Medley™
MEDICATION SAFETY SYSTEM
PUMP MODULE
8100 Series
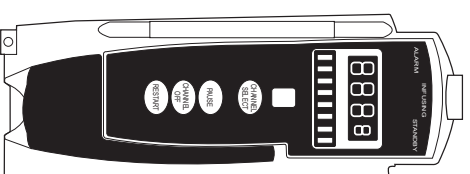
DIRECTIONS FOR USE

PUMP MODULE
8100 SERIES

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GETTING STARTED (Continued)

Customer Advocacy

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

Phone, toll-free, within the United States and Canada: (800) 854-7128, Ext. 7812
E-Mail: CustomerFeedback@alarismed.com

Technical Support

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

United States:

Phone:

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

Canada:

Phone, Toll-free:

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

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

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About the System

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

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

> 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 irrigation 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.

Features and Definitions

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.

Symbols

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

IPX1 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 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.

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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.

℞ Only

WARNING

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

CAUTION

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

Warnings and Cautions

For WARNINGS and CAUTIONS for 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.

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).

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.
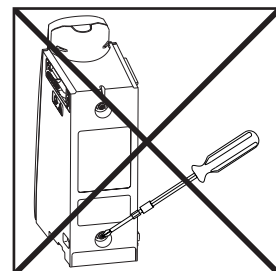
Administration Sets

- 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.*

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.

User Precautions (Continued)

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.
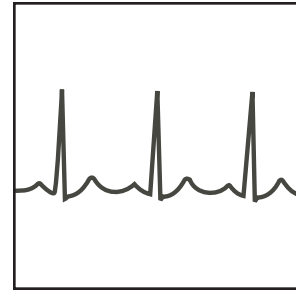
Dropping/Jarring

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.
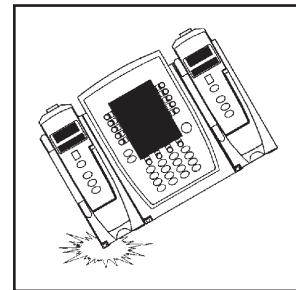
Operating Environment

Not for use in the presence of flammable anesthetics.

◄ DANGER ►

Explosion risk if used in the presence of flammable anesthetics.

GETTING STARTED

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Radio Frequency Interference

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

WARNING

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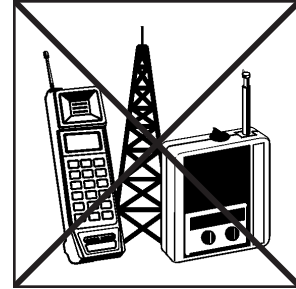
Controls and Indicators

Front/Side View - Door Closed

Status Indicators

Alarm (red)   Infusing (green)   Standby (yellow)

IUI Connector, Right (not visible)

IUI Connector, Left

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.

Door Handle

Channel Release Latch

Front View - Door Open

IUI Connector, Left
(not visible)

Upper Tubing
Fitment Retainer

Platen

IUI Connector, Right

Upper Pressure Sensor

Upper Occluder

Upper Pumping Finger

Door Latch Cam/Slide

Lower Occluder

Lower Pumping Finger

Lower Pressure Sensor

Flo-Stop® Recess

Tubing Keeper

Air-in-Line Sensor

Installation

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

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

Midtown Hospital
Adult ICU

A VTBI = 250.0 mL
B
C
D

VOLUME INFUSED   AUDIO ADJUST

Channel Selected Indicator

"Inactive" Soft Key

Nonhighlighted indicates a nonselected soft key.

"Active" Soft Key

Highlighted indicates a selected soft key.

Prompt Bar

Look here for user prompts.

A Infusion Setup

RATE   40 mL/h
VTBI   _250 mL

>*Press START*

PAUSE   SECOND-ARY   START

Dynamic Pressure Display

Midtown Hospital
Adult ICU

VTBI = 250.0 mL

Dynamic Pressure Display

Current operating pressure is indicated by solid bar.

Patient-side occlusion pressure set point is indicated by tick mark.

VOLUME INFUSED

AUDIO ADJUST

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).

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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 <u>open</u> position (white slide clamp aligned with blue fitment). In this open position, flow is <u>not occluded</u> 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 <u>closed</u> position (white slide clamp projects out from under blue fitment). In this closed position, flow <u>is occluded</u>.

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.)

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

6. Close Pump Module door.
   • Flo-Stop® Device is automatically disengaged.

7. Open roller clamp.

8. Verify no fluid is flowing through drip chamber.

CAUTION

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

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.

3. Firmly push tubing toward back of Air-in-Line Detector.
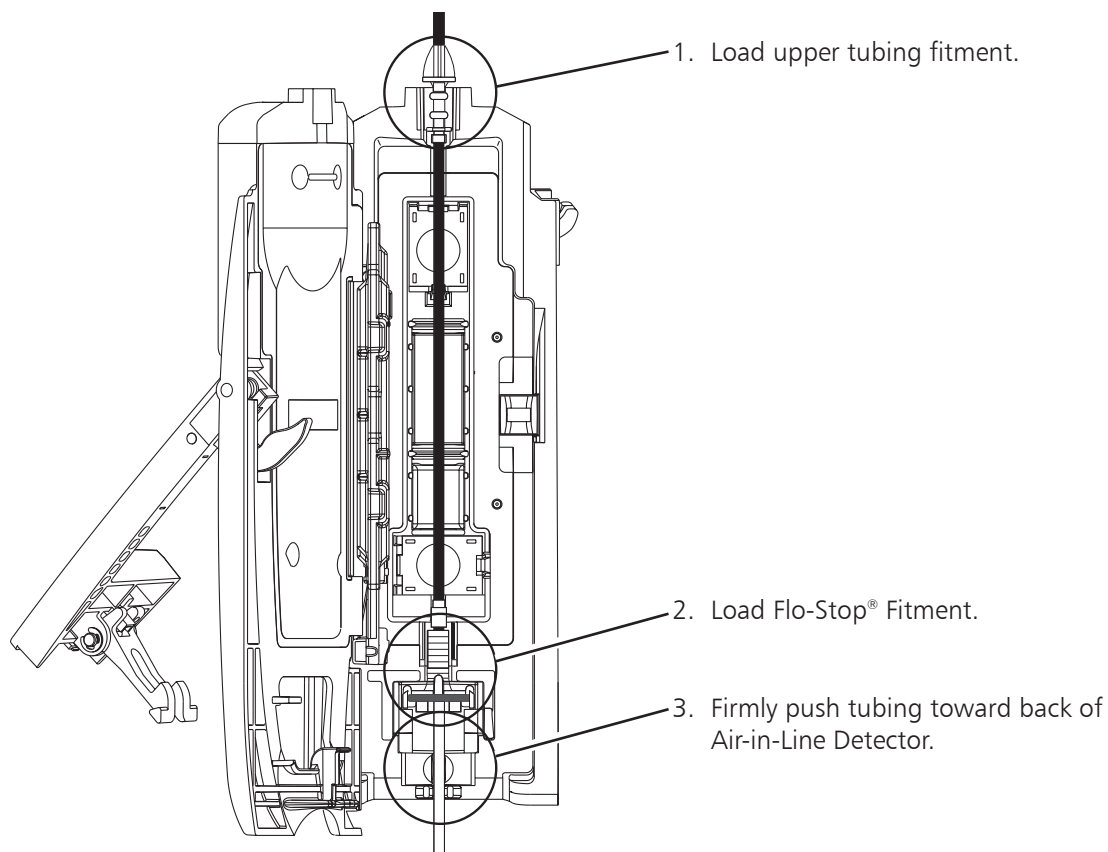
Removing Administration Set

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.

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.

GETTING STARTED

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.

```
A  Infusion Menu
Guardrails Drug Library
Basic infusion



>Select an Option or EXIT

RESTORE   EXIT
```

Starting Rate / Volume Infusion

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

```
A  Infusion Setup
RATE  _ _ _ mL/h
VTBI  _ _ _ _ mL




 >Select Rate or Restore
  Previous Infusion
RESTORE  VOLUME
         DURATION
```

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

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

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




>Select VTBI

         VOLUME
         DURATION
```

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.*

```
A  Infusion Setup
RATE  40 mL/h
VTBI  _ 250 mL




>Press START

PAUSE  VOLUME  SECOND-  START
       DURATION  ARY
```

-- Continued on Next Page --

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.

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


VOLUME          AUDIO
INFUSED         ADJUST
```
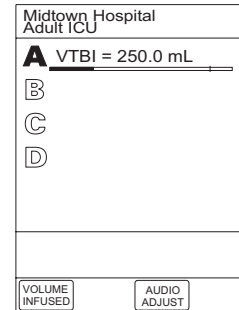
Starting Volume / Duration Infusion

1. Press **VOLUME DURATION** soft key.
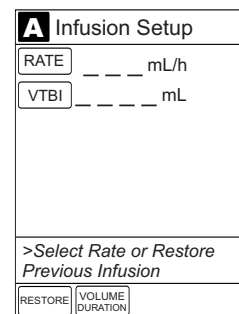
```
A Infusion Setup
RATE    _ _ _ mL/h
VTBI  _ _ _ _ mL




>Select Rate or Restore
Previous Infusion
RESTORE  VOLUME
         DURATION
```

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

```
A Infusion Setup
RATE =    _ _ _ mL/h
VTBI    _ _ _ _ mL
DURATION _ _ h _ _ min



>Select VTBI

RESTORE  RATE
         VOLUME
```
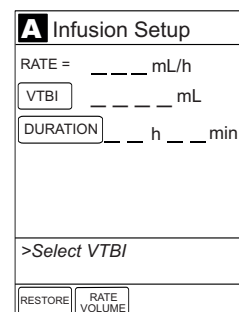
GETTING STARTED

Starting Volume / Duration Infusion (Continued)

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.

```
A  Infusion Setup

RATE =  _ _ _  mL/h
VTBI     1000 mL
DURATION  _ _ h _ _ min



>Select DURATION
        RATE
        VOLUME
```

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.

```
A  Infusion Setup

RATE =    125 mL/h
VTBI      1000 mL
DURATION  _8:00 hh:mm



>Press START
PAUSE  RATE   SECOND-  START
       VOLUME  ARY
```

> **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.

```
A  Infusion Setup

RATE      125 mL/h
VTBI      875 mL
Time Left: 07 h 00 min



>Press START
PAUSE  VOLUME   SECOND-  START
       DURATION  ARY
```

```
Midtown Hospital
Adult ICU

A  VTBI = 250.0 mL
B
C
D



VOLUME          AUDIO
INFUSED         ADJUST
```

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).

A Infusion Setup
RATE 40 mL/h
VTBI 500 mL
>Press START
PAUSE | VOLUME DURATION | SECONDARY | START

Midtown Hospital
Adult ICU
A PAUSED
B VTBI = 497.0 mL
C VTBI = 57.0 mL
D VTBI = 249.0 mL
VOLUME INFUSED | AUDIO ADJUST

A Infusion Setup
RATE 40 mL/h
VTBI 500 mL
>Press START
PAUSE | VOLUME DURATION | SECONDARY | START

GETTING STARTED

Restarting Infusion Following Infusion Complete

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".

A Infusion Menu
Guardrails Drug Library
Basic infusion
>Select an Option or EXIT
RESTORE   EXIT

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.

A Infusion Setup
RATE   40 mL/h
VTBI   500 mL
>Press START
PAUSE VOLUME DURATION SECONDARY START

Changing Rate or VTBI During Infusion

1. Press **CHANNEL SELECT** key.

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

```
┌─────────────────────────┐
│ A Infusion Setup        │
│ ┌──────┐                │
│ │ RATE │   40 mL/h      │
│ └──────┘                │
│ ┌──────┐                │
│ │ VTBI │  240 mL        │
│ └──────┘                │
│                         │
│                         │
│                         │
│ >Press START            │
│ ┌─────┐┌──────┐┌──────┐┌─────┐ │
│ │PAUSE││VOLUME││SECOND-││START│ │
│ │     ││DURATION││ ARY ││     │ │
│ └─────┘└──────┘└──────┘└─────┘ │
└─────────────────────────┘
```

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.

```
┌─────────────────────────┐
│ A Infusion Setup        │
│ ┌──────┐                │
│ │ RATE │  _50 mL/h      │
│ └──────┘                │
│ ┌──────┐                │
│ │ VTBI │  240 mL        │
│ └──────┘                │
│                         │
│                         │
│                         │
│ >Press START            │
│ ┌─────┐┌──────┐┌──────┐┌─────┐ │
│ │PAUSE││VOLUME││SECOND-││START│ │
│ │     ││DURATION││ ARY ││     │ │
│ └─────┘└──────┘└──────┘└─────┘ │
└─────────────────────────┘
```

Stopping Infusion

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

> *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.*

Selecting Pressure Mode - Pump / Selectable

1. Press **CHANNEL SELECT** key.

2. Press **OPTIONS** key.

3. Press **Pressure Limit** soft key.

A Channel Options 1 of 1
Guardrails Drug Library
Multidose
Pressure Limit - P
Channel Labels
>*Select an Option or EXIT*
EXIT

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

A
Pressure Limit Selection
Pump
Selectable
>*Select an Option or EXIT*
EXIT

5. To select occlusion pressure limit, press either **Up** or **Down** soft key.

6. Verify correct occlusion pressure limit input and press **CONFIRM** soft key.

7. Press **START** soft key.

A
Pressure Limit Selection
Selectable Pressure
525 mmHg   Up
Down
CONFIRM

Viewing and Clearing Volume Infused

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.

```
Midtown Hospital
Adult ICU

A    PAUSED
B    VTBI = 497.0 mL
C    VTBI =  57.0 mL
D    VTBI = 249.0 mL



VOLUME              AUDIO
INFUSED             ADJUST
```

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

```
Volume Infused

TOTAL VOLUME (mL)        LAST
                       CLEARED
A          401.1     08:00
                     2002-03-10
B           42.5     07:30
                     2002-03-11
C          478.1     08:00
                     2002-03-10
D          789.1     12:00
                     2002-03-10

>Select Channels to Clear
or Press CLEAR ALL
PRI/SEC   CLEAR            MAIN
VOLUME     ALL           SCREEN
```

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.

```
Volume Infused

   PRI (mL)      SEC (mL)
A  401.1           0.0
B   42.5           0.0
C  428.1          50.0
D  739.1          50.0

>Select Channels to Clear
or Press CLEAR ALL
PRI/SEC   CLEAR            MAIN
VOLUME     ALL           SCREEN
```

```
Volume Infused

   PRI (mL)      SEC (mL)
A   0.0           0.0
B   0.0           0.0
C   0.0           0.0
D   0.0           0.0

>Select Channels to Clear
or Press CLEAR ALL
PRI/SEC   CLEAR            MAIN
VOLUME     ALL           SCREEN
```

GETTING STARTED

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.
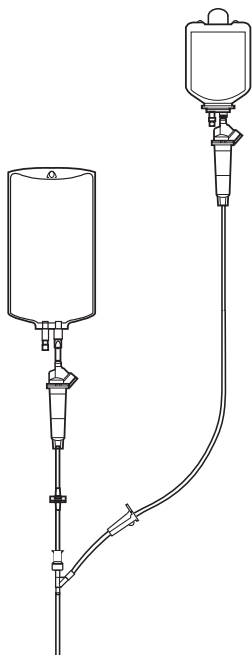
1. Open secondary administration set package, remove set and close clamp.

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.

4. Open secondary administration set and prime set. Close clamp.

- 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.

GETTING STARTED

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 9^1/$_2$ 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.

   A Infusion Setup
RATE	40 mL/h
VTBI	240 mL

   >*Press START*

   | PAUSE | | SECOND-ARY | START |

   OR

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

   A Infusion Setup
   SECONDARY
RATE	_ _ _ mL/h
VTBI	_ _ _ _ mL

   >*Select Rate or Restore Previous Infusion*

   RESTORE

9. To enter secondary infusion rate, press **RATE** soft key and use numeric data entry keys.

   A Infusion Setup
   SECONDARY
RATE	_ _ _ mL/h
VTBI	_ _ _ _ mL

   >*Select RATE*

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

```
A Infusion Setup
SECONDARY           ⬚┐
RATE  100 mL/h
VTBI  _ _ _ _ _ mL



>Select VTBI

```
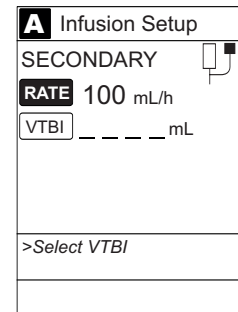
11. Open clamp on secondary administration set.

12. Verify correct infusion parameters and press **START** soft key.

```
A Infusion Setup
SECONDARY           ⬚┐
RATE   100 mL/h
VTBI  _ _ 55 mL



>Press START

PAUSE        PRIMARY  START
```
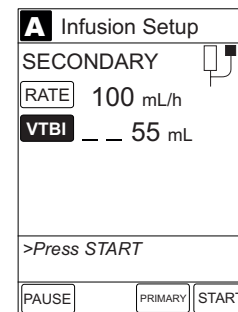
- During infusion:
  - ♦ Green Infusing Status Indicator illuminates.
  - ♦ Secondary rate appears in Channel Rate Display.
  - ♦ Secondary VTBI counts down on Main Display.
  - ♦ **SECONDARY** scrolls in Channel Message Display.
- At completion of infusion:
  - ♦ Switchover alert sounds with six beeps (unless disabled in system configuration).
  - ♦ Primary rate displays.
  - ♦ Infusion continues at primary rate.

```
Midtown Hospital
Adult ICU
A  SEC VTBI = 55.0 mL
B  VTBI = 497.0 mL
C  VTBI =  57.0 mL
D  VTBI = 249.0 mL


VOLUME        AUDIO
INFUSED       ADJUST
```

GETTING STARTED
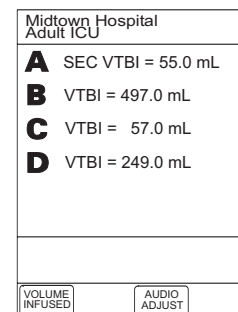
Changing Primary Infusion Parameter During Secondary Infusion

1. Press **CHANNEL SELECT** key.

2. Press **PRIMARY** soft key.

> **A** Infusion Setup
>
> SECONDARY
> RATE 100 mL/h
> VTBI   55 mL
>
> >*Press START*
>
> PAUSE   PRIMARY   START
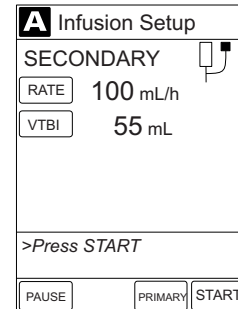
3. To change primary infusion parameter, press applicable soft key (**RATE** or **VTBI**), and use numeric data entry keys.

> **A** Infusion Setup
>
> PRIMARY
> RATE   40 mL/h
> VTBI 240 mL
>
> >*Press START*
>
> PAUSE   SECOND-ARY   START
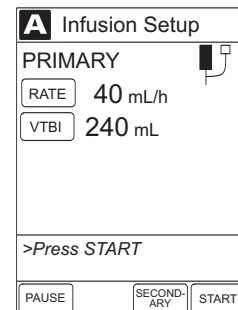
4. Verify correct primary infusion parameters and press **SECONDARY** soft key

   • Secondary setup screen displays.

> **A** Infusion Setup
>
> PRIMARY
> **RATE** _ 50 mL/h
> VTBI 240 mL
>
> >*Press START*
>
> PAUSE   SECOND-ARY   START
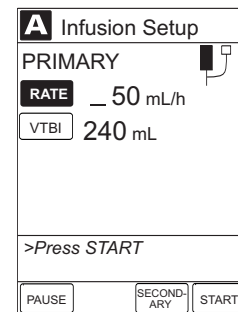
5. To resume secondary infusion, press **START** soft key.

> **A** Infusion Setup
>
> SECONDARY
> RATE 100 mL/h
> VTBI   55 mL
>
> >*Press START*
>
> PAUSE   PRIMARY   START
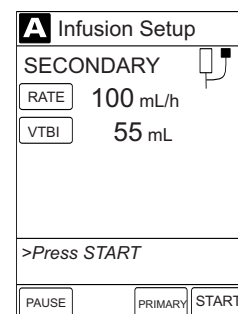
Stopping Secondary Infusion and Returning to Primary Infusion

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.

```
┌─────────────────────┐
│ A  Infusion Setup   │
│ ─────────────────── │
│ SECONDARY        ⬛  │
│ ┌──────┐            │
│ │ RATE │  100 mL/h  │
│ └──────┘            │
│ ┌──────┐            │
│ │ VTBI │   43.4 mL  │
│ └──────┘            │
│                     │
│                     │
│ >Press START        │
│ ─────────────────── │
│ ┌─────┐ ┌───────┐┌─────┐│
│ │PAUSE│ │PRIMARY││START││
│ └─────┘ └───────┘└─────┘│
└─────────────────────┘
```

4. Press **START** soft key.

```
┌─────────────────────┐
│ A  Infusion Setup   │
│ ─────────────────── │
│ PRIMARY          ⬛  │
│ ┌──────┐            │
│ │ RATE │   50 mL/h  │
│ └──────┘            │
│ ┌──────┐            │
│ │ VTBI │  240 mL    │
│ └──────┘            │
│                     │
│                     │
│ >Press START        │
│ ─────────────────── │
│ ┌─────┐ ┌───────┐┌─────┐│
│ │PAUSE│ │SECOND-││START││
│ │     │ │ ARY   ││     ││
│ └─────┘ └───────┘└─────┘│
└─────────────────────┘
```

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.*

```
┌─────────────────────┐
│ A  Infusion Setup   │
│ ─────────────────── │
│ PRIMARY          ⬛  │
│ ┌──────┐            │
│ │ RATE │   50 mL/h  │
│ └──────┘            │
│ ┌──────┐            │
│ │ VTBI │  240 mL    │
│ └──────┘            │
│ Stop Secondary and ┌───┐│
│ Infuse Primary?    │Yes││
│                    └───┘│
│                    ┌───┐│
│                    │No ││
│                    └───┘│
│ >Select Yes or No   │
│ ─────────────────── │
│                     │
└─────────────────────┘
```

GETTING STARTED

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.

```
┌─────────────────────────────┐
│ [A] Infusion Setup          │
│ ┌──────┐                    │
│ │ RATE │   40 mL/h          │
│ └──────┘                    │
│ ┌──────┐                    │
│ │ VTBI │   240 mL           │
│ └──────┘                    │
│                             │
│                             │
│                             │
│ >Press START                │
│ ┌─────┐┌───────┐┌──────┐┌─────┐│
│ │PAUSE││VOLUME ││SECOND││START││
│ │     ││DURATION││-ARY ││     ││
│ └─────┘└───────┘└──────┘└─────┘│
└─────────────────────────────┘
```

Channel Labels

Selecting Channel Label

1. Press **CHANNEL SELECT** key.

2. Press **OPTIONS** key.

3. Press **Channel Labels** soft key.

```
┌─────────────────────────────┐
│ [A] Channel Options 1 of 1  │
│ Guardrails Drug Library     │
│ Multidose                   │
│ Pressure Limit - P          │
│ Channel Labels              │
│                             │
│                             │
│ >Select an Option or EXIT   │
│         ┌──────┐            │
│         │ EXIT │            │
│         └──────┘            │
└─────────────────────────────┘
```

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.

A Channel Label Display Adult ICU	
0.9% NaCl	A-E
3% NaCl	F-J
CVVHDF Dialysate	K-O
D5 1/2 NS	P-T
Epidural	U-Z

>*Select Channel Label*

| EXIT | PAGE DOWN |

A Channel Label Display Adult ICU	
Peripherial Art Line	P
Replacement Solution	Q
Swan	R
Triple Lumen	S
	T

>*Select Channel Label*

| PAGE UP | BACK | PAGE DOWN |

5. To continue infusion, press **START** soft key.

    OR

    Program infusion as previously described.

A Infusion Setup
RATE 50 mL/h
VTBI 240 mL

>*Press START*

| PAUSE | VOLUME DURATION | SECOND-ARY | START |

Removing Channel Label

1. Press **CHANNEL SELECT** key.

2. Press **OPTIONS** key.

3. Press **Channel Labels** soft key.

A Channel Options 1 of 1
Guardrails Drug Library
Multidose
Pressure Limit - P
Channel Labels
>*Select an Option or EXIT*
EXIT

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

A Channel Label Display Adult ICU	
0.9% NaCl	A-E
3% NaCl	F-J
CVVHDF Dialysate	K-O
D5 1/2 NS	P-T
Epidural	U-Z
>*Select Channel Label*	
EXIT CLEAR LABEL PAGE DOWN	

5. To begin infusion, press **START** soft key.

    OR

    Program infusion as previously described.

A Infusion Setup
RATE 50 mL/h
VTBI 240 mL
>*Press START*
PAUSE VOLUME DURATION SECOND-ARY START

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).

-- Continued on Next Page --

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.

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.

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

```
[A] Infusion Menu

Guardrails Drug Library

Basic infusion




>Select an Option or EXIT

[RESTORE] [EXIT]
```

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.*

```
[A] Guardrails Drug Library
    Adult ICU

Aminophylline 500mg/250mL   A-E

Bretylium 500 mg/250mL       F-J

Dobutamine 500mg/250mL       K-O

Dopamine 400mg/250mL         P-T

Dopamine 800mg/250mL         U-Z


>Select Drug/Concentration

        [EXIT] [DRUG CALC] [PAGE DOWN]
```

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.

```
[A] Guardrails Drug Library
    Adult ICU

Lidocaine                    Yes
2 gram/250mL was
selected.                    No
Is this correct?

DOSING
UNITS      mg/min
BOLUSABLE

BOLUS
DOSING     mg/kg
UNITS

>Press Yes or No
```

   - 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.

```
[A] Guardrails Drug Library
    Lidocaine

Clinical Advisory:

  Watch IV site carefully for
  signs of extravasation.




>Press CONFIRM

              [CONFIRM]
```

-- Continued on Next Page --

Using Guardrails® Drug Library (Continued)

- 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).

```
┌─────────────────────────────────┐
│ A  Guardrails Drug Library      │
│    Lidocaine                    │
│ DRUG                            │
│ AMOUNT    2 gram                │
│ DILUENT                         │
│ VOLUME    250 mL                │
│ PATIENT                         │
│ WEIGHT    Not Used              │
│ TIME                            │
│ UNITS     min                   │
│ DOSING                          │
│ UNITS     mg/min                │
│ [Conc]: 8 mg/mL                 │
│ >Press NEXT to Confirm          │
│                                 │
│                        NEXT     │
└─────────────────────────────────┘
```

- 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.*

```
┌─────────────────────────────────┐
│ A  Guardrails Drug Library      │
│    Heparin                      │
│ DRUG                            │
│ AMOUNT    5000 units            │
│ DILUENT                         │
│ VOLUME    500 mL                │
│ PATIENT                         │
│ WEIGHT    _ _ _ _ kg            │
│ TIME                            │
│ UNITS     hour                  │
│ DOSING                          │
│ UNITS     units/kg/h            │
│ [Conc]: 10 units/mL             │
│ >Enter Patient Weight           │
│                                 │
│                        NEXT     │
└─────────────────────────────────┘
```

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).

```
┌─────────────────────────────────┐
│ A  Guardrails Drug Library      │
│    Lidocaine                    │
│ CONTINUOUS INFUSION             │
│ RATE    _ _ _ mL/h              │
│ VTBI    _ _ _ _ mL              │
│ DOSE    _ _ _ _ _ mg/min        │
│                                 │
│ [Conc]: 8 mg/mL                 │
│ >Select Rate or Dose            │
│                                 │
│              SETUP  BOLUS       │
└─────────────────────────────────┘
```

Using Guardrails® Drug Library (Continued)

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.*

A Guardrails Drug Library
Lidocaine

CONTINUOUS INFUSION

RATE 67.5 mL/h
VTBI _ _ _ _ mL
DOSE _ _ _9 mg/min

[Conc]: 8 mg/mL
>Select VTBI

SETUP BOLUS

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

A Guardrails Drug Library
Lidocaine

CONTINUOUS INFUSION

RATE 67.5 mL/h
VTBI 250 mL
DOSE 9 mg/min

[Conc]: 8 mg/mL
>Press START

PAUSE SETUP BOLUS START

> *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.*

A Guardrails Drug Library
Lidocaine

Dose exceeds Guardrail limit of 8 mg/min. Proceed?   Yes   No

>Press Yes or No

> *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.*

A Guardrails Drug Library
Lidocaine

Dose exceeds Guardrails hard limit of 8 mg/min.   Reprogram

>Press REPROGRAM

-- Continued on Next Page --

GETTING STARTED

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.
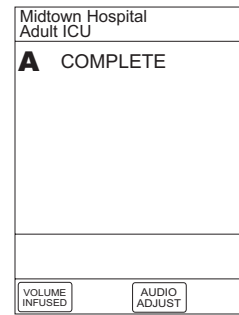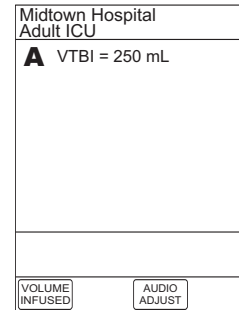
Using Non-Library Drug

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.

Midtown Hospital
Adult ICU

A   VTBI = 250 mL

VOLUME INFUSED   AUDIO ADJUST

Midtown Hospital
Adult ICU

A   COMPLETE

VOLUME INFUSED   AUDIO ADJUST

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.

A Infusion Menu
Guardrails Drug Library
Basic infusion
>Select an Option or EXIT
RESTORE   EXIT

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

A Guardrails Drug Library Adult ICU	
Aminophylline 500mg/250mL	A-E
Bretylium 500 mg/250mL	F-J
Dobutamine 500mg/250mL	K-O
Dopamine 400mg/250mL	P-T
Dopamine 800mg/250mL	U-Z
>Select Drug/Concentration	
EXIT DRUG CALC PAGE DOWN	

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

A Drug Calculation	
DRUG AMOUNT _ _ _ _ _	mcg
DILUENT VOLUME	mg
PATIENT WEIGHT	gram
TIME UNITS	unit
DOSING UNITS	mEq
>Enter Amount of Drug in Container	
DRUG LIBRARY	

7. Press soft key for appropriate unit of measure for drug amount.

A Drug Calculation	
DRUG AMOUNT _ _250	mcg
DILUENT VOLUME	mg
PATIENT WEIGHT	gram
TIME UNITS	unit
DOSING UNITS	mEq
>Select Unit of Measure	
DRUG LIBRARY	

GETTING STARTED

Using Non-Library Drug (Continued)

8. To enter diluent volume, use numeric data entry keys.


```
A  Drug Calculation
DRUG
AMOUNT    250 mg
DILUENT
VOLUME    _ _ _ _ mL
PATIENT
WEIGHT
TIME
UNITS
DOSING
UNITS

>Enter Diluent Volume

              DRUG
              LIBRARY
```

9. Press **PATIENT WEIGHT** soft key.


```
A  Drug Calculation
DRUG
AMOUNT    250 mg
DILUENT
VOLUME    _ 250 mL
PATIENT
WEIGHT
TIME
UNITS
DOSING
UNITS
[Conc]: 1000 mcg/mL
>Select PATIENT
WEIGHT
              DRUG
              LIBRARY
```

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.


```
A  Drug Calculation
DRUG
AMOUNT    250 mg
DILUENT
VOLUME    250 mL       Yes
PATIENT
WEIGHT    > > >        No
Note: Press "Yes" only if Patient
weight is used in the calculation.
For Example: Dosing Units =
mg/kg/h.
>Use Patient Weight in
Calculation?
              DRUG
              LIBRARY
```

11. To enter patient weight (if required) in kilograms, use
    numeric data entry keys.


```
A  Drug Calculation
DRUG
AMOUNT    250 mg
DILUENT
VOLUME    250 mL
PATIENT
WEIGHT    _ _ _ _ kg
TIME
UNITS
DOSING
UNITS
[Conc]: 1000 mcg/mL
>Enter Patient Weight
              DRUG
              LIBRARY
```

Using Non-Library Drug (Continued)

12. Press **TIME UNITS** soft key.

> **A** Drug Calculation
> DRUG AMOUNT   250 mg
> DILUENT VOLUME   250 mL
> PATIENT WEIGHT   _ _ 70 kg
> TIME UNITS
> DOSING UNITS
> [Conc]: 1000 mcg/mL
> >*Select TIME UNITS*
> DRUG LIBRARY

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

> **A** Drug Calculation
> DRUG AMOUNT   250 mg
> DILUENT VOLUME   250 mL
> PATIENT WEIGHT   70 kg | Min |
> TIME UNITS   > > > > | Hour |
> DOSING UNITS | Day |
> [Conc]: 1000 mcg/mL
> >*Select Time Units*
> DRUG LIBRARY

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

> **A** Drug Calculation
> DRUG AMOUNT   250 mg
> DILUENT VOLUME   250 mL
> PATIENT WEIGHT   70 kg
> TIME UNITS | mcg/kg/min |
> DOSING UNITS   > > | mg/kg/min |
> [Conc]: 1000 mcg/mL
> >*Select the Desired Dosing Units*
> DRUG LIBRARY

15. Verify correct drug calculation infusion parameters and press **NEXT** soft key.

> **A** Drug Calculation
> DRUG AMOUNT   250 mg
> DILUENT VOLUME   250 mL
> PATIENT WEIGHT   70 kg
> TIME UNITS   Min
> DOSING UNITS   mcg/kg/min
> [Conc]: 1000 mcg/mL
> >*Press NEXT to Confirm*
> DRUG LIBRARY   NEXT

GETTING STARTED

Using Non-Library Drug (Continued)

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).

```
[A] Drug Calculation
CONTINUOUS INFUSION
[RATE]  _ _ _ mL/h
[VTBI]  _ _ _ _ mL
[DOSE]  _ _ _ _ _ mcg/kg/min

 [Conc]: 1000 mcg/mL
>Select RATE or DOSE

        [SETUP] [BOLUS]
```

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.*

```
[A] Drug Calculation
CONTINUOUS INFUSION
[RATE]  21 mL/h
[VTBI]  _ _ _ _ mL
[DOSE]  _ _ _ _5 mcg/kg/min

 [Conc]: 1000 mcg/mL
>Select VTBI

        [SETUP] [BOLUS]
```

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.

```
[A] Drug Calculation
CONTINUOUS INFUSION
[RATE]  21 mL/h
[VTBI]  250 mL
[DOSE]  5 mcg/kg/min

 [Conc]: 1000 mcg/mL
>Press START

[PAUSE][SETUP][BOLUS][START]
```

-- Continued on Next Page --

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.

```
Midtown Hospital
Adult ICU
┌─────────────────────────┐
│ A   COMPLETE            │
│                         │
│                         │
│                         │
│                         │
├─────────────────────────┤
│ VOLUME        AUDIO     │
│ INFUSED       ADJUST    │
└─────────────────────────┘
```
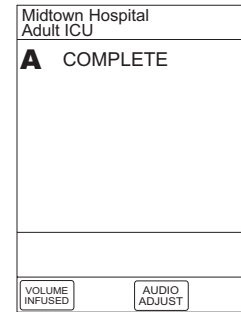
Programming Bolus Dose

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.*

Using Guardrails® Drug Library Calculation

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. ➤

```
┌──────────────────────────────┐
│ A  Guardrails Drug Library   │
│    Lidocaine                 │
├──────────────────────────────┤
│ CONTINUOUS INFUSION          │
│                              │
│ RATE   67.5 mL/h             │
│ VTBI   250 mL                │
│ DOSE    9 mg/min             │
│                              │
│ [Conc]: 8 mg/mL              │
│ >Press START                 │
├──────────────────────────────┤
│ PAUSE SETUP BOLUS START      │
└──────────────────────────────┘
```

Weight-based example. ➤

```
┌──────────────────────────────┐
│ A  Guardrails Drug Library   │
│    Heparin                   │
├──────────────────────────────┤
│ CONTINUOUS INFUSION          │
│                              │
│ RATE   20.0 mL/h             │
│ VTBI   500 mL                │
│ DOSE   20 unit/kg/h          │
│                              │
│ [Conc]: 10 units/mL          │
│ >Press START                 │
├──────────────────────────────┤
│ PAUSE SETUP BOLUS START      │
└──────────────────────────────┘
```

*   **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.*

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.

```
┌─────────────────────────────┐
│ A  Guardrails Drug Library  │
│    Lidocaine                │
│ BOLUS DOSE                  │
│                             │
│ DOSE  _ _ _ _ mg/kg         │
│ PATIENT                     │
│ WEIGHT                      │
│ DURATION                    │
│                             │
│                             │
│ [Conc]: 8 mg/mL             │
│ >Enter Bolus Dose           │
│                             │
│              SETUP          │
└─────────────────────────────┘
```

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

```
┌─────────────────────────────┐
│ A  Guardrails Drug Library  │
│    Heparin                  │
│ BOLUS DOSE                  │
│                             │
│ DOSE  _ _ _ _ unit/kg       │
│ PATIENT                     │
│ WEIGHT     10 kg            │
│ DURATION                    │
│                             │
│                             │
│ [Conc]: 10 units/mL         │
│ >Enter Bolus Dose           │
│                             │
│              SETUP          │
└─────────────────────────────┘
```

- 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 <u>not weight-based</u>:
  a. Press **PATIENT WEIGHT** soft key.

```
┌─────────────────────────────┐
│ A  Guardrails Drug Library  │
│    Lidocaine                │
│ BOLUS DOSE                  │
│                             │
│ DOSE  _ _ _ 5 mg/kg         │
│ PATIENT                     │
│ WEIGHT  _ _ _ kg            │
│ DURATION                    │
│                             │
│                             │
│ [Conc]: 8 mg/mL             │
│ >Select PATIENT WEIGHT      │
│                             │
│              SETUP          │
└─────────────────────────────┘
```

GETTING STARTED

Using Guardrails® Drug Calculation (Continued)

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

```
┌─────────────────────────────┐
│ [A] Guardrails Drug Library │
│     Lidocaine               │
│  BOLUS DOSE                 │
│  ┌────┐                     │
│  │DOSE│  5 mg/kg            │
│  └────┘                     │
│  ┌───────┐                  │
│  │PATIENT│ _ _ _ kg         │
│  │WEIGHT │                  │
│  └───────┘                  │
│  ┌────────┐                 │
│  │DURATION│                 │
│  └────────┘                 │
│                             │
│  [Conc]: 8 mg/mL            │
│  >Select DURATION           │
│                             │
│         ┌─────┐             │
│         │SETUP│             │
│         └─────┘             │
└─────────────────────────────┘
```

-- OR --

• When continuous dose is <u>weight-based</u>:

a. Press **SETUP** soft key.

```
┌─────────────────────────────┐
│ [A] Guardrails Drug Library │
│     Heparin                 │
│  BOLUS DOSE                 │
│  ┌────┐                     │
│  │DOSE│ _ _ 50 unit/kg      │
│  └────┘                     │
│  PATIENT                    │
│  WEIGHT   10 kg             │
│  ┌────────┐                 │
│  │DURATION│                 │
│  └────────┘                 │
│  TOTAL DOSE = 500 units     │
│  [Conc]: 10 units/mL        │
│  >Select DURATION           │
│         ┌─────┐             │
│         │SETUP│             │
│         └─────┘             │
└─────────────────────────────┘
```

b. Press **PATIENT WEIGHT** soft key.

```
┌─────────────────────────────┐
│ [A] Guardrails Drug Library │
│     Heparin                 │
│  DRUG                       │
│  AMOUNT   5000 units        │
│  DILUENT                    │
│  VOLUME   500 mL            │
│  PATIENT                    │
│  WEIGHT   10 kg             │
│  TIME                       │
│  UNITS    Hour              │
│  DOSING                     │
│  UNITS    units/kg/h        │
│  [Conc]: 10 units/mL        │
│  >Press NEXT to Confirm     │
│     ┌───────┐ ┌────┐        │
│     │ DRUG  │ │NEXT│        │
│     │LIBRARY│ └────┘        │
│     └───────┘               │
└─────────────────────────────┘
```

c. To change patient weight, use numeric data entry keys.

d. Press **NEXT** soft key.

```
┌─────────────────────────────┐
│ [A] Guardrails Drug Library │
│     Heparin                 │
│  DRUG                       │
│  AMOUNT   5000 units        │
│  DILUENT                    │
│  VOLUME   500 mL            │
│  ┌───────┐                  │
│  │PATIENT│ _ _ 11 kg        │
│  │WEIGHT │                  │
│  └───────┘                  │
│  TIME                       │
│  UNITS    Hour              │
│  DOSING                     │
│  UNITS    units/kg/h        │
│  [Conc]: 10 units/mL        │
│  >Press NEXT to Confirm     │
│     ┌───────┐ ┌────┐        │
│     │ DRUG  │ │NEXT│        │
│     │LIBRARY│ └────┘        │
│     └───────┘               │
└─────────────────────────────┘
```

-- 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.

GETTING STARTED

Screen displays:

A Guardrails Drug Library — Heparin
Dose will recalculate based on new weight. Adjust Dose or Rate if required. Accept weight change?
Yes
No
>Select Yes or No

A Guardrails Drug Library — Heparin
CONTINUOUS INFUSION
RATE 20.0 mL/h
VTBI 500 mL
DOSE 18.18 unit/kg/h
[Conc]: 10 units/mL
>Press START
PAUSE SETUP BOLUS START

A Guardrails Drug Library — Heparin
BOLUS DOSE
DOSE _ _ _ _ unit/kg
PATIENT WEIGHT 11 kg
DURATION
[Conc]: 10 units/mL
>Enter Bolus Dose
SETUP

A Guardrails Drug Library — Lidocaine
BOLUS DOSE
DOSE 5 mg/kg
PATIENT WEIGHT _ _ 71 kg
DURATION
TOTAL DOSE = 355 mg
[Conc]: 8 mg/mL
>Select DURATION
SETUP

Using Guardrails® Drug Calculation (Continued)

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.

```
┌──────────────────────────────┐
│ A  Guardrails Drug Library    │
│    Lidocaine                  │
│  BOLUS DOSE                   │
│ ┌──────┐                      │
│ │ DOSE │  5 mg/kg             │
│ └──────┘                      │
│ ┌────────┐                    │
│ │PATIENT │  71 kg  (999 mL/h) │
│ │WEIGHT  │            ┌──────┐│
│ └────────┘            │ Max  ││
│ ┌──────────┐          │ Rate ││
│ │ DURATION │ _ _ min  └──────┘│
│ └──────────┘                  │
│ TOTAL DOSE = 355 mg           │
│ BOLUS VTBI = 44.4 mL          │
│ >Enter Duration               │
│           ┌───────┐           │
│           │ SETUP │           │
│           └───────┘           │
└──────────────────────────────┘
```

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.

```
┌──────────────────────────────┐
│ A  Guardrails Drug Library    │
│    Lidocaine                  │
│  BOLUS DOSE                   │
│ ┌──────┐                      │
│ │ DOSE │  5 mg/kg             │
│ └──────┘                      │
│ ┌────────┐                    │
│ │PATIENT │  71 kg  (999 mL/h) │
│ │WEIGHT  │            ┌──────┐│
│ └────────┘            │ Max  ││
│ ┌──────────┐          │ Rate ││
│ │ DURATION │ 2 min    └──────┘│
│ └──────────┘                  │
│ INFUSE AT: 133.2 mg/min       │
│ [Conc]: 8 mg/mL               │
│ >Press START to Begin         │
│ Infusing Bolus Dose           │
│┌─────┐┌─────┐┌─────┐┌───────┐ │
││PAUSE││SETUP││CONT-││ START │ │
││     ││     ││INUOUS││       │ │
│└─────┘└─────┘└─────┘└───────┘ │
└──────────────────────────────┘
```

```
┌──────────────────────────────┐
│ Midtown Hospital              │
│ Adult ICU                     │
│ A  BOLUS VTBI = 44.4 mL       │
│                               │
│                               │
│                               │
│                               │
│                               │
│                               │
│ ┌────────┐      ┌────────┐    │
│ │VOLUME  │      │AUDIO   │    │
│ │INFUSED │      │ADJUST  │    │
│ └────────┘      └────────┘    │
└──────────────────────────────┘
```

```
┌──────────────────────────────┐
│ Midtown Hospital              │
│ Adult ICU                     │
│ A  Lidocaine                  │
│    5 mg/kg Bolus              │
│                               │
│                               │
│                               │
│                               │
│                               │
│ ┌────────┐      ┌────────┐    │
│ │VOLUME  │      │AUDIO   │    │
│ │INFUSED │      │ADJUST  │    │
│ └────────┘      └────────┘    │
└──────────────────────────────┘
```

-- Continued on Next Page --

Using Guardrails® Drug Calculation (Continued)

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

```
┌─────────────────────────┐
│ A  Guardrails Drug Library│
│    Lidocaine             │
│ BOLUS DOSE              │
│ Dose                    │
│ Remaining:  5 mg/kg     │
│ Pt. Weight:  71 kg      │
│                (999 mL/h)│
│ Time Left:  2 min   Max │
│                      Rate│
│ TOTAL DOSE = 355 mg     │
│ BOLUS VTBI = 44.4 mL    │
│ >Press START to Continue│
│ Infusing Bolus Dose     │
│ PAUSE  STOP      START  │
│        BOLUS            │
└─────────────────────────┘
```

- 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.

```
┌─────────────────────────┐
│ A  Drug Calculation     │
│  CONTINUOUS INFUSION    │
│  RATE   21 mL/h         │
│  VTBI   250 mL          │
│  DOSE   5 mcg/kg/min    │
│                         │
│  [Conc]: 1000 mcg/mL    │
│ >Press START            │
│                         │
│ PAUSE SETUP BOLUS START │
└─────────────────────────┘
```

Using Non-Library Drug 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.*

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.

-- Continued on Next Page --

Using Non-Library Drug Calculation (Continued)

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

A Drug Calculation
BOLUS DOSE
Dose Remaining: **400** mcg
Pt. Weight: Not Used _(999 mL/h)
Time Left: **<1** min   Max   Rate
TOTAL DOSE: 500 mcg
BOLUS VTBI = 0.5 mL
>*Press START to Continue* *Infusing Bolus Dose*
PAUSE STOP   BOLUS   START

- 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.

Stopping Bolus Dose (Continued)

2. Press **STOP BOLUS** soft key.

```
┌─────────────────────────────┐
│ A  Guardrails Drug Library   │
│    Lidocaine                 │
│ BOLUS DOSE                   │
│ Dose                         │
│ Remaining:  5 mg/kg          │
│ Pt. Weight:  71 kg  (999 mL/h)│
│ Time Left:  2 min    Max     │
│                      Rate    │
│ TOTAL DOSE = 355 mg          │
│ BOLUS VTBI = 44.4 mL         │
│ >Press START to Continue     │
│ Infusing Bolus Dose          │
│ PAUSE  STOP      START       │
│        BOLUS                 │
└─────────────────────────────┘
```

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

```
┌─────────────────────────────┐
│ A  Guardrails Drug Library   │
│    Lidocaine                 │
│ Stop Bolus and Start  ┌─────┐│
│ Continuous infusion?  │ Yes ││
│                       ├─────┤│
│                       │ No  ││
│                       └─────┘│
│                              │
│                              │
│ >Press Yes or No             │
│                              │
└─────────────────────────────┘
```

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

```
┌─────────────────────────────┐
│ Midtown Hospital             │
│ Adult ICU                    │
│ A  VTBI = 250 mL             │
│                              │
│                              │
│                              │
│                              │
│                              │
│ VOLUME        AUDIO          │
│ INFUSED       ADJUST         │
└─────────────────────────────┘
```

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.

Restoring Bolus Dose (Continued)

Bolus Dose Completed - Channel Not Turned Off

1. Press **CHANNEL SELECT** key.

2. Verify infusion parameters and press **BOLUS** soft key.

```
[A] Guardrails Drug Library
    Lidocaine
CONTINUOUS INFUSION
[RATE]  67.5 mL/h
[VTBI]  250 mL
[DOSE]   9 mg/min

[Conc]: 8 mg/mL
>Press START

[PAUSE][SETUP][BOLUS][START]
```

3. Press **RESTORE** soft key.

```
[A] Guardrails Drug Library
    Lidocaine
 BOLUS DOSE
[DOSE]  _ _ _ _ mg/kg
[PATIENT
 WEIGHT]    71 kg
[DURATION]

[Conc]: 8 mg/mL
>Enter Bolus Dose

[RESTORE][SETUP]
```

4. Verify dosing parameters and press **START** soft key.

```
[A] Guardrails Drug Library
    Lidocaine
 BOLUS DOSE
[DOSE]  5 mg/kg
[PATIENT
 WEIGHT]  71 kg   (999 mL/h)
[DURATION] 2 min          Max
                          Rate
INFUSE AT: 133.2 mg/min
[Conc]: 8 mg/mL
>Press START to Begin
Infusing Bolus Dose
[PAUSE][SETUP][CONT-
              INUOUS][START]
```

Bolus Dose Completed - Channel Turned Off

1. Press **CHANNEL SELECT** key.

2. Press **RESTORE** soft key.

```
[A] Infusion Menu
Guardrails Drug Library
Basic infusion




>Select an Option or EXIT

[RESTORE][EXIT]
```

GETTING STARTED

Restoring Bolus Dose (Continued)

Bolus Dose Completed - Channel Turned Off
(Continued)

3. Verify parameters and press **NEXT** soft key.

> **A** Guardrails Drug Library
> Lidocaine
>
> DRUG AMOUNT   2 gram
> DILUENT VOLUME   250 mL
> PATIENT WEIGHT   Not Used
> TIME UNITS   min
> DOSING UNITS   mg/min
> [Conc]: 8 mg/mL
> >*Press NEXT to Confirm*
>
> NEXT

4. Verify infusion parameters and press **BOLUS** soft key.

> **A** Guardrails Drug Library
> Lidocaine
>
> CONTINUOUS INFUSION
>
> RATE 67.5 mL/h
> VTBI 250 mL
> DOSE 9 mg/min
>
> [Conc]: 8 mg/mL
> >*Press START*
>
> PAUSE | SETUP | BOLUS | START

5. Press **RESTORE** soft key.

> **A** Guardrails Drug Library
> Lidocaine
>
> BOLUS DOSE
>
> **DOSE** _ _ _ _ mg/kg
> PATIENT WEIGHT   71 kg
> DURATION
>
> [Conc]: 8 mg/mL
> >*Enter Bolus Dose*
>
> RESTORE | SETUP

6. Verify dosing parameters and press **START** soft key.

> **A** Guardrails Drug Library
> Lidocaine
>
> BOLUS DOSE
>
> DOSE 5 mg/kg
> PATIENT WEIGHT   71 kg   (999 mL/h)
> DURATION 2 min   **Max Rate**
> INFUSE AT: 133.2 mg/min
> [Conc]: 8 mg/mL
> >*Press START to Begin Infusing Bolus Dose*
>
> PAUSE | SETUP | CONT-INUOUS | START

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.

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.

GETTING STARTED

Enabling Anesthesia Mode

1. From Main Display, press **OPTIONS** key.

2. Press **Anesthesia Mode** soft key.

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

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

Enabling Anesthesia Mode (Continued)

3. Press **Enable** soft key.

4. Press **CONFIRM** soft key.

```
System Options
Anesthesia Mode
                        Enable
                        Disable

Pump Module        Change
Air Detection =
75 microliters
>Select an Option or Press
CONFIRM

            CONFIRM
```

5. Press **Channel Select** key.

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

```
Midtown Hospital
Adult ICU
Ⓐ
Ⓑ
Ⓒ
Ⓓ


Anesthesia Mode

VOLUME          AUDIO
INFUSED         ADJUST
```

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.

```
System Options 1 of 3

Display Contrast

Patient ID

Time of Day

Power Down All Channels

Anesthesia Mode

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

Disabling Anesthesia Mode (Continued)

From System Options Menu (Continued)

3. Press **Disable** soft key.

4. Press **CONFIRM** soft key.

    • **Anesthesia Mode** no longer appears on Main Display, indicating it has been disabled.

```
System Options
─────────────────────
Anesthesia Mode
                    ┌──────────┐
                    │  Enable  │
                    ├──────────┤
                    │ Disable  │
                    └──────────┘
Pump Module      ┌────────┐
Air Detection =  │ Change │
75 microliters   └────────┘
>Select an Option or Press
CONFIRM
           ┌─────────┐
           │ CONFIRM │
           └─────────┘
```

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.

```
Anesthesia mode was discontinued
when AC power cord was
disconnected. Press CONFIRM to
continue normal operation.



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

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.

```
AC power cord was      ┌───────┐
connected.             │  Yes  │
Continue               ├───────┤
ANESTHESIA MODE?       │  No   │
                       └───────┘

>Select Yes or No
```

GETTING STARTED

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.

```
┌─────────────────────────┐
│ [A] Infusion Setup      │
│ ┌──────┐                │
│ │ RATE │  40 mL/h       │
│ └──────┘                │
│ ┌──────┐                │
│ │ VTBI │  250 mL        │
│ └──────┘                │
│                         │
│                         │
│                         │
│ >Press START            │
│ ┌──────┐ ┌───────┐┌─────┐│
│ │DELAY │ │SECOND-││START││
│ │OPTIONS│ │ ARY  ││     ││
│ └──────┘ └───────┘└─────┘│
└─────────────────────────┘
```
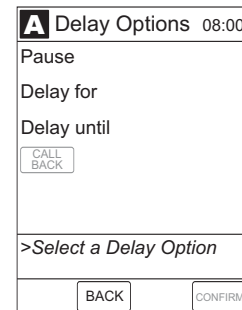
2. Press **Delay for** soft key.

```
┌─────────────────────────┐
│ [A] Delay Options 08:00 │
│ Pause                   │
│ Delay for               │
│ Delay until             │
│ ┌──────┐                │
│ │ CALL │                │
│ │ BACK │                │
│ └──────┘                │
│                         │
│ >Select a Delay Option  │
│      ┌──────┐  ┌───────┐│
│      │ BACK │  │CONFIRM││
│      └──────┘  └───────┘│
└─────────────────────────┘
```

Delaying Infusion (Continued)

Specifying by Minutes (Continued)

3. To enter number of minutes (up to 120) infusion is to be delayed for, use numeric data entry keys.

> **A** Delay Options 08:00
> Pause
> **Delay for** _ _ _ minutes
> Delay until
> CALL BACK
>
> >Enter Delay Time
> (1 - 120 min)
> BACK   CONFIRM

4. Press **CONFIRM** soft key.

> **A** Delay Options 08:00
> Pause
> **Delay for** _ 20 minutes
> Delay until
> CALL BACK   None
>
> >Select Callback or Press
> CONFIRM
> BACK   CONFIRM

• Delay period counts down on Main Display.

> Midtown Hospital
> Adult ICU   08:00
> **A**   Start in 20 min
>
> VOLUME INFUSED   AUDIO ADJUST

• If a **Before** callback has not been scheduled (reference "Scheduling a Callback" section), infusion automatically initiates at end of delay period.

> Midtown Hospital
> Adult ICU   09:00
> **A**   VTBI = 259.0 mL
>
> VOLUME INFUSED   AUDIO ADJUST

Delaying Infusion (Continued)

Specifying by Time of Day

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.

    ```
    ┌─────────────────────────┐
    │ A Infusion Setup        │
    ├─────────────────────────┤
    │ RATE    40 mL/h         │
    │ VTBI    250 mL          │
    │                         │
    │                         │
    │                         │
    │ >Press START            │
    ├─────────────────────────┤
    │ DELAY        SECOND- START│
    │ OPTIONS      ARY        │
    └─────────────────────────┘
    ```

2. Press **Delay until** soft key.
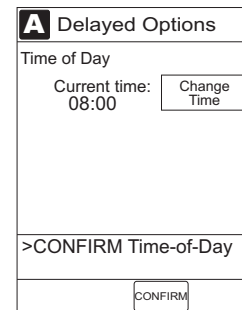
    ```
    ┌─────────────────────────┐
    │ A Delay Options  08:00  │
    ├─────────────────────────┤
    │ Pause                   │
    │ Delay for               │
    │ Delay until             │
    │ CALL                    │
    │ BACK                    │
    │                         │
    │ >Select a Delay Option  │
    ├─────────────────────────┤
    │         BACK    CONFIRM │
    └─────────────────────────┘
    ```

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.
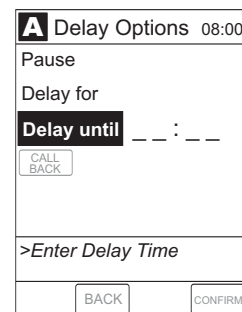
    ```
    ┌─────────────────────────┐
    │ A Delayed Options       │
    ├─────────────────────────┤
    │ Time of Day             │
    │   Current time: Change  │
    │      08:00      Time    │
    │                         │
    │                         │
    │ >CONFIRM Time-of-Day    │
    ├─────────────────────────┤
    │         CONFIRM         │
    └─────────────────────────┘
    ```

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

    ```
    ┌─────────────────────────┐
    │ A Delay Options  08:00  │
    ├─────────────────────────┤
    │ Pause                   │
    │ Delay for               │
    │ Delay until _ _ : _ _   │
    │ CALL                    │
    │ BACK                    │
    │                         │
    │ >Enter Delay Time       │
    ├─────────────────────────┤
    │         BACK    CONFIRM │
    └─────────────────────────┘
    ```

Delaying Infusion (Continued)

Specifying by Time of Day (Continued)

5. Press **CONFIRM** soft key.

A Delay Options 08:00
Pause
Delay for
Delay until _ 9:00
CALL BACK   None
>*Select Callback or Press CONFIRM*
BACK   CONFIRM

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

Midtown Hospital Adult ICU   08:00
A   Start at 09:00
VOLUME INFUSED   AUDIO ADJUST

- If a **Before** callback has not been scheduled (reference "Scheduling a Callback" section), infusion automatically initiates at end of delay period.

Midtown Hospital Adult ICU   09:00
A   VTBI = 259.0 mL
VOLUME INFUSED   AUDIO ADJUST

GETTING STARTED

Scheduling a Callback

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 <u>and</u> 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. <u>Prior to</u> pressing **CONFIRM** soft key to initiate delay during **Delay for** or **Delay until** programming process, press **CALL BACK** soft key.

```
A Delay Options  08:00
Pause
Delay for
Delay until  _ 9:00
CALL
BACK    None


>Select Callback or Press
CONFIRM
           BACK      CONFIRM
```
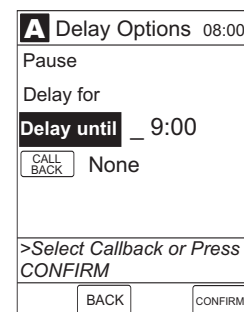
2. Press soft key corresponding to desired callback option.
   - Scheduled callback appears on Main Display.

```
A Delay Options  08:00
Pause
Delay for              Before
Delay until 09:00   Before
                    And After
CALL  > > > > > >     After
BACK
                      None
>Select a Callback Option
           BACK      CONFIRM
```
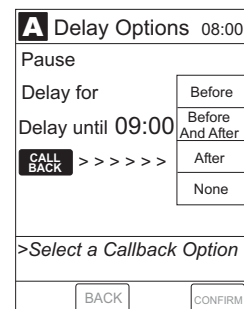
3. To initiate delay, press **CONFIRM** soft key.

```
A Delay Options  08:00
Pause
Delay for
Delay until 09:00
CALL
BACK    After


>Select Callback or Press
CONFIRM
           BACK      CONFIRM
```
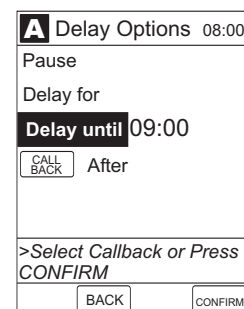
-- Continued on Next Page --

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.

GETTING STARTED

Midtown Hospital
Adult ICU   08:00

A   Start at 09:00

VOLUME
INFUSED   AUDIO
                 ADJUST

Midtown Hospital
Adult ICU   08:00

A   Start in 20 min

VOLUME
INFUSED   AUDIO
                 ADJUST

Midtown Hospital
Adult ICU   09:00

A DELAY COMPLETE

VOLUME
INFUSED   AUDIO
                 ADJUST

A

The current infusion has completed.
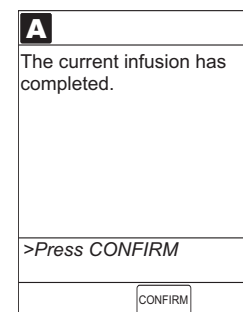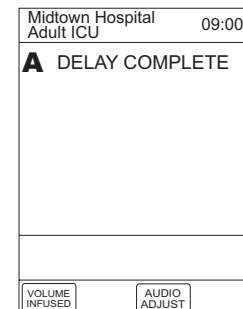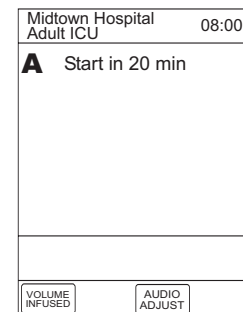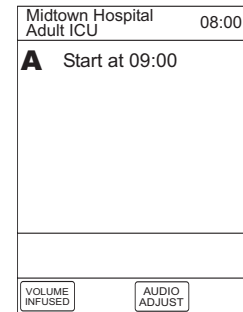
>*Press CONFIRM*

CONFIRM

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.

    ```
    ┌─────────────────────┐
    │ A Infusion Setup    │
    │ ┌──────┐            │
    │ │ RATE │  40 mL/h   │
    │ └──────┘            │
    │ ┌──────┐            │
    │ │ VTBI │  250 mL    │
    │ └──────┘            │
    │                     │
    │                     │
    │                     │
    │ >Press START        │
    │ ┌─────┐  ┌──────┐ ┌─────┐│
    │ │DELAY│  │SECOND│ │START││
    │ │OPTNS│  │ ARY  │ └─────┘│
    │ └─────┘  └──────┘       │
    └─────────────────────┘
    ```

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).

    ```
    ┌─────────────────────┐
    │ A Delay Options 09:30│
    │ Pause               │
    │ Delay for           │
    │ Delay until         │
    │ ┌──────┐            │
    │ │ CALL │            │
    │ │ BACK │            │
    │ └──────┘            │
    │ >Select a Delay Option│
    │      ┌─────┐ ┌───────┐│
    │      │BACK │ │CONFIRM││
    │      └─────┘ └───────┘│
    └─────────────────────┘
    ```
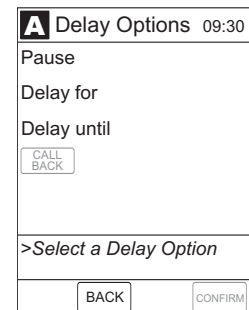
3. Press **CONFIRM** soft key.

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

    ```
    ┌─────────────────────┐
    │ A Delay Options 09:30│
    │ ▐Pause              │
    │ Delay for           │
    │ Delay until         │
    │ ┌──────┐            │
    │ │ CALL │            │
    │ │ BACK │            │
    │ └──────┘            │
    │ >Press CONFIRM      │
    │      ┌─────┐ ┌───────┐│
    │      │BACK │ │CONFIRM││
    │      └─────┘ └───────┘│
    └─────────────────────┘
    ```
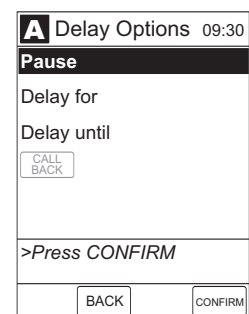
Pausing Infusion (Continued)

4. To reinitiate infusion:

   - Press **RESTART** key.

        OR

   - Press **CHANNEL SELECT** key and then **START** soft key.

```
A  Infusion Setup
RATE    40 mL/h
VTBI    250 mL



>Press START

DELAY       SECOND-   START
OPTIONS      ARY
```

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.

GETTING STARTED

Programming with Volume / Duration Enabled (Continued)

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.

A Infusion Menu
Guardrails Drug Library
Basic infusion
>*Select an Option or EXIT*
RESTORE   EXIT

5. Press **OPTIONS** key.

A Infusion Setup
RATE _ _ _ mL/h
VTBI _ _ _ _ _ mL
>*Select Rate or Restore Previous Infusion*
RESTORE   VOLUME DURATION

6. Press **Multidose** soft key.

A Channel Options 1 of 1
Guardrails Drug Library
Multidose
Pressure Limit - P
Channel Labels
>*Select an Option or EXIT*
EXIT

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.*

A Multidose
Time of Day
Current time: 13:00   Change Time
>CONFIRM Time-of-Day
CONFIRM

Programming with Volume / Duration Enabled (Continued)

8.   Press **VOLUME DURATION** soft key.

A Multidose	13:00
RATE _ _ _ _ mL/h	
VOLUME/ DOSE	
DOSE INTERVAL	
# OF DOSES	
>*Enter Rate*	
VOLUME DURATION	

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

A Multidose	13:00
RATE = _ _ _ mL/h	
VOLUME/ DOSE _ _ _ _ mL	
DURATION	
DOSE INTERVAL	
# OF DOSES	
>*Enter Volume/Dose*	
RATE VOLUME	

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**.

A Multidose	13:00
RATE = _ _ _ mL/h	
VOLUME/ DOSE 50 mL	
DURATION _ _ h _ _ min	
DOSE INTERVAL	
# OF DOSES	
>*Enter Duration*	
RATE VOLUME	

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

A Multidose	13:00
RATE = 100 mL/h	
VOLUME/ DOSE 50 mL	
DURATION 00 h 30 min	
DOSE INTERVAL every _ _ h	
# OF DOSES	
>*Enter Dose Interval*	
RATE VOLUME	

GETTING STARTED

Programming with Volume / Duration Enabled (Continued)

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.

```
| A  Multidose          13:00 |
| RATE = 100 mL/h             |
| VOLUME/  50 mL              |
| DOSE                        |
| DURATION  00 h 30 min       |
| DOSE                        |
| INTERVAL      every _6 h    |
| # OF                        |
| DOSES                       |
|                             |
| >Select NUMBER OF           |
| DOSES                       |
|           RATE              |
|           VOLUME            |
```

13. To begin multidose infusion, press **START** soft key.

```
| A  Multidose          13:00 |
| RATE = 100 mL/h             |
| VOLUME/  50 mL              |
| DOSE                        |
| DURATION  00 h 30 min       |
| DOSE                        |
| INTERVAL     every 06 h     |
| # OF                        |
| DOSES        _4 doses       |
|                             |
| >Press START                |
| DELAY   RATE        START   |
| OPTIONS VOLUME              |
```

    - Main Display shows remaining VTBI for that dose.

```
| Midtown Hospital      13:00 |
| Adult ICU                   |
| A  VTBI = 50.0 mL           |
|                             |
|                             |
|                             |
| VOLUME        AUDIO         |
| INFUSED       ADJUST        |
```

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

```
| Midtown Hospital       8:00 |
| Adult ICU                   |
| A  MULTIDOSE COMPLETE       |
|                             |
|                             |
|                             |
| VOLUME        AUDIO         |
| INFUSED       ADJUST        |
```
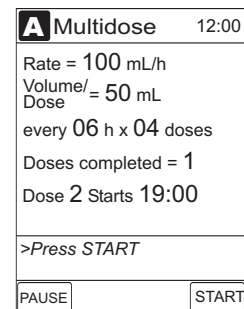
Programming with Volume / Duration Enabled (Continued)

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

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

```
[A] Multidose          12:30
Rate = 100 mL/h
Volume/
Dose  = 50 mL
Duration  = 00 h 30 min
every 06 h x 04 doses
Doses completed = 0
Volume remaining = 25 mL
>Press START

PAUSE                   START
```

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

```
[A] Multidose          12:00
Rate = 100 mL/h
Volume/
Dose  = 50 mL
Duration  = 00 h 30 min
every 06 h x 04 doses
Doses completed = 1
Dose 2 Starts 19:00
>Press START

PAUSE                   START
```

Programming with Volume / Duration Disabled

If Volume/Duration was <u>not</u> 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.

GETTING STARTED

Programming with Volume / Duration Disabled (Continued)

4. Press **Basic Infusion** soft key.

   • **Infusion Setup** screen appears.

```
A  Infusion Menu

Guardrails Drug Library

Basic infusion




>Select an Option or EXIT

[RESTORE]  [EXIT]
```

5. Press **OPTIONS** key.

```
A  Infusion Setup

[RATE]  _ _ _ mL/h

[VTBI]  _ _ _ _ mL




 >Select Rate or Restore
  Previous Infusion

[RESTORE]  [VOLUME DURATION]
```

6. Press **Multidose** soft key.

```
A  Channel Options 1 of 1

Guardrails Drug Library

Multidose

Pressure Limit - P

Channel Labels



>Select an Option or EXIT

        [EXIT]
```

7. To enter rate, use numeric data entry keys.

```
A  Multidose          13:00

[RATE]    _ _ _ _ mL/h
[VOLUME/ DOSE]


[DOSE INTERVAL]
[# OF DOSES]


>Enter Rate
```

Programming with Volume / Duration Disabled (Continued)

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

```
A  Multidose      13:00
RATE      100 mL/h
VOLUME/
DOSE      _ _ _ _ mL

DOSE
INTERVAL
# OF
DOSES

>Enter Volume/Dose
```

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

```
A  Multidose      13:00
RATE      100 mL/h
VOLUME/
DOSE      50 mL

DOSE
INTERVAL  every _ _ h
# OF
DOSES

>Enter Dose Interval
```

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.

```
A  Multidose      13:00
RATE      100 mL/h
VOLUME/
DOSE      50 mL

DOSE
INTERVAL  every _ 6 h
# OF
DOSES

>Select NUMBER OF DOSES
```

11. To begin multidose infusion, press **START** soft key.

```
A  Multidose      13:00
RATE      100 mL/h
VOLUME/
DOSE      50 mL

DOSE
INTERVAL  every 06 h
# OF
DOSES     _4 doses

>Press START

PAUSE            START
```

-- Continued on Next Page --

- Main Display shows remaining VTBI for that dose.

```
Midtown Hospital       13:00
Adult ICU
 A  VTBI = 50.0 mL




 VOLUME          AUDIO
 INFUSED         ADJUST
```

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

```
Midtown Hospital        8:00
Adult ICU
 A  MULTIDOSE COMPLETE




 VOLUME          AUDIO
 INFUSED         ADJUST
```

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

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

```
 A  Multidose          12:30
Rate = 100 mL/h
Volume/
Dose  = 50 mL
every 06 h x 04 doses
Doses completed = 0
Volume remaining = 25 mL

>Press START

PAUSE                    START
```
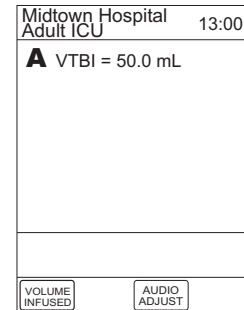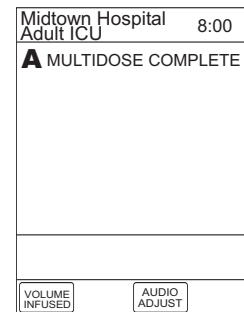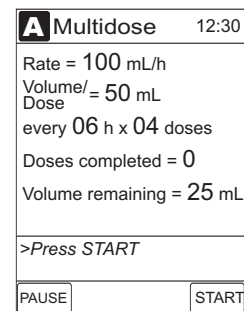
- Between infusions:
  - ◆ Number of doses completed and when next dose starts displays.
  - ◆ Yellow Standby Status Indicator illuminates.

```
 A  Multidose          12:00
Rate = 100 mL/h
Volume/
Dose  = 50 mL
every 06 h x 04 doses
Doses completed = 1
Dose 2 Starts 19:00

>Press START

PAUSE                    START
```

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).

> *NOTE: This feature is only available with Pump Module Versions 1.11.22.5 and greater.*

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.

Audio Characteristics

The Programming Module and Main Display provide various types of alert information. The characteristics of the accompanying audio sounds are as follows:

Type	Sound	Notes
Advisory	One short beep every two seconds	Variable volume; can be silenced for two minutes.
Alarm	Choice of three alarm audio profiles, selectable in System Configuration	Variable volume; can be silenced for two minutes.
Error (Hardware Detected)	Pairs of long beeps	Fixed maximum decibel volume; cannot be silenced.
Error (Software Detected)	Pairs of long beeps	Fixed maximum decibel volume; can be silenced for two minutes.
Illegal Key Press	Two short beeps	Variable volume; cannot be silenced.
Key Click	One short beep	Fixed minimum volume; can be silenced and disabled in System Configuration.
Prompt	One short beep every two seconds	Variable volume; can be silenced.
Switchover	Six short beeps: secondary switching to primary. Two short beeps: bolus switching to continuous.	Variable volume; can be silenced and disabled in System Configuration.

Alarms

Alarm	Meaning	Response
Accumulated Air-in-Line	A large number of air bubbles smaller than current air-in-line limit has recently passed detector.	Clear air from line. To continue infusion, press RESET soft key and then RESTART key.
Air-in-Line	Air has been detected in administration set during an infusion. Infusion stops on affected channel.	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.
Channel Disconnected	Channel(s) disconnected while in operation or has a communication problem.	To silence alarm and clear message from screen, press CONFIRM soft key. Reattach module, if desired, ensuring it is securely "clicked" into place at Channel Release Latch. If alarm is still present, replace channel with an operational instrument.
Check IV Set	Administration set is not properly installed. Infusion stops on affected channel.	Close roller clamp, remove and reinstall administration set, close door, open roller clamp, and then press RESTART key.
Close Door	Door opened during an infusion. Infusion stops on affected channel.	Close door. Press RESTART key, or press CHANNEL SELECT key and then START soft key.
Flo-Stop Open - Close Door	Flo-Stop® Device is in open position while door is open.	Close roller clamp on administration set or close door.
Occluded - Fluid Side/Empty Container	Indicates either upstream occlusion or empty container. Infusion stops on affected channel.	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.
Occluded - Patient Side	Increased back pressure sensed while infusing in pump delivery mode. Infusion stops on affected channel.	Clear occlusion. Press RESTART key, or press CHANNEL SELECT key and then START soft key.
Partial Occlusion - Patient Side	Partial occlusion of patient side of IV line detected by AutoRestart feature.	Clear occlusion. Press RESTART key, or press CHANNEL SELECT key and then START soft key.
Pump Chamber Occluded	Blocked pump chamber detected.	Open door and inspect pump chamber. To open blockage, as required, massage tubing. To continue infusion, press RESET soft key and then RESTART key.

Alarms (Continued)

Alarm	Meaning	Response
Restart Channel	Door opened and closed during an ➤ infusion. Infusion stops on affected channel.	Close door. Press **RESTART** key, or press **CHANNEL SELECT** key and then **START** soft key.
	Channel paused for 2 minutes. ➤	Press **RESTART** key, or press **CHANNEL SELECT** key and then **START** soft key

Errors

Error	Meaning	Response
Channel Error	Error detected. Operation stops on affected channel.	To silence alarm and continue operation of unaffected channels, press **CONFIRM** soft key . Replace channel with an operational instrument, as required. Service by qualified personnel is required.

Messages

Message	Meaning	Response
Anesthesia Mode	Anesthesia Mode discontinued when disconnected from AC.	Press **CONFIRM** soft key.
Bolus Dose Complete	Channel running in continuous infusion mode if programmed.	None
Checking Line	Patient-side occlusion occurred; AutoRestart feature monitoring downstream pressure to determine if infusion can continue.	None
Delay Complete	Delay time completed.	Press **RESTART** key, or press **CHANNEL SELECT** key and then **START** soft key.
Infusion Complete	Current infusion completed.	Set up a new infusion or press **CHANNEL OFF** key.
Infusion Complete - KVO	Programmed volume-to-be-infused delivered; channel running at KVO rate.	Set up a new infusion or press **CHANNEL OFF** key.
Panel Locked	Tamper Resist feature is active and a key was pressed.	If appropriate, deactivate Tamper Resist feature using Tamper Resist Control on back of Programming Module.

Message	Meaning	Response
Panel Unlocked	Tamper Resist feature deactivated.	None.
Pause	Pause control pressed; infusion stopped.	To resume infusion, press **RESTART** key, or press **CHANNEL SELECT** key and then **START** soft key.
Secondary	Secondary infusion in progress on indicated channel.	None. When secondary VTBI="0", infusion will revert to programmed primary parameters.
Start time for next dose has passed.	Start of next dose passed.	Press **CONFIRM** soft key.

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

Specifications

Accumulated Air Window:

Single Bolus Setting	Volume Window (mL)	% Air that Causes Alarm
50	2.8	10%
75	8.0	20%
250	8.0	30%
*500	12.0	30%

* In Anesthesia Mode only.

Bolus Volume following Occlusion, Maximum:

	Pressure Limit (mmHg)	
Rate (mL/h)	50	525
25	≤0.3 mL	≤0.6 mL

Critical Volume: The maximum over-infusion which can occur in the event of a single fault condition is 0.6 mL.

Dimensions: 3.3"W x 8.9"H x 5.5"D

Environmental Conditions:

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

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

Electrical Classification: Class 1, Type CF Defibrillator Proof

Flow Rate Programming Increments:

Rate Range (mL/h)	Increments (mL/h)	
	User Input Rates	Device Calculated Rates
0.1 - 9.99	0.1	0.01
10 - 99.9		0.1
100 - 999	1	1

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.

Time to Alarm, Maximum:

	Pressure Limit (mmHg)	
Rate (mL/h)	50	525
1	≤5 minutes	≤45 minutes
25	≤15 seconds	≤2 minutes

Specifications (Continued)

**Volume to be Infused
Programming Increments**:

Range (mL)	Increments (mL)
0.1 - 9.99	0.01
10 - 999.9	0.1
1000 - 9999	1

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)

Feature	Default Setting	Options
Delay Options	Disabled	Enabled - Disabled
• Callback	None	None, Before, After, Before and After
Drug Calculation	Disabled	Enabled - Disabled
• Bolus Dose	Disabled	Enabled - Disabled
Multidose	Disabled	Enabled - Disabled
• Callback	None	None, Before, After, Before and After
Pressure Dynamic ("*Dynamic Pressure Display*")	Disabled	Enabled - Disabled
Volume/Duration	Disabled	Enabled - Disabled

Pump Module Settings

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

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.

REGULAR INSPECTIONS

PROCEDURE	FREQUENCY
INSPECT FOR DAMAGE:	
Exterior Surfaces	Each usage
Keypad	Each usage
Seal	Each usage
Mechanical Parts	Each usage
CLEANING	As required
START-UP	Each usage

1. Exterior Surfaces - examine for overall condition and verify:

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

2. Keypad

    Check membrane switches for damage.

MAINTENANCE

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.

CAUTION

Periodic inspections should only be performed by qualified service personnel.

Service Information

Refer to the Medley™ Programming Module Directions for Use.

WARRANTY

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;

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

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

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.

MAINTENANCE

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Trumpet and Start-Up Curves

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.
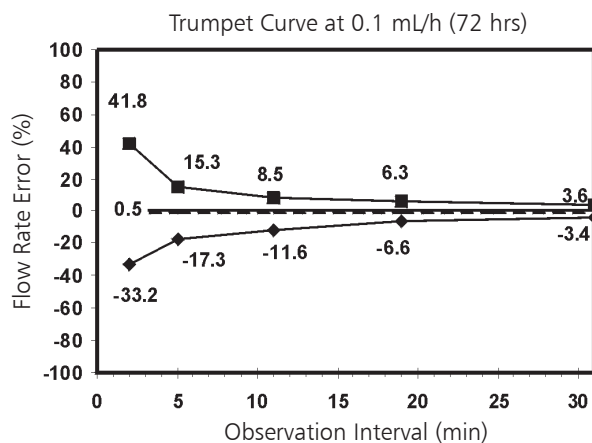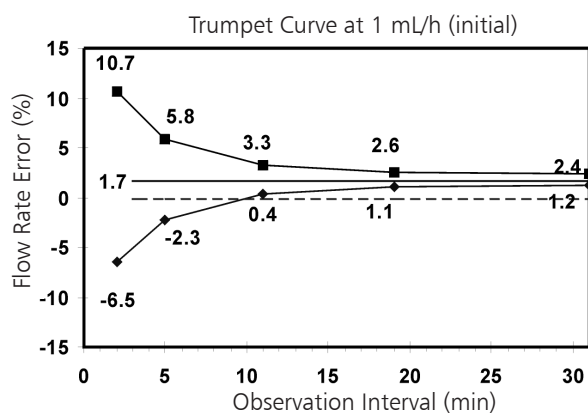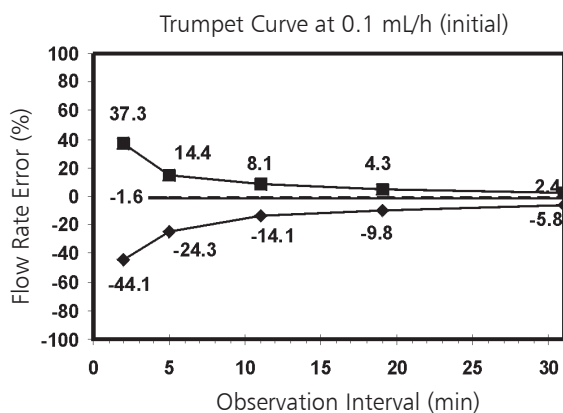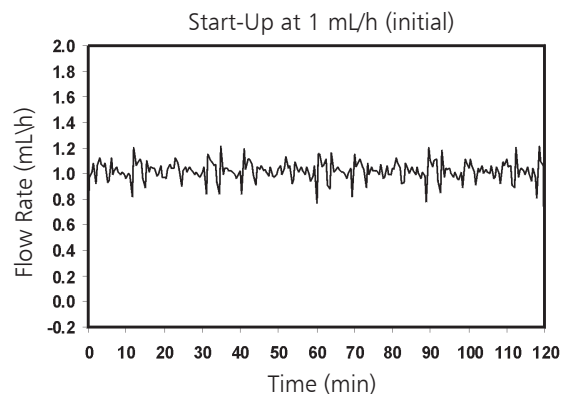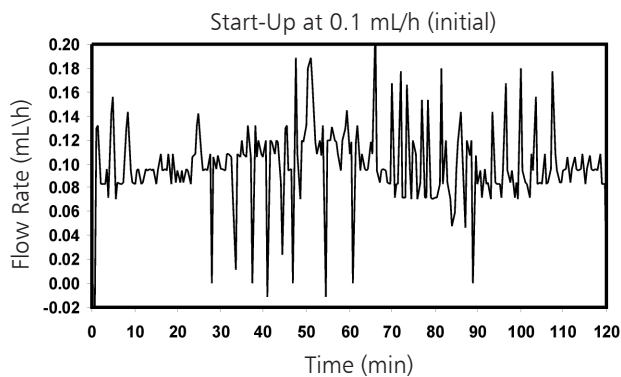
Effects of Negative Solution Container Heights

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.*
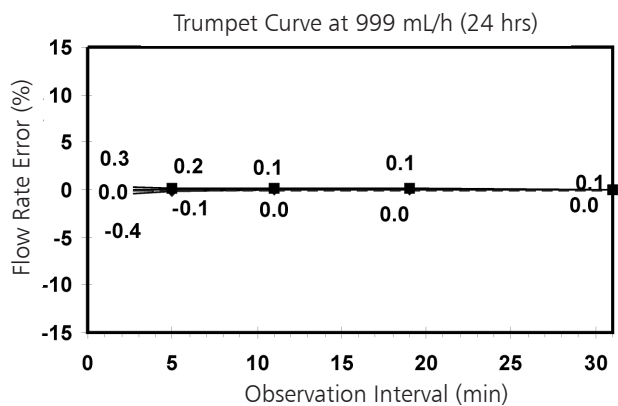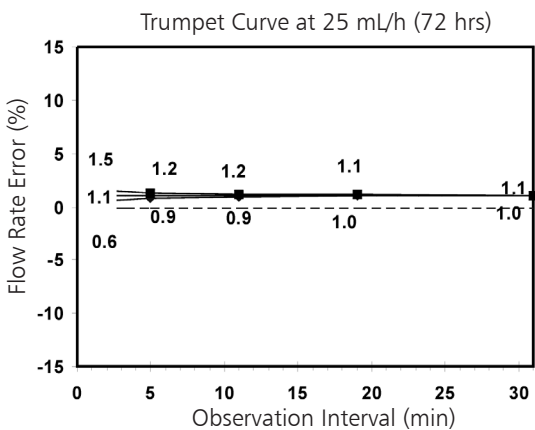
Start-Up at 0.1 mL/h (initial)

Start-Up at 1 mL/h (initial)

Trumpet Curve at 0.1 mL/h (initial)

Trumpet Curve at 1 mL/h (initial)
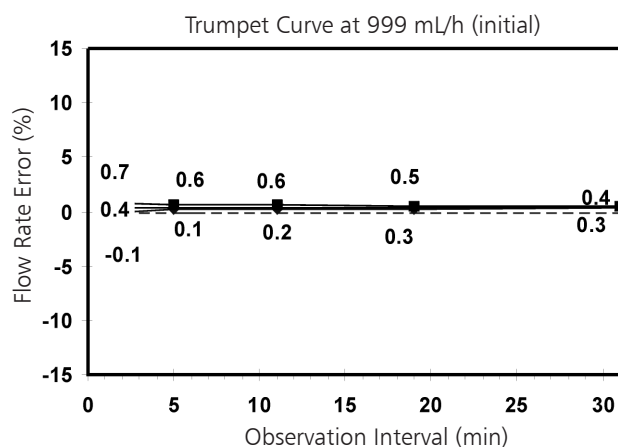

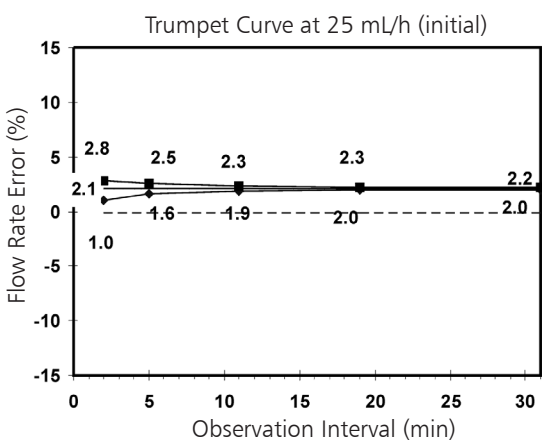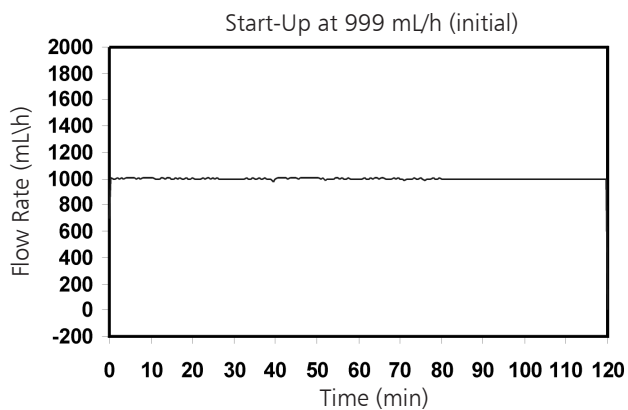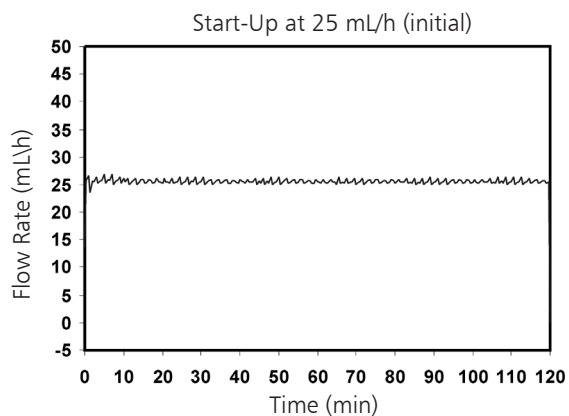Trumpet Curve at 0.1 mL/h (72 hrs)

Trumpet Curve at 1 mL/h (72 hrs)
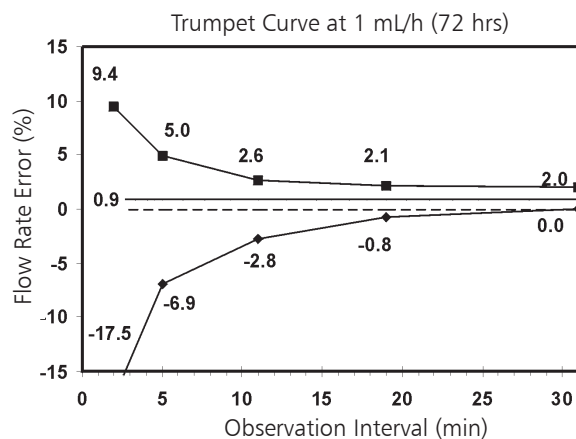
NOTE: The plot range has been increased to ±100%, to allow visualization of the graph.

Legend:
- ■ Maximum rate error
- ▬ Overall rate error
- ◆ Minimum rate error

Start-Up at 25 mL/h (initial)

Flow Rate (mL\h) vs Time (min)

Start-Up at 999 mL/h (initial)

Flow Rate (mL\h) vs Time (min)

Trumpet Curve at 25 mL/h (initial)

Flow Rate Error (%) vs Observation Interval (min)

2.8 2.5 2.3 2.3 2.2
2.1
1.6 1.9 2.0 2.0
1.0

Trumpet Curve at 999 mL/h (initial)

Flow Rate Error (%) vs Observation Interval (min)

0.7 0.6 0.6 0.5 0.4
0.4
0.1 0.2 0.3 0.3
-0.1

Trumpet Curve at 25 mL/h (72 hrs)

Flow Rate Error (%) vs Observation Interval (min)

1.5 1.2 1.2 1.1 1.1
1.1
0.9 0.9 1.0 1.0
0.6

Trumpet Curve at 999 mL/h (24 hrs)

Flow Rate Error (%) vs Observation Interval (min)

0.3 0.2 0.1 0.1 0.1
0.0
-0.1 0.0 0.0 0.0
-0.4

Legend:
- ■ Maximum rate error
- ▬ Overall rate error
- ◆ Minimum rate error

APPENDIX

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