

FLEXIFLO® Companion®

Enteral Nutrition Pump

OPERATING MANUAL

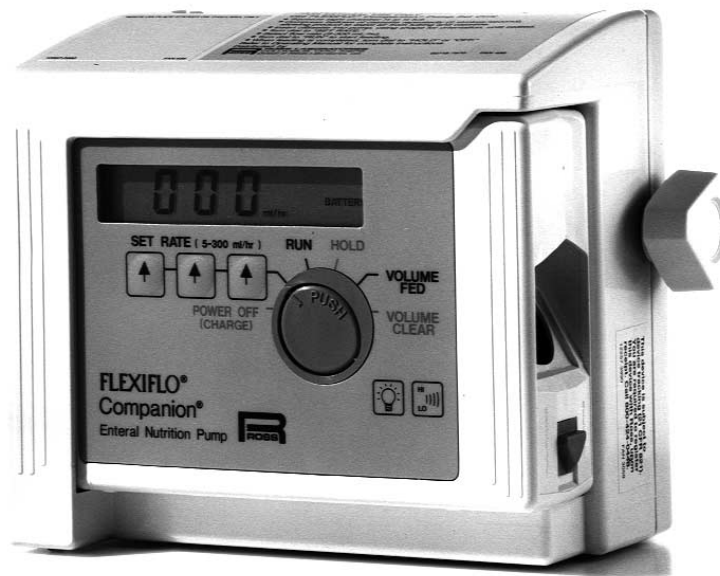


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PUMP CHARACTERISTICS

Uniquely designed and constructed, the FLEXIFLO® Companion® Enteral Nutrition Pump is a volumetric infusion 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 clamps to an IV pole and carries the permanently attached power cord.

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 Companion Pump offers these features:

- Alarms:
 - occlusion
 - empty container/missing or improperly loaded cassette
 - low battery
 - start reminder
- Accuracy to $\pm 10\%$ (5 to 300 mL/hr). See page 12.
- 8-hour battery operation at 150 mL/hr, when fully charged
- Fluid flow and fluid monitoring independent of pump position (no drop counting)
- Adjustable alarm volume for low or high setting
- Flow rate selection of 5 to 300 mL/hr in 1-mL/hr increments
- VOLUME FED accumulation display
- Automatic retention of values
- User-friendly operating controls
- Small and lightweight
- Simple setup (one-hand cassette loading)
- "Backlit" visual display for easier viewing in a darkened room
- 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 FLEXIFLO 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), and verify the following before initiating feeding:

- A FLEXIFLO Companion Pump Set is being used.
- Cassette is properly seated in pump.
- When on AC power, pump is fully seated in charger.
- Flow rate is set at the prescribed mL/hr.
- Pump dial is turned to RUN.

FLEXIFLO Companion ENTERAL NUTRITION PUMP

Pump

Arrow Buttons: Select the numerical value of flow rate from 5 to 300 mL/hr in 1-mL increments.

Display Panel: Shows flow rate, accumulated volume, running indicator, visual explanation of all intermittent audio alarms.

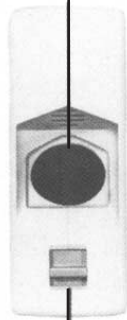
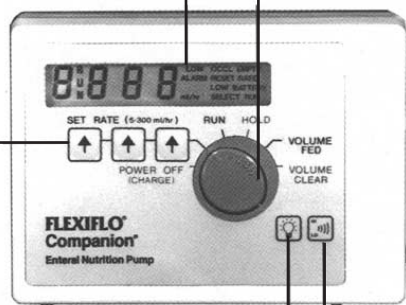
Control Dial: Select pump functions.

Pump Cavity: Insert cassette into pump, using shape for orientation, until seated.

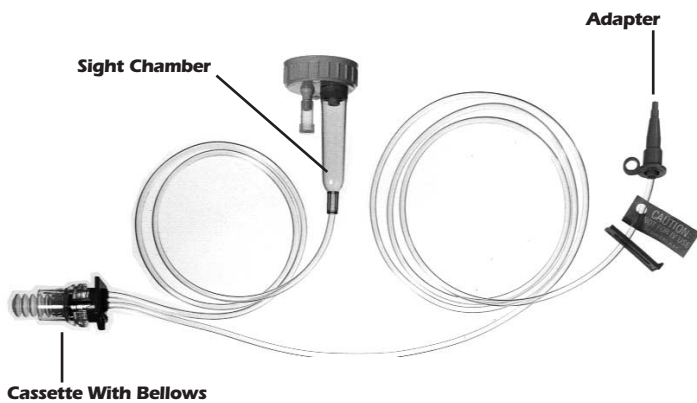
Display Light: Press to temporarily illuminate display panel while on battery power.

Hi/Lo Alarm Volume: Select volume level of audio alarm.

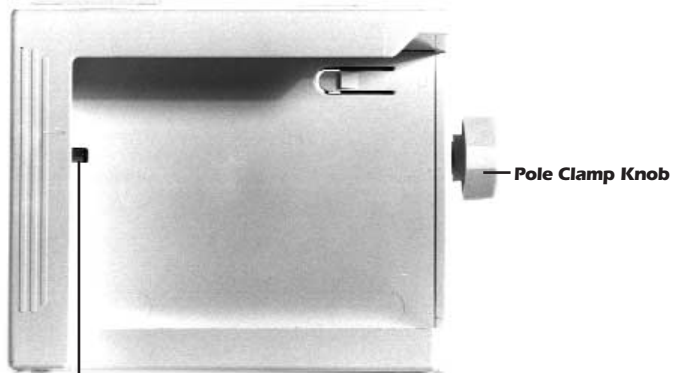
Cassette Release Latch: Press down to release cassette for removal.



Pump Set



Charger

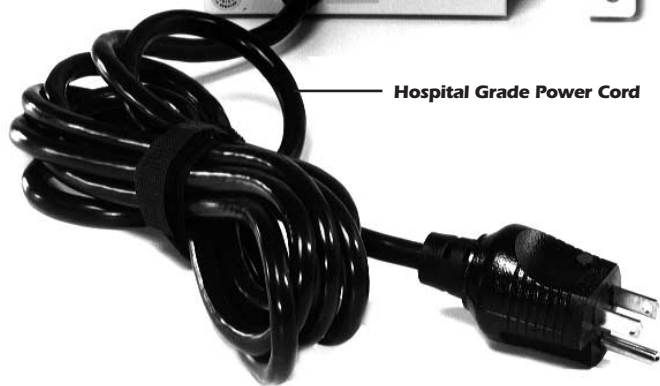


Pump/Charger Connector

Pump Release Latch

Pole Clamp

Carrying Handle



DANGER POSSIBLE EXPLOSION HAZARD IF USED IN THE PRESENCE OF FLAMMABLE ANESTHETICS.
CAUTION ELECTRICAL SHOCK HAZARD. DO NOT REMOVE BACK. REFER SERVICING TO QUALIFIED SERVICE PERSONNEL.
FLEXIFLO® COMPANION® 083
Distributed by:
HOSS LABORATORIES
CIRCLE KIPAK, CO., INC. #138185
P.O. Box 2, Division of Almed Laboratories, USA
Made in U.S.A. by FRANTZ MEDICAL
U.S. Patents 4,945,487 and 4,895,807
Other U.S. and Foreign patents pending

CONTROL DIAL SETTINGS

POWER OFF (Charge):	This setting stops all pump functions and erases all memory. Battery charges in all Control Dial settings when pump is plugged in. See BATTERY OPERATION section, page 12.
SET RATE:	This setting allows flow rate to be set (5 to 300 mL/hr in 1-mL increments) by using the arrow buttons (active only in this mode). No pumping action occurs in this mode.
RUN:	This is the ONLY setting that activates pumping action. Visual display shows flashing RUN and rate of flow in mL/hr.
HOLD:	This setting stops pumping action and audio alarm (if one has occurred) without erasing previous commands or memory functions. 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).
VOLUME FED:	This setting stops pumping action and displays accumulated numerical value of volume fed in mL since pump power was turned on. (NOTE: If 9999 mL is fed without turning off pump, numerical value turns to 0000 and a new accumulation begins.)
VOLUME CLEAR:	This setting stops pumping action and automatically clears to zero any accumulated numerical value of volume fed to that point.

NOTE: Pump activates flow only in RUN setting. Pump maintains memory in any setting except POWER OFF and VOLUME CLEAR.

VISUAL DISPLAYS AND AUDIO ALARMS

Visual Displays

Control Dial Setting	Visual Display	Audio Alarm
POWER OFF (Charge)	None	None
SET RATE (No pumping action)	Previous flow rate or 000 mL/hr	None
RUN	Numerical rate in mL/hr and RUN	None
HOLD (No pumping action)	Existing flow rate or 000 mL/hr Visual alarm display remains visible (if one occurred)	None (Any previous audio alarm ceases)
VOLUME FED (No pumping action)	Numerical value of accumulated volume fed in mL or 0000	None
VOLUME CLEAR (No pumping action)	Numerical value of accumulated volume fed is automatically cleared to zero (0000 mL)	None

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's indwelling feeding tube for flow restriction.
EMPTY	Empty feeding container or missing or improperly seated 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 seated.
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.)	<ul style="list-style-type: none"> 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 30 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.

NOTE: 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.

SPECIAL FEATURES

Small Size: The Companion Pump is small and lightweight. The pump weighs 1.5 lbs; the charger weighs 2.5 lbs. With the FLEXIFLO® Companion® Ambulatory Transporter (see page 9), a patient can easily carry the pump and up to 500 mL of enteral formula during routine activities.

Position Independent: The Companion Pump fluid delivery and alarm systems will function when the pump is in any position that might be normal for ambulatory or non-IV pole use—a real advantage for ambulatory patients in an institution or at home.

Easy Setup: Unlike some other systems, priming and seating of the cassette and setting the control dial on the Companion Pump can be done simply. Setup is easy to learn and easy to teach to staff and patient.

Self-Test Procedure: Each time the pump is turned on, the micro-processor initiates a self-test procedure. Audio alarm, visual displays, and readout (8888) will turn on for 5 seconds. If the self-test fails, F1 will appear. **DO NOT USE THE PUMP. SERVICING IS REQUIRED.**

Flashing Displays: Three flashing visual displays indicate need for immediate attention:

- EMPTY
- OCCL
- LOW BATTERY

Pump/Charger Connection:

To Separate: When properly seated, the pump is held firmly within the charger. In order to separate pump and charger, locate pump release latch on back of charger within handle cavity. Pull pump toward opening while pressing latch in the same direction until pump is free. Grasp pump securely to withdraw it from charger.

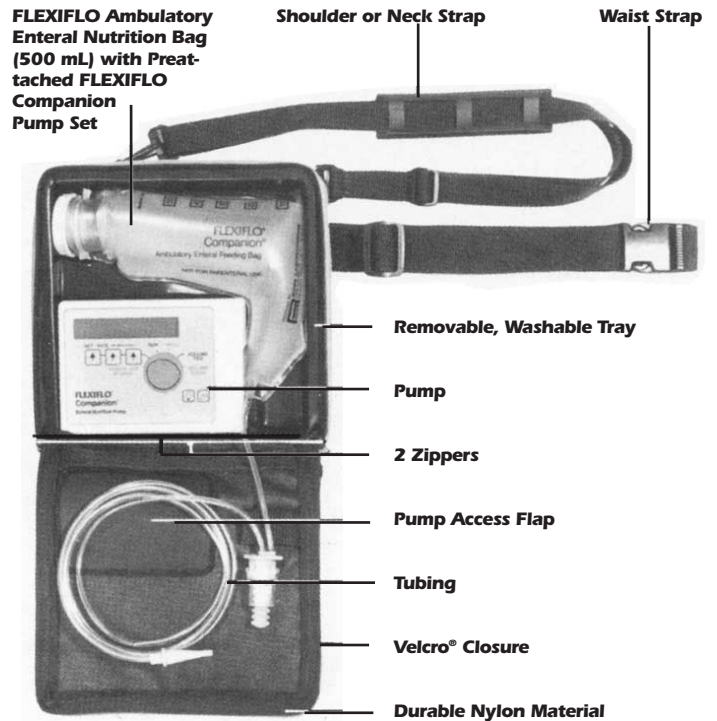
To Reconnect: With pump display panel facing outward, slide pump into charger, using built-in guides for alignment. Slide pump in until it snaps into position, then verify that it is locked in place. When properly seated, pump case will not protrude from charger.

Pole Clamp: NOTE—Pump must be inserted into charger for pole attachment.

Pole clamp mechanism is controlled by knob on right side of charger. Align pole cavity (located at back of charger) with pole; turn knob clockwise until pole is firmly captured.

FLEXIFLO® Companion® AMBULATORY TRANSPORTER

Ambulatory transporter enables patient to carry pump, bag and tubing without an IV pole.



Refer to insert with feeding bag for specific setup instructions.

INSTRUCTIONS FOR USE

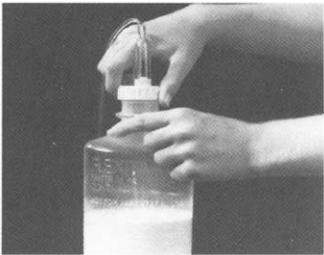
1. Attach to, or place on, appropriate feeding stand. If IV pole is used, be sure pump is properly seated in charger, and then clamp charger to pole.

2. Plug in cord if AC power is available.



NOTE: 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 12-15 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.



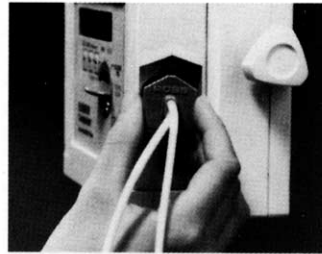
5. Squeeze sight chamber 1/3 to 1/2 full.

6. Remove cap from adapter at distal end of pump set tubing. Compress bellows of cassette repeatedly (2 strokes/second) until fluid has expelled air from cassette and tubing, leaving 2 to 3 inches of tubing near adapter unprimed to avoid product dripping during setup.

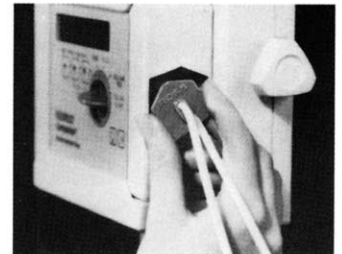


7. CONFIRM PROPER PLACEMENT AND FUNCTION OF PATIENT'S ENTERAL FEEDING TUBE (NASOGASTRIC, JEJUNOSTOMY, GASTROSTOMY, ETC). Refer to feeding tube label for complete instructions. Connect adapter to enteral feeding tube.

8. Insert cassette into pump, using shape for orientation. Be sure to exactly match shape of blue plastic base of cassette to shape of pump cavity. Press until cassette is seated. Grasp base of cassette tubing and pull gently to confirm that cassette is seated.

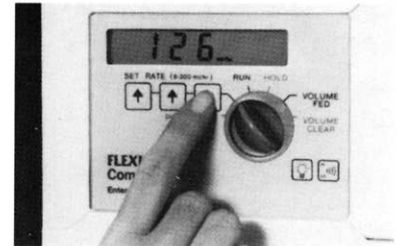


RIGHT



WRONG

9. Access pump control dial by pressing at PUSH. Turn dial to SET RATE and select flow rate from 5 to 300 mL by pressing individual arrows.



10. Turn pump dial to RUN to start feeding. If cassette is not properly seated, the EMPTY alarm will sound. For example, the alarm will sound within 30 seconds at 100 mL/hr.



11. 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.)

12. 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.)

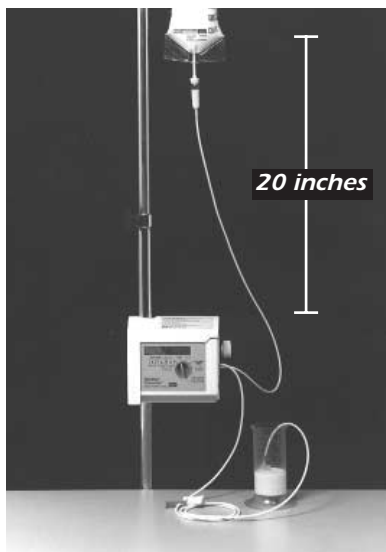
PRECAUTIONS: This pump set and container should be replaced as needed, or at least every 24 hours, to avoid product contamination problems. For single-patient use only.

CHECKING PUMP ACCURACY

Fluid 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 enteral container. Using Ensure® or Osmolite®, 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 a new pump set and repeat procedure.

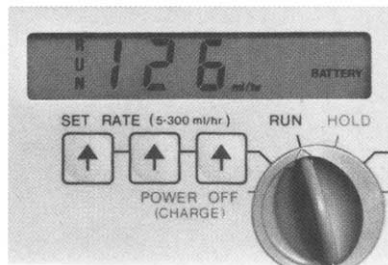
If the pump fails the accuracy test consistently, return it for service.

Refer to SPECIFICATIONS, page 15, for accuracy rate.

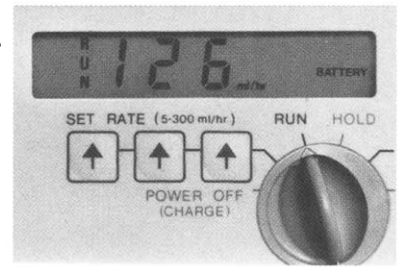


BATTERY OPERATION

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



2. LOW BATTERY flashing display indicates battery voltage is low. Pump should be plugged in as soon as possible. From the time LOW BATTERY message first appears, pump will run for approximately 30 minutes before it shuts down completely to prevent further battery discharge.



3. Pump can be used while battery is recharging.

4. To charge pump, seat in charger and plug charger into 110/120 AC outlet for 12-15 hours. This should be done as soon as LOW BATTERY display appears. To ensure maximum battery capacity, keep pump plugged in when it will not be used for an extended period of time. Battery will charge in any dial setting, including OFF, when plugged in.

NOTE: A new pump should be charged for 12-15 hours before initial use on battery power, to assure full battery charge.

CLEANING

The pump and charger are specially designed for easy cleaning. The outside surfaces can be cleaned with warm, soapy water. For trouble-free operation, the surfaces should be cleaned immediately after spills occur.

The pump cavity can be cleaned with a cotton swab or soft cloth and warm, soapy water. (Do not clean pump cavity with alcohol). Dry thoroughly. Be sure no soap film or residue is left in the pump cavity.

NOTE: DO NOT SUBMERGE OR AUTOCLAVE THE PUMP OR CHARGER.

DISINFECTANTS

Recommended for all external parts and surfaces. Allow to air-dry after disinfecting.

General

Cidex® (Arbrook Inc)
pHisoHex® (Winthrop-
Breon Laboratories)
Hibiclens® (Stuart
Pharmaceuticals)
Isopropyl alcohol

AIDS and Hepatitis

10% concentration of
5.25% sodium hypo-
chlorite (household
bleach)

Tuberculosis

70% concentration
of isopropyl alcohol

These recommendations for disinfecting the pump are not substitutes for official procedures that may differ among institutions. Contact the local infection control officer to determine proper procedure in your institution.

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 FLEXIFLO® Companion® Enteral Nutrition 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, that has been subjected to accident, alteration, abuse, 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 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 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.

SERVICE

This FLEXIFLO pump is designed to be highly reliable. As with any electromechanical device, however, minor problems may occur.

For assistance, contact the Ross Device Call Center.

TROUBLE-SHOOTING

1. Check for proper electrical hookup. (Is pump plugged in? Is electrical outlet functioning? Is battery properly charged?)
2. If electrical outlet usage is intended, be sure pump is properly positioned within charger. See Pump/Charger Connection, page 8.
3. Be sure a FLEXIFLO Companion Pump Set is being used, and that cassette is properly seated in pump cavity.
4. Check visual display and correct situation as indicated.

SPECIFICATIONS

Power

Voltage:	120 VAC, 60 Hz, 1 Phase
Power:	2 Watts
Fuse:	1 AMP, 3AG type
Line Cord:	Hospital grade (10 feet), nondetachable from charger
Leakage:	Less than 100 microamps

Mechanical

	Pump Only	Pump With Charger
Height:	4.3 inches	6.0 inches
Width:	6.0 inches	6.7 inches
Depth:	1.7 inches	3.3 inches
Weight:	1.5 lbs	4.0 lbs

Operational Specifications

Flow Rates

Range:	5 to 300 mL/hr
Increments:	1 mL/hr
Accuracy:	± 10% with measured flow rates of 1 Liter of enteral product from 5 to 300 mL/hr using Companion Pump Set at zero back pressure (atmospheric). See page 12.
Pressure:	Pumps against 24 PSI (mean) back pressure before occlusion alarm.

Battery Operation

Type:	1.0 Ah rechargeable sealed lead-acid.
Voltage:	4V; recharge rate: 1 ½ hours for every 1 hour of battery use.
Expected Life:	When fully charged, 8 hours at 150 mL/hr.

Standards

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



**A total commitment
to enteral nutrition.**

14671.5910
FAN 7016

ROSS ROSS PRODUCTS DIVISION
ABBOTT LABORATORIES
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LITHO IN USA