

## Start-Up

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

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

## Preparing Infusion

### Administration Set

The Medley™ Pump Module uses a wide variety of Medley™ System/Gemini Administration Sets. The sets are designed for use with the Pump Module as well as for gravity-flow, stand-alone use.

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

### WARNING

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

## Preparing Infusion (Continued)

### Administration Set (Continued)

#### SmartSite® Needle-Free System

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

#### NOTES:

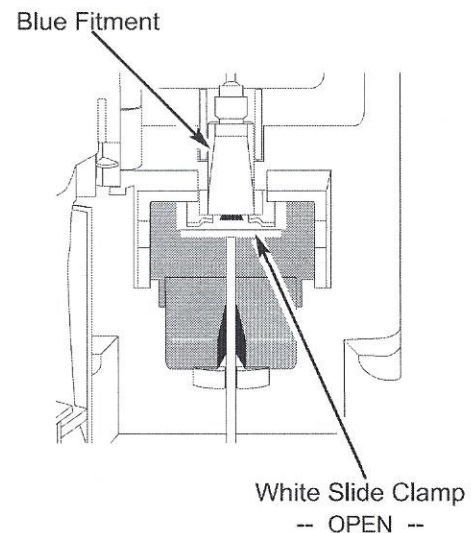
- If applicable, attach syringe to SmartSite® Needle-Free Valve Port and aspirate minute air bubbles.
- In an emergency, SmartSite® Valve may be accessed by a needle and will leak if punctured. To access port with needle without causing leakage, attach a "PRN" adapter of sufficient length to SmartSite®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

### Flo-Stop® Device

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

#### Flo-Stop® Device in Open Position

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

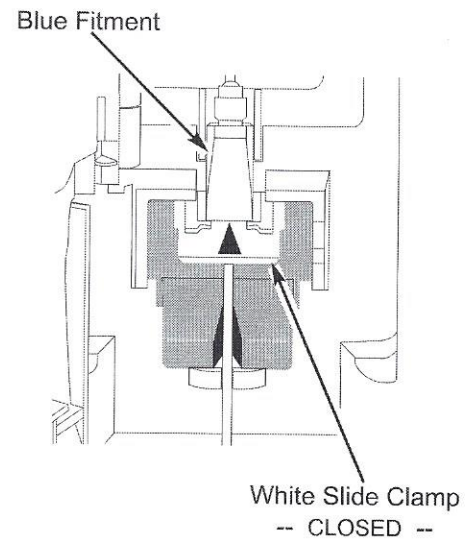


## Preparing Infusion (Continued)

### Flo-Stop® Device (Continued)

#### Flo-Stop® Device in Closed Position

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



GETTING STARTED

### Priming Primary Administration Set

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

## Preparing Infusion (Continued)

### Loading and Removing Primary Administration Set

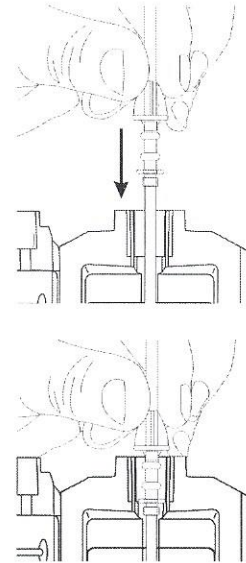
#### Loading Administration Set

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

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

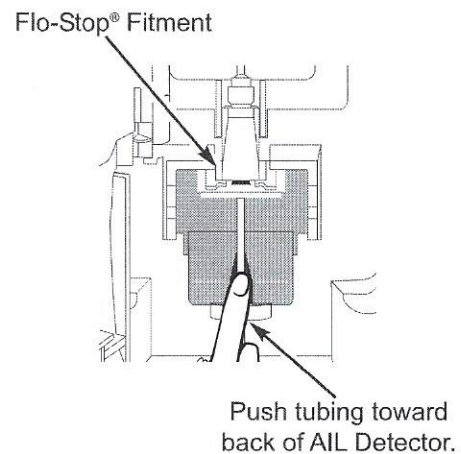
#### CAUTION

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



#### CAUTION

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

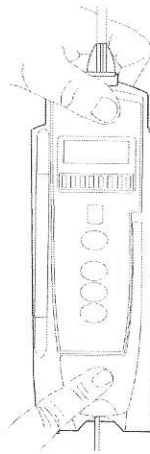


## Preparing Infusion (Continued)

### Loading and Removing Primary Administration Set (Continued)

#### Loading Administration Set (Continued)

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



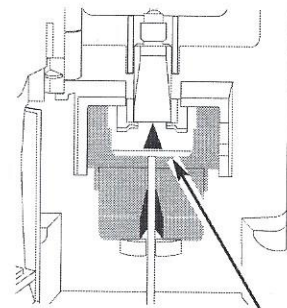
#### WARNINGS

- Do not touch the administration set while closing the door. Failure to follow this instruction may result in infusion rate inaccuracy.
- To prevent a potential free-flow condition, ensure no extraneous object (for example, bedding, tubing, glove) is enclosed or caught in the Medley™ Pump Module door.

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

#### Removing Administration Set

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



White Slide Clamp  
-- CLOSED --

## Preparing Infusion (Continued)

### Loading and Removing Primary Administration Set (Continued)

#### Removing Administration Set (Continued)

3. Remove set, as follows:
  - a. Gently pull tubing below Air-in-Line Detector forward and out.
  - b. Lift upper fitment from upper fitment receptacle.
4. If set is being removed to begin a gravity flow:
  - a. Depress blue ridged release tab on upper side of Flo-Stop® Device.
  - b. Slide white slide clamp into blue fitment (open position).
  - c. Adjust flow rate using set's roller clamp.

### Setting Up Primary Administration Set for Gravity Infusion

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