Invivo

Expression MRI Patient Monitoring System

(Model 865214)

INSTRUCTIONS FOR USE

Revision G

English

989803162691

Manufacturer

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Chapter 1
Important Information

About This Manual

Important user information about the Expression MRI Patient Monitoring System (Model 865214) and contact information for Invivo is discussed here. The terms “Cart” and “Patient Management Configuration” (PMC) are used throughout this manual to refer to the available configurations of the Expression MRI Patient Monitoring System. Specific differences between the configurations are noted where applicable.

Information regarding the safety, accessories, installation, and operation of a fully equipped Expression MRI Patient Monitoring System (Model 865214) can be found in this document. Some information may depict monitoring features not present on your system. For information on all features and enhancements, contact Invivo or your Invivo sales representative:

Invivo

Orlando, FL 32826

877-468-4861

www.invivocorp.com

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

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

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

Intended Audience

The Expression MRI Patient Monitoring System (Model 865214) is intended for use by healthcare professionals trained in the use of the equipment and vital signs monitoring.

Conventions

Certain conventions are used throughout the Expression MRI Patient Monitoring System (Model 865214) to speed use and familiarity with the device. This accompanying Instructions for Use also employs document conventions to assist you in finding and understanding information.

System Conventions

These conventions are used when operating the Expression MRI Patient Monitoring System (Model 865214):

- The display panel includes a keypad and knob:
  - Press a key to activate or deactivate its function or to view its menu.
  - Turn the knob to navigate vital signs, parameters and menu options, or to increment or decrement fields, where the current item will be displayed in a highlighted field or background.
  - Press the knob to select a parameter, menu option or setting.
- Most menus employ a time-out feature where, if no action is taken for approximately 60 seconds, an open menu will automatically close.
- To protect against accidental changes, a YES/NO decision prompt is associated with certain menu options. When displayed, you must confirm or cancel this prompt; otherwise, a delay of approximately 30 seconds will be equivalent to selecting NO. (Note that the “NO” equivalent is also accomplished by pressing the NORMAL SCREEN key or the STANDBY key.)
- To protect against unauthorized changes, some menu items feature password protection. You must enter the correct numeric code for access, where a delay of approximately 30 seconds is equivalent to making no entry.

Document Conventions

These conventions are used in this document.

- All procedures are numbered, and all sub-procedures are lettered. Complete the steps in the sequence presented to ensure success. Procedures are indicated by the table below.

Step	Action
1	
2	
3	

- During procedures, control names, menu items and titles are spelled and punctuated as they appear in the system.
- The selection path to an option in the menu system is sometimes abbreviated with the greater than symbol (>) between menu items in the procedural string.
- Bulleted lists indicate general information about a particular menu function or procedure, and do not imply sequential order or operation.
- Where LCD images are presented, for clarity some of the black screen backgrounds have been replaced with a white background in this document for legibility.
- The left side of the system is on your left as you stand in front of the system, facing it. The front of the system is nearest you as you operate it.
- The front of the module is nearest you as you operate it.

Warnings

WARNING

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

Cautions

CAUTION

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

Notes

NOTE

Notes provide additional information you should know regarding system usage.

Accessories

Accessories are listed in the tables below. Only use recommended Invivo accessories as other brands may compromise the safety and accuracy of the system.

CO_2/Anesthetic Agents

Description	REF
CANNULA, DISP, ADULT	989803152561
CANNULA, DISP, ADULT,	989803152601
CANNULA, DISP, INT INF, (DIVIDED)	989803152621
CANNULA, DISP, PED, (DIVIDED)	989803152631
CANNULA, DISP, INFANT, (DIVIDED)	989803152611
CANNULA, DISP, INT INFANT	989803152591
CANNULA, DISP, PED	989803152571
ADPTR, ENDOTRACHEAL TUBE, 50 PK	989803152691
CAL GAS, AEROSOL CO-2	989803152641
KIT, WASTE GAS HOSE W/ADAPTER	989803152681

CO_2 (Low Flow)/Anesthetic Agents

Description	REF
KIT, WATER TRAP, ETCO2, 3160	989803152551
KIT, STARTER, ETCO2, 3160	989803152531
KIT, SAMPLE, ETCO2, 3160	989803152541

CO_2 (Standard Flow)/Anesthetic Agents

Description	REF
ANESTHETIC OXYGEN (O2) SENSOR	989803162051
ANESTHETIC OXYGEN (O2) SENSOR, INSTALLATION TOOL	989803162961
KIT, DISPOSABLE WATER TRAP	989803152671
KIT, STARTER, AGENTS, 3160	989803152651
KIT, SAMPLE, AGENTS	989803152661

ECG

Description	REF
ADVANCED FILTER ECG CABLE	989803170121
KIT, STARTER, QUADTRODE CV, 3160	989803152261
CAB, 4 LD, CV MRI ECG	989803152351
KIT, STARTER, NEONATAL, MRI	989803152441
CAB, 4 LD, NEO.MRI ECG	989803152331
GEL, ECG/EEG, SKIN PREP, TUBE, 3-PACK	989803152291
KIT, STARTER, STANDARD ECG, 3160	989803152251
CAB, 4 LD, MRI ECG	989803152301
WIRELESS WECG MODULE	989803163121
QUADTRODE MRI ECG PAD, 25/BOX	989803179031
ELCTRD, MRI ECG, QUTRD.CV, 25/BOX	989803179041
ELCTRD, MRI,NEO.QUDTRD, 25/BOX	989803179051

Gating Options

Description	REF
CAB, DIGITAL GATING, GE, 3160	989803152821
CAB, DIG.GATING, HIT/TOSH, 3160	989803152851
CAB, GATING, SIEMENS, 3160	989803152831
CAB, GATING, PHILIPS ACH, 3160	989803152841

Invasive Blood Pressure

Invivo recommends using the **Edwards Lifesciences Transducer, Model PX260,** and adapter cables. Please contact Edwards Lifesciences for an adapter cable that is compatible with Invivo devices. For additional questions, please contact your sales representative.

Mounting Options

Description	REF
WALL CHANNEL,POLYMOUNT,19"	989803152951
DOVETAIL CHAN,PIVOT ARM,OHMEDA	989803152961
WALL CHANNEL,PIVOT ARM,DRAEGER	989803152971
COLUMN, MOUNTING, DUAL CHANNEL, 8	453564215481
BRACKET, MOUNTING, NARCOMED,WPU	453564215491
KNOB,BAR,1/4-20 X 3/4 LG	453564240801
MRI MOUNTING ARM	989803162551
ASSEMBLY,WALL MOUNT,DCU	989803172451
NARKOMED STAINLESS STEEL HARDWARE KIT	989803172811

Non-Invasive Blood Pressure (NIBP)

Description	REF
KIT, STARTER, NEONATAL, MRI	989803152441
HOSE, NEO, 15 FT, MRI	989803169421
HOSE, ADULT, 18', MRI	989803169411
KIT, ACCESSORIES, NIBP, MRI	989803152451
CUFF, NIBP, DISP, SAMPLE KIT	989803170501
CUFF, INFANT, MRI, COLDER CONN	989803169431
CUFF, CHILD, MRI, COLDER CONN	989803169441
CUFF, ADULT, MRI, COLDER CONN	989803169451
CUFF, LARGE ADULT, MRI, COLDER CONN	989803169461
CUFF, DISP, NEO, MRI SIZE#3	989803170401
CUFF, DISP, NEO, MRI SIZE#5	989803170421
CUFF, NIBP, DISP, INFANT, 10 - 15CM	989803170431
CUFF, NIBP, DISP, PEDIATRIC, 14 - 21CM	989803170441
CUFF, NIBP, DISP, SMALLADULT, 20 - 28CM	989803170451
CUFF, NIBP, DISP, ADULT, 27 - 36CM	989803170461

NIBP (continued)

Description	REF
CUFF, NIBP, DISP, ADULT EXTRA-LONG, 27 - 36CM	989803170471
CUFF, NIBP, DISP, LARGE ADULT, 35 - 45CM	989803170481
CUFF, NIBP, DISP, LARGE ADULT EXTRA-LONG, 35-45CM	989803170491

Pneumatic Respiration

Description	REF
PNEUMOGRAPH, CHEST, NM, 3160	989803152791

Replacement Power

Description	REF
BATTERY, MRI, 14.8V, 5.08 AH, UL	989803169491
CAB, POWER, ADAPTER, 25FT, 3155	989803152231
CAB,POWER,ADAPTER,5FT,3155 SER	989803152221
NORTH AMERICAN LINE CORD	989803168211
EUROPEAN LINE CORD	453564177501
UK LINE CORD, 3 METER	989803174171
BRAZILIAN POWER CORD, 3 METER	989803173901
ASSEMBLY, POWER CORD SET 220V	989803152191
MR COMPATIBLE POWER CONVERTER	989803168201
BATT.3.7V, WRLS. PAT. MDLE.	989803152881
ASSY, 3.7V BATTERY CHARGER, 3160	989803152891
DCU POWER CONVERTER KIT	453564123631
KIT,POWER CONVERTER,MRFUSION	989803171721
ASSY,LINE CORD,110 V,TESTED	989803152181
POWER CORD, AUS/NZL, 3 METER	989803181291
POWER CORD, S AFRICA, 3 METER	989803181321

Replacement Power (continued)

Description	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

SpO_2

Description	REF
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
QUICK CONNECT SPO2 STARTER KIT	989803167111
QUICK CONNECT SPO2 PROBE, MRI	989803161991
SPO2 SENSOR GRIP ADULT/NEONATAL 2 PACK	989803162501
SPO2 SENSOR GRIP INFANT/PEDIATRIC 2 PACK	989803162511
WIRELESS SP02 MODULE (GEN 2)	989803163111
GRIP SENSOR STARTER KIT	989803162491

Temperature

Description	REF
FLEXTEMP SYSTEM, SENSOR	989803178171
SURGICAL LUBRICANT, 12 PACK	989803168891
FLEXTEMP SYSTEM, JACKET	989803178181
APPLICATOR,TEMP.SNSR,F.O.	989803152811

Miscellaneous

Description	REF
2.4 GHZ, ANTENNA	453564125581
ADVANCED COMMUNICATIONS OPTION	989803176521
CONTROL ROOM FLEX ANTENNA	989803176511
HOLDER, ACCESSORIES, CART	453564145951
PAPER,THERM ARRAY PRNTR (10PK)	989803152911
3160P OPERATORS MANUAL	989803162691
MANUAL, OPERATIONS, 3160P, DANISH	989803169211
MANUAL, OPERATIONS, 3160P, DUTCH	989803169221
MANUAL, OPERATIONS, 3160P, FRENCH	989803169231
MANUAL, OPERATIONS, 3160P, GERMAN	989803169241
MANUAL, OPERATIONS, 3160P, ITALIAN	989803169251
MANUAL, OPERATIONS, 3160P, NORWEGIAN	989803169261
MANUAL, OPERATIONS, 3160P, BRAZILIAN POR	989803169271
MANUAL, OPERATIONS, 3160P, SPANISH	989803169291
MANUAL, OPERATIONS, 3160P, SWEDISH	989803169301
MANUAL, OPERATIONS, 3160P, RUSSIAN	989803170271
MANUAL, OPERATIONS, 3160P, POLISH	989803173101
MANUAL, OPERATIONS, 3160P, JAPANESE	989803173171

Miscellaneous (continued)

Description	REF
MANUAL, OPERATIONS, 3160P, SIMPLIFIED CH	989803173181
MANUAL, OPERATIONS, 3160P, TRADITIONAL C	989803173191
MANUAL, OPERATOR, EXPRESSION, FINNISH	989803179331
MANUAL, OPERATIONS, EXPRESSION, CZECH	989803179351
QUICK REFERENCE GUIDE, ENGLISH	989803162711
3160P SERVICE MANUAL	989803162701
EXPRESSION PLUS	989803180471
FILTER,13MM,1.0UM HYDRO.,M/F	453564181961

Safety

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.

Radios

Radio Frequency (RF) Range: 2402 to 2482 MHz

Modulation Type: GMSK

WPU EIRP: 4.2 dBm (peak)

wECG and $WSPO_2$ EIRP: 0 dBm (peak)

WARNINGS

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

Electromagnetic Emissions

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

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

Electromagnetic Immunity

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

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The Expression MRI Patient Monitoring System is intended for use in the electromagnetic environment specified below. The customer or the user of the Expression 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; and, if covered with synthetic material, the relative humidity should be at least 30 percent.
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	Less than 5% *U*t (Greater than 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 Less than 5% *U*t (Greater than 95% dip in *U*t) for 5 seconds	Less than 5% *U*t (Greater than 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 Less than 5% *U*t (Greater than 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 MRI Patient Monitoring System requires continued operation during power mains interruptions, it is recommended that the Expression MRI Patient Monitoring System be powered from an uninterruptable power supply or battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE *U*t *is the AC mains voltage prior to application of the test level.*			

Guidance and Manufacturer's Declaration - Electromagnetic Immunity (continued)			
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 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 this symbol:

NOTES

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

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

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the Expression MRI Patient Monitoring System

The Expression MRI Patient Monitoring System is intended for use in the electromagnetic environment specified below. The customer or the user of the Expression MRI Patient Monitoring System should assure that it is used in such an environment.

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

NOTES

- *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.*

Battery Disposal

The system and modules use lithium-polymer and lithium-ion batteries that are subject to strict disposal regulations for user and environmental safety.

CAUTION

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

Disposing of Batteries in Europe

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

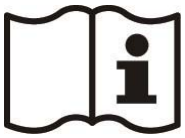
Disposing of Batteries in the United States

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

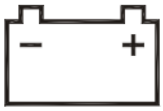
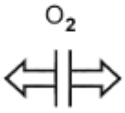
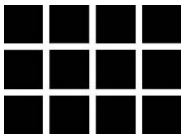
Used Accessory Disposal

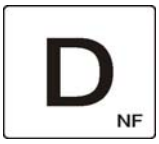
The disposal of used patient accessories should be handled in accordance with your hospital guidelines for medical waste.

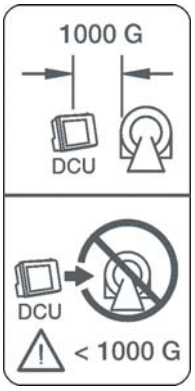
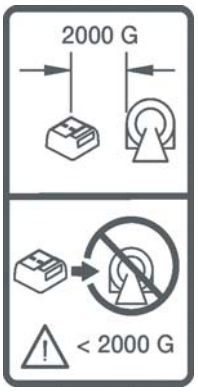
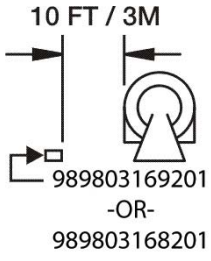
List of Symbols

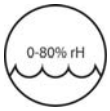
Symbol	Meaning	Symbol	Meaning
	Attention, consult accompanying documents		Breathing Effort Detected
	Non-ionizing radiation		Not MR safe
	Fuse	$\%SpO_2$	Percent oxygen pulse saturation
REF	Part number		Earth ground
	Alternating current		DANGER! High Voltage
	Direct current		Antenna
	Up/Increment		Down/Decrement
EC REP	Authorized representative in the European Community	STERILE R	Sterilized using radiation

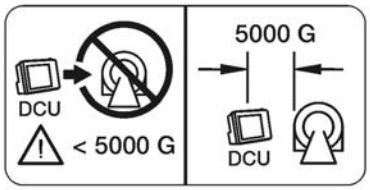
Symbol	Meaning	Symbol	Meaning
CE CE 0413	Device conforms to the Medical Device Directive		I (Rotate counterclockwise to OPEN) O (Rotate clockwise to CLOSE)
SN	Product serial number		Locked
	Caution! **NOTE** *UL 60601-1 designates this symbol as "consult accompanying documents".*		Unlocked
	Date of manufacture year-month		Latex-free materials used
	Defibrillator-proof type CF equipment (IEC 60601-1) protection against shock		Weight
	Potential restrictions for equipment including radios may apply within one or more European (EU) member states.		Dangerous voltage
	Type CF Applied Part		Patient
	Alarms sound on		Alarms sound off

Symbol	Meaning	Symbol	Meaning
	Alarms on hold		Alarms silenced
	Single patient use only DO NOT REUSE		Replace fuses as marked
	Heart beat detected		Attention: Electrostatic safety device Observe precautions
	Input/Output		Battery
	Non-invasive Blood Pressure		Universal Serial Bus (USB) port
	Oxygen sensor access here		Keyboard
	On AC power		ECG
	On battery power		Low battery
	Serial communications port		Remote display
	Fiber-optic temperature		End-tidal CO_2 /O_2/anesthetic agents

Symbol	Meaning	Symbol	Meaning
	Warning Shock Hazard		Pneumatic respiration
	Do not adjust without referring to service manual		Radio network (wireless modules)
	Hard wire link		Network A
	Waste gas output		Network B
	End-Tidal CO_2 /O_2/anesthetic agents input		Network C
	Cardiac (ECG) gating output		Network D
	MR Conditional: Use in the MR environment is restricted to certain conditions of use to ensure patient and operator safety		Network E
	Non-sterile device		Use by date

Symbol	Meaning	Symbol	Meaning
	Radio network (WPU to DCU)		Cart wheel brake
	Device conforms to the R&TTE Directive (Radio & Telecommunications Terminal Equipment)		Underwriters Laboratories (UL) Classified mark for the United States and Canada
	Dispose of in accordance with your country's requirements.		Manufacturer
	DO NOT move the Expression DCU with printer inside the 1,000 Gauss Line (as measured from the center line of the bore).		DO NOT move the Expression Patient Management Configuration inside the 2,000 Gauss Line (as measured from the center line of the bore).
	MR Safe		Device storage range, temperature
	Federal Communications Commission		Ensure the power converter (REF 989803169201 or 989803168201) remains 10 feet (3 meters) or more from the MR system.

Symbol	Meaning	Symbol	Meaning
	Device storage range, humidity		DO NOT move the Expression Cart configuration inside the 5,000 Gauss Line (as measured from the center line of the bore).
LOT	Batch code (lot number)		
	Correct		

Symbol	Meaning
	DO NOT move the Expression DCU inside the 5,000 Gauss Line (as measured from the center line of the bore).

Installation

This section provides important information about installation and system requirements.

Unpacking the System

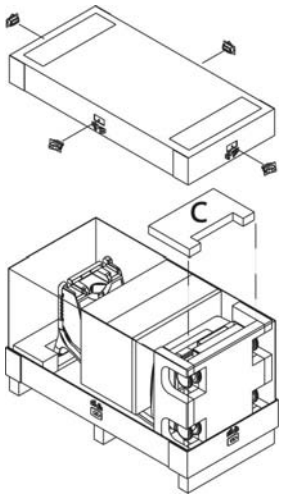
Remove the contents from the shipping containers. Carefully examine all items for signs of damage that may have occurred during shipment. Also, check all items against the included packing list and the purchase request. To report shipping damage, or to resolve any issues or concerns with your order, contact Customer Service. (Save all packing materials and related shipping documents, as these can be required to process a shipping damage claim with the carrier.)

CAUTION

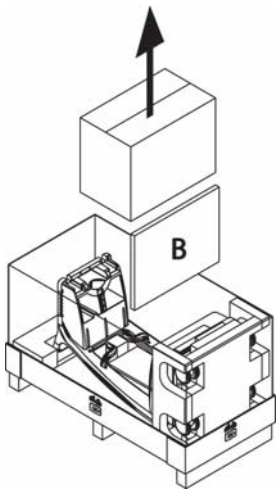
The system must be used and stored according to the environmental specifications in Appendix A. Failure to follow these specifications may affect system accuracy.

To unpack the Cart, follow the steps below.

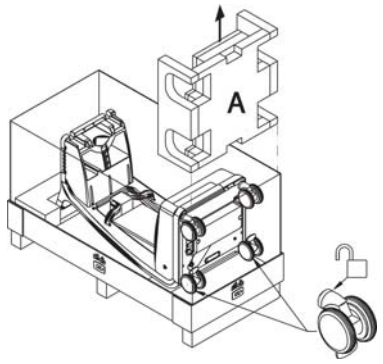
1. Open the four snaps that secure the lid to the crate. Remove the lid and foam insert C from the crate.



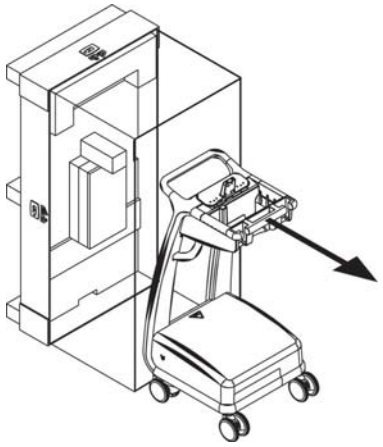
2. Remove the accessories box and foam insert B.



3. Remove foam insert A and unlock the wheels of the Cart.



4. Carefully raise the crate and then roll out the Cart.



Packaging Disposal

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

Equipment Classification

EQUIPMENT CLASSIFICATION (According to IEC 60601-1)	
According to the type of protection against electrical shock	Class I equipment
According to the degree of protection against electrical shock:	Type CF (defibrillator-proof) equipment
According to the degree of protection against harmful ingress of water:	Ordinary equipment (enclosed equipment without protection against ingress of water).
According to the methods of sterilization or disinfection:	Non-sterilizable. Use of liquid surface disinfectants only.
According to the mode of operation:	Continuous operation
Equipment not suitable for use in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide.	

NOTE

Laws in the United States, Canada and the European Union restrict this device to sale by or on the order of a physician.

Defibrillation

A patient can be defibrillated with the wECG module connected to the patient.

WARNINGS

- **The patient connection inputs for all parameters are protected against the use of a defibrillator by internal circuitry when the recommended patient cables or accessories are used. The use of this circuitry and these recommended cables and accessories also protects against the hazards resulting from use of high frequency surgical equipment.**
- **Defibrillation and Electrosurgery: Do not touch the patient, or table, or instruments, during defibrillation.**
- **The Expression MRI Patient Monitoring System can be used in the presence of defibrillators or electrosurgery units, provided the equipment being used is in good working order, meeting appropriate safety standards, is properly grounded, and is operated correctly in the appropriate manner and environment. Improperly grounded equipment can be a safety hazard and also cause interference to the ECG signal and result in a noisy ECG signal waveform and inaccurate heart rate measurements.**

CAUTION

When using a defibrillator, do not introduce discharges of 360 joules or more, repeated 5 times over 5 minutes. Read safety instructions provided with the defibrillator. The Expression is designed to withstand defibrillation and will recover within 5 seconds (per IEC 60601-1, General Requirements for the Safety of Medical Electrical Equipment).

NOTE

The Expression MRI Patient Monitoring System has a defibrillation-proof type degree of protection. When using a defibrillator, make sure to follow all precautions related to both the system and the defibrillator equipment. During a defibrillation procedure, the ECG waveform will saturate then recover within 5 seconds in accordance with AAMI/ANSI EC13.

System Installation

System installation is explained below. If questions arise, please contact Technical Support for guidance.

WARNINGS

- **Do not use the Expression MRI Patient Monitoring System in the presence of flammable anesthetics.**
- **Always verify proper communication of the Expression with the corresponding DCU prior to patient use.**

CAUTIONS

- Avoid the use of cellular phones or other radio frequency transmitters in the proximity of an operating Expression MRI Patient Monitoring System.
- Do not use two Expression MRI Patient Monitoring Systems in the same MR room. This will lead to communication errors.
- A minor but noticeable degradation in the Wireless ECG and Wireless SpO_2 radio communications will occur in the presence of high-powered radios.
- Where the integrity of the external protective conductor in the installation or its arrangement is in doubt, the system shall be operated from batteries (REF 989803169491).

Installing the Cart

WARNING

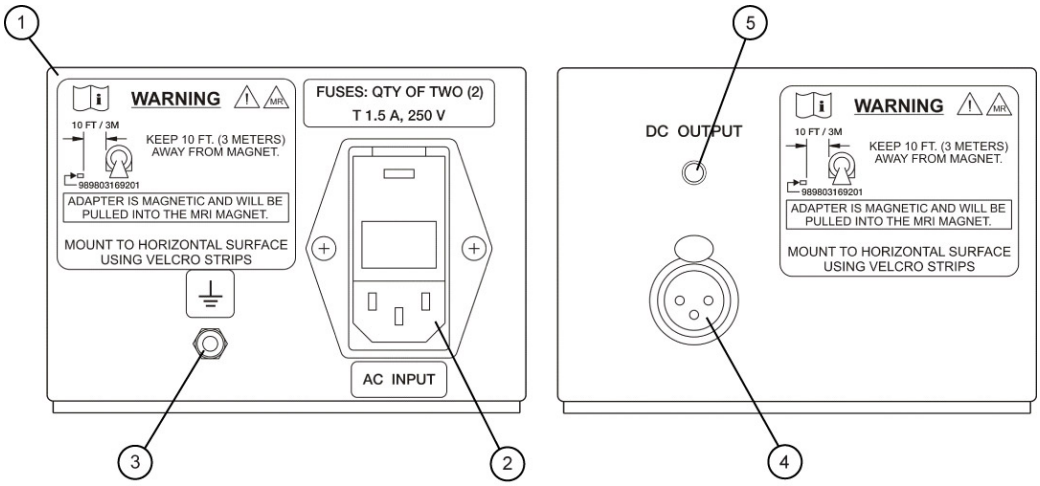
The Expression MRI Patient Monitoring System (Cart configuration) may be used inside the MR system room in a location at or outside the 5,000 (5,000 or less) Gauss (0.5T) field line of the MR system, as measured from the center line of the MR bore. Failure to properly place the Expression and its accessories in the MR system room will result in system or accessory failure, and possible patient or user injury. Always secure the Cart's wheel locks when the unit is placed within the MR system room.

CAUTIONS

- If the Expression MRI Patient Monitoring System (Cart configuration) rolls to the face of the MR system due to magnetically induced pull force, DO NOT ATTEMPT TO DISLODGE THE EXPRESSION BY PULLING FROM THE DOCKED DCU OR GUIDE HANDLE AT THE TOP OF THE EXPRESSION. Dislodge the Expression by gently pulling from the base of the system at its lowest point. This will prevent the base of the unit from experiencing higher MR pull forces in the vertical direction.
- 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 Cart away from the MR system if system abnormalities or malfunctions are observed. Prior to clinical use, ensure that the allowable distance of the Expression components from the MR system is maintained for proper operation.

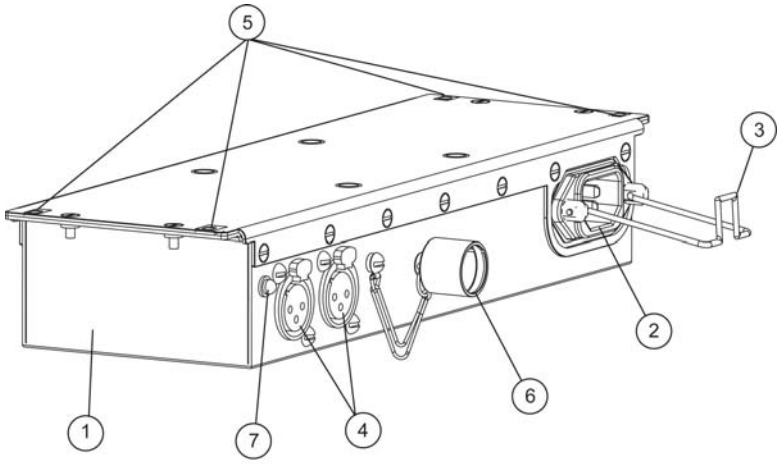
Two different types of Power Supplies are available for use with the system:

- Power converter REF 989803169201 (shown below) is an externally fused device.



	Description
1	Power converter REF 989803169201
2	AC input
3	Ground terminal
4	DC output
5	LED indicator (illuminated = powered on)

- Power converter REF 989803168201 (shown below) is an internally fused, auto-resetting device.



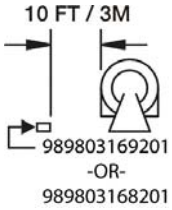
	Description
1	Power converter REF 989803168201
2	AC input
3	AC cord strain relief
4	DC output (2)
5	Mounting holes (4)
6	Shield cap
7	LED indicator (illuminated = powered on)

WARNING

Cover any unused DC output with a shield cap in order to prevent noise artifacts from appearing on the MR image.

Begin installation by following the steps below.

Step	Action
1	Install the batteries; see Chapter 2, Installing the Cart Batteries, page 2-13.
2	Connect the AC power cord to the AC input of the power converter.
3	Connect the male end of the 25-foot power adapter cable (REF 989803152231) to the DC output of the power converter.
4	Position and secure the power converter in the MR system room near an approved AC outlet at a distance of at least 10 feet (3 meters) from the MR system.
5	Connect the female end of the DC power cable into the power receptacle on the Cart. 
6	Connect the AC power cord to the AC outlet.



WARNING

Ensure the power converter (REF 989803169201 or 989803168201) remains 10 feet (3 meters) or more from the MR system. Mount the power converter to a horizontal surface using the pre-applied Velcro strips on the supply.

CAUTION

Avoid use of electrical power extension cords or multiple portable socket outlets which may create a safety hazard by compromising the grounding integrity of the Expression MRI Patient Monitoring System.

Installing the Display Control Unit

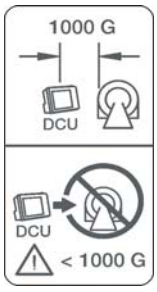
The Display Control Unit (DCU) may be used in the MR system room, MR control room, or the MR holding area. Warnings and cautions must be observed to ensure safe use and system reliability. The DCU can be docked to Cart-based Expression systems, or it can operate independently from battery or AC mains power with the following provisions:

- If the DCU must be located in the MR system room, it should be operated on battery power or docked on the Cart.
- If the DCU will be located in the MR system room and connected to AC mains, use the power converter only.
- Additional power cords and power supplies may be purchased from your Invivo sales representative.

WARNING

None of the interconnection ports on the rear of the DCU (for example, communication ports, auxiliary input/output port, USB port, keyboard port, etc.) are intended for direct patient connection. An electric shock hazard can exist if the patient is electrically connected to any of these connections.

Docking a DCU to the Cart



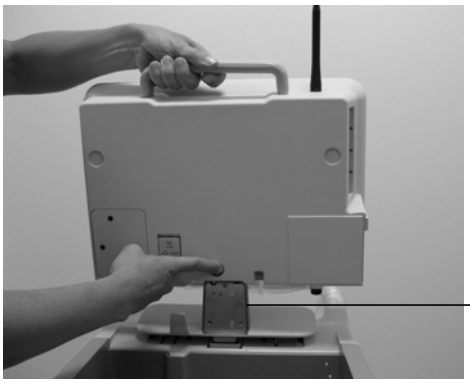
WARNING

The DCU contains some ferrous materials that are attracted to the MR magnetic field. DO NOT install or remove the DCU from the Cart when the Expression MRI Patient Monitoring System system is closer than the 1,000 Gauss (0.1 T) field line as measured from the center line of the MR bore. The DCU will be attracted to the magnetic field, possibly causing patient or user injury.

CAUTIONS

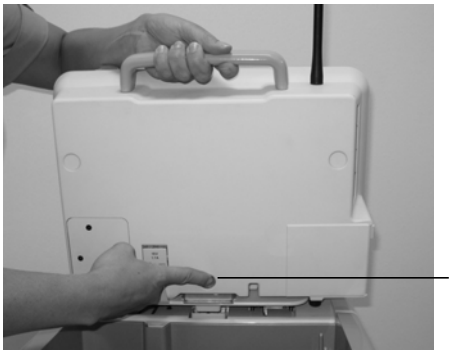
- If the printer option is present in the DCU, it may be used in the MR system room at or outside the 1,000 Gauss (0.1T) field line (as measured from the enter line of the MR bore) of the MR system. Do not move the DCU closer than the specified Gauss field line or damage to the printer (failure to operate) may result. If operation of the DCU is necessary in close proximity to the 1,000 Gauss (0.1T) field line, position the DCU so that the printer is on the opposite side of the gurney.
- If the printer option is not present, the DCU may be used at or outside the 5,000 Gauss (0.5T) field line as measured from the center line of the MR bore.

To dock the DCU onto the Cart, complete the steps below.

Step	Action
1	Ensure that AC power is disconnected from the DCU. **CAUTION** Do not dock the DCU to the Cart if the DCU is connected to AC mains power. Damage to the DCU or the power cable may result.
2	Center the DCU over the mounting shoe on the Cart.
3	While holding the DCU handle, gently slide the DCU over the mounting shoe. 
4	Do not force the DCU onto the Cart. When properly positioned, the DCU will latch into place.
5	Install the batteries; see Installing the DCU Batteries on page 2-16.

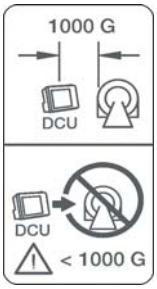
Undocking a DCU from the Cart

To remove the DCU from the Cart, complete the steps below.

Step	Action
1	Tilt the DCU all the way back.
2	Grasp the handle on the DCU then, on the back of the unit, press the button at the bottom center. 
3	With the button depressed, lift the DCU off the Cart until clear of the shoe. Then place the DCU on firm level surface.

Using an Undocked DCU in the MR System Room

The DCU can be used when undocked from the Cart.



WARNING

The DCU contains some ferrous materials that are attracted to the MR magnetic field. DO NOT install or remove the DCU from the Cart when the Expression MRI Patient Monitoring System system is closer than the 1,000 Gauss (0.1 T) field line as measured from the center line of the MR bore. The DCU will be attracted to the magnetic field, possibly causing patient or user injury.

CAUTIONS

- If the printer option is present in the DCU, it may be used in the MR system room at or outside the 1,000 Gauss (0.1T) field line (as measured from the enter line of the MR bore) of the MR system. Do not move the DCU closer than the specified Gauss field line or damage to the printer (failure to operate) may result. If operation of the DCU is necessary in close proximity to the 1,000 Gauss (0.1T) field line, position the DCU so that the printer is on the opposite side of the gurney.
- If the printer option is not present, the DCU may be used at or outside the 5,000 Gauss (0.5T) field line as measured from the center line of the MR bore.

Follow the steps below to use an undocked DCU in the MR system room using AC mains power.

Step	Action
1	Place the DCU on a firm, stable surface. ***NOTE*** *If mounting the DCU, contact customer service for information and guidance on the available mounting options or see Accessories on page 1-3.*
1	Install the batteries; see Chapter 2, Installing the DCU Batteries, page 2-16.
2	With the power converter positioned and secured in the MR system room at least 10 feet (3 meters) from the MR system, connect the AC power cord to the AC input of the power converter.
3	Connect the male end of the 25-foot power adapter cable (REF 989803152231) to the DC output of the power converter.
4	Plug the female end of the DCU power cable into the power receptacle on the back of the DCU.  Power receptacle
5	Repeat the above steps for each additional DCU that will be used in the MR control or holding room.
6	Connect the AC power cord to the AC outlet.

Using a DCU in the MR Control Room

Follow the steps below to use the DCU in the MR control or holding room using AC mains power.

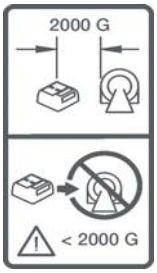
Step	Action
1	Place the DCU on a firm, stable surface. ***NOTE*** *If mounting the DCU, contact customer service for information and guidance on the available mounting options or see Accessories on page 1-3.*
2	Install the batteries; see Chapter 2, Installing the DCU Batteries, page 2-16.
3	Locate the DCU Power Converter Kit (REF 453564123631) provided in the DCU package. Attach the AC power cord to the AC input on the Power Converter (REF 453563464761).
4	Connect the male end of the DCU power cable (REF 453564109681) to the DC output on the power converter.
5	Position the DCU and power converter in the MR control room or MR holding room near an approved AC outlet.
6	Plug the female end of the DCU power cable into the power receptacle on the back of the DCU.  Power receptacle
7	Repeat the above steps for an additional DCU if used in the MR control or holding room.
8	Connect the AC power cord to the AC outlet.

WARNING

Do not use the DCU Power Converter Kit (REF 453564123631) inside the MR system room. The device is magnetic and will be pulled into the MR system. Never take the DCU Power Converter Kit into the MR system room. The device is intended for use with the Display Control Unit (DCU) only when used outside the MR system room.

Installing the Patient Management Configuration

Contact customer service for information and guidance on available mounting options for the Patient Management Configuration (PMC) or see Accessories on page 1-3.



WARNING

The Patient Management Configuration (PMC) may be used inside the MR system room at or outside the 2,000 Gauss (0.2T) field line as measured from the center line of the MR bore. Always ensure that no portion of the PMC is closer than 2,000 Gauss (0.2T) field line and that the PMC is securely fastened to the mounting surface. System failure or patient injury may result if the PMC is brought closer than 2,000 Gauss (0.2T) field line.

Proceed with installation depending upon the type of power converter included with the system, as outlined in the steps below.

Step	Action
1	Install the batteries; see Chapter 2, Installing the PMC Batteries, page 2-14.
2	Connect the AC power cord to the AC input of the power converter.
3	Connect the male end of the 25-foot power adapter cable (REF 989803152231) to the DC output of the power converter.
4	Position and secure the power converter in the MR system room near an approved AC outlet at a distance of at least 10 feet (3 meters) from the MR system.
5	Plug the female end of the DC output into the power receptacle on the PMC.  Power receptacle

Step	Action
6	Plug the AC power cord into the AC outlet.
7	Install the DCU; see Installing the Display Control Unit on page 1-29.

Additional Installation Options

Additional installation options can increase operator ease or facilitate data sharing, as the Cart (or PMC) and DCU have input/output ports that permit external equipment connections to an external projector or monitor, or to facility information systems. Consult your biomed or Invivo-authorized service personnel with specific requests.

CAUTIONS

- Performance of the Expression MRI Patient Monitoring System and any other devices within the room may be degraded if the ground terminal is used against Invivo's intended use as listed above.
- When using the input/output connections at the rear of the Cart (or PMC) and DCU verify that the final installation complies with IEC/EN 60601-1-1, *General Requirements for the Safety of Medical Electrical Systems*, to assure operator and patient safety. Always check the summation of leakage currents when the Expression MRI Patient Monitoring System is connected to additional external equipment.
- Do not remove the input/output door or leave the input/output port uncovered while in the MR system room during procedures. Degradation of system performance may result.
- The manufacturer is not responsible for any radio or TV interference caused by unauthorized modifications to the radios within this equipment. Such modification could inhibit proper system communication.

Chapter 2
System Overview

Indications for Use

The Expression MRI Patient Monitoring System (Model 865214) is designed to assist clinicians in monitoring patient vital signs in the dynamic magnetic resonance environment. The Expression combines wireless communication, radio frequency shielding, digital signal processing and adaptable mounting technologies to address the challenges associated with patient monitoring in the MR environment. The Expression provides accurate, continuous, reliable performance during MRI applications, as well as signals for MR scanner synchronization.

NOTE

The Expression MRI Patient Monitoring System (Model 865214) is not intended for use on a patient being transported outside of a health care facility.

System Parameters

The Expression MRI Patient Monitoring System facilitates simultaneous processing and display of up to eight parameters, six waveforms, and associated numeric values from each parameter. All patient monitoring information is displayed on the Display Control Unit (DCU):

- Dual Channel Electrocardiogram (ECG)
- Pulse Oximetry (SpO_2)
- Non-invasive Blood Pressure (NIBP)
- End-tidal CO_2 (CO_2) and Respiration
- Invasive Blood Pressure (IBP)
- Pneumatic Respiration
- Body Temperature
- Anesthetic Agents

The standard monitoring parameters include ECG, SpO_2, NIBP and pneumatic respiration. Optional monitoring parameters are end-tidal CO_2, CO_2- derived respiration, anesthetic agents, IBP, and body and surface temperature.

Device Configurations

The Expression is available as a Cart-based system (traditional roll-around) or in a Patient Management Configuration (PMC) for adaptable mounting to meet your specific patient monitoring needs, including the following:

- Critically ill patients
- Sedation
- Anesthesia
- Pediatrics
- Neonates
- Cardiac gating
- Interventional procedures
- Intraoperative procedures
- Patient transport within the MR environment

NOTE

This equipment is suitable for use in the presence of electrosurgical units (ESU).

Warnings

Before using the Expression MRI Patient Monitoring System, read these warnings and Chapter 1, Safety, page 1-10. These warnings refer to the Expression MRI Patient Monitoring System (Model 865214) in its entirety.

WARNINGS

- **Thoroughly read and understand the Instructions for Use prior to use.**
- **A shock hazard exists if the Expression MRI Patient Monitoring System (Model 865214) is operated without the system covers installed.**
- **Use only supplied power cords and connect only to properly grounded AC outlets to avoid electrical shock.**
- **Ensure that the monitor settings are appropriate for the patient being monitored.**
- **Patient motion or position of the accessories may affect measurement accuracy. Always consult a physician for interpretation of measurements provided by the system.**
- **Perform operational verification prior to use. If the system fails to function properly, remove it from use and contact Technical Support personnel.**
- **Screen all patients for metallic wires, implants, stents, etc. prior to MR procedures. These electrical conductors will react with the MR environment or with the Invivo accessory (if applied directly over the conductor), thus increasing the risk of heating.**

System Overview

An Expression MRI Patient Monitoring System consists of the following primary components:

- Cart or Patient Management Configuration
- Display Control Unit
- Wireless ECG Module
- Wireless SpO_2 Module

The Cart-based system features an integrated wheeled pedestal design; alternately, the mount-based Patient Management Configuration (PMC) system allows for custom installation into MR environments with limited space or patient mobility requirements.

Various accessories for both system types are available to meet specific patient monitoring needs.

CAUTION

Use only recommended Invivo patient cables, lead cables, cuffs, hoses, sensors, tubing, etc. Using other brands may compromise the safety and accuracy of the Expression MRI Patient Monitoring System. A list of accessories can be found in Chapter 1, Accessories, page 1-3.

The Cart (or PMC) houses the Wireless Processing Unit (WPU) and the patient connection area. The WPU contains circuitry and hardware for support of the monitoring parameters, including the transceivers and antennas for wireless communications. System power is supplied by AC mains power, or by two removable batteries (which, if installed, are automatically charged). Refer to Battery Operation, page 2-11, for more information.

NOTE

The Expression MRI Patient Monitoring System and listed accessories may be safely powered by the voltages 100-240 VAC at 50 or 60 Hz.

The Display Control Unit (DCU) contains the user interface, consisting of a color LCD, keypad, knob and optional printer to provide display, control, and documentation of monitored parameters.

The wireless ECG (wECG) module monitors ECG, converting ECG signals into radio signals for transmission to the WPU for use by the system.

The wireless SpO_2 ($WSpO_2$) module monitors SpO_2 and pneumatic respiration converting the signals into radio signals for transmission to the WPU for use by the system.

The Cart or the Patient Management Configuration (PMC), DCU, wECG module, and $wSpO_2$ module communicate via a bidirectional 2.4 GHz spread-spectrum link. Communication is automatically established between the Cart (or PMC), DCU and wireless modules upon power-up. Status indicators are described in DCU Status Indicator, page 2-24.

Cart Configuration

The Cart-based Expression MRI Patient Monitoring System system consists of these primary components:

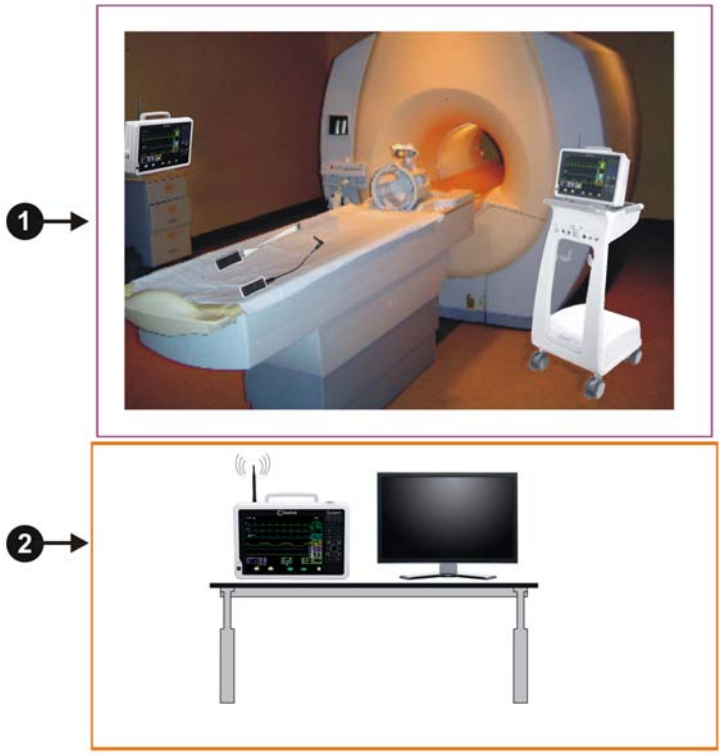
- Cart
- DCU
- Wireless ECG module
- Wireless SpO_2 module
- Two module batteries
- Four Cart/DCU batteries
- DCU power converter kit
- System power converter

The Cart (shown with the DCU mounted) has the following components and features.

CAUTION

Do not place more than 20 pounds (9 kg) of accessories in the storage basket.

A use model example of the Cart configuration within the MR system room is provided in the illustration below where the Cart, a docked DCU and an additional DCU are used. A third DCU, located in the control room, is set to communicate with the Cart and DCUs in the MR system room.



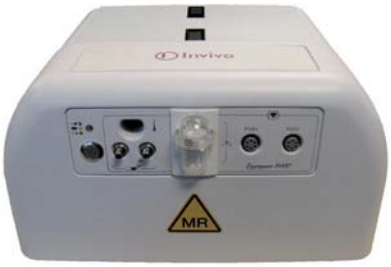
Patient Management Configuration

The Patient Management Configuration (PMC), available in horizontal and vertical models, consists of the following primary components:

- PMC
- DCU
- Wireless ECG module
- Wireless SpO_2 module
- Two module batteries
- Four PMC/DCU batteries
- DCU power converter kit
- System power converter

NOTE

Several options are available for mounting the PMC; see Chapter 1, Mounting Options, page 1-6 for details.



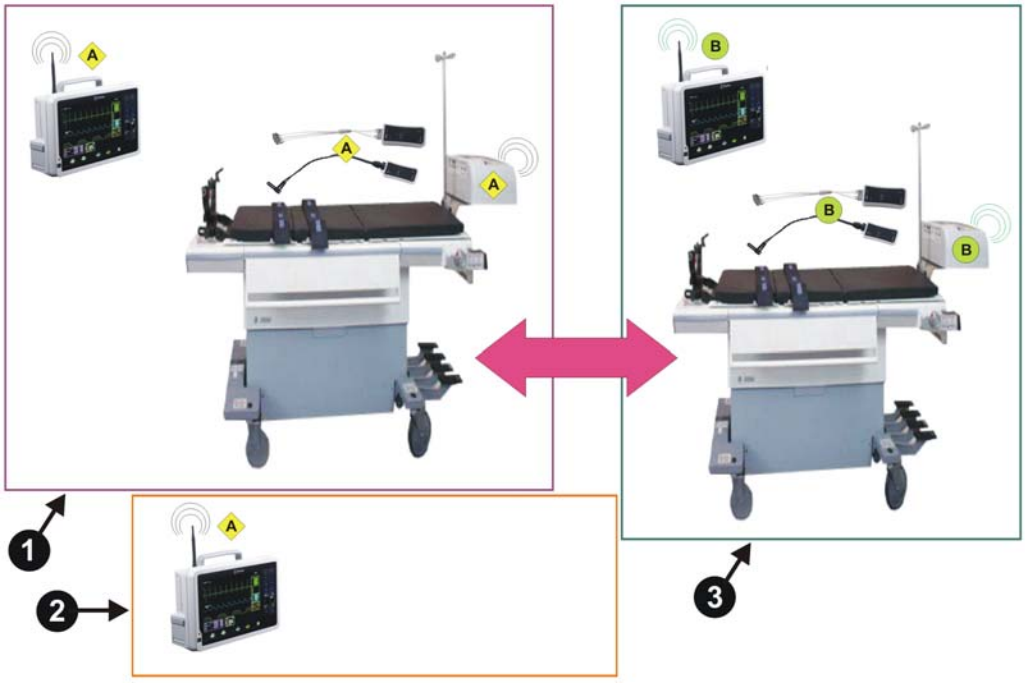
Horizontal model

Vertical model

An use model example of the PMC is shown in the illustration below, where the potential locations are as follows:

1. MR suite
2. Control room
3. Induction / recovery areas

The PMC may be transferred between the MR suite and the induction or recovery areas throughout an intraoperative MRI procedure. An additional DCU may be located in the control room to ease operator use. (A and B denote the different network settings used for the PMC components in this workflow depiction.)



Display Control Unit

The Display Control Unit (DCU) consists of a color LCD, keypad, and (optional) printer for display, control, and documentation of monitored patient parameters. The DCU can be docked to the Cart or used as a standalone component.

A DCU can be located in the MR system room, control room or holding area. And, for added flexibility the system can be configured with up to two additional DCUs.

When multiple DCUs are used, commands which control the alarm limits and patient parameters are synchronized between DCUs through the WPU in the Cart (or PMC). The following settings, however, are not synchronized between DCUs:

- Printer functions
- Alarm volume
- Pulse volume
- Click tone
- Click volume
- Time of day
- Alarm silence
- Alarm hold
- Network settings
- Printer configuration
- Data logging interval
- Trace sweep speed
- Trend data
- Trend configuration
- Blood pressure display format
- CO_2 grids
- System configuration printer setting
- System configuration analog output setting
- System configuration language setting

The following rules further dictate the behavior of the system when multiple DCUs are used:

- Commands that do not directly control patient parameters will only affect the individual DCU where the command was initiated. If the Cart (or PMC) is off, no information is exchanged between multiple DCUs, and any changes made to the parameter, alarm or other settings will only affect the DCU upon which those changes were made.
- If the Cart (or PMC) and one DCU is turned on and communicating, and another DCU is turned on and communicating on the same network, the second DCU will inherit the settings from the first DCU. If multiple DCUs are already on but the Cart (or PMC) is off, the Cart (or PMC) upon power up will acquire the settings from the first DCU with which it communicates, and then these settings will be relayed to the remaining DCU(s).

NOTE

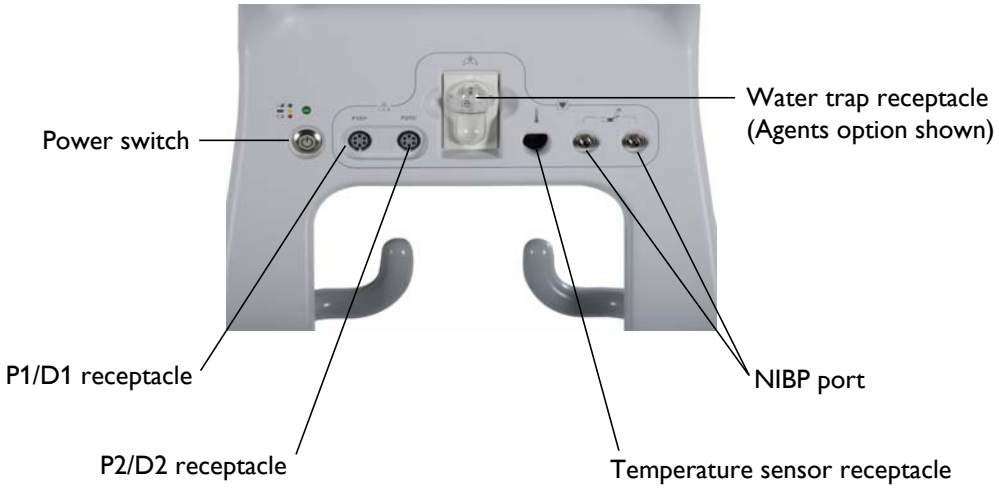
Several options are available for standalone mounting of the DCU, see Chapter 1, Accessories, page 1-3 for details.

DCU Alarm Light

The DCU alarm light is located atop the DCU (see below). The alarm light illuminates when the Expression enters an alarm condition. For illumination specifications, see Appendix A.

Patient Connection Area

The patient connection area houses the power switch for the Cart (or PMC), and the receptacles for the water trap and hardware (hoses, sensors, etc.) for parameters not communicated by wireless link.

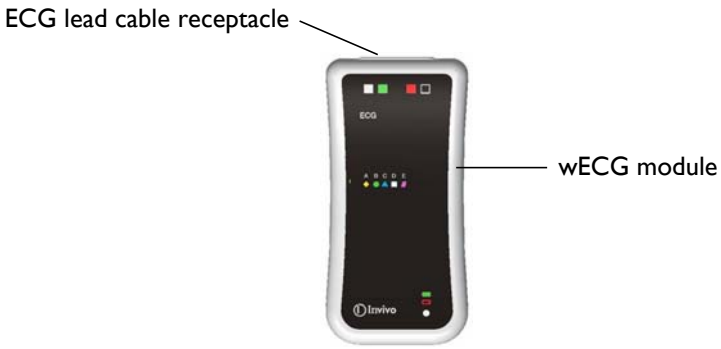


Wireless Modules

The wireless modules are used to transmit monitored ECG and SpO2 data from the patient to the Cart (or PMC). Module communications with the Cart (or PMC) are automatically established upon power-up. A status indicator provides operational information about the module, including the status of the rechargeable batteries, as described in Understanding the Module Status Indicator, page 2-18.

WEGC Module

The wireless ECG (wECG) module communicates two channels of ECG simultaneously to the WPU. Both channels of ECG can be displayed by the DCU and are gating outputs for interfacing to the MR system. The module also receives data through the wireless link to perform commanded tasks (for example, lead configuration and/or filter mode changes). The wECG module houses the receptacle for various ECG lead cables and Quadtrode electrodes listed in Chapter 1, ECG, page 1-5. Refer to Chapter 4, Attaching the Lead Cable to the Wireless Module, page 4-2 for connection details.



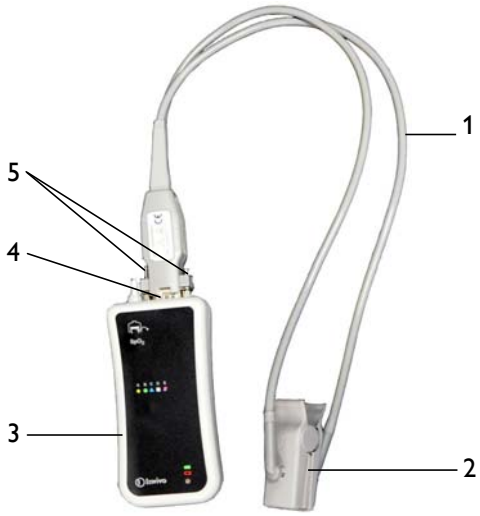
wSpO2 Module

The wireless SpO_2 ($wSpO_2$) communicates SpO_2, pneumatic respiration values and a pulse waveform to the WPU. This data can be displayed by the DCU and is a gating output for interfacing to the MR system. The $wSpO_2$ module uses a fiber-optic SpO_2 sensor for pulse oximetry and a chest pneumograph for respiration measurement. The $wSpO_2$ module houses connections for pneumatic respiration and the SpO_2 sensor.

Attaching the SpO_2 Sensor to the Wireless Module

Attach the SpO_2 sensor to the $wSpO_2$ module, as detailed below,

Step	Action
1	Connect a SpO_2 sensor to the sensor receptacle.
2	Secure the sensor to the receptacle using the 2 screws.
3	Connect the leads of the SpO_2 sensor to the SpO_2 clip (or grip). This completes the procedure.



	Definition
1	SpO_2 quick connect sensor
2	SpO_2 quick connect clip (or grip)
3	wSpO2 module
4	Sensor receptacle
5	Screws

Battery Operation

The Cart (or PMC) and DCU batteries (REF 989803169491) are interchangeable. The Cart has two batteries located in the bottom of the unit. The PMC has two batteries located under the top latched cover of the unit. The DCU has two batteries located in the left and right side of the unit. When the Cart is connected to AC mains power and the DCU is docked, the batteries (if installed) are automatically charged.

WARNING

The batteries (REF 989803169491) used in the Cart, the PMC and the DCU contain some ferrous materials that are attracted to the MR magnetic field. DO NOT install or remove the batteries from the devices when these units are closer than the 1,000 Gauss (0.1 T) field line as measured from the center line of the MR bore. The batteries will be attracted to the magnetic field, possibly causing patient or user injury.

CAUTION

Never force a battery into the battery compartment as it will damage the battery or the Expression MRI Patient Monitoring System.

When the AC mains power is interrupted, the equipment automatically switches to internal battery power (if batteries are installed). To prevent unintentional power interruption, Invivo recommends keeping batteries installed, even when operating on AC mains power. Maximum operation time of the Cart (or PMC) and DCU batteries is approximately 8 hours when NIBP, ECG, and SpO_2 parameters are running on 5-minute intervals, and anesthetic agents and CO_2 are turned off. The DCU displays of the battery status for each device; see System Status Group, page 2-32 for details.

NOTE

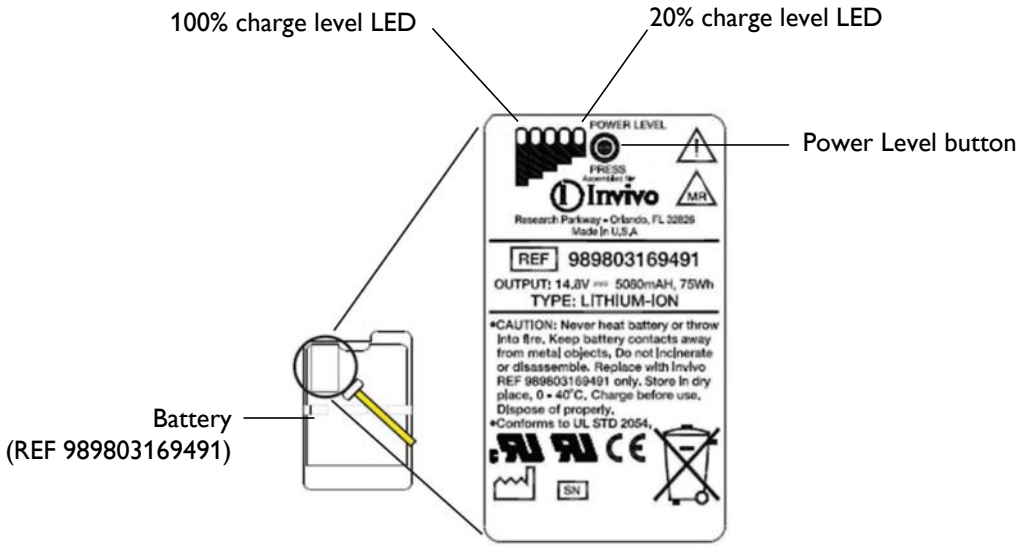
Cart (or PMC) battery operation time will be reduced by up to 2 hours when monitoring anesthetic agents, printing or running short automatic NIBP cycles.

Charging Batteries

Charge the batteries before initial use. When installing the Expression MRI Patient Monitoring System (Model 865214) for the first time, all batteries must be charged at least 12 hours with the system turned off to be fully charged and conditioned for operation.

The Cart (or PMC) and DCU batteries are charged by integrated intelligent battery chargers, which automatically provide the appropriate current and conditioning profiles. When the Cart (or PMC) and DCU are plugged into AC mains power and turned off, the battery charger is functional, charging the batteries automatically. When the Cart (or PMC) and DCU are turned on, the devices operate from AC power, while the batteries are simultaneously charged.

Current indications of the battery charge levels are provided by the DCU; see System Status Group, page 2-32 for details. And, if the Cart (or PMC) and DCU batteries are removed, the charge level can also be determined by pressing the Power Level button on the battery, where LEDs will indicate the charge from 0 to 100 percent in 20 percent increments when the Power Level button is pressed (see the illustration below). The minimum voltage for normal battery operation of the Cart (or PMC) and DCU is 14.8 Vdc.



The module batteries must be charged by Invivo battery charger (REF 989803152891). Refer to the instructions and cautions provided with the charger for information. The minimum voltage for module battery is 3.4 Vdc.

Using Batteries Safely

The following warnings shall be observed to ensure the safety of operators and patients:

WARNING

Stop using any battery that exhibits abnormal heat, odor, color, deformation or is in an abnormal condition. If a battery is punctured or liquid leaks onto your skin or clothing, wash skin and clothing with fresh water immediately. If liquid leaks from a battery and gets into your eyes, do not rub your eyes. Wash eyes well with clean water and consult a doctor immediately.

CAUTIONS

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

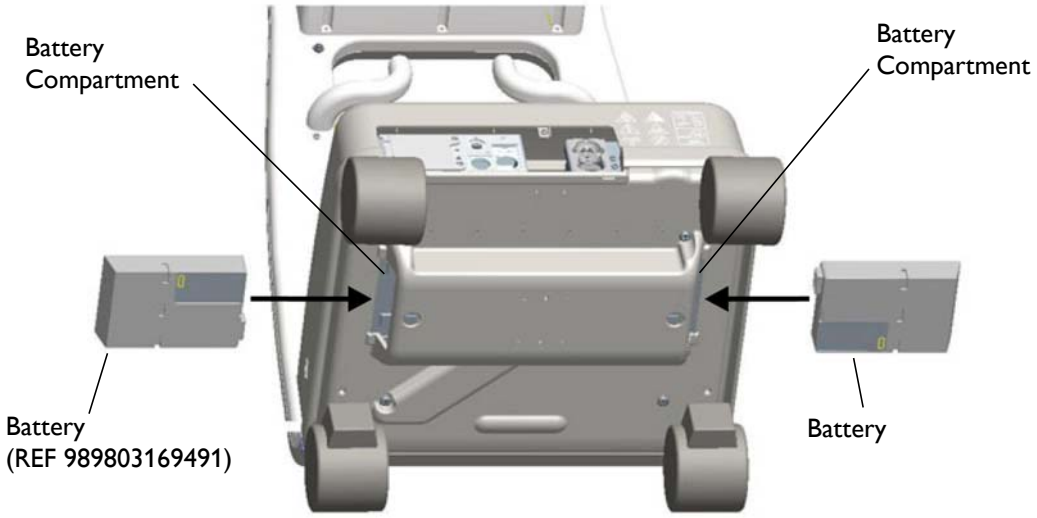
NOTE

Batteries have life cycles. If the time that the battery is powering the equipment becomes much shorter than usual, the battery life is at an end. Remove a battery whose life cycle has expired from equipment immediately. Replace the battery with a new Invivo-specified battery. Refer to Chapter 1, Replacement Power, page 1-7 for part numbers and descriptions.

Installing the Cart Batteries

The Cart batteries slide into the battery compartments in the bottom of the unit (see the illustration below) and then automatically latch into place. When installing batteries, they must be oriented properly in the compartments to latch into place, as the battery shape is designed to fit the contour of the device geometry. If the battery does not latch when inserted then it is not positioned properly. Orient the battery in the other direction then reinstall it.

To install the Cart batteries, move the Cart away from the MR system, outside of the 1,000 Gauss (0.1T) field line (as measured from the center line of the MR bore) and then slide the batteries into the battery compartments.

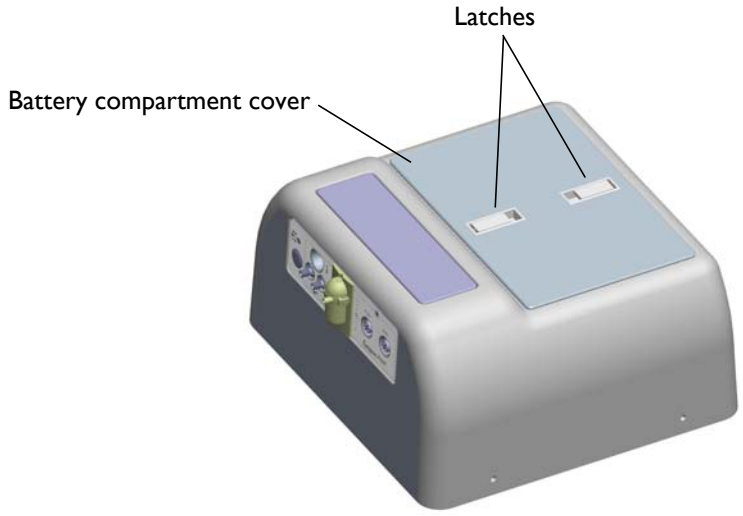
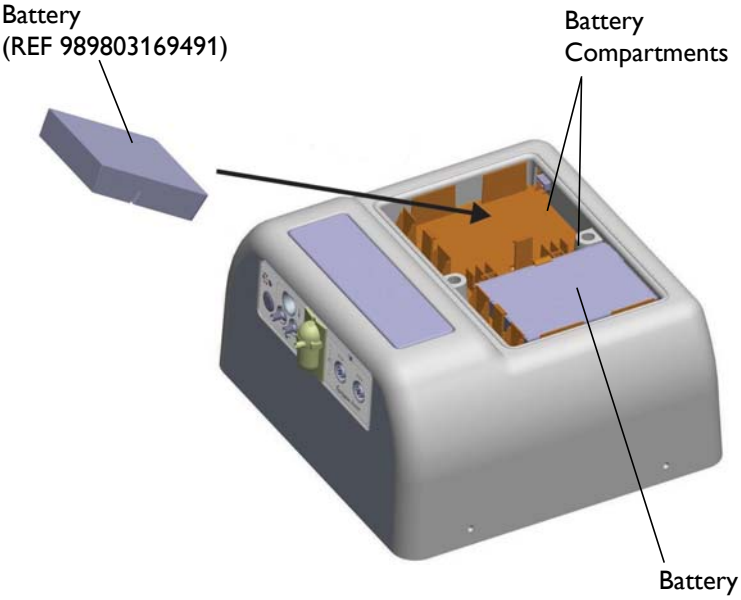


Removing the Cart Batteries

To remove the Cart batteries, move the Cart away from the MR system, outside the 1,000 Gauss (0.1T) field line (as measured from the center line of the MR bore) and then press the battery eject buttons. The batteries will be partially ejected for easy grasping and removal.

Installing the PMC Batteries

The PMC batteries slide into battery compartments under the top cover and then automatically latch into place. When installing batteries, they must be properly oriented to latch into the compartments, as the battery shape is designed to fit the contour of the device. To install batteries in the PMC, complete the steps below.

Step	Action
1	Move the PMC away from the MR system, to a location outside of the 1,000 Gauss (0.1T) field line (as measured from the center line of the MR bore), prior to installing batteries.
2	Pull the latches then remove the battery compartment cover. 
3	Slide a battery into a battery compartment until it rests in place, and then repeat the process for the other battery. 
4	Replace the battery compartment cover.
5	Assure that the battery compartment cover is latched into place.

Removing the PMC Batteries

To remove a battery from the PMC, complete the steps below.

Step	Action
1	Move the PMC away from the MR system, outside of the 1,000 Gauss (0.1T) field line (as measured from the center line of the MR bore), prior to battery removal.
2	Remove the battery compartment cover by pulling on the latches.
3	Pull the latch holding the battery in place with one hand.
4	Using the other hand, pull the battery on the side opposite the connector away from the connector and remove it from the PMC.
5	Repeat Steps 3 and 4 to remove the remaining battery.

Installing the DCU Batteries

The DCU batteries slide into their respective battery compartments in the left and right side of the unit (see the illustration below) and then automatically latch into place. When installing batteries, they must be oriented properly in the compartments to latch into place, as the battery shape is designed to fit the contour of the device geometry. If the battery does not latch when inserted then it is not positioned properly. Orient the battery in the other direction then reinstall it.

Removing the DCU Batteries

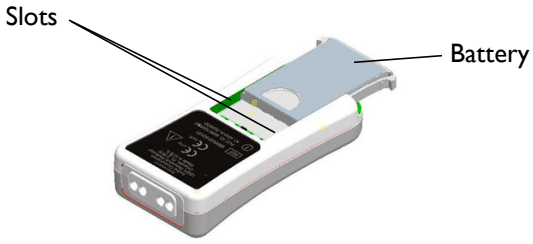
To remove batteries, move the DCU away from the MR system, outside of the 1,000 Gauss (0.1T) field line (as measured from the center line of the MR bore) and then press the battery eject buttons. The batteries will be partially ejected for easy grasping and removal.

Installing a Module Battery

Module batteries (REF 989803152881) are interchangeable, non-magnetic, and can be removed and replaced while in the MR magnetic field.

To install a module battery

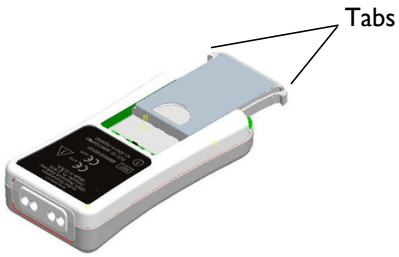
Insert a module battery between the slots in the module housing and then slide the battery forward until both tabs latch into place.



Removing a Module Battery

To remove a module battery

Simultaneously press both tabs then slide the battery out of the module.



CAUTION

The wireless module and module battery should not be placed in the Field of View to minimize the chance of an image artifact.

Understanding the Module Status Indicator

Each module has a status indicator, a two-color LED, which denotes the battery power and the communication status between that module and the WPU, as described in the table below.

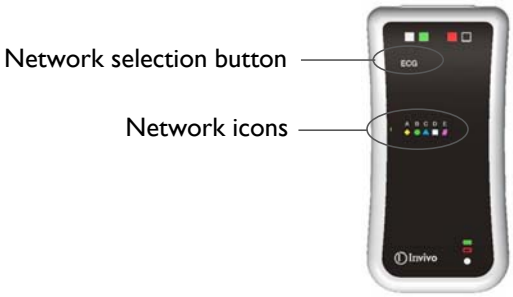
NOTE

Though the illustration below depicts the wECG module, the status indicator on the wSpO2 module is located in the same area.

Indicator		Module Status	
Color	**State**	**Battery Power**	**Module / WPU Communications**
None	Not applicable	No battery is inserted or the battery has an insufficient charge to power the module.	Not applicable
Green	Flashing	Good	Not communicating
Green	Solid	Good	Good communications
Red	Flashing	Low	Not communicating
Red	Solid	Low	Good communications

Changing the Module Network Setting

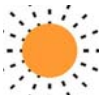
The network setting of a module is indicated by the illuminated network icon on the device (see the illustration below). This network setting can be changed via the network selection button (concealed under the overlay) on the front upper-left corner of the module. (A slight bump can be felt when you pass a finger over this button.)



To make it as easy as possible to press and release the button while observing the network icons, either place the module on a flat steady surface, or hold the module as shown in the figure right, and use your thumb to press the network selection button.

Illustrations are used in some steps to show the network change sequence. In these steps the following symbols are used to convey the state of a network icon.

Icon is illuminated



Icon is blinking

Additionally, the pictographs below are used to convey actions concerning the network selection button.

Press the button

Release the button

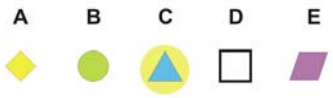
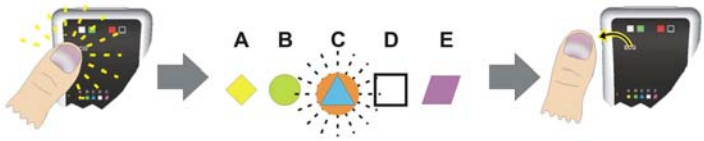
Press and HOLD the button

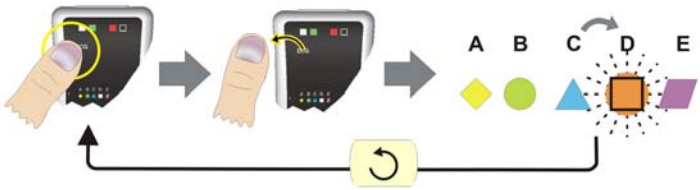
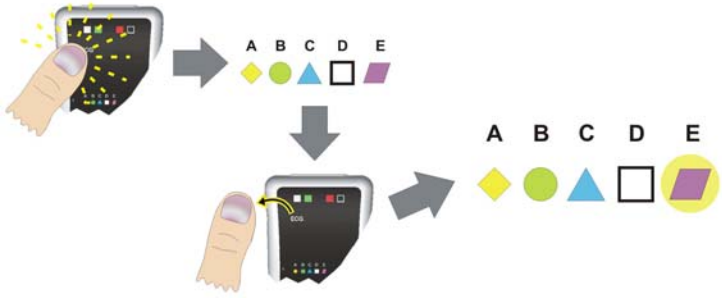
Repeat as desired

Follow the steps below to change the network setting of a module.

NOTE

The directions for changing the network setting of a module applies to both module types.

Step	Action
1	If the module is turned on, turn off the module by removing it's battery (see Chapter 2, Removing a Module Battery, page 2-17 above).
2	Turn on the module by inserting a battery. The network icons will flash briefly, and then the icon of the current network (C in this example) will illuminate, as shown below. 
3	Enter the network change mode: After the current network icon has illuminated and within 15 seconds of turning on the module, press and hold the network selection button until the current network's icon begins blinking rapidly. Then, release (lift your finger from) the network selection button.  ***NOTE*** *If the network change sequence has not started within 15 seconds after turning on the module, no network change will be allowed until the module has been turned off and then on.*

Step	Action
4	Change networks: Press the network selection button again, until the icon stops blinking, then release the button. This will cause the next network icon in the sequence to blink rapidly (for example, if the module was originally using network B, now the C icon will be blinking). Repeat this sequence of pressing and releasing the network selection button until the icon of the desired network is rapidly blinking. If you pass the desired network, simply continue pressing and releasing the button until the desired network is again blinking. 
5	Save the new network setting: When you reach the desired network, press and hold the network selection button for approximately 5 seconds. The selected network's icon will briefly turn off and then illuminate (not blink). Once illuminated, release the button. The module will now communicate using the selected network.  ***NOTE*** *Any part of the above sequence not completed will cause the module revert to the network previously set 30 seconds after the network selection button was last released.*

Turning On the System

Follow the steps below to turn on the Expression MRI Patient Monitoring System.

Step	Action
1	Install batteries into the modules; see Installing a Module Battery, page 2-17.
2	Turn on the Cart (or PMC) by pressing the power switch (⏻).  Power switch (Cart shown)
3	Turn on the DCU by pressing the power switch (⏻).  Power switch
4	Verify proper communications between the WPU of the Cart (or PMC), the DCU, and the wireless modules. Check the display panel status indicators on the DCU; see the System Status Group on page 2-32.
5	Verify proper operation of each patient parameter; see Chapter 3.

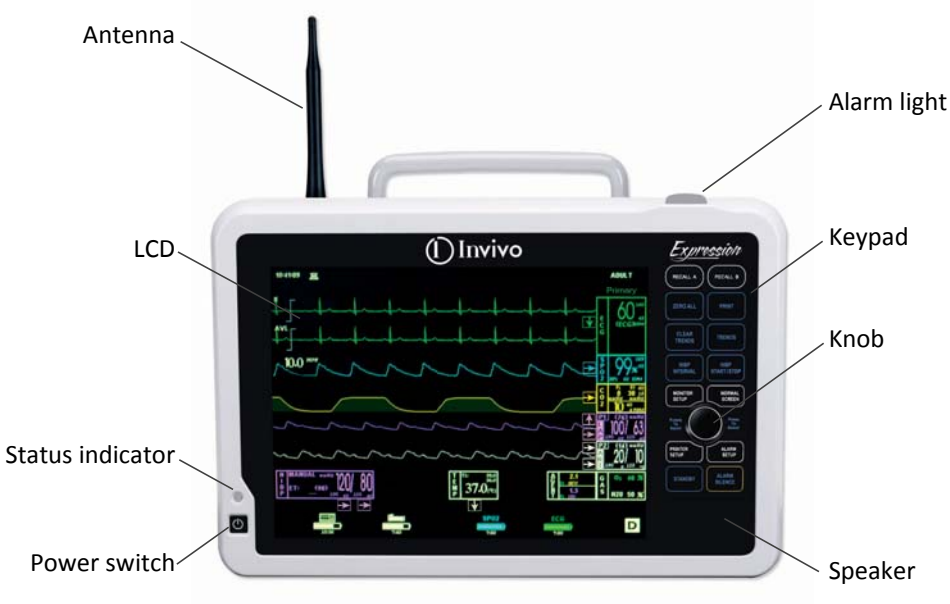
Removing AC Mains Power

To remove AC Mains Power from the Expression DCU, Cart, or PMC, disconnect the AC power cord from the AC Mains outlet or disconnect the DC power cord from the Cart (or PMC).

User Interface

Display, control and documentation of the monitored parameters is provided by the DCU. The front panel of the DCU contains controls for complete patient monitoring:

- DCU power switch (see below)
- Status indicator (see page 2-24)
- LCD (see Displayed Groups on page 28)
- Speaker (see page 2-25)
- Alarm light (see page 2-8)
- Keypad and knob (see page 2-25)
- Antenna (keep unobstructed)



CAUTION

Never apply unnecessary pressure to the LCD screen. Severe pressure applied to the screen could result in damage or failure of the LCD.

DCU Power Switch

DCU power is controlled by the power switch (⏻) located on the front panel of the DCU. (The power switch on the Cart [or PMC], controls power to the Cart [or PMC]; see page 2-22.) Press the power switch for more than a half second to turn on the device, and for more than 1 second to turn off the device.

DCU Status Indicator

The DCU status indicator is a three-color LED that provides a visual indication of DCU power, and the communication status between the DCU and WPU, as described below.

Indicator		DCU Status		
Color	**State**	**Power Source**	**DCU / WPU Communications**	**Power Switch**
None	Not applicable	Operating on battery power	Not applicable	Off
Green	Solid	Operating on AC power and batteries (if inserted) are charging	Good	On
Green	Fast flashing	Operating on AC power and batteries (if inserted) are charging	No communications	On
Green	Slow flashing	Operating on AC power and batteries (if inserted) are charging	Not applicable	Off
Yellow	Solid	Operating on battery power	Good	On
Yellow	Flashing	Operating on battery power	No communications	On
Red	Solid	Operating on battery power with a low battery condition	Good	On
		WARNING **A solid red light indicates that the batteries in the Cart (or PMC) or DCU have fallen below the required operational output and system shutdown with loss of monitoring will occur. Locate an AC wall outlet and plug in the Cart (or PMC) and/or DCU immediately using the appropriate power converter.**		
Red	Flashing	Operating on battery power with a low battery condition	No communications	On
		WARNING **A flashing red light indicates that a loss of monitoring has occurred. The Cart (or PMC) or DCU has lost communication with the other system components, and the batteries have fallen below the required operational output and system shutdown will occur. Locate an AC wall outlet and plug in the Cart, (or PMC) and/or DCU immediately using the appropriate power converter and verify communication status. Refer to System Status Group, page 2-32.**		

Speaker

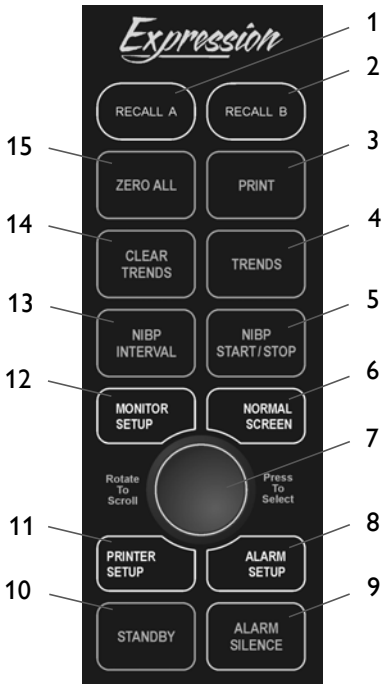
The speaker communicates audible alarms at a maximum volume of 85 dB. Keep this area unobstructed. The speaker volume is adjustable in the **SOUND ADJUST** menu.

Keypad and Knob

The keypad includes 14 push keys that provide direct control of system features, menu access and patient parameter adjustments. The knob, near the middle of the keypad, has functions that are menu specific.

NOTE

*In various menus, to protect against accidental selections that have significant irreversible effects (for example, erasing patient data), a Yes/No dialog will be encountered. You must select YES or NO to confirm the change or to cancel the change. A delay of approximately 30 seconds without any selection is equivalent to selecting NO. The Yes/No dialog is removed upon operator selection, at the end of the time-out feature, or by pressing the **NORMAL SCREEN** key or the **STANDBY** key.*



1. **RECALL A key:** Opens a dialog box asking for confirmation of the recall of settings for group A, where selecting YES causes those settings to be recalled and selecting NO causes the dialog window to close without recall.
2. **RECALL B key:** Opens a dialog box asking for confirmation of the recall of settings for group B, where selecting YES causes those settings to be recalled and selecting NO causes the dialog window to close without recall.

NOTE

Recalls and modifications to a parameter value require a few seconds to propagate through the system. Performing another recall within 3 seconds after a recall or after a parameter value has been set results in the new setting not being recalled properly. Wait at least 3 seconds after performing a recall or setting a parameter value before recalling a setting.

3. **PRINT key:** Prints the record trace selections as selected in the **Print** menu, stopping automatically after about 30 seconds or when the key is pressed again, ending with a snapshot of the active patient parameter data.

4. **TRENDS key:** Allows setup of the trend monitoring feature: If a feature is highlighted, pressing the key will open a feature-specific graphical trend; and, if a feature is not highlighted, pressing the key will open the **History** menu (see Chapter 12, History File Page, page 12-10).

5. **NIBP START/STOP key:** Starts a new NIBP measurement or stops a current NIBP measurement.

6. **NORMAL SCREEN key:** Returns the system from any menu to the Normal screen.

7. **Knob:** Allows you to navigate and select items and parameters in the menu system, where the currently selectable item will be displayed in a highlighted field or background:

   – Rotate the knob to scroll to a parameter, menu, option, or numeric (where a clockwise rotation will cause clockwise movement and counterclockwise rotation will cause a counterclockwise movement), and;

   – Press the knob to select the highlighted parameter, menu, option, or numeric.

8. **ALARM SETUP key:** Allows setup of the Alarms monitoring function two ways: 1)If in the Normal screen, pressing this key will open the **Alarms** menu. 2)If a vital sign box is highlighted, pressing this key will open the alarm setup menu for that parameter.

9. **ALARM SILENCE key:** Silences an audible alarm (when enabled) and deactivates the alarm light. (See Chapter 13, Controlling the Alarm Tone, page 13-5, for additional information and warnings.)

Audible Alarm Status and Symbol	Results of Pressing the ALARM SILENCE Key	
	New Audible Alarm State	Other Actions Taken
Disabled 	Sound Off	The **ALARM SILENCE** key has no effect. **WARNING**  **When an X appears in the Alarm Status symbol, the audible alarm tone will NOT sound for any reason.**

Audible Alarm Status and Symbol	Results of Pressing the ALARM SILENCE Key	
	New Audible Alarm State	Other Actions Taken
Armed 	• If one or more alarm conditions exist, then silence; or, • If no alarm conditions exist, then ALARM HOLD.	***NOTE*** *In Latched mode, an alarm condition can exist even though the parameter value is no longer outside the alarm envelope.*
On Hold 	Armed	Any new alarm condition that occurred after entering the On Hold state will cause the alarm tone to be generated when re-entering the Armed state.
Silenced 	On Hold	If in Latched mode, this action will also clear any visual alarm whose alarm condition has been alleviated.

10. **STANDBY key:** Places the system in standby mode, where operation remains normal and current patient information is displayed except for the following functions:

NOTE

In standby mode all audible alarms and alarm lights are disabled, as indicated by the symbol  *. However, the parameter waveform and/or vital sign numerics continue to operate normally and will turn red if any active parameter violates its alarm limits.*

- All audible alarms and alarm lights are disabled;
- Active NIBP automatic measurements are suspended;
- No automatic printout is generated; and,
- Default NIBP inflation pressures are used for all manual NIBP readings.

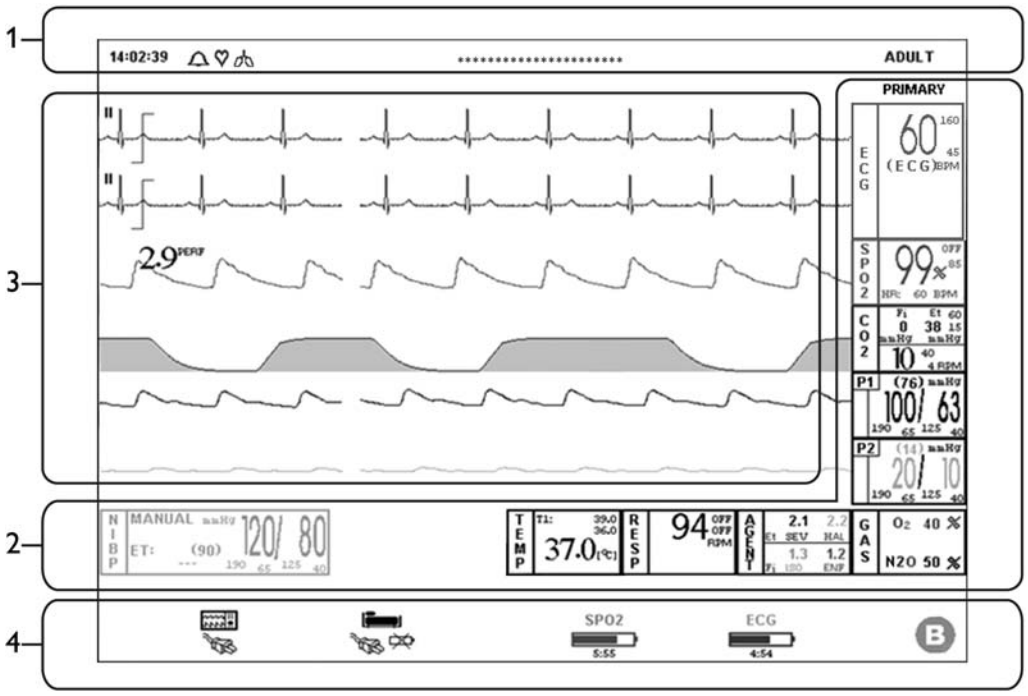
When the **STANDBY** key is pressed again, normal operation will be restored.

11. **PRINTER SETUP key:** Allows setup of the printer option trace sweep functions.
12. **MONITOR SETUP key:** Allows access to the setup options.
13. **NIBP INTERVAL key:** Opens the **NIBP Interval** menu.
14. **CLEAR TRENDS key:** Clears all stored data from memory.
15. **ZERO ALL key:** Initiates zeroing of the pressure transducer of all available invasive pressure channels.

Displayed Groups

The Normal screen (when no menus are displayed) is the standard operating mode for the monitor. Four kinds of data, grouped by type, are displayed in Normal screen mode:

1. Informational group
2. Vital sign box group
3. Vital sign trace group
4. System status group



Informational Group

The informational group (1), displayed along the topmost area of the Normal screen, provides important user data, as follows:

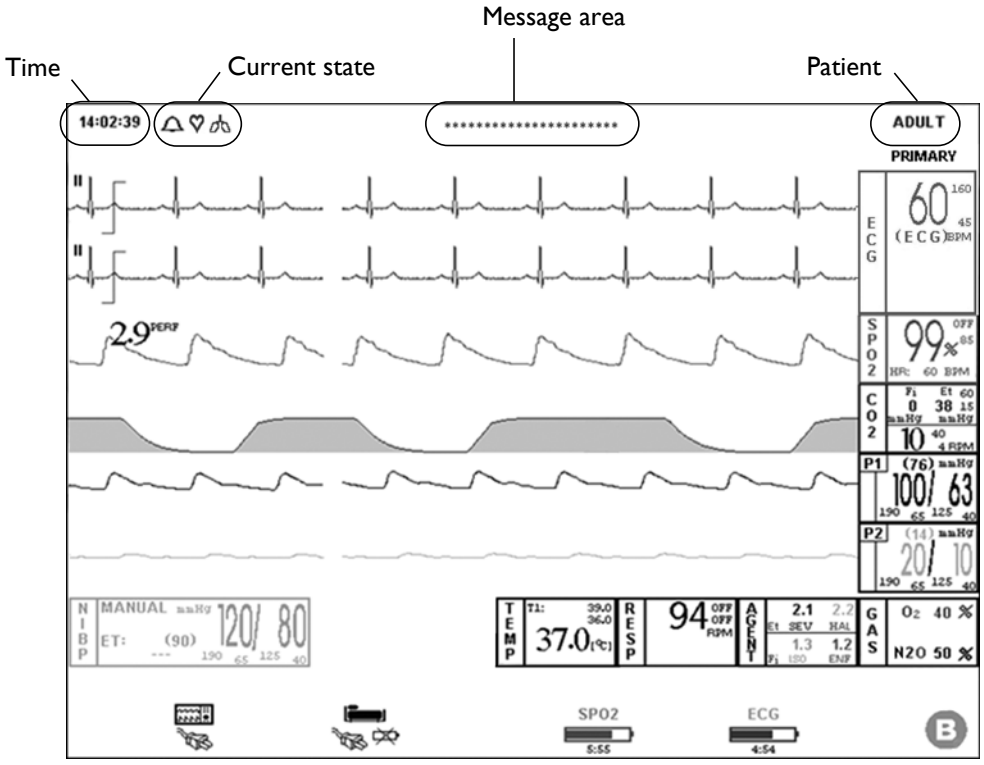
Time: Displays the current time in a 12- or 24-hour format (hh:mm:ss) as adjusted in the **Set Time** menu; see Chapter 3, Set Time, page 3-10.

Current state: Provides indications of alarm status, and heart beat and respiration detection.

- A bell symbol( ) indicates an active alarm; see Chapter 13, Alarm Violations, page 13-1 for additional information and warnings.)
- A heart symbol ( ) indicates heart beat detection, flashing and sounding a tone with each detected heart beat (when turned on in the **ECG** or **SPO2** menu).
- A lung symbol ( ) indicates respiration detection, flashing at the end of each detected breath when CO_2 monitoring is on.

Message area: Displays informational and technical messages to assist you in operation.

Patient: Indicates the selected patient type (adult, pediatric or neonatal); see Chapter 3, Patient, page 3-7.



Vital Sign Box Group

The vital sign (VS) box group (2) is displayed along the right side and lower area of the Normal screen.

Filter mode: Indicates the ECG filter mode setting; see Chapter 4, ECG Menu Options, page 4-14 for details.

VS boxes: Indicate the vital sign numeric, alarm limits settings and other measurement data for each selected parameter. A VS box also accesses associated menu options for the parameter.

NOTES

- *The color of a VS box matches the corresponding trace waveform.*
- *If the VS box is not displayed, refer to Chapter 3, Parameter Selection, page 3-5.*

No Data Available Indication (---)

Under certain conditions one or more of the numerics in the vital sign boxes may display three dashes (---) to indicate that no data is available. Depending upon the nature of this indication, an alarm condition may be generated if no parameter data is available. In this case, the dashes will be displayed in red and an alarm will sound.

No data available indications can happen for any of the following reasons and may generate an alarm.

An alarm condition is generated when:

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

No alarm condition is generated when:

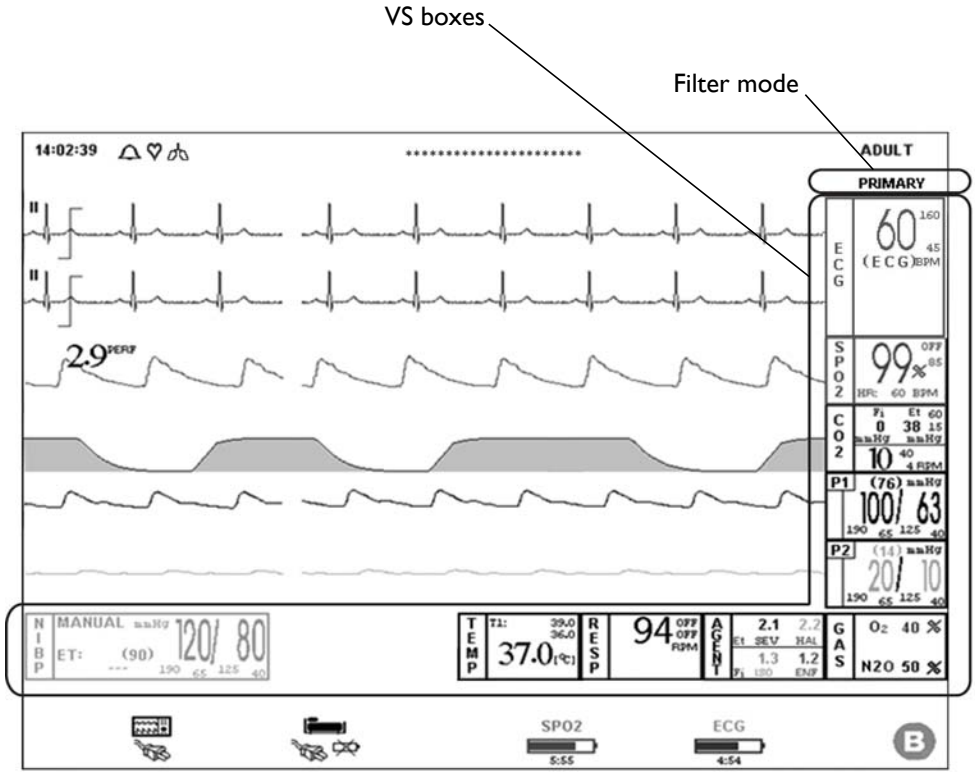
- A module or another measurement device was just turned on or applied to the patient (allow a few seconds for communication to be established).
- The first reading has not yet been taken or the parameter is in a start-up condition.
- The measurement values are distorted or the signal is inadequate.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

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 (except for the ECG vital sign, where **OVR** will also be displayed alternately with a numeric value that is more than the highest specified heart rate).

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 (except for the ECG vital sign, where **UND** will also be displayed alternately with a numeric value that is less than the lowest specified heart rate).



Vital Sign Trace Group

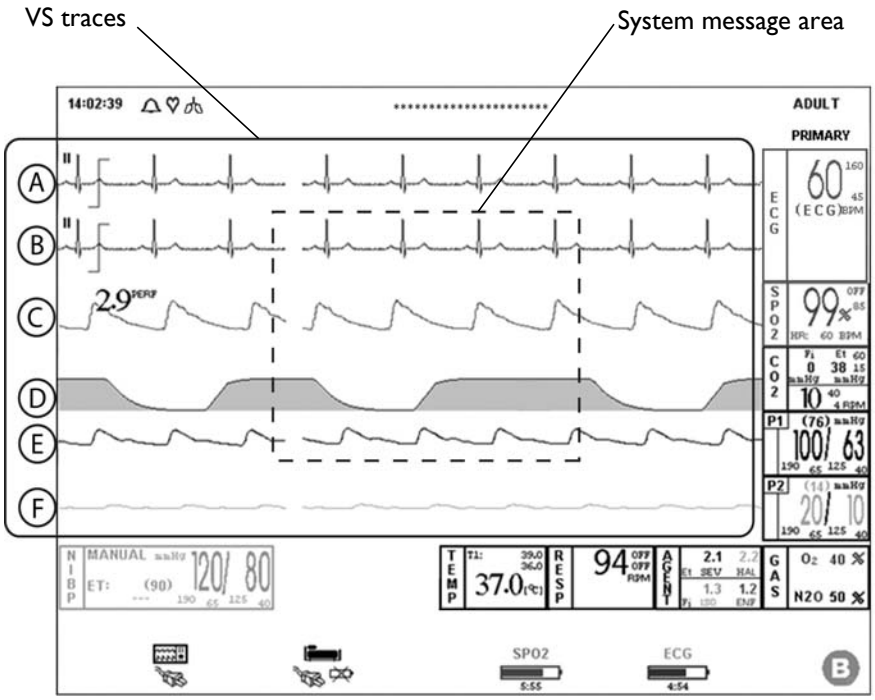
The vital sign (VS) trace group (3), displayed in the middle area of the Normal screen, provides vital sign waveforms for each of the selected parameters, fixed across the screen, updated with an erase bar and divided into six trace areas (A – F):

- **A:** Trace A is assigned by parameter and displayed depending upon the ECG selection (see Chapter 4, ECG Menu Options, page 4-14 for details) or the **SETUP** menu options (see Chapter 3, Parameter Selection, page 3-5 for details).
- **B:** Trace B displays ECG2 when two ECG sources are on (see Chapter 4, ECG Menu Options, page 4-14 for details).
- **C:** Trace C displays the SpO_2 waveform, not proportional to pulse volume but automatically amplitude adjusted for proper viewing.
- **D:** Trace D displays the respiration waveform if CO_2 is enabled.
- **E:** Trace E displays the P1 waveform if invasive pressure P1 is enabled.
- **F:** Trace F displays the P2 waveform if invasive pressure P2 is enabled.

NOTES

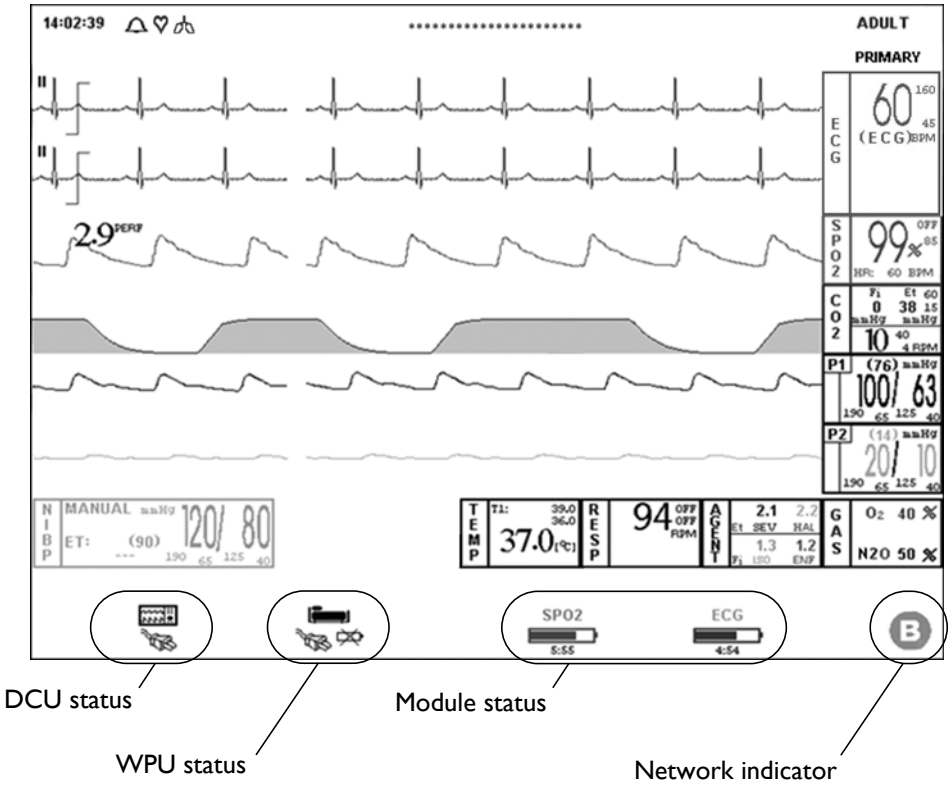
- *The color of the parameter's waveform matches its corresponding VS box.*
- *If a trace has been turned off, that portion of the LCD will be blank. Refer to Chapter 3, Parameter Selection, page 3-5 to turn on the trace.*
- *When IBP is turned on, the VS boxes will be displayed at a slightly reduced size.*

System message area: Displays system status, functions, and error messages within this area.



System Status Group

The System status group (4), displayed along the bottom area of the Normal screen, provides the following operational indications:



DCU status: Indicates the power status of the DCU( ) and the symbol displayed below it (for additional indications, see DCU Status Indicator, page 2-24):

- When the DCU is operating on AC power, the power cord symbol ( ) is displayed.
- When the DCU is operating from battery power, a battery gauge symbol ( ) with the battery power time remaining is displayed. If less than thirty (30) minutes of battery operating time remain, an alarm tone is sounded and LOW appears in a red flashing battery gauge symbol.
- If batteries are not installed in the DCU, a battery not installed symbol ( ) is displayed next to the power cord symbol.

WPU status: Indicates the communication and power status of the Cart (or PMC):

The WPU symbol indicates the communication status:

- When communication is good between the Cart (or PMC) and the DCU, the WPU symbol ( ) is displayed.
- When communication has not been established or is lost between the Cart (or PMC) and the DCU, the WPU symbol surrounded by a slashed enclosure ( ) is displayed.

The area below the WPU symbol indicates the power status of the Cart (or PMC):

- When the Cart (or PMC) is operating from AC power, a power cord symbol ( ) is displayed.
- When the Cart (or PMC) is operating from battery power, a battery gauge symbol ( ) with the battery power time remaining is displayed. If less than thirty (30) minutes of battery operating time remain, an alarm tone is sounded and LOW appears in a red flashing battery gauge symbol.
- If batteries are not installed in the Cart (or PMC), a battery not installed symbol ( ) is displayed next to the power cord symbol.

Module status: Indicates the communication and power status of the wireless modules:

A label indicates the communication status:

- When communications are good between the module and the WPU, the name of the module (ECG and/or SPO2) is displayed.
- When communication has not been established or is lost between the module and the WPU, a slashed enclosure over the name is displayed (ECG and/or SPO2).

The battery gauge symbol ( ) indicates the power status:

- When less than 30 minutes of battery operating time remain an alarm tone is sounded, and the battery gauge symbol turns red and flashes for the respective module.

Network indicator: Indicates the wireless network setting of the DCU. Each network indicator features a unique color-coded letter (A–E) and shape for easy identification, as shown below.

(Yellow) (Green) (Blue) (White) (Purple)

For proper system communications, all devices must use the same network. The factory programmed network setting is given on the back of the WPU. This network setting should be used for all devices (DCUs and wireless modules) in the system.

Factory programmed network indicator location on the WPU

WARNING

In environments where multiple Expression systems are being used, the operator must be aware of each system's network setting. Operating on the same or wrong communication network will interfere with another system and incorrect vital sign data may be obtained and displayed.

CAUTION

Care should taken against inadvertent changes made to the network setting. Before use, always ensure that all devices are communicating properly.

NOTE

For details about wireless module network settings, see Changing the Module Network Setting on page 2-18.)

Chapter 3
Preparation for Use

The system provides the ability to monitor patient parameters, select options, control functions, store and recall different operating configurations, and set testing routines through the **SETUPS** menu.

WARNINGS

- **Do not use the system in the presence of flammable anesthetics.**
- **If equipped with a DCU, always verify proper system communication with the DCU prior to patient use.**

CAUTIONS

- Use of multiple systems in the same MR room may lead to communication errors.
- A minor but noticeable degradation in the wECG and wSpO2 module communications may occur in the presence of high-powered radios.
- Where the integrity of the external protective conductor in the installation or its arrangement is in doubt, the system shall be operated from batteries.
- Prior to clinical use, the operator must be aware of the minimum distance from the MR system for proper operation; refer to Chapter 1, Installing the Cart, page 1-26.

NOTES

- *If a particular parameter is not installed and configured, it cannot be enabled in the **PARAMETER SELECTION** menu.*
- *Once configured for a particular procedure or user, the store and recall feature can be used to instantly restore the monitor.*
- *A display is restored to its pre-configured initialization whenever the Cart (or PMC) or DCU is turned off and on.*

Monitor Initialization

The system can begin monitoring functions from an initial factory default setting state or from a pre-configured state, depending upon the way the stored configuration and patient data are treated at startup.

Setups Menu

From the **SETUPS** menu, you can configure the system to meet your patient monitoring needs:

- Individual setup configurations can be saved and recalled.
- Available parameters can be turned on and off.
- Sounds can be adjusted.
- Patient type can be switched between adult, pediatric, and neonate.
- Date and time can be adjusted.
- Network designation can be set.
- System can be set to default to the factory or a user configuration.
- Sweep and respiration speeds can be selected.
- Pediatric ECG mode can be turned on and off only while using the Adult/Pediatric patient type.

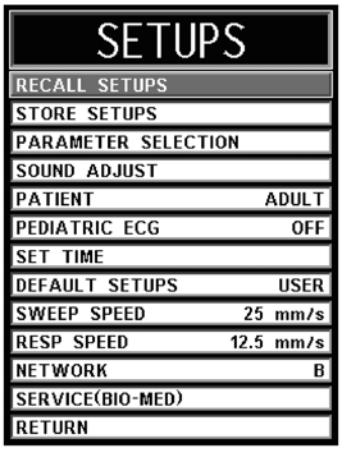
NOTE

Wait at least 3 seconds after performing a recall or setting a parameter value, as these require a few seconds to propagate through the system. Performing another recall within 3 seconds after a previous recall, or after a parameter value has been set, may result in the new setting not being recalled properly.

Setups Menu Options

The following options are available:

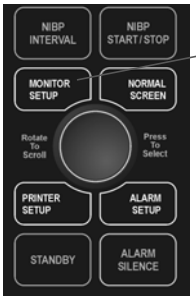
- RECALL SETUPS
- STORE SETUPS
- PARAMETER SELECTION
- SOUND ADJUST
- PATIENT
- PEDIATRIC ECG
- SET TIME
- DEFAULT SETUPS
- SWEEP SPEED
- RESP SPEED
- NETWORK
- SERVICE(BIO-MED)
- RETURN



To enter the SETUPS menu

Press the **MONITOR SETUP** key.

The available options are listed below. To change a menu option, turn the knob to the desired selection and then press the knob. Next, select RETURN or press the **NORMAL SCREEN** key to exit the menu.



MONITOR SETUP key

Recall Setups

RECALL SETUPS allows you to use stored monitor setups (see *Store Setups* on page 3-3 for details).

To enter the RECALL SETUPS menu

Press the **MONITOR SETUP** key then turn the knob to RECALL SETUPS and press the knob.

To recall a setup:

Turn the knob to the desired RECALL SETUPS memory block then press the knob.

The following options are available:

- **A, B, C, D, E, F:** Recalls system setups from the chosen memory block (A–F) after making a YES/NO confirmation.
- **USER:** Recalls the setups from the user defaults memory block. If DEFAULT SETUPS are set to USER, the system will automatically recall the setups stored in this memory block when the system is turned on. If no user defaults have been set, this will recall the factory defaults.
- **PRINT SETUPS:** Opens the **PRINT SETUPS** menu, providing a selection of system setups for printing.
- **RETURN:** Exits the menu.

Store Setups

STORE SETUPS allows you to store up to seven monitor setups. Settings can be stored for different procedures, patient types or multiple users. These settings can then be recalled without repeatedly entering frequently used setups before monitoring. USER DEFAULTS is also used for recall when the system is turned on. The memory blocks are maintained by a long life battery or static RAM, saving the setups even when the system is turned off, for each of the following:

- Alarms
  - Minimum and maximum values
  - Auto-set percentage

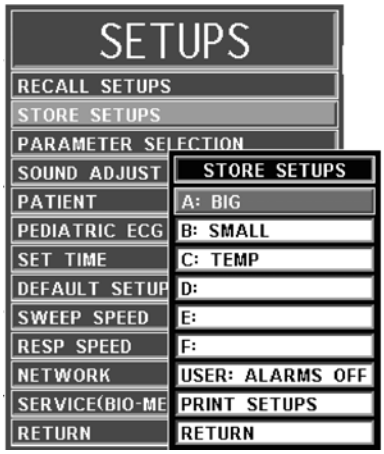
  - Latched or unlatched selection for alarms
  - Alarm tone level

- System Setups
- ECG
  - Selected lead
  - Scale setting
  - Trace speed
  - Filter mode
  - QRS tone on/off
  - Heart rate source
- Print Setups
  - Off or auto
  - Trace delay
  - Printer speed
  - Selected traces
- NIBP
  - Manual
  - Off or auto
  - Automatic time interval
- CO_2
  - Size
  - Grids
  - Flow
- Trend graphs
  - Time bases
  - Scales
- SpO_2
  - Size

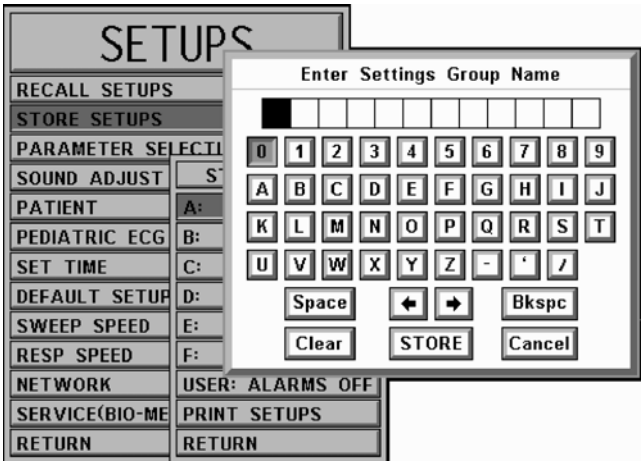
To enter the STORE SETUPS menu

Press the **MONITOR SETUP** key then turn the knob to STORE SETUPS and press the knob.

The following options are available:



- **A, B, C, D, E, F:** Stores setups for the system in the chosen memory block. To store a setup in memory, configure the system with the desired setup (see the listing above) then turn the knob to the desired memory block, then press the knob. A keypad is displayed so that a name can be assigned to this setup.



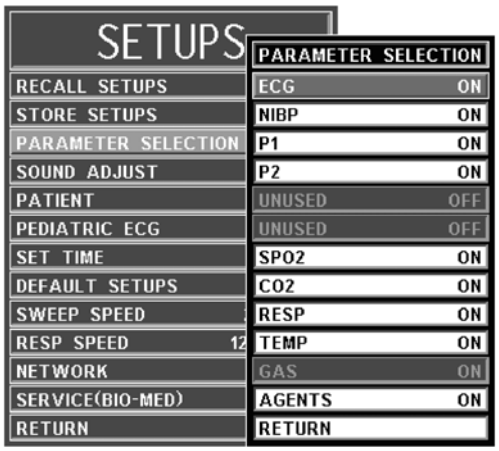
- **USER:** Stores setups for the system in the USER memory block. If DEFAULT SETUPS is set to USER, the system will automatically recall the setup stored here. A keypad is displayed so that a name can be assigned to this setup.
- **RETURN:** Exits the menu.

Parameter Selection

PARAMETER SELECTION allows you to control various monitoring functions, as indicated by the absence or presence of the VS box for that parameter, except ECG (see below).

To enter the PARAMETER SELECTION menu

Press the **MONITOR SETUP** key then turn the knob to PARAMETER SELECTION and press the knob.



NOTE

*If a parameter is not installed or configured in the system, attempting to turn it on will cause **NOT INSTALLED** or **IS NOT ENABLED** to be displayed.*

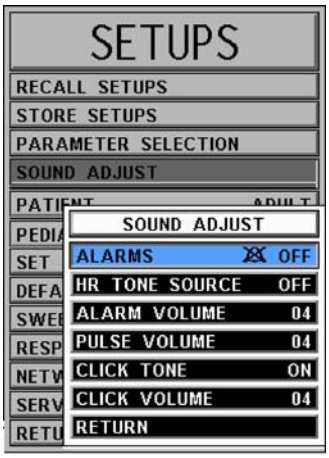
The following options are available:

- **ECG:** Turns the ECG parameter on (default) or off. The heart rate will remain in the VS box allowing it to be displayed from another selected source, or if the heart rate source (HR SOURCE) option is set to AUTO and ECG is in a Lead Fail condition.
- **NIBP:** Turns the NIBP parameter on (default) or off.

- **P1:** Turns invasive pressure parameter P1 on or off (default).
- **P2:** Turns invasive pressure parameter P2 on or off (default).
- **SPO2:** Turns SpO_2 parameter on (default) or off.
- **CO2:** Turns CO_2 parameter on or off (default).
- **RESP:** Turns respiration parameter on or off (default). (Bellows respiration has no waveform or user-adjustable options.)
- **TEMP:** Turns the temperature parameter on or off (default).
- **GAS:** Turns the gas parameter on or off (default).
- **AGENTS:** Turns the anesthetic agents parameter on or off (default).
- **RETURN:** Closes the menu.

Sound Adjust

SOUND ADJUST allows you to switch the alarm tone on and off, select the heart rate tone source, and set the sound volume. (While in this menu, all real tones are disabled and **REAL TONES DISABLED** will be displayed.)



To enter the SOUND ADJUST menu

Press the **MONITOR SETUP** key then turn the knob to SOUND ADJUST and press the knob.

The following options are available:

- **ALARMS:** Turns the alarm sound on (default) and off; see Chapter 13, Alarms Menu Options, page 13-7 for details.

WARNING

The alarm tone can be turned off. Always ensure that the alarm tone setting is appropriate for each patient. The alarm sound volume is adjustable for suitability to various clinical environments. When you use the system, always verify that the alarm sound can be heard above the ambient noise level.

NOTES

- *Control of alarms is localized to the unit Cart (or PMC) or DCU indicating the alarm condition.*
- *Only the alarm sound will be disabled; the source of the violated alarm still flashes in red on the display when an alarm limit is violated.*

- **HR TONE SOURCE:** Sets the source used for the heart rate tone, and is identical to and interactive with the same option in the **ECG** and **SpO_2** menus:
  - **OFF** (default) removes the heart symbol from the display and no pulse tone will be sounded.
  - **QRS** provides the source, the tone is modulated by the QRS detection from the ECG parameter.
  - **SPO2** provides the source, the tone is modulated by the SpO_2 measurement, where the lower the SpO_2 value, the lower the pitch.
  - **RETURN** closes the submenu.
- **ALARM VOLUME:** Sets the alarm tone volume. The range is 1 - 10 (default is 4). During adjustment, the system sounds the corresponding setting level.
- **PULSE VOLUME:** Sets the pulse tone volume. The range is 1 - 10 (default is 4). During adjustment, the system sounds the corresponding setting level.
- **CLICK TONE:** Turns the click tone generation of the keypad on (default) and off.
- **CLICK VOLUME:** Sets the click tone volume. The range is 1 - 10 (default is 4). During adjustment, the system sounds the corresponding setting level.
- **RETURN:** Closes the menu.

Patient

PATIENT allows you to set the patient type for monitored parameters.

Determining the Patient Type

IEC 60601-2-30 Edition 2.0, 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 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, as indicated below.

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	N/A	Greater than 21 years

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 system uses several operational parameters, including cuff inflation pressure and pulse sensitivity, that vary depending on the selection:

- ADULT and PEDIATRIC use a higher pump volume, while NEO uses a lower pump volume.
- ADULT and PEDIATRIC dictate use of a larger cuff circumference, while NEO dictates use of a smaller cuff circumference.
- PEDIATRIC and NEO options employ a higher pulse sensitivity to detect low pulse amplitudes.

NOTE

Refer to the corresponding monitoring parameter for other possible considerations regarding patient type determination.

To enter the PATIENT menu

Press the **MONITOR SETUP** key then turn the knob to PATIENT and press the knob.

To set the patient type, turn the knob to the desired option and press the knob. The following options are available:

- **ADULT** (default)**:** Sets the monitoring functions for adult patients.

- **PEDIATRIC:** Sets the monitoring functions for pediatric patients.
- **NEO:** Sets the monitoring functions for neonatal patients.

NOTE

While in the NEO patient type, pediatric ECG is always on.

- **RETURN:** Exits the menu.

CAUTION

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

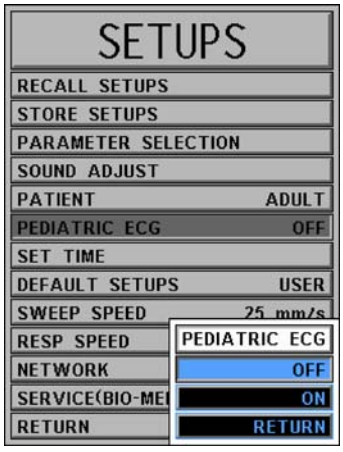
NOTES

Changing the PATIENT type causes

- *an alarm tone to sound.*
- ***CHANGE NIBP CUFF** to be displayed.*
- *the patient type to be revised.*
- *the alarm limits to change; see the Chapter 13, Low and High Alarm Limits, page 13-2 for details.*

Pediatric ECG

PEDIATRIC ECG provides additional ECG filtering when patients, particularly pediatric patients, present with narrow QRS complexes and/or high heart rates.



To enter the PEDIATRIC ECG menu

Press the **MONITOR SETUP** key then turn the knob to PEDIATRIC ECG and press the knob.

The following options are available:

- **OFF** (default)**:** Turns the pediatric ECG function off.

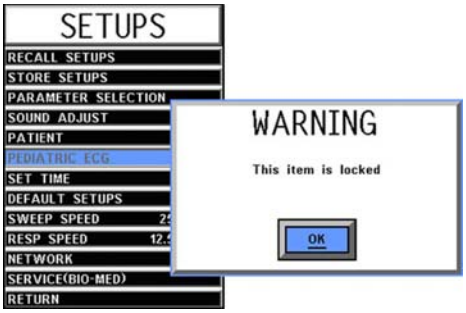
- **ON:** Processes ECG data using a pediatric algorithm in addition to the current gradient filter setting, and operates under the following conditions:
  - When an ECG trace is printed, the following annotation will be appear in the strip after the ECG filter indication: **PED ECG=ON** (if on) or **PED ECG=OFF** (if off).
  - The setting will be placed in **STORE SETUPS** when you save settings.
  - The setting will be recalled from one of the stored settings when **RECALL SETUPS** is performed or if the system is booted from **USER**.
  - The setting will be synchronized between the Cart (or PMC) and the DCU.
  - If the **PATIENT** is set to **NEO** then **PEDIATRIC ECG** is locked **ON**.

NOTE

*When **PATIENT** is set to **NEO**, **PEDIATRIC ECG** will automatically be turned **ON** and locked, as indicated by the warning message (right).*

Setting changes will not be allowed when the system is in this configuration.

*Upon transition from the **NEO** setting, this lock will be removed.*



- **RETURN:** Exits the menu.

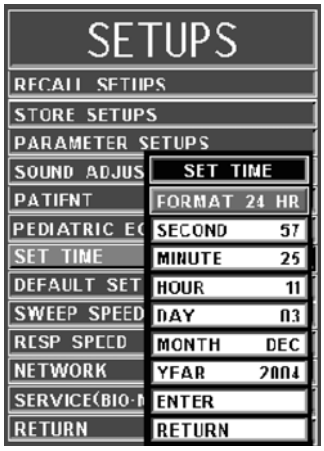
Set Time

SET TIME allows you to set the time and date, a function that continues to operate while the system is turned off. The time is displayed in the upper left corner of the LCD in a MMM DD, YYYY (month, day, year) format.

To enter the SET TIME menu

Press the **MONITOR SETUP** key then turn the knob to SET TIME and press the knob.

The following options are available:



NOTE

For the following options, the setting to be adjusted becomes highlighted within the existing menu.

- **FORMAT** (default)**:** Changes the time display between a 12-hour and 24-hour format.
- **SECOND:** Scrolls through the seconds counter.
- **MINUTE:** Scrolls through the minutes counter.
- **HOUR:** Scrolls through the hours counter.
- **DAY:** Scrolls through the days counter.
- **MONTH:** Scrolls through the months counter.
- **YEAR:** Scrolls through the years counter.
- **ENTER:** Saves all changes made to the time and date counters, if pressed; otherwise, the previous settings will be restored upon exiting the menu.
- **RETURN:** Exits the menu.

Default Setups

DEFAULT SETUPS allows you to change the default mode of the settings used by the system upon power-up.

To enter the DEFAULT SETUPS menu

Press the **MONITOR SETUP** key then turn the knob to DEFAULT SETUPS and press the knob.

The following options are available:

- **FACTORY** (default)**:** Causes the system to power-up with parameters that are set to the factory default values.
- **USER:** Causes the system to power-up with parameters that are recalled from stored settings in the USER memory block (see *Store Setups* on page 3-3).
- **RETURN:** Exits the menu.

Sweep Speed

SWEEP SPEED allows you to change the displayed (and printed) sweep rate of all traces, except CO_2. This is identical to and interactive with the same option in the **PRINTER** menu (see Chapter 12, Printer Menu Options, page 12-4).

To enter the SWEEP SPEED menu

Press the **MONITOR SETUP** key then turn the knob to SWEEP SPEED and press the knob.

The following options (given in millimeters per second) are available:

- **50 MM/S**
- **25 MM/S** (default)
- **RETURN:** Exits the menu.

Resp Speed

RESP SPEED allows you to set the sweep speed of the CO_2 trace.

To enter the RESP SPEED menu

Press the **MONITOR SETUP** key then turn the knob to RESP SPEED and press the knob.

The following options (given in millimeters per second) are available:

- **25 MM/S**
- **12.5 MM/S** (default)
- **6.25 MM/S**
- **3.125 MM/S**
- **1.5625 MM/S**
- **0.33333 MM/S**
- **RETURN:** Exits the menu.

Network

NETWORK allows you to set the wireless network used by the DCU.

NOTE

For proper communications, all devices must use the same network. The WPU determines the network setting that must be used by the modules and DCU(s). The WPU network setting is pre-programmed, as indicated on the rear panel of the Cart (or PMC); see Network Indicator *on page 2-34.*

To enter the NETWORK menu

Press the **MONITOR SETUP** key then turn the knob to NETWORK and press the knob.

The following options are available:

- **A, B, C, D, E:** Sets the wireless network channel used by the system.
- **RETURN:** Exits the menu.

Service(Bio-Med)

SERVICE(BIO-MED) allows limited access to setup options. (For details about the menu options not covered below, see Chapter 14, Service(Bio-Med) Menu Options, page 14-7).

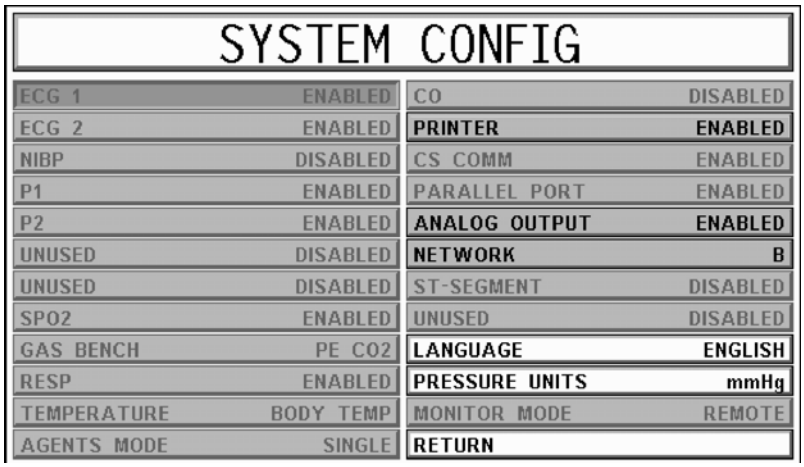
To enter the SERVICE(BIO-MED) menu

Press the **MONITOR SETUP** key then turn the knob to SERVICE(BIO-MED) and press the knob.

(Depending upon the option desired, access may require the correct entry of a 5-digit password.)

NOTE

Grayed-out options cannot be changed at the DCU; changes can only be made (to installed options) using a with a VGA display and keyboard connected to the WPU.



- **PRINTER:** Enables or disables the printer (DCU only).
- **ANALOG OUTPUT:** Enables or disables analog outputs.
- **NETWORK:** Sets the network used (A, B, C, D, or E) for communication.
- **LANGUAGE:** Sets the language used by the system for menus, options and messages:
  - **ENGLISH** (default)
  - **DEUTSCH**
  - **ESPANOL**
  - **FRANCAIS**
  - **PORTUGUES**
  - **ITALIANO**
  - **DANSK**
  - **SVENSKA**
  - **NORSK**
  - **NLD**
  - **RETURN:** Exits the menu.
- **PRESSURE UNITS:** Sets the unit of measurement used for pressure-related readings and indications, where mmHg (millimeters of mercury) and kPa (kilopascals) are the available options (default is mmHg).

NOTE

When Pressure Units are changed, the value format is immediately changed on the display. However, it can take up to 2 seconds for the new unit of measure to be propagated through the entire system, which can result in the brief display of an erroneous value. If data capturing or printing is performed during this 2 second period, a possible erroneous value may be conveyed.

- **RETURN:** Exits the menu.

Chapter 4
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 patient lead cables) are placed in the MR system bore. By following the operating precautions, warnings and guidelines, heating risks can be minimized. The ECG parameter is intended for ECG monitoring mode and not diagnostic ECG monitoring.

WARNINGS

- **The system is not intended for use with patients using pacemakers or electrical stimulators.**
- **Arrhythmias, erratic heart beats, 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 system and may be treated as part of the 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.

Wireless ECG Module and Patient Lead Cables

The wireless ECG module and the ECG patient lead cables can be used in the MR system bore, although the module must not be placed within the MRI field of view (FOV).

The ECG Patient Lead Cables are constructed of special materials to reduce the amount of radio frequency (RF) energy that can flow through these wires to avoid patient heating. The ECG Patient Lead Cables must always be kept in a straight line and must not touch the MR system bore. Any loop (circular, U-shaped, S-shaped) in the cables or contact with the MR system bore will cause heating of the lead cables or the patient electrodes.

CAUTION

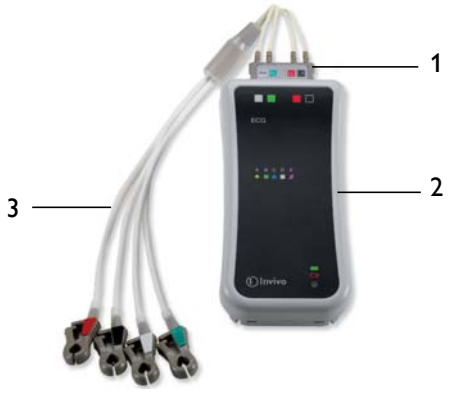
Placing the wireless ECG module within the FOV may interrupt ECG monitoring during the MRI procedure and cause MRI image artifacts.

WARNINGS

- **Never use any ECG Patient Lead Cables other than Invivo MRI ECG Patient Lead Cables.**
- **High levels of RF energy may cause patient heating or burns.**
- **Patient Lead Cables which become inadvertently looped during an MRI examination may act as conductive lines for RF induced currents, resulting in excessive heating and possible burns. When Patient 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, and follow steps to minimize heating risks as detailed on page 4-10.**

Attaching the Lead Cable to the Wireless Module

Depending upon the Quadtrode electrode you will be using, securely insert the appropriate lead cable into the cable receptacle on the wECG module.



	Definition
1	Cable receptacle
2	wECG module
3	wECG lead cable

Quadtrode Electrodes

Only use Invivo Quadtrode MRI ECG electrodes with this system. Quadtrode electrodes are available to meet the needs of different patient types to provide the best ECG performance.

- **Invivo CV Quadtrode MRI ECG electrodes** (REF 989803179041) are designed for Cardiovascular (CV) MRI procedures.
- **Invivo Standard Quadtrode MRI ECG electrodes** (REF 989803179031) are designed for general MRI procedures for adult and pediatric patients above 10 kg (22 pounds).
- **Invivo Neonatal Quadtrode MRI ECG electrodes** (REF 989803179051) are designed for general MRI procedures for neonatal or infant patients weighing under 10 kg (22 pounds).

NOTE

Use of the Invivo Quadtrode electrodes will minimize the possible risk of ECG electrode and cable heating during MRI procedures, and reduce the amount of MRI-generated artifacts on the ECG waveform.

Electrode Selection

Electrode selections, when paired with a correct ECG cable, are available to meet all of your monitoring needs.

CV Quadtrode (REF 989803179041) with the CV ECG Lead Cable (REF 989803152351):

–Use during cardiovascular procedures

–Provides the best ECG performance for all procedures

Standard Quadtrode (REF 989803179031) with the Standard ECG Lead Cable (REF 989803152301):

–For all patients over 10 kg (22 pounds)

–Use with all scans except cardiovascular scans

Neonatal Quadtrode (REF 989803179051) with the Neonatal ECG Lead Cable (REF 989803152331):

–Designed specifically for infants under 10 kg (22 pounds)

–Sedation and general anesthesia

CV Quadtrode (REF 989803179041) with the Advanced Filter ECG Cable (REF 989803170121):

–Designed to minimize the gradient artifact on the ECG trace

Electrode Site Selection

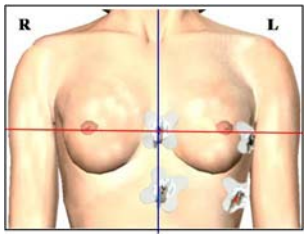
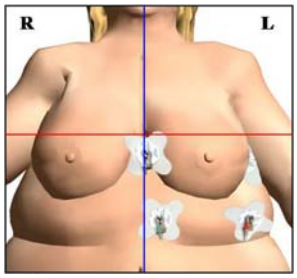
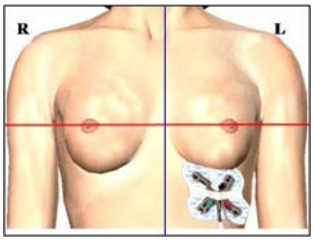
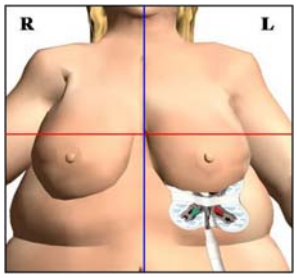
Monitoring ECG in the MR environment is particularly challenging because of the inherent distortion of the ECG waveform caused by the MR magnetic field. These blood flow induced distortions of the ECG are due to the large amount of blood moving through the vessels of the heart (aorta). Blood (a very good electrical conductor) moving through the large magnetic field of the MR produces an electrical potential that adds to the ECG signal. This induced electrical potential is seen primarily as an augmentation of the ECG T-wave amplitude, although other non-specific waveform changes are also apparent on the ECG. Since an elevated T-wave or ST segment will be associated with true physiologic disorders, the static magnetic field-induced ECG-distortions will be problematic. For this reason, a baseline recording of the ECG prior to placing the patient inside the MR system room will be necessary.

The proper placement of the ECG electrodes in the MRI is critical to reducing the blood flow induced distortion of the ECG waveform. With proper strategic placement of the ECG electrodes and minimization of the electrode lead cable length, this blood flow induced distortion can be kept to a minimum. Following the instructions provided on the specific Quadtrode foil packaging will minimize the blood flow induced distortion on the ECG signal. Additional artifacts caused by the static, gradient, and RF electromagnetic fields can severely distort the ECG, making observation of the morphologic changes and detection of arrhythmia quite difficult. Monitoring a different ECG lead (I, II, III, AVL, AVR, AVF) will minimize some of these artifacts. For optimal performance, use the illustrations below as a guideline for proper placement when applying electrodes to the patient.

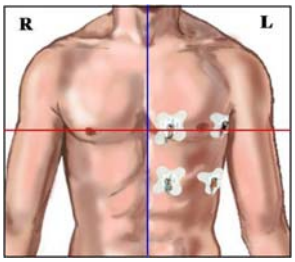
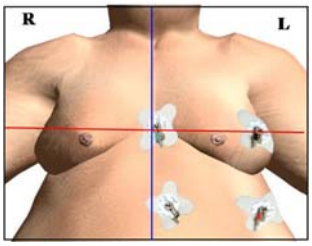
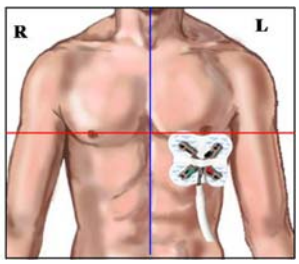
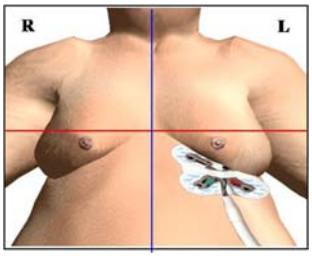
NOTE

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

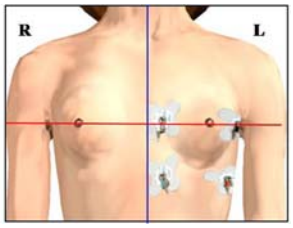
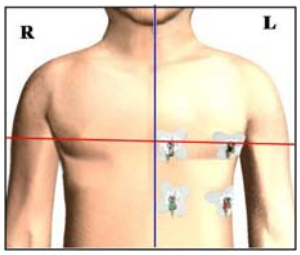
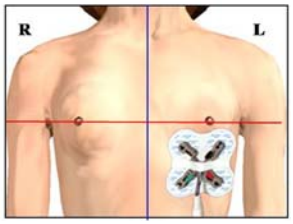
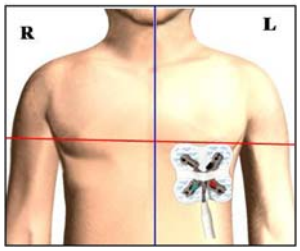
Selecting sites on adult females

Average weight adult female	**Overweight adult female**
CV Quadtrode (preferred)	CV Quadtrode (preferred)
	
Standard Quadtrode	Standard Quadtrode
	

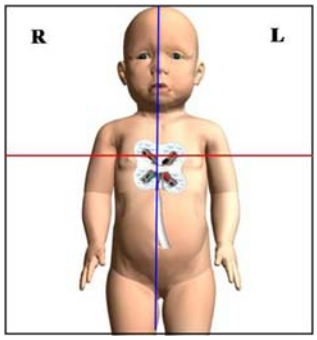
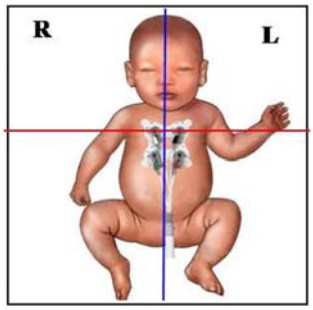
Selecting sites on adult males

Average weight adult male	**Overweight adult male**
CV Quadtrode (preferred)	CV Quadtrode (preferred)
	
Standard Quadtrode	Standard Quadtrode
	

Selecting sites on pediatrics

Pediatric female	Pediatric male
CV Quadtrode (preferred)	CV Quadtrode (preferred)
	
Standard Quadtrode	Standard Quadtrode
	

Selecting sites on neonates

Neonate	
*Over 10 kg (22 pounds)	*Under 10 kg (22 pounds)
Standard Quadtrode	Neonatal Quadtrode
	

Prepping the ECG Patient Site and Placing the Quadtrode Electrode

Preparing the patient for MRI ECG monitoring is detailed below. Complete the following steps when preparing an electrode site and placing the quadtrode on a patient.

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

NOTES

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

Checking the Electrode Contact Quality

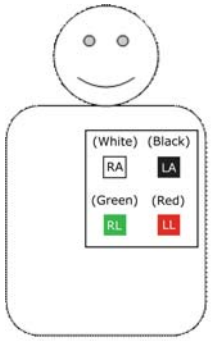
Proper electrode preparation is critical to ECG performance. The result of poor electrode preparation will be poor ECG monitoring performance. If electrode contact is poor, then remove and discard the electrode and repeat the site preparation according to the instructions above. Never reuse a removed electrode since its adhesive will not securely fasten the Quadtrode electrode to the patient's skin.

WARNING

No other electrical conductor (wires, leads, probes, etc.) can be placed inside the MR system bore at the same time as the Invivo MRI ECG Patient Lead Cables as the risk of lead cable and electrode heating increases.

Connecting the Lead Cable to the Electrode and Positioning the wECG Module

The diagram (right) provides an illustration of lead cable wire connections using designators. These designators are location-based by the areas on the torso where the electrode should reside in correlation with the patient's extremities.



Note that the medical industry refers to the respective electrode leads as RA (right arm), LA (left arm), RL (right leg), and LL (left leg). Our electrode leads are labeled with this designation and color-coded as follows:

- RA (white)
- LA (black)
- RL (green)
- LL (red)

CAUTION

The electrode leads identified as RL, LL, RA, and LA should not be placed on the patient's extremities.

The system monitors the ECG connections. Complete the following steps to attach the lead wires to patient and position the wECG module for scanning.

Step	Action
1	While referring to the designators (see the connection diagram above), attach the wECG lead cable wires to the Quadtrode electrodes on the patient. **WARNING** **When applying electrodes or connecting the patient lead cable, ensure that the electrodes or connectors never contact other conductive materials including grounded conductors. In order to prevent contact with other conductors or earth ground, make sure all the electrodes or connectors are properly attached to the patient.**
2	Position the module for scanning. Keep the module outside the field of view (FOV) by placing it in one of the two locations. (Refer to *Positioning Suggestions*, on page 4-9.)
3	Check the status indicator of the module (see Chapter 2, Understanding the Module Status Indicator, page 2-18 for details): • Solid green = Battery power OK/Good communication • Flashing green = Battery power OK/No communication • Solid red = Low battery power/Good communication • Flashing red = Low battery power/No communication

If a faulty or disconnected ECG lead or electrode/Quadtrode application is detected during monitoring, the system will immediately notify you so that quick action can be taken to identify the source of the failure and proceed with an informed response. The system will display **LEAD FAIL** (see ECG Messages on page 4-22 for details) and a red indicator will appear in the ECG VS box identifying the specific electrode(s) (LL, LA, or RA) that have lost connection (see the note and example below).

NOTE

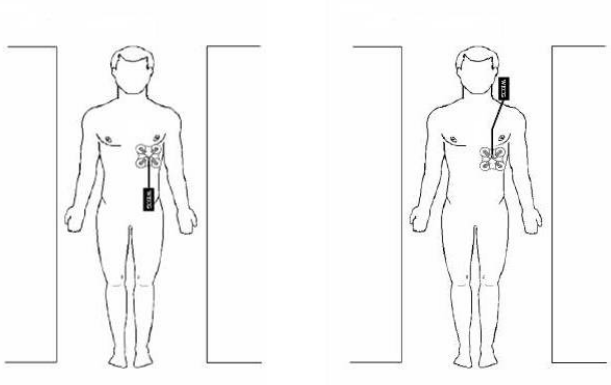
If the RL electrode has lost contact (or if all electrodes have lost contact) then LL, LA, RA will be the displayed indication.

Example, Lead Fail indicator (left arm)

Positioning Suggestions

To ensure the best possible performance of the wireless ECG module, especially during harsh scan sequences (with PNS-peripheral nerve stimulation-levels above 80 percent), the instructions below should be followed:

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



WARNING

If the wECG module is positioned incorrectly when used within the MR system room, the following factors may cause ECG waveform distortion and ECG 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, and**
- **The distance from the bore iso-center in the x, y, or z directions.**

Minimizing MRI-Related Heating Risks

Follow these steps to minimize the risk of MRI-related heating.

Step	Action
1	Arrange the Patient Lead Cables neatly, in a straight alignment, with no looping. **WARNING** **Circular, U-shaped or S-shaped loops in the patient lead cable should be avoided to reduce the risk of heating.** 
2	Avoid contact between Patient Lead Cables and bare skin.
3	Use only the ECG Patient Lead Cables designated for use with this product. See Chapter 1, Accessories, page 1-3 for details.
4	Minimize the use of multiple cables.
5	The wireless ECG module, ECG Patient Lead Cables, and Quadtrode ECG electrodes are acceptable for use within MR systems with static magnetic field strengths of 3.0 Tesla or less within the MR system bore using a MR system reported whole body average Specific Absorption Rates (SAR) up to 4.0 W/kg.
6	Monitoring of ECG at power levels of greater than a MR system reported, whole body averaged SAR of 4 W/kg is not recommended for the general patient population. Such monitoring must only be attempted with conscious patients with normal thermoregulatory capabilities so that they may warn you of possible excessive heat at the monitoring sites.
7	Use caution for scan times (that is, per pulse sequence) greater than 15 minutes. For MRI scans with average SAR > 1 W/kg, limit scan time to 15 minutes and pause at least 3 minutes between scans to allow the ECG electrodes to cool.

Monitor Setup

The following sections provide guidelines for setting up ECG monitoring.

ECG Filter Selection

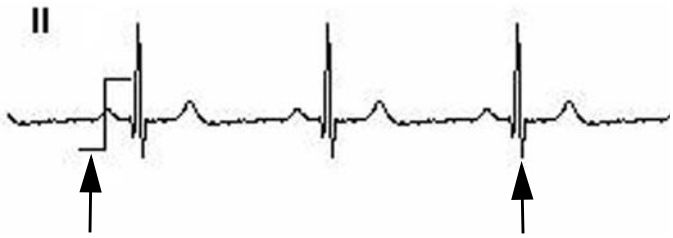
Choose the appropriate filter for your MRI study, as described in FILTER MODE (in *ECG Menu Options* on page 4-14).

Checking the ECG Signal

Evaluate each patient before they enter the MRI scanner, the optimum time to correct any problem. A good ECG signal is determined by the following stipulations:

- The minimum amplitude of the displayed QRS complex should be approximately 2 times the size of the scale indicator (a 1 mV reference at any given SCALE setting), as shown below. Signals smaller in amplitude may be prone to gradient interference.

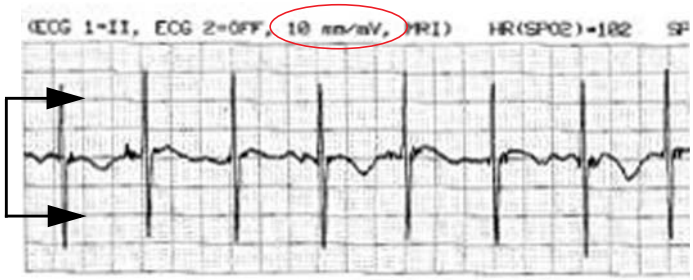
The displayed QRS complex should be twice the size of the scale indicator.



Scale indicator QRS complex

- A minimum of 4 bars should be present for the peak to peak QRS complex when utilizing a SCALE setting of 10 mm/mV, as shown below in the strip chart printout.

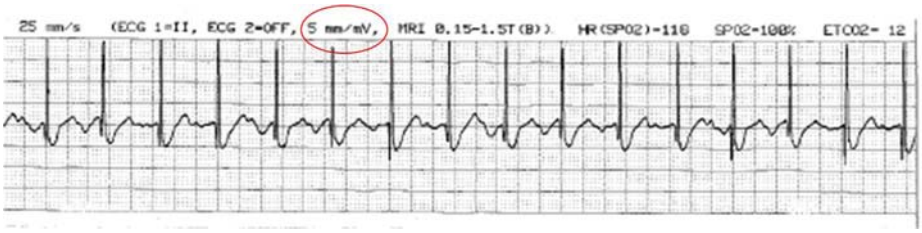
Using a 10 mm/mV SCALE setting, a minimum of 4 bars for the QRS complex provides optimum performance



NOTE

The SCALE setting only changes the way the ECG trace appears on the LCD, reducing or amplifying the ECG signal as well as any noise.

Recommended setup: Only use a SCALE setting of 5 mm/mV or 10 mm/mV (do not exceed 15mm/mV), as shown below.



Default to lead II

If the QRS does not equal a minimum of 2 bars (10 mV), complete the steps below.

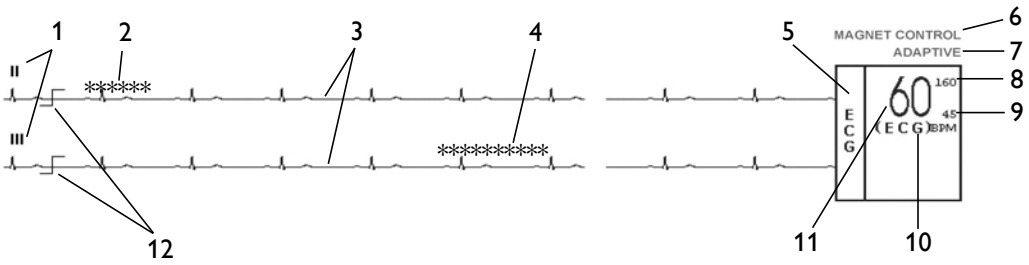
Step	Action
1	Ensure you are using the preferred Quadtrode electrodes and placement site.
2	Check Quadtrode dates, quality, and packaging.
3	Try cycling lead views to a different lead (I, II, III, AVL, AVR, or AVF) to account for patient variability; see *ECG Menu Options* on page 4-14.
4	Pull the electrodes off and prep the application site again.

NOTE

*PEDIATRIC ECG (designed for patients 10 years and younger) can be enabled in the **SETUPS** menu (see Chapter 3, Pediatric ECG, page 3-9) if experiencing a low heart rate from ECG or poor gating, as this mode will enable the monitor to recognize a narrow QRS complex that is sometimes present in pediatrics.*

ECG Waveforms and VS Box

ECG information is displayed as a waveform in Trace A (and Trace B) locations, and as numeric data in the ECG VS box, as detailed below.

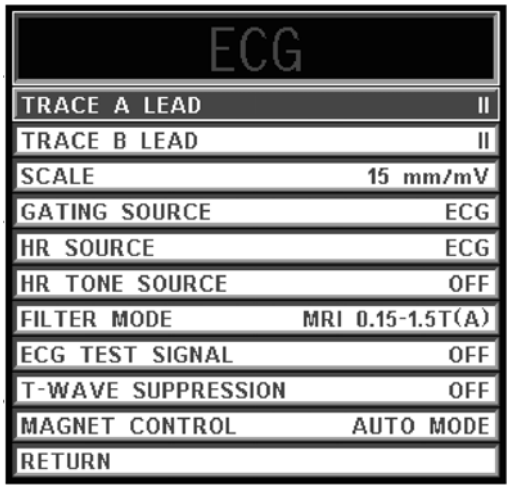


	Name	Definition
1	Lead type	Identifies the selected ECG lead type
2	Lead condition message area	Indicates an abnormal ECG lead condition; see ECG Messages, on page 4-22
3	Trace waveform	Is the detected ECG waveform(s)
4	Error condition message area	Indicates abnormal ECG monitoring condition; see ECG Messages, on page 4-22
5	Parameter	Identifies the ECG parameter
6	Magnet control	Indicates (when present) that the MR magnet has control of the ECG filter mode
7	Filter mode	Indicates the current ECG filter
8	Heart rate alarm limit, high	Indicates the high limit of the ECG heart rate alarm setting
9	Heart rate alarm limit, low	Indicates the low limit of the ECG heart rate alarm setting
10	HR source and unit of measure	Indicates the selected heart rate source and given in beats per minute (BPM)
11	Heart rate numeric	Indicates the patient's detected heart rate
12	Scale indicator	Represents a 1 millivolt signal amplitude for the selected scale

ECG Menu Options

The **ECG** menu allows you to control ECG functions and settings. The following options are available:

- TRACE A LEAD
- TRACE B LEAD
- SCALE
- GATING SOURCE
- HR SOURCE
- HR TONE SOURCE
- FILTER MODE
- ECG TEST SIGNAL
- T-WAVE SUPPRESSION
- MAGNET CONTROL
- RETURN



To enter the ECG menu

Rotate the knob to highlight the ECG VS box then press the knob.

The following options are available:

- **TRACE A LEAD:** Allows you to choose the ECG A lead. For best ECG and heart rate monitoring, always select the optimal lead configuration, one that provides the least artifact and largest waveform detection for monitoring use. The options are I, II (default), III, AVL, AVR, AVF and OFF.
- **TRACE B LEAD:** Allows you to choose the ECG B lead to view 2 ECG waveforms simultaneously. The options are I, II, III, AVL, AVR, AVF, and OFF (default).

NOTE

For best ECG, heart rate, and/or respiration monitoring, always select the optimal lead configuration which has the least artifact and largest waveform(s) being detected for monitoring use.

- **SCALE:** Allows you to set the scale for the ECG waveforms. The selected scale will remain in effect until another scale is selected. Take note of the scale indicator. If the selected scale results in an ECG trace that is so large that the peaks of the waveform are distorted or clipped, OVERSCALE will flash in the ECG waveform area, overriding other ECG messages. In this case, use this menu to resize the waveform until OVERSCALE stops flashing. The options are AUTO, 1, 5, 10 (default), 15, 20, 25, 30, and 40 mm/mV. If AUTO is selected, a

scale that makes the current waveform fill the ECG viewing area is enabled. This mode is not recommended for use in the MRI.

NOTE

Changing the scale only changes the appearance of the ECG waveform on the screen. It does not affect the ECG signal analyzed by the monitor for QRS detection and gating.

- **GATING SOURCE**: Allows you to set the gating source. The feature provides facilities for low latency MRI triggering and synchronization based on the measured ECG signal. ECG data measured and transmitted by the wECG module is processed and output via the gating connector on the rear panel of the Cart (or PMC) that can then be used as an input to trigger or synchronize the image gathering process of the MRI system. (An optional gating interface cable is required to connect to various MRI systems; for details see Chapter 1, Accessories, page 1-3.) Either ECG channel can be used for interfacing with the cardiac gating input: Trace A is the default output. To use Trace B, set Trace A to off and ensure that Trace B is active (not off); see ECG Gating on page 4-20. The following options are available:
  - **ECG** (default) is a pulse that represents the detection of the R-peak of a QRS complex, a signal the MRI system can use directly for triggering.
  - **Pulse** is a signal that represents the detection of the peak of the peripheral pulse complex.
  - **RETURN** closes the menu.
- **HR SOURCE:** Allows you to select the source used to produce the heart rate displayed in the ECG VS box (for example, 60 ECG indicates a heart rate of 60 bpm as derived from ECG). This is identical to and interactive with the same option in the **SpO_2**, **NIBP**, and **P1**/**P2** menus:
  - **AUTO** automatically selects the HR source from the highest priority active input, and the system searches for another source for rate only when Lead Fail occurs or when the ECG parameter is turned off. The system examines the highest priority active input. If not found, next highest priority parameter is sought. The priority ranking (highest to lowest) is ECG, ART (P1 or P2), SpO_2, and NIBP. If no parameters are presenting a heart rate and NIBP is off, then NONE is displayed in the heart rate position.
  - **ECG** (default) selects the electrocardiogram for the HR source.
  - **ART** selects one of the invasive pressure channels for the HR source. P1 or P2 must be displayed and labeled as ART for this option to be selected; see Chapter 6, IBP Menu Options, page 6-3.
  - **SPO2** selects SpO_2 for the HR source.
  - **NIBP** selects NIBP for the HR source.
  - **RETURN** closes the menu.

- **HR TONE SOURCE:** Allows you to set the source used for the heart rate tone. This is identical to and interactive with same option in the **SOUND ADJUST** menu:
  - **OFF** (default) removes the heart symbol from the display and no pulse tone will be sounded.
  - **QRS** provides a tone modulated by the QRS detection from the ECG vital sign.
  - **SPO2** provides a tone modulated by the SpO_2 measurement, where the lower the SpO_2 value, the lower the pitch.
  - **RETURN** closes the menu.

- **FILTER MODE:** Allows you to set the ECG filter used (as indicated on the LCD; see filter mode on page 29) during the MRI sequences. All filter modes except the MONITOR utilize an adaptive filter scheme for removal of gradient artifact generated by MR systems.

NOTES

- *Due to the variety of MRI sequence characteristics, the filter mode recommendations below may not provide optimum performance in all cases; therefore, in situations where the recommended mode does not provide the best results, the selection of other filter modes may improve ECG performance.*
- *ECG performance can be affected by the ECG electrode placement, the MRI procedure, the image slice angle, and the image slice thickness. In situations where ECG performance is not optimal, select the ECG lead (I, II, III, AVL, AVR, or AVF) that provides the best ECG performance.*
- *For cases not requiring cardiac gating, start with a 0.15 to 3.0T mode (depending on the MRI sequence) and switch filters if gradient artifact is noticed. If gradient artifact is still present, check signal strength and try Lead I or III.*

  - **MONITOR** provides filtering characteristics that meet the specification of the Association for the Advancement of Medical Instrumentation (AAMI). Note that this filter will not provide optimum performance during active MRI sequences.
  - **PRIMARY** (default) provides the best possible performance on 0.15 to 3.0T MR systems during Echo Train type MRI sequences.
  - **SECONDARY** provides the best possible performance on 0.15 to 3.0T MR systems during most non-cardiovascular MRI sequences.
  - **CARDIAC** provides the best possible ECG performance during cardiovascular (CV) MRI procedures that involve steady-state free precession imaging with balanced gradient (True-FISP, FIESTA, or Balanced FFE) sequences on 1.5 and 3.0T MR systems.

NOTE

For cases requiring cardiac gating, start with the Cardiac filter in Lead II and switch filters if gradient artifact is noticed. If gradient artifact is still present, check signal amplitude and try Lead I or III.

– **ADVANCED** provides the best possible performance on 1.5 and 3.0T MR systems during MRI sequences such as neurological and cardiovascular. This MRI filter utilizes an adaptive filter scheme for removal of gradient artifact generated by MR systems.

NOTES

- *Best performance in the Advanced filter mode is achieved using the Advanced Filter ECG Lead Cable (REF 989803170121), which allows placement of the wECG module outside of the bore.*
- *Advanced filtering operates on one lead at a time from a restricted set of leads and cannot be applied to AVR, AVL or AVF leads. To provide the most convenient transition to this filter and lead configuration, the system will automatically select the lead to use by applying the following rules in the order shown below:*

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

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

- **ECG TEST SIGNAL:** Allows you to generate an ECG calibration waveform (this is identical to and interactive with the same option in the **PRINTER** menu:

NOTE

ECG TEST SIGNAL is available on all leads, except Lead III.

– **OFF** (default) turns the calibration feature off.

– **PRINTER** sends a 1 mV pulse calibration waveform to the ECG parameter and the printer (if configured), where **ECG TEST SIGNAL** will be superimposed over the waveform.

– **ECG** sends a 60 bpm, 1 mV peak to peak calibration square wave from the wECG module to the ECG parameter and the printer (if configured), where **ECG TEST SIGNAL** will be superimposed over the waveform and 60 bpm will be displayed in the ECG VS box.

– **RETURN** closes the menu.

- **T-WAVE SUPPRESSION:** Allows you to reduce the T-wave amplitude when it becomes extremely large due to the magnetohydrodynamic effect (MHD), which can prevent the monitor from gating the MR system as required by the MRI study. Use when seeing an unusually high amplitude T-wave relative to the R-wave amplitude for accurate gating of the MR system using the QRS obtained from the monitor. (Off is the default setting.)

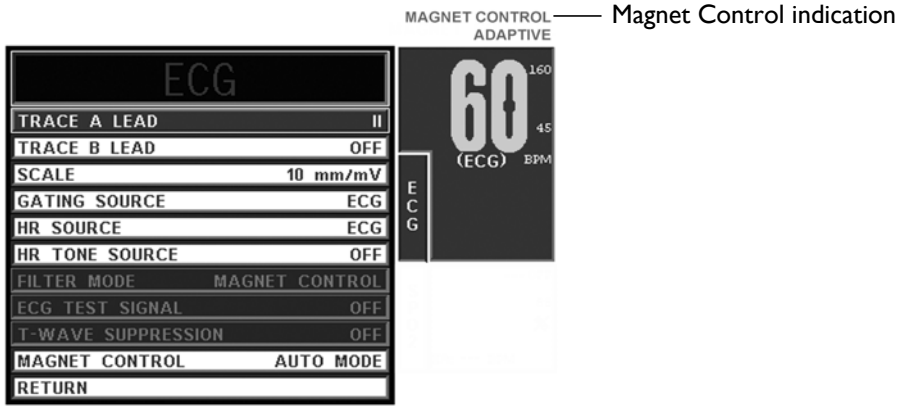
NOTE

T-WAVE SUPPRESSION is not available when FILTER MODE is set to MONITOR.

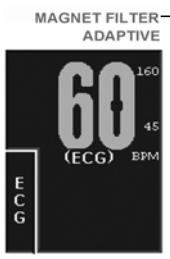
- **MAGNET CONTROL:** Allows gradient removal on certain MR systems equipped with vector ECG gating. On these systems, only one wECG module needs to be connected to the patient in order for the Expression and the MR system to monitor the patient's vital signs and gate the magnet.
  - **AUTO MODE** (default) allows the MR system to work, if capable, with the Expression to effectively remove gradient artifacts from the ECG waveform.

    When selected and with the wECG in radio contact with the MR system, this will disable and lock FILTER MODE, T-WAVE SUPPRESSION and ECG TEST SIGNAL.

    MAGNET CONTROL will be displayed to indicate that filter mode selection has been preempted by the MR system, as shown below:



In addition if **HR SOURCE** is set to **ECG**, the heart rate as derived from the MR system will be displayed (a brief interruption in the displayed waveform is possible) and **MAGNET FILTER** will be displayed, as shown below.



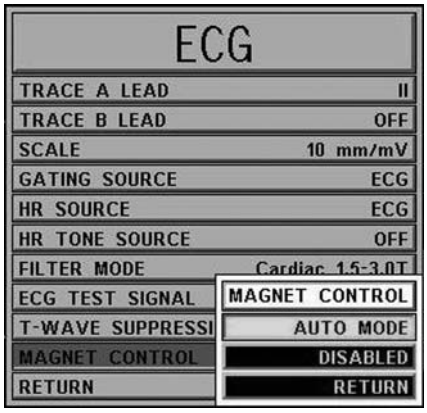
Magnet Filter indication

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

NOTES

- *This menu option is not a storable setup.*
- *The ECG filter and T-wave suppression settings will not be recalled when a system recall is performed in either Magnet Control or Magnet Filter mode. If a system recall is performed but then the Expression is moved from the MR environment, the ECG filter and T-wave suppression options will revert to the prior settings.*

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



– **RETURN** closes the menu.

- **RETURN:** Exits the menu and returns the display to the Normal screen.

Additional Functions

These selections support additional ECG monitoring features. Press the key described below to open the associated menu:

- **ALARM SETUP key -** See *Setting Alarm Limits*, below.
- **PRINTER SETUP key -** Used to select printer functions; see *Printer Menu Options* on page 12-4.
- **TRENDS key -** Used to setup and print trended information; see *Trending Feature* on page 12-8.
- **Pediatric ECG menu:** Used to provide specific ECG filtering for patients with narrow QRS complexes and heart rates greater than 120 beats per minute that may cause disruption of normal ECG processing.

Setting Alarm Limits

Alarm limits can be set two ways (see Chapter 13, Alarms Menu Options, page 13-7 for details):

- To set the alarm limits for every available parameter, press the **ALARM SETUP** key.
- To set the alarm limits for ECG only, highlight the ECG VS box then press the **ALARM SETUP** key.

ECG Gating

The ECG gating feature provides for low latency MRI triggering and synchronization based on the measured ECG signal. ECG data measured and transmitted by the wECG module is processed and output via the gating cable connector (as identified by the  symbol) on the rear of the Cart (or PMC) for use as inputs to trigger or synchronize the image gathering process of the MR system (see Appendix A for technical information regarding gating). Analog and digital gating signals are available.

Analog gating provides a continuous analog representation of the ECG waveform that is ultimately displayed in the Trace A position of the DCU. The MR system can process this data as desired to control triggering or extract other information.

Digital gating provides a digital pulse that represents the detection of the R-peak of a QRS complex. The MR system may use this signal directly for triggering.

Using Analog Gating

To receive the analog ECG gating waveform through the gating connector, ensure that all of the following conditions have been met:

1. That the system is communicating with the wECG module,
2. That the wECG module is properly attached to the patient, and
3. That a Lead Fail condition does not exist for the measured ECG signal.

Using Digital Gating

To receive the digital ECG gating pulse through the gating connector, ensure that all of the following conditions have been met:

1. That the system is communicating with the wECG module,
2. That the wECG module is properly attached to the patient,
3. That a Lead Fail condition does not exist for the measured ECG signal,
4. That the ECG parameter has been activated in the menu system, and
5. That the ECG signal has been selected as the digital pulse source, as detailed below,

Step	Action
a.	Turn the knob until the ECG VS box is highlighted then press the knob.
b.	Turn the knob to GATING SOURCE and then press the knob.
c.	Turn the knob to ECG and then press the knob.

ECG Messages

The following messages could be displayed during ECG monitoring.

Message	Meaning	Probable Cause	Recommended Action
LEAD FAIL	Lead failure	A faulty or disconnected ECG lead or electrode/Quadtrode application is detected by the system. ***NOTE*** *An inoperative ECG parameter or wECG module is indicated by absence of an ECG waveform and a simultaneous LEAD FAIL message and indicator.*	Ensure that all cable leads are connected to the patient electrodes/Quadtrodes and that the lead cable is connected to the wECG module. (Also see the lead failure information in *Connecting the Lead Cable Wires to the Electrode and Positioning the wECG Module* on page 4-8.) Ensure proper application of ECG electrodes/ Quadtrodes. (Refer to *Quadtrode Electrodes* on page 4-3.) If the problem persists, replace the ECG leads and/or electrodes/Quadtrodes with another set; see Chapter 1, ECG, page 1-5.
WARNING **Failure to respond to a Lead Fail alarm will cause a lapse in the monitoring of the patient.**			
LEAD SATURATION	ECG signal saturation	The DC voltage offset of the ECG input signal is too large for the system to process and display the waveform. A saturation condition shall be reported by the system within 10 seconds of the loss of the ECG waveform.	Adjust the electrode or Quadtrode placement. (Refer to *ECG Electrodes - Electrode Placement Sites,* above.) ***NOTE*** *Until corrected, the ECG numeric values are removed from the VS box and an alarm tone is generated.*
OVERSCALE	The ECG waveform is too large.	The size of the ECG waveform is too large. The tops of the ECG waveforms are clipped (that is, cut off). ***NOTE*** *This condition will not generate an alarm tone.*	Reduce the size using the SCALE option in the **ECG** menu.

Chapter 5
Monitoring SpO_2

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

- Oxygen saturation of arterial blood (SpO_2) – The percentage of oxygenated hemoglobin in relation to the sum of oxyhemoglobin and deoxyhemoglobin (functional arterial oxygen saturation).
- 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 indicator – A numerical value for the pulsatile portion of the measured signal caused by arterial pulsation.

Wireless SpO_2 Module, Sensor and Attachments

The SpO_2 sensor and $wSpO_2$ module are designed for system use in the MR environment. Onlyuse specified fiber-optic SpO_2 sensors, clips and grips; see Chapter 1, Accessories, page 1-3. The $wSpO_2$ module and sensor can be used in the MR system bore, although the module must not be placed within the MRI field of view (FOV).

	Definition
1	SpO_2 sensor
2	Attachment, clip or grip (clip shown)
3	$wSpO_2$ module

WARNING

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

CAUTIONS

- If dropped, the wireless SpO_2 module must be verified for correct operation before use.
- Guard against the accidental ingress of liquid into the module, as measurements made by the device can be adversely affected.

NOTE

Refer to your facility's biohazard procedure for disposal of SpO_2 grip sensors when they become unusable. Usually sensors are disposed of as medical waste per facility procedures, as the devices are likely to be contaminated.

SpO_2 Patient Preparation

The monitoring site, the ambient environment, the sensor connection to the module, and the sensor position impact the performance and operation of the SpO_2 vital sign.

Applying and Positioning the SpO_2 Attachment on the Patient

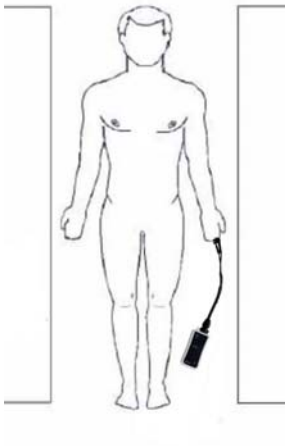
To apply the SpO_2 attachment to the patient

Step	Action
1	Follow the instructions for use provided with the SpO_2 attachment, adhering to all warnings and cautions. Choose the application site.
2	If present, remove any colored nail polish from the application site.
3	Check the wSpO_2 module status indicator; see Chapter 2, Understanding the Module Status Indicator, page 2-18: • Solid green = Battery power OK/Good communication • Flashing green = Battery power OK/No communication • Solid red = Low battery power/Good communication • Flashing red = Low battery power/No communication

Step	Action
4	Apply the attachment to the patient. The application site should match the sensor size so that the sensor is secure without applying excessive pressure to the site. **WARNINGS** • **GENERAL SENSOR FIT: If a sensor is too loose, it might compromise the optimal alignment or dislocate. If the sensor is too tight (for example, if the application site is too large or becomes large due to edema), excessive pressure may be applied resulting in venous congestion distal from the application site, which could lead to interstitial edema, hypoxemia, tissue malnutrition, and inaccurate measurements. Skin irritations may occur as a result of the sensor being attached to one location for too long. Periodically inspect the sensor application site and change the application site at least every four hours. Exercise care when using tape to secure the sensor, as the stretch memory properties of most tapes can apply unintended pressure to the sensor site easily.** • **EXTREMITIES TO AVOID: Avoid placing the sensor on extremities with an arterial catheter, intravascular venous infusion line, or inflated blood pressure cuff. Failure to do so may result in inaccurate readings or false alarm indications.**
5	Check that the light emitter and the photodetector are directly opposite each other, as the light from the emitter must pass through the patient's tissue to the photodetector for proper operation.

Positioning the wSpO2 Module for Scanning

To ensure best possible performance of the $wSpO_2$ module during harsh scan sequences (with peripheral nerve stimulation levels above 80 percent), follow the steps below.



Step	Action
1	Place the module on or near the patient as close as possible to the bore iso-center (considering the scan to be performed). Keep the $wSpO_2$ module and sensor outside the field of view.
2	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.)
3	Place the module on a cushioned surface to minimize MR vibrations.

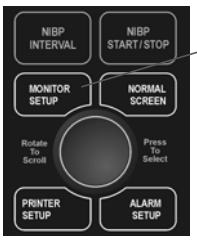
WARNING

If the wireless SpO_2 module is incorrectly positioned when used within the MR system room, the following factors can cause SpO_2 waveform distortion, SpO_2 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**

SpO_2 Adult, Pediatric and Neonatal Operations

The system allows you to establish SpO_2 sensitivity settings for the patient using the **PATIENT** menu; see Chapter 3, Setups Menu Options, page 3-2.



MONITOR SETUP key

To change the patient type:

Press the **MONITOR SETUP** key then turn the knob to PATIENT then press the knob. Next, highlight the patient type (Adult, Pediatric, or Neonatal) and press the knob.

To display SpO_2 values

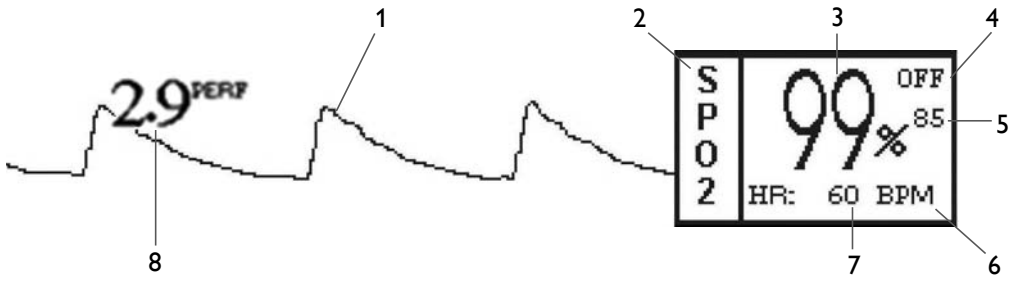
Step	Action
1	Ensure that the SPO2 VS box is displayed. (If not displayed, refer to Chapter 3, Parameter Selection, page 3-5.)
2	Select the patient setting option (Adult, Pediatric, or Neonatal). ***NOTE*** *PEDIATRIC and NEO options employ a higher sensitivity to detect low pulse amplitudes*.
3	During measurement, ensure that the application site • has a pulsatile flow, and • has not changed in thickness (for example, due to edema) causing an improper sensor fit.

NOTE

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

SPO2 Waveform and VS Box

The SpO_2 information is displayed as a waveform (Trace C) on the screen and as numeric data in the SPO2 VS box.



	Name	Definition
1	Trace waveform	Is the detected SpO_2 waveform
2	Parameter	Identifies the SpO_2 parameter
3	SpO_2 numeric	Indicates the patient's SpO_2 (saturation) reading, given as a percentage
4	SpO_2 alarm limit, high	Indicates the high limit of the SpO_2 alarm setting
5	SpO_2 alarm limit, low	Indicates the low limit of the SpO_2 alarm setting
6	Units of measure	Indicates beats per minute (BPM)
7	Heart rate measurement	Indicates the patient's heart rate, as derived from SpO_2
8	Perfusion index	Indicates the pulsatile portion of the measured signal caused by arterial blood flow

NOTE

If an error is detected, a message is displayed in the VS box; see SpO2 Messages on page 5-10.

SPO2 Menu Options

The SPO2 menu allows you to control SpO_2 functions and settings. The following options are available:

- SIZE
- AVERAGING TIME
- PERFUSION INDEX
- GATING SOURCE
- HR SOURCE
- HR TONE SOURCE
- RETURN

To enter the SPO2 menu

Rotate the knob to highlight the SPO2 VS box then press the knob.

The following options are available:

- **SIZE:** Allows you to change the vertical scale of the SpO_2 (pleth) waveform, so that too high an amplitude can be scaled down to avoid clipping of the peaks and too low an amplitude can be scaled up to view the peaks. The options are 10%, 20%, 40%, 60%, 80%, and 100% (default).
- **AVERAGING TIME:** Allows you to select how quickly (in seconds) 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 options are 5 S, 10 S (default), 15 S.
- **PERFUSION INDEX:** Indicates the perfusion index, a value for the pulsatile portion of the measured signal caused by the patient's pulsating arterial blood flow. If you need an indication of change in pulse volume, use perfusion index values. Also, this number can be used as a quality indicator for the SpO_2 measurement, according to the table below.

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

- **GATING SOURCE:** Allows you to select the source used to produce the gating pulse. The gating connector (on the rear panel of the Cart) requires an gating interface cable to connect the system to various manufacturers' systems; for details see Chapter 1, Accessories, page 1-3. The following options are available:
  - **ECG** (default) produces the gating pulses using the ECG vital sign data.

  - **PULSE** produces the gating pulses using the SpO_2 vital sign data.
  - **RETURN** closes the menu.

- **HR SOURCE:** Allows you to select the vital sign source used to produce the heart rate (HR) displayed in the ECG VS box. The displayed heart rate is displayed annotated with its source (for example, 60 ECG indicates a heart rate of 60 as derived from ECG). This is identical to and interactive with the same option in the **ECG**, **NIBP**, and **P1**/**P2** menus. The following options are available:
  - **AUTO** automatically selects the HR source from the highest priority active input, and the system searches for another source for rate only when Lead Fail occurs or when the ECG parameter is turned off. The priority ranking (highest to lowest) is ECG, ART (P1 or P2), SpO_2, and then NIBP. The system examines the highest priority active input. If not found, it will go to the next highest priority parameter. If none of the parameters are presenting a heart rate and NIBP is off, then NONE is displayed in the heart rate position.
  - **ECG** (default) selects the electrocardiogram for the HR source.
  - **ART** selects one of the invasive pressure channels for the HR source. P1 or P2 must be displayed and labeled as ART for this option to be selected; see Chapter 6, IBP Menu Options, page 6-3.
  - **SPO2** selects SpO_2 for the HR source.
  - **NIBP** selects NIBP for the HR source.
  - **RETURN** closes the menu.

- **HR TONE SOURCE:** Allows you to set the source to be used for the heart rate tone. (This is identical to and interactive with same option in the **SOUND ADJUST** menu, accessible by pressing the **MONITOR SETUP** key). The following options are available:
  - **OFF** (default) removes the heart symbol from the display and no pulse tone will be sounded.
  - **QRS** provides the source, the tone is modulated by the QRS detection from the ECG vital sign.
  - **SPO2** provides the source, the tone is modulated by the SpO_2 vital sign, where the lower the SpO_2 value, the lower the pitch.
  - **RETURN** closes the menu.

- **RETURN:** Exits the menu and returns the display to the Normal screen.

Setting Alarm Limits

Alarm limits can be set two ways (see Chapter 13, Alarms Menu Options, page 13-7 for details):

- To set the alarm limits for every available parameter, press the **ALARM SETUP** key.
- To set the alarm limits for SpO_2 only, turn the knob to the SPO2 VS box then press the **ALARM SETUP** key.

Trended Data

For information about trending of patient SpO_2 data, see Chapter 12, History Menu Options, page 12-9.

Assessing Suspicious SpO_2 Readings

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

WARNINGS

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

SpO_2 Messages

The following messages could be displayed during SpO_2 monitoring.

Message	Meaning	Probable Cause	Recommended Action
BAD PROBE	The system has detected a hardware failure in the sensor.	The SpO_2 sensor is defective.	Try another SpO_2 sensor.
ERRATIC	Erratic measurements are being produced by the system.	The SpO_2 sensor is not properly applied to the patient, is not properly positioned, or the sensor is faulty.	• Check the alignment of the sensor. • Try using a different sensor.
HW FAIL	SpO_2 hardware failure.	A hardware or other fatal error has occurred in the SpO_2 device inside the wireless module or the Cart.	Try another $wSpO_2$ module. If the failure persists, immediately remove the system from service and contact Invivo for repair, as the system must not be used on any patient requiring SpO_2 measurement.
INTRFERNCE	The signal quality of the light channel is inadequate for accurate saturation calculation.	The clip (or grip) light source may not be aligned with the its light receiver, or the sensor may be poorly positioned.	• Check the sensor alignment in the clip (or grip) connectors. • Try a different limb or site. • Try using a different clip (or grip).
LOW PERFUSION	(Low Perf) The perfusion measured is low enough to cause possible inaccuracies in the reported saturation value.	The tissue at the site may be too opaque and/or thick.	If the sensor is positioned on the finger, check the fingernails for nail polish, long or artificial fingernails. Remove any fingernail polish completely. For artificial nails try another location, like a toe.
NO PROBE	The $wSpO_2$ module cannot detect the SpO_2 sensor.	The sensor is not properly connected or no sensor is connected to the module.	Check the connection of the sensor to the wireless module. If connection appears sound, try another sensor.
NOISE	Patient motion or electrical interference is being experienced by the SpO_2 system.	Excessive patient motion or electrical interference.	• Check for patient motion, especially at the monitored site. • Ensure that the clip (or grip) is not exposed to excessive levels of ambient light.
NON PULSAT	Non pulsatile condition.	The patient pulse is too weak for the system to report reliable SpO_2 saturation and pulse measurements.	• Check the position and alignment of the clip (or grip) on the patient and re-position or re-apply as necessary • Try a different limb or site.
PROBE OFF	The system detects that the sensor is not applied to the patient.	The SpO_2 sensor is not properly applied to the patient.	Check the position and alignment of the clip (or grip) on the patient; reposition or reapply it as necessary.

Message	Meaning	Probable Cause	Recommended Action
PULSE?	The SpO_2-derived pulse rate is outside the detectable range.	The sensor may not be applied optimally, or the tissue at the applied site may be too opaque.	• Check the alignment of the clip (or grip). • Try a different limb or site.
SEARCHING	The system is searching for a good pulse.	The sensor was just applied to the patient, or the sensor has shifted position since being applied.	If the sensor was just applied, give the system time (usually less than 20 seconds) to lock onto a good pulse; otherwise, check the clip (or grip) position and re-position it if necessary.
WRONG PROBE	The system has detected that an incorrect sensor is connected to the module.	The sensor connected to the module is wrong.	Attach a correct SpO_2 sensor to the module.

Chapter 6
Monitoring Invasive Blood Pressure

The system provides two invasive blood pressure (IBP) channels. Most IBP monitoring functions, including site labeling, are contained in two corresponding menus, **P1** and **P2**.

CAUTION

Always reference the instructions included with the IBP transducer kit when monitoring invasive blood pressure.

IBP Transducer Preparation

This system is designed for compatibility with standard invasive blood pressure transducers having a 5 µV/V mmHg sensitivity. The transducer cable ports use six-pin connectors. Never place a pressure transducer within the MR bore, as transducer failure, inaccurate readings or noisy MRI images can result.

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.**

NOTES

- *If the transducer will not zero and an error condition occurs, verify that the transducer is used as described in the IBP transducer kit 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.*
- *Use only approved pressure transducers and cables, as listed in* Accessories *in Chapter 1. Follow the safe use instructions that are supplied with the pressure transducer.*

Follow the steps below to use a pressure transducer.

Step	Action
1	Insert the transducer connector cable into the P1/D1 or P2/D2 receptacle on the Cart (or PMC).
2	Connect the patient end of the pressure transducer according to the manufacturer's instructions.
3	Vent the transducer to atmospheric pressure according to the manufacturer’s instructions.
4	Press the **ZERO ALL** key.
5	After successful zeroing, close the transducer's stopcock as described in the kit instructions.

WARNING

Non-physiological pulsatile IBP waveforms (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 IBP, routinely inspect the catheter and/or pressure line for leaks after zeroing, and always follow the pressure transducer/catheter manufacturer’s use recommendations.

IBP Waveforms and VS Boxes

Upon activation of the invasive blood pressure vital sign, the associated waveform(s) (Trace E and/or F) and the VS box(es) will be displayed. The elements contained in the displayed invasive blood pressure VS boxes P1 and P2 are described below.

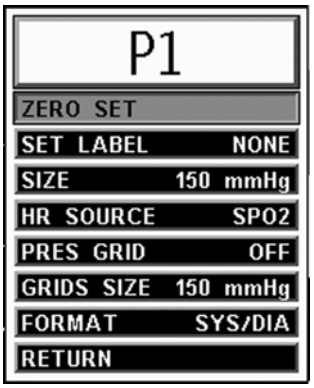
	Name	Definition
1	Trace waveform	Is the detected IBP waveform
2	Parameter	Identifies the IBP parameter
3	Systolic numeric	Indicates the patient's IBP systolic reading.
4	Mean numeric	Indicates the IBP mean reading
5	Unit of measure	Indicates the unit type for presentation of the IBP numeric data; see Chapter 3, Setups Menu, *page 3-2*
6	Diastolic numeric	Indicates the patient's IBP diastolic reading.
7	Diastolic alarm limit, low	Indicates the low limit of the diastolic alarm setting
8	Diastolic alarm limit, high	Indicates the high limit of the diastolic alarm setting
9	Systolic alarm limit, low	Indicates the low limit of the systolic alarm setting
10	Systolic alarm limit, high	Indicates the high limit of the systolic alarm setting
11	Site label	Indicates the set label name (e.g., ART, PAP, etc.) if entered

NOTE

Except for the indicated VS box (P1 or P2) and waveform location (Trace E or F), the elements described above will be identical for both IBP channels.

IBP Menu Options

The **P1** and **P2** menus allow you to control the invasive blood pressure functions and settings. The following options are available:



- ZERO SET
- SET LABEL
- SIZE
- HR SOURCE
- PRES GRID
- GRIDS SIZE
- FORMAT
- RETURN

To enter an invasive blood pressure menu

Rotate the knob to highlight the P1 (or P2) VS box and then press the knob.

NOTE

The operation and menu of P2 is identical to P1.

The following options are available:

- **ZERO SET:** Allows you to zero the pressure transducer on the channel. The transducer must be zeroed before each use and then at regular intervals during use. The transducer must be vented to atmospheric pressure before the ZERO SET option is selected. Upon completion, **DONE** will indicate success (See *Invasive Pressure Transducer Preparation* on page 6-1 for instructions.)

- **SET LABEL:** Allows you to label the pressure channel for easy identification of the transducer site, where the label becomes the pressure channel name and determines the color of the VS box, as listed below:
  - **NONE** (default) is white.
  - **ART** is pink.
  - **PAP** is yellow.
  - **CVP** is blue.
  - **LAP** is purple.
  - **ICP** is blue.
- **SIZE:** Allows you to set the trace scale for the pressure channel. The options are 40, 75, 100, 150 (default), 200, and 250 mmHg.

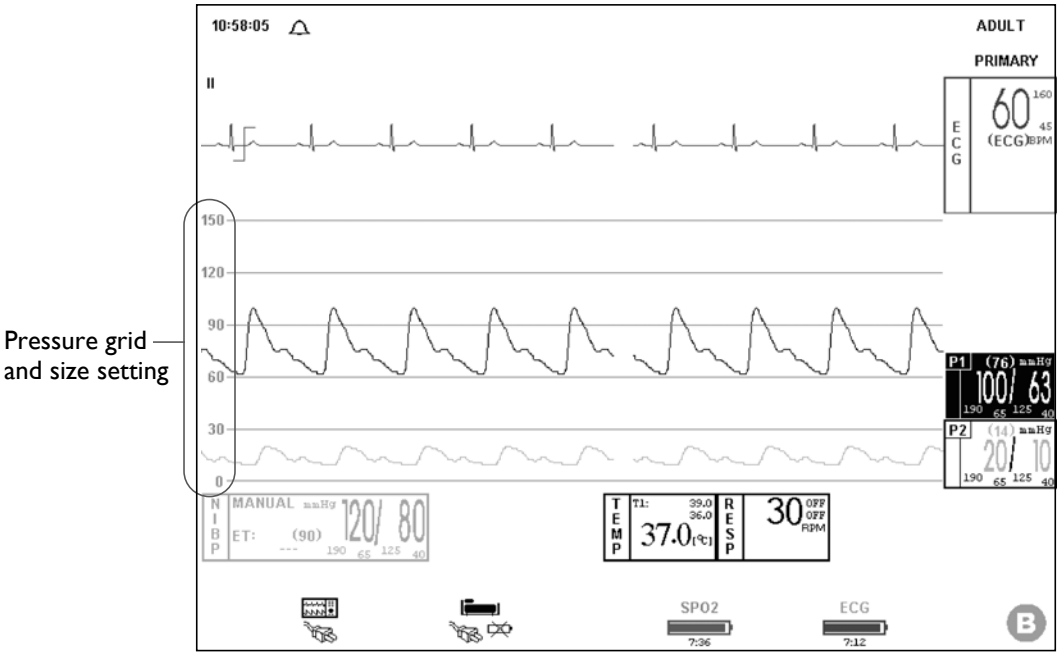
NOTE

For best invasive pressure monitoring, always select the appropriate scale per the observed waveform.

- **HR SOURCE:** Allows you to set the source used for the heart rate displayed in Trace A. This is identical to and interactive with the same option in the **ECG**, **SPO2**, and **NIBP** menus. The following options are available:
  - **AUTO** automatically selects the HR source from the highest priority active input, and the system searches for another source for rate only when Lead Fail occurs or when the ECG parameter is turned off. The priority ranking (highest to lowest) is ECG, SpO_2, and then NIBP. The system examines the highest priority active input. If not found, it will go to the next highest priority parameter. If none of the parameters are presenting a heart rate and NIBP is off, then NONE is displayed in the heart rate position.
  - **ECG** (default) selects the electrocardiogram for the HR source.

  - **ART** selects one of the invasive pressure channels for the HR source. P1 or P2 must be displayed and labeled as ART for this option to be selected; see *Set Label* on page 6-4.
  - **SPO2** selects SpO_2 for the HR source.
  - **NIBP** selects NIBP for the HR source.
  - **RETURN** closes the menu.

- **PRES GRID:** Allows you to view the pressure grid. When set to on, graticule lines are displayed along with associated pressure line numbers. The pressure traces align to their respective area of the grid so that comparisons can be made. This option can be set from either invasive pressure menu. The options are on and off (default).



- **GRIDS SIZE:** Allows you to change the scale size of the grids when PRES GRID is set to on (see above). The options are 40, 75, 100, 150 (default), 200, and 250 mmHg.
- **FORMAT:** Allows you to change the displayed format of the pressure numerics. The following options are available:
  - **SYS/DIA** (default) 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.
  - **MEAN** displays the mean numeric in a large font, and the systolic and diastolic numerics will be in a smaller font and separated by a slash. Also, labels that designate single pressures (for example, CVP and ICP) will automatically assume the mean format; and, you will be informed that the format is not changeable for the current label if a switch to the SYS/DIA format is attempted.
- **RETURN:** Exits the menu and returns the display to the Normal screen.

Additional Functions

These selections also support additional invasive pressure monitoring features (the Cart may contain limited selection and the DCU may contain a full compliment). Press the key described below to open the associated menu:

- **ALARM SETUP key -** See *Setting Alarm Limits*, below.
- **PRINTER SETUP key -** Used to select printer functions; see *Printer Menu Options* on page 12-4.
- **TRENDS key -** Used to setup and print trended information; see *Trending Feature* on page 12-8.

Setting Alarm Limits

Alarm limits can be set two ways (see See Paragraph for details):

- To set the alarm limits for every available parameter, press the **ALARM SETUP** key.
- To set the alarm limits for P1 or P2 only, turn the knob to the P1 (or P2) VS box then press the **ALARM SETUP** key.

IBP Messages

The following messages could be displayed during invasive blood pressure monitoring.

Message	Probable Cause	Recommended Action
DONE	Zeroing was successfully completed.	No action needed.
ERR: UNSTABLE	1) Unstable pressure or vibration during zero. 2) Faulty transducer connection.	Ensure that the transducer is vented to air, not to the patient, and try again. Make sure that there is no unstable pressure present during zero. Check the transducer for faulty connection. Replace the adapter cable and try again. If this fails, replace the transducer and retry. If the message persists, contact Technical Support or authorized service personnel.

Message	Probable Cause	Recommended Action
ZERO CAL ERR (LO)	1) The system has detected that the invasive pressure offset is too low for an IBP channel to be zeroed. 2) No transducer is connected to the pressure channel receptacle.	Ensure that the pressure transducer is attached to the pressure channel receptacle. Replace adapter cable and try again. If this fails, exchange the transducer and retry. If the message persists, contact Technical Support or authorized service personnel.
ZEROING ALL PRESSURE CHANNELS	The system is zeroing the pressures in all active invasive pressure channels.	No action needed.
ZEROING PRESSURE CHANNEL	The system is zeroing the pressure in the associated invasive pressure channel (1 or 2).	No action needed.

Chapter 7
Low Flow CO_2 Option

NOTE

Refer to Chapter 8 if your system is equipped with the anesthetic agents option.

The Low Flow CO_2 option feature provides sidestream measurement of CO_2 with a continuous real-time CO_2 waveform display, and will perform automatic zeroing at periodic intervals while continuously performing pressure corrections. CO_2 monitoring also provides respiration monitoring.

WARNING

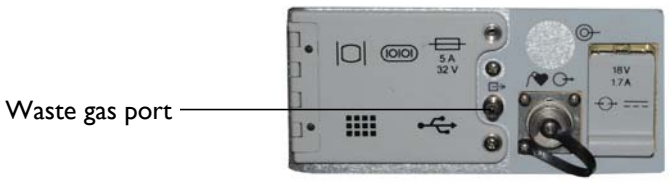
Returning sampled gas to the Cart (or PMC) will cause a positive pressure that can reduce flow, which can affect accuracy at higher breath rates. Accuracy is reduced because the CO_2 value will decrease and inspired CO_2 will, in turn, increase.

CAUTION

Mainstream cyclical pressure of 10kPa can damage the equipment since this system uses sidestream technology as the measurement technique.

NOTES

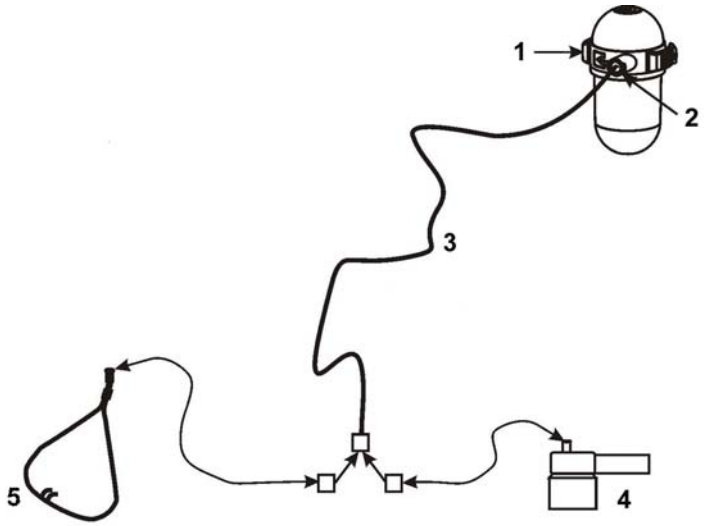
- *End-tidal CO_2 ($EtCO_2$) monitoring allows exhaled CO_2 to be measured non-invasively. A system with CO_2 feature is intended to monitor inspired and expired levels of CO_2 through a sampling line. Before using the CO_2 monitoring feature, connect the waste gas port at the rear panel to your facility's gas scavenging system utilizing 0.25 inch (6 mm) inside diameter tubing. Do not block the waste gas port. Follow your facility's guidelines for connecting to the scavenging system, including proper disposal of sampled gas.*



- *The time from switching on the CO_2 portion of the system until the specified operating performance is obtained is approximately 2 minutes.*

Water Trap and Sampling Line Preparation

The patient sampling circuit, as shown below, consists of the following components.



	Definition
1	Water trap containing a blue sample port inlet,
2	Water trap containing a blue port fitting, and
3	Blue sampling line measuring 15 feet long.
4	Airway adaptor connected to the patient airway, or
5	Nasal cannula connected to a patient airway.

NOTES

- *All fittings are the Luer Lock type.*
- *Connect an airway adaptor (Item 4, above) or a cannula (Item 5, above) only after **CO2 WARMING UP** is no longer displayed.*

CAUTIONS

- The accuracy of the data collected is greatly influenced by the proper use, fitting and maintenance of the sampling tubing, the water trap, and the nasal cannula or airway adapter. All fittings must be securely attached to keep them from separating during the procedure and to ensure proper sampling without the introduction of outside air.
- Do not block the waste gas port on the rear panel of the system.

CO_2 Warm-Up Period

The low flow CO_2 requires a warm-up period to thermally stabilize to achieve accurate gas identification and measurement. The warm-up period begins when the CO_2 vital sign is activated. Once this happens, the AGS will become fully operational according to the following sequence:

1. During the warm-up period, **CO2 WARMING UP** will be displayed.
2. Wait during this period, as the vital sign numeric values in the CO2 VS box will be displayed in the No Data Available state (---).
3. Within 2 minutes of activation, CO_2 will be able to operate at full accuracy.

Using the Patient Airway Adaptor

Complete the following steps when using the patient airway adaptor.

Step	Action
1	Attach the sampling line to the airway adapter.
2	Install the airway adapter into the patient circuit tubing.
3	Take care not to dislodge or move the patient circuit tube when attaching the adaptor.

WARNINGS

- **Do not allow the tubing to become kinked so that the sample flow is reduced or cut off. Keep the tubing clear of moving mechanisms (for example, table wheels) that can kink or cut the tubing. Leaks or internal venting of sampled gas into damaged tubing will cause inaccurate measurements.**
- **CO_2 patient tubing and its associated components are intended for single-patient use only. Do not clean or disinfect these items. Reuse of these items can lead to inaccurate gas measurements or patient injury.**

NOTES

- *Consult the instructions that accompany the CO_2 accessories for guidance regarding the length of time that the components may be used.*
- *Always inspect patient tubing after attachment to the system by following the tubing manufacturer's recommendations. A sampling line change after each patient use is recommended. An internal leak may result in condensation within the system; if this is suspected, please contact Technical Support.*

Water Trap Replacement

Remove the sampling line from the water trap port and then perform the following steps to replace the water trap.

Step	Action
1	To remove the water trap, simultaneously press both release tabs and pull the water trap from the water trap receptacle; see Chapter 2, Patient Connection Area, page 2-8 for the location.
2	To install the water trap, align it to the water trap receptacle and then press water trap into place until audible “clicks” are heard from both release tabs.
3	Attach the sampling line to the trap port.

WARNINGS

- **Always test sampling line adapter for a tight connection and proper operation before attaching to a patient. Overtightening the sampling line may damage the water trap. Tighten the sampling line no more than 1/2 turn. Overtightening this connector can cause failure of the water trap assembly and inaccurate patient gas measurements.**
- **Frequently inspect the patient sampling line. Keep the patient sampling line clear of any moving mechanisms which may cut or dislodge the patient tubing. Avoid kinking of the patient sampling line that can cause leaking, reduction, or cut off of the sample gas flow; inaccurate gas measurements could result.**

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 8 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 specified parts.*

Calibrating the CO_2 Measurement System

The system automatically performs Zero Calibration cycles as part of its normal function, as detailed below.

Zero Calibration Cycle

A zero calibration cycle realigns the CO_2 zero point. During this calibration, the system makes sure that a zero percent concentration is measured when room air is flowing through the sample chamber. During a Zero calibration cycle, the system performs these steps:

(1) The Input Gas Valve is switched to the CO_2 zero intake port.

(2) Room air is absorbed through the CO_2 zero intake port, flushing the pneumatic system for a few seconds.

(3) After the readings stabilize, a snapshot is taken and the zero point is realigned using these readings as a reference.

(4) The Input Gas Valve is returned to the normal position and the gas being measured is given a few seconds to flush the room air from the pneumatic system.

(5) After the readings stabilize, the CO_2 system begins its normal functioning routine.

WARNING

CO_2 and anesthetic agent calibration cylinders and test gas mixtures must be completely drained of pressure before disposal. Contents are under pressure and may cause hazard if container is punctured.

CAUTION

An internal leak may result in condensation within the system. If this problem is suspected, contact Technical Support.

Automatic Zero Cycle

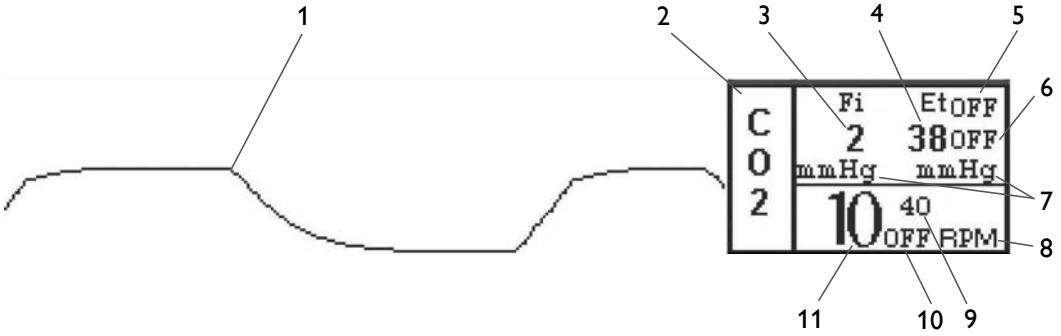
An automatic zero calibration cycle is triggered when certain time intervals have elapsed since the system completed its warm-up cycle. The timetable for automatic Zero calibration cycles begins when the CO_2 parameter is activated, with zeroing again at 30 minutes after activation and then at 90 minutes after activation. Thereafter, the automatic zero calibration cycle is triggered once every two hours.

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 CO_2. If the system is placed in an unventilated area that allows CO_2 (from the waste gas port on the rear panel, if not connected to a Gas Scavenging System) to accumulate, the result could be inaccurate zeroing of the CO_2 module and resulting inaccurate patient readings. Always place the Cart in a well ventilated area.

CO2 Waveform and VS Box

Upon activation of the CO_2 parameter, the associated waveform (Trace D) and the VS box will be displayed. The elements contained in the displayed CO_2 VS box are described below.



	Name	Definition
1	Trace waveform	Is the detected CO_2 waveform
2	Parameter	Identifies the CO_2 parameter
3	FiCO_2 reading	Indicates the patient's inspired CO_2 reading
4	EtCO_2 reading	Indicates the patient's expired CO_2 reading
5	EtCO_2 alarm limit, high	Indicates the high limit of the expired CO_2 alarm setting
6	EtCO_2 alarm limit, low	Indicates the low limit of the expired CO_2 alarm setting
7	Unit of measure	Indicates the unit type for presentation of the CO_2 numeric data; see Chapter 3, Setups Menu, *page 3-2*
8	Unit of measure	Indicates the unit type for presentation of the respiration data, in respirations per minute (RPM)
9	Respiration alarm limit, high	Indicates the upper respiration alarm limit for the inspired and expired CO_2-derived breath rate
10	Respiration alarm limit, low	Indicates the lower respiration alarm limit for the inspired and expired CO_2-derived breath rate
11	Respiration numeric	Indicates the patient's respiration reading as derived from the CO_2

CO_2 Menu Options

The **CO2** menu allows you to control CO_2 functions and settings. The following options are available:

- SIZE
- GRIDS
- ZERO CAL
- UNIT
- RETURN

To enter the CO_2 menu

Rotate the knob to highlight the CO2 VS box then press the knob.

The following options are available:

WARNING

Verify that the patient's breathing efforts and timing coincide with the displayed CO_2 waveform before completion of the patient setup.

- **SIZE:** Allows you to choose the scale used to display the CO_2 waveform, where the options are 40 (default), 60, or 80 mmHg.
- **GRIDS** (default)**:** Allows you to turn the CO_2 Grids on or off.
- **ZERO CAL:** Causes the system to perform a CO_2 zero calibration routine.
- **UNIT:** Allows you to select the unit of measurement used for presentation of the CO_2 numeric data, where the options are mmHg (default) and kPa.
- **RETURN:** Exits the menu and returns the display to the Normal screen.

Additional Functions

These selections also support additional CO_2 monitoring features (the Cart may contain limited selection and the DCU may contain a full compliment). Press the key described below to open the associated menu:

- **ALARM SETUP key -** See *Setting Alarm Limits*, below.
- **PRINTER SETUP key -** Used to select printer functions; see *Printer Menu Options* on page 12-4.
- **TRENDS key -** Used to setup and print trended information; see *Trending Feature* on page 12-8.

Setting Alarm Limits

CO_2 alarm limits change when the patient type is changed. Alarm limits can be set two ways; see Chapter 13, Alarms Menu Options, page 13-7 for details:

- To set the alarm limits for every available parameter, press the **ALARM SETUP** key.
- To set the alarm limits for CO_2 and/or respiration, turn the knob to the CO2 VS box then press the **ALARM SETUP** key.

Low Flow CO_2 Messages

The following messages could be displayed during CO_2 monitoring.

Message	Probable Cause	Recommended Action
CO2 OCCLUSION	1. A sampling line occlusion has been detected, or 2. The water trap may be full.	1. Check the patient sampling line for any bends, kinks or debris. Replace the line if problems are observed, or 2. Replace the water trap if full. If the message persists, contact Technical Support or authorized service personnel.
CO2: HW FAIL	The CO_2 hardware has failed.	Discontinue CO_2 monitoring and contact Technical Support or authorized service personnel.
CO2 WARMING UP	The CO_2 hardware is warming up for use.	Wait until ready; no action needed.
READJUSTING CO2 ZERO	The CO_2 hardware is performing an automatic zero adjustment.	Wait until ready; no action needed.
CO2: LOW FLOW	The alarm message indicates a low flow condition, usually caused by 1. A missing or wrong type sampling line, or 2. An obstruction in the sampling line, water trap, or exhaust port.	1. Ensure that the proper sampling line (REF 989803152541) is connected to the water trap, or 2. Ensure the sampling line is not kinked and that the water trap and exhaust port are unobstructed.

Chapter 8
Anesthetic Agents Option

The Agents option provides an Anesthetic Gas Sensor (AGS) system that uses infrared spectroscopy combined with digital signal processing to quickly and accurately identify multiple anesthetic agent gases and the concentrations. Additionally, the AGS provides monitoring of carbon dioxide (CO_2), oxygen (O_2) and nitrous oxide (N_2O) concentrations.

WARNING

Whenever a patient is under anesthesia or connected to a ventilator, constant attention by qualified medical personnel is needed.

Operation and Use

When monitoring anesthetic agents and gases, the typical operations and possible conditions that can arise may result in potential messages requiring your attention.

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.**

CO_2 Warm-Up Period

The Anesthetic Gas Sensor (AGS) requires a warm-up period to thermally stabilize to achieve accurate gas identification and measurement. The warm-up period begins when the Agents or the CO_2 vital sign is activated. Then, the AGS will become fully operational according to the following sequence:

1. During the warm-up period, **CO2 WARMING UP** will be displayed, flashing in red and white.
2. Within 45 seconds of activation, the AGS will be able to identify the gases and provide gas concentration information with ISO-level accuracy. Wait during this period, as the vital sign numeric values in the AGENTS, GAS, and CO2 VS boxes will be displayed in the No Data Available state (---).
3. Within 10 minutes of activation, the AGS will be able to operate at full accuracy.

Zero Reference Adjustment

The AGS will occasionally perform a zero reference adjustment, briefly interrupting gas monitoring to take in room air through the reference gas (CO_2 zero intake) port. Zeroing is performed to ensure the accuracy of the displayed gas concentrations, typically take 10–12 seconds, and will occur automatically as needed by the system, where most occur during the warm-up period.

Whenever a zero reference adjustment is being performed, **READJUSTING CO2 ZERO** will be displayed, flashing in red and white.

Once the AGS has become fully operational, zero reference adjustments will occur approximately once every four hours, or whenever the AGS temperature changes by at least ±1°C from the last stored stable temperature.

NOTES

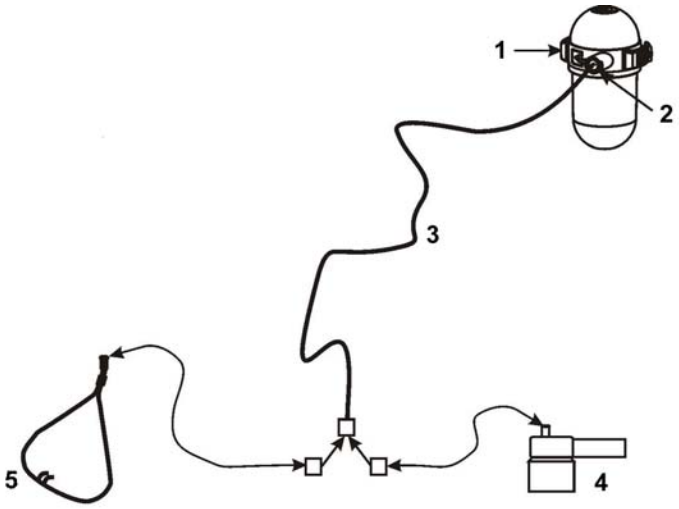
- *Whenever the Agents sensor changes from a steady state condition, the system will perform an zero reference adjustment to restabilize the sensor readings. During this time it is possible for a false identification and concentration value to occur. Change from a steady state condition may occur when:*
  - *Applying a sampling line for the first time.*
  - *Switching from one agent to another.*
  - *Going from high agent concentrations to low or off.*
- *During the first hour after the system has been turned on and flowing oxygen greater than 50 percent, the CO_2 waveform periodically baselines to complete reference measurement; however, the numeric values remain. Once the system reaches ambient temperature this condition will cease to occur.*

A zero reference adjustment can also be completed manually by following the steps below.

Step	Action
1	Turn the knob to highlight the CO2 VS box then press the knob.
2	Turn the knob to GAS CAL then press the knob.
3	Turn the knob to ZERO CAL then press the knob.

Agents Tubing Preparation

The pneumatic circuit used in the AGS system is shown in figure below and consists of the following components.



	Definition
1	Water trap containing a clear sample port inlet,
2	Water trap containing a clear port fitting, and
3	Clear sampling line measuring 15 feet long.
4	Airway adaptor connected to the patient airway, or
5	Nasal cannula connected to a patient airway.

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 Invivo sampling lines and accessories, as other sampling lines will cause inaccurate readings and malfunctions.**
- **Replace the sampling line, replace the airway adapter, and inspect the water trap between each patient use.**

CAUTION

- 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 gas exhaust/waste line for deterioration. Replace the line if needed.

Before using the Agents monitoring feature, ensure that the system is prepared as detailed below.

Step	Action
1	Connect the waste gas port (on the rear panel of the system) to your facility's gas scavenging system using 0.25 inch (6 mm) inside diameter tubing. 
2	Insert the Agents water trap into the water trap receptacle in the Cart. Ensure that the release tabs on each side of the water trap are fully inserted into the receptacle.
3	Connect the sampling line fitting to the trap port.
4	Test the sampling line adapter for a tight connection and proper operation before attaching the system to a patient.
5	Connect the sampling line to the patient.

Pre-Use System Checks

Prior to using the system for Agents monitoring of a patient, the following pre-use checks (to be performed at least once) are recommended.

Step	Action
1	Once the pneumatic tubing has been connected as directed above, turn on the system and activate the Agents vital sign; see Anesthetic Agents and Gas Vital Sign Activation on page 8-8.
2	Ensure that a working oxygen sensor is installed in the unit. If the oxygen sensor is missing or malfunctioning, **AGENT HW FAIL - O2 SENSOR** will be displayed shortly after activation of the Agents vital sign. If this happens, replace the oxygen sensor as described in Chapter 14, Replacing the Oxygen Sensor, page 14-4.

Step	Action
3	Allow the AGS to run and sample room air for at least one minute. The O_2 reading should be 21 percent. If the reading remains outside this range for more than one minute after first checking the reading, replace the oxygen sensor as described in Chapter 14.
4	After allowing the AGS to run for at least one minute, pinch or seal the input line for 5 seconds and verify that **CO2 OCCLUSION** is displayed. If this message does not appear, check all tubing connections for leakage and retest.

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

If questionable anesthetic agent gas measurements are observed, recheck the patient connections, the anesthesia gas machine, and/or the vaporizer before readjusting anesthesia delivery.

Water Trap Replacement

Remove the sampling line from the water trap port and then perform the following steps to replace the water trap.

Step	Action
1	To remove the water trap, simultaneously press both release tabs and pull the water trap from the water trap receptacle; see Chapter 2, Patient Connection Area, page 2-8 for the location.
2	To install the water trap, align it to the water trap receptacle and then press water trap into place until audible “clicks” are heard from both release tabs.
3	Attach the sampling line to the trap port.

WARNINGS

- **Always test sampling line adapter for a tight connection and proper operation before attaching to a patient. Overtightening the sampling line may damage the water trap. Tighten the sampling line no more than one half-turn. Overtightening this connector can cause failure of the water trap assembly and inaccurate patient gas measurements.**
- **Frequently inspect the patient sampling line. Keep the patient sampling line clear of any moving mechanisms which may cut or dislodge the patient tubing. Avoid kinking of the patient sampling line that can cause leaking, reduction, or cut off of the sample gas flow; inaccurate gas measurements could result.**

CAUTION

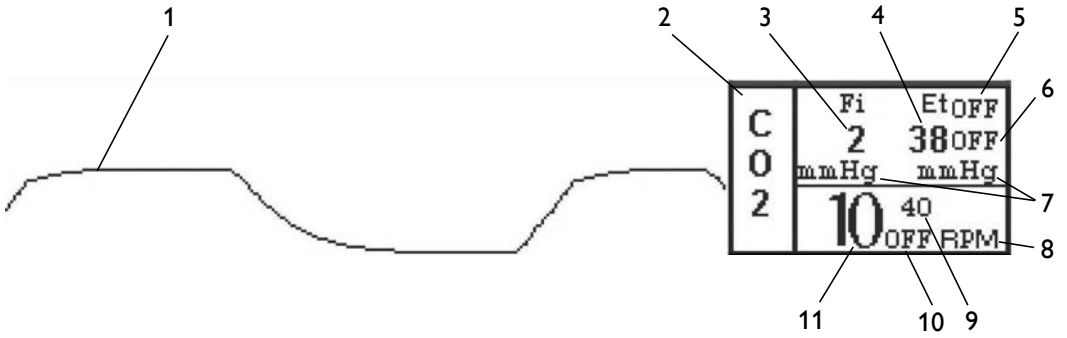
Always discard the water trap when it becomes filled. Do not attempt to clean or reuse the water trap. Accidental water ingress into the system can affect the gas measurements.

NOTES

- *The water trap must be checked every 8 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 specified parts.*

CO2 Waveform and VS Box

Upon activation of the CO_2 vital sign, its associated waveform (Trace D) and VS box will be displayed. The elements contained in the displayed CO_2 information are described below.



	Name	Definition
1	Trace waveform	Is the detected CO_2 waveform
2	Parameter	Indicates the CO_2 parameter
3	FiCO_2 reading	Indicates the patient's inspired CO_2 reading
4	EtCO_2 reading	Indicates the patient's expired CO_2 reading
5	EtCO_2 alarm limit, high	Indicates the high limit of the expired CO_2 alarm setting
6	EtCO_2 alarm limit, low	Indicates the low limit of the expired CO_2 alarm setting
7	Unit of measure	Indicates the selected unit type for presentation of the CO_2 numeric data; see Chapter 3, Setups Menu*, page 3-2*
8	Unit of measure	Indicates the unit type for presentation of the respiration data, in respirations per minute (RPM)
9	Respiration alarm limit, high	Indicates the upper respiration alarm limit for the inspired and expired CO_2-derived breath rate
10	Respiration alarm limit, low	Indicates the lower respiration alarm limit for the inspired and expired CO_2-derived breath rate
11	Respiration numeric	Indicates the patient's respiration reading as derived from the CO_2

CO_2 Menu Options

The **CO2** menu allows you to control CO_2 functions and settings. The following options are available:

- SIZE
- GRIDS
- ZERO CAL
- UNIT
- RETURN

To enter the CO_2 menu

Rotate the knob to highlight the CO2 VS box then press the knob (if the not displayed, refer to Chapter 3, Parameter Selection, page 3-5.)

The following options are available:

WARNING

Verify that the patient's breathing efforts and timing coincide with the displayed CO_2 waveform before completion of the patient setup.

- **SIZE:** Allows you to choose the scale used to display the CO_2 waveform, where the options are 40 (default), 60, or 80 mmHg.
- **GRIDS** (default)**:** Allows you to turn the CO_2 Grids on or off.
- **ZERO CAL:** Causes the system to perform a CO_2 zero calibration routine.
- **UNIT:** Allows you to select the unit of measurement used for presentation of the CO_2 numeric data, where the options are mmHg (default) and kPa.
- **RETURN:** Exits the menu and returns the display to the Normal screen.

Anesthetic Agents and Gas Vital Sign Activation

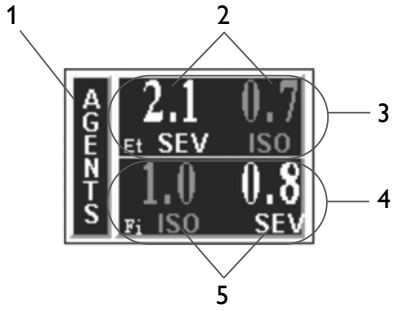
When the anesthetic agents vital sign parameter is activated, the AGENTS and the GAS VS boxes will appear near the bottom of the screen. The CO2 VS box will also be activated (if not already displayed). To activate the Agents vital sign, perform the steps below.

Step	Action
1	Press the **MONITOR SETUP** key.

Step	Action
2	Turn the knob to PARAMETER SELECTION then press the knob.
3	Turn the knob to AGENTS then press the knob.
4	Turn the knob to ON then press the knob.

Anesthetic Agents VS Box

Upon activation of anesthetic agents, the AGENTS VS box will be displayed. The elements contained in the displayed information are described below.



	Name	Definition
1	Parameter	Indicates the Agents vital sign parameter
2	Concentration numeric	Is the concentration of detected expired agent gas(es) in volume percent, rounded to the nearest 0.1 percent
3	Et breath gas	Is the concentration and identification of the anesthetic gas(es) detected in the expired breath phase
4	Fi breath gas	Is the concentration and identification of the anesthetic gas(es) detected in the inspired breath phase
5	Concentration numeric	Is the concentration of detected inspired agent gas(es) in volume percent, rounded to the nearest 0.1 percent

NOTE

These text strings are abbreviations for the specific detected and identified agent gas(es):

- *DES – Desflurane*
- *ENF – Enflurane*
- *HAL – Halothane*
- *ISO – Isoflurane*
- *SEV – Sevoflurane*

No Data Available Indication

Under certain conditions one or more numeric values in the AGENTS VS box may be displayed as a series of 3 dashes (---), indicating no data are currently available. This can happen for any of the following reasons:

- There is currently no communication with the Cart.
- The Agents hardware is warming up.
- The concentration of the anesthetic agent(s) is below the minimum volume percentage detectable by the system.

NOTE

A no gas reading is denoted by a white X in the agent identification area and 3 dashes (---) in the agent values area. With no gas reading when the agent vaporizer is first turned on, it may take 30–90 seconds for agent identification and a 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.

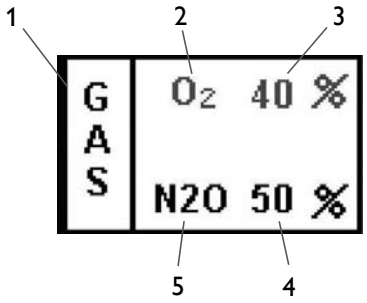
Multiple (Mixed) Agents

A multiple agents condition exists whenever two or more anesthetic agent gases of detectable concentrations are sensed by the AGS system. A multiple agent condition is also considered to exist even when the agent gases in the inspired and expired breath phases are pure but differ from one another.

Whenever a multiple agents condition exists, **MULTIPLE AGENTS** will be displayed, flashing in red and white. It is common 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.

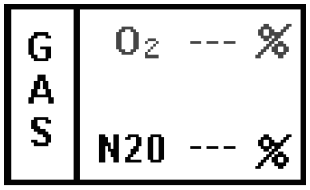
Gas VS Box

The AGS system also monitors the concentrations of O_2 and N_2O. This vital sign information is displayed in the GAS VS box. The elements of the GAS VS box are explained below.



	Name	Definition
1	Parameter	Indicates the Gas vital sign parameter
2	O_2 label	Indicates the corresponding reading for oxygen
3	Percent value	Is the oxygen concentration in percent, the detected average of Fi and Et
4	Percent value	Is the Fi nitrous oxide concentration in percent
5	N2O label	Indicates the corresponding reading for nitrous oxide

No Data Available Indication



Under certain conditions one or more numeric values in the Gas VS box may be displayed as a series of 3 dashes (---), indicating no data are currently available. This can happen for any of the following reasons:

- There is currently no communication with the Cart.
- The Agent hardware is warming up.
- The concentration of O_2 or N_2O is below the minimum volume percentage that is detectable by the system.

Setting Alarm Limits

Alarm limits can be set two ways (see Chapter 13, Alarms Menu Options, page 13-7 for details):

- To set the alarm limits for every available parameter, press the **ALARM SETUP** key. Then select GAS ALARMS.
- To set the alarm limits for Agents only, turn the knob to the AGENTS VS box then press the **ALARM SETUP** key.

NOTE

Some hydrocarbons (for example, acetone and methane) will cause a mixed agents alarm to occur.

MAC Window

The Minimum Alveolar Concentration (MAC) window, shown below, displays the MAC values for the gas that is currently being detected.

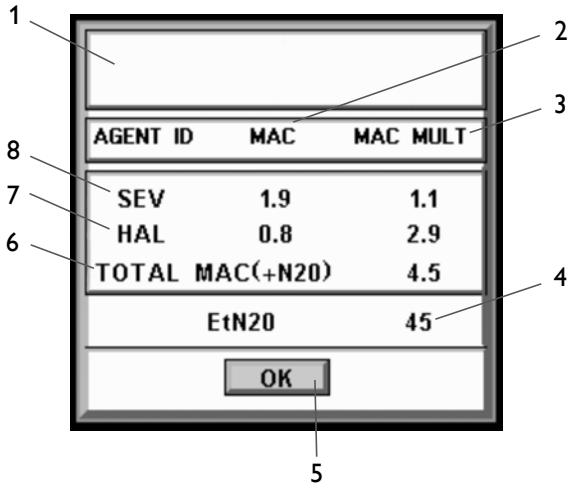
WARNING

MAC values are empirical, not absolute values. The Invivo 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.

The appearance of the MAC window is controlled as follows:

- To activate the MAC window, turn the knob to highlight the AGENTS VS box then press the knob.
- To close the MAC window, press the knob.

The MAC Window contains the information detailed below.



	Name	Definition
1	Note box	Will display **MIXED AGENTS NOT INCLUDED IN MAC CALCULATION** when multiple agents are detected in SINGLE AGENTS MODE is set to in the **SYSTEM CONFIG** menu.
2	MAC	Displays the MAC value of the primary and secondary gases and N_2O currently detected
3	MAC MULT	Displays the multiplier for the corresponding agent value. (The MAC multiplier is defined as the concentration percentage of the agent divided by the MAC value for that agent.)
4	EtN20	Is the nitrous oxide concentration (in percent) detected N_2O in the expired breath phase
5	OK button	Returns the display to the Normal screen
6	TOTAL MAC (+N20)	Is the total MAC value of the primary and secondary gases and N_2O currently detected by the system
7	Agent ID (secondary gas)	Is the Agent ID column which displays the currently detected secondary agent gas
8	Agent ID (primary gas)	Is the Agent ID column which displays the currently detected primary agent gas

MAC Calculation

NOTE

MAC window values are only valid when no more than two agents are present.

The 1 MAC values used for each agent gas are provided in the table below.

Gas	1 MAC Value
DES (Desflurane)	6.00 volume%
ENF (Enflurane)	1.68 volume%
HAL (Halothane)	0.76 volume%
ISO (Isoflurane)	1.12 volume%
SEV (Sevoflurane)	1.92 volume%
N2O (nitrous oxide)	100 percent

The total MAC value is 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 expired 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

Low Flow and Occlusion Conditions

A low flow condition exists whenever the gas flow falls to 10 percent less than the nominal flow for the currently selected patient type, as shown in the table below.

Patient Type	Sample Flow Rate	Flow Rate When Low Flow Declared
Adult	200 ml/min	≤ 180 ml/min
Pediatric	200 ml/min	≤ 180 ml/min
Neonate	150 ml/min	≤ 135 ml/min

Whenever a low flow condition exists, **CO2: LOW FLOW** will be displayed, flashing in red and white. The alarm tone will also sound.

An occlusion condition exists when the AGS hardware has detected that the gas flow has fallen below 40 ml/min for at least 1 second. Whenever an occlusion condition exists, **CO2 OCCLUSION** will be displayed, flashing in red and white. The alarm tone will also sound.

The typical cause of these conditions is due to a pinched or blocked (usually from excessive moisture from patient expiration) sampling line.

Oxygen Sensor Depletion

The oxygen sensor uses galvanic technology and has a limited shelf life, as indicated by the expiration date printed on the packaging and sensor. When installing an oxygen sensor, take note its expiration date and plan accordingly. If the O_2 sensor reaches the point where replacement is necessary, **TURN OFF CO2, REPLACE O2 SENSOR** will be displayed. To replace the sensor, follow the procedure on page 14-4.

Anesthetic Agents Messages

The following messages can be displayed during anesthetic agents and gas monitoring.

Message	Probable Cause	Recommended Action
AGENT HW FAIL – O2 SENSOR	A hardware failure associated with the O_2 sensor has occurred.	Ensure that the O_2 sensor has not become loose or dislodged; if so, tighten it with the O_2 sensor tool. If the message persists, contact Technical Support or authorized service personnel.
TURN OFF CO2, REPLACE O2 SENSOR	The O_2 sensor has expired.	Replace the O_2 sensor; see Chapter 14, Replacing the Oxygen Sensor, page 14-4.
AGENTS MOTOR SPEED ERROR	1) The system is too close to the magnet and Agents operation is impacted. 2) A problem is detected in the Agents hardware.	Move the system away from the magnetic field. If the message persists, contact Technical Support or authorized service personnel.
CO2 OCCLUSION	1) A sampling line occlusion is detected and flow is <40 ml/ min. 2) The water trap may be full of fluid.	1) Check the patient sampling line for any bends, kinks or debris; and, if observed, replace the line. 2) Replace the water trap. If the message persists, contact Technical Support or authorized service personnel.
CO2: HW FAIL	The system CO_2/Agents hardware has failed.	Discontinue use of the CO_2/Agents monitoring and contact Technical Support or authorized service personnel.
CO2: LOW FLOW	1) Sampling line flow is reduced 10 percent from nominal. 2) This message may appear when a sampling line is first connected.	Check the patient sampling line for any bends, kinks or debris; and, if observed, replace the line. If the message persists, contact Technical Support or authorized service personnel.
CO2 WARMING UP	The Agents bench is warming up.	No action needed.
MAGNETIC FIELD TOO HIGH	The system is too close to the magnet and Agents operation is impacted.	Move the system away from the magnetic field. If the message persists, contact Technical Support or authorized service personnel.
MULTIPLE AGENTS	Two or more anesthetic agent gases are detected by the Agents circuit.	No action needed.

Message	Probable Cause	Recommended Action
OCCLUSION WHILE ZEROING: ATTEMPTING TO RESTART	A sample line occlusion was detected by the system at start up.	1) Check the patient sampling line for any bends, kinks or debris; and, if observed, replace the line. 2) Replace the water trap. If the message persists, contact Technical Support or authorized service personnel.
READJUSTING CO2 ZERO	Agent hardware is performing an automatic Zero adjustment	No action needed.
WARNING: Unable to monitor patient airway gases, temporarily move WPU away from magnet	The Agents function is unable to start properly due to the presence of a high magnetic field.	Move the Cart (or PMC) away from the magnetic field. If the message persists, contact Technical Support or authorized service personnel.

Chapter 9
Bellows Respiration

Respiration (RESP) is monitored by detecting abdominal or chest wall movement using a pneumatic bellows system, where the motion of the air inside the bellows modulates a sensor that produces the signal for analysis and calculation of values.

NOTE

The Respiration parameter has no menu options or alarm settings as it is not intended for vital sign monitoring.

Respiration Preparation

Perform the following steps to position the pneumograph on the patient.

Step	Action
1	Place the pneumograph on the patient's upper abdomen or lower chest (whichever expands most during inspiration).
2	While the patient has exhaled, place the velcro strap around the patient's trunk then snuggly secure the pneumograph. **CAUTION** Always apply the pneumograph to the patient before connecting the pneumograph hose to the $wSpO_2$ module. Connecting the hose to the $wSpO_2$ module port prior to applying the pneumograph can result in damage to the $wSpO_2$ module.
3	Connect the hose to the pneumograph port on the $wSpO_2$ module (see Chapter 2, Wireless Modules, page 2-9).
4	Check the status indicator of the module (see Chapter 2, Understanding the Module Status Indicator, page 2-18 for details): • Solid green = Battery power OK/Good communication • Flashing green = Battery power OK/No communication • Solid red = Low battery power/Good communication • Flashing red = Low battery power/No communication

Step	Action
5	Check the RESP VS box for pneumograph function before placing the patient into the MR system. **CAUTION** Avoid excessive bending of the flexible hose, as this will impair detection of respiration.
6	Position the patient in the MR system, while ensuring that the pneumograph hose does not get caught (for example, between the tabletop and the patient support). ***NOTE*** *If the respiratory signal appears to weaken between scans, instruct the patient to breathe more deeply during the scan in order to create more movement at the sensor site.*

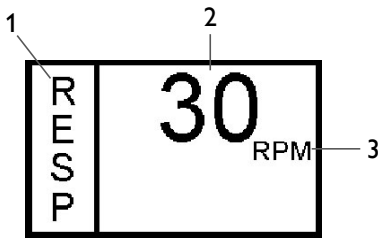
Respiration Activation

To activate the Respiration parameter, perform the steps below.

Step	Action
1	Press the **MONITOR SETUP** key.
2	Turn the knob to PARAMETER SELECTION then press the knob.
3	Turn the knob to RESP then press the knob.
4	Turn the knob to ON then press the knob.

Respiration Box

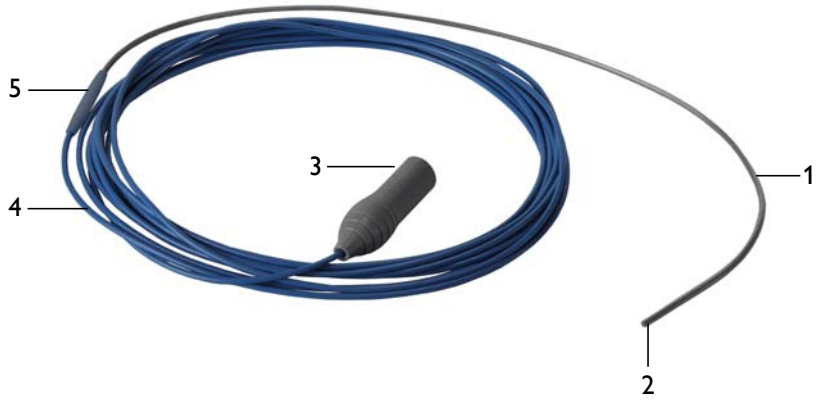
After RESP is turned on in the **PARAMETER SELECTION** menu, the Respiration VS box is displayed near the bottom of the screen. The elements contained in the Respiration VS box are described below.



	Name	Definition
1	Parameter	Identifies respiration parameter
2	Respiration numeric	Indicates the bellows-derived respiration measurement
3	Unit of measure	Indicates the unit type, in respirations per minute (RPM)

Chapter 10
Monitoring Temperature

When the Expression is equipped with the temperature option, the surface or body temperature of a patient can be monitored using a reusable temperature sensor. The major components of the temperature sensor are shown below.



	Description
1	Patient segment (gray portion)
2	Sensing tip
3	Connector
4	Leader (blue portion)
5	Jacket retainer

CAUTION

The sensor is constructed of fiber-optic glass and must always be handled 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).

General Usage Precautions

WARNING

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.

The following general precautions should be observed when using the sensor:

- 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, etc) and always discard a damaged sensor.

Sensor Use

Initial Usage

Always handle the sensor with care. Upon receiving your sensor, thoroughly clean and disinfect the device before using it on a patient; see *Cleaning and Disinfecting the Sensor*, on page 10-7, for details. Afterward, connect the sensor to the Expression.

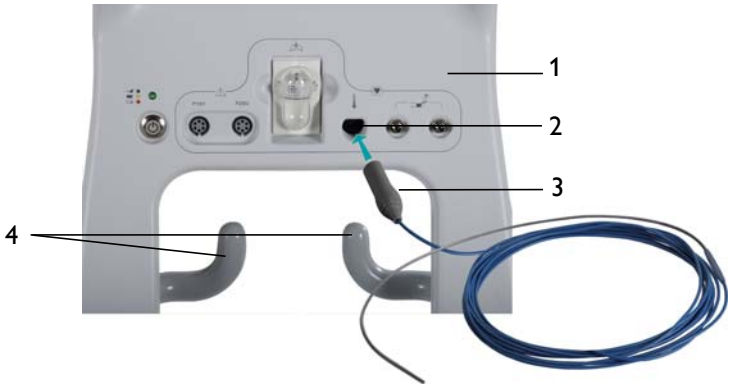
Connecting and Storing the Sensor

CAUTION

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

To connect the sensor

Grasp the sensor connector then align the connector to the temperature sensor receptacle on the Expression (see illustration) and push the connector forward until you feel or hear it click into place. Store the sensor on the Expression, as detailed below.



	Description
1	Expression
2	Temperature sensor receptacle
3	Sensor connector
4	Accessory hooks

To store the sensor

When not in use, loop the sensor and then drape it over an accessory hook.

To disconnect the sensor

Grasp then pull the sensor connector from the temperature sensor receptacle.

Temperature Measurements

Depending upon the monitoring method (surface or body), follow the corresponding procedure below to make a temperature measurement.

NOTES

- *There is a temperature difference between a patient's surface and body temperatures.*
- *On MRI systems, you will witness up to a -0.5°C (-0.9°F) shift in the temperature measurement when the sensor is inside the magnet bore. Confirming changes in a measurement against other vital sign measurements should be standard routine during use.*

Making Surface Temperature Measurements

When making surface temperature measurements, place the 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 and Disinfecting the Sensor*, on page 10-7, 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 *Temperature Menu Options*, on page 10-10, for details.
6	Perform the monitoring procedure, allowing time for the measurement to stabilize; see *Temperature Display Indications,* on page 10-10, 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 10-7).

Making Body Temperature Measurements

FlexTEMP System Jackets are mandatory for use when making endotracheal or endorectal (body) temperature measurements.

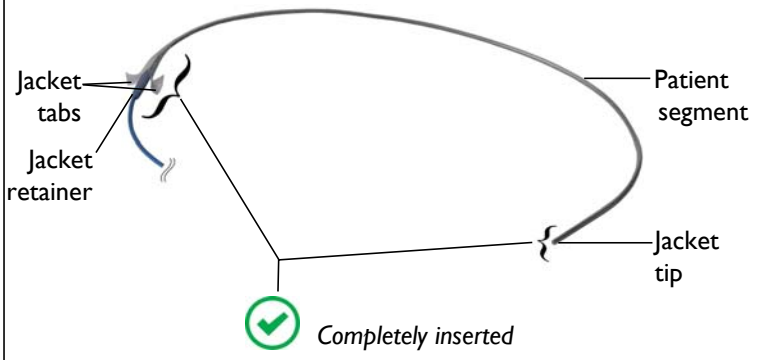
WARNINGS

- **Use of FlexTEMP System Jackets are mandatory when using the sensor for body (i.e., endotracheal or endorectal) 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 endotracheal or endorectal 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 Sensor in a Jacket

FlexTEMP System Jackets are sterile 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. Before making an endotracheal or endorectal temperature measurement, place the sensor in a jacket. 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 sensor, as described in the steps below.

To place the 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 and Disinfecting the Sensor*, on page 10-7, 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.
5	Ensure that the patient segment of the sensor is completely inserted. There should be not 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.

To make body temperature measurements

NOTE

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

Step	Action
1	Ensure that a jacket has been placed on the sensor (see *Placing the Sensor in a Jacket,* on page 10-5).
2	If needed, apply lubricant to the jacket for insertion into the patient. **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.** 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 *Temperature Menu Options*, on page 10-10, for details.
5	Perform the monitoring procedure, allowing time for the measurement to stabilize; see *Temperature Display Indications,* on page 10-10, for details.

Step	Action
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 10-7).

Post-Measurement Processing

After monitoring temperature, process the sensor as follows.

To process the sensor after use

Step	Action
1	If a jacket was placed on the sensor, remove the jacket and any medical tape (if used); see *Disposing of Used Jackets*, on page 10-9, for details.
2	Thoroughly clean and disinfect the sensor; see *Cleaning and Disinfecting the Sensor,* on page 10-7, for details.
3	Store the sensor; see *Connecting and Storing the Sensor*, on page 10-2, for details.

Cleaning and Disinfecting the Sensor

CAUTION

The FlexTEMP System Sensor is sold non-sterile.

Clean and disinfect the sensor before initial use, and then after each use to protect patients and personnel from a variety of pathogens. 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.

NOTE

For answers to questions regarding infection control:

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

To clean and disinfect the sensor

Step	Action
1	Ensure that no jacket is on the sensor.
2	Remove all visible debris from the sensor using soap and water. Never immerse the entire sensor in liquid.
3	Clean the sensor by thoroughly wiping the patient segment of the device using CaviWipes® Disinfectant towelettes for a minimum of 30 seconds. 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 sensor.*
4	Disinfect the sensor by thoroughly wetting the patient segment of the device using CaviWipes® Disinfectant towelettes and allowing the surface to remain wet for 3 minutes. 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 sensor.*
5	Allow the sensor to dry. (No rinsing is required.)
6	Check the sensor for any residual debris. If any debris is present, repeat steps 2 through 5 then re-examine the sensor before proceeding.
7	Check the sensor for damage and discard it if damage is found; see *Inspecting the Sensor for Damage*, on page 10-9, for details.
8	Store the sensor; see *Connecting and Storing the Sensor*, on page 10-2, for details.

Sterilizing

CAUTION

The sensor cannot be sterilized. Severe damage, not covered by the warranty, will result.

Inspecting the Sensor for Damage

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 the sensor, immediately discontinue use of the sensor.

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

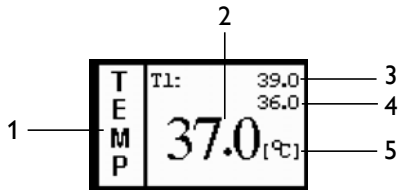
- Cracks, holes, tears, cuts, etc. along the patient segment
- Cracks, holes, cuts, etc on the sensing tip
- Cuts or gouges on the jacket retainer
- Cracks, holes, tears, cuts or other signs of damage to the leader
- Cracks or other signs of damage to the connector, including bent or damaged pins

Disposing of Used Jackets

Refer to your facility's biohazard procedure for disposal of used jackets. Typically, jackets are disposed of as medical waste per facility procedures due to contamination concerns.

Temperature Display Indications

The elements displayed in the TEMP (temperature) vital sign box are described below. For other possible display indications, see *Temperature Messages* on page 10-11.



	Name	Definition
1	Parameter name	Identifies the temperature parameter
2	Temperature numeric	Is the numeric indication of the patient's temperature
3	Temperature alarm limit, high	Indicates the high limit of the temperature alarm setting
4	Temperature alarm limit, low	Indicates the low limit of the temperature alarm setting
5	Unit of measure	Indicates the unit type used for measurement

Temperature Menu Options

The **TEMP** menu allows you to control the unit of measure for the temperature reading.

To enter the TEMP menu

Rotate the rotary knob to highlight the TEMP VS box then press the knob.

NOTE

*If the TEMP VS box is not displayed, activate the parameter: Press the **MONITOR SETUP** key then using the rotary knob, go to **PARAMETER SELECTION** > **TEMP** > **ON** and press the knob.*

The following options are available:

- **UNIT:** Allows you to switch the unit of measurement for temperature between degrees (°) Fahrenheit and degrees Celsius (default).
- **RETURN:** Exits the menu and returns the display to the Normal screen.

Additional Functions

These selections also support additional temperature monitoring features. Press the key described below to open the associated menu:

- **ALARM SETUP key -** See Setting Alarm Limits, below.
- **TRENDS key -** Used to setup and print trended information; see Trending Feature on page 12-8.

Setting Alarm Limits

Alarm limits can be set two ways (see Chapter 13, Alarm Limits, page 13-2 for details):

- To set the alarm limits for every available parameter, press the **ALARM SETUP key**.
- To set the alarm limits for temperature only, turn the knob to the TEMP VS box and press the **ALARM SETUP** key.

Temperature Messages

The following messages could be displayed during temperature monitoring.

NOTE

In event of a temperature system failure, three flashing red dashes (---) will be displayed as the temperature numeric and an alarm will sound. If this occurs, contact Technical Support or authorized service personnel.

Message	Message Location	Probable Cause	Recommended Action
OVR	Displayed in place of the temperature numeric.	The temperature has risen above 44.0°C (111.2°F); or, the sensor, the temperature module or both have become inoperative.	Check the patient's condition. If the message persists, contact Technical Support or authorized service personnel.
UND	Displayed in place of the temperature numeric.	The temperature has fallen below 20.0°C (69.8°F); or, the sensor, the temperature module, or both have become inoperative.	Check the patient's condition. If the message persists, contact Technical Support or authorized service personnel.

Chapter 11
Monitoring Non-Invasive Blood Pressure

The non-invasive blood pressure (NIBP) feature measures and displays systolic, diastolic, and mean arterial pressures, and pulse rate. Low and high alarm limits are available for all three pressures. When the system is configured to obtain the patient's heart rate from the NIBP, the heart rate alarm is also applicable to this parameter. The system can be set to take NIBP readings at automatic intervals, ranging from 1 to 240 minutes or readings can be manually taken. A counter indicates the elapsed time since initiation of the last successful reading cycle and a time until next measurement counter indicates when the next automatic measurement will be made (a manual reading will not restart this cycle time).

WARNINGS

- **Use clinical judgment to decide whether to perform a repeated series of NIBP measurements, such as with NIBP STAT mode, because of the risk of purpura, ischemia and neuropathy in the limb with the cuff.**
- **Arrhythmias, erratic heart beats, 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.**

CAUTIONS

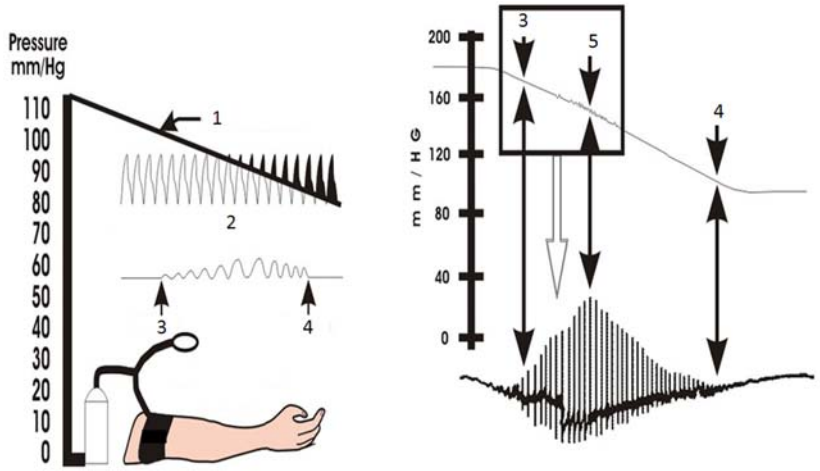
- Substitution of components different from those supplied can result in measurement errors.
- NIBP accuracy has not been verified in the presence of some common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation.

NOTES

- *When using NIBP to measure blood pressure, remember that the patient's readings are not continuous but are updated each time a blood pressure measurement is taken by the system. When necessary, set a shorter interval for more frequent updating of the patient's blood pressure.*
- *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.*
- *If NIBP circuitry errors are detected, an NIBP message will preclude the determination of blood pressure.*

Theory of Oscillometric Measurement

This system obtains blood pressure measurements based on the oscillometric principle. In basic terms, oscillometric monitors use a pressure transducer that is connected to the cuff via a hose. The transducer transforms the oscillations induced into the cuff pressure by the movement of the arterial wall into electrical currents that are measured and correlated to determine arterial blood pressure. The description below details the oscillometric measurement method.



a. As the occlusive cuff is inflated to a suprasystolic pressure, the artery is occluded so that no blood can pass. At this point, there are small pulsations induced into the cuff pressure by the partially-occluded proximal portion of the artery lying under the cuff.

b. As cuff pressure (1, above) is reduced to just below the systolic pressure, the peak of the systolic pressure wave (3, above) forces the occluded artery open, and the blood surges through the artery and the amplitude of the oscillations (2, above) increases sharply. This is the systolic pressure.

c. With further reductions in cuff pressure, the artery opens for a longer time during each cardiac cycle, which causes increasingly larger oscillations in the cuff pressure until they reach a point of maximum oscillation amplitude. This point of maximum oscillations has been well demonstrated to be mean arterial pressure (5, above).

NOTE

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 this reason it is advisable to keep the cuff air volume to a minimum by using the smallest cuff size possible for each patient.

d. With continued cuff pressure reductions, the underlying artery is open throughout the cardiac cycle, and the arterial wall movement is less. The cuff pressure oscillations begin to decrease in amplitude until they become uniform. The point at which the amplitudes become uniform is diastolic pressure (4, above).

NIBP Patient and Cuff Preparation

WARNING

The patient must remain calm and motionless while the system is being used. If the patient is overactive, prolonged or inaccurate readings will result.

Selecting the Cuff

The cuff should be selected and positioned as it would be for an auscultatory blood pressure determination, and 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:

- For a correct disposable cuff fit on adult and pediatric patients, the index line at the end of the cuff must fall between the two range lines printed on the cuff.
- For correct cuff fit on neonatal patients, choose a size with the stated circumference range that fits the circumference of the limb of the neonate.

WARNING

To ensure accurate reliable measurements, use only recommended patient cuffs/hoses (see Chapter 1, Accessories, page 1-3). Use the appropriate cuff size for each patient, as recommended by the current American Heart Association guidelines for blood pressure monitoring, to ensure safety and accuracy.

Positioning the Cuff

Wrap the cuff firmly (but not snug) around the arm or leg of the patient. If the cuff is not at heart or leg level, add 1.8 mmHg to the displayed readings for each inch (2.54 cm) that the center of the cuff is located above the patient's heart level. Subtract 1.8 mmHg from the displayed readings for each inch (2.54 cm) that the cuff is located below the patient's heart level.

WARNING

Avoid compression or restriction of NIBP cuff hose. Do not use the NIBP cuff on a limb with an intravenous infusion or arterial catheter in place. This could cause tissue damage around the catheter when the infusion is slowed or blocked during cuff inflation.

Connecting the Cuff

Select the proper hose (twin-lumen for adults and pediatrics, single-lumen for neonates). Attach the hose to the cuff. Route the hose from the cuff to the patient connection area on the Cart (or PMC) in a manner that does not kink or tangle the hose, or limit access to the patient.

WARNING

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

NIBP VS Box

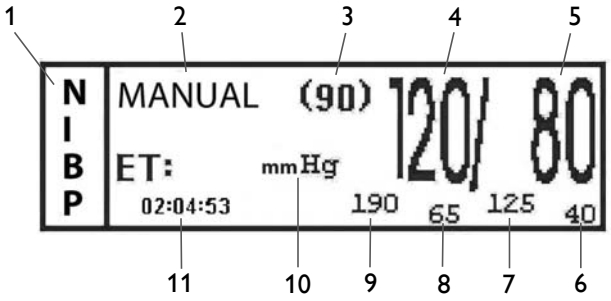
Upon activation of non-invasive blood pressure, the NIBP VS box will be displayed. Depending upon the selected format (SYS/DIA or Mean) of the NIBP display, the elements contained in the displayed NIBP information will vary as described below.

NOTE

Visually checking the patient, checking other vital signs, and checking the limb where the cuff is attached must be standard routines with NIBP use.

NIBP Systolic/Diastolic Display

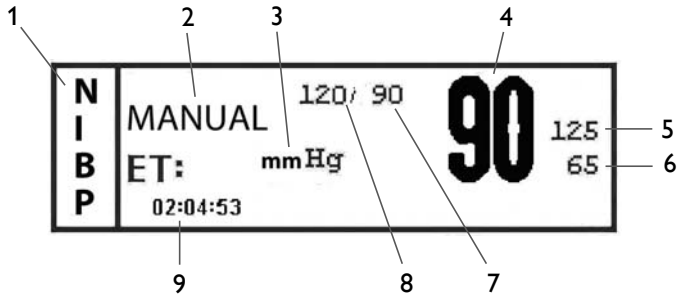
The elements contained when the SYS/DIA format is selected for the NIBP VS box are described below.



	Name	Definition
1	Parameter	Identifies the NIBP parameter
2	Mode indication	Indicates the mode: • If in auto mode, then **NEXT** and the time until the next measurement is displayed; or, • If in manual mode, then **MANUAL** is displayed ***NOTE*** *If a problem occurs, NIBP messages will be displayed in place of the next measurement or the MANUAL fields.*
3	Mean numeric	Indicates the patient's mean pressure reading
4	Systolic numeric	Indicates the patient's systolic pressure reading
5	Diastolic numeric	Indicates the patient's diastolic pressure reading
6	Diastolic alarm limit, low	Indicates the low limit setting of the diastolic alarm
7	Diastolic alarm limit, high	Indicates the high limit setting of the diastolic alarm
8	Systolic alarm limit, low	Indicates the low limit setting of the systolic alarm
9	Systolic alarm limit, high	Indicates the high limit setting of the systolic alarm
10	Unit of measure	Indicates the unit type used for measurement
11	Elapsed time	Indicates the time since the last NIBP determination; and, during NIBP measurement, this displays the cuff pressure.

NIBP Mean Display

The elements contained when the Mean format is selected for the NIBP VS box are described below.

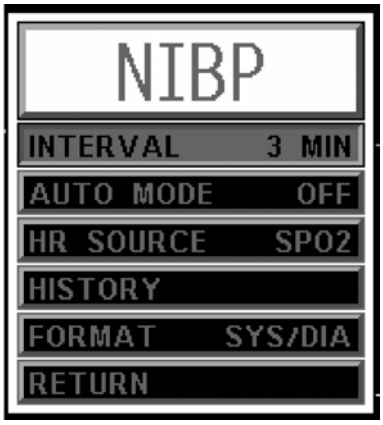


	Name	Definition
1	Parameter	Identifies the NIBP vital sign parameter
2	Mode indication	Identifies the mode: • If in auto mode, then **NEXT** and the time until the next measurement is displayed; or, • If in manual mode, then **MANUAL** is displayed. ***NOTE*** *If a problem occurs, NIBP messages will be displayed in place of the next measurement or the **MANUAL** fields.*
3	Unit of measurement	Indicates the unit type used for measurement
4	Mean numeric	Is the patient's mean pressure reading
5	Mean alarm limit, high	Is the high limit setting of the mean alarm
6	Mean alarm limit, low	Is the low limit setting of the mean alarm
7	Diastolic numeric	Is the patient's diastolic pressure reading
8	Systolic numeric	Is the patient's systolic pressure reading
9	Elapsed time	Indicates the time since the last NIBP determination; and, during NIBP measurement, this displays the cuff pressure.

NIBP Menu Options

The **NIBP** menu allows you to control NIBP functions and settings. The following options are available:

- INTERVAL
- AUTO MODE
- HR SOURCE
- HISTORY
- FORMAT
- RETURN



To enter the NIBP menu

Rotate the knob to highlight the NIBP VS box then press the knob.

The following options are available:

- **INTERVAL:** Sets the automatic measurement interval (also accessible by pressing the **NIBP INTERVAL** key), where the options are 1, 2, 2.5, 3 (default), 5, 10, 15, 20, 30 or 45 minutes, and 1, 2 or 4 hours.
- **AUTO MODE:** Sets the way that NIBP readings are initiated.
  - **ON** selects automatic reading intervals. When switched from off to on, the first reading must be initiated by pressing the **NIBP START/STOP** key then all subsequent readings will be taken automatically at the selected interval. The systolic, diastolic, and mean blood pressure values are displayed with measurement information such as the elapsed time (ET) since the last measurement and the time until the next measurement.
  - **OFF** (default) selects readings to be initiated by pressing the **NIBP START/STOP** key. **MANUAL** will be displayed in the NIBP VS box. A reading cycle may be stopped at any time by pressing the key again or by pressing the **STANDBY** key.

NOTE

NIBP AUTO MODE is suspended while the system is in STANDBY mode.

- **HR SOURCE:** Allows you to select the vital sign source used to produce the heart rate displayed in the ECG VS box. (This is identical to and interactive with the same option in the **ECG**, **SPO2**, and **P1**/**P2** menus.) The following options are available:
  - **AUTO** automatically selects the HR source from the highest priority active input, and the system searches for another source for rate only when Lead Fail occurs or when the ECG parameter is turned off. The priority ranking (highest to lowest) is ECG, ART (P1 or P2), SpO_2, and then NIBP. The system examines the highest priority active input. If not found, it will go to the next highest priority parameter. If none of the

parameters are presenting a heart rate and NIBP is off, then NONE is displayed in the heart rate position.

  - **ECG** (default) selects the electrocardiogram for the HR source.
  - **ART** selects one of the invasive pressure channels for the HR source. P1 or P2 must be displayed and labeled as ART for this option to be selected; see Chapter 6, IBP Menu Options, page 6-3.
  - **SPO2** selects SpO_2 for the HR source.
  - **NIBP** selects NIBP for the HR source.
  - **RETURN** closes the menu.

- **HISTORY:** Displays the last 48 NIBP readings with the time, heart rate, SpO_2, CO_2 and respiration values in a tabular form (6 per page). This data is retained in non-volatile memory, protected in the event of a power loss.
- **FORMAT:** Allows you to change the displayed format of the pressure numerics. The following options are available:
  - **SYS/DIA** (default) displays the systolic and diastolic numerics in large font separated by a slash, and the mean numeric will be in a smaller font bracketed with parenthesis.
  - **MEAN** displays the mean numeric in large font, and the systolic and diastolic numerics will be in a smaller font and separated by a slash.
- **RETURN:** Exits the menu and returns the display to the Normal screen.

NIBP Adult, Pediatric and Neonatal Operations

The system allows you to determine pressures for a wide range of patients using the **PATIENT** menu; see Chapter 3, Setups Menu Options, page 3-2.

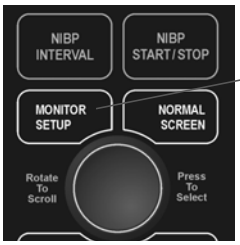
- The ADULT option is used for most adult patients.
- The NEO option is used for most neonatal patients
- The PEDIATRIC option is used for any patient exhibiting low pulse amplitudes (a condition exhibited by most patients of pediatric size).

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, cuff size or measurement technique. The clinical decision shall be based on all of the factors listed in Chapter 3, Determining the Patient Type, page 3-7, to ensure the best possible and most timely NIBP measurement acquisition.

To change the patient type:

Press the **MONITOR SETUP** key then turn the knob to PATIENT and press the knob. Next, turn the knob to the desired patient type (Adult, Pediatric, or Neonatal) then press the knob.



WARNING

The cuff inflation rate increases and the initial pressure increases up to 170 mmHg when changing the patient type.

NOTES

- *ADULT and PEDIATRIC use a higher pump volume, while NEO uses a lower pump volume.*
- *ADULT and PEDIATRIC dictate use of a larger cuff circumference, while NEO requires a smaller cuff circumference.*

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

For more information, refer to Accessories in Chapter 1 for cuff patient type, and refer to Appendix A for specifications of maximum pump volume and initial cuff inflation.

Additional Functions

These 3 selections also support additional NIBP monitoring features. Press the key described below to open the associated menu:

- **ALARM SETUP key -** See *Setting Alarm Limits*, below.
- **PRINTER SETUP key -** Used to select printer functions; see *Printer Menu Options* on page 12-4.
- **TRENDS key -** Used to setup and print trended information; see *Trending Feature* on page 12-8.

Setting Alarm Limits

Alarm limits can be set two ways (see Chapter 13, Alarms Menu Options, page 13-7 for details):

- To set the alarm limits for every available parameter, press the **ALARM SETUP** key.
- To set the alarm limits for NIBP only, turn the knob to the NIBP VS box then press the **ALARM SETUP** key.

Controlling the Reading Cycle

Auto Mode

Multiple methods are available to control the automatic reading cycle.

The **NIBP INTERVAL** key can be pressed for immediate access to the automatic cycle time options (see page 11-7). Turn the knob to the desired cycle time then press the knob.

Alternately, the NIBP VS box can be used to access the cycle time options as detailed below,

Step	Action
1	Turn the knob to highlight the NIBP VS box then press the knob.
2	Turn the knob to INTERVAL then press the knob.
3	Turn the knob to the desired cycle time then press the knob.

NOTE

*Once AUTO MODE is set to on, press the **NIBP START/STOP** key to begin the measurements.*

Manual Mode

When using NIBP in manual mode, control the NIBP cycle intervals by pressing the **NIBP START/ STOP** key or the **STANDBY** key.

NIBP Messages

NOTE

NIBP error messages are displayed inside the VS box.

The following messages may be displayed during NIBP monitoring.

Message	Probable Cause	Recommended Action
CALIB	This message is displayed if a pressure offset is detected in the NIBP system when a new measurement is initiated. The message may take up to 25 seconds to be displayed. An offset can be caused by the following conditions: • 1) Existing pressure in the system; or, • 2) NIBP hardware is uncalibrated.	1) Verify the hose and cuff are totally deflated before initiating a new NIBP measurement. 2) If the message is still displayed, then disconnect the hose from the system and start a new reading. If the message is still displayed with the hoses disconnected, then contact Technical Support or authorized service personnel.
CHANGE NIBP CUFF	This message is displayed for 30 seconds whenever the patient type is switched as a reminder to use the proper cuff.	No action needed.
CUFF LEAK	1) A leak in the cuff or hose was detected; or, 2) Too much patient movement is causing excessive pressure changes to the cuff during the measurement.	1) Check the cuff and hoses for leaks. 2) Make sure the hose fittings are tight. 3) Try to minimize patient movement during the measurement. For assistance, contact Technical Support or authorized service personnel.
CUFF=XXX	Displays the cuff pressure during the NIBP determination.	No action needed.
ET=XXX	Displays the elapsed time since the last NIBP measurement was completed.	No action needed.
HW FAIL	NIBP hardware failure or another fatal error has occurred.	If the failure persists, immediately remove the system from service and contact Invivo for repair, as the system must not be used on any patient requiring NIBP measurement.

Message	Probable Cause	Recommended Action
LONG PRESS	1) Displayed when cuff pressure remains the same during a measurement for more than 30 seconds; or, 2) Displayed if a measurement has been in progress for more than 150 seconds for Adult / Pediatric, or 80 seconds for Neo.	1) Verify there are no kinks or obstructions in the cuff and hoses. 2) If the LONG PRESS message is displayed at the upper time limit, it usually means the system is having difficulty making the measurement. Ensure the selected patient type is appropriate for the patient and the cuff. Also, ensure that the cuff is well fitted and properly placed and try to minimize patient movement during the measurement.
NOT INFLATING	Displayed if the cuff inflation cycle is longer than 30 seconds for Adult / Pediatric or 6 seconds in Neo	1) Ensure that the proper cuff size is being used for the selected patient type. 2) Make sure the hose fittings are tight. 3) Make sure there are no leaks in the cuff or hoses. For assistance contact Technical Support or authorized service personnel.
OVER PRES	Displayed if the cuff pressure exceeds 285 mmHg for Adult / Pediatric mode, or 150 mmHg for Neo mode, and can be caused by the following: 1) A hose restriction or wrong cuff size. 2) The patient is shifting their weight onto the cuff when the cuff pressure is near the upper limit.	1) Ensure that the proper cuff size is being used for the selected patient type. 2) Try to minimize patient movement during the measurement. For assistance, contact Technical Support or authorized service personnel.
RESIDUAL PRES	Displayed if the NIBP system detects that cuff pressure remains above 20 mmHg for more than 150 seconds.	Check the NIBP hose and cuff hoses for kinks or obstructions that could restrict the cuff from deflating.
WRONG CUFF	Displayed if the NIBP system detects that an incorrect cuff is being used for the selected patient type.	Select the appropriate patient type and use the correct cuff size for the patient.

Chapter 12
Printing, Trending, and Exporting Data

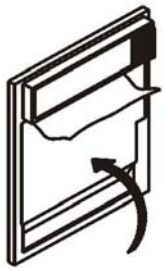
When equipped with a printer, the DCU can output hard copies of patient monitoring information, including waveforms and data captures for a single point in time. The DCU can also export the parameter data stream to a computer for patient record management.

Loading Paper

To print charts or trend data, the printer must be enabled (see Chapter 3, Service(Bio-Med), page 3-13) and loaded with paper.

To load paper, perform the steps below.

Step	Action
1	On the DCU, press the button on the printer to open the printer door. 
2	Remove the old paper roll. 
3	Place the paper into the holder, with the leader oriented as shown. 
4	Pull out approximately 2 inches (50 mm) of leader from the roll. 

Step	Action
5	Close the printer door. 
6	Tear off any excess paper. 

Printing Charts

The system prints four format types:

- Strip charts
- Tabular charts
- Trend charts
- Data reports

NOTE

*A SWEEP SPEED setting (in the **PRINTER** menu) of 25 mm/second presents the most printed data.*

Controlling Printer Outputs

The **PRINT** key starts and stops the printing process. If the printer is left running, it will continue to output paper for approximately 30 seconds before automatically stopping.

PRINT key

Printer Menu Options

The **PRINTER** menu allows you to control printing functions and settings. The following options are available:

- TRACE 1
- TRACE 2
- TRACE DELAY
- PRINT DATA REPORT
- PRINT NIBP REPORT
- CLEAR ALL
- DATA INTERVAL
- OFF/AUTO/RUN
- AUTO STRIP
- AUTO RUN TIME
- SWEEP SPEED
- ECG TEST SIGNAL
- RETURN

To enter the PRINTER menu

Press the **PRINTER SETUP** key.

PRINTER SETUP key

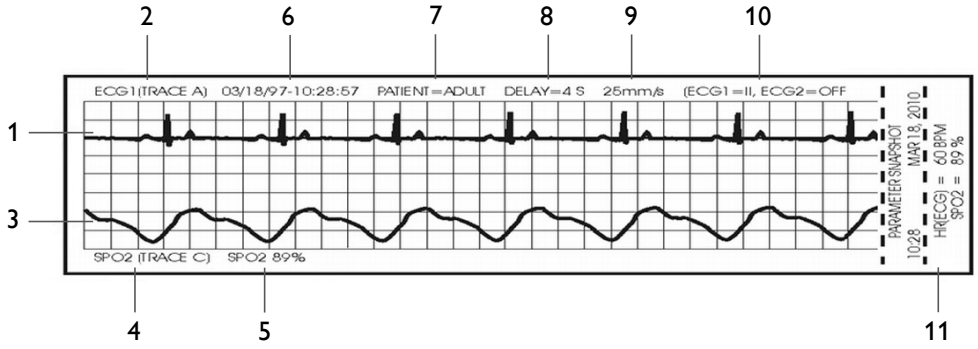
NOTE

PRINTER OPTION NOT INSTALLED *will be displayed if the printer is not enabled or configured; see* Chapter 3, Service(Bio-Med), page 3-13 *for details.*

The following printing options are available:

- **TRACE 1:** Enables the first trace that is output to the printer. The options (depending on installed parameters) are as follows:
  - **ECG1** (default)
  - **ECG2**
  - **P1**
  - **P2**
  - **SPO2**
  - **RESP (CO_2)**
  - **RETURN**

  Elements in the printout are detailed below.



	Definition
1	Trace 1
2	Trace 1 parameter
3	Trace 2
4	Trace 2 parameter
5	Trace 2 parameter information
6	Date and time (MM/DD/YY-HH:MM:SS)
7	Patient type
8	Trace delay
9	Trace speed
10	Parameter information
11	Current values of active parameters at the moment of print

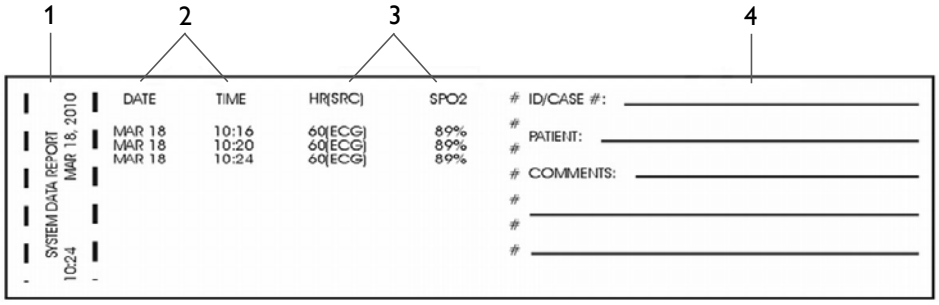
- **TRACE 2:** Enables a second trace to be output to the printer (see example above) from the following options (depending on installed parameters):
  - **OFF** (default)
  - **ECG1**
  - **ECG2**

- **P1**
- **P2**
- **SPO2**
- **RESP (CO_2)**
- **RETURN**

NOTE

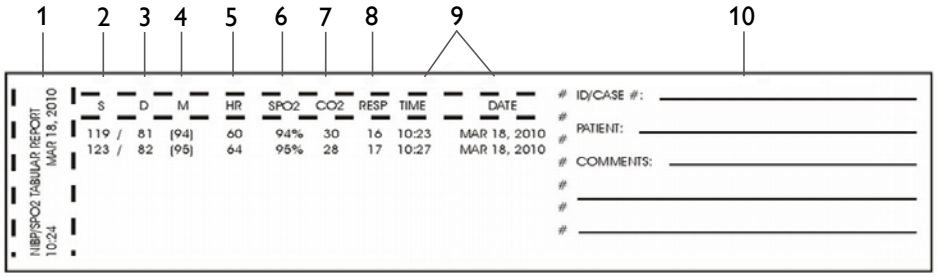
If Trace 2 is off, Trace 1 is printed using the full 40 mm width of the paper.

- **TRACE DELAY:** Sets a time delay for the trace data being sent to the printer. The options are 0, 4 (default), 8, and 16 seconds.
- **PRINT DATA REPORT:** Prints a system data report of up to 60 stored patient parameter readings governed by the time preselected in the DATA INTERVAL option. Only those parameters which have been turned on will be printed. If a parameter is off during any portion of the data storage period, ---/--- is printed in place of a value. Elements in the report are detailed in the example below.



	Definition
1	Chart type with time and date of printout
2	Date and time of determination (MMM/DD and HH:MM)
3	Parameter values
4	Patient information

- **PRINT NIBP REPORT:** Prints a report of the last 48 readings for NIBP, heart rate, SpO_2, CO_2 and respiration in tabular form (6 per page). The system stores the data until cleared; however, new readings will overwrite older readings when the total exceeds 48. Cycling the system's power has no effect on stored data in the NIBP history file. Elements in the report are detailed in the example below.



	Definition
1	Chart type with time and date of printout
2	Systolic NIBP
3	Diastolic NIBP
4	Mean NIBP
5	Heart rate
6	SpO_2
7	CO_2
8	Respiration
9	Time and date of determinations (HH:MM and MM/DD/YYYY)
10	Patient information

- **CLEAR ALL:** Allows you to erase all data stored for the data reports in the system. (A YES/NO prompt must be answered before the data erased.)
- **DATA INTERVAL:** Allows the data interval to be set from 1 to 60 minutes, which dictates the number of patient parameter readings printed in the report (as activated by selecting PRINT DATA REPORT, above). The options are 1 through 10 (4 is default), 12, 15, 18, 24, 30, and 60. The first data stored occurs when the system is turned on or 2 seconds after a new interval is selected.
- **OFF/AUTO/RUN:** Allows the printer to be toggled between modes, where:
  - **OFF** (default) switches Auto mode off, where the printer can be activated by pressing the **PRINT** key.
  - **AUTO** automatically activates the printer and writes ECG Trace A when a violation of an alarm limit for HR, P1, P2, NIBP, CO_2, SpO_2, or temperature occurs. In addition, a second trace will be written below when the parameter is in a trace location. The priority of the second trace record is RESP(CO_2). SpO_2 is written as the second trace record when its alarm limit is violated and it is the only other parameter in the trace location. The printing continues for 20 seconds or until the printer is deactivated by pressing the **PRINT** key or by changing the AUTO mode to off.
  - **RUN** activates the printer, which prints the selected traces.
  - **RETURN** closes the menu.

- **AUTO STRIP:** Allows you to control the automatic report feature of the printer:
  - **DISABLED** (default) turns the automatic report feature off.
  - **ENABLED** turns the automatic report feature on.
  - **RETURN** closes the menu.
- **AUTO RUN TIME:** Allows you to select the automatic strip run time. The options are 8, 12 (default), 16, 20, and 30 seconds.
- **SWEEP SPEED:** Switches the printer and the display trace speed between 25 mm/second (default) and 50 mm/second.
- **ECG TEST SIGNAL:** Selects the ECG Test Signal and is identical to and interactive with the same option in the **ECG** menu, where:
  - **OFF** (default) turns the ECG Test Signal feature off.
  - **PRINTER** applies a 1 mV calibration pulse to the ECG waveform. **ECG TEST SIGNAL** is superimposed over the displayed ECG waveform and if the printer is configured to print the ECG waveform, the calibration pulse can be printed.
  - **ECG** sends (from the wECG module) a hardware-generated 1 mV peak-to-peak calibration signal to the ECG vital sign and to the printer for the ECG waveform (if configured), where the message **ECG TEST SIGNAL** is superimposed.
  - **RETURN** closes the menu.
- **RETURN:** Exits the menu and returns the display to the Normal screen.

Trending Feature

The trend feature may be operated to graph individual or multiple trends. The system automatically stores trend information for heart rate, NIBP, SpO_2, P1/P2, $EtCO_2$, respiration (CO_2) and temperature.

NOTE

During trend or graph printing, recognition of a pressed key or knob will not occur until printing completion (approximately 30 seconds). To cancel printing and restore use, open the printer door.

History Menu Options

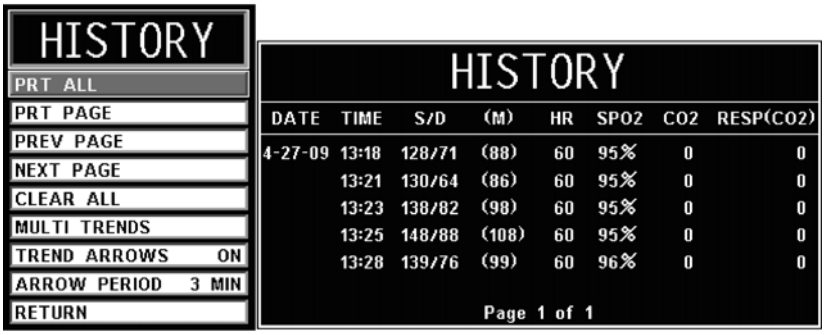
The **TRENDS** key function is conditional:

TRENDS key

- Pressing the **TRENDS** key while in the Normal screen will open the **HISTORY** menu, providing the option to move through the pages and print all or part of the file.
- Pressing TRENDS while any patient parameter is highlighted will open the **TRENDS** menu for that parameter.

To enter the HISTORY menu

Press the **TRENDS** key (while in the Normal screen).



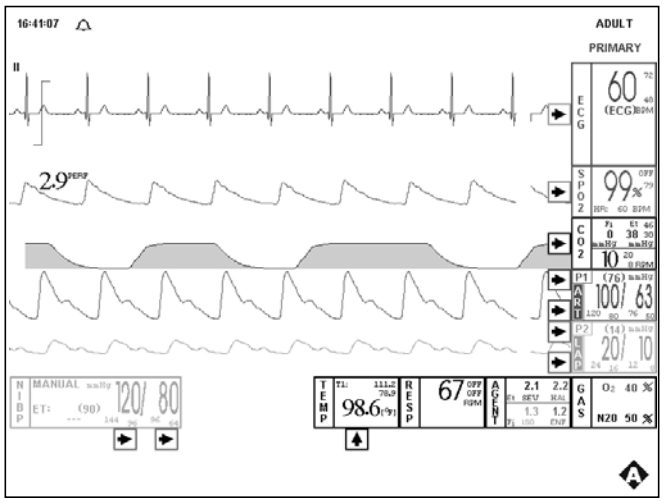
The following options are available:

- **PRT ALL:** Prints a complete history file.
- **PRT PAGE:** Prints the currently displayed history file page.
- **PREV PAGE:** Displays the previous page of the history file.
- **NEXT PAGE:** Displays the next page of the history file.
- **CLEAR ALL:** Clears all data from the history file. History data is retained when a new patient is connected to the system. Therefore, to avoid confusion, all previously acquired data should be cleared prior to connection of a new patient.
- **MULTI TRENDS:** Displays the **MULTI TRENDS** menu (see page 12-11).
- **TREND ARROWS:** Displays a visual depiction of the trend of the vital sign, where a directional arrow indicates a rising, declining, or stable vital sign.

Vital Sign Trend Meaning	Trend Arrow
Rising	↑
Declining	↓

Vital Sign Trend Meaning	Trend Arrow
Stable	→
None declared	---

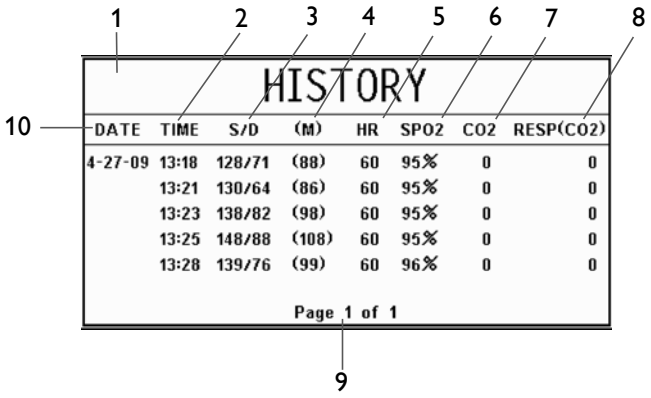
A sample screen with TREND ARROWS enabled is shown below.



- **ARROW PERIOD:** Is the time (30 seconds, and 1, 3 [default], 5, or 10 minutes) that must lapse before a display change occurs in trend arrows.
- **RETURN:** Exits the menu and returns the display to the Normal screen.

History File Page

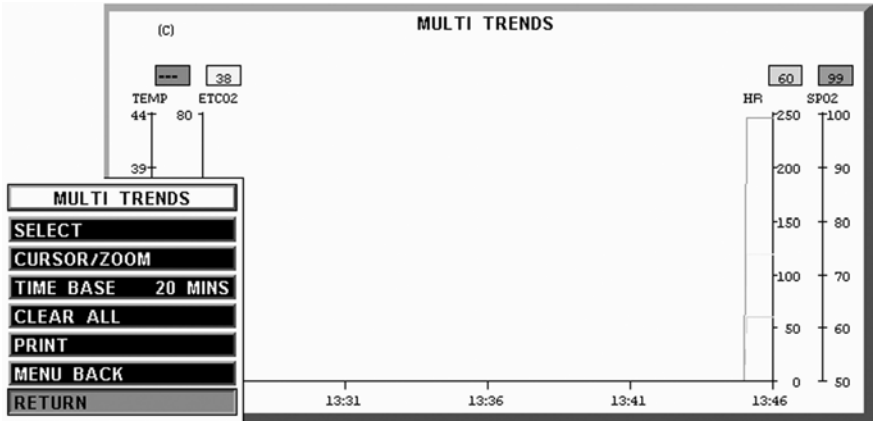
The **HISTORY** menu includes a history file page (displayed alongside the menu) of a patient's NIBP determinations. The elements contained in a history file page are described below.



	Name	Definition
1	Page title	Identifies the history file page
2	Time	Identifies the time of the reading
3	S/D	Identifies the NIBP systolic/diastolic reading
4	(M)	Identifies the NIBP mean reading
5	HR	Identifies the heart rate
6	SPO2	Identifies the SpO_2 reading
7	CO2	Identifies the CO_2 reading
8	RESP(CO2)	Identifies the respiration source and rate
9	Page	Indicates the page number and total pages
10	Date	Identifies the date of the readings

Multi Trends Menu

The **MULTI TRENDS** menu displays a graphical representation (see the example below) of selected parameters.



The following options are available:

- **SELECT:** Allows you to configure up to 4 simultaneous trends, which are plotted on the same graph with respect to time, from among the following options:
  - **HR**
  - **NIBP**
  - **P1**
  - **P2**
  - **SPO2**
  - **ETCO2**
  - **RESP[CO2]**

  - **TEMP[T1]**
  - **RETURN**

- **CURSOR/ZOOM:** Zooms into the trend chart, opening a 20-minute wide window where individual points in time can be measured. (To exit this feature, turn the knob until the vertical line is as far to the right as possible then press the knob.)
- **TIME BASE:** Allows you to set the time axis intervals of 20 minutes (default), 2 hours, 4 hours, 8 hours, and 24 hours.
- **CLEAR ALL:** Clears all data from the trend history (also see *Clearing Trend Data*, below).
- **PRINT:** Prints a trend chart that includes the currently selected trend.
- **MENU BACK:** Moves the **MULTI TRENDS** menu behind the graph.
- **RETURN:** Exits the menu and returns the display to the Normal screen.

Parameter Specific Trend Charts

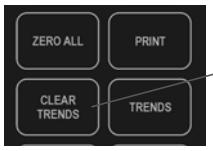
Trend charts can be printed for every parameter except Respiration and Agents. Trends are stored in memory that is not saved when the system is turned off. A loss in power will result in a loss of trend data.

To print a parameter trend chart

Turn the knob to the desired parameter and then press TRENDS and select PRINT.

Clearing Trend Data

The **CLEAR TRENDS** key allows you to clear all stored data without opening a **TRENDS** menu.



CLEAR TRENDS key

To clear stored trended data

Press the **CLEAR TRENDS** key.

Exporting Data

The data stream from the monitor is output from the DB9 receptacle (COM6/COM2) located behind the rear access panel of the DCU.


DCU RS232 port

Connect an null serial communications cable to interface the DCU with your computer system. The serial data output of the DCU uses the following protocol:

9600 Baud, 8 data bits, no parity, and 1 stop bit, no flow control

All data values, whether textual or numeric, are in the ASCII character format. Each data item is separated from the next by a comma and contains no extraneous spaces. Data output items are in the order, format and units as given in the table below. Each of the items in the table are sent as a single record at the rate of once per second (1 Hz).

Values with selectable units (such as kPa or mmHg) are sent in the currently selected units. Nonnumeric data is sent as it appears on the DCU, untrimmed of leading or trailing spaces. Unless noted, numeric data that is output have the same format and value as that displayed on the DCU.

Different formats can be selected through the **SYSTEM CONFIG** menu. The difference between the INVIVO format and the OVR-UND format is primarily in the way that over and under conditions are handled:

- The INVIVO format prints one number outside of the maximum or minimum number in the range when the display shows OVR and UND. If the parameter has no value to display (indicated as 3 dashes [---] in the VS box) or when the parameter is turned off or not installed, the output will be 0 for the value (0.0 for those with floating points).
- The OVR-UND format prints an O after the upper range value and a U after the lower range value when the display show OVER or UND. If the parameter has no value to display (indicated as 3 dashes [---] in the VS box) or when the parameter is turned off or not installed, the output will be a dash (-) for that value.

Data Output Format				
	Definition	**Format**	**Units**	**Notes**
1	Date	mm/dd/yyyy Where, mm = month, dd = day, yyyy = year	None	Months and days are preceded by a leading 0 if <10.
2	Time	hh:mm:ss Where hh = hours (military format 00—23), mm = minutes, ss = seconds	None	
3	Heart Rate Integer	Integer	Beats per minute (BPM)	
4	Heart Rate Source	Character string	None	
5	P1, Systolic	Number (Integer for Floating Point)	mmHg or kPa	
6	P1, Mean	Number (Integer for Floating Point)	mmHg or kPa	
7	P1, Diastolic	Number (Integer for Floating Point)	mmHg or kPa	
8	P2, Systolic	Number (Integer for Floating Point)	mmHg or kPa	
9	P2, Mean	Number (Integer for Floating Point)	mmHg or kPa	
10	P2, Diastolic	Number (Integer for Floating Point)	mmHg or kPa	
11	NIBP, Systolic	Number (Integer for Floating Point)	mmHg or kPa	

Data Output Format (continued)				
	Definition	**Format**	**Units**	**Notes**
12	NIBP, Mean	Number (Integer for Floating Point)	mmHg or kPa	
13	NIBP, Diastolic	Number (Integer for Floating Point)	mmHg or kPa	
14	SPO_2	Integer	Percent	
15	Respiration (RESP) Rate	Integer	Respirations per minute (RPM)	
16	CO_2	Integer	mmHg	
17	Inspired CO_2	Integer	mmHg	
18	N_2O	Integer	Percent	
19	FiO_2	Integer	Percent	
20	Primary Expired Agent	Floating Point	Percent	See note 1, below
21	Primary Inspired Agent	Floating Point	Percent	See note 1, below
22	Primary Agent ID	Character string (HAL,ISO,ENF,SEV,DES)	None	
23	Temperature (TEMP)	Floating Point	°C or °F	See note 2, below

NOTES

*1. In the INVIVO format, in the event that the primary agent gas value is displayed as **OVR** (over) on the DCU, the value provided through the RS232 serial port will be 10.1.*

*In the OVR-UND format, if the primary agent gas value is displayed as **OVR** (over) on the DCU, the value provided though the RS232 port will be as follows: Hal: 6.0O, Iso:6.0O, etc.*

*2. In the INVIVO format, if the temperature value is displayed as **OVR** on the DCU, the temperature value provided through the RS232 port will be 45.0 °C or 112.0 °F (depending on the units). If the temperature value is displayed as **UND** (under) on the DCU, the temperature value provided through the RS232 port will be 19.0 °C or 67.0 °F (depending on the units).*

*In the OVR-UND format, if the temperature value is displayed as **OVR** on the DCU, the temperature value provided through the RS232 port will be 44.0O °C or 111.2.O °F (depending on the units). If the temperature value is displayed as **UND** (under) on the DCU, the temperature value provided through the RS232 port will be 20.0U °C or 68.0U °F (depending on the units).*

Sample of INVIVO or OVR-UND Serial Data (all parameters readings within normal limits)

```
01/28/2011,16:30:32,60,ECG,60,100,80,125,105,85,115,95,75,99,15,36,3,10,23,3.0,3.0,HAL,37.7
01/28/2011,16:30:33,60,ECG,60,100,80,125,105,85,115,95,75,99,15,36,3,10,23,3.0,3.0,HAL,37.7
01/28/2011,16:30:34,60,ECG,60,100,80,125,105,85,115,95,75,99,15,36,3,10,23,3.0,3.0,HAL,37.7
01/28/2011,16:30:35,60,ECG,60,100,80,125,105,85,115,95,75,99,15,36,3,10,23,3.0,3.0,HAL,37.7
```

Sample of INVIVO Serial Data (only ECG, SPO2, FiO2 displaying readings)

```
01/28/2011,16:30:37,60,ECG,0,0,0,0,0,0,0,0,99,0,0,0,0,21,0.0,0.0,X,0.0
01/28/2011,16:30:38,60,ECG,0,0,0,0,0,0,0,0,99,0,0,0,0,21,0.0,0.0,X,0.0
```

```
01/28/2011,16:30:39,60,ECG,0,0,0,0,0,0,0,0,99,0,0,0,0,21,0.0,0.0,X,0.0
01/28/2011,16:30:40,60,ECG,0,0,0,0,0,0,0,0,99,0,0,0,0,21,0.0,0.0,X,0.0
```

Sample of OVR-UND Serial Data (ECG [over], SPO2, FiO2 displaying readings)

```
01/28/2011,16:30:42,250O,ECG,60,ECG,□,□,□,□,□,□,□,□,99,□,□,□,□,21,□,□,□,□
01/28/2011,16:30:43,250O,ECG,60,ECG,□,□,□,□,□,□,□,□,99,□,□,□,□,21,□,□,□,□
01/28/2011,16:30:44,60,ECG,60,ECG,□,□,□,□,□,□,□,□,99,□,□,□,□,21,□,□,□,□
01/28/2011,16:30:45,60,ECG,60,ECG,□,□,□,□,□,□,□,□,99,□,□,□,□,21,□,□,□,□
```

Sending Data to External Systems

Selectable Data Output Formatting

Selectable data output formatting allows the data output from the DCU's RS232 port to be formatted in one of two ways:

1. INVIVO
2. OVR-UND

Selectable data output formatting is accessible via the SERIAL DATA option within the **SYSTEM CONFIG** menu. Selecting INVIVO causes the Expression to output data on the RS232 port using a basic data format chosen by Invivo. Selecting OVR-UND causes the Expression to output data on the RS232 port using a format that is compatible with Centricity Critical Care software.

Formatting can be changed at any time during system operation by navigating to the SERIAL DATA option and selecting the format of interest. Output data will begin to use the new format on the next record output after the selection has been recognized by the Expression.

Selectable data output formatting may be saved and restored using the current recall-setups and save-setups feature. Refer to Chapter 3, Setups Menu Options, page 3-2.

Specifications

The OVR-UND data output format retains the comma delimited text output with one record per line of text, the original parameter fields within a line, and the same field ordering as the INVIVO format. However, the OVR-UND format makes the following changes:

- A parameter that is normally present in an output record whose value is not present will be reported as a dash character (-). (This may occur because the monitor is powering on, the parameter is present but not enabled, or the parameter is not present within the system as purchased.)
- Otherwise, a parameter will be reported according to the following tables.

Parameter	UND Displayed	OVR Displayed	Output when UND is displayed	Output when OVR is displayed	Output when parameter is within displayable range
Heart Rate	Yes	Yes	See the Heart Rate UND/OVR Source Configurations table, below.	See the Heart Rate UND/OVR Source Configurations table, below.	Identical to displayed value
P1 Systolic	Yes	Yes	Lower limit of displayable range per product specification with a “U” character appended: -9U (mmHg or equivalent for other physical units)	Upper limit of displayable range per product specification with an “O” character appended: 249O (mmHg or equivalent for other physical units)	Identical to displayed value (same as INVIVO format)
P1 Mean	Yes	Yes	Lower limit of displayable range per product specification with a “U” character appended: -9U (mmHg or equivalent for other physical units)	Upper limit of displayable range per product specification with an “O” character appended: 249O (mmHg or equivalent for other physical units)	Identical to displayed value (same as INVIVO format)
P1 Diastolic	Yes	Yes	Lower limit of displayable range per product specification with a “U” character appended: -9U (mmHg or equivalent for other physical units)	Upper limit of displayable range per product specification with an “O” character appended: 249O (mmHg or equivalent for other physical units)	Identical to displayed value (same as INVIVO format)
P2 Systolic	Yes	Yes	Lower limit of displayable range per product specification with a “U” character appended: -9U (mmHg or equivalent for other physical units)	Upper limit of displayable range per product specification with an “O” character appended: 249O (mmHg or equivalent for other physical units)	Identical to displayed value (same as INVIVO format)

Parameter	UND Displayed	OVR Displayed	Output when UND is displayed	Output when OVR is displayed	Output when parameter is within displayable range
P2 Mean	Yes	Yes	Lower limit of displayable range per product specification with a "U" character appended: -9U (mmHg or equivalent for other physical units)	Upper limit of displayable range per product specification with an "O" character appended: 249O (mmHg or equivalent for other physical units)	Identical to displayed value (same as INVIVO format)
P2 Diastolic	Yes	Yes	Lower limit of displayable range per product specification with a "U" character appended: -10U (mmHg or equivalent for other physical units)	Upper limit of displayable range per product specification with an "O" character appended: 249O (mmHg or equivalent for other physical units)	Identical to displayed value (same as INVIVO format)
Temperature	Yes	Yes	Lower limit of displayable range per product specification with a "U" character appended: 20U (C or equivalent for other physical units)	Upper limit of displayable range per product specification with an "O" character appended: 44O (C or equivalent for other physical units)	Identical to displayed value (same as INVIVO format)
Agent 1 Primary Inspired	No	Yes	Identical to displayed value	Upper limit of displayable range per product specification with an "O" character appended: 20.0O for Desflurane 6.0O for Isoflurane 6.0O for Halothane 9.0O for Sevoflurane	Identical to displayed value (same as INVIVO format)

Parameter	UND Displayed	OVR Displayed	Output when UND is displayed	Output when OVR is displayed	Output when parameter is within displayable range
Agent 1 Primary Expired	No	Yes	Identical to displayed value (same as INVIVO format)	Upper limit of displayable range per product specification with an "O" character appended: 20.0O for Desflurane 6.0O for Isoflurane 6.0O for Halothane 9.0O for Sevoflurane	Identical to displayed value (same as INVIVO format)
NIBP Systolic	No	No	Identical to displayed value (same as INVIVO format)	Identical to displayed value (same as INVIVO format)	Identical to displayed value (same as INVIVO format)
NIBP Mean	No	No	Identical to displayed value (same as INVIVO format)	Identical to displayed value (same as INVIVO format)	Identical to displayed value (same as INVIVO format)
NIBP Diastolic	No	No	Identical to displayed value (same as INVIVO format)	Identical to displayed value (same as INVIVO format)	Identical to displayed value (same as INVIVO format)
SPO2	No	No	Identical to displayed value (same as INVIVO format)	Identical to displayed value (same as INVIVO format)	Identical to displayed value (same as INVIVO format)
RESP (CO2)	No	No	Identical to displayed value (same as INVIVO format)	Identical to displayed value (same as INVIVO format)	Identical to displayed value (same as INVIVO format)
ETCO2	No	No	Identical to displayed value (same as INVIVO format)	Identical to displayed value (same as INVIVO format)	Identical to displayed value (same as INVIVO format)
FiCO2	No	No	Identical to displayed value (same as INVIVO format)	Identical to displayed value (same as INVIVO format)	Identical to displayed value (same as INVIVO format)

Parameter	UND Displayed	OVR Displayed	Output when UND is displayed	Output when OVR is displayed	Output when parameter is within displayable range
EtN2O	No	No	Identical to displayed value (same as INVIVO format)	Identical to displayed value (same as INVIVO format)	Identical to displayed value (same as INVIVO format)
O2	No	No	Identical to displayed value (same as INVIVO format)	Identical to displayed value (same as INVIVO format)	Identical to displayed value (same as INVIVO format)

Heart Rate UND/OVR Source Configurations			
Parameter Conditions	**Serial output UND condition**	**Serial output OVR condition**	**Serial Output when in valid range**
Heart Rate is sourced to ECG and Pediatric ECG is on	28U	300O	Identical to displayed value (same as INVIVO format)
Heart Rate is sourced to ECG and Pediatric ECG is off	28U	249O	Identical to displayed value (same as INVIVO format)
Heart Rate is sourced to SPO2 (all Pediatric ECG settings)	-	-	Identical to displayed value (same as INVIVO format)
Heart Rate is sourced to Arterial IBP and Pediatric ECG is on	28U	300O (True, even though the maximum displayable value is 249)	Identical to displayed value (same as INVIVO format)
Heart rate is sourced to arterial IBP and Pediatric ECG is off	28U	249O	Identical to displayed value (same as INVIVO format)
Heart Rate is sourced to NIBP (all Pediatric ECG settings)	None	None	Identical to displayed value (same as INVIVO format)

Chapter 13
Managing Alarms

The system provides technical and physiological alarms. The system permits access to every parameter alarm with a single key stroke. The system can be set to provide visual alarm signals only (Alarm Limits set, with Alarm Sound off), or both visual and audible alarm signals (Alarm Limits set, with Alarm Sound on). All settings in the **Alarms** menu (except Alarm Sound) can be stored and recalled.

WARNINGS

- **All alarms are categorized as high priority.**
- **Always respond promptly to any alarm condition.**
- **Setting the alarm limits to extreme values can render alarm monitoring useless. A potential hazard can exist if different alarm monitoring settings are used for the same or similar equipment in any single patient care unit.**

NOTES

- *A delay time making visual alarms available from the alarming equipment to the remote equipment takes an average of 2 seconds.*
- *The alarms system can be tested using a patient simulator (ECG, NIBP and SpO_2) to exceed the individual parameter alarm limits.*
- *If a problem with the alarm tone or messaging system is suspected, this system must be referred to authorized service personnel for evaluation.*

Alarm Violations

An active alarm limit is violated when a patient parameter exceeds the high setting or goes below the low setting. The reaction of the system to an alarm condition depends upon the settings described below and generally as follows:

a. The displayed numerics and trace (if enabled) of the violated parameter flash in red.

b. If enabled, the alarm tone sounds.

c. The numerics continue to flash while the parameter violates its alarm limit, even after the alarm tone has been silenced by pressing the **ALARM SILENCE** key.

d. If the printer is in the Auto mode, it begins printing. For further information, refer to Chapter 12.

e. If the alarms TYPE has been set to UNLATCHED, the numerics stop flashing after the parameter returns to within its alarm limits. Or, if the alarms TYPE has been set to LATCHED, the numerics continue to flash after the parameter returns to within its alarm limits, until the **ALARM SILENCE** key is pressed.

f. The displayed numerics of the violated parameter flash and the audible alarm, once silenced, will not sound again until the alarm condition has been corrected. Only a second different parameter alarm will cause the alarm sound to reactivate.

Alarm Limits

The system provides access to parameter alarm limits in the **ALARMS** menu, where the alarm limits may be turned on, adjusted, or turned off; see Alarms Menu Options on page 13-7.

Low and High Alarm Limits

Each parameter (except bellows-derived respiration) has a low and high alarm limit value as indicated in the table below**.** The alarm limits displayed in this table can be changed manually or automatically after the patient parameter is selected. (If a parameter has been turned off in the **SETUPS** menu, then its low and high positions will be off.)

NOTE

The system automatically prevents crossover of the low and high alarm limit settings.

Vital Sign Parameter	Unit	Low Alarm Limit*		High Alarm Limit*	
		Minimum	Maximum	Minimum	Maximum
Heart Rate	BPM	Off, 30	249	60	249, Off
SpO_2	Percent	Off, 50	99	70	99, Off
P1/P2 Systolic, Mean, & Diastolic	mmHg kPa	Off, -9 Off, -1.2	249 33.1	-9 -1.2	249, Off 33.1, Off
CO_2 Respiration Agent Low Flow CO_2	RPM	 Off, 4 Off, 4	 40 40	 20 20	 99, Off 150, Off
$EtCO_2$	mmHg kPa	Off, 5 Off, 0.7	60 8.0	5 0.6	80, Off 10.7, Off
Temperature	°C °F	Off, 20.0 Off, 68.0	44.0 111.2	20.0 68.0	44.0, Off 111.2, Off
NIBP Systolic - Adult/Pediatric	mmHg kPa	Off, 46 Off, 6.1	254 33.9	46 6.1	254, Off 33.9, Off
NIBP Mean - Adult/Pediatric	mmHg kPa	Off, 26 Off, 3.5	239 31.9	26 3.5	239, Off 31.9, Off

Vital Sign Parameter	Unit	Low Alarm Limit*		High Alarm Limit*	
		Minimum	Maximum	Minimum	Maximum
NIBP Diastolic - Adult/Pediatric	mmHg kPa	Off, 16 Off, 2.1	224 29.9	16 2.1	224, Off 29.9, Off
NIBP Systolic - Neonate	mmHg kPa	Off, 46 Off, 6.1	124 16.5	46 6.1	124, Off 16.5, Off
NIBP Mean - Neonate	mmHg kPa	Off, 26 Off, 3.5	94 12.5	26 3.5	94, Off 12.5, Off
NIBP Diastolic - Neonate	mmHg kPa	Off, 16 Off, 2.1	84 11.2	16 2.1	84, Off 11.2, Off
Et Halothane	Percent	Off, 0.1	5.0	0.1	5.0, Off
Fi Halothane	Percent	Off, 0.1	5.0	0.1	5.0, Off
Et Isoflurane	Percent	Off, 0.1	5.0	0.1	5.0, Off
Fi Isoflurane	Percent	Off, 0.1	5.0	0.1	5.0, Off
Et Enflurane	Percent	Off, 0.1	5.0	0.1	5.0, Off
Fi Enflurane	Percent	Off, 0.1	5.0	0.1	5.0, Off
Et Sevoflurane	Percent	Off, 0.1	8.0	0.1	8.0, Off
Fi Sevoflurane	Percent	Off, 0.1	8.0	0.1	8.0, Off
Et Desflurane	Percent	Off, 0.1	18.0	0.1	18.0, Off
Fi Desflurane	Percent	Off, 0.1	18.0	0.1	18.0, Off
O_2	Percent	15	99	16	99, Off

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

Default Alarm Limits

All alarm limits are automatically programmed to the default settings when the system is turned on. The table below provides a listing of the factory default alarm settings.

NOTE

In the event of power loss, upon power-up the system will automatically set all alarm limits to the default settings as follows:

- *If Default Setups was set to User, then the alarm limits will be restored to the user default settings; or,*
- *If Default Setups was set to Factory, then the alarm limits will be restored to the factory default settings.*

Any settings revised from the default values will be lost. After restoring power, all settings that may have been modified to suit a particular patient should be confirmed before using the system.

Vital Sign Parameter	Unit	Default Alarm Limits*					
		Neonate		Pediatric		Adult	
		Low Limit	High Limit	Low Limit	High Limit	Low Limit	High Limit
Heart Rate	BPM	90	210	75	160	45	160
SpO_2	Percent	90	Off	90	Off	85	Off
P1/P2 Systolic	mmHg kPa	70 9.3	100 13.3	70 9.3	120 15.9	65 8.6	190 25.3
P1/P2 Mean	mmHg kPa	40 5.3	90 11.9	50 6.6	90 11.9	55 7.3	135 17.9
P1/P2 Diastolic	mmHg kPa	35 4.6	50 6.6	40 5.3	70 9.3	40 5.3	125 16.6
CO_2 Respiration Agent Low Flow CO_2	RPM	 30 30	 70 70	 4 4	 40 40	 4 4	 40 40
$EtCO_2$	mmHg kPa	30 3.9	45 5.9	15 1.9	60 7.9	15 1.9	60 7.9
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
NIBP Systolic	mmHg kPa	70 9.3	100 13.3	70 9.3	120 15.9	65 8.6	190 25.3
NIBP Mean	mmHg kPa	40 5.3	90 11.9	50 6.6	90 11.9	55 7.3	135 17.9
NIBP Diastolic	mmHg kPa	35 4.6	50 6.6	40 5.3	70 9.3	40 5.3	125 16.6
Et Halothane	Percent	Off	1.5	Off	1.5	Off	1.5
Fi Halothane	Percent	Off	2.2	Off	2.2	Off	2.2
Et Isoflurane	Percent	Off	2.3	Off	2.3	Off	2.3
Fi Isoflurane	Percent	Off	3.4	Off	3.4	Off	3.4
Et Enflurane	Percent	Off	3.4	Off	3.4	Off	3.4
Fi Enflurane	Percent	Off	5.0	Off	5.0	Off	5.0
Et Sevoflurane	Percent	Off	4.1	Off	4.1	Off	4.1
Fi Sevoflurane	Percent	Off	6.1	Off	6.1	Off	6.1
Et Desflurane	Percent	Off	12.0	Off	12.0	Off	12.0
Fi Desflurane	Percent	Off	18.0	Off	18.0	Off	18.0
O_2	Percent	15	99	15	99	15	99

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

Fixed Alarm Limits

The system has fixed alarm settings that cannot be modified, as indicated in the table below.

Vital Sign Parameter	Unit	Fixed Alarm Limit*
$FiCO_2$	mmHg kPa	25 3.3
N_2O	Percent	80

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

Controlling the Alarm Tone

The alarm tone may be disabled permanently in the **ALARMS** menu (see Alarms Menu Options on page 13-7) or temporarily by pressing the **ALARM SILENCE** key (see Chapter 2, Keypad and Knob, page 2-25). Alarm Silence has four functions depending on the setting or condition of the alarm.

WARNING

When an X appears in the Alarm Status symbol ( ), the audible alarm tone will NOT sound for any reason.

Unlatched alarms

If the system has been set to UNLATCHED in the **ALARMS** menu (see Alarms Menu Options on page 13-7) and an alarm limit is violated, the **ALARM SILENCE** key will mute the alarm tone. While the parameter continues to violate its limits, the displayed numeric of the violated parameter will flash.

Latched alarms

If the system has been set to LATCHED in the **ALARMS** menu (see Alarms Menu Options on page 13-7) and an alarm limit is violated, while the parameter continues to violate its limits, the **ALARM SILENCE** key will mute the alarm tone. The numeric will continue to flash, even after the parameter returns to within its alarm limits.

When the alarm has been silenced and the parameter returns to within limits, pressing the **ALARM SILENCE** key a second time will stop the numeric from flashing and will put audible alarms into Alarm Hold mode.

Silenced alarms - Unlatched

When the audible alarms are enabled, pressing the **ALARM SILENCE** key disables the audible alarm only for the current alarm. Alarm Silence is also used to activate Alarm Hold.

- If the alarm tone is sounding, pressing ALARM SILENCE once stops the alarm tone.
- Alarm Silence is denoted by the S in the Alarm Status symbol ().
- Any new alarm condition will cause the alarm to reactivate.

NOTES

- *Control of alarms, including sound level, is localized to the DCU indicating the alarm condition.*
- *A currently silenced alarm condition will not sound again unless the condition returns within limits and then violates its limit again.*

While alarms are silenced, the following conditions can apply:

- Unlatched Alarms - If the alarm system has been set to UNLATCHED in the **ALARMS** menu and an alarm limit is violated, pressing the **ALARM SILENCE** key will silence the alarm tone and put the letter S in the Alarm Status symbol. While the parameter continues to violate its limits, the displayed numerics of the violating parameter continue to flash in red. Once the parameter returns to within its alarm limit, the numerics return to their designated color and no longer flash.
- Latched Alarms - Latched alarms allow an alarm state to persist even after the vital sign parameter has returned to within the set alarm limits. If the alarm system has been set to LATCHED in the **ALARMS** menu and an alarm limit is violated, pressing **ALARM SILENCE** key stops the alarm tone while the parameter continues to violate its limits, but the numerics remain red and continue to flash, even after the parameter returns to within its alarm limits.

WARNING

Once an alarm condition has been silenced () it will not sound again for any reason as long as that alarm condition continues. For example, if a patient's heart rate drops below the set limit and that alarm is silenced, the alarm will never sound for that condition again unless the heart rate returns to within limits and then drops below the limit again.

Alarm Hold

Alarm Hold can only be activated when the alarm tone is active (that is, when no X appears in the Alarm Status symbol). Alarm Hold is useful for temporarily disabling the alarm tone. This may be useful when changing ECG leads or for other user activities that might cause a false alarm. Alarm Hold is denoted by the H through the Alarm Status symbol ().

Alarm Hold can be activated two ways:

- If the alarm tone is *not* sounding, pressing the **ALARM SILENCE** key enables Alarm Hold.
- If the alarm tone *is* sounding, pressing the **ALARM SILENCE** key once activates the Alarm Silence mode. Pressing the key a second time enables Alarm Hold mode.

When Alarm Hold is activated, **SOUND ON HOLD** appears in the system message area of the display with a countdown timer starting at 120 (counting down at a 1-second rate) denoting that the alarm tone is being temporarily held silent.

During the Alarm Hold period, the audible alarm will be suspended for any new alarm conditions that occur. After the 120-second suspension period, the auditory alarm for the physiological alarm is restored. Alarm conditions that were previously silenced by pressing the **ALARM SILENCE** key will not trigger an audible alarm when the Alarm Hold period times out. The Alarm Hold duration is not user-adjustable. Alarm Hold is deactivated in two ways:

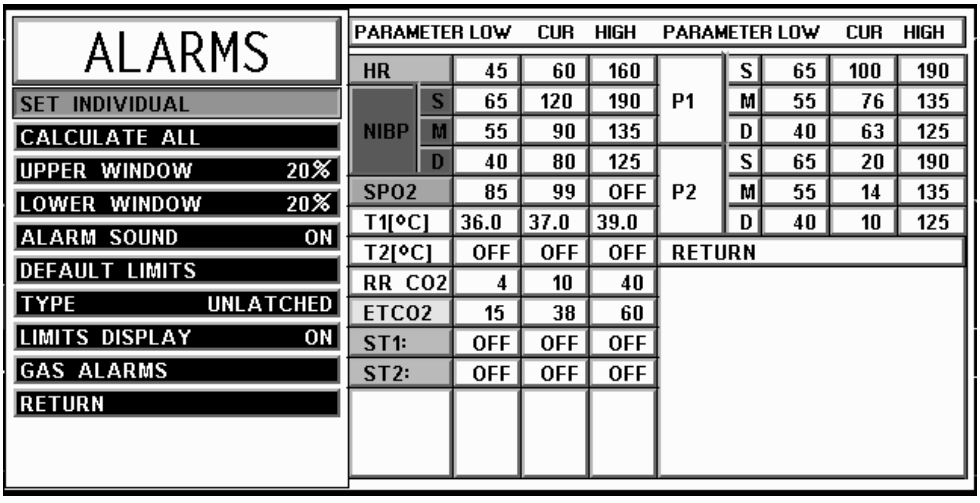
- Automatically, after the 120-second countdown has occurred; or,
- Manually, before the 120-second countdown completes, by pressing the **ALARM SILENCE** key.

WARNING

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

Alarms Menu Options

The **ALARMS** menu allows you to control alarm functions and settings.



The following options are available:

- SET INDIVIDUAL
- CALCULATE ALL

- UPPER WINDOW
- LOWER WINDOW
- ALARM SOUND
- DEFAULT LIMITS
- TYPE
- LIMITS DISPLAY
- GAS ALARMS
- RETURN

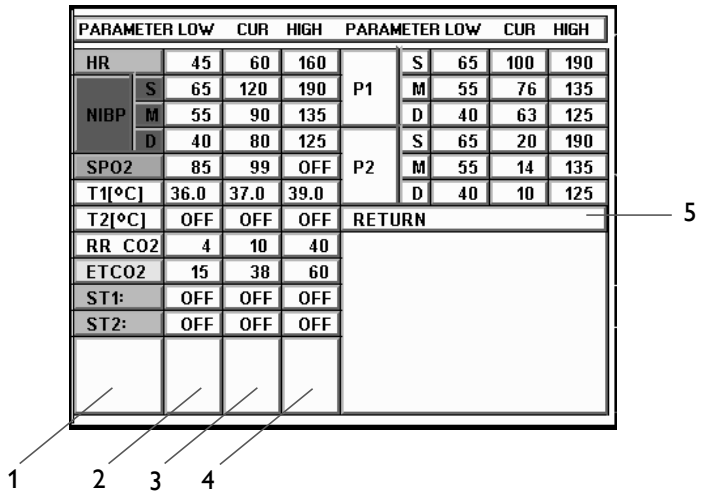
To enter the ALARMS menu

ALARM SETUP key

Press **ALARM SETUP**

The following options are available:

- **SET INDIVIDUAL:** Allows you to set individual alarm limits. This menu provides the low, current and high alarm limit settings for all parameters, except gases (see below). Turn the knob to scroll through the individual low and high alarm limits. After highlighting the limit to be modified, press the knob to select the limit then turn the knob to change the setting. When the desired value is shown, press the knob to make the setting effective and return to the scrolling function. Select RETURN to exit this menu.



	Name	Definition
1	PARAMETER	Identifies the associated parameter for the alarm
2	LOW	Indicates the current setting of the parameter's low alarm limit
3	CUR	Indicates the patient's current reading
4	HIGH	Indicates the current setting of the parameter's high alarm limit
5	RETURN	Saves adjusted settings and exits the menu.

- **CALCULATE ALL:** Causes the system to calculate new alarm limit values for all active parameters as described in the UPPER WINDOW and LOWER WINDOW options, below.

  For example, if the patient's heart rate is 60, and both UPPER WINDOW and LOWER WINDOW percentages have been set to 10%, selecting CALCULATE ALL will set the high limit to 66 and the low alarm limit to 54 (plus and minus 10 percent of the current heart rate). Corresponding low and high calculations will be performed for each of the other active patient parameters, with the exception of the Gas Alarm limits.

- **UPPER WINDOW:** Sets the percent value that is used in calculating the high alarm limits when CALCULATE ALL is selected. The system uses the current parameter value and brackets it with the percentages set in this menu and the LOWER WINDOW setting. The options are 5%, 10%, 15%, 20% (default), or 30%.

NOTE

If the value from the patient being monitored is so high that it would exceed the range of the system alarm limits (see Low and High Alarm Limits on page 13-2), the high value is set to the highest alarm limit for that parameter.

- **LOWER WINDOW:** Sets the percent value that is used in calculating the low alarm limits when CALCULATE ALL is selected. The options are 5%, 10%, 15%, 20% (default), or 30%. The system uses the current parameter value and brackets it with the percentages set in this menu and the UPPER WINDOW setting.

NOTE

If the value from the patient being monitored is so low that it would exceed the range of the system alarm limits (see Low and High Alarm Limits on page 13-2), the low value is set to the lowest alarm limit for that parameter.

- **ALARM SOUND:** Controls the audio alert for the alarms. When off is selected, an X appears in the Alarm Status symbol() and in the menu indicating that the alarm sound has been disabled. This is identical to and interactive with the MONITOR SETUP > SOUND ADJUST, ALARMS option.

- **DEFAULT LIMITS:** Automatically sets the low and high alarm limits for all parameters based upon the system defaults (see the Low and High Alarm Limits on page 13-2).

- **TYPE:** Determines whether the audio and visual alarms are latched or unlatched, where:
  - **UNLATCHED** alarms cease the audio and visual alerts if the violated parameter returns within its limits, or if the **ALARM SILENCE** key is pressed.
  - **LATCHED** alarms cease the audio and visual alerts only when the **ALARM SILENCE** key is pressed.

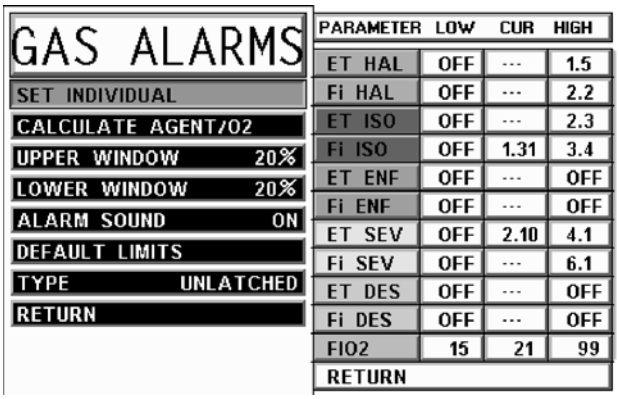
- **LIMITS DISPLAY:** Determines if the alarm limits are shown in the VS box (default is on).

- **GAS ALARMS:** See *Gas Alarms Options* (below) for details.

- **RETURN:** Exits the menu and returns the display to the Normal screen.

Gas Alarms Options

The **GAS ALARMS** menu allows you to control gas (agents) alarm functions and settings.



The following options are available:

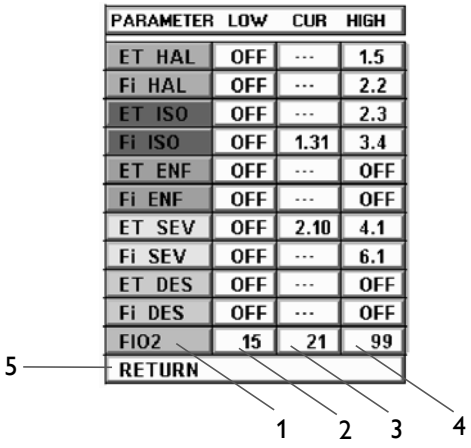
- SET INDIVIDUAL
- CALCULATE AGENT/O2
- UPPER WINDOW
- LOWER WINDOW
- ALARM SOUND
- DEFAULT LIMITS
- TYPE
- RETURN

To enter the GAS ALARMS menu

Press the **ALARM SETUP** key then rotate the knob to GAS ALARMS and press the knob. (Or, rotate the knob to highlight the GAS [or AGENTS] VS box then press the **ALARM SETUP** key.)

The following options are available:

- **SET INDIVIDUAL:** Allows you to set individual anesthetic agent alarm limits. This menu provides the low, current and high alarm limit settings for gases. Turn the knob to scroll to the individual low and high alarm limits then press the knob. Turn the knob to change the low and high alarm limit settings. When the desired settings are entered, press the knob to make the settings effective and return to the scrolling function.



	Name	Definition
1	PARAMETER	Identifies the associated gas for the alarm
2	LOW	Indicates the current setting of the gas's low alarm limit
3	CUR	Indicates the patient's current reading
4	HIGH	Indicates the current setting of the gas's high alarm limit
5	RETURN	Saves any adjusted setting then returns the Normal screen

- **CALCULATE AGENT/O2:** Causes the system to calculate new alarm limit values for all active Agent and O_2 settings. These calculations are as described in the UPPER WINDOW and LOWER WINDOW options, below. (See Chapter 13, Alarms Menu Options, page 13-7 for a description of the similar function.)
- **UPPER WINDOW:** Sets the percent value that is used in calculating the high alarm limits when CALCULATE AGENT/O2 is selected. The options are 5%, 10%, 15%, 20% (default), or 30%. The system uses the current parameter value and brackets it with the percentages set in this menu and the LOWER WINDOW setting.
- **LOWER WINDOW:** Sets the percent value that is used in calculating the low alarm limits when CALCULATE AGENT/O2 is selected. The options are 5%, 10%, 15%, 20% (default), or 30%. The system uses the current parameter value and brackets it with the percentages set in this menu and the UPPER WINDOW setting.
- **ALARM SOUND:** Controls the audio alert for the alarms. This is identical to and interactive with the ALARM SOUND in the **ALARMS** menu (see above).
- **TYPE:** Determines whether the audio and visual alarms are latched or unlatched:
  - **UNLATCHED** alarms cease the audio and visual alerts if the violated parameter returns within its limits, or if the **ALARM SILENCE** key is pressed.
  - **LATCHED** alarms cease the audio and visual alerts only when the **ALARM SILENCE** key is pressed.
- **RETURN:** Exits the menu and returns the display to the Normal screen.

Controlling Individual Parameter Alarms

WARNING

Alarm limits can be set to a wide range of values, including off. It is the responsibility of the operator of the system to ensure that alarm limit values appropriate for each patient are established and set.

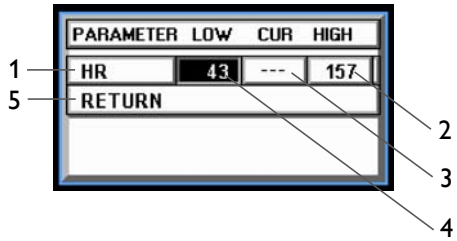
Control individual alarm parameters two ways:

- Press the **ALARM SETUP** key. Turn the knob to SET INDIVIDUAL, then press the knob. Next, turn the knob to scroll to the desired parameter in ALARMS STATUS.
- Alarms can also be controlled by highlighting the associated VS box then pressing the **ALARM SETUP** key.

The following sample illustrates an individual parameter alarm setup menu.

To change an alarm limit

Rotate the knob to highlight the desired setting then press the knob to select it. Turn the knob to adjust the setting. When the desired setting is entered, press the knob to make the setting effective and return to the scrolling function.



	Name	Definition
1	PARAMETER	Identifies the associated parameter for the alarm
2	HIGH	Indicates the current setting of the high alarm limit
3	CUR	Indicates the patient's current reading
4	LOW	Indicates the current setting of the low alarm limit
5	RETURN	Saves any adjusted setting then returns the Normal screen

Chapter 14
Maintenance and Repair

Maintenance

CAUTION

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

Cleaning

Use only the Invivo approved substances and methods listed in this section to clean or disinfect your equipment. Warranty does not cover damage caused by using unapproved substances or methods.

Invivo makes no claims regarding the efficacy of the listed chemicals or methods as a means for controlling infection.

Consult your facility's Infection Control Officer or Epidemiologist. For comprehensive details on cleaning agents and their efficacy refer to "*Guidelines for Prevention of Transmission of Human Immunodeficiency Virus and Hepatitis B Virus to Health Care and Public-Safety Workers*" issued by the U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, February 1989. Also refer to any policies that apply within your facility and country.

Cleaning the Patient Monitoring System

The system is not sterilizable. Do not immerse any part of the system in any fluid or attempt to clean it with liquid cleaning agents.

Remove dirt and dust from the Cart (or PMC), the DCU, and the wireless module housings by wiping them with a lint-free cloth, moistened with warm water (40°C/104°F maximum) gently wiping all surfaces to be cleaned briefly (30 seconds to 1 minute) as needed to ensure proper cleaning.

Stains can be removed from the Cart (or PMC), the DCU, and the wireless module housings by scrubbing briskly with the moistened cloth.

WARNING

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

CAUTIONS

- Avoid ammonia-based, phenol-based, and acetone-based cleaners. They will damage the system surfaces.
- Do not permit liquid to contact the front or rear of the display panels. Do not permit liquid to drip into the printer or around the LCD screen. Contact Technical Support if liquid enters any component.
- If the system 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.

Cleaning Accessories

Any reusable patient accessories must be cleaned after each use. Disposable patient accessories must be discarded and replaced with new items. The accessories are not sterilizable.

WARNING

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

CAUTION

Never immerse an accessory in any cleaning fluid.

To clean reusable accessories (such as ECG cables, NIBP cuffs, chest bellows, and SpO_2 sensors, clips and grips), complete the steps below. (For cleaning and disinfecting instructions for the temperature sensor, see page 10-7.)

Step	Action
1	Remove the accessory from use.
2	Remove dirt and dust from the accessory using a lint-free cloth, moistened with warm water (40°C/104°F maximum) gently wiping all surfaces to be cleaned briefly (30 seconds to 1 minute) as needed to ensure proper cleansing. Stains can be removed from the accessory by scrubbing briskly with the moistened cloth.

Step	Action
3	Inspect the accessory for any cracks, holes, tears, cuts, etc. that could affect operation and replace as necessary.
4	If disinfection is required, use only the recommended liquid surface disinfectants, unless otherwise specified in the accessory's instructions for use. Recommended surface disinfectants include dilute solutions of any of the following: • CaviWipes • Alcohol (70 percent) • Antibacterial Soap (0.1 percent Triclosan) **CAUTION** Disinfect the accessory as determined by your facility's policy.

Performing the CO_2 Gas Verification Test

Perform the steps below to verify the CO_2 gas system.

Step	Action
1	Turn on CO_2 as follows: a. Press the **MONITOR SETUP** key. b. Turn the knob to PARAMETER SELECTION then press the knob. c. Turn the knob to CO2 then press the knob. d. Turn the knob until ON is highlighted then press the knob. e. Press the **NORMAL SCREEN** key.
2	Allow the CO_2 bench to warm up for approximately 25 minutes.
3	Perform CO_2 verification test as follows: a. Connect the patient sampling line to the water trap. b. Connect CO_2 calibration gas to the patient sampling line. c. Apply the gas to the GAS port for a minimum of 30 seconds, then verify the following upper numeric value in the CO2 VS box: CO_2 = 76 (± 9) mmHg.* (If out of range, contact Technical Support.) d. Disconnect the maintenance check gas from the system.

*This CO_2 upper numeric value reading varies according to altitude. The above reading indicates the expected observed CO_2 value when conducting this test on a system located at sea level (zero altitude).

WARNING

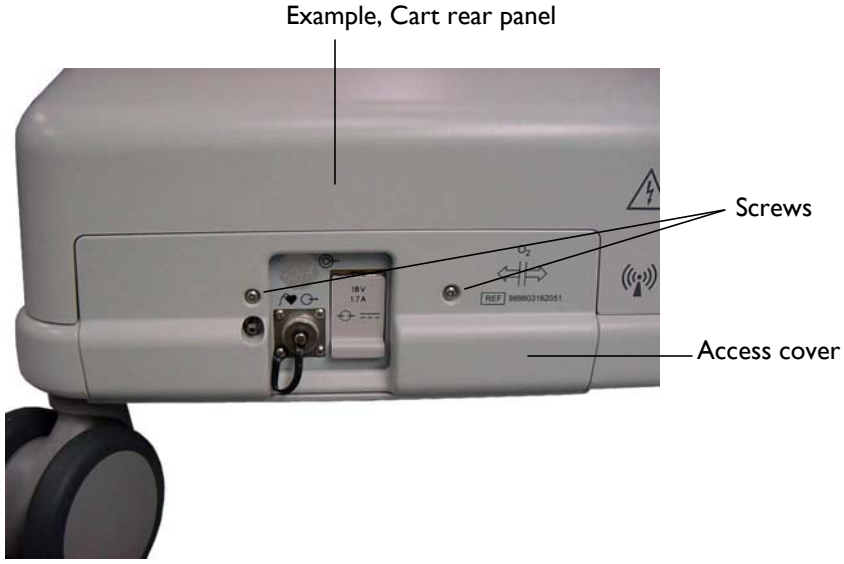
CO_2 calibration gas must be completely drained of pressure before disposal. Contents are under pressure and may cause hazard if container is punctured.

CAUTION

An internal leak may result in condensation within the system. If this is suspected, contact Technical Support.

Replacing the Oxygen Sensor

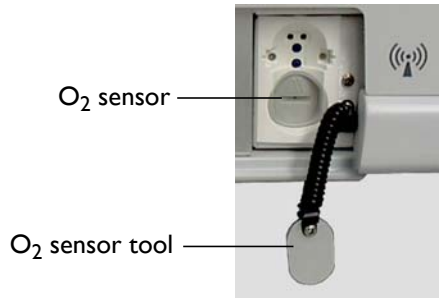
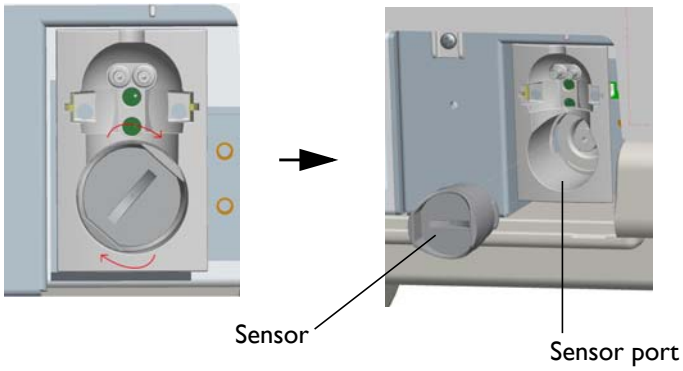
The oxygen (O_2) sensor is located behind the access cover on the rear panel of Cart-based systems (or behind the access door on the rear panel of the PMC).



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 O_2 reading.

Perform the steps below to replace the O_2 sensor.

Step	Action
1	Turn off the system.
2	Disconnect the gas sampling line.
3	Loosen the two captivated screws that secure the access cover to the rear panel of the Cart. (If replacing the O_2 sensor on the PMC, lift and remove the access door.)
4	Pull out the tethered O_2 sensor tool from behind the cover, 
5	Place the tool into the slot in the O_2 sensor, then turn the tool counterclockwise until the sensor disengages from the sensor port. Remove the sensor. 
6	Thread a new O_2 sensor into the sensor port then, using the tool, turn the sensor clockwise until secure. 

Step	Action
7	Stow the tool then replace the O_2 sensor access cover and secure it to the rear panel using the two screws. (If replacing the O_2 sensor in the PMC, replace the access door.)
8	Connect a gas sampling line to the water trap.
9	Turn on the system.
10	Turn on the Agents parameter and allow the system to run until the **CO2 WARMING UP** message is no longer displayed.
11	Calibrate the O_2 pressure by performing the following steps: a. Press the **MONITOR SETUP** key. b. Turn the knob to SERVICE (BIO-MED) then press the knob. c. Turn the knob to GAS CAL then press the knob. d. Turn the knob to O2 CAL then press the knob. e. Turn then press the knob to answer the displayed prompt: **FLOW ROOM AIR FOR 10 SECONDS, Do you wish to continue?** Select YES to proceed or NO to cancel the procedure. (If YES, then **READJUSTING CO2 ZERO** will be displayed until calibration is complete.)

WARNING

CO_2 calibration gas must be completely drained of pressure before disposal. Contents are under pressure and may cause hazard if container is punctured.

NOTE

In order to ensure oxygen sensor stability, the manufacturer recommends waiting at least 1 hour (after the package has been opened) before using the sensor.To avoid this wait time, we recommend removing the sensor from the packaging as soon as it is received or prior to beginning monitoring. Always take note of the expiration date (printed on the container and the sensor).

Factory Default Initialization

The display will revert to factory default settings by pressing and holding the knob and the **NORMAL SCREEN** key, while turning on the system. After initialization, the following are displayed:

- The Alarm Status symbol (on hold) appears in the upper portion of the LCD.
- ECG 1 is on Trace A and set to Lead II.
- SpO_2 is on with waveform displayed in Trace C.
- NIBP is on, displayed in the lower left portion of the LCD.
- All other parameters are off.
- **SOUND ON HOLD** is displayed, counting down from 120, in the center of the LCD.

NOTE

The alarm sound is enabled when the hold count reaches zero.

Service(Bio-Med) Menu Options

The **SERVICE(BIO-MED)** menu allows you to check the firmware revision level, to place the system into Simulation mode, to perform training, certain maintenance functions and to review the configuration of the system. Some selections must only be used by authorized service personnel thoroughly familiar with the operation and service of the system.

To enter the SERVICE(BIO-MED) menu

Press the **MONITOR SETUP** key then turn the knob to SERVICE(BIO-MED) and press the knob.

- **S/W REV:** Allows you to examine information about the operating software, including the revision level and the build date. (To exit this window, select OK or press the **NORMAL SCREEN** key.)
- **SIMULATION MODE:** Allows you enter Simulation mode. (A YES/NO prompt must be answered before entry.) To exit Simulation mode, turn off the system. Note that to simulate P1 and P2 pressures, ZERO SET must first be performed; see Chapter 6, IBP Menu Options*, page 6-3*.

WARNING

The system 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 system when in Simulation mode and do not activate Simulation mode when a patient is connected to the system. The system will not monitor patients while in the Simulation mode. Failure to properly monitor the patient could result. To exit Simulation mode, turn off the system.

- **NIBP TESTS:** Opens NIBP setup and testing options.
  - **CALIBRATE** performs calibration of the NIBP system.
  - **LEAK TEST** tests NIBP system for pressure leaks.

WARNING

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

- **GAS CAL:** Opens calibration menu of the gas monitoring feature and allows control of the following gas-related functions:
  - **ZERO CAL** performs a zero calibration of the Agents and CO_2 systems.
  - **O2 CAL** performs a one-minute calibration of the O_2 sensor.
  - **O2 INIT CAL** performs a two-minute calibration of the O_2 sensor, a process that must be performed after the O_2 sensor has been replaced.

NOTE

O2 INIT CAL is available on systems that have only the CO_2 monitoring feature installed. (If a system includes Agents and CO_2 monitoring features, O_2 initialization calibration is performed automatically and UNUSED is displayed instead of O2 INIT CAL.)

  - **RETURN** closes the menu.
- **SERVICE UTILITIES:** Allows control of the service-related functions:

NOTE

The correct password is required for some access to the options listed below, as these are for use only by authorized service personnel thoroughly familiar with the operation and service of the system.

  - **WPU LOCK:** Controls the WPU lock feature. (A password is not required to turn off the WPU lock feature.) WPU LOCK locks the WPU from outside influences of any DCU,

where all DCU settings or commands received by the WPU will be ignored. Also, the WPU will have the ability to initiate NIBP readings while not connected to a DCU.

  - **RADIO INFO** performs a test of the wireless communications.
  - **ECG DIAGNOSTICS** performs a communications test of the wECG module.
  - **SPO2 DIAGNOSTICS** performs a communications test of the wSpO2 module.
  - **RETURN** closes the menu.

- **SYSTEM CONFIG:** Configures system parameters and options. With the exception of the options listed in Chapter 3, Service(Bio-Med)*, page 3-13*, all are for factory use only and require a password for access.
  - **ECG 1** configures the ECG 1 parameter (default is ENABLED).
  - **ECG 2** configures the ECG 2 parameter (default is ENABLED).
  - **NIBP** configures the NIBP parameter (default is ENABLED).
  - **P1** configures the invasive pressure parameter, channel P1 (default is ENABLED).
  - **P2** configures the invasive pressure parameter, channel P2 (default is ENABLED).
  - **SPO2** configures the SPO2 parameter (default is ENABLED).
  - **GAS BENCH** configures the CO2 or AGENTS parameter (default is DISABLED).
  - **AGENTS MODE** configures the system for single or dual agents (default is SINGLE).
  - **RESP** configures the bellows respiration parameter (default is ENABLED).
  - **TEMPERATURE** configures the temperature parameter for surface or body measurements (default is SURFACE).
  - **CO** is for factory use only.
  - **PARALLEL PORT** is for factory use only.
  - **PRINTER** configures the printer option (default is DISABLED).
  - **ANALOG OUTPUT** is for factory use only.
  - **NETWORK** configures the WPU network setting. Factory use only. (See NETWORK in the Chapter 3, Setups Menu*, page 3-2* for setting changes to the DCU.)
  - **ST-SEGMENT** is for factory use only.
  - **LANGUAGE** see SERVICE(BIO-MED) in the Chapter 3, Setups Menu*, page 3-2*.
  - **PRESSURE UNITS** see SERVICE(BIO-MED) in the Chapter 3, Setups Menu*, page 3-2*.
  - **RETURN** closes the menu.

Repair

All repairs on products under warranty must be performed by authorized personnel or in an authorized Service and Repair Center.

If the system fails to function properly or requires maintenance, contact Technical Support:

1-877-INVIVO1

-or-

1-877-468-4861

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

Unauthorized repairs will void the warranty. Refer to Appendix B for additional information.

WARNING

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

CAUTIONS

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

The ground terminal (⏚) on the power converter has specific uses:

- Allows the bio-med to connect equipment for testing of leakage currents.
- Allows authorized service personnel to connect a ground strap to prevent ESD discharge during servicing.

CAUTION

Performance of the Expression MRI Patient Monitoring System and other devices may be degraded if the ground terminal is used against Invivo's intended use as listed above.

NOTE

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

Appendix A: Specifications

GENERAL

PATIENT SAFETY

Conforms to UL STD 60601-1. Certified to CAN/CSA STD C22.2 No. 601.1

Defibrillator protection up to 5 KV

According to degree of protection against harmful ingress of water: ordinary equipment, 1PX0 (enclosed equipment without protection against ingress of water)

This equipment complies to the following international industry standards for safety and performance:

- IEC 60601-1, *General Requirements for Safety of Medical Electrical Equipment*
- IEC 60601-1-2, *General Requirements for Safety - Electromagnetic Compatibility*
- IEC 60601-1-4, *General Requirements for Safety of Programmable Electrical Medical Systems*
- IEC 60601-1-8, *General Requirements, Tests and Guidance for Alarm Systems in Medical Electrical Equipment and Medical Electrical Systems*
- IEC 60601-2-27, *Particular Requirements for Safety - Specification for Electrocardiographic Monitoring Equipment*
- IEC 60601-2-30, *Particular Requirements for the Safety, Including Essential Performance, of Automatic Cycling Non-Invasive Blood Pressure Monitoring Equipment*
- IEC 60601-2-34, *Particular Requirements for the Safety, Including Essential Performance, of Invasive Blood Pressure Monitoring Equipment*
- IEC 60601-2-49, *Particular Requirements for the Safety of Multifunction Patient Monitoring Equipment*

Where appropriate, the equipment complies to worldwide standards for safety and performance of each system feature, when considering the indications for use within the MR environment.

POWER REQUIREMENTS

Operating Voltage Range	100 VAC to 240 VAC
Frequency	50/60 Hz
Current	1.5 A
Power Consumption, Maximum	< 100 Watts
DC Output Voltage, Nominal	18.3 VDC

BATTERY	
Type	Lithium-Ion
Operation Time	**REF 989803169491:** As indicated by battery status display, the maximum operation time of battery is approximately 8 hours when ECG and SpO_2 parameters are on, CO_2 and Agents are off, and NIBP is on and running at a 5-minute measurement interval. (Battery operation may be reduced by up to 2 hours under certain conditions such as having the Agent parameter on, printing charts and trends, and running short NIBP cycles.) **REF 989803152881:** Approximate battery operation time is 8 hours
Charge Time	**REF 989803169491:** Recharge time required when fully discharged is approximately 12 hours with the Expression MRI Patient Monitoring System turned off. **REF 989803152881:** Recharge time when fully discharged is approximately 3 hours.
ENVIRONMENT	
Operating Temperature	15°C to 35°C (59°F to 95°F)
Storage Temperature	**Batteries (REF 989803169491):** 0°C to 40°C (32°F to 104°F) **Anesthetic Oxygen (O_2) Sensor (REF 989803162051):** -40°C to 35°C (-40°F to 95°F) **Cart, PMC, DCU, wireless modules, and accessories (except the Temperature sensor):** -20°C to 60°C (-4°F to 140°F) **Temperature sensor:** -25°C (-13°F) to 70°C (158°F) (When storing the system in temperatures beyond these ranges, remove the designated component and store it appropriately.)
Relative Humidity	15% to 80%, non-condensing
Transport Temperature	**Cart, PMC, DCU, wireless modules, and accessories (except Temperature):** -20 to 60°C (-4 to 140°F) **Temperature sensor:** -25°C (-13°F) to 70°C (158°F)

DIMENSIONS/WEIGHTS (Note: All measurements made without accessories)	
Height	**Cart:** 42.3 inches (107.4 cm) **PMC:** Mounted vertically: 15.3 inches (38.9 cm); mounted horizontally: 8.5 inches (21.6 cm) **DCU:** 11.5 inches / 15.5 inches with antenna (29.2 cm / 39.4 cm) **Wireless ECG Module**: 5.0 inches (12.8 cm) **Wireless SpO_2 Module:** 5.6 inches (14.3 cm)
Width	**Cart:** 18.7 inches (47.5 cm) **PMC:** 15.7 inches (39.9 cm) **DCU:** 15.4 inches (39.1 cm) **Wireless ECG Module**: 2.5 inches (6.4 cm) **Wireless SpO_2 Module:** 2.5 inches (6.4 cm)
Depth	**Cart:** 19.5 inches (49.5 cm) **PMC:** Mounted vertically: 8.3 inches (21.1 cm); mounted horizontally: 15.1 inches (38.4 cm) **DCU:** 5.5 inches (14.0 cm) **Wireless ECG Module**: 1.1 inches (2.9 cm) **Wireless SpO_2 Module:** 1.1 inches (2.9 cm)
Weight	**Cart:** 80 pounds (36.3 Kg) **PMC:** 31 pounds (14.0 Kg) **DCU:** 17 pounds (7.7 Kg) **Wireless ECG Module**: 5.4 oz (153 g) **Wireless SpO_2 Module:** 5.2 oz (147 g)
DISPLAY CONTROL UNIT (DCU)	
Type	LCD, color, 800 x 600 pixels
Screen Size	12 inch (30.5 cm) diagonal
Sweep Speed	25 or 50 mm/S gives 9.2 S or 4.6 S of display, respectively. For respiration, a speed of 0.33, 1.56, 3.13, 6.25, 12.5 or 25 mm/S is used
Waveform Display Mode	Fixed trace, moving erase bar
Waveform Display Height	≥ 19 mm
"Full-Screen" Display Height	≥ 75 mm
Alarm Light	
Color	Red
Size	Height: 0.24 inches (0.6 cm) Width: 1.06 inches (2.7 cm) Depth: 0.20 inches (0.5 cm)
Flashing Frequency	1.7 Hz
Duty Cycle	50%

PRINTER (Thermal Array)	
Chart Speeds	25 mm/second or 50 mm/second
Number of Channels	2
Paper Type and Size	Non-grid thermal paper, 50 mm wide
Alphanumeric annotation of date, time delay, paper speed, scales, lead configuration, patient mode, heart rate, SpO_2, $EtCO_2$, respiration rate (bellows), respiration rate (CO_2), (NIBP (systolic, mean, diastolic), invasive pressure P1 and P2 (systolic, mean, diastolic), temperature, primary and secondary agent Et and Fi, and O_2	
Automatic activation on alarm with alarm parameter printed at the beginning of trace.	

DISPLAYED PARAMETERS	
Time	Battery-backed quartz crystal clock
Alarms	High and low limits selectable on patient parameters
ECG	ECG waveform scale, displayed leads (2)
Heart Rate	Normally derived from ECG. May be manually selected to be derived from invasive blood pressure, pulse oximeter, NIBP or automatically selected in order of priority.
Pulse Oximeter	Pulse rate, pulse waveform, and percent saturation
Invasive Pressures	Systolic, mean, diastolic, and waveform
Temperature	Body temperature (°C or °F)
Trends	Heart rate, respiration rate, NIBP (systolic, mean, diastolic), IBP (systolic, mean, diastolic), temperature, CO_2, and SpO_2
Respiration Rate (CO_2)	Respiration rate derived from CO_2
CO_2	Both $EtCO_2$ and inspired CO_2
N_2O	EtN_2O available in Agent MAC box
O_2	Inspired, expired (averaged percent)
Agents	Automatic identification of primary and secondary agents (Desflurane, Isoflurane, Enflurane, Halothane or Sevoflurane) displaying both end-tidal (Et) and fractional inspired (Fi) concentrations.
NIBP	Pressures (systolic, mean, diastolic), pulse rate, status
Respiration Rate (bellows)	Respiration rate derived from bellows

ECG CHANNEL	
ECG AMPLIFIER	
Protected against defibrillator and electrosurgery potentials	
Standard Lead Configurations	I, II, III, AVR, AVL, AVF
Lead Fail	Passive, sensing signal imbalance
ECG Input Impedance	>2.5 MΩ (according to IEC 60601-2-27, 50.102.3)
HEART RATE	
Range	30 bpm to 240 bpm (Adult) 30 bpm to 300 bpm (Neonate, Pediatric)
Accuracy	In the absence of MRI gradient artifact: ±1% or ±1 bpm, whichever is greater In the presence of MRI gradient artifact: ±1% from 30–200 bpm, ±1.5% from 200–250 bpm, and ±2% from 251–300 bpm (neonatal only)
Resolution	1 bpm
CARDIOTACH	
Sensitivity (Monitor filter)	Adult ECG mode: > 200 µV Neonate/Pediatric ECG mode: > 100 µV
Bandwidth	Monitor: 0.5 Hz to 40 Hz
Tall T-Wave Rejection Capability for Heart Rate Indication	2 mV with a 1 mV QRS amplitude
ALARMS	
Lower Alarm Limit	30 bpm to 249 bpm (or Off)
Upper Alarm Limit	60 bpm to 249 bpm (or Off)
TEST/CALIBRATION	
Square Wave Test Signal	60 bpm ±1 bpm, 1 mV ±10%

ECG Supplemental Information, as required by IEC 60601-2-27

Heart Rate Averaging Method	Mean filtering is applied to the output of the median filter of a continuously updating group of QRS complexes. The ECG heart rate numeric is updated twice a second.
Time to Alarm for Tachycardia	
B1 - Vent Tachycardia 1 mVpp, 206 bpm	Gain 0.5 (12.03, 11.04, 14.1, 11.8, 11.4) Avg: 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) Avg: 10.6 sec Gain 2.0 (8.8, 9.1, 10.3, 9.4, 12.1) Avg: 9.9 sec
B2 - Vent Tachycardia 2 mVpp, 195 bpm	Gain 0.5 (9.0, 10.4, 12.3, 8.1, 10.4) Avg: 10.0 sec Gain 1.0 (8.4, 7.7, 12.5, 7.7, 8.3) Avg: 8.9 sec Gain 2.0 (9.7, 12.6, 8.9, 11.8, 8.3) Avg: 10.3 sec

NOTE

Measurements made in Monitor filter mode outside of the MR environment. The alarm condition response time of some arrhythmia complexes may be affected by MRI gradient artifact.

Response Time of Heart Rate Meter to Change in Heart Rate	HR change from 80 bpm to 120 bpm: 8.3 sec avg. HR change from 80 bpm to 40 bpm: 7.9 sec avg.
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 bpm - 125 bpm A4: Bidirectional systoles 58 bpm - 85 bpm

NOTE

Measurements made in Monitor Filter mode outside of the MR environment. The accuracy of the indicated heart rate may be affected by MRI gradient artifact.

PULSE OXIMETER

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

ALARM LIMITS

SpO_2 Alarm Limits	Low: 50 to 99 or Off High: 70 to 99 or Off
PULSE Alarm Limits (when "HR" is derived from SpO_2)	Low: 30 to 249 High: 60 to 249

NOTE

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

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

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

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

NON-INVASIVE BLOOD PRESSURE

GENERAL	Oscillometric method (with inflatable cuff). Determines systolic, diastolic and mean arterial pressures, and pulse rate.
Patient Types	Adult, Pediatric and Neonate

NOTE

The displayed mean arterial pressure is based on the measured and validated values for systolic and diastolic pressures according to the following formula cited from Cywinski J. *in* The Essentials in Pressure Monitoring*; Boston: Martinus Nijhoff Publishers b.v., 1980; 23-24:*

$$MAP \simeq \frac{(2 \times DP) + SP}{3}$$

The displayed mean arterial pressure is an approximation only and may not be applicable to all patients.

NOTE

This equipment complies in full to EN 1060-1:1996 + A1:2002, Specification for non-invasive sphygmomanometers - Part 1: General Requirements.

PNEUMATIC SYSTEM	
Cuff Inflation Pressure	Initially 170 mmHg for Adult, 130 mmHg for Pediatric 120 mmHg for Neonate. Subsequent inflation pressures determined by last NIBP measurement.
Overpressure Protection	Adult and Pediatric modes: Automatically releases cuff pressure if inflation pressure exceeds 285 mmHg Neonate mode: 150 absolute, or greater than 142 but less than 150 for 15 seconds
Unit of Measurement	mmHg or KPa
MEASUREMENT RANGE	
Systolic	45 mmHg to 255 mmHg for Adult and Pediatric 45 mmHg to 125 mmHg for Neonate
Diastolic	15 mmHg to 225 mmHg for Adult and Pediatric 15 mmHg to 85 mmHg for Neonate
Mean Arterial	25 mmHg to 240 mmHg for Adult and Pediatric 25 mmHg to 95 mmHg for Neonate
Pulse Rate Range	Adult and Pediatric: 40 bpm to 200 bpm Neonate: 40 bpm to 230 bpm
ACCURACY	
Pulse Rate	Within 2% of the pulse rate range
Pressure Transducer Accuracy (per ANSI/AAMI SP10:2002)	±3 mmHg or 2% of the reading above 200 mmHg
Pressure Transducer Range	0 to 307 mmHg

ALARM LIMITS	
Systolic	46 mmHg to 254 mmHg for Adult and Pediatric 46 mmHg to 124 mmHg for Neonate
Mean	26 mmHg to 239 mmHg for Adult and Pediatric 26 mmHg to 94 mmHg for Neonate
Diastolic	16 mmHg to 224 mmHg for Adult and Pediatric 16 mmHg to 84 mmHg for Neonate
Pulse (when Heart Rate is derived from NIBP)	Minimum: 30 bpm to 249 bpm Maximum: 60 bpm to 249 bpm
MODES	
Manual	Immediate upon operator command
Automatic	Determinations automatically made with selectable intervals of 1, 2, 2.5, 3, 5, 10, 15, 20, 30 and 45 minutes, and 1, 2 and 4 hours

INVASIVE PRESSURE CHANNELS (Optional)	
PRESSURE AMPLIFIER	
Range	-10 mmHg to +248 mmHg
Sensitivity	5 µV/V/mmHg
Gain Accuracy	±0.5% or ±1 mmHg, whichever is greater
Bandwidth	0 to 10 Hz (-3 dB)
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
ART, 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 bpm to 249 bpm
Accuracy	2% of full scale
Resolution	1 bpm

ALARMS

Transducer Disconnect	Alarm delay 6 seconds
Pressure Disconnect	Alarm delay 6 seconds
High and Low Pressure	Alarm delay 10 seconds.

ALARM LIMITS

Heart Rate	Low: 30 bpm to 249 bpm High: 60 bpm to 249 bpm
Systolic, Mean, Diastolic	Low: -10 mmHg to 249 mmHg (-1.3 KPa to 33.2 KPa) High: -10 mmHg to 249 mmHg (-1.3 KPa to 33.2 KPa)

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 made or ordered from various transducer adapter cable manufacturers.

Connector Pin #	Signal Name
A	- Signal
B	+ Excitation
C	+ Signal
D	- Excitation
E	Shield

LOW-FLOW END-TIDAL CO_2 (Optional)

Side stream, non-dispersive infrared absorption technique. Including multiple water trapped filtration system and microprocessor logic control of sample handling and calibration.

Output	CO_2 Waveform, $EtCO_2$, $FiCO_2$, Respiration Rate
CO_2 Units of measurement	mmHg or KPa
CO_2 Measurement Range	0 to 76 mmHg (0-10.1 KPa)
CO_2 Measurement Resolution	1 mmHg or 0.1 KPa
Accuracy	CO_2: ±4 mmHg or ±12%, whichever is greater Resp: ±1 respiration per minute (rpm) or ±3%, whichever is greater
Warm-up Time	≤ 1 minute
Zero Calibration Interval	Automatic or user requested
Flow Rate	80 mL/minute ± 16 mL/minute
Full Accuracy Respiration Range (Rate permitting specified CO_2 accuracy)	Accuracy: 4 rpm to 60 rpm
Total Respiration Range	4 rpm to 100 rpm

Total System Response Time	Adult, Pediatric: ≤ 800 ms Neonate: ≤ 320 ms (Response time measured from step change of 10% to 90% of measured CO_2 level through complete pneumatic system including patient line.)
Operating temperature	15°C to 35°C (59°F to 95°F)

ALARM LIMITS

CO_2 Alarm Limits	Low: Off, or 5 mmHg to 60 mmHg High: 5 mmHg to 80 mmHg, or Off
Inspired CO_2	25 mmHg (Fixed)
Respiration Alarm Limits	Low: Off, or 4 rpm to 40 rpm High: 20 rpm to 150 rpm, or Off

MEASURED GAS	INTERFERING GASES AND EFFECTS											
	N20	HAL	ENF	ISO	SEVO	Xenon	Helium	DES	Ethanol	Isopropanol	Acetone	Methane
Carbon Dioxide	NE @ 60%	NE @ 4%	NE @ 5%	NE @ 5%	NE @ 5%	ME @ 80%	ME @ 50%	NE @ 15%	NE @ 5%	NE @ 0.548%	NE @ 2%	NE @ 2%

No Effect (NE) = Total Error < 10%.

Minimal Effect (ME) = Total Error > 10%, but within specification.

Interferes (INT) = Total Error > 15% of Measured Value + 0.2 of the Interfering Gas Value, or False Positive ID occurs.

ANESTHETIC AGENTS (Optional)

Technique	Side Stream, non-dispersive infrared (NDIR) absorption technique, including water trap filtration system and microprocessor logic control of sample handling and calibration
Measurement Range (after maximum warm-up period)	Halothane: 0 to 5.0 Vol.% Isoflurane: 0 to 5.0 Vol.% Sevoflurane: 0 to 8.0 Vol.% Desflurane: 0 to 18.0 Vol.% Enflurane: 0 to 5.0 Vol.% Carbon Dioxide: 0 to 10.0 Vol.% Nitrous Oxide: 0 to 100 Vol.%

Accuracy* (includes stability and drift)	Halothane:	±0.15 Vol.% at 0-1.00 Vol% ±0.20 Vol% at 1.00-5.00 Vol%
	Isoflurane:	±0.15 Vol.% at 0-1.00 Vol% ±0.20 Vol% at 1.00-5.00 Vol%
	Sevoflurane:	±0.15 Vol.% at 0-1.00 Vol% ±0.20 Vol% at 1.00-5.00 Vol% ±0.40 Vol% at 5.00-8.00 Vol%
	Desflurane:	±0.15 Vol% at 0-1.00 Vol% ±0.20 Vol% at 1.00-5.00 Vol% ±0.40 Vol% at 5.00-10.00 Vol% ±0.60 Vol% at 10.00-15.00 Vol% ±1.0 Vol% at 15.00-18.00 Vol%
	Enflurane:	±0.15 Vol.% at 0-1.00 Vol% ±0.20 Vol% at 1.00-5.00 Vol%
	Carbon Dioxide:	±0.10 Vol% at 0-1.00 Vol% ±0.20 Vol% at 1.00-5.00 Vol% ±0.30 Vol% at 5.00-7.00 Vol% ±0.50 Vol% at 7.00-10.00 Vol%
	Nitrous Oxide:	±2.0 Vol% at 0-20 Vol% ±3.0 Vol% at 20.0-100 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	
Display Resolution	0.1% Volume	
Flow Rate	200 ±20 ml/min (Adult, Pediatric) 150 ±15 ml/min (Neonate)	
Response Time	Agents: Not specified CO_2: < 330 ms for Adult and Pediatric, < 290 ms for Neonatal (10% - 90% step change of measured CO_2 level through pneumatic system including patient line)	
Full Accuracy Respiration Rate (Range permitting specified gas accuracy)	2 rpm to 60 rpm	
Total Respiration Range	2 to 100 rpm, accuracy is unspecified from 60 rpm to 100 rpm	
Relevant Interference	0.5 mmHg equivalent with 37.5°C saturated with H_2O (0.1% relative max)	
Display Resolution	0.1% Volume	
Maximum Warm-up Time	10 minutes, ISO accuracy is achieved in < 45 seconds	
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
Calibration Interval	Calibration verification (as described in Chapter 14) must be performed at 1 year intervals.
ALARM LIMITS	
CO_2 Alarm Limits	Low: Off, or 5 mmHg to 60 mmHg High: 5 mmHg to 80 mmHg, or Off
Inspired CO_2	25 mmHg (Fixed)
N_2O	80% (Fixed)
Et Halothane	Low: Off, 0.1 to 5.0 High: 0.1 to 5.0, Off
Fi Halothane	Low: Off, 0.1 to 5.0 High: 0.1 to 5.0, Off
Et Isoflurane	Low: Off, 0.1 to 5.0 High: 0.1 to 5.0, Off
Fi Isoflurane	Low: Off, 0.1 to 5.0 High: 0.1 to 5.0, Off
Et Enflurane	Low: Off, 0.1 to 5.0 High: 0.1 to 5.0, Off
Fi Enflurane	Low: Off, 0.1 to 5.0 High: 0.1 to 5.0, Off
Et Sevoflurane	Low: Off, 0.1 to 8.0 High: 0.1 to 8.0, Off
Fi Sevoflurane	Low: Off, 0.1 to 8.0 High: 0.1 to 8.0, Off
Et Desflurane	Low: Off, 0.1 to 18.0 High: 0.1 to 18.0, Off
Fi Desflurane	Low: Off, 0.1 to 18.0 High: 0.1 to 18.0, Off
O_2	Low: 15 to 99 High: 16 to 99, Off

OXYGEN	
Range	0 - 100%
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 0-40% ±2% at 40-60% ±3% at 60-80% ±4% at 80-100%
*Gas measurement performance requirements are met after the maximum warm-up period.	
Offset	±1%
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
Operating Temperature	15°C to 35°C (59°F to 95°F)
Ambient Humidity (Non-Condensing)	10% to 99% RH (non-condensing)
Oxygen Sensor, Storage Temperature	-40°C to 35°C (-40°F 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 O2). Exchange recommended every 12 months
Oxygen Sensor, Shelf Life	3 months in sealed container

TEMPERATURE (Optional), 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)
Accuracy	±0.5°C (±0.9°F) except inside the MR system magnet bore where the field creates up to a -0.5°C shift (-1.0°C to 0.0°C, -1.8°F to 0.0°F) ***NOTE*** *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 150 seconds, compliant to BS EN 12470-4, *Clinical thermometers – Part 4: Performance of electrical thermometers for continuous measurement*.
Numeric Display Update Time	2 seconds
Sensor Type	Fiber-optic, multiple-use (when used with single-use sterilized jackets)
Application site	Axillary, endotracheal, endorectal
ALARM LIMITS	
Degrees °C	Low: Off, 20.0 to 44.0 High: 20.0 to 44.0, off
Degrees °F	Low: Off, 68.0 to111.2 High: 68.0 to 111.2, off

MODULE 3.7 V BATTERY CHARGER (REF 989803152891)	
POWER REQUIREMENTS	
Input Voltage (to AC adapter)	Universal AC, 85 to 265 VAC @ 47 to 63 Hz
Input Power	40W without power factor correction
Grounding Connection	Hospital grade (with earth ground)
Protection	Over/under voltage, reverse voltage, under current
DC Connector	5 VDC power pack
ENVIRONMENT	
Location	Console room (outside the MR magnet room)
Operating Temperature	10°C to 40°C (50°F to 104°F)
CHARGING CHARACTERISTICS	
Battery Charge Time	Approximately 3 hours from fully discharged to fully charged
Battery Presence Detection	Micro switch, charging and LED indication start immediately upon detection.
Battery Type	3.7 V lithium-polymer, 800 mAH
Battery Charge Control	Constant current/constant voltage format, “wake-up” charge on fully discharged batteries, battery data communication verification
DIMENSIONS	
Height	3.2 inches (8.20 cm)
Width	8.0 inches (20.3 cm)
Depth	5.5 inches (14.1 cm)

GATING CONNECTOR		
Pin Designator	**Name**	**Description and Characteristics**
A	DIGITAL GATING PULSE	ECG/SpO_2 digital gating pulse • Peak to peak voltage: 3.3V to 5.0V • Pulse duration: 10 ± 3 ms • Delay < 10 ms, ECG: Monitor, Primary, and Secondary Filter Modes • Delay < 12 ms, ECG: Cardiac Filter Mode • Delay < 14 ms, ECG: Advanced Filter Mode • Delay < 50 ms, SpO_2
B	SIGNAL GROUND	Return voltage reference for all other signal pins
C	RESP 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 1V 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	IBP 200mV ANALOG	Analog IBP gating waveform signal • Maximum output voltage: 200 mV
F	NEGATIVE GATING PULSE	ECG/SpO_2 negative digital gating pulse • Peak-to-peak signal voltage: -3.3 V to -5 V • All other signal characteristics are identical to Pin A (Digital Gating Pulse)
G	SPO2 40mV ANALOG	SpO_2 IR/red analog gating waveform signal • Signal scaling: 1 V/mV • Maximum output voltage: 40 mV • Delay = 250 ms
H	ECG 1mV 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 2V ANALOG	SpO_2 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

Koninklijke Philips N.V. warrants this product, other than its expendable parts, to be free from defects in materials and workmanship for a period of twelve (12) months from the date of original delivery to the buyer or to buyer's order, provided that same is properly operated under conditions of normal use, and that periodic maintenance and service is performed. This same warranty is made for a period of ninety (90) days on expendable parts. This warranty shall become null and void if the Expression MRI Patient Monitoring System 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 a Expression MRI Patient Monitoring System which has been reported to Invivo's 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.

Authorized Representative

EC REP

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: Electromagnetic Compatibility

Electromagnetic Compatibility (EMC)

The following information is mandated by IEC 60601-1-2, the international standard for the electromagnetic compatibility (EMC) of medical electrical equipment:

Frequency Range: 2402 to 2482 MHz

Modulation Type: GMSK

WPU EIRP: 4.2 dBm (peak)

wECG and $WSPO_2$ EIRP: 0 dBm (peak)

WARNINGS

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

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

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The Expression MRI Patient Monitoring System is intended for use in the electromagnetic environment specified below. The customer or the user of the Expression 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 MRI Patient Monitoring System requires continued operation during AC power interruptions, power from an uninterruptable power supply or battery is recommended.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: *U*t *is the AC mains voltage prior to application of the test level.*			

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The Expression MRI Patient Monitoring System is intended for use in the electromagnetic environment specified below. The customer or the user of the Expression 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	3 Vrms 150 KHz to 80 MHz	V1 = 3 Vrms	Portable and mobile RF communications equipment should not be used no closer to any part of the Expression MRI Patient Monitoring System, including the cabling, 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 this symbol  .
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	E1 = 3 V/m	

NOTES

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

The Expression 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 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 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.

NOTES

- *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.*

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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