PHILIPS

Expression **MR400** MRI Patient Monitoring System

INSTRUCTIONS FOR USE

Revision A

English

989803193211

Manufacturer

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Invivo, a division of Philips Medical Systems, reserves the right to make changes to both this *Instructions for Use* and to the product it describes. Product specifications are subject to change without notice. Nothing contained within this *Instructions for Use* is intended as any offer, warranty, promise or contractual condition, and must not be taken as such.

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USA

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Regulatory

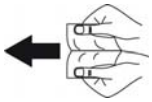
Compliance

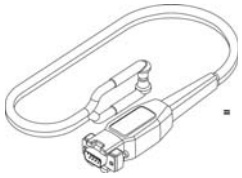
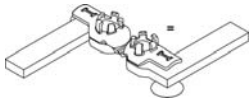
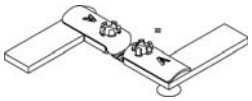
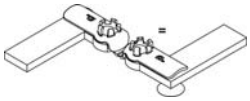
The Expression MR400 MRI Patient Monitoring System complies with relevant international and national standards and laws. Information on compliance will be supplied on request by your local Royal Philips representative, or by the manufacturer.

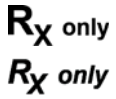
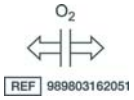
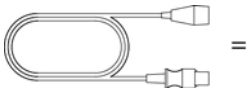
Explanation of Symbols

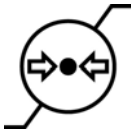
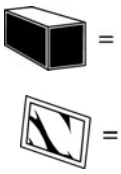
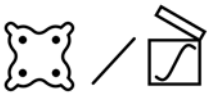
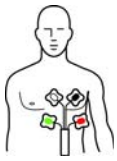
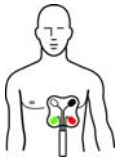
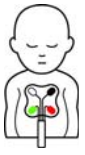
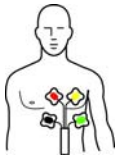
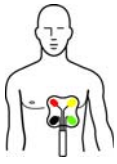
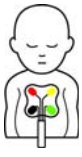
The symbols in the following table may appear on the Expression MR400 MRI Patient Monitoring System, the accessories, or the packing material.

Symbol		Symbol	
c US	Underwriters Laboratories Component Recognition Mark for both the U.S. and Canadian markets	FC	Federal Communications Commission radio certification
	Ministry of Internal Affairs and Communications Japanese Radio Law Certification	CLASSIFIED c UL us MEDICAL – PATIENT-MONITORING EQUIPMENT AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH 60601-1 60601-1-8 60601-2-27 80601-2-30 60601-2-34 60601-2-49 60601-2-55 60601-2-56 80601-2-61 <E359677>	UL has determined that the product meets requirements
	Korean Communications Commission radio certification		Taiwan National Communications Commission certification
CE CE 0413 CE 0123	Conforms to the European Medical Devices Directive	CE 0889 CE 0979	Conforms to the R&TTE Directive (Radio & Telecommunications Terminal Equipment)
EC REP	Authorized representative in the European Community	SN	Serial number
REF	Catalog, reorder or reference part number	LOT	Batch code / lot number

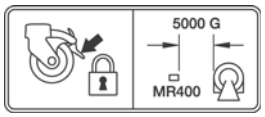
Symbol		Symbol	
	Sterilized using radiation		Unique device identifier
	Sterilized using ethylene oxide		In vitro diagnostics compliant
	MR Conditional: Use in the MR environment is restricted to certain conditions of use to ensure patient and operator safety.		MR unsafe: Must not be used in an MRI environment
	MR safe: Completely safe for use with no potential for interaction with the MR field.		Warning! Specific warnings associated with the devices that are not otherwise found on the label; and, on the connector of the wireless ECG patient module, this indicates that only specified ECG lead cables shall be used to ensure safe use in the MR and defibrillation protection.
	Consult the *Instructions for Use*		Caution! See *Instructions for Use* for specific warnings or precautions associated with the devices that are not otherwise found on the label
	The *Instructions for Use* must be consulted		Separate to open then insert
	Do not adjust without referring to the service manual		Single use only, disposable one-time-use product; do not reuse
	Do not use if container is damaged		Defibrillator-proof type CF equipment (IEC 60601-1) protection against shock

Symbol		Symbol	
YYYY-MM-DD	Use by date; do not use after the year (YYYY), month (MM) and day (DD) indicated	= YYYY-MM	Cable tag marked with use by date; do not use after the year (YYYY) and month (MM) indicated
YYYY-MM	Use by date; do not use after the year (YYYY), month (MM)		AC receptacle, below
	Do not push		Correct
	Alternating current	NON STERILE	Not sterile
	SPO2 probe quantity equals		Direct current
	Adult SPO2 clip quantity equals		Pediatric SPO2 clip quantity equals
	Infant SPO2 grip quantity equals		Neonatal SPO2 grip quantity equals
	Adult SPO2 grip quantity equals		Pediatric SPO2 grip quantity equals
	Infant		Neonate
	Toe site		Thumb site
	Finger site		Big toe site

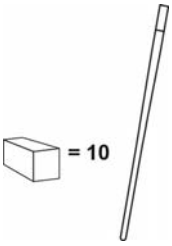
Symbol		Symbol	
	Prescription only		Foot site
	NIBP cuff, correct side out		Temperature range
	Non-pyrogenic fluid path		NIBP cuff, wrong side out
	Airway adapter quantity equals		NIBP cuff circumference range
	Anesthetic oxygen (O2) sensor location and part number		IBP transducer cable quantity equals
	Weight		Cannula quantity equals
	Humidity range		Humidity range, non condensing
	For indoor use only		Equipotential (earth) ground
	Fragile		Keep dry

Symbol		Symbol	
	Keep away from heat		Atmospheric pressure limitation
	Packages per box		Up
	Quantity equals		Non-invasive blood pressure (NIBP) connection
	Not manufactured with natural latex rubber		Quadtrode electrode
	Contains or presence of phthalate: bis (2-ethylhexyl) phthalate		Quadtrode electrode per package
	Non-ionizing radiation		ECG
	AAMI ECG CV lead cable connections		AAMI ECG lead cable connections
	AAMI ECG NEO lead cable connections		IEC ECG CV lead cable connections
	IEC ECG lead cable connections		IEC ECG NEO lead cable connections

Symbol		Symbol	
	Cardiac gating output		Universal Serial Bus (USB)
	Conforms to the RoHS directive		Not for general waste
	Center positive connection: Positive (+) center pin, negative (-) outer ring		Pneumatic respiration connection
	Gas input indicator		Gas output indicator
	Electrical input indicator		Electrical output indicator
	Temperature connection		Electrostatic discharge (ESD) warning
	Manufacturer name and address		Date of manufacture (year-month)
	Non-magnetic part		Battery
	Main battery (left side)		Main battery (right side)

Symbol		Symbol	
	Do not move the Expression MR400 MRI Patient Monitoring System inside the 5000 gauss field line of the MR magnet or up to the face of a 3T magnet, whichever is greater, as measured from the center line of the bore.		Apply wheel locks and do not move the Expression MR400 MRI Patient Monitoring System inside the 5000 gauss field line of the MR magnet or up to the face of a 3T magnet, whichever is greater, as measured from the center line of the bore.
	Charge indicator, cart battery		Wheel lock
	Power level button, cart battery		MRI compatible, up to 2500 gauss
	**Setup** key		**Main Screen** key
	**Zero All** key		**Print** key, printer ready indication
	**Clear Trends** key		**Print** key, printing in process (and time remaining) indication
	**NIBP Interval** key		**Print** key, no printer available indication
	**1-Touch Alarms** key		**Print** key, printer error indication
	**Suspend** key		**Trends** key
	**NIBP Start/Stop** key		**ECG Filter** key
	Connected to AC mains		**Audio Pause** key
	Alarm audio armed		**Alarm** key

Symbol		Symbol	
	Alarm audio paused		After opening, allow at least 1 hour to pass before use
	Alarm audio off		Current setups have changed
	Power switch (Standby switch)		Heartbeat detected
	Module battery adequate charge indication		Breathing effort detected
	Module battery low charge indication		Battery 1 indicator, wireless ECG patient module,
	Battery 2 indicator, wireless ECG patient module,		Battery indicator, wireless SpO2 patient module
	No communication		IP5 connected
	Network channel 1		Network channel 6
	Network channel 2		Network channel 7
	Network channel 3		Network channel 8
	Network channel 4		Network channel 9

Symbol		Symbol	
5	Network channel 5	10	Network channel 10
	Ten FlexTEMP System Jackets per box		

Conventions

Certain conventions are used throughout the Expression MR400 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:

- Operational control is accomplished using the touch screen, where active elements are provided and touching that element will activate, open or execute the related menu, function or item.
- Most menus employ a time-out feature where, if no action is taken for approximately 30–60 seconds, an open menu will automatically close.
- To protect against accidental changes, a dialog prompt is associated with some menu options. When displayed, you must answer this prompt; otherwise, a delay of approximately 30–60 seconds will be equivalent to selecting No (this can also be accomplished by pressing the **Main Screen** 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 30–60 seconds is equivalent to making no entry.

Document Conventions

These document conventions are used:

- 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.
- Select means to press on an active element on the touch screen LCD (menu or sub-menu item, button, key, vital sign box, et cetera).
- Bulleted lists indicate general information about a particular feature, menu function or procedure, and do not imply sequential order or operation.
- Control names, menu items, vital sign references, messages, et cetera, are spelled as they appear on the Expression MR400 MRI Patient Monitoring System.
- Menu items, key names and messages are provided in **bold** font.
- The “greater than” (>) symbol is used when navigation of items within a menu is indicated.
- The front of the Expression MR400 MRI Patient Monitoring System is nearest you as you operate it; the left and right sides are respectively to your left and right as you stand in front of the system, facing it.
- The front of a wireless module is nearest you as you operate it. The top of the device points up or away when the labeling nearest you during operation is correctly oriented for reading, while the left and right sides of the device are respectively to your left and right as you hold the device for operation, facing it.

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Chapter 7: Monitoring CO2 (LoFlo Option)

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Chapter 9: Monitoring Agents and Gases (AGENT Option)

Chapter 10: Monitoring RESP

Chapter 11: Monitoring Temperature

Chapter 12: Monitoring NIBP

Chapter 1:3 Trend Data and Printing

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Appendix A: Specifications

Appendix B: Warranty

Appendix C: Regulatory Information

Appendix D: Gating Feature

Appendix E: Guidelines and References

CHAPTER 1

Important Information

About

About the Expression MR400 MRI Patient Monitoring System and this *Instructions for Use*

This *Instructions for Use* is intended to assist users in the safe and effective operation of the Expression MR400 MRI Patient Monitoring System.

Before attempting to operate the product, you must read this *Instructions for Use*, noting and strictly observing all **WARNINGS** and **CAUTION** notices.

Pay special attention to all the information given and procedures described in the ***SAFETY*** section.

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

A **CAUTION** alerts you to where special care is necessary for the safe and effective use of the product. Failure to observe a caution may result in minor or moderate personal injury or damage to the product or other property, and possibly in a remote risk of more serious injury, and/or cause environmental pollution.

A **Note** highlights an unusual point as an aid to a user.

This *Instructions for Use* describes the most extensive configuration of the product, with the maximum number of options and accessories. Not every function described may be available on your product.

This product will perform in conformity with the description contained in this manual and accompanying labeling when 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.

Intended Use

This Philips product is intended to be used and operated only in accordance with the safety procedures and operating instructions given in this *Instructions for Use* for the purposes for which it was designed. The purposes for which the product is intended is given below. However, nothing stated in this *Instructions for Use* reduces users' responsibilities for sound clinical judgment and best clinical procedure.

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

Use and operation of this product is subject to the law in the jurisdiction(s) in which the product is being used. Users must only install, use and operate the product in such ways as do not conflict with applicable laws, or regulations, which have the force of law. Uses of the product for purposes other than those intended and expressly stated by the manufacturer, as well as incorrect use or operation, may relieve the manufacturer (or his agent) from all or some responsibility for resultant non-compliance, damage or injury.

CAUTION

R_X only

Federal law restricts this device to sale by or on the order of a physician.

Compatibility

The product described in this manual should not be used in combination with other products or components unless such other products or components are expressly recognized as compatible by Philips Medical Systems. [A list of such products and components is available from the manufacturer]. Changes and/or additions to the product should only be carried out by Philips Medical Systems or by third parties expressly authorized by Philips Medical Systems to do so. Such changes and/or additions must comply with all applicable laws and regulations that have the force of law within the jurisdiction(s) concerned, and with best engineering practice.

WARNING

Changes and/or additions to the product that are carried out by persons without the appropriate training and/or using unapproved spare parts may lead to the PMS warranty being voided. As with all complex technical products, maintenance by persons not appropriately qualified and/or using unapproved spare parts carries serious risks of damage to the product and of personal injury.

Indications for Use

The Expression MR400 MRI Patient Monitoring System is intended for use by healthcare professionals to monitor vital signs of patients undergoing MRI procedures and to provide signals for synchronization for the MRI scanner (also referred to as “triggering” or “gating”). The Expression MR400 provides monitoring for the following vital signs and parameters: electrocardiogram (ECG), pulse oximetry (SpO_2), non-invasive blood pressure (NIBP); and optionally, invasive blood pressure (IBP), carbon dioxide (CO_2) and respiration rate, anesthetic agents, oxygen (O_2), nitrous oxide (N_2O), and temperature.

Notes

- *The MR400 is intended to be used to monitor the vital signs of a patient in an MR magnet room. Monitoring outside the magnet room (e.g., the MR induction and/or MR recovery areas) is acceptable for the short duration of time in which the patient is being prepared for the MR scan and during the recovery period within the MR. This system is not intended for use on a patient being transported outside of a health care facility.*
- *The MR400 is intended for use on patients receiving MR scans, which may include neonatal, pediatric, or adult patients. If determined by a qualified healthcare provider, this may also include pregnant patients.*
- *The bellows-derived respiration rate measurement is not intended for vital sign monitoring.*

Contra-indications

This Philips product should not be used if any of the following contra-indications exist or are thought to exist. This device is contra-indicated for patients with metallic wires, implants, stents, et cetera. Screen all patients for metallic wires, implants, stents, et cetera prior to MR procedures. These electrical conductors will react with the MR environment or with the accessory (if applied directly over the conductor), thus increasing the risk of heating. The warnings below refer to the Expression MR400 MRI Patient Monitoring System in its entirety.

WARNINGS

- **The Expression MR400 MRI Patient Monitoring System is not intended for use with patients using pacemakers or electrical stimulators.**
- **Do not use if MR workers are present who have metallic wires, implants, stents, et cetera. Screen all MR workers for metallic wires, implants, stents, et cetera, prior to MR procedures when using the Expression MR400 MRI Patient Monitoring System in the MR magnet room.**
- **Do not use on patients with metallic wires, implants, stents, et cetera. Screen all patients for metallic wires, implants, stents, et cetera, prior to MR procedures. These electrical conductors will react with the MR environment or with the accessory (if applied directly over the conductor), thus increasing the risk of heating.**

Training

Users of this product must have received adequate training on its safe and effective use before attempting to operate the product described in this *Instructions for Use*. Training requirements for this type of device will vary from country to country. Users must make sure they receive adequate training in accordance with local laws or regulations. If you require further information about training in the use of this product, please contact your local Philips Medical Systems representative. Alternatively, contact the manufacturer.

ADEQUATE TRAINING

WARNINGS

- **Do not use the product for any application until you have received adequate and proper training in its safe and effective operation. If you are unsure of your ability to operate this product safely and effectively DO NOT USE IT. Operation of this product without proper and adequate training could lead to fatal or other serious personal injury. It could also lead to clinical mis-diagnosis or to clinical mistreatment.**
- **Do not operate the product with patients unless you have an adequate understanding of its capabilities and functions. Using this product without such an understanding may compromise its effectiveness and/or reduce the safety of the patient, you and others.**

Safety

Before using the Expression MR400 MRI Patient Monitoring System, read the safety information below. The warnings below refer to the Expression MR400 MRI Patient Monitoring System in its entirety.

MAINTENANCE & FAULTS

WARNING

Do not use the product for any application until you are sure that the user routine-checks have been satisfactorily completed, and that the periodic maintenance of the product is up to date. If any part of the product is known (or suspected) to be defective or wrongly adjusted, DO NOT USE the product until a repair has been made. Operation of the product with defective or wrongly adjusted components could expose the user or the patient to safety hazards. This could lead to fatal or other serious personal injury, or to clinical misdiagnosis, or to clinical mistreatment.

SAFETY AWARENESS

WARNING

Do not use the product for any application until you have read, understood and know all the safety information, safety procedures and emergency procedures contained in this SAFETY section. Operation of the product without a proper awareness of how to use it safely could lead to fatal or other serious personal injury. It could also lead to clinical misdiagnosis or to clinical mistreatment.

SAFETY DEVICES

WARNING

Never attempt to remove, modify, or over-ride or frustrate any safety device on the product. Interfering with safety devices could lead to fatal or other serious personal injury.

INTENDED USE AND COMPATIBILITY

WARNING

Do not use the product for any purpose other than those for which it is intended. Do not use the product with any product other than that which Philips Medical Systems recognizes as compatible. Operation of the product for unintended purposes, or with incompatible product, could lead to fatal or other serious injury. It could also lead to clinical misdiagnosis or to clinical mistreatment.

ELECTRICAL SAFETY

WARNING

Do not remove covers or cables from this product (unless expressly instructed to do so in this *Instructions for Use*). Dangerous electrical voltages are present within this product. Removing covers or cables could lead to serious or fatal personal injury.

Covers or cables should [normally] only be removed by qualified and authorized service personnel. Use this product in rooms or areas that comply with all applicable law (or regulations having the force of law) concerning electrical safety for this type of product.

Electrically isolate this product from the mains electrical supply before cleaning or disinfecting.

Equipotential ground connection: An equipotential ground (earth) connection point is provided. Use this product in areas meeting local standards for electrical safety in rooms used for medical purposes, for example the US National Electrical Code. IEC 60601 also gives guidance about an equipotential ground (earth) connection point.

Additional equipotential ground connection: An additional equipotential ground (earth) connection point is provided, because the product is transportable and the reliability of the main equipotential ground connection point might be insufficient.

MECHANICAL SAFETY

WARNING

Do not remove covers from this product unless expressly instructed to do so in this *Instructions for Use*. Moving parts are present within this product. Removing covers could lead to serious or fatal personal injury.

Covers should normally only be removed by qualified and authorized service personnel. In this context, qualified means those legally permitted to work on this type of medical electrical product in the jurisdiction(s) in which the product is being used, and authorized means those authorized by the user of the product.

FIRE SAFETY

Use of an electrical product in an environment for which it was not designed can lead to fire or explosion. Fire regulations for the type of medical area being used should be fully applied, observed and enforced. Fire extinguishers should be available for both electrical and non-electrical fires.

WARNING

Only use extinguishers on electrical or chemical fires, which are specifically labeled for those purposes. Using water or other liquids on an electrical fire can lead to fatal or other serious personal injury.

If it is safe to do so, attempt to isolate the product from electrical and other supplies before attempting to fight a fire. This will reduce the risk of electric shocks.

ELECTROSTATIC DISCHARGE

Electrostatic discharge (ESD) can amount to a significant voltage, which may cause damage to PCBs or other system components.

CAUTIONS

- Always wait at least ten seconds after the product is switched OFF before switching the product back to ON.
- Always use proper static procedures, protection, and product prior to opening and during handling of this product. This product contains components that are electrostatic sensitive. Failure to use ESD procedures may cause damage to these components. Such damage to components is not covered by Philips warranties.

Connections to sensitive parts are identified by the ESD warning symbol (see inset).ESD damage is cumulative and may not be apparent at first, as indicated by a hard failure, but can cause degraded performance. Therefore, always use proper ESD handling procedures. ESD can result from low humidity conditions, use of electrical equipment on carpeting, linens, and clothing.

ELECTROMAGNETIC COMPATIBILITY (EMC)

This Philips product complies with relevant international and national law and standards on EMC (electromagnetic compatibility) for this type of product when used as intended. Such laws and standards define both the permissible electromagnetic emission levels from product and its required immunity to electromagnetic interference from external sources.

Other electronic products exceeding the limits defined in such EMC standards could, under unusual circumstances, affect the operation of the product.

- Medical electrical products needs special precautions regarding EMC, and needs to be installed and put into service according to EMC information provided in this *Instructions for Use*.
- The use of accessories and cables other than those specified, may result in increased emission or decreased immunity levels.
- The product should not be used adjacent to or stacked with other products and that if adjacent or stacked use is necessary, it should be observed to verify normal operation.

CAUTION

Portable and Mobile Phones

Portable and mobile RF communications can affect medical electrical equipment. Use caution when using such communication devices within the specified range of medical electrical devices. The Expression MR400 MRI Patient Monitoring System may be interfered with by other equipment with CISPR emission requirements.

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 ingress protection:	Rated IP21: Protected against access to hazardous parts and the ingress of solid foreign objects greater than 12.5mm (0.5 inch); and, protected against vertically dripping liquid.
According to the methods of sterilization or disinfection:	Non-sterilizable; use of liquid surface disinfectants only
According to the mode of operation:	Continuous operation
Equipment not suitable for use in the presence of flammable anesthetic mixture with air, oxygen or nitrous oxide.	

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

INDUSTRY CANADA STATEMENT

This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes : (1) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

FCC COMPLIANCE STATEMENT

CAUTION

Changes or modifications not expressly approved could void your authority to use this equipment

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Frequency Range: 2402–2482 MHz

Modulation Type: GFSK

WPU EIRP: 4.2 dBm (peak)

wECG and wSpO2 EIRP: 0 dBm (peak)

WARNING

The use of accessories, transducers and cables other than those specified in the accessory list accompanying this *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.

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
The Expression MR400 MRI Patient Monitoring System 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 Expression MR400 MRI Patient Monitoring System uses RF energy only for its internal functions. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions, CISPR 11	Class B	The Expression MR400 MRI Patient Monitoring System is suitable for use in all establishments, other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions, IEC 61000-3-2	Class B	
Voltage Fluctuations / Flicker Emissions, IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The Expression MR400 MRI Patient Monitoring System is intended for use in the electromagnetic environment specified below. The customer or the user of the Expression MR400 MRI Patient Monitoring System should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 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 Expression MR400 MRI Patient Monitoring System requires continued operation during AC power interruptions, power from an uninterruptible 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 *Ut is the AC mains voltage prior to application of the test level.*			

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The Expression MR400 MRI Patient Monitoring System is intended for use in the electromagnetic environment specified below. The customer or the user of the Expression MR400 MRI Patient Monitoring System should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 KHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	V1 = 3 Vrms E1 = 3 V/m	Portable and mobile RF communications equipment should not be used no closer to any part of the Expression MR400 MRI Patient Monitoring System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d = (3.5/V1) $\sqrt{P}$ d = (3.5/E1) $\sqrt{P}$ (80 MHz to 800 MHz) d = (7/E1) $\sqrt{P}$ (800 MHz to 2.5 GHz) Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the  symbol.

- 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 Expression MR400 MRI Patient Monitoring System is used exceeds the applicable RF compliance level above, the Expression MR400 MRI Patient Monitoring System should be observed to ensure normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Expression MR400 MRI Patient Monitoring System.

[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 Expression MR400 MRI Patient Monitoring System			
The Expression MR400 MRI Patient Monitoring System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Expression MR400 MRI Patient Monitoring System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Expression MR400 MRI Patient Monitoring System 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 $d = (3.5/V1)\sqrt{P}$	**80 MHz to 800 MHz** $d = (3.5/E1)\sqrt{P}$	**800 MHz to 2.5 GHz** $d = (7/E1)\sqrt{P}$
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. The battery life is at an end when the equipment operating time provided by battery power becomes much shorter than usual (i.e., when the total battery capacity has only 70 percent its initial capacity). For optimal battery life, please follow these guidelines:

- Do not store the batteries in a discharged condition. Always charge a battery to at least 40 percent of capacity before storing.
- Charge the batteries once a month when not in use.

Immediately remove any battery that has an expired life cycle and replace it with a new battery of the same type. (Refer to page 1-37 for part numbers.) To ensure the safety of operators and patients, observe the following warnings and cautions.

WARNING

Do not use a damaged battery. Periodically check batteries, stop using and replace 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. Do not immerse in a battery in water or other liquids.
- Store batteries in a dry place, between 0 to 40°C (32 to 104°F) . Do not expose a battery to temperatures above 60°C (140°F).
- Do not short the external battery contacts. Keep metal objects away from the battery contacts.
- Store each battery in a manner that prevents shorting with the container or another cell/ battery.
- Only use the Philips specified charger.

Examining the Shipment

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:

- Expression MR400 MRI Patient Monitoring System
- Two main batteries
- *Instructions for Use* (IFU) manual
- Quick Reference Guide (included in English-localized shipments only)
- Power Cord

A separate container may include additional items:

- Wireless ECG patient module (Gen 3)
- Wireless SpO2 patient module (Gen 3)

- Module battery charger
- Module batteries

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.

Initial Setup

The instructions below detail the initial setup process for a fully-equipped Expression MR400 MRI Patient Monitoring System (hereafter referred to as the MR400)—including the wireless ECG patient module (hereafter referred to as the wECG module) and the wireless SpO2 patient module (hereafter referred to as the wSpO2 module) and hereafter referred to collectively as wireless modules.

Depending upon the needs of your facility and the MR400 options purchased, the steps you follow may differ and some may not be required. For the location of components not detailed below, see chapter 2.

WARNINGS

- **Only perform initial setup of the MR400 at a location outside of the MR magnet room. Failure to observe this warning may result in serious injury.**
- **No modification of this equipment is allowed. Failure to observe this warning may result in serious injury.**

CAUTION

The MR400 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.

To perform initial setup of the MR400

Step	Action
1	Perform a visual inspection of the MR400, checking for loose or missing hardware or damage. If loose or missing hardware or damage is observed, contact technical support.
2	Install the main batteries into the cart and connect the reserve batteries; see page 1-16.
3	Connect AC mains power to the MR400, but DO NOT turn on the power switch. Allow the batteries to charge for at least 12 hours before use; see page 1-20. ***Note*** *Before initial use, charge the batteries in the cart for at least 12 hours with the MR400 turned off and connected to AC mains power.*
4	If wECG and wSpO2 modules were included, perform a visual inspection of the devices for loose or missing hardware or damage.
5	If a wSpO2 module was included, attach an SPO2 probe to it; see page 1-18.
6	If module batteries were included, charge the module batteries using the Philips-specified battery charger. (Refer to the instructions provided with the charger.) ***Note*** *Before initial use, charge the module batteries for at least 4 hours.*
7	Press the power switch (on the front of the cart) then verify that the MR400 has successfully powered-up and that the power LED is steady green. For other possible indications, see page 2-7.
8	If equipped with an IP5, verify that the MR400 and IP5 are set to the same wireless network channel by checking the network icon (see examples below) that is displayed by each device. See page 1-27 for MR400 network setting instructions; and, refer to the IFU for the IP5 for network setting instructions.
9	If wECG and wSpO2 modules were included, install the charged module battery (or batteries) into the device(s); see page 1-24 for the wECG module and see page 1-26 for wSpO2 module.

Step	Action
10	Verify that the status indicator on the wECG and wSpO2 modules is illuminated steady green: • For the wECG module, see page 2-9. • For the wSpO2 module, see page 2-11.
11	Verify that the wireless network channels on the wECG and wSpO2 modules are set to the channel used by the MR400; see page 1-29.
12	Place the wECG and wSpO2 modules into the module holders on the MR400; see page 2-12. This completes the initial setup process. For information regarding other possible MR400 connections; see *Rear Panel Connections* on page 1-19.

Installing and Connecting 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 MR400. The batteries will be attracted to the magnetic field, possibly causing patient or user injury.

CAUTION

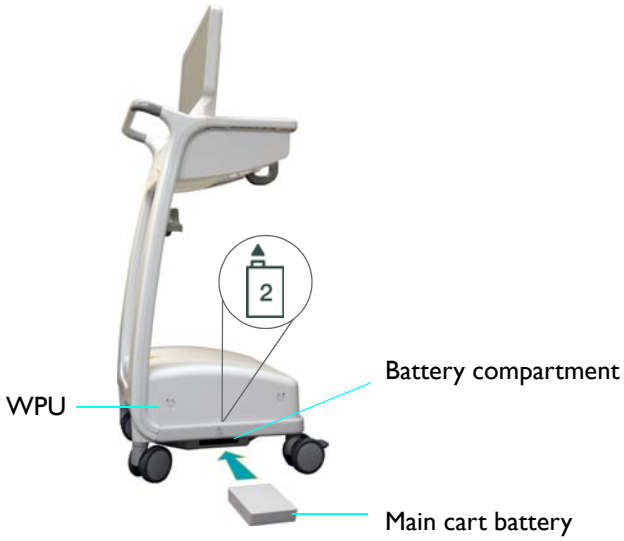
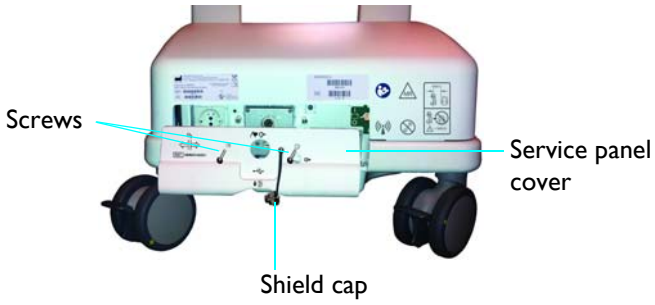
Never force a main battery into a battery compartment as it will damage the battery and/or the cart.

Four batteries are used in the MR400:

- Two main batteries must be inserted—one into the left battery compartment and one into the right battery compartment of the cart; and,
- Two reserve batteries, internally-housed in the cart, must be switched on.

To install and connect the main and reserve batteries

Step	Action
1	Locate the battery compartments, which are underneath the WPU on the left and right sides of the cart.

Step	Action
2	Hold a main cart battery with the label side down and with its connector facing forward. (Silk screening above each battery compartment provides the correct battery orientation—the left side is shown in the example below.) Then, slide the battery completely into the battery compartment until a “click” is heard as the battery latches into place.  (If the battery does not latch into place when inserted, then it is not properly oriented. In this case, remove, reorient correctly, and then reinsert the battery.)
3	Repeat steps 1 and 2 to install the remaining main cart battery on the opposite side of the cart.
4	Remove the shield cap from the gating connector and the two screws that secure the service panel cover to the back of the WPU then remove the service panel cover. 

Step	Action
5	Locate the battery switch and toggle it into the On (I) position. 
6	Reinstall the service panel cover, and secure it to the WPU using the two screws.
7	Replace the shield cap. This completes the installation and connection of the main and reserve batteries. Connect AC mains power then allow these batteries to charge for at least 12 hours before initial use; see page 1-21.

Attaching the SpO2 Probe to the wSpO2 Module

The SpO2 probe, necessary for taking SpO2-related measurements using the wSpO2 module, must be connected prior use.

WARNINGS

- **Only perform this attachment at a location outside of the MR magnet room. Failure to observe this warning may result in serious injury.**
- **Connecting an other than specified SPO2 probe to the wSpO2 module can cause inaccurate SPO2 readings and damage the module.**

To attach the SPO2 probe

Insert the SPO2 probe connector into the DB-9 connector on the wSpO2 module then securely tighten both screws.

1 wSpO2 module
2 DB-9 connector
3 SPO2 probe connector
4 Screws

Rear Panel Connections

Depending upon the options included with your MR400 or the use model, some connections may be required after moving the MR400 into the MR magnet room. In addition to the connection for AC mains power, connections for the waste gas port and the gating cable are available on the rear panel of the MR400. (For information about the placement of the MR400 in the MR magnet room, see page 3-2.)

CAUTION

When making connections to the rear panel of the MR400, ensure that the final installation complies with IEC 60601-1, clause 16, *Medical Electrical (ME) Systems*, to assure operator and patient safety. Always check the summation of leakage currents when the MR400 is connected to additional external equipment.

Where the integrity of the external protective conductor in the installation or its arrangement is in doubt, the MR400 shall be operated from batteries.

1 **Gating connector** for gating control connections to the MR system. (Gating cables are type-dependent; see page 1-35.)

2 **Waste gas port** (if equipped) for connection of exhausted sampled respiratory gases from the MR400 to your facility's gas scavenging system; suggested tubing requirement: 3.175 mm (0.125 inch) outer diameter, 1.6 mm (0.063 inch) inner diameter.

3 **Ground lug** (equipotential ground [earth] connection point)

- allows for electrical safety testing; and,
- allows authorized service personnel to connect a ground strap for prevention of ESD during servicing.

4 **Strain relief** for retention of the power cord.

5 **AC receptacle** for connection of the power cord.

Connecting AC Mains Power

When connecting the MR400 to the mains electrical supply, do not route the detachable power cord where it will be an obstruction or stepped upon. Do not block access to the MR400 with other equipment and never position the MR400 in such a way that would make it difficult to unplug.

WARNINGS

- **Only use the supplied power cord and connect to properly grounded AC outlets to avoid electrical shock.**
- **Avoid use of electrical extension cords or multiple portable socket outlets, which may create a safety hazard by compromising the grounding integrity of the MR400.**

To connect AC mains power

Step	Action
1	Ensure that all cart batteries are installed and switched on; see page 1-16 for details.
2	If placing the MR400 in the MR magnet room, position the MR400 at a proper location; see page 3-2.
3	Raise the strain relief; see page 1-20 for the location.
4	Plug the power cord into the AC receptacle on the MR400; see page 1-20 for the location. For added mobility, the power cord extension (REF 989803168221) can also be connected.
5	Lower the strain relief over the power cord.
6	Plug the power cord into an approved AC mains outlet.

To remove the MR400 from AC mains power

Pull the plug of power cord from the AC wall outlet. Then, lift the strain relief and remove the power cord from the AC receptacle on the rear of the MR400. Store the cord in a safe place.

Understanding Battery Operations

Cart Batteries

WARNING

Do not touch the patient and the circuitry in the battery compartments of the MR400 simultaneously.

Cart batteries, when installed (main) and switched on (reserve), are charged and conditioned by an integrated charging system. When turned on and connected to AC mains, the MR400 operates from AC power and simultaneously charges all cart batteries. When turned off and connected to AC mains, battery charging functions continue.

If at any time, AC mains is lost, the MR400 will automatically switch to battery power to provide uninterrupted service—then, when AC mains is restored, the MR400 will automatically, without delay, revert back to AC power functions. If the reserve batteries are fully depleted and AC mains is lost, then the unit will power off.

The MR400's maximum operating time on battery power depends upon the enabled parameters and the type and frequency of monitoring functions (see the Battery, Operation Time on page A-4 for a listing).

Charging Cart Batteries

Cart batteries must be charged before initial use. During initial setup or when installing new batteries, charge the cart batteries for at least 12 hours so that they are fully charged and conditioned for operation.

Notes

- *Use only with the specified battery charger.*
- *The main batteries **must** always be inserted and the reserve batteries **must** always be switched on to prevent loss of patient monitoring during a power outage. If main batteries are not inserted and if the reserve batteries are not switched on, then during power outage unsaved user settings will revert to factory defaults.*
- *We recommend plugging the MR400 into a backup generator or equivalent means to prevent a lapse in patient monitoring during a power loss.*

To charge the cart batteries

Step	Action
1	Ensure that all cart batteries are installed and switched on. See *Installing and Connecting Cart Batteries* on page 1-16 for details.
2	Connect the MR400 to AC mains power. See *Connecting AC Mains Power* on page 1-20.
3	Ensure that the MR400 is turned off and that it remains off for the next 12 hours.

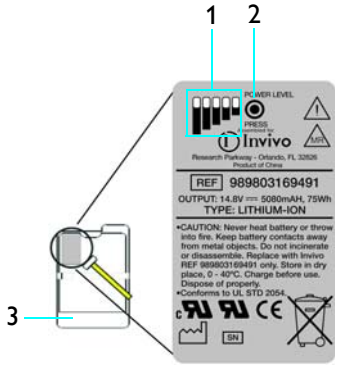
Charged capacity of all cart batteries can be displayed; see the *Status Information Panel* on page 2-18).

Charged capacity can also be found by pressing the power level button on each main cart battery, where the current level is provided by the charge indicator; see *Removing Cart Batteries*, below.

1 Charge indicator

2 Power level button

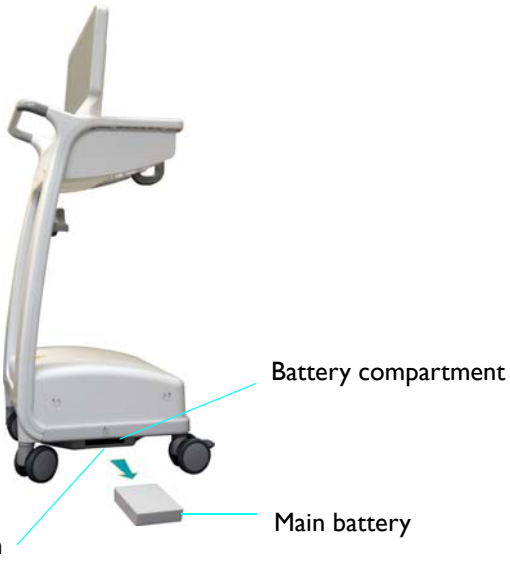
3 Cart battery



Removing Cart Batteries

To remove the main batteries

Step	Action
1	Locate the battery eject button, which is in a recessed area under each battery compartment on the left and right sides of the cart.

2	Press the battery eject button to partially eject a main battery from the battery compartment, and then grasp the battery and pull to remove it completely from the MR400.  (If the battery does not release, apply a slight forward pressure to the battery while pressing the battery eject button.)
3	Repeat steps 1 and 2 to remove the other main cart battery on the opposite side of the MR400.

Note

The reserve batteries cannot be removed, but can be switched off. For instructions on the complete removal of power to the MR400, see page 14-2.

Wireless Module Batteries

Module batteries provide power to the wECG and wSpO2 modules. Module batteries are interchangeable, non-magnetic, and can be handled safely in the MR magnet room.

CAUTION

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

Charging Module Batteries

Module batteries must be charged for at least 4 hours before initial use. Module batteries are charged in the Philips-specified battery charger. Refer to the instructions provided with this battery charger for information.

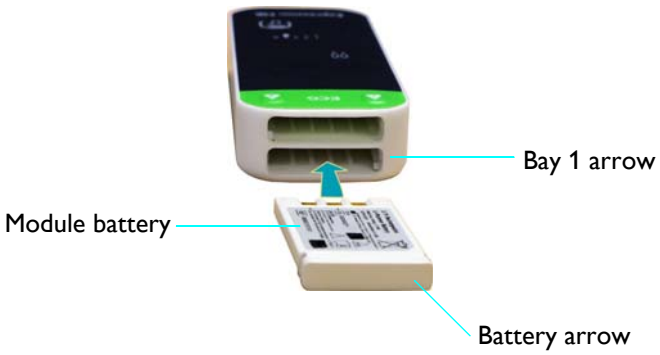
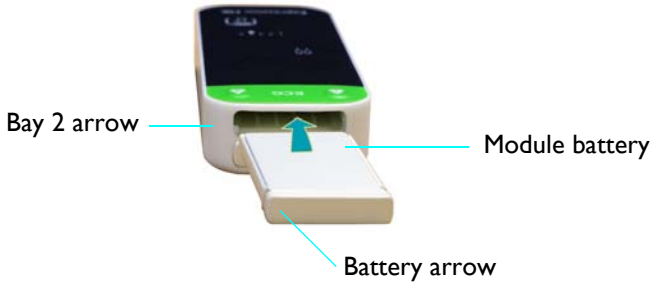
Installing Batteries in the wECG Module

The wECG module can accept up to two batteries. Depending upon the number of batteries installed, the wECG module provide different operational features:

- If one battery is installed, then the wECG module will turn on and function normally—but before its charge is exhausted, a second battery must be installed in order to continue the ECG study.
- If two batteries are installed, then seamless operation is possible—one battery will provide power until its charge is exhausted, at which time the wECG module will automatically switch to the remaining battery for continued operation. As long as sufficient power is provided by the second battery, continued operation is possible. And, an exhausted battery can be replaced at any time without interruption to the ECG study, provided that sufficient charge is present on the remaining battery.
- Indicators identify the source battery being used by the wECG module; see page 2-9.
- When both batteries are removed, the wECG module will turn off.

To install batteries in the wECG module

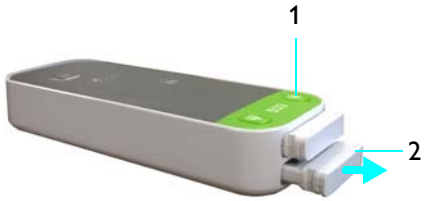
Step	Action
1	Hold the wECG module so that its battery bays are oriented as shown, with battery bay 1 in the lower position and battery bay 2 in the upper position. 

Step	Action
2	Orient a module battery so that the tip of the battery arrow aligns with the tip of the bay 1 arrow on the wECG module. Then slide the module battery into bay 1, pressing until it seats completely. 
3	Orient a module battery so that the tip of the battery arrow aligns with the tip of the bay 2 arrow on the wECG module. Then slide the module battery into bay 2, pressing until it seats completely. 

Removing Batteries from the wECG Module

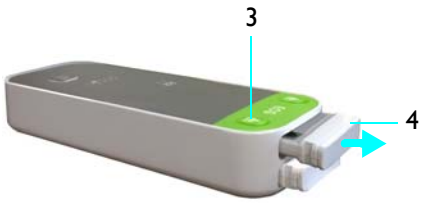
To remove battery 1 from the wECG module

Press a battery eject button 1 (item 1, right). Then grasp the partially ejected module battery (item 2) and pull to remove it.



To remove battery 2 from the wECG module

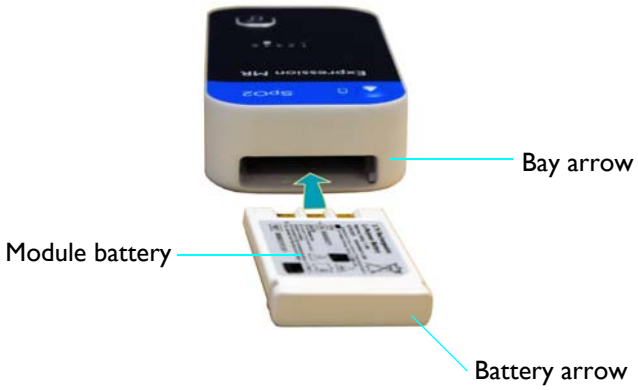
Press a battery eject button 2 (item 3, right). Then grasp the partially ejected module battery (item 4) and pull to remove it.



Installing a Battery in the wSpO2 Module

The wSpO2 module uses one battery. When a module battery is inserted, the wSpO2 module will turn on. And, when the battery is removed, the wSpO2 module will turn off.

To install a battery in the wSpO2 module

Step	Action
1	Hold the wSpO2 module so that its battery bay is oriented as shown. 
2	Orient a module battery so that the tip of the battery arrow aligns with the tip of the bay arrow on the wSpO2 module. Then slide the module battery into the battery bay, pressing until it seats completely. 

Removing the Battery from the wSpO2 Module

To remove the battery from the wSpO2 module

Press the battery eject button (item 1, right). Then grasp the partially ejected module battery (item 2) and pull to remove it.

Understanding Wireless Network Operations

A wireless network channel is used for system communication between the MR400 cart and the wECG and wSpO2 modules (and, if equipped, the IP5). All wireless devices must use the same wireless network channel for proper system communications. Also, where multiple Invivo (Royal Philips) MRI patient monitoring systems are in use, the selected wireless network channel should be not used by any other system in your facility (for the frequency range, see page 1-8).

Setting the Wireless Network Channel of the Cart

All controls for selecting the wireless network channel of the MR400 are located on the cart's touch screen. Unique symbols and numbers are used to identify each available channel for the MR400, as shown below.

Network channel 1		Network channel 6
Network channel 2		Network channel 7
Network channel 3		Network channel 8
Network channel 4		Network channel 9
Network channel 5		Network channel 10

WARNINGS

- **Care should be taken to guard against inadvertent changes to the network channel setting. Before use, always ensure that all devices are communicating properly. Failure to do so may cause a lapse in patient monitoring.**
- **An MR400 system is comprised of one MR400 cart, one wECG module, and one wSpO2 module, and optionally an IP5. In environments where multiple MR400 MRI patient monitoring systems are being used, you must be aware of each component's network setting. Operating multiple MR400 systems 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.**

Notes

- *If a patient is currently admitted, a warning dialog box will prompt you before a change to the monitor network is allowed.*
- *After changing the wireless network channel of the MR400, you must wait a minimum of 5 seconds before removing power from the system; otherwise, the change will be lost.*

To set the wireless network channel for the MR400 cart

Step	Action
1	Press the power switch (see page 2-7 for the location) then allow the MR400 to initialize. The main screen appears.
2	Select the network icon. Network menu  Network icon The network menu appears.

Step	Action
3	Select the desired setting from the options: **1** **2** **3** **4** **5** **6** **7** **8** **9** **10** The setting is entered and the network icon is changed to the current selection.
4	Ensure that the network channel used by the wECG and wSpO2 modules (see page 1-29) and the IP5 (if equipped) are identical to the network setting of the cart.

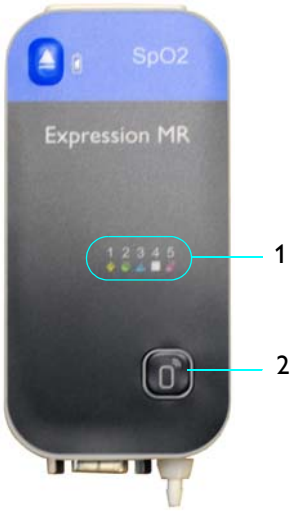
Setting the Wireless Network Channel of the wECG and wSpO2 Modules

All indicators and controls for wireless network channel selection are located on the front of the wireless modules. Two different groups of five wireless network channels are available (channels 1–5, or channels 6–10) and both modules must be of the same group, depending upon your selection at time of purchase.

Note

The wECG and wSpO2 modules may arrive preprogrammed to match the network channel setting of your MR400, thus eliminating the need to change the channel setting.

The wireless network channel for a module is changed by using the network selection button. The wireless network channel for a module should be set to match the wireless network channel used by the MR400; see page 1-27.



1 Network channel indicators

2 Network selection button

The following directions for changing the wireless network channel apply to both wireless modules and to either channel group, though the process below depicts the wSpO2 module and channel group 1–5. (For more operational details about the wECG module, see page 2-9; and, for the wSpO2 module, see page 2-11.)

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

- The following symbols are used to convey the state of the network channel indicator on a wireless module.

Symbol illuminated

Symbol blinking

- The following illustrations are used to convey actions concerning the use of the network selection button.

Pressing the button

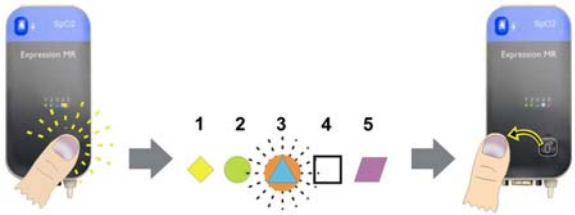
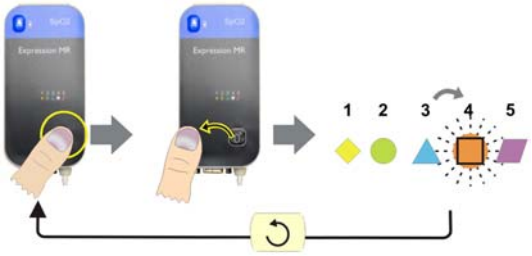
Pressing and holding the button

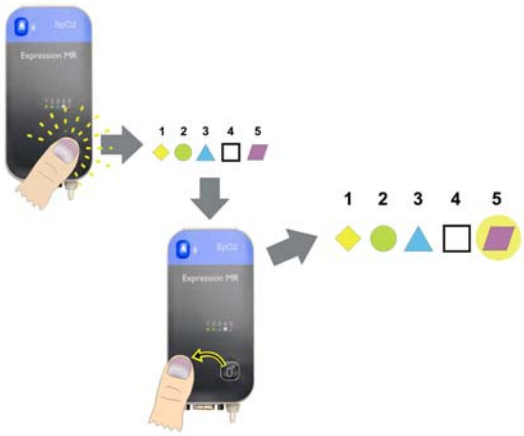
Releasing the button

Repeating

To set the wireless network channel of the wECG or wSpO2 module

Step	Action
1	Turn off the wireless module: • wECG module—see *Removing Batteries from the wECG Module* on page 1-25. • wSpO2 module—see *Removing the Battery from the wSpO2 Module* on page 1-27.
2	Turn on the wireless module: • wECG module—see *Installing Batteries in the wECG Module* on page 1-24. • wSpO2 module—see *Installing a Battery in the wSpO2 Module* on page 1-26. The network channel indicators will flash briefly and then the current network channel indicator will illuminate (for example, “3” in the illustration below). 

Step	Action
3	Enter the network channel change mode: After the current network channel indicator has been illuminated (and within 10 seconds of module power-up), press and hold the network selection button until the current network channel indicator begins to rapidly blink then release the button.  1 2 3 4 5 ***Note*** *If the network channel change sequence was not started within 10 seconds after the module has been turned on, network channel changes will not be allowed. In this case, you must cycle module power and restart the sequence.*
4	Press down again on the network selection button until the symbol stops blinking and then release the button to change the network channel setting. When you do this, the next network channel indicator in the sequence will blink rapidly. (In other words, if the module was originally using network channel "3," now the "4" symbol will be blinking.) Repeat this sequence of pressing down and releasing the button until the symbol of the network channel you prefer is rapidly blinking. If you pass the desired channel, simply continue pressing and releasing the button until the desired network channel indicator is blinking again.  1 2 3 4 5

Step	Action
5	When you reach the desired symbol, press and hold the button for approximately 5 seconds to lock and save the new setting. The selected network channel's symbol will turn off while the button is depressed. Then it will illuminate (not blink) when the new network channel setting is saved. Once illuminated, release the button. The module will begin using the selected network channel.  ***Note*** *Any part the network channel change sequence not completed will cause the module to revert to the network channel previously set 30 seconds after the network selection button was last released.*

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.

The MR400 uses a wireless connection for communication with the IP5. The IP5's connection to the hospital information system (HIS) is explained in detail in the IP5 IFU. When using the IP5 to connect to the HIS, adhere to all cautions and safety instructions found in the IP5 IFU.

Additional Options

Additional options may be suggested by your biomedical technician to increase user ease. Consult your biomedical technician or technical support with specific requests.

CAUTIONS

- When adding equipment to an MR400 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, et cetera.
- Unauthorized modification to the radios/and/or antennas may cause the device to no longer be in compliance with applicable regulatory standards
- 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 MR400 system or device communications.

Accessory List

Accessories are listed in the tables below with part number (REF) information. Where applicable, the original part number has also been included for reference. For additional information about these accessories, please consult the documentation that accompanies the accessory.

WARNING

The MR400 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 MR400. Patient injury or loss of monitoring may result if incorrect accessories are used.

WARNING

Do not use sterile items if the packaging is damaged. Patient injury may result if non-sterile accessories are used.

CAUTION

Modifications to the MR400 System during its service life are required to be evaluated to the requirements of IEC 60601-1.

AGENT	Original Part Number	REF
CANNULA, DISP, ADULT	9012	989803152561
CANNULA, DISP, ADULT	9016	989803152601
CANNULA,DISP,INT INF,(DIVIDED)	9016B	989803152621
CANNULA,DISP,PED,(DIVIDED)	9016C	989803152631
CANNULA,DISP,INFANT,(DIVIDED)	9016A	989803152611
CANNULA, DISP, INT INFANT	9015	989803152591
CANNULA, DISP, PED	9013	989803152571
CANNULA, DISP, INFANT	9014	989803152581
ANESTHETIC OXYGEN (O2) SENSOR	—	989803162051
KIT,DISPOSABLE WATER TRAP,3160	94012	989803152671
KIT,SAMPLE,AGENTS,3160	94018	989803152661

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

CO2	REF
LOFLO LINE, PED DVD CANNULA, BOX 20	989803183281
LOFLO LINE, ADU AIRWAY ADPT, BOX 20	989803183291
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	Original Part Number	REF
GEL, ECG/EEG, SKIN PREP, TUBE, 3-PACK	9009	989803152291
EXPRESSION MR ECG LEADS, AAMI, CV	—	989803193721
EXPRESSION MR ECG LEADS, AAMI, STANDARD	—	989803193731
EXPRESSION MR ECG LEADS, AAMI, NEONATAL	—	989803193741
EXPRESSION MR ECG LEADS, IEC, CV	—	989803193751
EXPRESSION MR ECG LEADS, IEC, STANDARD	—	989803193761
EXPRESSION MR ECG LEADS, IEC, NEONATAL	—	989803193771
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 (GEN 3) 1-5	—	989803192761
WIRELESS ECG PATIENT MODULE (GEN 3) 6-10	—	989803194341

Gating	Original Part Number	REF
CAB, DIGITAL GATING, GE, 3160	9292	989803152821
CAB, GATING, SIEMENS, 3160	9291	989803152831
UNIVERSAL GATING INTERFACE	—	989803195521
CAB, DIG.GATING, HIT/TOSH, 3160	9293	989803152851

Invasive Blood Pressure	REF
EXPRESSION MR IBP TRANSDUCER CABLE, 5FT	989803194601
EXPRESSION MR IBP DPT KIT, A/P, BOX 20	989803194631
EXPRESSION MR IBP DPT KIT, I/N, BOX 20	989803194641
(Note that Hospira [Transpac models], and Edwards Lifesciences [Transducer, Model PX260 and adapter cables], have also been qualified for use. Please contact Hospira or Edwards Lifesciences for information about Invivo-compatible devices, and contact your sales representative with any questions.)	

Non-invasive Blood Pressure (NIBP)	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, 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

Non-invasive Blood Pressure (NIBP)	REF
ADULT PRESSURE INTERCONNECT HOSE	989803183221
NEONATAL PRESSURE INTERCONNECT HOSE	989803183231

Respiration (Pneumatic)	Original Part Number	REF
PNEUMOGRAPH,CHEST,NM,3160	94023	989803152791

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 (GEN 3) 1-5	989803192771
WIRELESS SPO2 PATIENT MODULE (GEN 3) 6-10	989803194331

System	REF
BATTERY, MODULE (GEN 3)	989803191341
BATTERY, MRI, 14.8V, 5.08 AH, UL	989803169491
EXPRESSION INFORMATION PORTAL (IP5)	865471
ADVANCED COMMUNICATIONS OPTION	989803176521
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

System	REF
POWER CORD, DANISH, 3 METER	989803181331
POWER CORD, ISRAELI, 3 METER	989803181341
POWER CORD, ARGENTINA, 3 METER	989803181351
POWER CORD, SWISS, 3 METER	989803181361

Temperature	REF
FLEXTEMP II SENSOR (ESOPHAGEAL/RECTAL/AXILLARY, DIRECT MODE)	989803194511
SURGICAL LUBRICANT, 12 PACK	989803168891
FLEXTEMP SYSTEM, JACKET (BOX 10)	989803178181

Miscellaneous	REF
MR400 QUICK REFERENCE GUIDE	453564557591
MANUAL, SERVICE, MR400	989803195211
MANUAL, OPERATOR, MR400, DANISH	989803193191
MANUAL, OPERATOR, MR400, DUTCH	989803193201
MANUAL, OPERATOR, MR400, ENGLISH	989803193211
MANUAL, OPERATOR, MR400, FINNISH	989803193221
MANUAL, OPERATOR, MR400, FRENCH	989803193231
MANUAL, OPERATOR, MR400, GERMAN	989803193241
MANUAL, OPERATOR, MR400, INDONESIAN	989803193251
MANUAL, OPERATOR, MR400, ITALIAN	989803193261
MANUAL, OPERATOR, MR400, JAPANESE	989803193271
MANUAL, OPERATOR, MR400, KOREAN	989803193281
MANUAL, OPERATOR, MR400, NORWEGIAN	989803193291
MANUAL, OPERATOR, MR400, POLISH	989803193301
MANUAL, OPERATOR, MR400, PORTUGUESE	989803193311
MANUAL, OPERATOR, MR400, RUSSIAN	989803193321
MANUAL, OPERATOR, MR400, SPANISH	989803193331
MANUAL, OPERATOR, MR400, SWEDISH	989803193341

Miscellaneous	**REF**
MANUAL, OPERATOR, MR400, TRAD. CHINESE	989803193351
MANUAL, OPERATOR, MR400, TURKISH	989803193361

CHAPTER 2

System Overview

The MR400 is designed to provide multi-vital sign patient monitoring and MRI gating capability in the MRI environment while in close proximity to an MRI scanner magnet. The monitoring capabilities of the MR400 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 MR400 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

Note

We recommend the establishment of a program for supervision appropriate to the classes and types of patients, and that all patients should receive at least routine monitoring when the MR400 is in use.

System Parameters

The MR400 simultaneously processes and displays multiple parameters, waveforms, measurement numeric values and alarms. All patient information is provided on the touch screen. A fully equipped MR400 includes monitoring for the following parameters:

- Electrocardiogram (ECG), dual channel
- Heart rate (HR)
- Blood oxygen saturation/pulse oximetry (SPO2)
- End-tidal and fractional inspired CO2 (EtCO2 and FiCO2)
- Invasive blood pressure (P1 and P2)
- Anesthetic agents (AGENT)
- Fractional inspired O2 (FiO2), and end-tidal and fractional inspired N2O (EtN2O and FiN2O)
- Temperature (TEMP)

- Non-invasive blood pressure (NIBP)
- Respiration rate (CO2 or bellows)

Note

Depending upon the equipped options, your MR400 may not have all indicated parameters.

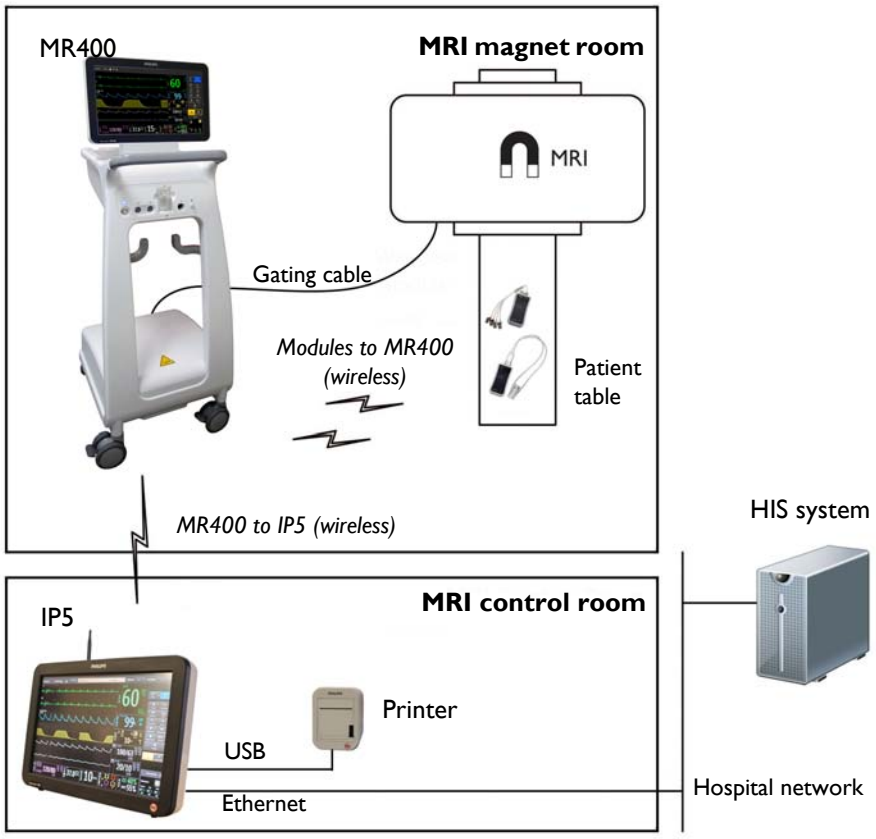
System Components

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

- MR400 cart
- wECG module
- wSpO2 module
- Module battery charger
- Batteries and other accessories as needed
- Optional: IP5 with or without a printer

Use Model

The MR400 is intended to be used to monitor the vital signs of a patient in an MR magnet room, as illustrated below. The wECG and wSpO2 modules communicate via wireless links to supply the patient's measured ECG, SPO2, and bellows-derived respiration signals to the MR400. The gating cable is only required for MRI triggering and synchronization based on the patient's ECG or SPO2 signals. When paired with an optional IP5, monitoring capability can be extended via wireless link to an MR control room, induction room, or recovery room environment. Data transmitted from the MR400 to an IP5 can be output to an optional strip chart printer or to the hospital information system (HIS).



Acquisition and Control

Use of the MR400 is restricted to one patient at a time. The MR400 displays patient measurements acquired during monitoring. Controls and settings for patient monitoring are provided locally on the touch screen 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 MR400 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 according to the start-up sequence:

- If the MR400 boots and communicates first, then its settings will be reflected at the IP5.
- If an IP5 boots and communicates first, then its settings will be reflected at the MR400.

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

WARNINGS

- **The use model specifies one IP5 per MR400 system. If more than one IP5 is present on the MR400 system, there is an increased risk of units within the system not synchronizing and displaying incorrect or corrupted settings.**
- **The MR400 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.**

CAUTION

If the monitor's settings are adjusted since they were last recalled or stored (manually, or via synchronization if using an IP5), the **User Settings** key (see page 2-15) will be appended with a plus symbol (+). The symbol will only be removed if the current settings are saved (see page 3-15) or if different settings are recalled (see page 3-26). Always confirm the proper settings for the MR400 and IP5 to ensure expected monitoring functionality.

Note

See Default Settings (on page 3-7) for information about the system's power-on setup.

Device Control

Menu commands that control parameter functions for patient monitoring are synchronized between the MR400 and IP5. Commands that do not directly control patient parameters (for example, printer functions) will only affect the IP5. Other control settings remain localized to the IP5 and are not synchronized with the MR400, including the alarm audio off and alarm audio pause functions, and the volume settings; see the IP5 IFU for a complete listing.

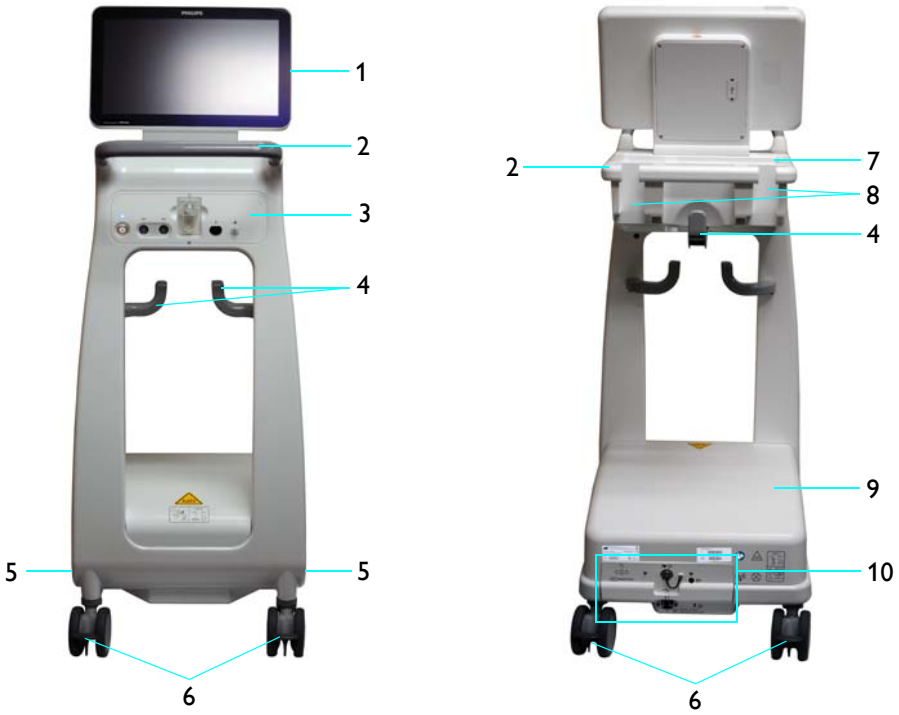
Note

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 portion of the MR400. This will result in the removal of all patient data and displayed information, and a continuous alarm will sound until power to the MR400 is turned off. If this problem persists, contact technical support.

Hardware Features

Cart

Designed for use in the MR magnet room and throughout the MR suite, the MR400 is a self-contained mobile patient monitoring system. The MR400 features a wheeled-cart design with four large lockable casters under its aluminum frame and includes integrated systems for processing, power, display and control, as outlined below.



1 Display panel (see page 2-6 for details).

2 Guide handles provides the means for positioning the cart; see page 3-2 for details.

3 Patient connection panel (see page 2-7 for details).

4 Accessory hooks provide storage for sampling lines, cables, et cetera.

5 Battery compartments house the main batteries; see page 1-16 details.

6 Casters with wheel locks that, when engaged, prevent movement of the cart.

7 Storage basket provides storage for Quadtrodes, cuffs, SPO2 attachments and other small accessories; see page 2-12 for details.

8 Module holders provide storage for the wECG and wSpO2 modules; see page 2-12 for details.

9 Wireless processing unit (WPU) houses the communication, processing and power systems for the MR400.

10 Rear panel houses connections for AC mains power, earth ground, gating, USB port (service use only), (optional) waste gas output, and (optional) O2 sensor.

Display Panel

The display panel includes a touch screen LCD (liquid crystal display), the alarm indicators and an audio speaker. The display panel can be tilted backward or forward to achieve the best viewing angle and reduce any glare on the touch screen produced by ambient lighting.

CAUTION

Never use the display panel to position the MR400; severe damage or failure can result. Only use the guide handle to position the MR400. If breakage of the display panel glass does occur and you contact the liquid crystal by chance, please wash it from your skin using soap and water.

1 Touch screen provides displayed information and control of the MR400, and can be used with gloved fingers.

2 Alarm light provides a visual indication of an alarm condition.

3 Speaker provides all audible indications.

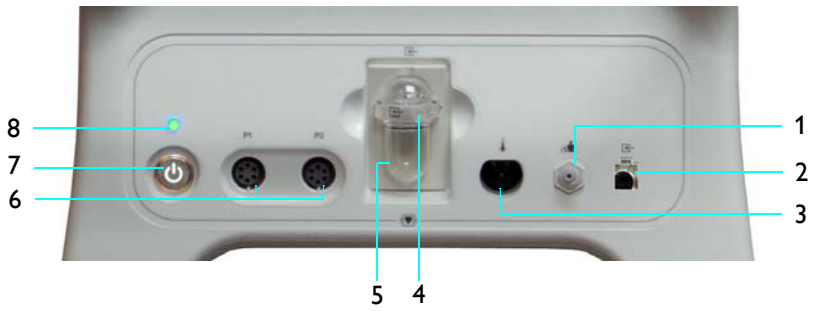
4 USB port provides service-related functions.

Patient Connection Panel

The patient connection panel contains the power switch and LED, and input connections for various patient accessories.

Note

The illustration shown below features a composite of all available options. Your MR400 will not have all of these options.



1 NIBP interconnect hose port

2 (Optional) Loflo CO2 sampling line port

3 (Optional) Temperature port

4 (Optional) AGENT sample port

5 (Optional) AGENT water trap

6 (Optional) Invasive blood pressure ports (P1 and P2)

7 Power switch (standby switch) is a push-type latching switch that controls power (AC mains or batteries) to the MR400

8 Power LED indicates the power source and power status of the MR400, as detailed in the table below

Power LED		**Condition / Meaning**	
Color	**State**	**Power Source**	**Power Switch**
None	Off	None (batteries may be installed)	Off
Green	Steady	Depending upon power source: • If AC is present, then AC mains • If AC is not present, then batteries	On

Power LED		Condition / Meaning	
Color	**State**	**Power Source**	**Power Switch**
Red	Steady	Power fault detected; contact technical support.	N/A
Blue	Blinking	Batteries are charging	Off
Blue	Steady	Batteries at full charge	Off

wECG and wSpO2 Modules

The wECG and wSpO2 modules are battery powered and communicate with the MR400 through a bidirectional 2.4 GHz RF link, which is automatically established approximately 30 seconds after power is applied to the module. These wireless modules operate at a distance of up to 9.1 m (30 feet) from the MR400 cart when all devices are placed within the same MRI room or within the same shielded room.

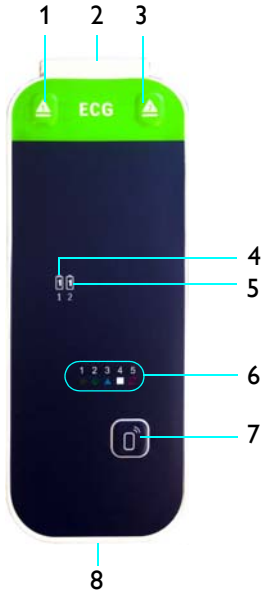
The network channel and battery indicators denote the selected network channel and the battery status for each wireless module. After communications have been established, all module-dependent vital sign information will be displayed within 10 seconds on the MR400.

WARNING

The system use model specifies one wECG module and one wSpO2 module per MR400 system network channel. If more than one type of each module is communicating on the same network channel, then waveform and measurement corruption will occur.

wECG Module

The wECG module transmits measured ECG signals through the RF link to the MR400, where two ECG signals can be displayed and are available for interfacing with the MR system cardiac gating input. The module also receives information from the MR400 to perform commanded tasks (for example, lead view and filter mode selections).



1 Battery 1 eject button

2 Batteries

3 Battery 2 eject button

4 Battery 1 indicator

5 Battery 2 indicator

6 Network channel indicators (1–5, in this example)

7 Network selection button

8 ECG lead cable connector

wECG Module Indicators

Battery indicators provide charge status indications for each battery used by the wECG module, as detailed in the table below.

Notes

- *A battery time-remaining counter is displayed by the MR400; see page 2-16 for details.*
- *For battery replacement details, see page 1-24.*

wECG Battery Indicator	Color	Charge Status
	None	Battery not installed in battery bay 1, or the battery's charge is insufficient to power the module
	Green	Battery installed in battery bay 1 has sufficient charge
	Red	Battery installed in battery bay 1 has low charge
	None	Battery not installed in battery bay 2, or the battery's charge is insufficient to power the module
	Green	Battery installed in battery bay 2 has sufficient charge
	Red	Battery installed in battery bay 2 has low charge

Network channel indicator illuminates to provide the wireless network channel indication and the status of the wECG module to MR400 communications, as detailed in the table below.

Notes

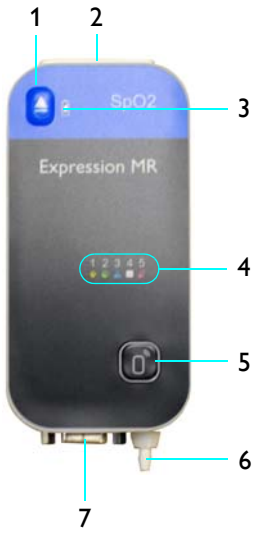
- *The communication status is also displayed by the MR400; see page 2-16 for details.*
- *For network channel selection details, see page 1-29.*

Network Channel Indicator	Channel Selected	Network Channel Indicator	Channel Selected
	Channel 1		Channel 6
	Channel 2		Channel 7
	Channel 3		Channel 8
	Channel 4		Channel 9
	Channel 5		Channel 10

Network Channel Indicator State	Communication Status
Steady	Good communication
Flashing	No communication

wSpO2 Module

The wSpO2 module transmits measured blood oxygen saturation, plethysmography, peripheral pulse data and pneumatic respiration rate values through the RF link to the MR400, where the processed information can be displayed and output for interfacing to the MR system pulse peripheral and respiration gating input.



1 Battery eject button
2 Battery
3 Battery indicator
4 Network channel indicators (1–5, in this example)
5 Network selection button
6 Pneumatic respiration port; see page 10-2
7 SPO2 probe connector; see page 1-18

wSpO2 Module Indicators

Battery indicator provides charge status indications for the wSpO2 module, as detailed in the table below.

Notes

- *A battery time-remaining counter is displayed by the MR400; see page 2-16 for details.*
- *For battery replacement details, see page 1-26.*

wSpO2 Battery Indicator	Color	Charge Status
	None	Battery not installed or its charge is insufficient to power the module
	Green	Battery charge sufficient
	Red	Battery charge low

Network channel indicator illuminates to provide the wireless network channel selection indication and the status of the wSpO2 module to MR400 communications, as detailed in the table below.

Notes

- *The communication status is also displayed by the MR400; see page 2-16 for details.*
- *For network channel selection details, see page 1-29.*

Network Channel Indicator	Channel Selected	Network Channel Indicator	Channel Selected
	Channel 1		Channel 6
	Channel 2		Channel 7
	Channel 3		Channel 8
	Channel 4		Channel 9
	Channel 5		Channel 10

Network Channel Indicator State	Communication Status
Steady	Good communication
Flashing	No communication

Storing Modules and Accessories

WARNINGS

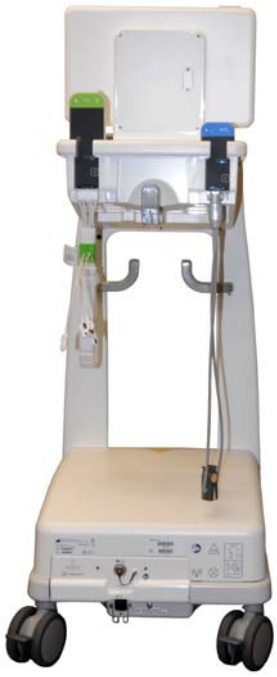
- **Never store items containing ferrous materials on the cart or in the storage basket. Failure to observe this warning may result in serious injury.**
- **To reduce the spread of infection, never store accessories on the cart guide handles.**

CAUTION

When storing or removing the wECG and wSpO2 modules from the module holders, grasp only the module and never pull or apply excessive force or tension to any connected attachment.

To store the wECG module and a connected ECG lead cable

Loop the ECG cable trunk with foam insulator and secure it using the Velcro storage strap (see page 5-2). Then, place the wECG module into a module holder and allow the ECG lead cable to drape.



WARNING

Do not use the Velcro storage strap to loop the ECG lead cable during MR scanning; otherwise, there is a risk of cable heating and possibly skin burns.

CAUTION

Failure to loop the Velcro storage strap on the ECG cable trunk may result in damage to the lead cable due to contact with the floor.

To store the wSpO2 module and a connected probe

Place the wSpO2 module into a module holder and allow the SPO2 probe to drape.

To store small accessories, sample lines and the temperature sensor

- Use the removable storage basket to hold small accessories (Quadtrodes, SPO2 clips and grips, et cetera). To remove the storage basket from the cart, grasp the basket and lift.
- Use the accessory hooks to hang looped sample lines, the temperature sensor, et cetera.

CAUTIONS

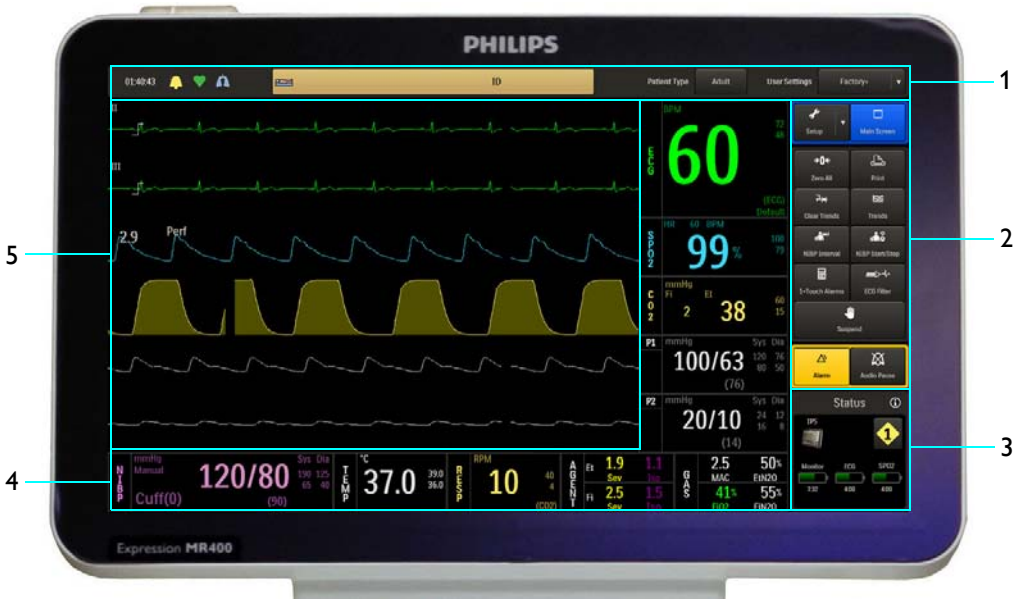
- Do not place more than 2.2 kg (5 pounds) of combined weight of items in the storage basket, module holders and accessory hooks.
- Never stack items onto or drape objects over the guide handle.

Displayed Information and Controls

The displayed information and controls for the MR400 are grouped on the touch screen according to function.

Note

The example below depicts information displayed by a fully-equipped MR400. Information displayed by the MR400 will vary according to the equipped options and activated parameters. If a parameter (or an ECG trace) has been turned off, its portion of the display will be blank. To turn a parameter on or off, use ***Parameters*** *in the* ***Monitor Setup*** *menu; see page 3-18 for details.*



1 Information bar

2 Soft keypad

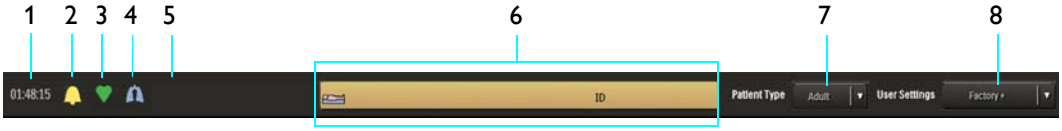
3 Status information pane

4 Vital sign boxes

5 Vital sign traces

Information Bar

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



1 **Set Time** indication, and when pressed accesses the date; see page 3-13.

2 Alarm sound state indication; see page 4-4.

3 Heart beat detection indication (and provides a detection tone) according to the **HR Tone Source** setting; see page 3-21.

4 Respiration detection indication when CO2-derived respiration is on and within specified limits, flashing at a frequency that matches the current breath rate.

5 **Alarm Light** setting indication; see 4-20.

6 Patient information area, which displays the patient's name and identifier (ID) when available from an IP5.

7 **Patient Type** key and the current patient type setting indication; and, when pressed, accesses the **Patient Type** menu (see page 3-11).

8 **User Settings** key and user settings file name indication (where the plus symbol [+] indicates that changes have occurred); and, when pressed, allows you to select a factory or a stored user setup (see *Edit User Settings* on page 3-15).

Soft Keypad

The soft keypad provides immediate access to frequently used menus and functions.

1 **Main Screen** key returns the MR400 to normal mode, closing any open menu, option or dialog box

2 **Print** key controls the remote print function and indicates the current state of the printer

3 **Trends** key accesses the **Tabular Trends** menu

4 **NIBP Start/Stop** key starts or stops an NIBP measurement

5 **ECG Filter** key accesses the **ECG Filter Mode** options

6 **Suspend** key places the MR400 in suspend mode

7 **Audio Pause** key temporarily deactivates alarms

8 **Alarm** key acknowledges an active alarm

9 **1-Touch Alarms** key sets all alarm limits according to preset calculation values

10 **NIBP Interval** key accesses the automatic measurement **Interval** options

11 **Clear Trends** key clears stored trend data

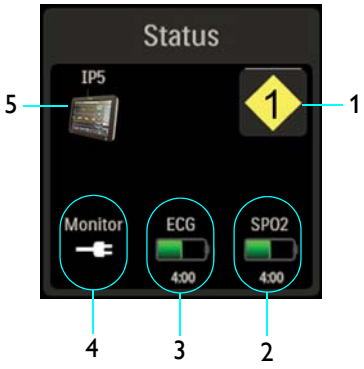
12 **Zero All** key zeros all active invasive blood pressure channels

13 **Setup** key accesses the **Monitor Setup**, **Printer**, and **Alarms** menus

Status Information Pane

The status information pane provides indications for the MR400 and wireless devices:

- Communication and power indications will be displayed within 2 seconds.



1 Monitor network icon, which indicates the selected wireless network channel (1, in this example) and, when pressed, allows you to select the channel used by the MR400; see *Setting the Wireless Network Channel of the Cart* on page 1-27 for details.

2 Indicates the battery time-remaining (given in an hours:minutes format) until power will be exhausted for the wSPO2 module; also, indicates that the wSPO2 module's communication with the MR400 is good.

3 Indicates the battery time-remaining (given in an hours:minutes format) until power will be exhausted for the wECG module; also, indicates that the wECG module's communication with the MR400 is good. For detailed battery information regarding the wECG module batteries, see *Status Information Panel* on page 2-18.

4 Indicates the current power type used by the MR400 (AC power in this example).

5 Indicates that an IP5 is communicating with the MR400.

- Power source change-of-state indications are displayed.

1 Indicates a low battery condition and the approximate time (given in an hours:minutes format) until power will be exhausted for a module battery (wSpO2 in this example); also, indicates that the module's communication with the MR400 is good.

WARNING

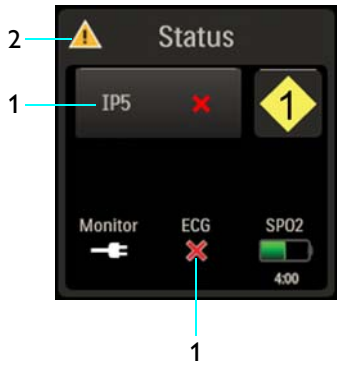
A red battery symbol indicates that the module batteries have fallen below the required operational output and module shutdown with loss of monitoring will occur. Immediately replace the module batteries to avoid a loss in monitoring.

2 Indicates that the cart batteries are the current power type used by the MR400 and the approximate time (given in an hours:minutes format) until power will be exhausted.

WARNING

A red battery symbol indicates that the main batteries in the MR400 have fallen below the required operational output and system shutdown with loss of monitoring will occur. Immediately locate an AC outlet and connect the MR400 to avoid a loss in monitoring.

- Indications are provided for a loss of communication, which is indicated within 2 seconds, and a no data condition (see page 2-20) will be displayed within 10 seconds for all vital sign information missing due to a non-communicating wireless module.



1 Indicates that no communication is occurring between the MR400 and a wireless module (wECG in this example), or between the MR400 and the IP5.

2 Indicates a status warning when a communication error between the MR400 and a wireless module, or between the MR400 and an IP5 is detected.

Status Information Panel

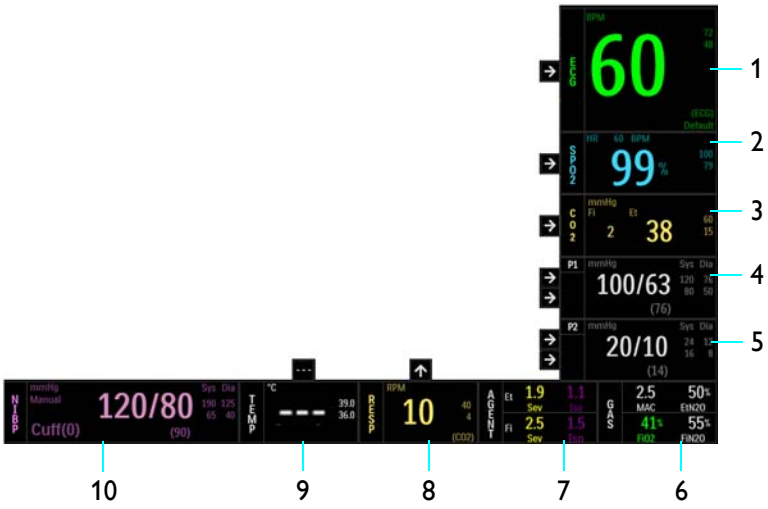
The status information panel provides wireless communication and power details, including the charge level of all connected batteries.

To open the status information panel

Select the title area (1, below) on the status information pane.

Vital Sign Boxes

Vital sign (VS) boxes are uniquely colored and labeled graphic frames that contain the numeric measurements and current alarm limits settings for each monitored parameter. Trending indications (arrows) are available for each monitored vital sign, except NIBP. In addition, the VS boxes (except AGENT and GAS) access the associated parameter's menu.



1 **ECG VS box** provides electrocardiogram and heart rate measurements.

2 **SPO2 VS box** provides blood oxygen saturation/pulse oximetry and the heart rate measurements from pulse detection.

3 **CO2 VS box** provides CO_2 measurements and can also provide respiration measurements.

4 **P1 VS box** provides invasive blood pressure measurements for channel 1 when equipped with the invasive blood pressure option.

5 **P2 VS box** provides invasive blood pressure measurements for channel 2 when equipped with the invasive blood pressure option.

6 **GAS VS box** provides the total MAC value, O_2 and N_2O measurements when equipped with the AGENT option.

7 **AGENT VS box** provides anesthetic agent measurements when equipped with the AGENT option.

8 **RESP VS box** provides respiration rate measurements from CO2 or the bellows accessory.

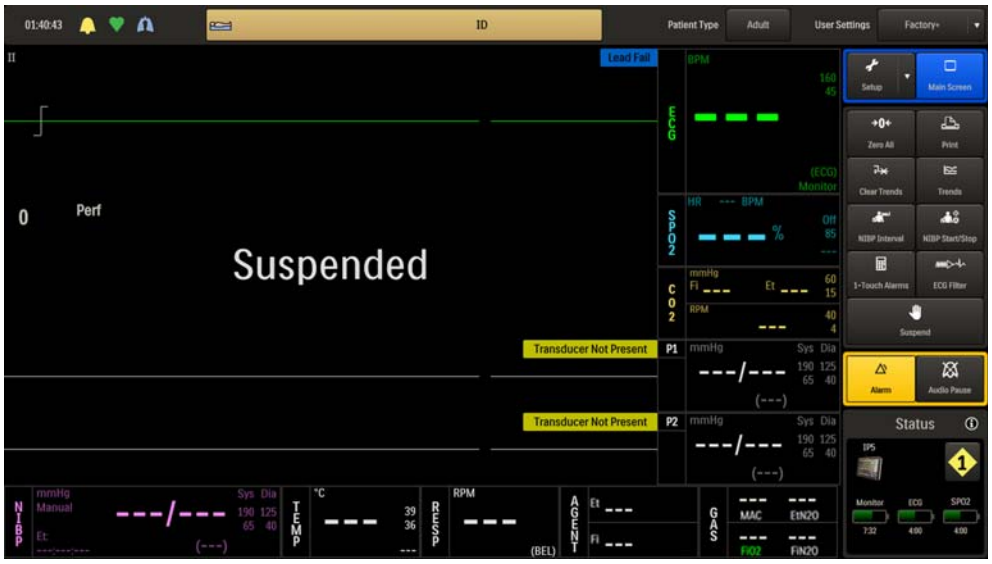
9 **TEMP VS box** provides temperature measurements when equipped with the temperature option.

10 **NIBP VS box** provides non-invasive blood pressure measurements.

No Data Indications

Under certain conditions, no waveforms and one or more vital sign numerics may display three dashes (---), which indicates that no data is available for the parameter(s).

Depending upon the cause of this missing data, an alarm condition may be generated.



No data indications that may not generate an alarm

- If a module or another measurement device was just turned on or applied to the patient, allow a few seconds for communication to be established, or for any required warm-up period to occur.
- The first reading has not yet been taken or the parameter is in a start-up condition (for example, the AGENT or CO2 monitoring hardware may be warming up).
- The measurement values are distorted or the signal is inadequate (for example, the concentration of gases may be below the minimum volume percentage detectable).
- Suspend mode was just exited.

No data indications that may generate an alarm

- Parameter data was present but can no longer be produced (for example, an attachment applied to a patient may have become disconnected).
- The hardware associated with a parameter has experienced a problem or failure that prevents proper operation.

Other Data Indications

The Over State Indication (OVR)

If the value of the numeric data item in the vital sign box is greater than the highest value specified for the item, OVR will be displayed in an alarm condition in place of the numeric. See the table on page 4-25 for measurement range and declaration information.

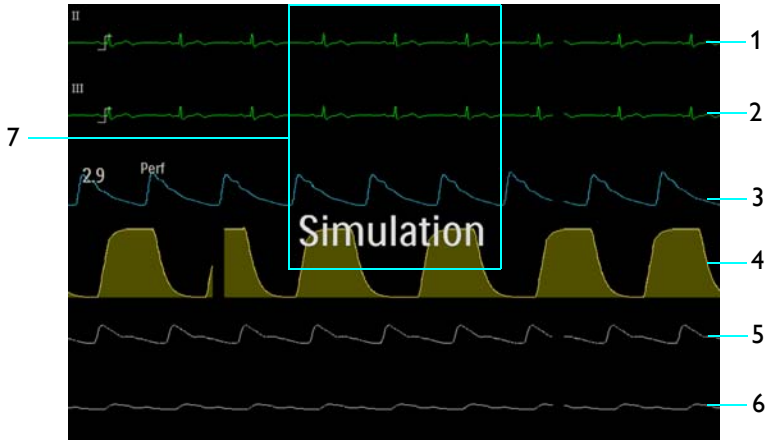
The Under State Indication (UND)

If the value of the numeric data item in the vital sign box is less than the lowest value specified for the item, UND will be displayed in place of the numeric in an alarm condition. See the table on page 4-25 for measurement range and declaration information.

Vital Sign Traces and System Message Area

Vital sign (VS) traces are uniquely colored waveforms for the ECG, SPO2, CO2 and invasive blood pressure parameters. These traces are fixed across the screen, adjustable and updated from left to right with an erase bar. The waveform color corresponds to the color of the associated VS box numeric data for that parameter. Up to six waveforms can be displayed, but if a parameter is turned off then that trace portion of the screen and VS box will be blank.

System messages and some alarm flags, as detailed throughout this manual, are displayed in the center and top portions of the vital sign traces area. Multiple system messages or alarm flags will be stacked in this area.



1 **Trace A** displayed as the ECG 1 waveform depending upon the selected source

2 **Trace B** displayed as the ECG 2 waveform when two ECG sources are selected

3 **Trace C** displays the SpO2 waveform

4 **Trace D** displays the CO2 respiration waveform (breath rate)

5 **Trace E** displays invasive blood pressure, channel 1 (P1) waveform

6 **Trace F** displays invasive blood pressure, channel 2 (P2) waveform

7 **System message area** displays system messages and alarm flags; see chapter 4.

Navigation and Operation

Everything needed to navigate and operate the MR400 can be performed by selecting an active element on the touch screen (including soft keys and buttons, icons, menus, VS boxes and alarm limits settings). When an active element is touched with a finger or a passive object (such as a stylus), the MR400 will highlight that option or item, produce a tone and enact the selection.

CAUTION

Never apply unnecessary pressure or use sharp objects on the touch screen as damage or failure can result. If breakage of the display panel glass does occur and you contact the liquid crystal by chance, please wash it from your skin using soap and water.

Notes

- *Simultaneously touching two or more screen areas may produce unpredictable results and is not recommended.*
- *The design of the MR400 allows access to the same menus in different ways.*
- *The MR400 monitors all application processes. If a software process or an application monitoring failure is detected, then an audible alarm will sound and all visual information will be removed from the display. To restore normal operation, you must turn the power switch off and then on. If the problem persists, contact technical support.*

Specialized Control Buttons and Keys

In addition to the control methods described above, some menus, options and items include specialized soft keys and buttons that control menus, settings and entries:

- To decrement a numeric value, select  .
- To increment a numeric value, select  .

- To close a menu or item, select  .
- To clear an entry field, select  .
- To save entered data and close a menu or item, select 

.
- To enter data, save changes and close a menu or item, select  .

Default Setting Indications

The default setting of a menu appears as the highlighted item, or as the item with an asterisk in a menu.

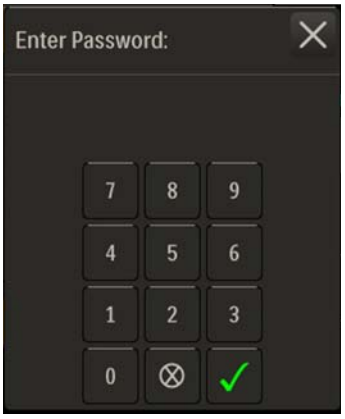
System Messages

System messages are displayed to inform you about a current operation or condition, as discussed throughout this manual. Also see *System Status Indications* on page 4-31.

Password Protection

Entry of a six-digit password is required for access to some menus, especially service-related menus. (Contact technical support for information.)

When **Enter Password:** is displayed, use the keypad to enter the correct password to continue to the desired menu.



Modes of Operation

The MR400 has three operating modes: normal, suspend, and simulation.

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 Screen** key.

Any open menu will close and any highlighted VS box will be deselected (that is, the normal screen will be displayed). See page 2-14 for an illustration.

Suspend Mode

WARNING

Suspend mode should never be used to silence alarms or when a patient is being actively monitored as a delay in treatment and possible patient injury could result.

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,
- If equipped with an IP5 and printer, automatic printouts will not be generated.

To enter suspend mode

Press the **Suspend** key.

Suspended will be displayed at the center of the screen. See page 2-20 for an illustration.

To exit suspend mode

Press the **Suspend** key.

Simulation Mode

Simulation mode, a password protected function, supports training and testing needs by displaying internally-generated data for vital sign waveforms, numeric values and statuses. In simulation mode, all patient monitoring is discontinued. See page 3-29 for menu details.

CHAPTER 3

Getting Started

Initial setup is important to achieve expected results and seamless operation.

WARNINGS

- **Perform operational verification prior to use. If the MR400 fails to function properly, remove it from use and contact technical support personnel.**
- **Do not allow the patient to move while the MR400 is being used as over-activity may result in prolonged or inaccurate readings.**
- **Position of the accessories may affect measurement accuracy. Always consult a physician for interpretation of measurements provided by the MR400.**
- **Do not operate the MR400 outside the specifications indicated in Appendix A as it will cause inaccurate results.**

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 MR400* on page 3-2 for details.

Defibrillator and Electrosurgical Use

The MR400 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 MR400 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.

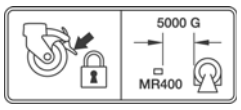
WARNINGS

- **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. This equipment does not provide protection against burning of the patient.**
- **The MR400 can be used in the presence of defibrillators or electrosurgery units, provided the equipment being used is in good working order, meets 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.**
- **Electrosurgical unit overloads may cause damage to this device.**
- **To minimize risk of damage to the MR400 during defibrillation, use only the manufacturer's specified accessories and supplies.**
- **This equipment does not meet electrosurgical interference suppression (ESIS) requirements as stated in EC13, sub clause 4.2.9.14, as the ECG trace will temporarily disappear from the display during cut or coagulation bursts.**

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 MR400 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*).

Positioning the MR400



During use, station the cart at a safe monitoring distance in the MR magnet room then press down on each wheel lock to engage it. (When the cart needs to be moved, raise each wheel lock before proceeding). Use the guide handle to move and position the MR400. Always place the MR400 so that your view of the screen and alarm light will remain unobstructed during use.

CAUTION

Never lean against or apply excessive force to the guide handle.

When positioning the MR400 for use, observe the following warning and cautions:

WARNING

.The MR400 shall meet its full function and performance specifications when positioned in the MR room of a 3T magnet, up to the 5000 gauss line, 4W/kg SAR, and 7.2 µT $B1_{rms}$ in all orientations. Always secure the MR400's wheel locks when the unit is placed within the MR system room. Failure to properly position the MR400 and its accessories in the MR system room will result in system or accessory failure, and possible patient or user injury.

CAUTIONS

- If the MR400 rolls to the face of the MR system due to magnetically induced pull force, do not attempt to dislodge the MR400 by pulling from the display panel or guide handle; instead, dislodge the MR400 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.
- Position the MR400 in a manner which does not block access to the device or wall plug connectors.
- Field strength variations in a particular MR system room (which may be due to active shielding technology, manufacturer variability, future enhancements, etc.) can make distinguishing the 5,000 gauss level (as measured from the center line of the MR bore) difficult. These variations may require moving the MR400 away from the MR system if system abnormalities or malfunctions are observed. Prior to clinical use, ensure that the allowable distance of the MR400 from the MR system is maintained for proper operation.

Operating the MR400

SAFETY AWARENESS

WARNING

Do not start up the product unless you and all other users present have read, fully understood and know all the safety information and emergency procedures given in the Safety section of this *Instructions for Use*. Operation of the product without having read, understood and knowing ALL the safety information and procedures in the *SAFETY* section could lead to fatal or other serious personal injury. It could also lead to clinical mis-diagnosis or clinical mistreatment.

Follow the steps below when operating the MR400.

Step	Action
1	Press the power switch ⏻ ; see page 2-7 for the location.
2	Ensure that the wECG and wSpO2 modules (and IP5, if equipped) have established good communications, and that sufficient power exists for the MR400 and the wireless modules. Also verify proper operation of the patient parameters. See *System Power-up and Communications Verification*, below.

System Power-up and Communications Verification

WARNING

Always perform operational verification prior to use and during monitoring by ensuring proper communications between the MR400, the wireless modules and 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 MR400 reaches an operational state within 60 seconds after power-up and attains full measurement accuracy according to the equipped options:

- After approximately 2 minutes when equipped with the CO2 LoFlo option
- After approximately 10 minutes if equipped with the AGENT option.

When any displayed warm-up message disappears, the MR400 is ready for use.

To apply power to the MR400 and verify system communications

Step	Action
1	Ensure that batteries are installed in the wECG module (see page 1-24).
2	Check the battery indicators on the wECG module to ensure that enough charge exists in at least one of the installed batteries: • Green battery indicator = Charge sufficient; proceed to step 4. • Red battery indicator = Charge low; proceed to step 3. See page 2-9 for details. (Also, you can reference the status information pane; see page 2-16.)
3	According to the red battery indicator(s) present on the wECG module, insert a charged module battery into the corresponding battery bay(s) and then recheck the battery indicator(s) to ensure a sufficient charge before proceeding; see page 1-24.

Step	Action
4	Ensure that batteries are installed in the wSpO2 module (see page 1-26).
5	Check the battery indicator on the wSpO2 module to ensure that enough charge exists: • Green battery indicator = Charge sufficient; proceed to step 7. • Red battery indicator = Charge low; proceed to step 6. See page 2-11 for details. (Also, you can reference the status information pane; see page 2-16.)
6	Insert a charged module battery into the wSpO2 module and then recheck the battery indicator to ensure a sufficient charge before proceeding; see page 1-26.
7	With the cart batteries installed and with the MR400 connected to AC mains power (see page 1-20), press the power switch. Allow the MR400 to initialize.
8	(Optional) If equipped, turn on the IP5.
9	Check the network channel indicator on the wECG module to ensure communication is established with the MR400: • Steady = Good communication; proceed to step 11. • Flashing = No communication; proceed to step 10. See page 2-9 for details. (Also, you can reference the status information pane; see page 2-16.) An inoperative ECG parameter or wECG module is indicated by absence of an ECG waveform and a simultaneous Lead Fail alarm.
10	Ensure that the wECG module is within 9.1 m (30 feet) of the MR400, in the same MRI room or in the same shielded room, and is set to the same wireless network channel used by the MR400; see page 1-29.
11	Check the network channel indicator on the wSpO2 module to ensure communication is established with the MR400: • Steady = Good communication; proceed to step 13. • Flashing = No communication; proceed to step 12. See page 2-11 for details. (Also, you can reference the status information pane; see page 2-16.)
12	Ensure that the wSpO2 module is within 9.1 m (30 feet) of the MR400, in the same MRI room or in the same shielded room, and is set to the same wireless network channel used by the MR400; see page 1-29.
13	(Optional) If equipped with an IP5, ensure that the wireless network channel of the IP5 is the same as the wireless network channel setting of the MR400; see the IP5 IFU for details.

Step	Action
14	(Optional) If equipped with an IP5, ensure good communication between the MR400 and the IP5 by checking the status information pane (see page 2-16).
15	Ensure proper operation of each patient parameter and alarms. Refer to appropriate chapters in this manual.

CAUTION

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

Cart Power-down

To turn power off to the MR400, press then hold the power switch for approximately 2 seconds.

NOTE

For instructions on the complete removal of power to the MR400, see page 14-2.

Wireless Module Power-down

To turn power off to a wireless module, remove the battery (wSpO2 module) or batteries (wECG module).

Monitor Initialization

After power-up and until the initialization process completes, the touch screen may remain blank. After initialization completes, the MR400 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 User Settings option matches that of the MR400 option, and that the same option is selected as the default setup on both systems (see page 3-26). This is important because the device first booted will determine the power-on settings of the system (that is, the MR400 and optional IP5).

Viewing the Displayed Information

The high resolution touch screen LCD facilitates waveform analysis and vital sign numeric interpretation, with important display elements which are designed to be legible at a minimum distance of 1 meter by users with a visual acuity of 20/20. When using the MR400, always adjust the viewing angle of the touch screen to complement your line of sight and always ensure that your view remains unobstructed.

CAUTION

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

NOTE

To change the language displayed by the MR400, see ***System Config*** *page 3-30.*

Default Settings

At power up, the MR400 will automatically set all monitor setup options as determined by the default selection in the **Edit User Settings** menu. By default, the factory settings are used when the system is turned on, unless a custom setting has been selected. Also, as discussed earlier, due to the use model, the power-on default settings for the MR400 can depend upon a communicating IP5 and the start-up sequence of the devices.

Default Setting Indications

The **User Settings** key indicates the current default setup (where the plus symbol [+] indicates that changes have occurred) and it allows you to select a factory or a stored user setup; see page 2-14.

When a menu is displayed, the default will be highlighted or will appear with an asterisk. For the factory default settings, see the menu listings throughout this IFU.

User Settings

In the **Edit User Settings** menu, up to ten customized user settings can be saved and one can be selected for use as the default at power-on. User settings can include any of the following menu options:

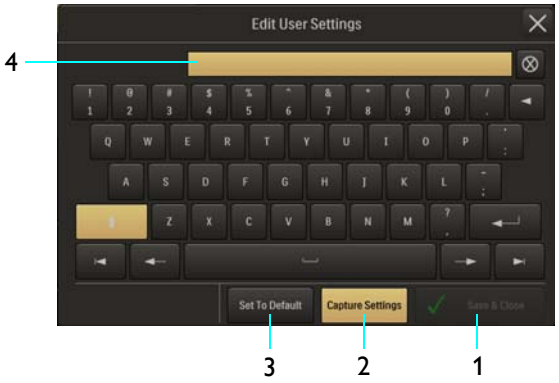
- Alarms
  - Minimum and maximum values
  - Auto-set percentage
  - Alarm sound level
  - Extreme HR alarm values
  - Desat alarm values
- System Setups
- ECG
  - Selected lead
  - Scale setting
  - Trace speed
  - Filter mode
  - QRS tone on/off
  - Heart rate source
  - Pediatric ECG on/off
  - Extreme HR alarm function setting
- SpO2
  - Size
  - Desat alarm function settings
- CO2
  - Size
  - Grids
- CO2 (RESP)
  - Apnea alarm function settings
- NIBP
  - Manual
  - Off or Auto
  - Automatic time interval
- Trend graphs
  - Time bases
  - Scales
- Print Setups
  - Off or Auto
  - Trace delay
  - Printer speed
  - Selected traces

NOTE

*When a setting is changed in an active user settings file, a plus sign (+) will appear on the **User Settings** key. And when edits have been made to an existing user settings file, a warning box and setting change list will appear, prompting you to accept or cancel the changes to proceed.*

Soft Keyboard—Add New

Names can be assigned to your user settings files using the soft keyboard that is displayed when the **Add New** option is selected; see page 3-15. This soft keyboard (see illustration below) functions like standard QWERTY keyboard, but with additional features for data captures and default setting selection.



1 **Save & Close button** assigns the captured settings to the entered file name then saves the file in memory and closes the menu.

2 **Capture Settings button** saves the current settings data of the MR400.

3 **Set To Default button** selects the settings of the current entry for use following power-up of the MR400.

4 **Entry field** displays the currently entered file name for the captured user settings.

Soft Keyboard—Edit Existing

Existing user settings files can be edited using the soft keyboard that is displayed when a stored file is selected; see page 3-15. The file name and data contents can be changed, and the default setting can be updated. The illustration below highlights these additional file management features of the soft keyboard.

1 **Remove as Default button** removes the file as the default user settings file

2 **Delete Settings button** deletes the file.

Initial Alarm Indications

After power-up and immediately following the recall of a stored setup, the MR400 provides an indication of the alarm volume by sounding the alarm tone at its currently adjusted setting for 5 seconds and displaying **Check Alarm Volume**.

After power-up, the initial alarm state is paused and then, following a wait period of 120 seconds, armed becomes the normal alarm state (as indicated by the displayed symbol, shown in the table below):

Displayed Symbol	Alarm Sound State
	Alarm audio armed
	Alarm audio paused
	Alarm audio off

In the armed state:

- An alarm will sound while an alarm condition exists, provided that any pre-alarm wait period has expired and the alarm audio armed symbol is displayed.

- Alarm flags related to other alarm sound states will be removed from the display.
- An alarm condition not previously placed in an audio off state will cause the alarm to sound.

Selecting the Patient Type

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 the 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:

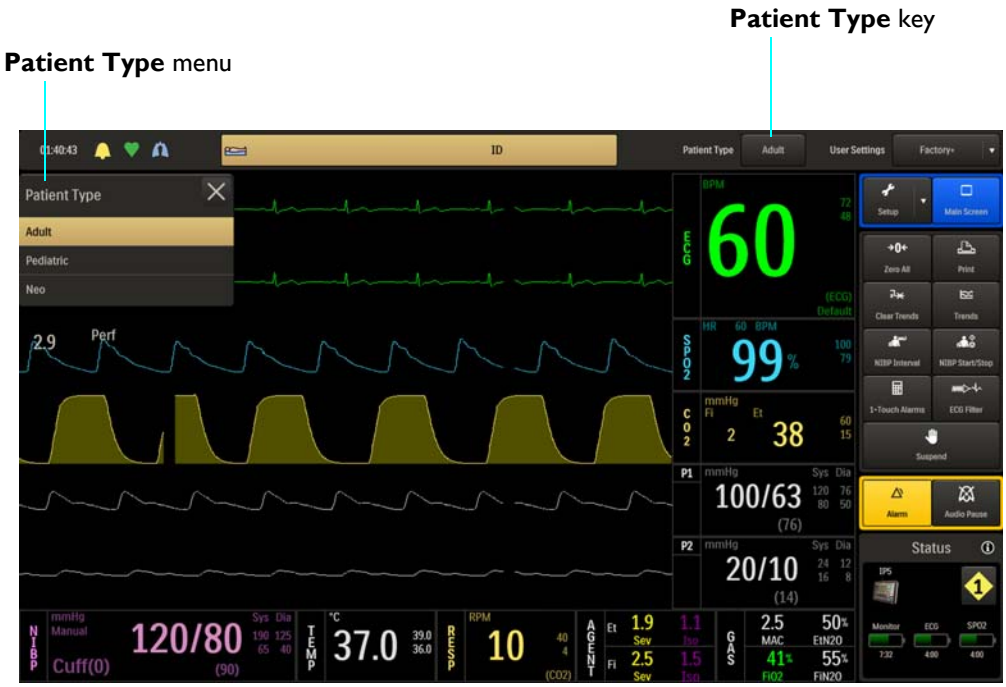
- Weight
- Body size
- Limb circumference
- Physiological development
- Neurological development
- Neuromuscular coordination

Accordingly, the MR400 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 **Patient Type** key allows you to set the MR400 for the type of patient to be monitored.

To open the Patient Type menu

Press the **Patient Type** key.



The following patient types are available:

- **Adult** (Default)
- **Pediatric**

- **Neo** (when selected, **Pediatric ECG** will also be set to **On**)

NOTE

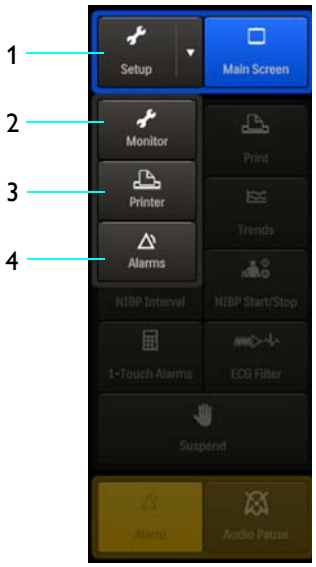
*Changing the **Patient Type** causes the alarm to sound, **Change NIBP Cuff** to be displayed for 30 seconds, the initial cuff inflation to be reset to the initial pressure for the patient type selected, **NIBP** > **Auto Mode** to be set to off, and the alarm limit settings to revert to the default values24).*

To select the patient type

Step	Action
1	Press the **Patient Type** key. (The current setting is displayed.) The **Patient Type** menu appears. The current setting is highlighted.
2	Select the **Patient Type**: **Adult** **Pediatric** **Neo** The setting is entered.

Setup Menus

Pressing the **Setup** key will display the **Monitor**, **Printer**, and **Alarms** keys.



1 **Setup** key

2 **Monitor** key

3 **Printer** key

4 **Alarms** key

The **Monitor**, **Printer**, and **Alarms** keys open associated menus for setup and control, including:

- Saving and recalling setup configurations
- Controlling parameters
- Adjusting sounds
- Switching patient types
- Setting time and date

- Setting sweep speeds
- Controlling ECG modes
- Controlling alarms
- Controlling remote printing

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.

NOTE

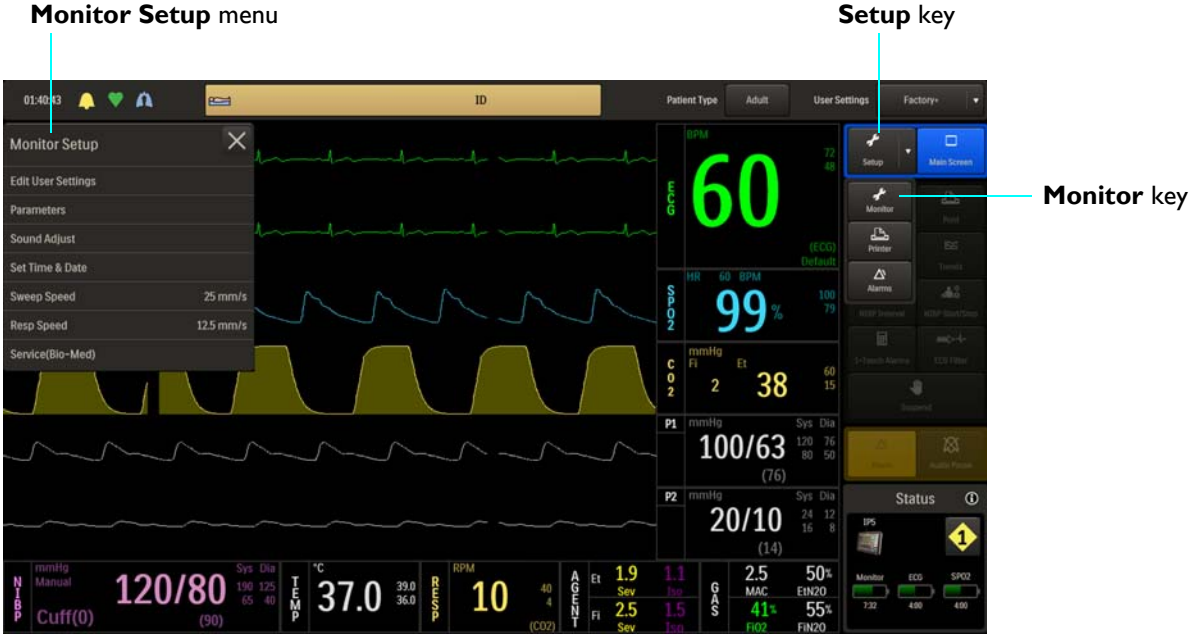
Grayed out items in the menu system, indicate features or options that are inaccessible due to current settings, or that are not configured or installed.

Monitor Setup Menu

The **Monitor Setup** menu allows you to configure the MR400 for patient monitoring.

To open the Monitor Setup menu

Press the **Setup** key and then the **Monitor** key.



The following **Monitor Setup** menu items are available:

- **Edit User Settings**
- **Parameters**
- **Sound Adjust**
- **Set Time & Date**
- **Sweep Speed**
- **Resp Speed**
- **Service(Bio-Med)**

To change settings in the Monitor Setup menu

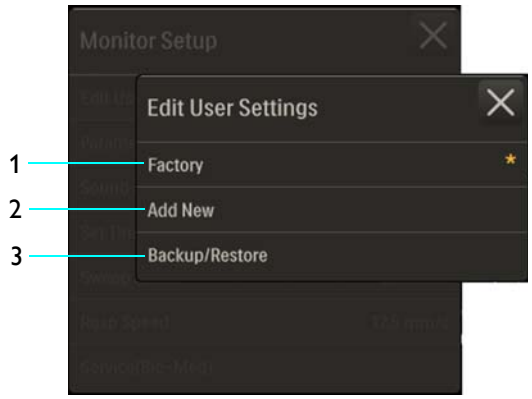
Step	Action
1	Press the **Setup** key and then the **Monitor** key. The **Monitor Setup** menu appears. Current settings are displayed.
2	Select any of the following menu items: **Edit User Settings** **Parameters** **Sound Adjust** **Set Time & Date** **Sweep Speed** **Resp Speed** **Service(Bio-Med)** The selected menu appears. Current settings are displayed.
3	Select the desired menu item. The current setting is highlighted.
4	Select the desired sub-menu or setting from the menu options. The setting is entered.
5	To change other settings, repeat steps 2, 3 and 4.

Edit User Settings

Allows you to capture, store and manage multiple user setups, and to select an operational or power-up default setup. A backup and restore selection also allows you to save these user settings to an external device.

To open the Edit User Settings menu

Press the **Setup** key and then the **Monitor** key. On the **Monitor Setup** menu, select **Edit User Settings.**



1 Factory

2 Add New

3 Backup/Restore

The following options are available:

- **Factory** recalls the factory settings from memory, which cannot be modified. (Default)
- **Add New** allows you to assign a file name, select a default setting, and store a current setup in the memory (up to ten setups can be stored); see page 3-7 for more information.
- **Backup/Restore** allows you to backup and restore settings using a USB flash drive; see the service manual (REF 989803181911) for details.

To add and save new user settings

Step	Action
1	Setup the MR400 for the configuration to which these settings will pertain.
2	Press the **Setup** key and then the **Monitor** key. The **Monitor Setup** menu appears. Current settings are displayed.
3	On the **Monitor Setup** menu, select **Edit User Settings**. The **Edit User Settings** menu appears.
4	Select **Add New**. The soft keyboard appears.
5	Enter a unique file name (of up to twenty characters) for the user settings using the soft keyboard.
6	Press the **Capture Settings** button to enter the current setup data.

Step	Action
7	If desired, press the **Set to Default** button to save the current file as the default setup for use at power-up. **WARNING** **If you choose to boot the device from a user settings file, confirm that alarm presets are appropriate for the patient prior to monitoring. Failure to do so may cause false or missed alarm conditions.**
8	Press the **Save & Close** button to save the current setup and exit the menu. A warning box will appear, prompting you to accept the changes: press the **Accept** button to save the current settings, or press the **Cancel** button to reject the changes.

To edit saved user settings

Step	Action
1	Configure the MR400 for the desired settings.
2	On the **Monitor Setup** menu, select **Edit User Settings**.
3	Select the file name that you want to change.
4	Press the **Capture Settings** button to change the user setup to the current settings.
5	Press the **Save & Close** button to save the current setup. A warning box will appear, prompting you to accept the changes—press **Accept** to save the current settings or press **Cancel** to reject the changes.

To delete saved user settings

Step	Action
1	On the **Monitor Setup** menu, select **Edit User Settings**.
2	Select the file name that you want delete.

Step	Action
3	Press the **Delete Settings** key.
4	Press the **Save & Close** button to save the current setup. A warning box will appear, prompting you to accept the changes—press **Accept** to save the current settings or press **Cancel** to reject the changes.

Parameters

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

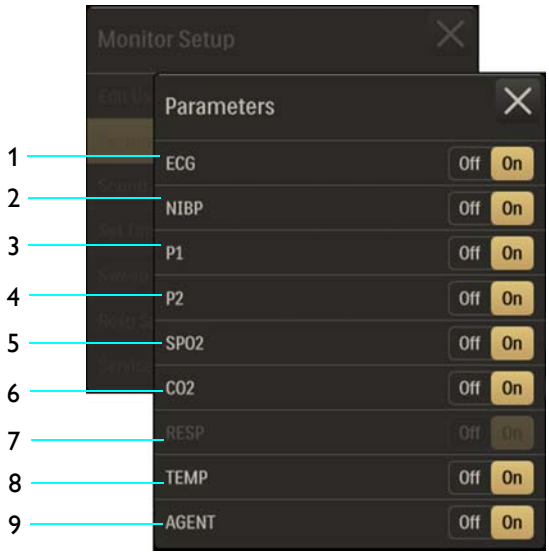
NOTE

*Some parameters require optional equipment that may not be enabled or present on your system; see **System Config** for details.*

To open the Parameters menu

Press the **Setup** key and then the **Monitor** key. On the **Monitor Setup** menu, select **Parameters**.

1 **ECG**
2 **NIBP**
3 **P1**
4 **P2**
5 **SPO2**
6 **CO2**
7 **RESP**
8 **TEMP**
9 **AGENT**



The following parameters are available:

- **ECG** allows electrocardiogram monitoring:
  - **Off** turns off the ECG parameter. (Heart rate (HR) will remain in the VS box, allowing it to be displayed from another source or if **HR Source** is set to **Auto**.)

  - **On** turns on the ECG parameter. (Default)

- **NIBP** allows non-invasive blood pressure monitoring (does not have an associated waveform):
  - **Off** turns off the NIBP parameter.
  - **On** turns on the NIBP parameter. (Default)
- **P1** allows invasive blood pressure monitoring:
  - **Off** turns off the P1 parameter. (Default)
  - **On** turns on the P1 parameter.
- **P2** allows invasive blood pressure monitoring:
  - **Off** turns off the P2 parameter. (Default)
  - **On** turns on the P2 parameter.
- **SPO2** allows oxygen saturation of arterial blood monitoring:
  - **Off** turns off the SPO2 parameter.
  - **On** turns on the SPO2 parameter. (Default)
- **CO2** allows CO2 and CO2-derived respiration rate monitoring:
  - **Off** turns off the CO2 parameter. (Default)
  - **On** turns on the CO2 parameter.

NOTE

*If **CO2** is turned Off, **AGENT** and **GAS** will also be deactivated.*

- **RESP** allows respiration rate monitoring using the bellows (does not have an associated waveform):
  - **Off** turns off the bellows-derived respiration parameter. (Default)
  - **On** turns on the bellows-derived respiration parameter.

NOTE

*If **CO2**-derived respiration is on, then **RESP** will not be selectable. To use bellows respiration, select **BEL** in the **RESP** menu; see page 10-5.*

- **TEMP** allows temperature monitoring (does not have an associated waveform):
  - **Off** turns off the temperature parameter. (Default)
  - **On** turns on the temperature parameter.

- **AGENT** allows anesthetic agent and gas monitoring (but does not have an associated waveform), and CO2 and CO2-derived respiration rate monitoring:
  - **Off** turns off the AGENT parameter. (Default)
  - **On** turns on the AGENT parameter.

NOTE

*When **AGENT** is turned on, **CO2** will also be activated, including **GAS**; however, if **AGENT** is then turned Off, **CO2** will remain active.*

To control parameters

Step	Action
1	Press the **Setup** key and then the **Monitor** key. The **Monitor Setup** menu appears. Current settings are displayed.
2	On the **Monitor Setup** menu, select **Parameters**. The **Parameters** menu appears. Current settings are displayed.
3	Locate the parameter that you want to control then select the desired setting: **Off** **On** The setting is entered. To change other settings, repeat step 3.

Sound Adjust

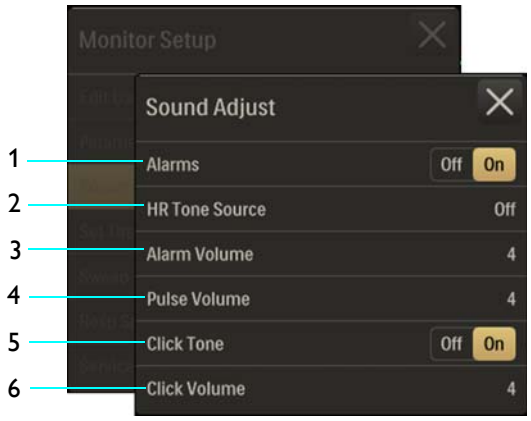
Controls alarm, heart rate and touch screen tones, and the volume settings for the sounds generated by the MR400.

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 MR400, always ensure that the alarm sound can be heard above the ambient noise level; otherwise, treatment of the patient could be delayed.

To open the Sound Adjust menu

Press the **Setup** key and then the **Monitor** key. On the **Monitor Setup** menu, select **Sound Adjust**.



1 **Alarms**

2 **HR Tone Source**

3 **Alarm Volume**

4 **Pulse Volume**

5 **Click Tone**

6 **Click Volume**

The following menu items are available:

- **Alarms** controls the alarm sound (identical to and interactive with **Alarm Sound** in the **Alarms** menu):
  - **Off** turns off the alarm sound, as indicated by the alarm audio off symbol (see page 4-4). (Only the alarm sound will be disabled; visual alarm indications will continue.)
  - **On** turns on the alarm sound, as indicated by the alarm audio armed symbol (see page 4-4). (Default)
- **HR Tone Source** sets the source used for the heart rate tone (identical to and interactive with same option in the **ECG** menu and **SPO2** menu):
  - **Off** removes the heartbeat detected symbol from the display and sounds no pulse tone. (Default)
  - **QRS** provides the heartbeat detected symbol and a tone triggered by the QRS detection from the ECG vital sign.
  - **SPO2** provides the heartbeat detected symbol and a tone modulated by the SPO2 vital sign, where the lower the SPO2 value, the lower the pitch.
- **Alarm Volume** sets the alarm sound level from 1–10. (Default = 4)
- **Pulse Volume** sets the pulse sound level from 1–10. (Default = 4)
- **Click Tone** controls an audio indication that is produced when an active area of the touch screen is contacted:
  - **Off** does not produce a click tone.
  - **On** produces a click tone. (Default)
- **Click Volume** sets the click tone sound level from 1–10. (Default = 4)

To control the sounds

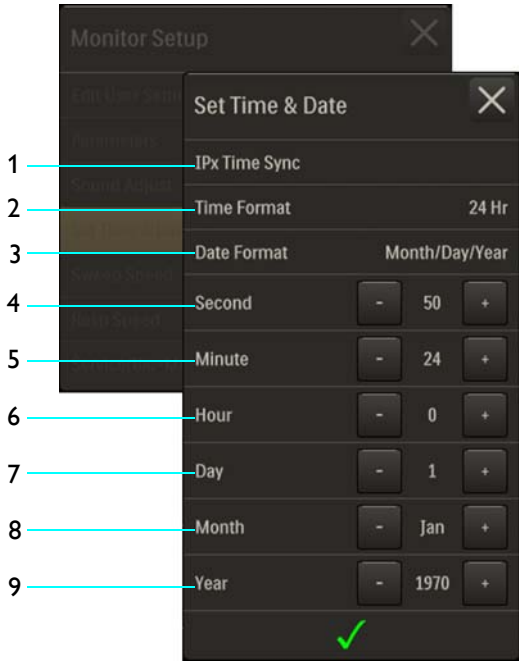
Step	Action
1	Press the **Setup** key and then the **Monitor** key. The **Monitor Setup** menu appears. Current settings are displayed.
2	On the **Monitor Setup** menu, select **Sound Adjust**. The **Sound Adjust** menu appears. Current settings are displayed.
3	Select the menu item for the sound function that you want to control: **Alarms** **HR Tone Source** **Alarm Volume** **Pulse Volume** **Click Tone** **Click Volume** The menu item appears. The current setting is highlighted.
4	Select the desired setting from the menu options (except **Alarms** and **Click Tone**, which are selectable on the **Sound Adjust** menu.) The setting is entered. ***NOTE*** *When making adjustments to the volume settings,* ***Real Tones Disabled*** *will be displayed and a momentary sound at the setting level will be produced. To your save changes and close the menu select* ✓.
5	To change other settings, repeat steps 3 and 4.

Set Time & Date

Sets the time and date, and the displayed time and date formats; see page 2-14.

To open the Set Time & Date menu

Press the **Setup** key and then the **Monitor** key. On the **Monitor Setup** menu, select **Set Time & Date**.



1	**IPx Time Sync**
2	**Time Format**
3	**Date Format**
4	**Second**
5	**Minute**
6	**Hour**
7	**Day**
8	**Month**
9	**Year**

The following menu items are available:

- **IPx Time Sync** synchronizes the time and date settings of the MR400 to that of an IP5 (IP5 option required).
- **Time Format** changes the format of the displayed (and printed) hours:minutes:seconds (hh:mm:ss):
  - 12 Hr uses the 12-hour (hh) convention (01 – 12) with the AM or PM designation.
  - 24 Hr uses the 24-hour (hh) convention (00 – 23). (Default)
- **Date Format** changes the format of the displayed (and printed) date:
  - Month/Day/Year: Uses a <mm>/<dd>/<yyyy> format
  - Day/Month/Year: Uses a <dd>/<mm>/<yyyy> format
  - Month Day, Year: Uses a <m name> <dd>, <yyyy> format
- **Second** scrolls the second counter.
- **Minute** scrolls the minute counter.
- **Hour** scrolls the hour counter.
- **Day** scrolls the day counter.
- **Month** scrolls the month counter.
- **Year** scrolls the year counter.

To set the format of the displayed time or date

Step	Action
1	Press the **Setup** key and then the **Monitor** key. The **Monitor Setup** menu appears. Current settings are displayed.

Step	Action
2	On the **Monitor Setup** menu, select **Time and Date**. The **Time and Date** menu appears. Current settings are displayed.
3	Select the menu item for the time or date function that you want to change: **Time Format** **Date Format** The menu item appears. The current setting is highlighted.
4	Select the desired setting from the menu options. The setting is entered.
5	To change other settings, repeat steps 3 and 4.

To set the time or date

Step	Action
1	Press the **Setup** key and then the **Monitor** key. The **Monitor Setup** menu appears. Current settings are displayed.
2	On the **Monitor Setup** menu, select **Time and Date**. The **Time and Date** menu appears. Current settings are displayed.
3	Use the arrow keys associated with each time or date function that you want to change (left arrow decreases the setting, right arrow increases the setting): **Second** **Minute** **Hour** **Day** **Month** **Year** The setting is changed.
4	To adjust other settings, repeat step 3.
5	When finished, select the check mark  . The changes are saved and the displayed time is adjusted.

Sweep Speed

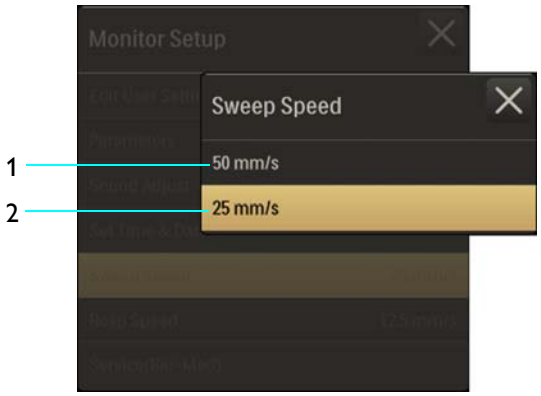
Sets the sweep rate for all waveforms (displayed and printed), except CO2.

To open the Sweep Speed menu

Press the **Setup** key and then the **Monitor** key. On the **Monitor Setup** menu, select **Sweep Speed**.

1 50 mm/s

2 25 mm/s



The following speeds (in millimeters per second) are available:

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

To adjust the sweep rate for all waveforms (except CO2)

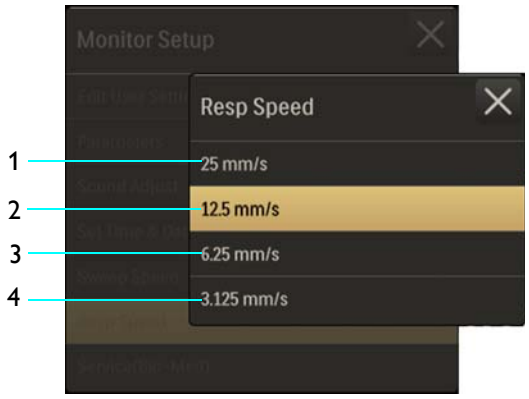
Step	Action
1	Press the **Setup** key and then the **Monitor** key. The **Monitor Setup** menu appears. Current settings are displayed.
2	On the **Monitor Setup** menu, select **Sweep Speed**. The **Sweep Speed** menu appears. The current setting is highlighted.
3	Select the desired setting from the menu options: **50 mm/s** **25 mm/s** The setting is entered.

Resp Speed

Sets the sweep rate for the CO2 waveform.

To open the Resp Speed menu

Press the **Setup** key and then the **Monitor** key. On the **Monitor Setup** menu, select **Resp Speed**.



1	**25 mm/s**
2	**12.5 mm/s**
3	**6.25 mm/s**
4	**3.125 mm/s**

The following speeds (in millimeters per second) are available:

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

To adjust the sweep rate for the CO2waveform

Step	Action
1	Press the **Setup** key and then the **Monitor** key. The **Monitor Setup** menu appears. Current settings are displayed.
2	On the **Monitor Setup** menu, select **Resp Speed**. The **Resp Speed** menu appears. The current setting is highlighted.
3	Select the desired setting from the menu options: **25 mm/s** **12.5 mm/s** **6.25 mm/s** **3.125 mm/s** The setting is entered.

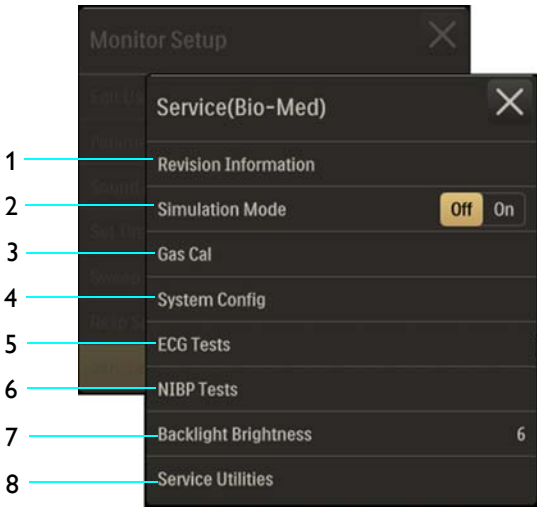
Service(Bio-Med)

Accesses a sub-menu that contains software and firmware information about the system, and options for NIBP and P1 (and P2) pressures, diagnostics and configuration.

To open the Service(Bio-Med) menu

Press the **Setup** key and then the **Monitor** key. On the **Monitor Setup** menu, select **Service(Bio-Med)**.

1 **Revision Information**
2 **Simulation Mode**
3 **Gas Cal**
4 **System Config**
5 **ECG Tests**
6 **NIBP Tests**
7 **Backlight Brightness**
8 **Service Utilities**



NOTE

Some menu items require entry of a password for access; see page 2-23.

To access the SERVICE(BIO-MED) menu items

Step	Action
1	Press the **Setup** key and then the **Monitor** key. The **Monitor Setup** menu appears. Current settings are displayed.
2	On the **Monitor Setup** menu, select **Service(Bio-Med)**. The **Service(Bio-Med)** sub-menu appears.
3	Select the desired menu item (some menus are password protected): **Revision Information** **Simulation Mode** **Gas Cal** **System Config** **ECG Tests** **NIBP Tests** **Backlight Brightness** **Service Utilities** The selection is entered (or enter the correct password for access).
4	Select the desired menu or item, except **Simulation Mode**, which is selectable on the **Service(Bio-Med)** menu. The setting is entered.

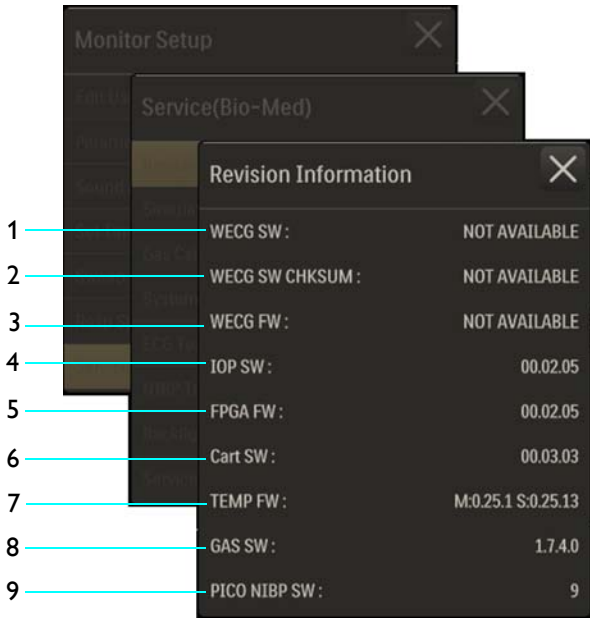
Step	Action
5	To change other settings, repeat steps 2, 3 and 4.

Revision Information

Depending upon the installed options, displays revision information for the software and firmware used in the MR400 and wireless modules.

To view the revision information

Press the **Setup** key and then the **Monitor** key. On the **Monitor Setup** menu, select **Service(Bio-Med)**. On the **Service(Bio-Med)** menu, select **Revision Information**.



1 **WECG SW:**

2 **WECG SW CHKSUM:**

3 **WECG FW:**

4 **IOP SW:**

5 **FPGA FW:**

6 **Cart SW:**

7 **TEMP FW:**

8 **GAS FW:**

9 **PICO NIBP SW:**

The definitions for the items displayed in **Revision Information** are provided below.

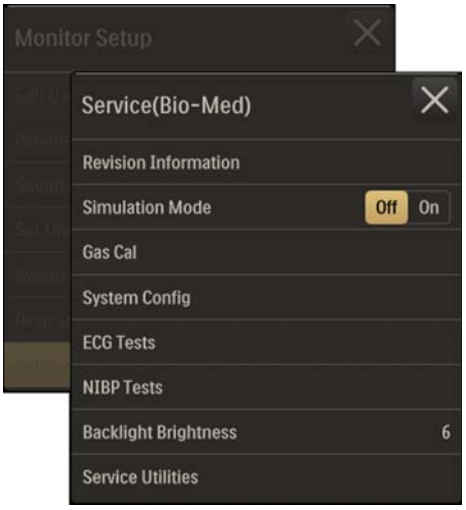
Name	Definition
WECG SW	Software revision of the wECG module
WECG SW CHKSUM	Checksum of the software of the wECG module
WECG FW	Firmware revision of the wECG module
IOP SW	Software revision of the input / output processor
FPGA FW	Software revision of the processing element of the MR400
Cart SW	Software revision of the MR400 cart
TEMP FW	Firmware revision of TEMP system
GAS SW	Software revision of gas system
PICO NIBP SW	Software revision of the NIBP system

Simulation Mode

WARNING

The MR400 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 MR400 when in simulation mode and never activate simulation mode when a patient is connected. The MR400 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.

Allows the MR400 to operate using internally-generated data instead of patient data.



To open the Simulation Mode menu

Press the **Setup** key and then the **Monitor** key. On the **Monitor Setup** menu, select **Service(Bio-Med)**. On the **Service(Bio-Med)** menu, locate **Simulation Mode** and select **On**. Enter the password.

The following controls are available:

- **Off** displays normal monitoring functions. (Default)
- **On** displays simulations of monitoring functions.

To enter simulation mode

Step	Action
1	Ensure that no patient is connected to the MR400.
2	Press the **Setup** key and then the **Monitor** key. The **Monitor Setup** menu appears. Current settings are displayed.
3	On the **Monitor Setup** menu, select **Service(Bio-Med)**. The **Service(Bio-Med)** menu appears. Current settings are displayed.
4	Locate **Simulation Mode** and select **On**.
5	When **Enter Password** is displayed, enter the correct six-digit code. **Simulation** will be displayed in the system message area of the simulated screen.

To exit simulation mode, turn off the power switch.

Gas Cal

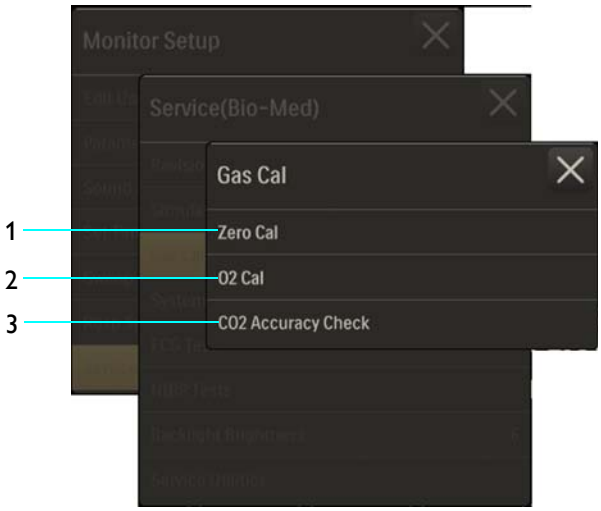
Calibrates the gas function(s) when equipped with the CO2 or the AGENT option.

NOTE

As indicated by displayed message, allow any warm-up to complete before calibrating.

To open the Gas Cal menu

Press the **Setup** key and then the **Monitor** key. On the **Monitor Setup** menu, select **Service(Bio-Med)**. On the **Service(Bio-Med)** menu, select **Gas Cal**.



1 Zero Cal

2 O2 Cal

3 CO2 Accuracy Check

The following menu items are available:

- **Zero Cal** Initiates a zero calibration (a function that occurs automatically during normal use). For LoFlo CO2 option details, see page 7-2; and for the AGENT option details, see page 9-2.
- **O2 Cal** performs a 1-minute pressure calibration of the O2 sensor for the AGENT option. Connection of a sample line is required for this test.
- **CO2 Accuracy Check** tests the LoFlo CO2 accuracy (a 5% gas source must be connected to the MR400). Provides a CO2 waveform value (as a percentage), an atmospheric pressure reading and a numeric CO2 value (in mmHg).

NOTE

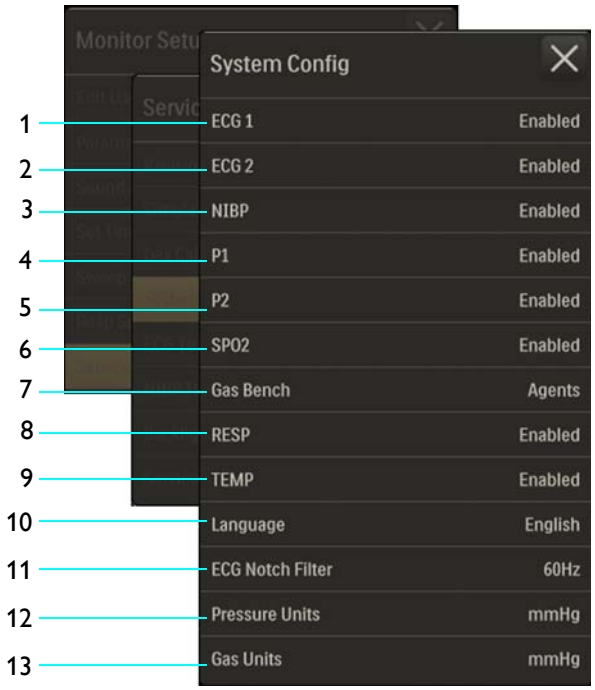
During the CO2 Accuracy Check, to alert you that the indicated values are not actual patient measurements, the following message will be displayed: ***CO2 test in progress. Do not use CO2 values for patient monitoring during test. Pressing close will cancel test.***

System Config

Controls the configuration of the MR400 including options, language and unit of measurement for pressures.

To open the System Config menu

Press the **Setup** key and then the **Monitor** key. On the **Monitor Setup** menu, select **Service(Bio-Med)**. On the **Service(Bio-Med)** menu, select **System Config**.



1 ECG 1

2 ECG 2

3 NIBP

4 P1

5 P2

6 SPO2

7 Gas Bench

8 RESP

9 TEMP

10 Language

11 ECG Notch Filter

12 Pressure Units

13 Gas Units

The following menu items are available:

- **ECG 1** configures the MR400 for ECG 1
- **ECG 2** configures the MR400 for ECG 2
- **NIBP** configures the MR400 for NIBP
- **P1** configures the MR400 for P1
- **P2** configures the MR400 for P2
- **SPO2** configures the MR400 for SPO2
- **Gas Bench** configures the MR400 for the gas bench option, where **CO2 only** selects the CO2 Loflo option, **Agents** selects the AGENT option
- **RESP** sets the configuration of the unit for bellows-derived RESP
- **TEMP** configures the MR400 for TEMP
- **Language** sets the language for the displayed information:
  - **English** (Default)
  - **Deutsch**
  - **Espanol**
  - **Francais**

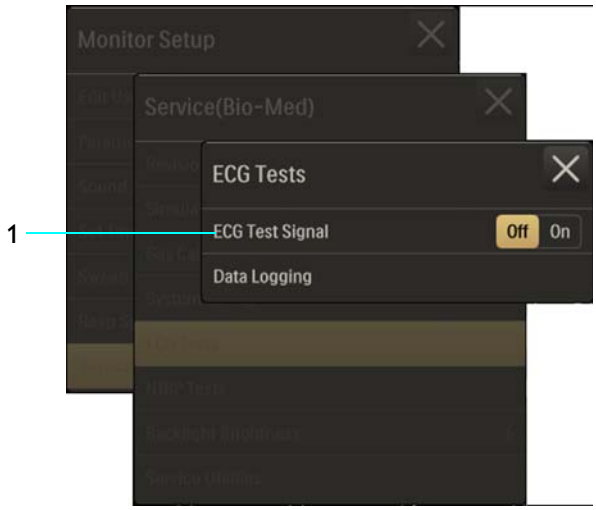
  - **Portuguese**
  - **Italiano**
  - **Dansk**
  - **Svenska**
  - **Norsk**
  - **NLD**
- **ECG Notch Filter** applies a notch filter to the ECG signal:
  - **Off**
  - **50Hz**
  - **60Hz** (Default)
- **Pressure Units** sets the unit of measure for P1, P2, and NIBP pressure readings:
  - **mmHg (Default)**
  - **kPa**
- **Gas Units** sets the unit of measure for CO2 pressure readings:
  - **mmHg** (Default)
  - **kPa**

ECG Tests

Accesses testing functions for ECG.

To open the ECG Tests menu

Press the **Setup** key and then the **Monitor** key. On the **Monitor Setup** menu, select **Service(Bio-Med)**. On the **Service(Bio-Med)** menu, select **ECG Tests**.



1 ECG Signal Test

The following menu items are available:

- **ECG Test Signal** controls a wECG module-generated 1 mV peak-to-peak square wave, where 60 BPM will be displayed in the ECG VS box and **ECG Test Signal** will be displayed in the alarm flag area (and printed when output to the printer, if equipped):
  - **Off** does not transmit the test signal. (Default)
  - **On** transmits the test signal.

NOTE

ECG Test Signal *is unavailable when* ***Filter Mode > Advanced 2*** *is selected; see 5-31.*

To control the ECG Test Signal

Step	Action
1	Ensure that the wECG module is communicating with the MR400.
2	Press the **Setup** key and then the **Monitor** key. The **Monitor Setup** menu appears. Current settings are displayed.
3	On the **Monitor Setup** menu, select **Service(Bio-Med)**. The **Service(Bio-Med)** menu appears. Current settings are displayed.
4	Locate **ECG Test Signal** and select the desired setting: **Off** **On** The setting is entered.

NIBP Tests

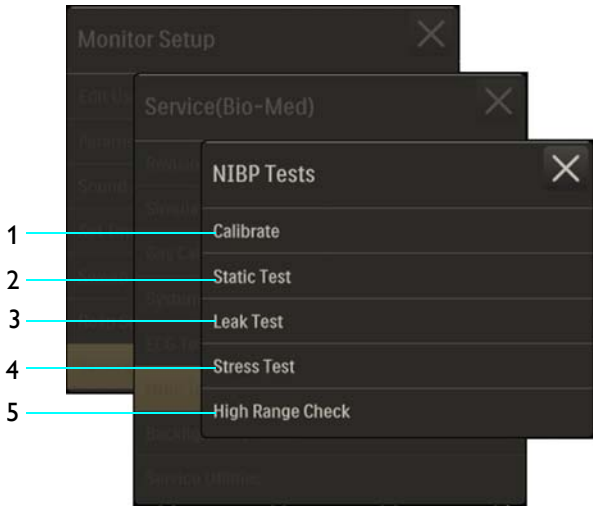
Accesses calibration and testing functions for NIBP.

NOTE

If ***Module Not Calibrated*** *is displayed, then all options in the* ***NIBP Tests*** *menu will be locked until NIBP is successfully calibrated.*

To open the NIBP Tests menu

Press the **Setup** key and then the **Monitor** key. On the **Monitor Setup** menu, select **Service(Bio-Med)**. On the **Service(Bio-Med)** menu, select **NIBP Tests**.



1 Calibrate

2 Static Test

3 Leak Test

4 Stress Test

5 High Range Check

The following menu items are available:

- **Calibrate** performs calibration of the NIBP system. (Password required)
- **Static Test** performs a static pressure test of the NIBP system. (Password required)
- **Leak Test** performs a pressure leak test of the NIBP system (see note below).
- **Stress Test** performs a pressure stress test of the NIBP system. (Password required)
- **High Range Check** performs a high pressure test of the NIBP system. (Password required)

NOTE

*If an error is reported while the **Leak Test** is in progress, the test will be canceled and user will be prompted with the message: **NIBP Bench Error. Press Start to try again.***

To perform these tests

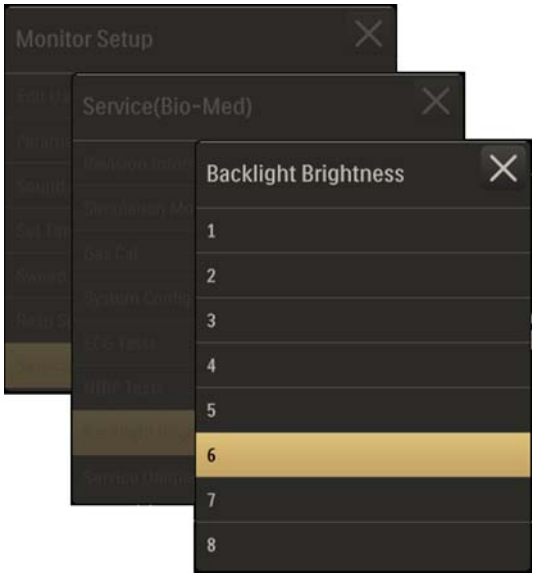
See reference the service manual for details.

Backlight Brightness

Adjusts the brightness of the touch screen.

To open the Backlight Brightness menu

Press the **Setup** key and then the **Monitor** key. On the **Monitor Setup** menu, select **Service(Bio-Med)**. On the **Service(Bio-Med)** menu, select **Backlight Brightness**.



The following brightness levels are available:

- **1** (Minimum)
- **2**
- **3**
- **4**
- **5**
- **6** (Default)
- **7**
- **8** (Maximum)

To control the brightness of the display backlight

Step	Action
1	Press the **Setup** key and then the **Monitor** key. The **Monitor Setup** menu appears. Current settings are displayed.
2	On the **Monitor Setup** menu, select **Service(Bio-Med)**. The **Service(Bio-Med)** menu appears. Current settings are displayed.
3	Select **Backlight Brightness** and then enter the desired brightness level: **1 – 8** The setting is entered.

Service Utilities

Accesses service-related functions (a password is required for access).

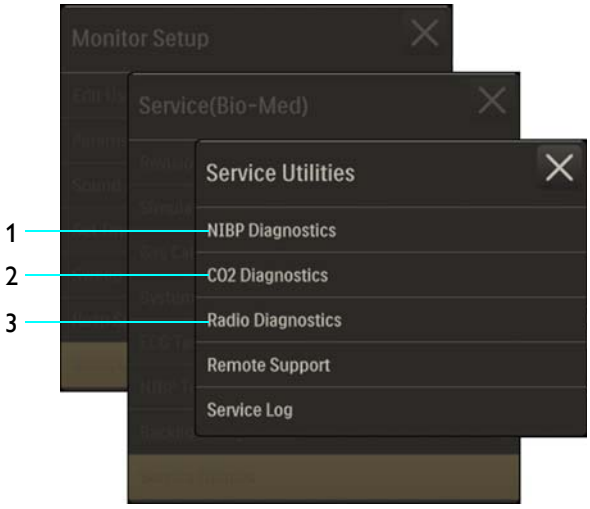
To open the Service Utilities option

Press the **Setup** key and then the **Monitor** key. On the **Monitor Setup** menu, select **Service(Bio-Med)**. On the **Service(Bio-Med)** menu, select **Service Utilities**. Enter the password.

1 NIBP Diagnostics

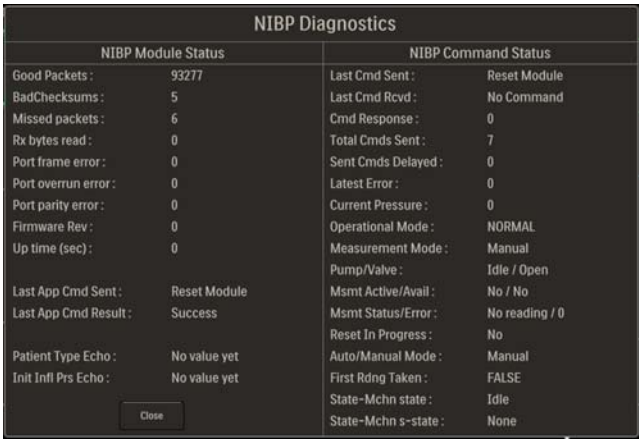
2 CO2 Diagnostics

3 Radio Diagnostics

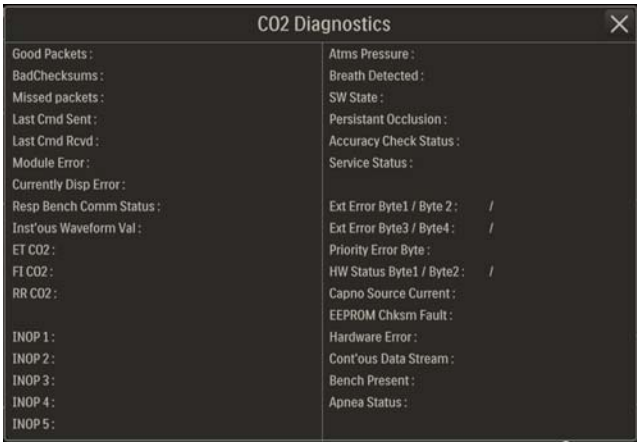


The following menu items are available:

- **NIBP Diagnostics** opens a window that displays NIBP diagnostic data.



- **CO2 Diagnostics** opens a window that displays CO2 diagnostic data.



- **Radio Diagnostics** opens a window that displays radio diagnostic data.

CHAPTER 4

Alarms

The alarm information here applies to all measurements. Measurement-specific alarm information is discussed in the sections on individual measurements. The monitor provides patient alarms and INOP alarms.

Patient Alarms

Patient alarms will illuminate a red or yellow alarm light, where a red alarm light indicates a high priority alarm to alert you to potentially life threatening situations for your patient (for example, a disconnected catheter). A yellow alarm light indicates a lower priority patient alarm (for example, a respiration alarm limit violation).

Patient alarms may also generate flashing numeric values or other indications, alarm flags and sound an audible alarm (provided that a higher priority alarm sound does not override it).

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

1 Medium priority alarm example (ECG heart rate value)

2 Violated (high) alarm limit setting

INOPs

INOPs are status and technical alarms—they indicate that the monitor cannot measure or detect alarm conditions reliably; see page 4-31 for a listing. Depending upon the nature of the condition detected, INOPs will illuminate the alarm light, generate an alarm flag, and sound an audible indicator tone (provided that a higher priority alarm sound does not override it). Other status and technical alarms have a medium or high priority depending upon the nature of the condition detected.

Multiple Alarms

Patient alarms are mutually exclusive and the highest priority alarm will be indicated by the alarm light; if a high priority alarm and a medium priority alarm are present simultaneously. the red alarm light will be on, but the yellow alarm light will not be.

The blue alarm light can be on at the same time as the red or yellow alarm light. When a numeric value becomes missing due to an INOP, the INOP alarm will be present as well as the patient alarm (due to the missing value), with both originating from the same cause.

Alarm Delays

There is an alarm sound and an alarm light illumination delay of no more than 4 seconds following the displayed alarm flag, 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 MR400. 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 MR400 so that you maintain a clear view of the display.**

Visual Alarm Indications

Depending upon the alarm condition, visual alarm indications can include an alarm flag, a flashing numeric, and an illuminated alarm light; when multiple alarms are detected, multiple visual indications may be presented.

Alarm Flags

Alarm flags are visual indicators that contain an alarm message displayed on a background color that identifies the priority of the alarm (see table below). An alarm flag is displayed for the duration of an alarm condition. Multiple alarm flags are displayed when multiple alarm conditions exist.

Alarm Priority	Displayed Background Color
High (patient alarm)	Red
Medium (patient alarm)	Yellow
INOP (status or technical alarm)	Blue

Alarm flags associated with a vital sign are displayed alongside the VS box of that parameter (see illustration below), while alarm flags associated with the system are displayed in the system message area (middle and top center of the touch screen, see page 2-21). When multiple alarm flags are present, they will be stacked in a column.

1 Alarm flag (an INOP in this example)

Flashing Numeric

During an patient alarm condition, the vital sign numeric will change color and flash to indicate the source, type and priority of the alarm:

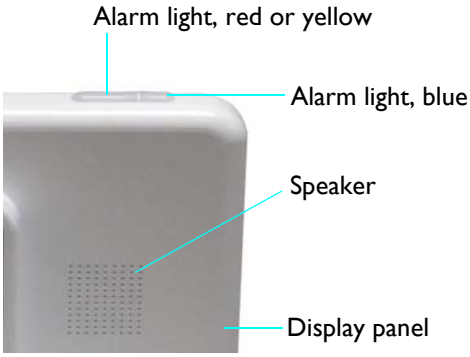
- High priority patient alarm—red numeric, flashing at 1.5 Hz with a 50% duty cycle.
- Medium priority patient alarm—yellow numeric, flashing at 0.75 Hz with a 50% duty cycle.

While the violation continues, the numeric of the violated parameter will flash in priority color of the detected alarm.

Alarm Light

During an alarm condition, the alarm light (see inset) can illuminate to provide a 360 degree, visual indication of the alarm priority, as detailed in the table below.

Multiple colors can be illuminated when multiple alarm conditions exist. The alarm light is a menu-controlled feature; see page 4-20 for setting details.



Alarm Priority	Light Color	Indication
High (patient alarm)	Red	Flashing, 1.5 Hz with a 50% duty cycle
Medium (patient alarm)	Yellow	Flashing, 0.75 Hz with a 50% duty cycle
INOP (status or technical alarm)	Blue	Steady

Audible Alarm Indications

WARNING

Do not rely exclusively on the audible alarm system for patient monitoring. Adjustment of alarm volume to a low level or off during patient monitoring may result in patient danger. Remember that the most reliable method of patient monitoring combines close personal surveillance with correct operation of monitoring equipment.

Depending upon the severity and type of the alarm condition, alarm priority tones with distinct pitches are sounded by the speaker (see illustration on page 4-3). When multiple alarms are detected, the highest priority alarm is announced.

Alarm priority	Fixed Pitch Mnemonic Notes
High	c c c – c c
Medium	c c c
INOP	e c

Once activated, an audible alarm indication continues as long as the alarm condition is present or until you acknowledge the alarm by pressing the **Audio Pause** key or the **Alarm** key (or by placing the MR400 in suspend mode).

Alarm Sound State Indication

Depending upon the current setting, one of three possible symbols are provided to indicate the alarm sound state, which is displayed at all times in the information bar (see page 2-14). Symbol definitions for the alarm sound state are provided in the table below.

Displayed Symbol	Alarm Sound State
	Alarm audio armed
	Alarm audio paused
	Alarm audio off

Initial Audible Alarm Setting Indications

After power-up and immediately following the recall of a stored setup, the MR400 provides an indication of the alarm volume by sounding the alarm tone at its currently adjusted setting for 5 seconds and by displaying **Check Alarm Volume**.

Audio paused is the initial alarm state and then, following a wait period of 120 seconds, armed becomes the normal alarm state, where:

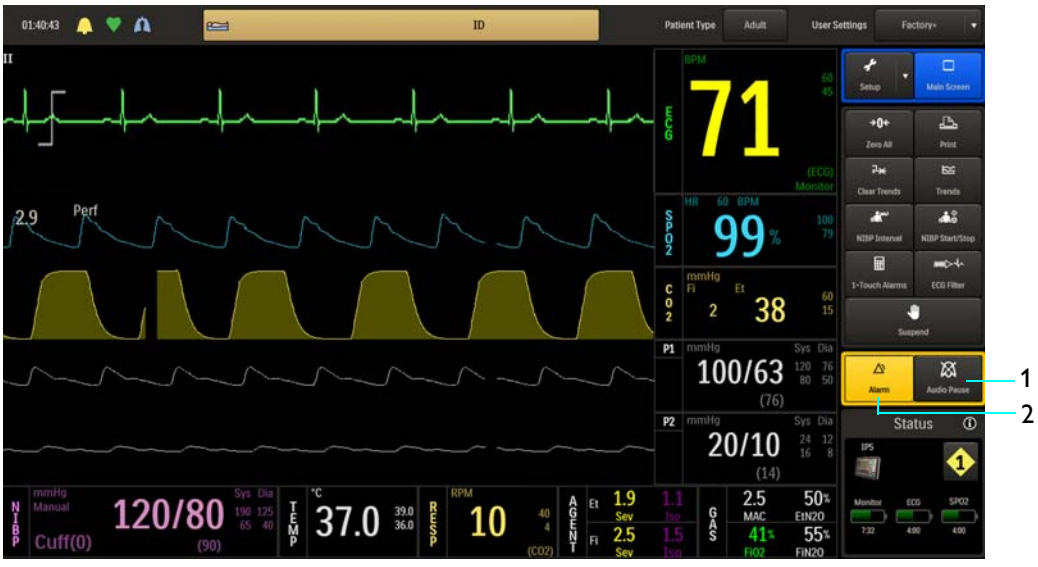
- An alarm will sound while an alarm condition exists, provided that any pre-alarm sound delay has expired and that the alarm audio armed symbol is displayed.
- Alarm flags related to other alarm sound states will be removed from the display.
- An alarm condition not previously placed in an alarm audio off state will cause the alarm to sound.

Controlling the Alarm Audio and Light Indications

Alarm audio indications and the alarm light can be controlled to meet the desired level of response using the **Audio Pause** key or the **Alarm** key.

Note

When an alarm is indicated, always confirm the alarm conditions with clinical observations of the patient before administering interventions. Failure to do so may result in inappropriate intervention.



1 **Audio Pause** key

2 **Alarm** key

Audio Pause Mode

Audio pause mode can is useful to temporarily silence alarms and to temporarily extinguish the alarm light (for example, when changing ECG leads or during other user activities that might cause a “false” alarm).

Audio pause mode is indicated when the **Audio Paused** alarm flag, the audio paused symbol (see page 4-4) and a countdown timer are displayed. (The 120-second countdown timer period is not user adjustable.) During this period, the audible alarm will be suspended for any new alarm conditions that occur. Any messages related to other alarm sound states will be removed.

To activate Audio Pause

Press the **Audio Pause** key:

- If the alarm is not sounding, press the key once.
- If the alarm is sounding, press the key twice.

To deactivate Audio Pause

- Wait until the 120-second countdown reaches zero (0), or
- Press the **Audio Pause** key.

Audio Off Mode

In audio off mode, the alarm tone will cease, the alarm light will be extinguished, and the **Audio Off** message and the audio off symbol (see page 4-4) will be displayed. Any new alarm condition will cause audio off mode to be exited and the alarm tone to be sounded. However, a current alarm condition previously silenced will not sound again unless the condition returns within limits and then violates a limit again.

Audio off mode allows you to disable the alarm tone and alarm light during an alarm condition, while allowing new alarm conditions to reactivate all alarm functions. While the violation continues, the numeric of the violated parameter will flash in priority color of the detected alarm.

WARNING

An active silenced alarm may not be accompanied by the Audio Off message and symbol , if Audio Paused has been activated, or if a subsequent additional alarm has occurred and was self-corrected.

To activate Audio Off

Press the **Alarm** key.

To deactivate Audio Off

Press the **Alarm** key again.

Alarm Volume

The loudness of the alarm sounds can be adjusted (45–86 dB, typical).

WARNING

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 MR400, 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.

To control the alarm volume

Step	Action
1	Press the **Setup** key and then the **Monitor** key. The **Monitor Setup** menu appears. Current settings are displayed.
2	On the **Monitor Setup** menu, select **Sound Adjust**. The **Sound Adjust** menu appears. Current settings are displayed.
3	Select **Alarm Volume**. **1–10** The menu item appears. The current setting is highlighted.
4	Select the desired setting from the menu options. The setting is entered and a momentary sound at the corresponding level is produced

Alarm Reset

Resetting the alarm results in the following alarm system behaviors:

- The auditory alarm signals of physiological alarm conditions cease, enabling the alarm system to respond to a subsequent alarm condition.
- Alarm light indications cease.
- Alarm flags for any existing alarms continue as long as those alarm conditions exist.
- The alarm system is enabled immediately so that it can respond to a subsequent alarm condition.
- The visual alarm signals of INOP conditions do not cease as long as the INOP alarm condition exists.

The alarm can be reset by pressing the **Audio Pause** key one time.

Managing Alarm Functions

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 MR400 can be set to provide visual alarm signals only, or both visual and audible alarm signals. The audible alarm states will have no effect on any of the visual alarms displayed by the MR400 (or IP5, if equipped).

All settings in the **Alarms** menu (except **Alarm Sound**) can be stored and recalled.

Restrictions to alarm presets are not provided due to the fast paced work flow, short average duration time of MRI scans, different patient types scheduled for MRI procedures, and direct patient supervision provided during MRI procedures.

Note

If the MR400 is networked to an IP5, alarm indications occur at both the MR400 and the IP5; and control of alarms, including sound level, is localized to the device (MR400 or IP5) indicating the alarm condition.

Showing or Hiding Current Alarm Limits

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

To control the display function for the alarm limit settings

Step	Action
1	Press the **Setup** key and then the **Alarms** key. The **Alarms** menu appears. Current settings are displayed.

Step	Action
2	Select **Limits Display**. The **Limits Display** menu appears. The current setting is highlighted.
3	Select the desired option for display of the alarm limit settings: **Off** **On** The setting is selected.

Adjusting the Alarm Limits

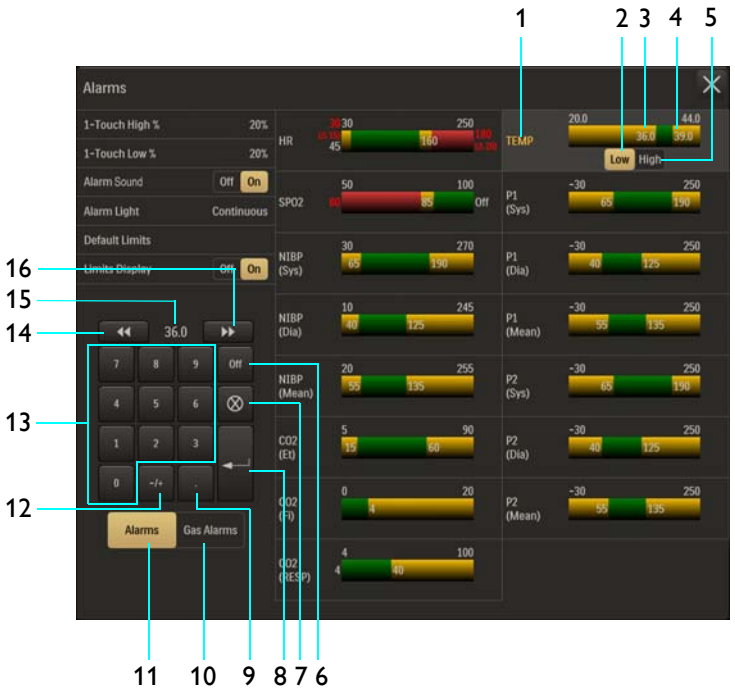
WARNING

Alarm limits can be set to a wide range of values, including off (with the exception of O2, N2O and FiCO2). It is the responsibility of the operator of the MR400 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 MR400 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 4-22), which can be changed manually or automatically, unless the parameter is off.

Alarm Limit Controls

Individual alarm limit settings can be adjusted by touching the respective parameter label in the **Alarms** or the **Gas Alarms** menu.



1 Parameter label for alarm limit settings (active adjustment shown)

2 **Low** button

3 Lower alarm limit setting

4 Upper alarm limit setting

5 **High** button

6 **Off** button

7 **Clear entry** button

8 **Enter** button

9 **Decimal point** button

10 **Gas Alarms** button

11 **Alarms** button

12 **Plus / minus** button

13 Keypad

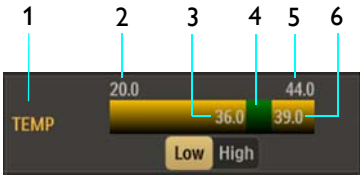
14 **Decrement** button

15 Current adjustment

16 **Increment** button

The Alarm Window

Alarm limits have minimum and maximum values that are not adjustable (see page 4-22). Within the minimum and maximum alarm limits, adjustable lower and upper limit settings establish an alarm window. Vital sign measurements that fall within the alarm window will not result in an physiological alarm. It is only when a vital sign measurement exceeds the alarm window for a monitored parameter that a physiological alarm will be declared. (An illustration is shown below.)



1 Parameter name (TEMP in this example)

2 Alarm limit, minimum

3 Lower alarm limit setting

4 Alarm window

5 Alarm limit, maximum

6 Upper alarm limit setting

Advanced Alarm Functions

The MR400 features advanced alarm functions that can alert you to specific or more extreme physiological conditions. When adjusting these advanced function alarms, the following rules govern the alarm settings:

Extreme Bradycardia Alarm Setting

The Extreme Bradycardia alarm setting is established by the setting of the Extreme Bradycardia delta value. The Extreme Bradycardia delta value cannot be greater than the difference between the HR low alarm limit setting and the alarm limit minimum. The maximum allowable delta value is 50. See page 5-24 for setting details.

The Extreme Bradycardia delta value will retain its adjusted value as the HR low alarm limit setting is adjusted upward, but will begin to shrink in value as the low alarm limit setting is adjusted closer to the alarm limit minimum.

Extreme Tachycardia Alarm Setting

The Extreme Tachycardia alarm setting is established the setting of the Extreme Tachycardia delta value. The Extreme Tachycardia delta value cannot be greater than the difference between the HR alarm limit maximum and the high alarm limit setting. The maximum allowable delta value is 50. See page 5-24 for setting details.

The Extreme Tachycardia delta value will retain its adjusted value as the HR high alarm limit setting is adjusted downward, but will begin to shrink in value as the high alarm limit setting is adjusted closer to the alarm limit maximum.

Desat Alarm Setting

The Desat alarm setting is restricted to a maximum value that is 2 less the SPO2 low alarm limit setting, while the minimum setting can be as low as the alarm minimum. See page 6-11 for setting details.

As long as the SPO2 parameter is on, the Desat alarm value will retain this setting even if the function is turned off and on.

The SPO2 alarm adjustments are designed to give priority to the Desat alarm setting. Therefore, the SPO2 low and high alarm limits may also be adjusted based on a change made to the Desat alarm setting. Whenever the Desat alarm setting is changed, the following rules determine the lower and upper SPO2 alarm limits:

- If the Desat alarm was turned on after being set and turned off, then if the last set value of the SPO2 low alarm limit is less than the Desat alarm setting plus 2, the SPO2 low alarm limit will be set to the Desat alarm setting plus 2.
- If the Desat alarm is adjusted upward so that the setting is greater than or equal to the SPO2 low alarm limit minus 2, then the SPO2 low alarm limit will be increased by the system such that the Desat alarm setting plus 2 is always maintained (i.e., the low alarm limit will always move to stay two greater than Desat alarm setting). If low alarm limit is altered due to this scenario, low alarm limit will retain this altered value even if the Desat alarm setting is adjusted downward.
- The SPO2 high alarm limit will be adjusted as necessary in relation to the low alarm limit as per the normal behavior of low and high alarm limits.
- The SPO2 low alarm limit will be allowed to be adjusted downward only until it is equal to the Desat alarm setting plus 2. No further downward adjustment of low alarm limit will be allowed until the Desat alarm setting is adjusted downward.

Setting Alarm Limits Globally

Global changes to all of the lower and upper alarm limit settings can be made automatically by pressing the using the **1-Touch Alarms** key. These global changes are calculated using percentages selected in the **1-Touch High %** and the **1-Touch Low %** options; see page 4-17.

During calculations if a patient's monitored value is so high or low that it would exceed the alarm limit range for the parameter, then the alarm limit will be set to the highest or lowest possible value but not off, as indicated in the table on page 4-22. For example, if after pressing the **1-Touch Alarms** key, a patient's SPO2 upper alarm limit setting was 99 (the highest allowable value), then an alarm will be generated if the patient's reading reaches 100. (To turn off an alarm limit, see *Setting Alarm Limits Individually* on page 4-13.)

Also note that setting alarm limits globally may result in a lower SPO2 alarm 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 **1-Touch High %** of **20** (factory default).

To adjust the upper and lower alarm limit settings for all monitored parameters

Step	Action
1	Press the **Setup** key and then the **Alarms** key. The **Alarms** menu appears. Current settings are displayed.
2	Select **1-Touch High %**. The **1-Touch High %** menu appears. The current setting is highlighted.
3	Select the desired percentage: **5%** **10%** **15%** **20%** **30%** The setting is selected.
4	Select **Lower Window**. The **Lower Window** menu appears. The current setting is highlighted.
5	Select the desired percentage: **5%** **10%** **15%** **20%** **30%** The setting is selected.
6	Press the **1-Touch Alarms** key. All active alarm limit settings are changed.

Setting Alarm Limits Individually

Lower and upper alarm limit settings for each parameter can be individually adjusted in the **Alarms** menu (or in the menu of the parameter that you want to change, by touching the alarm limit settings in parameter's VS box).

In the **Alarms** menu, lower and upper alarm limit settings for parameters are provided, as shown below. (For information about gas alarms, see chapter 9.) An individual alarm limit setting can be adjusted by touching the lower or upper alarm limit of the respective parameter in the **Alarms** menu.

1 TEMP – (Temperature)

2 P1 (Sys) – (P1 [Systolic])

3 P1 (Dia) – (P1 [Diastolic])

4 P1 (Mean)

5 P2 (Sys) – (P2 [Systolic])

6 P2 (Dia) – (P2 [Diastolic])

7 P2 (Mean)

8 CO2 (RESP) – (CO2 [Respiration])

9 CO2 (Fi) – (CO2 [Fractional inspired])

10 CO2 (Et) – (CO2 [End-tidal])

11 NIBP (Mean)

12 NIBP (Dia) – (NIBP [Diastolic])

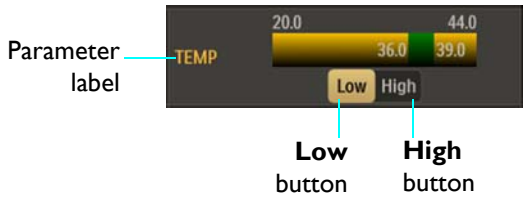
13 NIBP (Sys) – (NIBP [Systolic])

14 SPO2

15 HR – (Heart rate)

To adjust the alarm limit settings for a single parameter in the Alarms menu

Step	Action
1	Press the **Setup** key and then the **Alarms** key. The **Alarms** menu appears. Current settings are displayed.

Step	Action
2	Press the desired parameter label on the **Alarms** menu: **HR** **SPO2** **NIBP (Sys)** **NIBP (Dia)** **NIBP (Mean)** **CO2 (Et)** **CO2 (Fi)** **CO2 (RESP)** **TEMP** **P1 (Sys)** **P1 (Dia)** **P1 (Mean)** **P2 (Sys)** **P2 (Dia)** **P2 (Mean)** The background of the selected parameter becomes highlighted (TEMP in this example).
3	Depending upon the alarm limit to be modified, press the **Low** button or the **High** button.  In this example, the **Low** button was selected to adjust the lower alarm limit setting.

Step	Action
4	Use the **increment** or the **decrement** button to adjust the setting. Or, directly input the value using the keypad, the **plus / minus** button and/or the **decimal point** button then press the **Enter** button. (For item locations, see *Alarm Limit Controls* on page 4-9.)  The current adjustment will reflect the setting. (In this example, the lower limit setting was adjusted from 36 to 33.) 
5	To change the remaining setting, repeat steps 3 and 4.
6	To change any remaining parameters, repeat steps 2, 3, and 4.
7	Press the **Main Screen** key to close the menu. New limit settings will be indicated in the parameter's VS box.

Restoring Alarm Limit Defaults

Whenever the **Patient Type** setting is changed (see page 3-11), the MR400 automatically restores the default values to all the alarm limit settings; see page 4-24 for a listing of the default values.

To immediately restore the alarm limits to the default settings

Step	Action
1	Press the **Setup** key and then the **Alarms** key. The **Alarms** menu appears. Current settings are displayed.
2	Select **Default Limits**. The alarm limit settings are returned to the default values.

Enabling Print on Alarm

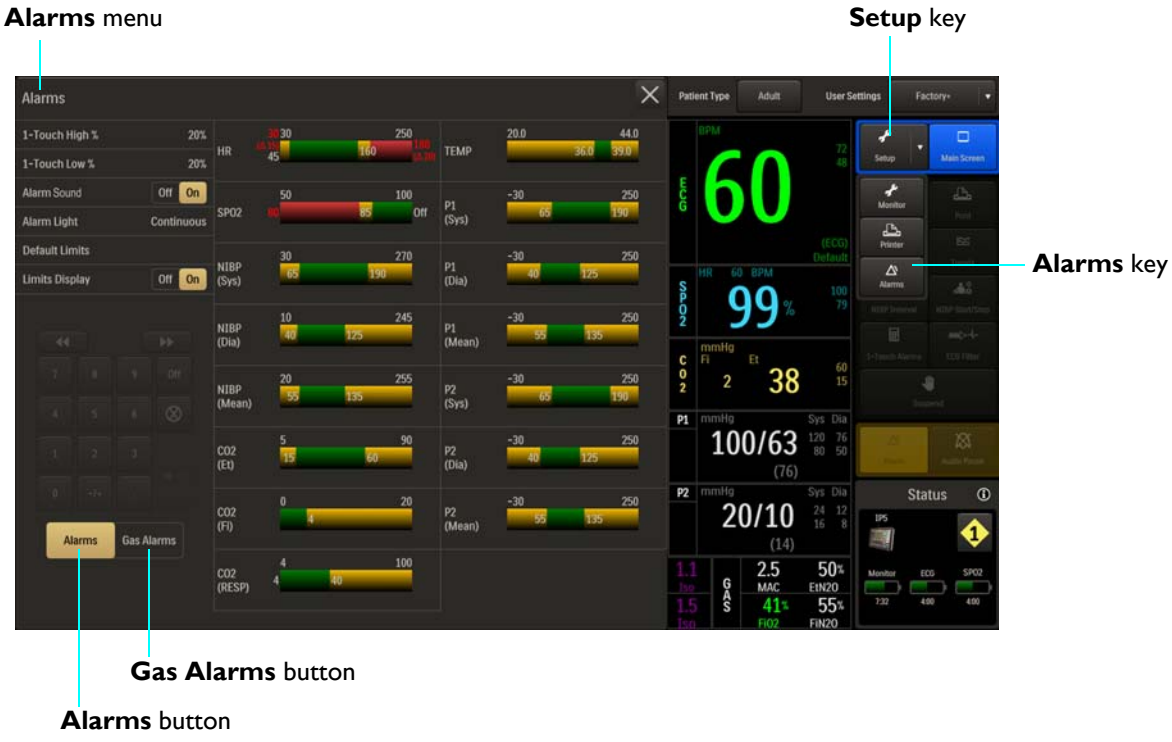
If the MR400 is connected to an IP5 that is equipped with a printer, a printout can be automatically generated when a physiological alarm occurs. See the IP5 IFU for details.

Alarms Menu

The **Alarms** menu allows you to configure the MR400 for setup and control of the vital sign alarms.

To open the Alarms menu

Press the **Setup** key and then the **Alarms** key.



Notes

- *Select the **Alarms** button to access the alarm limits settings for parameters.*
- *Select the **Gas Alarms** button to access the alarm limits settings for AGENT and GAS.*

The following **Alarms** menu items are available:

- **1-Touch High %**
- **1-Touch Low %**
- **Alarm Sound**
- **Alarm Light**
- **Default Limits**
- **Limits Display**

To change settings in the Alarms menu

Step	Action
1	Press the **Setup** key and then the **Alarms** key. The **Alarms** menu appears. Current settings are displayed.
2	Select any of the following menu items: **1-Touch High %** **1-Touch Low %** **Alarm Sound** **Alarm Light** **Default Limits** **Limits Display** For information about these options, see the appropriate sections below.
3	Select the desired menu item. The current setting is highlighted.
4	Select the desired setting from the menu options. The setting is entered.
5	To change other settings, repeat steps 2, 3 and 4.

1-Touch High %

Sets a percent value used to calculate the high alarm limits when the **1-Touch Alarms** key is pressed. The current parameter value is bracketed with the percentages set in this menu and in the **1-Touch Low %** menu.

The following options are available:

- **5%**

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

To set the upper window

See *Setting Alarm Limits Globally* on page 4-12.

Note

If, during calculation, a patient's monitored value is so high that it exceeds the alarm limit range for the parameter, then the respective alarm limit will be set to the highest value but not off, as indicated in the table on page 4-22.

1-Touch Low %

Sets a percent value used to calculate the low alarm limits when the **1-Touch Alarms** key is pressed. The current parameter value is bracketed with the percentages set in this menu and in the **1-Touch High %** menu.

The following options are available:

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

To set the lower calculation value

See *Setting Alarm Limits Globally* on page 4-12.

Note

If, during calculation, a patient's monitored value is so low that it exceeds the alarm limit range for the parameter, then the respective alarm limit will be set to lowest possible value but not off, as indicated in the table on page 4-22.

Alarm Sound

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 MR400, always ensure that the alarm sound can be heard above the ambient noise level; otherwise, treatment of the patient could be delayed.

Controls the alarm sound (identical to and interactive with **Alarms** in the **Monitor Setup > Sound Adjust** menu).

The following options are available:

- **Off** turns off the alarm sound, as indicated by the alarm audio off symbol (see page 4-4). (Only the alarm sound will be disabled; visual alarm indications will continue.)
- **On** turns on the alarm sound, as indicated by the alarm audio armed symbol (see page 4-4). (Default)

To control the alarm sound

Step	Action
1	Press the **Setup** key and then the **Alarms** key. The **Alarms** menu appears. Current settings are displayed.
2	Locate **Alarm Sound** and select the desired setting: **Off** **On** The setting is entered.

Alarm Light

Sets the behavior of the alarm light following the detection of an alarm.

The following options are available:

- **Continuous** illuminates the alarm light for the duration of an alarm condition. (Default)
- **Temporary** illuminates the alarm light for 25 seconds during an alarm condition. (If the MR400 is placed in suspend mode or if the alarm is silenced or paused during this period, then upon exiting the alarm light will restart for 25 seconds.)
- **Off** does not illuminate the alarm light during an alarm condition.

Note

*As defined in the table below, the current **Alarm Light** setting is indicated by the displayed symbol on the information bar (see page 2-14).*

Alarm Light Setting	Displayed Symbol
Continuous	
Temporary	
Off	

To adjust the alarm light setting

Step	Action
1	Press the **Setup** key and then the **Monitor** key. The **Monitor Setup** menu appears. Current settings are displayed.
2	On the **Monitor Setup** menu, select **Alarm Light**. The **Alarm Light** menu appears. The current setting is highlighted.
3	Select the desired setting from the menu options: **Continuous** **Temporary** **Off** The setting is entered.

Default Limits

Automatically sets the low alarm limits and high alarm limits for all parameters to the default values (see the table on page 4-24).

To set the alarm limit settings to the default limits

See *Restoring Alarm Limit Defaults* on page 4-16.

Limits Display

Controls the visibility of the alarm limit settings in the VS boxes.

The following options are available:

- **Off** does not display the alarm limit settings.
- **On** displays the alarm limit settings. (Default)

To control the display function for the alarm limit settings

Step	Action
1	Press the **Setup** key and then the **Alarms** key. The **Alarms** menu appears. Current settings are displayed.
2	Select **Limits Display**. The **Limits Display** menu appears. The current setting is highlighted.
3	Select the desired option for display of the alarm limit settings: **Off** **On** The setting is selected.

Adjustable Alarm Limit Ranges

With the exception of bellows respiration, each parameter alarm has adjustable limits as indicated in the tables below**.** Note that the alarm limit numeric values can be set to off, with the exception of O2, N2O, FiCO2. The MR400 also prevents crossover of low and high alarm limit settings, and a minimum number of units separates these low and high settings. When a parameter has been turned off, its alarm limits will be off. Alarm limits are adjustable by the same resolution specified in each parameter's measurement resolution set forth in Appendix A.

Note

The minimum and maximum values for the low and high limits represent the most extreme settings possible. For some vital signs, these values can be obtained for a low or high alarm limit only if the other limit is off.

The table below provides the alarm limit ranges for the MR400.

Vital Sign or Parameter	Unit	Patient Type	Low Alarm Limit*		High Alarm Limit*		Low and High Limit Separation
			Minimum	Maximum	Minimum	Maximum	
HR	BPM	All	Off, 30	250	60	250, Off	2
SPO2	Percent	All	Off, 50	100	70	100, Off	2
CO2 (Et)	mmHg kPa	All	Off, 5 Off, 0.7	60 8.0	5 0.7	90, Off 12.0, Off	2

Vital Sign or Parameter	Unit	Patient Type	Low Alarm Limit*		High Alarm Limit*		Low and High Limit Separation
			Minimum	Maximum	Minimum	Maximum	
CO2 (Fi)	mmHg kPa	All	No low alarm		0	20, Off 2.7, Off	2
CO2 (Resp)	RPM	All	Off, 4	40	20	100, Off	2
P1 and P2	mmHg kPa	All	Off, -30 Off, -4.0	250 33.3	-30 -4.0	250, Off 33.3, Off	2
Temperature	°C °F	All	Off, 20.0 Off, 68.0	44.0 111.2	20.0 68.0	44.0, Off 111.2, Off	1
NIBP — Systolic	mmHg kPa	Adult	Off, 30 Off, 4.0	270 36.0	30 4.0	270, Off 36.0, Off	2
— Mean	mmHg kPa	Adult	Off, 20 Off, 2.7	255 34.0	20 2.7	255, Off 34.0, Off	2
— Diastolic	mmHg kPa	Adult	Off, 10 Off, 1.3	245 32.7	10 1.3	245, Off 32.7, Off	2
NIBP — Systolic	mmHg kPa	Pediatric	Off, 30 Off, 4.0	180 24.0	30 4.0	180, Off 24.0, Off	2
— Mean	mmHg kPa	Pediatric	Off, 20 Off, 2.7	160 21.3	20 2.7	160, Off 21.3, Off	2
— Diastolic	mmHg kPa	Pediatric	Off, 10 Off, 1.3	150 20.0	10 1.3	150, Off 20.0, Off	2
NIBP — Systolic	mmHg kPa	Neo	Off, 30 Off, 4.0	130 17.3	30 4.0	130, Off 17.3, Off	2
— Mean	mmHg kPa	Neo	Off, 20 Off, 2.7	120 16.0	20 2.7	120, Off 16.0, Off	2
— Diastolic	mmHg kPa	Neo	Off, 10 Off, 1.3	100 13.3	10 1.3	100, Off 13.3, Off	2

**For all alarm limit values that may be displayed in units of kPa, allow +/- 0.1 kPa of variance to account for rounding error that may occur when converting from mmHg to kPa.*

The following table provides the alarm limit ranges for the anesthetic agent gases and oxygen for all patient types.

Breath Phase and Gas	Unit	Low Alarm Limit		High Alarm Limit		Low and High Limit Separation
		Minimum	Maximum	Minimum	Maximum	
DES (Et), Expired Desflurane	Vol. %	Off, 0.1	18.0	0.1	18.0, Off	1
DES (Fi), Inspired Desflurane	Vol. %	Off, 0.1	18.0	0.1	18.0, Off	1
ENF (Et) Expired Enflurane	Vol. %	Off, 0.1	5.0	0.1	5.0, Off	1
ENF (Fi) Inspired Enflurane	Vol. %	Off, 0.1	5.0	0.1	5.0, Off	1
HAL (Et) Expired Halothane	Vol. %	Off, 0.1	5.0	0.1	5.0, Off	1
HAL (Fi) Inspired Halothane	Vol. %	Off, 0.1	5.0	0.1	5.0, Off	1
ISO (Et) Expired Isoflurane	Vol. %	Off, 0.1	5.0	0.1	5.0, Off	1
ISO (Fi) Inspired Isoflurane	Vol. %	Off, 0.1	5.0	0.1	5.0, Off	1

Breath Phase and Gas	Unit	Low Alarm Limit		High Alarm Limit		Low and High Limit Separation
		Minimum	Maximum	Minimum	Maximum	
SEV (Et) Expired Sevoflurane	Vol. %	Off, 0.1	8.0	0.1	8.0, Off	1
SEV (Fi) Inspired Sevoflurane	Vol. %	Off, 0.1	8.0	0.1	8.0, Off	1
N2O (Fi) Inspired Nitrous Oxide	Percent	No low alarm		0	80	1
O2 (Fi) Inspired Oxygen	Percent	18	100	18	100	1

Alarm Limit Factory 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 MR400 will automatically set all alarm limits as determined by the default selected in the **Edit User Settings** menu; see page 3-15. The factory default alarm limits are listed in the table below.

Note

You are restricted from making changes to the factory default settings.

Vital Sign or Parameter	Unit	Adult		Pediatric		Neo	
		Low Limit	High Limit	Low Limit	High Limit	Low Limit	High Limit
Heart Rate	BPM	45	160	75	160	90	210
Heart Rate - Extreme Bradycardia	BPM	20	20	20	20	20	20
Heart Rate - Extreme Tachycardia	BPM	20	20	20	20	20	20
SPO2	Percent	85	Off	90	Off	90	Off
SPO2 - Desat	Percent	80	80	80	80	80	80
CO2 (Et)	mmHg kPa	15 2.0	60 8.0	15 2.0	60 8.0	30 4.0	45 6.0
CO2 (Fi)	mmHg kPa	No low alarm	4 0.5	No low alarm	4 0.5	No low alarm	4 0.5
CO2 (Resp)	RPM	4	40	4	40	30	70
P1 / P2 Systolic	mmHg kPa	65 8.7	190 25.3	70 9.3	120 16.0	70 9.3	100 13.3
P1 / P2 Mean	mmHg kPa	55 7.3	135 18.0	50 6.7	90 12.0	40 5.3	90 12.0
P1 / P2 Diastolic	mmHg kPa	40 5.3	125 16.7	40 5.3	70 9.3	35 4.7	50 6.7

Vital Sign or Parameter	Unit	Adult		Pediatric		Neo	
		Low Limit	High Limit	Low Limit	High Limit	Low Limit	High Limit
NIBP Systolic	mmHg kPa	65 8.7	190 25.3	70 9.3	120 16.0	70 9.3	100 13.3
NIBP Mean	mmHg kPa	55 7.3	135 18.0	50 6.7	90 12.0	40 5.3	90 12.0
NIBP Diastolic	mmHg kPa	40 5.3	125 16.7	40 5.3	70 9.3	35 4.7	50 6.7
Temperature	°C °F	36.0 96.8	39.0 102.2	36.0 96.8	39.0 102.2	36.0 96.8	39.0 102.2
DES (Et), Expired Desflurane	Vol. %	Off	12.0	Off	12.0	Off	12.0
DES (Fi), Inspired Desflurane	Vol. %	Off	18.0	Off	18.0	Off	18.0
ENF (Et) Expired Enflurane	Vol. %	Off	3.4	Off	3.4	Off	3.4
ENF (Fi) Inspired Enflurane	Vol. %	Off	5.0	Off	5.0	Off	5.0
HAL (Et) Expired Halothane	Vol. %	Off	1.5	Off	1.5	Off	1.5
HAL (Fi) Inspired Halothane	Vol. %	Off	2.2	Off	2.2	Off	2.2
ISO (Et) Expired Isoflurane	Vol. %	Off	2.3	Off	2.3	Off	2.3
ISO (Fi) Inspired Isoflurane	Vol. %	Off	3.4	Off	3.4	Off	3.4
SEV (Et) Expired Sevoflurane	Vol. %	Off	4.1	Off	4.1	Off	4.1
SEV (Fi) Inspired Sevoflurane	Vol. %	Off	6.1	Off	6.1	Off	6.1
N2O (Fi) Inspired Nitrous Oxide	Percent	No low alarm	80	No low alarm	80	No low alarm	80
O2 (Fi) Inspired Oxygen	Percent	18	99	18	99	18	99

**For all alarm limit values that may be displayed in units of kPa, allow +/- 0.1 kPa of variance to account for rounding error that may occur when converting from mmHg to kPa.*

Measurement Limits and Over / Under Values

In the table below, the range of values that can be measured for a vital sign item are provided along with the high and low values that, beyond which, an over or under indication will be given. Specifically, a value will be marked as Over (OVR) if the VS value is greater than the given over value, and marked as Under (UND) if the VS value is less than the given under value.

Vital Sign or Parameter	Numeric Item	Units	Patient Type	Measurement Range		Over / Under Values	
				Low	High	Under	Over
ECG	Heart Rate	BPM	Adult	30	250	30	250
ECG	Heart Rate	BPM	Ped	30	300	30	300
ECG	Heart Rate	BPM	Neo	30	300	30	300
SPO2	Heart Rate	BPM	All	30	250	30	250

Vital Sign or Parameter	Numeric Item	Units	Patient Type	Measurement Range		Over / Under Values	
				Low	High	Under	Over
SPO2	Saturation	%	All	1	100	none	none
P1 and P2	Systolic	mmHg	Adult	-30	250	-30	250
P1 and P2	Mean	mmHg	Ped	-30	250	-30	250
P1 and P2	Diastolic	mmHg	Neo	-30	250	-30	250
P1 and P2	Pulse Rate	BPM	All	30	250	30	250
NIBP	Systolic	mmHg	Adult	30	270	30	270
NIBP	Systolic	mmHg	Ped	30	180	30	180
NIBP	Systolic	mmHg	Neo	30	130	30	130
NIBP	Mean	mmHg	Adult	20	255	20	255
NIBP	Mean	mmHg	Ped	20	160	20	160
NIBP	Mean	mmHg	Neo	20	120	20	120
NIBP	Diastolic	mmHg	Adult	10	245	10	245
NIBP	Diastolic	mmHg	Ped	10	150	10	150
NIBP	Diastolic	mmHg	Neo	10	100	10	100
Temperature	Temperature	°C	All	20.0	44.0	20.0	44.0
CO2 (LoFlo option)	CO2 (Et)	mmHg	All	0	90	none	90
CO2 (LoFlo option)	CO2 (Fi)	mmHg	All	0	90	none	90
CO2 (LoFlo option)	Resp. Rate	RPM	All	4	100	none	100
CO2 (AGENT option)	CO2 (Et)	mmHg	All	0	90	none	90
CO2 (AGENT option)	CO2 (Fi)	mmHg	All	0	90	none	90
CO2 (AGENT option)	Resp. Rate	RPM	All	4	100	4	100
AGENT	Desflurane (Et & Fi)	%	All	0	18.0	none	18.0
AGENT	Enflurane (Et & Fi)	%	All	0	5.0	none	5.0
AGENT	Halothane (Et & Fi)	%	All	0	5.0	none	5.0
AGENT	Isoflurane (Et & Fi)	%	All	0	5.0	none	5.0
AGENT	Sevoflurane (Et & Fi)	%	All	0	8.0	none	8.0
AGENT	N2O (Et)	%	All	0	100	none	none
AGENT	N2O (Fi)	%	All	0	100	none	none
AGENT	O2 (Fi)	%	All	0	100	none	none
Bellows Respiration	Resp. Rate	RPM	All	4	150	4	150

Listing of Alarms

This section lists patient alarms alphabetically, and technical alarms (INOPs) arranged by the source of the INOP and then alphabetically, irrespective of priority. All alarms and INOPs are listed here; those which can appear on your MR400 will depend on the installed options.

Vital Sign Value State

A vital sign value is considered missing (as indicated by three dashes, - - -) when the vital sign has produced a value since the monitor was turned on, but can no longer produce a value. Examples of the values that could become missing during normal use, include:

- ECG heart rate value if the leads are removed.
- SPO2 value during **No Probe**, **Probe Off**, et cetera.
- Temperature value if the probe was removed.
- Invasive pressure values if the transducer is removed.

When a value becomes missing due to an INOP, an INOP alarm will be present. And, a patient alarm—due to the missing value—will be present as well. Therefore, the system can have an INOP alarm, and a patient alarm, active at the same time and from the same cause.

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.

Patient and INOP Alarms

The measurement labels and abbreviations for pressure, temperature, SpO2, CO2 and anesthetic agent alarms are explained in the individual chapters. The following table contains a listing of patient alarms arranged by vital sign or parameter. The parameter must be on for the respective alarm detections to be enabled; see page 3-18.

Note

In the case of missing data (- - -), an alarm will occur only if a valid numeric was previously displayed but can no longer be produced; see page 2-20 for details.

Patient Alarm	From	Condition	Indication
Extreme Brady	ECG, SPO2, P1 (or P2)	The heart rate measurement has violated the Extreme Bradycardia alarm setting.	Red flag in ECG alarm flag area, flashing red heart rate numeric in the ECG VS box and in the SPO2 VS box, red alarm light, high priority alarm tone
Extreme Tachy	ECG, SPO2, P1 (or P2)	The heart rate measurement has violated the Extreme Tachycardia alarm setting.	Red flag in ECG alarm flag area, flashing red heart rate numeric in the ECG VS box and in the SPO2 VS box, red alarm light, high priority alarm tone
Violated heart rate value	ECG, SPO2, P1 (or P2)	The heart rate measurement has violated an alarm limit setting.	Flashing yellow heart rate numeric in the ECG VS box and in the SPO2 VS box, yellow alarm light, medium priority alarm tone

Patient Alarm	From	Condition	Indication
Missing heart rate data	ECG, SPO2, P1 (or P2)	The heart rate data, once present, can no longer be produced.	Flashing yellow dashes (- - -) in the heart rate numeric in the ECG VS box and in the SPO2 VS box, yellow alarm light, medium priority alarm tone
Over maximum heart rate value	ECG, SPO2, P1 (or P2)	The heart rate measurement has violated the upper parameter range.	Flashing red heart rate numeric alternating between **OVR** and the heart rate value in the ECG VS box and in the SPO2 VS box, red alarm light, high priority alarm tone
Under minimum heart rate value	ECG, SPO2, P1 (or P2)	The heart rate measurement has violated the lower parameter range.	Flashing red heart rate numeric alternating between **UND** and the heart rate value in the ECG VS box and in the SPO2 VS box, red alarm light, high priority alarm tone
Desat	SPO2	SPO2 has detected a desaturation event.	Red flag in ECG alarm flag area, flashing red SpO2 numeric, red alarm light, high priority alarm tone
Violated arterial oxygen saturation value	SPO2	The arterial oxygen saturation measurement has violated an alarm limit setting.	Flashing yellow SpO2 numeric in the SPO2 VS box, yellow alarm light, medium priority alarm tone
Missing arterial oxygen saturation data	SPO2	The arterial oxygen saturation data, once present, can no longer be produced.	Flashing yellow dashes (- - -) in the SpO2 numeric in the SPO2 VS box, yellow alarm light, medium priority alarm tone
Apnea	CO2, AGENT	The apnea time delay setting has been exceeded.	Red flag in the CO2 or RESP alarm flag area, Flashing red respiration rate numeric, red alarm light, high priority alarm tone ***Note*** *Apnea alarm flag appears in either the CO2 or the RESP alarm flag area, based on the RESP source.*
Violated EtCO2 value	CO2, AGENT	The end-tidal CO2 measurement has violated an alarm limit setting.	Flashing yellow EtCO2 numeric in the CO2 VS box, yellow alarm light, medium priority alarm tone, where **OVR** displayed if the value is greater than the highest specified
Missing EtCO2 data	CO2, AGENT	The end-tidal CO2 data, once present, can no longer be produced.	Flashing yellow dashes (- - -) in the EtCO2 numeric in the CO2 VS box, yellow alarm light, medium priority alarm tone
Violated FiCO2 value	CO2, AGENT	The fractional inspired CO2 measurement has violated an alarm limit setting.	Flashing yellow FiCO2 numeric in the CO2 VS box, yellow alarm light, medium priority alarm tone, where **OVR** displayed if the value is greater than the highest specified
Missing FiCO2 data	CO2, AGENT	The fractional inspired CO2 data, once present, can no longer be produced.	Flashing yellow dashes (- - -) in the FiCO2 numeric in the CO2 VS box, yellow alarm light, medium priority alarm tone

Patient Alarm	From	Condition	Indication
Violated CO2 respiration rate value	CO2, AGENT	The CO2 respiration rate measurement has violated an alarm limit setting.	Depending upon RESP VS box configuration: • Flashing yellow respiration rate numeric in the CO2 VS box, yellow alarm light, medium priority alarm tone, or • Flashing yellow respiration rate numeric in the RESP VS box, yellow alarm light, medium priority alarm tone • And where **OVR** displayed if the value is greater than the highest specified • And where **UND** if the value is less than the lowest specified (AGENT option only)
Missing CO2 respiration rate data	CO2, AGENT	The CO2 respiration rate data, once present, can no longer be produced.	Depending upon RESP VS box configuration: • Flashing yellow dashes (- - -) in the respiration rate numeric in the CO2 VS box, yellow alarm light, medium priority alarm tone, or • Flashing yellow dashes (- - -) in the respiration rate numeric in the RESP VS box, yellow alarm light, medium priority alarm tone
Violated invasive blood pressure systolic value	P1 (and P2)	The P1 (or P2) invasive blood pressure systolic measurement has violated an alarm limit setting.	Flashing yellow systolic numeric in the P1 VS box, yellow alarm light, medium priority alarm tone, where **OVR** displayed if the value is greater than the highest specified or **UND** if the value is less than the lowest specified
Violated invasive blood pressure mean value	P1 (and P2)	The P1 (or P2) invasive blood pressure mean measurement has violated an alarm limit setting.	Flashing yellow mean numeric in the P1 VS box, yellow alarm light, medium priority alarm tone, where **OVR** displayed if the value is greater than the highest specified or **UND** if the value is less than the lowest specified
Violated invasive blood pressure diastolic value	P1 (and P2)	The P1 (or P2) invasive blood pressure diastolic measurement has violated an alarm limit setting.	Flashing yellow diastolic numeric in the P1 VS box, yellow alarm light, medium priority alarm tone, where **OVR** displayed if the value is greater than the highest specified or **UND** if the value is less than the lowest specified
Missing invasive blood pressure data	P1 (and P2)	The P1 (or P2) invasive blood pressure data, once present, can no longer be produced.	Flashing yellow dashes (- - -) in the systolic, diastolic and mean numerics in the P1 VS box, yellow alarm light, medium priority alarm tone
Violated primary agent Et value	AGENT	The end-tidal measurement for the primary agent gas has violated an alarm limit setting.	Flashing yellow primary agent Et numeric in the AGENT VS box, yellow alarm light, medium priority alarm tone, where **OVR** displayed if the value is greater than the highest specified
Violated primary agent Fi value	AGENT	The fractional inspired measurement for the primary agent gas has violated an alarm limit setting.	Flashing yellow primary agent Fi numeric in the AGENT VS box, yellow alarm light, medium priority alarm tone, where **OVR** displayed if the value is greater than the highest specified

Patient Alarm	From	Condition	Indication
Violated secondary agent Et value	AGENT	The end-tidal measurement for the secondary agent gas has violated an alarm limit setting.	Flashing yellow secondary agent Et numeric in the AGENT VS box, yellow alarm light, medium priority alarm tone, where **OVR** displayed if the value is greater than the highest specified
Violated secondary agent Fi value	AGENT	The fractional inspired measurement for the secondary agent gas has violated an alarm limit setting.	Flashing yellow secondary agent Fi numeric in the AGENT VS box, yellow alarm light, medium priority alarm tone, where **OVR** displayed if the value is greater than the highest specified
Missing primary and secondary agent data	AGENT	The primary and secondary agent data, once present, can no longer be produced.	Flashing yellow dashes (- - -) in the primary and secondary numerics in the AGENT VS box, yellow alarm light, medium priority alarm tone
Violated N2O value	AGENT	The N2O measurement has violated an alarm limit setting.	Flashing yellow N2O numeric in the GAS VS box, yellow alarm light, medium priority alarm tone
Missing N2O data	AGENT	The N2O data, once present, can no longer be produced.	Flashing yellow dashes (- - -) in the N2O numeric in the GAS VS box, yellow alarm light, medium priority alarm tone
Violated O2 value	AGENT	The O2 measurement has violated an alarm limit setting.	Flashing yellow O2 numeric in the GAS VS box, yellow alarm light, medium priority alarm tone
Violated O2 value	AGENT	The O2 measurement is less than 18 percent.	Flashing red O2 numeric in the GAS VS box, red alarm light, high priority alarm tone
Missing O2 data	AGENT	The O2 data, once present, can no longer be produced.	Flashing yellow dashes (- - -) in the O2 numeric in the GAS VS box, yellow alarm light, medium priority alarm tone
Missing bellows respiration rate data	RESP	The bellows respiration data, once present, can no longer be produced.	Flashing yellow dashes (- - -) in the respiration rate numeric in the RESP VS box, yellow alarm light, medium priority alarm tone
Violated temperature value	TEMP	The temperature measurement has violated an alarm limit setting.	Flashing yellow temperature numeric in the TEMP VS box, yellow alarm light, medium priority alarm tone, where **OVR** displayed if the value is greater than the highest specified or **UND** if the value is less than the lowest specified
Missing temperature data	TEMP	The temperature data, once present, can no longer be produced.	Flashing yellow dashes (- - -) in the temperature numeric in the TEMP VS box, yellow alarm light, medium priority alarm tone, where **OVR** displayed if the value is greater than the highest specified or **UND** if the value is less than the lowest specified
Violated non-invasive blood pressure systolic value	NIBP	The non-invasive blood pressure systolic measurement has violated an alarm limit setting.	Flashing yellow systolic numeric in the NIBP VS box, yellow alarm light, medium priority alarm tone, where **OVR** displayed if the value is greater than the highest specified or **UND** if the value is less than the lowest specified

Patient Alarm	From	Condition	Indication
Violated non-invasive blood pressure mean value	NIBP	The non-invasive blood pressure mean measurement has violated an alarm limit setting.	Flashing yellow mean numeric in the NIBP VS box, yellow alarm light, medium priority alarm tone, where **OVR** displayed if the value is greater than the highest specified or **UND** if the value is less than the lowest specified
Violated non-invasive blood pressure diastolic value	NIBP	The non-invasive blood pressure diastolic measurement has violated an alarm limit setting.	Flashing yellow diastolic numeric in the NIBP VS box, yellow alarm light, medium priority alarm tone, where **OVR** displayed if the value is greater than the highest specified or **UND** if the value is less than the lowest specified
Missing non-invasive blood pressure data	NIBP	The non-invasive blood pressure data, once present, can no longer be produced.	Flashing yellow dashes (- - -) in the systolic, diastolic and mean numerics in the NIBP VS box, yellow alarm light, medium priority alarm tone

Technical (INOP) Alarms and Other Status Flags

The following table contains a listing of the INOP and other status alarm flag messages, locations, tone indications, and where applicable possible solutions.

ECG

Message, Location, Indication	What to Do
Lead Fail ECG alarm flag area, blue alarm light, INOP alarm tone	An ECG lead (or electrode) required to measure the lead view is faulty or disconnected: • Ensure that the ECG lead cable is connected to the wECG module, and that the wECG module has sufficient battery power. • Ensure that each ECG lead cable clip is connected to the Quadtrode electrode contact. (Examine the ECG VS box for indications of a contact problem, where LL = left leg, LA = left arm, and RA = right arm, and LL, LA, RA, = RL [right leg] or all leads.) • Replace the ECG lead cable. • Replace the Quadtrode electrode. ***Notes*** • *The error message can be displayed for trace A and/or for trace B.* • *May also be displayed when high DC offsets are present on an input lead.*

Message, Location, Indication	What to Do
Lead Saturation ECG alarm flag area, blue alarm light, INOP alarm tone	Baseline offset of the ECG input signal is too large for process and display of the waveform. Replace the Quadtrode electrode. ***Note*** *The error message can be displayed for trace A and/or for trace B.*

SPO2

Message, Location, Indication	What to Do
Bad Probe SPO2 alarm flag area, blue alarm light, INOP alarm tone	The SpO2 probe is defective. Replace the SpO2 probe.
Erratic SPO2 alarm flag area, blue alarm light, INOP alarm tone	The SpO2 attachment may be improperly applied or positioned on the patient; or, the probe is faulty. • Check the alignment of the clip (or grip) on the patient. • Replace the SpO2 probe. If the message persists, contact technical support or authorized service personnel.
HW Fail SPO2 alarm flag area, blue alarm light, INOP alarm tone	A hardware or other failure has occurred in the wSpO2 module. Replace the wSpO2 module. If the failure persists, immediately remove the MR400 and the wSpO2 module from service then contact technical support or authorized service personnel, as the system must not be used on any patient requiring SpO2 measurement.
Intrfernce SPO2 alarm flag area, blue alarm light, INOP alarm tone	Interference due to attachment misalignment or incorrect attachment positioning: • Check the alignment of the clip (or grip) on the patient site. • Try a different limb or site. • Ensure that the module is placed outside of the MR bore. • Reposition the wSpO2 module (see page 6-6. • Replace the clip (or grip).
Low Perf SPO2 alarm flag area, blue alarm light, INOP alarm tone	Accuracy may be compromised due to low perfusion. The tissue at the SpO2 attachment site may be too opaque, thick or cold. • If the clip (or grip) is positioned on a finger, check for long, artificial or polished nails. Remove any nail polish or relocate the attachment if needed. • Try another attachment site, like a toe. • Try rubbing or warming the limb to stimulate circulation.
No Probe SPO2 alarm flag area, blue alarm light, INOP alarm tone	The SpO2 probe is not attached or is improperly attached to the wSpO2 module. Check the connection of the probe to the module. Reconnect the probe or, if the connection was good, replace the probe.

Message, Location, Indication	What to Do
Noise SPO2 alarm flag area, blue alarm light, INOP alarm tone	Excessive patient motion, the MRI scan sequence or electrical interference is causing noise in the SpO2 system: • Stop any 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 in a way that does not expose it to bright ambient light.
Non-Pulsat SPO2 alarm flag area, blue alarm light, INOP alarm tone	The detected pulse is too weak for reliable reporting of SpO2 measurements: • 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.
Probe Off SPO2 alarm flag area, blue alarm light, INOP alarm tone	The SpO2 attachment is not properly applied to the patient. Reposition the clip (or grip) on the patient.
Pulse? SPO2 alarm flag area, blue alarm light, INOP alarm tone	Pulse reading is questionable. The SpO2 attachment may not be applied optimally or the tissue at the application site may be too opaque: • Check the alignment of the clip (or grip) on the patient. • Try a different limb or site.
Searching SPO2 alarm flag area, blue alarm light, INOP alarm tone	The SpO2 attachment was just applied or it has shifted position on the patient: • If the clip (or grip) 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 probe. If the message persists, contact technical support or authorized service personnel.
Wrong Prb SPO2 alarm flag area, blue alarm light, INOP alarm tone	The probe attached to the wSpO2 module is not the correct type. Attach the correct probe to the module.

CO2 / CO (RESP) / AGENT

Message, Location, Indication	What to Do
Check CO2 Sampling Line CO2 alarm flag area, blue alarm light, INOP alarm tone	Reduced flow has been detected by the CO2 system. Check the sampling line for pinches or obstructions then clear any pinch or replace if necessary.
CO2 Cal Fail CO2 alarm flag area, blue alarm light, INOP alarm tone	CO2 failed to calibrate. Retry calibration. If the message persists, contact technical support or authorized service personnel.

Message, Location, Indication	What to Do
CO2 Low Flow CO2 alarm flag area, blue alarm light, INOP alarm tone	Message may appear when the sampling line is initially connected; allow the a few seconds for the flow to be established. Otherwise, the detected flow rate is 10 percent less than nominal; in this case, check the sampling line for pinches or obstructions then clear any pinch or replace if necessary. If the message persists, contact technical support or authorized service personnel.
Check for CO2 Occlusion CO2 alarm flag area, blue alarm light, INOP alarm tone	Detected flow through the sampling line is less than 40 ml/min or the water trap may be full of fluid: • Check the sampling line for obstructions and replace it if necessary. • Check the fluid level in the water trap and replace it if necessary. If the message persists, contact technical support or authorized service personnel.
CO2 Out Of Range CO2 alarm flag area, blue alarm light, INOP alarm tone	The calculation value is greater than the upper CO2 limit. Perform readings to confirm patient's physiological condition. If the message persists, contact technical support or authorized service personnel.
CO2 Sensor Faulty CO2 alarm flag area, blue alarm light, INOP alarm tone	CO2 bench detected a hardware or sensor error. Cycle AC mains power. If the message persists, contact technical support or authorized service personnel.
CO2 Sensor Over Temp CO2 alarm flag area, blue alarm light, INOP alarm tone	The CO2 sensor is above the specified operating temperature. Confirm that the MR400 is operating within the required environmental conditions (see Appendix A); if outside the specified range, move the MR400 to an area that is within limits. If the problem persists, stop all monitoring activities and contact technical support or authorized service personnel.
CO2 Warming Up CO2 alarm flag area, blue alarm light, INOP alarm tone	CO2 is warming to operating temperature. Allow the process to complete, about 2 minutes.
CO2 Zero Required CO2 alarm flag area, blue alarm light, INOP alarm tone	Zero calibration of the CO2 module is needed; see page 7-15 for details.
Magnetic Field Too High CO2 alarm flag area, blue alarm light, INOP alarm tone	The gauss limit has been exceeded, and the AGENT option can no longer function. Position the MR400 per the product labeling; see page 3-2.
HW Fail CO2 alarm flag area, blue alarm light, INOP alarm tone	CO2 module was not found during initialization. Cycle AC mains power. If the message persists, contact technical support or authorized service personnel.
Low O2 AGENT alarm flag area, blue alarm light, INOP alarm tone	The inspired O2 value has dropped below 18.0
Motor Speed Error CO2 alarm flag area, blue alarm light, INOP alarm tone	The MR400 is too close to the MR magnet. Ensure that the MR400 has been positioned correctly; see page 3-2. If the message persists, contact technical support or authorized service personnel.

Message, Location, Indication	What to Do
Multiple Agents AGENT alarm flag area, blue alarm light, INOP alarm tone	More than one anesthetic agent gas was detected in a given breath phase, with a total MAC of the detected mix is less than 3 MAC. ***Note*** *If multiple agents have been detected with a total MAC of the detected mix greater than 3 MAC then this message will be accompanied by a yellow alarm light and medium priority alarm tone.*
O2 Sensor Not Present AGENT alarm flag area, blue alarm light, INOP alarm tone	Possible hardware failure associated with the O2 sensor. Ensure that the O2 sensor is secure in the receptacle; see page 14-13. If the message persists, contact technical support or authorized service personnel.
Occlusion CO2 alarm flag area, blue alarm light, INOP alarm tone	Occluded sample line detected at start up: • Check the sampling line for obstructions and replace it if necessary. • Check the fluid level in the water trap and replace it if necessary. If the message persists, contact technical support or authorized service personnel.
O2 Sensor Fail CO2 alarm flag area, blue alarm light, INOP alarm tone	O2 sensor has failed or expired. Replace the O2 sensor; see page 14-13. If the message persists, contact technical support or authorized service personnel.
Occlusion at Start CO2 alarm flag area, blue alarm light, INOP alarm tone	Occluded sample line detected at start up: • Check the sampling line for obstructions and replace it if necessary. • Check the fluid level in the water trap and replace it if necessary. If the message persists, contact technical support or authorized service personnel.
Performing CO2 Zero CO2 alarm flag area, blue alarm light, INOP alarm tone	Displayed while zeroing CO2. Allow the process to complete.
Persistent CO2 Occlusion CO2 alarm flag area, blue alarm light, INOP alarm tone	Reduced CO2 flow has been detected for over 2 minutes. Check for pinches or obstructions in the sampling line. Clear any pinch, or replace the accessory if necessary. If the message persists, contact technical support or authorized service personnel.

P1 (or P2)

Message, Location, Indication	What to Do
Catheter Disconnected P1 (or P2) alarm flag area, yellow alarm light, medium priority alarm tone	The catheter cannot be detected. Check all catheter connections to and from the transducer.
Hardware Error P1 (or P2) alarm flag area, blue alarm light, INOP alarm tone	A hardware error has been detected in the IBP system. Contact technical support or authorized service personnel.

Message, Location, Indication	What to Do
Transducer Faulty P1 (or P2) alarm flag area, yellow alarm light, medium priority alarm tone	A electrical transducer malfunction has been detected. • Check the transducer cable connection. • Replace the transducer. • Contact technical support or authorized service personnel if the message persists.
Transducer Not Present P1 (or P2) alarm flag area, yellow alarm light, medium priority alarm tone	An IBP transducer was not found. Ensure that the transducer cables are connected to the transducer and MR400. If the message persists, contact technical support or authorized service personnel.

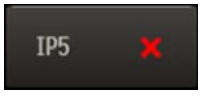
TEMP

Message, Location, Indication	What to Do
Cal Error TEMP alarm flag area, blue alarm light, INOP alarm tone	Calibration error. Reconnect the sensor and then retry. Contact technical support or authorized service personnel if the message persists.
Chk Probe TEMP alarm flag area, blue alarm light, INOP alarm tone	The temperature sensor connection is bad, has a sharp bend, or is damaged: • Ensure that the sensor is inserted completely in the temperature port on the patient connection panel. • Remove any sharp bends in the temperature sensor. • If the message persists after performing the above actions, then the temperature sensor most likely is damaged and readings cannot be provided. Try a new sensor.
Exp Probe TEMP alarm flag area, blue alarm light, INOP alarm tone	The temperature probe connected to the MR400 is not the proper type. Insert the correct type of temperature probe into the temperature port.
HW Fail TEMP alarm flag area, blue alarm light, INOP alarm tone	Temperature hardware failure detected. Contact technical support or authorized service personnel.
No Probe TEMP alarm flag area, blue alarm light, INOP alarm tone	The temperature probe is not properly connected to the MR400. Insert a temperature probe into the temperature port on the patient connection panel.
Wrong Prb TEMP alarm flag area, blue alarm light, INOP alarm tone	The temperature probe connected to the MR400 is not the proper type. Insert the correct type of temperature probe into the temperature port.

NIBP

Message, Location, Indication	What to Do
Communication Error NIBP alarm flag area, blue alarm light, INOP alarm tone	An internal NIBP error has occurred. Discontinue use of NIBP and contact technical support or authorized service personnel.
Deflation Timeout NIBP alarm flag area, red alarm light, high priority alarm tone	Cuff deflation has timed out; displayed if the NIBP cuff deflation period is greater than 80 seconds (neonatal patient type) or is greater than 150 seconds (adult and pediatric patient types): • Check the patient. • Check for proper cuff size and placement. • Check the cuff and hoses for pinching. If the message persists, contact technical support or authorized service personnel.
Hardware Error NIBP alarm flag area, blue alarm light, INOP alarm tone	NIBP hardware failure detected. Discontinue use of NIBP and contact technical support or authorized service personnel.
Inflation Timeout NIBP alarm flag area, blue alarm light, INOP alarm tone	Cuff inflation has timed out: • Check the patient. • Check the cuff and hoses for pinching or leaks. If the message persists, contact technical support or authorized service personnel.
Measurement Failed NIBP alarm flag area, blue alarm light, INOP alarm tone	The NIBP measurement has failed: • 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 or authorized service personnel.
Measurement Timeout NIBP alarm flag area, blue alarm light, INOP alarm tone	The NIBP measurement has timed out: • Check the patient. • Check for proper cuff size and placement. • Check the cuff and hoses for pinching or leaks. Check the cuff condition and placement on the patient.
Module Not Calibrated NIBP alarm flag area, blue alarm light, INOP alarm tone	NIBP is not calibrated. Contact technical support or authorized service personnel.
Over Pressure NIBP alarm flag area, blue alarm light, INOP alarm tone	The allowed pressure for the type of patient has been exceeded: • 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 or authorized service personnel.
Pressure Correction NIBP alarm flag area, blue alarm light, INOP alarm tone	A pressure correction error has been detected: • Ensure that the patient is immobilized and not applying pressure to the cuff. • Check the cuff condition and placement on the patient.
Residual Pressure NIBP alarm flag area, blue alarm light, INOP alarm tone	Residual pressure remains in the NIBP system. Disconnect the NIBP hose from the patient connection panel and then restart the procedure.

Other Status Indications

Message, Location, Indication	Condition
All Alarms Are Off System message area, no alarm light, no alarm tone	All alarm limits have been turned off.
Audio Off System message area, no alarm light, no alarm tone	Alarm sound is silenced.
Audio Paused System message area, no alarm light, no alarm tone	Alarm sound is paused.
Change NIBP Cuff System message area, no alarm light, no alarm tone	The **Patient Type** was changed so the NIBP cuff should be changed.
Check Alarm Vol System message area, no alarm light, no alarm tone	Power was just turned on, settings were recalled.
 status information pane, blue alarm light, INOP alarm tone	The charge level is low for the wECG module battery (or batteries). Install at least one charged battery into the wECG module. **WARNING** **A red battery symbol indicates that the module batteries have fallen below the required operational output and module shutdown with loss of monitoring will occur. Immediately replace the module batteries to avoid a loss in monitoring.**
 Status information pane, no alarm light, no alarm tone	No communication between the MR400 and wECG module. Ensure that the wECG module is set to the same network channel as the MR400 cart. If both are the same, use an alternate setting. If the indication persists, contact technical support or authorized service personnel.
ECG Test Signal System message area, no alarm light, no alarm tone	The ECG Test Signal is on.
 Status information pane, no alarm light, no alarm tone	No communication between the MR400 and IP5. Ensure that the IP5 is set to the same network channel as the MR400 cart. If both are the same, use an alternate setting. If the indication persists, contact technical support or authorized service personnel.

Message, Location, Indication	Condition
 Status information pane, blue alarm light, INOP alarm tone	Charge level of the cart batteries is low. Connect the MR400 cart to external power and allow the batteries to charge. **WARNING** **A red battery symbol indicates that the main batteries in the MR400 have fallen below the required operational output and system shutdown with loss of monitoring will occur. Immediately locate an AC outlet and connect the MR400 to avoid a loss in monitoring.**
Overscale ECG alarm flag area, no alarm light, no alarm tone	The size of the ECG waveform is too large and the tops of the ECG waveforms are clipped (that is, cut off). Reduce the size using the **Scale** setting; see page 5-28.
Real Tones Disabled System message area, no alarm light, no alarm tone	Normal audio sounds are suspended as a volume adjustment is in progress.
Simulation System message area, no alarm light, no alarm tone	The system is in simulation mode. Turn off power to exit this mode.
 Status information pane, blue alarm light, INOP alarm tone	Charge level of the wSpO2 module battery is low. Install a charged battery into the wSpO2 module. **WARNING** **A red battery symbol indicates that the module batteries have fallen below the required operational output and module shutdown with loss of monitoring will occur. Immediately replace the module batteries to avoid a loss in monitoring.**
 Status information pane, no alarm light, no alarm tone	No communication between the MR400 and wSpO2 module. Ensure that the wSpO2 module is set to the same network channel as the MR400 cart. If both are the same, use an alternate setting. If the indication persists, contact technical support or authorized service personnel.

CHAPTER 5

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 MR400 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 MR400 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.

ECG Monitoring Considerations for the MR Environment

Monitoring ECG in the MR environment is particularly challenging because of the inherent distortion of the ECG waveform caused by the combined electromagnetic fields generated by the MRI scanner. In particular, certain ECG interference appears when the patient is placed inside the bore before scanning begins. 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 may prohibit effective ECG monitoring in the MRI. For this reason, a baseline recording of the ECG prior to sliding the patient inside the bore or outside 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 ECG lead cable length, this blood flow induced distortion can be kept to a minimum, as discussed in this section. 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 using a different ECG lead view (I, II, III, AVL, AVR, AVF) will minimize some of these artifacts.

wECG Module and ECG 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 28 cm (11 inches) of the MRI field of view (FOV). For wECG module details, see page 2-9. The components of the ECG lead cable are detailed below.

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1 Connector

2 ECG lead cable label identifier

3 Velcro storage strap

4 Cable trunk with foam insulator

5 Lead wires

6 Lead cable clips

CAUTIONS

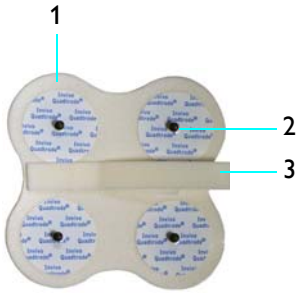
- If dropped, the wECG module must be verified for correct operation before use; see page 14-12.
- Guard against the accidental ingress of liquid into the module, as measurements made by the device can be adversely affected.

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.

Quadtrode Electrodes

The Quadtrode electrodes serve as patient connection points for the ECG lead cable clips. Different Quadtrode electrodes are available to meet each monitoring requirement. The components of a Quadtrode electrode are detailed below.



1 Foam insulator

2 Electrode contact (four contacts are provided on the standard and neonatal types, and one contact on the CV type

3 Lead retainer (not present on CV and neonatal types)

Work Flow for ECG Monitoring

When monitoring ECG, many factors will impact the performance and operation of the parameter, including:

- The site selected on the patient,
- The ECG lead cable and Quadtrode electrode pairing,
- The selected filter and lead view setting for the monitor,
- Module placement and ECG lead cable routing; and,
- Scan sequence selection and scan sequence parameters on the MRI console.

To prepare a patient for ECG monitoring

Step	Action
1	Select the **Patient Type**. See *Selecting the Patient Type* on page 3-11.
2	According to the patient type, their body mass, and the study to be performed, choose a recommended ECG lead cable and Quadtrode electrode pair. See *Selecting the ECG Lead Cable and Quadtrode Electrode Type* on page 5-5.
3	Decide where to apply the Quadtrode electrode to the patient. See *Identifying the Placement Site for the Quadtrode Electrode* on page 5-7.

Step	Action
4	Prep the placement site(s) on the patient and then apply the Quadtrode electrode to the patient. See *Preparing the Quadtrode Electrode Site* on page 5-11.
5	Attach the lead cable clips to the contacts on the Quadtrode electrode. See *Attaching the ECG Lead Cable* on page 5-12.
6	Evaluate the ECG signal strength and make adjustments as needed before the patient enters the scanner. See *Checking the ECG Signal Strength* on page 5-16.
7	Position the patient, the lead cable and the wECG module for scanning. See *Positioning the ECG Lead Cable and wECG Module for Scanning* on page 5-19.
8	Select the lead view and **Filter Mode** for the study. See *Changing the Lead View* on page 5-17 and *Filter Mode* on page 5-31.
9	Before sliding patient inside the bore, or outside the MR magnet room, establish a baseline recording of the patient's ECG signal.
10	Slide the patient into the bore, but do not start scanning. Then, recheck the ECG waveform for usability by evaluating it for distortion. If ECG waveform has become excessively distorted and the heart rate numeric is not functioning properly in the bore, then the ECG lead cable may require rerouting and / or a new electrode placement site must be selected before starting the scan sequence. (Also see *Minimizing ECG Waveform Noise* on page 5-18.)

Step	Action
11	Begin scan sequence and observe the ECG waveform. If the ECG waveform becomes compromised during scanning, then change the lead view and/or the **Filter Mode** on the MR400. ***Note*** *ECG performance during MRI scanning can be further improved by modifying scan sequence parameters at the MRI console. Changing any of these parameters directly alters image quality so precaution must be taken to not overwhelmingly affect the desired image characteristics:* • *Increase TE (Echo Time)* • *Increase TR (Repetition Time)* • *Increase TI (Inversion Time)* • *Increase / change the imaging plane (for example, sagittal to axial)* • *Turn off fat suppression* • *Decrease the PNS level* • *Decrease the gradient strength*
12	After scanning, disconnect the wECG module from the patient. Then store the wECG module in the module holder. Loop the cable trunk with foam insulator then secure it using the Velcro storage strap to keep the excess cable length from touching the floor; see page 2-12.

Selecting the ECG Lead Cable and Quadtrode Electrode Type

ECG lead cables and Quadtrode electrodes are proton emissions compliant, will not distort the MR image, and are designed to provide the maximum patient safety and MRI performance:

- Only use the specified ECG lead cables with the MR400, as these are specially constructed to avoid patient heating by reducing the amount of radio frequency (RF) energy that can flow through the wires and with a shorter length to reduce the potential for cable looping. The type of lead cable needed will depend upon the type of Quadtrode electrode being used.
- Only use the specified Quadtrode electrode with the MR400, as this will minimize the possible risk of electrode heating during MRI procedures and reduce the amount of MRI-generated artifacts on the ECG waveform. The type of Quadtrode electrode needed will depend generally upon the patient type, gender and weight. (Regardless of the type, the Quadtrode electrode will be considered a single item when discussed in this text.)

The table below highlights the recommended uses of ECG lead cables and Quadtrode electrodes.

<table>
<tr><th colspan="2">ECG Lead Cables and Quadtrode Electrodes - Recommended Pairings</th></tr>
<tr><td>CV ECG lead cable
 
Purpose:
• For patients weighing more than 10 kg (22 pounds)
• Best for female and overweight patients (that is, in situations where placement would be difficult using the standard Quadtrode electrode)
Version and Part Number:
AAMI: REF 989803193721
IEC: REF 989803193751</td><td>CV Quadtrode Electrode
 
Part Number:
REF 989803179041</td></tr>
<tr><td>Standard ECG lead cable
 
Purpose:
• For patients weighing more than 10 kg (22 pounds)
• Quick application
Version and Part Number:
AAMI: REF 989803193731
IEC: REF 989803193761</td><td>Quadtrode Electrode (standard)
 
Part Number:
REF 989803179031</td></tr>
<tr><td>Neonatal ECG lead cable
 
Purpose:
• For infants weighing less than 10 kg (22 pounds)
• Quick application
Version and Part Number:
AAMI: REF 989803193741
IEC: REF 989803193771</td><td>Neonatal (Neo) Quadtrode Electrode
 
Part Number:
REF 989803179051</td></tr>
</table>

Identifying the Placement Site for the Quadtrode Electrode

WARNING

Ensure that the location of the electrodes is compliant to the requirements of your electrosurgical equipment to reduce the possibility of burns; however, note that monitoring in the MR environment requires specific electrode placement. (See page 5-3 to ensure the highest quality ECG signal. For questions and guidance regarding placement, contact technical support; see page 14-16 for contact information.)

According to the patient type or weight, placement of the Quadtrode electrode over the heart is important for optimal ECG performance.

Note

For placement purposes, we define to the breast line as an imaginary horizontal line that extends across the nipple areas of a patient of normal weight.

Adult and pediatric patients:

- If using a standard Quadtrode electrode, place it slightly to the left of the patient's sternum, with the top two electrodes on the breast line and the bottom two electrodes below the breast line.
- If using a CV Quadtrode electrode, attempt to keep a small separation between individual electrodes—a distance that is wide enough to properly capture the ECG vector, but not so wide as to cause excessive noise pickup. (Increasing the loop area between electrodes has a negative effect on ECG quality unique to the MRI environment that causes more noise to be picked up by the ECG leads).

Neonatal and infant patients:

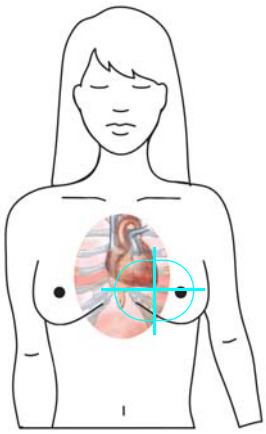
- Depending on the patient's weight, center a standard Quadtrode electrode or a neonate Quadtrode electrode over the sternum and the breast line.

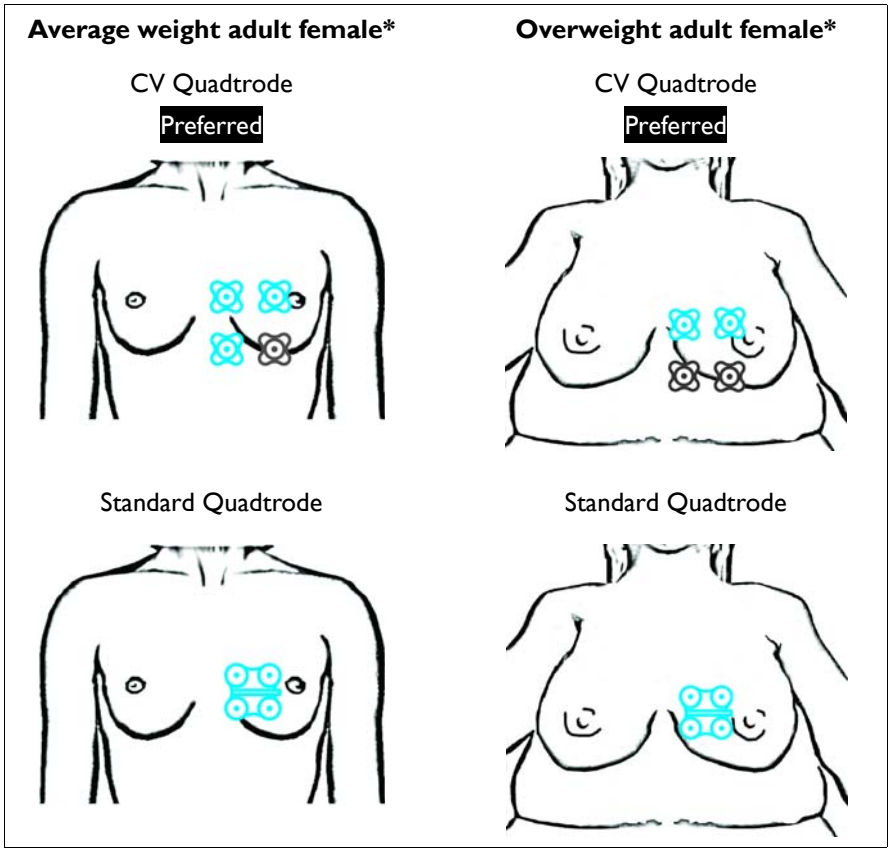
Deviations from the guidelines for Quadtrode electrode placement can affect the produced ECG signal as follows:

- **Placements offset above the breast line:** Increases the T-wave amplitude and the susceptibility to static field (B0) effects.
- **Placements offset below the breast line:** Decreases the T-wave amplitude, increase the distance from the aortic valve, the susceptibility to static field (B0) effects and the ECG wave amplitude.
- **Placements closer to the sternum:** Increases the ECG wave amplitude and also any respiration-induced noise.
- **Placements farther from the sternum:** Decreases the ECG wave amplitude and any respiration-induced noise.

The diagrams below illustrate Quadtrode electrode placement site(s) according to patient type, including the preferred Quadtrode electrode type and location for different patient body sizes.

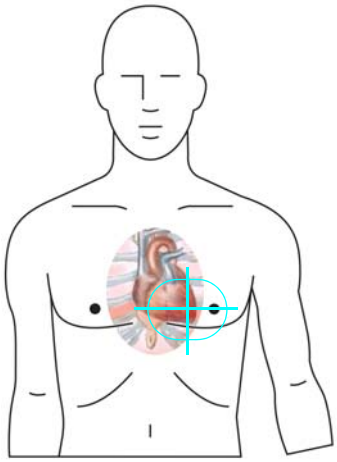
Selecting sites on adult female patients

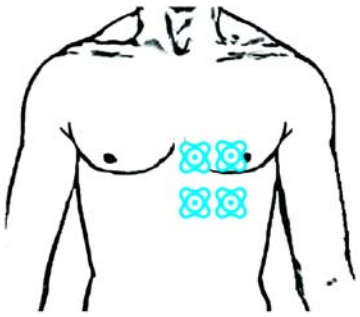
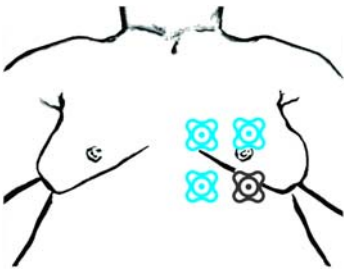
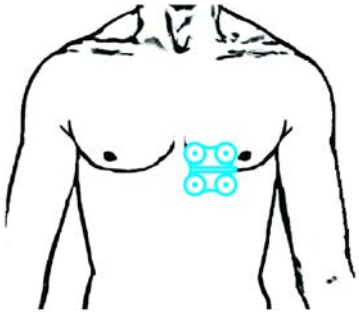
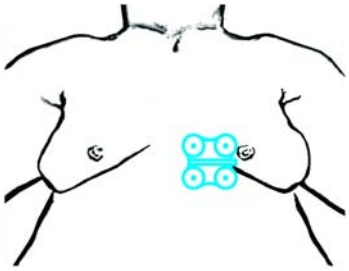




**Where grayed images indicate placement sites against the ribcage under the breast.*

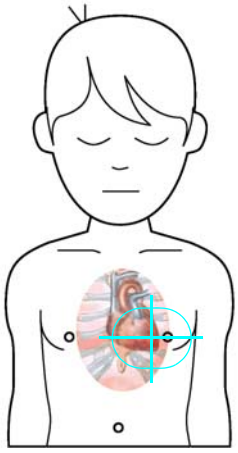
Selecting sites on adult male patients

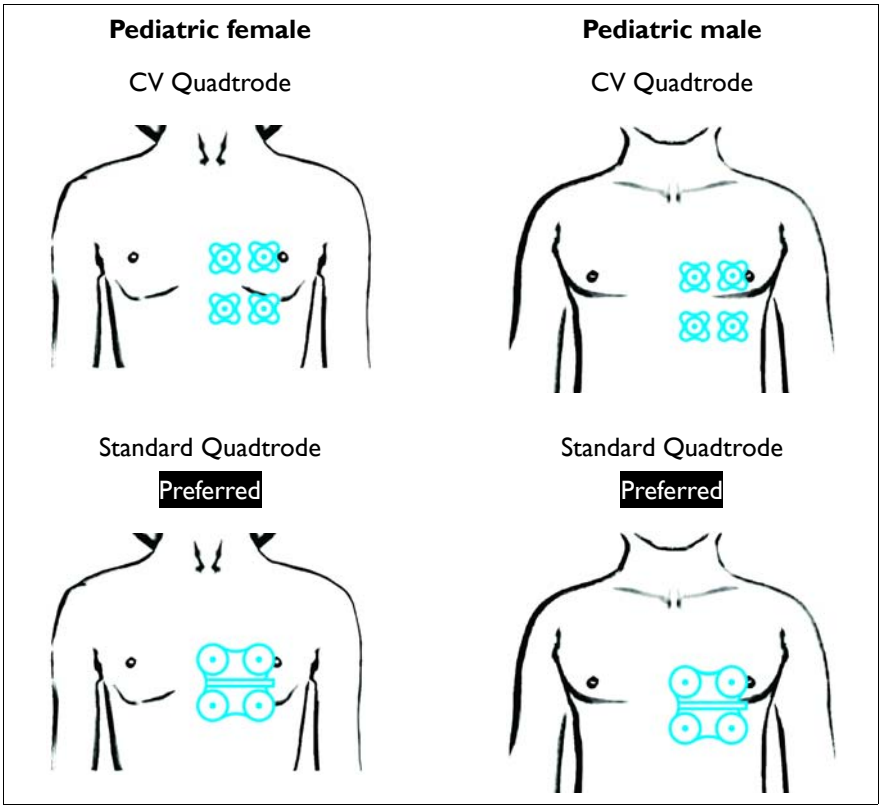


Average weight adult male	Overweight adult male*
CV Quadtrode	CV Quadtrode Preferred
	
Standard Quadtrode Preferred	Standard Quadtrode
	

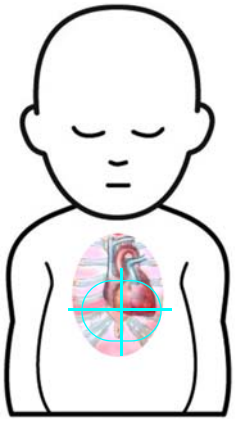
**Where the grayed image indicates a placement site against the ribcage under the breast.*

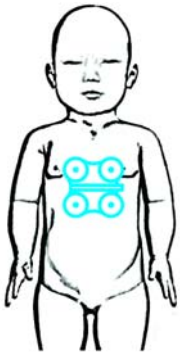
Selecting sites on pediatric patients





Selecting sites on infants and neonatal patients



Infants and Neonates	
Standard Quadtrode	Neonatal Quadtrode
	

Preparing the Quadtrode Electrode Site

Proper preparation for the application of the Quadtrode electrode is critical to ECG performance. The result of poor application preparation will be poor ECG monitoring performance. If electrode contact with the skin is poor, then remove and discard the Quadtrode electrode, and repeat the site preparation process again according to the instructions below. Never reuse a Quadtrode electrode because it will not securely adhere to the skin.

To prepare a Quadtrode electrode site on a patient

Step	Action
1	Check the expiration date of the Quadtrode electrode package.
2	Select the application area(s), avoiding the areola and nipple when possible, for the Quadtrode electrode site(s) as provided on page 5-7.

Step	Action
3	If necessary, shave the application area to remove hair from the selected Quadtrode electrode site(s).
4	Apply ECG Skin Prep Gel (REF 989803152291) to a gauze pad.
5	Briskly rub the selected site(s) with the gauze pad (the skin may turn pink).
6	Remove any excess gel with a clean gauze pad.
7	Place the Quadtrode electrode at the prepared site(s) on the patient.

Notes

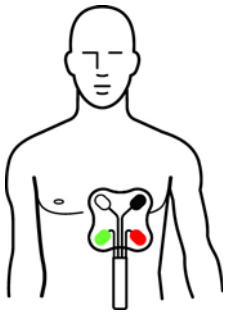
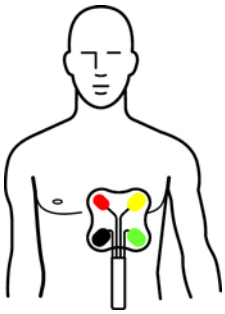
- *The ECG Skin Prep gel contains light abrasive pumice and saline that clean and enhance the conductive properties of the skin, thus enhancing ECG performance. This practice also helps remove ambient artifacts.*
- *Isopropyl/rubbing alcohol must not be used to prep the site as it breaks down the conductive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

Attaching the ECG Lead Cable

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.**
- **An ECG lead cable that becomes 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 E to prevent excessive heating associated with MRI procedures. Follow steps to minimize the risks of MRI-related heating on page 5-20.**

Given in relation to the patient's limbs, designators and colors of the ECG lead cable clips reference connection locations on the Quadtrode electrode. Also, note that depending upon the lead cable version, AAMI (Association for the Advancement of Medical Instrumentation) or IEC (International Electrotechnical Commission), different designators and colors are used for these references. The diagrams below illustrate the lead cable attachment locations to the Quadtrode, according to the ECG lead cable version and limb.

AAMI ECG Lead Cable Connections	IEC ECG Lead Cable Connections
	

AAMI ECG Lead Cable Clip Designator / Color	IEC ECG Lead Cable Clip Designator and Color	Associated Limb
RA / White	R / Red	Right arm
RL / Green	N / Black	Right leg
LA / Black	L / Yellow	Left arm
LL / Red	F / Green	Left leg

CAUTION

ECG lead cable clips should not be placed on the patient's extremities.

To attach the ECG lead cable to the wECG module and then to the Quadtrode electrode contacts

Step	Action
1	Insert the connector of the ECG lead cable into the cable port on the wECG module. **CAUTION** When inserting or removing the lead cable, only use the connector as a finger-hold; never pull or apply excessive force to the wires. 

Step	Action
2	Depending upon the ECG lead cable type, attach the clips to the Quatrode electrode contacts, as shown in the appropriate connection diagram on page 5-12. Squeeze each clip open then place the clip onto the electrode contact and release. **CAUTION** When inserting or removing the clip leads, use the clip as the finger-hold; never pull or apply excessive force to the wires.
3	If using a standard Quadtrode electrode, secure the lead cable wires using the lead retainer. See page 5-3 for the location.
4	Check the battery indicators on the wECG module to ensure that enough charge exists in at least one of the installed batteries: • Green battery indicator = Charge sufficient; proceed to step 6. • Red battery indicator = Charge low; proceed to step 5. See page 2-9 for details. (Also, you can reference the status information pane; see page 2-16.)
5	According to the red battery indicator(s) present on the wECG module, insert a charged module battery into the corresponding battery bay(s) and then recheck the battery indicator(s) to ensure a sufficient charge before proceeding; see page 1-24.
6	Check the network channel indicator on the wECG module to ensure communication is established with the MR400: • Steady = Good communication; proceed to step 8. • Flashing = No communication; proceed to step 7. See page 2-10 for details. (Also, you can reference the status information pane; see page 2-16.) An inoperative ECG parameter or wECG module is indicated by absence of an ECG waveform and a simultaneous Lead Fail alarm.
7	Ensure that the wECG module is within 9.1 m (30 feet) of the MR400, in the same MRI room or in the same shielded room, and is set to the same wireless network channel used by the MR400; see page 1-29.

Step	Action
8	Ensure that the ECG signal has the necessary amplitude by checking the displayed waveform; see *Checking the ECG Signal Strength* on page 5-16. If **Lead Fail** is displayed, see page 5-15 for troubleshooting details; or, if **Lead Saturation** is displayed, replace the Quadtrode electrode, see page 5-11. ***Note*** *During a Lead Fail condition, if the **HR Source** is set to ECG, then no HR measurement numeric will be displayed in the ECG and SPO2 VS boxes; see page 5-15 for an example.*
9	Keep the module outside the MR system bore by placing it in one of the two locations shown in *Positioning the ECG Lead Cable and wECG Module for Scanning* on page 5-20.

Lead Fail Indication

Lead Fail (illustrated below) is an INOP alarm that will be displayed when the ECG trace can no longer be produced because one of the electrodes required for measurement is disconnected—either an electrode came off of the patient, an ECG lead cable clip came off of the electrode, or a wire in the ECG lead cable has failed. Depending upon the **Trace A Lead** (or **Trace B Lead**) setting (see page 5-27), the electrode fault indicator(s), LL, LA, or RA, may be displayed in the ECG VS box (see the example below); see page 4-31 for more information.

WARNING

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

1 **Lead Fail** message indication

2 Electrode fault indication, example

Checking the ECG Signal Strength

Evaluate the ECG signal produced by the patient before entry into the MRI scanner, the optimum time to correct any problem.

A minimum signal strength should be present, as weaker signals may be prone to gradient interference:

- Select **Scale** to adjust the displayed size of the waveform(s), where the scale indicator provides, a 1 millivolt (mV) reference at any given setting; see *Selecting the Scale*, below).

- Select **Trace A Lead** (or **Trace B Lead**) to adjust the configuration of the leads used for ECG signal detection, where the best signal strength is indicated by the displayed peak-to-peak amplitude of the QRS complex, which should be at least 1 mV (that is, the waveform should be equal to the size of the scale indicator). In some cases, a 1 mV ECG signal cannot be achieved due to patient physiology. In these cases, try to achieve the largest amplitude attainable. See *Changing the Lead View*, on page 5-17.

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, refer to *Changing the Lead View* on page 5-17.

To change the SCALE setting

Step	Action
1	Ensure that the correct **Patient Type** has been selected; see page 3-11 for details.
2	Select the ECG VS box. The **ECG** menu appears. Current settings are displayed.
3	Select **Scale**. The **Scale** menu appears; see page 5-28.

Step	Action
4	Select the setting. Only a setting of **5x** or **10x** is recommended. **Auto** **1x** **5x** **10x** **15x** **20x** **25x** **30x** **40x** The setting is applied.
5	Take note of the scale indicator; see page 5-22. 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 1 mV peak-to-peak, then complete the following steps to make the waveform amplitude increase.

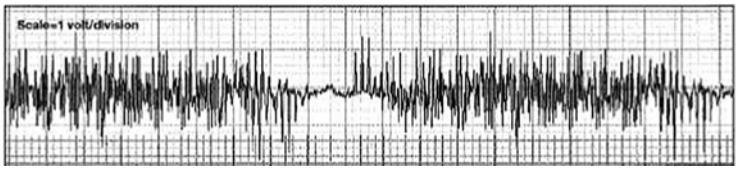
To change the lead view

Step	Action
1	Verify that a Quadtrode electrode or Quadtrode electrodes are being used, and verify the expiration date, quality and packaging for the electrode.
2	Ensure that the preferred Quadtrode electrode is being used; see page 5-5.
3	Ensure that the suggested placement site (or sites) is being used; see page 5-7.
4	Select the ECG VS box. The **ECG** menu appears. Current settings are displayed.
5	Depending upon the trace being examined, select **Trace A Lead** or **Trace B Lead**. The respective menu appears. The current setting is highlighted.

Step	Action
6	Select the desired lead view setting. **I** **II** **III** **AVL** **AVR** **AVF** The setting is changed. ***Note*** *When presented with poor gating or heart rate performance, it may be necessary to use the **Pediatric ECG** setting; see page 5-32.*
7	If the amplitude did not improve, repeat step 5 and cycle through the remaining lead view settings until a 1 mV signal amplitude is attained.
8	If the amplitude did not improve, remove the ECG lead cable and the Quadtrode electrode. Then prep the application site again and apply a new Quadtrode electrode.

Minimizing ECG Waveform Noise

Noise can render an ECG waveform unusable, as shown in the example below.



Many causes can result in a noisy ECG waveform, including:

- Use of alcohol-based products during patient prep.
- Use of a Quadtrode electrode that is expired or dried-out.
- Use of wrong or damaged ECG cable leads.
- Improper placement of the Quadtrode electrode.
- Placing the MR400 inside the 5000 gauss line.
- Placing the wECG module inside the bore.
- MR vibrations affecting the wECG module.
- Incorrect notch filter setting; see page 5-22.

- Selecting **Monitor** as the **Filter Mode** for the scan sequence; see page 5-31.
- Scan sequence parameters.
- Improper connection of ECG lead cable to Quadtrode electrode contact locations.
- Routing the ECG lead cable adjacent to the body coil or underneath an extremity coil.
- Excessive distance between electrodes when using CV Quadtrode electrodes.

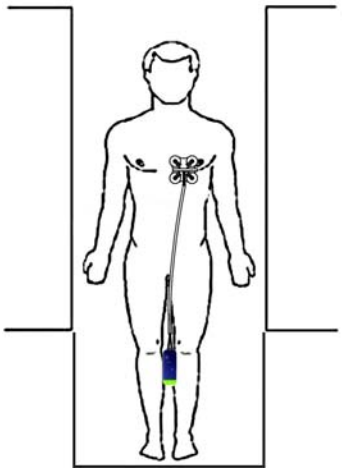
Positioning the ECG Lead Cable and wECG Module for Scanning

WARNINGS

- **When applying electrodes or connecting the ECG 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, et cetera) 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 probes are placed in the bore with the patient. Mixing of conductors from various manufacturers (catheters, temperature sensors, et cetera) 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, et cetera. 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, et cetera—including NIBP cuffs and hoses, EtCO2 and/or oxygen air-lines, and SpO2 probes—can be used safely as these items do not include electrically conductive materials. The MR400 has been validated for use with all accessories specified in the accessory list; see page 1-33.**
- **Circular, U-shaped or S-shaped loops in the ECG lead cable should be avoided to reduce the risk of heating.**
- **Do not use the Velcro storage strap to loop the ECG lead cable during MR scanning; otherwise, there is a risk of cable heating and possibly skin burns.**

Positioning the ECG lead cable

Position and keep the ECG lead cables in a straight line. Never allow the ECG lead cables to 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.



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. Cushion the wECG module.
3	Use only the ECG lead cables designated for use with this product; see page 1- 35.
4	Minimize the use of multiple cables. (See the warnings on page 5-19 for details.)
5	The wECG module, ECG lead cables and Quadtrode 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. Ensure that $B1_{rms} < 7.2$ µT.
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.

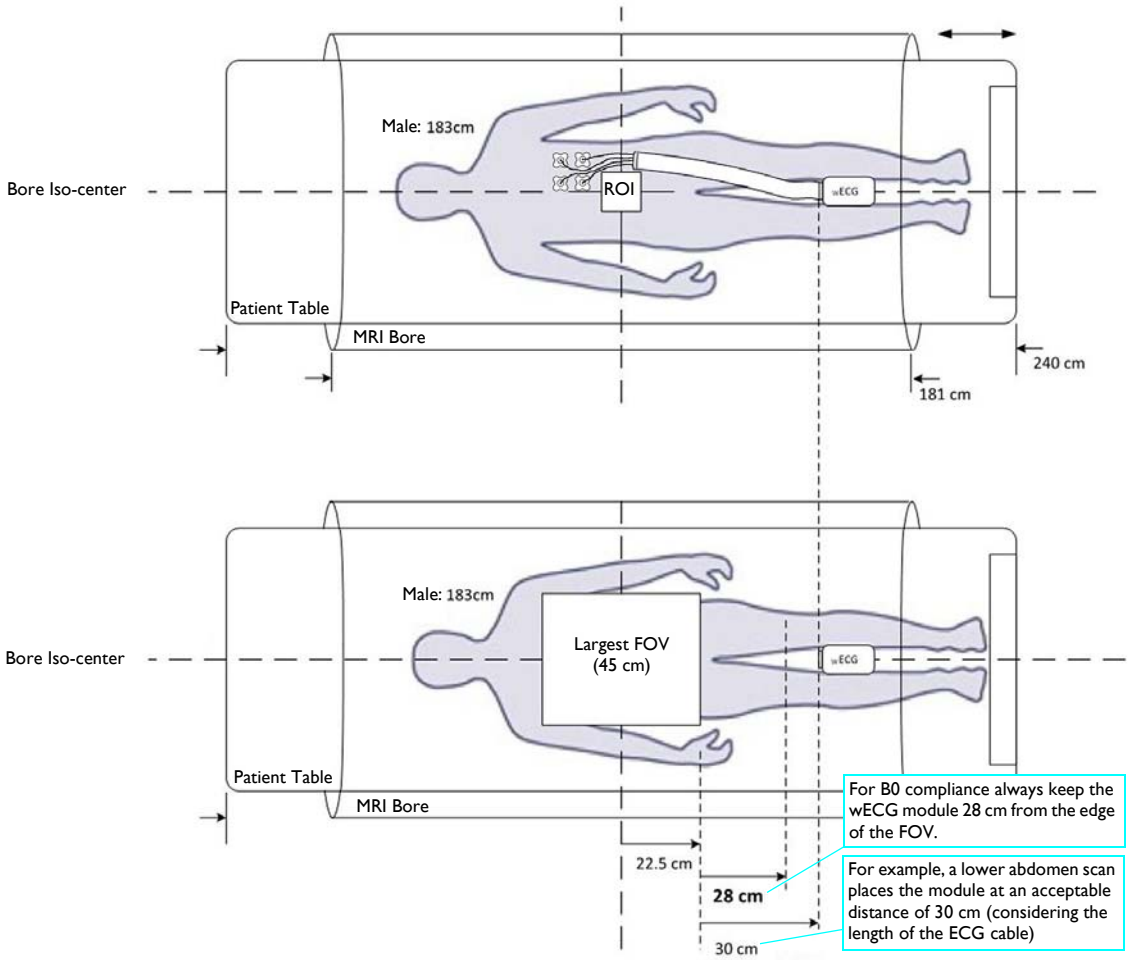
Positioning the wECG module

WARNING

The wECG module must be kept outside the system bore or image distortion may result. This is a result of proton emissions from the ECG module.

Depending upon your region of interest (ROI) and the largest field of view being examined (see illustration below), follow these guidelines to ensure the best performance of the wECG module, especially during harsh scan sequences:

- For static field (B0) compliance, keep the module at least 28 cm (11 inches) outside the MRI field of view.
- Considering the scan to be performed, place the module on or near the patient and as close to the bore iso-center as possible.
- Place the module as close to the bore opening as possible. (If the module can be placed outside the bore, positioning at the bore iso-center is not necessary.)
- Place the module on a cushioned surface to minimize MR vibrations.



Magnet type: Achieva 3.0T XR Series

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.**

Selecting the Filter Mode

Choose the appropriate ECG filter mode for your MRI study; see page 5-31 for mode details.

To change the filter mode setting

Step	Action
1	Press the **ECG Filter** key. The **Filter Mode** menu appears. The current setting is highlighted.
2	Select the desired filter. **Monitor** **Default** **Advanced 1** **Advanced 2** The setting is applied, as indicated in ECG VS box.

ECG Waveforms and VS Box

The ECG measurement is displayed as waveforms in the VS trace area of the screen and as numeric information in the ECG VS box. Other data, including ECG-related alarm information, are also provided in this area of the screen, as detailed below.

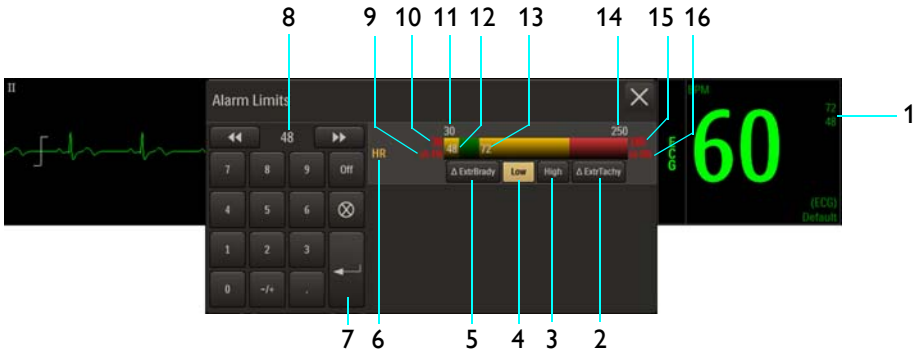
Item	Name	Definition
1	ECG VS waveform	Is the ECG waveform (Trace A, when enabled) ***Note*** *To change the waveform speed, see Sweep Speed on page 3-25.*
2	Alarm flag area	Displays ECG alarm flags when detected; see page 4-31.
3	ECG VS box label	Indicates the ECG vital sign parameter, and accesses the **ECG** menu
4	Unit of measure	Indicates that the heart rate numeric is given in BPM (beats per minute)
5	Heart rate numeric	Is the patient's detected heart rate measurement
6	Magnet indication	Indicates **Magnet Filter** when engaged.
7	HR upper alarm limit	Is the upper limit setting for the heart rate alarm, and accesses the **HR Alarm Limits** menu
8	HR lower alarm limit	Is the lower limit setting for the heart rate alarm, and accesses the **HR Alarm Limits** menu
9	HR source	Indicates the source used to measure the heart rate
10	Filter mode	Indicates the active ECG filter mode; see page 5-31.
11	Electrode fault indication	Displays the electrode fault indicator(s) when a disconnected ECG lead or bad electrode is detected, where LL = left leg, LA = left arm, and RA = right arm; and, LL, LA, RA, = RL right leg or all leads

Item	Name	Definition
12	ECG VS waveform	Is the ECG waveform (Trace B, when enabled) ***Note*** *To change the waveform speed, see* ***Sweep Speed*** *on page 3-25.*
13	Scale indicator	Represents a 1 millivolt signal amplitude for the selected scale of Trace B*
14	Lead type	Is the selected ECG lead for Trace B
15	Lead type	Is the selected ECG lead for Trace A
16	Scale indicator	Represents a 1 millivolt signal amplitude for the selected scale of Trace A*

* *The displayed waveform should at least be equal to the size of this indicator, as signals with lower amplitudes may be prone to gradient interference; see* Checking the ECG Signal Strength *on page 5-16 for details.*

Changing the Heart Rate Alarm Limits

The **Heart Rate Alarm Limits** menu can be accessed by touching the alarm limit settings in the ECG VS box.



1 Alarm limit settings, ECG VS box

2 **Extreme Tachycardia** button

3 **High** button

4 **Low** button

5 **Extreme Bradycardia** button

6 **HR Alarm Limits** menu label

7 **Enter** button

8 Current adjustment

9 Extreme Bradycardia delta value

10 Extreme Bradycardia alarm setting

11 Alarm limit, minimum

12 Lower alarm limit setting

13 Upper alarm limit setting

14 Alarm limit, maximum

15 Extreme Tachycardia alarm setting

16 Extreme Tachycardia delta setting

To change the heart rate alarm limit settings

Step	Action
1	Select the alarm limit settings in the ECG VS box. The **HR Alarm Limits** menu appears. Current settings are displayed.
2	Select the **Low**, **High**, **Δ ExtrBrady**, or **Δ ExtrTachy** button. The selected button will be highlighted and the current adjustment will be displayed.
3	Using the keypad, or the **increment**, **decrement**, or **Off** buttons, enter the desired setting. The current adjustment will reflect the setting.
4	Press the **Enter** button to save the setting. The alarm limit setting is updated.
5	To change other alarm limit settings, repeat steps 2, 3, and 4. The current adjustment will reflect the change.

Note

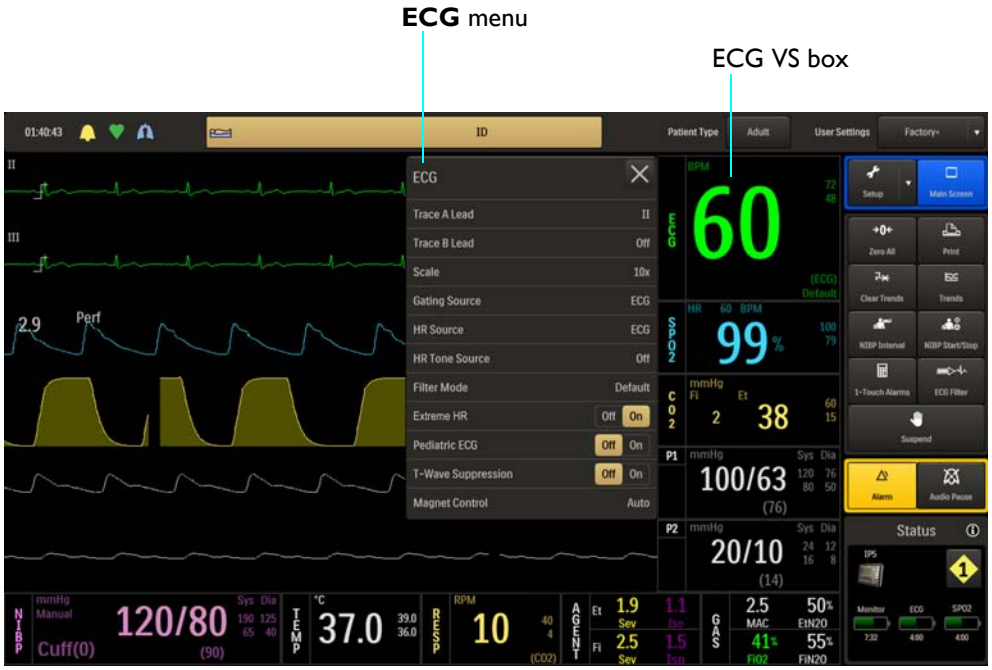
See chapter 4 for detailed alarm limit setting instructions and options.

ECG Menu

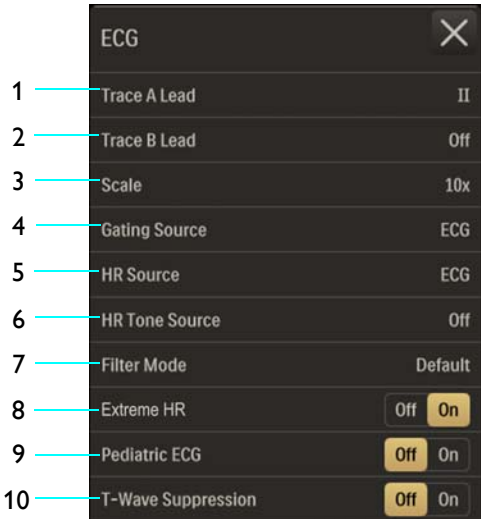
ECG menu items allow you to control ECG traces, functions and settings.

To open the ECG menu

Select the ECG VS box.



The following **ECG** menu items are available:.



1. **Trace A Lead**
2. **Trace B Lead**
3. **Scale**
4. **Gating Source**
5. **HR Source**
6. **HR Tone Source**
7. **Filter Mode**
8. **Extreme HR**
9. **Pediatric ECG**
10. **T-Wave Suppression**

To change settings in the ECG menu

Step	Action
1	Select the ECG VS box. The **ECG** menu appears. Current settings are displayed.
2	Select from the following **ECG** menu items: **Trace A Lead** **Trace B Lead** **Scale** **Gating Source** **HR Source** **HR Tone Source** **Filter Mode** **Extreme HR** **Pediatric ECG** **T-Wave Suppression** The menu item appears. The current setting is highlighted.
3	Select the desired setting from the menu options (except **Extreme HR**, **Pediatric ECG** and **T-Wave Suppression**, which are selectable on the **ECG** menu). The setting is entered.
4	To change other settings, repeat steps 2 and 3.

Trace A Lead

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

The following options are available:

- **Off**
- **I**
- **II** (Default)
- **III**
- **AVL**
- **AVR**
- **AVF**

To set the ECG A lead

See *Changing the Lead View* on page 5-17.

Trace B Lead

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

The following options are available:

- **Off** (Default)
- **I**
- **II**
- **III**
- **AVL**
- **AVR**
- **AVF**

To set the ECG B lead

See *Changing the Lead View* on page 5-17.

Scale

Sets the scale for the ECG waveforms. After making this setting, take note of the scale indicator (see page 5-22). 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 options are available:

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

To set the ECG scale

See *Selecting the Scale* on page 5-16.

Note

Scale *does not affect the signal analyzed by the MR400 for QRS detection and ECG gating.*

Gating Source

Sets the cardiac gating source based on a measured signal that is used for MR system triggering. (This is the same option as in the **SPO2** menu.)

The following options are available:

- **ECG** outputs a signal that represents the detection of the R-peak of a QRS complex. (Default)
- **Pulse** outputs a signal that represents the detection of the peak of the peripheral pulse complex.

To set the gating source

See Appendix D for details.

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 5-28.

HR Source

Selects the source that produces the heart rate, as displayed in the ECG and SPO2 VS boxes (identical to and interactive with same option in the **SPO2**, **P1** and **P2** menus).

The following options are available:

- **Auto** sets the source automatically according to the highest priority active input that is first to report valid patient data. The priority ranking (highest to lowest) is ECG, P1, P2, SPO2 (provided that the P1 and P2 channels have been labeled ABP; see *Set Label* on page 8-24 for details). The source will become unavailable when it has produced no valid data for a period of ten (10) or more seconds. The system examines the highest priority active input. If not found, the second-highest priority input is chosen, et cetera. If none are present, then **None** is displayed as the heart rate measurement numeric.
- **ECG** sets ECG as the source. (Default)
- **ABP** sets ABP as the source (if no pressure channel is labeled ABP, a warning box will allow automatic renaming and selection before proceeding; also see *Set Label* on page 8-24).

- **SPO2** sets SPO2 as the source.

To set the heart rate source

Step	Action
1	Select the ECG VS box. The **ECG** menu appears. Current settings are displayed.
2	Select **HR Source**. The **HR Source** menu appears. The current setting is highlighted.
3	Select the desired setting for the heart rate source: **Auto** **ECG** **ABP** **SPO2** The source is changed.

HR Tone Source

Sets the source used for the heart rate tone (identical to and interactive with the same option in the **Monitor Setup > Sound Adjust** menu and in the **SPO2** menu).

The following options are available:

- **Off** removes the heartbeat detected symbol from the display and sounds no pulse tone. (Default)
- **QRS** provides the heartbeat detected symbol and a tone triggered by the QRS detection from the ECG vital sign.
- **SPO2** provides the heartbeat detected symbol and a tone modulated by the SPO2 vital sign, where the lower the SPO2 value, the lower the pitch.

To control the heart rate tone source

Step	Action
1	Select the ECG VS box. The **ECG** menu appears. Current settings are displayed.

Step	Action
2	Select **HR Tone Source**. The **HR Tone Source** menu appears. The current setting is highlighted.
3	Select the desired setting for the tone source: **Off** **QRS** **SPO2** The setting is changed.

Filter Mode

Sets the filtering mode for the ECG signal. All filtering mode except Monitor utilize an adaptive filter scheme for removal of gradient artifacts generated by MR systems.

Notes

- *Due to the variety of MRI sequence characteristics, if the filter recommendations below do not provide optimum performance in all cases, the selection may improve ECG performance during a specific scan sequence.*
- *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 view (I, II, III, AVL, AVR, or AVF) that provides the best performance; see page 5-17.*
- *For cases not requiring cardiac gating, start with the Default filter (depending on the MRI sequence) then switch filters if a gradient artifact is noticed. If a gradient artifact is still present, check ECG signal strength and try lead I or III.*

The following options are available:

- **Monitor** is a mode that provides filtering characteristics that meet the specification of the AAMI and IEC. This mode is useful during patient preparation, transporting, base-lining, et cetera, but is not meant for use during active MRI sequences due to noise; see page 5-18.
- **Default** provides the best possible performance on 0.15 to 3.0T MR systems during Echo Train type MRI sequences. (Default)
- **Advanced 1** provides the best possible performance during cardiovascular (CV) MRI scans 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 a gradient artifact is noticed. If gradient artifact is still present, check signal amplitude and try Lead I or III.

- **Advanced 2** provides the best possible performance on 1.5 and 3.0T MR systems for removal of gradient artifacts generated by MR systems during MRI sequences such as neurological and cardiovascular scans.

To set the filter mode

See *Selecting the Filter Mode* on page 5-22.

Extreme HR

Controls the alarm function for Extreme Bradycardia (where a decrease in heart rate by a selectable value lower than the low HR limit setting will result in an alarm), and for Extreme Tachycardia (where an increase in heart rate by a selectable value higher than the high HR limit setting will result in an associated alarm).

The following options are available:

- **Off** does not report an extreme HR alarm event.
- **On** reports an extreme HR alarm event when detected and displays the **Δ ExtrBrady** button (for Extreme Bradycardia) and the **Δ ExtrTachy** button (for Extreme Tachycardia) on the **ECG Alarm Limits** menu and the controls for the extreme HR alarm adjustments. (Default)

To control the Extreme HR alarm function

Step	Action
1	Select the ECG VS box. The **ECG** menu appears. Current settings are displayed.
2	Locate **Extreme HR** and select the desired setting: **Off** **On** The setting is entered.

Pediatric ECG

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

The following options are available:

- **Off** does not apply the pediatric ECG filter. (Default)
- **On** processes ECG data using a pediatric algorithm, in addition to the gradient filter setting (and when if the ECG trace is printed, **PED ECG = ON** or **PED ECG = OFF** will appear on the strip).

Note

*If **Patient Type** is set to **Neo** then **Pediatric ECG** is set to **On** and locked. When **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 pediatric ECG filtering

Step	Action
1	Press the **Setup** key and then the **Monitor** key. The **Monitor Setup** menu appears. Current settings are displayed.
2	Locate **Pediatric ECG** and select the desired setting: **Off** **On** The setting is entered.

T-Wave Suppression

Allows you to reduce 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 produced.

The following options are available:

- **Off** (Default)
- **On**

Note

***T-Wave Suppression** is unavailable when **Filter Mode** is set to **Monitor**; see page 5-31.*

To control T-wave suppression

Step	Action
1	Select the ECG VS box. The **ECG** menu appears. Current settings are displayed.
2	Locate **T-Wave Suppression** and select the desired setting: **Off** **On** The setting is entered.

CHAPTER 6

Monitoring SPO2

The pulse oximetry feature of the MR400 uses a motion-tolerant signal processing algorithm based on Fourier Artifact Suppression Technology (FAST) and is calibrated to display oxygenated hemoglobin measurements, a visual pulse indication and a pulse rate, 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.
- Perfusion index value – A numerical indication of the pulsatile portion of the measured signal caused by arterial pulsation.

CAUTION

Before use, verify that the wSpO2 module is operating correctly and communicating by checking the displayed SPO2 numeric and waveform. Also, ensure that the wSpO2 module has a sufficiently charged battery by checking its displayed status symbol; see page 2-16.

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, SpO2 Probe and SpO2 Attachment

The wSpO2 module, SpO2 probe and SpO2 attachment (clip or grip) are intended for patient uses when non-invasive arterial oxygen saturation, pulse rate monitoring or pulse gating are required. The wSpO2 module, SpO2 probe and SpO2 attachment may not be used within the MR system bore.

WARNING

Philips has verified the compatibility of the monitor, probe, and cable specified in the Accessory List. The user should verify that only Philips accessories specified in the Accessory List are used. Otherwise, patient injury can result.

CAUTION

If dropped, the wSpO2 module must be verified for correct operation before use; see page 14-12.

Note

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

Patient Preparation for SpO2 Monitoring

When monitoring SpO2, the SpO2 attachment, the site selected on the patient, the SpO2 attachment's position on the patient, and the ambient environment will impact the performance and operation of the parameter.

Selecting the Site and SpO2 Attachment

When applying the clips or grips to the patient, site preparation and the pressure and alignment of the SpO2 attachment are important factors to consider. Select the most appropriate limb that best fits the attachment's size. For measurements to be accurate and reliable, the optimum fit is reached when the fiber head windows on the attachment oppose each other while covering skin or nail. Refer to the instructions provided with the SpO2 attachment when selecting and connecting the clip or grip.

Attaching the Clip or Grip to the SpO2 Probe

To attach a clip (or grip) to the SpO2 probe

Carefully snap the fiber heads on the SpO2 probe into the receptacles (windows) on the SpO2 attachment (clip or grip). Either fiber head can be inserted into either window on a clip or grip.

1 SpO2 probe

2 SpO2 attachment (clip shown)

3 Fiber heads

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 probe from contact with any liquid. If the probe, 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.**

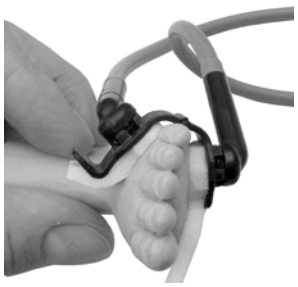
To apply a reusable SpO2 clip to the patient

Step	Action
1	Select the application site. It should match the SpO2 clip size so that the attachment 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. 
5	Ensure that the finger is touching the stop at the cushion and lays nicely centered in the clip.

To apply a disposable SpO2 grip (all, except neonate) to the patient

Step	Action
1	Select the application site. It should match the SpO2 grip size so that the attachment 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 SpO2 grip to the patient

Step	Action
1	Select the application site. It should match the SpO2 grip size so that the attachment 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: • 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. 
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 SpO2 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.

Perfusion Index Value

When enabled, the displayed perfusion index value (see page 6-8) is an indication of the pulsatile portion of the SpO2 signal caused by the patient's arterial blood flow. If you need an indication of change in pulse volume, use perfusion index value. This value can also be used as a quality indicator of the SpO2 measurement from the module. The table below provides general guidelines regarding this index value.

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

Note

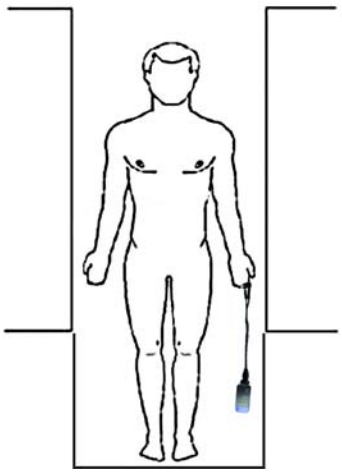
*If a **Low Perf** alarm is generated, see page 4-32 for corrective actions.*

Positioning the wSpO2 Module for Scanning

WARNING

The wSpO2 module must be kept outside the MR system bore or image distortion may result.

To ensure the best performance, specific positioning considerations are required when using the wSpO2 module in the MR magnet room, including during harsh scan sequences with peripheral nerve stimulation levels above 80 percent.



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 SpO2 probe and wSpO2 module outside the MR system bore;
- Place the wSpO2 module on a cushioned surface to minimize MR vibrations; and,
- Cover the SpO2 attachment site on the patient with opaque material.

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.**

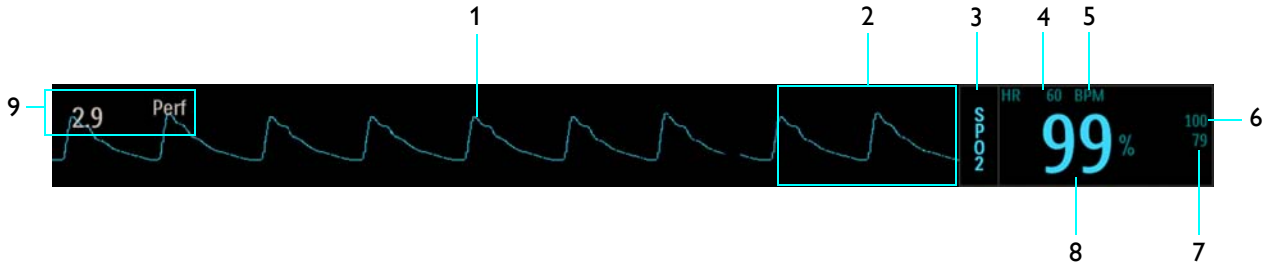
To ensure best performance during SPO2 measurements

Step	Action
1	Ensure that the fiber heads 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.
3	Check the battery indicator on the wSpO2 module to ensure that enough charge exists: • Green battery indicator = Charge sufficient; proceed to step 5. • Red battery indicator = Charge low; proceed to step 4. See page 2-11 for details. (Also, you can reference the status information pane; see page 2-16.)
4	Insert a charged module battery into the wSpO2 module and then recheck the battery indicator to ensure a sufficient charge before proceeding; see page 1-26.
5	Check the network channel indicator on the wSpO2 module to ensure communication is established with the MR400: • Steady = Good communication; proceed to step 7. • Flashing = No communication; proceed to step 6. See page 2-11 for details. (Also, you can reference the status information pane; see page 2-16.)
6	Ensure that the wSpO2 module is within 9.1 m (30 feet) of the MR400, in the same MRI room or in the same shielded room, and is set to the same wireless network channel used by the MR400; see page 1-29.
7	Check the perfusion index value for the quality of the SpO2 measurement from the module; see page 6-6 for details.

Step	Action
8	Select the **Patient Type**. See *Selecting the Patient Type* on page 3-11.
9	Check for any displayed SPO2 messages If a message is present, follow the recommended action to achieve better results (see page 4-26).
10	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.)
11	Keep the SpO2 probe and module outside the MR system bore.
12	Place the module on a cushioned surface.
13	Cover the patient SpO2 attachment site with opaque material.
14	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 SpO2 measurements are displayed as a waveform in the VS trace area of the screen and as numeric information in the SPO2 VS box. Other data, including SpO2-related alarm information, are also provided in this area of the screen, as detailed below.



Item	Name	Definition
1	SpO2 VS waveform	Is the detected SpO2 (pleth) pulsatile waveform (Trace C), automatically adjusted for proper viewing if above a minimum level ***Note*** *To change the waveform speed, see Sweep Speed on page 3-25.*
2	Alarm flag area	Displays SPO2 alarm flags when detected; see page 4-31.
3	SPO2 VS box label	Indicates the SpO2 vital sign parameter, and accesses the **SPO2** menu
4	Heart rate numeric	Is the patient's detected heart rate measurement
5	Unit of measure	Indicates that the heart rate numeric is given in BPM (beats per minute)
6	SpO2 upper alarm limit	Is the upper limit setting for the SpO2 alarm, and accesses the **SPO2 Alarm Limits** menu
7	SpO2 lower alarm limit	Is the lower limit setting for the SpO2 alarm, and accesses the **SPO2 Alarm Limits** menu
8	SpO2 numeric	Is the patient's detected arterial oxygen saturation measurement, given as a percentage
9	Perfusion index	Is the value for the portion of the measured signal caused by the pulsating arterial blood flow, which can be used as a measurement quality indicator; see page 6-15

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.

WARNING

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.

WARNINGS

- **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 probe is not attached to a patient. Bandage and grip attachment designs are particularly sensitive to minimal movement that might occur when the probe is dangling, not attached to the patient. An unapplied probe may cause readings to be displayed on the monitor. To avoid misdiagnosis, ensure the probe is applied to patient correctly.**

Changing the SPO2 Waveform Amplitude

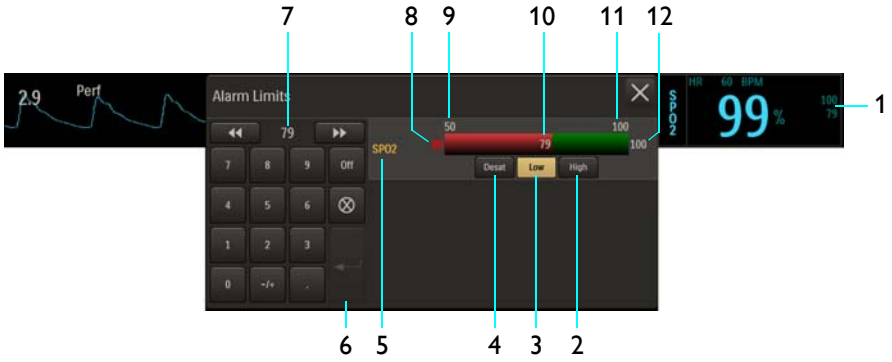
The vertical scale of the displayed SPO2 waveform can be changed to best suit the viewing requirements.

To change the SPO2 waveform amplitude

Step	Action
1	Select the SPO2 VS box. The **SPO2** menu appears. Current settings are displayed.
2	Select **Size**. The **Size** menu appears. The current setting is highlighted.
3	Select the desired size: **10%** **20%** **40%** **60%** **80%** **100%** The setting is changed.

Changing the SPO2 Alarm Limits

The **SPO2 Alarm Limits** menu can be accessed by touching the alarm limit settings in the SPO2 VS box.



1 Alarm limit settings, SPO2 VS box

2 **High** button

3 **Low** button

4 **Desat** button

5 **SPO2 Alarm Limits** menu label

6 **Enter** button

7 Current adjustment

8 Desat alarm setting

9 Alarm limit, minimum

10 Lower alarm limit setting

11 Upper alarm limit setting

12 Alarm limit, maximum

To change the SPO2 alarm limit settings

Step	Action
1	Select the alarm limit settings in the SPO2 VS box. The **SPO2 Alarm Limits** menu appears. Current settings are displayed.
2	Select the **Low**, **High**, or **Desat** button. The selected button will be highlighted and the current adjustment will be displayed. (**Desat** must be on; see page 6-15.)

Step	Action
3	Using the keypad, or the **increment**, **decrement**, or **Off** buttons, enter the desired setting. The current adjustment will reflect the setting.
4	Press the **Enter** button to save the setting. The alarm limit setting is updated.
5	To change other limit settings, repeat steps 2, 3, and 4. The current adjustment will reflect the change.

Note

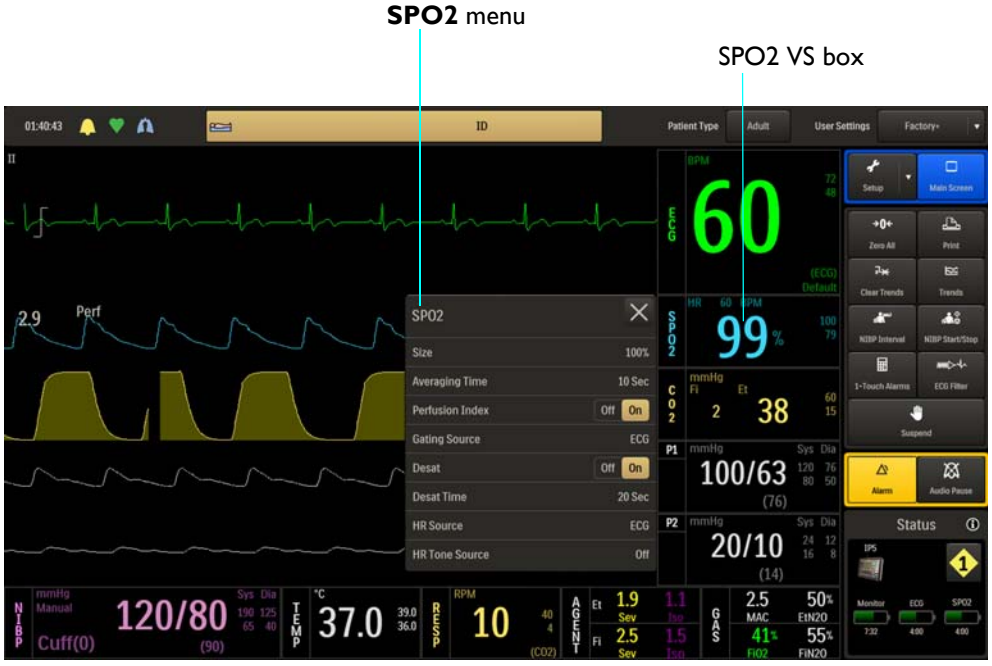
See chapter 4 for detailed alarm limit setting instructions and options.

SPO2 Menu

SPO2 menu items allow you to control SPO2 functions and settings.

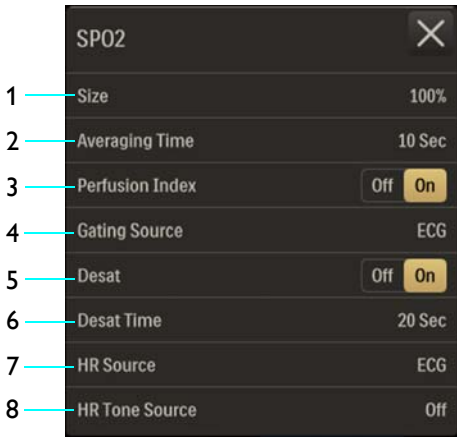
To open the SPO2 menu

Select the SPO2 VS box.



The following **SPO2** menu items are available:

1 **Size**
2 **Averaging Time**
3 **Perfusion Index**
4 **Gating Source**
5 **Desat**
6 **Desat Time**
7 **HR Source**
8 **HR Tone Source**



To change settings in the SPO2 menu

Step	Action
1	Select the SPO2 VS box. The **SPO2** menu appears. Current settings are displayed.
2	Touch the menu item to select one of the following SPO2 options: **Size** **Averaging Time** **Perfusion Index** **Gating Source** **Desat** **Desat Time** **HR Source** **HR Tone Source** The menu item appears. The current setting is highlighted.
3	Select the desired setting from the menu options (except **Perfusion Index** and **Desat**, which are selectable on the **SPO2** menu). The setting is entered.
4	To change other settings, repeat steps 2 and 3.

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 options 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 6-10.

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 options (in seconds) are available:

- **5 Sec**
- **10 Sec** (Default)
- **15 Sec**

To set the averaging time of the SPO2 reading

Step	Action
1	Select the SPO2 VS box. The **SPO2** menu appears. Current settings are displayed.
2	Select **Averaging Time**. The **Averaging Time** menu appears. The current setting is highlighted.
3	Select the desired time for averaging: **5 Sec** **10 Sec** **15 Sec** The setting is changed.

Perfusion Index

Controls the perfusion index value indication and alarm function (see page 5-6). The following options are available:

- **Off** disables the perfusion index functions.
- **On** enables the perfusion index functions. (Default)

To control the perfusion index functions

Step	Action
1	Select the SPO2 VS box. The **SPO2** menu appears. Current settings are displayed.
2	Locate **Perfusion Index** and select the desired setting: **Off** **On** The setting is entered.

Gating Source

Sets the cardiac gating source based on a measured signal that is used for MR system triggering. (This is the same option as in the **ECG** menu.)

The following options are available:

- **ECG** outputs a signal that represents the detection of the R-peak of a QRS complex. (Default)
- **Pulse** outputs a signal that represents the detection of the peak of the peripheral pulse complex.

To set the gating source

See Appendix D for details.

Desat

Controls the desaturation alarm and allows adjustment of the Desat alarm setting (see page 6-11), where a **Desat** alarm will be declared when the detected oxygenation condition has remained at or below the value for the period established by the **Desat Time** setting (see page 6-16).

The following options are available:

- **Off** disables the desat alarm function.

- **On** enables the desat alarm function. (Default)

To control the desat alarm function

Step	Action
1	Select the SPO2 VS box. The **SPO2** menu appears. Current settings are displayed.
2	Locate **Desat** and select the desired setting: **Off** **On** The setting is entered.

Desat Time

When **Desat** is on, this sets the time that must pass before declaring that a desaturation condition exists.

The following options (in seconds) are available:

- **20 Sec** (Default)
- **25 Sec**
- **30 Sec**
- **35 Sec**
- **40 Sec**

To set the desat time

Step	Action
1	Ensure that **Desat** is **On**. Select the SPO2 VS box. The **SPO2** menu appears. Current settings are displayed. (See page 6-15 for details.)

Step	Action
2	Select **Desat Time**. The **Desat Time** menu appears. The current setting is highlighted.
3	Select the desired time (in seconds) for the alarm indication: **20 Sec** **25 Sec** **30 Sec** **35 Sec** **40 Sec** The setting is changed.

HR Source

Selects the source that produces the heart rate, as displayed in the ECG and SPO2 VS boxes (identical to and interactive with same option in the **ECG, P1** and **P2** menus).

The following options are available:

- **Auto** sets the source automatically according to the highest priority active input that is first to report valid patient data. The priority ranking (highest to lowest) is ECG, P1, P2, SPO2 (provided that the P1 and P2 channels have been labeled ABP; see *Set Label* on page 8-24 for details). The source will become unavailable when it has produced no valid data for a period of ten (10) or more seconds. The system examines the highest priority active input. If not found, the second-highest priority input is chosen, et cetera. If none are present, then **None** is displayed as the heart rate measurement numeric.
- **ECG** sets ECG as the source. (Default)
- **ABP** sets ABP as the source (if no pressure channel is labeled ABP, a warning box will allow automatic renaming and selection before proceeding; also see *Set Label* on page 8-24).
- **SPO2** sets SPO2 as the source.

To set the heart rate source

Step	Action
1	Select the SPO2 VS box. The **SPO2** menu appears. Current settings are displayed.
2	Select **HR Source**. The **HR Source** menu appears. The current setting is highlighted.

Step	Action
3	Select the desired setting for the heart rate source: **Auto** **ECG** **ABP** **SPO2** The source is changed.

HR Tone Source

Sets the source used for the heart rate tone (identical to and interactive with same option in the in the **Monitor Setup > Sound Adjust** menu and in the **ECG** menu).

The following options are available:

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

To control the heart rate tone source

Step	Action
1	Select the SPO2 VS box. The **SPO2** menu appears. Current settings are displayed.
2	Select **HR Tone Source**. The **HR Tone Source** menu appears. The current setting is highlighted.
3	Select the desired setting for the tone source: **Off** **QRS** **SPO2** The setting is changed.

CHAPTER 7

Monitoring CO2 (LoFlo Option)

When equipped with the LoFlo CO2 option, the patient's airway respiratory gas can be monitored. The system uses sidestream measurements to produce:

- A fractional inspired CO2 (FiCO2) value (the lowest reading of the CO2 waveform in the previous 20 seconds) and an end-tidal CO2 (EtCO2) value measured during expiration.
- A respiration rate: The number of breaths per minute.
- A waveform of the concentration of carbon dioxide in the respiratory gases.

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 MR400 is too close to the MR magnet and shutdown of CO2 monitoring will occur. Always position the MR400 as indicated on page 3-2.**

Note

LoFlo option-equipped models do not feature a water trap (see page 7-4). If your MR400 is equipped with a water trap, refer to chapter 9 for CO2 monitoring instructions.

MR400 Preparation for CO2 Monitoring

When preparing the MR400 for CO2 monitoring, ensure that the waste gas port (see page 1-19) has been connected to your facility's gas scavenging system for disposal of sampled and calibration gases.

Note

Never route the waste gas tubing in a location that will allow it to be an obstruction or stepped on.

Operation and Use

When monitoring anesthetic agent gases, the typical operations and possible conditions that can arise may result in potential messages requiring your attention. See page 4-26 for a message listing and suggested actions.

Warm-Up Period

In order to achieve accurate identifications and measurements, the LoFlo system requires a warm-up period to thermally stabilize. This warm-up period begins when the **CO2** parameter is activated. Upon activation, **CO2 Warming Up** will be displayed until the LoFlo system becomes fully operational (about 2 minutes).

Zero Reference Adjustment

WARNING

During Zero calibration the system pulls ambient air through the zero intake port on the cart The calibration system assumes that the ambient air will contain normal trace amounts of CO2. If the system is placed in an unventilated area that allows CO2 (from the waste gas port on the rear panel, if not connected to a gas scavenging system) to accumulate, the result could be inaccurate CO2 zeroing and resulting inaccurate patient readings. Always place the cart in a well ventilated area.

The LoFlo system will occasionally perform a zero reference adjustment (**Zero Cal**) to ensure the accuracy of the displayed gas concentrations. **Performing CO2 Zero** will be displayed during a zero reference adjustment; allow the process to complete. The maximum time required for calibration is approximately 40 seconds. **Zero Cal** is not required when switching sampling lines.

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
- If the sampling line is disconnected from the CO2 port.

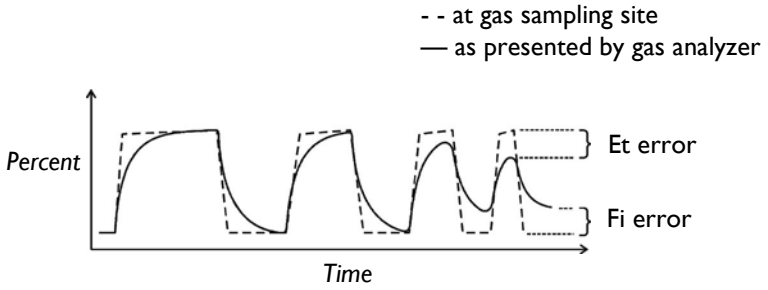
To perform a manual zero reference adjustment

Step	Action
1	If **CO2 Warming Up** is displayed, wait as the system thermally stabilizes. When the message is cleared, proceed.

Step	Action
2	Select the CO2 VS box. The **CO2** menu appears. Current settings are displayed.
3	Select **Zero Cal**. Calibration will begin and **Performing CO2 Zero** will be displayed. When complete, the message will be removed.

Breath Rate Distortion

The effect of rise time distortion to the gas curve becomes apparent when the breathing rate increases so that the time for a full inspiratory or expiratory event gets shorter. In those situations, due to the effect of the rise time, the gas curve does not reach the true end-tidal (or first inspired value) and the end-tidal gas value may then be underestimated. Correspondingly, the first inspired value may be overestimated. Below is an exaggerated illustration of the effect.



The breath rate limit for accurately resolved end-tidal gas values (at an I:E ratio of 1:1) may be found in Appendix A. The effect of other I:E ratios may be calculated by determining the length of the shortest inspiratory/expiratory event that can be resolved accurately:

$$t_{resolved} = 60 / (2 \times BR_{limit}(1:1)$$

$$BR_{limit}(I:E) = 60 / ((I + E) \times t_{resolved})$$

The difference in these results when compared to the rise time's specification is that rise time's only tests 10-90% performance. This specification is for (0 + accuracy) to (100 - accuracy) % and is thus much tougher. The ability to properly resolve end-tidal values can be measured by using the set-up described in ISO 80601-2- 55:2011 figure 201.101. In short, the method consists of sampling gas from two different sources connected to an electrically controlled pneumatic valve to permit rapid switching between the two sources. During the test, the valve is set to switch gas source at a number of frequencies (simulating the range of specified breath rates) and for each frequency the end-tidal value presented by the gas analyzer is noted. From a diagram of end-tidal value over frequency, the frequency at which the gas analyzer is no longer able to resolve end-tidal values according to specification is identified. This ability to properly resolve end-tidal values is listed in the specification.

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.

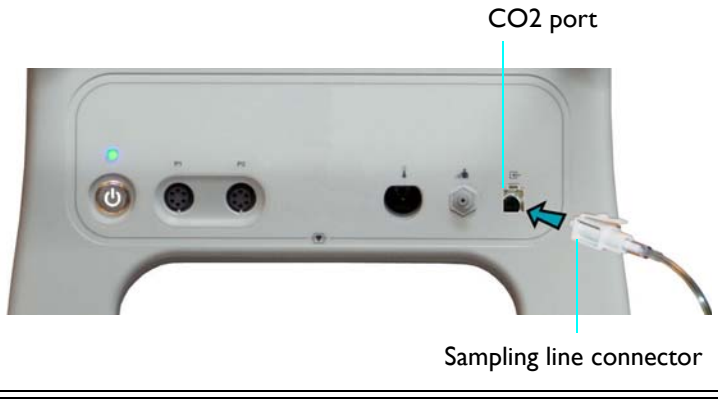
Selecting the CO2 Accessory

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 1-34 for a listing), 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	Insert the sampling line connector into the CO2 port on the patient connection panel and then push the connector forward until you feel or hear it click into place. 

2	If **CO2 Warming Up** is displayed, wait as the system thermally stabilizes (about 2 minutes). When the message is cleared, proceed.
3	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.) ***Note*** *To increase the life of the filter and pump, when CO2 will not be used to monitor a patient, we recommend turning the CO2 parameter off; see* ***Parameters*** *on page 3-18.*

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 the patient sampling line after attachment to the MR400.*

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 apply the sampling line to the patient

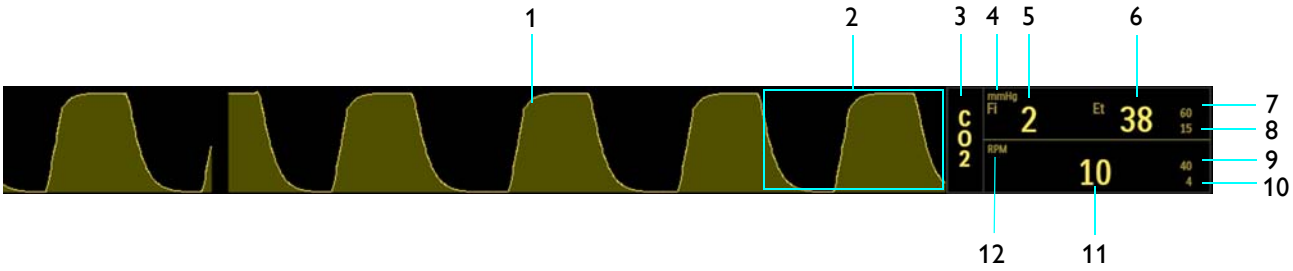
Step	Action
1	Ensure that the sampling line is clean, dry and undamaged. Replace the line if necessary.
2	Insert the sampling line connector into the CO2 port (see page 7-4). A click will be heard when properly inserted.
3	Position the cannula on the patient's face by inserting the nasal prongs into the nostrils. 
4	Pass the tubing over the ears and behind the head, ensuring the patient's head will not rest on any part of the cannula while the patient is lying down. 
5	Slide the sleeve toward the patient's head to assure a good fit of the cannula. 
6	If using the sampling line with the airway adapter, proceed to step 7; otherwise go to step 8.

Step	Action
7	Place the airway adapter at the proximal end of the airway circuit. **CAUTION** 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. ***Note*** *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.*
8	Select the **Patient Type**. See *Selecting the Patient Type* on page 3-11.
9	Check that the connections have been made correctly by verifying the patient's breathing efforts with the displayed waveform. **WARNING** **Before completion of patient setup, ensure that the patient's breathing efforts coincide with the displayed CO2 waveform.**
10	If the following warning is displayed: **Persistent CO2 occlusion detected.** **Please clear occlusion and press OK** **to resume using CO2** Clear any pinches or obstructions in the sampling line before proceeding.

CO2 Waveform and VS Box

The CO_2 measurement is displayed as a waveform in the VS trace area of the screen and as numeric information in the CO2 VS box. Other data, including CO2-related alarm information, are

also provided in this area of the screen. (CO2 [RESP] information can be displayed in the CO2 VS box or in the RESP VS box, as detailed below.)

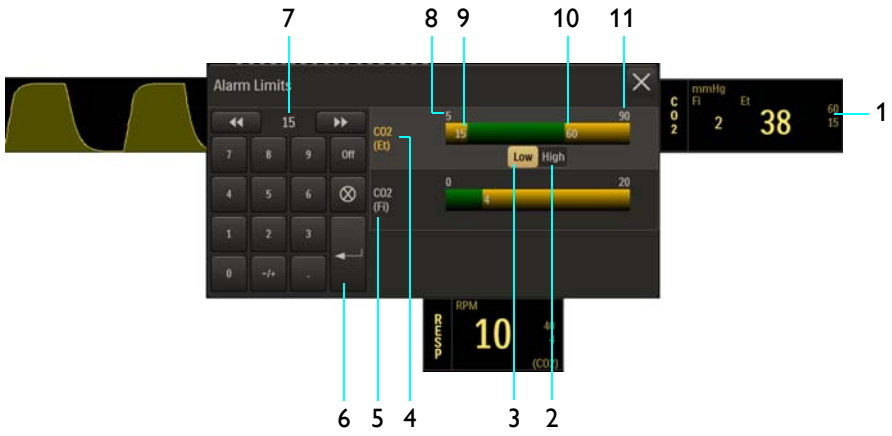


Item	Name	Definition
1	CO2 VS waveform	Is the detected CO2 waveform (Trace D) ***Note*** *To change the waveform speed, see Resp Speed on page 3-25.*
2	Alarm flag area	Displays CO2 alarm flags when detected; see page 4-31.
3	CO2 VS box label	Indicates the CO2 vital sign parameter, and accesses the **CO2** menu
4	Unit of measure	Indicates that the gas measurement numeric values are given in mmHg (millimeters of mercury) or kPa (kilopascals); see page 7-11.
5	FiCO2 numeric	Is the patient's detected fractional inspired CO2 measurement
6	EtCO2 numeric	Is the patient's detected end-tidal CO2 measurement
7	EtCO2 upper alarm limit	Is the upper limit setting for the end-tidal CO2 alarm, and accesses the **CO2 (Et) Alarm Limits** menu
8	EtCO2 lower alarm limit	Is the lower limit setting for the end-tidal CO2 alarm, and accesses the **CO2 (Et) Alarm Limits** menu
9	Respiration rate upper alarm limit	Is the upper limit setting for CO2-derived respiration rate alarm, and accesses the **CO2 (RESP) Alarm Limits** menu
10	Respiration rate lower alarm limit	Is the lower limit setting for CO2-derived respiration rate alarm, and accesses the **CO2 (RESP) Alarm Limits** menu
11	Respiration rate numeric	Is the patient's detected respiration rate measurement, as derived from CO2
12	Unit of measure	Indicates that the respiration rate numeric is given in RPM (respirations per minute)

*When **Source** is set to **BEL** in the **RESP** menu (see page 10-5), the CO2 VS box will also contain CO2-derived respiration rate elements, as indicated by the shaded rows and illustration above; otherwise, this information will be displayed in the RESP VS box (see page 7-10).*

Changing the CO2 and CO2 (RESP) Alarm Limits

The **CO2 (Et)** and **CO2 (Fi) Alarm Limits** menu can be accessed by touching the alarm limit settings in the CO2 VS box.



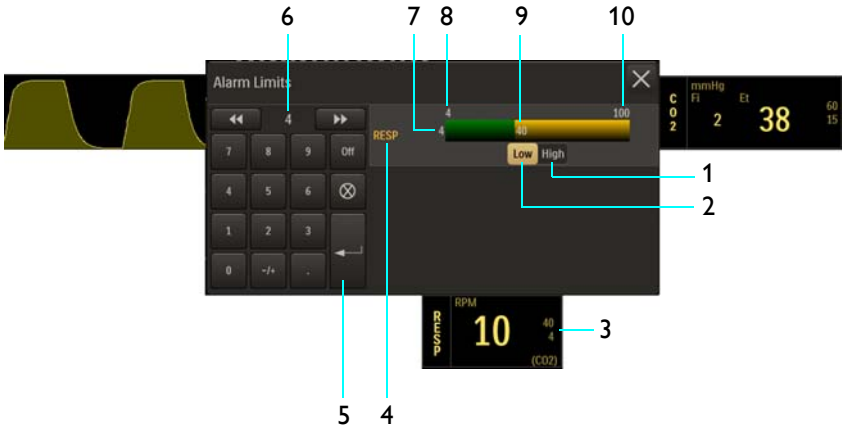
1. Alarm limit settings, CO2 (Et), CO2 VS box
2. **High** button
3. **Low** button
4. **CO2 (Et) Alarm Limits** menu label (active adjustment shown)
5. **CO2 (Fi) Alarm Limits** menu label
6. **Enter** button
7. Current adjustment
8. Alarm limit, minimum
9. Lower alarm limit setting
10. Upper alarm limit setting
11. Alarm limit, maximum

To change the CO2 (Et) and CO2 (Fi) alarm limit settings

Step	Action
1	Select the (Et) CO2 alarm limit settings in the CO2 VS box. The **CO2 Alarm Limits** menu appears. Current CO2 (Et) settings are displayed.
2	Select the CO2 alarm limits menu, **CO2 (Et)** or **CO2 (Fi)**, that you want to change. The associated menu appears. Current settings are displayed.

Step	Action
3	Select the **Low** button or the **High** button. The selected button will be highlighted and the current adjustment will be displayed.
4	Using the keypad, or the **increment**, **decrement**, or **Off** buttons, enter the desired setting. The current adjustment will reflect the setting.
5	Press the **Enter** button to save the setting. The alarm limit setting is updated.
6	To change the remaining settings, repeat steps 2–5. The current adjustment will reflect the change.

At the default setting, the **CO2 (RESP) Alarm Limits** menu can be accessed by touching the alarm limit settings in the RESP VS box.



1 **High** button

2 **Low** button

3 Alarm limit settings, CO2 (RESP), RESP VS box

4 **CO2 (RESP) Alarm Limits** menu label

5 **Enter** button

6 Current adjustment

7 Lower alarm limit setting

8 Alarm limit, minimum

9 Upper alarm limit setting

10 Alarm limit, maximum

To change the CO2 (RESP) alarm limit settings

Step	Action
1	Select the CO2 (RESP) alarm limit settings in the RESP VS box (or, in the CO2 VS box, see page 7-7.) The **CO2 (RESP) Alarm Limits** menu appears. Current settings are displayed.
2	Select the **Low** button or the **High** button. The selected button will be highlighted and the current adjustment will be displayed.
3	Using the keypad, or the **increment**, **decrement**, or **Off** buttons, enter the desired setting. The current adjustment will reflect the setting.
4	Press the **Enter** button to save the setting. The alarm limit setting is updated.
5	To change the remaining setting, repeat steps 2, 3, and 4. The current adjustment will reflect the change.

Note

See chapter 4 for detailed alarm limit setting instructions and options.

Changing the Unit of Measure

To change the unit of measure

Step	Action
1	Press the **Setup** key and then the **Monitor** key. The **Monitor Setup** menu appears. Current settings are displayed.
2	On the **Monitor Setup** menu, select **Service(Bio-Med)**. The **Service(Bio-Med)** sub-menu appears.
3	On the **Service(Bio-Med)** menu, select **System Config**. The **System Config** menu appears. Current settings are displayed.

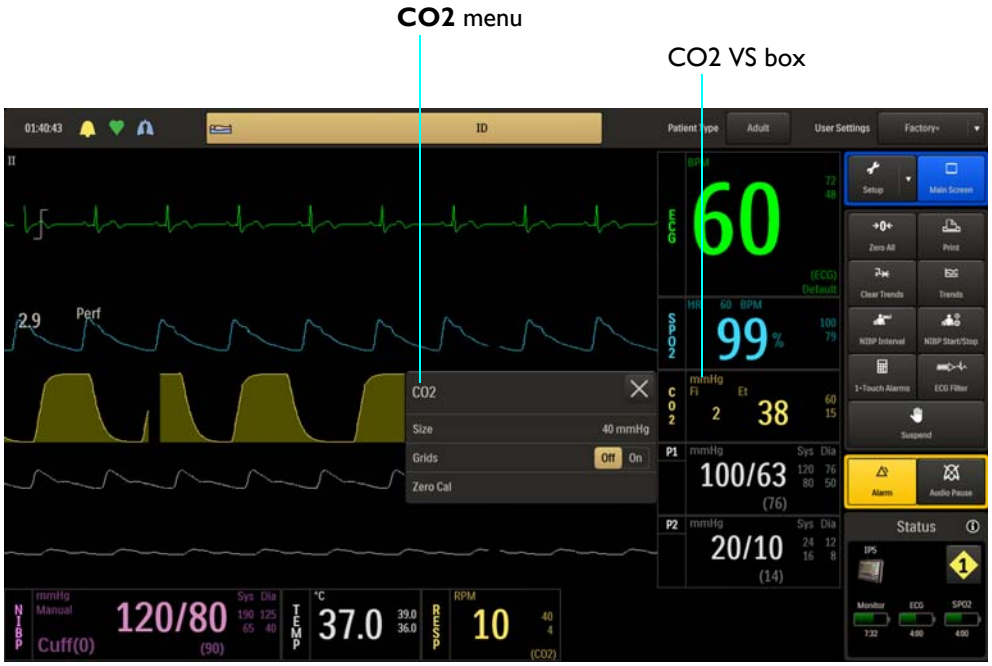
Step	Action
4	On the **System Config** menu, select **Gas Units**. The **Gas Units** menu appears. The current setting is highlighted.
5	Select the desired unit of measure: **mmHg** **kPa** The setting is changed.

CO2 Menu

The **CO2** menu allows you to control the CO2 and CO2 (RESP) monitoring functions and settings.

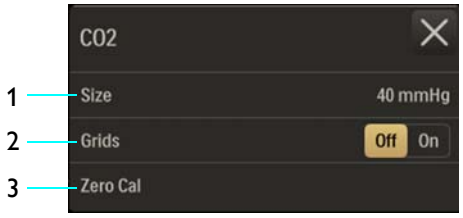
To open the CO2 menu

Select the CO2 VS box.



The following **CO2** menu items are available:

1 **Size**
2 **Grids**
3 **Zero Cal**



Note

Apnea *and* ***Apnea Time*** *will be in the* ***CO2*** *menu when bellows (****BEL****) is the selected* ***RESP*** *>* ***Source****; see page 10-7 for setting details.*

To change settings in the CO2 menu

Step	Action
1	Select the CO2 VS box. The **CO2** menu appears. Current settings are displayed.
2	Touch the menu item to select one of the following CO2 options: **Size** **Grids** **Zero Cal** The menu item appears. The current setting is highlighted.
3	Select the desired setting from the menu options (except **Grids**, which is selectable on the **CO2** menu). The setting is entered.
4	To change other settings, repeat steps 2 and 3.

Size

Controls the size of the CO2 waveform.

The following options are available:

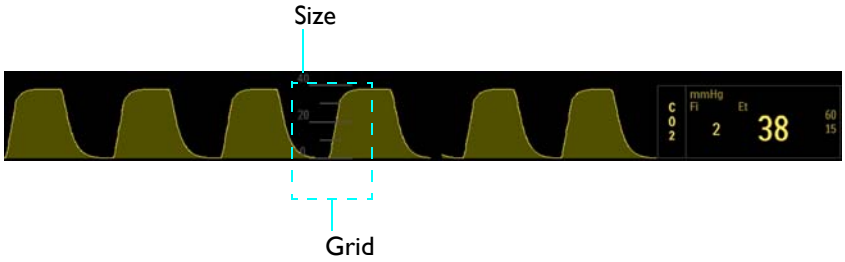
- **40 mmHg** (Default)
- **60 mmHg**
- **80 mmHg**

To adjust the size of the CO2 waveform

Step	Action
1	Select the CO2 VS box. The **CO2** menu appears. Current settings are displayed.
2	Select **Size**. The **Size** menu appears. The current setting is highlighted.
3	Select the desired size: **40 mmHg** **60 mmHg** **80 mmHg** The setting is changed.

Grids

Displays a scaled grid, which is graduated according to the **Size** selection for the CO2 waveform.



The following options are available:

- **Off** does not display a grid. (Default)
- **On** displays a grid.

Note

Grids *will not be displayed during a* ***CO2 Accuracy Check****; see page 3-30.*

To control the display function for the CO2 grid

Step	Action
1	Select the CO2 VS box. The **CO2** menu appears. Current settings are displayed.
2	Locate **Grids** and select the desired setting: **Off** **On** The setting is entered.

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. **Zero Cal** is not required when switching sampling lines.

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
- If the sampling line is disconnected from the CO2 port.

To perform a zero calibration

See page 7-2.

CHAPTER 8

Monitoring Invasive Blood Pressure

When equipped with the invasive blood pressure option, the MR400 provides compatibility with standard invasive blood pressure transducers having a 5 µV/V/mmHg sensitivity, and offers two invasive blood pressure channels, P1 and P2.

Indications and Contraindications

Adult and Pediatric Patients

Indications

- Direct arterial pressure monitoring
- Left atrial monitoring with an air-eliminating filter between solution source and continuous flush device
- Pulmonary artery monitoring (PA distal)
- Venous pressure monitoring (RA proximal)
- Cardiac catheterization

Contraindications

- Left atrial monitoring without an air-eliminating filter between solution source and continuous flush device
- Intracranial pressure monitoring
- Compartmental pressure monitoring
- Intrauterine pressure monitoring

Neonatal Patients

WARNING

Do not use a pressure administration cuff.

Indications

- Umbilical artery catheterization of neonates
- Invasive pressure monitoring with infusion pump

Contraindications

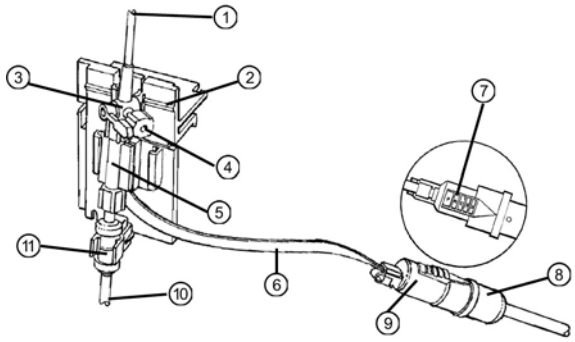
- Left atrial monitoring without an air-eliminating filter between the solution source and continuous flush device
- Intracranial pressure monitoring
- Compartmental pressure monitoring
- Intrauterine pressure monitoring

Patient Preparation for IBP Monitoring

When positioning the patient, routine IBP measurements (including for the condition hypertension) require the patient to remain silent, still and relaxed, with legs uncrossed and arms supported. Note that during MRI procedures, patients are typically laying down with their legs uncrossed and arms supported as needed for the MRI scan. We also recommend waiting 5 minutes before taking readings.

Transducer Component, Connection, and Feature Locations

The illustration below details the pressure transducer (REF 989803179721) component, feature, and connection locations. If using a different kit, refer to the manufacturers instructions which accompany that kit.



1 To patient

2 Site line

3 Zero reference stopcock

4 Zero port

5 Transducer

6 Transducer cable

7 Press here to disconnect transducer from reusable cable

8 Reusable cable connector

9 Transducer cable connector

10 To fluid source

11 Squeeze continuous flush device

MR 400 Preparation for IBP Monitoring

Follow the procedure below to prepare the MR400 for IBP monitoring when using the Expression MR IBP DPT Kits (Adult / Pediatric, REF 989803194631; and, Infant/Neonatal, REF 989803194641). As there are preparation differences, always follow the appropriate procedure.

To prepare the MR400 for IBP monitoring using transducer kits other than those referenced below, or for components added to the monitoring system, refer to applicable manufacturer's instructions for set up and use.

WARNINGS

- **Invasive blood pressure transducers are sensitive to vibrations that can occur during MRI scanning, which can lead to pressure reading inaccuracies. Always mount the invasive blood pressure transducer away from areas where vibration is likely to occur.**
- **The fluid within the pressure transducer system is a conductive connection to the patient, and must not contact other conductive parts, including earth ground.**
- **Do not allow fluids to enter the electrical connections of the transducer cables. Erratic readings may result.**
- **Always reference the manufacturer's instructions and follow the safe use instructions included with the IBP transducer kit when monitoring invasive blood pressure.**
- **Never attach the pressure transducer(s) directly to the patient as excessive heating can occur resulting in burn injuries to the patient.**
- **If air bubbles appear in the tubing system, flush the system with the infusion solution again. Air bubbles may lead to a wrong pressure reading.**
- **Transducers do not protect against burns when used with high-frequency (HF) surgical equipment.**
- **A transducer cable or other cable that becomes inadvertently looped during an MRI examination may act as conductive lines for RF induced currents, resulting in excessive heating and possible burns. When transducer cables or other cables form a conductive loop in contact with the patient's tissue, minor to severe burning can result. Do not allow the transducer cable or other cable to touch the patient or to become looped. Please refer to the additional information in Appendix E to prevent excessive heating associated with MRI procedures.**

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.

CAUTION

Use only approved pressure transducers and cables, as listed in Accessories in chapter 1, and follow the *Instructions for Use* that are supplied with the pressure transducer to set up and use the transducer monitoring kit.

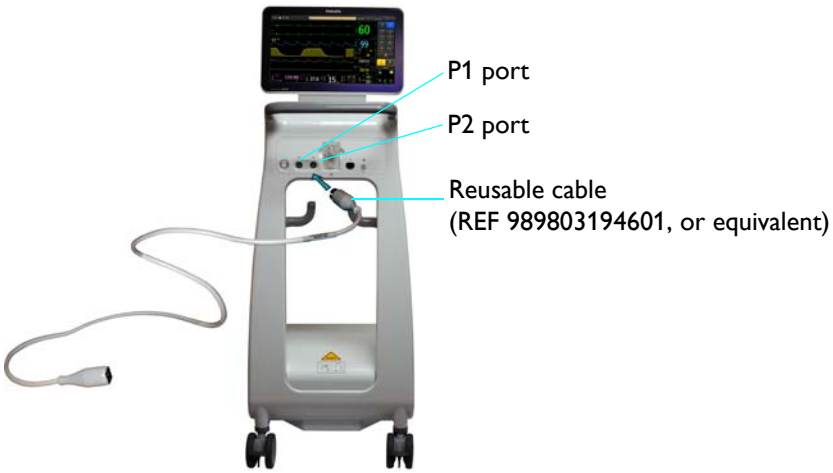
Note

The procedure below details the connection of a single transducer. To monitor two IBP channels, repeat the procedure to connect an additional transducer to the unused IBP port on the MR400.

Adult and Pediatric Patients: Expression MR IBP DPT Kit, A/P (REF 989803194631)

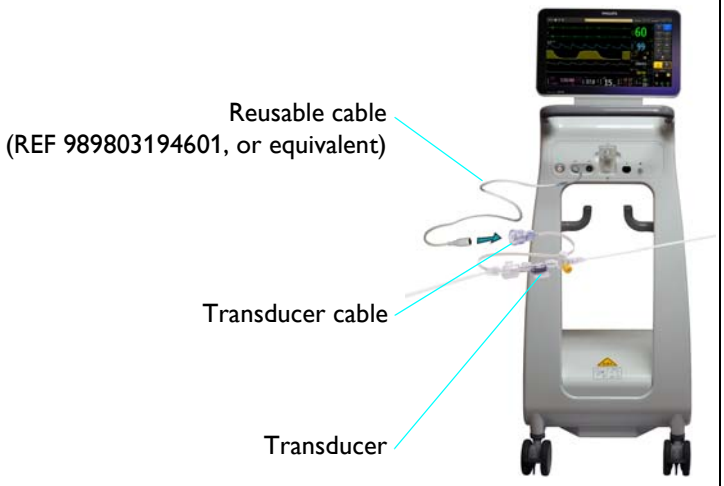
I. Connecting the Reusable Cable to the MR400

Connect the reusable cable, REF 989803194601 (or equivalent), to the P1 or the P2 port on the patient connection panel.



II. Kit Set Up

Set up the disposable transducer monitoring kit using aseptic technique.

Step	Action
1	Open package containing the sterile disposable transducer monitoring kit.
2	Remove transducer monitoring kit assembly from the package. Check all fittings to ensure tight connection.
3	Connect the reusable cable, REF 989803194601 (or equivalent), to the transducer cable. 
4	Prepare a collapsible I.V. solution bag by extracting all air from the bag. If heparinizing, add heparin prior to air removal. **CAUTION** If an air-free solution source is not used (i.e., air is not extracted from the fluid source), air may be forced into the monitoring line when solution is exhausted.
5	Close the clamp on the administration set and remove the protective cap from the administration set spike. Insert the spike carefully into the I.V. solution bag. **CAUTION** To prevent inadvertent puncture of the I.V. solution bag, insert the spike carefully using a twisting motion.

Step	Action
6	Insert the I.V. solution bag into the pressure administration cuff.
7	Hang the pressure administration cuff from an MR I.V. pole.
8	With the administration set clamp closed, gently squeeze the drip chamber and fill drip chamber approximately 1/2 full.
9	Open clamp on administration set.

III. Purging Air from the Monitoring Line

A. Attach the transducer to an MR IV pole mount.

B. Turn zero reference stopcock “off” to patient. Remove white vented cap from the side port of the zero reference stopcock.

C. Activate fast flush mechanism of the continuous flush device and fill transducer slowly (gravity prime only) until air-free. Flush fluid through transducer and side port of stopcock.

D. Turn handle of zero reference stopcock “off” to its side port. Place a yellow non-vented cap onto the side port of the stopcock.

E. Repeat priming steps B–D for any additional stopcocks.

F. Remove white cover at patient connector and flush the rest of the patient line. Place a yellow non-vented cover onto the patient connector.

Note

Take care to ensure no air is trapped in any components of the fluid pathway. The monitoring system must be totally air-free for maximum performance, i.e., optimal dynamic response.

G. Pressurize the I.V. solution source to 300 mmHg. Close clamp on pressure cuff.

CAUTIONS

- Make certain the drip chamber does not completely fill during pressurization. Air should remain in the drip chamber so that the continuous flush rate can be verified following a fast flush.
- Pulling a vacuum to purge bubbles from the lines is not recommended. This practice may entrain air or release air from solution. If the line is primed in a forward manner under pressure, care must be taken to assure the maximum pressure specifications for the transducer are not exceeded.

IV. Zeroing, Leveling and Calibration

A. After the system has been primed and mounted, zero the transducer using one of the following methods:

Step	Action
1	Turn the zero reference stopcock “off” to the patient and remove yellow non-vented cap from the side port which opens the zero reference stopcock to air. ***Note*** *The air-fluid interface of the zero reference stopcock should be at or near the right atrial (mid-axillary) level.*
2	Zero the transducer. Press the **Zero All** key. (Otherwise, to zero a single channel, use **Zero Set** in the respective **P1** or **P2** menu; see page 8-24). **Zeroing All Pressure Channels** (or **Zeroing Pressure Channel** for a single channel if **Zero Set** was used) will be displayed and zeroing will begin; where, upon completion, **Done** will be displayed to indicate success. ***Note*** *If the transducer will not zero and an error condition occurs, verify that the transducer is being used as described in the manufacturer’s instructions. Press **Retry** to attempt zeroing again. If the transducer still does not zero, try another transducer and/or cable; and, if condition persists, contact technical support or authorized service personnel.*
3	Turn the zero reference stopcock “off” to the side port and replace yellow non-vented cap.

—Or—

Step	Action
1	Attach desired catheter to distal end of monitoring kit and prime, purging all air bubbles from catheter.
2	Open stopcock(s) to the catheter. (The catheter tip is now the system air-fluid interface.)

Step	Action
3	Place transducer in the position (horizontal plane) it will maintain during pressure measurement.
4	Place the catheter tip at the right atrial (mid-axillary) level.
5	Zero the transducer. Zero the transducer. Press the **Zero All** key. (Alternatively, use **Zero Set** in the respective **P1** or **P2** menu to zero a specific channel connected to the transducer; see page 8-24). **Zeroing All Pressure Channels** (or **Zeroing Pressure Channel** for a single channel if **Zero Set** was used) will be displayed and zeroing will begin; where, upon completion, **Done** will be displayed to indicate success. ***Note*** *If the transducer will not zero and an error condition occurs, verify that the transducer is being used as described in the manufacturer's instructions. Press **Retry** to attempt zeroing again. If the transducer still does not zero, try another transducer and/or cable; and, if condition persists, contact technical support or authorized service personnel.*

B. Repeat this zeroing, leveling, and calibration procedure for each additional monitoring line as applicable.

C. Transducers are pre-calibrated to industry standards.

V. Connecting the Monitoring Kit to the Patient

WARNING

The IBP transducer must not be mounted to the patient, or patient burn may result.

A. Remove yellow non-vented cover at patient connector. A continuous flush of approximately 3 ml per hour should be observed in the drip chamber. Drop rate should be approximately 1 drop per minute. For each additional monitoring line, the continuous flush will increase by 3 ml/hr (i.e., 6 ml/hr for two lines).

B. For a systemic arterial blood pressure line, activate the fast flush mechanism of the continuous flush device, while allowing arterial cannula to backflow during attachment. For pulmonary artery catheters, the monitoring kit should be attached to the catheter and the

catheter filled with I.V. solution prior to insertion. Follow catheter manufacturer's insertion instructions.

VI. Fast Flushing

A. Activate the fast flush mechanism of the continuous flush device and check drip chamber to confirm fast flush.

B. FOLLOWING EACH FAST FLUSH, DRIP CHAMBER DROP RATE MUST BE OBSERVED TO VERIFY COMPLETE CLOSURE.

VII. Checking for Leaks

After approximately 1 minute has elapsed, the flow rate should be observed at the drip chamber to ensure that the continuous flush device is operating properly. A visual inspection for leaks should also be made since a small leak can misrepresent the actual continuous flow through the catheter. A protocol should be established according to the hospital standard of care for routinely checking the system for proper fluid source pressure, flow rate and leaks.

VIII. In the MR Room

WARNINGS

- **The IBP transducer must not be allowed past the 5,000 gauss line, or transducer failure, inaccurate readings, noisy MRI images or patient burn may result.**
- **Never place the pressure transducer's stopcocks or port covers within 8 cm (3.2 inches) of the field of view of the MR bore as inaccurate readings or noisy MRI images can result.**
- **An offset occurs when the pressure transducer is repositioned in the magnetic field. The transducer must be zeroed prior to the MRI examination after the transducer is in its final setup position. Moving the transducer after zeroing may cause a measurement offset to occur.**

In the MR room, ensure that the transducer is level with the heart that the transducer interface cabling is not looped or touching the patient (refer the Warnings on pages 8-3 and 8-4), and then re-zero the transducer; see page 8-16.

WARNING

Non-physiological pulsatile P1 (or P2) waveform (for example, those found during intra-aortic balloon pump use) can lead to inaccurate blood pressure readings. If questionable values are observed, recheck the patient's pressures by alternate means before administering medication or therapy.

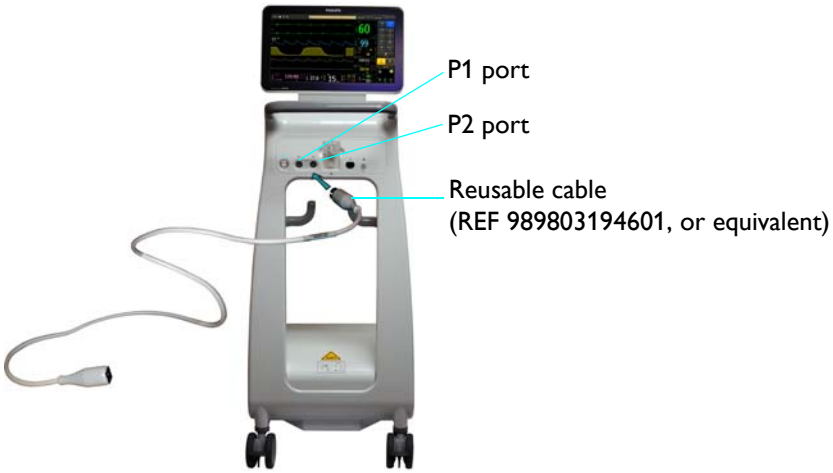
Note

When monitoring invasive blood pressure, routinely inspect the catheter and/or pressure line for leaks after zeroing, and always follow the pressure transducer/catheter manufacturer's use recommendations.

Neonatal Patients: Expression MR IBP DPT Kit, I/N (REF 989803194641)

I. Connecting the Reusable Cable to the MR400

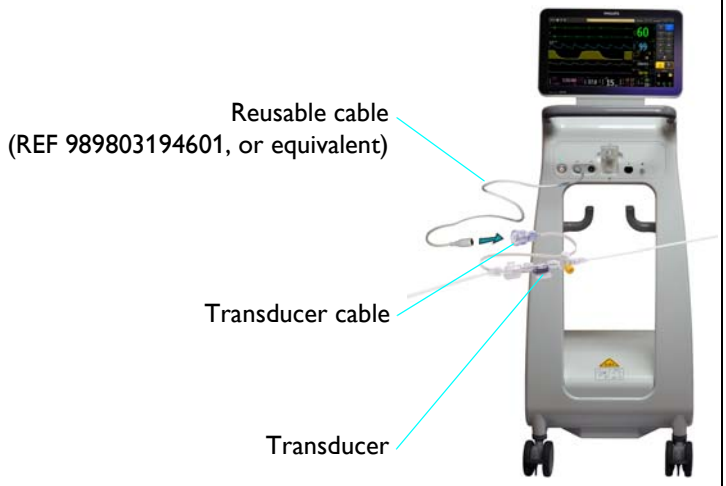
Connect the reusable cable, REF 989803194601 (or equivalent), to the P1 or the P2 port on the patient connection panel.



II. Kit Set Up

A. Set up the disposable transducer monitoring kit using aseptic technique

Step	Action
1	Open package containing the sterile disposable transducer monitoring kit.
2	Remove transducer monitoring kit assembly from package.
3	Attach additional monitoring components as desired.
4	Check all fittings to ensure tight connections.

Step	Action
5	Connect the reusable cable, REF 989803194601 (or equivalent), to the transducer cable. 

B. Preparing Solution

Step	Action
1	Assemble pump administration set appropriate for the infusion pump that is to be used.
2	If using heparin, add prior to air removal. **CAUTION** If an air-free solution source is not used (i.e., air is not extracted from the fluid source), air may be forced into the monitoring line when solution is exhausted.
3	Attach tubing to solution container and prime the tubing following pump manufacturer's instructions.

Note

If an air-free solution source is not used (i.e., air is not extracted from the fluid source), air may be forced into the monitoring line when solution is exhausted.

C. Connecting Kit to the Infusion Pump

Step	Action
1	Remove vented cap from the female port of flush device and connect flush device fluid line to distal connector of infusion pump administration set. **CAUTION** In this application, the flush device is not intended to control flow rate. Flow rate must be controlled by an infusion pump. Do not use with pressure administration cuff.

III. Purging Air from the Monitoring Line

A. Remove the vented cap from the stopcocks and the vented cover from the patient connector (distal stopcock).

B. Adjust the pump delivery regulator to a fluid flow rate sufficient to flush solution through the system.

C. Carefully fill fluid lines of the monitoring kit with I.V. solution until all air has been removed from the system. Activate flush device to facilitate filling and to remove air from flush device. Turn stopcock handles as applicable to prime through side ports of stopcocks. Non-vented caps and covers are provided in the spare parts bag to replace vented caps and covers as required.

CAUTION

Pulling a vacuum to purge bubbles from the lines is not recommended. This practice may entrain air or release air from solution. If the line is primed in a forward manner under pressure, care must be taken to assure the maximum pressure specifications for the transducer are not exceeded.

Note

Take care to ensure no air is trapped in any components of the fluid pathway. The monitoring system must be totally air-free for maximum performance, i.e., optimal dynamic response.

IV. Zeroing, Leveling and Calibration

A. After the system has been primed and mounted, zero the transducer using one of the following methods:

Step	Action
1	Turn the zero reference stopcock “off” to the patient and remove non-vented cap from the side port which opens the zero reference stopcock to air. ***Note*** *The air-fluid interface of the zero reference stopcock should be at or near the right atrial (mid-axillary) level.*
2	Zero the transducer. Press the **Zero All** key. (Otherwise, to zero a single channel, use **Zero Set** in the respective **P1** or **P2** menu; see page 8-24). **Zeroing All Pressure Channels** (or **Zeroing Pressure Channel** for a single channel if **Zero Set** was used) will be displayed and zeroing will begin; where, upon completion, **Done** will be displayed to indicate success. ***Note*** *If the transducer will not zero and an error condition occurs, verify that the transducer is being used as described in the manufacturer’s instructions. Press **Retry** to attempt zeroing again. If the transducer still does not zero, try another transducer and/or cable; and, if condition persists, contact technical support or authorized service personnel.*
3	Turn the zero reference stopcock “off” to the side port and replace non-vented cap.

—Or—

Step	Action
1	Attach desired catheter to distal end of monitoring kit and prime, purging all air bubbles from catheter.
2	Open stopcock(s) to the catheter. (The catheter tip is now the system air-fluid interface.)
3	Place transducer in the position (horizontal plane) it will maintain during pressure measurement.
4	Place the catheter tip at the right atrial (mid-axillary) level.

Step	Action
5	Zero the transducer. Press the **Zero All** key. (Alternatively, use **Zero Set** in the respective **P1** or **P2** menu to zero a specific channel connected to the transducer; see page 8-24). **Zeroing All Pressure Channels** (or **Zeroing Pressure Channel** for a single channel if **Zero Set** was used) will be displayed and zeroing will begin; where, upon completion, **Done** will be displayed to indicate success. ***Note*** *If the transducer will not zero and an error condition occurs, verify that the transducer is being used as described in the manufacturer's instructions. Press **Retry** to attempt zeroing again. If the transducer still does not zero, try another transducer and/or cable; and, if condition persists, contact technical support or authorized service personnel.*

B. Transducers are pre-calibrated to industry standards.

V. Connecting the Monitoring Kit to the Patient

WARNING

The IBP transducer must not be mounted to the patient, or patient burn may result.

A. Remove non-vented cover at patient connector.

B. Set the infusion pump to deliver the desired flow rate. Continuous low flow flush should be observed at the patient connector and drip chamber (if provided) at this time.

CAUTION

Kits with a 30 ml per hour flush device are not intended to control flow rate. Flow rate must be controlled by an infusion pump. Do not use with pressure administration cuff.

C. Activate pump delivery mechanism to pump solution through the flush device while allowing arterial cannula to back flow during attachment.

CAUTIONS

- Be certain not to introduce air into the system during connection procedure.
- If this product is used with fat emulsions, they must be introduced through the lipid compatible stopcock that is distal to the flush transducer assembly to avoid cracking of the transducer line.

VI. Checking for Leaks

After approximately 1 minute has elapsed, the flow rate should be observed at the drip chamber to ensure that the continuous flush device is operating properly. A visual inspection for leaks should also be made since a small leak can misrepresent the actual continuous flow through the catheter. A protocol should be established according to the hospital standard of care for routinely checking the system for proper fluid source pressure, flow rate and leaks.

VII. In the MR Room

WARNINGS

- **The IBP transducer must not be allowed past the 5,000 gauss line, or transducer failure, inaccurate readings, noisy MRI images or patient burn may result.**
- **Never place the pressure transducer's stopcocks or port covers within 8 cm (3.2 inches) of the field of view of the MR bore as inaccurate readings or noisy MRI images can result.**
- **An offset occurs when the pressure transducer is repositioned in the magnetic field. The transducer must be zeroed prior to the MRI examination after the transducer is in its final setup position. Moving the transducer after zeroing may cause a measurement offset to occur.**

In the MR room, ensure that the transducer is level with the heart that the transducer interface cabling is not looped or touching the patient (refer to the Warnings on pages 8-3 and 8-4), and then re-zero the transducer; see page 8-16.

WARNING

Non-physiological pulsatile P1 (or P2) waveform (for example, those found during intra-aortic balloon pump use) can lead to inaccurate blood pressure readings. If questionable values are observed, recheck the patient's pressures by alternate means before administering medication or therapy.

Note

When monitoring invasive blood pressure, routinely inspect the catheter and/or pressure line for leaks after zeroing, and always follow the pressure transducer/catheter manufacturer's use recommendations.

Zeroing the Pressure Transducer

WARNING

The transducer must be zeroed prior to the MRI examination after the transducer is in its final setup position. Moving the transducer after zeroing may cause a measurement offset to occur. Otherwise, inaccurate patient pressure readings may result.

To avoid inaccurate pressure readings, the monitor requires a valid zero. Zero the transducer in accordance with your hospital policy (at least once per day). You must perform a zero:

- when you use a new transducer or tubing,
- every time you reconnect the transducer cable to the monitor, or
- if you think the monitor's pressure readings are not correct.

To zero a pressure transducer

Refer to the appropriate procedure according to the patient type and application:

- Adult / Pediatric—see page 8-7.
- Neonate—see page 8-12.

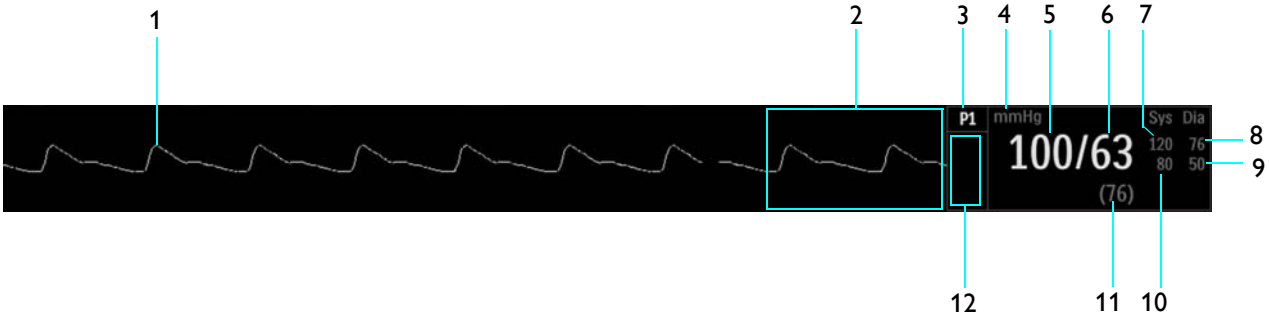
P1 and P2 Waveforms and VS Boxes

Invasive blood pressure measurements (P1 and P2) are displayed as waveforms (trace E and trace F, respectively) in the VS trace area of the screen and as numeric information in the P1 and P2 VS boxes. Other data, including P1- and P2-related alarm information, are also provided in these areas of the screen, as detailed below.

Note

Except for the VS box annotations and waveform locations, the definitions described below are applicable to both P1 and P2 channels.

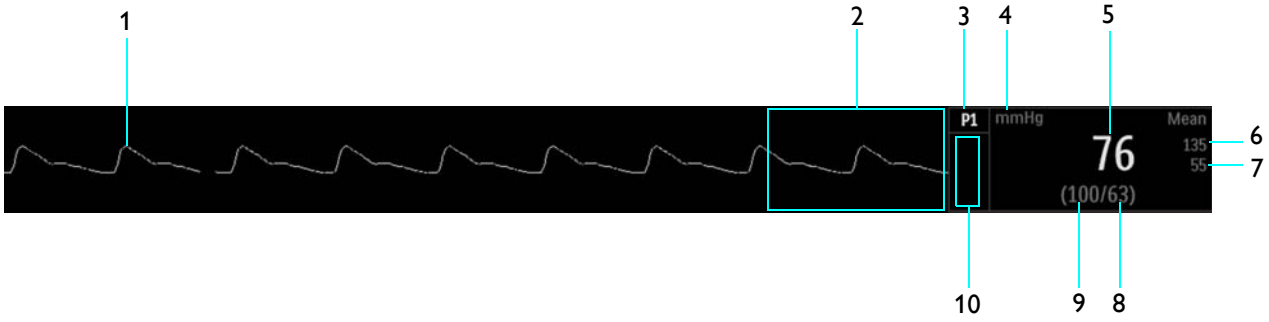
Systolic/Diastolic Format



Item	Name	Definition
1	P1 VS waveform, or P2 VS waveform	Is the detected P1 (or P2) waveform, Trace E (or Trace F) ***Note*** *To change the waveform speed, see Sweep Speed on page 3-25.*
2	Alarm flag area	Displays P1 (or P2) alarm flags when detected; see page 4-31.
3	P1 (or P2) VS box label	Indicates the P1 (or P2) vital sign parameter, and accesses the **P1** menu (or **P2** menu)
4	Unit of measure	Indicates that the pressure measurement numeric values are given in mmHg (millimeters of mercury) or kPa (kilopascals); see *Pressure Units* on page 3-32.
5	Systolic numeric	Is the patient's detected systolic invasive blood pressure measurement
6	Diastolic numeric	Is the patient's detected invasive diastolic blood pressure measurement
7	Systolic upper alarm limit	Is the upper limit setting for the P1 (or P2) systolic alarm, and accesses the **P1 Alarm Limits** menu (or the **P2 Alarm Limits** menu)
8	Diastolic upper alarm limit	Is the upper limit setting for the P1 (or P2) diastolic alarm, and accesses the **P1 Alarm Limits** menu (or the **P2 Alarm Limits** menu)

Item	Name	Definition
9	Diastolic lower alarm limit	Is the lower limit setting for the P1 (or P2) diastolic alarm, and accesses the **P1 Alarm Limits** menu (or the **P2 Alarm Limits** menu)
10	Systolic lower alarm limit	Is the lower limit setting for the P1 (or P2) systolic alarm, and accesses the **P1 Alarm Limits** menu (or the **P2 Alarm Limits** menu)
11	Mean numeric	Indicates the patient's detected mean invasive blood pressure measurement
12	<P1 label> or <P2 label>	Indicates the **Set Label** name, if assigned, for P1 (or P2)

Mean Format



Item	Name	Definition
1	P1 VS waveform, or P2 VS waveform	Is the detected P1 (or P2) waveform, Trace E (or Trace F) ***Note*** *To change the waveform speed, see Sweep Speed on page 3-25.*
2	Alarm flag area	Displays P1 (or P2) alarm flags when detected; see page 4-31.
3	P1 (or P2) VS box label	Indicates the P1 (or P2) vital sign parameter, and accesses the **P1** menu (or **P2** menu)
4	Unit of measure	Indicates that the pressure measurement numeric values are given in mmHg (millimeters of mercury) or kPa (kilopascals); see *Pressure Units* on page 3-32.
5	Mean numeric	Is the patient's detected mean invasive blood pressure measurement
6	Mean upper alarm limit	Is the upper limit setting for the P1 (or P2) mean alarm, and accesses the **P1 Alarm Limits** menu (or the **P2 Alarm Limits** menu)

Item	Name	Definition
7	Mean lower alarm limit	Is the lower limit setting for the P1 (or P2) mean alarm, and accesses the **P1 Alarm Limits** menu (or the **P2 Alarm Limits** menu)
8	Diastolic numeric	Is the patient's detected invasive diastolic blood pressure measurement
9	Systolic numeric	Indicates the patient's detected systolic invasive blood pressure measurement
10	<P1 label> or <P2 label>	Indicates the **Set Label** name, if assigned, for P1 (or P2)

Changing the P1 (or P2) Format

To control the format of the P1 (or P2) data

Step	Action
1	Select the P1 (or P2) VS box. The **P1** menu (or the **P2** menu) appears. Current settings are displayed.
2	Select **Format**. The **Format** menu appears. The current setting is highlighted.
3	Select the desired format: **SysDia** **Mean** The format is changed. ***Note*** *When using P1 (or P2) labels CVP or ICP, the displayed format cannot be changed; see page 8-28 for details.*

Changing the P1 (or P2) Waveform Amplitude

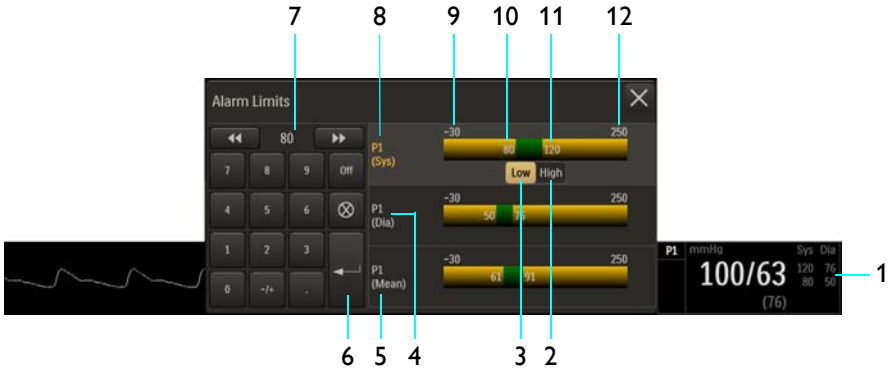
The vertical scale of the displayed P1 (or P2) waveform can be changed to best suit the viewing requirements. Always select the appropriate waveform scale for the waveform being observed.

To change the P1 (or P2) waveform amplitude

Step	Action
1	Select the P1 (or P2) VS box. The **P1** (or **P2**) menu appears. Current settings are displayed.
2	Select **Size**. The **Size** menu appears. The current setting is highlighted.
3	Select the desired size: **40 mmHg** **75 mmHg** **100 mmHg** **150 mmHg** (Default) **200 mmHg** **250 mmHg** The setting is changed.

Changing the P1 (or P2) Alarm Limits

The **P1 Alarm Limits** menu can be accessed by touching the alarm limit settings in the P1 vital sign box, and the **P2 Alarm Limits** menu can be accessed by touching the alarm limit settings in the P2 vital sign box. Except for menu labeling differences, the elements described below are applicable to both the P1 and P2 parameters.



1 Alarm limit settings, P1 VS box

2 **High** button

3 **Low** button

4 **P1 Diastolic Alarm Limits** menu label

5 **P1 Mean Alarm Limits** menu label

6 **Enter** button

7 Current adjustment

8 **P1 Systolic Alarm Limits** menu label (active adjustment shown)

9 Alarm limit, minimum

10 Lower P1 (Sys) alarm limit setting

11 Upper P1 (Sys) alarm limit setting

12 Alarm limit, maximum

To change the invasive blood pressure alarm limit settings

Step	Action
1	Select the alarm limit settings in the P1 (or P2) VS box. The **P1 Alarm Limits** (or the **P2 Alarm Limits**) menu appears. Current settings are displayed.
2	Select the desired pressure setting: **P1 (Sys)** **P1 (Dia)** **P1 (Mean)** The setting is selected.
3	Select the **Low** button or the **High** button. The selected button will be highlighted and the current adjustment will be displayed.
4	Using the keypad, or the **increment**, **decrement**, or **Off** buttons, enter the desired setting. The current adjustment will reflect the change.
5	Press the **Enter** button to save the setting. The alarm limit setting is updated.
6	To change the remaining settings, repeat steps 2, 3, 4 and 5. The current adjustment will reflect the change.

Note

See chapter 4 for detailed alarm limit setting instructions and options.

Changing the Unit of Measure

Note

*When using an 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 measurement 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 and then the **Monitor** key. The **Monitor Setup** menu appears. Current settings are displayed.
2	On the **Monitor Setup** menu, select **Service(Bio-Med)**. The **Service(Bio-Med)** menu appears. Current settings are displayed.
3	On the **Service(Bio-Med)** menu, select **System Config**. The **System Config** menu appears. Current settings are displayed.
4	On the **System Config** menu, select **Pressure Units**. The **Pressure Units** menu appears. The current setting is highlighted.
5	Select the desired setting: **mmHg** **kPa** The setting is entered.

P1 (and P2) Menu

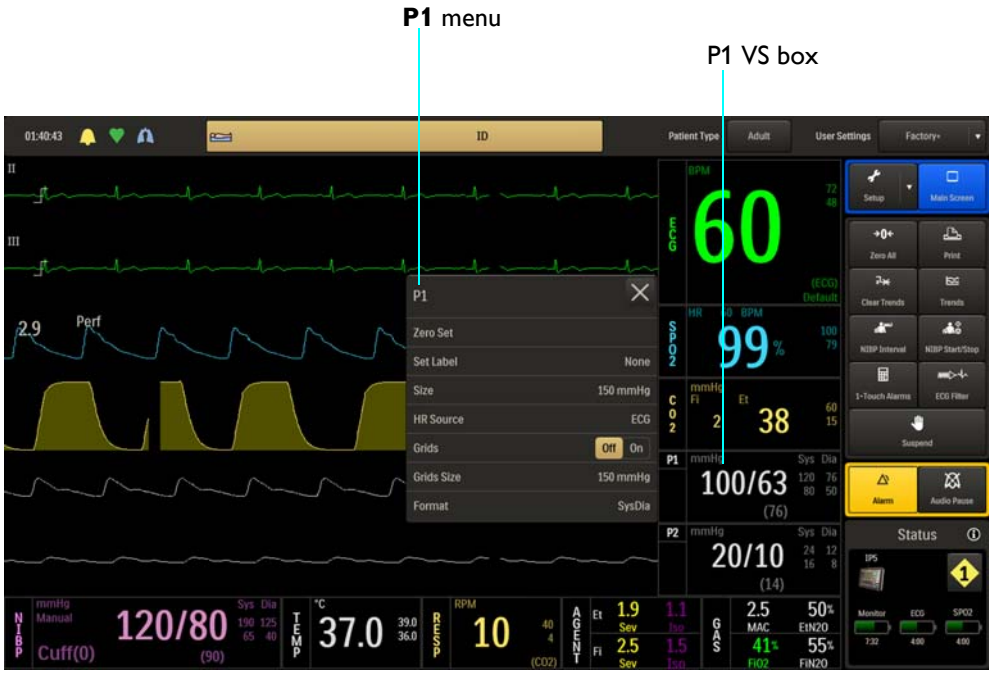
The **P1** and **P2** menus allow you to control invasive blood pressure traces, functions and settings. Each menu contains identical options for the control of the respective invasive blood pressure channel, P1 or P2.

Note

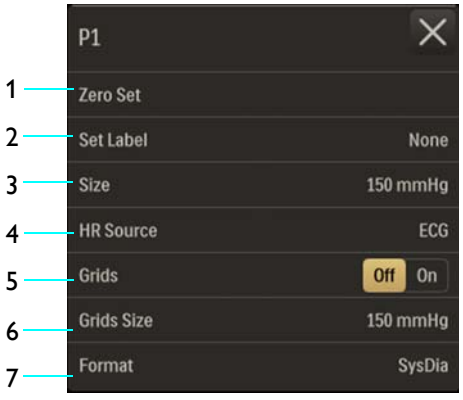
The operation and menus for P1 and P2 are identical.

To open the P1 menu (or P2 menu)

Select the P1 VS box (or the P2 VS box).



The following **P1** (and **P2**) menu items are available:.



1 **Zero Set**

2 **Set Label**

3 **Size**

4 **HR Source**

5 **Grids**

6 **Grids Size**

7 **Format**

To change settings in the P1 (or P2) menu

Step	Action
1	Select the P1 (or P2) VS box. The **P1** (or **P2**) menu appears. Current settings are displayed.

Step	Action
2	Touch the menu item to select one of the following P1 (or P2) options: **Zero Set** **Set Label** **Size** **HR Source** **Grids** **Grids Size** **Format** The menu item appears. The current setting is highlighted.
3	Select the desired setting from the menu options (except **Grids**, which is selectable on the **P1** [or **P2**] menu): The setting is entered.
4	To change other settings, repeat steps 2 and 3.

Zero Set

Zeros the pressure transducer for P1 (or P2). The pressure transducer must be zeroed before use and at regular intervals during use. (**Zero Pressure Channel** will be displayed during the process and **Done** will be displayed upon completion.)

To zero the pressure transducer

See *Zeroing the Pressure Transducer* on page 8-16.

Set Label

Assigns a label to the pressure channel for identification of the transducer site. The label will appear in the VS box and it will also determine the color used for the VS box.

The following names and colors are available:

- **None** displayed in white. (Default)
- **ABP** (arterial blood pressure) displayed in pink.

Note

In the event ABP is chosen as the heart rate source while there are multiple pressures labeled as ABP, the system will choose P1.

- **PAP** (pulmonary artery pressure) displayed in yellow.

- **CVP** (central venous pressure) displayed in blue.
- **LAP** (left atrial pressure) displayed in purple.
- **ICP** (intracranial pressure) displayed in light blue.

To assign a label to an P1 (or P2) channel

Step	Action
1	Select the P1 (or P2) VS box. The **P1** menu (or the **P2** menu) appears. Current settings are displayed.
2	Select **Set Label**. The **Set Label** menu appears. The current setting is highlighted.
3	Select the desired label: **None** **ABP** **PAP** **CVP** **LAP** **ICP** The label is changed. The annotation in the VS box and its color is updated.

Size

Changes the P1 (or P2) waveform amplitude, allowing low level signals to be scaled up or high level signals to be scaled down for better viewing.

The following options are available:

- **40 mmHg**
- **75 mmHg**
- **100 mmHg**
- **150 mmHg** (Default)
- **200 mmHg**
- **250 mmHg**

To change the amplitude of the P1 (or P2) waveform

See *Changing the P1 (or P2) Waveform Amplitude* on page 8-19.

HR Source

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

The following options are available:

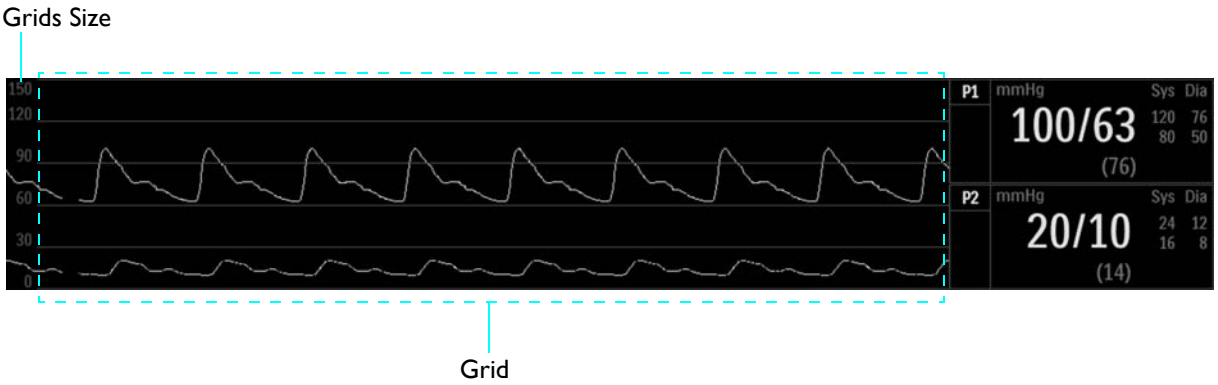
- **Auto** sets the source automatically according to the highest priority active input that is first to report valid patient data. The priority ranking (highest to lowest) is ECG, P1, P2, SPO2 (provided that the P1 and P2 channels have been labeled ABP; see *Set Label* on page 8-24 for details). The source will become unavailable when it has produced no valid data for a period of ten (10) or more seconds. The system examines the highest priority active input. If not found, the second-highest priority input is chosen, et cetera. If none are present, then **None** is displayed as the heart rate measurement numeric.
- **ECG** sets ECG as the source. (Default)
- **ABP** sets ABP as the source (if no pressure channel is labeled ABP, a warning box will allow automatic renaming and selection before proceeding; also see *Set Label* on page 8-24).
- **SPO2** sets SPO2 as the source.

To set the heart rate source

Step	Action
1	Select the P1 (or P2) VS box. The **P1** menu (or the **P2** menu) appears. Current settings are displayed.
2	Select **HR Source**. The **HR Source** menu appears. The current setting is highlighted.
3	Select the desired setting for the heart rate source: **Auto** **ECG** **ABP** **SPO2** The source is changed.

Grids

Controls the pressure grid display for IBP waveforms.



The following options are available:

- **Off** no grid is displayed. (Default)
- **On** displays a scaled grid (also see **Grids Size**, below).

To control the display function for the pressure grid

Step	Action
1	Select the P1 (or P2) VS box. The **P1** menu (or the **P2** menu) appears. Current settings are displayed.
2	Locate **Grids** and select the desired setting: **Off** **On** The setting is entered.

Grids Size

Sets the scale size when **Grids** is on (see **Grids**, above).

The following options are available:

- **40 mmHg**
- **75 mmHg**
- **100 mmHg**
- **150 mmHg** (Default)
- **200 mmHg**
- **250 mmHg**

To adjust the grid size for the P1 (or P2) waveform

Step	Action
1	Select the P1 (or P2) VS box. The **P1** menu (or the **P2** menu) appears. Current settings are displayed.
2	Select **Grids Size**. The **Grids Size** menu appears. The current setting is highlighted.
3	Select the desired size: **40 mmHg** **75 mmHg** **100 mmHg** **150 mmHg** **200 mmHg** **250 mmHg** The setting is changed.

Format

Sets the displayed format of the P1 (or P2) numeric data, except when using certain pressure channel labels.

The following options are available:

- **SysDia** displays the systolic and diastolic numerics in a large font (separated by a slash) and displays the mean numeric in a smaller font (bracketed with parenthesis). (Default)
- **Mean** displays the mean numeric in a large font, and the systolic and diastolic numerics in a smaller font and separated by a slash. Only mean alarms will be present in this format. Also, labels (i.e., CVP and ICP) that designate single pressures will automatically assume the mean format; see *Set Label* on page 8-24.

To control the format of the P1 (or P2) numeric data

See *Changing the P1 (or P2) Format* on page 8-19.

CHAPTER 9

Monitoring Agents and Gases (AGENT Option)

When equipped with the AGENT option, the patient's level of anesthetic agent gases, oxygen (O2), carbon dioxide (CO2), and nitrous oxide (N2O) concentrations can be monitored. An anesthetic gas sensor (AGS) system uses infrared spectroscopy combined with digital signal processing to quickly and accurately identify gas concentrations.

WARNING

Whenever a patient is under anesthesia or connected to a ventilator, constant attention by qualified medical personnel is required.

MR400 Preparation for AGENT Monitoring

When preparing the MR400 for AGENT monitoring, ensure that the waste gas port (see page 1-19) has been connected to your facility's gas scavenging system for disposal of sampled and calibration gases.

Notes

- *These instructions are for setting up a typical monitoring system. Exact components and set-up procedure used may vary, depending upon the application. For components added to the monitoring system, refer to applicable manufacturer's instructions for set up and use.*
- *Never route the waste gas tubing in a location that will allow it to be an obstruction or stepped on.*

Operation and Use

When monitoring anesthetic agent gases, the typical operations and possible conditions that can arise may result in potential messages requiring your attention. See page 4-26 for a message listing and suggested actions.

WARNINGS

- **Organic vapors (for example, from cleaning agents) in the sampling line or room air may alter anesthetic agent readings.**
- **Alcohol in the patient's breath can modify the anesthetic agent readings.**

Warm-Up Period

In order to achieve accurate identifications and measurements, the AGS system requires a warm-up period to thermally stabilize. This warm-up period begins when the **AGENT** or the **CO2** parameter is activated. Upon activation, the AGS system will become fully operational according to the following sequence:

1. During the warm-up period, **CO2 Warming Up** will be displayed.
2. Within 45 seconds of activation, the AGS system will be able to identify the gases and provide gas concentration information with ISO-level accuracy. Wait during this period, the measurement numeric values in the AGENT, GAS, and CO2 VS boxes will display three dashes (---); see *No Data Indication* on page 2-20 for details.
3. Within 10 minutes of activation, the AGS system will be able to operate at full accuracy.

Zero Reference Adjustment

WARNING

During Zero calibration the system pulls ambient air through the zero intake port on the cart The calibration system assumes that the ambient air will contain normal trace amounts of CO2. If the system is placed in an unventilated area that allows CO2 (from the waste gas port on the rear panel, if not connected to a gas scavenging system) to accumulate, the result could be inaccurate CO2 zeroing and resulting inaccurate patient readings. Always place the cart in a well ventilated area.

The AGS system will occasionally perform a zero reference adjustment, briefly interrupting gas monitoring to take in room air through a reference gas intake port to ensure the accuracy of the displayed gas concentrations.

Readjusting CO2 Zero will be displayed during a zero reference adjustment; allow the process to complete. A zero reference adjustment typically takes 10–12 seconds, and will occur automatically as needed, but mostly during the warm-up period. When the AGS system has become fully operational, these adjustments will occur approximately once every 4 hours or whenever the AGS system temperature changes by at least ±1°C from the last stored stable temperature.

Note

Whenever the Agent sensor changes from a steady state condition, the system will perform an zero reference adjustment to restabilize the sensor readings. During this time it is possible for a false identification and concentration value to occur. Change from a steady state condition may occur when:

- *Applying a sampling line for the first time.*
- *Switching from one agent to another.*
- *Going from high agent concentrations to low or off.*

Note

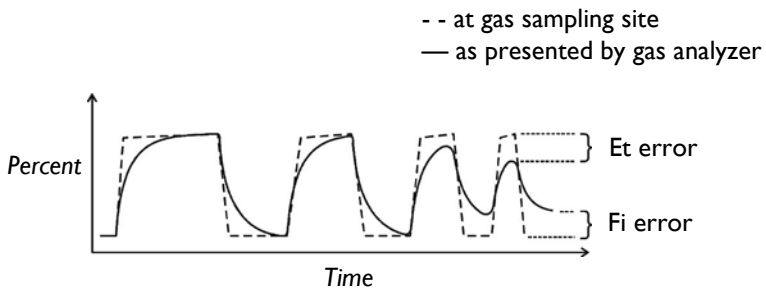
During the first hour after the system has been turned on and flowing oxygen greater than 50 percent, the CO2 waveform periodically baselines to complete reference measurement; however, the measurement numeric values remain. Once the system reaches ambient temperature this condition will cease to occur.

To perform a manual zero reference adjustment

Step	Action
1	Select the CO2 VS box. The **CO2** menu appears. Current settings are displayed.
2	Select **Zero Cal**. Allow the process to complete, typically 10–12 seconds.

Breath Rate Distortion

The effect of rise time distortion to the gas curve becomes apparent when the breathing rate increases so that the time for a full inspiratory or expiratory event gets shorter. In those situations, due to the effect of the rise time, the gas curve does not reach the true end-tidal (or first inspired value) and the end-tidal gas value may then be underestimated. Correspondingly, the first inspired value may be overestimated. Below is an exaggerated illustration of the effect.



The breath rate limit for accurately resolved end-tidal gas values (at an I:E ratio of 1:1) may be found in Appendix A. The effect of other I:E ratios may be calculated by determining the length of the shortest inspiratory/expiratory event that can be resolved accurately:

$$t_{resolved} = 60 / (2 \times BR_{limit}(1:1)$$

$$BR_{limit}(I:E) = 60 / ((I + E) \times t_{resolved})$$

The difference in these results when compared to the rise time's specification is that rise time's only tests 10-90% performance. This specification is for (0 + accuracy) to (100 - accuracy) % and is thus much tougher. The ability to properly resolve end-tidal values can be measured by using the set-up described in ISO 80601-2- 55:2011 figure 201.101. In short, the method consists of sampling gas from two different sources connected to an electrically controlled pneumatic valve to permit rapid switching between the two sources. During the test, the valve is set to switch gas source at a number of frequencies (simulating the range of specified breath rates) and for each frequency the end-tidal value presented by the gas analyzer is noted. From a diagram of end-tidal value over frequency, the frequency at which the gas analyzer is no longer able to resolve end-tidal values according to specification is identified. This ability to properly resolve end-tidal values is listed in the specification.

CO2 Low Flow and Occlusion Conditions

CO2 Low Flow will be displayed and an alarm will sound in the event of a low flow condition (whenever the gas flow falls to an amount that is 10 percent less than the sample flow rate for the selected patient type), as shown in the table below.

Patient Type	Sample Flow Rate	Flow Rate when Low Flow is Declared
Adult	200 ml/min	≤ 180 ml/min
Pediatric	200 ml/min	≤ 180 ml/min
Neonate	150 ml/min	≤ 135 ml/min

Occlusion will be displayed and an alarm will sound in the event of an occlusion condition (whenever the gas flow rate has fallen below 40 ml/min for at least 1 second. The typical cause of

the low flow or the occlusion condition is due to a pinched sampling line, or a blocked sampling line due to excessive moisture from patient expiration.

Selecting AGENT Accessories

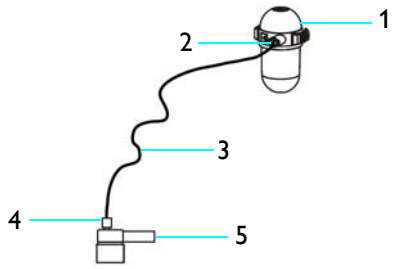
Various accessories are available for use with the AGENT option. For example, when monitoring patients on a breathing circuit, a sample of the respiratory gas is drawn from the patient's breathing circuit through an airway adapter and sampling line, or when patients are not on a breathing circuit, the sample is drawn through a nasal cannula. When selecting AGENT accessories (see page 1-34 for a listing), consider the following:

- The type of patient (adult, pediatric, or neonatal)
- The condition of the patient
- Whether the patient is on a breathing circuit
- Whether the patient is receiving supplemental oxygen
- All accessories are single use.

AGENT Tubing Preparation

Various pneumatic circuit configurations for use with the AGENT option are illustrated below:

- Monitoring using the airway adapter



1 Water trap

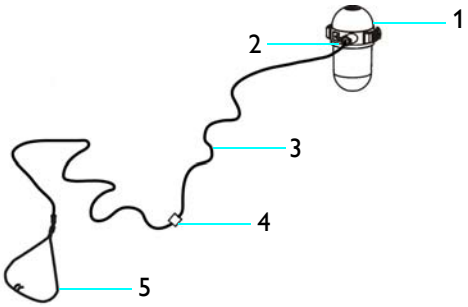
2 Sample port (with Luer lock connector)

3 Sampling line

4 Luer lock connector

5 Airway adapter connected to the patient airway

- Monitoring using the nasal cannula



1 Water trap

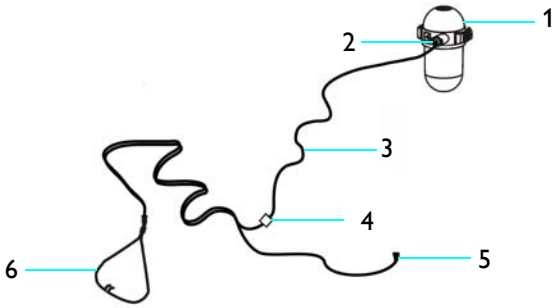
2 Sample port (with Luer lock connector)

3 Sampling line

4 Luer lock connector

5 Nasal cannula connected to a patient airway

- Monitoring using a divided nasal cannula (when delivering O2 to the patient)



1 Water trap

2 Sample port (with Luer lock connector)

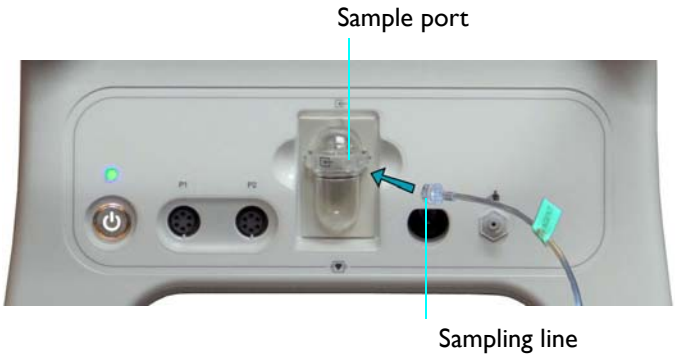
3 Sampling line

4 Luer lock connector

5 Large tubing connector to patient O2 source

6 Divided nasal cannula connected to a patient airway

To prepare the AGENT tubing

Step	Action
1	Ensure that the water trap has been installed in the water trap receptacle (see page 9-13 for installation instructions).
2	Insert the Luer lock connector on the sampling line (REF 94018) into the sample port on the water trap and then tighten the connector (no more than one half-turn should be required). 
3	According the type of pneumatic circuit required to perform AGENT monitoring, connect the pneumatic circuit items (see the diagrams above). Where equipped with a Luer lock, only a half-turn of the Luer lock connector should be required where equipped; otherwise, ensure that any tubing connector has been pressed firmly onto the associated adapter.
4	Verify that each connection is tight by holding the nasal prongs (or the patient airway adapter) close to your ear and listening for a hissing sound. Increase the flow temporarily if necessary and then reduce to the prescribed flow rate once the flow is verified.
5	On a daily basis, perform a system test; see page 9-8 for details.
6	Apply the sampling line to the patient (see page 9-10).

WARNINGS

- **Remove the sampling line from the patient airway whenever nebulized medications are being delivered.**
- **Continuous exposure to waste anesthetic gases (including halogenated agents and nitrous oxide) is not recommended. Always connect a line between the system's waste gas port and your facility's gas scavenging/evacuation system. Avoid venting any waste anesthetic gas directly into the room air as exposure to these gases above the recommended OHSA limits could result.**
- **Do not block the waste gas port on the system. Ensure that the exhaust gas is not removed from the system under too strong a vacuum. (To prevent this condition, there must always be an opening to the room air.) Too high a vacuum level will change the operating pressure of the system and cause inaccurate readings or internal damage.**
- **Use only approved sampling lines and AGENT accessories, as other sampling lines and accessories will cause inaccurate readings and malfunctions.**
- **Replace the sampling line, replace the airway adapter, and inspect the water trap between each patient use.**

CAUTIONS

- Do NOT over-tighten the sampling line connection to the water trap; only a half-turn should be needed. Over-tightening this connection may damage the water trap and cause failure of the trap assembly.
- Regularly inspect the line to facility's gas scavenging system for deterioration, and replace the line if necessary.

Pre-Use System Checks

Prior to using the system for AGENT monitoring, it is recommended that the following initial checks be performed at least once.

Step	Action
1	After the pneumatic tubing has been prepared as directed above (page 9-5), turn on the system and activate **AGENT** in the **Monitor Setup** > **Parameters** menu; see page 3-18. If **Agent HW Fail - O2 Sensor** is displayed after activation of the parameter, replace the O2 sensor as described on page 14-13.

Step	Action
2	Allow the AGS system to run and sample room air for at least 1 minute. The FiO2 reading displayed in the GAS VS box should be approximately 21 percent. If the reading remains outside this range for more than 1 minute after first checking the reading, replace the oxygen sensor as described in chapter 14.
3	After allowing the AGS system to run for at least 1 minute, pinch or seal the input line (to the water trap) for 5 seconds and verify that **Occlusion** is displayed. If this message does not appear, check all tubing connections for leakage and retest.

WARNINGS

- **Always test sampling line adapter for a tight connection and proper operation before attaching to a patient. Over-tightening the sampling line connection may damage the water trap. Tighten the sampling line connector no more than one half-turn. Over-tightening this connector can cause failure of the water trap assembly and inaccurate patient gas measurements.**
- **Inspect water trap and AGENT accessories before use. If the sampling line, connector or sample 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 patient tubing. Avoid kinking of the patient sampling line as 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 AGENT, CO2, O2, N2O values to be too low. Always connect all components securely and check for leaks according to standard clinical procedures. Displacement of the nasal cannula or patient airway adapter can cause lower than actual readings.**
- **If AGENT, CO2, O2, N2O 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.**

CAUTION

Routinely inspect the hose assemblies for proper attachment and orientation. Replace hose assemblies with cracks, holes, tears, or cuts that could cause leaks in the system. If hose assemblies with damage that could result in leaks are used, prolonged and/or inaccurate patient readings could result.

Note

Always inspect the patient sampling line after attachment to the MR400. If questionable anesthetic agent gas measurements are observed, recheck the patient connections, the anesthesia gas machine, and/or the vaporizer before readjusting anesthesia delivery.

Applying the Sampling Line to the Patient

Select the AGENT patient accessory that is appropriate for the patient size and application. Patient nasal cannulas and sampling lines with an 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.

CAUTION

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.

To apply the nasal cannula to the patient

Step	Action
1	Ensure that the nasal cannula is clean, dry and undamaged. Replace the cannula if necessary.
2	Position the cannula on the patient's face by inserting the nasal prongs into the nostrils. 

Step	Action
3	Pass the tubing over the ears and behind the head, ensuring the patient's head will not rest on any part of the cannula while the patient is lying down. 
4	Slide the sleeve toward the patient's head to assure a good fit of the cannula. 
5	Select the **Patient Type**. See *Selecting the Patient Type* on page 3-11.
6	Check that the connections have been made correctly by verifying the patient's breathing efforts with the displayed CO2 waveform. **WARNING** **Before completion of patient setup, ensure that the patient's breathing efforts coincide with the displayed CO2 waveform.**
7	After allowing the AGS system to run for at least 1 minute, pinch or seal the sampling line for 5 seconds and verify that **Occlusion** is displayed. If this message does not appear, check all tubing connections for leakage and retest.

To apply the sampling line airway adapter

Step	Action
1	Ensure that the sampling line is clean, dry and undamaged. Replace the sampling line if necessary.

Step	Action
2	Place the airway adapter at the proximal end of the airway circuit. **CAUTION** Always insert the patient sampling line into the water trap 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. ***Note*** *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.*
3	Select the **Patient Type**. See *Selecting the Patient Type* on page 3-11.
4	Check that the connections have been made correctly by verifying the patient's breathing efforts with the displayed CO2 waveform. **WARNING** **Before completion of patient setup, ensure that the patient's breathing efforts coincide with the displayed CO2 waveform.**
5	After allowing the AGS system to run for at least 1 minute, pinch or seal the sampling line for 5 seconds and verify that **Occlusion** is displayed. If this message does not appear, check all tubing connections for leakage and retest.

Water Trap Replacement

The water trap is intended to protect the AGENT system from humidity, secretions, bacterial contamination and dust. Replacement of the water trap is necessary when the contents in the water trap reach its full line.

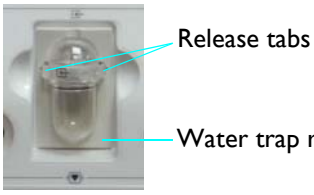
CAUTION

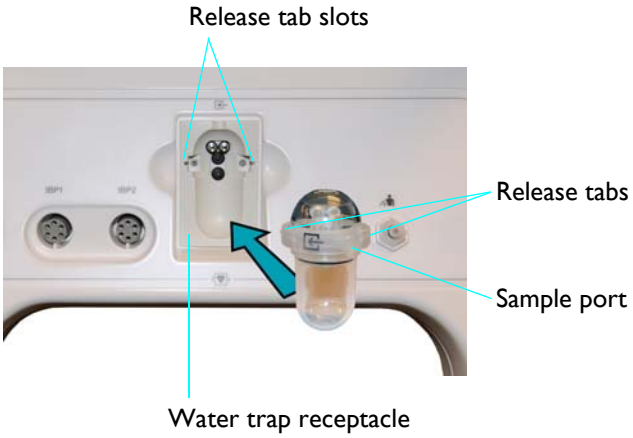
Always discard the water trap when it becomes filled. Do not attempt to clean or reuse the water trap. Accidental water ingress into the system can affect the gas measurements.

Notes

- *The water trap must be checked every 17 hours of use and replaced as necessary. (Dispose of the trap according to your facility's biohazard procedure.)*
- *For optimum fit and compatibility, use only Invivo (Royal Philips) specified parts.*

To replace the water trap

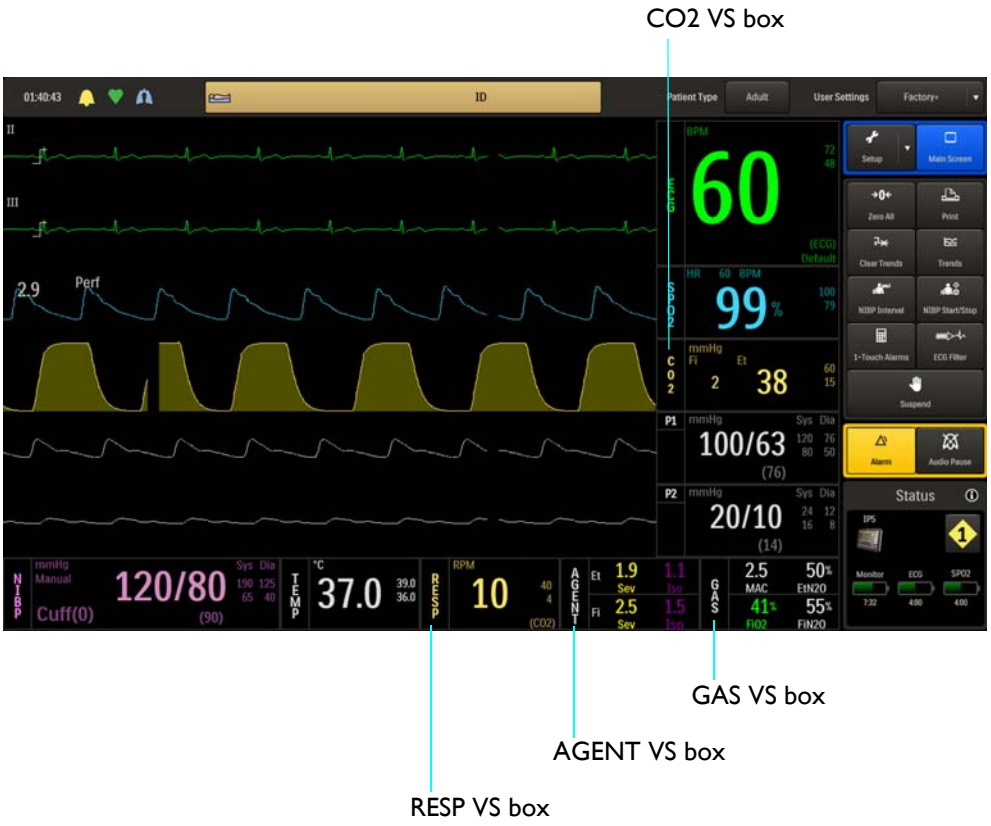
Step	Action
1	If a sampling line is connected, then remove the sampling line from the sample port on the water trap. 
2	While simultaneously pressing both release tabs on the water trap, remove the water trap from the water trap receptacle then dispose of the water trap properly. 

Step	Action
3	With the new water trap positioned so that the sample port is facing toward you, align the trap's release tabs to the release tab slots in the water trap receptacle. Press the water trap into the water trap receptacle until audible "clicks" are heard as both of the release tabs lock into the release tab slots. 
4	Attach the sampling line to the sample port.

AGENT and GAS VS Boxes

AGENT option measurements are displayed in several areas:

- Primary and secondary agent gas measurements are displayed as numeric information in the AGENT VS box.
- N2O, O2, and MAC measurements are displayed as numeric information in the GAS VS box.
- CO2 measurements are displayed as a waveform in the VS trace area of the screen and as numeric information in the CO2 VS box—where depending upon the **RESP** > **Source** setting, CO2-derived respiration information may appear in the RESP VS box.



Multiple (Mixed) Agents

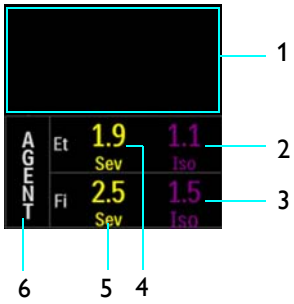
Whenever two or more anesthetic agent gases of detectable concentrations are sensed by the AGS system or when the agent gases in the inspired and end-tidal breath phases are pure but differ from one another, a multiple agents condition exists and **Multiple Agents** will be displayed.

It is common for a multiple agents condition to occur during the transition from one anesthetic agent to another, such as when one agent is used to induce a patient and another agent is used to maintain the sedated state.

Note

Some hydrocarbons (for example, acetone or methane) will cause a Multiple Agents alarm to occur.

AGENT VS Box



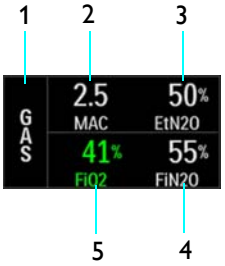
Item	Name	Definition
1	Alarm flag area	Displays AGENT alarm flags when detected; see page 4-31.
2	Secondary agent Et numeric	Is the patient's detected concentration and type of secondary end-tidal agent, in volume percent *
3	Secondary agent Fi numeric	Is the patient's detected concentration and type of secondary fractional inspired agent, in volume percent *
4	Primary agent Et numeric	Is the patient's detected concentration and type of primary end-tidal agent, in volume percent *
5	Primary agent Fi numeric	Is the patient's detected concentration and type of primary fractional inspired agent, in volume percent *
6	AGENT VS box label	Indicates the Agent parameter, and accesses the MAC window

** Values displayed to the nearest 0.1 percent*

Notes

- *No data indication is denoted by three dashes (---) in the agent measurement numeric values (see page 2-20 for an example). When the agent vaporizer is first turned on, it may take 30–90 seconds for agent identification and readings to be displayed. Once identification is established, changes in concentration readings are virtually immediate.*
- *With a 200 percent change in concentration, an auto zero will occur and full accuracy of the changed concentration will be accomplished within approximately 30 seconds.*
- *For the identified agent gases, these abbreviations (and colors) are used:*
  - *Desflurane – Des (light blue)*
  - *Enflurane – Enf (orange)*
  - *Halothane – Hal (pink)*
  - *Isoflurane – Iso (purple)*
  - *Sevoflurane – Sev (yellow)*

GAS VS Box



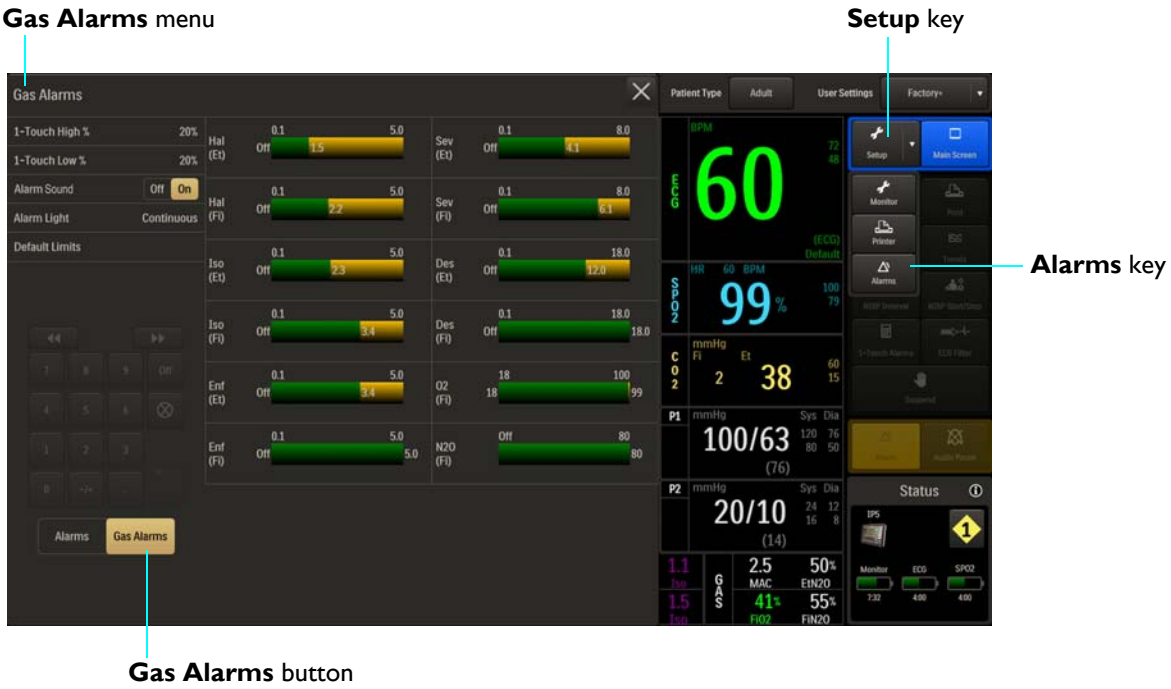
Item	Name	Definition
1	GAS VS box label	Indicates the gas parameter
2	MAC numeric	Is the total MAC value (see MAC Window on page 9-20)
3	EtN2O numeric	Is the patient's detected end-tidal nitrous oxide concentration in percent
4	FiN2O numeric	Is the patient's detected fractional inspired nitrous oxide concentration in percent
5	FiO2 numeric	Is the patient's detected fractional inspired oxygen concentration in percent

Note

No data indication is denoted by three dashes (---) in the numeric values (see page 2-20 for an example). When AGENT is turned on, it may take 30–90 seconds for gases identification and readings to be displayed. Once identification is established, changes in concentration readings will be virtually immediate.

Changing the AGENT and GAS Alarm Limits

The **Gas Alarms** menu can be accessed by touching the **Setup** key and then the **Alarms** key. On the **Alarms** menu, select the **Gas Alarms** button.



Lower and upper alarm limit settings for agents and gases are illustrated below.

1 Sev (Et) – (Sevoflurane [End-tidal])

2 Sev (Fi) – (Sevoflurane [Fractional inspired])

3 Des (Et) – (Desflurane [End-tidal])

4 Des (Fi) – (Desflurane [Fractional inspired])

5 O2 (Fi) – (Oxygen [Fractional inspired])

6 N2O (Fi) – (Nitrous oxide [Fractional inspired])

7 Enf (Fi) – (Enflurane [Fractional inspired])

8 Enf (Et) – (Enflurane [End-tidal])

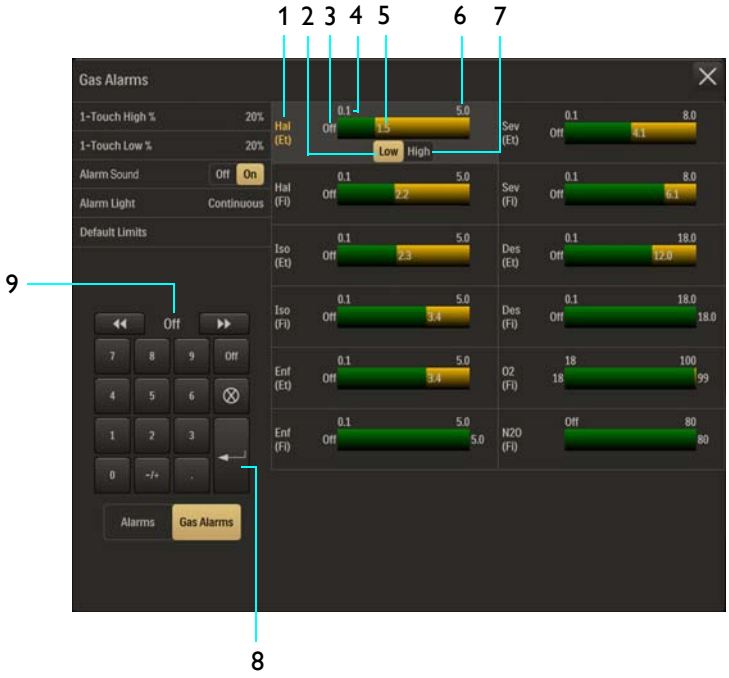
9 Iso (Fi) – (Isoflurane [Fractional inspired])

10 Iso (Et) – (Isoflurane [End-tidal])

11 Hal (Fi) – (Halothane [Fractional inspired])

12 Hal (Et) – (Halothane [End-tidal])

Individual alarm limit settings can be adjusted by selecting the parameter that you want to change on the **Gas Alarms** menu.



1 Agent or gas alarm limits label (active adjustment shown)

2 **Low** button

3 Lower alarm limit setting

4 Alarm limit, minimum

5 Upper alarm limit setting

6 Alarm limit, maximum

7 **High** button

8 **Enter** button

9 Current adjustment

To change an individual alarm limit setting in the Gas Alarms menu

Step	Action
1	Touch the agent or gas parameter that you want to change on the **Gas Alarms** menu. The selection appears on a highlighted background. (HAL [Et] was selected for this example.) Current settings are displayed.
2	Select the **Low** button or the **High** button. The selected button will be highlighted and the current adjustment will be displayed.
3	Using the keypad, or the **increment**, **decrement**, or **Off** buttons, enter the desired setting. The current adjustment will reflect the setting.
4	Press the **Enter** button to save the setting. The alarm limit setting is updated.
5	To change the remaining setting, repeat steps 2, 3, and 4. The current adjustment will reflect the change.
6	To change any remaining alarm limit settings, repeat steps 1, 2, 3, and 4.
7	Press the **Main Screen** key to close the menu.

Note

See chapter 4 for detailed alarm limit setting instructions and options.

MAC Window

Detected anesthetic vapor strengths of the expired gases contribute to the MAC (Minimum Alveolar Concentration) value and are provided in the MAC window.

WARNING

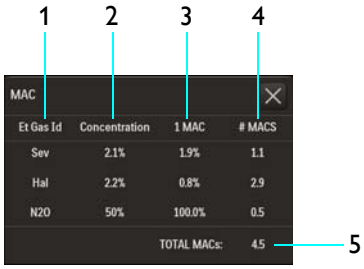
MAC values are empirical, not absolute values. The MAC values correspond to those of healthy adults and cannot be applied to children. Age and other individual factors influencing the behavior of volatile agents are not taken into account.

To open the MAC window

Select the AGENT or the GAS VS box (see page 9-14 for the location).

Note

*If **AGENT** is set to **Single** in the **System Config** menu, the MAC window will display **Mixed Agents Not Included In MAC Calculation**.*



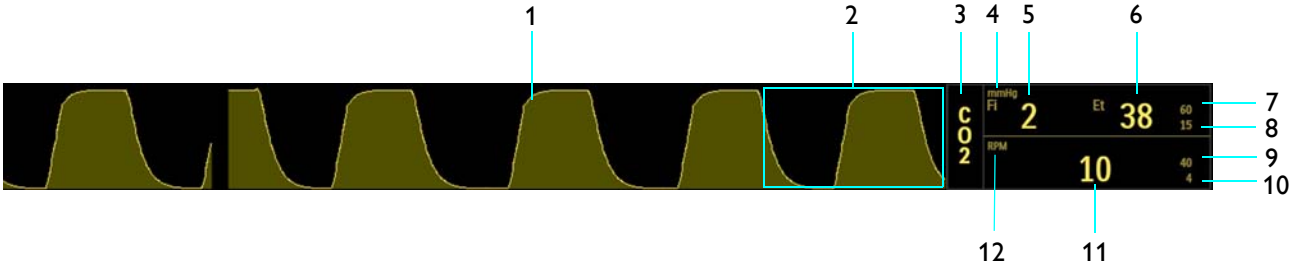
Item	Name	Definition
1	Et Gas Id	Is the identifier for the given end-tidal gas
2	Concentration	Is the current concentration of the given gas, in percent
3	1 MAC	Is the minimum alveolar concentration for the given gas at which 50 percent of a patient population does not respond with movement to a noxious stimulus, such as skin incision; see table below.

Gas	1 MAC Value
DES (Desflurane)	6.00 volume%
ENF (Enflurane)	1.70 volume%
HAL (Halothane)	0.77 volume%
ISO (Isoflurane)	1.15 volume%
SEV (Sevoflurane)	2.10 volume%
N2O (Nitrous oxide)	105 percent

Item	Name	Definition
4	# MAC	Is the MAC value that each individual gas contributes to the total MAC value, calculated by C/M, where: C = the current concentration of the given gas M = the 1 MAC value for the given gas
5	TOTAL MACs	Is the total MAC value, which is equal to the sum of the values in the # MAC column, calculated using the following formula: TOTAL MAC = EtN_2O / (1 MAC N_2O) + (Et 1^{st} Agt) / (1 MAC 1^{st} Agt) + (Et 2^{nd} Agt) / (2 MAC 2^{nd} Agt) Where: • EtN_2O = The current value of end-tidal nitrous oxide • 1 MAC N_2O = The 1 MAC value for nitrous oxide • Et 1^{st} Agt = The current concentration of the primary agent gas • Et 2^{nd} Agt = The current concentration of the secondary agent gas • 1 MAC 1^{st} Agt = The 1 MAC value for the current primary agent gas • 2 MAC 2^{nd} Agt = The 2 MAC value for the current secondary agent gas

CO2 Waveform and VS Box

The CO_2 measurement is displayed as a waveform in the VS trace area of the screen and as numeric information in the CO2 VS box. Other data, including CO2-related alarm information, are also provided in this area of the screen. (CO2 [RESP] information can be displayed in the CO2 VS box or in the RESP VS box, as detailed below.)

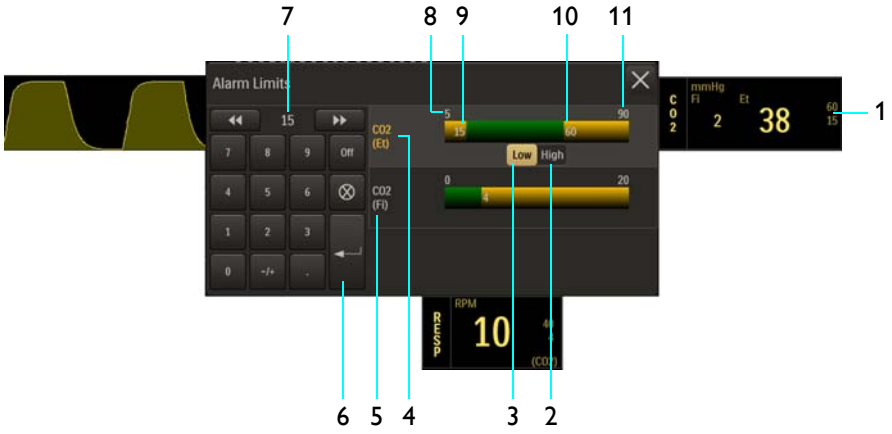


Item	Name	Definition
1	CO2 VS waveform	Is the detected CO2 waveform (Trace D) ***Note*** *To change the waveform speed, see Resp Speed on page 3-25.*
2	Alarm flag area	Displays CO2 alarm flags when detected; see page 4-31.
3	CO2 VS box label	Indicates the CO2 vital sign parameter, and accesses the **CO2** menu
4	Unit of measure	Indicates that the gas measurement numeric values are given in mmHg (millimeters of mercury) or kPa (kilopascals); see page 9-26.
5	FiCO2 numeric	Is the patient's detected fractional inspired CO2 measurement
6	EtCO2 numeric	Is the patient's detected end-tidal CO2 measurement
7	EtCO2 upper alarm limit	Is the upper limit setting for the end-tidal CO2 alarm, and accesses the **CO2 (Et) Alarm Limits** menu
8	EtCO2 lower alarm limit	Is the lower limit setting for the end-tidal CO2 alarm, and accesses the **CO2 (Et) Alarm Limits** menu
9	Respiration rate upper alarm limit	Is the upper limit setting for CO2-derived respiration rate alarm, and accesses the **CO2 (RESP) Alarm Limits** menu
10	Respiration rate lower alarm limit	Is the lower limit setting for CO2-derived respiration rate alarm, and accesses the **CO2 (RESP) Alarm Limits** menu
11	Respiration rate numeric	Is the patient's detected respiration rate measurement, as derived from CO2
12	Unit of measure	Indicates that the respiration rate numeric is given in RPM (respirations per minute)

*When **Source** is set to **BEL** in the **RESP** menu (see page 10-5), the CO2 VS box will also contain CO2-derived respiration rate elements, as indicated by the shaded rows and illustration above; otherwise, this information will be displayed in the RESP VS box (see page 9-25).*

Changing the CO2 and CO2 (RESP) Alarm Limits

The **CO2 (Et)** and **CO2 (Fi) Alarm Limits** menu can be accessed by touching the alarm limit settings in the CO2 VS box.



1 Alarm limit settings, CO2 (Et), CO2 VS box

2 **High** button

3 **Low** button

4 **CO2 (Et) Alarm Limits** menu label (active adjustment shown)

5 **CO2 (Fi) Alarm Limits** menu label

6 **Enter** button

7 Current adjustment

8 Alarm limit, minimum

9 Lower alarm limit setting

10 Upper alarm limit setting

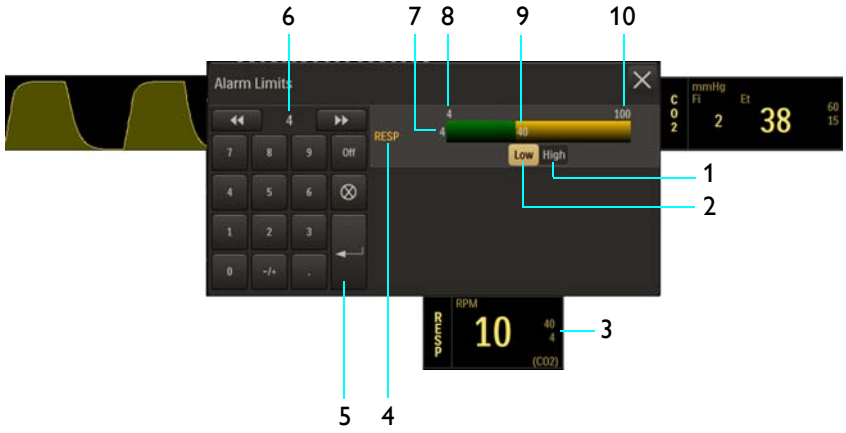
11 Alarm limit, maximum

To change the CO2 (Et) and CO2 (Fi) alarm limit settings

Step	Action
1	Select the (Et) CO2 alarm limit settings in the CO2 VS box. The **CO2 Alarm Limits** menu appears. Current CO2 (Et) settings are displayed.
2	Select the CO2 alarm limits menu, **CO2 (Et)** or **CO2 (Fi)**, that you want to change. The associated menu appears. Current settings are displayed.
3	Select the **Low** button or the **High** button. The selected button will be highlighted and the current adjustment will be displayed.

Step	Action
4	Using the keypad, or the **increment**, **decrement**, or **Off** buttons, enter the desired setting. The current adjustment will reflect the setting.
5	Press the **Enter** button to save the setting. The alarm limit setting is updated.
6	To change the remaining settings, repeat steps 2–5. The current adjustment will reflect the change.

At the default setting, the **CO2 (RESP) Alarm Limits** menu can be accessed by touching the alarm limit settings in the RESP VS box.



1 **High** button

2 **Low** button

3 Alarm limit settings, CO2 (RESP), RESP VS box

4 **CO2 (RESP) Alarm Limits** menu label

5 **Enter** button

6 Current adjustment

7 Lower alarm limit setting

8 Alarm limit, minimum

9 Upper alarm limit setting

10 Alarm limit, maximum

To change the CO2 (RESP) alarm limit settings

Step	Action
1	Select the CO2 (RESP) alarm limit settings in the RESP VS box (or, in the CO2 VS box, see page 9-22.) The **CO2 (RESP) Alarm Limits** menu appears. Current settings are displayed.
2	Select the **Low** button or the **High** button. The selected button will be highlighted and the current adjustment will be displayed.
3	Using the keypad, or the **increment**, **decrement**, or **Off** buttons, enter the desired setting. The current adjustment will reflect the setting.
4	Press the **Enter** button to save the setting. The alarm limit setting is updated.
5	To change the remaining setting, repeat steps 2, 3, and 4. The current adjustment will reflect the change.

Note

See chapter 4 for detailed alarm limit setting instructions and options.

Changing the Unit of Measure

To change the unit of measure

Step	Action
1	Press the **Setup** key and then the **Monitor** key. The **Monitor Setup** menu appears. Current settings are displayed.
2	On the **Monitor Setup** menu, select **Service(Bio-Med)**. The **Service(Bio-Med)** sub-menu appears.
3	On the **Service(Bio-Med)** menu, select **System Config**. The **System Config** menu appears. Current settings are displayed.

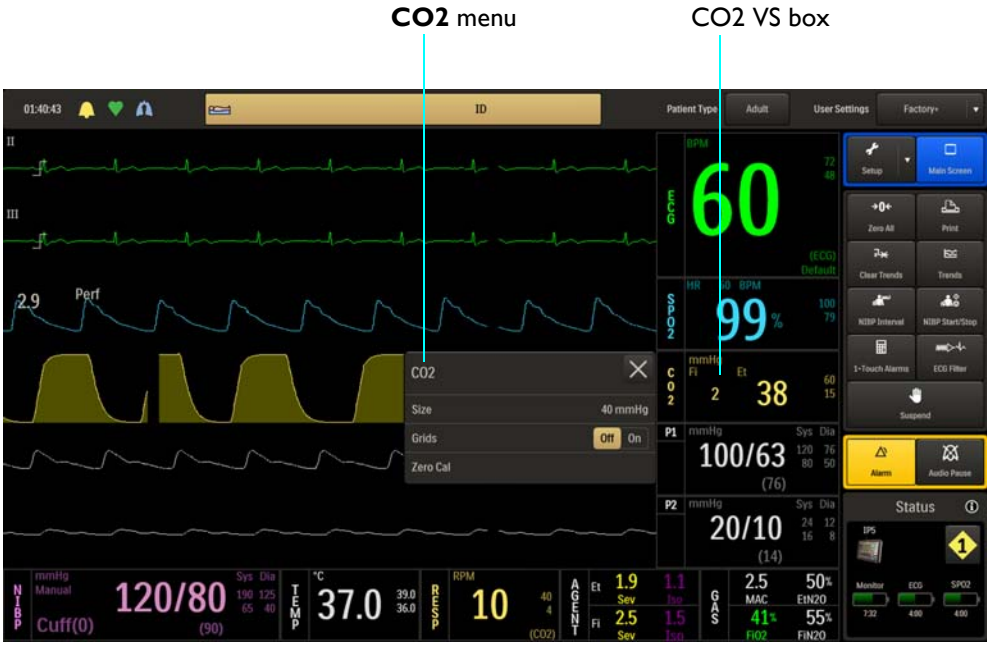
Step	Action
4	On the **System Config** menu, select **Gas Units**. The **Gas Units** menu appears. The current setting is highlighted.
5	Select the desired unit of measure: **mmHg** **kPa** The setting is changed.

CO2 Menu

The **CO2** menu allows you to control the CO2 (Et) and CO2 (RESP) monitoring functions and settings.

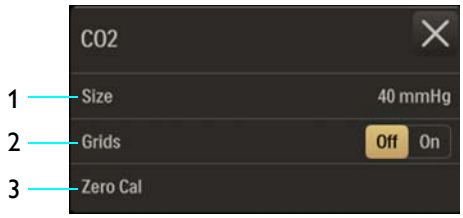
To open the CO2 menu

Select the CO2 VS box.



The following **CO2** menu items are available:

1 **Size**
2 **Grids**
3 **Zero Cal**



Note

Apnea *and* ***Apnea Time*** *will be in the* ***CO2*** *menu when bellows (****BEL****) is the selected* ***RESP > Source****; see page 10-7 for setting details.*

To change settings in the CO2 menu

Step	Action
1	Select the CO2 VS box. The **CO2** menu appears. Current settings are displayed.
2	Touch the menu item to select one of the following CO2 options: **Size** **Grids** **Zero Cal** The menu item appears. The current setting is highlighted.
3	Select the desired setting from the menu options (except **Grids**, which is selectable on the **CO2** menu). The setting is entered.
4	To change other settings, repeat steps 2 and 3.

Size

Controls the size of the CO2 waveform.

The following options are available:

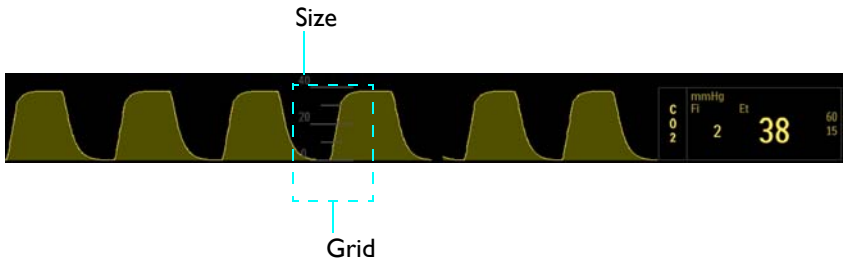
- **40 mmHg** (Default)
- **60 mmHg**
- **80 mmHg**

To adjust the grid size for the CO2 waveform

Step	Action
1	Select the CO2 VS box. The **CO2** menu appears. Current settings are displayed.
2	Select **Size**. The **Size** menu appears. The current setting is highlighted.
3	Select the desired size: **40 mmHg** **60 mmHg** **80 mmHg** The setting is changed.

Grids

Displays a scaled grid, which is graduated according to the **Size** selection for the CO2 waveform.



The following options are available:

- **Off** does not display a grid. (Default)
- **On** displays a grid.

Note

Grids *will not be displayed during a* ***CO2 Accuracy Check****; see page 3-30.*

To control the display function of the CO2 grid

Step	Action
1	Select the CO2 VS box. The **CO2** menu appears. Current settings are displayed.
2	Locate **Grids** and select the desired setting: **Off** **On** The setting is entered.

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. **Zero Cal** is not required when switching sampling lines. The maximum time required for calibration is approximately 10–12 seconds.

To perform a zero calibration

See page 9-2.

CHAPTER 10

Monitoring RESP

When equipped with the CO2 or AGENT option, the patient's respiration rate can be measured as the time interval between detected breaths. Alternatively, the patient's respiration rate can be measured using the pneumatic bellows and the wSpO2 module.

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

CO2-derived respiration is calculated by measuring the time interval between detected breaths; see chapter 7 (if equipped with the LoFlo option) or chapter 9 (if equipped with the AGENT option) for detailed monitoring information. For RESP VS box functions when CO2-derived respiration is the source, see page 10-3.

Monitoring Respiration using the Bellows

Bellows-derived respiration is monitored by detecting abdominal or chest wall motion using the pneumatic bellows device (REF 989803152791) and the wSpO2 module.

The bellows may be used in the MR system bore, although the module must not be placed within the MR system bore. Note that there are no alarms for the bellows-derived respiration rate as it is not intended for vital sign monitoring.

CAUTION

If dropped, the wSpO2 module must be verified for correct operation before use; see page 14-12.

Note

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

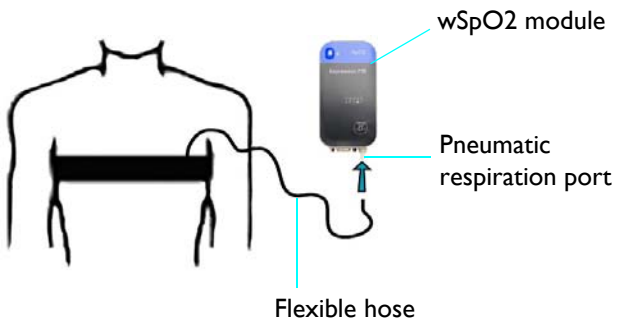
Bellows Preparation

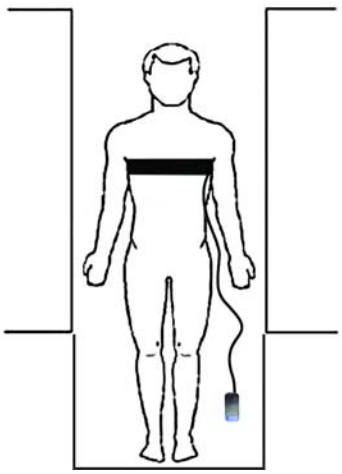
Respiration measurements that are determined using the bellows method make chest wall expansion very important for accurate monitoring of a patient's breathing. If the respiratory signal appears to weaken between scans, instruct the patient to breathe more deeply during the scan to create more movement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

CAUTIONS

- Avoid excessive bending of the flexible hose, as this can impair respiration detection.
- Always apply the bellows to the patient prior to connecting the pneumatic respiration hose to the port on the wSpO2 module; otherwise damage to the module can result.

To position the respiratory sensor

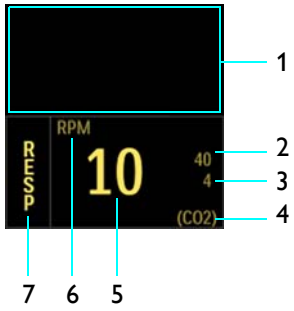
Step	Action
1	Place the sensor on the patient's upper abdomen or lower chest (whichever expands most during inspiration).
2	After the patient has exhaled, place the velcro strap around the patient's trunk and secure the sensor snuggly.
3	Connect the flexible hose from the bellows to the pneumatic respiration port on the wSpO2 module. 
4	Check the battery indicator on the wSpO2 module to ensure that enough charge exists: • Green battery indicator = Charge sufficient; proceed to step 6. • Red battery indicator = Charge low; proceed to step 5. See page 2-11 for details. (Also, you can reference the status information pane; see page 2-16.)
5	Insert a charged module battery into the wSpO2 module and then recheck the battery indicator to ensure a sufficient charge before proceeding; see page 1-26.

Step	Action
6	Check the network channel indicator on the wSpO2 module to ensure communication is established with the MR400: • Steady = Good communication; proceed to step 7. • Flashing = No communication; proceed to step 6. See page 2-11 for details. (Also, you can reference the status information pane; see page 2-16.)
7	Ensure that the wSpO2 module is within 9.1 m (30 feet) of the MR400, in the same MRI room or in the same shielded room, and is set to the same wireless network channel used by the MR400; see page 1-29.
8	Select the **Patient Type**. See *Selecting the Patient Type* on page 3-11.
9	Ensure that the parameter is working by checking the displayed respiratory numeric in the VS box.
10	Position the patient in the MR system, keeping the wSpO2 module outside the MR system bore. Ensure that the flexible hose is routed away from any moving parts so that it does not get caught in the mechanisms (for example, between the tabletop and the patient support). 
11	Place the wSpO2 module on a cushioned surface to minimize MR vibrations.

Respiration VS Box

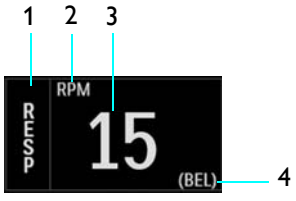
Depending upon the **Source** selection, respiration measurements are displayed as numeric information in the RESP VS box. Other data, including respiration-related alarm information, are also provided in this area of the screen, as detailed below.

- When **RESP > Source** > **CO2** is selected, the CO2-derived respiration measurement and alarm limit settings (displayed in the same color as the CO2 VS box data) will populate the RESP VS box.



Item	Name	Definition
1	Alarm flag area	Displays CO2 (RESP) alarm flags when detected; see page 4-31.
2	Respiration rate upper alarm limit	Is the upper limit setting for the CO2 (RESP) alarm, and accesses the **CO2 (RESP) Alarm Limits** menu (when **Source** is **CO2**)
3	Respiration rate lower alarm limit	Is the lower limit setting for the CO2 (RESP) alarm, and accesses the **CO2 (RESP) Alarm Limits** menu (when **Source** is **CO2**)
4	Source label	Is the source used for the respiration monitoring, where CO2 is CO2-derived; see page 10-7
5	Respiration rate numeric	Is the patient's detected respiration rate measurement
6	Unit of measure	Indicates that the respiration rate numeric is given in RPM (respirations per minute)
7	RESP VS box label	Indicates the respiration vital sign parameter, and accesses the **RESP** menu

- When **RESP > Source** > **BEL** is selected, the bellows-derived respiration measurement (displayed in white) will populate the RESP VS box.



Item	Name	Definition
1	RESP VS box label	Indicates the respiration parameter, and accesses the **RESP** menu

Item	Name	Definition
2	Unit of measure	Indicates that the respiration rate numeric is given in RPM (respirations per minute)
3	Respiration rate numeric	Is the patient's detected respiration rate measurement
4	Source label	Is the source used for the respiration monitoring, where BEL is bellows-derived; see page 10-7

Changing the CO2 (RESP) Alarm Limits

To change the CO2 (RESP) alarm limit settings:

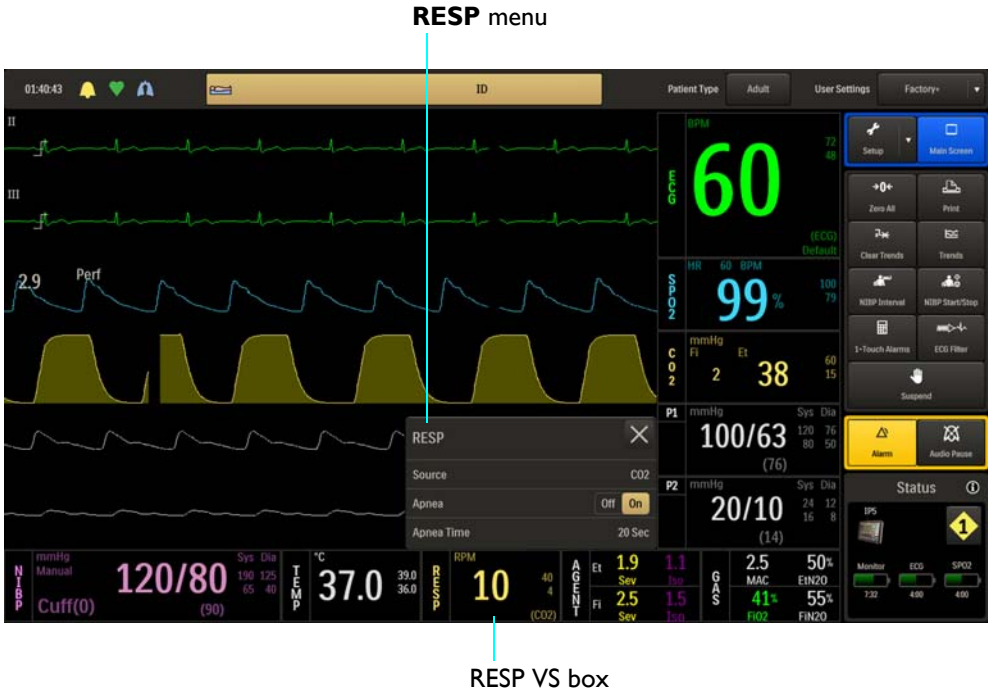
- If equipped with the CO2 LoFlo option, see page 7-9.
- If equipped with the AGENT option, see page 9-23.

RESP Menu

RESP menu items allow you to control respiration functions and settings.

To open the RESP menu

Select the RESP VS box.



The following **RESP** menu items are available:.

1 **Source**

2 **Apnea**

3 **Apnea Time**

Note

*If **RESP** > **Source** > **BEL**, then **Apnea** and **Apnea Time** will be in the **CO2** menu.*

To change settings in the RESP menu

Step	Action
1	Select the RESP VS box. The **RESP** menu appears. Current settings are displayed.

Step	Action
2	Touch the menu item to select one of the following RESP options: **Source** **Apnea** **Apnea Time** The menu item appears. The current setting is highlighted.
3	Select the desired setting from the menu options (except **Apnea**, which is selectable on the **RESP** menu). The setting is entered.
4	To change other settings, repeat steps 2 and 3.

Source

Selects the source used to acquire the respiration rate measurements displayed the RESP VS box.

The following options are available:

- **CO2** calculates the rate by measuring the time interval between detected breaths. (Default, when equipped with the CO2 or AGENT option)
- **BEL** calculates the rate using a pneumatic bellows that measures chest or abdominal movement. No waveform is provided. (If equipped with the CO2 or AGENT option, then the CO2 respiration rate elements will appear in the CO2 VS box.)

To control the source used for respiration

Step	Action
1	Select the RESP VS box. The **RESP** menu appears. Current settings are displayed.
2	Select **Source**. The **Source** menu appears. The current setting is highlighted.
3	Select the desired setting for the respiration rate source: **CO2** **BEL** The setting is changed.

Apnea

WARNING

The respiration measurement does not recognize obstructive and mixed apneas—it only indicates an alarm when a pre-adjusted time has elapsed since the last detected breath. The safety and effectiveness of the respiration measurement method in the detection of apnea, particularly the apnea of prematurity and apnea of infancy, has not been established.

Controls the apnea alarm function, which is declared when the pre-adjusted time (see **Apnea Time**, below) has elapsed since the last breath was detected. Determined from CO2 only, not bellows. Once activated, the alarm will be deactivated when the respiration rate goes above zero.

The following options are available:

- **Off** does not report an apnea alarm.
- **On** reports an apnea alarm when detected. (Default)

To control the apnea alarm function

Step	Action
1	Select the RESP VS box. The **RESP** menu appears. Current settings are displayed.
2	Locate **Apnea** and select the desired setting: **Off** **On** The setting is entered.

Apnea Time

Sets the amount of time to wait before declaring that the apnea condition exists.

The following options (in seconds) are available:

- **20 Sec** (Default)
- **25 Sec**
- **30 Sec**
- **35 Sec**
- **40 Sec**

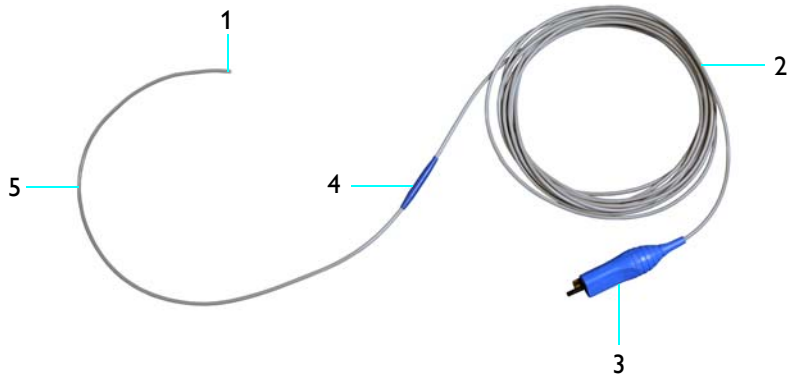
To set the apnea time delay

Step	Action
1	Select the RESP VS box. The **RESP** menu appears. Current settings are displayed.
2	Ensure that **Apnea** is **On**. If **Apnea** is not **On**, enable the setting as described on page 10-8.
3	Select **Apnea Time**. The **Apnea Time** menu appears. The current setting is highlighted.
4	Select the desired time delay (in seconds) for the alarm indication: **20 Sec** **25 Sec** **30 Sec** **35 Sec** **40 Sec** The setting is changed.

CHAPTER 11

Monitoring Temperature

When equipped with the temperature option, the patient's surface or body temperature can be monitored using the reusable sensor, FlexTEMP II Sensor (Esophageal/Rectal/Axillary, Direct Mode), REF 989803194511. The FlexTEMP II Sensor (Esophageal/Rectal/Axillary, Direct Mode), hereafter referred to as the temperature sensor, is designed specifically for use with MR400. The components of the temperature sensor are shown below.



1	Sensing tip
2	Leader
3	Connector
4	Jacket retainer
5	Patient segment

General Usage Precautions

WARNINGS

- **Only use specified temperature accessories as other types or brands may compromise the safety and accuracy of the MR400. Patient injury or loss of monitoring may result if incorrect accessories are used.**
- **During long term monitoring sessions (4 hours or more), frequent medical attention must be given to the sensor site for possible pressure tissue necrosis, especially on the tender skin of neonatal patients.**

CAUTION

The sensor contains no latex, and is constructed of fiber-optic glass. Always handle the sensor with care to prevent damage, as improper handling can result in inaccurate readings. Never bend any portion of the sensor into a radius of less than 15 mm (0.6 inches).

You should observe the following general precautions when using the temperature sensor:

- Ensure that only the FlexTEMP II Sensor (Esophageal/Rectal/Axillary, Direct Mode), REF 989803194511—and if needed sensor jackets (REF 989803178181)—are used with the MR400.
- Never immerse the entire sensor in liquid.
- Never sterilize the sensor.
- Do not tangle, pull or apply excessive force or tension to any portion of the sensor.
- Do not expose the sensing tip to temperatures above 50°C (122°F).
- Do not alter or modify the sensor, as this can affect performance and accuracy and void the warranty.
- Never use strong solvents such as acetone, freon or other industrial cleaners on the sensor.
- After each cleaning and before each use, inspect the sensor for damage (cracks, holes, tears, cuts, et cetera) and always discard a damaged sensor.

Initial Use

Always handle the temperature sensor with care. Upon receiving the temperature sensor, thoroughly clean and disinfect the device before using it on a patient. Use soap and water and CaviWipes® disinfectant towelettes and the suggested method to clean and disinfect the sensor, as the warranty does not cover damage caused by unapproved substances or methods; see *Cleaning, Disinfecting and Inspecting the Accessories*, on page 14-7, for details. Afterward, connect the sensor to the MR400.

CAUTION

The temperature sensor is sold non-sterile.

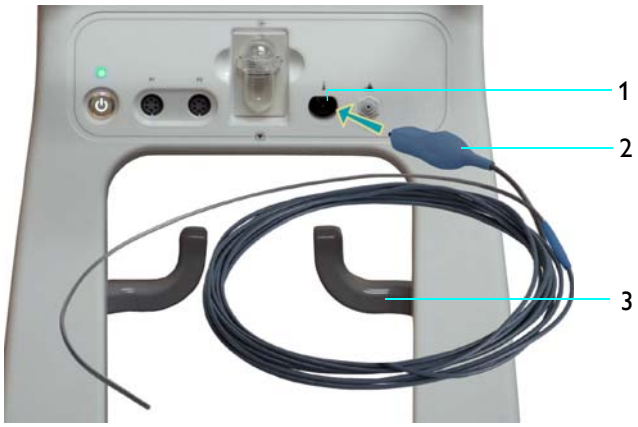
Connecting and Disconnecting the Sensor

CAUTION

When inserting or removing the temperature sensor from the MR400, only use the connector and never pull or apply excessive force or tension to any other portion of the device.

To connect the temperature sensor

Grasp the sensor connector then align the connector to the temperature port on the MR400 and push the connector forward until you feel or hear it “click” into place.



1 Temperature port

2 Sensor connector

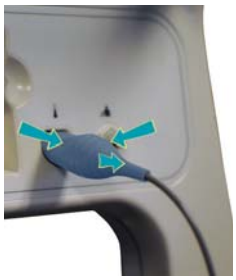
3 Accessory hook

To store the temperature sensor

When not in use, loosely loop the sensor and then drape it over an accessory hook.

To disconnect the temperature sensor from the MR400

Grasp the sides of the connector, and then pull the connector out of the temperature port.



Temperature Measurements

Depending upon the monitoring method (surface or body), follow the corresponding procedure below to make a temperature measurement. Allow at least 2 minutes for measurement stabilization, with or without the sensor cover (jacket).

Note

A temperature difference exists between a patient's surface temperature and body temperature.

Making Surface Temperature Measurements

When making surface temperature measurements, place the temperature sensor at an axillary site according to the steps below.

To make surface temperature measurements

Step	Action
1	Carefully uncoil the sensor, using care to avoid knotting or kinking the device.
2	Clean and disinfect the sensor; see *Cleaning, Disinfecting and Inspecting the Accessories*, on page 14-7, for details.
3	Thoroughly clean and dry the patient's axillary application site. **WARNING** **Do not place the sensor on or near an open wound. Failure to comply may result in patient infection.**
4	Position the sensing tip of the sensor at the axillary site then apply it to the patient.
5	If desired, change the unit of measure (Celsius is the default setting); see *TEMP Menu*, on page 11-10, for details.
6	Perform the monitoring procedure, allowing at least 2 minutes for the measurement to stabilize; see *TEMP VS Box,* on page 11-8, for details.
7	After the procedure, remove the sensor from the patient.
8	Immediately clean and disinfect the sensor (see *Post-Measurement Processing* on page 11-7).

Making Body Temperature Measurements

FlexTEMP System Jackets are mandatory for use with the temperature sensor when making esophageal or rectal (body) temperature measurements. Before making temperature measurements at esophageal or rectal sites, cover the sensor according to the steps below.

WARNINGS

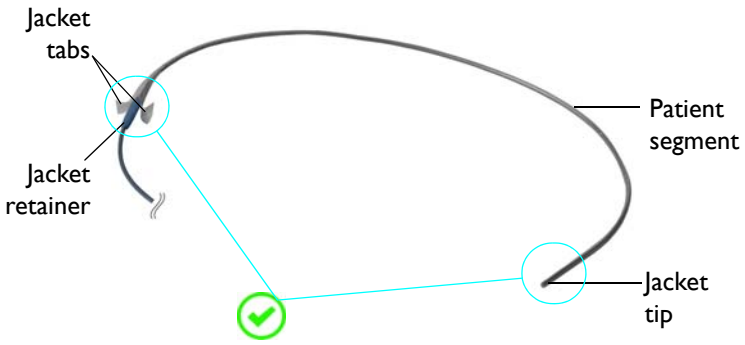
- **Use of FlexTEMP System Jackets are mandatory when using the sensor for body (i.e., esophageal or rectal) site temperature measurements. Failure to comply may result in patient infection.**
- **Always use a new jacket if a different placement area is desired. Once the sensor has been used for esophageal or rectal placement, do not change the location unless a new jacket is installed as patient injury or infection could result.**
- **Do not reuse a FlexTEMP System Jacket, as they are designed for single-use only. Failure to comply may result in patient infection.**

Placing the Temperature Sensor in a Jacket

FlexTEMP System Jackets are sterile polyurethane sensor covers and should be handled accordingly. For optimal storage, jackets should remain sealed in sterile packs in closed cabinets where a moderate temperature and low humidity are maintained. When placing the sensor in a jacket, ensure that the sensing tip is fully inserted and that the jacket tabs extend over the patient segment of the temperature sensor, as described in the steps below.

To place the temperature sensor in a jacket

Step	Action
1	Carefully uncoil the sensor, using care to avoid knotting or kinking the device.
2	Clean and disinfect the sensor; see *Cleaning, Disinfecting, and Inspecting the Accessories*, on page 14-7, for details.
3	Open the indicated end of a jacket package enough to expose the jacket tabs.
4	Insert the patient segment of the sensor into the jacket. Grasp the jacket tabs then carefully pull the jacket completely over the patient segment of the sensor.

Step	Action
5	Ensure that the patient segment of the sensor is completely inserted. There should be no excess space at jacket tip and the jacket tabs should extend over the sensor's jacket retainer. 
6	If needed, secure the jacket tabs to the jacket retainer using medical tape. Follow the steps below to make a body temperature measurement.
7	When ready to apply the sensor to the patient, peel the jacket package open and remove the jacketed sensor, using care not to soil the sterilized jacket. For sensor placement instructions, see *Placing the Sensor at the Body Site*, below.

Placing the Temperature Sensor at the Body Site

WARNING

When inserting the sensor into the mouth, use care not to scrape or tear the jacket on the patient's teeth and ensure that the patient does not bite the sensor, as this could expose the sensor and compromise the infection control features of the jacket.

Note

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

When making body temperature measurements, place the covered sensor at the esophageal or rectal site according to the steps below.

To make body temperature measurements

Step	Action
1	Ensure that a jacket has been placed on the sensor (see *Placing the Sensor in a Jacket,* on page 11-5).
2	If needed, apply lubricant to the jacket for insertion into the patient. **CAUTION** Never use petroleum-based lubricants. A water-based lubricant (for example, Surgical Lubricant, REF 989803168891) can be used to facilitate insertion.
3	Insert the sensing tip of the sensor into the patient at an appropriate depth. **WARNING** **Never insert the sensor beyond the patient segment of the sensor. Insertion beyond the patient segment can lead to difficulties removing the jacket from the patient.**
4	If desired, change the unit of measure (Celsius is the default setting); see *TEMP Menu*, on page 11-10, for details.
5	Perform the monitoring procedure, allowing at least 2 minutes for the measurement to stabilize; see *TEMP VS Box,* on page 11-8, for details.
6	After the procedure, remove the sensor from the patient. **WARNING** **Ensure that the entire jacket is removed from the patient when withdrawing the sensor. Failure to do so can potentially lead to jacket material being left inside the patient.**
7	Immediately clean and disinfect the sensor (see *Post-Measurement Processing* on page 11-7).

Post-Measurement Processing

After monitoring temperature, process the sensor as follows.

To process the temperature sensor after use

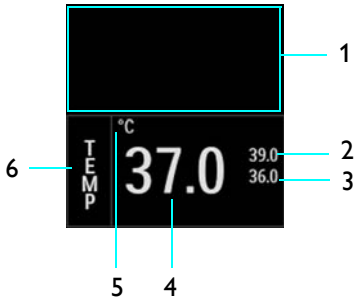
Step	Action
1	If a jacket was placed on the sensor, remove the jacket and any medical tape (if used). Refer to your facility's biohazard procedure for disposal of used jackets and medical tape. Typically, jackets and tape are disposed of as medical waste per facility procedures due to contamination concerns. 
2	Thoroughly clean and disinfect the sensor; see *Cleaning, Disinfecting, and Inspecting the Accessories*, on page 14-7, for details.
3	Store the sensor; see *Connecting and Disconnecting the Sensor*, on page 11-3, for details.

Accuracy Check

No calibration of the temperature sensor is required. If the accuracy of a measurement is in question or if a problem is suspected with the temperature option, perform the user routine-tests; see chapter 14.

TEMP VS Box

The temperature measurement is displayed as numeric information in the TEMP VS box. Other data, including temperature-related alarm information, are also provided in this area of the screen, as detailed below.

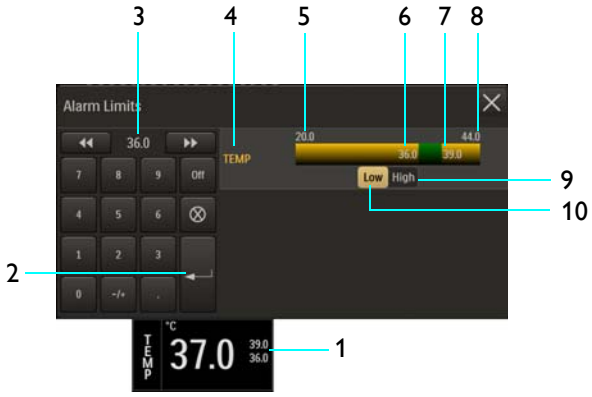


Item	Name	Definition
1	Alarm flag area	Displays TEMP alarm flags when detected; see page 4-31.

Item	Name	Definition
2	Temperature upper alarm limit	Is the upper limit setting for the TEMP alarm, and accesses the **TEMP Alarm Limits** menu
3	Temperature lower alarm limit	Is the lower limit setting for the TEMP alarm, and accesses the **TEMP Alarm Limits** menu
4	Temperature numeric	Is the patient's detected temperature measurement
5	Unit of measure	Indicates that the temperature numeric is given in degrees Celsius (°C) or degrees Fahrenheit (°F)
6	TEMP VS box label	Indicates the temperature vital sign parameter, and accesses the **TEMP** menu

Changing the TEMP Alarm Limits

The **TEMP Alarm Limits** menu can be accessed by touching the alarm limit settings in the TEMP VS box.



1 Alarm limit settings, TEMP VS box

2 **Enter** button

3 Current adjustment

4 **TEMP Alarm Limits** menu label

5 Alarm limit, minimum

6 Lower alarm limit setting

7 Upper alarm limit setting

8 Alarm limit, maximum

9 **High** button

10 **Low** button

Changing the Unit of Measure

To change the unit of measure

Step	Action
1	Select the TEMP VS box. The **TEMP** menu appears. Current settings are displayed.
2	Select **Units**. The **Units** menu appears. The current setting is highlighted.
3	Select the desired unit of measure: **°C** **°F** The setting is changed.

TEMP Menu

The **TEMP** menu item allows you to control the unit of measure for temperature.

To open the TEMP menu

Select the TEMP VS box.

The following **TEMP** menu items are available:

1 Units

Units

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

The following options are available:

- °C (Default)
- °F

To select the unit of measure for temperature

See *Changing the Unit of Measure* on page 11-10.

CHAPTER 12

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.

This monitor uses the oscillometric method for measuring NIBP. Studies show that, especially in critical cases (arrhythmia, vasoconstriction, hypertension, shock), oscillometric devices are more accurate and consistent than devices using other noninvasive measuring techniques.

In adult and pediatric mode, the blood pressure measurements determined with this device comply with the American National Standard for Electronic or Automated Sphygmomanometers (IEC 80601-2-30:2011) in relation to mean error and standard deviation, when compared to intra-arterial or auscultatory measurements (depending on the configuration) in a representative patient population. For the auscultatory reference, the fifth Korotkoff sound was used to determine the diastolic pressure.

In neonatal mode, the blood pressure measurements determined with this device comply with the American National Standard for Electronic or Automated Sphygmomanometers (IEC 80601-2-30:2011) in relation to mean error and standard deviation, when compared to intra-arterial measurements in a representative patient population. 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.**

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

WARNINGS

- **The NIBP cuff inflation rate may increase and the initial pressure may increase up to 180 mmHg when changing the patient type.**
- **Patient Category: Select the correct patient category setting for your patient. Do not apply the higher adult inflation, overpressure limits and measurement duration to neonatal patients as this may result in inaccurate readings or patient injury.**

The **Patient Type** should be selected, as this setting determines the inflation pressures of the NIBP cuff, reading times and appropriate alarm limit range.

When positioning the patient, routine NIBP measurements (including for the condition hypertension) require the patient to remain silent, still and relaxed, with legs uncrossed and arms supported. Note that during MRI procedures, patients are typically laying down with their legs uncrossed and arms supported as needed for the MRI scan, and a 5-minute waiting period is also recommended before starting readings. Ensure that the cuff is at the level of the right atrium of the heart.

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 3-11) 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 1-36.*

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.

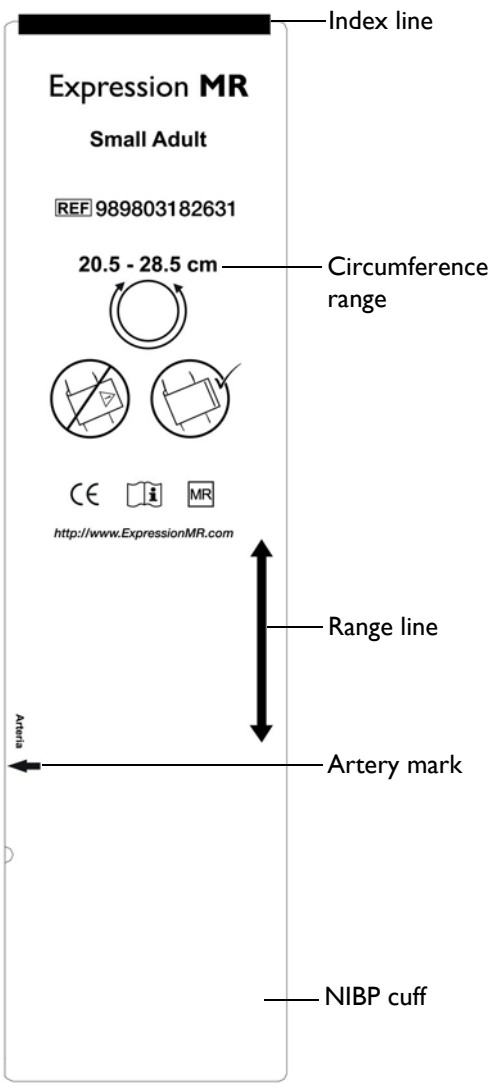
A wide variety of NIBP cuffs and interconnect hoses are available for your monitoring needs; see page 1-36 for details.

The NIBP cuff should be selected 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.
- All patients—the middle of the cuff should be placed at the level of the right atrium of the heart.



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.**

The NIBP cuff should be positioned as it would be for an auscultatory blood pressure determination. The current guidelines of the American Heart Association must be followed. Wrap the NIBP cuff firmly (not snuggly) 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. 

Step	Action
2	Attach a NIBP cuff appropriate for the patient type and size to the interconnect hose.
3	Position the cuff on the patient; see page 12-5.
4	Ensure that the cuff and interconnect hoses are not kinked.

Choosing the Measurement Mode

NIBP measurements can be taken automatically or manually, using the mode that best suits the needs of your patient. The following are frequently used functions related to NIBP; also refer to page 12-14 for other NIBP functions.

Making Automatic Measurements

You can automatically measure a patient's blood pressure at predefined 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	Select the **Patient Type**. See *Selecting the Patient Type* on page 3-11.
2	Press the **NIBP Interval** key. The **Interval** menu appears. The current setting is highlighted.
3	Select the desired minute(s) for the interval: **1 Min** **2 Min** **3 Min** **5 Min** **10 Min** **15 Min** **20 Min** **30 Min** The selection is entered.

Step	Action
4	Select the NIBP VS box. On the **NIBP** menu, toggle **Auto Mode** to **On**.
5	To begin automatic operation, press the **NIBP Start/Stop** key.

Making Manual Measurements

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

To control manual operation

Step	Action
1	Select the **Patient Type**. See *Selecting the Patient Type* on page 3-11.
2	To start or stop the measurement, press the **NIBP Start/Stop** key.

Initial Inflation Pressures and Reading Durations

WARNINGS

- **Performing NIBP measurements too frequently 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 Start/Stop** key to stop a reading cycle.

Suspend Mode during NIBP Measurements

When the **Suspend** key is pressed, NIBP functions will be affected as follows:

- Any reading in progress will be stopped.
- The system will pump to the initial inflation pressure for the selected patient type.
- Manual readings can be taken.
- Auto readings cannot be taken.
- The **"**NEXT**"** timer will not run.
- When exiting Suspend Mode, any manual reading will not be stopped.

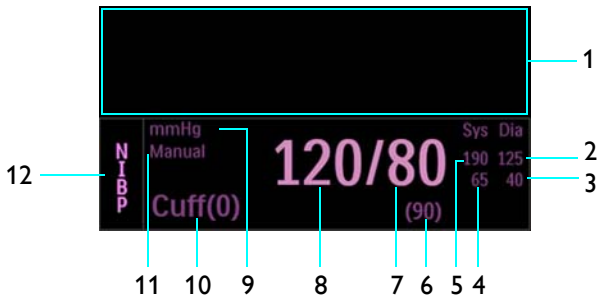
NIBP VS Box

The NIBP measurements are displayed as numeric information in the NIBP VS box. Other data, including NIBP-related alarm information, are also provided in this area of the screen, as detailed below.

Note

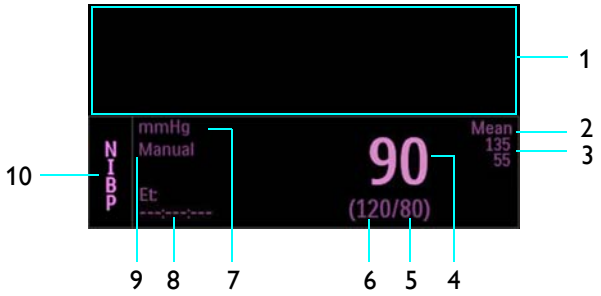
Depending upon the selected ***Format*** *(see page 12-17) of the data, the elements contained in the NIBP VS box are displayed in the Systolic/Diastolic format or in the Mean format.*

Systolic/Diastolic Format



Item	Name	Definition
1	Alarm flag area	Displays NIBP alarm flags when detected; see page 4-31.
2	Dia upper alarm limit	Is the upper limit setting for the diastolic alarm, and accesses the **NIBP Alarm Limits** menu
3	Dia lower alarm limit	Is the lower limit setting for the diastolic alarm, and accesses the **NIBP Alarm Limits** menu
4	Sys lower alarm limit	Is the lower limit setting for the systolic alarm, and accesses the **NIBP Alarm Limits** menu
5	Sys upper alarm limit	Is the upper limit setting for the systolic alarm, and accesses the **NIBP Alarm Limits** menu
6	Mean numeric	Is the patient's detected mean pressure measurement
7	Diastolic numeric	Is the patient's detected diastolic pressure measurement
8	Systolic numeric	Is the patient's detected systolic pressure measurement
9	Unit of measure	Indicates that the NIBP measurement numeric values are given in mmHg (millimeters of mercury) or kPa (kilopascals)
10	Elapsed time / cuff pressure	Is the time since the last completed NIBP reading, 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.*
11	**Auto Mode** setting	Indicates Manual when in manual mode; or, Next when in automatic mode along with 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
12	NIBP VS box label	Indicates the NIBP vital sign parameter, and accesses the **NIBP** menu

Mean Format



Item	Name	Definition
1	Alarm flag area	Displays NIBP alarm flags when detected; see page 4-31.
2	Mean upper alarm limit	Is the upper limit setting for the mean alarm, and accesses the **NIBP Alarm Limits** menu
3	Mean lower alarm limit	Is the lower limit setting for the mean alarm, and accesses the **NIBP Alarm Limits** menu
4	Mean numeric	Is the detected patient's mean pressure measurement
5	Diastolic numeric	Is the patient's diastolic pressure measurement
6	Systolic numeric	Is the patient's systolic pressure measurement
7	Unit of measure	Indicates that the NIBP measurement numeric values are given in mmHg (millimeters of mercury) or kPa (kilopascals); see **Pressure Units** in the **System Config** menu on page 3-30.
8	Elapsed time / cuff pressure	Is the time since the last completed NIBP reading, 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.*

Item	Name	Definition
9	**Auto Mode** setting	Indicates Manual when in manual mode; or, Next when in automatic mode along with 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	NIBP VS box label	Indicates the NIBP vital sign parameter, and accesses the **NIBP** menu

Changing the NIBP Format

To control the format of the NIBP data

Step	Action
1	Select the NIBP VS box. The **NIBP1** menu appears. Current settings are displayed.
2	Select **Format**. The **Format** menu appears. The current setting is highlighted.
3	Select the desired format: **SysDia** **Mean** The format is changed.

Changing the Unit of Measure

Note

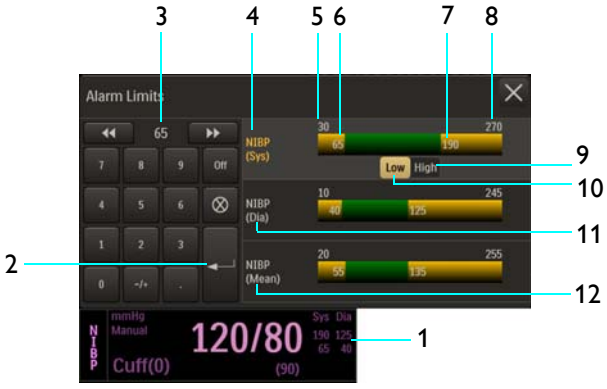
*When using an IP5 and **Pressure Units** is changed, the displayed formatting of the value and placement of the decimal point is changed immediately. However, it can take up to 2 seconds for the measurement numeric values to reflect the new unit of measure. Do not print or perform data captures during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

To change the unit of measure

Step	Action
1	Press the **Setup** key and then the **Monitor** key. The **Monitor Setup** menu appears. Current settings are displayed.
2	On the **Monitor Setup** menu, select **Service(Bio-Med)**. The **Service(Bio-Med)** menu appears.
3	On the **Service(Bio-Med)** menu, select **System Config**. The **System Config** menu appears. Current settings are displayed.
4	On the **System Config** menu, select **Pressure Units**. The **Pressure Units** menu appears. The current setting is highlighted.
5	Select the desired setting: **mmHg** **kPa** The setting is entered.

Changing the NIBP Alarm Limits

The **NIBP Alarm Limits** menu can be accessed by touching the alarm limit settings in the NIBP VS box.



1 Alarm limit settings, NIBP VS box

2 **Enter** button

3 Current adjustment

4 **NIBP Systolic Alarm Limits** menu label (active adjustment shown)

5 Alarm limit, minimum

6 Lower alarm limit setting

7 Upper alarm limit setting

8 Alarm limit, maximum

9 **High** button

10 **Low** button

11 **NIBP Diastolic Alarm Limits** menu label

12 **NIBP Mean Alarm Limits** menu label

To change the NIBP alarm limit settings

Step	Action
1	Select the alarm limit settings in the NIBP VS box. The **NIBP Alarm Limits** menu appears. Current settings are displayed.
2	Select the desired pressure: **NIBP (Sys)** **NIBP (Dia)** **NIBP (Mean)** The pressure is selected.
3	Select the **Low** button or the **High** button. The selected button will be highlighted and the current adjustment will be displayed.
4	Using the keypad, or the **increment**, **decrement**, or **Off** buttons, enter the desired setting. The current adjustment will reflect the change.
5	Press the **Enter** button to save the setting. The alarm limit setting is updated.
6	To change the remaining settings, repeat steps 2, 3, 4 and 5. The current adjustment will reflect the change.

Note

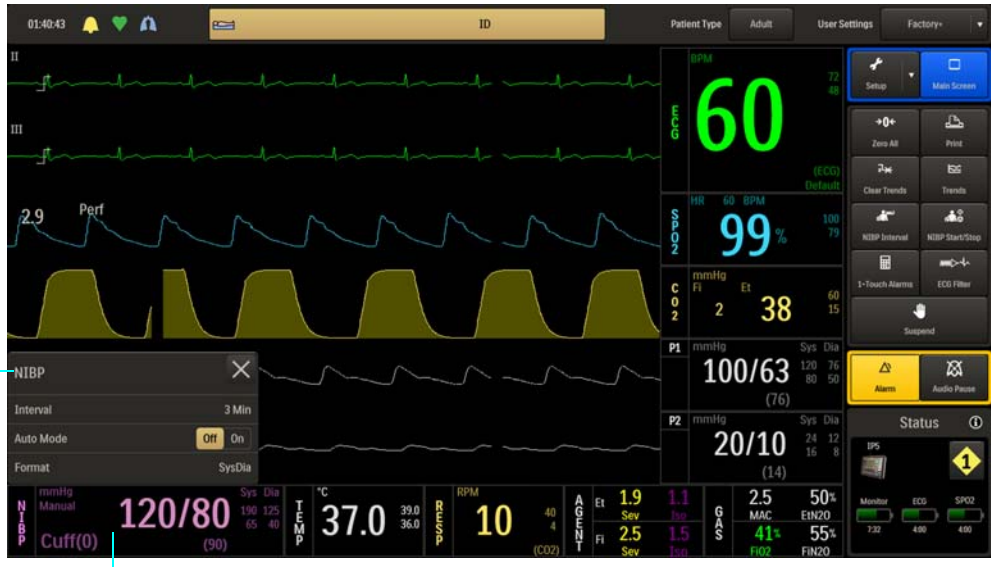
See chapter 4 for detailed alarm limit setting instructions and options.

NIBP Menu

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

To open the NIBP menu

Select the NIBP VS box.



NIBP menu

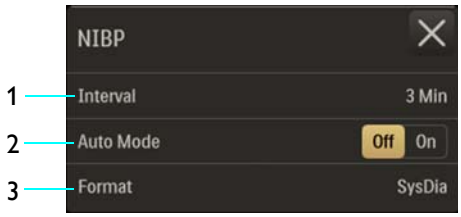
NIBP VS box

The following **NIBP** menu items are available:.

1 **Interval**

2 **Auto Mode**

4 **Format**



To change settings in the NIBP menu

Step	Action
1	Select the NIBP VS box. The **NIBP** menu appears. Current settings are displayed.

Step	Action
2	Touch the menu item to select one of the following NIBP options: **Interval** **Auto Mode** **Format** The menu item appears. The current setting is highlighted.
3	Select the desired setting from the menu options (except **Auto Mode**, which is selectable on the **NIBP** menu). The setting is entered.
4	To change other settings, repeat steps 2 and 3.

Interval

Sets the interval for automatic NIBP measurements.

The following options are available:

- **1 Min**
- **2 Min**
- **3 Min** (Default)
- **5 Min**
- **10 Min**
- **15 Min**
- **20 Min**
- **30 Min**

To set the interval for NIBP readings

Step	Action
1	Select the NIBP VS box. The **NIBP** menu appears. Current settings are displayed.

Step	Action
2	Select **Interval**. The **Interval** menu appears. The current setting is highlighted.
3	Select the desired minute(s) for the interval: **1 Min** **2 Min** **3 Min** **5 Min** **10 Min** **15 Min** **20 Min** **30 Min** The setting is changed.

Auto Mode

Sets the mode used to take NIBP readings.

Note

A manual reading will not restart this cycle time.

The following options are available:

- **Off** takes readings manually (Manual mode), where readings are initiated by pressing the **NIBP Start/Stop** key; see *Making Manual Measurements* on page 12-7 for details. (Default)
- **On** takes readings automatically, where when selected (or since leaving suspend mode), the first reading must be initiated by pressing the **NIBP Start/Stop** key and then all subsequent readings will be taken at the selected interval; see *Making Automatic Measurements* on page 12-6 for other setup details.

To set the mode for NIBP readings

Step	Action
1	Select the NIBP VS box. The **NIBP** menu appears. Current settings are displayed.
2	Locate **Auto Mode** and select the desired setting: **Off** **On** The setting is entered.

Format

Sets the displayed format of the NIBP numeric data.

The following options are available:

- **SysDia** displays the systolic and diastolic numerics in a large font separated by a slash and the mean numeric will be in a smaller font bracketed with parenthesis. (Default)
- **Mean** displays the mean measurement numeric in a large font, and the systolic and diastolic measurement numeric values in a smaller font and separated by a slash.

To control the format of the NIBP data

See *Changing the NIBP Format* on page 12-11.

CHAPTER 13

Trend Data and Printing

Trending Functions

The MR400 provides versatile trending features, including trend arrow indications for monitored parameters and tabular trends reporting. The MR400 stores up to 12 hours of historical trend data, retaining information when new patients are connected to the host and through short power cycles; however, if power is removed for 10 minutes or longer, all stored trend data will be lost.

Viewing Tabular Trend Data

To view tabular trend data for any available parameter

Step	Action
1	Press the **Trends** key. The **Tabular Trends** menu appears. Allow the trends data to refresh.
2	Select the corresponding button(s) of the parameter(s) that you want to examine.
3	Use the navigation buttons (see page 13-2) to move through the data pages.

Tabular Trends Menu

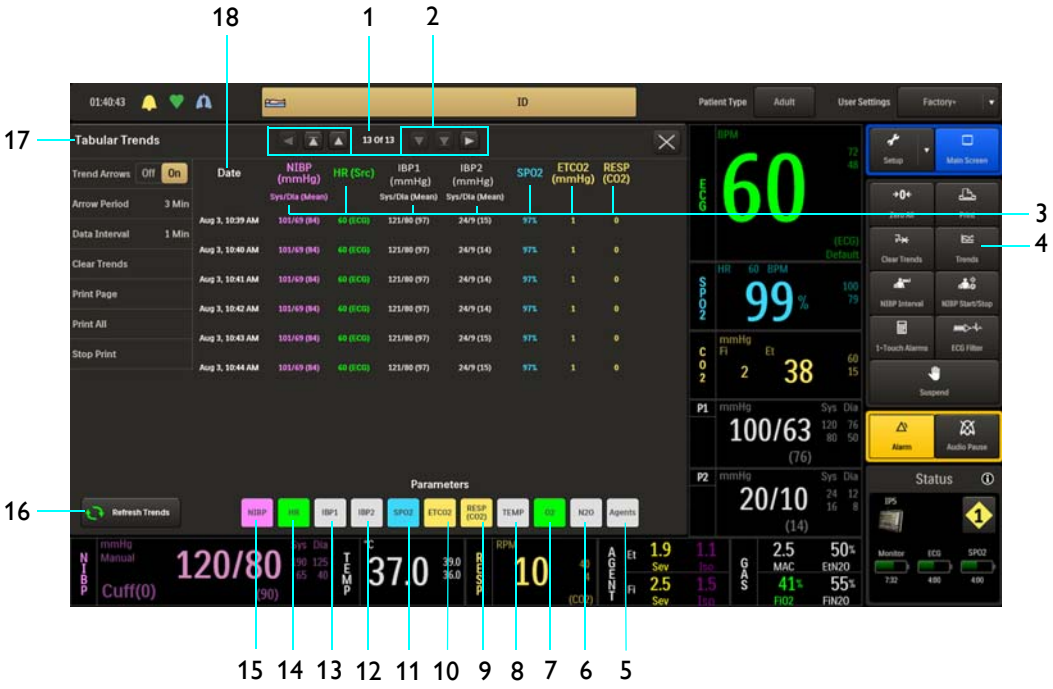
The **Tabular Trends** menu allows you to control trend functions, to display trended patient data, and to print data when connected to an IP5 and printer.

To open the Tabular Trends menu

Press the **Trends** key.

Notes

- ***Refreshing Trend Data*** *may be displayed while the information on the page is being populated.*
- *In the illustration below, the trend buttons for all parameters are shown in their selected state.*

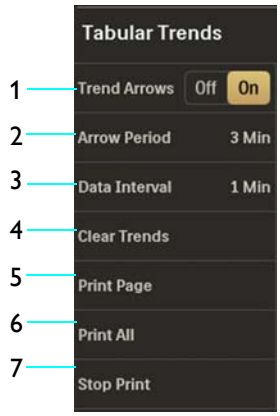


Item	Name	Definition
1	Page	Indicates the current page and the total page count of the file
2	Navigation buttons	Allows you to move through the listings as follows: Moves one column to the left Moves to the first (oldest) file page Moves up one file page Moves down one file page Moves to the last (most recent) file page Moves one column to the right

Item	Name	Definition
3	Parameter headings	Identifies the parameter reading for the associated column of data (in the same color as that of the vital sign)
4	**Trends** key	Opens the **Tabular Trends** menu
5	**Agents** trend button	Displays the AGENT parameter readings, where percentages for primary and secondary end-tidal (Et) and fractional inspired (Fi) gases (ID) are provided in the form: Et ID% Fi ID%
6	**N2O** trend button	Displays the N_2O parameter readings
7	**O2** trend button	Displays the O_2 parameter readings
8	**TEMP** trend button	Displays the temperature parameter readings (and the unit of measure)
9	**RESP (CO2)** trend button	Displays the CO2-derived respiration parameter readings (and source)
10	**ETCO2** trend button	Displays the end-tidal CO_2 parameter readings (and the unit of measure)
11	**SPO2** trend button	Displays the SPO2 parameter readings
12	**P2** trend button	Displays the P2 parameter readings (and the unit of measure)
13	**P1** trend button	Displays the P1 parameter readings (and the unit of measure)
14	**HR** trend button	Displays the heart rate parameter readings (and source)
15	**NIBP** trend button	Displays the NIBP parameter readings (and the unit of measure), given in the form: Systolic/Diastolic (Mean)
16	**Refresh Trends** button	Refreshes the readings ***Note*** *While **Refreshing Trend Data**, the screen will freeze momentarily; however, audible alarms will continue to function.*
17	**Tabular Trends** menu	Is the Tabular Trends menu (see below for details)
18	Date	Is the date (and time) of the readings

The following **Tabular Trends** menu items are available:.

1 **Trend Arrows**
2 **Arrow Period**
3 **Data Interval**
4 **Clear Trends**
5 **Print Page**
6 **Print All**
7 **Stop Print**



To change settings and control functions in the Tabular Trends menu

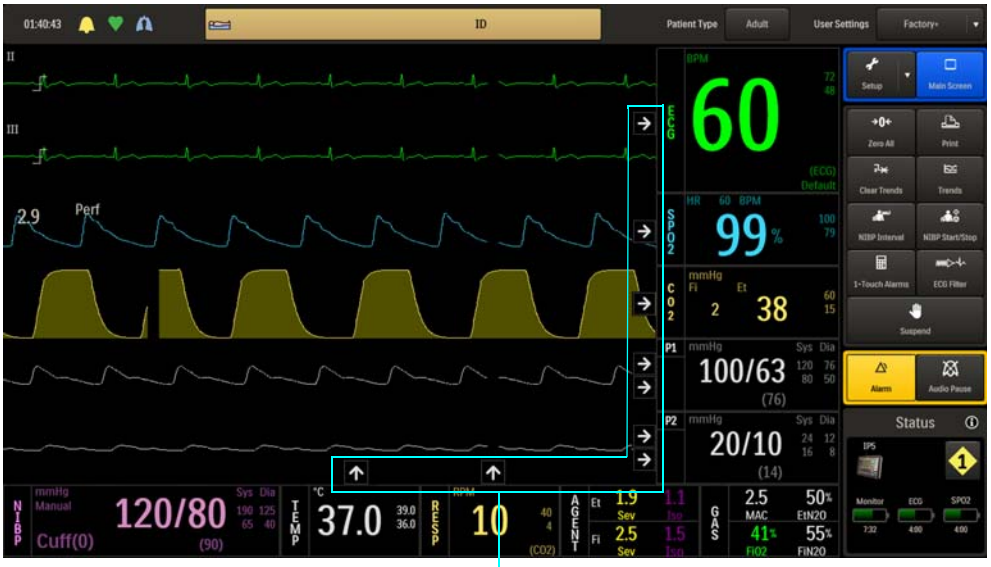
Step	Action
1	Press the **Trends** key. The **Tabular Trends** menu appears. Current settings are displayed.
2	Select from the following menu items: **Trend Arrows** **Arrow Period** **Data Interval** **Clear Trends** **Print Page** **Print All** **Stop Print** For menu item information, see the appropriate section below.
3	Select from the desired setting of menu options (except **Trend Arrows**, which is selectable on the **Tabular Trends** menu.) The setting is entered.
4	To change other settings, repeat steps 2 and 3.

Trend Arrows

Controls vital sign trend indications, where trend arrows are displayed alongside the VS boxes (except for NIBP and bellows-derived respiration), with a meaning as defined below.

WARNING

Depending upon the Arrow Period menu option and measurement cycles of the vital signs, NIBP trend arrow indications may not be representative of the current condition of the patient.



1 Trend arrow indications, where

- is rising
- is declining
- is stable
- is none declared

The following options are available:

- **Off** turns off the trend arrows. (Default)
- **On** turns on the trend arrows.

To control trend arrow indications

Step	Action
1	Press the **Trends** key. The **Tabular Trends** menu appears. Current settings are displayed.
2	On the **Tabular Trends** menu, select **Trend Arrows**. The **Trend Arrows** menu appears. The current setting is highlighted.
3	Select the desired setting: **Off** **On** The setting is changed, and the display is changed accordingly.

Arrow Period

Controls the time that must elapse before a trend arrow change can occur.

The following options are available:

- **30 Seconds**
- **1 Minute**
- **3 Minutes** (Default)
- **5 Minutes**
- **10 Minutes**

To control the trend arrow period

Step	Action
1	Press the **Trends** key. The **Tabular Trends** menu appears. Current settings are displayed.
2	On the **Tabular Trends** menu, select **Arrow Period**. The **Arrow Period** menu appears. The current setting is highlighted.

Step	Action
3	Select the desired setting: **30 Seconds** **1 Minute** **3 Minutes** **5 Minutes** **10 Minutes** The setting is changed. ***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. However, if the newly selected period is longer than the previous period, recalculation will occur using all available data.*

Data Interval

Controls the time that must elapse before trend data readings are taken.

The following options are available:

- **1 Minute**
- **5 Minutes** (Default)
- **10 Minutes**
- **15 Minutes**
- **20 Minutes**
- **25 Minutes**
- **30 Minutes**
- **45 Minutes**
- **60 Minutes**
- **Auto NIBP** (Occurs at the **Interval** selected for automatic NIBP measurements; see page 12-15 for details)

To control the data interval

Step	Action
1	Press the **Trends** key. The **Tabular Trends** menu appears. Current settings are displayed.
2	On the **Tabular Trends** menu, select **Data Interval**. The **Data Interval** menu appears. The current setting is highlighted.
3	Select the desired setting: **1 Minute** **5 Minutes** **10 Minutes** **15 Minutes** **20 Minutes** **25 Minutes** **30 Minutes** **45 Minutes** **60 Minutes** **Auto NIBP** The setting is changed.

Clear Trends

Removes all trend data, useful to ensure that the monitored information reflects data for only one patient.

To clear all trend data

Step	Action
1	Press the **Clear Trends** key. The **Tabular Trends** menu appears. Current settings are displayed.
2	On the **Tabular Trends** menu, select **Clear Trends**. The **Clear Trends** menu appears.
3	Follow all associated dialogs to clear the file. The data is erased.

Print Page

Prints the currently displayed Trends page when connected to a printer-equipped IP5.

To print the page

Step	Action
1	Press the **Trends** key. The **Tabular Trends** menu appears. Current settings are displayed.
2	On the **Tabular Trends** menu, select **Print Page**.

Print All

Prints all Trends pages when connected to a printer-equipped IP5.

To print the all pages

Step	Action
1	Press the **Trends** key. The **Tabular Trends** menu appears. Current settings are displayed.
2	On the **Tabular Trends** menu, select **Print All**.

Stop Print

Stops printing of the trends page(s) when connected to a printer-equipped IP5.

To stop a current print job

Step	Action
1	Press the **Trends** key. The **Tabular Trends** menu appears. Current settings are displayed.
2	On the **Tabular Trends** menu, select **Stop Print**.

Printing Functions

When equipped with an IP5 and printer, the MR400 can produce hard copies of up to two waveforms, trend information and patient data reports.

Notes

- *If a printer-equipped IP5 is not installed or connected, an indication is displayed on the **Print** key; see page 13-11.*
- *Any print command from the MR400 automatically initiates a 30-second print cycle at the IP5.*
- *Any print command initiated from the MR400 takes precedence over the IP5 print functions.*

Printing Parameter-Specific Trends

Trended information can be printed separately for every parameter (except bellows-derived respiration).

To print individual trend data

Step	Action
1	Press the **Trends** key. The **Tabular Trends** menu appears. Allow the trends data to refresh.
2	Select the trend button of the parameter that you want to print. The corresponding vital sign data appears. The current page is displayed.
3	Select **Print All** to print all the data for the parameter, or select **Print Page** to print the currently displayed data. The data is printed at the IP5.

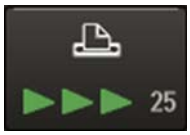
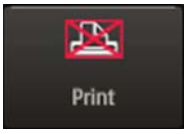
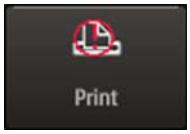
Controlling Printer Outputs

To start and stop the printing of a strip chart, press the **Print** key.

If the printer is allowed to run after printing, paper will continue to be output for about 30 seconds before automatically stopping.

Printer Indications

The symbol displayed on the **Print** key indicates the state of the remote printer, as shown in the table below.

Symbol	Indication
	The printer is ready.
	Printing is in process and seconds remain (25, in the example) until completion.
	No printer is available.
	There is a printer error condition.

Printer Menu

The **Printer** menu allows you to configure the MR400 for printing when an optional IP5 and printer are connected.

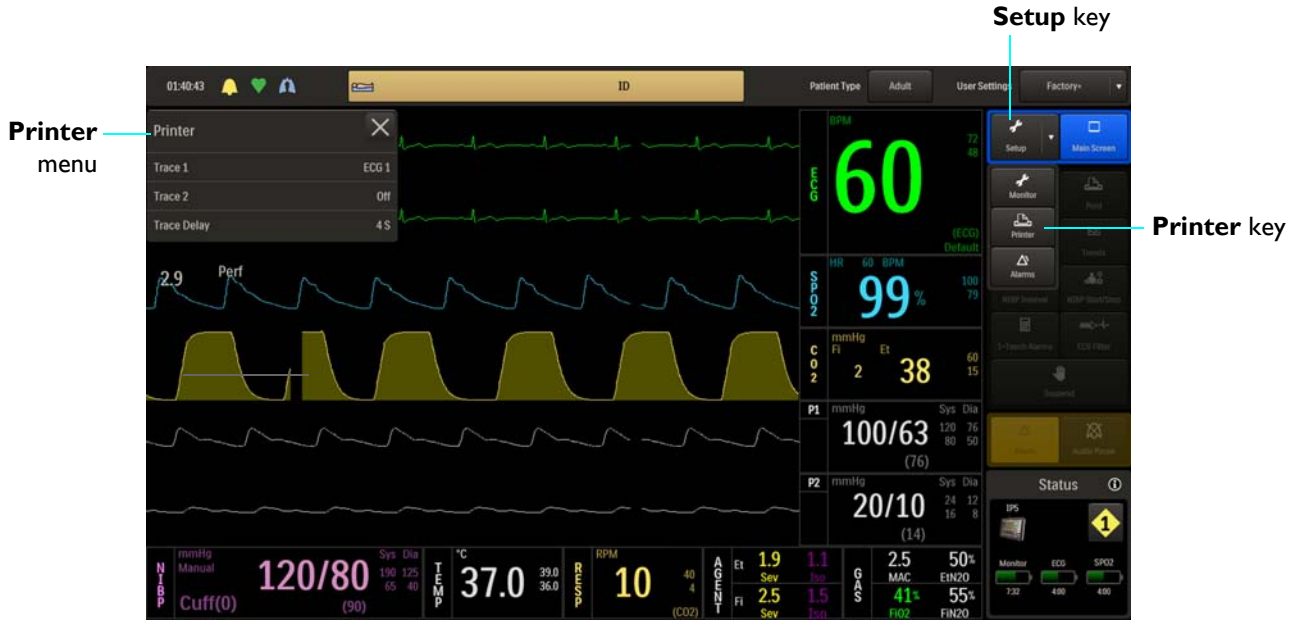
To open the Printer menu

Press the **Setup** key and then the **Printer** key.

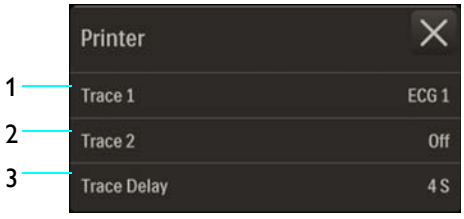
To open the Printer menu

Press the **Setup** key and then the **Printer** key.

.



The following **Printer** menu items are available:



1 **Trace 1**

2 **Trace 2**

3 **Trace Delay**

To change settings in the Printer menu

Step	Action
1	Press the **Setup** key and then the **Printer** key. The **Printer** menu appears. Current settings are displayed.
2	Select from the following menu items: **Trace 1** **Trace 2** **Trace Delay** The selected menu appears. Current settings are displayed. (For menu item information, see the appropriate section below.)
3	Select the desired menu item. The current setting is highlighted.

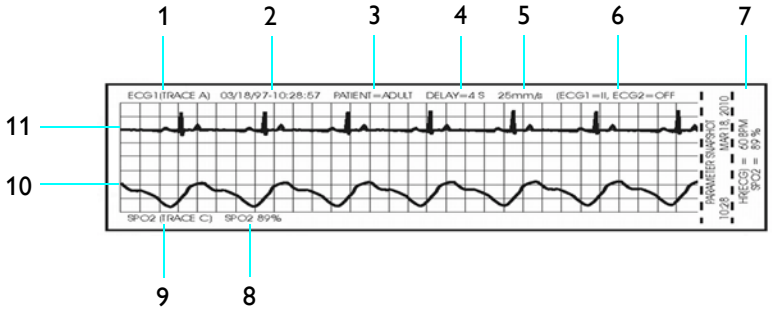
Step	Action
4	Select the desired setting from the menu options. The setting is entered.
5	To change other settings, repeat steps 2, 3 and 4.

Trace 1

Prints a selected parameter's waveform in the Trace 1 waveform location on a strip chart, as shown in the illustration below. (A strip can contain two waveforms.)

Note

*If **Trace 2** is off, then **Trace 1** is printed using the full 40 mm width of the strip.*



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

The following options are available:

- **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
- **P1** outputs the Trace E waveform
- **P2** outputs the Trace F waveform

To print a waveform in the Trace 1 location

Step	Action
1	Press the **Setup** key and then the **Printer** key. The **Printer** menu appears. Current settings are displayed.
2	Select **Trace 1**. The **Trace 1** menu appears. The current setting is displayed.
3	Select the desired setting from the menu options: **ECG 1** **ECG 2** **SPO2** **RESP (CO2)** **P1** **P2** The setting is entered.

Trace 2

Prints a waveform in the Trace 2 location on a strip chart (see example, on page 13-13).

Note

When printing two traces, the waveform to grid ratio will not correspond to the displayed waveform/scale indicator size.

The following options are available:

- **Off** (Default)
- **ECG 1** outputs the Trace A waveform.
- **ECG 2** outputs the Trace B waveform.
- **SPO2** outputs the Trace C waveform.
- **P1** outputs the Trace E waveform.

- **P2** outputs the Trace F waveform.
- **RESP(CO2)** outputs the Trace D waveform.

To print a waveform in the Trace 2 location

Step	Action
1	Press the **Setup** key and then the **Printer** key. The **Printer** menu appears. Current settings are displayed.
2	Select **Trace 2**. The **Trace 2** menu appears. The current setting is displayed.
3	Select the desired setting from the menu options: **Off** **ECG 1** **ECG 2** **SPO2** **P1** **P2** **RESP(CO2)** The setting is entered.

Trace Delay

Allows you to delay the time when sending the trace data to the printer.

The following options (in seconds) are available:

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

To set a printing time delay

Step	Action
1	Press the **Setup** key and then the **Printer** key. The **Printer** menu appears. Current settings are displayed.
2	Select **Trace Delay**. The **Trace Delay** menu appears. The current setting is displayed.

Step	Action
3	Select the desired setting from the menu options: **0 S** **4 S** **8 S** **16 S** The setting is entered.

CHAPTER 14

Maintenance and Troubleshooting

WARNINGS

- **Schedule: Failure on the part of the responsible individual hospital or institution employing the use of this equipment to implement a satisfactory maintenance schedule may cause undue equipment failure and possible health hazards.**
- **To reduce the possibility of damage to the equipment or injury to patients/personnel, perform all cleaning, disinfection, maintenance, software update, testing, disassembly and repair outside of the MR system room.**
- **Contact: If you discover a problem with any of the equipment, contact technical support or authorized service personnel.**

General Cleaning Guidelines

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

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

Note

For answers to questions regarding infection control, call us at (877) 468-4861 (inside the USA) or +31 (0) 499 378299 (outside the USA).

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

When cleaning the touch screen, wipe it gently using a soft non-woven cloth with 80% diluted alcohol mixture.

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**
Cavicide Disinfectant: CaviWipes®	Towelette
Coverage Disinfectant: Coverage® Spray TB, TB Plus, HB Plus*	Spray
Sani-Cloth Germicidal Wipes*	Towelette
Sklar Disinfectant*	Towelette, spray

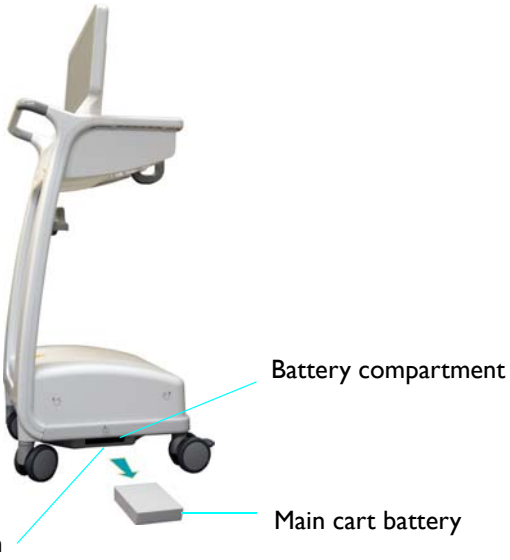
**Any product residue should be removed by wiping the surface.*

Removing all Power to the MR400

In order to clean, disinfect, inspect, test or service the MR400, it may be necessary to remove power to the cart.

To remove all power to the MR400 cart

Step	**Action**
1	Press then hold the power switch for approximately 2 seconds to turn off power to the cart.
2	Pull the plug of power cord from the AC wall outlet. Then, lift the strain relief and remove the power cord from the AC receptacle on the cart. Disconnect any gating connection from the cart; otherwise, remove the shield cap.

Step	Action
3	Press the battery eject button to partially eject a main cart battery from a battery compartment, and then grasp the battery and pull to remove it completely from the MR400.  (If the battery does not release, apply a slight forward pressure to the battery while pressing the battery eject button.)
4	Repeat steps 1 and 2 to remove the other main cart battery on the opposite side of the MR400.
5	Remove the two screws that secure the service panel cover to the MR400 and then remove the service panel cover. 

Step	Action
6	Locate the battery switch and toggle it into the Off (O) position. 

Restoring all Power to the MR400

To restore all power to the MR400, see page 1-16.

Removing Power from the Wireless Modules

In order to clean, disinfect or inspect a wireless module it may be necessary to remove power from the device. To turn power off to the wireless modules, proceed according to the module type:

- wECG module: Remove all installed batteries (see page 1-25).
- wSpO2 module: Remove the battery (see page 1-27).

Restoring Power to the Wireless Modules

To restore all power to the wireless modules, proceed according to the module type:

- wECG module: Install at least one battery (see page 1-24).
- wSpO2 module: Install one battery (see page 1-26).

User Routine-Checks and Planned Maintenance

This product requires routine checking, planned maintenance and testing that must performed on a scheduled basis to keep the product operating safely, effectively and reliably.

User Routine-Checks Program

The user of the product must institute a routine-checks program as detailed in the table below. The user of the product shall make sure that all checks and actions have been satisfactorily completed before using the product for its intended purpose.

Area / Item	Frequency	Required Action
Accessories	Daily	Clean and inspect for damage; see page 14-7.
Alarms	Daily	Confirm proper function; see *Testing Alarms* on page 14-11.
Module batteries	Every 8 hours of use	Recharge; see page 2-16 for displayed indications, and refer to the battery charger's IFU for recharging instructions.
Wireless module	If dropped	Inspect and clean (see page 14-9) then test (see page 14-12).

Planned Testing Program

Planned maintenance may only be carried out by qualified and authorized personnel, and is comprehensively described in the service documentation. Philips provides a full planned maintenance and repair service on both a call basis and a contract basis. Full details are available from your Philips Service Organization. A summary of service events and maintenance requirements appears in the table below.

Area / Item	Frequency	Required Action
Monitor cleaning	Every 6 months	Perform external cleaning
System - AGENT option	Once per year or as specified by local laws	Perform calibration.
System - CO2 (LoFlo option)	Once per year or as specified by local laws	Perform calibration.
System- NIBP	Once per year or as specified by local laws	Perform calibration.
System	Once per year or as specified by local laws, or after any type of repair or service event	Perform Visual Inspection, and Power On, Verification and Safety Tests

Area / Item	Frequency	Required Action
Cart batteries: two main and two reserve	Every 12 months	• Replace the main batteries; see page 1-16. • Replace the reserve batteries; contact technical support.
Module batteries	Every 12 months	Replace the module batteries; see page 1-23.

Cleaning, Disinfection, and Damage Inspection

Cleaning and disinfection of this product is required periodically. General guidelines for each are given below.

WARNING

Always isolate the product from the mains electrical supply and remove and disconnect batteries before cleaning, disinfecting or sterilizing to prevent electric shocks.

CAUTION

Never allow water or other liquids to enter the product, since these may cause electrical short-circuits or metal corrosion.

Cleaning and disinfection techniques for both the product and the room must comply with all applicable local laws and regulations.

Cleaning

Enameled parts and aluminum surfaces should only be wiped clean with a damp cloth and a mild detergent, and then rubbed down with a dry woolen cloth. Never use corrosive cleaning agents, solvents, abrasive detergents or abrasive polishes. If you are not sure about the properties of a cleaning agent, do not use it.

Disinfection

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

WARNING

Do not use flammable or potentially explosive disinfecting sprays. Such sprays create vapors, which can ignite, causing fatal or other serious personal injury.

CAUTION

Disinfecting a medical product room by means of sprays is not recommended, since the vapor could penetrate the product, causing electrical short-circuits, metal corrosion or other damage to the product.

Cleaning, Disinfecting, and Inspecting the Accessories

Any reusable patient accessory (such as ECG cables, SPO2 attachments and probes, temperature sensors, et cetera) must be cleaned and disinfected before initial use and 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.

During the cleaning process, inspect the accessory 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, et cetera.
- Cracks or other signs of damage to the connector, including bent or damaged pins.
- Disposable accessories must be discarded and replaced with new items.

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.

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.

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*** *Follow the Instructions for Use from the disinfectant manufacturer to clean the probe.*
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*** *Follow the Instructions for Use from the disinfectant manufacturer to disinfect the probe.*
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 item before proceeding. ***Note*** *Disposable SPO2 attachments: After some use, adhesive residue may accumulate at the fiber heads on the probe. Carefully remove any residue with alcohol to keep the glass fiber ends clean.*
7	Check the accessory for damage (cracks, holes, tears, cuts, et cetera) and discard the accessory if damage is found.
8	Store the accessory; see page 2-12 for details.

Cleaning, Disinfecting, and Inspecting MR400 and Wireless Modules

Follow the general guidelines to clean the MR400 cart and the wECG and wSpO2 modules. Always turn off the cart and the wireless modules to perform cleaning. Never immerse any portion of the cart or wireless modules in fluid or attempt to clean the devices by directly applying liquid cleaning agents.

During the cleaning process, inspect the MR400 and the wireless modules for damaged, loose or missing hardware; if found, take corrective action or contact technical support.

WARNING

Always disconnect the MR400 from AC mains 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 MR400 in any cleaning agent or attempt to clean it with 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 MR400.
- Disinfect the MR400 cart and wireless 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 touch screen. Contact technical support if liquid enters any component.
- If the MR400 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 MR400 and disconnect all power; see page 14-2.
2	Remove the battery from each wireless module; see page 14-4.
3	Clean the touch screen by wiping it gently using a soft non-woven cloth with 80% diluted alcohol mixture.
4	Remove all visible debris from the cart and wireless modules using soap and water. **CAUTIONS** Never pour liquid onto the equipment.

Step	Action
5	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 wireless modules.*
6	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 wireless modules.*
7	Allow the cart and the wireless modules to dry. (No rinsing is required.)
8	Check the cart and the wireless modules for any residual debris. If any debris is present, repeat steps 3 through 6 then re-examine the cart and wireless modules before proceeding.
9	Check the cart and wireless modules for damaged, loose or missing hardware. Contact technical support if necessary.
10	Store the module; see page 2-12 for details.

Sterilization

The MR400 cart, wireless modules and accessories are not sterilizable; do not immerse any part of these items in fluid or attempt to clean them with unspecified liquid cleaning agents. Severe damage, not covered by the warranty, will result.

Testing Alarms

Note

If a problem with the alarm sound or messaging system is suspected, discontinue use of the MR400 and immediately refer it to authorized service personnel for evaluation.

To verify the alarm functions

Step	Action
1	With the MR400 turned on and not in suspend mode, ensure that **Alarm Sound** is turned on in the **Alarms** menu.
2	Make sure that the lower alarm limit for SPO2 is not off.
3	Check the battery indicator on the wSpO2 module to ensure that enough charge exists: • Green battery indicator = Charge sufficient; proceed to step 5. • Red battery indicator = Charge low; proceed to step 4. See page 2-11 for details. (Also, you can reference the status information pane; see page 2-16.)
4	Insert a charged module battery into the wSpO2 module and then recheck the battery indicator to ensure a sufficient charge before proceeding; see page 1-26.
5	Check the network channel indicator on the wSpO2 module to ensure communication is established with the MR400: • Steady = Good communication; proceed to step 7. • Flashing = No communication; proceed to step 6. See page 2-11 for details. (Also, you can reference the status information pane; see page 2-16.)
6	Ensure that the wSpO2 module is within 9.1 m (30 feet) of the MR400, in the same MRI room or in the same shielded room, and is set to the same wireless network channel used by the MR400; see page 1-29.
7	Place the SPO2 attachment on your finger and wait for a value to appear in the SPO2 VS box.

Step	Action
8	Remove your finger from the attachment.
9	Verify the following: • **Non-Pulsat** or **Probe Off** appears in the SPO2 alarm flag area, • The SPO2 waveform flat lines. • The numeric flashes in yellow; and, • The alarm tone sounds. This completes the test of the alarm system.

Testing a Dropped Wireless Module

In the event that the wECG or wSpO2 module has been dropped, it is important to determine the functionality of the device before attempting to monitor a patient.

To verify the basic functions of a dropped wireless module

Step	Action
1	Perform a visual examination the dropped module for signs of breakage (cracked housings, damaged connectors, et cetera): • If no signs of damage are present, go to step 2; or, • If noticeable damage is present, go to step 6.
2	Ensure that a fresh module battery is installed. (If checking the wECG module, ensure that two fresh batteries are installed.) Then, check the module and proceed accordingly: • If the battery indicator(s) and network channel indicator are illuminated, go to step 3; or, • If the battery indicator(s) and network channel indicator are NOT illuminated, go to step 6.
3	Ensure that the module is within 9.1 m (30 feet) of the MR400, in the same MRI room or in the same shielded room, and is set to the same wireless network channel used by the MR400; see page 1-29.
4	Check the status information pane (see page 2-16) on the MR400 and proceed accordingly: • If the battery time-remaining indication and communication status are present for the dropped module, go to step 5; or, • If a red X is present (or if blank) for the dropped module, go to step 6.

Step	Action
5	This completes basic functional testing of the dropped module. However, if during further usage, problems are encountered, such as status messages (Lead Fail, No Probe, et cetera) then discontinue use of the module and replace it before using the MR400 system.
6	Discontinue use of the module and replace it before using the MR400 system.

Verification Testing

Verification testing for the MR400 can in some cases be performed by the user, provided the necessary accessories and test equipment are available. However, many verification tests require specialized equipment and training, and as a result must be performed by qualified service personnel; refer to the service manual (REF 989803181911) for a comprehensive testing procedure and contact technical support with any questions.

Anesthetic Oxygen (O2) Sensor Depletion

The anesthetic oxygen (O2) sensor uses galvanic technology and has a limited shelf life, as indicated by the expiration date printed on the packaging and sensor. Take note this expiration date and plan accordingly for replacement scheduling of the O2 sensor; see page 14-13 for instructions.

If the O2 sensor is missing or malfunctioning, **Agent HW Fail - O2 Sensor** will be displayed shortly after activation of the **AGENT** parameter; or, during CO2 use, **Turn Off CO2, Replace O2 Sensor** will be displayed. In each case, the O2 sensor must be replaced before Agent and gas monitoring can proceed.

Replacing the O2 Sensor

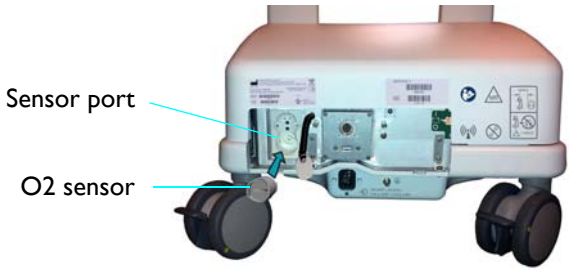
The O2 sensor is located behind the service panel cover at the back of the WPU.

WARNING

The gas sampling line must not be connected to the patient airway adapter or any other gas source during oxygen sensor replacement, as it will cause an incorrect calibration of the O2 reading.

To replace the O2 sensor.

Step	Action
1	Turn off the MR400.
2	Ensure that any gas sampling line has been disconnected from the water trap on the patient connection panel.
3	Remove the two screws that secure the service panel cover to the back of the WPU and then remove the service panel cover. 
4	Locate the sensor tool and the O2 sensor port. 
5	Place the sensor tool into the slot in the O2 sensor, then turn the sensor counterclockwise until it disengages from the sensor port. 

Step	Action
6	Insert a new O2 sensor into the sensor port and then, using the sensor tool, turn the sensor clockwise until secure. 
7	Replace the service panel cover and secure it using the two screws.
8	Connect a gas sampling line to the water trap.
9	Turn on the MR400.
10	Turn on the Agents parameter and allow the system to run until **CO2 Warming Up** is no longer displayed.
11	Calibrate the O2 sensor by performing the following steps: a. Press the **Monitor** key. b. On the **Monitor Setup** menu, select **Service(Bio-Med)**. c. On the **Service(Bio-Med)** menu, select **Gas Cal**. d. On the **Gas Cal** menu, select **O2 Cal**. e. When prompted: **Flow Room Air for 10 Seconds, Do you wish to continue?** Select **Yes** to proceed. **Readjusting CO2 Zero** will be displayed until calibration is complete.

Updating Software

As revisions to the software become available, the MR400 can be updated; refer to the service manual (REF 989803181911). It is recommended that you backup your settings prior to updating software, so that they can be restored afterward; see *Edit User Settings* on page 3-15.

WARNING

When performing software updates (or upgrades) to the operating software of the MR400, 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, et cetera.

Calibrating the Touch Screen

Note

Touch screen calibration is not routinely required, but will occur after installation of new operating software.

To calibrate the touch screen menu, refer to the service manual (REF 989803181911).

Troubleshooting

Methods for troubleshooting problems when the equipment seems to be functioning incorrectly include using displayed alarm messages as a starting point; see chapter 4 for a listing.

Planned maintenance and user routine-testing are also helpful ways to confirm device operations or to help identify a problem; see page 14-4.

Troubleshooting the MR400 is comprehensively described in the service documentation. Philips provides a full planned maintenance and repair service on both a call basis and a contract basis. Full details are available from your Philips Service Organization.

Repair

The MR400 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. Circuit diagrams, component part lists, descriptions, calibration instructions, and other information to assist service personnel in the repair of the serviceable parts of the device are available in the service manual (REF 989803181911) and on request.

WARNINGS

- **A shock hazard exists if the MR400 is operated without covers.**
- **Do not modify the MR400 Patient Monitoring System without authorization of the Invivo (Royal Philips).**

If the MR400 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.
- 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.

Environmental Requirements

Philips Medical Systems is concerned to help protect the natural environment, and to help ensure continued safe and effective use of this product, through proper support, maintenance and training.

Therefore Philips products are designed and manufactured to comply with relevant guidelines for environmental protection. As long as the product is properly operated and maintained, it presents no environmental risks. However, the product may contain material(s), which could be harmful to the environment if disposed of incorrectly. Use of such material(s) is essential to performing the functions of the product, and to meeting statutory and other requirements.

This section of the *Instructions for Use* is directed mainly at the user / owner of the product. Operators are not usually involved in disposal, except in the case of certain batteries; see page 14-22 for those details.

Passing the Product on to another User

If this product passes to another user, it must be in its complete state, including all product support documentation. Make the new user aware of the support services that Philips Medical Systems provides for installing, commissioning and maintaining the product. Before passing on the product or taking it out of service, all patient data must be (backed up elsewhere if necessary, and) unrecoverable be deleted on the product.

It must be remembered by all existing users that passing on medical electrical products to new users may create serious technical, medical and legal (e.g. on privacy) risks. Such risks can arise even if the product is given away. Existing users are strongly advised to seek advice from their local Philips Medical Systems representative before committing themselves to passing on any product. Alternatively, contact the manufacturer.

Once the product has been passed on to a new user, a previous user may still receive important safety-related information, such as 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 Philips Medical Systems about the new user, so that PMS can provide the new user with safety-related information.

Packaging the MR400

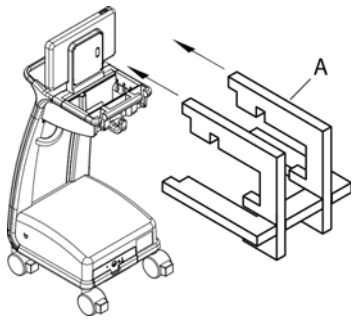
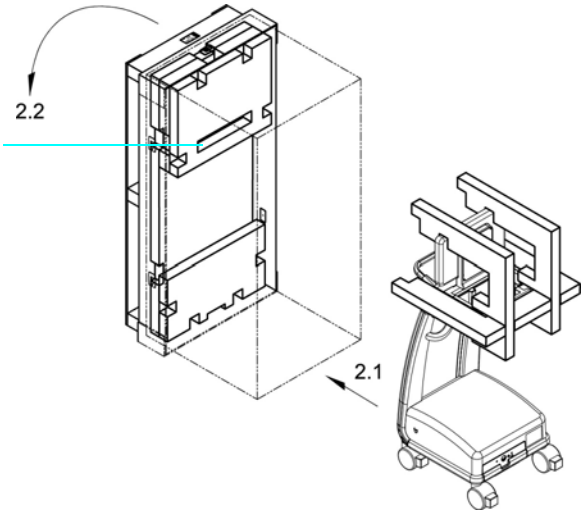
To package the MR400 for shipment, use the MR400 packing materials to safely transport the monitor. Remove all accessories before packaging.

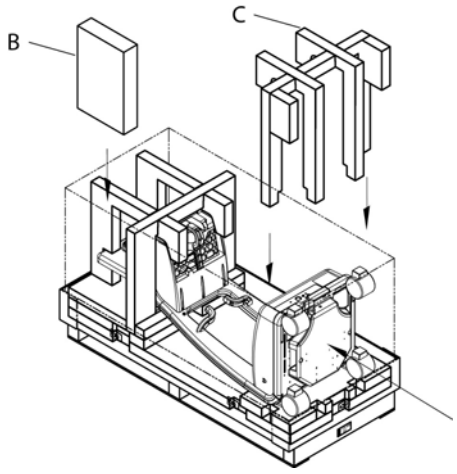
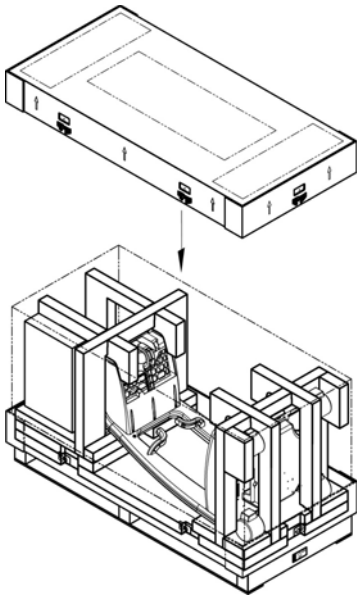
CAUTION

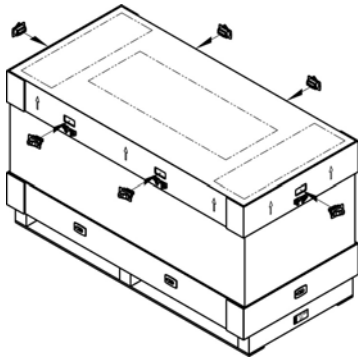
If shipment of the MR400 is required, batteries must be removed prior to transport and internal batteries must be disconnected.

To pack the MR400

Step	Action
1	In a location outside of the MR magnet room, ensure that the AC mains power is disconnected.
2	Ensure that both main batteries have been removed and that the battery switch for the reserve batteries is off; see page 14-2.

Step	Action
3	Cover the display panel and the WPU with protective film then install foam A over the display panel. 
4	With the packaging oriented so that the slotted foam will be nearest the top, raise the crate into an upright position. Roll the MR400 into the crate and then carefully lower the crate. 

Step	Action
5	Ensure that the guide handle is located in the slotted foam (see step 4)—if necessary, push the MR400 from the bottom. Pack the MR400 accessories in the accessory box (B) and then place the accessory box into the crate, alongside the display panel as shown below. Insert foam C over the WPU and between the base of the MR400 and the crate. 
6	Place the lid on the crate. 

Step	Action
7	Install all the clips into the lid on the crate, ensuring that each is locked and that the crate is secure. 

Final Disposal of the Product

Final disposal is when the user disposes of the product 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 product 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.

Philips Healthcare supports users in:

- Recovering reusable parts.
- Recycling of useful materials by competent disposal companies.
- Safe and effective disposal of equipment.

For advice and information, contact your Philips Service Organization first, or otherwise the manufacturer.

Disposal of the MR400 and Accessories

The MR400 cart, wireless modules 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 MR400 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 MR400 and accessories as described in the service manual.

Fitting, Removing and Disposing of Batteries

REACH requires Philips Healthcare (PH) to provide chemical content information for Substances of Very High Concern (SVHC) if they are present above 0.1% of the product weight. Components within electric and electronic equipment may contain phthalates above the threshold (e.g., bis 2-ethyl [hexyl] phthalate, CAS nr.: 117-81-7). The SVHC list is updated on a regular basis. Therefore, refer to the following Philips REACH website for the most up-to-date list of products containing SVHC above the threshold: http://www.philips.com/about/sustainability/reach.page

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 above.)

APPENDIX A

Specifications

General

Patient Safety

Conforms to ANSI/AAMI ES 60601-1. Certified to CAN/CSA C22.2 No. 60601-1-08; IEC 60601-1-2

Conforms to 93/42/EEC as amended by 2007/47/EEC, *Medical Device Directive*

Defibrillator protection up to 5 KVDC

According to the degree of ingress protection: Rated IP21

(Protected against access to hazardous parts and the ingress of solid foreign objects greater than 12.5mm (0.5 inch), and against vertically dripping liquid.)

Where appropriate, the equipment complies with worldwide standards for safety and performance of each system feature, when considering the indications for use within the MR environment. This equipment complies with the following international industry standards for safety and performance:

- ISO 14971, *Medical devices - Application of risk management to medical devices*
- IEC 60601-1, *Medical Electrical Equipment Part 1: General Requirements for Safety (Amendment 1) IEC 60601-1, clause 16, Medical Electrical (ME) Systems*
- ETSI EN 300-440-1, *Electromagnetic compatibility and Radio spectrum Matters (ERM); Short range devices; Radio equipment to be used in the 1 GHz to 40 GHz frequency range*
- ETSI EN 300-440-2, *Electromagnetic compatibility and Radio spectrum Matters (ERM); Short range devices; Radio equipment to be used in the 1 GHz to 40 GHz frequency range*
- ETSI EN 301-489-1, *Electromagnetic compatibility and Radio spectrum Matters (ERM); Electromagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements-V1.5.1*
- ETSI EN 301-489-3, *Electromagnetic Compatibility and Radio Spectrum Matters (ERM); Electromagnetic Compatibility (EMC) Standard for Radio Equipment and Services; Part 3: Specific Conditions for Short-Range Devices (SRD) Operating on Frequencies between 9 KHz and 40 GHz- V1.4.1*
- EN 980: *Symbols for use in labeling of medical devices*
- EN 1041: *Information supplied by the manufacturer of medical devices*
- BS EN 12470-4: 2001+A1:2009, *Clinical Thermometers – Part 4: Performance of Electrical Thermometers for Continuous Measurement*
- IEC 60068-2-1, *Environmental Testing – Part 2-1: Test–Test A: Cold*
- IEC 60068-2-2, *Environmental Testing – Part 2-2: Test–Test B: Dry Heat*
- IEC 60068-2-6, *Environmental Testing – Part 2: Tests–Test FE: Vibration (Sinusoidal)*
- IEC 60068-2-27, *Environmental Testing – Part 2: Tests–Test EB and Guidance: Bump*
- IEC 60068-2-64, *Environmental Testing – Part 2: Test Methods Test FH: Vibration Broad-band Random (Digital Control) and Guidance*
- IEC 60601-1-2, *Medical Electrical Equipment Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests*

General

- IEC 60068-2-64, *Environmental Testing – Part 2: Test Methods Test FH: Vibration Broad-band Random (Digital Control) and Guidance*
- IEC 60601-1-2, *Medical Electrical Equipment Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests*
- IEC 60601-1-6, *Medical Electrical Equipment - Part 1-6: General Requirements for Safety - Collateral Standard: Usability*
- IEC 60601-1-8, *Medical Electrical Equipment – Part 1-8: General Requirements for Basic Safety and Essential Performance – Collateral Standard: General Requirements, Tests and Guidance for Alarm Systems in Medical Electrical Equipment and Medical Electrical Systems*
- IEC 60601-2-27, *Particular Requirements for Safety - Specification for Electrocardiographic Monitoring Equipment*
- IEC 60601-2-33, *Particular requirements for the safety of magnetic resonance equipment for medical diagnosis*
- IEC 60601-2-34, *Medical Electrical Equipment – Part 2-34: Particular Requirements for the Safety, Including Essential Performance, of Invasive Blood Pressure Monitoring Equipment*
- IEC 60601-2-49, *Medical Electrical Equipment - Part 2-49: Particular Requirements for the Safety of Multifunction Patient Monitoring Equipment*
- IEC 80601-2-30, *Medical Electrical Equipment - Part 2-30: Particular Requirements for the Safety, Including Essential Performance, of Automatic Cycling Non-Invasive Blood Pressure Monitoring Equipment*
- ISO 80601-2-61, *Medical Electrical Equipment Particular Requirements for the Basic Safety and Essential Performance of Pulse Oximeter Equipment for Medical Use*
- ISO 80601-2-55, *Medical Electrical Equipment Particular Requirements for the Basic Safety and Essential Performance of Respiratory Gas Monitors and* Part 2-55
- Dangerous Goods Regulations 2008, *Dangerous Goods Regulations 2008 – UN ID 3090*
- UN DOT T1-T8, *UN Transport Testing for Secondary Lithium Cells*
- ISTA Procedure 1A, *Fixed Displacement Vibration and Shock Testing for Packaged Products weighing 150 lb (68 kg) or less*
- Directive 2011/65/EU, *Restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS2)*
- ISO 10993-1, *Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing*
- ISO 10993-5, *Biological Evaluation of Medical Devices - Part 5: Tests for Cytotoxicity: In vitro methods*
- ISO 10993-10, *Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Delayed-Type Hypersensitivity*
- 21 CFR Part 801, *Code of Federal Regulations – Medical Devices: Labeling*
- 49 CFR Part 173.185, *Code of Federal Regulations – Transportation – Other Regulations Relating to Transportation – Pipeline and Hazardous Materials Safety Administration, Department of Transportation – Hazardous Materials Regulations – Shippers-General Requirements for Shipments and Packagings – Non-bulk packaging for hazardous materials other than class 1 and class 7 – Lithium cells and batteries*
- 1999/5/EC, *R&TTE Directive (Radio and Telecommunications Terminal Equipment)*

General

- 2002/96/EC, *Directive on Waste of Electrical and Electronic Equipment*
- 2006/66/EC, *Battery Directive*
- ANSI/AAMI BP22, *Blood Pressure Transducers*
- ANSI/AAMI EC13, *Cardiac Monitors, Heart Rate Meters, and Alarms*
- ANSI / AAMI EC53, *ECG trunk cables and patient leadwires*
- ASTM E-1112—2000, *Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature*
- ASTM F2052-14, *Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Device in MR Environment*
- ASTM F2503-13, *Standard Practice for Marking Medical Devices and other Items for Safety in the MR Environment*
- FCC Part 15.249 (47 CFR Part 15.249), *Radio Frequency Devices – Operation within the bands 902-928 MHz, 2400-2483 MHz, 5725-5875 MHz, and 24.0-24.25 GHz*
- UL 2054, *Standard for Household and Commercial Batteries*
- IEC 62133, *Secondary cells and batteries containing alkaline or other non-acid electrolytes, Standard for Household and Commercial Batteries*
- RSS-210, Issue 7, *Low-power License-exempt Radio Communication Devices (All Frequency Bands): Category 1 Equipment*
- SAA AS/NZS 3200.1.2, *Medical Electrical Equipment Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests*
- ISO 14155-1, *Clinical investigation of medical devices for human subjects. Part 1: General requirements*
- IEC 62304, *Medical Device Software: Software life cycle processes*
- JIS T 0601-2-34, *Medical Electrical Equipment – Part 2-34: Particular Requirements for the Safety, Including Essential Performance, of Invasive Blood Pressure Monitoring Equipment*
- JIS T 1306, *Continuous Measuring Clinical Electrical Thermometers*
- ISO 80601-2-56, *Medical electrical equipment. Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement*

Power Requirements, Cart

Operating Voltage Range	100 to 240 VAC, ± 10 percent
Frequency Range	50 to 60 Hz, single phase
Current	1.4 A @ 100 VAC / 0.7 A @ 240 VAC
Power Consumption, Maximum	≤ 65 Watts
Protection	Internally fused (3.15 A, slow blow @ 250 VAC), AC line and neutral

General	
Battery	
Type	Cart: Lithium-Ion Module: Lithium polymer
Operation Time (Fully charged)	Cart: Dependent upon enabled parameters and settings: • All displays, alarms, and monitoring functions continuously for 8 hours • ECG & SPO2 continuously for 8 hours • CO2 continuously for 6 hours (with or without AGENT) • P1 and P2 continuously for 6 hours • AGENT analysis continuously for 6 hours • Temperature continuously for 6 hours • NIBP readings every 5 minutes for 6 hours Module: Approximately 8 hours
Charge Time	Cart: To recharge a fully discharged battery is approximately 12 hours with the MR400 turned off. Battery charge time to 90 percent of capacity is approximately 6 hours. Module: To recharge a fully discharged battery is approximately 4 hours. Battery charge time to 90 percent of capacity is less than 4 hours.
Minimum Voltage (For normal operation)	Cart: 14.4 V Module: 3.7 V
Capacity	Cart: 75 Wh Module: 3.1 Wh
Environment	
Operating Temperature Range	10 to 35°C (50 to 95°F)
Storage and Transport Temperature Range	Batteries: 0 to 40°C (32 to 104°F) Cart: -20 to 60°C (-4 to 140°F) Wireless modules and all other accessories not specified below: -20 to 60°C (-4 to 140°F) ECG skin prep gel: Follow instructions on tube Quadtrodes: 10 to 32°C (50 to 90°F) Transducer and cable (optional) (REF 989803179721): -15 to 60°C (-50 to 140°F) O2 sensor (AGENT option), Storage Temperature: +5 to 25 °C (+41 to 77 °F); Transport Temperature -40 to 50 °C (-40 to 122 °F) (When storing or transporting in temperatures beyond the ranges specified above, remove the designated component and store or move it appropriately.)

General	
Relative Humidity Range	5 to 80 percent, non-condensing Philips IBP Transducer and cable (optional): 15 to 80 percent, non-condensing
Operating Pressure Range	Up to 3,000 m (9,842 ft) above sea level (708 mbar or 531 mmHg)
Storage and Transport Pressure Range	708 mbar (708 hPA or 531 mmHg) to 1020 mbar (1020 hPA or 765 mmHg)
MRI System Range	0.7 to 3.0 Tesla, at RF power levels not exceeding 4W/kg SAR, and 7.2 µT $B1_{rms}$ in all orientations
Dimensions and Weights (All measurements made with batteries but without accessories; fully loaded cart weight also provided)	
Height	Cart: 127.3 cm (50.1 inches) Wireless ECG patient module: 18.2 cm (7.17 inches) Wireless SpO2 patient module: 13.0 cm (5.13 inches)
Width	Cart: 47.5 cm (18.7 inches) Wireless ECG patient module: 6.7 cm (2.65 inches) Wireless SpO2 patient module: 6.5 cm (2.55 inches)
Depth	Cart: 55.9 cm (22 inches) Wireless ECG patient module: 3.1 cm (1.24 inches) Wireless SpO2 patient module: 3.1 cm (1.24 inches)
Weight	Cart: 46.9 kg (103.3 pounds); fully loaded: 50.2 kg (110.7 pounds) Wireless ECG patient module: 340 g (12 ounces) Wireless SpO2 patient module: 204 g (7.2 ounces)
Display	
Type	Liquid Crystal Display (LCD), touch screen, color
Drive System	a-Si TFT active matrix
Screen Size	39.5 cm (15.6 inches) diagonal
Aspect Ratio	16:9
Area	344.2 (H) by 193.5 (V) mm
Pixels	1366 (H) by 768 (V) pixels
Dot Pitch	0.084 (H) by 0.252 (V) mm
Pixel Pitch	0.252 (H) by 0.252 (V) mm
Contrast Ratio	500:1 (typical)
Backlight	LED
Polarizer Surface	Anti-glare
Tilt	Adjustable, 5° to 35°

General	
Sweep Speed	For ECG, SPO2, and IBP, a speed of 25 mm/second gives 9.1 seconds of display time, while 50 mm/second gives 4.6 seconds. For respiration, a speed of 3.125, 6.25, 12.5 or 25 mm/second is provided.
Waveform Display Mode	Fixed trace, moving erase bar
Waveform Display Height (ECG, Single Trace)	≥ 40 mm
Waveform Display Height (ECG, Dual Trace)	≥ 20 mm
Waveform Display Height (SPO2, CO2, P1, P2)	≥ 25 mm
Waveform Display Length	≥ 228 mm
Battery Indication	Time remaining, red low warning
Alarm Light, Priority Indication	High: Red, flashing, 1.5 Hz with a 50% duty cycle Medium: Yellow, flashing, 0.75 Hz with a 50% duty cycle INOP: Blue, steady
Alarm Visibility	Legible at 1 meter (assuming a visual acuity of 20/20 and with no line of sight obstructions)
Alarm Sound Volume	At the maximum setting (10): 86 dB
Alarm Sound, Priority Indication	Three tones of fixed pitch mnemonic notes: High: c c c – c c Medium: c c c INOP: e c
Communication	
Attenuation	110 dB conducted

Displayed Information	
Time	Battery-backed quartz crystal clock
Alarms	High and low limits selectable for patient parameters ***Note*** *No algorithms were used to determine the manufacturer configured alarm presets.*
ECG	ECG waveform scale, displayed leads (2)

Displayed Information	
Heart Rate	Automatic mode selects the vital sign to provide the heart rate according to vital sign source availability and priority. If no source available (if no vital sign meets the criteria, then the heart rate source will be displayed as **None** and no heart rate will be produced. Manual mode selection to provide the heart rate is also available.
Pulse Oximeter	Pulse rate, pulse waveform (normalized) and percent saturation
Trends	Heart rate, respiration rate, P1 and/or P2(systolic, diastolic, mean), NIBP (systolic, diastolic, mean), EtCO2, O2, N2O, SpO2, and Agents
CO2	Both end-tidal and fractional inspired CO2
NIBP	Pressures (systolic, mean, diastolic) and status
Respiration Rate	Respiration rate derived from bellows or CO2
N2O	Et N_2O available in Agent MAC box Fi N_2O not displayed
O2	Inspired, end-tidal (averaged percent)
AGENT	Automatic identification of primary and secondary agents (Desflurane, Isoflurane, Enflurane, Halothane or Sevoflurane) displaying both end-tidal (Et) and fractional inspired (Fi) concentrations.
Temperature	Body temperature (°C or °F)

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, single-ended (according to IEC 60601-2-27, 50.102.3)
Electrode Contact Impedance	≤ 20K ohms @ 10 Hz
Heart Rate	
Resolution	1 beat per minute (BPM)
Pulse Rate Range	30 to 250 BPM (Adult) 30 to 300 BPM (Neonate, Pediatric)
Accuracy	± 1 percent or ± 1 BPM, whichever is greater.

ECG	
Cardiotach	
Sensitivity (Monitor filter mode)	Adult patient type: > 200 µV Neonate/Pediatric patient type: > 100 µV
QRS Duration	Adult patient type: 70 to 120 ms Neonate/Pediatric patient type: 40 to 120 ms
Bandwidth (Monitor filter mode)	0.5 to 40 Hz
Baseline Offset	Automatically removed
Tall T-Wave Rejection Capability for Heart Rate Indication	2 mV with a 1 mV QRS amplitude (Monitor mode)
Leads-off Sensing	Detection by DC current waveform of < 100 nA, not applied
Alarm Limits (HR)	
Lower Upper	Off, or 30 to 250 BPM 60 to 250 BPM, or off
Test/Calibrations	
Square Wave Test Signal	60 BPM ± 1 BPM, 1 mV ± 10 percent
ECG Supplemental Information, as required by IEC 60601-2-27	
Heart Rate (HR) Averaging Method	Fifteen-point median filter employed where the BPM heart rate is computed by taking the mean of the three middle elements. Update rate of the display is 2 Hz.
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 seconds Gain 2.0 (8.8, 9.1, 10.3, 9.4, 12.1) Average: 9.9 seconds
B2 - Vent Tachycardia 2 mVpp, 195 BPM	Gain 0.5 (9.0, 10.4, 12.3, 8.1, 10.4) Average: 10.0 seconds Gain 1.0 (8.4, 7.7, 12.5, 7.7, 8.3) Average: 8.9 seconds Gain 2.0 (9.7, 12.6, 8.9, 11.8, 8.3) Average: 10.3 seconds
Note *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.*	
Response Time of Heart Rate Meter to Change in Heart Rate	HR change from 80 to 120 BPM: 8.3 sec average HR change from 80 to 40 BPM: 7.9 sec average

ECG

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

*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.*

Pulse Oximeter

Pulse tone pitch is modulated by the saturation value.	
Saturation Range	1 to 100 percent, inclusive
Saturation Value Resolution	1 percent
Saturation Accuracy	± 3 percent at 70 – 100 percent
Pulse Accuracy	± 2 percent or ± 1 beat per minute (BPM), whichever is greater
Pulse Rate Range	30 to 250 BPM, inclusive
Pulse Rate Resolution	1 BPM
Data Update Period	5, 10, or 15 seconds (according to the SPO2 Averaging Time setting)
Data Update Period during Alarm	9, 14, or 19 seconds, maximum (4 seconds plus the SPO2 Averaging Time setting of 5, 10, or 15 seconds)
Wavelength Range	500 to 1000 nm

Note

Information about wavelength range can be especially useful to clinicians.

Emitted Light Energy	< 15 mW
Pulse Oximeter Calibration Range	70 to 100 percent

Alarm Limits

Lower	Off, or 50 to 100 percent
Upper	70 to 100 percent, or off

Pulse Oximeter

When "HR" is derived from SPO2	
Lower	Off, or 30 to 250 BPM
Upper	60 to 250 BPM, or off

Note

Measurement validation: SPO2 accuracy validated in human studies against arterial blood sample reference measured with a CO-oximeter. In a controlled desaturation study, healthy adult volunteers with saturation levels between 70–100 percent SPO2 were studied. The population characteristics for those studies were:

- *about 50% female and 50% male subjects*
- *19 – 27 years of age*
- *light to black skin tones*

Reference method for the computation of pulse rate accuracy made using an electronic pulse simulator. (A functional tester cannot be used for accuracy assessment of a pulse oximeter monitor; however, it can demonstrate that a pulse oximeter monitor reproduces a calibration curve that has been independently demonstrated to fulfill a particular accuracy specification.)

SPO2 measurements are statistically distributed; therefore, in accordance to 80601-2-61:2011, it is possible that only two-thirds of the measurements will fall within ± 3 percent of the value measured by the CO-Oximeter.

CO2 (Optional LoFlo)

Side stream, non-dispersive infrared absorption technique, includes multiple filtration system and microprocessor logic control of sample handling and calibration. Method for determining end-tidal CO2 measurement: Measures peak of the end-tidal CO2 waveform every 20 seconds.

Output	CO2 waveform, EtCO2 and FiCO2 measurement numeric values, and respiration rate
Initialization Time	Waveform displayed in less than 20 seconds, at an ambient temperature of 25°C (77°F); full specifications attained within 2 minutes
Zero Calibration Interval	Automatic or user requested
CO2 Unit of Measure	Millimeters of mercury (mmHg) or kilopascals* (kPa)
CO2 Resolution	1 mmHg (0.1 kPa)
Flow Rate	50 mL/minute ± 10 mL/minute
Data Sample Rate	100 Hz
End-tidal CO2 (EtCO2) Measurement Range (In which the CO2 accuracy specification is met)	0 to 76 mmHg (0 to 10.1 kPa) for respiration rates ranging from 4 to 60 breaths per minute, inclusive

CO2 (Optional LoFlo)	
Fractional inspired CO2 (FiCO2) Measurement Range	3 to 50 mmHg (0.4 to 6.7 kPa) Method: Lowest reading of the CO2 waveform in the previous 20 seconds
CO2 Accuracy (All measurements at gas temp of 25°C)	± 4 mmHg (± 0.5 kPa) or ± 12 percent, whichever is greater, after the specified warm-up period
CO2 Stability	
Short Term Drift	Not to exceed 0.8 mmHg (0.1 kPa) over a 4-hour period
Long Term Drift	Accuracy specification maintained over a 120-hour period
Respiration Accuracy	± 1 breath or ± 3 percent, whichever is greater
Respiration Resolution	1 breath per minute
Respiration Rate Range (In which the respiration accuracy specification is met) ***Note*** *A simulator was used to simulate breathing rates and calibrated gas was flowed through the simulator and into the system, and effects on accuracy were recorded to determine the rated respiration rate range and the corresponding effects of end-tidal gas reading accuracy as a function of respiratory rate.*	4 to 100 breaths per minute, inclusive
Accessory usage	Functional without changing accessories for a minimum of 6 hours
System Response and Rise Times (As measured from the patient gas input of the complete pneumatic circuit, including tubing, from 10 – 90 percent of the measured CO2 levels)	
Airway Adapter	System response: 10.89 seconds Rise time: 0.94 seconds
CO2 Cannula	System response: 12.44 seconds Rise time: 1.12 seconds
Divided Cannula	System response: 16.17 seconds Rise time: 2.01 seconds

CO2 (Optional LoFlo)	
Compensations (Automatic CO2 ambient pressure compensation 400– 800 mmHg [53.3 – 106.6 kPa])	For end-tidal O_2 balance gas (N_2, N_2O, O, He) and anesthetic agents[B] Uses gas compensation information to correct the raw carbon dioxide value
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 (60601-2-55)
Cross-sensitivity Compensation Error (Additional worst case error when compensation for O_2, N_2O, anesthetic agents, or helium is correctly selected for the actual fractional gas constituents present.)	0 to 40 mmHg: ± 1 mmHg additional error (0 to 5.3 kPa: ± 0.1 kPa additional error) 41 to 70 mmHg: ± 2.5 mmHg additional error (5.5 to 9.3 kPa: ± 0.3 kPa additional error) 71 to 100 mmHg: ± 4 mmHg additional error (9.5 to 13.3 kPa: ± 0.5 kPa additional error) 101 to 150 mmHg: ± 5 mmHg additional error (13.5 to 20 kPa: ± 0.6 kPa additional error)
Quantitative effects of gas sample humidity or condensate**:	0 to 40 mmHg: ± 2 mmHg (0 to 5.3 kPa: ± 0.2 kPa) 41 to 70 mmHg: ± 5 percent (5.5 to 9.3 kPa: ± 5 percent) 71 to 100 mmHg: ± 8 percent (9.5 to 13.3 kPa: ± 8 percent) 101 to 150 mmHg: ± 10 percent (13.5 to 20 kPa: ± 10 percent) **With appropriate compensations applied
Note *There are no known adverse effects on stated performance due to cyclical pressure of up to 10 kPa (100 cmH2O).*	
Calibration Interval	Calibration verification must be performed at 1 year intervals.

CO2 (Optional LoFlo)

Alarm Limits

End-tidal CO2	
Lower	Off, or 5 to 60 mmHg (Off, or 0.7 to 8.0 kPa)
Upper	5 to 90 mmHg, or off (0.7 to 12.0 kPa, or off)
Fractional inspired CO2	
Lower	No low alarm;
Upper	0 to 20 mmHg, or off (0 to 2.7 kPa, or off)
Respiration	
Lower	Off, or 4 to 40 RPM
Upper	20 to 100 RPM, or off

**For kilopascals (kPa), allow ± 1 least significant digit to accommodate round-off error for calculated values.*

A.

GAS or Vapor	Halothane	Enflurane	Isoflurane	Desflurane	Sevoflurane	N_2O
MAC Level, % vol fraction	0.77	1.70	1.15	6.00	2.10	105

(From ISO 80601-2-55. FDA recommended for a healthy 40-year old male.)

B.

Measured Gas	Quantitative Effects of Gas or Vapor											
	N_2O	**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

Invasive Blood Pressure (Optional)

Pressure Amplifier

Isolation Voltage	5 KVDC
Signal Range	-30 to +250 mmHg
Sensitivity	5 µV/V/mmHg
Gain Accuracy	±0.5 percent
Bandwidth	0 to 10 Hz (-3 dB)

Invasive Blood Pressure (Optional)	
Transducer Offset Range	± 300 mmHg
Transducer (REF 989803179721)	
Operating Pressure	-50 to 300 mmHg
Overpressure Limits	-400 to 5000 mmHg
Sensitivity	5 µV/V/mmHg ±1 @ 6 VDC and 22°C (71.6°F)
Zero Offset	< 25 mmHg
Zero Drift	< 2 mmHg in 8 hours
Input Impedance	300 to 350 ohms
Auto Zero	
Range	+300 mmHg
Zero Accuracy	±1.0 mmHg
Response Time	1 second, notifies operator when done
Pressure Wave Display	
Number of Channels	0, 1 or 2
ABP, PAP and LAP	Numeric display of systolic, mean and diastolic pressures
CVP and ICP	Numeric display of mean pressure only
Pressure Scale Ranges (User Selectable)	0 to 250 mmHg 0 to 200 mmHg 0 to 150 mmHg 0 to 100 mmHg 0 to 75 mmHg 0 to 45 mmHg
Pulse Rate (when derived from P1 or P2)	
Range	30 to 250 BPM
Accuracy	±2 percent of full scale
Resolution	1 BPM
Alarm Delay	
Transducer Disconnect	Six seconds
Pressure Disconnect	Six seconds
High and Low Pressure	Ten seconds
Alarm Limits	
When “HR” is derived from P1 or P2	
Lower	Off, or 30 to 250 BPM
Upper	60 to 250 BPM, or off
Systolic, Mean, Diastolic	
Lower	Off, or -30 mmHg to 250 mmHg (Off, or -4.0 to 33.3 kPa)
Upper	-30 mmHg to 250 mmHg, or off (-4.0 to 33.3 kPa, or off)

Invasive Blood Pressure (Optional)

Transducer Adapter Cable Compatibility

Invasive pressure input mates with an Amphenol connector (MS-3106A 14S-6P). With this connector and the following connection information, transducer adapter cables may be fabricated or ordered from various manufacturers.

Connector Pin Number	Signal Name
A	- Signal
B	+ Excitation
C	+ Signal
D	- Excitation
E	Shield

AGENT (Optional)

Side Stream, non-dispersive infrared (NDIR) absorption technique, including water trap filtration system and microprocessor logic control of sample handling and calibration

Simultaneously measured gases	Any two of the following, inspired or expired, while also measuring CO2, N2O, and O2: Halothane Isoflurane Sevoflurane Desflurane Enflurane
Measurement Range (after maximum warm-up period)	Halothane: 0 to 5.0 Vol.% Isoflurane: 0 to 5.0 Vol.% Sevoflurane: 0 to 8.0 Vol.% Desflurane: 0 to 18.0 Vol.% Enflurane: 0 to 5.0 Vol.% Carbon Dioxide: 0 to 10.0 Vol.% Nitrous Oxide: 0 to 100 Vol.%

AGENT (Optional)		
Accuracy* (includes stability and drift)	Halothane:	±0.15 Vol.% at 0 to 1.00 Vol% ±0.20 Vol% at 1.00 to 5.00 Vol% Unspecified > 5.00
	Isoflurane:	±0.15 Vol.% at 0 to 1.00 Vol% ±0.20 Vol% at 1.00 to 5.00 Vol% Unspecified > 5.00
	Sevoflurane:	±0.15 Vol.% at 0 to 1.00 Vol% ±0.20 Vol% at 1.00 to 5.00 Vol% ±0.40 Vol% at 5.00 to 8.00 Vol% Unspecified > 8.00
	Desflurane:	±0.15 Vol% at 0 to 1.00 Vol% ±0.20 Vol% at 1.00 to 5.00 Vol% ±0.40 Vol% at 5.00 to 10.00 Vol% ±0.60 Vol% at 10.00 to 15.00 Vol% ±1.0 Vol% at 15.00 to 18.00 Vol% Unspecified > 18.00
	Enflurane:	±0.15 Vol.% at 0 to 1.00 Vol% ±0.20 Vol% at 1.00 to 5.00 Vol% Unspecified > 5.00
	Carbon Dioxide:	±0.10 Vol% at 0 to 1.00 Vol% ±0.20 Vol% at 1.00 to 5.00 Vol% ±0.30 Vol% at 5.00 to 7.00 Vol% ±0.50 Vol% at 7.00 to 10.00 Vol% Unspecified > 10.00
	Nitrous Oxide:	±2.00 Vol% at 0 to 20 Vol% ±3.00 Vol% at 20.0 to 100 Vol%
Interference Gas	CO_2: N_2O, O_2, Any Agent = 0.1%$_{ABS}$ inaccuracy allowance for each N_2O: CO_2, O_2, Any Agent = 0.1%$_{ABS}$ inaccuracy allowance for each Agents: CO_2 = 0%$_{ABS}$ inaccuracy allowance N_2O, O_2, 2nd Agent = 0.1%$_{ABS}$ inaccuracy allowance for each	
Flow Rate (fixed)	200 ± 20 ml/min (Adult, Pediatric) 150 ± 15 ml/min (Neonate)	
Maximum specified interval for intervention of water (hours at specified minimum sample flow rate)	AGENT mode: Adult and pediatric is 17 hours @ 200 ml/min, 37°C, 100% RH; neonate is 17 hours @ 120 ml/min, 37°C, 100% RH CO2 mode: 8 hours @ 50 mL/min +/- 10 ml/min	

AGENT (Optional)	
System Response and Rise Times (As measured from patient gas input of the complete pneumatic circuit, including tubing, from 10 – 90 percent of measured levels)	
Cannula, Adult	Halothane— System response: 11.56 seconds Rise time: 5.77 seconds Enflurane— System response: 7.55 seconds Rise time: 1.75 seconds Isoflurane— System response: 6.71 seconds Rise time: 0.88 seconds Sevoflurane— System response: 6.45 seconds Rise time: 0.62 seconds Desflurane— System response: 6.63 seconds Rise time: 0.57 seconds Oxygen— System response: 6.99 seconds Rise time: 1.02 seconds Nitrous oxide— System response: 6.28 seconds Rise time: 0.25 seconds CO2— System response: 6.62 seconds Rise time: 0.61 seconds

AGENT (Optional)	
Cannula, Infant	Halothane— System response: 15.95 seconds Rise time: 8.63 seconds Enflurane— System response: 11.98 seconds Rise time: 4.75 seconds Isoflurane— System response: 9.26 seconds Rise time: 1.70 seconds Sevoflurane— System response: 6.48 seconds Rise time: 0.62 seconds Desflurane— System response: 6.47 seconds Rise time: 0.61 seconds Oxygen— System response: 8.61 seconds Rise time: 1.13 seconds Nitrous oxide— System response: 7.95 seconds Rise time: 0.72 seconds CO2— System response: 6.51 seconds Rise time: 0.48 seconds

AGENT (Optional)	
Divided Cannula, Adult	Halothane— System response: 20.81 seconds Rise time: 14.18 seconds Enflurane— System response: 13.83 seconds Rise time: 7.11 seconds Isoflurane— System response: 10.99 seconds Rise time: 3.91 seconds Sevoflurane— System response: 7.48 seconds Rise time: 0.78 seconds Desflurane— System response: 7.38 seconds Rise time: 0.64 seconds Oxygen— System response: 8.02 seconds Rise time: 1.07 seconds Nitrous oxide— System response: 7.16 seconds Rise time: 0.51 seconds CO2— System response: 7.57 seconds Rise time: 0.64 seconds

AGENT (Optional)	
Divided Cannula, Infant	Halothane— System response: 9.98 seconds Rise time: 3.95 seconds Enflurane— System response: 7.32 seconds Rise time: 1.37 seconds Isoflurane— System response: 6.75 seconds Rise time: 0.89 seconds Sevoflurane— System response: 5.45 seconds Rise time: 0.67 seconds Desflurane— System response: 6.25 seconds Rise time: 0.60 seconds Oxygen— System response: 7.25 seconds Rise time: 0.84 seconds Nitrous oxide— System response: 6.51 seconds Rise time: 0.39 seconds CO2— System response: 5.49 seconds Rise time: 0.49 seconds
Data Sample Rate	25 Hz
Full Accuracy Respiration Rate (Range permitting specified gas accuracy)	2 to 60 rpm
Note *A simulator was used to simulate breathing rates and calibrated gas was flowed through the simulator and into the system, and effects on accuracy were recorded to determine the rated respiration rate range and the corresponding effects of end-tidal gas reading accuracy as a function of respiratory rate.*	
End-tidal gas readings, calculation method	End tidal CO2 concentration readings are identified by using the highest value of the temporal CO2-curve. Corresponding readings of N2O and anesthetic agents are taken at the same point in time. End-tidal O2 concentration readings are identified by the O2 mean value during the respiratory phase as identified by the temporal CO2 curve. Once correctly identified, the lowest O2 concentration reading during the phase will be presented as end-tidal O2.
Total Respiration Range	2 to 100 rpm; accuracy is unspecified from 60 to 100 rpm

AGENT (Optional)	
Relevant Interference	0.5 mmHg equivalent with 37.5°C saturated with H_2O (0.1% relative max)
Display Resolution	0.1 percent volume
Maximum Warm-up Time	10 minutes; ISO accuracy achieved in < 45 seconds of activation
Auto ID Threshold (full accuracy mode)	Primary Agent ID: 0.15% Secondary Agent ID: 0.3%
Multiple Agents Alarm Threshold	0.3% (0.5% during ISO accuracy mode) or $5\%_{REL}$ (10% for Isoflurane) of primary agent if primary agent > 10% (For Hal add $0.1\%_{ABS}$ to threshold values)
CO_2 Ambient Pressure Compensation Range	500 mmHg to 900 mmHg
Pressure Compensation	Unaffected by cyclical pressures of up to 10 kPa as, apart from the described automatic pressure compensation, the pump automatically regulates flow so that not only gas readings but also gas sample flow is unaffected
Calibration Interval	Calibration verification must be performed at 1 year intervals.
Alarm Limits	
Et CO_2	
Lower	Off, or 5 to 60 mmHg (Off, or 0.6 – 8.0 kPa)
Upper	5 to 90 mmHg, or off (0.7 – 12.0 kPa, or off)
Fi CO_2	
Lower	No low alarm;
Upper	0 to 20 mmHg, or off (0 to 2.7 kPa, or off)
Fi N_2O	
Lower	No low alarm;
Upper	0 to 80 percent
Et Halothane	
Lower	Off, or 0.1 to 5.0 Vol. %
Upper	0.1 to 5.0 Vol. %, or off
Fi Halothane	
Lower	Off, or 0.1 to 5.0 Vol. %
Upper	0.1 to 5.0 Vol. %, or off
Et Isoflurane	
Lower	Off, or 0.1 to 5.0 Vol. %
Upper	0.1 to 5.0 Vol. %, or off

AGENT (Optional)	
Fi Isoflurane	
Lower	Off, 0.1 to 5.0 Vol. %
Upper	0.1 to 5.0 Vol. %, Off
Et Enflurane	
Lower	Off, 0.1 to 5.0 Vol. %
Upper	0.1 to 5.0 Vol. %, Off
Fi Enflurane	
Lower	Off, 0.1 to 5.0 Vol. %
Upper	0.1 to 5.0 Vol. %, Off
Et Sevoflurane	
Lower	Off, 0.1 to 8.0 Vol. %
Upper	0.1 to 8.0 Vol. %, Off
Fi Sevoflurane	
Lower	Off, 0.1 to 8.0 Vol. %
Upper	0.1 to 8.0 Vol. %, Off
Et Desflurane	
Lower	Off, 0.1 to 18.0 Vol. %
Upper	0.1 to 18.0 Vol. %, Off
Fi Desflurane	
Lower	Off, 0.1 to 18.0 Vol. %
Upper	0.1 to 18.0 Vol. %, Off
Fi O_2	
Lower and upper	18 to 100 percent
O2	
Resolution	1 percent
Range	0 to 100 percent
Signal Output (at constant temperature and pressure)	10 mV ±1.5 mV @ 20°C / 20.95% O_2
Maximum Response Time (21% to 100% step change through patient sampling line as seen in WPU gas monitor window)	Adult/Pediatric < 7.3 seconds Neonate: < 8.2 seconds
Accuracy (includes stability and drift), full scale*	±1% at 0 to 40% ±2% at 40 to 60% ±3% at 60 to 80% ±4% at 80 to 100%
*Gas measurement performance requirements are met after the maximum warm-up period.	

AGENT (Optional)	
Offset	±1 percent
O_2 Interfering Gas Effects:	
N_2O	< 0.3 vol% @ 80 vol% N_2O
CO_2	< 0.3 vol% @ 5 vol% CO_2
Halothane	< 0.3 vol% @ 5 vol% HAL
Enflurane	< 0.3 vol% @ 5 vol% ENF
Isoflurane	< 0.3 vol% @ 5 vol% ISO
Desflurane	< 0.3 vol% @ 18 vol% DES
Sevoflurane	< 0.3 vol% @ 8 vol% SEV
Acetone	< 0.3 vol% @ 1 vol% Acetone
Ethanol	< 0.3 vol% @ 0.1 vol% Ethanol
Helium	< 0.3 vol% @ 80 vol% HE
Methane	< 0.3 vol% @ 0.1 vol% Methane
Nitric Oxide	< 0.3 vol% @ 50 ppm NO
Oxygen Sensor, Operating Temperature	15 to 35°C (59 to 95°F)
Oxygen Sensor, Expected Operating Life	Product labeled with a use-by date; 15 months from manufacturing date (2500 hours at 100 percent O_2). Exchange recommended every 12 months.
CO2	
Resolution	1 percent
Range	0 to 100 percent

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

Temperature (Optional)	
(All measurements made with or without a sterile jacket)	
Channel	One
Units	Celsius (°C) or Fahrenheit (°F)
Range	20.0°C to 44.0°C (68.0°F to 111.2°F)
Resolution	0.1°C (0.1°F)

Temperature (Optional)

(All measurements made with or without a sterile jacket)

Accuracy	±0.5°C (±0.9°F) *Confirming changes in a measurement against other vital sign measurements should be standard routine during use.*
Response Time	The measuring time to obtain a steady-state reading within the manufacturer's accuracy specifications is within 15 seconds, compliant to ISO 80601-2-56, *Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement.*
Numeric Display Update Time	2 seconds
Sensor Type	Fiber-optic, multiple-use (when used with single-use sterilized jackets)
Application Site	Axillary, esophageal, rectal
Measurement Mode	Direct

Alarm Limits

Lower	Off, or 20.0 to 44.0°C (Off, or 68.0 to 111.2°F)
Upper	20.0 to 44.0°C, or off (68.0 to 111.2°F, or off)

Non-Invasive Blood Pressure

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 (22 kPa) for Adult, 130 mmHg (17.3 kPa) for Pediatric, and 100 mmHg (13.3 kPa) for Neonate; all pressures are ± 15 mmHg (2 kPa) Subsequent inflation pressures determined by last NIBP measurement
Overpressure Protection	Automatic cuff pressure release if inflation pressure exceeds 300 mmHg (40 kPa) for Adult and Pediatric modes, and 150 mmHg (20 kPa) for Neonate mode
Unit of Measure	Millimeters of mercury (mmHg) or kilopascals* (kPa)

Measurement Range

Systolic	
Adult	30 to 270 mmHg (4.0 to 36 kPa)
Pediatric	30 to 180 mmHg (4.0 to 24 kPa)
Neonate	30 to 130 mmHg (4.0 to 17.3 kPa)

Non-Invasive Blood Pressure	
Mean	
Adult	20 to 255 mmHg (2.7 to 34 kPa)
Pediatric	20 to 160 mmHg (2.7 to 21.3 kPa)
Neonate	20 to 120 mmHg (2.7 to 16 kPa)
Diastolic	
Adult	10 to 245 mmHg (1.3 to 32.7 kPa)
Pediatric	10 to 150 mmHg (1.3 to 20 kPa)
Neonate	10 to 100 mmHg (1.3 to 13.3 kPa)
Accuracy	
Pressure Measurement Accuracy	Maximum mean error ± 5 mmHg (± 0.6 kPa) with a standard deviation of less than 8 mmHg (1 kPa)
Pressure Measurement Resolution	1 mmHg (0.1 kPa)
Pressure Transducer Range	0 to 300 mmHg (0 to 40 kPa)
Modes	
Manual	Immediate upon operator command
Automatic	Determinations automatically made with selectable intervals of 1, 2, 3, 5, 10, 15, 20, and 30 minutes

Non-Invasive Blood Pressure

Notes

- *The effectiveness of NIBP has not been established in the presence of any dysrhythmias included in the exclusion criteria.*
- *The NIBP clinical study was performed on adult and pediatric patients with the following attributes:*
  - *The effectiveness of NIBP has not been established in the presence of any dysrhythmias included in the exclusion criteria.Gender: 61% male, 39% female.*
  - *No patients less than 29 days of age.*
  - *Patients with limb circumferences ranged from 10.5 cm to 39 cm, with a distribution of 46 percent below 25 cm and 7 percent above 35 cm.*
  - *The arterial systolic pressure ranges from 58 mmHg to 211 mmHg, with an average of 115 mmHg and with a distribution of 32.7 percent below 100 mmHg and 2.4 percent above 180 mmHg. The arterial diastolic pressure ranges from 34 mmHg to 131 mmHg, with an average of 65 mmHg and with a distribution of 42.3 percent below 60 mmHg and 3.9 percent above 100 mmHg.*
  - *Patients with any sign of arterial disease were excluded.*
  - *Patients with a heart beat greater than 180 BPM were excluded.*
  - *The radial artery was acceptable as a reference site for all patients but one which used the femoral artery.*
  - *The effectiveness was not validated on pregnant, including pre-eclamptic, patient populations.*
- *The NIBP clinical study was performed on neonatal patients with the following attributes:*
  - *No specified gender.*
  - *All patients 28 days or less if born at term (37 gestation or more); otherwise, up to 44 gestational weeks.*
  - *Patients with limb circumferences ranged from 5.75 cm to 13 cm with an average of 7.9 cm.*
  - *The arterial systolic pressure ranged from 42 mmHg to 89 mmHg, with an average of 57 mmHg. The arterial diastolic pressure ranged from 20 mmHg to 62 mmHg, with an average of 34 mmHg.*
- *Arterial reference sites included the umbilical, femoral, brachial and radial artery.*

Non-Invasive Blood Pressure	
Alarm Limits	
Systolic	
Adult	
Lower	Off, or 30 to 270 mmHg (Off, or 4.0 to 36.0 kPa)
Upper	30 to 270 mmHg, or off (or 4.0 to 36.0 kPa, or off)
Pediatric	
Lower	Off, or 30 to 180 mmHg (Off, or 4.0 to 24.0 kPa)
Upper	30 to 180 mmHg, or off (or 4.0 to 24.0 kPa, or off)
Neonate	
Lower	Off, or 30 to 130 mmHg (Off, or 4.0 to 17.3 kPa)
Upper	30 to 130 mmHg, or off (4.0 to 17.3 kPa, or off)
Mean	
Adult	
Lower	Off, or 20 to 255 mmHg (Off, or 2.7 to 34.0 kPa)
Upper	20 to 255 mmHg, or off (2.7 to 34.0 kPa, or off)
Pediatric	
Lower	Off, or 20 to 160 mmHg (Off, or 2.7 to 21.3 kPa)
Upper	20 to 160 mmHg, or off (2.7 to 21.3 kPa, or off)
Neonate	
Lower	Off, or 20 to 120 mmHg (Off, or 2.7 to 16.0 kPa)
Upper	20 to 120 mmHg, or off (2.7 to 16.0 kPa, or off)
Diastolic	
Adult	
Lower	Off, or 10 to 245 mmHg (Off, or 1.3 to 32.7 kPa)
Upper	10 to 245 mmHg, or off (1.3 to 32.7 kPa, or off)
Pediatric	
Lower	Off, or 10 to 150 mmHg (Off, or 1.3 to 20.0 kPa)
Upper	10 to 150 mmHg, or off (1.3 to 20.0 kPa, or off)
Neonate	
Lower	Off, or 10 to 100 mmHg (Off, or 1.3 to 13.3 kPa)
Upper	10 to 100 mmHg, or off (1.3 to 13.3 kPa, or off)

**For kilopascals (kPa), allow ± 1 least significant digit to accommodate round-off error for calculated values.*

Gating Outputs

Gating connector pin-outs

Pin Designator	Signal Name	Description and Characteristics
A	Digital gating pulse	ECG/SPO2 digital gating pulse: • Peak to peak voltage: 3.3 V to 5.0 V • Pulse duration: 10 ± 3 ms • Delay < 10 ms, ECG: Monitor and Default filter modes • Delay < 12 ms, ECG: Advanced 1 filter mode • Delay < 14 ms, ECG: Advanced 2 filter mode • Delay < 50 ms, SPO2
B	Signal ground	Return voltage reference for all other signal pins
C	RESP 1 V Analog	Analog respiration gating waveform signal: • Maximum output voltage: ± 5 V • Maximum current: 5 mA • Peak-to-peak signal voltage: 1 V • Delay = 200 ms
D	ECG 1 V Analog	Analog ECG 1-Volt waveform signal: • Bandwidth 0.5 to 40 Hz (Monitor filter mode) • Output signal scaling: 1 V/mV • Maximum output voltage: ± 5 V • Maximum current: 5 mA • Delay < 10 ms
E	P1 200mV Analog	Analog P1 gating waveform signal: • Maximum output voltage: 200 mV
F	Negative gating pulse	ECG/SPO2 negative digital gating pulse: • Peak-to-peak signal voltage: -3.3 V to -5.0 V • All other signal characteristics same as Pin A (see above)
G	SPO2 40 mV Analog	SPO2 IR/red analog gating waveform signal: • Signal scaling: 1 V/mV • Maximum output voltage: 40 mV • Delay = 250 ms
H	ECG 1 mV Analog	ECG analog gating waveform signal: • Signal scaling: 1 mV/mv • Maximum current: 5 mA • Maximum output voltage: 20 mV • Bandwidth 0.5 to 40 Hz (Monitor filter mode) • Delay < 10 ms
J	SPO2 2 V Analog	SPO2 IR/red analog gating waveform signal: • Maximum output voltage: 2 V • Delay = 250 ms
K, L, M, N, O	Unused	Unused pins

APPENDIX B

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 MR400 has been repaired by someone other than Koninklijke Philips N.V. or if the product has been subject to misuse, accident, negligence or abuse.

Koninklijke Philips N.V.'s sole obligation under this warranty is limited to repairing an MR400 which has been reported to the Technical Service Center during normal business hours and shipped transportation prepaid. Koninklijke Philips N.V. shall not be liable for any damages including but not limited to incidental damages, consequential damages or special damages.

This warranty is in lieu of any other warranties, guarantees or conditions, including merchantability or fitness for a particular purpose. The remedies under this warranty are exclusive and 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.

APPENDIX C

Regulatory Information

European Union

Declaration of Conformity

To obtain a copy of the Declaration of Conformity to the European Union Medical Device Directive (93/42/EEC) and Radio & Telecommunications Terminal Equipment Directive (1999/5/EC), and/or Restriction on Hazardous Substance (RoHS) Directive, contact the Regulatory Affairs Department at Invivo:

407-275-3220

-or-

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

Internationally, please contact your Key Market representative. Go to www.invivocorp.com for a listing. In addition, copies may be obtained from InCenter.

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
Hewlett-Packard Straße 2
71034, Böblingen
Germany

Australia

The Australia Sponsor is as follows:

Philips Electronics Australia Ltd
65 Epping Road, North Ryde NSW 2113
Australia

APPENDIX D

Gating Feature

The gating feature in the MR400 outputs data and discrete signals to the MRI scanner system resulting from the collection and processing of data from a monitored parameter. The scanner system uses these signals and data to precisely control the times that it collects MR image data from the patient.

Two types of data can be output by the gating facility of the MR400:

- Analog waveforms, which are analog electronic representations of waveforms collected from monitored parameters; and,
- Gating pulses, which are discrete electronic signals that indicate that some physiological event associated with a monitored parameter has occurred.

MR400 Preparation for Gating

When preparing the MR400 for gating of the MR system, ensure that the correct type of gating cable is connected between the rear panel of the MR400 and the MR system.

1 **Gating connector** for connection of the gating cable to the MR system.

Gating Connector Pin-outs

Gating signals from the MR400 are available through the shielded gating connector located on the rear panel of the cart (see above). Connections are made using a gating cable. Gating cables are available for each manufacturer's MRI system (GE Horizon LX, Siemens Harmony, Siemens

Symphony, Siemens Alvanto, Philips Intera, et cetera; see page 1-35). For detailed signal characteristics of the gating outputs, see A-28.

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 MR400 and output at the gating connector; see page 1-19 for the location, and see the table at the end of this appendix for signal details. (Signals can also transmitted by the optional wBTU.)

Using ECG Gating

To receive ECG gating signals

Step	Action
1	Check the battery indicators on the wECG module to ensure that enough charge exists in at least one of the installed batteries: • Green battery indicator = Charge sufficient; proceed to step 3. • Red battery indicator = Charge low; proceed to step 2. See page 2-9 for details. (Also, you can reference the status information pane; see page 2-16.)
2	According to the red battery indicator(s) present on the wECG module, insert a charged module battery into the corresponding battery bay(s) and then recheck the battery indicator(s) to ensure a sufficient charge before proceeding; see page 1-24.
3	Check the network channel indicator on the wECG module to ensure communication is established with the MR400: • Steady = Good communication; proceed to step 5. • Flashing = No communication; proceed to step 4. See page 2-10 for details. (Also, you can reference the status information pane; see page 2-16.)
4	Ensure that the wECG module is within 9.1 m (30 feet) of the MR400, in the same MRI room or in the same shielded room, and is set to the same wireless network channel used by the MR400; see page 1-29.
5	Ensure that the lead cable is properly attached to the patient; see *Attaching the ECG Lead Cable* on page 5-12. (ECG outputs are enabled by default; see page 5-29.)
6	It may be necessary to use **T-Wave Suppression**, see page 5-33.

Step	Action
7	Proceed according to the type of gating being used: **Analog Gating** — To receive the analog ECG gating waveform through the MR400, ensure that all of the following conditions have been met: • The correct gating cable is installed between the MR400 and the MR system; • The system is communicating with the wECG module; • The wECG module is properly attached to the patient; and, • **Lead Fail** does not exist for the measured ECG signal. **Digital Gating** — To receive the digital ECG gating pulse from the MR400, ensure that all of the following conditions have been met: • The correct gating cable is installed between the MR400 and the MR system; • The system is communicating with the wECG module; • The wECG module is properly attached to the patient; • **Lead Fail** does not exist for the measured ECG signal; • The ECG parameter has been activated in the menu system; and, • The ECG signal has been selected as the digital pulse source, as follows: a. Select the ECG VS box. b. Select **Gating Source**. c. Select **ECG**.

Using SPO2 Gating

To receive SPO2 gating signals

Step	Action
1	Check the battery indicator on the wSpO2 module to ensure that enough charge exists: • Green battery indicator = Charge sufficient; proceed to step 5. • Red battery indicator = Charge low; proceed to step 4. See page 2-11 for details. (Also, you can reference the status information pane; see page 2-16.)
2	Insert a charged module battery into the wSpO2 module and then recheck the battery indicator to ensure a sufficient charge before proceeding; see page 1-26.
3	Check the network channel indicator on the wSpO2 module to ensure communication is established with the MR400: • Steady = Good communication; proceed to step 7. • Flashing = No communication; proceed to step 6. See page 2-11 for details. (Also, you can reference the status information pane; see page 2-16.)
4	Ensure that the correct gating cable is installed between the MR400 and the MR system.
5	Ensure that the wSpO2 module is within 9.1 m (30 feet) of the MR400, in the same MRI room or in the same shielded room, and is set to the same wireless network channel used by the MR400; see page 1-29.
6	Ensure that the SPO2 attachment is properly attached; see *Applying the SPO2 Attachment to the Patient* on page 6-3.
7	Select the SPO2 VS box (see page 6-8). The **SPO2** menu appears. Current settings are displayed.
8	Select **Gating Source**. The **Gating Source** menu appears; see page 5-15.
9	Select **Pulse**. The setting is applied.

APPENDIX E

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 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, et cetera).

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, et cetera), 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, et cetera).

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, et cetera).

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, et cetera) 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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