FLEXIFLO® QUANTUM™
Enteral Pump

OPERATING MANUAL

For Enteral Use Only
Not For Parenteral Use

ROSS
MEDICAL
NUTRITIONAL
SYSTEM®
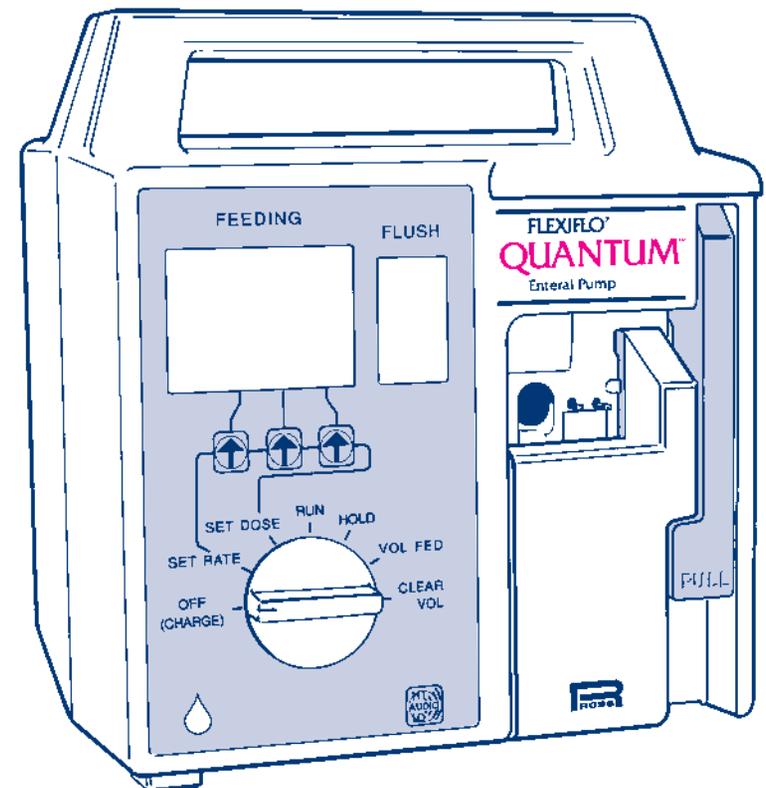
ROSS
ROSS PRODUCTS DIVISION
ABBOTT LABORATORIES INC.
COLUMBUS, OHIO 43215-1724

Rev. 1/97

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USER QUALIFICATIONS

The Flexiflo Quantum Enteral Pump is for use at the direction of or under the supervision of licensed physicians, and by licensed or certified health care professionals who are trained in the use of the pump and the administration of enteral fluids.

PUMP CHARACTERISTICS

The FLEXIFLO® QUANTUM™ Enteral Pump is a microprocessor-(computer-) controlled pump that provides for accurate, controlled enteral feeding in a safe, user-friendly system. The Quantum Pump is a volumetric pump that uses a specially designed feeding set, which includes a cassette that delivers measured amounts of enteral product. As an optional feature, the Quantum Pump will flush the feeding set and indwelling feeding tube each hour with a 25-mL flush.

PRECAUTION: This pump is designed to deliver only a liquid enteral feeding product (standard liquid product, infant formula or reconstituted powder product that has been thoroughly mixed into solution).

The Quantum Pump offers these features:
1. Automatic priming (no manual priming is necessary)
2. Automatic flush feature
3. Dose setting
4. Protection against overdelivery:
   - Motor speed is continuously monitored
   - Senses malfunctions that could result in gravity flow
5. Volume-fed accumulation displays for enteral product and flush solution
6. Flow-rate selection from 1 to 300 mL/hr in 1 mL/hr increments
7. Accuracy to ± 10% (refer to CHECKING PUMP ACCURACY, page 13)
8. 8-hour battery operation at 125 mL/hr, when fully charged
9. Alarms:
   - OCCLUSION
   - EMPTY
   - DOSE COMPLETE
   - TURN TO RUN
   - LOW BATTERY
   - DOOR/CASSETTE
   - SET RATE
10. System self-check
11. Adjustable alarm volume
12. User-friendly operating controls
13. Simple setup (one-hand cassette loading)
14. Memory—Automatic retention of the following values until turned off and disconnected from AC power:
    - **FEED** and **FLUSH** volume accumulations **(VOL FED)**
    - **SET RATE**
    - **SET DOSE** values

PEDIATRIC USE

Because the Flexiflo® 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 on 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 ± 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 patient's enteral feeding tube (nasogastric, jejunostomy, gastrostomy, etc). Failure to do so may result in vomiting and/or aspiration. Verify the following before initiating feeding:
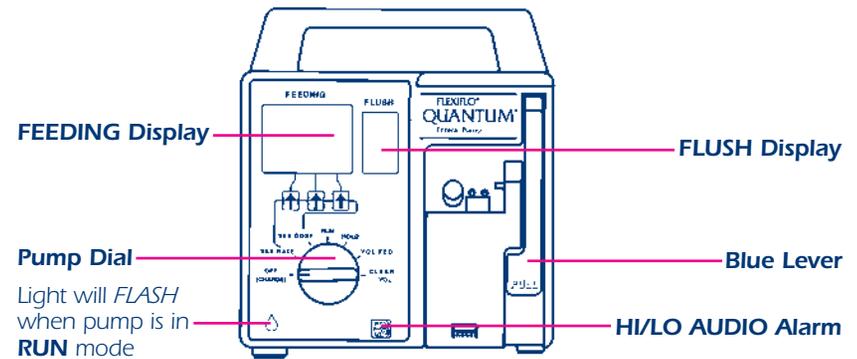1. A Quantum Pump Set is being used.
2. Cassette is properly seated in pump and door is closed.
3. Flow rate is set at the prescribed mL/hr.
4. Before putting pump in RUN mode, be sure line clamps are fully open.
5. If a pump set with flush bag is used, be sure both line clamps are closed during setup 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.
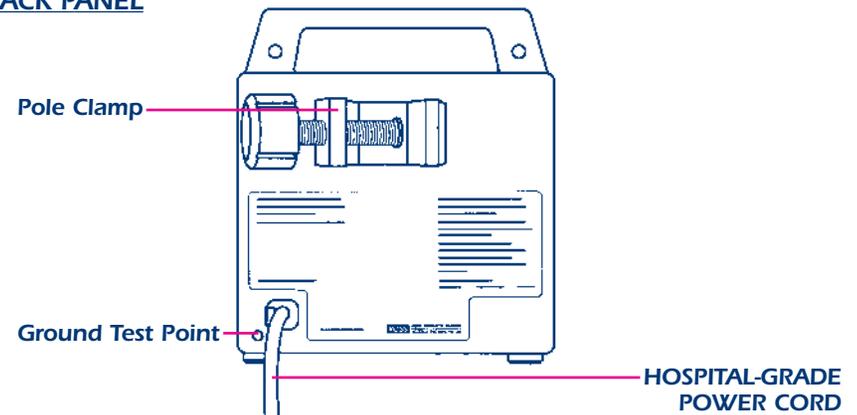
PANEL DISPLAYS

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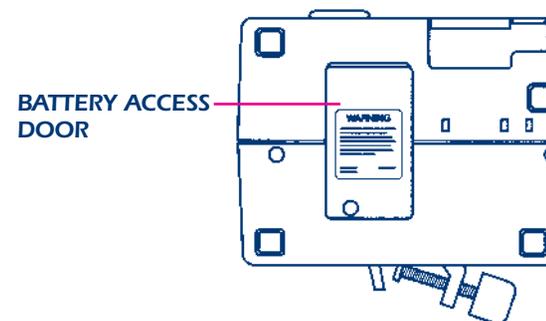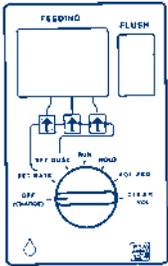
FRONT PANEL

FEEDING Display
FLUSH Display
Pump Dial
Blue Lever
Light will *FLASH* when pump is in **RUN** mode
HI/LO AUDIO Alarm

BACK PANEL

Pole Clamp
Ground Test Point
HOSPITAL-GRADE POWER CORD

BOTTOM VIEW

BATTERY ACCESS DOOR
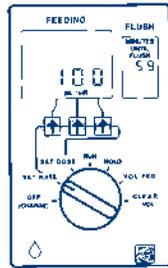
CONTROL DIAL SETTINGS

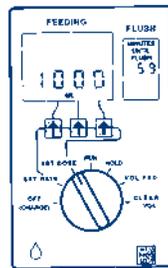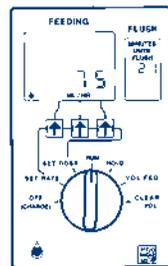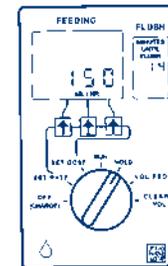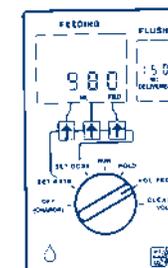| DIAL:	FUNCTION:
OFF (CHARGE)	Stops all pump functions. Battery charges in all dial settings when pump is plugged in. The pump will retain current **RATE, DOSE** and **VOL FED** values indefinitely *unless* the pump is unplugged from an AC power source while in the **OFF (CHARGE)** setting.
SET RATE	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)
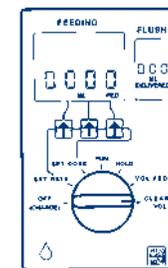
| DIAL:	FUNCTION:
HOLD	Stops pumping action and audio alarms. **HOLD** is used when correcting an alarm condition or whenever temporary cessation of pumping action is desired (such as when connecting a new feeding container). If pump dial is left on **HOLD** for more than 5 minutes, an alarm will sound 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
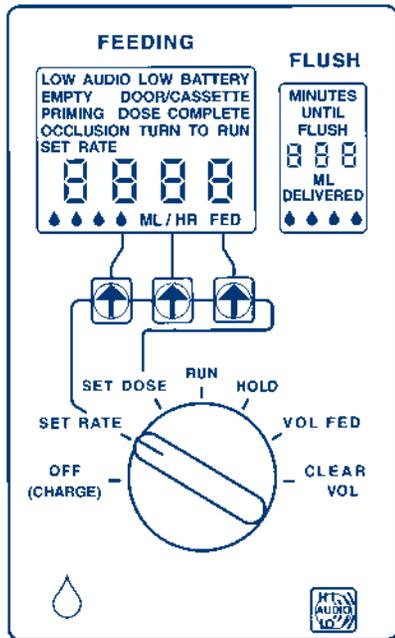
System Self-Check Display
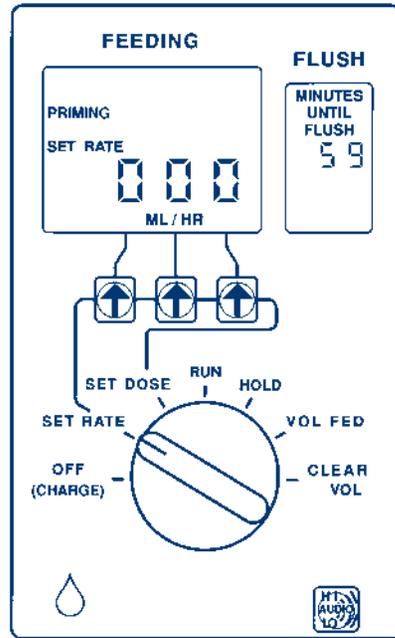
Priming Display

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 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

From Feeding Container

Pumping Chamber

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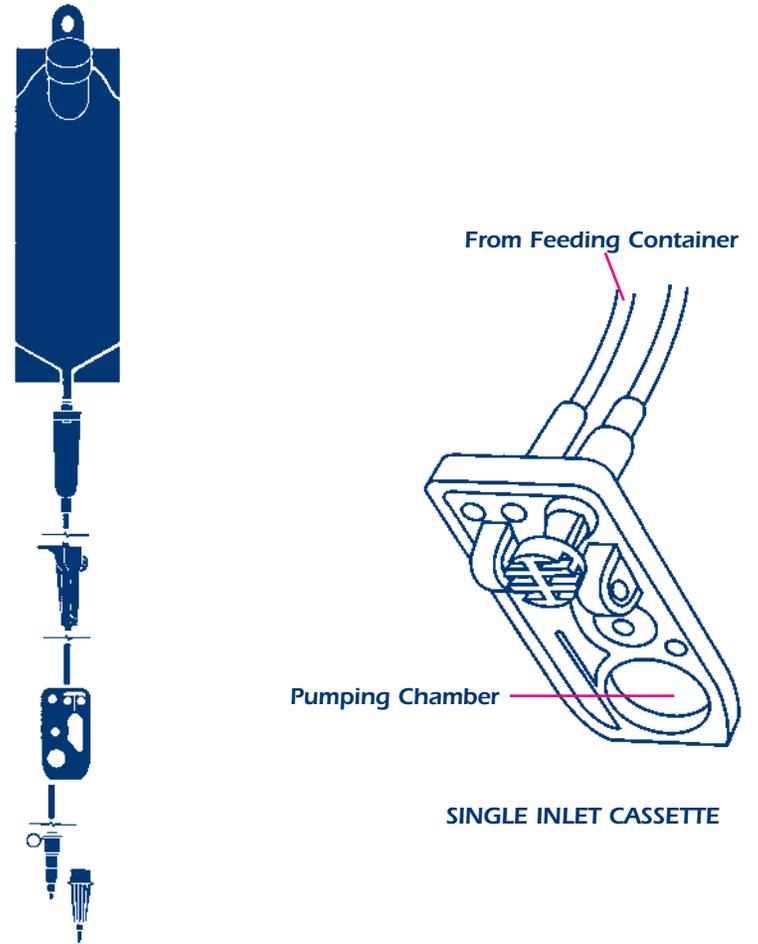
IMPORTANT REMINDER WHEN USING A PUMP SET (WITHOUT FLUSH BAG):
▪ **FLUSH** display will be blank when a single inlet cassette is used.

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

From Feeding Container
From Flush Bag

Pumping Chamber

DUAL INLET CASSETTE

IMPORTANT REMINDER WHEN USING FEED/FLUSH SETS:

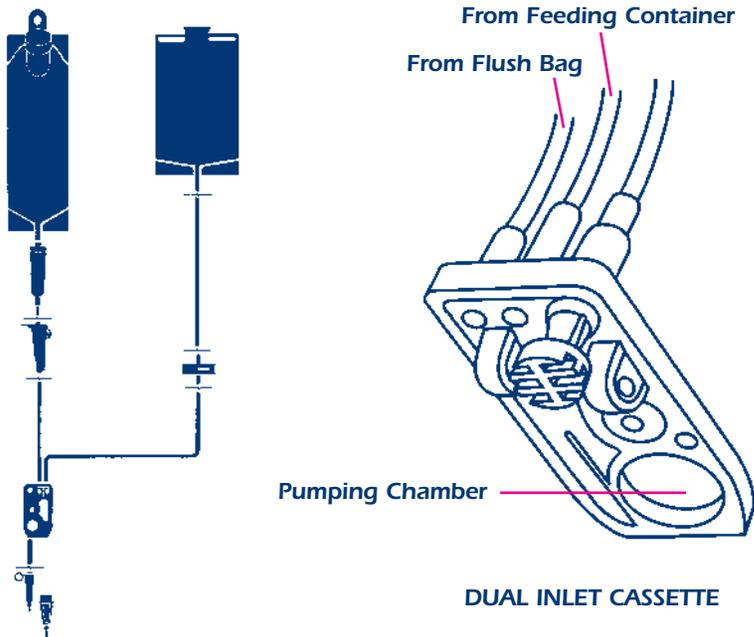- Every 60 minutes of continuous feeding *AND* before the pump alarms **EMPTY**, **DOSE COMPLETE** or **LOW BATTERY**, 25 mL of flush solution will be delivered over 1½ minutes. Flush rate is fixed at 999 mL/hr.
  NOTE: The **FLUSH** cycle will be aborted if the control knob is turned to any position other than **RUN, HOLD** or **VOL FED.**
- Assure 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.
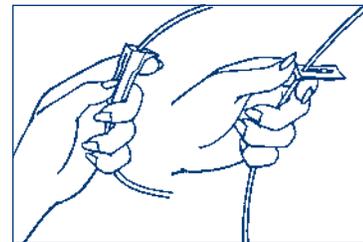
INSTRUCTIONS FOR USE

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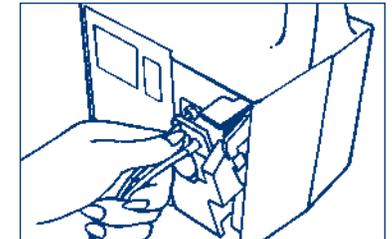
DANGER: Possible explosion hazard if used in the presence of flammable anesthetics.
ASSURE THAT ALL CLAMPS ON FEED AND FLUSH SETS ARE CLOSED BEFORE SETUP.
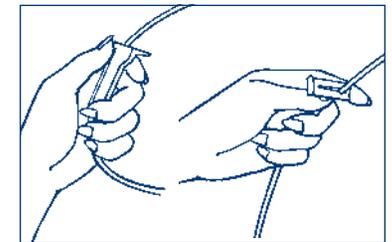
TO ASSEMBLE:

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 CAIR® 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).

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 ⅓ to ½ 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.

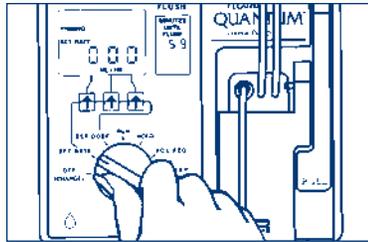(See illustration top of next column.)

TO PRIME:

**Pump automatically primes**

7. **Remove adapter cover.**

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.)

INSTRUCTIONS FOR USE (continued)

NOTE: Automatic priming expels air from the set, which results in a small amount of fluid being expelled beyond the adapter.

9. Confirm proper placement and function of enteral feeding tube.

10. Attach adapter to enteral feeding tube.

11. Select flow rate, from 1 to 300 mL/hr, by pressing individual arrows. Never use sharp objects such as pens, pencils, fingernails or paper clips to depress the keypad arrows.

12. If desired, turn dial to **SET DOSE** and select dose by pressing individual arrows.
   NOTE: If zero dose is entered (0000), this feature is deactivated.

13. Turn dial to **RUN** to start feeding.

14. To see feeding volume delivered (and flush volume delivered, if this feature is used), turn dial to **VOL FED.**
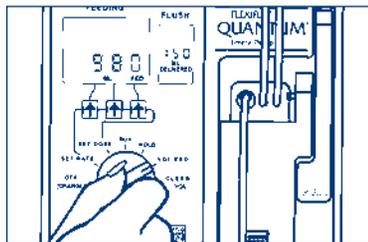

15. To clear the feeding and flush volume delivered, turn dial to **CLEAR VOL.** (This occurs after four beeps.)
   NOTE: If alarm sounds, turn pump dial to **HOLD.** Correct alarm condition indicated by visual display, then turn pump dial to **RUN** to restart feeding. (For explanation of alarms, see pages 14-15.)

16. When desired, disconnect pump-set tubing from patient's enteral feeding tube. Close clamp on feeding bag (and flush bag, if used). Lift blue lever on face of pump, remove cassette and discard set and container.

17. When feeding is complete, turn pump dial to **OFF.**
   NOTE: Pump stops and sounds an alarm automatically when the container is empty. If the DOSE function is in use, the pump will stop, sound the alarm and display the **DOSE COMPLETE** message when the selected dose is reached.
   PRECAUTION: The pump set and container should be replaced as needed, or at least every 24 hours, to avoid product-contamination problems. For single-patient use only.

TO GRAVITY FEED OR MANUALLY PRIME:

1. Completely close CAIR® clamp (and slide clamp, if flush set is used).

2. Remove cassette from pump.

3. Pull out orange plunger knob and regulate flow with CAIR clamp.
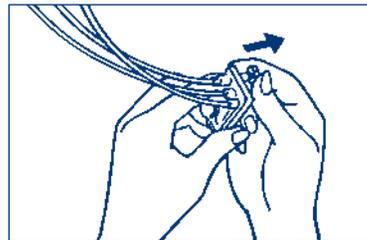
* CAIR® clamp manufactured under license from Adelberg Laboratories, Inc. Covered by one or more of the following U.S. Patent Nos: 3,685,787; 3,893,468; 4,013,263; 4,047,694; 4,238,108; 4,181,476.

† If desired, CAIR clamp may be used to regulate flow rate by gravity, but all tubing must be completely disconnected from pump. This set delivers approximately 14 drops per mL.

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 pump set *without a flush bag* (or fully close clamp on flush bag, if using a feeding pump set with flush bag). Be sure to use a graduated cylinder for volume measurement—not an enteral container. Using Ensure® Complete, Balanced Nutrition™ or Osmolite® Isotonic Liquid Nutrition, fill the feeding container only and set up pump according to instructions. Suspend bag to side or behind and 20 inches above pump (see illustration). With a test pump connected to AC power, start the pump and let it run for 15 minutes. Then run product into a graduated cylinder for 30 minutes and compare to rate set on pump:

Rate Set		Amount Expected 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 flow rate is incorrect, try a new pump set and repeat procedure.
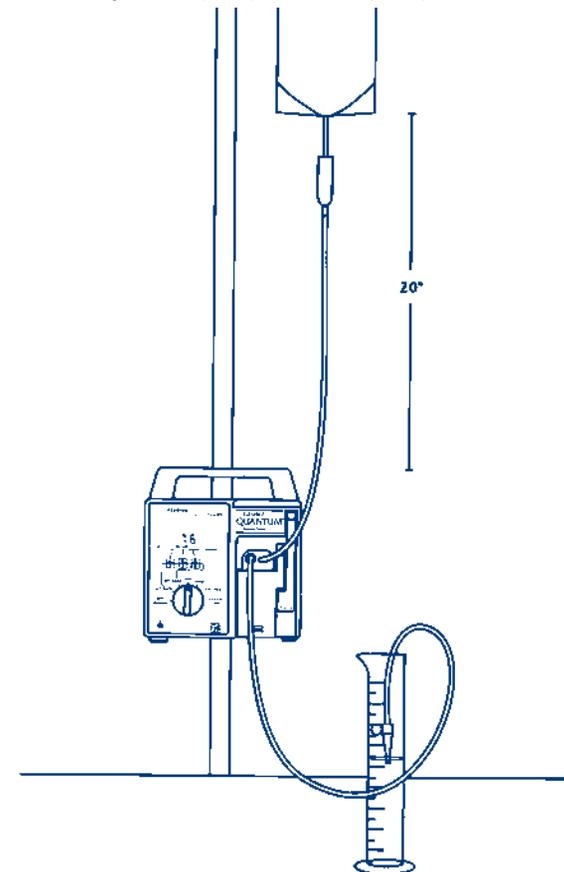
TROUBLE-SHOOTING

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
OCCLUSION—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 (1 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.

CLEANING

There are no routine calibration or adjustment procedures required with the Quantum Pump. All servicing or adjustments should be referred to qualified technical personnel (refer to Service Manual).

For trouble-free operation, check the pump daily and clean immediately after spills occur.

While cleaning, pump should be turned off and unplugged.
Do not submerge, autoclave, heat, steam, ETO or radiation sterilize the pump.

THE PUMP CAN BE CLEANED AS FOLLOWS:

HOUSING
- Clean outside surface with soft cloth and warm, soapy water.
- For general cleaning, use dishwashing detergent (nonchlorine-based) or isopropyl alcohol.
- For general disinfecting, use 70% concentration isopropyl 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. **DO NOT SPRAY THIS SOLUTION INTO PUMP CAVITY.** After exposure to tuberculosis, use 70% concentration isopropyl alcohol. These recommendations are not substitutes for official procedures that may differ among institutions.

PUMP CAVITY
To facilitate cleaning, the cassette receptacle door may be disconnected from the face of the pump. However, this should be removed only by a qualified service technician, in the following manner:
- Tilt pump back.
- Lift blue lever so cassette door is in open position.
- Push out on door-release tab to release cassette door.
- Allow door to open fully.
- Lift up on door to remove completely from brown hinge.

Reinstall cassette door by following above procedures in reverse order.
- Do not spray water or cleaning solution into pump cavity.
- Clean with a cotton swab, soft brush or soft cloth and warm soapy water.
- Dry thoroughly.
- Be sure no soap film or residue is left in the pump cavity.

Blue Lever
Door-Release Tab
Door

Open Position
Pump Cavity
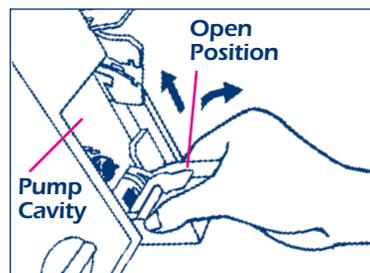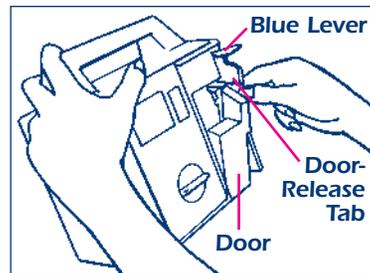
STORAGE

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

SERVICE

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

FLEXIFLO QUANTUM Enteral Delivery System

PUMPS

50596	Enteral Pump—Purchase
50598	Enteral Pump—Lease/Rent

PUMP SETS

50600	Pump Set w/Piercing Pin
50602	Pump Set w/40mm Screw Cap
50604	Pump Set w/Piercing Pin With Flush Bag

CONTAINERS WITH PREATTACHED PUMP SETS

50608	1000 mL Top-Fill Bag w/Pump Set
50610	1000 mL Toptainer® w/Pump Set
50606	1000 mL Top-Fill Bag w/Pump Set With Flush Bag
50614	1000 mL Toptainer w/Pump Set With Flush Bag

All Quantum pump sets and containers with preattached pump sets can be used in the gravity mode of feeding.

SPECIFICATIONS

Power
Voltage:	100 to 130 VAC, 47-63 Hz, 1 Phase
Power:	4 watts (average)
Fuse:	½ AMP, SB type
Line Cord:	Hospital-grade, nondetachable (10 feet)
Leakage:	Less than 100 microamps

Mechanical
Height:	8.25 inches
Width:	7.5 inches
Depth:	6.0 inches (8.0 inches with pole clamp)
Weight:	7.2 lbs

Operational Specifications—Flow Rates
Range:	1-300 mL/hr
Increments:	1 mL/hr
Accuracy:	± 10% (refer to CHECKING PUMP ACCURACY, page 13).
Pressure:	Pumps against 15 psi (mean) back pressure before occlusion alarm.

Battery Operation
Type:	2.1 Ah rechargeable sealed lead acid
Voltage:	8V; the pump will fully recharge in a maximum of 8 hours if turned off, or a maximum of 12 hours if running.
Expected Life:	When fully charged, 8 hours at 125 mL/hr.

Standards
Designed and manufactured to meet requirements of UL 544 (1976).

LIMITED WARRANTY PLAN

Ross warrants the Flexiflo® Quantum™ 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.

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 loaners, shall be paid by the customer. Ross Authorization Forms should be completed and accompany the returned unit.