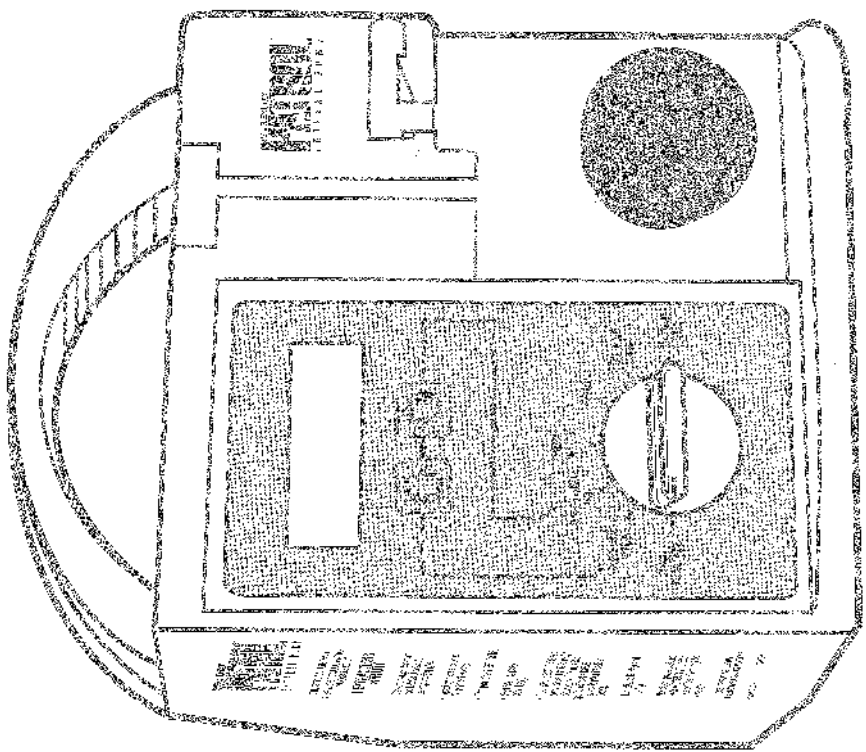


FLEXIFLO®
ENTERAL
 P U M P

OPERATING MANUAL

For Enteral Use Only
 Not For IV Use



ROSS
 MEDICAL
 NUTRITIONAL
 SYSTEM®

ROSS PRODUCTS DIVISION
 ABBOTT LABORATORIES INC.
 COLUMBUS, OHIO 43215-4724 USA

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LIMITED WARRANTY PLAN

Ross Products Division of Abbott Laboratories warrants the Flexiflow Patrol® Enteral Pump against defects in material and workmanship for a one (1) year period from date of delivery. This warranty is valid only to the original purchaser and does not extend to any product or part thereof, which has been subjected to accident, alteration, damage, misuse, repair by other than Ross authorized representatives, or has not been operated and maintained in the manner prescribed in the Operating Manual or which at the time of pump failure was being used with pump sets or containers other than Ross pump sets and containers. Examples of damage or misuse include, but are not limited to, pumps that have been dropped, have had fluid spilled into or onto the casing or have been submerged.

In no event shall Ross be liable for any incidental, indirect or consequential damages in conjunction with the purchase or use of the pump, even if advised of the possibility of the same.

Ross reserves the right to repair or replace (at its option) any pump that fails to meet the foregoing warranty.

THE WARRANTIES HEREUNDER ARE IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING, WITHOUT LIMITATION, THE WARRANTIES OF MERCHANTABILITY AND OF FITNESS FOR A PARTICULAR PURPOSE.

NOTE:

When repairs on the unit are made under warranty because of faulty material or workmanship within one year from the date of delivery to the customer, the customer will not be billed for parts repaired or replaced. Also, the customer will not be charged for labor involved in connection with the installation of such parts furnished under warranty.

Shipping costs for units returned to Ross, including insurance, shall be paid by the customer. The units should be promptly returned, properly packaged. Loss or damage in return shipment to Ross shall be at the customer's risk. Ross authorization should be obtained to return the unit.

PUMP CHARACTERISTICS

The Flexflo® Patrol® Enteral Pump is a microprocessor- (computer) controlled, rotary peristaltic pump that provides for accurate, controlled enteral feeding in a safe, user-friendly system. It has a large, easy-to-read display and simple controls. The Patrol Pump uses a specially designed feeding set, which includes a hose-prevention feature to provide safe, accurate control of enteral feeding.

PRECAUTION: This pump is designed to deliver liquid enteral feeding products only (standard liquid products, infant formulas, or reconstituted powder products that have been thoroughly mixed into solution).

The Flexflo Patrol Pump offers these features:

1. Alarms for free-flow
2. Flowrate selection from 1 to 300 mL/hr in 1 mL/hr increments
3. Accuracy to $\pm 1.0\%$ or ± 0.5 mL/hr, whichever is greater (refer to CHECKING PUMP ACCURACY, page 12)
4. Dose setting
5. Volume feed accumulator
6. 8-hour battery operation at 125 mL/hr, when fully charged
7. Alarms:
 - **FREE FLOW** (free flow)
 - **NO FLOW** (no flow)
 - **DOSE FEED** (dose feed)
 - **LOW BATTERY** (low battery)
 - **SET RATE** (invalid rate, select rate)
 - **SET RUN** (inactive, select run)
 - **E1 TO E9** (failed pump select)
8. Programmable **HOLD** timer
9. Lock-out feature
10. System self-check
11. User-friendly operating controls
12. Simple set up
13. Memory -Automatic retention of the following values until turned off and disconnected from AC power:
 - **VOL FEED** (volume accumulator)
 - **DATE**
 - **DOSE**

SPECIFICATIONS

Power
Voltage: 100 to 150 VAC, 60 Hz, 1-phase
Power: 1.5 watts, average
Hose: 200 mL, break-delay type
Line Cord: Hospital-grade, non-detachable (10 feet)
Leakage: Less than 100 microns

Mechanical
Height: 8.5 inches
Width: 6.5 inches
Depth: 4.6 inches
Weight: 6.6 lbs

Operational Specifications - Flow Rates

Range: 1 - 300 mL/hr
Increments: 1 mL/hr
Accuracy: $\pm 1.0\%$ or ± 0.5 mL/hr, whichever is greater (refer to CHECKING PUMP ACCURACY, page 12)
Pressure: Pumps against 18 psi nominal back pressure before no FLO alarm. Refer to PATROL MAINTENANCE AND REPAIR MANUAL for test procedure.

Battery Operation

Type: Rechargeable sealed-lead acid
Voltage: 6 V; the pump will fully recharge in a maximum of 4.5 hours while pump is off, or 12 hours if the pump is operating.
Expected life: When fully charged, 8 hours at 125 mL/hr

Standards

Designed and manufactured to meet requirements of UL 544.

STORAGE

- The pump should be stored away from excessive heat, cold or humidity.
- Be sure pump dial is in the OFF position.

SERVICE

- The Patrol® Enteral Pump is designed to be highly reliable. As with any electro-mechanical device, however, minor problems may occur. In the event of a pump malfunction, need for technical assistance or parts, please contact Ross Products Division, Abbott Laboratories.
- OPERATING INSTRUCTION VIDEOTAPE
An instructional videotape in VHS format assists caregivers and medical professionals in learning procedures for operating the FLEXIFLO® Patrol® Enteral Delivery System. This videotape is available for your use through a Ross Representative.

INDICATIONS FOR USE

The Flexiflo® Patrol® Pump can be used for adult and pediatric patients provided the patients can tolerate a feeding range within the pump operational specifications. Those specifications are:

- The flow rate range is 1-300 ml/hr in 1 ml/hr increments.
- The flow rate accuracy is $\pm 1.0\%$, or ± 0.5 ml/hr, whichever is greater.
- Pumps against 150ml nominal back pressure before the FLO alarm.

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

PRECAUTIONS

▪ 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.

NOTE: Do not rely on free-flow alarm as a criterion for use with volume-sensitive patients.

▪ NOT FOR IV USE

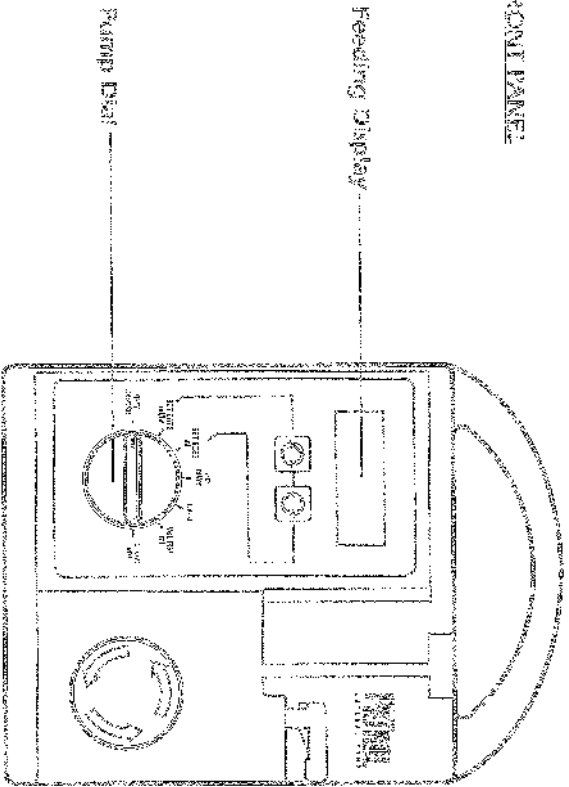
- Confirm proper placement and function of patient's enteral feeding tube (nasogastric, nasojejunal, gastrostomy, etc). Failure to do so may result in vomiting and/or aspiration. Verify the following before initiating feeding:
 1. Only a Flexiflo® Patrol® Pump Set is being used.
 2. Pump set tubing is properly stretched counterclockwise under red and blue connector is secured in the pump.
 3. If the feeding set is damaged in any way (eg, broken, cut, torn, parts separated), replace the set immediately.
 4. Flow rate is set at the prescribed ml/hr (refer to page 7 **USUAL SET RATE**).

Pump set and container should be replaced as needed, or at least every 24 hours, to avoid fluid-contamination problems. For single-patient use only.

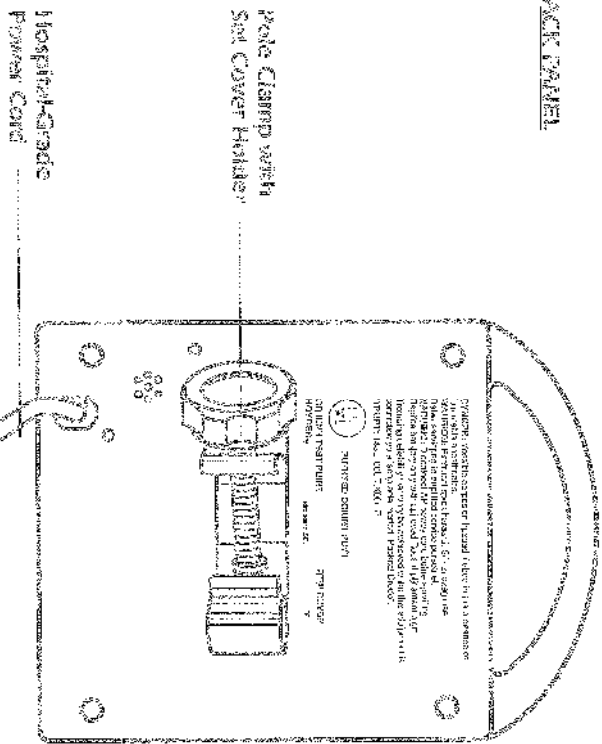
PANEL DISPLAYS

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

FRONT PANEL



BACK PANEL



CLEANING

There are no routine calibration or adjustment procedures required with the Patient Pump. All servicing or adjustments should be referred to qualified technical personnel (refer to Service Manual). For routine operation, check the pump daily and clean immediately after spills occur. **When cleaning, pump should be turned off and unplugged. Do not immerse, submerge, heat, steam, ETO or radiation sterilize the pump.**

THE PUMP CAN BE CLEANED AS FOLLOWS:

HOUSING:

- * Do not spray water or cleaning solution into pump.
- * Clean outside surface only. Use soft cloth and warm, soapy water.
- * For general cleaning, use disinfecting detergent (nonchlorinated) or (propyl) alcohol.
- * For general disinfecting, use 70% concentration (propyl) alcohol.
- * For disinfecting after exposure to AIDS or hepatitis, use 10% concentration of 5.25% sodium hypochlorite (household bleach). This solution may discolor the pole clamp. After exposure to tuberculosis, use 70% concentration (propyl) alcohol. These recommendations are not substitutes for official procedures that may differ among institutions.

DROP DETECTOR:

- * Clean the drop sensors with a soft brush, soft lint-free cloth or cotton swab and warm, soapy water. Then rinse the drop sensors with cotton wash and warm water. Be sure no soapy film or residue is left on lenses. **Dry thoroughly. DO NOT CLEAN WITH ALCOHOL.**

ROTOR ASSEMBLY:

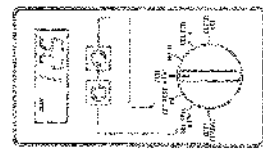
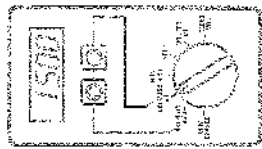
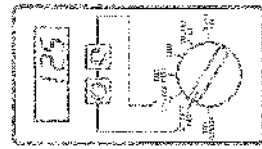
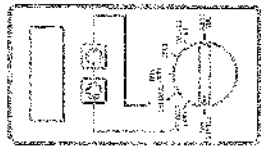
- * Clean the pump with a soft lint-free cloth to avoid damaging the surface. Be especially careful with the operator's panel and drop detector area. If necessary, mild warm, soapy water may be used sparingly. Avoid the use of all strong solvents or cleaners as these will damage the pump.
- * Detach the pump rotor from the pump by loosening the Allen screw. The pump rotor can then be immersed in mild, warm, soapy water or detergent and rinsed under a faucet. Dry excessive moisture from the pump rotor before reassembly.
- * After cleaning, plug the pump into an AC grounded electrical outlet to maintain factory charge.

TROUBLE-SHOOTING (continued)

CONTROL DIAL SETTINGS

CONDITION OR PROBLEM	VISUAL DISPLAY	EXPLANATION OR CORRECTIVE ACTION
HOLD time-out	SEL H00	Turn dial to RUN
Electronics error	E1 - E9	Remove pump from patient immediately and contact Ross
Approximately 30 minutes of battery operation remain	LO bat	<ul style="list-style-type: none"> Turn dial to HOLD, then RUN. Plug power cord into AC outlet for 12 hours, then continue feeding NOTE: After 30 minutes, pump alarms continuously for one minute and then shuts down
HOLD countdown	H5	<ul style="list-style-type: none"> Turn dial to HOLD. If desired, program the HOLD timer for 1 - 90 minutes by depressing the up or down arrow.
Lock-out disables SET RATE, SET DOSE and CLEAR VOL. dial settings	LOC	<ul style="list-style-type: none"> Turn dial to SET RATE. Depress up and down arrows simultaneously to deactivate. Repeat steps to activate.
Display test	8888	All segments should be illuminated.

DIAL	FUNCTION
OFF/CHARGE	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	<p>Allows flow rate to be set (1 to 300 ml/hr in 1-ml/hr increments) by pressing the keypad arrows when the pump is in the SET RATE mode. The up arrow increases the rate. The down-arrow decreases the rate.</p> <p>NOTE: The LOC feature may be activated by depressing both arrows simultaneously when the dial is in the SET RATE position. Repeat procedure to deactivate. The SET RATE, SET DOSE, and CLEAR VOL. values cannot be changed while the LOC feature is activated.</p>
SET DOSE	<p>Allows dose to be limited (1 to 9999 mL in 1-ml increments) by pressing the keypad arrows when the pump is in the SET DOSE mode. The up-arrow increases the dose. The down-arrow decreases the dose.</p> <p>Completion of this dose triggers the DOSE FED alarm. Refer to DOSE FED (page 14)</p> <p>NOTE: Pump will operate without a DOSE selected (SET DOSE at 0000).</p>
RUN	<p>Only setting that activates feeding. Visual display shows rate of flow in ml/hr and the dash on the left side of the display scrolls from top to bottom when pump is in RUN mode</p> <p>NOTE: It is normal for motor movement to be intermittent (eg. starts, stops, starts, stops, etc) while in the RUN mode. This intermittent movement regulates the rate of flow, conserves battery life and does not affect the accuracy of the pump. The RUN mode should always be verified by the top to bottom scrolling bars on the left side of the display window.</p>



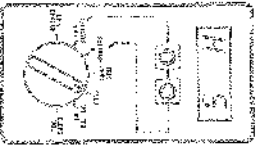
CONTROL DIAL SETTINGS (continued)

HALT

FUNCTION

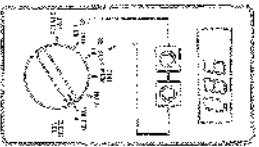
Stops pumping action and audio alarms. **HALT** is used when correcting an alarm condition or whenever pumping action is temporarily interrupted (such as when unclogging a new feeding container). If pump is left on **HALT** for more than 5 minutes, an alarm will sound and the message **SEE ME!** (select **RUN**) will be displayed.

NOTE: The **HALT** timer may be programmed for a duration of 1–90 minutes (in 1 minute intervals) by depressing the keypad arrows either up or down when the dial is in the **HALT** position.



VOL FEED

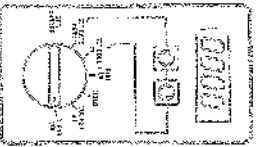
Stops pumping action. The display will show the volume delivered. Pump accumulates volume delivered up to 9999 mL unless the volume is reset to zero by turning to **CLEAR VOL** (or the pump is unclogged while in the **OFF CHARGE** mode). Upon exceeding the maximum volume allowed on the display, the value turns to zero and a new accumulation begins. This is not accompanied by an alarm.



CLEAR VOL

Stops pumping action and resets the volume fed to zero.

NOTE: The pump will “beep” four times before clearing the volume to alert users 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 loss of accumulated volume.



TROUBLESHOOTING

The FlexFlow Pump or Oral Pump is designed to be highly reliable. As with any electromechanical device, however, problems may occur. Intermittent audio alarms are accompanied by messages on the front panel indicating the cause of the alarm for all alarm conditions. The following tips will help correct problems that may arise:

CONDITION OR PROBLEM	VISUAL DISPLAY	EXPLANATION OR CORRECTIVE ACTION
Flow has stopped due to activation of empty container	NO FLOW	<ul style="list-style-type: none"> ▶ Turn dial to HALT. ▶ Clear obstruction/check for kinked tubing or empty container. ▶ Be sure sight chamber is not overfilled or covered with a film of product. ▶ Turn dial to RUN to start pump.
Dose complete – VOL FEED is equal to the SET DOSE	DOSE FEED	<ul style="list-style-type: none"> ▶ Turn dial to HALT. ▶ Turn dial to SET DOSE and depress up arrow to increase dose. OR - depress down arrow to zero the dose setting. OR - turn dial to CLEAR VOL (after four beeps, volume fed will be cleared). ▶ Turn dial to RUN to start pump.
Free-flow alarm	FREE FLOW	<ul style="list-style-type: none"> ▶ Remove from service immediately. ▶ Verify pump set is properly installed. Replace set if necessary. ▶ Confirm no drops fall when in HALT. ▶ Check accuracy per page 12.

Dial turned to **RUN** without selecting a rate

SEE RATE

- ▶ Turn dial to **SET RATE**.
- ▶ Enter a rate using the up or down arrows.

CHECKING PUMP ACCURACY

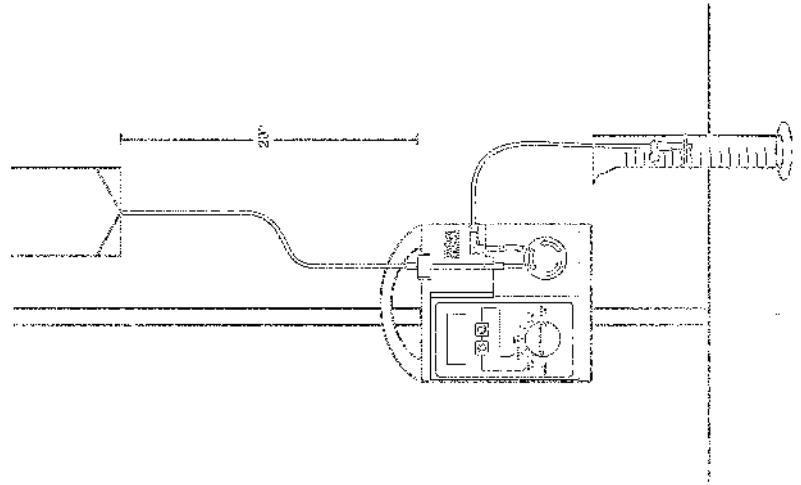
Fluid head height and viscosity are two variables that can affect flow rate. To check flow rate, use the following procedure:

Select a **new pump set for this test**. Be sure to use a graduated cylinder for volume measurement, not an enteral container or other uncalibrated vessel. Using Ensure® Complete, Balanced Nutrition™, Osmolite® Isotonic Liquid Nutrition or tap water, fill the feeding container and set up pump according to instructions. Suspend bag to side or behind and 20 inches above pump (see illustration). With the test pump connected to AC power, start the pump and let it run for 15 minutes. Then run fluid into the graduated cylinder for 30 minutes and compare to **SET RATE** on pump.

**Amount Expended in Graduated Cylinder
@ 30 minutes**

76 mL/hr	≈	34.2 mL to 41.8 mL
150 mL/hr	=	67.5 mL to 82.5 mL

If amount in graduated cylinder is incorrect based on **SET RATE**, try a new pump set and repeat procedure.

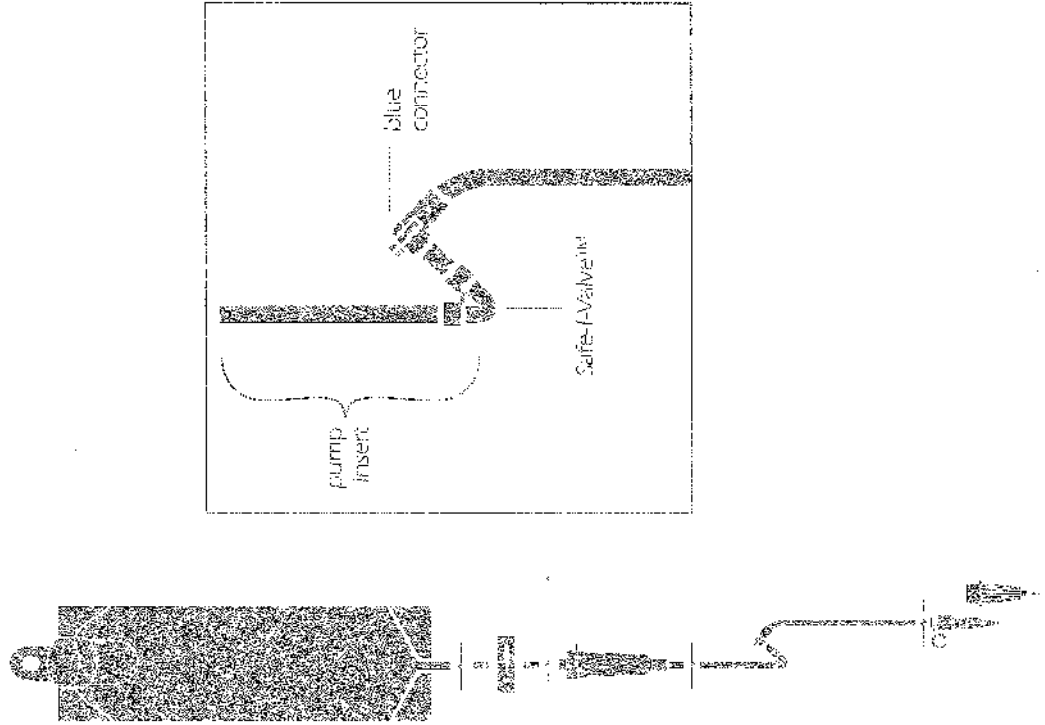


PUMP SETS

The Flexflo® Pump® Pump offers a wide choice of feeding sets.

PUMP SET EXAMPLE SHOWN:

FLEXFLO® Top-Fill Enteral Nutrition Bag
With Freatchanged Parvole® Pump Set



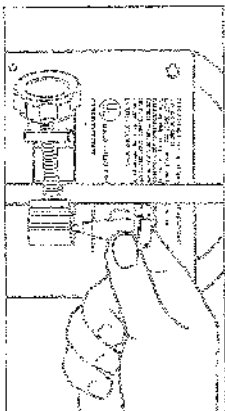
INSTRUCTIONS FOR USE

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 12 hours (pump may be operated during this time). Use AC power whenever possible. Plug in during storage to assure a fully charged battery for emergencies.

WARNING: Possible explosion hazard if used in the presence of flammable anesthetics.

TO ASSEMBLE:

1. Attach pump to sterna 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 (LOW BATT) appears, the battery has approximately 30 minutes of energy left for pump operation.*
2. Complete self-adhesive delivery label and stick to bag.*
3. Attach the Paricle® Pump Set securely onto a filled external musthion container. If it is not pre-attached. Suspend container 20 inches above and to the side or behind pump.
4. Place sight chamber into drop detector and seat in place before priming.



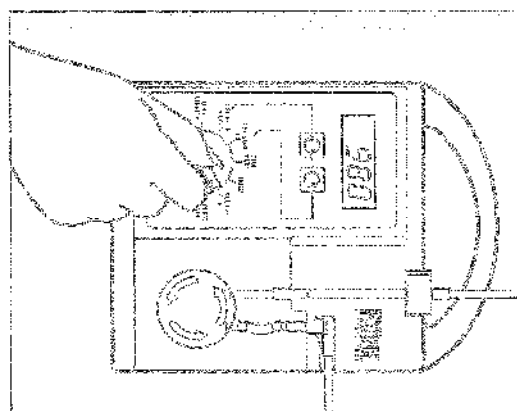
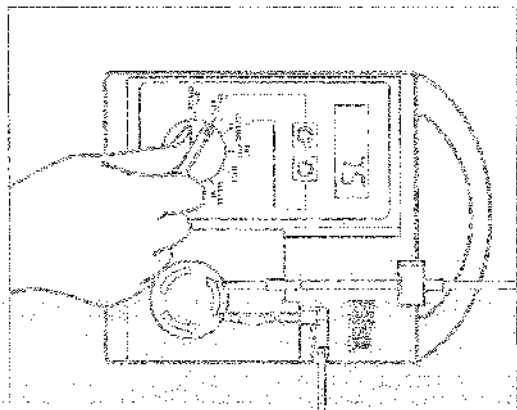
5. Remove cover from adapter and discard or place into set cover holder on the pump pole clamp.

*Product is not used in bedside. It is advised to clear side chairs before unspooling. Make sure side chairs are clear to set-up.

TO PRIME SET:

6. With one hand on the blue connector of the pump set, gently pull until fluid flows.
7. Completely prime the set by allowing fluid to expel air from the tubing.
8. Let fluid slowly enter sight chamber to fill line (1/4 full). **NOTE:** If sight chamber is filled above the line after priming (overfilled), invert container, holding all tubing above sight chamber and container with one hand on the sight chamber and the other hand on the blue connector. Gently pull until fluid drains from tubing. Suspend container and reprime.
9. Grasp the blue connector on the pump insert. Loop the pump insert under the rotor (counter-clockwise).
10. Gently pull up and then seat the blue connector in the slot above the rotor.
11. Confirm proper placement and function of external feeding tube.
12. Attach feeding set adapter to external feeding tube. **NOTE:** If adapter is used with cover in place, assure that set is connected **snugly** to an external feeding tube (eg. needle-connector [ejunostomy]).

INSTRUCTIONS FOR USE (continued)



TO START FEEDING:

13. Turn pump dial to **SET RATE**. Pump will initiate system self-check procedure.
14. Select flow rate from 1 to 300 mL/hr by pressing the arrow and observing the entry on the display. Holding down an arrow will center the numbers to scroll. Never use sharp objects such as pens, pencils, fingernails or paper clips to depress the keypad arrows.
15. If desired, turn dial to **SET DOSE** and adjust dose by pressing the arrows. **NOTE:** Pump will operate without a DOSE selection (SET DOSE at 0/000).
16. Turn dial to **RUN** to start feeding.
17. To see feeding volume delivered, turn dial to **VOL. FED.**
18. To clear the volume delivered, turn dial to **CLEAR VOL.** (This occurs after four beeps.)
19. When feeding is complete, turn pump dial to **OFF**. **NOTE:** If alarm sounds, turn pump dial to **WORLD**. Correct alarm condition indicated by visual display. Then turn dial to **RUN** to restart feeding. (For explanation of alarms, see pages 13 and 14.)

PRECAUTION: The pump set and container should be replaced as needed, or at least every 24 hours, to avoid fluid-contaminated problems for single-patient use only. Do not store for prolonged periods at extreme temperatures.