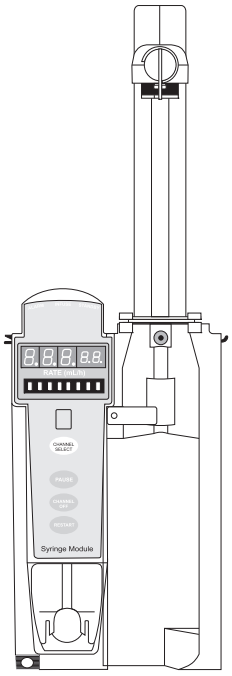
Directions for Use

Syringe Module, 8110 Series



ALARIS Medical Systems, Inc.

Medley™ Medication Safety System

SYRINGE MODULE
MODEL 8110

GENERAL CONTACT INFORMATION

Customer Advocacy - North America

Clinical and technical feedback.

Phone: (800) 854-7128, Ext. 7812
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Maintenance and service information support; troubleshooting.

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Customer Care - North America

Instrument return, service assistance, and order placement.

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About the Syringe Module

The Medley™ Syringe Module (Model 8110) 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™ Syringe Module uses standard, single-use, disposable syringes (with luer-lock connectors) and administration sets, designed for use on syringe pumps. For specific administration set instructions, reference the directions for use provided with the set. For set priming and loading instructions, reference the “Preparing Infusion” section in the “Getting Started” chapter of this document.

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.

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

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

About the Syringe Module (Continued)

Electromagnetic Compliance: When using the Syringe Module in combination with a Point-of-Care Unit which is interconnected to hospital/facility data communications equipment and/or nurse call systems (signal input and signal output ports), the external systems must be certified to applicable standards to ensure correct operation and electromagnetic compliance integrity.

Interconnected data communications systems must be certified to IEC 950 (data processing equipment) or IEC 60601–1 electromedical equipment. **Nurse call systems** must be certified to UL 1069 (hospital signaling and nurse call equipment) or comply with the requirements specified in IEC 60601–1.

EMC: Compliance with the electromagnetic compatibility (EMC) standard (IEC 60601-1-2) is a function of all interconnected equipment including cabling and, as such, it is the responsibility of the hospital/facility to ensure external equipment complies with the applicable EMC standards. Failure to verify that external equipment meets applicable EMC standards may result in degraded electromagnetic compatibility.

Compliance with Federal Aviation Regulations: The Medley™ Syringe 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™ Syringe Module.

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

WARNING

Read all instructions, for both the Syringe 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.

All Mode

When **ALL** is selected as the volume to be infused (VTBI), the entire contents of the syringe will be delivered.

Auto Pressure

When enabled and a pressure sensing disc is in use, the Auto Pressure option is displayed in the Pressure Limit screen. Auto Pressure automatically sets the alarm limit for a shorter time to alarm, as follows:

- If current pressure is 100 mmHg or less, system adds 30 mmHg to current pressure, to create a new alarm limit.
- If current pressure is greater than 100 mmHg, system adds 30% to current pressure, to create a new alarm limit.

Auto Pressure Limit Adjustment

When a bolus is delivered, the pressure alarm limits are temporarily raised to the maximum limit.

Auto Syringe Size Identification

The system automatically detects the syringe size and narrows down the syringe selection list.

Back Off

This feature is only available when the administration set in use has a pressure sensing disc. When enabled, the motor reverses plunger movement during an occlusion until the pressure returns to preocclusion levels, automatically reducing bolus flow.

Bolus Dose

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

Channel Labels

The Channel Labels feature is available when the Profiles feature is enabled. It provides a hospital-defined list of labels, displayed in the Message Display, and identifying the module with the solution being infused, the 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

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

Features and Definitions (Continued)

Drug Calculation

The Drug Calculation mode allows:

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

  OR

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

Dynamic Pressure Display

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

Event Logging

Event Logging records instrument operations.

Fast Start

When Fast Start is enabled and an administration set having a pressure sensing disc is used, the instrument runs at an increased rate when an infusion is first started, taking-up any slack in the drive mechanism.

Guardrails® Drug Library

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

Guardrails® Limit

A Guardrails® Limit is a programming limit or best-practice guideline determined by the hospital/facility and entered into the 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 the hospital/facility 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.

Multidose Mode

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

Features and Definitions (Continued)

Near End of Infusion (NEOI)

The NEOI option allows an alert to be configured to sound anywhere from 1 to 60 minutes before the infusion is complete. The alert will occur at the configured time or when 25% of the VTBI remains, whichever comes later.

Occlusion Pressure

A complete range of downstream occlusion detection options is provided.

- With pressure sensing disc: Downstream occlusion alarm threshold is selectable between 25 and 1000 mmHg, in 1 mmHg increments.
- Without pressure sensing disc: Downstream occlusion alarm threshold can be set to low, medium, or high.

Pressure Sensing Disc

When installed, the pressure sensing disc significantly improves the instrument's pressure sensing capabilities for a faster occlusion detection time, and makes the following features available:

Auto Pressure
Back-Off
Customizable Pressure Alarm Settings (see "Occlusion Pressure")
Fast Start
Pressure Tracking

Pressure Tracking

The dynamic current pressure display is only available when the pressure sensing disc is inserted.

Priming

The Priming option allows a limited volume of fluid to be delivered in order to prime the administration set prior to being connected to a patient or after changing a syringe. When priming, a single continuous press of the **PRIME** soft key delivers up to 2 mL of priming fluid.

Rapid Bolus

Fastest rate at which bolus dose should be delivered, as defined by facility's clinical best-practice guidelines.

Restore

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

Selectable KVO

The Selectable KVO option allows some infusions to automatically switch into KVO mode upon completion. The KVO option setting cannot be changed after the instrument is powered on and a profile selected.

Syringe Empty

The instrument gives an alert and stops when an empty syringe is detected.

Syringe Volume Detection

The system automatically detects the fluid volume in a syringe when it is inserted.

Volume/Duration

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

Symbols

Canadian and U.S. Certification Mark: Products bearing this mark have been tested and certified in accordance with applicable U.S. and Canadian electrical safety and performance standards (CSA C22.2 No. 601.1, UL 2601-1 and IEC 60601–2–24).

Electrical Shock Protection Rating: Type CF, Defibrillation-proof

IPX1

Protection against fluid ingress: Drip Proof

Attention: Refer to accompanying documentation.

IUI Connector: Inter-Unit Interface connector used to establish power and communications between the Point-of-Care Unit and attached modules.

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

Consult operating instructions.

℞ Only

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

Single-Use

Single-Use. Do not re-use.

Product contains micron filter, where XX represents filter size.

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

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

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

General

WARNINGS

- The Medley™ Syringe 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.
- **Each time the Medley™ System is turned on**, verify and/or set the monitoring mode, resistance alert, and/or pressure alarm limit. If the monitoring mode, resistance alert, and/or pressure alarm limit are not verified, the instrument may not operate within the desired occlusion detection parameter(s).

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 syringe, administration set, and Syringe 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 standard, single-use, disposable syringes (with luer-lock connectors) and administration sets, designed for use on syringe pumps. The use of any other **syringe or administration set** may cause improper instrument operation, resulting in an inaccurate fluid delivery or pressure sensing, or other potential hazards. For a list of compatible syringes, reference the “Compatible Syringes” section in the “Maintenance” chapter. For a list of compatible sets, reference the Set Compatibility Card (provided separately).
- **Before loading or unloading the syringe**, always turn off fluid flow to the patient, using the tubing clamp or stopcock. Uncontrolled fluid flow can occur when the administration set is not clamped or turned off, and may cause serious injury or death.
- When the **pressure sensing disc is not being used** and an occlusion occurs, there is a risk of infusing pressurized buildup of infusates upon correction of the occlusion. To avoid an inadvertent bolus, relieve the pressure before restarting the infusion.
- **When priming**:
  - Ensure patient is not connected.
  - Ensure air is expelled from line prior to beginning infusion (unexpelled air in line could have serious consequences).

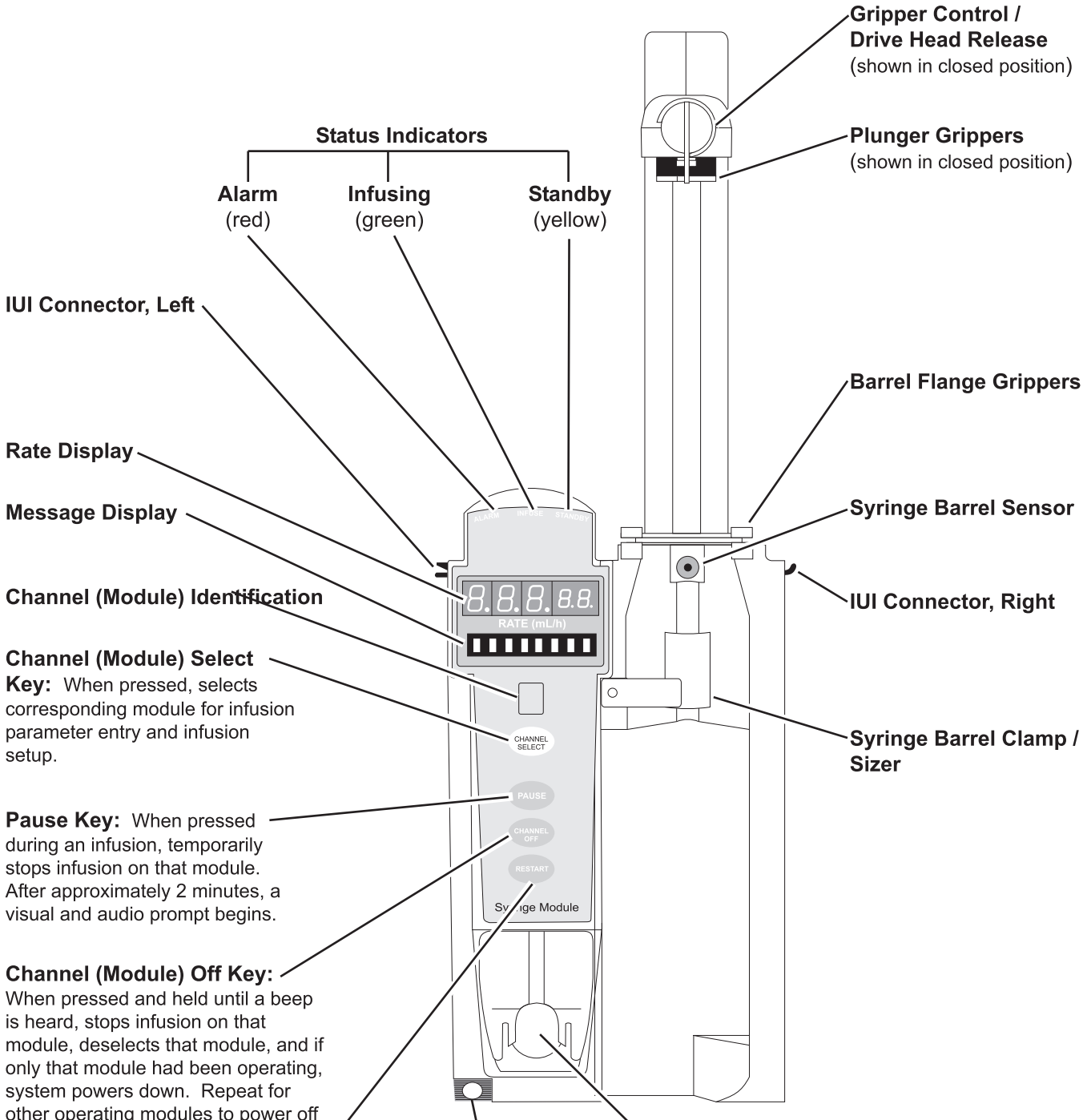
  Failure to prime correctly can delay infusion delivery and cause the total volume to be infused to read higher than the actual total delivered to the patient.
- Ensure the syringe manufacturer and syringe size displayed matches **syringe manufacturer and syringe size installed** in the Medley™ Syringe Module. Mismatches may cause an under-infusion or over-infusion to the patient that could result in serious injury and/or death. For a list of compatible syringes, reference the “Compatible Syringes” section in the “Maintenance” chapter.
- **Installing a pressure sensing disc** after an infusion has started can result in a bolus to the patient.
- **Discard if** packaging is not intact or protector caps are unattached.

Administration Sets (Continued)

CAUTIONS

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

Operating Features, Controls and Indicators



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 into 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

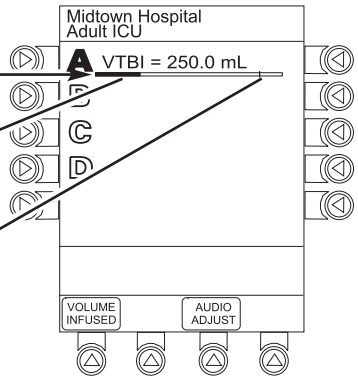
Reference the Medley™ Point-of-Care Unit DFU.

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 Syringe Module's range is 0 to 1000 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™ Syringe Module uses standard, single-use, disposable syringes (with luer-lock connectors) and administration sets, designed for use on syringe pumps.

- For specific administration set instructions, reference the directions for use provided with the set.
- For a list of compatible syringes, reference “Compatible Syringes” section in “Maintenance” chapter.
- For a list of compatible administration sets, refer to Set Compatibility Card (provided separately).
- Syringe Module 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 the United States).
- Discard administration set per facility protocol.
- For IV push medication (put instrument on hold), clamp tubing above the port.
- Flush port(s) per facility protocol.
- Use aseptic techniques when handling sets and syringes.

Preparing Syringe and Administration Set

1. Prepare syringe (reference “Compatible Syringes” section in “Maintenance” chapter) in accordance with manufacturer’s directions for use.
2. Prepare administration set (refer to Set Compatibility Card, provided separately) in accordance with manufacturer’s directions for use.
3. Attach upper fitting of administration set to syringe tip.

WARNING

Use only standard, single-use, disposable syringes (with luer-lock connectors) and administration sets, designed for use on syringe pumps. The use of any other syringe or administration set may cause improper instrument operation, resulting in inaccurate fluid delivery or pressure sensing, or other potential hazards. For a list of compatible syringes, reference the “Compatible Syringes” section in the “Maintenance” chapter. For a list of compatible administration sets, reference the Set Compatibility Card (provided separately).

Loading Syringe and Administration Set

WARNINGS

- Before loading the syringe, check it for damage or defects.
- Ensure syringe barrel, flange, and plunger are installed and secured correctly. Failure to install syringe correctly can result in uncontrolled fluid flow to the patient, and may cause serious injury or death.
- Before loading or unloading the syringe, always turn off fluid flow to the patient, using the tubing clamp or stopcock. Uncontrolled fluid flow can occur when the administration set is not clamped or turned off, and may cause serious injury or death.

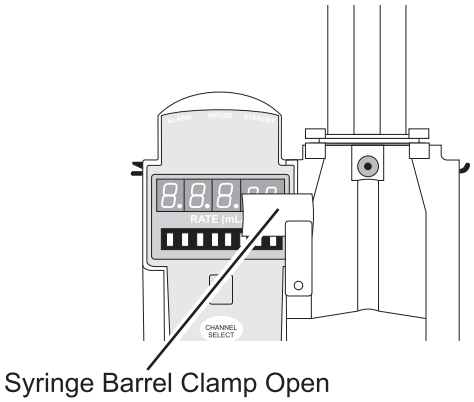
CAUTION

When initially loading the syringe, allow for the volume of fluid contained in the administration set and retained in the syringe at the end of an infusion, as this “dead space” will not be infused.

Preparing Infusion (Continued)

Loading Syringe and Administration Set (Continued)

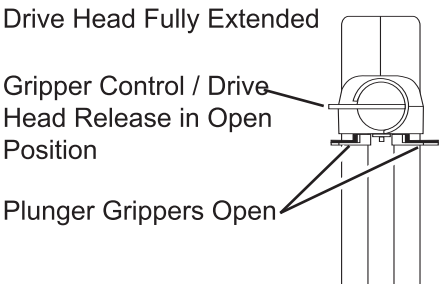
1. Open syringe barrel clamp.
   a. Pull syringe barrel clamp out and hold.
   b. Rotate clamp to left (clockwise or counter clockwise) until it clears syringe chamber.
   c. Gently release clamp.



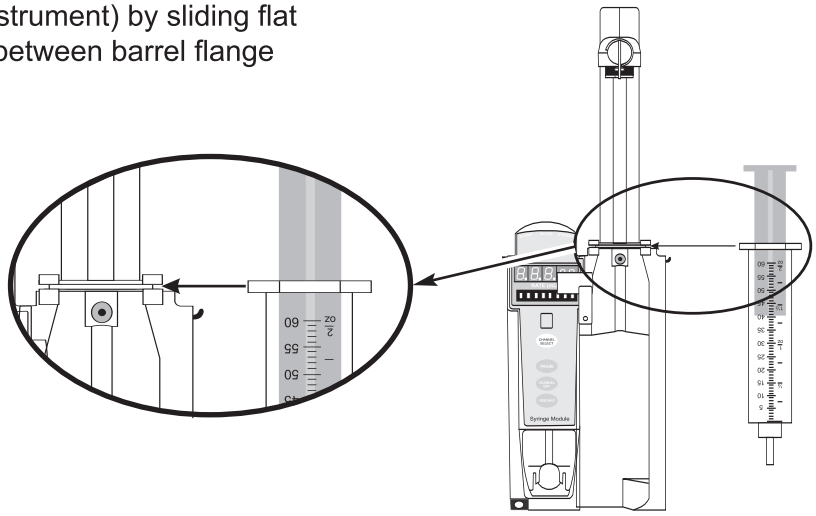
2. Raise drive head to its fully extended position.
   a. Twist gripper control clockwise and hold in position.

   NOTE: The gripper control is spring loaded. When twisted to the open position and then released, it (and the plunger grippers) will return to the closed position.

   b. While holding gripper control in open position, raise drive head to full extension.
   c. Gently release gripper control.

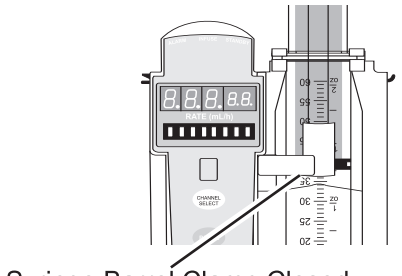


3. Insert syringe (from front of instrument) by sliding flat edge of syringe barrel flange between barrel flange grippers.



Loading Syringe and Administration Set (Continued)

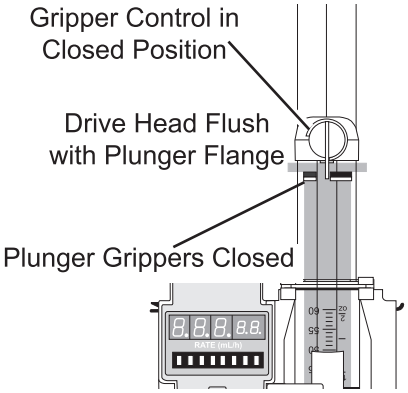
4. Lock syringe in place.
   a. Pull syringe barrel clamp out and hold.
   b. Rotate clamp to right (clockwise or counter clockwise) until it lines up with syringe.
   c. Gently release clamp against syringe.



5. Lower drive head and lock plunger in place with plunger grippers.
   a. Twist gripper control clockwise and hold in position.

   > **NOTE:** The gripper control is spring loaded. When twisted to the open position and then released, it (and the plunger grippers) will return to the closed position.

   b. While holding gripper control in open position, gently lower drive head until it makes contact with plunger flange.
   c. Gently release gripper control.
   d. Ensure plunger grippers lock and hold plunger in place.



CAUTIONS

- To avoid an occlusion when loading a smaller size syringe, use extra care to close off administration set tubing and gently lower drive head against syringe plunger.
- For smaller syringes (such as; 1, 3, or 5 cc), stabilize the syringe plunger with thumb and index finger while carefully lowering the drive head. Ensure the syringe plunger head makes contact with the small black sensor, located on the bottom of the drive head (between the plunger grippers).

Loading Syringe and Administration Set (Continued)

6. Insert pressure sensing disc (if used), as follows:

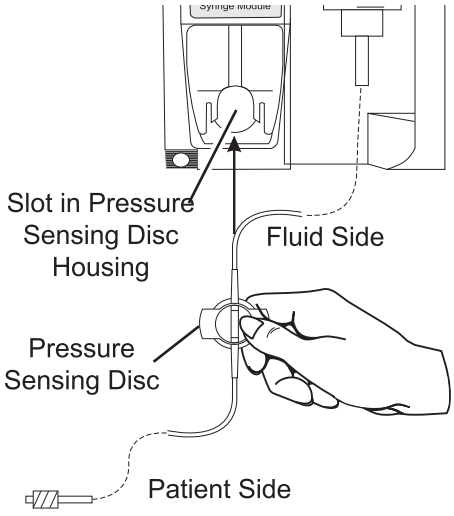
> **NOTE:** The following are special Syringe Module features available only with extension sets fitted with a pressure sensing disc: (Reference the "Features and Definitions" section in the "Introduction" chapter for definitions.)
>
> Auto Pressure
>
> Back Off (Upon Occlusion)
>
> Customizable Pressure Alarm Settings (see "Occlusion Pressure" feature definition)
>
> Dynamic Pressure Display (see "Pressure Tracking" feature definition)
>
> Fast Start

WARNING

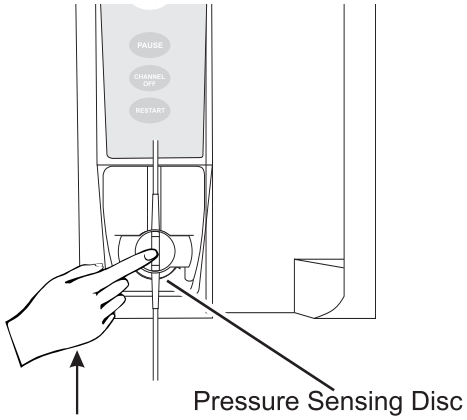
When the pressure sensing disc is not being used and an occlusion occurs, there is a risk of infusing pressurized buildup of infusates upon correction of the occlusion. To avoid an inadvertent bolus, relieve the pressure before restarting the infusion.

a. Orient pressure sensing disc, as follows:
   - fluid side up (patient side down)
   - cavity forward (membrane toward instrument)

b. Gently slide pressure sensing disc up into slot in pressure sensing disc housing.



c. Apply firm upward pressure on pressure sensing disc (not tubing) until disc snaps into place.



Selecting Syringe Type and Size

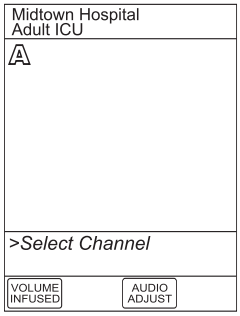
At the start of an infusion program, the system prompts to select and confirm the syringe type and size.

NOTE: The system automatically detects the syringe size, and lists syringe types and sizes that most closely match the installed syringe. If the syringe is not recognized, "Syringe not recognized" displays. Use a syringe that is recognized and accepted by the system.

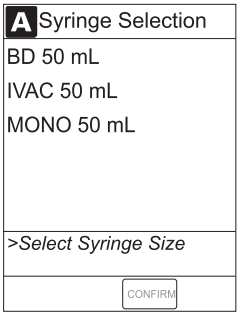
WARNING

Ensure the displayed syringe manufacturer and size correctly identifies the installed syringe. Mismatches may cause an under-infusion or over-infusion to the patient that could result in serious injury and/or death. For a list of compatible syringes, reference the "Compatible Syringes" section in the "Maintenance" chapter. If the installed syringe is displayed and selected, but is not recognized, servicing is required (reference "Service Information" section in "Maintenance" chapter).

1. Press **CHANNEL SELECT** key.

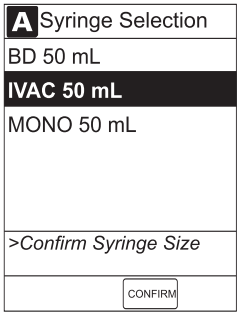


2. Press soft key next to installed syringe type and size.
   - Selection is highlighted.



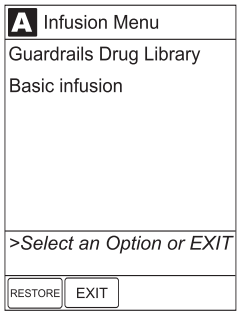
Selecting Syringe Type and Size (Continued)

3. To accept, press **CONFIRM** soft key.

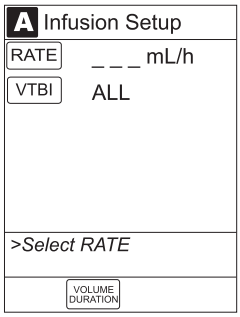


4. Press soft key next to applicable infusion type, **Basic Infusion** or **Guardrails Drug Library**.

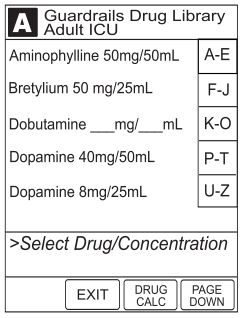
> **NOTE:** The **RESTORE** soft key appears only if there had been a previous infusion programmed for the same patient.



- If **Basic Infusion** was selected, **Infusion Setup** screen displays and title alternates between **Infusion Setup** and identifying syringe model and size.



- If **Guardrails Drug Library** was selected, **Guardrails Drug Library** screen displays.



Priming

The Priming option can be enabled at the time the Medley™ System is configured for use. The Priming selection (**PRIME** soft key) is available only after the syringe and infusion type have been selected, and prior to beginning an infusion.

If a pressure sensing disc is in use, it must be removed from instrument before priming. Refer to the applicable section, as follows, depending on whether or not a pressure sensing disc is used.

> **NOTE:** When manually priming (per hospital/facility protocol) and an administration set having a pressure sensing disc is in use, depress the disc between 2 fingers while priming and prime uphill (distal end of pressure sensing disc/tubing pointing upward).

WARNING

When priming:

- Ensure patient is not connected.
- Ensure air is expelled from line prior to beginning infusion (unexpelled air in line could have serious consequences).

Failure to prime correctly can delay infusion delivery and cause the total volume to be infused to read higher than the actual total delivered to the patient.

CAUTION

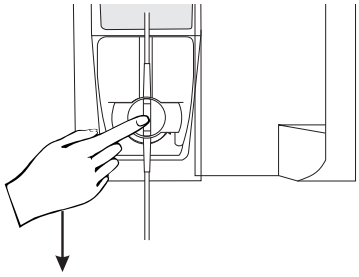
During priming, the pressure limit alarms are temporarily increased to their maximum level.

Pressure Sensing Disc Used/Installed

1. Remove pressure sensing disc from instrument.
   - Using a finger, apply firm downward pressure on pressure sensing disc (not tubing) until disc snaps loose from slot in pressure sensing disc housing.

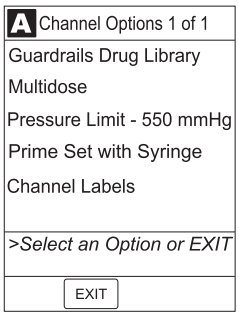
CAUTION

The pressure sensing disc, if left installed during priming, can trap air that may not be totally expelled. To ensure entrapped air is eliminated, it is recommended that the pressure sensing disc be removed prior to priming and the membrane massaged with a finger while priming. After priming is completed, reinstall the pressure sensing disc.



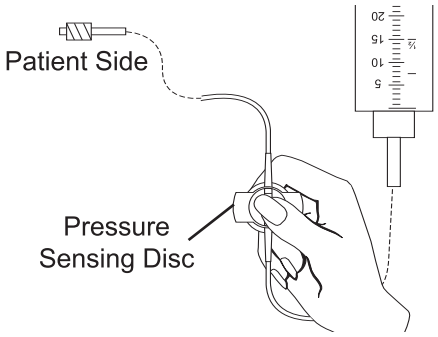
Priming (Continued)

2. Press **OPTIONS** key.
3. Press **Prime Set with Syringe** soft key.

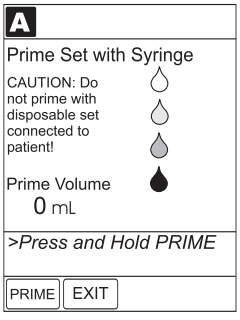


- If pressure sensing disc was not removed prior to pressing **Prime Set with Syringe** soft key, a pressure sensing disc removal prompt displays.

4. Prime, as follows:
   a. Orient pressure sensing disc with patient side up.
   b. Depress and hold pressure sensing disc between 2 fingers.



   c. Press and hold **PRIME** soft key until fluid flows and priming of syringe administration set is complete.
   d. Release pressure sensing disc.

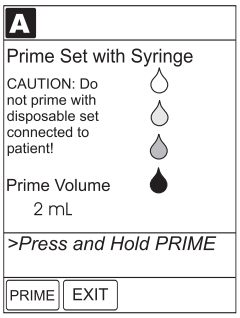


> **NOTE:** Fluid is delivered during priming only while the **PRIME** soft key is pressed. Each press of the **PRIME** soft key delivers up to 2 mL of priming fluid per continuous press. To deliver additional amounts, press the **PRIME** soft key again.

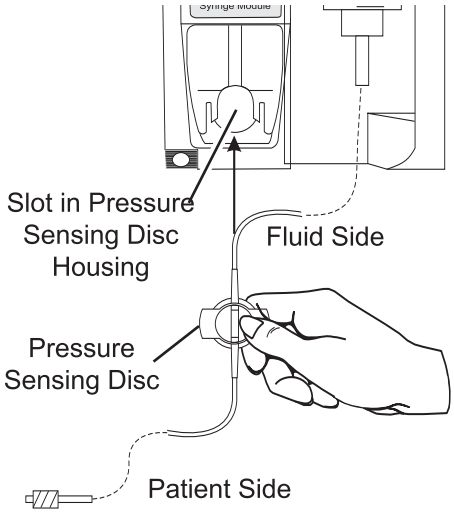
- Volume used during priming is displayed but not added to VTBI.

Pressure Sensing Disc Used/Installed (Continued)

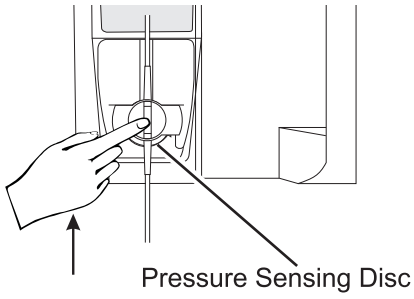
5. When priming is complete, release **PRIME** soft key.



6. Reinstall pressure sensing disc, as follows:
   a. Orient pressure sensing disc, as follows:
      - fluid side up (patient side down)
      - cavity forward (membrane toward instrument)
   b. Gently slide pressure sensing disc up into slot in pressure sensing disc housing.



   c. Apply firm upward pressure on pressure sensing disc (not tubing) until disc snaps into place.

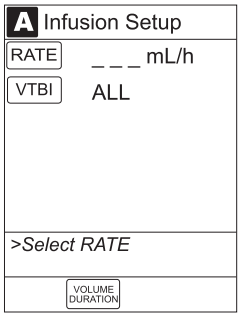


Pressure Sensing Disc Used/Installed (Continued)

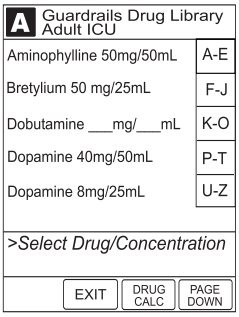
7. To return to main screen, press **EXIT** soft key.

   - If **EXIT** soft key is pressed before pressure sensing disc is reinstalled, a prompt to reinstall pressure sensing disc displays.

   - If **Basic Infusion** was selected, **Infusion Setup** screen displays and title alternates between **Infusion Setup** and identifying syringe model and size.

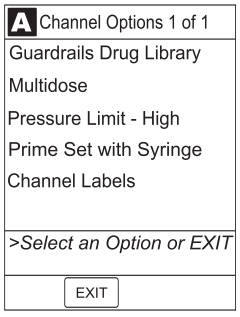


   - If **Guardrails Drug Library** was selected, **Guardrails Drug Library** screen displays.



Pressure Sensing Disc <u>Not</u> Used/Installed

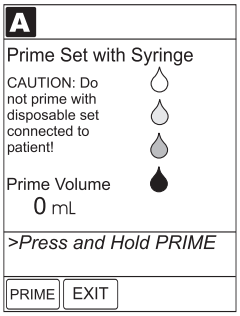
1. Press **OPTIONS** key.
2. Press **Prime Set with Syringe** soft key.



Priming (Continued)

Pressure Sensing Disc Not Used/Installed (Continued)

3. Press and hold **PRIME** soft key until fluid flows and priming of syringe administration set is complete.

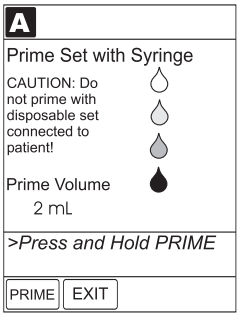


> **NOTE:** Fluid is delivered during priming only while the **PRIME** soft key is pressed. Each press of the **PRIME** soft key delivers up to 2 mL of priming fluid per continuous press. To deliver additional amounts, press the **PRIME** soft key again.

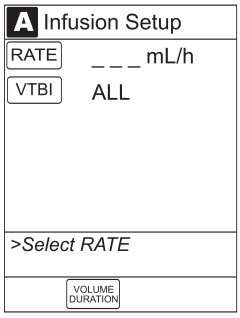
- Volume used during priming is displayed but not added to VTBI.

4. When priming is complete, release **PRIME** soft key.

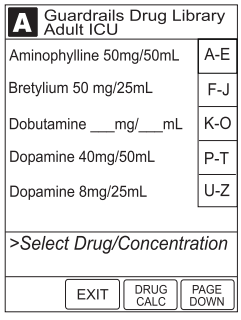
5. To return to main screen, press **EXIT** soft key.



- If **Basic Infusion** was selected, **Infusion Setup** screen displays and title alternates between **Infusion Setup** and identifying syringe model and size.



- If **Guardrails Drug Library** was selected, **Guardrails Drug Library** screen displays.



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.

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:

- ALL Mode, Drug Calculation, Dynamic Pressure Display, Profiles, and Volume Duration configurable settings are enabled.
- Delay Options and NEOI configurable settings are disabled.

If Delay Options is enabled, the **PAUSE** soft key becomes **DELAY OPTIONS**.

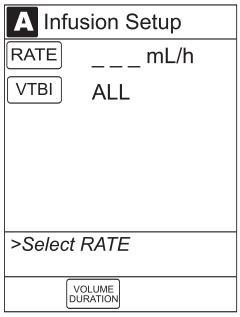
1. Perform steps in "Start-Up" section, to:
   a. Power on system.
   b. Choose **Yes** or **No** to **New Patient?**.
   c. Confirm current profile or select a new profile.
   d. Enter patient identifier, if required.
2. Perform steps in "Preparing Infusion" section, to:
   a. Prepare syringe and administration set.
   b. Load syringe and administration set.
   c. Select syringe type and size, and **Basic Infusion** as infusion type.
   d. Prime.
3. Start an infusion, as described in following "Starting Rate / Volume Infusion" or "Starting Volume / Duration Infusion"section.

WARNING

When the pressure sensing disc is not being used and an occlusion occurs, there is a risk of infusing pressurized buildup of infusates upon correction of the occlusion. To avoid an inadvertent bolus, relieve the pressure before restarting the infusion.

Starting Rate / Volume Infusion

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



2. To enter a numeric **VTBI** value (instead of infusing **ALL**), press **VTBI** soft key and use numeric data entry keys.

   OR

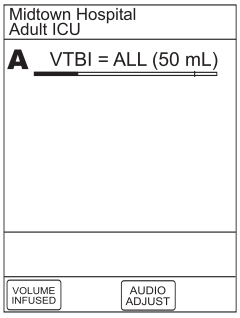
   To deliver entire contents of syringe, leave **VTBI** as **ALL**.

   > **NOTE:** When ALL MODE is disabled, the VTBI ALL option is not available.

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

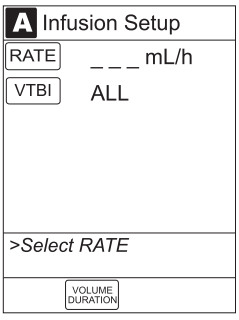
4. Verify correct infusion parameter entry and press **START** soft key.

   > **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.

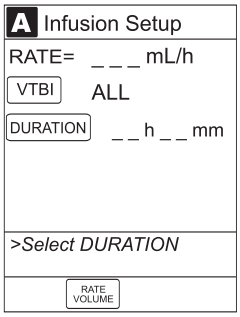


Starting Volume / Duration Infusion (Continued)

2. To enter a numeric **VTBI** value (instead of infusing **ALL**), press **VTBI** soft key and use numeric data entry keys.

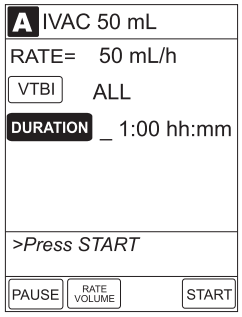
   OR

   To deliver entire contents of syringe, leave **VTBI** as **ALL**.

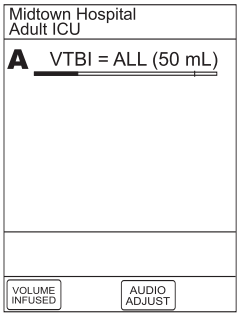


> **NOTE:** When ALL MODE is disabled, the VTBI ALL option is not available.

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.



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

Possible End of Infusion Messages and Alerts

KVO	VTBI	Delayed	Point-of-Care Unit Display	Module Display	Audio / Visual Alert
N/A	All	Yes	Syringe Empty	Syringe Empty	Yes / Yes
On	All	No	Syringe Empty	Syringe Empty	Yes / Yes
Off	All	No	Syringe Empty	Syringe Empty	Yes / Yes
N/A	Numeric	Yes	Complete	Infusion Complete	Yes / Yes (if an **After** callback is scheduled)
N/A	Numeric	Yes	Syringe Empty	Syringe Empty	Yes / Yes
Off	Numeric	No	Complete	Infusion Complete	Yes / Yes
Off	Numeric	No	Syringe Empty	Syringe Empty	Yes / Yes
On	Numeric	No	Syringe Empty	Syringe Empty	Yes / Yes

Pausing Infusion

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

1. Press **PAUSE** key (on Syringe Module).

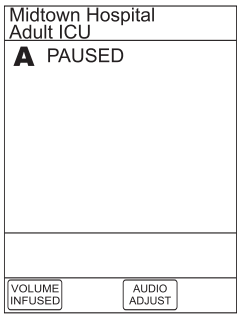
   OR

   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 Syringe Module).



   OR

-- Continued on Next Page --

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 syringe requires replacement, reference “Preparing Infusion” section in “Getting Started” chapter to:
   a. Remove existing syringe and prepare new syringe (reference “Preparing Infusion”, “Preparing Syringe and Administration Set” section in “Getting Started” chapter).
   b. Load syringe and administration set.
   c. Select syringe type and size.

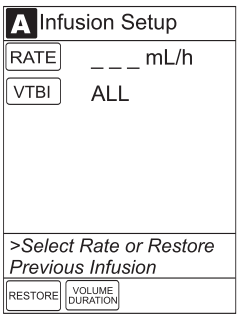
   > **NOTE:** Since the system is already in a basic infusion mode, the Infusion Menu screen does not appear after the syringe type and size are confirmed.

   d. Prime.

2. 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”.



3. 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 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 Limit

Pressure Sensing Disc Installed

1. Ensure pressure sensing disc is installed correctly.
2. Press **CHANNEL SELECT** key.
3. Press **OPTIONS** key.

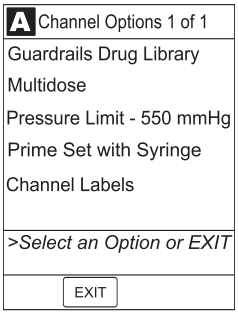
WARNING

Installing a pressure sensing disc after an infusion has started can result in a bolus to the patient.

Selecting Pressure Limit (Continued)

Pressure Sensing Disc Installed (Continued)

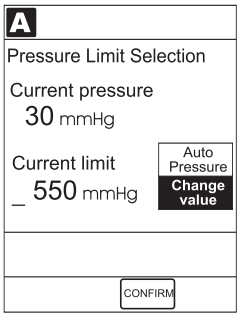
4. Press **Pressure Limit** soft key.



5. To enter a new pressure limit value, press **Change Value** soft key.

   OR

   If Auto Pressure feature is enabled, press **Auto Pressure** soft key.

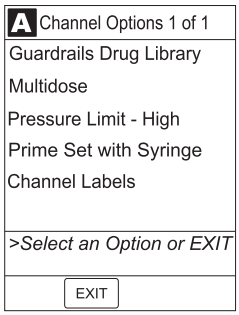


> **NOTE:** If Auto Pressure is selected and current pressure is:
>
> - 100 mmHg or less – system adds 30 mmHg to current pressure, to create a new alarm limit
> - greater than 100 mmHg – system adds 30% to current pressure, to create a new alarm limit

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

Pressure Sensing Disc Not Installed

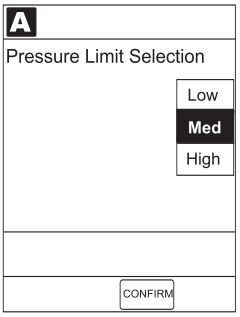
1. Press **CHANNEL SELECT** key.
2. Press **OPTIONS** key.
3. Press **Pressure Limit** soft key.



Selecting Pressure Limit (Continued)

Pressure Sensing Disc Not Installed (Continued)

4. To select a pressure limit, press appropriate soft key (**Low**, **Med**, or **High**).
5. Press **CONFIRM** soft key.

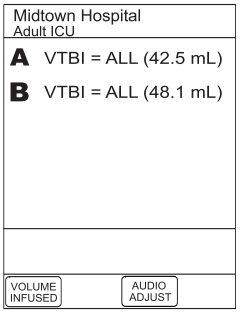


Viewing and Clearing Volume Infused

1. To view volume infused, press **VOLUME INFUSED** soft key.
   - Total volume infused, and time and date volume infused was last cleared, display for each module.

     NOTES:
     - Date format is year-month-day.
     - If a Pump Module is attached, a **PRI/SEC VOLUME** soft key is available to allow secondary volume infused to be displayed.

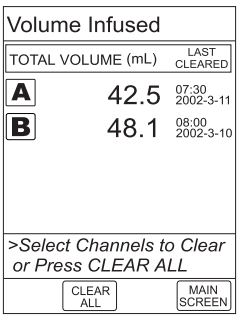
   - If no key is pressed, main screen appears after 30 seconds.



2. 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.



Changing Syringe During Infusion

1. To stop infusion, press **PAUSE** key (on Syringe Module).
2. Open plunger grippers and syringe barrel clamp.
   - An audio prompt sounds (to silence, press **SILENCE** key).
   - Red Alarm Status Indicator flashes.
   - **CHECK SYRINGE** scrolls in Message Display.
3. Remove syringe and separate administration set from syringe.
4. Reattach administration set to new syringe (reference “Preparing Infusion” section in “Getting Started” chapter).
5. Load new syringe (reference “Preparing Infusion” section in “Getting Started” chapter).
6. Select syringe type and size (reference “Preparing Infusion” section in “Getting Started” chapter).
7. Press **CONFIRM** soft key.
8. Prime administration set (reference “Preparing Infusion” section in “Getting Started” chapter).
9. Press **RESTORE** soft key.

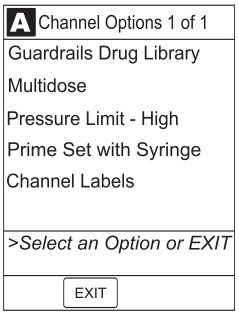
   OR

   To enter VTBI and rate, press **RATE** soft key and use numeric data entry keys, and then **VTBI** soft key and use numeric data entry keys.
10. To begin infusion, press **START** soft key.

Channel Labels

Selecting Channel Label

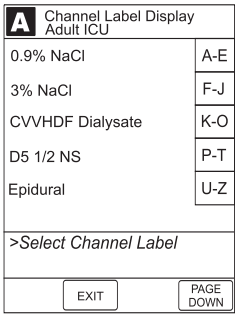
1. Press **CHANNEL SELECT** key.
2. Press **OPTIONS** key.
3. Press **Channel Labels** soft key.

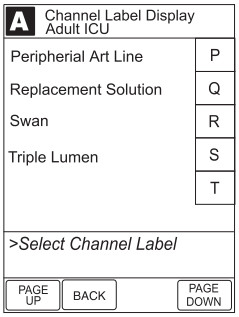


4. Press soft key for desired label.

   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.

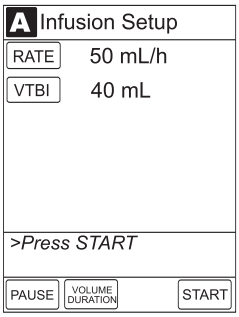




5. To continue infusion, press **START** soft key.

   OR

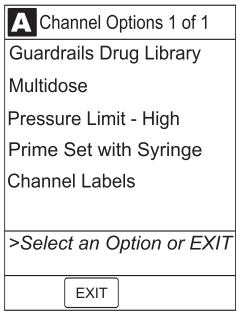
   Program infusion as previously described.



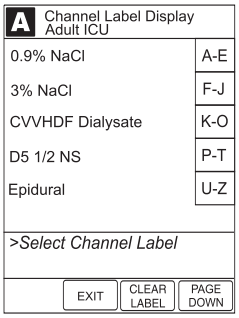
Channel Labels (Continued)

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.

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).

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.

-- Continued on Next Page --

WARNINGS

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

Drug Calculation Parameters (Continued)

- 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

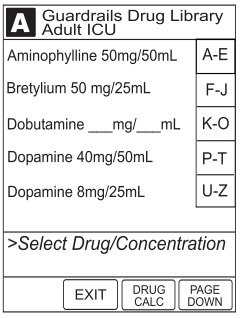
When using a drug listed in the Guardrails® Drug Library, the Guardrails® Software automatically calculates the drug parameters, based on:

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

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:
   a. Prepare syringe and administration set.
   b. Load syringe and administration set.
   c. Select syringe type and size, and **Guardrails Drug Library** as infusion type.
   d. Prime.

Using Guardrails® Drug Library (Continued)

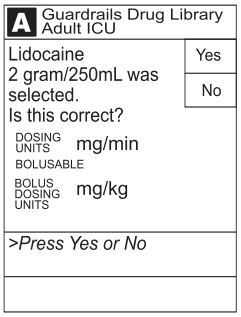
3. Press soft key next to desired drug and concentration.



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.

4. To continue programming, press **Yes** soft key.

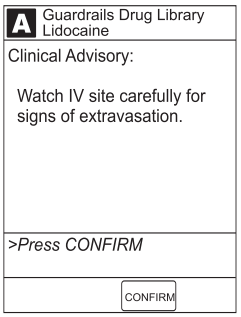


- Bolus dose units appear if Bolus Dose is enabled.

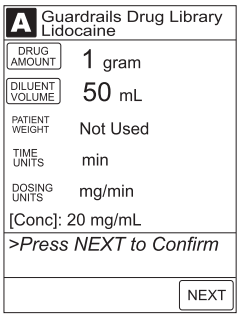
  OR

  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.



- 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).



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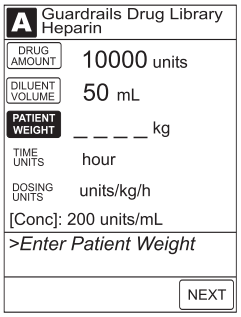
Using Guardrails® Drug Library (Continued)

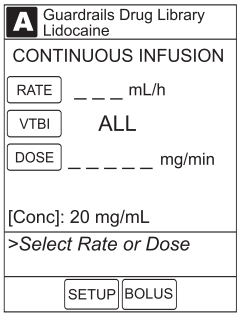
- If hospital/facility practice guidelines identify selected drug as weight-based, prompt for a patient weight in kilograms appears (as in illustrated example, which reflects use of Heparin in Pediatrics ICU).

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

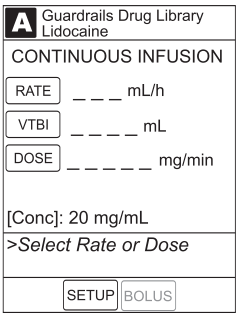


5. Verify parameters are correct and press **NEXT** soft key to confirm.

> **NOTE:** If the ALL Mode is enabled, **VTBI ALL** displays.

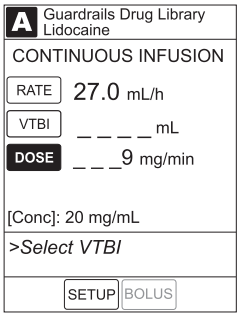


6. To make a rate or dose entry, press applicable soft key, **RATE** or **DOSE**, and use numeric data entry keys (other value is calculated and displayed).



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

> **NOTE:** The **BOLUS** soft key appears only if Bolus Dose is enabled within the selected profile, the drug is bolusable, and a VTBI is entered.



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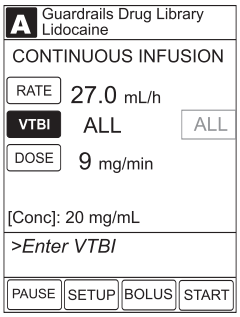
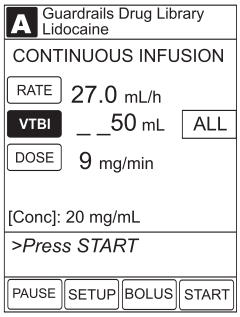
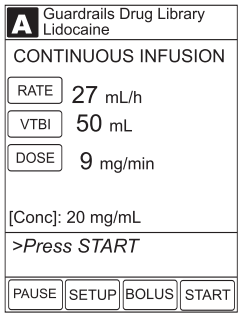
NOTE: When VTBI equals ALL, the **ALL** soft key appears inactive when the **VTBI** soft key is pressed and active when a value is entered.

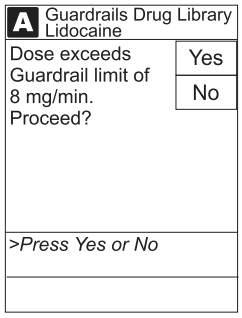




8. Verify parameters are correct and press **START** soft key.



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.



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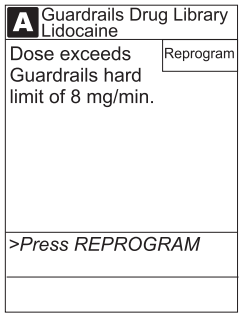
Using Guardrails® Drug Library (Continued)

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.

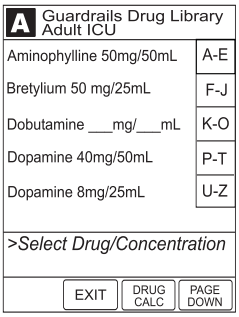


Using Non-Library Drug

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.

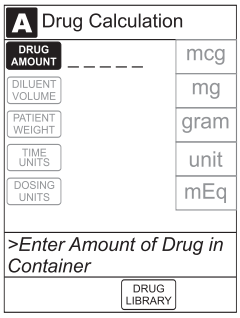
1. Perform steps in "Start-Up" section, to:
   a. Power on system.
   b. Choose **Yes** or **No** to **New Patient?**.
   c. Confirm current profile or select a new profile.
   d. Enter patient identifier, if required.
2. Perform steps in "Preparing Infusion" section, to:
   a. Prepare syringe and administration set.
   b. Load syringe and administration set.
   c. Select syringe type and size, and **Guardrails Drug Library** as infusion type.
   d. Prime.

3. Press **DRUG CALC** soft key.

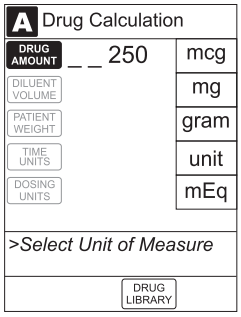


Using Non-Library Drug (Continued)

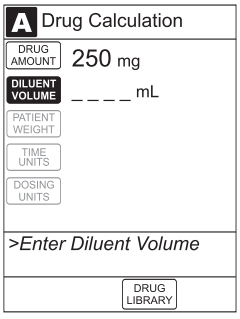
4. To enter **DRUG AMOUNT** in syringe, use numeric data entry keys.



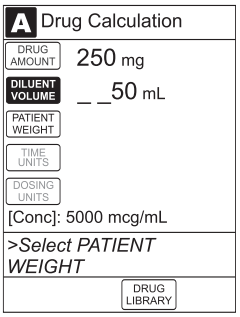
5. Press soft key for appropriate unit of measure for drug amount.



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



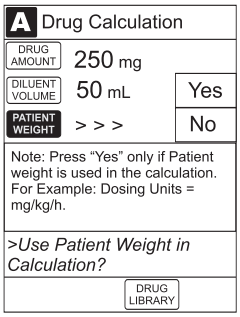
7. Press **PATIENT WEIGHT** soft key.



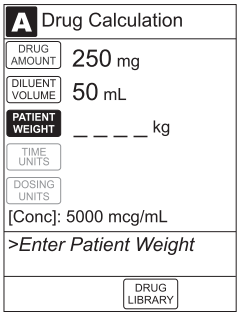
Using Non-Library Drug (Continued)

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

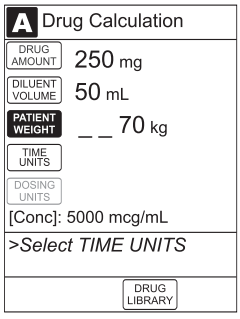
> **NOTE:** Do not enter a patient weight if weight is not used in the calculation.



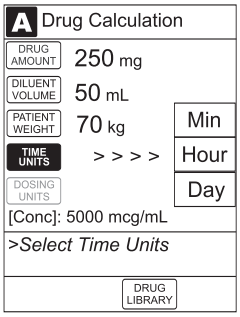
9. To enter patient weight (if required) in kilograms, use numeric data entry keys.



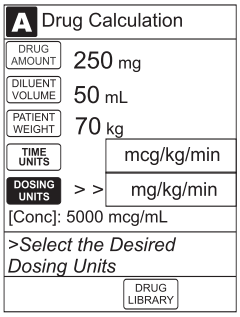
10. Press **TIME UNITS** soft key.



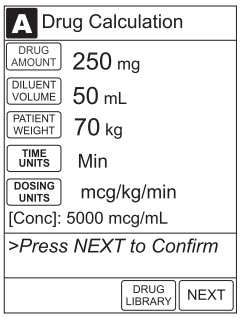
11. To select time base for drug calculation, press either **Min**, **Hour**, or **Day** soft key.



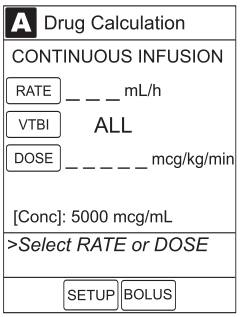
12. Press soft key next to desired **DOSING UNITS**.



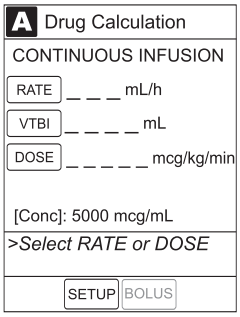
13. Verify correct drug calculation infusion parameters and press **NEXT** soft key.



NOTE: If the ALL Mode is enabled, **VTBI ALL** displays. In the following illustrated examples, the ALL Mode is disabled.

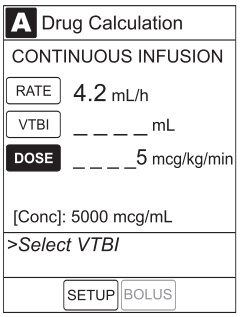


14. To make a rate or dose entry, press applicable soft key, **RATE** or **DOSE**, and use numeric data entry keys (other value is calculated and displayed).



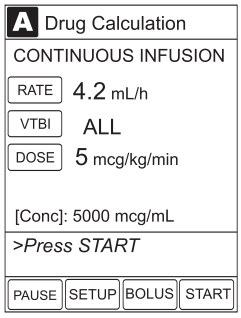
Using Non-Library Drug (Continued)

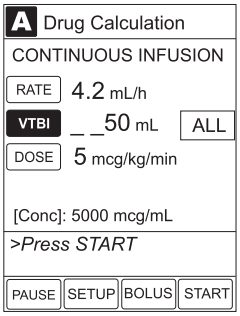
15. To enter volume to be infused, press **VTBI** soft key and use numeric data entry keys.



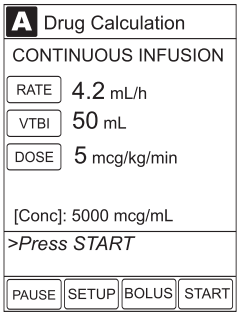
> **NOTE:** The **BOLUS** soft key appears only if Bolus Dose is enabled within the selected profile and a VTBI is entered.

> **NOTE:** When VTBI equals ALL, the **ALL** soft key appears inactive when the **VTBI** soft key is pressed and active when a value is entered.





16. 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.

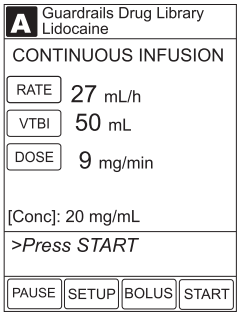
NOTES:

- 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.

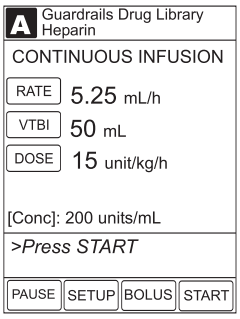
Using Guardrails® Drug Library Calculation

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. ➤



Weight-based example. ➤



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Using Guardrails® Drug Library Calculation (Continued)

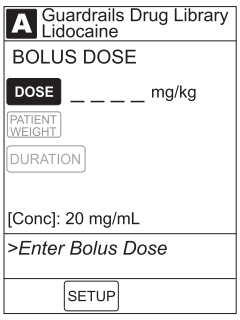
- **DOSE** is highlighted.

> **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.

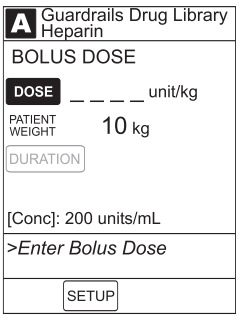
3. To enter bolus dose, use numeric data entry keys.

> **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.



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



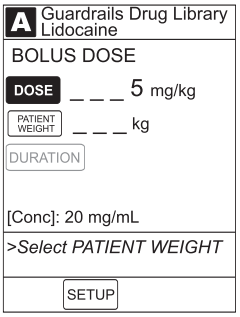
- If bolus dose is not weight-based, **Not Used** displays in **PATIENT WEIGHT** field.

Using Guardrails® Drug Library Calculation (Continued)

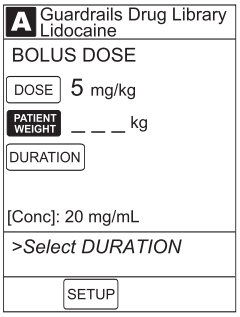
4. To enter or change patient weight (if used), use applicable following procedure, depending on whether or not continuous dose is weight-based.

   - When continuous dose is <u>not weight-based</u>:

     a. Press **PATIENT WEIGHT** soft key.



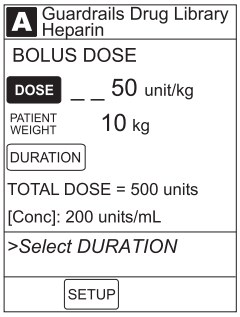
     b. To enter patient weight, use numeric data entry keys.



-- OR --

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

     a. Press **SETUP** soft key.



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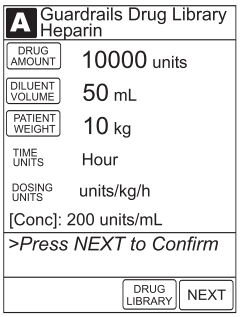
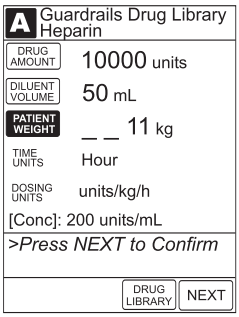
Using Guardrails® Drug Library Calculation (Continued)

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

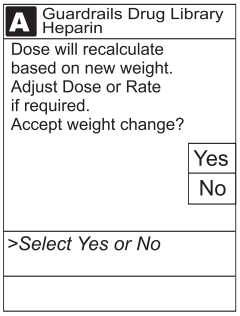


c. To change patient weight, use numeric data entry keys.

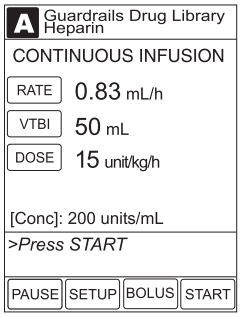
d. Press **NEXT** soft key.



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



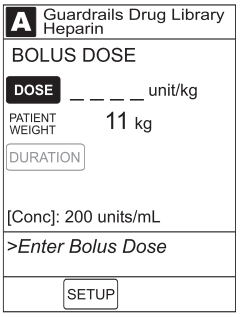
e. Press **BOLUS** soft key.



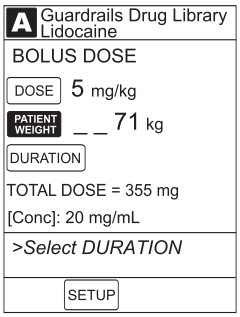
-- Continued on Next Page --

Using Guardrails® Drug Library Calculation (Continued)

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



5. Press **DURATION** soft key.

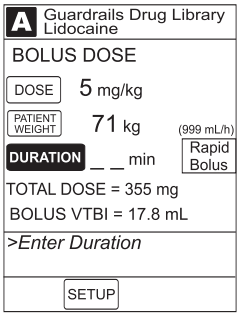


6. To enter bolus duration, use numeric data entry keys.

   OR

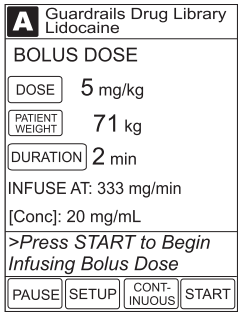
   To deliver bolus dose at maximum safe rate possible for selected drug and setup, and automatically calculate bolus duration, press **Rapid Bolus** soft key.

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



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

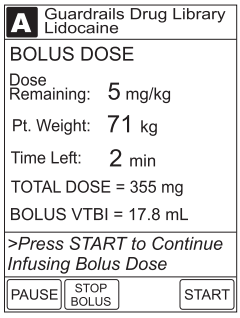
> **NOTE:** If a continuous dose outside of the Guardrails® Soft Limits has been entered and verified as correct, the Message Display also shows either "LLL" for a low dose or "↑↑↑" for a high dose.



-- Continued on Next Page --

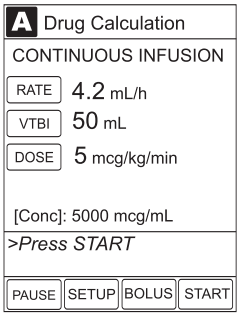
Using Guardrails® Drug Library Calculation (Continued)

NOTE: To see details during the bolus infusion, press the **CHANNEL SELECT** key. The screen title alternates between "Guardrails Drug Library (drug name)" and identifying syringe model and size.



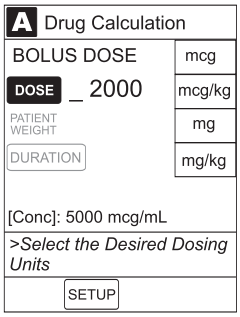
Using Non-Library Drug Calculation

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



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

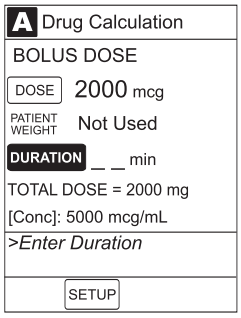
NOTE: After a bolus dose and weight (if used) are entered, bolus VTBI and concentration [conc] alternate in the Main Display.



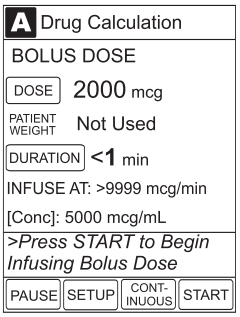
4. Press soft key for appropriate unit of measure for dose.

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.

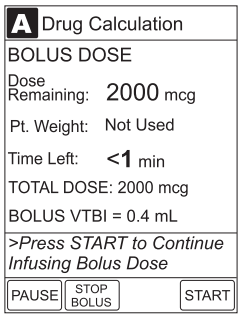
5. To enter bolus duration, use numeric data entry keys.
   - **TOTAL DOSE** alternates with **INFUSE AT** rate.



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



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



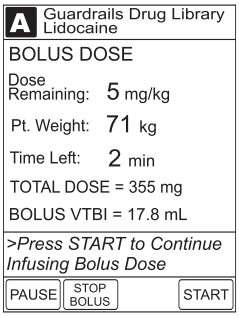
Stopping Bolus Dose

> **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.

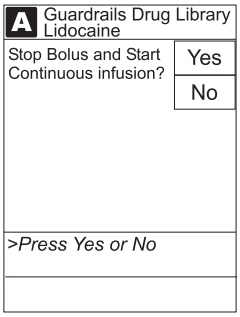
1. Press **CHANNEL SELECT** key.

Stopping Bolus Dose (Continued)

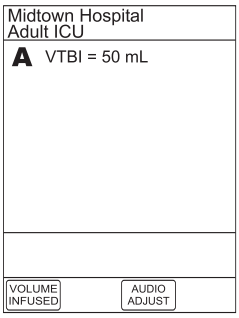
2. Press **STOP BOLUS** soft key.



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



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



Restoring Bolus Dose

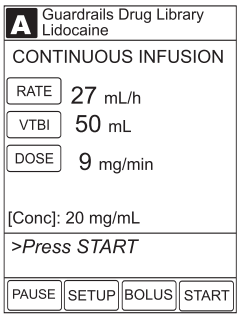
A bolus dose can be restored after it has completed, either prior to or after the module has been turned off, as indicated in the following sections.

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.

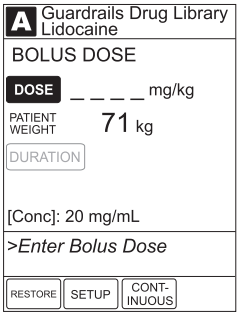
Restoring Bolus Dose (Continued)

Bolus Dose Completed - Module Not Turned Off

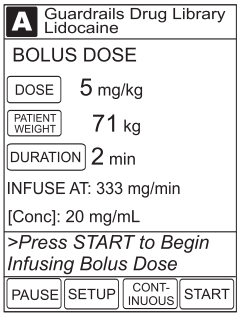
1. Press **CHANNEL SELECT** key.
2. Verify infusion parameters and press **BOLUS** soft key.



3. Press **RESTORE** soft key.

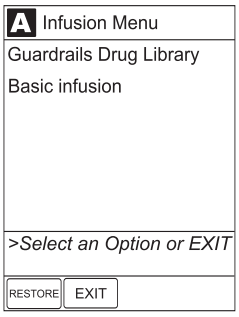


4. Verify dosing parameters and press **START** soft key.



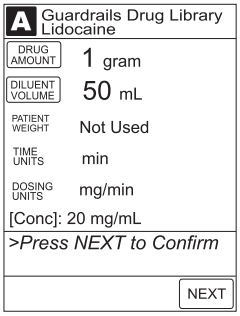
Bolus Dose Completed - Module Turned Off

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

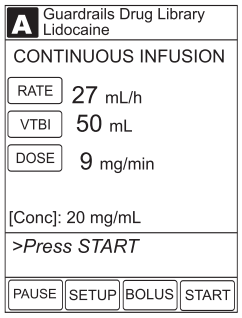


Bolus Dose Completed - Module Turned Off (Continued)

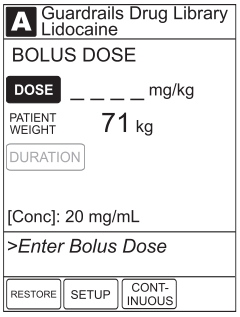
3. Verify parameters and press **NEXT** soft key.



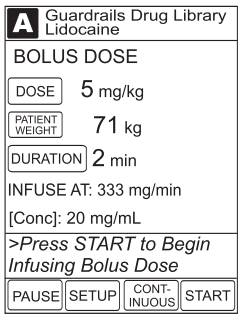
4. Verify infusion parameters and press **BOLUS** soft key.



5. Press **RESTORE** soft key.



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 Syringe Module is paused, the Syringe Module remains in an indefinite pause, until the module is restarted.

When Anesthesia Mode is enabled:

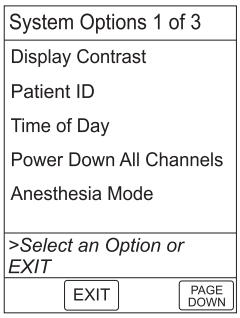
- All Guardrails® Limits are set to “Soft”.
- Dose checking mode is set to “Smart”.
- Key-press audio is turned off.
- Tamper Resist Mode (panel locked) is not available.
- All Guardrails® Drug Library entries are available for selection.
- Bolus dose is automatically available for:
  - drugs in Guardrails®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

CAUTION

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

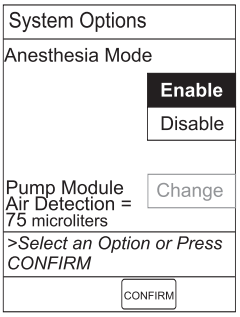
Enabling Anesthesia Mode

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

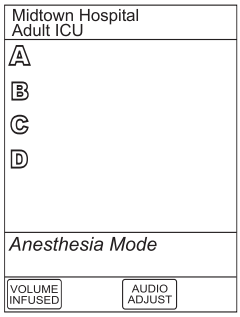


Enabling Anesthesia Mode (Continued)

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



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



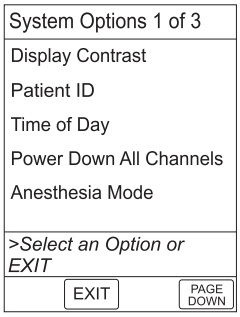
Disabling Anesthesia Mode

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

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

From System Options Menu

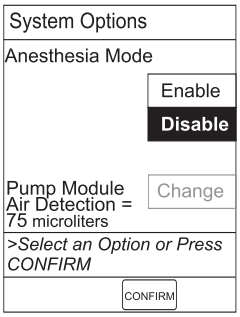
1. While operating in Anesthesia Mode, press **OPTIONS** key.
2. Press **Anesthesia Mode** soft key.



Disabling Anesthesia Mode (Continued)

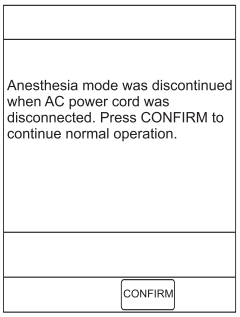
From System Options Menu (Continued)

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



Disconnecting System from AC Power While in Anesthesia Mode

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

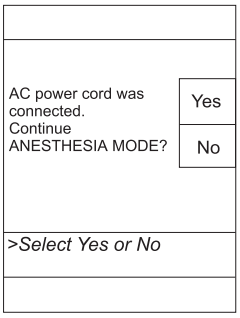


Connecting System to AC Power While in Anesthesia Mode

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

   OR

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



Delay Options

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

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

Delaying Infusion

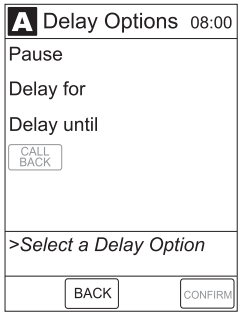
The delay period for an infusion can be programmed as a specific number of minutes or a time of day, as described in the following sections. An infusion delay can be programmed prior to or after an infusion is initiated.

Specifying by Minutes

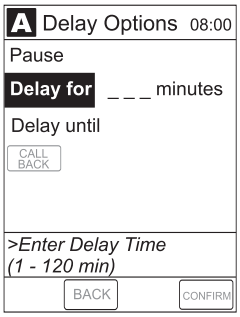
The **Delay for** option is used to program an infusion delay for a minimum of 1 minute and up to 120 minutes.

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

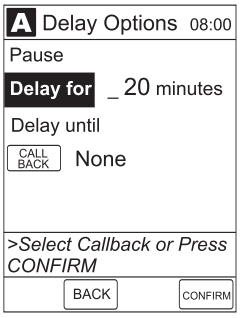
2. Press **Delay for** soft key.



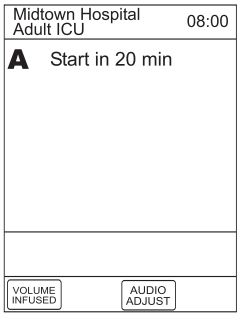
3. To enter number of minutes (up to 120) infusion is to be delayed for, use numeric data entry keys.



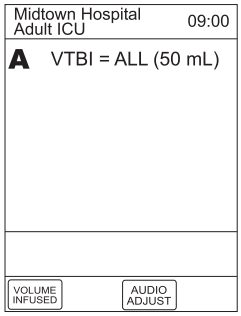
4. Press **CONFIRM** soft key.



- 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.



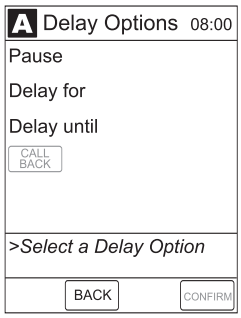
Delaying Infusion (Continued)

Specifying by Time of Day

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

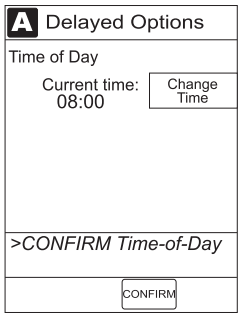
1. Press **DELAY OPTIONS** soft key.

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

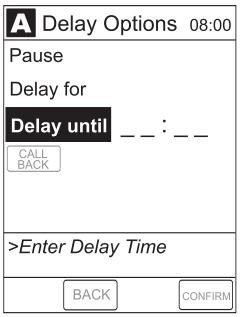


3. If **Current time** displayed is correct, press **CONFIRM** soft key; otherwise, press **Change Time** and enter correct time. (Reference "Setting Up Time of Day" procedure in Medley™ Point-of-Care Unit DFU.)

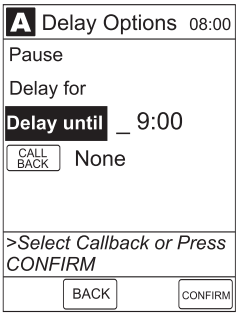
> **NOTE:** If the current time has been previously confirmed, the **Time of Day** screen will not be displayed.



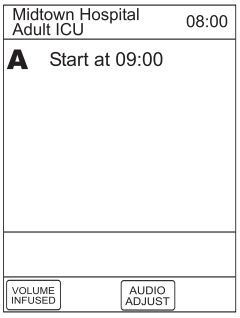
4. To enter time of day infusion is to be initiated (up to 23 hours 59 minutes), use numeric data entry keys.



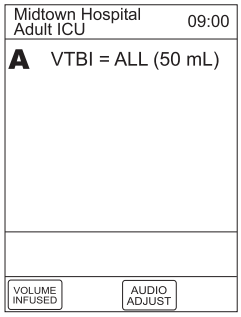
5. Press **CONFIRM** soft key.



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



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



Delay Options (Continued)

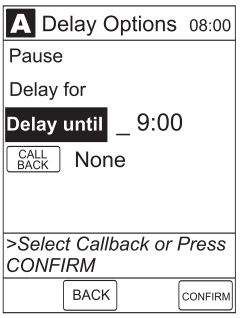
Scheduling a Callback

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

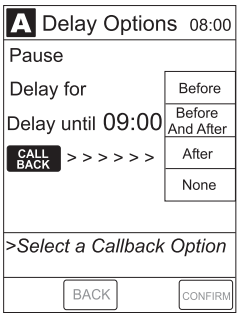
- **Before** - gives an alert when delay is completed and infusion needs to be initiated.
- **After** - gives an alert when delayed infusion has completed.
- **Before** and **After** - gives an alert when delay is completed and infusion needs to be initiated and when delayed infusion has completed.

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

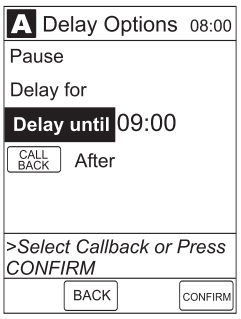
1. Prior to pressing **CONFIRM** soft key to initiate delay during **Delay for** or **Delay until** programming process, press **CALL BACK** soft key.



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



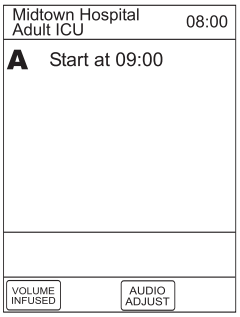
3. To initiate delay, press **CONFIRM** soft key.



-- **Continued on Next Page** --

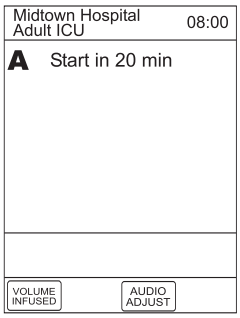
Scheduling a Callback (Continued)

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



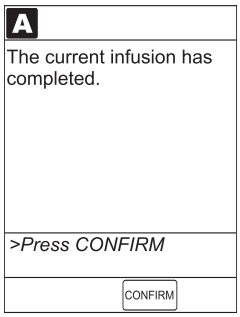
OR

- 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.



Delay Options (Continued)

Scheduling a Callback (Continued)

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

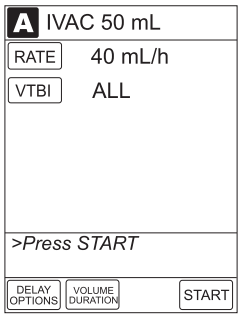
     Press **CHANNEL SELECT** key and then **START** soft key.

     OR

     Press **RESTART** key.
   - **After** callback: Press **CONFIRM** soft key.
   - **Before and After** callback: Respond as indicated above for both **Before** and **After**.

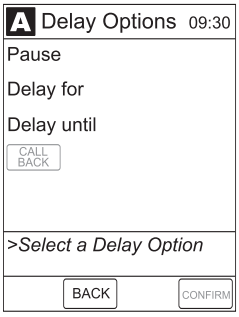
Pausing Infusion

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

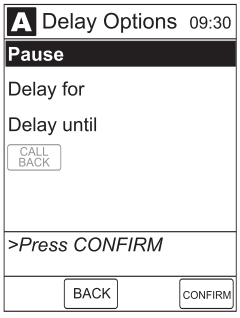


2. Press **Pause** soft key.

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



3. Press **CONFIRM** soft key.
   - **PAUSE** scrolls in 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.



Delay Options (Continued)

Pausing Infusion (Continued)

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.
- ALL Mode is not supported in Multidose Mode.
- The Delay Options function for multidose infusions is similar to Delay Options for continuous drug infusions, with the following differences:
  - **Delay for** option (when scheduling a callback) 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.

Programming with Volume / Duration Enabled

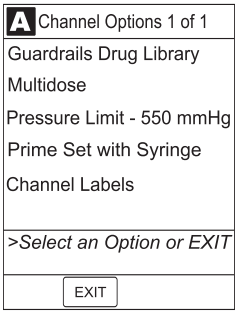
If Volume/Duration was enabled at the time the Medley™ System was configured for use, use the following procedure to program a multidose infusion.

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.

Programming with Volume / Duration Enabled (Continued)

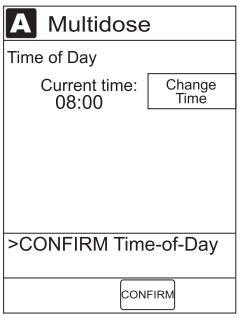
2. Perform steps in “Preparing Infusion” section, to:
   a. Prepare syringe and administration set.
   b. Load syringe and administration set.
   c. Select syringe type and size (and **Basic Infusion** as infusion type).
   d. Prime.
3. Press **OPTIONS** key.

4. Press **Multidose** soft key.

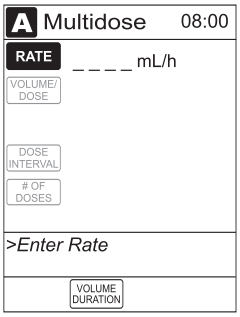


5. If **Current time** displayed is correct, press **CONFIRM** soft key; otherwise, press **Change Time** and enter correct time. (Reference “Setting Up Time of Day” procedure in Medley™ Point-of-Care Unit DFU.)

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



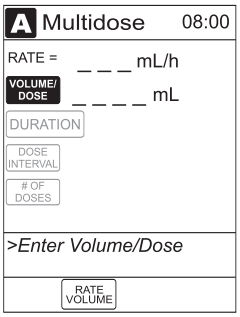
6. Press **VOLUME DURATION** soft key.



PROGRAMMING

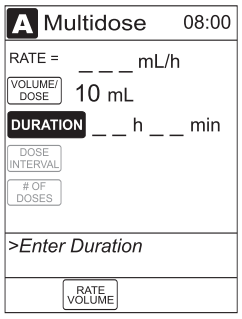
Programming with Volume / Duration Enabled (Continued)

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

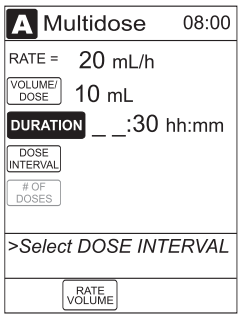


8. To enter duration for each dose, press **DURATION** soft key and use numeric data entry keys.

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

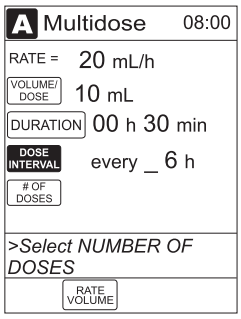


9. To enter time interval (1 to 24 hours) between doses, press **DOSE INTERVAL** soft key and use numeric data entry keys.



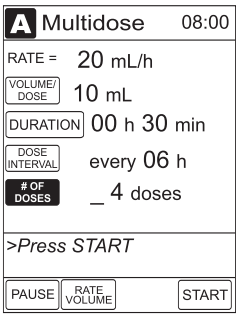
10. To enter number of doses, press **#OF DOSES** soft key and use numeric data entry keys.
    - If Delay Options is enabled, **DELAY OPTIONS** soft key appears.

> **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.

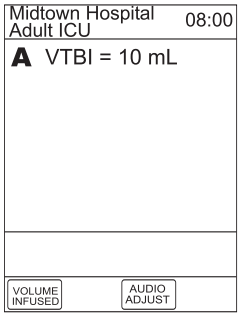


Programming with Volume / Duration Enabled (Continued)

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



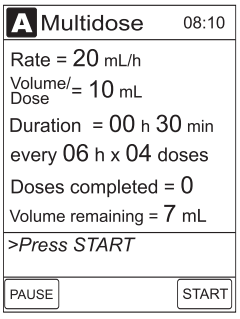
- Main Display shows remaining VTBI for that dose.



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

> **NOTE:** If NEOI is enabled, the Near End of infusion message appears near the end of the last dose.

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



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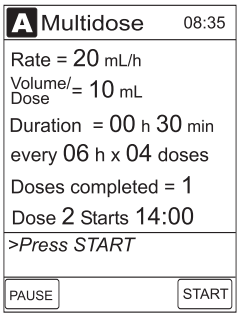
Programming with Volume / Duration Enabled (Continued)

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



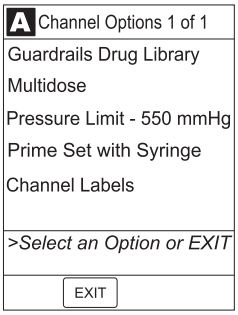
Programming with Volume / Duration Disabled

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:
   a. Prepare syringe and administration set.
   b. Load syringe and administration set.
   c. Select syringe type and size (and **Basic Infusion** as infusion type).
   d. Prime.
3. Press **OPTIONS** key.

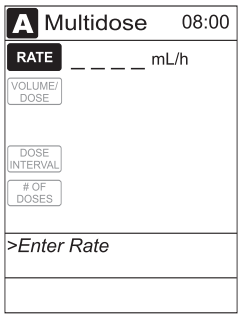
---

4. Press **Multidose** soft key.

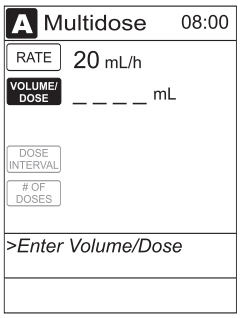


Programming with Volume / Duration Disabled (Continued)

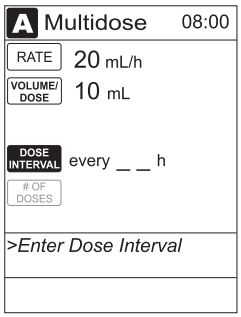
5. To enter rate, use numeric data entry keys.



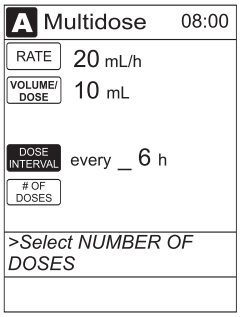
6. To enter volume to be infused for each dose, press **VOLUME/DOSE** soft key and use numeric data entry keys.



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



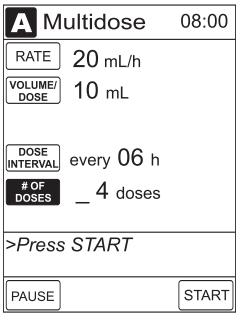
8. To enter number of doses, press **#OF DOSES** soft key and use numeric data entry keys.
   - If Delay Options is enabled, **DELAY OPTIONS** soft key appears.



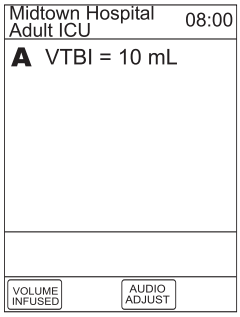
> **NOTE**: Reference "Delay Options" section to program an infusion delay. When delaying an infusion, a multidose cannot be delayed for more than 8 hours, and all doses in the multidose program must be completed within a 24-hour program.

Programming with Volume / Duration Disabled (Continued)

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



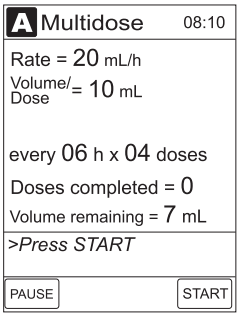
- Main Display shows remaining VTBI for that dose.



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

> **NOTE:** If NEOI is enabled, the Near End of infusion message appears near the end of the last dose.

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



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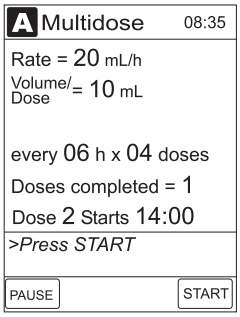
Multidose Mode (Continued)

Programming with Volume / Duration Disabled (Continued)

- 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

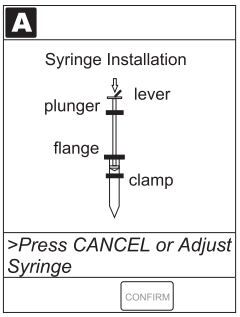
Reference the Medley™ Point-of-Care Unit DFU.

Alarms

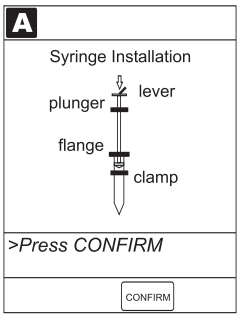
Alarm	Meaning	Response
Channel Disconnected	Module(s) disconnected while in operation or have a communication problem.	To silence alarm and clear message from screen, press **CONFIRM** soft key. Reattach module if desired, ensuring it is securely “clicked” into place at Module Release Latch. If alarm is still present, replace module with an operational instrument.
Occlusion	Increased back pressure sensed while infusing. Infusion stops on affected module.	Clear occlusion. Press **RESTART** key, or press **CHANNEL SELECT** key and then **START** soft key.
Pressure Disc Installed	Pressure sensing disc installed during an infusion. Infusion stops on affected module.	Press **CONFIRM** soft key and **RESTART** key.
Pressure Disc Removed	Pressure sensing disc removed. Infusion stops on affected module.	Reinsert pressure sensing disc and press **RESTART** key.
Syringe Empty	Syringe is empty. ➤	Set up new infusion or press **CHANNEL OFF** key.
	If syringe is not empty, other possibilities are:	
	• Pressure sensing disc inappropriate/defective. ➤	Verify appropriate pressure sensing disc is in use and functioning properly.
	• Syringe plunger travel impeded. ➤	Verify syringe plunger movement is unimpeded.
	• Pressure transducer defective. ➤	If syringe is not empty and above actions do not correct alarm, contact qualified service personnel.

Syringe Adjustment Alarms

When a syringe installation problem is detected, a visual signal is displayed. Text in the display blinks to indicate the location of the problem.



- When problem is corrected, press **CONFIRM** soft key.



Alarm	Meaning	Response
Check Syringe	Plunger grippers opened during infusion and then closed. Infusion stops on affected module.	Securely lock plunger grippers, press **CHANNEL SELECT** key, and reselect syringe.
	Syringe barrel clamp opened during infusion and then closed. Infusion stops on affected module.	Securely lock syringe barrel clamp and press **RESTART** key.
	Syringe plunger not captured while in idle state. System alarms after 30 seconds, to indicate potential siphoning condition.	Check for potential siphoning. Ensure administration set clamp (roller/slide) is in closed position. Securely lock plunger grippers over syringe plunger.
Drive Not Engaged	Drive system disengaged during operation.	Open and close plunger grippers and syringe barrel clamp. Ensure syringe is properly installed.

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.
Syringe Calibration Required	Error on infusing module indicating calibration is required. Infusion stops on affected module. **CALIBRATE** scrolls in Message Display.	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.
Syringe Driver Head Error	Noninfusing module, with plunger grippers open, senses excessive pressure being applied downward on Drive Head. **OCCLUSION** scrolls in Message Display.	To silence alarm and continue normal operation, press **CONFIRM** soft key.

Messages

Message	Meaning	Response
After Call Back	Infusion completed.	Press **CONFIRM** soft key.
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
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.
NEOI (Near End of Infusion)	Syringe almost empty.	None. This is a timed event that can be set. To set or change this option, reference “Configurable Settings” section in “Maintenance” chapter.

Messages (Continued)

Message	Meaning	Response
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.
Start time for next dose has passed	Start of next dose passed.	Press **CONFIRM** soft key.
Syringe Not Recognized	Installed syringe of unknown type and size.	Select and confirm correct syringe type and size, and then press **CONFIRM**; or use a syringe type and size that system can automatically and correctly identify.

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.

Specifications

Bolus Volume following Occlusion (at intermediate rate):

Without Pressure Sensing Disc:

Pressure Setting	Bolus (g)
Low	0.329
Medium	0.523
High	0.736

With Pressure Sensing Disc:

	Back Off Disabled	Back Off Enabled
300 mmHg	0.277	0.098
500 mmHg	0.416	0.136
1000 mmHg	0.764	0.137

The Medley™ System has a back-off safety feature which, when enabled and a pressure sensing disc is in use, is designed to reduce bolus volume on occlusion release.

WARNING

Installing a pressure sensing disc after an infusion has started can result in a bolus to the patient.

Critical Volume: The maximum over-infusion which can occur in the event of a single-fault condition will not exceed 2% of nominal syringe fill volume during loading and 1% of maximum syringe travel after syringe loading.

Dimensions: 4.5"W x 15.0"H x 7.5"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 Point-of-Care Unit must remain in an upright position.

Specifications (Continued)

Flow Rate Programming: The flow rate range is from 0.01 to 999 mL/h and can be selected as follows:

Flow Rates (mL)	Selectable Increments (mL/h)
0.01 - 9.99	0.01
10 - 99.9	0.1
100 - 999	1

Rate Restriction by Syringe Size:

Syringe Size (mL)	Flow Rate Range (mL/h)
50/60	0.1 - 999
30	0.1 - 650
20	0.1 - 500
10	0.1 - 250
5	0.1 - 150
3	0.01 - 100
1	0.01 - 30

Fluid Ingress Protection: IPX1, Drip Proof

Infusion Pressure, Maximum:

Without Pressure Sensing Disc: Approximately 800 mmHg

> **NOTE:** On a high setting, the actual occlusion pressure will vary based on the syringe size and manufacturer.

With Pressure Sensing Disc: 1060 mmHg

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 0.01-2.5 mL/h in 0.01 mL/h increments.

> **NOTE:** Flow rates as low as 0.01 mL/h are available only with 1cc and 3cc syringes. For larger syringes, the lower limit adjusts to 0.1 mL/h.

Occlusion Alarm Thresholds:

Without Pressure Sensing Disc: Three settings: Low, Medium, High

With Pressure Sensing Disc: User selected from 25 to 1000 mmHg in 1 mmHg increments.

Operating Principle: Positive displacement

Specifications (Continued)

Rate Accuracy:

Rate accuracy of the Medley™ Syringe Module is ±2% of full scale plunger travel (not including syringe variation).

WARNING

Syringe size and running force, variations of back pressure, or any combination of these may affect rate accuracy. Factors that can influence back pressure are: Administration set configuration, IV solution viscosity, and IV solution temperature. Back pressure may also be affected by type of catheter. Reference "Trumpet and Start-Up Curves" section in "Appendix" chapter for data on how these factors influence rate accuracy.

Shock Protection:

Type CF, Defibrillator Proof

Time to Alarm, Maximum:

	Pressure Limit	
Rate (mL/h)	No Disc High Setting	With Disc Highest (1000 mmHg) Setting
1	120 minutes	105 minutes
5	30 minutes	30 minutes

NOTE: The Maximum Time to Alarm specifications are based on ALARIS Medical Systems' standard operating conditions:

Atmospheric Pressure: 645 - 795 mmHg
Back Pressure: 0 mmHg before producing occlusion
Humidity: 20 - 90%
Temperature: 68 ±4°F

Volume to be Infused Programming Increments:

Range (mL)	Increments (mL)
0.1 - 9.99	0.01
10 - 60	0.1

Weight:

4.5 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).

Shared Infusion Settings
(Pump Module and Syringe Module)

Feature	Default Setting	Options
ALL Mode	Disabled	Enabled - Disabled
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
NEOI	Disabled	Enabled - Disabled
• Alert Time	60	1 - 60 minutes or 25% of remaining infusion time, whichever comes later
Pressure Dynamic ("Dynamic Pressure Display")	Disabled	Enabled - Disabled
Priming	Disabled	Enabled - Disabled
Volume/Duration	Disabled	Enabled - Disabled

Configurable Settings (Continued)

Syringe Module Settings

Feature	Default Setting	Options
Auto Pressure	Disabled	Enabled - Disabled
Back Off After Occlusion	Enabled	Enabled - Disabled
Fast Start	Enabled	Enabled - Disabled
KVO ("Keep Vein Open")	Disabled	Enabled - Disabled
• Rate Adjust	1 mL/h	0.1 - 2.5 mL/h
• Volume Adjust	5%	0.5 - 5%
Max Rate	999 mL/h	0.1 - 99.9 mL/h in 0.1 mL/h increments; 100 - 999 mL/h in 1 mL/h increments
Occlusion Pressure Set Point:		
• With Disc	1000 mmHg	25 - 1000 mmHg in 1 mmHg increments
• No Disc	High	Low, Medium, High

Compatible Syringes

The Medley™ Syringe Module is calibrated and labeled for use with the following single-use disposable luer-lock syringes. Use only the syringe size and type specified on the Main Display. The full list of permitted syringe models is dependent on the Syringe Module's software version.

CAUTION

When using a 10cc or smaller syringe, ALARIS Medical Systems strongly recommends using an extension set with a pressure disc, for improved pressure monitoring and shorter times to occlusion alarm.

Manufacturer	1cc	3cc	5cc	6cc	10cc	12cc	20cc	30cc	35cc	50cc	60cc
AstraZeneca										✘ [1]	✘ [1]
B-D Plastipak	✘	✘	✘		✘		✘	✘		✘	✘
IVAC										✘	
Monoject		✘ [2]		✘		✘	✘		✘		✘
Terumo		✘	✘ [3]		✘ [3]		✘	✘		✘	✘

1 Prefilled Diprivan.

2 The Monoject SoftPack Luer-Lock Syringe (blister pack) is the only currently supported Monoject 3cc.

3 The Terumo 5cc doubles as a 6cc and the 10cc doubles as a 12cc.

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
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™ Syringe 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.

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Trumpet and Start-Up Curves

In this instrument, as with all infusion systems, the action of the pumping mechanism and variations in individual syringes and 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 and start-up curves have been provided for 1.0 mL/h and 5.0 mL/h. Measurements for trumpet curve rates below 1.0 mL/h are not provided because of the difficulty in measuring extremely small volumes over a large duration of time. In this case, the linear relationship of the plunger position and velocity to syringe volume and rate is verified, and is a function of the accuracy of the design. Measurements for trumpet curve rates above 5.0 mL/h are also not provided, as the volume of the syringe will be displaced in a very short time with a rate of up 999 mL/h. Accuracy, however, is assured with the design implementation.

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.

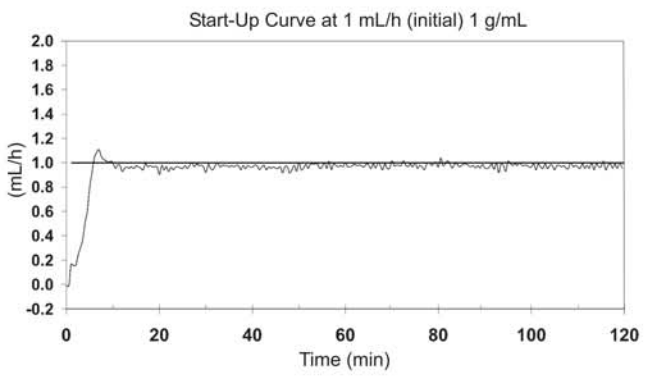
Because the clinical impact of short-term fluctuations on rate accuracy depends on the half-life of the drug being infused and on the degree of intravascular integration, the clinical effect cannot be determined from the trumpet curves alone. Knowledge of the start-up characteristics should also be considered.

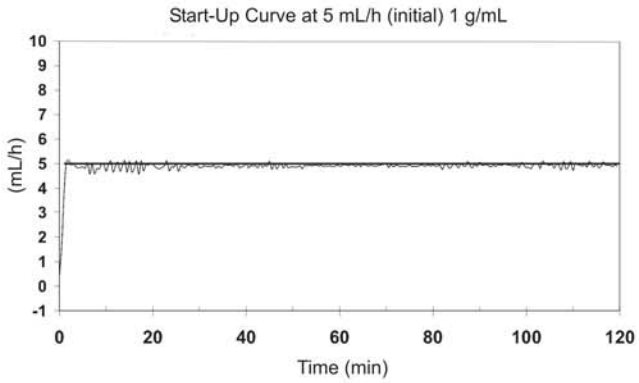
The start-up curves represent continuous flow rate versus operating time for 2 hours from the start of the infusion. They exhibit the delay in onset of delivery due to mechanical compliance and provide a visual representation of uniformity. Trumpet curves are derived from the second hour of this data.

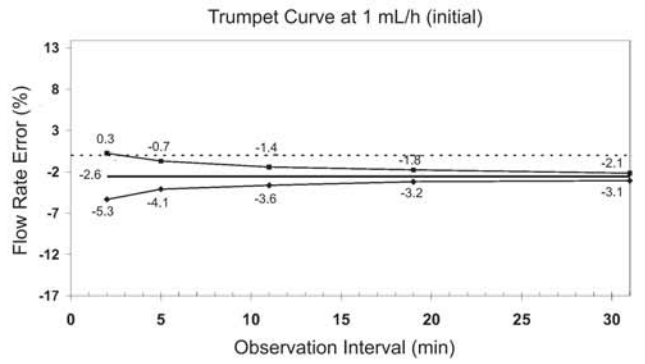
Under conditions of -100 mmHg, +100 mmHg, and +300 mmHg pressures, the Medley™ Syringe Module typically exhibits a long-term accuracy offset of approximately 0.2% or less from the mean value.

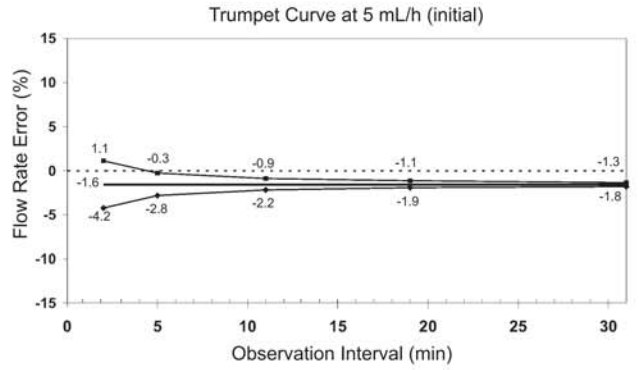
NOTE: Tests conducted in accordance with IEC/EN 60601–2–24, “Particular requirements for safety of infusion pumps and controllers” and AAMI ID26–1998 “Medical electrical equipment - Part 2: Particular requirements for the safety of infusion pumps and controllers”, using B-D Plastipak 60cc Syringe and ALARIS Medical Systems® Administration Set (30910).

Trumpet and Start-Up Curves (Continued)









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

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Patents, Patented/Brevets, Brevetti, Patente, Patenten, Patenter, Patentes, 特許, 專利, 专利:
US – 4,690,673; 4,764,166; 5,096,385; 5,165,873; 5,601,445; 5,681,285; 5,713,856; 5,800,387; 5,836,910; 5,941,846; 6.269,340.
AU – 596,552; 634,811; 693,662; 703,178; 703,203; 719,254; 728,366. **CA** – 1,258,212; 1,296,092; 2,026,518; 2,029,267; 2,2125,693.
DE – P3686558.3; P690244923; 69007003T2; 69329774. **ES** – 2,154,651. **HK** – 1,006,006. **JP** – 1,816,872; 2,594,604; 7,502,678.
SG – 49,695. **TW** – NI–107963. EP0225158 (**AT**, **BE**, **CH**, **FR**, **IT**, **NL**, **SE**, **UK**). EP0649316 (**DK**). EP0422855 (**FR**, **UK**).
EP0431310 (**FR**, **UK**). Other Patents Pending

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