



OPERATOR'S MANUAL



ZEVEEX[®]
THERAPEUTICS

EnteraLite[®]

Ambulatory Enteral Feeding Pump

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LIST OF WARNINGS and CAUTIONS



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- WARNING:** Use ONLY feeding solutions prescribed by the responsible physician, registered dietitian, registered nurse, or other licensed practitioner.
- WARNING:** Use ONLY EnteraLite® Disposable Sets to ensure proper fluid delivery. Others won't deliver the correct dose, may allow dangerous free-flow conditions, and may generate hazardous fluid pressures which may activate occlusion alarms at unpredictable pressures.
- WARNING:** Replace the disposable set every 24 hours to maintain delivery accuracy and prevent the growth of harmful bacteria.
- WARNING:** Low flow rates, combined with high dose settings may exceed the life of the disposable set. The disposable set must be replaced every 24 hours to maintain delivery accuracy and prevent the growth of bacteria. DO NOT PROGRAM RATE AND DOSE COMBINATIONS WHICH EXCEED A 24 HOUR FEED REGIMEN.
- WARNING:** The battery capacity is an approximation. If you're unsure that enough capacity remains for your intended use, recharge it!
- WARNING:** To avoid electrical shock, never clean the pump or the EnteraLite® AC Adapter/Charger with the charger plugged in or the pump on.
- WARNING:** Never immerse the pump or the EnteraLite® AC Adapter/Charger in liquids. Electrical shock or pump damage can result.
- WARNING:** The EnteraLite® must be periodically calibrated to ensure proper fluid delivery.
- WARNING:** Do not use the EnteraLite® Enteral Feeding Pump for the delivery of non-enteral solutions. Serious injury may result. For enteral feeding only. Not for IV use.
- WARNING:** The Total Volume may be incorrect due to an interruption of battery power if the overcurrent or temperature protection circuits are triggered. In such a case one of the following conditions occurs:

During Single Feeding

The pump enters pause mode, but does not display "DOSE DONE" or turns off (but not due to a low battery).

During Interval Feeding

The pump enters pause mode or turns off (but not due to a low battery).

LIST OF WARNINGS and CAUTIONS

WARNING: When simultaneously charging and operating the pump, position the pump to avoid contact with the patient's skin.

(Place the pump on a table top, in an EnteraLite® pack, or secure the pump to an appropriate fixture using a pole clamp).

WARNING: Make sure the EnteraLite® AC Adapter/Charger is completely dry before plugging into an electrical outlet.

WARNING: Do not use an extension cord with the AC Adapter/Charger.

WARNING: The AC Adapter/Charger is intended for indoor, dry area use only. Do not allow adapter to be exposed to liquids.

WARNING: Possible explosion hazard if used in the presence of flammable anesthetics!

WARNING: U.S. law restricts this device to sale by or on the order of a physician, registered dietitian, registered nurse, or other licensed practitioner.

WARNING: Dispose of the packaging properly. The plastic bag and band could be a hazard to children.

CAUTION: Dispose of EnteraLite® Disposable Sets properly, as required by local law.

CAUTION: Gently clean the pressure sensors. Excessive pressure due to aggressive cleaning can damage them.

CAUTION: Never press fingers or other objects into the cavities over the pressure sensors. Load only the silicone tubing of the disposable set into these sensors.

CAUTION: When feeding human milk, fat separation may occur. The feeding solution should be periodically checked during the feed regimen.

CAUTION: If the pump is dropped or falls onto a hard surface from a height of 3 feet or more, it is recommended that it be returned for service.

CHAPTER 1 - GENERAL INFORMATION



WARNING: U.S. law restricts this device to sale by or on the order of a physician, registered dietitian, registered nurse, or other licensed practitioner.

The EnteraLite® is a rotary peristaltic enteral feeding pump (order number Z-11583-1) designed to deliver programmed doses of enteral nutrition solutions at selectable rates. This small, lightweight pump operates in any orientation, making it ideal for ambulatory use.

SIZE

Pump Dimensions: 4.97" H x 4.47" W x 2.00" D
13cm H x 11cm W x 5cm D
Pump Weight: 1.30 lb. (590g)

BATTERY

Type: NiMH
(Nickel Metal Hydride)
Life: 24 hours @ 125 ml/hr
Charge Time: approximately 5 hours
(see * note in Chapter 2, *Running on Battery Power*)
Charge Level Indicator
Compact Charger 105 to 129 VAC, 60 Hz, 0.22A

DISPLAY

Backlit LCD

OPERATING ORIENTATION

Any

FLOW RATE

Range: 1 - 600 ml/hr
Increment: 1 ml/hr over full range
Accuracy: ± 5%,
including high
viscosity solutions

DOSE

Maximum: 3000 ml
Increment: 10 ml

VOLUME DISPLAY

Current Dose Status
Accumulated (Pump on or off)

INTERVAL FEED

Interval Feed Indication
Time To Next Feed Indication

PROGRAM MEMORY RETAINED

When Pump is on or off

LIFE EXPECTANCY

The pump will survive a minimum of 5,000 loadings. At a typical use of 1-3 loads per day, this is equivalent to 5 - 10 years.

PRIME (approximately 600 ml/hr)

ALARMS

Chek	Programming error
Load Set	Set not loaded properly
Low Batt	Battery Low
No Flow In	Upstream occlusion
No Flow Out	Downstream occlusion, Select 8 psi (55 kPa) or 12 psi (83 kPa) Tolerance = ± 2psi (14 kPa) psi (pounds per square inch) kPa (kilopascals)
No Food	Bag or set is empty
Pump Won't Run	Motor slow or jammed
Push Run To Feed	Pump unused for 2 minutes
ERRA - ERRZ	Self-test error

DISPOSABLE SET FEATURES

Automatic Anti-free-flow
Drip Chamber Eliminated

ACCESSORIES

Multi-purpose EnteraLite® packs
Multi-position Pole Clamp (rotatable 360°)
EnteraLite® AC Adapter/Charger

WARRANTY

2 years

OPERATING ENVIRONMENT

(specified per IEC 60601-1)
Temperature: 50 °F to 104 °F
(10 °C to 40 °C)
Humidity: 30% to 75%

STORAGE ENVIRONMENT

Temperature: -4 °F to 149 °F
(-20 °C to 65 °C)
Humidity: 10% to 95% noncondensing

Atmospheric
pressure: 700 hPa to 1060 hPa

IEC 60601-1 CLASSIFICATIONS

Class I and Internally Powered
BF Applied Part

CHAPTER 2 - DIRECTIONS FOR USE

Pump Features

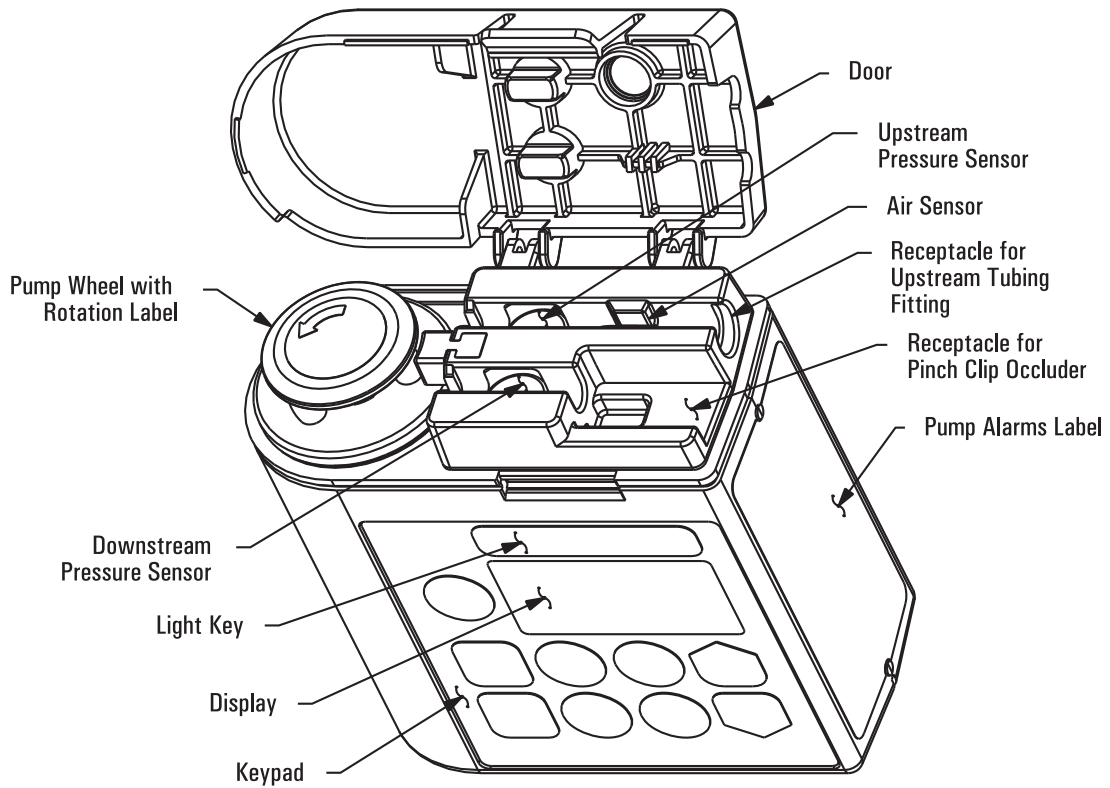


Figure 2-1: Pump Features - Front

CHAPTER 2 - DIRECTIONS FOR USE

Pump Features

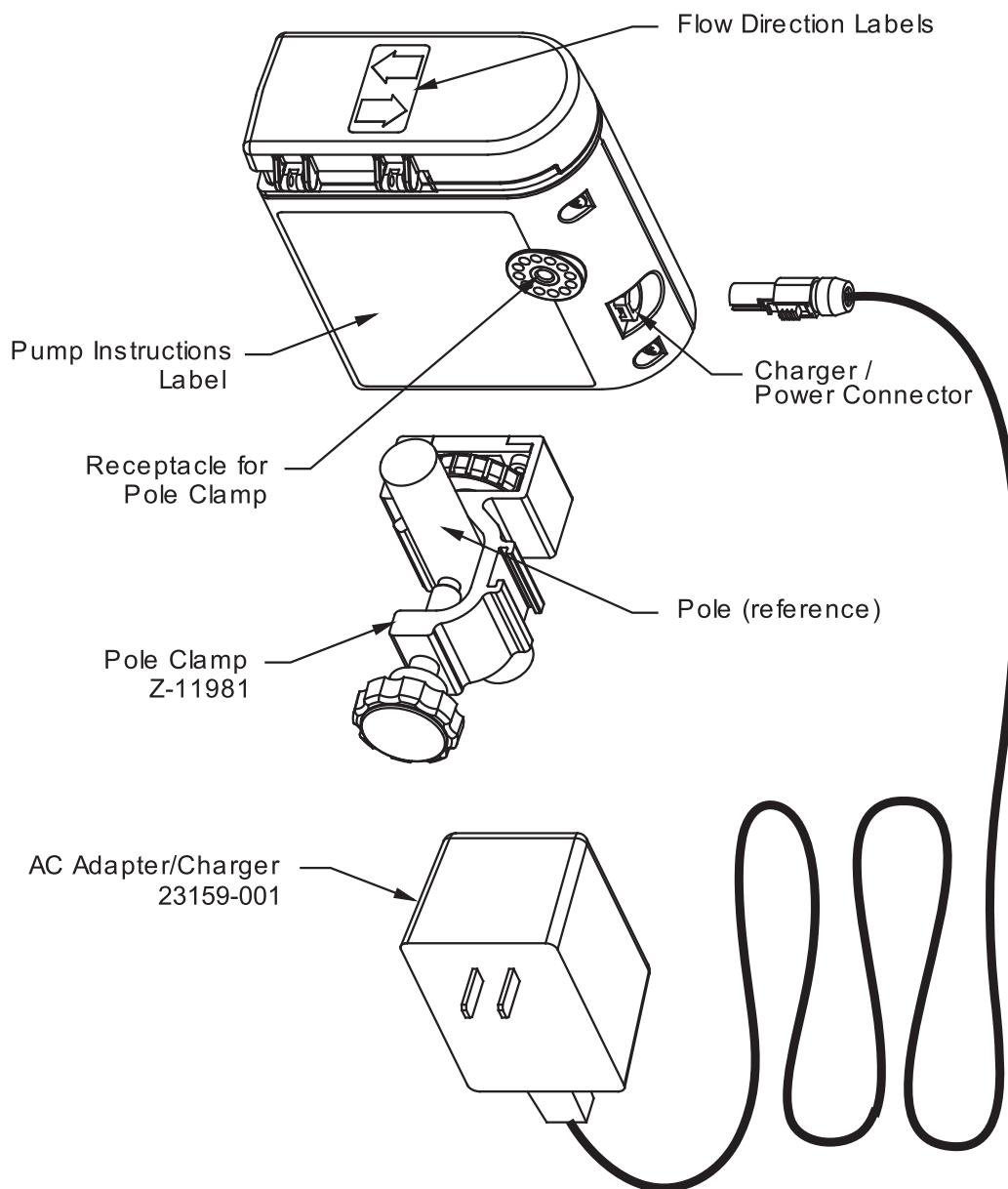


Figure 2-2: Pump Features - Rear

CHAPTER 2 - DIRECTIONS FOR USE

The Keypad

ON / OFF

Press this key for 2 seconds to either turn the EnteraLite® on or off. When the charger is plugged in, the pump is not completely off, instead it displays the battery charge status.

RUN / PAUSE

Press this key to either start the pump or place it in pause mode. When you press the key to run, the pump resumes operation with the current rate, dose, feed interval, and volume delivered (the rate, dose or feed interval can be changed while in pause mode, in which case the volume is cleared and the pump begins a new feed cycle).

PRIME

Press this key to fill or prime the disposable set once it is loaded into the pump (approximately 13 ml). Press and hold the PRIME key to rapidly fill the disposable set with fluid. Release the key to stop. The PRIME key operates only while the pump is in pause mode. Use this key to fill the tubing set when air has been introduced into the tubing (indicated by the **NO FOOD** alarm).

VOL / TOTAL

Press this key once to display the current volume delivered for this feed cycle. Press this key again to display the total cumulative volume delivered in all feed cycles since the total volume was last cleared (in this mode the display flashes **TOTL**, then the total cumulative volume).

FEED INT

Press this key to display the feed interval. **FEED INTERVAL** flashes and the display indicates the number of hours in which the pump will repeat the programmed dose at the selected rate.

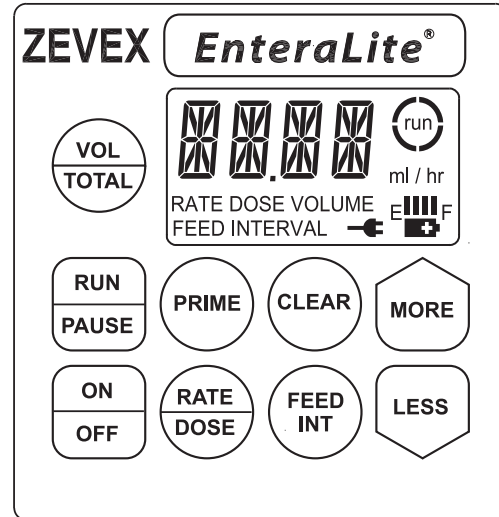


Figure 2-3: Keypad Layout

CHAPTER 2 - DIRECTIONS FOR USE

The Keypad

RATE / DOSE

If the rate is displayed, press this key to display the dose, or, if the dose is displayed, press this key to display the rate. If neither is displayed, press once to display the rate and again to display the dose.

MORE

Press this key to increase the displayed feed parameter; either rate, dose, or feed interval. Press and hold this key to increase the value rapidly. This key operates only when the pump is in pause mode.

LESS

Press this key to decrease the displayed feed parameter; either rate, dose, or feed interval. Press and hold this key to decrease the value rapidly. This key operates only when the pump is in pause mode.

CLEAR

Press this key when volume or total volume is displayed to set either to zero. Press this key when rate or dose is displayed to set either to its minimum value (Minimum Rate: 1 ml/hr, Minimum Dose: 10 ml). Press this key when **FEED INTERVAL** is displayed to disable interval feed operation. This key operates only when the pump is in pause mode.

EnteraLite® (Light)

Press the key labeled EnteraLite® to light the display to view in a dark room. The pump will automatically turn the display light off 10 seconds after the last key is pressed. The light is on constantly when the battery charger is connected between the pump and a wall outlet and the pump is turned on.

NOTE: On early versions of the pump, the display light turns off after 10 seconds even when the battery charger is connected between the pump and a live wall outlet.

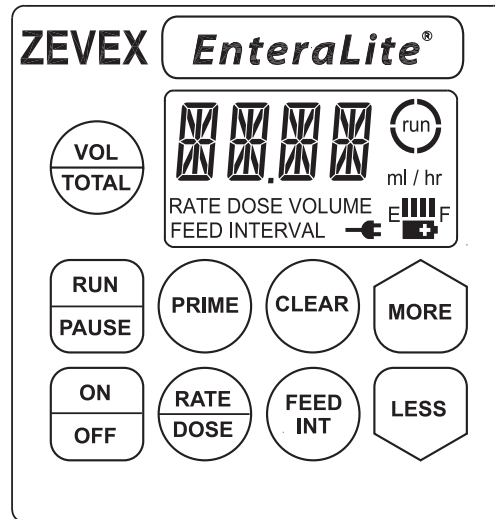


Figure 2-3: Keypad Layout

CHAPTER 2 - DIRECTIONS FOR USE

The Display

The pump communicates to the user through the display, which includes large alphanumeric characters, as well as smaller symbols and words. All the segments and symbols in the display are shown in *Figure 2-4*.



Figure 2-4: Display Segments

Important information is displayed through the large alphanumeric characters shown in *Figure 2-5*. When the pump displays the rate with these characters it indicates **ml/hr** to the right of the value, for the dose it indicates **ml**, and for the feed interval it indicates **hr**. The pump also communicates messages with the large alphanumeric characters. For example, the characters will display **DOSE**, then **DONE**, when the pump has finished delivering a single feed dose.

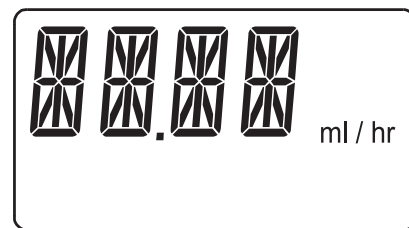


Figure 2-5: Alphanumeric Characters and Units

When the large alphanumeric characters display numbers, the smaller words below the characters, shown in *Figure 2-6*, describe what the numbers mean. For example, if **FEED INTERVAL** is displayed, then the number of hours between the beginning of each dose will be displayed by the large characters.

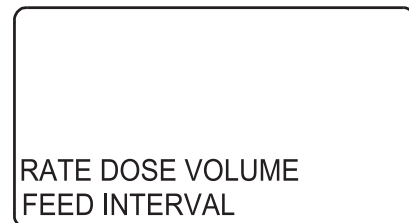


Figure 2-6: Setting Indicators

The **run** symbol, shown in *Figure 2-7*, indicates that the pump is running. The arcs around the **run** symbol rotate when the pump is in the process of delivering fluid. The arcs are off but the **run** symbol blinks when the pump is between feeding intervals (only if a feed interval has been selected).



Figure 2-7: Run Indicator

The wall plug symbol, shown in *Figure 2-8*, indicates that the charger is plugged in, the battery symbol indicates that the pump is running on only the battery, and the "fuel gauge" symbol indicates how much battery charge remains. More information is available in the sections of this chapter titled: *Charging the Battery*, and *Running on Battery Power*.

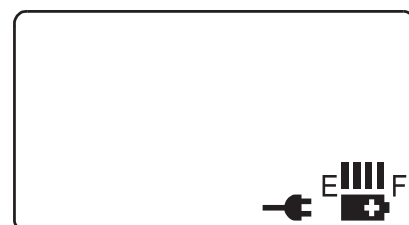


Figure 2-8: Power Indicators

CHAPTER 2 - DIRECTIONS FOR USE

Preparing the Disposable Set



WARNING: Use ONLY EnteraLite® Disposable Sets to ensure proper fluid delivery. Others won't deliver the correct dose, may allow dangerous free-flow conditions, and may generate hazardous fluid pressures which may activate occlusion alarms at unpredictable pressures.



WARNING: Use ONLY feeding solutions prescribed by the responsible physician, registered dietitian, registered nurse, or other licensed practitioner.

Follow your health care provider's instructions regarding cleanliness in preparing the feeding solution and the disposable set.

Remove the disposable set from the package. Remove any plastic band around the tubing.



WARNING: Dispose of the packaging properly. The plastic bag and band could be a hazard to children.

Remove the Stepped Enteral Adapter cover from the pinch clip occluder to prevent solution free-flow. Leave the cover on the Stepped Enteral Adapter until ready to connect to the patient's enteral feeding tube.

If you are using the spike set with a vented bottle or a pre-filled bag:

- ▶▶ Insert the spike into the spike adapter of the vented bottle or the pre-filled bag.

If you are using the 500 ml or 1200 ml disposable set:

- ▶▶ Hold the bag upright and pour the feeding solution into it.

NOTE: Allow blenderized solutions to sit for 10 to 15 minutes before pouring them into the bag.

- ▶▶ Firmly seal the bag closure.

If you are using the mini backpack, waistpack, or sports pack, remove excess air from the bag. To remove excess air from the bag:

- ▶▶ Invert the bag so that the outlet is at the top.
- ▶▶ Squeeze the buttons on the Pinch Clip Occluder to allow flow.
- ▶▶ Squeeze the bag until all of the air has passed out of the bag and feeding solution extends beyond the Pinch Clip Occluder. If you wish, continue to squeeze the bag to prime the tubing set.
- ▶▶ Release the Pinch Clip Occluder.

CHAPTER 2 - DIRECTIONS FOR USE

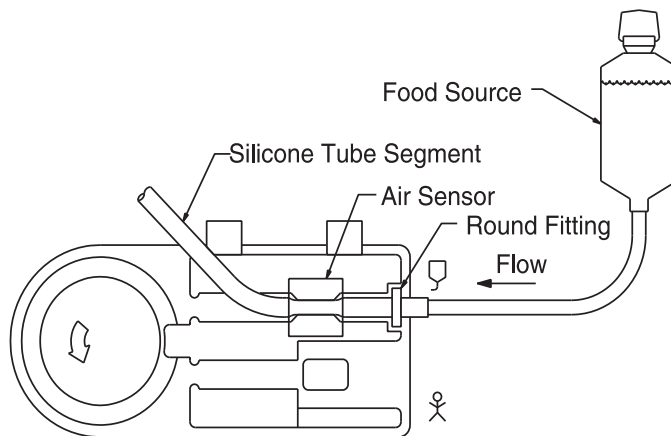
Loading the Disposable Set



CAUTION: Never press fingers or other objects into the cavities over the pressure sensors. Load only the silicone tubing of the disposable set into these sensors.

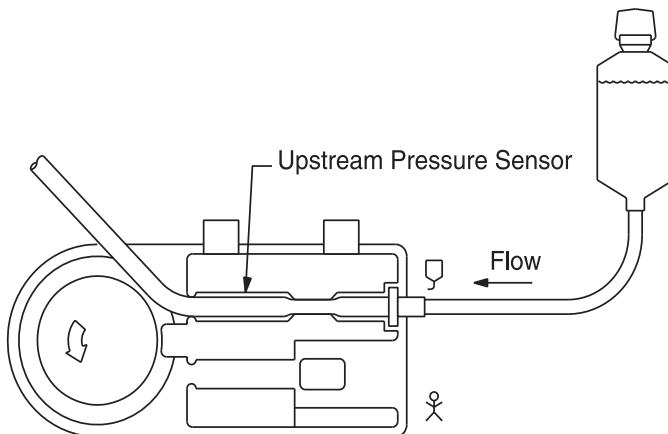


CAUTION: Dispose of EnteraLite® Sets Properly, as required by local law.



To load the disposable set, start with the tube fitting closest to the feed bag. Position the round fitting on the outside of the pump and then press the silicone tubing into the air sensor as shown in *Figure 2-9*.

Figure 2-9: Load Tubing in Air Sensor

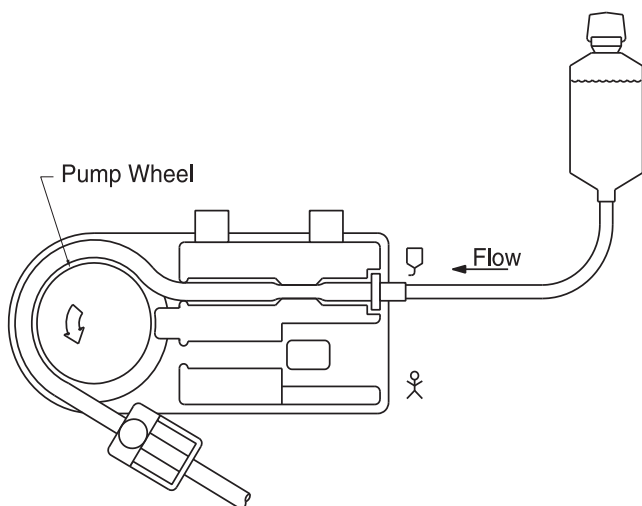


Next, route the silicone tubing segment through the upstream pressure sensor area and toward the pump wheel as shown in *Figure 2-10*. Do not stretch the tubing at this point.

Figure 2-10: Load Tubing in Upstream Pressure Sensor

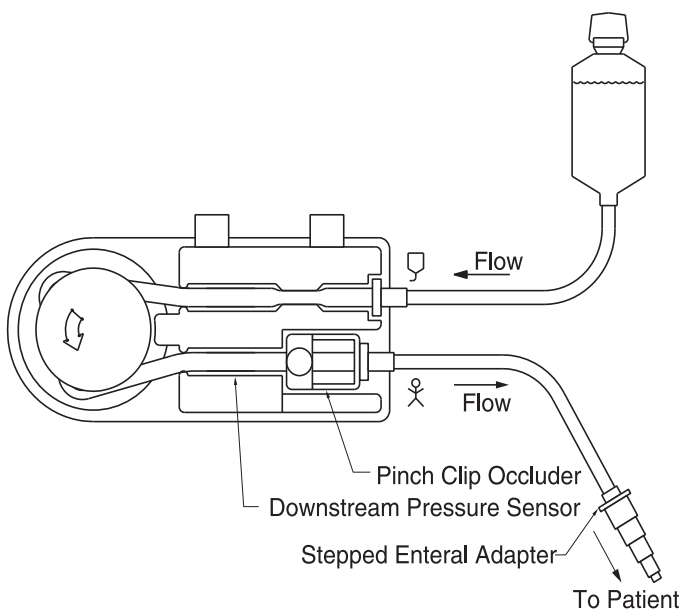
CHAPTER 2 - DIRECTIONS FOR USE

Loading the Disposable Set



Wrap the silicone tubing around the pump wheel (against the pump rollers) as shown in *Figure 2-11*. Minimize the stretching of the silicone tubing when loading the set into the pump.

Figure 2-11: Load Tubing around Pump Wheel



As shown in *Figure 2-12*, guide the silicone tubing in the downstream pressure sensor area. Only stretch the silicone tubing enough to place the pinch clip occluder of the disposable set into the rectangular slot, with either button facing up. Close the door.

Figure 2-12: Load Tubing in Downstream Pressure Sensor and Load Pinch Clip Occluder

CHAPTER 2 - DIRECTIONS FOR USE

A Single Feeding Example

Suppose you want to deliver 500 ml of enteral feeding solution at a rate of 120 ml/hr and then stop the pump:

Turn the pump on by pressing the ON/OFF key.

Verify that all the display segments and symbols are active as shown in *Figure 2-4* and that the audible alarm sounds.

The rate will be displayed by the large characters after the pump's self-test.

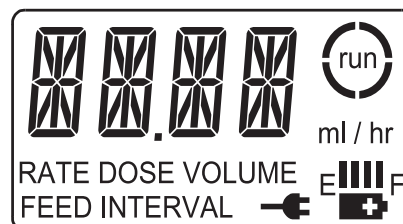


Figure 2-4: Display Segments

Press the MORE or LESS key to change the rate to **120 ml/hr**. Hold down either key to change rapidly.

Press the RATE/DOSE key to display the dose. Press the MORE or LESS key until a dose of **500 ml** is displayed. The pump should stop when the dose has been delivered, so press the FEED INT key and then press the CLEAR key. This disables interval feed operation. The pump will display **NONE** with the large characters.

Prepare the disposable set and enteral feeding solution as described in *CHAPTER 2 - PREPARING THE DISPOSABLE SET* and load the set into the pump as described in *CHAPTER 2 - LOADING THE DISPOSABLE SET*. Close the pump's door. Hang the feeding bag or container so that the bottom of the bag is at or above the level of the pump door. If any of the Enteralite® packs are to be used, load the pump and feeding bag into the proper compartments, securing the pump, bag and tubing with the pack's straps.

Prime the set by pressing and holding the PRIME key until the set is filled with enteral feeding solution (approximately 13 ml). Connect the stepped enteral adapter at the patient end of the set to the patient's enteral feeding tube. Press the RUN/PAUSE key and the pump will begin delivering fluid. If you want to stop the pump at any time, press the RUN/PAUSE key. When the dose has been delivered, **DOSE DONE** will appear and the pump will beep (or mute, depending upon the pump's configuration - contact your healthcare provider if a change is desired).

CHAPTER 2 - DIRECTIONS FOR USE

An Interval Feeding Example

Suppose you want to deliver 300 ml of enteral feeding solution at a rate of 80 ml/hr, and repeat this feeding every 6 hours:

Turn the pump on by pressing the ON/OFF key. Verify that all display segments and symbols are active as shown in *Figure 2-4*, and that the audible alarm sounds. Once the pump finishes its self-test the rate will be displayed by the large characters.



Figure 2-4: Display Segments

Press the MORE key or the LESS key to increase or decrease the rate to **80 ml/hr**.

Press the RATE/DOSE key to display the dose. Press the MORE or LESS key until a dose of **300 ml** is displayed.

Now press the FEED INT key. Press the MORE or LESS key until the feed interval is set to **6 hr**.



WARNING: Replace the disposable set every 24 hours to maintain delivery accuracy and prevent growth of harmful bacteria.



WARNING: Low flow rates, combined with high dose settings may exceed the life of the disposable set. The disposable set must be replaced every 24 hours to maintain delivery accuracy and prevent the growth of bacteria. DO NOT PROGRAM RATE AND DOSE COMBINATIONS WHICH EXCEED A 24 HOUR FEED REGIMEN.

CHAPTER 2 - DIRECTIONS FOR USE

An Interval Feeding Example

Prepare the disposable set and enteral feeding solution as described in *CHAPTER 2 - PREPARING THE DISPOSABLE SET*. If a feeding bag is to be used, pour the **total amount of enteral food to be delivered** into the feeding bag.

Next, load the EnteraLite® Disposable Set into the pump as described in *CHAPTER 2 - LOADING THE DISPOSABLE SET* and close the door. Hang the feeding bag or container so that the bottom of the bag is at or above the level of the pump door. If any of the EnteraLite® packs are to be used, load the pump and feeding bag into the proper compartments, securing the pump, bag and tubing with the pack's straps.

Prime the set by pressing and holding the PRIME key until the set is filled with enteral feeding solution (approximately 13 ml).

Connect the stepped enteral adapter at the patient end of the set to the patient's enteral feeding tube.

Press the RUN/PAUSE key to begin feeding. The pump will deliver 300 ml every 6 hours at a rate of 80 ml/hr, **until the bag is empty**.

If you want to stop the pump at any time, press the RUN/PAUSE key. You may resume the feed interval by pressing the RUN/PAUSE key as long as the rate, the dose, and the feed interval remain unchanged (clearing the volume will cause the pump to restart the feed cycle).

Additional notes regarding interval feeding:

Once the pump is running, the volume display, which can be accessed by pressing the VOL/TOTAL key once, shows the volume being delivered for the current feed cycle. In 6 hours the next feed cycle will begin. If you would like to display the total cumulative volume, press the VOL/TOTAL key once more. Now the display indicates the total volume delivered since last cleared, alternating with **TOTL**.

You cannot set the feed interval shorter than the current rate and dose settings will allow. To set a shorter feed interval, first change the rate and dose settings, then set the feed interval.

If you want to start with the total volume from zero, then the volume must be cleared. This can be done any time that the pump is in the pause mode. Press the VOL/TOTAL key twice so the total volume is displayed. Press the CLEAR key. The total volume is reset to zero.

There is a limit to the total volume that the pump can count. It will display up to **9998 ml**. If the maximum value of **9998 ml** is exceeded, **OVER FLOW** will be displayed by the large characters instead of the total volume. Clear it to start over.

CHAPTER 2 - DIRECTIONS FOR USE

An Interval Feeding Example

Once the feed interval, dose, and rate have been set and the RUN/PAUSE key is pressed, the pump will keep running until the bag or solution container is empty. Between interval feed cycles, the words **run** and **FEED INTERVAL** will blink, but the arcs around **run** will not appear. Also, the large characters will display the message **NEXT DOSE ###.### hr**, where the format **###.###** indicates the time in hours.minutes until the next dose. An example is shown in *Figure 2-13* (3.59 hr equals three hours and fifty-nine minutes).

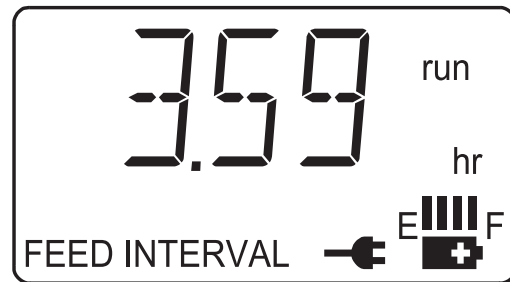


Figure 2-13: Time Displayed Between Interval Feedings

NOTE: On early versions of the pump, the next dose timer is displayed using the format **##.# hr** (As an example 3.9 hours equals 3 hours and 54 minutes. Every 0.1 hr equals 6 minutes).

CHAPTER 2 - DIRECTIONS FOR USE

Charging the Battery

To charge the battery, insert the plug from the EnteraLite® AC Adapter/Charger into the matching jack on the pump marked "CHARGER". Plug the charger into a wall outlet rated at:

105 to 129 VAC, 60 Hz, 0.22A

When using the international charger, plug the power cord into a wall outlet rated at:

100 to 250 VAC, 50-60 Hz, 0.39A

The pump can continue to operate while charging the battery or charge when the pump is turned off.

The EnteraLite® AC Adapter/Charger may be left continuously connected to the wall outlet. The battery charging circuit stops automatically when the battery is fully charged.

When the charger is plugged in and charging, the plug symbol will appear in the display as shown in *Figure 2-14a*. The "fuel gauge" then indicates that the battery is charging by displaying the segments in an ascending low to high pattern starting with the leftmost segment. This pattern continuously repeats while the pump is charging. Refer to *Figures 2-14a* through *2-14e*.

To check the status of the battery, disconnect the charger from the pump and then turn the pump on.

See *Chapter 2 - Running on Battery Power* for information on battery life and charge times.



WARNING: When simultaneously charging and operating the pump, position the pump to avoid direct contact with the patient's skin.

(Place the pump on a table top, in an EnteraLite® pack, or secure the pump to an appropriate fixture using a pole clamp).

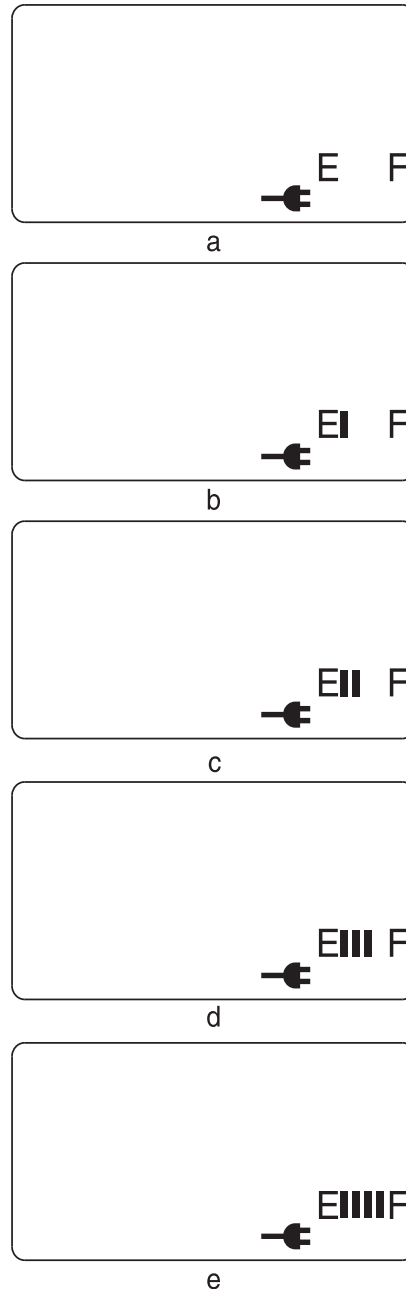


Figure 2-14: "Fuel Gauge" Displays Ascending Low to High Pattern While Charging

CHAPTER 2 - DIRECTIONS FOR USE

Running on Battery Power



WARNING: The battery capacity is an approximation. If you're unsure that enough capacity remains for your intended use, recharge it!

When the pump is running on battery power the battery symbol will appear in the display as shown in *Figure 2-15*.

The segments or bars between E and F represent the “fuel gauge” of the battery. Each block is approximately 1/4 of a 24-hour charge. If two blocks appear, then the battery is half full and the battery operation time remaining is roughly 12 hours. As the battery charge decreases, the blocks will blink before they disappear. When the last block is gone, the battery symbol will blink to indicate that there is approximately 1 hour of charge left, based on a flow rate of 125 ml/hr. At higher flow rates, this time will be reduced, while at lower flow rates, this time will increase.



Figure 2-15: Battery Power Indicator

When the battery symbol blinks, the display will flash **LOW BATT** every 7 seconds, alternating with the active display and the pump will beep every 3 minutes to remind the user of the low battery charge condition. Plug in the charger to continue to run and recharge the batteries. When the battery is fully depleted the pump will turn off automatically.

NOTE: As battery charge level decreases the pump may not be able to deliver enteral fluid at rates greater than 300 ml/hr, even though some battery capacity remains. The pump will alarm and indicate **PUMP WONT RUN** or **RATE TOO FAST FOR BATT**. If this happens, either recharge the battery or select a lower rate to complete the feed cycle.

NOTE: Some pumps contain an updated battery that can store a larger charge when charged for more than 5 hours. When charged for 5 hours, the first two bars will last for approximately 4 hours while the remaining two bars will last approximately 10 hours each.

***NOTE:** Battery life approximation is based on a battery with full charge range (charged for approximately 5 hours) and a flow rate of 125 ml/hr. Higher flow rates will reduce battery life, while lower flow rates and interval feeding will increase the battery life. Also, longer charging will increase battery life.

NOTE: The battery may take longer to charge if the temperature is below 50°F (10°C) or above 85°F (30°C).

CHAPTER 2 - DIRECTIONS FOR USE



WARNING: The Total Volume may be incorrect due to an interruption of battery power if the overcurrent or temperature protection circuits are triggered. In such a case one of the following conditions occurs:

During Single Feeding

The pump enters pause mode, but does not display "DOSE DONE" or turns off (but not due to a low battery).

During Interval Feeding

The pump enters pause mode or turns off (but not due to a low battery).

If one of these conditions occurs, check the disposable set feed bag to estimate how much volume was actually delivered. If these conditions occur frequently, contact your healthcare provider or refer the pump for service.

CHAPTER 3 - LABELS

Brief instructions for the operation of the pump as well as a brief explanation of each alarm message which the pump may communicate are printed on labels attached to the pump. These are not intended to be used in place of the Operator's Manual. They are simply a quick reference guide. Please read the Operator's Manual before operating the EnteraLite®!



Figure 3-1: Pump Label - Warning

The bag symbol, shown in *Figure 3-2*, is printed on the side label under the port where the loaded set leads directly to the feeding bag.

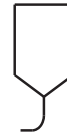


Figure 3-2: Pump Label - Feeding Bag Connection

The patient symbol, shown in *Figure 3-3*, is printed on the side label under the port where the loaded set leads directly to the stepped enteral adapter. The stepped enteral adapter attaches to the patient's enteral feeding tube.



Figure 3-3: Pump Label - Patient Connection

There are no user serviceable or replaceable components inside the EnteraLite® or the EnteraLite® AC Adapter/Charger. Do not open the pump or the EnteraLite® AC Adapter/Charger because there is risk of electrical shock.

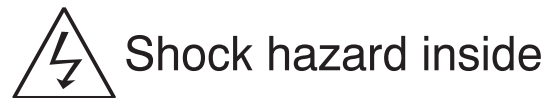


Figure 3-4: Pump Label - Shock Hazard

CHAPTER 4 - ALARMS and INDICATIONS

The audible alarm will sound to call attention to situations which must be corrected. The following messages may be displayed by the large display characters.

CHEK

The three smaller indicators: **RATE**, **DOSE**, and **FEED INTERVAL** are displayed with this message. One of the three was programmed so that the pump cannot execute the combination of commands. The pump divides the dose by the rate and if the result is greater than the feed interval, this message is displayed.

For example, if rate is 100 ml/hr, and dose is 200 ml, then the pump will take 2 hours to deliver the dose. However, if the feed interval is 1 hour, the pump cannot complete the first interval feed before the next is due to start.

Press the RUN/PAUSE key, and reprogram the settings. The pump will not run until the rate, dose, and feed interval are compatible.

DOSE DONE

This message indicates that a single feed dose has been delivered.

ERRA - ERRZ

The pump displays **ERR** followed by a letter to indicate that a self-test has failed. Turn the pump off and then back on. If the problem persists, contact your healthcare provider or refer the pump for service (see *CHAPTER 11 - WHO TO CALL*).

LOAD SET

The pump attempted to run with the set improperly installed or missing.

Check the following:

- ▶ Make sure an EnteraLite® Disposable Set is installed properly and the door is closed.
- ▶ Check for spillage, especially around the pressure sensors. If cleaning is necessary, refer to *CHAPTER 5 - CLEANING*.

LOW BATT

The battery is low and the pump will soon stop running. Plug in the EnteraLite® AC Adapter/Charger to recharge the battery. The pump can continue to operate while the battery is charging.

NEXT DOSE

The next dose will be delivered in **##.##** hr, where the format **##.##**, indicates the time in hours and minutes until the next dose.

NO FLOW IN

The pump has detected an occlusion upstream in the set, between the pump and the bag. Check the tubing set for blockage and correct the blockage. Also check for spillage where the set is routed under the door. If there is spillage, refer to *CHAPTER 5 - CLEANING*.

CHAPTER 4 - ALARMS and INDICATIONS

NO FLOW OUT

The pump has detected an occlusion downstream in the set, between the pump and the patient. Check the tubing set for blockage and correct the blockage. Also check for spillage where the set is routed under the door. If there is spillage, refer to *CHAPTER 5 - CLEANING*.

NO FOOD

The air sensor detects an empty tubing set. Check for the following problems.

- ▶▶ If the feeding bag is empty, refill the bag and continue feeding. If necessary, prime the set.
- ▶▶ Make sure the air sensor is clean.
- ▶▶ Make sure an EnteraLite® Disposable Set is installed properly, seated in the air sensor, with the door closed.
- ▶▶ Replace worn tubing with a new tubing set.

NOTE: The air sensor can be sensitive to foamy and/or blenderized solutions. Allow blenderized solutions to sit for 10 to 15 minutes prior to pouring into the bag and priming the disposable set. Small air bubbles from the foam may get trapped in the air sensor region and must be cleared in order to avoid a **NO FOOD** alarm.



WARNING: Replace the disposable set every 24 hours to maintain delivery accuracy and prevent the growth of harmful bacteria.

PUMP WONT RUN or RATE TOO FAST FOR BATT

The pump is inhibited from operating at the selected rate. Check for the following problems.

- ▶▶ Make sure an EnteraLite® Disposable Set is installed properly and the door is closed.
- ▶▶ Check that the battery is fully charged or that the EnteraLite® AC Adapter/Charger is plugged in.
- ▶▶ Try reducing the rate below 300 ml/hr. The pump may not be able to deliver highly viscous (thick) fluids at high rates with the present charge level of the battery.
- ▶▶ Check for contamination around the pump wheel and clean according to *CHAPTER 5 - CLEANING*.

CHAPTER 4 - ALARMS and INDICATIONS

PUSH RUN TO FEED

This battery-saving feature indicates that the pump has been inactive in the pause mode for 2 minutes. Program and use the pump or turn it off.

TO STOP LET GO

The pump displays this message when priming the set. To stop priming, release the PRIME key.

WONT PRIM IN RUN

The PRIME key was pressed while the pump was running. If you wish to prime the pump, press the RUN/PAUSE key; then press and hold the PRIME key.

Battery Doesn't Hold Its Charge

The battery will lose its charge if stored for a long period of time or if stored at high temperatures (such as in an automobile during the summer). Recharge the battery.

If you've charged the battery and the battery life is still less than expected, contact your healthcare provider or refer the pump for service. The battery is not user-replaceable (see *CHAPTER 11 - WHO TO CALL*).

Charger Installed but No Plug Symbol Visible

If the plug symbol remains off after the AC EnteraLite® Adapter/Charger is plugged into the pump, the charger isn't charging the battery. Verify that the wall outlet works by plugging in another appliance, such as a lamp. If the charger is connected properly and the outlet works, then the pump or charger may be damaged. Contact your healthcare provider or refer the pump for service (see *CHAPTER 11 - WHO TO CALL*).

NOTE: There are no user serviceable or replaceable components inside the EnteraLite® pump or EnteraLite® AC Adapter/Charger.

CHAPTER 5 - CLEANING



WARNING: To avoid electrical shock, never clean the pump or the EnteraLite® AC Adapter/Charger with the charger plugged in or the pump on.



WARNING: Never immerse the pump or the EnteraLite® AC Adapter/Charger in liquids. Electrical shock or pump damage can result.



WARNING: Make sure the EnteraLite® AC Adapter/Charger is completely dry before plugging into an electrical outlet.



CAUTION: Gently clean the pressure sensors. Excessive pressure due to aggressive cleaning can damage them.

- ▶▶ Don't use abrasive materials to clean the EnteraLite®.
- ▶▶ Clean the pump only with warm soapy water, a 5% bleach solution in water, or a multipurpose disinfectant cleaner. When using the cleaner or bleach solution, apply for approximately 10 minutes and then wipe the pump clean with water.
- ▶▶ Carefully clean debris from each of the 3 rollers on the roller assembly on a regular basis. This will help ensure accurate volumetric delivery.
- ▶▶ Use a soft cloth or sponge to clean the pump surfaces, including the keypad.
- ▶▶ Use a cotton swab to **gently** clean the pathways under the door and the air and pressure sensors.
- ▶▶ The compartments of the EnteraLite® packs can be cleaned with a damp sponge.
- ▶▶ The EnteraLite® packs are machine-washable. Use warm water and the gentle cycle, whenever possible.
- ▶▶ The EnteraLite® AC Adapter/Charger normally does not require cleaning. When desired, a dry or slightly damp cloth may be used to clean the outside surface of the EnteraLite® AC Adapter/Charger while it is disconnected from the wall outlet. Do not allow liquid to enter the EnteraLite® AC Adapter/Charger through the vents.

CHAPTER 6 - MAINTENANCE and CALIBRATION



WARNING: The EnteraLite® must be periodically calibrated to ensure proper fluid delivery.



CAUTION: If the pump is dropped or falls onto a hard surface from a height of 3 feet or more, it is recommended that it be returned for service.

ZEVEX recommends that the EnteraLite® be calibrated by authorized personnel at least every 12 months. Please contact your health care provider to arrange for this service (see *CHAPTER 11 - WHO TO CALL*).

CHAPTER 7 - DISPOSABLE SETS and ACCESSORIES



WARNING: Replace the disposable set every 24 hours to maintain delivery accuracy and prevent the growth of harmful bacteria.



WARNING: Use only EnteraLite® Disposable Sets to ensure proper fluid delivery. Others won't deliver the correct dose, may allow dangerous free-flow conditions, and may generate hazardous fluid pressures which may activate occlusions alarms at unpredictable pressures.



CAUTION: Dispose of EnteraLite® Disposable Sets properly, as required by local law.

The disposable set consists of several parts, as illustrated in *Figure 7-1*.

- ▶▶ The bag is filled with the enteral solution. The spike is used to pierce pre-filled containers.
- ▶▶ The pump fitting holds the silicone tubing in place in the pump.
- ▶▶ The silicone tubing passes through the air sensor and around the pump wheel, passing over pressure sensors on either side of the pump wheel.
- ▶▶ The pinch clip occluder blocks solution flow when the set is out of the pump or when the pump door is open.
- ▶▶ The stepped enteral adapter connects to most common patient feeding tubes, but is not I.V. compatible.
- ▶▶ The Enteral Adapter Protective Cover contains a feature which is used to hold the Pinch Clip Occluder open while the set remains packaged, to avoid kinking of the silicone tubing.

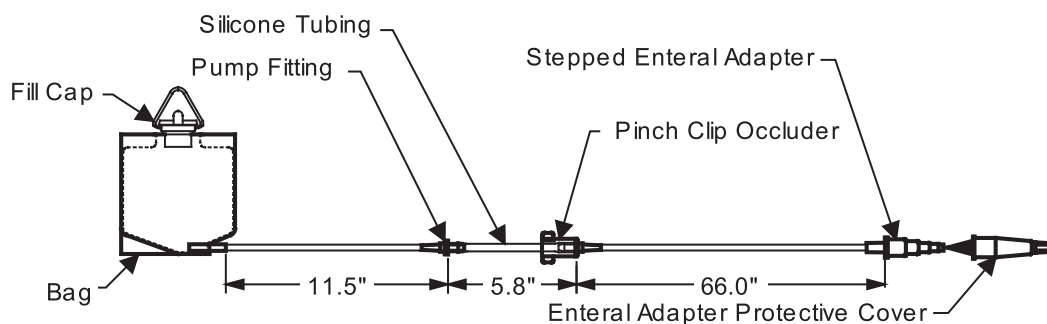
The only disposable sets approved for use with this pump are:

EnteraLite® 500 ml Bag Set, Order Number EL0500

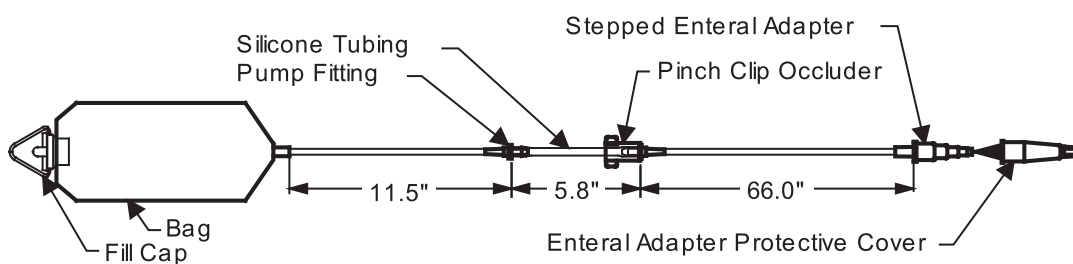
EnteraLite® 1200 ml Bag Set, Order Number EL1200

EnteraLite® Spike Set, Order Number EL0010

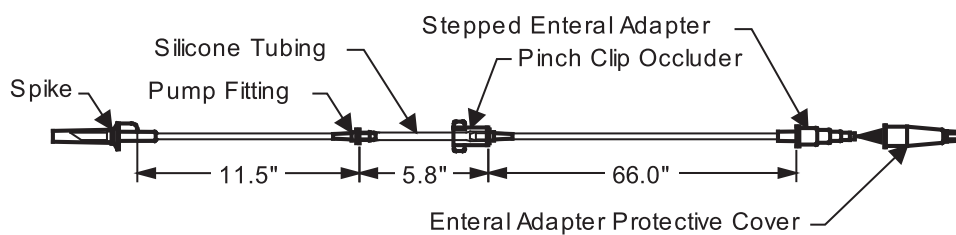
CHAPTER 7 - DISPOSABLE SETS and ACCESSORIES



500 ml Bag Set, P/N EL0500



1200 ml Bag Set, P/N EL1200



Spike Set, P/N EL0010

Figure 7-1: Disposable Sets

CHAPTER 7 - DISPOSABLE SETS and ACCESSORIES

Additional accessories are available for use with the EnteraLite®:

EnteraLite® Pole Clamp, Order Number Z-11981

Tighten the black wheel to mount the clamp on a pole. Thread the bolt into the receptacle on the back of the pump and tighten the gray wheel to mount the pump on the clamp. If the gray wheel is slightly loosened, the pump can be rotated to snap into different positions. Retighten the gray wheel when the pump is in the desired position.

EnteraLite® Waistpack, Order Number 11939-001

This pack provides two ways to carry the EnteraLite®:

Waistpack with 500 ml bag.

An elastic strap secures the neck of the 500 ml bag with a clip in the compartment on the right side. The pump fits in the left side. The tubing is loaded into the pump and any excess length of tubing can be secured with a Velcro® strap inside the right-hand compartment. The patient end of the tubing then feeds through a gap in the zipper and through a button hole in the right-hand waist strap of the pack.

Waistpack expanded to become a backpack with 1200 ml bag.

An elastic strap secures the neck of the 1200 ml bag with a clip in the backpack portion of the pack. An elastic strap can be used to secure the body of the bag with a clip. The pump is placed in the Waistpack portion. The tubing is fed through a button hole from the backpack into the Waistpack and loaded into the pump. Any excess length of tubing can be secured with a Velcro® strap inside the right-hand compartment of the Waistpack. The patient end of the tubing then feeds through a gap in the zipper and through a button hole in the waist strap of the pack. A hook is also available in the expanded backpack to secure pre-filled containers of formula.

EnteraLite® Mini-backpack, Order Number 12501-001 (black), 12501-002 (teal), 12501-003 (red), 12501-004 (purple), 12501-005 (pink)

This pack holds the EnteraLite® with a 500 ml bag. The pump is secured within a clear pouch by a Velcro® strap. An elastic strap secures the neck of the 500 ml bag with a clip above the pump. The tubing is loaded into the pump and any excess length of tubing can be secured with a Velcro strap behind the bag. The patient end of the tubing then feeds through a button hole at the bottom of the pack (either side).

CHAPTER 7 - DISPOSABLE SETS and ACCESSORIES

EnteraLite® Sportpack, Order Number EL3000

This pack holds the EnteraLite® with a 500 ml bag. The tubing is loaded in the pump, then the pump is placed in the pack with the display facing the clear window and with the charger port facing the hole at the bottom of the bag. The 500 ml bag is placed inside the pack with the neck of the bag secured by an elastic strap with a clip above the pump. Any excess length of tubing can be secured with a Velcro® strap inside the bag. The patient end of the tubing then feeds through a gap in the zipper, or through a special hole at the bottom of the bag. The EnteraLite® AC Adapter/Charger may also be plugged into the pump through this hole in the pack. The sportpack is designed to be worn on a belt. It is barely noticeable when worn under a jacket.

EnteraLite® Wheelchair pack, Order Number Z-12634

An elastic strap secures the neck of the 500ml or 1200ml bag with a clip at the top right side of the bag. A hook is also available to secure pre-filled containers of formula. The pump is secured within a clear pouch at the bottom left side of the bag by a Velcro® strap. The tubing is loaded in the pump and any excess length of tubing can be secured by a Velcro® strap. The patient end of the tubing then feeds through a gap in the zipper. The EnteraLite® AC Adapter/Charger may be stored in a pouch on the left side of the bag. There is also room in the bag to store an extra container of formula or other personal items.

EnteraLite® AC Adapter/Charger, Order Number 23159-001

Use only the EnteraLite® AC Adapter/Charger with this pump. Plug the EnteraLite® AC Adapter/Charger into a wall outlet and plug the connector of the EnteraLite® AC Adapter/Charger into the pump to operate on AC power and/or recharge the battery.

Note 1: The button on the connector must be pressed in to remove the charger from the pump.

Note 2: Several optional EnteraLite® AC Adapter/Chargers and power cords are available for use in various countries.



WARNING: Do not use an extension cord with the AC Adapter/Charger.



WARNING: The AC Adapter/Charger is intended for indoor, dry area use only. Do not allow adapter to be exposed to liquids.

Please contact your health care provider to obtain additional disposable sets and accessories (see *CHAPTER 11 - WHO TO CALL*).

CHAPTER 8 - IMPORTANT PEDIATRIC CONSIDERATIONS



WARNING: Low flow rates, combined with high dose settings may exceed the life of the disposable set. The disposable set must be replaced every 24 hours to maintain delivery accuracy and prevent the growth of bacteria. **DO NOT PROGRAM RATE AND DOSE COMBINATIONS WHICH EXCEED A 24 HOUR FEED REGIMEN.**



CAUTION: When feeding human milk, fat separation may occur. The feeding solution should be periodically checked during the feed regimen.

The EnteraLite® can be used on pediatric patients provided that the specifications of the pump meet the delivery requirements of these patients. Those specifications of primary importance are:

- ▶▶ The flow rate range of the EnteraLite® is 1 ml/hr to 600 ml/hr in 1 ml/hr increments.
- ▶▶ The EnteraLite® pump delivers the dose at the specified rate, both programmed by the user, within +/- 5% volumetric flow-rate accuracy under the following conditions:

NOTE: For test methodology refer to ANSI/AAMI ID26-1992 American National Standard for Infusion Devices. The reported accuracy is based upon a generic volume accuracy calculation:

$$\text{Accuracy \%} = \frac{(\text{Volume Delivered} - \text{Volume Programmed})}{\text{Volume Programmed}} \times 100$$

- utilizing ZEVEX disposable sets
- fluid head height at +6.0 inches ± 0.3 inches (+15 cm ± 0.75 cm) with respect to the top of the pump.
- downstream back pressure range from -1.9 psi to +5.8 psi (-13 kPa to +40 kPa)
- over the range of environmental operating conditions (Specified per IEC 60601-1)
Operating Temperature Range: 50 °F to 104 °F (10 °C to 40 °C)
Operating Humidity Range: 30 to 75% noncondensing

Accuracy for the range of 1 to 250 ml/hr is illustrated in *Figure 8-1*.

- ▶▶ The occlusion alarm pressure of the EnteraLite® is 8 psi (55 kPa) or 12 psi (83 kPa), as set by authorized service personnel.

If these specifications are consistent with the required feed regimen, the EnteraLite® can be used to deliver enteral formulas to pediatric patients. **ALWAYS VERIFY THE RATE, DOSE AND FEED INTERVAL BEFORE PROCEEDING TO FEED.**

CHAPTER 8 - IMPORTANT PEDIATRIC CONSIDERATIONS

The EnteraLite® contains safety features which reduce the incidence of free-flow and over-infusion. When the set is improperly loaded, the pump will display a **LOAD SET** alarm, and the pump will not start. Additionally, the pinch clip mechanism on the set will automatically occlude the tubing when the set is removed from the pump, thus preventing the possibility of free-flow.



WARNING: The Total Volume may be incorrect due to an interruption of battery power if the overcurrent or temperature protection circuits are triggered. In such a case one of the following conditions occurs:

During Single Feeding

The pump enters pause mode, but does not display "DOSE DONE" or turns off (but not due to a low battery).

During Interval Feeding

The pump enters pause mode or turns off (but not due to a low battery).

If one of these conditions occurs, check the disposable set feed bag to estimate how much volume was actually delivered. If these conditions occur frequently, contact your healthcare provider or refer the pump for service.

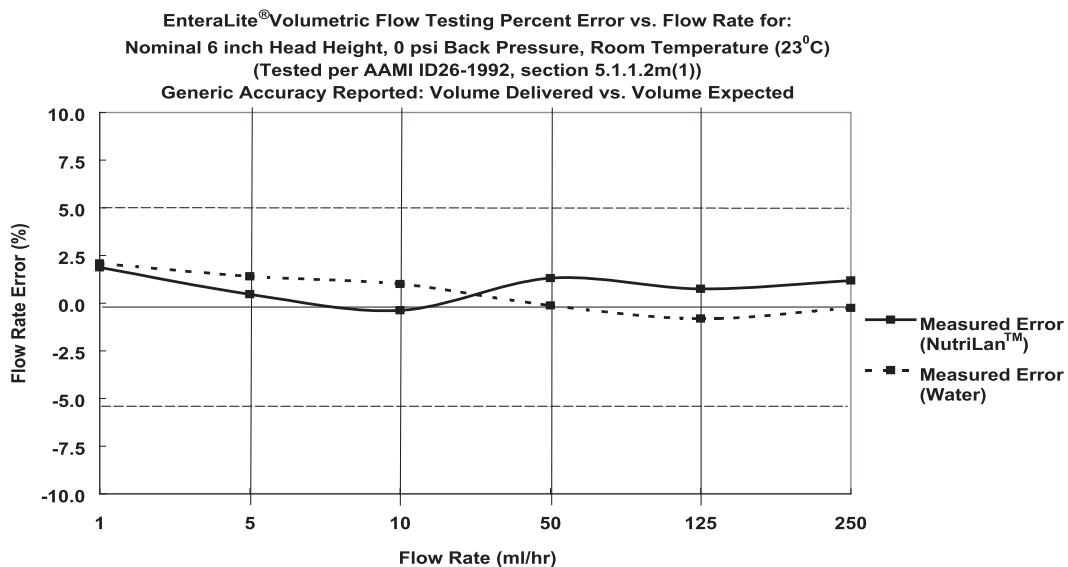


Figure 8-1: Flow Rate Accuracy

CHAPTER 9 - TECHNICAL INFORMATION



WARNING: Do not use the EnteraLite® Enteral Feeding Pump for the delivery of non-enteral solutions. Serious injury may result. For enteral feeding only. Not for IV use.



WARNING: Use **ONLY** feeding solutions prescribed by the responsible physician, registered dietitian, registered nurse, or other licensed practitioner.

Indications

The EnteraLite® is to be used only with EnteraLite® Disposable Sets for the delivery of enteral feeding solutions. The pump's sensitivity to occlusion and its low flow rate capability allow the pump to be used on adult and pediatric patients. This pump must not be used for the delivery of non-enteral solutions.

Volumetric Flow Rate Accuracy

WARNING: Use **ONLY** EnteraLite® Disposable Sets to ensure proper fluid delivery. Others won't deliver the correct dose, may allow dangerous free-flow conditions, and may generate hazardous fluid pressures which may activate occlusion alarms at unpredictable pressures.

The EnteraLite® pump delivers the dose at the specified rate, both programmed by the user, within +/- 5% volumetric flow-rate accuracy under the following conditions:

- utilizing ZEVEX disposable sets
- fluid head height at +6.0 inches ± 0.3 inches (+15 cm ± 0.75 cm) with respect to the top of the pump.
- downstream back pressure range from -1.9 psi to +5.8 psi (-13 kPa to +40 kPa)
- over the range of environmental operating conditions (Specified per IEC 60601-1)
Operating Temperature Range: 50 °F to 104 °F (10 °C to 40 °C)
Operating Humidity Range: 30 to 75% noncondensing

NOTE: For test methodology refer to [ANSI/AAMI ID26-1992 American National Standard for Infusion Devices](#). The reported accuracy is based upon a generic volume accuracy calculation:

$$\text{Accuracy \%} = \frac{(\text{Volume Delivered} - \text{Volume Programmed})}{\text{Volume Programmed}} \times 100$$

CHAPTER 9 - TECHNICAL INFORMATION

Occlusion Pressure



WARNING: Use ONLY EnteraLite® Disposable Sets to ensure proper fluid delivery. Others won't deliver the correct dose, may allow dangerous free-flow conditions, and may generate hazardous fluid pressures which may activate occlusion alarms at unpredictable pressures.

The occlusion alarm pressure of the EnteraLite® is 8 psi (55 kPa) or 12 psi (83 kPa) as set by authorized service personnel. The pump produces both audible and visual alarms when the downstream fluid pressure reaches the preset limit, within a 2 psi (14 kPa) tolerance.

Battery Operation Time

The EnteraLite® will deliver fluid at 125 ml/hr for more than 24 hours, when running on a fully charged battery. Adequate charge of a depleted battery is accomplished in approximately 5 hours of uninterrupted battery charge time.

Fluid Delivery Characteristics

The EnteraLite® delivers a bolus of solution at a nominal flow rate of 600 ml/hr while plugged into the charger. The flow rate will decrease to approximately 440 ml/hr when the battery is low. The minimum delivery volume is approximately 0.08 ml each fractional turn of the pump wheel.

When the flow rate is set to 300 ml/hr or less, increments of volume are delivered once every 20 seconds. At higher flow rates, increments of volume are delivered once each minute. Note that at very low flow rates the pump won't deliver fluid every 20 seconds because of the minimum volume increment (1 ml/hr at the minimum delivery volume of 0.08 ml means that the pump wheel must rotate only thirteen times during the hour, or once every 4 to 5 minutes).

Amount of Air Before the Bag Is Considered Empty

Generally, the amount of air which must pass the air sensor before the bag is considered empty is 1 ml, but this figure varies with battery condition (it is approximately 0.5 ml when the battery is low). The range of 0.5 to 1 ml relates to a bubble which is approximately 2.5 to 5 inches (6 to 13 cm) in continuous length within the silicone tubing segment of an EnteraLite® Disposable Set.

CHAPTER 9 - TECHNICAL INFORMATION

Power Requirements

The EnteraLite® AC Adapter/Charger, 11938-001, requires 105 to 129 VAC, 60 Hz, and a minimum current capacity of 0.22 Amp. Output is 12 VDC and 1.5 Amp.

Where the integrity of the external protective conductor in the installation or its arrangement is in doubt, equipment shall be operated from its internal electrical power source.

The Universal AC Adapter/Charger, 19162-002, 19162-003, 19162-010 requires 100 to 240 VAC, 50-60 Hz, and a minimum current capacity of 0.75 Amp (for 100 VAC) or 0.35 Amp (for 240 VAC).

Operational Conditions

The EnteraLite® is designed in accordance with IEC 60601-1 to operate in a temperature range of 50 °F to 104 °F (10 °C to 40 °C) and in a relative humidity range of 30% to 75%.

EnteraLite® Disposable Set Displacement

The EnteraLite® Disposable Set displaces approximately 13 ml of fluid when primed. Approximately 3 ml of air is drawn into the tubing before the enteral pump detects that the bag is empty. Therefore, approximately 10 ml of fluid remains in the disposable set when the pump stops feeding. (These values vary by approximately 0.5 ml, depending on whether the batteries are low or fully charged).

CHAPTER 10 - WARRANTY

Solely for the benefit of the original buyer, ZEVEX® INCORPORATED ("ZEVEX®"), warrants all new EnteraLite® products of its manufacture to be free from defects in material and workmanship, and will replace or repair, F.O.B., at its factory in Salt Lake City, Utah, USA or other location designated by ZEVEX®, any EnteraLite® products returned to it within twenty-four (24) months of original purchase by the buyer. Such repair or replacement shall be free of charge.

ZEVEX® warrants to the original buyer, all repaired or replaced products to be free from defects in material and workmanship and will replace or repair such products F.O.B., at its factory in Salt Lake City, Utah, USA or other location designated by ZEVEX®. Such repair or replacement shall carry a warranty of ninety (90) days from the date of repair or replacement or the balance of the new product warranty as described above, whichever is greater.

This Warranty applies to all EnteraLite® products manufactured by ZEVEX® and is the ONLY WARRANTY GIVEN FOR THE SALE OF PRODUCTS OR SERVICES. NO WARRANTIES IMPLIED IN LAW, INCLUDING, BUT NOT LIMITED TO THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR PARTICULAR PURPOSE, SHALL APPLY. ZEVEX® WILL BE LIABLE, IN ANY EVENT, ONLY FOR THE PURCHASE PRICE OF THE DEFECTIVE PRODUCT, BUT NOT FOR ANY CONSEQUENTIAL DAMAGES.

This Warranty may not be modified, amended or otherwise changed, except by a written document properly executed by a corporate officer of ZEVEX®.

ZEVEX®, Inc. voids the warranty if the EnteraLite® pump is opened or tampered with in any way without prior authorization from ZEVEX®, Inc.

CHAPTER 11 - WHO TO CALL

This manual is intended to answer the most common questions which may arise during ordinary use of the EnteraLite® Enteral Feeding Pump. If further assistance is needed, contact your health care provider.

ADDITIONAL INFORMATION:

YOUR HEALTHCARE PROVIDER:

YOUR PHYSICIAN:

NOTES

EnteraLite[®]

Ambulatory Enteral Feeding Pump

OPERATOR'S MANUAL

Also available in other languages



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FAX: 801-264-1051**

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U.S. PATENT NO'S: 5514102, 5531680, 5704584, 5720721,
5733061, 5810323, 6142979 AND D389228.

INTERNATIONAL PATENT NO'S: 0959920, 0900106, and
69619282.9-08.

OTHER U.S. AND FOREIGN PATENTS PENDING

MADE IN USA
PART NO. DI-0278-1/G



EnteraLite[®] is the first
enteral feeding pump to be
awarded the Seal of
Acceptance for Superior
Pediatric Product Quality
from the Alliance of
Children's Hospitals.