO, a division of Philips Medical Systems
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