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

Phone, toll-free, within the United States and Canada: (800) 854-7128, Ext. 7812
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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INTRODUCTION

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.

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

The Medley™ Pump Module (8100 Series) is intended for facilities that utilize infusion pumps for the delivery of fluids, medications, blood, and blood products using continuous or intermittent delivery through clinically acceptable routes of administration; such as, intravenous (IV), intra-arterial (IA), subcutaneous, epidural, enteral, or irritation of fluid spaces.

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™ Pump Module. Read all instructions, for both the Pump Module and Programming Module, before using the Medley™ System.

The Medley™ Pump Module uses a wide variety of Medley™ System/ Gemini Administration Sets. The sets are designed for use with the Pump Module as well as for gravity-flow, stand-alone use. For specific administration set instructions, refer to the directions for use provided with the set. For set priming and loading instructions, refer to the “Start-Up” section in the “Getting Started” chapter of this document.

Contraindications: None known.
Refer to the “Alarms, Errors, Messages” chapter of this Directions for Use for the definitions of various alerts. Refer to the Medley™ Programming Module Directions for Use for system features and definitions.

**AutoRestart**

The AutoRestart feature is part of the Medley™ System’s advanced Downstream Occlusion Detection system. If enabled, the AutoRestart feature minimizes nuisance patient-side occlusion alarms caused by momentary kinking of tubing, IV pushes, etc.

**Bolus Dose**

The Bolus Dose mode allows a bolus infusion to be programmed using either the Guardrails® Drug Library or the drug calculation feature. The bolus infusion can be programmed with or without a continuous infusion following the bolus.

**Channel Labels**

The Channel Labels feature is available when the Profiles feature is enabled. It provides a hospital-defined list of labels, displayed in the Channel Message Display, and identifying the channel with the solution being infused, the catheter location, or other helpful information.

**Delay Options**

The Delay Options feature allows the system to be programmed to delay the start of an infusion (a) for up to 120 minutes or (b) for a specific time up to 23 hours 59 minutes. A callback for a programmed delay can be scheduled to give an alert Before an infusion is to be initiated, After an infusion is completed, Before and After an infusion, or no alert (None).

**Drug Calculation**

The Drug Calculation mode allows:

- entry of drug dose (Medley™ System calculates correct flow rate to achieve desired dose),
  OR
- entry of flow rate (Medley™ System calculates corresponding drug dose).

**Dynamic Pressure Display**

The Dynamic Pressure Display appears on the Main Display. If enabled, it graphically displays the current patient-side occlusion pressure set point and the current patient-side operating pressure for that module. (Reference “Displays” section in “Getting Started” chapter for additional “Dynamic Pressure Display” information.)

**Free Flow Protection**

All Medley™ System/Gemini administration sets utilize a unique clamping device, the Flo-Stop® Device, to prevent inadvertent free flow when the administration set is removed from the instrument.

**Guardrails® Clinical Advisory**

A Guardrails® Clinical Advisory is a visual message that appears when a designated drug is selected, to remind a 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.

**Guardrails® Drug Library**

The Guardrails® Drug Library feature is a drug calculation mode available when the Profiles feature is enabled. It provides a hospital-defined list of drugs and concentrations appropriate for use in as many as 10 profiles. Using the Drug Library automates programming steps, including the drug name, drug amount and diluent volume, and activates the hospital-established best-practice Guardrails® Limits.
Guardrails® Limit

A Guardrails® Limit is a programming limit or best-practice guideline determined by the hospital/health system and entered into the system’s data set. Profile-specific limits are defined for flow rate, patient weight, and maximum and minimum continuous dose for each drug in a Guardrails® Drug Library. Dose limits can be defined by the hospital/health system as either “hard” or “soft” limits.

- A Guardrails® Hard Limit is a programmed limit that cannot be overridden.
- A Guardrails® Soft Limit is a programmed limit that can be overridden.

KVO Rate Adjust

The KVO Rate Adjust option is used to select the KVO (Keep Vein Open) rate (0.1 to 20 mL/h allowed). This determines the rate of fluid flow after an “Infusion Complete” occurs. The KVO rate will never exceed the infusion rate.

Multidose Mode

The Multidose Mode option allows 2 - 24 doses to be programmed at equally spaced intervals on the same Pump Module over a 24-hour period. This mode is designed to allow delivery of multiple, equal doses from the same IV container at regularly scheduled intervals.

Occlusion Pressure

A complete range of downstream occlusion detection options is provided.

- **Pump mode**: Downstream occlusion alarm threshold is 525 mmHg at flow rates of 30 mL/h or greater. For rates <30 mL/h, the occlusion pressure is rate-dependent, to ensure rapid response to occlusions.
- **Selectable pressure mode**: Downstream occlusion alarm threshold can be adjusted in 25 mmHg increments, up to the maximum occlusion pressure of 525 mmHg.
- **AutoRestart**: (See “AutoRestart” definition.)

In addition, the Medley™ System provides fluid-side occlusion detection.

Restore

To simplify programming, the Restore feature can be used to recall previous rate and volume settings for the same patient. This option is only available if the patient is not new and the system is powered up within 8 hours of last usage.

Secondary Infusions

Dual rate sequential piggyback (Secondary) infusions may be infused at delivery rates and volumes independent of the primary infusion parameters. Automatic changeover occurs to the primary infusion parameters when the secondary infusion is complete if a Medley™ System/Gemini Check Valve Administration Set is used.

Volume/Duration

The Volume/Duration infusion option allows a volume-to-be-infused (VTBI) and duration (infusion time) to be programmed. The flow rate is automatically calculated.
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).

Electrical Shock Protection Rating: Type CF, Defibrillation-proof

Protection against fluid ingress: Drip Proof

Attention: Refer to accompanying documentation.

IUI Connector: Inter-Unit Interface connector used to establish power and communications between the Programming Module and attached modules.

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

Consult operating instructions.

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

Single-Use. Do not re-use.

Product contains a particular element; such as, DEHP = DEHP in fluid pathway.

Product DOES NOT contain a particular element; such as, LATEX = administration set is latex-free.

Drops per milliliter specification for product will be identified on drop symbol.

Product incorporates SmartSite® Needle-Free Valve Ports and should not be accessed by a needle.

Approximate administration set priming volume.

Expiration date for product will be identified near hour glass symbol.

Do not use if package is damaged.
NOTE: Although the Medley™ Medication Safety System is built and tested to exacting specifications, it is not intended to replace the supervision of IV infusions by medical personnel. The user should become thoroughly familiar with the features and operation of the Medley™ System and exercise vigilance in its utilization.

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 the Programming Module, refer to its Directions for Use.

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

Epidural Administration

The Medley™ System can be used for epidural administration of anesthetic and analgesic drugs. This application is only appropriate when using analgesics and anesthetics labeled for continuous epidural administration and catheters intended specifically for epidural use. Use only a Medley™ System/Gemini Series administration set, without a "Y" connector or injection port, for epidural infusions.

- Epidural administration of anesthetic drugs: Use indwelling catheters specifically indicated for short-term (96 hours or less) anesthetic epidural drug delivery.
- Epidural administration of analgesic drugs: Use indwelling catheters specifically indicated for either short-term or long-term analgesic epidural drug delivery.

WARNING

Epidural administration of drugs other than those indicated for epidural use could result in serious injury to the patient.

WARNING

It is strongly recommended that the source container, Medley™ System/Gemini Administration Set, and Pump Module used for epidural drug delivery be clearly differentiated from those used for other types of administration.

WARNING

This instrument is designed to stop fluid flow under alarm conditions. Periodic patient monitoring must be performed to ensure the infusion is proceeding as expected.
When loading a data set with the Guardrails® Safety Software, ensure the correct profile (for patient care area) is selected prior to starting an infusion. Failure to use the appropriate profile could cause serious consequences.

**WARNING**

The Guardrails® Safety Software incorporates dosing limits and instrument configuration parameters based on hospital protocol. The software adds a test of reasonableness to drug programming based on the limits defined by the hospital. Qualified personnel must ensure the appropriateness of the drug dosing limits, the compatibility of the drugs, and the performance of each instrument, as part of the overall infusion. Potential hazards include drug interactions, and inappropriate delivery rates and pressure alarms.

**WARNING**

When loading a data set with the Guardrails® Safety Software, ensure the correct profile (for patient care area) is selected prior to starting an infusion. Failure to use the appropriate profile could cause serious consequences.

**WARNING**

This Medley™ Pump Module is a positive displacement delivery system, capable of developing positive fluid pressures to overcome widely varying resistances to flow encountered in practice, including resistances to flow imposed by small gauge catheters, filters and intra-arterial infusion. It is neither designed nor intended to detect infiltrations and will not alarm under infiltration conditions.

**WARNING**

Hospital/facility personnel must ensure the compatibility of the drugs as well as the performance of each module as part of the overall infusion. Potential hazards include drug interactions, inaccurate delivery rates, inaccurate pressure alarms and nuisance alarms.

**WARNING**

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

**WARNING**

Use only Medley™ System/Gemini Series Administration Sets. The use of any other set may cause improper instrument operation, resulting in an inaccurate fluid delivery or other potential hazard. For a list of compatible sets, refer to the Set Compatibility Card (provided separately).
Warnings and Cautions (Continued)

**WARNING**
To prevent a potential free-flow condition, ensure no extraneous object (for example, bedding, tubing, glove) is enclosed or caught in the Medley™ Pump Module door.

**WARNING**
The use of positive displacement infusion devices ported together with gravity flow infusion systems into a common IV site may impede the flow of common “gravity only” systems, affecting their performance. Hospital/facility personnel must ensure the performance of the common IV site is satisfactory under these circumstances.

**WARNING**
References in this document to specific drugs and drug doses are for illustration purposes only. Refer to specific drug product labeling for information concerning appropriate administration techniques and dosages.

**Parallel Infusions**
There are no contraindications regarding the use of the Medley™ System with any other positive displacement infusion device when ported together into a common IV site location.

**User Precautions**
To ensure proper performance of the Medley™ System and to reduce potential injury to the operator, observe the following precautions:

- Disconnect from main (AC) power when performing maintenance.
- The instrument case should only be opened by qualified service personnel using proper grounding techniques.
Administration Sets

- For a list of compatible administration sets, refer to Set Compatibility Card (provided separately).
- For specific administration set instructions, refer to directions for use provided with set. For set loading instructions, refer to “Preparing Infusion” section of this document.
- Before operating instrument, verify that administration set is free from kinks and installed correctly in instrument.
- Pump Module administration sets are supplied with a sterile fluid path for one-time use. Do not resterilize.
- Fluid path is STERILE and NONPYROGENIC.
- Discard if packaging is not intact or protector caps are unattached.
- For administration set replacement interval, refer to facility protocol and/or government standards (such as, CDC guidelines in the United States).
- For IV push medication (put instrument on hold), clamp tubing above the port.
- Flush port(s) per facility protocol.
- Discard administration set per facility protocol.

SmartSite® Needle-Free System:

- SmartSite® Needle-Free Valve Port is contraindicated for blunt cannula systems.
- Swab top of SmartSite® Needle-Free Valve Port with preferred antiseptic prior to each access.

NOTES:

- If applicable, attach syringe to SmartSite® Needle-Free Valve Port and aspirate minute air bubbles.
- In an emergency, SmartSite® Valve may be accessed by a needle and will leak if punctured. To access port with needle without causing leakage, attach a “PRN” adapter of sufficient length to SmartSite® Needle-Free Valve Port.
**Artifacts**

It is normal for an infusion device to produce nonhazardous currents when infusing electrolytes. These currents vary proportional to the infusion device flow rate. When the ECG monitoring system is not functioning under optimal conditions, these currents may appear as artifacts, simulating actual ECG readings. To determine if ECG abnormalities are caused by patient condition or the ECG equipment, place the infusion device on hold. If the ECG readings become normal, the ECG equipment requires attention. Proper setup of the ECG equipment should eliminate these artifacts. Reference the appropriate ECG monitoring system documentation for instructions on setup and maintenance.

**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.
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.
Controls and Indicators

Front/Side View - Door Closed

- **IUI Connector, Left**
- **Alarm (red)**
- **Infusing (green)**
- **Standby (yellow)**

**Status Indicators**

- **Rate Display**
- **Channel Message Display**
- **Channel Identification**

**Channel Select Key** - When pressed, selects corresponding channel for infusion parameter entry and infusion setup.

**Pause Key** - When pressed during an infusion, temporarily stops infusion on that channel. (After ≈2 minutes, "PRESS START" visual and audio prompt begins.)

**Channel Off Key** - When pressed and held until a beep is heard, stops infusion on that channel, deselects that channel, and if only that channel had been operating, system powers down. Repeat for other operating channels to power off each channel.

**Restart Key** - When pressed, resumes operation of a previously paused or alarmed infusion on that channel.
Front View - Door Open

- Platen
- Upper Tubing and Fitment Retainer
- IUI Connector, Right
- Upper Pressure Sensor
- Upper Occluder
- Upper Pumping Finger
- Lower Occluder
- Lower Pumping Finger
- Lower Pressure Sensor
- Flo-Stop® Recess
- Air-in-Line Sensor
- Tubing Keeper
- Door Latch Cam/Slide
- IUI Connector, Left (not visible)
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.

### Unpacking Pump Module

1. Remove Pump Module from its carton.
2. Verify door operates freely.
3. Verify membrane covering inside surface of pumping unit is not cut or torn.
4. Check for loose parts.
5. Perform Periodic Inspection (see “Inspection Requirements” section in “Maintenance” chapter).
6. Perform check-in procedure [reference Medley™ Maintenance Software User Manual (included with 8970C, or later) for details].

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

### Attaching and Detaching Channels

Refer to the Medley™ Programming Module Directions for Use.
Displays

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

Main Display

Title Bar

Channel Status

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

Soft Keys

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.
Displays (Continued)

Dynamic Pressure Display

Current operating pressure is indicated by solid bar.
Patient-side occlusion pressure set point is indicated by tick mark.

Dynamic Pressure Display

CAUTION
Although the dynamic pressure display bars for the Medley™ Syringe Module and Pump Module both use the full width of the screen for display, they each represent different ranges. The Pump Module’s range is 50 mmHg to 525 mmHg.

Start-Up

Refer to the Medley™ Programming Module Directions for Use for the following procedures:

Powering On System
Responding to Maintenance Reminder
Selecting New Patient and Profile Options
Entering Patient ID
Modifying Patient ID

Preparing Infusion

The primary administration set must be primed before use (see “Priming Primary Administration Set” section). It can be loaded into the Pump Module to deliver a large volume infusion (see “Loading and Removing Primary Administration Set” section) or it can be set up to deliver a gravity infusion (see “Setting Up Primary Administration Set for Gravity Infusion” section).

The Flo-Stop® Device is a tubing fitment that is part of all Medley™ System/Gemini administrations sets (see “Flo-Stop® Device” section).

WARNING
Use only Medley™ System/Gemini Series Administration Sets. The use of any other set may cause improper instrument operation, resulting in an inaccurate fluid delivery or other potential hazard. For a list of compatible sets, refer to the Set Compatibility Card (provided separately).
Preparing Infusion (Continued)

Flo-Stop® Device

The primary administration set’s Flo-Stop® Fitment is a unique clamping device that prevents inadvertent free-flow when the administration set is removed from the instrument.

Flo-Stop® Device in Open Position

When a new Medley™ System/Gemini administration set is removed from the package, the Flo-Stop® Device is in the open position (white slide clamp aligned with blue fitment). In this open position, flow is not occluded but is allowed as required for the priming process. The roller clamp is used to control flow during the priming process (see “Priming Primary Administration Set” section).

Flo-Stop® Device in Closed Position

When a Medley™ System/Gemini administration set is removed from the Pump Module, the instrument automatically engages the Flo-Stop® Device in the closed position (white slide clamp projects out from under blue fitment). In this closed position, flow is occluded.

Priming Primary Administration Set

1. Prepare primary solution container in accordance with manufacturer’s directions for use.
2. Open administration set package, remove set, and close roller clamp. (Reference set’s Directions For Use.)
3. Insert administration set spike into prepared fluid container, following accepted hospital procedure, and hang container 20 inches above Pump Module.
4. Fill drip chamber to 2/3 full.
5. If container requires venting, open vent cap on administration set spike.
6. To prime tubing and clear air from injection sites and tubing fitments, slowly open roller clamp.
7. When priming is complete, close roller clamp.
8. Verify no fluid flow.
Loading and Removing Primary Administration Set

**Loading Administration Set**

1. If a new set is being loaded, prime set (see “Priming Primary Administration Set” section).

2. Open Pump Module door.

3. Install administration set pumping chamber by properly positioning upper fitment into fitment recess. (See figure at end of this section.)

4. Holding tubing below pumping segment, insert Flo–Stop® Fitment into recess below mechanism, with arrow pointing into Pump Module. (See figure at end of this section.)

   **CAUTION**
   When reloading an administration set, leave the Flo-Stop® Fitment in the closed position (see “Flo-Stop® Device section).

5. Using a finger tip, firmly push tubing toward back of Air-in-Line Detector. (See figure at end of this section.)

   - Flo-Stop® Device is automatically disengaged.

7. Open roller clamp.

8. Verify no fluid is flowing through drip chamber.

   **WARNING**
   To prevent a potential free-flow condition, ensure no extraneous object (for example, bedding, tubing, glove) is enclosed or caught in the Medley™ Pump Module door.
Loading and Removing Primary Administration Set (Continued)

Loading Administration Set (Continued)

1. Load upper tubing fitment.

2. Load Flo-Stop® Fitment.


Removing Administration Set

1. Close roller clamp.

2. Open Pump Module door.
   - Set’s Flo–Stop® Device automatically closes to prevent accidental free-flow.

3. Remove set by gently pulling tubing below Air-in-Line Detector forward and out, and then lifting upper fitment vertically from upper fitment recess.

4. If set is being removed to begin a gravity flow:
   a. Depress blue ridged release tab on upper side of Flo–Stop® Device.
   b. Slide white slide clamp into blue fitment (open position).
   c. Adjust flow rate using set’s roller clamp.
### Preparing Infusion (Continued)

#### Setting Up Primary Administration Set for Gravity Infusion

1. Prime administration set (“Priming Primary Administration Set”).
2. Adjust container to hang 20 inches above patient’s vascular access device.
3. Attach administration set to patient’s vascular access device.
4. Adjust flow rate with administration set roller clamp.

#### Primary Mode - Basic Infusion

The following procedures should be used only when programming a **Basic Infusion**. To program an infusion using the Guardrails® Drug Library, go to the “Setting Up Drug Calculation” section.

**NOTES:**
- The illustrations in this section assume the following:
  - Drug Calculation, Dynamic Pressure Display, Profiles, and Volume Duration configurable settings are enabled.
  - Delay Options configurable setting is disabled.
- If Delay Options is enabled, the **PAUSE** soft key becomes **DELAY OPTIONS**.
- The **RESTORE** soft key appears only if a previous infusion was programmed for the same patient.

1. Perform steps in “Start-Up” section, to:
   a. Power on system.
   b. Choose **Yes** or **No** to **New Patient**?
   c. Confirm current profile or select a new profile.
   d. Enter patient identifier, if required.
2. Perform steps in “Preparing Infusion” section, to prime and load primary administration set.
3. Press **CHANNEL SELECT** key.
4. Press **Basic Infusion** soft key.
   - **Infusion Setup** screen appears.

5. Start an infusion, as described in following “Starting Rate / Volume Infusion” or “Starting Volume / Duration Infusion“section.

---

**Starting Rate / Volume Infusion**

1. To enter flow rate, press **RATE** soft key and use numeric data entry keys.

2. To enter VTBI, press **VTBI** soft key and use numeric data entry keys.

3. Attach administration set to patient’s vascular access device.

4. Verify correct infusion parameter entry and press **START** soft key.

   **NOTE:** The infusion may be paused by pressing the **PAUSE** soft key. Refer to “Pausing Infusion” section.
Primary Mode - Basic Infusion  (Continued)

Starting Rate / Volume Infusion  (Continued)

- During infusion:
  - Green Infusing Status Indicator illuminates.
  - Rate appears in Channel Rate Display.
  - Remaining VTBI appears on Main Display.
- At completion of infusion:
  - If infusion ends in KVO:
    An audio prompt sounds.
    Red Alarm Status Indicator flashes.
    Channel Rate Display changes to KVO rate.
    **INFUSION COMPLETE—KVO** scrolls in Channel Message Display.
    KVO appears on Main Display.
  - If infusion was delayed, **COMPLETE** scrolls in Channel Message Display and appears on Main Display.

Starting Volume / Duration Infusion

1. Press **VOLUME DURATION** soft key.

2. To enter VTBI, press **VTBI** soft key and use numeric data entry keys.

---

Midtown Hospital
Adult ICU

**VTBI = 250.0 mL**

**Audio**

**Adjust**

---

<table>
<thead>
<tr>
<th>Volume Infused</th>
<th>Audio Adjust</th>
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<tbody>
<tr>
<td>VTBI 250.0 mL</td>
<td></td>
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---

Infusion Setup

RATE = mL/h

VTBI

DURATION h min

> Select VTBI

Previous Infusion

RESTORE VOLUME

DURATION

> Select Rate or Restore Previous Infusion

RESTORE VOLUME
3. To enter volume duration, press **DURATION** soft key and use numeric data entry keys.
   - Rate is automatically calculated.

4. Attach administration set to patient’s vascular access device.

5. Verify correct infusion parameter entry and press **START** soft key.
   - During infusion:
     - Green Infusing Status Indicator illuminates.
     - Rate appears in Channel Rate Display.
     - VTBI counts down on Main Display.

   **NOTE:** To view infusion **Time Left**, press **CHANNEL SELECT** key. To return to previous screen, press **START** soft key.

   - At completion of infusion:
     - If infusion ends in KVO:
       - An audio prompt sounds.
       - Red Alarm Status Indicator flashes.
       - Channel Rate Display changes to KVO rate.

       **INFUSION COMPLETE–KVO** scrolls in Channel Message Display.
       - **KVO** appears on Main Display.
     - If infusion was delayed, **COMPLETE** scrolls in Channel Message Display and appears on Main Display.
Pausing Infusion

**NOTE:** To pause an infusion when Delay Options is enabled, reference “Delay Options”, “Pausing Infusion” section.

1. Press **PAUSE** key (on Pump Module).
   
   **OR**
   
   Press **CHANNEL SELECT** key and then press **PAUSE** soft key (on Programming Module).
   
   - **PAUSE** scrolls in Channel Message Display.
   - **PAUSED** appears on Main Display.
   - Yellow Standby Status Indicator illuminates.
   - After two minutes, “PAUSE-RESTART CHANNEL” visual and audio prompts begin, and yellow Standby Status Indicator flashes.

2. To reinitiate infusion:
   
   - Press **RESTART** key (on Pump Module).
   
   **OR**
   
   - Press **CHANNEL SELECT** key and then press **START** soft key (on Programming Module).

<table>
<thead>
<tr>
<th>Infusion Setup</th>
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<tbody>
<tr>
<td><strong>A</strong></td>
</tr>
<tr>
<td>RATE</td>
</tr>
<tr>
<td>VTBI</td>
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Midtown Hospital

<table>
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<td>D</td>
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VTBI = 497.0 mL
VTBI = 57.0 mL
VTBI = 249.0 mL
PAUSED
VOLUME INFUSED
AUDIO ADJUST

### Infusion Setup

<table>
<thead>
<tr>
<th>A Infusion Setup</th>
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<tbody>
<tr>
<td><strong>A</strong> Infusion Setup</td>
</tr>
<tr>
<td>RATE</td>
</tr>
<tr>
<td>VTBI</td>
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</tbody>
</table>

**Press START**

PAUSE | VOLUME | SECOND | START
1. If solution container and/or administration set require replacement, reference “Preparing Infusion” section to:
   a. Prepare solution container.
   b. Prime and load primary administration set.

2. Press CHANNEL SELECT key.

3. To restart infusion using stored parameters, press RESTORE soft key and continue with next step.

   OR

To start a new infusion, follow steps for “Starting Rate / Volume Infusion” or “Starting Volume / Duration Infusion”.

4. Verify parameters are valid and press START soft key.

   NOTE: To change a restored parameter:
   a. Press applicable soft key, VTBI or RATE.
   b. Enter desired parameter using Up/Down Arrows for rate titration, or numeric data entry keys.
   c. Press START soft key.
Primary Mode - Basic Infusion  (Continued)

Changing Rate or VTBI During Infusion

1. Press **CHANNEL SELECT** key.

2. Press either **RATE** or **VTBI** soft key.

3. To enter desired parameter, use Up/Down Arrows for rate titration or use numeric data entry keys.

4. Verify correct infusion parameter entry and press **START** soft key.

**NOTES:**

- If no other channel is active, the system powers down when the **CHANNEL OFF** key is released.
- To interrupt the power down sequence, quickly press any one of the numeric keys on the Programming Module.

Stopping Infusion

Press and hold **CHANNEL OFF** key until a beep is heard (approximately 1.5 seconds) and then release to initiate power down.
1. Press CHANNEL SELECT key.
2. Press OPTIONS key.
3. Press Pressure Limit soft key.

4. Press either Pump or Selectable pressure soft key. If Selectable is pressed, continue with next step; otherwise, proceed to step 7.

5. To select occlusion pressure limit, press either Up or Down soft key.
7. Press START soft key.
1. To view volume infused, press VOLUME INFUSED soft key.
   - Total volume infused (primary + secondary), and time and date volume infused was last cleared, display for each channel.
     
     **NOTE:** Date format is year-month-day.
   - If no key is pressed, main screen appears after 30 seconds.

2. To view primary and secondary volume(s) infused, press PRI/SEC VOLUME soft key.

3. To clear volume infused:
   
   **NOTE:** If no key is pressed, main screen appears after 30 seconds.
   - If only selected channels are to be cleared, press soft key next to applicable channel(s) and press CLEAR CHANNEL soft key.
     - Volume clears on selected channel(s).
   - If all channels are to be cleared, press CLEAR ALL soft key.
   - To return to main screen, press MAIN SCREEN soft key.
AutoRestart

The AutoRestart feature is part of the Medley™ System’s Downstream Occlusion Detection system designed to minimize nuisance, patient-side occlusion alarms. It allows the system to automatically continue an infusion following detection of a patient-side occlusion if downstream pressure falls to an acceptable level within a 15-second “Checking Line” period.

If this feature is enabled, the “Checking Line” function will occur when downstream pressure exceeds the Pressure Limit.

- In Selectable Pressure Mode, the Pressure Limit will be either user adjustable or “locked” in system configuration.
- In Pump Pressure Mode, the Pressure Limit is a function of flow rate and is automatically determined by the device.

If the downstream pressure decreases to a predetermined level, (below 50% of the Pressure Limit) during the 15-second “Checking Line” period, the infusion automatically continues.

If the condition is not cleared within 15 seconds, a “Partial Occlusion - Patient Side” alarm occurs.

Qualified Service personnel can configure the system to allow from zero (0) to nine (9) restart attempts within a rolling 10 minute period. If the allowable number of restarts is exceeded or if the feature is set to zero, an “Occluded - Patient Side” alarm will occur when the system detects downstream pressure over the Pressure Limit.
Secondary Mode

This mode is designed to support automatic secondary infusions ("piggybacking") in the same instrument channel. When the secondary VTBI reaches zero, an audio tone will sound indicating completion of the secondary infusion. The primary infusion resumes automatically.

When the instrument is programmed and delivering in the secondary mode, the primary infusion is temporarily stopped and fluid is drawn from the secondary container. Delivery from the primary container resumes when the fluid level in the secondary line is level with the fluid in the primary container.

**NOTE:** Prepare the secondary container and administration set. Lower the primary container using the hanger included with the secondary set.

1. Open secondary administration set package, remove set and close clamp.
2. Insert administration set spike into prepared fluid container and hang secondary container, following accepted hospital procedure.
3. Fill drip chamber to 2/3 full.

**WARNINGS**

- Secondary applications require the use of a check valve set on the primary IV line.
- The secondary solution container must be higher than the primary solution container.
- The secondary VTBI settings require consideration of such variables as factory overfill, medication additions, etc. Underestimating the volume will cause the remaining secondary solution to be infused at the primary rate; overestimating will result in the primary solution being infused at the secondary rate. Multiple doses from a single container are not possible.
- The clamp on the secondary administration set must be opened. If the clamp is not opened, the fluid will be delivered from the primary container.
- The secondary administration set must be primed prior to beginning the secondary infusion.
5. Attach secondary administration set to upper injection site on primary set.

6. Lower primary fluid container using hanger provided with secondary administration set.

   **NOTE:** The secondary container should be at least 9½ inches above the top of the fluid level in the primary container.

7. Set up and start primary infusion (reference “Primary Mode - Basic Infusion” section), using a check valve administration set.

8. Press **SECONDARY** soft key and continue with next step.

   **OR**

   To use previous secondary infusion parameters (if available), press **RESTORE** soft key and proceed to step 12.

9. To enter secondary infusion rate, press **RATE** soft key and use numeric data entry keys.
10. To enter secondary volume to be infused, press VTBI soft key and use numeric data entry keys.

11. Open clamp on secondary administration set.


- During infusion:
  - Green Infusing Status Indicator illuminates.
  - Secondary rate appears in Channel Rate Display.
  - Secondary VTBI counts down on Main Display.
  - SECONDARY scrolls in Channel Message Display.

- At completion of infusion:
  - Switchover alert sounds with six beeps (unless disabled in system configuration).
  - Primary rate displays.
  - Infusion continues at primary rate.
1. Press CHANNEL SELECT key.

2. Press PRIMARY soft key.

3. To change primary infusion parameter, press applicable soft key (RATE or VTBI), and use numeric data entry keys.

4. Verify correct primary infusion parameters and press SECONDARY soft key
   - Secondary setup screen displays.

5. To resume secondary infusion, press START soft key.
Secondary Mode (Continued)

Stopping Secondary Infusion and Returning to Primary Infusion

1. Press CHANNEL SELECT key.
2. Press PRIMARY soft key.
3. Close clamp on secondary administration set.
   OR
   Disconnect secondary administration set from upper injection port.

4. Press START soft key.

5. To stop secondary infusion and begin infusing primary, press Yes soft key.
   • Secondary infusion stops and primary infusion begins.
   • Main screen appears.

   NOTE: The SEC to PRI alert does NOT sound when the infusion is manually ended and returned to primary.
Changing Primary Solution Container

1. To stop infusion, press **PAUSE** key (on Pump Module).
2. Close roller clamp.
3. Remove empty solution container.
4. Insert administration set spike into prepared fluid container, following accepted hospital procedure, and hang container 20 inches above Pump Module.
5. Press **CHANNEL SELECT** key.
6. To enter VTBI, press **VTBI** soft key and use numeric data entry keys.
7. Open roller clamp.
8. To resume infusion, press **START** soft key.

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Channel Labels

Selecting Channel Label

1. Press **CHANNEL SELECT** key.
2. Press **OPTIONS** key.
3. Press **Channel Labels** soft key.

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<td>Guardrails Drug Library</td>
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<td>Pressure Limit - P</td>
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<tr>
<td>Channel Labels</td>
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</table>

>Select an Option or **EXIT**

EXIT
Channel Labels  (Continued)

Selecting Channel Label  (Continued)

4. Press soft key for desired label.

   NOTE: To view additional labels, press a soft key next to a letter group to navigate through alphabet, and/or PAGE UP and PAGE DOWN soft keys.

   • Selected label is highlighted and scrolls in Channel Message Display.

5. To continue infusion, press START soft key.

   OR

   Program infusion as previously described.
Removing Channel Label

1. Press **CHANNEL SELECT** key.
2. Press **OPTIONS** key.
3. Press **Channel Labels** soft key.

4. Press **CLEAR LABEL** soft key.
   - Label stops scrolling in Channel Message Display.

5. To begin infusion, press **START** soft key.
   
   OR
   
   Program infusion as previously described.
GETTING STARTED

Powering Off

Refer to the Medley™ Programming Module Directions for Use to the following procedures:

Powering Off System
Powering Off Channel

Setting Up Drug Calculation

The drug calculation can be set up for a drug stored in the Guardrails® Drug Library or for a non-library drug, as described in the following sections. To access the drug library, a hospital-defined best-practice data set must be uploaded, using the Guardrails® Safety Software, and the Profiles feature must be enabled.

Drug Calculation Parameters

The Medley™ System uses the following parameters, entered during the drug calculation setup procedure:

- **Bolus dose duration**: Time period over which bolus dose is to be administered.
- **Bolus dose units**: Units used in calculating bolus dose. Bolus dose units are selected from alternatives provided.
- **Diluent volume**: Volume of fluid used as diluent for drug (mL).
- **Dosing units**: Units used to calculate continuous infusion drug dose. Dosing Units are selected from alternatives provided.
- **Drug amount**: Amount of drug in IV container (gram, mg, mcg, mEq, or units).
- **Patient weight**: Weight of patient (kg); this is an optional parameter that is not needed unless drug dose is normalized for patient weight.
- **Time units**: Time base for all calculations (minute, hour, or day).

WARNINGS

- The Drug Calculation feature is to be used only by personnel properly trained in the administration of continuously infused medications. Extreme caution should be exercised to ensure the correct entry of the drug calculation infusion parameters.
- References in this document to specific drugs and drug doses are for illustration purposes only. Refer to specific drug product labeling for information concerning appropriate administration techniques and dosages.

-- Continued on Next Page --
The bolus dose, drug dose, and flow rate parameters are calculated using the above parameters, as follows:

- Bolus dose = bolus dose x patient weight (if used).
- Bolus dose administration rate (INFUSE AT): When duration is entered = total dose / duration in minutes. When Max Rate is used = Max Rate / 60 x concentration.
- Bolus dose duration = bolus VTBI / bolus rate.
- Bolus dose VTBI = bolus dose / drug concentration.
- Bolus rate = bolus VTBI / duration.
- Continuous drug dose = flow rate x drug concentration (normalized for patient weight if specified by entering a patient weight).
- Continuous flow rate = drug dose / drug concentration (normalized for patient weight if specified by entering a patient weight).
- Drug concentration = drug amount / diluent volume.
- Total bolus dose:
  - Bolus dose not weight-based = bolus dose entered.
  - Bolus dose weight-based = bolus dose x patient weight.

Using Guardrails® Drug Library

When using a drug listed in the Guardrails® Drug Library, the Guardrails® Software automatically calculates the drug parameters, based on:

- drug selected
- weight entry (if required)
- rate or dose entry, and
- VTBI entry

1. Perform steps in “Start-Up” section, to:
   a. Power on system.
   b. Choose Yes or No to New Patient?.
   c. Confirm current profile or select a new profile.
   d. Enter patient identifier, if required.
Using Guardrails® Drug Library (Continued)

2. Perform steps in “Preparing Infusion” section, to prime and load primary administration set.

3. Press CHANNEL SELECT key.


5. Press soft key next to desired drug and concentration.

   **NOTES:**
   - To view additional drugs/concentrations, press a soft key next to a letter group to navigate through alphabet, and/or **PAGE UP** and **PAGE DOWN** soft keys.
   - The facility may choose to to prepopulate standard drug concentrations, or leave an open entry (_ _/_ _ mL) and allow the clinician to enter the desired concentration.

6. To continue programming, press **Yes** soft key.
   - Bolus dose units appear if Bolus Dose is enabled.
   - OR
   - To change selection, press **No** soft key.

   - If **Yes** was selected and facility has defined a Clinical Advisory for that drug, a message appears. To indicate information has been noted and continue programming, press **CONFIRM** soft key.

   -- Continued on Next Page --
• If Yes was selected to continue programming, drug amount and diluent volume (if defined in Guardrails® Drug Library) are automatically entered for selected drug.

• If selected drug had “__/__/mL” concentration, drug amount and diluent volume need to be entered.

• If selected drug is not weight-based, Not Used displays in PATIENT WEIGHT field (as in illustrated example).

• If hospital practice guidelines identify selected drug as weight-based, prompt for a patient weight in kilograms appears (as in illustrated example, which reflects use of Heparin in Pediatrics ICU).

**NOTE:** Once a patient weight is entered, for any module, it is automatically entered for any subsequent weight-based calculation.

7. Verify parameters are correct and press NEXT soft key to confirm.

8. To make a rate or dose entry, press applicable soft key, RATE or DOSE, and use numeric data entry keys (other value is calculated and displayed).
9. To enter volume to be infused, press VTBI soft key and use numeric data entry keys.

**NOTES:**
- At rates less than 10 mL/h, the rate is displayed to two decimal places, and the VTBI can be entered and is displayed to two decimal places.
- The **BOLUS** soft key appears only if Bolus Dose is enabled within the selected profile, the drug is bolusable, and a VTBI is entered.
- In the Drug Calculation mode, the system infuses at the calculated rate rounded to the nearest one-hundredth of a mL per hour (as displayed on the Channel Programming screen). The rate shown in the Channel Rate Display will be rounded to the nearest one-tenth of a mL per hour.

10. Verify parameters are correct and press **START** soft key.

**NOTE:** If the programmed continuous dose infusion is outside the Guardrails® Soft Limit for that care area, a prompt appears before programming can continue. If the **Yes** soft key is pressed, programming continues; if the **No** soft key is pressed, the infusion needs to be reprogrammed.

**NOTE:** If the programmed continuous dose infusion is outside the Guardrails® Hard Limit for that care area, a prompt appears before programming can continue. The infusion needs to be reprogrammed.

--- Continued on Next Page ---
Setting Up Drug Calculation (Continued)

Using Guardrails® Drug Library (Continued)

- During infusion:
  - Green Infusing Status Indicator illuminates.
  - Rate appears in Channel Rate Display.
  - Dose and drug name scroll in Channel Message Display.

  **NOTE:** If a dose outside of the Guardrails® Soft Limits has been entered and verified as correct, the Channel Message Display also shows either “LLL” for a low dose or “↑↑↑” for a high dose.

  - Main Display alternates between VTBI and drug name with dose.

- At completion of infusion:
  - If infusion ends in KVO:
    An audio prompt sounds.
    Red Alarm Status Indicator flashes.
    Channel Rate Display changes to KVO rate.
    **INFUSION COMPLETE–KVO** (with drug name) scrolls in Channel Message Display.
    **KVO** appears on Main Display.
  - If infusion was delayed, **COMPLETE** scrolls in Channel Message Display and appears on Main Display.

Using Non-Library Drug

The following procedure should be used only when the drug to be infused is not listed in the Guardrails® Drug Library. When programming a drug not listed in the Guardrails® Drug Library, the drug calculation must be programmed using the **DRUG CALC** soft key within the Guardrails® Drug Library. There are no Guardrails® Limits associated with any non-library drug calculation.

1. Perform steps in “Start-Up” section, to:
   a. Power on system.
   b. Choose **Yes** or **No** to New Patient?
   c. Confirm current profile or select a new profile.
   d. Enter patient identifier, if required.
2. Perform steps in “Preparing Infusion” section, to prime and load primary administration set.

3. Press **CHANNEL SELECT** key.

4. Press **Guardrails Drug Library** soft key.

5. Press **DRUG CALC** soft key.

6. To enter **DRUG AMOUNT** in IV container, use numeric data entry keys.

7. Press soft key for appropriate unit of measure for drug amount.
8. To enter diluent volume, use numeric data entry keys.


10. To indicate whether or not patient weight is to be used in Drug Calculation, press either Yes or No soft key.

   NOTE: Do not enter a patient weight if weight is not used in the calculation.

11. To enter patient weight (if required) in kilograms, use numeric data entry keys.
12. Press **TIME UNITS** soft key.

13. To select time base for drug calculation, press either **Min**, **Hour**, or **Day** soft key.

14. Press soft key next to desired **DOSING UNITS**.

15. Verify correct drug calculation infusion parameters and press **NEXT** soft key.
16. To make a rate or dose entry, press applicable soft key, RATE or DOSE, and use numeric data entry keys (other value is calculated and displayed).

17. To enter volume to be infused, press VTBI soft key and use numeric data entry keys.

**NOTES:**
- At rates less than 10 mL/h, the rate is displayed to two decimal places, and the VTBI can be entered and is displayed to two decimal places.
- The BOLUS soft key appears only if Bolus Dose is enabled within the selected profile and a VTBI is entered.
- In the Drug Calculation mode, the system infuses at the calculated rate rounded to the nearest one-hundredth of a mL per hour (as displayed on the Channel Programming screen). The rate shown in the Channel Rate Display will be rounded to the nearest one-tenth of a mL per hour.

18. Verify parameters are correct and press START soft key.
- During infusion:
  - Green Infusing Status Indicator illuminates.
  - Rate appears in Channel Rate Display.
  - VTBI counts down on Main Display.
  - Dose scrolls in Channel Message Display.
Using Non-Library Drug (Continued)

- At completion of infusion:
  - If infusion ends in KVO:
    - An audio prompt sounds.
    - Red Alarm Status Indicator flashes.
    - Channel Rate Display changes to KVO rate.
    - **INFUSION COMPLETE–KVO** scrolls in Channel Message Display.
    - **KVO** appears on Main Display.
  - If infusion was delayed, **COMPLETE** scrolls in Channel Message Display and appears on Main Display.

Programming Bolus Dose

A bolus dose can be programmed at the beginning of, or during, an infusion. The drug being programmed must be a bolusable drug selected from the Guardrails® Drug Library or a non-library drug, as described in the following sections.

**NOTES:**
- If the **Bolus Dose** feature is enabled, the **BOLUS** soft key appears in the Continuous Infusion screen and becomes active when a VTBI is entered.
- The bolus VTBI cannot exceed the programmed continuous infusion VTBI.
- Programming and starting a bolus dose deletes any programmed delay.
- If no continuous rate is entered, the infusion will end when the bolus has been delivered. No KVO infusion will follow.
1. Set up Drug Calculation as described in “Setting Up Drug Calculation”, “Using Guardrails® Drug Library” section, but do not start infusion.

2. Press BOLUS soft key.

   Nonweight-based example.

   Weight-based example.

   • **DOSE** is highlighted.

**NOTES:**

- If the programmed continuous dose infusion is outside the Guardrails® Soft Limit for that care area, a prompt appears before programming can continue. If the **Yes** soft key is pressed, programming continues; if the **No** soft key is pressed, the infusion needs to be reprogrammed.

- If the programmed continuous dose infusion is outside the Guardrails® Hard Limit for that care area, a prompt appears before programming can continue. The infusion needs to be reprogrammed.
Programming Bolus Dose (Continued)

Using Guardrails® Drug Library Calculation (Continued)

3. To enter bolus dose, use numeric data entry keys.

   **NOTE:** After a bolus dose and weight (if used) are entered, bolus VTBI and concentration [conc] alternate in the Main Display.

   - If no weight has previously been programmed in system and bolus dose is weight-based, weight entry is empty.

   - If programmed continuous dose is weight-based, programmed weight displays (as in illustrated example, which reflects use of Heparin in Pediatrics ICU).

   - If bolus dose is not weight-based, Not Used displays in PATIENT WEIGHT field.

4. To enter or change patient weight (if used), use applicable following procedure, depending on whether or not continuous dose is weight-based.

   - When continuous dose is not weight-based:
     a. Press PATIENT WEIGHT soft key.
Programming Bolus Dose (Continued)

Using Guardrails® Drug Calculation (Continued)

b. To enter patient weight, use numeric data entry keys.

-- OR --

• When continuous dose is weight-based:
  a. Press SETUP soft key.
  b. Press PATIENT WEIGHT soft key.
  c. To change patient weight, use numeric data entry keys.
  d. Press NEXT soft key.

-- Continued on Next Page --
Programming Bolus Dose (Continued)

Using Guardrails® Drug Calculation (Continued)

NOTE: If a continuous infusion is running, a prompt to confirm the weight change appears.

e. Press BOLUS soft key.

f. To enter bolus dose, use numeric data entry keys.

5. Press DURATION soft key.
6. To enter bolus duration, use numeric data entry keys.

   OR

   To deliver bolus dose at maximum rate possible for selected profile and setup, and automatically calculate bolus duration, press **Max Rate** soft key.

   • **TOTAL DOSE** alternates with **INFUSE AT** rate.

7. Verify parameters are correct and press **START** soft key.

   • During infusion:
     ♦ Green Infusing Status Indicator illuminates.
     ♦ Rate appears in Channel Rate Display.
     ♦ Dose and drug name scroll in Channel Message Display.

     **NOTE:** If a continuous dose outside of the Guardrails® Soft Limits has been entered and verified as correct, the Channel Message Display also shows either “LLL” for a low dose or “↑↑↑” for a high dose.

     ♦ Main Display alternates between Bolus VTBI and drug name with dose.
Programming Bolus Dose (Continued)

Using Guardrails® Drug Calculation (Continued)

NOTE: To see details during the bolus infusion, press the CHANNEL SELECT key.

- At completion of bolus infusion:
  - System beeps twice.
  - BOLUS DOSE COMPLETE scrolls in Channel Message Display.

  NOTE: If the bolus dose infusion is not followed immediately by a continuous dose infusion, BOLUS COMPLETE appears on the Main Display.

  - Continuous dose infusion (if programmed) initiates.
  - VTBI counts down on Main Display.

- At completion of continuous infusion:
  - An audio prompt sounds.
  - Red Alarm Status Indicator flashes.
  - Channel Rate Display changes to KVO rate.
  - INFUSION COMPLETE–KVO scrolls in Channel Message Display.
  - KVO appears on Main Display.

Using Non-Library Drug Calculation

1. Set up Drug Calculation as described in “Setting Up Drug Calculation”, “Using Non-Library Drug” section, but do not start infusion.

2. Press BOLUS soft key.
   - DOSE is highlighted.
3. To enter bolus dose, use numeric data entry keys.

   **NOTE:** After a bolus dose and weight (if used) are entered, bolus VTBI and concentration \([\text{conc}]\) alternate in the Main Display.

4. Press soft key for appropriate unit of measure for dose.

   **NOTE:** If mcg or mg is selected as the dosing unit, a **PATIENT WEIGHT** entry cannot be made. If mcg/kg or mg/kg is selected as the dosing unit, a **PATIENT WEIGHT** entry is required.

5. To enter bolus duration, use numeric data entry keys.

   OR

   To deliver bolus dose at maximum rate possible for selected profile and setup, and automatically calculate bolus duration, press **Max Rate** soft key.

   • **TOTAL DOSE** alternates with **INFUSE AT** rate.

6. Verify parameters are correct and press **START** soft key.

   • During infusion:
     - Green Infusing Status Indicator illuminates.
     - Rate appears in Channel Rate Display.
     - Dose scrolls in Channel Message Display.
     - Bolus VTBI counts down on Main Display.
Programming Bolus Dose (Continued)

Using Non-Library Drug Calculation (Continued)

NOTE: To see details during the bolus infusion, press the CHANNEL SELECT key.

- At completion of bolus infusion:
  - System beeps twice.
  - BOLUS DOSE COMPLETE scrolls in Channel Message Display.

  NOTE: If the bolus dose infusion is not followed immediately by a continuous dose infusion, BOLUS COMPLETE appears on the Main Display.

  - Continuous dose infusion (if programmed) initiates.
  - VTBI counts down on Main Display.

- At completion of continuous infusion:
  - An audio prompt sounds.
  - Red Alarm Status Indicator flashes.
  - Channel Rate Display changes to KVO rate.
  - INFUSION COMPLETE–KVO scrolls in Channel Message Display.
  - KVO appears on Main Display.

Stopping Bolus Dose

NOTE: The display examples in this section represent stopping a bolus dose which was programmed using the Guardrails® Drug Library. Even where the displays are different when stopping a bolus dose which was programmed using a non-library drug, the procedure is the same.

1. Press CHANNEL SELECT key.
2. Press **STOP BOLUS** soft key.

3. To stop bolus and start continuous infusion, press **Yes** soft key.

4. To stop continuous infusion, press and hold **CHANNEL OFF** key until a beep is heard (approximately 1.5 seconds).

### Restoring Bolus Dose

A bolus dose can be restored after it has completed, either prior to or after the channel has been turned off, as indicated in the following sections.

**NOTE:** The display examples in this section represent restoring a bolus dose which was programmed using the Guardrails® Drug Library. Even where the displays are different when restoring a bolus dose which was programmed using a non-library drug, the procedure is the same.

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58 **GETTING STARTED**
1. Press CHANNEL SELECT key.
2. Verify infusion parameters and press BOLUS soft key.

Bolus Dose Completed - Channel Not Turned Off

3. Press RESTORE soft key.

Bolus Dose Completed - Channel Turned Off

1. Press CHANNEL SELECT key.
2. Press RESTORE soft key.
3. Verify parameters and press NEXT soft key.


5. Press RESTORE soft key.

When the Medley™ System is operating in Anesthesia Mode, a channel can be paused indefinitely without an alarm. Anesthesia Mode also makes it possible to have additional drugs in each profile, which are only accessible when operating in Anesthesia Mode.

**NOTE:** When the Anesthesia Mode is disabled while a Pump Module is paused, the Pump Module remains in an indefinite pause, until the module is restarted.

When Anesthesia Mode is enabled:

- All Guardrails® Limits are set to “Soft”.
- Dose checking mode is set to “Smart”.
- Key-press audio is turned off.
- Tamper Resist Mode (panel locked) is not available.
- All Guardrails® Drug Library entries are available for selection.
- Bolus dose is automatically available for:
  - drugs in Guardrails® Drug Library that have bolus dose limits defined, and
  - generic drug calculation setup, regardless of system configuration settings.
- **Anesthesia Mode**, alternating with other required prompts, displays in prompt bar of Main Display.
- Callback audio for paused channels is permanently silenced.
- Review of drug calculation setup page is omitted when restoring a stopped drug calculation.

### Enabling Anesthesia Mode

1. From Main Display, press **OPTIONS** key.
2. Press **Anesthesia Mode** soft key.

### CAUTION

When the Medley™ System is set up for use in Anesthesia Mode, it is important to select the profile that corresponds with the care area the patient will be taken to when the Anesthesia Mode is discontinued. This ensures that the Medley™ System will be in the correct profile following the use of the Anesthesia Mode.
Anesthesia Mode (Continued)

Enabling Anesthesia Mode (Continued)

3. Press **Enable** soft key.

4. Press **CONFIRM** soft key.

5. Press **Channel Select** key.

6. Program Anesthesia Mode infusion using same procedure as for any other continuous infusion.

Disabling Anesthesia Mode

The Anesthesia Mode can be disabled, and normal operation resumed, using either of the following three methods:

- System Options menu.
- Disconnecting system from AC power.
- Connecting system to AC power.

From System Options Menu

1. While operating in Anesthesia Mode, press **OPTIONS** key.

2. Press **Anesthesia Mode** soft key.
Anesthesia Mode (Continued)

Disabling Anesthesia Mode (Continued)

3. Press Disable soft key.
4. Press CONFIRM soft key.
   • **Anesthesia Mode** no longer appears on Main Display, indicating it has been disabled.

Disconnecting System from AC Power While in Anesthesia Mode

1. Disconnect system from AC.
   • Anesthesia Mode is automatically disabled.
   • All currently running infusions continue.
   • A prompt appears as an alert that Anesthesia Mode has been discontinued.
2. Press CONFIRM soft key.

Connecting System to AC Power While in Anesthesia Mode

1. Connect system to AC power.
2. To continue using Anesthesia Mode, press Yes soft key.
   OR
   To discontinue Anesthesia Mode, press No soft key.
Delay Options

Delay Options can be enabled at the time the Medley™ System is configured for use. If Delay Options is enabled, an infusion can be programmed to be delayed for a specified period of time and a callback can be scheduled, as described in the following sections.

**NOTE:** Since by definition, an infusion with Delay Options will not be infusing for a programmed period of time, it is assumed that another infusing IV line will keep the vein open until the delayed infusion begins. When a delay is programmed, the infusion stops when complete and no KVO is delivered.

Delaying Infusion

The delay period for an infusion can be programmed as a specific number of minutes or a time of day, as described in the following sections. An infusion delay can be programmed prior to or after an infusion is initiated.

### Specifying by Minutes

The **Delay for** option is used to program an infusion delay for a minimum of one minute and up to 120 minutes.

1. Press **DELAY OPTIONS** soft key.

<table>
<thead>
<tr>
<th>Infusion Setup</th>
<th>RATE 40 mL/h</th>
<th>VTBI 250 mL</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt;Press START</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DELAY OPTIONS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SECONDARY START</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DELAY OPTIONS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DELAY OPTIONS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DELAY OPTIONS</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2. Press **Delay for** soft key.

<table>
<thead>
<tr>
<th>Delay Options 08:00</th>
<th>Delay Options 08:00</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pause</td>
<td>Delay until</td>
</tr>
<tr>
<td>Delay for</td>
<td></td>
</tr>
<tr>
<td>Delay Options</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt;Select a Delay Option</td>
<td></td>
</tr>
<tr>
<td>BACK</td>
<td>CONFIRM</td>
</tr>
</tbody>
</table>
3. To enter number of minutes (up to 120) infusion is to be
delayed for, use numeric data entry keys.

4. Press CONFIRM soft key.

- Delay period counts down on Main Display.

- If a Before callback has not been scheduled (reference
  “Scheduling a Callback” section), infusion automatically
  initiates at end of delay period.
The **Delay until** option is used to program an infusion delay for a minimum of one minute and up to 23 hours 59 minutes.

1. Press **DELAY OPTIONS** soft key.

    **Infusion Setup**
    
    | RATE | VTBI |
    |------|------|
    | 40 mL/h | 250 mL |

    >Press START

2. Press **Delay until** soft key.

3. If **Current time** displayed is correct, press **CONFIRM** soft key; otherwise, press **Change Time** and enter correct time.  
   (Reference “Setting Up Time of Day” procedure in Medley™ Programming Module Directions for Use.)

   **NOTE:** If the current time has been previously confirmed, the **Time of Day** screen will not be displayed.

4. To enter time of day infusion is to be initiated (up to 23 hours 59 minutes), use numeric data entry keys.
5. Press CONFIRM soft key.

- Time infusion is scheduled to start appears on Main Display.

- If a Before callback has not been scheduled (reference “Scheduling a Callback” section), infusion automatically initiates at end of delay period.
When programming a Delay for or Delay until infusion, a callback can be scheduled for that infusion. There are three types of callback:

- **Before** - gives an alert when delay is completed and infusion needs to be initiated.
- **After** - gives an alert when delayed infusion has completed.
- **Before and After** - gives an alert when delay is completed and infusion needs to be initiated and when delayed infusion has completed.

The default callback (None), or the callback for the current profile, appears on the Main Display. To schedule a different callback:

1. **Prior to** pressing CONFIRM soft key to initiate delay during Delay for or Delay until programming process, press CALL BACK soft key.

2. Press soft key corresponding to desired callback option.
   - Scheduled callback appears on Main Display.

3. To initiate delay, press CONFIRM soft key.

-- Continued on Next Page --
Delay Options (Continued)

Scheduling a Callback (Continued)

- If Delay until programming, time infusion is scheduled to start appears on Main Display.

OR

- If Delay for programming, delay period counts down on Main Display.

- If Before option was selected:
  - An audio prompt sounds when delay period has ended.
  - Yellow Standby Status Indicator flashes.
  - DELAY COMPLETE scrolls in Channel Message Display and appears on Main Display.

- If After option was selected:
  - An audio prompt sounds when delayed infusion completes, and continues to sound until responded to.
  - Yellow Standby Status Indicator flashes until audio is silenced.
  - Infusion completed message appears on Main Display.
  - Infusion Complete scrolls in Channel Message Display.

- If Before and After option was selected, same prompts and indicators mentioned above for both Before and After options are exhibited.
Delay Options (Continued)

Scheduling a Callback (Continued)

4. To respond to a callback:
   • **Before** callback
     Press CHANNEL SELECT key and then START soft key.
     OR
     Press RESTART key.
   • **After** callback
     Press CONFIRM soft key.
   • **Before and After** callback
     Respond as indicated above for both **Before** and **After**.

Pausing Infusion

1. Press DELAY OPTIONS soft key.

   ▶ Press START
   40 mL/h
   ▶ RATE
   ▶ VTBI
   250 mL
   ▶ SecondARY START

2. Press **Pause** soft key.

   - **NOTES:**
     • *Using the Pause function in the Delay Options screen is the same as pressing the PAUSE key on the Pump Module.*
     • *The time displayed in the upper right corner of the screen is the time of day in a 24-hour clock format (military time).*

3. Press **CONFIRM** soft key.

   - **PAUSE** scrolls in Channel Message Display.
   - **PAUSED** appears on Main Display.
   - Yellow Standby Status Indicator illuminates.
   - After two minutes: **PAUSE - RESTART** visual and audio prompts begin, and yellow Standby Status Indicator flashes.
Multidose Mode

NOTES:

• Since, by definition, a multidose infusion will not be infusing for a programmed period of time, it is assumed that another infusing IV line will keep the vein open until the beginning of the first dose and between subsequent doses. There is no keep vein open (KVO) infusion at the completion of a programmed Delay until infusion.

• The Delay Options function for multidose infusions is similar to Delay Options for continuous drug infusions, with the following differences:
  • Delay for (when scheduling a callback) option is not available in Multidose Mode.
  • Maximum allowable delay on a multidose infusion is 8 hours.

WARNINGS

• The Multidose feature is to be used only by personnel properly trained in using multidose infusions.

• Caution labels, which clearly differentiate single dose and multidose containers, must be utilized.

• Single dose piggybacking systems employing check valve sets are not designed for use with multidose containers.

Programming with Volume / Duration Enabled

If Volume/Duration was enabled at the time the Medley™ System was configured for use, use the following procedure to program a multidose infusion.

1. Perform steps in “Start-Up” section, to:
   a. Power on system.
   b. Choose Yes or No to New Patient?
   c. Confirm current profile or select a new profile.
   d. Enter patient identifier, if required.
2. Perform steps in “Preparing Infusion” section, to prime and load primary administration set.

3. Press CHANNEL SELECT key.

4. Press Basic Infusion soft key.
   - **Infusion Setup** screen appears.

5. Press OPTIONS key.

6. Press Multidose soft key.

7. If **Current time** displayed is correct, press **CONFIRM** soft key; otherwise, press **Change Time** and enter correct time. (Reference “Setting Up Time of Day” procedure in Medley™ Programming Module Directions for Use.)

   **NOTE:** If the current time has been previously confirmed, the Time of Day screen will not be displayed.
Multidose Mode (Continued)

Programming with Volume / Duration Enabled (Continued)

8. Press VOLUME DURATION soft key.

9. To enter volume to be infused for each dose, use numeric data entry keys.

10. To enter duration for each dose, press DURATION soft key and use numeric data entry keys.

   **NOTE:** RATE is calculated with each keystroke for DURATION.

11. To enter time interval (1 to 24 hours) between doses, press DOSE INTERVAL soft key and use numeric data entry keys.
12. To enter number of doses, press **#OF DOSES** soft key and use numeric data entry keys.
   - If Delay Options is enabled, **DELAY OPTIONS** soft key appears.

**NOTE:** Reference “Delay Options” section to program an infusion delay. When delaying an infusion, a multidose cannot be delayed for more than 8 hours, and all doses in the multidose program must be completed within a 24-hour program.

13. To begin multidose infusion, press **START** soft key.
   - Main Display shows remaining VTBI for that dose.
   - At completion of a multidose program, **MULTIDOSE COMPLETE** appears on Main Display.
14. To see detail screen during or between infusions, press CHANNEL SELECT key.

- During infusion, **Volume Remaining** displays.

- Between infusions:
  - Number of doses completed and when next dose starts display.
  - Yellow Standby Status Indicator illuminates.

---

### Programming with Volume / Duration Disabled

If Volume/Duration was not enabled at the time the Medley™ System was configured for use, use the following procedure to program a multidose infusion.

1. Perform steps in “Start-Up” section, to:
   a. Power on system.
   b. Choose **Yes** or **No** to New Patient?
   c. Confirm current profile or select a new profile.
   d. Enter patient identifier, if required.

2. Perform steps in “Preparing Infusion” section, to prime and load primary administration set.

3. Press **CHANNEL SELECT** key.
4. Press **Basic Infusion** soft key.
   - **Infusion Setup** screen appears.

5. Press **OPTIONS** key.

6. Press **Multidose** soft key.

7. To enter rate, use numeric data entry keys.
8. To enter volume to be infused for each dose, press VOLUME/DOSE soft key and use numeric data entry keys.

9. To enter time interval (1 to 24 hours) between doses, press DOSE INTERVAL soft key and use numeric data entry keys.

10. To enter number of doses, press #OF DOSES soft key and use numeric data entry keys.
   • If Delay Options is enabled, DELAY OPTIONS soft key appears.

   **NOTE:** Reference “Delay Options” section to program an infusion delay. When delaying an infusion, a multidose cannot be delayed for more than 8 hours, and all doses in the multidose program must be completed within a 24-hour program.

11. To begin multidose infusion, press START soft key.
Multidose Mode (Continued)

Programming with Volume / Duration Disabled (Continued)

- Main Display shows remaining VTBI for that dose.

- At completion of a multidose program, MULTIDOSE COMPLETE appears on Main Display.

12. To see detail screen during or between infusions, press CHANNEL SELECT key.

- During infusion, Volume Remaining displays.

- Between infusions:
  - Number of doses completed and when next dose starts displays.
  - Yellow Standby Status Indicator illuminates.
Reviewing Serial Number

Refer to the Medley™ Programming Module Directions for Use.

Reviewing Software Version

Refer to the Medley™ Programming Module Directions for Use.
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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.

**NOTE:** This feature is only available with Pump Module Versions 1.11.22.5 and greater.
The Programming Module and Main Display provide various types of alert information. The characteristics of the accompanying audio sounds are as follows:

<table>
<thead>
<tr>
<th>Type</th>
<th>Sound</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advisory</td>
<td>One short beep every two seconds</td>
<td>Variable volume; can be silenced for two minutes.</td>
</tr>
<tr>
<td>Alarm</td>
<td>Choice of three alarm audio profiles, selectable in System Configuration</td>
<td>Variable volume; can be silenced for two minutes.</td>
</tr>
<tr>
<td>Error (Hardware Detected)</td>
<td>Pairs of long beeps</td>
<td>Fixed maximum decibel volume; cannot be silenced.</td>
</tr>
<tr>
<td>Error (Software Detected)</td>
<td>Pairs of long beeps</td>
<td>Fixed maximum decibel volume; can be silenced for two minutes.</td>
</tr>
<tr>
<td>Illegal Key Press</td>
<td>Two short beeps</td>
<td>Variable volume; cannot be silenced.</td>
</tr>
<tr>
<td>Key Click</td>
<td>One short beep</td>
<td>Fixed minimum volume; can be silenced and disabled in System Configuration.</td>
</tr>
<tr>
<td>Prompt</td>
<td>One short beep every two seconds</td>
<td>Variable volume; can be silenced.</td>
</tr>
<tr>
<td>Switchover</td>
<td>Six short beeps: secondary switching to primary. Two short beeps: bolus switching to continuous.</td>
<td>Variable volume; can be silenced and disabled in System Configuration.</td>
</tr>
<tr>
<td>Alarm</td>
<td>Meaning</td>
<td>Response</td>
</tr>
<tr>
<td>------------------------------------</td>
<td>------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Accumulated Air-in-Line</td>
<td>A large number of air bubbles smaller than current air-in-line limit has recently passed detector.</td>
<td>Clear air from line. To continue infusion, press RESET soft key and then RESTART key.</td>
</tr>
<tr>
<td>Air-in-Line</td>
<td>Air has been detected in administration set during an infusion. Infusion stops on affected channel.</td>
<td>Ensure tubing is properly installed in Air-in-Line Detector. If air is present, clear air from administration set. Press RESTART key, or press CHANNEL SELECT key and then START soft key.</td>
</tr>
<tr>
<td>Channel Disconnected</td>
<td>Channel(s) disconnected while in operation or has a communication problem.</td>
<td>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.</td>
</tr>
<tr>
<td>Check IV Set</td>
<td>Administration set is not properly installed. Infusion stops on affected channel.</td>
<td>Close roller clamp, remove and reinstall administration set, close door, open roller clamp, and then press RESTART key.</td>
</tr>
<tr>
<td>Close Door</td>
<td>Door opened during an infusion. Infusion stops on affected channel.</td>
<td>Close door. Press RESTART key, or press CHANNEL SELECT key and then START soft key.</td>
</tr>
<tr>
<td>Flo-Stop Open - Close Door</td>
<td>Flo-Stop® Device is in open position while door is open.</td>
<td>Close roller clamp on administration set or close door.</td>
</tr>
<tr>
<td>Occluded - Fluid Side/Empty Container</td>
<td>Indicates either upstream occlusion or empty container. Infusion stops on affected channel.</td>
<td>Clear occlusion on fluid side of instrument. If necessary, refill drip chamber. Press RESTART key, or press CHANNEL SELECT key and then START soft key.</td>
</tr>
<tr>
<td>Occluded - Patient Side</td>
<td>Increased back pressure sensed while infusing in pump delivery mode. Infusion stops on affected channel.</td>
<td>Clear occlusion. Press RESTART key, or press CHANNEL SELECT key and then START soft key.</td>
</tr>
<tr>
<td>Partial Occlusion - Patient Side</td>
<td>Partial occlusion of patient side of IV line detected by AutoRestart feature.</td>
<td>Clear occlusion. Press RESTART key, or press CHANNEL SELECT key and then START soft key.</td>
</tr>
<tr>
<td>Pump Chamber Occluded</td>
<td>Blocked pump chamber detected.</td>
<td>Open door and inspect pump chamber. To open blockage, as required, massage tubing. To continue infusion, press RESET soft key and then RESTART key.</td>
</tr>
</tbody>
</table>
### Alarms (Continued)

<table>
<thead>
<tr>
<th>Alarm</th>
<th>Meaning</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Restart Channel</td>
<td>Door opened and closed during an infusion. Infusion stops on affected channel. Channel paused for 2 minutes.</td>
<td>Close door. Press RESTART key, or press CHANNEL SELECT key and then START soft key. Press RESTART key, or press CHANNEL SELECT key and then START soft key</td>
</tr>
</tbody>
</table>

### Errors

<table>
<thead>
<tr>
<th>Error</th>
<th>Meaning</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Channel Error</td>
<td>Error detected. Operation stops on affected channel.</td>
<td>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.</td>
</tr>
</tbody>
</table>

### Messages

<table>
<thead>
<tr>
<th>Message</th>
<th>Meaning</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anesthesia Mode</td>
<td>Anesthesia Mode discontinued when disconnected from AC.</td>
<td>Press CONFIRM soft key.</td>
</tr>
<tr>
<td>Bolus Dose Complete</td>
<td>Channel running in continuous infusion mode if programmed.</td>
<td>None</td>
</tr>
<tr>
<td>Checking Line</td>
<td>Patient-side occlusion occurred; AutoRestart feature monitoring downstream pressure to determine if infusion can continue.</td>
<td>None</td>
</tr>
<tr>
<td>Delay Complete</td>
<td>Delay time completed.</td>
<td>Press RESTART key, or press CHANNEL SELECT key and then START soft key.</td>
</tr>
<tr>
<td>Infusion Complete</td>
<td>Current infusion completed.</td>
<td>Set up a new infusion or press CHANNEL OFF key.</td>
</tr>
<tr>
<td>Infusion Complete - KVO</td>
<td>Programmed volume-to-be-infused delivered; channel running at KVO rate.</td>
<td>Set up a new infusion or press CHANNEL OFF key.</td>
</tr>
<tr>
<td>Panel Locked</td>
<td>Tamper Resist feature is active and a key was pressed.</td>
<td>If appropriate, deactivate Tamper Resist feature using Tamper Resist Control on back of Programming Module.</td>
</tr>
<tr>
<td>Message</td>
<td>Meaning</td>
<td>Response</td>
</tr>
<tr>
<td>-------------------------------------</td>
<td>----------------------------------------------</td>
<td>-----------------------------------------------</td>
</tr>
<tr>
<td>Panel Unlocked</td>
<td>Tamper Resist feature deactivated.</td>
<td>None.</td>
</tr>
<tr>
<td>Pause</td>
<td>Pause control pressed; infusion stopped.</td>
<td>To resume infusion, press RESTART key, or press CHANNEL SELECT key and then START soft key.</td>
</tr>
<tr>
<td>Secondary</td>
<td>Secondary infusion in progress on indicated channel.</td>
<td>None. When secondary VTBI=“0”, infusion will revert to programmed primary parameters.</td>
</tr>
<tr>
<td>Start time for next dose has passed.</td>
<td>Start of next dose passed.</td>
<td>Press CONFIRM soft key.</td>
</tr>
</tbody>
</table>
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

<table>
<thead>
<tr>
<th>Accumulated Air Window:</th>
<th>Single Bolus Setting</th>
<th>Volume Window (mL)</th>
<th>% Air that Causes Alarm</th>
</tr>
</thead>
<tbody>
<tr>
<td>50</td>
<td>2.8</td>
<td>10%</td>
<td></td>
</tr>
<tr>
<td>75</td>
<td>8.0</td>
<td>20%</td>
<td></td>
</tr>
<tr>
<td>250</td>
<td>8.0</td>
<td>30%</td>
<td></td>
</tr>
<tr>
<td>*500</td>
<td>12.0</td>
<td>30%</td>
<td></td>
</tr>
</tbody>
</table>

* In Anesthesia Mode only.

<table>
<thead>
<tr>
<th>Bolus Volume following Occlusion, Maximum:</th>
<th>Rate (mL/h)</th>
<th>Pressure Limit (mmHg)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>50</td>
<td>525</td>
</tr>
<tr>
<td></td>
<td>25 ≤0.3 mL</td>
<td>≤0.6 mL</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Critical Volume:</th>
<th>The maximum over-infusion which can occur in the event of a single fault condition is 0.6 mL.</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Dimensions:</th>
<th>3.3&quot;W x 8.9&quot;H x 5.5&quot;D</th>
</tr>
</thead>
</table>

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

<table>
<thead>
<tr>
<th>Equipment Orientation:</th>
<th>To ensure proper operation, the system must remain in an upright position.</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Electrical Classification:</th>
<th>Class 1, Type CF Defibrillator Proof</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Flow Rate Programming Increments:</th>
<th>Rate Range (mL/h)</th>
<th>Increments (mL/h)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>User Input Rates</td>
<td>Device Calculated Rates</td>
</tr>
<tr>
<td>0.1 - 9.99</td>
<td>0.1</td>
<td>0.01</td>
</tr>
<tr>
<td>10 - 99.9</td>
<td>0.1</td>
<td>0.1</td>
</tr>
<tr>
<td>100 - 999</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>
Specifications (Continued)

Fluid Ingress Protection: IPX1, Drip Proof

Infusion of Air, Means to Protect Patient from: Ultrasonic Air-in-Line Detection
Maximum single bolus size = selectable 50, 75 or 250 microliters nominal (500 microliters in Anesthesia Mode)

Infusion Pressure, Maximum: 654 mmHg (Maximum Occlusion Alarm Threshold plus tolerance)

KVO (Keep Vein Open) Rate: Factory Default Setting is 1 mL/h if set rate is 1 mL/h or above; or set rate, if rate is 0.9 mL/h or below.

KVO Selection Range: KVO rate can be set in System Configuration from 0.1-20 mL/h in 0.1 mL/h increments.

Occlusion Alarm Thresholds:
- Pump Mode: 525 mmHg at rates ≥30 mL/h Varying level based on rate and patient back-pressure at rates <30 mL/h.
- Selectable Mode: User selected from 50 to 525 mmHg in 25 mmHg increments.

Operating Principle: Positive displacement

Rate Accuracy: Rate accuracy of the Medley™ Medication Safety System is ±5% at rates between 1 and 999 mL/h and ±5.5% at rates <1 mL/h, 95% of the time with 95% confidence, under the conditions listed below.

Infusion Rate Range: 0.1 to 999 mL/h
Ambient Temperature: 68 ±4°F (20 ±2°C)
Source Container Height: 20 inches above the top of the Pump Module
Test Solution: Distilled Water
Distal Back pressure: 0 mmHg (0 kPa)
Needle: 18 gauge
Administration Set Model 2210

**WARNING**

Variations of head height, back pressure or any combination of these may affect rate accuracy. Factors that can influence head height and back pressure are: Administration set configuration, IV solution viscosity and IV solution temperature. Back pressure may also be affected by type of catheter. Refer to the “Trumpet and Start-Up Curves” section in “Appendix” chapter for data on how these factors influence rate accuracy.

<table>
<thead>
<tr>
<th>Rate (mL/h)</th>
<th>50</th>
<th>525</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>≤5 minutes</td>
<td>≤45 minutes</td>
</tr>
<tr>
<td>25</td>
<td>≤15 seconds</td>
<td>≤2 minutes</td>
</tr>
</tbody>
</table>
Specifications (Continued)

Volume to be Infused
Programming Increments:

<table>
<thead>
<tr>
<th>Range (mL)</th>
<th>Increments (mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.1 - 9.99</td>
<td>0.01</td>
</tr>
<tr>
<td>10 - 999.9</td>
<td>0.1</td>
</tr>
<tr>
<td>1000 - 9999</td>
<td>1</td>
</tr>
</tbody>
</table>

Weight: 2.5 lbs

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

Configurable Settings

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.

System Settings

Refer to the Medley™ Programming Module Directions for Use.
### Configurable Settings (Continued)

#### Shared Infusion Settings
(Pump Module and Syringe Module)

<table>
<thead>
<tr>
<th>Feature</th>
<th>Default Setting</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Delay Options</td>
<td>Disabled</td>
<td>Enabled - Disabled</td>
</tr>
<tr>
<td>• Callback</td>
<td>None</td>
<td>None, Before, After, Before and After</td>
</tr>
<tr>
<td>Drug Calculation</td>
<td>Disabled</td>
<td>Enabled - Disabled</td>
</tr>
<tr>
<td>• Bolus Dose</td>
<td>Disabled</td>
<td>Enabled - Disabled</td>
</tr>
<tr>
<td>Multidose</td>
<td>Disabled</td>
<td>Enabled - Disabled</td>
</tr>
<tr>
<td>• Callback</td>
<td>None</td>
<td>None, Before, After, Before and After</td>
</tr>
<tr>
<td>Pressure Dynamic</td>
<td>Disabled</td>
<td>Enabled - Disabled</td>
</tr>
<tr>
<td>(&quot;Dynamic Pressure Display&quot;)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Volume/Duration</td>
<td>Disabled</td>
<td>Enabled - Disabled</td>
</tr>
</tbody>
</table>

#### Pump Module Settings

<table>
<thead>
<tr>
<th>Feature</th>
<th>Default Setting</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accumulated Air-in-Line</td>
<td>Enabled</td>
<td>Enabled - Disabled</td>
</tr>
<tr>
<td>Air-in-Line Settings (single bolus)</td>
<td>75 microliters</td>
<td>50, 75 or 250 microliters</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Anesthesia Mode only: 500 microliters</td>
</tr>
<tr>
<td>AutoRestart Attempts</td>
<td>0</td>
<td>0 - 9 attempts</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Anesthesia Mode only: 9 attempts</td>
</tr>
<tr>
<td>KVO Rate Adjust (&quot;Keep Vein Open&quot;)</td>
<td>1 mL/h</td>
<td>0.1 - 20 mL/h</td>
</tr>
<tr>
<td>Max Rate</td>
<td>999 mL/h</td>
<td>0.1 - 99.9 mL/h in 0.1 mL/h increments;</td>
</tr>
<tr>
<td></td>
<td></td>
<td>100 - 999 mL/h in 1.0 mL/h increments.</td>
</tr>
<tr>
<td>Max VTBI</td>
<td>9999 mL</td>
<td>0.1 - 9999 mL</td>
</tr>
<tr>
<td>Pressure Mode</td>
<td>Pump</td>
<td>Pump, Selectable</td>
</tr>
<tr>
<td>• Mode Selection</td>
<td>Unlocked</td>
<td>Locked, Unlocked</td>
</tr>
<tr>
<td>• Lock Status</td>
<td>525 mmHg</td>
<td>50 - 525 mmHg in 25 mmHg increments (adjustable only in Selectable Pressure Mode)</td>
</tr>
<tr>
<td>SEC to PRI Alert</td>
<td>Enabled</td>
<td>Enabled - Disabled</td>
</tr>
<tr>
<td>Secondary (&quot;Dual Rate Sequential Piggybacking&quot;)</td>
<td>Disabled</td>
<td>Enabled - Disabled</td>
</tr>
</tbody>
</table>
Cleaning

Refer to the Medley™ Programming Module Directions for Use.

Inspection Requirements

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

**Regular inspections** consist of a visual inspection for damage and cleanliness, and performing the procedure described in the “Start-Up” 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.

**WARNING**

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

### REGULAR INSPECTIONS

<table>
<thead>
<tr>
<th>PROCEDURE</th>
<th>FREQUENCY</th>
</tr>
</thead>
<tbody>
<tr>
<td>INSPECT FOR DAMAGE:</td>
<td></td>
</tr>
<tr>
<td>Exterior Surfaces</td>
<td>Each usage</td>
</tr>
<tr>
<td>Keypad</td>
<td>Each usage</td>
</tr>
<tr>
<td>Seal</td>
<td>Each usage</td>
</tr>
<tr>
<td>Mechanical Parts</td>
<td>Each usage</td>
</tr>
<tr>
<td>CLEANING</td>
<td>As required</td>
</tr>
<tr>
<td>START-UP</td>
<td>Each usage</td>
</tr>
</tbody>
</table>

1. Exterior Surfaces - examine for overall condition and verify:
   - No damage, cracks or deformities.
   - Case is clean and free from IV solution residue, especially near moving parts.
   - Accessible areas of air-in-line sensor, pressure transducers and latch mechanism are clean and free from IV solution residue.
   - Labels and markings are legible.
   - No tape or other foreign material is on sides of case; anything of this nature could prevent proper latching of channels.
   - IU1 Connectors have not been damaged.

2. Keypad
   Check membrane switches for damage.
3. Seal and Mechanical Parts
   • Mechanism seal is not torn or worn.
   • Mechanical parts move freely, do not hang up or bind, and function properly.
   • Torsion Spring on door functions properly. Open Door and ensure Door Latch stays up and does not sag.

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

Refer to the Medley™ Programming Module Directions for Use.
ALARIS Medical Systems, Inc., (hereinafter referred to as “ALARIS Medical Systems”) warrants that:

A. Each new ALARIS Medical Systems® Medley™ Pump 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. 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.
DESCRIPTION AND EXPLANATION OF TRUMPET AND START-UP CURVES

In this instrument, as with all infusion systems, the action of the pumping mechanism and variations in individual administration sets cause short-term fluctuations in rate accuracy. The following graphs show typical performance of the system for both Pressure and Resistance Modes in two ways:

1. Accuracy during various time periods over which fluid delivery is measured (trumpet curves).
2. Delay in onset of fluid flow when infusion commences (start-up curves).

Trumpet curves are named for their characteristic shape. They display discrete accuracy data averaged over particular time periods or “observation windows”, not continuous data versus operating time.

Over long observation windows, short-term fluctuations have little effect on accuracy, as represented by the flat part of the curve. As the observation window is reduced, short-term fluctuations have greater effect, as represented by the “mouth” of the trumpet. Knowledge of system accuracy over various observation windows may be of interest when certain drugs are being administered.

Because the clinical impact of short-term fluctuations on rate accuracy depends on the half-life of the drug being infused and on the degree of intravascular integration, the clinical effect cannot be determined from the trumpet curves alone. Knowledge of the start-up characteristics should also be considered.

The start-up curves represent continuous flow rate versus operating time for two hours from the start of the infusion. They exhibit the delay in onset of delivery due to mechanical compliance and provide a visual representation of uniformity. Trumpet curves are derived from the second hour of this data.

FLOW CHARACTERISTICS UNDER VARYING DELIVERY CONDITIONS

Effects of Pressure Variations

Under conditions of +100 mmHg pressure, the Medley™ Pump Module typically exhibits a long-term accuracy offset of approximately –0.7% from mean values.

Under conditions of +300 mmHg pressure, the Medley™ Pump Module typically exhibits a long-term accuracy offset of approximately –4.2% from mean values.

Under conditions of -100 mmHg pressure, the Medley™ Pump Module typically exhibits a long-term accuracy offset of approximately +4.4% from mean values.

Resulting trumpet observation points typically track those of accuracy; therefore, no significant change in short-term variations result under these pressure conditions.

Effects of Negative Solution Container Heights

With a negative head height of -0.5 meters, the Medley™ Pump Module typically exhibits a long-term accuracy offset of approximately –3.1% from mean values.

Resulting trumpet observation points typically track those of accuracy; therefore, no significant change in short-term variations result under negative head height conditions.

NOTE: Tests conducted in accordance with IEC/EN 60601–2–24, “Particular requirements for safety of infusion pumps and controllers” and AAMI ID26–1998 “Medical electrical equipment - Part 2: Particular requirements for the safety of infusion pumps and controllers”, using Medley™ System/Gemini Model 2210 Administration Sets.
Trumpet and Start-Up Curves (Continued)

**NOTE:** The plot range has been increased to ±100%, to allow visualization of the graph.

Legend:
- ■ Maximum rate error
- ♦ Overall rate error
- ◆ Minimum rate error
Trumpet and Start-Up Curves (Continued)

Legend:
- Maximum rate error
- Overall rate error
- Minimum rate error

Start-Up at 25 mL/h (initial)

Start-Up at 999 mL/h (initial)

Trumpet Curve at 25 mL/h (initial)

Trumpet Curve at 999 mL/h (initial)

Trumpet Curve at 25 mL/h (72 hrs)

Trumpet Curve at 999 mL/h (24 hrs)