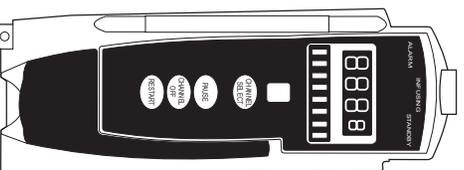


Directions for Use

Pump Module, 8100 Series



PUMP MODULE
8100 SERIES

ALARIS Medical Systems, Inc.
Medley™ Medication Safety System

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About the Pump Module

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. The Medley™ Pump Module is indicated for use on adults, pediatrics, and neonates.

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 an 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.

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

Contraindications: None known.

This document provides directions for use for the Medley™ Pump Module.

NOTE: The Medley™ Point-of-Care Unit was formerly known as the Medley™ Programming Module.

WARNING

Read all instructions, for both the Pump Module and Point-of-Care Unit, before using the Medley™ System.

Features and Definitions

Reference the “Alarms, Errors, Messages” chapter of the Medley™ Point-of-Care Unit Directions for Use (DFU) for the definitions of various alerts. Reference the Point-of-Care Unit DFU for system features and definitions.

Auto-Restart	Part of Medley™ System’s advanced Downstream Occlusion Detection system. If enabled, it minimizes nuisance patient-side occlusion alarms caused by momentary kinking of tubing, IV pushes, etc.
Bolus Dose	Allows a bolus infusion to be programmed using either the Guardrails® Drug Library or drug calculation feature. It can be programmed with or without a continuous infusion following a bolus.
Channel Labels	Available when Profiles feature is enabled. It provides a hospital-defined list of labels, displayed in Channel (Module) Message Display, and identifies module with the solution being infused, catheter location, or other helpful information.
Concentration Limits	Limits specified for the range of concentrations allowed for a particular drug in a profile.
Delay Options	Allows system to be programmed to delay 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	Allows: <ul style="list-style-type: none">• entry of drug dose (Medley™ System calculates correct flow rate to achieve desired dose), <p style="text-align: center;">OR</p> <ul style="list-style-type: none">• entry of flow rate (Medley™ System calculates corresponding drug dose).
Dynamic Pressure Display	Appears on Main Display. If enabled, it graphically displays current patient-side occlusion pressure set point and 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® Drug Library	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. Drug Library use automates programming steps, including drug name, drug amount and diluent volume, and activates hospital-established best-practice Guardrails® Limits.
Guardrails® Limit	<p>A programming limit or best-practice guideline determined by hospital/health system and entered into system's data set. Supports concentration limits for all infusions that utilize concentration. 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 hospital/health system as either "hard" or "soft" limits.</p> <ul style="list-style-type: none"> • A Guardrails® Hard Limit is a programmed limit that cannot be overridden, except in anesthesia mode. • A Guardrails® Soft Limit is a programmed limit that can be overridden.
KVO Rate Adjust	Used to select KVO (Keep Vein Open) rate (0.1 to 20 mL/h allowed), which is the rate of fluid flow after an "Infusion Complete" occurs. The KVO rate will never exceed the infusion rate.
Multidose Mode	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	<p>A complete range of downstream occlusion detection options is provided.</p> <ul style="list-style-type: none"> • 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 maximum occlusion pressure of 525 mmHg. • Auto-Restart: (See "Auto-Restart" definition.) <p>In addition, the Medley™ System provides fluid-side occlusion detection.</p>
Rapid Bolus	Fastest rate at which bolus dose should be delivered, as defined by facility's clinical best-practice guidelines.

Features and Definitions (Continued)

Restore	To simplify programming, 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 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	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 Point-of-Care Unit and attached modules.
	Manufacturing Date: Number adjacent to symbol indicates month and year of manufacture.
	Consult operating instructions.
Rx Only	CAUTION: Federal (U.S.A.) law restricts this device to sale by or on order of a physician.
Single-Use	Single-Use. Do not re-use.
	
	Product contains micron filter, where XX represents filter size.

Symbols (Continued)



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



Product DOES NOT contain a particular element; such as,  = 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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Warnings and Cautions

Warnings and Cautions provided throughout this Directions for Use (DFU) provide information needed to safely and effectively use the Medley™ Pump Module and accessories. Medley™ System Warnings and Cautions, and definitions, are covered in the Point-of-Care Unit DFU.

Rx Only

General

WARNINGS

- The Medley™ Pump Module is designed to **stop fluid flow** under alarm conditions. Periodic patient monitoring must be performed to ensure the infusion is proceeding as expected. It 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.
- 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.
- 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.

Warnings and Cautions (Continued)

Guardrails® Safety Software

WARNINGS

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

Epidural Administration

WARNINGS

- **Epidural administration** of drugs other than those indicated for epidural use could result in serious injury to the patient.
- 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.
- The Medley™ System can be used for epidural administration of **anesthetic and analgesic drugs**. This application is only appropriate when using anesthetics and analgesics 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.

Warnings and Cautions (Continued)

Administration Sets

WARNINGS

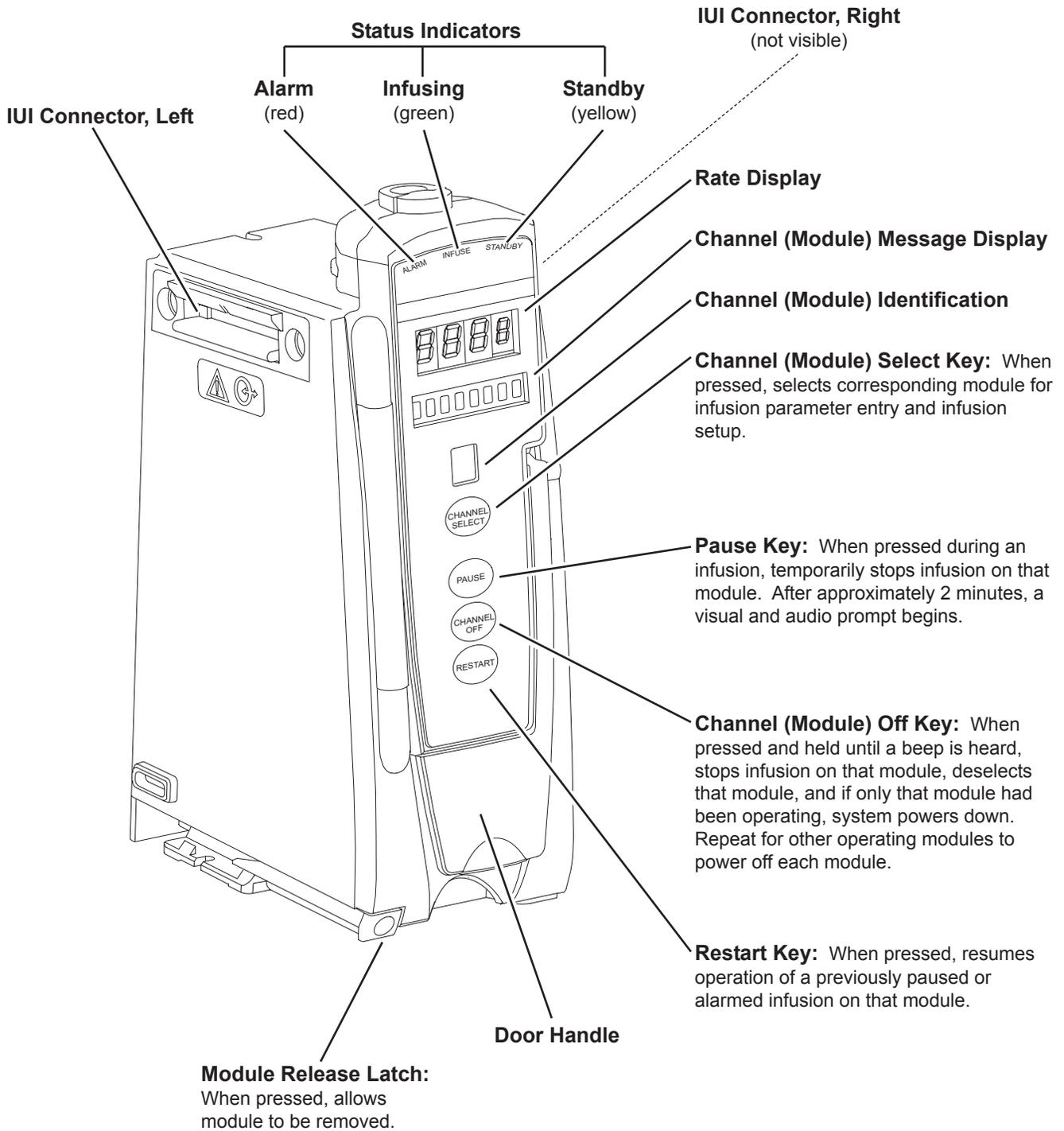
- Use only **Medley™ System/Gemini Series Administration Sets**. The use of any other set may cause improper instrument operation, resulting in an inaccurate fluid delivery or other potential hazard. For a list of compatible sets, reference the Set Compatibility Card (provided separately).
- **Discard** if packaging is not intact or protector caps are unattached.

CAUTION

Before operating instrument, verify that administration set is **free from kinks and installed correctly** in instrument.

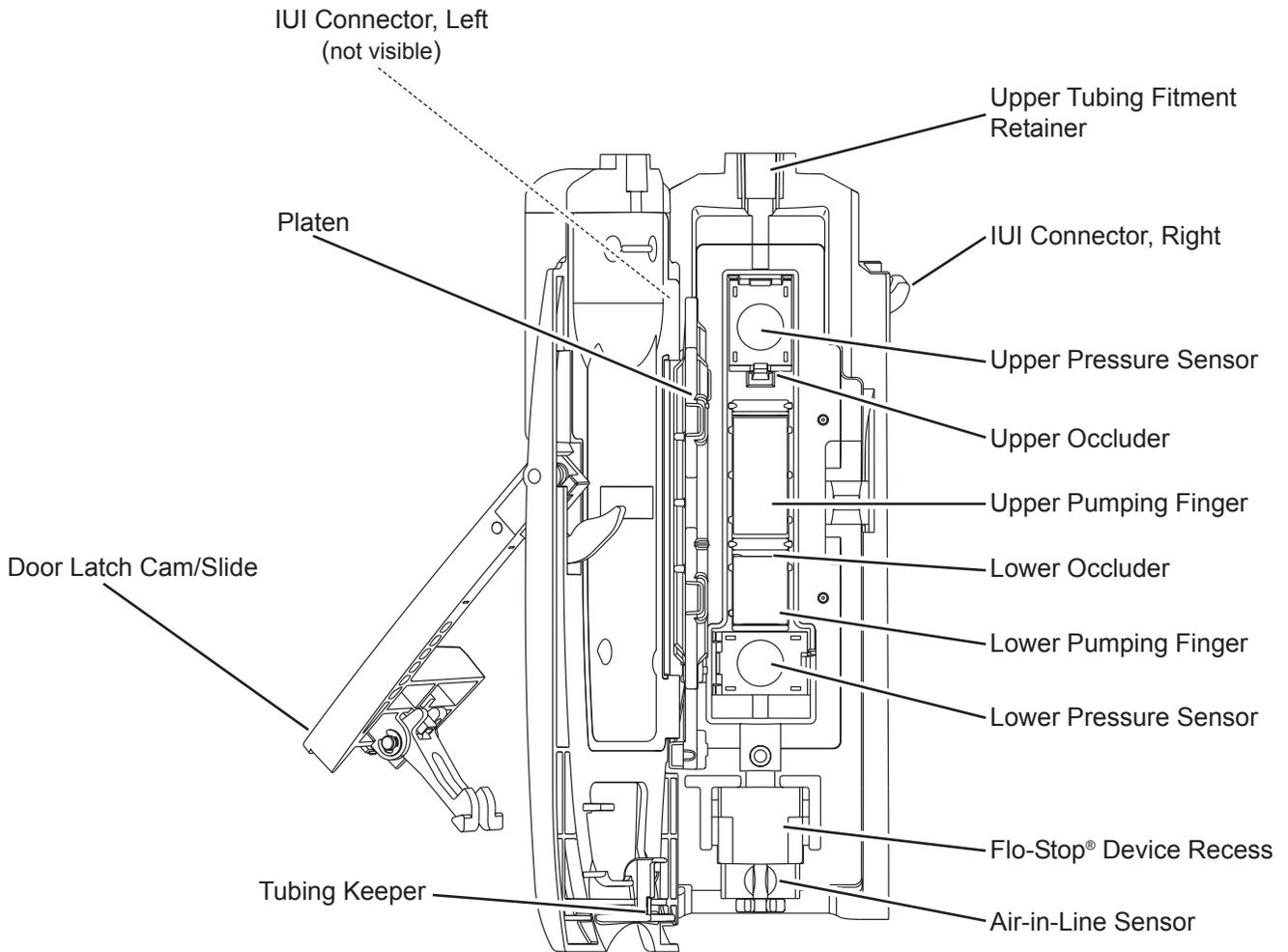
Operating Features, Controls and Indicators

Front/Side View - Door Closed



Operating Features, Controls and Indicators (Continued)

Front View - Door Open



GETTING STARTED

Installation

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

Prior to placing the Medley™ System in use: Perform check-in procedure per Medley™ Maintenance Software/User Manual (Model 8970C, or later).

Attaching and Detaching Modules

Reference the Medley™ Point-of-Care Unit DFU.

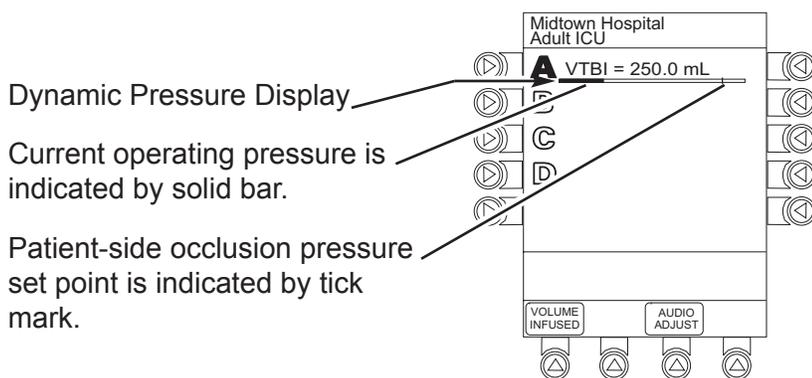
Displays

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. Refer to specific drug product labeling for information concerning appropriate administration techniques and dosages.

Main Display

Reference the Medley™ Point-of-Care Unit DFU.

Dynamic Pressure Display



CAUTION

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

Start-Up

Reference the Medley™ Point-of-Care Unit DFU 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

Administration Set

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, reference directions for use provided with set.
- The primary set must be primed before use (reference “Priming Primary Administration Set” section). It can be loaded into Pump Module to deliver a large volume infusion (reference “Loading and Removing Primary Administration Set” section) or it can be set up to deliver a gravity infusion (reference “Setting Up Primary Administration Set for Gravity Infusion” section).
- Use aseptic technique when handling sets.
- Administration sets are supplied with a sterile and nonpyrogenic fluid path for one-time use. Do not resterilize.
- For administration set replacement interval, refer to facility protocol and/or government standards (such as, CDC guidelines in United States).
- Discard administration set per facility protocol.
- For IV push medication (put instrument on hold), clamp tubing above port.
- Flush port(s) per facility protocol.
- Flo-Stop® Device is a tubing fitment that is part of all Medley™ System/Gemini sets (reference “Flo-Stop® Device” section).

WARNING

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

Preparing Infusion (Continued)

Administration Set (Continued)

SmartSite® Needle-Free System

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

NOTES:

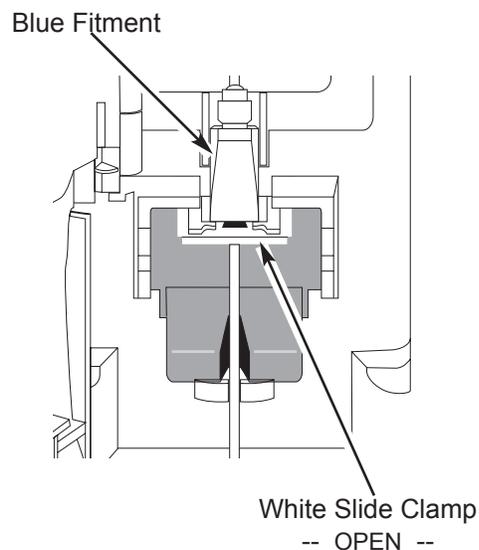
- If applicable, attach syringe to SmartSite® Needle-Free Valve Port and aspirate minute air bubbles.
- In an emergency, SmartSite® Valve may be accessed by a needle and will leak if punctured. To access port with needle without causing leakage, attach a “PRN” adapter of sufficient length to SmartSite®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

Flo-Stop® Device

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

Flo-Stop® Device in Open Position

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

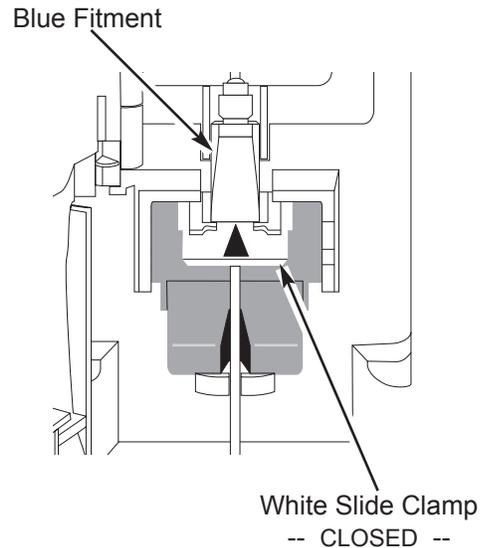


Preparing Infusion (Continued)

Flo-Stop® Device (Continued)

Flo-Stop® Device in Closed Position

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



Priming Primary Administration Set

1. Prepare primary solution container in accordance with manufacturer's directions for use.
2. Open administration set package, remove set, and close roller clamp. (Reference set's Directions For Use.)
3. Insert administration set spike into prepared fluid container, following accepted hospital/facility 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.

Preparing Infusion (Continued)

Loading and Removing Primary Administration Set

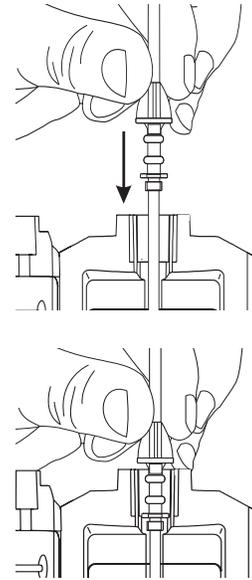
Loading Administration Set

1. If a new set is being loaded, prime set (reference “Priming Primary Administration Set” section).
2. Open Pump Module door.
3. Load administration set, as follows:
 - a. Hold upper fitment above fitment recess and lower into recess.
 - b. Ensure tubing is not twisted.

- c. Press Flo-Stop® Fitment into recess below mechanism.
- d. Using a finger tip, firmly push tubing toward back of Air-in-Line (AIL) Detector.

CAUTION

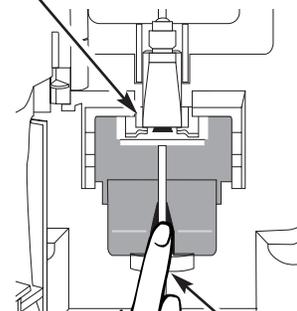
Insert upper fitment **BEFORE** installing the Flo-Stop® Fitment.



CAUTION

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

Flo-Stop® Fitment



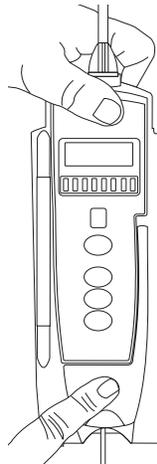
Push tubing toward back of AIL Detector.

Preparing Infusion (Continued)

Loading and Removing Primary Administration Set (Continued)

Loading Administration Set (Continued)

4. Close door and latch, as follows:
 - a. Close door and hold in a closed position by grasping door and instrument case with 1 hand.
 - b. Gently lower latch.
 - Flo-Stop® Device is automatically disengaged.



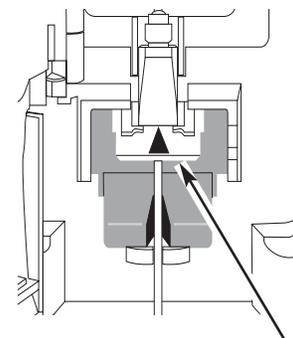
WARNINGS

- Do not touch the administration set while closing the door. Failure to follow this instruction may result in infusion rate inaccuracy.
- 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.

5. Open roller clamp.
6. Verify no fluid is flowing through drip chamber.

Removing Administration Set

1. Close roller clamp.
2. Open Pump Module door.
 - Set's Flo-Stop® Fitment automatically closes to prevent accidental free-flow.



White Slide Clamp
-- CLOSED --

Preparing Infusion (Continued)

Loading and Removing Primary Administration Set (Continued)

Removing Administration Set (Continued)

3. Remove set, as follows:
 - a. Gently pull tubing below Air-in-Line Detector forward and out.
 - b. Lift upper fitment from upper fitment receptacle.
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.

References throughout this chapter 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.

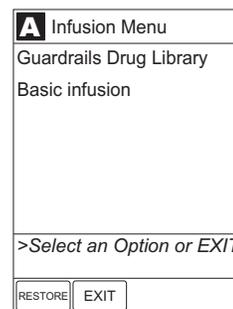
Primary Mode - Basic Infusion

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

NOTES:

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

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



Primary Mode - Basic Infusion (Continued)

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	_ 250 mL
>Press START	
PAUSE	VOLUME DURATION
SECOND-ARY	START

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

NOTE: The infusion may be paused by pressing the **PAUSE** soft key. Reference "Pausing Infusion" section.

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

Primary Mode - Basic Infusion (Continued)

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

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.

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

-- Continued on Next Page --

PROGRAMMING

Primary Mode - Basic Infusion (Continued)

Starting Volume / Duration Infusion (Continued)

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

A Infusion Setup			
RATE	125 mL/h		
VTBI	875 mL		
Time Left: 07 h 00 min			
>Press START			
PAUSE	VOLUME DURATION	SECONDARY	START

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 Point-of-Care Unit).

- **PAUSE** scrolls in Message Display.
- **PAUSED** appears on Main Display.
- Yellow Standby Status Indicator illuminates.
- After 2 minutes, **PAUSE-RESTART CHANNEL** visual and audio prompts begin, and yellow Standby Status Indicator flashes.

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

2. To reinitiate infusion:

- Press **RESTART** key (on Pump Module).

OR

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

-- Continued on Next Page --

Primary Mode - Basic Infusion (Continued)

Pausing Infusion (Continued)

- Press **CHANNEL SELECT** key and then press **START** soft key (on Point-of-Care Unit).

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

Restarting Infusion Following Infusion Complete

1. If solution container and/or administration set require replacement, reference “Preparing Infusion” section in “Getting Started” chapter 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	SECOND- ARY	START

Primary Mode - Basic Infusion (Continued)

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 DURATION	SECONDARY	START

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 DURATION	SECONDARY	START

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 module 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 Point-of-Care Unit.

Primary Mode - Basic Infusion (Continued)

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

Primary Mode - Basic Infusion (Continued)

Viewing and Clearing Volume Infused

- 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 module.

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 INFUSED	AUDIO ADJUST

- 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 VOLUME	CLEAR ALL	MAIN SCREEN

- To clear volume infused:

NOTE: If no key is pressed, main screen appears after 30 seconds.

- If only selected modules are to be cleared, press soft key next to applicable module(s) and press **CLEAR CHANNEL** soft key.
 - Volume clears on selected module(s).
- If all modules 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 VOLUME	CLEAR ALL	MAIN 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 VOLUME	CLEAR ALL	MAIN SCREEN

Auto-Restart

The Auto-Restart 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.

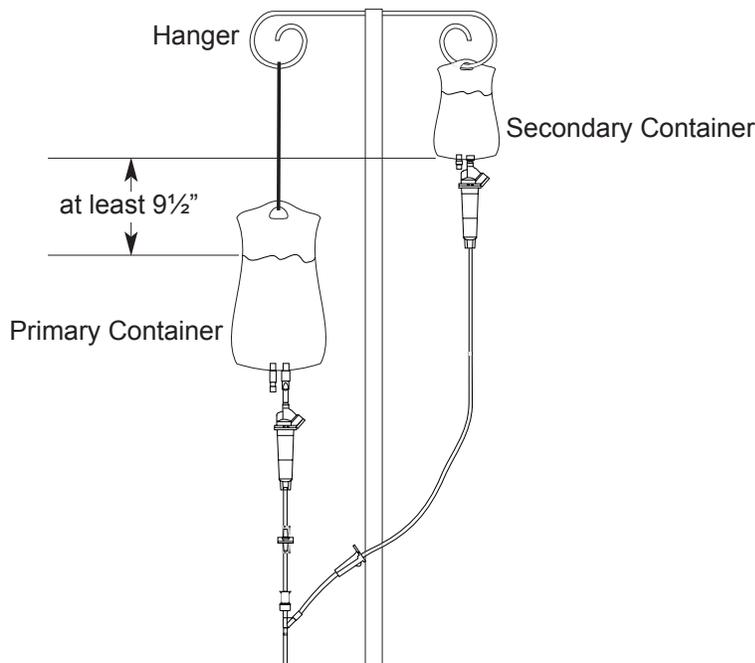
Qualified Service personnel can configure the system to allow from 0 (zero) to 9 restart attempts within a rolling 10 minute period. If the allowable number of restarts is exceeded or if the feature is set to zero, an "Occluded - Patient Side" alarm will occur when the system detects downstream pressure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

Secondary Mode

This mode is designed to support automatic secondary infusions (“piggybacking”) in the same instrument. 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.



WARNINGS

- Secondary applications require the use of a check valve set on the primary IV line.
- The secondary solution container must be higher than the primary solution container.
- The secondary VTBI settings require consideration of such variables as factory overflow, 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.

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/facility procedure.
3. Fill drip chamber to 2/3 full.
4. Open secondary administration set and prime set. Close clamp.

Secondary Mode (Continued)

5. Attach secondary administration set to upper injection site on primary set.
6. Lower primary fluid container using hanger provided with secondary administration set.

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

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

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

OR

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

A Infusion Setup		
RATE	40 mL/h	
VTBI	240 mL	
>Press <i>START</i>		
PAUSE	SECOND- ARY	START

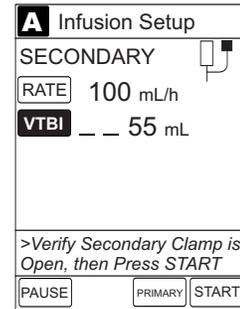
A Infusion Setup		
SECONDARY		
RATE	___ mL/h	
VTBI	___ mL	
>Select Rate or Restore Previous Infusion		
RESTORE		

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

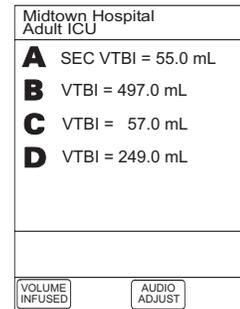
A Infusion Setup		
SECONDARY		
RATE	___ mL/h	
VTBI	___ mL	
>Select <i>RATE</i>		

Secondary Mode (Continued)

- To enter secondary volume to be infused, press **VTBI** soft key and use numeric data entry keys.
- Open clamp on secondary administration set.

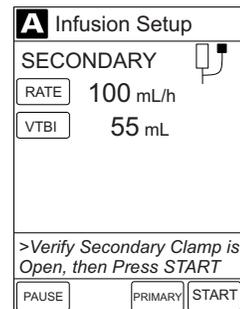


- Verify correct infusion parameters and press **START** soft key.

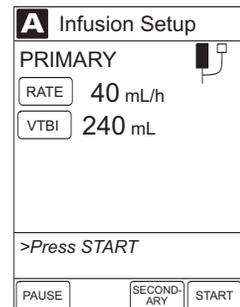


Changing Primary Infusion Parameter During Secondary Infusion

- Press **CHANNEL SELECT** key.
- Press **PRIMARY** soft key.



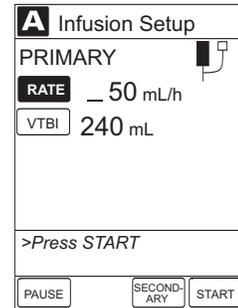
- To change primary infusion parameter, press applicable soft key (**RATE** or **VTBI**), and use numeric data entry keys.



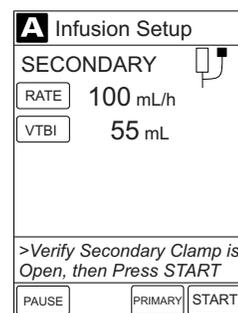
Secondary Mode (Continued)

Changing Primary Infusion Parameter During Secondary Infusion (Continued)

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



- To resume secondary infusion, press **START** soft key.

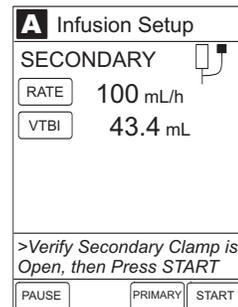


Stopping Secondary Infusion and Returning to Primary Infusion

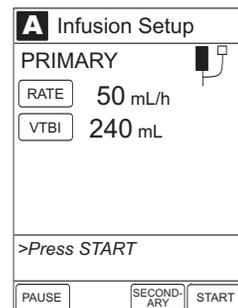
- Press **CHANNEL SELECT** key.
- Press **PRIMARY** soft key.
- Close clamp on secondary administration set.

OR

Disconnect secondary administration set from upper injection port.



- Press **START** soft key.



Secondary Mode (Continued)

Stopping Secondary Infusion and Returning to Primary Infusion (Continued)

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	

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/facility 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 DURATION	SECOND-ARY	START

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	

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 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	
Peripheral 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	SECONDARY	START

Channel Labels (Continued)

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 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 SECONDARY START

Powering Off

Reference the Medley™ Point-of-Care Unit DFU for the following procedures:

- Powering Off System
- Powering Off Module

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 --

WARNING

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.

Setting Up Drug Calculation (Continued)

Drug Calculation Parameters (Continued)

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.

Setting Up Drug Calculation (Continued)

Using Guardrails® Drug Library (Continued)

- Perform steps in “Preparing Infusion” section, to prime and load primary administration set.
- Press **CHANNEL SELECT** key.
- Press **Guardrails Drug Library** soft key.

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

- 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
Bretylum 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

- 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 UNITS mg/kg	
>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 --

Setting Up Drug Calculation (Continued)

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

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

7. Verify parameters are correct and press **NEXT** soft key to confirm.
-
8. To make a rate or dose entry, press applicable soft key, **RATE** or **DOSE**, and use numeric data entry keys (other value is calculated and displayed).

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	

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	

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

Setting Up Drug Calculation (Continued)

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 2 decimal places, and the VTBI can be entered and is displayed to 2 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 programming screen). The rate shown in the 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	250 mL
DOSE	9 mg/min
[Conc]: 8 mg/mL	
>Press START	
PAUSE	SETUP BOLUS START

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

Midtown Hospital Adult ICU	
A VTBI = 250 mL	
VOLUME INFUSED	AUDIO ADJUST

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	

NOTES:

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

A Guardrails Drug Library Lidocaine	
Dose exceeds Guardrails hard limit of 8 mg/min.	Reprogram
>Press REPROGRAM	

Setting Up Drug Calculation (Continued)

Using Non-Library Drug

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

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

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

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	

Setting Up Drug Calculation (Continued)

Using Non-Library Drug (Continued)

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	

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	

PROGRAMMING

Setting Up Drug Calculation (Continued)

Using Non-Library Drug (Continued)

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
<small>Note: Press "Yes" only if Patient weight is used in the calculation. For Example: Dosing Units = mg/kg/h.</small>		
>Use Patient Weight in Calculation?		
<input type="button" value="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		
<input type="button" value="DRUG LIBRARY"/>		

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		
<input type="button" value="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		
<input type="button" value="DRUG LIBRARY"/>		

Setting Up Drug Calculation (Continued)

Using Non-Library Drug (Continued)

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	

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	21 mL/h
VTBI	_____ mL
DOSE	_____5 mcg/kg/min
[Conc]: 1000 mcg/mL	
>Select VTBI	
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 2 decimal places, and the VTBI can be entered and is displayed to 2 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 programming screen). The rate shown in the 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	250 mL
DOSE	5 mcg/kg/min
[Conc]: 1000 mcg/mL	
>Press START	
PAUSE SETUP BOLUS START	

Setting Up Drug Calculation (Continued)

Using Non-Library Drug (Continued)

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

Midtown Hospital Adult ICU	
A VTBI = 250 mL	
VOLUME INFUSED	AUDIO ADJUST

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

-- Continued on Next Page --

Bolus Dose (Continued)

Using Guardrails® Drug Library Calculation (Continued)

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.

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

-- Continued on Next Page --

Bolus Dose (Continued)

Using Guardrails® Drug Library Calculation (Continued)

- 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 not weight-based:
 - 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

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

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

-- OR --

-- Continued on Next Page --

Bolus Dose (Continued)

Using Guardrails® Drug Library Calculation (Continued)

- When continuous dose is weight-based:
 - 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 LIBRARY NEXT	

- 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 WEIGHT	__ _ 11 kg
TIME UNITS	Hour
DOSING UNITS	units/kg/h
[Conc]: 10 units/mL	
>Press NEXT to Confirm	
DRUG LIBRARY NEXT	

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

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	

-- Continued on Next Page --

PROGRAMMING

Bolus Dose (Continued)

Using Guardrails® Drug Library Calculation (Continued)

e. Press **BOLUS** soft key.

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

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

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

5. Press **DURATION** soft key.

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

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

OR

To deliver bolus dose at maximum safe rate possible for selected drug and setup, and automatically calculate bolus duration, press **Rapid Bolus** soft key.

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

A Guardrails Drug Library Lidocaine
BOLUS DOSE
DOSE 5 mg/kg
PATIENT WEIGHT 71 kg (999 mL/h)
DURATION _ _ min Rapid Bolus
TOTAL DOSE = 355 mg
BOLUS VTBI = 44.4 mL
>Enter Duration
SETUP

Bolus Dose (Continued)

Using Guardrails® Drug Library Calculation (Continued)

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

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

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

A Guardrails Drug Library Lidocaine			
BOLUS DOSE			
DOSE	5 mg/kg		
PATIENT WEIGHT	71 kg		
DURATION	2 min		
INFUSE AT: 133.2 mg/min			
[Conc]: 8 mg/mL			
>Press START to Begin Infusing Bolus Dose			
PAUSE	SETUP	CONTINUOUS	START

A Guardrails Drug Library Lidocaine			
BOLUS DOSE			
Dose Remaining:	5 mg/kg		
Pt. Weight:	71 kg		
Time Left:	2 min		
TOTAL DOSE = 355 mg			
BOLUS VTBI = 44.4 mL			
>Press START to Continue Infusing Bolus Dose			
PAUSE	STOP BOLUS	START	

Using Non-Library Drug Calculation

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

Bolus Dose (Continued)

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.

A Drug Calculation	
BOLUS DOSE	mcg
DOSE _ _ 500	mcg/kg
PATIENT WEIGHT	mg
DURATION	mg/kg
[Conc]: 1000 mcg/mL	
>Select the Desired Dosing Units	
SETUP	

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

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

A Drug Calculation	
BOLUS DOSE	
DOSE 500 mcg	
PATIENT WEIGHT	Not Used
DURATION _ _ min	
TOTAL DOSE = 500 mcg	
[Conc]: 1000 mcg/mL	
>Enter Duration	
SETUP	

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

A Drug Calculation			
BOLUS DOSE			
DOSE 500 mcg			
PATIENT WEIGHT	Not Used		
DURATION <1 min			
INFUSE AT: >9999 mcg/min			
[Conc]: 1000 mcg/mL			
>Press START to Begin Infusing Bolus Dose			
PAUSE	SETUP	CONTINUOUS	START

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		
Time Left: <1 min		
TOTAL DOSE: 500 mcg		
BOLUS VTBI = 0.5 mL		
>Press START to Continue Infusing Bolus Dose		
PAUSE	STOP BOLUS	START

Bolus Dose (Continued)

Stopping Bolus Dose

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

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

A Guardrails Drug Library Lidocaine	
BOLUS DOSE	
Dose	Remaining: 5 mg/kg
Pt. Weight:	71 kg
Time Left:	2 min
TOTAL DOSE = 355 mg	
BOLUS VTBI = 44.4 mL	
>Press START to Continue Infusing Bolus Dose	
PAUSE	STOP BOLUS
START	

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 INFUSED	AUDIO ADJUST

PROGRAMMING

Bolus Dose (Continued)

Restoring Bolus Dose

A bolus dose can be restored after it has completed, either prior to or after the module 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.

Bolus Dose Completed - Module 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	CONT- INUOUS

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

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

Bolus Dose (Continued)

Restoring Bolus Dose (Continued)

Bolus Dose Completed - Module 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

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 CONTINUOUS

Bolus Dose (Continued)

Restoring Bolus Dose (Continued)

Bolus Dose Completed - Module Turned Off (Continued)

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

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

Anesthesia Mode

When the Medley™ System is operating in Anesthesia Mode, a module 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.

CAUTION

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

Anesthesia Mode (Continued)

- Callback audio for paused modules is permanently silenced.
- Review of drug calculation setup page is omitted when restoring a stopped drug calculation.

Enabling Anesthesia Mode

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

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

3. Press **Enable** soft key.
4. Press **CONFIRM** soft key.

System Options
Anesthesia Mode
Enable
Disable
Pump Module Air Detection = 75 microliters
Change
>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
A
B
C
D
Anesthesia Mode
VOLUME INFUSED AUDIO ADJUST

Anesthesia Mode (Continued)

Disabling Anesthesia Mode

The Anesthesia Mode can be disabled, and normal operation resumed, using either of the following 3 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

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 = 75 microliters
Change
>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.

Anesthesia Mode (Continued)

Disabling Anesthesia Mode (Continued)

Disconnecting System from AC Power While in Anesthesia Mode (Continued)

2. Press **CONFIRM** soft key.

Anesthesia mode was discontinued when AC power cord was disconnected. Press CONFIRM to continue normal operation.	
<input type="button" value="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. Continue ANESTHESIA MODE?	<input type="button" value="Yes"/>
	<input type="button" value="No"/>
>Select Yes or No	

Delay Options

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

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

Delay Options (Continued)

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 1 minute and up to 120 minutes.

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



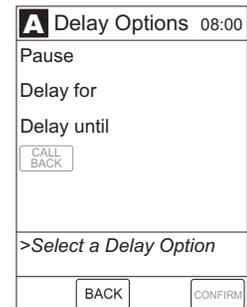
A Infusion Setup

RATE	40 mL/h
VTBI	250 mL

>Press START

DELAY OPTIONS SECONDARY START

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



A Delay Options 08:00

Pause

Delay for

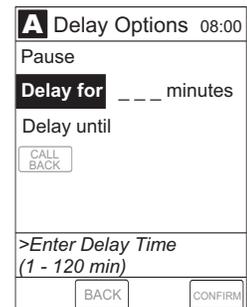
Delay until

CALL BACK

>Select a Delay Option

BACK CONFIRM

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)

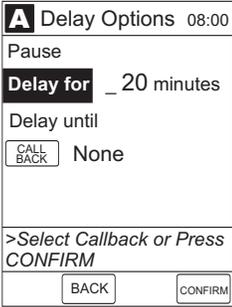
BACK CONFIRM

Delay Options (Continued)

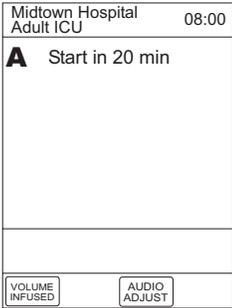
Delaying Infusion (Continued)

Specifying by Minutes (Continued)

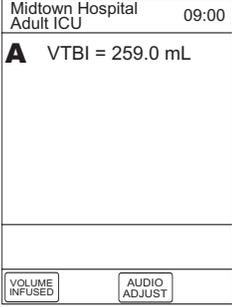
4. Press **CONFIRM** soft key.



- Delay period counts down on Main Display.



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



Delay Options (Continued)

Delaying Infusion (Continued)

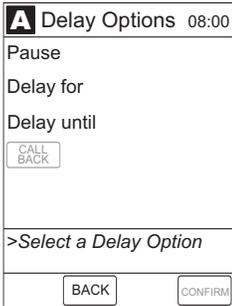
Specifying by Time of Day

The **Delay until** option is used to program an infusion delay for a minimum of 1 minute and up to 23 hours 59 minutes.

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

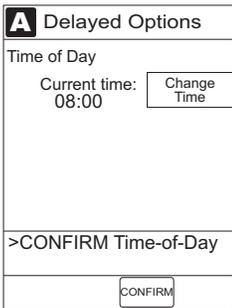


2. Press **Delay until** soft key.

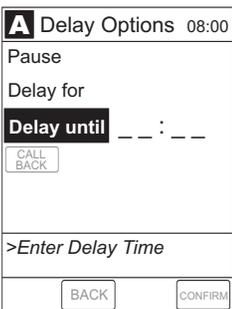


3. If **Current time** displayed is correct, press **CONFIRM** soft key; otherwise, press **Change Time** and enter correct time. (Reference "Setting Up Time of Day" procedure in Medley™ Point-of-Care Unit DFU.)

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



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



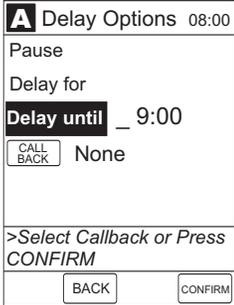
Delay Options (Continued)

Delaying Infusion (Continued)

Specifying by Time of Day (Continued)

5. Press **CONFIRM** soft key.

- Time infusion is scheduled to start appears on Main Display.
- If a **Before** callback has not been scheduled (reference “Scheduling a Callback” section), infusion automatically initiates at end of delay period.



Delay Options (Continued)

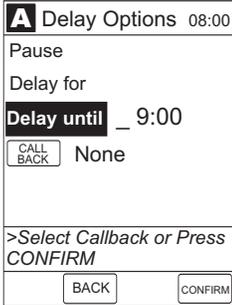
Scheduling a Callback

When programming a **Delay for** or **Delay until** infusion, a callback can be scheduled for that infusion. There are 3 types of callback:

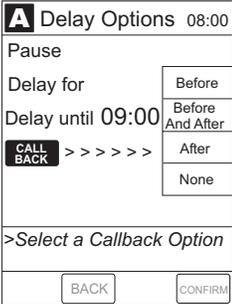
- **Before** - gives an alert when delay is completed and infusion needs to be initiated.
- **After** - gives an alert when delayed infusion has completed.
- **Before and After** - gives an alert when delay is completed and infusion needs to be initiated and when delayed infusion has completed.

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

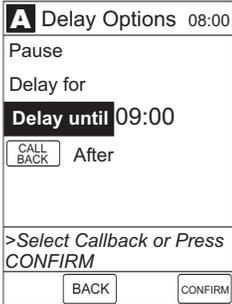
1. Prior to pressing **CONFIRM** soft key to initiate delay during **Delay for** or **Delay until** programming process, press **CALL BACK** soft key.



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



3. To initiate delay, press **CONFIRM** soft key.



-- Continued on Next Page --

Delay Options (Continued)

Scheduling a Callback (Continued)

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

OR

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

- If **Before** option was selected:
 - ◆ An audio prompt sounds when delay period has ended.
 - ◆ Yellow Standby Status Indicator flashes.
 - ◆ **DELAY COMPLETE** scrolls in 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 Message Display.
- If **Before and After** option was selected, same prompts and indicators mentioned above for both **Before** and **After** options are exhibited.

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	

Delay Options (Continued)

Scheduling a Callback (Continued)

- 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

- Press **DELAY OPTIONS** soft key.

A Infusion Setup
RATE 40 mL/h
VTBI 250 mL
>Press START
DELAY OPTIONS SECOND-ARY START

- Press **Pause** soft key.

NOTES:

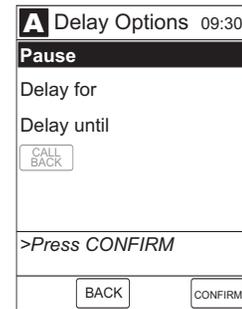
- Using the **Pause** function in the Delay Options screen is the same as pressing the **PAUSE** key on the Pump Module.
- The time displayed in the upper right corner of the screen is the time of day in a 24-hour clock format (military time).

A Delay Options 09:30
Pause
Delay for
Delay until
CALL BACK
>Select a Delay Option
BACK CONFIRM

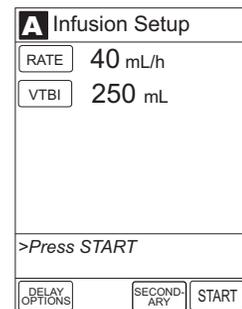
Delay Options (Continued)

Pausing Infusion (Continued)

- Press **CONFIRM** soft key.
 - PAUSE** scrolls in Message Display.
 - PAUSED** appears on Main Display.
 - Yellow Standby Status Indicator illuminates.
 - After 2 minutes: **PAUSE - RESTART CHANNEL** visual and audio prompts begin, and yellow Standby Status Indicator flashes.



- To reinitiate infusion:
 - Press **RESTART** key.
OR
 - Press **CHANNEL SELECT** key and then **START** soft key.



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.

Multidose Mode (Continued)

Programming with Volume / Duration Enabled

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

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

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

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

Multidose Mode (Continued)

Programming with Volume / Duration Enabled (Continued)

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™ Point-of-Care Unit DFU.)

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

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

Multidose Mode (Continued)

Programming with Volume / Duration Enabled (Continued)

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

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/ DOSE 50 mL
DURATION 00 h 30 min
DOSE INTERVAL every _6 h
OF DOSES
>Select NUMBER OF DOSES
RATE VOLUME

Multidose Mode (Continued)

Programming with Volume / Duration Enabled (Continued)

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

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

- Main Display shows remaining VTBI for that dose.

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

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

Midtown Hospital Adult ICU		8:00
A	MULTIDOSE COMPLETE	
VOLUME INFUSED	AUDIO ADJUST	

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/ = 50 mL		
Dose		
Duration = 00 h 30 min		
every 06 h x 04 doses		
Doses completed = 0		
Volume remaining = 25 mL		
>Press START		
PAUSE	START	

-- Continued on Next Page --

Multidose Mode (Continued)

Programming with Volume / Duration Enabled (Continued)

- 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/ = 50 mL	
Dose	
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 not enabled at the time the Medley™ System was configured for use, use the following procedure to program a multidose infusion.

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

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

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

Multidose Mode (Continued)

Programming with Volume / Duration Disabled (Continued)

5. Press **OPTIONS** key.

A Infusion Setup	
RATE	___ mL/h
VTBI	___ mL
<p>>Select Rate or Restore Previous Infusion</p>	
RESTORE	VOLUME DURATION

6. Press **Multidose** soft key.

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

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

A Multidose	13:00
RATE	___ mL/h
VOLUME/ DOSE	
DOSE INTERVAL	
# OF DOSES	
<p>>Enter Rate</p>	

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	
<p>>Enter Volume/Dose</p>	

Multidose Mode (Continued)

Programming with Volume / Duration Disabled (Continued)

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	

- Main Display shows remaining VTBI for that dose.

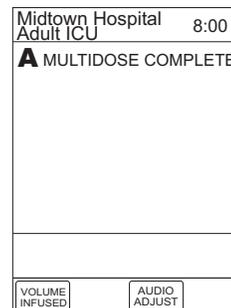
Midtown Hospital		13:00
Adult ICU		
A	VTBI = 50.0 mL	
VOLUME INFUSED	AUDIO ADJUST	

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Multidose Mode (Continued)

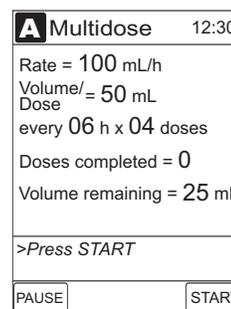
Programming with Volume / Duration Disabled (Continued)

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

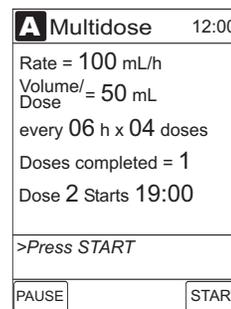


12. To see detail screen during or between infusions, press **CHANNEL SELECT** key.

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



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



Reviewing Serial Number

Reference the Medley™ Point-of-Care Unit DFU.

Reviewing Software Version

Reference the Medley™ Point-of-Care Unit DFU.

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ALARMS, ERRORS, MESSAGES

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

Definitions

Reference the Medley™ Point-of-Care Unit Directions for Use (DFU).

Audio Characteristics

Reference the Medley™ Point-of-Care Unit DFU.

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 module.	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	Module(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 Module Release Latch. If alarm is still present, replace module with an operational instrument.
Check IV Set	Administration set is not properly installed. Infusion stops on affected module.	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 module.	Close door. Press RESTART key, or press CHANNEL SELECT key and then START soft key.

Alarms (Continued)

Alarm	Meaning	Response
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 module.	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 module.	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 Auto-Restart feature.	Clear occlusion. Press RESTART key, or press CHANNEL SELECT key and then START soft key.
Pump Chamber Blocked	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.
Restart Channel	Door opened and closed during an infusion. Infusion stops on affected module. ➤	Close door. Press RESTART key, or press CHANNEL SELECT key and then START soft key.
	Module 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 module.	To silence alarm and continue operation of unaffected modules, press CONFIRM soft key . Replace module with an operational instrument, as required. Service by qualified personnel is required.

Messages

Message	Meaning	Response
Anesthesia Mode	Anesthesia Mode discontinued when disconnected from AC.	Press CONFIRM soft key.
Bolus Dose Complete	Module running in continuous infusion mode if programmed.	None
Checking Line	Patient-side occlusion occurred; Auto-Restart 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; module 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 Point-of-Care Unit.
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 module.	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:

Rate (mL/h)	Pressure Limit (mmHg)	
	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:

	<u>Operating</u>	<u>Storage/Transport</u>
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

Specifications (Continued)

Fluid Ingress Protection:	IPX1, Drip Proof
Infusion of Air, Means to Protect Patient from:	Ultrasonic Air-in-Line Detection Maximum single bolus size = selectable 50, 75 or 250 microliters nominal (500 microliters in Anesthesia Mode)
Infusion Pressure, Maximum:	654 mmHg (Maximum Occlusion Alarm Threshold plus tolerance)
KVO (Keep Vein Open) Rate:	Factory Default Setting is 1 mL/h if set rate is 1 mL/h or above; or set rate, if rate is 0.9 mL/h or below.
KVO Selection Range:	KVO rate can be set in System Configuration from 0.1-20 mL/h in 0.1 mL/h increments.
Occlusion Alarm Thresholds:	
Pump Mode:	525 mmHg at rates ≥ 30 mL/h Varying level based on rate and patient back-pressure at rates < 30 mL/h.
Selectable Mode:	User selected from 50 to 525 mmHg in 25 mmHg increments.
Operating Principle:	Positive displacement
Rate Accuracy:	Rate accuracy of the Medley™ Medication Safety System is $\pm 5\%$ at rates between 1 and 999 mL/h and $\pm 5.5\%$ 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: $68 \pm 4^\circ\text{F}$ ($20 \pm 2^\circ\text{C}$) 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. Reference the "Trumpet and Start-Up Curves" section in "Appendix" chapter for data on how these factors influence rate accuracy.

Specifications (Continued)

Time to Alarm, Maximum:

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

**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 60601-1; CSA C22.2 No. 601.1, including A1 and A2; IEC/EN 60601-2-24; IEC/EN 60601-1-2, and AAMI ID26.

Configurable Settings

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

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

System Settings

Reference the Medley™ Point-of-Care Unit Directions for Use (DFU).

Configurable Settings (Continued)

Shared Infusion Settings (Pump Module and Syringe Module)

Feature	Default Setting	Options
Delay Options • Callback	Disabled None	Enabled - Disabled None, Before, After, Before and After
Drug Calculation • Bolus Dose	Disabled Disabled	Enabled - Disabled Enabled - Disabled
Multidose • Callback	Disabled None	Enabled - Disabled 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	Enabled	Enabled - Disabled
Air-in-Line Settings (single bolus)	75 microliters	50, 75 or 250 microliters Anesthesia Mode only: 500 microliters
Auto-Restart 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 • Lock Status • Max Occlusion Pressure	Pump Unlocked 525 mmHg	Pump, Selectable Locked, Unlocked 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

Reference the Medley™ Point-of-Care Unit (DFU).

Inspection Requirements

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

REGULAR INSPECTIONS

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

WARNING

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

CAUTION

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

Service Information

Reference the Medley™ Point-of-Care Unit DFU.

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

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

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

See packing inserts for international warranty, if applicable.

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, as follows:

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 2 hours from the start of the infusion. They exhibit the delay in onset of delivery due to mechanical compliance and provide a visual representation of

uniformity. Trumpet curves are derived from the second hour of this data.

FLOW CHARACTERISTICS UNDER VARYING DELIVERY CONDITIONS

Effects of Pressure Variations

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

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

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

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

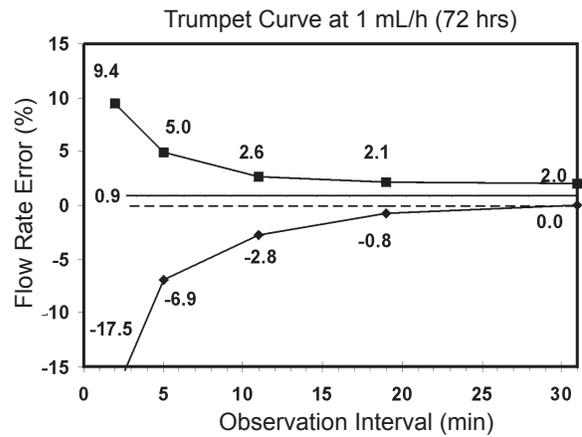
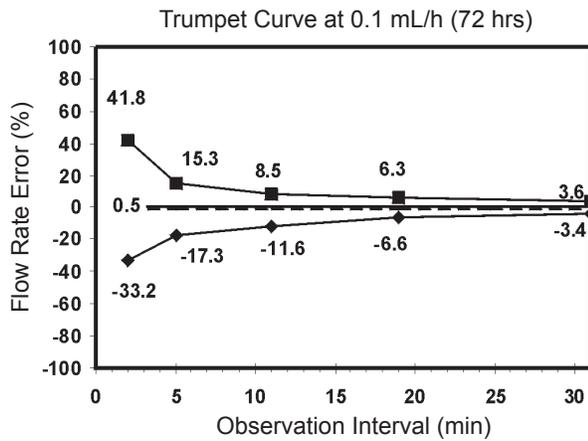
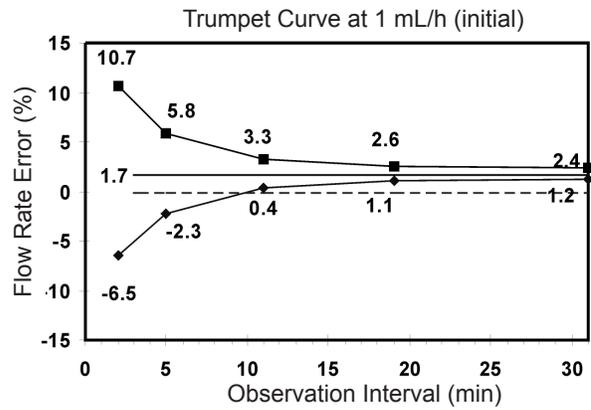
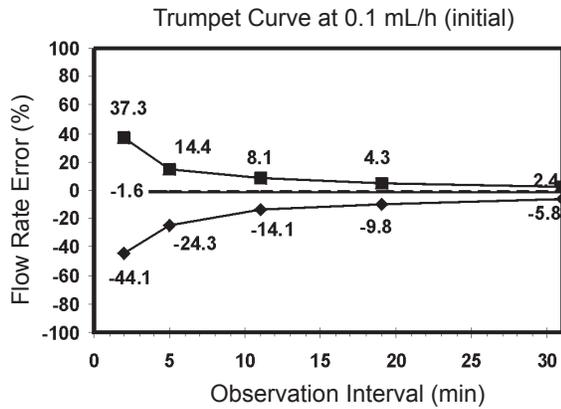
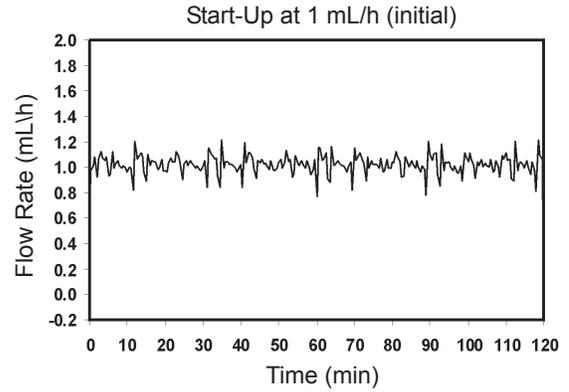
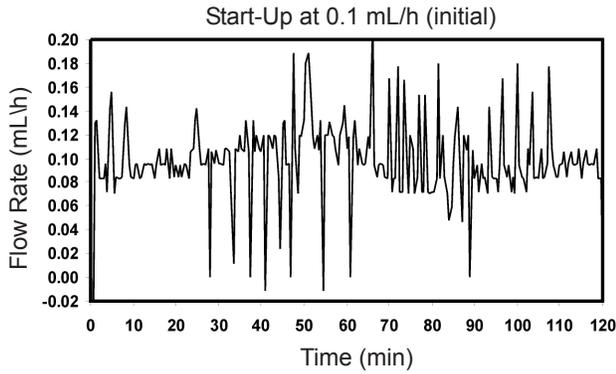
Effects of Negative Solution Container Heights

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

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

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

Trumpet and Start-Up Curves (Continued)

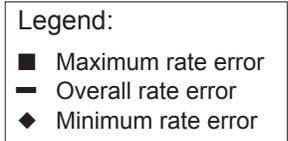
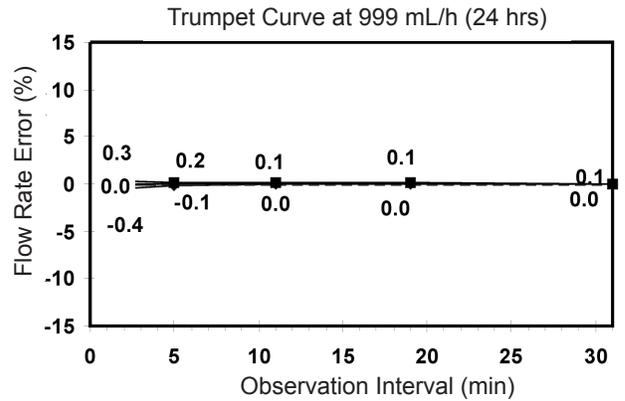
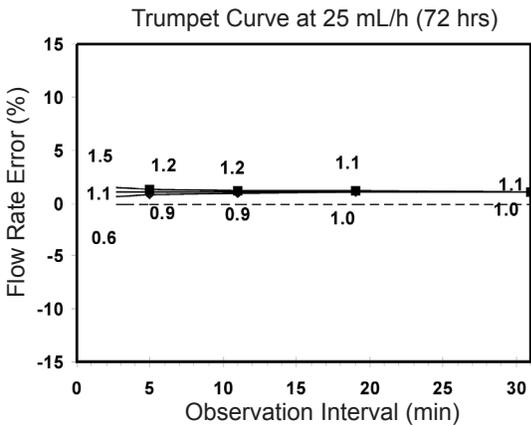
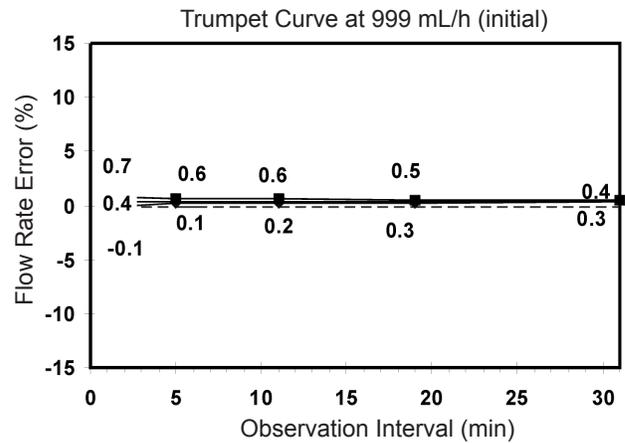
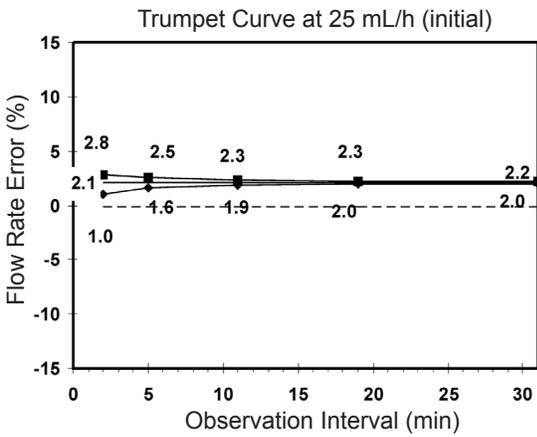
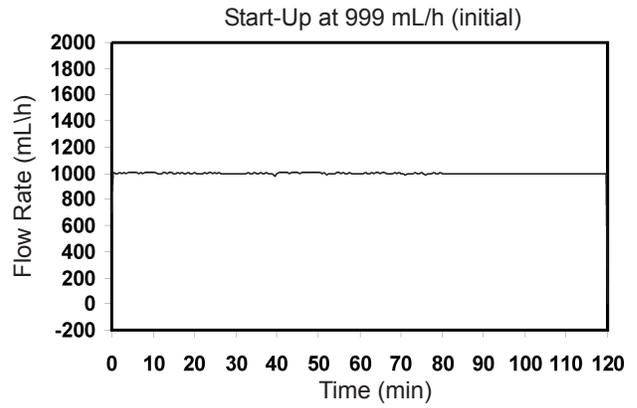
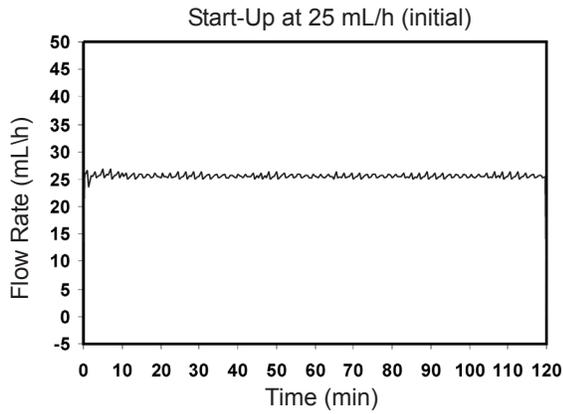


NOTE: The plot range has been increased to $\pm 100\%$, to allow visualization of the graph.

Legend:

- Maximum rate error
- Overall rate error
- ◆ Minimum rate error

Trumpet and Start-Up Curves (Continued)



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Patents, Patented/Brevets, Brevetti, Patente, Patenten, Patenter, Patenten, Patentit, Πατέντες, 特許, 專利, 專利:

US – D362,062; RE35841; 4,689,043; 4,764,166; 4,690,673; 5,096,385; 5,165,873; 5,360,413; 5,453,098; 5,601,445; 5,676,346; 5,681,285; 5,699,821; 5,713,856; 5,800,387; 5,836,910; 5,941,846; 6,267,559; 6,269,340. **AU** – 596,552; 604,477; 634,811; 682,789; 686,942; 693,662; 703,178; 703,203; 719,254; 728,366. **CA** – 1,238,832; 1,258,212; 1,296,092; 2,026,518; 2,029,267; 2,125,693; 2,145,266; 2,175,021. **DE** – P3686558.3; P3774598; 69329774; 69007003T2; 690244923; 69512464T2; 69624982.0-08. **ES** – 2,154,651. **HK** – 1,006,006. **JP** – 1,816,872; 2,594,604; 3,133,640; 7,502,678. **NZ** – 286,445. **SG** – 49,695. **TW** – NI-107963. EP0225158 (**AT, BE, CH, FR, IT, NL, SE, UK**). EP0748635B1 (**AT, BE, CH, DK, FI, FR, GR, IE, IT, LU, MC, NL, PT, SE, UK**). EP0686405 (**BE, FR, IT, LU, NL, SE, UK**). EP0649316 (**DK**). EP0238227 (**FR, UK**). EP0422855 (**FR, UK**). EP0431310 (**FR, UK**). Other Patents Pending