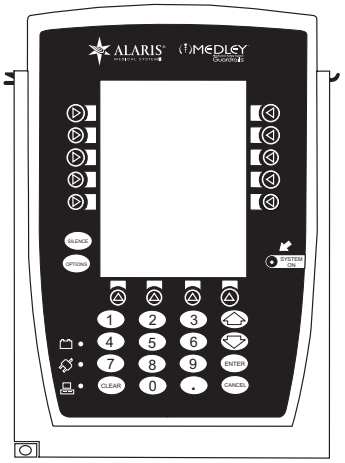
MEDLEY™

MEDICATION SAFETY SYSTEM

PROGRAMMING MODULE

Model 8000



DIRECTIONS FOR USE

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Customer Advocacy

For clinical and technical questions, feedback, and troubleshooting assistance.

Phone, toll-free, within the United States and Canada:

(800) 854-7128, Ext. 7812

Technical Support

For technical information related to maintenance procedures and service manual support.

Phone:

(858) 458-6003

Toll-free, within the United States: (800) 854-7128, Ext. 6003

Toll-free, within Canada:
Eastern: (800) 227-7215
Western: (800) 667-2335

For more detailed information, refer to the "Service Information" section of this document.

INTRODUCTION

About the System

The MEDLEY™ Medication Safety System is a modular infusion and monitoring system designed to provide SpO_2 monitoring capabilities and accurate, automated infusion of a broad range of intravascular fluids, medications and blood products.

Guardrails® Safety Software for the MEDLEY™ Medication Safety System brings a new level of medication error prevention to the point of patient care. The PC-based Guardrails® Software allows the hospital to develop a best-practice data set of IV medication dosing guidelines for up to ten patient-specific care areas, referred to as profiles. Each profile contains a specific formulary of up to 100 drugs, as well as instrument configurations appropriate for the care area. A profile also contains either Guardrails® Hard Limits that cannot be overridden during infusion programming, or Guardrails® Soft Limits that can be overridden, based on clinical requirements.

The MEDLEY™ Medication Safety System consists of the Programming Module (Model 8000), the Guardrails® Safety Software, and detachable modules (or "channels") which provide infusion or monitoring capabilities. The MEDLEY™ System is intended for use in hospitals and healthcare facilities on adult, pediatric and neonatal patients.

This document provides directions for use for the Model 8000 Programming Module. Read all instructions before using the system. For additional operating instructions, indications for use and contraindications, refer to the system Directions for Use for the individual module(s).

Features

Battery Run Time Display

The Battery Run Time Display is located on the Main Display prompt bar. If enabled, this feature provides a visual display of the estimated remaining battery run time under the current operating conditions, when operating on battery.

Ease of Use Features

To enhance safety and ease of operation, the MEDLEY™ System provides a full range of audio and visual alarms, advisories and prompts.

Guardrails® Software Prompts

The Guardrails® Software is designed to help prevent programming errors by:

- Customizing device configurable settings to meet the need of the selected hospital area/unit (profile).
- Comparing user programming with hospital-defined best practice guidelines.
- Providing an advisory prompt if an out-of-limits entry is made.

Pole Clamp Feature

The MEDLEY™ Programming Module pole clamp adapts to a wide variety of surfaces, to provide versatility. The pole clamp features include:

- Ergonomically designed knob.
- Accommodates diameters from 5/8 to 1 3/8 inches (15.9 to 34.9 mm).
- Vertical or horizontal orientation, allowing it to adapt to both IV poles and bed rails.

Profiles Feature

A profile is a unique set of device options configured to optimize device function for a specific hospital area or patient type. A profile is comprised of a configuration, with device settings and defaults customized by the user to best meet the needs of the profile area/patient type.

System Configuration

The System Configuration mode provides the ability for qualified personnel to maintain multiple customized configurations. If the Profiles Feature is enabled, the system settings defined for the selected profile are automatically activated.

Tamper Resist

The Tamper Resist feature provides a quick one-touch lockout of the front panel keypad.

Symbols

Alternating Current: Indicates that device should be attached to alternating current source, 50/60 Hz only.

Attention: Refer to accompanying documentation.

Canadian and U.S. Certification Mark: Products bearing this mark have been tested and certified in accordance with applicable U.S. and Canadian electrical safety and performance standards (CSA C22.2 No. 601.1, UL 2601-1 and IEC 60601–2–24).

Communications Connector: For RS-232 attachment.

IPX1

Protection against fluid ingress: Drip Proof

Fuse Replacement: Replace fuse only with same type and rating.

IUI Connector: Inter-Unit Interface connector used to establish power and communications between the Programming Module and add-on channels.

Main Power: Connected to alternating current, 100-240 VAC.

Manufacturing Date: Number adjacent to symbol indicates the month and year of manufacture.

Potential Equalization Conductor (if so equipped). Note: If the integrity of the PEC or Hospital Earth System is in question, operate the instrument using internal battery power.

℞ Only

CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

"SYSTEM ON"

Tamper Resist activate/deactivate switch.

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NOTE: Although the MEDLEY™ System is built and tested to exacting specifications, it is not intended to replace the supervision by medical personnel. The user should become thoroughly familiar with the features and operation of the MEDLEY™ System and exercise vigilance in its utilization.

℞ Only

Definitions

WARNING

This heading alerts the user to potential serious outcomes (death, injury or serious adverse events) to the patient or user.

CAUTION

This heading alerts the user to take special care for the safe and effective use of the device.

Warnings and Cautions

For WARNINGS and CAUTIONS for detachable channel(s), refer to the individual channel's Directions for Use.

To ensure proper performance of the MEDLEY™ System and to reduce potential injury, observe the following precautions:

WARNING

When properly secured/snapped, the bottom latch provides a very secure connection. If not properly latched, the channel can be dislodged during operation.

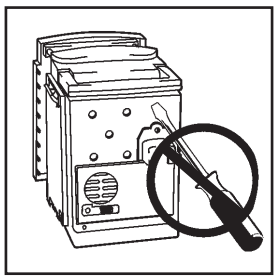
User Precautions

To ensure proper performance of the MEDLEY™ System and to reduce potential injury to the operator, observe the following precautions:

- Always use a grounded, three wire receptacle. Where the integrity of the protective earth grounding system is in doubt, operate on internal battery.
- Disconnect from main (AC) and battery power when performing maintenance.

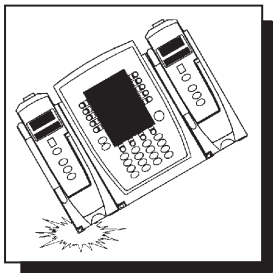
User Precautions (Continued)

- The instrument case should only be opened by qualified service personnel using proper grounding techniques. When the case is opened, an electrical shock hazard exists which can result in serious injury to persons and instrument component damage.



Dropping/Jarring

Should an instrument be dropped or severely jarred, it should be immediately taken out of use and inspected by qualified service personnel, to ensure its proper function prior to reuse.



Operating Environment

Not for use in the presence of flammable anesthetics.

◄ DANGER ►

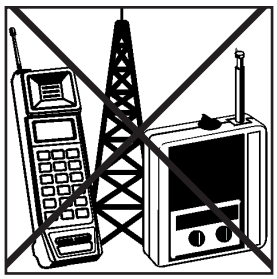
Explosion hazard. Do not use in the presence of flammable anesthetics.

Radio Frequency Interference

Operating the system near equipment which radiates high energy radio frequencies (electrosurgical/cauterizing equipment, portable radios, cellular telephones, etc.) may cause false alarm conditions. If this happens, reposition the device away from the source of interference or turn off the device and manually regulate the flow with the clamp and/or monitor the vital parameters using an appropriate clinical alternative.

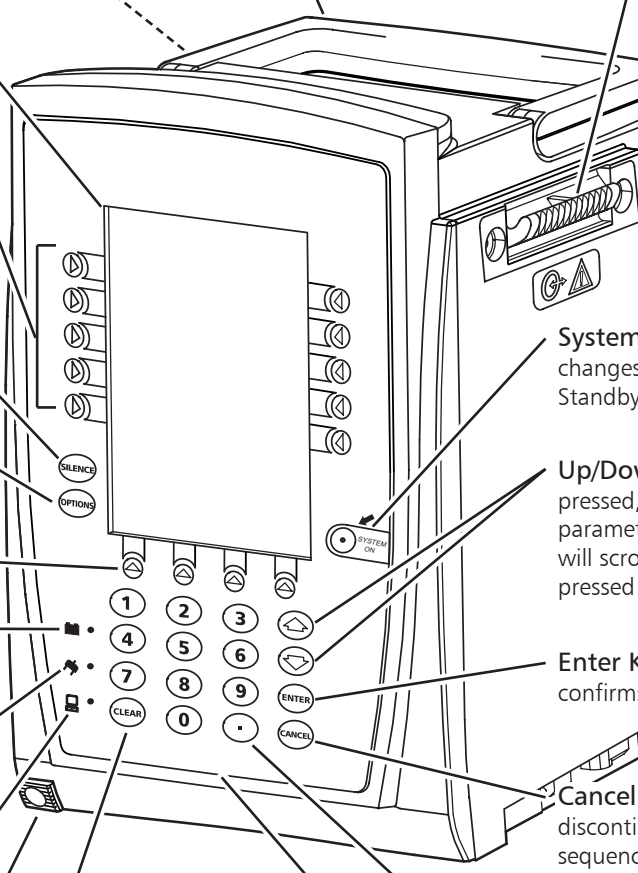
WARNING

Use of accessories or cables other than those specified may result in degraded electromagnetic compatibility performance of this device.



Controls and Indicators

Front/Side View



IUI Connector, Left (not visible)

Handle

IUI Connector, Right

Main Display

Soft Keys - When pressed, allows selection of options or infusion parameters displayed in Main Display adjacent to soft key.

Silence Key - When pressed during an alarm, silences audio for two minutes.

Options Key - When pressed, allows access to available System or Channel Options.

Soft Keys (see above).

Battery Indicator - When illuminated, indicates MEDLEY™ System is operating on battery power.

Power Indicator - When illuminated, indicates MEDLEY™ System is connected to an AC power source.

Computer Monitor Mode Indicator - When illuminated, indicates MEDLEY™ System is operating in Computer Monitor mode.

Channel Release Latch - When pressed, allows channel to be removed.

System On Key - When pressed, changes MEDLEY™ System from Standby to Operating mode.

Up/Down Arrows - When pressed, will increase or decrease parameter with each key press or will scroll up and down when pressed and held.

Enter Key - When pressed, confirms current parameter entry.

Cancel Key - When pressed, discontinues current programming sequence and returns Main Display to previous display screen.

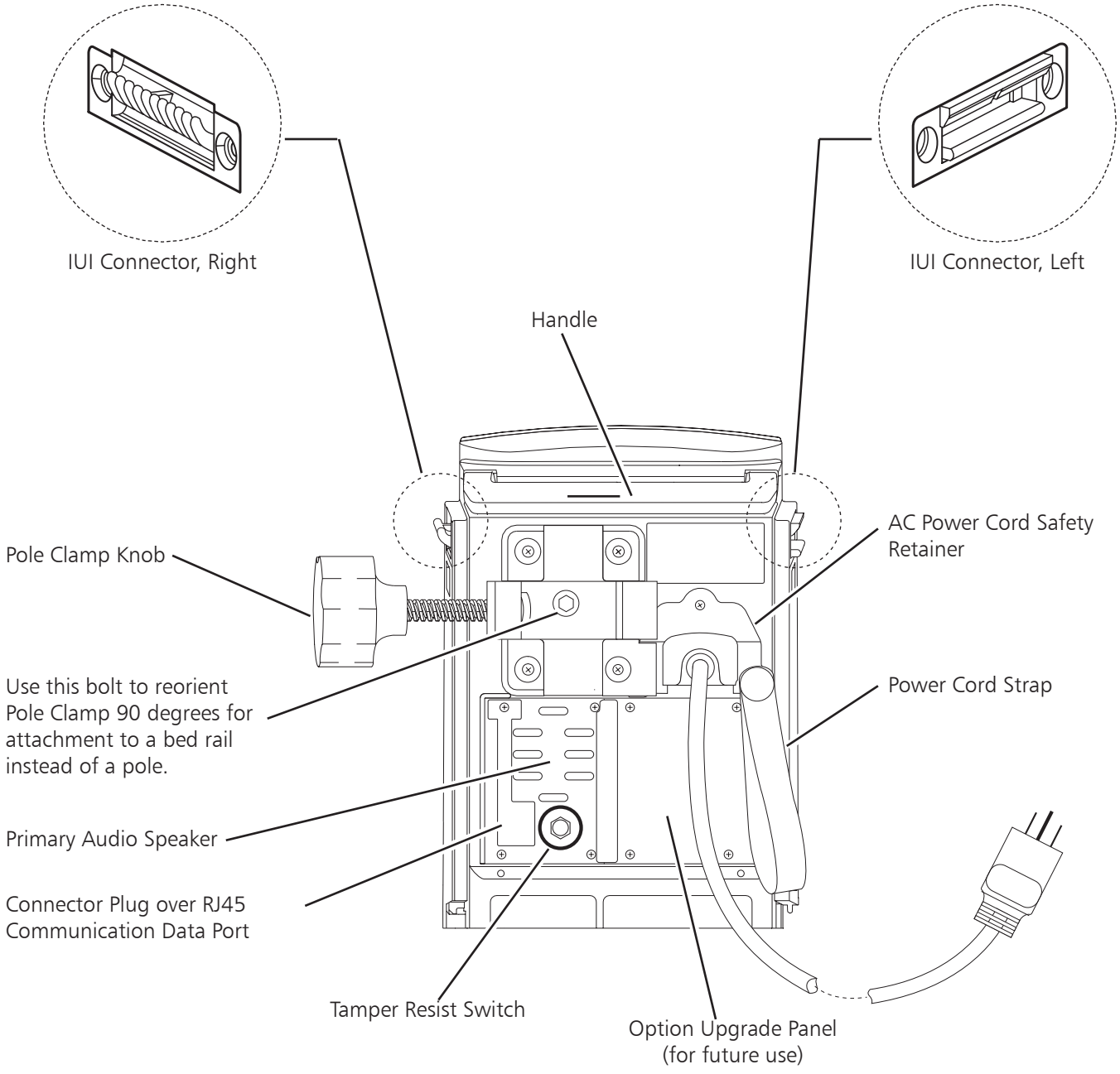
Clear Key - When pressed, clears current selected parameter setting to "0".

Decimal Key - When pressed, inserts a decimal point in numeric data.

Numeric Keypad

Controls and Indicators (Continued)

Rear View



Installation Procedure

Instruments are tested before they are packaged for shipment. They met the specifications listed in the Directions for Use at that time. To ensure proper operation after shipment, it is recommended that an incoming inspection is performed by your facility before putting the instrument into use (see "Check-In and Configuration" section in "Maintenance" chapter).

To enable the Profiles Feature, your facility would have used the Guardrails® Safety Software to upload a hospital-defined best-practice data set to the Programming Module. This should be verified prior to placing the MEDLEY™ System in use.

Unpacking Programming Module

1. Remove Programming Module from its carton.
2. Plug module into an AC outlet for six hours prior to use.

   Maximum battery capacity, as well as gauge accuracy, is reached after several charge/discharge/charge cycles. For best results, fully charge/discharge/charge battery before placing in use.
3. Perform Periodic Inspections as indicated in "*Inspection Requirements*" section of this document.
4. Check pole clamp for freedom of operation.
5. Check power cord for nicks and bent prongs.
6. Check AC power entry module for contamination.
7. Check for loose parts.

If the Programming Module is damaged, contact ALARIS Medical Systems for authorization to return the equipment for repair, whether damage or malfunction is the responsibility of the carrier or of ALARIS Medical Systems.

Attaching and Detaching Channels

Channels can be attached to either side of the Programming Module or to either side of another channel. The process to attach or detach is the same for either side, whether attaching/detaching to/from a Programming Module or another channel.

Attaching Channel(s)

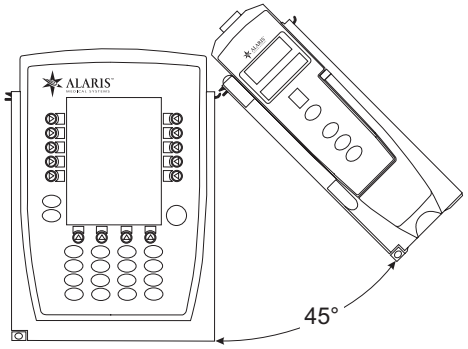
1. Position free channel at a 45° angle, aligning IUI Connectors.
2. Rotate free channel down against Programming Module or attached channel, until bottom latch snaps in place.

NOTES:

- *Individual hospitals may choose to permanently attach channels. To remove permanently attached channels, contact qualified service personnel.*
- *Application of adhesive tape or other materials to the sides of the Programming Module and channels may prevent proper latching.*

WARNING

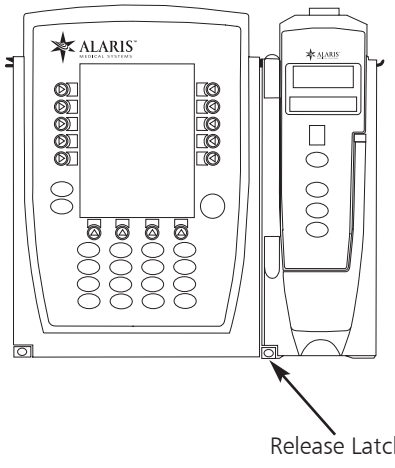
When properly secured/snapped, the bottom latch provides a very secure connection. If not properly latched, the channel can be dislodged during operation.



Detaching Channel(s)

1. Ensure channel(s) is powered off before detaching.
2. Push channel release latch (located directly below IUI Connectors) and then rotate channel(s) up and away from Programming Module or attached channel (opposite to motion shown above) to disengage connectors.
   - If channel(s) remains to right of detached channel(s), it reidentifies and shows appropriate channel identification (A, B, C or D).
   - Appropriate channel position (A, B, C or D) for remaining channel(s) display in Main Display.

NOTE: *The MEDLEY™ Medication Safety System is designed to operate a maximum of four channels. Channels added in excess of four will not be recognized by the system. The channel(s) can be attached in any position; however, when mounted on an IV pole, it is recommended that a balanced configuration be maintained.*

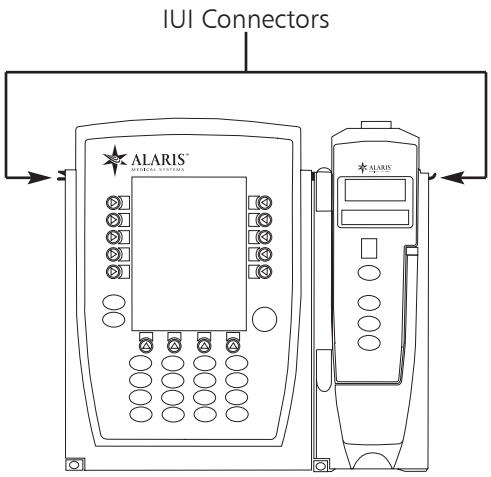


Attaching and Detaching Channels (Continued)

Adding Channel(s) While System is Powered On

Add channel as described in "*Attaching Channel(s)*".

- System tests channel, causing all LED segments and Indicator lights of channel displays to illuminate briefly.
- Appropriate channel identification display (A, B, C or D) illuminates. Channels are always labeled left to right, so if a channel is added to left of other channels, all channels will be reidentified. Channel reidentification does NOT interrupt or affect infusion or monitoring on active channels.
- Channel positions (A, B, C or D) display in Main Display.



NOTE: *If any of the following conditions are observed, the affected channel must be removed from use and inspected by qualified personnel:*

- *LED segments are not illuminated on channel displays during power-on test.*
- *Indicator lights do not illuminate.*
- *Appropriate channel identification (A, B, C or D) is not displayed.*

If the affected channel operates normally when it is attached via the alternate IUI connector, it may be used until a replacement channel can be substituted.

Start-Up Sequence

Powering On System

1. Connect Programming Module to an external AC power source.
2. Press **SYSTEM ON**.
3. System self test begins:
   - Diagnostics test causes all LED display segments and Status Indicator lights of attached channel(s) to illuminate briefly.
   - Power Indicator illuminates.
   - Appropriate channel identification (A, B, C or D) displays on attached channel(s).
   - An Audio tone sounds.
   - At completion of system-on test, "New Patient?" screen appears.

Powering On the System (Continued)

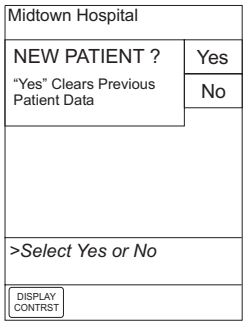
NOTE: If any of the following conditions are observed, the Programming Module or the affected channel must be removed from use and inspected by qualified personnel:

- *LED segments are not illuminated on channel displays during system-on test.*
- *Indicator lights do not illuminate.*
- *Appropriate channel identification (A, B, C or D) is not displayed.*
- *Audio tone does not sound.*
- *Main Display does not appear backlit, appears irregular, or has evidence of a row of pixels not functioning properly.*

If the affected channel operates normally when it is attached via the alternate IUI connector, it may be used until a replacement channel can be substituted.

Choosing Yes or No to New Patient? and Profile?

*NOTE: The display contrast can be adjusted at this time by pressing the **DISPLAY CONTRST** soft key and following the directions on the screen (also see "Adjusting Display Contrast" in "Displays and Audio" section).*

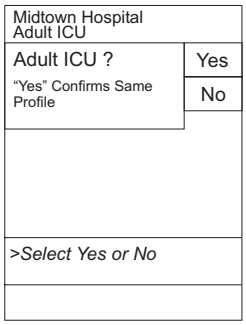


1. To assign Programming Module to a new patient and clear all stored patient parameters from memory, press **Yes** soft key.

   OR

   To confirm Programming Module is still in use on same patient and retain all stored patient parameters, press **No** soft key.

   - If Profiles Feature is disabled, main screen appears.
   - If Profiles Feature is enabled, last profile displays.



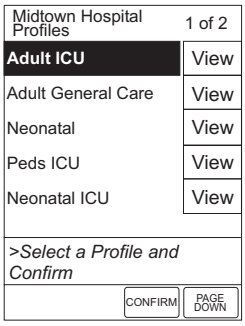
2. To confirm profile and proceed to main screen, press **Yes** soft key.

   OR

   To change profile and proceed to profile selection screen, press **No** soft key.

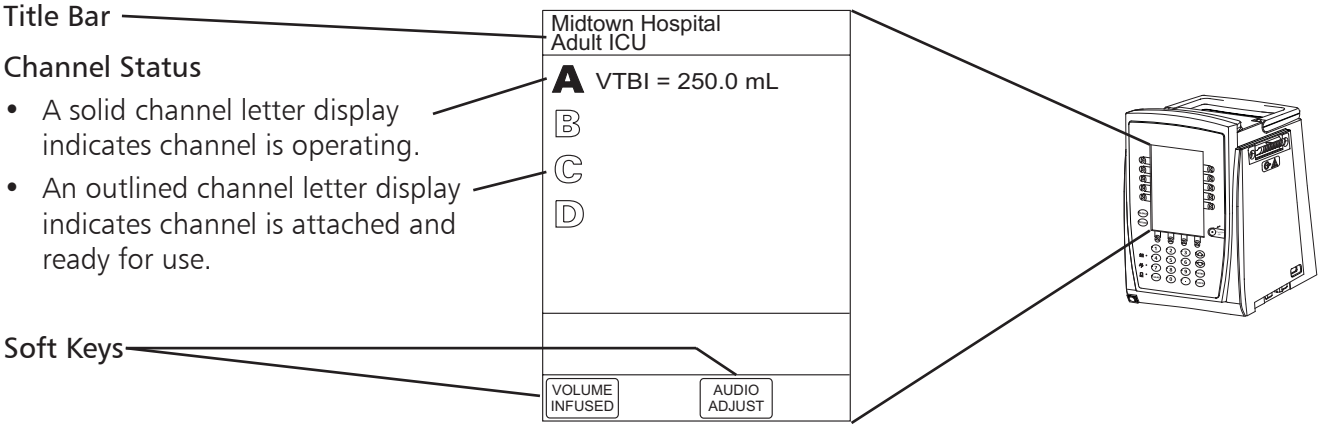
Selecting Profile

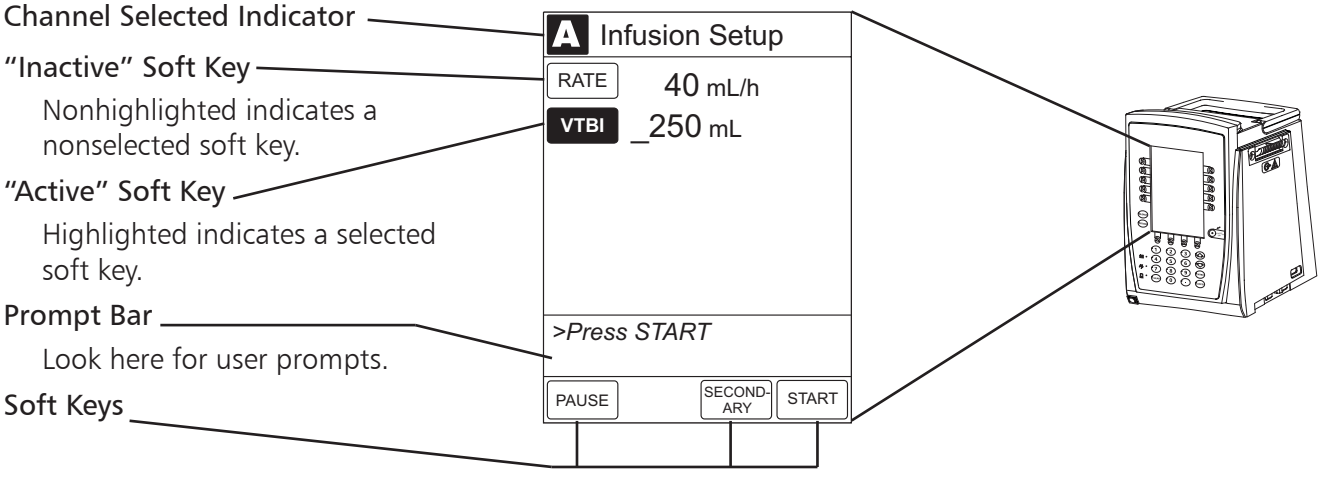
1. Select desired profile by pressing its soft key.
   a. If more than five profiles are available, press **PAGE UP** and **PAGE DOWN** soft keys to review all choices.
   b. Press **View** soft key for desired profile to review system configuration settings for that profile.
2. Press **CONFIRM** soft key to confirm profile selection and proceed to main screen.



Displays and Audio

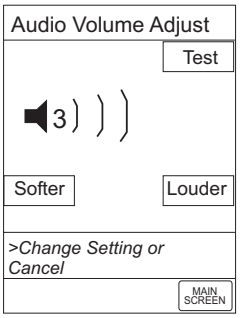
Main Display





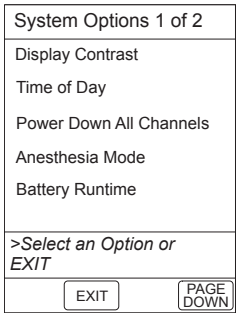
Adjusting Audio Volume

1. Press **Audio Adjust** soft key in Programming Module Display.
2. Press either **Louder** or **Softer** soft key to change volume to desired level. **Test** soft key may be pressed to sample alarm loudness level.
3. Press **MAIN SCREEN** soft key to return to Programming Module screen.
   - After 30 seconds without a key press, Main Display appears.

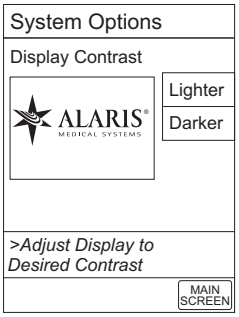


Adjusting Display Contrast

1. Press **OPTIONS** key.
2. Select **Display Contrast** soft key.

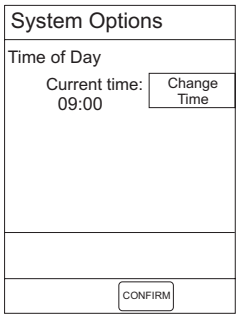


3. Use **Lighter/Darker** soft keys to adjust display for optimum viewing.
4. Press **MAIN SCREEN** soft key to return to main screen.

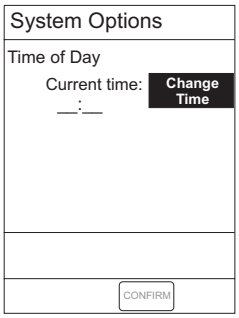


Setting Up Time of Day

1. Press **OPTIONS** key.
2. Press **Time of Day** soft key.

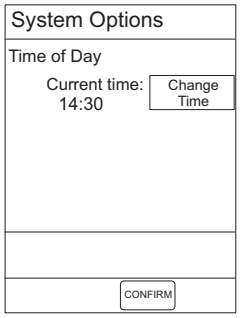


3. Press **Change Time** soft key.



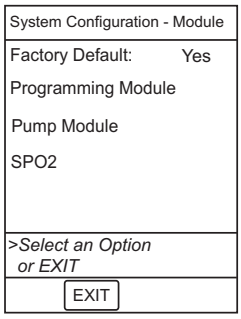
4. Enter current Time of Day.
5. Press **Confirm** soft key.

> ***NOTE:*** *The format is a 24-hour clock (military time).*



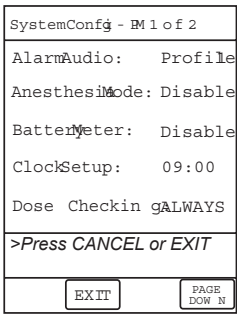
Reviewing System Configuration

1. Press **OPTIONS** key.
2. Press **PAGE DOWN** soft key.
3. Press **System Configuration** soft key.
4. Select **Programming Module**.



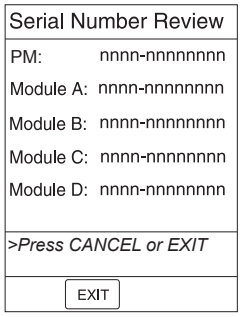
Reviewing System Configuration (Continued)

5. Press **PAGE UP** and **PAGE DOWN** soft keys to review various system configuration settings.
6. Press **CANCEL** key or **EXIT** soft key to return to main screen.



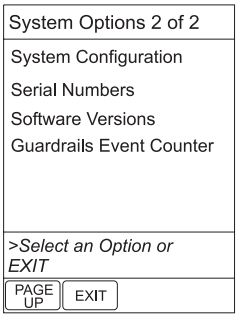
Reviewing Serial Number

1. Press **OPTIONS** key.
2. Press **PAGE DOWN** soft key.
3. Press **Serial Numbers** soft key.
   - Serial numbers for Programming Module and all attached channels display.
4. Press **EXIT** soft key to return to main screen.

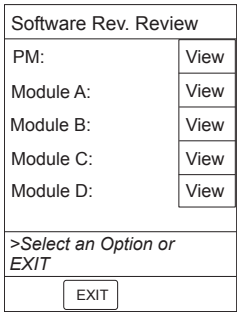


Reviewing Software Version

1. Press **OPTIONS** key.
2. Press **PAGE DOWN** soft key.
3. Press **Software Versions** soft key.



4. Press **View** soft key next to desired channel.
5. Press **EXIT** soft key to return to Software Review screen.
6. Press **EXIT** soft key to return to main screen.

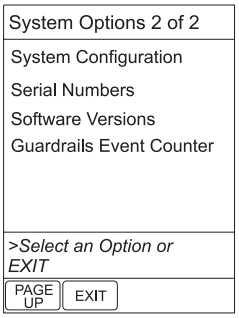


Viewing and Clearing Guardrails® Event Counter

1. Press **OPTIONS** key.
2. Press **PAGE DOWN** soft key.
3. Press **Guardrails Event Counter** soft key.
4. To clear event counter information, press **CLEAR** key and then **EXIT** soft key.

   OR

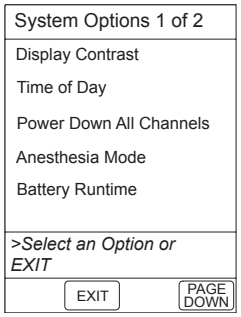
   To retain event counter information and return to main screen, press **EXIT** soft key.



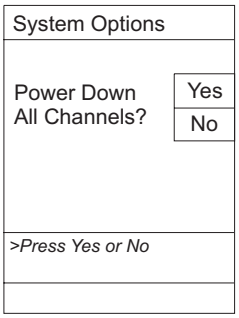
Powering Off

Powering Off System

1. Press **OPTIONS** key.
2. Press **Power Down All Channels** soft key.



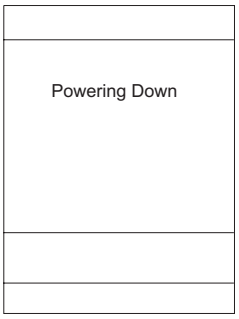
3. Press **Yes** soft key.
   - During power off sequence, Main Display flashes "Powering Down".



Powering Off (Continued)

Powering Off One Channel at a Time

Press and hold **CHANNEL OFF** key on each operating channel for one second.

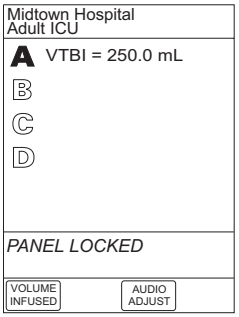


> ***NOTE:*** *The channel will initiate the power down at the release of the* ***CHANNEL OFF*** *key.*

- Once all attached channels are powered off, Programming Module automatically powers down.
- During power off sequence, Main Display flashes "Powering Down".

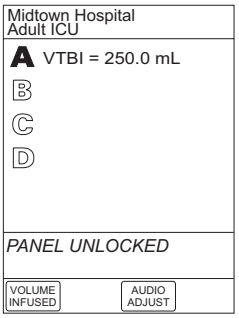
Locking/Unlocking Tamper Resist

1. Initiate operation of desired channels.



2. Press and hold Tamper Resist Switch, on back of Programming Module, for three to four seconds. An advisory tone and a three second "PANEL LOCKED" prompt in Main Display confirm activation. When Tamper Resist is active, keypad panel is locked; however, clinician may:
   - Silence key for audio alarm.
   - View Total and Pri/Sec Volume Infused.
   - View and test Audio Alarm Setting.
   - View selected parameters on SpO_2 Module.

   Any other key press will result in a visual "PANEL LOCKED" prompt and, if **Key Click Audio** is enabled, an illegal key press audio advisory.



3. To unlock keypad panel, press and hold Tamper Resist Switch for three to four seconds. A three second "PANEL UNLOCKED" prompt in Main Display and, if **Key Click Audio** is enabled, an advisory tone will confirm Tamper Resist is off.

Computer Link

The optional Computer Link feature allows a hospital computer to interact with the instrument. The computer cannot start or stop the instrument, set the rate, or make any change in status. If the feature is off, the computer cannot communicate with the instrument.

The Computer Link option is available in the Maintenance Mode.

CAUTION

Only systems that have been tested and certified in compliance to IEC 601–1/EN 60601–1 standard should be connected to the MEDLEY™ System Computer/ Connections port.

CAUTION

Use of accessories or cables other than those specified may result in degraded electromagnetic compatibility performance of this device.

The computer interface uses a three wire RS-232 signal definition through an RJ45 type connector. The table to the right shows the pin definition. **Do not connect anything to the unused pins.**

Pin Number	Description
4	Ground
5	RS-232 TxD (Out of Programming Module)
7	RS-232 RxD (Into Programming Module)

Qualified service personnel can turn the Computer Link feature on or off.

NOTE: To assure continued electromagnetic compatibility performance, the communications cable which attaches to the instrument should be a category 5 type cable, no longer than 1.5 meters.

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ALARMS, ADVISORIES AND PROMPTS

Definitions

Advisory	A sequence of audio and/or visual signals indicating the operating status of the MEDLEY™ Medication Safety System. The audio may be silenced for approximately two minutes by pressing the **SILENCE** key.
Alarm	An audio and visual signal that a potentially unsafe condition is present. Immediate action is required. The audio may be silenced for approximately two minutes by pressing the **SILENCE** key.
Error	An audio and/or visual signal that a failure has been detected. Immediate action is required.
Guardrails® Software Prompt	A visual programming prompt requiring a "Yes" or "No" response; designed to help prevent programming errors.
Prompt	An audio and/or visual signal, appearing on the bottom line of the Main Display or the Channel Message Display, to perform some action. The audio may be silenced for twelve seconds by pressing the **SILENCE** key.

Audio Characteristics

The Programming Module and Main Display provide four types of alert information: advisories, prompts, alarms, and malfunctions. The characteristics of the accompanying audio sounds are as follows:

Type	Sound	Notes
Advisory	One short beep every two seconds	Variable volume; can be silenced for two minutes.
Alarm	Choice of three alarm audio profiles, selectable in System Configuration	Variable volume; can be silenced for two minutes.
Error (Hardware Detected)	Pairs of long beeps	Fixed maximum decibel volume; cannot be silenced.
Error (Software Detected)	Pairs of long beeps	Fixed maximum decibel volume; can be silenced for two minutes.
Illegal Key Press	Two short beeps	Variable volume; cannot be silenced.
Key Click	One short beep	Fixed minimum volume; can be silenced and disabled in System Configuration.
Prompt	One short beep every two seconds	Variable volume; can be silenced.
SpO_2 Alarm	Unique alarm pattern.	Different sound than other alarms.
Switchover	Six short beeps	Variable volume; can be silenced and disabled in System Configuration.

Alarms

Alarm	Meaning	Response
Battery Discharged	Operation of all channels has stopped due to insufficient battery charge.	Connect AC power cord to power source; alarm will be silenced. Press **RESTART** key on Pump Module to continue operation of paused channels.
Channel Disconnected	Channel(s) have either been disconnected while in operation or have a communication problem.	Press **CONFIRM** soft key to silence alarm and clear message from screen. Reattach channel if desired. If alarm is still present, replace channel with an operable instrument.
Very Low Battery <5 minutes to system shutdown	Battery has five minutes or less of power at current rates before operation will stop.	Connect AC power cord to power source; alarm will be silenced.

Advisories

Advisory	Meaning	Response
Battery Run Time = X.X hours	AC power cord is disconnected from power source. Approximate remaining battery run time under current operating conditions is displayed.	None. Connect AC power cord to power source as soon as possible.
Low Battery	Low battery threshold sensed; remaining battery run time is limited.	Connect AC power cord to power source; alarm will be silenced.
Panel Locked	Occurs following a key press when Tamper Resist feature is active.	If appropriate, deactivate Tamper Resist feature using Tamper Resist Control on back of Programming Module.
Panel Unlocked	Occurs when Tamper Resist feature is deactivated.	None.
Powering Down	Last channel has been powered off. System will shut off in indicated number of seconds.	Press any key, except SYSTEM ON key, to cancel power down sequence.
Replace Battery	Occurs at System On. Battery has less than 50% of original capacity.	Press either SYSTEM OFF or CONFIRM soft key to continue normal operation with reduced battery capacity. Service by qualified personnel is required.

Errors

Error	Meaning	Response
Channel Error	System has detected an error on an attached channel. Operation of affected channel stops.	Press **CONFIRM** soft key to silence alarm and continue operation of unaffected channels. Replace channel with an operational system, as required. Service by qualified personnel is required.
Defective Battery	System has detected a defective battery.	Press **SYSTEM OFF** soft key to power down system, or press **SILENCE** key to continue temporary operation while an operational Programming Module can be located to replace malfunctioning system. Service by qualified personnel is required.
Hardware Detected Error	System has detected an error on Programming Module. Operation stops on all channels.	Press **SYSTEM ON** key to power down system. Replace Programming Module with an operational system. Service by qualified personnel is required.
Missing Battery	System has detected that a battery is not present or not connected.	Press **SYSTEM OFF** soft key to power down system, or press **SILENCE** key to continue temporary operation while an operational Programming Module can be located to replace malfunctioning system, if desired. If battery is still present, remove it and replace with an operable battery. Service by qualified personnel is required.
Power Supply Error	System has detected a malfunction of power supply system.	Disconnect AC power immediately. Press **SYSTEM OFF** soft key to power down system, or press **SILENCE** key to continue operation under battery power while an operational Programming Module can be located to replace malfunctioning system. Service by qualified personnel is required.
System Error	System has detected an error on Programming Module. Operation continues on all channels.	Press **SYSTEM OFF** soft key to power down system, or press **SILENCE** key to continue temporary operation while an operational Programming Module can be located to replace malfunctioning system. Service by qualified personnel is required.

ALARMS, ADVISORIES AND PROMPTS 25

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MAINTENANCE

The MEDLEY™ System Technical Service Manual is available from ALARIS Medical Systems. It includes routine service schedules, circuit diagrams, component parts lists and descriptions, calibration and test procedures, and other technical information, to assist qualified service personnel in repair and maintenance of the instrument's repairable components. Maintenance procedures are intended to be performed only by qualified personnel.

Specifications

Battery Operation: Battery run time is a function of the number of channels attached and channel activity.

With a new, fully charged battery, the system will operate:

- 8 hours with one Pump Module infusing at 25 mL/h
- 4 hours with four Pump Modules infusing at 25 mL/h
- 6 hours with one active SpO_2 Module

before a "BATTERY DISCHARGED" message occurs.

Communication Data Port: RS-232 with a RJ45 connector.

Dimensions: 6.9"W x 8.8"H x 9"D (including pole clamp)

Electric Classification: Class 1, Internally Powered Equipment

> ***NOTE:*** *Refer to module specific Directions for Use for shock protection type and defibrillation-proof rating information.*

Electronic Memory: System configuration parameters stored in volatile memory will be retained for at least 6 months by the internal backup lithium battery. Additionally, channel specific parameters are stored for 8 hours by the Programming Module and then automatically purged by the system.

Environmental Conditions:	Operating	Storage/Transport
Temperature Range:	41 to 104°F (5 to 40°C)	-4 to 140°F (-20 to 60°C)
Relative Humidity: *(Avoid prolonged exposure to relative humidity >85%)*	20 to 90% Noncondensing	5 to 85% Noncondensing
Atmospheric Pressure:	525 to 4560 mmHg (700 to 6080 hPa)	375 to 760 mmHg (500 to 1013 hPa)

Equipment Orientation: To ensure proper operation, the instrument must remain in an upright position.

Fluid Ingress Protection: IPX1, Drip Proof

Leakage Current: Less than 100 microamps

Power Requirements: 100 - 240V ~, 50/60 Hz, 150 VA MAX (See Notes 1 and 2)

Weight: 7.2 lbs

Specifications (Continued)

NOTES:

1. *Power Cords; North America:*

   To ensure correct polarity and grounding reliability, use power cords that incorporate a NEMA 5-15P (125V) or NEMA 6-15P (250V) plug only.

2. *Power Cords; International:*

   Use only cords that comply with IEC 60245, or IEC 60227, designation #53 and local electrical codes and/or regulations.

3. *Compliance to Standards:*

   The MEDLEY™ Medication Safety System has been assessed and complies with the following standards: UL 2601–1, including A1 and A2; CSA C22.2 No. 601.1, including A1 and A2; IEC/EN 60601–2–24; IEC/EN 60601–1–2 and AAMI ID26.

Configurable Settings

NOTE: *With the Profiles Feature enabled, the settings are configured independently for each profile. A hospital-defined best-practice data set must be uploaded to enable the Profiles Feature. Date and Time is a system setting and is the same in all profiles.*

Feature	Default Setting	Options
Alarm Audio	Profile 1	Profile 1, 2 or 3
Anesthesia Mode	Disabled	Enabled - Disabled
Battery Meter	Disabled	Enabled - Disabled
Clock Setup (Date and Time)*	N/A	Set date and time
Key Click Audio	Enabled	Enabled - Disabled
Max Patient Weight	500 kg	0.1 - 500 kg
Profiles	Disabled	Enabled - Disabled
Tamper Resist	Disabled	Enabled - Disabled

Check-In and Configuration

This is a Quick Reference Procedure for check-in and configuration of a new and recently serviced MEDLEY™ Medication Safety System. The following check-in and configuration procedures are taken from the current service manual.

- Instrument Configuration
- Pre-Operational Battery Charge
- Regular Inspection
- Ground Current Leakage Test
- Ground Resistance Test
- Functional Tests
- Rate Accuracy Verification
- Pressure/Occlusion Test
- Flo-Stop® Device Test
- Air-in-Line Test
- Battery Run-Time Test

References (used in conjunction with this document):

- Model 8000/8100 Technical Service Manual
- Model 8000 and 8100 Directions for Use

Equipment Required

NAME	MANUFACTURER	MODEL NUMBER	APPLICATION
Air-in-Line Simulator (see figure in "Air-in-Line Test" section)	N/A	N/A	Air-in-Line testing.
Burette, 50 ml, 0.1 ml increment	Fischer Scientific Kymex	Class A or B* 113 Sec A*	Rate verification.
Electrical Safety Tester	Bio-Tek, Inc	260*	Used to test AC wiring and instrument grounding.
Hemostat	N/A	N/A	Fluid Side Occlusion test.
IV Infusion Set	ALARIS Medical Systems	2210-0500 Gemini	Rate accuracy verification.
IV Pole (standard)	ALARIS Medical Systems	903 (or equivalent)	Instrument testing.
IV Solution Container (bag preferred)	N/A	N/A	Rate/Volume and Pressure testing.
Pressure Gauge (peak hold)	PSI Tronics 1-559-686-0558	PG 5000-30-G-4001-0*	Pressure verification.
Silicon Tubing	ALARIS Medical Systems	303109*	Pressure verification setup.
T-Fitting	ALARIS Medical Systems	303815*	Pressure verification setup.
Timing Device (stop watch), accurate to at least ±0.1 second	N/A	N/A	Timing for Rate/Volume test.

* or equivalent

Check-In and Configuration (Continued)

Instrument Configuration

If the configuration settings need to be changed from the "Factory Default" settings, refer to the applicable Directions for Use or contact ALARIS Medical Systems® Technical Support for technical, troubleshooting, and preventive maintenance information.

Pre-Operational Battery Charge

Before the MEDLEY™ Medication Safety System is released for use, the Programming Module should be plugged into a hospital grade AC outlet and the battery charged for at least eight hours. This will ensure proper battery operation when the MEDLEY™ Medication Safety System is first set-up for patient use.

Regular Inspections

Regular inspections consist of a visual inspection for damage and cleanliness, and performing the procedure described in the "Start Up Sequence" section of the applicable Directions for Use before each usage of the instrument. Regular inspections are not covered under any contract or agreement offered by ALARIS Medical Systems and must be performed by the user.

1. Exterior Surfaces

   Examine Programming Module and Pump Module for overall condition and verify:

   - There is no shipping damage, cracks or deformities.
   - Case is clean and free from IV solution residue, especially near moving parts.
   - Accessible areas of air-in-line sensor, pressure transducers and latch mechanism are clean and free from IV solution residue.
   - Labels and markings are legible.
   - No tape or other foreign material is on sides of case; anything of this nature could prevent proper latching of channels.
   - IUI Connectors have not been damaged.

2. Pole Clamp

   Pole Clamp should be secure and functioning.

Regular Inspections (Continued)

3. Power Cord Assembly

   Examine power cord assembly for:

   - Signs of damage, cuts or deformities in cord. If damaged, replace entire cord.
   - Integrity of hospital-grade power plug. Attempt to wiggle blades, to verify they are secure. If any damage is suspected, replace entire cord.

4. Keypad

   Check membrane switches for damage. During course of inspection, be sure to check that each switch performs its proper function.

5. Door/Platen

   Clean any surfaces where solution or obstructions have accumulated and verify:

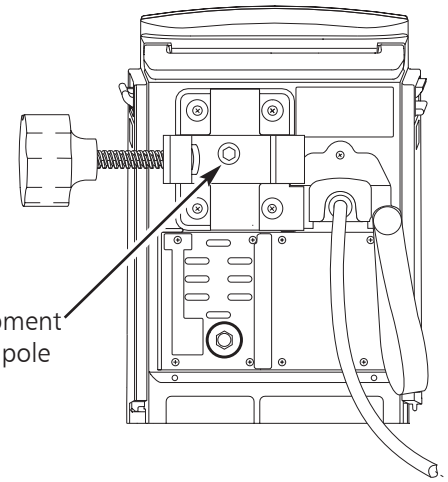
   - Mechanism seal is not torn or worn.
   - Door/Platen moves freely and does not hang up or bind.
   - Torsion Spring on Pump Module door functions properly. Open Door and ensure Door Latch stays up and does not sag.

Ground Current Leakage Test

Use a BIO-TEK Model 260 (or equivalent) to measure the ground leakage current. Refer to the test equipment's operation manual for the proper setup and measurement technique. Leakage current must be ≤100mA for normal and reversed line polarity.

Ground Resistance Test

Use a BIO-TEK Model 260 (or equivalent) to measure the ground resistance. Measure resistance between the grounding pin on the power cord plug and the grounding point on the rear case. Refer to the test equipment's operation manual for the proper setup and measurement technique. Resistance must be ≤0.20W.



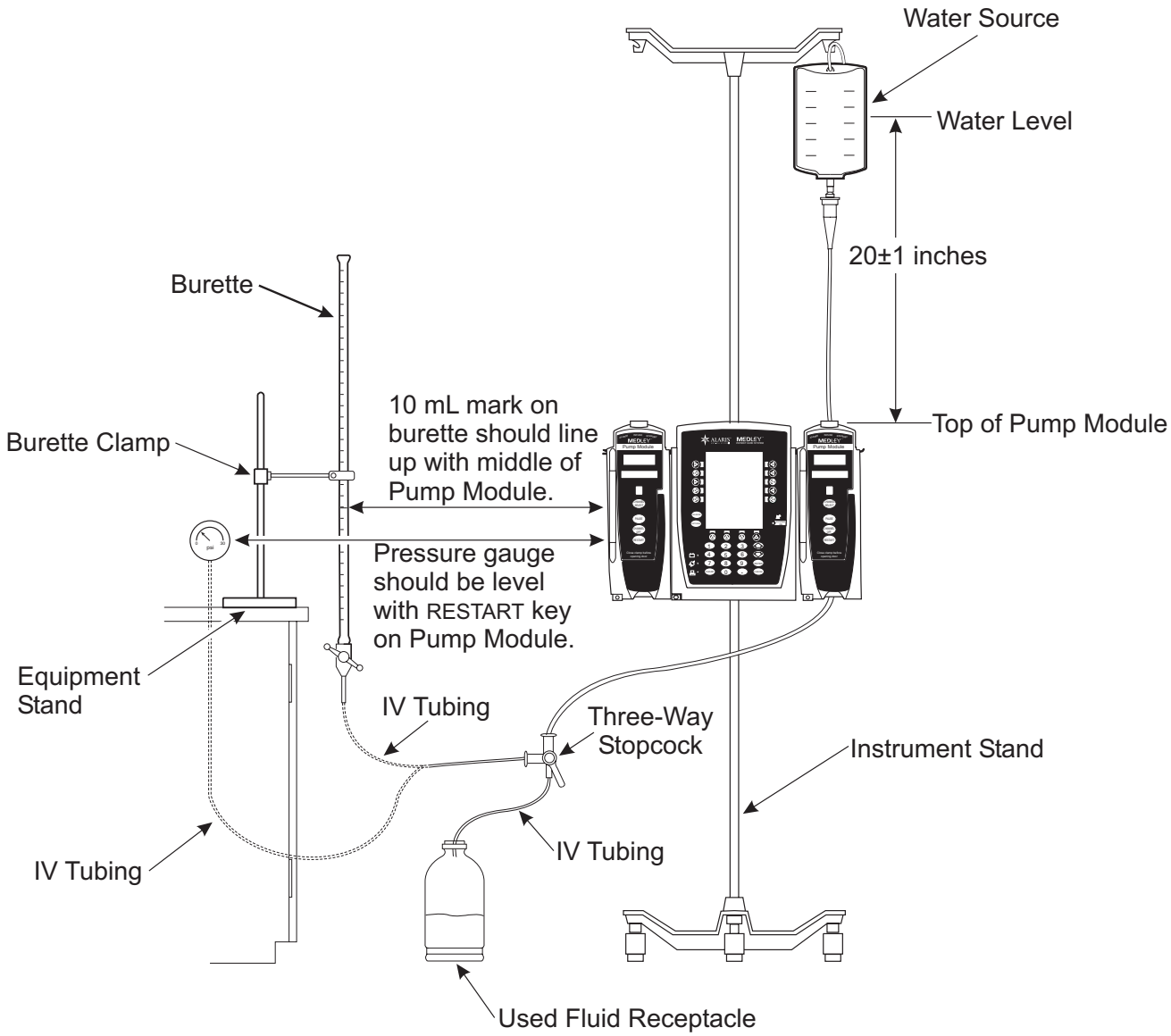
Functional Tests

During the following tests:

- Check and ensure keypad and all displays are functioning correctly.
- Ensure IUI Connectors are functional by attaching a module to each connector on module being tested.

NOTE: *When performing the following tests, if a set is required, the MEDLEY™/Gemini Standard Administration Set, Model 2210, must be used.*

Rate Accuracy Verification and Patient Side Pressure Test Setup



Functional Tests (Continued)

Rate Accuracy Verification

NOTE: Connect the Pump Module to a Programming Module and ensure that the Programming Module is connected to a properly grounded AC outlet.

1. Fill solution container with clean tap water. Close slide clamp on IV set and insert spike into solution container.
2. Open slide clamp and prime set. Pay particular attention to ensure that all air is expelled from set. Close slide clamp.
3. Connect output of set to one side of three-way stopcock.
4. Power instrument on and load set into instrument.
5. Close door and ensure door is completely closed and latch is secure.
6. Verify there is no fluid flow or drops falling in drip chamber.
7. Set stopcock to output into a class A or B burette.
8. Press Pump Module's **CHANNEL SELECT** key to turn instrument on.
9. Set primary infusion rate to 500 mL/h. Set VTBI to 20 mL.
10. Adjust height of instrument and/or fluid container as necessary to attain a head height of 20±1 inches from top of instrument to fluid level in bag.

    NOTE: Bottles are not recommended for these tests.

11. Adjust fluid level in burette so that meniscus is level with zero mark on burette.

    NOTE: Instrument may need to be run to prime line to "0" level of burette.

12. Verify primary infusion rate is 500 mL/h. Reset VTBI to 20 mL and clear volume infused.
13. Prepare timing device to time fluid delivery.
14. Press Programming Module's **START** soft key, to start primary infusion, and start timing device at same time.

Functional Tests (Continued)

Rate Accuracy Verification (Continued)

15. Using timing device, check time (rate) to complete delivery; this should be 2 minutes 16 seconds to 2 minutes 32 seconds. If time falls outside these limits, contact ALARIS Medical Systems® Technical Support.

16. At end of infusion, instrument will go into KVO and "INFUSION COMPLETE - KVO" will scroll on Pump Module's display.

> ***NOTE:*** *Pause the Pump Module by pressing the* ***PAUSE*** *key on the Pump Module within one second of its entering KVO mode.*

17. Make a note of volume collected in burette.

    If volume accuracy does not fall within required range of ±5% (19-21 mL) from expected volume, contact ALARIS Medical Systems® Technical Support.

18. Set stopcock to drain fluid in burette into a used fluid receptacle.

Patient Side Pressure Test

> ***NOTE:*** *The time to Patient Side Occlusion should not exceed two minutes when using recommended equipment. Possible reasons why time to occlusion may vary are:*
>
> - *air in system*
> - *air in pressure gauge*
> - *tubing too compliant*
> - *manifold or adapter in use that may cause restrictions or contain air*
> - *pressure gauge accuracy*
> - *leak in setup*
>
> *There may be other causes not captured here.*

1. While Pump Module is still paused from Rate Test, connect pressure gauge to distal end of set.

2. Press channel select key on Pump Module.

3. Set rate to 125 mL.

4. Set VTBI to 100 mL.

5. Press **START** soft key on Programming Module.

Functional Tests (Continued)

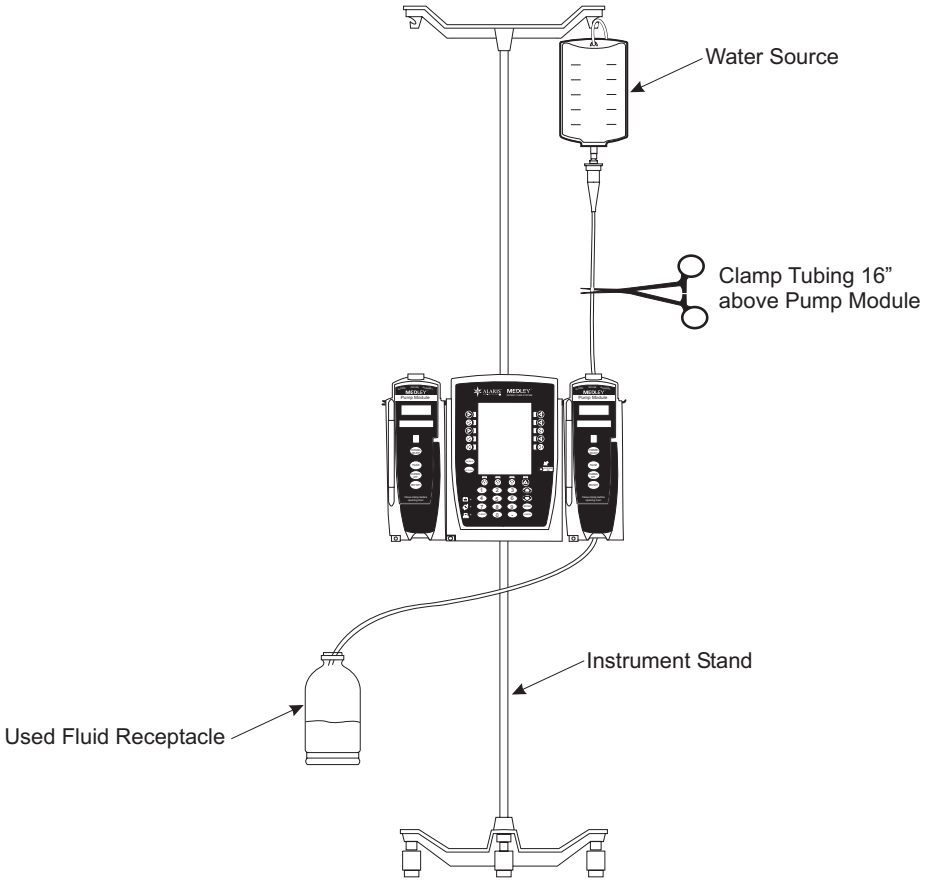
Patient Side Pressure Test (Continued)

6. When Pump Module occludes, meter should read 10.2±2.5 PSI.
7. Verify Pump Module stops running, alarms, and displays "OCCLUSION PATIENT SIDE" within two minutes.
8. If pressure is outside limits, contact ALARIS Medical Systems® Technical Support.
9. Press **SILENCE** key on Programming Module to silence alarm.

Fluid Side Occlusion Test

NOTE: *Ensure pressure gauge is removed/disconnected before conducting following test.*

Fluid Side Occlusion Test Setup



Functional Tests (Continued)

Fluid Side Occlusion Test (Continued)

1. While Pump Module is still on hold from Patient Side Pressure Test, verify rate is set to 125 mL/h and VTBI is greater than 50 mL.
2. Press **RESTART** key on Pump Module to resume infusion.
3. Clamp off IV line approximately 16" along proximal set tubing to simulate a fluid side occlusion.
4. Verify instrument stops running, alarms and displays "OCCLUSION FLUID SIDE/EMPTY CONTAINER" within 30 seconds.
5. Press **SILENCE** key on Programming Module to silence alarm.
6. Remove or open clamp on line.
7. Press **RESTART** key on Pump Module to resume infusion. Alarm should not reoccur.
8. Open Pump Module door.
9. Verify Pump Module displays "CLOSE DOOR" and Programming Module displays "ALARM".
10. Remove set from Pump Module.
11. Close Pump Module door.
12. Verify Pump Module displays "CHECK IV SET".

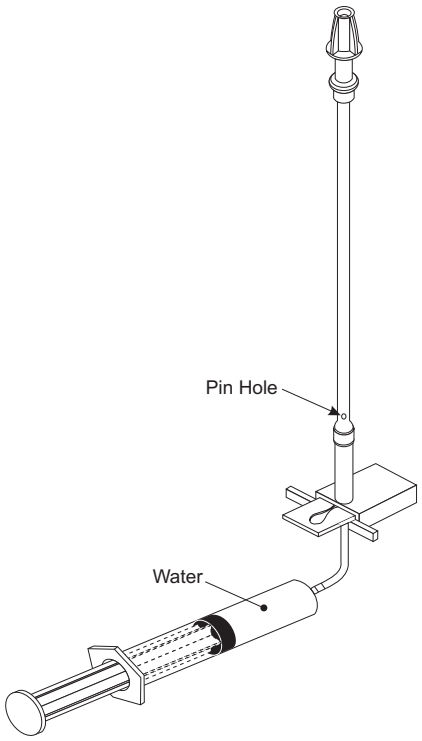
Flo-Stop® Device Test

1. Turn power off with administration set primed and loaded in instrument.
2. With all tubing clamps open and fluid container two or more feet above instrument, verify no fluid flows out of set.
3. Remove set. Verify no fluid flows out of set.

Functional Tests (Continued)

Air-in-Line Test

Fluid Side Occlusion Test Setup



1. Fill Air-in-Line Simulator with water. Push plunger until water drips from hole in tubing.
2. Install Air-in-Line Simulator into Pump Module.
3. Set rate to 125 mL/h. Set VTBI to 1000 mL.
4. Start Pump Module, pull plunger back until water is no longer in Air-in-Line Simulator and immediately start to count. Air-in-line alarm should sound after two seconds.

Functional Tests (Continued)

Battery Run-Time Test

NOTE: *This test is only required when performing a check-in on a "recently serviced" instrument.*

Nickel Metal Hydride batteries lose capacity over time, dependent on usage patterns; such as, frequency and depth of discharge. Since rate of loss increases as capacity diminishes, ALARIS Medical Systems recommends replacement of batteries if the run-time for one channel operating at 125 mL/h is less than four hours. To check run-time:

1. Ensure battery is fully charged by connecting Programming Module to AC power for a minimum of five hours.
2. Disconnect instrument from AC.
3. Power instrument on and verify battery icon flashes on front panel.
4. Set up a primary infusion. Set rate to 125 mL/h and VTBI to 9999 mL. Start instrument.
5. When instrument system voltage falls below 11.9 VDC, a low battery message will flash in Main Display, accompanied by a short beep every two seconds. At 11.5 VDC, instrument will pause all channels, display a Battery Discharged screen in Main Display and emit a constant alarm audio. This indicates a Low Battery-2 condition and constitutes completion of run-time test.

Inspection Checklist

I.D. Number: _____ Instrument Serial Number: _____

	Pass	Fail	Date Completed
Regular Inspection			
Ground Current Leakage Test			
Ground Resistance Test			
Functional Test			
Rate Accuracy Verification			
Patient Side Pressure Test			
Fluid Side Occlusion Test			
Flo-Stop® Device Test			
Air-in-Line Test			
Battery Run-Time Test			

I.D. Number: _____ Instrument Serial Number: _____

	Pass	Fail	Date Completed
Regular Inspection			
Ground Current Leakage Test			
Ground Resistance Test			
Functional Test			
Rate Accuracy Verification			
Patient Side Pressure Test			
Fluid Side Occlusion Test			
Flo-Stop® Device Test			
Air-in-Line Test			
Battery Run-Time Test			

If an instrument fails any test, contact ALARIS Medical Systems® Technical Support.

Storage

Plug the Programming Module into an AC outlet during storage, to ensure a fully charged battery when needed.

(AC indicator light) will be on whenever the Programming Module is plugged in.

Battery Care and Maintenance

Battery Type and Charging

The MEDLEY™ Programming Module is equipped with a 12 volt, 4200 mAh nickel metal hydride battery. The battery is charging whenever the instrument is plugged into an AC receptacle. The life expectancy of the battery is dependent on the amount of use, the depth of discharge, and the state of the charge that is maintained. Generally, the battery will have the longest life (recommended replacement = 2 years) if the instrument is plugged in and battery use is infrequent. Frequent use of battery power and insufficient battery charge cycles will significantly decrease the life of the battery.

The quality of the battery is also a significant factor in determining battery life and runtime. The battery cannot be repaired and should not be opened. Replace the battery with the same type, size and voltage rating. Use of any other brand may yield poor performance and is not recommended.

The battery pack can only be installed when orientated properly. Ensure the battery contacts are facing inward (between Programming Module and battery pack) and the notches on the battery case are oriented to match with those on the Programming Module.

Batteries should be charged in a room with a temperature between 50 - 80.6°F (10 - 27°C), to minimize charge time and maximize battery life.

Battery run time is a function of the number of attached channels and the channel activity. A fully charged battery will provide approximately eight hours of operation with one Pump Module infusing at 25 mL/h, four hours of operation with four Pump Modules infusing at 25 mL/h, and six hours of operation with one active SpO_2 Module. Fully discharged batteries will recharge to 90% of capacity in three hours and will return to a fully charged condition within six hours in an ambient temperature between 50 - 80.6°F (10 - 27°C). Charging at temperatures outside of the specified range will increase charge time considerably and may reduce battery cycle life.

Battery Care and Maintenance (Continued)

Battery Care

The battery capacity should be checked at least once every six months. Refer to the MEDLEY™ System Technical Service Manual for test and replacement procedures.

If the Programming Module is to be stored at temperatures in excess of 86°F (30°C) for one or more months, the battery should be removed and placed in an environment between 50 – 86°F (10 – 30°C).

If the batteries are to be stored for more than one year, they should be charged at least once per year to prevent leakage and deterioration in performance due to self-discharge.

When the battery is first being put into use, or has been out of use for one or more months, it will not have full capacity due to deactivation of reactants.

Restore such batteries to original performance by repeating one or two cycles of fully charging and fully discharging.

Some temporary reduction in capacity might become apparent if the battery is repeatedly discharged less than completely. Doing one or two cycles of full discharge and full charge can restore full performance.

Battery Cautions and Disposal

Battery replacement should be performed by qualified service personnel while the instrument is not in use.

CAUTION

DO NOT open, incinerate or short circuit. Worn–out batteries must be disposed of properly, according to local regulations.

Battery Charge

- The MEDLEY™ Programming Module is shipped with the battery in a discharged condition. Connect the power cord to an AC receptacle and allow the battery to charge for six hours.
- Whenever possible, leave the power cord connected to an external AC power source while operating.

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Cleaning

DO NOT spray cleaning fluids directly onto the instrument or immerse the instrument in fluids.

DO NOT use solutions containing phosphoric acid (Foamy Q&A*), aromatic solvents (naphtha, paint thinner, etc.), chlorinated solvents* (Trichloroethane, MEK, Toluene, etc.), ammonia, acetone, benzene, xylene or alcohol, other than as specified below.

DO NOT use hard or pointed objects to clean any part of the instrument.

Acceptable cleaning solutions are:

Warm water
Mild detergent (such as, Manu-Klenz)
10% bleach solution (1 part bleach to 9 parts water)
Compublend II
Envirocide
2% Glutaraldehyde in water
Hydrogen Peroxide 3%
70% Isopropyl Alcohol
2% Phenols in water (O-Syl 1:128, Pheno-Cen 1:256, Vesphene)
10% Providone Iodine (Betadine)
Quaternaries 1:512
WEX-CIDE

NOTE: *All recommended solutions must be diluted per the Manufacturer's recommendation.*

1. Keep instrument upright and do not allow any part of instrument to become saturated with or submersed in fluid during cleaning operation.
2. Use a soft cloth dampened with warm water and a mild nonabrasive cleaning solution to clean all exposed surfaces. For sanitizing or antibacterial treatment, use 10% bleach solution and water.

   NOTE: *A soft-bristled brush may be used to clean hard to reach and narrow areas.*
3. Use a soft cloth dampened with water to rinse off cleaning solution.

WARNING

Turn the instrument off and unplug the power cord from the AC power source before cleaning. Do not spray fluids directly onto the rear case of the instrument. Do not steam autoclave, EtO sterilize, immerse the instrument or allow fluids to enter the instrument case. Failure to follow these instructions may result in an electrical hazard.

CAUTION

The solutions/solvents identified as NOT to be used can damage the surfaces of the instrument.

* *Excluding 10% bleach solution in water.*

Inspection Requirements

To ensure the system remains in good operating condition, both regular and periodic inspections are required.

Regular inspections consist of a visual inspection for damage and cleanliness, and performing the procedure described in the Start-Up Sequence section of this Directions for Use before each usage of the instrument. Regular inspections are not covered under any contract or agreement offered by ALARIS Medical Systems and must be performed by the user.

WARNING

Failure to perform these inspections may result in improper instrument operation.

REGULAR INSPECTIONS

PROCEDURE	FREQUENCY
INSPECT FOR DAMAGE:	
Enclosure	Each usage
Power Cord	Each usage
Communication Cable	Each usage
I/O Connector	Each usage
CLEANING	As required
START-UP SEQUENCE	Each usage

Periodic inspections of the hardware are required. For detailed instructions on performing periodic inspections and maintenance, refer to the MEDLEY™ System Technical Service Manual and supplemental service bulletins. A service agreement may be obtained from ALARIS Medical Systems for the performance of all required periodic inspections.

NOTE: *Periodic inspections should only be performed by qualified service personnel.*

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Service Information

NOTE: If the instrument shows evidence of damage in transit, notify the carrier's agent immediately. Do not return damaged equipment to the factory before the carrier's agent has authorized repairs.

If the instrument fails to respond as described in this document and the cause cannot be determined, do not use the instrument. Contact qualified ALARIS Medical Systems® service personnel.

WARNING

Instruments returned from the service depot to your facility may be set to factory defaults and not have a hospital-defined data set loaded. Biomedical personnel in the facility are responsible for checking-in the instrument and ensuring the current hospital-approved data set is loaded.

Customer Service

Within the United States and Canada, information or assistance may be obtained by calling one of the following Customer Service toll–free numbers:

United States:	(800) 482-4822
Canada:	
Eastern	(800) 908-9918
Western	(800) 908-9919

Technical Support

Technical Support can be contacted by calling one of the following toll–free numbers:

United States:	(800) 854-7128, extension 6003
Canada:	
Eastern	(800) 227-7215
Western	(800) 667-2335

Outside the United States and Canada, service information, applications, and manuals may be obtained by contacting your local ALARIS Medical Systems® Service Department or distribution center.

When submitting any request for service, include:

- a description of difficulty experienced
- Programming Module serial number, and description and serial number of all attached channels
- administration set/lot number
- solution(s) used
- message displayed at time of difficulty

Product Return

If it is necessary to return the instrument for service, obtain a return authorization number prior to shipment. Carefully package the instrument (preferably in the original packaging), reference the return authorization information, and return it to the appropriate service or distribution center. ALARIS Medical Systems does not assume any responsibility for loss of, or damage to, returned instruments while in transit.

WARRANTY

ALARIS Medical Systems, Inc., (hereinafter referred to as "ALARIS Medical Systems") warrants that:

A. Each new ALARIS Medical Systems® MEDLEY™ Medication Safety System is free from defects in material and workmanship under normal use and service for a period of one (1) year from the date of delivery by ALARIS Medical Systems to the original purchaser.

B. The battery and each new accessory is free from defects in material and workmanship under normal use and service for a period of ninety (90) days from the date of delivery by ALARIS Medical Systems to the original purchaser.

If any product requires service during the applicable warranty period, the purchaser should communicate directly with the relevant account representative to determine the appropriate repair facility. Except as provided otherwise in this warranty, repair or replacement will be carried out at ALARIS Medical Systems' expense. The product requiring service should be returned promptly, properly packaged and postage prepaid by purchaser. Loss or damage in return shipment to the repair facility shall be at purchaser's risk.

In no event shall ALARIS Medical Systems be liable for any incidental, indirect or consequential damages in connection with the purchase or use of any ALARIS Medical Systems® product. This warranty shall apply solely to the original purchaser. This warranty shall not apply to any subsequent owner or holder of the product. Furthermore, this warranty shall not apply to, and ALARIS Medical Systems shall not be responsible for, any loss or damage arising in connection with the purchase or use of any ALARIS Medical Systems® product which has been:

(a) repaired by anyone other than an authorized ALARIS Medical Systems service representative;

(b) altered in any way so as to affect, in ALARIS Medical Systems' judgment, the product's stability or reliability;

(c) subjected to misuse or negligence or accident, or which has had the product's serial or lot number altered, effaced or removed;

or

(d) improperly maintained or used in any manner other than in accordance with the written instructions furnished by ALARIS Medical Systems.

This warranty is in lieu of all other warranties, express or implied, and of all other obligations or liabilities of ALARIS Medical Systems, and ALARIS Medical Systems does not give or grant, directly or indirectly, the authority to any representative or other person to assume on behalf of ALARIS Medical Systems any other liability in connection with the sale or use of ALARIS Medical Systems® products.

ALARIS MEDICAL SYSTEMS DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR APPLICATION.

See packing inserts for international warranty, if applicable.

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