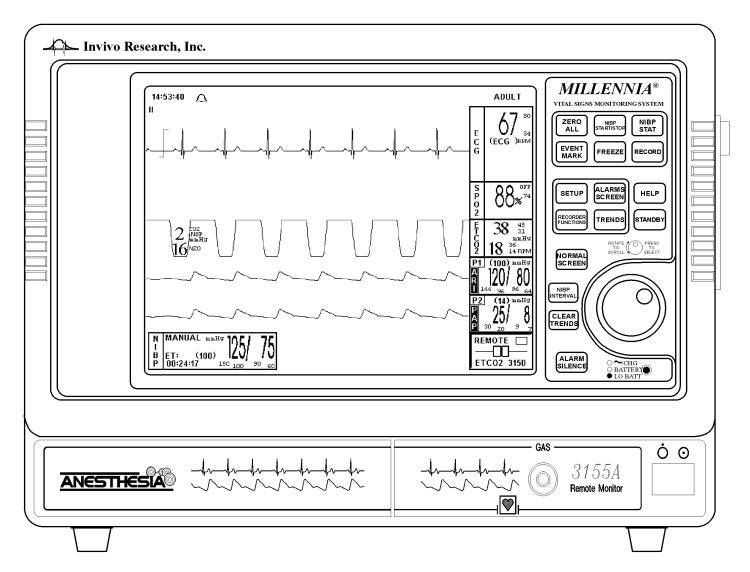
Millennia® 3155A/3155MVS Monitor



Operations Manual



Invivo Research, Incorporated

Millennia® 3155A/3155MVS Monitor

Operations Manual







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European Authorized Representative

Invivo Research UK, Ltd. Halifax, West Yorkshire United Kingdom

<u>Paragraph Number</u>		<u>Page Number</u>
List	of Figures.	iv
List	of Tables	V
	ipment Classification	
-	eautions	
	r Responsibility	
	-	
Acce	essory List	XII
1.0	INTRODUCTION	1-1
1.1	Product Description	1-1
	1.1.1 System Parameters	
	1.1.2 User Interface	
	1.1.3 Versatility	
1.2	Controls	
	1.2.1 Front Panel Controls	1-2
	1.2.2 The Side Panel	1-7
	1.2.3 Back Panel Connections and Inputs	1-7
1.3	Display	
	1.3.1 Informational Display	
	1.3.2 Vital Signs Trace Display	
	1.3.3 NIBP, Agents and Remote Display	
1.4	Yes/No Menu	
1.5	Cleaning	1-11
	1.5.1 Cleaning Accessories	1-12
2.0	INSTALLATION	2_1
2.1	Introduction	
2.2	Monitor Installation	
2.2	2.2.1 Monitor Mounting	
	2.2.2 Monitor Location	
	2.2.3 Preparing the 3155A/3155MVS Monitor for Use	
	2.2.4 Monitor Start Up	
	2.2.5 3150(M) and 3155A/3155MVS Remote Monitor Communicat	
2.3	Software Installation	
2.5	2.3.1 Program Update/Upgrade	
	2.3.2 Monitor Setup Storage	
	2.3.3 Monitor Setup Recall	
3.0	MONITOR PREPARATION FOR USE	3-1
3.1	Introduction.	
3.2	SETUPS Menu	
	3.2.1 Recall Setups	
	3.2.2 Store Setups	
	3.2.3 Parameter Selection	
	3.2.4 Display Setup	
	3.2.5 Sound Adjust	
	3.2.6 Patient	3-6

Paragraph Number		<u>Page Number</u>	
	3.2.7	Set Time	3-6
	3.2.8	Default Setups	3-7
	3.2.9	Sweep Speed	
	3.2.10	Respiration Speed	3-7
		Service (Bio-Med)	
		Return	
3.3	Store/	Recall Setups	3-10
3.4		or Initialization	
	3.4.1	Default Initialization	3-10
	3.4.2	Pre-Configured Initialization	3-11
4.0	PATI	ENT PARAMETERS	4-1
4.1	Introd	uction	4-1
4.2	ECG 1	Monitoring	4-1
	4.2.1	Associated Waveforms and Displays	4-1
	4.2.2	The ECG Menu	
	4.2.3	Alarm Limits	4-4
	4.2.4	Trended Data	4-4
	4.2.5	ECG Messages	4-4
4.3	Invasi	ve Pressure Monitoring	4-5
	4.3.1	Associated Waveforms and Displays	
	4.3.2	The Invasive Pressure Menu	
	4.3.3	Alarm Limits	4-7
	4.3.4	Trended Data	4-7
4.4	Non-I	nvasive Blood Pressure (NIBP) Monitoring	4-7
	4.4.1	Theory of Oscillometric Measurement	
	4.4.2	Associated Displays	
	4.4.3	The NIBP Menu.	
	4.4.4	NIBP Menu Options	4-10
	4.4.5	Using the Automatic Interval Mode	
	4.4.6	Manually Starting/Stopping a Reading Cycle	
	4.4.7		
	4.4.8	Alarm Limits	
	4.4.9	Adult vs. Neonatal Mode Operation	4-13
	4.4.10	Trended Data	
4.5		Monitoring	
	4.5.1	Associated Waveforms and Displays	
	4.5.2	SpO2 Menu	
	4.5.3	Alarm Limits	
	4.5.4	Trended Data	4-15
4.6	End-T	idal CO2 (ETCO2) Monitoring	
	4.6.1	Patient and Tubing Preparation.	
	4.6.2	Associated Waveforms and Displays	
	4.6.3	ETCO2 Menu.	
	4.6.4	Calibration of CO2/N2O Measurement System	
	4.6.5	Alarm Limits	
	4.6.6	Trended Data	

<u>Para</u>	graph Number	<u>Page Number</u>
4.7	Anesthetic Agent/Oxygen Monitoring.	4-18
	4.7.1 Patient and Tubing Preparation	
	4.7.2 Associated Displays	
	4.7.3 Agent Menu	
	4.7.4 Gas Calibration	
	4.7.5 Alarm Limits	
	4.7.6 Trended Data	
	4.7.7 Agent/O2 Messages	4-20
	4.7.8 Oxygen Sensor Replacement	
5.0	PRINTING AND TRENDING	5-1
5.1	Introduction	5-1
	5.1.1 Record Key	5-1
5.2	The RECORDER Menu	5-2
5.3	Printing Charts	5-3
	5.3.1 Strip Chart Printouts	5-3
	5.3.2 Tabular Chart Printouts	5-4
	5.3.3 System Data Report	5-5
5.4	Loading Printer Paper	5-5
5.5	Trending Feature	5-5
	5.5.1 HISTORY Menu Options	5-5
	5.5.2 Theory of Operation	5-6
	5.5.3 Trend Options	5-7
6.0	ALARMS	
6.1	Introduction	6-1
6.2	Alarm Limits	
	6.2.1 Default (Pre-Set) Alarm Limits	
	6.2.2 Range of High and Low Alarm Limits	
6.3	Alarms Menu	6-2
	6.3.1 Individual Parameter Alarm Limits Box	
6.4	Turning Alarms Off on Individual Parameters	6-7
6.5	Alarm Violations	
6.6	Adjusting the Alarm Tone Volume	6-7
	6.6.1 Disabling the Alarm Tone	6-8
6.7	Standby Mode	6-9
7.0	BATTERY OPERATION	
7.1	Introduction	
7.2	Battery Location and Access	7-1
7.3	Loading and Unloading Battery(s)	7-1
7.4	Battery Charging	
7.5	Battery Operation Time	
	7.5.1 Battery Low Indication	
	7.5.2 Maintaining Battery Life	
7.6	Battery Replacement	7-1

Paragraph Number		<u>Page Number</u>
App	endix A. Specifications	A-1
	endix B. Repair	
	endix C. Warranty	
	endix D. Declaration of Conformity	
	endix E. KpA to mmHg Conversion Chart	
	endix F: List of Symbols	
App	endix F. List of Symbols	1 ⁻ 1
	LIST OF FIGURES	
<u>Figu</u>	<u>re Number</u>	<u>Page Number</u>
1-1	The Front Panel	1-2
1-2	The Direct Control Keys	1-3
1-3	Menu-Select and Operation Keys	1-4
1-4	The Back Panel	
1-5	The Normal Screen	1-8
1-6	The Informational Display	1-8
1-7	The Middle Screen Vital Signs Trace Display	
1-8	The Bottom Vital Signs Numeric Display	1-10
3-1	The SETUPS Menu	
3-2	The RECALL SETUPS Menu	3-2
3-3	The STORE SETUPS Menu	3-3
3-4	The PARAMETER SELECTION Menu	3-3
3-5	The SOUND ADJUST Menu	3-4
3-6	The SET TIME Menu	3-6
3-7	The SERVICE (BIO-MED) Menu	3-7
3-8	The SYSTEM CONFIG Menu	3-8
4-1	ECG Display	4-1
4-2	The ECG Menu	4-2
4-3	The ECG SCALE Menu	4-2
4-4	The HR SOURCE Menu	4-3
4-5	Invasive Pressure Display	4-5
4-6	The P1 Menu (ART Selected)	
4-7	Invasive Pressure SET LABEL Menu	4-6
4-8	Oscillometric Measurement Method	4-8
4-9	The NIBP Display	4-9
4-10	The NIBP Menu	4-10
4-11	The NIBP INTERVAL Menu	4-10
4-12	The HISTORY Menu	4-11
4-13	The SpO2 Display	4-13
4-14	The SpO2 Menu	4-14
4-15	Patient Sample Circuit	
4-16	The ETCO2 Display	4-16
4-17	The ETCO2 Menu	4-17
4-18	The AGENT Display	
4-19	Oxygen Sensor Installation Diagram	
5-1	The RECORDER Menu.	5-1

LIST OF FIGURES

<u>Figur</u>	<u>e Number</u>	<u>Page Number</u>
5-2	Sample Strip Chart	5-3
5-3		5-4
5-4		5-4
5-5	Loading the Printer Paper	5-5
5-6	The HISTORY Menu	5-5
5-7	The MULTI TRENDS Menu	5- 6
5-8	The Trend SELECT Menu	5-7
5-9	Sample Mult Trends Printout	5-8
6-1	The ALARMS Menu	6-4
6-2	Anesthetic Agents Alarm Limits Menu	6-5
	LIST OF	TABLES
Table	Number	<u>Page Number</u>
6-1	Alarm Limit Factory Default Settings	6-2
6-2	Range of Alarm Limits	6-3
EQ	UIPMENT CLASSIFICATION	
Clas	sification according to IEC-601-1	
Acco	ording to the type of protection against trical shock:	Class I equipment.
Acce	ording to the degree of protection against trical shock:	Type CF (defibrillator-proof) equipment.
Acco	ording to the degree of protection against nful ingress of water:	Ordinary equipment (enclosed equipment without protection against ingress of water).
	ording to the methods of sterilization or affection:	Non0sterilizable. Use of Liquid surface disinfectants only.
Acce	ording to the mode of operation:	Continuous operation.
	ipment not suitable for use in the presence	e of a flammable anesthetic mixture with air or

General

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

The **Millennia**® **3155A/3155MVS Monitor** supplied with your Omni-TrakTM 3150/MagnitudeTM 3150M monitor is factory set to communicate **only** with the specific monitor it came with.

The Omni-TrakTM 3150/MagnitudeTM 3150M MRI Patient Monitoring System is comprised of the 3150(M) and a Millennia[®] 3155A/3155MVS Remote Monitor. Always operate the Omni-TrakTM 3150/MagnitudeTM 3150M MRI Patient 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 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 completely before attempting to operate the Millennia[®] 3155A/3155MVS 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 an "X" appears in the Alarm Bell symbol, 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, use only recommended Invivo Research patient cable, lead wires, cuffs, hoses, sensors, tubing, etc. A listing of these can be found in the Accessory Listing within the 3150(M) manual (Part Number 9538), 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.

Organic vapors (e.g. from cleaning agents) in sampling line or room air may alter anesthetic agent readings.

Alcohol in patient's breath may modify the anesthetic agent readings.

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 DC 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.

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

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

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 $110-120/220-240 \sim$ having a frequency of 50 or 60 Hz.

Occupational Safety

Connect the sample gas outlet on the monitor's rear panel to scavenging system to prevent pollution of room air.

Handle the Patient Sampling Line and its contents as you would any body fluid. Infectious hazard may be present.

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 **Millennia**® 3155A/3155MVS Monitor 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.

Always verify proper communication of the Omni-TrakTM 3150/MagnitudeTM 3150M MRI Patient Monitor with the Millennia[®] 3155A/3155MVS Monitor prior to patient use.

MRI Magnet Room Placement. The Omni-TrakTM 3150 MRI/MagnitudeTM 3150M MRI Patient Monitor is designed to be used in conjunction with a remotely located Millennia[®] 3155A/3155MVS Monitor. The Omni-TrakTM 3150/MagnitudeTM 3150M MRI Patient 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.

ECG

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.

For other ECG related precautions, refer to the 3150(M) Monitor Operations Manual (IRI Part Number 9538).

NIBP

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

For other NIBP related precautions, refer to the 3150(M) Monitor Operations Manual (IRI Part Number 9538).

SpO₂

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 volume, but adjusts the waveform amplitude as needed for proper viewing.

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

For other SpO2 related precautions, refer to the 3150(M) Monitor Operations Manual (IRI Part Number 9538).

EtCO₂

Always select the appropriate EtCO2 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.

The N2O measurements are automatically pressure compensated over an ambient pressure minimum range from 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.

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.

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.

Respiration rate measurement errors could result during ventilation rates above 80 breaths per minute.

Anesthetic Agents

Inadequate ventilation of the monitor may cause inaccurate readings or damage to electronic components.

Ensure that the exhaust gas is not removed from the monitor under too strong suction. To prevent suction, there must always be an opening to the room air. Strong suction may change the operating pressure of the monitor and cause inaccurate readings or internal damage.

Inspect waste gas line for deterioration on a routine basis. Replace as needed.

Remove sampling line from patient airway whenever nebulized medications are being delivered.

Use only Invivo Research, Inc. sampling lines and accessories; other sampling lines may cause inaccurate readings and malfunctions.

In Desflurane Gas Mixtures, the change in concentration of the other anesthetic may become clinically significant before a gas mixture alarm is given.

Some Hydrocarbons (e.g. Acetone, Methane) may cause a mixed agent alarm to occur.

Replace the sampling line and filter between each patient use.

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

If questionable oxygen or anesthetic agent gas measurements are observed, recheck patient connections, anesthesia gas machine and/or vaporizer before re-adjusting oxygen or anesthesia delivery.

Always respond to patient tubing disconnect alarms immediately to prevent lapse in patient monitoring.

Routinely verify the monitor's internal barometric pressure reading with local conditions during the initial start-up period.

Gas mixtures of Desflurane and Sevoflurane will not cause a multiple agent alarm. The optical filters used to determine Desflurane and Sevoflurane are very similar, making it very difficult to determine the presence of Desflurane and Sevoflurane at the same time. The identification could be either Desflurane or Sevoflurane in concentration values (Fi and ET) greater than either of the actual concentrations of Desflurane and Sevoflurane.

During the 15 minute warm-up with no sample line connected to the monitor it is possible to have a false identification and value display of Enflurane.

With no gas reading (Agent Icon box with white X for agent identification and agent values of "--") when Agent Vaporizer is first turned on, it may take 30 seconds to 1.5 minutes for agent identification and reading to be displayed. Once identification is established, changes in concentration are virtually immediate. With a 200% change in concentration, an auto Zero will occur, and full accuracy of the changed concentration will be accomplished within approximately 30 seconds.

Whenever the Millennia[®] 3155A's Agent sensor changes from steady state condition, the Millennia[®] 3155A will perform an auto zero to restabilize the sensor readings. During this time, 15 seconds to 1.5 minutes, it is possible for a false identification and concentration value to occur. Examples are as follows:

- a. No gas, during warm-up and when sample line is disconnected.
- b. Applying sample line for the first time.
- c. When switching from one Agent to another.
- d. Applying N2O in concentrations of 70% or more.
- e. Going from N2O of greater than 50% to 0%.
- f. When going from high Agent concentrations to low or off.

Pressures

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.

Other

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 including MRI Scanners. 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 contained in this operators manual and accompanying labels and/or inserts, when assembled, operated, maintained and repaired in accordance with the instructions provided. This product must be checked and calibrated periodically. A malfunctioning 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 refer unit to qualified service personnel. This product or any of its parts should not be repaired other than in accordance with written instructions provided by the manufacturer, or altered without written approval of Invivo Research, Incorporated (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 Invivo Research or Invivo Research authorized service personnel.

Using this Manual. Whenever the various options are discussed, "XXX" is used to indicate a variable setting. It is required that every operator read this manual completely, including any patient information in sections about monitoring features the operators monitor does not have, before attempting to operate the Millennia® 3155A/3155MVS Monitor.

Precautions (listed earlier in this section) cover of wide ranges of information crucial to the safe monitoring of patients. It is required that every operator read the PRECAUTIONS completely, including the Precautions associated with monitoring features that the operators monitor does not have, before attempting to operate the Millennia® 3155A/3155MVS Monitor.

For further information or assitance with this product: Invivo Research, Incorporated 407-275-3220 or 800-331-3220

Accessory List END -TIDAL CO2

<u>Item Description</u>	Part Number
ETCO2 Sampling Kit	9010D
Contains 20 foot co-extruded sampling tube polyethylene inner core with PVC tube, elbow adapter, 0.8 micron disk filter.	
Nasal ETCO2 Sampling Kit	9010DA
Contains 10 foot co-extruded sampling tube, polyethylene inner core with PV Nafion® tube, elbow adapter, 0.8 micron disk filter.	'C jacket,
Nasal ETCO2 Sampling Kit Replacements	
Co-extruded Nasal ETCO2 Sampling Line	9028 cking luer,
Co-extruded Nasal ETCO2 Sampling Line	9041
20 foot co-extruded polyethylene inner core with PVC jacket, male/female lo package of 25.	cking luer,
Endotracheal Tube Adapter, package of 50	9025
Hydrophobic Disk Filter, 0.8 Micron, Male / Female Locking Luer, package of 50	9026
Nafion® tube, ME dryer (1 replacement)	9010H
Nasal ETCO2 Supplies	
ETCO2 Calibration Gas, aerosol 10% CO2, 50% N2O, Bal. N2	9010F
Adult Nasal ETCO2 Sampling Cannula 7 foot line	9012
Pediatric Nasal ETCO2 Sampling Cannula 7 foot line	9013
Infant Nasal ETCO2 Sampling Cannula 7 foot line	9014
Intermediate Infant Nasal ETCO2 Sampling Cannula 7 foot line	9015
Adult Bifurcated/Divided Cannula-O2 and ETCO2	
Infant Bifurcated/Divided Cannula -O2 and ETCO2	9016A
7 foot O2 line and 7 foot CO2 line. For simultaneous delivery of oxygen and sampling.	
Intermediate Infant Bifurcated/Divided Cannula-O2 and ETCO2	
Pediatric Bifurcated/Divided ETCO2 Cannula -O2 and ETCO2	9016C ETCO2

Accessories

End-Tidal CO2 (Continued)

<u>Item Description</u>	Part Number
Nasal ETCO2 Supplies (Continued)	
Adapter, Luer Lock, Female/Female	
Water Trap Start Up Kit, Disposable	drophobic disk filter
Waste Gas Scavenger Line	9471
Anesthetic Agent	
Anesthetic Oxygen Sensor Kit	9461 Sensor Adapter.
Oxygen Sensor, Galvanic	9445
Inspired 02 Sensor Kit, Disposable	9464 e O2 directly in the
Water Trap Kit, Disposable	9436 ophobic disk filter 0.08
Waste Gas Scavenger Line	9471
Anesthetic Agent Check Gases:	
QC Check Gas: 7% Desflurane, 5% CO2, 60% N2O, 21% O2, Balance N2 Container	9034A
QC Check Gas: 1% Enflurane, 5% CO2, 60% N2O, 21% O2, Balance N2; Container	9034B
QC Check Gas: 1.5% Sevoflurane, 5% CO2, 60% N2O, 21% O2, Balance Container	9034C
QC Check Gas: 1% Isoflurane, 5% CO2, 60% N2O, 21% O2, Balance N2; Container	9034D
	9034E
OC Check Gas: 5% CO2 45% N2O 50% O2: 11 Liter Aerosol Container	9034F

Accessories CARTS AND MOUNTS

<u>Item Description</u>	<u>Part Number</u>
GCX Wall Mount Bracket/3155 Millennia® Series	riewing from any d permitting easy oning of the
Invivo Bed Rail Mount Bracket	er a bed rail arts and Mounts.
Invivo Anesthesia Gas Machine Mounting Bracket	n Anesthesia gas
GCX 3155 Millennia® Flat Surface/Table Top Mount (Requires 9003E Mounting Bra GCX manual tilt polymount bracket and stand allows for installation on a flat countertop that can support the 3155 Millennia® weight (fully configures maximulated mounting hardware, but requires the Invivo Bed Rail Mounting Bracket	surface or imum of 19 lbs.).
PRODUCT NOTE	
For Millennia® 3155A Anesthesia Gas Machine Mounting options and pricing, Marketing Department.	contact Invivo
MISCELLANEOUS	
Thermal Array Recorder Paper, 10 rolls pr box	9180T
Millennia® 3155A/3155MVS AC Power Supply, 120 VAC, 50/60Hz	
Millennia® 3155A/3155MVS AC Power Supply, 100 VAC, 50/60Hz	
Millennia® 3155A/3155MVS Rechargeable Battery Pack, 12V	
Millennia [®] 3155A/3155MVS Software Upgrade Kit	9458
Millennia® 3155A/3155MVS PCMCIA Card, AM46	9465
Millennia® 3155A/3155MVS PCMCIA Card, AM55	® 3155A/ Millennia® t values, recorder
Millennia® 3155A/3155MVS Operations Manual	9545
Millennia® 3155A/3155MVS Service Manual	9546
AS153 Fuse, 120 VAC, 3/4 A Slo-Blo	FU13
AS153 Fuse, 250 VAC, 2/5 A, Slo-Blo	FU25

SECTION 1 INTRODUCTION

1.0 INTRODUCTION.

Product Description. The Millennia® 3155A/3155MVS Monitor is the Remote Control 1.1 Unit in the Invivo Research, Incorporated 3150 Series MRI Monitoring System. This monitor provides Remote Control (through a cable or RF Radio Link) to a Omni-TrakTM 3150/MagnitudeTM 3150M MRI Patient Monitor (located in the MRI Magnet Room). Used with the Omni-TrakTM 3150 MRI Patient Monitor, the Millennia® 3155A/3155MVS Monitor provides four waveform traces compiling, processing, analyzing and displaying patient data from up to seven different patient parameters. The information that this Monitoring System 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. There is no direct patient connection to the Millennia® 3155A/3155MVS Monitor (patient connection is performed in the Magnet Room with the Omni-TrakTM 3150/MagnitudeTM 3150M MRI Patient **Monitor**) except in the case of Agent monitoring when the Millennia[®] 3155A is used with the patient sample line connected directly into the front of the monitor. The Millennia® 3155A/3155MVS **Monitor** is compact, comes equipped with up to three batteries to supply emergency and/or transport power plus may "float" between the Magnet Room and Control Room (as determined by the needs of each unique monitoring situation). It also contains (as a optional feature) a recorder designed to provide printouts of the concise charts and trends required by today's specialists for analysis and documentation. The Millennia® 3155A/3155MVS can be used inside the MRI Magnet Room when positioned at or outside the 1000 Gauss (0.1T) Field Line. For the purposes of this manual, the Omni-TrakTM 3150 and MagnitudeTM 3150M MRI Patient Monitors will be referred to as the 3150(M) and the Millennia[®] 3155A and 3155MVS Monitors will be referred to as the 3155A/3155MVS.

During MRI procedures that require anesthetic agents monitoring, where the 3155A is used in the MRI exam room, the dual monitor system (software MDC01 and higher) allows the operator to add a 3155MVS to the MRI monitoring system. The 3155MVS and 3155A interact through the 3150(M) to allow monitoring at a remote site (such as the MRI control room).

NOTE

The 3150(M) ETCO2 is turned Off when the Agent/ETCO2 is turned On at the Millennia[®] 3155A. When the Millennia[®] 3155A is used to monitor Agent/ETCO2, it must be located in the Magnet Room with the gas sample line connected directly to the front of the 3155A.

If operating a dual monitor system, the 3155MVS and 3155A patient monitors are interactive with one another though the 3150(M). As the "communication unit" the 3150(M) acts to keep the commands that control patient parameter function synchronized throughout the MRI monitoring system. Should the 3150(M) 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(M) is turned on the system will synchronize and all patient configurations will reflect the 3155A configuration.

The **3155A/3155MVS Monitor** provides control and display of the following Vital Sign Parameters:

ECG
 NIBP
 Two Invasive Blood Pressures

Pulse Oximetry
 ETCO2
 Respiration

• N2O • O2 • Identifies and measures Five (5) Major Anesthetic Agents

- 1.1.1 System Parameters. The 3155A/3155MVS 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.
- 1.1.2 <u>User Interface</u>. A simple to use interface has been developed to minimize operator learning time. A *Rotary Knob*, which detents from selection to selection, is used to access the parameter menu's, access the various setup features and finalize any changes to the setup of the monitor. Frequently used menus (such as: **Alarms, Trends** and **Recorder**) have a *Control Key* which, when pressed, will open the associated menu.
- <u>1.1.3</u> <u>Versatility.</u> With its complete offering of vital sign parameters, the **3155A/3155MVS Monitor** may be configured to meet the monitoring needs of a wide spectrum of patients from Neonate to Adults. Every available parameter may be easily accessed and adjusted to the unique needs, condition and situation of each patient.
- **1.2 Controls.** Control of the Monitoring Features is provided through the use of a Rotary Knob; as the operator turns the Rotary Knob (either clockwise or counterclockwise), with each detent the next Vital Signs Display will become highlighted (selected) and, when the appropriate display is selected, pressing the Rotary Knob will bring up the menu for the desired parameter. For adjustment of the Operational Features, the front panel provides two different sets of control keys: the menu-select keys bring up operational menus, while the direct control and operational keys provide manual control of selected patient parameters.

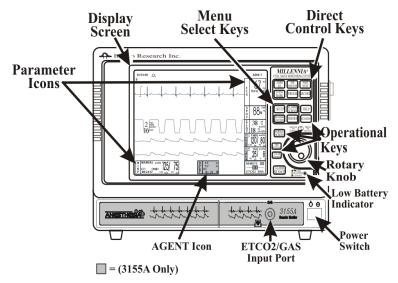


Figure 1-1. The Front Panel

- 1.2.1 <u>Front Panel Controls.</u> (See Figure 1-1) The 3155A/3155MVS Monitor front panel consists of one Rotary Knob, six Direct Control keys, four Menu-Select keys, five Operational keys, one **Alarm Silence** key and the Power On/Off switch. The 3155A also contains an ETCO2/Gas Input Port and additional graphics on the bottom of the front panel. The following is a general description of the front panel controls.
 - a. **The Rotary Knob.** The Rotary Knob is located to the right of the Display Screen. The function of the Rotary Knob is menu specific. For this reason, its various functions are described throughout this document where it is used; in general, however, the Rotary Knob operates as described below:
 - (1) As the Rotary Knob is rotated, either clockwise or counterclockwise, the monitor display "scrolls" through the various screen items (screen icons, menu options and patient parameters) which are available for selection. When the appropriate item is "highlighted," it may be selected by pressing and releasing the Rotary Knob. All menus have a **RETURN** option which will return the monitor to the previous menu selection.

During normal operation each active parameter has a Menu-Select icon on the screen. When the Rotary Knob is rotated, the Menu-Select icon which is being pointed at becomes "highlighted." Rotating the Rotary Knob will cause the monitor to "scroll through" the available menu selections. Once the appropriate Menu-Select icon is highlighted, pressing the Rotary Knob completes the selection and brings up the required menu. Once the menu is selected, the Rotary Knob is used to scroll through the available choices and make adjustments to the selected parameter. The following Menu-Select Icons may be available on the Normal Screen (depending on which parameters are available, enabled and turned on): ECG, P1, P2, NIBP, ETCO2, Agents and SpO2.

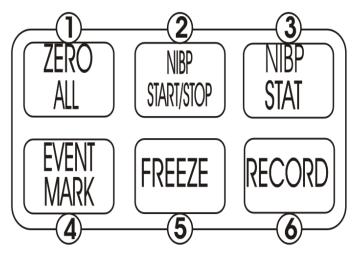


Figure 1-2. The Direct Control Keys

- b. **Direct Control Keys.** (See Figure 1-2) There are six Direct Control keys: **ZERO ALL, NIBP START/STOP, NIBP STAT, EVENT MARK, FREEZE** and **RECORD**. These keys provide the operator with direct control of the following features: Starting/Stopping NIBP Readings, Starting/Stopping the NIBP STAT Mode, Freezing all Traces, Starting the Recorder, Adding a Marker to the Recorder and Zeroing all Invasive Pressure Channels.
 - (1) **ZERO ALL. (Item 1)** The Pressure Transducer is zeroed by the **3150(M) MRI Patient Monitor** in the MRI Magnet Room, therefore this key is inactive and pressing it will display a message to indicate that this function is not available in the Remote Mode of Operation. See the 3150/3150M MRI Patient Monitor Operation Manual (Part Number 9538) for further information.
 - (2) **NIBP START/STOP.** (Item 2) This key starts a new NIBP measurement, or stops a measurement that is already in progress.
 - (3) **NIBP STAT.** (**Item 3**) This key starts the NIBP STAT Mode measurements. This mode may be terminated by depressing the **NIBP START/STOP** key. The STAT Mode performs up to five (5) NIBP measurements in rapid succession (with a short pause between readings) within a maximum time frame of five (5) minutes. This feature is not available with dual monitor software (MPC01 or higher).
 - (4) **EVENT MARK.** (Item 4) The **EVENT MARK** key prints a marker on the ECG Recorder Strip when the printer is running. If the printer is not running, pressing this key has no effect.

- (5) **FREEZE.** (**Item 5**) The **3155A/3155MVS Monitor** freezes the ECG waveform from Trace A for closer examination upon user demand. When the ECG trace is active, pressing the **FREEZE** key will freeze it into the Trace B location while Trace A remains active. When the trace is frozen, pressing the **FREEZE** key will release it. A "Blue Box" appears around the frozen waveform as a visual indication that the waveform is not active. While the Freeze feature is active, the monitor will not allow any changes to the Parameter Setups or Recall Setups; if the operator attempts to access the PARAMETER SELECTION or RECALL SETUP menus, a WARNING Box alerts the operator that entry to the selected menu is not allowed while FREEZE is enabled.
- (6) **RECORD.** (Item 6) Pressing this key records the Single Trace or Dual Trace selections (as specified by operator adjustments made in the **RECORDER** Menu). The recorder stops automatically after approximately 30 seconds, or when the **RECORD** key is pressed again; in either case, the printout ends with a "Snap Shot" of the active patient parameter data.

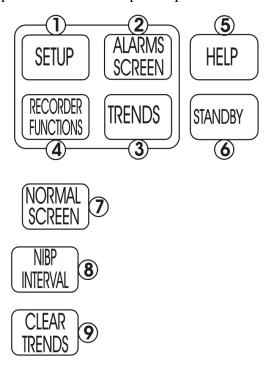


Figure 1-3. Menu-Select and Operation Keys

- c. **Menu-Select Keys.** (See Figure 1-3) The Menu-Select keys allow the operator to specialize the operation of the 3155A/3155MVS Monitor to suit specific procedures and/or situations. Pressing a Menu-Select key will activate the "pop-up" menu for the selected feature which is then controlled by the Rotary Knob so that the associated parameters may be adjusted. The four Menu-Select keys are SETUP, ALARMS SCREEN, RECORDER FUNCTIONS and TRENDS.
 - (1) **SETUP.** (Item 1) The **SETUP** key allows the operator to access the various available setup options (See Section 3).
 - (2) ALARMS SCREEN. (Item 2) The ALARMS SCREEN key allows the operator to setup the Alarms monitoring feature (See Section 6). If operating a dual monitor system, with a 3155A and 3155MVS communicating with the 3150(M), the adjustments made here are interactive between the two 3155 monitors to ensure that the monitored parameters remain consistent between all components of the MRI monitoring system.

- (3) **TRENDS.** (**Item 3**) The **TRENDS** key allows the operator to setup the Trend monitoring feature. The exact operation of the **TRENDS** key is based on whether or not a feature is currently highlighted. If a feature is currently highlighted, pressing the **TRENDS** key will bring up a Trend which is specific to the highlighted feature; if a feature is not currently highlighted, pressing the **TRENDS** key will bring up the HISTORY Menu and Tabular Display (**See Section 5**).
- (4) **RECORDER FUNCTIONS.** (Item 4) The **RECORDER FUNCTIONS** key allows the operator to setup the Recorder option (See Section 5).
- d. **Operational Keys.** (See Figure 1-3) The are five Operational keys: HELP, STANDBY and NORMAL SCREEN.
 - (1) **HELP.** (Item 5) The **HELP** key is for future operational enhancement.
 - (2) **STANDBY.** (**Item 6**) Pressing the **STANDBY** key places the **3155A/3155MVS Monitor** into the Standby Mode. The monitor stays in Standby Mode until the **STANDBY** key is pressed a second time. Except for the three (3) key features given below, the monitor operates normally by continuing to provide current patient information on the Display Screen. If operating a dual monitor system, with a 3155A and 3155MVS communicating with the 3150(M), pressing this key will place both monitors into the Standby Mode.

While in Standby Mode:

- All audible alarms are disabled. The disabled alarms are indicated on the screen by the "X" through the bell shaped Alarm Status Symbol.
- Active NIBP automatic measurements are suspended.
- No automatic printout is generated.
- (3) **NORMAL SCREEN.** (Item 7) Pressing the **NORMAL SCREEN** key returns the **3155A/3155MVS Monitor** from any menu to the normal screen.
- (4) **NIBP INTERVAL.** Pressing the **NIBP INTERVAL** key brings up the **NIBP INTERVAL** Menu where the cycle time (time between readings) of the NIBP Automatic Reading Mode may be adjusted.
- (5) **CLEAR TRENDS.** Pressing the **CLEAR TRENDS** key allows the operator to clear all the stored data from memory. To prevent accidental erasure of patient data, there is a Yes/No box associated with this key that appears to ensure that the operator meant to clear the trend data. If operating a dual monitor system, with a 3155A and 3155MVS communicating with the 3150(M), pressing this key will clear the trend file of both monitors.
- e. **Alarm Silence Key.** Pressing the **ALARM SILENCE** key will silence any active alarm. The letter "S" appears in the Alarm Bell and an "Alarm Silenced" message appears in the center of the screen as visual indications that an alarm has been silenced. If operating a dual monitor system, with a 3155A and 3155MVS communicating with the 3150(M), the **ALARM SILENCE** key is interactive throughout the MRI monitoring system. The details of this key's function depend on the monitor's settings:
 - (1) Unlatched Alarms. If the alarm system has been set to UNLATCHED in the ALARMS Menu and an Alarm Limit is violated, pressing the ALARM SILENCE key will silence the Alarm Tone when an active Alarm Limit has been violated. While the parameter continues to violate its limits, the numerics of the violating parameter continue to flash on the screen. If operating a dual monitor system, with a 3155A and 3155MVS communicating with the 3150(M), the adjustments made here are interactive between the two 3155 monitors to ensure that the monitored parameters remain consistent between all components of the MRI monitoring system.

- (2) **Latched Alarms.** If the alarm system has been set to LATCHED in the **ALARMS** Menu and an Alarm Limit is violated, while the parameter continues to violate its limits, pressing **ALARM SILENCE** key stops the Alarm Tone, but the numerics remain red and continue to flash, even after the parameter returns to within its Alarm Limits. If operating a dual monitor system, with a 3155A and 3155MVS communicating with the 3150(M), the adjustments made here are interactive between the two 3155 monitors to ensure that the monitored parameters remain consistent between all components of the MRI monitoring system.
- (3) ALARM HOLD. If the ALARM SILENCE key is pressed when the Alarm Tone is enabled but no alarm condition currently exists, a "SOUND ON HOLD" message appears in the upper center of the screen with a count down timer starting at 180 (counting down at a 1 second rate) denoting that the Alarm Tone is being temporarily held silent. In addition, an "H" will appear in the Alarm Status Symbol to further alert the operator that the Alarm System is on Hold.

If the Alarm Tone is sounding, the first pressing of the **ALARM SILENCE** key stops the Alarm Tone and puts the letter "S" in the Alarm Bell, and a second pressing enables Alarm Hold.

The monitor automatically exits alarm hold after three minutes, and the "SOUND ON HOLD" message disappears from the screen, reactivating the Alarm Tone. Pressing the ALARM SILENCE key before the three minute period is over will also reactivate the Alarm Tone and remove the "SOUND ON HOLD" message from the screen.

The user is able to put alarms on hold (**SOUND ON HOLD**) only when the Alarm Tone is active (no **X** appears in the bell symbol in the upper left of the screen). Alarm Hold is useful for temporarily disabling the Alarm Tone. This might be useful, for example, when changing ECG leads, when drawing blood from an arterial pressure line, or for any user activity which might cause a "false" alarm.

- f. **ETCO2/Gas Input Port.** (3155A only) Located on the bottom of the monitor front panel, the ETCO2 Input Port is for the connection of the ETCO2 or Gas connector.
- g. **Low Battery Indicator.** The Low Battery Indicator (located beneath the Rotary Knob) is a three color LED that indicates the DC/Battery Power condition of the monitor. The Power Light will illuminate Green, Yellow and Red as described below:
 - (1) **Green Light.** A Green Light indicates that the monitor is operating on DC Power from the AS153 AC Power Adapter. In normal operation, this light will be illuminated Green.
 - (2) **Yellow Light.** A Yellow Light indicates **Caution** because the monitor is operating on the internal batteries. The internal batteries are intended for temporary use only (such as during patient transport or brief outages of facility power) with an operating time dependent on the number of batteries your monitor has.
 - (3) **Red Light.** A Red Light indicates **Warning** because monitor shutdown is soon to occur. The internal batteries have fallen below the required operational output and an AC Wall Outlet should be located, and the monitor plugged into it through the AS153 AC Power Adapter, immediately.
- h. **ETCO2 Waste Gas Exhaust.** (3155A only) Located on the monitor back panel, the ETCO2 Waste Gas Exhaust Port is used for release of waste gas from the optional ETCO2 module and, when equipped with the Anesthetic Agent option, provides for the connection of the O2 Sensor (Invivo Research, Inc. Part Number 9445). This port is constructed to allow for connection into any existing Gas Scavenge system.

- i. **Power Switch.** The Power Switch allows the operator to apply and remove power from the **3155A/3155MVS Monitor**.
- <u>1.2.2</u> The Side Panel. The Side Panel contains the I/O Port for the PCMCIA "Flash" Card and the optional Recorder Unit.
 - a. **PCMCIA I/O Port.** The PCMCIA I/O Port allows for reloading of the monitor software and also for monitor upgrade.
 - b. **Recorder Unit.** The Recorder provides a printout of patient parameter data either automatically or upon operator demand.
 - c. **Batteries.** To install the monitor batteries, turn the retainer screw on the side panel to open the door then push the battery into the slot until it snaps into place. To remove the batteries, turn the retainer screw on the side panel to open the door then push the battery clip away from the battery and pull the battery out of the slot.

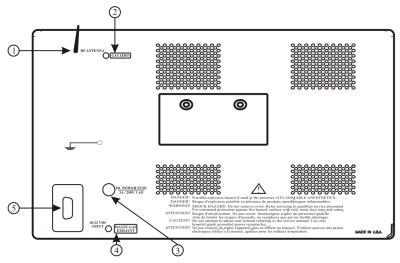


Figure 1-4. The Back Panel

- <u>1.2.3</u> <u>Back Panel Connections and Inputs.</u> (**See Figure 1-4**) The following is a description of the Back Panel Connections and Inputs:
 - a. **RF ANTENNA.** (**Item 1**) The antenna that receives the information from the 3150(M) monitor.
 - b. **GAS ZERO.** (Item 2) (3155A only) The GAS ZERO Port is used for zeroing of the optional ETCO2 and/or Anesthetic Agent Gas module.
 - c. **DC POWER FUSE.** (Item 3) The DC Power Fuse protects the monitor from surges in DC Power.
 - d. **WASTE GAS EXHAUST.** (Item 4) (3155A only) The Waste Gas Exhaust Port is used for release of waste gas from the optional ETCO2 module and, when equipped with the Anesthetic Agent option, provides for the connection of the O2 Sensor (Invivo Research, Inc. Part Number 9445). This port is constructed to allow for connection into any existing Gas Scavenge system.
 - e. **DC Power Connection.** (**Item 5**) The DC Power Connection is where the AS153 AC Power Adapter is connected to this monitor.
- **1.3 Display.** The **3155A/3155MVS Monitor** display screen (**See Figure 1-5**) displays three groups of data: 1) the Informational Display, 2) the Vital Signs Trace Display and 3) the Vital Signs Numeric Display. The entire display screen, with its three different display groups, is called the "**Normal Screen**." The three displays are described below.

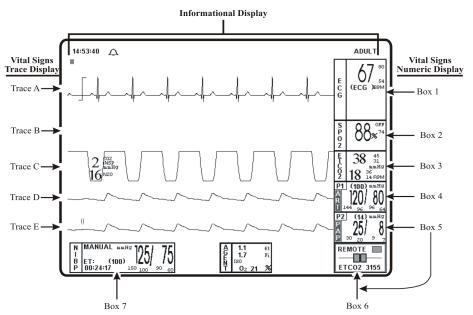


Figure 1-5. The Normal Screen

1.3.1 <u>Informational Display.</u> (See Figure 1-6) The Informational Display is located at the top of the Normal Display. This display provides the operator with the current time, the Alarm Status Bell Symbol, a flashing Heart Rate Symbol, a flashing Lung Symbol, any current user messages and the current Patient Selection.

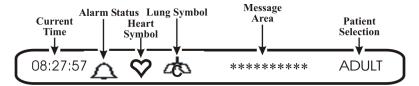


Figure 1-6. The Informational Display

- a. **Time.** The current time is displayed in a 12 or 24 hour format (hh:mm:ss). The time, date and clock mode (12 or 24 hour) is adjusted in the **TIME** Menu.
- b. **Alarm Status Symbol.** The **3155A/3155MVS Monitor** sounds an Alarm Tone when any monitored parameter violates its programmed Alarm Limits. The status of the Alarm Tone is indicated by the bell shaped Alarm Status Symbol.

WARNING

When an "X" appears in the Alarm Status Symbol, the audible Alarm Tone will **NOT** sound for any reason.

- (1) The letter "H" appearing in the bell indicates that the alarms have been placed on temporary Hold with the **ALARM SILENCE** key. Similarly, during power-up the "**SOUND ON HOLD**" message displayed in the center of the screen indicates that the Alarm Tone is temporarily placed on hold. A 180 second countdown timer is also displayed under the message.
- (2) The letter "X" appearing in the bell symbol indicates that the alarms have been turned off from the **ALARMS** Menu or that **Standby** Mode has been engaged. In this case the Alarm Tone will not sound for any reason.

- (3) The letter "S" appearing in the bell indicates that a current alarm has been silenced with the **ALARM SILENCE** key. This feature will disable only the alarms that were current when the **ALARM SILENCE** key was pressed, any new alarms will cause the Alarm Tone to sound.
- c. **Heart Symbol.** The Heart Symbol flashes on the screen each time a heart beat is detected. A tone is sounded at the same time (unless turned off in the **ECG** Menu or the **SPO2** Menu).
- d. **Messages.** These messages assist the operator in various aspects of the operation of this monitor.
- e. **Patient Selection.** Indicates the selected patient (ADULT or NEONATAL) for the ECG, ETCO2 and NIBP monitoring features. If operating a dual monitor system, with a 3155A and 3155MVS communicating with the 3150(M), the adjustments made here are interactive between the two 3155 monitors to ensure that the monitored parameters remain consistent between all components of the MRI monitoring system.

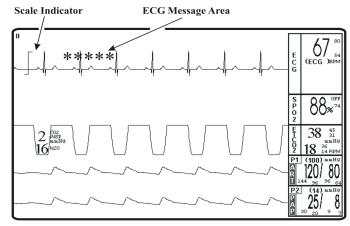


Figure 1-7. The Middle Screen Vital Signs Trace Display

- <u>1.3.2</u> <u>Vital Signs Trace Display.</u> (**See Figure 1-7**) The Vital Signs Trace Display is located in the middle of the Display Screen. This Display provides the operator with a trace of the selected parameters and also contains Numerical Vital Sign indications for the selected patient parameter.
 - a. The Vital Signs Trace Display portion of the screen is divided into six separate trace areas. When turned on, the traces (A through E) are fixed on the screen and updated with an Erase Bar. When a trace has been turned off, that portion of the screen is blank. The numeric values for each trace appear near the right screen boundary.
 - b. If the value is greater than or equal to a maximum calculable value, "**OVR**" (Over Range) is alternately displayed with the numeric value.
 - The following is a description of each Trace:
 - c. **TRACE A.** The ECG 1 trace is displayed in this position, unless turned off from either the **ECG** Menu or the **SETUPS** Menu. The main menu for this trace and for the Heart Rate are brought up with the selection of the **ECG** Menu-Select Icon. If operating a dual monitor system, with a 3155A and 3155MVS communicating with the 3150(M), the adjustments made here are interactive between the two 3155 monitors to ensure that the monitored parameters remain consistent between all components of the MRI monitoring system.
 - (1) The heart rate is displayed near the right screen boundary in the Trace A position. The numerics turn Red and flash if a Heart Rate Alarm Limit is violated. The color of the numerics is that of the selected HR source.

- The annotation below the heart rate value indicates the source of the heart rate, as selected from the **ECG** Menu, the **NIBP** Menu, the **P1** or **P2** Menus or the **SPO2** Menu. Heart rate source choices are AUTO, ECG, ART (P1 or P2), SPO2 and NIBP.
- (3) A red flashing numeric value on the screen indicates that an alarm for this value has been violated. This provides a visual indication of alarm violations, even when the Alarm Tone is turned off.
- (4) If **AUTO** is selected as the **HR SOURCE**, the highest-priority active input is utilized for displaying the heart rate, in the following order: ECG, P1, P2, SpO2 and NIBP. The ECG trace must be off, or lead fail present, for the Auto heart rate source not to be the ECG trace.
- (5) If the monitor does not find a valid heart rate source when set to **AUTO** and NIBP is OFF, the heart rate is annotated with "**NONE**."
- (6) The displayed lead for the ECG is indicated near the left screen boundary.
- (7) A scale indicator is displayed near the left screen boundary in the ECG waveform area(s). It represents a 1mV amplitude in the currently selected scale.
- d. **TRACE B.** The SpO2 waveform is displayed in this trace location unless it is turned off in the **SETUPS** Menu or P2 is ON. If operating a dual monitor system, with a 3155A and 3155MVS communicating with the 3150(M), the adjustments made here are interactive between the two 3155 monitors to ensure that the monitored parameters remain consistent between all components of the MRI monitoring system.
- e. **TRACE C.** The ETCO2 waveform is displayed in this trace location unless it is turned off in the **SETUPS** Menu. If operating a dual monitor system, with a 3155A and 3155MVS communicating with the 3150(M), the adjustments made here are interactive between the two 3155 monitors to ensure that the monitored parameters remain consistent between all components of the MRI monitoring system.
- f. **TRACE D.** The P1 waveform is displayed in this trace location unless it is turned off from the **SETUPS** Menu. If operating a dual monitor system, with a 3155A and 3155MVS communicating with the 3150(M), the adjustments made here are interactive between the two 3155 monitors to ensure that the monitored parameters remain consistent between all components of the MRI monitoring system.
- g. **TRACE E.** The P2 waveform is displayed in this trace location unless it is turned off from the **SETUPS** Menu. If operating a dual monitor system, with a 3155A and 3155MVS communicating with the 3150(M), the adjustments made here are interactive between the two 3155 monitors to ensure that the monitored parameters remain consistent between all components of the MRI monitoring system.

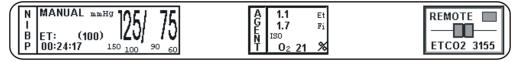


Figure 1-8. The Bottom Vital Signs Numeric Display

1.3.3 NIBP, Agents and Remote Display. (See Figure 1-8) The NIBP, Agents and Remote Displays are located at the bottom of the display screen with the NIBP Icon located to the left, the Agents Icon in the center and Remote to the right. While not in "dual monitor" mode and using a 3155MVS alone, the Agents Icon will not be available for display. This Display is divided with boxes that provide the operator with numerical indications of the NIBP, Agents and a visual indication that the monitor is in the Remote Operation Mode along with the source of ETCO2 (3155 or 3150).

The following is a description of the possible selections for the Vital Signs Display:

a. **Non-Invasive Blood Pressure (NIBP).** NIBP is displayed on the bottom left of the display screen. The Systolic, Diastolic and Mean blood pressure values are displayed along with measurement information such as the Elapsed Time (ET) since the last measurement and the time until the next measurement (if in the Automatic Mode). While in the Manual mode, MANUAL is shown in the place of the time until the next measurement.

The NIBP error messages are shown in place of the "NEXT: 00:00:00." If errors are detected by the NIBP circuitry, one of the following messages are displayed which preclude the determination of the blood pressure (if operating a dual monitor system, these messages are interactive throughout the MRI monitoring system):

- (1) **OVR-PRES:** Cuff inflation pressure has exceeded 270 ± 5 mmHg.
- (2) **CALIB:** The monitor cannot zero the pressure transducer.
- (3) **HDW-FAIL:** The NIBP electronic or pneumatic circuitry has failed.
- (4) **LONG PRESS:** The monitor has taken more than three minutes to make a Blood Pressure determination or cuff inflation runs longer than 30 seconds.

During a reading cycle the current cuff pressure is displayed ("CUFF: XXX").

Between the measurements the elapsed time (time since the last reading) is displayed (ET= 00:00:00) instead of the cuff pressure.

b. **Anesthetic Agents.** ("Dual monitor" mode or 3155A only) The Agents Icon is located between the Remote Status and NIBP boxes depending upon the screen display; if P1 and P2 and both off the Agents box is located right next to the Remote Status box and if either P1 or P2 is on then the box is centered between the Remote Status and NIBP boxes.

The Agents Icon box displays the identification of the gas being monitored, the inspired and expired gas value numerics and the Oxygen value numerics.

c. **Remote Status.** The Remote Status box is located on the bottom right of the display screen to indicate that the monitor is in Remote Communication Status. The connectors in the center of the Icon box will disconnect whenever there is a communication loss from the **3150(M) MRI Patient Monitor** greater than three seconds. The Remote Status box is green whenever communication with the **3150(M) MRI Patient Monitor** is good and red whenever communication is lost at any time (which provides a visual indication of all communication losses of less than three seconds).

If operating a dual monitor system, or using a 3155A alone, the bottom of the Remote Status box is an indication of the ETCO2 source. When ETCO2 is derived from the 3155A/3155MVS Monitor this message area will indicate "ETCO2 3155," when ETCO2 is derived from the 3150(M) this message area will indicate "ETCO2 3150," and when ETCO2 is Off on both monitors, or when using the 3155MVS alone, this message area is blank.

- **1.4** Yes/No Menu. In various menus, the operator may accidentally make a selection that has significant irreversible effects (e.g.: erasing patient data). To protect against such accidents a Yes/No Menu is associated with these selections. When one of these selections is made, the Yes/No Menu is displayed in the center of the display screen. This menu has only two active selections: YES and NO. The operator must select one of the two choices to either confirm the change to take place, or to cancel it. A delay of approximately 30 seconds without any selection is equivalent to selecting NO. The Yes/No Menu is removed upon operator selection or at the end of the time-out feature.
- **1.5** Cleaning. 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 and remove the batteries before cleaning. Do not permit liquid to contact the front or rear of the monitor, or permit liquid to drip into the printer or cooling slots. Allow the unit to dry completely before returning it to operation.

WARNING

Electrical shock hazard: Turn off Monitor and disconnect from the AS153 AC Power Adapter before cleaning. Do not immerse the monitor in any water or liquid for any reason. Do not apply excessive pressure to the monitor display screen.

<u>1.5.1</u> <u>Cleaning Accessories.</u> 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

2.0 INSTALLATION.

- **2.1 Introduction.** This monitor has been designed to be operated within the MRI Monitoring Area. The precise patient parameter information that this monitor is capable of processing is gathered through a Remote RF Link with the **3150(M) MRI Patient Monitor**.
- **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.
- <u>2.2.1</u> <u>Monitor Mounting.</u> This monitor can provide either portable or fixed operation. When mounting your **3155A/3155MVS Monitor** use caution that hardware will not penetrate the unit too deeply and come in contact with internal components. Also ensure that the mounting locations and hardware are mechanically robust enough to adequately and securely hold the unit.

WARNING

The **3155A/3155MVS Monitor** contains **Magnetic** Material. This monitor must be located at least 10 ft. (>3 m.) from the MRI System, outside the 1000 Gauss (0.1T) Magnetic Field Lines of the MRI System.

The **3155A Monitor** should be securely mounted to the anesthesia machine or mounting bar outside the 1000 Gauss (0.1T) Field Line.

- a. **Site Selection.** Select a location where the monitor will not come in contact with liquids and where the heat will not raise the monitor's temperature above 44°C. Maintain adequate air flow around the unit to help keep it within the normal operating temperature range. Also, there are air holes on the bottom and rear of the monitor that must not become clogged or closed off. Humidity and temperature must never combine to cause condensation to form in or on this monitor.
- <u>2.2.2</u> <u>Monitor Location.</u> This monitor has been designed to be mobile between the patient bedside and the MRI Magnet Room. When the 3155A is used to monitor Agent/ETCO2, it must be located in the Magnet Room with the gas sample line connected directly to the front of the 3155A and the Waste Gas Port connected to the Anesthesia Machine's Waste Gas Scavenge System. The only locational restriction is that the 3155A must be placed beyond the 1000 gauss (0.1T) line while in the Magnet Room.
- <u>2.2.3</u> <u>Preparing the 3155A/3155MVS Monitor for Use.</u> Connect the antenna to the monitor back panel, ensuring that the connections are tight and secure. Perform the following steps to prepare the monitor for use:
 - a. Ensure that you have read the Precautions and User Responsibility sections of this and the 3150(M) manual (Part Number 9538). These sections provide important safety information.
 - b. Ensure that there are no cracks in the monitor case or display.
 - c. Report any problems to Invivo Research Inc., or an authorized Invivo Research, Inc. Service Representative.
 - d. Ensure that all patient tubing 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.
- g. Verify that the Waste Gas Port (on the back of the monitor) is connected to the Gas Scavenging System.

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.

- 2.2.4 Monitor Start Up. Perform the following steps to bring the monitor on line for use:
 - a. Connect the AS153 AC Power Adapter to the DC Power Connection plug on the monitor back panel.
 - b. Ensure that the AS153 and 3155A/3155MVS Power Switches are both set to the OFF position.
 - c. Install the Sealed Lead Acid Battery(s). **At least one battery** *must* **be installed for this monitor to operate** (Refer to Section 7 for installation instructions).
 - d. Plug the Power Cord from AC Adaptor (AC 153) into an appropriate facility power source.
 - e. Set the AS153 and 3155A/3155MVS Main Power Power Switches (located on the monitor back panel) to the ON position.
 - f. Allow the Battery(s) to charge a minimum of 8 hours before placing the monitor into use.

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) and the 3155A/3155MVS 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.

- 2.2.5 3150(M) and 3155A/3155MVS Remote Monitor Communication. The Remote Transmission System, if installed on your equipment, turns on with each monitor (3150(M) or 3155A/3155MVS 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 Patient Monitor**, turn the Power Switch to the ON position.
 - Once the 3150(M) has come on line, turn the front panel Power Switch on the 3155A/3155MVS Monitor to the ON position.

NOTE

If operating a dual monitor system, the first 3155 to establish a communication link with the 3150(M) will become the "system master." This means that all interactive parameters throughout the system will synchronize with this 3155. Therefore the operator needs to ensure that the 3155 that contains the desired setup is turned on, and linked, before power is applied to the second 3155.

- (3) After the 3155A/3155MVS is on line, verify that the signal is received from the 3150(M).
- (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 3155A/3155MVS.
- (6) Verify that an NIBP Determination is initiated on the 3150(M).
- (7) Depress (press and release) the **NIBP START/STOP** Control Key on the 3155A/3155MVS.
- (8) Verify that the NIBP Determination being taken on the 3150(M) stops.

NOTE

Loss of communication, or no communication, between the 3150(M) and 3155A/3155MVS is indicated by the 3150(M) displaying "COMMAND LINK: LOST" and "DATA LINK: UNKNOWN," and on the 3155A/3155MVS by a gap appearing between the squares in the Remote box and the STATUS changing to Red with no waveforms being displayed.

- b. **Remote Parameter Verification**. Verify Remote Parameter monitoring as follows:
 - (1) Connect Patient Simulators to the 3150(M).
 - (2) Verify ECG Waveform and Rate are the same on both the 3150 and 3155A/3155MVS.
 - (3) Verify P1 Waveform and Values are the same on both the 3150(M) and 3155A/3155MVS.
 - (4) Verify P2 Waveform and Values are the same on both the 3150(M) and 3155A/3155MVS.
 - (5) With P2 still ON, verify that the SpO2 Value is shown with no waveform and is the same on both the 3150(M) and 3155A/3155MVS.
 - (6) Turn P2 OFF and verify SpO2 waveform is now displayed.
 - (7) Verify EtCO2/Agents Waveform and Values are present on the 3155A/3155MVS (Agent Monitoring Only).
- c. **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) has an unobstructed line of sight to the 3155A/3155MVS antenna. If reception improves then an object within the previous line of sight was interfering with transmission.
 - (c) If possible, move the 3150(M) and/or 3155A/3155MVS 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.
- **2.3 Software Installation.** The **3155A/3155MVS Monitor** has a slot on the side into which Data Cards may be inserted for update/upgrade of the monitor software. There are two kinds of cards available: the PCMCIA Card is used for update and upgrade of the software while the SRAM Card is used for storing user setups prior to update/upgrade for restoration after the PCMCIA Card is used.

CAUTION

Power can not be interrupted while the PCMCIA card is reprogramming your monitor. Do not turn power off to the monitor during the Load or Verification process. If power is turned off the monitor will have to be returned to Invivo Research, Inc. Technical Service for internal programming.

2.3.1 <u>Program Update/Upgrade.</u> Before beginning Program Update/Upgrade, ensure that the monitor is plugged into facility power. Do not attempt to perform the following procedure on battery power as a low battery shutdown will erase internal programming and the monitor will have to be returned to the factory for internal reprogramming. Perform the following procedure to Update/Upgrade the monitor software with the Program/Data Storage Card (Invivo Research, Inc. Part Number AM46 or AM69):

NOTE

During program update/upgrade the Agents parameter must be off and communication with the 3150(M) should not be established.

- a. Turn the power on and verify that the power LED is Green.
- b. Once the **3155A/3155MVS Monitor** Normal Screen appears, plug the Program/Data Storage Card into one of the two slots (with the arrow pointing toward the receptacle slot) on the side of the monitor pressing the card in until the ejector button pops out.
- c. Observe that the "PCMCIA PROGRAM UPDATE" message appears with a bar showing the process of the software update.
- d. Once the bar has advanced to 100%, observe that an additional "PROGRAM UPDATED Verifying update" message appears with another process bar.
- e. Once the Verifying Update process bar reaches 100%, observe that the message "Remove card to finish update" appears.

f. Remove the card by pressing the ejector button and observe that the monitor now contains the message "For changes to take effect turn power off then back on."

WARNING

To ensure proper monitor operation, a System Cold Start is **required** after a program update/upgrade.

- g. Perform System Cold Start as follows:
 - (1) Turn the 3155A/3155MVS power switch Off.
 - (2) Press and hold the Rotary Knob while turning the front panel power switch to On.
 - (3) When the display screen flashes white (in approximately 3 seconds), release the Rotary Knob then press and hold the **HELP** Control Key.
 - (4) When the Cold Start message appears on the lower left of the screen, release the **HELP** Control Key.
- <u>2.3.2</u> <u>Monitor Setup Storage</u> The 1MB SRAM PCMCIA Card (Invivo Research, Inc. Part Number AM55) is used to store and recall system setups. This card eliminates the need to reconfigure the monitor whenever it is updated/upgraded with the Program/Data Storage Card described above. Perform the procedure below to Store monitor setups:
 - a. Turn the power on.
 - b. Once the **3155A/3155MVS Monitor** Normal Screen appears, plug the 1MB SRAM Card into one of the two slots (with the arrow pointing toward the receptacle slot) on the side of the monitor pressing the card in until the ejector button pops out.
 - c. Observe that a menu box appears on the display screen with two selections: Store and Recall.

NOTE

Care is required to ensure that Recall is not accidently selected as current Setups will be overwritten by those contained on the SRAM Card.

- d. Select the Store option by turning the Rotary Knob until all the letters in the word STORE have turned red then pressing the Rotary Knob.
- e. Wait until the message DONE appears on the screen.
- f. Remove the 1MB SRAM Card from the slot by pressing the ejector button.
- <u>2.3.3</u> <u>Monitor Setup Recall</u> The 1MB SRAM PCMCIA Card (Invivo Research, Inc. Part Number AM55) is used to store and recall system setups. This card eliminates the need to reconfigure the monitor whenever it is updated/upgraded with the Program/Data Storage Card described above. Perform the procedure below to Recall monitor setups:
 - a. Turn the power on.
 - b. Once the **3155A/3155MVS Monitor** Normal Screen appears, plug the 1MB SRAM Card into one of the two slots (with the arrow pointing toward the receptacle slot) on the side of the monitor pressing the card in until the ejector button pops out.
 - c. Observe that a menu box appears on the display screen with two selections: Store and Recall.

- d. Select the Recall option by turning the Rotary Knob until all the letters in the word RECALL have turned red then pressing the Rotary Knob.
- e. Wait until the message DONE appears on the screen.
- f. Remove the 1MB SRAM Card from the slot by pressing the ejector button.
- g. Use the monitor Recall feature (in the Setup Menu) to verify that the monitor configurations have been restored.

SECTION 3 MONITOR PREPARATION FOR USE

3.0 MONITOR PREPARATION FOR USE.

3.1 Introduction. This monitor provides the operator with the ability to store and recall different system configurations, select and display the available parameters, select special system functions, set the date and time and select test menus. Access to this wide array of features is available through the **SETUPS** Menu which is accessed by pressing the **SETUP** Menu-Select Key.

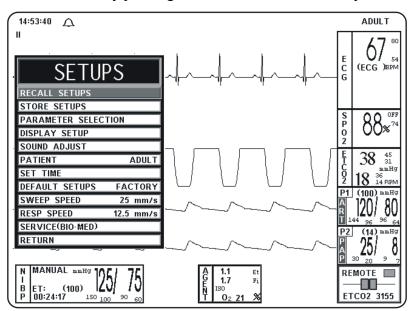


Figure 3-1. The SETUPS Menu

3.2 SETUPS Menu. (See Figure 3-1) Pressing the SETUP Menu-Select key brings up the SETUPS Menu. From this menu, the operator has the ability to fine tune the operation of the 3155A/3155MVS Monitor to suit individual situations. While in the SETUPS Menu, individual setup configurations may be saved and recalled, the available parameters may be turned off and on, the display may be setup, the monitor sounds may be adjusted, the patient mode may be switched between adult and neonate, the date and time may be adjusted, the monitor may be set to default to the Factory or any User configuration. In addition to control over these features, this menu allows the sweep speed and respiration speed to be selected, and provides Qualified Service Personnel with Service and Calibration Information. *This menu has a time-out feature. If no action is taken for approximately 60 seconds, the monitor will automatically return to the Normal Screen.*

The following is a description of the operation of the **SETUPS** Menu options:

3.2.1 <u>Recall Setups.</u> To select this menu option, turn the Rotary Knob until the **RECALL SETUPS** option is highlighted, then press the Rotary Knob to select. Selecting this menu option will bring up the **RECALL SETUPS** submenu and allow the operator to Recall a previously stored Monitor Setup (See Figure 3-2). This menu has a time-out feature. If no action is taken for approximately 60 seconds, the monitor will automatically return to the Normal Screen.

The following is a description of the **RECALL SETUPS** Menu options:

- a. **A.** To select this menu option, turn the Rotary Knob until **A** is highlighted, then press the Rotary Knob to select. Selecting this menu option will recall the setups for the monitor from the Memory Block A.
- b. **B.** Except for using the Memory Block B, this menu option is identical in function to menu option A.

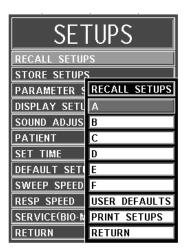


Figure 3-2. The RECALL SETUPS Menu

- c. C. Except for using the Memory Block C, this menu option is identical in function to menu option A.
- d. **D.** Except for using the Memory Block D, this menu option is identical in function to menu option A.
- e. **E.** Except for using the Memory Block E, this menu option is identical in function to menu option A.
- f. **F.** Except for using the Memory Block F, this menu option is identical in function to menu option A.
- g. **USER DEFAULTS.** Selecting this menu option recalls the setups for the monitor from the USER DEFAULTS memory block. If no USER DEFAULTS have been set, this selection will Recall the Factory Defaults.
 - If the power-up DEFAULTS is set to USER in the **SETUPS** Menu (**See Paragraph 3.2.8**), the monitor will automatically recall the setups stored in this memory block for new patients upon monitor power-up.
- h. **PRINT SETUPS.** To select this menu option, turn the Rotary Knob until **PRINT SETUPS** is highlighted, then press the Rotary Knob to select. Selecting this menu option brings up the **PRINT SETUPS** Menu, which provides a selection of system setups to print.
- i. **RETURN.** Selecting this menu option returns the monitor to the Normal Screen.
- 3.2.2 Store Setups. To select this menu option, turn the Rotary Knob until the STORE SETUPS option is highlighted, then press the Rotary Knob to select. Selecting this menu option will bring up the STORE SETUPS Menu and allow the operator to Store up to seven (7) sets of Monitor Setups for future Recall (See Figure 3-3). This menu has a time-out feature. If no action is taken for approximately 60 seconds, the monitor will automatically return to the Normal Screen.

The following is a description of the **STORE SETUPS** Menu options:

- a. **A.** Selecting this menu option will store all setups for the monitor in the storage Memory Block A.
- b. **B.** Except for using the Memory Block B, this menu option is identical in function to menu option A.
- c. C. Except for using the Memory Block C, this menu option is identical in function to menu option A.
- d. **D.** Except for using the Memory Block D, this menu option is identical in function to menu option A.



Figure 3-3. The STORE SETUPS Menu

- e. **E.** Except for using the Memory Block E, this menu option is identical in function to menu option A.
- f. **F.** Except for using the Memory Block F, this menu option is identical in function to menu option A.
- g. **USER DEFAULTS.** Selecting this menu option will store all setups for the monitor in the storage Memory Block USER DEFAULTS.

If the power-up DEFAULTS is set to USER in the **SETUPS** Menu (**See Paragraph 3.2.8**), the monitor will automatically recall the setups stored by this menu option for new patients upon warm start.

- h. **PRINT SETUPS.** Selecting this menu option brings up the **PRINT SETUPS** Menu which provides a selection of system setups to print.
- i. **RETURN.** Selecting this menu option returns the monitor to the Normal Screen.

CE.	PARAMETER	SELECTION
	ECG	ON
RECALL SETU	NIBP	ON
STORE SETUP	P1	ON
PARAMETER :	P2	ON
DISPLAY SETU	P3	OFF
SOUND ADJUS	P4	OFF
PATIENT	SP02	ON
SET TIME	ETC02	ON
DEFAULT SET	RESP	OFF
SWEEP SPEED	TEMP	OFF
RESP SPEED	AUX	OFF
SERVICE(BIO-N	AGENTS	OFF
RETURN	RETURN	

Figure 3-4. The PARAMETER SELECTION Menu

<u>3.2.3 Parameter Selection.</u> To select this menu option, turn the Rotary Knob until the **PARAMETER SELECTION** option is highlighted, then press the Rotary Knob to select. Selecting this menu option will bring up the **PARAMETERS SELECTION** Menu and (**See Figure 3-4**).

Selection of this menu allows the operator to turn various parameters ON and OFF. If the parameter selected is not available, attempting to turn it ON will cause the message "XXX IS NOT ENABLED" to be displayed. If the Freeze feature is enabled, changes to parameter selections are not allowed; if Freeze is enabled, the monitor displays a WARNING Box that alerts the operator that this menu may not be accessed

The following is a description of the **PARAMETERS SELECTION** Menu options:

- a. **ECG** Selecting this menu option will turn the ECG display ON (default) or OFF. The heart rate will remain on the screen, allowing it to be displayed from another source, if the heart-rate source (the HR SOURCE selection) is set to AUTO.
- b. **NIBP.** Selecting this menu option switches the NIBP ON (default) and OFF.
- c. **P1.** Selecting this menu option switches P1 ON and OFF.
- d. **P2.** Selecting this menu option switches P2 ON and OFF.
- e. **P3.** This selection is not available in the **3155A/3155MVS Monitor**.
- f. **P4.** This selection is not available in the 3155A/3155MVS Monitor.
- g. **SPO2.** Selecting this menu option switches SpO2 ON and OFF.
- h. **ETCO2.** Selecting this menu option switches ETCO2 ON and OFF.
- i. **RESP.** This selection is not available in the 3155A/3155MVS Monitor.
- j. TEMP. This selection is not available in the 3155A/3155MVS Monitor.
- k. AUX. This selection is not available in the 3155A/3155MVS Monitor.
- l. **AGENTS.** Selecting this menu option switches Agents ON and OFF.
- m. **RETURN.** Selecting this menu option returns the monitor to the Normal Screen.
- 3.2.4 Display Setup. This selection is not available in the 3155A/3155MVS Monitor.

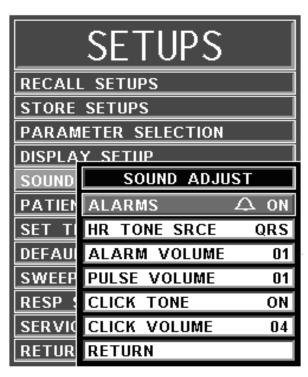


Figure 3-5. The SOUND ADJUST Menu

3.2.5 Sound Adjust. Selecting this menu option will bring up the **SOUND ADJUST** Menu (**See Figure 3-5**) which allows the user to switch the Alarm Tone ON and OFF, set the heart-rate tone source and set the volume for the different sounds the **3155A/3155MVS Monitor** produces. While in this menu, all real tones are disabled and the message "**REAL TONES DISABLED**" is displayed at the top of the screen. Note that only the sound is disabled and the violated alarms will still flash on the screen if the parameter's Alarm Limit is violated. *This menu has a time-out feature. If no action is taken for approximately 60 seconds, the monitor will automatically return to the Normal Screen*.

WARNING

The Alarm Tone can be set to OFF. Always check that the Alarm Tone setting is appropriate for each particular patient. Alarm Sound volume is adjustable for suitability to various clinical environments (where background noise may range from relatively quiet to noisy). Always verify that the user/attendant of this monitor can hear the Alarm Sound above the ambient noise (particularly during MRI Scanning).

The **3150(M) MRI Patient Monitor** will not alarm unless it is connected to this monitor. Always verify proper operation of the entire 3150 Alarm System (**3150(M) MRI Patient Monitor** and **3155A/3155MVS Monitor**) before performing any patient monitoring.

The following is a description of this menu's options:

- a. **ALARMS.** Selecting this menu option will turn the alarm sound ON and OFF. When turned off, an "X" appears in the bell symbol on the screen, and on the one in the menu option area, indicating that the alarm sound has been disabled. This menu option is identical to, and interactive with, the **SOUND** menu option in the **ALARMS** Menu.
- b. **HR TONE SRCE.** Selecting this menu option will select the heart rate tone source. The options are OFF (default), QRS and SPO2. When source is QRS, the tone sounds at the detection of QRS from the ECG parameter. When source is SpO2, the tone sounds at the detection of the pulse from the Pulse Oximeter parameter.
 - The pulse tone is modulated by the SpO2 value. The lower the SpO2 value the lower the pitch of the pulse tone will be. The pitch will be at the lowest frequency when SpO2 is not used.
 - This menu option is identical to, and interactive with, the **HR TONE SOURCE** Menu option in the **ECG** and **SPO2** Menus.
- c. **ALARM VOLUME.** Selecting this menu option allows the selection of volume for the Alarm Tone. The range is 1 10 (default is 4).
 - The 3155A/3155MVS Monitor generates the Alarm Tone (while in the VOLUME Menu) to provide the user with an audible indication of the current volume-level setting.
- d. **PULSE VOLUME.** Selecting this menu option allows the selection of volume for the pulse tone. The range is 1 10 (default is 4).
 - The 3155A/3155MVS Monitor generates the pulse tone (while in the VOLUME Menu) to provide the user with an audible indication of the current volume-level setting.
- e. **CLICK TONE.** Selecting this menu option turns the click tone generation of the device ON and OFF without affecting the adjusted volume for the click tone.
- f. **CLICK VOLUME.** Selecting this menu option allows the selection of volume for the click tone. The range is 1 10 (default is 4).
 - The 3155A/3155MVS Monitor generates the click tone (while in the VOLUME Menu) to provide the user with an audible indication of the current volume-level setting.

- g. **RETURN.** Selecting this menu option returns the monitor to the Normal Screen.
- <u>3.2.6</u> <u>Patient.</u> Selecting this menu option determines the Adult (default) or the Neonatal Mode for the operation of the ECG and NIBP parameters. If operating a dual monitor system, with a 3155A and 3155MVS communicating with the 3150(M), the adjustments made here are interactive between the two 3155 monitors to ensure that the monitored parameters remain consistent between all components of the MRI monitoring system.
 - a. **ADULT.** The initial NIBP inflation pressure is 170 mmHg. The maximum inflation pressure is 245 mmHg. Also, the adult NIBP pre-amplifier and the adult NIBP algorithm are used. 3150(M) ETCO2 Flow Rate is 230 mL/minute.
 - b. **NEONATE.** The initial inflation pressure is 110 mmHg. The maximum inflation pressure is 210 mmHg. Also, the neonatal NIBP pre-amplifier and the neonatal NIBP algorithm are used. 3150(M) ETCO2 Flow Rate is 150 mL/minute.

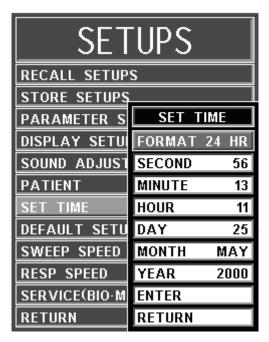


Figure 3-6. The SET TIME Menu

3.2.7 Set Time. Selecting this menu option will bring up the **SET TIME** Menu (**See Figure 3-6**). From the **SET TIME** Menu the time and date may be set. The time is displayed in the upper left corner of the screen. The clock continues to operate when the power is off. The date format is MMM DD, YYYY (e.g., Jan. 01, 2001). When a hard copy printout is made, the time and date is printed on the edge of the printout

The following is a description of the operation of the **SET TIME** Menu options:

NOTE

No new window is provided for the following selections. The setting to be adjusted becomes highlighted within the existing menu.

- a. **FORMAT.** Selecting this menu option switches the format of the time display between 12 hour and 24 hour.
- b. **SECOND.** Selecting this menu option allows scrolling through seconds.
- c. **MINUTE.** Selecting this menu option allows scrolling through minutes.
- d. **HOUR.** Selecting this menu option allows scrolling through hours.
- e. **DAY.** Selecting this menu option allows scrolling through days.

- f. **MONTH.** Selecting this menu option allows scrolling through months.
- g. YEAR. Selecting this menu option allows scrolling through years.
- h. **ENTER.** Selecting this menu option enters the newly-selected time and date when all changes are completed.

Pressing **ENTER** after the new time and date are completely set puts the newly set time and date into effect. Otherwise, the old time is restored upon exiting the **SET TIME** Menu.

- i. **RETURN.** Selecting this menu options returns the monitor to the Normal Screen.
- 3.2.8 <u>Default Setups.</u> Selecting this menu option will switch the power-on defaults between FACTORY and USER modes. If set to FACTORY, the monitor will power up with the entire system reset to factory default values. If set to USER, the monitor will power up and automatically recall the user-selected defaults from memory.
- 3.2.9 <u>Sweep Speed.</u> Selecting this menu option will bring up the **SWEEP SPEED** Menu. The **SWEEP SPEED** Menu allows the operator to switch the recorder and the screen trace speed between 25 and 50 mm/second. This menu option is identical to, and interactive with, the SWEEP SPEED menu option in **RECORDER** Menu.
- 3.2.10 Respiration Speed. Selecting this menu option will bring up the **RESP SPEED** Menu. The **RESP SPEED** Menu allows the operator to set the ETCO2 Respiration Speed at the following predetermined levels: 25 mm/s, 12.5 mm/s, 6.25 mm/s, 3.125 mm/s, 1.5625 mm/s and 0.33333 mm/s.

NOTE

The **SERVICE** (**BIO-MED**) Menu should only be used by qualified service personnel thoroughly familiar with the operation and service of this monitor.

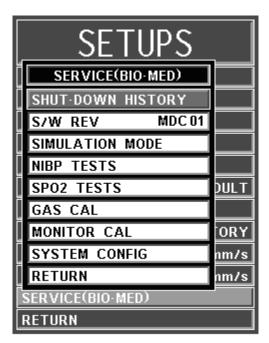


Figure 3-7. The SERVICE (BIO-MED) Menu

3.2.11 Service (Bio-Med). Selecting this menu option will bring up the **SERVICE (BIO-MED)** Menu (**See Figure 3-7**).

The following options are available from the **SERVICE** (**BIO-MED**) Menu:

a. **SHUT-DOWN HISTORY.** This menu option is for future service enhancement.

b. **S/W REV.** This menu item displays the Revision Level of the monitor software.

WARNING

The Simulation Mode will display real looking waveforms which are computer generated. The monitor will not monitor patients while in the Simulation Mode. **Do not activate the Simulation Mode when this monitor is connected to a patient.**

- c. **SIMULATION MODE.** Selecting this menu item allows the operator to switch the Simulation Mode ON. While in the Simulation Mode the displayed patient information is computer generated and not actual patient determinations. As a safety feature, while in the Simulation Mode the message "**SIMULATION**" is displayed in the center of the screen and, when printing any strip or chart, "**SIMULATION**" will appear on the printout. To exit the Simulation Mode, the monitor must be powered Off. If operating a dual monitor system, with a 3155A and 3155MVS communicating with the 3150(M), selecting Simulation on any component of the system will place the entire system into the Simulation mode.
- d. **NIBP TESTS.** This selection is not available in the **3155A/3155MVS Monitor**.
- e. **SPO2 TESTS.** This selection is not available in the **3155A/3155MVS Monitor**.
- f. **GAS CAL.** (3155A only) Selecting this menu option will bring up the **GAS CAL** Menu.

The following menu options are provided in this menu:

- (1) **ZERO CAL.** Selecting this menu option will cause the monitor to perform a Zero Cal of the Agent System.
- (2) **SPAN CAL.** Selecting this menu option will bring up a box to inform the operator that no Span Cal is required for this monitor.
- (3) **O2 CAL.** Selecting this menu option will cause the monitor to perform a one (1) minute calibration of the O2 Sensor.
- (4) **O2 INIT CAL.** Selecting this menu option will cause the monitor to perform a two (2) minute calibration of the O2 Sensor. This calibration should be performed after every replacement of the O2 Sensor.
- (5) **GAS MONITOR.** Selecting this menu option brings up the Gas Monitor Calibration Box. This box contains Agent Sensor Calibration characteristics which are used for factory calibration.
- (6) **RETURN.** Selecting this menu option returns the monitor to the **SERVICE** (**BIO-MED**) Menu.
- g. **MONITOR CAL.** This selection is not available in the 3155A/3155MVS Monitor.

SYSTEM CONFIG						
ECG 1	ENABLED	CO	DISABLED			
ECG 2	DISABLED	RECORDER	ENABLED			
NIBP	ENABLED	CS COMM	ENABLED			
P1	ENABLED	PARALLEL PORT	ENABLED			
P2	ENABLED	ANALOG OUTPUT	ENABLED			
P3	DISABLED	KYBD/PEN PORT	DISABLED			
P4	DISABLED	ST-SEGMENT	DISABLED			
SP02	ENABLED	LINE FREQUENCY	60 HZ			
ETC02	ENABLED	LANGUAGE	ENGLISH			
RESP	DISABLED	PRESSURE UNITS	mmHg			
T1 AND T2	DISABLED	MONITOR MODE	REMOTE			
AUX	DISABLED	RETURN				

Figure 3-8. The SYSTEM CONFIG Menu

h. **SYSTEM CONFIG.** The hidden **SYSTEM CONFIG** Menu (**See Figure 3-8**) becomes active when a five (5) digit service code is entered after the **SYSTEM CONFIG** Menu option is selected. The Language and Pressure Units options are the only options in this menu which do not require that the service code be entered.

The following options are available in this menu:

- (1) **ECG 1:** Selecting this menu option will enable/disable the ECG module.
- (2) ECG 2: This selection is not available in the Millennia® 3155A/ 3155MVS Monitor.
- (3) **NIBP:** Selecting this menu option will enable/ disable the NIBP module.
- (4) **P1:** Selecting this menu option will enable/ disable the Pressure 1 module.
- (5) **P2:** Selecting this menu option will enable/ disable the Pressure 2 module.
- (6) **P3:** This selection is not available in the **3155A/3155MVS Monitor**.
- (7) **P4:** This selection is not available in the **3155A/3155MVS Monitor**.
- (8) **SPO2:** Selecting this menu option will enable/disable the SpO2 module.
- (9) **ETCO2:** Selecting this menu option will enable/disable the ETCO2 module.
- (10) **RESP**: This selection is not available in the 3155A/3155MVS Monitor.
- (11) **TEMP 1 AND 2:** This selection is not available in the **3155A/3155MVS Monitor**.
- (12) AUX: This selection is not available in the 3155A/3155MVS Monitor.
- (13) CO: This selection is not available in the 3155A/3155MVS Monitor.
- (14) **RECORDER:** Selecting this menu option will enable/disable the RECORDER module.
- (15) CS COMM: This selection is not available in the 3155A/3155MVS Monitor.
- (16) **PARALLEL PORT:** This selection is not available in the **3155A/3155MVS Monitor**.
- (17) **ANALOG OUTPUT:** This selection is not available in the **3155A/3155MVS Monitor**.
- (18) **KEYBOARD/PEN PORT:** This selection is not available in the **3155A/3155MVS Monitor**.
- (19) **ST-SEGMENT:** This selection is not available in the **3155A/3155MVS Monitor**.
- (20) LINE FREQUENCY: This selection is not available in the 3155A/3155MVS Monitor.
- (21) **LANGUAGE:** Selecting this menu option allows the Language of the monitor to be switched between the available languages (English, German, Spanish, Portuguese, Italian and French). To enable the language change, the operator must exit the **SYSTEM CONFIG** menu by selecting Return or pressing the **NORMAL SCREEN** control key, and then turn the monitor Off then On.
- (22) **PRESSURE UNITS:** Selecting this menu option allows the Blood Pressure units to be switched between mmHg and kPa. See Appendix E for a kPa to mmHg Conversion Chart.

- (23) **MONITOR MODE:** Selects Remote or Remote 1 operation. This selection is preset at the Factory dependent upon the monitor configuration. The Factory preset for a single monitor system or for a dual 3155A/3155MVS system is Remote. The Factory preset for a dual 3155MVS system is one monitor set to Remote and the other set to Remote 1.
- (24) **RETURN:** Selecting this menu option returns the monitor to the **Service (Bio-Med)** Menu.
- i. **RETURN.** Selecting this menu option returns the monitor to the **SETUPS** Menu.
- 3.2.12 Return. Selecting this menu option returns the monitor to the Normal Screen.
- **3.3 Store/Recall Setups.** The **3155A/3155MVS Monitor** has seven (7) memory blocks, each of which has enough capacity for the current setting of every control setup, alarm limits, trend time base, etc. on the monitor. The operator is able to store and recall seven different configurations of the monitor. The seventh (User Defaults) is also used for recall at monitor power up. The memory blocks are maintained by a long-life battery and static RAM memory, which keep the memory contents intact even when power is off.

Settings for the monitor can be stored for different procedures, different types of patients, etc., or multiple users of the monitor can store and recall their own preferred configurations without having to individually set each limit, status, etc., before each use.

Each storage memory block maintains the settings for:

- a. **ALARMS.** The setting of MIN and MAX values. auto-set percentage, latched or non-latched selection for alarms, and alarm tone enabled/disabled.
- b. **SYSTEM SETUPS.** All Settings.
- c. **ECG.** Selected lead, scale setting, trace speed, filter mode, QRS tone ON/OFF and heart rate source.
- d. **RECORDER.** Off or auto, trace delay, recorder speed and the selected traces.
- e. **P1 and P2.** Trace scale, trace label and cal grid or normal display.
- f. **NIBP.** Manual, off or auto and the automatic time interval.
- g. ETCO2. Size and grids.
- h. **AGENTS.** On and off.
- TREND GRAPHS. Time bases and scales.

Once the monitor is setup properly, the setups may be stored in one of the available memory blocks. The stored setups can be brought up via the **RECALL SETUPS** Menu.

- **3.4 Monitor Initialization.** The monitor may start its monitoring functions from either an initial (Default Settings) state or a pre-configured state depending on how the stored configuration information and patient data (trends, tabular data, and reports) are treated on start-up.
- <u>3.4.1</u> <u>Default Initialization.</u> The monitor's master processor is "cold-started" by pressing and holding the white **HELP** key while turning power on. The **HELP** key should be held until the normal screen appears. **If the monitor is cold started, it will revert to Factory Default Settings.** The screen displays the following:
 - a. The Bell Symbol with "H" in it appears in the upper portion of the screen under ALARM STATUS.
 - b. ECG 1 is on in Trace A and set to Lead II.
 - c. SpO2 is on in Trace C.
 - d. NIBP is on and displayed in the lower left portion of the screen.
 - e. The "**SOUND ON HOLD**" message is displayed in the center of the screen and counts down starting from 180.
 - f. The alarm sound is enabled when the **SOUND ON HOLD** count reaches 0.

- 3.4.2 Pre-Configured Initialization. A "warm-start" can occur in one of the following ways:
 - a. **Power Cycling.** The power is turned off and back on.
 - b. **Standby.** The monitor may be put in the Standby Mode. While in the Standby Mode, the monitor has all its standard operations except that:
 - (1) All audible alarms are disabled. The fact that the Alarm Sounds are disabled is indicated on the screen by the "X" through the bell shaped Alarm Status Symbol.
 - (2) The NIBP automatic measurements as well as STAT Mode measurements are suspended.
 - (3) No automatic printout is generated.

SECTION 4 PATIENT PARAMETERS

4.0 PATIENT PARAMETERS.

- **4.1 Introduction.** This section describes a fully equipped monitor and your monitor may, or may not, have every feature described below. For information on features your monitor does not contain, contact Invivo Research, Incorporated.
- **4.2 ECG Monitoring.** Unless it has been turned off in the **ECG** Menu, the selected ECG leads are displayed as TRACE A. Most ECG functions are contained in the **ECG** Menu. Additional features useful with ECG monitoring are found in three secondary menus:
 - **RECORDER Menu.** Used to select all recorder functions and to set the recorder and trace speed.
 - **ALARMS Menu.** Used to set and/or disable the ECG alarms. The range of Alarm Limits for the ECG Heart Rate is 0 to 249 bpm.
 - **TREND Menu.** Used to setup and print Trended information.

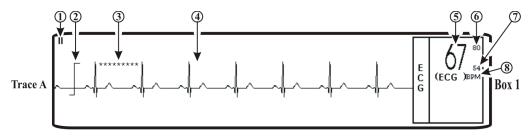


Figure 4-1. ECG Display

- 4.2.1 <u>Associated Waveforms and Displays.</u> (See Figure 4-1) ECG information is displayed as a waveform in the Trace A location and as numeric data in the Box 1 location. The following is a description of the items contained within the ECG Display.
 - a. **ECG Lead.** (**Item 1**) Displays the ECG Lead selected for use.
 - b. **Scale Indicators.** (**Item 2**) Displays an Scale Indicator for reference. This indicator represents a 1 millivolt signal amplitude.
 - c. **Message Area.** (Item 3) Displays ECG related messages.
 - d. **Waveform Traces.** (Item 4) Displays the ECG waveform of the patient.
 - e. **Heart Rate Numeric.** (Item 5) Displays the current Heart Rate indication for the patient.
 - f. **Alarm Limit High.** (Item 6) Displays the value set for the High Limit of the ECG Alarm
 - g. **Alarm Limit Low.** (**Item 7**) Displays the value set for the Low Limit of the ECG Alarm.
 - h. **Heart Rate Source.** (Item 8) Displays the source selected for the Heart Rate.
- 4.2.2 The ECG Menu. (See Figure 4-2) Selecting the ECG Menu-Select Icon brings up the ECG Menu. This menu has a time-out feature. If no action is taken for approximately 60 seconds, the monitor will automatically return to the Normal Screen.

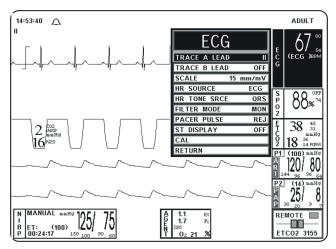


Figure 4-2. The ECG Menu

The following selections are available in the **ECG** Menu:

- a. **TRACE A LEAD.** Selecting this menu option allows the selection of the ECG 1 lead (Figure 4-1). The options are I, II (default), III, AVL, AVR, AVF, CAL and OFF. If operating a dual monitor system, with a 3155A and 3155MVS communicating with the 3150(M), the adjustments made here are interactive between the two 3155 monitors to ensure that the monitored parameters remain consistent between all components of the MRI monitoring system.
- b. TRACE B LEAD. This selection is not available in the 3155A/3155MVS Monitor.

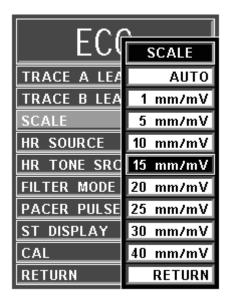


Figure 4-3. The ECG SCALE Menu

c. **SCALE.** Selecting this menu option allows the selection of the scale for the ECG waveform(s). The options are AUTO, 5, 10, 15 (default), 20, 25, 30, and 40 mm/mV (**See Figure 4-3**). The selected scale appears on the right hand side of this menu option. If AUTO is selected, a scale is picked that would make the current waveform(s) fill the ECG viewing area. This scale will be in effect until another scale is selected (AUTO or any other selection). A Scale Indicator associated with each Trace is displayed on the left side of the screen, and denotes a 1 millivolt signal amplitude. If operating a dual monitor system, with a 3155A and 3155MVS communicating with the 3150(M), the adjustments made here are interactive between the two 3155 monitors to ensure that the monitored parameters remain consistent between all components of the MRI monitoring system.

(1) If the scale of the ECG trace is so large that the top or bottom of the ECG waveform is distorted or flattened, the "OVERSCALE" message flashes in the ECG waveform area. This message will override other ECG error messages. Use the SCALE menu option (in the ECG Menu) to resize the waveform until the "OVERSCALE" message stops flashing. If this continues, the Auto Scale option should be selected to prevent further waveform distortion.

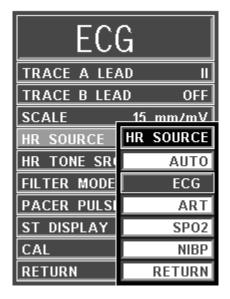


Figure 4-4. The HR SOURCE Menu

- d. **HR SOURCE.** Selecting this menu option allows the selection of the source to be used for the heart-rate display in TRACE A area. The options are AUTO, ECG (default), ART (arterial pressure), SPO2 and NIBP (See Figure 4-4). If operating a dual monitor system, with a 3155A and 3155MVS communicating with the 3150(M), the adjustments made here are interactive between the two 3155 monitors to ensure that the monitored parameters remain consistent between all components of the MRI monitoring system.
 - (1) The heart rate is displayed in the ECG parameter box. It is annotated with its source (e.g., "60 P1" indicates a heart rate of 60, derived from the Invasive Pressure 1).
 - (2) If AUTO is chosen, the heart rate is selected automatically from the highest-priority active input. When set to AUTO the 3155A/3155MVS Monitor searches for another source for rate only when LEAD FAIL occurs or the ECG parameter is turned OFF. The priority, from highest to lowest, is ECG, P1, P2, SpO2, and NIBP.
 - (3) The **3155A/3155MVS Monitor** examines the highest-priority active input. If not found, it will go to the next-highest priority parameter. If none of the parameters are presenting a heart rate and NIBP is shut off, then "**NONE**" is displayed on the screen in the heart rate position.
 - (4) When the HR Source is set, the HR TONE SRCE (the next option) is automatically set to the same selection.
 - (5) This menu option is identical to, and interactive with, the similarly named menu options under ART, SPO2, and NIBP.

- e. **HR TONE SRCE.** Selecting this menu option selects the source to be used for the heart-rate tone. The options are QRS, SPO2 and OFF (default). When this parameter is set to OFF, the Heart Symbol will not be displayed. If operating a dual monitor system, with a 3155A and 3155MVS communicating with the 3150(M), the adjustments made here are interactive between the two 3155 monitors to ensure that the monitored parameters remain consistent between all components of the MRI monitoring system.
 - (1) When the SpO2 parameter provides the heart rate tone, the tone is modulated by the SpO2 value.
 - (2) If the Heart Rate Tone source is turned off, the Heart Symbol is removed from the display.
 - (3) This menu option is identical to, and interactive with, the HR TONE SOURCE option in the **SOUND ADJUST** Menu.
- f. **FILTER MODE.** (Available with MAGNITUDETM 3150M only) Selecting this option allows the selection of the ECG Filter. The options are MON, MRI, MR2, MR3 and MR4. MON is the default and is the basic filter. The MR options are selected where robust sophisticated gradient artifact is present. MRI is 0.5 to 10 Hz adaptive (0.5 to 40 Hz for QRS, MR2 (Cardiovascular Mode 1) has a hardware slew rate of 0.5 to 40Hz, MR3 (Cardiovascular Mode 2) has a hardware slew rate of 0.5 to 40 Hz and MR4 is the high magnet field mode with a hardware slew rate of 10 to 40 Hz. If operating a dual monitor system, with a 3155A and 3155MVS communicating with the 3150(M), the adjustments made here are interactive between the two 3155 monitors to ensure that the monitored parameters remain consistent between all components of the MRI monitoring system.
- g. PACER PULSE. This selection is not available in the 3155A/3155MVS Monitor.
- h. ST DISPLAY. This selection is not available in the 3155A/3155MVS Monitor.
- i. **CAL.** Selecting this menu option allows for checking the calibration of the ECG feature. When pressed, a train of 1 mV Square Waves are displayed on the waveform. This feature is for Service use only.
- j. **RETURN.** Selecting this menu option will return the monitor to the Normal Screen.
- 4.2.3 <u>Alarm Limits.</u> Alarm Limits may be set two ways. To set the Alarm Limits for every available parameter, press the **ALARMS SCREEN** Menu-Select Key to access the **ALARMS** Menu. To set the Alarm Limits for ECG Heart Rate only, highlight the ECG Icon and press the **ALARMS SCREEN** Menu-Select Key to access the individual parameter Alarm Limits Box. The range of Alarm Limits for the ECG Heart Rate is 30 to 249 bpm. If operating a dual monitor system, with a 3155A and 3155MVS communicating with the 3150(M), alarm limit changes are interactive between the two monitors to ensure that the monitoring parameters remain consistent between all components of the MRI monitoring system.
- <u>4.2.4</u> <u>Trended Data.</u> For complete information on the trending of patient ECG data, see Section 5: Printing and Trending.
- <u>4.2.5</u> <u>ECG Messages.</u> The following is a list of messages that may be displayed during ECG monitoring (if operating a dual monitor system, with a 3155A and 3155MVS communicating with the 3150(M), these messages are interactive between all components of the MRI monitoring system):

LEAD FAIL LEAD FAIL is displayed when a faulty ECG Lead is detected by the system.

OVERSCALE is displayed if the scale of the ECG Trace is so large that the tops of the ECG waveforms are being "clipped" (the tops and bottoms cut off). This message suppresses all other ECG Error Messages and the Alarm Tone will not sound. To reduce the scale, and remove the OVERSCALE message, access the SCALE menu option in the ECG Menu.

4.3 Invasive Pressure Monitoring. The **3155A/3155MVS Monitor** provides up to two invasive pressure channels. Most invasive pressure monitoring functions are contained in two primary menus: **P1** and **P2** (if the operator has selected labels for these, the menu name will be the selected Label). These menus are brought up by selecting the corresponding Menu-Select Icons.

There are three secondary menus (**RECORD**, **ALARMS** and **TRENDS**) associated with invasive pressure monitoring:

- **RECORDER Menu.** Used to select all recorder functions and to set the recorder and trace speed.
- **ALARMS Menu.** Used to set and/or disable the pressure alarms. The range of Alarm Limits for the pressure channels is -10 to 249 mmHg.
- **TREND Menu.** Used to setup and print Trended information.

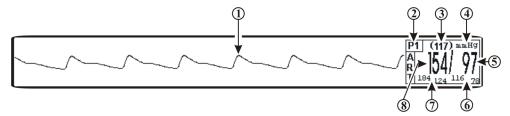


Figure 4-5. Invasive Pressure Display

- <u>4.3.1</u> <u>Associated Waveforms and Displays.</u> (**See Figure 4-5**) Invasive Pressure information is displayed as a waveform if selected for Trace location E or F and as numeric data in Boxes 4 and 5. The following is a description of the items contained within the Invasive Pressure Display.
 - a. **Invasive Pressure Waveform.** (Item 1) The Invasive Pressure Waveforms are displayed in Trace locations D and E.
 - b. **Icon Label.** (**Item 2**) This label identifies the parameter numerics that are displayed within this box. Invasive Pressure may be monitored using boxes 4 and 5.
 - c. **Mean Numeric.** (**Item 3**) A numeric indication of the patient's Invasive Pressure Mean reading.
 - d. **Unit of Measurement.** (**Item 4**) Displays the Unit of Measurement being used for presentation of the numeric data.
 - e. **Diastolic Numeric.** (**Item 5**) A numeric indication of the patient's Invasive Pressure Diastolic reading.
 - f. **Diastolic Alarm Limits.** (**Item 6**) A numeric indication of the settings of the High (on top in the example) and Low (bottom in the example) Diastolic Alarm Limits.
 - g. **Systolic Alarm Limits.** (**Item 7**) A numeric indication of the settings of the High (on top in the example) and Low (bottom in the example) Systolic Alarm Limits.
 - h. **Systolic Numeric.** (**Item 8**) A numeric indication of the patient's Invasive Pressure Systolic reading.
- 4.3.2 The Invasive Pressure Menu. Selecting the P1 Menu-Select Icon will bring up the P1 Menu (See Figure 4-6). The title of his menu is dependent upon the operator selected label for P1; if "NONE" is selected the title will be P1; if any other available label is selected the title will be the selected label (for example, the label ART is selected in Figure 4-6 and the menu title is ART). This menu has a time-out feature. If no action is taken for approximately 60 seconds, the monitor will automatically return to the Normal Screen.

The following is a description of the options provided in this menu:

a. **ZERO-SET.** This selection is not available in the **Millennia**® 3155A/ 3155MVS **Monitor**.

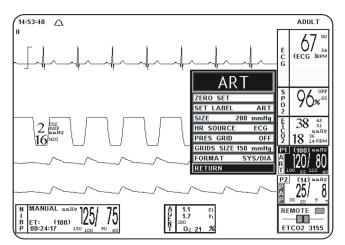


Figure 4-6. The P1 Menu (ART Selected)

b. **SET LABEL.** (See Figure 4-7) Scrolls through a list of labels to be put next to the mean pressure numerics to help the user to identify the transducer site. The options are ART, PAP, CVP, LAP, ICP, and NONE (default). The selected label, not only becomes the Pressure Channel menu title, it determines the color of the visual display. If **NONE** is selected, the Menu-Select Icon highlight is White; **ART** is Pink, **PAP** is Yellow, **CVP** is Blue, **LAP** is Purple and **ICP** is Blue. If operating a dual monitor system, with a 3155A and 3155MVS communicating with the 3150(M), the adjustments made here are interactive between the two 3155 monitors to ensure that the monitored parameters remain consistent between all components of the MRI monitoring system.

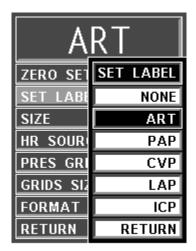


Figure 4-7. Invasive Pressure SET LABEL Menu

- c. **SIZE.** Selecting this menu option sets the scale of the trace for this pressure channel. The options are 40, 75, 100, 150, 200 (default), and 250 mmHg. If operating a dual monitor system, with a 3155A and 3155MVS communicating with the 3150(M), the adjustments made here are interactive between the two 3155 monitors to ensure that the monitored parameters remain consistent between all components of the MRI monitoring system.
- d. **HR SOURCE.** Selecting this menu option allows the selection of the source to be used for the heart-rate display in TRACE A area. The options are AUTO, ECG (default), ART (first encountered arterial pressure), SPO2 and NIBP. If operating a dual monitor system, with a 3155A and 3155MVS communicating with the 3150(M), the adjustments made here are interactive between the two 3155 monitors to ensure that the monitored parameters remain consistent between all components of the MRI monitoring system.

- (1) The heart rate is displayed in the ECG parameter box, and it is annotated with its source (e.g., "60 (P1)" indicates a heart rate of 60, derived from the arterial pressure).
- (2) If AUTO is chosen, the heart rate is obtained automatically from the highest priority active input. When set to AUTO the monitor searches for another source for rate only when LEAD FAIL occurs or the ECG parameter is turned OFF. The priority, from highest to lowest, is ECG, P1, P2, SpO2, and NIBP.
- (3) The monitor examines the highest-priority input for a heart rate. If not found, it will go to the next highest priority parameter and determine if a valid heart rate is present. If none of the parameters are presenting a heart rate and NIBP is shut off, then "NONE" is displayed on the screen in the heart rate position.

This menu option is identical to, and interactive with, the similarly named menu options under ECG, SPO2, and NIBP.

- e. **PRES GRIDS.** This selection is not available on the 3155A/3155MVS Monitor.
- f. **GRIDS SIZE.** This selection is not available on the **3155A/3155MVS Monitor**.
- g. **FORMAT.** Selecting this menu option allows the operator to change the display format of the Pressure numerics. If **SYS/DIA** is selected, the Systolic and Diastolic numerics will be in a large font separated by a "slash" and the Mean numeric will be in a smaller font bracketed with parenthesis. If **MEAN** is selected, the Mean numeric is displayed in the large font with the Systolic and Diastolic numerics separated by a "slash" in a smaller font. For pressure labels that designate only a single pressure (e.g., CVP and ICP), the mode is automatically changed to the Mean format and the operator is informed that the format cannot be changed for the current label if a change to the Sys/Dia format is attempted.
- h. **RETURN.** Selecting this menu option will return the monitor to the Pressure menu.

The operation of the **P2** Menu is identical to the operation of P1 as described above.

- 4.3.3 Alarm Limits. Alarm Limits may be set two ways. To set the Alarm Limits for every available parameter, press the **ALARMS SCREEN** Menu-Select Key to access the **ALARMS** Menu. To set the Alarm Limits for Invasive Pressure only, highlight the Invasive Pressure Icon and press the **ALARMS SCREEN** Menu-Select Key to access the individual parameter Alarm Limits Box. The range of Alarm Limits for the pressure channels is -10 to 249 mmHg. If operating a dual monitor system, with a 3155A and 3155MVS communicating with the 3150(M), alarm limit changes are interactive between the two monitors to ensure that the monitoring parameters remain consistent between all components of the MRI monitoring system.
- <u>4.3.4</u> <u>Trended Data.</u> For complete information on the trending of patient Invasive Pressure data, see Section 5: Printing and Trending.
- **4.4 Non-Invasive Blood Pressure (NIBP) Monitoring.** The NIBP feature measures and displays systolic, diastolic and mean arterial pressures, and pulse rate. LOW and HIGH Alarm Limits are available for all three pressures. When the **3155A/3155MVS Monitor** is configured to obtain the patient's heart rate from the NIBP, the heart rate alarm is also applicable to this parameter. The monitor may be set to take NIBP readings at automatic intervals from 1 to 60 minutes (there is a 20 second pause between readings to allow for peripheral perfusion), or the operator can manually initiate a reading at any time.

When a successful reading is taken, the elapsed time display indicates the beginning of this cycle. The time until next measurement indicates when the next automatic measurement will be made. A manual reading does not restart this cycle time. The **NIBP INTERVAL** key may be used to adjust the cycle time. The **NIBP START/STOP** key may be used to manually start/stop a measurement. The **NIBP STAT** key, which allows the start of STAT Mode (which makes up to five (5) NIBP determinations in rapid succession), is unavailable in the "dual monitor" mode.

If an error is detected, the Alarm Tone will sound, and an error message will be written on the screen. The old values, along with the elapsed time associated with it, remain on the screen.

Non-Invasive blood pressure monitors are sensitive to patient motion artifact. Such artifact can cause readings to be slow or even an incorrect pressure reading.

Visual checks of the patient, other vital signs and checking the limb to which the cuff is attached should be standard routines with NIBP use.

Most NIBP functions are contained in the primary **NIBP** Menu. However, additional features useful with NIBP monitoring can be found in the three secondary menus associated with this parameter:

- **RECORDER Menu.** Used to select recorder functions and print the NIBP Report.
- **ALARMS Menu.** Used to set and/or disable the NIBP alarms. The range of Alarm Limits for the NIBP is 5 to 249 mmHg.
- **TREND Menu.** Used to setup and print Trended information.

4.4.1 Theory of Oscillometric Measurement. 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:

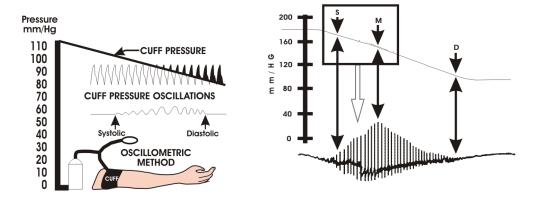


Figure 4-8. Oscillometric Measurement Method

- 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 4-8).
- 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.

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.

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.

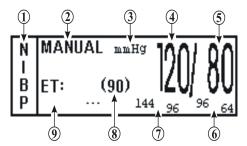


Figure 4-9. The NIBP Display

- 4.4.2 <u>Associated Displays.</u> When NIBP is selected, the display is located at the lower left of the normal screen (**See Figure 4-9**). This is a specialized display panel which includes the information concerning the NIBP status. The following is a description of the items contained in the NIBP Display.
 - a. **Icon Label.** (**Item 1**) This label identifies the parameter whose numeric data is being displayed within the Icon Box. Box 11 (in the lower left of the Bottom Numeric Display) is dedicated to the display of NIBP information.
 - b. **Manual.** (**Item 2**) While in the Automatic Mode, "**NEXT**" is shown and the time until the next NIBP determination is displayed here; in the Manual Mode, the word "**MANUAL**" is displayed here.
 - c. **Unit of Measurement.** (**Item 3**) Displays the Unit of Measurement being used for presentation of the numeric data.
 - d. **Systolic Numeric.** (**Item 4**) A numeric indication of the patients NIBP Systolic reading.
 - e. **Diastolic Numeric.** (**Item 5**) A numeric indication of the patients NIBP Diastolic reading.
 - f. **Diastolic Alarm Limits.** (**Item 6**) A numeric indication of the settings of the High (on top in the example) and Low (bottom in the example) Diastolic Alarm Limits.
 - g. **Systolic Alarm Limits.** (**Item 7**) A numeric indication of the settings of the High (on top in the example) and Low (bottom in the example) Systolic Alarm Limits.

WARNING

Mean Pressure Alarm Limits are only displayed within the **Alarms** Menu when the pressure display format is set to SYS/DIA.

- h. **Mean Numeric.** (Item 8) A numeric indication of the patient's Mean pressure reading.
- i. **ET.** (Item 9) The Elapsed Time (ET) since the last NIBP determination is displayed here. During an NIBP determination, this message changes to display the cuff pressure.

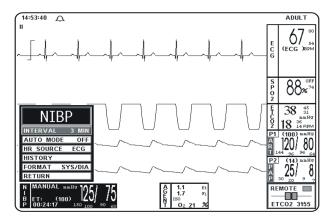


Figure 4-10. The NIBP Menu

4.4.3 The NIBP Menu. Selecting the NIBP Menu-Select Icon will bring up the NIBP Menu (See Figure 4-10). This menu provides the operator with the ability to switch the Automatic Mode On and OFF, set the automatic reading interval, set the Heart Rate source and bring up a Tabular Chart containing a History of the NIBP, Heart Rate, ETCO2/Respiration and SpO2 determinations. This menu has a time-out feature. If no action is taken for approximately 60 seconds, the monitor will automatically return to the Normal Screen.

<u>4.4.4</u> <u>NIBP Menu Options.</u> The following is a description of the operation of the **NIBP** Menu options:

	INTERVAL
	1 MIN
	2 MIN
	2.5 MIN
	3 MIN
	5 MIN
	10 MIN
l NI	15 MIN
	20 MIN
INTERVA	30 MIN
AUTO M	45 MIN
HR SOUF	1 HOUR
HISTORY	2 HOUR
FORMAT	4 HOUR
RETURN	RETURN

Figure 4-11. The NIBP INTERVAL Menu

a. **INTERVAL.** Selecting this menu option allows the operator to change the automatic-measurement time interval setting (**See Figure 4-11**). The active options contained in this menu are 1, 2, 3 (default), 5, 10, 15, 20, 30 or 45 minutes, and 1 hour; this menu also contains three (3) inactive options: 2.5 minutes, 2 hours and 4 hours, selecting any of these options will cause the monitor to display a message indicating that these selections are inactive. The **INTERVAL** Menu is also accessed by pressing the **NIBP INTERVAL** key. If operating a dual monitor system, with a 3155A and 3155MVS communicating with the 3150(M), the adjustments made here are interactive between the two 3155 monitors to ensure that the monitored parameters remain consistent between all components of the MRI monitoring system.

- (1) There is a 20-second period in between the measurements to allow for peripheral perfusion.
- (2) As the Rotary Knob turns clockwise, the interval will increase. After reaching "**RETURN**," the interval will "roll over" to "**1 MIN**" and continue to increase.
- (3) As the Rotary Knob turns counter-clockwise, the interval will decrease. After reaching "1 MIN," the interval will "roll over" to "RETURN" and continue to decrease.
- b. **AUTO MODE.** Selecting this menu option switches the **NIBP Automatic Mode** between ON and OFF (default). When switched from OFF to ON, the operator must manually initiate the first reading (by pressing the **NIBP START/STOP** control key; subsequent readings are taken automatically at the operator selected interval. When in MANUAL mode, readings may only be initiated from the **NIBP START/STOP** or **NIBP START/STOP** Control keys. A reading cycle may be stopped at any time by pressing the **NIBP START/STOP** Control Key while it is in progress. If the operator wants to put the monitor into the Standby Mode of Operation, a reading in progress will stop when the **STANDBY** Control Key is pressed. If operating a dual monitor system, with a 3155A and 3155MVS communicating with the 3150(M), the adjustments made here are interactive between the two 3155 monitors to ensure that the monitored parameters remain consistent between all components of the MRI monitoring system.
- c. **HR SOURCE.** Selecting this menu option allows the selection of the source to be used for the heart-rate display in the ECG area. The options are AUTO, ECG (default), ART (arterial pressure), SPO2 and NIBP. If operating a dual monitor system, with a 3155A and 3155MVS communicating with the 3150(M), the adjustments made here are interactive between the two 3155 monitors to ensure that the monitored parameters remain consistent between all components of the MRI monitoring system.

This menu option is identical to, and interactive with, similarly named menu options under ECG, P1, P2 and SPO2.

HISTORY	HISTORY							
PRT ALL	DATE	TIME	S/D	(M)	HR	SP02	C02	RESP
PRT PAGE	5-11-00	12:16	112/71	(85)	59	98%	31	11
PREV PAGE		12:19	115/78	(91)	60	97%	31	15
NEXT PAGE		12:22	114774	(87)	64	97%	31	11
CLEAR ALL		12:25	116773	(88)	64	97%	31	12
MULTI TRENDS		12:28	126/76	(93)	63	98%	31	15
OCRG		12:31	118/73	(88)	67	97%	31	14
RETURN	Page 1 of 8							

Figure 4-12. The HISTORY Menu

d. **HISTORY.** Selecting this menu option brings up the **HISTORY** Menu (**See Figure 4-12**), and displays the last 48 NIBP readings together with the SpO2, ETCO2/Respiration and heart rate values at the time in a tabular form (6 readings per page). The tabular data is retained in battery-backed memory when power is interrupted.

The following options are available in the **HISTORY** Menu:

- (1) **PRT ALL.** Selecting this menu option prints all stored Tabular Data.
- (2) **PRT PAGE.** Selecting this menu option prints the current page.
- (3) **PREV PAGE.** Selecting this menu option allows the selection of the previous page of tabular data.
- (4) **NEXT PAGE.** Selecting this menu option allows the selection of the next page of the tabular data.

(5) **CLEAR ALL.** Selecting this menu option clears the patient Trend Data. If operating a dual monitor system, with a 3155A and 3155MVS communicating with the 3150(M), selecting this option will clear the trend data throughout the entire system.

NOTE

History Data is retained when a new patient is connected to the monitor. Therefore, to avoid confusion, all previously acquired data should be cleared prior to connection to a new patient.

- (6) **MULTI TRENDS.** Selecting this menu option will bring up the **MULTI TRENDS** Menu (See Section 5 for further information).
- (7) **OCRG.** This option is not available in remote mode.
- (8) **RETURN.** Selecting this menu option will return the monitor to the **NIBP** Menu
- e. **FORMAT.** Selecting this menu option allows the operator to change the display format of the Pressure numerics. If **SYS/DIA** is selected, the Systolic and Diastolic numerics will be in a large font separated by a "slash" and the Mean numeric will be in a smaller font bracketed with parenthesis. If **MEAN** is selected, the Mean numeric is displayed in the large font with the Systolic and Diastolic numerics separated by a "slash" in a smaller font. If operating a dual monitor system, with a 3155A and 3155MVS communicating with the 3150(M), the adjustments made here are interactive between the two 3155 monitors to ensure that the monitored parameters remain consistent between all components of the MRI monitoring system.
- f. **RETURN**. Selecting this menu option will return the monitor to the Normal Screen.
- 4.4.5 <u>Using the Automatic Interval Mode.</u> This monitor may be setup to take NIBP readings automatically at intervals set by the operator. To set this monitor to make automatic NIBP determinations, turn the Rotary Knob until the NIBP Menu-Select Icon is highlighted and then press the Rotary Knob to bring up the **NIBP** Menu. To set the Interval Time, highlight the **INTERVAL** menu selection and press the Rotary Knob to access the time selection menu. To turn the Automatic Mode of Operation ON or OFF, highlight the **AUTO MODE** menu selection, press the Rotary Knob and select ON or OFF. Once the Automatic Mode has been turned On, press the **NIBP START/STOP** Control Key to activate. If operating a dual monitor system, with a 3155A and 3155MVS communicating with the 3150(M), the adjustments made here are interactive between the two 3155 monitors to ensure that the monitored parameters remain consistent between all components of the MRI monitoring system.
- 4.4.6 <u>Manually Starting/Stopping a Reading Cycle.</u> An NIBP determination may be started or stopped by pressing the **NIBP START/STOP** Control Key. If operating a dual monitor system, with a 3155A and 3155MVS communicating with the 3150(M), the adjustments made here are interactive between the two 3155 monitors to ensure that the monitored parameters remain consistent between all components of the MRI monitoring system.
- 4.4.7 <u>Stat Mode Operation.</u> The STAT Mode is specifically intended for clinicians who need to obtain successive readings for rapid assessment of the trend of a patient's pressures. To initiate a series of up to five STAT Readings, the operator presses the **NIBP STAT** Control Key. The monitor will perform up to five NIBP determinations in a period of five (5) minutes. At the end of the five (5) minute period, the STAT Mode will terminate (even if a reading is in progress) regardless of how many readings have been completed. This feature is not available in the "dual monitor" mode.

4.4.8 Alarm Limits. Alarm Limits may be set two ways. To set the Alarm Limits for every available parameter, press the **ALARMS SCREEN** Menu-Select Key to access the **ALARMS Menu**. To set the Alarm Limits for NIBP only, highlight the NIBP Icon and press the **ALARMS SCREEN** Menu-Select Key to access the individual parameter Alarm Limits Box. The range of Alarm Limits for the NIBP pressure channels is 5 to 249 mmHg. If operating a dual monitor system, with a 3155A and 3155MVS communicating with the 3150(M), alarm limit changes are interactive between the two monitors to ensure that the monitoring parameters remain consistent between all components of the MRI monitoring system.

WARNING

The patient's blood pressure determinations are not continuous. The blood pressure determinations are only updated immediately after a blood pressure measurement is taken. When using the 3155A/3155MVS Monitor to monitor critical situations, set the Automatic Reading mode to a short period for more frequent updating of the blood pressure determinations. When set to the shortest of the automatic intervals, the constant measurements can cause blood pooling in the limb, and blood pooling in the limb may artificially increase the value of the blood pressure determinations.

4.4.9 Adult vs. Neonatal Mode Operation. This monitor allows the operator to determine pressures on a wide range of patients by allowing the Patient Type to be switched from Adult to Neonate (Adult Mode is used for Adult and Pediatric patients and Neonate Mode is used for Neonates only). Several operational parameters (including cuff inflation pressure) are varied depending on the setting of the **PATIENT** menu option in the **SETUPS** Menu. The **Adult/Pediatric Mode** uses a higher pump volume and a much larger cuff is used on the patient; in the **Neonatal Mode** the pump rate is lower and a much smaller cuff is used on the patient (reference page xi of this manual for cuff selection and sizes). The Alarm Limits and settings may also change when the patient type is switched from adult to neo (or neo to adult).

Whenever the **NIBP Patient Mode** is switched (either from **Adult** to **Neo** or **Neo** to **Adult**), the Alarm Tone will sound while the informational display message area indicates "**Change NIBP Cuff**" (If operating a dual monitor system, with a 3155A and 3155MVS communicating with the 3150(M), this message is interactive between the 3155 monitors). To change the patient type, press the **SETUP** control key, scroll to the **PATIENT** menu selection and press the Rotary Knob.

- <u>4.4.10</u> <u>Trended Data.</u> For complete information on the trending of patient NIBP data, see Section 5: Printing and Trending.
- **4.5 SpO2 Monitoring.** The **SPO2** Menu is brought up (if this parameter is turned on through the **SETUPS** Menu) with the SPO2 Menu-Select Icon.

The following three secondary menus support the SpO2 monitoring feature:

- **RECORDER Menu.** Used to select recorder functions and to set the recorder and trace speed.
- **ALARMS Menu.** Used to set and/or disable the SpO2 alarms. The range of Alarm Limits for SpO2 is 50 to 99%, Off.
- **TREND Menu.** Used to setup and print Trended information.

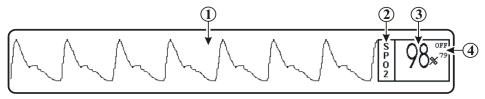


Figure 4-13. The SpO2 Display

4.5.1 <u>Associated Waveforms and Displays.</u> (See Figure 4-13) SpO2 information is displayed as a waveform in Trace location B and as numeric data in Box 2. The following is a description of the items contained within the SpO2 Display:

- a. **SpO2 Waveform.** (**Item 1**) The SpO2 Waveform is displayed in Trace location B (only if P2 has been turned off by the operator).
- b. **Icon Label.** (**Item 2**) This label identifies the parameter numerics that are displayed within this box. SpO2 is monitored using Box 2.
- c. **SpO2 Numeric.** (Item 3) A numeric indication of the patient's SpO2 reading.
- d. **SpO2 High Alarm Limits.** (**Item 4**) A numeric indication of the settings of the High SpO2 Alarm Limit.

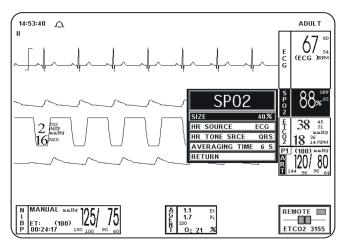


Figure 4-14. The SpO2 Menu

4.5.2 SpO2 Menu. (See Figure 4-14) The menu for the SpO2 is brought up with the selection of the SPO2 Menu-Select icon. *This menu has a time-out feature. If no action is taken for approximately 60 seconds, the monitor will automatically return to the Normal Screen.*

The following is a description of the **SPO2** Menu options:

- a. SIZE. This selection is not available in the 3155A/3155MVS Monitor.
- b. **HR SOURCE.** Selecting this menu option allows the selection of the source to be used for the heart-rate display in ECG area. The options are AUTO, ECG (default), ART (arterial pressure), SPO2 and NIBP. If operating a dual monitor system, with a 3155A and 3155MVS communicating with the 3150(M), the adjustments made here are interactive between the two 3155 monitors to ensure that the monitored parameters remain consistent between all components of the MRI monitoring system.

This menu option is identical to, and interactive with, similarly named menu options under ECG, ART and NIBP.

c. **HR TONE SRCE.** Selecting this menu option selects the Heart Rate tone source. The options are QRS (default), SPO2 and OFF. When the source is the QRS, the tone sounds at the detection of QRS from the ECG parameter. When the source is the SpO2, the tone sounds at the detection of the pulse from the SpO2 parameter. If operating a dual monitor system, with a 3155A and 3155MVS communicating with the 3150(M), the adjustments made here are interactive between the two 3155 monitors to ensure that the monitored parameters remain consistent between all components of the MRI monitoring system.

The pulse tone is modulated by the SpO2 value. If SpO2 is turned off, the pitch of the tone remains at the last modulated frequency set by SpO2

This menu option is identical to, and interactive with, the HR TONE SOURCE option in the **SOUND ADJUST** Menu.

- d. **AVERAGING TIME.** This selection is not available in the 3155A/ 3155MVS **Monitor**.
- e. **RETURN.** Selecting this menu option will return the monitor to the Normal Screen.

- 4.5.3 <u>Alarm Limits.</u> Alarm Limits may be set two ways. To set the Alarm Limits for every available parameter, press the **ALARMS SCREEN** Menu-Select Key to access the **ALARMS Menu.** To set the Alarm Limits for SpO2 only, highlight the SpO2 Icon and press the **ALARMS SCREEN** Menu-Select Key to access the individual parameter Alarm Limits Box. The range of Alarm Limits for the SpO2 is 50 to 99%. If operating a dual monitor system, with a 3155A and 3155MVS communicating with the 3150(M), alarm limit changes are interactive between the two monitors to ensure that the monitoring parameters remain consistent between all components of the MRI monitoring system.
- <u>4.5.4</u> <u>Trended Data.</u> For complete information on the trending of patient SpO2 data, see Section 5: Printing and Trending.
- **4.6 End-Tidal CO2 (ETCO2) Monitoring.** The **ETCO2** Menu is brought up (if this parameter is turned on through the **SETUPS** Menu) with the ETCO2 Menu-Select Icon. The ETCO2 feature provides side stream measurement of CO2 and mean N2O with a continuous real time CO2 Waveform Display. This feature will perform an automatic zeroing and correction for barometric pressure at periodic intervals. ETCO2 monitoring also provides Respiration Monitoring. Respiration is measured using the ETCO2 module (infrared plethysmography). During any respiration monitoring, a Lung Symbol will flash on the screen (in the information display to the right of the heart symbol) on the detection of each breath.
- <u>4.6.1</u> <u>Patient and Tubing Preparation.</u> 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.

CAUTION

Before using the ETCO2 analyzer, read the PRECAUTIONS and USER RESPONSIBILITIES which follow the Table of Contents.

a. The patient sampling circuit consists of the external moisture filter, sampling tube, nafion moisture filter tube and 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.

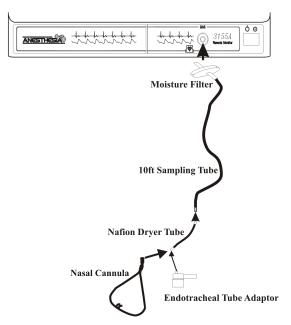


Figure 4-15. Patient Sample Circuit

b. Perform the following to assemble the patient sampling circuit (See Figure 4-15):

- (1) Connect the moisture filter to the ETCO2 connection on the monitor front panel.
- (2) Connect the 20 foot sampling tube to the moisture filter.
- (3) Connect the Nafion® Dryer Tube to the sampling tube (at the patient end).
- (4) Connect the Nafion® Dryer Tube to the endotracheal tube adaptor.
- c. **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.

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.

Always use a microbial moisture filter in the patient circuit to keep biological and water condensate contamination out of the Gas Sensor Sample Cell.

Always inspect patient tubing after attachment to the monitor following the patient circuit's manufacturer's recommendations.

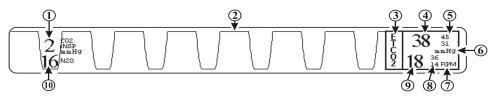


Figure 4-16. The ETCO2 Display

- 4.6.2 <u>Associated Waveforms and Displays.</u> (See Figure 4-16) ETCO2 information is displayed as a waveform in Trace location C and as numeric data in Box 3. The following is a description of the items contained within the ETCO2 Display:
 - a. **Inspired CO2 Numeric.** (**Item 1**) A numeric indication of the patient's Inspired CO2 reading.
 - b. **Respiration Waveform.** (**Item 2**) The ETCO2 derived Respiration Waveform is displayed in Trace location C.
 - c. **Icon Label.** (**Item 3**) This label identifies the parameter numerics that are displayed within this box. ETCO2 is monitored using Box 3.
 - d. **ETCO2 Numeric.** (Item 4) A numeric indication of the patient's ETCO2 reading.
 - e. **ETCO2 Alarm Limits.** (**Item 5**) A numeric indication of the settings of the High (on top in the example) and Low (bottom in the example) ETCO2 Alarm Limits.
 - f. **Unit of Measurement. (Item 6)** Displays the Unit of Measurement being used for presentation of the ETCO2 numeric data.
 - g. **Unit of Measurement. (Item 7)** Displays the Unit of Measurement being used for presentation of the ETCO2 derived Respiration numeric data.
 - h. **Respiration Alarm Limits.** (**Item 8**) A numeric indication of the settings of the High (on top in the example) and Low (bottom in the example) Respiration Alarm Limits when derived from the ETCO2 module.
 - i. **Respiration Numeric.** (Item 9) A numeric indication of the patient's Respiration reading derived from the ETCO2 module.
 - j. **N2O Numeric.** (**Item 10**) A numeric indication of the patient's N2O reading in percent.

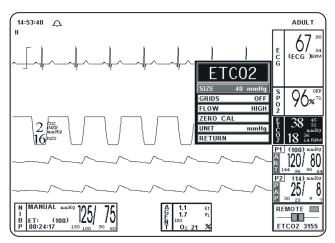


Figure 4-17. The ETCO2 Menu

4.6.3 ETCO2 Menu. (See Figure 4-17) The menu for the ETCO2 is brought up with the selection of the ETCO2 Menu-Select icon. This menu has a time-out feature. If no action is taken for approximately 60 seconds, the monitor will automatically return to the Normal Screen.

The following is a description of the **ETCO2** Menu options:

- a. **SIZE.** Selecting this menu option brings up the **SIZE** Menu where the operator may select 40, 60 or 80 mmHg for the Scale Size of the ETCO2 Waveform Display. If operating a dual monitor system, with a 3155A and 3155MVS communicating with the 3150(M), the adjustments made here are interactive between the two 3155 monitors to ensure that the monitored parameters remain consistent between all components of the MRI monitoring system.
- b. **GRIDS.** Selecting this menu option brings up the **GRIDS** Menu where the operator may turn the ETCO2 Grids ON or OFF.
- c. **FLOW.** This feature is for future operational enhancement. The only way currently available to change the 3150(M) Flow Rate from High to Low (or vice versa) is to change the patient from Adult to Neo (or vice versa).
- d. **ZERO CAL.** This option is not available on the 3155A/3155MVS.
- e. **UNIT.** Selecting this menu options brings up the **UNIT** Menu where the operator may toggle the monitor between mmHg and kPa. If operating a dual monitor system, with a 3155A and 3155MVS communicating with the 3150(M), the adjustments made here are interactive between the two 3155 monitors to ensure that the monitored parameters remain consistent between all components of the MRI monitoring system.
- f. **RETURN.** Selecting this menu option will return the monitor to the Normal Screen.
- 4.6.4 Calibration of CO2/N2O Measurement System. No field span calibration is required.
- 4.6.5 <u>Alarm Limits.</u> Alarm Limits may be set two ways. To set the Alarm Limits for every available parameter, press the **ALARMS SCREEN** Menu-Select Key to access the **ALARMS** Menu. To set the Alarm Limits for ETCO2 only, highlight the ETCO2 Icon and press the **ALARMS SCREEN** Menu-Select Key to access the individual parameter Alarm Limits Box. The range of Alarm Limits for the ETCO2 is 5 to 60 mmHg and Off for the Low Limit and 5 to 80 mmHg and Off for the High Limit. The range of Alarm Limits for Respiration is 4 to 40 for the Low Limit and 20 to 150 for the High Limit. If operating a dual monitor system, with a 3155A and 3155MVS communicating with the 3150(M), alarm limit changes are interactive between the two monitors to ensure that the monitoring parameters remain consistent between all components of the MRI monitoring system.
- <u>4.6.6</u> <u>Trended Data.</u> For complete information on the trending of patient ETCO2 data, see Section 5: Printing and Trending.

- **4.7 Anesthetic Agent/Oxygen Monitoring.** (3155A only) The Anesthesia Gas Sensor (AGS) is a non-dispersive, single path Infra-Red spectrometer based upon a high stability IR sensor technology known as Stabilized Thermopile Bridge (STB). Utilizing the STB technology, the Invivo Research AGS yields high output, low noise and ultra stable gas measurements.
- <u>4.7.1</u> <u>Patient and Tubing Preparation.</u> Use only original Invivo Research, Inc. sampling lines and accessories; other sampling lines may cause inaccurate readings and malfunctions. Change sampling line and airway adapter for each patient.

WARNING

Always test sampling line adapter for a tight connection and proper operation before attaching to a patient.

Patient sampling line length must be 20 feet (6.1 meters) or less for accurate measurement.

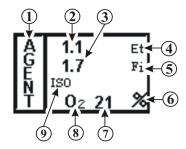


Figure 4-18. The AGENT Display

- <u>4.7.2</u> <u>Associated Displays.</u> (**See Figure 4-18**) Anesthetic Agent information can only be displayed as numeric data. Agent data is displayed in Box 7. The following is a description of the items contained within the Anesthetic Agent Display.
 - a. **Icon Label.** (**Item 1**) This label identifies the parameter numerics that are displayed within this box. Anesthetic Agents may be monitored in Box 7 only.
 - b. **Agent Expired Numeric.** (**Item 2**) A numeric indication of the value of the gas being expired.
 - c. **Agent Inspired Numeric.** (**Item 3**) A numeric indication of the value of the gas being inspired.
 - d. **Et.** (**Item 4**) Indicates that the top row of numerics are End Tidal (expired) values of the gases being monitored.
 - e. **Fi.** (**Item 5**) Indicates that the bottom row of numerics are the fraction of inspired (Fi) values of the gases being monitored.
 - f. **Unit of Measurement.** (**Item 6**) Displays the Unit of Measurement being used for presentation of the Anesthetic Agents and Oxygen numeric data (i.e. Percentage).
 - g. **Oxygen Numeric.** (**Item 7**) A numeric indication of the patient's Oxygen measurement.
 - h. **O2.** (Item 8) Indicates that the patient's oxygen is being monitored in this row.
 - i. **Anesthetic Agent Designation.** (Item 9) Displays the identification of the gas being monitored. The Agent Identifications are as follows:
 - (1) Halothane HAL
 - (2) Isoflurane ISO
 - (3) Enflurane ENF
 - (4) Sevoflurane SEV
 - (5) Desflurane DES

WARNING

Minimum Alveolar Concentration (MAC) values are empirical and are not absolute values. Invivo Research, Inc.'s AGS MAC values correspond to those of healthy adults and cannot be applied to children. Age and other individual factors influencing the behavior of volatile agents are not taken into account.

<u>4.7.3</u> <u>Agent Menu.</u> The Anesthetic Agent monitoring feature does not have a menu like the other monitoring features on this monitor. Pressing the Rotary Knob while the AGENTS icon is highlighted brings up a box which displays the Minimum Alveolar Concentration (MAC) values. 1 MAC Values used to Calculate the displayed MAC are as follows: HAL=0.76%, ENF=1.68%, ISO=1.12%, SEV=1.92%, DES=6.0% and N2O=100%.

Calculation of displayed MAC value: Cal. MAC = (EtN2O / 1 MAC N2O) + (Et Agent / 1 MAC Agent).

- 4.7.4 Gas Calibration. No field span calibration for Anesthetic Agent monitoring is required. The monitor will perform a Zero Calibration periodically and the operator may also manually initiate a Zero Calibration cycle. There is a two (2) minute warmup period when Agents is first turned on during which there is no monitoring. If monitor power is turned off and on, the warm-up cycle will be repeated. The entire warmup period is 15 minutes during which the monitor will perform an automatic Zero Calibration at the two minute mark in the warmup period, then will run again in the following sequence: 4, 6, 8, 10, 12, 14, 16, 18, 20, 40 and 60 minutes. After the 60 minutes has expired the Zero Calibration will run once an hour, or whenever an anesthetic agent change is detected. The Oxygen System calibration automatically occurs during the first two (2) minutes each time the monitor is turned on. If the Agents option is run over a continuous 12 hour period with an O2 concentration of 22% or greater there is a Warning Box that will appear to alert the operator that a one (1) minute O2 Calibration sequence must be run. The Warning Box will offer the operator a Yes/No option of running the one (1) minute O2 Calibration sequence, if the operator selects NO, the message will reappear in 30 minutes. An O2 Calibration message will also appear if the O2 Sensor detects a reading greater than 103%. Any time a calibration message appears on the 3155A, a notification box will appear on the 3155MVS to alert the operator that attention is required on the 3155A. The notification box reads: "ATTENTION IS REQUIRED ON OTHER 3155."
 - a. **Anesthetic Agent QC Check.** Perform a QC Check at least once a month, or whenever Agent accuracy is questionable.
 - (1) Before perform the Anesthetic Agent QC Check, the monitor must be at a stable operating temperature. The monitor must be turned on, with ETCO2 and Agent parameters active, for a minimum of 45 minutes before the QC check is performed.
 - (2) Each QC Check Gas can comes with a nozzle and tubing with a "T" fitting for connecting to the gas (ETCO2) input port in the monitors front panel.
 - (3) See the Accessories List in the Table of Contents Section of this manual for selection of the QC Check Gas for the Anesthetic Agents you are using.

WARNING

Patient Waste Gas Removal. Continuous exposure of Health Care workers to waste anesthetic gases (including halogenated agents and nitrous oxide) is not recommended. Always attach the waste gas connection on the rear of the monitor to the room's gas evacuation system. Avoid venting any waste anesthetic gas directly into the room air as exposure to waste anesthetic gases above the recommended OHSA limits could result.

- 4.7.5 Alarm Limits. The Agent Alarm Limits are set by selecting the AGENT/O2 ALM menu option in the **ALARMS** Menu, which is accessed by pressing the **ALARMS SCREEN** Menu-Select Key, or by highlighting the AGENT Icon and pressing the **ALARMS SCREEN** Menu-Select Key to access the **ALARMS** Menu. The range of Alarm Limits for each Agent is shown in Table 6-2. If operating a dual monitor system, with a 3155A and 3155MVS communicating with the 3150(M), alarm limit changes are interactive between the two monitors to ensure that the monitoring parameters remain consistent between all components of the MRI monitoring system.
- <u>4.7.6</u> <u>Trended Data.</u> For complete information on the trending of patient Agent data, see Section 5: Printing and Trending.
- 4.7.7 <u>Agent/O2 Messages</u>. The following messages are used for Anesthetic Agent/O2 monitoring (if operating a dual monitor system, with a 3155A and 3155MVS communicating with the 3150(M), all these messages except REPLACE O2 SENSOR are interactive throughout the MRI monitoring system):

Flashing Insp CO2 Numeric	(Fixed CO2 Rebreathing Alarm) The Inspired CO2 numeric turns red and flashes with Alarm sound. Occurs when Inspired CO2 is greater than 25 mmHg. This alarm is a fixed, non-adjustable alarm.
Flashing N2O Numeric	(Fixed N2O Alarm) N2O numeric turns red and flashes with Alarm sound. Occurs when N2O is greater than 80%. This alarm is a fixed, non-adjustable alarm.
ETCO2 WARMING UP	Message flashing red. Occurs during CO2/Anesthesia Gas Sensor warmup.
CO2 OCCLUSION	Message flashing red with Alarm sound. Occurs when sample line is occluded.
MULTIPLE AGENTS	Message flashes red with Alarm sound. Occurs when more than one Anesthetic Agent is identified.
READJUSTING CO2 ZERO	Message flashing red. Occurs during CO2/Anesthesia Gas Sensor zeroing operation.
REPLACE O2 SENSOR	The Anesthetic Oxygen Sensor is bad and must be replaced.

4.7.8 Oxygen Sensor Replacement. The Oxygen Sensor (Invivo Research, Inc. Part Number 9445) is located on the rear of the monitor at the Waste Cell Exhaust location (See Figure 1-4 for location and Figure 4-19 for Installation Diagram). The Oxygen Sensor has an expected life of greater then six months with expected life inversely proportional to changes in Oxygen Concentration, Temperature and Pressure. The Oxygen Sensor begins aging immediately upon the opening of the package and should, therefore, not be opened until ready for use. The Oxygen Sensor should be replaced periodically as part of routine maintenance. This monitor cannot be connected to the scavenge gas system without the Oxygen Sensor installed, never operate without the monitor connected to the scavenge gas system. Always operate the monitor with the Oxygen Sensor installed.

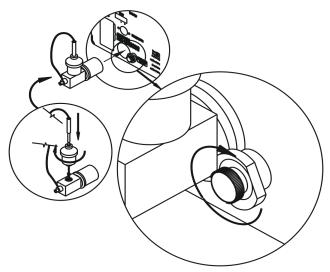


Figure 4-19. Oxygen Sensor Installation Diagram

- a. **Oxygen Sensor Installation Instructions.** Install the Oxygen Sensor as follows:
 - (1) Install (plug-in) the Oxygen Sensor Adapter Subassembly into the Waste Gas Exhaust port on the rear of the monitor. Ensure that the large threaded hole in the block is facing upwards.
 - (2) Lock subassembly to the monitor by securing with Swivel Lock Nut provided on the rear panel of the monitor.
 - (3) Open bag containing disposable Oxygen Sensor (IRI #9445).
 - (4) Screw Oxygen Sensor into threaded port on Adaptor Subassembly.
 - (5) Plug adapter cable assembly into the top of the Oxygen Sensor.
 - (6) Connect facility Gas Scavenge System to the Waste Gas Exhaust port.

SECTION 5 PRINTING AND TRENDING

5.0 PRINTING AND TRENDING.

5.1 Introduction. The **3155A/3155MVS Monitor** optional thermal array strip recorder can record one or two waveforms (as selected from the **RECORDER** Menu). The recorder prints patient parameters on the edge of the strip chart and ends with a "snapshot" patient data report.

The Recorder option provides the following features:

- Selection of the traces (A through F in Single or Dual Trace Mode) to be sent to the recorder.
- High frequency response (Single = 800 samples/second at 25 mm/second speed and Dual = 400 samples/second at 25 mm/second speed) with a bandwidth of 100 Hz.
- Transmitting a calibration waveform to the recorder.
- Total control over the Recorder mode (OFF/AUTO/RUN).
- Selection of patient data report for printing.
- Selection of data collection intervals for report.
- 0 to 16 seconds of trace delay in four increments.
- Selection of 25 or 50 mm/second recorder speed (and screen trace speed).
- The paper record is automatically annotated with the alphanumeric indication of date, time delay, paper speed, scales, lead configuration, mode, pressures (systolic, mean, and diastolic), heart rate, NIBP (systolic, diastolic, mean blood pressures, and the elapsed time since the last measurement), ETCO2 and SpO2.
- If an active alarm limit is violated, the numeric value of the corresponding parameter is printed at the beginning of the automatically activated record.
- The recorder uses plain (i.e., un-ruled) paper.
- <u>5.1.1</u> Record Key. The **RECORD** key starts/stops the Recorder upon operator demand. If left running the recorder will continue to supply hard copy output for approximately 25 seconds before it automatically shuts off.

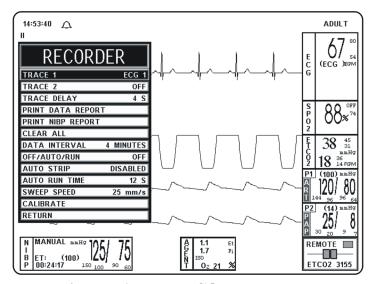


Figure 5-1. The RECORDER Menu

5.2 The RECORDER Menu. The **RECORDER** Menu provides adjustments that will allow this monitor to supply concise and up to date printouts suitable to a wide variety of situations. Pressing the **RECORDER FUNCTIONS** Menu-Select key brings up the **RECORDER** Menu (**See Figure 5-1**). If the optional recorder is not installed, the message "**THIS OPTION NOT INSTALLED**" is displayed on the screen. *This menu has a time-out feature. If no action is taken for approximately 60 seconds, the monitor will automatically return to the Normal Screen.*

The following is a description of the options in the **RECORDER** Menu:

- a. **TRACE 1.** Selecting this menu option allows the selection of the first trace to be output to the recorder. The options [depending on currently active parameters] are ECG1 (default), P1, P2, SPO2 and RESP(CO2) (when option is installed). If TRACE 2 is off, TRACE 1 is output to the recorder using the full 40 mm width of the print-out.
- b. **TRACE 2.** Selecting this menu option allows the selection of the second trace to be output to the recorder. The options [depending on the currently active parameters] are OFF (default), ECG1, P1, P2, SPO2 and RESP(CO2) (when option is installed).
- c. **TRACE DELAY.** Selecting this menu option allows the selection of the time delay for the trace data being sent to the recorder. The options are 0, 4 (default), 8 and 16 seconds.
- d. **PRINT DATA REPORT.** Selecting this menu option activates the recorder to print a patient data report (in tabular form) of up to 60 stored patient parameter readings stored in the time interval pre-selected by the DATA INTERVAL menu option in this menu. Only those parameters which have been turned on will be printed.
 - (1) The Data Report print-out consists of the minute-by-minute updates of the patient parameters (that are on during the data storage time) up to 60 measurements. The current date and the time of the recording are clearly marked on the left of the print-out.
 - (2) If a parameter is off during any portion of the data storage period, the message `---/---' shall be printed in place of its value.
 - (3) The Data Report print-out ends with a lined area for writing in the ID/CASE number, the Patient's Name and the Operator Comments.
- e. **PRINT NIBP REPORT.** Selecting this menu option activates the recorder to print the NIBP report, with the last 48 NIBP readings in tabular form (6 readings per page).
- f. **CLEAR ALL.** Pressing this function key erases all data stored for trend graphs and the data report in the monitor. It does not affect the time base or scale of the graphs. The operation of this function key requires confirmation by the user. If operating a dual monitor system, with a 3155A and 3155MVS communicating with the 3150(M), selecting this option will clear the trend data throughout the entire MRI monitoring system.
- g. **DATA INTERVAL.** Selecting this menu option selects the data interval (1 60 minutes) for stored patient parameter readings to be printed in the Data Report (activated by pressing the PRINT DATA REPORT menu option in this menu). The options (in minutes) are 1 through 10 (4 being the default), 12, 15, 18, 24, 30 and 60. The first data stored occurs either at power up, or 2 seconds after a new interval is selected.
- h. **OFF/AUTO/RUN.** Selecting this menu option allows the switching of the mode of the Recorder. The options are OFF, AUTO and RUN. The following is an explanation of the possible selections:
 - (1) **OFF.** Switches the Recorder Auto Mode OFF (the recorder may be activated by pressing the **RECORD** Control Key.

- (2) **AUTO.** If AUTO is selected, violation of an alarm limit for HR, P1, P2, NIBP, RESP, ETCO2 and SpO2 automatically activates the recorder trace and writes ECG Trace A. In addition to ECG Trace A, a second trace will be written below it when the parameter is in a trace location. The priority of the second trace recording is P1, P2, RESP(ETCO2). SpO2 is written as the second trace recording when its alarm limit is in violation and is the only other parameter in a trace location.
 - (a) The recording continues for 20 seconds or until the recorder is deactivated by pressing the **RECORD** key or by changing the Recorder Auto Mode to Off.
- (3) **RUN.** RUN activates the recorder and writes the traces which have been selected.
- i. **AUTO STRIP.** Selecting this menu option allows the Automatic Strip Chart feature of the Recorder to be switched On and Off. The options are DISABLED, ENABLED and RETURN. The following is a description of the possible selections:
 - (1) **DISABLED.** Selecting this menu option will turn the Automatic Strip Chart Feature OFF.
 - (2) **ENABLED.** Selecting this menu option will turn the Automatic Strip Chart Feature ON. The Recorder will automatically activate at the interval selected in the Data Interval Menu (See Paragraph 5.3.1).
 - (3) **RETURN.** Selecting the menu option will return the monitor to the **RECORDER** Menu.
- j. **AUTO RUN TIME.** Selecting this menu option brings up the **AUTO RUN TIME** Menu where the operator can select the Automatic Strip Run Time. The options are 8, 12, 16, 20 and 30 seconds.
- k. **SWEEP SPEED.** This menu option switches the recorder **and** the screen trace speed between 25 and 50 mm/second.
- 1. **CALIBRATE.** Pressing and holding the rotary knob when this menu option is high-lighted shall send a 1 mm/mV square-wave calibration signal to the recorder and to the ECG waveform(s) display on the monitor screen. The message "CAL" flashes on the screen over the ECG waveform(s). This feature is for Service use only. If operating a dual monitor system, with a 3155A and 3155MVS communicating with the 3150(M), this option is interactive between the two 3155 monitors.
- m. **RETURN.** Selecting this menu option will return the monitor to the Normal Screen.
- **5.3 Printing Charts.** This monitor will print four different types of charts upon operator demand. The four types are Strip Chart, Tabular Chart, Trend Chart and System Data Report. The Sweep Speed of the printout may be set to 25 mm/second or 50 mm/second with the slower speed (25 mm/second) presenting the most data on a Strip Chart. The three types of charts are discussed below.

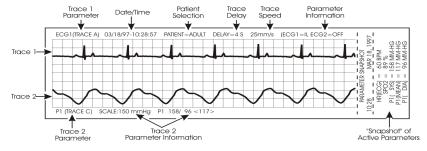


Figure 5-2. Sample Strip Chart

<u>5.3.1</u> <u>Strip Chart Printouts.</u> (**See Figure 5-2**) The Strip Chart may be configured to contain one or two parameter waveforms and also contains the numerical value of every active parameter as well as a "Parameter Snapshot" of the current values of every active parameter at the end of the printout strip.

- a. **Setting Up the Strip Chart.** Perform the following procedure to configure the Strip Chart to the appropriate application:
 - (1) Press the **RECORDER FUNCTIONS** Menu-Select Key.
 - (2) To change Trace 1, which is defaulted to ECG1: press the Rotary Knob, highlight the desired parameter and press the Rotary Knob to accept the new selection.
 - (3) To change Trace 2, which is defaulted to OFF: highlight Trace 2 then press the Rotary Knob, highlight the desired parameter and press the Rotary Knob to accept the new selection.
 - (4) To set the Trace Delay, which is defaulted to 4 seconds: highlight Trace Delay then press the Rotary Knob, highlight the desired delay (the options are 0, 4, 8 and 16 seconds) and press the Rotary Knob to accept the new selection.
 - (5) To set the monitor to provide a Strip Chart automatically, perform the following:
 - (a) Select the desired time between automatic strips by highlighting the Data Interval menu selection, pressing the Rotary Knob, highlighting the desired time interval and pressing the Rotary Knob to accept the selection.
 - (b) Set the Auto Strip to On by highlighting the Auto Strip menu selection, pressing the Rotary Knob, highlighting Enabled and pressing the Rotary Knob to accept the selection.
 - (6) To manually print a Strip Chart, press the **RECORD** control key.

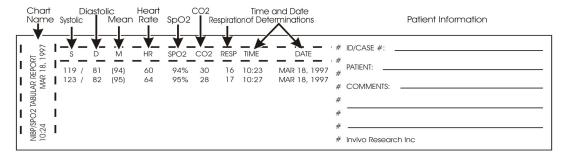


Figure 5-3. Sample Tabular Chart

<u>5.3.2</u> <u>Tabular Chart Printouts.</u> (See Figure 5-3) The NIBP/SpO2 Tabular Report provides a hardcopy printout of the numerical indications of NIBP, Heart Rate, SpO2, CO2 and RESP along with the date and time of the determination.

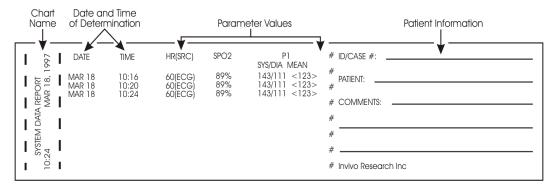


Figure 5-4. System Data Report

- <u>5.3.3</u> <u>System Data Report.</u> (**See Figure 5-4**) The System Data Report provides a hardcopy printout of the numerical indications of all the active patient parameters along with the date and time of the determination.
- **5.4 Loading Printer Paper.** Perform the procedure in Figure 5-5 to load the printer paper.

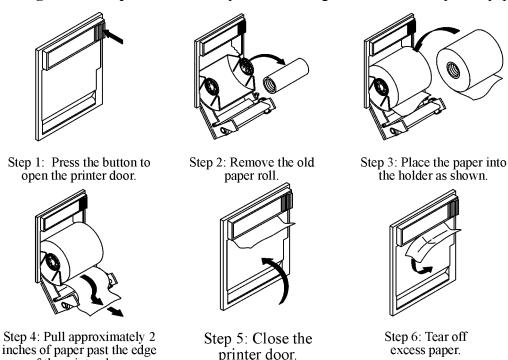


Figure 5-5. Loading the Printer Paper

of the printer door.

5.5 Trending Feature. The Trend Feature may be operated to graph Multiple or Individual Trends. Pressing the **TRENDS** Menu-Select Key, while in the Normal Screen, will bring up the **HISTORY** Menu (**See Figure 5-6**). Pressing it while any Patient Parameter is highlighted will bring up the Trend Menu for the Selected Patient Parameter. **3155A/3155MVS Monitor** automatically stores the parameter trend information for the heart rate, NIBP, P1, P2, ETCO2/RESP and SpO2. There is also an operational key, **CLEAR TRENDS**, on the monitor front panel that allows the operator to clear all trends without bringing up any of the **TREND** Menus (Software MPC20 or later).

HISTORY		HISTORY						
PRT ALL	DATE	TIME	S/D	(M)	HR	SP02	C02	RESP
PRT PAGE	5-11-00	12:16	112/71	(85)	59	98%	31	11
PREV PAGE		12:19	115/78	(91)	60	97%	31	15
NEXT PAGE		12:22	114/74	(87)	64	97%	31	11
CLEAR ALL		12:25	116/73	(88)	64	97%	31	12
MULTI TRENDS		12:28	126/76	(93)	63	98%	31	15
OCRG		12:31	118/73	(88)	67	97%	31	14
RETURN			Р	age 1	of 8			

Figure 5-6. The HISTORY Menu

<u>5.5.1</u> <u>HISTORY Menu Options.</u> The HISTORY Screen is a Tabular Listing of a patient's NIBP determinations. The menu provides the option to move from page to page and to print all or part of the History File. This menu also provides access to the Neonatal OxiCardioRespiroGram Trend Screen and to the Multi-Trends Screen. The following is a description of the options available in the **HISTORY** Menu:

- a. **PRT ALL.** Selecting this menu item will print a complete NIBP History File.
- b. **PRT PAGE.** Selecting this menu item will print the NIBP History File page that the screen is currently at.
- c. **PREV PAGE.** Selecting this menu item will change the display to the previous page of the NIBP History File.
- d. **NEXT PAGE.** Selecting this menu item will change the display to the next page of the NIBP History File.
- e. **CLEAR ALL.** Selecting this menu item will clear all the data from the NIBP History File. If operating a dual monitor system, with a 3155A and 3155MVS communicating with the 3150(M), this feature is interactive throughout the MRI monitoring system.
- f. **MULTI TRENDS.** Selecting this menu item will bring up the Multi Trend Menu and Display.
- g. **OCRG.** This option is not available in remote mode.
- h. **RETURN.** Selecting this menu item will return the monitor to the Normal Screen.
- 5.5.2 Theory of Operation. Patient Samples are collected every five (5) seconds. Patient Sample's become Data Points to provide a plot point for the Trend Graph. This rate of sampling provides a time base of 240 Data Points for every 20 minutes of Patient Sampling. Each patient parameter has five selectable time-bases (20 minutes and 2, 4, 8 and 24 hours). The Trend Graph for each parameter is displayed upon user demand. The trend data, as well as other patient data, may be cleared upon operator demand.

Based upon the above stated Patient Sampling Rate and Data Point Selection, the following can be calculated:

- a. **20 Minute Time Base.** Each five (5) second Data Point (collected over the last 20 minutes) is plotted on the graph.
- b. **All Other Time Bases.** A single five (5) second Patient Sample is picked for one plot point. The rate of sampling is based upon the selected Time Base as follows:
 - (1) Time Base = 1 Hour: every third Patient Sample.
 - (2) Time Base = 2 Hours: every sixth Patient Sample.
 - (3) Time Base = 4 Hours: every twelveth Patient Sample.
 - (4) Time Base = 8 Hours: every twentyfourth Patient Sample.
 - (5) Time Base = 24 Hours: every seventysecond Patient Sample.

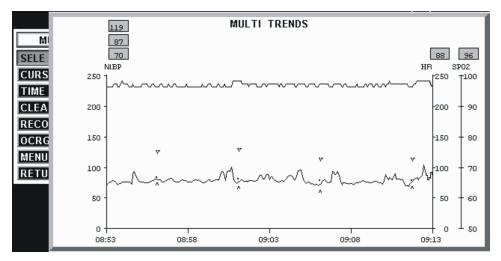


Figure 5-7. The MULTI TRENDS Menu

The following items are displayed on the Multi-Trends Graph Screen (See Figure 5-7):

- c. From one (1) to four (4) Patient Parameters.
- d. The Scale of the graph.
- e. The Time Base (how far back in time the graph displays) is shown at the bottom of the Trend Display, with the newest time on the right. Once the selected time base is exceeded, the first data (oldest) that was collected is "pushed" from the display every patient sample as newer Patient Samples enter the equation. Up to 24 hours of patient data is stored into memory.
- <u>5.5.3</u> <u>Trend Options.</u> The Trend Screen is identical for all parameters. The following description of the menu options available in the **MULTI TRENDS** Menu (**See Figure 5-7**) uses specific parameter trends for reference, but applies equally to all other trends.

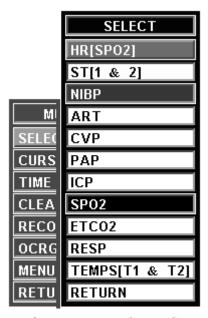


Figure 5-8. The Trend SELECT Menu

- a. **SELECT.** Selecting this menu option brings up the **SELECT** Menu (**See Figure 5-8**) from which either a single parameter (e.g., P1(ART) which includes systolic, diastolic, and mean arterial pressures) or up to four parameters may be selected. Once the selection is made and the RETURN option selected, the **SELECT** Menu is taken off and the Trend Graph for the selected parameter(s) is displayed. This menu also contains three (3) inactive selections: P3, P4 and TEMPS (T1 & T2), selecting any of these options will cause the monitor to display a message indicating that the parameter is not available on this monitor.
 - (1) **NIBP Trend Display.** (See Figure 5-7) Since NIBP is not a continuous reading system, when selected the NIBP Trend Display is different from the other trend displays. The NIBP Trend Display consists of a set of three symbols display positioned at the time location when the reading was performed: the top symbol is a V and indicates the NIBP Systolic Value, the middle symbol is a black dot and indicates the NIBP Mean Value, the bottom symbol is an upside down V and indicates the NIBP Diastolic Value.

NOTE

The Data Scan Cursor must be returned to the vertical axis and clicked to further access the **Multi-Trend** Menu items.

- b. CURSOR/ZOOM. This menu option allows the operator to select the Data Scan Cursor and "Zoom" the display to expand any 20 minute period of stored trend data. The Data Scan Cursor may be moved back in time to select any time period of interest in the Trend Graph. The actual time of the cursor is provided inside a Red window that is displayed in the middle of the MULTI TRENDS Screen whenever the Data Scan Cursor is selected. To Zoom, the operator moves the Data Scan Cursor to the approximate center of the period of interest then presses and releases the Rotary Knob; the display will immediately be expanded to a 20 minute period of time centered on the time selected with the Data Scan Cursor (which is provided at the top of the Zoom Display and inside the Red window mentioned above). The Zoom Display is retained on the screen until the operator turns it off by pressing and releasing the Rotary Knob a second time to return to the MULTI TRENDS display screen.
- c. **TIME BASE.** Selecting this menu option allows the operator to chose a Time Base for the Trend Graph Display. The options are 20 minutes and 2, 4, 8 and 24 hours. This setting determines the time span of the Trend Graph Display.
- d. **CLEAR ALL.** This menu option allows the operator to Clear All the Data Points from the Trend Memory. This removes old data from memory and prepares the monitor for use with new patients. The operation of this menu option is subject to user confirmation. This menu option is identical to, and interactive with, the CLEAR REPORTS AND TRENDS menu option in the **RECORD** Menu. If operating a dual monitor system, with a 3155A and 3155MVS communicating with the 3150(M), selecting this option will clear the trend data throughout the entire MRI monitoring system.
 - (1) The NIBP tabular data is retained during power interruptions. It may be cleared during power-up if the operator so chooses.

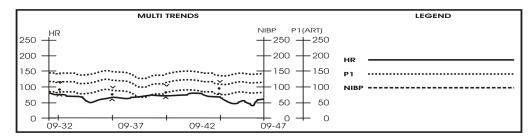


Figure 5-9. Sample Mult Trends Printout

- e. **RECORD.** Selecting the **RECORD** menu option will print a strip (**See Figure 5-9**) containing multiple parameters as selected by the operator using the **SELECT** menu option in the **MULTI TRENDS** Menu. Since the printer is black and white only, a legend is provided on the right hand side of the strip that allows the operator to distinguish between the selected parameter waveforms on the printout.
 - (1) **NIBP Trend Printout.** (See Figure 5-9) Since NIBP is not a continuous reading system, when selected the NIBP Trend Printout is different from the other trend printouts. The NIBP Trend Printout consists of a set of three symbols shown positioned at the time location when the reading was performed: the top symbol is a V and indicates the NIBP Systolic Value, the middle symbol is a black dot and indicates the NIBP Mean Value, the bottom symbol is an upside down V and indicates the NIBP Diastolic Value.
- f. **OCRG.** This option is not available in remote mode.
- g. **MENU BACK.** This menu selection allows the operator to move the **MULTI TRENDS** Menu to the back of the display (behind the MULTI TRENDS display screen).
- h. **RETURN.** Selecting this menu item will return the monitor to the Normal Screen.

SECTION 6 ALARMS

6.0 ALARMS.

- **6.1 Introduction.** The **3155A/3155MVS Monitor** permits user access to every parameter alarm with a single select key. Alarm Limits may be turned on, adjusted (manually or automatically) or turned off in the **ALARMS** Menu. Individual parameter alarms may also be turned on and/or adjusted by highlighting the parameter icon and pressing the ALARMS SCREEN Menu-Select key (MPC24 or later).
 - The 3155A/3155MVS Monitor may be set to give visual alarm signals only (Alarm Limits set, but Alarm Tone off), or both visual and audible signals (Alarm Limits set, with Alarm Tone on).
 - All settings in the **ALARMS** Menu, as well as the Alarm Tone enable/disable, can be stored and recalled.

WARNING

The 3150(M) MRI Patient Monitor does not alarm unless it is connected to this monitor. Always verify proper operation of the entire 3150 Alarm System (3150(M) MRI Patient Monitor and 3155A/3155MVS Monitor) before performing any patient monitoring.

- **6.2 Alarm Limits.** The Alarm Limits may be set either manually or automatically. The **3155A/3155MVS Monitor** provides access from the Main Screen to parameter Alarm Limits through a menu accessed by pressing the **ALARMS SCREEN** Menu-Select Key. Specific parameters may be accessed by pressing the **ALARMS SCREEN** Menu-Select Key with the desired parameter icon highlighted. In the **ALARMS** Menu and individual parameter Alarm Limits Boxes, Alarm Limits may be turned on, adjusted (manually or automatically in the **ALARMS** Menu and manually only in an individual parameters Alarm Limits Box) or turned off. If operating a dual monitor system, with a 3155A and 3155MVS communicating with the 3150(M), alarm limit changes are interactive between the two monitors to ensure that the monitoring parameters remain consistent between all components of the MRI monitoring system.
- 6.2.1 <u>Default (Pre-Set) Alarm Limits.</u> This monitor will automatically set all the Alarm Limits to Default settings upon monitor power up. **Table 6-1** provides a listing of Factory Default Settings; it is important to note the Table 6-1 will not represent the Default Values of your monitor if the Default Values are selected by the User. Care should be taken anytime the Default Values are changed to ensure that the new defaults represent an accurate picture of the needs of the facility this monitor is being used in; the patient range and parameter expectations should be carefully considered before changing from the Factory Default to the User Default.

NOTE

The Alarm System automatically prevents the crossover of High and Low Limit settings.

<u>6.2.2</u> Range of High and Low Alarm Limits. Each patient parameter has a LOW and HIGH Alarm Limit value position as indicated by numerics in the LOW and HIGH columns of Table 6-2. The Alarm Limits displayed in this menu may be changed manually or automatically using the rotary knob, after the patient parameter is selected. If a parameter has been turned off from the **SETUPS** Menu, then its LOW and HIGH positions will be OFF on this menu.

6.3 Alarms Menu. Pressing the **ALARMS SCREEN** Menu-Select Key will bring up the **ALARMS** Menu (**See Figure 6-1**). While in the **ALARMS** Menu, the Alarm Tone is disabled, (and will not sound for any reason). The previously selected status of the Alarm Tone will return upon exiting this menu. This menu also displays parameters which are not contained on this series monitor (e.g.: P3 and P4), the Alarm Setting for the parameters not contained in this monitor will alway be OFF and, if the operator attempts to select any inactive parameter, the monitor will display a message that indicates the selected feature is not available.

Table 6-1. Alarm Limit Factory Default Settings

		Adult Values		Neonatal Valu	ues
Parameter		Low Limit	High Limit	Low Limit	High Limit
Heart Rate		45 bpm	160 bpm	90 bpm	210 bpm
P1 and P2	Systolic Mean Diatolic	65 mmHg 55 mmHg 40 mmHg	190 mmHg 135 mmHg 125 mmHg	70 mmHg 40 mmHg 35 mmHg	100 mmHg 90 mmHg 50 mmHg
NIBP	Systolic Mean Diastolic	65 mmHg 55 mmHg 40 mmHg	190 mmHg 135 mmHg 125 mmHg	70 mmHg 40 mmHg 35 mmHg	100 mmHg 90 mmHg 50 mmHg
SpO2		85%	Off	90%	98%
ET Halothane		Off	1.5	Off	1.5
Fi Halothane		Off	2.2	Off	2.2
ET Isoflurane		Off	2.3	Off	2.3
Fi Isoflurane		Off	3.4	Off	3.4
ET Enflurane		Off	3.4	Off	3.4
Fi Enflurane		Off	5.1	Off	5.1
ET Sevoflurane		Off	4.1	Off	4.1
Fi Sevoflurane		Off	6.1	Off	6.1
ET Desflurane		Off	12	Off	12
Fi Desflurane		Off	18	Off	18
FiO2		15	99	15	99
CO2 Inspired (Final adjustable)	ixed non-	N/A	25 mmHg	N/A	25 mmHg
N20 (Fixed non-adj	ustable)	N/A	80%	N/A	80%
ETCO2		15 mmHg	60 mmHg	30 mmHg	45 mmHg
RESP		4 rpm	40 rpm	30 rpm	70 rpm

Table 6-2. Range of Alarm Limits

Input	Adult Limits		Neonatal Limits		Unit
	Low Limit	High Limit	Low Limit	High Limit	
Heart Rate	30 to 249	30 to 249	30 to 249	30 to 249	bpm
NIBP	5 to 249	5 to 249	5 to 249	5 to 249	mmHg
P1 and P2	-10 to 249	-10 to 249	-10 to 249	-10 to 249	mmHg
SpO2	50 to 99	70 to 99	50 to 99	70 to 99	%
ETCO2	5 to 60	5 to 80	5 to 60	5 to 80	mmHg
ET Halothane	Off, 0.1 to 8.4	0.1 to 8.5, Off	Off, 0.1 to 8.4	0.1 to 8.5, Off	%
Fi Halothane	Off, 0.1 to 8.4	0.1 to 8.5, Off	Off, 0.1 to 8.4	0.1 to 8.5, Off	%
ET Isoflurane	Off, 0.1 to 8.4	0.1 to 8.5, Off	Off, 0.1 to 8.4	0.1 to 8.5, Off	%
Fi Isoflurane	Off, 0.1 to 8.4	0.1 to 8.5, Off	Off, 0.1 to 8.4	0.1 to 8.5, Off	%
ET Enflurane	Off, 0.1 to 9.9	0.1 to 10, Off	Off, 0.1 to 9.9	0.1 to 10, Off	%
Fi Enflurane	Off, 0.1 to 9.9	0.1 to 10, Off	Off, 0.1 to 9.9	0.1 to 10, Off	%
ET Sevoflurane	Off, 0.1 to 9.9	0.1 to 10, Off	Off, 0.1 to 9.9	0.1 to 10, Off	%
Fi Sevoflurane	Off, 0.1 to 9.9	0.1 to 10, Off	Off, 0.1 to 9.9	0.1 to 10, Off	%
ET Desflurane	Off, 0.1 to 17.9	0.1 to 18, Off	Off, 0.1 to 17.9	0.1 to 18, Off	%
Fi Desflurane	Off, 0.1 to 17.9	0.1 to 18, Off	Off, 0.1 to 17.9	0.1 to 18, Off	%
O2	15 to 99	15 to 99, Off	15 to 99	15 to 99, Off	%
RESP	4 to 40	20 to 150	4 to 40	20 to 150	rpm

This menu has the following menu options associated with it:

a. **SET INDIVIDUAL.** Selecting this menu option allows the operator to adjust individual Alarm Limits. Once this menu option is selected, turning the knob will allow the operator to scroll through the individual HIGH and LOW Alarm Limits for manual modification. Once the limit to be modified is highlighted, pressing the knob selects the limit and turning the knob changes the value. When the desired setting is shown in the window, pressing the knob again will make the change effective and return to scrolling through the individual HIGH and LOW Alarm Limits. If operating a dual monitor system, with a 3155A and 3155MVS communicating with the 3150(M), the adjustments made here are interactive between the two 3155 monitors to ensure that the monitored parameters remain consistent between all components of the MRI monitoring system.

b. **CALCULATE ALL.** Selecting this menu option causes the monitor to calculate new alarm limit values on all active parameters at once. The calculations are as described under UPPER WINDOW and LOWER WINDOW menu options. If operating a dual monitor system, with a 3155A and 3155MVS communicating with the 3150(M), the adjustments made here are interactive between the two 3155 monitors to ensure that the monitored parameters remain consistent between all components of the MRI monitoring system.

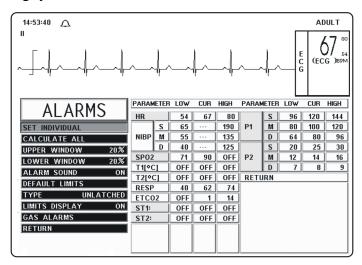


Figure 6-1. The ALARMS Menu

- c. **UPPER WINDOW.** Selecting this menu option selects the percent value used in calculating the HIGH Alarm Limits with the CALCULATE ALL menu option and the LOWER WINDOW menu option. The menu options are 5%, 10%, 15%, 20% (default), or 30%. If operating a dual monitor system, with a 3155A and 3155MVS communicating with the 3150(M), the adjustments made here are interactive between the two 3155 monitors to ensure that the monitored parameters remain consistent between all components of the MRI monitoring system.
 - (1) For example, if the patient's heart rate is 60, and both percentages have been set to 10%, activating CALCULATE ALL menu option will set the LOW Alarm Limit to 54 and the HIGH to 66 (plus and minus 10 percent of the current heart rate). Corresponding calculations would be used on each of the other active patient parameters to set their LOW and HIGH values.
 - (2) The following exceptions apply:
 - If the value being monitored from the patient is so high or low that it would exceed the range of **3155A/3155MVS Monitor** Alarm Limits (see below), the LOW or HIGH value is set to the highest or lowest Alarm Limit for that parameter.
- d. **LOWER WINDOW.** Selecting this menu option shall select percent value that is used in calculating the LOW Alarm Limits with the CALCULATE ALL menu option. The menu options are 5%, 10%, 15%, 20% (default), or 30%. The monitor uses the current value of the parameter and brackets it with the percentages set by this menu option and the UPPER WINDOW menu option. If operating a dual monitor system, with a 3155A and 3155MVS communicating with the 3150(M), the adjustments made here are interactive between the two 3155 monitors to ensure that the monitored parameters remain consistent between all components of the MRI monitoring system.
 - (1) For example, if the patient's heart rate is 60, and both percentage have been set to 10%, activating CALCULATE ALL would set the LOW Alarm Limit to 54 and the HIGH to 66 (plus and minus 10 percent of the current heart rate). Corresponding calculations would be used on each of the other active patient parameters to set their LOW and HIGH values.

- (2) The following exceptions apply:
 - If the value being monitored from the patient is so high or low that it would exceed the range of 3155A/3155MVS Monitor Alarm Limits (see below), the LOW or HIGH value is set to the highest or lowest Alarm Limit for that parameter.
- e. **ALARM SOUND.** Selecting this menu option will turn the alarm sound On/Off. When turned off, an "X" appears in the bell symbol on the screen and the one in the menu indicating that the alarm sound has been disabled. This menu option is identical to, and interactive with, the ALARMS menu option in the **SOUND ADJUST** Menu.
- f. **DEFAULT LIMITS.** Selecting this menu option causes the monitor to automatically set the LOW and HIGH Alarm Limits for all parameters at once based on the system defaults (See Default Limits in Appendix A or Table 6-1 for a listing of the System Default Values). If operating a dual monitor system, with a 3155A and 3155MVS communicating with the 3150(M), the adjustments made here are interactive between the two 3155 monitors to ensure that the monitored parameters remain consistent between all components of the MRI monitoring system.
- g. **TYPE.** Selecting this menu option will select whether the audio and visual alarms are latched or unlatched (see definitions below). This does not apply to the asystole alarm (that is always latched). Each time the menu option is selected it switches between the LATCHED and UNLATCHED (default) modes. If operating a dual monitor system, with a 3155A and 3155MVS communicating with the 3150(M), the adjustments made here are interactive between the two 3155 monitors to ensure that the monitored parameters remain consistent between all components of the MRI monitoring system.
 - (1) **UNLATCHED.** The Alarm Tone stops if the violated parameter returns to within its limits, or the **ALARM SILENCE** key is pressed.
 - (2) **LATCHED.** The Alarm Tone will cease only when the **ALARM SILENCE** key is pressed, even if the violating parameter has returned to within its limits.
- h. **LIMITS DISPLAY.** Selecting this menu option will select whether or not the Alarm Limits are displayed next to the parameter value in the Normal Screen. The default is ON.

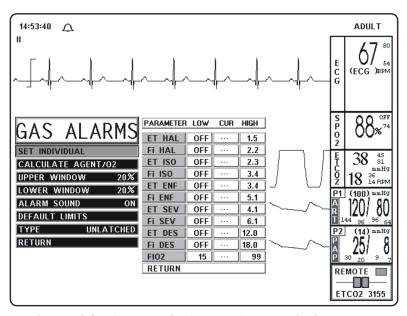


Figure 6-2. Anesthetic Agents Alarm Limits Menu

i. **GAS ALARMS.** Selecting this menu option will bring up the GAS ALARMS (Anesthetic Agent Alarm Limits) Menu (**See Figure 6-2**). All the Alarm Limits associated with the Anesthetic Agent System are adjusted in this menu. The following is a description of the GAS ALARMS Menu:

This menu has the following menu options associated with it (if operating a dual monitor system, with a 3155A and 3155MVS communicating with the 3150(M), these menu options, except for ALARM SOUND, are interactive to ensure that the settings remain consistent throughout the MRI monitoring system):

- (1) **SET INDIVIDUAL.** Selecting this menu option allows the operator to adjust individual Anesthetic Agent Alarm Limits. Once this menu option is selected, turning the knob will allow the operator to scroll through the individual Agent Alarm Limits for manual modification. Once the limit to be modified is highlighted, pressing the knob selects the limit and turning the knob changes the value. When the desired setting is shown in the window, pressing the knob again will make the change effective and return to scrolling through the individual Agent Alarm Limits.
- (2) **CALCULATE AGENT/O2.** Selecting this menu option causes the monitor to calculate new alarm limit values on all active Agent and O2 settings at once. The calculations are as described under UPPER WINDOW and LOWER WINDOW menu options.
- (3) **UPPER WINDOW.** Selecting this menu option selects the percent value used in calculating the HIGH Alarm Limits with the CALCULATE ALL menu option and the LOWER WINDOW menu option. The menu options are 5%, 10%, 15%, 20% (default), or 30%.
- (4) **LOWER WINDOW.** Selecting this menu option shall select percent value that is used in calculating the LOW Alarm Limits with the CALCULATE ALL menu option. The menu options are 5%, 10%, 15%, 20% (default), or 30%. The monitor uses the current value of the parameter and brackets it with the percentages set by this menu option and the UPPER WINDOW menu option.
- (5) **ALARM SOUND.** Selecting this menu option will turn the alarm sound on/ off. When turned off, an "X" appears in the bell symbol on the screen and the one in the menu indicating that the alarm sound has been disabled. This menu option is identical to, and interactive with, the ALARMS menu option in the **SOUND ADJUST** Menu.
- (6) **DEFAULT LIMITS.** Selecting this menu option causes the monitor to automatically set the LOW and HIGH Alarm Limits for all parameters at once based on the system defaults (See Default Limits in Appendix A or Table 6-1 for a listing of the System Default Values).
- (7) **TYPE.** Selecting this menu option will select whether the audio and visual alarms are latched or unlatched (see definitions below). This does not apply to the asystole alarm (that is always latched). Each time the menu option is selected it switches between the LATCHED and UNLATCHED (default) modes.
 - (a) **UNLATCHED.** The Alarm Tone stops if the violated parameter returns to within its limits, or the **ALARM SILENCE** key is pressed.
 - (b) **LATCHED.** The Alarm Tone will cease only when the **ALARM SILENCE** key is pressed, even if the violating parameter has returned to within its limits.
- (8) **RETURN.** Selecting this menu option will return the monitor to the Normal Screen
- j. **RETURN.** Selecting this menu option will return the monitor to the Normal Screen.

- <u>6.3.1</u> <u>Individual Parameter Alarm Limits Box.</u> Alarm Limits may also be adjusted by selecting an individual parameter Alarm Limits Box. To select an Alarm Limits Box, highlight the icon of the parameter to be adjusted and then press the **ALARMS SCREEN** Menu-Select Key. If operating a dual monitor system, with a 3155A and 3155MVS communicating with the 3150(M), alarm limit changes are interactive between the two monitors to ensure that the monitoring parameters remain consistent between all components of the MRI monitoring system.
- **6.4** Turning Alarms Off on Individual Parameters. Alarms may be set to OFF by pressing the ALARMS SCREEN Menu-Select Key, selecting the SET INDIVIDUAL menu option and then scrolling to the desired parameter to select it and turn it OFF. If operating a dual monitor system, with a 3155A and 3155MVS communicating with the 3150(M), alarm limit changes are interactive between the two monitors to ensure that the monitoring parameters remain consistent between all components of the MRI monitoring system.

WARNING

Alarm Limits can be set to a wide range including **Off**. It is the responsibility of the operator of this monitor to ensure that Alarm Limit values appropriate to each particular patient are established and set.

Alarm Sound Volume is adjustable for suitability to various clinical environments (where background noise may range from relatively quiet to noisy). It is the responsibility of the operator of this monitor to ensure that the Alarm Tone setting is appropriate for the conditions and that it can be heard above the ambient noise level (particularly during MRI Scanning).

Alarm Sound may be set to OFF. When the Alarm Sound is off the letter "X" will appear in the bell shaped Alarm Status Symbol. Alarm Sound should only be turned off when performing tasks which may cause false alarms to sound (such as changing ECG Leads, SpO2 Probes, etc.).

- **6.5 Alarm Violations.** An active Alarm Limit is violated when a patient parameter either exceeds its HIGH setting or goes below its LOW setting. The alarm system's exact reaction depends on the settings described in the remainder of this section, but, in general, all alarms operate as follows:
 - a. The numerics of the violated parameter flash on the screen.
 - b. The numerics and the trace (if displayed) turn red.
 - c. The Alarm Tone sounds, if it is enabled.
 - d. The numerics continue to flash while the parameter violates its Alarm Limit, even after the Alarm Tone has been silenced by pressing the **ALARM SILENCE** key.
 - e. If the Printer is in the AUTO mode, it begins recording. For further information, see Section 5.
 - f. If the Alarm System has been set to UNLATCHED, the numerics stop flashing after the parameter returns to within its Alarm Limits. If the alarm system has been set to LATCHED, the numeric continues to flash after the parameter returns to within its Alarm Limits, until the **ALARM SILENCE** control key is pressed.
 - g. If operating a dual monitor system, with a 3155A and 3155MVS communicating with the 3150(M), alarm violations are interactive (meaning that any alarm violation will be displayed on both 3155's).
- **6.6 Adjusting the Alarm Tone Volume.** The Alarm Tone is adjusted in the **SOUND ADJUST** Menu, which is accessed by selecting the SOUND ADJUST menu option in the **SETUPS** Menu.

- <u>6.6.1</u> <u>Disabling the Alarm Tone.</u> The Alarm Tone may be disabled permanently in the **ALARMS** Menu or it may be disabled temporarily by pressing the **ALARM SILENCE** control key.
 - a. The **ALARM SILENCE** control key has four functions as follows:
 - (1) **WITH UNLATCHED ALARMS.** If the alarm system has been set to UNLATCHED in the **ALARMS** menu and an Alarm Limit is violated:
 - It silences the alarm tone when an active Alarm Limit has been violated.

WHILE THE PARAMETER CONTINUES TO VIOLATE ITS LIMITS:

- The numeric of the violated parameter will continue to flash on the screen.
- (2) **WITH LATCHED ALARMS.** If the alarm system has been set to LATCHED in the **ALARMS** menu and an alarm is violated:

WHILE THE PARAMETER CONTINUES TO VIOLATE ITS LIMITS:

- It will silence the Alarm Tone.
- The numeric will continue to flash, even after the parameter returns to within its Alarm Limits.

WHEN THE PARAMETER GOES BACK WITHIN LIMITS:

- It will silence the Alarm Tone.
- The numeric of the violated parameter will continue to flash. Pressing **ALARM SILENCE** will now stop the numeric from flashing.
- (3) ALARM SILENCE. When the monitor goes into Alarm, pressing the ALARM SILENCE control key silences the Alarm Tone for the current alarm only. While the monitor is in the Silence mode, the letter "S" is displayed within the Alarm Status Symbol (Alarm Bell), the Alarm Bell flashes and the text "Alarm Silenced" is displayed in the middle of the display screen. If any of the silenced alarm conditions return to acceptable limits, the monitor will respond according to the above described Latched and or Unlatched operation. If a new alarm occurs after the Silence mode is entered, the monitor will sound the Alarm Tone for the new alarm. Pressing the ALARM SILENCE control key a second time (after entering the Silence mode) will place the monitor into the Alarm Hold mode.

If operating a dual monitor system, with a 3155A and 3155MVS communicating with the 3150(M), alarm silence is interactive throughout the MRI monitoring system. Pressing the **ALARM SILENCE** control key on one 3155 will also silence the alarm on the other one.

(4) **ALARM HOLD "SOUND ON HOLD"**. The Alarm Tone must be turned on (no "X" in the bell shaped Alarm Status Symbol) to enter **SOUND ON HOLD**. The Sound on Hold feature is used to temporarily disable the Alarm Tone. This might be useful, for example, when changing ECG leads, when drawing blood from an arterial pressure line or for any user activity which might cause an unwarranted alarm.

If operating a dual monitor system, with a 3155A and 3155MVS communicating with the 3150(M), it is possible for the monitor's to become out of sync while using "SOUND ON HOLD" FUNCTION. If this occurs, the 3155's may be returned to proper sync by pressing the **STANDBY** control key on either monitor. This will suspend NIBP measurements and, if active, the current measurement will abort. No automatic printout is generated.

WHEN NO ALARM CONDITION EXISTS:

• Pressing the ALARM SILENCE key will activate Sound on Hold (a "SOUND ON HOLD" message appears in the middle of the screen and an "H" appears in the Alarm Status Symbol). Just under the message these is a count down timer starting at 180 (counting down at a 1 second rate) giving the time left before the Alarm Tone is reactivated.

WHEN AN ALARM CONDITION EXISTS:

 If the Alarm Tone is sounding, the first press of the ALARM SILENCE key stops the Alarm Tone, and a second press enables Sound on Hold.

AUTOMATIC EXIT FROM ALARM HOLD:

• The monitor will automatically exit alarm hold after 180 seconds, and the "SOUND ON HOLD" message will disappear from the screen, reactivating the Alarm Tone.

MANUAL EXIT FROM ALARM HOLD:

- To exit from Sound on Hold before 180 seconds, press the **ALARM SILENCE** key (which will remove the "**SOUND ON HOLD**" message from the screen).
- 6.7 Standby Mode. Pressing the STANDBY Control Key will place the monitor into the Standby Mode. While in the Standby Mode the monitor will continue to track and update the active patient parameters but three key features will be disabled: 1) All audible alarms are disabled; the fact that the alarms are disabled is indicated on the Display Screen by an X through the bell shaped Alarms Status Symbol; it is also important to note that the Parameter Waveform and/or Numeric Display continue to operate normally and will turn Red if any active parameter violates its Alarm Limits, 2) NIBP Measurements are suspended (if active, the current measurement will abort), and 3) No Automatic Printout is generated.

SECTION 7 BATTERY OPERATION

7.0 BATTERY OPERATION.

7.1 Introduction. This monitor is equipped with a Lead Acid Gel Cell Battery (and may be equipped with three if the two additional optional batteries are present) which will provide battery power for short periods of time. The battery is 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.

NOTE

For proper operation of this monitor, one (1) battery must be installed at all times.

- **7.2 Battery Location and Access.** The battery(s) is/are located behind a panel on the left side of the monitor (looking at the monitor front panel). The battery door is opened by using a coin (or fingernail) to turn the screw to unlatch the door and allow it to open.
- **7.3** Loading and Unloading Battery(s). To load a battery, align it into an open slot and push it until the holding latch snaps into place. To unload, press the holding latch to free the battery and pull it out of the slot.
- **7.4 Battery Charging.** The battery(s) automatically charge anytime the AS153 AC Power Adapter is used and its Power Switch is ON. Initial charging time for new batteries is a minimum of eight (8) hours before using the monitor.
- 7.5 **Battery Operation Time.** With three (3) batteries the monitor will operate for approximately 25 minutes. **Battery operation time may be affected by certain operations (i.e.:** Anesthetic Agents turned on or printing of charts and trends).
- 7.5.1 <u>Battery Low Indication.</u> The LED under the Rotary Knob on the monitor front panel is a three color LED which provides a visual indication of the power status of this monitor. If the LO BATT light comes on (the LED illuminates RED) the monitor will run out of battery power in approximately three (3) minutes.
- 7.5.2 <u>Maintaining Battery Life.</u> For optimum battery life, connect the monitor to the main AC Power Source through the AS153 AC Power Adapter as soon as possible following the appearance of the Red LO BATT warning light. Continued use on battery power during low battery periods can reduce the overall life of the battery.

WARNING

All batteries must be removed prior to shipping the monitor for any reason.

7.6 Battery Replacement. If during operation, the monitor will not operate on battery power for the approximate times given above (depending on if your monitor has one (1), two (2) or three (3) batteries), replacement of the battery is recommended.

APPENDIX A SPECIFICATIONS

GENERAL			
PATIENT SAFETY			
Designed to meet the requirement	ents of CSA, UL 2601 and IEC 601-1		
POWER REQUIREMENTS			
Operating Voltages	120 VAC ±10%, 50/60 Hz 240 VAC ±10%, 50/60 Hz		
Power Consumption	50 Volt-Amperes maximum (using AS153 Power Adapter)		
Battery Voltage	10.5 to 15 VDC		
Battery Life	25 Minutes Minimum (with Agents operating)		
BATTERY OPERATION			
Battery Type	3 - 12 V, Rechargable Lead-Acid (HB10)		
Battery Operation Time	25 Minutes Minimum (with Agents operating)		
Battery Charge Time	Charged to 85% capacity within 8 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	-17 to +51° C. (0 to 125° F.)		
Relative Humidity	0 to 80%, non-condensing		
DIMENSIONS			
Height	10 in. (25.4 cm)		
Width	13.5 in. (34.3 cm)		
Depth	6 in. (15.2 cm)		
Weight	14.4 lbs. (without batteries) to 20 lbs. (with three batteries). 6.53 kg (without batteries) to 9.06 kg (with three batteries).		

	GENERAL			
DISPLAY				
Туре	640 x 480 pixel color LCD			
Screen Size	10.4 inch diagonal			
Sweep Speed	25 or 50 mm/S gives 7 S or 3.5 S of display respectively. For respiration, a speed of .33333, 1.5625, 3.125, 6.25, 12.5 or 25 mm/S is used.			
Waveform Display Mode	Fixed Trace, Moving Erase Bar			
Waveform Display Height	21 mm (±10%)			
"Full-Screen" Display Height	84 mm (±10%)			
Resolution Per Waveform	1.6 %			
Display Bandwidth	33 Hz			
REMOTE COMMUNICATION	ON (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)			

RECORDER (3007-2 Thermal Array Recorder)		
Chart Speeds	25 or 50 mm/second	
Width	40 mm	
Paper Type and Size	Thermal Paper, 50mm wide	
Alphanumeric annotation of date, time delay, paper speed, scales, lead configuration, mode, pressures (systolic, mean, diastolic), heart rate, respiration rate, and SpO2.		
Automatic activation on alarm with alarm parameter printed at the beginning of trace.		
SINGLE TRACE MODE		
Resolution	800 dots/in (32 dots/mm) time axis	
requency Response 0.05 to 100 Hz (-3db)		

	DISPLAYED PARAMETERS
Time	Battery-backed quartz crystal clock
Alarms	High and low limits selectable on patient parameters
ECG	ECG Waveform Scale, displayed lead.
Heart Rate	Normally derived from ECG. May be manually selected to be derived from invasive pressures, pulse oximeter, NIBP or automatically selected in order of priority.
Pressures	systolic, mean and diastolic
Pulse Oximeter	Pulse Rate, Pulse waveform, percent saturation.
CO2	Both ETCO2 and Inspired CO2.
N2O	Inspired N2O, EtN2O available in Agent MAC Box.
Agents	Automatic ID of Agent (Desflurane, Isoflurane, Halothane, Enflurane or Sevoflurane) displaying both ET and Fi.
O2	Oxygen average.
NIBP	Pressures (systolic, mean, diastolic), pulse rate, status
ETCO2	CO2, CO2 inspired, N2O, Respiration Rate and waveform.
Trends	Heart rate, respiration rate, NIBP (systolic, mean, diastolic), Invasive Pressures, ETCO2 and SpO2.
Trace Freeze	Trace A

ECG CHANNEL			
Standard Lead Configurations	I, II, III, AVR, AVL or AVF.		
Sensitivity	-5 mV to +5 mV		
Display Gain Scales (mm/mV)	5, 10, 15, 20, 25, 30, 40 and Autoscale.		
Display	Single height (Trace A only): 20mm Double height (Trace B off): 40mm On Screen Bandwidth: 35 HZ Six seconds shown on screen at 25 mm/second. Moving Erase Bar.		
ALARMS			
Asystole	Alarm delay: 4 seconds		
Heart Rate	Alarm delay: high and low rates <12 seconds		
Lower Alarm Limit	30 to 249 bpm (or Off)		
Upper Alarm Limit	30 to 249 bpm (or Off)		
TEST/CALIBRATION (From the 3	150)		
Square Wave Test Waveform	146 bpm ±1 bpm.		
Calibration Signal	1 mV ±10%		
PRESSURE CHANNELS			
PRESSURE WAVE DISPLAY			
Number of Channels	0, 1 or 2		
Waveform Display Height	21 mm, ±10%		
ART, PAP and LAP	Numeric display of systolic, mean and diastolic pressures.		
CVP and ICP	Numeric display of mean pressure only.		
PRESSURE SCALE RANGES	0 to +250 mmHg (0 to 33.3 kPa) 0 to +200 mmHg (0 to 26.7 kPa) 0 to +150 mmHg (0 to 20.0 kPa) 0 to +75 mmHg (0 to 10.0 kPa) 0 to +45 mmHg (0 to 6.0 kPa)		
PULSE RATE (When derived from	P1 or P2)		
Range	0 to 150 bpm		
Accuracy	±0.5%		
Resolution	1 bpm		

PRESSURE CHANNELS		
ALARMS		
High and Low Pressure	Alarm delay 8 seconds	
Alarm Limits	Pulse Lower: 30 to 249 bpm Upper: 60 to 249 bpm Systolic, Mean and Diastolic: Lower: -10 to 249 mmHg Upper: -10 to 249 mmHg	
NON-INVASIVE	BLOOD PRESSURE	
ALARM LIMITS		
Systolic, Mean and Diastolic	Minimum: 5 to 249 mmHg Maximum: 5 to 249 mmHg	
Pulse (when "HR" derived from NIBP)	Minimum: 30 to 249 bpm Maximum: 60 to 249 bpm	
MODES		
Manual	Immediate upon operator command.	
Automatic	Determinations automatically made with selectable intervals of 1, 2, 3, 5, 10, 15, 20, 30 and 45 minutes, and 1 hour.	
END-TI	DAL CO2	
ALARM LIMITS		
ETCO2 Alarm Limits	Lower: Off or 5 to 60 Upper: 5 to 80 or Off	
Inspired CO2	25mmHg (Fixed)	
N2O	80% (Fixed)	
PULSE C	XIMETER	
ALARM LIMITS		
SpO2 Alarm Limits	Lower: 50 to 98 Upper: 70 to 99 or Off	
PULSE Alarm Limits (when "HR" derived from SpO2)	Lower: 30 to 249 Upper: 60 to 249	

Aı	nesthetic Agents (Optional)
TECHNIQUE	
Side Stream, non-dispersive in	frared (NDIR) absorption technique.
Measurement Range	Halothane: 0.15 to 8.5 Vol. % Enflurane: 0.15 to 10 Vol. % Isoflurane: 0.15 to 8.5 Vol. % Sevoflurane: 0.15 to 10 Vol. % Desflurane: 0.15 to 22 Vol. % Carbon Dioxide: 0 to 10 Vol. % Nitrous Oxide: 0 to 99 Vol. %
Accuracy	Halothane: ±0.15 Vol. % + 15% relative. Enflurane: ±0.15 Vol. % + 15% relative. Isoflurane: ±0.15 Vol. % + 15% relative. Sevoflurane: ±0.15 Vol. % + 15% relative. Desflurane: ±0.15 Vol. % + 15% relative. Carbon Dioxide: (measured with agent option) ±4mmHg 12% relative, whichever is greater. Nitrous Oxide: (measured with agent option) ±(2% Vol. 8% relative)
Zero Drift Rate	CO2 < 1mmHg/Hr (Automatically auto zeroes at least every hour) N2O < 2%/Hr to < 5%/24Hr maximum
Calibration Interval	No field calibration required.
Flow Rate	230 mL/min
Response Time (10-90% step change)	Agents: Not specified CO2: < 270 mSec
Respiration Rate (Range permitting specified gas accuracy):	4 to 20 Breaths/minute
Respiration Rate:	4 to 60 Breaths/minute (based on C02 measurements)
Sample Cell Volume	< 300 micro liters
Relevant Interference	0.5 mmHg equivalent with 37.5 °C saturated with H2O (0.1% relative max)
Display Resolution:	0.1% Volume
Operating Temperature	15°C to 35 °C
Minimum Warm-up Time:	15 minutes.

Oxygen Monitoring			
Range	0 - 100 %		
Signal Output	$14 \pm 4 \text{ mV}$		
Maximum Response Time (Step Response 10 to 90%)	Less than or equal to 10 Seconds.		
Accuracy, Full Scale	± 3 %		
Accuracy, Full Scale, Over Operating Temperature	± 3 %		
Drift	< 1 % / Month		
Linearity	± 1 % of Full Scale		
Temperature Compensation	Yes		
Operating Temperatures	0 to +40 °C		
Ambient Humidity (Non-Condensing)	0 - 99 % RH (Non-Condensing)		
Oxygen Sensor, Operating Life	> 100,000 Oxygen %/Hours		
Storage Temperature	-10 ^O to 45 ^O C		
Sensor Shelf Life	< 6 Months (in unopened bag)		
Interfering Gas Effects:			
N2O	< 2 Vol. % @ 80 Vol. % N2O		
CO2	< 2 Vol. % @ 5 Vol. % CO2		
Halothane	< 2 Vol. % @ 4 Vol. % Halothane		
Enflurane	< 2 Vol. % @ 5 Vol. % Enflurane		
Isoflurane	< 2 Vol. % @ 5 Vol. % Isoflurane		
Sevoflurane	< 2 Vol. % @ 5 Vol. % Sevoflurane		
Desflurane	< 2 Vol. % @ 15 Vol. %		
Helium	Desflurane		
Methoxyflurane	< 2 Vol. % @ 50 Vol. % Helium No Known Effects		
Diethyl Ether	< 2 Vol. % @ 20 Vol. % Diethyl		
Trichloroethylene	Ether		
Nitric Oxide	No Known Effects		
	< 2 Vol. % @ 100 PPM Nitric Oxide		

TRENDING			
GENERAL			
than 60 seconds. Data points are points averaged from the 5 second bases from 20 minutes to 24 ho	ly stored and is retained during power interruptions of less collected every 5 seconds and each time base has 240 data nd collected data. Each parameter has five selectable time ours and selectable trend scales. Trends may be displayed with other parameters (Multi Trending).		
Available Trends	Heart Rate, NIBP, P1, P2, ETCO2/RESP and SpO2.		

SYSTEM DEFAULTS			
MISCELLANEOUS			
Heart Rate Source	ECG		
Patient	Adult		
Pacer Pulse	Reject		
Trace Speed	25 mm/second		
Pulse Tone Source	QRS		
Sound Volume Levels	Alarm Tone: 4 Heart Rate Tone: 4 Key Click: 4		
ECG			
Status	On		
Scale	15 mm/mV		
Lead Configuration	II		
Frequency Response	Monitor		
SPO2			
Status	On		
Scale	40% (Relative)		
Pulse Tone Source	Off		
Trace Location	Trace B		

SYS	STEM D	EFAUL	ΓS		
NON INVASIVE BLOOD PRESSURE					
Status	On				
Patient	Adult				
Reading Mode	Manual				
Reading Interval	3 Minutes				
P1					
Status	Off				
Scale	150 mm/Hg	Ş			
Type Designation Label	None				
P2					
Status	Off				
Scale	150 mm/Hg	5			
ETCO2					
Status	Off				
AGENTS					
Status	Off				
ALARM LIMITS					
	L	0W	Hi	gh	Unit
	Adult	Neo	Adult	Neo	
Heart Rate	45	90	160	210	bpm
NIBP Systolic	65	70	190	100	mmHg
NIBP Mean	55	40	135	90	mmHg
NIBP Diastolic	40	35	125	50	mmHg
SPO2	85	90	Off	98	%
Pressure 1 Systolic	65	70	190	100	mmHg
Pressure 1 Mean	55	40	135	90	mmHg
Pressure 1 Diastolic	40	35	125	50	mmHg
Pressure 2 Systolic	65	70	190	100	mmHg
Pressure 2 Mean	55	40	135	90	mmHg
Pressure 2 Diastolic	40	35	125	50	mmHg
Respiration	4	30	40	70	rpm
ETCO2	15	30	60	45	mmHg

SYSTEM DEFAULTS					
ALARM LIMITS (Continued)					
	I	low	Hi	gh	Unit
	Adult	Neo	Adult	Neo	
Agent, ET Halothane	Off	Off	1.5	1.5	%
Agent, Fi Halothane	Off	Off	2.2	2.2	%
Agent, ET Isoflurane	Off	Off	2.3	2.3	%
Agent, Fi Isoflurane	Off	Off	3.4	3.4	%
Agent, ET Enflurane	Off	Off	3.4	3.4	%
Agent, Fi Enflurane	Off	Off	5.1	5.1	%
Agent, ET Sevoflurane	Off	Off	4.1	4.1	%
Agent, Fi Sevoflurane	Off	Off	6.1	6.1	%
Agent, ET Desflurane	Off	Off	12.0	12.0	%
Agent, Fi Desflurane	Off	Off	18.0	18.0	%
O2	15	15	99	99	%
ALARM MODES					
Mode	Unlatched				
Window Size	20%				
RECORDER					
Trace 1 Assignment	ECG1				
Trace 2 Assignment	Off				
Trace Time Delay	4 Seconds				
Data Acquisition Interval	4 Minutes				
TREND GRAPHS					
	Time Base	e		Scale	
Heart Rate	20 minutes			0-250 t	opm
Pressure 1	20 minutes			-10-250	0 mmHg
Pressure 2	20 minutes			-10-250	0 mmHg
ETCO2	20 minutes			0-80 m	mHg
Respiration	20 minutes			0-150 r	pm
SPO2	20 minutes			50-100	% Saturation
NIBP	20 minutes			0-250 r	nmHg

SYSTEM DEFAULTS			
TIME			
Clock Request	On		
GRIDS			
Pressures (P1 and P2)	Off		
Pressure Grid Scale	150 mm/Hg		
ETCO2	Off		
SCREEN TRACE CHARACTERISTICS			
Mode	Fixed with moving erase bar		

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:

- Obtain a Return Authorization Number. This will ensure proper routing and facilitate timely repair of your monitor.
- Package the monitor with adequate protection. If available, use the original carton and packing materials in which the Monitor was shipped from IRI.
- 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.
- 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.
- Ship the monitor (with the batteries removed), 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.

INVIVO RESEARCH, INCORPORATED PRODUCTS CONTAIN PROPRIETARY COPY WRITTEN MATERIAL; ALL RIGHTS ARE RESERVED BY INVIVO RESEARCH LABORATORIES, INCORPORATED.

APPENDIX D DECLARATION OF CONFORMITY

DECLARATION OF CONFORMITY

Application of Council Directive	e(s)89/336/EEC			
Standard(s) to which Conformity	r 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	3150 Series			
Model Number	odel NumberMillennia 3155A and 3155MVS Monitors			
Serial Number	rial Number Refer to accompanying Packing Slip			
Year of Manufacture Refer to accompanying Packing Slip				
Directive(s) and Standard(s).	e that the equipment specified above conforms to the above			
Place Orlando, FL	(Signature)			
Date January 12, 1998	Francis Casey (Full Name)			
	Director, Regulatory Affairs (Position)			

DECLARATION OF CONFORMITY

Application of Council Directive(s) <u>Medical Device</u>	Directive 93/42/EEC
Standard(s) to which Conformity is Declared93/42/	/EEC
Manufacturer's Name Invivo Researc	h, Inc.
Manufacturer's Address 12601 Research Parkway, Or	lando FL 32826, USA
Importer's Name Refer to accompanying P	acking Slip
Importer's Address Refer to accompanying	Packing Slip
Type of Equipment3150 Series	S
Model Number Millennia 3155A and 3155M	IVS Monitors
Serial Number Refer to accompanying Pa	cking Slip
Year of Manufacture Refer to accompanying	Packing Slip
Certification Method(s) Annex I	I
Equipment Class Class IIb	
MDD Conformity Assessed By Semko	0 (0413)
I, the undersigned, hereby declare that the equipment specified Directive(s) and Standard(s).	d above conforms to the above
Place Orlando, FL	(Signature)
Date September 18, 1996	Francis Casey (Full Name)
Direct	tor, Regulatory Affairs (Position)

APPENDIX E

kPa to mmHg Conversion Chart

kPa	mmHg	kPa	mmHg	kPa	mmHg	kPa	mmHg	kPa	mmHg	kPa	mmHg
0.1	0.8	3.1	23.3	6.1	45.8	9.1	68.3	12.1	90.8	15.1	113.3
0.2	1.5	3.2	24.0	6.2	46.5	9.2	69.0	12.2	91.5	15.2	114.0
0.3	2.3	3.3	24.8	6.3	47.3	9.3	69.8	12.3	92.3	15.3	114.8
0.4	3.0	4.4	25.5	6.4	48.0	9.4	70.5	12.4	93.0	15.4	115.5
0.5	3.8	3.5	26.3	6.5	48.8	9.5	71.3	12.5	93.8	15.5	116.3
0.6	4.5	3.6	27.0	6.6	49.5	9.6	72.0	12.6	94.5	15.6	117.0
0.7	5.3	3.7	27.8	6.7	50.3	9.7	72.8	12.7	95.3	15.7	117.8
0.8	6.0	3.8	28.5	6.8	51.0	9.8	73.5	12.8	96.0	15.8	118.5
0.9	6.8	3.9	29.3	6.9	51.8	9.9	74.3	12.9	96.8	15.9	119.3
1.0	7.5	4.0	30.0	7.0	52.5	10.0	75.0	13.0	97.5	16.0	120.0
1.1	8.3	4.1	30.8	7.1	53.3	10.1	75.8	13.1	98.3	16.1	120.8
1.2	9.0	4.2	31.5	7.2	54.0	10.2	76.5	13.2	99.0	16.2	121.5
1.3	9.8	4.3	32.3	7.3	54.8	10.3	77.3	13.3	99.8	16.3	122.3
1.4	10.5	4.4	33.0	7.4	55.5	10.4	78.0	13.4	100.5	16.4	123.0
1.5	11.3	4.5	33.8	7.5	56.3	10.5	78.8	13.5	101.3	16.5	123.8
1.6	12.0	4.6	34.5	7.6	57.0	10.6	79.5	13.6	102.0	16.6	124.5
1.7	12.8	4.7	35.3	7.7	57.8	10.7	80.3	13.7	102.8	16.7	125.3
1.8	13.5	4.8	36.0	7.8	58.5	10.8	81.0	13.8	103.5	16.8	126.0
1.9	14.3	4.9	36.8	7.9	59.3	10.9	81.8	13.9	104.3	16.9	126.8
2.0	15.0	5.0	37.5	8.0	60.0	11.0	82.5	14.0	105.0	17.0	127.5
2.1	15.8	5.1	38.3	8.1	60.8	11.1	83.3	14.1	105.8	17.1	128.3
2.2	16.5	5.2	39.0	8.2	61.5	11.2	84.0	14.2	106.5	17.2	129.0
2.3	17.3	5.3	39.8	8.3	62.3	11.3	84.8	14.3	107.3	17.3	129.8
2.4	18.0	5.4	40.5	8.4	63.0	11.4	85.5	14.4	108.0	17.4	130.5
2.5	18.8	5.5	41.3	8.5	63.8	11.5	86.3	14.5	108.8	17.5	131.3
2.6	19.5	5.6	42.0	8.6	64.5	11.6	87.0	14.6	109.5	17.6	132.0
2.7	20.3	5.7	42.8	8.7	65.3	11.7	87.8	14.7	110.3	17.7	132.8
2.8	21.0	5.8	43.5	8.8	66.0	11.8	88.5	14.8	111.0	17.8	133.5
2.9	21.8	5.9	44.3	8.9	66.8	11.9	89.3	14.9	111.8	17.9	134.3
3.0	22.5	6.0	45.0	9.0	67.5	12.0	90.0	15.0	112.5	18.0	135.0

1 kPa = 7.501 mmHg

kPa	mmHg	kPa	mmHg	kPa	mmHg	kPa	mmHg	kPa	mmHg	kPa	mmHg
18.1	135.8	21.1	158.3	24.1	180.8	27.1	203.3	30.1	225.8	33.1	248.3
18.2	136.5	21.2	159.0	24.2	181.5	27.2	204.0	30.2	226.5	33.2	249.0
18.3	137.3	21.3	159.8	24.3	182.3	27.3	204.8	30.3	227.3	33.3	249.8
18.4	138.0	21.4	160.5	24.4	183.0	27.4	205.5	30.4	228.0	33.4	250.5
18.5	138.8	21.5	161.3	24.5	183.8	27.5	206.3	30.5	228.8	33.5	251.3
18.6	139.5	21.6	162.0	24.6	184.5	27.6	207.0	30.6	229.5	33.6	252.0
18.7	140.3	21.7	162.8	24.7	185.3	27.7	207.8	30.7	230.3	33.7	252.8
18.8	141.0	21.8	163.5	24.8	186.0	27.8	208.5	30.8	231.0	33.8	253.5
18.9	141.8	21.9	164.3	24.9	186.8	27.9	209.3	30.9	231.8	33.9	254.3
19.0	142.5	22.0	165.0	25.0	187.5	28.0	210.0	31.0	232.5	34.0	255.0
19.1	143.3	22.1	165.8	25.1	188.3	28.1	210.8	31.1	233.3	34.1	255.8
19.2	144.0	22.2	166.5	25.2	189.0	28.2	211.5	31.2	234.0	34.2	256.5
19.3	144.8	22.3	167.3	25.3	189.8	28.3	212.3	31.3	234.8	34.3	257.3
19.4	145.5	22.4	168.0	25.4	190.5	28.4	213.0	31.4	235.5	34.4	258.0
19.5	146.3	22.5	168.8	25.5	191.3	28.5	213.8	31.5	236.3	34.5	258.8
19.6	147.0	22.6	169.5	25.6	192.0	28.6	214.5	31.6	237.0	34.6	259.5
19.7	147.8	22.7	170.3	25.7	192.8	28.7	215.3	31.7	237.8	34.7	260.3
19.8	148.5	22.8	171.0	25.8	193.5	28.8	216.0	31.8	238.5	34.8	261.0
19.9	149.3	22.9	171.8	25.9	194.3	28.9	216.8	31.9	239.3	34.9	261.8
20.0	150.0	23.0	172.5	26.0	195.0	29.0	217.5	32.0	240.0	35.0	262.5
20.1	150.8	23.1	173.3	26.1	195.8	29.1	218.3	32.1	240.8	35.1	263.3
20.2	151.5	23.2	174.0	26.2	196.5	29.2	219.0	32.2	241.5	35.2	264.0
20.3	152.3	23.3	174.8	26.3	197.3	29.3	219.8	32.3	242.3	35.3	264.8
20.4	153.0	23.4	175.5	26.4	198.0	29.4	220.5	32.4	243.0	35.4	265.5
20.5	153.8	23.5	176.3	26.5	198.8	29.5	221.3	32.5	243.8	35.5	266.3
20.6	154.5	23.6	177.0	26.6	199.5	29.6	222.0	32.6	244.5	35.6	267.0
20.7	155.3	23.7	177.8	26.7	200.3	29.7	222.8	32.7	245.3	35.7	267.8
20.8	156.0	23.8	178.5	26.8	201.0	29.8	223.5	32.8	246.0	35.8	268.5
20.9	156.8	23.9	179.3	26.9	201.8	29.9	224.3	32.9	246.8	35.9	269.3
21.0	157.5	24.0	180.0	27.0	202.5	30.0	225.0	33.0	247.5	36.0	270.0

1 kPa = 7.501 mmHg

APPENDIX F LIST OF SYMBOLS

1000 G 3155A Do Not Brin 1000 Gauss				No European for the transn medical telem		harmonized standard exists mission frequencies used for netry. Potential restrictions may one or more European (EU)		
SN	SN Product Serial		REF		Product Part Number		IPX7	Watertight Equipment
-6) >	Input/ Output		Fuse	.		2	Single Patient Use Only Do Not Reuse
•	Down	/Decrement	4	Eart	Earth (Ground)		-00-	Communication is Linked
	Up/In	crement	%SpO ₂		Percent Oxygen Pulse Saturation		-00-	Communication is Not Linked
	Class II Equipment		(NR)	Not I Com	MRI ipatib	le	İ	Patient
~	Alternating Current		00	Brea Dete		Effort	4	Dangerous Voltage
Ċ	"OFF" (For Part of the Equipment		•		Heart Beat Detected			Weight
0	"ON" (For Part of the Equipment)		X		Alarms Silenced			Direct Current
0	OFF ((Main Power)	Д	Alar	Alarms ON		LANEX	Latex-free Materials Are Used
I	ON (N	Main Power)	<u>-</u>	Batte	ery			Unlocked
GAS	Patient Gas Input		┤ ★	Type (IEC	e BF l	tor-proof Equipment 1) Protection hock		Locked
\triangle	Attention, Consult Accompanying Documents		- ♥ F	Type (IEC	e CF	tor-proof Equipment 1) Protection hock	0	1 (Rotate Counter- clockwise to Open) 0 (Rotate Clockwise to Close)

NOTES