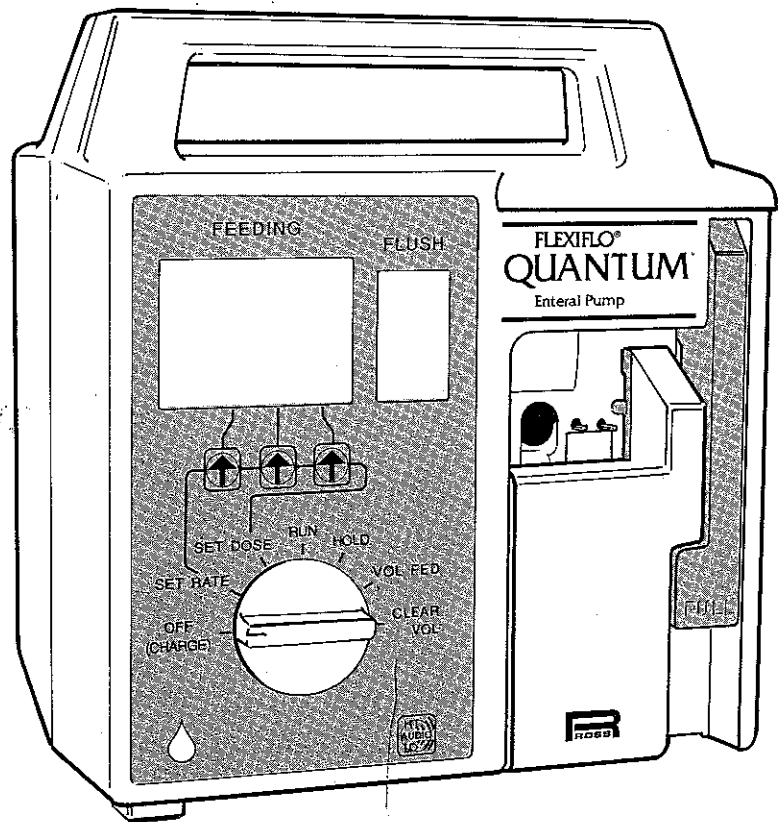


No. 50596—Purchase
No. 50598—Lease/Rent

FLEXIFLO® QUANTUM™ Enteral Pump

OPERATING MANUAL

**For Enteral Use Only
Not For Parenteral Use**



PEDIATRIC USE

Because the Flexflo® Quantum™ Pump (when FLUSH sets are used in the Optional FLUSH MODE) will deliver at least 600 mL of additional fluid (flush solution) per day of continuous feeding, **the FLUSH sets must NOT be used for feeding infants under 12 months of age. In addition, use of the FLUSH feature in all pediatric patients 12 months of age or older must be carefully evaluated:** A physician, who has training in pediatrics, must take into account the effect of this additional volume on intestinal tolerance and overall fluid balance of the individual patient and should, accordingly, determine the maximum amount of flush solution to be hung.

CAUTION

The Quantum Pump can be used on pediatric patients provided the patients can tolerate a feeding range within the pump operational specifications. Those specifications are:

- The flow rate range of the Quantum Pump is 1-300 mL/hr in 1 mL increments.
- The flow rate accuracy of the pump is $\pm 10\%$ (see page 13 of the Quantum operating manual for checking pump accuracy).
- The mean occlusion pressure limit of the Quantum Pump is 15 PSI.

If these specifications are not appropriate for a given patient, the Quantum Pump should not be used.

All enteral pumps have the potential to bolus-feed or overdeliver, which is an important consideration in feeding volume-sensitive patients. In these patients, a volume of product no more than four times the hourly feeding rate should be hung.

PRECAUTIONS

Caution should be exercised in the use of this pump in the Automatic Flush Mode for patients with volume sensitivity or fluid restriction (ie, cardiac, renal, pulmonary or pediatric patients). For such patients, the Feed Only Mode (using the system without automatic flush feature) may be desired.

NOT FOR PARENTERAL USE

Confirm proper placement and function of patients enteral feeding tube (nasogastric, jejunostomy, gastrostomy, etc). Failure to do so may result in vomiting and/or aspiration. Verify the following before initiating feeding:

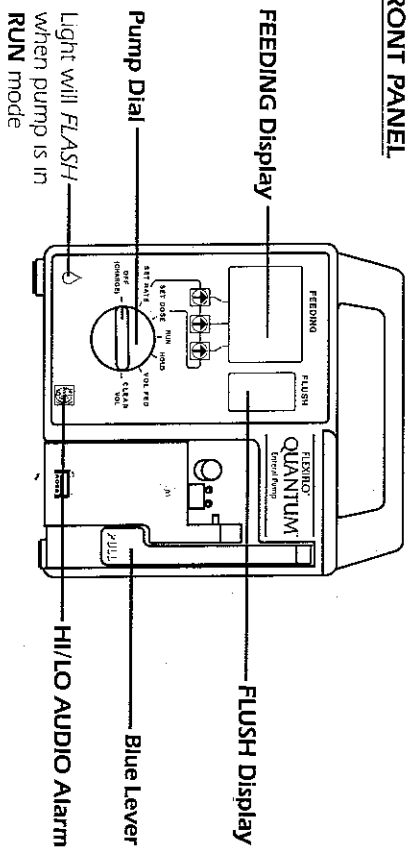
1. A Quantum Pump Set is being used.
2. Cassette is properly seated in pump and door is closed.
3. Flow rate is set at the prescribed mL/hr.
4. Before putting pump in RUN mode, be sure both line clamps are closed during setup and when the door on the pump is open. Otherwise, the fluids will mix.
5. If a pump set with flush bag is used, be sure both line clamps are closed during setup and when the door on the pump is open. Otherwise, the fluids will mix.

For optimum operation, observe the following precautions: Low level electrical emissions are commonly observed when fluids are administered using an enteral feeding pump. The emissions observed with the QUANTUM pump may create artifacts on voltage sensing equipment such as ECG, EMG, and EEG monitoring devices if the monitoring device is not operating correctly or has loose or defective connections to its sensing electrodes. These artifacts may be mistaken as actual physiologic signals, and may vary at a rate that is associated with the delivery rate set on the pump. To determine if the abnormality in the monitoring device is caused by the QUANTUM pump, set the pump so it is temporarily not delivering fluid. Disappearance of the artifact indicates it was probably caused by the pump. Proper setup and maintenance of the **monitoring device** should eliminate the artifact.

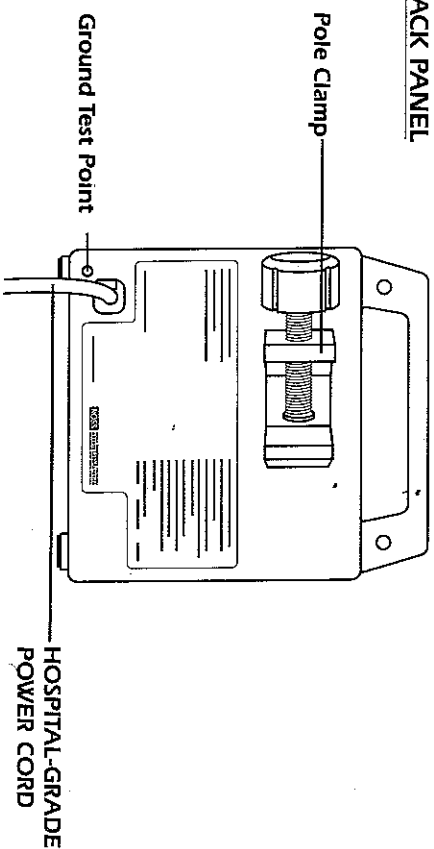
PANEL DISPLAYS

Here is a simple explanation of the panel displays. Understanding them is necessary for successful operation of the pump.

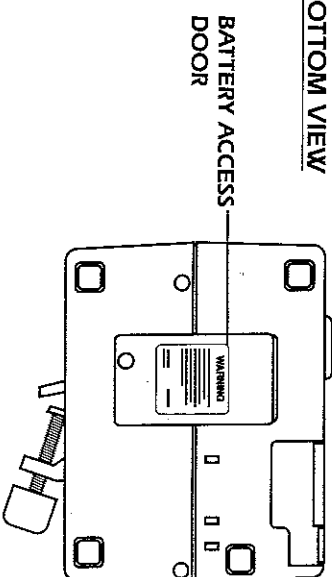
FRONT PANEL



BACK PANEL



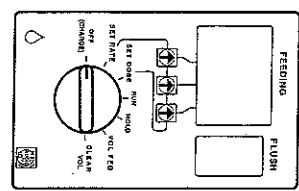
BOTTOM VIEW



CONTROL DIAL SETTINGS

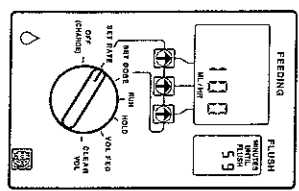
DIAL: OFF (CHARGE) **FUNCTION:**

Stops all pump functions. Battery charges in all dial settings when pump is plugged in. The pump will retain current **RATE**, **DOSE** and **VOL FED** values indefinitely unless the pump is unplugged from an AC power source while in the **OFF (CHARGE)** setting.



SET RATE

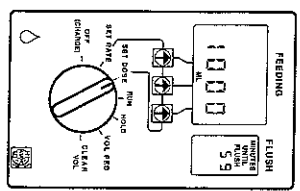
Allows flow rate to be set (1 to 300 mL/hr in 1-mL increments) by pressing the keypad arrows when the pump is in the **SET RATE** mode. Rate may be set during or after the automatic priming phase.



SET DOSE

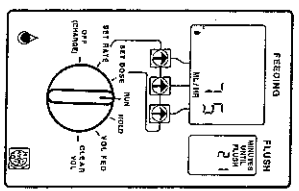
Allows dose to be limited (1 to 1999 mL for Models A, B & C and 1 to 9999 mL for Model D and higher; in 1-mL increments) by pressing the keypad arrows. Completion of this dose triggers **DOSE COMPLETE** alarm. Refer to **DOSE COMPLETE** (page 14). DOSE may also be set during the automatic priming phase.

NOTE: If zero dose is entered (0000), this feature is deactivated.



RUN

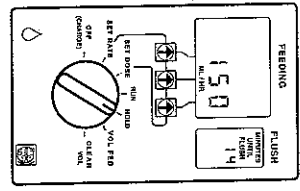
Only setting that activates feeding. Visual display shows rate of flow in mL/hr and a droplet-shaped image will move across the bottom of the visual display. Also, a small green light on lower left-hand corner of pump will flash when pump is in **RUN** mode.



CONTROL DIAL SETTINGS (continued)

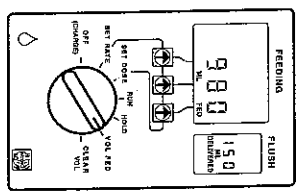
DIAL: HOLD **FUNCTION:**

Stops pumping action and audio alarms. **HOLD** is used when correcting an alarm condition or whenever temporary cessation of pumping action is desired (such as when connecting a new feeding container). If pump dial is left on **HOLD** for more than 5 minutes, an alarm will sound and the message **TURN TO RUN** will be displayed.



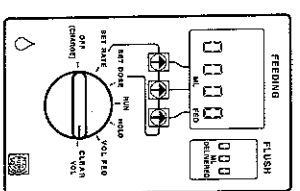
VOL FED

Stops pumping action. The **FEEDING** display will show feed volume delivered and the **FLUSH** display will show flush volume delivered. Pump accumulates feed volume delivered up to 9999 mL and flush volume up to 999 mL unless these volumes are reset to zero by turning to **CLEAR VOL** (or the pump is unplugged while in the **OFF (CHARGE)** mode). Upon exceeding the maximum feed or flush volume allowed on the display, the value turns to zero and a new accumulation begins.

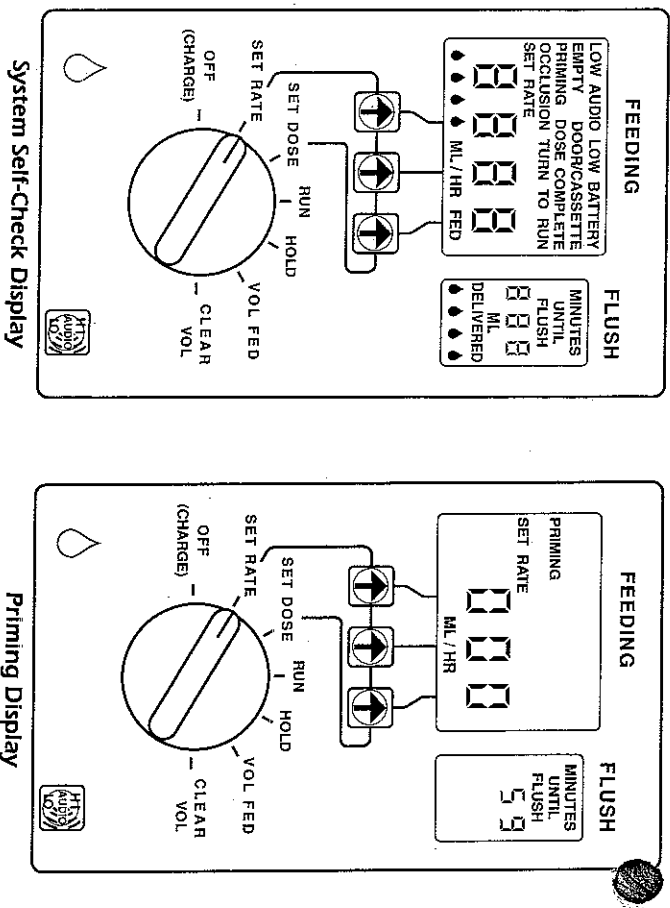


CLEAR VOL

Stops pumping action and clears to zero both the feed and flush volume fed. **NOTE:** The pump will "beep" four times before erasing volumes to alert the user that the dial has been turned to **CLEAR VOL**. The user must turn dial away from **CLEAR VOL** (to any other setting) before the fourth beep to avoid an unintentional erasure of volume total(s). **CLEAR VOL** does not work while pump is priming.



AUTOMATIC PRIME



Automatic Priming is initiated when:

Pump dial is turned from **OFF (CHARGE)** position to **SET RATE**, **SET DOSE** or **RUN** position. The system self-check on the pump is followed by automatic priming of the set. Fluid fills the tubing during this priming sequence. This fluid is not counted in **VOL FED**.

NOTE: Automatic priming expels air from the set, which may result in a small amount of fluid being expelled beyond the adapter on the feeding set. Automatic Priming does not occur in the following dial settings:

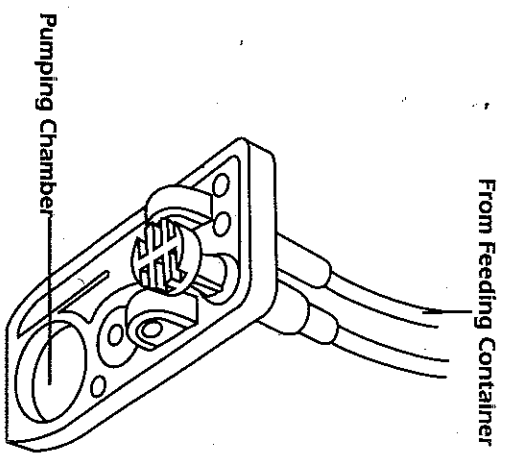
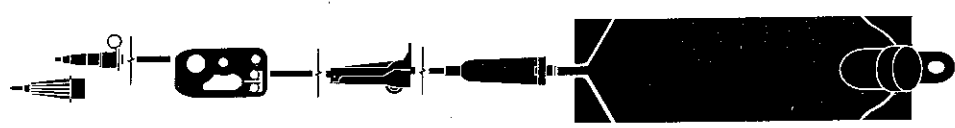
- HOLD**
- VOL FED**
- CLEAR VOL**

PUMP SETS

The Quantum Pump offers a wide choice of feeding sets with either a Pump Set (without Flush Bag [single inlet cassette] or a Pump Set With Flush Bag [dual inlet cassette]).

PUMP SET (WITHOUT FLUSH BAG) — SINGLE INLET CASSETTE

EXAMPLE SHOWN:
FLEXIFLO® Top-Fill Enteral Nutrition Bag
 With Preattached Quantum™ Pump Set

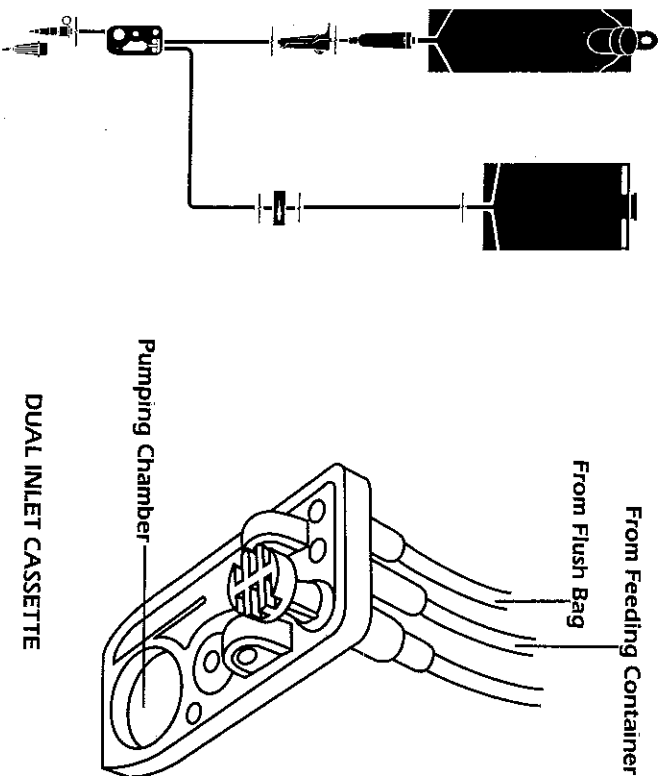


IMPORTANT REMINDER WHEN USING A PUMP SET (WITHOUT FLUSH BAG):
 ■ **FLUSH** display will be blank when a single inlet cassette is used.

PUMP SETS (continued)

PUMP SET WITH FLUSH BAG—DUAL INLET CASSETTE

EXAMPLE SHOWN:
FLEXIFLO® Top-Fill Enteral Nutrition Container
With Preattached Quantum™ Pump Set With Flush Bag



INSTRUCTIONS FOR USE

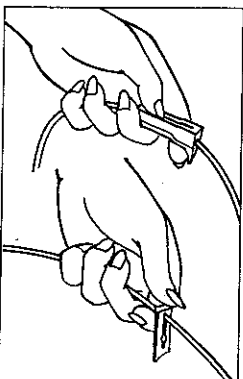
Before initial use on battery power and after extended storage periods, the pump must be plugged into an AC power source for a minimum of 8 hours (pump may be operated during this time). The pump should be operated on battery power for a minimum of 6 continuous hours at least once every 6 months for best performance and battery life. Use AC power whenever possible. Plug in during storage to assure a fully charged battery for emergencies.

⚠ DANGER: Possible explosion hazard if used in the presence of flammable anesthetics. ASSURE THAT ALL CLAMPS ON FEED AND FLUSH SETS ARE CLOSED BEFORE SETUP.

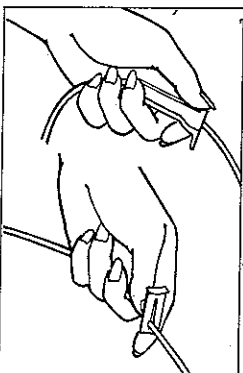
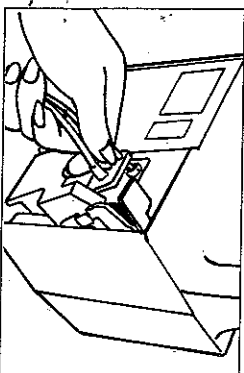
TO ASSEMBLE:

1. Attach pump to stand using pole clamp. Plug in cord if power is available. If using battery power, do not let battery run down. When the low battery message appears, the battery has approximately 30 minutes of energy left.

2. Close CALP® Clamp* (flow regulator)† on Quantum Pump feeding bag (and slide clamp on flush bag, if used).

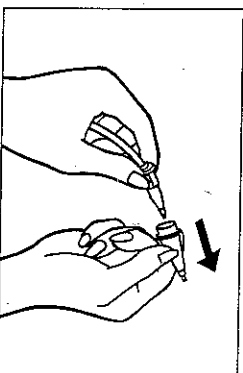


6. Fully open clamp on feeding set (and slide clamp on flush bag, if used).



TO PRIME:

7. Remove adapter cover.



3. Attach the Quantum Pump Set securely onto a filled enteral nutrition container, if it is not preattached. Suspend container to side or behind and 20 inches above pump. Squeeze sight chamber 1/3 to 1/2 full.
4. Fill flush bag with enteral flush solution (**DO NOT USE CARBONATED SOLUTIONS**). Suspend bag to side or behind and 20 inches above pump.
5. Lift blue lever on face of pump to open door. Make sure orange plunger knob is oriented to the left as you firmly seat cassette into pump cavity. Close door on pump by pushing the blue lever down.

[See illustration top of next column.]

8. Turn pump dial to **SET RATE**. Pump will initiate system self-check procedure, followed by automatic priming of the set.

[See illustration top of next page.]

IMPORTANT REMINDER WHEN USING FEED/FLUSH SETS:

- Every 60 minutes of continuous feeding **AND** before the pump alarms **EMPTY DOSE COMPLETE** or **LOW BATTERY**, 25 mL of flush solution will be delivered over 1½ minutes. Flush rate is fixed at 999 mL/hr.

NOTE: The **FLUSH** cycle will be aborted if the control knob is turned to any position other than **RUN, HOLD** or **VOL FED**.

- Assume that the clamp on the filled flush bag is open during priming. Otherwise, the pump will "decide" that a Pump Set (Without Flush Bag) is in place and the **FLUSH** display will remain blank.

- When the door on the pump is open, be sure both clamps are closed. Otherwise, the fluids will mix.

- Use of the Quantum Pump replaces the need for *routine* flushing procedures (eg, 20-30 mL of warm water every 3-4 hours during *continuous* feeding).

- Flushing with 20-30 mL of warm water (using a 30-mL or greater syringe) before and after medications is still recommended.

- If pump feeding is manually stopped or turned off, automatic flushing does not occur. If pump remains in the **OFF (CHARGE)** mode (not on **HOLD**), it is recommended to flush with 20-30 mL of warm water (using a 30-mL or greater syringe) to rinse remaining product from the feeding set.

- Additional information or action may be included in your facility's required procedures.

TROUBLE-SHOOTING

The Quantum Enteral Pump is designed to be highly reliable. As with any electro-mechanical device, however, problems may occur. The following tips will help correct minor in-service problems that may arise:

Intermittent audio alarms are accompanied by messages on the front panel indicating the cause of the alarm for all alarm conditions except **LOW AUDIO** (visual only), which indicates low alarm volume has been selected.

VISUAL DISPLAY OR PROBLEM

CORRECTIVE ACTION

OCCUSION—Flow has stopped.

- Turn dial to **HOLD**.
- Clear obstruction/check for kinked tubing or closed clamps.
- Turn dial to **RUN** to start pump.

EMPTY—Feed or flush bag empty.

- Turn dial to **HOLD**.
- Refill container(s).
- Turn dial to **RUN** to start pump.

DOSE COMPLETE—**VOL FED** is equal to the **SET DOSE**. Pump stops.

- Turn dial to **SET DOSE**.
- Press keypad arrows to increase dose OR to zero dose setting OR turn dial to **CLEAR VOL**.
- To silence alarm, turn dial to **HOLD**, then **RUN**.

SET RATE—Dial turned to **RUN** without entering rate.

- Select flow rate (l to 300 mL/hr).
- To silence alarm, turn dial to **HOLD**, then **RUN**.

TURN TO RUN—Pump dial in setting other than **RUN** or **OFF** more than 5 minutes.

- Turn the dial to **HOLD** or **RUN** to reset.

DOOR/CASSETTE—Door open, cassette not properly loaded or excess foam or air in cassette.

- Confirm cassette in place and close door.
- Manually reprime to remove foam or air from cassette.
- Replace set.
- If alarm condition persists, pump requires service.

TROUBLE-SHOOTING

(continued)

VISUAL DISPLAY OR PROBLEM

CORRECTIVE ACTION

LOW BATTERY—Pump has approximately 30 minutes of battery operation before complete shutdown. A completely blank front panel (no lights, symbols, message) indicates that the battery is depleted and the unit is not plugged into a live AC circuit.

NOTE: Complete shutdown is preceded by a continuous alarm for 1 minute.

- Plug power cord into AC outlet.
- Turn dial to **HOLD**, then **RUN**. Pump will operate normally while battery is charging.

ERR—System Malfunction.

- Must turn pump **OFF** to reset. If alarm condition persists, pump requires service.

FLUSH Display Blank with

FEED/FLUSH SET In use—

Clamp is closed on the Flush Bag or Flush Bag is empty.

- Turn pump **OFF**.
- Fill Flush Bag.
- Open clamp.
- Restart pump.