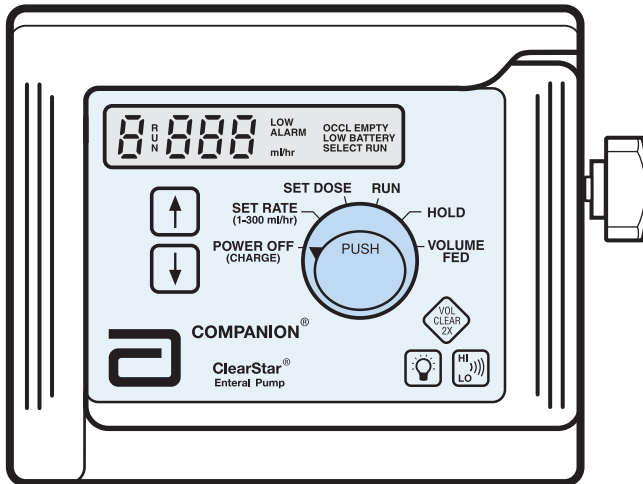




Companion[®] ClearStar[®] Enteral Pump



Operating Manual

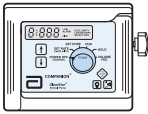
*For Enteral Use Only
Not for IV Use*

English

CE 0470

 **Abbott**

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

CE 0470

**This device complies with the requirements of
Council Directive 93/42/EEC**

PUMP CHARACTERISTICS

Uniquely designed and constructed, the Companion[®] ClearStar[®] 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 feed. The pump will operate on earthed mains / 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 appropriate feeding stand or pole. The volume-monitoring device does not depend on drop counting, so the pump is versatile in adapting to patient activities.

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

The Companion ClearStar Pump offers these features:

The Companion ClearStar Pump has a feature that automatically clears most clogs in the distal tubing (outlet of the cassette through the patient's indwelling feeding tube) without user intervention. Should a clog occur in the distal tubing, the occlusion detection system will sense the clog at feeding rates from 30 to 300 mL/hr and cause the pump to enter the automatic clog clearing mode. The pump will automatically resume the feeding mode after the clog has been cleared. If the clog is not cleared within 10 minutes the pump will alarm (audible and visual) and stop pumping. As a safety feature, the pump can only enter the automatic clog clearing mode for a maximum of 10 minutes for any single occurrence and for a maximum of 20 minutes or 10 occurrences in any consecutive 4-hour period.

The Companion ClearStar Pump offers these features:

- 1) Automatic clog clearing with feeding rates from 30 to 300 mL/hr
- 2) Dose setting
- 3) Accuracy to $\pm 10\%$ or 0.5 mL/hr, whichever is greater, (1-300 mL/hr) with standard liquid enteral feed products 1 Kcal/mL similar to Osmolite 1 CAL. Thoroughly mix all powder feeds.
- 4) 24-hour battery operation at 125 mL/hr when fully charged
- 5) Alarms:
 - **OCCCLUSION (IF CLOG CLEARING IS UNSUCCESSFUL)**
 - **EMPTY CONTAINER/MISSING OR IMPROPERLY LOADED CASSETTE**
 - **DOSE COMPLETE**
 - **SELECT RUN**
 - **LOW BATTERY**
- 6) Fluid flow and fluid monitoring independent of pump position (no drop counting)
- 7) Adjustable alarm volume for low or high setting

- 8) Flow rate selection of 1 to 300 mL/hr in 1 mL/hr increments
- 9) VOLUME FED accumulation display
- 10) User-friendly operating controls
- 11) Small and lightweight
- 12) Simple setup (one-hand cassette loading)
- 13) "Backlit" visual display for easier viewing in a darkened room
- 14) Self-test capability
- 15) Memory - Automatic retention of the following values when turned off and disconnected from AC power.
 - Set Rate (feeding rate)
 - Set Dose value
 - Volume Fed accumulation
- 16) Memory reminder message of Set Rate, Set Dose and Volume Fed Values. Each time the pump is turned on the LCD displays rAtE (value), doSE (value) and FED (value).

INDICATIONS FOR USE

- **NOT FOR IV USE.**
- For enteral use only.
- Suitable for CONTINUOUS operation.
- Automatic clog clearing does not function below 30 mL/hr set rate.
- The Companion[®] ClearStar[®] Pump can be used for adult and paediatric (pediatric) patients provided the patients can tolerate a feeding range within the pump operational specifications. These specifications are:
 1. The flow rate range is 1-300 mL/hr in 1 mL/hr increments.
 2. The flow rate accuracy is $\pm 10\%$ (1-300 mL/hr) or ± 0.5 mL/hr, whichever is greater, with standard liquid enteral feed products 1 Kcal/mL similar to Osmolite 1 CAL. Thoroughly mix all powder feeds.
 3. The occlusion pressure limit is 172 kPa (25 psi) nominal.
- If these specifications are not appropriate for a given patient, the Companion ClearStar Pump should not be used.
- **POWER CONDITION - MAINS POWER/BATTERY**
In a situation where the battery is discharged and AC power fails during feeding the pump will shutdown and no alarm will be given.
- **PROPER SET PRIMING**
 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.

- **USE COMPANION® PUMP FEEDING SET ONLY**
- Connect new pump in its charger unit to earthed mains /AC power for 8 hours to charge battery before operating in battery mode.
- Confirm proper placement and function of patient's enteral feeding tube (nasogastric, jejunostomy, gastrostomy, etc.). Verify the following before initiating feeding:
 1. A Companion Pump Feeding Set is being used.
 2. Cassette is properly seated in pump.
 3. When on AC power, verify the pump is fully seated in charger.
 4. Flow rate is set at the prescribed mL/hr.
- 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.**

Note: The Power Supply Cord is the DISCONNECT DEVICE.

PRECAUTIONS

Paediatric (Pediatric) Use

The Companion® ClearStar® Pump provides accurate delivery of feeds at rates of 1 to 300 mL/hr.

Use of the Companion ClearStar Pump for paediatric patients should only be done on the advice of a physician trained in paediatrics. Intestinal tolerance and overall fluid balance of the paediatric patient should be considered when selecting the pump.

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 a physician.

Use of Reconstituted Powder

If reconstituted powder feed is used, ensure that the product is mixed thoroughly.

Pump Servicing

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

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:

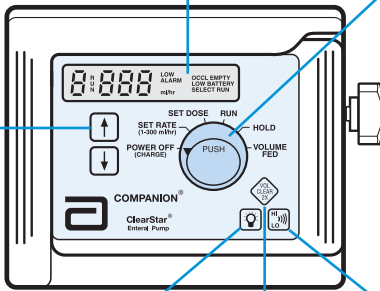
Select the numerical value of flow rate from 1 to 300 mL/hr in 1 mL increments.

Display Panel:

Shows flow rate, set dose accumulated volume, RUN indicator, visual explanation of all intermittent audio alarms.

Control:

Select pump functions.



Display Light:

Press to temporarily illuminate display panel while on battery power.

VOL CLEAR:

Turn control to VOLUME FED and press Vol Clear twice to zero volume.

Hi/Lo Alarm Volume:

Select volume of audio alarm.

SIDE VIEW

Cassette Cavity:

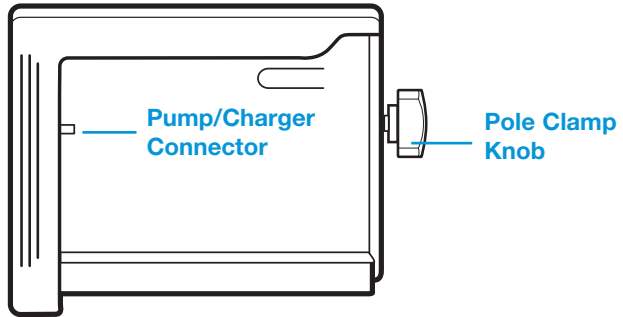
Insert Cassette into pump, using shape for orientation, until seated.



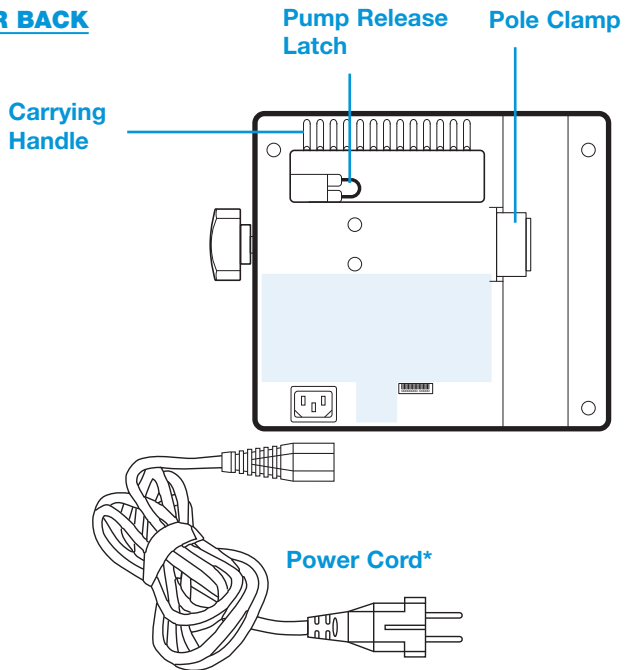
Cassette Release Latch:

Press down to release cassette for removal.

CHARGER FRONT

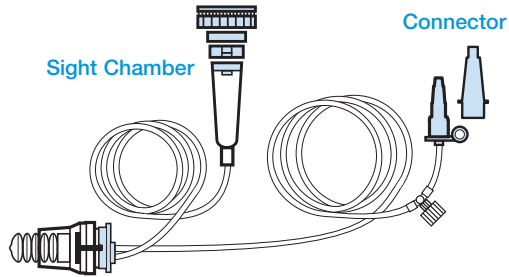


CHARGER BACK



* Note: Power Cord and Plug will differ depending on local electrical standards.

PUMP SET*



Cassette With Bellows

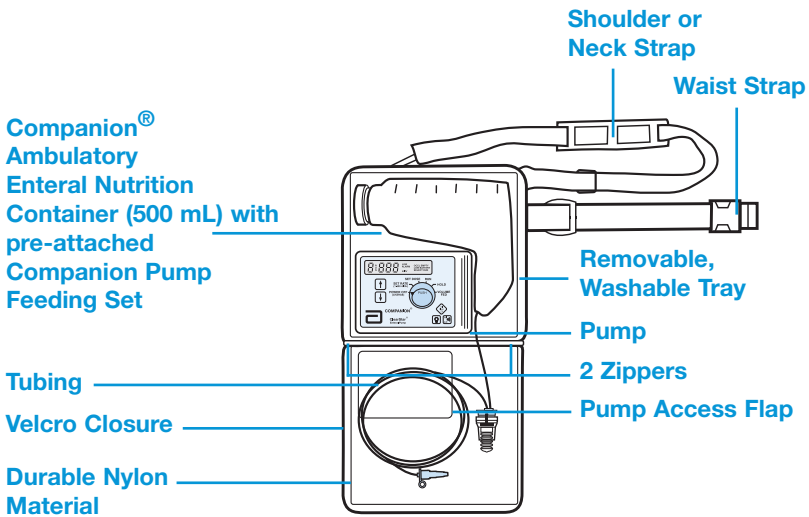
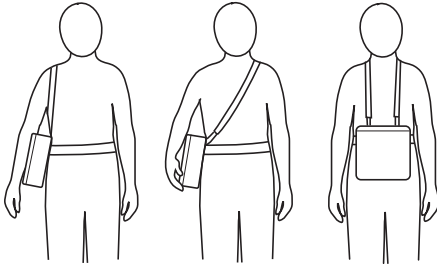
** Sets are also available with a piercing pin (except in the UK) and with pre-attached feeding containers for hospital use (1,000 mL) or ambulatory use (500 mL)*

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

Ambulatory transporter enables patient to carry pump, bag and tubing without an IV pole. Refer to transporter and set Instructions for Use.



CONTROL DIAL SETTINGS

POWER OFF: (Charge)	This setting stops all pump functions. Battery charges in all Control Dial settings when pump is connected to earthed mains / AC power.
SET RATE:	This setting allows flow rate to be set (1 to 300 mL/hr in 1 mL increments) by pressing the arrow keypad buttons. No pumping action occurs in this mode.
SET DOSE:	This setting allows dose to be limited (1 to 9999 mL in 1-mL increments) by pressing the arrow keypad buttons. Completion of this dose triggers DOSE alarm. NOTE: If zero dose is entered (0), this feature is deactivated.
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 feeding is temporarily interrupted (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, or this value was last cleared. (NOTE: If 9999 mL is fed numerical value turns to 0 and a new accumulation begins). To clear the VOLUME FED press the VOL. CLEAR touchswitch twice.

***NOTE:** Pump activates flow only in RUN setting. Pump maintains memory in all settings including when pump is turned OFF and disconnected from earthed mains / AC power.*

VISUAL DISPLAYS AND AUDIO ALARMS

Visual Displays

<i>Control Dial Setting</i>	<i>Visual Display</i>	<i>Audio Alarm</i>
POWER OFF (Charge)	None	None
SET RATE (No pumping action)	Previous flow rate or 1 mL/hr	None
SET DOSE (No pumping action)	Numerical value of dose set or 0 mL	Alarms when volume fed equals dose set
RUN	Numerical rate in mL/hr and flashing "RUN"	None
HOLD (No pumping action)	Existing flow rate or 1 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 0	None

Audio Alarms

Intermittent audio alarms are always accompanied by a visual message on display panel indicating the 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.

<i>Visual Display</i>	<i>Condition or Problem</i>	<i>Explanation or Corrective Action</i>
OCCL	Flow has stopped. Automatic clog clearing has not cleared the obstruction.	Turn control dial to HOLD. Check pump set tubing and patient's indwelling feeding tube for flow restriction, e.g. kinked tubing. This is a distal occlusion alarm between the pump and the patient. Verify that the occlusion is cleared after re-starting the pump by verifying the presence of drops in the sight chamber.
EMPTY	Empty feeding container or missing or improperly seated cassette.	Turn control dial to HOLD. Check the fluid, fluid container, the set tubing (between the container and the pump) for particle accumulation or tube kinks that would prevent fluid flow. Assure that cassette is present and properly seated.
doSE-numerical value	Volume Fed is equal to the Set Dose.	Turn dial to SET DOSE. Press keypad arrow buttons to increase dose or to zero dose setting or turn dial to VOLUME FED and press the VOL. CLEAR touchswitch twice. To silence alarm, turn dial to HOLD.
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.
LOW BATTERY	Approximately 30 minutes of battery power remain.	Turn the control dial to HOLD, then back to RUN to stop audio alarm. Pump should be seated in charger and connected to earthed mains /AC power immediately. See Page 19 for additional battery information.

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[®] ClearStar[®] Pump is small and lightweight. The pump weighs 0.60 kgs (1.3 pounds); the charger weighs 0.70 kgs (1.6 pounds). With the Ambulatory Transporter, a patient can easily carry the pump and up to 500 mL of enteral formula during routine activities.

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

Electromagnetic Emissions/Interference: The Companion ClearStar Pump is compliant with the following standards: EMC; EN55011, Group 1, Class B; EN61000-3-3; EN61000-3-2 Ed. 2:2001 and EN60601-1-2.

Self-Test Procedure: Each time the pump is turned on, the microprocessor initiates a self-test procedure. Audio alarm, visual displays, and readout (8888) will turn on for 5 seconds followed by the numerical values of rate, dose and volume fed in memory. If the self-test fails, F1 will appear. **DO NOT USE THE PUMP. SERVICING IS REQUIRED.**

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

- EMPTY
- OCCL
- LOW BATTERY
- doSE-numerical value
- Select Run

Ambulatory or Appropriate Feeding Stand or Pole Use: The Companion[®] ClearStar[®] Pump can be used in an ambulatory mode or with the charger on an appropriate feeding stand or pole.

PUMP/CHARGER CONNECTION

The Companion® ClearStar® pump/charger units are NOT interchangeable with the original Companion pump/charger units. The pump/charger connector for ClearStar has a different shape and location, and does not allow improper coupling. Do not force connection of non-like components or damage may occur. Verify the ClearStar name on both components (pump front panel and top of charger) before connecting.

To Separate: When properly seated, the pump is held firmly within the charger. In order to separate the pump and charger; locate the pump release latch on the back of the charger within handle cavity. Pull pump towards opening while pressing the 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, and 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 before pole attachment.

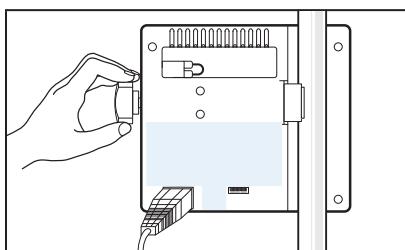
Pole Clamp mechanism is controlled by knob on right side of charger. Align pole cavity (located at back of charger) with pole; turn knob clockwise until pole is firmly captured.

INSTRUCTIONS FOR USE

The Companion® ClearStar® Pump has an automatic memory retention feature which stores feeding rate, dose set and volume fed. When the pump is turned on (SET RATE) it will go through a self-check (3 BEEPS OF THE ALARM). Following the self-check it will sequence through each value in memory [SET RATE (rAtE), SET DOSE (doSE) and VOLUME FED (Fed)] and go back to SET RATE. To change the values in memory (SET RATE or SET DOSE) turn the dial to the setting and change through the arrow buttons. To clear Volume Fed turn the dial to VOLUME FED and press the VOL. Clear touchswitch twice.

Note: Pump must be inserted into charger **before** pole attachment.

1. Attach to, or place on, appropriate feeding stand or pole. Be sure the pump is properly seated in charger, and then clamp to pole.



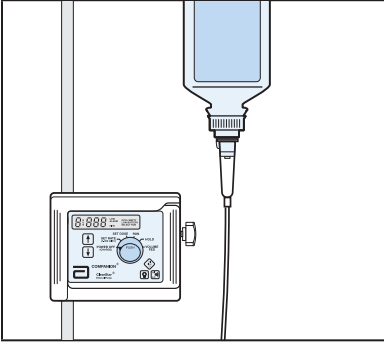
2. Connect power cord to earthed mains /AC power if available.

NOTE: If quality of the earth/ground source is in doubt use battery power. See battery operation section.

3. Prepare enteral feed. Use the following guidelines for the most accurate feed delivery:
 - Thoroughly mix all ready to feed and ready to hang products before use. Settling may occur during shipping and storage.
 - Thoroughly reconstitute all powder feeds. Over delivery may result from large particles preventing cassette valve closure.
 - Flush the feeding tube before and after administering medications to prevent unpredictable deliveries.
 - Monitor the patient closely and adjust the feeding rate since underdelivery may result from:
 - low viscosity or clear fluids unless the set is pre-primed and emptied with a complete enteral formula.
 - high viscosity liquid products.
 - overly diluted powder feeds.
 - Do not use liquids at extreme temperatures as damage may occur to the set.
 - In volume sensitive 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 a physician.

In cases of underdelivery, the product delivered may be less than the amount indicated on the volume fed display. (See section "Checking Pump Accuracy".)

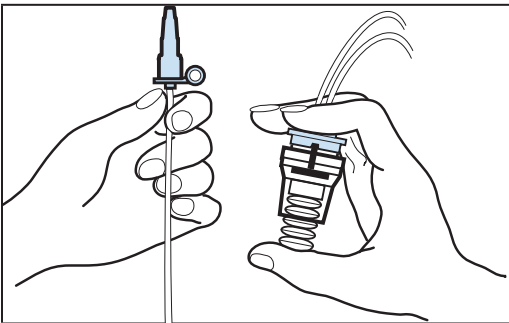
4. Suspend container to side of or behind pump and 51 cm (20 inches) above pump.



5. Squeeze and release the sight chamber until the fluid level has reached the $\frac{1}{3}$ to $\frac{1}{2}$ way mark on the sight chamber.

6. **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.



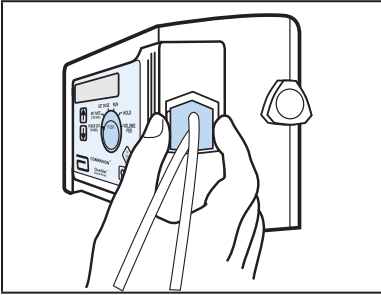
Warning:

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.

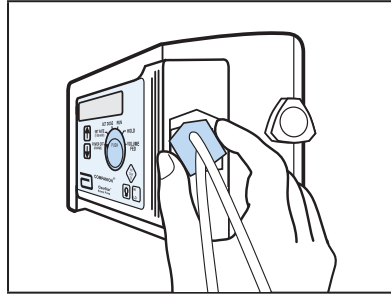
***NOTE:** You may leave 5 to 8 cm (2 to 3 inches) near the end of the tubing unprimed to avoid product dripping during the setup.*

7. CONFIRM PROPER PLACEMENT AND FUNCTION OF PATIENT'S ENTERAL FEEDING TUBE (NASOGASTRIC, JEJUNOSTOMY, GASTROSTOMY, ETC). Attach connector to enteral feeding tube.

8. Insert cassette into pump, using shape for orientation. Press until cassette clicks into place. Grasp base of cassette tubing and pull gently to confirm that cassette is seated.
 - Check the set, cassette and tubing for:
 - clogging or kinked tubing
 - trapped air in the bellows (Re-prime the set as needed. If no improvement, use a new tubing set).

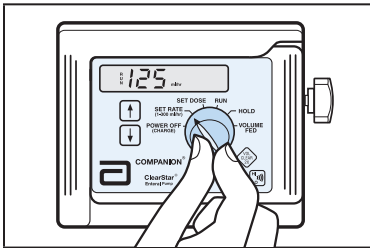


Right

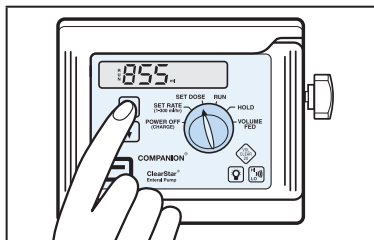


Wrong

9. Push control dial to expose tab and then turn to SET RATE and select flow rate from 1 to 300 mL/hr by pressing arrow buttons.



10. If desired, turn dial to SET DOSE and select dose by pressing arrow buttons.



NOTE: If no dose is entered (0 mL) this feature is deactivated.

11. Turn pump control dial to RUN and start feeding. If cassette is not properly seated, the EMPTY alarm will sound after a short delay.

NOTE: Always check the sight chamber of the Companion® Pump Feeding Set when starting feed, to verify that the feed is dripping before leaving the patient. If no drops are detected, check the fluid, fluid container, the set tubing (between the pump and the enteral feeding container) and the patient's feeding tube for particles, clumping or kinking that would prevent fluid flow.

12. To see feed volume delivered, turn dial to **VOLUME FED**.
13. To clear the feed volume delivered turn dial to **VOLUME FED** and press the **VOL. CLEAR** touchswitch twice.
14. Turn pump dial back to RUN to restart feeding.

***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.*

15. When feeding is completed, turn pump dial to HOLD or POWER 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 alternately display the message doSE and the volume fed in mLs.*

16. 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.

PRECAUTIONS: 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.**

CAUTION: TO REDUCE THE RISK OF ELECTRIC SHOCK, DO NOT REMOVE THE BACK COVER. REFER SERVICING TO QUALIFIED SERVICE PERSONNEL.

DANGER: POSSIBLE EXPLOSION HAZARD IF USED IN THE PRESENCE OF FLAMMABLE ANESTHETICS. EQUIPMENT NOT SUITABLE FOR USE IN THE PRESENCE OF A FLAMMABLE ANAESTHETIC (ANESTHETIC) MIXTURE WITH AIR OR WITH OXYGEN OR NITROUS OXIDE.

BATTERY OPERATION

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 15 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 24 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 8 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.

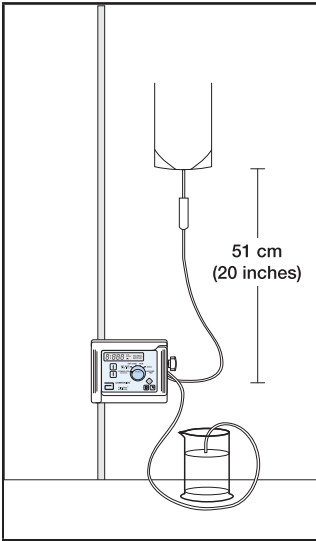
CHECKING PUMP FUNCTION

1. To check SET RATE function turn main control dial to the SET RATE position. After self check (three beeps of the alarm) the previous set rate should be displayed.
2. To check EMPTY (no cassette) alarm, set rate 300 mL/hr and select RUN. Watch for upward movement of the black piston at the bottom of the cassette chamber (pump strokes). After two pump strokes, "EMPTY" will display and an audio alarm will sound. Select HOLD, audio alarm is muted. **"EMPTY" (no cassette) alarm is OK.**
3. To check EMPTY (no feed) alarm, fit an empty cassette into the pump. Set the rate to 300 mL/hr and select RUN. After approximately 9 strokes, "EMPTY" will display and an audio alarm will sound. Select HOLD, audio alarm is muted. **"EMPTY" (no feed) alarm is OK.**
4. To check the distal occlusion alarm, remove the empty cassette and prime the Companion[®] Pump Feeding Set with water or feed. See Instructions For Use section. Place the cassette into pump and set the rate at 300 mL/hr. Select RUN. After one pump stroke, occlude the patient tubing at the distal end of the set. After approximately 10.75 minutes "OCCL" will display and an audio alarm will sound. **OCCLUSION alarm is OK.**
5. Stroke timing can be checked by testing the stroke interval time. Repeat test four but do not occlude the tubing. Time the pump stroke interval from start of one stroke to the start of the next stroke at a rate of 300 mL/hr. The stroke interval should equal 6 seconds. **Stroke timing is OK.**

NOTE: If malfunctions are detected, contact an Abbott sales/service representative.

CHECKING PUMP ACCURACY

Please use a new Companion Pump Feeding Set for this test.



The height of the enteral feeding bag, diameter of the feeding tube, and feed viscosity are three variables that can affect the flow rate. To check the flow rate, use the following procedure. Fill the container with Osmolite 1 CAL and set the bag so that the bottom of the bag/container is 51 cm (20 inches) above the cassette. See diagram. Set up pump per the instructions for use section.

Operate the pump at 50 mL/hr for 15 minutes and discard the feed delivered. Increase the rate to 100 mL/hr and run enteral product into a graduated cylinder or measuring cup for 1 hour. The volume delivered should be between 90 and 110 mLs.

If the volume delivered is outside this range, repeat the procedure with a new administration Companion[®] Pump Feeding Set.

If it is still out of range, the pump should not be used. Contact an Abbott sales/service representative.

Clean and disinfect as needed, prior to transportation or service, and at end life.

CLEANING

The pump and charger are specifically designed for easy cleaning. Remove the pump from the charger for cleaning. Clean the outside surfaces, behind the pump, inside the charger cavity and the cassette release lever with warm, soapy water. 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: 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

- The Companion® ClearStar® 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 ClearStar enteral nutrition 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 batteries and 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:

	220/240 VAC, 50 Hz, 1 Phase, 12 watts	110/120 VAC, 60 Hz, 1 Phase, 9 watts
Fuse:	2 A/250 V (F1, F2); non-serviceable	2 A/250 V (F1, F2); non-serviceable
Power Cord:	Hospital grade (3.0 m/10 feet) detachable from charger	Hospital grade (3.0 m/10 feet) attached
Leakage:	Less than 100 microamps	Less than 100 microamps

MECHANICAL

	<u>Pump Only</u>	<u>Pump With Charger</u>
Height:	10.9 cm (4.3 inches)	15.2 cm (6.0 inches)
Width:	15.2 cm (6.0 inches)	17.0 cm (6.7 inches)
Depth:	4.3 cm (1.7 inches)	8.3 cm (3.3 inches)
Weight:	0.6 kg (1.3 pounds)	1.3 kg (2.9 pounds)

Note: The 110/120 VAC pump has an attached power cord. The weight of this pump and charger is 1.5 kg (3.4 pounds).

OPERATION SPECIFICATIONS - FLOW RATES

Range:	1 to 300 mL/hr
Increments:	1 mL/hr
Accuracy:	±10% or ±0.5 mL/hr, whichever is greater, with measured flow rates of 1 Litre of standard liquid enteral feed products (1 Kcal/mL similar to Osmolite 1 CAL) from 1 to 300 mL/hr using Companion Pump Set at zero back pressure (atmospheric).
Pressure:	Pumps against 172 kPa (25 psi) nominal back pressure in clog clearing mode, before occlusion alarm.
Operating Temperature:	16°C to 32°C (60°F to 90°F)
Operating Humidity:	30% RH - 90% RH, non-condensing

The system is capable of operating as specified at elevations up to 3,050 meters (10,000 feet) above sea level.

STORAGE

- Be sure pump dial is in the **OFF** position.

Storage Temperature: -18°C to 43°C (0°F to 110°F)

Storage Humidity: 15% RH- 90% RH, non-condensing

Storage Altitude: The system is able to withstand and operate after exposure to elevations up to 6,100 meters (20,000 feet) above sea level.

BATTERY

Type: 1.0 Ah rechargeable sealed lead-acid

Voltage: 4 V

**CAUTION: RISK OF FIRE, REPLACE ONLY WITH BATTERY
MARKED 2A X 2K OR WP1-4 (4 V. 1.0 Ah)**

Reference Battery Operation section on Page 19.

STANDARDS

Europe/Australia

Designed and manufactured to meet requirements of IEC 601-1-1 and -2.

WEEE regulations and EU Battery Directive Compliant

United States/Canada

**MEDICAL EQUIPMENT - WITH RESPECT TO ELECTRICAL SHOCK,
FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH
CAN/CSA C22.2 No. 601.1 and UL 60601-1 <48BA>.**



EXPLANATION OF SYMBOLS



Type BF: (Type B Equipment with an F-Type Isolated (Floating) Applied Part).

IPX1

Drip Proof: (Equipment protected against ingress of falling liquid.)



Attention, consult ACCOMPANYING DOCUMENTS



Protective earth (ground)



Separate collection of waste at end of life as required by European directives

LIMITED WARRANTY

Subject to the terms and conditions herein, Abbott Laboratories, herein referred to as Abbott, warrants that (a) the product shall conform to Abbott's standard specifications and be free from defects in material and workmanship under normal use and service for a period of one year after date of delivery, and (b) the replaceable battery shall be free from defects in material and workmanship under normal use and service for a period of 90 days after date of delivery. Abbott makes no other warranties, express or implied, as to merchantability, fitness for a particular purpose, or any other matter.

When repairs are made under warranty, the customer will not be billed for parts repaired or replaced, or for labor involved.

Purchaser's exclusive remedy shall be, at Abbott's option the repair or replacement of the product. In no event shall Abbott's liability arising out of any case whatsoever (whether such cause be based in contract, negligence, strict liability, other tort, or otherwise) exceed the price of such product, and in no event shall Abbott be liable for incidental, consequential, or special damages or losses or for loss of business, revenues, or profits. Warranty product returned to Abbott must be properly packaged. Loss or damage in return shipment shall be at the customer's risk. Authorization to return the unit should be obtained by contacting the local Abbott representative.

The foregoing warranty shall be void in the event the product has been misused, damaged, altered, or used other than in accordance with product manuals so as, in Abbott's judgement, to affect its stability or reliability, or in the event the serial number or lot number has been altered, effaced, or removed.

The foregoing warranty shall also be void in the event any non-Abbott personnel, including the Purchaser, performs or attempts to perform any repair or other service on the product. For purposes of the preceding sentence, "repair or other service" means any repair or service other than the replacement of accessory items such as detachable AC power cords and patient pendants.

NOTES

Authorized EU Representative:
Abbott Logistics B.V. (Subsidiary of Abbott Laboratories)
8000 AJ Zwolle
Netherlands



Manufactured by:
Frantz Medical Development Ltd.
Mentor, Ohio 44060 USA

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

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P/N 200813C

Eur. Pat. 296, 124