Medley™

MEDICATION SAFETY SYSTEM

PROGRAMMING MODULE
8000 Series
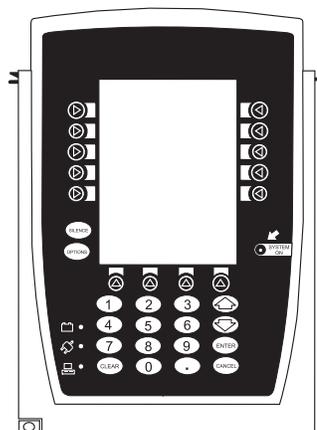
DIRECTIONS FOR USE

TABLE OF CONTENTS

MAINTENANCE (Continued)

GENERAL CONTACT INFORMATION

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
E-Mail: CustomerFeedback@alarismed.com

Technical Support

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

United States:

Phone:

  (858) 458-6003
  Toll-free: (800) 854-7128, Ext. 6003

Canada:

Phone, Toll-free:

  Eastern: (800) 908-9918
  Western: (800) 908-9919

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

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About the System

The Medley™ Medication Safety System is a modular infusion and monitoring system intended for use in today's growing professional healthcare environment, for use in adult, pediatric and neonatal care.

The Medley™ Medication Safety System consists of the Programming Module (8000 Series), the Guardrails® Safety Software, and up to four detachable modules (or "channels") which provide infusion or monitoring capabilities.

The Medley™ Programming Module is the core of the Medley™ System and provides a common user interface for programming infusions and monitoring, which helps to reduce complexity at the point of care.

> NOTE: The Medley™ Programming Module name will be changing in the near future to Medley™ Point-of-Care Unit.

Guardrails® Safety Software for the Medley™ System brings a new level of medication error prevention to the point of patient care. The Guardrails® Safety Software features medication dosing guidelines for up to ten patient-specific care areas, referred to as profiles. Each profile contains a specific drug library and channel labels, as well as instrument configurations appropriate for the care area. Optional drug-specific Guardrails® Clinical Advisories provide visual messages. Dosing limits for each drug entry may be either Guardrails® Hard Limits that cannot be overridden during infusion programming or Guardrails® Soft Limits that can be overridden, based on clinical requirements.

A data set is developed and approved by the facility's own multi-disciplinary team using the Guardrails® Editor, the PC-based authoring tool. A data set is then electronically transferred to the Medley™ System by qualified personnel. The approved data sets are maintained by the Guardrails® Editor for future updates and reference.

Information about Guardrails® Alerts that occur during use is stored within the Medley™ Programming Module, and can be accessed using the Guardrails® Continuous Quality Improvement (CQI) Event Tracker and Guardrails® CQI Event Reporter.

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

Refer to the "Alarms, Errors, Messages" chapter of this Directions for Use for the definitions of various alerts. Refer to the Directions for Use that applies to the attached Medley™ Module(s) for features and definitions specific to that module.

Anesthesia Mode	The Anesthesia Mode allows the anesthesiologist to access additional drugs, in each profile, that are appropriate to anesthesiology. It also features permanent pause.
Battery Run Time Display	The Battery Run Time Display appears on the Main Display prompt bar when the Programming Module is disconnected from AC. If enabled, this feature provides a visual display of the estimated remaining battery run time under the current operating conditions, when operating on battery.
Data Set	A data set is created using the Guardrails® Editor authoring tool and then electronically transferred to the Medley™ Programming Module. A data set reflects the facility's best-practice guidelines for IV drug administration and includes: profile drug libraries, clinical advisories, instrument configurations, and channel label libraries.
Dose Checking	The Always Dose Checking option causes a Guardrails® Soft Alert to occur each time a dose limit is exceeded. The drug label in the Channel Message Display provides an indicator ("↑↑↑" or "LLL") that the infusion is beyond the current Guardrails® Soft Limit.
	The Smart Dose Checking option causes an initial Guardrails® Soft Alert to occur when a dose limit is exceeded. Subsequent programming beyond the dose limit will not receive an alert. The drug label in the Channel Message Display provides an indicator ("↑↑↑" or "LLL") if the infusion is beyond the current Guardrails® Soft Limit.
Ease of Use	To enhance safety and ease of operation, the Medley™ System provides a full range of audio and visual alarms, errors, and messages.
Guardrails® Safety Software	The Guardrails® Safety 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 a Guardrails® Prompt if an out-of-limits entry is made.

Patient ID Entry	An optional alphanumeric 16-character patient identifier can be entered and displayed.

- When enabled, the ID entry defaults to the Startup screen.
- When disabled, the ID entry is only accessible from the System Options screen.

Pole Clamp	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.

Profile	A Profile is a unique set of system configuration settings and best-practice guidelines for a specific patient population or patient type, and consists of the following three components:

- Instrument configuration settings.
- A Guardrails® Drug Library, which includes drug names, standard concentrations, dosing units, Guardrails® Limits, and optional associated clinical advisories for both continuous and bolus dose infusion.
- A Channel Label Library with text (alphanumeric) labels, that allows identification of channels that are actively infusing nondrug therapies (for example, saline or TPN). Channel labels can also be used to identify the route of delivery (for example, epidural).

Profile settings are established by the facility's own multi-disciplinary team prior to system implementation. Profile parameters are used to create a data set, which is then electronically transferred to the Programming Module.

System Configuration	System Configurations allow system settings to be customized. 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.

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 attached modules.

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.

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.

NOTE: Although the Medley™ Medication Safety 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

WARNING

A warning is an alert to potential serious outcomes (death, injury or serious adverse events) to the patient or user.

CAUTION

A caution is an alert to take special care for the safe and effective use of the device.

Warnings and Cautions

For **WARNINGS** and **CAUTIONS** for detachable module(s), refer to the individual module'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 between modules. If not properly latched, a module can be dislodged during operation.

WARNING

Do not use the Medley™ System in close proximity of Magnetic Resonance Imaging (MRI).

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.

- The instrument case should only be opened by qualified service personnel using proper grounding techniques.

WARNING

Electrical shock hazard. Do not open case. Refer to qualified service personnel.
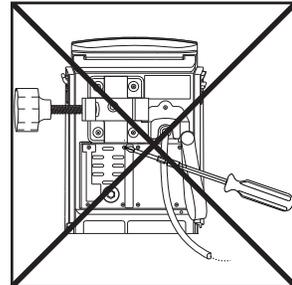
Dropping/Jarring

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.
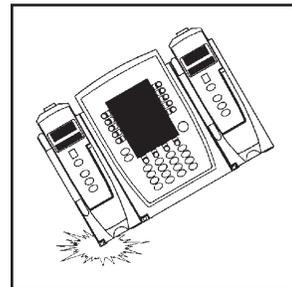
Operating Environment

Not for use in the presence of flammable anesthetics.

◄ DANGER ►

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

DANGER

EXPLOSION HAZARD

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.

Front/Side View

IUI Connector, Left
(not visible)

IUI Connector, Right

Handle

Main Display

Soft Keys - When pressed, allows selection of options or infusion parameters appearing on 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, sequentially backs out of current setup sequence.

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

Numeric Keypad

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

Rear View

IUI Connector, Right

IUI Connector, Left

Handle

Pole Clamp Knob

AC Power Cord Safety Retainer

Use this bolt to reorient Pole Clamp 90° for attachment to a bed rail instead of a pole.

Power Cord Strap

Primary Audio Speaker

Connector Plug over RJ45 Communication Data Port

Tamper Resist Switch

Option Upgrade Panel (for future use)

Installation

Instruments are tested and calibrated before they are packaged for shipment. To ensure proper operation after shipment, it is recommended that an incoming inspection be performed before placing the instrument in use.

To enable the Profiles feature, a hospital-defined best-practice data set must be uploaded to the Programming Module. Prior to placing the Medley™ System in use, verify whether or not the Profiles feature has been enabled (reference "Reviewing System Configuration" section in "Getting Started" chapter).

Unpacking Programming Module

1. Remove Programming Module from its carton.

2. Check pole clamp for freedom of operation.

3. Check AC power entry module for contamination.

4. Check for loose parts.

5. Plug module into an AC outlet for 24 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.

6. Perform Periodic Inspections (see "Inspection Requirements" section in "Maintenance" chapter).

7. Perform check-in procedure [reference Medley™ Maintenance Software User Manual (included with 8970C, or later) for details].

If the Programming Module is damaged, contact ALARIS Medical Systems for authorization to return the equipment for repair.

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.
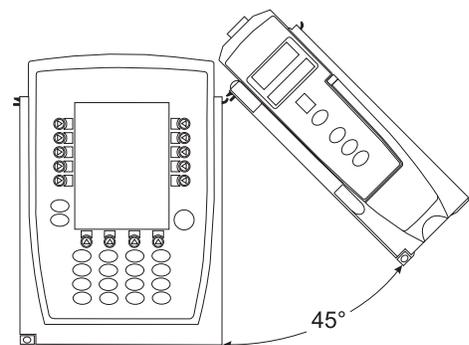
Attaching Channel(s)

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.*

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

45°

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.

    *   Medley™ System reidentifies and shows appropriate channel identification (A, B, C or D), from left to right.

    *   Appropriate channel position(s) (A, B or C) for remaining channel(s) appear on 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.*

Release Latch
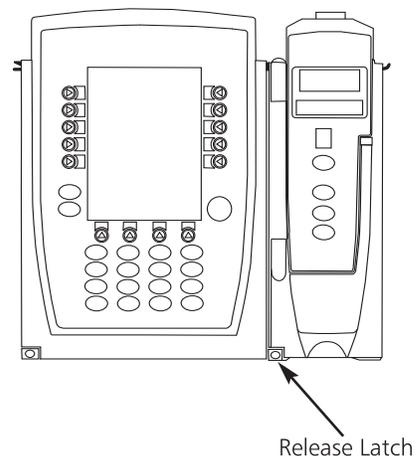
Adding Channel(s) While System is Powered On

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

IUI Connectors

- 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) appear on 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.
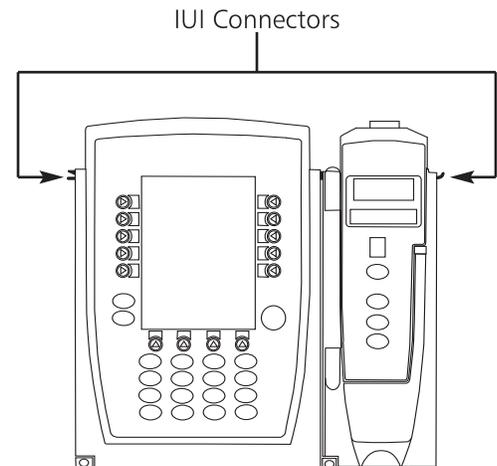
Displays

The displays illustrated throughout this document are for illustration purposes only. The display content will vary, depending on configuration settings, hospital-defined data set uploaded using the Guardrails® Safety Software, and many other variables.

Main Display

Title Bar

Midtown Hospital
Adult ICU

Channel Status

A VTBI = 250.0 mL
B
C
D

- A solid channel letter display indicates channel is operating.
- An outlined channel letter display indicates channel is attached and ready for use.

Soft Keys

VOLUME INFUSED

AUDIO ADJUST

Main Display (Continued)

Channel Selected Indicator

"Inactive" Soft Key

Nonhighlighted indicates a nonselected soft key.

"Active" Soft Key

Highlighted indicates a selected soft key.

Prompt Bar

Look here for user prompts.

```
A  Infusion Setup
      RATE        40 mL/h
      VTBI       _250 mL

   >Press START

   PAUSE    SECOND-    START
             ARY
```
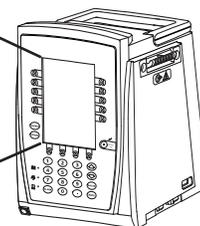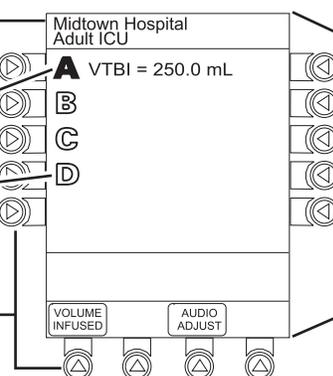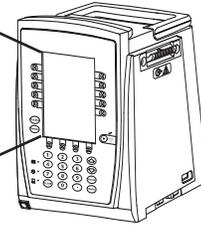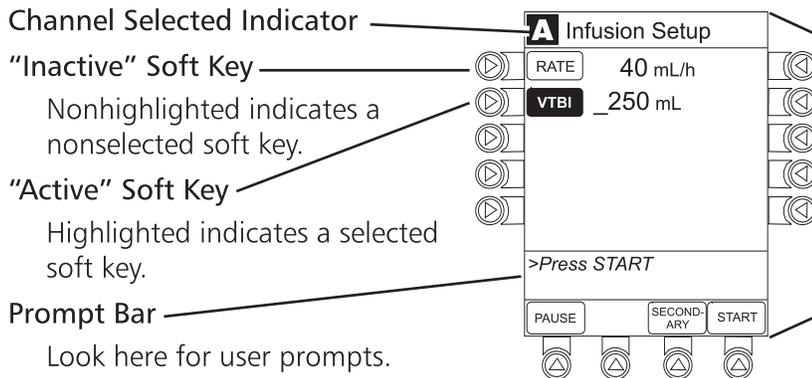
Adjusting Display Contrast

1. Press **OPTIONS** key.

2. Select **Display Contrast** soft key.

```
System Options 1 of 3
Display Contrast
Patient ID
Time of Day
Power Down All Channels
Anesthesia Mode

>Select an Option or
EXIT
      EXIT          PAGE
                    DOWN
```
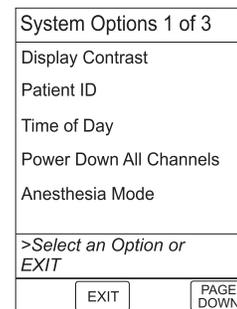
3. To adjust display for optimum viewing, use **Lighter/Darker** soft keys.

4. To return to main screen, press **MAIN SCREEN** soft key.

```
System Options
Display Contrast

ALARIS®        Lighter
Medley™        Darker
Medication Safety System

>Adjust Display to
Desired Contrast
                MAIN
                SCREEN
```
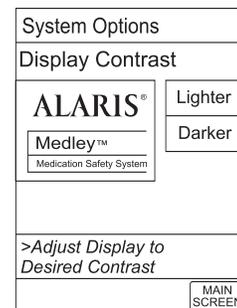
Powering On System

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.

    *   If PM Reminder option is enabled and scheduled preventive maintenance is due, **MAINTENANCE REMINDER** screen appears.

> *NOTES:*
>
> *   *Previous infusion parameters are automatically cleared after eight (8) hours.*
>
> *   *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 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 an alternate IUI connector, it may be used until a replacement channel can be substituted.*

Responding to Maintenance Reminder

If the Preventive Maintenance (PM) Reminder option is enabled and the Programming Module or an attached module is due for preventive maintenance, a **MAINTENANCE REMINDER** message appears at power up.

> *NOTES:*
>
> - *If necessary, the reminder can be temporarily bypassed by pressing the **CONFIRM** soft key.*
> - *Notify the appropriate facility personnel when a **MAINTENANCE REMINDER** occurs.*

1. Remove and, if needed, replace module requiring maintenance with a new module (reference "Attaching and Detaching Channels" section).

2. If "system" (Programming Module and attached modules) was powered off to replace Programming Module, reinitiate start-up process.

    OR

    If an "attached module" (such as, a Pump Module) was powered off and removed, **MAINTENANCE REMINDER** display reflects removal of that channel. To continue start–up process, press **CONFIRM** soft key.

```
MAINTENANCE REMINDER

Module(s) due for routine
preventative maintenance:

Module A:   YYYY-MM-DD



CONFIRM
```

```
MAINTENANCE REMINDER

Module(s) due for routine
preventative maintenance:




CONFIRM
```

Selecting New Patient and Profile Options

The option to enter and display a 16-character alphanumeric patient identifier is always available. The instrument may be configured to automatically display the **Patient ID Entry** screen during start up or to provide access only through the **Systems Options** menu.

The following procedures assume the Profiles feature is enabled.

> *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 "Displays", "Adjusting Display Contrast" section).*

GETTING STARTED

Selecting New Patient and Profile Options (Continued)

Patient ID Entry Feature <u>Disabled</u>

1. Select required **NEW PATIENT?** option.

   To indicate programming is for a new patient and clear all stored patient parameters from memory, press **Yes** soft key.

       OR

   To confirm programming is for same patient and retain all stored patient parameters, press **No** soft key.

   - Last used profile displays.

   > **NOTE:** If the Profiles feature is disabled, the main menu appears.

Midtown Hospital	
NEW PATIENT ?	Yes
"Yes" Clears Previous Patient Data	No
>*Select Yes or No*	
DISPLAY CONTRST	

2. Select correct profile.

   To accept current profile, press **Yes** soft key and proceed to step 5.

   - Main screen appears.

       OR

   To change profile, press **No** soft key and continue with next step.

   - Profile selection screen appears.

Midtown Hospital Adult ICU	
Adult ICU ?	Yes
"Yes" Confirms Same Profile	No
>*Select Yes or No*	

3. To select a profile, press corresponding left soft key.

   > **NOTES:**
   >
   > - To view additional choices, press **PAGE DOWN** soft key.
   >
   > - To view system configuration settings for desired profile, press **View** soft key for that profile.

4. To confirm profile selection, press **CONFIRM** soft key.

   - Main screen appears.

5. To enter Patient ID, if desired, see "Entering Patient ID" section.

Midtown Hospital Profiles	1 of 2
Adult ICU	View
Adult General Care	View
Neonatal	View
Peds ICU	View
Neonatal ICU	View
>*Select a Profile and Confirm*	
CONFIRM	PAGE DOWN

Selecting New Patient and Profile Options (Continued)

Patient ID Entry Feature Enabled

1. Select required **NEW PATIENT?** option.

    - To indicate programming is for a new patient and clear all stored patient parameters from memory:

        a. Press **Yes** soft key.

            ◆ **Patient ID Entry** screen appears.

    ```
    Midtown Hospital
    ┌──────────────────────┬──────┐
    │ NEW PATIENT ?        │ Yes  │
    │ "Yes" Clears Previous├──────┤
    │ Patient Data         │ No   │
    └──────────────────────┴──────┘




    >Select Yes or No

    ┌──────────┐
    │ DISPLAY  │
    │ CONTRST  │
    └──────────┘
    ```

        b. If patient identifier is not required, press **CONFIRM** soft key.

            OR

            Enter patient identifier (reference "Entering Patient ID" section).

            ◆ Last used profile displays.

    ```
    Patient ID Entry

    A                        A-E

    B                        F-J

    C                        K-O

    D                        P-T

    E                        U-Y
    _____
    >Enter Patient ID and Press
    CONFIRM
    ┌──────┬─────────┬──────┐
    │ EXIT │ CONFIRM │ PAGE │
    │      │         │ DOWN │
    └──────┴─────────┴──────┘
    ```

    -- **OR** --

    - To confirm programming is for same patient and retain all stored patient parameters, press **No** soft key.

        ◆ Last used profile displays.

        > *NOTE: If the Profiles feature is disabled, the main menu appears.*

2. Select correct profile.

    To accept current profile, press **Yes** soft key.

    - Main screen appears.

        OR

    To change profile, press **No** soft key and continue with next step.

    - Profile selection screen appears.

    ```
    Midtown Hospital
    Adult ICU
    ┌──────────────────────┬──────┐
    │ Adult ICU ?          │ Yes  │
    │ "Yes" Confirms Same  ├──────┤
    │ Profile              │ No   │
    └──────────────────────┴──────┘




    >Select Yes or No
    ```

GETTING STARTED

Selecting New Patient and Profile Options (Continued)

Patient ID Entry Feature Enabled (Continued)

3. To select a profile, press corresponding left soft key.

> *NOTES:*
>
> • *To view additional choices, press **PAGE DOWN** soft key.*
>
> • *To view system configuration settings for desired profile, press **View** soft key for that profile.*

4. To confirm profile selection, press **CONFIRM** soft key.

    • Main screen appears.

Midtown Hospital Profiles	1 of 2
Adult ICU	View
Adult General Care	View
Neonatal	View
Peds ICU	View
Neonatal ICU	View

>Select a Profile and Confirm

CONFIRM PAGE DOWN

Entering Patient ID

When the Patient ID Entry feature is disabled, the **Patient ID Entry** screen can only be accessed through the **Systems Options** menu. To enter a patient ID, begin with step 1 of the following procedure.

When the Patient ID Entry feature is enabled, the **Patient ID Entry** screen appears after responding **Yes** to **New Patient?** prompt. To enter a patient ID, begin with step 2 of the following procedure.

1. To access **Patient ID Entry** screen:

    a. Press **OPTIONS** key.

        • **System Options** menu appears.

    b. Press **Patient ID** soft key.

        • **Patient ID Entry** screen appears.

System Options 1 of 3
Display Contrast
Patient ID
Time of Day
Power Down All Channels
Anesthesia Mode

>Select an Option or EXIT

EXIT PAGE DOWN

Entering Patient ID (Continued)

2. To enter patient identifier, use numeric data entry keys and/or alpha speed keys.

> *NOTES:*
>
> *   *An alphanumeric identifier, of up to 16 characters, can be entered.*
> *   *Press the soft key next to a letter group to list letters in that group. Press the soft key next to an individual letter to enter that letter.*
> *   *To access the letter "Z" and special characters (hyphen, underscore, space), press the **PAGE DOWN** soft key.*
> *   *To clear an entire entry, press **CLEAR** key.*
> *   *To back up a single character at a time, press **CANCEL** key.*

```
Patient ID Entry
A                          A-E
B                          F-J
C                          K-O
D                          P-T
E                          U-Y
_ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _
>Enter Patient ID and Press
CONFIRM
            EXIT   CONFIRM   PAGE
                             DOWN
```

3. To verify correct entry, press **CONFIRM** soft key.

    *   If accessed from **New Patient?** screen, last used profile appears.
    *   If accessed from **Systems Options** menu, main screen appears.
    *   Patient ID appears on main screen, current profile screen, and **New Patient?** screen.

```
Patient ID Entry
A                          A-E
B                          F-J
C                          K-O
D                          P-T
E                          U-Y
 123456789CD_ _ _ _ _
>Enter Patient ID and Press
CONFIRM
            EXIT   CONFIRM   PAGE
                             DOWN
```

Modifying Patient ID

1. Press **OPTIONS** key.

    *   **System Options** menu appears.

2. Press **Patient ID** soft key.

    *   **Patient ID Entry** screen appears.

```
System Options 1 of 3
Display Contrast
Patient ID
Time of Day
Power Down All Channels
Anesthesia Mode

>Select an Option or
EXIT
            EXIT           PAGE
                           DOWN
```

GETTING STARTED

Modifying Patient ID (Continued)

3. To clear entire entry, press **CLEAR** key.

    OR

    To back up a single character at a time, press **CANCEL** key.

```
Patient ID Entry

A                      A-E
B                      F-J
C                      K-O
D                      P-T
E                      U-Y
 123456789CD
>Enter Patient ID and Press
CONFIRM
              EXIT  CONFIRM  PAGE
                             DOWN
```

4. To enter modified patient identifier, use numeric data entry keys and/or alpha speed keys.

    > **NOTES:**
    > - *An alphanumeric identifier, of up to 16 characters, can be entered.*
    > - *Press the soft key next to a letter group to list letters in that group. Press the soft key next to an individual letter to enter that letter.*
    > - *To access the letter "Z" and special characters (hyphen, underscore, space), press the **PAGE DOWN** soft key.*

```
Patient ID Entry

A                      A-E
B                      F-J
C                      K-O
D                      P-T
E                      U-Y
_ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _
>Enter Patient ID and Press
CONFIRM
              EXIT  CONFIRM  PAGE
                             DOWN
```

5. To verify correct entry, press **CONFIRM** soft key.

    - Patient ID Entry verification screen appears.

```
Patient ID Entry

A                      A-E
B                      F-J
C                      K-O
D                      P-T
E                      U-Y
 234567891EF_ _ _ _ _
>Enter Patient ID and Press
CONFIRM
              EXIT  CONFIRM  PAGE
                             DOWN
```

6. To accept modified Patient ID, press **Yes** soft key.

    - Main screen appears with new Patient ID.
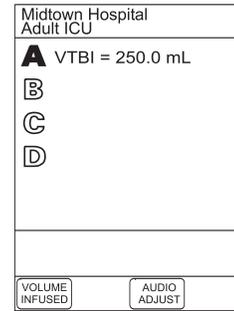
        OR

    To retain original (old) Patient ID, press **No** soft key.

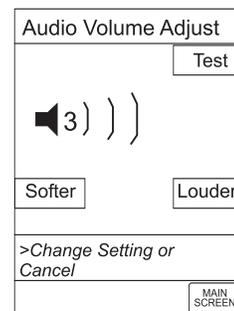   - Main screen appears with old Patient ID.

```
Patient ID Entry

Patient ID              Yes
123456789CD
will be changed to      No
234567891EF

Is this correct?



>Press Yes or No

```

Adjusting Audio Volume

1. Press **Audio Adjust** soft key.

```
Midtown Hospital
Adult ICU

A  VTBI = 250.0 mL
B
C
D


┌─────────┐        ┌────────┐
│VOLUME   │        │AUDIO   │
│INFUSED  │        │ADJUST  │
└─────────┘        └────────┘
```
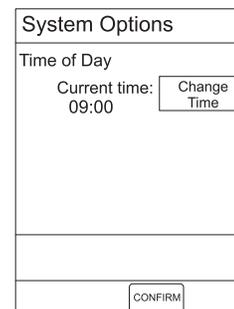
2. To change volume to desired level, press either **Louder** or **Softer** soft key. To sample alarm loudness level, **Test** soft key may be pressed.

3. To return to Programming Module screen, press **MAIN SCREEN** soft key.

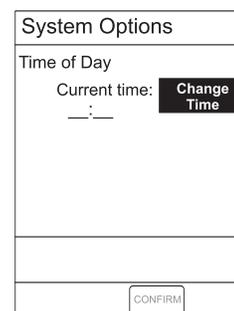   • After 30 seconds without a key press, Main Display appears.

```
Audio Volume Adjust
                    ┌──────┐
                    │ Test │
                    └──────┘

      ◀3 ) ) )

┌────────┐          ┌────────┐
│ Softer │          │ Louder │
└────────┘          └────────┘

>Change Setting or
Cancel
                    ┌──────┐
                    │ MAIN │
                    │SCREEN│
                    └──────┘
```

Setting Up Time of Day

1. Press **OPTIONS** key.

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

```
System Options

Time of Day
           Current time:  ┌────────┐
               09:00      │ Change │
                          │  Time  │
                          └────────┘




                    ┌─────────┐
                    │ CONFIRM │
                    └─────────┘
```

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

```
System Options

Time of Day
           Current time:  ┌────────┐
               __:__      │ Change │
                          │  Time  │
                          └────────┘




                    ┌─────────┐
                    │ CONFIRM │
                    └─────────┘
```

4.   Enter current Time of Day.

5.   Press **Confirm** soft key.

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

```
System Options
─────────────────────────────
Time of Day
        Current time:   ┌────────┐
             14:30      │ Change │
                        │  Time  │
                        └────────┘



─────────────────────────────

                       ┌─────────┐
                       │ CONFIRM │
                       └─────────┘
```

Reviewing System Configuration

1.   Press **OPTIONS** key.

2.   Press **PAGE DOWN** soft key.

3.   Press **System Configuration** soft key.

4.   Select **Programming Module**.

```
System Config - Module 1 of 2
─────────────────────────────
Factory Default:        Yes

Shared Infusion Settings

Programming Module

Pump Module

SPO2 Module

>Press CANCEL or EXIT
─────────────────────────────
   ┌──────┐        ┌──────┐
   │ EXIT │        │ PAGE │
   └──────┘        │ DOWN │
                   └──────┘
```

5.   To review various system configuration settings, press **PAGE UP** and **PAGE DOWN** soft keys.

6.   To return to main screen, press **CANCEL** key or **EXIT** soft key.

```
System Config - PM 1 of 2
─────────────────────────────
Alarm Audio:          Profile 1

Anesthesia Mode:  Disabled

Battery Meter:        Disabled

Clock Setup:          09:00

Dose Checking:      ALWAYS
─────────────────────────────
>Press CANCEL or EXIT
   ┌──────┐        ┌──────┐
   │ EXIT │        │ PAGE │
   └──────┘        │ DOWN │
                   └──────┘
```

```
System Config - PM 2 of 2
─────────────────────────────
Patient ID Entry:   Enabled
Max Pt. weight:     100 kg

PM reminder:        Enabled

Profiles:           Disabled

Tamper resist:      Disabled


>Press CANCEL or EXIT
   ┌──────┐ ┌──────┐
   │ PAGE │ │ EXIT │
   │  UP  │ └──────┘
   └──────┘
```

1. Press **OPTIONS** key.

2. Press **Page Down** soft key.

System Options 1 of 3
Display Contrast
Patient ID
Time of Day
Power Down All Channels
Anesthesia Mode
>*Select an Option or EXIT*
[EXIT]　　　　　[PAGE DOWN]

3. Press **Serial Numbers** soft key.

System Options 2 of 3
Battery Runtime
System Configuration
Serial Numbers
Software Versions
Guardrails Event Counter
>*Select an Option or EXIT*
[PAGE UP]　[EXIT]　　　[PAGE DOWN]

- Serial numbers for Programming Module and all attached modules display.

  > **NOTE:** *"nnnn-nnnnnnnn" in the illustrated display represents a serial number.*

Serial Number Review
PM:　　　　nnnn-nnnnnnnn
Module A:　nnnn-nnnnnnnn
Module B:　nnnn-nnnnnnnn
Module C:　nnnn-nnnnnnnn
Module D:　nnnn-nnnnnnnn
>*Press CANCEL or EXIT*
[EXIT]

4. To return to main screen, press **EXIT** soft key.

GETTING STARTED

1. Press **OPTIONS** key.

2. Press **PAGE DOWN** soft key.

System Options 1 of 3
Display Contrast
Patient ID
Time of Day
Power Down All Channels
Anesthesia Mode
>*Select an Option or EXIT*
EXIT   PAGE DOWN
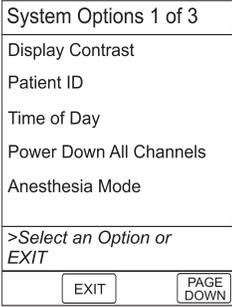
3. Press **Software Versions** soft key.

System Options 2 of 3
Battery Runtime
System Configuration
Serial Numbers
Software Versions
Guardrails Event Counter
>*Select an Option or EXIT*
PAGE UP   EXIT   PAGE DOWN
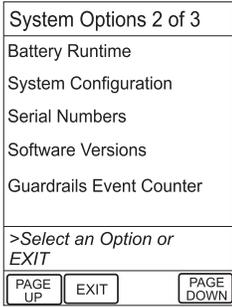
4. To review software version information, press **View** soft key next to desired channel.

   OR

   To return to main screen, press **EXIT** soft key

Software Rev. Review	
APM:	View
Module A:	View
Module B:	View
Module C:	View
Module D:	View
>*Select an Option or EXIT*	
EXIT	
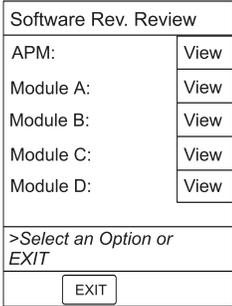
5. To return to previous screen, press **EXIT** soft key.

   > **NOTE:** *"nn.nn" in the illustrated display represents a software version.*
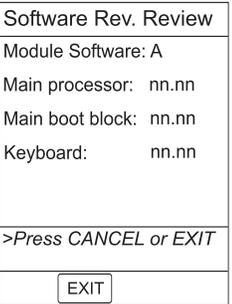
Software Rev. Review
Module Software: A
Main processor: nn.nn
Main boot block: nn.nn
Keyboard: nn.nn
>*Press CANCEL or EXIT*
EXIT

1. Press **OPTIONS** key.

2. Press **PAGE DOWN** soft key.

3. Press **Guardrails Event Counter** soft key.

4. To <u>clear</u> event counter information, press **CLEAR** key and then **EXIT** soft key.

    OR

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

```
System Options 2 of 3

Battery Runtime
System Configuration
Serial Numbers
Software Versions
Guardrails Event Counter

>Select an Option or
EXIT

[PAGE UP]  [EXIT]        [PAGE DOWN]
```

Powering Off

Powering Off System

1. Press **OPTIONS** key.

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

```
System Options 1 of 3

Display Contrast
Patient ID
Time of Day
Power Down All Channels
Anesthesia Mode

>Select an Option or
EXIT

         [EXIT]          [PAGE DOWN]
```

3. Press **Yes** soft key.

   • During power off sequence, Main Display flashes **POWERING DOWN**.

```
System Options


Power Down        Yes
All Channels?     No



>Press Yes or No
```

GETTING STARTED

Powering Off (Continued)

Powering Off Channel

Press and hold **CHANNEL OFF** key until a beep is heard (approximately 1.5 seconds) and then release to initiate power down.

> *NOTE: To interrupt the power down sequence, quickly press any one of the numeric keys on the Programming Module.*

- During power off sequence, Main Display flashes **Powering Down**.

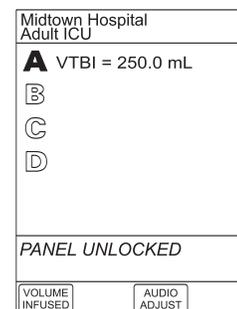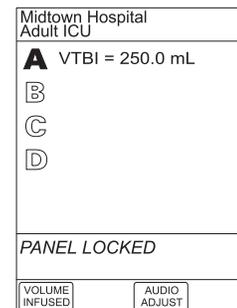- Once all attached channels are powered off, Programming Module automatically powers down.

Powering Down
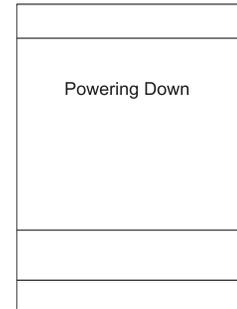
Locking/Unlocking Tamper Resist

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 on Main Display confirm activation. When Tamper Resist is active, keypad panel is locked; however, clinician may:

   - Silence key for audio alarm.
   - View volume(s) 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 on Main Display and, if **Key Click Audio** is enabled, an advisory tone confirms Tamper Resist is off.

Midtown Hospital
Adult ICU
A VTBI = 250.0 mL
Ⓑ
Ⓒ
Ⓓ
PANEL LOCKED
VOLUME INFUSED   AUDIO ADJUST

Midtown Hospital
Adult ICU
A VTBI = 250.0 mL
Ⓑ
Ⓒ
Ⓓ
PANEL UNLOCKED
VOLUME INFUSED   AUDIO ADJUST

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.

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.**

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 3 meters.*

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.

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

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To enhance safety and ease of operation, the Medley™ System provides a full range of audio and visual alarms, errors, and messages.

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® Alert

A visual message to help reduce programming errors by indicating a Guardrails® Limit ("soft" or "hard") has been exceeded. A response is required before programming can continue.

Guardrails® Clinical Advisory

A visual message when a designated drug is selected, to remind clinician of specific hospital standards of practice when programming an IV medication. A specific clinical advisory can be associated with a selected drug within any of the patient care profiles.

Maintenance Reminder

A visual message that, when enabled, appears at module startup when scheduled preventive maintenance is due/overdue for any part of the Medley™ System (Programming Module or attached module).

Prompt

A visual message, appearing on the bottom line of the Main Display or in the Channel Message Display. The message may be accompanied by an audio signal that can be silenced for twelve seconds by pressing the **SILENCE** key.

The Programming Module and Main Display provide various types of alert information. 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: secondary switching to primary. Two short beeps: bolus switching to continuous.	Variable volume; can be silenced and disabled in System Configuration.

Alarms		
Alarm	Meaning	Response
Battery Discharged	Operation of all channels 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) disconnected while in operation or have a communication problem.	To silence alarm and clear message from screen, press **CONFIRM** soft key. Reattach module, if desired, ensuring it is securely "clicked" into place at Channel Release Latch. If alarm is still present, replace channel with an operational instrument.
Very Low Battery <5 minutes to system shutdown	Battery has five minutes or less of power at current power consumption rate before operation stops.	Connect AC power cord to power source; alarm will be silenced.

ALARMS, ERRORS, MESSAGES

Errors

Error	Meaning	Response
Channel Error	Error detected. Operation stops on affected channel.	To silence alarm and continue operation of unaffected channels, press **CONFIRM** soft key . Replace channel with an operational instrument, as required. Service by qualified personnel is required.
Defective Battery	Defective battery detected.	To power down system, press **SYSTEM OFF** soft key; or to continue temporary operation while an operational Programming Module can be located, press **SILENCE** key. Service by qualified personnel is required.
Hardware Detected Error	Error detected 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	Battery detected as not present or not connected.	To power down system, press **SYSTEM OFF** soft key; or to continue temporary operation while an operational Programming Module can be located, press **SILENCE** key. Service by qualified personnel is required.
Power Supply Error	Power supply system malfunction detected.	Disconnect AC power immediately. To power down system, press **SYSTEM OFF** soft key; or to continue operation under battery power while an operational Programming Module can be located, press **SILENCE** key. Service by qualified personnel is required.
System Error	Error detected on Programming Module. Operation continues on all channels.	To power down system, press **SYSTEM OFF** soft key; or to continue temporary operation while an operational Programming Module can be located, press **SILENCE** key. Service by qualified personnel is required.

Messages

Message	Meaning	Response
Battery Run Time = X.X hours	AC power cord is disconnected from power source. Approximate remaining battery run time under current power consumption rate 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	Tamper Resist feature is active and key was pressed.	If appropriate, deactivate Tamper Resist feature using Tamper Resist Control on back of Programming Module.
Panel Unlocked	Tamper Resist feature deactivated.	None.
Powering Down	Last channel powering off. System shuts 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.

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The Medley™ System Technical Service Manual is available from ALARIS Medical Systems. It includes routine service schedules, interconnect diagrams, component parts lists and descriptions, 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, using the service manual and Medley™ Maintenance Software.

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 as follows before a "BATTERY DISCHARGED" message occurs:

- 8 hours with 1 Pump Module infusing at 25 mL/h
- 4 hours with 4 Pump Modules infusing at 25 mL/h
- 6 hours with 1 active SpO$_2$ Module
- 8 hours with 1 Syringe Module infusing at 5 mL/h
- 4 hours with 4 Syringe Modules infusing at 5 mL/h

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

> *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.*

System Configurable Settings

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

> *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	Profile 1	Profile 1, 2 or 3
Anesthesia Mode	Disabled	Enabled - Disabled
Battery Meter Display	Disabled	Enabled - Disabled
Clock Setup (Date and Time)	N/A	Set date and time
Dose Checking	Always	Always, Smart (only with Profiles feature)
Key Click Audio	Enabled	Enabled - Disabled
Max Patient Weight	500 kg	0.1 - 500 kg
Patient ID Entry	Disabled	Enabled - Disabled
Preventive Maintenance (PM) Reminder	Enabled	Enabled - Disabled
Profiles	Disabled	Enabled - Disabled
Tamper Resist	Disabled	Enabled - Disabled

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.

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 Charge

- The Medley™ Programming Module is shipped with the battery in a discharged condition.
- Before the Programming Module is released for use, it 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™ System is first set up for patient use.
- Whenever possible, leave the power cord connected to an external AC power source while operating the instrument.

MAINTENANCE

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 of 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 partially discharged repeatedly. 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.

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.

* *Excluding 10% bleach solution in water.*

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.

MAINTENANCE

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" section of this Directions for Use before each usage of the instrument. Regular inspections must be performed by the hospital/facility and if any damage is found, service is required.

REGULAR INSPECTIONS

PROCEDURE	FREQUENCY
INSPECT FOR DAMAGE:	
Exterior Surface	Each usage
Pole Clamp	Each usage
Power Cord	Each usage
Keypad	Each usage
CLEANING	As required
Start-Up	Each usage

1. Exterior Surfaces - examine for overall condition and verify:
    - No damage, cracks or deformities.
    - Case is 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.

3. Power Cord Assembly - examine 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.

Periodic inspections of the hardware are required. For detailed instructions on performing periodic inspections and maintenance, refer to the Medley™ Medication Safety System Technical Service Manual and supplemental service bulletins, and Medley™ Maintenance Software User Manual.

Service Information

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.

Customer Service

Information or assistance may be obtained by calling one of the following Customer Service numbers:

United States:	(800) 482-4822
Canada:	(800) 387-8309

Technical Support

Technical support, service information, applications, and manuals may be obtained by contacting an ALARIS Medical Systems representative.

United States:	(800) 854-7128, extension 6003
Canada:	
Eastern	(800) 908-9918
Western	(800) 908-9919

When submitting any request for service, include:

- Model number
- a description of difficulty experienced
- instrument settings
- 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.

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.

MAINTENANCE

WARRANTY

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

A. Each new ALARIS Medical Systems® Medley™ Programming Module 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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