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A detailed list of specifications is provided in the technical appendix at the back of this document.
STORAGE

The pump should be stored away from excessive temperatures or humidity. When pump will not be used for an extended period of time, keep it plugged in to ensure maximum battery capacity.

LIMITED WARRANTY

Ross Products Division, Abbott Laboratories warrants the FLEXILO® Companion Intraluminal Enteral Feeding pump against defects in material and workmanship for a period of one (1) year from date of delivery. The warranty is valid only to the original purchaser and does not extend to any product or part thereof that has been subjected to accident, alteration, abuse, misuse, repair by one other than Ross authorized representatives, or that 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 abuse or misuse include, but are not limited to, pumps that have been dropped, have had fluid spilled into or onto the casing, have been submerged or have had the back removed.

In no event shall Ross be liable for any incidental, indirect, or consequential damages in connection 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 HEREBY ARE IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION, THE WARRANTIES OF MERCHANTABILITY AND OR FITNESS FOR A PARTICULAR PURPOSE.

SERVICE

This FLEXILO® pump is designed to be highly reliable. As with any electronic/mechanical device, however, minor problems may occur. For assistance, contact the Ross Device Call Center.

PUMP CHARACTERISTICS

Uniquely designed and constructed, the FLEXILO® Companion Intraluminal Enteral Feeding Pump is a volumetric infusional pump that uses a specially designed administration set, including a cassette with bellows to deliver measured amounts of enteral formula. The pump will operate on AC power or battery. The fluid delivery system and safety alarms function when the pump is used by an ambulatory patient or is mounted on an IV pole. The volume monitoring device does not depend on drop counting, so the pump is more versatile in adapting to patient activities.

The pump is microprocessor (computer)-controlled, which provides accurate delivery rates, easy-to-read displays, and simple controls. The Companion Pump comes with a charger unit that charges the M pole and carries the permanently attached power cord.

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

The Companion Pump offers these features:

1. Alarms: inaccurate, low battery, empty container, missing or improperly loaded cassette
2. Accuracy to ± 10% (± 50 ml/hr). See page 12
3. Battery operation at 150 ml/hr, when fully charged
4. Fluid flow and fluid monitoring independent of pump position (no drop counting)
5. Adjustable arm volume for low or high setting
6. Flow rate selection of 5 to 300 ml/hr in 5-ml/hr increments
7. Volume LED acumulation display
8. Automatic retention of values
9. User-friendly operating controls
10. Small and lightweight
11. Simple setup and cassette loading
12. "Read" visual display for easier viewing in a darkened room
13. Self-test capability

PEDIATRIC USE

Do not use this pump for feeding newborn infants or infants in a neonatal intensive care unit (NICU). All enteral pumps have the potential to bolus feed small amounts, which is an important consideration in feeding volume-sensitive patients. The FLEXILO® Companion Pump should normally be used only for children 12 months of age or older, and only if the rate of feeding is 25 ml/hr or greater. In these cases, small-volume containers should be used that contain a volume of product no more than four times the hourly feeding rate.

PRECAUTIONS

Confirm proper placement and function of patient's enteral feeding tube (nasogastric, jejunostomy, gastrostomy, etc.); verify the following before initiating feeding:
1. A FLEXILO® Companion Pump Set is being used.
2. Cassette is properly seated in pump.
3. When on AC power, pump is fully seated in charger.
1. When feeding is completed, turn dial to HOLD or POWER OFF.
   (If pump is switched to POWER OFF, it loses memory of RATE and VOLUME FED.)

2. When desired, disconnect pump set tubing from patient's enteral feeding tube, release cassette from pump by pressing release latch downward, and discard set and container.

**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 page 7.)

**PRECAUTIONS:** This 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.

**CHECKING PUMP ACCURACY**

Head, head height, and viscosity are two variables that can affect flow rate.

To check flow rate, use the following procedure: Be sure to use a graduated cylinder for volume measurement—not an erasable container.

Using Ensure® or Omnil® II, fill the container and set up pump according to instructions. Start the pump and let it run for 15 minutes. Then run product into graduated cylinder for 1 hour and compare to rate set on pump. If flow rate is incorrect, try new pump set and repeat procedure.

If the pump fails the accuracy test consistently, return it for service.

Refer to SPECIFICATIONS, page 15, for accuracy rate.

**BATTERY OPERATION**

Battery power can be used with or without charger attached. If battery power is in use, BATTERY is visually displayed.
INSTRUCTIONS FOR USE

1. Attach to, or place on, appropriate feeding stand. If IV pole is used, be sure pump is properly seated in charger, and then clamp charger to pole.

2. Plug in cord if AC power is available.

FACF: When LOW BATTERY message appears, pump will run for approximately 30 minutes before shutting down completely. However, if battery is not getting the proper charge or no charge from the charger, or if pump is running 30 minutes after LOW BATTERY alarm, pump will then shut down while running on AC or DC power. When fully charged, pump can operate on battery power for 8 hours. A new pump should be plugged into an AC outlet for 17-15 hours before initial use on battery power, to assure full battery charge.

3. Fill feeding container with enteral nutrition product. If an 8-oz glass bottle is used, place bottle in provided suspension bag. Attach Companion Pump Set securely onto filled enteral nutrition container if it is not preattached.

4. Suspend container to side of or behind pump so that sight chamber is at or above level of pump.

Audio Alarms

Intermittent audio alarms are always accompanied by a visual message on display panel indicating cause of alarm. The visual display LOW ALARM indicates alarm volume level is low. If louder alarm volume is desired, select HI on volume switch, lower right front corner of pump face.

Visual Display Cause of Audio Alarm Action

OCCL Flow has stopped Turn dial to HOLD. Check fluid container, pump set tubing and patient tubing-well-feeding tube for flow restriction.

EMPTY Empty feeding container or missing or improperly sealed cassette Turn dial to HOLD. If container is empty, provide new feeding or turn dial to POWER OFF. If no additional feeding is desired, assure that cassette is present and properly sealed.

SELECT RUN Pump is on, but control dial is not set to RUN. (Pump was left in setting other than POWER OFF, or RUN for longer than 5 minutes.)

- If pumping is desired, turn dial to RUN.
- If additional time is desired in HOLD, turn dial briefly to RUN, then to HOLD. Alarm will sound again in 5 minutes.
- If feeding is completed, turn dial to POWER OFF.

RESET RATE Flow rate selected is less than 5 mL/hr. Turn dial to SET RATE. Select rate of flow from 5 to 300 mL/hr.

LOW BATTERY Approximately 10 minutes of battery power remain Turn dial to HOLD, then back to RUN to stop audio alarm. Pump should be seated in charger and plugged in as soon as possible.

ROUTE: In case microprocessor or motor malfunctions, pump will stop pumping action, all visual displays will cease, and a continuous audio alarm will be sounded. Continuous alarm will not cease even if pump dial is turned to HOLD. TURN PUMP DIAL TO POWER OFF SERVICING IS REQUIRED.