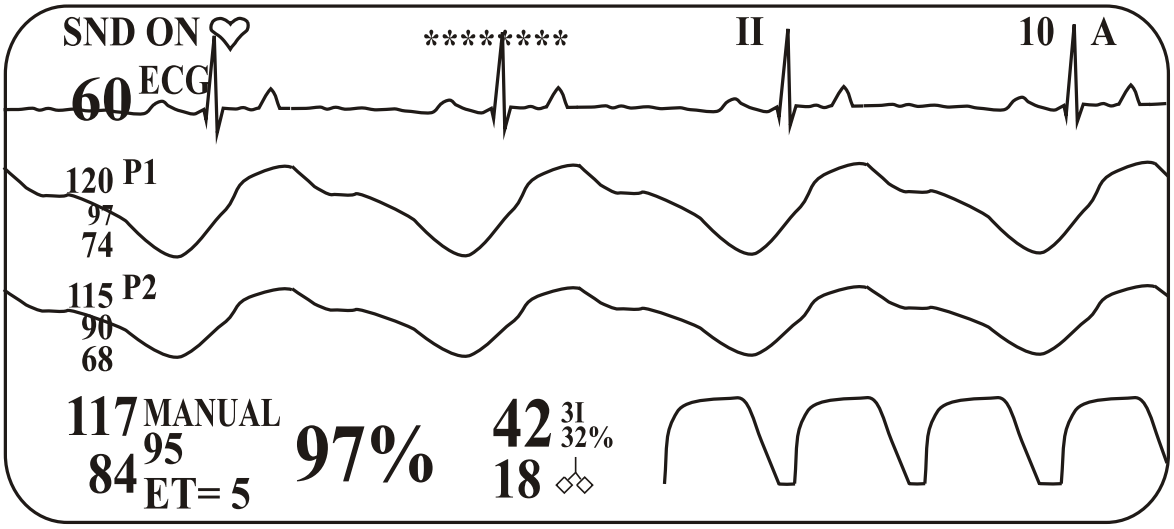
9538

Magnitude™ 3150M MRI Monitor
Omni-Trak™ 3150 MRI Monitor



Operations Manual

INVIVO
RESEARCH, INC.

Invivo Research, Inc

Magnitude™ 3150M MRI Monitor
Omni-Trak™ 3150 MRI Monitor

Operations Manual

INVIVO
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EQUIPMENT CLASSIFICATION	
Classification according to IEC-601-1	
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 a flammable anesthetic mixture with air or with oxygen or nitrous oxide.	

PRECAUTIONS

NOTE

This Operations Manual will describe both the **Magnitude™ 3150M** and **Omni-Trak™ 3150 MRI Monitors** in detail. For simplicity the manual will refer to both these systems by the name "**3150(M) MRI Monitor**" except in the cases where a feature applies only to one of the two systems, in which case the specific 3150(M) MRI system will be referenced.

General

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

The **3150(M) MRI Patient Monitoring System** is comprised of the 3150(M) MRI Monitor and a Remote Monitor (Millennia® 3155MVS or 3155A). Always operate the **3150(M) MRI Monitor** with its designated remote monitor.

The accuracy of the measurements can be affected by the position of the patient, the patient's physiological condition, and other factors. Always consult a physician for interpretation of measurements made by this monitor.

To avoid remote monitor fall, secure monitor on the shelf or bracket prior to use.

An explosion hazard exists if this monitor is used in the presence of flammable anesthetics.

The operator should read and thoroughly understand this manual and the associated remote monitor manual (Invivo Research, Inc. Part Number 9545) completely before attempting to operate the **3150(M) MRI Monitor**.

If any system failure occurs (e.g. an unexplained continuous audible alarm) remove the monitor from use, and refer it to qualified service personnel.

When the message "SOUND OFF"is displayed on the 3150(M) MRI Monitor (an "X" is displayed on the screen of the remote 3155 MVS or 3155A monitor), the audible alarm tone will not sound for any reason.

Perform operational checkout before each use. If monitor fails to function properly, refer to qualified service personnel.

For safe and accurate operation and MRI compatibility, use only recommended Invivo Research patient electrodes, cabling, lead wires, cuffs, hoses, sensors, tubing, etc. A listing of these can be found in the Accessory Listing within this manual, or by contacting Invivo Research directly.

For continued operation, always connect the monitor to AC Main Power through the AS153 AC Power Adapter when a Low Battery indication occurs. Failure to do this can lead to interruption of monitoring and/or damage to the monitor's battery(s).

The system may not conform to all performance specifications if stored or used outside the environmental specifications identified in Appendix A in the rear of this manual.

Do not apply any unnecessary pressure to the screen area of the monitor. Severe pressure applied to this portion of the monitor could result in damage or failure of this screen.

All equipment not complying with IEC 601-1 should be placed outside the patient environment. Only connect IEC 601-1 compliant equipment to this monitor. To avoid potentially hazardous leakage currents, always check the summation of leakage currents when several items of equipment are interconnected.

For proper equipment maintenance, perform the service procedures at the recommended intervals as described in the monitor's service manual.

Single use devices should never be reused.

PRECAUTIONS (Continued)

Electrical Safety

To avoid an electrical hazard, never immerse the unit in any fluid or attempt to clean it with liquid cleaning agents. Always disconnect monitor from AC Main Power before performing cleaning or maintenance.

Shock hazard exists if operated without chassis cover. Refer servicing to qualified service personnel only.

For continued protection against fire hazard, replace fuses with same type and rating only.

Avoid use of electrical power extension cords. Electrical power extension cords may create a safety hazard by compromising the grounding integrity of the monitor.

If the integrity of the earth conductor of the AC main power cable is in doubt, operate the monitor on internal battery power until proper earth connection is confirmed.

If monitor becomes accidentally wet during use, discontinue operation of the monitor until all affected components have been cleaned and permitted to dry completely. Contact your local Invivo Research, Inc. representative if additional information is required.

This monitor and its listed accessories may be safely powered by the voltages 110-120/220-240 VAC having a frequency of 50 or 60 Hz.

MRI Use Precautions

Certain components of this device will be affected by the magnetic and radio frequency fields present in your MRI System. Confer with your MRI physicist and/or Radiology staff to identify the proper placement and use areas for the monitor and its accessories, as defined on the monitor or accessory labeling. Failure to properly place the monitor and its accessories in the Magnet Room will result in monitor failure, and possible patient or user injury. Always position the **3150(M) MRI Monitor** at, or outside, the 5000 Gauss (0.5T) field line of the MRI system. A slight distortion of the MRI magnetic field homogeneity could result or possible damage to either the monitor's NIBP or EtCO2 pump could occur.

Always verify proper communication of the **3150(M) MRI Monitor** with the Remote Monitor(s) prior to patient use.

MRI Magnet Room Placement. The **3150(M) MRI Monitor** is designed to be used in conjunction with one or two remote monitor(s). The **3150(M) MRI Monitor** is specially designed not to interfere with MRI operations and may be used inside the MRI Magnet Room in any location at or outside the 5000 Gauss (0.5T) Field Line of the MRI System. If brought closer than the 5000 Gauss Field Line, the NIBP monitor pump and EtCO2 pump may fail to operate.

The **Remote Monitor(s)** are also specifically designed not to interfere with MRI operations, and may be used in the Magnet Room at or outside the 1000 Gauss (0.1T) Field Line of the MRI System. If brought closer than the 1000 Gauss Field Line, monitor damage (failure to operate) may result.

Risk of RF current burn. Cables which become inadvertently looped during MRI act as conductive lines for RF induced currents. When lead wires or other cables form a conductive loop in contact with the patient's tissue, minor to severe burning can result.

PRECAUTIONS (Continued)

MRI Use Precautions (Continued)

Perform the following to minimize risk of RF current burn:

1. Place cables and lead wires neatly in straight alignment with no looping.
2. Keep the length of lead wires and patient cable within the bore to a minimum.
3. RF burn risk increases when multiple sensors/cables are in use. Such combinations are not recommended.
4. The high radio frequency (RF) power used in MRI scanning poses an ever-present risk of excessive heat at the monitoring sites and, therefore, the risk of RF current burn. **Should power levels greater than S.A.R. of 4 w/kg peak (0.4 w/kg average) be used, the risk of patient burn greatly increases.** As a result, monitoring of ECG or Respiration (derived from ECG leads) at power levels of greater than 4 w/kg peak (0.4 w/kg average) is not recommended for the general patient population. Such monitoring should only be attempted on conscious patients with good temperature reflex so they may warn the operator of excessive heat at the monitoring sites.
5. High RF Power may cause patient heating or burns. For scans with average S.A.R. > 1 w/kg, limit scan time to 5 minutes and pause at least 3 minutes between scans to allow ECG Cable to cool.

MRI Compatibility

The Quadtrode® MRI ECG Electrode Pad, and ECG Patient Lead Wires and Cable, are compatible with Magnetic Resonance Imaging (MRI) Systems within the following guidelines:

- MRI systems with static magnetic field strengths up to 1.5 Tesla.
- Usable within the MRI system bore with Specific Absorption Ratios (S.A.R.'s) up to 4.0 w/kg (peak). Use with higher S.A.R.'s greatly increases the risk of patient burns.
- Non-Magnetic materials are used in the construction of these assemblies.
- If scanned directly across the plane of the ECG electrode element, a slight image distortion may be seen at the skin surface where the electrode element is positioned.

ECG

For best ECG and Heart Rate monitoring, always select the optimum lead configuration which has the least artifact and largest waveform(s) being detected for monitoring use.

Failure to respond to a Lead Fail alarm will cause a lapse in your patient's monitoring. Always respond promptly to this and any other alarms.

MRI induced radiofrequency artifact can sometimes cause inaccurate heart rates. Inspect the ECG waveform during MRI scanning if spurious heart rates are observed.

PRECAUTIONS (Continued)

ECG (Continued)

B_o (static) magnetic field artifact can present artificially-induced augmented T waves during ECG monitoring. Due to the effects of the magnetic field on the moving blood of the patient, follow the recommended ECG Electrode Placement to minimize this type of artifact.

An inoperative ECG monitor is indicated by absence of an ECG waveform and a simultaneous Lead Fail alarm.

Heart rate values may be adversely affected by cardiac arrhythmia, or by operation of electrical stimulators.

Pressures

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

For invasive pressure monitoring, routinely inspect the catheter and/or pressure line for leaks after zeroing. Always follow the pressure transducer/catheter manufacturer's use recommendations.

Never place the pressure transducer(s) within the MRI bore. Transducer failure or noisy MRI images can result.

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.

Always zero the pressure transducer(s) prior to patient use.

Non-physiological pulsatile invasive pressure waveforms (e.g., such as found during intra-aortic balloon pump use) can lead to inaccurate blood pressure readings. If questionable values are observed, re-check patient's pressures by alternate means before administering medication or therapy.

Air that may be trapped within the pressure transducer or its associated tubing should be removed by flushing the system following established hospital or catheter lab procedures.

The fluid within the pressure transducer system is a conductive connection to the patient, and should not contact other conductive parts, including earth ground.

NIBP

Use only MRI Compatible NIBP Accessories (See MRI Accessory list in this Section).

When using the NIBP portion of this instrument to measure blood pressure, remember that the patient's blood pressure readings are not continuous, but are updated each time a blood pressure measurement is taken. Set a shorter interval for more frequent updating of the patient's blood pressure.

Do not attach the cuff to a limb being used for infusion. Cuff inflation can block infusion, possibly causing harm to the patient.

Frequent NIBP measurements can cause pooling of the blood in the limb (hemostasis), and peripheral tissue/nerve damage. Allow sufficient time for blood recirculation to prevent pooling of the blood in the limb.

Arrhythmic and/or erratic heart beats (or severe motion artifact, such as tremors or convulsions) can result in inaccurate readings and/or prolonged measurements. If questionable readings are obtained, re-check patient's vital signs by alternate means before administering medication.

PRECAUTIONS (Continued)

NIBP (Continued)

To prevent possible nerve damage to the limb, apply the NIBP cuff as recommended by current AHA guidelines for blood pressure monitoring.

To ensure accurate and reliable measurements, use only recommended patient cuffs/hoses. For best accuracy, use the appropriate cuff size for each patient as recommended by the current AHA guidelines for blood pressure monitoring.

Always tighten the cuff air hose connections snugly into place for proper operation.

Some reusable NIBP cuffs contain a medical-grade latex rubber. Patients sensitized to latex rubber can have an allergic reaction when exposed to this material. Avoid the use of cuffs which contain latex rubber on patients who are allergic to this material.

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

To prevent skin abrasion, apply and remove cuff carefully. Keep Velcro® (hook and latch) retention areas away from the skin.

Always use recommended NIBP cuffs and hoses. Avoid compression or restriction of NIBP cuff hose.

SpO2

Use only MRI compatible fiberoptic SpO2 accessories (See MRI Accessory list in this Section).

Use only the Fiberoptic SpO2 sensors recommended by Invivo Research, Inc. A listing of these can be found in the Accessory List within this manual, or by contacting Invivo Research, Inc. directly.

The Fiberoptic SpO2 sensors are constructed of fiberoptic glass and should always be handled with care to prevent damage. Improper handling can reduce both the signal transmission quality and the SpO2 measurement sensitivity. Improper handling can also shorten the SpO2 sensor's useful life.

The numeric measurement values are updated every 1 second on the monitor display.

The pulse oximeter feature in this monitor is designed to display functional SpO2 values.

The pulse oximeter pulsatile waveform is not proportional to the pulse amplitude, but adjusts the waveform amplitude as needed for proper viewing.

All monitor alarms are categorized as medium priority, unless otherwise specified.

Avoid placement of the SpO2 probe on the same limb with an inflated blood pressure cuff. Cuff inflation could result in inaccurate readings and false alarm violations.

SpO2 monitoring requires the detection of valid pulses to correctly determine SpO2 and Heart Rate values. During conditions of gross artifact, or in the absence of valid pulses, the SpO2 /rate values may not be correct.

PRECAUTIONS (Continued)

SpO2 (Continued)

The SpO2 monitoring portion of this monitor is intended to measure arterial hemoglobin oxygen saturation of functional hemoglobin (saturation of hemoglobin functionally available for transporting oxygen in the arteries). Significant levels of dysfunctional hemoglobins, such as carboxyhemoglobin or methemoglobin, may affect the accuracy of the measurement. Also, Cardiogreen and other intravascular dyes may, depending on their concentration, affect the accuracy of the SpO2 measurement.

Always shield the SpO2 sensor from extraneous incident light sources. Such extraneous light can cause SpO2 reading or pulse detection errors.

Frequently inspect the SpO2 sensor site for possible pressure tissue necrosis during prolonged monitoring. Reposition the sensor at least every 4 hours. Special care should be exercised when tape is used to secure the sensor, as the stretch memory properties of most tapes can easily apply unintended pressure to the sensor site.

EtCO2

Always select the appropriate EtCO2 Tubing Set and gas sampling flow rate for the patient being monitored. Verify that the patient's breathing efforts and timing coincide with the monitor's waveform before completion of the patient set-up.

Frequently inspect the EtCO2 patient tubing for proper gas flow. Avoid kinking of the EtCO2 patient tubing that can result in leaking, reduction, or cut-off of the sample gas flow. Inaccurate gas measurements could result.

During EtCO2 monitoring, always use the appropriate water vapor evacuating tubing (i.e. Nafion® tubing) included in the patient circuit tubing kit to prevent inaccurate EtCO2 readings due to water vapor content of the patient's exhaled breath.

For proper operation, check the EtCO2 calibration during routine service. Routine calibration should not be required, but if the specified operation does not occur, have a qualified service person recheck the calibration. Proper re-calibration can only be performed during factory service.

EtCO2 patient tubing and its associated components are intended for single-patient use only. Avoid cleaning or disinfecting these items for reuse. Inaccurate gas measurements could result.

To prevent inaccurate or missed readings, keep the EtCO2 patient tubing clear of any moving mechanisms which may kink, cut or dislodge the patient tubing.

Avoid connecting the EtCO2 calibration gas canister to the monitor by any method other than with the designated calibration tubing. Connecting by any other method could invalidate the calibration, and/or damage the monitor.

The EtCO2/N2O measurements are automatically pressure compensated over an ambient pressure range of <645 to >795 mmHg.

The EtCO2/N2O measurement displays the sampled value within 1 second of when the gas was sampled.

The alarm tone volume exceeds 60 dBA at a distance of 1 meter when the alarm tone volume adjustment is set above selection number 4.

PRECAUTIONS (Continued)

Other

Always secure the **3150(M) MRI Monitor's** wheel locks when placed within the MRI Magnet Room.

This product, or any of its parts, should not be repaired other than in accordance with written instructions provided by Invivo Research Inc., or altered without prior written approval of Invivo Research Inc.

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 Research Inc., or its authorized service personnel.

This monitor is equipped with a demonstration mode which displays simulated electronic patient data for training or demonstration purposes. Do not attach a patient to the monitor whenever this simulation is present on the monitor display ("SIMULATION" can also be seen in the screen center). Failure to properly monitor the patient could result.

The patient connector inputs for all parameters are protected against the use of a defibrillator by internal circuitry, and 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.

There are no known electromagnetic or other hazardous interference between the monitor and other devices. However, care should be taken to avoid the use of cellular phones or other unintended radio-frequency transmitters in the proximity of the monitoring system.

This monitor uses rechargeable batteries which contain lead, which must be recycled, or disposed of properly. For proper disposal methods, contact your local Invivo Research, Inc. representative or distributor.

USER RESPONSIBILITY

This product will perform in conformity with the description thereof contained in this operating manual and accompanying labels and/or inserts, when assembled, operated, maintained, and repaired in accordance with the instructions provided.

This product must be checked periodically for proper operation. A defective or questionable product should not be used. Parts that are broken, missing, plainly worn, distorted, or contaminated should be replaced immediately.

Should such repair or replacement become necessary, Invivo Research Incorporated (IRI) recommends that a telephone call or written request for service be made to the factory or nearest service center. IRI's toll free number is: (800) 331 - 3220 or (407) 275 - 3220, ask for Technical Assistance.

This product or any of its parts should not be repaired other than in accordance with written instructions provided by IRI or altered without the prior written approval of IRI.

The user of the 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 IRI or IRI authorized service personnel.

MRI ACCESSORIES

ECG

Item Description	Model Number
Quadtrode® MRI ECG Patient Cable and Lead Wire Set	9240
Quadtrode® MRI ECG Electrodes, 50/box	9303N
MRI ECG Patient Cable, unshielded, safety, 10 foot	9240B
MRI ECG Patient Lead Wire Set	9240A
Electrode Impedance Meter / Patient Prep-Check	9392
ECG/EEG Skin Prep Gel, 1 tube 4 ounce	9009
Siemens Wireless Telemetry Option	3153-1

NON-INVASIVE BLOOD PRESSURE

Reusable BP Cuffs and Hoses

Twin-Lumen Adult Air Hose (18 ft. length)	9010M
Single-Lumen Neonatal NIBP Air Hose (18 ft. length)	9010NM
Infant MRI BP Cuff	9050M
Pediatric MRI BP Cuff	9060M
Adult Standard MRI BP Cuff	9070M
Adult Large Arm MRI BP Cuff	9080M
Adult Thigh MRI BP Cuff	9090M

Disposable BP Cuffs

Single-Lumen Cuffs With Hook-and-Loop (Velcro) Closures

Premature Infant BP Cuff, Size A, Circumference range 5.5 to 7.5 cm.	
Box of 20 Cuffs	9020NV
Case of 200 Cuffs	9020CV
Neonatal BP Cuff, Size B, Circumference range 7.5 to 10.5 cm.	
Box of 20 Cuffs	9030NV
Case of 200 Cuffs	9030CV
Infant BP Cuff, Size C, Circumference range 10.5 to 15.0 cm.	
Box of 20 Cuffs	9040NV
Case of 200 Cuffs	9040CV

Single-Lumen Cuffs With Tape Closures

Premature Infant BP Cuff, Size A, Circumference range 5.5 to 7.5 cm.	
Box of 20 Cuffs	9020N
Case of 200 Cuffs	9020C
Neonatal BP Cuff, Size B, Circumference range 7.5 to 10.5 cm.	
Box of 20 Cuffs	9030N
Case of 200 Cuffs	9030C
Infant BP Cuff, Size C, Circumference range 10.5 to 15.0 cm.	
Box of 20 Cuffs	9040N
Case of 200 Cuffs	9040C

PULSE OXIMETRY

Item Description — Model Number

MRI Fiberoptic Finger Sensor w/cable (16 ft. length) 9367

MRI Fiberoptic Wrap Sensor w/cable (16 ft. length) 9399
Oxi-Wrap Sensor Wrap, Large Fabric, 50/box 9374
Oxi-Wrap Sensor Wrap, Large Foam, 50/box 9375
Oxi-Wrap Sensor Wrap, Small Fabric, 50/box 9376
Oxi-Wrap Sensor Wrap, Small Foam, 50/box 9377

SpO2 Grip™ MRI Sensor Kit 9399A
Fiberoptic SpO2 Grip™ Sensor Kit includes the fiberoptic cable and two (2) medium (Pediatric) and one (1) large (Adult) size Grips. Cable is 16 foot in length.
SpO2 Grip™ MRI Large (Adult) Replacements 9399AA
Replacement Grips for use with 9399A SpO2 Grip™ MRI Sensor (Box of 3).
SpO2 Grip™ MRI Medium (Pedriatric) Replacements 9399AP
Replacement Grips for use with 9399A SpO2 Grip™ MRI Sensor (Box of 3).

END-TIDAL CO2

EtCO2 Sampling Kit 9010D
Contains 20 foot co-extruded sampling tube polyethylene inner core with PVC jacket, Nafion® tube, elbow adapter and 0.8 micron disk filter.
Nasal ETCO2 Sampling Kit 9010DA
Contains 10 foot co-extrude sampling tube, polyethylene inner core with PVC jacket, Nafion® tube, elbow adapter and 0.8 micron disk filter.
EtCO2 Calibration Gas: aerosol 10% CO2, 50% N2O, Balance N2 . . . . . 9010F
QC Check Gas: 5% CO2, 45% N2O, 50% O2; 11 Liter Aerosol Container 9034F

Sampling Kit Replacements

Nafion® tube, ME dryer (1 replacement) 9010H
Endotracheal Tube Adapter, package of 50 9025
Hydrophobic Disk Filter, 0.8 Micron, Male/Female Locking Luer, package of 50 9026
Co-extruded Nasal ETCO2 Sampling Line 9028
10 foot co-extruded polyethylene inner core with PVC jacket, male/female locking luer, package of 50.

Nasal ETCO2 Supplies

Adult EtCO2 Cannula 9012
Pediatric EtCO2 Cannula 9013
Infant EtCO2 Cannula 9014
Intermediate Infant EtCO2 Cannula 9015
Large Adult EtCO2 Cannula 9016

Item Description — Model Number

Nasal ETCO2 Supplies (Continued)

Infant Bifurcated/Divided Cannula -O2 and ETCO2 . . . . . 9016A
7 foot O2 line and 7 foot CO2 line. For simultaneous delivery of oxygen and ETCO2 sampling.

Intermediate Infant Bifurcated/Divided Cannula-O2 and ETCO2 . . . . . 9016B
7 foot O2 line and 7 foot CO2 line. For simultaneous delivery of oxygen and ETCO2 sampling.

Pediatric Bifurcated/Divided ETCO2 Cannula -O2 and ETCO2 . . . . . 9016C
7 foot O2 line and 7 foot CO2 line. For simultaneous delivery of oxygen and ETCO2 sampling.

Adapter, Luer Lock, Female/Female 9027
For conversion of Millennia male front panel connector for use with non-Invivo sampling lines. Package of 10.

Water Trap Start Up Kit, Disposable 9436
Includes water trap and connection tubing, Nafion® tube ME dryer, Hydrophobic disk filter 0.08 micron.

Waste Gas Scavenger Line 9471
Includes 8 foot waste gas line to redirect the waste gas.

INVASIVE BLOOD PRESSURE

Pressure Transducer Cable Assembly Kit 9390K

Transducer Domes, bag of 10, disposable 9390L

Pressure Transducer Cable Pole Mount Kit 9462
Includes modular transducer mounting plate and horizontal manifold pole clamp. Enables the Invasive pressure domes to be mounted on the 3150 MRI Pole and is adjustable to heart level.

CARTS AND MOUNTS

Magnitude™ 3150M and 3150 MRI Pole Mounting Replacement Basket Kit 9456
Includes accessory storage basket, pole mounting bracket and all mounting hardware.

Pressure Transducer Cable Pole Mount Kit 9462
Includes modular transducer mounting plate and horizontal manifold pole clamp. Enables the Invasive pressure domes to be mounted on the Magnitude® or the 3150 MRI Pole and is adjustable to heart level.

MRI GATING OPTIONS FOR MAGNITUDE™ 3150M

MRI GATING OPTIONS FOR 3150

Item Description — Model Number

GE Horizon/LX 3150 MRI Gating Option 9244
Provides cardiac and peripheral gating. Connects 3150 MRI Patient Monitor to GE Horizon / LX 0.5T, 1.0T and 1.5T Magnets.

GE Signa 5X 3150 MRI Gating Option 9253
Provides cardiac and peripheral gating. Connects 3150 MRI Patient Monitor to GE Signa 5X 0.5T, 1.0T and 1.5T Magnets.

Hitachi Aris and Celeris Connection for 3150 MRI Gating Option 9572
Provides cardiac and peripheral gating.

Marconi Polaris, Infinion, Eclipse and Infinion Connection for 3150 MRI Gating Option . . 9572
Provides cardiac and peripheral gating.

Siemens Vision & Expert 1.0T Connection for 3150 MRI Gating Option 9243
Provides cardiac and peripheral gating.

Siemens Symphony & Harmony Connection for 3150 MRI Gating Option 9270
Provides cardiac and peripheral gating.

Phillips NT 1.5T Connection for 3150 MRI Gating Option 9247
Provides cardiac and peripheral gating.

Phillips Intera 1.5 and 3.0T / InteraCV 1.5T Connection for 3150 MRI Gating Option . . . 9247A
Provides cardiac and peripheral gating.

Toshiba Opart and Excelart Connection for 3150 MRI Gating Option 9272
Provides cardiac and peripheral gating.

MISCELLANEOUS

Item Description	Model Number
Magnitude™ 3150M and 3150/3155 Repeater Kit *Service Technician Installation fee quoted separately.*	9454
3155 Millennia® Series Rechargeable Battery Pack, 12V	HB10
Magnitude™ 3150M or 3150 battery Pack 12 V 6.5 AH	HB02
3155 Millennia® Software Upgrade Kit Includes both the current AM46 PCMCIA revision upgrade and a AM55 PCMCIA SRAM Data Storage card and all instructions.	9458
3155 Millennia® PCMCIA Card, AM46 Contains the latest software revision.	9465
3155 Millennia® PCMCIA Card, AM55 SRAM Data Storage / Recall AM55 is used to Store and Recall the 3155 Millennia system setups. This will eliminate the need to manually set up the 3155 Millennia to the user preferred selections of display setup, alarm limit values, recorder functions, patient type, NIBP interval, or other initial settings after a software update is done with the PCMCIA card or to set up multiple monitors with identical settings.	9466
AC Power Supply, 120 VAC, 50/60 Hz	AS153
AC Power Supply, 220-240 VAC, 50/60 Hz	AS153-C
AC Power Supply, 100 VAC, 50/60 Hz	AS153-J
AC Power Cord	AS18
3150/AS153 Interconnect Cable	AC348
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SECTION 1
INTRODUCTION

1. INTRODUCTION

The **Magnitude™ 3150M MRI Monitor** is an evolution of the **Omni-Trak™ 3150 MRI Monitor**. Among other features, the **Magnitude™ 3150M MRI Monitor** includes Digital Signal Processing (DSP) and an MRI View Mode. DSP provides improved ECG performance and reduction of MRI gradient artifact. The MRI View Mode provides adaptive ECG gradient filtering techniques for enhanced ECG display during MRI sequences. Both models of the 3150 MRI Monitor provide the operator with ECG, Respiration, SpO2, NIBP, EtCO2 and Invasive Pressures monitoring. Full control of patient monitoring is provided via the Invivo Research, Inc. **Millennia® 3155A/3155MVS Monitor** equipped with MRI shielding and set to Remote Communication Mode.

If operating a dual monitor system, the 3155MVS and 3155A patient monitors are interactive with one another through the 3150/3150M. As the "communication unit" the 3150/3150M acts to keep the commands that control patient parameter function synchronized throughout the MRI monitoring system. Should the 3150/3150M be turned off, it is possible to have patient parameters on the 3155A set to a particular configuration with the 3155MVS set to a different configuration; when the 3150/3150M is turned on the system will synchronize and all patient configurations will reflect the 3155A configuration.

This Operations Manual will describe both the **Magnitude™ 3150M** and **Omni-Trak™ 3150 MRI Monitors** in detail. For simplicity the manual will refer to both these systems by the name "**3150(M) MRI Monitor**" except in the cases where a feature applies only to one of the two systems, in which case the specific 3150(M) MRI system will be referenced. Also, in the case of the Millennia® 3155MVS and 3155A Remote Monitors, they will be referred to (in this manual) only as "Remote Monitor(s)."

CAUTION

For continued patient safety and image integrity, use only those Invivo Research accessories and equipment specifically designated for MRI.

1.1 Features. The **3150(M) MRI Monitor** has been carefully engineered to take full advantage of the most advanced technology.

- **Integrated Control.** Every feature of the **3150(M) MRI Monitor** is synchronized with the Remote Monitor. This removes the need to manually check each monitor before beginning a scan.
- **Software Control.** The integration of the **3150(M) MRI Monitor** and the Remote Monitor into a cohesive ***MRI Monitoring System*** is controlled by advanced software.
- **Alarms and Trending.** The **3150(M) MRI Monitor** sends patient information to the Remote Monitor, where it can be analyzed and stored. Setting of Alarm High and Low Limits, Alarm Latching/Non-Latching, Alarm Tone and Volume, as well as all Trend Information Storage, is performed at the Remote Monitor.
- **Complete Parameter Monitoring.** This monitor will provide accurate and up-to-the-minute monitoring of a patient's ECG, NIBP, Invasive Blood Pressure, SpO2 and ETCO2.
- **Digital Signal Processing (Magnitude™ 3150M MRI Monitor only).** Digital Signal Processing (DSP) of the ECG waveform is an innovative approach in removal of MRI gradient interference artifact from the ECG waveform.

1.2 Use of this Manual. For detailed information on any feature which the **3150(M) MRI Monitor** provides, consult the Table of Contents and, after you have located the particular paragraph which you want to read, turn to the appropriate page. Every item in this document (such as pages, paragraphs, figures, tables, etc.) is numbered with the Section Number first followed with the Sequential Number of the item being numbered. For instance, if you want to look at **Figure 3-1**: turn to the List of Figures in the Table of Contents, find **Figure 3-1** in the list and follow the dotted line to the page number where **Figure 3-1** can be found. **Appendix A** contains the Specifications for this monitor.

1.3 Product Description. The **3150(M) MRI Monitor** is a comprehensive MRI Patient Monitoring System that displays up to six (6) different patient parameters. The information that this monitor is capable of supplying to the physician may be used as an aid in the determination of a diagnosis concerning the condition of a patient. This monitor has been designed to perform to specification in MRI Magnet rooms where observation of a patient's parameters is necessary. This monitor is mounted on a four (4) wheeled base for stability during patient movement to and from the Magnet Room.

The **3150(M) MRI Patient Monitor** includes the following Vital Sign Parameters:

- **ECG**
- **Invasive Blood Pressure**
- **Non-Invasive Blood Pressure**
- **SpO2**
- **ETCO2**
- **Respiration**

1.3.1 System Parameters. The **3150(M) MRI Monitor System Parameters** allow simultaneous processing and display of up to four parameter waveforms and associated numeric values from each different parameter. All the Patient Information is clearly displayed on a Flat Panel Display Screen.

1.3.2 User Interface. The Control Panel, located to the right of the display screen, provides user interface with this monitor. From this Control Panel the operator may select the Lead and Size for ECG, Zero Invasive Blood Pressure 1 and 2, select the Patient Type for NIBP, set the NIBP automatic Cycle Time, Start/Stop an NIBP reading and turn monitor power On and Off.

1.3.3 Versatility. With its complete offering of vital sign parameters, the **3150(M) MRI Monitor** may be configured to meet the MRI monitoring needs of a wide spectrum of patients from Neonate to Adult. Every available parameter may be easily accessed and adjusted from the MRI Control Room utilizing the Remote Monitor.

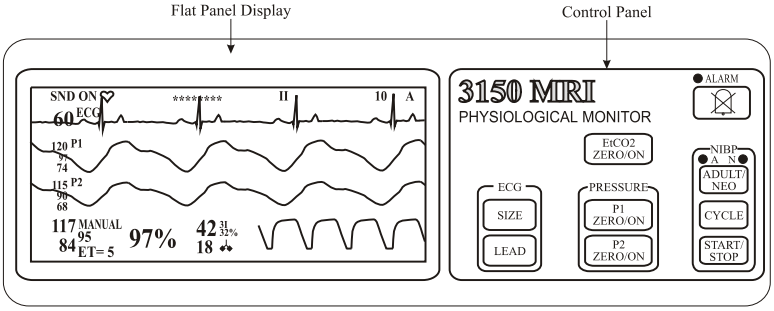

Figure 1-1. 3150(M) MRI Monitor Top Panel

1.4 Top Panel. (**See Figure 1-1**) The **3150(M) MRI Monitor** has limited control of the parameters which it monitors. Primary control is provided by the Remote Monitor. The Top Panel of the **3150(M) MRI Monitor** consists of a Flat Panel Display and a Control Panel. The Flat Panel Display provides clear and accurate waveforms of monitored parameters. The Control Panel has nine control keys to provide secondary control over some of the features of this monitor.

1.4.1 Control Panel. (**See Figure 1-2**) The **3150(M) MRI Monitor** control panel provides secondary control over some of the features of the monitor. The following is a description of the Control Keys.

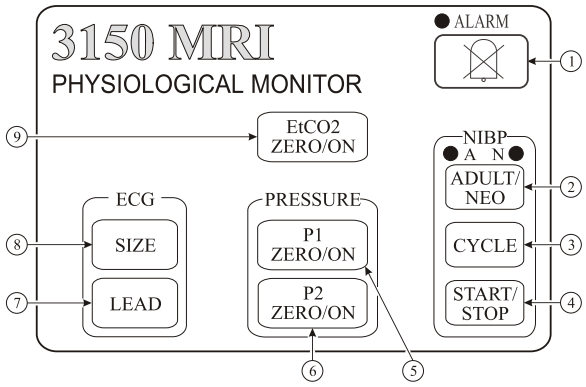

Figure 1-2. Control Panel

a. **ALARM. (Item 1)** The **ALARM** Silence Control Key may be used to silence an existing alarm or, if no alarm condition exists, to place the Alarms on Hold. If an Alarm Limit is violated, pressing the **ALARM** Silence Control Key will silence the Alarm Tone. While the parameter continues to violate its limits, the numerics of the violating parameter continue to flash on the screen, and a short "reminder" tone sounds every 60 seconds. The Red LED next to the word ALARM illuminates whenever an active alarm limit is violated. The **ALARM** Silence Control Key may also be used to access the system screen by pressing and holding the key until the screen appears.

b. **NIBP Patient Selection. (Item 2)** The NIBP Patient Selection Control Key allows the operator to change the patient from Adult to Neo and vice versa.

c. **NIBP CYCLE. (Item 3)** The **NIBP CYCLE** Control Key allows the operator to switch between the automatic and manual mode of operation and adjust the Time Cycle in the Automatic Measurement Mode of the NIBP System.

d. **NIBP START/STOP. (Item 4)** The **NIBP START/STOP** Control Key allows the operator to manually start an NIBP measurement and, if a measurement is in progress, allows the operator to stop an NIBP measurement.

e. **P1 ZERO/ON. (Item 5)** The **P1 ZERO ON** Control Key allows the operator to turn P1 On or Off, and, when P1 is first turned On, this key will zero the P1 Pressure Transducer.

f. **P2 ZERO/ON. (Item 6)** The **P2 ZERO ON** Control Key allows the operator to turn P2 On or Off, and, when P2 is first turned On, this key will zero the P2 Pressure Transducer.

g. **ECG LEAD. (Item 7)** The **ECG LEAD** Control Key allows the operator to switch between the available ECG leads.

h. **ECG SIZE. (Item 8)** The **ECG SIZE** Control Key allows the operator to adjust the size of the waveform for different amplitudes.

i. **EtCO2 ZERO/ON. (Item 9)** The **EtCO2 ZERO/ON** Control Key allows the operator to initiate a rezero of the EtCO2 System when pressed momentarily and, when pressed and held for three (3) seconds, will turn EtCO2 ON or OFF.

1.4.2 Flat Panel Display. The Flat Panel Display Screen displays up to four (4) Parameter Waveforms of approximately five (5) seconds of patient data. The Normal Screen (**See Figure 1-3**) contains three (3) different display groups: the first located along the top of the screen and is called the **Information Display**, the second is located in the middle of the screen is called the **Vital Signs Trace Display** and the third is located at the bottom of the screen and is called the **Vital Signs Numeric Display**.

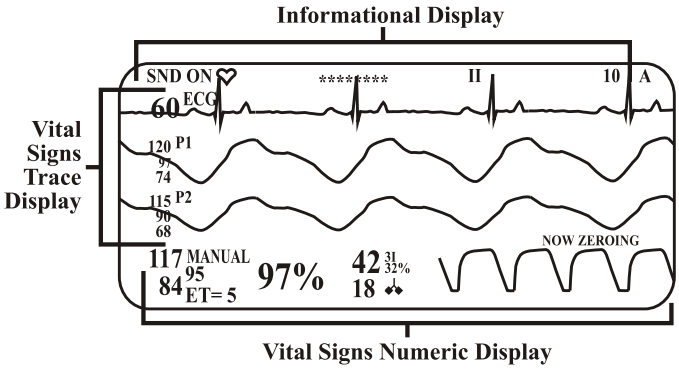

Figure 1-3. The Normal Screen

a. **Informational Display.** (**See Figure 1-4**) The Informational Display provides the operator with a visual status of the setup and operation of the monitoring system. This display contains the Alarm Status, a Heart Symbol, a Lung Symbol, any active Alarm Messages, the selected ECG Lead and the selected ECG Scale.

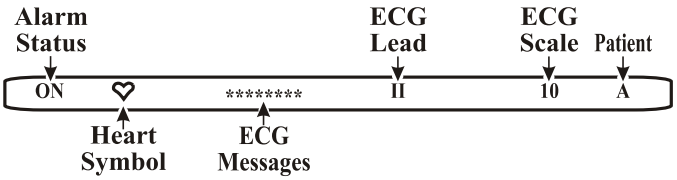

Figure 1-4. The Informational Display

(1) **Alarm Status.** This area provides a visual indication of the Alarm Tone Status. The Alarm Tone, which is set at the Remote Monitor, could be set to SND ON, SND OFF and NO ALMS (flashing).

(2) **Heart Symbol.** The Heart Symbol provides a visual indication of the patient's monitored Heart Rate. This symbol flashes on the screen each time a Heart Beat is detected if a Heart Rate Tone Source is selected at the Remote Monitor.

(3) **ECG Messages.** The ECG Message area provides a visual indication of any violation of system parameters which could require the operator's attention. Possible messages include: **LEAD FAIL**, which indicates that the system has detected a faulty ECG Lead, **OVER-SCALE**, which is displayed when the selected scale is too large for the amplitude of the trace, **ASYSTOLE,** which is displayed when no QRS is detected while ECG is selected as the Heart Rate Source and **ECG = PMU,** which is displayed when the 3150 detects radio communications with the Siemens Wireless Option (IRI Part Number 3153-1) containing a valid ECG from the Siemens PMU. The Alarm Tone, if ON, will sound with the appearance of **LEAD FAIL** or **ASYSTOLE**.

(4) **ECG Lead.** ECG Lead provides a visual indication of the ECG Lead Selection. The Lead options are: I, II, III, AVR, AVL, AVF and CAL.

(5) **ECG Scale.** ECG Scale provides a visual indication of the ECG Scale Selection. The Size options are: 5, 10, 15, 20, 25, 30, 40 and A (Auto).

(6) **Patient.** The Patient area provides a visual indication of the selected Patient Mode of Operation.

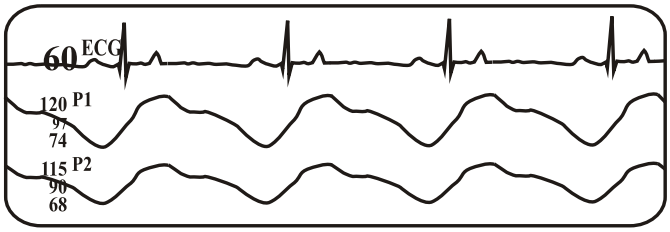

Figure 1-5. Vital Signs Trace Display

b. **Vital Signs Trace Display.** (**See Figure 1-5**) The Vital Signs Trace Display is located in the central area of the Normal Screen. This area contains up to three waveform traces as follows:

(1) **Trace A.** The top trace on the display is designated Trace A. The ECG waveform trace is displayed in this area with a numeric indication of the patient's Heart Rate to the left beside a visual indication of the parameter being monitored.

(2) **Trace B.** The middle trace on the display is designated Trace B. The P1 Pressure waveform trace is displayed in this area with a numeric indication of the Systolic, Mean and Diastolic pressures to the left next to a visual indication of the parameter being monitored.

(3) **Trace C.** The bottom trace on the display is designated Trace C. This area may contain either the P2 Pressure waveform trace or, if P2 is OFF, the SpO2 waveform trace. A numeric indication of the measurement value of the parameter is on the left next to a visual indication of the parameter being monitored.

Figure 1-6. Vital Signs Numeric Display

c. **Vital Signs Numeric Display.** (**See Figure 1-6**) The Vital Signs Numeric Displays provides numeric indications for NIBP and SpO2 along with numerics and a waveform trace for EtCO2/Respiration. The following is a description of the Vital Signs Numeric Display:

(1) **NIBP Numerics.** The patient's Non-Invasive Systolic, Mean and Diastolic pressures are displayed here along with a visual indication of the operational status of the NIBP System (Automatic or Manual) and the Elapsed Time (ET) since the last NIBP determination.

(2) **SpO2 Numeric.** The patient's Oxygen Saturation value is displayed here if P2 is On.

(3) **EtCO2/Respiration Display.** (If EtCO2 Option is installed) The patients EtCO2/Respiration values are displayed to the right of NIBP and, if P2 is On, the SpO2 numeric. This display consists of numeric values concerning EtCO2 and Respiration plus Respiration Waveform Trace.

1.5 System Screen. The System Screen may be accessed by pressing and holding the Alarm Silence control key for approximately 3 seconds. It displays the NIBP diagnostic readings, system voltages, software revision and provides the following menu items:

a. **Sound Volume Adjustment.** The Pulse Tone and Alarm Volume may be adjusted by pressing the **SIZE** control key to increase the volume and the **LEAD** control key to decrease the volume.

b. **ECG Filter Selection.** (**Magnitude™ 3150M MRI Monitor only**) This option allows the ECG Filter to be changed between MON and MRI View mode by pressing the **P1** control key.

c. **Leak Test Selection.** Refer to Service Manual (IRI Part Number 9539).

d. **Exit.** Pressing the **ALARM SILENCE** control key will exit the system screen.

1.6 Parameter Input Panel. (**See Figure 1-7**) The Parameter Input Panel is located on the monitor column below the Control Panel and Display. This panel provides for the future connection of cabling from the **3150(M) MRI Monitor**. The panel contains connections for ECG, P1, P2, SpO2, NIBP and EtCO2.

1.7 Monitoring System Location. The Remote Monitor may be used in either the Control Room or in the Magnet Room outside the 1000 Gauss (0.1T) Field Line. The **3150(M) MRI Monitor** is used in the MRI Magnet Room with the patient. The connection is wireless with communication between the two monitors achieved with an RF Radio Link.

a. The Remote Monitor can be connected to the **3150(M) MRI Monitor** with a specially filtered RF Radio Link.

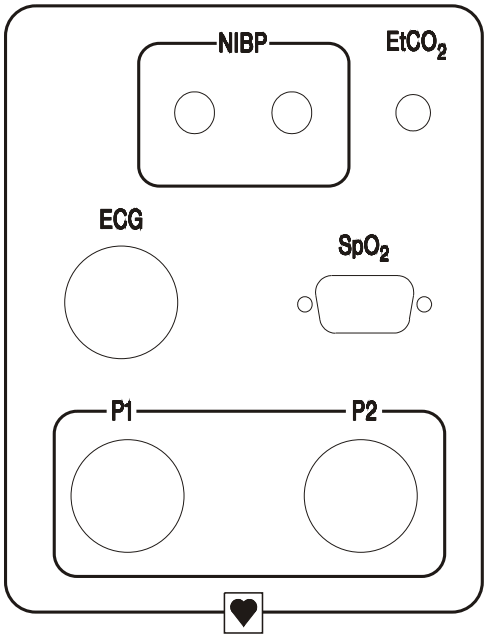

Figure 1-7. Parameter Input Panel

NOTE

The Magnet Room is typically a specially constructed, copper-lined, "RF quiet" room which houses the magnet and filters out signals and radio frequency interferences from the outside environment. The Invivo Research cabling from the monitors inside the Magnet Room runs through a special Filter Block mounted on the wall (penetration panel) outside the Magnet Room designed to filter out noise-producing artifact from the Remote Monitor signals.

1.7.1 MRI Monitoring Components. Complete MRI Patient Monitoring Requirements are met with the **3150(M) MRI Monitor** and Remote Monitor. No other monitor or device is necessary.

NOTE

The **3150(M) MRI Monitor** should be securely mounted (wheel locks engaged) and at least five (5) feet from the bore (outside the 5000 Gauss <0.5T> Field Line of the MRI System), never directly in line with the bore.

The Remote Monitor should be securely mounted to the anesthesia machine or mounting bar outside the 1000 Gauss (0.1T) Field Line.

If in doubt about the exact location of the 1000 and 5000 Gauss Field Lines, check with your MRI Physicist or Radiologist.

1.7.2 3150(M) MRI Monitoring Precautions. The **3150(M) MRI Monitor** has been specifically designed to permit the monitoring of several basic vital signs of patients undergoing MRI scans. However, since MRI involves very high magnetic and Radio Frequency (RF) energy fields, the following precautions must be followed:

a. In general, safe MRI monitoring can only be accomplished with 1) MRI compatible equipment, and 2) properly trained and informed MRI suite personnel, staff well informed of the possible complications and hazards associated with improper use of patient monitoring equipment in the MRI environment.

b. MRI compatible monitors must contain a minimum amount of ferromagnetic material so that the strong attraction from mid and high-field scanners does not pose a serious hazard to the patient, staff and possible damage to the scanner.

c. Equipment should always be placed to avoid magnetic pull by securely mounting or permanently fixing the devices.

d. The high RF power used in MRI scanning poses the ever-present risk of excessive heat at the monitoring sites and therefore the risk of RF current burn.

e. Of particular importance are the precautions associated with monitor sensor cables and ECG lead wires. Cables, of electrical conductive material, that become inadvertently looped during MRI scanning act as conductive lines for RF-induced currents. When lead wires or other cables form this conductive loop in contact with the patient's tissue, minor to severe burning can result.

   To minimize RF current risk:

   (1) Place cables and lead wires neatly in straight alignment with no looping.

   (2) Keep the length of ECG lead wires and patient cable within the bore to a minimum.

   (3) RF burn risk increases when multiple sensor/cables are in use. Such combinations are not recommended.

   (4) In general, excessive power should be avoided. Should power levels greater than S.A.R. of 4 w/kg peak (0.4 w/kg average) be used, the risk of patient burn greatly increases.

(5) High RF Power may cause patient heating or burns. For scans with average S.A.R. > 1 w/kg, limit scan time to 5 minutes and pause at least 3 minutes between scans to allow ECG Cable to cool.

f. Integrity of the ECG waveforms and readouts should be maintained at their optimum. To ensure quality ECG performance:

(1) Use only Invivo Research Quadtrode® MRI ECG Electrode Pad (IRI Part Number 9303N). Never use alcohol to prepare the skin for electrode application, as it removes electrolytes required for good electrode contact. Electrode Pad may be installed on the chest or back (chest for best monitoring). Careful patient prep is required as ECG will be severely degraded by poor electrode contact. Ensure that the skin in the area of the Quadtrode® Pad is dry. Follow the Patient Preparation and Electrode Pad Placement instructions that come with each Quadtrode® Pad. (Shave site if necessary, removing any chest hair.) Use skin prep gel (IRI Part Number 9009) for skin preparation. Place Quadtrode® Pad directly over the heart (**See Figure 4-2**). Ensure contact resistance is less than 8000 ohms (< 2000 ohms for best results) as measured with the electrode Impedance Meter (IRI Part Number 9392). Connect ECG leadwires and secure cable yoke to Quadtrode® Pad with adhesive tab provided on back of Quadtrode® Pad. **Cable may become hot during scanning.** Always keep patient gown and insulative padding between cable and patient's skin.

(2) Large, heavily-breathing patients upon which chest-mounted electrodes and lead wires move vertically with respirations may cause a respiratory artifact on the ECG baseline. Use back mounted electrode setup for better results.

(3) Use all four leads on the patient. Select the "cleanest" lead for monitoring during scan (I, II, III, AVL, AVR, AVF).

(4) The "T" wave may become excessively large (due to electromagnetic flow induced voltage at the leads) and may interfere with QRS detection. Try other leads and/or electrode placement for best results.

1.8 Cleaning Instructions. The monitor is not sterilizable. Never immerse the unit in any fluid or attempt to clean it with liquid cleaning agents. Remove dirt and dust from the monitor by wiping it with a soft, damp cloth.

Stains can be removed from the case by scrubbing it briskly with a damp cloth. Unplug the monitor before cleaning. Do not permit liquid to contact the front or rear of the monitor, or permit liquid to drip into the cooling slots. Allow the unit to dry completely before returning it to operation.

WARNING

Electrical shock hazard: Turn off Monitor and disconnect from AC Power before cleaning. Do not immerse the monitor in any water or liquid for any reason.

1.8.1 Cleaning Accessories. Any reusable patient accessories should be cleaned after each use. Disposable patient accessories should be discarded and replaced with new items.

To clean reusable accessories, first, remove the accessory from the monitor. Remove any dirt or debris using soap and water. Avoid immersing accessory in any fluid for cleaning.

Inspect the accessory for any cracks, holes, tears, cuts, etc., that could affect operation, and replace as necessary.

If disinfection is required, use only the recommended liquid surface disinfectants, unless otherwise specified in the accessories listing. Recommended surface disinfectants include dilute solutions of either quaternary ammonium compounds, iodophors or gluteraldehydes.

SECTION 2

INSTALLATION

2. INSTALLATION

2.1 Introduction. This monitor has been designed to provide a wide variety of patient monitoring parameters. Because the monitor is on a mobile platform, the patient may be connected to the monitor at the bedside before transportation to the MRI Magnet Room.

2.2 Monitor Installation. Remove the monitor from the shipping carton and examine for any damage which may have occurred during shipment. Check all materials against the packing list and purchase request. Save all packing materials, invoice and bill of lading as these may be required to process a claim with the carrier if damage during shipment occurred. Contact Invivo Research, Inc. Customer Service for prompt assistance in resolving shipping problems. Once satisfied that all the listed parts are present and that no damage has occurred during shipment, follow the instructions provided in the shipping carton for the required assembly procedure of this monitor.

a. If N2O or other Anesthetic Gases are used, the **3150(M) MRI Monitor** must be connected to a Gas Scavenging System. This will prevent venting of gases into the room environment and also inaccurate zeroing of the EtCO2 module (as the EtCO2 Intake port, through which ambient air is drawn for zero reference, is located on the base near the Gas Exhaust Port).

CAUTION

The **3150(M) MRI Monitor** should be securely mounted (wheel locks engaged) and at least five (5) feet from the bore (outside the 5000 Gauss <0.5T> Field Line of the MRI System), never directly in line with the bore.

The Remote Monitor should be securely mounted to the anesthesia machine or mounting bar outside the 1000 Gauss (0.1T) Field Line.

The **AC Power Adapter** (**AS153**), if used inside the Magnet Room, must be kept outside the 1000 Gauss (0.1T) Field Line.

If in doubt about the exact location of the 1000 and 5000 Gauss Field Lines, check with your MRI Physicist or Radiologist.

2.2.1 Monitor Location. This monitor has been designed to be mobile between the patient bedside and the MRI Magnet Room. The only locational restriction is that the 3150(M) MRI Monitor must be placed beyond the 5000 Gauss Line while in the Magnet Room.

2.2.2 Preparing the 3150(M) MRI Monitor for Use. Some minor assembly of this monitor is required upon unpacking. Follow the instructions for assembly that come packed with this monitor carefully. Upon assembly, perform the following steps to prepare the monitor for use.

a. Ensure that you have read the Precautions and User Responsibility sections of this manual. This provides important safety information.

b. Ensure that there are no cracks in the monitor case or display.

c. Ensure that all the patient connections are intact.

d. Ensure that all patient cables meet manufacturers recommended condition for patient use. Visually inspect for breaks, cracks and/or fraying.

e. Report any problems to Invivo Research, Inc., or an authorized Invivo Research, Inc. Service Representative.

f. Verify the accuracy and proper functioning before using the monitor on a patient. Never use a monitor that is suspected of being inaccurate or out of calibration.

CAUTION

The AC Power Adaptor (Part Number AS153) is used inside the Magnet Room. It must be kept outside the 1000 Gauss (0.1T) Field Line of the MRI System (this means at least 10 feet away from the MRI Magnet for most 1.5T magnets). Consult with your MRI Physicist/Radiologist for the exact location of the Field Line.

2.2.3 Monitor Start Up. Perform the following steps to bring the monitor on line for use:

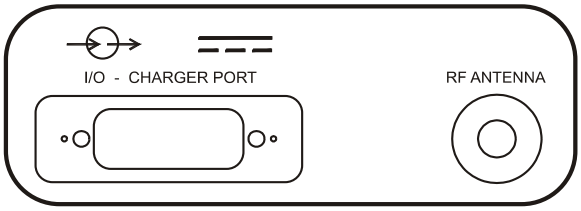

Figure 2-1. The Power Adapter and RF Antenna Connectors

a. Connect the AC Power Adapter to the I/O Port connector on the monitor back panel (**See Figure 2-1**).

b. Plug the AC Power Adapter into facility line power.

c. Allow the battery to charge a minimum of 16 hours before using the monitor.

NOTE

The monitoring systems' wireless transmitter power is regulated by the FCC and allows for only a limited transmission range. To ensure continuous monitoring, maintain the appropriate distance between the 3150(M) MRI Monitor and its remote monitor.

The recommended maximum distance between the two monitor's inside the Magnet Room is 35 feet and outside the Magnet Room the recommended maximum distance is 125 feet.

2.2.4 3150(M) MRI Monitor/Remote Monitor Communication. The Remote Transmission System, if installed on your equipment, turns on with each monitor (3150(M) MRI Monitor or remote monitor) as they are powered up. There is no restriction as to which monitor needs to be turned on first, the Radio Transmitter and Receiver will link when both monitors are on line.

a. **Remote Communication Verification.** Perform proper operation of the Communication Link as follows:

(1) On the **3150(M) MRI Monitor**, turn the Power Switch to the ON position.

(2) Once the 3150(M) MRI Monitor has come on line, turn the front panel Power Switch on the Remote Monitor to the ON position.

(3) After the Remote Monitor is on line, verify that the signal is received from the 3150(M) MRI Monitor

(4) Verify that the lower right hand box on the Display Screen is labeled REMOTE, both squares inside the box are together and the STATUS box is Green.

(5) Depress (press and release) the **NIBP START/STOP** Control Key on the Remote Monitor.

(6) Verify that an NIBP Determination is initiated on the 3150(M) MRI Monitor.

(7) Verify that the NIBP Determination is taken and displayed on the 3150(M) MRI Monitor and Remote Monitor.

(8) Verify P2 Waveform and Values are the same on both the 3150(M) MRI Monitor and Remote Monitor.

(9) With P2 still ON, verify that the SpO2 Value is shown with no waveform and is the same on both the 3150(M) MRI Monitor and Remote Monitor.

(10) Turn P2 OFF and verify SpO2 waveform is now displayed.

(11) Verify EtCO2 Waveform and Values are the same on both the 3150(M) MRI Monitor and Remote Monitor.

b. **Remote Transmission Failures.** If the Remote Transmission System fails to operate properly, consult the following guidelines for possible causes.

(1) **Transmission System will not Link.** An inability to link is most often cause by a loose antenna or a faulty power up. If the system will not link first check the Antenna Connections to ensure a proper tight mounting and, if the system still fails to link, cycle the power by turning the power OFF, waiting 5 seconds and then turning the power ON. If Remote Transmission is still not possible, contact a Qualified Service Representative for further assistance.

(2) **Transmission System Drops Out.** A Drop Out is any momentary loss of communication between the monitors that comprise this system. Drop Outs can be caused by any number of variables present in the local environment. If Drop Outs occur, consult the following guidelines:

(a) Ensure the Antenna Connections are tight and secure.

(b) Attempt to position the monitor's so that the base of the 3150(M) MRI Monitor has an unobstructed line of sight to the remote monitor's antenna. If reception improves then an object within the previous line of sight was interfering with transmission.

(c) If possible, move the 3150(M) MRI Monitor and/or remote monitor to different locations. If reception improves it is possible that the

interference is coming from another machine (or machines) within the immediate environment.

(d) If Remote Transmission is still not possible, contact a Qualified Service Representative for further assistance.

SECTION 3

MONITOR PREPARATION FOR USE

3. MONITOR PREPARATION FOR USE.

3.1 Introduction. The **3150(M) MRI Monitor** is fundamentally a Data Acquisition Monitor, that is, most of the operational parameters are set remotely at the **Millennia® 3155MVS or 3155A Remote Monitor**. The operator is provided some limited control of the patient monitoring with Control Keys to select the ECG Lead and Waveform Size, Zero EtCO2, P1 and P2 and, for the NIBP Parameter, the ability to change the selected Patient Type, to select the Automatic Mode Cycle Time and to Start/Stop NIBP readings. The operator also may Silence an active alarm using the **ALARM SILENCE** Control Key. Sound volume and MRI View Mode may be selected from the System Screen (which is accessed by pressing and holding the Alarm Silence key for approximately three (3) seconds).

WARNING

It is important to note that in Stand Alone Mode, or whenever this monitor is not in communication with the Remote Monitor, there is NO Patient Parameter Alarm Monitoring.

3.2 ECG Setup. Control Keys are provided to allow limited setup of the ECG parameter. The ECG **LEAD** Control Key allows the operator to change the selected ECG Lead. The ECG **SIZE** Control Key allows the operator to adjust the size of the waveform to compensate for various amplitudes. For more information, see Section 4.

3.3 Pressure Zeroing. Before Invasive Pressure Monitoring, the Pressure Transducer must be zeroed to ensure accuracy. Pressing the P1 **ZERO/ON** Control Key will zero the Pressure 1 Transducer and pressing the P2 **ZERO/ON** Control Key will zero the Pressure 2 Transducer. A successful Zero Cycle is confirmed by the message "**P-CAL: DONE**" being displayed in the waveform area. For more information, see Section 4.

3.4 NIBP Setup. Control Keys are provided to allow limited setup of the NIBP parameter. The NIBP **ADULT/NEO** Control Key will switch the selected patient between the Adult and Neonatal settings. The NIBP **CYCLE** Control Key will allow the operator to select the time between NIBP determinations while the system is in the Automatic Mode. The NIBP **START/STOP** Control Key allow the operator to manually initiate an NIBP determination or to stop a determination in progress. For more information, see Section 4.

3.5 Alarm System. The only control the operator has over the Alarm System at this monitor is the ability to adjust the 3150(M) MRI Monitor's alarm volume and to silence an active alarm by pressing the **ALARM SILENCE** Control Key. All Alarm Limits are set at the remote monitor and, if no remote monitor is present, the Alarm System at this monitor is turned OFF and NO ALARMS WILL SOUND (as indicated by a flashing NO ALM message above the Heart Rate area). For further information on the setup of Alarms, consult the Operations Manual of your remote monitor. To adjust the Alarm Volume, press and hold the Alarm Silence control key until the system screen appears, then use the ECG Size control key to increase the volume and the ECG Lead control key to decrease the volume.

SECTION 4

PATIENT PARAMETERS

4. PATIENT PARAMETERS.

4.0 Introduction. The **3150(M) MRI Monitor** provides accurate determinations of a patients ECG, Non-Invasive Blood Pressure, Invasive Blood Pressure, Oxygen Saturation (SpO2) and End-Tidal CO2 (EtCO2).

4.1 ECG Monitoring. The **3150(M) MRI Monitor** will provide high quality ECG data while the patient is in the MRI Magnet Room. Special care must be taken by the operator to ensure safe monitoring of the patient. In addition to the following instructions, first time users of MRI ECG Monitoring should also refer to **Appendix E: Primer for Patient ECG Monitoring During MRI Procedures** for further background information.

a. **Digital Signal Processing (MAGNITUDE™ 3150M MRI Monitor only).** Digital Signal Processing (DSP) of the ECG waveform is an innovative approach of removing MRI gradient interference from the ECG waveform. Gradient interference is a byproduct of the gradient magnetic fields that are developed during a MRI procedure. DSP differs from traditional ECG waveform analog filtering in that the DSP converts the ECG waveform to a digital format with the digital format then filtered through computer software for enhanced presentation on the display screen. The filtering characteristics of these digital filters are determined by the use of computer software. Digital filtering is advantageous because as MRI system manufacturers develop new and more sophisticated scanning techniques, the gradient interference filtering is easily adapted. Traditional analog filters will have difficulty removing this sophisticated gradient interference while the digital filters of the Digital Signal Processor can be adapted simply with the software.

NOTE

There is waveform distortion of the ECG (caused by the static magnetic field when the patient is monitored inside the bore) which produces a superimposed potential manifested as an augmented T-Wave. The "T" wave may become excessively large (due to electromagnetic flow induced voltage at the leads) and may interfere with QRS detection. Try other leads and/or electrode placement for best results.

4.1.1 Monitoring Precautions. The high radio frequency (RF) power used in MR scanning poses an ever-present risk of excessive heat at the monitoring sites and, therefore, the risk of RF current burn. **Should power levels greater than S.A.R. of 4 w/kg peak (0.4 w/kg average) be used, the risk of patient burn greatly increases.** As a result, monitoring of ECG or Respiration (derived from ECG leads), at power levels of greater than 4 w/kg peak (0.4 w/kg average) is not recommended for the general patient population. Such monitoring should only be attempted on conscious patients with good temperature reflex so they may warn the operator of excessive heat at the monitoring sites.

Of particular importance are the precautions associated with monitor sensor cables and ECG lead wires. Cables, of electrically conductive material, that become inadvertently looped during MRI scanning act as conductive lines for RF induced currents. When lead wires or other cables form this conductive loop in contact with the patient's tissue, minor to severe burning can result.

a. Use only with the Invivo Research Patient Cable, #9240, which consists of both the 9240A (MRI Lead Wire Cable) and the 9240B (MRI ECG Cable) Assemblies.

CAUTION

High RF power may cause patient heating or burns. Invivo strongly recommends that every user become familiar with these ECG monitoring precautions.

b. Manual pre-scanning, high TGs, large patients, body coil transmit/surface coil receive type scans and fast scan techniques are clues that should alert you to be especially cautious about potential electrode heating. The following precautionary measures should also be taken to minimize RF current risk:

(1) Place cables and lead wires neatly in straight alignment from ECG electrodes to bore exit with no loops (loops are not only closed but U shaped or S shaped) in the ECG cable (**See Figure 4-1**), inside or just outside the bore of the magnet. **Never connect two ECG patient cables to patient, contact Invivo Technical Service for information on gating interface to MRI magnet.**

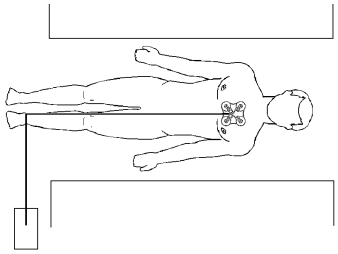

Figure 4-1. Patient Placed in Magnet Bore Head First

(2) Do not cross conductive cables inside the bore, and keep them well separated but away from sides of bore. Since RF burn risk increases when multiple conductive cables are in use, such combinations are not recommended. Do not run any cable in the area of a metal prosthesis.

(3) Position the patient so that there is no direct contact between the patient and the bore of the magnet. This may be accomplished by having the patient place their arms over their head or by using elbow pads and foam padding.

(4) Use only Invivo Research Quadtrode® MRI ECG Electrode Pad (IRI Part Number 9303N). Never use alcohol to prepare the skin for electrode application, as it removes electrolytes required for good electrode contact. Electrode Pad may be installed on the chest or back (chest for best monitoring). Careful patient prep is required as ECG will be severely degraded by poor electrode contact. Ensure that the skin in the area of the Quadtrode® Pad is dry. Follow the Patient Preparation and Electrode Pad Placement instructions that come with each Quadtrode® Pad. (Shave site if necessary, removing any chest hair. Use skin prep gel (IRI Part Number 9009) for skin preparation.) Place Quadtrode® Pad directly over the heart (**See Figure 4-2**). Ensure contact resistance is less than 8000 ohms (< 2000 ohms for best results) as measured with the electrode Impedance Meter (IRI Part Number 9392). Connect ECG leadwires and secure cable yoke to Quadtrode® Pad with adhesive tab provided on back of Quadtrode® Pad. **Cable may become <u>hot</u> during scanning.** <u>Always keep patient gown and insulative padding between cable and patient's skin.</u>

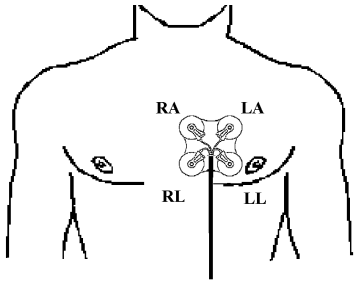

Figure 4-2. Electrode Placement

(5) Route ECG patient cable down the center of the bore, not touching the sides. **To further reduce RF current pickup, keep the length of the ECG patient cable within the bore to a minimum. This can very often be accomplished and is strongly recommended for large patients of "L" spine or similar exams by placing the patient in the bore feet first and routing the patient cable directly from the electrodes over the patients shoulder and out the bore (See Figure 4-3).** This configuration often results in a lesser length of ECG patient cable in the bore and a resulting lessened propensity to pick up RF energy.

(6) **High RF Power may cause patient heating or burns. For scans with average S.A.R. > 1 w/kg, limit scan time to 5 minutes and pause at least 3 minutes between scans to allow ECG cable to cool.** Confirm that there is no heating of the cable after each sequence by asking the patient or by feeling the electrode lead wires yourself.

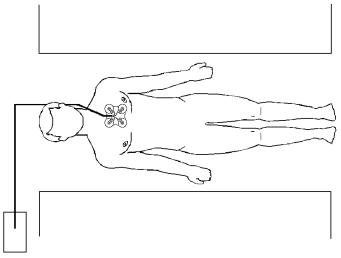

Figure 4-3. Patient Placed in Magnet Bore Feet First

4.1.2 Maintenance of Optimum ECG Waveform Integrity.
Integrity of the ECG waveforms and readouts should be maintained at their optimum. To ensure quality ECG performance perform the following:

a. **Electrode Prep:** Carefully prep the patient for ECG electrode placement (Refer to instructions on Quadtrode® Pad pouch). Poor electrode contact will severely degrade the ECG. Never use alcohol to prepare the skin for electrode application, as it removes electrolytes required for good electrode contact. (Shave site if necessary, removing any chest hair. Use skin prep gel (IRI Part Number 9009) for skin preparation.) Use only Quadtrode® MRI ECG Electrode Pad. Ensure contact resistance is less than 8,000 ohms (< 2000 ohms for best results) as measured with an electrode impedance meter.

b. **Electrode Placement.** Place electrode pad directly over the heart (Refer to instructions on Quadtrode® Pad pouch). Connect ECG leadwires and secure cable yoke to Quadtrode® Pad with adhesive tab provided on back of Quadtrode® Pad. **Ensure that the lead wires are running straight with no looping.**

c. **Respiratory Artifact.** Large heavy breathing patients upon which chest mounted electrodes and lead wires move vertically with respirations may cause a respiratory artifact on the baseline. Use back mounted electrode setup for better results.

d. **Lead Selection.** Use all four leads on patient. Select the "cleanest" lead for monitoring during scan (I, II, III, AVL, AVR or AVF). The "T" may become excessively large (due to electromagnetic flow induced voltage at the leads) and may interfere with QRS detection. Try another lead selection and/or electrode placement for best results.

e. **ECG Filter Selection.** (MAGNITUDE™ 3150M MRI Monitor only) Select the filter that provides the cleanest waveform during the scan. The ECG Filter may be selected at the Magnitude™ System Screen menu or the Millennia® 3155 ECG Menu.

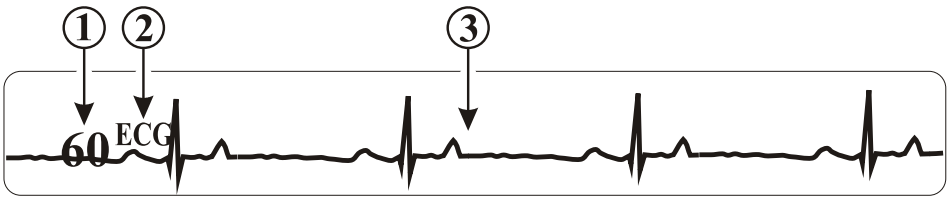

Figure 4-4. The ECG Display

4.1.3 Associated Displays. (**See Figure 4-4**) ECG information is displayed as a waveform in the Trace A location and as numerical data on the left side of the waveform trace. The following is a description of the items located within the ECG Display:

a. **Heart Rate Numeric.** (**Item 1**) Displays the current Heart Rate indication for the patient.

b. **Heart Rate Source.** (**Item 2**) Displays the name of the parameter selected as the Heart Rate Source.

c. **ECG Waveform Trace.** (**Item 3**) The ECG waveform for the connected patient.

4.1.4 ECG Control Keys. Two ECG Control Keys are provided on the Control Panel of the **3150(M) MRI Monitor**, they are ECG **LEAD** and ECG **SIZE**. Pressing the ECG **LEAD** control key allows the operator to change the input between the available ECG Lead Settings: CAL, I, II (default), III, AVL, AVR and AVF) and pressing the ECG **SIZE** allows the operator to adjust the display of the waveform trace for varying amplitudes of signal input (options include 5, 10, 15, 20, 25, 30, 40 and A <automatic>).

4.1.5 Alarm Limits. **Alarm Limits are set at the Remote Monitor, no adjustment of Alarm Limits is available at this monitor.**

4.2 NIBP Monitoring. The **3150(M) MRI Monitor** provides non-invasive blood pressure monitoring which automatically measures and displays a patient's systolic, diastolic and mean arterial blood pressures at preset intervals. It may also display information upon operator demand. This monitor makes blood pressure measurements based on the Oscillometric principle. Oscillometric Monitors use an inflatable occlusive cuff which is also used in the manual auscultatory technique; however, rather than monitoring Korotkoff sounds, Oscillometric Monitors detect and measure oscillations induced in the cuff by the movement of the arterial wall.

4.2.1 Simplified Theory of Operation. This monitor obtains blood pressure measurements based on the Oscillometric principle. Oscillometric Monitors use an inflatable occlusive cuff which can also be used in the manual auscultatory technique; however, rather than monitoring Korotkoff sounds, Oscillometric Monitors detect and measure oscillations induced in the cuff by the movement of the arterial wall. In basic terms, oscillometric monitors utilize a pressure transducer which is connected to the cuff via a hose. The transducer transforms the oscillations induced into the cuff pressure into electrical currents. Under control of a microprocessor and software algorithms, the electrical current can then be measured and correlated with the cuff pressure to determine arterial blood pressure. The following describes the process of Oscillometric Measurement:

a. As the occlusive cuff is inflated to a suprasystolic pressure the artery is occluded so that no blood passes through. At this point, even though no blood flows under the cuff, there are small pulsations induced into the cuff pressure by the partially-occluded proximal portion of the artery lying under the cuff (**See Figure 4-5**).

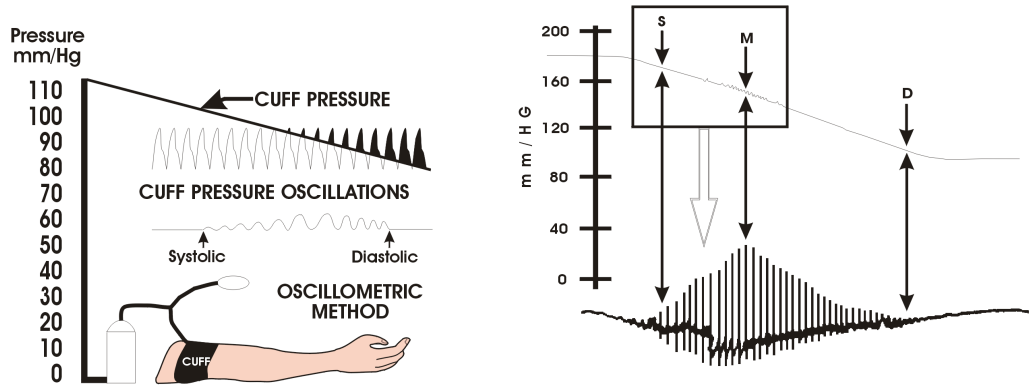

Figure 4-5. Oscillometric Measurement Method

b. As cuff pressure is reduced to just below the systolic pressure, the force of the height of the systolic pressure wave forces the occluded artery open, blood spurts through the artery and the amplitude of the oscillations increase sharply. This is the systolic pressure.

c. With further reduction 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.

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.

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d. With continued cuff-pressure reduction, 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.

4.2.2 Patient and Cuff Preparation. The patient should remain calm and motionless while the monitor is being used. If the patient is overactive, prolonged or inaccurate readings may result. Perform the following to prepare the patient and cuff for monitoring:

a. **Cuff Selection.** The cuff is selected and positioned as it would be for an auscultatory blood pressure determination, and the current guidelines of the American Heart Association should be followed. The bladder width of the cuff should be 40% of the circumference of the limb. For a correct fit on adult and pediatric cuffs, the Index line on the end of the cuff must fall between the two Range lines printed on the inside of the cuff. For correct fit on neonatal cuffs, choose the size with the stated circumference range that fits the circumference of the limb of the neonate.

WARNING

Do not attach the cuff to a limb being used for infusion. Cuff inflation can block the infusion causing possible harm to patient.

b. **Cuff Positioning.** The cuff should be wrapped firmly (not snug) around the arm of the patient and positioned as close to heart level as possible. If the cuff is not at heart level, add 1.8 mmHg to the displayed readings for each inch 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 that the cuff is located below the patient's heart level.

c. **Cuff Connections.** Select the proper hose (twin-lumen for adults, single-lumen for neonates), and attach hose to cuff. *Route the hose from the cuff to the monitor so it does not kink, tangle or limit access to the patient.*

4.2.3 Associated Displays. There is no waveform associated with NIBP, therefore only numerics are provided as an indication of the measured value of this parameter. NIBP numerics are always displayed on the bottom left of the Normal Screen. The following is a description of the NIBP Display Area (**See Figure 4-6**):

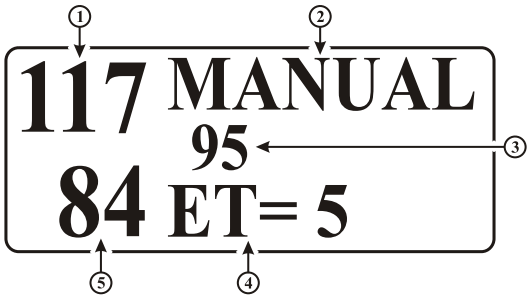

Figure 4-6. The NIBP Display

a. **Systolic Numeric.** (**Item 1**) A numeric indication of the patient's NIBP Systolic reading.

b. **Measurement Mode.** (**Item 2**) Displays the Measurement Mode selected by the operator (either Manual or Cycle).

c. **Mean Numeric.** (**Item 3**) A numeric indication of the patient's NIBP Mean reading.

d. **Elapsed Time.** (**Item 4**) The Elapsed Time since the last NIBP determination.

e. **Diastolic Numeric.** (**Item 5**) A numeric indication of the patient's Diastolic reading.

4.2.4 Adult/Neonate Selection. Adult/Neonate selection, which allows the monitor to determine pressures on a wide range of patients, is available through this monitor by using the NIBP Adult/Neo Control Key. Several operational parameters (including cuff inflation pressure) are varied depending on the selection of Adult/Neonate. This allows the appropriate operation for each patient selected. The control key has a set of LED's just above it, one for the Adult Mode and one for the Neonatal Mode, which light up to visually indicate which type of patient is selected.

4.2.5 NIBP Control Keys. In addition to the Adult/Neo Control Key mentioned in subparagraph 4.2.4 above, this monitor contains an NIBP **CYCLE** Control Key (which allows the operator to change the time between readings while in the Automatic Mode) and an NIBP **START/STOP** Control Key (which allows the operator to manually initiate NIBP readings and stop readings in progress). The automatic times available through the NIBP **CYCLE** Control Key are 1, 2, 3, 5 (default), 10, 15, 20, 30, 45 and 60 minutes.

4.2.6 Alarm Limits. Alarm Limits for Systolic, Diastolic and Mean arterial pressures, as well as pulse rate, are set at the Remote Monitor.

4.2.7 Blood Pressure Reading Intervals. A blood pressure reading may be taken at automatic intervals, or the operator can take manual control of the monitor's determination cycles at any time using the **NIBP START/STOP** Control Key on the **3150(M) MRI Monitor** Control panel. The automatic interval is set at the Remote Monitor or by using the NIBP **CYCLE** Control Key on this monitors control panel.

WARNING

The patient's blood pressure determinations are updated each time a blood pressure measurement is taken and are not continuous. When using this instrument to monitor critical conditions set the INTERVAL display to shorter periods for more frequent updating of the blood pressure determinations.

4.2.8 NIBP Normal Operation. During normal operation, the displayed blood pressures and pulse rate indicate the patient's condition at the time of the last measurement. Depending on the interval setting, as long as 60 minutes may elapse between blood pressure measurement cycles; during this time the patient's condition may change. Correspondingly, the alarms reflect only the patient's condition during the last blood pressure measurement, and not changes that may occur between measurements.

4.3 Invasive Pressure Monitoring. The **3150(M) MRI Monitor** provides two channels of Invasive Blood Pressure monitoring.

CAUTION

Never place the pressure transducer(s) within the MRI Bore. Transducer failure or noisy MRI images can result.

4.3.1 Probe Preparation. This monitor is designed for compatibility with standard pressure transducers having a 5 μV/V/mmHg sensitivity. The transducer cable connection is a six pin connector. Perform the following to use the pressure transducer:

a. Insert the transducer connector cable into the appropriate Invasive Pressure Connector (P1 or P2) on the monitor Parameter Input Panel.

b. Connect the patient end of the pressure transducer according to the transducer manufacturer's instructions for catheter insertion, flushing and care.

c. Wait a few seconds to allow the transducer to vent to atmospheric pressure.

d. Press the **ZERO/ON** Control Key that corresponds to the Pressure Channel being used.

e. After successful Zeroing, indicated by the "**P-CAL: DONE**" message, close the transducer's stopcock.

4.3.2 Zeroing Pressure Channels. The transducer must be zeroed before each use and at regular intervals during use. The transducer must be vented to atmospheric pressure before the transducer may be successfully zeroed. Upon completion of the zeroing cycle, a message appears momentarily to inform the operator if the transducer has been successfully zeroed (See Paragraph 4.3.5).

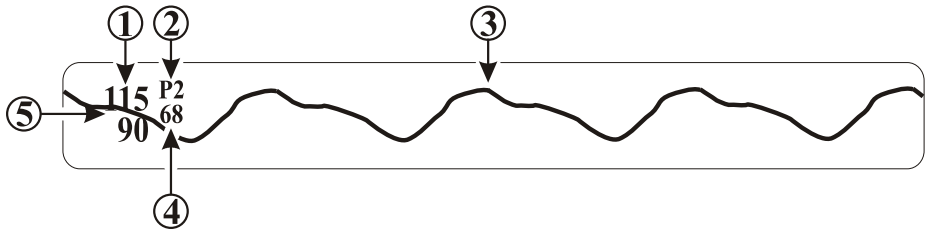

Figure 4-7. The Invasive Pressure Display

4.3.3 Associated Displays. (**See Figure 4-7**) Invasive Pressure is displayed in the Trace B and Trace C location. Invasive Pressure 1 (P1) is located in Trace B and Invasive Pressure 2 (P2) is located in Trace C. The following is a description of the Invasive Pressure display:

a. **Systolic Numeric.** (**Item 1**) A numeric indication of the patient's Invasive Pressure Systolic reading.

b. **Display Name.** (**Item 2**) Displays the name of the waveform being displayed in this location.

c. **Invasive Pressure Waveform Trace.** (**Item 3**) The Invasive Pressure waveform for the connected patient. The size of this waveform may be selected at the Remote Monitor.

d. **Mean Numeric.** (**Item 4**) A numeric indication of the patient's Invasive Pressure Mean reading.

e. **Diastolic Numeric.** (**Item 5**) A numeric indication of the patient's Invasive Pressure Diastolic reading.

4.3.4 Alarm Limits. Alarm Limits are set at the Remote Monitor, no adjustment of Alarm Limits is available at this monitor.

4.3.5 Invasive Pressure Messages. The following is a list of messages that may be displayed during Invasive Pressure monitoring:

P-CAL:UNSTABLE	Appears if the transducer is not within the stability range. This indicates that the transducer is picking up some vibration, possibly caused by incomplete closure of a patient's stopcock.
P-CAL:DONE	Appears after a successful zero of the pressure transducer.
P-CAL: HI RANGE	Appears if the transducer offset is too high to be zeroed.
P-CAL: LO RANGE	Appears if the transducer offset is too low to be zeroed.

4.4 SpO2 Monitoring. Select the Fiberoptic SpO2 sensor to be used and connect to the SpO2 isolated patient connector on the Parameter Input Panel. Place probe in desired location on patient. After four to six pulses, the oxygen saturation value (percent of saturation) and pulse waveform (if selected) will appear on the display.

a. **Pulse Tone Modulation.** The Pulse Tone is modulated over a range of 70 to 100% saturation level by the SpO2 value with the volume adjustment located in the System Screen. To access the System Screen, press and hold the Alarm Key until the system Screen appears then use the ECG Size control key to increase the volume and the ECG Lead control key to decrease the volume. The Pulse Tone Modulation Volume is adjustable from 1 to 10 with Default set at 6.

4.4.1 SpO2 Monitoring Considerations. The pulse oximeter requires the detection of valid pulses to correctly determine saturation and rate values. This monitor incorporates both audible and visual pulse indicators. Operators should become familiar with the interpretation of these indicators (i.e.: when no pulses are being detected, saturation/rate values may not be beat-to-beat and when gross artifact is received, incorrect values could result).

Do not place the probe on the same limb with an inflated blood pressure cuff. Cuff inflation could result in inaccurate readings and false alarm limit violations.

Sensor should be shielded from excessive extraneous incident light sources. Such extraneous light can cause reading error or pulse detection failure.

WARNING

Frequent medical attention to sensor site for possible pressure tissue necrosis should be given during longer term monitoring sessions (4 hours or more), especially on tender skin of neonatal patients. Special care should be exercised when tape is used to secure the sensor, as the stretch memory property of most tapes can easily apply unintended levels of pressure to the mounting site.

4.4.2 Patient and Probe Preparation. Ensure that the patient is not wearing fingernail polish, and does not have artificial or long fingernails. These may cause a reduction in transmitted light levels, result in low signal levels and inaccurate readings.

Insert the patient's finger into the probe housing until it touches the raised finger stop inside the probe. Ensure that the surface of the finger tip covers the detector window inside the probe.

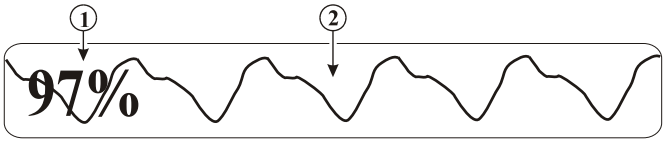

Figure 4-8. The SpO2 Display

4.4.3 Associated Displays. (**See Figure 4-8**) SpO2 is displayed in the Trace C location when Invasive Pressure 2 (P2) is turned Off; if P2 is On it is displayed in the Trace C location and the SpO2 numeric ONLY is displayed to the right of the NIBP numerics on the bottom of the Normal Screen. The following is a description of the SpO2 Display:

a. **SpO2 Numeric.** (**Item 1**) A numeric indication of the patient's SpO2 reading.

b. **SpO2 Waveform Trace.** (**Item 3**) The SpO2 waveform for the connected patient.

4.4.4 Alarms. Alarm Limits are set at the Remote Monitor, no adjustment of Alarm Limits is available at this monitor.

4.4.5 SpO2 Messages. The following is a list of message which may be displayed during SpO2 monitoring:

Searching The monitor is searching for a good pulse. Give the monitor time to lock onto a good pulse.

No Probe The monitor does not detect an SpO2 probe. Verify proper connection of the SpO2 probe.

Noise The photo sensor is receiving extraneous optical or electrical noise. Check the routing of the probe cable and move it away from all other optical and electrical wiring.

Low Light The transmission of the light is partially blocked. The tissue at the site may be too opaque and/or thick. If the probe is positioned on the finger, check the fingernails for nail polish, long fingernails and artificial fingernails; remove fingernail polish completely, for artificial nails: use a Multi-Site probe at another location, and, for long fingernails: either trim the nails or use a Multi-site probe at another location.

WARNING

The Pulse Oximeter is calibrated to read arterial hemoglobin oxygen saturation of functional hemoglobin (saturation of hemoglobin functionally available for transporting oxygen in the arteries). Significant levels of dysfunctional hemoglobins such as carboxy-hemoglobin or methemoglobin may affect the accuracy of the measurement. Also, cardiogreen and other intravascular dyes may, depending on concentration, affect the accuracy of the measurement.

4.5 End Tidal CO2 Monitoring (EtCO2). The **3150(M) MRI Monitor** includes a self contained EtCO2 measurement module which provides the following:

a. Side stream measurement of CO2, inspired CO2 and mean N2O, with continuous real time CO2 waveform display.

b. Selectable trend period up to 24 hours including data scan back for trend data point recall on remote monitor.

c. Automatic zero at periodic intervals, and self calibration, which allows the unit to operate with no manual adjustment.

d. Automatic correction for barometric pressure.

e. Selectable adult or neonatal flow and response ranges.

NOTE

To perform Zero Calibration, the monitor pulls ambient air through the CO2 Zero Intake Port located on the top of the base directly behind the column. The Calibration system assumes that the ambient air will contain normal amounts of trace CO2. If this monitor is placed in an unventilated area that allows CO2 (from the rear panel CO2 Exhaust Port - if not connected to a Gas Scavenging System) to accumulate, the result could be inaccurate Zeroing of the EtCO2 module and resulting inaccurate patient readings.

Whenever N2O or Anesthetic Agents are used, to prevent pollution of the MRI room by these gases and inaccurate EtCO2 zeroing, always connect the Exhaust Port of the **3150(M) MRI Monitor** to a Gas Scavenging System.

4.5.1 Theory of Capnography. This monitor determines the CO2 and N2O by measuring the absorption of two selected wavelengths of infrared light. A beam of infrared light is passed through optical filters. Each filter permits a specific wavelength of light to pass through the sample cell. Each filter is specific for the gas to be measured.

The different gases absorb infrared light energy at these different wavelengths. The amount of energy absorbed is a function of the concentration of the gas. The amount of infrared energy that remains is then measured by a detector, enabling a calculation to be made regarding the amount of energy absorbed by each gas. The amount of infrared energy absorbed is related to the amount of CO2 and N2O gases present.

4.5.2 Patient Circuit Preparation. The accuracy of the data collected is greatly influenced by the proper use, fitting and maintenance of the sampling tubing, moisture filters and patient breathing apparatus. The Patient Circuit should be connected to the monitor prior to End-Tidal CO2 start up to ensure accurate readings.

CAUTION

Before using the EtCO2 analyzer, read the PRECAUTIONS and USER RESPONSIBILITIES which follow the Table of Contents.

The patient sampling circuit consists of the external moisture filter, sampling tube, nafion moisture filter tube and either a sampling nasal cannula or a side stream adaptor to an endotracheal tube connector. All fittings in the circuit are Luer-Lock type. All fittings should be fitted together securely to keep them from separating during the procedure, and to ensure proper sampling without the introduction of outside air.

a. Connect the moisture filter to the EtCO2 PORT on the Parameter Input Panel.

b. Connect the 10ft sampling tube to the moisture filter.

c. Connect the Nafion Dryer Tube to the sampling tube (at the patient end).

d. Connect the Nafion Dryer Tube to the nasal cannula or endotracheal tube adaptor.

For best fit and compatibility, Invivo Research strongly recommends the use of the Invivo CO2 Sampling Kit (Part No. 9010D), which contains all the above tubing and endotracheal tube adaptor.
The following sizes of sampling nasal cannulae are available:

Part No.	Description
9012	Adult CO2 Cannula
9013	Pediatric CO2 Cannula
9014	Infant CO2 Cannula
9015	Intermediate Infant CO2 Cannula

CAUTION

Do not allow the tubing to become kinked so that the sample flow is reduced or cut off. Be careful that the tubing remains clear of any table moving mechanisms which may kink or cut the tubing.

(1) **Nasal Cannula.** The nasal cannula is of the "around-the-ear" type. Place the nasal pieces gently inside the nose, loop the excess tubing over the patient's ears and then down under the chin. The tubing may then be fitted by sliding the plastic ring up until the cannula is secure and comfortable.

(2) **Endotracheal Adaptor.** When using the endotracheal adaptor, attach the Nafion Dryer Tube before attaching the endotracheal adaptor to the endotracheal tube. Take great care not to dislodge or move the endotracheal tube when attaching the adaptor.

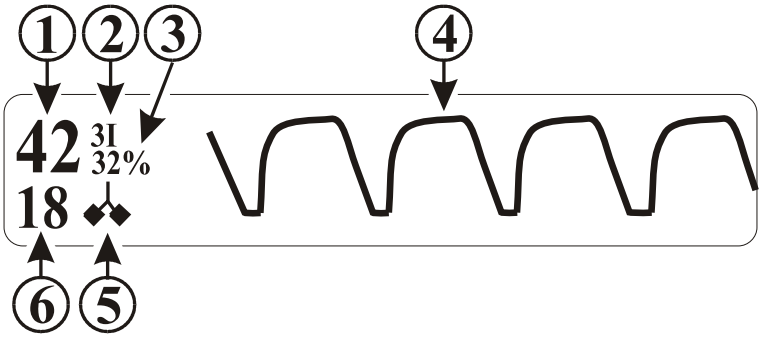

Figure 4-9. The EtCO2 Display

4.5.3 Associated Displays. (**See Figure 4-9**) The EtCO2 Display is located to the right of NIBP (if P2 is Off) or SpO2 (if P2 is On) on the bottom of the Normal Screen. The following is a description of the EtCO2 display:

a. **EtCO2 Numeric.** (**Item 1**) A numeric indication of the patient's EtCO2 reading in mmHg or, if option is installed, kPa.

b. **Inspired CO2 Numeric.** (**Item 2)** A numeric indication of the patient's inspired CO2 reading in mmHg or, if option is installed, kPa.

c. **N2O Numeric.** (**Item 3**) A numeric indication of the patient's N2O reading.

d. **EtCO2 Waveform Trace.** (**Item 4**) The EtCO2 waveform for the connected patient. The size of this waveform may be selected at the Remote Monitor.

e. **Lung Symbol.** (**Item 5**) (If EtCO2 Option is installed) The Lung Symbol provides a visual indication of the patient's monitored Respiration Rate. This symbol flashes on the screen each time the patient is detected taking a respiration breath.

f. **Respiration Numeric.** (**Item 6**) A numeric indication of the patient's Respiration reading in breaths per minute.

4.5.4 EtCO2 Alarms. Alarm Limits are set at the Remote Monitor, no adjustment of Alarm Limits is available at this monitor.

4.5.5 EtCO2 Messages. The following is a list of messages that may be displayed during End Tidal CO2 monitoring:

ETCO2 Bench Warmup	This message is displayed during the first three minutes the EtCO2 System is turned ON.
NOW ZEROING	This message is displayed for 1.5 seconds, during which time the waveform is blanked. The EtCO2 System will zero frequently during the first two minutes it is ON and, after that, will zero at longer intervals until at the two hour mark it begins to zero once an hour only.
STATIC PRESS	This message is displayed for 0.8 seconds after every three hours of operation as the EtCO2 System automatically adjusts for any change in barometric pressure.
OCCLUSION	The air lines have become blocked. Check exposed hose for kinks and blockages. If blockage appears to be internal to the unit, contact a Qualified Service Representative.

4.6 Cardiac/Peripheral Gating Option. Gating is provided by a DB15 connector located on the rear side of the base on the **3150(M) MRI Monitor**. There are two Gating options provided: Heart Rate Source and SpO2 Pulse. This option requires custom cabling specific to each MRI System. For assistance installing proper cabling to operate the Gating System, contact Invivo Research, Inc. Technical Support at (888) 221-1593.

SECTION 5

BATTERY OPERATION

5.0 BATTERY OPERATION.

5.1 Introduction. This monitor is equipped with four (4) Lead Acid Gel Cell Batteries which provide battery power for eight hours with fully charged batteries. The batteries are designed to be used whenever the monitor is being moved or when the monitor cannot be readily connected to an AC Power Source through the AS153 AC Power Adapter.

5.2 Battery Location and Access. The battery(s) is/are located in the base of the monitor. The batteries are accessed by removing the top panel on the base of the unit.

5.3 Battery Charging. The batteries automatically charge anytime the AS153 AC Power Adapter is connected to an AC Power Source and the monitor with the AS153 Power Switch ON. Proper connected to the AC Power Source is indicated by the AS153 Power LED illuminating Green. Initial charging time for new batteries is a minimum of 16 hours before using the monitor.

5.4 Battery Operation Time. This monitor will operate for approximately eight (8) hours on battery power. **Battery operation time may be affected by certain operations (i.e.: Short Automatic NIBP Cycle times).**

5.4.1 Battery Low Indication. When there is approximately twenty (20) minutes of battery power left, the 3150(M) MRI Monitor Display Screen displays the "**LOW BATTERY**" message. Once the battery power has diminished below operational limits, the display screen on the monitor will turn off except for the message "**A LOW BATTERY SHUTOFF HAS OCCURRED,**" the pumps and other monitoring equipment in the base of the monitor will continue to operate until the batteries are further depleted.

5.4.2 Maintaining Battery Life. For optimum battery life, connect the monitor to the AS153 AC Power Adapter as soon as possible following the appearance of the LOW BATTERY message on the monitor's display. Continued use on battery power during low battery periods can reduce the overall life of the batteries.

5.5 Battery Replacement. If during operation, the monitor will not operate on battery power for the approximate times given above replacement of the batteries is recommended.

APPENDIX A

SPECIFICATIONS

GENERAL

PATIENT SAFETY	
Designed to meet the requirements of CSA, UL 2601 and IEC 601-1.	
Defibrillator protection up to 5 KV.	
POWER REQUIREMENTS	
Operating Voltages	120 VAC ±10%, 50/60 Hz 240 VAC ±10%, 50/60 Hz
Power Consumption	50 Volt-Amperes nominal, 90 Volt-Amperes maximum (using AS153 Power Adapter)
BATTERY OPERATION	
Battery Type	4 - 12 V @ 7.0 AH, Rechargable Lead-Acid
Battery Operation Time	> 8 Hours of operation with 80% battery capacity, with EtCO2 operating and NIBP readings every 5 minutes
Battery Charge Time	Charged to 85% capacity within 18 Hours.
Battery Life	Minimum 80 Charge/Discharge Cycles.
Fuse	Internal DC: 7 amp, 250V Slow Blow, 3 AG
ENVIRONMENT	
Operating Temperature	10 to 44° C. (50 to 110° F.)
Storage Temperature	-40 to +75° C. (0 to 125° F.)
Relative Humidity	0 to 80%, non-condensing
DIMENSIONS	
Height	44 in. (112 cm.)
Width	24 in. (61 cm.)
Depth	28 in. (71 cm.)
Weight	70 lbs nominal (32 kg. nominal) - with batteries
REMOTE COMMUNICATION (2.4 GHz Spread Spectrum)	
FCC Certification	Part 15.247, no license required
ETS (European) Certification	brETS 300.328, no license required
Rated RF Output Power	+18 dBm
Frequency Range	2400-2480 MHz (France: 2448-2480 MHz)
Number of Channels	80 (France: 34)

GENERAL

DISPLAY	
Type	LCD: 240 x 128 pixels
Screen Size	122 x 65 mm. 138 mm (5.64 in.)
Sweep Speed	25 mm/S. 3.125 mm/S (Respiration Only).
Waveform Display Mode	Fixed trace with moving Erase Bar
Waveform Display Height	25 mm (±10%)
Display Bandwidth	33 Hz minimum

ECG CHANNEL

ECG AMPLIFIER	
Overvoltage Protection	Protected against defibrillator and electrosurgery potentials.
Standard Lead Configurations	I, II, III, AVR, AVL or AVF. Full lead selector with right-leg drive.
Differential Input Impedance	8 Megohm (at 10 Hz).
Common Mode Rejection Ratio	104 dB minimum with a patient cable connected and an imbalance of 51 KΩ/45 nF at the line frequency.
Electrode Offset Potential	Maximum ±0.4 VDC
Baseline Recovery	1 second after defibrillation, using special fast recovery circuits.
CARDIOTACH	
Digital Cardiotachometer	12 second average with 50% response time of 6 seconds.
Range	0 to 250 bpm.
Accuracy	±0.5% ±1 bpm.
Resolution	1 bpm
Maximum Sensitivity	200 uV peak for adults and 100 uV peak for neonates.
QRS Detection	Spectral. Discriminates signal for frequency content, minimum signal and width (with 60 Hz notch).

ECG CHANNEL

CARDIOTACH (Continued)		
Sensitivity	-5 mV to +5 mV	
Display Gain Scales (mm/mV)	5, 6, 7, 8, 9, 10, 12, 15, 18, 20, 25, 30, 35, 40 and Autoscale.	
Bandwidth	Monitor:	0.5 to 40 Hz
	MRI View:	0.5 to 10 Hz adaptive, 0.5 to 40 Hz for QRS
	Baseline Offset:	Automatically nulled.
Display	Single height (Trace A only):	25 mm
	Double height (Trace B off):	50 mm
	On Screen Bandwidth:	35 Hz
	Six seconds shown on screen at 25 mm/second.	
	Moving Erase Bar.	
ALARMS		
Set at the Remote Monitor		
TEST/CALIBRATION		
Square Wave Test Waveform	146 bpm ±16 bpm.	
Calibration Signal	1 mV ±2%	

NON-INVASIVE BLOOD PRESSURE

GENERAL	Oscillometric method (with inflatable cuff). Determines systolic, diastolic and mean arterial pressures, and pulse rate.
PNEUMATIC SYSTEM	
Cuff Inflation Time	3 to 20 seconds depending on cuff size. Alarms if inflation time exceeds 150 seconds.
Cuff Inflation Pressure	Initially 170 mmHg for Adult/Pediatric. (110mmHg for Neonate). Subsequent inflation pressures determined by last measured systolic pressure.
Cuff Inflation Pressure Range	50 to 250 mmHg (50 to 210 mmHg for Neonate).
Deflation Time	Typically 25 seconds. Varies with patient's pulse rate, pulse pressure and amount of artifact present. Alarms if deflation time exceeds 3 minutes.
Overpressure Valve	Automatically released if inflation pressure exceeds 270 mmHg, ±14 mmHg.

NON-INVASIVE BLOOD PRESSURE

MEASUREMENT RANGE	
Systolic	30 to 250 mmHg.
Diastolic	10 to 240 mmHg.
Mean	15 to 250 mmHg.
Pulse Rate	40 to 238 bpm
(Measurements are possible only in pulse rate range of 40 to 238 bpm.)	
ACCURACY	
Pulse Rate	2% full scale
Pressure Zero Offset	6 mmHg, ±5 mmHg
Pressure Span Accuracy	±2 mmHg
Pressure Transducer Range	0 to 255 mmHg
ALARM LIMITS	
Set at the Remote Monitor	
MODES	
Manual and Automatic	

PRESSURE CHANNELS (Optional)

PRESSURE AMPLIFIER	
Range	-10 to +250 mmHg
Sensitivity	5 µV/V/mmHg.
Gain Accuracy	±0.5%
Bandwidth	0 to 12 Hz
AUTO ZERO	
Range	±300 mmHg
Zero Accuracy	±1.0 mmHg
Response Time	1 second, notifies operator when done.
PRESSURE WAVE DISPLAY	
Number of Channels	2
Simultaneous Display	20 mm, ±10%
P1 and P2	Numeric display of systolic, mean and diastolic pressures.

PRESSURE CHANNELS (Optional)

PRESSURE SCALE RANGES (Set at Remote Monitor)	0 to +250 mmHg, 0 to +200 mmHg, 0 to +150 mmHg, 0 to +100 mmHg 0 to + 75 mmHg, -10 to + 40 mmHg

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

The pressure amplifier is shipped configured for 5μV/V/mmHg standard transducer sensitivities.

PULSE RATE (When derived from P1 or P2)

Range	0 to 250 bpm.
Accuracy	±0.5% ±1 bpm
Resolution	1 bpm

ALARMS

Set at the Remote Monitor

PULSE OXIMETER	
High sensitivity proven pulse oximetery design.	
Single plug-in board with sophisticated space saving surface mount technology.	
Supports adult and neonatal fiberoptic sensors.	
Real time pulse waveform display selected from Trace C and numerical display of SpO_2% on lower portion of screen.	
Pitch of pulse tone is modulated by saturation values from 70 to 100%.	
Saturation Range	50 to 100%
Saturation Accuracy	With Invivo Research Fiberoptic Probes: 2% at 90 to 100% 2.2% at 80 to 90% 2.5% at 70 to 80% 2.8% at 60 to 70% 3.3% at 50 to 60%
Pulse Range	20 to 200 bpm
Pulse Accuracy	2% of full scale
ALARM LIMITS	
Set at the Remote Monitor	

END-TIDAL CO2 (Optional)

TECHNIQUE

IR absorption, using a single IR source and three detector channels on a single substrate. Temperature of the IR source is feedback-controlled. Internal design and software algorithms make the sensor largely self-compensating, precluding the need for mechanical choppers or temperature compensation/control. Includes a water trapped/filtration system and microprocessor control.

Measurement Range	CO2: 0 to 76 mmHg N2O: 0 to 99 %
Accuracy (after 15 minute warm-up and mean airway O2 at 30% concentration)	CO2: 3 mmHg N2O: 5% of full scale
Zero Drift	CO2: 0.5 mmHg/Hr to 1.5 mmHg/24Hr N2O: 2%/Hr to 5%/24Hr maximum
Calibration Interval	Zero Cal: Automatic or user requestable Span Cal: None required
Flow Rate	150 mL/min (Neonatal) 230 mL/min (Adult)
Response Time (10-90%)	CO2: 300mS @ 230mL/min, 700mS @ 115mL/min N2O: 300mS @ 230mL/min, 700mS @ 115mL/min
Respiration	Rate: 4 to 85 Breaths/minute
Sample Cell Volume	25 micro liters
Relevant Interference	0.5 mmHg equivalent with 37.5 °C sat H2O (0.1% relative max)
Operating Temperature	15 to 40 °C

CARDIAC AND PERIPHERAL GATING OUTPUTS

Cardiac (ECG) Gating Analog Output	Low level: 1 mV. High level: 1 V. Output delay: < 10 ms.
Peripheral (Pulse) Gating Analog Output	Low level: 20 mV. High level: 1 V.
Digital Trigger Pulse. (Selectable Cardiac or Peripheral Gating output through selection of ECG of SpO2 respectively in the ECG Heart Rate Source menu at the 3155 Remote Monitor.)	Amplitude: 3.3 to 5 Vpp. Duration: 13 ±3 ms. Output delay: < 10 ms.

NOTE

Patient Gating requires use of a Gating Cable that is unique to your MRI System. Contact Invivo Research Technical Support for further information.

EQUIPMENT CLASSIFICATION

Classification according to IEC-601-1	
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 a flammable anesthetic mixture with air or with oxygen or nitrous oxide.	

APPENDIX B

REPAIR

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

If a monitor fails to function properly or requires maintenance, contact IRI Technical Service at 1-800-331-3220 during normal business hours EST or 24 hour emergency technical assistance. IRI Technical Service will advise you of the corrective action required. If you are advised to return the monitor to IRI for repair, please do the following:

1. Obtain a Return Authorization Number. This will ensure proper routing and facilitate timely repair of your monitor.
2. Package the monitor with adequate protection. If available, use the original carton and packing materials in which the Monitor was shipped from IRI.
3. Include a brief description of the problem as well as the name, address and phone number of the person to be contacted for additional information.
4. Include a purchase order with the monitor being returned if it is out of warranty; IRI Technical Services can advise you of your monitor's warranty status, if need be. Repairs will be made at IRI's current list price for the replacement part(s) plus a reasonable labor charge.
5. Ship the monitor, transportation prepaid, to the location specified by your IRI Technical Service Representative with the Return Authorization Number written on the outside of the shipping carton. Repairs will be made, normally, within two weeks, and the monitor will be returned to you prepaid.

   Technical Service Department
   Invivo Research, Incorporated
   12601 Research Parkway
   Orlando, FL 32826
   (407) 275-3220

To ensure full reliability, it is recommended that all repairs be made by an IRI Authorized Service and Repair center. For repair at your facility, a competent individual experienced in the repair of monitors can repair the monitor **if** it is authorized by IRI Technical Service prior to the repair.

CAUTION

No repair should ever be undertaken or attempted by anyone not having a thorough knowledge of the repair of IRI monitors. Only replace damaged parts with components manufactured or sold by Invivo Research, Inc. Contact the IRI Technical Service and Repair Center for service and technical assistance.

APPENDIX C

WARRANTY

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

IRI's sole obligation under this warranty is limited to repairing a product which has been reported to IRI's Technical Service Center during normal business hours and shipped transportation prepaid. IRI 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 IRI neither assumes nor authorizes anyone to assume for it any other obligation in connection with the sale or repair of its products.

APPENDIX D

DECLARATION OF CONFORMITY

DECLARATION OF CONFORMITY

Application of Council Directive(s) 89/336/EEC

Standard(s) to which Conformity is Declared EN55011, EN 60601-1-2

Manufacturer's Name Invivo Research, Inc.

Manufacturer's Address 12601 Research Parkway, Orlando FL 32826, USA

Importer's Name Refer to accompanying Packing Slip

Importer's Address Refer to accompanying Packing Slip

Type of Equipment Omni-Trak™ Patient Monitor

Model Number 3150 and 3155 Series

Serial Number Refer to accompanying Packing Slip

Year of Manufacture Refer to accompanying Packing Slip

I, the undersigned, hereby declare that the equipment specified above conforms to the above Directive(s) and Standard(s).

Place Orlando, FL

Date January 12, 1998

(Signature)

Francis Casey
(Full Name)

Director, Regulatory Affairs
(Position)

DECLARATION OF CONFORMITY

Application of Council Directive(s) Medical Device Directive 93/42/EEC

Standard(s) to which Conformity is Declared 93/42/EEC

Manufacturer's Name Invivo Research, Inc.

Manufacturer's Address 12601 Research Parkway, Orlando FL 32826, USA

Importer's Name Refer to accompanying Packing Slip

Importer's Address Refer to accompanying Packing Slip

Type of Equipment Omni-Trak™ 3150 Series Monitors

Model Number 3150 and 3155 Series

Serial Number Refer to accompanying Packing Slip

Year of Manufacture Refer to accompanying Packing Slip

Certification Method(s) Annex II

Equipment Class Class IIb

MDD Conformity Assessed By Semko (0413)

I, the undersigned, hereby declare that the equipment specified above conforms to the above Directive(s) and Standard(s).

Place Orlando, FL

Date June 5, 1998

(Signature)

Francis Casey
(Full Name)

Director, Regulatory Affairs
(Position)

APPENDIX E

PRIMER FOR PATIENT ECG MONITORING DURING MRI PROCEDURES

This primer is being provided for the first-time MRI monitoring applications to explain the reasons for the needed precautions for safe monitoring of the patient during MRI procedures, and to explain the methods used to prepare the patient's skin prior to monitoring during MRI.

Although it may appear that ECG monitoring in the MRI area is similar to that performed in other areas of the hospital, the special environmental conditions found inside the MRI Area are unique, and require additional precautions to be followed to permit safe monitoring during MRI scans or procedures. It is always important to remember that the risk of electrode heating is ever-present when any electrical conductors, for example an ECG cable, are placed in the MRI bore, and by following our operating precautions and warnings these risks can be minimized. The guidelines identified below, in conjunction with the instruction found in this Operator's manual and the Operator's Precaution Card (Invivo Research part number L2010) can help minimize these potential risks:

1. Electrode Site Selection - (Refer to the Figure 1 on MRI Monitoring Precautions Card - Invivo Research Part Number L2010). The placement of the ECG electrode should be around the heart of the patient, as shown in Figure 1 of the Monitoring Precautions Card. Four electrodes are used to allow acquisition of the patient's electrical ECG signal from a standard 3 lead system with a second reference (usually Right Leg) lead. Placement is critical to avoid any electrical signal artifact that can arise from the motion of the moving blood, which is an electrical conductor, in the MRI magnetic field. By having the ECG electrodes close around the heart, and keeping the electrode lead wires as physically short as possible, this magnetic field induced electrical artifact can be kept to a minimum. This artifact can be seen on the ECG waveform, and will present a distorted looking waveform. By modifying the ECG Lead Configuration, the best waveform with minimal blood-flow artifact can be selected for monitoring.

2. Electrode Site Preparation - If there is hair at the sites where an electrode is to be placed, then the area must be shaved. Following shaving the skin, abrade the skin using Trace Aid ECG Abrasive Skin Prepping Gel (Invivo Research part number 9009). This gel can provide a conductive paste as well as abrade the upper surface of the skin. Separate instructions are provided with this gel, and should be followed accordingly.

3. ECG Electrode Attachment - (Refer to the Figure 1 illustration on MRI Monitoring Precautions Card - Invivo Research part number L2010). For best results, only appropriate (i.e. MRI-compatible) ECG electrodes should be used to minimize the possible risk of ECG electrode heating, with subsequent patient burns, during MRI scanning. Appropriate electrodes must have a large conductive surface area with a minimum diameter of 3/4 inch for electrode pad saturated with conductive gel. Only wet gel type electrode should be used in order to ensure good electrical conductivity is present between the electrode and the patient's skin. We recommend use of the Invivo Research 9303N Quadtrode® Electrodes because these electrodes possess these key characteristics in their design. Without a good electrical connection with a large contact area between the electrode and skin surface, any Radio frequency (RF) induced currents that can flow in the ECG patient lead wires and/or cable during MRI scanning can contribute to electrode heating, and possibly skin burns.

4. Checking electrode contact quality with Electrode Impedance Meter (IRI part number 9392) - In addition to the reasons described above, electrode contact is also important when assessing ECG signal quality. A standard means to evaluate electrode contact quality is to measure the electrical impedance between electrodes to verify the impedance is acceptable low (usually below 8000 ohms, but below 2000 ohms for best results). An Electrode Impedance Meter is provided with each Omni-Trak 3150 Monitoring System to permit these electrode contact quality checks. The Electrode Impedance Meter is attached to the patient skin electrodes and each set of readings (i.e. LA, RA, LL, RL) must be evaluated. Since only 3 lead wires can be connected simultaneously, the user will need to check the fourth lead wire by reattaching one of the 3 lead wires from the other electrodes to the fourth electrode (refer to the instructions on the Electrode Impedance Meter). If electrode contact is poor (impedance greater than 8000 ohms), remove and discard the electrode, abrade the skin further using the Trace Aid gel, and always apply a new Quadtrode® Electrode. Never reuse a removed electrode since its adhesive may not securely fasten the Quadtrode® Electrode to the skin. Re-check electrodes' impedance with Electrode Impedance Meter for the acceptable impedance level.

5. ECG Patient Cable and Lead Wires - The Invivo Research 9240 ECG Patient Cable and Lead wires are specially designed for use in the MRI bore. The 9240A Lead Wires are constructed of special material to help reduce the amount of radio frequency energy which can flow through these wires. This lead sire set must always be used during monitoring in the MRI bore. The gray 9240B ECG Patient Cable is constructed of similar materials as other standard ECG cable, and no portion of this gray cable should be placed within the MRI bore. If this is done excessive currents could flow through the cable and lead wires, which can result in skin burns. Always use the Invivo Research 9240 ECG Patient Cable Set when monitoring with the Omni-Trak 3150 Monitor in the MRI bore.

6. Other Electrical Conductors Inside the MRI Bore - No other electrical conductors (e.g. wires, leads, probes, etc.) should be placed within the MRI bore at the same time as the ECG Lead Wires. Electrode heating risk increases when multiple conductive cables and sensors are placed in the bore with patient. Mixing of conductors from various manufacturers (catheters, temperature sensors, etc.) is not recommended. Multiple electrical conductors within the MRI bore can allow cross-coupling between these various conductors, and appear as a large antenna for RF energy pick-up, which **will** result in electrode heating, and possibly, skin burns. It is always important to identify if the patient has any metallic wires, conductors, implants, stents, etc. within his/her body which will act as cross-coupling conductors. If these are present, ECG monitoring may not be able to be performed without experiencing electrode heating. It is important to note that non-conductive tubes, air-lines, etc. can be used without any problems. These include NIBP cuffs and air-lines, End-Tidal Carbon Dioxide and/or Oxygen air-lines, and fiberoptic pulse oximetry sensors. These items usually do not include electrically conductive materials in their construction, and can be safely used within the MRI bore with the ECG Lead Wires.

7. Proper Cable Placement inside the MRI Bore - (Refer to the Figures 2 and 3 illustrations on MRI Monitoring Precautions Card - Invivo Research part number L2010). **The ECG Lead Wires must always be kept in a straight line inside the MRI bore. No loops of any kind (circular, "U" shaped, "S" shaped, or any partially close loop) in these lead wires should be permitted**. Large cable loops become antennas for Radio Frequency (RF) emitted by the MRI and significantly increase induced currents in the cable, and therefore the potential for heating at the patient cable and/or electrodes. If the lead wires are looped in any way, the wires **will** pick-up RF energy during the MRI scanning process, and **will** cause ECG patient cable and/or electrode heating. Heating of the electrodes can result in patient skin burns, which can be as severe as third degree. The ECG Lead Wires or any portion of the patient's body (e.g. arms, legs, shoulders, etc.) should not touch Magnet Bore at any time. Contact or close proximity of the Lead Wires or patient body can allow increased RF current to flow in these Lead Wires, with subsequent cable and/or electrode heating.

8. MRI System Scanning Power - Should power levels greater than a Specific Absorption Ratio (S.A.R.) Of **4 Watts/kilogram (peak)**, or **1.0 Watts/kilogram (average)** be used, the risk of cable heating increases greatly. If ECG must be monitored on a patient where these power levels are exceeded for any of the proposed scan sequences, and the risk of heating is accepted, then it is imperative t keep the length of the ECG Lead Wires within the bore to a minimum. For many MRI scan, patients are commonly placed into the MRI bore in a head-in first position. When these S.A.R. power levels are exceeded, placement of the patient into the MRI bore in a feet-in first position should be considered. This patient placement will keep the length of the ECG Lead Wires inside the MRI bore to a minimum, and reduce the possible RF energy that the Lead Wires can pick-up. During this patient positioning, the patient cable must be routed directly from the electrodes over the patients shoulder and out the MRI bore with no loops present in the wires. Also, it is important for patients undergoing anesthesia, who cannot report any electrode heating to the operator, that between scanning sequences the operator feel the electrodes in order to detect any heating. This is also more easily accomplished when the patient is positioned feet-in first inside the MRI bore.

9. Other Contributing Factors - Other factors related to the patient himself, or prescribed MRI scan sequences, can contribute to the potential risk of ECG electrode heating. The following factors can greatly increase this risk:

   - Use of ECG Electrodes with diameter smaller than 3/4 inch - This can reduce the contact area which any RF energy induced currents can be "concentrated" over a smaller area, which causes an increase in the current density at the skin/electrode interface. This will result in cable and/or electrode heating.

   - Use of non-wet gel type electrodes - Use of dry-conductive electrodes does not always provide uniform contact between the skin and electrode, which can reduce the effective area between the skin and electrode. Again, this can reduce the contact area which any RF energy induced currents can be "concentrated" over a smaller area, which causes an increase in the current density at the skin/electrode interface. This will result in electrode heating.

- Dry or expired electrodes - Use of dried out or expired electrodes will reduce the conductive path and possibly the contact surface area between the skin and electrode, which can reduce the effective area between the skin and electrode. Also, if the expired electrode adhesive ring does not allow the electrode to be firmly secured to the skin, any "lifting" of the electrode will cause partial contact with the skin, and reduce the effective area between the skin and electrode. Again, these conditions can reduce the contact area which any RF energy induced currents can be "concentrated" over a smaller area, which causes an increase in the current density at the skin/electrode interface. This will result in electrode heating.

- Large patient size and/or weight - Large patient size or weight will normally require higher S.A.R. levels during MRI scanning, with the increased risk of higher RF energy currents being induced into the ECG Lead Wires. For large patients, minimizing the Lead Wire length inside the MRI bore, Feet-in first placement, and frequent feeling of the ECG electrodes, and cable for warming should be planned prior to the MRI scan should be considered, particularly for patients under anesthesia who are not responsive to heating stimuli.

- Deep body scans (Lumber spine, Thoracic spine, Cervical spine, Aorta, etc.) - Deep body MRI scans will also normally require higher S.A.R. levels during MRI scanning, with the increased risk of higher RF energy currents being induced into the ECG Lead Wires. Again, for these patients during these types of scans, minimizing the Lead Wire length inside the MRI bore, Feet-in first placement, and frequent feeling of the ECG electrodes and cable for warming should be planned prior to the MRI scan.

- Surface coil usage - MRI scan with surface coils placed inside the MRI bore scans normally require higher S.A.R. levels during MRI scanning, with the increased risk of higher RF energy currents being induced into the ECG Lead Wires. Again, for these patients during these types of scans, minimizing the Lead Wire length inside the MRI bore, Feet-in first placement, and frequent feeling of the ECG electrodes and cable for warming should be planned prior to the MRI scan.

- Close proximity of cable or patient to the MRI bore - The ECG Lead Wires or any portion of the patient body (e.g. arms, legs, shoulder, etc.) should not touch the inside surface of the MRI bore at any time. Contact or close proximity of the Lead Wires or patient body can allow increased RF current to flow in these Lead Wires, with subsequent cable and/or electrode heating.

- Presence of any cable loops - Any cable loops can become antennas for Radio Frequency (RF) energy emitted by the MRI and will significantly increase induced currents in the cable, and therefore the potential for heating at the electrodes. If the lead wires are looped in any way, the wires **will** pick-up RF energy during the MRI scanning process, and **will** cause ECG electrode or cable heating. Heating of the electrodes can cause patient skin burns which can be as severe as third degree. The ECG Lead Wires or any portion of the patient body (e.g. arms, legs, shoulders, etc.) should not touch Magnet Bore at any time. Contact or close proximity of the Lead Wires or patient body can allow increased RF current to flow in these Lead Wires, with subsequent cable and/or electrode heating.

APPENDIX F

LIST OF SYMBOLS

Attention, Consult Accompanying Documents

Defibrillator-proof Type CF Equipment (IEC 601-1) Protection Against Shock

1 (Rotate Counter-clockwise to Open)
0 (Rotate Counter-clockwise to Close)

ON (Main Power)

Date of Manufacture

Battery

OFF (Main Power)

Alarms ON

Latex-free Materials Are Used

"ON" (For Part of the Equipment)

Alarms Silenced

Direct Current

"OFF" (For Part of the Equipment

Heart Beat Detected

Weight

Alternating Current

Breathing Effort Detected

Dangerous Voltage

Class II Equipment

Not MRI Compatible

Patient

Up/Increment

Percent Oxygen Pulse Saturation

Communication is Not Linked

Down/Decrement

Earth (Ground)

Communication is Linked

Input/ Output

Fuse

Single Patient Use Only Do Not Reuse

Do Not Bring Within 1000 Gauss Line

No European harmonized standard exists for the transmission frequencies used for medical telemetry. Potential restrictions may apply within one or more European (EU) member states.

NOTES