

Operating Instructions

Gas Module 3™

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Passport 2® is a U.S. registered trademark of Mindray DS USA, Inc.

Spectrum® is a U.S. registered trademark of Mindray DS USA, Inc.

Spectrum OR™ is a U.S. trademark of Mindray DS USA, Inc.

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Foreword

The **Gas Module 3** Operating Instructions manual is intended to provide information for proper operation.

General knowledge of monitoring of airway gases and an understanding of the features and functions of the Mindray DS **Gas Module 3** are prerequisites for its proper use.

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

Information for servicing this instrument is contained in the **Gas Module Service Manual Addendum**, part number 0070-00-0522. For additional information or assistance, please contact an authorized Mindray DS 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 bedside monitor.

Patents

This device is covered under one or more of the following U.S. Patents: 6,589,028, 6,896,713, 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, Cautions and Notes

Please read and adhere to all Warnings, Cautions 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 Gas Module 3, 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 3 exhaust output should be connected to a medical gas-scavenging system.
- WARNING:** Do not use this device 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:** 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 put MPSO (Multiple Portable Socket Outlets i.e. Multiple outlet extension cords) used with the Gas Module 3 on the floor. Connect only a bedside monitor to the same MPSO as the Gas Module 3. Do not overload the MPSO.
- WARNING:** Do not connect other equipment to the same MPSO with the Gas Module 3, as it may increase system leakage current.
- WARNING:** Reliably attach Potential Equalization connector to the safety ground when interconnecting the Gas Module 3 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:** Do not use a damaged or broken unit or accessory.
- WARNING:** When using the Gas Module 3, the maximum sampling rate at the nasal cannula is 200 ml/min with an Adult/Pediatric water trap and 120 ml/min 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 3 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 Module's internal pump.
- WARNING:** The use of gas sampling accessories in Gas Module 3 other than specified by Mindray DS 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 under a bedside monitor 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:** 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.

Cautions

- CAUTION:** Use recommended Mindray DS supplied power cords. If a substitute is necessary use only hospital grade power cords.
- 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:** To avoid permanent damage, do not expose metal components (pins, sockets, snaps) to disinfectants, soaps or chemicals.
- 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 CO₂, N₂O or Anesthetic Agent in the air surrounding the Gas Module 3 may cause significant measurement errors.

Notes

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




















Indication For Use

The indications for use for the Gas Module 3 include monitoring of airway gases during anesthesia and/or assisted respiration. The intended environment of use is the anesthesia department, including the Operating Room (OR) and post anesthesia care units (PACU), etc.

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 Mindray DS Service Department at (800) 288-2121 or (201) 995-8237 for prompt assistance in resolving shipping problems.

Symbols and Descriptions

SYMBOL	DESCRIPTION	SYMBOL	DESCRIPTION
	Attention, Consult Accompanying Documents / Refer to Manual		Type BF Equipment
	Dangerous Voltage		Gas Port Input
	Equipotentiality		Gas Port Output
	Alternating Current (AC)		Direct Current (DC)
	Data Input / Output		Interference may occur in the vicinity of equipment marked with this symbol
	Crossed out wheelie bin indicates separate treatment from general waste at end of life		Manufacturer's reference/catalogue number
	For single-patient use only, do not reuse.		Manufacturer's batch number
	For Neonatal use		Serial number
	Not for Neonatal use		Software Version
	Conformité Européenne (CE) Marking of Conformity to European Medical Device Directive. CE _{XXXX} represents the Notified Body number		

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1.1 Front Panel

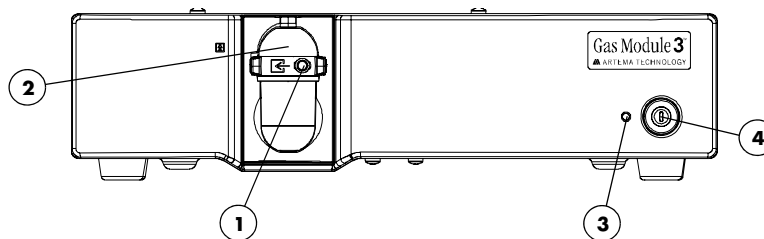


FIGURE 1-1 Gas Module 3 - Front Panel

1. Input Port

This port is used to connect the sampling tubing to the Gas Module 3.

2. Water Trap Assembly (includes Water Trap Reservoir)

(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 3.1 for more details.

3. Power Indicator Lamp

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

4. Power Switch

A switch used to power the unit ON and OFF.

1.2 Rear Panel

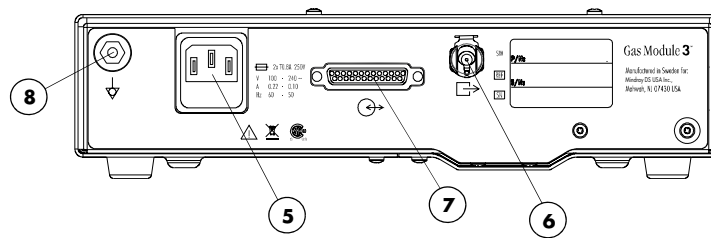


FIGURE 1-2 Gas Module 3 - Rear Panel

5. AC Power Input

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

6. 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 3.

7. External Interface Port

A communication interface port used to connect the Gas Module 3 to a Mindray DS bedside monitor (Passport 2[®], Spectrum[®], and Spectrum OR[™]).

8. Equipotential lug

Provides Equipotential grounding of hospital equipment.

The menus shown in the following sections are from Mindray DS Passport 2[®], Spectrum[®], and Spectrum OR[™] bedside monitors.

2.1 Gas Monitoring with Gas Module 3

The Gas Module option in Mindray DS bedside monitors allows for the measurement of anesthetic gases, O₂, N₂O and CO₂ levels. Measurement can be acquired via a nasal cannula (non-intubated) for oxygen and CO₂ only or through a sampling line connected to a breathing circuit (intubated).

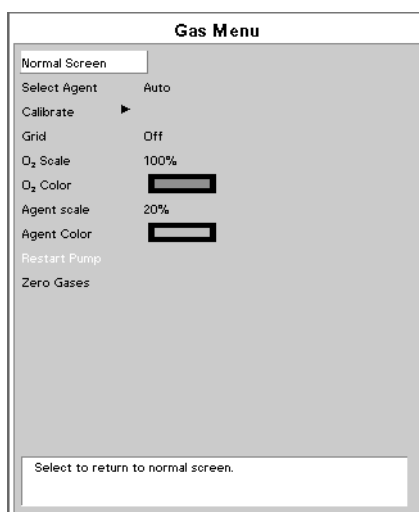


FIGURE 2-1 Gas Menu

NOTE: The bedside monitor will interface to the Gas Module 3 via the Serial Port Connector on the Comm-Port that is mounted in the rear of the bedside monitor.

WARNING: When using the Gas Module 3, the maximum sampling rate at the nasal cannula is 200 ml/min with an Adult/Pediatric water trap and 120 ml/min 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 H₂O 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, O₂, N₂O and/or CO₂

NOTE: To prevent moisture from entering the pneumatic system, ensure that the Gas Module 3 is always installed and operated in the horizontal orientation shown in all graphical depictions.

1. Turn on the Gas Module 3 and the bedside monitor, and configure the bedside monitor serial port to be used with the Gas Module. Hold the **DISCHARGE** key in while powering unit on. Set alarms as desired.

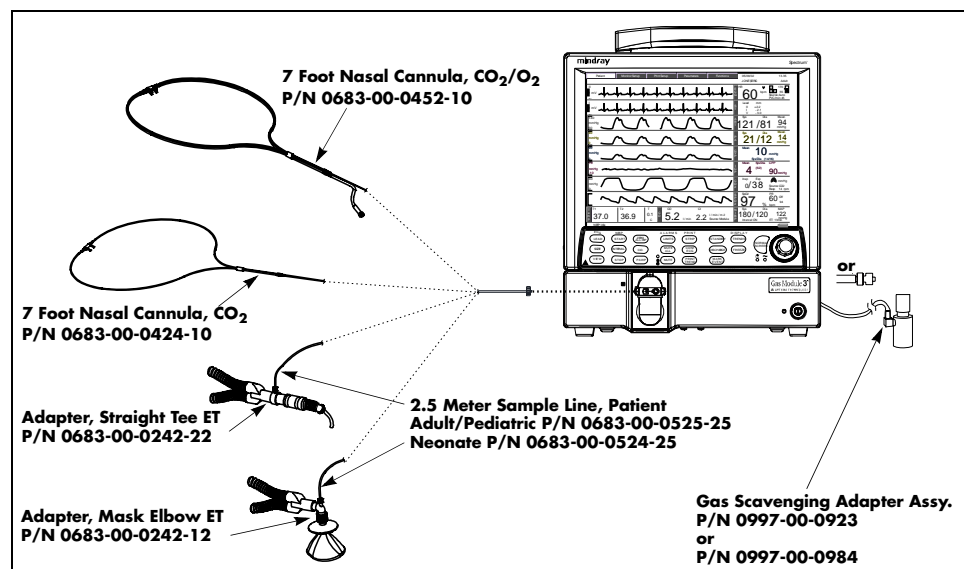


FIGURE 2-2 Gas Module 3 Airway Adapter

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

2. 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.
3. Connect the other end of the nasal cannula or sample line to the Gas Module at the input port. Ensure all tubing connections are tight.

WARNING: Connection of the Gas Module 3 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 Module's internal pump.

CAUTION: Contamination with CO₂, N₂O or Anesthetic Agent in the air surrounding the Gas Module 3 may cause significant measurement errors.

4. Check for a clean water trap.
5. Select **CO₂** or **AUTO** as the **Resp Source** in the **Resp Menu**.
6. Observe the capnogram on the monitor's display. On bedside monitor powerup, O₂, Agent and N₂O numbers will display. CO₂ numbers will be displayed when a valid breath is detected.

NOTE: The Gas Module 3 must be warmed up a minimum of 45 seconds for ISO accurate CO₂, O₂, N₂O, and agent readings.

7. If not already set, use the **Display Setup Menu** to select the gas waveforms to be displayed.
8. If desired, the gas waveform speed can be changed via the **Monitor Setup Menu** and the scale can be changed in the **Gas Menu**.

2.1.1 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 CO₂ 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).

2.1.2 Gas Monitor Calibration - Passport 2[®]/Spectrum[®]/Spectrum OR[™]

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) within the Mindray DS 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 Mindray DS approved precision calibration gas, after calibration is performed. Never use calibration gas that has expired, has a different concentration, or a canister that is indicating low pressure. The pressure indicator on the Mindray DS gas regulator must operate in the green zone during the entire calibration session.

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.

2.1.2.1 Passport 2[®]/Spectrum[®]

1. Select **Calibrate** from the **Gas Menu**. The **Calibration Menu** opens.
2. Select **Gas Selection** from the **Calibration Menu** and choose the calibration gas type. Choices are: Mixture, 5% CO₂, 55% O₂, 33% N₂O and 2% Des.
3. Select **Start** to begin calibration.
4. At the start of the calibration, the Gas Module will zero the gas channels. After successful zeroing, the Gas Module will request the calibration gas.

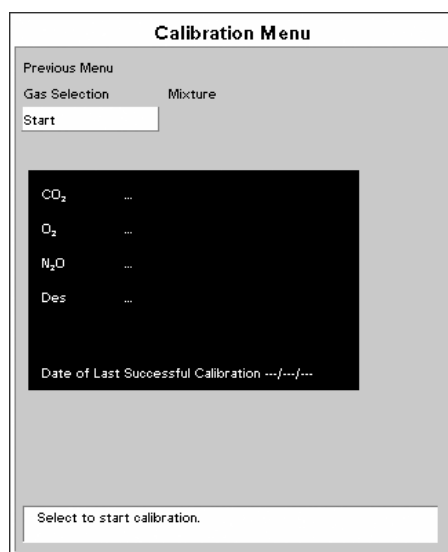


FIGURE 2-3 Calibration Menu

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 Mindray DS Technical Support.

- The message **Feed Calibration Gas** will appear. 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.

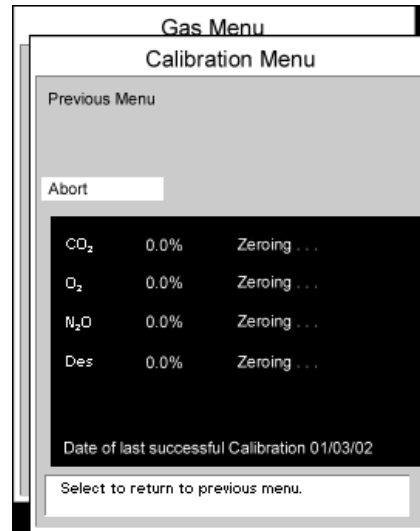


FIGURE 2-4 Gas Calibration Menu

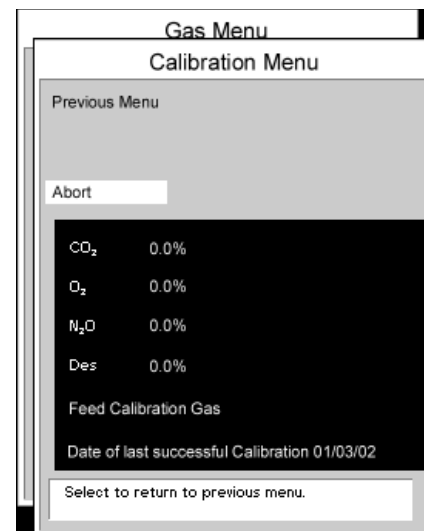


FIGURE 2-5 Gas Calibration Menu

- When sampling is complete, the **Feed Calibration Gas** message will disappear and **Adjusting** will appear next to each value. An **Accept** menu item will also appear. If the values are acceptable, select **Accept**. To cancel calibration and re-install the previous calibration values, select **Abort**.

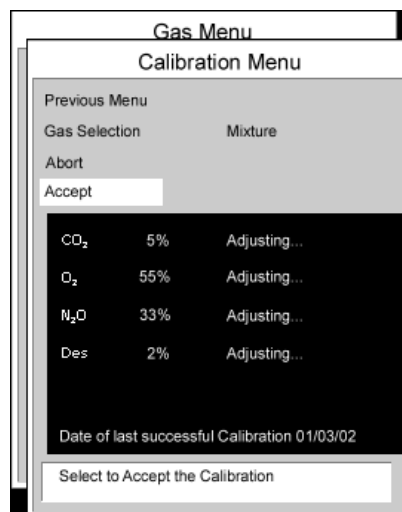


FIGURE 2-6 Gas Calibration Menu

NOTE: To avoid premature emptying of the gas canister, always remove the regulator at the end of the procedure.

NOTE: 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.

2.1.2.2 Spectrum OR™

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

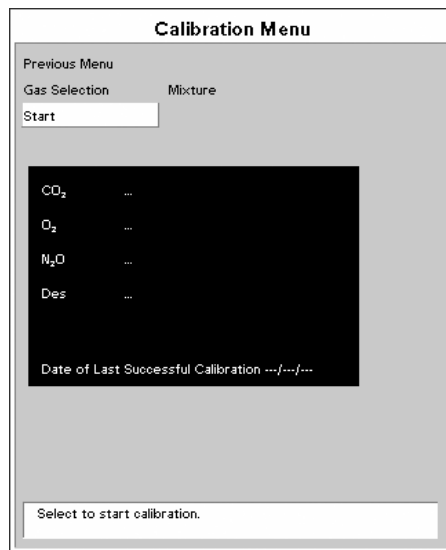


FIGURE 2-7 Calibration Menu

2. Select **Gas Selection** from the **Calibration Menu** and choose the calibration gas type. Choices are: Mixture, 5% CO₂, 55% O₂, 33% N₂O 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 Mindray DS Technical 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.

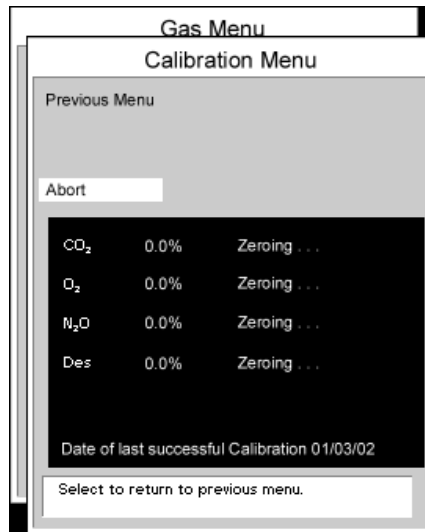


FIGURE 2-8 Gas Calibration Menu

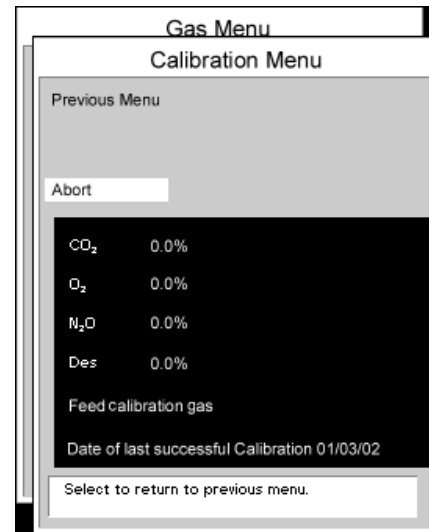


FIGURE 2-9 Gas Calibration Menu

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**.

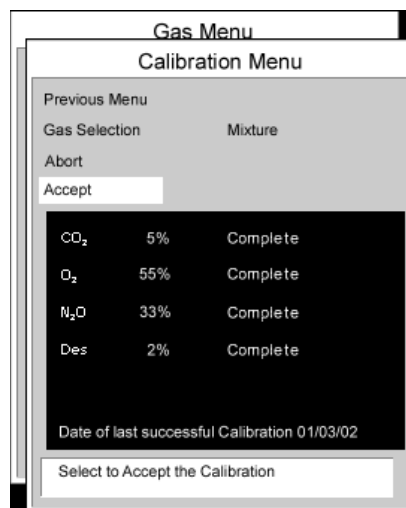


FIGURE 2-10 Gas Calibration Menu

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: 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.

2.1.2.3 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: 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 Mindray DS Technical 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. Also may appear when the Gas Module has been turned on without a sample line attached. Gas Module has been on for a long period of time without the bedside monitor being on.	Turn Gas Module and bedside monitor Off. Install/check sample lines, filters, water trap and electrical connections. Turn off Gas Module. Turn on Gas Module and bedside 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 Mindray DS Technical Support.
GM: Zero In Progress	Appears when the system is zeroing all of its 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 Mindray DS Technical Support.

MESSAGE/PROBLEM	REASON	SOLUTION
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 Mindray DS Technical Support.
GM: N ₂ O Zero Error	Appears when the system has been unable to successfully zero the N ₂ O sensor.	Manually start zeroing the system again. If problem persists, contact Mindray DS Technical 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 Mindray DS Technical 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 Mindray DS Technical 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 bedside monitor 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 Mindray DS Technical 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 Mindray DS Technical Support.

MESSAGE/PROBLEM	REASON	SOLUTION
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 Mindray DS Technical Support.
GM: N ₂ O Uncalibrated	Appears after an unsuccessful calibration attempt of the N ₂ O sensor. The numeric data for N ₂ O will appear as ---, and the N ₂ O waveform will be a flatline	Ensure proper gas mixture is attached tightly and regulator is on. Repeat calibration procedure. If problem persists, contact Mindray DS Technical 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 Mindray DS Technical Support.
GM: Failed	Appears when the Gas Module detects an unrecoverable error in its own operation	Contact Mindray DS Technical Support.
GM: Disconnected	Appears when the bedside monitor 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 Mindray DS Technical 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 Mindray DS Technical Support.
Not Ready For Calibration	Appears when the Gas Module is unable to initialize calibration	Repeat calibration procedure. If problem persists, contact Mindray DS Technical 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 Mindray DS Technical Support.
Calibration Error, Zeroing Error	Appears when the Gas Module cannot perform a Zeroing during calibration	Repeat calibration procedure. If problem persists, contact Mindray DS Technical Support.

3.1 Care and Cleaning of Gas Module

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).

DESCRIPTION	PART NUMBERS
Calibration Gas	0075-00-0028
Calibration Gas Regulator	0119-00-0166
Mounting Bracket, Gas Module to Bedside Monitors (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 Bedside Monitors (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 Bedside Monitor Serial Port, short (0.3 m)	0012-00-1276-01
Cable, Gas Module to Bedside Monitor Serial Port, long (1.8 m)	0012-00-1276-02
Nasal Cannula, CO ₂ , 7' (2.1 m) (box of 10)	0683-00-0424-10
Nasal Cannula, CO ₂ /O ₂ , 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
Bedside Monitor/Gas Module Mounting Kit	0040-00-0287-03
Wall Mount	0436-00-0061-01

* For U.S. use only.

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5.1 Environmental and Safety Characteristics

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 1A
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

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.

Transport and Storage Temperature: -40 °C to +70 °C

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.

5.2 Agency Compliance

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 60601-1-4/IEC 60601-1-4
- ISO 21647

The **Gas Module 3** has been certified by CSA.

5.3 Electromagnetic Capability

The **Gas Module 3** meet the requirements of IEC 60601-1-2/EN 60601-1-2.

NOTE: The **Gas Module 3** 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 **Gas Module 3**. See tables 5-1 through 5-4 that follow.

TABLE 5-1

GUIDANCE AND MINDRAY DS USA, INC. DECLARATION - ELECTROMAGNETIC EMISSIONS

The **Gas Module 3** is intended for use in the electromagnetic environment specified below. The customer or the user of the **Gas Module 3** should assure it is used in such an environment.

EMISSIONS TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
RF emissions CISPR 11	Group 1	The Gas Module 3 uses 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 3 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 MINDRAY DS USA, INC. DECLARATION - ELECTROMAGNETIC IMMUNITY

The **Gas Module 3** is intended for use in the electromagnetic environment specified below. The customer or the user of the **Gas Module 3** 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 Gas Module 3 requires continued operation during power mains interruptions, it is recommended that the 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 5-3

GUIDANCE AND MINDRAY DS USA, INC. DECLARATION - ELECTROMAGNETIC IMMUNITY

The **Gas Module 3** is intended for use in the electromagnetic environment specified below. The customer or the user of the **Gas Module 3** 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 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: 

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 3 is used exceeds the applicable RF compliance level above, the 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 3.
- 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 GAS MODULE 3

The **Gas Module 3** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **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 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.

5.4 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 Mindray DS 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'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's option at the factory or at an authorized Mindray DS 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, 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's option at the factory or at an authorized Mindray DS 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, 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.

5.5 Phone Numbers and How To Get Assistance

Mindray DS 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 Mindray DS 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 location. A list of international offices, along with their phone numbers, is provided at the end of this manual.

NOTE: Upon request, Mindray DS 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 Mindray DS equipment which are designated by Mindray DS as repairable.

5.6 Mindray DS's Responsibility

Mindray DS 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; 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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