

PHILIPS

Expression **MR200** MRI Patient Monitoring System

INSTRUCTIONS FOR USE

Revision B

English



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Manufacturer



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Notes

Important Information

Important user information about the Expression MR200 MRI Patient Monitoring System and contact information for Royal Philips is discussed here.

Information regarding the safety, accessories, assembly and operation of a fully equipped Expression MR200 MRI Patient Monitoring System can be found in this document. Some information may depict monitoring features not present on your MR200. For information about all features and enhancements, contact us or your sales representative:

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For additional information about your accessories, please consult the documentation that accompanies the accessory.

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

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

NOTE

R_x only *Laws in the United States restrict sale of this device on the order of a physician.*

Intended Audience

This Instructions for Use (IFU) manual for the Expression MR200 MRI Patient Monitoring System is intended for use by healthcare professionals trained in the use of the equipment and vital signs monitoring.

Indications for Use

The Expression MR200 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 synchronization of the MRI scanner. The Expression MR200 provides monitoring for the following vital sign parameters: ECG, pulse oximetry (SpO₂), non-invasive blood pressure (NiBP), and (optional) carbon dioxide (CO₂).

NOTE

The Expression MR200 is intended to be used to monitor the vital signs of a patient in an MR magnet room. This system is not intended for use on a patient being transported outside of a health care facility.

Conventions

Certain conventions are used throughout the Expression MR200 MRI Patient Monitoring System to speed use and familiarity with the device. This accompanying user information also uses document conventions to assist you in finding and understanding information.

System Conventions

The following system conventions are used:

- The display panel includes a control knob and a keypad.
 - Press a key to activate or deactivate its function or to view its menu.
 - Turn and press the control knob to navigate and select menu options, submenus, items or values.
- All menus contain a **RETURN** option that closes the open menu.
- Most menus employ a time-out feature where, if no action is taken for approximately 60 seconds, an open menu will automatically close.
- To protect against accidental changes, a YES/NO prompt is associated with some menu options. When displayed, you must answer this prompt; otherwise, a delay of approximately 60 seconds will be equivalent to selecting **NO** (this can also be accomplished by pressing the **Main** key.)
- To protect against unauthorized changes, some menu items feature password protection. You must enter the correct numeric code for access and a delay of approximately 60 seconds is equivalent to making no entry.

Document Conventions

These document conventions are used:

- The Expression MR200 MRI Patient Monitoring System will hereafter be referred to as the MR200.
- All procedures are numbered and any sub-steps are lettered. Complete the steps in the sequence presented to ensure success. Procedures are indicated by the following table:

| Step | Action |
|------|--------|
| 1 | |
| 2 | |
| 3 | |

- Unless noted, all procedures start from the normal mode of operation.
- Control names, menu items, vital sign references, etc., are spelled as they appear in the MR200.
- Bulleted lists indicate general information about a particular menu function or procedure, and do not imply sequential order or operation.
- Messages regarding a condition or system information are given in bold uppercase letters.
- The left side of the MR200 is on your left as you stand in front of the system, facing it. The front of the MR200 is nearest you as you operate it.
- The front of the module is nearest you as you operate it.

Warnings

WARNING

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

Cautions

CAUTION

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

Notes

NOTE

Notes provide additional information you should know regarding usage.

Contraindications

Refer to all warnings. Before using the MR200, read the warnings and the safety information below. The warnings below refer to the MR200 in its entirety.



WARNINGS

- **Thoroughly read and understand these Instructions for Use prior to use of the MR200.**
 - **A shock hazard exists if the MR200 is operated without the covers installed.**
 - **Only use only supplied power cords and connect to properly grounded AC outlets to avoid electrical shock.**
 - **Ensure that the monitor settings are appropriate for the patient being monitored.**
 - **The patient must remain calm and motionless while the MR200 is being used. If the patient is overactive, prolonged or inaccurate readings may result.**
 - **Position of the accessories may affect measurement accuracy. Always consult a physician for interpretation of measurements provided by the MR200.**
 - **Perform operational verification prior to use. If the MR200 fails to function properly, remove it from use and contact technical support personnel.**
 - **Screen all patients for metallic wires, implants, stents, etc. prior to MR procedures. These electrical conductors will react with the MR environment or with the accessory (if applied directly over the conductor), thus increasing the risk of heating.**
-

Safety

| Equipment Classification (According to IEC 60601-1) | |
|---|--|
| According to the type of protection against electrical shock: | Class I equipment |
| According to the degree of protection against electrical shock: | Type CF (defibrillator-proof) equipment |
| According to the degree of protection against harmful ingress of water: | IPX0 (ordinary) protection against ingress of fluids |
| According to the methods of sterilization or disinfection: | Non-sterilizable; use of liquid surface disinfectants only |
| According to the mode of operation: | Continuous operation |
| Equipment not suitable for use in the presence of flammable anesthetic mixture with air, oxygen or nitrous oxide. | |

CAUTION

To minimize risk of damage to the monitor during defibrillation use only approved supplies.

Electromagnetic Compatibility (EMC)

The device is intended for use in the electromagnetic environment specified below. Given the device's electromagnetic emissions and immunity characteristics, the customer or user should assure that the device is used within such an environment. The following information is mandated by IEC 60601-1-2, the international standard for the electromagnetic compatibility (EMC) of medical electrical equipment.

Radios

Frequency Range: 2401.7–2469.8 MHz

Modulation Type: GFSK

WPU EIRP: 4.2 dBm (peak)

wECG and wSPO2 EIRP: 0 dBm (peak)



WARNINGS

- Operation of the MR200 outside the specifications indicated in Appendix A will cause inaccurate results.
- The use of portable and mobile radio-frequency (RF) communications equipment can affect the operation of this device.
- The use of accessories, transducers and cables other than those specified in the accessory list accompanying these instructions for use (with the exception of transducers and cables sold by Invivo (Royal Philips) for the equipment or system as replacement parts for internal components) will result in increased emissions or decreased immunity of the equipment or system.
- The MR200 should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the equipment or system must be observed to ensure normal operation in the configuration in which it will be used.
- The MR200 needs to be installed and put into service according to the EMC information provided in the instructions for use. Portable and mobile RF communications equipment can affect medical electrical equipment. The MR200 may be interfered with by other equipment with CISPR emission requirements.

Guidance and Manufacturer's Declaration - Electromagnetic Emissions

The MR200 is intended for use in the electromagnetic environment specified below, and the customer or the user should assure that it is used in such an environment.

| Emissions Test | Compliance | Electromagnetic Environment - Guidance |
|---|------------|---|
| RF Emissions CISPR 11 | Group 1 | The MR200 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 B | The MR200 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 B | |
| Voltage Fluctuations/flicker emissions IEC 61000-3-3 | Complies | |

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The MR200 is intended for use in the electromagnetic environment specified below. The customer or the user of the MR200 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 | ± 6kV contact ± 8kV air | ± 6kV contact ± 8kV air | 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 | ± 2kV for power supply lines ± 1kV for input/output lines | ± 2kV for power supply lines ± 1kV for input/output lines | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge IEC 61000-4-5 | ± 1kV differential mode ± 2kV common mode | ± 1kV differential mode ± 2kV common mode | Mains power quality should be that of a typical commercial or hospital environment. |
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 | < 5% U_t (> 95% dip in U_t) for 0.5 cycle 40% U_t (60% dip in U_t) for 5 cycles 70% U_t (30% dip in U_t) for 25 cycles < 5% U_t (> 95% dip in U_t) for 5 seconds | < 5% U_t (> 95% dip in U_t) for 0.5 cycle 40% U_t (60% dip in U_t) for 5 cycles 70% U_t (30% dip in U_t) for 25 cycles < 5% U_t (> 95% dip in U_t) for 5 seconds | Mains power quality should be that of a typical commercial or hospital environment. If the user of the MR200 requires continued operation during AC power interruptions, power from an uninterruptable power supply or battery is recommended. |
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 3 A/m | 3 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |

NOTE

U_t is the AC mains voltage prior to application of the test level.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The MR200 is intended for use in the electromagnetic environment specified below. The customer or the user of the MR200 should assure that it is used in such an environment.

| Immunity Test | IEC 60601 Test Level | Compliance Level | Electromagnetic Environment - Guidance |
|--|--|--------------------------------------|---|
| <p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p> | <p>3 Vrms 150 KHz to 80 MHz</p> <p>3 V/m 80 MHz to 2.5 GHz</p> | <p>V1 = 3 Vrms</p> <p>E1 = 3 V/m</p> | <p>Portable and mobile RF communications equipment should not be used no closer to any part of the MR200, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance</p> $d = (3.5/V1) \sqrt{P}$ $d = (3.5/E1) \sqrt{P}$ <p>(80 MHz to 800 MHz)</p> $d = (7/E1) \sqrt{P}$ <p>(800 MHz to 2.5 GHz)</p> <p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the  symbol.</p> |

- 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.

^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the MR200 is used exceeds the applicable RF compliance level above, the MR200 should be observed to ensure normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the MR200.

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

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the MR200

The MR200 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the MR200 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the MR200 as recommended below, according to the maximum output power of the communications equipment.

| Rated Maximum Output Power Of Transmitter (W) | Separation Distance According To Frequency Of Transmitter (m) | | |
|---|---|--|---|
| | 150 KHz to 80 MHz $d = (3.5/\sqrt{f1})\sqrt{P}$ | 80 MHz to 800 MHz $d = (3.5/\sqrt{f1})\sqrt{P}$ | 800 MHz to 2.5 GHz $d = (7/\sqrt{f1})\sqrt{P}$ |
| 0.01 | 0.117 | 0.117 | 0.233 |
| 0.1 | 0.369 | 0.369 | 0.738 |
| 1 | 1.167 | 1.167 | 2.333 |
| 10 | 3.689 | 3.689 | 7.379 |
| 100 | 11.667 | 11.667 | 23.333 |

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

- At 80 MHz and 800 MHz, the separation distance for 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.

Using Batteries Safely

Batteries have life cycles. When the equipment operating time provided by battery power becomes much shorter than usual, the battery life is at an end. Immediately remove any battery that has an expired life cycle and replace it with a new battery of the same type. (Refer to page 1-28 for part numbers.) To ensure the safety of operators and patients, observe the following warnings and cautions.



WARNING











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




















CAUTIONS













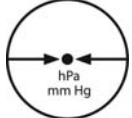




- If the battery contacts become dirty, wipe them clean with a dry cloth before use.
- Store batteries in a dry place, between 0°C to 40°C.
- Keep metal objects away from the battery contacts.












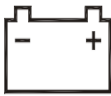



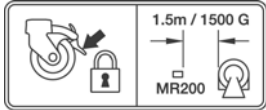



List of Symbols

The symbols in the following table may appear on the MR200, the packing materials, or in this manual.









| Symbol | Meaning | Symbol | Meaning |
|---|---|---|---|
|  | CSA certified for both the U.S. and Canadian markets |  | Federal Communications Commission radio certification |
|  | Underwriters Laboratories Component Recognition Mark for both the U.S. and Canadian markets |  | Taiwan National Communications Commission certification |
|  | Korean Communications Commission radio certification |  | Conforms to the Medical Device Directive |
|  | MR Conditional: Use in the MR environment is restricted to certain conditions of use to ensure patient and operator safety. |  | Conforms to the R&TTE Directive (Radio & Telecommunications Terminal Equipment) |
|  | MR Conditional: Use in the MR environment is restricted to certain conditions of use to ensure patient and operator safety. |  | MR unsafe |

| Symbol | Meaning | Symbol | Meaning |
|---|---|--|---|
|  | Warning! Specific warnings associated with the devices that are not otherwise found on the label; when located on the wECG module connector, indicates that only specified ECG cables shall be used to ensure safe use in the MR and defibrillation protection. |  | Caution! Specific warnings or precautions associated with the devices that are not otherwise found on the label |
| | |  | MR safe |
|  | MR safe |  | Mandatory action: Follow the Instructions for Use |
|  | Consult the Instructions for Use |  | Single use only, disposable one-time-use product; do not reuse |
|  | Do not adjust without referring to the service manual |  | Defibrillator-proof type CF equipment (IEC 60601-1) protection against shock |
|  | Use by date (do not use after the year, month or day shown) |  | Serial number |
|  | Authorized representative in the European Community |  | Batch code/lot number |
|  | Catalog, reorder or reference part number |  | Direct current |
|  | Alternating current |  | Neonate |
|  | Infant |  | Adult / Pediatric |

| Symbol | Meaning | Symbol | Meaning |
|---|-----------------------------|---|---------------------------------|
|  | Toe site |  | Thumb site |
|  | Finger site |  | Foot site |
|  | Toe site |  | Temperature range |
| R_x only | Prescription only |  | NiBP cuff, wrong side out |
|  | NiBP cuff, correct side out |  | NiBP cuff circumference range |
|  | Weight |  | Keep dry |
|  | Humidity range |  | Atmospheric pressure limitation |
|  | Fragile |  | Up |
|  | Patient |  | ECG |

| Symbol | Meaning | Symbol | Meaning |
|---|--|--|--|
|  | Non-invasive blood pressure (NiBP) |  | Universal Serial Bus (USB) |
|  | Contains no latex |  | Dispose of the battery or electronic waste in accordance with your country's requirements |
|  | Non-ionizing radiation |  | Pneumatic respiration |
|  | Cardiac gating output |  | Input connection |
|  | Manufacturer name and address information |  | Date of manufacture, YYYY-MM |
|  | Conforms to the RoHS directive |  | Battery |
|  | Non-magnetic part |  | Wheel lock, press to engage |
|  | Do not move the MR200 inside the 1,500 gauss field line of the MR magnet or within 1.5 m (4.9 feet), whichever is greater, as measured from the center line of the bore. |  | Apply wheel locks and do not move the MR200 inside the 1,500 gauss field line of the MR magnet or within 1.5 m (4.9 feet), whichever is greater, as measured from the center line of the bore. |
| | |  | Main key |
|  | NiBP key |  | Trends key |

| Symbol | Meaning | Symbol | Meaning |
|---|---|---|--|
|  | Print key |  | Patient key |
|  | Silence key |  | Setup key |
|  | Alarm sound on |  | Suspend key |
|  | Alarm sound on hold |  | Power switch |
|  | Alarm sound silenced |  | Alarm sound off |
|  | Current setups have changed |  | Heartbeat detected |
|  | On AC power |  | Breathing effort detected |
|  | wECG battery time remaining |  | Good battery power |
|  | wSPO2 battery time remaining |  | No AC, on battery power |
|  | No MR200 communication with the wECG module |  | Low battery power |
|  | Network channel A |  | No MR200 communication with the wSPO2 module |
|  | Network channel B |  | Network channel C |

| Symbol | Meaning | Symbol | Meaning |
|---|---|--|---|
|  | Network channel D |  | Network channel E |
|  | Cart connected to AC mains, batteries installed |  | Cart connected to AC mains, batteries not installed |
|  | Printer ready |  | Printing in progress and time remaining, in seconds |
|  | No printer available |  | Printer not ready |

Examining the Contents

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

After removing the contents from the shipping containers, carefully examine all items for signs of damage that may have occurred during shipment. Also, check all items against the included packing list and the purchase request.

The contents of the crate should include:

- MR200
- Two cart batteries
- Instructions For Use (IFU) manual
- Quick Reference Guide
- Power Cord

A separate container could include additional items:

- **Wireless ECG module**
- Wireless SPO2 module
- Module battery charger
- **Module batteries**

Assembly

This section provides important information about assembly and system requirements. Observe the warnings and cautions that appear throughout this manual when assembling and using the MR200. For the location of cart components not detailed below, see the illustration on page 2-3.



WARNING

Only perform assembly of the MR200 at a location outside of the MR magnet room. Failure to observe this warning may result in serious injury.

CAUTION

The MR200 and accessories must be used and stored according to the environmental specifications detailed in Appendix A. Failure to adhere to the specified environmental requirements may affect system and/or accessory performance and accuracy.

Disposing of the Packaging

The packaging can be retained for future use. Otherwise, the packaging for the system (which is made of recyclable materials that include corrugated paper, polyethylene [PE] foam and plastic) may be subject to disposal regulations for user and environmental safety. For disposal, it may be necessary to separate these materials by type. Always observe and adhere to your current local regulations when disposing of the packaging material.

Rear Panel Connections

Hardware interface and power connections are provided on the rear panel of the cart.

Gating connector

Presents outputs for gating connections to the MR system. Remove the shield cap from the gating connector then install a gating cable. (Cables are type-dependant; see page 1-26.)

USB port

Allows USB thumb drive connections for MR200 software updates only. (See *Updating Software* on page 11-10.)



AC Inlet

Is the input connection for AC voltage to the cart.

Strain relief

Secures the AC power cord to the cart.

CAUTIONS

- When making connections to the rear panel of the MR200, ensure that the final installation complies with IEC/EN 60601-1-1, *General Requirements for the Safety of Medical Electrical Systems*, to assure operator and patient safety. Always check the summation of leakage currents when the MR200 is connected to additional external equipment.
 - Where the integrity of the external protective conductor in the installation or its arrangement is in doubt, the MR200 shall be operated from batteries.
-

Replacing Cart Batteries



WARNING

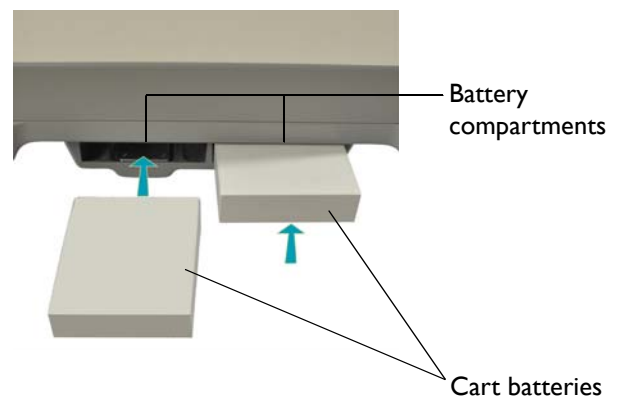
Cart batteries contain ferrous materials that are attracted to the MR magnetic field. Do not install or remove the cart batteries when closer than the 1,000 gauss (0.1 T) field line, as measured from the center line of the MR bore to the MR200. The batteries will be attracted to the magnetic field, possibly causing patient or user injury.

CAUTION

Never force a battery into a battery compartment as it will damage the battery and/or the cart.

Cart batteries will slide and latch into place in the battery compartments in the base of the unit:

- When installing batteries they must be oriented properly, as the battery shape is designed to fit the contour of the battery compartment.
- If the battery does not latch into place when fully inserted in the battery compartment, then it is not properly oriented. In this case, remove and reorient the battery then reinsert it into the battery compartment.



To install cart batteries

Orient a battery for insertion (label side down, connector facing forward) then slide it into a battery compartment. When properly inserted, the battery will latch into place. A “click” will be heard and the battery will be flush with the face of the battery compartment. Repeat the process for the remaining battery.

NOTE

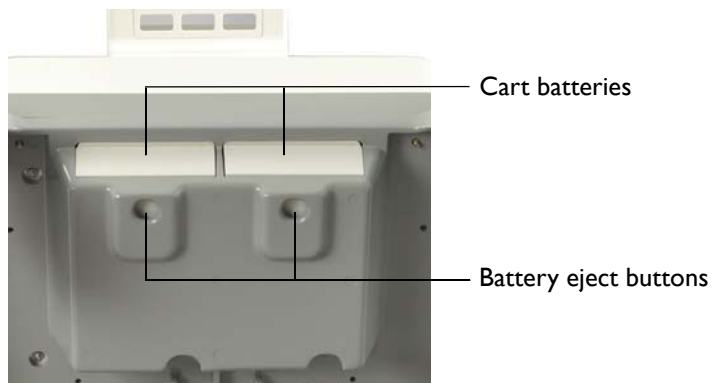
Before initial use, charge the batteries for at least 12 hours with the MR200 turned off and connected to AC mains power.

To remove a cart battery

Press the battery eject button (located on the underside of the battery compartment).

(If the battery does not release, apply a slight forward pressure on the battery while pressing the eject button.)

Repeat the process to remove the remaining battery.



Connecting AC Mains Power

CAUTION

Avoid use of electrical extension cords or multiple portable socket outlets, which may create a safety hazard by compromising the grounding integrity of the MR200.

To connect AC mains power

| Step | Action |
|------|--|
| 1 | Ensure that the cart batteries are installed; see page 1-18 for details. |
| 2 | Position the MR200; see page 2-6. |
| 3 | Raise the strain relief. |
| 4 | Connect the AC power cord to the AC inlet on the MR200. For added mobility, the power cord extension (REF 989803168221) can also be connected. |

| Step | Action |
|------|---|
| 5 | Lower the strain relief over the AC power cord. |
| 6 | Connect the AC power cord to an approved AC mains outlet. |

To remove the MR200 from AC mains power

Pull out the plug at the wall outlet and then remove the AC power cord from the MR200. Store the cord in a safe place.

MR200 Battery Operation



WARNING

Do not touch the internal battery compartments of the cart and the patient simultaneously.

Cart batteries are charged and conditioned by an integrated intelligent charging system. When turned on, the MR200 operates from AC power and simultaneously charges the batteries. When connected to AC power and turned off, the battery charger remains functional and charging occurs automatically. If AC voltage is lost, the MR200 will automatically switch to battery power to provide uninterrupted service.

NOTES

- *To prevent unintentional power interruptions, it's highly recommended to always keep the batteries inserted in the MR200 even when operating on AC power.*
- *If the MR200 will not be used for more than 3 days, remove the batteries or keep AC power connected.*

Maximum MR200 operation time under battery power is approximately 8 hours, but this may be reduced by up to 2 hours when certain operations are performed—such as running NiBP cycles at less than 5-minute intervals.

Visual indication of the charged capacity is displayed by the cart status icon (see page 2-16).

Charged capacity can also be seen by pressing the power level button on each cart battery, where the capacity is indicated in 20 percent increments.



Attaching the SPO2 Sensor to the wSPO2 Module



WARNINGS

- Only perform this assembly at a location outside of the MR magnet room. Failure to observe this warning may result in serious injury.
 - Connecting other than specified SPO2 sensors to the wSPO2 module can cause inaccurate SPO2 readings and damage the module.
-

To attach the SPO2 sensor to the wSPO2 module

Insert the SPO2 sensor to the DB-9 connector on the wSPO2 module. Then, using a standard screwdriver, securely tighten both screws.



Charging Module Batteries

Module batteries are charged in the module battery charger. Refer to the instructions provided with the module battery charger for placement and use information.

Replacing a Module Battery

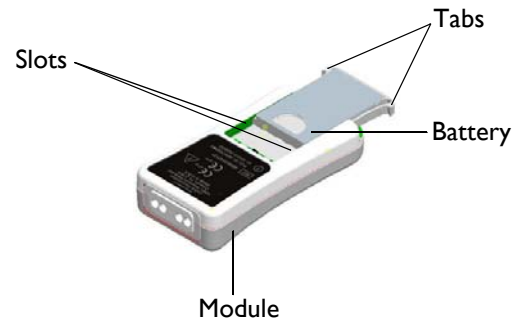
Each wireless module has slots located on back of the device to house the battery. Module batteries are interchangeable, non-magnetic, and can be handled in the MR magnet room. For operational information about the wireless modules, see page 2-7.

CAUTION

To minimize the chance of image artifacts, never place module batteries in the MRI field of view.

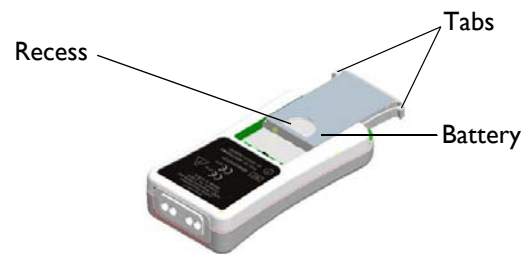
To install a module battery

Orient the battery as shown and then slide the battery between the slots on back of the module until both tabs latch into place. Store the modules in the module holders on the cart; see 2-5 for details.



To remove a module battery

Using the thumb and index finger of one hand, press the tabs inward and hold. Then place the thumb or a finger of your other hand on the recess and push the battery out of the module.



Assigning the Network Channel of a Module

NOTE

The modules for your system may arrive pre-programmed to match the network setting of the cart.

In order for a module to communicate with the MR200, the wireless network setting of each must be the same.

The current setting of a module is indicated by its illuminated network icon. For ease of recognition, each network icon has a unique letter (A–E), shape and color. (The setting for the MR200 is displayed on the LCD; see page 2-16.)



The wireless network channel for the module is changed by using the network button located underneath the label in the front upper left corner of the device; see the illustration below. (You will be able to feel a slight bump when you pass a finger over the button area.)

The following directions for changing the network channel apply to both wireless modules, though the process below depicts only the wECG module.

To press the network button

Place the module on a flat steady surface (or hold the module as shown in the figure, right) and then use your thumb to press the network button.



Changing the Network Channel of a Module

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

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

.



Icon illuminated



Icon blinking

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



Pressing the button



Releasing the button




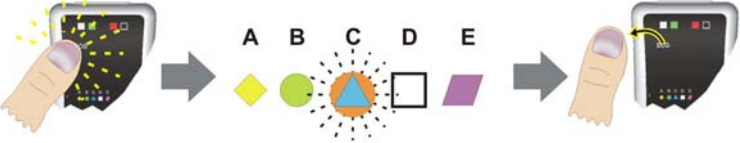
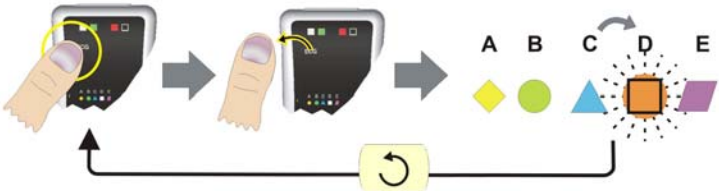
Pressing and holding the button

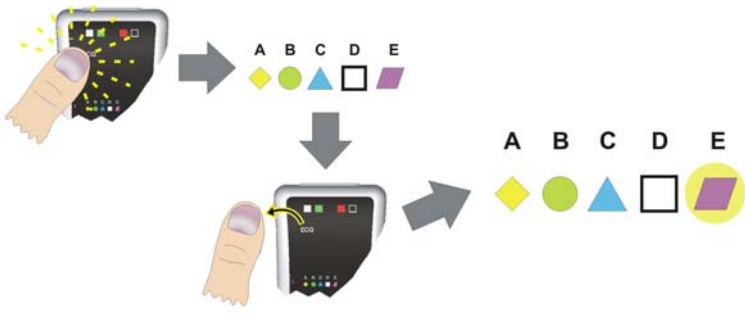


Repeating

To change the network channel of a wireless module

| Step | Action |
|------|---|
| 1 | Turn off the module by removing the battery; see page 1-21. |

| Step | Action |
|------|---|
| 2 | <p>Insert a battery into the module; see page 1-21.</p> <p>The network icons will flash briefly and then the current network icon will illuminate (for example, "C" in the illustration below).</p> <div style="text-align: center;">  </div> |
| 3 | <p>Enter the network change mode: After the current network icon has been illuminated (and within 15 seconds from module power-up) press and hold the network button until the current network icon begins to rapidly blink then release the button.</p> <div style="text-align: center;">  </div> <p>NOTE</p> <p><i>If the network change sequence was not started within 15 seconds after the module has been turned on, network changes will not be allowed. In this case, you must cycle module power and restart the sequence.</i></p> |
| 4 | <p>Press down again on the button until the icon stops blinking and then release the button to change the network setting.</p> <p>When you do this, the next network icon in the sequence will blink rapidly. (In other words, if the module was originally using network "C," now the "D" icon will be blinking.) Repeat this sequence of pressing down and releasing the button until the icon of the network you prefer is rapidly blinking. If you pass the desired network, simply continue pressing and releasing the button until the desired network is blinking again.</p> <div style="text-align: center;">  </div> |

| Step | Action |
|------|--|
| 5 | <p data-bbox="683 352 1377 415">When you reach the desired icon, press and hold the button for approximately 5 seconds to lock and save the new setting.</p> <p data-bbox="683 447 1417 573">The selected network's icon will turn off while the button is depressed. Then it will illuminate (not blink) when the new network setting is saved. Once illuminated, release the button. The module will begin using the selected network channel.</p>  <p data-bbox="683 972 1417 1108">NOTE Any part the network change sequence not completed will cause the module to revert to the network previously set 30 seconds after the network button was last released.</p> |

Advanced User Options

Expression Information Portal (Model IP5)

Providing system control outside the MR magnet room, the Expression Information Portal (Model IP5), hereafter referred to as the IP5, is a wireless device that also features printing capabilities and HL7 data output options.



Additional Options

Additional options, such as those listed below, may be suggested by your biomedical technician to increase user ease. The MR200 is configured with input/output ports to permit the connection of external equipment, including:

- Facility information systems
- Gating source for MRI functions
- USB port for software installation

Consult your biomedical technician or technical support with specific requests.

CAUTIONS

- When adding equipment to an MR200 system (for example, an IP5), be aware that all devices should be at the same or a compatible software revision level. Contact technical support if you have questions or to upgrade software. Failure to observe this requirement could result in compatibility conflicts, communication problems, etc.
 - The manufacturer is not responsible for any radio frequency interference caused by unauthorized modifications to the radios and/or antennas within this equipment. Such modification could inhibit proper MR200 system or device communications.
-

Accessory List

Accessories are listed in the tables below with part number (REF) information.

CAUTION

The MR200 has been validated with all of the accessories listed below. Only use these specified accessories as other types or brands may compromise the safety and accuracy of the MR200.

| CO2 | 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 |
| LOFLO LINE, ADU DVD CANNULA, BOX 20 | 989803183271 |
| LOFLO LINE, PED DVD CANNULA, BOX 20 | 989803183281 |
| LOFLO LINE, ADU AIRWAY ADPT, BOX 20 | 989803183291 |

| CO2 | REF |
|--|--------------|
| LOFLO SAMPLE LINE, ADULT CANNULA,BOX 100 | 989803185331 |
| LOFLO SAMPLE LINE, PED CANNULA, BOX 100 | 989803185341 |
| LOFLO SAMPLE LINE, NEO CANNULA, BOX 100 | 989803185351 |
| LOFLO LINE, ADU DVD CANNULA, BOX 100 | 989803185361 |
| LOFLO LINE, PED DVD CANNULA, BOX 100 | 989803185371 |
| LOFLO LINE ADU AIRWAY ADPT, BOX 100 | 989803185381 |

| ECG | REF |
|---------------------------------------|--------------|
| GEL, ECG/EEG, SKIN PREP, TUBE, 3-PACK | 989803152291 |
| CAB, 4 LD, MRI ECG | 989803152301 |
| CAB, 4 LD, NEO.MRI ECG | 989803152331 |
| CAB, 4 LD, CV MRI ECG | 989803152351 |
| ADVANCED APPS ECG CABLE | 989803176381 |
| ADVANCED FILTER ECG CABLE | 989803170121 |
| QUADTRODE MRI ECG PAD, 25/BOX | 989803179031 |
| ELCTRD, MRI ECG, QUTRD.CV, 25/BOX | 989803179041 |
| ELCTRD, MRI, NEO.QUDTRD, 25/BOX | 989803179051 |
| WIRELESS ECG PATIENT MODULE | 989803183661 |
| CAB, 4 LD, NEO.MRI ECG, IEC | 989803185441 |
| CAB, 4 LD, CV MRI ECG, IEC | 989803185451 |
| CAB, 4 LD, MRI ECG, IEC | 989803185461 |
| ADVANCED FILTER ECG, IEC | 989803185471 |
| ADVANCED APPS ECG CABLE, IEC | 989803185481 |

| Gating Cables | REF |
|---------------------------------|--------------|
| CAB, DIGITAL GATING, GE, 3160 | 989803152821 |
| CAB, GATING, SIEMENS, 3160 | 989803152831 |
| CAB, GATING, PHILIPS ACH, 3160 | 989803152841 |
| CAB, DIG.GATING, HIT/TOSH, 3160 | 989803152851 |

| Non-invasive Blood Pressure | REF |
|--|--------------|
| NIBP CUFF, SINGLE LUMEN, INFANT | 989803182611 |
| NIBP CUFF, SINGLE LUMEN, PEDIATRIC | 989803182621 |
| NIBP CUFF, SINGLE LUMEN, SMALL ADULT | 989803182631 |
| NIBP CUFF, SINGLE LUMEN, ADULT | 989803182641 |
| NIBP CUFF, SINGLE LUMEN, ADULT-L | 989803182651 |
| NIBP CUFF, SINGLE LUMEN, LRG ADULT | 989803182661 |
| NIBP CUFF, SINGLE LUMEN, LRG ADULT-L | 989803182671 |
| NIBP CUFF, SINGLE LUMEN, THIGH | 989803182681 |
| NIBP CUFF, SINGLE LUMEN, INFANT, DISP | 989803182511 |
| NIBP CUFF, SINGLE LUMEN, PEDIATRIC, DISP | 989803182521 |
| NIBP CUFF, SINGLE LUMEN,SMALL ADULT,DISP | 989803182531 |
| NIBP CUFF, SINGLE LUMEN, ADULT, DISP | 989803182541 |
| NIBP CUFF, SINGLE LUMEN, ADULT-L, DISP | 989803182551 |
| NIBP CUFF, SINGLE LUMEN, LRG ADULT, DISP | 989803182561 |
| NIBP CUFF, SINGLE LUMEN,LRG ADULT-L,DISP | 989803182571 |
| NIBP CUFF, SINGLE LUMEN, THIGH, DISP | 989803182581 |
| NIBP CUFF, SINGLE LUMEN, SAMPLE KIT,DISP | 989803182591 |
| NIBP CUFF, SINGLE LUMEN, NEO #1, DISP | 989803183171 |
| NIBP CUFF, SINGLE LUMEN, NEO #2, DISP | 989803183181 |
| NIBP CUFF, SINGLE LUMEN, NEO #3, DISP | 989803183191 |
| NIBP CUFF, SINGLE LUMEN, NEO #4, DISP | 989803183201 |
| NIBP CUFF, SINGLE LUMEN, INFANT #5, DISP | 989803183211 |
| ADULT PRESSURE INTERCONNECT HOSE | 989803183221 |
| NEONATAL PRESSURE INTERCONNECT HOSE | 989803183231 |

| Pneumatic Respiration | REF |
|------------------------------|--------------|
| PNEUMOGRAPH,CHEST,NM,3160 | 989803152791 |

| Power | REF |
|--------------------------------|--------------|
| EUROPEAN LINE CORD | 453564177501 |
| NORTH AMERICAN LINE CORD | 989803168211 |
| CORD, JUMPER, 25 FEET | 989803168221 |
| BRAZILIAN POWER CORD, 3 METER | 989803173901 |
| UK LINE CORD, 3 METER | 989803174171 |
| 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 |

| SPO2 | REF |
|---|--------------|
| QUICK CONNECT SPO2 PROBE, MRI | 989803161991 |
| QUICK CONNECT SPO2 CLIP, ADULT | 989803166531 |
| QUICK CONNECT SPO2 CLIP, PEDIATRIC | 989803166541 |
| QUICK CONNECT SPO2 GRIP, ADULT, 20/BOX | 989803166551 |
| QUICK CONNECT SPO2 GRIP, PED, 20/BOX | 989803166561 |
| QUICK CONNECT SPO2 GRIP, INFANT, 20/BOX | 989803166571 |
| QUICK CONNECT SPO2 GRIP, NEO, 20/BOX | 989803166581 |
| WIRELESS SPO2 PATIENT MODULE | 989803183541 |

| System | REF |
|-------------------------------------|--------------|
| ASSY, 3.7V BATTERY CHARGER, 3160 | 989803152891 |
| BATT.3.7V,WRLS.PAT.MDLE | 989803152881 |
| BATTERY, MRI, 14.8V, 5.08 AH, UL | 989803169491 |
| HANDLE HOOK, HOSE MANAGEMENT | 989803185121 |
| EXPRESSION INFORMATION PORTAL (IP5) | 865471 |

| Miscellaneous | REF |
|---------------------------------------|--------------|
| PAPER, THERMAL ARRAY, BLK, 50MM, OMNI | MP05 |
| QUICK REFERENCE GUIDE, MR200 | 453564357851 |
| MANUAL, SERVICE, MR200 | 989803181911 |
| MANUAL, OPERATORS, MR200, ENGLISH | 989803184961 |
| MANUAL, OPERATOR, MR200, DANISH | 989803181971 |
| MANUAL, OPERATOR, MR200, DUTCH | 989803181981 |
| MANUAL, OPERATOR, MR200, FINNISH | 989803181991 |
| MANUAL, OPERATOR, MR200, FRENCH | 989803182001 |
| MANUAL, OPERATOR, MR200, GERMAN | 989803182011 |
| MANUAL, OPERATOR, MR200, ITALIAN | 989803182041 |
| MANUAL, OPERATOR, MR200, NORWEGIAN | 989803182051 |
| MANUAL, OPERATOR, MR200, POLISH | 989803182061 |
| MANUAL, OPERATOR, MR200, PORTUGUESE | 989803182071 |
| MANUAL, OPERATOR, MR200, SPANISH | 989803182091 |
| MANUAL, OPERATOR, MR200, SWEDISH | 989803182101 |
| MANUAL, OPERATOR, MR200, TURKISH | 989803182111 |
| MANUAL, OPERATOR, MR200, JAPANESE | 989803190941 |
| MANUAL, OPERATOR, MR200, RUSSIAN | 989803190951 |
| MANUAL, OPERATOR, MR200, KOREAN | 989803191221 |
| MANUAL, OPERATOR, MR200, TRADITIONAL | 989803191231 |
| MANUAL, OPERATOR, MR200, INDONESIA | 989803191351 |

System Overview

Familiarize yourself with the MR200 and its components. The MR200 combines wireless communications, radio frequency shielding and digital signal processing technologies to provide accurate, continuous and reliable patient monitoring performance in the dynamic magnetic resonance environment.

The monitoring capabilities of the MR200 can be configured to meet the needs of a wide spectrum of patients from neonate to adult. Every parameter can be accessed and adjusted for the unique condition of each patient. The MR200 accommodates specific monitoring needs, including:

- Adult, pediatric and neonatal patients
- Critically ill patients
- Patient undergoing sedation
- Patient transport within the MR environment
- Interventional procedures
- Cardiac gating

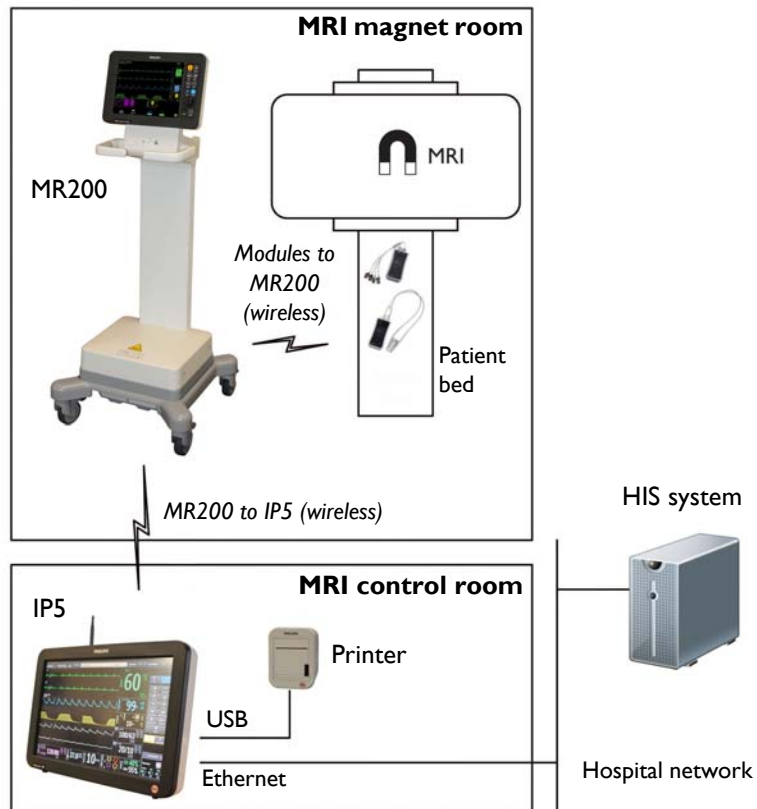
System Components

A complete MR200 system consists of the following components:

- Cart
- **Wireless ECG module**
- Wireless SPO2 module
- Module battery charger
- Batteries and other accessories as needed
- Optional IP5 and printer

Use Model

As illustrated below, the MR200 is intended to be used to monitor the vital signs of a patient in an MR magnet room. When paired with the optional IP5, monitoring capability can be extended to an MR control room, induction room, or recovery room environment and the gathered data can be output to a strip chart printer or hospital information system (HIS).



Acquisition and Control

The use of the MR200 is restricted to one patient at a time. The MR200 displays patient measurements acquired during monitoring. Controls and settings for patient monitoring are provided locally at the display panel or remotely (for example, in the MRI control room) when equipped with the IP5, where connections for the printer and the hospital network are also available.

Synchronization

The MR200 will automatically establish communication with the wireless modules and IP5 (if equipped). However, due to the use model, the devices can establish communication and synchronize power-on settings depending upon the start-up sequence:

- If the MR200 boots first, then its settings will be reflected at the IP5.
- If the IP5 boots first, then its settings will be reflected at the MR200.

If using an IP5, patient identifiable information (name, ID number, etc.) will be available after synchronization occurs.



WARNING

The use model specifies one IP5 per MR200 system. If more than one IP5 is present on the MR200 system, there is an increased risk of units within the system not synchronizing and displaying incorrect or corrupted settings.

CAUTION

If the monitor's settings are adjusted since they were last recalled or stored (manually, or via synchronization - if using an IP5), the current setup name (see page 2-14) will be appended with a plus symbol (+). The symbol will only be removed if the current settings are saved (see page 3-5) or if different settings are recalled (see page 3-4). Always confirm the proper settings for the MR200 and IP5 to ensure expected monitoring functionality.

NOTE

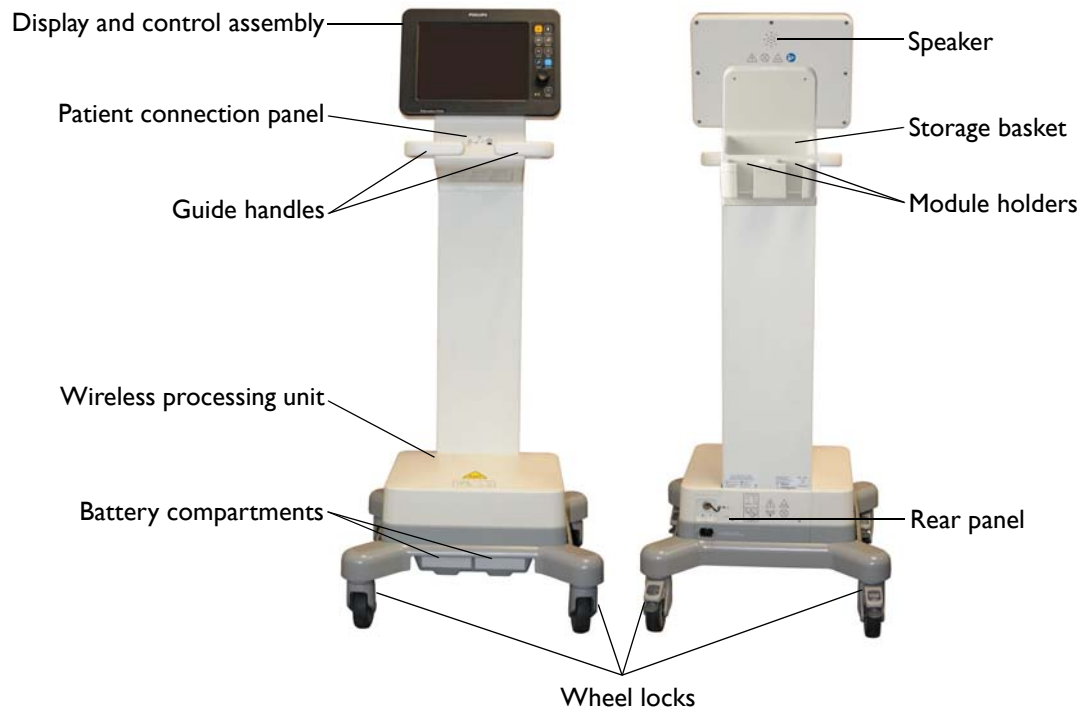
See **DEFAULT SETUPS** (on page 3-13) for information about power-on settings.

Device Control

Menu commands that control the parameter functions for patient monitoring are synchronized between the MR200 and IP5. Commands that do not directly control the patient parameters (for example, printer functions) will only affect IP5. Other control settings remain localized to the IP5 and are not synchronized with the MR200, including alarm silence and hold functions and volume settings (for a complete listing, see the IP5 IFU).

Cart

Designed for use in the MR magnet room and throughout the MR suite, the cart is a wheeled patient monitor with integrated processing, power, display and control assemblies. As illustrated below, this self-contained mobile system also includes storage solutions for accessories.



WARNING

Never store ferrous items on the cart or in the storage basket. Failure to observe this warning may result in serious injury.

CAUTION

Do not place more than 4 pounds (1.8 kg) of combined weight in the storage basket, module holders and on the optional hose management handle hooks (not shown).

Speaker

The speaker communicates all audible signals; see **SOUND ADJUST** on page 3-8 for details.

Storage Basket

The storage basket provides convenient placement for CO2 cannulas, NiBP cuffs, SPO2 attachments and Quadtrode electrodes.

Module Holders

The module holders provide safe storage for the wireless modules. Place a wireless module in a module holder so that a connected accessory hangs downward through the opening.



Wireless Processing Unit

The wireless processing unit (WPU) houses the communication, processing and power systems for the MR200.

Rear Panel

The rear panel contains the AC inlet, gating connector and USB port; see page 1-16 for details.

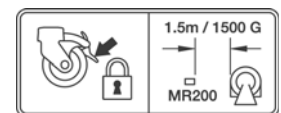
Wheel Locks

Locks are provided on each wheel to prevent movement of the cart. During use in the MR magnet room, station the cart at a safe monitoring distance then press down on each wheel lock to engage it. When the cart needs to be moved, raise each wheel lock before proceeding. (See page 2-6 for positioning details.)



WARNING

Do not move the MR200 inside the 1,500 gauss field line of the MR magnet or within 1.5 m (4.9 feet), whichever is greater, as measured from the center line of the bore. Always secure the wheel locks when the MR200 is located in the MR magnet room. Failure to properly place the MR200 in the MR magnet room will result in monitoring system failure, and possible patient or user injury.



Battery Compartments

The battery compartments house the cart batteries; see page 1-17 details.

Guide Handles

The guide handles provide the means for positioning the cart.

CAUTIONS

- Never apply excessive force, lean against, stack or drape objects over the guide handles; instead, use specially designed hose management handle hooks; see page 1-28 for details.
 - If the MR200 rolls to the face of the MR system due to magnetically induced pull force, Do not attempt to dislodge the MR200 by pulling from the display panel or guide handles; instead, dislodge the MR200 by gently pulling from the lowest point of the base. This will prevent the base of the unit from experiencing higher MR pull forces in the vertical direction.
-

Patient Connection Panel

The patient connection panel contains ports for the NiBP and CO2 attachments.



NOTE

Depending upon the equipped options, your MR200 may not have all indicated connections.

Display and Control Assembly

The display and control assembly houses the display panel and speaker, which provide user information and system control; see page 2-10 for details.

CAUTION

Never use the display and control assembly to position the cart; severe damage or failure can result. Only use the guide handles and, if necessary, the storage basket to position the cart.

Positioning the MR200

Use the guide handles to move and position the cart. Always position the cart so that your view of the LCD remains unobstructed during use.

The MR200 has an internal gauss sensor which, in close proximity to the MR magnet, automatically shuts down NiBP and CO2 monitoring functions. To alert you to move the cart away when it is too close to the MR magnet, the MR200 will display the following warning dialog box message:

Move monitor away from magnet. NiBP and CO2 (if installed) have been shut down.

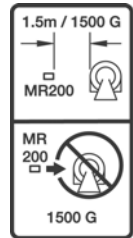


When positioning the MR200 for use, observe the warning and cautions below.

WARNING



Do not move the MR200 inside the 1,500 gauss field line of the MR magnet or within 1.5 m (4.9 feet), whichever is greater, as measured from the center line of the bore. Always secure the wheel locks when the MR200 is located in the MR magnet room. Failure to properly place the MR200 in the MR magnet room will result in monitoring system failure, and possible patient or user injury.



CAUTIONS

- If the MR200 rolls to the face of the MR system due to magnetically induced pull force, do not attempt to dislodge the MR200 by pulling from the display panel or guide handles; instead, dislodge the MR200 by gently pulling from the lowest point of the base. This will prevent the base of the unit from experiencing higher MR pull forces in the vertical direction.
- Field strength variations may require you to move the MR200 away from the MR system if patient monitoring abnormalities or malfunctions are observed. Prior to clinical use, ensure that the allowable distance from the MR system is maintained for proper operation because variations in a particular MR magnet room (due to magnetic shielding techniques, manufacturer variability, future enhancements, etc.) can make it difficult to distinguish the 1,500 gauss level, as measured from the center line of the MR bore. The MR200's gauss sensor can be used to determine the correct position of the cart in the MR magnet room.

Wireless Modules

The wireless modules are battery operated and communicate with the MR200 through a bidirectional 2.4 GHz digital modulation link, which is automatically established approximately 30 seconds after power is applied to the module. The wireless modules operate at up to 30 feet (9.1 m) from the MR200 in the MRI room or in the same shielded room.

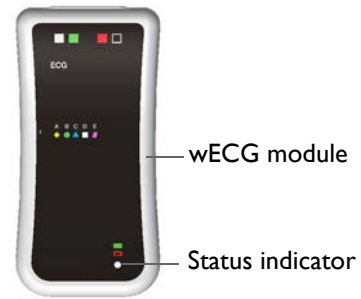
WARNING



The system use model specifies one wECG module and one wSPO2 module per MR200 system network. If more than one type of each module is communicating on the same network, then waveform and measurement corruption will occur.

wECG Module

The wireless ECG module (wECG) transmits measured ECG signals through a wireless link to the MR200. The module also receives information to perform commanded tasks (for example, lead configuration and filter mode changes). Two ECG channels can be displayed and are available for interfacing with the MR system cardiac gating input.



wSPO2 Module

The wireless SPO2 module (wSPO2) transmits measured blood oxygen saturation, plethysmography, peripheral pulse data (SPO2) and pneumatic respiration values through a wireless link to the MR200. The processed information can be displayed and output for interfacing to the MR system pulse peripheral and respiration gating input.



Module Status Indicator

Each module has a status indicator, a two-color LED, that denotes the following conditions.

| Indicator | | Module Status | |
|-----------|----------------|--|--------------------|
| Color | State | Power | Communications |
| None | Not applicable | No battery is installed or the charge is insufficient to power the module. | Not applicable |
| Green | Flashing | Battery power good | Not communicating |
| Green | Solid | Battery power good | Good communication |
| Red | Flashing | Low battery condition | Not communicating |
| Red | Solid | Low battery condition | Good communication |

NOTE

For battery details, see page 1-20; and, for communications details, see page 1-21.

System Power-Up and Communications Verification



WARNING

Always perform operational verification prior to use and during monitoring by ensuring proper communications between the MR200, the wireless modules and the IP5 (if equipped). Failure to ensure proper communications can result in the loss of patient monitoring and the loss of data transfer in networked systems equipped with an IP5. If a device fails to function properly, remove it from use and contact technical support.

The MR200 reaches an operational state within 60 seconds power-up and attains full measurement accuracy after 2 minutes.

To apply power to the MR200 and verify system communications

| Step | Action |
|------|--|
| 1 | Ensure that a battery is installed in each wireless module (see page 1-20). |
| 2 | With the cart batteries installed and with the MR200 connected to AC power (see page 1-18), press the power switch. |
| 3 | (Optional) if equipped, turn on the IP5. |
| 4 | Ensure that the network setting of each module (see page 1-21) matches the network setting of the MR200 (see on page 2-16). |
| 5 | Ensure that the network setting of the IP5 (if turned on in step 3, above) matches the network setting of the MR200 . |
| 6 | Ensure good communication between each module and the MR200 by checking the module's status icon on the LCD (see on page 2-16). |
| 7 | (Optional) if equipped with an IP5, proceed according to the printer option: <ul style="list-style-type: none">• If equipped with a printer, ensure good communication between the MR200 and the IP5 by checking the printing status icon on the LCD (see page 2-16).• If not equipped with a printer, check the display panel of the IP5 for host connection to the MR200. |
| 8 | Ensure proper operation of each patient parameter and alarms. Refer to appropriate chapters in this manual. |

CAUTION

If power to wireless device with established communications is lost or removed, its network connection will be dropped.

System Parameters

The MR200 simultaneously processes and displays multiple parameters, waveforms, numeric values and alarms. All patient information is provided on the display panel. A fully equipped MR200 includes monitoring for the following parameters:

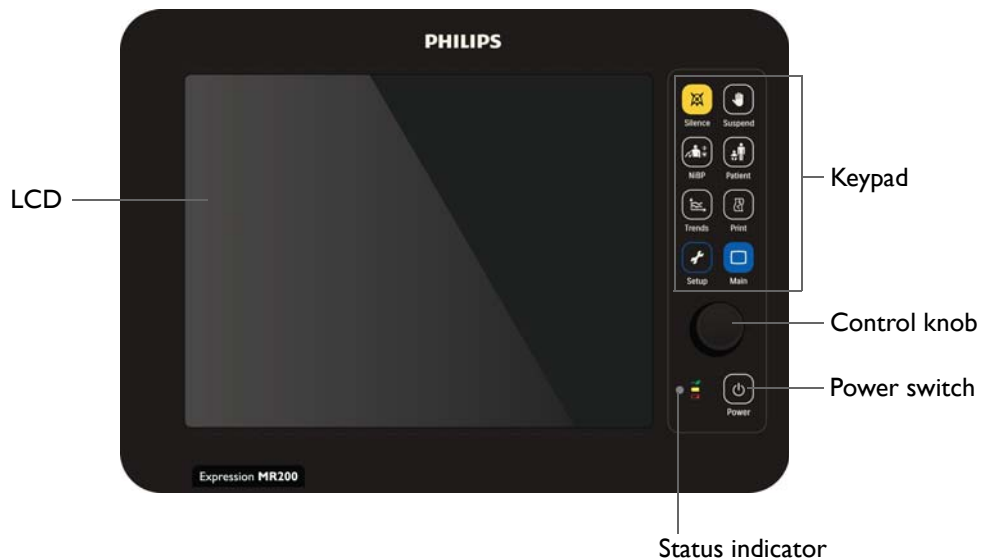
- Electrocardiogram (ECG), dual channel
- Heart rate
- Blood oxygen saturation/pulse oximetry (SPO2)
- Non-invasive blood pressure (NiBP)
- End-tidal and inspired CO2 (CO2)
- Respiration (CO2 or bellows)

NOTE


Depending upon the equipped options, your MR200 may not have all indicated parameters.

Display Panel

The display panel, which includes the LCD, keypad and control knob, forms the user interface of the MR200.











Power Switch

Power is controlled by the power switch :

- Press the power switch to turn on the MR200.
- Press and hold the power switch for approximately two seconds to turn off the MR200.

Keypad

The keypad has eight keys for quick access to frequently used functions.

| Key | Function |
|---|---|
|  Silence | Controls the alarm sound; see page 9-7 for details. |
|  Suspend | Enters suspend mode; see page 2-19 for details. |
|  NiBP | Begins a new NiBP measurement if no reading is in progress, or ends a current measurement; see chapter 4. |
|  Patient | Selects the type of patient to be monitored; see page 3-10 for details. |
|  Trends | Accesses the HISTORY menu when in normal mode (see page 2-18) and an individual graphic trend when a vital sign box is highlighted (see chapter 10). |
|  Print | Initiates a 30 second print when using an equipped IP5. |
|  Setup | Accesses the SETUP menu; see page 3-2 for details. |
|  Main | Closes any menu and returns to the normal operating mode (see page 2-18) |

Control Knob

The control knob allows you to navigate and select options, items and settings in the menu system:


- Rotating the control knob clockwise moves the “cursor” down and rotating the knob counterclockwise moves the “cursor” up.
- In the normal mode, rotate the knob to highlight different vital sign boxes and press the knob to open the associated menu.
- When a menu is displayed, rotate the knob to highlight options and items and press the knob to select that option or item.
- When a option is displayed, rotate the knob to highlight settings and items, and press the knob to select that setting or item.

NOTE

*In the menu system, grayed out panes, options labelled **UNUSED** or **THIS ITEM IS LOCKED** when selected, reflect features or options that are inaccessible, not configured, or not installed.*

Status Indicator

The status indicator is a multi-color LED that denotes the power condition of the cart, as detailed in the table below.

| Indicator | | Power Status | |
|-----------|----------------|--|--------------|
| Color | State | Definition | Power Switch |
| None | Not applicable | Not on external power (batteries may be installed) | Off |
| Green | Flashing | AC power connected (batteries may be installed) | Off |
| Green | Solid | On AC power (batteries, if installed, are charging) | On |
| Yellow | Solid | On battery power | On |
| Red | Solid | On battery power with a low battery condition WARNING  A solid red light indicates battery power has fallen below the required limit and system shutdown with loss of monitoring will occur. Immediately locate an AC outlet and connect the MR200. | On |

LCD

The display panel features a color liquid crystal display (LCD). Always adjust the cart so that your view of the LCD complements your line of sight.

CAUTION

Never apply unnecessary force to the LCD as it can result in screen damage or failure.

NOTE

To change the language displayed by the MR200, see page 11-16.

Display Areas

Four data areas are displayed in the normal operating mode (see page 2-18 for details):

- Informational area (1, below)
- Vital sign boxes area (2, below)
- Communication and power status display area (3, below)
- Vital sign traces area (4, below)

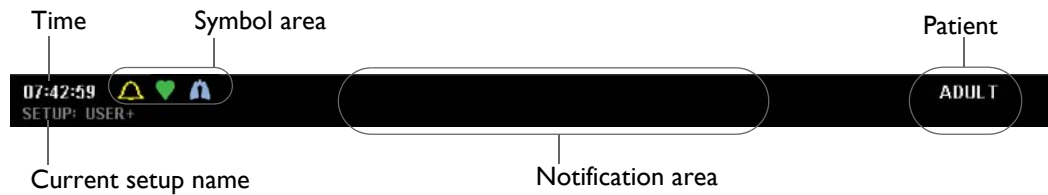


NOTE

If a parameter (or an ECG trace) has been turned off, its portion of the LCD will be blank. To turn a parameter on or off, use the **PARAMETER SELECTION** menu; see page 3-7 for details.

Informational Area

The informational area, along the top of the screen, provides user and patient information:



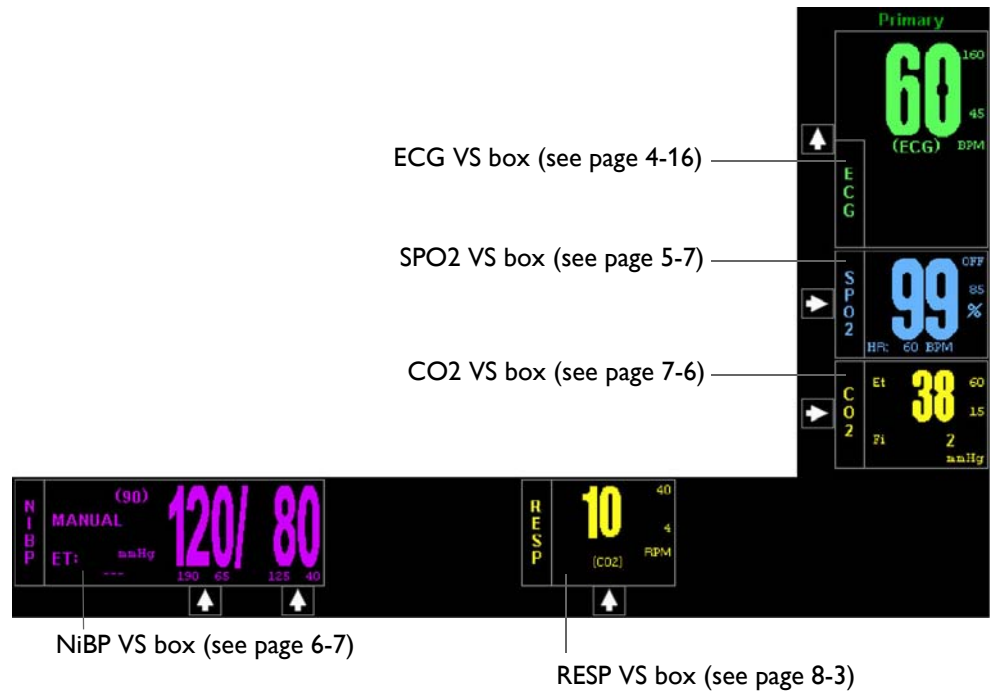
- **Time** provides current time, given in a 12- or 24-hour format (hh:mm:ss); see *Set Time* on page 3-12 for details.
- **Symbol area** provides indications of the alarm sound setting, configuration status, and heartbeat and respiration detection.
 - The indicates an active alarm sound setting, displayed at all times (unless temporarily obscured by a menu or dialog box); see chapter 9.
 - When enabled, the indicates heartbeat detection, flashing for each detected pulse; see *HR TONE SOURCE* on page 3-9.
 - When CO2 is on and within specified limits, the indicates respiration detection, flashing at a frequency that matches the current breath rate; see chapter 7.
- **Patient** displays the selected patient type; see page 3-10.
- **Current setup name** displays the power-on default (see page 3-13) or the memory block that was used (see page 3-4) for the current setup of the monitor, where the plus symbol (+) indicates a setting change has taken place; see *Synchronization* on page 2-2.
- **Notification area** displays up to two informational, status and/or technical messages at a time; and, if three or more exist, the messages will cycle.



(Two messages are shown in the example above; see *Listing of Alarms* on page 9-16 for messages and details.)

Vital Sign Boxes Area

The vital sign (VS) boxes area, along the right side and the lower portion of the screen, contains individual panes that provide vital sign numeric data, alarm limit settings and violation indications, trend arrow indications, and menu access for each of the parameters.



No Data Available Indication

Under certain conditions one or more of the numerics in the VS boxes may display three dashes (---) to indicate that no data is available.



Depending upon the nature of this indication, an alarm may be generated if no parameter data is available. In this case, the dashes will be displayed in red and an alarm will sound.

An alarm is generated when:

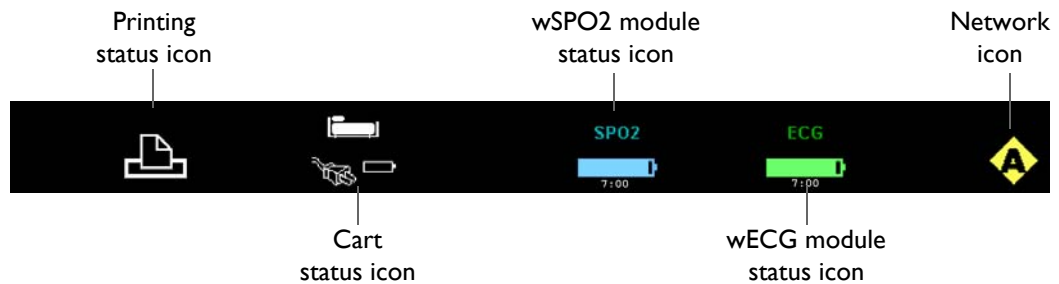
- Parameter data was present but is no longer available (for example, a sensor that was applied may no longer be connected to the patient).
- The hardware associated with a parameter has experienced a problem or failure that prevents proper operation.







No alarm is generated when:


- A module or another measurement device was just turned on or applied to the patient (allow a few seconds for communication to be established).
- The first reading has not yet been taken or the parameter is in a start-up condition.
- The measurement values are distorted or the signal is inadequate.
- Suspend mode was just exited.

Communication and Power Status Display Area

The communication and power status display area, along the bottom of the screen, provides indications of the system network setting, printing status, and the communication and power status of the cart and the wireless modules:







- **Printing status icon** displays the status of the IP5 printer, when equipped:
 - When ready to print,  is displayed.
 - When printing,  is displayed, indicating the time remaining (in seconds) until completion.
 - When not installed or if a communication problem exists,  is displayed.
 - When available but unable to print,  is displayed.
- **Cart status icon** indicates the power status of the cart:
 - Where  indicates the cart has batteries installed and is operating on AC power.
 - Where  indicates the cart has no batteries installed and is operating on AC power.

- When on battery power, the battery level with a time remaining counter is displayed; and, if less than 45 minutes of operating time remain, then  is displayed and an alarm is sounded.

NOTE

After the start of battery power mode, the time remaining counter may take several minutes to stabilize.

- **wSPO2 module status icon** indicates the communication and battery status of the wSPO2 module:
 - Where  indicates the battery level (with a time remaining counter, formatted in hours:minutes). If less than 45 minutes of operating time remain, then the icon turns red, flashes, and an alarm is sounded.
 - Where  indicates there is no communication between the cart and module.
- **wECG module status icon** indicates the communication and battery status of the wECG module:
 - Where  indicates the battery level (with a time remaining counter, formatted in hours:minutes). If less than 45 minutes of operating time remain, then the icon turns red, flashes, and an alarm is sounded.
 - Where  indicates there is no communication between the cart and module.
- **Network icon** indicates the current wireless network channel of the MR200. Five network channels are available (A–E), as shown below. This channel setting can be changed to meet the needs of your facility and operating environment, but you must also change the setting of the wireless modules (and IP5, if equipped) to match the new MR200 channel for proper system communications; see page 3-15.



Network channel A



Network channel B



Network channel C



Network channel D



Network channel E

WARNINGS



- **Care should be taken to guard against inadvertent changes to the network setting. Before use, always ensure that all devices are communicating properly. Failure to do so may cause a lapse in patient monitoring.**
- **In environments where multiple MR200s are being used, you must be aware of each system’s network setting. Operating multiple MR200s on the same network or with a wrong network setting will interfere with communications, and incorrect or corrupted patient vital signs information will be displayed as a result.**

Vital Sign Traces Area

The vital sign traces area, in the middle of the screen, provides vital sign (VS) waveforms and system status messages. Trace waveforms (A–D) are uniquely colored to match their corresponding VS box, and are fixed across the LCD and updated with an erase bar:



- **Trace A** is assigned and displayed depending upon the **ECG** menu options; see page 4-16.
- **Trace B** displays ECG2 when two ECG sources are on.
- **Trace C** displays the SPO2 waveform; see page 5-7.
- **Trace D** displays the CO2 waveform; see page 7-6.
- **System message area** provides system messages, as detailed throughout this manual and in *Listing of Alarms* on page 9-16.

Modes of Operation

The MR200 has three different operating modes.

Normal Mode

Normal mode is the standard operating mode. In normal mode there are no open menus or highlighted vital sign boxes; the system is ready for monitoring.

To enter normal mode

Press the **Main** key .

Any open menu will close and any highlighted VS box will be deselected (the normal screen will be displayed; see page 2-13).

Suspend Mode

Suspend mode supports patient-clinician interaction without nuisance alarms, which is useful where minimal user interaction is required (for example, while a patient is not being monitored, during transitions when removing the monitor from one patient and connecting it on another, or if certain adjustments are being made to the device or other equipment). In suspend mode, current patient information is provided, but with the following operational exceptions:

- Audible alarms are disabled;
- Active automatic NiBP measurements are suspended;
- Default inflation pressures are used for all manual NiBP readings; and,
- Automatic printouts will not be generated.

To enter suspend mode

Press the **Suspend** key .

SUSPENDED will be displayed (in red, near the center of the screen).

To exit suspend mode

Press the **Suspend** key.

Simulation Mode

Simulation mode supports training and testing functions by displaying internally-generated data for vital sign waveforms, numerics and statuses. In simulation mode, all patient monitoring is discontinued. For simulation mode details, see page 11-14.

Getting Started

Initial setup is important to achieve expected results and seamless operation. Setup menus provide the ability to select monitoring options, control functions, store and recall operating configurations and access test routines.

CAUTIONS

- A minor but noticeable degradation in wireless module communications may occur in the presence of high-powered radios.
 - Prior to clinical use, the user must be aware of the minimum distance from the MR magnet that must be maintained for proper operation; see *Positioning the MR200* on page 2-6 for details.
-

Monitor Initialization

After power-up, the MR200 typically takes a few seconds to initialize. During this period, the LCD may remain blank until the process completes. The MR200 can begin monitoring functions from an initial factory default state or from a pre-configured state, depending upon the way the stored configurations and patient data are programmed for startup.

Visually checking the patient and confirming changing measurements against other vital signs should be standard routines during use.



WARNING


When using an IP5, make sure that the content of the RECALL SETUPS option matches that of the MR200 option, and that the same option is selected as the default setup on both systems (see page 3-4). This is important because the device first booted will determine the power-on settings of the system (that is, the MR200 and IP5).

Initial Alarm Setting Indication

After power-up and immediately following the recall of a stored setup, the MR200 provides an initial indication of the alarm volume by sounding the tone at its current setting for 5 seconds. During this interval, **CHECK ALARM VOL** will be displayed.

Alarm Hold is the initial state of the alarm functions following power-up, and then after the wait period (120 seconds) Armed becomes the normal state. In the Armed state, the alarm functions

operate as follows:

- The alarm tone will sound while an alarm condition exists, provided that any pre-alarm sound delay has expired and the  symbol is displayed.
- Messages related to other alarm sound states will be removed from the display.
- An alarm condition not previously placed in a silenced state will cause the alarm to sound (provided that any pre-alarm sound delay has expired).

SETUP Menu

From the **SETUP** menu, you can configure the MR200 to meet your patient monitoring needs:

- Individual setup configurations can be saved and recalled.
- Available parameters can be turned on and off.
- Patient type can be selected.
- Sounds can be adjusted.
- Date and time can be set.
- Network designation can be set.
- Sweep and respiration speeds can be selected.
- Default configuration for start-up can be selected.
- Alarm limits can be set.
- Remote printer functions can be selected.

WARNING



When using an IP5, wait at least 4 seconds if performing a recall or setting a parameter value, as these require a few seconds to propagate through the system. Performing another recall within 4 seconds of a previous recall or after a value change, may result in improperly recalled data.

The **SETUP** menu accesses menus for setup and control of the MR200.

To enter the SETUP menu

Press the **Setup** key .



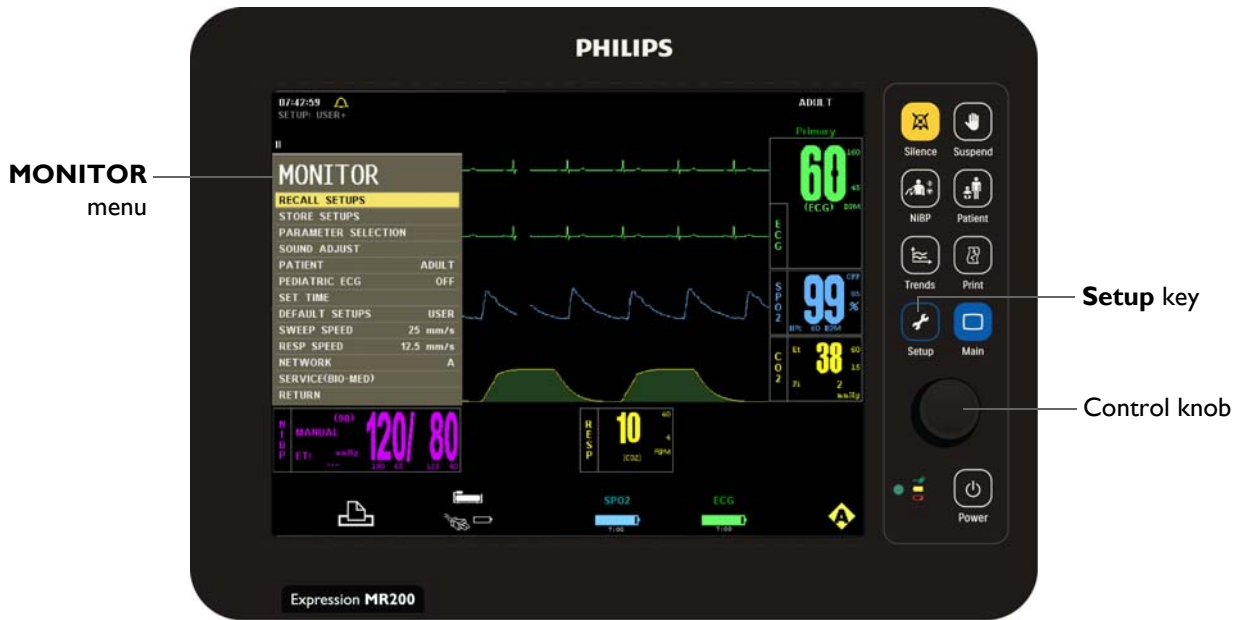
The following options are available in the **SETUP** menu:

- **ALARM SETUP** (see chapter 9 for details)


- **MONITOR SETUP** (see below)
- **PRINTER SETUP** (see chapter 10 for details)


MONITOR Menu

The **MONITOR SETUP** option (in the **SETUP** menu) opens the **MONITOR** menu, which contains options for setup and control of patient monitoring.



To change settings in the MONITOR menu

| Step | Action |
|------|---|
| 1 | Press the SETUP key  . The SETUP menu appears. |
| 2 | Turn the control knob to MONITOR SETUP and then press the knob. The MONITOR menu appears. Current settings are displayed. |

| Step | Action |
|------|--|
| 3 | <p>Turn the control knob to select any of the following system-wide options and then press the knob:</p> <p>RECALL SETUPS STORE SETUPS PARAMETER SELECTION SOUND ADJUST PATIENT PEDIATRIC ECG SET TIME DEFAULT SETUPS SWEEP SPEED RESP SPEED NETWORK SERVICE(BIO-MED)</p> <p>For options information, see the appropriate sections below.</p> |
| 4 | Turn the knob to the desired setting and then press the knob. |
| 5 | To change other settings, repeat steps 3 and 4. |
| 6 | <p>Press the Main key  to close the menu.</p> <p>Alternative: Turn the knob to RETURN and then press the knob, or wait approximately 60 seconds.</p> |

RECALL SETUPS

Restores the monitor to a particular setup that was previously saved (see **STORE SETUPS** on page 3-5 for configuration details, and see **DEFAULT SETUPS** on page 3-13 for the power-on setting.)

NOTE


The name of the current setup is displayed in the top left corner of the screen (see page 2-14). If a setup was changed, a plus symbol (+) will appear next to the setup name (A–F, User or Factory).

The following memory block choices are available:

- A
- B
- C
- D

- E
- F
- **USER** (Factory programming will be recalled if this option is selected but was not previously stored; see page 3-5.)

To recall a setup from memory

| Step | Action |
|------|---|
| 1 | Press the SETUP key  . The SETUP menu appears. |
| 2 | Turn the control knob to MONITOR SETUP and then press the knob. The MONITOR menu appears. Current settings are displayed. |
| 3 | Turn the control knob to RECALL SETUPS and then press the knob: The RECALL SETUPS menu appears. |
| 4 | Turn the control knob to select one of the following memory blocks and then press the knob: A B C D E F USER The selected memory block is recalled for the settings of the MR200. (If displayed, the “+” symbol is removed.) |

STORE SETUPS

Stores up to seven setups for different procedures, patient types or users, which can then be recalled without the need of extra setup. These memory blocks are maintained by a long life battery or static RAM, saving the data, even when powered off. Storable settings include:


- System setups
- Patient type, alarms settings, auto-set calculation percentage, latched or unlatched and sound level
- ECG selected lead, scale, trace speed, filter mode, magnet control, QRS tone control and heart rate source
- SPO2 size, averaging time and HR tone source
- CO2 size, grids, units and respiration speed

- NiBP manual or auto setting and automatic time interval
- Trend graph time base and scale
- Print control, trace delay, speed and selected traces

The following memory block choices are available:

- A
- B
- C
- D
- E
- F
- USER

To store a setup in memory

| Step | Action |
|------|---|
| 1 | Configure the settings and options of the MR200 as desired. |
| 2 | Press the SETUP key  . The SETUP menu appears. |
| 3 | Turn the control knob to MONITOR SETUP and then press the knob. The MONITOR menu appears. Current settings are displayed. |
| 4 | Turn the control knob to STORE SETUPS and then press the knob: The STORE SETUPS menu appears. |
| 5 | Turn the control knob to select one of the following memory blocks and then press the knob: A B C D E F USER The configuration is stored in the selected memory block. (If displayed, the “+” symbol is removed.) |


PARAMETER SELECTION

Controls monitoring functions, as indicated by the absence or presence of the VS box for the parameter, except **ECG** (see below).

The following choices are available:

- **ECG** allows electrocardiogram monitoring:
 - **ON** turns on the ECG parameter. (Default)
 - **OFF** turns off the ECG parameter. Heart rate will remain in the VS box allowing it to be displayed from another selected source or if **HR SOURCE** is set to **AUTO** and **ECG** is in a **LEAD FAIL** condition.
- **NiBP** allows non-invasive blood pressure monitoring:
 - **ON** turns on the NiBP parameter. (Default)
 - **OFF** turns off the NiBP parameter.
- **SPO2** allows oxygen saturation of arterial blood monitoring:
 - **ON** turns on the SPO2 parameter. (Default)
 - **OFF** turns off the SPO2 parameter.
- **CO2** allows CO2 and respiration monitoring (if installed):
 - **ON** turns on the CO2 and the CO2-derived respiration parameter.
 - **OFF** turns off the CO2 parameter. (Default)
- **RESP** allows bellows respiration monitoring:
 - **ON** turns on the bellows-derived respiration parameter.
 - **OFF** turns off the respiration parameter. (Default)

To control a parameter


| Step | Action |
|------|---|
| 1 | Press the SETUP key  . The SETUP menu appears. |
| 2 | Turn the control knob to MONITOR SETUP and then press the knob. The MONITOR menu appears. Current settings are displayed. |
| 3 | Turn the control knob to PARAMETER and press the knob. The PARAMETER menu appears. |

| Step | Action |
|------|--|
| 4 | Turn the control knob to select one of the following parameters and then press the knob: ECG NiBP SPO2 CO2 (if installed) RESP The parameter's activation menu appears. |
| 5 | Turn the knob to the desired setting and then press the knob. |

SOUND ADJUST



WARNING



The alarm sound can be turned off, as indicated by the  symbol. Always ensure that the alarm sound setting is appropriate for the monitoring environment and for each patient. The alarm sound volume is adjustable for suitability to various clinical environments. When you use the MR200, always ensure that the alarm sound can be heard above the ambient noise level; otherwise, treatment of the patient could be delayed.


Controls alarm, heart rate and keypad tones, and the volume settings for each.

NOTE

While in this menu, tones generated during patient monitoring are disabled and **REAL TONES DISABLED** will be displayed.


The following choices are available:

- ALARMS** controls the alarm sound (identical to and interactive with **ALARM SOUND**; see page 9-12):
 - ON** turns on the alarm sound, where  indicates that the sound has been enabled. (Default)
 - OFF** turns off the alarm sound, where  indicates that the sound has been disabled. (Only the alarm sound will be disabled; the visual alert from the source of the violation still flashes in red.)

| MONITOR | |
|--------------|---|
| RECALL | SETUPS |
| STORE | SETUPS |
| PARAMETER | SELECTION |
| SOUND ADJUST | |
| PATI | |
| PEDI | SOUND ADJUST |
| SET | ALARMS  ON |
| DEFA | HR TONE SOURCE OFF |
| SWEI | ALARM VOLUME 04 |
| RESP | PULSE VOLUME 04 |
| NETV | CLICK TONE ON |
| SERV | CLICK VOLUME 04 |
| RETI | RETURN |

- **HR TONE SOURCE** sets the source used for the heart rate tone (identical to and interactive with the same option in the **ECG** and **SPO2** menus):
 - **OFF** removes the heart symbol from the display and produces no tone. (Default)
 - **QRS** provides a tone modulated by the QRS detection from the ECG vital sign.
 - **SPO2** provides a tone modulated by the SPO2 vital sign, where a lower value produces a lower pitch.
- **ALARM VOLUME** sets the alarm sound level from 1–10. (Default = 4)
- **PULSE VOLUME** sets the pulse tone volume from 1–10. (Default = 4)
- **CLICK TONE** controls the keypad tone generation. (Default = On)
- **CLICK VOLUME** sets the click tone volume from 1–10. (Default = 4)

To adjust the sounds

| Step | Action |
|------|---|
| 1 | Press the SETUP key  . The SETUP menu appears. |
| 2 | Turn the control knob to MONITOR SETUP and then press the knob. The MONITOR menu appears. Current settings are displayed. |
| 3 | Turn the control knob to SOUND ADJUST and press the knob. The SOUND ADJUST menu appears. |
| 4 | Turn the control knob to select one of the following menus and then press the knob: ALARMS HR TONE SOURCE ALARM VOLUME PULSE VOLUME CLICK TONE CLICK VOLUME The selected menu appears. |
| 5 | Turn the knob to the desired setting and then press the knob. The setting is entered and a brief sound at the corresponding level is produced. |

PATIENT

Selects the type of patient to be monitored.

Determining the Patient Type

IEC 80601-2-30 Edition 1.0, the international standard regarding particular requirements for safety, including essential performance of automatic cycling non-invasive blood pressure monitoring equipment, defines patient types in two categories: neonatal and adult. Neonatal patients are defined by the approximate age range of birth to a few weeks. All other patients are identified as adults.

ANSI/AAMI SP10:2008, the American National Standard for manual, electronic, or automated sphygmomanometers, defines patient types according to age limitations, as indicated in the table below.

| Patient Type | Age |
|--------------|-----------------------|
| Neonatal | Birth to 28 days |
| Pediatric | 29 days to 12 years |
| Adult | Greater than 12 years |

Similarly, the Food & Drug Administration defines patients within two categories: pediatrics and adults. Each category is further defined into subgroups according to approximate age.

| Patient Type | Subgroup | Approximate Age Range |
|--------------|-------------------|---------------------------------|
| Pediatric | Newborn (neonate) | Birth to 1 month |
| Pediatric | Infant | Greater than 1 month to 2 years |
| Pediatric | Child | Greater than 2 to 12 years |
| Pediatric | Adolescent | Greater than 12 to 21 years |
| Adult | --- | Greater than 21 years |

CAUTION

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

Regardless of the definition, each agency recognizes that the patient type descriptions can be arbitrary and that the following patient factors are more accurate in determining the appropriate method of patient monitoring and treatment:

- Weight
- Body size

- Limb circumference
- Physiological development
- Neurological development
- Neuromuscular coordination

Accordingly, the MR200 uses several operational parameters, including cuff inflation pressure and pulse sensitivity, that vary depending on the selected patient type. (Always refer to information about the corresponding parameter for other possible considerations when determining the patient type.)


The following patient types are available:

- **ADULT** (Default)
- **PEDIATRIC**
- **NEO** (when selected, **PEDIATRIC ECG** is always on.)

NOTE

*Changing the **PATIENT** type causes the alarm to sound, the **PATIENT** indication to be revised, **CHANGE NiBP CUFF** to be displayed for 30 seconds, and the alarm limit settings to revert to the default values (see the table on page 9-15 for details).*

To select the patient type

Press the Patient key . Turn the control knob to the desired type and then press the knob.

PEDIATRIC ECG

Provides additional ECG filtering when patients, particularly pediatrics, present with narrow QRS complexes and/or high (120 BPM) heart rates.

The following choices are available:


- **OFF** turns the pediatric ECG filter off. (Default)
- **ON** processes ECG data using a pediatric algorithm, in addition to the gradient filter setting, and operates under the following conditions:
 - When an ECG trace is printed, **PED ECG=ON** or **PED ECG=OFF** will appear on the strip.
 - The setting will be saved during **STORE SETUPS** and recalled during **RECALL SETUPS**.

NOTE

When **PATIENT** is set to **NEO**, **PEDIATRIC ECG** is set to **ON** and locked. When the **PATIENT** type is changed to **ADULT**, **PEDIATRIC ECG** will be set to **OFF** and unlocked.

| Pediatric ECG | Patient Type | Condition |
|----------------------|---------------------|------------------|
| Off | Adult | Unlocked |
| On | Pediatric | Unlocked |
| On | Neonatal | Locked |

To control the pediatric ECG filter

| Step | Action |
|-------------|--|
| 1 | Press the SETUP key  . The SETUP menu appears. |
| 2 | Turn the control knob to MONITOR SETUP and then press the knob. The MONITOR menu appears. Current settings are displayed. |
| 3 | Turn the control knob to PEDIATRIC ECG and press the knob. The PEDIATRIC ECG menu appears. |
| 4 | Turn the control knob to the desired setting and then press the knob. |

SET TIME


Sets the time and date. The time, continuously operating, is displayed on LCD and the date format is MMM DD, YYYY (for example, JAN 01, 2013).

The following choices are available:

- **FORMAT** changes the format of the displayed time
 - 12 hour
 - 24 hour (Default)
- **SECOND** sets the second.
- **MINUTE** sets the minute.
- **HOUR** sets the hour.
- **DAY** sets the day.

- **MONTH** sets the month.
- **YEAR** sets the year.
- **ENTER** saves any changes.

To set the time and date

| Step | Action |
|------|---|
| 1 | Press the SETUP key  . The SETUP menu appears. |
| 2 | Turn the control knob to MONITOR SETUP and then press the knob. The MONITOR menu appears. Current settings are displayed. |
| 3 | Turn the control knob to SET TIME and press the knob. The SET TIME menu appears. |
| 4 | Turn the control knob to select any of the following time options and then press the knob: FORMAT SECOND MINUTE HOUR DAY YEAR The selected option appears. |
| 5 | Turn the knob to the desired setting and then press the knob. |
| 6 | To change other settings, repeat steps 4 and 5. |
| 7 | Turn the control knob to ENTER and then press the knob. The changes are saved. |


DEFAULT SETUPS

Selects the initial settings used when power is applied to the MR200.

The following choices are available:

- **FACTORY** uses the factory programmed settings. (Default)
- **USER** uses settings from the **USER** memory block; see **RECALL SETUPS** on page 3-4.

To set the default setups

| Step | Action |
|------|--|
| 1 | Press the SETUP key  . The SETUP menu appears. |
| 2 | Turn the control knob to MONITOR SETUP and then press the knob. The MONITOR menu appears. Current settings are displayed. |
| 3 | Turn the control knob to DEFAULT SETUPS and press the knob. The DEFAULT SETUPS menu appears. |
| 4 | Turn the control knob to select one of the following options and then press the knob: FACTORY USER The power-on default is set. |

SWEEP SPEED

Changes the trace speed of all waveforms except CO2.

The following sweep speed choices (in millimeters per second) are available:

- **50 mm/s**
- **25 mm/s** (Default)

To adjust the sweep rate

See *Changing the Waveform Speed* on page 4-17.

RESP SPEED

Sets the trace speed of the CO2 waveform.

The following sweep speed choices (in millimeters per second) are available:

- **25 mm/s**
- **12.5 mm/s** (Default)
- **6.25 mm/s**
- **3.125 mm/s**
- **1.5625 mm/s**

- **0.33333 mm/s**

To adjust the sweep rate for CO2 respiration

See *Changing the Waveform Speed* on page 7-6.


NETWORK

Sets the wireless communications channel for the cart. The network used by the cart and the wireless modules must be the same.

The following network choices are available:

- **A (Default)**
- **B**
- **C**
- **D**
- **E**

To set the network

| Step | Action |
|------|--|
| 1 | Press the SETUP key  . The SETUP menu appears. |
| 2 | Turn the control knob to MONITOR SETUP and then press the knob. The MONITOR menu appears. Current settings are displayed. |
| 3 | Turn the control knob to NETWORK and press the knob. The NETWORK menu appears. |
| 4 | Turn the control knob to select one of the following options and then press the knob: A B C D E The MR200 network channel is set. |
| 5 | If equipped with an IP5, ensure that the network used by the wireless modules (see page 1-21) and the IP5 are identical to the selection made in step 4. |

SERVICE(BIO-MED)

Allows access to pressure and miscellaneous configuration settings, diagnostic routines and firmware information; see page 11-12 for details.

Monitoring ECG

Electrocardiogram (ECG) monitoring inside the MRI environment is unique and requires additional precautions to permit safe patient procedures. It is always important to remember that the risk of radio frequency (RF) heating is ever present when any electrical conductors (for example, ECG lead cables) are placed in the MR system bore. By following the operating precautions, warnings and the guidelines below, these risks can be minimized. The ECG parameter is intended for ECG monitoring mode and not diagnostic ECG monitoring.



WARNINGS

- **The MR200 is not intended for use with patients using pacemakers or electrical stimulators.**
 - **Arrhythmias, erratic heartbeats, operation of electrical stimulators, pacemakers and patient motion can result in inaccurate readings. Rate meters may continue to count pacemaker rates during occurrences of cardiac arrest or some arrhythmias. Do not rely entirely upon rate meter alarms. If questionable readings are obtained, check the patient's vital signs by alternate means before administering medication.**
-

CAUTION

Pacer pulses are not specifically rejected by the MR200 and may be treated as part of MRI gradient noise. Gradient filtering attempts to remove high frequency pulse shaped waveforms from the ECG signal which may resemble pacer waveforms, and it is possible that the pacer waveform may be removed with the gradient noise.

wECG Module and Lead Cable

The wECG module and lead cable are intended for patient uses when continuous ECG monitoring or cardiac gating are required. The wECG module and lead cable may be used in the MR system bore, although the module must not be placed within the MRI field of view (FOV).

CAUTIONS

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

NOTE

Refer to your facility's biohazard procedure for disposal of ECG lead cables when they become unusable. Usually cables are disposed of as medical waste per facility procedures.

Defibrillator Use

The MR200 has a defibrillation-proof degree of protection that allows a patient to be defibrillated while connected to the wECG module and leads. When using a defibrillator, follow all precautions related to both the MR200 and the defibrillator equipment. During a defibrillation procedure, the ECG waveform will saturate then recover in less than 5 seconds in accordance with AAMI/ANSI EC13 and IEC 60601-2-27.



WARNINGS

- The patient connector inputs for all parameters are protected against the use of a defibrillator by internal circuitry when the recommended patient cables or accessories are used.
 - Defibrillation and electrosurgery: Do not touch the patient, or table, or instruments, during defibrillation.
 - The MR200 can be used in the presence of defibrillators or electrosurgery units, provided the equipment being used is in good working order, meeting appropriate safety standards, is properly grounded and is operated correctly in the appropriate manner and environment. Improperly grounded equipment can be a safety hazard and can also cause interference to the ECG signal and result in a noisy ECG signal waveform and inaccurate heart rate measurements.
-

CAUTION

When using a defibrillator, do not introduce discharges of 360 joules or more, repeated five times over 5 minutes. Read the safety instructions provided with the defibrillator. The MR200 Cart is designed to withstand defibrillation and will recover within 5 seconds (per IEC 60601-1, *Requirements for the Safety of Medical Electrical Equipment*), and IEC 60601-2-49, Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment).

Patient Preparation for ECG Monitoring

When monitoring ECG, the site selected on the patient, the Quadtrode electrode and ECG lead cable, the filter and lead view setting of the monitor, and the ambient environment will impact the performance and operation of the parameter.

ECG Site Considerations

Monitoring ECG in the MR environment is particularly challenging because of the inherent distortion of the ECG waveform caused by the MR magnetic field. These blood flow induced distortions of the ECG are due to the large amount of blood moving through the vessels of the heart (aorta). Blood (a very good electrical conductor) moving through the large magnetic field of the MR produces an electrical potential that adds to the ECG signal. This induced electrical potential is seen primarily as an augmentation of the ECG T-wave amplitude, although other non-specific waveform changes are also apparent on the ECG. Since an elevated T-wave or ST segment will be associated with true physiologic disorders, the static magnetic field-induced ECG-distortions will be problematic. For this reason, a baseline recording of the ECG prior to placing the patient inside the MR magnet room will be necessary. The proper placement of the ECG electrodes in the MRI is critical to reducing the blood flow induced distortion of the ECG waveform. With proper strategic placement of the ECG electrodes and minimization of the lead cable length, this blood flow induced distortion can be kept to a minimum. Following the instructions provided on the specific Quadtrode foil packaging will minimize the blood flow induced distortion on the ECG signal. Additional artifacts caused by the static, gradient and RF electromagnetic fields can severely distort the ECG, making observation of the morphologic changes and detection of arrhythmia quite difficult. Monitoring a different ECG lead (I, II, III, AVL, AVR, AVF) will minimize some of these artifacts.

ECG Quadtrode Electrode Types

Only use specified Quadtrode electrodes with the MR200 as this will minimize the possible risk of ECG electrode and cable heating during MRI procedures, and reduce the amount of MRI-generated artifacts on the ECG waveform. Three Quadtrode electrode types are available to meet the different patient and ECG performance needs:

- **Quadtrode MRI ECG PAD** (REF 989803179031) for general MRI procedures for adults and pediatric patients weighing more than 10 kg (22 pounds).
- **ELCTRD, MRI ECG, CV** (REF 989803179041) for cardiovascular (CV) MRI procedures.
- **ELCTRD, MRI, NEO** (REF 989803179051) for general MRI procedures for infants and neonatal patients weighing less than 10 kg (22 pounds).

Selecting the Quadrode Electrode and ECG Lead Cable

ECG lead cables are specially constructed to avoid patient heating by reducing the amount of radio frequency (RF) energy that can flow through the wires. Suggested applications and the recommended lead cable (for part numbers, see page 1-26) and electrode pairings are provided below.



Cable, 4 LD, MRI ECG with Quadrode electrode (REF 989803179031):

- For all patients weighing over 22 pounds (10 kg)
- Use with all scans except cardiovascular scans



Cable, 4 LD, CV MRI ECG with Quadrode electrode (REF 989803179041):

- Provides the best ECG performance for all procedures
- Works best on females and overweight patients



Cable, 4 LD, NEO. MRI ECG with Quadrode electrode (REF 989803179051):

- Designed for infants and neonates weighing under 22 pounds (10 kg)
- For sedation and general anesthesia applications



Cable, Advanced Filter ECG with Quadrode electrode (REF 989803179041):

- Designed to minimize the gradient artifact on the ECG trace



Cable, Advanced Apps ECG with Quadrode electrode (REF 989803179041):

- Designed to allow for wide electrode placement

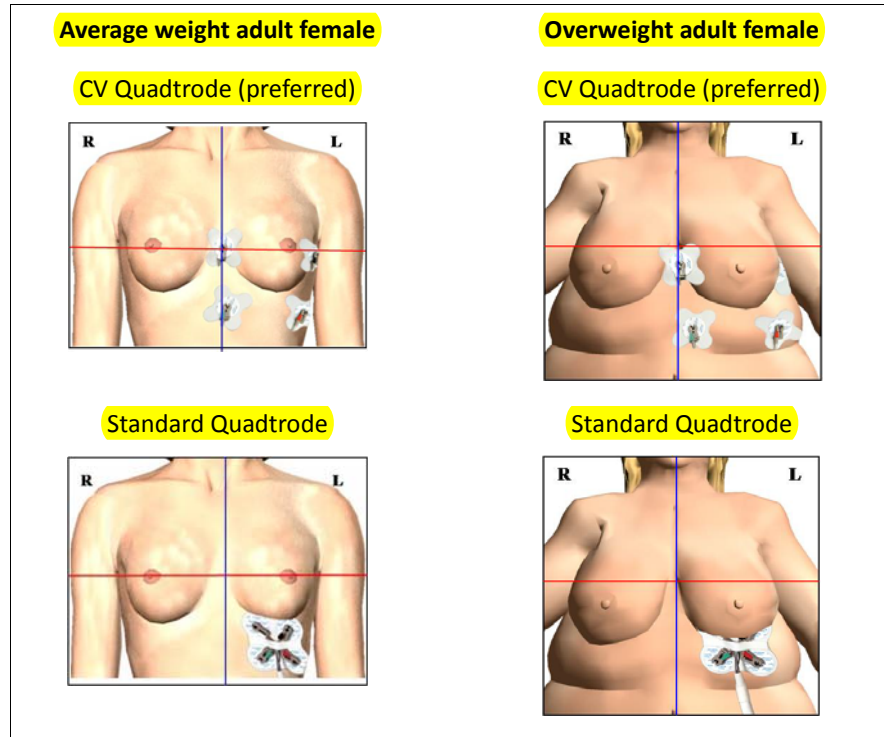
Selecting the Quadrode Electrode Placement Site

For optimal performance, use the illustrations below as placement guidelines when applying the Quadrode electrode to the patient.

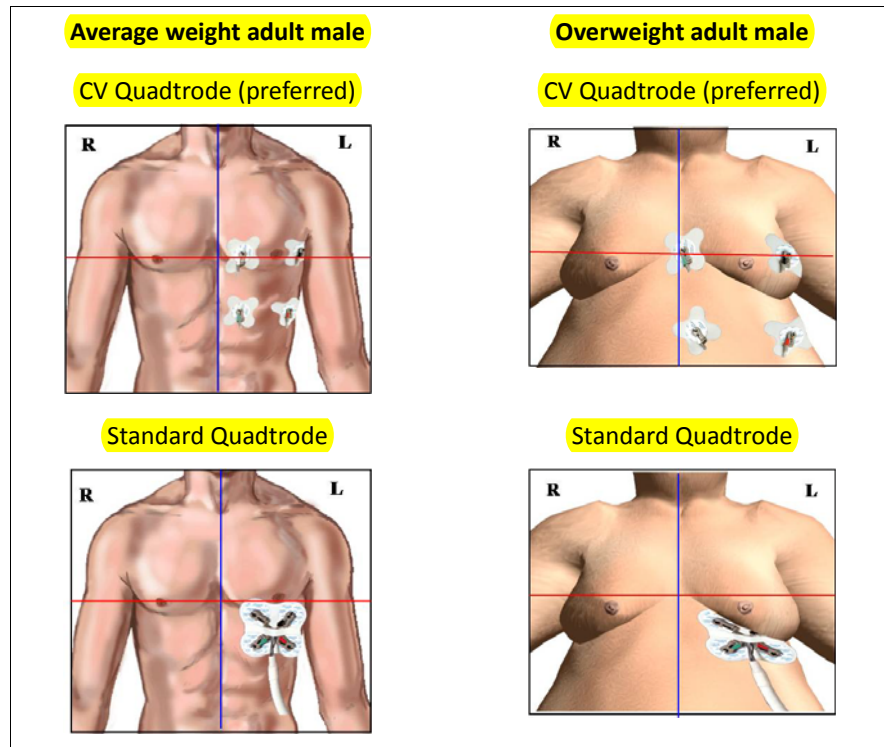
NOTE

In the illustrations below, an imaginary nipple line is denoted by the horizontal axis.

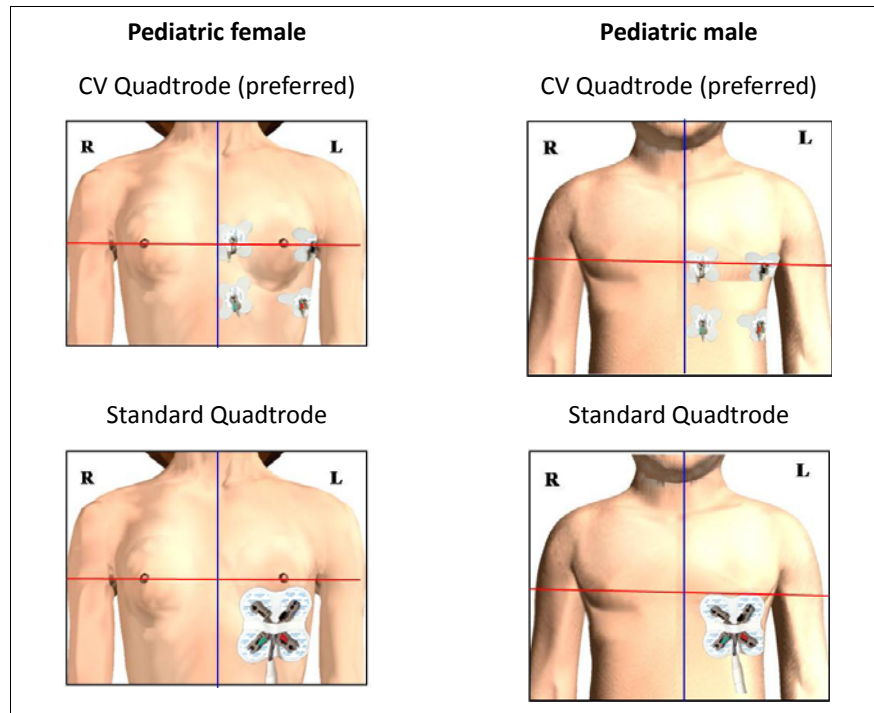
Selecting sites on adult female patients



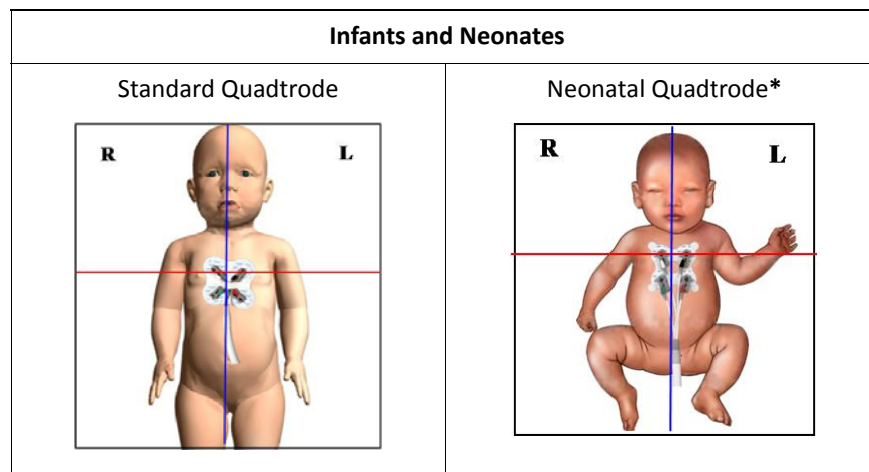
Selecting sites on adult male patients



Selecting sites on pediatric patients



Selecting sites on infants and neonatal patients



**For patients weighing less than 22 pounds (10 kg)*

Preparing the ECG Site

To prepare an electrode site on a patient

| Step | Action |
|------|--|
| 1 | Check the expiration date of the Quadrode electrode package. |
| 2 | If necessary, shave the application area to remove hair from the selected electrode site(s). |
| 3 | Apply ECG Skin Prep Gel (REF 989803152291) to a gauze pad. |
| 4 | Briskly rub the selected site(s) with the gauze pad (the skin may turn pink). |
| 5 | Remove any excess gel with a clean gauze pad. |
| 6 | Follow the placement instructions provided on each Quadrode package. (Also reference the illustrations above.) |

NOTES

- *The ECG Skin Prep gel contains light abrasive pumice and saline that clean and enhance the conductive properties of the skin, thus enhancing ECG performance. This practice also helps remove ambient artifacts, such as the 50/60 hertz noise generated by the MR environment.*
- *Isopropyl/rubbing alcohol must not be used to prep the site as it breaks down the conductive properties of the skin, thus degrading ECG performance.*

Checking Electrode Contact Quality

Proper Quadrode electrode preparation is critical to ECG performance. The result of poor electrode preparation will be poor ECG monitoring performance. If electrode contact is poor, then remove and discard the electrode, and repeat the site preparation process according to the instructions above. Never reuse an electrode as its adhesive will not securely fasten to the skin.

Attaching the Lead Cable

Designators on the lead cable reference places on the torso where the electrodes should reside in relation to the patient's extremities. However, depending upon the cable type (IEC or AHA), the respective cables use different designators and colors to reference lead placement.

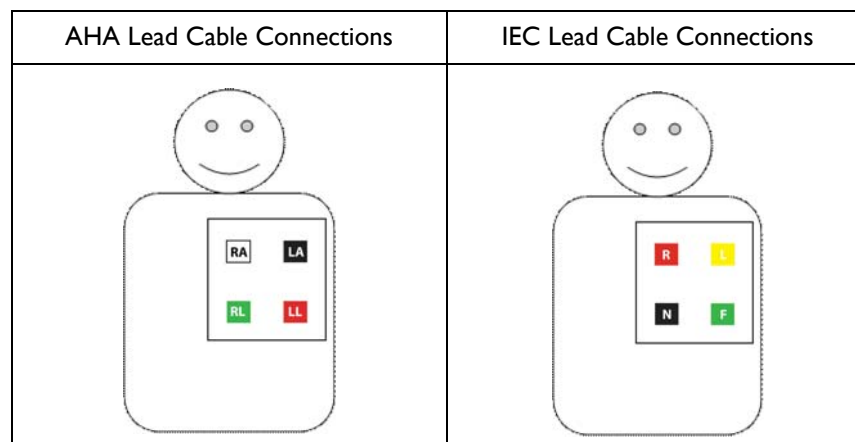
WARNINGS



- Never use any ECG lead cables other than the specified ECG lead cables.
- High levels of RF energy may cause patient heating or burns.
- Lead cables that become inadvertently looped during an MRI examination may act as conductive lines for RF induced currents, resulting in excessive heating and possible burns. When lead cables or other cables form a conductive loop in contact with the patient's tissue, minor to severe burning can result. Please refer to the additional information in Appendix D to prevent excessive heating associated with MRI procedures. Follow steps to minimize the risks of MRI-related heating on page 4-12.

| Limb | AHA Lead Designator, Color | IEC Lead Designator, Color |
|-----------|----------------------------|----------------------------|
| Right arm | RA, White | R, Red |
| Right leg | RL, Green | N, Black |
| Left arm | LA, Black | L, Yellow |
| Left leg | LL, Red | F, Green |


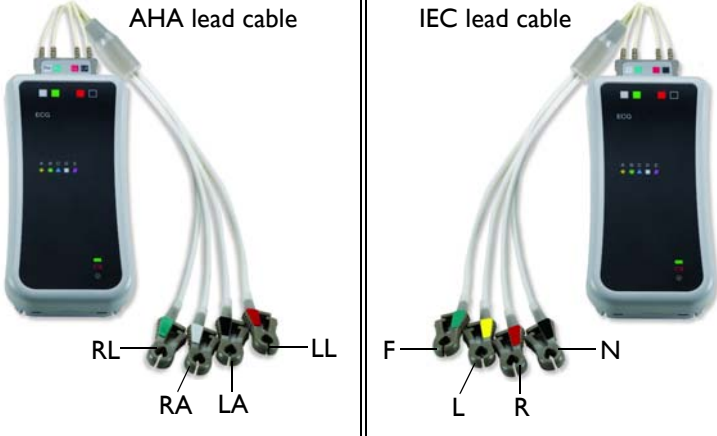
The connection diagrams below illustrate placement of each type of ECG lead cable.



CAUTION

ECG clip leads should not be placed on the patient's extremities.

To attach the lead cable to the wECG module and lead cable clips to the Quadrode electrode

| Step | Action |
|------|--|
| 1 | <p>Align the color coding on the lead cable connector (A) with color coding on the wECG module (B) then insert the connector into the module. (An AHA lead cable is shown in the example.)</p>  <p>CAUTION</p> <p>When inserting or removing the lead cable or clip leads, only use the connector or clip; never pull or apply excessive force to the wires.</p> |
| 2 | <p>Depending upon the type of the ECG lead cable and referencing the diagrams on page 4-8, attach the ECG clip leads to the Quatrode electrode.</p>  |
| 3 | <p>Keep the module outside the field of view (FOV) by placing it in one of the two locations shown in <i>Positioning the wECG Module and Lead Cable for Scanning</i> on page 4-11.</p> |
| 4 | <p>Check the status indicator of the module; see page 2-8:</p> <ul style="list-style-type: none"> • Solid green = Battery power good/Good communication • Flashing green = Battery power good/No communication • Solid red = Low battery power/Good communication • Flashing red = Low battery power/No communication |

Lead Failure Indication

If a disconnected or faulty Quadrode electrode or ECG lead is detected during monitoring, the system will immediately notify you so that quick action can be taken to identify the source of the failure and proceed with an informed response. As shown in the example below, **LEAD FAIL** will be displayed and a red Lead Fail indicator will appear in the ECG VS box identifying the specific location (LL, LA, or RA); see page 9-18 for troubleshooting information.



WARNING

Failure to respond to a Lead Fail alarm will result in a lapse of patient monitoring.



LEAD FAIL indicator
(Example, left arm)

NOTE

If the RL electrode has lost contact (or if all electrodes have lost contact) then LL, LA, RA will be the displayed indication.

Positioning the wECG Module and Lead Cable for Scanning

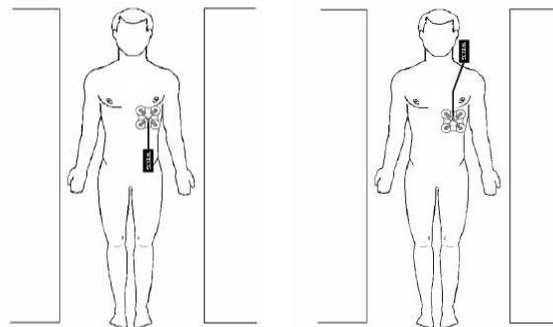


WARNINGS

- When applying electrodes or connecting the patient lead cable, ensure that the electrodes or connectors never contact other conductive materials including grounded conductors. In order to prevent contact with other conductors or earth ground, make sure all the electrodes or connectors are properly attached to the patient.
- No other electrical conductors (e.g. wires, leads, probes, etc.) should be placed within the MRI bore at the same time as the ECG lead wires. Electrode heating risk increases when multiple conductive cables and sensors are placed in the bore with the patient. Mixing of conductors from various manufacturers (catheters, temperature sensors, etc.) is not recommended. Multiple electrical conductors within the MRI bore can allow cross-coupling between these various conductors, and appear as a large antenna for RF energy pick-up, which will result in electrode heating, and possibly skin burns. It is always important to identify if the patient has any metallic wires, conductors, implants, stents, etc. within their body which will act as cross-coupling conductors. If these are present, ECG monitoring may not be able to be performed without experiencing electrode heating. Non-conductive tubes, air-lines, etc.—including NiBP cuffs and hoses, EtCO₂ and/or oxygen air-lines, and SPO₂ sensors—can be used safely as these items do not include electrically conductive materials. The MR200 has been validated for use with all accessories specified in the accessory list.
- Circular, U-shaped or S-shaped loops in the patient lead cable should be avoided to reduce the risk of heating.

The wECG module may be used in the MR system bore, although the module must not be placed within the MRI field of view (FOV).

Lead cables must always be kept in a straight line and must not touch the MR system bore. Any loop (circular, U-shaped, S-shaped) in the cables or cable contact with the MR system bore will cause heating in the cables or in the patient electrodes. Follow the steps below to minimize the cable heating risk.



NOTE

Follow these guidelines to ensure the best possible performance of the wECG module, especially during harsh scan sequences (with PNS-peripheral nerve stimulation-levels above 80 percent):

1. Place the modules on or near the patient as close to the bore iso-center as possible (considering the scan to be performed).
 2. Keep the wireless module outside the field of view.
 3. Place the modules as close to the bore opening as possible. (If the modules can be placed outside the bore, positioning at the bore iso-center is not necessary.)
 4. Place the modules on a cushioned surface to minimize MR vibrations.
-

WARNING

If the wECG module is positioned incorrectly when used within the MR magnet room, the following factors may cause ECG waveform distortion and numeric inaccuracies:

- Fast magnetic field changes usually found with, but not limited to, scan sequences using Peripheral Nerve Stimulation (PNS) levels above 80 percent.
 - Severe vibrations induced by scan sequences using PNS levels above 80 percent.
 - The distance from the bore iso-center in the x, y, or z directions.
-

Minimizing the Risk of MRI-Related Heating

CAUTION

Placing the wECG module within the FOV may interrupt ECG monitoring during the MRI procedure and cause MRI image artifacts.

To minimize the risk of MRI-related heating

| Step | Action |
|------|---|
| 1 | Arrange the ECG lead cable and the clip leads neatly, in a straight alignment, with no looping. |
| 2 | Avoid contact between cables and bare skin. |
| 3 | Use only the ECG lead cables designated for use with this product; see page 1- 26. |
| 4 | Minimize the use of multiple cables. (See the warnings on page 4- 11 for details.) |

| Step | Action |
|------|---|
| 5 | The wECG module, ECG lead cables and Quadrode electrode are acceptable for use within MR systems with static magnetic field strengths of 3.0 Tesla or less within the MR system bore using a MR system reported whole body average Specific Absorption Rates (SAR) up to 4.0 W/kg. |
| 6 | Monitoring of ECG at power levels of greater than a MR system reported, whole body averaged SAR of 4 W/kg is not recommended for the general patient population. Such monitoring must only be attempted with conscious patients with normal thermoregulatory capabilities so that they may warn you of possible excessive heat at the monitoring sites. |
| 7 | Use caution for scan times (that is, per pulse sequence) greater than 15 minutes. For MRI scans with average SAR > 1 W/kg, limit scan time to 15 minutes and pause at least 3 minutes between scans to allow the ECG electrodes to cool. |
| 8 | During measurement, check the patient to ensure that MRI-related heating is not occurring. |

Checking the ECG Signal Strength

A minimum signal strength (amplitude) should be present, as smaller signals may be prone to gradient interference. Evaluate the ECG signal produced by the patient before entry into the MRI scanner, the optimum time to correct any problem.


A proper ECG signal is determined by the peak-to-peak amplitude of the QRS complex. The QRS complex should be approximately 2 millivolts on the display (that is, the signal should be twice the size of the scale indicator, a 1 mV reference, at any given **SCALE** setting).



Selecting the Scale

The **SCALE** setting only changes how the ECG trace appears on the screen, increasing or decreasing the waveform and any artifacts. To increase the amplitude of the QRS Complex, see *Changing the Lead View* on page 4-14.

To change the SCALE setting

| Step | Action |
|------|--|
| 1 | Press the Patient key  and then select the appropriate PATIENT type; see page 3-10 for details. |
| 2 | Turn the control knob to highlight the ECG VS box (see page 4-18) and then press the knob. The ECG menu appears. Current settings are displayed. |
| 3 | Turn the control knob to SCALE and then press the knob. The SCALE menu appears; see page 4-21. |
| 4 | Turn the knob to select the setting and then press the knob. Only a setting of 5 mm/mV or 10 mm/mV is recommended. AUTO 1 mm/mV 5 mm/mV 10 mm/mV 15 mm/mV 20 mm/mV 25 mm/mV 30 mm/mV 40 mm/mV The setting is applied. |
| 5 | Take note of the scale indicator; see page 4-16. If the selected scale results in an ECG trace so large that the waveform peaks are distorted or clipped, OVERSCALE will be displayed. In this case, select another setting to resize the waveform until the message stops. |

Changing the Lead View

If the QRS Complex does not equal a minimum of 2 mV, then complete the following steps.

To change the lead view

| Step | Action |
|------|---|
| 1 | Verify the Quadtrode electrode date, quality and packaging. |
| 2 | Ensure that the preferred Quadtrode electrode and placement site(s) are being used; see page 4-4. |

| Step | Action |
|------|---|
| 3 | <p>Turn the control knob to highlight the ECG VS box (see page 4-18) and then press the knob.</p> <p>The ECG menu appears. Current settings are displayed.</p> |
| 4 | <p>Depending upon the trace being examined, turn the control knob to TRACE A LEAD or TRACE B LEAD and then press the knob.</p> <p>The respective menu appears; see page 4-20 or 4-20.</p> |
| 5 | <p>Change the setting to a different lead view to account for patient variability and then press the knob.</p> <p>I II III AVL AVR AVF</p> <p>The lead view changes; see page 4-16.</p> <p>NOTE</p> <p><i>When presented with a low QRS amplitude from ECG or poor gating, it may be necessary to use the PEDIATRIC ECG setting; see page 3-11.</i></p> |
| 6 | <p>If the amplitude did not improve, cycle through the remaining lead views to a find the best signal amplitude by repeating step 5.</p> |
| 7 | <p>If the amplitude does not improve, remove the lead cable and Quadrode electrode and then prep the application site again.</p> |

Selecting the Filter Mode

Choose the appropriate ECG filter mode for your MRI study.

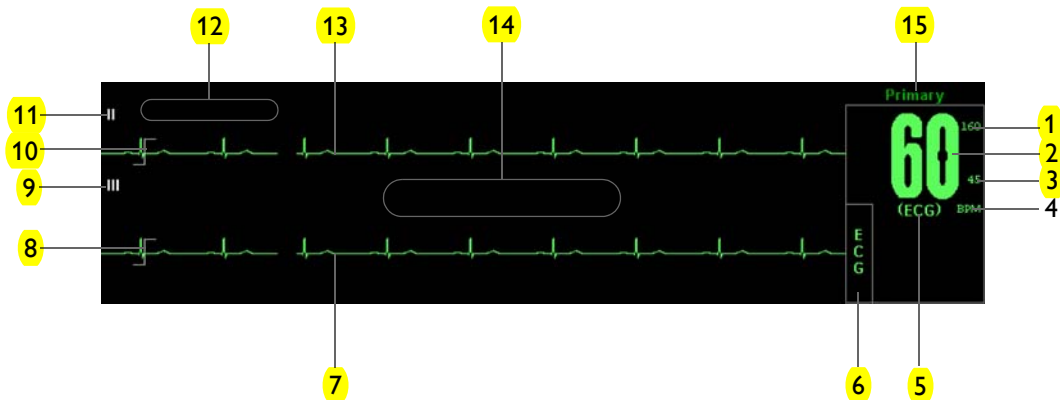
To change the filter mode setting

| Step | Action |
|------|--|
| 1 | <p>Turn the control knob to highlight the ECG VS box (see page 4-18) and then press the knob.</p> <p>The ECG menu appears. Current settings are displayed.</p> |
| 2 | <p>Turn the control knob to FILTER MODE and then press the knob.</p> <p>The FILTER MODE menu appears; see page 4-23.</p> |

| Step | Action |
|------|--|
| 3 | Turn the knob to select the filter and then press the knob. MONITOR PRIMARY SECONDARY CARDIAC ADVANCED The setting is applied, as indicated above the ECG VS box. |

ECG Waveforms and VS Box

The elements contained in the displayed ECG waveform (Trace A, and B if enabled) and VS box are described below:




| Definition | |
|------------|--|
| 1 | Is the high limit setting of the HR (heart rate) alarm; see page 4-19 |
| 2 | Is the heart rate measurement (numeric) |
| 3 | Is the low limit setting of the HR alarm; see page 4-19 |
| 4 | Is the unit of measure for the heart rate, where BPM is beats per minute |
| 5 | Is the selected HR SOURCE ; see page 4-22 |
| 6 | Is the name of the vital sign |
| 7 | Is the detected ECG Trace B waveform |
| 8 | Is the scale indicator, a 1-millivolt signal reference (see SCALE on page 4-21) |
| 9 | Is the selected TRACE B LEAD ; see page 4-20 |
| 10 | Same as 8, above |
| 11 | Is the selected TRACE A LEAD ; see page 4-20 |
| 12 | Displays LEAD FAIL when detected; see the example on page 4-10 |

| Definition | |
|------------|--|
| 13 | Is the detected ECG Trace A waveform |
| 14 | Displays messages; see page 9-16 for details |
| 15 | Is the selected FILTER MODE ; see page 4-23 |

Changing the Waveform Speed

To change the ECG (and SPO2) waveform speed

| Step | Action |
|------|--|
| 1 | Press the SETUP key  . The SETUP menu appears. |
| 2 | Turn the control knob to MONITOR SETUP and then press the knob. The MONITOR menu appears. Current settings are displayed. |
| 3 | Turn the knob to SWEEP SPEED and then press the knob. The SWEEP SPEED menu appears; see page 3-14. |
| 4 | Turn the control knob to select either of the following settings and then press the knob: 50 mm/s 25 mm/s The selection is entered. |

Changing the Heart Rate Alarm Limits

To change the heart rate alarm limit settings

| Step | Action |
|------|---|
| 1 | Turn the control knob to highlight the ECG VS box (see page 4-18) and then press the knob. The ECG menu appears. Current settings are displayed. |
| 2 | Turn the control knob to ALARM LIMITS and then press the knob. The ALARM LIMITS menu appears. Current settings are displayed; see page 4-19 for details. |
| 3 | Turn the knob to the low or high setting and then press the knob. The setting is selected. |

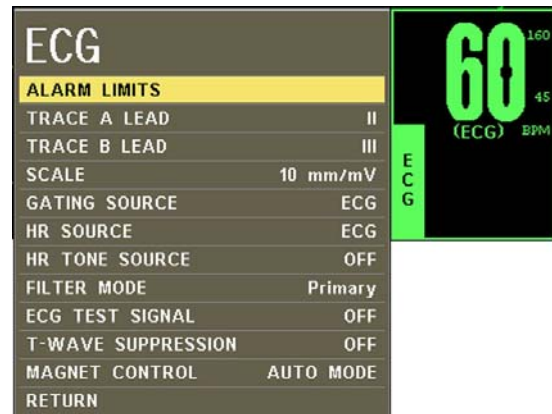
| Step | Action |
|------|---|
| 4 | Turn the knob to change the setting value and then press the knob to make the change effective and return to the scrolling function. The setting is changed. |
| 5 | To change the remaining setting, repeat steps 3 and 4. |

NOTE

To make global changes to the parameter alarm limit settings based upon the patient's current vital sign readings, see Setting Alarm Limits Globally on page 9-4.


ECG Menu

The ECG menu allows you to control ECG traces, functions and settings.



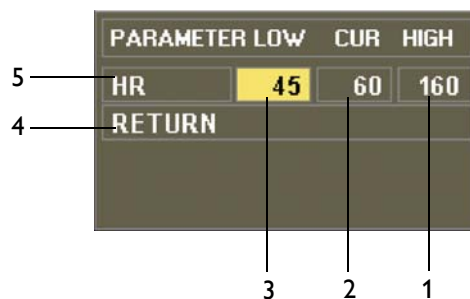
To change settings in the ECG menu

| Step | Action |
|------|---|
| 1 | Turn the control knob to highlight the ECG VS box and then press the knob. The ECG menu appears. Current settings are displayed. |

| Step | Action |
|------|--|
| 2 | <p>Turn the control knob to select any of the following ECG options:</p> <p>ALARM LIMITS TRACE A LEAD TRACE B LEAD SCALE GATING SOURCE HR SOURCE HR TONE SOURCE FILTER MODE ECG TEST SIGNAL T-WAVE SUPPRESSION MAGNET CONTROL</p> <p>For information about these options, see the appropriate sections below.</p> |
| 3 | Turn the knob to the desired setting and then press the knob. |
| 4 | To change other settings, repeat steps 2 and 3. |
| 5 | <p>Press the Main key  to close the menu.</p> <p>Alternative: Turn the knob to RETURN and then press the knob, or wait approximately 60 seconds.</p> |

ALARM LIMITS

Controls the alarm limit settings for heart rate. (See the table on page 9-15 for a listing.)



| Definition | |
|------------|--|
| 1 | Is the setting of the high alarm limit |
| 2 | Is the current measurement |
| 3 | Is the setting of the low alarm limit |

| Definition | |
|------------|--|
| 4 | Saves the settings then returns to the normal mode |
| 5 | Identifies heart rate alarm limits |

To set an alarm limit for heart rate

See *Changing the Heart Rate Alarm Limits* on page 4-17.

TRACE A LEAD

Sets the ECG A lead configuration. For best ECG and heart rate monitoring, always select the optimal lead configuration, the one that provides the least artifact and largest waveform detection for monitoring use.

The following choices are available:

- I
- II (Default)
- III
- AVL
- AVR
- AVF
- OFF

To set the ECG A lead

See *Changing the Lead View* on page 4-14.

TRACE B LEAD

Sets the ECG B lead configuration, allowing you to view two ECG waveforms simultaneously.

The following choices are available:

- I
- II
- III
- AVL
- AVR
- AVF
- OFF (Default)

To set the ECG B lead

See *Changing the Lead View* on page 4-14.

SCALE

Sets the scale for the ECG waveforms. After making this setting, take note of the scale indicator; see page 4-16. If the selected scale results in a waveform with distorted or clipped peaks, **OVERSCALE** will be displayed and another setting should be selected until the message stops.

The following choices (in millimeters per millivolt) are available:

- **AUTO** makes the waveform fill the ECG trace area (not recommended for use in the MR).
- **1 mm/mV**
- **5 mm/mV**
- **10 mm/mV (Default)**
- **15 mm/mV**
- **20 mm/mV**
- **25 mm/mV**
- **30 mm/mV**
- **40 mm/mV**

To set the ECG scale

See *Selecting the Scale* on page 4-13.

NOTE

This setting does not affect the signal analyzed by the monitor for QRS detection and ECG gating.

GATING SOURCE

Sets the cardiac gating source based on a measured signal. (This is the same option as in the **SPO2** menu.)

The following choices are available:

- **ECG** are outputs that represent the detection of the R-peak of a QRS complex, a signal the MR system can use directly for triggering. (Default)
- **PULSE** are signals that represent the detection of the peak of the peripheral pulse complex.

To set the gating source

See *Using the Gating Feature* on page 4-26.

NOTE

Trace A is the default output channel for interfacing the cardiac gating input. To use Trace B, set Trace A to off, and ensure that Trace B is active (that is, not off); see page 4-20.

HR SOURCE

Selects the source that produces the heart rate, as displayed in the ECG VS box (identical to and interactive with the same option in the **SPO2** menu).

The following choices are available:

- **AUTO** selects the source automatically from the highest priority active input, where the MR200 searches for another source only when **LEAD FAIL** occurs or when ECG is off. If the highest priority input is not found, the next ranked parameter is sought. The priority ranking is ECG and then SPO2. If no parameters present a heart rate, then NONE is displayed in the heart rate position.
- **ECG** (Default)
- **SPO2**

To set the heart rate source

| Step | Action |
|------|--|
| 1 | Turn the control knob to highlight the ECG VS box (see page 4-18) and then press the knob. The ECG menu appears. Current settings are displayed. |
| 2 | Turn the control knob to HR SOURCE and then press the knob. The HR SOURCE menu appears. |
| 3 | Turn the control knob to select one of the following options and then press the knob: AUTO ECG SPO2 The setting is changed. |

HR TONE SOURCE

Sets the source used for the heart rate tone (identical to and interactive with same option in the **MONITOR > SOUND ADJUST** menu and in the **SPO2** menu).

The following choices are available:

- **OFF** removes the heart symbol from the display and no pulse tone will be sounded. (Default)
- **QRS** provides a tone triggered by the QRS detection from the ECG vital sign.
- **SPO2** provides a tone modulated by the SPO2 vital sign, where the lower the SPO2 value, the lower the pitch.

To set the heart rate tone source

Enter the **ECG** menu. Turn the control knob to **HR TONE SOURCE** and press the knob. Scroll to the desired setting and press the knob. (See page 3-9 for detailed instructions.)

FILTER MODE

Sets the filtering mode for the ECG signal.

NOTES

- *Due to the variety of MRI sequence characteristics, if the filter recommendations below do not provide optimum performance in all cases, the selection of another filter mode may improve ECG performance.*
 - *ECG performance can be affected by electrode placement, the MRI procedure, the image slice angle and slice thickness. In situations where ECG performance is not optimal, select the ECG lead (I, II, III, AVL, AVR, or AVF) that provides the best performance.*
 - *For cases not requiring cardiac gating, start with the Primary filter mode (depending on the MRI sequence) and switch filters if a gradient artifact is noticed. If a gradient artifact is still present, check signal strength and try lead I or III.*
-

The following choices are available:

- **MONITOR** provides filtering characteristics that meet the specification of the Association for the Advancement of Medical Instrumentation (AAMI). Note that this filter will not provide optimum performance during active MRI sequences.
- **PRIMARY** provides the best possible performance on 0.15 to 3.0T MR systems during Echo Train type MRI sequences. (Default)
- **SECONDARY** provides the best possible performance on 0.15 to 3.0T MR systems during most non-cardiovascular MRI sequences.
- **CARDIAC** provides the best possible performance during cardiovascular (CV) MRI procedures that involve steady-state free precession imaging with balanced gradient (True-FISP, FIESTA, or Balanced FFE) sequences on 1.5 and 3.0T MR systems. For cases requiring cardiac gating, start with the Cardiac filter in lead II and switch filters if gradient artifact is noticed. If gradient artifact is still present, check signal amplitude and try lead I or III.
- **ADVANCED** provides the best possible performance on 1.5 and 3.0T MR systems during MRI sequences such as neurological and cardiovascular. This MRI filter utilizes an adaptive filter scheme for removal of gradient artifact generated by MR systems. Best performance

is achieved using the Advanced Filter ECG lead cable, which allows placement of the wECG module outside of the bore.

Advanced filtering operates on one lead at a time from a restricted set of leads and cannot be applied to AVR, AVL or AVF leads. To provide the most convenient transition to this filter and lead configuration, the system will automatically select the lead to use by applying the following rules in the order shown below:

1. If Trace A is displayed, the currently selected lead on Trace A will be used but only if it is lead I, II or III.
2. If Trace B is displayed, the currently selected lead on Trace B will be used but only if it is lead I, II or III.
3. If neither rule 1 nor rule 2 apply, then lead II will be used.

The system displays the selected lead on Trace A and disables display of Trace B. You can change which lead is filtered, while the **ADVANCED** filter operates by changing lead selection for Trace A. However, only leads I, II and III will be available while the **ADVANCED** filter is engaged. (To deselect **ADVANCED**, select a different filter option from the menu. The display will remain unchanged; however, Trace B can be re-enabled at this point if desired.)

To set the filter mode

See *Selecting the Filter Mode* on page 4-15.

ECG TEST SIGNAL

Generates an ECG calibration waveform.

The following choices are available:

- **OFF** turns the calibration feature off. (Default)
- **PRINTER** sends a 1 mV pulse calibration waveform to the ECG vital sign and also to the printer, if so configured, where **ECG TEST SIGNAL** will be printed below the waveform.
- **ECG** sends a wECG module generated 1 mV peak to peak calibration square wave to the ECG vital sign and also to the printer, if so configured, where **ECG TEST SIGNAL** will be superimposed over the waveform and 60 BPM will be displayed in the ECG VS box.

To generate the ECG test signal

Enter the **ECG** menu. Turn the control knob to **ECG TEST SIGNAL** and press the knob. Scroll to the desired output and press the knob.

NOTES

- Available on all lead configurations, except Lead III.
 - Unavailable when **FILTER MODE** is set to **ADVANCED**.
 - Automatically set to off during interoperability; see **GATING SOURCE** on page 4-21.
-

T-WAVE SUPPRESSION

Reduces the T-wave amplitude when extremely large due to the magnetohydrodynamic effect (MHD), which can prevent gating. Use for accurate gating when an unusually high T-wave amplitude, relative to the R-wave amplitude, is seen.

The following choices are available:

- **OFF** (Default)
- **ON**

To apply T-wave suppression

Enter the **ECG** menu. Turn the control knob to **T-WAVE SUPPRESSION** and press the knob. Scroll to the desired setting and press the knob.

NOTES

- *Unavailable when **FILTER MODE** is set to **MONITOR**; see page 4-23.*
- *Controlled by the gating box through the wECG module during interoperability; see **GATING SOURCE** on page 4-21. With the wBTU, **T-WAVE SUPPRESSION** will be set to off; and, with other OEM gating boxes, it will be set as it is in the gating box.*

MAGNET CONTROL

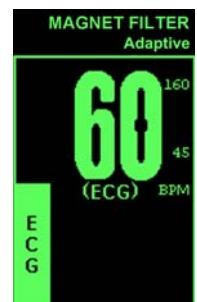
Removes gradient artifacts on certain MR systems equipped with vector ECG gating. On these systems, only one wECG module needs to be connected to the patient in order for the MR200 and the MR system to monitor the patient's vital signs and gate the magnet.

The following choices are available:

- **AUTO MODE** allows the MR system to work, if capable, with the MR200 to effectively remove gradient artifacts from the ECG waveform. When selected and with the wECG module in radio contact with the MR system, **FILTER MODE**, **T-WAVE SUPPRESSION** and **ECG TEST SIGNAL** will be disabled and locked. (Default)

MAGNET CONTROL will be displayed to indicate that filter mode selection has been preempted by the MR system. In addition, if **HR SOURCE** is set to **ECG**, the heart rate as derived from the MR system will be displayed (a brief interruption in the displayed waveform is possible) and **MAGNET FILTER** will be displayed.

If the MR200 or the wECG module cease radio contact with the MR system, the MR200 will reset its filter and T-wave suppression options to the settings held prior to contact with the MR system.



NOTE

FILTER MODE and T-WAVE SUPPRESSION settings will not be recalled when in MAGNET CONTROL or MAGNET FILTER mode. And, if a system recall is performed and then the MR200 is moved from the MR environment, the filter and T-wave suppression options will revert to their previous settings.

- **DISABLED** allows the MR200 to control filtering and T-wave suppression.

To allow magnet control

Enter the **ECG** menu. Turn the control knob to **MAGNET CONTROL** and press the knob. Scroll to the desired setting and press the knob.

Using the Gating Feature

The gating feature provides facilities for low latency MRI triggering and synchronization based on the measured ECG or SPO2 signal. Data measured and transmitted by the wECG or wSPO2 module is processed by the MR200 and then output from the gating connector; see page 1-16 for the location, and see page A-11 for signal details. (Signals can also be transmitted by the optional wBTU.)

Using ECG Gating

To receive ECG gating signals

| Step | Action |
|------|---|
| 1 | Verify the wECG module status by checking the status indicator: <ul style="list-style-type: none">• Solid green = Battery power OK/Good communication• Flashing green = Battery power OK/No communication• Solid red = Low battery power/Good communication• Flashing red = Low battery power/No communication |
| 2 | Ensure that the lead cable is properly attached to the patient; see <i>Attaching the Lead Cable</i> on page 4-8. (ECG outputs are enabled by default; see page 4-21.) |

Using SPO2 Gating

To receive SPO2 gating signals

| Step | Action |
|------|--|
| 1 | Verify the wSPO2 module status by checking the status indicator: <ul style="list-style-type: none">• Solid green = Battery power OK/Good communication• Flashing green = Battery power OK/No communication• Solid red = Low battery power/Good communication• Flashing red = Low battery power/No communication |
| 2 | Ensure that the SPO2 attachment is properly attached; see <i>Applying the SPO2 Attachment to the Patient</i> on page 5-3. |
| 3 | Turn the control knob to highlight the SPO2 VS box (see page 5-7) and then press the knob. The SPO2 menu appears. Current settings are displayed. |
| 4 | Turn the control knob to GATING SOURCE and then press the knob. The GATING SOURCE menu appears; see page 5-12. |
| 5 | Turn the knob to PULSE and then press the knob. The setting is applied. |

Monitoring SPO2

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

- Oxygen saturation of arterial blood (SPO2): The percentage of oxygenated hemoglobin in relation to the sum of oxyhemoglobin and deoxyhemoglobin (functional arterial oxygen saturation).
- Plethysmography (pleth) waveform: A visual indication of the patient's pulsatile blood flow.
- Pulse rate (as derived from the pleth waveform): The number of detected pulsations per minute.

NOTE

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

wSPO2 Module, Sensor and Attachment

The wSPO2 module, sensor and attachment (clip or grip) are intended for patient uses when continuous non-invasive arterial oxygen saturation, pulse rate monitoring or pulse gating are required. The wSPO2 module, sensor and attachment may be used in the MR system bore, although the module must not be placed within the MRI field of view (FOV).

CAUTION

If dropped, the wSPO2 module must be verified for correct operation before use.

NOTE

Refer to your facility's biohazard procedure for disposal of SPO2 attachments and sensors when they become unusable. Usually sensors are disposed of as medical waste per facility procedures.

Patient Preparation for SPO2 Monitoring

When monitoring SPO2, the site selected on the patient, the SPO2 attachment, the attachment's position on the patient, and the ambient environment will impact the performance and operation of the parameter.

Selecting the Site and Attachment

When applying the clips or grips to the patient, site preparation and the pressure and alignment of the attachment are important factors to consider. Select the most appropriate limb that best fits the attachment size. For measurements to be accurate and reliable, the optimum fit is reached when the fiber head windows oppose each other and are covered by skin or nail. Refer to the instructions provided with the attachment when selecting and connecting the clip or grip.

Attaching the Clip or Grip to the SPO2 Sensor

To attach the clips (or grips) to the SPO2 sensor

Snap the fiber heads on the SPO2 sensor into the receptacles (windows) on the SPO2 attachment (clip or grip).



Applying the SPO2 Attachment to the Patient

Read the warnings before applying an SPO2 attachment to the patient.



WARNINGS

- **General fit:** If a clip or grip is too loose, it might compromise the optimal alignment or dislocate. If the clip or grip is too tight (for example, if the application site is too large or becomes large due to edema), excessive pressure may be applied resulting in venous congestion distal from the application site, which could lead to interstitial edema, hypoxemia, tissue malnutrition, and inaccurate measurements. Skin irritations may occur as a result of the clip or grip being attached to one location for too long. Periodically inspect the clip or grip application site and change the application site at least every 4 hours. Exercise care when using tape to secure the clip or grip, as the stretch memory properties of most tapes can apply unintended pressure to the site easily.
- **Extremities to avoid:** Avoid placing the clip or grip on extremities with an arterial catheter, intravascular venous infusion line, or inflated blood pressure cuff. Failure to do so may result in inaccurate readings or false alarm indications.
- **Protect the sensor from contact with any liquid.** If the sensor, clips or grips show signs of damage like exposed fibers, replace the part immediately. Do not use damaged equipment.
- **Keep detached grips and clips away from small children to avoid possibility of swallowing.**


To apply a reusable clip to the patient

| Step | Action |
|------|--|
| 1 | Select the application site. It should match the clip size so that the sensor does not fall off or apply excessive pressure at the site. |
| 2 | If present, remove any colored nail polish from the application site. |
| 3 | Press the clip to open. |
| 4 | Push the clip over a finger so either fiber head is on the top over the root of the nail and the other fiber head opposite to it. (It does not matter which head is on top.) |
| 5 | Ensure that the finger is touching the stop at the cushion and lays nicely centered in the clip. |




To apply a disposable clip to the patient

| Step | Action |
|------|---|
| 1 | Select the application site. It should match the clip size so that the sensor does not fall off or apply excessive pressure at the site. |
| 2 | If present, remove any colored nail polish from the application site. |
| 3 | Lift off the release liners that protect the adhesive. |
| 4 | Put the finger (or toe) onto either side of the attachment - they are symmetrical - such that the tip covers the window completely and does not protrude over the hinge. |
| 5 | Close the grip. If the fit is good, press the attachment firmly on the finger or toe. If the fit is not good, reposition the attachment. Make sure the limb is centered nicely in the attachment. |
| 6 | Wrap the foam wings around the finger and attachment and stick to the opposing grip side. Do not stretch the foam to apply excessive pressure. |



To apply a disposable neonate clip to the patient

| Step | Action |
|------|--|
| 1 | Select the application site. It should match the clip size so that the sensor does not fall off or apply excessive pressure at the site. |
| 2 | Lift off the release liners that protect the adhesive. |
| 3 | Proceed according to the application site: <ul style="list-style-type: none"> • Foot application: Align the hinge on the outside facing ridge of the foot. Make sure the attachment is as far as possible toward the small toe but not over it. • Hand/Wrist application: Align the hinge on the outside facing ridge of the hand or wrist. You may have to swivel the fiber heads to an optimal position to ease the application. |
| 4 | With the hinge aligned with the ridge of the foot/hand/wrist, press one side to the skin and then wrap the other side around the limb pulling the long foam piece gently. |
| 5 | Press both fiber heads gently to attach the adhesives. |



| Step | Action |
|------|---|
| 6 | Secure the longer foam piece by pressing it firmly to the foam/adhesive of the opposing side. |
| 7 | Ensure that the two fiber heads are opposing and have good skin contact. The angle between the two fiber heads should be as small as possible, not exceeding 45°. If the attachment opens too much, reattach or try another site. |

WARNING



Disposable attachments are designed for single patient use and must be disposed after use. They must not be cleaned and reused. Follow your hospital's guidelines for appropriate disposal. Reuse of single-use devices can result in spread of patient infection, degradation of monitoring performance, or inaccurate measurements.



Positioning the wSPO2 Module for Scanning

To ensure the best performance, specific positioning considerations are required when using the wSPO2 module in the MR magnet room, including harsh scan sequences with peripheral nerve stimulation levels above 80 percent.

WARNING


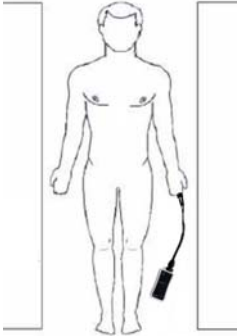


If the wSPO2 module is incorrectly positioned when used within the MR magnet room, the following factors can cause SPO2 waveform distortion and numeric inaccuracies, and respiration numeric inaccuracies:

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

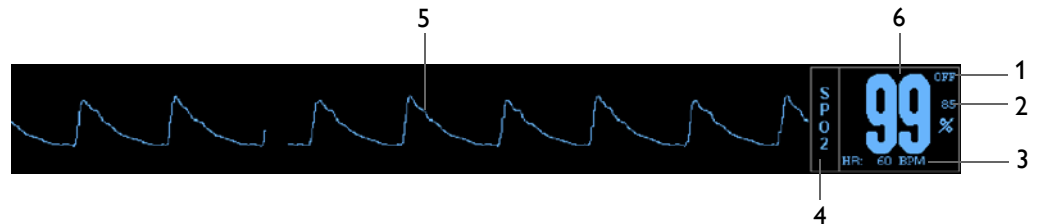
To ensure best performance during SPO2 measurements

| Step | Action |
|------|---|
| 1 | Ensure that the fiber heads (the light emitter and the photodetector in the clip or grip) are directly opposite each other, as the light must pass through the patient's tissue and be received for proper operation. |
| 2 | Swivel each fiber head into a position that causes the least bending of the cable while providing the most comfort to the patient. |

| Step | Action |
|------|---|
| 3 | Verify the wSPO2 module status by checking the status indicator: <ul style="list-style-type: none"> • Solid green = Battery power OK/Good communication • Flashing green = Battery power OK/No communication • Solid red = Low battery power/Good communication • Flashing red = Low battery power/No communication |
| 4 | Press the Patient key  and then select the appropriate PATIENT type; see page 3-10 for details. |
| 5 | Check for any displayed SPO2 messages and, if a message is present, follow the recommended action to achieve better results (see page 9-16). |
| 6 | While considering the scan to be performed, place the wSPO2 module on or near the patient and as close as possible to the bore opening. Keep the sensor and module outside the field of view.  |
| 7 | Place the module as close as possible to the bore opening. (If the module can be placed outside the bore, positioning at the iso-center is not necessary.) |
| 8 | Place the module on a cushioned surface to minimize MR vibrations. |
| 9 | Cover the attachment site on the patient with opaque material. |
| 10 | During measurement, check the patient to ensure that the application site has a pulsatile flow and that the site has not changed in thickness (for example, due to edema) causing an improper fit. |

SPO2 Waveform and VS Box


The elements contained in the SPO2 waveform (Trace C) and VS box are described below:



| Definition | |
|------------|--|
| 1 | Is the high limit setting of the SPO2 alarm; see page 5-10 |
| 2 | Is the low limit setting of the SPO2 alarm; see page 5-10 |
| 3 | Is the heart rate numeric and the unit of measure, where BPM is beats per minute. |
| 4 | Is the name of the vital sign |
| 5 | Is the detected SPO2 waveform, not proportional to pulse volume and can be amplitude-adjusted for viewing; see page 5-8. |
| 6 | Is the SPO2 measurement (numeric), given as a percentage |

Changing the Waveform Speed

To change the SPO2 (and ECG) waveform speed

| Step | Action |
|------|--|
| 1 | Press the SETUP key  . The SETUP menu appears. |
| 2 | Turn the control knob to MONITOR SETUP and then press the knob. The MONITOR menu appears. Current settings are displayed. |
| 3 | Turn the knob to SWEEP SPEED and then press the knob. The SWEEP SPEED menu appears; see page 3-14. |
| 4 | Turn the control knob to select either of the following settings and then press the knob: 50 mm/s 25 mm/s The selection is entered. |

Changing the SPO2 Waveform Amplitude

To change the SPO2 waveform amplitude

| Step | Action |
|------|--|
| 1 | Turn the control knob to highlight the SPO2 VS box (see page 5-9) and then press the knob. The SPO2 menu appears. Current settings are displayed. |
| 2 | Turn the control knob to SIZE and then press the knob. The SIZE menu appears; see page 5-11 for details. |
| 3 | Turn the control knob to select one of the following options and then press the knob: 10, 20, 40, 60, 80 or 100 percent The setting is changed. |

Changing the SPO2 Alarm Limits

To change the SPO2 alarm limit settings

| Step | Action |
|------|---|
| 1 | Turn the control knob to highlight the SPO2 VS box (see page 5-9) and then press the knob. The SPO2 menu appears. Current settings are displayed. |
| 2 | Turn the control knob to ALARM LIMITS and then press the knob. The ALARM LIMITS menu appears. Current settings are displayed; see page 5-10 for details. |
| 3 | Turn the knob to the low or high setting and then press the knob. The setting is selected. |
| 4 | Turn the knob to change the setting value and then press the knob to make the change effective and return to the scrolling function. The setting is changed. |
| 5 | To change the remaining setting, repeat steps 3 and 4. |

NOTE

To make global changes to the parameter alarm limit settings based upon the patient's current vital sign readings, see Setting Alarm Limits Globally on page 9-4.

Assessing Suspicious SPO2 Readings

Pulse oximetry measurements are statistically distributed. With newer algorithms, such as FAST-SPO2, the calculation of SPO2 is not directly linked to the correct detection of each pulse. When the pulse rate is very low or a strong arrhythmia is present, the SPO2/plethysmography pulse rate may differ from the heart rate calculated from ECG. This does not indicate an inaccurate SPO2 value. If you doubt the measured SPO2, use the plethysmography wave to assess the signal quality.



WARNINGS


- Always shield (for example, cover with opaque material) the SPO2 clip or grip from extraneous incidental light sources, as such light can cause erroneous SPO2 readings or pulse detection errors.
 - SPO2 monitoring requires the detection of valid pulses to correctly determine SPO2 and heart rate values. Any of the following items can lead to inaccuracies of the SPO2 readings and/or prolonged measurement time: Ambient light (including photodynamic therapy), physical movement (patient and imposed motion), arrhythmias and/or erratic heartbeats, diagnostic testing, electromagnetic interference, electrosurgical units, dysfunctional hemoglobin, intravascular dyes, presence of dyes or pigments at the application site, and inappropriate positioning of the pulse oximeter attachment. If questionable readings are obtained, check the patient's vital signs by alternate means before administering medication.
 - Attachment movement, ambient light (especially strobe or flashing lights) or electromagnetic interference can give unexpected intermittent readings when the sensor is not attached to a patient. Bandage and grip attachment designs are particularly sensitive to minimal movement that might occur when the sensor is dangling, not attached to the patient. An unapplied sensor may cause readings to be displayed on the monitor. To avoid misdiagnosis, ensure the sensor is applied to patient correctly.
-

SPO2 Menu

The **SPO2** menu allows you to control SPO2 functions and settings.



To change settings in the SPO2 menu

| Step | Action |
|------|--|
| 1 | Turn the control knob to highlight the SPO2 VS box and then press the knob. The SPO2 menu appears. Current settings are displayed. |
| 2 | Turn the control knob to select any of the following SPO2 options and then press the knob: ALARM LIMITS SIZE AVERAGING TIME GATING SOURCE HR SOURCE HR TONE SOURCE For information about these options, see the appropriate sections below. |
| 3 | Turn the knob to the desired setting and then press the knob. |
| 4 | To change other settings, repeat steps 2 and 3. |
| 5 | Press the Main key  to close the menu. Alternative: Turn the knob to RETURN and then press the knob, or wait approximately 60 seconds. |

ALARM LIMITS

Controls the SPO2 alarm limit settings. (See the table on page 9-15 for a listing.)

| | PARAMETER | LOW | CUR | HIGH |
|---|-----------|-----|-----|------|
| 5 | SPO2 | 85 | 99 | OFF |
| 4 | RETURN | | | |
| | | 3 | 2 | 1 |

| Definition | |
|------------|---|
| 1 | Is the setting of the high alarm limit |
| 2 | Is the current measurement |
| 3 | Is the setting of the low alarm limit |
| 4 | Saves the settings and returns to the normal mode |
| 5 | Identifies SPO2 alarm limits |

To set the alarm limits for SPO2

See *Changing the SPO2 Alarm Limits* on page 5-8.

SIZE

Changes the vertical scale of the SPO2 (pleth) waveform so that high amplitudes can be scaled down to avoid clipping of the peaks and low amplitudes can be scaled up to view the peaks.

The following choices are available:

- 10%
- 20%
- 40%
- 60%
- 80%
- 100% (Default)

To adjust the size of the SPO2 waveform

See *Changing the SPO2 Waveform Amplitude* on page 5-8.

AVERAGING TIME

Selects how quickly the reading responds to changes in the patient's saturation, where selecting a longer duration will prevent the saturation value from changing quickly which can be useful for avoiding alarm triggering in patients with very dynamic conditions such as neonatal and pediatrics.

The following choices (in seconds) are available:

- 5 S
- 10 S (Default)
- 15 S

To set the averaging time of the SPO2 reading

Enter the **SPO2** menu. Turn the control knob to **AVERAGING TIME** and press the knob. Scroll to the desired time and press the knob.

GATING SOURCE

Sets the cardiac gating source based on a measured signal. (This is the same option as in the **ECG** menu.)

The following choices are available:

- **ECG** is an output that represents the detection of the R-peak of a QRS complex, a signal the MR system can use directly for triggering. (Default)
- **Pulse** is a signal that represents the detection of the peak of the peripheral pulse complex.

To set the gating source

See *Using the Gating Feature* on page 4-26.

HR SOURCE

Selects the source that produces the heart rate, as displayed in the ECG and SPO2 VS boxes (identical to and interactive with the same option in the **ECG** menu).

The following choices are available:

- **AUTO** selects the source automatically from the highest priority active input, where the MR200 searches for another source only when **LEAD FAIL** occurs or when ECG is off. If the highest priority input is not found, the next ranked parameter is sought. The priority ranking is ECG and then SPO2. If no parameters present a heart rate, then NONE is displayed in the heart rate position.
- **ECG** selects ECG. (Default)
- **SPO2** selects SPO2.

To set the heart rate source

| Step | Action |
|------|---|
| 1 | Turn the control knob to highlight the SPO2 VS box (see page 5-7) and then press the knob. The SPO2 menu appears. Current settings are displayed. |
| 2 | Turn the control knob to HR SOURCE and then press the knob. The HR SOURCE menu appears. |

| Step | Action |
|------|--|
| 3 | Turn the control knob to select one of the following options and then press the knob: AUTO ECG SPO2 The setting is changed. |

HR TONE SOURCE

Sets the source used for the heart rate tone (identical to and interactive with same option in the **MONITOR > SOUND ADJUST** menu and in the **ECG** menu).

The following choices are available:

- **OFF** removes the heart symbol from the display and no pulse tone will be sounded. (Default)
- **QRS** provides a tone modulated by the QRS detection from the ECG vital sign.
- **SPO2** provides a tone modulated by the SPO2 vital sign, where the lower the SPO2 value, the lower the pitch.

To set the heart rate tone source

Enter the **SPO2** menu. Turn the control knob to **HR TONE SOURCE** and press the knob. Scroll to the desired setting and press the knob. (See page 3-8 for detailed instructions.)

Monitoring NiBP

The NiBP (non-invasive blood pressure) parameter measures and displays systolic, diastolic and mean arterial pressures. Alarm limit settings are available for all three pressures. When using NiBP to measure blood pressure, readings are not continuous but are updated each time a blood pressure measurement is taken. Set a shorter interval when frequent updating of the patient's blood pressure is needed. Visually checking the patient, confirming NiBP measurements against other vital sign measurements and attention to the limb where the cuff is attached must be standard routines during NiBP use.

Adult and pediatric blood pressure measurements determined with this device are equivalent to those obtained by a trained observer using the cuff/stethoscope auscultatory method, within the limits prescribed by the American National Standard, *Manual, electronic, or automated sphygmomanometers*.

Neonatal blood pressure measurements determined with this device are equivalent to those obtained by an intra-arterial blood pressure measurement device, within the limits prescribed by the American National Standard, *Manual, electronic, or automated sphygmomanometers*.



WARNINGS

- **Use clinical judgment to decide whether to perform a repeated series of NiBP measurements because of the risk of purpura, ischemia and neuropathy in the limb with the NiBP cuff.**
 - **Arrhythmias, erratic heartbeats and patient motion can result in inaccurate readings and/or prolonged measurements. If questionable readings are obtained, check the patient's vital signs by alternate means before administering medication.**
 - **The performance of the automated sphygmomanometer can be affected by extremes of temperature, humidity and altitude.**
 - **An alarm will sound when the MR200 is too close to the MR magnet and shutdown of NiBP monitoring will occur. Always position the MR200 as indicated on page 2-6.**
-

CAUTIONS

- Substitution of components or accessories different from those supplied or recommended can result in measurement errors.
 - NiBP accuracy has not been verified in the presence of some common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation.
-

Patient Preparation for NiBP Monitoring



WARNING

The NiBP cuff inflation rate may increase and the initial pressure may increase up to 180 mmHg when changing the patient type.

The **PATIENT** type setting determines the inflation pressures of the NiBP cuff and the reading times.

In some cases, a patient may exhibit a low pulse amplitude due to any of the following conditions. The list provides only *some* examples of potential causes of low pulse amplitudes that can make NiBP difficult to measure in a convenient and timely manner:

- Medication
- Sedation
- Disease or illness
- Physiological or neurological conditions
- Obesity (or any occurrence of metabolism with extreme variations)
- Stress
- Size

CAUTION

There may be occasions when a particular mode is not suitable for its apparent category of patients based on age alone. In these cases, a clinical decision shall be made to use another patient type, NiBP cuff size or measurement technique. The clinical decision shall be based on all of the factors listed in *Determining the Patient Type* (see page 3-10) to ensure the best possible and most timely NiBP measurement acquisition.

NOTE

***ADULT** and **PEDIATRIC** types dictate use of a larger NiBP cuff and interconnect hose size, while **NEO** uses smaller sizes; see the cuff and hose information on page 1-27.*

A wide variety of NiBP cuffs and interconnect hoses are available for your monitoring needs; see page 1-27 for details.

Selecting the NiBP Cuff



WARNING

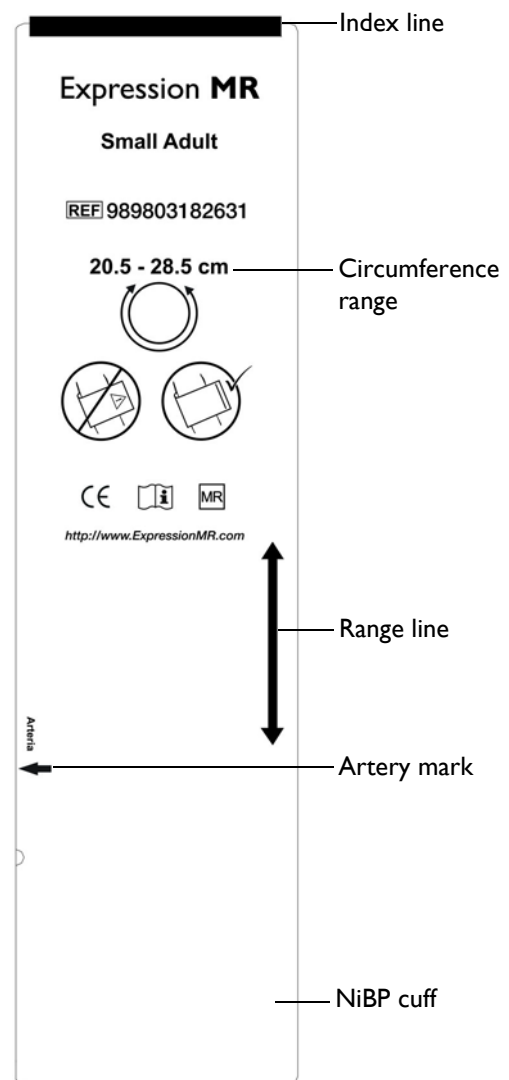
To ensure accurate reliable measurements, use only the recommended NiBP accessories. Use the appropriate NiBP cuff size for each patient, as recommended by the current American Heart Association guidelines for blood pressure monitoring, to ensure safety and accuracy.

The NiBP cuff should be selected and positioned as it would be for an auscultatory blood pressure determination. The current guidelines of the American Heart Association must be followed.

The bladder width of the cuff must be 40 percent of the circumference of the limb. It is also advisable to keep the air volume to a minimum by using the smallest cuff size possible for each patient. The point of maximum oscillations is coincident with mean arterial pressure regardless of arterial elasticity so long as the ratio of air volume in the cuff to the volume of the artery under compression does not greatly exceed ten (10) to one (1).

For a correct NiBP cuff fit:

- Adult and pediatric patients—the index line on the size chosen should fall within the range line when placed on the patient.
- Neonatal patients—the size chosen should be within the stated circumference range for the limb of the neonate.
- All patients—align the cuff to ensure the artery mark is placed over the artery.



WARNING

Single use devices, as indicated on the device packaging, should be disposed of after use and must never be reused. Follow your hospital's guidelines for appropriate disposal. Reuse of single-use devices can result in spread of patient infection, degradation of monitoring performance, or inaccurate measurements.



Positioning the NiBP Cuff



WARNINGS

- **Avoid compression, kinking or restriction of the NiBP cuff hose, as the effect of blood flow interference can result in patient injury caused by continuous cuff pressure.**
- **Do not use the NiBP cuff on a limb with an intravenous infusion or where an arterial catheter or arterio-venous (A-V) shunt is in place because of temporary interference to blood flow. This could result in injury to the patient.**
- **Do not place the NiBP cuff over a wound, as this can cause further injury.**
- **Do not place the NiBP cuff on the same or adjacent arm to a mastectomy, or where the lymph nodes were removed, or if a shunt is on that arm. This can lead to bruising, inaccurate readings, or negatively impact the drainage of fluids because of temporary interference to blood flow.**

Wrap the NiBP cuff firmly (not snugly) around the arm or leg of the patient, making sure that the cuff is at the approximate level of the heart to ensure accuracy of the obtained values.

Connecting the NiBP Cuff



WARNING

Routinely inspect the NiBP cuff and hose assemblies for proper connection and orientation. Replace accessories that have cracks, holes, tears, or cuts that could cause leaks in the system. If such damaged NiBP cuff or hose assemblies are used, prolonged and/or inaccurate patient readings could result.

To connect the NiBP cuff and hose

| Step | Action |
|------|--|
| 1 | Insert the appropriate interconnect hose connector onto the NiBP port. Push the hose connector forward and then turn it clockwise. |
| 2 | Attach a NiBP cuff appropriate for the patient type and size to the interconnect hose. |



| Step | Action |
|------|---|
| 3 | Position the cuff on the patient; see page 6-4. |
| 4 | Ensure that the cuff and interconnect hoses are not kinked. |



Choosing the Measurement Mode

NiBP measurements can be taken using a mode (auto or manual) that best suits the needs of your patient.

Selecting Auto Mode

You can automatically measure a patient's blood pressure at pre-defined intervals, which are measured from the start of one NiBP measurement to the start of the next.

To turn on automatic operation

| Step | Action |
|------|--|
| 1 | Press the Patient key  and then select the appropriate PATIENT type; see page 3-10 for details. |
| 2 | Turn the control knob to highlight the NiBP VS box (see page 6-11) and then press the knob. The NiBP menu appears. Current settings are displayed. |
| 3 | Turn the control knob to INTERVAL and then press the knob. The INTERVAL menu appears. The current setting is highlighted. |
| 4 | Turn the control knob to select any of the following settings and then press the knob: 1, 2, 2.5, 3, 5, 10, 15, 20, 30 and 45 minutes, and 1, 2 and 4 hours. The selection is entered. |
| 5 | Turn the control knob to AUTO MODE and then press the knob. |
| 6 | Turn the control knob to ON and then press the knob. |
| 7 | Press the NiBP key  to begin measurements. |



NOTE

If gauss shutdown occurs during an **AUTO MODE** measurement, NiBP readings will stop. When at a safe distance, operation will resume—a reading will be taken and then the intervals will begin again.

Making Manual Measurements

You can manually define the measurement interval of a patient's blood pressure.

To control manual operation

| Step | Action |
|------|--|
| 1 | Press the Patient key  and then select the appropriate PATIENT type; see page 3-10 for details. |
| 2 | Press the NiBP key  to start and stop a manual NiBP measurement. |

Initial Inflation Pressures and Reading Durations



WARNINGS

- **Too frequent NiBP measurements can cause injury to the patient due to blood flow interference.**
 - **Always monitor the NiBP cuff site (for example, by observation of the limb concerned) to ensure that operation of the automated sphygmometer does not result in prolonged impairment of the circulation of the blood of the patient.**
 - **Pressurization of the NiBP cuff can temporarily cause loss of function of simultaneously used monitoring ME equipment on the same limb.**
-

The initial inflation pressure is the amount that the NiBP cuff will inflate for the first NiBP measurement:

- **ADULT** is used for most adult patients: Initial inflation pressure: 165 ± 15 mmHg
- **PEDIATRIC** is used for any patient exhibiting low pulse amplitudes (a condition exhibited by pediatric-size patients): Initial inflation pressure: 130 ± 15 mmHg
- **NEO** is used for most neonatal patients: Initial inflation pressure: 100 ± 15 mmHg

When subsequent NiBP measurements are taken on the same patient (and if not in suspend mode), the monitor adjusts the inflation value up or down based on the previous reading results.

Stopping an NiBP Measurement

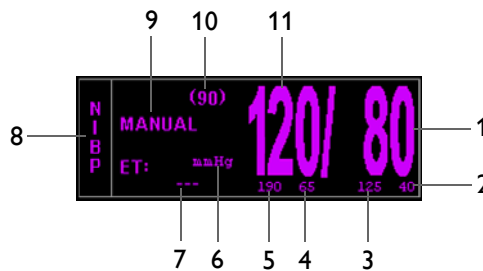
Press the **NiBP** key  to stop a reading cycle.

NiBP VS Box

Depending upon the selected **FORMAT** (see page 6-14), the NiBP VS box is displayed accordingly.

Systolic/Diastolic Format

The elements contained in the SYS/DIA format are described below.

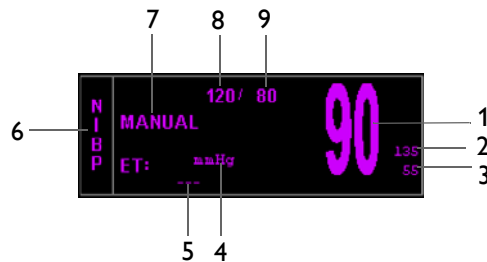


| Definition | |
|------------|---|
| 1 | Is the NiBP diastolic pressure measurement (numeric) |
| 2 | Is the low limit of the NiBP diastolic alarm setting; see page 6-12 |
| 3 | Is the high limit of the NiBP diastolic alarm setting; see page 6-12 |
| 4 | Is the low limit of the NiBP systolic alarm setting; see page 6-12 |
| 5 | Is the high limit of the NiBP systolic alarm setting; see page 6-12 |
| 6 | Is the unit of measure for the NiBP pressure readings, where mmHg is millimeters of mercury and kPa is kilopascals; see PRESSURE UNITS on page 11-16 |
| 7 | Is the time since the last completed NiBP reading, displayed in the following format: <hh>:<mm>:<ss>, where <hh> = Two-digit hours field <mm> = Two-digit minutes field <ss> = Two-digit seconds field NOTE During a reading, this displays the cuff pressure. |

| Definition | |
|------------|---|
| 8 | Is the name of the vital sign |
| 9 | Is the mode: where MANUAL is displayed when in Manual mode, and NEXT when in Auto mode. In Auto mode, indicates the time until the next NiBP measurement, displayed in the following format: <hh>:<mm>:<ss>, where <hh> = Two-digit hours field <mm> = Two-digit minutes field <ss> = Two-digit seconds field |
| 10 | Is the NiBP mean pressure measurement (numeric) |
| 11 | Is the NiBP systolic pressure measurement (numeric) |

Mean Format

The elements contained in the MEAN format are described below.



| Definition | |
|------------|--|
| 1 | Is the NiBP mean pressure measurement (numeric) |
| 2 | Is the high limit of the NiBP mean alarm setting; see page 6-12 |
| 3 | Is the low limit of the NiBP mean alarm setting; see page 6-12 |
| 4 | Is the unit of measure for the NiBP pressure readings, where mmHg is millimeters of mercury and kPa is kilopascals; see PRESSURE UNITS on page 11-16 |
| 5 | Is the time since the last completed NiBP reading, displayed in the following format: <hh>:<mm>:<ss>, where <hh> = Two-digit hours field <mm> = Two-digit minutes field <ss> = Two-digit seconds field <i>NOTE</i> — <i>During a reading, this displays the cuff pressure.</i> |
| 6 | Is the name of the vital sign |

| Definition | |
|------------|---|
| 7 | Is the mode: where MANUAL is displayed when in Manual mode, and NEXT when in Auto mode. In Auto mode, indicates the time until the next NiBP measurement, displayed in the following format: <hh>:<mm>:<ss>, where <hh> = Two-digit hours field <mm> = Two-digit minutes field <ss> = Two-digit seconds field |
| 8 | Is the NiBP systolic pressure measurement (numeric) |
| 9 | Is the NiBP diastolic pressure measurement (numeric) |

Changing the NiBP Alarm Limits

To change the NiBP alarm limit settings

| Step | Action |
|------|---|
| 1 | Turn the control knob to highlight the NiBP VS box (see page 6-11) and then press the knob. The NiBP menu appears. Current settings are displayed. |
| 2 | Turn the control knob to ALARM LIMITS and then press the knob. The ALARM LIMITS menu appears. Current settings are displayed; see page 6-12 for details. |
| 3 | Turn the knob to the low or high setting and then press the knob. The measurement and setting are selected. |
| 4 | Turn the knob to change the setting value and then press the knob to make the change effective and return to the scrolling function. The setting is changed. |
| 5 | To change other alarm settings, repeat steps 3 and 4. |

NOTE



To make global changes to the parameter alarm limit settings based upon the patient's current vital sign readings, see Setting Alarm Limits Globally on page 9-4.

Changing the Unit of Measure

NOTE

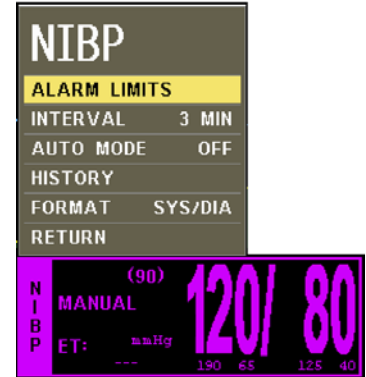
When using the IP5 and **PRESSURE UNITS** is changed, the displayed formatting of the value and placement of the decimal point is changed immediately. However, it can take up to 2 seconds for the numeric values to reflect the new unit of measure. Do not print or perform data captures during this period.

To change the unit of measure


| Step | Action |
|------|---|
| 1 | Press the SETUP key  . The SETUP menu appears. |
| 2 | Turn the control knob to MONITOR SETUP and then press the knob. The MONITOR menu appears. Current settings are displayed. |
| 3 | Turn the control knob to SERVICE(BIO-MED) and press the knob. The SERVICE(BIO-MED) menu appears. |
| 4 | Turn the control knob to SYSTEM CONFIG and press the knob. The SYSTEM CONFIG submenu appears. Current settings are displayed. |
| 5 | Turn the control knob to PRESSURE UNITS and then press the knob. The PRESSURE UNITS menu appears. The current setting is highlighted. |
| 6 | Turn the knob to the desired setting and then press the knob. mmHg kPa The setting is selected. |
| 7 | Press the Main key  to close the menu. Alternative: Turn the knob to RETURN and then press the knob. |

NiBP Menu

The **NiBP** menu allows you to control non-invasive blood pressure functions and settings.

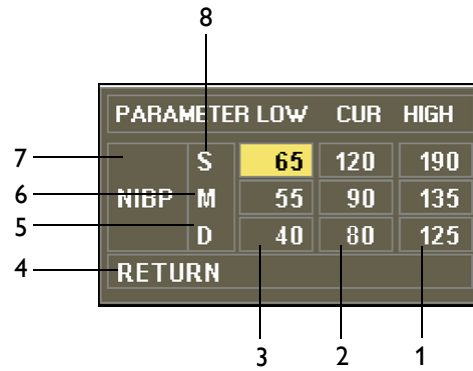


To change settings in the NiBP menu

| Step | Action |
|------|--|
| 1 | <p>Turn the control knob to highlight the NiBP VS box and then press the knob.</p> <p>The NiBP menu appears. Current settings are displayed.</p> |
| 2 | <p>Turn the control knob to select any of the following NiBP options and then press the knob:</p> <p>ALARM LIMITS INTERVAL AUTO MODE HR SOURCE HISTORY FORMAT</p> <p>For information about these options, see the appropriate sections below.</p> |
| 3 | Turn the knob to the desired setting and then press the knob. |
| 4 | To change other settings, repeat steps 2 and 3. |
| 5 | <p>Press the Main key  to close the menu.</p> <p>Alternative: Turn the knob to RETURN and then press the knob, or wait approximately 60 seconds.</p> |

ALARM LIMITS

Controls the alarm limit settings for NiBP. (See the table on page 9-15 for a listing.)



| Definition | |
|------------|---|
| 1 | Are the settings of the high alarm limits |
| 2 | Are the current measurements |
| 3 | Are the settings of the low alarm limits |
| 4 | Saves the settings and returns to the normal mode |
| 5 | Identifies diastolic alarm limits |
| 6 | Identifies mean alarm limits |
| 7 | Identifies NiBP alarm limits |
| 8 | Identifies systolic alarm limits |

To set the alarm limits for NiBP

See *Changing the NiBP Alarm Limits* on page 6-9.

INTERVAL

Sets the interval for automatic measurements.

The following choices are available:

- **1 Minute**
- **2 Minutes**
- **2.5 Minutes**
- **3 Minutes (Default)**
- **5 Minutes**
- **10 Minutes**

- **15 Minutes**
- **20 Minutes**
- **30 Minutes**
- **45 Minutes**
- **1 Hour**
- **2 Hours**
- **4 Hours**

To set the interval for NiBP readings

Enter the **NiBP** menu. Turn the control knob to **INTERVAL** and press the knob. Scroll to the desired time and press the knob.

AUTO MODE

Sets the mode used to take NiBP readings.

NOTE

A manual reading will not restart this cycle time.

The following choices are available:

- **ON** takes readings automatically. When switched from off to on, the first reading must be initiated by pressing the **NiBP** key. All subsequent readings will be taken automatically at the selected interval.
- **OFF** takes readings manually (Manual mode), where readings are initiated by pressing the **NiBP** key. (Default)

To set the mode for NiBP readings

Enter the **NiBP** menu. Turn the control knob to **AUTO MODE** and press the knob. Scroll to the desired method and press the knob.

HISTORY

Displays the last 48 NiBP readings with the time, heart rate, SPO2, CO2 and respiration values in a tabular form (6 per page). This data is retained in non-volatile memory, protected against power loss.

To view previous NiBP readings

Enter the **NiBP** menu. Turn the control knob to **HISTORY** and press the knob.

FORMAT

Changes the format of the displayed pressure numerics.

The following choices are available:

- **SYS/DIA** displays the NiBP readings in the systolic/diastolic format; see page 6-7. (Default)
- **MEAN** displays the NiBP readings in the mean format; see page 6-8.

To change the format

| Step | Action |
|------|--|
| 1 | Turn the control knob to highlight the NiBP VS box (see page 6-11) and then press the knob. The NiBP menu appears. Current settings are displayed. |
| 2 | Turn the control knob to FORMAT and then press the knob. The FORMAT menu appears. The current setting is highlighted. |
| 3 | Turn the control knob to select from the following settings and then press the knob: SYS/DIA MEAN The selection is entered. |

Monitoring CO₂

When equipped with the CO₂ option, the MR200 samples and analyzes the patient's airway respiratory gas using sidestream measurement to produce:

- An inspired (FiCO₂) value derived during inspiration and an end tidal (EtCO₂) value measured during expiration.
- A respiration rate (RESP): The number of breaths per minute; see chapter 8 for details.
- A waveform of the concentration of carbon dioxide in the respiratory gases.

NOTE

Inspired CO₂ (FiCO₂) is the lowest reading of the CO₂ waveform in the previous 20 seconds.

WARNINGS



- **Do not use on patients that cannot tolerate the withdrawal of 50ml/min ± 10 ml/min from the airway or patients that cannot tolerate the added dead space to the airway.**
 - **An alarm will sound when the MR200 is too close to the MR magnet and shutdown of CO₂ monitoring will occur. Always position the MR200 as indicated on page 2-6.**
-

Patient Preparation for CO₂ Monitoring

When preparing a patient, the accessory position on the patient will impact the performance and operation of the CO₂ parameter.

Selecting the CO₂ Accessory

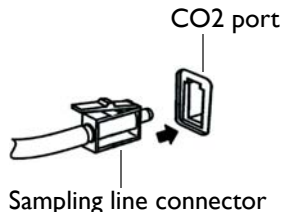
In patients on a breathing circuit, a sample of the respiratory gas is drawn from the patient's breathing circuit through an airway adapter and a gas sampling line. In patients who are not on a breathing circuit, the gas sample is drawn through a nasal cannula. These specially designed cannulas and on-airway adapters incorporate a filter and sample cell to provide maximum filtration of fluids and contaminants to protect against system intake. When selecting CO₂ accessories (see page 1-25), consider the following:

- The type of patient (adult, pediatric, or neonatal)
- Whether the patient is receiving supplemental oxygen
- The condition of the patient

- All accessories are single use.

Connecting the Sampling Line

To connect the sampling line

| Step | Action |
|------|---|
| 1 | <p>Insert the sampling line connector into the CO2 port and then push the connector forward until you feel or hear it click into place.</p>  <p style="text-align: right;">CO2 port</p> <p style="text-align: center;">Sampling line connector</p> |
| 2 | <p>If CO2 WARMING UP is displayed, wait as the system thermally stabilizes. When the message is cleared, CO2 is fully operational.</p> |
| 3 | <p>Always remove the patient sampling line from the CO2 port when not in use. (To remove the sampling line, press down on the locking tab and pull the connector from the port.)</p> <p>NOTE _____</p> <p><i>To increase the life of the filter and pump, when CO2 will not be used to monitor a patient, it is recommended to turn off CO2 in the PARAMETER SELECTION menu; see page 3-7.</i></p> <p>_____</p> |



WARNINGS

- **Inspect CO2 port and accessories before use. If the sampling line, connector or port show signs of damage, replace the part immediately or discontinue use and contact technical support. Never use damaged equipment.**
- **Frequently inspect the patient sampling line and keep it clear of any moving mechanisms (for example, table wheels) which could cut, pinch, or dislodge the sampling line. Leaks, reduced or stopped flow, or internal venting of sampled gas into damaged tubing will cause inaccurate measurements.**
- **Do not position the sampling line in any manner that may cause entanglement or strangulation.**
- **Replace the sampling line if excessive secretions are observed, as inaccurate measurements could result if the flow is reduced or stopped.**
- **Leakages in the breathing system or sampling system may cause the displayed EtCO2 values to be too low. Always connect all components securely and check for leaks according to standard clinical procedures. Displacement of the sampling line cannula or airway adapter can cause lower than actual EtCO2 readings.**

- **If CO2 values for patients who are not on a breathing circuit appear extremely low, check whether the patient is breathing through the mouth or whether one nostril is blocked.**

NOTES

- *For optimum fit and compatibility, use only specified parts.*
- *Always inspect patient sampling line after attachment to the MR200.*

Applying the Sampling Line to the Patient

Select the patient sampling line that is appropriate for the patient size and application. Patient sampling lines with the airway adapter are intended for use with breathing circuits and anesthesia circuits that have an integrated airway adapter.

WARNING



Patient sampling lines are intended for single-patient use only. Do not clean or disinfect these items. Follow your hospital's guidelines for appropriate disposal. Reuse of single-use devices can result in spread of patient infection, degradation of monitoring performance, or inaccurate measurements.

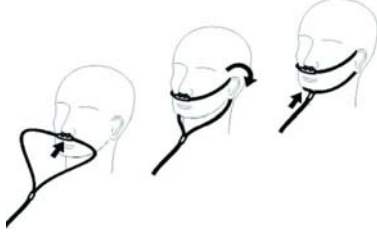
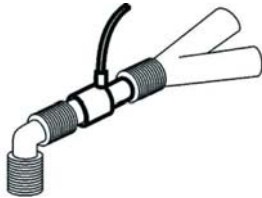




CAUTIONS

- The accuracy of the data is greatly influenced by the proper use and fitting of the patient sampling line to ensure proper sampling without the introduction of outside air.
- Remove the patient sampling line from the CO2 port when not in use.

To place the sampling line on the patient

| Step | Action |
|------|--|
| 1 | Ensure that the sampling line is clean, dry and undamaged. Replace the line if necessary. |
| 2 | Insert the sampling line connector into the CO2 port (see page 7-2). A click will be heard when properly inserted. |

| Step | Action |
|------|--|
| 3 | <p>Place the sampling line onto the patient, as shown below.</p>  |
| 4 | <p>If using the sampling line with the airway adapter, proceed to step 5; otherwise go to step 7.</p> |
| 5 | <p>Place the airway adapter at the proximal end of the airway circuit between the elbow and the breathing circuit wye, as shown below.</p>  <p>CAUTION</p> <p>Always insert the patient sampling line into the CO₂ port before inserting the airway adapter into the breathing circuit. Failure to follow this may introduce a leak in the circuit, thereby reducing set minute volume.</p> <p>NOTE</p> <p><i>Do not place the airway adapter between the ET tube and the elbow as this may allow patient secretions to accumulate in the adapter. If pooling does occur, replace the airway adapter. To prevent moisture from draining into the airway adapter, always place the adapter tubing in a up position, as shown above.</i></p> |
| 6 | <p>Press the Patient key  and then select the appropriate PATIENT type; see page 3-10 for details.</p> |

| Step | Action |
|------|--|
| 7 | <p data-bbox="732 338 1446 396">Check that the connections have been made correctly by verifying the patient's breathing efforts with the displayed waveform.</p> <p data-bbox="732 422 1446 447">WARNING</p> <div data-bbox="732 470 813 541">  </div> <p data-bbox="829 464 1442 554">Before completion of patient setup, ensure that the patient's breathing efforts coincide with the displayed CO2 waveform.</p> |
| 8 | <p data-bbox="732 611 1127 636">If the following warning is displayed:</p> <p data-bbox="902 657 1292 747" style="text-align: center;">Persistent CO2 occlusion detected. Please clear occlusion and press OK to resume using CO2</p> <p data-bbox="732 783 1386 842">Clear any pinches or obstructions in the sampling line before proceeding.</p> |

CO2 Waveform and VS Box


The elements contained in the CO2 waveform (Trace D) and VS box are described below.



| Definition | |
|------------|---|
| 1 | Is the high limit setting of the CO2 alarm; see page 7-9 |
| 2 | Is the low limit setting of the CO2 alarm; see page 7-9 |
| 3 | Is the inspired FiCO2 (inspired CO2) measurement (numeric) |
| 4 | Is the unit of measure for the CO2 numeric data, where mmHg is millimeters of mercury and kPa is kilopascals; see page 7-11 |
| 5 | Is the label for the FiCO2 measurement |
| 6 | Is the name of the vital sign |
| 7 | Is the detected CO2 waveform |
| 8 | Is the label for the EtCO2 measurement |
| 9 | Is the EtCO2 (expired CO2) measurement (numeric) |

Changing the Waveform Speed

To change the CO2 waveform speed

| Step | Action |
|------|--|
| 1 | Press the SETUP key  . The SETUP menu appears. |
| 2 | Turn the control knob to MONITOR SETUP and then press the knob. The MONITOR menu appears. Current settings are displayed. |

| Step | Action |
|------|---|
| 3 | Turn the knob to RESP SPEED and then press the knob. The RESP SPEED menu appears. The current setting is highlighted. |
| 4 | Turn the control knob to select any of the following settings (see page 3-14 for details) and then press the knob: 25 mm/s 12.5 mm/s 6.25 mm/s 3.125 mm/s 1.5625 mm/s 0.33333 mm/s The selection is entered. |

Changing the CO2 Alarm Limits

To change the End-tidal CO2 alarm limit settings

| Step | Action |
|------|--|
| 1 | Turn the control knob to highlight the CO2 VS box (see page 7-8) and then press the knob. The CO2 menu appears. Current settings are displayed. |
| 2 | Turn the control knob to ALARM LIMITS and then press the knob. The ALARM LIMITS menu appears. Current settings are displayed; see page 7-9 for details. |
| 3 | Turn the knob to the low or high setting and then press the knob. The setting is selected. |
| 4 | Turn the knob to change the setting value and then press the knob to make the change effective and return to the scrolling function. The setting is changed. |
| 5 | To change the remaining setting, repeat steps 3 and 4. |

NOTES

- To make global changes to the parameter alarm limit settings based upon the patient's current vital sign readings, see Setting Alarm Limits Globally on page 9-4.
- The high alarm limit for inspired CO2 is fixed.

Changing the Unit of Measure

To change the unit of measure

| Step | Action |
|------|--|
| 1 | Turn the control knob to highlight the CO2 VS box (see below) and then press the knob. The CO2 menu appears. Current settings are displayed. |
| 2 | Turn the control knob to UNIT and then press the knob. The UNIT menu appears. The current setting is highlighted. |
| 3 | Turn the knob to select one of the following CO2 settings: mmHg kPa The setting is selected. |


CO2 Menu

The **CO2** menu allows you to control CO2 and CO2-derived respiration functions and settings.



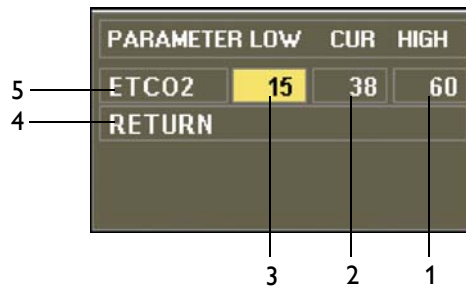
To change settings in the CO2 menu

| Step | Action |
|------|--|
| 1 | Turn the control knob to highlight the CO2 VS box and then press the knob. The CO2 menu appears. Current settings are displayed. |

| Step | Action |
|------|---|
| 2 | Turn the control knob to select any of the following CO2 options and then press the knob: ALARM LIMITS SIZE GRIDS ZERO CAL UNIT For information about these options, see the appropriate sections below. |
| 3 | Turn the knob to the desired setting and then press the knob. |
| 4 | To change other settings, repeat steps 2 and 3. |
| 5 | Press the Main key  to close the menu. Alternative: Turn the knob to RETURN and then press the knob, or wait approximately 60 seconds. |

ALARM LIMITS

Controls the alarm limit settings for CO2. (When **SOURCE** is set to **BEL** in the **RESP** menu, the CO2 respiration alarm limit settings will also be displayed; see page 8-5.)



| Definition | |
|------------|---|
| 1 | Is the setting of the high alarm limit |
| 2 | Is the current measurement |
| 3 | Is the setting of the low alarm limit |
| 4 | Saves the settings and returns to the normal mode |
| 5 | Identifies expired CO2 alarm limits |

To set the alarm limits for CO2

See *Changing the CO2 Alarm Limits* on page 7-7.

SIZE

Sets the CO2 waveform size.

The following choices are available:

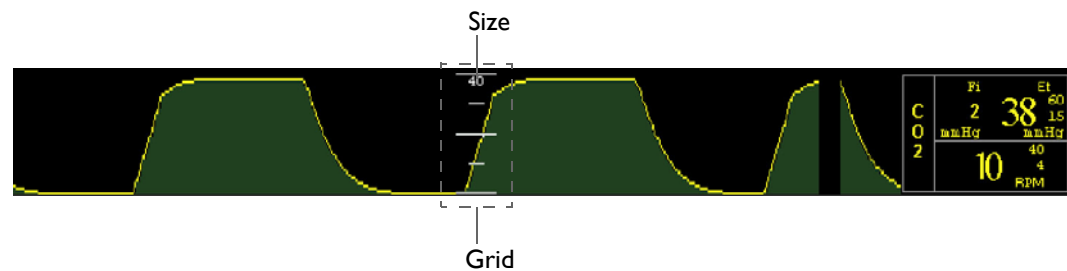
- **40 mmHg** (Default)
- **60 mmHg**
- **80 mmHg**

To adjust the grid size for the CO2 waveform

Enter the **CO2** menu. Turn the control knob to **SIZE** and press the knob. Scroll to the desired size and press the knob.

GRIDS

Controls the CO2 grid display.



The following choices are available:

- **ON**
- **OFF** (Default)

To control CO2 grid display

Enter the **CO2** menu. Turn the control knob to **GRIDS** and press the knob. Scroll to the desired setting and press the knob.

NOTE

Grids will not be displayed during a CO2 ACCURACY CHECK; see page 11-14.

ZERO CAL

Initiates a zero calibration (an automatic function during normal use) of the CO₂ system to allow for the different characteristics of each accessory type. The maximum time required for is approximately 40 seconds.

Under certain conditions, **ZERO CAL** will not be allowed:

- If less than 20 seconds have passed since detection of the last breath;
- If the CO₂ temperature is unstable; or
- When the sampling line is disconnected from the CO₂ port.

NOTE

***ZERO CAL** is not required when switching sampling lines.*

To perform a zero calibration

| Step | Action |
|-------------|---|
| 1 | Ensure that CO₂ WARMING UP is not displayed. |
| 2 | Turn the control knob to highlight the CO ₂ VS box and then press the knob. The CO₂ menu appears. Current settings are displayed. |
| 3 | Turn the control knob to select ZERO CAL and then press the knob. PERFORMING CO₂ ZERO will be displayed during calibration. And then, when complete, the message will be removed. |

UNIT

Selects the unit of measure used for presentation of the CO₂ numeric data.

The following choices are available:

- **mmHg** (Default)
- **kPa**

To select the unit of measure for CO₂

Enter the **CO₂** menu. Turn the control knob to **UNIT** and press the knob. Scroll to the desired setting and press the knob.

Monitoring RESP

If equipped with the CO₂ option, the patient's respiration rate will be calculated by measuring the time interval between detected breaths. When monitoring respiration derived from CO₂, alarm functions are provided for monitoring.

Respiration rate can also be measured using the bellows device; however, alarm functions for this method are not provided.

Patient Preparation for RESP Monitoring

When preparing a patient, the monitoring method used will impact the performance and operation of the RESP parameter.

Monitoring Respiration using CO₂

Respiration using the CO₂ parameter is calculated by measuring the time interval between detected breaths; refer to chapter 7 for details.

Monitoring Respiration using the Bellows

The wSPO₂ module and bellows are intended for patient uses as an alternate to CO₂-derived respiration when respiration rate measurements are required. The wSPO₂ module and bellows may be used in the MR system bore, although the module must not be placed within the MRI field of view (FOV).

CAUTION

If dropped, the wSPO₂ module must be verified for correct operation before use.

NOTE

Refer to your facility's biohazard procedure for disposal of the bellows when it becomes unusable. Usually the bellows is disposed of as medical waste per facility procedures.

Respiration is monitored by detecting abdominal or chest wall motion using a pneumatic bellows device. Note that there are no user adjustable options or alarms for bellows-derived respiration as it is not intended for vital sign monitoring.



NOTE


If bellows respiration is turned on while the CO2 is on, bellows respiration data will appear in the RESP VS box and CO2 respiration data will appear in the CO2 VS box.

Bellows Preparation

Respiration measurements that are determined using the bellows method make chest wall expansion very important for accurate monitoring of a patient’s breathing. If the respiratory signal appears to weaken between scans, instruct the patient to breathe more deeply during the scan to create more movement at the sensor site.

To position the respiratory sensor

| Step | Action |
|------|--|
| 1 | Place the sensor on the patient’s upper abdomen or lower chest (whichever expands most during inspiration). |
| 2 | After the patient has exhaled, place the velcro strap around the patient’s trunk and secure the sensor snugly. |
| 3 | Connect the flexible hose to the pneumatic respiration port on the wSPO2 module. <div style="text-align: center;"> <p>Pneumatic respiration port</p> <p>Status indicator</p> </div> |
| 4 | Check the status indicator of the module; see page 2-8: <ul style="list-style-type: none"> • Solid green = Battery power good/Good communication • Flashing green = Battery power good/No communication • Solid red = Low battery power/Good communication • Flashing red = Low battery power/No communication |

| Step | Action |
|------|--|
| 5 | Press the Patient key  and then select the appropriate PATIENT type (see page 3-10 for details). |
| 6 | Check the respiratory signal before the patient is placed in the MR system. |
| 7 | Position the patient in the MR system. Ensure that the flexible hose does not get caught (for example, between the tabletop and the patient support). |

CAUTIONS

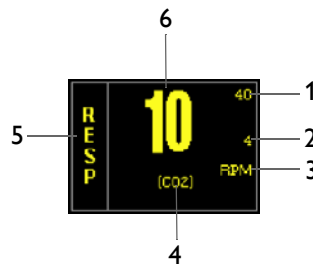
- Avoid excessive bending of the flexible hose, as this will impair detection of the patient's respiration.
- Always apply the respiration sensor to the patient prior to connecting to the pneumatic respiration port on the wSPO2 module. Connecting the pneumatic respiration sensor hose to the port prior to applying the sensor to the patient can result in damage to the wSPO2 module.

Respiration VS Box

The elements contained in the RESP VS box are described below.

NOTE

CO₂-derived respiration is shown in the example below. When bellows-derived respiration is selected, the related elements and VS box are displayed in white.



| Definition | |
|------------|---|
| 1 | Is the high limit setting of the respiration alarm (not present with bellows respiration); see page 8-5 |
| 2 | Is the low limit setting of the respiration alarm (not present with bellows respiration); see page 8-5 |

| Definition | |
|------------|---|
| 3 | Is the unit type for the respiration numeric data, where RPM is respirations per minute |
| 4 | Is the source used for the respiration monitoring, where CO2 is CO2-derived, and BEL is bellows-derived; see page 8-6 |
| 5 | Is the name of the vital sign/parameter |
| 6 | Is the respiration rate measurement (numeric) |

Changing RESP Alarm Limits

To change the RESP alarm limit settings

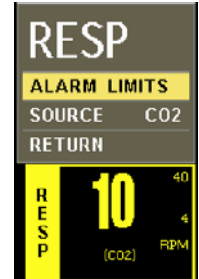
| Step | Action |
|------|--|
| 1 | Turn the control knob to highlight the RESP VS box (see page 8-5) and then press the knob. The RESP menu appears. Current settings are displayed. |
| 2 | Turn the control knob to ALARM LIMITS and then press the knob. The ALARM LIMITS menu appears. Current settings are displayed; see page 8-5 for details. |
| 3 | Turn the knob to the low or high setting and then press the knob. The setting is selected. |
| 4 | Turn the knob to change the setting value and then press the knob to make the change effective and return to the scrolling function. The setting is changed. |
| 5 | To change the remaining setting, repeat steps 3 and 4. |

NOTE


To make global changes to the parameter alarm limit settings based upon the patient's current vital sign readings, see Setting Alarm Limits Globally on page 9-4.

RESP Menu

The **RESP** menu allows you to control respiration functions and settings.

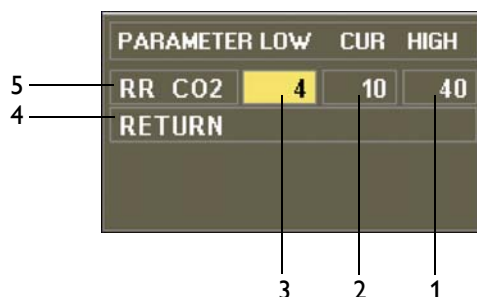


To change settings in the RESP menu

| Step | Action |
|------|--|
| 1 | Turn the control knob to highlight the RESP VS box and then press the knob. The RESP menu appears. Current settings are displayed. |
| 2 | Turn the control knob to select any of the following RESP options and then press the knob: ALARM LIMITS SOURCE For information about these options, see the appropriate sections below. |
| 3 | Turn the knob to the desired setting and then press the knob. |
| 4 | To change other settings, repeat steps 2 and 3. |
| 5 | Press the Main key  to close the menu. Alternative: Turn the knob to RETURN and then press the knob, or wait approximately 60 seconds. |

ALARM LIMITS

Controls the alarm limit settings for CO₂-derived respiration. (See the table on page 9-15 for a listing.)



| Definition | |
|------------|---|
| 1 | Is the setting of the high alarm limit |
| 2 | Is the current measurement |
| 3 | Is the setting of the low alarm limit |
| 4 | Saves the settings and returns to the normal mode |
| 5 | Identifies CO ₂ -derived respiration rate alarm limits |

To set the alarm limits for respiration

See *Changing the RESP Alarm Limits* on page 8-4.

SOURCE

Selects the source used to acquire respiration measurements.

The following choices are available:

- **CO₂** calculates the rate by measuring the time interval between detected breaths. (Default, when CO₂-equipped)
- **BEL** calculates the rate using a pneumatic bellows that measures chest or abdominal movement.

To select the source for respiration

Enter the **RESP** menu. Turn the control knob to **SOURCE** and press the knob. Scroll to the desired source and press the knob.

The MR200 alerts the user to physiological, technical and status alarms which may require attention or intervention.

Alarm Indications

Active alarms consist of both visual and audible components, where visual indications are provided by the LCD and audible indications are provided by the speaker. The alarm tone is user-adjustable with a typical sound pressure level of 48–83 decibels, and will sound after a delay of no more than 4 seconds following a visual alarm indication, provided that the alarm condition still exists after this delay.

Alarm Safety Information



WARNINGS

- **The monitor detects and responds almost immediately to most out-of-limits conditions, except when averaging of the physiological signal is required to reduce unwanted noise signals (for example, respiration rates and measurements derived from SPO2 signals.)**
 - **Set the alarm volume based upon the ambient noise levels in the MR environment. Some areas in the MR environment, such as the MR system room, may have ambient noise levels louder than the maximum volume of the MR200. Therefore, displayed data should be continuously monitored. Otherwise, if sound was inaudible, treatment of the patient could be delayed. For visual alarms, adjust the position of the cart so that you maintain a clear view of the display.**
-

Status and Technical Alarms

Conditions or events (such as low batteries or hardware errors) can result in alarms, which generate messages that will be displayed in a parameter's VS box and/or in the system message area or the notification area of the LCD (see page 2-13).

NOTE

If a systemic failure of the processing hardware, software or communications renders an intended task incomplete and unperformed, a watchdog circuit will automatically shutdown power to the WPU. This will result in the removal of all patient data and displayed information, and a continuous alarm will sound until power to the MR200 is turned off. If this problem persists, contact technical support.

Physiological Alarms

During monitoring, if a patient's vital sign measurement violates an active alarm limit setting, a physiological alarm will be declared. The monitor responds by sounding an alarm (if enabled) and by flashing the numeric and waveform (if provided) of the violated parameter in red on the LCD.

For example, if a patient's heart rate climbs to 71 BPM (which is above the setting of 60 for the upper alarm limit of the ECG vital sign) an alarm condition is declared.



| Definition | |
|------------|----------------------|
| 1 | Violated numeric |
| 2 | Violated alarm limit |
| 3 | Violated waveform |

Enabling Print on Alarm

If the MR200 is connected to an IP5 printer, you can automatically generate a printout when a physiological alarm occurs. See the IP5 IFU for setting details.

Controlling Alarm Indications



WARNINGS

- Always respond promptly to any alarm condition; otherwise, treatment of the patient could be delayed.
 - You should ensure that the current alarm preset is appropriate prior to use on each patient. Failure to do so may cause a lapse in patient monitoring.
 - Setting the alarm limits to extreme values can render alarm monitoring useless. Also, potential hazard can exist if different alarm monitoring settings are used for the same or similar equipment in any single patient care unit. Ignoring these restrictions may cause a lapse in patient monitoring.
-

The MR200 can be set to provide visual alarm signals only, or both visual and audible alarm signals. All settings in the **ALARMS** menu (except **ALARM SOUND**) can be stored and recalled.

NOTE

If the MR200 is networked to an IP5, alarm indications occur at both the cart and the IP5; and control of alarms, including sound level, is localized to the unit (cart or IP5) indicating the alarm condition.

Latched and Unlatched Alarms


When an unlatched alarm occurs, the alarm stops when the condition that triggered the alarm ends. For example, if a battery becomes low, the alarm ends when the battery is replaced. The majority of MR200 alarms are unlatched.

On the other hand, a latched alarm continues even after the condition that caused the alarm was resolved. **LOW PERF** is an example of a latched alarm. If **LOW PERF** occurs but then returns to within a normal range, the alarm will continue to display to notify the clinician of the SPO2 event. (To clear a latched alarm, see page 9-7.)

Showing or Hiding Current Alarm Limits

Current high and low alarm limits are displayed in the VS box of each monitored parameter by default (except bellows-derived respiration).

To change the alarm limit display

| Step | Action |
|------|--|
| 1 | Press the SETUP key  . The SETUP menu appears. |
| 2 | With ALARM SETUP highlighted, press the control knob. The ALARMS menu appears. Current settings are displayed. |
| 3 | Turn the knob to LIMITS DISPLAY and then press the knob. |
| 4 | Scroll to the desired setting and press the knob. The setting is selected. |

Setting Alarm Limits



WARNING

Alarm limits can be set to a wide range of values, including **off**. It is the responsibility of the operator of the MR200 to ensure that alarm limit values appropriate for each patient are established and set. Failure to do so may cause a lapse in patient monitoring.


The MR200 provides versatile methods to control the settings for the patient parameter alarms. Each patient parameter (with the exception of bellows respiration) has a low and high alarm limit setting (see the table on page 9-14), which can be changed manually or automatically, unless the parameter is off.

Setting Alarm Limits Globally

Global changes can be made to all parameter alarm limit settings based upon the patient's current vital sign reading using **CALCULATE ALL**; see page 9-10 for details. During this process, if a patient's monitored value is so high or low that it will exceed the alarm limit range for the parameter, the respective alarm limit will be set to the highest or lowest possible value, but not to off. For example, if after performing **CALCULATE ALL**, a patient's SPO2 upper alarm limit was automatically set to 99 (the highest allowable value), then an alarm will be generated if the patient's reading reaches 100. If you want to turn off the upper limit, then it must be done manually; see *Setting Alarm Limits Individually* on page 9-5.

Also note that when using **CALCULATE ALL** it will almost always result in a lower SpO2 limit than the default setting. For a patient that has an SpO2 reading of 99% the new upper limit will be 99, but the new lower limit will be 79 (instead of 85) at a **CALCULATE ALL** offset of 20% (factory default).


To adjust the alarm limit settings for all monitored parameters

| Step | Action |
|-------------|---|
| 1 | With the patient connected to the MR200 and with the desired parameters turned on, press the SETUP key  . The SETUP menu appears. |
| 2 | With ALARM SETUP highlighted, press the control knob. The ALARMS menu appears. Current settings are displayed. |
| 3 | Turn the knob to UPPER WINDOW and then press the knob. The current setting is highlighted. |
| 4 | Scroll to the desired percentage and press the knob. The following choices are available: 5% 10% 15% 20% 30% The setting is selected. |
| 5 | Turn the knob to LOWER WINDOW and then press the knob. The current setting is highlighted. |
| 6 | Scroll to the desired percentage and press the knob. The following choices are available: 5% 10% 15% 20% 30% The setting is selected. |
| 7 | Scroll to CALCULATE ALL then press the knob. All active alarm limit settings are changed. |

Setting Alarm Limits Individually

Individual parameter alarm limit settings can be controlled in the **ALARMS** menu or in the parameter's menu (see the appropriate monitoring chapter for details).


To adjust the alarm limit settings for a single parameter (using the ALARMS menu)

| Step | Action |
|------|---|
| 1 | Press the SETUP key  . The SETUP menu appears. |
| 2 | With ALARM SETUP highlighted, press the control knob. The ALARMS menu appears. Current settings are displayed. |
| 3 | With SET INDIVIDUAL highlighted, press the knob. The cursor highlights a low alarm limit setting in the menu. |
| 4 | Turn the control knob to select the alarm limit to be changed and then press the knob. The setting is selected and the highlighting changes color. |
| 5 | Turn the knob to change the setting value and then press the knob to make the change effective and return to the scrolling function. The setting is changed. |
| 6 | To change any remaining settings, repeat steps 4 and 5. |

Restoring Default Alarm Limit Settings

The system automatically restores default values when you change the patient type. (See page 9-15 for the default settings.)


To restore the alarm limits to the default settings

| Step | Action |
|------|---|
| 1 | With a monitored patient connected to the MR200, press the SETUP key  . The SETUP menu appears. |
| 2 | With ALARM SETUP highlighted, press the control knob. The ALARMS menu appears. Current settings are displayed. |
| 3 | Turn the knob to DEFAULT LIMITS and press the knob. The alarm settings are returned to the default values. |

Controlling the Alarm Sound


The alarm volume can be adjusted. In addition, the alarm sound can be temporarily disabled by pressing the **Silence** key, or it can be permanently disabled in the **ALARMS** menu (although the numeric and waveform will continue to flash while the parameter violates its alarm limit).

Once silenced, an alarm will not sound again for any reason as long as that condition continues. Only a different parameter violation will cause the alarm sound to reactivate. (For example, if a patient's heart rate drops below the set limit and that alarm is silenced, the alarm will not sound for that condition again unless the heart rate returns to within limits and then drops below the limit again.)


An active silenced alarm may not be accompanied by an **ALARM SILENCED** message or  symbol if the Alarm Hold sequence has been activated, or if a subsequent alarm has occurred and self-corrected.

Adjusting the Alarm Volume

To increase or decrease the alarm volume

| Step | Action |
|------|---|
| 1 | Press the SETUP key  . The SETUP menu appears. |
| 2 | Turn the knob to MONITOR SETUP and press the control knob. The MONITOR menu appears. Current settings are displayed. |
| 3 | Turn the knob to SOUND ADJUST and press the knob. The SOUND ADJUST menu appears. The current settings are displayed. |
| 4 | Turn the knob to ALARM VOLUME and press the knob. 1–10 (48–83 decibels, typical) The current setting is highlighted. For verification during adjustment, an acknowledgement is sounded at the selected level. |

Silencing the Alarm

Pressing the **Silence** key  during an alarm will silence all active alarms, depending upon the **TYPE** setting (see page 9-13):

- If **UNLATCHED**, the **Silence** key will mute the alarm sound and, while the violation continues, the displayed numeric and waveform of the parameter will flash in red. Any new alarm condition will cause the alarm to reactivate. Once the parameter returns to

within its alarm limit, the numeric and waveform will stop flashing and return to their designated color.


- If **LATCHED**, while the parameter continues to violate its limit, the **Silence** key will mute the alarm sound. The numeric and waveform will continue to flash in red after the parameter returns to within its alarm limits, then upon pressing the **Silence** key a second time the numeric flashing stops and the audible alarm is placed into Alarm Hold mode.

To silence audible alarms

Press the **Silence** key.

Alarm Hold Mode

Alarm Hold can be useful to temporarily silence alarms when changing ECG leads or for other user activities that might cause a “false” alarm.

Alarm Hold is indicated when  is displayed and **SOUND ON HOLD** appears in the system message area with a countdown timer starting at 120 seconds. The hold period is not user-adjustable. During the hold period, the audible alarm will be suspended for any new alarm conditions that occur.

To activate Alarm Hold

Press the **Silence** key  :

- If the alarm is not sounding, pressing the key enables hold mode.
- If the alarm is sounding, pressing the key twice enables hold mode.

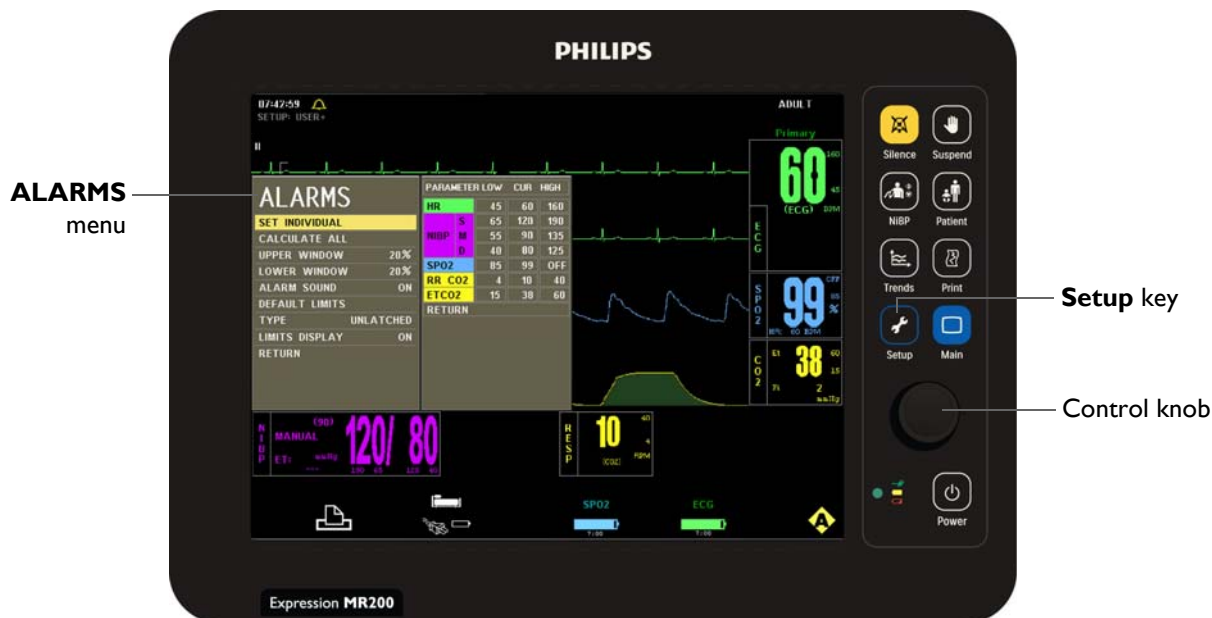
After the hold period expires, the sound for the physiological alarms are restored. Alarm conditions previously silenced by pressing the **Silence** key will not trigger an audible alarm when the hold period times out.

To deactivate Alarm Hold


- Wait until the countdown completes; or,
- Press the **Silence** key.


ALARMS Menu

The **ALARM SETUP** option (in the **SETUP** menu) opens the **ALARMS** menu, which contains options for setup and control of the vital sign alarms.



To change settings in the ALARMS menu

| Step | Action |
|------|---|
| 1 | Press the SETUP key  . The SETUP menu appears. |
| 2 | With ALARM SETUP highlighted, press the control knob. The ALARMS menu appears. Current settings are displayed. |
| 3 | Turn the control knob to select any of the following system-wide or individual alarm options and then press the knob: SET INDIVIDUAL CALCULATE ALL UPPER WINDOW LOWER WINDOW ALARM SOUND DEFAULT LIMITS TYPE LIMITS DISPLAY For information about these options, see the appropriate sections below. |
| 4 | Turn the knob to the desired setting and then press the knob. |

| Step | Action |
|------|---|
| 5 | To change other options, repeat steps 3 and 4. |
| 6 | Press the Main key  to close the menu. Alternative: Turn the knob to RETURN and then press the knob, or wait approximately 60 seconds. |

SET INDIVIDUAL

Controls the alarm limit settings for individual parameters.

| | 1 | 2 | 3 | 4 |
|-----------------------|-----------|-----|-----|------|
| ALARMS | | | | |
| SET INDIVIDUAL | | | | |
| CALCULATE ALL | | | | |
| UPPER WINDOW 20% | | | | |
| LOWER WINDOW 20% | | | | |
| ALARM SOUND ON | | | | |
| DEFAULT LIMITS | | | | |
| TYPE UNLATCHED | | | | |
| LIMITS DISPLAY ON | | | | |
| RETURN | | | | |
| | PARAMETER | LOW | CUR | HIGH |
| | HR | 45 | 60 | 160 |
| | S | 65 | 120 | 190 |
| | HIBP | 55 | 90 | 135 |
| | M | 40 | 80 | 125 |
| | D | 85 | 99 | OFF |
| | SP02 | 4 | 10 | 40 |
| | RR CO2 | 15 | 38 | 60 |
| | ETCO2 | | | |
| | RETURN | | | |

| Definition | |
|------------|---|
| 1 | Identifies the parameter |
| 2 | Are the current settings of the low alarm limits |
| 3 | Are the current readings of the patient |
| 4 | Are the current settings of the high alarm limits |
| 5 | Exits the menu |

To individually adjust the alarm limit settings

See page 9-5.

CALCULATE ALL

Calculates new alarm limit settings for all active parameters according to the settings in **UPPER WINDOW** and **LOWER WINDOW** options (see below). Corresponding low and high calculations will be performed for each active parameter.

To globally adjust the low and high alarm limit settings

See *Setting Alarm Limits Globally* on page 9-4.

NOTE

If a patient's monitored value is so high or low that it exceeds the alarm limit range for the parameter, the respective alarm limit will be set to the highest or lowest possible value, but not to off, as indicated in the table on page 9-14.

UPPER WINDOW

Sets a percent value used to calculate the high alarm limits when **CALCULATE ALL** is selected. The current parameter value is bracketed with the percentages set in this menu and the **LOWER WINDOW** setting.

The following choices are available:

- 5%
- 10%
- 15%
- 20% (Default)
- 30%

To set the upper calculation value

Enter the **ALARMS** menu. Turn the control knob to **UPPER WINDOW** and press the knob. Scroll to the desired percentage and press the knob.

LOWER WINDOW

Sets a percent value used to calculate the low alarm limits when **CALCULATE ALL** is selected. The current parameter value is bracketed with the percentages set in this menu and the **UPPER WINDOW** setting.

The following choices are available:

- 5%
- 10%
- 15%
- 20% (Default)
- 30%

To set the lower calculation value

Enter the **ALARMS** menu. Turn the control knob to **LOWER WINDOW** and press the knob. Scroll to the desired percentage and press the knob.

ALARM SOUND





WARNING


The alarm sound can be turned off. Always ensure that the alarm sound setting is appropriate for each patient. The alarm sound volume is adjustable for suitability to various clinical environments. When you use the MR200, always ensure that the alarm sound can be heard above the ambient noise level. Failure to do so may cause a lapse in patient monitoring.

Controls the audio alert for the alarms (identical to and interactive with **MONITOR > SOUND ADJUST > ALARMS**; see page 3-8).

The following choices are available:

- **ON** turns on the alarm sound, where  indicates that the sound has been enabled. (Default)
- **OFF** turns off the alarm sound, where  indicates that the sound has been disabled. (Only the alarm sound will be disabled; the visual alert from the source of the violation still flashes in red.)

To set the alarm sound

| Step | Action |
|------|--|
| 1 | Press the SETUP key  . The SETUP menu appears. |
| 2 | With ALARM SETUP highlighted, press the control knob. The ALARMS menu appears. Current settings are displayed. |
| 3 | Turn the control knob to ALARM SOUND and then press the knob: |
| 4 | Turn the knob to the desired setting and then press the knob. |

DEFAULT LIMITS

Automatically sets the low and high alarm limits for all parameters to the alarm limit defaults (see the table on page 9-15).

To set the alarm limit settings to the default limits

See *Restoring Default Alarm Limit Settings* on page 9-6.

TYPE

Determines the response of an alarm when the **Silence** key is pressed.

The following choices are available:

- **UNLATCHED** alarms cease audio and visual alerts if the violated parameter returns within its limits or if the **Silence** key is pressed. (Default)
- **LATCHED** alarms cease audio and visual alerts only when the **Silence** key is pressed.

To set the type of the alarm

Enter the **ALARMS** menu. Turn the control knob to **TYPE** and press the knob. Scroll to the desired setting and press the knob.

LIMITS DISPLAY

Determines if the alarm limit settings are shown in the VS boxes.

The following choices are available:

- **ON** displays the alarm limit settings. (Default)
- **OFF** hides the alarm limit settings.

To control the presence of the alarm limit settings

Enter the **ALARMS** menu. Turn the control knob to **LIMITS DISPLAY** and press the knob. Scroll to the desired setting and press the knob.

Testing Alarms

To verify that the alarm system is working

| Step | Action |
|------|--|
| 1 | With the monitor turned on and not in suspend mode, make sure all alarms are enabled (ALARM SOUND is not off, silenced, or on hold). |
| 2 | Make sure the lower SPO2 alarm limit is not set to OFF. |

| Step | Action |
|------|---|
| 3 | Verify the wSPO2 module status by checking the status indicator: <ul style="list-style-type: none"> • Solid green = Battery power OK/Good communication • Flashing green = Battery power OK/No communication • Solid red = Low battery power/Good communication • Flashing red = Low battery power/No communication |
| 4 | Place the SPO2 attachment on your finger and wait for a value to appear in the SPO2 VS box. |
| 5 | Remove the clip from your finger. |
| 6 | Ensure that the NON-PULSAT or PROBE OFF message appears in the SPO2 VS box, the waveform flat lines and turns red, the numeric flashes in red, and the alarm tone sounds. |

NOTE

If a problem with the alarm sound or messaging system is suspected, discontinue use of the MR200 and refer it to authorized service personnel for evaluation.

Adjustable Alarm Limit Ranges

With the exception of bellows respiration, each parameter alarm has adjustable limits as indicated in table below. The MR200 prevents crossover of low and high alarm limit settings; and, if a parameter has been turned off, its alarm limits will be off.

| Adjustable Alarm Limit Ranges | | | | | |
|-------------------------------|-------------|---------------------|-------------|--------------------|-----------------------|
| Vital Sign or Parameter | Unit | Low Alarm Limit * | | High Alarm Limit * | |
| | | Minimum | Maximum | Minimum | Maximum |
| Heart Rate | BPM | Off, 30 | 249 | 60 | 249, Off |
| CO2 (End-tidal)** | mmHg kPa | Off, 5 Off, 0.7 | 60 8.0 | 5 0.7 | 80, Off 10.7, Off |
| CO2 Respiration | RPM | Off, 4 | 40 | 20 | 99, Off |
| NiBP Systolic, Adult | mmHg kPa | Off, 46 Off, 6.1 | 254 33.9 | 46 6.1 | 254, Off 33.9, Off |
| NiBP Systolic, Pediatric | mmHg kPa | Off, 46 Off, 6.1 | 254 33.9 | 46 6.1 | 254, Off 33.9, Off |
| NiBP Systolic, Neonate | mmHg kPa | Off, 46 Off, 6.1 | 124 16.5 | 46 6.1 | 124, Off 16.5, Off |

| Adjustable Alarm Limit Ranges | | | | | |
|-------------------------------|-------------|---------------------|-------------|--------------------|-----------------------|
| Vital Sign or Parameter | Unit | Low Alarm Limit * | | High Alarm Limit * | |
| | | Minimum | Maximum | Minimum | Maximum |
| NiBP Mean, Adult | mmHg kPa | Off, 26 Off, 3.5 | 239 31.9 | 26 3.5 | 239, Off 31.9, Off |
| NiBP Mean, Pediatric | mmHg kPa | Off, 26 Off, 3.5 | 239 31.9 | 26 3.5 | 239, Off 31.9, Off |
| NiBP Mean, Neonate | mmHg kPa | Off, 26 Off, 3.5 | 94 12.5 | 26 3.5 | 94, Off 12.5, Off |
| NiBP Diastolic, Adult | mmHg kPa | Off, 16 Off, 2.1 | 224 29.9 | 16 2.1 | 224, Off 29.9, Off |
| NiBP Diastolic, Pediatric | mmHg kPa | Off, 16 Off, 2.1 | 224 29.9 | 16 2.1 | 224, Off 29.9, Off |
| NiBP Diastolic, Neonate | mmHg kPa | Off, 16 Off, 2.1 | 84 11.2 | 16 2.1 | 84, Off 11.2, Off |
| SPO2 | Percent | Off, 50 | 99 | 70 | 99, Off |

*Allow \pm one least significant digit to accommodate the round-off error for calculated values.

**High alarm limit for inspired CO₂ is fixed.

Alarm Limit Defaults

In the event of power loss, any alarm limit settings that were changed will be lost. All settings that may have been modified to suit a particular patient should be confirmed before monitoring.

At power up, the MR200 will automatically set all alarm limits as determined by the setting in the **DEFAULT SETUPS** menu; see page 3-13.

| Factory Default Alarm Limits* | | | | | | | |
|-------------------------------|-------------|-----------|-------------|-----------|-------------|-----------|-------------|
| Vital Sign or Parameter | Unit | Neonate | | Pediatric | | Adult | |
| | | Low Limit | High Limit | Low Limit | High Limit | Low Limit | High Limit |
| Heart Rate | BPM | 90 | 210 | 75 | 160 | 45 | 160 |
| CO ₂ (End-tidal) | mmHg kPa | 30 4.0 | 45 6.0 | 15 2.0 | 60 8.0 | 15 2.0 | 60 8.0 |
| CO ₂ Respiration | RPM | 30 | 70 | 4 | 40 | 4 | 40 |
| NiBP Systolic | mmHg kPa | 70 9.3 | 100 13.3 | 70 9.3 | 120 16.0 | 65 8.7 | 190 25.3 |
| NiBP Mean | mmHg kPa | 40 5.3 | 90 12.0 | 50 6.7 | 90 12.0 | 55 7.3 | 135 18.0 |

| Factory Default Alarm Limits* | | | | | | | |
|-------------------------------|-------------|-----------|------------|-----------|------------|-----------|-------------|
| Vital Sign or Parameter | Unit | Neonate | | Pediatric | | Adult | |
| | | Low Limit | High Limit | Low Limit | High Limit | Low Limit | High Limit |
| NiBP Diastolic | mmHg kPa | 35 4.7 | 50 6.7 | 40 5.3 | 70 9.3 | 40 5.3 | 125 16.7 |
| SPO2 | Percent | 90 | Off | 90 | Off | 85 | Off |

* Allow \pm one least significant digit to accommodate the round-off error for calculated values.

Listing of Alarms

All alarms are categorized as high priority.



WARNING

If, during use, an alarm condition listed below results in a loss of patient monitoring capability, employ an alternate means as needed to prevent a lapse in patient monitoring; otherwise, treatment of the patient could be delayed.

NOTE

In the tables below, abbreviations used in the Type column have these meanings: C = conditional; L = latched; S = selectable; and, U = unlatched.

Status and Technical Alarm Indications and Messages

The following table contains a listing of the status and technical alarm indications and messages.

| Displayed Message/ Indication | Message Location | Type | Probable Cause | Recommended Action |
|-------------------------------|--|------|-------------------------------------|--|
| ALARM SILENCED | System message area | U | The Silence key was pressed. | Wait until the 120-second countdown completes or press the Silence key. |
| | <i>NOTE</i> <i>No alarm sound generated</i> | | | |
| BAD PROBE | SPO2 VS box | U | The SPO2 sensor is defective. | Replace the SPO2 sensor. |


| Displayed Message/ Indication | Message Location | Type | Probable Cause | Recommended Action |
|----------------------------------|---------------------|------|--|--|
| CHANGE NiBP CUFF | Notification area | L | The PATIENT type was changed and this message is displayed as a reminder. | Ensure the correct cuff size is used for the patient. |
| CHECK ALARM VOL | System message area | U | Power was just turned on, settings were recalled, or an adjustment was made to a sound setting | No action necessary. Allow the process to complete. |
| CHECK CO2 SAMPLING LINE | Notification area | U | Reduced flow has been detected by the CO2 system. | Check for pinches or obstructions in the sampling line. Clear any pinch, or replace the accessory if necessary. |
| COMM ERR | NiBP VS box | L | NiBP internal error | Discontinue use of NiBP and contact technical support. |
| CO2 CAL FAIL | Notification area | C | CO2 calibration has failed. | Retry calibration. If the problem persists, contact technical support. |
| CO2 Hardware Fail | Notification area | C | CO2 module was not found during initialization | Contact technical support. |
| CO2 OUT OF RANGE | Notification area | U | The calculation value is greater than the upper CO2 limit . | Perform patient readings to confirm physiological condition. |
| CO2 SENSOR FAULTY | Notification area | L | CO2 bench detected a hardware or sensor error. | Contact technical support. |
| CO2 SENSOR OVER TEMP | Notification area | U | CO2 sensor is above the specified operating temperature. | Confirm that the MR200 is operating within required environmental conditions (see Appendix A). If outside the specified range, move the cart to an area that is within limits. If the problem persists, stop all monitoring activities and contact technical support. |
| CO2 WARMING UP | Notification area | U | Displayed during the warm-up period of the CO2 module | Allow the module to complete its warm-up cycle, about two minutes. |
| CO2 ZERO REQUIRED | Notification area | U | Zero calibration of the CO2 module is needed | Perform a zero calibration; see page 7-11. |
| DEFL TO | NiBP VS box | L | NiBP deflation has timed out. | <ul style="list-style-type: none"> • Check the patient. • Check for proper cuff size and placement. • Check the cuff and hoses for pinching. • If the message persists, contact technical support. |
| ERRATIC | SPO2 VS box | U | The SPO2 clip (or grip) is not properly applied to the patient, is not properly positioned, or the sensor is faulty. | <ul style="list-style-type: none"> • Check the alignment of the clip (or grip). • Replace the SPO2 sensor. • If the message persists, contact technical support. |
| HW ERR | NiBP VS box | L | NiBP hardware failure | Discontinue use of NiBP and contact technical support. |




| Displayed Message/ Indication | Message Location | Type | Probable Cause | Recommended Action |
|----------------------------------|---|------|--|---|
| HW FAIL | NiBP VS box | L | A hardware or other error has occurred in the NiBP system. | Discontinue use of NiBP and contact technical support. |
| HW FAIL | SPO2 VS box | L | A hardware or other error has occurred in the wSPO2 module. | Replace the wSPO2 module. If the failure persists, immediately remove the MR200 and wSPO2 module from service and contact technical support, as the system must not be used on any patient requiring SPO2 measurement. |
| INFL TO | NiBP VS box | L | NiBP inflation has timed out. | <ul style="list-style-type: none"> • Check the patient. • Check the cuff and hoses for pinching or leaks. • If the message persists, contact technical support. |
| Internal CO2 Occlusion | Notification area | U | The internal filter has become polluted or disconnected. | Contact technical support. |
| INTRFERENCE | SPO2 VS box | U | Interference due to misalignment of the attachment's light source and receiver, or incorrect positioning of the attachment on the patient. | <ul style="list-style-type: none"> • Ensure that the module is placed outside of the MR bore. • Reposition the wSPO2 module (see page 5-5). • Check the alignment of the clip (or grip). • Try a different limb or site. • Replace the clip (or grip). |
| LEAD FAIL | ECG trace area NOTE _____ <i>If the heart rate source is set to ECG, no HR value will be displayed in the ECG VS box.</i> _____ | U | A faulty or disconnected ECG lead is detected. NOTES _____ <i>An inoperative ECG parameter or wECG module is indicated by absence of an ECG waveform and a simultaneous Lead Fail alarm.</i> _____ | Ensure all clip leads are connected to the Quadrode electrode and that the ECG lead cable is properly connected to the wECG module. Also, ensure that the wECG module has sufficient battery power. If the problem persists, replace the ECG lead cable. |

| Displayed Message/ Indication | Message Location | Type | Probable Cause | Recommended Action |
|----------------------------------|---|------|--|---|
| LEAD SATURATION | ECG trace area NOTE _____ <i>If the heart rate source is set to ECG, no HR value will be displayed in the ECG VS box.</i> _____ | U | Reported within 10 seconds, the baseline offset of the ECG input signal is too large for the system to process and display the waveform. | Replace the Quadtrode electrode. |
| LOW PERF | SPO2 VS box NOTE _____ <i>No alarm sound generated</i> _____ | U | Accuracy may be compromised due to low perfusion. The tissue at the site may be too opaque, thick or cold. | <ul style="list-style-type: none"> • If the attachment is positioned on the finger, check the fingernails for nail polish, long or artificial fingernails. Remove any fingernail polish completely. • Try another location, like a toe. • Try rubbing or warming the limb. |
| Module Not Calibrated | NiBP VS box | L | NiBP is not calibrated. | Contact technical support. |
| MSMT FAIL | NiBP VS box | L | The NiBP measurement has failed. | <ul style="list-style-type: none"> • Check the patient. • Check for proper cuff size and placement. • Check the cuff and hoses for pinching or leaks. • If the message persists, contact technical support. |
| MSMT TO | NiBP VS box | L | The NiBP measurement has timed out. | <ul style="list-style-type: none"> • Check the patient. • Check for proper cuff size and placement. • Check the cuff and hoses for pinching or leaks. • If the message persists, contact technical support. |
| NiBP: COMMUNICATION ERROR | Notification area | L | Same as COMM ERR | See COMM ERR for details. |
| NiBP: DEFLATION TIMEOUT | Notification area | L | Same as DEFL TO | See DEFL TO for details. |
| NiBP: HARDWARE ERROR | Notification area | L | Same as HW ERR | See HW ERR for details. |
| NiBP: INFLATION TIMEOUT | Notification area | L | Same as INFL TO | See INFL TO for details. |

| Displayed Message/ Indication | Message Location | Type | Probable Cause | Recommended Action |
|--|---|------|---|---|
| NiBP: MEASUREMENT FAILED | Notification area | L | Same as MSMT FAIL | See MSMT FAIL for details. |
| NiBP: MEASUREMENT TIMEOUT | Notification area | L | Same as MSMT TO | See MSMT TO for details. |
| NiBP: OVER PRESSURE | Notification area | L | Same as OVR PRESS | See OVR PRESS for details. |
| NiBP: PRESSURE CORRECTION ERROR | Notification area | L | Same as PRESS CORR | See PRESS CORR for details. |
| NiBP: RESIDUAL PRESSURE | Notification area | L | Same as RESID PRESS. | See RESID PRESS for details. |
| NO PROBE | SPO2 VS box | U | The SPO2 sensor is not present or is improperly connected to the wSPO2 module. | Check the connection of the sensor to the module. Reconnect it; or if the connection is good, replace the sensor. |
| NOISE | SPO2 VS box | U | Excessive patient motion; MRI scan sequence; or, electrical interference is being experienced by the SPO2 system. | <ul style="list-style-type: none"> • Check for patient motion, especially at the monitored site. • Ensure that the module is placed outside of the MR bore. • Ensure the clip (or grip) is positioned so that it is not exposed to excessive levels of ambient light. |
| NON-PULSAT | SPO2 VS box | U | The patient's pulse is too weak for the system to report reliable SPO2 saturation and pulse measurements. | <ul style="list-style-type: none"> • Check the patient's condition. • Check the clip (or grip) position and alignment on the patient then re-position or re-apply as necessary • Try a different limb or site. |
| OVERSCALE | ECG trace area NOTE ——— <i>No alarm sound generated</i> ————— | U | The ECG waveform is too large and the peaks are being clipped. | Reduce the waveform size by choosing a setting in the ECG Scale menu. |
| OVR PRESS | NiBP VS box | L | NiBP has exceeded the allowed pressure for the patient type. | <ul style="list-style-type: none"> • Ensure that the patient is immobilized and not applying pressure to the cuff. • Check the cuff condition and placement on the patient. • Make sure that the hose is not pinched. • If the message persists, contact technical support. |

| Displayed Message/ Indication | Message Location | Type | Probable Cause | Recommended Action |
|----------------------------------|---|------|--|---|
| PERFORMING CO2 ZERO | Notification area | U | Displayed while performing CO2 zeroing. | No action necessary. Allow the process to complete. |
| PRESS CORR | NiBP VS box | L | An NiBP pressure correction error has been detected. | <ul style="list-style-type: none"> • Ensure that the patient is immobilized and not applying pressure to the cuff. • Check the cuff condition and placement on the patient. |
| PROBE OFF | SPO2 VS box <i>NOTE</i> ——— <i>Alarm sounds only if reported after a valid numeric is displayed.</i> ————— | U | The SPO2 attachment is not properly applied to the patient. | Check the position of the clip (or grip) and its alignment on the patient; reposition or reapply the clip (or grip). |
| PULSE? | SPO2 VS box | U | The clip (or grip) may not be applied optimally; or, the tissue at the application site may be too opaque. | <ul style="list-style-type: none"> • Check the alignment of the clip (or grip). • Try a different limb or site. |
| RESID PRESS | NiBP VS box | L | Residual pressure remains in the NiBP system. | Disconnect the NiBP hose and restart the procedure. |
| REAL TONES DISABLED | Notification area <i>NOTE</i> ——— <i>No alarm sound generated</i> ————— | U | Displayed when in the SOUND ADJUST > ALARMS menu | Exit the menu. |
| SEARCHING | SPO2 VS box <i>NOTE</i> ——— <i>Alarm sounds only if reported after a valid numeric is displayed.</i> ————— | U | The SPO2 attachment was just applied to the patient or it has shifted position since attachment. | <ul style="list-style-type: none"> • If SPO2 was just applied, allow about 20 seconds for the system to lock on to a good pulse. • Check the clip (or grip) position and reposition it if necessary. • Replace the SPO2 sensor. • If the message persists, contact technical support. |

| Displayed Message/ Indication | Message Location | Type | Probable Cause | Recommended Action |
|---|--|------|---|---|
| SIMULATION | System message area <i>NOTE</i> <i>No alarm sound generated</i> | L | Simulation mode is running. | Cycle power off and on. |
| SOUND ON HOLD | System message area <i>NOTE</i> <i>No alarm sound generated</i> | U | Power was turned on, or the Silence key was pressed. | Wait until the 120-second countdown completes or press the Silence key. |
| SUSPENDED | System message area <i>NOTE</i> <i>No alarm sound generated</i> | U | The Suspend key was pressed and alarms are now suspended. | Press the Suspend key to exit the mode. |
| WARNING Move monitor away from magnet. NiBP and CO2 (if installed) have been shut down. | Dialog box | U | The gauss limit has been exceeded, and now NiBP and CO2 can no longer function. | Position the MR200 per the product labeling; see page 2-6. |
| WARNING Persistent CO2 occlusion detected. Please clear occlusion and press OK to resume using CO2 | Dialog box | U | Reduced flow has been detected by the CO2 system for over 2 minutes. | Check for pinches or obstructions in the sampling line. Clear any pinch, or replace the accessory if necessary. Afterward, press OK to restart the CO2 parameter. If the message persists, contact technical support. |
| WRONG PRB | SPO2 VS box | U | The SPO2 sensor connected to the wSPO2 module is not the correct type. | Attach the correct sensor to the module. |
|  | Communication and power status display area | U | No communication between the cart and wSPO2 module | Ensure that the wSPO2 module is set to the same network channel as the cart. If both are the same, use an alternate setting. If the indication persists, contact technical support. |

| Displayed Message/ Indication | Message Location | Type | Probable Cause | Recommended Action |
|---|---|------|---|---|
|  | Communication and power status display area | U | No communication between the cart and wECG module | Ensure that the wECG module is set to the same network channel as the cart. If both are the same, use an alternate setting. If the indication persists, contact technical support. |
|  | Communication and power status display area | U | Low cart battery | Connect the cart to external power and allow the batteries to charge. |
|  | Communication and power status display area | U | Low module battery | Install a charged battery into the module. |

Physiological Alarm Indications and Messages


The following table contains an alphabetical listing of physiological alarm indications and messages.

| Displayed Message/ Indication | Message Location | Type | Probable Cause | Recommended Action |
|---|---|------|--|--|
| Red flashing VS numeric, and waveform (if applicable) | VS box of associated parameter | S | Alarm limit violation | Check the patient. |
| - - - | VS box of associated parameter <i>NOTE</i> — <i>Alarm sounds only if reported after a valid numeric is displayed.</i> | U | Parameter data once present is no longer available or a hardware failure has occurred. If occurring in the NiBP VS box, may indicate the measurement is out of range. | If an alarm was generated: <ul style="list-style-type: none"> • Ensure that the wireless modules are still communicating; see page 2-16 for status indications. • Ensure that all patient attachments are still connected. • A parameter's hardware may have experienced a problem; contact technical support. • Perform patient readings to confirm physiological condition. If no alarm was generated: <ul style="list-style-type: none"> • Allow a few seconds for the system to complete its processes. • A measurement value may be distorted or the signal may be inadequate; recheck all patient connections. |

| Displayed Message/ Indication | Message Location | Type | Probable Cause | Recommended Action |
|----------------------------------|--|------|---|---|
| OVR | ECG or SPO2 VS box (Replaces the numeric, except for ECG, which will alternate with a numeric value that is more than the highest specified heart rate.) | U | The heart rate measurement was greater than the upper measurement range of the parameter | Check the patient. If the indication persists, contact technical support. |
| UND | ECG or SPO2 VS box (Replaces the numeric, except for ECG, which will alternate with a numeric value that is less than the lowest specified heart rate.) | U | The heart rate measurement was less than the lower measurement range of the parameter | Check the patient. If the indication persists, contact technical support. |

Trend Data and Printing

Trend Data

The trend feature, accessed using the **TRENDS** key , provides options that include tabular and graphical trends reporting and trend arrow indications. Trend data is useful for assessing a patient over a period of time. The trend data captures the following information:

- Time and date at which each set of measurements was recorded
- Heart rate value and source
- NiBP
- SPO2
- CO2
- CO2-derived respiration

Trend data is stored from the time you begin monitoring and continues until the data is cleared or the monitor is turned off. All stored trend data, with the exception of tabular trend data, will be lost if power is removed. Trend data can displayed in a selectable format and interval.

Tabular Trend Data

Tabular trend data is provided on a page layout.

| HISTORY | | | | | | | |
|---------|-------|--------|------|----|------|-----|-----------|
| DATE | TIME | S/D | (M) | HR | SPO2 | CO2 | RESP(CO2) |
| 3-18-13 | 12:16 | 112/71 | (82) | 59 | 98% | 31 | 11 |
| | 12:19 | 115/78 | (91) | 60 | 97% | 32 | 15 |
| | 12:22 | 114/74 | (92) | 64 | 97% | 30 | 11 |
| | 12:25 | 116/73 | (89) | 64 | 96% | 32 | 12 |
| | 12:28 | 126/76 | (93) | 63 | 98% | 30 | 15 |
| | 12:31 | 118/73 | (88) | 67 | 97% | 31 | 14 |


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| Definition | |
|------------|---|
| 1 | Is the name of the dialog |
| 2 | Are the CO ₂ -derived respiration readings |
| 3 | Are the CO ₂ readings |
| 4 | Are the SPO ₂ readings |
| 5 | Are the heart rate readings |
| 6 | Is the page number, displayed oldest (first) to newest (last) |
| 7 | Are the NiBP mean readings |
| 8 | Are the NiBP systolic/diastolic readings |
| 9 | Is the time of the reading |
| 10 | Is the date of the reading |

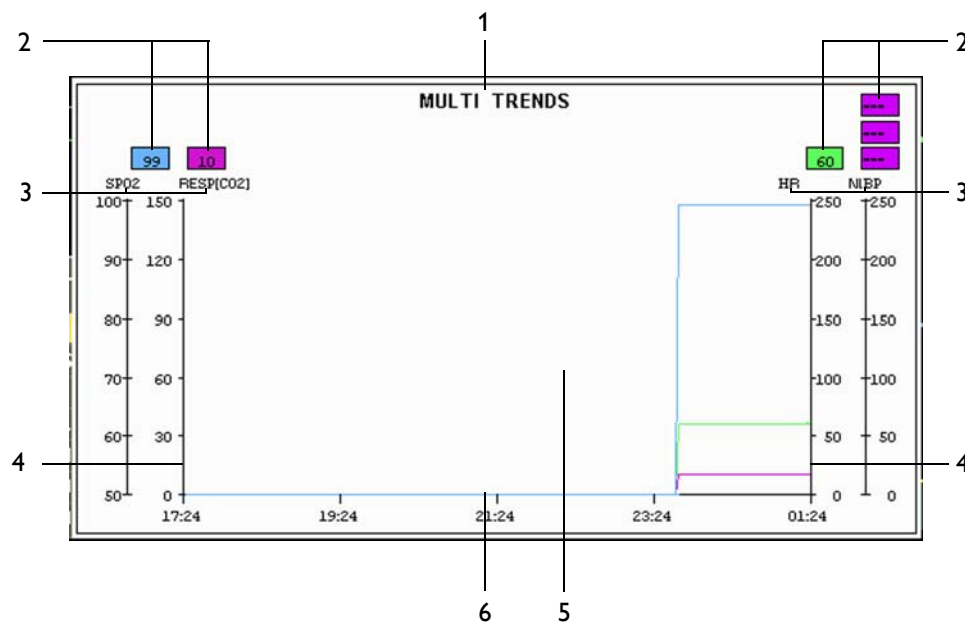
Viewing Multi-Parameter Tabular Trend Data

To view tabular trend data for multiple parameters

| Step | Action |
|------|--|
| 1 | Press the TRENDS key  (while in the normal mode). The HISTORY menu appears and the first page of trend data are displayed. |
| 2 | Turn the control knob to select any of the following options and then press the knob: PREV PAGE NEXT PAGE For information about these options and settings, see the appropriate sections below. |
| 3 | To view other pages, repeat step 2. |

Graphical Trend Data


Graphical trend data is plotted on a measured value versus time scale. Up to 24 hours of graphical trend data can be stored. After 24 hours, the oldest data is deleted to make room for newer data.



| Definition | |
|------------|--|
| 1 | Is the name of the graph |
| 2 | Are the numeric values of the selected parameters (y-axes) and plotted in the same color |
| 3 | Are the selected parameters (y-axis labels) |
| 4 | Is the y-axis plot |
| 5 | Is the plot grid |
| 6 | Is the x-axis plot |



Viewing Individual Trend Graphical Data

To view graphical trend data for a single parameter

Rotate the control knob to highlight the VS box of the desired parameter and then press the TRENDS key .

Viewing Multi Trend Graphical Data

To view graphical trend data for multiple parameters


| Step | Action |
|------|---|
| 1 | Press the TRENDS key  (while in the normal mode). The HISTORY menu appears and the first page of trend data are displayed. |
| 2 | Turn the control knob to MULTI TRENDS and then press the knob. The MULTI TRENDS submenu appears. |
| 3 | Turn the control knob to SELECT and then press the knob to choose the parameters used in the plot. |
| 4 | Turn the control knob to select any of the following parameters then press the knob to select the parameter. HR NiBP SPO2 ETCO2 RESP[CO2] This will form the y-axis of the plot. |
| 5 | If desired, repeat step 4 to select additional parameters (up to four can be plotted simultaneously). Then turn the control knob to RETURN and press the knob. |
| 6 | Turn the control knob to TIME BASE and then press the knob to set the time base used for the plot. |
| 7 | Turn the control knob to select one of the following intervals and then press the knob. 20 SEC 2 HOURS 4 HOURS 8 HOURS 24 HOURS This will be the x-axis of the plot. |
| 8 | Turn the control knob to MENU BACK and then press the knob to position the menu behind the graph for unobstructed viewing. |
| 9 | Turn the control knob to CURSOR/ZOOM and then press the knob to examine individual points in time. |
| 10 | While the cursor is in the most right side of the plot, press the knob again to exit the zoom function. |
| 11 | Press the Main key  to exit the menu. |


HISTORY Menu

The **HISTORY** menu provides options to select pages. Up to 48 trend records can be stored. A history file can be viewed for all parameters. The elements contained in the history file page are described below.



To change settings in the HISTORY menu

| Step | Action |
|------|--|
| 1 | Press the TRENDS key  (while in the normal mode). The HISTORY menu appears. Current settings are displayed. |
| 2 | Turn the control knob to select any of the following options and then press the knob: PREV PAGE NEXT PAGE CLEAR ALL MULTI TRENDS TREND ARROWS ARROW PERIOD For information about these options, see the appropriate sections below. |
| 3 | Turn the knob to the desired setting or item and then press the knob. |
| 4 | If MULTI TRENDS was selected, go to step 5; otherwise, go to step 7. |
| 5 | Turn the control knob to select any of the following options and then press the knob: SELECT CURSOR/ZOOM TIME BASE CLEAR ALL TREND ARROWS MENU BACK For information about these options, see MULTI TRENDS , below. |
| 6 | Turn the knob to the desired setting or item and then press the knob. |

| Step | Action |
|------|---|
| 7 | Press the Main key  to close the menu. Alternative: Turn the knob to RETURN and then press the knob, or wait approximately 60 seconds. |

PREV PAGE

Displays the previous page of the history file.

To display the previous page of the history file

See *Viewing Multi-Parameter Tabular Trend Data* on page 10-2 for details.

NEXT PAGE

Displays the next page of the history file.

To display the next page of the history file

See *Viewing Multi-Parameter Tabular Trend Data* on page 10-2 for details.

CLEAR ALL

Removes all trend data. As trend data is retained when a new patient is connected for monitoring, to avoid confusion, all previously acquired data should be cleared prior to connection of a new patient.

Before data erasure, a dialog box will prompt you for confirmation. Use the control knob to highlight the desired action and then press the knob to proceed.

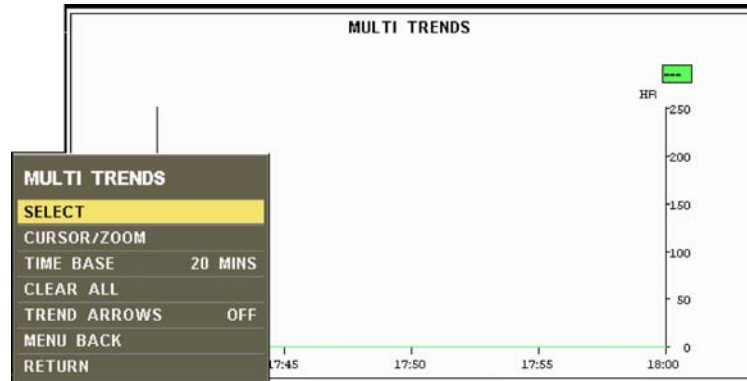


To clear all trend data

Press the **TRENDS** key. Turn the control knob to **CLEAR ALL** and press the knob.

MULTI TRENDS

Displays a graphical representation of selected monitored parameters.



The following choices are available:

- **SELECT** configures up to four simultaneous trends used to plot the y-axis of the graph.

The following choices are available:

- **HR** plots heart rate
 - **NiBP** plots NiBP
 - **SPO2** plots SPO2
 - **ETCO2** plots EtCO2
 - **RESP[CO2]** plots CO2-derived respiration
- **CURSOR/ZOOM** zooms into the trend chart, opening a window where individual points in time can be viewed. (To exit this feature, turn the control knob until the vertical line is as far to the right as possible and then press the knob.)

- **TIME BASE** configures the interval used to plot the x-axis of the graph.

The following choices are available:





- **20 SEC** (Default)
 - **2 HOURS**
 - **4 HOURS**
 - **8 HOURS**
 - **24 HOURS**
- **CLEAR ALL** deletes all data from the trend history.
 - **MENU BACK** moves the menu behind the graph window.

To display the Multi Trends graph and submenu

Press the **TRENDS** key. Turn the control knob to **MULTI TRENDS** and press the knob.

TREND ARROWS

Controls a vital sign trend indication, where a trend arrow is displayed alongside the VS box (not available for bellows-derived respiration) with a meaning as defined in the table below. (See page 2-14 for an example.)

| Indication | Meaning |
|---|---------------|
|  | Rising |
|  | Declining |
|  | Stable |
|  | None declared |

The following choices are available:

- **ON** turns on the trend arrows.
- **OFF** turns off the trend arrows. (Default)

To display trend arrows

Press the **TRENDS** key. Turn the control knob to **TREND ARROWS** and press the knob. Then turn the control knob to **ON**.



WARNING

Depending upon the **ARROW PERIOD** and measurement cycles of the vital signs, NiBP trend arrow indications may not be representative of the current condition of the patient.

ARROW PERIOD

Sets the time used to calculate and declare the direction for the trend arrows.

The following choices are available:

- **30 SEC**
- **1 MIN**
- **3 MIN** (Default)
- **5 MIN**
- **10 MIN**

To set the arrow period

Press the **TRENDS** key. Turn the control knob to **ARROW PERIOD** and press the knob. Then turn the control knob to the desired interval.


NOTE

If a newly selected period is shorter than the previous period (and the arrows have been on for the longer of the two periods) then immediate recalculation using the new period will occur. Alternately, if the newly selected period is longer than the previous period, recalculation will occur using all available data.

Print Functions

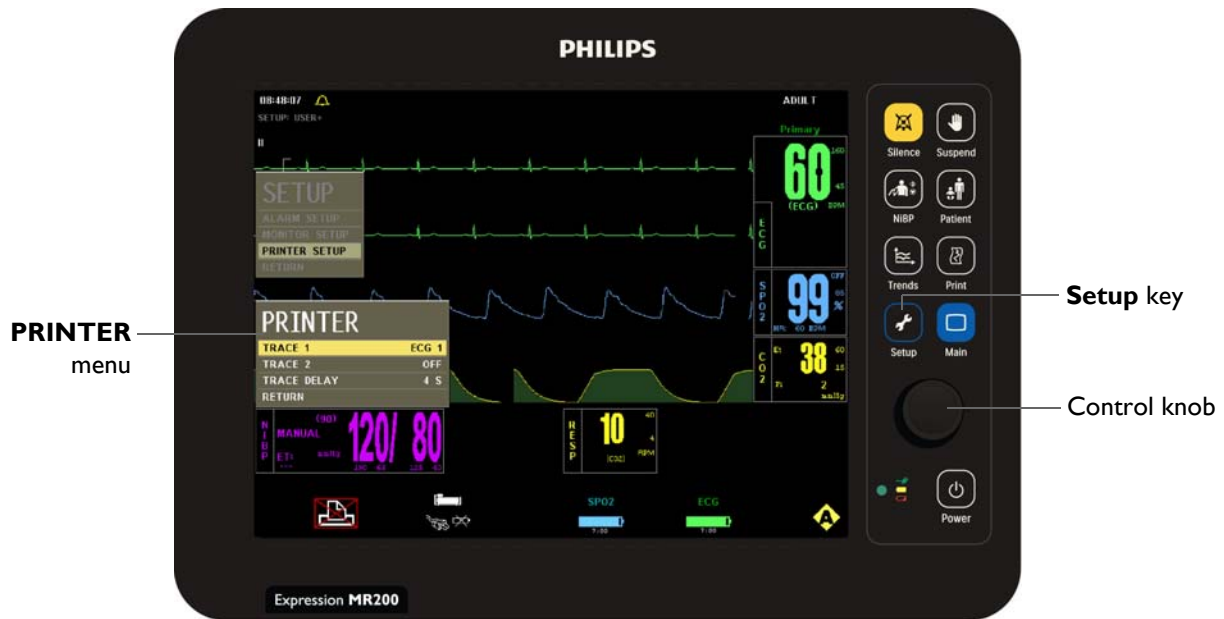
When equipped with an IP5 printer, the MR200 can provide single or dual waveform strip charts.

NOTES



- *If a printer-equipped IP5 is not installed or connected to the system,  will be displayed in the communication and power status display area on the LCD. For a listing of printer icons, see page 2-16.*
 - *Any print command from the MR200 automatically initiates a 30-second print cycle at the IP5.*
 - *Any print command initiated from the MR200 takes precedence over the IP5 print functions.*
-

PRINTER Menu

The **PRINTER SETUP** option (in the **SETUP** menu) opens the **PRINTER** menu, which contains options for printer setup and control when the MR200 is equipped with an optional IP5 and printer. For expanded printing options not covered in this manual, consult the IP5 IFU.

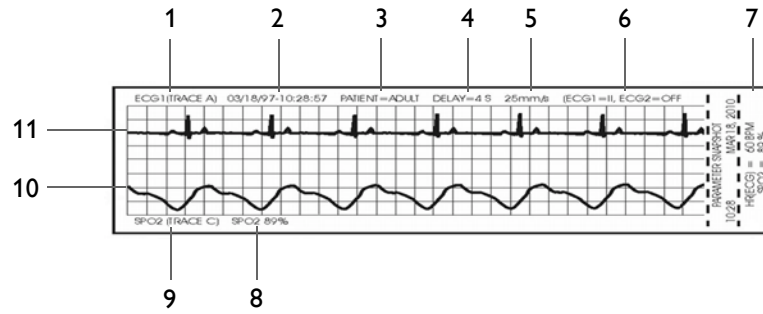


To change settings in the PRINTER menu

| Step | Action |
|------|---|
| 1 | Press the SETUP key  . The SETUP menu appears. |
| 2 | Turn the control knob to PRINTER SETUP and then press the knob. The PRINTER menu appears. Current settings are displayed. |
| 3 | Turn the control knob to select any of the following printer options and then press the knob: TRACE 1 TRACE 2 TRACE DELAY For information, see the appropriate sections below. |
| 4 | Turn the knob to the desired setting and then press the knob. |
| 5 | To change other options, repeat steps 3 and 4. |
| 6 | Press the Main key  to close the menu. Alternative: Turn the knob to RETURN and then press the knob, or wait approximately 60 seconds. |

TRACE 1

Enables the first trace to be output by the printer. The strip chart may be configured to contain one or two waveforms (see TRACE 2, below). A description of each item printed on the strip chart is provided below.



| Definition | |
|------------|---|
| 1 | Trace 1 parameter |
| 2 | Date and time (formatted as MM/DD/YY-HH:MM:SS) |
| 3 | Patient type |
| 4 | Trace delay |
| 5 | Trace speed |
| 6 | Parameter information |
| 7 | Values of active parameters at time of printing |
| 8 | Trace 2 parameter information |
| 9 | Trace 2 parameter |
| 10 | Trace 2 waveform |
| 11 | Trace 1 waveform |

The following choices are available:

- **ECG 1** (Trace A) (Default)
- **ECG 2** (Trace B)
- **SPO2** (Trace C)
- **RESP (CO2)** (Trace D)

To print a Trace 1 waveform

Enter the **PRINTER** menu. Press the control knob to select **TRACE 1** and press the knob. Scroll to the desired output and press the knob.

TRACE 2

Enables the second trace to be output by the printer.

The following choices are available:

- **OFF** (Default)
- **ECG 1** outputs the Trace A waveform. (Default)
- **ECG 2** outputs the Trace B waveform.
- **SPO2** outputs the Trace C waveform.
- **RESP (CO2)** outputs the Trace D waveform.

To print a Trace 2 waveform

Enter the **PRINTER** menu. Turn the control knob to **TRACE 2** and press the knob. Scroll to the desired output and press the knob.

NOTE

*If **TRACE 2** is Off, a single trace is printed using the full 40 mm width of the strip chart. When printing two traces, the waveform to grid ratio will not correspond to the waveform/scale indicator size displayed on the LCD.*

TRACE DELAY

Sets a delay period for the printed trace.

The following choices (in seconds) are available:

- **0** (Default)
- **4**
- **8**
- **16**

To set a printing time delay

Enter the **PRINTER** menu. Turn the control knob to **TIME DELAY** and press the knob. Scroll to the desired setting and press the knob.

Cleaning and Maintenance

Environmental Requirements

Royal Philips Healthcare is concerned about protecting the natural environment and to help ensure continued safe and effective use of this product through proper support, maintenance and training. Royal Philips equipment is therefore designed and manufactured to comply with relevant guidelines for environmental protection. As long as the equipment is properly operated and maintained, it presents no risk to the environment. However, the equipment may contain materials which could be harmful to the environment if disposed of incorrectly. Use of such materials is essential for the implementation of certain functions and for meeting certain statutory and other requirements.

This section of the Instructions for Use is directed mainly at the user of the equipment or system, the body with legal authority over the equipment. Operators are not usually involved in disposal, except in the case of certain batteries, see page 11-7.

General Cleaning Guidelines

Keep the MR200 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:

- *Users inside USA, call us at (877) 468-4861*
 - *Users outside USA, call us at +31 (0) 499 378299*
-

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.

Use only the Royal Philips-approved substances and methods listed in this chapter to clean or disinfect the equipment. Royal Philips makes no claims regarding the efficacy of the listed chemicals or methods as a means for controlling infection. Warranty does not cover damage caused by using unapproved substances or methods.

The recommended types of disinfecting agents are listed in the table below. We make 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 |
|--|--------------|
| Actichlor™ Plus | Tablet* |
| CaviWipes® Disinfectant | Towelette |
| Coverage® Spray TB, TB Plus, HB Plus** | Spray |
| Sklar Disinfectant** | Towelette |
| Sani-Cloth Plus Wipes** | Towelette |

*Follow manufacturer's instructions for mixing; we recommend a solution of 5,000 ppm.

**Any product residue should be removed by wiping.

Cleaning the Cart and Modules



WARNING

Always disconnect the MR200 from AC power, and remove the batteries from the cart and the wireless modules, before performing any cleaning or maintenance. To avoid an electrical hazard, never immerse any part of the MR200 in any cleaning agent or attempt to clean it with liquid cleaning agents.

Follow the general guidelines to clean the cart and the wECG and wSPO2 modules. Always turn off the cart and the modules to perform cleaning. Never immerse portion of the cart or the modules in fluid or attempt to clean the devices by directly applying liquid cleaning agents.

CAUTIONS

- Other than those specified in the preceding table, avoid ammonia-, phenol- and acetone-based cleaners as they will damage the surfaces of the MR200.
- Disinfect the cart and modules as determined by your hospital's policy to avoid long term damage to the product.
- Do not permit liquid to contact the front or rear of the display panel. Do not permit liquid to drip into or around the LCD. Contact technical support if liquid enters any component.
- If the MR200 becomes accidentally wet during use, discontinue operation until all affected components have been cleaned and permitted to completely dry. Contact technical support if additional information is required.

To clean and disinfect the cart and wireless modules

| Step | Action |
|------|--|
| 1 | Turn off the cart and unplug the AC power cord. Remove the batteries, if installed. |
| 2 | Remove the battery from each wireless module. |
| 3 | Remove all visible debris from the cart and wireless modules using soap and water. CAUTIONS Never pour liquid onto the equipment. |
| 4 | Clean the cart and modules by thoroughly wiping the devices using CaviWipes Disinfectant towelettes. Discard the used towelettes (refer to your facility's biohazard procedure for disposal). NOTE Follow the instructions for use from the disinfectant manufacturer to clean the cart and modules. |
| 5 | Disinfect the cart and modules by thoroughly wetting the devices using CaviWipes Disinfectant towelettes. Discard the used towelettes (refer to your facility's biohazard procedure for disposal). NOTE Follow the instructions for use from the disinfectant manufacturer to disinfect the cart and modules. |

| Step | Action |
|------|--|
| 6 | Allow the cart and the modules to dry. (No rinsing is required.) |
| 7 | Check the cart and the modules for any residual debris. If any debris is present, repeat steps 3 through 6 then re-examine the cart and modules before proceeding. |
| 8 | Check the cart and modules for damage and contact technical support if damage is found. |

Sterilizing the Cart and Wireless Modules

The cart and the modules are not sterilizable; do not immerse any part of these devices in fluid or attempt to clean them with liquid cleaning agents. Severe damage, not covered by the warranty, will result.

Cleaning the Accessories

Any reusable patient accessory (such as SPO2 attachments and sensors, ECG cables, NiBP cuffs, chest bellows, etc.) must be cleaned and disinfected before initial use, and then after each use, to protect patients and personnel from a variety of pathogens. Use soap and water, and a suggested disinfectant and method, to clean and disinfect the accessories. The warranty does not cover damage caused by unapproved substances or methods.

Disposable accessories must be discarded and replaced with new items.

WARNING



Single-use devices, as indicated on the device packaging, should be disposed of after use and must never be reused. Reuse of single-use devices can result in spread of patient infection, degradation of monitoring performance, or inaccurate measurements.



CAUTIONS

- Never immerse an accessory in any cleaning fluid.
- Do not autoclave any part of the equipment. Disinfect the accessory as determined by your facility's policy.

NOTE

Disposable SPO2 attachments: After some use, adhesive residue may accumulate at the fiber heads on the sensor cable. Remove carefully any residue with some alcohol. The glass fiber ends must always be clear and free from residuals.

To clean a reusable accessory

| Step | Action |
|-------------|--|
| 1 | Remove the accessory from use. |
| 2 | Remove all visible debris from the accessory using soap and water. CAUTION _____ Never pour liquid onto the accessory. _____ |
| 3 | Clean the accessory by thoroughly wiping it using CaviWipes Disinfectant towelettes. Discard the used towelettes (refer to your facility's biohazard procedure for disposal). NOTE _____ <i>Follow the instructions for use from the disinfectant manufacturer to clean the sensor.</i> _____ |
| 4 | Disinfect the accessory by thoroughly wetting it using CaviWipes Disinfectant towelettes. Discard the used towelettes (refer to your facility's biohazard procedure for disposal). NOTE _____ <i>Follow the instructions for use from the disinfectant manufacturer to disinfect the sensor.</i> _____ |
| 5 | Allow the accessory to dry. (No rinsing is required.) |
| 6 | Check the accessory for any residual debris. If any debris is present, repeat steps 2 through 5 then re-examine the sensor before proceeding. |
| 7 | Check the accessory for damage and discard the accessory if damage is found; see page 11-6 for details. |
| 8 | Store the accessory; see page 11-6 for details. |
| 9 | Inspect the accessory for any cracks, holes, tears, cuts, etc. that could affect operation and replace as necessary. |

Sterilizing the Accessories

The accessories are not sterilizable. Severe damage, not covered by the warranty, will result.

Inspecting the Accessories for Damage

The accessories are exposed to potentially damaging situations during use and cleaning. Before each use, carefully inspect the accessories for the following signs of damage:

- Cracks, holes, tears, gouges, cuts, etc.
- Cracks or other signs of damage to the connector, including bent or damaged pins.



WARNING

Cracks, tears, cuts and gouges interfere with standard cleaning procedures and therefore pose a potential risk to patients and personnel. If you see any sign of damage to any accessory, immediately discontinue use.

Storing the Accessories

The cart has built-in storage features to house wireless modules and accessories used during monitoring; see page 2-3.



WARNING

To reduce the spread of infection, do not store accessories directly on the MR200 handles.

CAUTION

When inserting or removing the accessories from the cart or wireless modules, only use the connector and never pull or apply excessive force or tension to any other portion of the device.

To store the wireless modules and sensors and cables

When not in use, slide the wECG and wSPO2 modules into the module holders on the cart.

To store the other accessories

When not in use, loop sample lines and then place them in the storage basket or drape them over an optional accessory hook.

Final Disposal

Final disposal is when the user disposes of the equipment (system, accessories and batteries) in such a way that it can no longer be used for its intended purposes.



WARNING

Do not dispose of this product (or any parts of it) in industrial or domestic waste. The system may contain materials and hazardous substances that can cause serious environmental pollution. The system also contains privacy sensitive information. It is advisable to contact your Royal Philips Service Organization before disposing of this product.



Royal Philips Healthcare gives support for:

- Recovery of reusable parts.
- The recycling of useful materials by competent disposal companies.
- Safe and effective disposal of equipment.

For detailed disposal information, go to the following web page:

<http://www.healthcare.philips.com/main/about/sustainability/recycling/pm.wpd>

The recycling passports located there contain information on the material content of the equipment, including potentially dangerous materials which must be removed before recycling (for example, batteries).

Disposal of the Device and Accessories

The MR200 and accessories are subject to strict disposal regulations for user and environmental safety. Never dispose of waste electrical and electronic equipment as unsorted municipal waste. Collect it separately so that it can be safely and properly reused, treated, recycled or recovered.

WARNING

To avoid contaminating or infecting personnel, the environment or other equipment, make sure you disinfect and decontaminate the MR200 appropriately before disposing of it in accordance with your country's laws for equipment containing electrical and electronic parts. Do not dispose of this product (or any parts of it) in industrial or domestic waste. The system may contain materials such as lead, tungsten or oil, or other hazardous substances that can cause serious environmental pollution. The system also contains privacy sensitive information. It is advisable to contact your Royal Philips Service Organization before disposing of this product. You can disassemble the MR200 and accessories as described in the service manual.

Disposing of Batteries

The lithium batteries found in the system and some of the accessories or optional equipment may be subject to strict disposal regulations for user and environmental safety. Observe and adhere to your current local regulations when disposing of batteries.

CAUTIONS

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

Maintenance

Periodic maintenance for the MR200, as outlined below, must be followed.

CAUTION

Annual preventative maintenance is recommended unless stated otherwise in the service manual. For proper equipment maintenance, perform the service procedures at the recommended intervals as described in the service manual.

Testing CO2 Accuracy

The CO2 flow rate accuracy should be verified by direct measurement using a calibrated flow meter every 12 months. (See **GAS CAL** on page 11-14.)

CAUTION

An internal leak may result in condensation within the system. If this is suspected or if condensation is observed, discontinue use and contact technical support.

Testing the NiBP System



The NiBP system should be tested at least once every 12 months to ensure proper operation.



WARNING


Never initiate the LEAK TEST while the cuff is applied to a patient. Continuous cuff pressure can lead to patient injury.

To test the NiBP system for leakage

| Step | Action |
|------|---|
| 1 | Attach a normal adult cuff and interconnect hose, or a test volume to the MR200. |
| 2 | Press the PATIENT key  . The PATIENT menu appears. |
| 3 | Turn the control knob to ADULT (or PEDIATRIC) and then press the knob. |
| 4 | Press the SETUP key  . The SETUP menu appears. |
| 5 | Turn the control knob to MONITOR SETUP and then press the knob. The MONITOR menu appears. Current settings are displayed. |
| 6 | Turn the control knob to SERVICE(BIO-MED) and press the knob. The SERVICE(BIO-MED) menu appears. |
| 7 | Turn the control knob to NiBP TESTS and press the knob. The NiBP TESTS menu appears. |
| 8 | Turn the control knob to LEAK TEST and then press the knob. The NiBP LEAK TEST dialog box appears. |
| 9 | Turn the knob to the desired action and then press to proceed. <div data-bbox="857 1255 1334 1465" data-label="Image"> </div> |
| 10 | Results are provided on the LCD as the routine progresses through the different tests. |

Default Initialization

The settings for the MR200 can be restored to factory default values.

| Step | Action |
|------|--|
| 1 | Press the SETUP key  . The SETUP menu appears. |
| 2 | Turn the control knob to MONITOR SETUP and then press the knob. The MONITOR menu appears. Current settings are displayed. |
| 3 | Turn the control knob to DEFAULT SETUPS and press the knob. |
| 4 | Scroll to FACTORY and press the knob. All current settings will be lost. |
| 5 | Turn off the MR200. |
| 6 | Turn on the MR200. The monitor's settings are returned to the factory default values. |

Updating Software

As revisions to the software become available, the MR200 can be updated. It is recommended that you save your settings prior to updating software, so that they can be restored afterward; see **STORE SETUPS** on page 3-5.

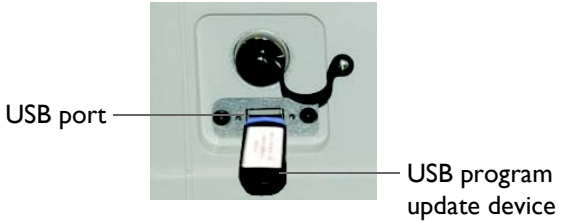
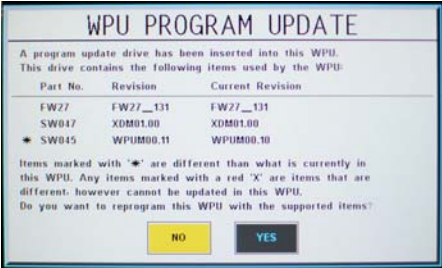





WARNING

When performing software updates (or upgrades) to the operating software of the MR200, ensure that all remaining devices in the monitor's network are at the same or a compatible software revision level. Failure to observe this requirement could result in compatibility conflicts, communication problems, etc.

To update the operating software

| Step | Action |
|------|---|
| 1 | Connect AC power to the cart and insert at least one fully charged battery. |
| 2 | Turn on the cart then wait until the normal mode is displayed; see LCD on page 2-13. |

| Step | Action |
|------|--|
| 3 | <p>Insert the USB program update device that contains the desired software into the USB port.</p> <div style="text-align: center;">  </div> |
| 4 | <p>The WPU Program Update window appears.</p> <div style="text-align: center;">  </div> <p>Current software revisions are displayed, where any needed update will be denoted by an asterisk.</p> |
| 5 | <p>Turn the control knob to YES and then press the knob to proceed.</p> <p>The software update begins. A progress bar is displayed and when all applicable program updates have finished, the WPU Program Update window changes to indicate completion.</p> |
| 6 | <p>Turn off the cart and remove the USB program update device from the USB port.</p> |
| 7 | <p>Press and hold the control knob while turning on power to the cart.</p> |
| 8 | <p>Observe the LCD. When the cursor moves to the upper left corner of the screen (approximately 10–15 seconds after power-up), release the control knob then immediately press and hold the Main key .</p> |
| 9 | <p>When the cold start banner is momentarily displayed, release the Main key</p> <div style="text-align: center;">  </div> <p>The MR200 will boot to the normal mode.</p> |
| 10 | <p>If the cold start banner was not displayed, repeat steps 7–9.</p> |

| Step | Action |
|------|---|
| 11 | Press the Setup key  . The SETUP menu appears. |
| 12 | Turn the control knob to MONITOR SETUP and then press the knob. The MONITOR menu appears. Current settings are displayed. |
| 13 | Turn the control knob to SERVICE(BIO-MED) and then press the knob. The SERVICE(BIO-MED) menu appears. Current settings are displayed. |
| 14 | With S/W REV highlighted, press the control knob. Verify that the displayed REVISION INFORMATION includes the version number for the software that was updated. |

SERVICE(BIO-MED) Menu

The **SERVICE(BIO-MED)** menu contains software and firmware information about the system and options for pressure, diagnostics and configuration.





NOTE

*Some **SERVICE(BIO-MED)** menu options require entry of a password for access. For password assistance, contact technical support. For details regarding these password-protected options, reference the service manual.*

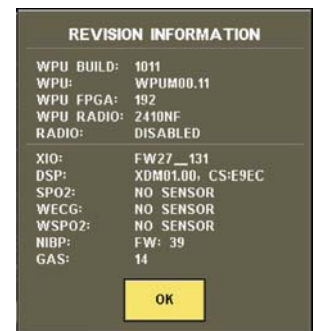


To enter the SERVICE(BIO-MED) menu

| Step | Action |
|------|--|
| 1 | Press the SETUP key  . The SETUP menu appears. |
| 2 | Turn the control knob to MONITOR SETUP and then press the knob. The MONITOR menu appears. Current settings are displayed. |
| 3 | Turn the control knob to SERVICE(BIO-MED) and then press the knob. The SERVICE(BIO-MED) menu appears. Current settings are displayed. |
| 4 | Turn the control knob to select any of the following options and then press the knob: S/W REV SIMULATION MODE NIBP TESTS GAS CAL SERVICE UTILITIES SYSTEM CONFIG For information about these options, see the appropriate sections below. |
| 5 | Press the Main key  to close the menu. Alternative: Turn the knob to RETURN and then press the knob. |

S/W REV

Opens a window that contains revision level and build date information for the software components. (To close the window, press the control knob or wait 60 seconds.)




SIMULATION MODE

Places the MR200 into simulation mode.

To enter simulation mode

Press the control knob. A dialog box will prompt you for confirmation. Use the control knob to highlight the desired action and then press the knob to proceed.



While in simulation mode, to initiate simulated NiBP functions, press the  NiBP key.

To exit simulation mode

Turn off the power switch.



WARNING

The MR200 is equipped with a simulation mode that displays computer generated data for training or demonstration. As a safety feature, **SIMULATION** is displayed and appears on all printouts while in simulation mode. Do not attach a patient to the MR200 when in simulation mode and never activate simulation mode when a patient is connected. The MR200 will not monitor patients while in the simulation mode. Activating simulation mode when a patient is connected will result in a lapse in patient monitoring and could result in a delay in treatment.

NiBP TESTS

Accesses NiBP calibration and testing functions.

- **CALIBRATE** performs calibration of the NiBP system. (Password required)
- **LEAK TEST** tests the NiBP system for pressure leaks.

To perform the leak test

See page 11-8.

- **STATIC TEST** tests the pressure of the NiBP system. (Password required)

GAS CAL

Accesses the CO2 calibration and testing functions.

NOTE

Wait 2 minutes for CO2 warm-up before calibrating or performing an accuracy check.

The following choices are available:

- **ZERO CAL** performs a zero calibration of the CO2 system. (Also see page 7-11.)

To start zero calibration

Enter the **SERVICE(BIO-MED)** menu. Turn the control knob to **GAS CAL** and press the knob. Scroll to **ZERO CAL** and press the knob.

- **CO2 ACCURACY CHECK** tests the CO2 function (a 5% source must be connected). Provides a CO2 waveform value (as a percentage), an atmospheric pressure reading and a numeric CO2 value (in mmHg).



To perform an accuracy check

Connect the 5% CO2 source to the CO2 port. Enter the **SERVICE(BIO-MED)** menu and scroll to **GAS CAL**. Press the control knob then scroll to **CO2 ACCURACY CHECK** and press the knob again. (A warning dialog will appear: **CO2 BENCH SHOULD BE WARMED UP PRIOR TO STARTING ACCURACY TEST**. Press the control knob when ready to proceed.)

NOTE

*During the accuracy check, to alert you that the indicated values are not actual patient numerics, the following dialog box message will be displayed: **CO2 test in progress. Do not use CO2 values for patient monitoring during test. Pressing close will cancel test.***

SERVICE UTILITIES

Accesses service-related functions (password required); see the service manual for details.

SYSTEM CONFIG

Configures the parameters and options of the MR200. (For password protected functions, see the service manual for details.)

| SYSTEM CONFIG | | | | |
|---------------|-----------|-------------|----------------|----------|
| MONITOR | ECG 1 | ENABLED | UNUSED | DISABLED |
| RECALL SE | ECG 2 | ENABLED | PRINTER | ENABLED |
| STORE SET | NIBP | ENABLED | UNUSED | ENABLED |
| SERVICE | S/W REV | DISABLED | UNUSED | ENABLED |
| SIMULATI | SIMULATI | DISABLED | UNUSED | ENABLED |
| NIBP TES | NIBP TES | DISABLED | NETWORK | A |
| GAS CAL | GAS CAL | DISABLED | UNUSED | DISABLED |
| SERVICE | SPO2 | ENABLED | UNUSED | DISABLED |
| SYSTEM | GAS BENCH | RESPIRONICS | LANGUAGE | ENGLISH |
| RETURN | RESP | ENABLED | PRESSURE UNITS | mmHg |
| SERVICE(BI | UNUSED | DISABLED | MONITOR MODE | LOCAL |
| RETURN | UNUSED | DISABLED | RETURN | |

- **LANGUAGE** sets the language displayed by the MR200 (to make the selection effective, cycle power after saving your changes):
 - **ENGLISH** (Default)
 - **DEUTSCH**
 - **ESPAÑOL**
 - **FRANCAIS**
 - **PORTUGUES (Br)**
 - **ITALIANO**
 - **DANSK**
 - **SVENSKA**
 - **NORSK**
 - **NLD**
- **PRESSURE UNITS** sets the unit of measure for NiBP readings:
 - **mmHg** provides readings in millimeters of mercury. (Default)
 - **kPa** provides readings in kilopascals

Repair

The MR200 contains no user-serviceable parts. All repairs must be performed by trained service personnel. All repairs on products under warranty must be performed by authorized personnel or in an authorized Service and Repair Center. Unauthorized repairs will void the warranty.



WARNING

A shock hazard exists if the MR200 is operated without covers.

If the MR200 fails to function properly or requires maintenance, contact technical support:

1-877-INVIVO1

or

1-877-468-4861

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

CAUTIONS

- This product, or any of its parts, must not be repaired other than in accordance with written instructions provided by Invivo (Royal Philips), or altered without prior written approval.
- No repair should ever be undertaken or attempted by anyone not having a thorough knowledge of the repair of Invivo (Royal Philips) patient monitoring systems. Only replace damaged parts with components manufactured or sold by Invivo (Royal Philips). Contact the Technical Service and Repair Center for assistance and service.

CAUTION

The user of this product shall have the sole responsibility for any malfunction which results from improper use, faulty maintenance, improper repair, damage, or alteration by anyone other than Invivo (Royal Philips) or its authorized service personnel.

Passing This Product on to Another User

If this product is to be passed on to another user who is to use it for its intended purpose, then it should be passed on in its complete state. In particular, the existing user should make sure that all the product support documentation—including all Instructions for Use—are passed on to the new user. A new user should be made aware of the support services that Royal Philips Healthcare provides for installing, commissioning and maintaining the equipment or system, and for the comprehensive training of operators. Existing users must bear in mind that passing on medical electrical equipment to new users may present serious technical, medical, privacy and legal risks. The original user may remain liable even if the equipment is given away.

Existing users are strongly advised to seek advice from their local Royal Philips Healthcare representative before agreeing to pass on any equipment.

Once the equipment has been passed on to a new user, the previous user may still receive important safety-related information, such as service bulletins and field change orders. In many jurisdictions, there is a clear duty on the previous user to communicate such safety-related information to new users.

Previous users who are not able or prepared to do this should inform Royal Philips Healthcare about the new user, so that Royal Philips Healthcare can provide the new user with safety-related information.

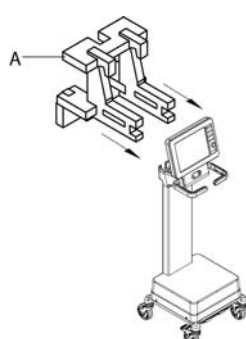
Packaging the MR200

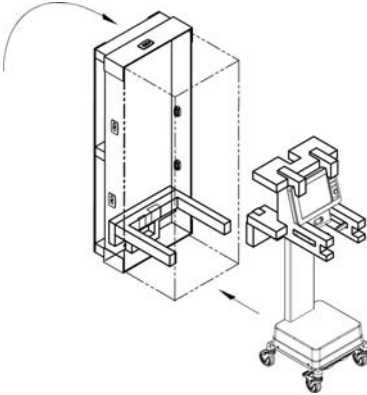
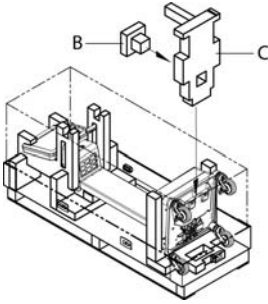
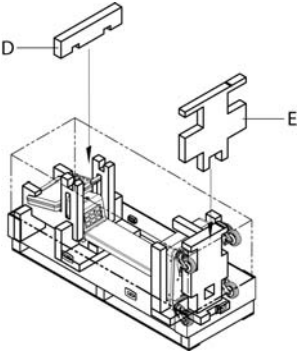
To package the MR200 for shipment, use the MR200 packing materials to safely transport the monitor.

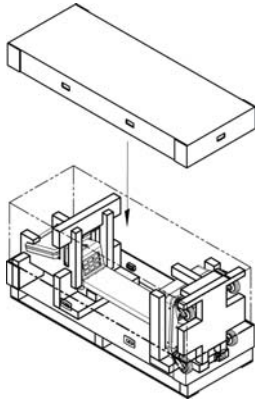
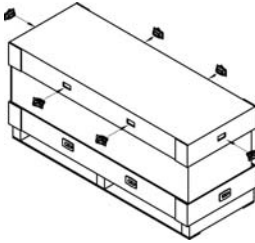
CAUTION

If shipment of the MR200 is required, batteries must be removed prior to transport.

To pack the MR200

| Step | Action |
|------|---|
| 1 | In a location outside of the MR magnet room, ensure that power is disconnected and that both batteries are removed from the cart. |
| 2 | Cover the LCD. Install foam A over the upper portion of the cart.  |

| Step | Action |
|------|--|
| 3 | <p data-bbox="732 338 1450 394">With the crate oriented as shown, place it into an upright position. Roll the cart into the crate.</p>  |
| 4 | <p data-bbox="732 846 1425 903">Carefully lower the crate. Slide foam B into foam C then insert it between the base of the cart and the crate.</p>  |
| 5 | <p data-bbox="732 1272 1446 1329">Insert foam D into foam A, and insert foam E between foam C and the crate.</p>  |

| Step | Action |
|------|--|
| 6 | <p data-bbox="683 338 959 363">Place the lid on the crate.</p>  |
| 7 | <p data-bbox="683 825 1377 884">Install all the clips into the lid on the crate, ensuring that each is locked.</p>  |

Specifications

| General |
|---|
| Patient Safety |
| Conforms to ANSI/AAMI ES60601-1. Certified to CAN/CSA C22.2 No. 60601-1. |
| Conforms to 93/42/EEC as amended by 2007/47/EEC |
| Defibrillator protection up to 5 KV |
| According to degree of protection against harmful ingress of water: ordinary equipment, IPX0 (enclosed equipment without protection against ingress of fluids) |
| <p>Where appropriate, the equipment complies to worldwide standards for safety and performance of each system feature, when considering the indications for use within the MR environment. This equipment complies to the following international industry standards for safety and performance:</p> <ul style="list-style-type: none"> • IEC 60601-1, <i>General Requirements for Safety of Medical Electrical Equipment</i> • IEC 60601-1-2, <i>General Requirements for Safety - Electromagnetic Compatibility</i> • IEC 60601-1-6, <i>General Requirements for Safety - Collateral Standard: Usability</i> • IEC 60601-1-8, <i>General Requirements, Tests and Guidance for Alarm Systems in Medical Electrical Equipment and Medical Electrical Systems</i> • IEC 60601-2-27, <i>Particular Requirements for Safety - Specification for Electrocardiographic Monitoring Equipment</i> • IEC 60601-2-49, <i>Particular Requirements for Safety - Specification for Multifunction Patient Monitoring Equipment</i> • IEC 80601-2-30, <i>Medical Electrical Equipment - Part 2-30: Particular Requirements for the Safety, Including Essential Performance, of Automatic Cycling Non-Invasive Blood Pressure Monitoring Equipment</i> • ISO 80601-2-61, <i>Medical Electrical Equipment Particular Requirements for the Basic Safety and Essential Performance of Pulse Oximeter Equipment for Medical Use</i> • ISO 80601-2-55, <i>Medical Electrical Equipment Particular Requirements for the Basic Safety and Essential Performance of Respiratory Gas Monitors</i> • ISO 10993-1, <i>Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing</i> • ISO 10993-5, <i>Biological Evaluation of Medical Devices - Part 5: Tests for Cytotoxicity: In vitro methods</i> • ISO 10993-10, <i>Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Delayed-Type Hypersensitivity</i> |

Additionally, this equipment complies to the following national or regional industry standards for safety and performance:

- 1999/5/EC, *Radio & Telecommunications Terminal Equipment Directive*
- SAA AS/NZS 3200.1.2, *General Requirements for Safety - Electromagnetic Compatibility*
- ANSI/AAMI EC13: 2002/(R) 2007, *Cardiac Monitors, Heart Rate Meters, and Alarms*
- ANSI/AAMI SP10: 2008, *Manual, Electronic, or Automated Sphygmomanometers*
- 2006/66/EC, *Battery Directive*
- UL 2054: 2004 Secondary cells and batteries containing alkaline or other non-acid electrolytes, *Standard for Household and Commercial Batteries*
- IEC 62133:2002, Secondary cells and batteries containing alkaline or other non-acid electrolytes, *Standard for Household and Commercial Batteries*
- 2002/96/EC, *Directive on Waste of Electrical and Electronic Equipment*
- ASTM F2503-08, *Standard Practice for Marking Medical Devices and other Items for Safety in the MR Environment*
- ASTM F2052-06, *Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Device in MR Environment*

Power Requirements, Cart

| | |
|----------------------------|-----------------------------------|
| Operating Voltage Range | 100 VAC to 240 VAC |
| Frequency Range | 47 Hz to 63 Hz |
| Current | 1.5 A @ 115 VAC / 0.7 A @ 240 VAC |
| Power Consumption, Maximum | ≤ 65 Watts |

Battery

| | |
|---|---|
| Type | Cart: Lithium-Ion Module: Lithium polymer |
| Operation Time | Cart: Maximum operation time is approximately 8 hours when ECG and SPO2 are on, CO2 is off, and NiBP is running at 5-minute intervals (time may be reduced by up to 2 hours under certain conditions, such as running shorter NiBP cycles). With the cart off, inserted and fully charged batteries will not completely discharge for at least 72 hours. Module: Approximate operation time of the battery is 8 hours. |
| Charge Time | Cart: To recharge a fully discharged battery is approximately 12 hours with the MR200 turned off. Module: To recharge a fully discharged battery is approximately 3 hours. |
| Minimum Voltage (For normal operation) | Cart: 14.8 V Module: 3.4 V |

| Environment | |
|---|--|
| Operating Temperature Range | 10°C to 35°C (50°F to 95°F) |
| Storage/Transport Temperature Range | Batteries: 0°C to 40°C (32°F to 104°F) Cart: -20°C to 50°C (-4°F to 122°F) Wireless modules: -25°C to 75°C (-13°F to 167°F) Accessories: -20°C to 60°C (-4°F to 140°F) (When storing or transporting in temperatures beyond the ranges specified above, remove the designated component and store or move it appropriately.) |
| Relative Humidity Range | 15% to 80%, non-condensing |
| Operating Altitude Range | From sea level up to 10,000 feet (3048 m) (708 mbar) |
| Storage/Transport Altitude Range | From 1020 mbar to 708 mbar |
| Dimensions and Weights | |
| (All measurements made without accessories) | |
| Height | Cart: 54.22 inches (137.71 cm) Wireless ECG module: 4.7 inches (11.9 cm) Wireless SPO2 module: 5.5 inches (13.9 cm) |
| Width | Cart: 22.15 inches (56.26 cm) Wireless ECG module: 2.5 inches (6.4 cm) Wireless SPO2 module: 2.5 inches (6.4 cm) |
| Depth | Cart: 25.25 inches (64.14 cm) Wireless ECG module: 0.91 inches (2.3 cm) Wireless SPO2 module: 0.91 inches (2.3 cm) |
| Weight | Cart: 74.06 pounds (33.59 kg) Wireless ECG module: 5.4 ounces (158.8 g) Wireless SPO2 module: 5.4 ounces (158.8 g) |
| Liquid Crystal Display | |
| Type | 800 x 600 pixels, color |
| Screen Size | 12.1 inches (30.7 cm) diagonal |
| Sweep Speed | For ECG and SPO2, a speed of 25 mm/second gives 9.2 seconds of display time, while 50 mm/second gives 4.6 seconds. For respiration, a speed of 0.33, 1.56, 3.13, 6.25, 12.5 or 25 mm/second is used. |
| Waveform Display Mode | Fixed trace, moving erase bar |
| Waveform Display Height | ≥ 19 mm |
| “Full Screen” Display Height | ≥ 75 mm |
| Battery indication | Time remaining, red low warning |
| Alarm indication | One hertz flashing frequency with 50 percent duty cycle, visible at 4 meters and legible at 1 meter (assuming a visual acuity of 20/20 and with no line of sight obstructions). |

| Displayed Parameters | |
|----------------------|---|
| Time | Battery-backed quartz crystal clock |
| Alarms | High and low limits selectable for patient parameters |
| ECG | ECG waveform scale, displayed leads (2) |
| Heart Rate | Normally derived from ECG. May be manually selected to be derived from pulse oximetry, or automatically in order of priority. |
| Pulse Oximeter | Pulse rate, pulse waveform and percent saturation |
| Trends | Heart rate, respiration rate, NiBP (systolic, mean, diastolic), CO2 and SPO2 |
| CO2 | Both end-tidal and inspired CO2 |
| NiBP | Pressures (systolic, mean, diastolic) and status |
| Respiration Rate | Respiration rate derived from bellows or CO2 |

| ECG | |
|---|---|
| ECG Amplifier | |
| Protected against defibrillator and electrosurgery potentials | |
| Standard Lead Configurations | I, II, III, AVR, AVL, AVF |
| Lead Fail | Passive, sensing signal imbalance |
| ECG Input Impedance | > 2.5 MΩ (according to IEC 60601-2-27, 50.102.3) |
| Heart Rate | |
| Range | 30 to 249 BPM (Adult) 30 to 300 BPM (Neonate, Pediatric) |
| Accuracy | In the absence of an MRI gradient artifact: ± 1% or ± 1 BPM, whichever is greater. In the presence of an MRI gradient artifact: ± 1% from 30-200 BPM, ± 1.5% from 200-250 BPM, and (neonatal only) ± 2.0% from 251-300 BPM |
| Resolution | 1 BPM |
| Cardiotach | |
| Sensitivity (Monitor filter) | Adult ECG mode: > 200 μV Neonate/Pediatric ECG mode: > 100 μV |
| Bandwidth | Monitor: 0.5 Hz to 40 Hz |
| Tall T-Wave Rejection Capability for Heart Rate Indication | 2 mV with a 1 mV QRS amplitude |

| | |
|--|---|
| Alarm Limits (HR) | |
| Lower | Off or 30 to 249 |
| Upper | 60 to 249 or off |
| Test/Calibrations | |
| Square Wave Test Signal | 60 BPM \pm 1 BPM, 1 mV \pm 10% |
| ECG Supplemental Information, as required by IEC 60601-2-27 | |
| Heart Rate Averaging Method | Mean filtering is applied to the output of the median filter of a continuously updating group of QRS complexes. The ECG heart rate numeric is updated twice a second. |
| Time to Alarm for Tachycardia | |
| B1 - Vent Tachycardia 1 mVpp, 206 BPM | Gain 0.5 (12.03, 11.04, 14.1, 11.8, 11.4) Average: 12.1 sec (The monitoring system may temporarily exit the alarm condition during the arrhythmia waveform duration.) Gain 1.0 (11.9, 11.6, 9.2, 9.6, 10.9) Average: 10.6 sec Gain 2.0 (8.8, 9.1, 10.3, 9.4, 12.1) Average: 9.9 sec |
| B2 - Vent Tachycardia 2 mVpp, 195 BPM | Gain 0.5 (9.0, 10.4, 12.3, 8.1, 10.4) Average: 10.0 sec Gain 1.0 (8.4, 7.7, 12.5, 7.7, 8.3) Average: 8.9 sec Gain 2.0 (9.7, 12.6, 8.9, 11.8, 8.3) Average: 10.3 sec |
| NOTE | |
| <i>Measurements made in FILTER MODE - MONITOR, outside of the MR environment. The alarm condition response time of some arrhythmia complexes may be affected by MRI gradient artifacts.</i> | |
| <hr/> | |
| Response Time of Heart Rate Meter to Change in Heart Rate | HR change from 80 BPM to 120 BPM: 8.3 sec average HR change from 80 BPM to 40 BPM: 7.9 sec average |
| Heart Rate Meter Accuracy and Response to Irregular Rhythm | A1: Ventricular bigeminy: 40 BPM A2: Slow alternating ventricular bigeminy: 30 BPM A3: Rapid alternating ventricular bigeminy: 115–125 BPM A4: Bidirectional systoles 58–85 BPM |
| NOTE | |
| <i>Measurements made in FILTER MODE - MONITOR, outside of the MR environment. The accuracy of the indicated heart rate may be affected by MRI gradient artifacts.</i> | |
| <hr/> | |

| Non-Invasive Blood Pressure | |
|------------------------------------|---|
| General | Oscillometric technology (with an inflatable cuff) determines systolic, diastolic and mean arterial pressures |
| Patient Types | Adult, Pediatric and Neonate |
| Pneumatic Systems | |
| Cuff Inflation Pressure | Initial: 165 mmHg for Adult, 130 mmHg for Pediatric, and 100 mmHg for Neonate (all pressures are ± 15 mmHg) Subsequent inflation pressures determined by last NiBP measurement |
| Overpressure Protection | Automatic release of cuff pressure if inflation pressure exceeds 300 mmHg for Adult and Pediatric modes, and 150 mmHg for Neonate mode |
| Unit of Measure | mmHg or kPa |
| Measurement Range | |
| Systolic | |
| Adult | 30 mmHg to 270 mmHg |
| Pediatric | 30 mmHg to 180 mmHg |
| Neonate | 30 mmHg to 130 mmHg |
| Mean | |
| Adult | 20 mmHg to 255 mmHg |
| Pediatric | 20 mmHg to 160 mmHg |
| Neonate | 20 mmHg to 120 mmHg |
| Diastolic | |
| Adult | 10 mmHg to 245 mmHg |
| Pediatric | 10 mmHg to 150 mmHg |
| Neonate | 10 mmHg to 100 mmHg |
| Accuracy | |
| Pressure Measurement Accuracy | Maximum mean error ± 5 mmHg with a standard deviation of less than 8 mmHg |
| Pressure Measurement Resolution | 1 mmHg |
| Pressure Transducer Range | 0 to 300 mmHg |

| Alarm Limits | |
|---------------------|--|
| Systolic | |
| Adult & Pediatric | |
| Lower | Off or 46 to 254 |
| Upper | 46 to 254 or off |
| Neonate | |
| Lower | Off or 46 to 124 |
| Upper | 46 to 124 or off |
| Mean | |
| Adult & Pediatric | |
| Lower | Off or 26 to 239 |
| Upper | 26 to 239 or off |
| Neonate | |
| Lower | Off or 26 to 94 |
| Upper | 26 to 94 or off |
| Diastolic | |
| Adult & Pediatric | |
| Lower | Off or 16 to 224 |
| Upper | 16 to 224 or off |
| Neonate | |
| Lower | Off or 16 to 84 |
| Upper | 16 to 84 or off |
| Modes | |
| Manual | Immediate upon operator command |
| Automatic | Determinations automatically made with selectable intervals of 1, 2, 2.5, 3, 5, 10, 15, 20, 30 and 45 minutes; and, 1, 2 and 4 hours |

| CO ₂ (Optional) | |
|---|---|
| Side stream, non-dispersive infrared absorption technique. Including multiple filtration system and microprocessor logic control of sample handling and calibration. | |
| Output | CO ₂ waveform, EtCO ₂ and FiCO ₂ numeric values, and respiration rate |
| CO ₂ Unit of Measure | mmHg or kPa |
| Initialization Time | Waveform displayed in less than 20 seconds, at an ambient temperature of 25°C; full specifications attained within 2 minutes |
| Inspired CO ₂ Measurement | Range: 3 mmHg to 50 mmHg Method: Lowest reading of the CO ₂ waveform in the previous 20 seconds |
| CO ₂ Accuracy (All measurements at gas temp of 25°C) | ± 4 mmHg or ± 12%, whichever is greater, after the specified warm-up period |
| CO ₂ Measurement Range (In which the CO ₂ accuracy specification is met) | 0 to 76 mmHg for respiration rates ranging from 4 to 60 breaths per minute, inclusive |
| CO ₂ Resolution | 1 mmHg |
| CO ₂ Stability | Short Term Drift: Drift not to exceed 0.8 mmHg over 4 hours Long Term Drift: Accuracy specification maintained over a 120-hour period |
| Zero Calibration Interval | Automatic or user requested |
| Flow Rate | 50 mL/minute ± 10 mL/minute |
| Respiration Accuracy | ± 1 breath or ± 3% whichever is greater |
| Respiration Rate Range (In which the respiration accuracy specification is met) | 4 to 100 breaths per minute, inclusive |
| Respiration Resolution | 1 breath per minute |
| Response (Rise) Time Adult & Pediatric Neonate (As measured from the patient gas input of the complete pneumatic circuit [including tubing], from 10% to 90% of the measured CO ₂ levels) | ≤ 800 ms ≤ 440 ms |
| Compensations (Automatic CO ₂ ambient pressure compensation 400 to 800 mmHg) | Compensations for expired O ₂ Balance gas (N ₂ , N ₂ O, O, He) and Anesthetic Agents ^B Uses gas compensation information to correct the raw carbon dioxide value |

| | |
|---|---|
| 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 (i.e., ISO 21647, ASTM F1456, IEC/CDV 60601-2-55) currently in process. |
| Cross-sensitivity Compensation Error* | 0 to 40 mmHg: ± 1 mmHg additional error 41 to 70 mmHg: ± 2.5 mmHg additional error 71 to 100 mmHg: ± 4 mmHg additional error 101 to 150 mmHg: ± 5 mmHg additional error *Additional worst case error when compensation for O ₂ , N ₂ O, anesthetic agents, or helium is correctly selected for the actual fractional gas constituents present. |
| Alarm Limits | |
| End-tidal CO ₂ Lower Upper | Off or 5 to 60 5 to 80 or off |
| Inspired CO ₂ | 25 (Fixed) |
| Respiration Lower Upper | Off or 4 to 40 20 to 99 or off |

A.

| | | | | |
|-------------------|-----------|-----------|------------|------------|
| GAS or Vapor | Halothane | Enflurane | Isoflurane | Desflurane |
| MAC Level % (v/v) | 0.74 | 1.68 | 2.00 | 6.30 |

(From Olivier C. Wenker: *Review of Currently Used Inhalation Anesthetics: Part I*. The Internet Journal of Anesthesiology, 1999, Volume 3 Number.)

B.

| Measured Gas | Quantitative Effects of Gas or Vapor | | | | | | | | | | | |
|--|--------------------------------------|---------|---------|---------|---------|-----------|----------|-----------|-----------|-------------|-----------|---------|
| | N ₂ O | 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 *Metered dose inhaler propellants: Unspecified | | | | | | | | | | | | |

Bellows Respiration

| | |
|------------------------------------|----------------------------|
| Respiration Rate Measurement Range | 0 to 60 breaths per minute |
| Respiration Rate Resolution | 1 breath per minute |
| Respiration Rate Accuracy | ± 1 breath per minute |

Gating Connector



Wiring view

| Pin Designator | Signal Name | Description and Characteristics |
|------------------|-----------------------|--|
| A | DIGITAL GATING PULSE | ECG/SPO2 digital gating pulse <ul style="list-style-type: none"> • Peak to peak voltage: 3.3 V to 5.0 V • Pulse duration: 10 ± 3 ms |
| B | SIGNAL GROUND | Return voltage reference for all other signal pins |
| C | RESP ANALOG | Analog respiration gating waveform signal <ul style="list-style-type: none"> • Maximum output voltage: ± 5 V • Maximum current: 5 mA • Peak-to-peak signal voltage: 1 V |
| D | ECG 1V ANALOG | Analog ECG 1-Volt waveform signal <ul style="list-style-type: none"> • Output signal scaling: 1 V/mV • Maximum output voltage: ± 5 V • Maximum current: 5 mA |
| F | NEGATIVE GATING PULSE | ECG/SPO2 negative digital gating pulse <ul style="list-style-type: none"> • Peak-to-peak signal voltage: -3.3 V to -5.0 V • All other signal characteristics same as Pin A (above) |
| G | SPO2 40mV ANALOG | SPO2 IR/red analog gating waveform signal <ul style="list-style-type: none"> • Signal scaling: 1 V/mV • Maximum output voltage: 40 mV |
| H | ECG 1mV ANALOG | ECG analog gating waveform signal <ul style="list-style-type: none"> • Signal scaling: 1 mV/mV • Maximum current: 5 mA • Maximum output voltage: 20 mV |
| J | SPO2 2V ANALOG | SPO2 IR/red analog gating waveform signal, maximum output voltage: 2 V |
| E, K, L, M, N, O | UNUSED | Unused pins |

Warranty

Warranty Statement

Koninklijke Philips N.V. warrants this product, other than its consumable parts, to be free from defects in materials and workmanship for a period of twelve (12) months from the date of original delivery to the buyer or to buyer's order, provided that same is properly operated under conditions of normal use, and that periodic maintenance and service is performed. This same warranty is made for a period of ninety (90) days on consumable parts. This warranty shall become null and void if the MR200 has been repaired by someone other than Koninklijke Philips N.V. or if the product has been subject to misuse, accident, negligence or abuse.

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This warranty is in lieu of any other warranties, guarantees or conditions, including merchantability or fitness for a particular purpose. The remedies under this warranty are exclusive and Koninklijke Philips N.V. neither assumes nor authorizes anyone to assume for it any other obligation in connection with the sale or repair of its products.

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Regulatory Information

European Union

Declaration of Conformity

To obtain a copy of the Declaration of Conformity to the European Union Medical Device Directive (93/42/EEC) and Radio & Telecommunications Terminal Equipment Directive (1999/5/EC), and/or Restriction on Hazardous Substance (RoHS) Directive, contact the Regulatory Affairs Department at Invivo:

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Authorized Representative



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

Philips Medizin Systeme Böblingen GmbH
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71034, Böblingen
Germany

Australia

The Australia Sponsor is as follows:

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65 Epping Road, North Ryde NSW 2113
Australia

Guidelines and References

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

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

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

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

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

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

1. Prepare the patient for the MR procedure by ensuring that there are no unnecessary metallic objects contacting the patient's skin (e.g., metallic drug delivery patches, jewelry, necklaces, bracelets, key chains, etc.).
2. Prepare the patient for the MR procedure by using insulation material (i.e., appropriate padding) to prevent skin-to-skin contact points and the formation of "closed-loops" from touching body parts.
3. Insulating material (minimum recommended thickness, 1 cm) should be placed between the patient's skin and transmit RF coil that is used for the MR procedure (alternatively, the RF coil itself should be padded). For example, position the patient so that there is no direct contact between the patient's skin and the body RF coil of the MR system. This may be accomplished by having the patient place his/her arms over his/her head or by using elbow pads or foam padding between the patient's tissue and the body RF coil of the MR system. This is especially important for those MR examinations that use the body coil or other large RF coils for transmission of RF energy.
4. Use only electrically conductive devices, equipment, accessories (e.g., ECG leads, electrodes, etc.), and materials that have been thoroughly tested and determined to be safe and compatible for MR procedures, as listed in this IFU.
5. Carefully follow specific MR safety criteria and recommendations for implants made from electrically-conductive materials (e.g., bone fusion stimulators, neurostimulation systems, etc.).
6. Before using electrical equipment, check the integrity of the insulation and/or housing of all components including surface RF coils, monitoring leads, cables, and wires. Preventive maintenance should be practiced routinely for such equipment.
7. Remove all non-essential electrically conductive materials from the MR system (i.e., unused surface RF coils, ECG leads, cables, wires, etc.).
8. Keep electrically conductive materials that must remain in the MR system from directly contacting the patient by placing thermal and/or electrical insulation between the conductive material and the patient.
9. Keep electrically conductive materials that must remain within the body RF coil or other transmit RF coil of the MR system from forming conductive loops. Note: The patient's tissue is conductive and, therefore, may be involved in the formation of a conductive loop, which can be circular, U-shaped, or S-shaped.
10. Position electrically conductive materials to prevent "cross points". For example, a cross point is the point where a cable crosses another cable, where a cable loops across itself, or where a cable touches either the patient or sides of the transmit RF coil more than once. Notably, even the close proximity of conductive materials with each other should be avoided because some cables and RF coils can capacitively-couple (without any contact or crossover) when placed close together.
11. Position electrically conductive materials to exit down the center of the MR system (i.e., not along the side of the MR system or close to the body RF coil or other transmit RF coil).

12. Do not position electrically conductive materials across an external metallic prosthesis (e.g., external fixation device, cervical fixation device, etc.) or similar device that is in direct contact with the patient.
13. Allow only properly trained individuals to operate devices (e.g., monitoring equipment) in the MR environment.
14. Follow all manufacturer instructions for the proper operation and maintenance of physiologic monitoring or other similar electronic equipment intended for use during MR procedures.
15. Electrical devices that do not appear to be operating properly during the MR procedure should be removed from the patient immediately.
16. Closely monitor the patient during the MR procedure. If the patient reports sensations of heating or other unusual sensation, discontinue the MR procedure immediately and perform a thorough assessment of the situation.
17. RF surface coil decoupling failures can cause localized RF power deposition levels to reach excessive levels. The MR system operator will recognize such a failure as a set of concentric semicircles in the tissue on the associated MR image or as an unusual amount of image non-uniformity related to the position of the RF coil.

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

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