ALARIS®
MEDICAL SYSTEMS

Medley™
Medication Safety System

Programming Module, 8000 Series

Directions for Use

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MAINTENANCE (Continued)

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. It 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.

> **NOTE:** The Medley™ Programming Module name will be changing in the near future to Medley™ Point-of-Care Unit. During this transition, there will be a period of time when screen displays, software, and instrument labeling might reflect either "Programming Module" or "Point-of-Care Unit".

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.

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 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) Standard Software.

About the System (Continued)

Compliance with Federal Aviation Regulations: The Medley™ Programming Module has received a Statement of Compliance with Federal Aviation Regulations for use as a "Portable Electronic Device Aboard Aircraft". This is pursuant to the FAA Advisory Circular No. 91-21-1A and attested by an FAA Designated Engineering Representative with an FAA form 8110-3, "Statement of compliance with the Federal Aviation Regulations".

Contraindications: None known.

This document provides directions for use for the Medley™ Programming Module. For additional operating instructions, reference the Directions for Use (DFU) for the individual Medley™ Module(s).

> **WARNING**
>
> Read all instructions before using the Medley™ System.

Features and Definitions

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

Anesthesia Mode	Allows anesthesiologist to access additional drugs, in each profile, that are appropriate to anesthesiology. It also features permanent pause. Clinical Advisories will not be displayed in this mode.
Battery Run Time Display	Appears on Main Display prompt bar when Programming Module is disconnected from AC. If enabled, this feature provides a visual display of estimated remaining battery run time under current operating conditions, when operating on battery.
Data Set	Created using Guardrails® Editor authoring tool and then transferred to Programming Module. A data set reflects facility's best-practice guidelines for IV drug administration and includes: Profile Drug Libraries, Clinical Advisories, instrument configurations, and Channel Label Libraries.
Dose Checking	Always Dose Checking option causes a Guardrails® Soft Alert to occur each time a dose limit is exceeded. Drug label in Message Display provides an indicator ("---" or "LLL") that infusion is beyond current Guardrails® Soft Limit.
	Smart Dose Checking option causes an initial Guardrails® Soft Alert to occur when a dose limit is exceeded. Subsequent programming beyond dose limit will not receive an alert. Drug label in Message Display provides an indicator ("---" or "LLL") if infusion is beyond current Guardrails® Soft Limit.

Features and Definitions (Continued)

Guardrails® Safety Software

Designed to help prevent programming errors by:

- Customizing device configurable settings to meet need of selected hospital/facility 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, ID entry defaults to Startup screen.
- When disabled, ID entry is only accessible from System Options screen.

Profile

A unique set of system configuration settings and best-practice guidelines for a specific patient population or patient type, and consists of 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 modules that are actively infusing nondrug therapies (for example, saline or TPN). Channel labels can also be used to identify 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 transferred to the Programming Module.

System Configuration

Allow system settings to be customized. If Profiles feature is enabled, system settings defined for selected profile are automatically activated.

Tamper Resist

Provides a quick one-touch lockout of front panel keypad.

Symbols

∿ Alternating Current: Indicates 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 Programming Module and attached modules.

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

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

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

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

⊙ "SYSTEM ON"

🔒 Tamper Resist activate/deactivate switch.

Warnings and Cautions

Warnings and Cautions are provided throughout this Directions for Use (DFU) to provide information needed to safely and effectively use the Medley™ Medication Safety System and its accessories. Module-specific Warnings and Cautions are covered in the applicable module's DFU.

℞ Only

A [◄ **DANGER** ►] is an alert to an <u>imminent</u> hazard which could result in <u>serious</u> personal injury and/or product damage if proper procedures are not followed.

A [**WARNING**] is an alert to a <u>potential</u> hazard which could result in <u>serious</u> personal injury and/or product damage if proper procedures are not followed.

A [**CAUTION**] is an alert to a <u>potential</u> hazard which could result in <u>minor</u> personal injury and/or product damage if proper procedures are not followed.

[◄ DANGER ►]

Explosion risk if used in the presence of flammable anesthetics.

[WARNINGS]

- 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.

- Do not use the Medley™ System near Magnetic Resonance Imaging (**MRI**).

- Disconnect from main (AC) and battery power when performing **maintenance**.

- Electrical shock hazard. **Do not open case**. Refer to qualified service personnel.

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

CAUTIONS

- The Medley™ System is not intended to replace **supervision by medical personnel**. The user must become thoroughly familiar with the Medley™ System features, operation and accessories prior to use.

- Always use a grounded, **three wire receptacle**. Where the integrity of the protective earth grounding system is in doubt, operate on internal battery.

- 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.

- If an instrument appears **damaged**, contact ALARIS Medical Systems for authorization to return it for repair.

GETTING STARTED

IUI Connector, Left
(not visible)

IUI Connector, Right

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 connected to a server or computer. When blinking, indicates data transfer.

System On Key: When pressed, changes Medley™ System from Standby to Operating mode.

Up/Down Arrows: When pressed, increases or decreases parameter with each key press or scrolls 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".

Module Release Latch: When pressed, allows module to be removed.

Rear View

IUI Connector, Right

IUI Connector, Left

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

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.

Prior to placing the Medley™ System in use:

1. Perform check-in procedure per Medley™ Maintenance Software/User Manual (Model 8970C, or later).

2. Verify whether or not Profiles feature has been enabled. Reference "Reviewing System Configuration" section in "Getting Started" chapter.

> **NOTE:** To enable the Profiles feature, a hospital-defined best-practice data set must be uploaded to the Programming Module.

Attaching and Detaching Modules

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

Attaching Module(s)

1. Position free module at a 45° angle, aligning IUI connectors.

2. Rotate free module down against Programming Module or attached module, until bottom latch snaps in place.

> **NOTES:**
>
> • Individual hospital/facility may choose to permanently attach modules. To remove permanently attached modules, contact qualified service personnel.
>
> • Application of adhesive tape or other materials to the sides of the Programming Module and modules may prevent proper latching.

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.

45°
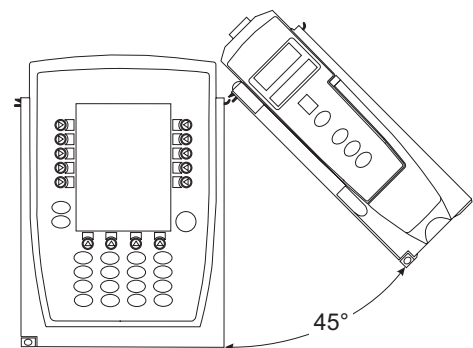
Detaching Module(s)

1. Ensure module(s) is powered off before detaching.

2. Push module release latch (located directly below IUI connectors) and then rotate module(s) up and away from Programming Module or attached module (opposite to motion shown above) to disengage connectors.

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

   • Appropriate module position(s) (A, B or C) for remaining module(s) appear on Main Display.

NOTE: The Medley™ Medication Safety System is designed to operate a maximum of four infusion or monitoring modules. Modules added in excess of four will not be recognized by the system. The module(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
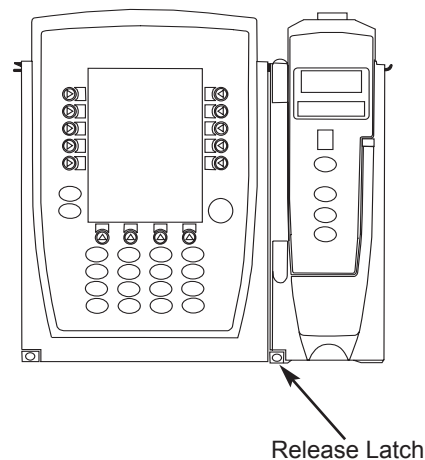
Adding Module(s) While System is Powered On

Add module as described in "Attaching Module(s)".

IUI Connectors

• System tests module, causing all LED segments and indicator lights of displays to illuminate briefly.

• Appropriate module identification display (A, B, C or D) illuminates. Modules are always labeled left to right, so if a module is added to left of other modules, all modules will be reidentified. Module reidentification does NOT interrupt or affect infusion or monitoring on active modules.

• Module positions (A, B, C or D) appear on Main Display.

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

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

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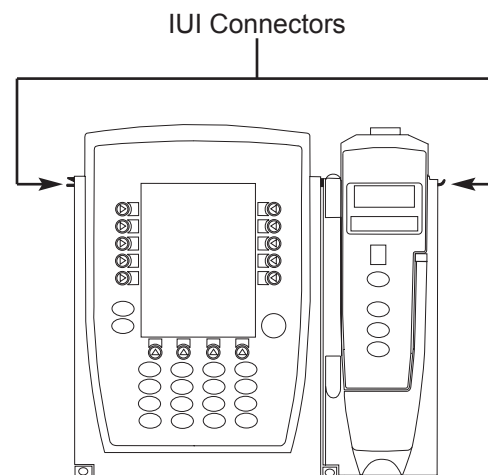
Displays

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

Module Status

- A solid letter display indicates module is operating.

- An outlined letter display indicates module is attached and ready for use.

Soft Keys

Midtown Hospital
Adult ICU

A VTBI = 250.0 mL
B
C
D

VOLUME INFUSED   AUDIO ADJUST

Module 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-ARY   START

GETTING STARTED

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 ]
```
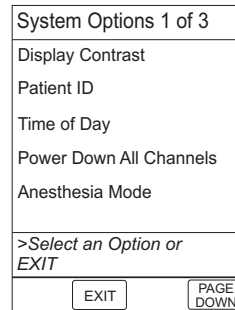
3. To adjust display for optimum viewing, use
   Lighter/Darker soft keys.

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 ]
```
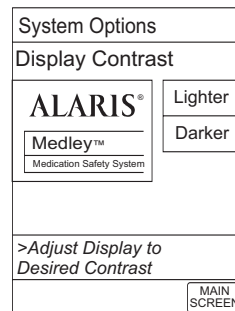
Start-Up

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 module(s) to
     illuminate briefly.

   • Power Indicator illuminates.

   • Appropriate module identification (A, B, C or D)
     displays on attached module(s).

   • An Audio tone sounds.

-- Continued on Next Page --

Powering On System (Continued)

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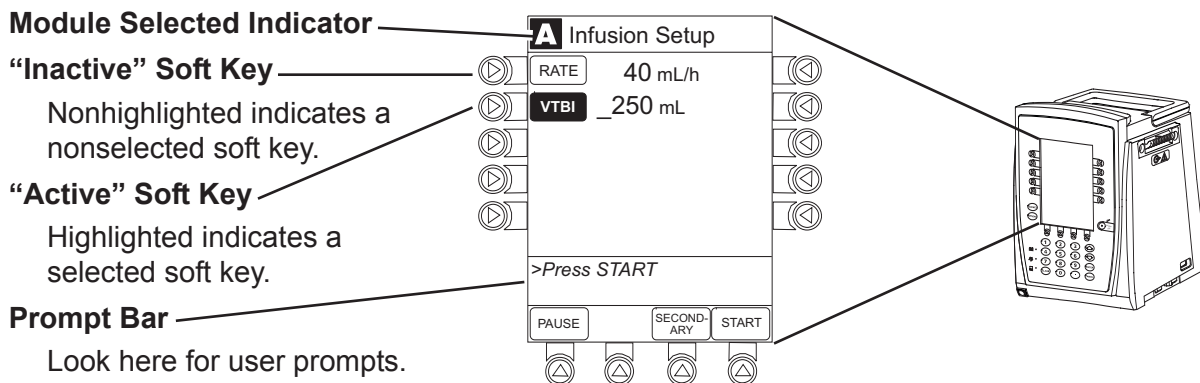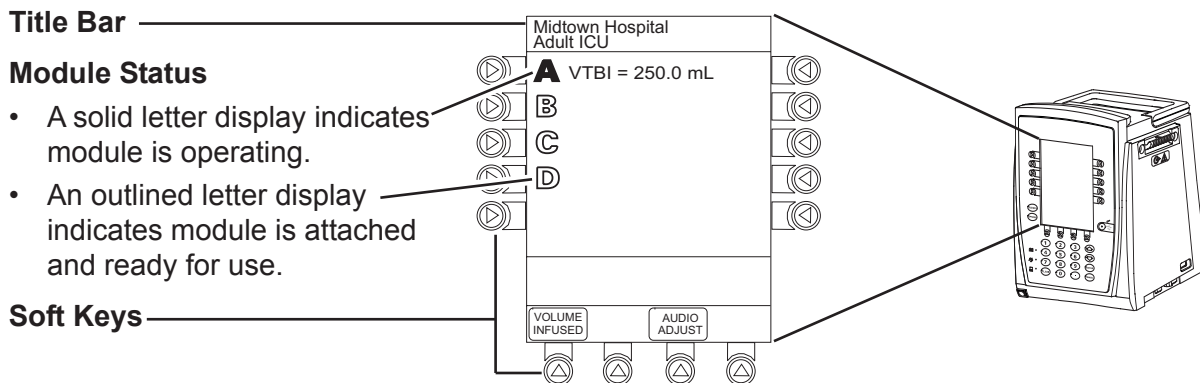
   If the affected module operates normally when it is attached via an alternate IUI connector, it may be used until a replacement module can be substituted.

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 Modules" section).

MAINTENANCE REMINDER
Module(s) due for routine preventative maintenance:
Module A: YYYY-MM-DD
CONFIRM

GETTING STARTED

Responding to Maintenance Reminder (Continued)

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 module. To continue start–up process, press **CONFIRM** soft key.

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 reference "Displays", "Adjusting Display Contrast" section).

Selecting New Patient and Profile Options (Continued)

Patient ID Entry Feature Disabled

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.

    > **NOTE:** To view additional choices, press **PAGE DOWN** soft key.

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

    • Main screen appears.

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

```
Midtown Hospital
Profiles              1 of 2
┌───────────────────────────┐
│ Adult ICU                 │
│ Adult General Care        │
│ Neonatal                  │
│ Peds ICU                  │
│ Neonatal ICU              │
│                           │
│ >Select a Profile and     │
│  Confirm                  │
│ ┌─────────┐ ┌──────┐      │
│ │ CONFIRM │ │ PAGE │      │
│ │         │ │ DOWN │      │
│ └─────────┘ └──────┘      │
```

GETTING STARTED

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.

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

        OR

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

        ♦ Last used profile displays.

   -- 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	

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	

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*	

Selecting New Patient and Profile Options (Continued)

> **Patient ID Entry Feature Enabled**
> (Continued)

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

    > **NOTE:** To view additional choices, press **PAGE DOWN** soft key.

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

    • Main screen appears.

```
Midtown Hospital        1 of 2
Profiles
Adult ICU

Adult General Care

Neonatal

Peds ICU

Neonatal ICU

>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
```

GETTING STARTED

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

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.
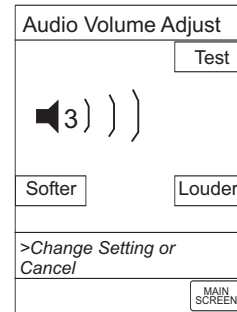
   - Main screen appears with old Patient ID.

```
┌─────────────────────────┐
│ Patient ID Entry        │
│                         │
│ Patient ID      ┌─────┐ │
│ 123456789CD     │ Yes │ │
│ will be changed │─────│ │
│ to              │ No  │ │
│ 234567891EF     └─────┘ │
│                         │
│ Is this correct?        │
│                         │
│                         │
│ >Press Yes or No        │
│                         │
└─────────────────────────┘
```

GETTING STARTED

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
```
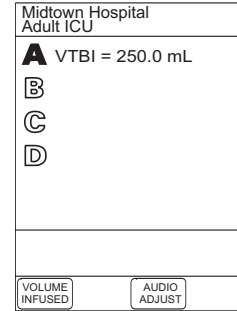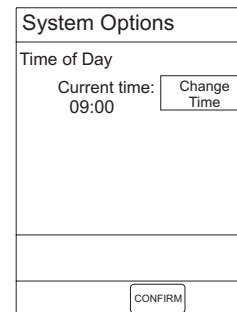
2. To change volume to desired level, press either **Louder** or **Softer** soft key. To sample alarm loudness level, **Test** soft key may be pressed.

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

    •   After 30 seconds without a key press, Main Display appears.
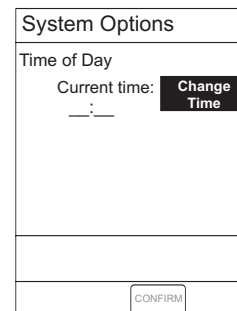
```
Audio Volume Adjust
                        Test

  ◀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:    Change
        09:00          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:    Change
        14:30         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.

> **NOTES:**
> • The **Profiles** option is listed only if it is **disabled**.
> • The **Dose Checking** option is listed only if the **Profiles**
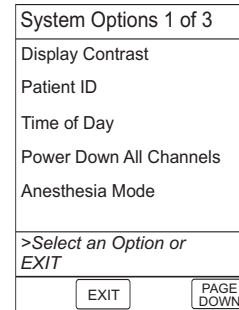>   option is **enabled** and a valid data set is present.

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

Anesthesia Mode: Disabled

Battery meter:      Disabled

Clock setup:        09:00

Key click audio:    Enabled
>Select an Option
or EXIT
        EXIT        PAGE
                    DOWN
```

```
System Config - PM 2 of 2
─────────────────────
Max Pt. weight:     500 kg

Patient ID Entry:   Disabled

PM Reminder:        Disabled

Profiles:           Disabled

Tamper resist:      Disabled


>Select an Option
or EXIT
   PAGE    EXIT
   UP
```
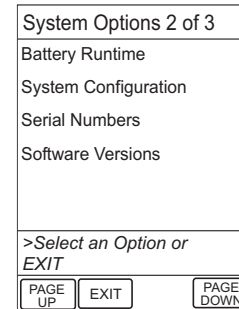
6.   To return to main screen, press **CANCEL** key or **EXIT** soft
     key.

GETTING STARTED

Reviewing Serial Number

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.

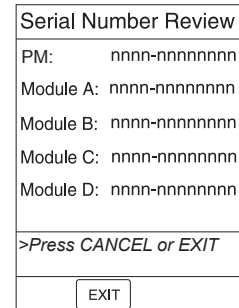| System Options 2 of 3 |
| --- |
| Battery Runtime |
| System Configuration |
| Serial Numbers |
| Software Versions |
| |
| *>Select an Option or EXIT* |
| PAGE UP · EXIT · PAGE DOWN |

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

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

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

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	

Reviewing Software Version

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


>Select an Option or
EXIT

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

4. To review software version information, press **View** soft key next to desired module.

    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 ]
```

GETTING STARTED

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 All Channels?   Yes   No
>Press Yes or No

Powering Off Module

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**.

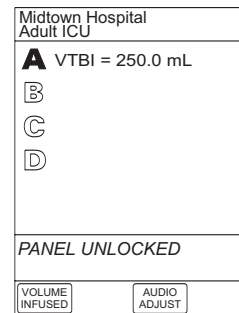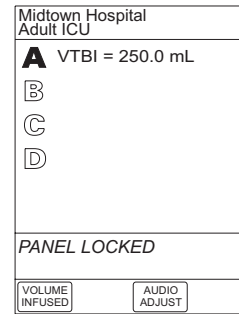• Once all attached modules are powered off, Programming Module automatically powers down.

Powering Down

Locking/Unlocking Tamper Resist

1. Initiate operation of desired modules.

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
B
C
D


PANEL LOCKED

VOLUME          AUDIO
INFUSED         ADJUST
```

```
Midtown Hospital
Adult ICU
A  VTBI = 250.0 mL
B
C
D


PANEL UNLOCKED

VOLUME          AUDIO
INFUSED         ADJUST
```

GETTING STARTED

Computer Link

The optional Computer Link feature allows a hospital/facility 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.

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

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

CAUTION

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.

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

> **NOTE:** 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.

Definitions

Advisory / Message
A sequence of audio and/or visual signals indicating operating status of Medley™ Medication Safety System. Audio may be silenced for approximately two minutes by pressing **SILENCE** key.

Alarm
An audio and visual signal that a potentially unsafe condition is present. Immediate action is required. Audio may be silenced for approximately two minutes by pressing **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/facility standards of practice when programming an IV medication. A specific clinical advisory/message can be associated with a selected drug within any of the patient care profiles. Clinical Advisories will not be displayed in Anesthesia mode.

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

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

ALARMS, ERRORS, MESSAGES

Audio Characteristics

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 / Message	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 modules 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 modules.
Channel Disconnected	Module(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 Module Release Latch. If alarm is still present, replace module 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.

Errors

Error	Meaning	Response
Channel Error	Error detected. Operation stops on affected module.	To silence alarm and continue operation of unaffected modules, press **CONFIRM** soft key . Replace module 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 modules.	Press **SYSTEM ON** key to power down system. Replace Programming Module with an operational system. Service by qualified personnel is required.

Errors (Continued)

Error	Meaning	Response
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 attached modules.	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.

Message	Meaning	Response
Powering Down	Last module 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.

ALARMS, ERRORS, MESSAGES

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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 modules attached and module 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 an RJ45 connector.

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

Electric Classification: Class 1, Internally Powered Equipment

> **NOTE:** Reference 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, module-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

MAINTENANCE

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 60601–1; 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, reference 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 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
Dose Checking	Always	Always, Smart
Key Click Audio	Enabled	Enabled - Disabled
Max Patient Weight	500 kg	0.1 - 500 kg
Patient ID Entry	Disabled	Enabled - Disabled
PM Reminder (Preventive Maintenance)	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, 4000 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 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 and Maintenance (Continued)

Battery Care

The battery capacity should be checked at least once every six months. Reference 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.

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.

* 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

Inspection Requirements

To ensure the system remains in good operating condition, both regular and preventive maintenance inspections are required. Reference the Medley™ Maintenance Software/User Manual (Model 8970C, or later) for detailed instructions.

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

WARNING

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

CAUTION

Regular and preventive maintenance inspections should only be performed by qualified service personnel.

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.

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

During servicing, an instrument's configuration settings might be reset to the factory defaults. Qualified hospital/facility personnel are responsible for checking in the instrument and ensuring the current hospital-approved data set is loaded.

Service Information (Continued)

Technical Support

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

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

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;

<div align="center">or</div>

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

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