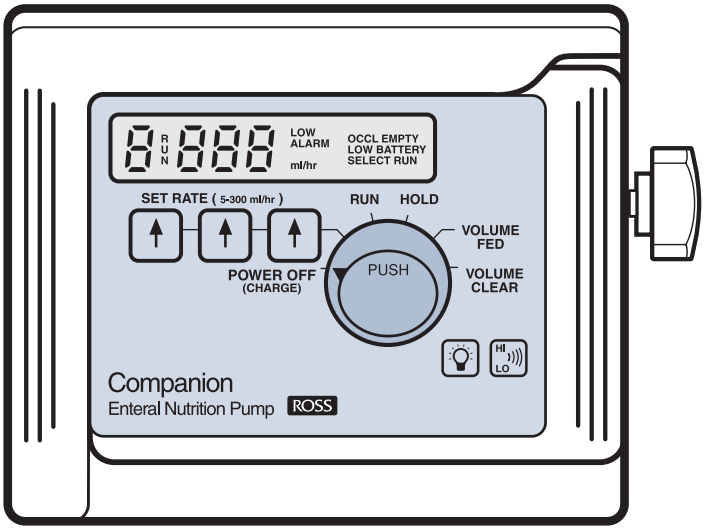
No. 54748–Purchase

No. 00084–Lease/Rent

Companion®

Enteral Nutrition Pump



Operating Manual

For Enteral Use Only
Not for IV Use

ROSS NUTRITION

CONTENTS

USER QUALIFICATIONS

The Ross Companion® 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 Ross 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 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 Pump. The charger may be clamped to a feeding stand or pole or positioned on a flat surface.

Additionally, the Companion Pump offers these features:

1. Accuracy to ±10% at rates of 5 to 300 mL/hr
2. 8-hour battery operation at 150 mL/hr, when fully charged
3. Alarms:
   - **OCCLUSION**
   - **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 Ross Companion Enteral Nutrition 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 ±10%
- Pumps against 24 psi nominal back pressure before **no FLO** 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® Pump should not be used.

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 Ross Companion Enteral Nutrition 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.

PRECAUTIONS

This pump is not for IV (intravenous) use.

Confirm proper placement and function of patient's enteral feeding tube (nasogastric, jejunostomy, gastrostomy, etc) and verify the following before initiating feeding:

1. Only a Ross Companion® Pump 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.

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 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 Pump fluid delivery and alarm systems function when pump is in any position that might be customary for ambulatory use.

ROSS COMPANION® ENTERAL NUTRITION PUMP

Illustrations

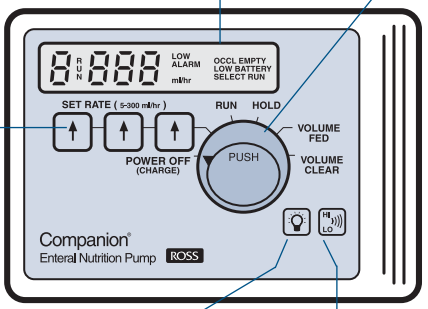
Touch Pads
Select the numerical value of flow rate from 5 to 300 mL/hr in 1-mL increments.

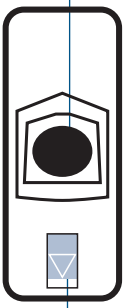
Display Panel
Shows flow rate, cumulative **VOLUME FED**, **RUN** indicator, and visual explanation of all intermittent audio alarms.

Control Dial
Select pump functions.

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

Pump



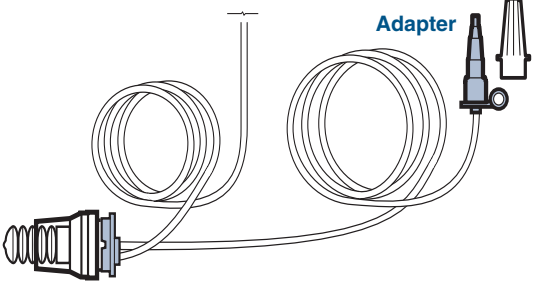


Display Light
Press to temporarily illuminate display panel while on battery power.

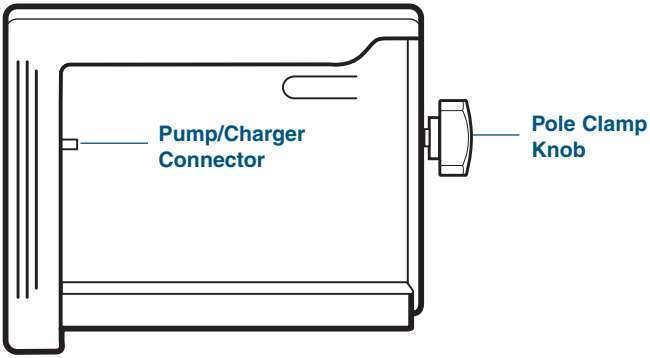
HI/LO Alarm Volume
Select volume of audio alarm.

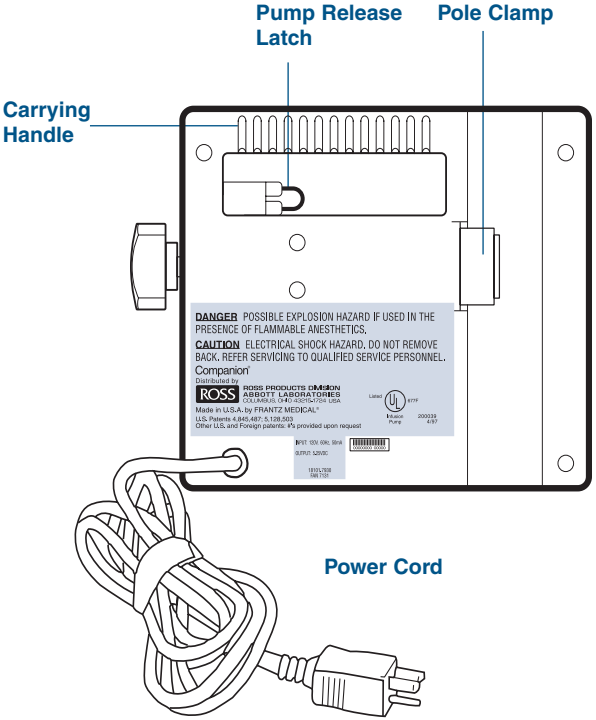
Cassette Release Latch
Press down to release cassette for removal.

Pump Set



Charger


Pump/Charger
Connector
Pole Clamp
Knob


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.
Companion
Distributed by
ROSS PRODUCTS DIVISION
ABBOTT LABORATORIES
Made in U.S.A. by FRANTZ MEDICAL
U.S. Patents 4,845,487; 5,128,503
Other U.S. and Foreign patents: #'s provided upon request
Power Cord

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**

CONTROL DIAL SETTINGS

POWER OFF	Stops all pump functions. Battery charges in all control dial settings when pump is plugged into AC power.
SET RATE	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.
RUN	Only setting that activates pumping action. Visual display shows flashing **RUN** and rate of flow in mL/hr.
HOLD	Stops pumping action and silences audio alarm (if one has occurred) without erasing previous commands or memory functions. **HOLD** is used when correcting an alarm condition, or whenever feeding is temporarily interrupted (such as when connecting a new feeding container).
VOLUME FED	Stops pumping action and displays cumulative volume fed in mL, since this value was last cleared. (**NOTE:** If 9999 mL is fed, numerical value turns to 0 and a new accumulation begins.) To clear **VOLUME FED**, turn knob to **VOLUME CLEAR** and wait for 4 beeps to sound.
VOLUME CLEAR	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

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

VISUAL DISPLAYS AND AUDIO ALARMS (continued)

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 too 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**.

VISUAL DISPLAY	CAUSE OF AUDIO ALARM	ACTION
OCCL	Flow has stopped because of a distal occlusion.	Turn control dial to **HOLD**. 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.
EMPTY	Empty feeding container or missing or improperly seated cassette.	Turn control dial to **HOLD**. If container is empty, provide new feeding or turn dial to **POWER OFF** if no additional feeding is administered. Assure that cassette is in place 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 5 minutes or longer.	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 the control dial to **SET RATE**. Select rate of flow from 5 to 300 mL/hr.
LOW BATTERY	Approximately 30 minutes of battery power remain.	Turn the control dial to **HOLD**, then back to **RUN** 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.

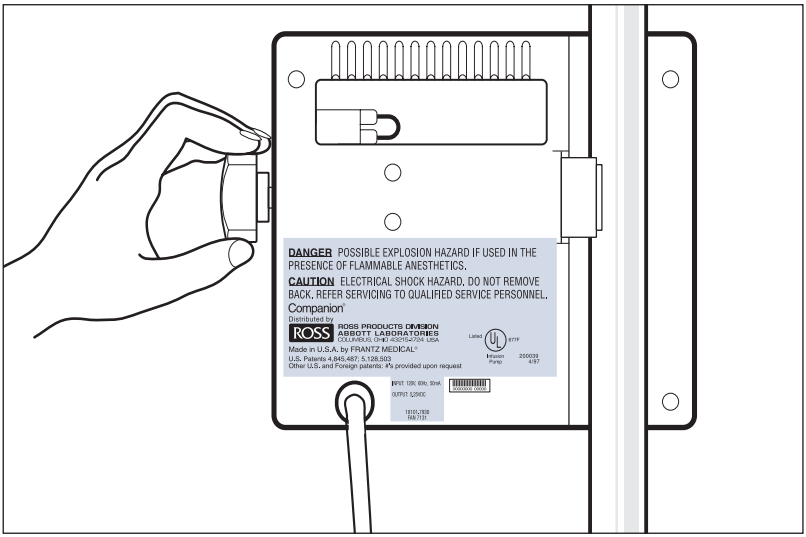
To Reconnect: With pump display panel facing outward, slide pump into charger, using built-in guides for alignment. Slide pump in until it snaps into position, and verify that it is locked in place. When properly seated, pump case will not protrude from charger.

Pole Clamp: Pump must be inserted into charger for 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 Ross Companion® Enteral Pump Charger is not interchangeable with the ClearStar™ Enteral Pump Charger.

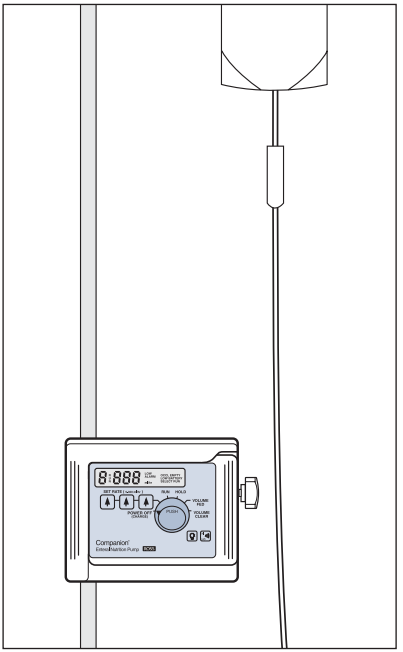
INSTRUCTIONS FOR USE

1. Confirm proper placement and function of patient's enteral feeding tube (nasoenteric, 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.

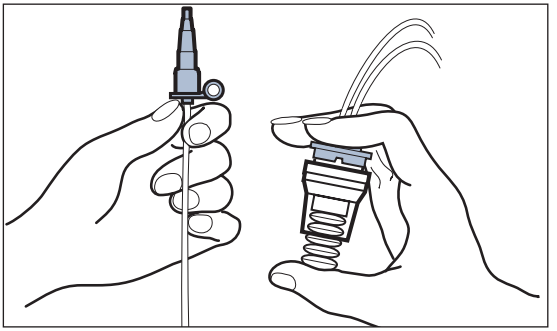


3. Plug in power cord unless battery operation is desired.
4. Fill feeding container with enteral nutritional product or use a prefilled enteral feeding container. Attach Companion® Pump set securely onto filled container if it is not preattached.

5. Suspend container to the side of or behind, and 20 inches above pump.

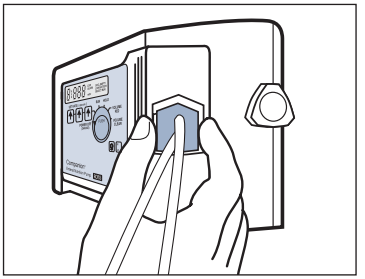


6. Squeeze sight chamber 1/3 to 1/2 full.
7. To prime pump, open the slide clamp on the tubing distal to the bellows and remove cap from adapter at distal end of pump set tubing. Compress bellows of cassette repeatedly (2 strokes/second) until the fluid has expelled all air from cassette and tubing.

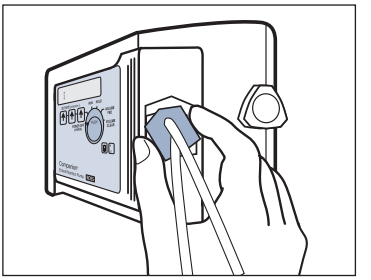


NOTE: Proper priming is critical to assure accurate delivery.

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.

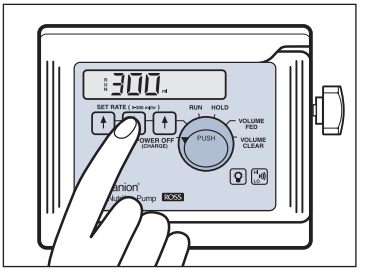


Right



Wrong

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 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 9.

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.

PRECAUTION: To avoid bacterial contamination of enteral product in open systems, pump set should be changed as needed, or at least every 24 hours. Refer to product labeling for closed systems. Pump sets and containers are for **single-patient use only.**

BATTERY OPERATION

When pump is removed from the charger base, power is supplied by the internal, rechargeable battery. No routine maintenance is required for the battery.

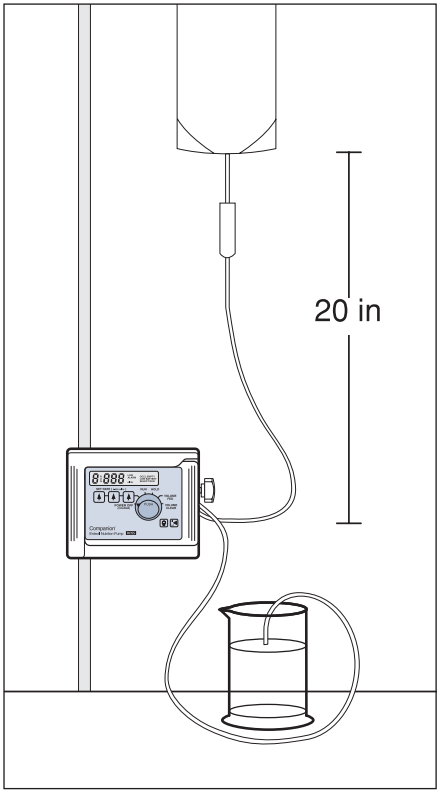
1. Before using pump, remove it from the charger base, turn pump on, and confirm that **BATTERY** appears on the display. If the display fails to illuminate or low battery alarm sounds, charge pump for 8 hours before operating on battery power. If battery is discharged and AC power fails during feeding, pump will shut down and no alarm will sound.
2. While pumping in battery mode, the display light turns off after approximately 15 seconds to save power. Press the light symbol in the lower right corner of pump front panel to turn on the display light temporarily.
3. When the **LOW BATTERY** message first appears, pump will run for approximately 30 minutes before shutting down completely. To continue operation without interruption, place pump in its charger base and connect to AC power within 30 minutes of alarm.
4. Pump can be used while the battery is recharging. To charge battery, seat pump in the charger base and connect to AC power. A pump can operate on a new, fully charged battery for approximately 8 hours at 150 mL/hr flow rate. Battery operation time will diminish with partially charged or older batteries. A new pump should be plugged in for 12-15 hours before initial use to fully charge the battery. The battery will charge in any control dial setting including the **POWER OFF** position when connected to AC power.

NOTE:

- A battery that has repeatedly been fully discharged and/or left in a discharged state for an extended period may not recharge properly.
- If battery is rarely used, occasionally operating pump on battery power may extend battery life.
- When not being used on battery power, pump should **ALWAYS** remain plugged in to AC power to maintain battery charge and performance.

CHECKING PUMP ACCURACY

The height of the enteral feeding container, diameter of the feeding tube, and formula viscosity are three variables that can affect pump accuracy. To check accuracy, use the following procedure. Use a new pump set for this test.



Fill the feeding container with 8 fl oz of Osmolite®, and set the container so that the level indicator on the sight chamber 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.

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

CLEANING

The pump and charger base are specifically designed for easy cleaning. Unplug and turn off pump before cleaning. Remove pump from the charger for cleaning. Clean the outside surfaces, behind pump, inside the charger cavity and the cassette release lever with warm, soapy water. **Do not immerse in water.** Rinse and dry thoroughly. For trouble-free operation, the surfaces should be cleaned immediately after spills occur.

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

NOTE: Do not submerge, autoclave, heat, steam, ETO, or radiation sterilize pump or charger.

DISINFECTANTS

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

GENERAL	AIDS AND HEPATITIS	TUBERCULOSIS
Cidex® (Arbrook Inc) pHisoHex® (Winthrop-Breon Laboratories) Hibiclens® (Stuart Pharmaceuticals) 70% concentration of isopropyl alcohol	10% concentration of 5.25% sodium hypochlorite (household bleach)	70% concentration isopropyl alcohol

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

STORAGE

- The pump should be stored away from extreme temperatures or humidity.
- In order to assure maximum battery capacity while in storage, plug unit into AC power source (standard wall outlet).

SERVICE

The Ross Companion® Enteral Nutrition Pump is designed to be highly reliable. However, in the event of a pump malfunction, or for technical assistance or parts, please contact your pump provider or the Ross Device Call Center. Be prepared to provide pump name, serial number found on back, and specifics of problem.

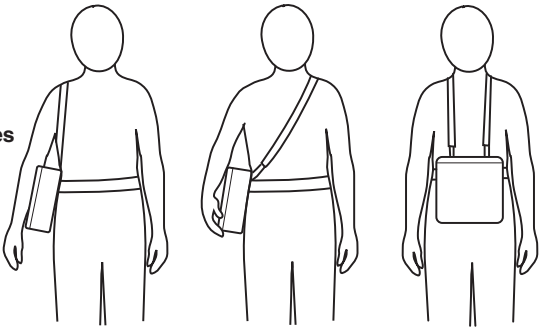
Service, if required, should be performed by trained service representatives.

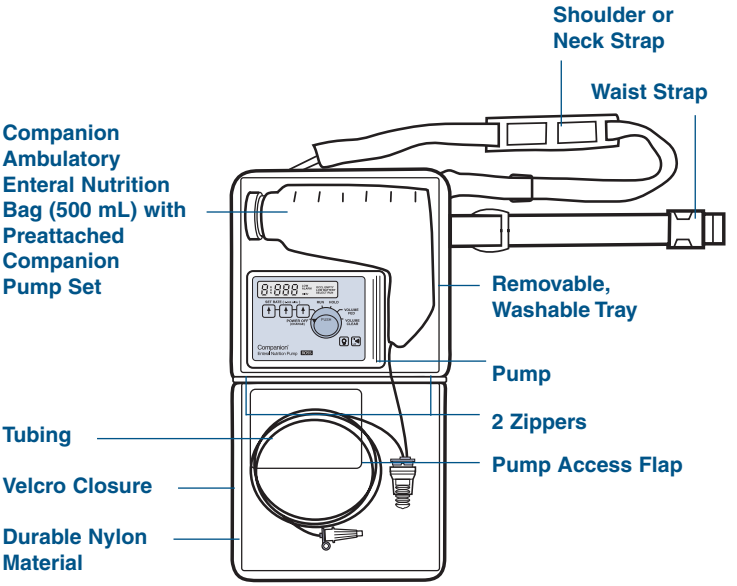
Before calling, do a few simple checks:

1. Check for proper electrical connection. (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 base. Be sure that a Companion charger is being used.
3. Be sure a Companion® Pump set is being used and that the cassette is properly seated in cassette cavity.
4. Check visual display and correct situation as indicated.

AMBULATORY TRANSPORTER

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





SPECIFICATIONS

POWER

Power:	120 VAC, 60 Hz, 1 Phase, 2 watts
Fuse:	1 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.

BATTERY OPERATION

Type:	1.0 Ah rechargeable sealed lead-acid
Voltage:	4V
Recharge Rate:	1½ hours for every 1 hour of battery use
Operating Life:	8 hours at 150 mL/hr when fully charged. When low battery alarm occurs, the pump will operate for approximately 30 minutes before shutting down.

STANDARDS

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

LIMITED WARRANTY

Ross Products Division of Abbott Laboratories warrants each Ross 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 repaired by someone other than an individual appropriately trained in the repair of these devices, such as a biomedical engineer (BME), biomedical electronic technician (BMET), or other qualified technician, 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 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 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 (at its option) to repair, provide field replaceable parts for, 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, provided, or replaced. Also, the customer will not be charged for labor involved in connection with the installation by Ross of such parts furnished under warranty.

Shipping costs for units returned to Ross, including loaners, 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 prior to return of the unit.

NOTES

ROSS #1 IN ENTERAL FEEDING

Digitally signed by Renee Cook
DN: CN = Renee Cook, C = US, O = Abbott Laboratories, OU = Ross Products Division
Reason: I am approving this document
Date: 2004.10.01 14:04:18 -04'00'

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ROSS NUTRITION