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Vigilance® is a US registered trademark of Edwards Lifesciences Corporation.

Foreword

The **Spectrum OR** Operating Instructions are intended to provide information for proper operation.

General knowledge of monitoring and an understanding of the features and functions of the **Spectrum OR** Monitor are prerequisites for its proper use.

NOTE: Do not operate this monitor before reading these instructions.

Information for servicing this instrument is contained in the **Spectrum** Monitor Service Manual, part number 0070-00-0556-02. For additional information or assistance, please contact an authorized service representative in your area.

CAUTION: U.S. Federal Law restricts this device to sale by or on the order of a physician or other practitioner licensed by state law to use or order the use of this device.

NOTE: Figures in this manual are provided for reference purposes only. Screens will likely differ based on the monitoring device configuration, licenses available, parameters selected and patient configuration of the Spectrum OR Monitor.

Patents: This device is covered under one or more of the following U.S. Patents 4,621,643, 4,653,498, 4,700,708, 4,770,179, 4,869,254, 4,911,167, 4,928,692, 4,934,372, 5,078,136, 5,368,224, 5,482,036, 5,490,505, 5,632,272, 5,685,299, 5,758,644, 5,769,785, 6,002,952, 6,036,642, 6,067,462, 6,157,850, 6,206,830, 6,247,674, 6,377,845, 4,802,486, 4,960,126, 5,485,847, 5,743,263, 5,865,736, 6,035,223, 6,298,252, 6,463,310, 6,591,123, 6,675,031, 6,708,049, 6,801,797, 4,907,597, 5,010,891, 5,320,109, 5,368,041, 5,381,804, 5,458,117, 5,792,069, 6,298,255, 6,985,837, 6,882,166, 5,813,404, 6,032,072, 6,236,874, 6,589,028, 6,896,713, Re.35,122 and foreign equivalents. Possession or purchase of this device does not convey any express or implied license to use the device with replacement parts which would, alone, or in combination with this device, fall within the scope of one or more of the patents relating to this device.

Warnings, Precautions and Notes

Please read and adhere to all warnings, precautions and notes listed here and in the appropriate areas throughout this manual.

A **WARNING** is provided to alert the user to potential serious outcomes (death, injury, or serious adverse events) to the patient or the user.

A **CAUTION** is provided to alert the user to use special care necessary for the safe and effective use of the device. They may include actions to be taken to avoid effects on patients or users that may not be potentially life threatening or result in serious injury, but about which the user should be aware. Cautions are also provided to alert the user to adverse effects on this device of use or misuse and the care necessary to avoid such effects.

A **NOTE** is provided when additional general information is applicable.

Warnings

WARNING: Internal Electrical Shock Hazard - This unit does not contain any user-serviceable parts. Do not remove instrument covers. Refer Servicing to qualified personnel.

WARNING: Trace Gas Hazard - When using the optional Gas Module, a health hazard exists when trace amounts of vaporized anesthetic agents are chronically inspired by operating room personnel. See Appendix A in NFPA 56A on Inhalation Anesthetics. During any procedure where such agents are employed, the Gas Module exhaust output should be connected to a medical gas-scavenging system.

WARNING: Do not use this monitor during MRI (Magnetic Resonance Imaging) scanning. Induced current could potentially cause burns. Accuracy of measurements on this unit and the MRI unit may also be affected.

WARNING: For continued protection against a fire hazard, replace all fuses with the specified type and rating.

WARNING: This unit uses a common isolation path for the ECG leads and the Invasive Pressure Channels. Ensure that conductive parts of the ECG electrodes do not contact other conductive parts including earth ground. Do not connect any non-isolated accessories to the Spectrum OR or to the ECG or invasive pressure channel inputs when connected to a patient. Insure that the total chassis leakage currents of all connected units does not exceed 300µA. Use an IEC 60601-1 approved isolation / separation transformer if required. Do not simultaneously touch the patient and any piece of electrical equipment if any cover has been removed from the equipment.

WARNING: The AC line cord and interface cables (i.e. non-patient cables) may utilize the same ground. Therefore, removal of the AC line cord does not necessarily isolate the Spectrum OR, if non-patient interface cables are attached.

WARNING: Observe extreme caution when a defibrillator is used on a patient. Do not touch any part of patient, table, or monitor when a defibrillator is in use.

WARNING: Do not incinerate battery, possible explosion may occur.

WARNING: To ensure that alarms can sound if the Gas Module/ Spectrum OR lose power, charged batteries must be installed in the Spectrum OR at all times.

WARNING: Do not put MPSO (Multiple Portable Socket Outlets i.e. Multiple outlet extension cords) used with the Spectrum OR or its accessories on the floor. Connect only Spectrum OR accessories to the same MPSO as the Spectrum OR. Do not overload the MPSO.

WARNING: Do not connect other equipment to the same MPSO with the Spectrum OR, as it may increase system leakage current.

WARNING: Reliably attach Potential Equalization connector to the safety ground when interconnecting Spectrum OR with other medical or non-medical electrical equipment to minimize the risk of excessive leakage current and/or shock hazard.

WARNING: Do not reuse disposable devices.

WARNING: Compressed gasses are considered Dangerous Goods/ Hazardous Materials per I.A.T.A. And D.O.T. regulations. It is a violation of federal and international law to offer any package or over pack of dangerous goods for transportation without the package being appropriately identified, packed, marked, classified, labeled and documented according to D.O.T. and I.A.T.A. regulations. Please refer to the applicable I.A.T.A. Dangerous Goods Regulations and/or the Code of Federal Regulations 49 (Transportation, Parts 171-180) for further information.

WARNING: Route cables neatly. Ensure cables, hoses and wires are kept away from patient's neck to avoid strangulation. Keep floors and walkways free of cables to reduce risk to hospital personnel, patients and visitors.

WARNING: Do not use a damaged or broken unit or accessory.

WARNING: Inaccurate Cardiac Output measurements may be caused by:

- **Incorrect placement or position of the catheter**
- **Excessive variation in pulmonary artery blood temperature**
- **Clot formation on the thermistor**
- **Anatomical abnormalities, (for example, cardiac shunts)**
- **Excessive patient movement**
- **Repeated intermittent flushes of cold fluid through the fluid lumens of the catheter**
- **Use of a manual pump such as the Abbott® Blood Set with Pump and CAIR clamp**
- **Electrocautery or electrosurgical unit interference**
- **Rapid changes in cardiac output**
- **Using an incorrect computation constant**

WARNING: Ensure that the conductive parts of ECG electrodes do not contact other conductive parts, including earth ground.

WARNING: Pacemaker patients' rate meters may continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias. Do not rely entirely upon rate meter alarms. Keep pacemaker patients under close surveillance. See the Appendix section of this manual for disclosure of the pacemaker pulse rejection capability of this instrument.

WARNING: Due to physiologic differences in the patient population, the Spectrum OR may occasionally not alarm or may sound a false alarm for some arrhythmia patterns. The arrhythmia analysis feature is intended to detect ventricular rhythms only. High-risk patients should be kept under close surveillance.

WARNING: When monitoring CO_2 with a Spectrum OR, the maximum sampling rate at the nasal cannula is 58 ml/min. This device should not be used on patients whose breathing could be impaired by this vacuum flow rate.

WARNING: When monitoring CO_2, connection from the exhaust port of the Spectrum OR to the hospital's waste gas scavenging system is recommended to prevent exposure of hospital personnel to the patient's respiratory sample.

WARNING: When using the Gas Module, the maximum sampling rate at the nasal cannula is 200 ml/min (120 ml/min for Gas Module 3 with a neonatal water trap). This device should not be used on patients whose breathing could be impaired by this vacuum flow rate.

WARNING: Connection of the Gas Module exhaust port to the hospital's waste gas scavenging system is strongly recommended to prevent exposure of hospital personnel to the patient's respiratory sample. Vacuum (negative pressure) should not exceed 1 mmHg at the Gas Module Pump Exhaust fitting. Excessive scavenge vacuum may result in damage to the Gas Modules internal pump.

WARNING: Do not clean the monitor while it is on and/or plugged in.

WARNING: Operation of the Spectrum OR below the minimum amplitude or value of PATIENT physiological signal may cause inaccurate results.

WARNING: Use of ACCESSORIES, transducers and cables other than those specified in the manual may result in increased Electromagnetic Emissions or decreased Electromagnetic Immunity of the Spectrum OR. It can also cause delayed recovery after the discharge of a cardiac defibrillator.

WARNING: The use of gas sampling accessories in Gas Module 3 other than those specified may cause significant measurement errors and patient risk.

WARNING: Use of accessories, transducers and cables other than those specified in the manual may result in increased Electromagnetic Emissions or decreased Electromagnetic Immunity of the Gas Module 3.

WARNING: With the exception of stacking on a Gas Module with the appropriate mounting brackets, the Spectrum OR should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the Spectrum OR should be observed to verify normal operation in the configuration in which it will be used.

WARNING: With the exception of stacking under a Spectrum OR with the appropriate mounting brackets, the Gas Module 3 should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the Gas Module 3 should be observed to verify normal operation in the configuration in which it will be used.

WARNING: The arrhythmia analysis feature is intended to detect ventricular rhythms, however, due to physiologic differences in patient populations, the Spectrum OR may occasionally sound a false alarm or may not recognize some arrhythmia patterns.

WARNING: Ensure that the ECG lead wires are neatly secured in a manner that will prevent them from encircling the patient's neck, creating a strangulation hazard.

WARNING: Perform the decontamination process with the unit powered down and power cord removed.

WARNING: The conductive parts of BIS electrodes or sensor and connectors, including the neutral electrode, should not contact other conductive parts, including earth.

WARNING: To reduce the hazard of burns in the high-frequency surgical neutral electrode connection, the BIS sensor or electrodes should not be located between the surgical site and the electro-surgical unit return electrode.

WARNING: The BIS sensor must not be located between defibrillator pads when a defibrillator is used on a patient connected to the BISx module.

WARNING: To minimize the risk of patient strangulation, the BIS Patient Interface Cable (PIC) must be carefully placed and secured.

WARNING: Ensure against prolonged contact between the patient's skin and the BISx Module. The heat that may be generated could cause discomfort.

WARNING: If the water trap breaks or becomes damaged during operation, there is a risk that bacteria and/or mucus may contaminate the Gas Module.

WARNING: Do not use Adult/Pediatric type water traps and/or sampling lines with neonates to avoid high sampling flow.

WARNING: The Gas Module must not be used with flammable anesthetic agents.

WARNING: The Gas Module water trap, sampling line and airway adapter should be disposed of in accordance with local regulations for contaminated and biologically hazardous items.

WARNING: Do not clean the Gas Module while it is on and/or plugged in.

WARNING: Connect only DRYLINE™ gas sampling lines to the water trap. Note that there may be other compatible tubes present that must not be used, e.g. IV lines.

WARNING: Do not use DRYLINE™ Neonatal sampling lines (blue Luer lock nuts) with DRYLINE™ Adult/Pediatric water traps as this could result in incorrect measurement data.

WARNING: Do not use DRYLINE™ Adult/Pediatric sampling lines (colorless Luer lock nuts) with DRYLINE™ Neonatal water traps as this could result in incorrect measurement data.

WARNING: The contents of the water trap should be handled as a potential infection hazard.

WARNING: Do not use other cleaning methods for the DRYLINE™ water traps. Do not clean or wash the filter housing of the water trap. Never allow alcohol to enter the filter housing. Never force air through the water trap.

WARNING: This Spectrum OR monitor uses a component modular device in deriving the Bispectral Index (BIS) purchased from Aspect Medical Systems, Inc. It is important to recognize that this index is derived using solely that company's proprietary technology. It is recommended that clinicians have reviewed applicable information on its utility and/or risks in published articles and literature/web site information from Aspect Medical Systems, Inc. or contact that company itself if they have clinical-based BIS questions relating to this module portion of the Spectrum OR monitor. Failure to do so could potentially result in the incorrect administration of anesthetic agents and/or other potential complications of anesthesia or sedation. We recommend that clinicians also review the following practice advisory (that includes a section on BIS monitoring): The American Society of Anesthesiologists, Practice Advisory for Intra-operative Awareness and Brain Function Monitoring (Anesthesiology 2006;104:847-64). Clinicians are also recommended to maintain current knowledge of FDA or other federal-based regulatory, practice or research information on BIS and related topics.

Precautions

CAUTION: **Always place the monitor on a rigid, flat surface or on approved mounts. Do not block ventilation or speaker vents.**

CAUTION: **Never place fluids on top of this monitor. In case of accidental spillage, wipe clean immediately and have the monitor serviced to ensure no hazard exists.**

CAUTION: **This unit must only be operated with approved software.**

CAUTION: **To avoid possible damage to the Spectrum OR, use only approved ECG cables and approved accessories.**

CAUTION: **Operation of the Spectrum OR below the minimum amplitude or value of patient physiological signal may cause inaccurate results.**

CAUTION: **Use of accessories, transducers and cables other than those specified in the manual may result in increased Electromagnetic Emissions or decreased Electromagnetic Immunity of the Spectrum OR. It can also cause delayed recovery after the discharge of a cardiac defibrillator.**

CAUTION: **Dispose of single use items in accordance with hospital policy.**

CAUTION: **To prevent condensation, allow the Spectrum OR to warm up and dry if it is moved from a cold area to a warm one.**

CAUTION: **The Spectrum OR may not meet its performance specifications if stored or operated outside of specified temperature and humidity ranges.**

CAUTION: **Prior to use, be sure the rail supporting the bed rail mounting hook can support the weight of the monitor. Consult the bed manufacturer's specifications if necessary. The Company is not responsible for injury or damage resulting from improper or inadequate support of the monitor.**

CAUTION: **Use the power cord provided with the product. If a substitute is necessary, use only hospital grade power cords.**

CAUTION: **Sudden changes in PA blood temperature such as those caused by patient movement or bolus drug administration may cause a CO or CI value to be computed. To avoid falsely triggered curves, you should inject as soon as possible after the INJECT message appears.**

CAUTION: **Line Isolation Monitor transients may resemble actual cardiac waveforms, thus inhibiting heart rate alarms. Check lead wires for damage and ensure good skin contact prior to and during use. Always use fresh electrodes and follow proper skin preparation techniques.**

CAUTION: **Follow the balloon pump manufacturer's recommendations when connecting the unit to an intra-aortic balloon pump.**

CAUTION: Cuffs must be used with the manufacturer's correct and approved hoses.

CAUTION: Please consult a physician for interpretation of blood pressure measurements.

CAUTION: A blood pressure measurement can be affected by the position of the patient, and his / her physiological condition as well as other factors, such as patient movement.

CAUTION: Observe caution on all patients (Neonates, Pediatrics, and Adults) when NIBP is set to the Continuous Mode and the 1 minute interval. When the NIBP continuous interval is selected, the Spectrum OR will continually take back to back blood pressure readings. As a safety precaution, a limit is placed on continuous and 1 minute interval measurements. In continuous mode, after 5 minutes, the NIBP interval will automatically switch to one measurement taken every 5 minutes. In 1 minute mode, after 10 minutes the NIBP interval automatically switches to measurements taken once every 10 minutes. Reports have been made of nerve injury occurring during use of automatically cycled blood pressure cuffs.

CAUTION: Tissue damage or inaccurate measurements may be caused by incorrect sensor application or use, such as wrapping too tightly, applying supplemental tape, failing to inspect the sensor site periodically, or failing to position appropriately. Carefully read the sensor directions for use, the Spectrum OR Operating Instructions, and all precautionary information before use.

CAUTION: Inaccurate SpO_2 measurements may be caused by:

- **Incorrect sensor application or use**
- **Significant levels of dysfunctional hemoglobins, (e.g., carboxyhemoglobin or methemoglobin)**
- **Intra-vascular dyes such as indocyanine green or methylene blue**
- **Exposure to excessive illumination such as surgical lamps (especially ones with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, or excessive ambient light. In such cases, cover the sensor site with opaque material.**
- **Excessive patient movement**
- **Venous pulsations**
- **Electro-surgical interference**
- **Placement of a sensor on an extremity that has a blood pressure cuff, arterial catheter, or intra-vascular line.**
- **Nail polish or fungus**

CAUTION: In certain situations in which perfusion and signal strength are low, such as in patients with thick or pigmented skin, inaccurately low SpO_2 readings will result. Verification of oxygenation should be made, especially in preterm infants and patients with chronic lung disease, before instituting any therapy or intervention.

CAUTION: Many patients suffer from poor peripheral perfusion due to hypothermia, hypovolemia, severe vasoconstriction, reduced cardiac output, etc. These symptoms may cause a loss in vital sign readings.

CAUTION: Prolonged and continuous monitoring may increase the risk of skin erosion and pressure necrosis at the site of the sensor. Check the SpO2 sensor site frequently to ensure proper positioning, alignment and skin integrity at least every eight (8) hours; with the Adult and Pediatric re-usable finger sensor, check every four (4) hours; for neonates and patients of poor perfusion or with skin sensitive to light, check every 2 - 3 hours; more frequent examinations may be required for different patients. Change the sensor site if signs of circulatory compromise occur.

CAUTION: When equipped with Masimo SET® SpO_2, use only Masimo SET Oxygen Transducers including Masimo SET LNOP® and LNCS® Patient Dedicated Adhesive Sensors and Masimo SET PC Series Patient Cables. Use of other oxygen transducers may cause improper oximeter performance.

CAUTION: When equipped with Nellcor® SpO_2, use only Nellcor oxygen transducers including Nellcor Oxisensor® and OxiMax® patient dedicated adhesive sensors. Use of other oxygen transducers may cause improper oximeter performance.

CAUTION: Vacuum (negative pressure) should not exceed 1 mmHg at the Spectrum OR Pump Exhaust fitting. Excessive scavenge vacuum may result in an Occlusion message or damage to the Spectrum OR's internal pump. The scavenging system must be on during calibration.

CAUTION: Microstream® CO_2 waste and CO_2 FilterLine® should be treated as biohazardous waste.

CAUTION: When cleaning sensors, do not use excessive amounts of liquid. Wipe the sensor surface with a soft cloth, dampened with cleaning solution. Do not attempt to sterilize.

CAUTION: Some disinfectants may cause skin irritation. Please rinse cuff thoroughly with water to remove any residual disinfectants.

CAUTION: The internal sampling system of the Gas Module does not need to be cleaned or sterilized. There is no reverse flow back to the patient. If the internal sampling system is suspected to be clogged or dirty, the module should be serviced by an authorized service person only.

CAUTION: If the dust filter for the fan cannot be cleaned or is damaged, replace it with part number 0378-00-0040. Use of another type of filter may decrease the cooling effectivity and cause damage to the Gas Module.

CAUTION: To avoid permanent damage, do not expose metal components (pins, sockets, snaps) to disinfectants, soaps or chemicals.

CAUTION: Only connect NIBP Luer fittings to Blood Pressure Cuff or Monitor.

CAUTION: Sudden changes in blood temperature such as those caused by bolus drug administration may cause a CO or CI value to be computed. To avoid falsely triggered curves, inject as soon as possible after the "Inject when Ready" message is displayed.

CAUTION: Some pacemakers may contain a respiratory sensor that may produce artifact on an ECG waveform.

CAUTION: During the decontamination process, do not get the LpH SE Germicidal detergent into any vent openings.

CAUTION: The BISx Module has been designed to operate with a BIS sensor. The sensor is a silver/silver chloride electrode array that utilizes Aspect's patented Zipprep technology and uses a proprietary connector. Use of other electrodes is not recommended.

CAUTION: Do not open the BISx Module for any reason. The seal to prevent liquids from entering the module may be damaged if opened. Service or repairs must be performed by qualified biomedical technicians only.

CAUTION: Operation of the BISx module may interfere with other equipment such as Evoked Potential Monitors, Cerebral Oximeters, and Trans-Cranial Dopplers.

CAUTION: The monitor display provides data and waveform information over its entire area. Do not cover any part of the monitor display with tape or labels.

CAUTION: A functional tester cannot be used to assess the accuracy of the pulse oximeter probe or a pulse oximeter monitor.

CAUTION: Replace sealed lead acid batteries with P/N 0146-00-0043 ONLY. Replace lithium-ion batteries with P/N 0146-00-0069 ONLY.

CAUTION: Gas Module 3 must be moisture protected whenever transported. This can be done with a protective plastic bag in which water-absorbing materials (e.g. silica gel) have been included.

CAUTION: Contamination with CO_2, N_2O or Anesthetic Agent in the air surrounding the Gas Module 3 may cause significant measurement errors.

Notes

NOTE: This unit is not designed to be used with a peripheral pulse sensor. SpO_2 is a standard function in this monitor, and may be used to obtain a plethysmograph waveform and heart rate.

NOTE: The comparison testing conducted via the auscultatory method used both Phase 4 and Phase 5 Korotkoff sounds. Reports of study findings for both the auscultatory method as well as the intra-arterial methods are available by contacting Technical Support (800) 288-2121, ext. 8116 or (201) 995-8237.

NOTE: Potential hazards due to errors in software or hardware have been minimized by actions taken in accordance with IEC 60601-1-4.

Intended Use

The Spectrum OR Monitor is intended for intra hospital use under the direct supervision of a licensed healthcare practitioner. The indications for use for the Spectrum OR Monitor include the monitoring of the following human physiological parameters:

- ECG waveform derived from 3 or 5 lead measurements
- Heart Rate derived from selected sources (ECG, SpO_2, IBP, NIBP)
- Pulse Oximetry (SpO_2)
- ST Segment Analysis derived from 3 or 5 ECG lead measurements
- Arrhythmia Detection derived from 3 or 5 ECG lead measurements
- Non Invasive Blood Pressure (NIBP)
- Invasive Blood Pressure (IBP) - up to four (4) channels
- Cardiac Output
- Respiration Rate/waveform derived from ECG or CO_2
- CO_2, inspired and end tidal microstream/waveform
- Temperature - up to two (2) channels
- Hemodynamic Calculations
- IV Drug Calculations
- Bispectral Index (BIS)

The target populations are adult, pediatric and neonate with the exception of:

- Arrhythmia detection, ST Segment Analysis, Cardiac Output, Hemodynamic Calculations, Pulmonary Artery Wedge Pressure measurements, and
- IV Drug Calculations, for which the target population is adult only.

- Bispectral Index. The BISx is intended for use under direct supervision of a licensed healthcare practitioner or by personnel trained in its proper use. It is intended for use on adult and pediatric patients within a hospital or medical facility providing patient care to monitor the state of the brain by data acquisition of EEG signals. **NOTE:** The clinical utility, risk/benefit, and application of the device have not undergone full evaluation in the pediatric population. The Bispectral Index from available information is a complex technology, intended for use only as an adjunct to clinical judgment and training. The BIS may be used as an aid in monitoring the effects of certain anesthetic agents. Use of BIS monitoring to help guide anesthetic administration may be associated with the reduction of the incidence of awareness with recall in adults during general anesthesia and sedation.

The Spectrum OR Monitor has the capability of interfacing with the Company's Panorama Central Stations and Gas Module products. For interfacing with Intra Aortic Balloon Pumps, contact the manufacturer for compatability requirements.

Unpacking

Remove the instrument from the shipping carton and examine it for signs of shipping damage. Save all packing materials, invoice and bill of lading. These may be required to process a claim with the carrier. Check all materials against the packing list. Contact the Service Department at (800) 288-2121 or (201) 995-8237 (U.S.A and Canada), or (201) 265-8800 (outside U.S.A. and Canada) for prompt assistance in resolving shipping problems.

Symbols and Descriptions

SYMBOL	DESCRIPTION
	Attention, Consult Accompanying Documents / Refer to Manual
	Dangerous Voltage
	Equipotentiality
	Alternating Current (AC)
	Direct Current (DC)
	On (only for a part of the equipment)
	Off (only for a part of the equipment)
	Data Input
	Data Output
	Data Input/Output
	Gas Port Input
	Gas Port Output
	NIBP Connection
IABP	Analog ECG output for communication to an Intra-Aortic Balloon Pump
	Caution: Hot Surface
	Crossed out wheelie bin indicates separate treatment from general waste at end of life

SYMBOL	DESCRIPTION
	Type B Equipment
	Type BF Equipment
	Defibrillator Proof Type BF Equipment
	Defibrillator Proof Type CF Equipment
	Alarm Off Icon
	Alarm Mute Icon
	Earth (Ground)
	Protective Earth (Ground)
	Battery Charging
	Full Battery
	Low Battery
	No Battery Present
	Latex-free product
DEFIB	Analog ECG out and Sync Pulse for connection to a Defibrillator
	Manufacturer
	Interference may occur in the vicinity of equipment marked with this symbol

For single-patient use only, do not reuse.

For Neonatal use

Not for Neonatal use

Conformité Européenne (CE) Marking of Conformity to European Medical Device Directive. CE_{XXXX} represents the Notified Body number

Manufacturer's reference/catalogue number

Manufacturer's batch number

Serial number

Software Version

1.0 General Product Description

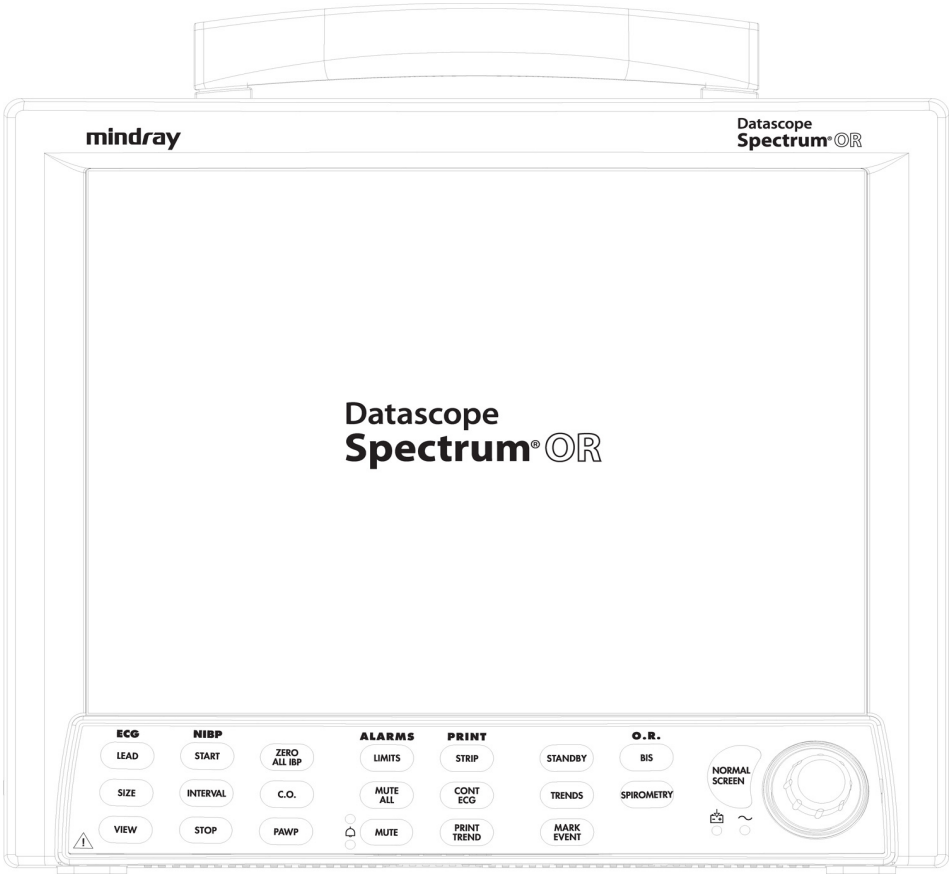


FIGURE 1-1 The **Spectrum OR** Patient Monitor

1.1 General Product Description

The **Spectrum OR** is a vital signs monitor intended for intrahospital use on human patients. The **Spectrum OR** is a three (3) to eight (8) trace monitor. The unit has many features and functions, yet is easy to use through an integrated keypad, Navigator™ Knob and an intuitive menu system.

The **Spectrum OR** has a 12.1 inch color display and comes standard with 3 or 5-lead ECG, Masimo SET® SpO_2, Non-invasive Blood Pressure, Respiration, Continuous Temperature and IV Drug Calculations.

The **Spectrum OR** may be configured to suit your department by adding software and hardware optional features. Optional software features include ST and Arrhythmia analysis. Optional hardware features include up to 4 Invasive Blood Pressure Channels, MicroStream® CO_2, Anesthetic Gases, Nellcor® OxiMax® SpO_2, a second temperature channel, dual trace recorder, Cardiac Output and BIS. A comprehensive calculation package, including hemodynamic calculations, is available if the **Spectrum OR** is equipped with an External Parameter Module.

Digital displays are provided for Heart Rate, Non-invasive Blood Pressure (NIBP), Pulse Oximetry (SpO_2), Respiration Rate and Temperature (T1). Optional digital areas provided for Invasive Blood Pressure (up to four), Anesthetic Agents, O_2 and N_2O, ST, CO_2, and MAC. The optional internal recorder provides hard copies of all digital data and waveforms as well as trend information.

The **Spectrum OR** Monitor can be mounted on a rolling stand, a wall mount bracket, gas machine arm, bedrail, Gas Module or operated as a tabletop instrument.

The **Spectrum OR** has the capability of interfacing with Panorama Central Stations, Gas Modules, Edwards Vigilance® Monitor, Remote Displays, and Nurse Call Systems. For interfacing with IABP systems, contact the manufacturer for compatability requirements.

The **Spectrum OR** monitor is powered by an AC connection or internal batteries.

1.2 Key Features

FEATURES	STANDARD	OPTIONAL
Display	12.1 inch color liquid crystal display	External Remote Color Display
	Automatic Sensor Detection and Waveform Display	Viewstation OR™
	8-trace erase bar refresh	
ECG	3 or 5-lead (I, II, III, aVR, aVL, aVF, V)	3-lead ST Analysis
	ECG Cascade	Arrhythmia Analysis
	ESIS Capability (3 or 5-lead)	
Blood Pressure	Non-Invasive Blood Pressure	Up to 4 channels of Invasive Blood Pressure
		Wedge Pressure with reference line
Cardiac Output		External Parameter Module (EPM)
		Edwards Vigilance® Monitor
SpO_2	Masimo SET®	Nellcor® OxiMax®
Temperature	One YSI 400/700 channel	Second YSI 400/700 channel
Respirations	Lead-selectable Impedance	Microstream® CO_2
		Gas Module with Automatic Agent ID
Trend	Tabular and Graphic trends with 120 entries	Extended trend display with up to 500 entries
Power	Internal isolated power module	
	Lithium-ion batteries	
Printing		Internal recorder
External Interfaces	Panorama Central Stations, Gas Module, Remote Displays, Nurse Call Systems, Serial Communications	Edwards Vigilance® Monitor IABP Systems
Calculation	IV drug calculations	Hemodynamic calculations
SvO_2		Edwards Vigilance® Monitor
SVR		Edwards Vigilance® Monitor
BIS		BISx™ Module
Other	Soft Grip Handle	Mounting kits
	Navigator™ Knob	Patient and monitor data transfer
	Dedicated keys	
	Dual PCMCIA Ports	

1.3 Keys and Front Panel

The front panel keys are used to access many main functions quickly and easily. The figure below shows the keys and a brief explanation follows.

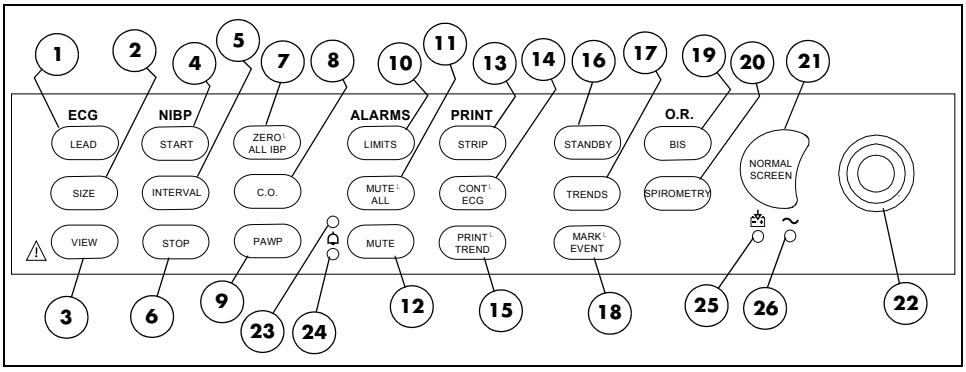


FIGURE 1-2 Keypad

1. LEAD

Press this key to select the next ECG lead to display in Waveform 1. Each time you press this key, the next available ECG lead displays.

2. SIZE

Press this key to select the next available size of ECG for Waveform 1. Each time you press this key, the next available ECG size displays. When the largest ECG size is displayed, the next key press displays the smallest size.

3. VIEW

Press the **VIEW** key to see multiple leads of ECG when using the 5-lead ECG cable. Press this key to toggle between multi-lead view and normal display.

4. START

Press this key to begin an NIBP measurement or to begin or re-start automatic interval measurements.

5. INTERVAL

Press this key to modify the NIBP interval measurement time. The choices are: **Off, Continuous, 1 min, 2 min, 2.5 min, 3 min, 5 min, 10 min, 15 min, 20 min, 30 min, 1 hr, 2 hr** or **4 hr**. The **Off** selection means that NIBP measurements can only be initiated manually. The **Continuous** selection means that measurements will be continuous (one right after the other). The continuous measurement interval will only last for 5 minutes and then automatically change to a 5 minute interval. The 1 minute interval will last for 10 minutes and then automatically change to a 5 minute interval.

6. STOP

Press this key to stop any NIBP measurement. If the interval mode is activated, pressing this key disables the interval mode measurements. An **NIBP: Manual Mode** message displays until the interval mode is restarted. If a **Press STOP to clear.** message is displayed, pressing this key will clear a Cuff Overpressure condition.

7. ZERO ALL IBP

Press this key to set the current pressure for all invasive pressure channels to zero. This key does not affect any channels monitoring pressure. During the zeroing process, the message **Zeroing** is displayed. The message **Zero Complete** displays when the zeroing process is successful. If the zero process is not successful, the message **Unable to Zero** is displayed.

8. C.O.

Press this key to open the **Cardiac Output Menu** or the **Vigilance CO Menu**. If the **Cardiac Output Menu** is already open and the "Ready" message is displayed, pressing the **C.O.** key activates the CO run sequence. Pressing the **C.O.** key while the **Vigilance CO Menu** is open will have no effect.

9. PAWP

Press this key to open the **Pulmonary Artery Wedge Pressure (PAWP) Menu** and measure the PAWP. The key is active if a pressure channel has been labeled PA.

10. LIMITS

Press this key to display the **Alarm Limits Menu**. The **Alarm Limits Menu** provides access to view or change alarm values.

11. MUTE ALL

Press this key to suspend audio alarms on all parameters. The alarms remain suspended for a user selected amount of time. This amount of time is set in the **Alarms Setup Menu**. While the alarms are suspended, an Alarm Mute icon is displayed next to each silenced parameter. Also, the message **ALL ALARMS MUTED FOR XX:XX mins** displays. XX:XX is the time remaining in minutes and seconds. Press this key again during the suspended alarm time to re-enable the audio alarm. If the suspend time was set to **Permanent**, the message **ALL ALARMS MUTED PERMANENTLY** is displayed.

12. MUTE

Press this key to suspend audio alarms on all currently alarming parameters. The alarms remain suspended for a user selected amount of time as set in the **Alarms Setup Menu** or until the alarm condition is no longer present. Any new alarms that occur while the alarm tone is silenced will disable the silence and sound the alarm tone. While the alarms are suspended, an Alarm Mute icon is displayed next to each silenced parameter.

13. STRIP

Press this key to initiate a printout to the selected device.

- If the print destination is the internal recorder, then pressing this key will produce a 16-second strip of up to two (2) waveforms. Pressing this key during a print job will abort the strip printout.
- If the print destination is a remote Central Station, then pressing this key will initiate a printout at the Central Station.

14. CONT ECG

Press this key to initiate a continuous ECG 1 and 2 waveform printout from the internal printer. Press this key again to abort printing.

15. PRINT TREND

Press this key to initiate printing of the desired trend. By default, the monitor's stored trend information will be printed by the internal printer. Pressing this key during a print job will abort printing.

If the print destination is a remote Central Station, then pressing this key will initiate a trend report at the Central Station.

16. STANDBY

Press this key to place the **Spectrum OR** into a STANDBY mode. While in STANDBY mode, monitoring is discontinued and the alarms are in permanent suspension, interval NIBP measurements are placed in idle mode, CO_2 pump is shut off, and the display shuts down. When in the STANDBY mode, the message **STANDBY**. **TO BEGIN MONITORING, PRESS STANDBY** is displayed. Press the **STANDBY** key or the **NORMAL SCREEN** key to exit the STANDBY mode and return to the normal screen.

NOTE: **Trend data is not cleared in the STANDBY mode. When the STANDBY mode is released, NIBP INTERVAL is in IDLE MODE and requires reactivation via the START key. The CO_2 pump automatically reactivates if the Microstream® sensor is in place.**

17. TRENDS

Press this key to display the **Quick Trend** screen. Press this key a second time to display the **List Trend** screen. Press this key a third time to display the **Graph Trend** screen. Press this key a fourth time to return to the normal display.

18. MARK EVENT

Press this key to cause a time stamp event marker to be noted in the trend memory. If connected to a Panorama Central Station, a time stamp event marker will also be noted in the Central Station's trend memory.

19. BIS

This key has multiple functions that are contingent upon certain hierarchical conditions as listed in the following table:

	HIERARCHICAL CONDITION	BIS KEY FUNCTION
I.	The **BIS Sensor Check** menu is open.	Pressing this key will always close the menu.
II.	The **BIS Sensor Check** menu is not open, but the "BIS: Check Sensor" message is displayed.	Pressing this key will open the **BIS Sensor Check** menu.
III.	If the **BIS Sensor Check** menu is not open, and the "BIS: Check Sensor" message is not displayed, but the BIS/EMG graphic trend is displayed.	Pressing this key will toggle the view of the BIS/EMG graphic trend between its normal height and an Expanded View. In the Expanded View, the height of the BIS/EMG graphic trend expands to improve its resolution.
IV.	If the **BIS Sensor Check** menu is not open, and the "BIS: Check Sensor" message is not displayed, and the BIS/EMG graphic trend is not displayed.	Pressing this key will open the **BIS Menu**.

NOTE: The BIS key will be inactive when patient size is Neonate or when the BISx module is not connected. Each press of this key while it is inactive will produce a double beep tone.

20. SPIROMETRY

This key toggles the display between the waveform window and the three loop display configurations of the **Spirometry Loop Window** described in section 2.4.10.4.

The first key press displays the "Pressure-Volume" loop display configuration. The second key press displays the "Flow-Volume" loop display configuration. The third key press displays the "Both" loop display configuration. After all three configurations have been cycled through the display, a fourth key press returns the display to the Normal Screen.

NOTE: This key is inactive when patient size is Neonate or if a Serial Port is not configured to Gas Module. Each press of this key while it is inactive will produce a double beep tone.

21. NORMAL SCREEN

Press this key at any time to return the screen to the normal monitoring mode. All menus are closed.

22. Navigator™ Knob

Rotate this knob to highlight the various menus on the display. Press the center of the knob to display the highlighted menu. Once a menu is displayed, rotate the knob to highlight the menu items listed. Press the center of the knob to select a highlighted item.

23. Warning LED

LED used to indicate that an alarm has been tripped. The WARNING (or Priority 1) LED is red.

24. Caution LED

LED used to indicate that an alarm has been tripped. The CAUTION (or Priority 2) LED is yellow.

25. Battery Charging LED

A green LED located below the battery icon indicates that the battery charger is active. The charger will not always be active when AC power is present. It is dependent on the battery type (sealed lead acid vs. lithium-ion) and battery charge condition. The LED is not an indication of the condition of the batteries or their charge level. Charged batteries must be installed in the monitor to ensure uninterrupted operation while switching from AC to battery power.

26. AC Power LED

A green LED beside the Battery Charging LED that is used to indicate that the unit is connected to the AC Power within the facility.

1.4 Display

The display of the **Spectrum OR** provides menus, waveforms, parameter information, and messages. The **Spectrum OR** includes a display setup function that allows customization of the display. Preferred setup details can be programmed and saved.

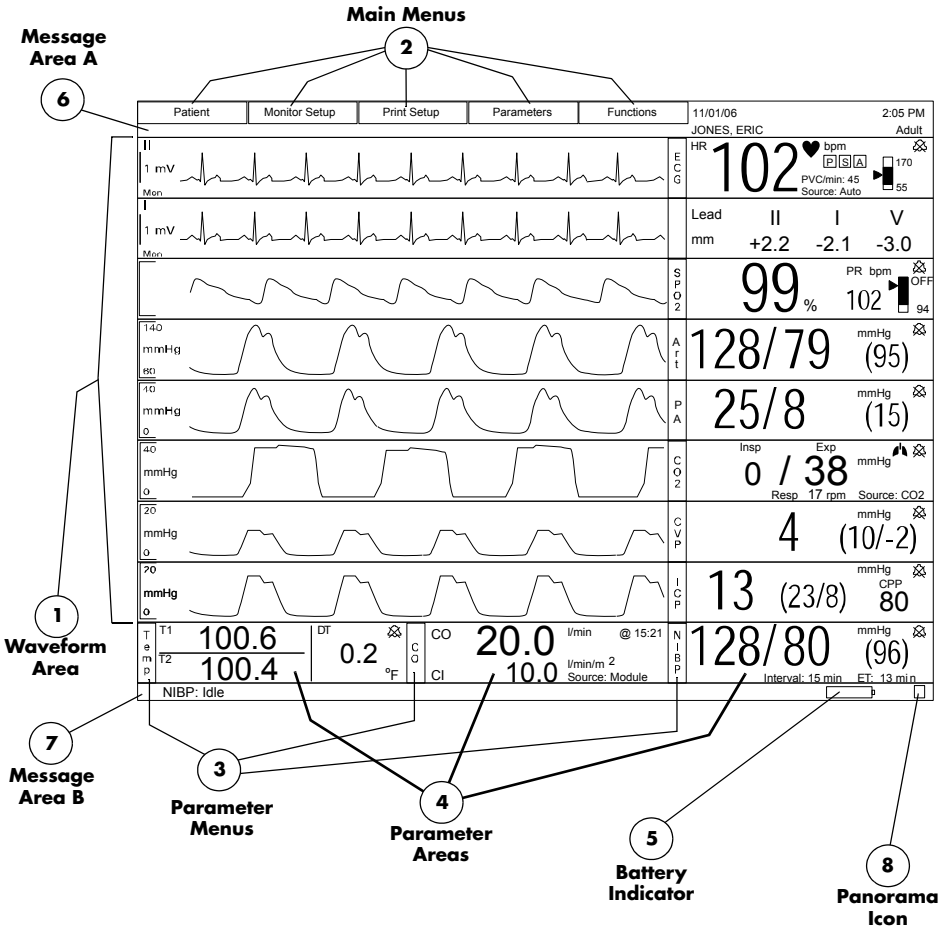


FIGURE 1-3 Display

1. Waveform Area

The waveform area is used to display windows which contain parameter waveforms. Up to 8 waveforms may be displayed. The top window is always set to display the ECG waveform and cannot be changed. By default, SpO_2 (Pleth) waveform will appear as the second waveform, if connected. Respiration or CO_2 will appear as the third waveform. If pressure transducers are plugged into IBP1 and IBP2 the screen will reformat to display additional waveforms and the IBP waveforms will appear as the fourth and fifth waveform. The setup can be changed to display any of the available parameters and waveforms.

2. Main Menus

The Main Menus enable the user to enter patient specific data, customize the monitor, setup printing or transfer patient data. Use the Navigator™ Knob to access these functions.

3. Parameter Menus

The Parameter Menus enable the user to review and customize various parameter display and alarm attributes. Use the Navigator Knob to access these menus.

4. Parameter Areas

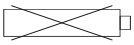
The parameter area contains the digital data for each available parameter.

5. Battery Indicator

When batteries are installed and the monitor is functioning on battery power, the battery indicator provides a visual reference for the approximate charge level of the batteries. See the following examples.

Full Battery

Low Battery



No Battery Present (Lithium-Ion batteries only)

If the monitor is configured for lithium-ion batteries, when there are no batteries installed, the battery indicator will be displayed with an "X" through it as shown in the example.

When the battery charge is low, but not below the cutoff voltage, the battery indicator will begin to flash and a low pitched double beep will be generated every minute.

NOTE: When the battery indicator begins to flash, less than 15 minutes of operating time remains, depending upon the number of functions that are operational.

NOTE: The internal recorder may not be operational when the battery charge is low.

WARNING: To ensure that alarms can sound if the Gas Module/ Spectrum OR lose power, charged batteries must be installed in the Spectrum OR at all times.

6. Message Area A

This message area is located above the ECG waveform window. Messages regarding the ECG/heart rate and alarm status are displayed here.

7. Message Area B

This message area is located below the last row of parameter tiles. Messages regarding NIBP, IBP, printer status, SpO_2, CO_2, BIS and Gas Module are displayed here.

8. Panorama Icon

If the **Spectrum OR** data is being displayed at a Panorama Central Station, then this icon will display the capital letter "V".

1.5 Rear View

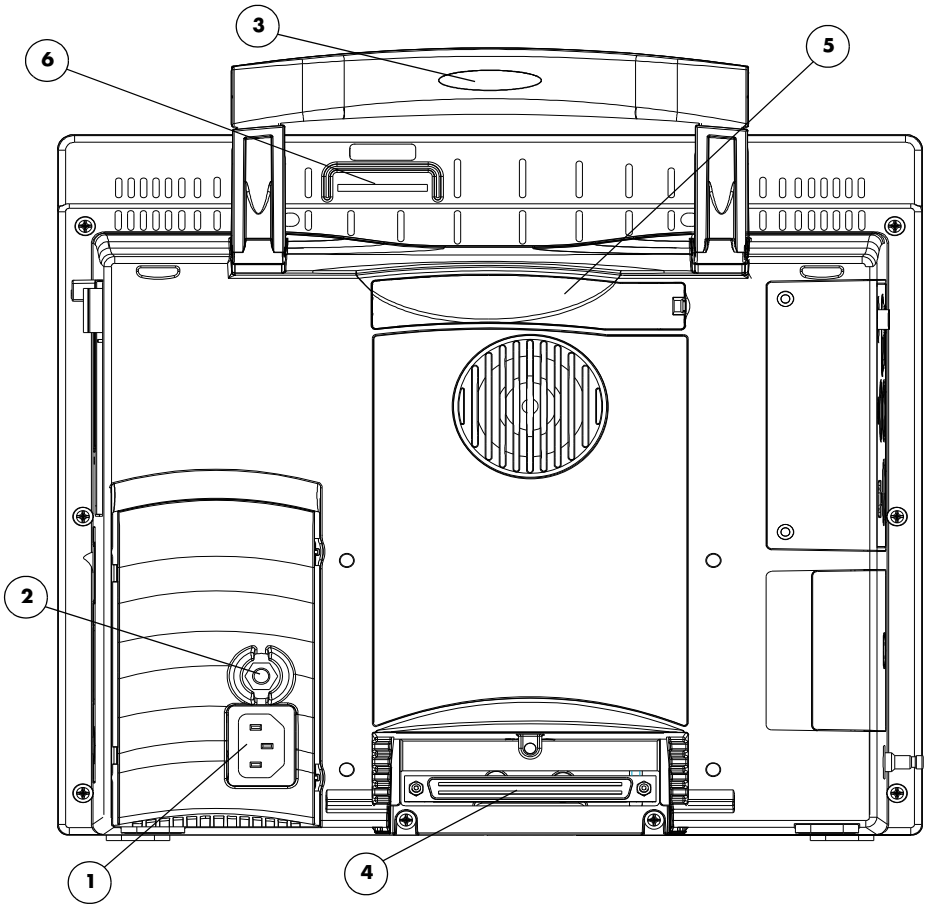


FIGURE 1-4 Rear Panel

1. AC Receptacle

Insert an AC power cord into this connector.

2. Equipotential Lug

Provides Equipotential grounding of hospital equipment.

3. Soft Grip Handle

Used for carrying the monitor.

4. Main I/O Connector Port (DM1)

Area dedicated for the use of an optional communication port.

5. Expansion Slot

Used for future expansion.

6. External Parameter Module Port (EM1)

Port used to connect the External Parameter Module to the **Spectrum OR**.

1.6 Left Side Panel

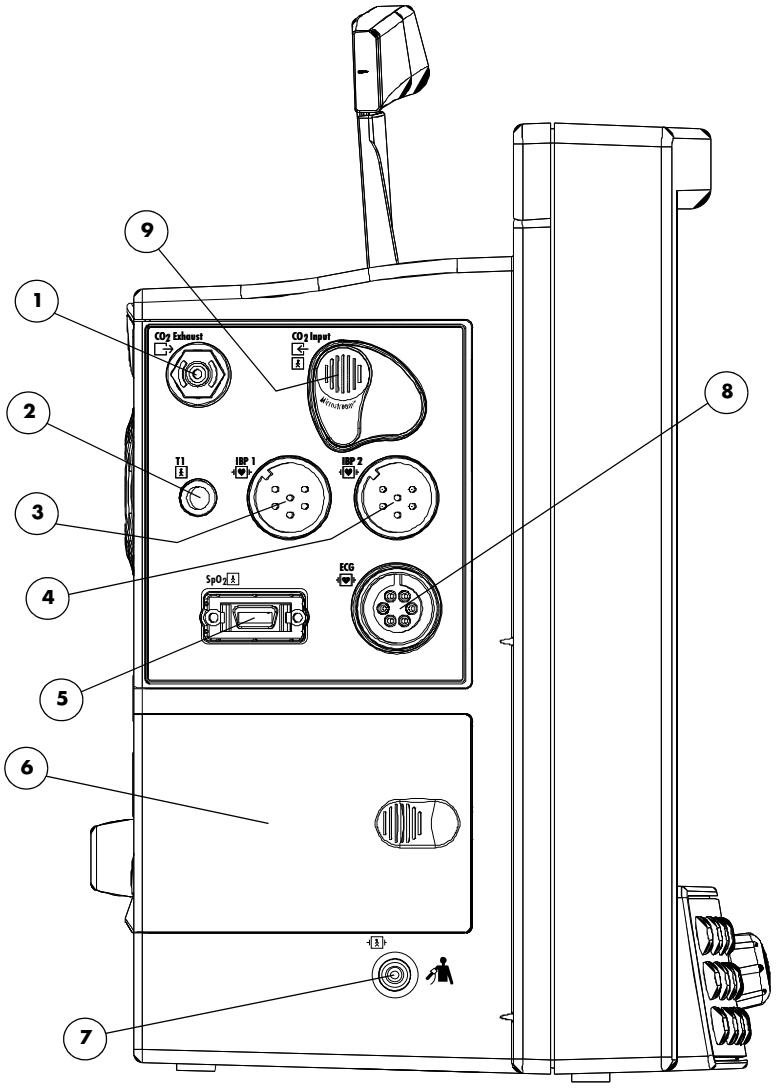


FIGURE 1-5 Left Side Panel

1. CO_2 Exhaust Connector (Optional)

This connector is used to attach an exhaust line which can be used to connect to a gas scavenging system.

2. T1 Connector

This connector mates with either the YSI series 400 or series 700 temperature probes. The monitor automatically detects which probe is connected.

3. IBP 1 Connector (Optional)

This connector is used for Channel 1 Pressure Transducer connection.

4. IBP 2 Connector (Optional)

This connector is used for the Channel 2 Pressure Transducer connection.

5. SpO_2 Connector

This connector is used to attach the SpO_2 sensor to the monitor, either Masimo SET® or Nellcor® OxiMax® technology.

6. Battery Compartment

This compartment houses the two optional, user replaceable, rechargeable batteries (sealed lead acid or lithium-ion). These batteries provide power to the unit when it is not connected to an AC receptacle. The batteries can be independently removed and replaced while the unit is operating.

7. NIBP Rectus Connector

This connector is used to attach the NIBP hose to the unit.

8. ECG Connector

This connector is used to attach a 3 or 5-lead ECG cable.

9. CO_2 Input Connector (Optional)

This connector is used to attach a Microstream® CO_2 FilterLine® to the unit.

1.7 Right Side Panel

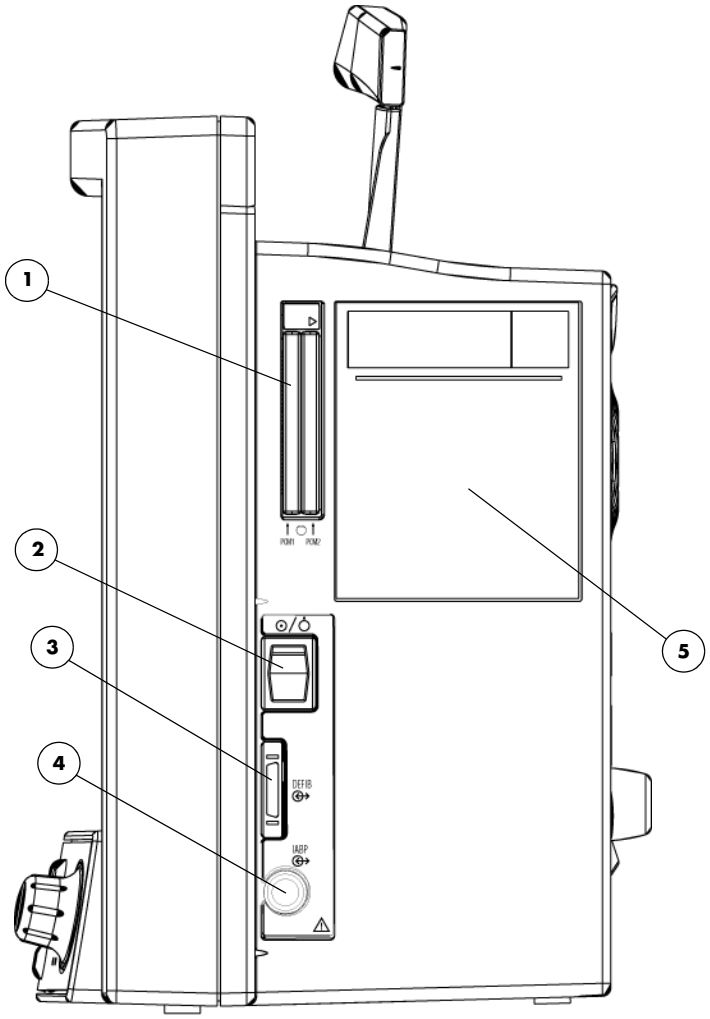


FIGURE 1-6 Right Side Panel

1. PCM1 and PCM2 Card Slots

These sockets are used for extended trend memory, software download to the CPU, patient data transfer and monitor setup transfers.

2. Power Switch

A momentary switch that turns power ON or OFF but does not prevent charging of the batteries. Press the top of the switch once to turn the unit ON. Press the top of the switch again to turn the unit OFF.

3. DEFIB Connector

Used to connect a defibrillator sync cable.

4. IABP Connector

Used for triggering an Intra-Aortic Balloon Pump from the **Spectrum OR** when using a 3-lead or 5-lead ECG cable or an invasive blood-pressure catheter.

5. Recorder (Optional)

A two trace thermal strip chart recorder with integral paper spool.

1.8 Gas Module (Optional)

NOTE: The following models are referenced in this manual: Gas Module II, Gas Module SE, Gas Module SE with Spirometry, and Gas Module 3. When information is common to all models, the generic name "Gas Module" is used. Information that is unique to a specific model is identified accordingly.

1.8.1 Front Panel

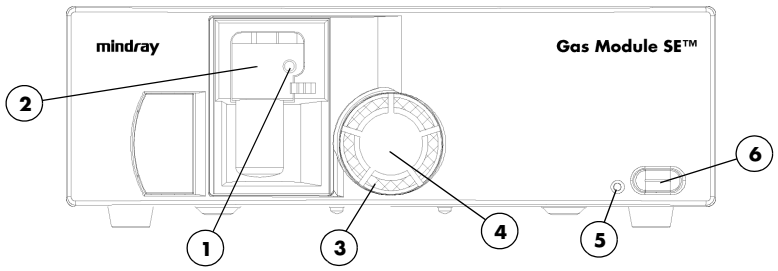


FIGURE 1-7 Gas Module II, Gas Module SE, and Gas Module SE with Spirometry

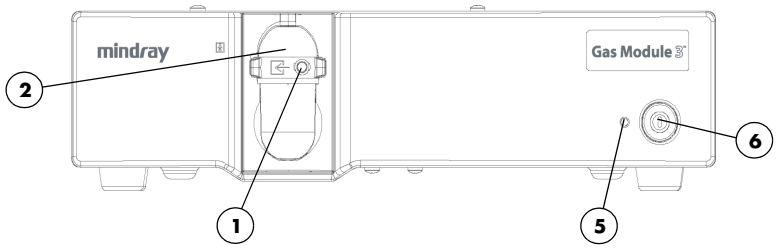


FIGURE 1-8 Gas Module 3

1. Input Port

This port is used to connect the sampling tubing to the Gas Module.

2. Water Trap Assembly (includes Water Trap Reservoir)

- **Gas Module II and SE** – (P/N 0202-00-0129)
- **Gas Module 3** – (Adult/Pediatric P/N 0202-00-0182-10, Neonate P/N 0202-00-0181-10)

The Water Trap Assembly is used to capture moisture drawn in with the patient sample. The Water Trap Reservoir must be emptied and rinsed (with water only) whenever more than half full or whenever changing patients. Refer to section 3.9 for more details.

3. Dust Filter

The Dust Filter (P/N 0378-00-0040) protects the Gas Module from airborne dust. It should be removed and cleaned on a regular basis. Refer to section 3.9 for more details.

4. Dust Filter Cover

The Dust Filter Cover is removed to access the filter.

5. Power Indicator Lamp

This lamp illuminates when the Power Switch is in the ON position.

6. Power Switch

A switch used to power the unit ON and OFF. It is located on the front of the Gas Module SE, Gas Module SE with Spirometry, and Gas Module 3. It is located on the back of the Gas Module II.

1.8.2 Rear Panel

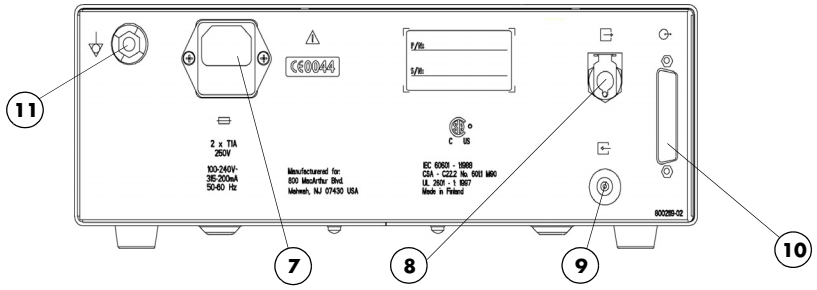


FIGURE 1-9 Gas Module II, Gas Module SE, and Gas Module SE with Spirometry

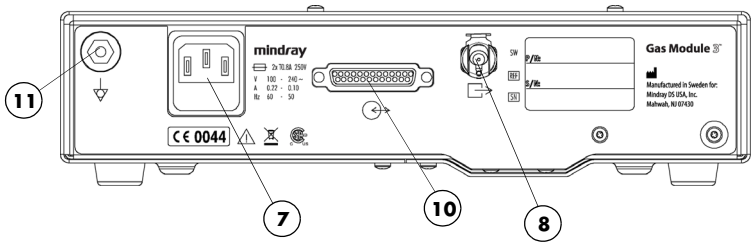


FIGURE 1-10 Gas Module 3

7. AC Power Input

This input is used to attach the special "Y" Shaped Power Cord.

8. Exhaust Port

This panel mount coupling is used for attaching a gas scavenging system (P/N 0997-00-0923 or P/N 0997-00-0984) to the Gas Module.

9. Reference Port

This port is used only to measure room air. This port is not to be connected to anything. **Do not** block this port.

10. External Interface Port

A communication interface port used to connect the Gas Module to the **Spectrum OR**.

11. Equipotential lug

Provides Equipotential grounding of hospital equipment.

1.9 Comm-Ports

NOTE: Figures 1-12 to 1-15 depict four distinct sub-models of the Comm-Port that have different interface capabilities. Only one sub-model at a time can be connected to the Spectrum.

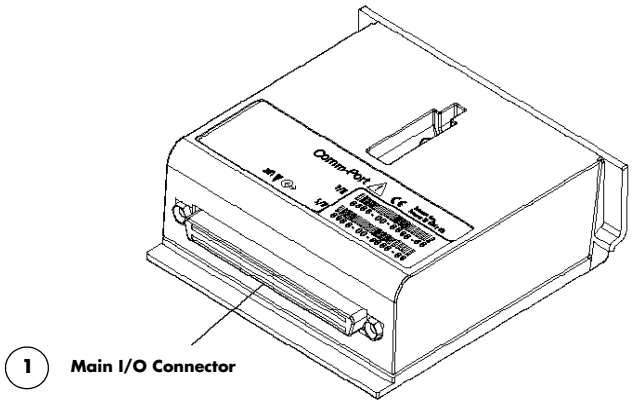


FIGURE 1-11 Comm-Port

1. Comm-Port to Main I/O Connector (DB1)

This is the female connector that will engage the equivalent male connector when connected to the **Spectrum OR**.

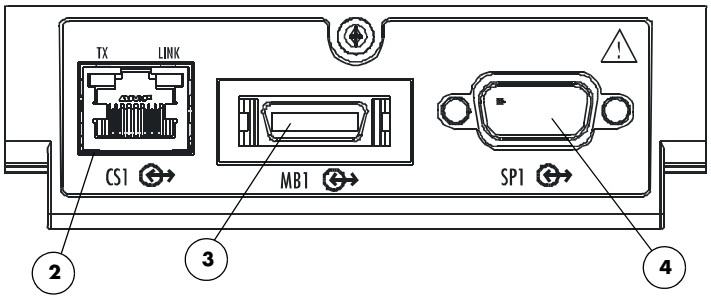


FIGURE 1-12 CS1/MB1/SP1Comm-Port

2. Ethernet Connector (CS1)

Ethernet connection port used for networking connections or devices requiring ethernet communication such as the Panorama® Central Station or the Viewstation OR™.

3. Module Bus Connector (MB1)

Port used to connect the BISx™ Module.

4. Serial Port Connector (SP1/SP2)

Proprietary serial port used to connect to the Gas Module SE, Edwards Vigilance® Monitor, or other devices.

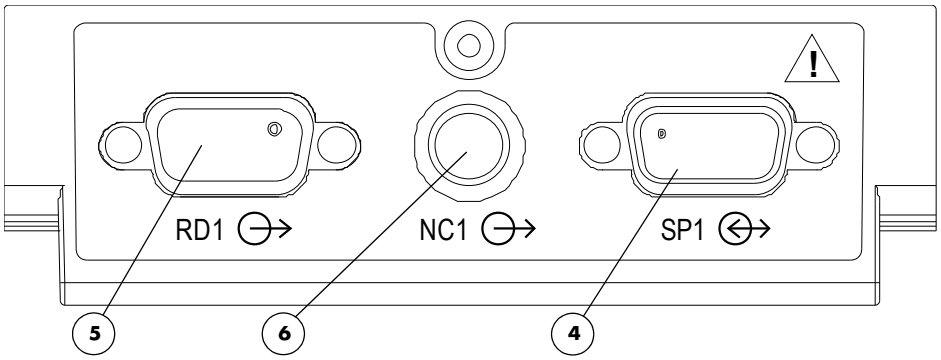


FIGURE 1-13 RD1/NC1/SP1 Comm-Port

5. Remote Display Connector (RD1)

Port used to connect a remote display to the **Spectrum OR** monitor.

6. Nurse Call Connector (NC1)

Port used to connect a nurse call cable to the **Spectrum OR** monitor.

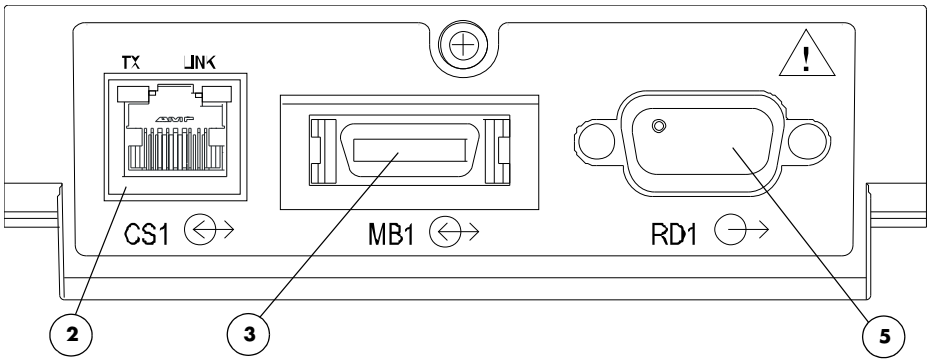


FIGURE 1-14 CS1/MB1/RD1 Comm-Port

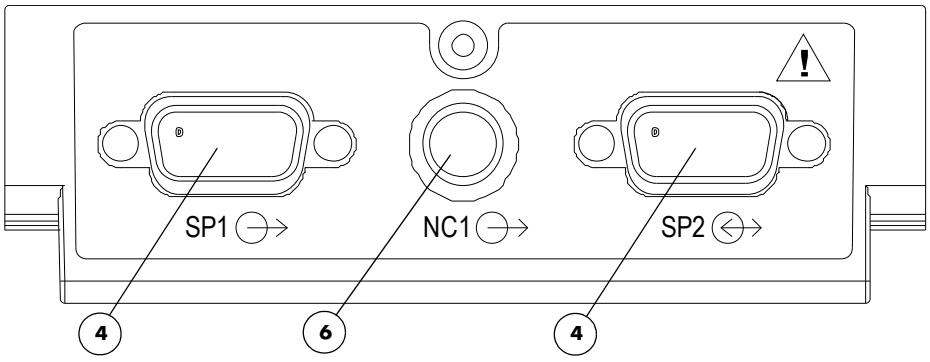


FIGURE 1-15 SP1/NC1/SP2 Comm-Port

1.10 External Parameter Modules (Optional)

The module contains a YSI 400/700 temperature port and may also contain one or both of the following:

- Two Invasive Blood pressure ports
- Cardiac Output port

To connect the External Parameter Module to the **Spectrum OR**:

1. Line up the connectors on the front of the Module (security posts, module hooks and EM1 port).
2. Slide the module forward, towards the monitor front until an audible “click” is heard as the module hooks are engaged.

To remove the External Parameter Module from the **Spectrum OR**:

1. Press the two release buttons on the top of the module.
2. Slide the module straight back until all connectors are clear.
3. Lift the module straight up for complete disengagement.

1.10.1 External Parameter Module Top View

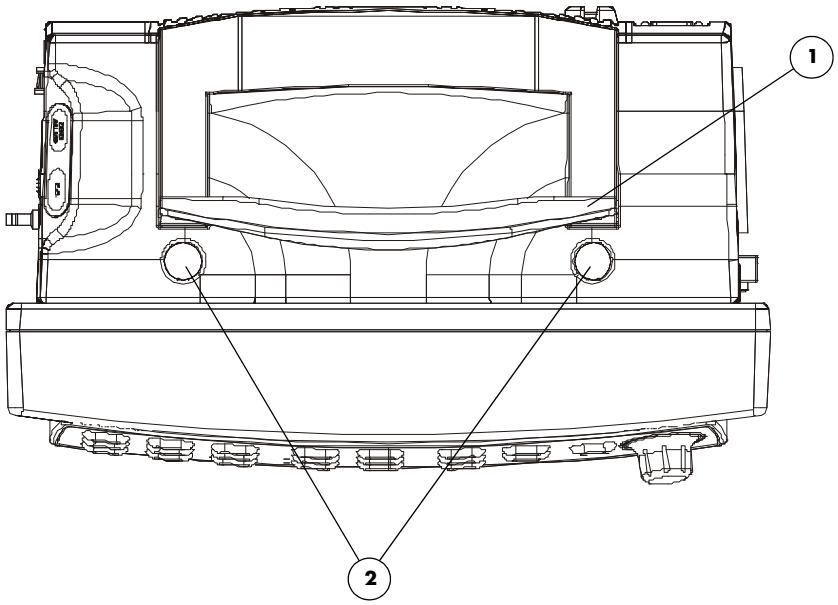


FIGURE 1-16 Diagram of Top View

1. Soft Grip Module Handle

This integrated grip handle is used for carrying the **Spectrum OR** with the External Parameter Module attached.

2. Release Buttons

There are two release buttons at the top. Press these two release buttons, simultaneously during the removal of the External Parameter Module from the **Spectrum OR**.

1.10.2 External Parameter Module Front View

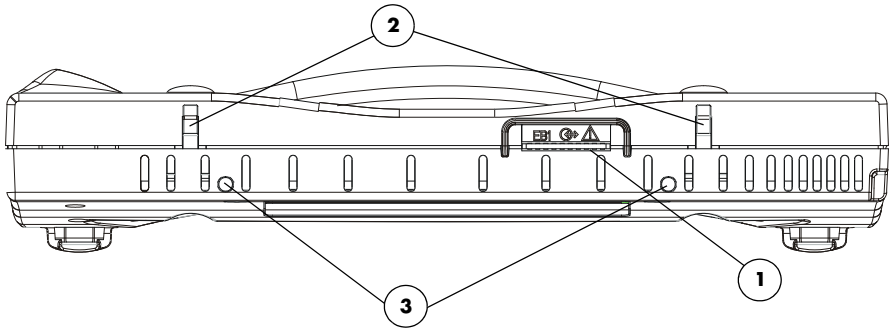


FIGURE 1-17 Front View of EPM

1. Module Connector (EB1)

This module bus port connects the External Parameter Module to the EM1 port on the **Spectrum OR**.

2. Module Latches

These latches secure the module to the **Spectrum OR.**

3. Guide Pins

These pins guide the EB1 connector into the EM1 port on the **Spectrum OR**.

1.10.3 Left Side View with External Parameter Module

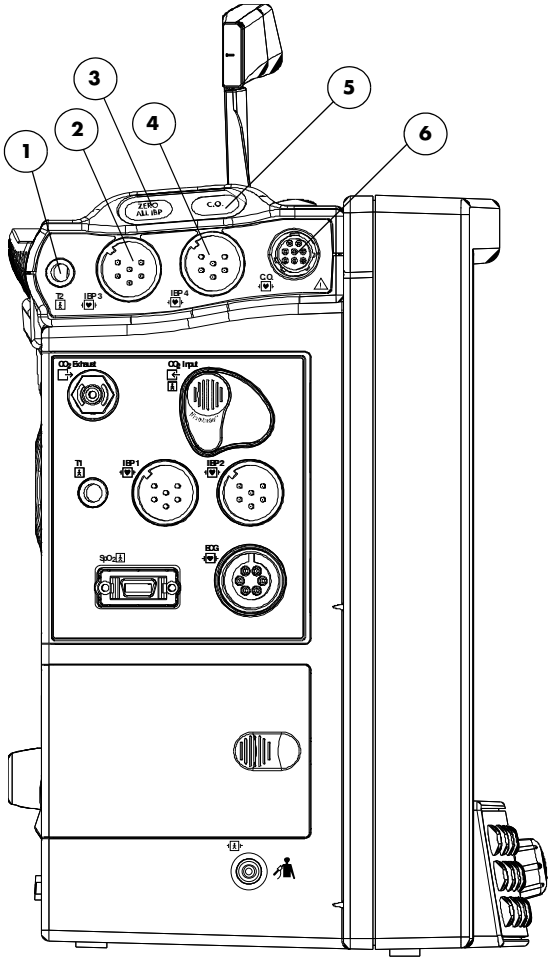


FIGURE 1-18 Left Side View with External Parameter Module

1. T2 Connector

This connector mates with either the YSI series 400 or 700 temperature probes. The monitor automatically detects which probe is connected.

2. IBP3 Connector

This connector is used for the Channel 3 Pressure Transducer connection.

3. ZERO ALL IBP Key

Press this key to zero all invasive blood pressure simultaneously. This key operates the same as the **ZERO ALL IBP** key on the monitor keypad.

4. IBP4 Connector

This connector is used for the Channel 4 Pressure Transducer connection.

5. C.O. Key

Press this key to open the **Cardiac Output Menu**. If the **Cardiac Output Menu** is already open and the "Ready" message is displayed, pressing the **C.O.** key activates the CO run sequence.

NOTE: Pressing this key will not open the Vigilance CO Menu.

6. CO Connector

A port used to connect the Cardiac Output cable.

1.10.4 Rear View with External Parameter Module

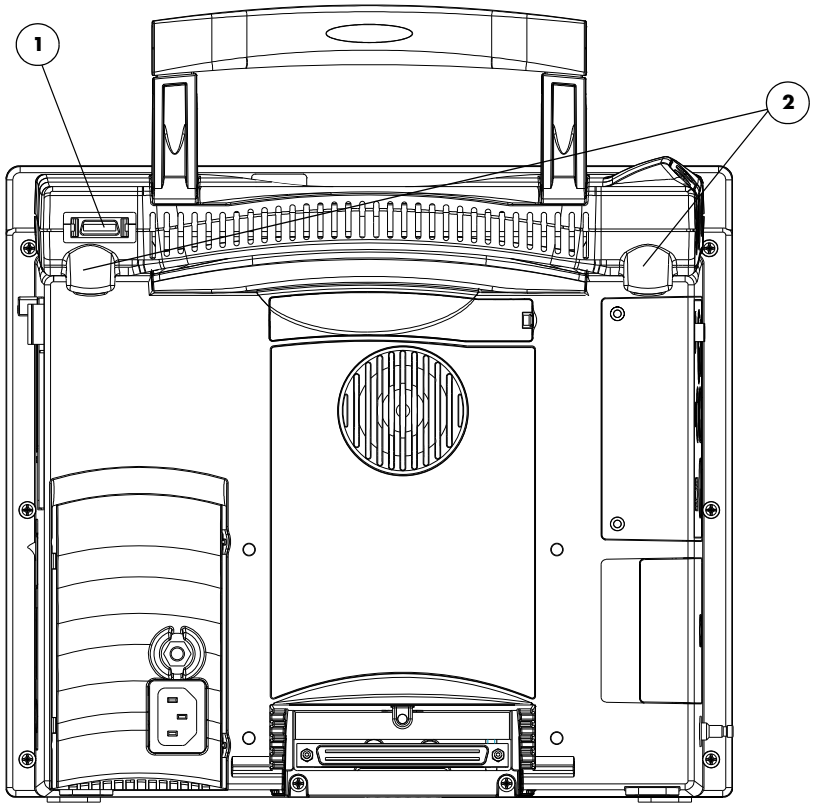


FIGURE 1-19 Rear View with External Parameter Module

1. Module Bus Port (MB2)

Port used to connect the BISx™ Module.

2. Rear Module Hooks

These two hooks secure the module to the **Spectrum OR**.

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2.0 *Operations*

2.1 Getting Started

The **Spectrum OR** comes with default factory settings which enable you to begin monitoring without setting any of the waveforms, parameters, alarms, or functions. However, all of these settings can be changed for specific patient or departmental needs.

Certain operating characteristics are based on the selected patient size (e.g. NIBP start pressure). The patient size selection should be matched to the actual patient before monitoring begins.

Setting-up Patients

1. Turn the monitor on using the **ON/OFF** switch. Ensure the previous patient's data has been removed from the monitor by discharging previous patient.
2. Connect the patient to the monitor, apply appropriate accessories such as ECG electrodes, blood pressure cuff, SpO_2 probe, CO_2 Fiterline®, etc.
3. Enter patient information into the **Spectrum OR** via the **Patient Menu**, check patient size.
4. If desired, press the **START** key to initiate a non-invasive blood pressure measurement.

How to Set the Clock / Date and Time

The date and time are set in the **Monitor Setup Menu**.

1. Using the Navigator™ Knob, highlight **Monitor Setup**. Press the Navigator Knob to open the menu.
2. Use the Navigator Knob to select **Advanced Setup**, then select either **Date** or **Time**.
3. Turn the Navigator Knob to select a new setting. Once the desired choice is highlighted, press the Navigator Knob.
4. This setting is saved when **Yes** is selected via the confirmation prompt.

NOTE: Patient trend data is cleared if the Time and/or Date are changed on the monitor.

If the Spectrum OR is connected to a Panorama Central Station, the Time and Date settings of the Central Station will be acquired by the Spectrum OR in one of three ways as follows:

- the Time and/or Date are changed on the Spectrum OR
- "Clear Trends" is chosen from the **Quick Trend**, **List Trend** or **Graph Trend** menus
- the patient is discharged

Transferring Monitor Default Settings

When installing several **Spectrum OR** monitors with identical display and alarm settings it is not necessary to set each unit separately. Only Transfer Card P/N 0996-00-0171-01 may be used to copy the settings from monitor to monitor.

1. Insert the Transfer Card into the PCM2 slot on the right side of the source monitor.
2. Enter the **Installation Menu**, (Press and hold the **TRENDS** key during power-up). Select "**Copy Monitor defaults to card**" from the menu. A status message will report completion of the transfer.
3. Remove the card and insert it into the PCM2 slot of the receiving monitor.
4. Enter Installation Mode on the receiving monitor (Press and hold the **TRENDS** key during power-up), and select "**Copy monitor defaults from card**". A status message will report completion of the transfer.
5. Select "**Save Current**" and power-cycle the receiving monitor to enter normal monitoring mode.

2.2 Installation Mode

2.2.1 Installation Menu

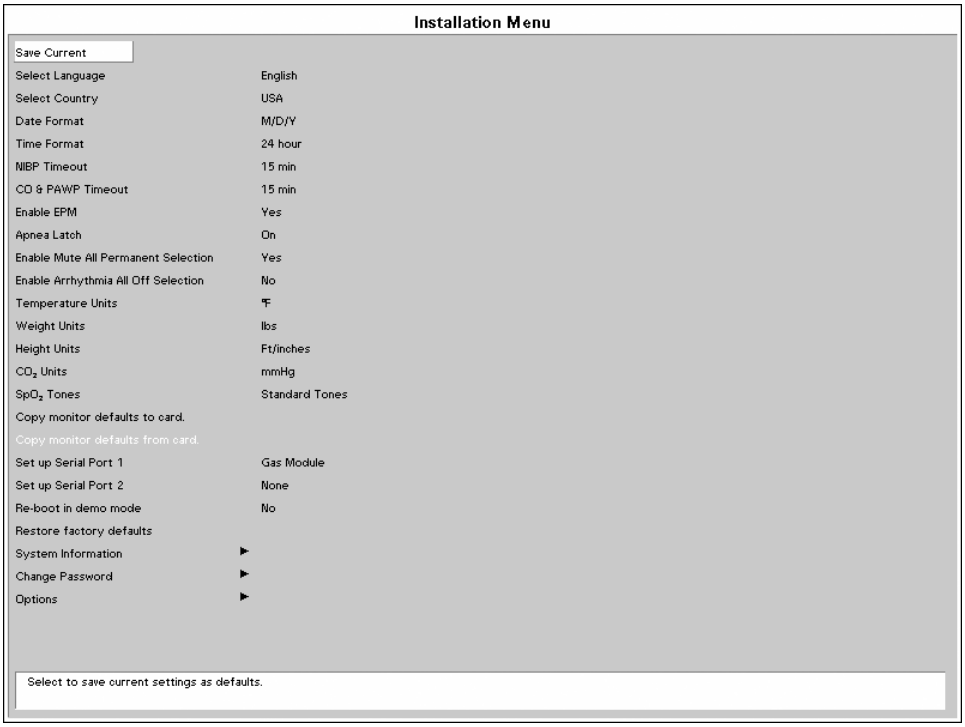


FIGURE 2-1 Installation Menu

The Installation Mode is accessed by pressing and holding the **TRENDS** key during power on. See the table that follows for descriptions of the **Installation Menu** choices.

To enter Installation Mode proceed as follows:

1. Power up the **Spectrum OR** while holding down the **TRENDS** key.
2. Set each item as necessary. To save all of the chosen settings, choose “Save Current” before leaving this menu. To return to normal operating mode, power the unit Off and On again.

The following table describes the **Installation Menu** structure:

MENU TITLE ON SCREEN	MENU CHOICES	DEFAULT	ACTIONS/COMMENTS
Save Current			Select to save current settings as defaults.
Select Language		Set up at factory	Select to change language.
Select Country		Set up at factory	Select to change country.
Date Format	M/D/Y, D/M/Y, Y/M/D	Per country	Select to change date format.
Time Format	12, 24 hour	Per country	Select to change time format.
NIBP Timeout	15, 30, 45, 60 mins	15 min	Select to change NIBP display time out.
CO & PAWP Timeout	15, 30, 45 mins, 1, 2, 4 hr	15 min	Select to change CO and PAWP timeout.
Enable EPM	No, Yes	No	Select to enable or disable the External Parameter Module.
Apnea Latch	On, Off	On	Select to turn apnea alarm latching on or off.
Enable Mute All Permanent Selection	Yes, No	Yes	Select to enable or disable the Permanent Audio Off menu selection.
Enable Arrhythmia All Off Selection	Yes, No	No	Select to enable or disable the Arrhythmia All Off menu selection.
Temperature Units	°F, °C	°F - USA °C - All others	Select to change temperature units.
Weight Units	lbs, kg	lbs - USA kg - All others	Select to change weight units.
Height Units	Ft/inches, cm	Ft/inches - USA cm - All others	Select to change height units.
CO_2 Units	mmHg, %, kPa	mmHg	Select to change CO_2 units.
SpO_2 Tones	Standard Tones, Alternate Tones	Standard Tones	Select to change the SpO_2 tones.
Copy monitor defaults to card.			Select to copy the monitor defaults and settings to a data transfer card.
Copy monitor defaults from card.			Select to copy the monitor defaults and settings from a data transfer card inserted into PCM2.
Set up Serial Port 1	None, DIAP, Gas Module, Vigilance[1]	None	Select to set up a serial output protocol port. An item enabled in Set up Serial Port 1 will be removed from the selections in Set up Serial Port 2.

1 "Vigilance" will only be available as a menu choice if it has been installed.

2 Country, language and system information are not affected by restoring defaults.

MENU TITLE ON SCREEN	MENU CHOICES	DEFAULT	ACTIONS/COMMENTS
Set up Serial Port 2	None, DIAP, Gas Module, Vigilance[1]	None	Select to set up a serial output protocol port. An item enabled in Set up Serial Port 2 will be removed from the selections in Set up Serial Port 1.
Re-boot in demo mode	No, Yes	No	Set to "YES" to start the monitor in demonstration mode on next power-up. Normal monitoring will resume after cycling power in demonstration mode.
Restore factory defaults[2]			Select to restore factory defaults
System Information			Select to setup owner's screen.
Change Password			Select to change password.
Options			Select to add/view options.

1 "Vigilance" will only be available as a menu choice if it has been installed.

2 Country, language and system information are not affected by restoring defaults.

2.2.2 System Information Menu

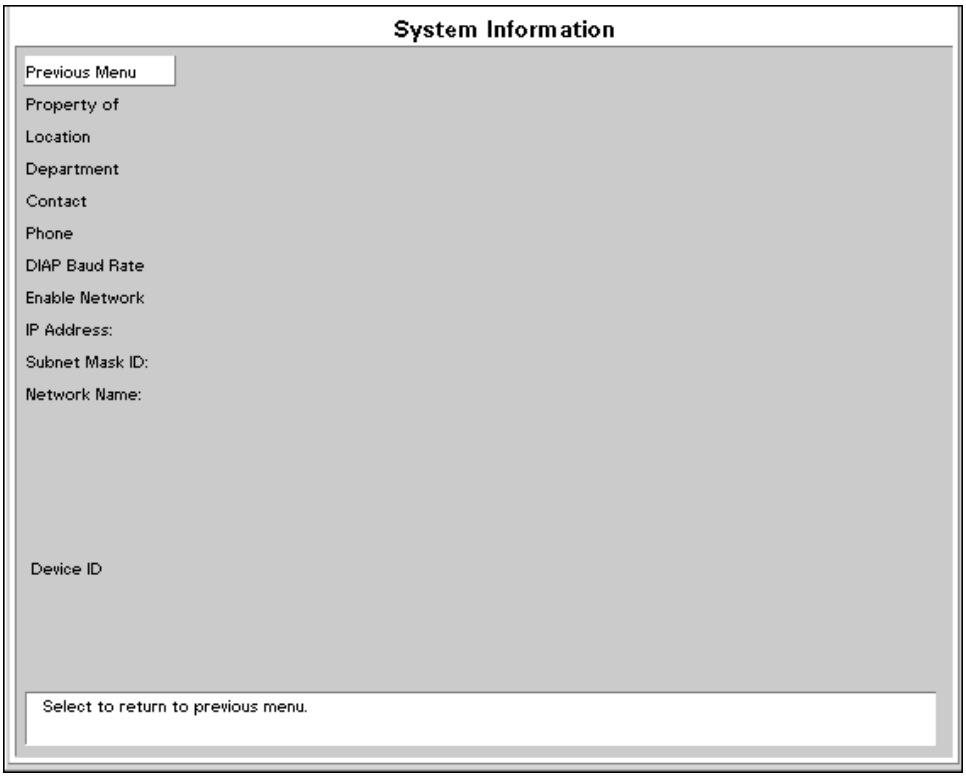


FIGURE 2-2 System Information Menu

This screen is accessed by rotating to the **System Information** selection on the **Installation Menu** and pressing the Navigator™ Control Knob. Each item on this screen is accessed in the same manner as the other menus on the monitor. Some items provide menu choices while others require information to be entered via a keypad-like entry screen. To enter information, rotate to the desired letter or number and then press the Navigator™ Control Knob to select. When finished, rotate to the **Previous Menu** choice and press the Navigator™ Control Knob. See the table that follows for descriptions of the **System Information** menu choices.

MENU TITLE ON SCREEN	MENU CHOICES	DEFAULT	TEXT STRINGS
Previous Menu			Select to return to Previous Menu
Property Of			Select to set up Property name
Location			Select to set up Location
Department			Select to set up Department
Contact			Select to set up Contact
Phone			Select to set up Phone
DIAP Baud Rate	9600, 19200	9600	Select to change the DIAP protocol baud rate
Enable Network	No, Wired	No	Select to enable Panorama communications
IP Address:[1]			Select to set up IP Address
Subnet Mask ID:[1]			Select to set up Subnet Mask ID
Network Name:[1]			Select to set up Network name
Device ID[2]			

1 Refer to the Panorama Service Manual for information on network settings.

2 Device ID is an information field that displays a unique, factory defined, device ID number. It is not user selectable.

2.3 Main Menus

The Main Menus of the **Spectrum OR** are always displayed at the top of the screen and are accessed using the Navigator™ Knob. The Main Menu headings are **Patient**, **Monitor Setup**, **Print Setup**, **Parameters** and **Functions**.

2.3.1 Patient Menu

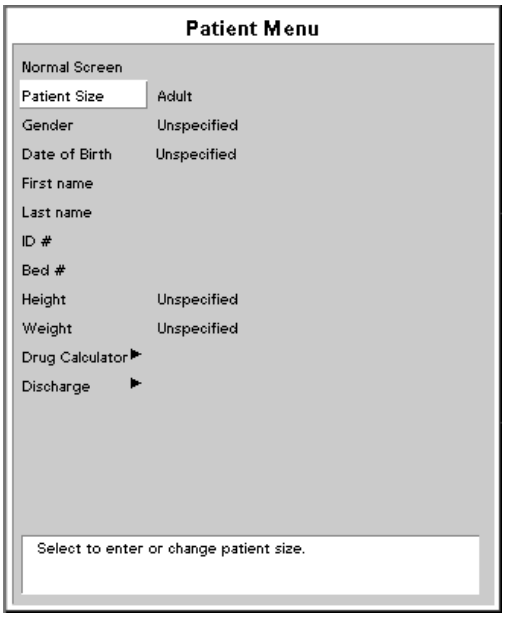


FIGURE 2-3 Patient Menu

The **Patient Menu** stores patient demographic data, identification data and room number.

The **Patient Menu** contains the following patient information: Patient's Size (Adult, Pediatric or Neonate), Gender, Date of Birth, First Name, Last Name, Identification Number, Bed Number, measurements of Height and Weight, IV Drug Calculations and Discharge.

NOTE: Verify monitoring settings when the patient size is changed.

Entering a Patient's First / Last Name, ID Number and Bed Number

To enter the patient's **First Name**, **Last Name**, **ID Number** and **Bed Number** complete the following steps:

1. Open the **Patient Menu** and scroll down through the menu using the Navigator Knob.
2. Select the patient data you wish to enter or change.
3. Press the Navigator Knob and a keypad will appear on the screen.
4. To enter patient information highlight the appropriate characters.

5. When finished entering the data select **Done** and press the Navigator™ Knob to close the keypad.
6. The patient information will appear in the upper right hand corner of the display. This data will also appear on printouts.

NOTE: Since Remote View requires selecting a "Bed #", a unique number for each bed should be used. The following standard format for this demographic is recommended:

- Start the string with a room # that has a fixed number of digits. For example, if the maximum number of digits that is used in numbering the rooms is 4, then for room 102, a leading zero would be added to get the 4th digit - 0102.
- Follow the room # with a letter to identify the particular bed within the room. For example, a room with 2 beds would have bed A and bed B.
- An example of a complete "Bed #": Bed B in room 513 (in a facility where the maximum number of digits that is used in numbering the rooms is 4) would be identified as 0513B.

NOTE: If the monitor is communicating with the EMR (Electronic Medical Records) system through a Panorama Gateway, any changes to patient demographics made at the monitor will not be sent to the EMR system. For further explanation, refer to section 2.11, "Connection to Panorama® Gateway".

Entering a Patient's Date of Birth

To enter the patient's **Date of Birth** complete the following steps:

1. Open the **Patient Menu** and scroll down through the menu using the Navigator Knob.
2. Select **Date of Birth** from the menu. Press the Navigator Knob and a pop-up window will emerge with day, month and year choices for **Date of Birth.**
3. To enter the patient's **Date of Birth**, turn the Navigator Knob and scroll until you reach the desired dates.
4. When finished with the **Date of Birth**, press the Navigator Knob to return to the **Patient Menu**.

Discharging a Patient

Discharging a patient from the monitor causes the following to occur:

- With the exception of the Bed #, all patient demographic data is cleared.
- All patient trend data is cleared.
- All currently calculated information is cleared.
- Cardiac Output waveforms and data are cleared.
- PAWP, ST, minitrends and average ST data is cleared.
- All print requests are aborted.

- The monitor default values are restored for the current patient size.
- The monitor is placed into a local discharge state.
- The message **DISCHARGED - TO RESUME MONITORING, PRESS NORMAL SCREEN** is displayed.

Select **Discharge** from the **Patient Menu**. A message will display to confirm the discharge. If **Yes** is selected, the patient will be discharged as described at the beginning of this sub-section. If **No** is selected, the discharge is aborted.

Pressing either the **STANDBY** or **NORMAL SCREEN** key while the monitor is in the local discharge state will return to normal monitoring.

2.3.2 Monitor Setup Menu

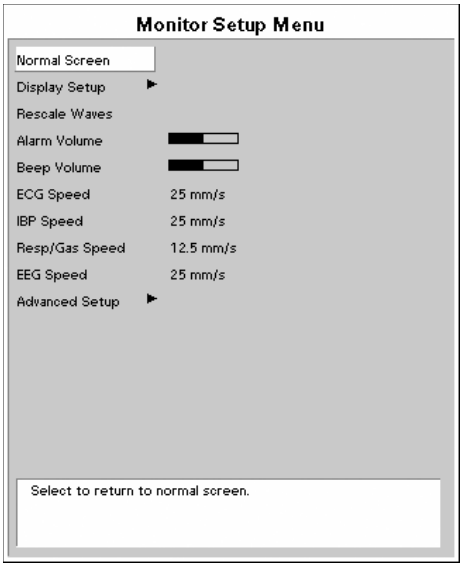


FIGURE 2-4 Monitor Setup Menu

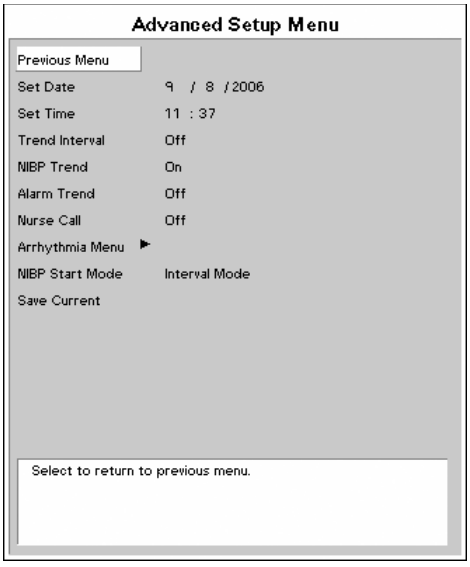


FIGURE 2-5 Advanced Setup Menu

Monitor Setup Menu

MENU ITEM	SELECTIONS	FACTORY DEFAULT/COMMENTS
Normal Screen		Select to return to normal screen.
Display Setup		Open an additional menu that enables changing the positions of the parameters and waveforms.
Rescale Waves		Select to auto-scale all waveforms.
Alarm Volume	Variable from Minimum to Maximum	Mid-Scale / Displays a slide bar to adjust the setting of the alarm volume. Use the Navigator™ Control Knob to adjust the volume.
Beep Volume	Variable from Off to Maximum	Mid-Scale / Displays a slide bar to adjust the setting of the systole beep volume. Use the Navigator™ Control Knob to adjust the volume.
ECG Speed	6.25, 12.5, 25, 50 mm/sec	25 mm/sec / Select to change trace speed of ECG & Pleth waveforms.
IBP Speed	6.25, 12.5, 25, 50 mm/sec	25 mm/sec / Select to change trace speed of pressure waveforms.
Resp/Gas Speed	3.125, 6.25, 12.5, 25 mm/sec	12.5 mm/sec / Select to change trace speed.
EEG Speed	6.25, 12.5, 25, 50 mm/sec	25 mm/sec / Select to change trace speed of EEG waveform.
Advanced Setup		Opens the Advanced Setup Menu outlined in the following table.

Advanced Setup Menu

MENU ITEM	SELECTIONS	FACTORY DEFAULT/COMMENTS
Previous Menu		Select to return to previous menu.
Set Date		Select to change date. Changing the date will clear the trend information. A confirmation message will display.
Set Time		Select to change time. Changing the date will clear the trend information. A confirmation message will display.
Trend Interval	Off, 1, 2, 2.5, 5, 10, 15, 20, 30 min, 1 hr, 2 hr	Off / Select to change time of trend data collection.
NIBP Trend	On, Off	On / Select to save numeric data to trend on NIBP measurements.
Alarm Trend	On, Off	Off / Select to save numeric data to trend on Alarms.
Nurse Call	Off, 1 second, Continuous	Off / Select to choose the Nurse Call activation time.
Arrhythmia Menu		This selection will open the **Arrhythmia Menu**.
NIBP Start Mode	Interval Mode, Timer Mode	Interval Mode / Select the Interval mode to synchronize NIBP start with the integral clock. Select Timer Mode to synchronize NIBP start with the interval selected in relation to the real time clock.
Save Current		Selecting this button displays an alpha-numeric entry screen for entering a password to allow this action. Asterisks will be displayed for each character that is entered. An invalid password entry will be indicated to the user with a prompt to retry. A correct password entry will display a confirmation prompt. Select **Yes** to save the current settings as the "monitor" defaults.

Arrhythmia Menu (Optional)

MENU ITEM	SELECTIONS	FACTORY DEFAULT/COMMENTS
Previous Menu		Select to return to previous menu.
Arrhythmia	All On, All Off, Non-lethals Off	Factory default is All On. Use Navigator Control knob to turn arrhythmia analysis on or off.
Irregular HR	On, Off	Factory default is On. Use Navigator Control knob to turn Irregular HR on or off.
V-Tach	3 to 15 beats	Factory default is 3 beats. Use Navigator Control knob to select how many ventricular beats in a row will constitute V-Tach.
V-Tach Rate	100 to 180 bpm	Factory default is 120 bpm. Use Navigator Control knob to select the heart rate threshold which must be reached to constitute V-Tach.

Arrhythmia Menu (Optional) (Continued)

MENU ITEM	SELECTIONS	FACTORY DEFAULT/COMMENTS
Asystole Delay	3 to 10 seconds	Factory default is 4 seconds. Use Navigator Control knob to select the number of seconds with an absence of an R wave that will constitute asystole.
Relearn		Use Navigator Control knob to select to relearn Arrhythmia and ST.

2.3.3 Print Setup Menu

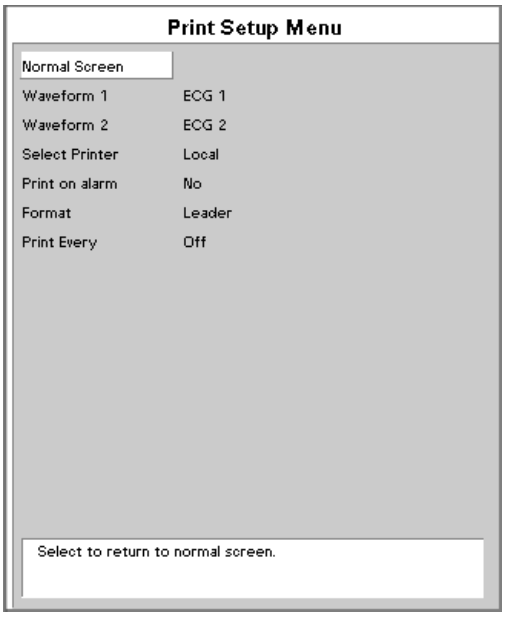


FIGURE 2-6 Print Setup Menu

Printing of Waveform Data

The **Print Setup Menu** allows the user to set up waveforms for printing and gives the user the ability to change the print destination.

Waveforms may be printed at the time of an alarm by selecting **Yes** in response to **Print on Alarm**. Waveforms may also be printed at regular intervals by selecting **Print Every**. Available selections are **1, 5, 10, 15, 20, 30, 60** and **120 min**.

To choose which waveform will print to the internal printer select Waveform 1 or 2 and then select any of the waveforms: **ECG 1 - 6, IBP 1 - 4, Pleth, Resp, CO_2, O_2,** and **Agent**.

NOTE: If a 3-lead cable is installed, the ECG 2 through ECG 6 references will not be displayed.

The following printer options may be available: **Local** and **Remote**. A default printer or combination of printers can be set.

Local printing will initiate a printout delivered via the internal printer.

Remote printing will send a printout to the printer associated with the Central Station.

2.3.4 Parameters Menu

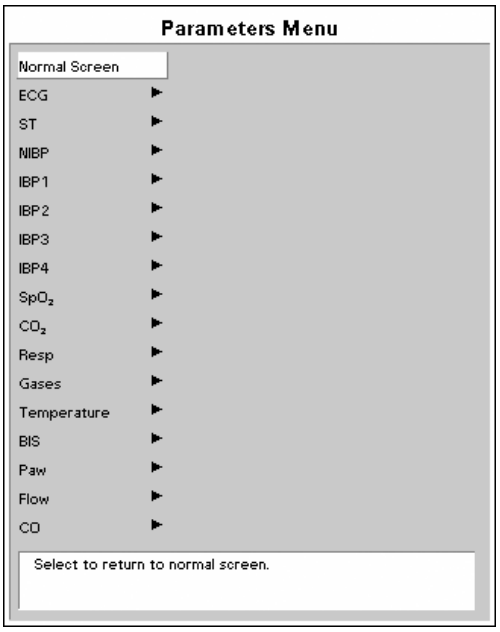


FIGURE 2-7 Parameters Menu

The **Parameters Menu** selections vary according to the optional features installed on the the monitor. The possible selections are: ECG, ST, NIBP, IBP1, IBP2, IBP3, IBP4, SpO_2, CO_2, Resp, Gases, Temperature, BIS, Paw, Flow and CO.

2.3.5 Functions Menu

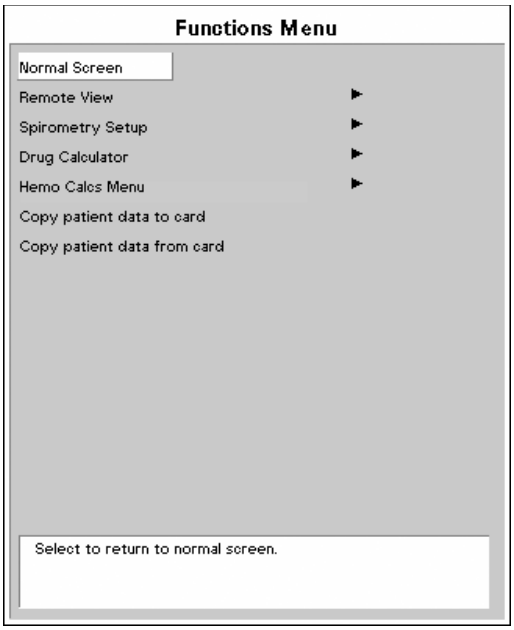


FIGURE 2-8 Functions Menu

The **Functions Menu** provides the following choices: **Normal Screen**, **Remote View**, **Spirometry Setup**, **Drug Calculator**, **Hemo Calcs Menu**, **Copy patient data to card** and **Copy patient data from card**.

The **Normal Screen** selection returns the view to the normal screen.

The **Remote View** selection opens the **Remote View Menu** shown in FIGURE 2-10. This menu enables the user to view the numeric and waveform data of another patient who is being monitored at a remote location. A more detailed description of this function is provided in the next subsection.

The **Spirometry Setup** selection opens the **Spirometry Setup Menu** shown in FIGURE 2-53. This menu is described in section 2.4.10.4.

The **Drug Calculator** selection opens the (IV) **Drug Calculation Menu**. This menu calculates both the infusion rate and the concentration rate of IV medications.

The **Hemo Calcs Menu** selection opens the **Hemodynamic Calculations Menu**. This menu calculates the patient's hemodynamic status.

There are two options for data transfer. **Copy patient data to card** and **Copy patient data from card** options allow for the transfer of patient specific data from monitor to monitor.

2.3.5.1 Remote View

The Remote View feature allows the simultaneous display of data from two patients on a single monitor. The monitor at the user's current location is defined as the host monitor. While maintaining visibility of the primary patient at the host monitor, the **Remote View Menu** enables the user to view the numeric data and two selectable waveforms of another patient who is being monitored at a remote location. The monitor at the remote location is defined as the remote monitor. Visual and audio alarms occurring at the remote monitor are also received through the **Remote View Menu** at the host monitor.

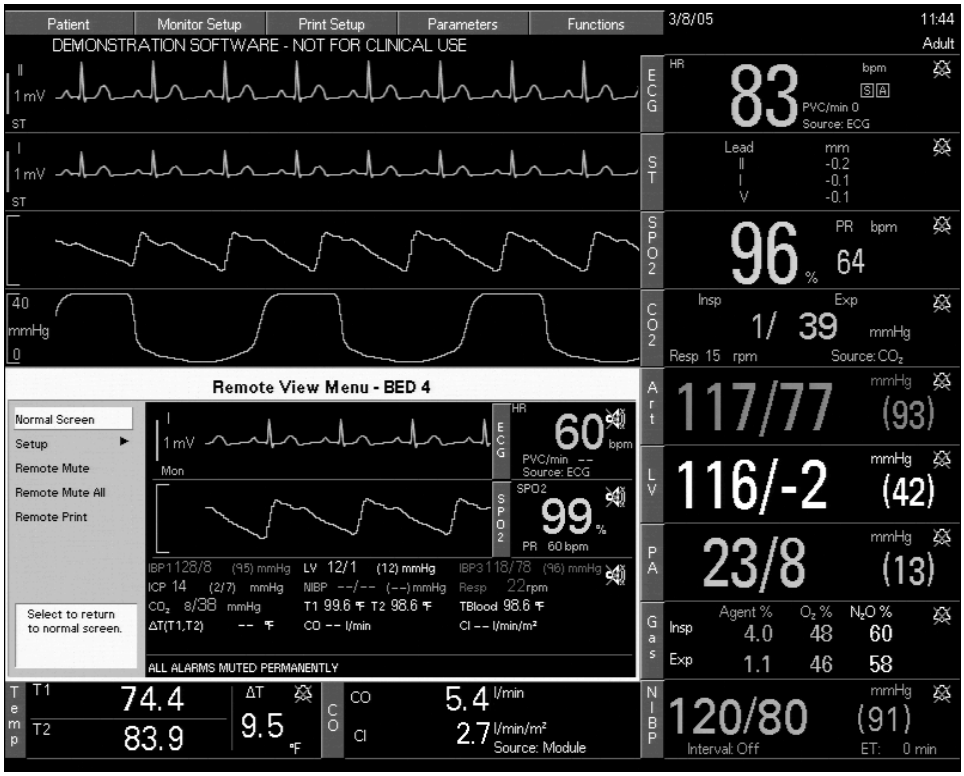


FIGURE 2-9 Remote View Menu on Main Display

The "Enable Network" option in the **System Information** menu must be set to "Wired" for Remote View capability to be available. Only **Spectrum** and **Spectrum OR** monitors on a Company approved hardwired network can be viewed remotely.

All Remote View controls are contained within the **Remote View Menu**. Opening other menus from the monitor's keypad or by pressing the **NORMAL SCREEN** key will close the **Remote View Menu**.

Remote View Menu Display

The **Remote View Menu** displays data as follows:

- The waveforms that are displayed are user-selectable through the **Remote View Setup Menu**, as described in the table on page 2-20. Corresponding numeric tiles are displayed to the right of the waveforms. The numeric data for a maximum of fifteen (15) parameters that are not related to the waveforms is displayed in the "Numeric Data Area" located directly below the waveforms. The following is a hierarchical listing of the parameters as they will display if they are not assigned to numeric tiles.
    - HR and PVC/min
    - SpO_2 and PR
    - IBP1, IBP2, IBP3, IBP4
    - CPP
    - PAWP
    - NIBP
    - Resp
    - CO_2
    - SvO_2
    - ST1
    - ST2
    - ST3
    - O_2
    - N_2O
    - Agent
    - T1, T2, TBlood, ΔT
    - CO
    - CI

NOTE: Respiration alarm text messages are also displayed in the "Numeric Data Area" as follows:

- If Apnea is detected, the message "APNEA" is displayed.
- If CVA is detected, the message "CVA" is displayed.
- If high impedance is detected from the ECG electrodes, the message "CHK LEAD" is displayed.

- The colors of the waveforms and all numeric data correspond to the settings of the host monitor (not the remote monitor).
- When numeric data for a particular parameter is unavailable, dashes (– –) are displayed.
- If a high or low alarm limit has not been set, an Alarm Off icon is displayed.
- Remote View alarms follow the alarm settings at the remote monitor, displaying in a priority-appropriate, reverse video color.
- If the remote monitor is placed into Standby mode, the message "Viewed Monitor is Currently in Standby" is displayed in the message area.

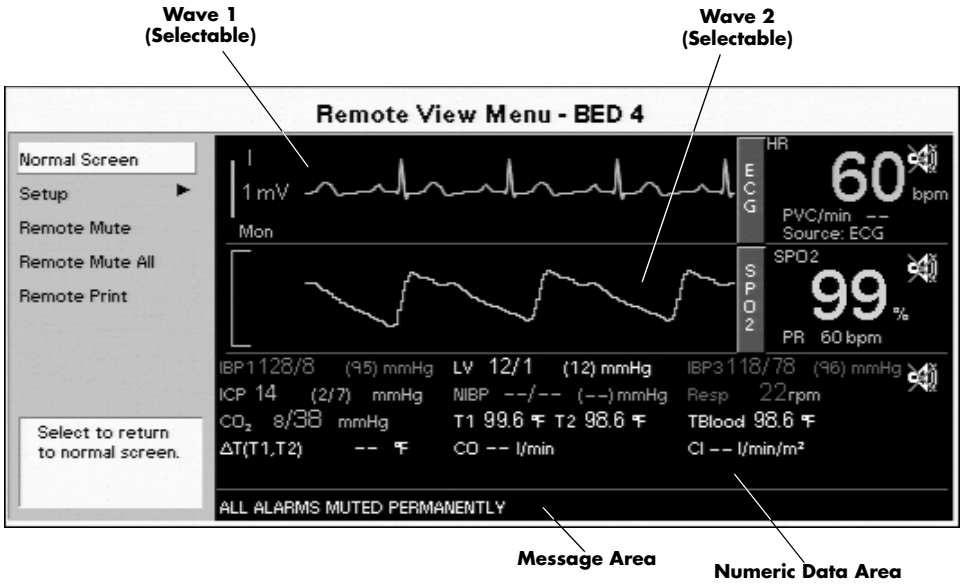


FIGURE 2-10 Remote View Menu

The **Remote View Menu** also provides the following menu choices: **Normal Screen**, **Setup**, **Remote Mute**, **Remote Mute All**, and **Remote Print**.

1. **Normal Screen** — this selection removes the **Remote View Menu** from the display.
2. **Setup** — this selection opens the **Remote View Setup Menu** shown in FIGURE 2-11. This menu enables the user to configure the display and functionality of the **Remote View Menu**.

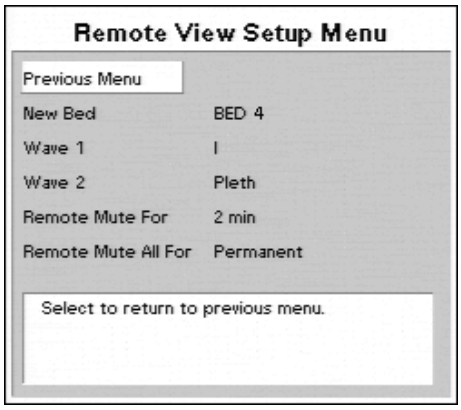


FIGURE 2-11 Remote View Setup Menu

NOTE: **With the exception of the "New Bed" menu choice, the current settings in the Remote View Setup Menu are saved when "Save Current" is selected from the Host Monitor. There is one set of saved settings for each patient size.**

NOTE: **The saved settings in the Remote View Setup Menu are transferable with the monitor defaults via a PCMCIA card.**

The following table provides a listing of the **Remote View Setup Menu** items:

Remote View Setup Menu

MENU ITEM	SELECTIONS	FACTORY DEFAULT/COMMENTS
Previous Menu		Select to return to previous menu.
New Bed	All available beds on a single network.	This menu item provides a list of monitor devices that are available in the approved hardwired network and have Bed numbers assigned. The chosen Bed # displays at the top of the **Remote View Menu**.
Wave 1	All waveforms (except Flow, Paw and EEG) available on the remote monitor.	Only waveforms available on the remote monitor will be listed as selections for this menu item. The menu selections for Wave 1 will not include the waveform that is currently selected as Wave 2.
Wave 2	All waveforms (except Flow, Paw and EEG) available on the remote monitor.	Only waveforms available on the remote monitor will be listed as selections for this menu item. The menu selections for Wave 2 will not include the waveform that is currently selected as Wave 1.
Remote Mute For	1 min, 2 min, 5 min*, 10 min*	Select to choose duration of Remote Mute.
Remote Mute All For	Permanent*, 1 min, 2 min, 5 min*, 10 min*	Select to choose duration of Remote Mute All.

* *These selections will not be available if the country chosen in the Installation Menu is France.*

3. **Remote Mute** — this selection silences the audio portion of a remote alarm for the duration that is selected from the **Remote Mute For** list in the **Remote View Setup Menu**. The factory default is 2 minutes. While the audio alarm is silenced:

   - the visual alarm indicators remain displayed
   - the message **ALARMS MUTED FOR XX:XX mins** is displayed in the message area of the **Remote View Menu**. The **XX:XX** in the message is a digital timer for the mute time remaining
   - if a new remote alarm occurs during this time, the current alarm will remain silenced while its digital timer continues to count down, and the new alarm tone will sound
   - an Alarm Mute icon (resembling a crossed speaker) is displayed in the numeric tile of each muted parameter, and in the "Numeric Data Area" if one or more parameters in that area are muted

   If **Remote Mute** is selected again, the digital timer is reset.

NOTE: **The Remote Mute selection silences only the alarms indicated in the Remote View Menu. It does not silence the primary patient's alarms or alarm sounds at the remote location.**

4. **Remote Mute All** — this selection silences the audio alarm tones of all remote alarms for the duration that is selected from the **Remote Mute All For** list in the **Remote View Setup Menu**. The factory default is 2 minutes. While the audio alarms are silenced:

   - the visual alarm indicators remain displayed
   - the message **ALL ALARMS MUTED FOR XX:XX mins** is displayed in the message area of the **Remote View Menu**. The **XX:XX** in the message is a digital timer for the mute time remaining

NOTE: **If "Permanent" is selected from the Remote Mute All For list, "ALL ALARMS MUTED PERMANENTLY" is displayed in the message area of the Remote View Menu. If a new bed is chosen while all remote alarms are permanently muted, the permanent mute condition will continue for the new bed.**

   - an Alarm Mute icon (resembling a crossed speaker) is displayed in the numeric tiles and in the "Numeric Data Area"

   If **Remote Mute All** is selected again, the audio alarm tones are re-enabled.

NOTE: **The Remote Mute All selection silences only the alarms indicated in the Remote View Menu. It does not silence the primary patient's alarms or alarm sounds at the remote location.**

5. **Remote Print** — this selection sends a print request to the remote monitor. The printout will be as configured in the **Print Setup** menu of the remote monitor.

NOTE: **When a Remote Print is requested, there is no indication that the printout was completed as requested. The user should verify the successful print at the printer.**

Remote View Message Area

The Message Area shown in FIGURE 2-10 displays status and alarm messages as follows:

- If more than one message is being received, they are alternately displayed.
- All arrhythmia alarms, priority one and priority two alarms generate the appropriate audio alerts at the host monitor and the associated alarm text messages are displayed in the Remote View Message Area. Refer to section 2.4.2.5, "Arrhythmia Alarms" for the specific arrhythmia alarm text messages that can be displayed.

NOTE: **The Lethal Arrhythmia alarms (V-Tach, V-Fib, and Asystole) are latched alarms. Even after the alarming condition is resolved at the remote monitor, a latched alarm will continue at the host monitor until it is acknowledged by selecting "Remote Mute" or "Remote Mute All" from the "Remote View Menu". If the alarm is acknowledged while the lethal condition still exists, the audio portion of the alarm will be muted for the duration that is selected from the "Remote Mute For" list or the "Remote Mute All For" list of the "Remote View Setup Menu", but the alarm message will remain in the Remote View Message Area. If a new lethal condition occurs while the initial lethal alarm is muted, the new lethal alarm will not break through and will be muted for the remainder of the mute duration. If the lethal condition is resolved while the alarm is muted, the alarm will be terminated.**

- Only alarm text messages for parameters that are not currently displayed in a Wave 1 or Wave 2 numeric tile or in the "Numeric Data Area" are displayed in the Remote View Message Area.
- If Apnea is detected, the message "Respiratory Apnea alarm." is displayed.
- If CVA is detected, the message "CVA" is displayed.
- Status Messages that are supported by the Remote View are:
    - Leads Off
    - SpO_2: Sensor Fault
    - SpO_2: Check Sensor
    - SpO_2: Failure
    - SpO_2: Interference
    - SpO_2: Low Perfusion
    - SpO_2: Motion
    - SpO_2: No Pulse
    - SpO_2: No Sensor
    - SpO_2: Pulse Search
    - SpO_2: Sensor Off

NOTE: **Status Messages are not displayed if high priority alarms are alternately displaying.**

2.4 Parameter Menus and Monitoring

Each parameter's menu can be accessed from the **Parameters** menu or by selecting its menu target on the normal operating screen.

2.4.1 ECG Monitoring

ECG is a continuous waveform of a patient's cardiac electrical activity. The ECG waveform will display in the first waveform area of the **Spectrum OR**.

The quality of an ECG signal is directly affected by electrode site skin preparation, electrode patch quality and ECG lead placement. If artifact is present on the ECG waveform, then the arrhythmia processing, alarm processing, and quality of the monitoring function may be affected. The presence of artifact can prevent the monitor from establishing an accurate ECG reference waveform, increasing the difficulty experienced in assessing the ECG rhythm.

Optimizing the ECG signal is imperative for accurate monitoring. Use high quality electrodes, designed to acquire the ECG with excellent base line stability, recovery from defibrillation and minimum artifact from patient movement.

With the **Spectrum OR**, ECG can be obtained by using a 3 Lead or 5 Lead ECG cable in conjunction with a lead set and skin electrodes. For best performance and safety, inspect the ECG cables and electrodes daily.

2.4.2 ECG Menu

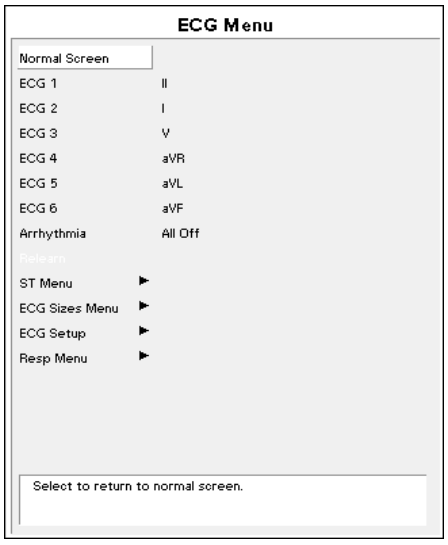


FIGURE 2-12 ECG Menu

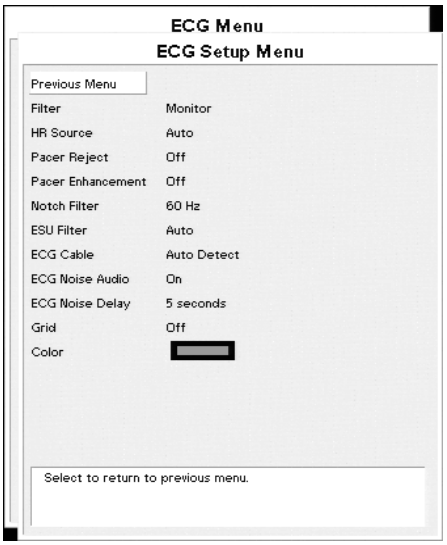


FIGURE 2-13 ECG Setup Menu

The **ECG Menu** provides the following choices: **Normal Screen**, **ECG 1 — ECG 6**, **Arrhythmia Menu**, **Relearn**, **ST Menu**, **ECG Sizes Menu**, **ECG Setup** and **Resp Menu**.

- The **Normal Screen** selection returns the view to the normal screen.
- The **ECG 1 — ECG 6** selections define the ECG labels for printing and trends.
- The **Arrhythmia Menu** selection opens the **Arrhythmia Menu**.
- The **Relearn** selection is only available if the ST or Arrhythmia options are installed and is used to manually initiate the learning process for ST measurements or Arrhythmia analysis.
- The **ST Menu** selection opens the **ST Menu**.
- The **ECG Sizes Menu** selection opens the **ECG Sizes Menu**.
- The **ECG Setup** selection opens the **ECG Setup Menu** that is detailed in the following table.
- The **Resp Menu** selection opens the **Resp Menu**.

ECG Setup Menu

MENU ITEM	SELECTIONS	FACTORY DEFAULT/COMMENTS
Previous Menu		Returns to the previous menu.
Filter	Monitor, Extended, ST	Select to change the filter mode for ECG. Extended or ST must be used for ST analysis. The filter setting affects both the display output and the printer output. Monitor = 0.5 - 40 Hz Extended, 3 or 5-lead = 0.05 - 100 Hz ST = 0.05 - 40 Hz
HR Source	Auto, ECG, <IBP1 Label>, <IBP2 Label>, <IBP3 Label>, <IBP4 Label>, SpO_2	Dependent on current settings, the IBP Label selections may remain as numbered or may be substituted with one of the following: Art, PA, CVP, ICP, RA, UA, LV, LA, IABP.
Pacer Reject	On, Off	When set to On, pacers are eliminated from the display.
Pacer Enhancement	On, Off	When set to On, all detected pacemaker spikes are displayed.
Notch Filter	Off, 50 Hz, 60 Hz	This menu item is used to filter out AC line noise from the ECG waveform. The Off selection is not saved with the Save Current function and will be reset when the monitor is power cycled.
ESU Filter	Auto, Disable	This menu item is used to filter out high frequency electrosurgical noise from the ECG waveform. The Disable selection is not saved with the Save Current function and will be reset when the monitor is power cycled.
ECG Cable	Auto Detect, 3 lead, 5 lead	This menu item is used to manually set the mode of operation for the chosen ECG cable type. **NOTE**: When using Mindray cables, the Auto Detect selection will automatically detect the cable type and switch the mode of operation accordingly.
ECG Noise Audio	On, Off	Factory default is On. This menu item enables (On) or disables (Off) the audio portion of the ECG Noise Alarm. One saved setting is available for each patient size.

ECG Setup Menu

MENU ITEM	SELECTIONS	FACTORY DEFAULT/COMMENTS
ECG Noise Delay	3 to 30 seconds	Factory default is 5 seconds. Use Navigator Control knob to select the number of seconds to delay the ECG Noise Alarm audio in the event that ECG noise is detected. Only available for 3 lead or 5 lead. One saved setting is available for each patient size.
Grid	On, Off	Select to turn the ECG grid On or Off.
Color	List of 16 colors	Select to change the display color for all ECG waves and for the HR and ST parameters.

WARNING: Ensure that the conductive parts of ECG electrodes do not contact other conductive parts, including earth ground.

CAUTION: To avoid possible damage to the Spectrum OR, use only approved ECG cables and approved accessories.

CAUTION: Line Isolation Monitor transients may resemble actual cardiac waveforms, thus inhibiting heart rate alarms. Check lead wires for damage and ensure good skin contact prior to and during use. Always use fresh electrodes and follow proper skin preparation techniques.

NOTE: This device is not intended for direct cardiac application.

CAUTION: Follow the balloon pump manufacturer's recommendations when connecting the unit to an intra-aortic balloon pump.

ECG Messages

A **Lead Fault** message will be displayed if an ECG lead becomes disconnected from the patient.

A **Check Lead Connection** message will be displayed if 3-lead or 5-lead ECG has an intermittent or poor connection.

An **ESU – Resp Off** or **ECG Noise** message will be displayed and ECG analysis (HR, arrhythmia, ST) will be interrupted if there is excessive interference. If HR from another source is available, it will be displayed automatically. If no other HR source is available, the last valid measurement will be displayed as a hollow number. If the interference continues, the HR will be invalidated (i.e., displayed as dashes).

Symbols in Heart Rate Tile

The following symbols can appear in the HR Parameter tile.

A	Arrhythmia	This indicates arrhythmia option is installed and active.
S	ST Analysis	This indicates ST Analysis option is installed and active.
P	Pacemaker	This indicates pacemaker rejection is **On**.

2.4.2.1 Skin Preparation

Proper skin preparation is essential in obtaining an accurate ECG reading. Electrode sites should be clean and dry and should provide a smooth flat surface. Incidental electrical activity and inaccurate readings may arise from incorrect skin preparation.

The following procedure is recommended for secure electrode patch application:

1. Shave the chest hair from the electrode sites in a circular area with a diameter of 2 – 4 inches.
2. Use a dry gauze pad to remove excess skin oils, skin cells and residue from the electrode sites. Never rub the skin until it is raw or bleeding.

NOTE: Prepare the electrode site with alcohol only if the skin is extremely greasy. If alcohol is used as a drying agent, always allow the skin to dry before placing the electrode patch on the skin.

2.4.2.2 Electrode Patch Location

NOTE: Store electrode patches at room temperature and open just prior to use.

NOTE: Avoid more than one type of electrode on a patient because of variations in electrical resistance.

NOTE: Avoid placing electrode patches directly over bone prominences or over any high activity movement areas such as shoulders or arms because muscle motion produces electrical activity. If an electrode patch is placed over a large muscle such as the pectorals, the monitor may detect this additional muscle activity and could lead to false arrhythmia calls.

1. To prevent evaporation of the contact gel medium, peel the backing off of the electrode patch only when it is ready for use. Visually inspect the contact gel medium for moistness. If the gel medium is not moist, do not use the electrode patch. Dry electrode patches are not conductive.

NOTE: If using the snap type electrode wires, attach the electrode patch to the lead wire before placing patch on the patient.

2. Attach the electrode patch to the skin at the prepared site. Smooth the electrode patch down in a circular motion to ensure proper skin contact. If using soft gel electrodes, never push down directly over the contact gel medium as this may displace the gel and cause monitoring artifact. If using hard gel electrodes, it is recommended that during application, the center of the electrode should be slightly pressed onto the skin to ensure direct contact. Consult the electrode patch manufacturer's instructions for specific use.
3. Secure the lead wires to the patient according to hospital practice. For additional information see section 2.4.2.3, "Lead Placement".

WARNING: Ensure that the ECG lead wires are neatly secured in a manner that will prevent them from encircling the patient's neck, creating a strangulation hazard.

NOTE: **It is recommended that electrode patches be changed at least every 24 – 36 hours to maintain proper contact with the skin. Some patients may require electrodes to be changed more often. Electrode patches are disposable and should be applied only once. Try to avoid reusing the exact same electrode site during reapplication. If an electrode becomes wet with fluid, change the electrode patch.**

2.4.2.3 Lead Placement

The computerized arrhythmia algorithm works best when the patient's R wave is significantly larger than the P wave or the T wave. If the R wave is not significantly larger than other lower voltage waves on the ECG tracing, the computer may have some difficulty in identifying the appropriate waves. On some patients, electrode patch placement and/or the viewed ECG lead may need to be adjusted in order to obtain a significant R wave.

This section outlines lead placement according to the guidelines of the American Heart Association (AHA) and the International Electro-Technical Commission (IEC).

Standard 3-wire Lead Sets

A 3-wire lead set can monitor one of three ECG vectors (I, II, or III). The recommended 3-wire lead placement is as follows.

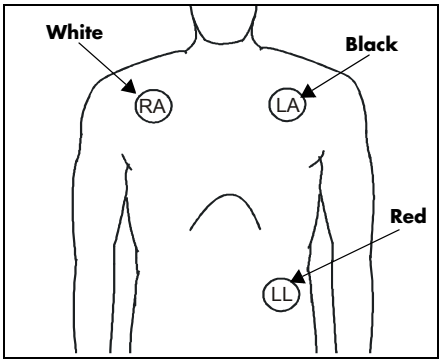


FIGURE 2-14 3-wire Lead Placement (AHA)

- Place the RA (white) electrode under the patient's right clavicle, at the mid-clavicular line within the rib cage frame.
- Place the LA (black) electrode under the patient's left clavicle, at the mid-clavicular line within the rib cage frame.
- Place the LL (red) electrode on the patient's lower left abdomen within the rib cage frame.

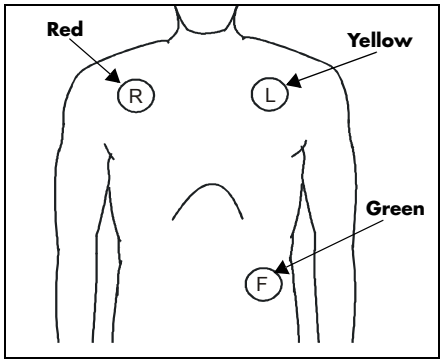


FIGURE 2-15 3-wire Lead Placement (IEC)

- Place the R (red) electrode under the patient's right clavicle, at the mid-clavicular line within the rib cage frame.
- Place the L (yellow) electrode under the patient's left clavicle, at the mid-clavicular line within the rib cage frame.
- Place the F (green) electrode on the patient's lower left abdomen within the rib cage frame.

Standard 5-wire Lead Sets

A 5-wire lead set can monitor seven ECG vectors (I, II, III, aVR, aVL, aVF, and V) simultaneously. The recommended 5-wire lead placement is as follows.

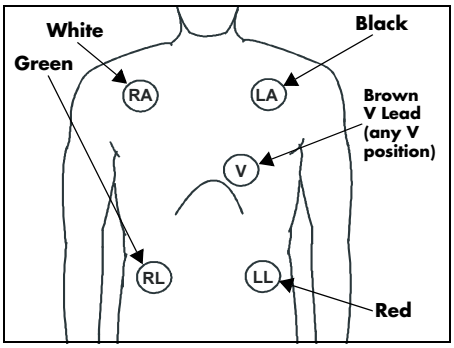


FIGURE 2-16 5-wire Lead Placement (AHA)

- Place the RA (white) electrode under the patient's right clavicle, at the mid-clavicular line within the rib cage frame.
- Place the LA (black) electrode under the patient's left clavicle, at the mid-clavicular line within the rib cage frame.
- Place the LL (red) electrode on the patient's lower left abdomen within the rib cage frame.
- Place the RL (green) electrode on the patient's lower right abdomen within the rib cage frame.
- Place the V (brown) electrode in one of the V-lead positions (V1 – V6) depicted in the following section.

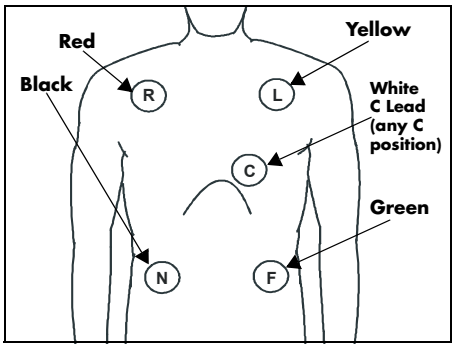


FIGURE 2-17 5-wire Lead Placement (IEC)

- Place the R (red) electrode under the patient's right clavicle, at the mid-clavicular line within the rib cage frame.
- Place the L (yellow) electrode under the patient's left clavicle, at the mid-clavicular line within the rib cage frame.
- Place the F (green) electrode on the patient's lower left abdomen within the rib cage frame.
- Place the N (black) electrode on the patient's lower right abdomen within the rib cage frame.
- Place the C (white) electrode in one of the C-lead (C1 – C6) positions depicted in the following section.

Lead II Monitoring

The recommended lead placement for Lead II monitoring is as follows.

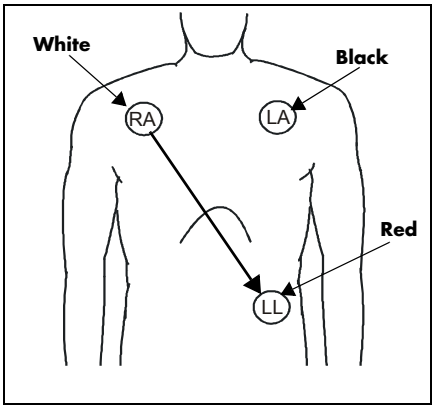


FIGURE 2-18 Lead II Monitoring (AHA)

- Place the RA (white) electrode under the patient's right clavicle, at the mid-clavicular line within the rib cage frame.
- Place the LA (black) electrode under the patient's left clavicle, at the mid-clavicular line within the rib cage frame.
- Place the LL (red) electrode on the patient's lower left abdomen within the rib cage frame.

Select ECG Lead II on the monitor. Lead II is the direct electrical line between the RA (white) electrode and the LL (red) electrode.

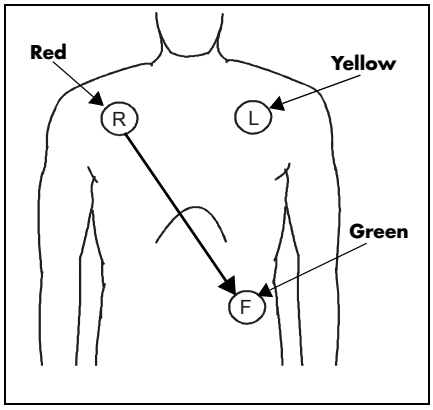


FIGURE 2-19 Lead II Monitoring (IEC)

- Place the R (red) electrode under the patient's right clavicle, at the mid-clavicular line within the rib cage frame.
- Place the L (yellow) electrode under the patient's left clavicle, at the mid-clavicular line within the rib cage frame.
- Place the F (green) electrode on the patient's lower left abdomen within the rib cage frame.

Select ECG Lead II on the monitor. Lead II is the direct electrical line between the R (red) electrode and the F (green) electrode.

Modified Chest Lead (MCL) Monitoring

The recommended lead placement for MCL monitoring is as follows.

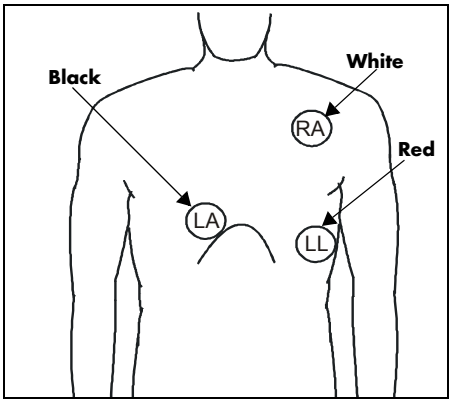


FIGURE 2-20 MCL Monitoring with a 3-wire Lead Set (AHA)

- Place the RA (white) electrode under the patient's left clavicle, at the mid-clavicular line within the rib cage frame.
- Place the LA (black) electrode on the right sternal border, at the fourth intercostal space within the rib cage frame.
- Place the LL (red) electrode on the patient's lower left abdomen within the rib cage frame.

Select ECG Lead I for MCL_1 monitoring. Lead I is the direct electrical line between the RA (white) electrode and the LA (black) electrode.

Select ECG Lead II for MCL_6 monitoring. Lead II is the direct electrical line between the RA (white) electrode and the LL (red) electrode.

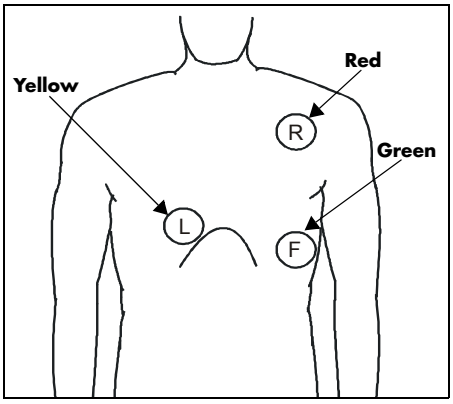


FIGURE 2-21 MCL Monitoring with a 3-wire Lead Set (IEC)

- Place the R (red) electrode under the patient's left clavicle, at the mid-clavicular line within the rib cage frame.
- Place the L (yellow) electrode on the right sternal border, at the fourth intercostal space within the rib cage frame.
- Place the F (green) electrode on the patient's lower left abdomen within the rib cage frame.

Select ECG Lead I for MCL_1 monitoring. Lead I is the direct electrical line between the R (red) electrode and the L (yellow) electrode.

Select ECG Lead II for MCL_6 monitoring. Lead II is the direct electrical line between the L (red) electrode and the F (green) electrode.

Neonatal Electrode Placement

Using a 3-wire lead set, ECG lead placement on a neonate is usually directed towards obtaining the best possible respiration data through the ECG thoracic impedance technique. Thoracic impedance is usually measured between the Right Arm and Left Arm electrode patches. These patches should be placed on the chest directly across from each other to optimize the measuring of the neonate's chest movement. The recommended lead placement for neonate monitoring is as follows.

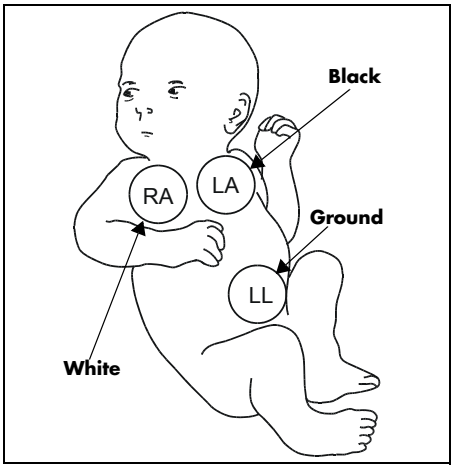


FIGURE 2-22 Neonatal 3-wire Lead Placement (AHA)

- Place the RA (white) electrode under the patient's right clavicle, at the mid-clavicular line within the rib cage frame.
- Place the LA (black) electrode under the patient's left clavicle, at the mid-clavicular line within the rib cage frame.
- Place the LL (red) electrode on the patient's lower left abdomen within the rib cage frame.

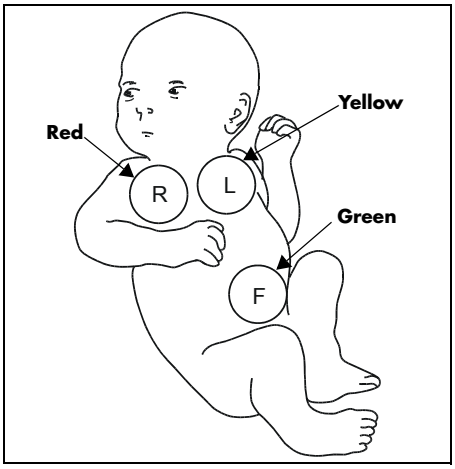


FIGURE 2-23 Neonatal 3-wire Lead Placement (IEC)

- Place the R (red) electrode under the patient's right clavicle, at the mid-clavicular line within the rib cage frame.
- Place the L (yellow) electrode under the patient's left clavicle, at the mid-clavicular line within the rib cage frame.
- Place the F (green) electrode on the patient's lower left abdomen within the rib cage frame.

Monitoring a Pacemaker Patient

The recommended lead placement for monitoring a pacemaker patient is as follows.

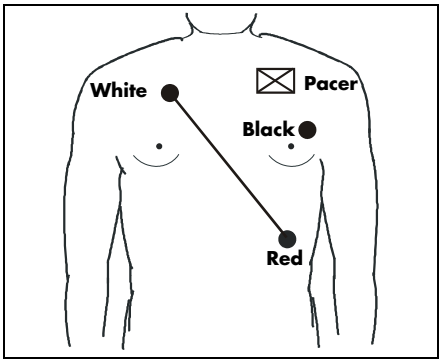


FIGURE 2-24 3-wire Lead Placement for a Pacemaker Patient (AHA)

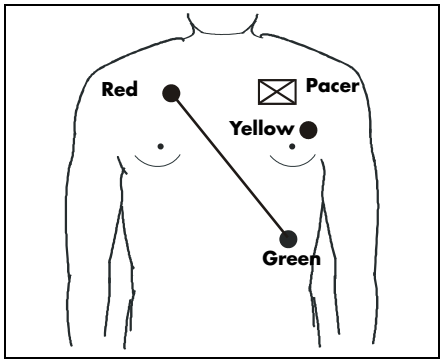


FIGURE 2-25 3-wire Lead Placement for a Pacemaker Patient (IEC)

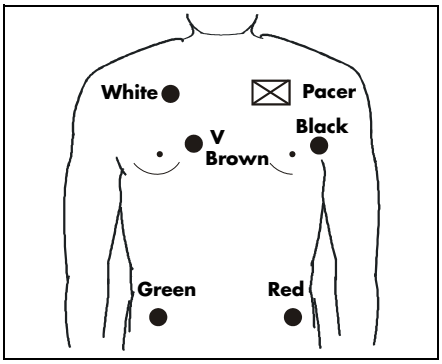


FIGURE 2-26 5-wire Lead Placement for a Pacemaker Patient (AHA)

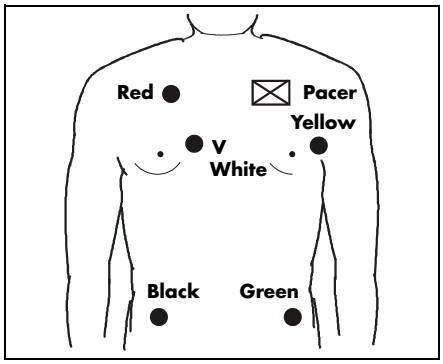


FIGURE 2-27 5-wire Lead Placement for a Pacemaker Patient (IEC)

A pacemaker patient usually requires a different electrode patch placement configuration than a non-pacemaker patient.

Do not place an ECG electrode directly over the pacemaker generator. Place the electrode patches 3 – 5 inches away from the pacemaker generator area. For example, if the pacemaker generator is located in the right subclavian area, relocate the Right Arm electrode closer in towards the center of the chest.

WARNING: Pacemaker patients' rate meters may continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias. Do not rely entirely upon rate meter alarms. Keep pacemaker patients under close surveillance. See the Appendix section of this manual for disclosure of the pacemaker pulse rejection capability of this instrument.

CAUTION: Some pacemakers may contain a respiratory sensor that may produce artifact on an ECG waveform.

Using a Transcutaneous Electrical Nerve Stimulator (TENS)

Since a TENS unit transmits electrical impulses, avoid placing ECG electrode patches near the TENS electrodes. ECG electrode patches may need to be repositioned and the ECG lead viewed may need to be adjusted until the optimum ECG tracing is obtained.

2.4.2.4 Arrhythmia Algorithm

The **Spectrum OR** uses an arrhythmia algorithm to monitor ECG waveform data. The algorithm creates ECG waveform templates based on a patient's normal ECG data and uses them to analyze newly received data. The algorithm verifies that data is free from noise and artifact, and that it does not deviate from the patient's normal ECG rhythms.

A normal ECG waveform typically includes consistent spacing between R waves, a sharp and well defined QRS complex, and an ECG baseline that is free of noise and artifact.

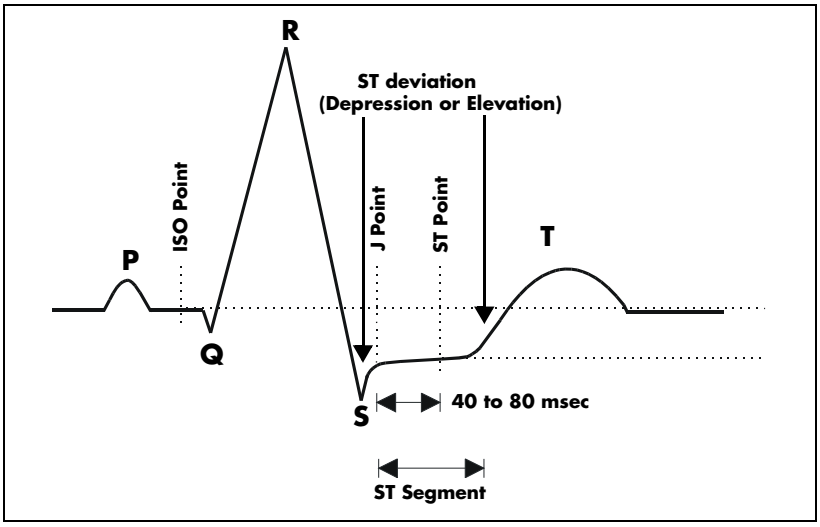


FIGURE 2-28 Sample Waveform

Noise and Artifact

The presence of noise or artifact in an ECG waveform makes the accurate detection and classification of heart beats difficult. To best optimize performance, all leads should be free of noise.

Some of the causes of ECG noise include poor skin preparation, improperly attached electrodes, dried electrode gel, defective lead wires, and patient movement. The algorithm uses several techniques to differentiate a patient's QRS complexes from noise sources.

If noise levels are too high for a particular lead, a message is posted, and the data is dropped from analysis until the signal quality is re-established.

If noise levels are too high, the following will occur until the signal quality is re-established:

- Beat detection is suspended
- All rhythm calls are suspended

- An **ECG Noise** message is displayed

Heart Rate Meter

Heart Rate is computed using the 16 most recent R-R intervals for heart rates above 48 beats per minute. If the heart rate calculated using the last 4 beats is less than 48 beats per minute, then this rate is used. All detected beats are used to compute the heart rate. A separate ventricular rate is used in the algorithm to determine rhythms like ventricular tachycardia and ventricular run.

Filtering Pacer Signals

In order to prevent pacer pulses from being mistaken for QRS complexes, they are removed from the ECG data that is sent to the arrhythmia algorithm for analysis. Pacer pulses are shown on the **Spectrum OR** as exaggerated vertical lines.

ECG Amplitude

The QRS detection threshold algorithm setting is fixed between 0.15 and 0.45 mV to avoid detecting noise spikes or P-waves as valid beats. Changing the display gain on the monitor does not affect the signal that is used by the algorithm for beat detection. For optimal performance, the leads selected for monitoring should have an amplitude of 0.5 to 1 mV or more.

Learning

The process of learning is used to establish a normal beat template for a patient. The learn period is dependent on the heart rate and the dominant pattern. Learning should not be initiated during a primarily ventricular rhythm because an ectopic beat may be established as normal.

A learn should be initiated when beats are not being properly detected, or when they are being erroneously classified. However, if a signal is not strong enough, or lead data is extremely noisy, better signal quality must be established before a learn can be effective.

Beat Detection and Typing

The following table describes the leads that are used to measure beat detection and beat typing.

DESCRIPTION	3-WIRE LEAD SET	5-WIRE LEAD SET
Leads used for Beat Detection	Determined by viewed lead	II and V
Leads used for Beat Typing	Determined by viewed lead	II, V, and I
Leads used for V-Fib Detection	Determined by viewed lead	II and V

The search for the next beat begins after a refractory period to avoid detecting T- waves as valid QRS complexes. For all patient sizes, the minimum QRS amplitude that can be detected is between 0.15 and 0.45 mV depending on the width of the QRS complexes.

Beat typing aligns and compares each new heart beat to reference templates that were previously stored in the system. A beat typing algorithm classifies the beats.

- If an incoming beat matches a template that has already been classified, it is given the same label as the template. The template parameters are updated with the features from this new beat.

The real time ECG analysis library incorporates ventricular ectopic beat detection as a part of arrhythmia analysis.

- Beats are measured for compensatory pause, QRS width, QRS positive and negative areas, and R wave positive and negative amplitudes. This process uses multiple leads when available.
- A scoring algorithm is then applied to those measurements to determine whether or not a beat is ectopic.

2.4.2.5 Arrhythmia Alarms

Arrhythmia alarms are activated based on the patterns in the patient ECG waveform rhythms. Beat detection for a 5-lead wire set is determined by using a combination of leads II and V. When using a 3-lead wire set, beat detection is determined by using the lead being viewed.

The following lethal and non-lethal arrhythmia alarms may be detected by the arrhythmia algorithm.

NOTE: Arrhythmia alarms are not available for the Neonate patient size.

2.4.2.5.1 Lethal Arrhythmia Alarms

A lethal arrhythmia is an arrhythmia that can be life threatening to a patient if left untreated. Ventricular Tachycardia (V-Tach), Ventricular Fibrillation (V-Fib), and Asystole alarms are classified as lethal arrhythmia alarms. These alarms automatically default to Alarm Priority 1.

NOTE: Lethal arrhythmia alarms are latched alarms. Even after the alarming condition is resolved, a latched alarm will continue until it is acknowledged by pressing the MUTE or MUTE ALL key on the front panel keypad. If the alarm is acknowledged while the lethal condition still exists, the audio portion of the alarm will be muted for the duration that is selected from the "Mute For" list in the "Alarm Setup" menu, but the alarm message will remain in message area A. If a new lethal condition occurs while the initial lethal alarm is muted, the new lethal alarm will not break through and will be muted for the remainder of the mute duration. If the lethal condition is resolved while the alarm is muted, the alarm will be terminated.

Asystole Alarm

An **Asystole** alarm is activated when no QRS complexes are detected for the configured time period in the absence of Ventricular Fibrillation.

The time period range for an **Asystole** alarm is user selectable from 3 to 10 seconds.

The Asystole alarm is a Priority 1 alarm event that produces:

- Alarm Priority 1 visual and audio alarm indicators.
- An **Asystole** text message above the ECG1 waveform area.

Ventricular-Fibrillation (V-FIB) Alarm

A **V-FIB** alarm is activated when a fibrillated waveform (P, QRS or T waves can no longer be identified) is detected. V-FIB is defined as "irregular, disorganized electrical activity of the heart". The V-FIB detection algorithm runs in parallel to the beat detection algorithm and continuously examines the incoming data.

The V-FIB alarm is a Priority 1 alarm event that produces:

- Alarm Priority 1 visual and audio alarm indicators.
- A **V-FIB** text message above the ECG1 waveform area.

Ventricular Tachycardia (V-TACH) Alarm

A **V-TACH** alarm is activated as follows:

- The range of the V-TACH rate is between 100 to 180 beats per minute.

AND

- The V-TACH lethal arrhythmia alarm is activated when the configured number of consecutive PVCs is reached. The range for the V-TACH threshold is 3 – 15 beats per minute.

A **V-TACH** alarm is a Priority 1 alarm event that produces:

- Alarm Priority 1 visual and audio alarm indicators.
- A **V-TACH** text message above the ECG1 waveform area.

2.4.2.5.2 Non-Lethal Arrhythmia Alarms

A Non-Lethal Arrhythmia is an arrhythmia that is most likely not life threatening to a patient. Bigeminy, Bradycardia, Couplet, Irregular Heart Rate, Pause, PVC/min, Run, Trigeminy, and Ventricular Rhythm (V-Rhythm) alarms are classified as non-lethal arrhythmia alarms. With the exception of PVC/min, all other Non-Lethal Arrhythmias are Alarm Priority 2. The Alarm Priority for PVC/min is user selectable between 1 and 2.

NOTE: Non-lethal arrhythmia alarms are not latched alarms and can be acknowledged at any time. To acknowledge a non-lethal arrhythmia alarm, press the MUTE key on the keypad.

Bigeminy Alarm

The **Bigeminy** alarm is activated when three or more cycles of one PVC coupled to one normal beat are detected.

The Bigeminy alarm is a Priority 2 alarm event that produces:

- Alarm Priority 2 visual and audio alarm indicators.
- A **BIGEMINY** text message above the ECG1 waveform area.

Bradycardia (Brady) Alarm

The **Brady** alarm is activated when the heart rate falls to a value 10% lower than the user selected value for low heart rate alarm.

The **Brady** alarm is an alarm event that produces:

- Alarm Priority 1 visual and audio alarm indicators.
- A **Brady** text message above the ECG1 waveform area.

Couplet Alarm

The **Couplet** alarm is activated when two consecutive PVCs are detected between normal beats.

The Couplet alarm is a Priority 2 alarm event that produces:

- Alarm Priority 2 visual and audio alarm indicators.
- A **COUPLET** text message above the ECG1 waveform area.

Irregular Heart Rate Alarm

The **Irregular Heart Rate** alarm is activated when the measured variations in the R-R interval over a period of time exceeds a preset limit established by the arrhythmia algorithm.

The Irregular Heart Rate alarm is a Priority 2 alarm event that produces:

- Alarm Priority 2 visual and audio alarm indicators.
- An **IRREGULAR HR** text message above the ECG1 waveform area.

PVC/minute Alarm

The **High PVC** alarm is activated when the number of PVCs detected per minute exceeds the configured threshold. The PVC limit can be set to Off, or 1 to 30 PVCs per minute.

The **High PVC** alarm has priority settings of **1** or **2**, and behaves as follows:

- If the High PVC alarm priority is set to **1**, Alarm Priority 1 visual and audio alarm indicators are produced.
- If the High PVC alarm priority is set to **2**, Alarm Priority 2 visual and audio alarm indicators are produced.
- A **High PVC** text message is produced above the ECG1 waveform area.

NOTE: PVC/min will not be displayed during periods of Ventricular Rhythms, V-TACH, V-FIB and Asystole.

Run Alarm

The **Run** alarm is activated when the number of consecutive PVCs occur at a rate that equals or exceeds the user defined V-Tach Rate. The number of consecutive PVCs that constitute a Run is one beat less than the minimum used to identify V-Tach.

The Run alarm is a Priority 2 alarm event that produces:

- Alarm Priority 2 visual and audio alarm indicators.
- A **RUN** text message above the ECG1 waveform area.

Trigeminy Alarm

The **Trigeminy** alarm is activated when three or more cycles of one PVC coupled to two normal beats are detected. This rhythm could also cause an Irregular HR alarm.

The Trigeminy alarm is a Priority 2 alarm event that produces:

- Alarm Priority 2 visual and audio alarm indicators.
- A **TRIGEMINY** text message above the ECG1 waveform area.

Ventricular Rhythm (V-Rhythm) Alarm

The **V-Rhythm** alarm is activated when more than 2 consecutive PVCs occur at a rate that is less than the user defined V-Tach Rate.

The V-Rhythm alarm is a Priority 2 alarm event that produces:

- Alarm Priority 2 visual and audio alarm indicators.
- A **VENTRICULAR RHYTHM** text message above the ECG1 waveform area.

2.4.2.6 Arrhythmia Analysis (Optional)

WARNING: The arrhythmia analysis feature is intended to detect ventricular rhythms, however, due to physiologic differences in patient populations, the Spectrum OR may occasionally sound a false alarm or may not recognize some arrhythmia patterns.

The **Spectrum OR** is capable of identifying ventricular arrhythmia patterns in Adult and Pediatric size patients. Arrhythmia analysis may be enabled or disabled via the **Arrhythmia Menu**. By default, arrhythmia analysis is enabled.

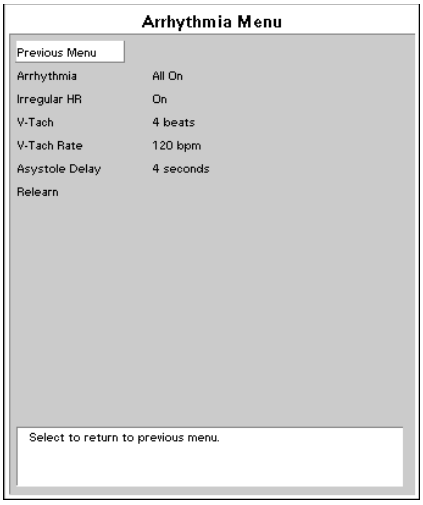


FIGURE 2-29 Arrhythmia Menu

Arrhythmia alarm calls are classified as Priority 1 or Priority 2.

Asystole, Ventricular Tachycardia, and Ventricular Fibrillation are classified as Priority 1 and the priority level cannot be changed by the user. In addition, these alarms will sound continuously until the user presses the **MUTE** or **MUTE ALL** key, regardless of whether the patient's condition has improved.

The other arrhythmia alarms (listed below) are classified as Priority 2 by default. The characteristics and priority level of the "PVC/min" alarm can be changed at the user's discretion via the **Alarm Setup** menu.

The following alarm calls can be made when Arrhythmia Analysis is set to "All On" (default setting):

- Asystole, Ventricular Tachycardia, Ventricular Fibrillation, Ventricular Rhythm, Run, PVC/Min, Couplet, Bigeminy, Trigeminy, Irregular HR and Bradycardia.

The following alarm calls will be made when Arrhythmia analysis is set to "Non-lethals Off":

- Asystole, Ventricular Tachycardia, and Ventricular Fibrillation.

When Arrhythmia analysis is set to "All Off," no arrhythmia alarm calls will be made.

The **Spectrum OR** initiates the Learning process for Arrhythmia measurements after one of the following:

- Unit Power-Up
- Return to normal monitoring from Standby mode
- Enabling Arrhythmia analysis
- The lead has been changed in ECG 1 waveform (3 lead only)
- Patient Size is changed
- Whenever the "Relearn" function is selected from the **ST**, **ECG** or **Arrhythmia Menus**.

It is recommended that a Relearn be initiated after one or more of the following:

- The ECG electrodes have been repositioned
- Sufficient time has passed since the last Relearn
- Any significant changes to the patient QRS complex
- Any significant changes to the patient ECG rhythm
- A clinician has observed clinically questionable arrhythmia calls

A Relearn must be initiated if "Learning" occurred during a "Leads Off" condition.

2.4.2.7 ST Analysis (Optional)

ST Analysis is available for Adult and Pediatric patients only.

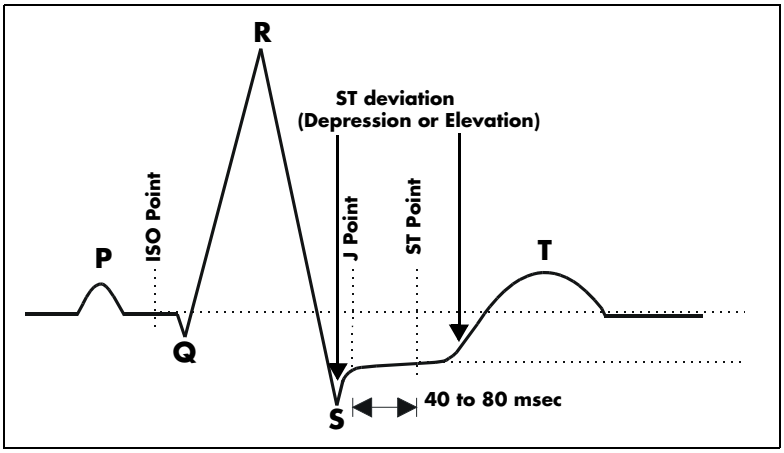


FIGURE 2-30 ST Monitoring

The depression or elevation of the ST segment is measured as the vertical distance between the isoelectric (ISO) point which provides the baseline, and the ST point (See figure above). ST measurements are available on a maximum of three user selected ECG leads at a point situated 80 ms (heart rate 120 bpm or less) or 60 ms (heart rate more than 120 bpm) from the algorithmically determined end point of the QRS (J Point). In addition, the user can also select from three (3) different settings for the ST measurement point (80, 60, or 40 ms) from the J-point and independent of heart rate. These measurements are valid only on normal beats. Abnormal beats, like ventricular beats, are excluded from the analysis of the ST segment. Ventricular paced beats are also rejected from the analysis of the ST segment, because pacemaker tails distort the shape of the ST segment.

ST segment changes are continuously measured by the monitor, but update of the displayed ST data is different depending on the ECG cable in use. When using a 3 or 5-lead ECG cable, the displayed ST data is updated approximately every 10 seconds.

NOTE: The ST algorithm has been tested for accuracy of the ST segment data. The significance of the ST segment changes must be determined by a clinician.

ST Minitrends or **Average ST** data may be displayed in any of the available waveform areas.

ST Minitrends are graphical displays of ST deviations. The data can be displayed at intervals of 15, 30 or 60 minutes, selectable via the **ST Setup Menu**. The ST scale is also adjustable with selections of ±2.5 mm, ±5 mm or ±10 mm.

Average ST is an on-screen display of both the learned ST complex and the current ST complex superimposed to show changes in ECG morphology over time. The learned ST complex will appear in white, with the current ST complex appearing in the ECG waveform color. (If the ECG waveform is white, then the learned complex will appear in green).

With a 3-lead cable, **ST Minitrends** and **Average ST** will display the ST data from ECG1. With a 5-lead cable, **ST Minitrends** and **Average ST** will display the ST data from ECG1, ECG2, and ECG3.

2.4.2.7.1 ST Analysis Setup

ST analysis begins when the feature is turned on from the **ST Menu**. By default, ST data will appear in the **Heart Rate Tile**, when using a 3-lead or 5-lead cable.

When using a 3-lead cable, ST Analysis is performed on the lead chosen as ECG1. With a 5-lead cable, ST Analysis is performed on the leads chosen as ECG 1, ECG 2 and ECG 3 on the **ECG Menu**.

To display ST data, set a waveform to display any ECG wave (i.e., ECG2, ECG3, etc.), or set any waveform to display **Average ST** or **Minitrends**, then set **Combine ST/HR** to **OFF**.

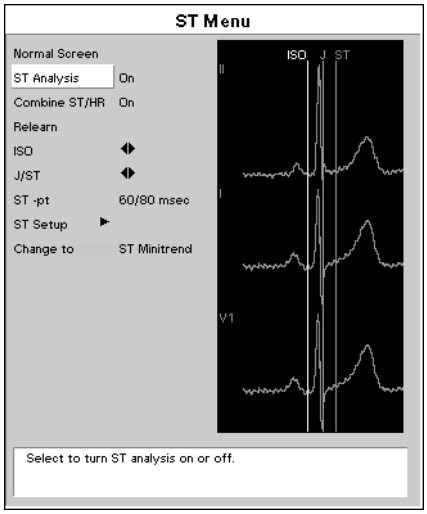


FIGURE 2-31 ST Menu

Adjusting the ISO and J/ST Point

1. Open the **ST Menu** by using the Navigator™ Knob to select the ST parameter heading. **ST Menu** can also be accessed through the **ECG Menu**.
2. Insure the **ST Analysis** selection in the **ST Menu** is **On**. The **Spectrum OR** will learn the patient's QRS complexes (one for a 3-lead cable or 3 for a 5-lead cable). These learned complexes will appear in the **ST Menu** with the monitor-selected **ISO** and **J/ST** points displayed.

3. Scroll to the **ISO** selection to adjust the isoelectric point on the learned QRS complex. The isoelectric point is the area of the QRS complex following the P-wave and before the start of the Q-wave.
4. Adjust the **ISO** point by pressing the Navigator™ Knob and turning to adjust the white **ISO** reference line. Press the Navigator Knob when the **ISO** point is satisfactory.
5. Scroll to the **J/ST** point heading. Adjust the **J/ST** point by pressing the Navigator Knob and turning to adjust the orange and green **J/ST** reference lines. Press the Navigator Knob when the **J/ST** points are satisfactory.
6. To adjust the **ST-pt**, scroll to the **ST-pt** heading and press the Navigator Knob to display a list of ST measurement point settings. Select the appropriate setting, then press the Navigator Knob when the **ST-pt** choice is satisfactory.

2.4.2.8 Relearning ST or Arrhythmia Analysis

The **Spectrum OR** initiates the learning process for ST measurements or Arrhythmia analysis after one of the following:

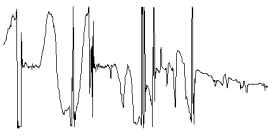
- Unit Power-Up
- Return to normal monitoring from **Standby** mode
- Enabling ST or Arrhythmia analysis
- The lead has been changed in ECG 1 waveform (3 lead only)
- **Patient Size** is changed
- Whenever the **Relearn** function is selected from the **ST**, **ECG** or **Arrhythmia Menus**

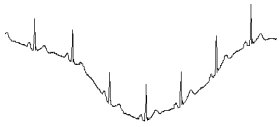
A **Relearn** is recommended after one or more of the following:

- ECG electrodes have been repositioned
- Eight hours have passed since the last **Relearn**
- After significant changes to the patient QRS complex
- A clinician has observed clinically questionable arrhythmia calls

A Relearn must be initiated if “Learning” occurred during a “Leads Off” condition.

2.4.2.9 ECG Troubleshooting

MESSAGE/PROBLEM	REASON	SOLUTION
Noisy ECG traces 	Loose or dry electrodes.	Apply fresh, moist electrodes.
	Defective electrode wires.	Replace wires as necessary.
	Patient cable or leads are routed too close to other electrical devices.	Eliminate 60Hz interference.
Excessive Electro-surgical Interference	Wrong ECG cable used.	Use ESIS ECG cable with internal filter block. **NOTE:** Respiration monitoring via the ECG electrodes will not be available when using the cable.

MESSAGE/PROBLEM	REASON	SOLUTION
Muscle Noise 	Inadequate skin preparation prior to application of electrode, tremors, tense subject, and/or poor electrode placement.	Repeat skin preparation and electrode location procedures. Apply fresh, moist electrodes. Avoid areas of the torso that are very muscular.
Intermittent Signal	Connections not tight and/or properly secured.	Ensure proper connection. (Electrode to lead, lead to cable, cable to monitor).
	Electrodes dry or loose.	Re-prep skin and apply fresh, moist electrodes.
	Cable or lead wires damaged.	Check with continuity tester.
Excessive alarms: heart rate, lead fault	Electrodes dry	Re-prep skin and apply fresh, moist electrodes.
	Alarm limits set too close to patient's normal heart rate.	Readjust
	R-wave wrong size	Must have a higher amplitude than the other ECG waves, like the P and T waves.
	Excessive patient movement or muscle tremor.	Reposition electrodes and secure with tape, if necessary.
Low Amplitude ECG Signal	Gain set too low.	Readjust as required - (Set via the **SIZE** key).
	Electrodes dry / old	Apply fresh, moist electrodes
	Skin improperly prepared	Abrade skin
	This could be the patient's normal QRS complex.	Verify with a 12-lead electro-cardiogram.
	Electrode could be positioned over a bone or muscle mass.	Move ECG patches closer towards each other.
No ECG Waveform	Gain set too low.	Readjust as required - (Set via the **SIZE** key).
	Lead wires and patient cable not fully or properly inserted.	Check for proper insertion.
	Cable or lead wires damaged.	Check with lead continuity tester.
Base Line Wander 	Patient moving excessively.	Secure lead wires and cable to patient.
	Patient's respiration	Reposition electrodes
	Electrodes dry or loose	Re-prep skin and apply fresh, moist electrodes.
	Static build up around patient.	Check with local biomedical personnel.
	ECG Filter set to "ST" or "Extended" mode.	Set ECG Filter to "Monitor" mode.

MESSAGE/PROBLEM	REASON	SOLUTION
"Artifact" Message	The 12-lead ECG is detecting muscle artifact, or electrical interference from auxiliary devices.	Check leads, follow skin preparation procedure. Check for electrical interferences, replace wires as necessary.
ECG erratic/monitor shuts down	When in auto-detect mode, the monitor switches between 3-lead and 5-lead mode because the leads are wet/ contaminated, the cable is wet/contaminated or the cable is damaged.	Clean the leads/cable and allow to dry completely. Change the cable.

2.4.3 Non-Invasive Blood Pressure Measurements (NIBP)

In the **Spectrum OR**, Non-Invasive Blood Pressure monitoring utilizes the oscillometric method of measurement. The NIBP measurement includes Systolic (Sys), Diastolic (Dia) and Mean Blood Pressure.

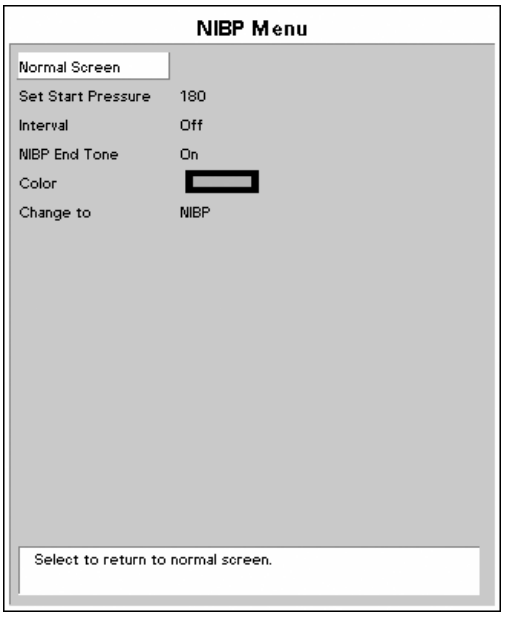


FIGURE 2-32 NIBP Menu

2.4.3.1 Manual NIBP Measurements

1. Select a blood pressure cuff that is appropriate for the size of the patient. Measure limb for the best results.

NOTE: **A cuff that is too narrow for the limb will result in erroneously high readings. The correct size of the pressure cuff for a given patient has, among other considerations, a direct bearing on the accuracy of the obtained NIBP measurements. Base selection of the cuff size on the limb circumference of the patient. The design dimensions of the cuffs and their intended uses are based on recommendations of the American Heart Association.**

NOTE: **Cuffs become brittle as they age and sometimes develop permanent folds that can leave temporary marks on the limb. Any cuffs that exhibit this effect should be replaced.**

NOTE: **Ensure that the pressure tubes are not compressed or restricted.**

NOTE: **The pressure on the limb may not fall to zero between measurements if the cuff is wrapped too tightly. Therefore, ensure that the cuff is properly applied.**

NOTE: The skin is sometimes fragile (i.e., on pediatrics, geriatrics, etc.). In these cases, a longer interval between measurements should be considered to decrease the number of cuff inflations over a period of time. In extreme cases, a thin layer of soft roll or cotton padding may be applied to the limb in order to cushion the skin when the cuff is inflated. This measure may affect NIBP performance and should be used with caution.

2. Attach cuff hose to NIBP Connector.

3. Apply the cuff to the patient. To reduce errors, the cuff should be adjusted for a snug fit. Little or no air should be present within the cuff. Be sure the cuff lies directly against the patient's skin. No clothing should come between the patient and the cuff.

NOTE: The NIBP cuff should not be placed on a limb that is being utilized for any other medical procedure. For example, an IV catheter or an SpO_2 sensor.

4. If not already selected, select the **Patient Size** through the **Patient Menu**. Choices are **Adult**, **Pediatric** or **Neonate**.

5. If necessary, change the initial cuff inflation pressure through the **NIBP Menu**. Initial cuff inflation pressures depend on the **patient size** setting. The values for cuff inflation are identified in the following table:

PATIENT SIZE SETTING	INITIAL CUFF INFLATION VALUES	DEFAULT SETTING	MAXIMUM INFLATION VALUES
Adult	100 - 280 mmHg	180 mmHg	300 mmHg
Pediatric	60 - 180 mmHg	140 mmHg	195 mmHg
Neonate	40 - 120 mmHg	100 mmHg	150 mmHg

6. Press **START** to begin an NIBP measurement.

CAUTION: Cuffs must be used with the manufacturer's correct and approved hoses.

CAUTION: Please consult a physician for interpretation of blood pressure measurements.

CAUTION: A blood pressure measurement can be affected by the position of the patient, and his / her physiological condition as well as other factors, such as patient movement.

NOTE: Inflate the cuff only after proper application to the patient's limb. Cuff damage can result if the cuff is left unwrapped and then inflated.

7. The cuff begins to inflate to the selected cuff pressure. After reaching the selected value the cuff begins to slowly deflate and the **Spectrum OR** collects oscillometric pulsations.

8. If the initial cuff inflation is found to be inadequate, the unit retries with a higher inflation pressure (+50 mmHg in adult or pediatric mode; +40 mmHg in neonate mode).

9. The patient should remain still to avoid the introduction of unnecessary motion artifact. After the cuff pressure drops below the diastolic pressure, the results of the measurement are displayed.

10. If **NIBP End Tone** is set to **On** in the **NIBP Menu**, a double tone (with the second tone higher in pitch than the first) will sound to indicate a successful NIBP measurement.

If NIBP is the only parameter being measured with the **Spectrum OR**, a heart rate can be derived from NIBP. The **HR Source Menu** selection must be in the **Auto Mode** (i.e., not selected for ECG, IBP or SpO_2) with no heart rate alarm limits set. If another heart rate source is available, the NIBP heart rate will be replaced by the heart rate from the other available source.

If NIBP is a selected trend source, then NIBP data will be recorded in the trend with the time stamp of the reading. If NIBP is not a selected trend source, then NIBP data will be recorded in the trend with the next entry into the trend caused by another trigger (i.e., **ALARM, INTERVAL**, or **MARK EVENT** key press). The time stamp will be that of the trigger causing the trend entry. The NIBP measurement and NIBP heart rate will be automatically removed from the display after a predetermined time interval. The NIBP timeout interval is 15 minutes by default and can be set to a different value through the **Installation Menu**.

2.4.3.2 Automatic Interval NIBP Measurements

There are two modes available for automatic NIBP measurements. They are the **Interval Mode** and the **Timer Mode**. The **Interval Mode** allows you to set the interval between measurements. For example, if the interval is set to 10 minutes and the **START** key is pressed at 10:12, the measurements will be taken at 10:12, 10:22, 10:32, etc. The **Timer Mode** allows you to set an interval that is synchronized with the real time clock. For example, if the timer is set to 30 and the **START** key is pressed at 10:12, the measurements will be taken at 10:12, 10:30, 11:00, 11:30, etc.

1. Select the **Interval Mode** or the **Timer Mode** in the **Monitor Setup Menu**.

2. Press **INTERVAL** until the desired time displays. The choices are: **OFF**, **Continuous**, **1**, **2.5**, **3**, **5**, **10**, **15**, **20**, **30**, **60**, and **120 minutes** and **4 hours**.

3. Press **START** to begin taking interval measurements.

NOTE: **If the monitor is in the interval mode when it is turned ON, no measurement will be taken until the START key is pressed.**

Automatic Adjustment in the Interval Mode

In the **Interval Mode**, the unit adjusts the inflation pressure according to the previous reading of the systolic pressure. After the first measurement in the timer mode, the inflation pressure is the previous systolic +50 mmHg in the **Adult Mode** or **Pediatric Mode** and +40 mmHg in the **Neonate Mode**.

Suspension of NIBP Measurements

1. Press **STOP** to suspend an automatically timed measurement sequence or to end a measurement cycle already in progress (deflate cuff).
2. Press **START** to take an immediate measurement and resume a suspended timed measurement sequence.

NOTE: **You can press STOP at any time to postpone a scheduled measurement or to terminate a measurement cycle already in progress.**

CAUTION: **Observe caution on all patients (Neonates, Pediatrics, and Adults) when NIBP is set to the Continuous Mode and the 1 minute interval. When the NIBP continuous interval is selected, the Spectrum OR will continually take back to back blood pressure readings. As a safety precaution, a limit is placed on continuous and 1 minute interval measurements. In continuous mode, after 5 minutes, the NIBP interval will automatically switch to one measurement taken every 5 minutes. In 1 minute mode, after 10 minutes the NIBP interval automatically switches to measurements taken once every 10 minutes. Reports have been made of nerve injury occurring during use of automatically cycled blood pressure cuffs.**

NIBP Pressure Limit Fail Safe

If the cuff is over-pressurized, the cuff will automatically vent to atmosphere and the **NIBP message window** will alternately read **Cuff Over Pressure** and **Unable to Measure**.

Cuff Inflation Time

If the cuff pressure does not attain 20 mmHg within 40 seconds of the start of inflation or if the target pressure is not reached within another 60 seconds, then the cuff is vented and the **Retry** or **Unable to Measure** message will display in the **NIBP message window**.

START and STOP Functions

The **START** and **STOP** functions have the following effects on the timed measurement sequence (**Interval** or **Timer Mode**).

INTERVAL is set and you press **START**:

An unscheduled measurement is made. Taking this unscheduled measurement does not affect the timing of the interval cycle, therefore, the scheduled measurements will be taken as if there were no interruptions. Only one measurement is taken for each measurement cycle - therefore, if the unscheduled measurement coincides with the scheduled measurement, it counts as the scheduled measurement. If the interval is changed without pressing the **STOP** key, interval measurements will continue at the newly chosen interval.

INTERVAL is set and you press **STOP** during the measurement:

1. The cuff deflates and interval measurements are suspended.
2. **INTERVAL** is set and you change the interval.
3. The measurement cycle is reset with the new interval. A measurement will be taken after you press the **START** key.

NIBP Auto Time Out Functions

The NIBP data will time out on the display under the following conditions:

- When the elapsed time exceeds the pre-set time out in the installation mode
- If a measurement is unsuccessful, the display values are replaced with "**XX**" and a tone sounds

Indirect BP Measurements and Associated Errors

Place the patient in a supine position to obtain true physiological pressure. If the cuff is not at the patient's heart level, the pressure values obtained will not reflect the true physiological pressure. Instead, the readings will be decreased by 1.86 mmHg for every inch the cuff is placed above the heart level and increased by 1.86 mmHg for every inch the cuff is placed below the heart level. This effect is due to hydrostatic pressure.

Blood weight influences blood pressure readings. The value of the weight of blood depends on where the measurement is taken with respect to the heart. When the patient is supine, on a flat surface, the arm is near enough to the heart level that no adjustment of the NIBP readings is necessary.

Recommendations for Automatic Blood Pressure Measurements

The following practices are recommended when making automatically cycled blood pressure measurements:

- Position and support the limb in such a way as to minimize stretching of and weight exertion on affected nerves
- Avoid cuff placement that applies pressure on the ulnar nerve. Cuff tubing should not exit the cuff over the course of the ulnar nerve at the elbow
- Select a measurement interval that provides adequate venous drainage during cuff deflation
- Periodically inspect the limb bearing the cuff in order to detect venostasis
- If necessary move cuff to another limb to relieve single-limb stress

Cuff Size

Using a narrow cuff gives erroneously high pressure readings. If a standard cuff is applied to an obese patient or a patient with large biceps, the extra tissue and fat will dissipate the applied pressure requiring an additional pressure increase to collapse the artery. On the other hand, over-wrapping a slender arm gives erroneously low pressure readings because too much force per unit area is exerted. This requires less pressure to collapse the artery.

Other Factors

An accurate determination of blood pressure by the **Spectrum OR** can be difficult if cardiac rhythm is irregular. Irregular cardiac rhythm changes the stroke volume from beat to beat. This changing stroke volume may increase the time it takes the **Spectrum OR** to take a measurement. The **Spectrum OR** makes up to four successive attempts to obtain a measurement. If a measurement cannot be taken after four tries, the numeric displays are zeroed.

User Verification of Spectrum OR Blood Pressure Measurements

Regular service to blood pressure equipment will help insure accurate measurements. Consult your Service Manual for appropriate information. If you question the accuracy of the **Spectrum OR**, verify the blood pressure with a manometer.

Auscultatory verification can be made at the same time the **Spectrum OR** is taking a measurement. Apply a bell stethoscope over the brachial artery. Do not allow the stethoscope to touch either the patient's clothing or the pressure cuff.

Newborn NIBP Technique

Newborn patients present unique obstacles to NIBP measurement. Their vital signs can change from moment to moment, and their tiny physiological signals are very prone to noise interference. The following suggestions will help you to obtain the best possible NIBP measurement:

1. Try to measure infants when they are calm. A kicking/crying baby may disturb or jiggle the cuff, causing noise within the system and resulting in unstable blood pressure readings. If necessary, hold the cuffed limb steady, without impeding circulation. Do not hold onto the cuff and do not pat the cuffed limb to comfort the child.
2. Try the calf. Irritable newborns will react to the cuff pressure but may tolerate the calf better than the arm. Place the cuff just above the ankle.
3. Use the correct **Newborn** and **Infant** size cuffs. When applying, verify the cuff's **Index** line falls between the **Range** lines.
4. Try disposable cuffs. Disposable cuffs are more pliant than reusable ones. They generally fit smaller infants better.
5. Place the cuff lightly. If the cuff is too snug, it won't work properly. On infants, you should be able to easily move the cuff over the limb.

NOTE: **NIBP cannot be taken under all conditions. Even manual methods, employing a sphygmomanometer and stethoscope, will not work on unstable or active patients.**

2.4.3.3 NIBP List Tile

The NIBP List tile can display up to five of the most recent NIBP measurements in row form. These measurements are displayed from newest (in the top row) to oldest (in the bottom row). As shown in the example of **FIGURE 2-33**, each row displays a time stamp, the three digit systolic and diastolic pressures separated with a "/", and the three digit mean pressure in parentheses.

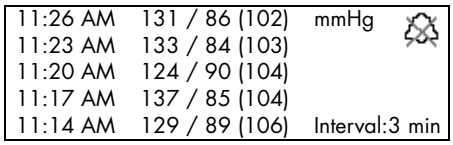


FIGURE 2-33 Example NIBP List Tile

The NIBP List tile can be configured from the **Display Setup Menu** to display in one of the parameter tiles (1 - 5) and it has a menu target labeled "NIBP" that opens the **NIBP Menu**.

2.4.3.4 NIBP Troubleshooting

MESSAGE/PROBLEM	REASON	SOLUTION
NIBP: Manual Mode	Displayed while system is idle. **Note: This is not displayed while in the interval mode.**	Press **START** to take a single measurement. Select an interval and start timed measurements.
NIBP: Deflate	Displayed when a measurement that is in process is stopped by pressing the **STOP** key.	Press **START** to take an immediate measurement and resume timed measurements.
NIBP: Interval	Displayed during the interval between two timed measurements.	Press **STOP** to suspend timed measurements. Change timer to **OFF** to stop timer.
NIBP: Failure	The system has detected an unrecoverable failure of the NIBP system.	Power cycle unit. If message reappears, contact Customer Support.
NIBP: Measuring	Displayed during a measurement. Cuff pressure is also displayed.	Press **STOP** to suspend a measurement and deflate the cuff.
NIBP: Retry Pump Higher	A measurement has been attempted but no reading was possible. This results from inadequate cuff inflation.	Retry will be attempted. Check that appropriate patient size is set. Preset initial inflation pressure.
NIBP: Retry	A measurement has been attempted but no reading was possible and the retry limit has not been reached.	Retry will be attempted. Check for leaks and quality of peripheral pulses. Decrease patient movement. Switch cuff to another limb.
Unable To Measure	An unsuccessful measurement cycle has been completed.	Switch cuff to another limb. Decrease patient movement. Press **START** to retry. Be prepared to auscultate BP manually. Contact Customer Support.

MESSAGE/PROBLEM	REASON	SOLUTION
NIBP: Cuff Overpressure	The hardware overpressure limit has been exceeded.	Power cycle unit. If message reappears, contact Customer Support.
NIBP: Cuff Overpressure/ Press STOP to clear.	The hardware overpressure limit has been exceeded.	Press **STOP** to clear the hardware overpressure. If message reappears, contact Customer Support.
NIBP: Check Calibration	The software has detected that the overpressure transducer is out of calibration.	Have the unit calibrated. If problem persists contact Customer Support.
Unable to obtain a BP	Patient movement	Wait until patient is calm or gently hold limb.
	Cuff or hose NOT attached / leaking	Check all connections.
	HR irregular / arrhythmia present	Check Patient and notify Physician.
	Blood pressure is out of range.	Check Patient and verify BP with manual method.
	Improper cuff size / brand	Measure patient limb. Use only properly sized approved accessories.
Reading too high or too low	Incorrect cuff size	Measure Patient limb, use correct cuff.
	Patient movement	Wait until patient is calm or gently hold limb.

NOTE: Always have an alternate method of BP verification available.

NOTE: On vasoconstricted patients, failure to evacuate air from the cuff can distort BP measurement.

NOTE: Cuff should be at heart level.

NOTE: The presence of an arrhythmia may increase the time required to complete a measurement and may cause measurement cycle to extend beyond a point where a measurement can be completed.

2.4.4 SpO_2 Pulse Oximetry

Pulse oximetry is a continuous and non-invasive measurement of the amount of oxygen attached to the hemoglobin in red blood cells. SpO_2 is an estimation of arterial oxygen saturation, SpO_2 may be used interchangeably with SaO_2. The **Spectrum OR** comes standard with Masimo SET® SpO_2. Nellcor® OxiMax® SpO_2 is an option.

SpO_2 Measurements

1. Select the appropriate sensor for the patient.
2. Attach the SpO_2 patient cable to the sensor and plug the other end of the patient cable into the SpO_2 connector located on the left side panel of the monitor.

NOTE: Do not place the sensor on an extremity with an IV catheter or blood pressure cuff in place.

NOTE: Ensure proper routing of patient cable to avoid entanglement and/or strangulation.

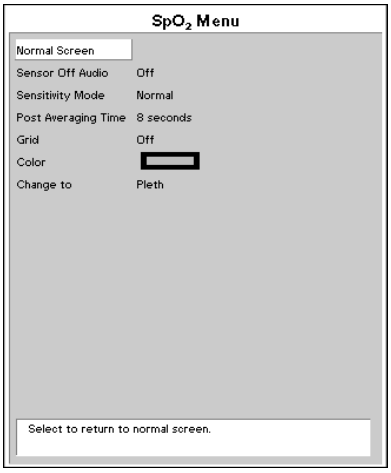


FIGURE 2-34 SpO_2 Menu-Masimo SET® equipped unit

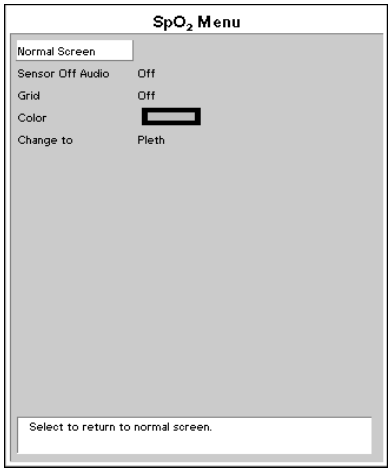


FIGURE 2-35 SpO_2 Menu-Nellcor® equipped unit

3. The pleth waveform and digital SpO_2 value will be displayed by default in the second waveform and parameter area.
4. Enter the **Display Setup Menu** to describe Pleth waveform and data in an alternate location.
5. Set **Sensor Off Audio** in the **SpO_2 Menu** to the desired setting. When set to **Off**, the **Spectrum OR** will not give an audio beep. When set to **On**, the **Spectrum OR** will sound a series of 5 triple beeps when the sensor is detected to be off of the patient.

Calibration

The oximetry sub-system incorporates automatic calibration mechanisms. No other calibration is required.

Auto Scaling

The pleth waveform is automatically scaled and is not proportional to the patient's pulse volume. There is no adjustment that can be made to the pleth waveform.

CAUTION: Tissue damage or inaccurate measurements may be caused by incorrect sensor application or use, such as wrapping too tightly, applying supplemental tape, failing to inspect the sensor site periodically, or failing to position appropriately. Carefully read the sensor directions for use, the Spectrum OR Operating Instructions, and all precautionary information before use.

CAUTION: Inaccurate SpO_2 measurements may be caused by:

- **Incorrect sensor application or use**
- **Significant levels of dysfunctional hemoglobins, (e.g., carboxyhemoglobin or methemoglobin)**
- **Intra-vascular dyes such as indocyanine green or methylene blue**
- **Exposure to excessive illumination such as surgical lamps (especially ones with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, or excessive ambient light. In such cases, cover the sensor site with opaque material.**
- **Excessive patient movement**
- **Venous pulsations**
- **Electro-surgical interference**
- **Placement of a sensor on an extremity that has a blood pressure cuff, arterial catheter, or intra-vascular line.**
- **Nail polish or fungus**

CAUTION: In certain situations in which perfusion and signal strength are low, such as in patients with thick or pigmented skin, inaccurately low SpO_2 readings will result. Verification of oxygenation should be made, especially in preterm infants and patients with chronic lung disease, before instituting any therapy or intervention.

CAUTION: Many patients suffer from poor peripheral perfusion due to hypothermia, hypovolemia, severe vasoconstriction, reduced cardiac output, etc. These symptoms may cause a loss in vital sign readings.

CAUTION: Prolonged and continuous monitoring may increase the risk of skin erosion and pressure necrosis at the site of the sensor. Check the SpO2 sensor site frequently to ensure proper positioning, alignment and skin integrity at least every eight (8) hours; with the Adult and Pediatric re-usable finger sensor, check every four (4) hours; for neonates and patients of poor perfusion or with skin sensitive to light, check every 2 - 3 hours; more frequent examinations may be required for different patients. Change the sensor site if signs of circulatory compromise occur.

CAUTION: When cleaning sensors, do not use excessive amounts of liquid. Wipe the sensor surface with a soft cloth, dampened with cleaning solution. Do not attempt to sterilize.

2.4.4.1 Masimo SET® SpO_2

Spectrum OR monitors equipped with Masimo SET SpO_2 allow the user to adjust **Sensitivity** and **Post Averaging Time**. The user should choose the sensitivity mode depending upon signal quality and patient motion. In most cases, the normal setting is appropriate. If patient motion is limited, high sensitivity can be used.

It is also possible to change the averaging time of the **Saturation** and **Pulse Rate** measurements. The **Post Average Time** can be changed to **6**, **8**, **10**, **12**, **14 or 16 seconds**.

CAUTION: When equipped with Masimo SET® SpO_2, use only Masimo SET Oxygen Transducers including Masimo SET LNOP® and LNCS® Patient Dedicated Adhesive Sensors and Masimo SET PC Series Patient Cables. Use of other oxygen transducers may cause improper oximeter performance.

Masimo SET Sensors

Masimo SET provides a family of sensors suitable for a wide variety of clinical settings and patients. Specific sensors have been developed for neonates, infants, children, and adults. All sensors are indicated for continuous non-invasive monitoring of arterial oxygen saturation (SpO_2) and pulse rate, all sensors are non-sterile and usable during patient movement.

The Adult Reusable Finger Sensors can also be used for spot check applications if needed. All sensors are intended for single-patient use only unless indicated as "reusable."

2.4.4.2 Nellcor® SpO_2

CAUTION: When equipped with Nellcor® SpO_2, use only Nellcor oxygen transducers including Nellcor Oxisensor® and OxiMax® patient dedicated adhesive sensors. Use of other oxygen transducers may cause improper oximeter performance.

Nellcor Sensors

Nellcor provides a family of sensors suitable for a wide variety of clinical settings and patients. Specific sensors have been developed for neonates, infants, children, and adults. Oxisensor® and OxiMax® oxygen transducers are sterile adhesive sensors with optical components mounted on adhesive tape. Oxiband® oxygen transducers and the Duraform® oxygen transducer system are reusable sensors that are applied with disposable adhesive. The Durasensor DS-100A Adult Digit Oxygen Transducer is a reusable sensor with its optical components mounted in a plastic casing. The Nellcor RS-10 and Max-Fast® oxygen transducers are adhesive sensors for application on the forehead or temples.

To order all Nellcor accessories and sensors call **1-888-744-1414.**

Selecting a Nellcor Sensor

Sensors are designed for specific sites on patients with designated weight ranges. To select the appropriate sensor, consider the patient's weight, level of activity, adequacy of perfusion, which sensor sites are available, whether sterility is required, and the anticipated duration of monitoring.

NOTE: Only Nellcor oxygen transducers should be used with the Spectrum OR monitors with Nellcor OxiMax® pulse oximetry.

2.4.4.3 SpO_2 Troubleshooting and SpO_2 Menu Performance Considerations

To ensure optimal performance, use an appropriate sensor, apply it as directed and observe all warnings and cautions.

If excessive ambient light is present, cover the sensor site with opaque material. Failure to do so may result in inaccurate measurements. Light sources that can affect performance include surgical lights, especially those with a xenon light source, bilirubin lamps, fluorescent lights, infrared heating lamps, and direct sunlight.

In the event that you are unable to get a reading, or the reading you get is inaccurate, consider the following:

CAUTION: A functional tester cannot be used to assess the accuracy of the pulse oximeter probe or a pulse oximeter monitor.

- If your patient is poorly perfused, try applying the sensor to another site - such as a different finger or toe
- Check that the sensor is properly aligned
- In electrosurgery, make sure sensor is not too close to ESU devices or cables
- Check to make sure the site area is clean/non-greasy. Clean site and sensor if needed.

MESSAGE/PROBLEM	REASON	SOLUTION
SpO_2: No Sensor	Sensor is not plugged in to the **Spectrum OR**.	Plug the sensor into the monitor.
SpO_2: Sensor Off (Masimo SET® Only)	Sensor may not be connected to the patient.	Check patient connection.
SpO_2: Interference	Noise detected on the pulse signal prevents pulse discrimination.	Decrease patient motion, check sensor.
SpO_2: Pulse Search	Hardware settings are being adjusted in order to discriminate a pulse waveform.	Change to site where pulse is stronger if patient is vasoconstricted. Change or readjust sensor if loose.
SpO_2: No Pulse (Nellcor Only)	No detectable pulse is measured	Check to patient connection and patient status.
SpO_2: Failure	The system has detected an unrecoverable failure of the SpO_2 system.	Power cycle unit. If message reappears, contact Customer Support.
SpO_2: Low Perfusion (Masimo SET Only)	Patient perfusion is low.	Check to patient connection and patient status.
SpO_2: Too Much Light (Masimo SET Only)	There is too much ambient room light for the sensor to function properly	Minimize the room light around the patient. Check sensor.
SpO_2: Unrecognized Sensor (Masimo SET Only)	The sensor is not recognized by the Monitor.	Replace the sensor with a Company recommended sensor.
SpO_2: Communication Error	The monitor and the SpO_2 modules are not communicating properly.	Power cycle unit. If problem persists, contact Customer Support.

MESSAGE/PROBLEM	REASON	SOLUTION
SpO_2: Board Fault	Masimo SET board failed to operate properly.	See Proper Service Menu: Suggestion.
SpO_2: Sensor Fault	Defective Sensor.	Replace Sensor.
SpO_2: Motion (Nellcor Only)	Motion is detected	Decrease patient motion, check sensor.
SpO_2: Check Sensor (Nellcor Only)	The SpO_2 module has sensed a poor connection or a bad sensor	Reconnect the same sensor. If problem persists, replace sensor
Unable to obtain SpO_2 reading	Patient has poor perfusion.	Switch limbs / Notify physician.
	Sensor not on Patient.	Reapply sensor.
	Cables loose / not connected.	Check connections, switch cable.
	Ambient light.	Switch limbs and cover sensor with opaque material.
No SpO_2 waveform	Waveform not selected to Display.	Go to the **Display Setup Menu**, choose to display **Pleth** in the waveform area.
	Cable or sensor not plugged in	Check cable and sensor
Low amplitude SpO_2 signal	SpO_2 sensor on same limb as cuff.	Check sensor placement, move as necessary.
	Patient has poor perfusion.	Switch limb / Notify physician.
"–" in Digital Data	Data is above maximum value Data is below maximum value Parameter is not available Lead or sensor is off	Check sensor placement, move as necessary. Switch limb/Notify physician.

2.4.5 Temperature Menu

The temperature measurement function of the **Spectrum OR** is designed to take a continuous temperature reading from YSI 400 or YSI 700 or compatible probes. To display the **Temperature Menu**, turn the Navigator™ Knob to the **Parameters Menu**. Press the Navigator Knob and rotate down to highlight **Temperature**. Press the Navigator Knob again and the **Temperature Menu** will appear.

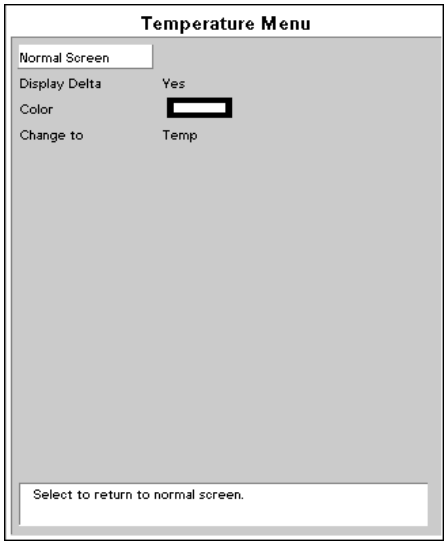


FIGURE 2-36 Temperature Menu

To display temperature in a parameter tile, go to **Display Setup Menu** and select a tile in which to display temperature.

Measuring Temperature

The **Spectrum OR** Monitor has three (3) potential temperature measurement sources: the TI connector on the monitor, the T2 connector on an External Parameter Module (EPM) and a PA catheter (T Blood) from an EPM or an Edwards Vigilance® Monitor. Data for up to two (2) of these sources may be simultaneously displayed.

T1 and TBlood data have display priority over T2 data. If all three (3) temperature sources are being used, T2 data will not appear on the display, although T2 alarms will still function and T2 data will appear on printouts and continue to accumulate in the trend data.

Whenever two (2) temperatures are being displayed, the difference between them (ΔT) may also be displayed.

To display ΔT in the **Temperature Parameter Area**:

1. Ensure that two temperature sources are connected.
2. Go to the **Temperature Menu** and select **Display Delta**, then select **Yes**.

2.4.5.1 Temperature Troubleshooting

MESSAGE/PROBLEM	REASON	SOLUTION
Temperature Probes not Working	Poor contact from probes to body	Check the body surface contact at the probe tip
		Reposition or apply thermoconductive gel
Temperature not displayed	Improper display setup	Check display setup in **Monitor Setup Menu** and change as desired
	Cable not plugged in	Check the cable

2.4.6 Respiration Menu

Respirations, or the amount of breaths per minute, are measured by 2 methods in the **Spectrum OR**. The first method is thoracic impedance through the ECG signal. The second is by CO_2 exchange via Microstream® CO_2 or via the Gas Module.

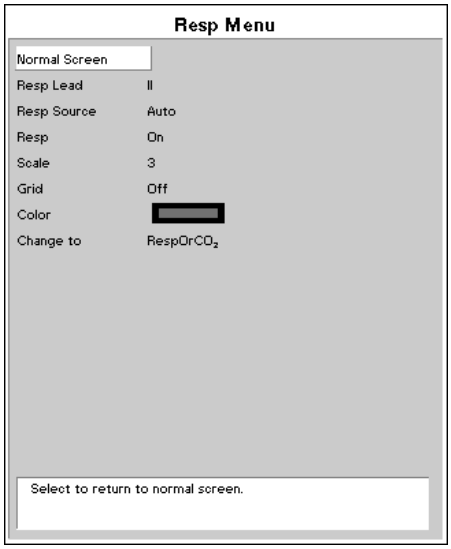


FIGURE 2-37 Respiration Menu

2.4.6.1 Thoracic Impedance

The **Spectrum OR** Monitor presents a small electrical signal across the RA and LA (or R & L) ECG limb leads. This signal changes as the patient's chest wall rises and falls during the breath cycle. The advantage of the thoracic impedance method is that respiration is obtained non-invasively. It is important to use cables with internal resistors for thoracic impedance.

ESIS choke block cables have electrical filters that may be used in electro-cautery environments where ECG interference can be substantial. These filters remove the electro-cautery noise, but also block the signal used by the **Spectrum OR** Monitor to measure respiration.

The filling and emptying of the heart chambers can interfere with the thoracic impedance signal, so called cardiovascular artifact (CVA), such that the respiratory signal matches the heart rate. The **Spectrum OR** warns the operator when the respiration value equals the heart rate by displaying "**CVA**".

If the patient's airway is obstructed and the patient attempts to breath, then the chest wall can move and create a respiratory signal even though no gas flow is occurring in the patient.

CAUTION: Some pacemakers may contain a respiratory sensor that may produce artifact on an ECG waveform.

2.4.6.2 Microstream® CO_2 Monitoring (Optional)

Microstream CO_2 modules provide **Expired CO_2**, **Inspired CO_2** and **Respiration Rate** monitoring utilizing a small lumen FilterLine® Microstream capnography that is acquired via a nasal cannula (non-intubated) or through an adapter set for use in a breathing circuit (intubated). Microstream can be used on adult, pediatric and neonatal patients.

To begin monitoring Microstream CO_2:

1. Connect one end of an exhaust line to the exhaust port on the **Spectrum OR** and the other end to the hospital gas scavenging system.
2. Select **CO_2** or **AUTO** as the **Resp. Source** in the **Resp Menu**.

CAUTION: Vacuum (negative pressure) should not exceed 1 mmHg at the Spectrum OR Pump Exhaust fitting. Excessive scavenge vacuum may result in an Occlusion message or damage to the Spectrum OR's internal pump. The scavenging system must be on during calibration.

3. Open CO_2 input door and connect the proper FilterLine® to the Monitor. Connect the opposite end to the patient.

WARNING: When monitoring CO_2 with a Spectrum OR, the maximum sampling rate at the nasal cannula is 58 ml/min. This device should not be used on patients whose breathing could be impaired by this vacuum flow rate.

WARNING: When monitoring CO_2, connection from the exhaust port of the Spectrum OR to the hospital's waste gas scavenging system is recommended to prevent exposure of hospital personnel to the patient's respiratory sample.

NOTE: Ensure all tubing connections are secure. Ensure that the nasal cannula is away from all sources of CO_2 (including the patient's and your own exhaled breath and ventilator exhaust valves) during the warm up period.

2.4.6.3 Microstream® CO_2 Menu

Accuracy verification of the Microstream CO_2 is recommended at one (1) year intervals, or whenever the readings appear to be in error. The date of the last successful calibration appears on the **CO_2 Calibration Menu**.

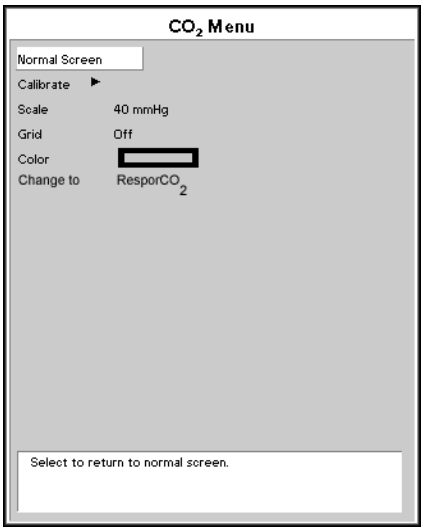


FIGURE 2-38 CO_2 Menu

NOTE: For maximum accuracy during calibration, a 20 minute warm-up time is recommended.

1. Connect the tubing that comes with the calibration gas to the gas canister and to the FilterLine. Use calibration gas, part number 0075-00-0033-01 and a Microstream FilterLine®. Attach the gas / tubing assembly to the CO_2 input port on the **Spectrum OR**.
2. Select the **CO_2 Parameter Tile** by rotating Navigator™ Knob and pressing the Navigator Knob after the **CO_2 Menu** is highlighted. The same menu can be accessed by using the **Parameters Tile** and selecting **CO_2**.
3. Select the **Calibrate** and press the button on the gas canister to begin releasing the gas mixture.

NOTE: Auto zero occurs at the start of the CO_2 monitoring session and periodically throughout the monitoring session. Auto zero will last approximately 15 seconds.

4. Select **Start** from the **Calibration Menu**. Once the **Start** option has been selected, no CO_2 waveform data will be displayed.
5. The message **Calibrating, continue to apply 5% CO_2** will appear in the **Calibration Menu**.

NOTE: If no gas is being delivered, or the mixture does not contain 5% CO_2, the message "Calibration error. Caused by no gas or wrong gas concentration" will appear. Obtain a new gas canister and return step 1.

6. When the proper gas mixture is applied, the message **Calibrating, continue to apply 5% CO_2** will appear in the **Calibration Menu** window. When the calibration is complete, the message will change to **Calculating, calibration gas can be removed**. Release the button and remove the connector from the canister.
7. After a moment, the message will change to **Calibration Completed Successfully**. The date and time of the successful calibration will appear in the **Calibration Menu**.
8. Rotate the Navigator™ Knob to **Previous Menu** and press to select.
9. Rotate the Navigator Knob to **Normal Screen** and press to return to the monitor's normal display screen.
10. When the **Spectrum OR** has detected valid breaths, numbers will display for the **CO_2**, **Inspired CO_2** and **Respiratory Rate**.
11. The CO_2 respiration waveform and data will automatically replace the ECG Respiration waveform and data on the display. If respiration wave or data is not displayed, use the **Display Setup Menu** to select **RESP** or **CO_2** to be displayed as desired.
12. If desired, the CO_2 waveform scale can be changed through the **CO_2 Menu**.

CAUTION: Microstream® CO_2 waste and CO_2 FilterLine® should be treated as biohazardous waste.

2.4.6.4 Respiration and CO_2 Troubleshooting

MESSAGE/PROBLEM	REASON	SOLUTION
Resp. Waveform Too Large	Scales set inappropriately.	Change lead selection.
		Change Respiration scale.
Resp. Waveform Too Small	Patient breathing is shallow or patient is turned on side.	Change lead selection.
	Scale set inappropriately.	Change respiration scale.
False Apnea Alarm	Apnea delay may be improperly set.	Choose an.other apnea delay
	Patient may be having frequent episodes of CVA.	Reposition electrodes to better detect respirations.
	Scale size may be too low.	Change Respiration scale
No Resp. Waveform or Rate Displayed	Respiration turned **Off.**	Turn respiration **On** (**Off** will be displayed in Resp. tile).
	Patient connected using ESIS choke cable.	Check that proper patient cable is used. Use approved non ESIS patient cable.
	Cable not connected.	Check cable.
CO_2: FilterLine® Disconnected	The FilterLine is not connected to the monitor.	Connect the FilterLine.
CO_2: Warming Up	The CO_2 sensor has not reached its operating temperature.	Wait for the message to go away.
	(The monitor was just turned on).	It takes typically 30 seconds for the sensor to warm up.
CO_2: Auto-zero In Progress	The CO_2 sensor is. performing an auto-zero	Wait for the auto-zero to complete.

MESSAGE/PROBLEM	REASON	SOLUTION
CO_2: Auto-zero Requested	An **Auto-zero** was automatically requested by the system.	Wait for the auto-zero to complete.
CO_2: Failure	CO_2 system failure.	Contact Technical Support.
CO_2: Occlusion	Sampling pump line is blocked while the CO_2 sidestream pump is on.	Check sampling line and filter for blockage, clear sampling line if possible. Replace sampling line if necessary. Disconnect and reconnect the FilterLine from the **Spectrum OR** in order to clear this message.
CO_2: Purge	The system has detected a blocked FilterLine® and has attempted to unblock it by temporarily increasing the flow rate.	Check FilterLine and replace if necessary.
CO_2: Check Flow Rate	The system has detected a high or low flow rate.	Check FilterLine and replace if necessary.
"CHK Lead" Message	Increased impedance caused by one of the following:	
	Chest hair under electrodes.	Prep chest.
	Dried electrode gel.	Change electrodes.
	Electrode off.	Replace electrode.
	Lead off.	Replace lead.
	Cracked lead wires.	Replace lead wires.
	Poor skin prep.	Clean and abrade skin before applying electrodes.
"CVA" Message	Can be caused by shallow breathing or an apnea event.	Check the patient.
	Patient HR and respiratory rate identical.	Adjust scales or leads if necessary. Check the patient.

2.4.7 Gas Monitoring with Gas Module

The Gas Module measures the concentrations of anesthetic gases, O_2, N_2O and CO_2 for display in a parameter tile. The inspired and expired concentrations of anesthetic gases, O_2 and N_2O are displayed in the Gas tile. The inspired and expired concentrations of CO_2 are displayed in the CO_2 tile. Measurements can be acquired via a nasal cannula (non-intubated) for oxygen and CO_2 only or through a sampling line connected to a breathing circuit (intubated).

The Minimum Alveolar Concentration (MAC) is also displayed in the Gas tile. MAC is a calculated value defined in ISO 21647:2004(E) as follows:

> **MAC - alveolar concentration of an inhaled anaesthetic agent that, in the absence of other anaesthetic agents and at equilibrium, prevents 50% of subjects from moving in response to a standard surgical stimulus.**

The MAC value is calculated using the following formula:

$$\text{MAC (AA)} = \frac{\%\ \text{(ET AA)}}{\text{x(AA)}} + \frac{\%\ \text{(ET N2O)}}{\text{x(N2O)}}$$

where AA is the anesthetic agent in use, ET AA is the end-tidal agent concentration, x(AA) is a clinically-derived coefficient based on anesthetic agent (known as 1MAC values), ET N2O is the end-tidal N_2O concentration and x(N2O) is a clinically-derived coefficient for N_2O (also known as the 1MAC value). From ISO 21647:2004(E), the 1MAC values used in the calculation are:

HALOGENATED AGENT	1MAC (IN OXYGEN) % VOLUME FRACTION
Halothane	0.77
Enflurane	1.7
Isoflurane	1.15
Desflurane	7.3
Sevoflurane	2.1
N_2O	105
With the exception of Desflurane, the 1MAC values shown in this table apply to an age sample of 40-years-old. The Desflurane 1MAC value applies to an age sample of 25-years-old.	

NOTE: The calculated MAC value is not corrected for ambient pressure (altitude & barometric effects), patient age, patient core temperature or any other individual factors influencing the effect of volatile anesthetic agents.

NOTE: If mixed agents are detected, the MAC value is invalidated (displayed as dashes).

2.4.8 Gas Menu

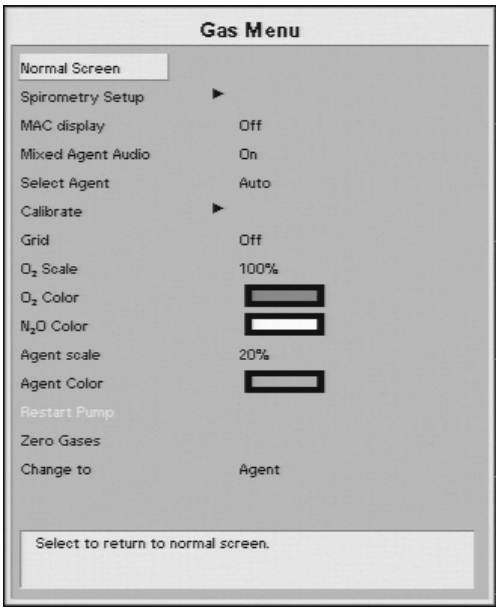


FIGURE 2-39 Gas Menu

The **Gas Menu** provides the following choices: **Normal Screen**, **Spirometry Setup**, **MAC display**, **Mixed Agent Audio**, **Select Agent**, **Calibrate**, **Grid**, **O_2 Scale**, **O_2 Color**, **N_2O Color**, **Agent scale**, **Agent Color**, **Restart Pump**, **Zero Gases**, and **Change to**.

- The **Normal Screen** selection returns the view to the normal screen.
- The **Spirometry Setup** selection opens the **Spirometry Setup Menu** shown in FIGURE 2-53. This menu is described in section 2.4.10.4.
- The **MAC display** selection enables the user to choose whether to display the MAC value in the parameter tile.
- The **Mixed Agent Audio** selection is used to enable or disable the audio portion of the Mixed Agent Alarm.
- The **Select Agent** selection enables the user to choose the agent that is being measured and displayed in the Gas tile. The choices are: Auto (automatically detects the gas type), Iso (Isoflurane), Enf (Enflurane), Des (Desflurane), Sev (Sevoflurane) and Hal (Halothane).
- The **Calibrate** selection opens the **Calibration Menu**. Section 2.4.9.1 provides a detailed calibration procedure.
- The **Grid** selection turns the grids on and off.
- The **O_2 Scale** selection is used to set the scale for O_2. The choices are: 30%, 60% and 100%.
- The **O_2 Color** selection is used to set the display color for O_2.
- The **N_2O Color** selection is used to set the display color for N_2O.
- The **Agent Scale** selection is used to set the scale for the agent. The choices are: 1%, 2.5%, 5%, 10%, 15% and 20%.
- The **Agent Color** selection is used to set the display color for the agent.
- The **Restart Pump** selection is used to restart the Gas Module pump. This selection is not available while the pump is functioning normally.
- The **Zero Gases** selection enables the user to re-zero the Gas Module at any time during use.
- The **Change to** selection is used to change the currently displayed parameter in the parameter tile.

NOTE: The Spectrum OR will interface to the Gas Module via the Serial Port Connector on the Comm-Port mounted onto the Spectrum OR.

WARNING: When using the Gas Module, the maximum sampling rate at the nasal cannula is 200 ml/min (120 ml/min for Gas Module 3 with a neonatal water trap). This device should not be used on patients whose breathing could be impaired by this vacuum flow rate.

NOTE: The Gas Module 3 is equipped with automatic barometric pressure compensation.

NOTE: The Gas Module 3 uses a fixed correction of 11 hPa to compensate for the influence of water vapor in the gas sample, when converting the gas readings to ATPD. An increase in the ambient H_20 partial pressure to 30 hPa (i.e. 28 °C, 80% RH or 33 °C, and 60% RH) will cause a general error for all gases of only -2% REL.

Monitoring Anesthetic Gases, O_2, N_2O and/or CO_2

NOTE: **To prevent moisture from entering the pneumatic system, ensure that the Gas Module is always installed and operated in the horizontal orientation shown in all graphical depictions.**

1. Power ON the Gas Module.
2. Power ON the patient monitor while holding down the **TRENDS** key to enter into its Installation Mode.
3. From the patient monitor **Installation Menu**, set a serial port to "Gas Module" and then select "Save Current".
4. Restart the patient monitor to enter normal monitoring mode.
5. Set alarms as desired.

NOTE: **The sample line must be connected to the Gas Module II, Gas Module SE, and Gas Module SE with Spirometry when turned on to avoid Air Leak message.**

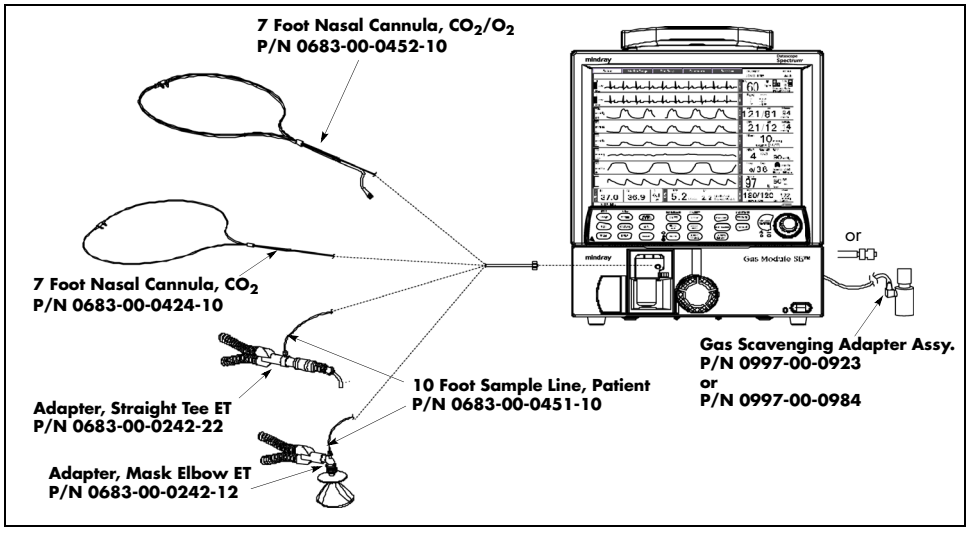


FIGURE 2-40 Gas Module II, Gas Module SE, and Gas Module SE with Spirometry Airway Adapter

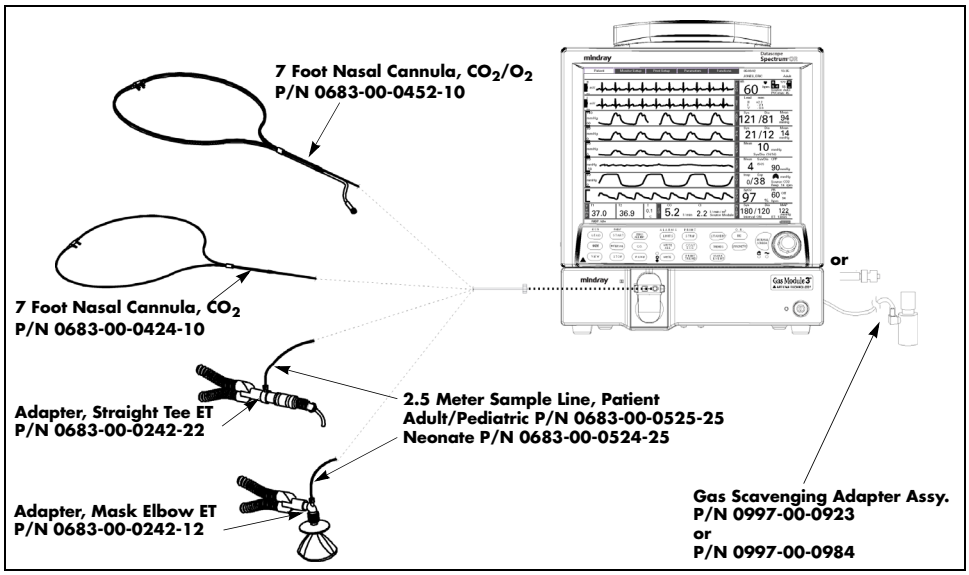


FIGURE 2-41 Gas Module 3 Airway Adapter

NOTE: DRYLINE™ Sample Lines are for use with Gas Module 3 only.

6. For non-intubated patients, apply the nasal cannula to the patient. For intubated patients connect the sample line to the breathing circuit. Refer to instruction provided in the sample line packets.

7. Connect the other end of the nasal cannula or sample line to the Gas Module at the input port. Do not connect anything to the reference port on the rear of the Gas Module II, Gas Module SE or Gas Module SE with Spirometry. This port is used to monitor the room air only. Ensure all tubing connections are tight.

WARNING: Connection of the Gas Module exhaust port to the hospital's waste gas scavenging system is strongly recommended to prevent exposure of hospital personnel to the patient's respiratory sample. Vacuum (negative pressure) should not exceed 1 mmHg at the Gas Module Pump Exhaust fitting. Excessive scavenge vacuum may result in damage to the Gas Modules internal pump.

CAUTION: Contamination with CO_2, N_2O or Anesthetic Agent in the air surrounding the Gas Module 3 may cause significant measurement errors.

8. Check for a clean water trap.

9. Select **CO_2** or **AUTO** as the **Resp Source** in the **Resp Menu**.

10. Observe the capnogram on the monitor's display. On **Spectrum OR** powerup, O_2, Agent and N_2O numbers will display. CO_2 numbers will be displayed when a valid breath is detected.

NOTE: The Gas Module II, Gas Module SE, and Gas Module SE with Spirometry must be warmed up a minimum of two minutes for accurate CO_2, O_2 and N_2O readings and five minutes for agent readings.

NOTE: **The Gas Module 3 must be warmed up a minimum of 45 seconds for ISO accurate CO_2, O_2, N_2O, and agent readings.**

11. If not already set, use the **Display Setup Menu** to select the gas waveforms to be displayed.

12. If desired, the gas waveform speed can be changed via the **Monitor Setup Menu** and the scale can be changed in the **Gas Menu**.

2.4.9 Gas Module 3 Pre-use Test

Prior to each use, perform the following test with the Gas Module 3 to verify that the gas analyzer and sample system are functioning properly:

1. Verify that the appropriate water trap is properly installed and that the appropriate sampling line is connected.

- DRYLINE™ Adult/Pediatric water trap used with DRYLINE™ Adult/Pediatric sampling line (colorless Luer lock nut)
- DRYLINE™ Neonatal water trap used with DRYLINE™ Neonatal sampling line (blue Luer lock nut)

2. Verify that the water trap container is less than half full.

3. Occlude the sampling line and verify that the occlusion alarm functions properly.

4. Breathe into the sampling line and verify that a CO_2 waveform is correctly displayed on the monitor.

5. Sample room air for 30 seconds and verify that the monitor oxygen output is 20.95% (± sensor inaccuracy).

2.4.9.1 Gas Monitor Calibration

Accuracy verification of the Gas Module II, Gas Module SE, and Gas Module SE with Spirometry is recommended at six (6) month intervals or whenever gas readings appear to be in error. Accuracy verification of the Gas Module 3 is recommended at one (1) year intervals or whenever gas readings appear to be in error. The date of the last successful mixture calibration appears at the bottom of the gas **Calibration Menu**. During the calibration session, gas readings and all other gas functions are not available. Span calibration is a set of prompted commands that enables the operator to align the gas display(s) to specific gas concentration(s) in the Calibration Gas canister. Span calibration can be initiated by the operator any time the gas module's readings are suspected to be inaccurate.

Always verify accuracy using a full canister of approved precision calibration gas, after calibration is performed. Never use calibration gas that has expired, or has a canister that is indicating low pressure. The pressure indicator on the gas regulator must operate in the green zone during the entire calibration session.

NOTE: **The Gas Module II, Gas Module SE, and Gas Module SE with Spirometry must be fully warmed up before performing a gas calibration. For maximum accuracy, a warm-up time of 30 minutes is recommended.**

NOTE: **The Gas Module 3 must be fully warmed up before performing a gas calibration. For maximum accuracy, a warm-up time of 10 minutes is recommended.**

1. Select **Calibrate** from the **Gas Menu**. The **Calibration Menu** opens.

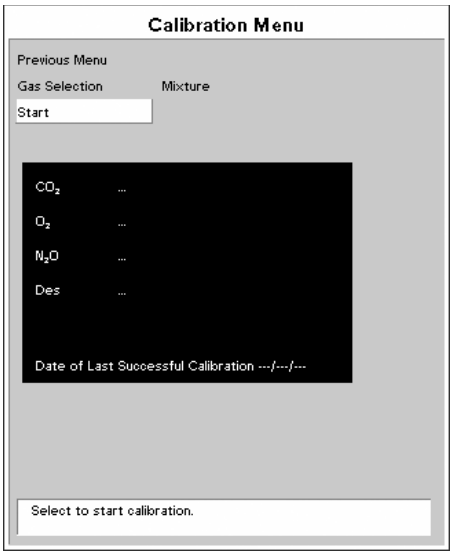


FIGURE 2-42 Calibration Menu

2. Select **Gas Selection** from the **Calibration Menu** and choose the calibration gas type. Choices are: Mixture, 5% CO_2, 55% O_2, 33% N_2O and 2% Des.

3. Select **Start** to begin calibration. At the start of the calibration, the message **Zeroing...** will be initially displayed for each of the gas labels as the Gas Module zeros the gas channels. After successful zeroing, the Gas Module will request the calibration gas as indicated in the next step.

NOTE: **If the Gas Module cannot zero, a zeroing error will be displayed and the previous calibration data will be restored. Repeat the calibration procedure from step 1. If problems persist, contact Customer Support.**

4. The message **Feed calibration gas** will be displayed. At this point, attach the calibration gas canister to the regulator and turn it on. Increasing gas values will appear in the window as the Gas Module samples the calibration gas.

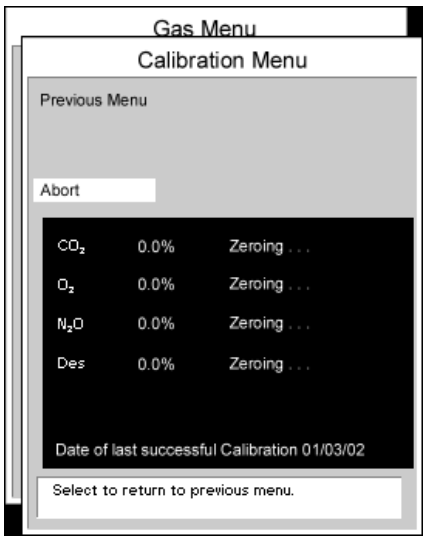


FIGURE 2-43 Gas Calibration Menu

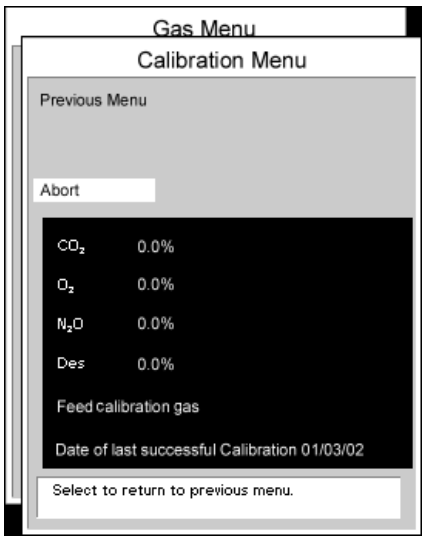


FIGURE 2-44 Gas Calibration Menu

5. When calibration is complete, the **Feed calibration gas** message will be removed from the display and the message **Complete** will be displayed next to each value that was successfully measured. If at least one gas was successfully measured, the **Accept** menu choice will become available. If the values are acceptable, select **Accept**. To cancel calibration and re-install the previous calibration values, select **Abort**.

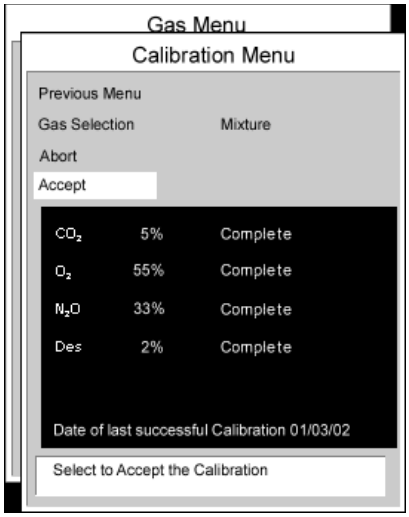


FIGURE 2-45 Gas Calibration Menu

NOTE: **When the "Accept" menu choice is selected, the message "Disconnect calibration gas." will be displayed. To avoid premature emptying of the gas canister, always remove the regulator at the end of the procedure.**

NOTE: **For Gas Module II, Gas Module SE, and Gas Module SE with Spirometry, if any channel cannot be calibrated due to a sampling error, the "Sampling Error" message will be displayed. Selecting the "Accept" button will calibrate only those channels that do not have a sampling error. If any channel fails calibration, the gas value will be "XXX". These channels will appear as "XXX" in the normal run mode as well. Repeat the procedure from step 1. If problems persist, contact Customer Support.**

NOTE: **For Gas Module 3, if any input data is corrupt or if there are other errors, a "Calibration Error" message will appear after the "Accept" button is selected. The Gas Module 3 will not accept span calibration with errors in any channel.**

2.4.9.2 Gas Module Troubleshooting

MESSAGE/PROBLEM	REASON	SOLUTION
GM: Warming Up	Appears when the system has been turned on, and the sensors have not reached their stable operating temperature.	Wait for the message to go away. It takes up to five minutes for the device to warm up.
GM: Agent Warming Up Does not apply to Gas Module 3.	This message appears after the **GM: Warming Up** message disappears. It indicates that the Agent ID Bench is warming up and readings will not be available.	Wait for the message to go away. It takes up to five minutes from power-up for the Agent ID Bench to warm up.
GM: Exhaust Blocked	Appears when the system detects a blockage at the exhaust gas outlet, as indicated by an increase in internal pressure.	Remove waste gas scavenging assembly, check if message disappears. Check exhaust line for blockage and clear if possible. If message persists contact Customer Support.
GM: Mixed Agents	Appears when more than one anesthetic agent is detected by the system.	Message will disappear when a single agent is detected again.
GM: Air Leak	Appears when the system detects a pneumatic leak.	Turn Gas Module and **Spectrum OR** Off.
	Also may appear when the Gas Module has been turned on without a sample line attached.	Install/check sample lines, filters, water trap and electrical connections.
	Gas Module has been on for a long period of time without the **Spectrum OR** Monitor being on.	Turn off Gas Module.Turn on Gas Module and **Spectrum OR** Monitor.
GM: Replace Trap	Indicates residue build-up on the water trap membrane that is decreasing air flow.	Replace water trap reservoir.
GM: Occlusion	Appears when the system detects an obstruction in the sampling line or the water trap bottle is full.	Empty and rinse water trap. Change water trap if necessary. Check sampling line and filter for blockage, clear sampling line if possible. Replace sampling line and/or filter if necessary. Check exhaust line for blockage and clear if possible. If problem persists, contact Customer Support.
GM: Zero In Progress	Appears when the system is zeroing all of it's channels. This appears whether initiated by the user or is automatic.	This is normal operation. Wait for message to clear.
GM: CO_2 Zero Error	Appears when the system has been unable to successfully zero the CO_2 sensor.	Manually start zeroing the system again. If problem persists, contact Customer Support.
GM: O_2 Zero Error	Appears when the system has been unable to successfully zero the O_2 sensor.	Manually start zeroing the system again. If problem persists, contact Customer Support.

MESSAGE/PROBLEM	REASON	SOLUTION
GM: N_2O Zero Error	Appears when the system has been unable to successfully zero the N_2O sensor.	Manually start zeroing the system again. If problem persists, contact Customer Support.
GM: Agent Zero Error	Appears when the system has been unable to successfully zero the anesthetic agent sensor.	Manually start zeroing the system again. If problem persists, contact Customer Support.
GM: Pump Off	Appears when the system has turned off the pump due to a pneumatic error.	Restart the pump from the **Gas Menu**. If problem persists, contact Customer Support.
GM: Agent Mismatch - HAL	Appears when the system detects Halothane as the primary agent and the manually selected agent is not Halothane.	Match the Agent administered with the Agent selected, or select **Agent Auto ID**.
GM: Agent Mismatch - ISO	Appears when the system detects Isoflurane as the primary agent and the manually selected agent is not Isoflurane.	Match the Agent administered with the Agent selected, or select **Agent Auto ID**.
GM: Agent Mismatch - ENF	Appears when the system detects Enflurane as the primary agent and the manually selected agent is not Enflurane.	Match the Agent administered with the Agent selected, or select **Agent Auto ID**
GM: Agent Mismatch - SEV	Appears when the system detects Sevoflurane as the primary agent and the manually selected agent is not Sevoflurane.	Match the Agent administered with the Agent selected, or select **Agent Auto ID**
GM: Agent Mismatch - DES	Appears when the system detects Desflurane as the primary agent and the manually selected agent is not Desflurane.	Match the Agent administered with the Agent selected, or select **Agent Auto ID**
GM: Unknown Agent	Appears when the system detects a gas that does not match the spectroscopic signatures of the five known anesthetic agents	Use recognized agent
GM: Cannot Zero... RETRYING	Appears when the **Spectrum OR** requests **Zeroing** (either on the automatic cycle or by a user request) and the Gas Module is unable to initialize the cycle	Allow system to retry without intervention. If problem persist, contact Customer Support.
GM: CO_2 Uncalibrated	Appears after an unsuccessful calibration attempt of the CO_2 sensor. The numeric data for CO_2 will appear as - - -, and the CO_2 waveform will be a flatline	Ensure proper gas mixture is attached tightly and regulator is on. Repeat calibration procedure. If problem persists, contact Customer Support.
GM: O_2 Uncalibrated	Appears after an unsuccessful calibration attempt of the O_2 sensor. The numeric data for O_2 will appear as - - -, and the O_2 waveform will be a flatline	Ensure proper gas mixture is attached tightly and regulator is on. Repeat calibration procedure. If problem persists, contact Customer Support.

MESSAGE/PROBLEM	REASON	SOLUTION
GM: N_2O Uncalibrated	Appears after an unsuccessful calibration attempt of the N_2O sensor. The numeric data for N_2O will appear as - - -, and the N_2O waveform will be a flatline	Ensure proper gas mixture is attached tightly and regulator is on. Repeat calibration procedure. If problem persists, contact Customer Support.
GM: Agents Uncalibrated	Appears after an unsuccessful calibration attempt of the agent sensor. The numeric data for all agents will appear as - - -, and the agent waveform will be a flatline	Ensure proper gas mixture is attached tightly and regulator is on. Repeat calibration procedure. If problem persists, contact Customer Support.
GM: Failed	Appears when the Gas Module detects an unrecoverable error in its own operation	Contact Customer Support.
GM: Disconnected	Appears when the **Spectrum OR** cannot detect signals being sent by the Gas Module	Ensure Gas Module is turned on and interface cable is properly connected. If problem persists, contact Customer Support.
Sampling Error	Appears when a sampling error occurs on one or more Gas Module channels during calibration	Repeat calibration procedure. If problem persists, contact Customer Support.
Not Ready For Calibration	Appears when the Gas Module is unable to initialize calibration	Repeat calibration procedure. If problem persists, contact Customer Support.
Calibration Error, Sampling Error	Appears when a sampling error occurs in all four Gas Module channels during calibration	Repeat calibration procedure. If problem persists, contact Customer Support.
Calibration Error, Zeroing Error	Appears when the Gas Module cannot perform a **Zeroing** during calibration	Repeat calibration procedure. If problem persists, contact Customer Support.

2.4.10 Spirometry (Optional)

Spirometry is a respiratory monitoring technology that provides continuous (breath-by-breath) measurement of patient lung mechanics. The resultant pressure, volume, flow, compliance and resistance data enables quick assessment of the patient's pulmonary status.

Spirometry can be monitored when Patient Size is set to either Adult or Pediatric and a serial port is set to Gas Module in the **Installation Menu**.

Spirometry cannot be monitored when Patient Size is set to Neonate.

2.4.10.1 Spirometry Setup

FIGURE 2-46 depicts the basic Spirometry monitoring components.

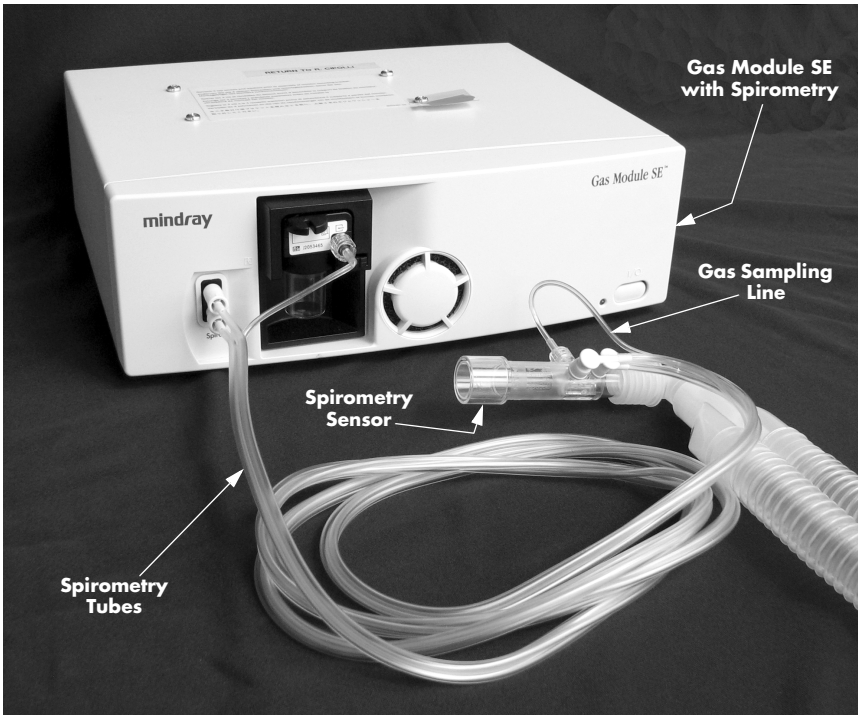


FIGURE 2-46 Spirometry Setup

1. The Gas Sampling Line and the Spirometry Tubes are separate pieces that must be used in conjunction with each other. Lay the Gas Sampling Line between the Right-Angle Spirometry Connectors of the Spirometry Tubes as shown in FIGURE 2-47.

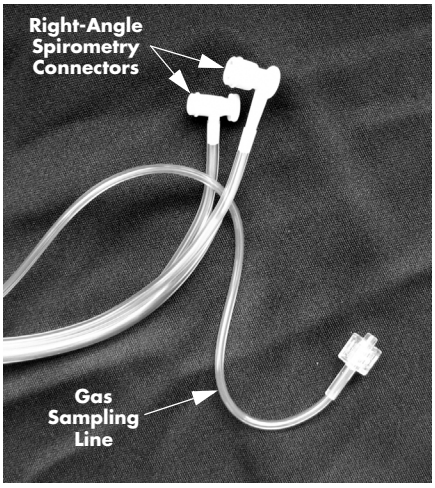


FIGURE 2-47

2. Press the Gas Sampling Line into the groove that runs between the Spirometry Tubes, along their entire length. The end of the Spirometry Tubes with the Right-Angle Spirometry Connectors should look similar to the picture shown in FIGURE 2-48. The opposite end of the Spirometry Tubes with the Straight Spirometry Connectors should have a similar appearance.

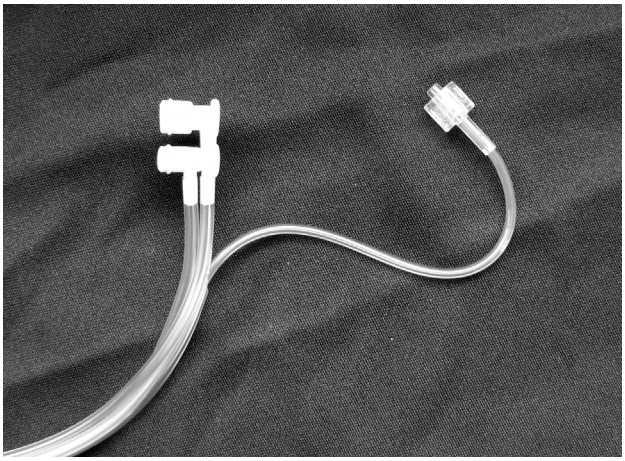


FIGURE 2-48

3. Connect the Gas Sampling Line and the Spirometry Tubes with the Right-Angle Spirometry Connectors to the Spirometry Sensor as shown in FIGURE 2-49.

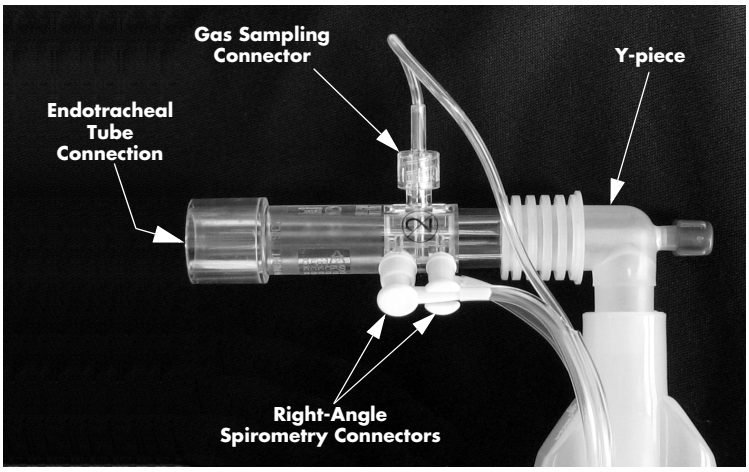


FIGURE 2-49 Connections on the Spirometry Sensor

4. Connect the Gas Sampling Line and the Spirometry Tubes with the Straight Spirometry Connectors to the connectors on the Gas Module SE (shown in FIGURE 2-50).

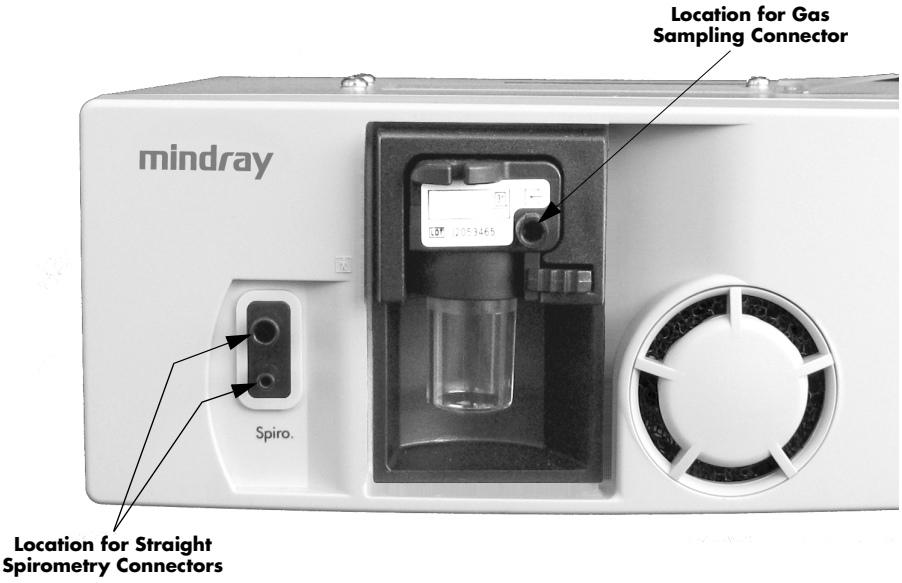


FIGURE 2-50 Connections on the Gas Module SE

NOTE: **In the following step, the Spirometry sensor should be positioned on an incline (45° is optimum) away from the patient to prevent water flow to the patient and to improve measurement accuracy.**

5. Connect the Spirometry sensor between the Y-piece and the endotracheal tube with all ports facing upwards. Ensure that the sensor is positioned on an incline, with the patient side higher than the machine side.
6. Power ON the patient monitor while holding down the **TRENDS** key to enter into its Installation Mode.
7. From the patient monitor **Installation Menu**, set a serial port to "Gas Module" and then select "Save Current".
8. Restart the patient monitor to enter normal monitoring mode.
9. From the **Patient Menu** of the main screen, set Patient Size to either Adult or Pediatric.

2.4.10.2 Spirometry Monitoring

Open the **Spirometry Loop Window** (shown in FIGURE 2-51) by pressing the **SPIROMETRY** key on the front panel keypad.

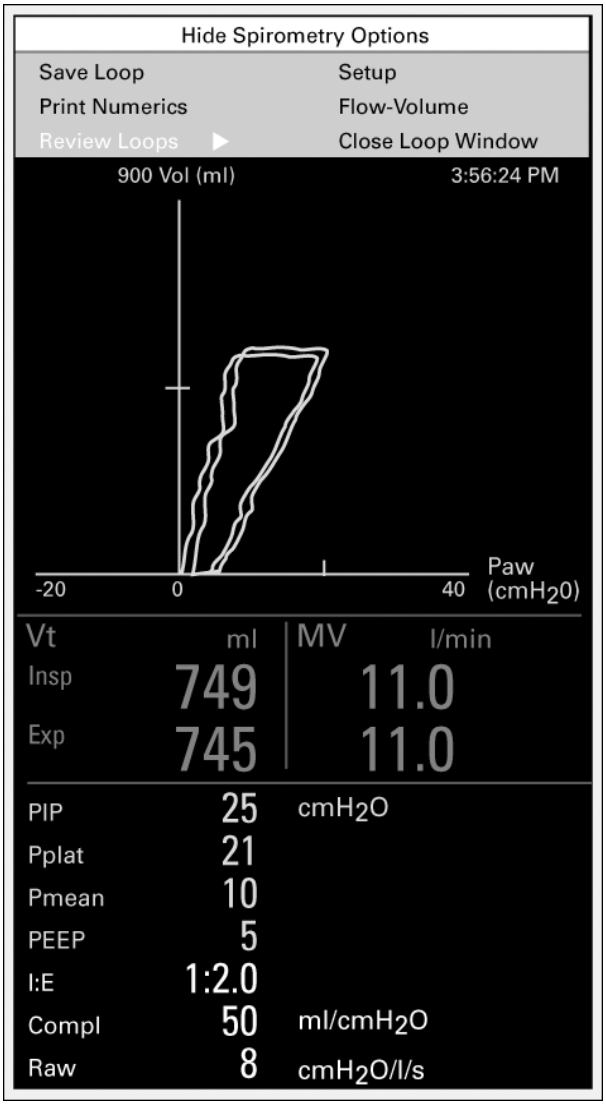


FIGURE 2-51 Spirometry Loop Window

The **Spirometry Loop Window** is divided into three areas: the Menu Area, the Loop Area and the Numeric Data Area.

Menu Area

When the **Spirometry Loop Window** initially opens, the **Spirometry Options** menu choice is the only choice available. Select **Spirometry Options** to display the following menu choices: **Save Loop**, **Print Numerics**, **Review Loops**, **Setup**, **Pressure-Volume/Flow-Volume/Both** and **Close Loop Window**.

- The **Save Loop** selection is used to save the currently plotting loop as either a Baseline loop or a Reference loop.
  - All numeric data associated with a saved loop will also be saved.
  - A Reference loop cannot be saved without first saving a Baseline loop.
  - Only one Baseline loop and corresponding numeric data will be saved.
    - When the user attempts another save, a confirmation dialog will be displayed with the following text, **Selecting Yes will replace the currently saved Baseline loop. Are you sure?** If **Yes** is chosen, the currently saved Baseline loop will be replaced. If **No** is chosen, the save will be aborted.
  - A maximum of five (5) sets of Reference loops and corresponding numeric data can be saved.
    - When the maximum of five (5) is reached, and the user attempts another save, a confirmation dialog will be displayed with the following text, **Selecting Yes will replace the currently saved Reference loop. Are you sure?** If **Yes** is chosen, the oldest data will be removed as the new data is added. If **No** is chosen, the save will be aborted.
- The **Print Numerics** selection is used to print all Spirometry numerics and the time stamp associated with the most recently completed loops.
- The **Review Loops** selection is used to open the **Review Loops Menu** (described in section 2.4.10.3).

NOTE: When no loops have yet been saved, this menu choice will be unavailable (grayed out).

- The **Setup** selection is used to open the **Spirometry Setup Menu** (described in section 2.4.10.4).
- The **Pressure-Volume/Flow-Volume/Both** selection is used to toggle the display of the currently viewed loops between Pressure-Volume, Flow-Volume and Both.

NOTE: The "Both" setting is for the simultaneous display of the Pressure-Volume loop above the Flow-Volume loop. In this display configuration, the Numeric Data is not available for display.

- The **Close Loop Window** selection is used to close the **Spirometry Loop Window**.

Loop Area

This area, below the menu choices, is used to display the Spirometry loops. Based on various menu settings in the **Spirometry Loop Window** and the **Review Loops Menu**, the Loop Area may display one loop set or two loop sets simultaneously. A loop set may be comprised of up to three loops as follows: the currently plotting loop (which will always be displayed), a saved Baseline Loop and a saved Reference loop.

Numeric Data Area

This area below the Loop Area is used to display the numerical data associated with the currently plotting loop. The parameters include: Peak Inspiratory Pressure (PIP), Plateau Pressure (Pplat), Positive End Expiratory Pressure (PEEP), Mean Pressure (Pmean), Dynamic Airway Compliance (Compl), Airway Resistance (Raw), Inspiratory Tidal Volume (Vtinsp), Expiratory Tidal Volume (Vtexp), Inspiratory Minute Volume (MVinsp), Expiratory Minute Volume (MVexp), and Ratio of Inspiratory time to Expiratory time (I:E).

2.4.10.3 Review Loops Menu

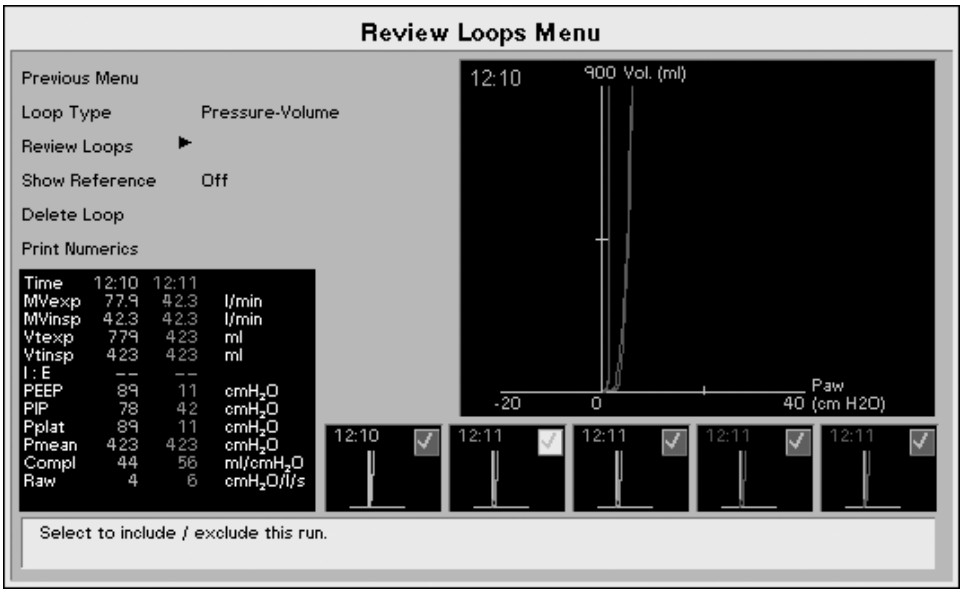


FIGURE 2-52 Example Review Loops Menu

The **Review Loops Menu** is divided into three areas: the Menu Area, the Numeric Data Area and the Loop Area.

Menu Area

The **Review Loops Menu** is accessed by choosing **Review Loops** from the **Spirometry Loop Window**. It provides the following choices: **Previous Menu**, **Loop Type**, **Review Loops**, **Show Reference**, **Delete Loop** and **Print Numerics**.

- The **Previous Menu** selection returns the view to the previous menu.
- The **Loop Type** selection is used to choose the type of loop to review. The choices are: Pressure-Volume and Flow Volume.
- The **Review Loops** selection is used to scroll through the smaller windows that are currently displayed in the Loop Area.
  - Pressing the Navigator Knob while a window is highlighted will toggle that window's check box between a green check mark and a red "X". The purpose of the check box is described in the **Loop Area** sub-section that follows.
  - Pressing the Navigator Knob while Review Loops is highlighted will return the cursor control to scrolling through the **Review Loops Menu** choices.
- The **Show Reference** selection is used to choose whether to display a saved Reference loop in the **Spirometry Loop Window**, along with the currently plotting loop. The Reference loops are listed by the time at which they were saved along with a choice for "Off". A maximum of five (5) possible Reference loops may be available from which to choose.
- The **Delete Loop** selection is used to delete a saved Reference loop. The Reference loops available for deletion are listed by the time at which they were saved.
- The **Print Numerics** selection is used to print the spirometry numerics associated with all smaller windows in the loop area having a green check mark in the check box as follows:
  - The numerics are printed in column form as they are displayed on the monitor, with the exception that reverse video fields are indicated by displaying the values between two square brackets "[ ]".
  - If the displayed loops are **Pressure-Volume** or **Both**, the Pressure-Volume numerics will print first, followed by the Flow-Volume numerics.
  - If the displayed loops are **Flow-Volume**, the Flow-Volume numerics will print first, followed by the Pressure-Volume numerics.
  - The Resp rate that corresponds to the time of the most recently completed loops will also be included on the printout.

Numeric Data Area

This area, below the Menu Area, is used to display the numerical data associated with a saved Baseline loop and saved Reference loops. The parameters listed in column form include: Time, Inspiratory Minute Volume (MVinsp), Expiratory Minute Volume (MVexp), Inspiratory Tidal Volume (Vtinsp), Expiratory Tidal Volume (Vtexp), Ratio of Inspiratory time to Expiratory time (I:E), Positive End Expiratory Pressure (PEEP), Peak Inspiratory Pressure (PIP), Plateau Pressure (Pplat), Mean Pressure (Pmean), Dynamic Airway Compliance (Compl), and Airway Resistance (Raw).

NOTE: **When using the Review Loops selection to scroll through the smaller windows that are currently displayed in the Loop Area, the Spirometry numerics associated with both the baseline loop and the currently highlighted reference loop will be displayed. The color of the numerics will be the same as the color of the corresponding loop.**

Loop Area

This area, to the right of the Menu Area, is used to review Baseline and Reference loops in an overlapping format. The large window in the upper portion of this area is always displays the currently saved Baseline loop. Using the **Review Loops** selection, this large window can be configured to also display a maximum of five (5) saved Reference loops.

Below the large window is an area allotted for a maximum of five (5) smaller windows to display the individual saved Reference loops. The number of smaller windows displayed corresponds to the number of saved Reference loops.

Each smaller window has a check box in the upper right corner that is accessed via the **Review Loops** selection described in the preceding **Menu Area** sub-section. The check boxes display either a green check mark (default) or a red "X". The green check mark indicates that the loop displayed in that window will also be displayed in the large window. The red "X" indicates that the loop displayed in that window will not be displayed in the large window.

2.4.10.4 Spirometry Setup Menu

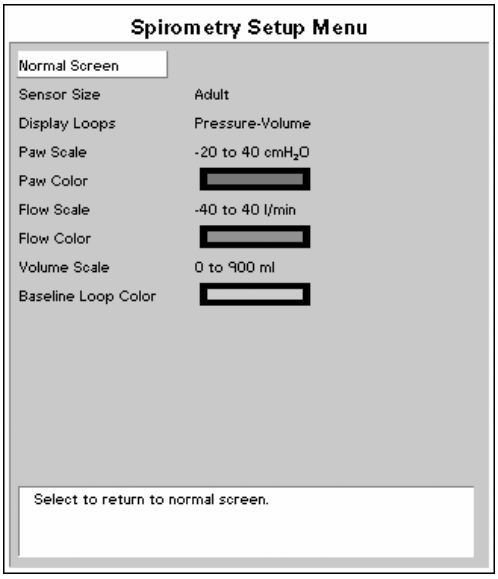


FIGURE 2-53 Spirometry Setup Menu

The **Spirometry Setup Menu** is accessed by choosing **Setup** from the menu choices in the **Spirometry Loop Window** or by choosing **Spirometry Setup** from the **Functions Menu**. It provides the following choices: **Normal Screen**, **Sensor Size**, **Display Loops**, **Paw Scale**, **Paw Color**, **Flow Scale**, **Flow Color**, **Volume Scale**, and **Baseline Loop Color**.

- The **Normal Screen** selection returns the view to the normal screen.
- The **Sensor Size** selection is used to select the size of the Spirometry sensor. When the Sensor Size is changed, the Volume Scale will be reset to the default for the new sensor size. The choices are: Adult and Pediatric.
- The **Display Loops** selection provides a list of settings for the loop display format that will be displayed in the **Spirometry Loop Window**. The choices are: **Off**, **Pressure-Volume**, **Flow-Volume** and **Both**.

NOTE: **The "Both" setting is for the simultaneous display of the Pressure-Volume loop above the Flow-Volume loop. The "Off" setting will close the Spirometry Loop Window if it is currently open.**

- The **Paw Scale** selection is used to set the scale for the Paw axis on the Pressure-Volume Spirometry loop plot.
  - The choices for the Adult Sensor Size are:
    - -10 to 10 cmH_2O
    - -20 to 20 cmH_2O
    - -20 to 40 cmH_2O
    - -20 to 60 cmH_2O
    - -20 to 80 cmH_2O
    - -20 to 120 cmH_2O
  - The choices for the Pediatric Sensor Size are:
    - -5 to 5 cmH_2O
    - -10 to 10 cmH_2O
    - -20 to 20 cmH_2O
    - -20 to 30 cmH_2O
    - -20 to 40 cmH_2O
- The **Paw Color** selection is used to set the color for the Paw waveform and digital parameters.
- The **Flow Scale** selection is used to set the scale for the Flow axis on the Flow-Volume Spirometry loop plot.
  - The choices for the Adult Sensor Size are:
    - -10 to 10 l/min
    - -20 to 20 l/min
    - -40 to 40 l/min
    - -60 to 60 l/min
    - -80 to 80 l/min
    - -100 to 100 l/min
    - -120 to 120 l/min
  - The choices for the Pediatric Sensor Size are:
    - -5 to 5 l/min
    - -10 to 10 l/min
    - -20 to 20 l/min
    - -30 to 30 l/min
    - -40 to 40 l/min

- The **Flow Color** selection is used to set the color for the Flow waveform and digital parameters.
- The **Volume Scale** selection is used to set the scale for the Volume axis on both Spirometry loop plots (described in the following paragraph).
  - The choices for the Adult Sensor Size are:
    0 to 300 ml
    0 to 600 ml
    0 to 900 ml
    0 to 1200 ml
    0 to 1800 ml
    0 to 2400 ml
  - The choices for the Pediatric Sensor Size are:
    0 to 50 ml
    0 to 100 ml
    0 to 200 ml
    0 to 300 ml
    0 to 400 ml
- The **Baseline Loop Color** selection is used to set the color for the Baseline Loop.

2.4.10.5 Paw Menu

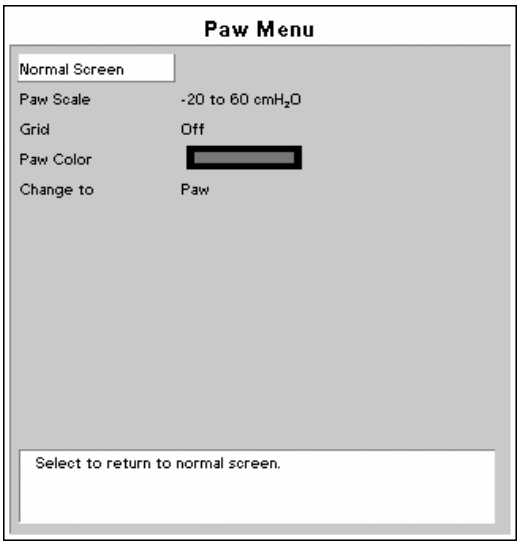


FIGURE 2-54 Paw Menu

The **Paw Menu** is accessed by choosing **Paw** from the **Parameters Menu** or by choosing the Paw menu target from the main screen. It provides the following choices: **Normal Screen**, **Paw Scale**, **Grid**, **Paw Color**, and **Change to**.

- The **Normal Screen** selection returns the view to the normal screen.
- The **Paw Scale** selection is used to set the scale for the vertical axis of the Paw waveform.
  - The choices for the Adult Sensor Size are:
    -10 to 10 cmH_2O
    -20 to 20 cmH_2O
    -20 to 40 cmH_2O
    -20 to 60 cmH_2O
    -20 to 80 cmH_2O
    -20 to 120 cmH_2O
  - The choices for the Pediatric Sensor Size are:
    -5 to 5 cmH_2O
    -10 to 10 cmH_2O
    -20 to 20 cmH_2O
    -20 to 30 cmH_2O
    -20 to 40 cmH_2O
- The **Grid** selection is used to toggle the display of the grids in the waveform area between On and Off.
- The **Paw Color** selection is used to set the color for the Paw waveform and digital parameters.
- The **Change to** selection is used to change the currently displayed parameter in the parameter tile.

2.4.10.6 Flow Menu

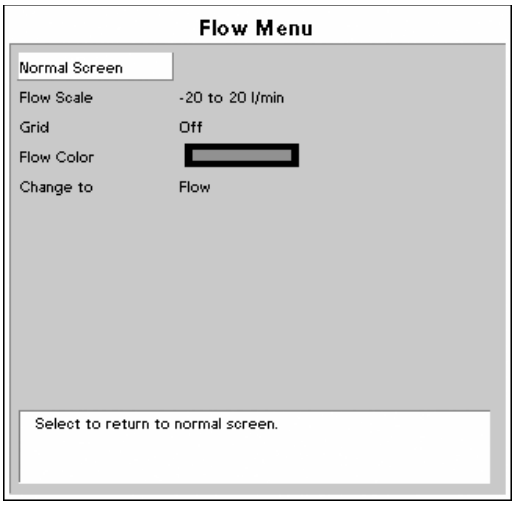


FIGURE 2-55 Flow Menu

The **Flow Menu** is accessed by choosing **Flow** from the **Parameters Menu** or by choosing the Flow menu target from the main screen. It provides the following choices: **Normal Screen**, **Flow Scale**, **Grid**, **Flow Color**, and **Change to**.

- The **Normal Screen** selection returns the view to the normal screen.
- The **Flow Scale** selection is used to set the scale for the vertical axis of the Flow waveform.
  - The choices for the Adult Sensor Size are:
    -10 to 10 l/min
    -20 to 20 l/min
    -40 to 40 l/min
    -60 to 60 l/min
    -80 to 80 l/min
    -100 to 100 l/min
    -120 to 120 l/min
  - The choices for the Pediatric Sensor Size are:
    -5 to 5 l/min
    -10 to 10 l/min
    -20 to 20 l/min
    -30 to 30 l/min
    -40 to 40 l/min
- The **Grid** selection is used to toggle the display of the grids in the waveform area between On and Off.
- The **Flow Color** selection is used to set the color for the Flow waveform and digital parameters.
- The **Change to** selection is used to change the currently displayed parameter in the parameter tile.

2.4.11 Spirometry Troubleshooting

PROBLEM	POSSIBLE CLINICAL CAUSE	POSSIBLE TECHNICAL CAUSE	ACTION
Insp Vt>Exp Vt	• Leak in lungs • ET tube cuff leak	• Spirometry tube leak • Water inside sensor or tubings • Another side stream gas sampling between sensor and patient	• Check leakages - perform leak test • Change tubings and sensor • Don't use active humidification • Connect gas sampling line only and always to spirometry sensor
Exp Vt>Insp Vt		• Spirometry tube leak • Water inside sensor or tubings	• Check leakages - perform leak test • Change tubings and sensor • Don't use active humidification
Loop overscale		• Wrong scale selected	• Change scaling
Monitored volumes <set volumes		• Leak between ventilator and sensor	• Check ventilator connections
Strongly vibrating loop	Mucus in ET tube	• Water or secretions in hoses of sensor	• Suction the patient • Change dry sensor and/or empty the water from hoses
Too large or too small volumes		• Wrong mode vs. sensor selection • Incompatible between selected sensor and sensor used	• Check mode and sensor size
Fluctuating Raw	• Mucus in airways or tubing • Breathing effort against the ventilator • Patient triggered breaths	• Ventilator exp. valve causes fluctuations during exp. flow	• Clean expiratory valve
Too high Raw	• Kink in tubing • Mucus • Asthmatic patient • Bronchospasm • Spontaneous breaths • Breathing efforts against the ventilator • Patient triggered breaths		

PROBLEM	POSSIBLE CLINICAL CAUSE	POSSIBLE TECHNICAL CAUSE	ACTION
Raw value invalid	• Spontaneous breaths • Breathing efforts against the ventilator • Patient triggered breaths		
Too high Ppeak	• Bronchospasm • Patient is coughing • Patient breaths against the ventilator • Obstruction in airway • HME obstructed		
Compl value invalid	• Spontaneous breaths		

2.4.12 IBP - Invasive Blood Pressure Menu (Optional)

Invasive Blood Pressure (IBP) is a direct measurement of the patient's arterial or venous blood pressure. IBP utilizes a catheter that is inserted directly into a vein, artery or other pressure access areas, and is connected to a transducer for interpretation of Systolic (Sys), Diastolic (Dia), and Mean blood pressures. Up to four Invasive Blood Pressure channels are available.

Invasive Blood Pressure measurement is an option for the **Spectrum OR**.

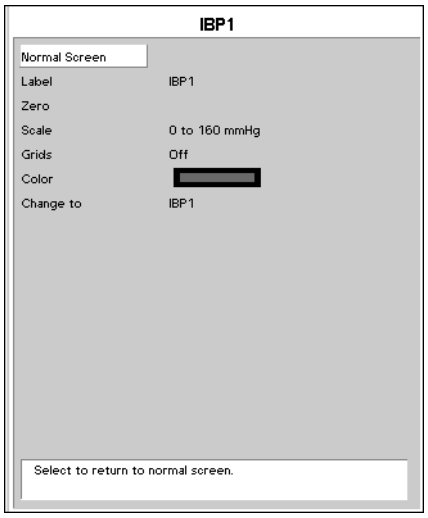


FIGURE 2-56 IBP Menu

IBP1, IBP2, IBP3, IBP4 waveforms may be labeled according to the site of insertion. The labels are identified in the following table:

LABEL	DEFINITION
Art	Arterial Blood Pressure
UA	Umbilical Artery Pressure
LV	Left Ventricular Pressure
PA	Pulmonary Artery Pressure
CVP	Central Venous Pressure
ICP	Intracranial Pressure
LA	Left Atrial Pressure
RA	Right Atrial Pressure

2.4.12.1 Measuring IBP

1. Plug the pressure transducer cable into the IBP port(s) on the left side panel, or into the IBP port(s) on the External Parameter Module.
2. The IBP1 and IBP2 waveforms will appear by default as the fourth and fifth waveform on the display with its associated data to the right of the waveform. The waveform may be moved to another location or turned off by accessing the **Display Setup Menu**. The IBP3 and IBP4 waveforms and/or data will not appear unless the External Parameter Module has been enabled and a location has been designated in the **Display Setup Menu**.

NOTE: The arterial pressure catheter should not be used on a limb that is being utilized for any other medical procedure. For example, an IV Catheter, NIBP Cuff or an SpO_2 sensor.

3. Connect catheter line with flushing device to a pressure transducer.
4. Zero pressure transducer as follows:
   a. Open transducer vent to atmosphere.
   b. Press **ZERO ALL IBP** or individually zero pressure lines by opening individual IBP menus.

After the automatic zero process is complete, the pressure display should indicate zeros.

NOTE: If the transducer offset should exceed 120 mmHg, it will not be possible to automatically zero the transducer. Pressure values will be xxx and an "Unable to Zero" message will be displayed.

5. Close the pressure transducer vent from atmosphere.
6. Select the desired pressure scale in the **IBP Menu**.
7. Zero and flush the pressure line at regular intervals per standard hospital procedure.

NOTE: Pressure transducers are protected against the effects of defibrillation, electrocautery and cerebral perfusion.

Cerebral Perfusion Pressure (CPP)

The monitor will calculate and display CPP under the following conditions:

1. The Hemodynamic Calculation option has been installed in the monitor.
2. One IBP channel has been labeled **Art**.
3. One IBP channel has been labeled **ICP**.
4. **Display CPP**, located on the ICP parameter menu, has been set to **Yes**.

NOTE: CPP data will be displayed in the same parameter tile as the ICP data.

2.4.12.2 IBP Troubleshooting

MESSAGE/PROBLEM	REASON	SOLUTION
Damped Invasive Waveform	Air bubbles in tubing.	Eliminate air from tubing.
	Kinked catheter.	Change position of catheter, check patient.
	Catheter against wall of blood vessel.	Check for leaks at connector, flush catheter.
	Blood in tubing	Pump pressure bag up to 300 mmHg.
	Catheter partially occluded with clot.	Consult physician.
IBP not Displayed / No IBP Waveform	Improper Setup.	Check display setup in monitor setup.
	Cable not plugged in	Check cable.
	Transducer not connected.	Check transducer connection.
	Stopcock turned improperly.	Check transducer.
	Transducer not zeroed.	Check and zero the transducer.
Abnormally High or Low readings	Transducer too HIGH or to LOW.	Check patient adjust transducer rezero.
Unable to Zero	Stopcock not open to atmosphere.	Check transducer.
	Cable/Transducer not plugged in.	Check cable.

2.4.13 Pulmonary Artery Wedge Pressure (PAWP)

Pulmonary Artery Wedge Pressure (PAWP) is a pressure measurement derived from a PA catheter when the PA distal balloon is inflated and the catheter advances and occludes a distal pulmonary artery. PAWP pressure is a reflection of the pressure in the left ventricle at end-diastole.

PAWP measurement is available if the Hemodynamic Calculation option has been installed on the monitor and one of the available invasive pressure channels has been labeled **PA**.

The **Wedge Menu** may be opened from the **PA Menu** or by pressing the **PAWP** key on the monitor keypad.

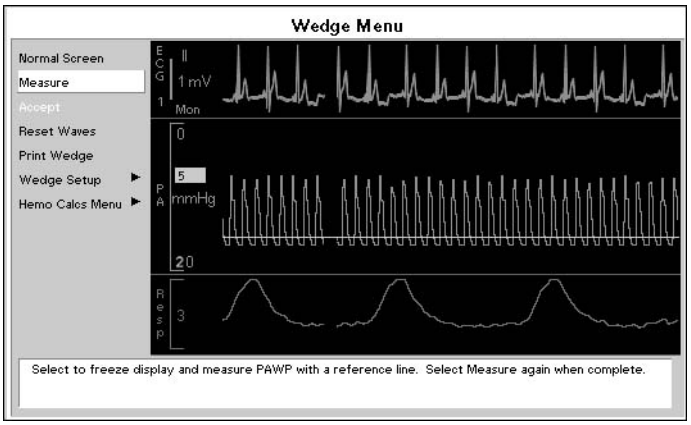


FIGURE 2-57 Wedge Menu

2.4.13.1 Measuring PAWP

NOTE: To ensure accurate wedge pressure readings, rezero the PA pressure channel and check the PA catheter for integrity, kinks and/or leaks prior to measurement.

1. Open the **PAWP Menu** by pressing the **PAWP** key or by selecting **Wedge Menu** from the **PA Menu.**

NOTE: Follow manufacturer's suggested procedures and hospital policy for PAWP balloon inflation.

2. Inflate balloon, watch PA waveform for wedge waveform.
3. Once a satisfactory wedge waveform is detected, press **Measure** to freeze the waveforms within the **PAWP Menu**.
4. Use the Navigator™ Knob to adjust the reference line to the estimated Wedge measurement.
5. Press the Navigator knob to return to **PAWP Menu** choices.
6. Press **Accept** to enter the PAWP measurement onto the **Hemodynamic Calculations Menu** and post the measurement in the PA parameter tile, or select **Measure** to further adjust the reference line.

The **Reset Waves** menu selection will restart the waves scrolling from the left side of the display. All waves will be restarted.

The **Print Wedge** menu selection will begin a continuous printout of the top two waveforms on the **Wedge Menu**. By default these waveforms are **ECG1** and **PA**. To stop the Wedge printout, select **Print Wedge** again.

The **Wedge Setup** menu selection opens the **Wedge Setup Menu**. This menu allows you to make the following changes to the waveforms displayed on the **Wedge Menu**:

1. Change the parameters displayed in the upper and lower waveform windows.
2. Change the scale of the PA waveform.
3. Change the speed of the waveforms displayed.

The monitor also allows you to use the PA Diastolic (PAD) reading as PAWP.

NOTE: Please check hospital policy concerning the use of PAD as a Wedge

To use the Pulmonary Artery Diastolic reading as PAWP, select **Accept PAD as Wedge** from the **PA Menu**. A confirmation prompt will appear. This menu selection will not be available if the PA Diastolic value is invalid or the pressure channel in use has not been zeroed.

2.4.13.2 PAWP Troubleshooting

MESSAGE/PROBLEM	REASON	SOLUTION
Unable to Wedge	Improper catheter position	Check PA catheter, notify physician
	Catheter against wall or blood vessel	Flush catheter, notify physician
PA catheter in Spontaneous Wedge	Catheter in too far	Notify physician immediately
"Overwedging" or dampened PAWP	Balloon overinflated	Deflate balloon, reinflate slowly, notify physician

2.4.14 Cardiac Output (CO) (Optional)

Cardiac Output (CO) is the amount of blood ejected from the left ventricle each minute, expressed in liters per minute (l/min). Cardiac Index (CI) is the Cardiac Output divided by the patient's body surface area. The following two sources can be used to measure CO:

- the External Parameter Module (EPM)
  (P/N 0998-00-0501-01X and 0998-00-0501-03X)
- the Edwards Vigilance® Monitor (Vigilance)

CO can be monitored when Patient Size is set to either Adult or Pediatric and:

1. When the Hemodynamics Option is installed and the EPM is enabled in the **Installation Menu**

   and/or

2. When the Vigilance Option is installed and a serial port is set to Vigilance in the **Installation Menu**

Cardiac Output cannot be monitored when Patient Size is set to Neonate.

2.4.14.1 External Parameter Module (EPM) (Optional)

Intermittent (bolus) CO can be monitored through an EPM. If a tile has been set to display CO from the **Display Setup Menu**, when measuring intermittent CO with the EPM, the CO tile will be displayed as shown in the example of FIGURE 2-58. The "@ 3:06 PM" label shown in the example is a "time stamp" that indicates the time at which the displayed measurement occurred. A "Source" label indicates the source of the CO. The units of measure for each parameter are: CO - l/min, CI - l/min/m^2

NOTE: **If the "CO & PAWP Timeout" setting in the Installation Menu is exceeded, the CO and CI numeric data in the CO tile will be replaced by dashes and the "time stamp" will be removed.**

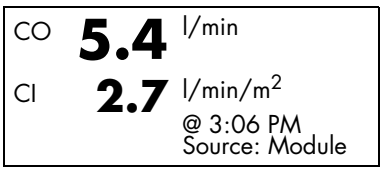


FIGURE 2-58 Example CO tile with Intermittent Cardiac Output from the EPM

Optimizing EPM Cardiac Output Measurements

1. From the PA catheter package insert, verify the correct computation constant for the catheter type, injectate volume, and injectate temperature. If the computation constant is different than the monitor's factory default of 0.500, it must be changed.
2. Verify proper PA catheter positioning.
3. Purge system of air.
4. Use correct injectate port.

5. Inject correct volume in smooth motion.
6. Edit erroneous values from average.

2.4.14.1.1 EPM Cardiac Output Setup

1. Ensure that the **Spectrum OR** is powered OFF.
2. Connect the EPM to the **Spectrum OR** as follows:
   a. Align the EB1 Module Connector on the EPM with the EM1 External Parameter Module Port on the rear of the **Spectrum OR**.
   b. Slide the EPM and the **Spectrum OR** together, using the Guide Pins on the EPM to guide the EB1 connector into the EM1 port. The Module Latches on the EPM will secure it to the **Spectrum OR**.
3. Power ON the **Spectrum OR** while holding down the **TRENDS** key to enter into its Installation Mode.
4. From the **Spectrum OR Installation Menu**, set "Enable EPM" to "Yes" and then select "Save Current".
5. Restart the **Spectrum OR** to enter normal monitoring mode.
6. From the **Patient Menu** of the main screen, set Patient Size to either Adult or Pediatric.
7. Open the **Cardiac Output Menu** (shown in FIGURE 2-59) in one of the following three ways:
   - by choosing **CO** from the **Parameters Menu**
   - by pressing the **C.O.** key on the front panel keypad
   - by pressing the **C.O.** key on the EPM keypad
8. Open the **CO Setup Menu** by choosing **CO Setup Menu** from the **Cardiac Output Menu**.

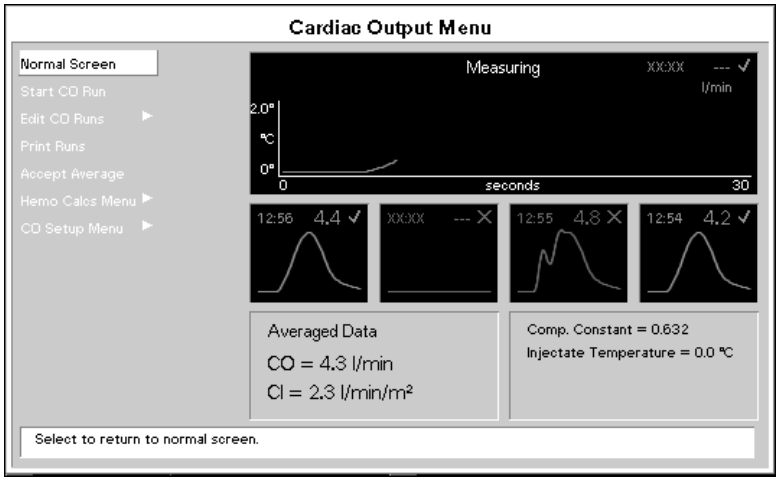


FIGURE 2-59 Cardiac Output Menu

2.4.14.1.2 CO Setup Menu

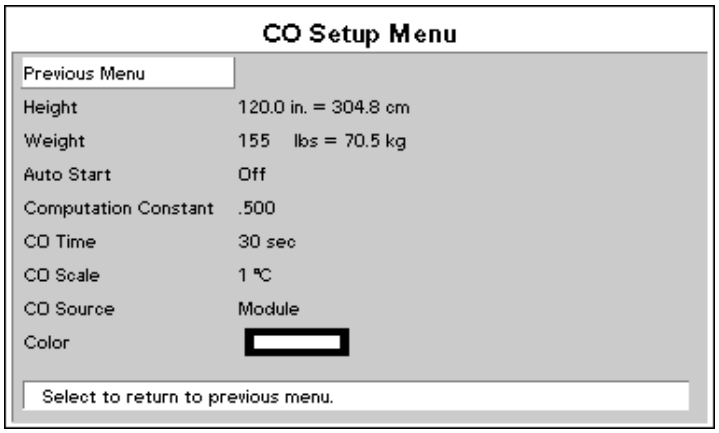


FIGURE 2-60 CO Setup Menu

Auto Start

With the EPM, there are two modes of operation: **Auto Start** and **Manual**. To choose the desired mode of operation, open the **CO Setup Menu** (shown in FIGURE 2-60) and set **Auto Start** to either **On** or **Off**.

In **Auto Start** Mode (when **Auto Start** is set to **On**), the monitor automatically displays the prompt **Inject when Ready** upon achieving a baseline blood temperature. When injection is completed, the Spectrum OR computes the CO and is ready to start another bolus injection.

In **Manual** Mode (when **Auto Start** is set to **Off**), the monitor will display the message **Ready** when a baseline blood temperature is achieved. **Manual** mode of operation is similar to **Auto Start** except that you must press **Start CO Run** or the **C.O.** key on the Monitor or EPM prior to each injection.

NOTE: **Refer to the catheter package insert provided with each PA catheter for the appropriate computation constant, specific instructions on catheter placement and use, warnings, cautions, and specifications.**

Computation Constant

Computation Constant is used to change the monitor's factory default of 0.500 with the appropriate computation constant from the PA catheter package insert.

CO Time

CO Time is used to adjust the time period for the current CO Run window shown in the top of the **Cardiac Output Menu**. Choices are 30 sec and 60 sec.

CO Scale

CO Scale is used to adjust the temperature scale for the current CO Run window shown in the top of the **Cardiac Output Menu**. Choices are 0.5 °C, 1 °C, 2 °C and 4 °C.

CO Source

As noted in the introduction to the Cardiac Output section, CO can also be measured through an Edwards Vigilance® Monitor. If both the EPM and the Vigilance are connected and the **Installation Menu** is properly configured, **CO Source** enables the user to choose either device as the source for CO. A detailed description of this configuration is provided in the **CO from both Vigilance and EPM** section.

2.4.14.1.3 Measuring Cardiac Output with the EPM

WARNING: Inaccurate Cardiac Output measurements may be caused by:

- **Incorrect placement or position of the catheter**
- **Excessive variation in pulmonary artery blood temperature**
- **Clot formation on the thermistor**
- **Anatomical abnormalities, (for example, cardiac shunts)**
- **Excessive patient movement**
- **Repeated intermittent flushes of cold fluid through the fluid lumens of the catheter**
- **Use of a manual pump such as the Abbott® Blood Set with Pump and CAIR clamp**
- **Electrocautery or electrosurgical unit interference**
- **Rapid changes in cardiac output**
- **Using an incorrect computation constant**

Auto Start On (Auto Mode)

1. Connect the proper Cardiac Output cable and PA catheter. Open the **CO Setup Menu** and set **Auto Start** to **On**. From the PA catheter package insert, verify the correct computation constant for the catheter type, injectate volume, and injectate temperature. Set the **Computation Constant** as necessary if it is different than the monitor's factory default of 0.500. Return to the **Cardiac Output Menu**.
2. When a stable baseline blood temperature is obtained, the **Inject when Ready** message will be displayed. Proceed with a bolus injection.

CAUTION: Sudden changes in blood temperature such as those caused by bolus drug administration may cause a CO or CI value to be computed. To avoid falsely triggered curves, inject as soon as possible after the "Inject when Ready" message is displayed.

3. Once a bolus is injected, the CO curve appears, the **Measuring** message is displayed, and the resultant CO measurement is displayed.

NOTE: If a measurement is compromised, as indicated by an Irregular Curve or Injectate Temp Error alert message, the curve will be displayed in Red and an X mark will be displayed in the box.

4. Note the injectate temperature and verify that the correct computation constant was set.
5. Subsequent cardiac output runs can be performed as desired when the **Inject when Ready** message reappears.
6. When sufficient CO runs are completed, use **Edit CO Runs** to choose the runs to be computed in the **CO Average**. Runs that have green waveform data and a check mark (✓) in the box will be included in the average. Runs that have red waveform data and an X mark (X) in the box will be excluded from the average.
7. Select the **Accept Average** key to accept and store the **CO Average**.
8. To display Cardiac Index (CI), the patient weight and height must be entered via the **CO Setup Menu** or the **Patient Menu**.

Auto Start Off (Manual Mode)

1. Connect the proper Cardiac Output cable and PA catheter. Open the **CO Setup Menu** and set **Auto Start** to **Off**. From the PA catheter package insert, verify the correct computation constant for the catheter type, injectate volume, and injectate temperature. Set the **Computation Constant** as necessary if it is different than the monitor's factory default of 0.500. Return to the **Cardiac Output Menu**.
2. When a stable baseline blood temperature is obtained, the **Ready** message will be displayed. Select **Start CO Run** or the **C.O.** key on the Monitor or Module and the **Inject Now** message will be displayed. Proceed with a bolus injection.

NOTE: **You have a maximum of 30 seconds in which to inject following Start CO Run. If no injection is detected within this time interval, the display returns to Ready until you choose to resume the measurement sequence.**

3. Once a bolus is injected, the CO curve appears, **Measuring** message is displayed, and the resultant CO measurement is displayed.

NOTE: **If a measurement is compromised, as indicated by an Irregular Curve or Injectate Temp Error alert message, the curve will be displayed in Red and an X mark will be displayed in the box.**

4. Note the injectate temperature and verify that the correct computation constant was set.
5. Subsequent CO runs can be performed as desired when the **Ready** message reappears.
6. When sufficient CO runs are completed, use **Edit CO Runs** to choose the runs to be computed in the CO Average. Runs that have green waveform data and a check mark (✓) in the box will be included in the average. Runs that have red waveform data and an X mark (X) in the box will be excluded from the average.
7. Select the **Accept Average** key to accept and store the **CO Average**.
8. To display Cardiac Index (CI), the patient weight and height must be entered via the **CO Setup Menu** or the **Patient Menu**.

2.4.14.1.4 EPM Cardiac Output Troubleshooting

MESSAGE/ PROBLEM	REASON	SOLUTION
CO value higher / lower than expected	Computation constant incorrect for PA catheter type, injectate temperature, and injectate volume.	Check computation constant and enter correct data.
	Catheter may be kinked or not in proper position.	Notify physician.
No measurement/ Unable to measure	Unstable temperature.	Check injectate temperature.
	No temperature or temperature out of range.	Flush PA catheter.
	Time elapsed for measurement.	Discard bolus fluid.
		Check patient.
		Wait for **Ready** or **Inject when Ready** message to appear. Rebolus when ready.
CO Signal Under Range	Appears if the CO curve is not sufficient for a CO calculation or if a curve is not detected within thirty (30) seconds	Rebolus if necessary
CO Out of Range	Appears if the CO is out of the measurable range (0.2 l/min to 20.0 l/min). Computation constant incorrect for PA catheter type, injectate temperature, and injectate volume.	Check computation constant and enter correct data. Rebolus when ready.
Irregular curve	Improper injection procedure.	Check hospital policy, inject in a smooth and fluid bolus.
	Catheter may be kinked or not in proper position.	Notify physician.
	Patient movement during injection.	Have patient lay still during bolus procedure.
	Measurement displayed if CO curve has multiple peaks, failure to return to baseline or irregularities in curve.	Rebolus when ready
Delayed Injection	Appears if the time between the start of the CO measurement and the onset of the temperature change is more than fifteen (15) seconds	Rebolus when ready.
		Ensure that the CO bolus is initiated within 15 seconds
		Check the temperature of the injectate
Injectate Temp Error	Appears when the temperature of the injectate is too warm (>27°C) or the difference between the injectate and the blood temperature is <8°C.	Check injectate fluid, insure fluid is not under warm lights, near a warming blanket or another warm source.
Noisy Baseline	Cardiac Output waveform baseline is unstable	Rebolus when ready.
Measuring	Appears once an injection is detected during the process of a CO run.	
Injectate Temp. Out of Range	Appears when the temperature of the injectate is too warm (>27°C) or the difference between the injectate and the blood temperature is <8°C.	Check injectate fluid, insure fluid is not under warm lights, near a warming blanket or over-chilled in the ice bath.

MESSAGE/ PROBLEM	REASON	SOLUTION
Inject When Ready	Appears if **Auto Start** is enabled, stable temperatures are detected	Bolus when ready
Ready	Appears if **Auto Start** is not enabled, and stable temperatures are detected	Press **START** when ready
Inject Now	Appears once **START** has been pressed, before bolus is initiated	Bolus when ready
Please Wait	Appears after fluid bolus is initiated and Cardiac Output is being calculated	Wait until message disappears

2.4.14.2 Edwards Vigilance® Monitor (Vigilance) (Optional)

For questions regarding the use and maintenance of the Edwards Vigilance® Monitor, refer to its operator's manual or contact Edwards Lifesciences Corporation for assistance. Within the USA: (800) 424-3278, Outside the USA: (949) 250-2500.

The standard Edwards Vigilance Monitor measures both intermittent and continuous cardiac output (CO), as well as TBlood. It can also be optionally configured to measure continuous mixed venous oxygen saturation (SvO_2). Intermittent CO uses the bolus thermodilution method, while continuous CO uses a pulmonary artery catheter to introduce small pulses of energy into the blood and then record the blood temperature. SvO_2 is measured by a spectrophotometric technique that uses light emitting diodes to transmit light in the red and infrared spectra through an optical fiber in a pulmonary artery catheter to the blood.

The Vigilance Monitor can be interfaced with the **Spectrum OR**. This enables Vigilance CO, TBlood and SvO_2 data to be displayed and trended at the **Spectrum OR**, as well as providing alarm control for these parameters. SVR also may be displayed, but not trended. The **Spectrum OR** uses TBlood data from Vigilance to derive ΔT which can also be displayed and trended, as well as providing alarm control.

At the **Spectrum OR**, the CO value is divided by the patient's BSA (Body Surface Area) to calculate and display a corresponding cardiac index (CI). The BSA is determined from the patient's height and weight as entered in the **Spectrum OR**.

Cardiac Output (CO)

When measuring continuous cardiac output, the CO tile on the main screen of the **Spectrum OR** will be displayed as shown in the example of FIGURE 2-61. The "@Cont" label in the example CO tile indicates that the displayed measurements are continuous. If the Vigilance is used for intermittent CO measurements, an "@XX:XX" label will be displayed. This label is a "time stamp" where XX:XX = the time at which the displayed measurements occurred. Although not displayed, the units of measure for each attribute are: CO - l/min, CI - l/min/m2, SVR - dynes/sec/cm-5, SvO2 - %.

NOTE: **If the Edwards Vigilance Monitor is powered off or disconnected from the Spectrum OR, the CO tile will be automatically removed from the display.**

NOTE: **If the Edwards Vigilance® Monitor is the source for CO, CCO, CI, CCI, SVR, SvO2, TBlood and DT measurements, this data will not be available at the Panorama Central Station.**

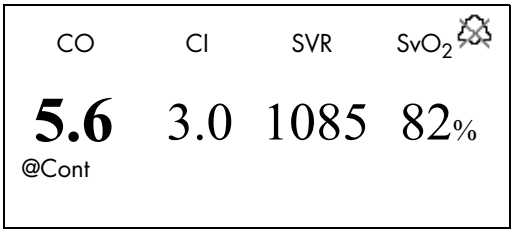


FIGURE 2-61 Example CO tile with Continuous Cardiac Output from Vigilance

The setup and patient connections for the Vigilance must be completed as instructed in the Vigilance Monitor Operator's Manual.

To display Vigilance cardiac output measurements at the **Spectrum OR**, the two devices must be physically configured as follows:

- the **Spectrum OR** must be equipped with an optional Comm-Port that contains serial port interface SP1 and/or SP2
- the two devices must be interfaced using the Vigilance/PC Interface cable (serial port to serial port) (P/N 0012-00-1275-01) as described in step 1 of the following section.

Systemic Vascular Resistance (SVR)

The **Spectrum OR** will calculate and display SVR (see FIGURE 2-61) under the following conditions:

- the CO source is set to Vigilance in the Vigilance CO Menu
- cardiac output (CO) is in continuous mode
- continous CO data is available from the Vigilance
- one of IBP1, IBP2, IBP3, or IBP4 is labled Art, and a valid value is available
- one of IBP1, IBP2, IBP3, or IBP4 is labled CVP, and a valid value is available

The SVR value is determined from the following calculation (See section 2.5.2, "Hemodynamic Calculations"): ((ART mean-CVP) / CO) x 79.96.

NOTE: **The real-time SVR value displayed in the CO tile (see FIGURE 2-61) is continuously recalculated, and may differ from the static SVR value displayed in the Hemodynamics Calculations Log.**

2.4.14.2.1 Vigilance CO Setup

1. Both ends of the Vigilance/PC Interface cable are identical. Before it is connected, ensure that the Vigilance and the **Spectrum OR** are powered OFF. Connect one end of the cable to the **Spectrum OR** at a serial port (SP1 or SP2) that is located on the optional Comm-Port. Connect the other end of the cable to the Vigilance at the COM 1 port.

2. Power ON the Vigilance and then power ON the **Spectrum OR** while holding down the **TRENDS** key to enter into its Installation Mode.
3. Set a serial port to "Vigilance" and then select "Save Current".
4. Restart the **Spectrum OR** to enter normal monitoring mode.
5. From the **Patient Menu** of the main screen, set Patient Size to either Adult or Pediatric.
6. Open the **Vigilance CO Menu** by choosing **CO** from the **Parameters Menu** or by pressing the **C.O.** key on the front panel keypad.

NOTE: **The C.O. key on the EPM keypad does not function when the Spectrum OR is configured to monitor Vigilance cardiac output measurements.**

2.4.14.2.2 Vigilance CO Menu

The **Vigilance CO Menu** enables the user to:

- set the patient height and weight to be used in calculating cardiac index (CI)

NOTE: **Other menus also use patient height and weight data. When this data is changed in any menu, it is automatically updated in the other menus.**

- choose the source for cardiac output
- access the **Hemodynamics Calculations Menu** (a description of the **Spectrum OR** Hemodynamics Calculation method is provided in section 2.5.2)
- choose the color of the data that will display in the CO tile

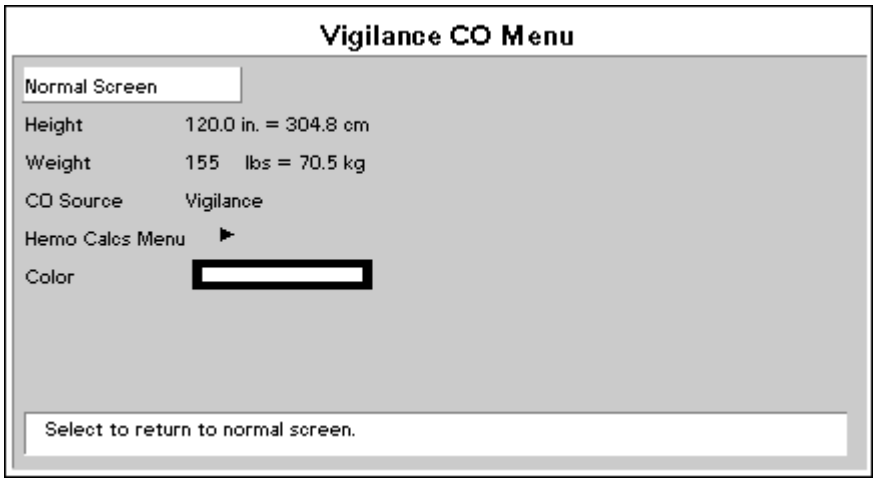


FIGURE 2-62 Vigilance CO Menu

CO Source

As noted in the introduction to the Cardiac Output section, CO can also be measured through an EPM. If both the EPM and the Vigilance are connected and the **Installation Menu** is properly configured, **CO Source** enables the user to choose between either device as the source for CO. A detailed description of this configuration is provided in the **CO from both Vigilance and EPM** section.

2.4.14.2.3 Vigilance Cardiac Output Troubleshooting

MESSAGE/ PROBLEM	REASON	SOLUTION
CO: Check Vigilance.	This message is displayed when an alert or alarm status has been sent from the Vigilance to the Spectrum OR.	Refer to the Edwards Vigilance® Monitor Operator's Manual or contact Edwards Lifesciences Corporation for assistance. Within the USA: (800)-424-3278 Outside the USA: (949)-250-2500

2.4.14.3 CO from both Vigilance and EPM

If switching between Vigilance CO and EPM CO is desired, proceed as follows:

1. Setup the EPM as described in steps 1 and 2 of the **EPM Cardiac Output Setup** section.
2. Setup the Vigilance as described in step 1 of the **Vigilance CO Setup** section.
3. Power ON the Vigilance and then power ON the **Spectrum OR** while holding down the **TRENDS** key to enter into its Installation Mode.
4. Set "Enable EPM" to "Yes", set a serial port to "Vigilance" and then select "Save Current".
5. Restart the **Spectrum OR** to enter normal monitoring mode.
6. From the **Patient Menu** of the main screen, set Patient Size to either Adult or Pediatric.
7. Open the **Cardiac Output Menu** (shown in FIGURE 2-59) in one of the following three ways:
   - by choosing **CO** from the **Parameters Menu**
   - by pressing the **C.O.** key on the front panel keypad
   - by pressing the **C.O.** key on the EPM keypad
8. Open the **CO Setup Menu** by choosing **CO Setup Menu** from the **Cardiac Output Menu**.

   EPM CO:

   Refer to the **CO Setup Menu** section.

   Vigilance CO:

   a. Choose "CO Source" from the **CO Setup Menu**, select "Vigilance" and then close the **CO Setup Menu**.

   b. Open the **Vigilance CO Menu** by choosing **CO** from the **Parameters Menu** or by pressing the **C.O.** key on the front panel keypad.

NOTE: **The C.O. key on the EPM keypad does not function when the Spectrum OR is configured to monitor Vigilance cardiac output measurements.**

   c. Refer to the **Vigilance CO Menu** section 2.4.14.2.2.

2.4.15 Bispectral Index (BIS)

The Bispectral Index™ (BIS™) is designed to monitor the hypnotic state of the brain based on acquisition and processing of EEG signals. The Aspect Medical Systems BISx™ Module processes raw EEG signals to produce a single number, called the Bispectral Index, or BIS, which correlates with the patient's level of hypnosis. The BIS may be used as an aid in monitoring the effects of certain anesthetic agents. Use of BIS monitoring to help guide anesthetic administration may be associated with the reduction of the incidence of awareness with recall in adults during general anesthesia and sedation.

WARNING: This Spectrum OR monitor uses a component modular device in deriving the Bispectral Index (BIS) purchased from Aspect Medical Systems, Inc. It is important to recognize that this index is derived using solely that company's proprietary technology. It is recommended that clinicians have reviewed applicable information on its utility and/or risks in published articles and literature/web site information from Aspect Medical Systems, Inc. or contact that company itself if they have clinical-based BIS questions relating to this module portion of the Spectrum OR monitor. Failure to do so could potentially result in the incorrect administration of anesthetic agents and/or other potential complications of anesthesia or sedation. We recommend that clinicians also review the following practice advisory (that includes a section on BIS monitoring): The American Society of Anesthesiologists, Practice Advisory for Intra-operative Awareness and Brain Function Monitoring (Anesthesiology 2006;104:847-64). Clinicians are also recommended to maintain current knowledge of FDA or other federal-based regulatory, practice or research information on BIS and related topics.

A sensor placed on the patient's head transmits EEG signals to the BISx Module. The BISx Module filters the data, analyzes it for artifact and processes it using digital signal processing techniques, then sends the data to the monitor for display. The purpose of processing the EEG waveform data is to extract characteristic features from the complex signal in order to provide easier pattern recognition of changes over time during the recording. The monitor can be configured to display the following BIS related information:

- A BIS Parameter Tile that displays the following:

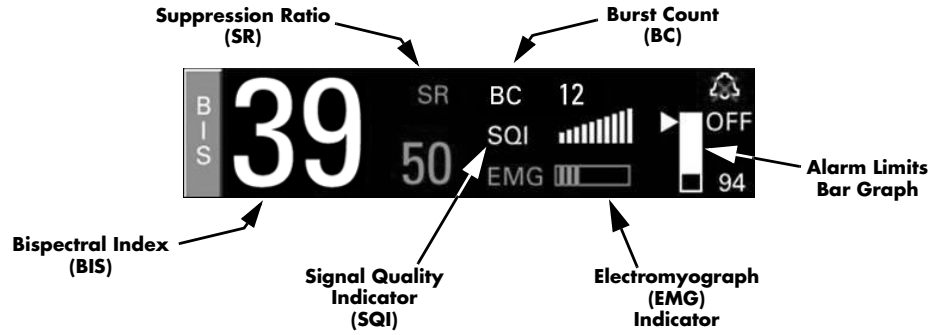


FIGURE 2-63 Example BIS Parameter Tile

- Bispectral Index (BIS) – a two-digit value ranging from 0 to 99 that represents the patient's hypnotic state. The BIS number is invalidated (displayed as dashes) when the SQI is less than 15 and is displayed as a hollow number when the SQI is less than 50.
- A Suppression Ratio (SR) Number – The Suppression Ratio (SR) is a calculated parameter designed to indicate when an isoelectric (flatline) condition may exist. Suppression ratio is the percentage of time over the last 63-second period that the signal is considered to be in the suppressed state. For example: SR=11 (isoelectric over 11% of the last 63 second review).
- A Burst Count (BC) – Only available when a BIS Extend Sensor is in use, the Burst Count is an alternative method of quantifying suppression, reported as the number of EEG bursts per minute. The Burst Count displays only when the Signal Quality Indicator (SQI) is greater than 15 and the Suppression Ratio (SR) is greater than 5.
- A Signal Quality Indicator (SQI) – The SQI bar graph is an indication of the quality of the EEG signal that is received and processed into onscreen data. Signal quality is optimal when all ten bars are gray.
- An Electromyograph (EMG) Indicator – The EMG bar graph displays the power (in decibels) in the frequency range 70 - 110 Hz. This frequency range contains power from muscle activity (i.e., electromyography or "EMG") as well as power from other high-frequency artifacts. When the graph is low, it indicates that EMG activity is low, which is desirable. High levels of EMG may bias the BIS number high.
- A vertically oriented alarm limits bar graph – The High and Low BIS alarm limits are user configurable from the **Alarm Setup** menu. These limits are displayed to the right of the bar graph with the High limit at the top and the Low limit at the bottom. The current BIS value is indicated with an arrowhead to the left of the bar graph.

- A Raw EEG Waveform Tile
- A BIS Trend Tile that simultaneously displays the following (see section 2.4.15.3 for a description of the BIS Trend Setup Menu):

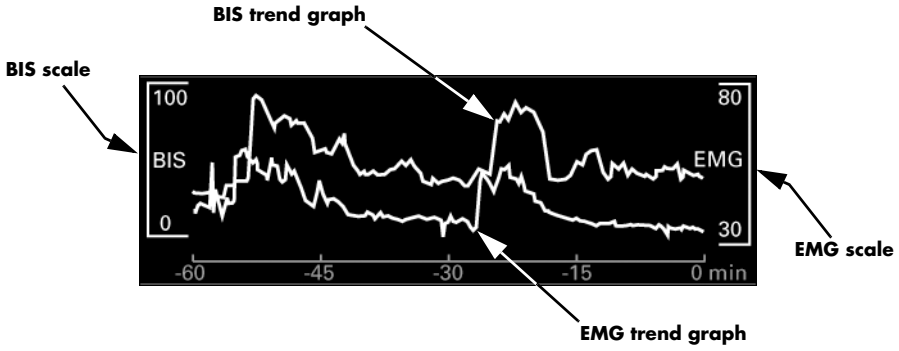


FIGURE 2-64 Example BIS Trend Tile

- A BIS trend graph
- An EMG trend graph
- A time scale along the horizontal axis

NOTE: **The BIS trend and EMG trend graphs are dynamically updated graphs that plot data points from right to left. Each successive data point is connected with the previous data point by a solid line. When the displayed data points have reached the boundary of the left end of the time scale, the oldest data point is removed from the graph as the newest data point is added to the graph.**

Considerations for Using BIS Monitoring

Clinical judgment should always be used when interpreting the BIS in conjunction with other available clinical signs. Reliance on the BIS alone for intraoperative anesthetic management is not recommended. As with any monitored parameter, artifacts and poor signal quality may lead to inappropriate BIS values. Potential artifacts may be caused by poor skin contact (high impedance), muscle activity or rigidity, head and body motion, sustained eye movements, improper sensor placement and unusual or excessive electrical interference. Due to limited clinical experience, BIS values should be interpreted cautiously in patients with known neurological disorders, those taking other psychoactive medications, and in children below the age of one.

2.4.15.1 BIS Setup

NOTE: **Please refer to the sensor manufacturer's instructions for use for detailed instructions on sensor application and use.**

1. Connect the BISx Module to the monitor

- Plug the BISx Monitor Interface Cable into the MB1 (Module Bus Port) connector on a Comm-Port installed in the back of the monitor or into the MB2 connector on an optional EPM (External Parameter Module).

2. Connect the Patient Interface Cable (PIC) to the BISx Module

- Attach the 10-pin connector from the PIC to the BISx Module.

NOTE: **The connector is designed with a keyway that ensures proper pin alignment. To disconnect the PIC, grasp the connector housing and pull firmly. DO NOT pull the cable.**

3. Attach the BIS Sensor to the patient

- In accordance with the instructions included on the sensor packaging, prepare the sensor site and place the BIS sensor on the patient.

CAUTION: **The BISx Module has been designed to operate with a BIS sensor. The sensor is a silver/silver chloride electrode array that utilizes Aspect's patented Zipprep technology and uses a proprietary connector. Use of other electrodes is not recommended.**

WARNING: **The conductive parts of BIS electrodes or sensor and connectors, including the neutral electrode, should not contact other conductive parts, including earth.**

WARNING: **To reduce the hazard of burns in the high-frequency surgical neutral electrode connection, the BIS sensor or electrodes should not be located between the surgical site and the electro-surgical unit return electrode.**

WARNING: The BIS sensor must not be located between defibrillator pads when a defibrillator is used on a patient connected to the BISx module.

WARNING: To minimize the risk of patient strangulation, the BIS Patient Interface Cable (PIC) must be carefully placed and secured.

4. Secure the BISx Module

- Using the BISx clamp, secure the BISx Module to a convenient location near the patient's head (e.g. IV pole, bed rail or bedsheet), ensuring that both the clamp and the module are not in direct contact with any part of the patient's body.

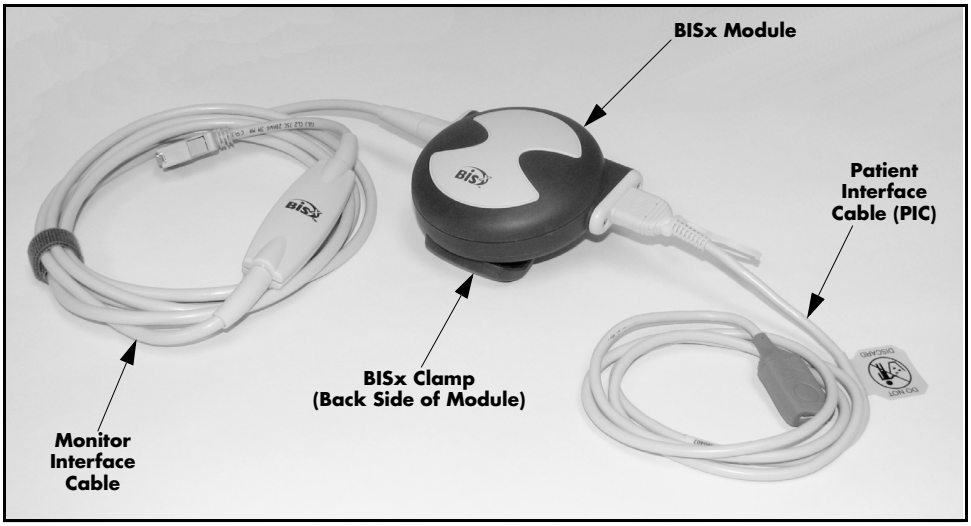


FIGURE 2-65 BISx Module with cables attached

WARNING: Ensure against prolonged contact between the patient's skin and the BISx Module. The heat that may be generated could cause discomfort.

CAUTION: Do not open the BISx Module for any reason. The seal to prevent liquids from entering the module may be damaged if opened. Service or repairs must be performed by qualified biomedical technicians only.

Acceptable service/repair of the BISx Module in the field is limited to:

- Replacement of the Monitor Interface Cable
- Replacement of the Patient Interface Cable (PIC)
- Replacement of the BISx integral connector for the Patient Interface Cable.

5. Power ON the **Spectrum OR**.
6. Connect the BIS Sensor to the PIC as shown in FIGURE 2-66.
   - One side of the PIC sensor connector has a release button. Align that side with the blank side of the sensor paddle (i.e. the side without the "Smart Chip"). Insert the sensor paddle into the PIC sensor connector until a "click" is felt.

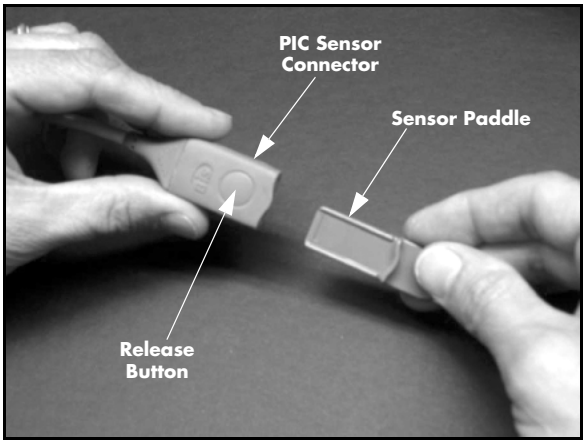


FIGURE 2-66 Connecting the Sensor to the PIC

NOTE: **To ensure that a valid, unexpired sensor is in use, an automatic Sensor Integrity Check is initiated each time that a sensor is connected to the PIC.**

2.4.15.1.1 Sensor Check

The Sensor Check tests the impedance of each electrode on the BIS sensor to verify that it is within an acceptable range for monitoring. There are two types of Sensor Checks as follows:

Background Sensor Check

If the initial Sensor Integrity Check is successful after connecting the BIS sensor, and while BIS monitoring is in process, impedance checking of the sensor occurs continuously in the background.

- If all of the background impedance values are within range, the monitor will begin displaying the BIS waveforms and numerics.
- If any of the background impedance values are out of range, the technical message "BIS: Check Sensor" will be displayed in the message area at the bottom of the main screen. A Manual Sensor Check should be performed as described in the next section.

Manual Sensor Check

When **Sensor Check** is chosen from the **BIS Menu**, the **BIS Sensor Check** menu shown in FIGURE 2-67 is displayed and the electrode impedance measurements immediately begin.

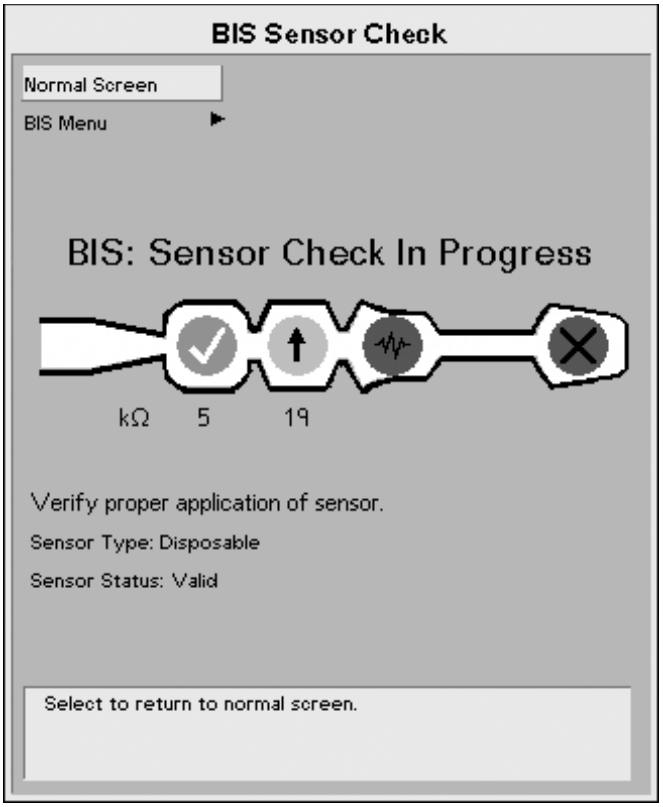


FIGURE 2-67 BIS Sensor Check Menu

The **BIS Sensor Check** menu provides the following choices: **Normal Screen** and **BIS Menu**.

- The **Normal Screen** selection returns the view to the normal screen.
- The **BIS Menu** selection returns the display to the **BIS Menu**.

Below the two menu choices, the **BIS Sensor Check** menu includes a graphical depiction of the BIS sensor and several areas for the display of messages. The area above the BIS sensor graphic may display either of the following messages that guide the user on how to proceed based on the icons that are currently being displayed for each electrode.

- The message "BIS: Sensor Check In Progress" will be displayed while the electrode impedance measurements are in progress and when an invalid sensor is detected.
  - When an invalid sensor is detected, the technical message "BIS: Invalid Sensor" will be displayed in the message area at the bottom of the main screen.
- When a Sensor Check is successful, the message "PASS" will be displayed.
  - Select the **Normal Screen** menu choice or press the **NORMAL SCREEN** key on the front panel keypad to return to the main screen.

The graphic depiction of the BIS sensor includes four circular fields at the locations of the electrodes that are positioned along the sensor's lengthwise axis. The circular fields will display any one of the following four circular icons based on measured electrode impedances. For purposes of interpretation of the icons and associated electrode impedances, the electrodes are numbered from left to right along the sensor's lengthwise axis as #1, #2, #4, and #3:

Icon	Description
	**PASS Icon** - a white check mark on a green background. An electrode passes if the impedance for that electrode is less than 7.5 kΩ. The ground electrode (electrode #2) must be less than 30 kΩ to pass.
	**HIGH Icon** - a black, upward facing arrow on a yellow background. This icon is displayed for electrode impedance values above 7.5 kΩ. **NOTE:** If the combined impedance of electrodes #1 and #3 is less than 15 kΩ and the combined impedance of electrodes #1 and #4 is less than 15 kΩ, the overall sensor check will be considered successful. If either of the combined impedances is over the 15 kΩ limit, re-prep the HIGH electrode(s) and check all connections. The impedance check will continue until it is acceptable.
	**NOISE Icon** - a black "waveform" (exhibiting noise) on a gray background. If the signal from the electrode exceeds the measurable range, the message **BIS: Noise** displays in message area B. Re-prep the electrode(s) and check all connections.
	**FAIL Icon** - a black "X" on a red background. Re-prep the electrode(s) and check all connections.

The impedance value (in kΩ) corresponding to each electrode will be displayed directly below its location on the BIS sensor graphic.

The following message is provided below the impedance values as a constant reminder to the user: "Verify proper application of sensor".

The area below that message will display information related to the specific BIS sensor that is in use.

- **Sensor Type:** - This field can display one of the following: Disposable, Extend, or SRS (Semi Reusable Sensor). SRS sensors are available for international distribution only.

NOTE: Not all sensor products are available in all markets.

- **Sensor Status:** - This field can display one of the following based on the Sensor Type:

Disposable or Extend Sensor	SRS Sensor
Valid	Valid
Invalid Sensor, Replace Sensor	Invalid Cable, Replace Cable
Too Many Uses, Replace Sensor	Too Many Uses, Replace Cable
Expired, Performance May Be Compromised	Not Connected

- **Uses Remaining:** - This field is only displayed when the Sensor Type is SRS. While there are greater than 50 uses remaining, this field will display "50+". When the number of uses remaining is below 50, this field will display the actual number.

To end the impedance test, select **Normal Screen** or **BIS Menu**. Regardless of whether or not the **BIS Sensor Check** menu is open, the impedance values continuously update. Normal BIS processing will not resume unless the Sensor Check (background or manual) is successfully completed.

2.4.15.2 BIS Measurement

1. There are four user-selectable display configurations for BIS:

- the BIS parameter tile by itself
- the BIS parameter tile with an associated BIS Trend window
- the BIS parameter tile with an associated EEG waveform window
- the BIS parameter tile with an associated BIS Trend window and an associated EEG waveform window

Choose **Display Setup** from the **Monitor Setup Menu** and designate the display configuration for BIS as follows:

- If only the BIS parameter tile by itself is desired, select **BIS** from the menu choices of one of the 5 lower parameter tiles.
- If the BIS parameter tile with an associated BIS Trend window is desired, select **BIS Trends** from the menu choices of one of the 7 configurable upper waveform associated tiles.
- If the BIS parameter tile with an associated EEG waveform window is desired, select **EEG** from the menu choices of one of the 7 configurable upper waveform associated tiles.
- If the BIS parameter tile with an associated BIS Trend window and an associated EEG waveform window is desired, select **BIS/EEG Combo** from the menu choices of one of the 7 configurable upper waveform associated tiles.

2. To make adjustments to certain BIS attributes or to initiate a manual sensor check, access the **BIS Menu** by choosing **BIS** from the **Parameters Menu** or by choosing its menu target from the main screen.

NOTE: **The trace speed of the EEG waveform can be adjusted using the EEG Speed menu choice in the Monitor Setup Menu.**

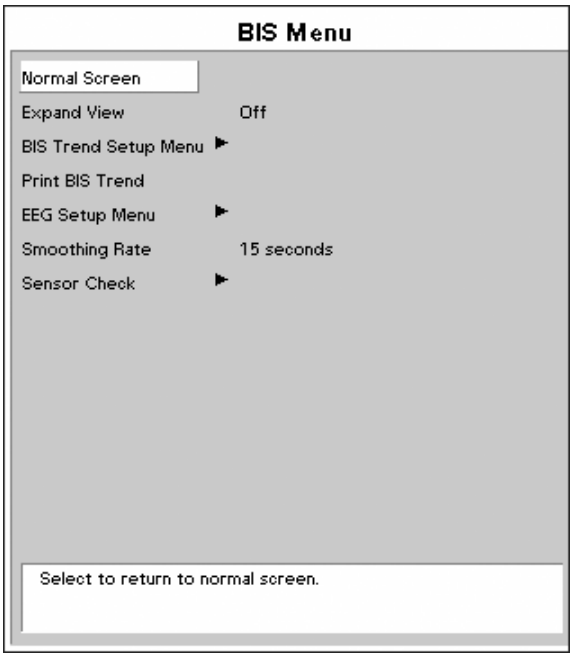


FIGURE 2-68 BIS Menu

The **BIS Menu** is accessed by choosing **BIS** from the **Parameters Menu** or by choosing its menu target from the main screen. It provides the following choices: **Normal Screen**, **Expand View**, **BIS Trend Setup Menu**, **Print BIS Trend**, **EEG Setup Menu**, **Smoothing Rate** and **Sensor Check**.

- The **Normal Screen** selection returns the view to the normal screen.
- When the **Expand View** selection is set to **On**, the height of the BIS/EMG graphic trend expands to improve its resolution.
- The **BIS Trend Setup Menu** selection is used to open the **BIS Trend Setup Menu**.
- The **Print BIS Trend** selection is used to print the BIS/EMG graphic trend to the internal printer. This menu choice is only available when the **Select Printer** menu choice in the **Print Setup Menu** is set to "Local".
- The **EEG Setup Menu** selection is used to open the **EEG Setup Menu**.
- The **Smoothing Rate** selection is used to change the smoothing rate over which the BIS value is averaged. The choices are: 10 seconds, 15 seconds and 30 seconds.

NOTE: **A faster smoothing rate will increase the responsiveness of the BIS number to state changes but will also cause more variability and sensitivity to artifact.**

- The **Sensor Check** selection opens the **BIS Sensor Check** menu.

2.4.15.3 BIS Trend Setup Menu

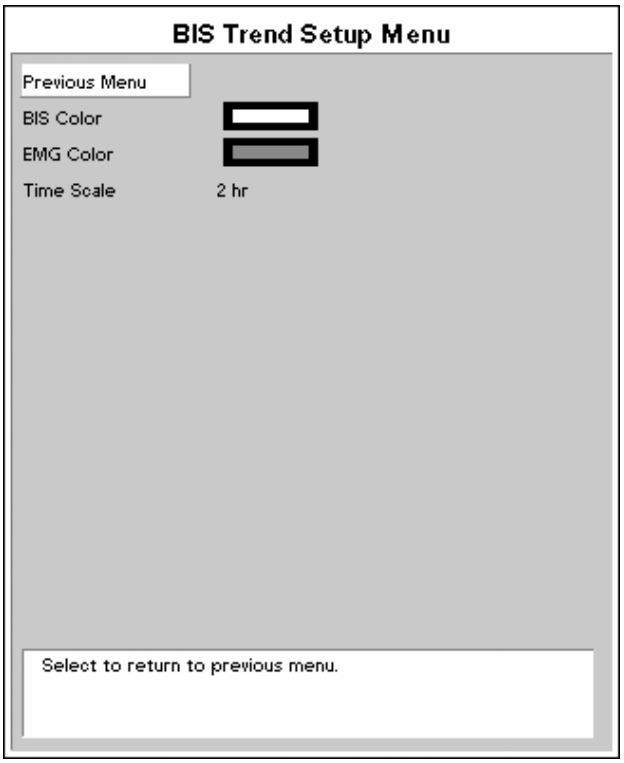


FIGURE 2-69 BIS Trend Setup Menu

The **BIS Trend Setup Menu** is accessed by choosing **BIS Trend Setup Menu** from the **BIS Menu**. It provides the following choices: **Previous Menu**, **BIS Color**, **EMG Color** and **Time Scale**.

- The **Previous Menu** selection returns the view to the previous menu.
- The **BIS Color** selection is used to set the color for the BIS Trend graph, and the following numerics in the BIS Parameter tile: BIS, Suppression Ratio (SR) and Burst Count (BC).
- The **EMG Color** selection is used to set the color for the EMG Trend graph and the EMG bar graph in the BIS Parameter tile.
- The **Time Scale** selection is used to set the time scale over which the BIS and EMG Trends are displayed. The choices are: 15 min, 30 min, 1 hr, 2 hr, 4 hr, 8 hr, 12 hr, 24 hr.

2.4.15.4 BIS Troubleshooting

MESSAGE/ PROBLEM	REASON	SOLUTION
BIS: Check Sensor	Incorrect sensor application.	Read Instructions on sensor package and re-prep sensor.
	Poor sensor connections.	Check sensor connections.
	Sensor Check fails.	Re-prep again or replace sensor. Verify Sensor Check passes.
	Defective PIC.	Replace the PIC.
	Defective BISx Module.	Replace the BISx Module.
	Problem is detected relating to sensor ground element. Sensor Overcurrent Sensor is using too much current.	Disconnect and examine sensor connection. Clean any contamination present. Replace sensor if necessary.
	One or more of the electrode impedances exceeds the threshold.	Reattach the sensor to the patient by following sensor instructions or replace the sensor. Verify Sensor Check passes.
BIS: No Sensor	Disconnected sensor.	Connect the sensor.
	Poor or contaminated connection between sensor and PIC.	Connect/clean connection between sensor and PIC.
	Disconnected PIC.	Connect the PIC.
	Defective PIC.	Replace the PIC.
	Defective BISx Module.	Replace the BISx Module.
BIS: Artifact	Artifact, such as those generated by motion or eye blinks, is causing loss of EEG recognition. The BIS value and other trend variables that are adversely affected by artifact are not displayed.	Attempt to identify and eliminate artifact source.
BIS: Check SQI Level	EMG Bar indicates electrical activity that may be interfering with EEG recognition.	If EMG bar is illuminated, attempt to determine and eliminate cause.
	Defective PIC.	Verify Sensor Check passes. If not, replace PIC.
	Defective BISx Module.	Replace the BISx Module.
	NOTE: This message is displayed when the Signal Quality is less than half of the level desirable for optimal monitoring conditions or when the signal quality is too low to accurately calculate a BIS value. This may occur as the result of artifact (non-EEG signal) such as that generated from motion (patient movement or eye blinks) or the presence of electrocautery, warming blankets, or other devices.	
BIS: Invalid Sensor	Poor or contaminated connection between sensor and PIC.	Connect/clean connection between sensor and PIC.
	Defective sensor.	Replace the sensor.
	Defective PIC.	Replace the PIC.
	Defective BISx Module.	Replace the BISx Module.

MESSAGE/ PROBLEM	REASON	SOLUTION
BIS: Noise	The signal from the electrode goes beyond the measurable range	Re-prep the electrodes and check all connections.
BIS: Communication Error	BISx Module communication errors have been detected.	Open the **BIS Sensor Check** menu to initiate a manual sensor check.
BIS: Replace Sensor	A BIS sensor overcurrent has been detected.	Replace the sensor and then open the **BIS Sensor Check** menu to initiate a manual sensor check. **NOTE:** The message will not be cleared from the display until these steps have been performed.
BIS: Expired Sensor	An expired sensor has been detected.	Ensure that a valid, unexpired sensor is in use.
BIS: Too Many Uses	A sensor with too many uses has been detected.	Ensure that a valid, unexpired sensor is in use.

2.4.16 Time

The Time tile displays the current time in a configurable format that is larger than the standard time display located in the upper right portion of the main display. From the **Display Setup** menu, this tile can be configured to be positioned in any one of the parameter tiles (1 - 5). The time that is displayed will follow the format as set in the **Installation Menu** (12 hour or 24 hour). See the example in FIGURE 2-70.

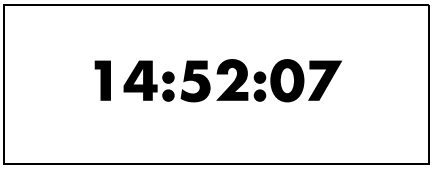


FIGURE 2-70 Example Time tile (24 hour format with seconds displayed)

The Time tile has a menu target labeled "Time" that opens the **Time Menu** shown in FIGURE 2-71.

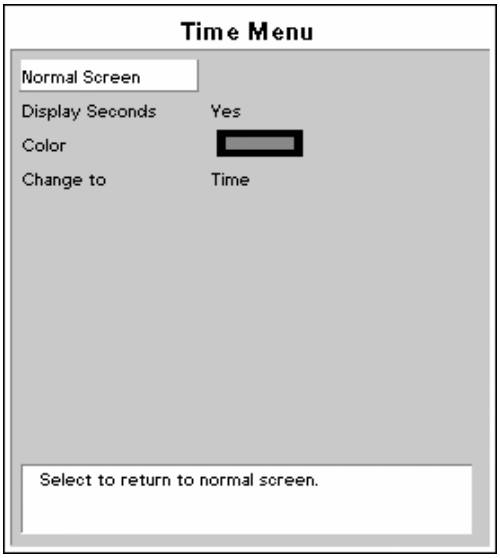


FIGURE 2-71 Time Menu

The **Time Menu** provides the following choices: **Normal Screen**, **Display Seconds**, **Color**, and **Change to**.

- The **Normal Screen** selection returns the view to the normal screen.
- The **Display Seconds** selection is used to set the display of Seconds in the tile.
- The **Color** selection is used to set the color for the Time in the tile.
- The **Change to** selection is used to change the currently displayed parameter in the parameter tile.

2.5 Calculations

The **Spectrum OR** supports two types of calculation packages: Drug / IV Medications and Hemodynamics. Calculations are accessible through the **Functions Menu**.

2.5.1 Drug Calculations

The **Spectrum OR** has the ability to calculate and display IV drug infusion rate and concentration based upon patient weight and/or drug dosage.

Drug calculations may also be accessed through the **Patient Menu**. Drug calculations are only available if the **Patient Size** is set to **Adult**.

Drug Calculation Formulas

For Drug Concentration, the **Spectrum OR** uses the following formula:

$$\frac{\text{(Drug Amount)}}{\text{(Solution Volume)}} = \text{Concentration}$$

For weight-based Drug Infusion Rate, the **Spectrum OR** uses the following formula:

$$\frac{\text{(Dose Ordered) x (Weight in kg) x (Solution Volume)}}{\text{(Drug Amount)}} = \text{Infusion Rate (ml/hr)}$$

For non-weight-based Drug Infusion Rate, the **Spectrum OR** uses the following formula:

$$\frac{\text{(Dose Ordered) x (Solution Volume)}}{\text{(Drug Amount)}} = \text{Infusion Rate (ml/hr)}$$

Drug Calculator

When "Drug Calculator" is chosen from the **Patient Menu** or the **Functions Menu**, the **Drug Calculator** is displayed. An example **Drug Calculator** that is set for a weight-based drug is shown in FIGURE 2-72.

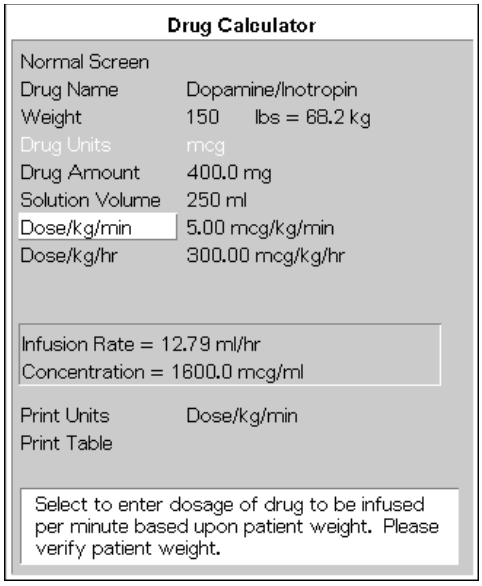


FIGURE 2-72 Drug Calculator set for a weight-based drug

The following table describes the menu structure of the Drug Calculator:

Drug Calculator Menu Structure

MENU TITLE ON SCREEN	MENU CHOICES	DEFAULT	ACTIONS/ COMMENTS
Normal Screen			Select to return to normal screen.
Drug Name	See the "GENERIC NAME" and "BRAND NAME" columns of the table in the **Adult Medication Choices** subsection. The Drug A – D choices are for drugs that are not listed in the table.	Unspecified	Select to choose medication.
Weight	1 to 1100 lbs or 1 to 500 kg	Unspecified	Select to enter or change patient weight.

* *When any one of the menu items marked with an asterisk (*) is changed, the others are automatically updated.*

Drug Calculator Menu Structure (Continued)

MENU TITLE ON SCREEN	MENU CHOICES	DEFAULT	ACTIONS/ COMMENTS
Drug Units	mcg, mg, g, units, mU	mcg for Drug A, B, C or D. For drugs listed in the table in the **Adult Medication Choices** subsection, see the "DEFAULT UNITS" column.	This menu item is only selectable if Drug A, B, C or D is chosen. Otherwise, the default unit for the specified drug is used. If Drug Units are changed for Drug A, B, C or D, Drug Amount, Solution Volume, Dose/ min, Dose/hr, Dose/kg/ min and Dose/kg/hr will be reset to blank fields and Infusion Rate and Concentration will be invalidated. Select to enter or change drug units.
Drug Amount	Based on current Drug Units setting.		Select to enter amount of drug in IV bag.
Solution Volume	10 to 1000 ml		Select to enter volume of solution in IV bag.
Dose/min*	0.01 to 10000.00	If the chosen drug is Vasopressin, the Default is 0.200 For all other drugs, the Default is 1.00	Select to enter dosage of drug to be infused per minute.
Dose/hr*	0.01 to 10000.00	If the chosen drug is Vasopressin, the Default is 12.00 For all other drugs, the Default is 60.00	Select to enter dosage of drug to be infused per hour.
Dose/kg/min*	If the chosen drug is Milrinone, 0.005 to 2.000 For all other drugs, 0.01 to 10000.00	If the chosen drug is Milrinone, the Default is 0.375 For all other drugs, the Default is 1.00	Select to enter dosage of drug to be infused per minute based upon patient weight. Please verify patient weight.
Dose/kg/hr*	If the chosen drug is Milrinone, 0.300 to 120.000 For all other drugs, 0.01 to 10000.00	If the chosen drug is Milrinone, the Default is 22.500 For all other drugs, the Default is 60.00	Select to enter dosage of drug to be infused per hour based upon patient weight. Please verify patient weight.
Infusion Rate			This menu item is automatically calculated as previously described in this section using the values entered for other menu items.

* *When any one of the menu items marked with an asterisk (*) is changed, the others are automatically updated.*

Drug Calculator Menu Structure (Continued)

MENU TITLE ON SCREEN	MENU CHOICES	DEFAULT	ACTIONS/ COMMENTS
Concentration			This menu item is automatically calculated as previously described in this section using the values entered for other menu items.
Print Units	Dose/min, Dose/hr, Dose/kg/min, Dose/kg/hr	Dose/kg/min (when the chosen drug is weight-based) Dose/min (when the chosen drug is non-weight-based)	This menu item is automatically populated with the appropriate default when: 1) a Drug Name is chosen, 2) the patient Weight is specified (for a weight-based drug), and 3) Dose/min, Dose/hr, Dose/kg/min or Dose/kg/hr is specified. If the dose is entered as Dose/min, then the menu choices will be Dose/min or Dose/hr. If the dose is entered as Dose/kg/min, then the menu choices will be Dose/kg/min or Dose/kg/hr. If the dose is entered as Dose/hr, then Dose/hr will be the only menu choice for the Print Units. If the dose is entered as Dose/kg/hr, then Dose/kg/hr will be the only menu choice for the Print Units. If the chosen drug is Milrinone, then Dose/kg/min will be the only menu choice for the Print Units.
Print Table			Select to print Drug Calculation data.

* *When any one of the menu items marked with an asterisk (*) is changed, the others are automatically updated.*

The following table details adult medication choices:

Adult Medication Choices

GENERIC NAME	BRAND NAME	IS THE PATIENT'S WEIGHT USED IN THE CALCULATION?	DEFAULT UNITS	DEFAULT SOLUTION VOLUME	DEFAULT DRUG AMOUNT
Aminophylline[1]	Theophylline	Y	mg	500 ml	500 mg
Diltiazem[1]	Cardizem	N	mg	125 ml	125 mg
Dobutamine[1]	Dobutrex	Y	mcg	250 ml	500 mg
Dopamine[1]	Inotropin	Y	mcg	250 ml	400 mg
Epinephrine HCL[1]	Adrenalin	N	mcg	250 ml	1mg
Esmolol HCL[1,2]	Brevibloc	Y	mcg	500 ml	5000 mg
Fentanyl Citrate[1]	Sublimaze	Y	mcg	100 ml	5 mg
Heparin Sodium[1]	Heparin	N	units	250 ml	12,500 units
Inamrinone Lactate[1]	Inocor	Y	mcg	250 ml	500 mg
Insulin, Regular[1]	Humulin	N	units	100 ml	100 units
Isoproterenol HCL[1]	Isuprel HCL	N	mcg	500 ml	2 mg
Labetalol HCL[1,2]	Normodyne	N	mg	200 ml	200 mg
Lidocaine HCL[1,2]	Xylocaine HCL	N	mg	500 ml	2000 mg
Lorazepam	Ativan	N	mg	500 ml	40 mg
Midazolam HCL[1,2]	Versed	Y	mg	125 ml	125 mg
Milrinone Lactate[1,2]	Primacor	Y	mcg	200 ml	20 mg
Nicardipine HCL[1]	Cardene	N	mg	250 ml	25 mg
Nitroglycerin[1]	Tridil	N	mcg	250 ml	50 mg
Nitroprusside Sodium[1]	Nipride	Y	mcg	250 ml	50 mg
Norepinephrine[1]	Levophed	N	mcg	250 ml	4 mg
Phenylephrine[1]	Neosynephrine	N	mcg	250 ml	10 mg
Procainamide HCL[1]	Pronestyl	N	mg	500 ml	2000 mg
Propofol[1]	Diprivan	Y	mcg	50 ml	500 mg
Vasopressin[2]	Pitressin	N	units	250 ml	250 units

1 Gahart B and Nazareno A. 2002 Intravenous Medications. St. Louis: Mosby, 2001.

2 Algozzine G, Algozzine R, and Lilly D. Critical Care Intravenous Infusion Drug Handbook. St. Louis: Mosby, 2002.

2.5.2 Hemodynamic Calculations

Hemodynamic calculations are a set of values that are used to determine the hemodynamic status of the patient. The values that are necessary for these calculations are **Patient Height**, **Patient Weight**, **Cardiac Output**, **Heart Rate**, **Mean Arterial Pressure**, **Mean PA, Wedge** and **Central Venous Pressure.**

All manually entered values (such as PAWP) are denoted with an asterisk (*). The following values are calculated and trended: CI, SV, SVI, SVR, SVRI, PVR, PVRI, LCW, LCWI, RCW, RCWI, LVSW, LVSWI, RVSW, and RVSWI.

NOTE: Calculated patient parameters contain more decimal places of accuracy than are displayed on the screen (e.g., a CO of 2.4 may be a CO of 2.4492). Consequently, attempts to verify the accuracy of the monitor's display using the following equations may produce results that are slightly different from the data computed by the monitor.

Hemodynamic Calculations

ABBREVIATION / UNITS	DESCRIPTION	FORMULA
CI (l/min/m^2)	Cardiac Index	CO / BSA
BSA (m^2)*	Body Surface Area	$Ht^{0.725}$(cm) x $Wt^{0.425}$(kg) x 0.007184
SV (ml)	Stroke Volume	(CO / HR) x 1000
SVI (ml/m^2)	Stroke Volume Index	SV / BSA
SVR (dyne-sec/cm^5)	Systemic Vascular Resistance	((ART mean-CVP) / CO) x 79.96
SVRI (dyne-sec/cm^5/m^2)	Systemic Vascular Resistance Index	SVR x BSA
PVR (dyne-sec/cm^5)	Pulmonary Vascular Resistance	((PA mean-PAWP) / CO) x 79.96
PVRI (dyne-sec/cm^5/m^2)	Pulmonary Vascular Resistance Index	PVR x BSA
LCW (kg-m)	Left Cardiac Work	0.0136 x ART mean x CO
LCWI (kg-m/m^2)	Left Cardiac Work Index	LCW / BSA
RCW (kg-m)	Right Cardiac Work	0.0136 x PA mean x CO
RCWI (kg-m/m^2)	Right Cardiac Work Index	RCW / BSA
LVSW (gm-m)	Left Ventricular Stroke Work	SV x (ART mean-PAWP) x 0.0136
LVSWI (gm-m/m^2)	Left Ventricular Stroke Work Index	LVSW / BSA
RVSW (gm-m)	Right Ventricular Stroke Work	SV x (PA mean - CVP) x 0.0136
RVSWI (gm-m/m^2)	Right Ventricular Stroke Work Index	RVSW / BSA

* *Dubois' equation*

2.6 Alarms

The **Spectrum OR** monitor provides a broad range of alarm settings. For detailed information see "Alarm Limits". Settings for alarm delay times are also available.

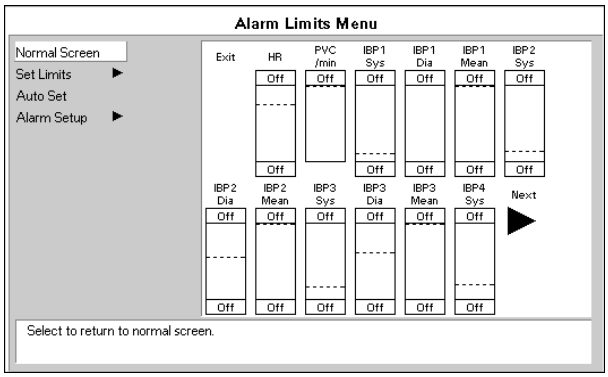


FIGURE 2-73 Alarm Limits Menu

2.6.1 Adjusting Alarms

Setting Parameter Alarm Limits

1. To access the **Alarms Limits Menu** press the **ALARMS LIMITS** key. The main **Alarm Limits Menu** displays.
2. Use the Navigator™ Knob to set alarm limits as desired for currently monitored parameters.
3. To save alarm limit settings as the default, select **Save Current** from the **Advanced Setup Menu.**

NOTE: **Alarm Limits are not saved when the monitor is turned off, unless you select Save Current from the Advanced Setup Menu.**

4. To set alarm limits for any parameter not currently monitored or to adjust the priority level of any alarm select **Alarm Setup** from the **Alarm Limits Menu**. The **Alarm Setup** menu also provides options for setting alarm delay times and alarm muting features.

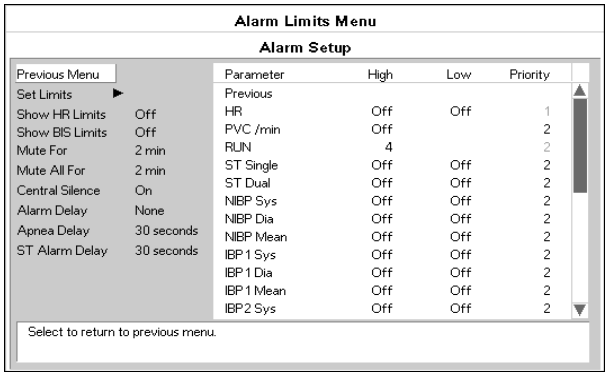


FIGURE 2-74 Alarm Setup Menu

2.6.2 Alarm Limits

A separate table of alarm limit settings is maintained for each patient size. When the patient size is changed, the appropriate selections are automatically used. See table below for alarm ranges. Default settings appear in bold text.

	HIGH			LOW		
PARAMETERS	**ADULT**	**PED**	**NEONATE**	**ADULT**	**PED**	**NEONATE**
Heart Rate (bpm) Except France	**150**, Off, 60-250	**180**, Off, 100-300	**200**, Off, 100-350	**50**, Off, 30-120	**80**, Off, 30-150	**100**, Off, 30-200
Heart Rate (bpm) France	**120**, 60-250	**150**, 100-300	**175**, 100-350	**30**, 30-120	**50**, 30-150	**70**, 30-200
PVC/min	**Off**, 1-30					
ST Single Lead (mm)	**Off**, +0.5 to +10.0 (Elevation)			**Off**, -0.5 to -10.0 (Depression)		
ST Dual Lead (mm)	**Off**, +0.5 to +10.0 (Elevation)			**Off**, -0.5 to -10.0 (Depression)		
NIBP Sys (mmHg)	**Off**, 70-240	**Off**, 40-180	**Off**, 40-180	**Off**, 50-150	**Off**, 15-130	**Off**, 15-130
NIBP Dia (mmHg)	**Off**, 40-130	**Off**, 50-100	**Off**, 50-100	**Off**, 30-120	**Off**, 10-50	**Off**, 10-50
NIBP Mean (mmHg)	**Off**, 60-200	**Off**, 50-180	**Off**, 40-160	**Off**, 40-140	**Off**, 10-100	**Off**, 10-70
IBP Sys (mmHg)	**Off**, 5-300	**Off**, 5-240	**Off**, 5-180	**Off**, 0-150	**Off**, 0-130	**Off**, 0-130
IBP Dia (mmHg)	**Off**, 0-140	**Off**, 0-100	**Off**, 0-70	**Off**, 0-120	**Off**, 0-100	**Off**, 0-50
IBP Mean (mmHg)	**Off**, 5-150	**Off**, 5-100	**Off**, 5-100	**Off**, 2-100	**Off**, 2-50	**Off**, 2-50
SpO_2 (%)	**Off**, 80-100	**Off**, 80-100	**Off**, 80-100	50-99 **85**	50-99 **85**	50-99 **85**
Temp (°F)	**Off**, 95-110			**Off**, 80-100		
Temp (°C)	**Off**, 35-43			**Off**, 26-38		
TBlood (°F)	**Off**, 95-110			**Off**, 80-100		
TBlood (°C)	**Off**, 35-43			**Off**, 26-38		
Delta Temp (°F)	**Off**, 2-10			**Off**, 2-10		
Delta Temp (°C)	**Off**, 1-5			**Off**, 1-5		
Resp Rate (rpm)	**Off**, 10-100	**Off**, 15-150	**Off**, 30-200	**Off**, 5-30	**Off**, 5-40	Off, **5**-50
PIP (cmH_2O)*	**Off**, -20-100	**Off**, -20-100		**Off**, -20-100	**Off**, -20-100	
Pplat (cmH_2O)*	**Off**, -20-100	**Off**, -20-100		**Off**, -20-100	**Off**, -20-100	
Pmean (cmH_2O)*	**Off**, -20-100	**Off**, -20-100		**Off**, -20-100	**Off**, -20-100	
PEEP (cmH_2O)*	**Off**, -20-100	**Off**, -20-100		**Off**, -20-100	**Off**, -20-100	
ET Vt (ml)*	**Off**, 150-2000	**Off**, 15-300		**Off**, 150-2000	**Off**, 15-300	

* *These Spirometry alarm limits are based on Spirometry sensor size, not patient size.*

	HIGH			LOW		
PARAMETERS	**ADULT**	**PED**	**NEONATE**	**ADULT**	**PED**	**NEONATE**
Insp Vt (ml)*	**Off**, 150-2000	**Off**, 15-300		**Off**, 150-2000	**Off**, 15-300	
ET MV (l/min)*	**Off**, 2.0-20.0	**Off**, 0.5-5.0		**Off**, 2.0-20.0	**Off**, 0.5-5.0	
Insp MV (l/min)*	**Off**, 2.0-20.0	**Off**, 0.5-5.0		**Off**, 2.0-20.0	**Off**, 0.5-5.0	
CCO (l/min)	**Off**, 1.0-20.0	**Off**, 1.0-20.0		**Off**, 1.0-20.0	**Off**, 1.0-20.0	
CCI (l/min/m^2)	**Off**, 1.0-20.0	**Off**, 1.0-20.0		**Off**, 1.0-20.0	**Off**, 1.0-20.0	
SvO_2 (%)	**Off**, 10-99	**Off**, 10-99		**Off**, 10-99	**Off**, 10-99	
ET CO_2 (mmHg)	Off, 20-80 **60**			**Off**, 5-50		
ET CO_2 (%)	Off, 2.0-10.0 **8.0**			**Off**, 1.0-6.0		
ET CO_2 (kPa)	Off, 2.0-10.0 **8.0**			**Off**, 1.0-6.0		
Insp CO_2 (mmHg)	Off, 5-30, **10**					
Insp CO_2 (%)	Off, **1.0** - 4.0					
Insp CO_2 (kPa)	Off, **1.0** - 4.0					
ET O_2 (%)	**Off**, 40-100	**Off**, 40-100	**Off**, 40-100	**Off**, 10-60	**Off**, 10-60	**Off**, 10-60
Insp O_2 (%)	**Off**, 40-100	**Off**, 40-100	**Off**, 40-100	**18**-60	**18**-60	**18**-60
ET N_2O (%)	**Off**, 10-80	**Off**, 10-80	**Off**, 10-80	**Off**, 5-70	**Off**, 5-70	**Off**, 5-70
Insp N_2O (%)	10-**80**	10-**80**	10-**80**	**Off**, 5-70	**Off**, 5-70	**Off**, 5-70
Apnea Delay (seconds)	10-60 **30**	10-20 **15**	10-20 **15**			
BIS	**Off**, 1-99	**Off**, 1-99	**Off**, 1-99	**Off**, 1-99	**Off**, 1-99	**Off**, 1-99

* *These Spirometry alarm limits are based on Spirometry sensor size, not patient size.*

Alarm Parameters (Gas Module)

PARAMETERS	HIGH	LOW
Insp. Hal	**Off**, 2-10	**Off**, 0.5-5
ET Hal	**Off**, 2-10	**Off**, 0.5-5
Insp. Iso	**Off**, 2-10	**Off**, 0.5-5
ET Iso	**Off**, 2-10	**Off**, 0.5-5
Insp. Enfl	**Off**, 2-10	**Off**, 0.5-5
ET Enfl	**Off**, 2-10	**Off**, 0.5-5
Insp. Sevo	**Off**, 2-10	**Off**, 0.5-5
ET Sevo	**Off**, 2-10	**Off**, 0.5-5

Alarm Parameters (Gas Module) (Continued)

PARAMETERS	HIGH	LOW
Insp. Des	**Off**, 2-20	**Off**, 0.5-10
ET Des	**Off**, 2-20	**Off**, 0.5-10

All Gas Module alarms are in units of % and increment in units of 0.5.

Auto Set Alarms

The alarm Auto Set function automatically sets High and Low alarm limits for active parameters as follows:

- +/- 20% of the absolute value for: CO_2, Gases, IBP's and NIBP
- +/- 30% of the value for: HR and Respiration
- +/- 3.0% of the value for: Temperature

When **Auto Set** is chosen from the **Alarm Limits Menu**, a Confirmation Dialog is displayed. Choosing **Yes** will initiate the alarm Auto Set.

Alarm Violations

Spectrum OR alarm violations are classified by severity:

For priority 1 or "Warning" alarms,

- The red alarm LED flashes
- The data in violation of the alarm flashes over a red background
- The priority 1 audio alarm sounds. The priority 1 audio alarm is a pattern of 10 tones repeated every 10 seconds

For priority 2 or "Caution" alarms,

- The amber alarm LED flashes
- The data in violation of the alarm flashes over an amber background
- The priority 2 audio alarm sounds. The priority 2 audio alarm is a pattern of 3 tones repeated every 10 seconds

For both priority 1 and priority 2 alarms,

- For any parameter that is being measured but is not currently displayed, or when a parameter tile (Parameter 2 through Parameter 5) is obstructed (either partially or fully), alarm messages that would normally be displayed in the tile will then be displayed in Message Area A.

If the "Print on Alarm" feature has been enabled and an alarm violation occurs,

- The internal recorder will print a 2-wave 16 second strip. The upper wave will be ECG1 and the lower wave will be that of the parameter associated with the alarm violation
- Any other printing in process at the time of the alarm will be aborted
- Data in violation of an alarm will be printed within brackets
- A bar will be printed along the top margin of the waveform area to mark the time the alarm was triggered.

A. Parameter Alarms

Individual alarm levels are adjustable for most of the parameters Spectrum OR is capable of monitoring. In addition, these alarms may be set by the user to either priority level 1 or 2 as desired.

NOTE: **The Heart Rate Alarm can be triggered only by the source identified in the Heart Rate data tile. In some circumstances, the pulse rate displayed in the SpO_2 data tile may differ from the heart rate displayed in the heart rate data tile. When the Spectrum OR detects that the SpO_2 pulse rate is in violation of the heart rate limit settings, the pulse rate data will flash over a red background, but the audio alarm will not sound.**

B. Heart Rate Fault Alarm

The Heart Rate Fault Alarm occurs if the selected heart rate source is no longer able to detect a heart rate. This alarm is only active if a low heart rate limit is set. The Spectrum OR may display a message to help identify the cause of the alarm (e.g., **"Lead Off"**, **"Sensor Off"**). The Heart Rate Fault Alarm is a priority 1 alarm.

C. Apnea Alarm

The Apnea Alarm is active when respiration is being monitored. The Apnea Alarm will be triggered if respiration is not detected for a time period longer than set in the **Alarm Setup** menu. The Apnea Alarm can be set as a "Latched" or "Non-latched" alarm via the **Advanced Setup** menu.

When "Apnea Latch" is set to "Off", the Apnea Alarm will silence and cancel itself if patient breathing is again detected.

When "Apnea Latch" is set to "On" (default), the Apnea Alarm will not be silenced unless the operator acknowledges the alarm by pressing the **MUTE** or **MUTE ALL** keys. The visual Apnea Alarm indications will not be cancelled unless patient breathing resumes.

The Apnea Alarm is a priority 1 alarm.

D. Arrhythmia Alarms

Arrhythmia Alarms, with the exception of the PVC Rate Alarm, are identified in message Area A.

"Lethal" Arrhythmia Alarms ("Asystole", "V-Fib", and "V-Tach") are priority 1 alarms and in addition are latched. Even after the alarming condition is resolved, a latched alarm will continue until it is acknowledged by pressing the **MUTE** or **MUTE ALL** key on the front panel keypad. If the alarm is acknowledged while the lethal condition still exists, the audio portion of the alarm will be muted for the duration that is selected from the "Mute For" list in the **Alarm Setup** menu, but the alarm message will remain in message area A. If a new lethal condition occurs while the initial lethal alarm is muted, the new lethal alarm will not break through and will be muted for the remainder of the mute duration. If the lethal condition is resolved while the alarm is muted, the alarm will be terminated.

"Non-Lethal" Arrhythmia Alarms are priority 2 alarms. These alarms will silence and cancel automatically if the patient's condition is corrected. The PVC Rate Alarm, although considered "non-lethal", may be set to either priority 1 or 2.

E. ST Alarms

ST alarms can be set for either single lead alarm or dual lead alarm. The ST single lead alarm will be initiated if one ST lead has exceeded the set alarm parameters. The ST dual lead alarm will be initiated if two ST leads have exceeded the set alarm parameters.

F. Indications of Disabled or Silenced Alarms

ALARM OFF ICON

If both high and low alarms are not set for a parameter, an **Alarm Off Icon**, resembling a bell with an "X" through it, will be displayed next to the numerical data for that parameter.

VOLUME - The audio level of the alarm can be adjusted through the **Monitor Setup Menu**.

ALARM MUTE

One or more alarms can be muted for a programmable length of time. The following is a description of how to enable the different mute modes.

MUTE - This key silences alarms on parameters for a programmed length of time (default is 2 minutes), or until the alarm condition is no longer present, whichever is shorter. Any new alarms that occur during the silenced period will disable the silence and the alarm will sound the tone. An **Alarm Mute Icon**, resembling a speaker with an "X" through it, is displayed next to each muted parameter. A message and digital timer counts down in the upper message area. Pressing **MUTE** again does not re-enable audio alarms.

MUTE ALL- This key suspends alarms on all parameters for a programmed period of time (default is 2 minutes). An **Alarm Mute Icon**, resembling a speaker with an "X" through it, is displayed next to each parameter. A message and timer appear in the upper message area showing the time remaining. Pressing **MUTE ALL** at any time re-enables audio alarm tones. If **Mute All For** is set to **Permanent** in the **Alarm Setup** menu, the message **ALL ALARMS MUTED PERMANENTLY** is displayed.

The time period for **MUTE** and **MUTE ALL** is adjustable via the **Alarm Setup** menu.

2.6.3 Alarm Troubleshooting

MESSAGE/PROBLEM	REASON	SOLUTION
High or Low or No Alarm Sound	Alarm limits not set	Go to **Alarm Setup** and adjust alarms
	Alarm **Mute All, On** time has not expired	Press **MUTE ALL** to reactivate alarms
No Arrhythmia Alarm Sound	Arrhythmia option not installed	Call Sales Rep to purchase option
	Arrhythmia Alarms off	Go to **Monitor Setup** / **Advanced Setup** to activate alarm
	Monitor is in learning mode	Wait until learning is concluded and monitor patient closely
Alarms continue to Sound despite pressing **MUTE**	More than one alarm is active	Press **MUTE** or **MUTE ALL** key to silence
		Check Patient
No Alarm printout with Alarm violation	**Print on Alarm** is set to **Off**	Go to **Print Menu** and set **Print on Alarm** to **On**

2.7 Trends

Three types of trend displays are available with the **Spectrum OR**. All trends are accessed via the **TRENDS** key and can be printed via the internal recorder.

2.7.1 Quick Trends

The **Quick Trend** display allows the user to view an abbreviated numeric listing of HR, SpO_2 and NIBP data only. To access this display from the normal monitoring screen, press the **TRENDS** key once. This display may also be accessed from the other trend displays via a menu choice. A maximum of 10 time-stamped entries may be stored. When the maximum number of entries has been reached, the oldest entry will be deleted from the trend record in order to allow storage of a new entry.

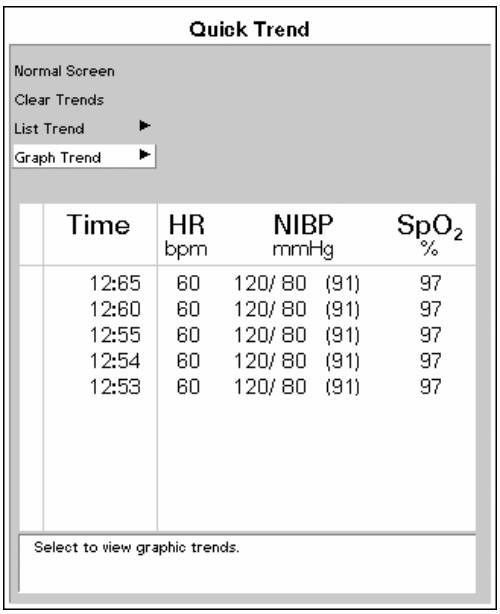


FIGURE 2-75 Quick Trends

Clearing Trend Data

To manually clear all trend data, including Graph trends, choose **Clear Trends** from the menu. A confirmation prompt will appear. Once cleared, the data cannot be restored.

- All trend data is automatically cleared when the patient is discharged from the monitor.
- All trend data is also cleared if the monitor's displayed time or date is changed.

Removing the Quick Trend Display

The **Quick Trend** display does not automatically time-out and must be manually removed to return to the normal waveform display. To remove the **Quick Trend** display, choose **Normal Screen** from the menu, or press the **NORMAL SCREEN** key.

2.7.2 List Trends

The **List Trend** display allows the user to view a tabular list of stored patient vital signs and anesthetic gas data. To access this display from the normal monitoring screen, press the **TRENDS** key twice. To access this display from the **Quick Trend** display, press the **TRENDS** key once. This display may also be accessed from the other trend displays via a menu choice. A maximum of 120 time-stamped entries may be stored. If the **Extended Trend** option is installed, a maximum of 500 time-stamped entries may be stored. When the maximum number of entries has been reached, the oldest entry will be deleted from the trend record in order to allow storage of a new entry.

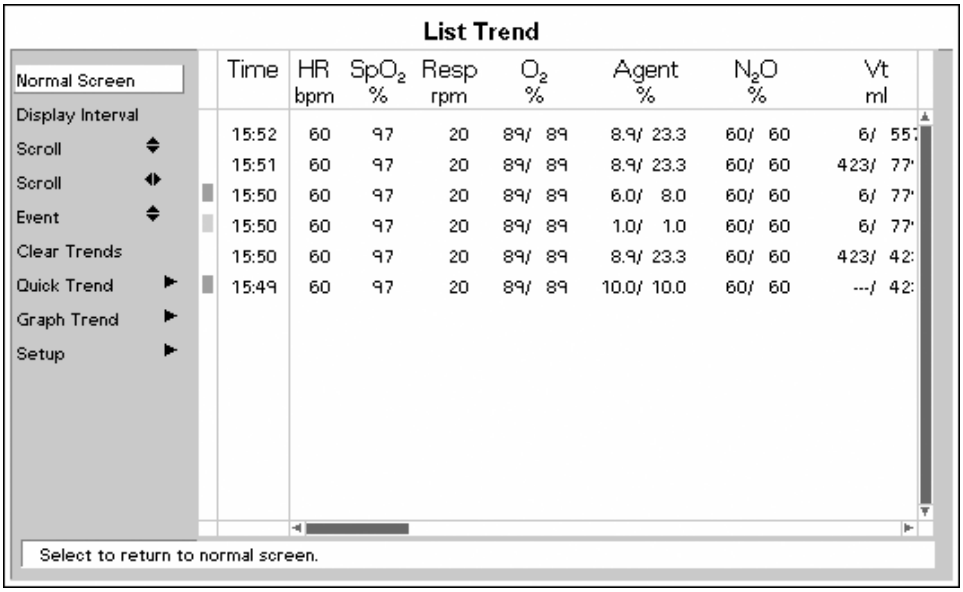


FIGURE 2-76 List Trends

The left side of the **List Trend** display contains menu items for scrolling and access to other displays. Trend data is listed from newest to oldest. Use the vertical scroll feature to view older data. Use the horizontal scroll feature to view all the columns of data.

NOTE: When scrolling horizontally, the first column of data remains displayed and does not scroll.

Scroll bars along the right and bottom sides of the trend display indicate the position of viewed data in relation to the rest of the database. Upon reopening of the **List Trend** display, the top of the trend screen will display the most recently viewed data.

The leftmost column of the **List Trend** display contains markers which indicate that the entry was triggered by an alarm violation or by pressing the **MARK EVENT** key. These markers are red for priority 1 alarms, yellow for priority 2 alarms, and green if initiated by pressing the **MARK EVENT** key.

Trend data in violation of an alarm is also highlighted according to the priority of the alarm. On color displays the data is red for priority 1 alarms and yellow for priority 2 alarms.

If data for a parameter is not available at the time of the trend entry, the data field will be dashed. If an NIBP reading could not be obtained or an invasive pressure channel was not zeroed at the time of the trend entry, the data field will contain **"xxx"**.

Modification of Parameters Displayed

The parameters displayed always include the currently active parameters and any others used since the time the patient was admitted to the monitoring system. The default order of parameters displayed from left to right is: HR, NIBP, SpO_2, Resp, CO_2, O_2, Agent, N_2O, MAC, Vt, MV, PEEP, Pmean, Pplat, PIP, Compl, Raw, I : E, BIS, EMG, SQI, IBP1, IBP2, IBP3, IBP4, ST 1, ST 2, ST 3, T1, T2, TBlood, ΔT, PVC, CO, CI and SvO_2.

When CO and CI data is obtained in continuous mode, the label "@Cont" will display next to the data entry in the CO and CI columns. When CO and CI data is obtained in intermittent mode, an "@XX:XX" label will display next to the data entry in the CO and CI columns. This label is a "time stamp" where XX:XX = the time at which the trended data was recorded.

To enable/disable the display (and subsequent ability to print) of specific parameters in List Trend, select **Setup** from the **List Trend** menu. From the **List Trend Setup** menu, select **Parameters To Trend**. When the current setting for a parameter is ON, it will be displayed in the List Trend. When the current setting for a parameter is OFF, it will not be displayed in the List Trend. To change the order in which parameters are displayed in each of the first 6 columns, return to the **List Trend Setup** menu, change the **Format** menu choice from **Auto** to **Manual**. Then, set **Param 1** through **Param 6** to the desired parameters.

Modification of Trend Entry Conditions

Trend entry conditions may be modified via the **Advanced Setup Menu**. The **Advanced Setup Menu** is accessed from the **Monitor Setup Menu**. Any combination of trend input triggers may be used.

TREND ENTRY TRIGGER	DEFAULT	COMMENT
Interval	Off	Trend entries will occur at the selected time interval
Alarm	Off	Trend entries will occur when an alarm violation occurs
NIBP	On	Trend entries will occur whenever an NIBP measurement is made

Filtering of List Trend Data Displayed

Pressing the **MARK EVENT** key will cause a **Trend Entry**.

Data corresponding to **MARK EVENT** key presses will be included in the displayed data. If the **Trend Entry Triggers** for **Alarms** and/or **NIBP** have been set to **On**, this data will also always be included.

Trend entries triggered by the **Interval** setting above may be filtered out from the displayed **List Trend** data. To change the amount of interval entries displayed, select **Setup** from the **List Trend Menu**. From the **Setup Menu**, select **Display Interval** and set as desired. The choices available for the **Display Interval** depend on the setting of the **Trend Entry Interval** setting above. (If the **Trend Entry Interval** is set to **Off**, there will be no choices available for **Display Interval**.)

NOTE: If the Display Interval remains set to Off while the Trend Entry Interval has been set to something other than Off, the trend may appear to clear itself or to have disappeared. This is because the trend has reached the maximum number of entries. New interval data (although not displayed) is causing older trend entries to be deleted from the database.

Transferring List Trend Data Between Different Spectrum OR Monitors

List and **Graph Trend** data, along with patient name and demographics may be transferred between **Spectrum OR** monitors with Transfer Card 0996-00-0171-01.

1. Insert the Transfer Card into the PCM2 slot on the right side of the source monitor.
2. Access the **Functions Menu** of the source monitor, and select **Copy patient data to card** from the menu. A status message will report completion of the transfer.
3. Remove the card and insert it into the PCM2 slot of the receiving monitor.
4. Access the **Functions Menu** of the receiving monitor, and select **Copy patient data from card**. A status message will report completion of the transfer.

NOTE: If the source monitor is equipped with the Extended Trend option and the receiving monitor is not, only the latest 120 trend entries will be transferred from the card.

NOTE: If the latest trend data stored on the card has a time stamp newer than the time displayed on the receiving monitor, data transfer will be prohibited. (This is possible when the time and date settings on the monitors have not been correctly set.)

Clearing Trend Data

To manually clear all trend data, including Graph trends, choose **Clear Trends** from the menu. A confirmation prompt will appear. Once cleared, the data cannot be restored.

- All trend data is automatically cleared when the patient is discharged from the monitor.
- All trend data is also cleared if the monitor's displayed time or date is changed.

Removing the List Trend Display

The **List Trend** display does not automatically time-out and must be manually removed to return to the normal waveform display. To remove the **List Trend** display, choose **Normal Screen** from the menu, or press the **NORMAL SCREEN** key.

2.7.3 Graph Trends

The **Graph Trend** display allows the user to view a graphic summary of stored patient vital signs and anesthetic gas data. To access this display from the normal monitoring screen, press the **TRENDS** key three times. To access this display from the **Quick Trend** display, press the **TRENDS** key twice. To access this display from the **List Trend** display, press the **TRENDS** key once. This display may also be accessed from the other trend displays via a menu choice.

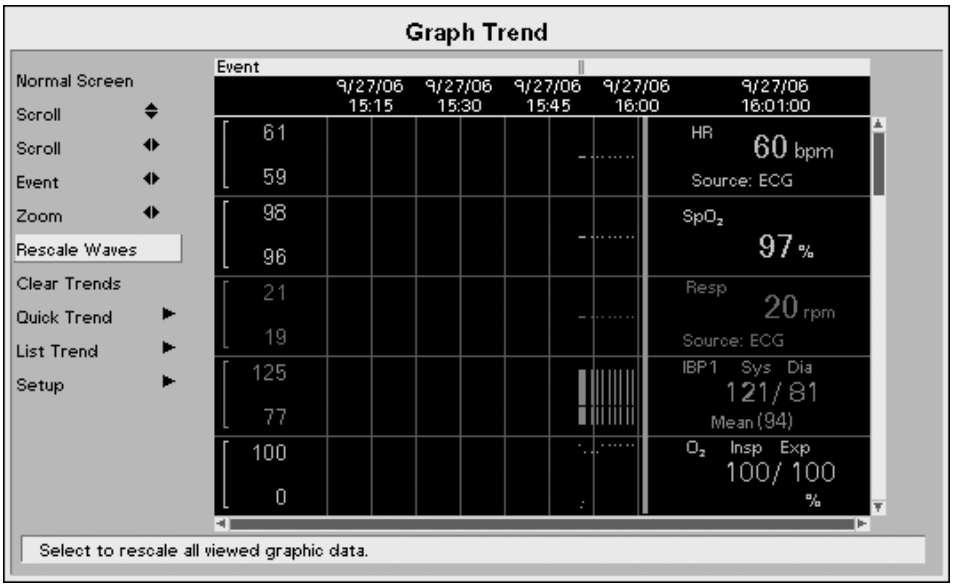


FIGURE 2-77 Graph Trends

The left side of the **Graph Trend** display contains menu items for **scrolling, setup** and **access to other displays**. The **Graph Trend** data window contains up to 4 parameter displays. Use the vertical **Scroll** feature to view other parameters.

NOTE: When scrolling vertically, the topmost parameter remains displayed and does not scroll.

Time stamps are included at the top of the window, with the most recent data appearing at the right end. Use the horizontal **Scroll** feature to move the cursor though time. Scroll bars along the right and bottom sides of the **Graph Trend** display indicate the position of viewed data in relation to the rest of the database. The **Event** feature may be used to scroll quickly between events (caused by Alarm entries and **MARK EVENT** keypresses).

The **Rescale Waves** feature automatically rescales the viewed parameters' graphs so all data is displayed. The **Zoom** feature may be used to adjust the amount of time shown in the trend window.

The top line of the **Graph Trend** display contains markers which indicate if the entry was triggered by an alarm violation or by pressing the **MARK EVENT** key. These markers are red for priority 1 alarms, yellow for priority 2 alarms, and green if initiated by pressing the **MARK EVENT** key.

As the cursor is scrolled horizontally, the digital data corresponding to the points in the graph is shown at the right side of the window. Trend data in violation of an alarm is highlighted according to the priority of the alarm.

On color displays:

- Priority 1 alarm data is shown in inverse video with red background.
- Priority 2 alarm data is shown in inverse video with yellow background.

If data for a parameter is not available at the time of the trend entry, the data field will be dashed. If an NIBP reading could not be obtained or an invasive pressure channel was not zeroed at the time of the trend entry, the data field will contain **"xxx"**.

Modification of Parameters Displayed

The parameters displayed always include the currently active parameters and any others used since the time the patient was admitted to the monitoring system. The default order of parameters displayed from top to bottom is: HR, NIBP, SpO_2, Resp, CO_2, O_2, Agent, N_2O, MAC, Vt, MV, PEEP, Pmean, Pplat, PIP, Compl, Raw, BIS, EMG, SQI, IBP1, IBP2, IBP3, IBP4, ST 1, ST 2, ST 3, T1, T2, TBlood, ΔT, PVC, CO, CI and SvO_2. To change the order in which parameters are displayed in each of the top 5 rows, select **Setup** from the **Graph Trend** menu. Once in the **Graph Trend Setup** menu, change the **Format** menu choice from **Auto** to **Manual**. Then, set **Param 1** through **Param 5** to the desired parameters.

Modification of Trend Entry Conditions

The **Graph Trend** data is the same as that stored for **List Trends**, arranged graphically. (If data is not available for time period, it appears as a gap in the **Graph Trend**.) Refer to the previous section (**List Trend**) for modification of trend entry conditions.

Transferring Graph Trend Data Between Different Spectrum OR Monitors

Graph Trend data is transferred together with **List Trend** and patient name and demographics. Refer to the **List Trend** section for details.

Clearing Trend Data

To manually clear all trend data, including List trends, choose **Clear Trends** from the menu. A confirmation prompt will appear. Once cleared, the data cannot be restored.

- All trend data is automatically cleared when the patient is discharged from the monitor.
- All trend data is also cleared if the monitor's displayed time or date is changed.

Removing the Graph Trend Display

The **Graph Trend** display does not automatically time-out and must be manually removed to return to the normal waveform display. To remove the Graph Trend display, choose **Normal Screen** from the menu, or press the **NORMAL SCREEN** key.

2.7.4 Trends Troubleshooting

MESSAGE/PROBLEM	REASON	SOLUTION
No Trends displayed	No Trend triggers set	Go to the **Monitor Setup Menu** and set **NIBP Trend, Trend Interval** or **Alarm Trend** as desired
	Trend page is scrolled	Use scroll button in **Trend Menu** to scroll to top of **Trend Menu**

2.8 Printing (Optional)

Spectrum OR data and waveforms may be printed to the following destinations: internal recorder or remote central station.

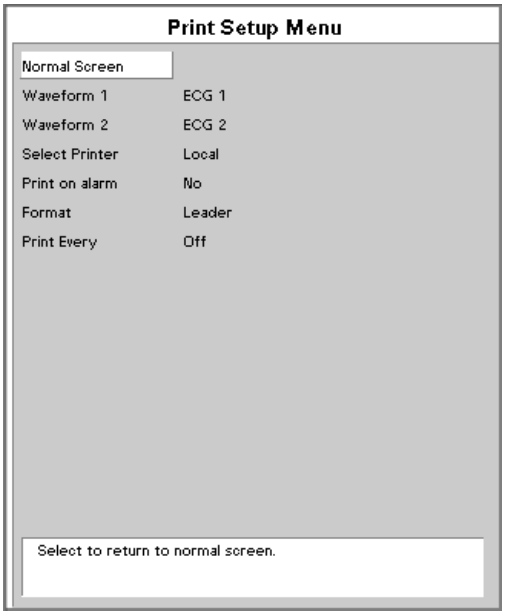


FIGURE 2-78 Print Setup Menu

2.8.1 Internal Recorder (Optional)

The **Spectrum OR** recorder can provide a printed record of all patient parameters. It is a two-trace thermal strip chart recorder with an integral paper spool. The recorder uses plain white thermal paper, 5 cm wide.

NOTE: All grid patterns and data are printed by the recorder.

Operation of the Recorder

1. Select the waveforms to print to the recorder via the **Print Setup Menu** using the Navigator™ Knob. To change the waveforms that appear, select **Waveform 1** or **Waveform 2** and choose from the available parameters.
2. To print to the recorder, select **Local** from the **Print Setup Menu**.
3. Press the **STRIP** key to initiate printing.
4. Press the **STRIP** key again to abort the printout. Select printouts will also require the use of alternate menus or keys.

During an ECG waveform printout, tic marks appear every one second, for reference.

Printouts from the Recorder

Print Formats

The print format can be changed from **Leader** to **Wave** in the **Print Setup Menu**. **Leader** will print all patient demographic data, date / time of printout, waveform speed, source of the printout and all patient parameter data prior to printing the waveform data. **Wave** will print all patient demographic data, date/time of printout, waveform speed and source of the printout in the space prior to the waveform printing. The patient parameter data will print above and below the waveform area. **Wave** format is not available if the speed of the upper printed waveform is less than 25 mm/sec. The waveform speed can be set via the **Monitor Setup Menu**.

Strip Printing

When the **STRIP** key is pressed a 16-second strip is printed. This strip consists of data 8-seconds prior to and 8-seconds after the printout is initiated. The source of the printout is indicated on the strip as **Key**.

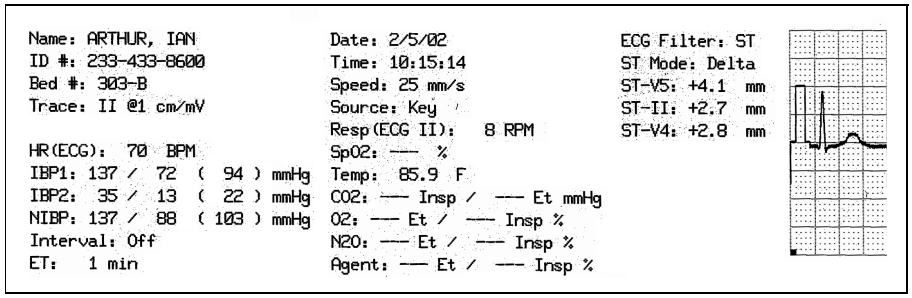


FIGURE 2-79 Sample Printout, Single Waveform

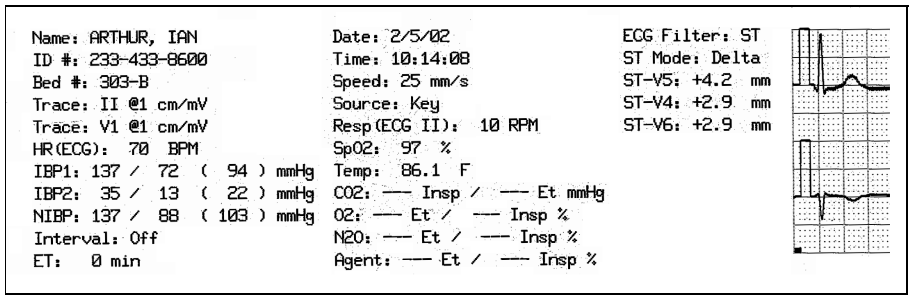


FIGURE 2-80 Sample Printout, Two Waveforms

Continuous ECG Printing

If a real-time, continuous printing of ECG data is required, press the **CONT ECG** key. Press **CONT ECG** again to abort printing.

Print on Alarm

If a waveform is initiated by an alarm violation, then the internal recorder will initiate a 16-second waveform strip. To activate this feature, go to the **Print Setup Menu**, highlight the **Print on Alarm** selection and select **Yes**. During an alarm printout, the data for the parameter which violated the alarm will be printed in brackets and the portion of the waveform triggering the alarm will have a bar printed above. If the recorder is printing a strip (or trend data) and an alarm is violated, then the currently printing waveform will be aborted and the alarm waveform will be printed. The source of the printout is indicated on the strip as **Alarm**.

Interval Printing

To print waveform strips at regular intervals, go to the **Print Setup Menu,** highlight **Print Every** and select a time interval to print. The selections are **Off, 1, 5, 10, 15, 20, 30 minutes, 1 hour** and **2 hours**. The source of the printout is indicated on the strip as **Periodic**.

Trend Printing

To print **Quick Trend**, **List Trend** or **Graph Trend** data to the recorder, press the **PRINT TREND** key while the trend is displayed. To abort printing these trends, press the **PRINT TREND** key again. To print the combined **BIS/EMG Trend** data to the recorder, select **Print BIS Trend** from the **BIS Menu**. To abort printing this trend, select **Print BIS Trend** again.

Quick Trend and List Trend print digital data information while Graph Trend and BIS/EMG Trend print graphic representations of the data in the respective menus.

Name: _____
ID #: _____
Bed #: _____
Date: 1/3/70
Time: 12:40:03 AM

Time:	HR BPM	SpO2 %	Resp RPM	IBP1 mmHg	IBP2 mmHg
'0:40	60	95	9	109 / 60 (69)	119 / 70
0:40	60	95	9	109 / 60 (69)	119 / 70
'0:39	60	95	9	109 / 60 (69)	119 / 70
0:39	60	95	8	109 / 60 (69)	119 / 70
'0:38	60	95	11	109 / 60 (69)	119 / 70
'0:38	60	95	11	109 / 60 (69)	119 / 70
'0:38	60	95	11	109 / 60 (69)	119 / 70
0:38	60	95	14	109 / 60 (69)	119 / 70

FIGURE 2-81 Sample Printout, List Trend Format

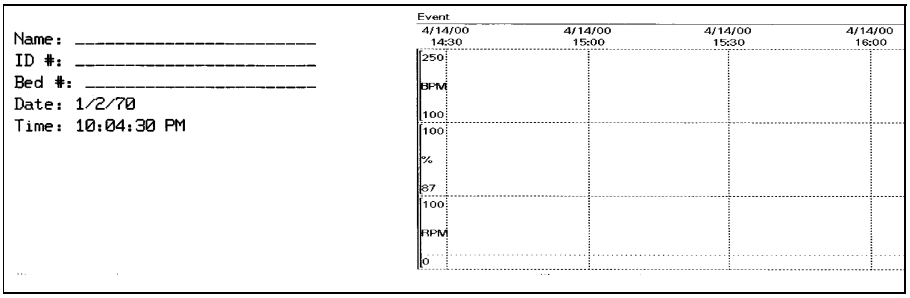


FIGURE 2-82 Graph Trend Format

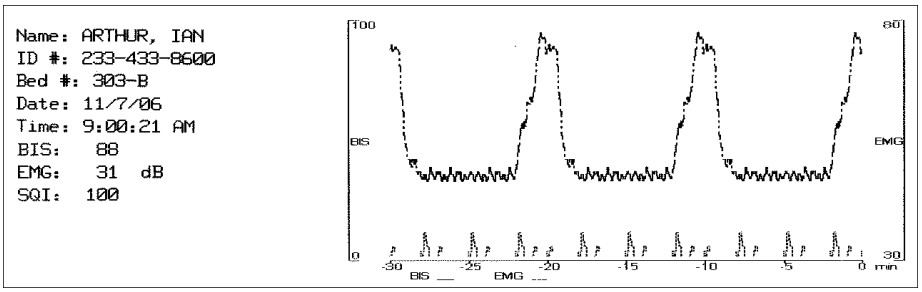


FIGURE 2-83 BIS/EMG Trend Format

Calculations

IV Drug and Hemodynamic printouts are initiated in the respective menu by using the Navigator™ Knob and scrolling to the **Print** function. The printout data will include patient demographic data, date / time of printout, data used to calculate the information and the calculated data. Drug Calculations will include the patient weight, IV fluid infusion rate and medication concentration.

Cardiac Output

Printing **Cardiac Output** waveforms and data is initiated from the **Cardiac Output Menu** by selecting **Print Runs**. Only valid **Cardiac Output** runs will be printed. The printout data will include patient demographic data, date of printout and patient parameter data prior to printing the waveform data. Following the digital information, up to five (5) **Cardiac Output** runs with time, **Cardiac Output** data and **Cardiac Index** data will be printed, followed by the **Average Cardiac Output / Cardiac Index** and catheter-specific data.

NOTE: **Cardiac Output report printing from the recorder is only available if the CO Source is the EPM.**

PAWP

To print **PAWP** (Pulmonary Artery Wedge Pressure) waveforms access the **PAWP Menu** and select **Print Wedge**. This printout is continuous and will only be aborted by pressing the **PRINT WEDGE** key again or by running out of recorder paper. The printout data will include patient demographic data, time/date of printout, and waveform speed just prior to printing the waveform data. Following the digital information, 2 waveforms will print continuously. These waveforms are the top two (2) waveforms appearing in the **Wedge Menu**. The printed strip will be annotated with the waveform names and scales every 18 seconds.

2.8.2 Printer / Recorder Troubleshooting

MESSAGE/PROBLEM	REASON	SOLUTION
Recorder Report Appears Totally Blank	Thermal paper may be installed incorrectly (up-side down)	Remove paper and re-install with paper feeding off of the spool from the bottom
Local Printer Door Open	The printer door is not closed	Close the printer door
Local Printer Out Of Paper	Printer out of paper	Replace with a new roll of paper
Printer Busy	Printer received multiple print requests at one time	Wait until the printer is not busy
Local Printer Unable To Print	The system has detected an unrecoverable printer failure	Power cycle unit. If message reappears, contact Customer Support.
No print on Alarm	Alarm printing not active	Go to **Print Setup Menu** and set **Print on Alarm** to **On**
Trends not printing	Print Trend not pressed	Press **PRINT TREND** when trend window is open
	No Trends displayed	Use **scroll** feature to scroll to the top of the trend then press **PRINT TREND**
	No paper	Check / Replace paper

2.9 Connection to Panorama® Central Station

The **Spectrum OR** will communicate with the Panorama Central Station via direct hardwire to a Comm-Port with a CS1 port. The "Enable Network" option in the **System Information** menu must be set to "Wired" when using a hardwire **Spectrum OR**.

Refer to the Panorama Operating Instructions Manual for a list of supported parameters.

The Spectrum OR is capable of transmitting a discharge command to a Panorama Central Station. It is also capable of bi-directional transmission of patient demographics and patient alarm settings with a Panorama Central Station.

When "Discharge" is selected from the **Patient Menu** and Enable Network is set to "Wired", the Panorama will discharge the patient.

If Trend is cleared or the patient is discharged at the Spectrum OR, the Spectrum OR time and date will be synchronized with the Panorama Central Station time and date.

NOTE: **If the Edwards Vigilance® Monitor is the source for CO, CCO, CI, CCI, SVR, SvO_2, TBlood and ΔT measurements, this data will not be available at the Panorama Central Station. BIS, MAC and Spirometry data are also not available at the Panorama Central Station.**

2.10 Connection to Viewstation OR™ Independent Display

The **Spectrum OR** will communicate with the Viewstation OR via direct hardwire to a Comm-Port with a CS1 port. The "Enable Network" option in the **System Information** menu must be set to "Wired" when using a hardwired **Spectrum OR**.

Refer to the Viewstation OR Operating Instructions Manual for a list of supported parameters.

2.11 Connection to Panorama® Gateway

The **Spectrum OR** can communicate with an EMR system through a Panorama Gateway via a hardwired network connection to a Comm-Port with a CS1 port. The "Enable Network" option in the **System Information** menu must be set to "Wired" when using a hardwire **Spectrum OR**.

For the **Spectrum OR** to be recognized by the EMR system, certain demographics content, referred to as the "Patient Key", must be entered from its **Patient Menu**. Each facility has its own unique "Patient Key" that must be entered before making a connection to the EMR. The "Patient Key" consists of the required ID # and, optionally, one or more of the following **Patient Menu** demographics fields:

- First name
- Last name
- Bed #

Once the "Patient Key" has been entered, communication with the EMR system must be verified. Since the Panorama Gateway can be purchased with ADT messaging only, Results messaging only or ADT messaging with Results messaging, this verification differs as follows:

ADT messaging

For a Panorama Gateway that has ADT messaging, verify that communication with the EMR system has been established as follows:

- After entering the "Patient Key" in the **Patient Menu**, select Normal Screen to close the menu.
- If demographics information corresponding to the following fields was not part of the "Patient Key" but is entered into the EMR system, these fields in the **Patient Menu** should auto-populate upon re-opening the menu:
  - First name
  - Last name
  - Bed #
  - Date of Birth
  - Gender
- In addition, the First Name and Last Name should populate in the upper right of the display.
- If the fields do not auto-populate, verify that the "Patient Key" has been correctly entered and that the patient demographics have been entered in the EMR system. If the fields still do not auto-populate, contact the EMR administrator.

Results messaging

For facilities with a Panorama Gateway that has Results messaging, verify that communication with the EMR system has been established by checking the charting system to ensure that vital signs data has been uploaded. If the charting system is not displaying the information, contact the EMR administrator.

2.12 Monitor/Display Troubleshooting

MESSAGE/PROBLEM	REASON	SOLUTION
No trace for a desired parameter	Improper attachment of transducer or cable to monitor	Check transducer / cable connection.
	Faulty transducer or cable.	Try a new transducer or cable.
Display Appears to be Off	Mains power switch may not be on.	Check mains power switch on side panel.
	Unit may not be plugged into an AC outlet.	Check power cord (Is it plugged in?)
	If used as a portable, battery pack may be drained.	If battery pack is drained, plug into an AC outlet to recharge the battery. A period of 5 hours is required for a full charge of lithium-ion batteries. A period of 16 hours is required for a full charge of sealed lead acid batteries.
		Power unit back on. Contact Customer Support.
Disabled Alarm Tone	**MUTE** key pressed.	Check for alarm mute symbol and message.
	Beep volume low.	Increase beep volume.
Cooling Fan Failure	The unit running on AC power and the cooling fan is not operational.	Contact Customer Support.
Patient Information did not appear on display	No data entered.	Enter proper patient data.
	Done was not selected from keypad after entering data.	Go to the proper keypad enter data, select **Done** when finished.
Incorrect Date or Time	Data not entered or entered incorrectly.	Follow instructions from **"How to Set the Clock / Date and Time"**.

3.0 *User Maintenance*

3.1 Introduction

This section of the manual outlines routine user maintenance guidelines.

The **Spectrum OR** Monitor is designed for stable operation over long periods of time. Under normal circumstances the monitor should not require technical maintenance beyond that described in this section. However, routine maintenance, calibration and safety checks are recommended at least once a year or more often as required by local statutory or hospital administration practice.

3.2 Care and Cleaning of Monitor

The monitor enclosure may be cleaned with a mild soap and water solution or ammoniated window cleaner. Apply cleaning solution to the cloth, not directly onto the monitor. DO NOT apply large amounts of liquid. DO NOT use abrasive cleaning agents or organic solvents.

WARNING: Do not clean the monitor while it is on and/or plugged in.

To prevent scratches on the screen carefully brush dust and dirt particles with a soft sponge moistened with cleaning solution or a fine, soft-hair brush. DO NOT use abrasive cleaning materials. Remove fingerprints and stains with a liquid lens cleaner and a soft cloth. DO NOT wipe a dry screen or use alcohol or solvents containing chlorinated hydrocarbon.

3.3 Decontamination of Monitor

WARNING: Perform the decontamination process with the unit powered down and power cord removed.

Decontamination of a unit that has come in contact with a biological material can be performed using LpH SE Germicidal detergent. Apply a small amount of detergent to a disposable wipe (paper based) and wipe down the outside of the unit. Discard the wipe appropriately. After waiting 10 minutes, use a clean dry wipe to dry the unit.

CAUTION: During the decontamination process, do not get the LpH SE Germicidal detergent into any vent openings.

3.4 Care and Cleaning of SpO_2 Sensors

NOTE: Refer to the individual instruction sheets that are packaged with each sensor.

- Check sensors and cables daily for signs of damage. Replace as required.
- Sensors should be cleaned before and after each new patient.
- Wipe the patient contact area using a soft cloth with mild soap and water solution or isopropyl alcohol. Hydrogen peroxide can be used to remove dried blood.
- Allow the sensor to completely dry before using.

CAUTION: When cleaning sensors, do not use excessive amounts of liquid. Wipe the sensor surface with a soft cloth, dampened with cleaning solution. Do not attempt to sterilize.

Cleaning and Re-use of a Nellcor® Sensor

Sensors may be reattached to the same patient if the emitter and detector windows are clear and the adhesive still adheres to the skin. The adhesive can be partially rejuvenated by wiping with an alcohol wipe and allowing the sensor to thoroughly air dry prior to replacement on the patient.

Do not immerse any Oxisensor®, OxiMax®, Durasensor®, Oxiband®, or Duraform® oxygen transducers, the Nellcor® RS-10 or Max-Fast® oxygen transducers, or any Nellcor® adhesive in water or cleaning solution. Clean Durasensor®, Oxiband®, and Duraform® oxygen transducers, and the Nellcor® RS-10 or Max-Fast® oxygen transducers by wiping with a disinfectant such as a solution containing 70% alcohol. Do not sterilize by irradiation, steam, or ethylene oxide. Use a new Oxiband® adhesive wrap or FORM-A adhesive bandage for each patient. Do not re-sterilize Oxisensor® or OxiMax® oxygen transducers.

3.5 Sterilization and Cleaning of Reusable Cuffs

3.5.1 Reusable Cuffs with Bladders

Take out the bladder before cleaning and disinfecting the cuff.

Cleaning

The cuff can be hand washed or machine washed in warm water or with mild detergent. The bladder can be cleaned with a damp cloth. Air dry the cuff thoroughly after washing.

NOTE: Machine washing may shorten the service life of the cuff.

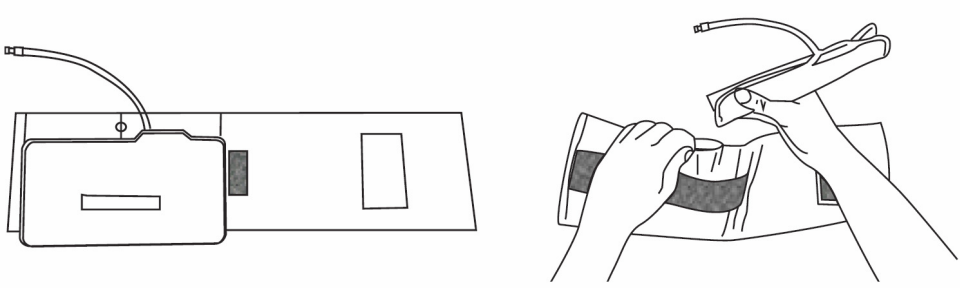
Disinfection

The cuff may be disinfected with a damp cloth with 70% ethanol or 70% isopropanol. It may also be disinfected with ultraviolet. The bladder can only be disinfected with ultraviolet.

NOTE: Prolonged use of disinfectant may cause discoloration of the cuff.

Replace the bladder after cleaning and disinfecting the cuff, as follows:

1. Place the bladder on the top of the cuff, as the figure shows.
2. Roll the bladder lengthwise and insert it into the large opening. See the figures below.
3. Hold the hose and the cuff and shake the complete cuff until the bladder is in position.
4. Thread the hose from inside the cuff, and out through the small hole under the internal flap.



CAUTION: Do not dry clean the cuff.
Do not press the cuff with a hot iron.
Do not use detergent and disinfectant other than fresh water, 70% ethanol or 70% isopropanol.
Clean and disinfect the cuff according to the instructions.

3.5.2 Reusable Bladderless Cuffs

Clean cuffs with warm water and a mild detergent. Do not use a detergent containing hand conditioners, softeners, or fragrances.

NIBP cuffs can be sterilized with gamma sterilization without effecting the repeated performance of the cuff. Steam sterilization is not recommended. Use of a washing liquid containing bleach is not recommended because chlorine will chemically break down the urethane on the inside of the cuff.

Antimicrobial Definition

Bladderless cuffs are treated with an antimicrobial coating. Antimicrobial technology effectively controls a broad spectrum of bacteria, fungi, algae and yeasts on a wide variety of treated substrates.

3.6 Battery Replacement and Maintenance

Battery Replacement

5. Open battery compartment door, on left side of unit, by pressing the finger grip area and sliding the door to the left.
6. Press the release button, located on the right side of the installed battery. This will eject the battery. Slide out and remove battery.
7. Slide in replacement battery until it clicks into place.
8. Close battery compartment door by sliding the door to the right until it firmly clicks into place.

CAUTION: Replace sealed lead acid batteries with P/N 0146-00-0043 ONLY. Replace lithium-ion batteries with P/N 0146-00-0069 ONLY.

Battery Maintenance

The batteries may be subject to local regulations regarding disposal. At the end of the battery life, dispose of the batteries in accordance with any local regulations.

NOTE: Spectrum OR batteries may only be charged within a Spectrum OR monitor. Do not attempt to use commercial rechargers.

Sealed Lead Acid

Due to the self-discharge characteristics of sealed lead acid batteries, it is imperative that they are charged after 3 months of storage (or unit not in use). If not, permanent loss of capacity may occur as a result of sulfation. Charge retention at 20°C is 6 months to 83%.

Lithium-Ion

Storage of the lithium-ion batteries depends on temperature, time period and the degree of cell charging state. After 6 months of storage at 23°C, fully charged lithium-ion batteries have a retention capacity of 93%.

3.7 Recorder Paper Replacement

The instructions below describe the replacement of recorder paper. Use only recommended recorder paper, P/N 0683-00-0422-XX. This ensures that the print quality is acceptable and reduces print head wear.

1. Open recorder door by pressing the paper eject button.
2. Remove empty paper spool.
3. Insert new paper roll between the two rounded tabs of the paper holder with the sensitive (shiny) side of the paper facing the print head at the top of the recorder (paper feeding off of the spool from the bottom).
4. Unroll approximately 4 inches of paper.
5. Align the paper across the top of the roller.
6. Holding the paper in place, close recorder door.
7. To ensure that the paper is aligned properly and has not been pinched in the door, pull the loose edge out a couple of inches. If the paper jams, open the door and return to step 5.

3.8 Care and Storage of Thermal Chart Paper

Thermal Chart Paper is chemically treated and the permanency of a recording is affected by storage and handling conditions. These conditions are:

- Ultraviolet Light

  We recommend storing the recordings in a filing cabinet within a few days of printing. Long term exposure to natural or artificial U.V. sources is detrimental.

- Storage Temperature and Humidity

  Keep the recordings in a cool and dry area for a longer lasting image. Extreme temperature and humidity (above 80° F/26° C and 80% Humidity) should be avoided.

- Solvent Reactions

  Do not store the recordings in plastic bags, acetate sheet protectors, and similar items made from petroleum products. These products emit a small amount of vapor which will, over a period of time, deteriorate the image on the chart paper.

- Adhesive Tape

  Never place adhesive tape over recordings. The reaction between the adhesive compound and the chemical/thermal paper can destroy the image within hours.

- Archives

  We recommend that if long term archives are required, make a photocopy of the recordings as back-up. Under normal office filing conditions the recordings should retain acceptable image quality for about 5 years.

3.9 Care and Cleaning of Gas Module

3.9.1 Gas Module II, Gas Module SE, and Gas Module SE with Spirometry

WARNING: Do not clean the Gas Module while it is on and/or plugged in.

1. The Gas Module enclosure may be cleaned with a mild soap and water solution or ammoniated window cleaner. Apply cleaning solution to the cloth, not directly onto the Gas Module. DO NOT apply large amounts of liquid. DO NOT use abrasive cleaning agents or organic solvents.

CAUTION: The internal sampling system of the Gas Module does not need to be cleaned or sterilized. There is no reverse flow back to the patient. If the internal sampling system is suspected to be clogged or dirty, the module should be serviced by an authorized service person only.

2. The fan dust filter should be checked and cleaned on a regular basis, at least once every two months.

- Locate fan on front panel.
- Remove the filter by pulling the dust filter cover.
- Remove the dust from the filter.
- Let the filter soak in a mild detergent solution.
- Rinse the filter and let dry completely before re-installing.

CAUTION: If the dust filter for the fan cannot be cleaned or is damaged, replace it with part number 0378-00-0040. Use of another type of filter may decrease the cooling effectivity and cause damage to the Gas Module.

3. The Water Trap Reservoir must be checked and emptied whenever changing patients or if it is more than half full.

- To remove the water trap, push the water trap latch to the right. The water trap is spring loaded and will pop out. An **Air Leak** message will be displayed. The monitor will suspend sampling.
- Detach the reservoir from the water trap assembly by pulling it down carefully.
- Empty the reservoir and rinse with water only.
- Re-attach the reservoir to the assembly tightly.
- Re-install the whole unit into the Gas Module making sure the latch is set. Check that the **Air Leak** message disappears and monitoring resumes.

NOTE: Do not disinfect or open the water trap. If an occlusion message appears, it may be necessary to replace the water trap assembly (P/N 0202-00-0129).

NOTE: The Water Trap Assembly must be replaced every two months.

3.9.2 Gas Module 3

WARNING: Do not clean the Gas Module while it is on and/or plugged in.

1. The Gas Module enclosure may be cleaned with a mild soap and water solution or ammoniated window cleaner. Apply cleaning solution to the cloth, not directly onto the Gas Module. DO NOT apply large amounts of liquid. DO NOT use abrasive cleaning agents or organic solvents.

CAUTION: The internal sampling system of the Gas Module does not need to be cleaned or sterilized. There is no reverse flow back to the patient. If the internal sampling system is suspected to be clogged or dirty, the module should be serviced by an authorized service person only.

2. The DRYLINE™ Water Trap Assembly consists of a filter housing and reservoir that must be checked and emptied whenever changing patients or if it is more than half full.

WARNING: The contents of the water trap should be handled as a potential infection hazard.

NOTE: Replace the complete DRYLINE™ Water Trap Assembly every month or more often if indicated on the monitor.

- To remove the DRYLINE™ Water Trap Assembly from its receptacle, press the lugs on its sides and pull out. An **Air Leak** message will be displayed. The monitor will suspend sampling.
- Detach the reservoir from the filter housing by twisting and separating these two parts.
- Empty the reservoir and rinse with water only.
- Tightly re-attach the reservoir to the filter housing.
- Re-install the DRYLINE™ Water Trap Assembly into the Gas Module, ensuring that it snaps into place. Check that the **Air Leak** message disappears and monitoring resumes.

NOTE: Only the reservoir of the DRYLINE™ Water Trap Assembly may be cleaned and/or disinfected.

NOTE: If an "Occlusion" message appears, it may be necessary to replace the DRYLINE™ Water Trap Assembly (Adult/Pediatric P/N 0202-00-0182-10; Neonate P/N 0202-00-0181-10).

3.10 Care and Cleaning of 3 and 5-lead ECG Cables and Leadwires

Recommended cleaning method of ECG cables and leadwires is a cloth wipe using ordinary alcohol-free hand soap or USP green soap tincture. When disinfection is required, a cloth wipe using disinfectants such as isopropyl alcohol, chlorine bleach in water (1:10 mixture) or 2% Glutaraldehyde solution (i.e., Cidex) is recommended. After cleaning, the ECG cables and leadwires should be wiped with water using a clean damp cloth then dried with a clean dry cloth. The ECG cables and leadwires must be allowed to dry thoroughly before use.

CAUTION: To avoid permanent damage, do not expose metal components (pins, sockets, snaps) to disinfectants, soaps or chemicals.

NOTE: ECG cables and leadwires must never be immersed, soaked in any fluids, and they should not be cleaned with harsh chemicals such as acetone or non-diluted bleach.

NOTE: Do not autoclave, radiation or steam sterilize ECG cables or leadwires.

NOTE: Extended exposure to Ethylene Oxide gas may shorten life of the ECG cables and leadwires, leading to poor signal quality.

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4.0 *Accessories*

4.1 Optional Accessories

4.1.1 NIBP Accessories

Hoses/Adapters

DESCRIPTION	PART NUMBERS
NIBP Hose, 60" (1.5 m), Female Rectus to Female Rectus	0683-04-0003
NIBP Hose, 138" (3.5 m), Female Rectus to Female Rectus	0683-04-0004

Color Coded Reusable Bladderless Cuffs (with Quick-Connect fittings)

DESCRIPTION	PART NUMBER
Variety Kit II, 6 cuffs [(1) Small Adult, (2) Adult, (2) Large Adult, (1) Adult Thigh]	0020-00-0082-33
Variety Kit III, 6 cuffs [(1) Small Child, (2) Child, (3) Small Adult]	0020-00-0082-32
Adult Thigh, Brown (45 - 56.5 cm circumference)	0998-00-0003-56
Large Adult Long, Burgundy (35.5 - 46 cm arm circumference)	0998-00-0003-58
Adult Long, Navy Blue (27.5 - 36.5 cm arm circumference)	0998-00-0003-57
Child, Green (13.8 - 21.5 cm arm circumference)	0998-00-0003-52
Small Child, Orange (9 - 14.8 cm arm circumference)	0998-00-0003-51

Disposable Bladderless Cuffs (with Quick-Connect fittings)

DESCRIPTION	PART NUMBER
Adult Thigh, White/Brown (5/box) (45 - 56.5 cm circumference)	0683-07-0036-01
Large Adult Long, White/Burgundy (10/box) (35.5 - 46 cm arm circumference)	0683-07-0038-01
Large Adult, White/Burgundy (10/box) (35.5 - 46 cm arm circumference)	0683-07-0035-01

Disposable Bladderless Cuffs (with Quick-Connect fittings)

DESCRIPTION	PART NUMBER
Adult Long, White/Navy Blue (10/box) (27.5 - 36.5 cm arm circumference)	0683-07-0037-01
Adult, White/Navy Blue (10/box) (27.5 - 36.5 cm arm circumference)	0683-07-0034-01
Small Adult, White/Light Blue (10/box) (20.5 - 28.5 cm arm circumference)	0683-07-0033-01
Child, White/Green (10/box) (13.8 - 21.5 cm arm circumference)	0683-07-0032-01
Small Child, White/Orange (10/box) (9 - 14.8 cm arm circumference)	0683-07-0031-01

Disposable Neonatal NIBP Cuffs - Quick Connect*

DESCRIPTION	PART NUMBERS
Neonatal Size 1: limb circumference 3 – 6 cm, Box of 10	0683-13-0001-01
Neonatal Size 2: limb circumference 5 – 8 cm, Box of 10	0683-13-0002-01
Neonatal Size 3: limb circumference 7 – 10 cm, Box of 10	0683-13-0003-01
Neonatal Size 4: limb circumference 9 – 13 cm, Box of 10	0683-13-0004-01
Neonatal Size 5: limb circumference 12 – 17 cm, Box of 10	0683-13-0005-01

* *Disposable neonatal cuffs require NIBP hose part number 0683-04-0003 (1.5 m).*

Reusable Cuffs - Quick Connect

DESCRIPTION	PART NUMBERS
Starter Kit: (1) child, (1) small adult, (1) adult, (1) large adult, (1) thigh)	0020-00-0184-01
Child, 10 – 19 cm (arm circumference), latex free	0683-15-0001-01
Small Adult, 18 – 26 cm (arm circumference), latex free	0683-15-0002-01
Adult, 25 – 35 cm (arm circumference), latex free	0683-15-0003-01
Large Adult, 33 – 47 cm (arm circumference), latex free	0683-15-0004-01
Thigh, 46 – 66 cm (arm circumference), latex free	0683-15-0005-01

Disposable Cuffs - Quick Connect

DESCRIPTION	PART NUMBERS
Child, 10 – 19 cm (arm circumference), latex free, box of 10	0683-14-0001-01
Small Adult, 18 – 26 cm (arm circumference), latex free, box of 10	0683-14-0002-01
Adult, 25 – 35 cm (arm circumference), latex free, box of 10	0683-14-0003-01
Large Adult, 33 – 47 cm (arm circumference), latex free, box of 10	0683-14-0004-01
Thigh, 46 – 66 cm (arm circumference), latex free, box of 5	0683-14-0005-01

4.1.2 Oximetry Sensors and Accessories

4.1.2.1 Pulse Oximetry-Masimo SET® LNOP® SpO_2

DESCRIPTION	PART NUMBER
LNOP® DCI Adult/Pediatric starter kit (one reusable adult sensor, 2 adult and 1 pediatric single patient adhesive sensors and one 12′ cable)	0020-00-0130
LNOP® DCI-Adult reusable finger sensor (with added "flaps" for ambient light shielding and 3′ cable)	0600-00-0047
LNOP® DC-12 Adult direct connect reusable finger sensor with attached 12' cable	0600-00-0120
LNOP® DCIP-Pediatric/slender digit reusable finger sensor	0600-00-0063
LNOP® TCI Tip Clip Ear Sensor	0600-00-0110
Ear Clip	0600-00-0086
Ear Hanger (pkg of 5)	0600-00-0087
LNOP® YI-Multisite reusable sensor	0600-00-0078
Multisite wrap (box of 100)	0600-00-0081
Multisite wrap, foam (pkg of 12)	0600-00-0083
LNOP® DCSC-Adult spot check reusable sensor	0600-00-0077
PC08-SpO_2 cable (2.44 m./8′)	0012-00-1099-01
PC12-SpO_2 cable (3.66 m./12′)	0012-00-1099-02
LNOP® Adt-Adult single patient adhesive sensors for patients more than 30 kgs. (pkg of 20)	0600-00-0043-01
LNOP® Pdt-Pediatric/slender digit single patient sensors for patients more than 10 kgs. and less than 50 kgs. (pkg of 20)	0600-00-0044-01
LNOP® II Inf-L-Infant L single patient adhesive sensors for patients more than 3 kgs. and less than 10 kgs. (pkg of 20)	0600-00-0100
Tape, Infant, L-Series (Package of 100)	0600-00-0108
LNOP® Neo-Neonatal Y single patient adhesive sensors for patients more than 1 kg. and less than 10 kgs. (pkg of 20)	0600-00-0045-01
Adhesive tapes for Neonatal Y single patient adhesive sensors (pkg of 100)	0600-00-0065
LNOP® II Neo-Neonatal L single patient adhesive sensors for patients more than 1 kg. and less than 10 kgs. (pkg of 20)	0600-00-0099
Adhesive tapes for Neonatal L single patient adhesive sensors (pkg of 100)	0600-00-0096
LNOP® NeoPt-Preterm neonatal Y single patient adhesive sensors-for patients less than 1 kg. (pkg 20)	0600-00-0046-01
Posey wraps for Preterm neonatal Y single patient adhesive sensors (pkg of 12)	0600-00-0064
LNOP® II NeoPt-L-Preterm neonatal L single patient adhesive sensors-for patients less than 1 kg. (pkg 20)	0600-00-0098
Posey wraps for Preterm neonatal L single patient adhesive sensors (pkg of 12)	0600-00-0097
Adult/Pediatric starter kit (two adult and two pediatric single patient adhesive sensors and one 3.66 m./12′ cable)	0020-00-0123-01
Neonatal Y starter kit (two neonatal and two preterm neonatal Y single patient adhesive sensors and one 3.66 m./12′ cable)	0020-00-0123-02
Clothing clips (pkg of 5)	0600-00-0084
Adhesive squares (12 cards/12 squares per card)	0600-00-0085

4.1.2.2 Pulse Oximetry-Masimo Set® LNCS® SpO_2

DESCRIPTION	PART NUMBER
LNCS DC-I Adult finger reusable sensor	0600-00-0126
LNCS DC-IP Pediatric finger reusable sensor	0600-00-0127
LNCS TC-I, Reusable Adult Ear Sensor	0600-00-0128
LNCS ADTX Adult single patient adhesive sensors (20/Box)	0600-00-0121
LNCS PDTX Pediatric single patient adhesive sensors (20/Box)	0600-00-0122
LNCS INF-L Infant single patient adhesive sensors (20/Box)	0600-00-0123
LNCS NEO-L Neonatal single patient adhesive sensors (20/Box)	0600-00-0124
LNCS NEO PT-L Neonatal preterm patient adhesive sensors (20/Box)	0600-00-0125
LNC-4 SpO2 Patient cable, 4'	0012-00-1652
LNC-10 SpO2 Patient cable, 10'	0012-00-1599
LNC-14 SpO2 Patient cable, 14'	0012-00-1653
LNCS to LNOP PC series adapter	0012-00-1651
Masimo SET MAC-1 LNCS adapter cable	0012-00-1656
LNCS Adult/Pediatric starter kit (one reusable Adult sensor, 2 Adult and 1 Pediatric single patient adhesive sensor and one 3.1 m cable)	0020-00-0154
LNCS Neonatal disposable starter kit (2 Neonate and 2 Neonate PreTerm single patient adhesive sensors and one 3.1 m cable)	0020-00-0155
LNCS Adult/Pediatric disposable starter kit (2 Adult and 2 Pediatric single patient adhesive sensors and one 3.1 m cable)	0020-00-0156

4.1.2.3 Pulse Oximetry-Nellcor® OxiMax® SpO_2*

DESCRIPTION	PART NUMBER
Reusable sensor	0600-00-0051
SpO_2 cable, DOC-10, OxiMax	0012-00-1464
Disposable OxiMax Sensor Kit (2 adult/2 neonatal)	0600-00-0103

* *Oximetry-Nellcor® OxiMax® SpO_2 Replacement sensors are available from Nellcor-Puritan Bennett. Phone: 1 800 NELLCOR or WWW.NELLCOR.COM*

4.1.3 Oridion CO_2 Accessories

DESCRIPTION	PART NUMBERS
FilterLine Set (short term), Adult/Pediatric (box of 25)	0683-00-0470-25
FilterLine Set, High Humidity, Infant/Neonatal (box of 25)	0683-00-0490-25
FilterLine Set, High Humidity, Adult/Pediatric (box of 25)	0683-00-0469-25
Smart CapnoLine™ Oral Nasal Cannula Pediatric (box of 25)	0683-00-0495-25
Smart CapnoLine™ O_2/CO_2 Oral Nasal Cannula Adult (box of 25)	0683-00-0496-25
Smart CapnoLine™ O_2/CO_2 Oral Nasal Cannula Pediatric (box of 25)	0683-00-0498-25
Smart CapnoLine Plus™ O_2/CO_2 Oral Nasal Cannula with O_2 tubing, Adult/Intermediate (box of 25)	0683-00-0516-25
Smart CapnoLine Plus™ O_2/CO_2 Oral Nasal Cannula with O_2 connector, Adult/Intermediate (box of 25)	0683-00-0517-25

DESCRIPTION	PART NUMBERS
NIV Line™ Adult (box of 25)	0683-00-0506-25
NIV Line™ Pediatric (box of 25)	0683-00-0507-25
CapnoLine™ H Adult (box of 25)	0683-00-0508-25
CapnoLine™ H Pediatric (box of 25)	0683-00-0509-25
CapnoLine™ H Infant/Neonatal (box of 25)	0683-00-0510-25
CapnoLine™ H O_2 Adult (box of 25)	0683-00-0511-25
CapnoLine™ H O_2 Pediatric (box of 25)	0683-00-0512-25
Calibration Gas	0075-00-0033-01
CO_2 Exhaust Connector, Male	0008-00-0332-01

4.1.4 Gas Module Accessories

4.1.4.1 Gas Module II, Gas Module SE, and Gas Module SE with Spirometry

DESCRIPTION	PART NUMBERS
Calibration Gas	0075-00-0028
Calibration Gas Regulator	0119-00-0166
Gas Module Rolling Stand Kit	0040-00-0232-01
Gas Module Wall Mount Kit	0040-00-0232-02
Y-Power Cord, 120V	0012-00-1081-01
Y-Power Cord, 220V	0012-00-1081-02
Y-Power Cord, 240V	0012-00-1081-03
Dust Filter	0378-00-0040
Nasal Cannula, CO2, 7' (2.1 m) (box of 10)	0683-00-0424-10
Nasal Cannula, CO2/O2, 7' (2.1 m) (box of 10)	0683-00-0452-10
Adapter, Straight Tee ET (box of 12)	0683-00-0242-22
Adapter, Mask Elbow ET (box of 12)	0683-00-0242-12
Sample Line, Patient, 10' (3.1 m) (box of 10)	0683-00-0451-10
DRYLINE™ Neonate Sample Line, Patient, (2.5 m) (box of 25)	0683-00-0524-25
DRYLINE™ Adult Sample Line, Patient, (2.5 m) (box of 25)	0683-00-0525-25
Water Trap Assembly (box of 10)	0202-00-0129
DRYLINE™ Neonate Water Trap Assembly (box of 10)	0202-00-0181-10
DRYLINE™ Adult Water Trap Assembly (box of 10)	0202-00-0182-10
Gas Scavenging Adapter Assembly, Quick Connect	0997-00-0923
Gas Scavenging Adapter Assembly, Luer	0997-00-0984
Spectrum OR/Gas Module Mounting Kit	0040-00-0287-03
Spirometry Tubing, 3 meter (pkg of 5)	0004-00-0075-005
Spirometry Sensor, Adult Reusable	0600-00-0073-001
Spirometry Sensor, Pediatric Reusable	0600-00-0074-001
Spirometry Sensor, Adult Disposable (box of 50)	0600-00-0075-050

4.1.4.2 Gas Module 3

DESCRIPTION	PART NUMBERS
Calibration Gas	0075-00-0028
Calibration Gas Regulator	0119-00-0166
Mounting Bracket, Gas Module to Spectrum OR (includes 4 screws, Part Number 0212-17-0606)	0040-00-0299-02
Mounting Plate, Gas Module to Wall Mount (includes 4 screws, Part Number 0211-03-5008)	0386-00-0344
Mounting Plate, Gas Module to Spectrum OR (requires 4 screws, Part Number 0211-04-4010)	0436-00-0160
Y-Power Cord, 120V	0012-00-1081-01
Y-Power Cord, 220V	0012-00-1081-02
Y-Power Cord, 240V	0012-00-1081-03
Cable, Gas Module to Spectrum OR Serial Port, short (0.3 m)	0012-00-1276-01
Cable, Gas Module to Spectrum OR Serial Port, long (1.8 m)	0012-00-1276-02
Nasal Cannula, CO2, 7' (2.1 m) (box of 10)	0683-00-0424-10
Nasal Cannula, CO2/O2, 7' (2.1 m) (box of 10)	0683-00-0452-10
Adapter, Straight Tee ET (box of 12)	0683-00-0242-22
Adapter, Mask Elbow ET (box of 12)	0683-00-0242-12
DRYLINE™ Neonate Sample Line, Patient, (2.5 m) (box of 25)	0683-00-0524-25
DRYLINE™ Adult/Pediatric Sample Line, Patient, (2.5 m) (box of 25)	0683-00-0525-25
DRYLINE™ Neonate Water Trap Assembly (box of 10)	0202-00-0181-10
DRYLINE™ Adult/Pediatric Water Trap Assembly (box of 10)	0202-00-0182-10
Gas Scavenging Adapter Assembly, Quick Connect*	0997-00-0923
Gas Scavenging Adapter Assembly, Luer*	0997-00-0984
Spectrum OR/Gas Module Mounting Kit	0040-00-0287-03
Wall Mount	0436-00-0061-01

* *For U.S. use only.*

4.1.5 Reusable Temperature Probes

YSI 400

DESCRIPTION	PART NUMBERS
Adult Rectal / Esophageal	0206-02-0001
Pediatric Rectal / Esophageal	0206-02-0002
Skin Surface	0206-02-0003

YSI 700

DESCRIPTION	PART NUMBERS
Adult Rectal / Esophageal	0206-00-0701
Skin Surface	0206-00-0709

4.1.6 Disposable Temperature Probes

400 Series Probes (boxes of 20)

DESCRIPTION	PART NUMBERS
Esophageal Stethoscope, 12 Fr, ES 400-12	0206-03-0112-02
Esophageal Stethoscope, 18 Fr, ES 400-18	0206-03-0118-02
Esophageal/Rectal, 9 Fr, ER 400-9	0206-03-0209-02
Esophageal/Rectal, 12 Fr, ER 400-12	0206-03-0212-02
Skin, SK 400	0206-03-0300-02
Instrument Cable, 400 Series	0012-00-0975

4.1.7 ECG Accessories

4.1.7.1 ECG Cables

3/5 Lead ECG Cables

DESCRIPTION	PART NUMBER
10′ (3.1 m) Straight	0012-00-1255-01
20′ (6.1 m) Straight	0012-00-1255-02
10′ (3.1 m) Right Angle	0012-00-1255-03
20′ (6.1 m) Right Angle	0012-00-1255-04
10′ (3.1 m) Straight, ESIS	0012-00-1255-05
20′ (6.1 m) Straight, ESIS	0012-00-1255-06
10′ (3.1 m) Right Angle, ESIS	0012-00-1255-07
20′ (6.1 m) Right Angle, ESIS	0012-00-1255-08
10′ (3.1 m) Neonate Cable, AAMI	0012-00-1265-01
10′ (3.1 m) Neonate Cable, IEC	0012-00-1265-02

Panorama Mobility Cable (ESIS and Non ESIS)

DESCRIPTION	PART NUMBER
Non-ESIS, 10′ (3.1 m), AAMI	0012-00-1502-01
Non-ESIS, 20′ (6.1 m), AAMI	0012-00-1502-02
ESIS, 10′ (3.1 m), AAMI	0012-00-1502-03
ESIS, 20′ (6.1 m), AAMI	0012-00-1502-04

4.1.7.2 ECG Leadwires

ECG Lead Wires - 3 Lead

DESCRIPTION	PART NUMBERS
3 Lead, Snap 18" (45.7 cm), AAMI	0012-00-1261-07
3 Lead, Snap 24" (61.0 cm), AAMI	0012-00-1261-08
3 Lead, Snap 40" (101.6 cm), AAMI	0012-00-1261-09
3 Lead, Snap 18" (45.7 cm), IEC	0012-00-1261-10

ECG Lead Wires - 3 Lead

DESCRIPTION	PART NUMBERS
3 Lead, Snap 24" (61.0 cm), IEC	0012-00-1261-11
3 Lead, Snap 40" (101.6 cm), IEC	0012-00-1261-12
3 Lead, Pinch Clip 18" (45.7 cm), AAMI	0012-00-1262-07
3 Lead, Pinch Clip 24" (61.0 cm), AAMI	0012-00-1262-08
3 Lead, Pinch Clip 40" (101.6 cm), AAMI	0012-00-1262-09
3 Lead, Pinch Clip 18" (45.7 cm), IEC	0012-00-1262-10
3 Lead, Pinch Clip 24" (61.0 cm), IEC	0012-00-1262-11
3 Lead, Pinch Clip 40" (101.6 cm), IEC	0012-00-1262-12

ECG Lead Wires - 5 Lead

DESCRIPTION	PART NUMBERS
5 Lead, Snap 18" (45.7 cm), AAMI	0012-00-1261-01
5 Lead, Snap 24" (61.0 cm), AAMI	0012-00-1261-02
5 Lead, Snap 40" (101.6 cm), AAMI	0012-00-1261-03
5 Lead, Snap 18" (45.7 cm), IEC	0012-00-1261-04
5 Lead, Snap 24" (61.0 cm), IEC	0012-00-1261-05
5 Lead, Snap 40" (101.6 cm), IEC	0012-00-1261-06
Snap, Extended Leg, 3/40" (3/101.6 cm), 2/60" (2/152.4 cm), AAMI	0012-00-1261-13
Snap, Extended Leg, 3/40" (3/101.6 cm), 2/60" (2/152.4 cm), IEC	0012-00-1261-14
5 Lead, Pinch Clip 18" (45.7 cm), AAMI	0012-00-1262-01
5 Lead, Pinch Clip 24" (61.0 cm), AAMI	0012-00-1262-02
5 Lead, Pinch Clip 40" (101.6 cm), AAMI	0012-00-1262-03
5 Lead, Pinch Clip 18" (45.7 cm), IEC	0012-00-1262-04
5 Lead, Pinch Clip 24" (61.0 cm), IEC	0012-00-1262-05
5 Lead, Pinch Clip 40" (101.6 cm), IEC	0012-00-1262-06

Panorama Mobility Lead Wires

DESCRIPTION	PART NUMBERS
5 Lead, Snap 24" (61.0 cm), AAMI	0012-00-1503-02
3 Lead, Snap 24" (61.0 cm), AAMI	0012-00-1503-05

4.1.7.3 Electrodes

DESCRIPTION	PART NUMBERS
Neo Pre-wired (3 Lead Combiner Clip) 18", AAMI box of 100 Pks of 3 Ea: Radio Opaque Set	0681-00-0098-01
Neo Pre-wired (3 Lead Combiner Clip) 18", AAMI box of 100 Pks of 3 Ea: Radio Translucent Set	0681-00-0098-02

DESCRIPTION	PART NUMBERS
Disposable pre-gelled ECG Electrodes, foam base and Hydrogel conductive adhesive, 1 case of 600/10 boxes of 60	0681-00-0100-01
Disposable pre-gelled ECG Electrodes, foam base and Hydrogel conductive adhesive, 1 case of 60	0681-00-0100-02

4.1.8 IBP Accessories

IBP

TRANSDUCERS	PART NUMBERS
P10EZ Miniature (Reusable)	0682-00-0085
P23XL-1 Transducer (Reusable)	0682-00-0084
Cable, Interface, Transducer	0012-00-1245

4.1.9 BISx Accessories

DESCRIPTION	PART NUMBERS
BISx Module (includes PIC)	0992-00-0236-01
BISx Quatro Sensors (box of 25)*	0600-00-0132-01
BISx Extend Sensors (box of 25)*	0600-00-0132-02
BISx Pediatric Sensors (box of 25)*	0600-00-0132-03
BISx Semi Reusable Sensors (1 programmed patient cable and 1 box of 100 disposable sensors)*	0600-00-0134-01
BISx Quatro Adult Disposable Sensor Starter Kit (box of 5)**	0020-00-0491-01
BISx ICU Extend Disposable Sensor Starter Kit (box of 5)**	0020-00-0491-02
BISx Pediatric XP Disposable Sensor Starter Kit (box of 5)**	0020-00-0491-03

* *Available for international distribution only.*

** *For USA, one sensor starter kit is available for sale with the purchase of each BISx Module only. Additional sensors must be ordered directly from Aspect Medical Systems, Inc. at 1-888-247-4633*

4.1.10 Comm-Port Accessories

Comm-Port

Comm-Port 2	CS1, MB1, RD1	0998-00-0178-03
Comm-Port 3	RD1, NC1, SP1	0998-00-0178-05
Comm-Port 4	CS1, MB1, SP1	0998-00-0178-04
Comm-Port 5	SP1, NC1, SP2	0998-00-0178-06

CS = Ethernet Port, MB = Module Bus, SP = Serial Port, RD = Remote Display, NC = Nurse Call

Nurse Call (NC1)

DESCRIPTIONS	PART NUMBER
Unterminated Cable, 9′ (2.7 m)	0012-00-1277-02

Remote Display (RD1)

DESCRIPTIONS	PART NUMBERS
Cable, 6′ (1.83 m), VGA Extension, Male D to Female D	0012-00-0852-01
Cable, 25′ (7.62 m), VGA Extension, Female to Unterminated	0012-00-0852-02
Cable, 50′ (15.24 m), VGA Extension, Female to Unterminated	0012-00-0852-03
Cable, 100′ (30.48 m), VGA Extension, Female to Unterminated	0012-00-0852-04
Cable, 10′ (3.05 m), VGA Male to Male	0012-00-0994-01
Cable, 25′ (7.62 m), VGA Male to Male	0012-00-0994-02
Cable, 50′ (15.24 m), VGA Male to Male	0012-00-0994-03
Cable, 75′ (22.86 m), VGA Male to Male	0012-00-0994-04
Display, 19.0″ LCD Flat Panel, Medical Grade, Desktop	0160-00-0093-03
Display, 19.0″ LCD Flat Panel, Medical Grade, Wall mount	0160-00-0093-04
Wall mount, adjustable, VHM, Flat Panel	0436-00-0210
Wall mount, flush, Flat Panel	0040-00-0368

Serial Port (SP1)

DESCRIPTIONS	PART NUMBERS
Cable, Serial Port to Gas Module, 12″ (30.48 cm)	0012-00-1276-01
Cable, Serial Port to Gas Module, 72″ (182.88 cm)	0012-00-1276-02
Cable, Interface, Vigilance/PC, Serial Port to Serial Port	0012-00-1275-01

Ethernet (CS1)

DESCRIPTIONS	PART NUMBERS
CAT 5 Ethernet Cable, Patch, STP, 6′ (1.83 m)	0012-00-1274-01
CAT 5 Ethernet Cable, Patch, STP, 25′ (7.62 m)	0012-00-1274-02
CAT 5 Ethernet Cable, Patch, STP, 50′ (15.24 m)	0012-00-1274-03
CAT 5 Ethernet Cable, Patch, STP, 1′ (0.30 m)	0012-00-1274-04
CAT 5 Ethernet Cable, Patch, STP, 2′ (0.61 m)	0012-00-1274-05
CAT 5 Ethernet Cable, Patch, STP, 3′ (0.91 m)	0012-00-1274-06
CAT 5 Ethernet Cable, Patch, STP, 10′ (3.05 m)	0012-00-1274-07
CAT 5 Ethernet Cable, Crossover, STP, 3′ (0.91 m)	0012-00-1392-05
CAT 5 Ethernet Cable, Crossover, STP, 6′ (1.83 m)	0012-00-1392-06
CAT 5 Ethernet Cable, Crossover, STP, 10′ (3.05 m)	0012-00-1392-07
CAT 5 Ethernet Cable, Crossover, STP, 20′ (6.10 m)	0012-00-1392-08

4.1.11 Base Station Accessories

DESCRIPTION	PART NUMBERS
Base Station kit with 110V line cord	BASESTATION110
Base Station kit with 220V line cord	BASESTATION220
Base Station kit with 240V line cord	BASESTATION240
Base Station 110V line cord	0012-25-0001

DESCRIPTION	PART NUMBERS
Base Station 220V line cord	0012-25-0002
Base Station 240V line cord	0012-25-0003
Base Station power supply	0014-00-0070
Base Station mounting kit	0386-00-0259
Base Station Operator's manual multilanguage	0073-00-1292

4.1.12 Miscellaneous Accessories

DESCRIPTIONS	PART NUMBERS
Recorder Chart Paper (10 Rolls)	0683-00-0422-02
Battery, Lithium-Ion	0146-00-0069
Battery, Sealed Lead Acid	0146-00-0043
AC Power Cord, 120V	0012-25-0001
AC Power Cord, 220V	0012-25-0002
AC Power Cord, 240V	0012-25-0003
Cable Assy, DPD Defibrillator, 8” (20.32 cm)	0012-00-1301-01
Cable Assy, DPD Defibrillator, 10’ (3.05 m)	0012-00-1301-02
Cable Assy, Analog Output (ECG only), 15’ (4.57 m)	CABLEANALOGOUT
Cable, ECG/IBP to IABP interface, for Software Version B.10 and above, 6-pin (4.6 m)	0012-00-1650-01
Transfer Card	0996-00-0171-01
Extended Trend Card	0996-00-0052-01

4.1.13 Mounting Kits and Accessories

DESCRIPTIONS	PART NUMBERS
Rolling Stand with mounting bracket	TRANSLBRKT
Rolling Stand with quick release plate	TRANSQRMTG
Wall Mount Kit	0040-00-0287-02
VHM Wall Mount	0040-00-0287-04
Bedrail Mount Kit	0040-00-0293
Quick Release Mounting Plate Kit	0040-00-0299-01
Stationary Mounting Bracket Kit	0040-00-0299-02
Gas Module Mounting Kit	0040-00-0287-03

4.1.14 Upgrade Kits

DESCRIPTION	PART NUMBERS
CO_2 Upgrade Kit with Masimo SpO_2	0040-00-0353-01
CO_2 Upgrade Kit with Nellcor® OxiMax® SpO_2, Nell-3	0040-00-0353-03
CO_2 MiniMedi Upgrade - For use in units with Masimo SpO_2 (includes installation at the Company's Repair Center)	0040-00-0353-04
CO_2 MiniMedi Upgrade - For use in units with Nellcor OxiMax SpO_2 (includes installation at the Company's Repair Center)	0040-00-0353-06
IBP Upgrade Kit (Add IBP1 and IBP2)	0040-00-0268-02
ST Software Option Enable Kit - 1 License	0040-00-0300-01
ST Software Option Enable Kit - 5 Licenses	0040-00-0300-02
ST Software Option Enable Kit - 10 Licenses	0040-00-0300-03
Arrhythmia Software Option Enable Kit - 1 License	0040-00-0300-11
Arrhythmia Software Option Enable Kit - 5 Licenses	0040-00-0300-12
Arrhythmia Software Option Enable Kit - 10 Licenses	0040-00-0300-13
ST & Arrhythmia Software Option Enable Kit - 1 License	0040-00-0300-21
ST & Arrhythmia Software Option Enable Kit - 5 Licenses	0040-00-0300-22
ST & Arrhythmia Software Option Enable Kit - 10 Licenses	0040-00-0300-23
Vigilance Software Option Enable Kit - 1 License	0040-00-0300-31
Vigilance Software Option Enable Kit - 5 Licenses	0040-00-0300-32
Vigilance Software Option Enable Kit - 10 Licenses	0040-00-0300-33
Vigilance & ST Software Option Enable Kit - 1 License	0040-00-0300-41
Vigilance & ST Software Option Enable Kit - 5 Licenses	0040-00-0300-42
Vigilance & ST Software Option Enable Kit - 10 Licenses	0040-00-0300-43
Vigilance & Arrhythmia Software Option Enable Kit - 1 License	0040-00-0300-51
Vigilance & Arrhythmia Software Option Enable Kit - 5 Licenses	0040-00-0300-52
Vigilance & Arrhythmia Software Option Enable Kit - 10 Licenses	0040-00-0300-53
Vigilance, ST & Arrhythmia Software Option Enable Kit - 1 License	0040-00-0300-61
Vigilance, ST & Arrhythmia Software Option Enable Kit - 5 Licenses	0040-00-0300-62
Vigilance, ST & Arrhythmia Software Option Enable Kit - 10 Licenses	0040-00-0300-63

4.1.15 External Parameter Module Accessories

DESCRIPTION	PART NUMBERS
External Parameter Module with Temperature	0998-00-0501-04X*
External Parameter Module with Temperature and Cardiac Output	0998-00-0501-03X*
External Parameter Module with Temperature and IBP	0998-00-0501-02X*
External Parameter Module with Temperature, Cardiac Output and IBP	0998-00-0501-01X*
Cable, Cardiac Output Y, two Temperature connections	0012-00-1447-01
Cable, Cardiac Output Edwards LifeSciences in-line injectate adapter	0012-00-1520
Cable, Cardiac Output Edwards LifeSciences Bath probe adapter	0012-00-1519
Cable, Cardiac Output Becton Dickinson in-line injectate adapter	0012-00-1532
Cable, Cardiac Output Abbott Labs in-line injectate adapter	0012-00-1533

* *NOTE: Please replace "X" with one of the following letters to designate language required: A-English; P-Spanish; T-Italian; D-Dutch; F-French; G-German; N-Danish*

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5.0 *Appendix*

5.1 Safety Designations

5.1.1 Safety designations per IEC 60601-1 Standard

Type of protection against electric shock:	Class 1 with internal electric power source. Where the integrity of the external protective earth (ground) in the installation or its conductors is in doubt, the equipment will be operated from its internal electric power source (batteries).
Degree of protection against electric shock:	ECG, IBP and Cardiac Output - Type CF defibrillation protected NIBP, EEG - Type BF defibrillation protected SpO_2, CO_2 and Temperature - Type BF
Supply Connection:	100 - 240 Volt 50 or 60 Hz 1.2 - 0.7 Amps 12 VDC Sealed Lead Acid Internal Battery or 11.1 VDC Lithium-Ion Internal Battery
Mode of Operation:	Continuous
Protection Against Hazards of Explosion:	Not protected (Ordinary)
Protection Against Ingress of Liquids:	Drip-proof (IPX1)

Degree of electrical connection between equipment and patient:	Equipment designed for direct electrical and non-electrical connection to the patient
Degree of Mobility:	Transportable

5.2 Patient Parameter Specifications

5.2.1 ECG

ECG Safety Requirements

The 3/5-lead ECG function is in accordance with the applicable requirements of EN 60601-2-27.

ECG Performance Requirements

The ECG meets the Section 3.2 Performance Requirements of ANSI/AAMI EC11-1991.

The ECG meets the Section 3.2 Performance Requirements of ANSI/AAMI EC13-1992.

Lead Definition

ECG Type	Acquired Leads	Displayable Leads
3-lead ECG	I, II, III	I, II, III (one vector at a time)
5-lead ECG	I, II, and V (n)	I, II, III, aVR, aVL, aVF, V (n)

Lead Fault: Lead resistances ≤ 51 kΩ in parallel with 0.047 µF capacitance will not cause a lead fault condition.

Differential offsets ≤ ±300 mV will not cause a lead fault condition.

3/5-lead ECG Cable Detection: Automatically detected using approved auto-detecting cables.

Frequency Response

	Bandwidth (-3 dB)		
ECG Type	**Monitor Mode**	**Extended Mode**	**ST Mode**
3/5-lead ECG	0.5 to 40 Hz	0.05 to 100 Hz	0.05 to 40 Hz

Electrical Surgical Unit (ESU) Use

Protection: 3 and 5-lead ECG meets IEC. 60601-2-25, clause 36.202.7 for functionality following ESU energy exposure.

The system is capable of withstanding ESU stress with no permanent damage and regain normal function within 10 seconds after removal of the disturbance.

Withstand:	3 and 5-lead ECG can withstand ESU stress from a High Frequency Surgical Unit operating at 300 Watts in cut mode and 100 Watts on coagulate mode.
Noise Suppression:	3 and 5-lead ECG peak noise is less than ± 2 mV from ECG baseline when used with AAMI compatible cables.
Noise Detection:	An ESU noise declaration will be asserted if signals detected as pacers are detected at a rate greater than 50 Hz. No noise declaration will be asserted if pacer-like signals are detected at a rate less than 10 Hz.

ECG Filters

ESU Interference Filtering:	An ESU Interference filter provides greater than 90 dB attenuation at 500 kHz. The ESU Filter may be turned off.
50/60 Hz Notch Filtering:	A Notch Filter is provided at 50 or 60 Hz. The Notch Filter may be turned off.

Pacemaker Pulse Display

Rejection:	Pacer signals from ± 2 mV to ± 700 mV (RTI) amplitude and 0.1 ms to 2 ms in duration, and a maximum of 100 μs rise time are rejected from the display when the Pacer Rejection Mode is On.
Enhancement:	Pacer signals within the range ± 2 mV and ± 700 mV (RTI) amplitude with a maximum rise time of 100 μs and with duration in the 0.1 ms to 2.0 ms range will be enhanced on the display when the Pacer Enhancement Mode is turned On.

ECG Systole Detector and Heart Rate Meter

The ECG heart rate meter function is derived from the ECG waveform. It provides a count of the number of R waves per minute that are detected in the ECG waveform.

ECG Derived Heart Rate Meter Performance Requirements

ECG SOURCE	NEONATAL RANGE (BPM)	PEDIATRIC RANGE (BPM)	ADULT RANGE: (BPM)
3/5-lead ECG	30 to 350	30 to 300	30 to 300

Resolution:	1 bpm
Accuracy:	± 3 bpm or ± 3% at 30 to 250 bpm, whichever is greater. ± 5% 251 to 350 bpm.
Trigger Indication:	There is an audible beep on every beat captured.
Tall T-Wave Rejection:	When tested in accordance with ANSI/AAMI EC13-1992 Section 4.1.2.1c, the heart rate meter rejects all T-waves with amplitudes less than 120% of a 1 mV, 100 ms QRS, and a T wave duration of 180 ms and a Q-T interval of 350 ms.
Step Change Response Time:	When tested in accordance with ANSI/AAMI EC13-1992 Section 4.1.2.1f, the response time of the heart rate meter to changes in heart rate is: Less then 10 sec for step increase from 80 to 120 bpm. Less then 11 sec for step decrease from 80 to 40 bpm.
Pacemaker Pulse Rejection:	When tested in accordance with ANSI/AAMI EC13-1992 Section 4.1.4, the heart rate meter rejects tall pulses of amplitude ± 2.0 mV to ± 700 mV and duration 0.1 ms to 2 ms with no tail. When tested in accordance with ANSI/AAMI EC13-1992 Section 4.1.4, the 3/5 Lead ECG derived heart rate meter will reject all pacer pulses ± 2.0 mV to ± 700 mV and duration 0.1 ms to 2 ms with 4 ms time constant tail of less than 2.0 mV.

Heart Rate Averaging:	3/5 Lead ECG: The average heart rate is calculated as follows: Mean R to R interval in the last 16 R to R intervals (HR > 48 bpm). Mean R to R interval in the last 4 R to R intervals (HR ≤ 48 bpm).

5.2.2 ECG Respiration Performance Requirements

Sensing Leads:	Lead II or I
Default Sensing Lead:	Lead II
Source:	3-lead or 5-lead ECG cable.
Range:	4 to 199 breaths per minute.
Accuracy:	± 2% or ± 2 breaths per minute, whichever is greater from 4 to 150. ± 4%, from 151 to 199.
Excitation:	< 550 μA RMS max.
Bandwidth:	0.1 Hz to 3 Hz (-3 dB) for adults. 0.2 Hz to 3 Hz (-3 dB) for pediatric and neonatal patients.
Baseline Impedance Range:	200 Ω to 2000 Ω at patient with 1 k resistor in the ECG cable.
High Impedance Indication:	Greater than 2.2 kΩ at patient.
Linear Signal Range:	8 Ω p-p minimum.
Noise:	Less than 0.05 Ω at 500 Ω patient impedance, using a standard ECG cable.
User Selectable Scales:	Function of respiration scale. Waveform needs to be greater than 0.1 Ω in order for breathes to be accurately detected.
Cardiovascular Artifact Rejection:	Detected by algorithm.

5.2.3 NIBP Performance and Functional Characteristics

The NIBP function is capable of providing systolic, diastolic, and mean blood pressure measurements in Neonate, Pediatric, and Adult modes non-invasively, using a blood pressure cuff.

The NIBP function is in accordance with the requirements of EN 60601-2-30, EN 1060-1, EN 1060-3, and SP 10.

Systolic Pressure Measurement

Accuracy:	Mean error is less than ± 5 mmHg, Standard Deviation is less than ± 8 mmHg.
Range:	
Adult Mode	55 to 235 mmHg
Pediatric Mode	55 to 160 mmHg
Neonatal Mode	45 to 120 mmHg

Diastolic Pressure Measurement

Accuracy:	Mean error is less than ± 5 mmHg, Standard deviation is less than ± 8 mmHg.
Range:	
Adult Mode	30 to 200 mmHg
Pediatric Mode	30 to 150 mmHg
Neonatal Mode	20 to 100 mmHg

Static Pressure Measurement

Range:	0-300 mmHg
Static Accuracy:	± 3 mmHg or 2% whichever is greater in the range of 20 to 275 mmHg.

Pulse Rate

Range:	
Adult Mode	35 - 245 bpm
Pediatric Mode	35 - 245 bpm
Neonatal Mode	70 - 245 bpm
Resolution:	1 bpm
Accuracy:	The greater of ± 3 bpm or ± 3%

Maximum Cuff Pressure

The software controlled maximum cuff pressure:

Adult Mode	300 mmHg
Pediatric Mode	195 mmHg
Neonatal Mode	150 mmHg

The hardware controlled maximum cuff pressure:

Adult Mode	330 mmHg
Pediatric Mode	220 mmHg
Neonatal Mode	165 mmHg

Cuff Inflation

The inflation source is capable of supplying sufficient air to bring a volume of 500 cc's to a pressure of 300 mmHg in no more than 35 seconds (Reference ANSI/AAMI SP10A-1996, EN60601-2-30:1995 does not have a requirement for this).

If the cuff is not inflated to the desired pressure within 60 seconds then the cuff is vented and a retry cycle is initiated, up to 3 times.

Maximum Leakage

The maximum allowed pressure drop with the bleed valves closed is 10 mmHg in 10 seconds as measured with a 500 cc volume at differential pressures of 250 mmHg, 150 mmHg and 50 mmHg (Reference ANSI/AAMI SP10-1992, EN1060-3, 1997).

Vent Rate

A volume of 500 cc, when vented, is reduced from a pressure of 260 mmHg to a pressure of 15 mmHg in a maximum of 10 seconds. For Neonate, from a pressure of 150 mmHg to a pressure of 5 mmHg in less then 5 seconds (Reference: EN1060-3, 1997).

Initial Conditions

The NIBP will power-up and go into a warm up state.

An NIBP Zero is performed automatically before the NIBP can be initiated.

An NIBP measurement will not initiate until the unit has been powered on for 20 sec. in order to allow time for the Zero. Afterwards it goes into an idle state.

NIBP Start Pressure Settings and Ranges

The Start Pressure is adjustable throughout the following ranges and is set to the following defaults:

PATIENT SIZE	USER SELECTABLE START PRESSURE RANGE	INCREMENT SIZE	DEFAULT SETTING
Adult Mode	100-280 mmHg	5 mmHg	180 mmHg
Pediatric Mode	60-180 mmHg	5 mmHg	140 mmHg
Neonatal Mode	40-120 mmHg	5 mmHg	100 mmHg

NIBP Measurement Cycle

There are two different modes of measurement operation: manual and interval modes. The manual mode requires the operator to initiate the measurement cycle. The interval mode follows a configured plan of automatically initiated measurement cycles.

The Maximum Measurement Cycle Duration is 180 sec for Adult and Pediatric patients (Reference: EN60601-2-30, 1995).

The Maximum Measurement Cycle Duration is 90 sec for Neonatal patients (Reference: EN60601-2-30, 1995).

During a measurement, if the initial cuff inflation pressure is found to be inadequate, the unit will retry with a higher inflation pressure (+ 50 ± 10 mmHg in Adult mode and Pediatric mode, + 40 ± 10 mmHg in Neonatal mode).

In interval mode only, the unit will adjust the inflation pressure according to the previous systolic pressure. After the first successful measurement is made, the subsequent inflation pressure becomes + 50 ± 10 mmHg in the Adult mode and Pediatric Mode and + 40 ±10 mmHg in Neonatal mode.

5.2.4 IBP Performance Characteristics

The **Spectrum OR** is capable of providing invasive blood pressure (IBP) measurements from a maximum of 4 IBP channels that can be used simultaneously.

Each IBP channel provides three pressure readings: systolic, diastolic, and mean pressures.

IBP Safety Requirements

The IBP function meets the safety requirements of EN 60601-2-34.

IBP Performance Requirements

Accuracy:	± 2mm Hg or 2% which ever is greater (excluding transducer error)

IBP Transducer Performance

Excitation:	5 Volts DC, ± 2% Minimum load resistance is 300 ohms per transducer.
Transfer Function:	Compatible with 5 μV/mmHg/Volt nominal excitation transducers.
Zero Offset Range:	The transducer zero offset range is ± 120 mmHg.
Zero Accuracy:	The zero accuracy is ± 1 mm Hg.
Linear Input Range:	Is -30 to +300 mmHg, after zeroing.
Noise:	< 0.5 mmHg RTI, DC to 15 Hz, 300 Ω source impedance.
Drift:	< 0.15 mmHg per degree Celsius.
Frequency Response:	DC to 16 Hz ± 1 Hz, -3 dB

IBP Heart Rate Meter

Range:	
Neonatal Range (bpm)	30 to 350
Pediatric Range (bpm)	30 to 300
Adult Range (bpm)	30 to 300
Resolution:	1 bpm
Accuracy:	± 3 bpm or ± 3% at 30 to 250 bpm ± 5 bpm or ± 5% from 251 to 350 bpm
Trigger Threshold:	18 mm ± 9 mmHg
Step Change Response Time:	When tested using methods similar to ANSI/AAMI EC13-1992 Section 4.1.2.1f, the response time of the heart rate meter to changes in heart rate is: Less then 10 sec for step increase from 80 to 120 bpm. Less then 11 sec for step decrease from 80 to 40 bpm.

5.2.5 Temperature Parameter Performance Characteristics

The **Spectrum OR** is capable of providing temperature measurements from a maximum of 2 temperature channels, used simultaneously, as measured from YSI 400 or YSI 700 probes.

Temperature Performance Requirements

Scale:	Celsius or Fahrenheit
Range:	
T1-T2:	15° C to 45° C 59° F to 113° F
Delta T:	0° C to 9.9° C 0° F to 9.9° F
Resolution:	0.1° C 0.1° F
Accuracy:	± 0.1° C (15° C - 45° C), exclusive of probe errors ± 0.2° F (59° F - 113° F), exclusive of probe errors
Accuracy inclusive of 400 Series probes:	± 0.1° C (25° C - 42° C) ± 0.2° C (otherwise) ± 0.2° F (77° F - 108° F) ± 0.4° F (otherwise)
Accuracy inclusive of 700 Series probes:	± 0.2° C (15° C - 45° C) ± 0.4° F (59° F - 113° F)
Probe Excitation: 400 Series:	< 200 μA, tip to sleeve.
Probe Excitation: 700 Series:	< 200 μA, tip to sleeve and <30 μA maximum, ring to sleeve.

5.2.6 SpO_2 Performance Requirements

The **Spectrum OR** is capable of providing SpO_2 measurements via an OEM Masimo SET® MS-3 or OEM Nellcor NELL-3 pulse oximeter.

The SpO_2 function is in accordance with the requirements of EN ISO 9919/ISO 9919.

The SpO_2 function is calibrated to display functional saturation.

Update Rate: Every 2 seconds

5.2.6.1 Masimo SET SpO_2 Performance Requirements

Sensor Compatibility: LNOP® and LNCS® Series

SpO_2 Accuracy

No motion conditions:

	SATURATION RANGE	
PATIENT SIZE	**70% TO 100%**	**0-69%**
Adult Mode	± 2 digits	unspecified
Pediatric Mode	± 2 digits	unspecified
Neonatal Mode	± 3 digits	unspecified

During motion conditions:

	SATURATION RANGE	
PATIENT SIZE	**70% TO 100%**	**0-69%**
Adult Mode	± 3 digits	unspecified
Pediatric Mode	± 3 digits	unspecified
Neonatal Mode	± 3 digits	unspecified

SpO_2 Response Time:

The response time is 18 seconds to 95% of final step change of % SpO_2 value from 60 to 95% at 75 bpm. Post averaging time is set at 8 seconds.

Low Perfusion Performance

LOW PERFUSION CONDITIONS			
PULSE AMPLITUDE	**% TRANSMISSION**	**SATURATION ACCURACY**	**PULSE RATE ACCURACY**
> 0.02%	> 5%	± 2 digits	± 3 digits

Pulse Rate Range and Accuracy

		ACCURACY	
PATIENT SIZE	**PULSE RATE RANGE**	**NO MOTION CONDITIONS**	**DURING MOTION CONDITIONS**
Adult / Pediatric / Neonate	30 to 235 bpm	± 3 digits	± 5 digits

Update Rate

Every 2 seconds

Masimo SET® Reference notes

The Masimo SET MS-3 pulse oximeter with LNOP®•Adt sensors has been validated for no motion accuracy in human blood studies on healthy adult volunteers in induced hypoxia studies in the range of 70% to 100% SpO_2 against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

The Masimo SET MS-3 pulse oximeter with LNOP®•Adt sensors has been validated for motion accuracy in human blood studies on healthy adult volunteers in induced hypoxia studies while performing rubbing and tapping motions at 2 to 4 Hz. At an amplitude of 1 to 2 cm and non-repetitive motion between 1 to 5 Hz. At an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70% to 100% SpO_2 against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

The Masimo SET MS-3 pulse oximeter with LNOP®•Neo and Neo•Pt sensors has been validated for neonatal motion accuracy in human blood studies on neonates while moving the neonate's foot at 2 to 4 Hz at an amplitude of 1 to 2 cm against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

The Masimo SET MS-3 pulse oximeter has been validated for low perfusion accuracy in bench top testing against a Biotek Index 2 simulator and Masimo's simulator with signal strengths of greater then 0.02% and a % transmission of greater than 5% for saturation's ranging from 70 to 100%. This variation equals plus or minus one standard deviation. Plus or minus on standard deviation encompasses 68% of the population.

The LNOP ear sensors have an SPO_2 accuracy of 70% to 100% ±3.5% for adults during no motion conditions, however, since the monitor cannot display ½ digits, the accuracy rounded to ±4 digits. The SPO_2 accuracy during motion conditions is not specified for the LNOP ear sensors.

NOTE: **The sensor measurement wavelengths are nominally 660 nm for the red LED and 940 nm for the infrared LED. Maximum optical power output for the LEDs is 4 mW.**

5.2.6.2 Nellcor SpO_2 Performance Requirements

Sensor Compatibility

Nellcor types: OxiCliq A, OxiCliq N, OxiCliq P, OxiCliq I, Oxiband A/N, Oxiband P/I, DS-100A, DY-S

Saturation Accuracy

Sensor	Accuracy
OxiCliq A, OxiCliq N, OxiCliq P, OxiCliq I, Oxiband A/N, Oxiband P/I, DS-100A, DY-S	70% to 100% ± 3 digits. Below 70% unspecified

Pulse Rate Range and Accuracy

Range	Accuracy
20 to 249 bpm	± 3 bpm

Update Rate

Every 2 seconds

NOTE: The sensor measurement wavelengths are nominally 660 nm for the red LED and 890 nm for the infrared LED. Maximum optical power output for the LEDs is 4 mW.

5.2.7 CO_2 Performance Characteristics

The **Spectrum OR** is capable of providing CO_2 measurements from either an Oridion MediCO_2 capnography module, or an Oridion MiniMediCO_2 capnography module.

The CO_2 function is in accordance with the requirements of EN 864 (MediCO_2) or ISO 21647 (MiniMediCO_2).

5.2.7.1 MediCO_2 Microstream® (Only in monitors with serial numbers below MS05000.)

Range: 0 - 99 mmHg

Accuracy specification of the measured CO_2 partial pressure is according to the following table

OPERATING TIME	CO_2 CONCENTRATION*	ACCURACY**
0 - 20 min.	0 - 38 mmHg	± 4 mmHg
	39 - 99 mmHg	± 12%
20 min. and up	0 - 38 mmHg	± 2 mmHg

OPERATING TIME	CO_2 CONCENTRATION*	ACCURACY**
	39 - 99 mmHg	± 5% to 39 - 40 mmHg + 0.08% for every 1 mmHg above 40 mmHg

* *At 760 mmHg*

** *Accuracy applies for respiration rates of up to 80 RPM. For respiration rates above 80 RPM, accuracy complies with EN ISO 21647/ISO 9918 (4 mmHg or ± 12% of reading whichever is greater) for $EtCO_2$ values exceeding 19 mmHg. To achieve the specified accuracy for respiration rates above 60 respirations/minute, an endotracheal tube adapter with low dead-space must be used in neonatal mode.*

The accuracy specification is maintained to within ± 4% for the following gas mixtures (all values are in Vol. %)

CO_2	N_2	O_2	N_2O	H_2O	ANESTHETIC AGENTS
0 to 13	0 to 97.5	0 to 100	0 to 100	Dry to saturated	According to EN864

Above 80% O_2, 1 mmHg has to be added to the upper tolerance of the accuracy specs.

Sampling Rate: Nominally 50 ml/minute, ± 7.5 ml/min

Respiration Rate Range: 0 - 150 RPM

Respiration Rate Accuracy

Respiration Rate	0 to 40 RPM	41 to 70 RPM	71 to 100 RPM	100 to 150 RPM
Accuracy	± 1 RPM	± 2 RPM	± 3%	± 5%

Auto Zero: The Auto Zero process is performed only during measurement mode. The MediCO2 PlusMediCO Plus 2001A updates the ambient pressure that is measured during the Auto Zero process. The Auto Zero is triggered:

1. During the first hour after entering measurement mode, periodically for durations of typically 15 seconds at a rate which limits the total time consumed by Auto Zeros to less then 2% of the time in which active measurements are taken. Following the first hour after entering measurement mode, periodically from or durations of typically 15 seconds at a rate of at most once per hour.
2. If a change of 8 degree C from the last Auto Zero is detected.
3. If a pressure change of 20 mmHg relative to the last Auto Zero (less than the purge threshold) for period of 30 seconds. is detected.

Pump Calibration: No routine calibration is required

Rise/Fall Time: < 190 ms to display 10 to 90% step change with a 5% CO_2/balance air test gas at 10 liters per minute flow through an airway adapter.

< 190 ms to display 90 to 10% step change with a 5% CO_2/balance air test gas at a 10 liters per minute flow through an airway adapter.

5.2.7.2 MiniMediCO$_2$ Microstream® (Only in monitors with serial number MS05000 and higher.)

Range: 0 - 99 mmHg

Accuracy specification of the measured CO_2 partial pressure is according to the following table (This testing is done according to ISO 21647 clauses 51.101.1 and 51.101.2.).

CO_2 PARTIAL PRESSURE *	**ACCURACY****
0 - 38 mmHg	± 2 mmHg
39 - 99 mmHg	± (5% of reading + 0.08% for every 1 mmHg above 38 mmHg)

* *At sea level.*

** *Accuracy applies for respiration rates of up to 80 RPM. For respiration rates above 80 RPM, accuracy is 4 mmHg or ± 12% of the reading, whichever is greater, for $EtCO_2$ values exceeding 18 mmHg. This is tested according to and is compliant with EN 864 and ISO 21647. To achieve the specified accuracies for respiration rates above 60 respirations/minute, the Microstream FilterLine H Set for Infant/Neonatal (p/n 006324) must be used. Above 55 degrees C module temperature, ± 1 mmHg or ± 2.5% (whichever is greater) has to be added to the tolerance of the accuracy specs.*

Accuracy in the presence of interfering gases:

The accuracy specification is maintained to within 4% of the values indicated in the table above in the presence of interfering gases according to ISO 21647 clauses 51.101.3 and 101.1.

Flow Rate: 50 ml/min -7.5 + 15 ml/min, flow measured by volume.

Respiration Rate Range: 0 - 150 RPM

Respiration Rate Accuracy:

Respiration Rate	0 to 70 RPM	71 to 120 RPM	121 to 150 RPM
Accuracy	± 1 RPM	± 2 RPM	± 3 RPM

Self Maintenance (SFM) Interval:

Self-Maintenance (SFM) is performed only during measurement mode. The module performs one or more of the following:

- Ambient pressure measurement
- Auto zero (AZ)
- Flow test

SFM is triggered under the following conditions:

- During the first hour after entering measurement mode, periodically for durations of typically 10 seconds at a rate which limits the total time consumed by SFMs to less than 2% of the time in which active measurements are taken. Following the first hour after entering measurement mode, periodically for durations of typically 10 seconds at a rate of at most once per hour.
- If a change of 8 °C from the last AZ is detected.
- If a pressure change of 20 mmHg relative to the last ambient pressure measurement (less than the purge threshold) for a period of 30 seconds is detected. The module will be able to detect a real change in the ambient pressure and a pressure change due to partial blockage of the FilterLine.

The module prevents the triggering of an SFM in the following situations:

- In case of purging until the end of this state.
- During a breath absence period which follows a valid breath.
- While waiting a minimum of 20 seconds for host SFM enable command. (After the 20-second opportunity given to the host to schedule the SFM passes, the module schedules the SFM according to a priority determined by current conditions).

System Response Time:	The system response time (with a standard-length FilterLine) which includes the delay time and rise time (10% to 90%) in response to a step change in the CO2 concentration is 2.9 seconds typical.
Rise Time (Adult and Neonatal):	190 msec maximum
Delay Time:	2.7 seconds typical
Pump Calibration Interval:	No routine calibration is required. The module should initially be calibrated after 1200 operating hours, then once a year or after 4,000 operating hours, whichever comes first.

5.2.8 Cardiac Output

The **Spectrum OR** is capable of providing thermal dilution Cardiac Output in Adult and Pediatric modes only.

Performance Requirements:

Cardiac output range:	0.2 - 20.0 liters/minute
Cardiac output resolution:	0.1 liters/minute
Cardiac Output Repeatability:	± 2% or 0.2 liters/minute from the mean value, whichever is greater, as measured using electronically generated flow curves.
Accuracy:	± 5% or 0.2 liters/minute, whichever is greater, as measured using electronically generated flow curves.
Blood Temperature Measurement:	
Range:	17.5 - 43° C (63.5° F - 109.4° F)
Accuracy:	Exclusive of probe errors: ± 0.2° C (± 0.4° F)
Resolution:	0.1° C (0.1° F)
Injected Temperature Measurement:	
Range:	0.1 - 30.0° C (30.2° F - 86° F)
Accuracy:	Exclusive of probe errors: ± 0.2° C (± 0.4° F)
Resolution:	0.1° C (0.1° F)
Modes of Operation:	Auto Start, Manual Start
Injectate volume:	3, 5, 10 cc

5.3 Special Functions

5.3.1 ST Segment Analysis Performance Requirements

Enabling:	Enabled in Adult and Pediatric modes only
Absolute ST Deviation Range:	-9.9 mm to 9.9 mm (-990 μV to 990 μV RTI)
Resolution:	0.1 mm (10 μV)
Default ST Measurement Point:	80 ms after J point for heart rates ≤ 120 bpm 60 ms after the J point for heart rates > 120 bpm
User Selectable ST Measurement Points:	40, 60 and 80 ms after J point (heart rate independent) or 60/80 (heart rate dependent)
Default ISO Point:	Located between the P and Q waves.
User adjustable ISO Point:	User adjustable from “R peak” - 10 ms to “R peak” - 200 ms in 8 ms increments.
Default J Point:	The end of the QRS complex.
User Selectable J Point:	User adjustable from “R peak” + 10 ms to “R peak” + 200 ms in 8 ms increments.
Excluded Beats:	Ectopic beats and ventricular paced beats are excluded from ST measurement.
Invalid ST	ST data is invalidated when the paced rhythm, Ventricular Rhythm or Ventricular Tachycardia persists for more than 45 seconds and/or during detected episodes of Asystole and Ventricular Fibrillation.

5.3.2 Arrhythmia Analysis

Arrhythmia analysis can be enabled in Adult and Pediatric modes. Arrhythmia analysis will identify ventricular arrhythmia only. Non-lethal or all arrhythmia alarms are capable of being disabled. The **Spectrum OR** will have the ability to make the following arrhythmia calls as applicable per ECG source:

3/5-lead ECG includes the following Arrhythmia Calls: Asystole, Irregular Heart Rate, Couplet, PVCs per minute, Run, Bigeminy, Trigeminy, Ventricular Tachycardia, Ventricular Fibrillation, Ventricular Rhythm and Bradycardia.

PVCs per minute are invalidated and the PVC counter is reset to 0 during periods of Ventricular Rhythm, Ventricular Tachycardia, Ventricular Fibrillation or Asystole.

5.3.3 Calculations

The **Spectrum OR** has the ability to calculate and display intravenous (IV) drug infusion rate and concentration based upon patient weight and drug dosage.

Drug Infusion Rate

Units:	ml/hr
Range:	0 to 9999 ml/hr
Resolution:	0.01 ml/hr

Drug Concentration

Units:	mcg/ml, mg/ml, g/ml, units/ml, or mU/ml
Range:	0.1 - 100
Resolution:	0.1

References

Source: Chulay M, Guzzetta C, Dossey B. *AACN Pocket Handbook of Critical Care Nursing*. Stamford: Appleton & Lange, 1997.

Source: Vallerand A, and Deglin J. D*avis's Guide to IV Medications, 3rd Edition.* Philadelphia: F.A. Davis Company, 1996.

5.3.4 Hemodynamic Calculations

The **Spectrum OR** will have the ability to calculate and display the following Hemodynamic parameters.

Cardiac Index (CI)

Range: 0.1 - 20.0 l/min/m^2

Resolution: 0.1 l/min/m^2

Stroke Volume (SV)

Range: 1 - 1000 ml

Resolution: 1 ml

Stroke Volume Index (SVI)

Range: 0.1 - 500.0 ml/m^2

Resolution: 0.1 ml/m^2

Systemic Vascular Resistance (SVR)

Range: 50 - 9999 dyne-sec/cm^5

Resolution: 1 dyne-sec/cm^5

Systemic Vascular Resistance Index (SVRI)

Range: 50 - 5000 dyne-sec /cm^5/m^2

Resolution: 1 dyne-sec /cm^5/m^2

Pulmonary Vascular Resistance (PVR)

Range: 1 - 1000 dyne-sec/cm^5

Resolution: 1 dyne-sec/cm^5

Pulmonary Vascular Resistance Index (PVRI)

Range: 1 - 2000 dyne-sec/cm^5/m^2

Resolution: 1 dyne-sec/cm^5/m^2

Left Cardiac Work (LCW)

Range: 0.1 - 100.0 kg-m

Resolution: 0.1 kg-m

Left Cardiac Work Index (LCWI)

Range: 0.1 - 50.0 kg-m/m^2

Resolution: 0.1 kg-m/m^2

Right Cardiac Work (RCW)

Range: 0.1 - 100.0 kg-m

Resolution: 0.1 kg-m

Right Cardiac Work Index (RCWI)

Range: 0.1 - 50.0 kg-m/m^2

Resolution: 0.1 kg-m/m^2

Left Ventricular Stroke Work (LVSW)

Range: 1 - 500 gm-m

Resolution: 1 gm-m

Left Ventricular Stroke Work Index (LVSWI)

Range: 1 - 500 gm-m/m^2

Resolution: 1 gm-m/m^2

Right Ventricular Stroke Work (RVSW)

Range: 1 - 50 gm-m

Resolution: 1 gm-m

Right Ventricular Stroke Work Index (RVSWI)

Range: 1 - 50 gm-m/m^2

Resolution: 1 gm-m/m^2

Cerebral Perfusion Pressure (CPP)

Range: -30 - 300 mmHg

Resolution: 1 mmHg

Reference Sources

Source: Kinney M, Dunbar S, Brooks-Brunn J, Molter N, and Vitello-Cicciu J. *AACN's Clinical Reference for Critical Care Nursing.* St. Louis: Mosby, 1996.

Source: DuBois D, Dubois EF. *A formula to estimate the approximate surface height and weight be known.* Arch Intern Medicing. 1916; 17:863-71.

Source: Baxter Healthcare Corporation. *Model COM-2 Cardiac Output Computer Operations Manual Software Version 2.2.* Santa Ana: 1989.

5.3.5 BIS Parameters

The Spectrum OR interfaces to the BISx Module from Aspect Medical Systems via the Module Bus. The BISx Module will be in accordance with Aspect Medical Systems documents ENG-25-0137 and 025-0066.

EEG Safety Requirements

The EEG function meets the safety requirements of EN 60601-2-26.

The following BIS-related parameters are supported:

PARAMETER	**RANGE**
Bispectral Index (BIS) Range:	0 - 99
Signal Quality Index (SQI) Range:	0 - 100%
EMG Range:	25 - 100 dB
Suppression Ratio (SR):	0 - 100%
Burst Count:	0 - 30
Input Impedance:	>50 Mohm
Noise (RTI):	<0.3 μV RMS 0.25 - 50 Hz
Input Range:	+/- 1 mV
EEG Bandwidth:	0.25 - 100 Hz (-3 dB)
Filters (ON):	High Pass: 2.0 Hz (-3 dB) Low Pass: 70 Hz (-3 dB) Notch: 50 Hz and 60 Hz
Filters (OFF):	High Pass: 0.25 Hz (-3 dB) Low Pass: None Notch: None

5.4 Information Display and Control

Front Panel Display, Indicators, and Controls

The front of the monitor will provide a keypad, display, rotary/push knob, and four LEDs.

Front Panel Display

DISPLAY TYPE	SIZE	MINIMUM RESOLUTION
Color active matrix TFT liquid crystal	12.1-inch diagonal	800 x 600 pixels

Anti-Glare/ Anti-Reflection Filter

The display is fitted with an anti-glare/anti-reflection filter.

Rotary Knob

The rotary knob is 16 position per revolution optical encoder with an integral push button switch.

LED Indicators

Alarm Indicators

Visual alarm indicators are in accordance with IEC60601-1-8.

A red LED will flash at 1.4 - 2.8 Hz (84 times/minute) at 50% duty cycle during a warning alarm (high priority).

A yellow LED will flash at a rate of 0.4 - 0.8 Hz at a 50% duty cycle during a caution alarm (medium priority).

If a warning and caution alarm are in force simultaneously, only the red LED is activated.

Power Indicators

A green **AC Mains** LED is illuminated whenever the unit is connected to AC Power.

A green **Battery Charging** LED is illuminated constantly when the batteries are charging.

Audio Indicators

An audio speaker is provided in order to annunciate alarms, key depresses, message tones, and systole beep tones.

Audio alarms are in accordance with IEC60601-1-8.

The measured sound pressure level for the audio alarm is 75 dB.

Real Time Clock

The Display Resolution for the Real Time Clock is:	1 minute
The Accuracy of the Real Time Clock is:	± 1 minute/month (30 days) @ 21± 3°C

The Real Time Clock has a dedicated independent power source that allows it to keep time whether or not the **Spectrum OR** has power provided.

5.5 Input/Output Communications

ECG Analog Output Specification

Bandwidth (-3 dB referenced to 10 Hz):	Same as ECG Filter Setting
Maximum Propagation Delay (Delay of QRS complex):	25 ms
Sensitivity (referenced to 10 Hz):	1 V/mV of input, ± 10%
Pacer Enhancement:	Pacer is summed at the output when pacer enhancement mode is turned ON. Pacer amplitude signal is a minimum of 2.5 V Pacer width is 10 ms, with a 5% tolerance. Pacer rise and fall times is 100 µs, maximum.

The **Spectrum OR** supports slaving of an IABP from the ECG analog output.

Arterial Blood Pressure Analog Output Specification

Bandwidth (-3 dB referenced to 10 Hz):	DC to 15 Hz minimum
Maximum Propagation Delay:	25 ms
Sensitivity:	1 V/100 mmHg, +10%

The **Spectrum OR** supports slaving of an IABP from Arterial Blood Pressure analog output.

Sync Pulse for Cardioversion

Source:	The Sync Pulse is derived from the active ECG source.
Propagation Delay:	35 ms maximum, between QRS peak and the rising edge of the Sync Pulse Amplitude: 2 Vp minimum into a 5 kΩ load
Width:	2 - 7 ms

5.6 Communication Protocols

DIAP Communication Protocol

The **Spectrum OR** supports the proprietary protocol DIAP (0070-00-0307) with the following exceptions:

1. The NIBP elapsed time is set to "—" when the elapsed time is greater than 999 minutes.
2. Though not specified in the protocol, the alarm limit values are at the same resolution as the parameter value. Example, temperature is 10X; therefore, the alarm limit values are also 10X.

Gas Module

The **Spectrum OR** supports the Gas Module Communication Protocol (0084-00-0025).

ELAN Communication Protocol

The **Spectrum OR** supports the ELAN Communication Protocol for communication to the Panorama Central Station, Viewstation OR™ and Panorama Gateway (0084-00-0007).

Vigilance Interface

The **Spectrum OR** supports the Vigilance IFMout communications protocol in accordance with Edwards Lifesciences specification ELS 1291.

Module Bus Communication Protocol

The **Spectrum OR** supports the Enterprise Module Serial Protocol Specification (0060-00-0991) for communication to the BISx Module.

Alarm Delay Time to Remote Equipment

The alarm delay time from the **Spectrum OR** to remote equipment is ≤ 2.7 seconds, measured at the **Spectrum OR** signal output connector.

5.7 Power Supply

Power Source

The **Spectrum OR** will auto-select its power source from those available. The monitor will use the following priority in choosing the power source:

1. AC Mains Power
2. Internal battery power

The monitor will operate from AC Mains power with or without the internal batteries installed.

AC Mains Power Source

Input Voltage:	100 - 240 VAC (± 10%)
Line Frequency:	50 or 60 Hz (± 3 Hz)
Current:	1.2 - 0.7 Amps

5.7.1 Battery Power

(required when used with Gas Module)

5.7.1.1 Sealed Lead Acid (P/N 0146-00-0043)

Battery Type:	Sealed Lead Acid
Number of Batteries:	2 (the unit is capable of operation with one battery for the sole purpose of changing batteries while in the normal operating mode.)
Minimum Battery Run Time:	1 hour and 20 minutes from two fully charged new batteries at 25° C for the following conditions: ECG, SpO_2, and NIBP running at the 15 minute interval
Battery Recharge Time:	16 hours maximum
Charging Method:	Parallel and independent
Time to Shutdown from Low Battery:	>10 minutes but < 20 minutes after indication, with 2 new, fully charged batteries

5.7.1.2 Lithium-Ion Battery (P/N 0146-00-0069)

Battery Type:	Lithium-ion
Number of Batteries:	2 (the unit is capable of operation with one battery for the sole purpose of changing batteries while in the normal operating mode.)
Minimum Battery Run Time:	4 hours and 30 minutes from two fully charged new batteries at 25°C for the following conditions: ECG, SpO_2, and NIBP running at the 15 minute interval
Battery Recharge Time:	5 hours maximum
Charging Method:	Parallel and independent
Time to Shutdown from Low Battery	>10 minutes after indication, with 2 new, fully charged batteries with no CO2 and printer

5.8 Data Storage

Monitor Configuration Data Storage and Transfer

Storage

The monitor has the ability to store, in non-volatile memory, the user selectable configuration. There is one (1) configuration available for each patient size and the following information is saved:

- Alarm Values
- Display Configurations
- NIBP Interval
- Parameter Settings, scaling
- Trace Speed
- Printer Settings
- Trend Configurations

Transfer

Transfer of monitor configuration data to and from the **Spectrum OR** using a PCMCIA card inserted into PCM2 is provided while in installation mode.

The Transfer PCMCIA card has the ability to be write protected

Patient Data Storage and Transfer

Storage

The current patient information and demographics is stored in non-volatile memory.

The monitor is capable of storing, in non-volatile memory, a maximum of 120 trend values for each active parameter.

Extended Trend

With the addition of a PCMCIA memory card inserted into PCM1, the monitor is capable of storing 500 list trend records for each active parameter.

The extended trend card is expected to be present at power-up and never removed.

All trend data not on the extended trend card when installed is lost and not accessible.

Transfer

Transfer of list trend data and demographics data to and from the **Spectrum OR** using a PCMCIA card inserted into PCM2 is provided while in monitoring mode. Only trended data for those parameters that are common between the monitors will be transferred.

The Transfer PCMCIA card has the ability to be write protected.

5.9 Printing

Integrated Thermal Printer

The integrated printer is a maximum 2- trace thermal strip chart printer with integral paper spool.

The printer uses plain white thermal paper 5 cm wide.

The printer supports 5 paper speeds: 3.125, 6.25, 12.5, 25, and 50 mm/sec., each within + 5%.

The printer sensitivity is ± 5% on a single trace, and 50% if scale for dual trace, + 5%.

5.10 Monitor Physical Characteristics

Mounting

The monitor has the capability to be carried as a portable unit, placed on a tabletop, or mounted to a wall mount, rolling stand, bed rail, Gas Module SE or Anestar Anesthesia Delivery System. The monitor is capable of having an External Parameter Module mounted to it.

Maximum Size

Without External Parameter Module	**With External Parameter Module mounted**
11.9" wide	11.9" wide
10.5" high	10.7" high
7.4" deep (including knob)	7.5" deep (including knob)

Maximum Weight

11.95 lbs. without optional accessories

15.52 lbs. with 2 Sealed Lead Acid batteries, without optional accessories

13.52 lbs. with 2 Lithium-Ion batteries, without optional accessories

PCMCIA Card Slot

PCMCIA Card Slot Functions

PCM1	**PCM2**
Extended Trend	Patient Data Transfer
	Monitor Configuration Transfer
	Software Download

A tool is needed to eject the card from PCM1.
Blank PCMCIA cards will fill the unused slots.

Cooling Fan Control

The cooling fan is ON when the unit is powered from an external source (AC).
The cooling fan is OFF when the unit is powered from the internal batteries.

Normal Operating Noise

The Sound Pressure Level (SPL) produced by the unit during normal operating conditions is 60 dBA at 1 meter when measured in accordance with ISO 3744. Maximum SPL is measured with no alarms sounding, but all internal mechanical devices (i.e., pumps, fans) running.

5.11 Comm-Port Physical Characteristics

Maximum Weight

0.5 lbs.

The CS1/MB1/RD1 Comm-Port supports the following connections

Ethernet Communication labeled CS1

Module Bus labeled MB1

Remote Display labeled RD1

The CS1/MB1/SP1 Comm-Port supports the following connections

Ethernet Communication labeled CS1

Module Bus labeled MB1

Serial Communication Channel, labeled SP1

The RD1/NC1/SP1 Comm-Port supports the following connections

Remote Display labeled RD1

Nurse Call labeled NC1

Serial Communication Channel, labeled SP1

The SP1/NC1/SP2 Comm-Port supports the following connections

Nurse Call labeled NC1

2 Serial Communication Channels, labeled SP1 and SP2

5.12 External Parameter Module Physical Characteristics

Mounting

The External Parameter Module mounts atop the monitor.

A means of quick disconnect is provided. It does not require a tool, yet requires more than one action in order to prevent accidental disconnect.

Connecting/disconnecting the external module from the Monitor will not disturb monitor operation.

Maximum Size

11.0" wide x 2.3" high x 5.0" deep.

Maximum Weight

1.75 lbs.

Power

The module receives power from the monitor.

5.13 Environmental and Safety Characteristics

5.13.1 Spectrum OR

Transport and Storage Temperature:	-20° C to 60° C
Transport and Storage Humidity:	10% to 95%, non-condensing
Transport and Storage Altitude:	(-1250 to 9,889 feet ASL) 1060 hPa to700 hPa (795 mmHg to 525 mmHg)
Operating Temperature:	5° C to 40° C
Operating Humidity:	15% to 95% non-condensing
Operating Altitude:	(-1250 to 9,889 feet ASL) 1060 hPa to 700 hPa (795 mmHg to 525 mmHg)
Shipping:	ISTA shipping procedure 1A
Shock:	15 g, 11 ms, half sine shock pulse tested per IEC 60068-2-27.
Vibration:	Sinusoidal Vibration per IEC 60068-2-6 1 g or 0.07 mm, 57 - 62 Hz crossover frequency 10 to 500 Hz, 10 sweep cycles in each axis Random Vibration per IEC 60068-2-64 0.02 g2/Hz 20 - 500 Hz low degree of reproducibility, 9 minutes per axis Frequency range: 10 Hz to 2,000 Hz Resolution: 10 Hz Acceleration amplitude:10 Hz to 100 Hz: 1.0 (m/s2) 2/Hz 100 Hz to 200 Hz: -3 dB/octave 200 Hz to 2,000 Hz: 0.5 (m/s2) 2/Hz Duration: 10 minutes per perpendicular axis (3 total)

Drop:	ECRI PB-296 892, section AIII 3.3 for Class III devices.
Impact:	ECRI PB-296 892, section AIIII 3.2 for Class 3 devices.
Spillage and Ingress of Fluids:	Non Protected Equipment (IPX0) as specified in EN60529.

5.13.2 Gas Module 3

Transport and Storage Temperature:	-40 °C to +70 °C
Transport and Storage Humidity:	5 to 100%, condensing[1]
Operating Temperature:	10 °C to 40 °C
Operating Humidity:	10 to 95% RH, non-condensing (in Airway: 0-100% RH, condensing)
Operating Altitude:	Sea Level to 8,000 feet
Shipping:	ISTA shipping procedure 2A
Shock:	IEC 60068-2-27 peak acceleration: 150 m/s^2 (15.3 g); duration: 11 ms; pulse shape: half-sine; number of shocks: 3 shocks per direction per axis (18 total).
Vibration:	IEC 60068-2-64
Drop:	IEC 60068-2-32
Spillage and Ingress of Fluids:	Non-protected Equipment (IPX0) as specified in IEC 60529.

1 After storage in a condensing atmosphere, the unit shall, before use, be kept for more than 24 hr. in an environment equivalent to the operating atmosphere.

CAUTION: Gas Module 3 must be moisture protected whenever transported. This can be done with a protective plastic bag in which water-absorbing materials (e.g. silica gel) have been included.

5.14 Agency Compliance

5.14.1 Spectrum OR

The **Spectrum OR** was designed to comply with the following industry standards:

- EN 60601-1
- UL 60601-1
- CSA Standard C22.2 No. 601.1M90
- EN 60601-1-1/IEC 60601-1-1
- EN 60601-1-4/IEC 60601-1-4
- EN 60601-2-27/IEC 60601-2-27
- EN 60601-2-30/IEC 60601-2-30
- EN 60601-2-34/IEC 60601-2-34
- EN 60601-2-25/IEC 60601-2-25
- EN 60601-2-26/IEC 60601-2-26
- EN 60601-2-49/IEC 60601-2-49

The View 12™ ECG Analysis Module complies with AAMI EC 11 for Diagnostic Electrocardiographic Devices.

The **Spectrum OR** has been certified by CSA.

The **Spectrum OR** has been tested for functionality following ESU (Electrosurgery Unit Interference) energy exposure as described in the draft Amendment A1 to IEC 60601-2-25.

5.14.2 Gas Module II, Gas Module SE and Gas Module SE with Spirometry

The **Gas Module II, Gas Module SE and Gas Module SE with Spirometry** were designed to comply with the following industry standards:

- EN 60601-1/IEC 60601-1
- UL 60601-1
- CSA Standard C22.2 No. 601.1M90

The **Gas Module II, Gas Module SE and Gas Module SE with Spirometry** have been certified by CSA.

5.14.3 Gas Module 3

The **Gas Module 3** was designed to comply with the following industry standards:

- EN 60601-1/IEC 60601-1
- UL 60601-1
- CSA Standard C22.2 No. 601.1M90
- EN 60601-1-1/IEC 60601-1-1
- EN 60601-1-4/IEC 60601-1-4
- ISO 21647

The **Gas Module 3** has been certified by CSA.

5.15 Electromagnetic Capability

5.15.1 Spectrum OR

The **Spectrum OR** meets the requirements of IEC 60601-1-2/EN 60601-1-2.

NOTE: The Spectrum OR needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.

NOTE: Portable and mobile RF communications equipment can affect the Spectrum OR. See tables 5-1 through 5-4 that follow.

TABLE 5-1

GUIDANCE AND DECLARATION - ELECTROMAGNETIC EMISSIONS

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

EMISSIONS TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
RF emissions CISPR 11	Group 1	The **Spectrum OR** uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The **Spectrum OR** is suitable for use in all establishments other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Complies	

TABLE 5-2

GUIDANCE AND DECLARATION - ELECTROMAGNETIC IMMUNITY

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

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines	±2 kV for power supply lines ±1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the **Spectrum OR** requires continued operation during power mains interruptions, it is recommended that the **Spectrum OR** be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

U_T is the A.C. mains voltage prior to application of the test level.

TABLE 5-3

GUIDANCE AND DECLARATION - ELECTROMAGNETIC IMMUNITY

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

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
			Portable and mobile RF communications equipment should be used no closer to any part of the **Spectrum OR**, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = 1.2 \times \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2 \times \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \times \sqrt{P}$ 800 MHz to 2.5 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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

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

TABLE 5-4

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE SPECTRUM OR

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

RATED MAXIMUM OUTPUT POWER (*P*) OF TRANSMITTER IN WATTS (W)	**SEPARATION DISTANCE (*d*) IN METERS (m) ACCORDING TO FREQUENCY OF TRANSMITTER**		
	150 kHz to 80 MHz	**80 MHz to 800 MHz**	**800 MHz to 2.5 GHz**
	$d = 1.2 \times \sqrt{P}$	$d = 1.2 \times \sqrt{P}$	$d = 2.3 \times \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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

NOTE: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

5.15.2 Gas Module SE, Gas Module SE with Spirometry, and Gas Module 3

The **Gas Module SE, Gas Module SE with Spirometry, and Gas Module 3** meet the requirements of IEC 60601-1-2/EN 60601-1-2.

NOTE: The Gas Module SE, Gas Module SE with Spirometry, and Gas Module 3 need special precautions regarding EMC and need to be installed and put into service according to the EMC information provided below.

NOTE: Portable and mobile RF communications equipment can affect the Gas Module SE, Gas Module SE with Spirometry, and Gas Module 3. See tables 5-5 through 5-8 that follow.

TABLE 5-5

GUIDANCE AND DECLARATION - ELECTROMAGNETIC EMISSIONS

The **Gas Module SE, Gas Module SE with Spirometry, and Gas Module 3** are intended for use in the electromagnetic environment specified below. The customer or the user of the **Gas Module SE, Gas Module SE with Spirometry, or Gas Module 3** should assure that they are used in such an environment.

EMISSIONS TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
RF emissions CISPR 11	Group 1	The **Gas Module SE, Gas Module SE with Spirometry, and Gas Module 3** use RF energy only for their internal function. Therefore, their RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The **Gas Module SE, Gas Module SE with Spirometry, and Gas Module 3** are suitable for use in all establishments other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Complies	

TABLE 5-6

GUIDANCE AND DECLARATION - ELECTROMAGNETIC IMMUNITY

The **Gas Module SE, Gas Module SE with Spirometry, and Gas Module 3** are intended for use in the electromagnetic environment specified below. The customer or the user of the **Gas Module SE, Gas Module SE with Spirometry, or Gas Module 3** should assure that they are used in such an environment.

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines	±2 kV for power supply lines ±1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the **Gas Module SE, Gas Module SE with Spirometry, or Gas Module 3** requires continued operation during power mains interruptions, it is recommended that the **Gas Module SE, Gas Module SE with Spirometry, or Gas Module 3** be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

U_T is the A.C. mains voltage prior to application of the test level.

TABLE 5-7

GUIDANCE AND DECLARATION - ELECTROMAGNETIC IMMUNITY

The **Gas Module SE, Gas Module SE with Spirometry, and Gas Module 3** are intended for use in the electromagnetic environment specified below. The customer or the user of the **Gas Module SE, Gas Module SE with Spirometry, or Gas Module 3** should assure that they are used in such an environment.

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
			Portable and mobile RF communications equipment should be used no closer to any part of the **Gas Module SE, Gas Module SE with Spirometry, or Gas Module 3**, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = 1.2 \times \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2 \times \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \times \sqrt{P}$ 800 MHz to 2.5 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

TABLE 5-7 (Continued)

GUIDANCE AND DECLARATION - ELECTROMAGNETIC IMMUNITY

The **Gas Module SE, Gas Module SE with Spirometry, and Gas Module 3** are intended for use in the electromagnetic environment specified below. The customer or the user of the **Gas Module SE, Gas Module SE with Spirometry, or Gas Module 3** should assure that they are used in such an environment.

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
NOTE:	**At 80 MHz and 800 MHz, the higher frequency range applies.**		
NOTE:	**These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.**		

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Gas Module SE, Gas Module SE with Spirometry, or Gas Module 3 are used exceeds the applicable RF compliance level above, the Gas Module SE, Gas Module SE with Spirometry, or Gas Module 3 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Gas Module SE, Gas Module SE with Spirometry, or Gas Module 3.

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

TABLE 5-8

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE GAS MODULE SE, GAS MODULE SE WITH SPIROMETRY, OR GAS MODULE 3

The **Gas Module SE, Gas Module SE with Spirometry, and Gas Module 3** are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **Gas Module SE, Gas Module SE with Spirometry, or Gas Module 3** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **Gas Module SE, Gas Module SE with Spirometry, or Gas Module 3** as recommended below, according to the maximum output power of the communications equipment.

RATED MAXIMUM OUTPUT POWER (P) OF TRANSMITTER IN WATTS (W)	**SEPARATION DISTANCE (*d*) IN METERS (m) ACCORDING TO FREQUENCY OF TRANSMITTER**		
	150 kHz to 80 MHz	**80 MHz to 800 MHz**	**800 MHz to 2.5 GHz**
	$d = 1.2 \times \sqrt{P}$	$d = 1.2 \times \sqrt{P}$	$d = 2.3 \times \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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

NOTE: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

5.16 Warranty Statements

Mindray DS USA, Inc. warrants that components within the monitor unit will be free from defects in workmanship and materials for the number of years shown on the invoice. Under this extended warranty, Mindray DS USA, Inc. will repair or replace any defective component at no charge for labor and/or materials. This extended warranty does not cover consumable items such as, but not limited to batteries, displays, external cables and sensors.

Recommended preventative maintenance, as prescribed in the Service Manual, is the responsibility of the user, and is not covered by this warranty.

Except as otherwise provided herein, the terms, conditions and limitations of Mindray DS USA, Inc.'s standard warranty will remain in effect.

USA, Canada, Mexico, and Puerto Rico

Mindray DS USA, Inc. warrants that its products will be free from defects in workmanship and materials for a period of one (1) year from the date of purchase except that disposable or one-time use products are warranted to be free from defects in workmanship and materials up to a date one year from the date of purchase or the date of first use, whichever is sooner. This warranty does not cover consumable items such as, but not limited to, batteries, external cables, sensors, cuffs, hoses, or mounts.

Mindray DS USA, Inc. will not be liable for any incidental, special, or consequential loss, damage, or expense directly or indirectly arising from the use of its products, liability under this warranty and the buyer's exclusive remedy under this warranty is limited to servicing or replacing at Mindray DS USA, Inc.'s option at the factory or at an authorized Distributor, any product which shall under normal use and service appear to the Company to have been defective in material or workmanship.

No agent, employee, or representative of Mindray DS USA, Inc. has any authority to bind Mindray DS USA, Inc. to any affirmation, representation, or warranty concerning its products, and any affirmation, representation or warranty made by any agent, employee, or representative shall not be enforceable by buyer.

This warranty is expressly in lieu of any other express or implied warranties, including any implied warranty or merchantability or fitness, and of any other obligation on the part of the seller.

Damage to any product or parts through misuse, neglect, accident, or by affixing any non-standard accessory attachments or by any customer modification voids this warranty. Mindray DS USA, Inc. makes no warranty whatever in regard to trade accessories, such being subject to the warranty of their respective manufacturers.

A condition of this warranty is that this equipment or any accessories which are claimed to be defective be returned when authorized by Mindray DS USA, Inc., freight prepaid to Mindray DS USA, Inc., Mahwah, New Jersey 07430. Mindray DS USA, Inc. shall not have any responsibility in the event of loss or damage in transit.

Calibration may be performed without the need to disassemble the instrument. It is the responsibility of the purchaser to perform calibration as necessary, in accordance with the instructions provided in this manual.

International (excluding North America)

Mindray DS USA, Inc. warrants that its products will be free from defects in workmanship and materials for a period of two (2) years from the date of purchase except that disposable or one-time use products are warranted to be free from defects in workmanship and materials up to a date one year from the date of purchase or the date of first use, whichever is sooner. This warranty does not cover consumable items such as, but not limited to, batteries, external cables, sensors, cuffs, hoses, or mounts.

Mindray DS USA, Inc. shall not be liable for any incidental, special, or consequential loss, damage, or expense directly or indirectly arising from the use of its products, liability under this warranty and the buyer's exclusive remedy under this warranty is limited to servicing or replacing at Mindray DS USA, Inc.'s option at the factory or at an authorized Distributor, any product which shall under normal use and service appear to the Company to have been defective in material or workmanship.

No agent, employee, or representative of Mindray DS USA, Inc. has any authority to bind Mindray DS USA, Inc. to any affirmation, representation, or warranty concerning its products, and any affirmation, representation or warranty made by any agent, employee, or representative shall not be enforceable by buyer.

This warranty is expressly in lieu of any other express or implied warranties, including any implied warranty or merchantability or fitness, and of any other obligation on the part of the seller.

Damage to any product or parts through misuse, neglect, accident, or by affixing any non-standard accessory attachments or by any customer modification voids this warranty. Mindray DS USA, Inc. makes no warranty whatever in regard to trade accessories, such being subject to the warranty of their respective manufacturers.

A condition of this warranty is that this equipment or any accessories which are claimed to be defective be returned when authorized by Mindray DS USA, Inc., freight prepaid to Mindray DS USA, Inc., Mahwah, New Jersey 07430. Mindray DS USA, Inc. shall not have any responsibility in the event of loss or damage in transit.

Calibration may be performed without the need to disassemble the instrument. It is the responsibility of the purchaser to perform calibration as necessary, in accordance with the instructions provided in this manual.

5.17 Phone Numbers and How To Get Assistance

Mindray DS USA, Inc. maintains a network of service representatives and factory-trained distributors. Prior to requesting service, perform a complete operational check of the instrument to verify proper control settings. If operational problems continue to exist, contact the Service Department at (800) 288-2121 or (201) 995-8116 for assistance in determining the nearest field service location.

Please include the instrument model number, the serial number, and a description of the problem with all requests for service.

Any questions regarding the warranty should be directed to the nearest Mindray DS USA, Inc. location. A list of international offices, along with their phone numbers, is provided at the end of this manual.

NOTE: **Upon request, Mindray DS USA, Inc. will provide circuit diagrams, component part lists, descriptions, calibration instructions, or other information which will assist the user's appropriately qualified technical personnel to repair those parts of the equipment which are designated by Mindray DS USA, Inc. as repairable.**

5.18 Manufacturer's Responsibility

Mindray DS USA, Inc. is responsible for the effects on safety, reliability and performance of the equipment only if:

- **a.** assembly operations, extensions, readjustments, modifications or repairs are carried out by persons authorized by Mindray DS USA, Inc; and
- **b.** the electrical installation of the relevant room complies with the appropriate requirements; and
- **c.** the equipment is used in accordance with the instructions for use

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6.0 *Glossary*

6.1 Glossary of Terms

$AaDO_2$	Alveolar-Arterial Oxygen Difference
ALVENT	Alveolar Ventilation
Art	Arterial - label for invasive blood pressure
$AvDO_2$	Arteriovenous Oxygen Difference
BC	Burst Count
BSA	Body Surface Area
CaO_2	Arterial Oxygen Content
CcO_2	Pulmonary Capillary Blood Oxygen Content
CI	Cardiac Index
CO	Cardiac Output
CO_2	Carbon Dioxide
Compl	Dynamic Compliance
CPP	Cerebral perfusion pressure - this is the calculated difference between cranial pressure and mean arterial pressure
CVA	Cardiovascular Artifact - this is any artifact in the respiratory waveform due to heartbeats, also message will occur if heart rate and respiration rate are the same
CvO_2	Venous oxygen content
CVP	Central Venous Pressure - label for invasive blood pressure
ECG	Electrocardiogram
EEG	Electroencephalography
EMG	Electromyography
EMR	Electronic Medical Records system. This may include a Hospital Information System (HIS) and/or a Clinical Information System (CIS).

EPM	External Parameter Module
$etCO_2$	End - tidal CO_2 . A patient's carbon dioxide level measured at end-expiration
FiO_2	Fraction of inspired oxygen
Hgb	Hemoglobin
I:E	Ratio of Inspiratory time to Expiratory time
IABP	Intra-aortic balloon pump
ICP	Intracranial pressure - label for invasive blood pressure
IBP	Invasive Blood pressure
ISO	Isoelectric point - reference point on ECG waveform for ST analysis
LA	Left atrium - label for invasive blood pressure
LCW	Left Cardiac Work - feature of hemodynamic calculations
LCWI	Left Cardiac Work Index - feature of hemodynamic calculations
LV	Left ventricle - label for invasive blood pressure
LVSW	Left Ventricular Stroke Work - feature of hemodynamic calculations
LVSWI	Left Ventricular Stroke Work Index - feature of hemodynamic calculations
MAC	Minimum Alveolar Concentration
MAP	Mean arterial pressure
MV	Minute Volume
MVexp	Expiratory Minute Volume
MVinsp	Inspiratory Minute Volume
NIBP	Non-invasive Blood Pressure
O_2AV	Oxygen Availability
O_2AVI	Oxygen Availability Index
O_2ER	Oxygen Extraction Ratio
PA	Pulmonary artery - label for invasive blood pressure
PAD	Pulmonary artery - diastolic
PAO_2	Partial pressure of alveolar oxygen
$PaCO_2$	Partial pressure of arterial carbon dioxide
PaO_2	Partial pressure of arterial oxygen
Paw	Airway Pressure
PAWP	Pulmonary Artery Wedge Pressure
PB	Atmospheric pressure
$PECO_2$	Partial pressure of end-tidal CO_2
PEEP	Positive End-Expiratory Pressure
PIP	Peak Inspiratory Pressure
Pmean	Mean pressure (refers strictly to ventilatory pressures) = average airway pressure of one breath cycle
Pplat	Plateau Pressure = pressure at end of inspiratory pause
PVC	Premature Ventricular Contractions
PvO_2	Partial pressure of venous oxygen
PVR	Pulmonary Vascular Resistance - feature of hemodynamic calculations

PVRI	Pulmonary Vascular Resistance Index - feature of hemodynamic calculations
Qs/Qt	Arteriovenous Shunt percent
RA	Right Atrium - label for invasive blood pressure
Raw	Dynamic Airway Resistance
RCW	Right Cardiac Work - feature of hemodynamic calculations
RCWI	Right Cardiac Work Index - feature of hemodynamic calculations
RVSW	Right Ventricular Stroke Work - feature of hemodynamic calculations
RVSWI	Right Ventricular Stroke Work Index - feature of hemodynamic calculations
SpO_2	Oxygen Saturation
SQI	Signal Quality Index
SR	Suppression Ratio
SV	Stroke volume - feature of hemodynamic calculations
SVI	Stroke Volume Index - feature of hemodynamic calculations
SvO_2	Mixed venous oxygen saturation
SVR	Systemic Vascular Resistance - feature of hemodynamic calculations
SVRI	Systemic Vascular Resistance Index - feature of hemodynamic calculations
UA	Umbilical Artery - label for invasive blood pressure
Vd	Dead Space
VO_2	Oxygen Consumption
VO_2I	Oxygen Consumption Index
Vt	Tidal Volume
Vtexp	Expiratory Tidal Volume
Vtinsp	Inspiratory Tidal Volume
Wedge	Pulmonary Artery Wedge Pressure. This term is used interchangeably with PAWP