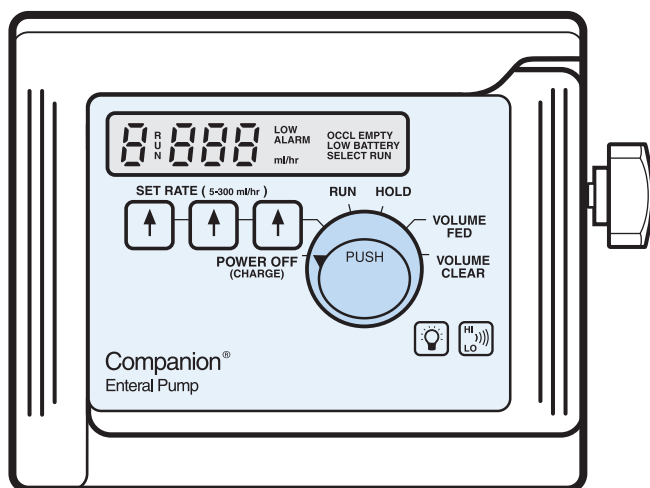


# Companion<sup>®</sup>

## Enteral Pump

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### *Operating Manual*

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*For Enteral Use Only  
Not for IV Use*

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**USER QUALIFICATIONS**

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician or other licensed practitioner.

## PUMP CHARACTERISTICS

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The Abbott Nutrition Companion® Enteral 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 operates on AC or battery power. The fluid delivery system and safety alarms function when the pump is used by an ambulatory patient or is mounted on a pole. The volume-monitoring device does not depend on drop counting, so pump adapts well to patient activities.

The pump is controlled by a microprocessor (computer), providing accurate delivery rates, easy-to-read displays, and simple controls. A charger unit with a power cord is provided with each Companion Enteral Pump. The charger may be clamped to a feeding stand or pole or positioned on a flat surface.

**Additionally, the Companion Enteral Pump offers these features:**

1. Accuracy to  $\pm 10\%$  at rates of 5 to 300 mL/hr
2. 8-hour battery operation at 125 mL/hr, when fully charged
3. Alarms:
  - **OCCCLUSION**
  - **EMPTY FEEDING CONTAINER/MISSING OR IMPROPERLY LOADED CASSETTE**
  - **SELECT RUN**
  - **LOW BATTERY**
  - **RESET RATE**
4. Fluid flow and fluid monitoring independent of pump position (no drop counting)
5. Adjustable alarm volume for low or high setting
6. Flow rate selection of 5 to 300 mL/hr in 1-mL/hr increments
7. **VOLUME FED** accumulation display
8. User-friendly operating controls
9. Small and lightweight
10. Simple setup
11. Backlit visual display for easier viewing in a darkened room
12. Self-test capability

## INDICATIONS FOR USE

---

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

- The flow rate range is 5-300 mL/hr in 1-mL/hr increments
- The flow rate accuracy is  $\pm 10\%$
- Pumps against 24 psi nominal back pressure before **OCCL (occlusion)** alarm.

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).

**If the specifications are not appropriate for a given patient, the Companion Enteral Pump should not be used.**

## PRECAUTIONS

---

### PEDIATRIC USE

**Do not use this pump for feeding newborn infants or infants in a neonatal intensive care unit (NICU).** Enteral pumps have the potential to bolus-feed small amounts, which is an important consideration in feeding volume-sensitive patients. The Companion Enteral 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 patients, do not hang more volume of nutritional product than can be tolerated as a bolus.

### NOT FOR IV 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. Only a Companion® Pump Feeding Set is being used.
2. Cassette is properly seated in pump.
3. When connected to AC power, the pump is fully seated in charger.
4. Flow rate is set at the prescribed mL/hr.

**CAUTION:** The variety of medical nutritional products used with enteral pumps may result in overdelivery or underdelivery outside the specified range for:

- Water
- Calorically dense, highly viscous, or fiber-containing liquid products
- Reconstituted powder products
- Formula with additives
- Closed delivery systems (e.g., Ready-To-Hang)

**Follow the guidelines below:**

1. Mix or shake products thoroughly prior to and periodically throughout delivery.
2. Do not mix medications and formula.
3. Frequently monitor the feeding bag/container for the amount of formula delivered.
4. Monitor patient clinically, particularly for signs of fluid imbalance.

## **BOLUS FEED**

Enteral pumps may have the potential to bolus-feed or overdeliver, which is an important consideration in feeding volume-sensitive patients. In these patients, do not hang more volume of nutritional product than can be tolerated as a bolus and monitor the patient closely, or as directed by physician.

## **PUMP SERVICING**

Only Abbott Nutrition-authorized personnel are permitted to service this medical device. Unauthorized personnel should not open the pump or repair/replace any components, including batteries and labeling.

## **PRODUCT CONTAMINATION**

**PRECAUTION:** To avoid product contamination problems, use a new Companion® Pump Feeding Set at least every 24 hours, or as needed. **For single-patient use only.**

## **SPECIAL FEATURES**

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

**Position Independent:** The Companion Enteral Pump fluid delivery and alarm systems function when pump is in any position that might be customary for ambulatory use.

**PANEL DISPLAYS**

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

**PUMP FRONT PANEL**

**Touch Pads**

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

**Display Panel**

Shows flow rate, cumulative **VOLUME FED**, **RUN** indicator, and visual explanation of all intermittent audio alarms.

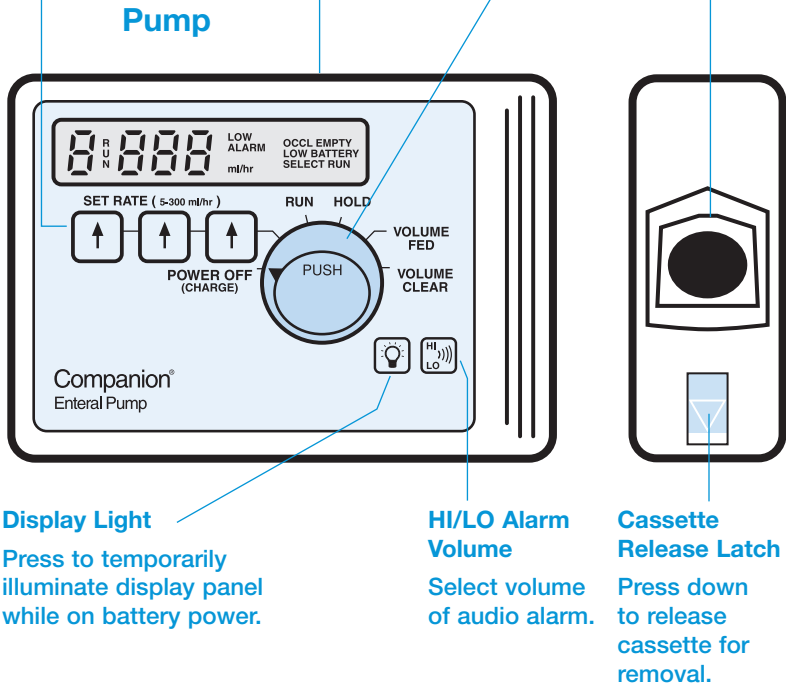
**Control**

Select pump functions.

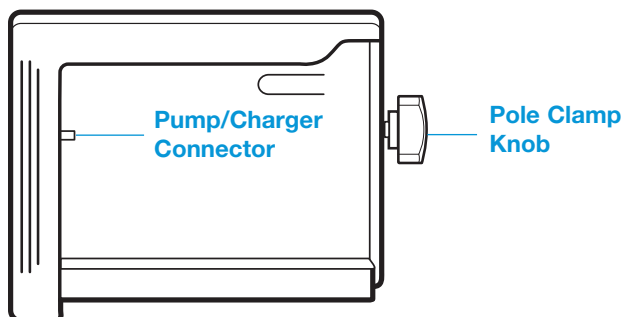
**SIDE VIEW**

**Cassette Cavity**

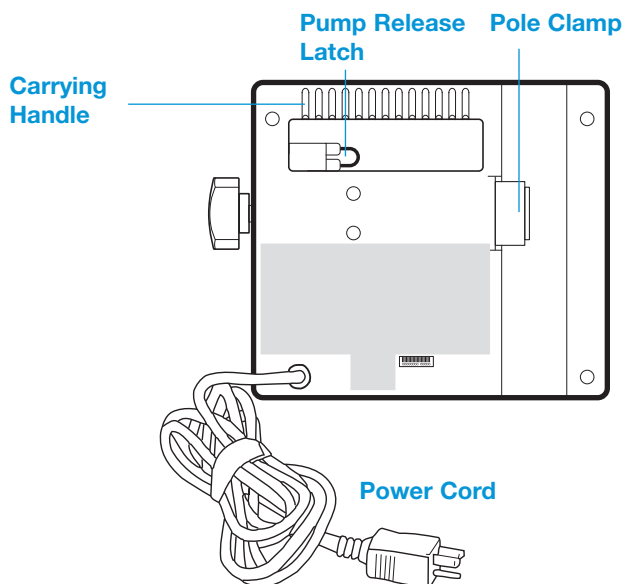
Using shape for orientation, insert cassette into pump until seated.



## **CHARGER FRONT**



## **CHARGER BACK**



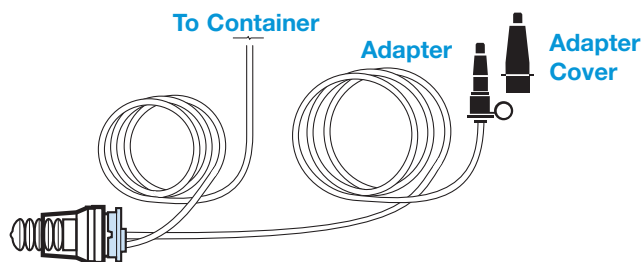
**Self-Test Procedure:** Each time pump is turned on, the microprocessor initiates a self-test procedure. Audio alarm, visual displays, and readout (8888) turn on for 5 seconds. If the self-test fails, **F1** may appear. If this happens, **DO NOT USE THE PUMP; SERVICING IS REQUIRED.**

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

- **EMPTY**
- **OCCL**
- **LOW BATTERY**

## PUMP SET

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### Cassette With Bellows

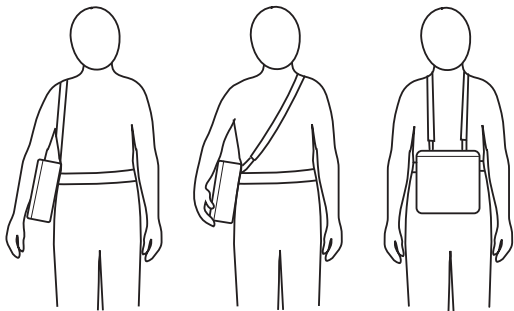
**Enteral Feeding Sets:** A wide range of Companion® Pump Feeding Sets is available. These include bag sets, screwcap sets, and ambulatory sets. Sets are disposable and for single use only. Sets other than Companion Pump Feeding Sets are not suitable for use. Please contact your local Abbott representative for information on set availability.

To avoid product contamination problems, the set should be replaced at least every 24 hours, or as needed.



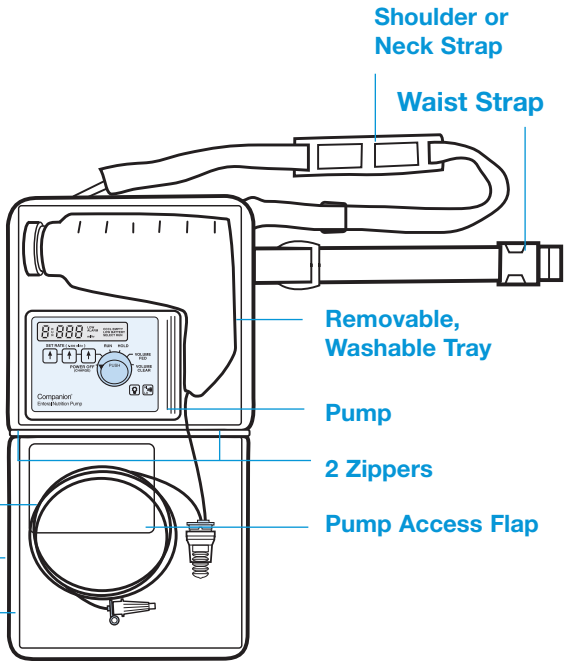
**AMBULATORY TRANSPORTER**

The Companion® Ambulatory Transporter enables patient to carry pump, bag, and tubing without a pole.



**Companion® Ambulatory Enteral Nutrition Bag (500 mL) with Preattached Companion Pump Set**

**Tubing**  
**Velcro Closure**  
**Durable Nylon Material**



**Shoulder or Neck Strap**

**Waist Strap**

**Removable, Washable Tray**

**Pump**

**2 Zippers**

**Pump Access Flap**

## CONTROL DIAL SETTINGS

---

DIAL:	FUNCTION:
<b>POWER OFF</b>	Stops all pump functions. Battery charges in all control dial settings when pump is plugged into AC power.
<b>SET RATE</b>	Allows flow rate to be set (5 to 300 mL/hr in 1-mL increments) by pressing the touch pads (arrow buttons). No pumping action occurs in this mode.
<b>RUN</b>	Only setting that activates pumping action. Visual display shows flashing <b>RUN</b> and rate of flow in mL/hr.
<b>HOLD</b>	Stops pumping action and silences audio alarm (if one has occurred) without erasing previous commands or memory functions. <b>HOLD</b> is used when correcting an alarm condition, or whenever feeding is temporarily interrupted (such as when connecting a new feeding container).
<b>VOLUME FED</b>	Stops pumping action and displays cumulative volume fed in mL, since this value was last cleared. ( <b>NOTE:</b> If 9999 mL is fed, numerical value turns to 0 and a new accumulation begins.) To clear <b>VOLUME FED</b> , turn knob to <b>VOLUME CLEAR</b> and wait for 4 beeps to sound.
<b>VOLUME CLEAR</b>	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 all settings except **POWER OFF** and **VOLUME CLEAR**.

**VISUAL DISPLAYS AND AUDIO ALARMS**

**VISUAL DISPLAYS**

<b>CONTROL DIAL SETTING</b>	<b>VISUAL DISPLAY</b>	<b>AUDIO ALARM</b>
<b>POWER OFF</b> <i>(Charge)</i>	None	None
<b>SET RATE</b> <i>(No pumping action)</i>	Previous flow rate or 000 mL/hr	None
<b>RUN</b>	Numerical rate in mL/hr and RUN	None
<b>HOLD</b> <i>(No pumping action)</i>	Existing flow rate or 000 mL/hr Visual alarm display remains visible (if one occurred)	None (Any previous audio alarm ceases)
<b>VOLUME FED</b> <i>(No pumping action)</i>	Numerical value of accumulated volume fed in mL or 0000	None
<b>VOLUME CLEAR</b> <i>(No pumping action)</i>	Numerical value of accumulated volume fed is automatically cleared to zero (0000 mL)	None

Intermittent audio alarms are always accompanied by a visual message on the display panel indicating the cause of the alarm. The visual display **LOW ALARM** indicates that the alarm volume is set to low. To change the alarm volume, press the **HI/LO** Alarm Volume button.

**NOTE:** If the microprocessor or motor malfunctions, pump will stop pumping action, all visual displays will cease, and a continuous audio alarm will sound. The continuous alarm will not cease even if pump dial is turned to **HOLD**. If this happens, **TURN PUMP DIAL TO POWER OFF; SERVICING IS REQUIRED.**

## TROUBLESHOOTING

---

The Companion® Enteral Pump is designed to be highly reliable. However, if problems occur, intermittent audio alarms accompanied by messages on the front panel indicate the cause of the alarm for all alarm conditions. The following tips will help correct problems that may arise:

<b>VISUAL DISPLAY</b>	<b>Condition or Problem</b>	<b>Explanation or Corrective Action</b>
<b>OCCL</b>	Flow has stopped because of a distal occlusion.	Turn control dial to <b>HOLD</b> . Check pump set tubing and patient's feeding tube for the flow restriction, eg, kinked tubing. Verify that the occlusion is cleared after restarting pump by confirming that formula is dripping in the sight chamber, if applicable.
<b>EMPTY</b>	Empty feeding container or missing or improperly seated cassette.	Turn control dial to <b>HOLD</b> . If container is empty, provide new feeding or turn dial to <b>POWER OFF</b> if no additional feeding is administered. Assure that cassette is in place and properly seated.
<b>SELECT RUN</b>	Pump is on, but control dial is not set to <b>RUN</b> . Pump was left in setting other than <b>POWER OFF</b> or <b>RUN</b> for 5 minutes or longer.	If additional time is desired in <b>HOLD</b> , turn dial briefly to <b>RUN</b> , then to <b>HOLD</b> . Alarm will sound again in 5 minutes. If feeding is completed, turn dial to <b>POWER OFF</b> .
<b>RESET RATE</b>	Flow rate selected is less than 5 mL/hr.	Turn the control dial to <b>SET RATE</b> . Select rate of flow from 5 to 300 mL/hr.
<b>LOW BATTERY</b>	Approximately 30 minutes of battery power remain.	Turn the control dial to <b>HOLD</b> , then back to <b>RUN</b> to stop audio alarm. Return pump to charger and plug in power cord.

## PUMP/CHARGER CONNECTION

---

**To Separate:** When properly seated, pump is held firmly within the charger base. To separate pump and charger, locate pump release latch on the back of the charger within the handle cavity. Pull the latch toward the pole clamp knob and slide pump out of the charger. 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, and verify that it is locked in place. When properly seated, pump case will not protrude from charger.

**Pole Clamp:** Pump must be inserted into charger before pole attachment. Pole clamp mechanism is controlled by a knob on the right side of the charger. Align pole cavity (located at back of charger) with the pole, turn knob clockwise until the pole is firmly captured.

**NOTE:** The Companion® Enteral Pump Charger is not interchangeable with the Companion™ ClearStar™ Enteral Pump Charger.

## 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).

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

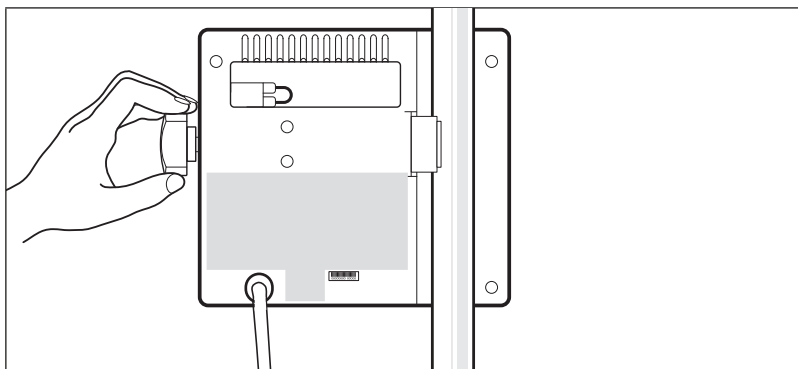
**PRECAUTION:** If the integrity of the power cord is in doubt, disconnect from AC power. Return pump for servicing.

1. Confirm proper placement and function of patient's enteral feeding tube (nasogastric, jejunostomy, gastrostomy, etc).
2. Attach to or place on an appropriate feeding stand or pole. If a pole is used, be sure pump is properly seated in charger before clamping to the pole. To ensure stability of a portable stand, position the pump no higher than 45 inches from the floor.

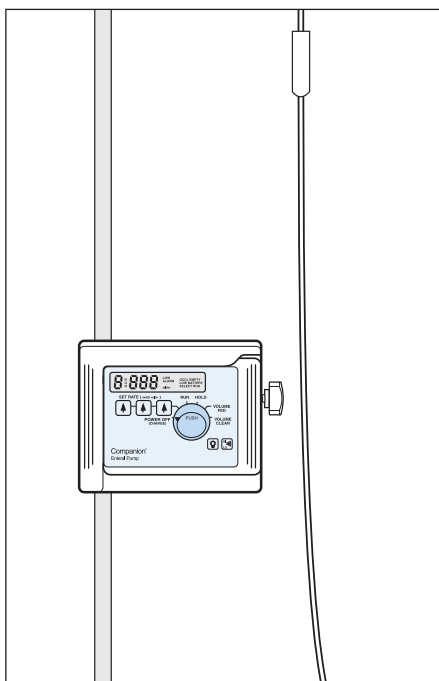
Note: If using the Companion Ambulatory Transporter, refer to Directions for Use included with the Transporter unit.

## INSTRUCTIONS FOR USE (continued)

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3. Plug in power cord unless battery operation is desired.
4. Fill feeding container with enteral nutritional product or use a prefilled enteral feeding container. Attach Companion® Pump set securely onto filled container if it is not preattached.
5. Suspend container to the side of or behind, and 20 inches above pump.



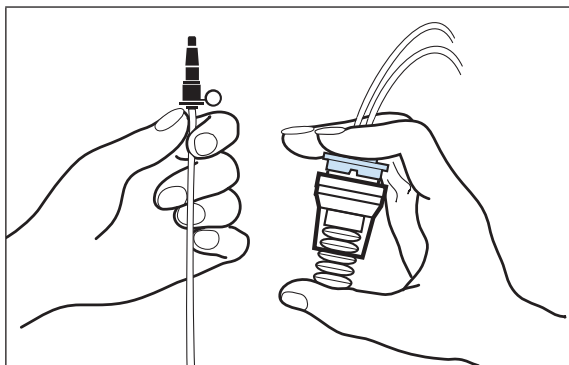
6. Squeeze sight chamber (if applicable)  $\frac{1}{3}$  to  $\frac{1}{2}$  full.

## INSTRUCTIONS FOR USE (continued)

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### 7. Priming Instructions:

Remove the cap from the connector at distal end of the pump set tubing. Hold the cassette with the tubing up and the bellows down. Compress the bellows of the cassette repeatedly until the fluid has expelled **all** the air from the cassette and tubing. Firmly tap the cassette to dislodge any remaining air bubbles that may or may not be visible.

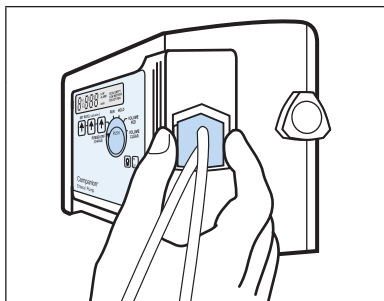


#### **Warning:**

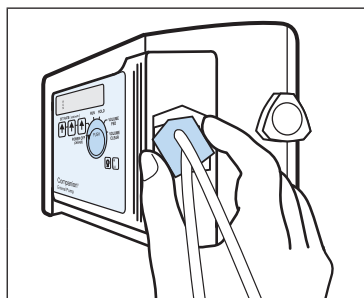
**Proper priming is critical since air in the cassette will reduce the volume delivered, and the amount delivered will be less than indicated on the volume fed display.**

*NOTE: You may leave 5 to 8 cm (2 to 3 inches) near the end of the tubing unprimed to avoid product dripping during the setup.*

8. Using shape for orientation, insert cassette into pump until seated. Press until cassette clicks into place. Grasp base of cassette tubing and pull gently to confirm that cassette is seated.



**Right**

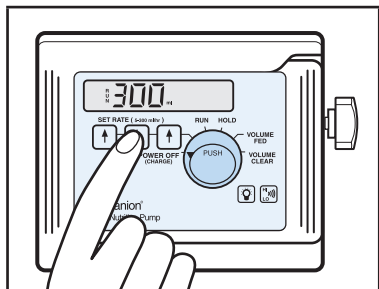


**Wrong**

## INSTRUCTIONS FOR USE (continued)

---

9. Access pump control dial by pressing **PUSH**. Turn to **SET RATE** and select flow rate from 5 to 300 mL/hr by pressing touch pads (arrow buttons). Confirm proper placement and function of enteral feeding tube. Attach adapter to enteral tube.



10. Turn dial to **RUN** to start feeding. If cassette is not properly seated, **EMPTY** alarm will sound after a short delay. For example, the alarm will sound within 30 seconds at 100 mL/hr. Always check sight chamber (if applicable) of pump set when starting feeding to verify that the formula is dripping. If no drops are detected, check the feeding container, the set tubing (between pump and the enteral feeding container), and the patient's feeding tube for particles, clumping, or kinking that would prevent fluid flow.

**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 an explanation of alarms, see Page 11.

11. When feeding is completed, turn pump dial to **HOLD** or **POWER OFF**. Pump stops and sounds an alarm automatically when the container is empty.
12. Disconnect pump set tubing from patient's enteral feeding tube, release cassette from pump by pressing release latch downward, and discard set and container.



## BATTERY OPERATION

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When pump is unplugged, power is supplied by the internal, rechargeable battery.

1. If battery is fully discharged and AC power fails during feeding, pump will shut down and no alarm will sound.
2. While pumping in battery mode, the display light turns off after approximately 90 seconds to save power.
3. Pump can be used while the battery is recharging. Pump automatically charges the battery when plugged into AC power.

### **Expected Life and**

### **Charge Time:**

1. When battery is fully charged, pump will operate for 8 hours at 125 mL/hr.
2. Battery will fully charge in 8 hours with the pump turned off and 12 hours with the pump turned on.
3. The battery will charge in any control dial setting including the POWER OFF position when connected to AC power.
4. When low battery alarm occurs, the pump will operate for approximately 30 minutes before shutting down.
5. Battery operating time will diminish with partially charged or older batteries. Operating on AC power and keeping the pump plugged into an AC outlet (even while OFF), will help maintain expected battery performance.

### **Battery Maintenance:**

1. 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.
2. A battery that has repeatedly been fully discharged and/or left in a discharged state for an extended period may not recharge properly.
3. If battery is rarely used, occasionally operating pump on battery power may extend battery life. The pump should be operated on battery for a minimum of 6 continuous hours at least once every 6 months for best performance and battery life.
4. The pump should be plugged into AC power whenever possible. When not being used on battery power, pump should **ALWAYS** remain plugged in to AC power to maintain battery charge and performance.

### **Battery Disposal:**

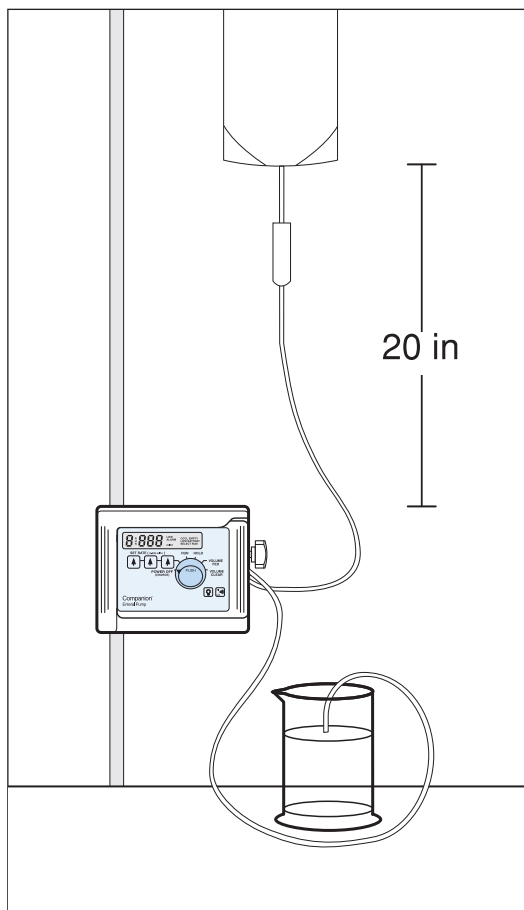
Appropriate disposal of batteries is required, and this can be done by an Abbott-authorized service center. In case of any questions on batteries, please contact the responsible Abbott representative.

## 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 Companion® Pump Feeding Set for this test.**



Fill the feeding container with 8 fl oz of Osmolite, and set the container so that the bottom of the container is 20 inches above the cassette (see diagram). Set up pump according to instructions. Operate pump at 50 mL/hr for 15 minutes and discard the formula delivered. Increase the rate to 100 mL/hr and run enteral product into a graduated cylinder for 1 hour. The volume of Osmolite delivered should be between 90 and 110 mL. If the volume delivered is outside this range, repeat the procedure with a new pump set.

## CLEANING

---

There are no routine calibration or adjustment procedures required with the Companion® Enteral Pump. 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 only (**DO NOT SPRAY WATER OR CLEANING SOLUTION INTO PUMP**).
- For general cleaning, use a soft, lint-free cloth to avoid damaging the surface. Be especially careful with the operator's panel. 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.
- Disinfection is recommended for all external parts and surfaces. Clean the pump before disinfecting it. Wipe on the disinfectant for at least one minute; then allow pump to air dry.
- Intermediate level disinfection is achieved by using one of the following: 10% concentration of 5.25% sodium hypochlorite (household bleach) or 70% isopropyl alcohol.

NOTE: These recommendations are not substitutes for official procedures that may differ among institutions.

## SERVICE

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- The Companion® Enteral Pump is designed to be highly reliable. However, in the event of a pump malfunction or for technical assistance, please contact Abbott Nutrition, Abbott Laboratories.
- **OPERATING INSTRUCTIONS VIDEO**  
An instructional video, which is available through an Abbott Nutrition Representative, assists caregivers and medical professionals in learning procedures for operating the Companion enteral delivery system.
- Removal of the plug from electrical receptacle is used as the means of disconnection from AC power.
- Only Abbott Nutrition-authorized personnel are permitted to service this medical device. Unauthorized personnel should not open the pump or repair/replace any components, including labeling.

### **Before calling, do a few simple checks:**

1. Check for proper electrical connection. (Is pump connected to mains? Is electrical outlet functioning? Is battery properly charged?)
2. If electrical outlet usage is intended, be sure pump is properly positioned within charger.
3. Be sure a Companion Pump Set is being used, and that cassette is properly seated in cassette cavity.
4. Check visual display, and correct situation as indicated.

SPECIFICATIONS

POWER

Power:	120 VAC, 60 Hz, 1 Phase, 6 watts
Fuse:	1/4 AMP, 3AG type
Power 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 pounds	4.0 pounds

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).
Pressure:	Pumps against 24 psi (mean) back pressure before occlusion alarm.
Operating Temperature:	60° F – 90° F (16° C – 32° C)
Operating Humidity:	30% RH – 90% RH, non-condensing
Operating Altitude:	The system is capable of successful operation during exposure to surface elevations from sea level to a pressure corresponding to 10,000 feet (3,050 meters) above sea level.

STORAGE

• Be sure pump dial is in the <b>OFF</b> position.	
Storage Temperature:	32° F – 95° F (0° C – 35° C)
Storage Humidity:	10% RH – 90% RH, non-condensing
Storage Altitude:	The system is able to withstand and operate after exposure to elevations up to 20,000 feet (6,100 meters) above sea level.

**SPECIFICATIONS (continued)**

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**BATTERY**

Battery Type: 1.0 Ah rechargeable sealed lead-acid

Voltage: 4 V

Reference Battery Operation section on Page 17.

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**STANDARDS**

Designed and manufactured to meet requirements of Underwriters Laboratories.

**ELECTROMAGNETIC COMPATIBILITY**

The Companion® Enteral Pump is compliant with the following standards: EN 55011 (1991), IEC 801–2 (1991-2004), IEC 801–3 (Second Edition), IEC 801–4 (1988), IEC 801–5 (Draft 5, 1992-2007)

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**EXPLANATION OF SYMBOLS**



Type BF Applied Part

## LIMITED WARRANTY

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The Abbott Nutrition Division of Abbott Laboratories warrants each Abbott Nutrition Companion® Enteral Pump purchased as a remanufactured unit against defects in materials and workmanship for a one (1)-year period from date of shipment. This warranty does not extend to any product, or part thereof, that has been subjected to accident, alteration, damage, misuse, or repair by any party other than Abbott Nutrition authorized personnel, or has not been used in the manner prescribed in the Operating Manual or that at the time of pump failure was being used with pump sets or containers other than Abbott Nutrition 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 the casing or have been submerged.

In no event shall Abbott Nutrition 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.

Abbott Nutrition reserves the right (at its option) to repair or replace 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 remanufactured unit are made under warranty because of faulty material or workmanship within one (1) year from the date of shipment, 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 by Abbott Nutrition of such parts furnished under warranty.

Abbott shall have no responsibility or liability for the actions or inactions of unauthorized personnel performing such repair or service.

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

## NOTES

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Distributed by:  
**Abbott Nutrition**  
Abbott Laboratories  
Columbus, Ohio 43229 USA

