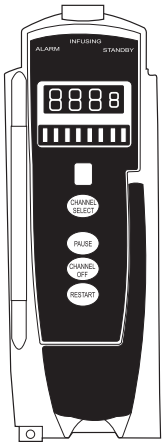
Directions for Use

Pump Module, 8100 Series



ALARIS Medical Systems, Inc.

Medley™ Medication Safety System

GENERAL CONTACT INFORMATION

Customer Advocacy - North America

Clinical and technical feedback.

Phone: (800) 854-7128, Ext. 7812
E-Mail: CustomerFeedback@alarismed.com

Technical Support - North America

Maintenance and service information support; troubleshooting.

United States:
Phone:
(858) 458-6003
(800) 854-7128, Ext. 6003

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

Customer Care - North America

Instrument return, service assistance, and order placement.

United States:
Phone:
(800) 482-4822

Canada:
Phone:
(800) 387-8309

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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:

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

  OR

- entry of flow rate (Medley™ System calculates corresponding drug dose).

Dynamic Pressure Display

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.

Features and Definitions (Continued)

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

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.

- 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

A complete range of downstream occlusion detection options is provided.

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

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

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.
	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

℞ Only

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.

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.

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.

Administration Sets

WARNINGS

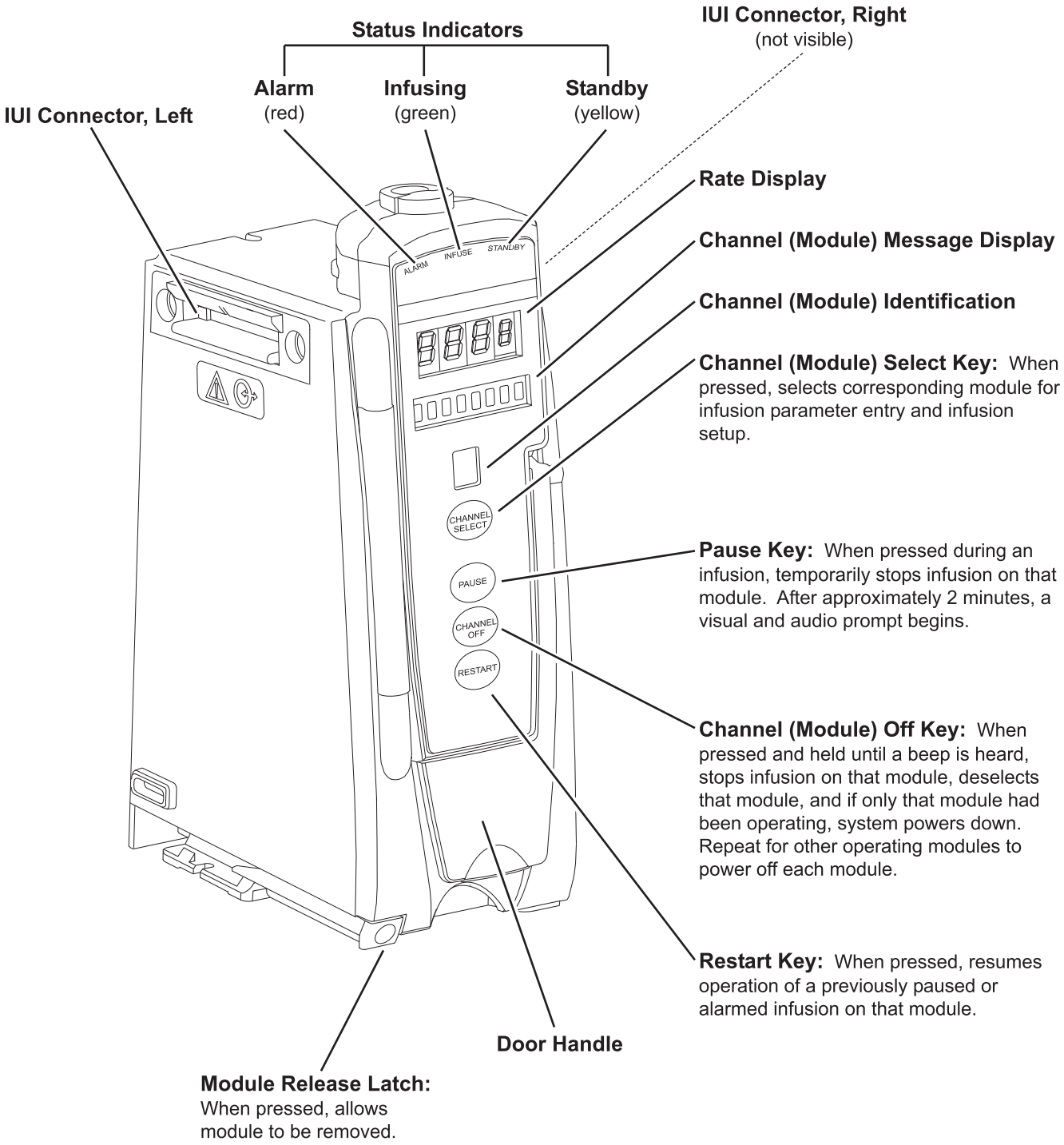
- Use only **Medley™ System/Gemini Series Administration Sets**. The use of any other set may cause improper instrument operation, resulting in an inaccurate fluid delivery or other potential hazard. For a list of compatible sets, reference the Set Compatibility Card (provided separately).
- **Discard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

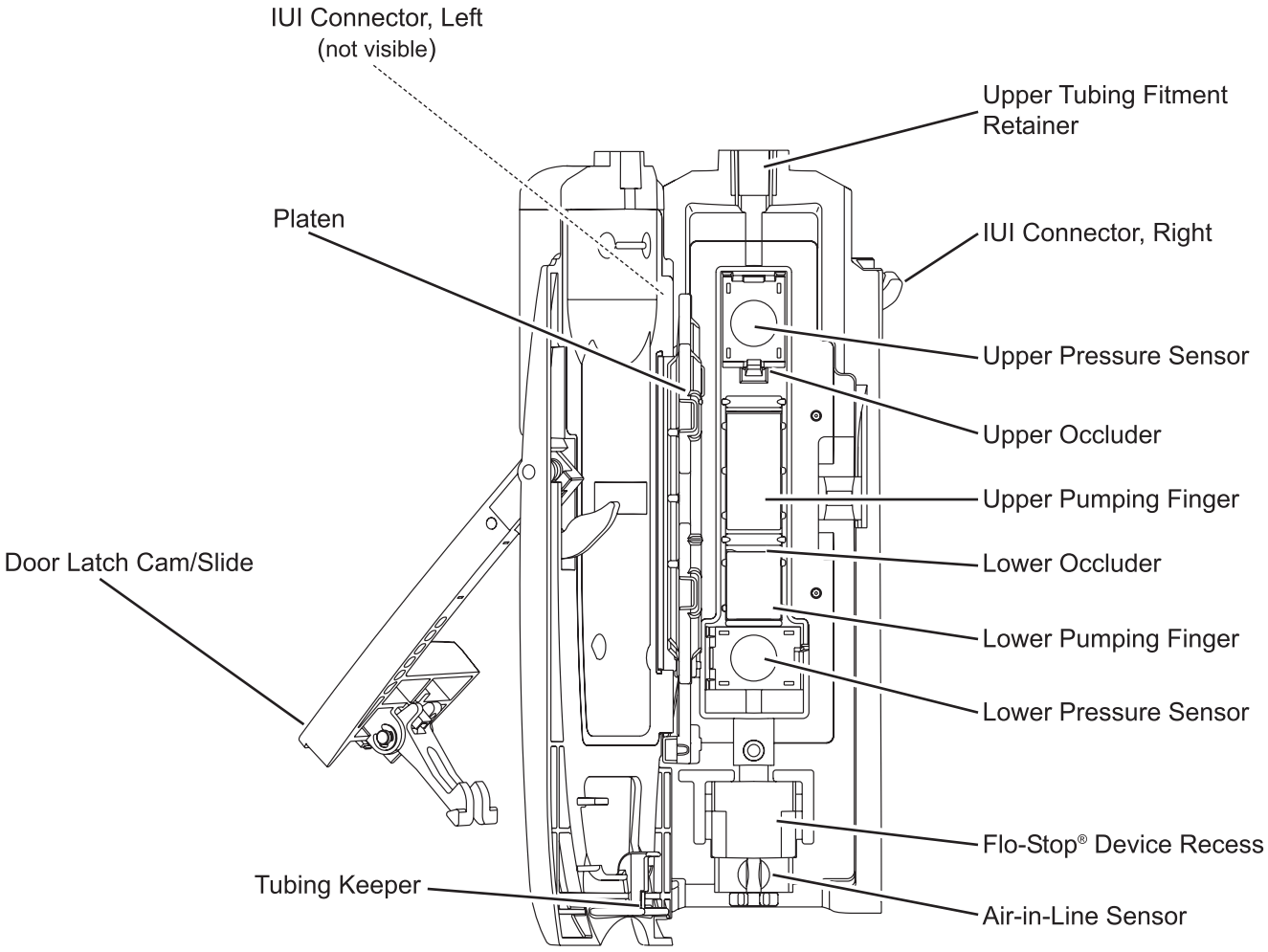
Operating Features, Controls and Indicators

Front/Side View - Door Closed



Operating Features, Controls and Indicators (Continued)

Front View - Door Open



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

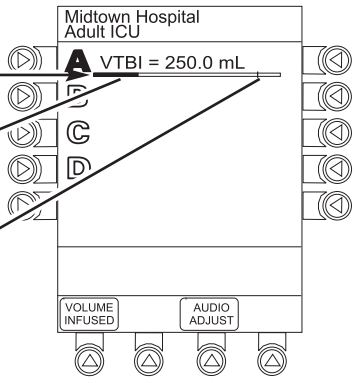
Reference the Medley™ Point-of-Care Unit DFU.

Dynamic Pressure Display

Dynamic Pressure Display

Current operating pressure is indicated by solid bar.

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



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).

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:

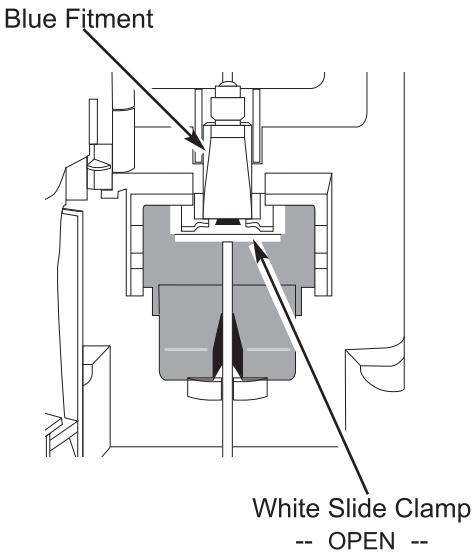
- If applicable, attach syringe to SmartSite® Needle-Free Valve Port and aspirate minute air bubbles.
- In an emergency, SmartSite® Valve may be accessed by a needle and will leak if punctured. To access port with needle without causing leakage, attach a "PRN" adapter of sufficient length to SmartSite®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

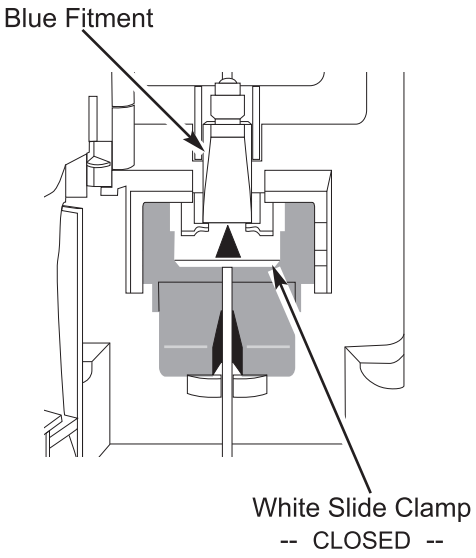
When a new Medley™ System/Gemini administration set is removed from the package, the Flo-Stop® Device is in the open position (white slide clamp aligned with blue fitment). In this open position, flow is not occluded but is allowed as required for the priming process. The roller clamp is used to control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



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.

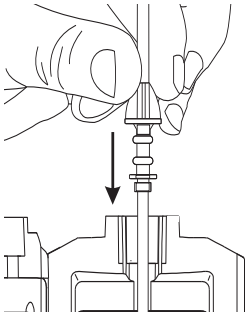
Loading and Removing Primary Administration Set

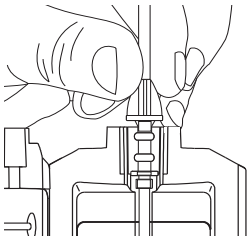
Loading Administration Set

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.

CAUTION

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

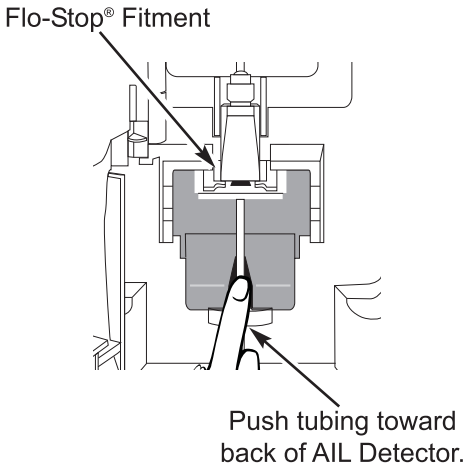




   c. Press Flo-Stop® Fitment into recess below mechanism.
   d. Using a finger tip, firmly push tubing toward back of Air-in-Line (AIL) Detector.

CAUTION

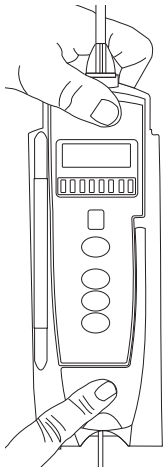
When reloading an administration set, leave the Flo-Stop® Fitment in the closed position (reference “Flo-Stop® Device” section).



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.



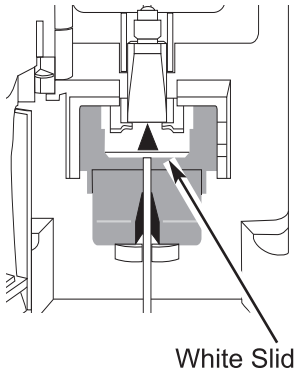
WARNINGS

- 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.



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.

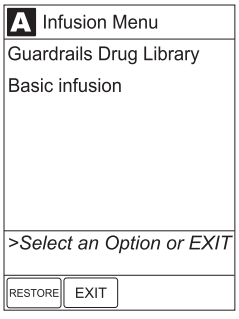
Primary Mode - Basic Infusion

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:

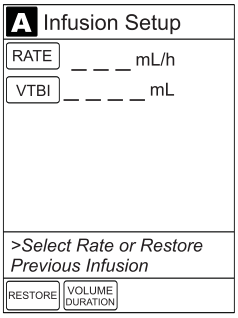
- The illustrations in this section assume the following:
  - Drug Calculation, Dynamic Pressure Display, Profiles, and Volume Duration configurable settings are enabled.
  - Delay Options configurable setting is disabled.
- If Delay Options is enabled, the **PAUSE** soft key becomes **DELAY OPTIONS**.
- 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.



Starting Rate / Volume Infusion

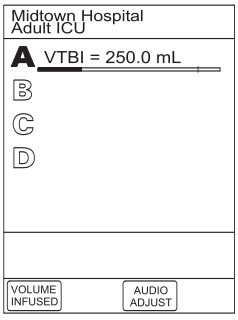
1. To enter flow rate, press **RATE** soft key and use numeric data entry keys.



2. To enter VTBI, press **VTBI** soft key and use numeric data entry keys.
3. Attach administration set to patient's vascular access device.

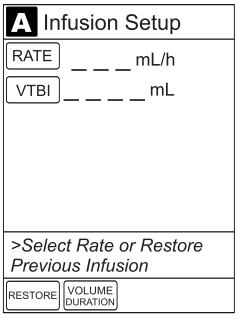
4. Verify correct infusion parameter entry and press **START** soft key.

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

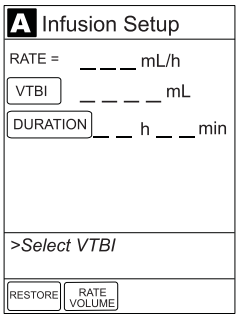


Starting Volume / Duration Infusion

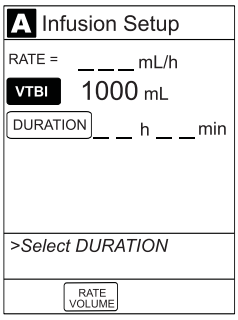
1. Press **VOLUME DURATION** soft key.



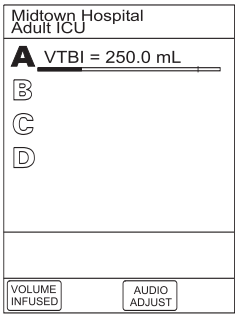
2. To enter VTBI, press **VTBI** soft key and use numeric data entry keys.



3. To enter volume duration, press **DURATION** soft key and use numeric data entry keys.
   - Rate is automatically calculated.
4. Attach administration set to patient's vascular access device.



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



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Starting Volume / Duration Infusion (Continued)

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

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

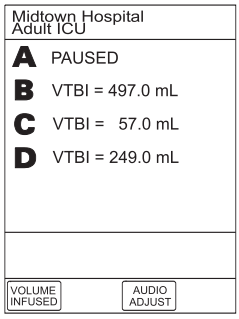
   Press **CHANNEL SELECT** key and then press **PAUSE** soft key (on Point-of-Care Unit).

   - **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.

2. To reinitiate infusion:

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

   OR



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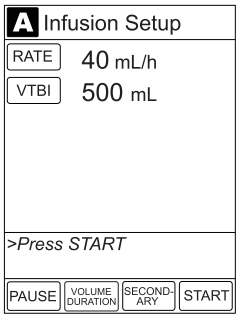
Pausing Infusion (Continued)

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



Restarting Infusion Following Infusion Complete

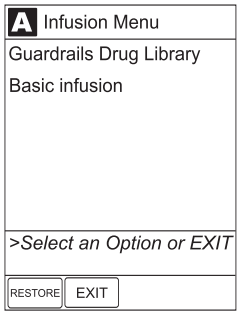
1. If solution container and/or administration set require replacement, reference “Preparing Infusion” section in “Getting Started” chapter to:
   a. Prepare solution container.
   b. Prime and load primary administration set.
2. Press **CHANNEL SELECT** key.

---

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”.



---

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.

Changing Rate or VTBI During Infusion

1. Press **CHANNEL SELECT** key.
2. Press either **RATE** or **VTBI** soft key.

3. To enter desired parameter, use Up/Down Arrows for rate titration or use numeric data entry keys.
4. Verify correct infusion parameter entry and press **START** soft key.

Stopping Infusion

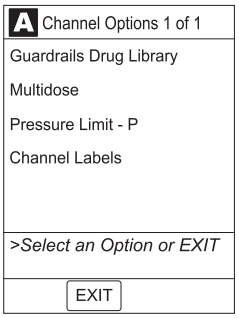
Press and hold **CHANNEL OFF** key until a beep is heard (approximately 1.5 seconds) and then release to initiate power down.

NOTES:

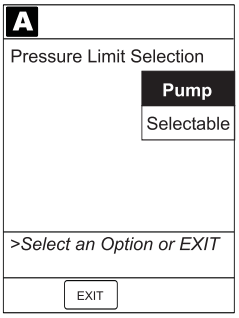
- If no other module is active, the system powers down when the **CHANNEL OFF** key is released.
- To interrupt the power down sequence, quickly press any one of the numeric keys on the Point-of-Care Unit.

Selecting Pressure Mode - Pump / Selectable

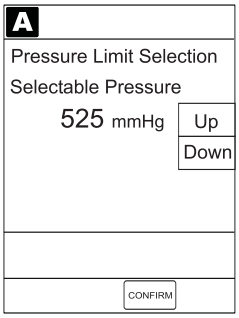
1. Press **CHANNEL SELECT** key.
2. Press **OPTIONS** key.
3. Press **Pressure Limit** soft key.



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



5. To select occlusion pressure limit, press either **Up** or **Down** soft key.
6. Verify correct occlusion pressure limit input and press **CONFIRM** soft key.
7. Press **START** soft key.



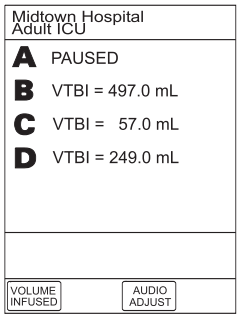
Viewing and Clearing Volume Infused

1. To view volume infused, press **VOLUME INFUSED** soft key.

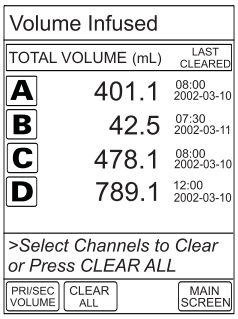
   - Total volume infused (primary + secondary), and time and date volume infused was last cleared, display for each module.

     NOTE: Date format is year-month-day.

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



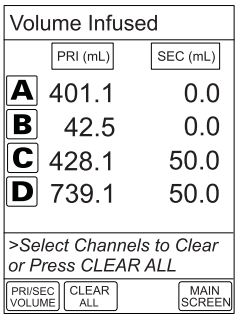
2. To view primary and secondary volume(s) infused, press **PRI/SEC VOLUME** soft key.

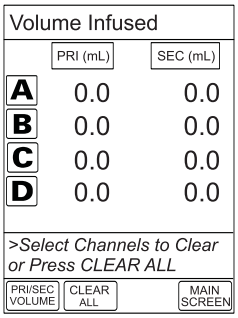


3. To clear volume infused:

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

   - If only selected 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.





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.

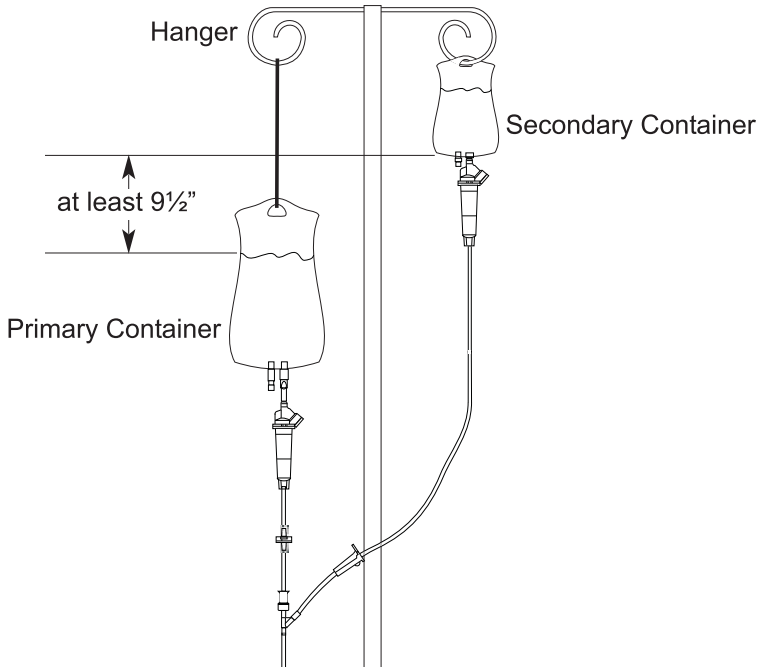
Qualified Service personnel can configure the system to allow from 0 (zero) to 9 restart attempts within a rolling 10 minute period. If the allowable number of restarts is exceeded or if the feature is set to zero, an "Occluded - Patient Side" alarm will occur when the system detects downstream pressure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



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.

WARNINGS

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

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

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

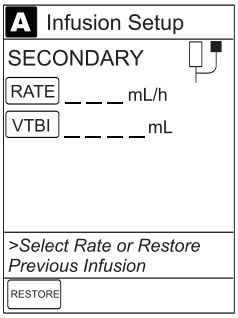
7. Set up and start primary infusion (reference “Primary Mode - Basic Infusion” section), using a check valve administration set.

---

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

OR

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



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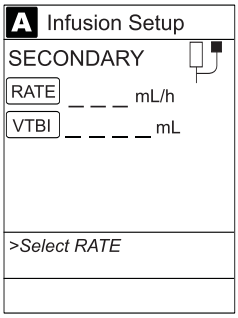
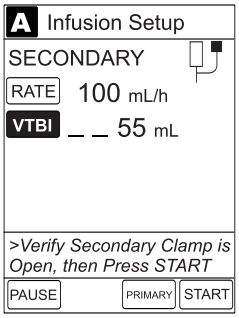
9. To enter secondary infusion rate, press **RATE** soft key and use numeric data entry keys.

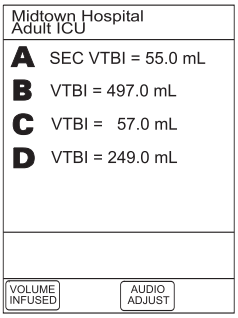


Secondary Mode (Continued)

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

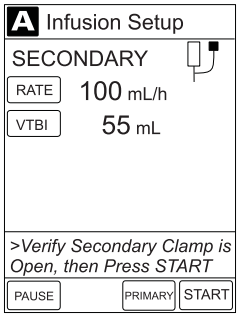


12. Verify correct infusion parameters and press **START** soft key.

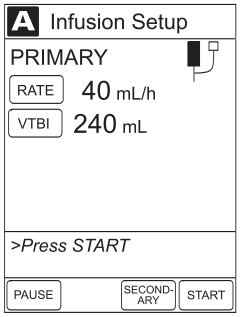


Changing Primary Infusion Parameter During Secondary Infusion

1. Press **CHANNEL SELECT** key.
2. Press **PRIMARY** soft key.

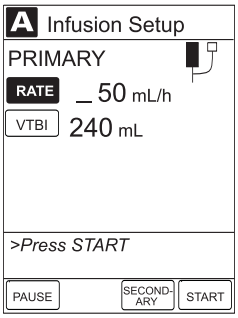


3. To change primary infusion parameter, press applicable soft key (**RATE** or **VTBI**), and use numeric data entry keys.

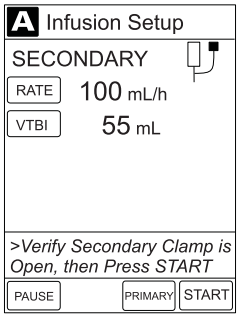


Changing Primary Infusion Parameter During Secondary Infusion (Continued)

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



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

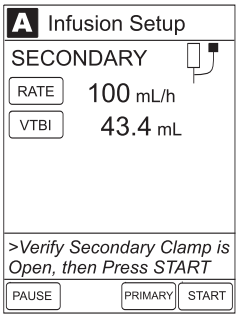


Stopping Secondary Infusion and Returning to Primary Infusion

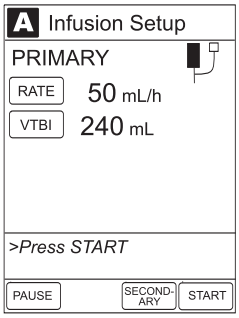
1. Press **CHANNEL SELECT** key.
2. Press **PRIMARY** soft key.
3. Close clamp on secondary administration set.

   OR

   Disconnect secondary administration set from upper injection port.

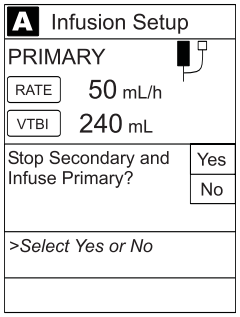


4. Press **START** soft key.



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.

Changing Primary Solution Container

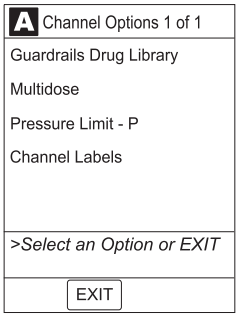
1. To stop infusion, press **PAUSE** key (on Pump Module).
2. Close roller clamp.
3. Remove empty solution container.
4. Insert administration set spike into prepared fluid container, following accepted hospital/facility procedure, and hang container 20 inches above Pump Module.
5. Press **CHANNEL SELECT** 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.

Channel Labels

Selecting Channel Label

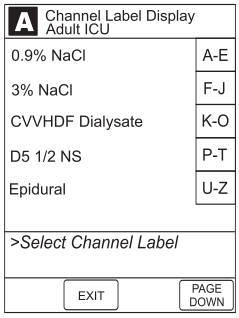
1. Press **CHANNEL SELECT** key.
2. Press **OPTIONS** key.
3. Press **Channel Labels** soft key.

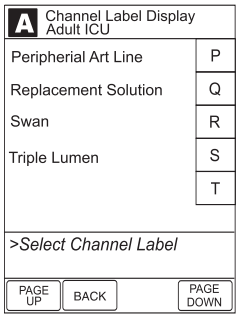


4. Press soft key for desired label.

> **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.





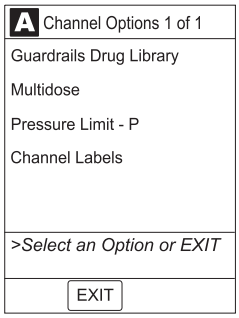
5. To continue infusion, press **START** soft key.

   OR

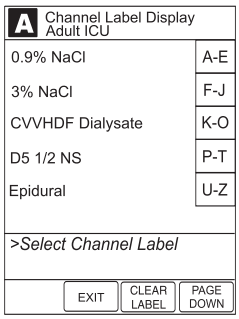
   Program infusion as previously described.

Removing Channel Label

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



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



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

   OR

   Program infusion as previously described.

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.

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.

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).

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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

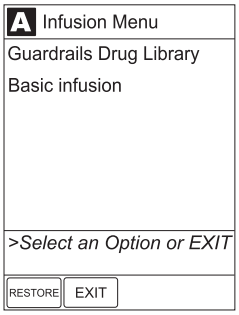
When using a drug listed in the Guardrails® Drug Library, the Guardrails® Software automatically calculates the drug parameters, based on:

- 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.

Using Guardrails® Drug Library (Continued)

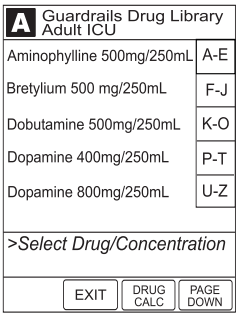
2. Perform steps in “Preparing Infusion” section, to prime and load primary administration set.
3. Press **CHANNEL SELECT** key.
4. Press **Guardrails Drug Library** soft key.



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

NOTES:

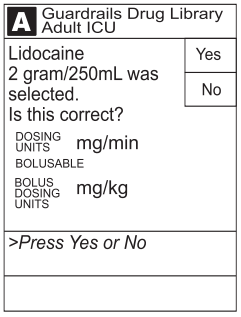
- To view additional drugs/concentrations, press a soft key next to a letter group to navigate through alphabet, and/or **PAGE UP** and **PAGE DOWN** soft keys.
- The facility may choose to to prepopulate standard drug concentrations, or leave an open entry (_ _ / _ _ mL) and allow the clinician to enter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



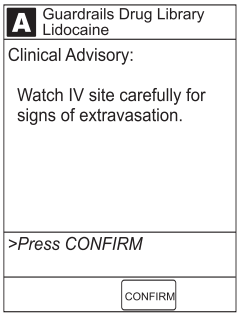
6. To continue programming, press **Yes** soft key.
   - Bolus dose units appear if Bolus Dose is enabled.

   OR

   To change selection, press **No** soft key.



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



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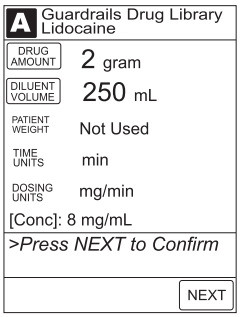
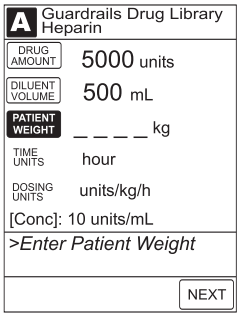
Using Guardrails® Drug Library (Continued)

- 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).

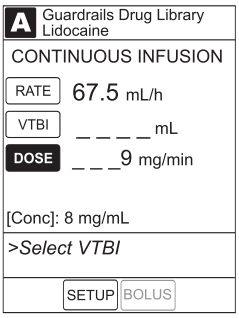




> **NOTE:** Once a patient weight is entered, for any module, it is automatically entered for any subsequent weight-based calculation.

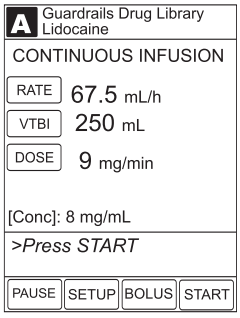
7. Verify parameters are correct and press **NEXT** soft key to confirm.

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).



Using Guardrails® Drug Library (Continued)

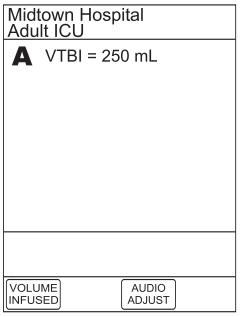
9. To enter volume to be infused, press **VTBI** soft key and use numeric data entry keys.



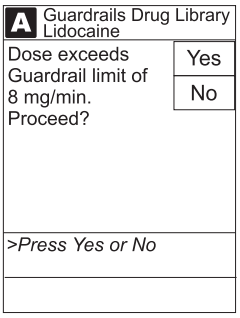
NOTES:

- 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.

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

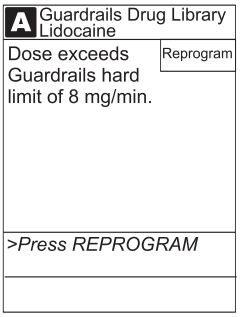


NOTE: If the programmed continuous dose infusion is outside the Guardrails® Soft Limit for that care area, a prompt appears before programming can continue. If the **Yes** soft key is pressed, programming continues; if the **No** soft key is pressed, the infusion needs to be reprogrammed.



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.

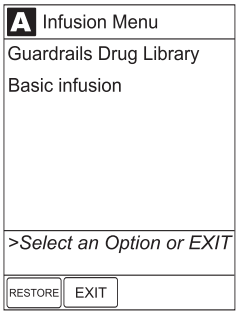


Using Non-Library Drug

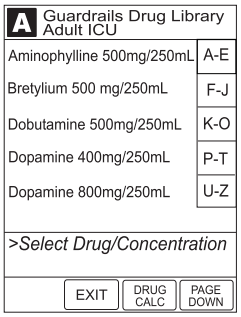
The following procedure should be used only when the drug to be infused is not listed in the Guardrails® Drug Library. When programming a drug not listed in the Guardrails® Drug Library, the drug calculation must be programmed using the **DRUG CALC** soft key within the Guardrails® Drug Library. There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

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

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

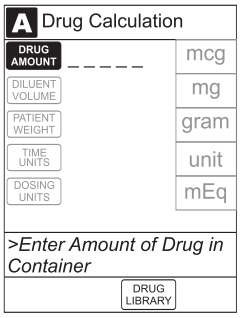


5. Press **DRUG CALC** soft key.

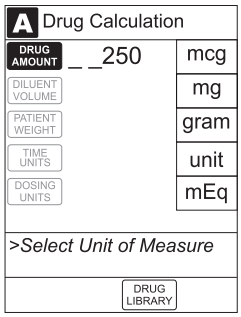


Using Non-Library Drug (Continued)

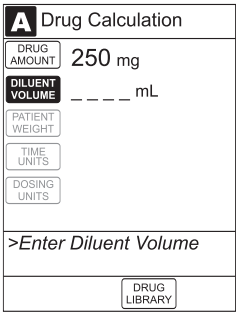
6. To enter **DRUG AMOUNT** in IV container, use numeric data entry keys.



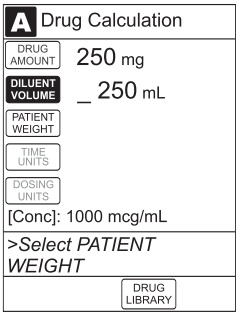
7. Press soft key for appropriate unit of measure for drug amount.



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



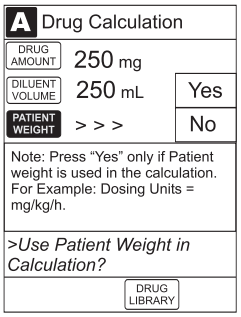
9. Press **PATIENT WEIGHT** soft key.



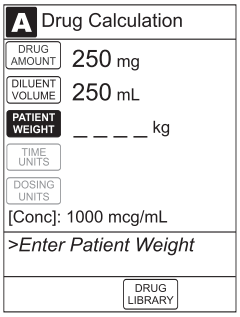
Using Non-Library Drug (Continued)

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

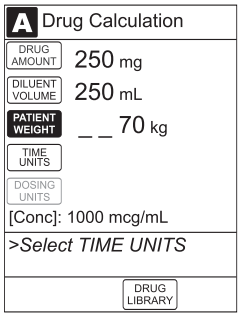
    NOTE: Do not enter a patient weight if weight is not used in the calculation.



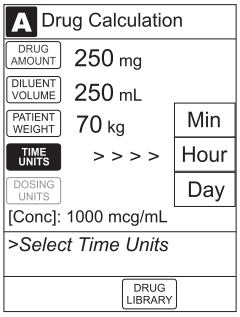
11. To enter patient weight (if required) in kilograms, use numeric data entry keys.



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

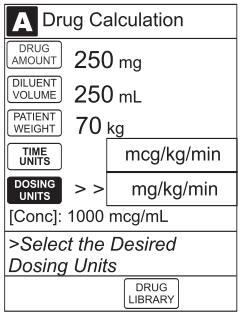


13. To select time base for drug calculation, press either **Min**, **Hour**, or **Day** soft key.

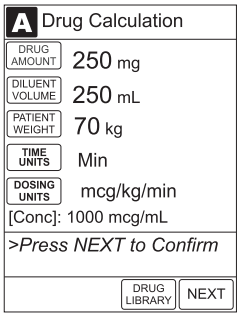


Using Non-Library Drug (Continued)

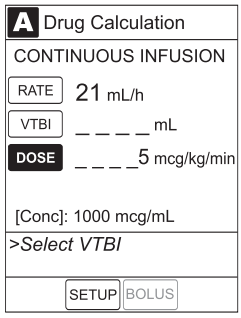
14. Press soft key next to desired **DOSING UNITS**.



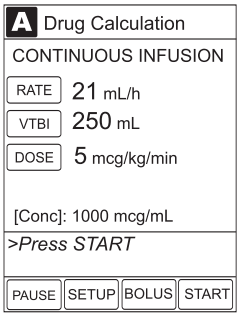
15. Verify correct drug calculation infusion parameters and press **NEXT** soft key.



16. To make a rate or dose entry, press applicable soft key, **RATE** or **DOSE**, and use numeric data entry keys (other value is calculated and displayed).



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



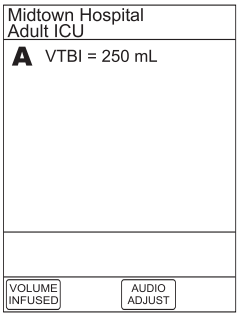
NOTES:

- At rates less than 10 mL/h, the rate is displayed to 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.

Setting Up Drug Calculation (Continued)

Using Non-Library Drug (Continued)

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



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.

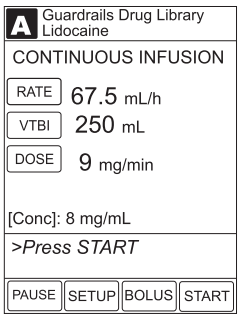
NOTES:

- 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. ➤



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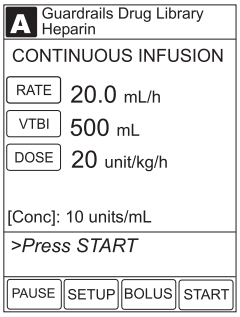
Using Guardrails® Drug Library Calculation (Continued)

Weight-based example. ➤



- **DOSE** is highlighted.

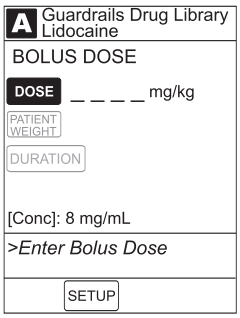
NOTES:

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

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.



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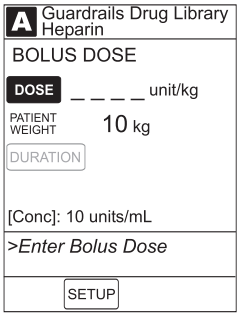
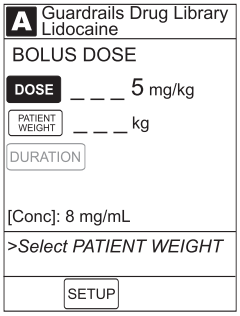
Using Guardrails® Drug Library Calculation (Continued)

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

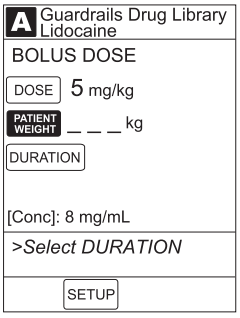


- If bolus dose is not weight-based, **Not Used** displays in **PATIENT WEIGHT** field.

4. To enter or change patient weight (if used), use applicable following procedure, depending on whether or not continuous dose is weight-based.
   - When continuous dose is <u>not weight-based</u>:
     a. Press **PATIENT WEIGHT** soft key.



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



-- OR --

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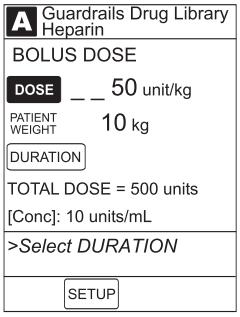
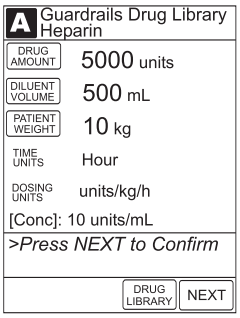
Using Guardrails® Drug Library Calculation (Continued)

- When continuous dose is weight-based:

a. Press **SETUP** soft key.

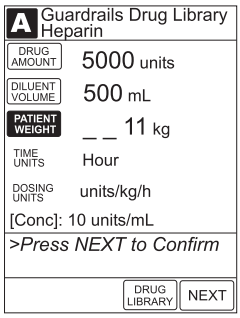


b. Press **PATIENT WEIGHT** soft key.

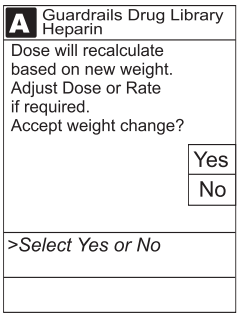


c. To change patient weight, use numeric data entry keys.

d. Press **NEXT** soft key.



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



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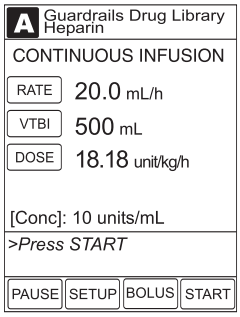
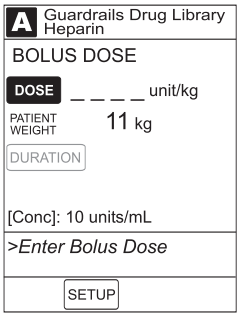
Using Guardrails® Drug Library Calculation (Continued)

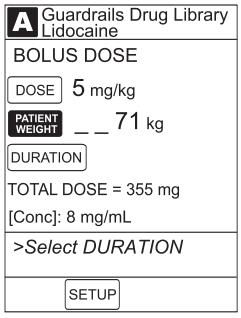
e. Press **BOLUS** soft key.



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



5. Press **DURATION** soft key.

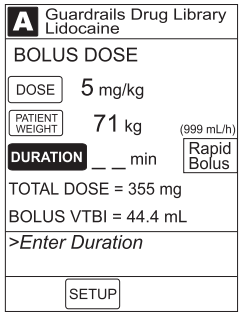


6. To enter bolus duration, use numeric data entry keys.

   OR

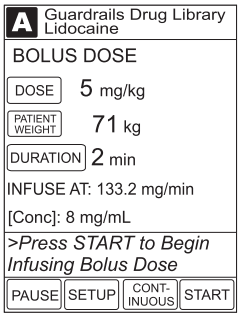
   To deliver bolus dose at maximum safe rate possible for selected drug and setup, and automatically calculate bolus duration, press **Rapid Bolus** soft key.

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



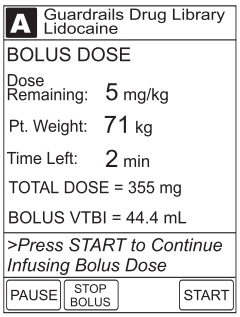
Using Guardrails® Drug Library Calculation (Continued)

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



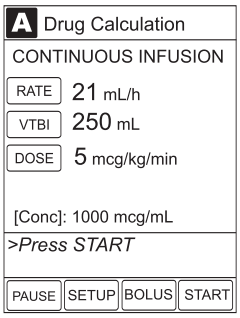
> **NOTE:** If a continuous dose outside of the Guardrails® Soft Limits has been entered and verified as correct, the Message Display also shows either "LLL" for a low dose or "↑↑↑" for a high dose.

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



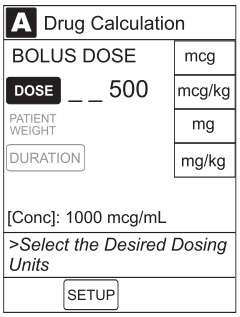
Using Non-Library Drug Calculation

1. Set up Drug Calculation as described in "Setting Up Drug Calculation", "Using Non-Library Drug" section, but do not start infusion.
2. Press **BOLUS** soft key.
   - **DOSE** is highlighted.



Using Non-Library Drug Calculation (Continued)

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

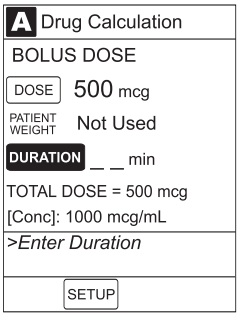


> **NOTE:** After a bolus dose and weight (if used) are entered, bolus VTBI and concentration [conc] alternate in the Main Display.

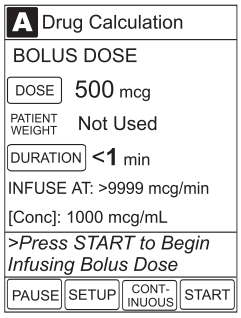
4. Press soft key for appropriate unit of measure for dose.

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

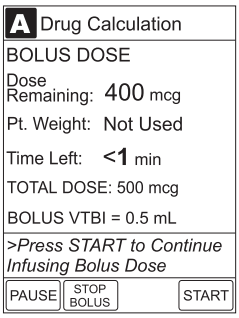
5. To enter bolus duration, use numeric data entry keys.
   - **TOTAL DOSE** alternates with **INFUSE AT** rate.



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



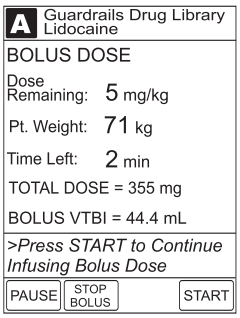
> **NOTE:** To see details during the bolus infusion, press the **CHANNEL SELECT** key.



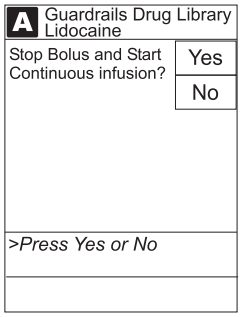
Stopping Bolus Dose

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

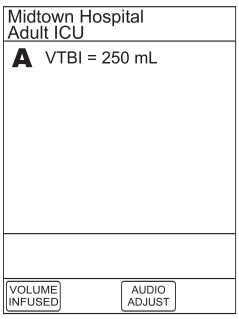
1. Press **CHANNEL SELECT** key.
2. Press **STOP BOLUS** soft key.



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



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



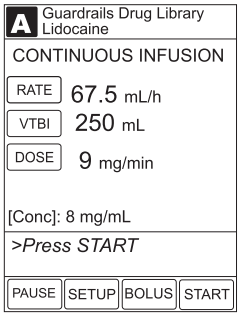
Restoring Bolus Dose

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

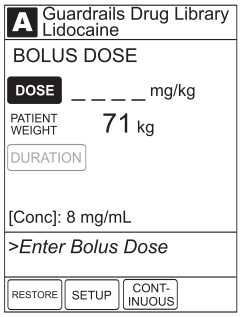
> **NOTE:** The display examples in this section represent restoring a bolus dose which was programmed using the Guardrails® Drug Library. Even where the displays are different when restoring a bolus dose which was programmed using a non-library drug, the procedure is the same.

Bolus Dose Completed - Module Not Turned Off

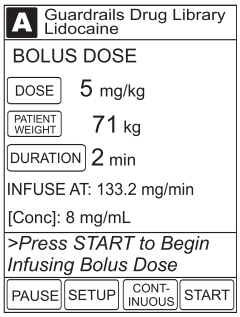
1. Press **CHANNEL SELECT** key.
2. Verify infusion parameters and press **BOLUS** soft key.



3. Press **RESTORE** soft key.

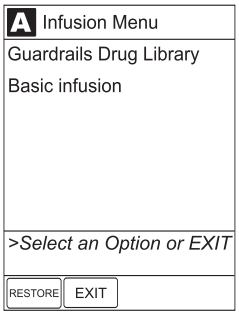


4. Verify dosing parameters and press **START** soft key.

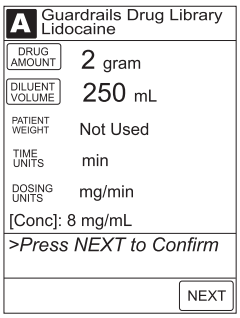


Bolus Dose Completed - Module Turned Off

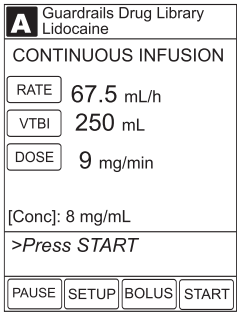
1. Press **CHANNEL SELECT** key.
2. Press **RESTORE** soft key.



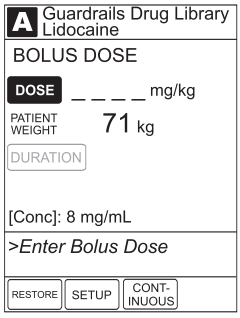
3. Verify parameters and press **NEXT** soft key.



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

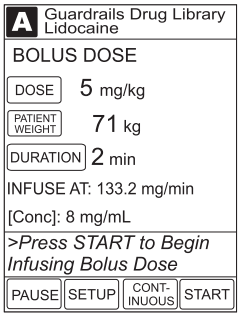


5. Press **RESTORE** soft key.



Bolus Dose Completed - Module Turned Off (Continued)

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



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

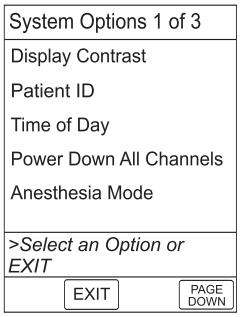
When the Medley™ System is set up for use in Anesthesia Mode, it is important to select the profile that corresponds with the care area the patient will be taken to when the Anesthesia Mode is discontinued. This ensures that the Medley™ System will be in the correct profile following the use of the Anesthesia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

Anesthesia Mode (Continued)

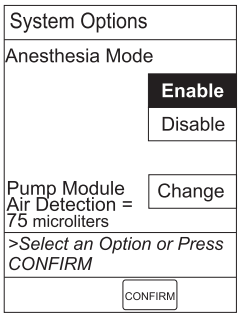
- Callback audio for paused modules is permanently silenced.
- Review of drug calculation setup page is omitted when restoring a stopped drug calculation.

Enabling Anesthesia Mode

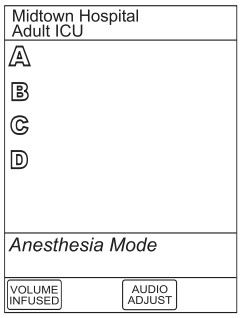
1. From Main Display, press **OPTIONS** key.
2. Press **Anesthesia Mode** soft key.



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



5. Press **Channel Select** key.
6. Program Anesthesia Mode infusion using same procedure as for any other continuous infusion.



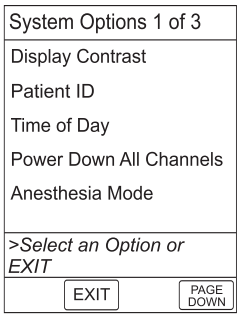
Disabling Anesthesia Mode

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

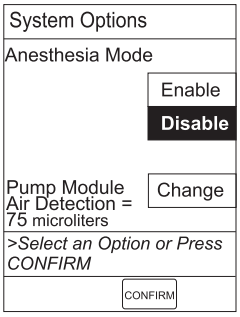
- System Options menu.
- Disconnecting system from AC power.
- Connecting system to AC power.

From System Options Menu

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



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

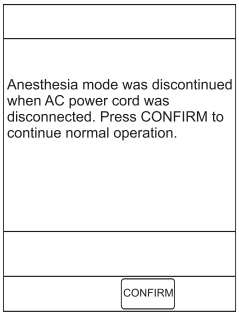


Disconnecting System from AC Power While in Anesthesia Mode

1. Disconnect system from AC.
   - Anesthesia Mode is automatically disabled.
   - All currently running infusions continue.
   - A prompt appears as an alert that Anesthesia Mode has been discontinued.

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

2. Press **CONFIRM** soft key.

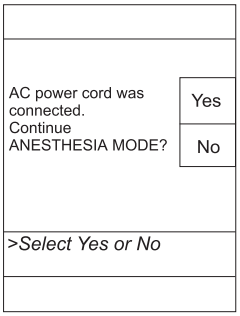


Connecting System to AC Power While in Anesthesia Mode

1. Connect system to AC power.
2. To continue using Anesthesia Mode, press **Yes** soft key.

   OR

   To discontinue Anesthesia Mode, press **No** soft key.



Delay Options

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

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

Delaying Infusion

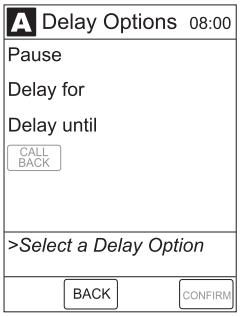
The delay period for an infusion can be programmed as a specific number of minutes or a time of day, as described in the following sections. An infusion delay can be programmed prior to or after an infusion is initiated.

Specifying by Minutes

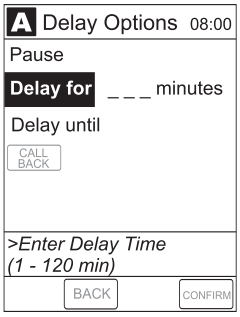
The **Delay for** option is used to program an infusion delay for a minimum of 1 minute and up to 120 minutes.

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

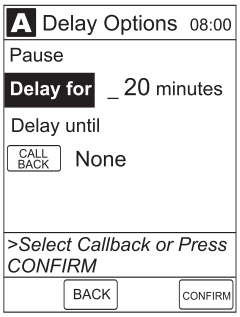
2. Press **Delay for** soft key.



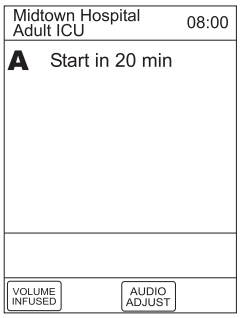
3. To enter number of minutes (up to 120) infusion is to be delayed for, use numeric data entry keys.



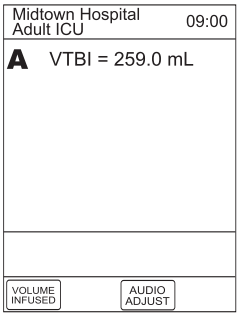
4. Press **CONFIRM** soft key.



- Delay period counts down on Main Display.



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

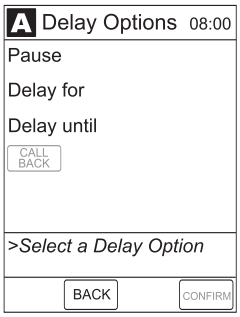


Specifying by Time of Day

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

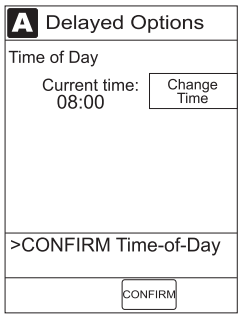
1. Press **DELAY OPTIONS** soft key.

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

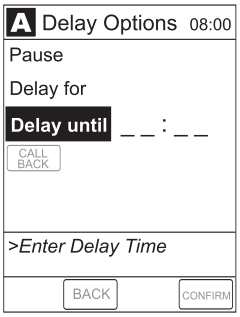


3. If **Current time** displayed is correct, press **CONFIRM** soft key; otherwise, press **Change Time** and enter correct time. (Reference "Setting Up Time of Day" procedure in Medley™ Point-of-Care Unit DFU.)

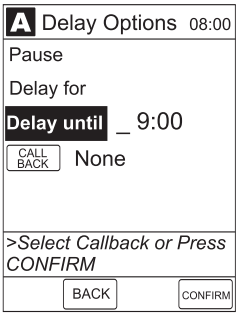
> **NOTE:** If the current time has been previously confirmed, the **Time of Day** screen will not be displayed.



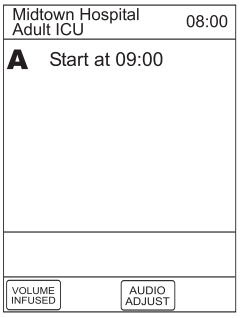
4. To enter time of day infusion is to be initiated (up to 23 hours 59 minutes), use numeric data entry keys.



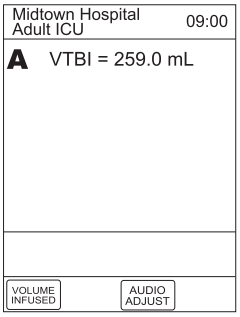
5. Press **CONFIRM** soft key.



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



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



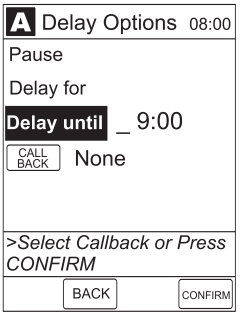
Scheduling a Callback

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

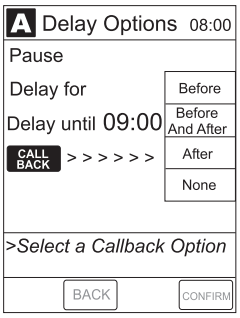
- **Before** - gives an alert when delay is completed and infusion needs to be initiated.
- **After** - gives an alert when delayed infusion has completed.
- **Before** and **After** - gives an alert when delay is completed and infusion needs to be initiated and when delayed infusion has completed.

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

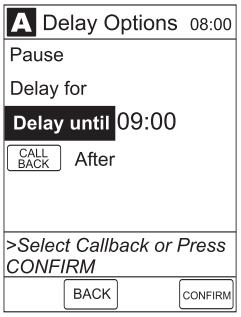
1. Prior to pressing **CONFIRM** soft key to initiate delay during **Delay for** or **Delay until** programming process, press **CALL BACK** soft key.



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



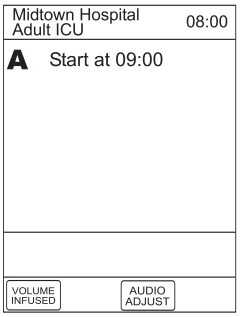
3. To initiate delay, press **CONFIRM** soft key.



-- Continued on Next Page --

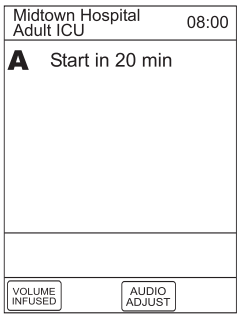
Scheduling a Callback (Continued)

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



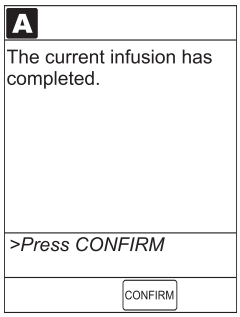
OR

- 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.

Scheduling a Callback (Continued)

4. To respond to a callback:
   - **Before** callback

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

     OR

     Press **RESTART** key.
   - **After** callback

     Press **CONFIRM** soft key.
   - **Before and After** callback

     Respond as indicated above for both **Before** and **After**.

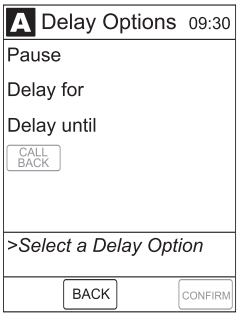
Pausing Infusion

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

2. Press **Pause** soft key.

NOTES:

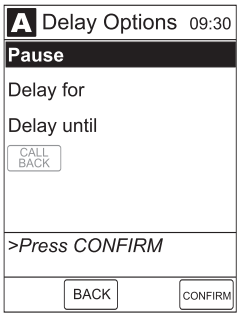
- Using the **Pause** function in the Delay Options screen is the same as pressing the **PAUSE** key on the Pump Module.
- The time displayed in the upper right corner of the screen is the time of day in a 24-hour clock format (military time).



Delay Options (Continued)

Pausing Infusion (Continued)

3. 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.



4. 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.

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.

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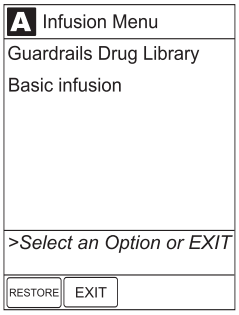
4. Press **Basic Infusion** soft key.
   - **Infusion Setup** screen appears.



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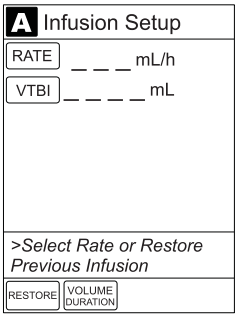
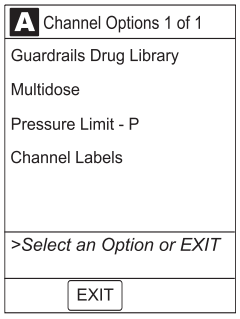
5. Press **OPTIONS** key.



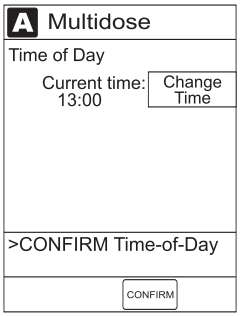
Programming with Volume / Duration Enabled (Continued)

6. Press **Multidose** soft key.

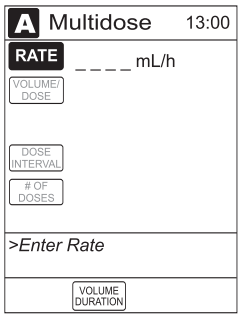


7. If **Current time** displayed is correct, press **CONFIRM** soft key; otherwise, press **Change Time** and enter correct time. (Reference "Setting Up Time of Day" procedure in Medley™ Point-of-Care Unit DFU.)

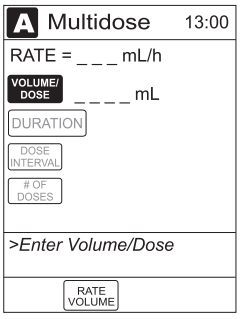
> **NOTE:** If the current time has been previously confirmed, the **Time of Day** screen will not be displayed.



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



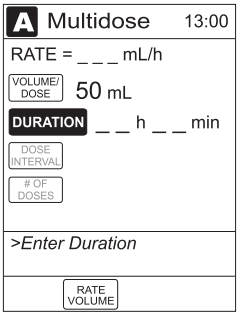
9. To enter volume to be infused for each dose, use numeric data entry keys.



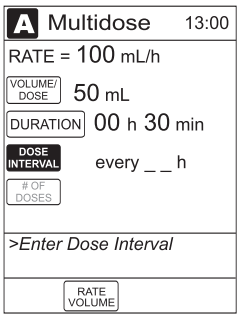
Programming with Volume / Duration Enabled (Continued)

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**.

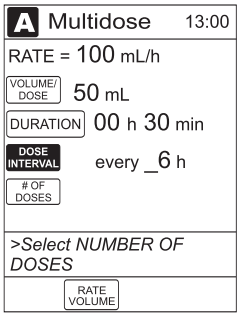


11. To enter time interval (1 to 24 hours) between doses, press **DOSE INTERVAL** soft key and use numeric data entry keys.



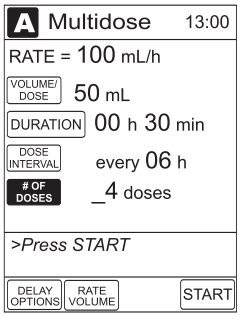
12. To enter number of doses, press **#OF DOSES** soft key and use numeric data entry keys.
    - If Delay Options is enabled, **DELAY OPTIONS** soft key appears.

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

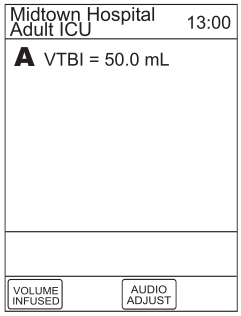


Programming with Volume / Duration Enabled (Continued)

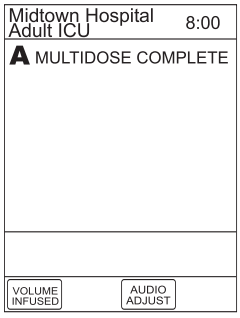
13. To begin multidose infusion, press **START** soft key.



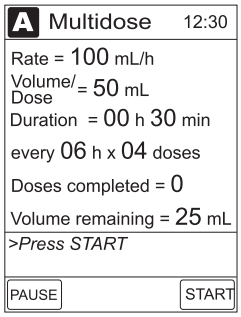
- Main Display shows remaining VTBI for that dose.



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



14. To see detail screen during or between infusions, press **CHANNEL SELECT** key.
    - During infusion, **Volume Remaining** displays.



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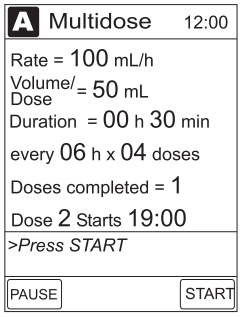
Programming with Volume / Duration Enabled (Continued)

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



Programming with Volume / Duration Disabled

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

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

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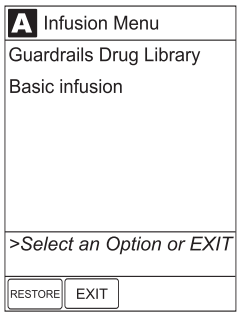
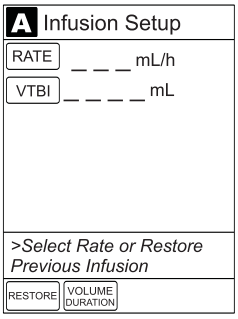
4. Press **Basic Infusion** soft key.
   - **Infusion Setup** screen appears.

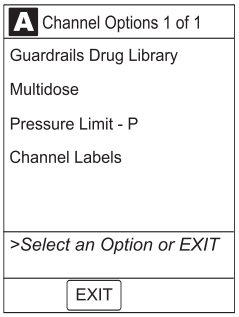


Programming with Volume / Duration Disabled (Continued)

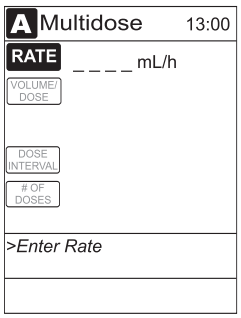
5. Press **OPTIONS** key.



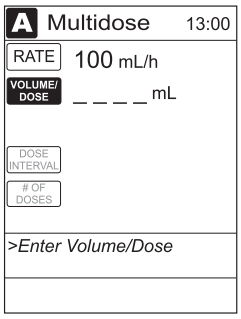
6. Press **Multidose** soft key.



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

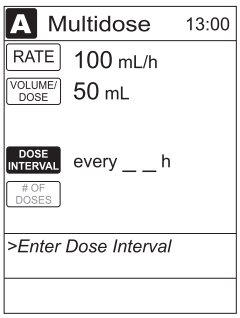


8. To enter volume to be infused for each dose, press **VOLUME/DOSE** soft key and use numeric data entry keys.



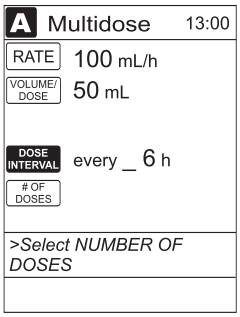
Programming with Volume / Duration Disabled (Continued)

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

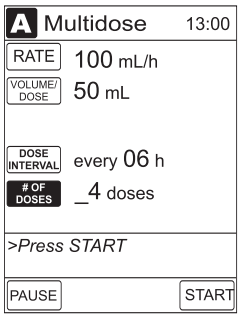


10. To enter number of doses, press **#OF DOSES** soft key and use numeric data entry keys.
    - If Delay Options is enabled, **DELAY OPTIONS** soft key appears.

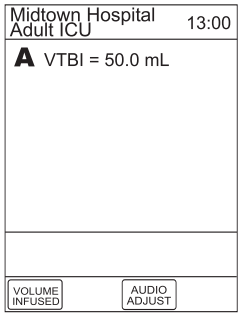
> **NOTE:** Reference "Delay Options" section to program an infusion delay. When delaying an infusion, a multidose cannot be delayed for more than 8 hours, and all doses in the multidose program must be completed within a 24-hour program.



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



- Main Display shows remaining VTBI for that dose.



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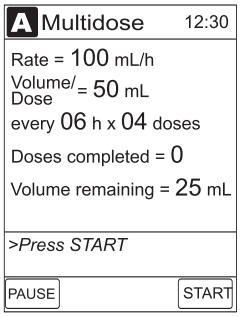
Multidose Mode (Continued)

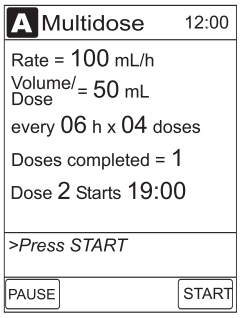
Programming with Volume / Duration Disabled (Continued)

- 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:

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

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

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

Environmental Conditions:

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

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

Electrical Classification: Class 1, Type CF Defibrillator Proof

Flow Rate Programming Increments:

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

Specifications (Continued)

Fluid Ingress Protection: IPX1, Drip Proof

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

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

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

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

Occlusion Alarm Thresholds:

Pump Mode: 525 mmHg at rates ≥30 mL/h
Varying level based on rate and patient back–pressure at rates <30 mL/h.

Selectable Mode: User selected from 50 to 525 mmHg in 25 mmHg increments.

Operating Principle: Positive displacement

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

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

WARNING

Variations of head height, back pressure or any combination of these may affect rate accuracy. Factors that can influence head height and back pressure are: Administration set configuration, IV solution viscosity and IV solution temperature. Back pressure may also be affected by type of catheter. 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:

	Pressure Limit (mmHg)	
Rate (mL/h)	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	Disabled	Enabled - Disabled
• Callback	None	None, Before, After, Before and After
Drug Calculation	Disabled	Enabled - Disabled
• Bolus Dose	Disabled	Enabled - Disabled
Multidose	Disabled	Enabled - Disabled
• Callback	None	None, Before, After, Before and After
Pressure Dynamic (Dynamic Pressure Display)	Disabled	Enabled - Disabled
Volume/Duration	Disabled	Enabled - Disabled

Pump Module Settings

Feature	Default Setting	Options
Accumulated Air	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	Pump	Pump, Selectable
• Lock Status	Unlocked	Locked, Unlocked
• Max Occlusion Pressure	525 mmHg	50 - 525 mmHg in 25 mmHg increments (adjustable only in Selectable Pressure Mode)
SEC to PRI Alert	Enabled	Enabled - Disabled
Secondary (Dual Rate Sequential Piggybacking)	Disabled	Enabled - Disabled

Cleaning

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

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

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

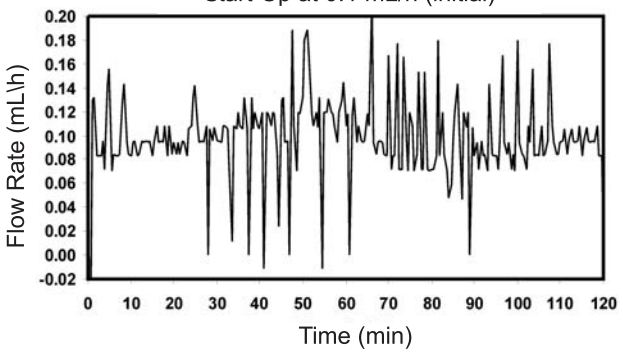
With a negative head height of -0.5 meters, the Medley™ Pump Module typically exhibits a long–term accuracy offset of approximately –3.1% from mean values.

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

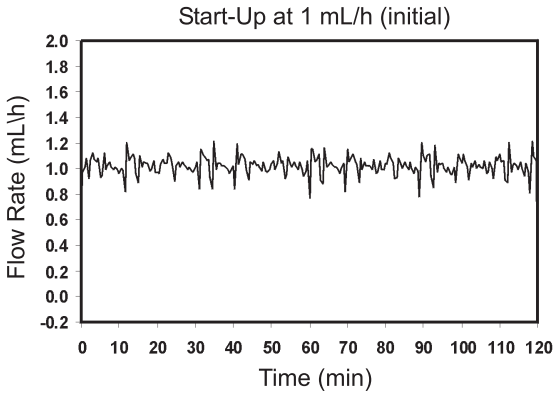
NOTE: Tests conducted in accordance with IEC/EN 60601–2–24, “Particular requirements for safety of infusion pumps and controllers” and AAMI ID26–1998 “Medical electrical equipment - Part 2: Particular requirements for the safety of infusion pumps and controllers”, using Medley™ System/Gemini Model 2210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

Trumpet and Start-Up Curves (Continued)

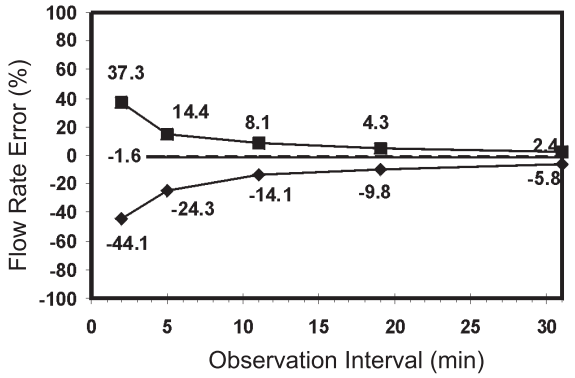
Start-Up at 0.1 mL/h (initial)



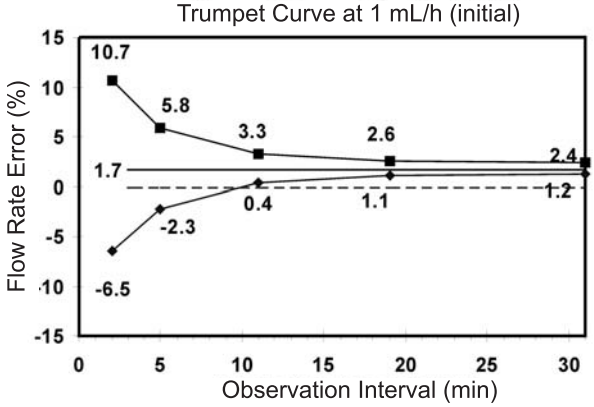
Start-Up at 1 mL/h (initial)



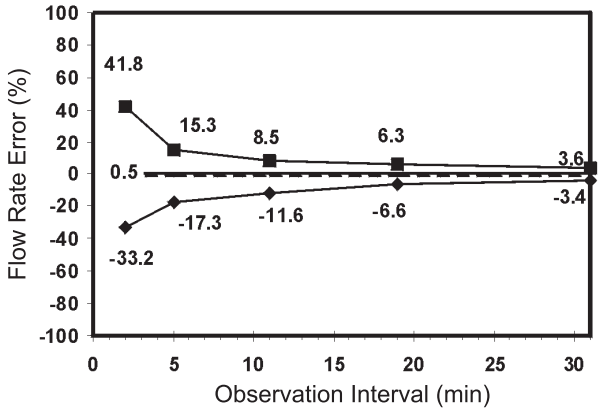
Trumpet Curve at 0.1 mL/h (initial)



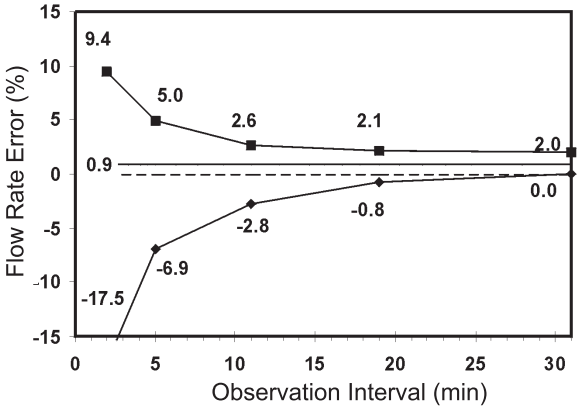
Trumpet Curve at 1 mL/h (initial)



Trumpet Curve at 0.1 mL/h (72 hrs)



Trumpet Curve at 1 mL/h (72 hrs)

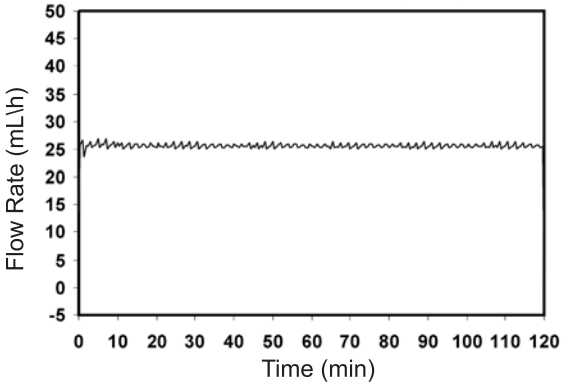


Legend:
- Maximum rate error
- Overall rate error
- Minimum rate error

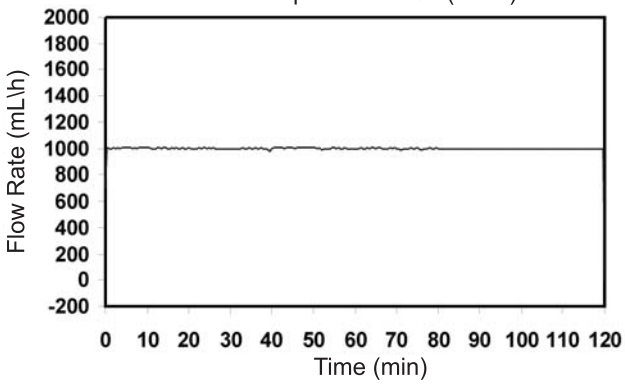
NOTE: The plot range has been increased to ±100%, to allow visualization of the graph.

Trumpet and Start-Up Curves (Continued)

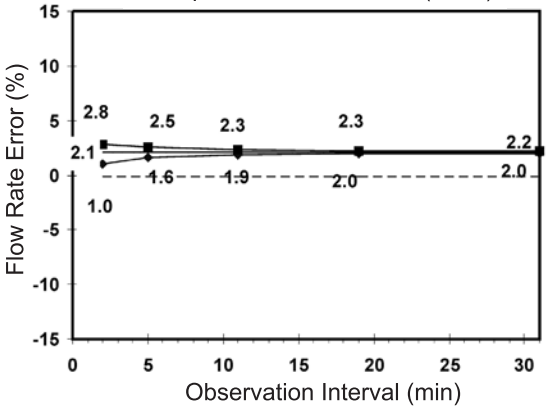
Start-Up at 25 mL/h (initial)



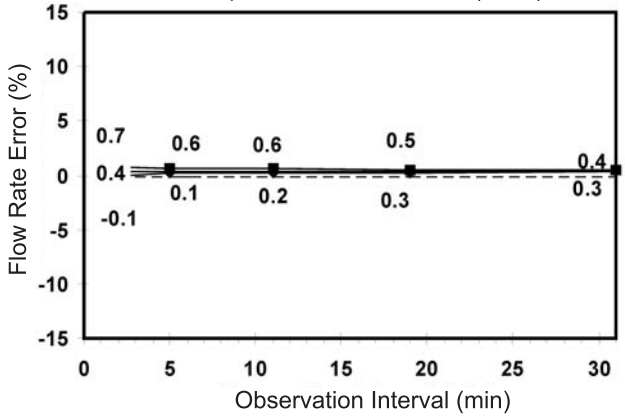
Start-Up at 999 mL/h (initial)



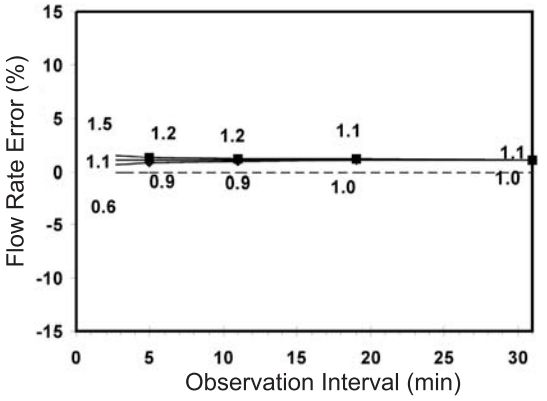
Trumpet Curve at 25 mL/h (initial)



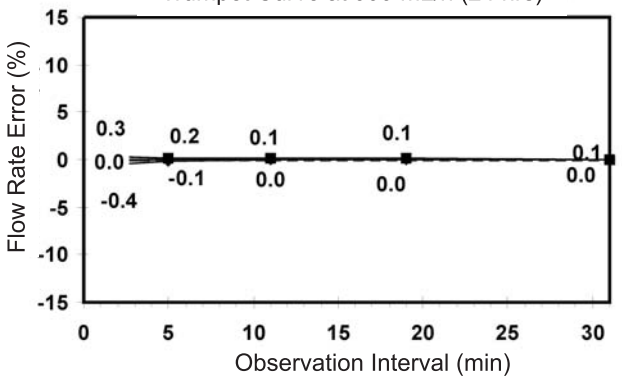
Trumpet Curve at 999 mL/h (initial)



Trumpet Curve at 25 mL/h (72 hrs)



Trumpet Curve at 999 mL/h (24 hrs)



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

APPENDIX

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ALARIS®
MEDICAL SYSTEMS

ALARIS Medical Systems, Inc.
10221 Wateridge Circle
San Diego, California 92121 U.S.A.

Mail:
P.O. Box 85335
San Diego, California 92186-5335 U.S.A.

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

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